

# DTX Studio™ Clinic 1.9

Instructions for Use

#### GTIN Information:

The following table lists the GTIN information for the devices described in this IFU.

Device	GTIN
300851_V1.9_WIN64	07332747185768
300851_V1.9_MAC	07332747185775



Manufacturer:

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Rx Only

Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

For Prescription Use Only. Caution: Federal (United States) law restricts this device to sale by or on the order of a clinician, medical professional or physician.

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### Welcome to DTX Studio™ Clinic

#### **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 imaging data from different devices (i.e. Intra Oral X-Rays, (CB)CT scanners, Intraoral scanners, intraoral and extraoral cameras).

#### **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 transfer and visualization of dental and craniomaxillofacial image information. It displays and enhances digital images from various sources to support the diagnostic process. It stores and communicates these images within the system or across computer systems at distributed locations.

#### 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.

#### REQUIRED COMPATIBILITY WITH OTHER DEVICES

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

Intraoral sensors: KaVo GXS-700™, KaVo IXS™, DEXIS™ Titanium, Gendex™ GXS-700™, DEXIS™ Platinum Intraoral cameras: KaVo DIAGNOcam™ Vision Full HD, KaVo DIAGNOcam™, CariVu™, DEXIS™ DexCAM™ 4HD, KaVo ErgoCAM™ One, Gendex™ GXC-300™, DEXIS™ DexCAM™ 3, DEXIS™ DexCAM™ 4

Intraoral scanner: Compatibility with Medit Link Software\* and Medit Scan for DTX Studio™\*, which supports the Medit i500/KaVo X 500 intraoral scanner or other compatible models.

DTX Studio™ Core

DTX Studio<sup>™</sup> Implant

DTX Studio™ Go

DTX Studio<sup>™</sup> Lab

CyberMed OnDemand3D™

Anatomage InVivo™

#### **DEVICES WITH MEASURING FUNCTION**

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.

#### CONTRAINDICATIONS

None identified for DTX Studio™ Clinic.

#### **CAUTIONS / PRECAUTIONS**

- 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.

<sup>\*</sup> Product is available for Windows operating systems only.

#### **WARNINGS**

Following warnings are shown in the software.

Warning	Explanation
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 scan to the current diagnosis.	The current diagnosis contains a 3D scan 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 scan 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.
Verify the scan request parameters on the device.	Before exposing the patient, make sure to check the parameters on the device.
Image has been flipped	Images which are manually flipped (horizontally mirrored) by user display this warning.

- 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.
- 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.

#### **CYBERSECURITY**

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. Furthermore, always lock the computer when it is left unattended.

#### COMPATIBILITY

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

#### **INTEROPERABILITY**

DTX Studio™ Clinic is interoperable with DTX Studio™ Implant and DTX Studio™ Lab.

#### INTENDED LIFETIME

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

#### PERFORMANCE REQUIREMENTS AND LIMITATIONS

DTX Studio™ Clinic has dependencies on the operating systems it is used with. It is therefore important to make sure DTX Studio™ Clinic is used only with approved operating systems. More information about which operating systems are approved can be found in the 'Computer Guidelines for DTX Studio™ Clinic'.

#### CLINICAL BENEFITS AND UNDESIRABLE SIDE EFFECTS

DTX Studio™ Clinic is a component of treatment with a dental implant system and/or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and/ or crowns restored.

None identified for DTX Studio™ Clinic.

#### **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. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more information please visit www.nobelbiocare.com.

#### 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

#### PROFESSIONAL USE

DTX Studio™ Clinic is for professional use only.

#### SYSTEM REQUIREMENTS

We advise to check the system requirements 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

To obtain information on how to install the software, please contact the authorized technician or customer support.

### Start

#### STARTING DTX STUDIO™ CLINIC

- 1. To open the DTX Studio™ Clinic application:

  - On macOS, click the shortcut icon 
     in the Finder application folder or the Dock.
- 2. Select the user.
- 3. Enter your password.

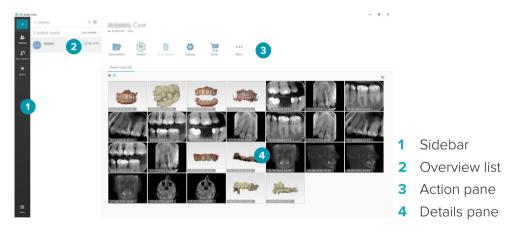
**Note**: If you forgot your password, click **Forgot password** to go to DTX Studio™ Go. Enter your username, select I'm not a robot and click Reset password. A link will be sent to your registered e-mail address where you can reset your password.

