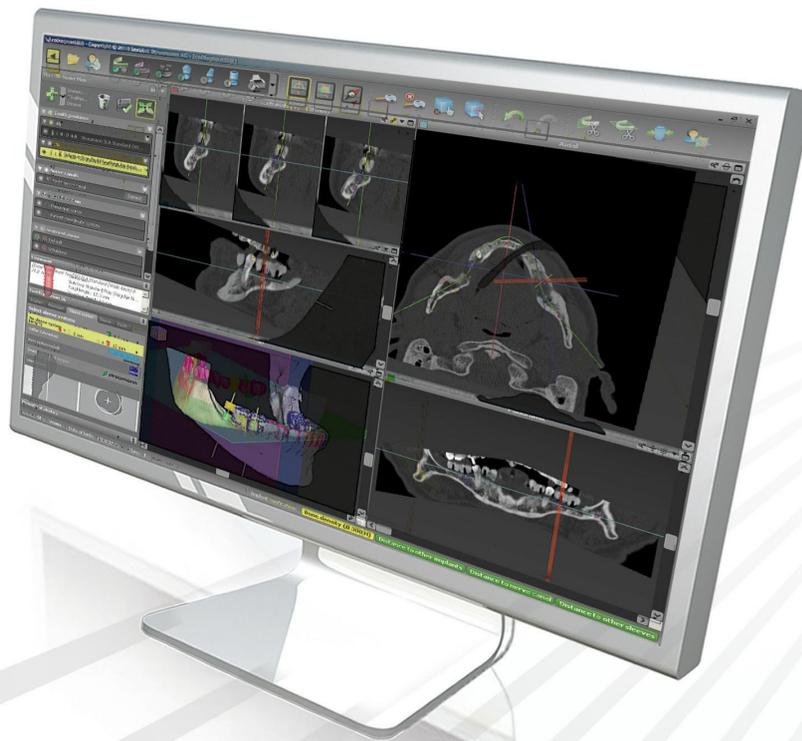


coDiagnostiX™ 9.0

INSTRUCTIONS FOR USE



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1. ABOUT THIS GUIDE

These Instructions for Use are valid for the product life cycle of coDiagnostiX™ 9.0 unless new instructions are published within this period.

Electronic Instructions for Use

coDiagnostiX™ 9.0 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.

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 digital 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.

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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.

However, legal and regulatory requirements change at regular intervals. The legal manufacturer does, therefore, not ensure compliance with the regulatory framework beyond the product life cycle period of 3 years. Update your software after the end of its product life cycle to maintain regulatory compliance.

Input data

The performance of coDiagnostiX™ depends on the quality and accuracy of the CT and/or DVT scan as well as IO, model or impression 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 scan. CT and DVT 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

Software 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.

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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 3D implant planning software allowing the import and processing of the 3D CT/DVT scan dataset (DICOM standard). Based on the finalized implant planning, the software allows for export of data for the production of drill guides using 3D manufacturing systems or the analog gonyX™ table. In the analog workflow the patient has to wear a scan template with reference pins during the CT/DVT scan.

Working with the software is based on a patient's medical image data such as a CT (Computed Tomography) and DVT (Digital Volume Tomography) that is processed by coDiagnostiX™ after being transferred via CD/DVD, network or various other storage mediums.

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 drilling sleeves.

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.

For drill guide fabrication with the gonyX™, a template plan from coDiagnostiX™ is required

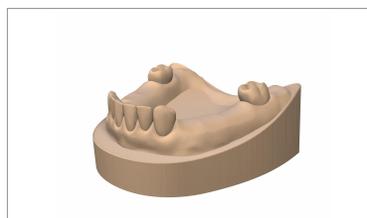
2.2.2 Principles of operation

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

- Analog workflow using gonyX™ and its accessories
- Digital workflow using 3D manufacturing systems

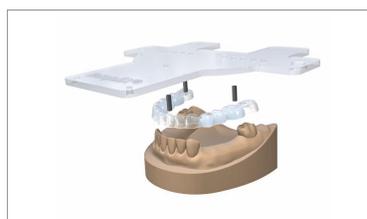
2.2.2.1 Analog workflow

The master model represents the patient situation and is the basis for the production of the scan template and drill guide [2, 5].



[1] Master model fabrication

The scan template contains information about the desired prosthetic outcome in form of radiopaque teeth (visible in CT/DVT scan [3]). The scan template has to be connected to the templiX plate containing three reference pins with the gonyX™ in order to ensure the link between digital implant planning and drill guide fabrication [4, 5].



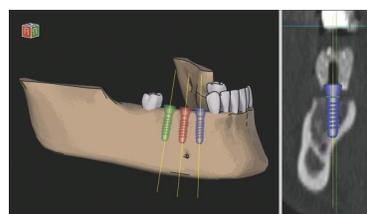
[2] Scan template fabrication

The patient is scanned wearing the scan template with a commercially available 3D CT/DVT scanner.



