

DTX Studio[™] Clinic

Version 3.3

Instructions for Use

Table of Contents

Disclaimer of Liability 6 Device Description 6 Intended Purpose 7 Intended Use / Indications for Use 7 Intended User and Intended Patient Target Group 7 Required Compatibility with Other Devices 7 Intraoral Seasons 7 Intraoral Cameras 7 Intraoral Seanning 7 Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Cybersecurity 8 Compatibility 8 Interoperability 8 Interoperability <t< th=""><th>Introduction</th><th>6</th></t<>	Introduction	6
Intended Purpose 7 Intended User Indications for Use 7 Intended User and Intended Patient Target Group 7 Required Compatibility with Other Devices 7 Intraoral Sensors 8 Contrained Cameras 8 Requirements 9 Intraoral Cameras 10	Disclaimer of Liability	6
Intended Use / Indications for Use 7 Intended User and Intended Patient Target Group 7 Required Compatibility with Other Devices 7 Intraoral Sensors 7 Intraoral Cameras 7 Intraoral Scanning 7 Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Coppersecurity 8 Compatibility 8 Interoperability 8 Interoperability 8 Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 10 Warnings, Cautions and Precautions 10 Warnings, Cautions and Precautions 15	Device Description	6
Intended User and Intended Patient Target Group 7 Required Compatibility with Other Devices 7 Intraoral Sensors 7 Intraoral Sensors 7 Intraoral Cameras 7 Intraoral Scanning 7 Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Contraindications 8 Compatibility 8 Interoperability 8 Interoperability 8 Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 14 Operating Systems 14 Start 15 Start 15 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio Home 15 Exploring the Notification Area 16 Exploring the Notification Area 16 Exploring the Notification Area 16 Contact 16 Requirements 16 Contact 16 Contact 16 Requirements 16 Contact 16	Intended Purpose	7
Required Compatibility with Other Devices 7 Intraoral Sensors 7 Intraoral Cameras 7 Intraoral Sensors 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Contraindications 8 Copherectivity 8 Compatibility 8 Interoperability 8 Interportance Requirements and Limitations 9 Interportance Requirements 9	Intended Use / Indications for Use	7
Intraoral Sensors 7 Intraoral Cameras 7 Intraoral Seanning 7 Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Coptsecurity 8 Compatibility 8 Interoperability 8 Interpolations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Warnings, Cautions and Precautions 10 Warnings 10 </th <th>Intended User and Intended Patient Target Group</th> <th>7</th>	Intended User and Intended Patient Target Group	7
Intraoral Cameras 7 Intraoral Scanning 7 Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Coperactrity 8 Compatibility 8 Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio" Home 15	Required Compatibility with Other Devices	7
Intraoral Scanning 7 Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Cybersecurity 8 Compatibility 8 Interoperability 8 Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring the Notification Area 16 </th <th>Intraoral Sensors</th> <th>7</th>	Intraoral Sensors	7
Software 7 Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Cybersecurity 8 Compatibility 8 Interoperability 8 Interoperability 8 Interoperability 8 Interoperability 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Exploring the Notification Area 16	Intraoral Cameras	7
Devices with Measuring Function / Performance Characteristics 8 Contraindications 8 Cybersecurity 8 Compatibility 8 Interoperability 8 Interoperability 8 Interoperability 8 Interoperability 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16		
Contraindications 8 Cybersecurity 8 Compatibility 8 Interoperability 8 Interoperability 8 Interoperability 8 Interoperability 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16		/
Cybersecurity 8 Compatibility 8 Interoperability 8 Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio* Home 15 Exploring the Notification Area 16	•	
Compatibility 8 Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio* Home 15 Exploring the Notification Area 16	Contraindications	
Interoperability 8 Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16		
Intended Lifetime 8 Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio* Home 15 Exploring the Notification Area 16		8
Performance Requirements and Limitations 8 Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16	Interoperability	
Clinical Benefits and Undesirable Side Effects 8 Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Operating the Software 15 Closing the Software 15 Exploring DTX Studio" Home 15 Exploring the Notification Area 16	Intended Lifetime	8
Facilities and Training 9 Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio" Home 15 Exploring the Notification Area 16	Performance Requirements and Limitations	8
Notice Regarding Serious Incidents 9 Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16		8
Professional Use 9 System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Warnings 10 Cautions / Precautions 12 System Requirements 12 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16	Facilities and Training	9
System Requirements 9 Installation of the Software 9 Handling Instructions 9 Warnings, Cautions and Precautions 10 Cautions / Precautions 12 System Requirements 14 Operating Systems 14 Start 15 Starting the Software 15 Closing the Software 15 Exploring DTX Studio™ Home 15 Exploring the Notification Area 16	Notice Regarding Serious Incidents	9
Installation of the Software9Handling Instructions9Warnings, Cautions and Precautions10Warnings10Cautions / Precautions12System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Professional Use	9
Handling Instructions9Warnings, Cautions and Precautions10Warnings10Cautions / Precautions12System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	System Requirements	9
Warnings, Cautions and Precautions10Warnings10Cautions / Precautions12System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Installation of the Software	9
Warnings10Cautions / Precautions12System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Handling Instructions	9
Warnings10Cautions / Precautions12System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Warnings, Cautions and Precautions	10
Cautions / Precautions12System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	• •	10
System Requirements14Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	•	
Operating Systems14Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Cautions / Precautions	12
Start15Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	System Requirements	14
Starting the Software15Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Operating Systems	14
Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Start	15
Closing the Software15Exploring DTX Studio™ Home15Exploring the Notification Area16	Starting the Software	15
Exploring DTX Studio™ Home		
Exploring the Notification Area 16		