4. Click Log in.

#### Notes

- If you select **Log in automatically**, the login dialog will not be shown anymore on the computer used.
- If two-factor authentication was set up on DTX Studio™ Go, every 30 days you will additionally need to enter a six-digit verification code to log in.
- The DTX Studio™ Clinic software 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.

#### **EXPLORING THE WORK AREA**



#### **EXPLORING THE NOTIFICATION AREA**

The DTX Studio™ Clinic icon 🕏 in the notification area grants access to the DTX Studio™ Clinic 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<sup>™</sup> Core (i), DTX Studio<sup>™</sup> Go (a), Exposure reports\*, QuickPrescribe\*, Scan Center\* or a linked third-party application. \*Requires DTX Studio™ Core
- **Devices**: lists the acquisition devices and their statuses (connected via USB , online ●, busy ● or offline ●). Click ••• to access the device settings.

#### **ADJUSTING SETTINGS**

To adjust the default DTX Studio™ Clinic settings:

- Click Menu ≡.
- 2. Click **Settings .**

#### Changing Language and Date/Time Format

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

- 1. In the settings sidebar, click **Regional**.
- 2. 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.

#### **Adjusting 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 settings sidebar, click **Practice**.
- 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 2020 tags always remain preserved.

#### **Setting Default Image Filters**

To set the default image filters in DTX Studio™ Clinic for the Clinic viewer and diagnostic module:

- 1. In the settings or diagnose preferences sidebar, click **Image settings**.
- 2. From the **Default image settings** list, select the image type for which you want to set the default filter settings.
- 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.

#### Connecting to DTX Studio™ Core

If DTX Studio™ Clinic is connected with DTX Studio™ Core, DTX Studio™ Clinic can be used in a network environment and enables the acquisition of images from other supported (Ethernet connected and supported TRIOS 3Shape) devices. DTX Studio™ Core is a software solution to store and retrieve patient media and image data types (2D X-ray, 3D X-ray, (CB)CT scans, photos) in a structured and centralized way, so that stored data is immediately accessible anywhere in the dental clinic. 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 settings sidebar, click **Core**.
- 2. Enter the **URL** (web address), **Login** and **Password** for DTX Studio™ Core.
- 3. Click Connect.

#### Adding an Application to the Action Pane

- 1. In the <u>settings</u> sidebar, click **Quick Launch**.
- 2. Click Add.
- 3. Select the executable file and click **Open**.
- 4. Select Launch with patient data to launch the third party application with patient data.
- 5. Click **Browse** to choose a location for the exported data. Click **Select folder**. Alternatively, enter the file path in the **Export directory** field. 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.

6. Click **OK**.

#### **Enabling Practice Management System (PMS) Integration**

Integrating DTX Studio™ Clinic with a PMS (i.e. through VDDS or OPP) allows you to create a patient record and acquire an image from within the PMS. Preview the PMS images in DTX Studio™ Clinic or directly in the DTX Studio™ Clinic diagnostic module.

- 1. In the settings sidebar, click **PMS integration**.
- 2. Select Enable PMS integration.

#### CLOSING DTX STUDIO™ CLINIC

Make sure to close all the instances of the diagnostic and scan modules\*.

To close DTX Studio™ Clinic:

- 1. Click **Menu**.
- 2. Click Close application.

Note: Using the closing button X, the software remains running in the background, to allow data synchronization and a quicker response when reopening DTX Studio™ Clinic.

\*Module might be licensed.

## From Scan to Diagnosis

Follow the steps below to diagnose a patient.

1	+	Create a patient record (see <u>page 14</u> ).
2		Request a scan (to delegate or acquire the scan later) (see page 17) or
		Acquire the scan now (see page 18).
3		Open the diagnostic module (see <u>page 20</u> ).
4	PI	Optionally, open DTX Studio™ Implant (see <u>page 28</u> ).
5	00	Optionally, order a restoration or a surgery plan (see page 29).
6	<	Optionally, share patient data (see page 15).

### Create a Patient Record

Click **Patients** Let in the sidebar to open the patients list, if not already open. If the workstation is not connected to DTX Studio™ Core, only the patient records that are stored on the local hard drive are shown. Patient records that are open in the diagnostic module are marked with a lock icon 🕒.

