DTX Studio™ Assist
Version 1.1

Instructions for Use

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Introduction

Disclaimer of Liability

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

Before using DTX Studio Assist, please read these Instructions for Use and retain it for future reference.

Device Description

DTX Studio Assist is a software development kit (SDK) that makes a selection of algorithms (including AI-based algorithms) available through a clean, well-documented API. DTX Studio Assist features are only available to licensed customers. The SDK has no user interface and is intended to be bundled with and used through other software products (hosting applications).

Key functionalities of DTX Studio Assist include:

– **Focus Area Detection on IOR images**: The software features the Focus Area Detection algorithm which analyzes intraoral radiographs for potential dental findings (caries, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, bone loss and calculus) or image artifacts.

– **Alveolar Bone Level Measurement**: The software enables the measurements of mesial and distal alveolar bone levels associated with each tooth.

– **Detection of historical treatments**: The software enables automated detection and segmentation of dental restorations in IOR images to support dental charting which can be used during patient communication. Following types are supported: amalgam fillings, composite fillings, prosthetic crowns, bridges, implants, implant abutments, root canal fillings and posts.

– **Anatomy Segmentation**: The software segments dental structures by assigning a unique label to each pixel in IOR images, including enamel, dentine, pulp, bone, and artificial structures.

Intended Use / Indications for Use

DTX Studio Assist is a Software Development Kit (SDK) designed to integrate with medical device software that displays two-dimensional dental radiographs. It contains a selection of algorithms that processes input data (two-dimensional radiographs) from the hosting application and returns a corresponding output to it.

DTX Studio Assist is intended to support the measurement of alveolar bone levels associated with each tooth. It is also intended to aid in the detection and segmentation of non-pathological structures (i.e., restorations and dental anatomy)

DTX Studio Assist contains a computer-assisted detection (CADe) function that analyzes bitewing and periapical radiographs of permanent teeth in patients aged 15 and older to identify and localize dental findings, including caries, calculus, periapical radiolucency, root canal filling deficiency, discrepancy at the margin of an existing restoration, and bone loss.

DTX Studio Assist is not intended as a replacement for a complete dentist's review nor their clinical judgment which takes into account other relevant information from the image, patient history, and actual in vivo clinical assessment.

Intended User and Intended Patient Target Group

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

Required Compatibility with Other Devices

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

DTX Studio Assist is connected with DTX Studio Clinic or other medical devices that integrate DTX Studio Assist.

Devices with Measuring Function

DTX Studio Assist reports the distance measurement value, rounded to one digit after the decimal point.

Contraindications

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

Cybersecurity

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

DTX Studio Assist is bundled with a hosting application. It is recommended to follow the cybersecurity instructions of the hosting application

in addition of the cybersecurity instructions for DTX Studio Assist.

DTX Studio Assist uses Hypertext Transfer Protocol Secure / Transport Layer Security (HTTPS / TLS) to encrypt the communication to the license server. We advise to check the Firewall Settings to ensure the necessary connection is enabled.
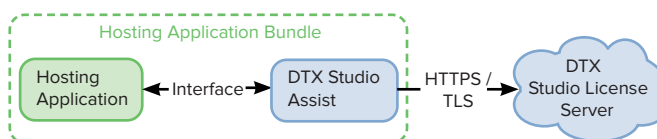
It is recommended that active and up-to-date anti-virus and anti-malware software, together with a correctly configured firewall, are installed on the computer where DTX Studio Assist is to be used. Failure to do so may lead to unauthorized access.

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

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

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

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

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

DTX Studio Assist is installed as an integrated component of the hosting application. Software updates are delivered via the hosting application to ensure consistency and security.

Technical logs are automatically saved to a directory specified by the hosting application. These logs support the identification and analysis of technical issues or error scenarios.