Adjust the Default DTX Studio Home Settings	. 16
Import or Export Settings	. 16
Change Language and Date/Time Format	. 16
Adjust the DICOM Compliance Settings	. 17
Set the Default Image Filters	. 17
Disable Auto-Rotation of Intraoral Images	. 17
Disable Automatically Set Level and Window Values	
Connect to DTX Studio Core	
Add an Application to the Action Pane	
Enable Practice Management System (PMS) Integration	
Add a TWAIN-supported Device	
Configure the Direct Folder for Detecting Third-Party Device Images	
Set the Default Export Folders	
Learning Resources and Contacting Support	
View all Learning Resources and Keyboard Shortcuts	
Contact Customer Support	20
Overview of the Main Features	21
Overview of the Main Fedtures	4 1
Patient Records	22
Creating a New Patient Record	22
Managing Patient Records	
Manage Privacy Options	
Searching and Sorting Patient Records	23
Sort the Patients List	23
Search for a Patient	23
Exporting a Patient Record	23
Exporting a radicitive cord	25
Manage Data	24
Importing Data	24
Import Images from Third-Party Devices	
Drag and Drop Images and Files into a Patient Record	24
Importing Data from Within DTX Studio Clinic	24
Import 3D X-rays	24
Import IO scans	25
Import Face Scans	25
Import 2D Images	25
Import from 3Shape Dental Desktop Software	25
Import a Surgery Plan	26
Sharing Data	26
	26
Share a 3D Presentation	. 27

Exporting Data	27
Export a Patient Record	27
Export Patient Data	27
Export Implant Plan to X-Guide	28
Request Scans	29
Scheduling a Scan	29
Searching and Sorting Scan Requests	29
74	29 29
Managing Scan Requests	30
Scan Workflows	30
Define a Scan Workflow	30
Apply a Scan Workflow	30
Perform a Scan	31
Perform a Scheduled Scan	31
Perform an Immediate Scan	31
Guided Acquisition with Intraoral Sensors or PSP Devices	31
Free Acquisition with Intraoral Sensors or PSP Devices	32
	33
	34
3Shape TRIOS® Scanner	34
DEXIS and Medit Scanners	34
Acquire Intraoral Scan Data	34
·	34
	35 35
Enable the Advanced ScanFlow Features	35
Make a Diagnosis or Plan a Treatment	36
Exploring DTX Studio Clinic	36
Working with the Patient Menu	37
Menu Options	37
Actions	37
Tooth Chart	37
	38
<u> </u>	38
<u> </u>	39
Interact with the Viewers	39

workspaces	40
Customize Workspaces	43
Show all Related Tooth Information with SmartFocus™	43
Customize Views with SmartLayout™	43
Fuse IO Scans with 3D X-rays	43
Use the Thumbnail Bar	44
Add Diagnostic Findings	44
SmartPanel™ Tooth Chart	44
Adjust Reslices	45
Clip the 3D Volume	45
Use Dental Intraoral Cameras in Workspaces	45
Tools	46
Reports	50
Create Reports	50
Add Custom Practice Logos	50
Opening DTX Studio Implant	51
Connect DTX Studio Clinic and DTX Studio Implant	51
Launch DTX Studio Implant	
Orders and Partner Collaborations	51
Order a Surgery Plan, Surgical Template or Restoration	51
Set up a Connection with a Partner	52
Order Directly from a Partner	52
View Partner Case or add new Data	52
Focus Area Detection	53
What is Focus Area Detection?	53
Using Focus Area Detection	53
Appendix I: Focus Area Detection Algorithm Performance Assessment	56
Clinical Performance Assessment	56
Stand-alone Performance Assessment	56

Introduction

Disclaimer of Liability

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

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

Device Description

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

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

The following dental findings can be detected by the device:

- Caries: Caries is defined as caries, showing as area with radiographically lower density on a tooth, but does not include occlusal secondary caries under dental fillings.
- Discrepancy at margin of an existing restoration: A discrepancy at margin is defined as radiographically visible discontinuities (gaps, spaces, overhangs) between outline/margin of dental restoration (e.g., fillings, inlays or crowns/bridges) and remaining tooth substance, also called as `misfit', `poor fit' or `not-perfectly seated'. Note that non-radiopaque cement/bonding material may radiographically appear as a space.
- Periapical radiolucency: A periapical radiolucency is defined as a radiolucent area or radiographic observation of low bone density related to the apical part of the root. A widening of the periodontal ligament is not included.
- Root canal filling deficiency: The root canal filling appears radiographically too short (more than 2mm from the radiographic apex) and/ or too small in diameter, or the root filling is not radiographically homogenously dense (e.g., with visible void in root filling or gaps between filling and root dentin), or otherwise show absence of radio-opaqueness.
- Bone loss: Bone loss is defined as a radiographically lower density of the marginal bone and/or a lower crest of the alveolar bone compared to what is considered normal for healthy natural dentition. Healthy natural dentition refers to teeth that have not experienced any marginal bone loss and have an alveolar bone that covers the root of the tooth. It is indicated by a focus area annotation, however, the size of the rectangular bounding box is not indicative of the amount of bone loss.
- Calculus: Calculus is a hard, mineralized form of dental plaque that is visible on radiographic images as radiopaque material attached to the tooth surface.