#### CREATING A NEW PATIENT RECORD

To create a patient record:

- 1. Click **Add patient** ±.
- 2. Select Create patient.
- 3. Enter basic patient details, like patient name, date of birth and gender.

Note: Required fields are marked with a red asterisk.

- 4. Click **Finish**.
- 5. The patient record is added to the **Patients** ♣ list. If DTX Studio™ Clinic is connected to DTX Studio<sup>™</sup> Core, the patient record is also added to DTX Studio<sup>™</sup> Core.

For patient records stored in DTX Studio™ Core, it is possible to make them available offline in advance. To do so, select the patient record in the patient list, click More ••• and turn on the Offline available switch button.

#### MANAGING PATIENT RECORDS

To edit basic patient information, select the patient record in the patients list, click More ••• and select Edit 2.

To delete a patient, select the patient record in the patients list, click **More ···** and select **Delete** ①. The notification area (see page 10) shows which patient records are being uploaded or synchronized.

#### **PRIVACY MODE**

To secure the patient privacy, hide the patient names, IDs and dates of birth from the patients list:

- 1. On the patients list, click the settings icon \( \sigma\_{\text{.}} \).
- 2. Select Privacy mode.
- 3. Click outside the settings menu to close the settings pane.
- 4. Only the patient's initials are shown. Other information is hidden. In the details pane of the selected patient record, the patient name and date of birth are visible.

Privacy settings remain enabled, even when restarting DTX Studio™ Clinic. To turn off the privacy mode, click the settings icon  $\stackrel{\bullet}{\sim}$  again and select **Privacy mode**.

#### SEARCHING AND SORTING PATIENT RECORDS

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

To sort the patients list:

- 1. Click the drop-down arrow next to the patients list header.
- 2. Select one of the available options:
  - Last created
  - Last modified
  - Last captured
- 3. Click the drop-down list again to close it.

To search for a patient:

- 1. On the patients list, click the settings icon \( \sigma\_{\text{.}} \)
- 2. Select Patient name, Date of birth or Patient ID.
- 3. Click outside the settings menu to close the settings pane.
- 4. Type (a part of) the patient name or the date of birth in the **Find a patient** field Q.
- 5. While typing text in the search box, the patients list is filtered automatically.

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

#### **EXPORTING A PATIENT RECORD**

Export a patient record to share the diagnoses and image data with another DTX Studio™ Clinic user. Additionally, the exported patient can be viewed in the Referral version of DTX Studio™ Clinic, freely available via DTX Studio™ Go.

To export a patient:

- 1. Select the patient record in the patients list.
- 2. Click More •••.
- 3. Click **Export patient 2**.
- 4. Select the diagnoses you want to export. To export the entire patient record, select Export full patient.
- 5. Browse to the location where to store the patient and click **Export**.

#### SHARING PATIENT DATA VIA DTX STUDIO™ GO

Share patient data with a dental office via DTX Studio™ Go. If patient data is shared, an additional **GoShare** tab shows an overview.

- 1. On a patient record's action pane, click **Share** \$\frac{1}{2}\$.
- 2. Select **Full patient**  $\triangle$  to share the entire patient record, or **Patient data**  $\blacksquare$  to share specific data.
- 3. Choose the preferred options. Click **Continue**.
- 4. The data is uploaded in the background to DTX Studio™ Go. When the upload is completed, a notification appears.
- 5. Click (\*) in the notification area and select **Continue**.
- 6. Follow the instructions in DTX Studio™ Go. The connection is notified by mail.

Note: If the connection owns a Select, Pro or Referral license, the data appears in the Orders list.

#### IMPORTING FROM 3SHAPE DENTAL DESKTOP SOFTWARE

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

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

1. Create a new patient record in DTX Studio™ Clinic with exactly the same first name, last name and date of birth of an existing patient in 3Shape Dental Desktop.

#### Notes

- A patient name is case-sensitive, so make sure that the patient names are correctly capitalized. Otherwise the 3Shape data will not merge with the DTX Studio™ Clinic patient record.
- 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. In the Patient section, click **Import from 3Shape** •.
- 5. If requested, confirm that the patient case 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.

## Request a Scan

To work with scan requests, a connection with DTX Studio™ Core needs to be established (see page 11).

