

DTX Studio[™] Clinic Version 4.3

Instructions for Use

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Introduction

Disclaimer of Liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendations of Nobel Biocare, hereinafter referred to as 'the Company'. Non-recommended use of products made by third parties in conjunction with products of the Company will void any warranty or other obligation, express or implied. The user has the duty to determine whether or not any product is suitable for the particular patient and circumstances. The Company disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of these products. The user is also obliged to study the latest developments in regard to this product and its applications regularly. In cases of doubt, the user has to contact the Company. Since the utilization of this product is under the control of the user, it is his/ her responsibility. The Company does not assume any liability whatsoever for damage arising thereof.

Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

Before using DTX Studio Clinic, please read these Instructions for Use and retain it for future reference. Please note that the information provided in this document is intended to get you up and running,

Device Description

DTX Studio Clinic is a software interface for dental/ medical practitioners used to analyze 2D and 3D imaging data, in a timely fashion, for the treatment of dental, craniomaxillofacial and related conditions. DTX Studio Clinic displays and processes imaging data from different devices (i.e. intraoral and extraoral X-rays, (CB)CT scanners, intraoral scanners, intraoral and extraoral cameras).

DTX Studio Clinic features an Al-powered Focus Area Detection algorithm which analyzes intraoral radiographs for potential dental findings or image artifacts. The detected focus areas can be converted afterwards to diagnostic findings after approval by the user.

The following dental findings can be detected by the device:

Caries: Caries is defined as caries, showing as area with radiographically lower density on a tooth, but does not include occlusal secondary caries under dental fillings.

Discrepancy at margin of an existing restoration: A discrepancy at margin is defined as radiographically visible discontinuities (gaps, spaces, overhangs) between outline/margin of dental restoration (e.g. fillings, inlays or crowns/bridges) and remaining tooth substance, also called as `misfit', `poor fit' or `not-perfectly seated'. Note that non-radiopaque cement/bonding material may radiographically appear as a space.

Periapical radiolucency: A periapical radiolucency is defined as a radiolucent area or radiographic observation of low bone density related to the apical part of the root. A widening of the periodontal ligament is not included.

Root canal filling deficiency: The root canal filling appears radiographically too short (more than 2mm from the radiographic apex) and/or too small in diameter, or the root filling is not radiographically homogenously dense (e.g., with visible void in root filling or gaps between filling and root dentin), or otherwise show absence of radio-opaqueness.

Bone loss: Bone loss is defined as a radiographically lower density of the marginal bone and/or a lower crest of the alveolar bone compared to what is considered normal for healthy natural dentition. Healthy natural dentition refers to teeth that have not experienced any marginal bone loss and have an alveolar bone that covers the root of the tooth. It is indicated by a focus area annotation, however, the size of the rectangular bounding box is not indicative of the amount of bone loss.

Calculus: Calculus is a hard, mineralized form of dental plaque that is visible on radiographic images as radiopaque material attached to the tooth surface.

Intended Purpose

Intended purpose of the software is to support the diagnostic process and treatment planning for dental and craniomaxillofacial procedures.

Intended Use / Indications for Use

DTX Studio Clinic is a software program for the acquisition, management, transfer and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental restorative solutions.

It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.

It can be used to support guided implant surgery whereby the results can be exported.

DTX Studio Clinic is a computer assisted detection (CADe) device that analyses intraoral radiographs to identify and localize dental findings, which include caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration and bone loss. The DTX Studio Clinic CADe functionality is indicated for use by dentists for the concurrent review of bitewing and periapical radiographs of permanent teeth in patients 15 years of age or older.

Intended User and Intended Patient Target Group

DTX Studio Clinic is used by an interdisciplinary treatment team, to support them in treating patients who are subject to dental, craniomaxillofacial or related treatments.

Supported Products

Surgical guide shape file (STL).

Required Compatibility with Other Devices

DTX Studio ecosystem is compatible with the most used operating systems Windows and Mac including the latest releases.

DTX Studio Clinic is connected with other medical devices and compatible with previous DTX Studio Clinic versions.

Intraoral Sensors

DEXIS[™] Titanium, DEXIS Platinum, GXS-700[™], DEXIS IXS[™], Gendex[™] GXS-700[™].

Intraoral Cameras

DEXIS DexCAM[™] 4 HD, DEXIS DexCAM 3, DEXIS DexCAM 4, Gendex GXC-300[™], KaVo DIAGNOcam[™] Vision Full HD, KaVo DIAGNOcam[™], CariVu[™], KaVo ERGOcam[™] One.

Intraoral Scanning

Compatibility with MEDIT Link Software* and MEDIT Scan for DTX Studio* which supports the MEDIT™ i500/X 500, MEDIT i700/X 700 intraoral scanner or other compatible models.

Compatibility with DEXIS[™] IS ScanFlow^{*} which supports the CS 3600/DEXIS IS 3600, CS 3700/ DEXIS IS 3700 intraoral scanner, CS 3800/DEXIS IS 3800 or other compatible models.

Software

DTX Studio Core*, DTX Studio Implant, DTX Studio Go, DTX Studio Lab*, CyberMed OnDemand3D™*, Osteoid (formerly Anatomage) InVivo™.

* Product available for Windows operating system only.

After updating the software version, it is recommended to verify the critical settings of the open patient cases and/or treatment plan to make sure these settings are correct in the new software version. Incorrect settings may lead to a delay in or the rescheduling of the diagnosis and planning or the actual treatment.

Devices with Measuring Function

The measurement accuracy and precision are 0.1 mm for linear measurements and 0.1 deg for angular measurements based on the input of (conebeam) CT-scans, acquired according to the instructions for use of the scanner equipment, with a voxel size of 0.5 mm x 0.5 mm x 0.5 mm.

DTX Studio Clinic reports the value, rounded to one digit after the decimal point, based on user-picked points.

Contraindications

The automatic detection of focus areas is intended to be used only for adult dentition without gemination, crowding and macrodontia

Cybersecurity

Protecting your practice against cybersecurity threats is a shared responsibility between us as the manufacturer and you as the health care provider. Nobel Biocare has taken precautions to ensure that the software is protected against such threats.

It is recommended that active and up-to-date antivirus and anti-malware software, together with a correctly configured firewall, are installed on the computer where DTX Studio Clinic is to be used. Failure to do so may lead to unauthorized access.

In a setup with DTX Studio Core, it is recommended to connect with DTX Studio Core through https. See the DTX Studio Core guidelines on how to set up this connection.

It is recommended to enable audit logging in the settings and ensure the protection of these logs against unauthorized access. Failure to do so may prevent malicious activity from being detected.

Use two-factor authentication to access the software and always lock the computer when it is left unattended. Failure to do so may lead to unauthorized access.

Make sure the office network is protected from unauthorized access and separated from the visitor network. Failure to do so may lead to unauthorized access.

To quickly recover from any unexpected system failure or malicious event that may cause data loss, it is advised to regularly back up the patient data.

It is recommended to start DTX Studio Clinic without administrative privileges. Failure to do so may lead to unintended starting of malicious third-party executables.

It is recommended to always update DTX Studio Clinic to the latest available software version. Failure to do so may lead to unauthorized access.

For more technical details concerning back-ups, firewall and security settings during installation, please refer to the DTX Studio Clinic installation quide.

The software bill of materials (SBOM) of the software is available upon request. Please contact customer support (www.dtxstudio.com/en-us/support) to receive your copy.

What to Do in Case of a Cybersecurity Event?

In the event of a potential system compromise by intrusion or malicious software, the user may note unfamiliar product behavior and/or performance impact. In this case the user is advised to contact customer support immediately

(www.dtxstudio.com/en-us/support).

Decommissioning and Disposal

When terminating the use of DTX Studio Clinic on your computer or when disposing your computer on which DTX Studio Clinic is installed:

- Make sure to back up all necessary data from the application in accordance with local laws and regulations concerning data protection and data privacy to avoid any loss of relevant information.
- Uninstall the application: You should uninstall the application from your device by following the instructions of your operating system provider to prevent unauthorized access to DTX Studio Clinic and the data stored in the software.

Interoperability

DTX Studio Clinic is interoperable with:

- DTX Studio Core.
- DTX Studio Implant.
- DTX Studio Go.
- DTX Studio Lab.
- CyberMed OnDemand3D.
- MEDIT Scan for DTX Studio.
- Medit Link.
- DEXIS IS ScanFlow.

Intended Lifetime

For software the intended lifetime is three years. When used on the supported operating systems, the software will keep performing according to its intended use.

Performance Requirements and Limitations

It is important to make sure DTX Studio Clinic is used only with approved operating systems. See the <u>System Requirements</u> in the IFU for more information.

Clinical Benefits and Undesirable Side Effects

DTX Studio Clinic is a component of dental or craniomaxillofacial treatment. Clinicians can expect the software to support the diagnostic and treatment planning process.

No undesirable side effects identified for DTX Studio Clinic.

Notice Regarding Serious Incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB

https://www.nobelbiocare.com/complaint-form

Facilities and Training

It is strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method.

The lack of knowledge and comprehension of the software may result in the delay in or rescheduling of the diagnosis and planning or the actual treatment.

Nobel Biocare offers a wide range of courses for various levels of knowledge and experience.

For more information please visit our training website on <u>tw.dtxstudio.com</u>.

Professional Use

DTX Studio Clinic is for professional use only.

System Requirements

We advise to check the <u>System Requirements</u> before starting the installation of the software. To obtain information on minimum and/or recommended requirements, please contact customer support. New versions of the software may require higher requirements for hardware or operating system.

Installation of the Software

Information on how to install the software, can be found in the [product] Installation Guide. This document can be downloaded from the User Documentation Library (ifu.dtxstudio.com). If any issues occur or you need assistance, please contact an authorized technician or customer support (support@dtxstudio.com).

Handling Instructions

For detailed information on how to use the software, please refer to the detailed instructions further on in this IFU.

Cautions / Precautions and Warnings

Cautions / Precautions



Caution(s) / Precaution(s)

Users are advised to obtain training before undertaking a new treatment method or using a new device.

When using a new device or treatment method for the first time, working with a colleague who is experienced with the new device or treatment method may help avoid possible complications. The user should ensure patient movement is kept to a minimum during the scanning process to reduce the risk of an incorrect scan.

The lack of knowledge and comprehension of the software may result in the delay in or rescheduling of the diagnosis and planning or the actual treatment.