TPL 414561 000 00 6

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.

DTX Studio Clinic is a computer assisted detection (CADe) device that analyses intraoral radiographs to identify and localize dental findings, which include caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at margin of an existing restoration and bone loss.

The DTX Studio Clinic CADe functionality is indicated for use by dentists for the concurrent review of bitewing and periapical radiographs of permanent teeth in patients 15 years of age or older.

Intended User and Intended Patient Target Group

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

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

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

Intraoral Cameras

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

Intraoral Scanning

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

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

Software

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

* Product available for Windows operating system only.

Devices with Measuring Function / Performance Characteristics

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

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

Contraindications

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

Cybersecurity

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. Failure to do so may lead to unintended handling of the diagnosis and planning or treatment.

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

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

Intended Lifetime

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

Performance Requirements and Limitations

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

Clinical Benefits and Undesirable Side Effects

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

No undesirable side effects identified for DTX Studio Clinic.

- en-us — zuzs-us-zv — DTX statio Cilinic Version 3.3 — instructions for use — © Copyright zuzs. All rights reserv

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 our training website on tw.dtxstudio.com.

Handling Instructions

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

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

Installation of the Software

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

Warnings, Cautions and Precautions

Warnings

Following warnings are shown in the software.



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

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

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

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

Cannot add the surgery plan to the current diagnosis.

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

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

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

Do not expose patient.

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

Preparing your sensor for the next exposure. Please wait.

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

Verify the scan request parameters on the device.

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

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

The actual shapes can be downloaded from DTX Studio Go.

Image has been flipped.

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

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

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

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

DTX Studio Clinic supports only a selection of implants to be exported to X-Guide $^{\mathbb{M}}$. Non-supported implants will not be included in the X-Guide file.

TPL 414561 000 00

Implant is too close to an annotated anatomical structure.

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

Implants are colliding.

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

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.

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

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

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

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.
- The lack of knowledge and comprehension of the software may result in the delay in or rescheduling of the diagnosis and planning or the actual treatment.
- When using the diagnostic and planning tools provided in the software, it is important to pay extra attention to:
 - the correctness of made indications (visualizations, measurements, critical structures, imported data, implant planning).
 - the correctness of the outcome of the automated functions (the alignment of dental scans, the autofilling of holes, and airway segmentation).
 - the correctness of the patient ID (after opening a patient record through PMS systems and when creating scan requests).
 - the data being up to date and not outdated.

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

- It is recommended to take extra care when working with image capturing devices.
 Incorrect use may result in the delay in or rescheduling of a diagnosis and planning or treatment or in unnecessary extra radiation exposure of the patient.
- When extracting a report or patient data from the software, it is important to know that not de-identified patient data can be used for incorrect purposes without the patient's consent.
- It is recommended to pay extra attention to the assigned tooth numbering and orientation markings of the viewers. A wrongly assigned tooth number or incorrect patient orientation may lead to incorrect treatment actions performed on the patient.
- After updating the software version, it is recommended to verify the critical settings
 of the open patient cases and/or treatment plan to make sure these settings are
 correct in the new software version. Incorrect settings may lead to a delay in or
 the rescheduling of the diagnosis and planning or the actual treatment.
- It is recommended 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. Failure
 to do so may lead to unintended handling of the diagnosis and planning or treatment.

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

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

System Requirements

Operating Systems

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

Note

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

	Basic setup (2D imaging only)	Recommended setup (2D and 3D imaging with better performance)
CPU	Dual or quad-core	2.8 GHz quad-core (Intel Core i5 or i7)
RAM	4 GB	8 GB or more
Graphics card	Entry-level dedicated add-in card or Intel integrated graphics. 6th generation Intel* CPUs or higher are supported (with embedded 9th generation GPU or higher). OpenGL® 3.3 support is required**. * Always use the latest integrated graphics card driver available from Intel for the respective model for best performance. ** To check the OpenGL® version of your graphics card, go to http://realtech-vr.com/admin/glview.	
Disk space	10 GB free disk space for installation and additional disk space for user-created data. A typical 2D patient dataset in DTX Studio Clinic is about 10 MB.	10 GB free disk space for installation and additional disk space for user-created data. A typical 3D patient dataset in DTX Studio Clinic is about 250 MB.
Network	Broadband Internet connection with 3Mbps upload and 30 Mbps download speed. It is recommended always to be connected to the Internet. If that is not possible, a connection should be established at least once every 14 days, because otherwise your access to DTX Studio Clinic may be temporarily suspended.	
Hard Disk	Only install DTX Studio Clinic onto an HFS+ or HFSJ non-case-sensitive drive on Mac devices.	
Monitor	Full HD (1920x1080) or higher. Information may appear missing if display scaling is used. For this reason, the equivalent scaled resolution should not be lower than 1920x1080.	
LAN	If DTX Studio Clinic is installed together with DTX Studio Core a local Gigabit Network is recommended.	