#### SCHEDULING A SCAN

To request a scan for a patient:

- 1. Select the patient record in the patients list.
- 2. Click **Scan request =**.
- 3. Hover over the picture tile of the image acquisition device and click **Select**.
- 4. Fill out the applicable information in the scan request form.

**Note**: Depending on the chosen modality, the form is different.

- 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.
- If needed, change the Scan date and the Requesting clinician.
- 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 **Layout**.
- Add Request notes for the operator if applicable.
- 5. Click **Create scan request(s)**. The scan request is added.

#### SEARCHING AND SORTING SCAN REQUESTS

To sort the scan request list:

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

To 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.

### Perform a Scan

Before, during or after diagnosing the patient, a scan can be taken — 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. Go to the device to perform the scan.
- 3. Click Finish to end the action, or click Open diagnose to open the diagnostic module.

#### PERFORM AN IMMEDIATE SCAN

- 1. Select the patient record in the patients list.
- 2. Click Capture .
- 3. Hover over a device tile and click **Select**.
- 4. Select which data you want to acquire with the chosen device.
  - Intraoral sensor or PSP device: specify to acquire images with or without following a template.
    - With a template: see "Guided Acquisition for Intraoral X-ray Images" below.
    - Without a template: stay on the Free tab and continue with the next step.
  - **Intraoral camera**: select the teeth you want to acquire and click **Start**.
  - Intraoral scanner: see "Intraoral Scanning" below.

#### Notes

- Upon importing or acquiring a 2D image, level and window values are automatically set. To disable this, go to the Image settings tab in the DTX Studio™ Clinic settings. In the top-right drop-down menu, select Pan, Intraoral or Ceph. Deselect Auto level window. Enter custom level and window values. Click **OK**.
- 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.
- 5. Go to the device and perform the scan.
- 6. Click Finish.

#### Guided Acquisition for Intraoral X-ray Images

If you selected an intraoral sensor or PSP device, a template for guided acquisition is available:

- 1. Perform an immediate scan.
- 2. When performing the scan, select the **Template** tab and select your preferred template.
- 3. Select the images you want to acquire and click **Start**.
- 4. Go to the device to perform the scan.
- 5. Click **Finish**.

#### Free Acquisition for Intraoral X-ray Images

- 1. Perform an immediate scan.
- 2. Select the **Free** tab.
- 3. Go to the device to perform the scan.
- 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.
  - Rotate the acquired image if necessary.

Action	lcon	Shortcut
Rotate image counterclockwise	-	Alt+ <b>←</b> , or R
Rotate image clockwise		Alt+➡, or Shift+R

#### INTRAORAL SCANNING

#### **3SHAPE TRIOS SCANNER**

1. Start the scan in the 3Shape Dental Desktop application.

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

- 2. Complete the scanning process.
- 3. 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 start a new diagnosis in the diagnostic module.

#### **KAVO AND MEDIT SCANNERS**

The scan module\* (for Windows only) allows you to use a supported Medit / KaVo intraoral scanner with DTX Studio™ Clinic and to reopen existing scan cases.

#### **Acquire Intraoral Scan Data**

- 1. Select the patient record in the patients list.
- 2. Click Capture .
- 3. Select the intraoral scanner and click **Select**.
- 4. The scan module is opened.
- 5. Follow the instructions in the scan module.
- 6. The processed data is added to the patient record.

#### 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, take additional scans, trim, measure and more:

- 1. In a patient record, click the dental scan tile.
- 2. Click Open in Scan app.

Note: if the intraoral scan data was previously opened in the diagnostic module, Open in Medit Scan is not shown. Instead, Open a copy is available.

\*For Windows computers only and on the computer which has been used for acquiring the intraoral scan data.

## Make a Diagnosis

The diagnostic module allows you to view and inspect the patient data and to add findings and measurements to the patient record.

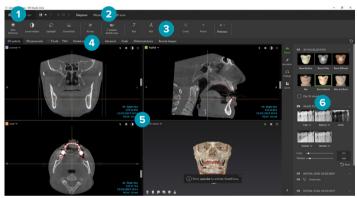
There are two versions:

- DTX Studio™ Clinic **Pro**: All (2D and 3D) features are available. 2D and 3D images can be acquired.
- DTX Studio™ Clinic Select: Only the 2D features are available. 2D images can be acquired.

To open the diagnostic module, select a patient in the **Patients** list and click **Open Patient**. Alternatively, double-click the patient in the patient list or press [O].