When support for DTX Studio Assist is discontinued (meaning no further software updates, upgrades, or technical assistance will be provided), users

will receive formal notification from the company specifying the applicable end-of-support and end-of-life dates. After these dates, the company may no longer be able to address emerging cybersecurity vulnerabilities or provide updates to mitigate them.

Users who continue to operate DTX Studio Assist beyond its supported lifecycle must be aware that cybersecurity risks may increase over time due to unresolved vulnerabilities.

To maintain device safety and data integrity, users are strongly advised to:

– follow all update instructions provided by the hosting application.

– discontinue use of unsupported software versions once the support period has ended.

What to Do in Case of a Cybersecurity Event?

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

Decommissioning and Disposal

When terminating the use of DTX Studio Assist integrated into the hosting application on your computer or when disposing your computer on which DTX Studio Assist is installed:

– Make sure to back up all necessary data from the application in accordance with local laws and regulations concerning data protection and data privacy to avoid any loss of relevant information.

– Uninstall the application: You should uninstall the hosting application from your device by following the instructions of your operating system provider to prevent unauthorized access to DTX Studio Assist and the data stored in the software.

Interoperability

DTX Studio Clinic or other medical devices that integrate with DTX Studio Assist.

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 Assist is used only with approved operating systems.

See the system requirements in the IFU for more information.

Clinical Benefits and Undesirable Side Effects

No undesirable side effects identified for DTX Studio Assist.

Notice Regarding Serious Incidents

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

Nobel Biocare AB

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

Facilities and Training

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

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

For more information, please visit our training website on https://tw.dtxstudio.com/.

Professional Use

DTX Studio Assist is for professional use only.

System Requirements

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

Handling Instructions

For detailed information on how to use the software, please refer to the Instructions for Use documents of the image viewing software that integrates DTX Studio Assist.

Warnings, Cautions and Precautions

Cautions / Precautions

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

It is recommended to pay extra attention to the assigned tooth numbering. A wrongly assigned tooth number may lead to incorrect treatment actions performed on the patient.

The alveolar bone level measurement results are generated by the ABL measurement algorithm and are provided for user reference only; users must verify the accuracy of the indicated points manually and adjust or delete measurements as necessary based on clinical judgment and radiographic interpretation.

Warnings

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.

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

The visual highlighting of dental regions by the IOR Anatomy Segmentation Algorithm is intended solely to support communication between dental professionals and patients; it is not designed for diagnostic or clinical decision-making purposes.

The detection of restoration regions by the IOR Restoration Detection Algorithm is intended solely to support communication between dental professionals and patients and to assist dental practices in managing patient operations. It is not designed for diagnostic or clinical decision-making purposes.

System Requirements

Operating System[1]	Windows® 11 or 10 64-bit (Pro and Enterprise edition) on desktop and notebook.
	macOS Sequoia (15), Sonoma (14), or Ventura (13) (Intel®-based Mac and Apple Silicon Mac with M1 Chip or Higher) on iMac, Mac Mini, Mac Pro, MacBook Pro, MacBook Air devices.

	Recommended setup
CPU	2.8 GHz quad-core (Intel Core i5 or i7)
RAM	8 GB or more
Graphics card	Dedicated add-in graphics card with optimal 3D support (OpenGL 3.3) and 2 GB VRAM or more.
	For hardware acceleration of the algorithms on Windows, a DirectX 12 capable GPU and Windows 10 version 1903 or higher is required.
	For hardware acceleration of the algorithms on Mac, macOS Sonoma (14) or higher is needed. For best performance an Apple Silicon Mac with M1 Chip or higher is recommended.
Network	Broadband Internet connection with 3Mbps upload and 30 Mbps download speed.

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

Firewall Settings

To connect DTX Studio Assist to external services and/or applications either a direct connection can be used or it can be configured to use a proxy. In case of a direct connection, the firewall should allow the connection to the specified servers. In case of a proxy setup, proxy settings should be set correctly on the client PC, as described below.