Start

Starting the Software

- 1. Open DTX Studio Clinic:
 - On Windows, double-click the shortcut icon so on the desktop.
- 2. Select the user.
- 3. Enter your password.
- 4. Click Log in.

Notes

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

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

Closing the Software

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

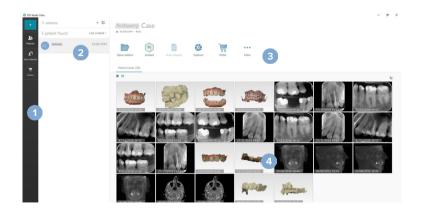
Click Menu and select Close application.

Note

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

Exploring DTX Studio™ Home

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



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

TPL 414561 000 00 15

^{*} Module might be licensed.

Exploring the Notification Area

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

- Notifications: shows which patient records are being uploaded or synchronized with DTX Studio Core.
- DTX: provides quick access to DTX Studio Core (), DTX Studio Go (), Exposure reports*, QuickPrescribe*, Scan Center* or a linked third-party application.
- Devices: lists direct folders for importing third-party device images, shows acquisition devices and their statuses (connected via USB or TWAIN [♠] , online ♠, busy ♠ or offline ♠). Click ··· to access the device settings, folder import settings or to disable unrequired devices.

Adjusting Settings

Adjust the Default DTX Studio Home Settings

- Click Menu ≡.
- Click Settings .

Import or Export Settings

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

Note

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

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

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

Change Language and Date/Time Format

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

- 1. In the DTX Studio Home settings sidebar, click General.
- 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.

^{*} Requires DTX Studio Core.

Adjust the DICOM Compliance Settings

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

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

Note

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

Set the Default Image Filters

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

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

Note

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

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

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

Disable Auto-Rotation of Intraoral Images

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

- 1. In the DTX Studio Home settings or DTX Studio Clinic preferences sidebar, click Image settings.
- 2. Deselect Apply auto-rotation in DTX Studio capture.

Disable Automatically Set Level and Window Values

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

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

Connect to DTX Studio Core

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

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

To establish a connection with DTX Studio Core:

- 1. In the DTX Studio Home <u>settings</u> sidebar, click Core.
- 2. Enter the URL (web address), Login and Password for DTX Studio Core.
- 3. Click Connect.

Add an Application to the Action Pane

To add an application shortcut to the action pane:

- 1. In the DTX Studio Home settings sidebar, click Quick Launch.
- Click Add.
- 3. Select the executable file and click Open.
- 4. If needed, change the Application name.
- 5. Optionally, select Launch with patient data to launch the third-party application with patient data.
 - Specify which data is exported by adding export parameters to the Export parameters field.

Note

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

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

Enable Practice Management System (PMS) Integration

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

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

- 1. In the DTX Studio Home <u>settings</u> sidebar, click <u>PMS</u> integration.
- Select Enable PMS integration.

Note

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

Add a TWAIN-supported Device

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

Configure the Direct Folder for Detecting Third-Party Device Images

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

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

Set the Default Export Folders

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

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

Learning Resources and Contacting Support

View all Learning Resources and Keyboard Shortcuts

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

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

Contact Customer Support

To reach out to customer support, click and select Contact support. The support website with all the contact options is opened.

Overview of the Main Features

To get started with the main features:

- Create or link a patient record + Create a patient record in DTX Studio Home (see page 22).
 - Integrate your Practice Management System (see page 18) and link an existing PMS patient record.
- Acquire scans, initiate multiple scan workflows (see page 30) or import third-party device images from direct folders (see page 19).
 - Request a scan or multiple scan workflows (see page 30).
 - Drag and drop images in a patient record (see page 22).
 - Migrate data on demand (for setups with database migration) (see page 38).
 - Import from 3Shape Dental Desktop Software (see page 25).

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

Optionally, open DTX Studio Implant (see page 51).

page 26) or collaborate with partners.

Share and communicate

Share patient records and patient data via DTX Studio Go (see

Share a 3D presentation with your patients (see page 27).

- Export a patient record (see page 23).
- Create a report or patient communication letter (see page 50).

Place orders

Optionally, order a restoration, surgical template or surgery plan (see page 51).

Patient Records

Creating a New Patient Record

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

Managing Patient Records

Click Patients & in the sidebar to open the patients list, if not already open.

Note

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

- Patient records opened in DTX Studio Clinic on a local or networkconnected workstation are marked with .
- To edit basic patient information, select the patient record in the patients list, click More ...
 and select Edit ...
- To delete a selected patient record, click More ... and select Delete 6.
- To make sure that a patient record stored in DTX Studio Core is also available offline, click More ••• and enable Offline available.

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

Manage Privacy Options

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

- 1. On the patients list, click \(\sigma \).
- 2. Select Privacy mode to show initials only or Hide patients list to completely hide it.

Notes

Click >> in the sidebar to re-show the patients list.

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

Searching and Sorting Patient Records

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

Sort the Patients List

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

Search for a Patient

- 1. On the patients list, click 🕽.
- 2. Select to search for the Patient name, Date of birth or Patient ID.
- 3. Type (a part of) the selected search option in the Find a patient field Q.
- 4. While typing text in the search box, the 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 manually share the diagnoses and image data with another DTX Studio Clinic user. Additionally, the exported patient record can be viewed in the free version of DTX Studio Clinic, available via DTX Studio Go. See page 27 for more information.