[3] CT/DVT scanning

The user can import the 3D dataset (DICOM) directly into coDiagnostiX™ planning software. Each implant is positioned with respect to the patient's anatomy and the desired prosthetic outcome. After completion of implant planning, the software provides the plan for drill guide production with the gonyX™ [5] as well as further print protocols [6].



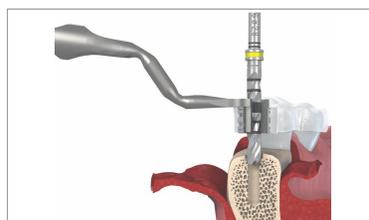
[4] 3D implant planning

The drill guide is produced with the gonyX™ according to the template plan that is provided by coDiagnostiX™ for each implant [4]. The drill guide contains the surgical sleeves that guide the surgical instruments and the implant [6]. There is no need to produce a new guide. If desired, the scan template [2] can be reworked into the drill guide.

During guided surgery, the drill guide [5] is fixed in the patient's mouth. Implant bed preparation and guided implant insertion is done using appropriate guided instruments which have to be compatible with the used implant and sleeve systems.



[5] Drill guide fabrication



[6] Guided surgery and implant insertion

2.2.2.2 Digital workflow

The patient is scanned with a commercially available 3D CT/DVT scanner [1]. A scan template is not necessary.

[1] CT/DVT scan without scan template

The patient's mouth is scanned with an intra-oral (IO) scanner. Alternatively, a surface scan of the master model or an impression scan can be used [2]. Such scan is required to ensure an accurate fit of the digital drill guide.

[2] IO scan of patient/surface scan of master model/impression scan

The CT/DVT scan (DICOM data) [1] and the IO/surface scan/impression scan (e.g. STL data) [2] are imported and matched in coDiagnostiX™. For partially edentulous cases use the remaining teeth for matching; for edentulous cases use temporary implants.

[3] 3D planning

Each implant is planned according to the patient's anatomy and the desired prosthetic outcome [3].

After completion of the planning process, the digital drill guide [4] has to be designed and is subsequently exported as STL file.

The STL file of the drill guide, which has been designed in coDiagnostiX™ [3], is sent to a calibrated 3D manufacturing system. The drill guide is produced and sleeves are inserted.

[4] 3D manufacturing and sleeve insertion

During guided surgery, the drill guide [4] is fixed in the patient's mouth. Implant bed preparation and guided implant insertion is done using appropriate guided instruments which have to be compatible with the used implant and sleeve systems.

[5] Guided surgery and implant insertion

2.2.3 Accessories and products used in combination

Analog workflow using gonyX™ and its accessories

The use of the following products and accessories in combination with coDiagnostiX™ has been validated:

gonyX™

Device for scan template and drill guide fabrication by the dental laboratory. gonyX™ accessories include:

Straumann® reference pin and templex reference plate

Devices for scan template production.

Straumann® scan control bar

Additional device for enhancement of quality of CT/DVT scans.

Straumann® generic sleeve positioner including closing lid

Device for sleeve positioning with gonyX™.

Other products may, in principle, be suitable as well. However, the user has to validate their compatibility with coDiagnostiX™.

Digital workflow using 3D manufacturing systems

3D manufacturing system

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

The digital workflow has been validated with the Objet Eden 260 V printer and the material Med 610. Each 3D manufacturing system which fulfills the requirements above may, in principle, be suitable. The validation of such other 3D manufacturing system's compatibility with coDiagnostiX™ lies within the responsibility of the user.

2.2.3.1 Computer hardware and software requirements

The following requirements are the minimum requirements recommended for smooth operation of coDiagnostiX™. However, under certain circumstances the software might also run on other configurations.

- Processor: Intel® Core™ or AMD Athlon™ 64 X2
- Main memory: 3 GB (of it 1.5 GB available for digital drill guide design and export)
- Hard disk: 1 GB of free storage space for installation and approx. 50 MB per patient case
- Monitor
- Keyboard and 2-button mouse
- DVD drive
- One free USB port
- Minimum screen resolution: 1024 x 768 pixels
- Operating system: Microsoft® Windows 8 recommended (other supported operating systems: Microsoft® Windows 7, Vista, XP)
- PDF reader

Optional components

- DVD burner
- Printer
- Internet connection
An internet connection is required, for instance, for online updates, remote support or online transfer.
- Network connection
A network connection is required for using the optional Network Database SQL or Network License.

Additional requirements for the coDiagnostiX™ Network Database

Working with the **Network Database SQL** module requires a Microsoft® SQL Server®.

