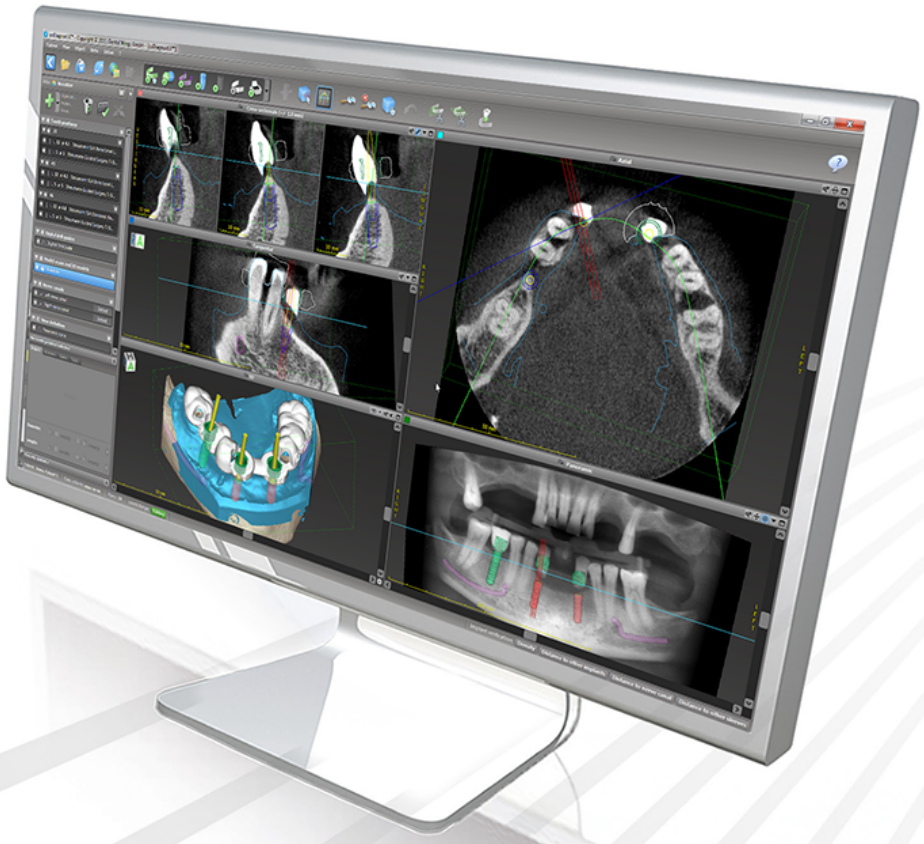
coDiagnostiX

Planning Software for Dentistry

Instructions for Use

Original



dental wings

Important! Keep this document for future reference.

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1. About this guide

> ⚠ **Caution**
>
> The provided instructions contain important information on the safe and appropriate use of the software. Make sure to have read and understood this document prior to installing and operating the software.

These Instructions for Use are valid for the *Product life cycle* (p. 7) of coDiagnostiX, version 10.0 and higher, unless new instructions are published within this period. In case of questions, contact your local distributor (see *Distributors and service* (p. 76)).

Electronic Instructions for Use

coDiagnostiX Instructions for Use are provided in electronic form. If a paper version is required, the user may print these instructions himself/herself or request a paper version from the manufacturer. For further information, delivery time and contact details see: http://ifu.dentalwings.com

1.1 Disclaimer

coDiagnostiX software is intended for use by dental professionals who have appropriate knowledge in the field of application. 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 surgical guide, the selection of appropriate material and an appropriate and calibrated 3D manufacturing system as well as the correct fabrication of scan templates and surgical 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.

Updates to hardware and software components are made regularly. Therefore, some of the instructions, specifications and pictures contained in these Instructions for Use may differ slightly from your particular situation. Dental Wings reserves the right to revise or make changes or improvements to this product or documentation at any time without obligation to notify any person of such revisions or improvements. 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 CBCT or 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. CBCT or 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 other rights

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 and/or other trademarks and registered trademarks from Dental Wings mentioned herein are the trademarks or registered trademarks of Dental Wings. All other trademarks are the property of their respective owners.

Copyright

Dental Wings documents may not be reprinted or published, in whole or in part, without the written authorization of Dental Wings.

2. Introduction and overview

2.1 Intended use

coDiagnostiX is intended to be used as preoperative planning software in dentistry.

2.2 Device description and features

coDiagnostiX is a planning software for virtual dentistry treatments taking into account the patient's anatomical structures and future prosthetic needs. coDiagnostiX can import and process 3D CBCT or CT scan data (DICOM standard) and model scan data and export planning and design data for the production of surgical guides.

Device variants and configuration

The product does not have any variants or configurations. Access to features of the software is restricted by the licensing system. (*Licensing Matrix* (p. 83)

coDiagnostiX is an open software system. The library contains implants (including abutments) and surgical instruments from a large number of manufacturers.

Surgical instruments are dentistry instruments which include e.g. endodontic drills, fixations pins and sleeves.

⚠ **Caution**

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

To be able to use the library (master database), the user has to accept the following terms and conditions.

1. The master database may contain implants and surgical instruments that are not registered in the country of the user. The user has to make sure to use only those items which have been properly registered.

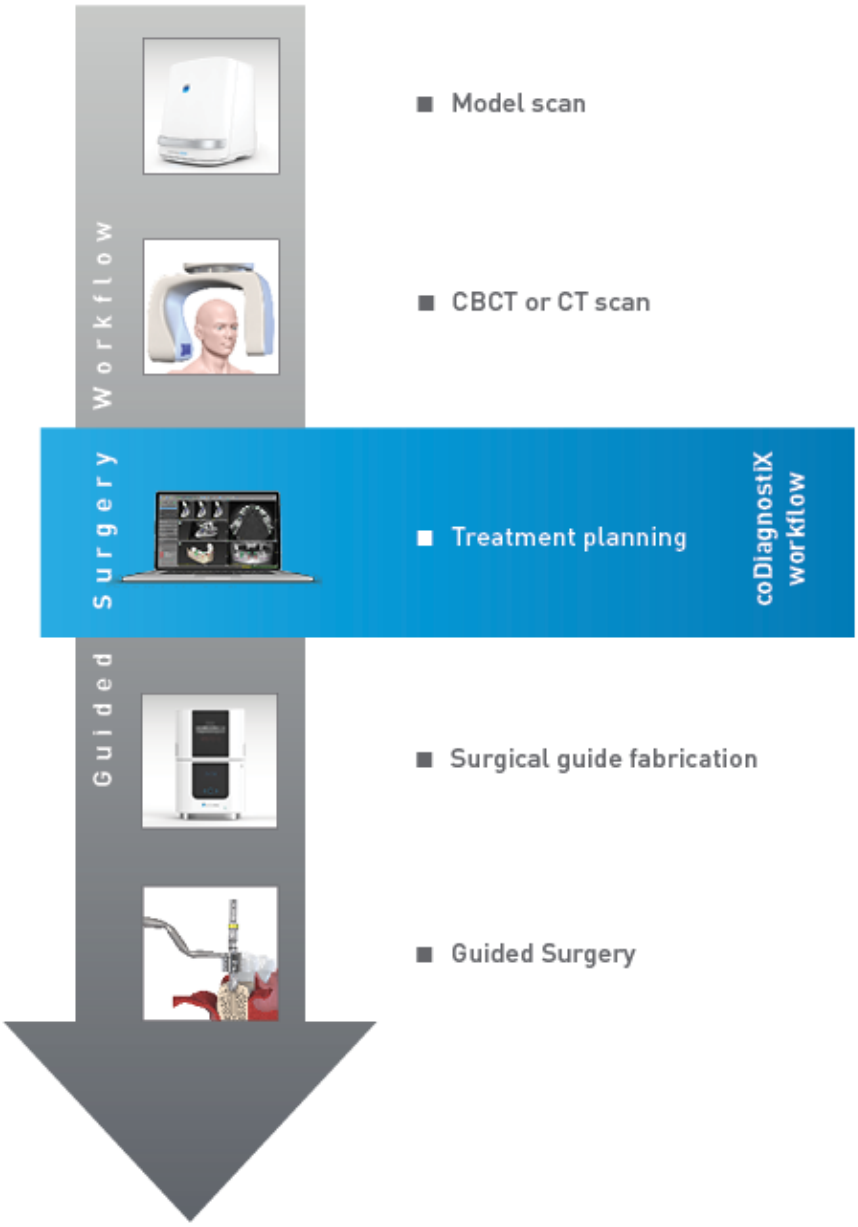
2. The user is obligated to always check that the data from the master database are similar equivalent with both the catalog values provided by the manufacturer and the information on the elements received.

Principles of operation

Planning with coDiagnostiX is part of a guided surgery workflow. The planning is based on a patient's medical image data such as CBCT or CT (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 and surgical instruments. Planning data are used for designing surgical guides which can be exported as manufacturing information in a 3D geometry (open format)[1]. The surgical guide transfers the virtual surgical plan from the computer to the patient's anatomy.

[1]For the legacy manufacturing system gonyX and its accessories, a plan for the creation of the drill guide is provided as printout. gonyX and its accessories must only be used for implant planning in combination with coDiagnostiX (for further details refer to Instructions for Use coDiagnostiX version 11.1).

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 *EXPERT mode: Step by step case planning* (p. 48)

- Import DICOM data & create dataset
- Align patient coordinate system
- Define panoramic curve
- Detect nerve canal
- Plan surgical treatment
- Import model scan
- Design & export surgical guide

2.3 Accessories and products used in combination

3D manufacturing system and print materials

There are many ways to produce surgical guides with 3D manufacturing systems (e.g. 3D printing system), provided the manufacturing system can read open STL format files and process biocompatible material. Each 3D manufacturing system and resulting guide which fulfills the requirements may, in principle, be suitable. The user needs to ensure that the surgical guide can be produced with sufficient accuracy and that the material used for fabrication is suitable for the use as a surgical guide in patients.