Note

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

Manage Data

Importing Data

Import Images from Third-Party Devices

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

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

Drag and Drop Images and Files into a Patient Record

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

Importing Data from Within DTX Studio Clinic

To import data, click Import

in the patient menu.

Import 3D X-rays

- 2. Select the DICOM data.
- 3. Click Next.
- 4. Set the isovalue.
- 5. Click Finish.
- 6. If MagicAssist is enabled (on by default), the Al detection process is started to automatically set up the (CB)CT data.
 - Click Skip MagicAssist to manually indicate the landmarks and OPG curve later.
 - The 3D image orientation can be optimized via the patient orientation wizard.
 - The OPG curve action (see page 46) allows you to adjust the 3D OPG.

Import IO scans

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

Import Face Scans

- 2. Select a face scan to import.
- 3. Click Open.
- 4. If needed, adjust the Brightness and Contrast.
- 5. Click Done.

Import 2D Images

- 2. Choose the image(s) and click Open.
- 3. Click OK.
- 4. Select the images you want to add.
- 5. Click Import.
 - Upon importing or acquiring a 2D image, level and window values are automatically set. To disable this, see page 17.
 - By default, MagicAssist autodetection is activated. This can be deactivated in the settings.

Import from 3Shape Dental Desktop Software

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

Note

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

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

Notes

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

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

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

Import a Surgery Plan

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

Sharing Data

Share Patient Data via DTX Studio Go

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

- 1. On a patient record's action pane, click Collaborate ❖.
- 2. Select what you want to share:
 - Patient $\hat{\mathcal{N}}$ to share the entire patient record (DTX Studio Clinic proprietary encrypted format), or
 - Select data to share specific data.
- 3. Choose the preferred options.
- 4. Click Continue.
- 5. DTX Studio Go opens in the web browser and the created GoShare case is shown. Meanwhile, the data is uploaded in the background.
 - Add notes to the Prescription card's text field.
 - To create a prescription note template, click Insert quick note and select Configure.
 Click Add quick note. Add a title, write the custom text and click Save. Click Close.
 - To change the default prescription image or to add annotations, hover over the prescription image and select Edit prescription. Click Change image to select another image.
 - To edit the patient information, click in the top-right corner.
 - If needed, provide further information or additional files of the (CB)
 CT images, clinical pictures, intraoral images, OPG, reports, etc.

- 6. Click Start sharing.
- 7. Select the connection with which you want to share patient data. Either by searching or selecting an existing connection in the Share with a connection field, or by entering an email address.
- 8. Click Send. The receiving account is notified by e-mail.
- The shared case is added to the GoShare overview in the patient record.
 Click View case to open the shared case in DTX Studio Go.

Share a 3D Presentation

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

Exporting Data

Export a Patient Record

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

Export Patient Data

- 1. Go to the export data action.
 - In DTX Studio Home, click More ••• in the action pane and select Export data.
 - In DTX Studio Clinic, click Export and select Data.
- 2. Select the images to export.

- 3. Click Browse and go to the desired export location.
- 4. Click Select folder.
- 5. Choose the export mode, patient anonymization, metadata and image file format.
- 6. Click Export.

Export Implant Plan to X-Guide

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

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

Request Scans

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

Scheduling a Scan

To request a scan for a patient:

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

Note

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

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

Searching and Sorting Scan Requests

Sort the Scan Request List

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

Search for a Scan Request

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

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

Managing Scan Requests

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

Scan Workflows

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

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

Define a Scan Workflow

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

Note

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

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

Apply a Scan Workflow

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

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

Notes

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

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

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

Perform a Scan

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

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

Perform a Scheduled Scan

To perform a scan for a scan request:

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

Perform an Immediate Scan

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

Notes

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

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

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

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

Guided Acquisition with Intraoral Sensors or PSP Devices

To acquire intraoral images with a template:

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

TPL 414561 000 00

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

Free Acquisition with Intraoral Sensors or PSP Devices

To acquire intraoral images without using a template:

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



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

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

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

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

Action	lcon	Shortcut
Rotate image counterclockwise	←	Alt + ♣, or R
Rotate image clockwise	_	Alt + →, or Shift+R
Flip intraoral image or clinical picture horizontally	1 1	U
Flip intraoral image or clinical picture vertically	=	Shift+U

Guided Image Acquisition with Intraoral Cameras

To acquire intraoral camera images with a template:

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

Note

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

6. Click Finish.

Free Image Acquisition with Intraoral Cameras

To acquire intraoral camera images without using a template:

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

Note

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

5. Click Finish.

Intraoral Scanning

3Shape TRIOS® Scanner

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

Note

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

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

DEXIS and Medit Scanners

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

Acquire Intraoral Scan Data

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

Reopen a Scan Case

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

Note

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

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

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

TPL 414561 000 00

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

Resume DEXIS IS ScanFlow Scan

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

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

Enable the Advanced ScanFlow Features

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

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

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

Make a Diagnosis or Plan a Treatment

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

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

The features depend on the DTX Studio Clinic license type:

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

Exploring DTX Studio Clinic



- Patient menu
- 2 Menu bar
- 3 Toolbar
- 4 Workspace bar
- 5 Workspace SmartLayout
- SmartPanel

Working with the Patient Menu

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

Menu Options

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

Actions

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

Tooth Chart

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



Note

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

Edit the Tooth Chart

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

if e	Exchange a primary tooth with an adult tooth. This option is available if the child tooth has a corresponding adult tooth. If the tooth is exchanged, all the findings of the primary tooth are deleted and the adult tooth is set to healthy. Note Child dentition is displayed for patients younger than eight years old.
	Child dentition is displayed for patients younger than eight years old.
n gap T	This tooth is missing and there is a gap on this location.
Т	This tooth will be impacted (often used for wisdom teeth).
Ir	nsert a tooth, e.g., adult molars in a child dentition.
	ndicate hypodontia.

Diagnosis Data

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

Click a tile to include or exclude the patient data.



OPG (panoramic image)

Intraoral images

Cephalogram

Clinical pictures

Screenshots

Face scan

IO scan

Set the 3D and IO scan Viewer Background

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

Set the Default Image Zoom Level

To set the default zoom level of shown images:

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

Interact with the Viewers

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

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

	Action	3D Viewer	Other Viewer Types
	Right-click	Context menu of objects and viewers	Context menu of objects and viewers
	Right-click and drag	Rotate the 3D model	Brightness/Contrast (default) or zoom in and out
Ctrl Cmd	Ctrl + click and drag, or Cmd + click and drag	Pan	Pan
Shift	Shift + click and drag	Zoom in and out	Zoom in and out
	Scroll the wheel button	Zoom in and out	In reslice viewer only: scroll through slices

Workspaces

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

Note

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

Workspace	Description	Shortcut key					
3D patient	To inspect the loaded model from all sides, use the mouse actions (see page 39) and the keyboard shortcuts. Alternatively, use the standard clinical view icons:	F2					
	Posterior						
	Left lateral						
	Right lateral						
	Cranial						
	Press F2 again to go to the IO scan workspace (if available).						
3D panoramic	The 3D panoramic radiograph is generated based on the loaded 3D X-ray.	F3					
Tooth	Navigate to a specific tooth and compare all 2D and 3D data using the SmartPanel™ Layout tab. Annotate the selected tooth (see page 44).	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:						
	Oral/Buccal (O / B)						
	Mesial/Distal (M / D)						
	Left/Right (L / R)						
	To adjust the rotation axis, see page 45.						
	Press F4 again to go to the endo workspace (if available).						

Workspace	Description					
Endo	Focus on a specific tooth for endodontic diagnostics and procedures. To display the tooth pulp, click the Endo 3D visualization on the SmartPanel™ Viewer tab.					
	Note					
	This workspace is available if a 3D X-ray is loaded and when tooth annotations are defined.					
	 The 3D viewer is focused on a tooth of interest. 					
	 The Tooth cross-sections viewer is a cross-sectional viewer that shows several horizontal tooth cross-sections. 					
	 Once the root morphology is defined (see page 46), the root canals are visualized. 					
	Press F4 again to go to the tooth workspace (if available).					
Implant	Plan and inspect implants. This workspace consists by default of 3 viewers, the OPG viewer, the snapped to implant viewer and the cross-sectional viewer.					
	Click and drag a cross-sectional reslice in the OPG viewer to navigate to a desired position.					
3D inspection	Navigate to a specific point outside the tooth range to inspect it.					
TMJ	Inspect the condyle heads and the temporomandibular joint areas.					
IO scan	Inspect and compare IO scans. Press F2 again to go to the 3D patient workspace (if available).					
OPG	View a 2D panoramic radiograph (panorex) or multilayer pan images.	F5				
Intraoral	Inspect the intraoral images on a layout, for inspecting e.g., a Full Mouth X-ray series.					
	 Double-click an image to use additional workspace functionalities: image filters and SmartLayout (see page 43). 					
	 To return to the initial layout overview, double- click the image again or press Esc. 					
	 Switch to another image by clicking on a thumbnail in the overview on the SmartPanel[™] Layout tab. Alternatively, use the arrow keys. 					
	 Multiple images can be stacked in the same placeholder. Click to show all the images and click > < to compare them. 					
Ceph	View the frontal and/or lateral cephalogram. Use the Generate the 3D Cephs tool to calculate cephalograms based on the loaded 3D X-ray, or import 2D cephalograms.	F7				

Workspace	Description	Shortcut key				
Clinical pictures	View the clinical pictures for the patient.	F8				
	 Double-click an image to use additional workspace functionalities: image filters and SmartLayout (see page 43). 					
	 To return to the initial layout overview, double- click the image again or press Esc. 					
	 Switch to another image by clicking on a thumbnail in the overview on the SmartPanel™ Layout tab. Alternatively, use the arrow keys. 					
	 Multiple images can be stacked in the same placeholder. Click to show all the images and click > 					
Intraoral pictures	Similar to Clinical pictures, but containing the intraoral camera pictures. When a tooth is selected on the tooth chart and the intraoral camera is used for image acquisition in the tooth workspace, the acquired images are automatically assigned to the selected tooth and the assigned tooth numbers are shown in the clinical pictures workspace.	N/A				
	 Double-click an image to use additional workspace functionalities: image filters and SmartLayout (see page 43). 					
	 To return to the initial layout overview, double- click the image again or press Esc. 					
	 Switch to another image by clicking on a thumbnail in the overview on the SmartPanel™ Layout tab. Alternatively, use the arrow keys. 					
	 Multiple images can be stacked in the same placeholder. Click to show all the images and click > 					
Intraoral camera	Dedicated workspace for intraoal camera acquisition.	F10				
Recent images	nt images The Recent images workspace shows all recently imported or acquired images. By default, the workspace shows the images of the last seven days. To change this, go to the DTX Studio Clinic preferences.					