Note

To allow DTX Studio Assist to connect to external services and/or applications, it is recommended always to be connected to the Internet. If that is not possible, a connection should be established at least once every 14 days. Otherwise your access to DTX Studio Assist may be temporarily suspended. When a connection to the internet is re-established, your access to DTX Studio Assist will be restored.

Server and Port Configuration

DTX Studio Go Server

The following table describes the URLs used by DTX Studio Assist The corresponding IP addresses of these URLs can be found by DNS lookup. For example, on Windows this can be done by opening a command prompt and using the nslookup command.

For example `"nslookup nobellicense.nobelbiocare.com"`.

Protocol	URL	Description
https	nobellicense.nobelbiocare.com	URL used to contact the DTX Studio Go license server.
https	nobelstats.nobelbiocare.com	URL used to send anonymous statistical information to DTX Studio Go.

Proxy Settings

DTX Studio Assist uses OS proxy settings to determine whether to directly communicate with servers or by using a proxy server.

On Windows different proxy settings are available:

– **User proxy settings**. These settings are available via Proxy settings of the System settings. Those proxy settings are typically used by simple desktop applications or by browsers. They are specified per user, not available for services, and DTX Studio Assist does not use those settings.

– **WinHTTP proxy settings**. Those settings are used by services, like Windows Updates service. DTX Studio Assist uses WinHTTP proxy settings to communicate with all the servers.

  WinHTTP proxy settings are usually set via command prompt. Examples:

  – `netsh winhttp show proxy` is a command to show the current WinHTTP proxy settings.

  – `netsh winhttp set proxy "<proxy>:<port>" bypass-list="<local-net>"` is a command to use the <proxy> proxy server at the <port> port and to avoid using a proxy when working with URLs/IP addresses of the <local-net> net.

  – `netsh winhttp reset proxy` is a command to reset proxy settings, and to use direct connection.

On macOS the relevant proxy configuration should be set in the secure Web Proxy (HTTPS) settings, as specified in the Apple Support documentation.

Examples

Windows with Local Proxy Server

This is an example of configuring Windows to use a proxy server located in the same local network as DTX Studio Assist with the proxy server available at the 10.0.1.100:8080 address.

Start command line as administrator. Execute the following command:

```
netsh winhttp set proxy proxy-server="10.0.1.100:8080"
```

Windows with an External Proxy Server

This is an example of configuring Windows to use a proxy server **sampleproxy.com:8080** located outside the local network and with the local network using IP addresses in the 10.*.*.* range.

Start command line as administrator. Execute the following command:

```
netsh winhttp set proxy proxy-server="sampleproxy.com:8080"
bypass-list="10.*.*.*"
```

Configure Proxy Server on macOS

1. Choose Apple menu.
2. Select System Settings.
3. Click Network in the sidebar.
4. Click a network service on the right.
5. Click Details.
6. Click Proxies.
7. Specify relevant proxy settings in the Secure Web Proxy (HTTPS) configuration.
8. If necessary, specify relevant proxy settings in the Web Proxy (HTTP) configuration as well.

Appendices

Appendix I: Focus Area Detection Algorithm Performance Assessment

DTX Studio Assist features an AI-powered Focus Area Detection algorithm which analyzes 2D intraoral radiographs for potential dental findings or image artifacts (overlap and scratches).

The following dental findings can be detected by the device:

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

- Discrepancy at the 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 nonradiopaque 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 2 mm from the radiographic apex) and/or too small in diameter, or the root filling is not radiographically homogeneously 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.

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 AI-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 image-level specificity. An increase of AUC (Area under the curve) of 8.7% was observed on dental finding level. Based on the ANOVA model t-test, 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.