When using the diagnostic and planning tools provided in the software, it is important to pay extra attention to:

the correctness of made indications (visualizations, measurements, critical structures, imported data, implant planning).

the correctness of the outcome of the automated functions (the alignment of dental scans, the autofilling of holes, airway segmentation and the dental curve).

the correctness of the patient ID (after opening a patient record through PMS systems and when creating scan requests).

the data being up to date and not outdated.

Failure to do so increases the risk of the need for revision of the diagnosis and planning or treatment which, in its turn, may lead to the delay in or rescheduling of the diagnosis and planning or the actual treatment.

It is recommended to take extra care when working with image capturing devices. Incorrect use may result in the delay in or rescheduling of a diagnosis and planning or treatment or in unnecessary extra radiation exposure of the patient.

When extracting a report or patient data from the software, it is important to know that not deidentified patient data can be used for incorrect purposes without the patient's consent.

It is recommended to pay extra attention to the assigned tooth numbering and orientation markings of the viewers. A wrongly assigned tooth number or incorrect patient orientation may lead to incorrect treatment actions performed on the patient.

After updating the software version, it is recommended to verify the critical settings of the open patient cases and/or treatment plan to make sure these settings are correct in the new software version. Incorrect settings may lead to a delay in or the rescheduling of the diagnosis and planning or the actual treatment.

It is recommended to pay extra attention to the created implant plan and the positioning of the implants with respect to each other and other important anatomical structures. Furthermore, always verify that the correct implant plan was selected for exporting and that the exported implant plan or surgical guide contains all necessary information for implant surgery.

Failure to do so increases the risk of the need for revision of the diagnosis and planning or treatment which, in its turn, may lead to the delay in or rescheduling of the diagnosis and planning or the actual treatment.

Warnings

Following warnings are shown in the software.

The name in the DICOM file(s) differs from the patient name.

To reduce the risk of using incorrect data to create the patient model, verify the patient name and check whether patient name and the name in the used DICOM set correspond.

Cannot add the 3D X-ray to the current diagnosis.

The current diagnosis contains a 3D X-ray linked to a surgery plan. Create a new diagnosis to import the 3D scan.

Cannot add the surgery plan to the current diagnosis.

Select a surgery plan based on the 3D X-ray included in the current diagnosis

Exporting images in 8 bit could potentially result in fidelity loss.

It is recommended to export images in another format to maintain their quality.

Do not expose patient.

Device could not be armed. In this state, the device cannot receive X-ray radiation. Retry by reconnecting or restarting the device. If the problem is not resolved, please contact the customer support of your device.

Preparing your sensor for the next exposure. Please wait.

Device is currently re-arming. In this state, the device cannot receive X-ray radiation.

Verify the scan request parameters on the device.

Before exposing the patient, make sure to check the parameters on the device.

It is not advised to modify the treatment plan without the use of the actual implant shapes.

The actual shapes can be downloaded from DTX Studio Go.

Image has been flipped.

This warning is displayed when images are manually flipped (horizontally or vertically) by users.

Image has been cropped.

This warning is displayed when images are manually cropped by users.

Automatic intraoral images sorting (MagicAssist[®]) is intended to be used only for adult dentition without gemination, crowding and macrodontia.

To reduce the risk of using MagicAssist™ on non-suitable patient images.

Please be aware that differences in visualization of data (e.g., viewer orientation, object colors) as well as warnings may exist between DTX Studio Clinic and the X-Guide software.

Non-supported implants.

DTX Studio Clinic supports only a selection of implants to be exported to X-Guide[™]. Non-supported implants will not be included in the X-Guide[™] file.

Implant is too close to an annotated anatomical structure.

An implant is planned too close to an annotated anatomical structure (e.g., an annotated nerve). Make sure the implant is not impacting the anatomical structure.

Implants are colliding.

Some implants are colliding. This can cause issues during surgery. Revision of the treatment plan is recommended.



The patient records are currently synchronizing. If you close the application now, the most recent changes will not be available on DTX Studio Core.

A patient record is updated and the synchronization to DTX Studio Core is not yet finished. The most recent changes for the patient will not be available for other users in the practice if synchronization is not finished first.

Furthermore, a number of technical warnings (e.g., inconsistent CT data) are visualized in DTX Studio Clinic.

It is strongly recommended that users follow the instructions and technical notifications within the software to reduce the risk of an inaccurate scan.

The clinician should not rely solely on the output identified by focus area detection, but should perform a full systematic review and interpretation of the entire patient dataset and other differential diagnostic methods.

Focus area detection is limited to images where detection can be performed.

Note

In the US, the physical surgical template for endosseous dental implant placement is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical surgical template for endosseous dental implant placement or to purchase a legally marketed, validated milling/printing system to create the physical implant surgical template and at an on-site location. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to manufacture of these implant surgical templates.

System Requirements

Operating System¹ Windows® 11 or 10 64-bit (Pro and Enterprise edition) on desktop and notebook. macOS Sonoma (14), Ventura (13) or Monterey (12) (Intel®-based Mac and Apple Silicon Mac with M1 Chip or Higher) on iMac, Mac Mini, Mac Pro, MacBook Pro, MacBook Air devices.²

| | Basic setup (2D imaging only) | Recommended setup (2D and 3D imaging with better performance) | | |
|---------------|--|---|--|--|
| CPU | Dual or quad-core | 2.8 GHz quad-core (Intel Core i5 or i7) | | |
| RAM | 4 GB | 8 GB or more | | |
| Graphics card | Entry-level dedicated add-in card or Intel integrated graphics. 6th generation Intel CPUs with built-in 9th generation Intel graphics or higher are supported. OpenGL [®] 3.3 support is required ³ . | Dedicated add-in graphics card with optimal 3D support (OpenGL 3.3) and 2 GB VRAM or more. For 4K displays, a minimum of 4 GB VRAM is advised. | | |
| Disk space | 10 GB free disk space for installation and additional disk space for user-created data. A typical 2D patient dataset in DTX Studio Clinic is about 10 MB. | 10 GB free disk space for installation and additional disk space for user-created data. A typical 3D patient dataset in DTX Studio Clinic is about 250 MB. | | |
| Network | Broadband Internet connection with 3Mbps upload and 30 Mbps download speed. To allow DTX Studio Clinic to connect to external services and/or applications it is recommended always to be connected to the Internet. If that is not possible, a connection should be established at least once every 14 days, because otherwise your access to DTX Studio Clinic may be temporarily suspended. When a connection to the Internet is re-established, your access to DTX Studio Clinic will be restored. | | | |
| Hard Disk | Only install DTX Studio Clinic onto an APFS, HFS+ or HFSJ non-case-sensitive drive on Mac devices. | | | |
| Monitor | Full HD (1920x1080) or higher. Information may appear missing if display scaling is used. For this reason, the equivalent scaled resolution should not be lower than 1920x1080. | | | |
| LAN | If DTX Studio Clinic is installed together with DTX St | tudio Core a local Gigabit Network is recommended. | | |
| C | 2 | | | |

1 It is strongly recommended to install the latest available update of your Operating System (OS) version, as this will fix known bugs or vulnerabilities, keeping users and computer systems more secure.

2 The graphics cards of some MacBook Air® and Mac® Mini configurations have restrictions with regard to volume rendering. Consider selecting low resolution volume rendering.

3 Always use the latest integrated graphics card driver available from Intel for the respective model for best performance. To check the OpenGL® version of your graphics card, go to http://realtech-vr.com/admin/glview

Start

Starting the Software

- 1. Open DTX Studio Clinic:
 - On Windows, double-click the shortcut icon is on the desktop.
 - On macOS, click the shortcut icon 🕏 in the Finder application folder or the Dock.
- 2. Select the user.
- 3. Enter your password.
- 4. Click Log in.

Notes

If two-factor authentication was set up on DTX Studio Go, every 30 days you will need to enter a six-digit verification code to log in.

DTX Studio Clinic should always be connected to the Internet. If that is not possible, a connection should be established at least once every 14 days, because otherwise your access to DTX Studio Clinic may be temporarily suspended.

Closing the Software

Make sure to close all active DTX Studio Clinic and scan module* instances.

Click Menu and select Close application.

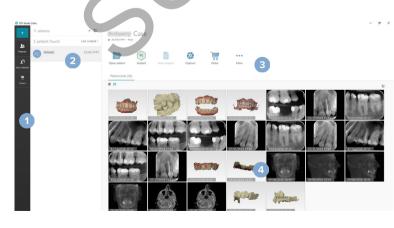
Note

When you use the close button \times , the software remains running in the background, to allow data synchronization and a quicker response when reopening DTX Studio Home / DTX Studio Clinic.

* Module might be licensed.

Exploring DTX Studio[™] Home

DTX Studio Home is the work area where you select and manage patient records, scan requests, orders and general settings.



- 1 Sidebar
- 2 Patient list
- 3 Action pane
- 4 Details pane

Start

Exploring the Notification Area

The 🕅 icon in the notification area grants access to the DTX Studio Home settings (🎝) and the following tabs:

- Notifications: shows which patient records are being uploaded or synchronized with DTX Studio Core.
- DTX: provides quick access to DTX Studio Core (), DTX Studio Go (), Exposure reports*, QuickPrescribe*, Scan Center* or a linked third-party application.

* Requires DTX Studio Core.

Adjusting Settings

Adjust the Default DTX Studio[™] Home Settings

- 1. Click Menu \equiv .
- 2. Click Settings ⁽²⁾.

Import or Export Settings

Create or import a settings file containing set preferences. This may be useful when exporting settings to a new installation, sharing settings with other DTX Studio Clinic users, or making a backup.

Note

Consult the "Share settings" topic in the help files for an extensive overview: Click and select Help.

In the DTX Studio Home Settings sidebar, click Share settings.

- To import a settings file, click Browse in the Import section. Select the settings file and click Save. Click Import to confirm.
- To export a settings file, click Browse in the Export section. Change the filename if needed and click Save. Click Export to confirm.

Change Language and Date/Time Format

To adjust the preferred language, date format and time format:

- 1. In the DTX Studio Home Settings sidebar, click General.
- Select the date and time format in the Short date format, Long date format and Time format lists.
- 3. Select the preferred language from the Application language list.
- 4. Click OK.
- 5. Restart DTX Studio Clinic for the changes to take effect.

Adjust the DICOM Compliance Settings

To ensure compliance with the DIN 6862-2 standard, enter the institution information. When exporting a DICOM file, the provided institution information replaces empty tags.