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

- D20II/D30II/D40II 3D printer with SHERAprint-sg (Rapid Shape GmbH/SHERA Werkstoff-Technologie GmbH & Co. KG)

For a complete list of validated materials and systems, contact your local distributor (see *Distributors and service* (p. 76)).

> ⚠ **Caution**
>
> Patients dental anatomy is subject to change. It is the user's responsibility to adhere to good dental practice in respect of time delays between data collection, treatment planning and surgery. In addition, the shelf life of fabricated guides shall be considered.

Software products

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

- **Dental Wings DWOS®**
  Dental CAD/CAM software
- **Straumann® CARES® Visual**
  Dental CAD/CAM software
- **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

Related product information material is listed in chapter *Further information* (p. 20). For details on compatibility see *Compatibility information* (p. 18).

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.

3D navigation systems

coDiagnostiX users may transfer treatment plans to 3D navigation systems in proprietary format.

The correct specification of coDiagnostiX proprietary file format has been verified by mininavident AG for the DENACAM system.

Input data requirements

The software supports a wide range of image sources, including Cone-Beam Computed Tomography (CBCT) and, optionally, surface scanners, 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 CBCT or 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. CBCT or 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 CBCT or CT scans* (p. 82).

2.4 Indications

coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professional who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners.

It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step.

For automated manufacturing of surgical guides in the dental laboratory environment, the coDiagnostiX software 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 Precautions

The provided instructions contain important information on the safe and appropriate use of the software. Make sure to have read and understood this document prior to installing and operating the software.

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 surgical guide and the selection of appropriate material lie within the sole responsibility of the user.

Make sure that the inspection windows placed in the digitally designed surgical guide do not affect the stability of the final surgical guide. Otherwise there is the risk of inaccurate 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 surgical guides may result in damage to vital anatomy at the time of surgical procedure.

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 surgical guide design. Matching accuracy directly influences the accuracy of the designed surgical guide.

Make sure to comply with all applicable standards and technical regulations for any computer hardware used. Computer hardware is not intended to be used in close proximity (within a distance of 1.5 meters) to the patient. Do not use multiple-socket extension cords to plug the hardware.

Before placing the scan template or surgical guide into the patient's mouth, make sure to prepare such template or guide according to standard operating procedures in dentistry and the instructions 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.

Patients dental anatomy is subject to change. It is the user's responsibility to adhere to good dental practice in respect of time delays between data collection, treatment planning and surgery. In addition, the shelf life of fabricated guides shall be considered.

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.
- 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.

2.7 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 your local distributor (see *Distributors and service* (p. 76))

In general, patient datasets from older versions of coDiagnostiX can be opened with coDiagnostiX (backward compatibility). Check your dataset carefully to avoid minor incompatibilities which might lead to failures in the planning and/or the production of surgical guides. Older versions of coDiagnostiX, however, cannot work with datasets from current coDiagnostiX versions.

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. Make sure to always work with the latest software versions on such scanner devices. For the compatibility of the software version contact your local distributor (see *Distributors and service* (p. 76)).

DWOS Synergy

DWOS Synergy allows for online case sharing between coDiagnostiX and Dental Wings DWOS/Straumann CARES Visual. For the compatibility of the software version contact your local distributor (see *Distributors and service* (p. 76)).

2.8 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

Data managed by the user may require a moderate or high level of protection to ensure privacy and avoid misuse:

- High level: Data with additional statutory requirements in many countries (e.g. patient personal data and medical information)
- Moderate level: Data protected or restricted by contract or other agreement (e.g. license information)

Bear in mind that the user is responsible for data protection on user side. Make sure to adequately protect such data.

> ⚠ **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.
> – Use the anonymization function to protect patient personal data if required.

2.9 Further information

There is no physical, chemical, electrical, mechanical, biological, electromagnetic or radiation 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.

Dental Wings and its products are registered in the main markets. The Declaration of Conformity for coDiagnostiX is available through our eIFU website at: https://ifu.dentalwings.com/. For further questions, please contact your local distributor (see *Distributors and service* (p. 76)).

For further information on products used in combination, please refer to the following documents or sources of information:

DWOS and DWOS Connect:

- DWOS Instructions for Use
- DWOS User Help

Straumann® CARES® Visual:

- Straumann® CARES® Visual Instructions for Use
- Straumann® CARES® Visual User Help

Dental Wings Intraoral Scanner:

- Intraoral Scanner Instructions for Use

2.10 Installation

> ⚠ **Caution**
>
> Make sure to comply with all applicable standards and technical regulations for any computer hardware used. Computer hardware is not intended to be used in close proximity (within a distance of 1.5 meters) to the patient. Do not use multiple-socket extension cords to plug the hardware.

Steps to install coDiagnostiX

1. Check that your hardware and software meet the specifications (see *Hardware and software requirements* (p. 77)).
2. Insert the installation medium into the computer.

3. If the installation process does not start automatically, start the program manually by executing the *setup.exe* file on your installation medium.
4. Follow the instructions on the screen.

In case of any questions or if you need further assistance during installation, contact your local distributor (see chapter *Distributors and service* (p. 76)).

Note

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

Installing optional software and configuring the network

Document reader: Choose an application that can read PDF files and is compatible with your operating system. Install in line with the routines of your operating system and as instructed by the document reader manufacturer.

Printer: Install in line with the instructions given by the printer manufacturer.

3D mouse: Follow the instructions given in the coDiagnostiX User Help (**coDiagnostiX EXPERT Mode** > **General tools** > **3D mouse**).

Microsoft® SQL Server®: Follow the instructions given in the coDiagnostiX User Help (**Advanced functionalities** > **Network Database SQL**).

DWOS Synergy: For installation and configuration see *DWOS Synergy* (p. 80).

Network configuration: Configure your system as described in chapter *Hardware and software requirements* (p. 77)

Languages

coDiagnostiX user interface is available in several languages. The language can be set in the coDiagnostiX Management (see section *Management* (p. 25) in chapter *coDiagnostiX start screen* (p. 25)).

Getting acquainted with the software

To learn how to work with coDiagnostiX and get acquainted with its functions, see *Getting acquainted* (p. 24).

Uninstallation

If you need to uninstall your coDiagnostiX software for any reason, use the tools and procedures provided by your operating system (refer to chapter *Hardware and software requirements* (p. 77)).

2.11 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. Basic principles

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.

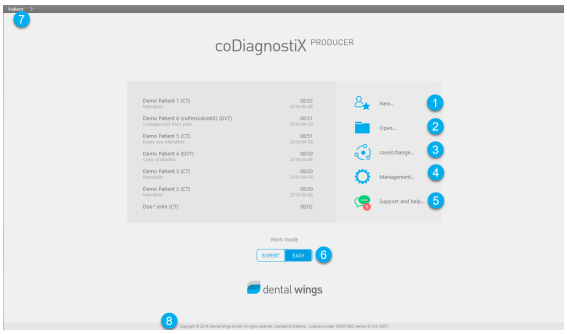
3.1 Getting acquainted

To learn how to work with coDiagnostiX and get acquainted with its functions and related workflows, the following instructions, training sessions and media are offered:

- coDiagnostiX Instructions for Use (this document)
- Regular online training courses which are open for all users with a valid coDiagnostiX license. Users can register for these webinars on our website at https://codiagnostix.com/training.
- Training videos which are available from within coDiagnostiX (see *Support and help* (p. 26) in chapter *coDiagnostiX start screen*).
- Context-sensitive coDiagnostiX User Help providing detailed explanations and additional information on advanced functions (see *Support and help* (p. 26) in chapter *coDiagnostiX start screen*).

3.2 coDiagnostiX start screen

Basic functionalities of the coDiagnostiX start screen



1 **Create New dataset**

Opens a dialog box to import DICOM data (e.g. from a CD) and to create a patient dataset.

2 **Open dataset**

Opens the Patient Database (DICOM already imported)

3 **caseXchange**

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 *Compatibility information* (p. 18))

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). For information on how to get acquainted with the software, see chapters *Distributors and service* (p. 76) and *Getting acquainted* (p. 24).

6 **Work Mode**

Select EXPERT or EASY to launch coDiagnostiX in your preferred work mode. EXPERT offers the full set of planning tools to support standard as well as advanced treatment workflows. EASY mode is a streamlined user interface with step-by-step guidance for users, who plan standard treatment cases, or outsource to a laboratory or planning center.

7 **Main menu**

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

8 **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 (see *Maintenance* (p. 75)).

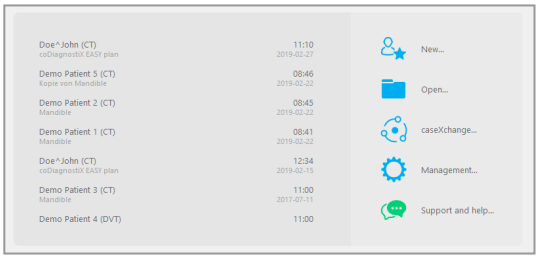
3.3 DICOM Import

Starting coDiagnostiX and loading a DICOM case

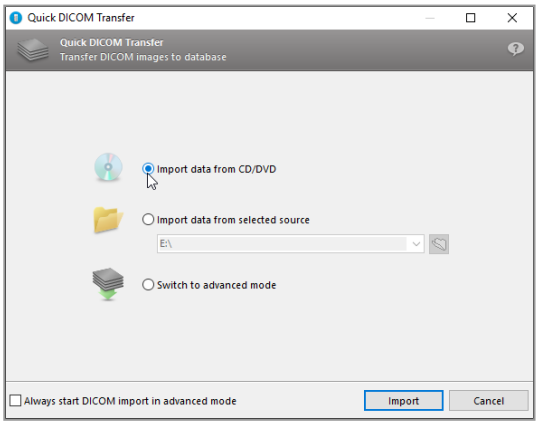
- Start the coDiagnostiX software; ensure that the dongle is connected.
- Transfer the DICOM data that you received from the CBCT or CT scanner to your computer (e.g. insert CD/DVD into your computer's disc drive).