Additional requirements for the coDiagnostiX™ Network License

- An 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)
- A permanent (W)LAN connection to the dongle server while running coDiagnostiX™ on the client computer
- Optional: Shared network drive to store the database

Network configuration requirements

- caseXchange™
Client: port 80, 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

Additional requirements for running coDiagnostiX™ on Apple® Mac OS® X

- Macintosh® computer with Intel® processor
- Mac OS® X 10.6 or newer
- 'Parallels Desktop' or 'VMWare Fusion' for Macintosh including valid Windows® license (software to be purchased separately)

Screen resolution requirements

For optimum usability of coDiagnostiX™, a screen resolution of 1680 x 1050 pixels or higher with 96 dpi is recommended. Color depth should be 32 bit, true color. The maximum resolution per view (3D reconstruction, virtual OPG, etc.) is 4096 x 3072 pixels.

2.2.3.2 Input data requirements

The software supports a wide range of image sources, including Computed Tomography (CT) and Digital Volume Tomography (DVT) as well as surface, intra-oral (IO) and impression scans from different manufacturers. It is also possible to work with other sliced image data or volume data.

Supporting information for CT/DVT scans

The production of CT/DVT 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.
- When using the analog workflow with the gonyX™, the patient must wear a scan template with reference pins during radiology. The reference pins must be completely visible in the CT/DVT scan (one slice above the pin is sufficient).
- Make sure that all components attached to the scan template are firmly fixed.
- Before placing the scan template into the patient's mouth, make sure to prepare such template according to dental standard operating procedures and the instruction for use provided for your material.

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.
- Block the opposite jaw bone using plastic material or cotton wool pads to avoid artifacts around the reference pins.
- Do NOT vary reconstruction parameters within a series (constant value for X and Y axis).
- Set a high-resolution bone algorithm, e.g.:
 - "Inner Ear"
 - "Bone"
 - "High"
 - No "EDGE"!
 - "AK 97"
 - "Ultra High"
- Parameters for a complete dataset when using dynamic mode:
 - Slices: 0.5 mm to 1.0 mm
- When using spiral mode, reconstruction to 1.0 mm slices or less 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.

Visualization of motion artifacts

In case of CT scans with scan template, motion artifacts can be visualized by attaching a scan control bar (available as accessory) to the template prior to scanning.

The performance of coDiagnostiX™ depends on the quality and accuracy of the CT and/or DVT scan as well as IO, model or impression 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 scan. CT and DVT devices must comply with the recommendations of ICRP97 (International Commission on Radiological Protection).

2.3 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 CT or DVT 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™ software allows for export of data to 3D manufacturing systems. Alternatively, coDiagnostiX™ provides printouts of template plans for the creation of drill guides using a manually operated gonyX™ table. The drill guide as well as a prior scan template are used in direct contact with the patient to facilitate accurate image registration within coDiagnostiX™ and the correct positioning and alignment of the implants as planned with the software.

2.4 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.

2.5 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.

Datasets with reference pins in both jaws (maxilla and mandible): The automatic pin detection of coDiagnostiX™ EASY cannot distinguish between pins in the maxilla and those in the mandible when scanned together. This can result in inaccurate planning. Accordingly, do not use the EASY mode to plan datasets with reference pins in both jaws (maxilla and mandible).

Automatic reference pin detection does not guarantee exact and accurate results. Make sure to always verify automatically detected reference pins manually.

Always visually check and verify the correctness and accuracy of reference pin detection.

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

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.

The gonyX™ verification should be printed directly from coDiagnostiX™ to a calibrated printer.

Correct dimensioning of the digital 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 digitally designed 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.

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 scan template or drill guide into the patient's mouth, make sure to prepare such template or 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.

2.6 Compatibility information

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™ 9.0 (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 scan templates or drill guides. Older versions of coDiagnostiX™, however, cannot work with datasets from coDiagnostiX™ 9.0 (no forward compatibility of older coDiagnostiX™ versions).

2.7 Further information

- gonyX™ Lab Manual
- coDiagnostiX™ Help

2.8 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.

2.9 Disposal

Use existing disposal systems to dispose of the data carriers and their packaging.

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.

1 Create dataset (DICOM)

Opens the **DICOM Transfer** 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 coDiagnostiX™ Management

coDiagnostiX™ Management provides access to a lot of administrative functions such as backup or language setting.

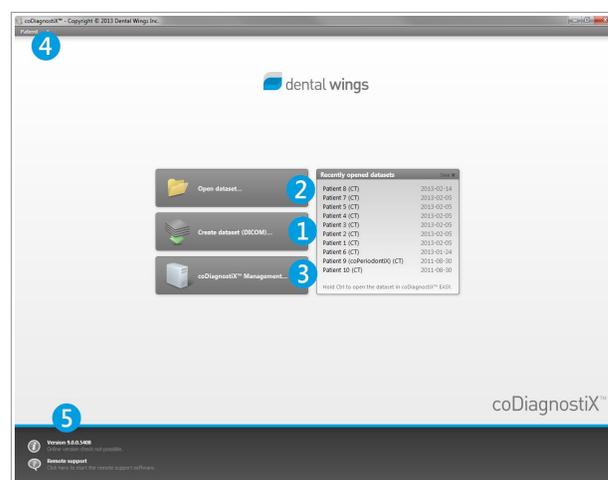
Archiving and restoring datasets in different versions of coDiagnostiX™ can cause compatibility problems.