- 1. In the DTX Studio Home Settings sidebar, click General.
- 2. Select Use DIN 6862-2 standard.
- 3. Provide the requested institution information.
- 4. Click OK.

Note

When importing and exporting a compliant DICOM file, the DIN 6862-2 tags always remain preserved.

Set the Default Image Filters

To set the default image filters for the DTX Studio Home viewer and DTX Studio Clinic:

- 1. In the DTX Studio Home Settings or DTX Studio Clinic preferences sidebar, click Image settings.
- From the Default image settings list, select the image type for which you want to set the default filter settings.

Note

To set custom values for the Gamma filter, select Pan, Intraoral or Ceph in the Default image settings list. Set the Gamma option to Manual.

- 3. Select the filters to be used by default for the selected image type and use the appearing slider to set the filter percentage.
- 4. Click OK.

If you wish to revert to the initial default values, click Reset.

Disable Auto-Rotation of Intraoral Images

Upon performing an immediate scan, intraoral images are automatically rotated in the correct position. To disable this:

- 1. In the DTX Studio Home Settings or DTX Studio Clinic preferences sidebar, click Image settings.
- 2. Deselect Auto-rotate intraoral X-rays in DTX Studio Capture.

Disable Automatically Set Level and Window Values

Upon importing or acquiring a 2D image, level and window values are automatically set. To disable this:

- 1. In the DTX Studio Home Settings or DTX Studio Clinic preferences sidebar, click Image settings.
- 2. In the top-right drop-down menu, select Pan, Intraoral or Ceph.
- 3. Deselect Auto level window.
- 4. Enter custom level and window values.
- 5. Click OK.

Connect to DTX Studio[™] Core

DTX Studio Core is a software solution to store and retrieve patient media and image data types (2D X-ray, 3D (CB)CT X-ray, dental optical scans, photos) in a structured and centralized way, so that stored data is immediately accessible anywhere in the dental clinic.

- If connected with DTX Studio Core, DTX Studio Clinic can be used in a network environment to acquire images from other supported Ethernet-connected and 3Shape TRIOS[®] devices.
- A connection with DTX Studio Core needs to be established to work with network devices, scan requests and access radiographic reports.

To establish a connection with DTX Studio Core:

- 1. In the DTX Studio Home Settings sidebar, click DTX Studio Core.
- 2. Enter the URL (web address) for DTX Studio Core, if it is not filled out yet.
- 3. Click Connect.
- 4. A connection request is sent, which can be accepted by the local administrator via the DTX Studio Core UI.

Important

DTX Studio Clinic 4.3.10 requires at least DTX Studio Core version 4.0. When upgrading, DTX Studio Core needs to be upgraded before the DTX Studio Clinic clients are upgraded.

Add an Application to the Action Pane

To add an application shortcut to the action pane:

- 1. In the DTX Studio Home Settings sidebar, click Quick Launch.
- 2. Click Add.
- 3. Select the executable file and click Open.
- 4. If needed, change the Application name.
- 5. Optionally, select lounch with patient data to launch the third-party application with patient data.

Specify which data is exported by adding export parameters to the Export parameters field.
 Note

Consult the Quick launch topic in the help files for an extensive overview of all patient data parameters.

- Click Browse to choose a location for the exported data.
- 6. Click OK.

Enable Practice Management System (PMS) Integration

Integrating DTX Studio Clinic with a PMS (i.e. through VDDS or OPP/OPP web) allows you to create a patient record and acquire an image from within the PMS.

Preview the PMS images in DTX Studio Home or view them directly in DTX Studio Clinic.

- 1. In the DTX Studio Home Settings sidebar, click PMS integration.
- 2. Select Enable PMS integration.

Note

Consult the "PMS integration" topic in the help files for detailed information: Click = and select Help.

Add a TWAIN-supported Device

- 1. In the DTX Studio Home Settings sidebar, click Devices.
- 2. Click Add.
- 3. Select the TWAIN device.
- 4. Configure the device settings.
- 5. Click Add.

Configure the Direct Folder for Detecting Third-Party Device Images

To add images from third-party camera devices or third-party (CB)CT devices, set up a direct folder in which new images will be detected. Add them with the Capture action in a patient record or from within DTX Studio Clinic.

- 1. Prepare your camera device settings:
 - If possible, set up your third-party camera device, (CB)CT device or wireless SD card to store images in a specific folder.
 - If the images are stored on a standard SD card, insert it and take note of the assigned drive letter.
- 2. In the DTX Studio Home Settings sidebar, click Devices.
- 3. Click Add.
- 4. Select the third-party device and click Open.
- 5. Click Browse to select the camera device folder and click Select folder.
- 6. Enter a specific name.
- 7. Change the modality and folder priorities, if needed.
- 8. Click Add.

Set the Default Export Folders

To specify the default export folder for reports, screenshots, and X-guide files:

- 1. In the DTX Studio Home Settings sidebar, click Export.
- 2. Click Browse for each export type and select the default folder.

Enable Autosave When Closing DTX Studio[™] Clinic

- 1. In the DTX Studio Clinic preferences, select General.
- 2. Enable Autosave when closing patient.

Learning Resources and Contacting Support

View all Learning Resources and Keyboard Shortcuts

To go to the help documentation, Instructions for Use and keyboard shortcuts, click and select Help, Keyboard shortcuts or Instructions for Use. Alternatively, click ⑦ in DTX Studio Clinic.

The training video website and product tour can only be opened in DTX Studio Clinic. Click = or ⑦ and select Training videos or Product tour.

Contact Customer Support

To reach out to customer support, click = and select Contact support. The support website with all the contact options is opened. Alternatively, go to www.dtxstudio.com/en-us/support.

Overview of the Main Features

To get started with the main features in DTX Studio Home:

| 1 | Create or link a patient record | + | Create a patient record (<u>see page 22</u>). |
|---|---------------------------------|----------|--|
| | | • | Integrate your Practice Management System (see page 18) and link an existing PMS patient record. |
| 2 | Acquire or import data | | Acquire scans, initiate multiple scan workflows (<u>see page 30</u>) or import third-party device images from direct folders (<u>see page 24</u>). |
| | | | Request a scan or multiple scan workflows (<u>see page</u> <u>30</u>). |
| | | | Drag and drop images into a patient record (<u>see page</u> <u>24</u>). |
| | | <u>+</u> | Import data from within DTX Studio Clinic (see page 24). |
| | | 9 | Import from 3Shape Dental Desktop Software (<u>see page</u> <u>26</u>). |

Once a patient record is created and data are added, continue to:

| | $\mathbf{\nabla}$ | Open the Clinic module (see page 35) to: | | |
|--|-------------------|--|--|--|
| | * | – Diagnose images | | |
| Diagnose and plan treatments | | Plan implants and treatments | | |
| | | Create a surgical template (see page 45) | | |
| 6 | | Share a 3D presentation with your patients (see page 27). | | |
| | PI | Optionally, open DTX Studio Implant (<u>see page 51</u>). | | |
| Share and communicate in DTX Studio Clinic | | Export a patient record (<u>see page 23</u>). | | |
| | | Export an implant plan to X-Guide (<u>see page 28</u>). | | |
| Place orders in | ¢ | Share patient records and patient data via DTX Studio Go (see page 26) or collaborate with partners. | | |
| DTX Studio Home | (| Optionally, order a restoration, surgical template or surgery plan (<u>see page 52</u>). | | |

Patient Records

Creating a New Patient Record

- 1. Click +.
- 2. Select Create patient.
- 3. Enter basic patient details, like patient name, date of birth and gender.
- 4. Click Create.
- 5. The patient record is added to the Patients 🖳 list. If DTX Studio Home is connected to DTX Studio Core, the patient record is also added to DTX Studio Core.

Managing Patient Records

Click Patients 🎎 in the sidebar to open the patient list, if not already open.

Note

If the workstation is not connected to DTX Studio Core, only locally-stored patient records are shown.

- Patient records opened in DTX Studio Clinic on a local or networkconnected workstation are marked with .
- To edit basic patient information, select the patient record in the patient list, click More ...
 and select Edit 2.
- To delete a selected patient record, click More --- and select Delete patient ¹
- To make sure that a patient record stored in DTX Studio Core is also available offline, click More ••• and enable Offline available.

The notification area (see page 16) shows which patient records are being uploaded or synchronized.

Manage Privacy Options

To ensure patient privacy by only showing patient initials in the patient list or completely hiding the patient list:

- 1. On the patient list, click 🛫
- 2. Select Privacy mode to show initials only or Hide patient list to completely hide it.

Notes

Click \gg in the sidebar to re-show the patient list.

Privacy mode remains enabled, even when restarting DTX Studio Clinic. To turn off the privacy mode, re-click 🦕 and uncheck Privacy mode.

Searching and Sorting Patient Records

To find a patient record, sort the patient list or use the search function.

Sort the Patient List

- 1. Click the drop-down arrow next to the patient list header.
- 2. Select Last created, Last modified or Last captured.
- 3. Click the drop-down list again to close it.

Search for a Patient Record

- 1. On the patient list, click 😓.
- 2. Select to search for the Patient name, Date of birth or Patient ID.
- 3. Type (a part of) the selected search option in the Find a patient field Q
- 4. While typing text in the search box, the patient list is filtered automatically.

To remove the search criteria, click x in the search field.

Exporting a Patient Record

Export a patient record to manually share the diagnoses and image data with another DTX Studio Clinic user. Additionally, the exported patient record can be viewed in the free version of DTX Studio Clinic, available via DTX Studio Go. <u>See page 26</u> for more information.

Note

When extracting a report or patient data from the software, it is important to know that not de-identified patient data may be used for incorrect purposes without the patient's consent.

Manage Data

Importing Data

Import Images from Third-Party Devices

To add images from third-party camera devices or third-party (CB)CT devices, make sure to configure a direct folder in which new images will be detected (see page 19).

- 1. Select the patient record in the patient list or open a patient record in DTX Studio Clinic.
- 2. Click Capture 💸.
- 3. Hover over a direct folder name and click Select.
 - For 2D images, select the images you want to import. Click Finish
 - For 3D (CB)CT devices, select the 3D data you want to import. Click Import.

Drag and Drop Images and Files into a Patient Record or DTX Studio[®] Clinic

- 1. Drag and drop a compatible image or file type from the file explorer into a patient record or DTX Studio Clinic.
- 2. If needed, change the modality and the acquisition date.
- 3. Click Import.
- 4. The image or file is added to the patient record.