> ⚠ **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.

- Click **New** on the start screen. This starts a DICOM transfer.



- Select **Import data from CD/DVD or other source** and click **Import**.
- In case of any problems (error messages, warnings, etc.), contact your local distributor (see *Distributors and service* (p. 76)).
- 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 EXPERT or EASY mode, as selected on the start screen.

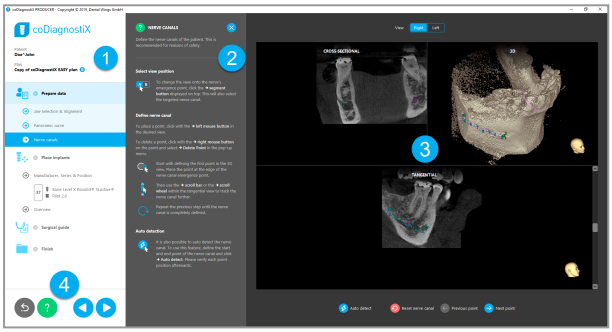
⚠ **Caution**

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. EASY mode

4.1 User interface

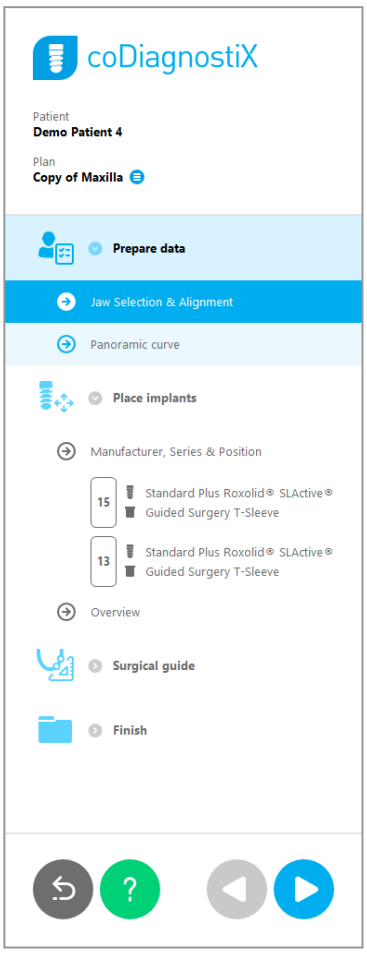
coDiagnostiX EASY planning screen



1. **Object tree**: All planning steps in order of workflow; current step highlighted, object overview.
2. **Help**: Collapsible inline help panel with instructions for current step.
3. **Views** : Tools and view manipulation for current step.
4. **Navigation and help tools**: Access to help and navigation between steps.

The object tree in coDiagnostiX EASY mode:

- Clear step-by-step overview of current case planning with collapsible sub-steps
- Call up any step at any time with one mouse click
- At-a-glance object data
- Quick access to plan management and help



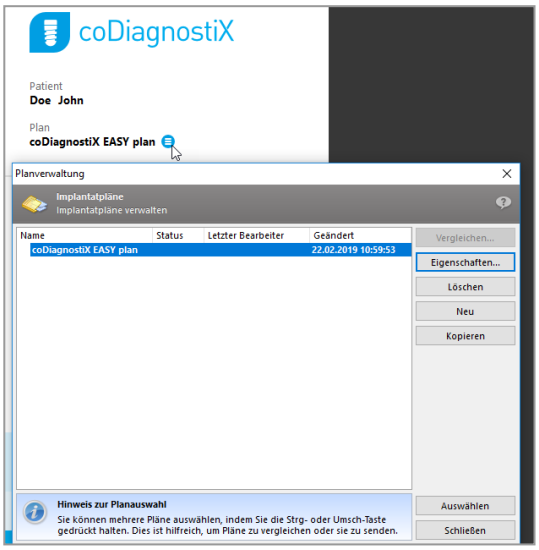
Navigation and help tools in coDiagnostiX EASY mode:

Description	Symbol
Returns to start screen. The current case planning will be saved automatically.	
The **Navigation buttons** allow you to move back and forth between individual steps of the case planning.	
Opens help dialog. A pop-up column with user instructions describing the current step appears.	
Launches the plan management dialog box.	

Managing plans in coDiagnostiX EASY mode

Planning data are managed in plans. You may create several plans for one patient, delete plans or copy plans.

- Access planning functions via the **Plan Management Button** (≡) in the object tree.
- Protect plans against changes, by selecting the **Plan Management Button** (≡) ⇨**Properties** and ticking **Protect this plan against changes**.
- **Finalize** plans by selecting the **Plan Management Button** (≡) ⇨**Properties** and ticking **Mark this plan as final**.



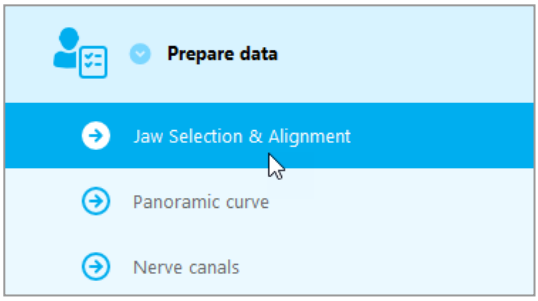
4.2 Case planning

The coDiagnostiX EASY mode is fully guided by the software in the order of workflow steps. The four main steps are **Prepare data**, **Place implants**, design **Surgical guide** and **Finish** the guide:

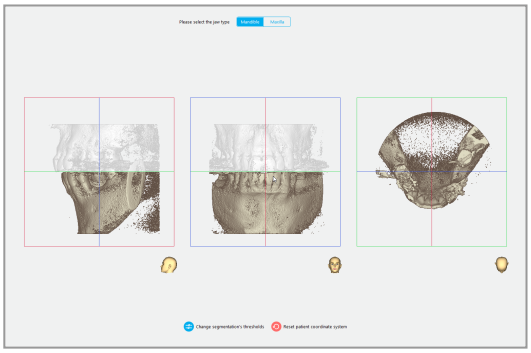
Step 1: Prepare data

Align patient coordinate system:

- Click **Prepare data**⇨ sub-step **Jaw Selection & Alignment** in the object tree.

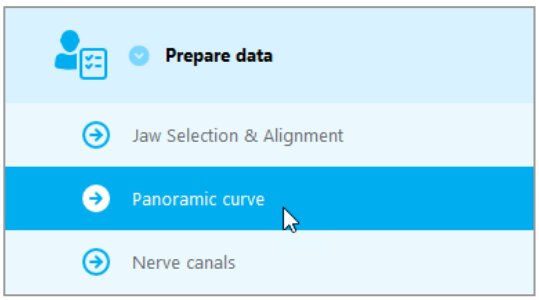


- Align as described on the screen. To move the patient coordinate system, click, hold, and drag with the left mouse button.
- To rotate the coordinate system, click, hold and, drag with the right mouse button.

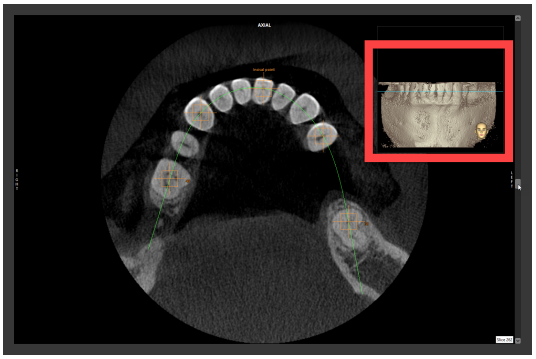


Define the panoramic curve:

- Click **Prepare data**⇨ sub-step **Panoramic curve** in the object tree.

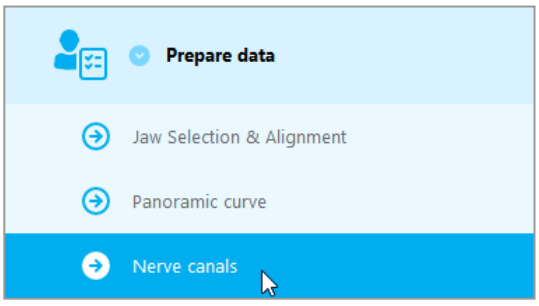


- Move points to create panoramic curve.
- A **pop-up window** in the upper right corner indicates the current axial position in the 3D view for better orientation.



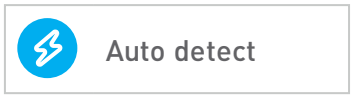
Define the nerve canal:

- In the object tree, navigate to **Prepare data**⇨ sub-step **Nerve canals**.



- Select the nerve canal position using the buttons at the top. 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 **Auto detect** at the bottom of the screen. coDiagnostiX will automatically detect the nerve canal.

Manual definition

- Define additional nerve canal points by clicking directly in the views.

For further information on safety distance to the nerve canal, see chapter *Safety checks* (p. 72).

⚠ 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.

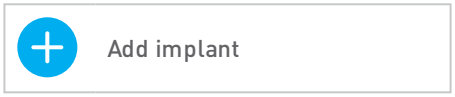
Always maintain an appropriate safety distance to the nerve canal.