4 Main menu

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

5 Updates and remote support

Shows information about updates and provides access to remote support (active internet connection required).



3.1 Toolbar



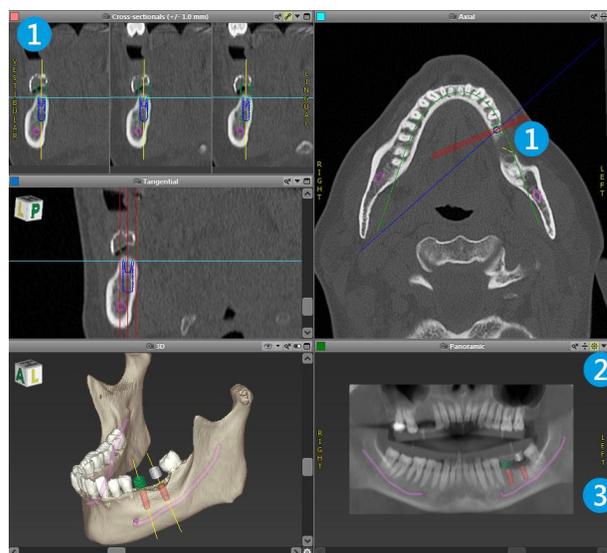
- 1 Tools of the interactive planning workflow.
- 2 Basic tools for view manipulation.
- 3 Menu with complete set of functions.

Customizing the toolbar

Right-click on the toolbar, select **Adjust** and drag the icon onto or from the toolbar.

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.
- 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.	
Resets all views and fits contents to 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)
- Comment field
- Tooth position pane (currently selected tooth position)
 - Provides all the information on the implant, abutment, sleeve and/or virtual tooth for the given tooth position and allows to adjust them.
- Density statistics

Moving/rotating objects

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



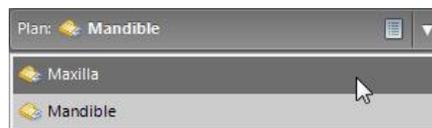
Objects: most important tree functions

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

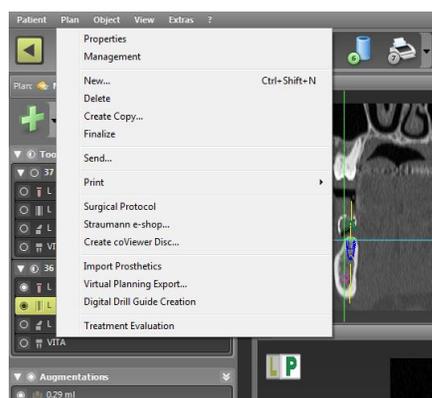
Working with different plans

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 you received from the CT/DVT scanner into the computer's disc drive.

- Click **Create dataset (DICOM)** 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 generate two separate plans.

coDiagnostiX™ switches to the standard planning screen.



⚠ 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.

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.

4.1 Import and match surface data

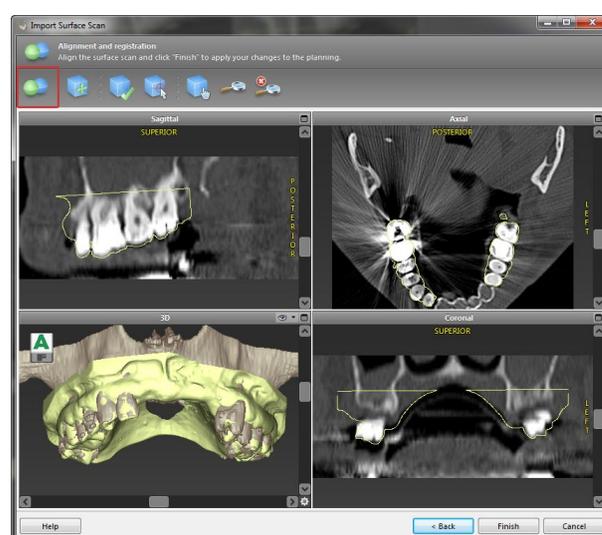
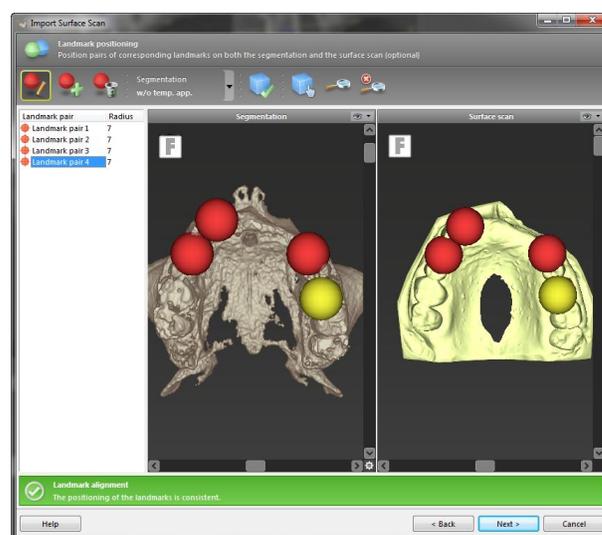
- Select **Object > Add > Surface Scan** from the main menu.
- Select the scan file you want to import and open the file.
- Choose the segmentation you want to use for surface matching. Scan and segmentation must cover analogous anatomical regions.
- Set a similar perspective for scan and segmentation using the sliders. Take care that the anatomical regions to be aligned are adequately visible.
- Set pairs of landmarks on the segmentation and the surface scan. To do so, select the landmark pair from the list, activate landmark positioning and click the appropriate position both on the segmentation and the scan.
 - For partially edentulous cases use the remaining teeth to place the landmarks.
 - For edentulous cases use temporary implants.