Multiple instances of the diagnostic module can be launched for separate patient records. Before making a diagnosis, manage the patient scans and images that you will use for the diagnosis.

#### **EXPLORING THE DIAGNOSTIC MODULE**



- Patient menu
- Menu bar
- Toolbar 3
- Workspace bar
- Workspace SmartLayout™
- SmartPanel™

#### **CUSTOMIZING WORKSPACES**

- 1. In the Preferences window, click **Workspace**.
- 2. In the **Default workspace** list, select the workspace to be shown by default when opening the diagnostic module. 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**.

#### WORKING WITH THE PATIENT MENU

In the diagnostic module, click in the upper-left corner to open the patient menu.

#### **Menu Options**

The menu in the left pane allows you to:

- New: create a new diagnosis,
- Open: open another existing diagnosis,
- Save: save the open diagnosis,
- Export report: export a report of the patient diagnosis,
- Preferences: change the settings, like the Default workspace, Performance, Image settings, 3D viewer and Tools.

Close application: close the diagnostic module.

#### **Diagnosis Tooth Chart**

The patient's tooth chart gives an overview of 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 that the clinician will have to change the teeth manually to go to an adult tooth chart when the patient is growing up.

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

Indicate hypodontia.

	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.
		<b>Note</b> : Child dentition is displayed for patients younger than eight
		years old.
X	Not present with gap	This tooth is missing and there is a gap on this location.
M	Impacted	This tooth will be impacted (often used for wisdom teeth).
+7	Insert	Insert a tooth, e.g., adult molars in a child dentition.

#### Diagnosis Data

III

Below the tooth chart, the scans and the images for the open diagnosis are shown per data type, and sorted by acquisition date.

- 3D scan
- Pan (panoramic image)

Not present without gap

- Intraoral images
- Cephalogram
- Clinical pictures
- Screenshots
- Dental scan
- Multiple images of a certain type are shown as a group. Click the group to show all the images of that group. Click outside the pop-up images to close the group.
- On the 3D scan, click the down arrow wand select another 3D scan to switch between 3D scans. Select **None** to remove the 3D scan from your diagnosis.

To start acquiring data directly from the diagnostic module and add it to the open diagnosis, click Data + and select **Capture** ②. Alternatively, click ② on the menu bar.

To import data to the open diagnosis or to manage it, click Data + and Import  $\frac{1}{2}$  or Manage data  $\boxed{2}$ . Acquiring intraoral images with a USB dental intraoral camera can also be done from within a workspace. Plug in the intraoral camera. Click the device tile on the **Devices** tab that appears on the SmartPanel™. Press the button on the device to acquire the image.

#### **WORKSPACES**

Select a workspace from the workspace bar or use the corresponding shortcut key. Only the workspaces for which images have been added to the diagnosis are shown.

Workspace	<b>Description</b>	Shortcut key
3D patient	To inspect the loaded model from all sides, use the mouse actions (see "Interact with the Mouse" on page 24) and the keyboard shortcuts (see "Appendix: Shortcut Keys" on page 30)  Or use the standard clinical view icons:	
	Posterior	
	Left lateral	
	Right lateral	
	Cranial	
	Press F2 again to go to the dental scan workspace (if available).	
Dental scan Inspect and compare dental scans.		F2
	Press F2 again to go to the 3D patient workspace (if available).	
3D panoramic	The 3D panoramic radiograph is generated based on the loaded 3D scan.	
Tooth	Navigate to a specific tooth and compare all 2D and 3D data using the SmartPanel™ <b>Layout</b> tab. Annotate the selected tooth (see page 24).	F4
	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:	
	<ul><li>Oral/Buccal (O / B)</li></ul>	
	<ul><li>Mesial/Distal (M / D)</li></ul>	
	<ul> <li>Left/Right (L / R).</li> </ul>	
	To adjust the rotation axis, click <b>Edit axis</b> ${}^{\dagger}$ or press [A]. An orange cross is drawn on top of the perpendicular and the parallel viewer. Drag the mouse inside the viewer to rotate the image data around the center point of the viewer. Press [A] again or right-click to finish the action.	
	To change the image center point, click the translate tooth annotation mode icon or press [T] and drag the image data.	
3D inspection	Navigate to a specific point outside the tooth range to inspect it.	
TMJ	Inspect the condyle heads and the temporomandibular joint areas.	
Pan	View a 2D panoramic radiograph (panorex) or multilayer pan images.	F5