Step 2: Place implants

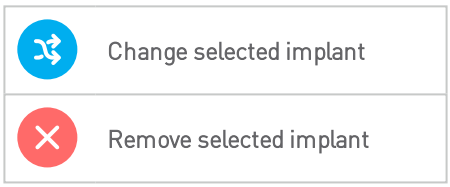
Plan implant:

- Navigate to step **Place Implants** in the object tree.

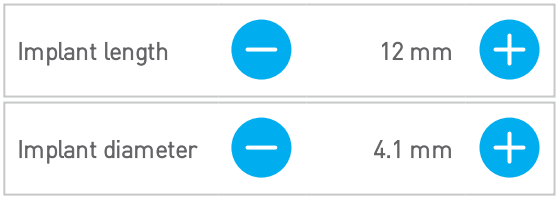
- Click **Add implant** at the bottom of the screen. The Master Database opens.
- Select manufacturer, series and tooth position.



- Move implant position via left mouse button; rotate implant via right mouse button.
- Change or remove implants via buttons at the screen bottom.



- Adjust implant length and diameter via buttons in the next sub-step.



Always verify the correct position of the implants.

Note

For other surgical items such as **endodontic drills** and **fixation pins** follow the same planning steps.

For further information on the safety distance between implants, see chapter *Safety checks* (p. 72).

⚠ **Caution**

Always maintain an appropriate distance around the implant.

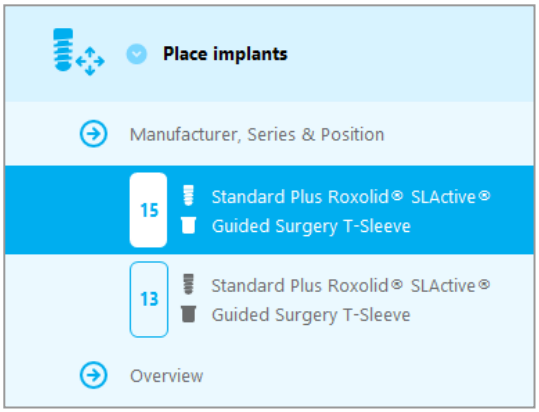
Keep in mind that coDiagnostiX endodontic planning is intended only for planning a straight path to the starting point of the root canal. The treatment of the root canal is not supported by the guide.

Add sleeves:

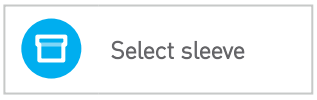
- Navigate to step **Place implants**.
- Select an implant in the object tree to add a sleeve or abutment for this implant

or

- select **Overview** in the object tree to add sleeves or abutments to all implants at once.



- Click on **Select sleeve** at the bottom of the screen to open the dialog box.
- Follow instructions in the dialog box.



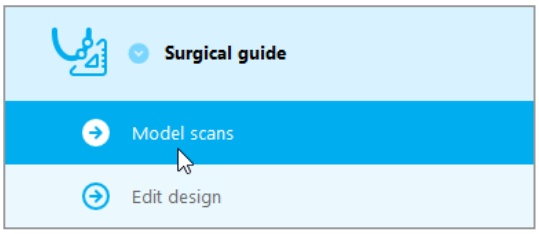
⚠ **Caution**

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.

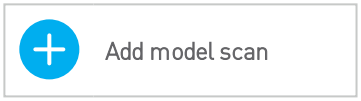
Step 3: Surgical guide

Import and match a model scan:

- Navigate to **Surgical guide**⇨ sub step **Model scan** in the object tree.



- Click **Add model scan** at the bottom of the planning screen.
- Follow instructions as described in the wizard.



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.

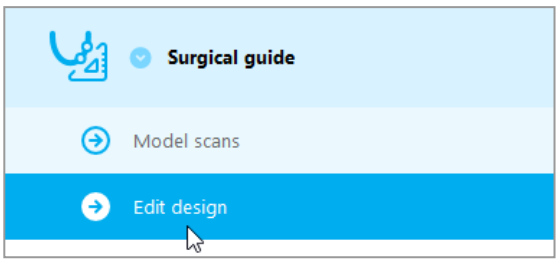
⚠ Caution

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 surgical guide design. Matching accuracy directly influences the accuracy of the designed surgical guide.

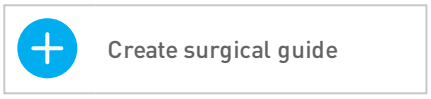
Inadequate surgical guides may result in damage to vital anatomy at the time of surgical procedure.

Design a surgical guide:

- Click **Surgical guide**⇨ sub-step **Edit design**.



- Select **Create surgical guide** at the bottom of the screen. The design wizard opens.
- Follow instructions as described in the wizard.



For further information on accuracy of surgical guides, see chapter *Safety checks* (p. 72).

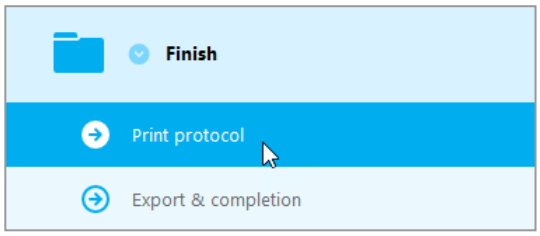
> ⚠ **Caution**
>
> Correct dimensioning of the surgical guide and the selection of appropriate material lie within the sole responsibility of the user.
>
> Make sure that the inspection windows placed in the digitally designed surgical guide do not affect the stability of the final surgical guide. Otherwise there is the risk of inaccurate 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.

> 🕮 **Note**
>
> Please note that you are also responsible for the selection of an appropriate and calibrated 3D manufacturing system and the correct fabrication of the surgical guide.

Step 4: Finish

Print protocols:

- Click **Finish**⇨ sub-step **Print protocol** in the object tree.

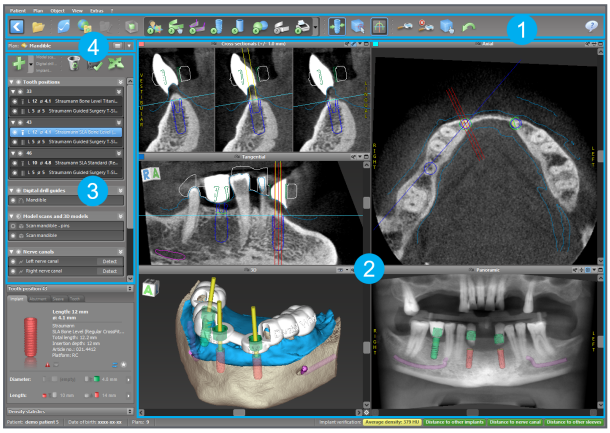


- **Select** the desired protocols from the planning screen menu.

> ⚠ **Caution**
>
> Printouts containing images of the dataset are not intended for diagnostic purposes.

5. EXPERT mode: User interface

coDiagnostiX EXPERT planning screen



1. **Toolbar** (for customizing, see *Toolbar* (p. 42))
2. **Views** (for basic information and view manipulation, see *Views* (p. 43))
3. **Object tree** (for tree functions and moving/manipulating objects, see *Object tree* (p. 45))
4. **Plan panel** (for working with plans, see *Plans* (p. 47))

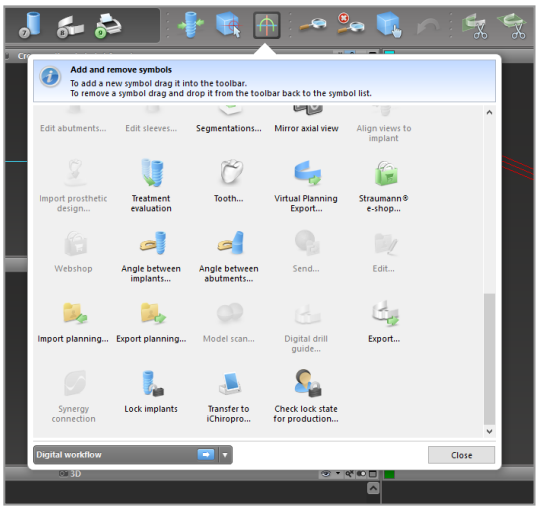
5.1 Toolbar

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.

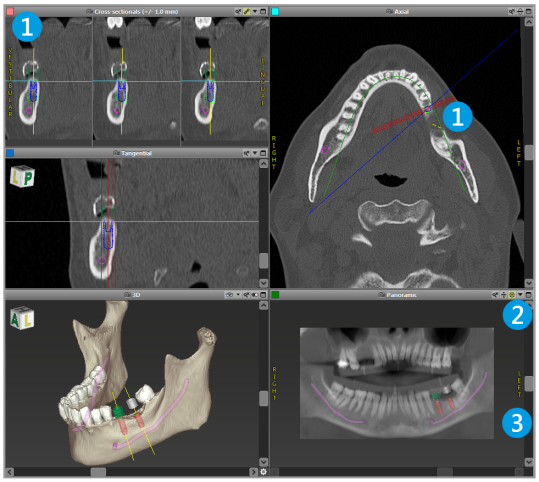
- To add further icons, drag and drop the icon from the box onto the toolbar.
- To remove icons from the toolbar, simply drag them off the toolbar (with the dialog box opened).



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.

5.2 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).