Landmarks 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.

- Perform automatic surface registration. 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 surface data is a prerequisite for digital drill guide design. Matching accuracy directly influences the accuracy of the digitally designed drill guide.

⚠ Caution

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 surface scan manually in all 4 views.
- Click the **Finish** button to apply the scan import to your case.

For more detailed information, consult the coDiagnostiX™ Help.

4.2 Define panoramic curve

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

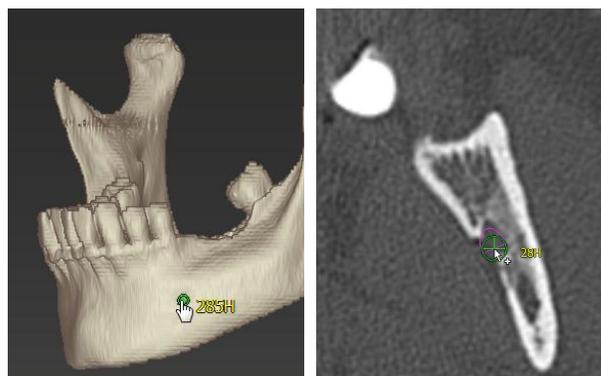


4.3 Detect nerve canal

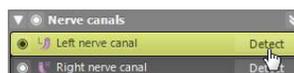
- Click the **Nerve Canal** icon to add the nerve canal objects. The positioning mode will be activated automatically.



- In the object tree, select the nerve canal you want to detect. Set the entry point foramen mentale and the exit point foramen mandibule directly in the views. Each nerve canal point can be moved and additional points can be added in all views. To support nerve canal detection, you can set as many nerve canal points as you want and in any view you like.



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



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.

4.4 Detect gonyX™ reference pins

- Click the **gonyX™ Registration** icon.

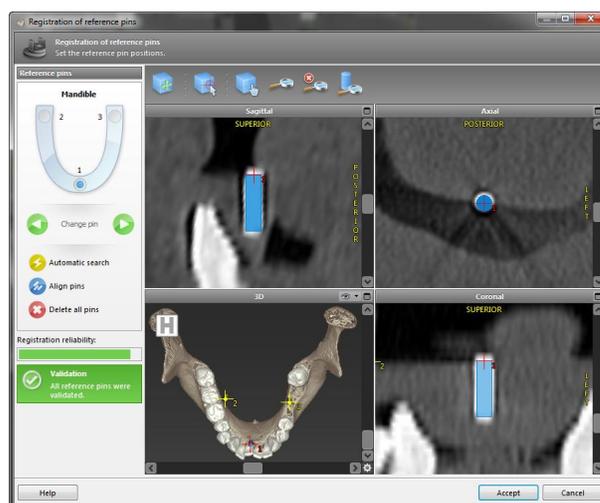


- Use the **Automatic Search** button to start automatic pin detection.
- Check your pin detection result for each reference pin. To do so, activate the reference pin in the work pane and check, in each single view, the correct alignment of the blue pin with the white pin in the scan. Adjust as necessary.

Adjusting reference pins with the mouse

- Move the reference pin with the left mouse button.
- Rotate the reference pin with the right mouse button.

- **Confirm** and **accept** reference pin validation.



⚠ Caution

Datasets with reference pins in both jaws (maxilla and mandible): The automatic pin detection of coDiagnostiX™ EASY cannot distinguish between pins in the maxilla and those in the mandible when scanned together. This can result in inaccurate planning. Accordingly, do not use the EASY mode to plan datasets with reference pins in both jaws (maxilla and mandible).

