

DTX Studio™ Clinic 2.3

Instructions for Use

GTIN Information:

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

Device	GTIN
300851_V2.3_WIN64	07332747185843
300851_V2.3_MAC	07332747185850



Manufacturer:

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Rx Only

www.nobelbiocare.com

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 and processes 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 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.

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: 3Shape TRIOS®, MEDIT i500/KaVo X 500 and MEDIT i700/KaVo X 700.

Software: DTX Studio™ Core, DTX Studio™ Implant, DTX Studio™ Go, DTX Studio™ Lab, CyberMed OnDemand3D™, Anatomage InVivo™ and Medit Link Software*, Medit Scan for DTX Studio™ software* (which supports MEDIT i500/KavoX 500 and MEDIT i700/KaVo X 700).

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

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

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.

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.

^{*} Product available for Windows operating systems only.

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

- 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 three years. 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 Windows, double-click the shortcut icon so 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.

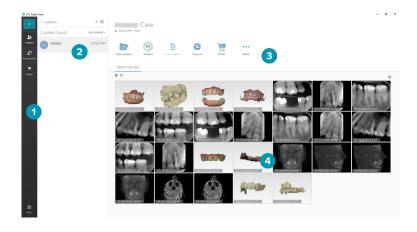
Note: If you forgot your password, click **Forgot password** to go to DTX Studio™ Go. Enter your username, select I'm not a robot and click Reset password. A link will be sent to your registered e-mail address where you can reset your password.

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



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

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™ Core (a), DTX Studio™ Go (a), Exposure reports*, QuickPrescribe*, Scan Center* or a linked third-party application.
- **Devices**: lists the acquisition devices and their statuses (connected via USB -1, online ●, busy ● or offline ●). Click ••• to access the device settings.

^{*}Requires DTX Studio™ Core

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.

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 patient 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**.

Note: Click Reset to revert to the initial default values.

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 3Shape TRIOS®) 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.
- 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 patient module.

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

Adding a TWAIN Device to DTX Studio™ Clinic

To add a TWAIN supported device to DTX Studio™ Clinic:

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

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 page 14).
2		Request a scan or scan workflow with multiple scan protocols (see page 17) or
		Acquire a scan or multiple scan workflows (see <u>page 19</u>).
3		Diagnose patient data and plan treatments (see page 22).
4	PI	Optionally, open DTX Studio™ Implant (see <u>page 30</u>).
5	00	Optionally, order a restoration or a surgery plan (see page 31).
6	<	Optionally, share patient data (see <u>page 15</u>).

Create a Patient Record

Click Patients L 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 patient module are marked with a lock icon $oldsymbol{0}$.

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 Create.
- 5. The patient record is added to the **Patients** ♣ list. If DTX Studio™ Clinic is connected to DTX Studio™ Core, the patient record is also added to DTX Studio™ 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** .

To delete a patient, select the patient record in the patients list, click **More** ••• and select **Delete** ①.

The notification area (see <u>page 10</u>) 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 🛫.
- 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, ID 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 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 \(\hstar*.
- 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** \leq .
- 2. Select **Full patient** 2 to share the entire patient record, or **Patient data** 1 to share specific data.
- 3. Choose the preferred options. Click **Continue**.
- 4. 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.
- 5. Click **Start sharing**.
- 6. 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.
- 7. Click **Send**. The receiving account is notified by e-mail.
- 8. 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.

IMPORTING 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™ Clinic 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™ Clinic with exactly the same first name, last name and date of birth as those 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** \$\mathbb{L}\$ list...
- 3. Click More •••.
- 4. In the Patient section, click **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.

Request scans

To work with scan requests or to initiate a scan workflow with multiple scan protocols (see page 18), 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. Optionally, initiate a scan workflow with multiple scan protocols: click QuickPrescribe. Hover over an available scan workflow and click Create scan requests. Continue with step 6.
- 4. Hover over the picture tile of the image acquisition device and click **Select**.
- 5. 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 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

To sort the scan request list:

- 1. In the sidebar, click **Scan requests** 2.
- 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.

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.

DEFINING A SCAN WORKFLOW

To define a scan workflow:

- 1. Click on the DTX Studio™ Clinic ® 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 now**.
- 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.