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

Appendix II: Restoration Detection Algorithm Performance Assessment

The restoration detection algorithm is an AI-based algorithm for the automated detection and segmentation of several types of dental restorations in an intraoral radiographic image (IOR); specifically, amalgam fillings, composite fillings, prosthetic crowns, bridges, implants, implant abutments, root canal fillings, and posts. The algorithm returns, for every detected instance, the restoration type and the corresponding segmentation mask, defining the location and shape of the instance within the image. The AI algorithm has been validated on an independent test dataset of 1,530 IOR images. The algorithm achieved an averaged sensitivity (a.k.a recall) of 88.8% and a specificity of 96.6%. The segmentation accuracy was high with a mean Dice score of 86.5%. Comparison with inter-expert agreement confirmed the solid segmentation performance of the algorithm. This study demonstrates that the IOR Restoration detection algorithm achieves high accuracy and expert-level segmentation performance across restoration types, supporting its integration into dental workflows. The table below provides sensitivity, specificity, and mean Dice score for each restoration type (and aggregate) in percentages, as well as the confidence interval (CI_{95}) for each performance metric.

	Sensitivity (%)	CI_{95}	Specificity (%)	CI_{95}	Mean Dice (%)	CI_{95}
Implant	97.4	[95.7,99.1]	99.4	[99.0,99.8]	94.1	[91.6, 96.6]
Abutment	92.4	[89.5,95.3]	97.3	[96.4,98.2]	84.8	[80.7,88.9]
Prosthetic crown	93.0	[91.8,94.2]	92.0	[90.0,94.0]	88.4	[86.9,89.9]
Bridge	96.6	[93.7,99.5]	98.1	[97.4,98.8]	96.0	[92.8,99.2]
Amalgam filling	96.0	[94.8,97.2]	95.6	[94.3,96.9]	94.6	[93.2,96.0]
Composite filling	81.3	[79.7,82.9]	85.6	[82.7,88.5]	79.5	[77.7,81.3]
Root canal filling	92.1	[90.3,93.9]	98.6	[97.8,99.4]	85.2	[82.7,87.7]
Post	68.4	[62.6,74.2]	98.3	[97.6,99.0]	85.2	[79.8,90.6]
Aggregate	88.8	[88.1,89.5]	96.6	[96.2,97.0]	86.5	[85.6,87.2]

Appendix III: Alveolar Bone Level Measurement Performance Assessment

The Alveolar Bone Level (ABL) Measurement algorithm generates mesial and distal ABL line segments and calculates the corresponding ABL measurements in intraoral IOR images. The measurement is made in image pixels, with an optional conversion to the actual length measurement (in mm) when the pixel size is known. A total of 274 radiographic images were used, with careful attention to demographic and geographic diversity to ensure generalizability. The IOR ABL measurement algorithm achieved a sensitivity (a.k.a. recall) of 92.0% while precision was 93.1% for the ABL end point generation. The subsequent generation of ABL line segments had an overall sensitivity of 93.2% and specificity of 88.6%. The ABL length measurements showed a mean average error of 0.26 (± 0.28) mm, confirming that the length is correctly measured by the algorithm.

Appendix IV: Anatomy Segmentation Performance Assessment

The IOR Anatomy Segmentation Algorithm is an AI-algorithm designed to automatically identify and segment key anatomical structures in intraoral radiograph images. The algorithm delineates the following structures: enamel, dentine, pulp, jaw bone, artificial structures = artificial origin (grouped under the label "artificial").

Each pixel in the IOR image is assigned a class label, and the output is a color-coded mask that overlays the original image, facilitating intuitive visualization of dental anatomy in the hosting application. The segmentation functionality is intended solely for visual support during dental consultations. It is not designed for diagnostic or clinical decision-making. The highlighted anatomical regions aim to improve understanding and communication between dental professionals and patients.

The performance evaluation on 220 IOR images demonstrated that the IOR Anatomy Segmentation Algorithm performs with high accuracy and reliability across a diverse set of intraoral radiographs. The algorithm achieved an overall average sensitivity of 89.0%, a specificity of 95.2% and Dice score of 86.5%. These metrics confirm the algorithm's robustness across diverse IOR datasets and support its integration into dental workflows for non-diagnostic purposes, such as enhancing patient communication.

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