Automatic reference pin detection does not guarantee exact and accurate results. Make sure to always verify automatically detected reference pins manually.

Always visually check and verify the correctness and accuracy of reference pin detection.

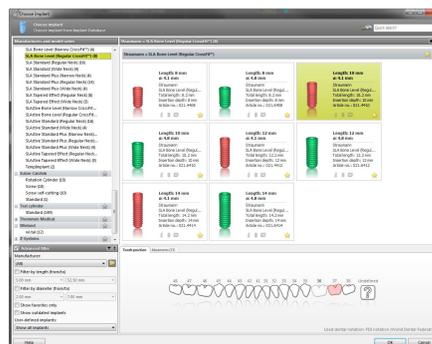
If pin detection is not clear due to poor image quality, the dataset must not be used.

4.5 Plan implant

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



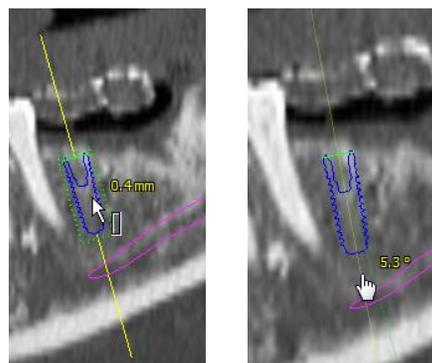
- Select the implant and the tooth position(s) where the implant(s) shall be placed. Click **OK** and the database closes.



- 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 with 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

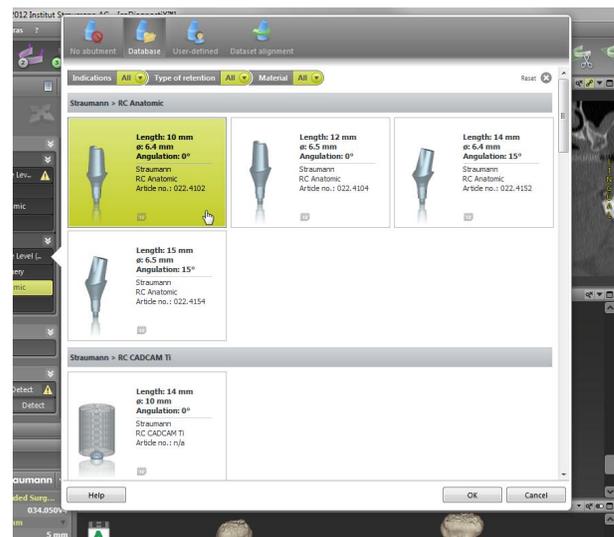
Always maintain an appropriate distance around the implant.

4.6 Plan abutments

- Select an implant in the object tree.
- Click the **Edit Abutments** icon.



- The dialog box opens.
- Switch to the **Database** tab and select the desired abutment.
- Click **OK** to apply your selection.



4.7 Plan sleeves

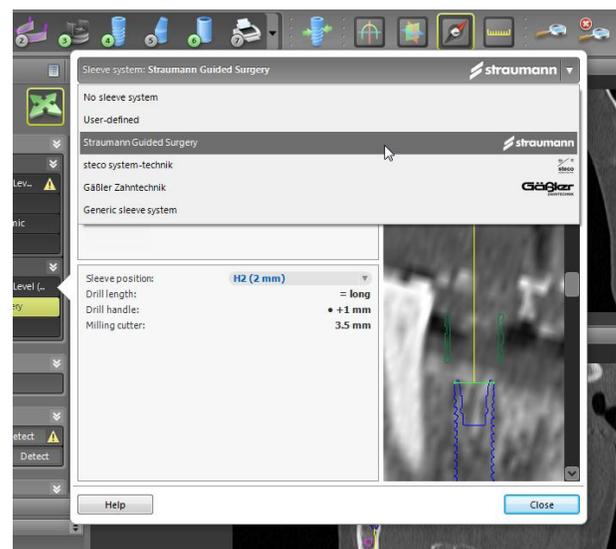
- Select your implant in the object tree and click the **Edit Sleeves** icon.



- 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.

Thoroughly verify all data before storing or using a preset for a generic sleeve system.



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 digital drill guide

Preparation

- Complete your planning.
- Import an IO scan, a surface scan of the plaster model or an impression scan. The scan must not include any wax-up or prosthetic setup.
- Match the scan and the corresponding segmentation.

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 surface data is a prerequisite for digital drill guide design. Matching accuracy directly influences the accuracy of the digitally designed drill guide.