APPLYING 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 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.
- 4. 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**.
- 3. Go to the device to perform the scan.
- 4. Click **Finish** to end the action, or click **Open diagnose** to open the patient 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.

If you have activated MagicSort autodetection, see the steps below:

- In the bottom-right corner, the MagicSort autodetection assistant is shown.
- In the capture wizard teeth are automatically detected. They are marked in blue. Click on a tooth to remove the MagicSort label.
- Intraoral images are automatically mapped on FMX charts.
- Manually indicate unidentified images on the tooth chart.

Note: By default, MagicSort autodetection is activated. To deactivate it, see 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.
 - Rotate the acquired image if necessary.

Action	Icon	Shortcut	
Rotate image counterclockwise	-	Alt+ ← , 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 TRIOS® 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 checkmark.
 - Click **Open diagnose** to start a new diagnosis in the patient 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.
- 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 Medit Scan.

^{*} For Windows computers only and on the computer which has been used for acquiring the intraoral scan data. A PRO IOS license type or a subscription to the Plus+ feature Medit Scan integration are required.

Make a Diagnosis or Plan a Treatment

Open the patient module to view and inspect the patient data and to add findings and measurements to the patient record.

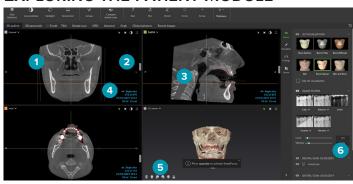
There are two versions:

- 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 patient 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 patient module can be launched for separate patient records. Before making a diagnosis or planning a treatment, manage the patient scans and images that you will use for the diagnosis.

EXPLORING THE PATIENT MODULE



- Patient menu
- Menu bar
- 3 Toolbar
- 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 patient 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 patient module, click in the upper-left corner to open the patient menu.

Menu Options

The menu in the left pane allows you to:

- Capture: acquire data directly from the patient module,
- **Import:** import data to the open diagnosis,
- 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 patient 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:

(n) 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

Not present with gap This tooth is missing and there is a gap on this location.

This tooth will be impacted (often used for wisdom teeth). Impacted

+ Insert Insert a tooth, e.g., adult molars in a child dentition.

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.

- 3D scan
- Pan (panoramic image)
- Intraoral images
- Cephalogram
- Clinical pictures
- Screenshots
- Face scan
- Dental scan
- Click another 3D scan to switch between 3D scans.
- To start acquiring data directly from the patient module and add it to the open diagnosis, click **Capture** Alternatively, click on the menu bar.
- To import data to the open diagnosis, click Import ±.

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.

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.

To inspect the loaded model from all sides, use the "Interact with the Mouse" on page 26) and the kee "Appendix: Shortcut Keys" on page 32) Or use the standard clinical view icons: Frontal Posterior Left lateral Right lateral Cranial Caudal	eyboard shortcuts (see	F2
Posterior Left lateral Right lateral Cranial Caudal	e (if available).	
Left lateral Right lateral Cranial Caudal	e (if available).	
Right lateral Cranial Caudal	e (if available).	
CranialCaudal	e (if available).	
	e (if available).	
	e (if available).	
	e (if available).	
Press F2 again to go to the dental scan workspace		
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.	F3
Tooth Navigate to a specific tooth and compare all 2D s SmartPanel™ Layout tab. Annotate the selected too	•	F4
The vertical slider on the perpendicular viewer rot the tooth rotation axis. Depending on the situation, indicate the orientation of the reslice:		
Oral/Buccal (O / B)		
Mesial/Distal (M / D)		
 Left/Right (L / R). 	[A] A	
To adjust the rotation axis, click Edit axis (1) or presis drawn on top of the perpendicular and the pamouse inside the viewer to rotate the image data at of the viewer. Press [A] again or right-click to finish	arallel viewer. Drag the around the center point	
To change the image center point, click the tran		
Implant Plan and inspect implants. This workspace consists		FQ
the Pan viewer, the snapped to implant viewer a viewer.	•	13
 Click and drag a cross-sectional reslice navigate to a desired position. 	in the Pan viewer to	
3D inspection Navigate to a specific point outside the tooth range	e to inspect it.	
TMJ Inspect the condyle heads and the temporomandib	oular joint areas.	
Pan View a 2D panoramic radiograph (panorex) or mult	ilayer pan images.	F5

Workspace	Description	Shortcut key
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 25). 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.	F6
Ceph	View the frontal and/or lateral cephalogram. Use the Generate the 3D Cephs tool to calculate cephalograms based on the loaded 3D scan, or import 2D cephalograms.	F7
Clinical pictures	View the clinical pictures for the patient.	F8
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 patient module preferences.	F12

Show all Related Tooth Information with 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.