Workspace	Description	
Intraoral	Inspect the intraoral images on a layout, for inspecting e.g., a Full Mouth X-ray series. Double-click an image to use additional workspace functionalities: image filters and SmartLayout™ (see page 23).  Switch to another image by clicking on a thumbnail in the tooth range on the SmartPanel™ Layout tab. To return to the initial layout overview, click on the top-right layout title.	
Ceph	View the frontal and/or lateral cephalogram. Use the <b>Generate the 3D Cephs</b> tool to calculate cephalograms based on the loaded 3D scan, or import 2D cephalograms.	
Clinical pictures	s View the clinical pictures for the patient.	
Recent images	The <b>Recent images</b> 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 diagnostic module preferences.	F12

#### SmartFocus™

To activate SmartFocus™ in the 3D patient, 3D panoramic, 3D inspection or the intraoral workspace, press the spacebar. Alternatively, click 🕆 on the top menu bar.

A line will visualize the occlusal plane and the tooth numbers will be shown. 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.

#### SmartLayout™

To add an image, viewer or reslice window to the workspace, click an image, Reslices or Viewers tile on the SmartPanel™ **Layout** tab. Click the tile again to remove the image, viewer or reslice window from the workspace. Up to 12 viewers can be displayed in SmartLayout™.

To change the proportion of the viewers, drag one of the window splitters. To reset the viewers, click the **Reset Layout** button **5**. 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 drop-down menu and select either Modality, Date or Selected first.

#### SmartFusion™

To align a dental scan with the 3D scan in the 3D patient workspace, click Align dental scan with the 3D scan in the Edit 3D scan tools menu. Select a dental scan and click Next.

#### 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

#### **Findings**

The Findings tab of the SmartPanel™ allows you to note your diagnostic findings on tooth level (see page 24).

#### Interact with the Mouse

Use the mouse to interact with the model in 3D viewers

	Right-click and drag	Temporarily switch to rotation mode.  If already in rotation mode, press the wheel button to temporarily switch to pan mode.
Ctrl	Ctrl + click and drag, or Cmd + click and drag	Temporarily switch to pan mode. Make sure the mouse pointer is not hovering over the model.
Shift	Shift + click and drag, or Scroll the wheel button	Temporarily switch to zoom mode. Make sure the mouse pointer is not hovering over the model.

#### **Diagnostic Findings**

Add dental pathologies, jaw problems or other diagnostic findings to the diagnosis.

- To add a predefined diagnostic finding to the tooth, go to the SmartPanel™ Findings tab. Click the search field to open a drop-down list, and select a finding.
- To add a custom diagnostic finding, enter the custom finding text in the search field and press Enter or click Add. To remove the finding, hover over the finding, click the ellipsis icon \*\*\* and select Delete.
- 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.

#### **Tooth Chart**

On the SmartPanel™ **Findings** tab of the tooth workspace, a tooth chart is shown in the upper-right corner.

The active tooth, for which the data are shown in the workspace, is highlighted in green. A tooth with at least one finding has a colored outline. The color depends on the treatment status of the finding.

Condition	Gray	The finding is not critical, but may need to be watched to track its evolution

over time.

Treatment plan The finding needs to be treated. Red

Follow-up Orange The finding is discovered at an early stage and should be watched.

The treatment for this finding has been completed. Completed Blue

Below the tooth chart, click the left arrow to go to the previous tooth, or click the right arrow to go to the next tooth. Alternatively, click a tooth on the tooth chart to select another tooth.

#### Clipping the 3D Volume

On the SmartPanel™ 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.

#### **DIAGNOSTIC TOOLS**

The toolbar provides you with tools to diagnose, measure 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.

#### Diagnose

Click the **Diagnose** tab to go to the following tools:

- Set the slice thickness of a 2D reslice viewer. Click on the 2D reslice viewer and drag horizontally to set the X-ray thickness. Right-click to finish.
- Adapt the brightness and contrast for color images or the level and window for grayscale images. The cursor changes into a brightness/contrast icon. Drag on a viewer to adjust the brightness and contrast or the level and window:
  - horizontally: to change the contrast of a color image or to set the range (window) of CT data or grayscale image.
  - vertically: to change the brightness of a color image or to set the range (level) of CT data or gray scale image.

Right-click to stop the action.