Caution

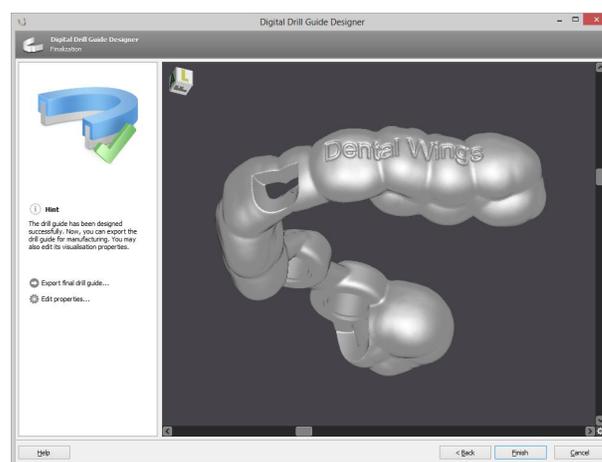
Inadequate drill guides may result in damage to vital anatomy at the time of surgical implant placement.

Design wizard

- Select **Plan > Digital Drill Guide Creation** from the main menu to open the wizard.
- Define the insertion direction for the drill guide.
- Set offset and wall thickness.
- Add inspection windows (optional).
- Export your drill guide.

For further information, see the coDiagnostiX™ Help.

Due to the completely digital workflow when calculating the digital drill guide there will be no practically relevant deviations. Measurements have shown a precision of 0.5 µm.



The accuracy of the drill guides and the location of the surgical site are also dependent on the following factors:

- The quality of the scanned CT/DVT/surface input data
- The planning accuracy on the part of the user
- The precision of aligning surface data with CT/DVT 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 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 digital 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 digitally designed 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.

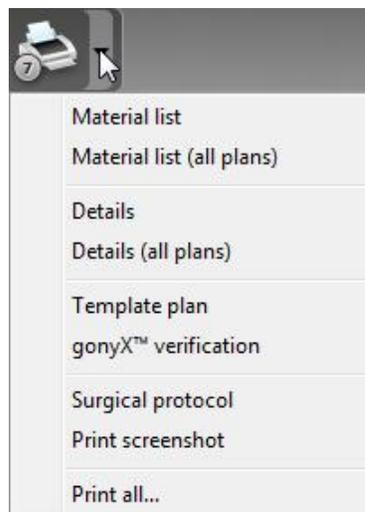
Please note that you are also responsible for the selection of an appropriate and calibrated 3D manufacturing system and the correct fabrication of the drill guide.

4.9 Print protocols

Click on the arrow of the **Print** icon in order to open the menu.

Most important print protocols

- **Template plan:** Required for drill guide fabrication with gonyX™ (analog workflow only).
- **gonyX™ verification:** Required to check the setting of the gonyX™ coordinates and to verify the final drill guide (analog workflow only).
- **Surgical protocol:** Protocol for using the guided instruments of Straumann® CARES® Guided Surgery.
- **Print all:** Defines a selection of protocols to be printed in one step.



⚠ Caution

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

The gonyX™ verification should be printed directly from coDiagnostiX™ to a calibrated printer.

Note that a gonyX™ verification protocol that is not printed on a calibrated printer, but saved as PDF instead, will not be calibrated.

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 DVT or CT data. The module offers 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

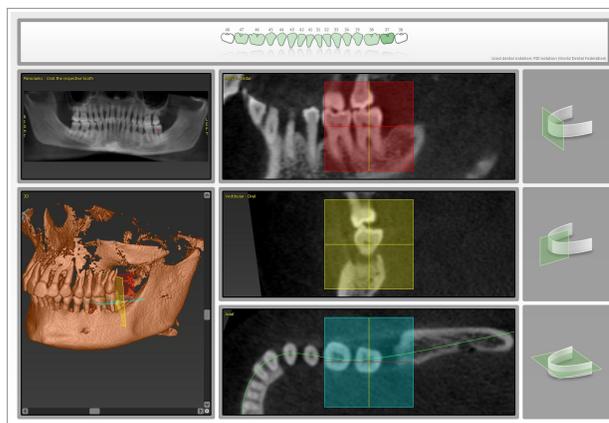
- Select the type of jaw (maxilla or mandible).
- Define the panoramic curve by placing panoramic curve points (see chapter Panoramic Curve).



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.

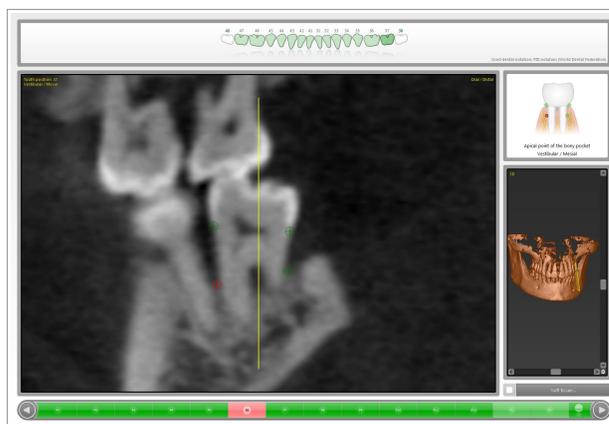


Set measuring points

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).