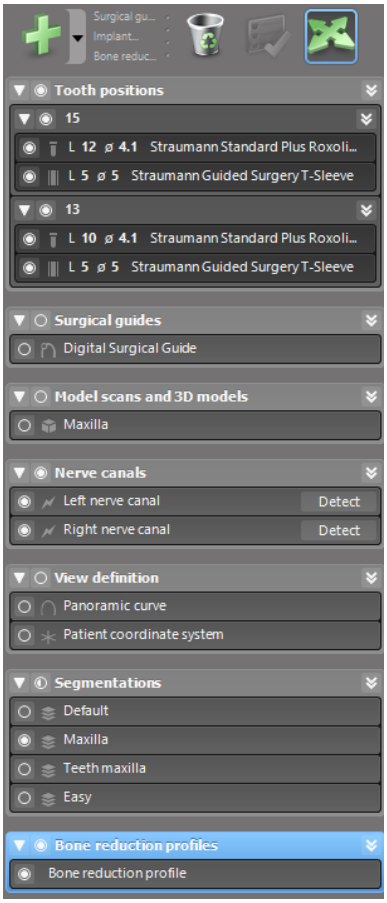
Manipulating the views: most important tools

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. Use this functionality to enhance visibility of details and accuracy of measurements, see chapter *Measurement functions* (p. 71)	
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 to the axis of the currently selected implant or other surgical instrument (at least one item must have been planned).	
Toggles **full screen mode** (maximizes view)	

5.3 Object tree

The Object tree contains:

- Tree functions (e.g. add, delete)
- All the objects (e.g. implants, other surgical instruments, nerve canals, measurements, model scans, cut bone profiles, surgical guides)
- Tooth position panel (currently selected tooth position)
- Provides all the information about the implant or other surgical instruments 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.
- 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.	

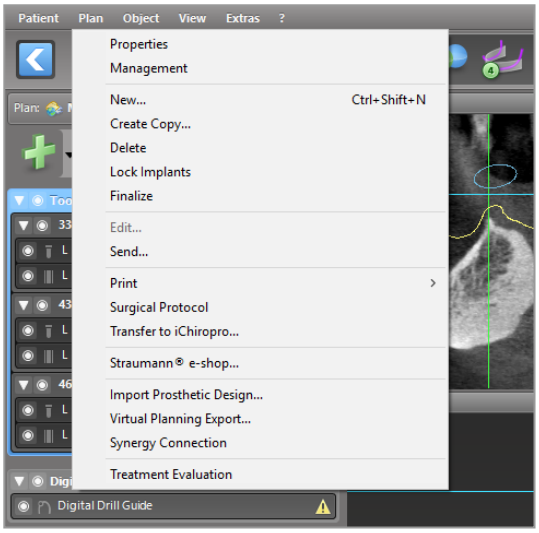
5.4 Plans

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.

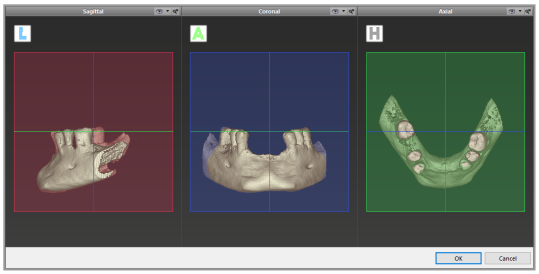


6. EXPERT mode: Step by step case planning

6.1 Align patient coordinate system

- Click **Align patient coordinate system** in the toolbar.

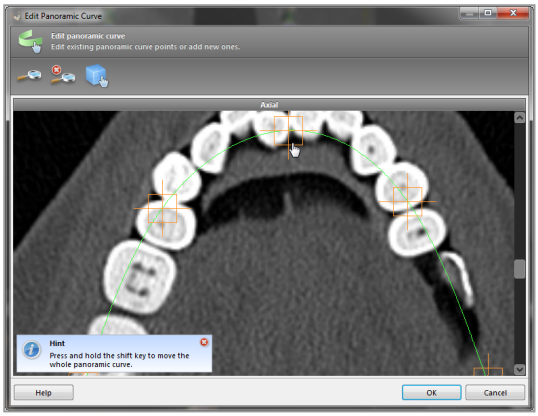
- Make the green plane coincide with the patient's occlusal plane and the red plane with the patient's sagittal plane.
  - Move the patient coordinate system (PCS) with the left mouse button.
  - Rotate the PCS with the right mouse button.
- Click **OK** to save the alignment.



6.2 Panoramic curve

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

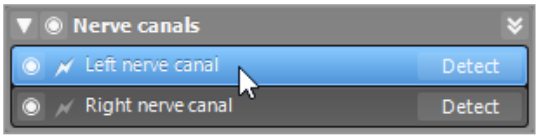
- Grab the points with the left mouse button and move the curve according to the patient's anatomy.
- To create additional points, click outside the existing five basic points.
- To delete additional points, right-click on the point and select **Delete Point** from the context menu. The five basic points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



6.3 Detect nerve canal

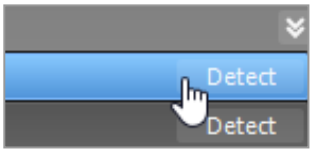
- Click the **Nerve Canal** icon from the toolbar to add the nerve canal objects. The positioning mode is activated automatically.

- 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.



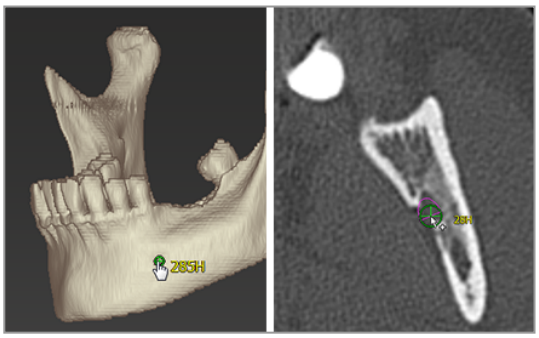
Automatic detection

- 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.



For further information on safety distance to the nerve canal, see chapter *Safety checks* (p. 72).

⚠ **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.

6.4 Plan surgical treatment

coDiagnostiX allows for surgical planning in dentistry for various treatments. The planning depends on the requirements of the treatment and the patient situation.

The planning follows - alone or in combination - basic principles:

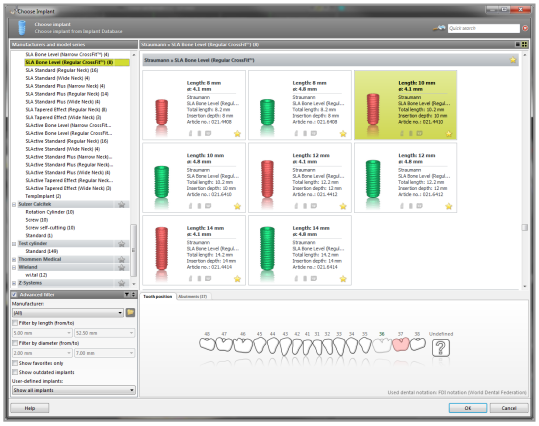
- Plan a surgical path along a trajectory
- Plan a surgical path along a profile
- Plan a form suitable to evaluate surgical preparation or other surgical steps

Plan implant

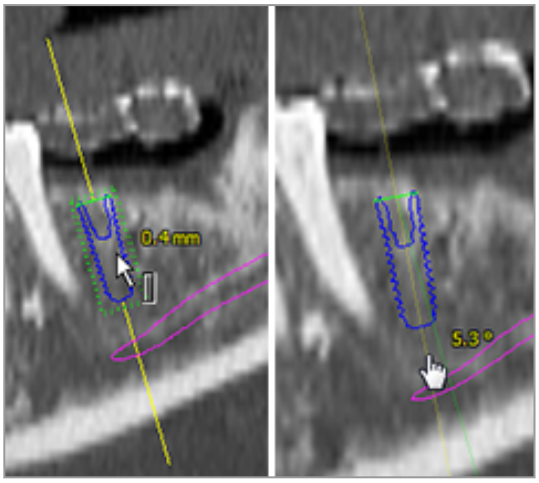
Planning an implant follows the basic principle of planning a surgical path along a trajectory. The planning defines the orientation of a surgical item (including surgical instruments).

- Click the **Add Implant** icon from the toolbar. The Master 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.

Note

The planning of **endodontic drills** and **fixation pins** follows the same principle.

For further information on safety distance between implants, see chapter *Safety checks* (p. 72).

> ⚠ **Caution**
>
> Always maintain an appropriate distance around the implant.
>
> Keep in mind that coDiagnostiX endodontic planning is intended only for planning a straight path to the starting point of the root canal. The treatment of the root canal is not supported by the guide.

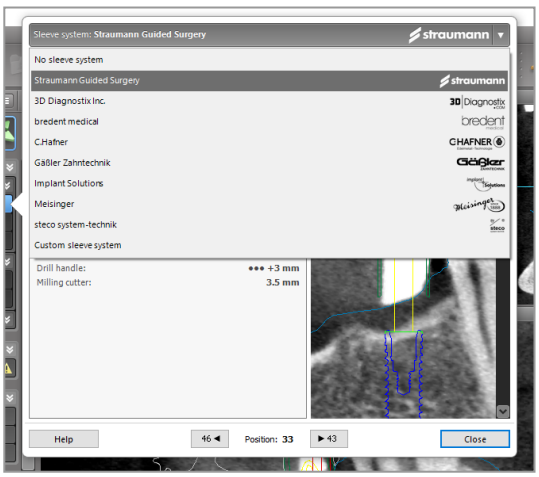
Plan sleeves

Planning a sleeve follows the basic principle of planning a surgical path along a trajectory.

- Select your implant or other surgical instrument 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.