Importing Data from Within DTX Studio™ Clinic

To import data, click Import in the patient menu.

Import 3D X-rays

- 1. Click Import 1 and select 3D X-ray.
- 2. Click Import DICOM file.
- 3. Browse to the location of the DICOM image file and select its folder.
- 4. Click Import.
- 5. The DICOM files are loaded. Use the slider on the right-hand side and scroll through the slices to check the DICOM images.
- 6. Click Done.
- 7. If MagicAssist[™] is enabled (on by default), the AI detection process is started to automatically set up the (CB)CT data.
 - Click Skip MagicAssist to set up the 3D X-ray manually.
 - The 3D X-ray orientation can be optimized via the patient orientation wizard.
 - The Pan curve action (see page 49) allows you to adjust the 3D Pan.

Import IO scans

- 1. Click Import \bot and select IO scan.
- 2. Select the IO scan model(s) and add acquisition details, if needed.
- 3. Click Next.
- 4. Click Finish.

Import Face Scans

- 1. Click Import \bot and select Face scan.
- 2. Select a face scan to import.
- 3. Click Open.
- 4. If needed, adjust the Brightness and Contrast.
- 5. Click Done.

Import 2D Images

- 1. Click Import \bot and select 2D images.
- 2. Choose the image(s) and click Import.
- 3. Select the images you want to add.
- 4. Click Import.
 - Upon importing or acquiring a 2D image, level and window values are automatically set. To disable this, <u>see</u>.
 - By default, MagicAssist[™] autodetection is activated. This can be deactivated in the DTX Studio Home MagicAssist settings.

Import from the Clipboard

- 1. Copy an image on your computer to add it to the clipboard.
- 2. Click Import 1 and select From clipboard.
- 3. Inspect the imported image. To change it to another modality, click ... and select a different modality.
- 4. Click Import.

Import from 3Shape Dental Desktop Software

To import a scan that was acquired with a 3Shape TRIOS intraoral scanner, a patient record needs to be created in DTX Studio Home first.

Note

For more information on how to integrate a 3Shape TRIOS intraoral scanner device, see the DTX Studio Core Quick Guide.

- 1. Create a new patient record in DTX Studio Home. To make sure that the 3Shape data will merge:
 - Use exactly the same first name, last name and date of birth as those of an existing patient record in 3Shape Dental Desktop.
 - Make sure that the patient names are correctly capitalized. Names are case-sensitive

Notes

Previously imported patient records cannot be re-imported. Duplicate the patient record in 3Shape Dental Desktop, and import the duplicated patient record instead.

The DTX Studio Clinic patient record ID is not exchanged with 3Shape. The link is created based on the user confirmation that the first name, last name and date of birth are identical.

- 2. Select the patient record in the Patients 🎎 list.
- 3. Click More •••.
- 4. Select Import from 3Shape 🤤.
- 5. If requested, confirm that the patient record matches the one in the 3Shape Dental Desktop.
- 6. The data is retrieved and added to the Patient data tab on the patient detail panel.

Import a Surgery Plan

- Select the patient record in the Patients A list.
- 2. Click More •••.
- 3. Select Import surgery plan
- 4. Select the surgery plan and report.
- 5. Click Import.

Sharing Data

Share Patient Data via DTX Studio[™] Go

Share patient data with a dental office via <u>DTX Studio Go</u>. If patient data is shared, an additional GoShare tab shows an overview.

- 1. On a patient record's action pane, click Collaborate A.
- 2. Select what you want to share:
 - Patient Ω to share the entire patient record (DTX Studio Clinic proprietary encrypted format), or
 - Select data v to share specific data.
- 3. Choose the preferred options.

4. Click Continue.

- 5. DTX Studio Go opens in the web browser and the created GoShare[™] case is shown. Meanwhile, the data is uploaded in the background.
 - Add notes to the Prescription card's text field.
 - To create a prescription note template, click Insert quick note and select Configure.
 Click Add quick note. Add a title, write the custom text and click Save. Click Close.
 - To change the default prescription image or to add annotations, hover over the prescription image and select Edit prescription. Click Change image to select another image.
 - To edit the patient information, click 🖍 in the top-right corner.
 - If needed, provide further information or additional files of the (CB) CT images, clinical pictures, intraoral images, pan, reports, etc.
- 6. Click Start sharing.
- 7. Select the connection with which you want to share patient data. Either by searching or selecting an existing connection in the Share with a connection field, or by entering an email address.
- 8. Click Send. The receiving account is notified by e-mail.
- 9. The shared case is added to the GoShare overview in the patient record. Click View case to open the shared case in DTX Studio Go.

Share a 3D Presentation

- 1. In the DTX Studio Clinic patient menu, click Share \leq and select 3D presentation.
- 2. Choose the preferred options:
- Include 3D data (DICOM); include the raw DICOM data, if legally required in your country.
- Include implant treatment plan: add more detailed implant information.
- 3. Click Share.
- 4. The 3D presentation is uploaded to DTX Studio Go and added to a case.
- 5. Complete the process in DTX Studio Go and provide the requested information.
- 6. The patient can access the 3D presentation online.
- 7. The 3D presentation is added to the patient data in the patient record.

Share 2D Images via Email or Transfer to a Third-party Application

- 1. In a workspace, right-click a 2D image and select Copy. Alternatively, click 💶 in the top-left viewer corner.
- 2. Open your email client or third-party application, right-click in the relevant place and select Paste.

Exporting Data

Export a Patient Record

- 1. Select the patient record in the patient list.
- 2. Click More
- 3. Click Export patient **2**.
- 4. Select the diagnosis you want to export, if applicable.
- 5. Choose the preferred options.
- 6. Click Browse to select the export data location and click Select folder.
- 7. Click Export.

Export Patient Data

- 1. Go to the export data action.
 - In DTX Studio Home, click More ••• in the action pane and select Export data.
 - In DTX Studio Clinic, click Export *L* and select Data.
- 2. Select the images to export.
- 3. Click Browse and go to the desired export location.
- 4. Click Select folder.
- 5. Choose the export mode, patient anonymization, metadata and image file format.
- 6. Click Export.

Export Implant Plan to X-Guide™

If you have completed an implant plan in DTX Studio Clinic, export it to X-Guide.

- 1. Select the patient record in the patient list.
- 2. Click More
- 3. Click Export to X-Guide Z.
- 4. Select the implant plan you want to export, if applicable.
- 5. Choose the preferred options.
- 6. Click Browse to select the export data location and click Select folder.
- 7. Click Export.

Request Scans

To work with scan requests or to initiate a scan workflow with multiple scan protocols (see page 30), a connection with DTX Studio Core needs to be established (see page 18).

Scheduling a Scan

To request a scan for a patient:

- Select the patient record in the patient list. 1.
- Click Scan request 2.
- 3. Optionally, initiate a scan workflow with multiple scan protocols (see page 30)
- 4. Hover over a device tile and click Select.
- Fill out the applicable information in the scan request form. 5.

Note

Depending on the chosen modality or chosen device, the form will be different.

- If needed, change the Scan date and the Requesting clinician.
- If the image acquisition device allows multiple modalities, select the required modalities: 3D, CEPH (Cephalogram), Pan, IOXRAY (2D intraoral scan), IOS (3D intraoral scan) and/or IOCAM (intraoral photo). If applicable, select an imaging program.
- On the tooth chart, select the regions you want to scan.
- Select Sinus if the sinus needs to be scanned.
- Select an image acquisition resolution if applicable.
- If the selected device is an intraoral device, select a Template, and specify the Imaging program.
- Add Request notes for the operator if applicable.
- 6. Click Create scan request(s). The scan request is added.

Searching and Sorting Scan Requests

Sort the Scan Request List

- In the sidebar, click Scan requests **1**. 1.
- 2. Click the drop-down arrow next to the Scan requests list header.
- Select to sort by Scheduled date or Creation date. 3.

Search for a Scan Request

- 1. Type (a part of) the scheduled date or the patient name in the Find a scan request field Q.
- 2. While typing text in the search box, the scan requests list is filtered automatically. The search results are sorted on the scheduled date.

To remove the search criteria, click X in the search field.

Managing Scan Requests

To edit, delete or mark scan requests as completed, select the scan request and click ••••. Select the corresponding action.

Scan Workflows

Use the QuickPrescribe feature to create a scan workflow consisting of multiple scans from different modalities with a particular set of pre-defined scan requests. These scan workflows can then be used on all workstations.

Define a scan workflow in DTX Studio Core first, and apply it during the schedule a scan or capture wizards.

Define a Scan Workflow

- Click the (*) icon in the notification area at the bottom of the screen (on the top of the screen if you use a Mac).
- 2. Click QuickPrescribe. If you have not set up any scan workflows yet, click Get started right away.
- 3. Complete the scan workflow configuration in DTX Studio Core.

Note

In DTX Studio Core, click Help in the bottom-left corner for more information.

4. Select a scan workflow from either the scan request or capture wizard.

Apply a Scan Workflow

Define a scan workflow in DTX Studio Core, and select it during the scan request wizard or capture wizard.

- 1. Select the patient record in the patient list.
- 2. Click Scan request a or Capture 🥸.
- 3. Click QuickPrescribe

Notes

Type (a part of) the scan workflow in the search field to narrow down the results.

To see all the modalities and parameters that are set, hover over a scan workflow name in the list. Click More info.

- Hover over a scan workflow name in the list, and click Create scan requests(#). The number indicates the number of scan requests created with the selected scan workflow.
- 5. On the tooth chart, select the diagnostic region that you want to scan.
- 6. Click Create scan requests.

Perform a Scan

Take a scan before, during or after diagnosing the patient — with or without creating a scan request first.

It is strongly recommended that users should follow the instructions and technical notifications within the software to reduce the risk of an inaccurate scan.

Perform a Scheduled Scan

To perform a scan for a scan request:

- 1. On the scan request card, click Start.
- 2. Hover over a device tile and click Select, if applicable.
- 3. The scan module or third-party scan application is opened.
- 4. Follow the instructions.
- 5. Click Finish to end the action, or click Open Diagnose to open the patient record in DTX Studio Clinic.

Perform an Immediate Scan

- 1. Select the patient record in DTX Studio Home or open a patient record in DTX Studio Clinic.
- 2. Click Capture 🕅.
- 3. Hover over a device or direct folder tile and click Select.