Note: Upon importing or capturing a 2D image, level and window values are automatically set. To disable this, go to the **Image settings** tab in the DTX Studio™ Clinic settings. In the top-right drop-down menu, select Pan, Intraoral or Ceph. Deselect Auto level window. Enter custom level and window values. Click **OK**.

- 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 diagnostic module preferences.
- $\simeq$ Capture a screenshot. The captured screenshot can be added to a report (see page 27).
- Analyze the airway. Indicate landmarks to create a box surrounding the region of interest. Click (0) **Done**. The airway volume and the constriction point is visualized in the 3D patient workspace.
- $_{ op}$ T Add text to an image.
- Draw segmented lines with the pen. All the lines will appear as one annotation on the On. SmartPanel™ **Annotation** tab

En	Draw free-form lines with the pencil.
0	Draw a circle.
$\rightarrow$	Draw an arrow.
=	Select the line thickness for an annotation.

#### Measure

Click the **Measure** tab to go to the following tools:

- Measure the HU value of a point. Click a point in the scene to measure the HU or the gray value.
- 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  $\checkmark$  is added on the SmartPanel<sup>™</sup> **Annotation** tab.

The measurement (and its accuracy) is shown.

- Measure segments. Click the first point. Then click every next point. Right-click to finish.
- Measure an angle. Click three points.

#### Edit 3D Scan

Click the **Edit 3D scan** tab to go to the following tools:

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. Click the pan icon under the rotation icon 5 or press the [Tab] key to switch between rotation and translation mode. The selected mode appears in green.

Drag the model until it is correctly aligned with the Occlusal reference line, with the Midline in the frontal view, and the **True vertical** in the lateral view. Click **Done**.

Adjust the Pan curve. Indicate the points and teeth as requested by the system. When the teeth are not clearly visible, use the 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).

To adjust the curve:

- Move individual control points to adjust the shape of the curve.
- Click and drag the surrounding area to move the complete curve.
- The indicated points appear in fuchsia. The intermediate points, visualizing the teeth between the indicated points, are displayed in gray. Drag and drop a fuchsia point to move the point to another location. Click a gray point to turn it into a moveable fuchsia point.

On the right viewer the Pan is shown. Click **Done**.

- 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.
- Adjust the tooth positions. On the tooth chart, select the tooth that you want to calibrate. Drag (e)the tooth indication to its correct position on the axial reslice. Adjust the axis of the tooth on the perpendicular reslice.
- Adjust the bone threshold. Click and drag on a 3D viewer to adjust the bone threshold value.
- Align or realign a dental scan with the 3D scan via SmartFusion™. (0,0)
- 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.
- Generate 3D cephalograms based on the imported 3D scan.  $\mathbf{Q}$

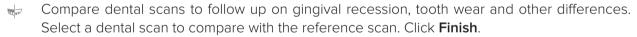
#### **Dental Scan**

Click the **Dental scan** tab to go to the following tools:



Fill the holes\* of all jaw scans and diagnostic scans currently visible in the dental scan workspace. Choose either to fill small or all holes. Click **Fill holes**. The added texture is indicated in blue.

\* For Windows only. Additional software has to be installed.



By default, a colored distance map is applied. On the SmartPanel™ Viewer tab, select Overlay to show the two scans aligned with each other. Disable the comparison by turning the Scan comparison switch off.

#### REPORTS

To create a diagnose report:

- 1. In the diagnostic module, open the patient menu.
- 2. Click Export report.
- 3. Select a report template. By default screen captures are included.
- 4. Click Export report.
- 5. The report is exported in an editable .odt format, so you can make modifications (in your default text editor, e.g., OpenOffice Writer) before saving and sending the report.

## **Open DTX Studio™ Implant**

To connect DTX Studio™ Clinic with the implant module DTX Studio™ Implant:

- 1. Click Menu.
- 2. Click Settings.
- 3. Click DTX Studio Implant.
- 4. 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 scan.

5. Click OK.

#### To launch DTX Studio™ Implant:

1. Select the patient record in the patients list.

Note: At least one 3D scan 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 scan, 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**

To order a restoration or a surgery plan:

- 1. Select the patient record in the patients list.
- 2. Click Order ...
- 3. Select **Restoration**  $\widetilde{\mathbb{W}}$  / **Surgery plan**  $\mathbb{I}$ .
- 4. Select the patient data to send to the lab or the clinician. Click **Continue**.
- 5. A draft order is created on DTX Studio™ Go. Add the missing data and send the order to the connected lab or clinician.
- 6. 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.