Plan bone reduction profile

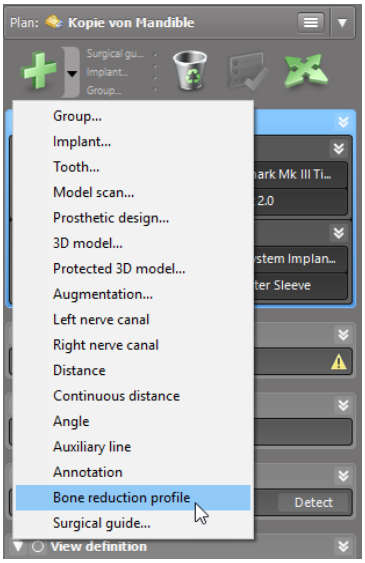
Planning a bone reduction profile follows the basic principle of planning a profile whereby the surface of the profile defines the orientation of the surgical instrument.

Preparation:

- Align the **patient coordinate system**.
- Define the **panoramic curve** close to the bone reduction.
- Define all **implants, pins and sleeves**.

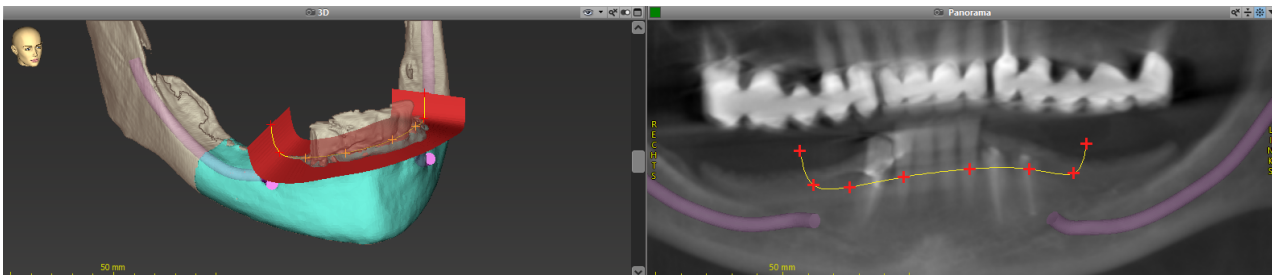
Creating the bone cut profile:

- Add a **bone reduction profile** from the object tree. A new panel will appear.



Place **reference points**:

- Click **Add implant base points** in the object tree to automatically create **reference points**, or click in the panoramic view to manually add, edit or delete **reference points**.



- Adjust parameters (offset, angulation) as needed and check the position of the cut profile in reference to the implant position. Create a segmentation of the jaw bone without teeth and convert to 3D model (for further instructions on segmentation, consult the coDiagnostiX User Help).

🕮 **Note**

The planning of **apicoectomy**, **external sinus lift** and **gingivectomy** procedures follows the same principle.

Plan tooth auto transplantation

Planning a tooth auto transplantation follows the basic principle of planning a form that is suitable for the evaluation of a surgical preparation or other surgical steps.

- Select a donor tooth in the segmentation mode
- Create a segmented STL file of the selected donor tooth and convert it into a model
- Plan virtual auto transplantation of the donor tooth with the correct angulation, rotation and accurate positioning

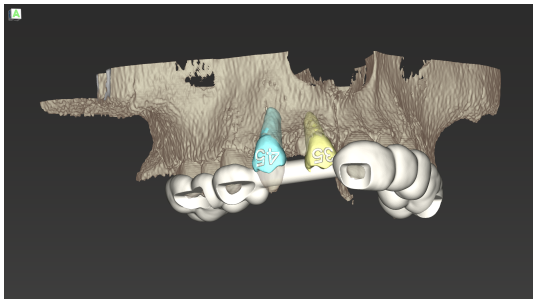


Figure 1: A finished tooth auto transplantation guide for two donor teeth

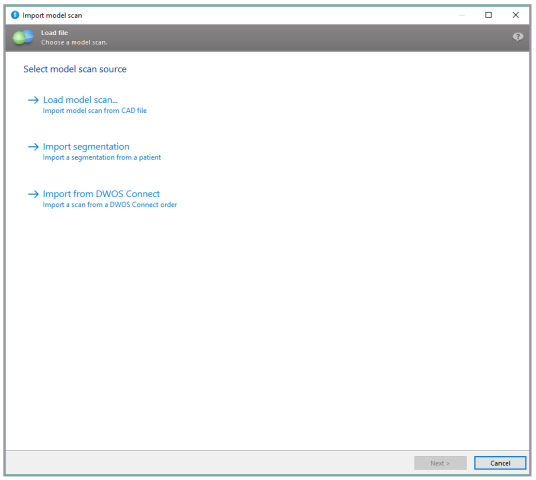
🕮 **Note**

Bone augmentation and **orthognatic planning** follow the same principles.

6.5 Import and match model scan data

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

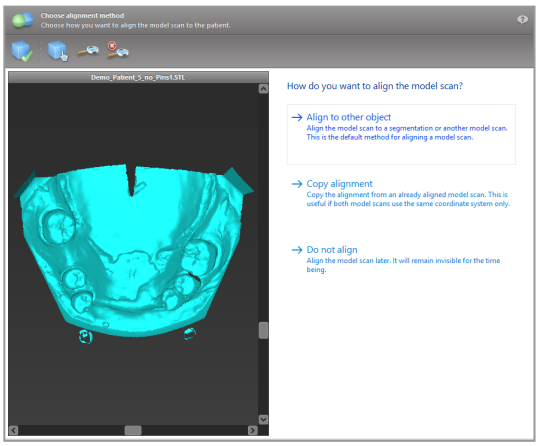
- Select the model scan source (CAD file, segmentation, DWOS Connect order).
- Select the file and load it.



Note

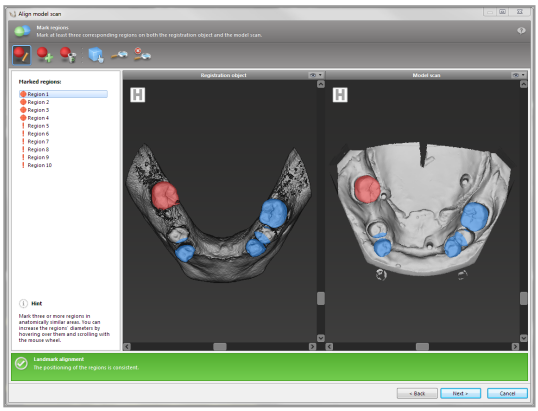
To import a DWOS Connect order, you need to log in to DWOS Connect first. Log-in credentials are provided to you with the scanner device.

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



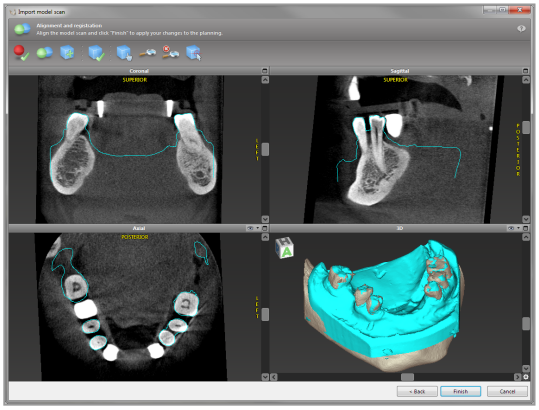
- Select the registration object (segmentation of volume data or previously imported model scan) that you want to use for matching. Model scan and registration object must cover analogous anatomical regions.

- 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 surgical guide design. Matching accuracy directly influences the accuracy of the designed surgical guide.

Inadequate surgical guides may result in damage to vital anatomy at the time of surgical procedure.

- 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.

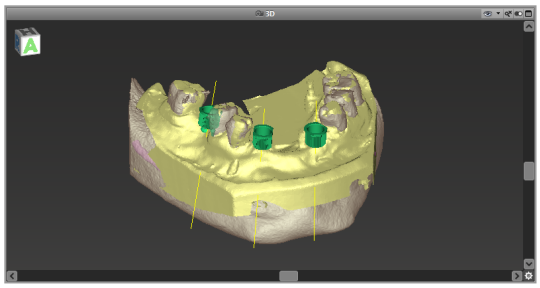
6.6 Design the surgical guide

The surgical guide - alone or in combination:

- assures that the path, which defines the alignment orientation of the surgical instrument, is followed during the surgical procedure
- assures that the profile, which defines the orientation of the surgical instrument along a profile, is followed during the surgical procedure
- evaluates the results of a surgery during the surgical procedure

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.
- For a **bone reduction guide**, prepare a 3D bone surface model (segmentation of jaw bone without teeth).



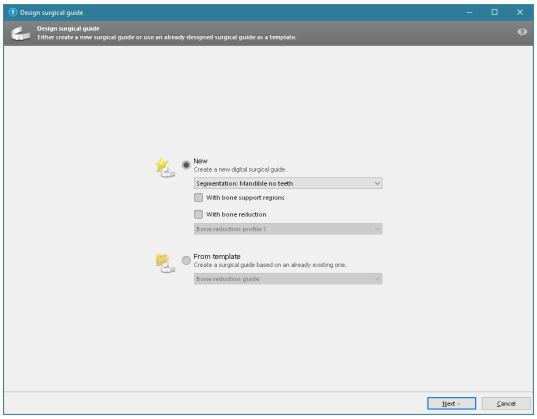
⚠ Caution

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 surgical guide design. Matching accuracy directly influences the accuracy of the designed surgical guide.

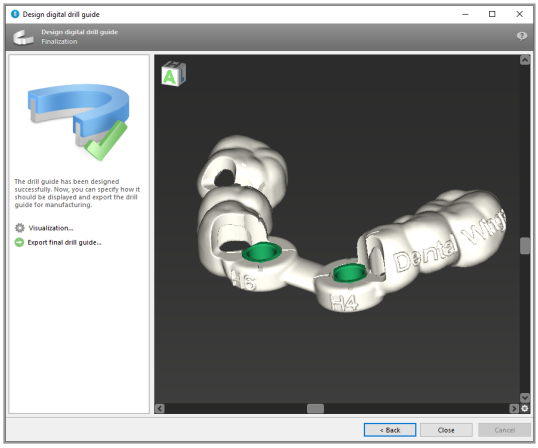
Inadequate surgical guides may result in damage to vital anatomy at the time of surgical procedure.