Notes

Intraoral images are automatically rotated in the correct position. To disable this, see page 17.

Upon importing or acquiring a 2D image, level and window values are automatically set. To disable this, see page 17.

Use multiple sensors with different sensor sizes by plugging them in or out during the capture wizard. The used sensor is shown in the top-right corner*.

If multiple sensors are plugged in, the + symbol appears*. All sensors which are connected and active, are ready to acquire the scan. X-ray triggers the image acquisition.

* For sensors and PSPs directly supported in DTX Studio Clinic. For devices connecting via TWAIN, this functionality will be limited.

Guided Acquisition with Intraoral Sensors or PSP Devices

To acquire intraoral images with a template:

- 1. Initiate an immediate scan.
- 2. Click the Template tab and select your preferred template.
- 3. Select the layout and images that you want to acquire.
- 4. Click Start.
- 5. Go to the device to perform the scan.
- 6. On the preview page, inspect the acquired images. Hover over a preview image to see the additional Rotate, Flip, show or hide Image filters and Capture again options. Make changes if needed.
- 7. Click Finish.

Free Acquisition with Intraoral Sensors or PSP Devices

To acquire intraoral images without using a template:

- 1. Initiate an immediate scan.
- 2. Select the Free tab.
- 3. Go to the device to perform the scan.



If you have activated MagicAssist[™] autodetection, see the steps below:

- In the bottom-right corner, the MagicAssist[™] autodetection icon is shown.
- In the capture wizard teeth are automatically detected. They are marked in blue. Click on a tooth to remove the MagicAssist[™] label.
- Intraoral images are automatically mapped on FMX charts.
- If needed, manually indicate unidentified images on the tooth chart.
 Note

By default, MagicAssist[™] autodetection is activated. This can be deactivated in the settings.

- 4. On the preview page, inspect the acquired image and assign a tooth range if necessary.
 - Click Clear selection to remove the indicated teeth on the tooth range.
 - Make changes if needed: hover over a preview image to see the additional Rotate, Flip, show or hide Image filters and Capture again options.
 - Rotate or flip the acquired image if necessary,

| Action | lcon | Shortcut |
|---|---------|--------------------|
| Rotate image counterclockwise | ſ | Alt + 🖛, or R |
| Rotate image clockwise | ∎) J | Alt + , or Shift+R |
| Flip intraoral image or clinical picture horizontally | i)i | U |
| Flip intraoral image or clinical picture vertically | ÷ | Shift+U |

Guided Image Acquisition with Intraoral Cameras

To acquire intraoral camera images with a template:

- 1. Initiate an immediate scan.
- 2. Stay on the Guided tab.
- 3. For intraoral cameras, select the teeth that you want to acquire.
- 4. Press the device button if available or click Capture image.
- 5. To select another tooth of which intraoral images will be taken, use the **t** or **b** keyboard buttons. Alternatively, click the tooth on the tooth range or click Previous or Next.

Note

When only one image per tooth is required, enable Proceed to the next tooth after cepture to automatically continue with the next tooth.

6. Click Finish.

Free Image Acquisition with Intraoral Cameras

To acquire intraoral camera images without using a template:

- 1. Initiate an immediate scan.
- 2. Click the Free tab.
- 3. Press the device button if available or click Capture image.
- 4. To assign acquired images to a tooth, click an image thumbnail at the bottom and select the corresponding tooth on the tooth range.

Note

Assign an image to multiple teeth by selecting the image, clicking a tooth and dragging over the other teeth.

5. Click Finish.

Intraoral Scanning

3Shape TRIOS[®] Scanner

- 1. Click Capture 🐼.
- 2. Hover over the 3Shape intraoral scanner tile and click Select.
- 3. Start the scan in the 3Shape Dental Desktop application.

Note

For more information on how to integrate a 3Shape TRIOS intraoral scanner device, see the DTX Studio Core Quick Guide.

- 4. Complete the scanning process.
- 5. The image is added to the Patient data tab on the patient detail panel.
 - The finished scan request is marked with a check mark.
 - Click Open Diagnose to open the patient record in DTX Studio Clinic.

DEXIS[™] and Medit Scanners

The scan module^{*} allows you to use a supported Medit / DEXIS intraoral scanner by integrating Medit Scan or DEXIS IS ScanFlow with DTX Studio Clinic.

Acquire Intraoral Scan Data

- 1. Select the patient record in the patient list.
- 2. Click Capture 💸.
- 3. Hover over the intraoral scanner tile and click Select.
- 4. Follow the instructions in the scan module*.
- 5. The processed data is added to the patient record.
- 6. If ScanFlow is used and multiple occlusion models were captured, right-click the upper or lower jaw in DTX Studio Clinic and click Occlusions to make a selection.

Reopen a Scan Case

Intraoral scan data that was locally captured can be reopened in the scan module*.

Note

This is only possible on the computer used to acquire the scan data.

To reopen the scan module* to edit the scan, trim, measure and more:

- 1. In a patient record, click the IO scan tile.
- 2. Click Open in Medit Scan or Edit in ScanFlow.

* For Windows computers only and on the computer which has been used for acquiring the intraoral scan data, where the folder with RAW scan data is available. An appropriate license type or a subscription to the Plus+ feature Medit Scan or DEXIS IS ScanFlow integration is required. The additional Medit Scan and DEXIS IS ScanFlow software module has to be installed.

Resume DEXIS[™] IS ScanFlow Scan

Intraoral scan data that was locally captured, can be reopened in ScanFlow to edit the scan, take additional scans, trim, measure and more:

- 1. In a patient record, select the IO scan tile of the DEXIS IS device.
- 2. Click ••• and select Resume in ScanFlow.

Enable the Advanced ScanFlow Features

Enable the advanced ScanFlow features to use the DEXIS IS 3800 in IO CAM* mode or to import raw DEXIS device data.

- 1. In the DTX Studio Home Settings sidebar, click DEXIS IS.
- 2. Disable Launch ScanFlow in scan mode.

* IO CAM is only available if you have a premium license and the DEXIS IS 3800 device to edit the scan, take additional scans, trim, measure and more.

Make a Diagnosis or Plan a Treatment

Open a patient record in DTX Studio Clinic to view and inspect the patient data and to add findings and measurements to the patient record.

In DTX Studio Home, select a patient record in the Patients list and click Open patient **D**. Alternatively, double-click the patient name in the patient list or press [O].

The features depend on the DTX Studio Clinic license type:

| License Type | Features | Image Acquisition |
|---|-------------------------------------|-------------------|
| DTX Studio Clinic Pro or Pro IOS | 2D and 3D | 2D and 3D |
| DTX Studio Clinic Select or Starter | 2D and selected 3D viewing features | 2D only |
| | | |

Exploring the Clinic Module



- Patient menu
- Menu bar

2

5

- 3 Toolbar
- 4 Workspace bar
 - Workspace SmartLayout
- 6 Smart panel

Working with the Patient Menu

To open the patient menu in DTX Studio Clinic, click \equiv in the upper-left corner.

Menu Options

- New: create a new diagnosis.
- Open: open another existing diagnosis.
- Save: save the open diagnosis.
- Help: open the help documentation website.
- Contact support: open the contact support website.
- Training videos: open the training video website.
- Keyboard shortcuts: show the keyboard shortcuts overview.
- Product tour: open the product tour that guides you through the DTX Studio Clinic functionality.
- Preferences: change the settings, like the Default workspace
 Performance, Image settings, 3D viewer and Tools.
- Close patient: close the DTX Studio Clinic window.

Actions

- Capture: acquire data directly. Alternatively, click on the menu bar.
- Import: import data to the open diagnosis.
- Export: export data or patient diagnosis reports.
- Share: share a 3D presentation.

Tooth Chart

The patient menu's tooth chart gives an overview of the teeth status in the open diagnosis.



Note

If the patient is younger than eight years old, the tooth chart for primary teeth is shown. Please keep in mind to change the teeth manually to go to an adult tooth chart when the patient is growing up.

Edit the Tooth Chart

To edit the tooth chart, click a tooth on the tooth chart and select one of the following:

| lcon | Action | Explanation |
|-------|-------------------------|---|
| (III) | Exchange | Exchange a primary tooth with an adult tooth. This option is available if the child tooth has a corresponding adult tooth. If the tooth is exchanged, all the findings of the primary tooth are deleted and the adult tooth is set to healthy. |
| | | Note |
| | | Child dentition is displayed for patients younger than eight years old. |
| Х | Not present with gap | This tooth is missing and there is a gap on this location. |
| Ħ | Impacted | This tooth will be impacted (often used for wisdom teeth). |
| +7 | Insert | Insert a tooth, e.g., adult molars in a child dentition. |
| Ŵ | Not present without gap | Indicate hypodontia. |

Diagnosis Data

Below the tooth chart, the scans and the images for the open diagnosis are shown per data type, and sorted by acquisition date. Any finalized implant plans are shown here as well.

Click a tile to include or exclude the patient data.

- 😭 3D X-ray
- Pan (panoramic image)
- Intraoral images
- Cephalogram
- Clinical pictures
- Screenshots
- Face scan
- 🔝 🛛 IO scan

Set the 3D and IO scan Viewer Background

- 1. In the Preferences window, click 3D viewer.
- 2. Select Solid color.
- 3. Select a color in the drop-down menu, or select Custom to select any other color.
- 4. Click OK.

Set the Default Image Zoom Level

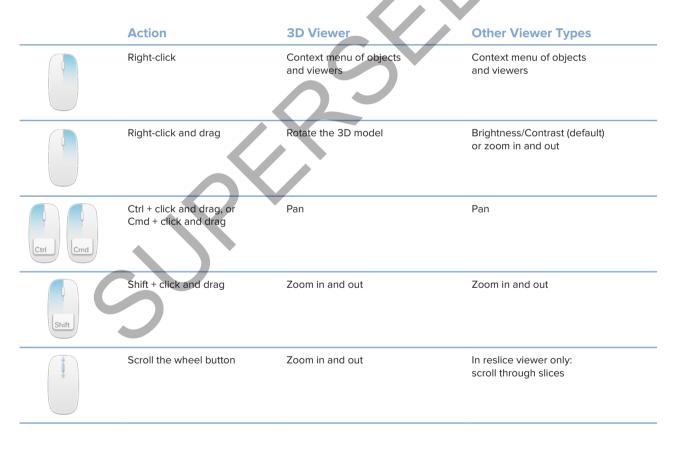
To set the default zoom level of shown images:

- 1. In the Preferences window, click Workspace.
- 2. In the Default image size list, select the default magnification value.
- 3. Click OK.