Customize Workspaces

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

Show all Related Tooth Information with SmartFocus™

To activate SmartFocus in a supported viewer, press the spacebar. Alternatively, click \oplus on the top menu bar.

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

Customize Views with SmartLayout™

Customize a workspace by adding or removing viewers via the SmartPanel[™] Layout tab and by changing the viewer proportions.

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

Fuse IO Scans with 3D X-ravs

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

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

Use the Thumbnail Bar

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

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

Add Diagnostic Findings

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

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

Notes

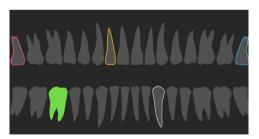
In the tooth workspace, the status is visually indicated on the tooth chart as well.

If the finding is added in the tooth workspace, the finding is added to the specific tooth.

If the finding is created in another workspace, click the tooth number placeholder and type the tooth number to assign the finding to a specific tooth.

SmartPanel[™] Tooth Chart

In the tooth workspace and endo workspace, a tooth chart is shown above the SmartPanel™ tab.



- The active tooth, for which the data are shown in the workspace, is highlighted in green.
- Select another tooth by clicking a tooth on the tooth chart.
- Below the tooth chart, click ⁵ to go to the previous tooth, or click ⁵ to go to the next tooth.
- A tooth with at least one finding has a colored outline. The color depends on the treatment status of the finding.

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

Adjust Reslices

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

Clip the 3D Volume

On the 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.

Use Dental Intraoral Cameras in Workspaces

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

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

10013

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

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



Warning

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

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

Diagnose tab



Set the slice thickness of a 3D reslice viewer. Click on the 3D reslice viewer and drag horizontally to set the X-ray thickness. Right-click to finish.

Note

To set a default slice thickness, go to the Image settings tab in the DTX Studio Home settings or DTX Studio Clinic preferences. In the top-right drop-down menu, select 3D Reslices, Panoramic or Tooth. Select a preferred thickness in the Slice thickness drop-down menu.

- Drag on a viewer to adjust the brightness and contrast:
- Horizontally: to change the contrast.
- Vertically: to change the brightness.

Note

When the brightness and contrast tool is used with grayscale images, the level and window values are updated accordingly.

- 0
- Magnify a certain area of an image (default setting) or compare applied filters to the original image. Use the minus and plus keys (or Shift + Plus key when using macOS) to adjust the magnification level. To change the default settings, go to the DTX Studio Clinic preferences.
- Inspect the underlying reslice when clicking on a 3D model.
- The reslice is shown in the overlay slice explorer window.
- Active image filters and the slice thickness are applied to the slice explorer view as well.
- Scroll to go through all the reslices.
- While inspecting the underlying reslice, the 3D model remains rotatable.
- Capture a screenshot. It is added to the clinical pictures workspace, the SmartPanel™ Layout tab and the patient data. The captured screenshot can be added to a report (see page 44).
- <u>≡</u>Q
- Add a finding to the SmartPanel™ Findings tab.
- (**L**)
- Analyze the airway. Indicate landmarks to create a box surrounding the region of interest. Click Done. The airway volume and the most narrowing area is visualized in the 3D patient workspace.

47

Diagnose tab



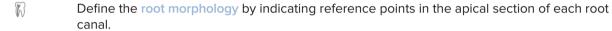
Indicate a nerve canal. Click the first anchor point. Then click every next anchor point. Right-click to finish.

- Adjust the nerve canal annotation by moving the anchor points on the viewer.
- All the anchor points will appear as one line on the 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 (CB)CT data in detail. For example to mark and inspect the root canals and to make annotations.

- Move the custom reslice by clicking and dragging the reslice line.
- Rotate the custom reslice by clicking and dragging one of the reslice endings.



1. Scroll through the slices to find an optimal position.

Note

If needed, re-indicate the tooth center in the Horizontal viewer by clicking and dragging the center.

- 2. Click a position in one of the viewers.
- 3. The root canal visualization is immediately shown in the Root canal viewer.
- 4. Click Add point to add a new reference point, if needed.
- 5. Click Done.



Detect focus areas that could potentially contain dental findings. See page 56.

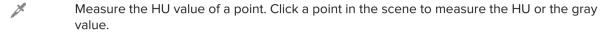


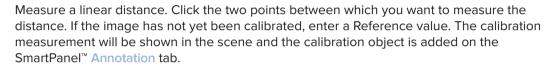
Ignore the detected focus areas.