Design wizard

- Click the **Add Surgical Guide** icon in the toolbar to open the wizard.
- Decide if you want to create a completely new surgical guide or use an existing guide as template.

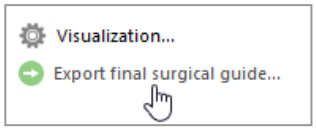


- Define the insertion direction for the surgical guide. If you are working with the dual scan method, tick **Use bottom side of dual scan**.
- If required, define regions for bone support.
- Define contact surfaces and adjust sleeve mount settings. If required, draw contact area for palatal support.
- Set offset, wall thickness and connector thickness.
- Specify the parameters for the bone reduction bars (only available if **With bone reduction** box was ticked in start screen of the wizard)
- Add inspection windows (optional).
- Add label text (optional).
- Finish your guide.



For further information on accuracy of surgical guides, see chapter *Safety checks* (p. 72).

Export



- Export your surgical guide (not applicable for all license models of coDiagnostiX, see *Licensing Matrix* (p. 83)).
  Make sure that the surgical guide you are going to export represents the final planning state.

For further information, see the coDiagnostiX User Help.

⚠ Caution

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

Make sure that the inspection windows placed in the digitally designed surgical guide do not affect the stability of the final surgical guide. Otherwise there is the risk of inaccurate 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.

🕮 Note

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

Combination guides

While designing, guides can be combined using different methods. They can either be integrated into each other or stacked onto each other.

Example for integrated guides

Implantation guides can be designed as such, that the guide design allows for the evaluation of the surgical situation as well. Figure 2 shows in yellow the form planned to evaluate bone augmentation. During the surgical procedure, a pin can be used to review whether the bone augmentation is sufficient.

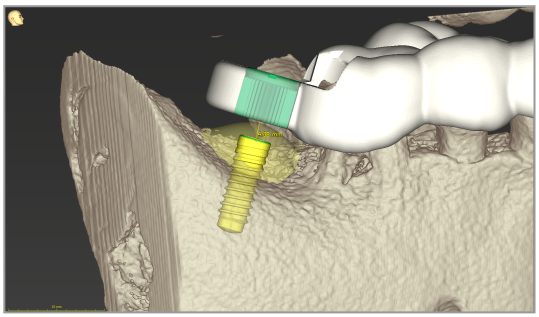


Figure 2: Integrated guide combining implantation and bone augmentation

Example for stacked guides

In cases where implant planning requires a prior bone reduction, the guides can be stacked.

This requires three guides:

- a pin guide
- a bone reduction guide
- an implantation guide

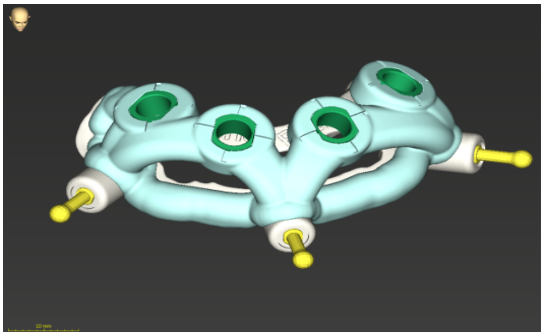


Figure 3: Stacked guides combining implantation and bone reduction

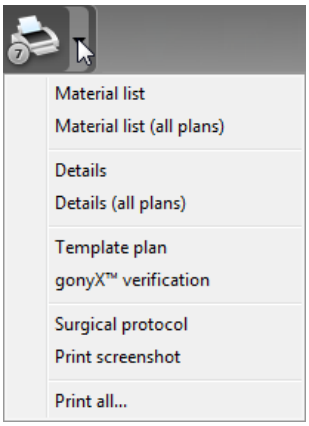
Design the bone reduction guide based on the location of the pins. Fix the bone reduction guide with the pins, then stack the implantation guide onto the bone reduction guide, as shown in figure 3.

It is possible to design the pin and bone reduction guides as integrated guides. In the stacked guides procedures as described here, the pin guide is not integrated, however. Remove it directly after drilling the pin holes.

6.7 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 or other surgical instrument providing detailed 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.

7. Optional and supporting functionalities

The following functionalities are only available in EXPERT mode.

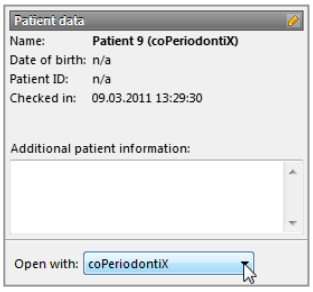
7.1 coPeriodontiX

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 CBCT or CT data. The tool 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.

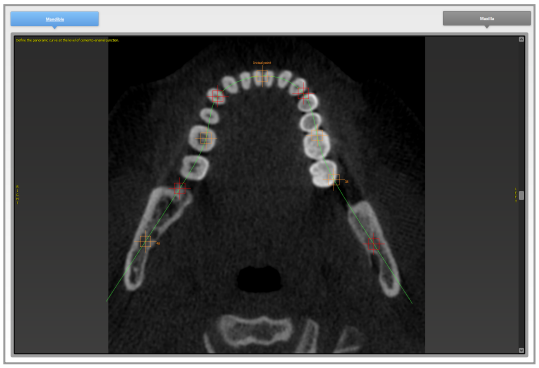
Open coPeriodontiX to start periodontal charting

- 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 *Panoramic curve* (p. 49)).

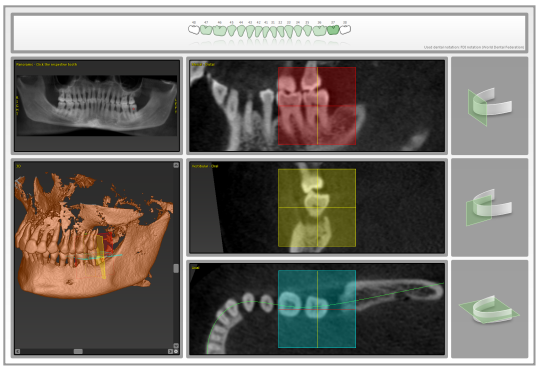


Define the tooth coordinate system

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.

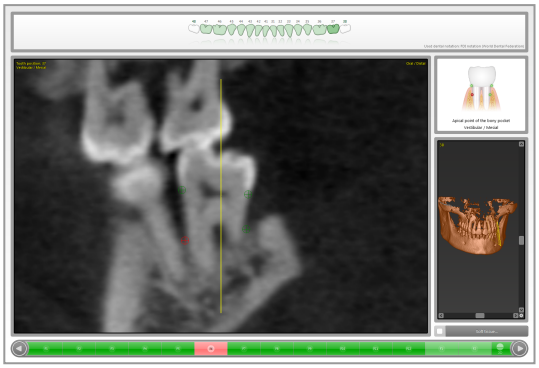


Set measuring points

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).

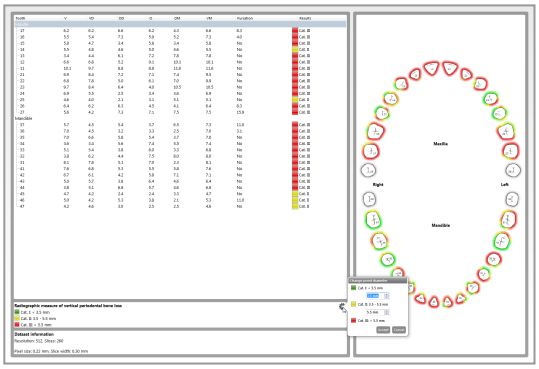
This way, four points can be set in one sectional plane.

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.

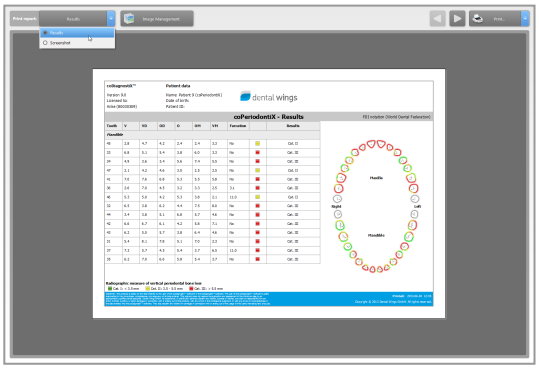


Print results

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.

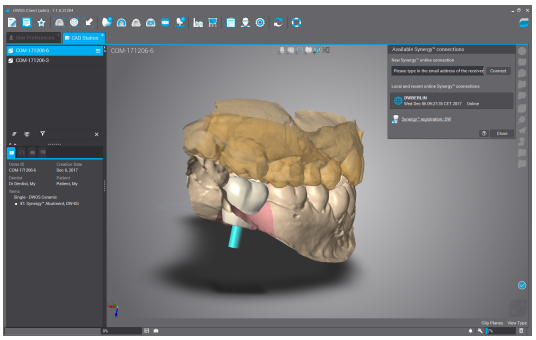
7.2 DWOS Synergy

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

Collaboration is possible:

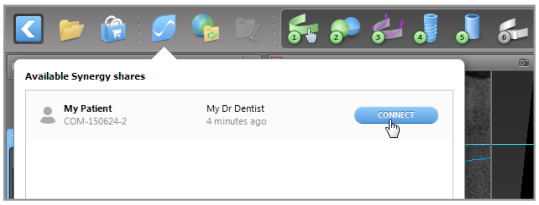
- in local networks
- through the internet (with a DWOS Synergy account)

DWOS resp. Straumann CARES Visual side



- Create an order.
  DWOS 4 & 5/CARES Visual 9 & 9.5:
  Indication group: **Others**; Indication: **coDiagnostiX abutment**
  DWOS 6 & 7/CARES Visual 10 & 11:
  Synergy order
- In the CAD application, 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

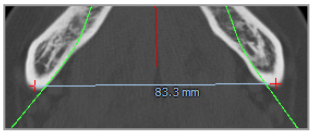


- Open the coDiagnostiX dataset for this patient.
- In the planning view, click the **Synergy** icon and connect with the shared dataset.
- Match the surface data with the patient's DICOM data.