Interact with the Viewers

Right-click anywhere in a viewer to access the general viewer actions. Right-click an object (e.g., Implant, annotation, focus area, ...) to see its specific actions.

Use the mouse to interact with the viewers. To change the default 3D viewer controls to those of DTX Studio Implant or Invivo, go to the 3D viewer preferences menu.



Workspaces

Select a workspace from the workspace bar or, if available, use the corresponding shortcut key (see "Learning Resources and Contacting Support" on <u>page 20</u>).

Note

Only the workspaces for which images or data have been added to the diagnosis are shown.

| Workspace | Description | Shortcut key |
|--------------|--|-----------------|
| 3D patient | To inspect the loaded model from all sides, use the mouse actions (see page 38) and the keyboard shortcuts. Alternatively, use the standard clinical view icons: | F2 |
| 3D panoramic | The 3D panoramic radiograph is generated based on the loaded 3D | F3 |
| | X-ray. | 15 |
| Tooth | Navigate to a specific tooth and compare all 2D and 3D data using the smart panel Layout tab. Annotate the selected tooth (see page 43). The vertical slider on the perpendicular viewer rotates the slices around the tooth rotation axis. Depending on the situation, the following slice hints indicate the orientation of the reslice: Oral/Buccal (O / B) | F4 |
| | Mesial/Distal (M / D) Loft/Pight (L / D) | |
| | Left/Right (L / R) | |
| | To adjust the rotation axis, <u>see page 44</u> . | |
| | Press F4 again to go to the endo workspace (if available). | |

| Workspace | Description | Shortcut key |
|---------------|--|-----------------|
| Endo | Focus on a specific tooth for endodontic diagnostics and procedures. To display the tooth pulp, click the Endo 3D visualization on the smart panel Viewer tab. | F4 |
| | Note | |
| | This workspace is available if a 3D X-ray is loaded and when tooth annotations are defined. | |
| | The 3D viewer is focused on a tooth of interest. | |
| | The Tooth cross-sections viewer is a cross-sectional viewer that shows several horizontal tooth cross-sections. | |
| | Once the root morphology is defined (see page 47), the root canals are visualized. | |
| | Press F4 again to go to the tooth workspace (if available). | |
| Implant | Plan and inspect implants. | F9 |
| | Click and drag a reslice or scroll through the reslices to navigate to a desired position. | |
| | Translate or rotate an implant or anchor pin from any 3D reslice viewer of the 3D (CB)CT data by clicking and dragging the object or tip or shoulder points. | |
| | Create a surgical template. | |
| 3D inspection | Navigate to a specific point outside the tooth range to inspect it. | N/A |
| TMJ | Inspect the condyle heads and the temporomandibular joint areas. | N/A |
| IO scan | Inspect and compare IO scans. Press F2 again to go to the 3D patient workspace (if available). | F2 |
| Pan | View a 2D panoramic radiograph (panorex) or multilayer pan images. | F5 |
| Intraoral | Inspect the intraoral images on a layout, for inspecting e.g., a Full Mouth X-ray series. | F6 |
| | Double-click an image to use additional workspace functionalities: image filters and SmartLayout (see page 42). | |
| | To return to the initial layout overview, double- click the image again or press Esc. | |
| | Switch to another image by clicking on a thumbnail in the overview on the smart panel Layout tab. Alternatively, use the T + arrow keys. | |
| | Multiple images can be stacked in the same placeholder. Click to show all the images and click > < to compare them. | |

| Workspace | Description | Shortcut key |
|-------------------|---|-----------------|
| Ceph | View the frontal and/or lateral cephalogram. Use the Generate 3D cephs tool to calculate cephalograms based on the loaded 3D X-ray, or import 2D cephalograms. | F7 |
| Clinical pictures | View the clinical pictures for the patient. | |
| | Double-click an image to use additional workspace functionalities: image filters and SmartLayout (see page 42). | |
| | To return to the initial layout overview, double- click the image again or press Esc. | |
| | Switch to another image by clicking on a thumbnail in the minimap overview on the smart panel Layout tab. Alternatively, use the ← ↑↓ → arrow keys. | |
| | Multiple images can be stacked in the same placeholder. Click to show all the images and click to compare them. | |
| | To select another layout (Orthodontic, Camera or Clinical pictures), click in the top-left workspace corner, select Layout and choose your preferred layout. | |
| Intraoral | Similar to Clinical pictures, but containing the intraoral camera pictures. | N/A |
| pictures | When a tooth is selected on the tooth chart and the intraoral camera is used for image acquisition in the tooth workspace, the acquired images are automatically assigned to the selected tooth. | |
| | The assigned tooth numbers are shown in the clinical pictures workspace. | |
| | Double-click an image to use additional workspace functionalities: image filters and SmartLayout (<u>see page 42</u>). | |
| C | To return to the initial layout overview, double- click the image again or press Esc. | |
| | Switch to another image by clicking on a thumbnail in the overview on the smart panel Layout tab. Alternatively, use the I arrow keys. | |
| | Multiple images can be stacked in the same placeholder. Click to show all the images and click > < to compare them. | |
| Intraoral camera | Dedicated workspace for intraoral camera acquisition. | F10 |
| Recent images | The Recent images workspace shows all recently imported or acquired images. By default, the workspace shows the images of the last seven days. To change this, go to the DTX Studio Clinic preferences. | F12 |

Customize Workspaces

- 1. In the Preferences window, click Workspace.
- 2. In the Default workspace list, select the workspace to be shown by default when opening DTX Studio Clinic. The standard setting is Most recent data, the workspace associated with the most recently acquired or imported image.
- 3. Optionally, change the number of days in the Recent images field for images to be displayed in the Recent images workspace. The default value is 7.
- 4. Click OK.

Show all Related Tooth Information with SmartFocus™

To activate SmartFocus in a supported viewer, press the space bar. Alternatively, click 🔿 on the top menu bar.

- Click on a tooth region to go to the tooth workspace and optionally load the data for the specific tooth in the viewers.
- Click on a region outside the tooth range to go to the 3D inspection workspace.

Customize Views with SmartLayout™

Customize a workspace by adding or removing viewers via the smart panel Layout tab and by changing the viewer proportions.

- To add another viewer to the workspace, click a tile on the smart panel Layout tab.
- Re-click the tile to remove the viewer from the workspace.
- To change the proportion of the viewers, drag one of the window splitters.
- To close a viewer, click on the top-left window title. Select Close viewer. Alternatively, press [Q].
- To sort by modality, date or to have selected images appear first, click the Sort by drop-down menu and select either Modality, Date or Selected first.
- To save the workspace layout, click ••• next to the workspace title and select Save workspace layout. This layout is set as default layout for new patient diagnoses. To reset the viewers, click Reset workspace.

Fuse IO Scans with 3D X-rays

To fuse an IO scan with a 3D X-ray in the 3D patient workspace:

- 1. Click Fuse with 3D X-ray 😒 in the IO scan tools menu.
- 2. Select an IO scan and click Next.
- 3. If needed, indicate corresponding points and use the **Bone threshold** slider to adjust the visualization.
- 4. Check the alignment.
- 5. Click Finish.

Mount Images from the Thumbnail Bar

At the bottom of the intraoral workspace and the clinical pictures workspaces, a thumbnail bar contains the images that are added to the diagnosis but not shown in the workspace viewer.

- Drag an image from the thumbnail bar and drop the image on a placeholder.
- If the placeholder already contained an image, this image is replaced by the new image and the old image is re-added to the thumbnail bar.

Add Diagnostic Findings

The smart panel Findings tab allows you to note dental pathologies, jaw problems or other diagnostic findings on tooth level.

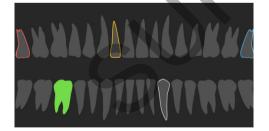
- − To add a predefined diagnostic finding to the tooth, click Add finding ^{EQ} in the Diagnose tools menu, or on the smart panel Findings tab. Optionally, include a screenshot by clicking Screenshots ^{CA} on a finding.
- To remove the finding, hover over or select the finding, click ••• and select Delete.
- To add a custom diagnostic finding, enter a custom name in the search field and press Enter or click Add.
- Click the drop-down menu to assign a status, if needed.

Notes

- In the tooth workspace, the status is visually indicated on the tooth chart as well.
- If the finding is added in the tooth workspace, the finding is added to the specific tooth.
- If the finding is created in another workspace, click the tooth number placeholder and type the tooth number to assign the finding to a specific tooth.

Smart Panel Tooth Chart

In the tooth workspace and endo workspace, a tooth chart is shown above the smart panel tab.



- The active tooth, for which the data are shown in the workspace, is highlighted in green.
- Select another tooth by clicking a tooth on the tooth chart.
- Below the tooth chart, click < to go to the previous tooth, or click > to go to the next tooth.
- A tooth with at least one finding has a colored outline. The color depends on the treatments status of the finding.

| Treatment status | Color | Description |
|------------------|--------|---|
| Condition | Gray | The finding is not critical, but may need to be watched to track its evolution over time. |
| Treatment plan | Red | The finding needs to be treated. |
| Follow-up | Orange | The finding is discovered at an early stage and should be watched. |
| Completed | Blue | The treatment for this finding has been completed. |

Adjust the Bone Threshold

To adjust the bone threshold, right-click CB(CT) data in the 3D viewer and select Bone threshold. Use the slider to set the preferred threshold.

Alternatively, on the smart panel Viewer tab, use the 3D visualization threshold slider.

Adjust Reslices

- Move a reslice by scrolling, clicking and dragging the reslice line.
 Alternatively, move the gray slider to the right side.
- Rotate a reslice by clicking and dragging one of the reslice endings. Drag the mouse inside the viewer to rotate the image data around the center point of the viewer.
- The reslice position is saved.
- To revert to the default position, right-click in the reslice viewer and select Reset reslice axis.

Clip the 3D Volume

On the smart panel Viewer tab of the 3D patient, Tooth and 3D Inspection workspace, select Clip 3D visualization, to hide a part of the 3D volume and inspect certain areas of the volume.