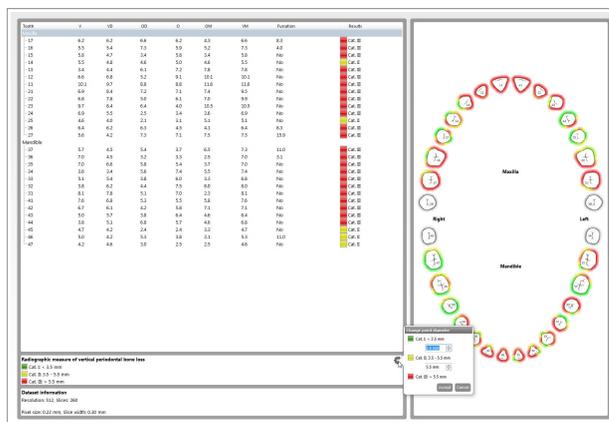
This way, four points can be set in one sectional plane.

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



Results

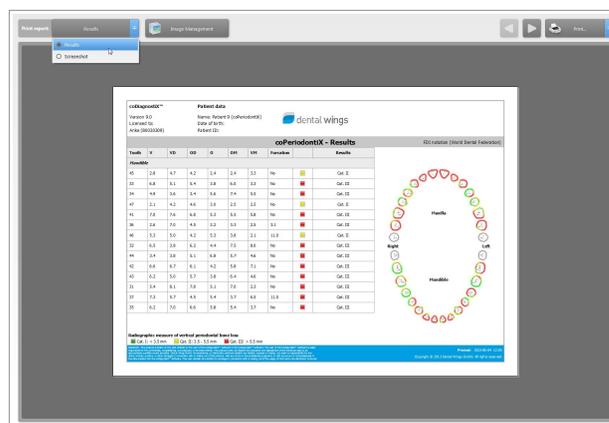
Radiographic vertical bone loss values are calculated and grouped in categories. Ranges for the categories can be defined by the user with the **cogwheel** button.



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**.

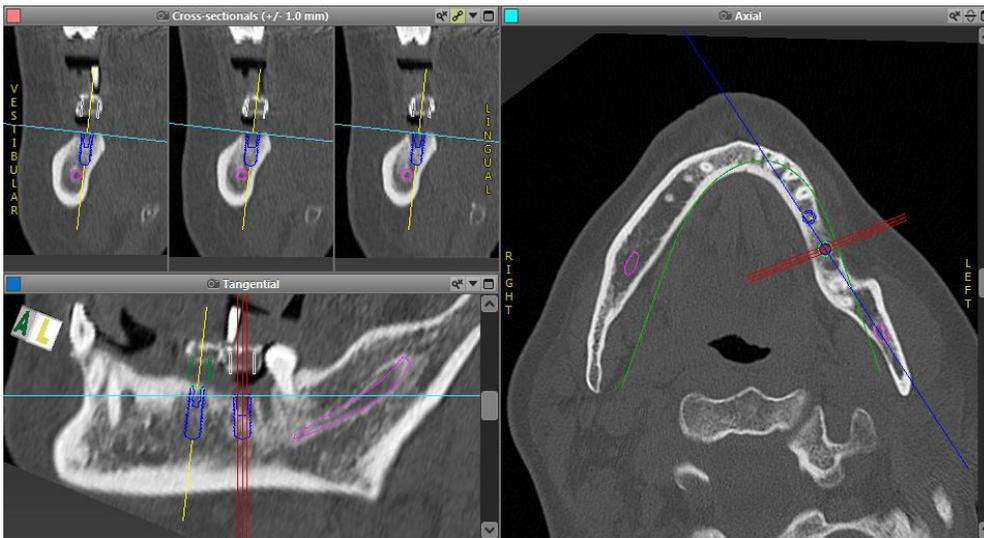


⚠ Caution

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

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.
- ✓ If the analog workflow is used, always ensure correct fit of scan template during radiology.
- ✓ Always give the information concerning CT/DVT scans (accessible via the **Help** menu in the software) to the radiologist before the first scan.
- ✓ Control all automatic functions of the software.
- ✓ After the planning is completed, always finalize the plan (**Plan > Finalize**) to ensure that the plan cannot be modified later.
- ✓ Check all printouts (template plan, gonyX™ verification, etc.) to ensure that they belong to the corresponding finalized plan.

coDiagnostiX™	Patient data
Version 9.0	Name: Patient 6
Licensed to:	Date of birth: 19591231
Institut Straumann AG, - (800...	Patient ID: 00143103
Status: Final 11/13/2012 10:38:01 AM	
Plan:	Mandible 1

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. 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

www.dental-wings.com



Dental Wings GmbH
Duesselderfer Platz 1
D-09111 Chemnitz
Germany

coDiagnostiX™ 9.0 INSTRUCTIONS FOR USE
18-06-2013 P003.02 v4