Annotate tab

тТ	Add text to an image
Ž,	Draw segmented lines with the pen. All the lines will appear as one annotation on the SmartPanel™ Annotation tab.
Ên	Draw free-form lines with the pencil.
0	Draw a circle.
\rightarrow	Draw an arrow.
=	Select the line thickness for an annotation.

Measure tab





The measurement (and its accuracy) is shown.



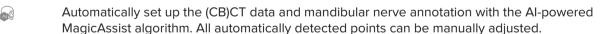
Measure an angle. Click three points.

Plan tab

- Place an implant. This tool can be used in any workspace that contains (CB)CT data.
- Manage which implants can be placed.
- Add another implant plan. Once completed, switch between implant plans via the SmartPanel™ Implant plan tab.

3D X-ray tab

?)



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

- Edit the orientation of the patient model. The 3D patient model can be orientated in the preferred position by translating and rotating the model in the 3D viewers.
 - 1. Click the pan icon wor the rotation icon or press the [Tab] key to switch between rotation and translation mode. The selected mode appears in green.
 - 2. Drag the model until it is correctly aligned with the reference lines.
 - 3. Click Done.

3D X-ray tab



Adjust the OPG curve. Indicate the points and teeth as requested. When the teeth are not clearly visible, scroll or use the gray slider at the right side to adjust the position of the axial reslice to a plane showing the tooth setup (approximately converging with the occlusal plane).

If needed, adjust the curve:

- Click and drag individual control points to adjust the shape of the curve.
- Click on the curve to add a new control point.
- Click and drag the surrounding area to move the complete curve.



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 horizontally on a 3D viewer to adjust the bone threshold value.



Clean up the patient model by cutting out redundant parts. Click a point in the scene to start drawing around the section that should be removed. Right-click to confirm.

Note

To restore the original patient model, click ••• next to 3D visualization on the SmartPanel $^{\text{\tiny M}}$ Viewer tab. Select Reset 3D model.



Generate an OPG. The panoramic (reslice) view is added to the patient data as a 2D image. The generated image is opened in the OPG workspace.



Generate 3D cephalograms based on the imported 3D X-ray.

IO Scan tab



Automatically set up IO scans.



Align or realign an IO scan on the 3D X-ray.



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

* For Windows only.

Compare IO scans to follow up on gingival recession, tooth wear and other differences. Select an IO scan to compare with the reference scan. Click Finish.

By default, a colored distance map is applied. On the 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

Create Reports

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

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

Add Custom Practice Logos

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

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

Opening DTX Studio Implant

Connect DTX Studio Clinic and DTX Studio Implant

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

Note

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

3. Click OK.

Launch DTX Studio Implant

1. Select the patient record in the patients list.

Note

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

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

Orders and Partner Collaborations

Order a Surgery Plan, Surgical Template or Restoration

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

Note

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

Set up a Connection with a Partner

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

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

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

Order Directly from a Partner

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

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

View Partner Case or add new Data

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

Focus Area Detection

What is Focus Area Detection?

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

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

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

Supported focus areas for capturing artifacts are overlap and scratches.

Using Focus Area Detection

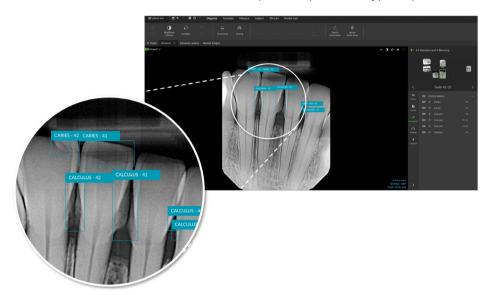
When intraoral images are captured or imported, Focus Area Detection is run automatically, to check whether the images contain areas that need special attention. You can see this by the blue line running over the images.

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

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

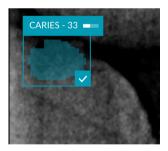


Click an image to open it. Focus areas are visualized on the intraoral images using focus area annotations. These annotations show the tooth number (if known), and the type of potential dental finding detected.



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

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

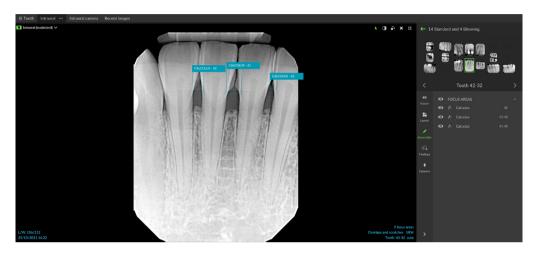


If you choose to accept it, the focus area changes to yellow and is turned into a diagnostic finding automatically. It will be added to the SmartPanel™ Findings tab.

The focus areas are listed on the SmartPanel^{$^{\text{M}}$} Annotation tab as well and can be shown or hidden using the visibility icons of the SmartPanel^{$^{\text{M}}$} 's visibility functionality.

Overlaps and scratches

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



Click View to check the notification.



Appendix I: Focus Area Detection Algorithm Performance Assessment

Clinical Performance Assessment

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

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

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

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

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

Stand-alone Performance Assessment

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





Nobel Biocare AB Box 5190, 402 26 Västra Hamngatan 1, 411 17 Göteborg, Sweden

www.nobelbiocare.com

Distributed in the United States by:

Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Rx only







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.