Use Dental Intraoral Cameras in Workspaces

Acquire intraoral images with a USB dental intraoral camera directly in the intraoral camera workspace or from within another workspace:

- 1. Click the Intraoral camera workspace tab or in any workspace, click the smart panel Cameras tab.
- 2. Click a camera device tile, if needed.
- 3. Press the device button to acquire the image. Alternatively, click Capture image at the bottom.

Edit Pictures in the Clinical Pictures Workspace

Double-click the image you want to modify.

- To flip, rotate, crop or straighten a clinical picture, right-click the picture and select the corresponding action. Alternatively, click 1 in the top-left workspace corner.
- To apply the same modification to other images, click another image on the minimap on the smart panel Layout tab.

Create and Modifying Implant Objects in the Implant Workspace

 To lock an implant or anchor pin, adjust the rotation or edit the object details, rightclick the object in one of the viewers and select the corresponding option.

Alternatively, to edit the object details or lock the implant plan or anchor pin, hover over a tile on the smart panel Implant plan tab and click \rightarrow . Edit the details or click \cdots and select Lock.

 To duplicate an implant plan, click … next to the title on the smart panel Implant plan tab and select Duplicate.

Note

Make sure to update a prepared surgical template after modifying an implant or anchor pin. Hover over a tile on the smart panel Implant plan tab and select Update.

Creating the Surgical Template

Once an implant plan has been finalized, the surgical template can be prepared.

Prepare the Surgical Template

- 1. Go to the Implant workspace.
- 2. Click Surgical template ⁽¹⁾ in the Plan tools menu.
- 3. Define the surgical template range, set the correct sleeve type, and click Next.
- 4. Add inspections windows, add a label, set the expert settings, and click Finish.
- 5. The low-resolution surgical template is added to the scene in blue.

Finalize the Surgical Template

When the design of the surgical template is ready, generate the high-resolution surgical template for printing.

- 1. On the Implant plan smart panel, hover over the surgical template, and select Generate template.
- 2. Choose the preferred settings, and click Next.
- 3. Read the agreement carefully. To accept, click I have read and agree all of the above.
- 4. Click Generate.
- 5. The surgical template and instruction documents are added to the patient record.

Note

In DTX Studio Home the surgical template can be sent to SprintRay via the Collaborate ኛ action.

Tools

The toolbar provides you with tools to diagnose, measure, plan treatments and edit the scan data.

Not all the tools will be available in all the workspaces. Unavailable tools are grayed out.



Warning

Measurement accuracy depends on the image data, the used scanner hardware, its calibration and acquisition settings. The measurement cannot be more precise than the resolution of the image. DTX Studio Clinic software reports the value, rounded to one digit after the decimal point, based on user-picked points.

Click one of the toolbar tabs to go to the underlying tools.

| Diagnose tab | | |
|--------------|---|--|
| | Set the slice thickness of a 3D reslice viewer. Click on the 3D reslice viewer and drag horizontally to set the X-ray thickness. Right-click to finish. | |
| | Note | |
| | To set a default slice thickness, go to the Image settings tab in the DTX Studio Home settings or DTX Studio Clinic preferences. In the top-right drop-down menu, select 3D Reslices, Panoramic or Tooth. Select a preferred thickness in the Slice thickness drop-down menu. | |
| • | Drag on a viewer to adjust the brightness and contrast: | |
| | Horizontally: to change the contrast. | |
| | Vertically: to change the brightness. | |
| | Note | |
| | When the brightness and contrast tool is used with grayscale images, the level and window values are updated accordingly. | |
| \bigcirc | Magnify a certain area of an image (default setting) or compare applied filters to the original image. Use the minus and plus keys (or Shift + Plus key when using macOS) to adjust the magnification level. To change the default settings, go to the DTX Studio Clinic preferences. | |
| C | Inspect the underlying reslice when clicking on a 3D model. | |
| | The reslice is shown in the overlay slice explorer window. | |
| | Active image filters and the slice thickness are applied to the slice explorer view as well. | |
| | Scroll to go through all the reslices. | |
| | While inspecting the underlying reslice, the 3D model remains rotatable. | |
| | Capture a screenshot. It is added to the clinical pictures workspace, the smart panel Layout tab and the patient data. The captured screenshot can be added to a report (<u>see page page 43</u>). | |
| <u>≡</u> Q | Add a finding to the smart panel Findings tab. | |
| 5 | Analyze the airway. Indicate landmarks to create a box surrounding the region of interest. Click Done. The airway volume and the most narrowing area is visualized in the 3D patient | |

workspace.

Diagnose tab

| V | Indicate a nerve canal. Click the first anchor point. Then click every next anchor point. Right- click to finish. | | |
|---------------|--|--|--|
| | Adjust the nerve canal annotation by moving the anchor points on the viewer. | | |
| | All the anchor points will appear as one line on the smart panel Annotation tab. | | |
| 5 | Draw a custom reslice line in any reslice viewer of the 3D patient workspace (coronal/sagittal/ axial) to create a custom reslice to inspect the (CB)CT data in detail. For example to mark and inspect the root canals and to make annotations. | | |
| | Move the custom reslice by clicking and dragging the reslice line. | | |
| | Rotate the custom reslice by clicking and dragging one of the reslice endings. | | |
| W | Define the root morphology by indicating reference points in the apical section of each root canal. | | |
| | Scroll through the slices to find an optimal position. Note | | |
| | If needed, re-indicate the tooth center in the Horizontal viewer by clicking and dragging the center. | | |
| | Click a position in one of the viewers. The most encoded in the immediate the base of the post encoded in the post encod | | |
| | The root canal visualization is immediately shown in the Root canal viewer. Click add asists add as successful as a sist if as a dat. | | |
| | 4. Click Add point to add a new reference point, if needed. | | |
| | 5. Click Done. | | |
| R | Detect focus areas on 2D intraoral X-ray images that could potentially contain dental findings. (See page 54). | | |
| Ì | Ignore the detected focus areas. | | |
| R | After having ignored the focus areas, make them appear again. | | |
| | | | |
| Annota | ate tab | | |
| ⊤⊤ | Add text to an image | | |
| û. | Draw segmented lines with the pen. All the lines will appear as one annotation on the smart panel Annotation tab. | | |
| În | Draw free-form lines with the pencil. | | |
| 0 | Draw a circle. | | |
| \rightarrow | Draw an arrow. | | |

Annotate tab

Select the line thickness for an annotation.

Measure tab

| × | Measure the HU value of a point. Click a point in the scene to measure the HU or the gray value. |
|-------|--|
| TIME | Measure a linear distance. Click the two points between which you want to measure the distance. If the image has not yet been calibrated, enter a Reference value. The calibration measurement will be shown in the scene and the calibration object is added on the smart panel Annotation tab. |
| | The measurement (and its accuracy) is shown. |
| ST ST | Measure segments. Click the first point. Then click every next point. Right-click to finish. |
| ٢ | Measure an angle. Click three points. |

Plan tab

This tab is only available on the Implant workspace.

| J | Place an implant. This tool can be used in any workspace that contains (CB)CT data. |
|----|---|
| / | Add an anchor pin. |
| R. | Manage which implants can be placed. |
| +0 | Add another implant plan. Once completed, switch between implant plans via the smart panel Implant plan tab. |
| U | Create a surgical template. Define the surgical template range and set the correct sleeve type. Click Done. |

3D X-ray tab

| | Automatically set up the (CB)CT data and mandibular nerve annotation with the AI-powered |
|---|--|
| - | MagicAssist™ algorithm. All automatically detected points can be manually adjusted. |

3D X-rays containing automatically detected attributes are indicated by an 'Auto' label in the bottom-right corner.

3D X-ray tab

| - () - | Adjust the tooth positions. On the tooth chart, select the tooth that you want to calibrate. Drag the tooth indication to its correct position on the axial reslice. Adjust the axis of the tooth on the perpendicular reslice. | | |
|-------------|--|--|--|
| ~ | Adjust the Pan curve. Indicate the points and teeth as requested. When the teeth are not clearly visible, scroll or use the gray slider at the right side to adjust the position of the axial reslice to a plane showing the tooth setup (approximately converging with the occlusal plane). | | |
| | If needed, adjust the curve: | | |
| | Click and drag individual control points to adjust the shape of the curve. | | |
| | Click on the curve to add a new control point. | | |
| | Click and drag the surrounding area to move the complete curve. | | |
| (2) | Edit the orientation of the patient model. The 3D patient model can be orientated in the preferred position by translating and rotating the model in the 3D viewers. | | |
| | 1. Click the pan icon) or the rotation icon () or press the [Tab] key to switch between rotation and translation mode. The selected mode appears in green. | | |
| | 2. Drag the model until it is correctly aligned with the reference lines. | | |
| | 3. Click Done. | | |
| R | Clean up the patient model by cutting out redundant parts. Click a point in the scene to start drawing around the section that should be removed. Right-click to confirm. | | |
| | To restore the original patient model, click •••• next to 3D visualization on the smart panel Viewer tab. Select Reset 3D model. | | |
| | Define the TMJ area. Indicate the condyle head position as shown in the wizard. Click Done. The TMJ workspace is opened, to compare the left and the right condyle head position and examine the temporomandibular joint area. | | |
| = | Generate a Pan. The panoramic (reslice) view is added to the patient data as a 2D image. The generated image is opened in the Pan workspace. | | |
| Q | Generate 3D cephalograms based on the imported 3D X-ray. | | |

IO Scan tab

| | Automatically set up IO scans. |
|---------|---|
| | Align or realign an IO scan on the 3D X-ray. |
| | Virtually create or extract teeth: Missing teeth are selected by default. To simultaneously extract and create a tooth, click an existing tooth position. To just extract a tooth or create a virtual tooth,right-click a tooth to select the Create tooth or Extract tooth action. Click Next and verify the end-result. Click Finish. |
| | Note |
| | To show the original IO scan, click the smart panel Viewer tab. Select the altered IO scan, click ••• and select Original scan model. Alternatively, right-click the intraoral scan model in the workspace viewer, select IO scans and select Original scan model. |
| 4 | Fill the holes [*] of all jaw scans and diagnostic scans currently visible in the IO scan workspace. Choose either to fill small or all holes. Click Fill holes. The added texture is indicated in blue. * For Windows only. |
| ter and | Compare IO scans to follow up on gingival recession, tooth wear and other differences. Select an IO scan to compare with the reference scan. Click Finish. |
| | By default, a colored distance map is applied. On the smart panel Viewer tab, select Overlay to show the two scans aligned with each other. Disable the comparison by turning the Scan comparison switch off. |
| | |

Reports

Create Reports

To create a report containing findings or as template for patient-related letters:

- 1. In DTX Studio Clinic, open the patient menu.
- 2. Click Export 1 and select Report.
- 3. Select a report template.
- 4. Click Export report.
- 5. The report is exported in an editable .odt format and opened in the default text editor, e.g., Microsoft Office, LibreOffice, OpenOffice Writer.
- 6. Make any changes, if needed.
- 7. Save the report.