Customize Views with 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 . 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.

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.

Align Dental Scans with SmartFusion™

To align a dental scan with the 3D scan in the 3D patient workspace, click Align dental scan 🐷 in the Edit 3D scan tools menu. Select a dental scan and click Next. If needed, indicate corresponding points and use the Bone threshold slider to adjust the visualization. Check the alignment. Click Finish.

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 <u>page</u> 26).

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 + 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 + 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, click Add finding [™] in the Diagnose tools menu. Alternatively, 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.

The finding needs to be treated. Treatment plan Red

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.

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 userpicked points.

Diagnose

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



Note: To set a default slice thickness, go to the Image settings tab in the DTX Studio™ Clinic settings. 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.

- 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 patient module preferences.
- Capture a screenshot. The captured screenshot can be added to a report (see page 29).
- <u>=</u>Q Add a finding to the SmartPanel[™] **Findings** tab.
- Analyze the airway. Indicate landmarks to create a box surrounding the region of interest. Click **Done**. **[** The airway volume and the constriction point is visualized in the 3D patient workspace.
- Indicate a nerve. Click the first anchor point. Then click every next anchor point. Right-click to finish.
 - Adjust the nerve annotation by moving the anchor points on the viewer.
 - All the anchor points will appear as one line on the SmartPanel™ Annotation tab.
- 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 CT data in detail. For example to mark and inspect the root canals and to make annotations.
- -Т Add text to an image.
- Draw segmented lines with the pen. All the lines will appear as one annotation on the SmartPanel™ On. Annotation tab.
- Draw free-form lines with the pencil. En

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 *\(\text{is added on the SmartPanel™ Annotation tab.} \) 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.

Plan

Click the Plan tab to go to the following tools:

- To place an implant. This tool can be used in any workspace that contains CB(CT) data.
- (± Manage which implants can be placed.

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 🖐 or the rotation icon Ø 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**.

- °LE 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 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. 2
- Align or realign a dental scan with the 3D scan via SmartFusion™.
- 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. \mathbb{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.

- Compare dental scans to follow up on gingival recession, tooth wear and other differences. Select a dental scan to compare with the reference scan. Click **Finish**.
 - 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.
- Calculate virtual teeth with SmartSetup.

REPORTS

To create a diagnose report:

- In the patient 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** ♥ / **Surgery plan** ♥ 1.
- 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 patient 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 the data viewer.
R or Shift+R	Rotate an image.

Patient module	
<	Import images.
A	Turn on/off Edit Axis.
В	If an intraoral sensor device is connected, start acquiring Bitewings.
С	Launch the capture module.
Ctrl+l or Cmd+l	Show or hide the info overlay on the viewers.
Ctrl+P or Cmd+P	Print viewer images and content.
Delete or Backspace	Delete an annotation.
Е	Apply or remove the crisp filter.
М	Measure a distance.
×	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.
F9	Go to Implant workspace
F12	Go to Recent images workspace.
Q	Close viewer.
Spacebar	To activate SmartFocus™ in the 3D patient, 3D panoramic, 3D inspection or the intraoral workspace.
*Only available in DTX Studio™ Clinic Pro	o, if performance setting 2D only viewing for low-performance 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 Brightness Contrast/Level Window

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 or numeric key 4 and 6: Rotate around the Y-axis. The property or numeric key 8 and 2: Rotate around the X-axis.
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.
+	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	
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









Catalog number





Consult Instructions for Use









Do not re-sterilize



Do not re-use



Do not use if package is damaged

Rx Only

For prescription use only



Patient identifier



Keep away from sunlight





Manufacturer



Medical device



Magnetic resonance conditional



Non-sterile



Patient number



Serial number



Sterilized using irradiation



Use-by date