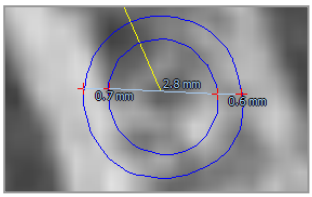
7.3 Measurement functions

coDiagnostiX offers the following measurement functions. They can be accessed by selecting **Object** > **Add** from the main menu.

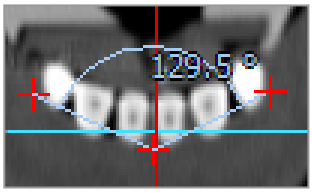
Distance measurement: Distance between two points in mm



Continuous distance: Distance between several points in mm



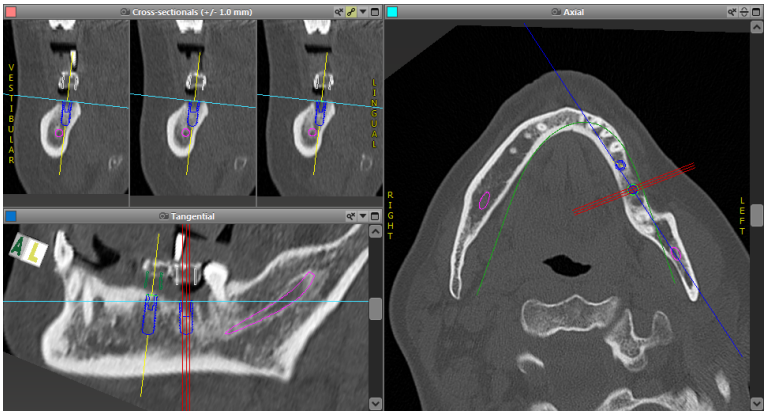
Angle measurement: Angle in degrees (°) spanned between two lines which are defined by three points



Using the **Zoom** tool increases measurement accuracy (see *Manipulating the views: most important tools* (p. 44)).

8. Safety checks

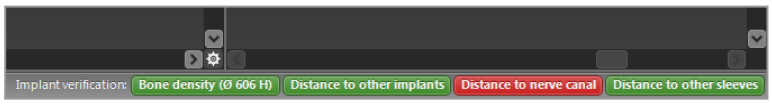
✓ Always align all 2D views to the implant axis and rotate around the implant to ensure correct positioning and to avoid any collisions. This also applies for other surgical instruments.



✓ Always consult collision warning and critical nerve distance warning.

Distance warning

EXPERT mode



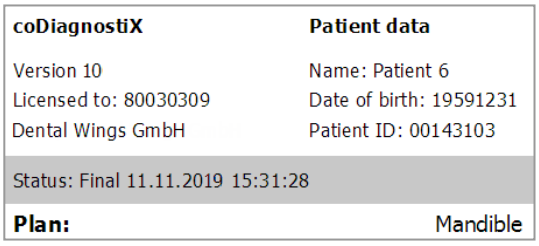
EASY mode

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).



Accuracy

- ✓ Always give the information concerning CBCT or 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. surgical 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.

- ✓ General prerequisite for accurate 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 planning with coDiagnostiX, the accuracy of the surgical guides and the location of the surgical site depend on the following factors:

  - The quality of the CBCT or CT/model scan data
  - The precision of aligning model scan data with CBCT or CT data by the user
  - Errors in design of the surgical guide software model such as using incorrect surgical instruments or inaccurate surgical instrument placement
  - Errors in production of surgical guide by the laboratory
  - Failure to check fit of the surgical guide on the model prior to use
  - Failure to check fit of the surgical guide on the patient prior to surgery
  - Surgical 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 surgical guide; instrument wear or incorrect surgical instrument selection can result in a loose fit and positional inaccuracy

9. Maintenance

coDiagnostiX does not require any maintenance by the manufacturer during its product life cycle (see *Product life cycle* (p. 7)).

However, the user is responsible to:

- Ensure that data are regularly backed up to prevent loss of data (see chapter *Data protection* (p. 19) and section *Management* (p. 25) of chapter *coDiagnostiX start screen* (p. 25)).
- Update the software as indicated under *Product life cycle* (p. 7) to maintain regulatory compliance beyond the original product life cycle. With an active internet connection, the user is automatically notified about pending updates. To check for updates manually, open the **Help (?)** menu and select **Dental Wings Online** > **Check for New Updates**.

10. Distributors and service

In case of questions, please contact your local distributor.
Alternatively, contact **coDiagnostiX.support@dental-wings.com** (in English or German).

11. Technical data and label

11.1 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

11.2 Hardware and software requirements

Mandatory hardware/software	
Memory	Minimum: 8 GB RAM
Hard disk	Minimum: 128 GB

Mandatory hardware/software	
Storage space	■ Installation: 5 GB of hard disk space required ■ Free disk space for patient datasets and swap/cache files: Make sure a minimum of 10 GB of free disk space is available prior to each start of coDiagnostiX. Note: If system and database are not located on the same drive, 10 GB of free disk space will be required on both the system and the database drives.
CPU	x86 compatible processor supported by the operating system (at least Intel® Core™ 2 Duo processor P8600)
Peripheral devices	■ Monitor ■ Keyboard ■ 2-button mouse (mouse with scroll wheel recommended) ■ One free USB port ■ Optional: 3Dconnexion SpaceNavigator
Operating system	■ Microsoft® Windows® 10, 64-bit recommended (other supported operating systems: Windows® 8, 64-bit, Windows® 7 64-bit) Additional requirements for running coDiagnostiX on Apple Mac OS X: ■ 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	■ 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	■ DVD drive ■ DVD burner ■ Printer ■ 3D mouse: 3D mouse by 3Dconnexion
Document reader	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 ■ WiFi: Transmission rate at least 11 MBit/s or ■ Network card: Transmission rate at least 10 MBit/s
Additional requirements for the coDiagnostiX Network Database SQL module	■ Microsoft® SQL Server® required
Additional requirements for a coDiagnostiX Network License	■ 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 Visual stations. For compatibility of coDiagnostiX and DWOS or CARES Visual versions, see *Compatibility information* (p. 18).

Network configuration	
caseXchange	■ Client: port 443, outgoing
Online Updater	■ 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	■ Client: TCP port 54237, UDP port 21945, both outgoing ■ Server: TCP port 54237, UDP port 21945, both incoming

DWOS Synergy

Unless you collaborate via internet, it might be useful, for performance reasons, to 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 (see *Distributors and service* (p. 76)).

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):

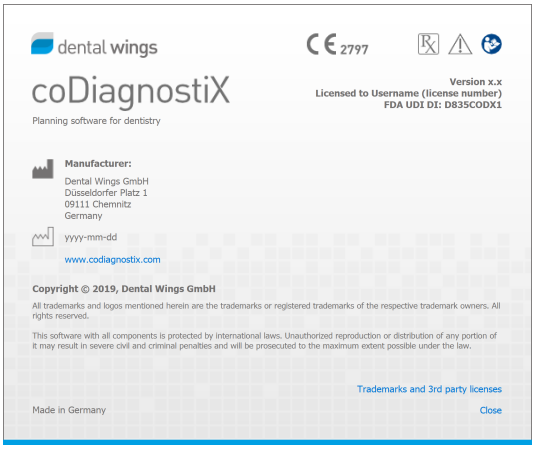
DWOS Synergy server		
Port 15672	RabbitMQ server administration interface	Incoming
Port 61613	STOMP protocol – communication with coDiagnostiX	Incoming
Port 5672	AMQP protocol – communication with Dental Wings DWOS or Straumann CARES Visual	Incoming
Port 61615	STOMP message queue dispatcher	Incoming
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

11.3 Label

The product label is found in the software **About** box.

On the start screen, select **Help (?)** > **About** from the main menu to open the About box.



11.4 Supporting information for CBCT or CT scans

The production of CBCT or 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 planning in dentistry 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.

11.5 Licensing Matrix

coDiagnostiX license features	PRODUCER	CLIENT	EASY	EASY CHAIRSIDE
Basic functionalities				
Planning	●	●	●	●
Safety	●	●	●	●
Data Import	●	●	●	●
Data Output	●	●	●	●
Surgical guide design	●	●	●	●
Export functionalities				
Surgical guide export	●			●
Collaboration				
Transfer cases via caseXchange	●	●	●	
Transfer cases via archive exchange	●	●		
Other Functionalities				
Advanced functions	●	●		

For an exhaustive licensing matrix please contact your local distributor (see *Distributors and service* (p. 76)). coDiagnostiX license features may be promoted in marketing material.

12. Explanation of symbols

Caution, consult Instructions for Use for important cautionary information

Device fulfills the requirements of the European directives given on the EU Declaration of Conformity

Consult Instructions for Use (On medical devices: *Follow Instructions for Use*)

Follow instructions for the User Manual.

Indicates the device's legal manufacturer

Indicates the date when the 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

Caution: US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

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coDiagnostiX
Instructions for Use
CDX-070-EN v. 14.1 2019-08-16

Distributor stamp