## **Appendix: Shortcut Keys**

Below you find an overview of the available keyboard shortcuts in DTX Studio™ Clinic.

For keyboard shortcuts where you press two or more keys simultaneously, the keys to press are separated by a plus sign (+). When alternative keyboard shortcuts are available, the alternatives are separated by 'or'. On macOS, use the Command key (Cmd) instead of the Control key (Ctrl).

General Shortcuts		
Alt+F4 or Cmd+Q	Exit the application.	
Ctrl+M or Cmd+M	Maximize or restore down the viewer (when multiple viewers are available).	
Ctrl+Z or Cmd+Z	Undo.	
Ctrl+Y or Cmd+Shift+Z	Redo.	
Ctrl+S or Cmd+S	Save.	
Esc	Cancel or close dialog or viewer.	
F1	Help	

In a Patient Record	
>	Export data.
В	If an intraoral sensor device is connected, start acquiring Bitewings.
С	Launch the capture module.
0	Open patient / Launch the diagnostic module.
F	If an intraoral sensor device is connected, start acquiring FMX.
Р	Open existing patient in DTX Studio™ Implant.
Shift+P	Export to new DTX Studio™ Implant patient.
X	If an intraoral sensor device is connected, launch the intraoral capture module. If no intraoral sensor device is connected, launch the capture module.
← →	Previous or next image in Clinic viewer.
Esc	Close a patient record.
R or Shift+R	Rotate an image

Diagnostic Module		
<	Import images.	
А	Turn on/off Edit Axis.	
В	If an intraoral sensor device is connected, start acquiring Bitewings.	
С	Launch the capture module.	
Ctrl+I or Cmd+I	Show or hide the info overlay on the viewers.	
Ctrl+P or Cmd+P	Print viewer images and content.	
Е	Apply or remove the crisp filter.	
М	Measure a distance.	
X	If an intraoral sensor device is connected, launch the intraoral capture module. If no intraoral sensor device is connected, launch the capture module.	
F2	Switch between 3D patient* and Dental scan* workspace.	
F3	Go to 3D panoramic* workspace.	
F4	Go to Tooth* workspace.	
F5	Go to Pan workspace.	
F6	Go to Intraoral workspace.	
F7	Go to Ceph workspace.	
F8	Go to Clinical pictures workspace.	
F12	Go to Recent images workspace.	
Q	Close viewer.	
*Only available in DTX Studio™ Clinic Pro, if performance setting <b>2D only viewing for low-performance</b>		

**computer** is not enabled.

General Viewer shortcuts		
+ or Z	Zoom in. Hold down the button to keep zooming in.	
- or Shift+Z	Zoom out. Hold down the button to keep zooming out.	
Ctrl+R or Cmd+R	Reset the zoom on the active viewer.	
Ctrl + click and drag, or Cmd + click and drag, or hold the left and the right mouse button and drag	Pan.	
L	Set Level Window/Brightness Contrast.	

3D Render Viewer Shortcuts	
Scroll the wheel button, or Press Shift + click and drag, or swipe up or down	Zoom.
Hold the right mouse button and drag.	Rotate.
Arrow keys or numeric keys	Rotate the model around the X- and Y-axis.  Every key press rotates the model by 1 degree. If one of the keys is pressed for longer than 1 second, the model is rotated continuously with a constant speed.  The property of t
1, 3, 5, 7, 9	Switch between the standard clinical views in the active viewer:  1 Left lateral view  3 Right lateral view  5 Frontal view  9 Caudal view  7 Cranial view
F + click	Focus all reslices on the clicked 3D position.

3D Reslice Shortcuts		
Ť	Go up 1 slice.	
<b>+</b>	Go down 1 slice.	
Page Up	Go up 10 slices.	
Page Down	Go down 10 slices.	
Home	Go to the first slice.	
End	Go to the last slice.	
Scroll or Swipe up/down	Scroll through the slices.	
F + click	Focus all reslices on the clicked 3D position.	

2D Image Viewer Shortcuts	D Image Viewer Shortcuts		
Alt + ← or Shift+R	Rotate the image counterclockwise.		
Alt + → or R	Rotate the image clockwise.		
U	Flip an intraoral image or a clinical picture horizontally.		
Shift+U	Flip an intraoral image or a clinical picture vertically.		
Ctrl+T or Cmd+T	Adjust tooth range.		

## **Symbols Glossary**