Add Custom Practice Logos

By default, the DTX Studio Clinic icon is added to a report header. To add a custom logo:

- 1. In the DTX Studio Home Settings sidebar, click General.
- 2. Click Browse.
- 3. Select a new logo.
- 4. Click Open.
- 5. Click OK.

Opening DTX Studio[™] Implant

Connect DTX Studio[™] Clinic and DTX Studio[™] Implant

- 1. In the DTX Studio Home Settings sidebar, click DTX Studio Implant.
- 2. Click Browse to go to the location on the computer where DTX Studio Implant is installed.

Note

Set the location for patient data in case you need to add patient data to the patient record in DTX Studio Implant manually; that is if a patient record already exists in DTX Studio Implant or if intraoral scans are exported to DTX Studio Implant but are not aligned with the 3D X-ray.

3. Click OK.

Launch DTX Studio[™] Implant

 Select the patient record in the patient list. Note

At least one 3D X-ray must be available for this patient.

- 2. Click Implant 🖻
- 3. Select Open existing patient or Export to new patient.
- 4. If there is more than one 3D X-ray, select the appropriate tile.
- 5. Click Export.
- 6. A success message appears. Click OK.
- 7. The patient record is created and/or opened in DTX Studio Implant.

Orders and Partner Collaborations

Order a Surgery Plan, Surgical Template or Restoration

- 1. Select the patient record in the patient list.
- 2. Click Collaborate ⇐.
- 3. Hover over Surgery plan \mathbb{I} , Surgical template \mathfrak{m} or Restoration \mathfrak{N} .
- 4. Click Select.
- 5. Select the patient data to send to the lab or the clinician.
- 6. Click Continue.
- 7. A draft order is created on DTX Studio Go. Add the missing data and send the order to the connected lab or clinician.
- 8. Click Orders . in the sidebar to view all your orders.

Note

Please note that some products described in the Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

Set up a Connection with a Partner

Some third-party partners can provide services directly integrated into DTX Studio Clinic. The order can be created in DTX Studio Clinic and submitted to the partner's framework.

If service providers are available in your region, start by connecting your partner account in DTX Studio Go.

- 1. Click Collaborate ¢.
- 2. Hover over the partner name and select Set up.
- 3. Click Continue.
- 4. Follow the instructions in DTX Studio Go to complete the connection.

Order Directly from a Partner

Once the partner account is connected in DTX Studio Go, you can use their services.

- 1. Click Collaborate ⇔.
- 2. Hover over the partner name and click Select.
- 3. Select the patient data that you want to send.
- 4. Click Continue.
- 5. The files are uploaded.
- 6. Continue the order process on the partner website.
- 7. Once submitted, the order is added to the Orders overview in the patient record.

View Partner Case or add new Data

- 1. Select the patient record in the patient list.
- 2. Click the Orders tab.
 - Click View case to open the case on the partner website.
 - Click Add new data to submit new data to the case.

Focus Area Detection

What is Focus Area Detection?

DTX Studio Clinic allows to automatically detect focus areas on 2D intraoral X-ray images (IOR). The IOR capturing devices can either be digital sensors or analogue PSP plates.

Focus Area Detection is an Al-powered algorithm (artificial intelligence) using a convolutional neural network for image segmentation to locate regions of interest where a dental finding or capturing artifact might exist. An approved focus area is automatically converted into a diagnostic finding for that patient.

Supported focus areas for dental findings are caries, periapical radiolucency, root canal filling deficiency, discrepancy at margin of existing restoration, bone loss and calculus.

Supported focus areas for capturing artifacts are overlap and scratches.

Using Focus Area Detection

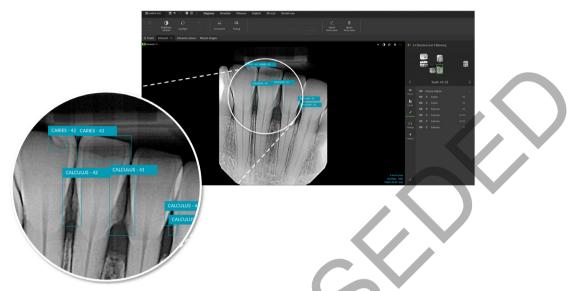
When intraoral images are captured or imported, Focus Area Detection is run automatically, to check whether the images contain areas that need special attention. You can see this by the blue line running over the images.

If an image shows potential dental findings, a blue Focus Area Detection icon : is shown in the top-left corner of the image combined with a number, indicating the amount of dental findings.

When an image does not contain the blue icon, either no possible dental findings have been detected or the image has not been checked. This does not mean that there are no potential dental findings. Caution should be exercised when using this feature.

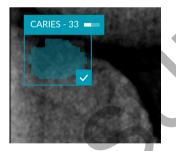


Click an image to open it. Focus areas are visualized on the intraoral images using focus area annotations. These annotations show the tooth number (if known), and the type of potential dental finding detected.



An indication of the whereabouts of the potential dental findings is visualized when hovering over the focus area.

After your analysis, choose either to accept the potential dental finding by left-clicking the focus area or reject it by right-clicking the focus area.

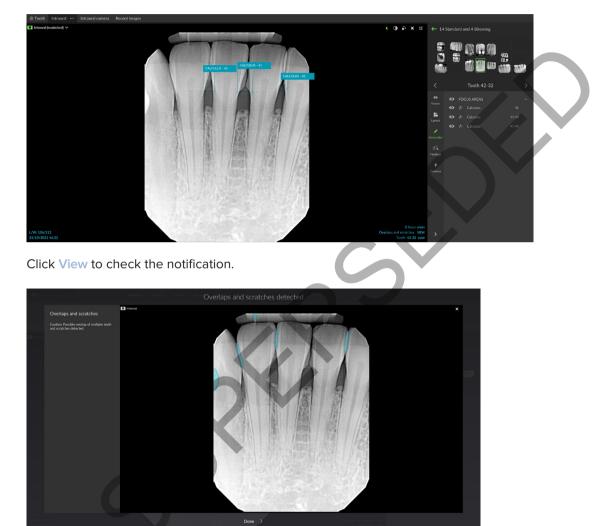


If you choose to accept it, the focus area changes to yellow and is turned into a diagnostic finding automatically. It will be added to the smart panel Findings tab.

The focus areas are listed on the smart panel Annotation tab as well and can be shown or hidden using the visibility icons of the smart panel 's visibility functionality.

Overlaps and scratches

Focus Area Detection also checks for possible overlap of multiple teeth and/or scratches. If overlaps or scratches are detected, a notification is displayed in the bottom-right corner.



Annex I: Focus Area Detection **Algorithm Performance Assessment**

Clinical Performance Assessment

A clinical performance assessment was performed on a US-based dataset of 216 IOR images, of patients above the age of 12 and with permanent teeth. Of those, 92 were male and 90 female, while 34 images were obtained with undisclosed patient gender. The capturing devices were either digital sensors (186 images) or PSP plates (32 images). A ground truth was established for this data set by four US expert dentists using a three out of four consensus voting.

The assessment was performed as a retrospective fully crossed Multi Reader Multi Case study. The reading performance of thirty US dentists using the Al-based Focus Area Detection algorithm for detection of dental findings was compared to the prior reading performance of the same clinicians evaluating the IOR images without algorithmic assistance. A four weeks period was secured between the two reading sessions to avoid any memory bias.

Based on all collected reading data, an AFROC (Alternative Free Response Receiver Operating Characteristic) curve was generated. AFROC curves depict sensitivity on dental finding level versus imagelevel specificity. An increase of AUC (Area under the curve) of 8.7% was observed on dental finding level. Based on the ANOVA model using t-test was this increase was determined to be statistically significant (p<0.001).

| | Sensiti | vity | 95% confidence intervals of sensitivity | | Specificity | | 95% confidence intervals for true sensitivity | |
|--|---------|-------|---|--------------|-------------|-------|---|--------------|
| Dental finding type | Control | Study | Control | Study | Control | Study | Control | Study |
| Caries | 65.1 | 82.7 | [57.3, 72.9] | [76.6, 88.9] | 94.9 | 93.0 | [93.6, 96.1] | [91.6, 94.5] |
| Periapical radiolucency | 63.6 | 84.3 | [49.3, 78.0] | [73.4, 95.1] | 99.3 | 97.8 | [98.8, 99.8] | [97.0, 98.6] |
| Root canal filling deficiency | 68.4 | 94.8 | [52.0, 84.8] | [87.1, 100] | 99.1 | 98.2 | [98.5, 99.6] | [97.5, 98.9] |
| Discrepancy at margin of existing restoration | 67.4 | 93.1 | [58.2, 76.6] | [88.2, 98.1] | 95.7 | 92.2 | [94.5, 96.8] | [90.7, 93.7] |
| Bone loss | 58.1 | 76.5 | [51.3, 64.9] | [70.6, 82.3] | 81.0 | 75.9 | [78.7, 83.2] | [73.4, 78.4] |
| Calculus | 67.1 | 85.0 | [58.5, 75.6] | [78.5, 91.5] | 97.9 | 97.6 | [97.1, 98.7] | [96.7, 98.4] |

Sensitivity increased overall and for each of the six dental finding types separately, indicating that a substantial proportion of additional dental findings was detected compared to the unaided reading.

Stand-alone Performance Assessment

The Focus Area Detection algorithm assigns each pixel in the IOR image to a labelled category of either background or one of the detectable findings or artifacts. Connected labelled pixel regions form the focus areas. The training dataset used for training the convolutional neural network consisted of 3202 annotated IOR images, with an additional 936 IOR images used for AI parameter tuning. The AI algorithm itself has been validated on an additional independent test dataset of 452 IOR images. The ratio of sensor to PSP images was respectively 1216 to 1986 (training), 365 to 571 (tuning) and 168 to 284 (testing). For both training and comparison, the locations were manually annotated once by various clinicians. The average sensitivity (a.k.a. recall) of the Focus Area Detection algorithm over the six types of findings equaled 80.8%, while the precision was 46.7%.

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