CORTEX®

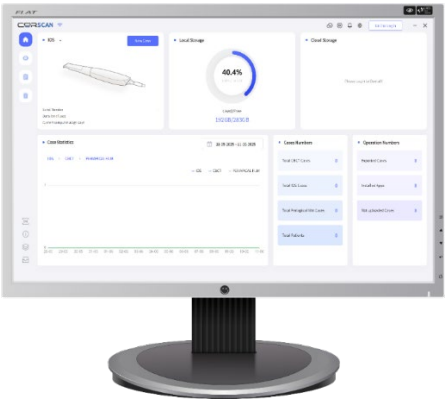
The Future of Dental Implants

Software Instructions for use

Digital Intraoral Scanner System

Model: S6500

CORSCAN



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1 Software description

1.1 Introduction

The instructions for use describe the performance attributes and operational procedures necessary for the proficient utilization of the dental practice management software - DentalFlex, and the image acquisition software - ScanFlex.

Prior to engaging with DentalFlex and ScanFlex, it is imperative to thoroughly review the comprehensive instructions for use, with particular attention to the Safety Instructions and the Handling chapter.

1.2 Description

DentalFlex is a user-friendly, window-based interface that seamlessly integrates multiple applications, offering dental practices an efficient management solution encompassing patient registration, image acquisition, case ordering, treatment protocol design, and more.

Serving as the central interface for the entire workflow, DentalFlex facilitates tasks ranging from adding new cases to placing dental orders. Conversely, ScanFlex serves as the dedicated interface for acquiring scan image data, automatically launching upon initiation of a scan.

Whether utilizing the touch screen or mouse, the DentalFlex and ScanFlex duo efficiently navigates users through each step

of the process, culminating in the production of high-quality digital intraoral images tailored to diverse requirements.

NOTE

In this Instruction for use, the word “case” and “scan task” are used synonymously.

1.2.1 User interfaces and modules

To optimize the digital intraoral scan's efficiency, the following user interfaces are utilized:

- DentalFlex: Primarily dedicated to the management, analysis, and visualization of dental clinic data and orders.
- ScanFlex: Specifically tailored to support digital intraoral scanner systems, ensuring the acquisition of high-quality image data to meet diverse medical requirements.
- ModelViewer: An additional module designed to streamline various analyses utilizing 3D models, including coordinate adjustment, 2D section measurement, bite analysis, undercut analysis, and more.
- DentalX: A cloud-based database engineered to streamline data storage, synchronization, and transmission processes.

NOTE

Please note that the country-specific requirements for data protection when using Cloud service.

1.2.2 System Requirements of Hardware and Software

CPU	Inteal i7or above
GPU	NVIDIA GeForce RTX 3060 - 6 GB or above
RAM	32 GB of RAM or above
Hard Disc	1 TB SSD or above
OS	Windows10/11 64bit
Resolution	1920*1080
Port	USB 3.0 Type-A

NOTE

Please note that the country-specific requirements for data protection and IT security are complied with.

NOTE

All peripherals (PC, monitor, printer) connected to the system must conform to standard IEC 60950 (EN 60950) or must be "UL-listed" and correspond to the system requirements. Not conformable components may cause problems or even an image lost.

1.2.3 License Conditions

The use of DentalFlex, ScanFlex, as well as ModelViewer and DentalX underlies the "General Software License Conditions" of CORTEX, which must be confirmed at the first installation.

1.2.4 General Legal Conditions

Legal guidelines in the form of laws, standards and directives have to be explicitly clarified for the respective site where the device is used. This mainly relates for guidelines concerning long term archiving, handling raw data and the use of suitable image viewing devices.

Furthermore, the user/reader of this manual must himself/herself see to it that the guidelines are kept to relating to his/her medical association and the panel union/association which is responsible in such matters.

2 Safety instructions

NOTE Contains information that must be observed during operation.

xxx

CAUTION! Contains information which, if not observed, can cause property damage.

xxx

WARNING! Contains information which, if not followed, can cause personal injury.

xxx

2.1 General Safety Notes

Settings that are not described in these instructions for use must be made by CORTEX customer service or a service provider authorized by CORTEX based on the technical description of the software.

NOTE

All instructions supplied with the software must be observed and the safety instructions contained therein must be carefully read and adhered to.

CAUTION!

The instructions for use contain all the information relevant to safety in order to generally put the software into operation. The software may only be operated by appropriately trained and authorized personnel. In this context, operation is ensured by clear symbols on the control elements.

The user himself/herself is responsible for the image quality while accepting the image.

The user is not allowed to modify the digital intraoral scanner system.

2.1.1 Requirements for Operation

In case of a malfunction, do not use the software anymore and notify CORTEX service department or a service company authorized by them.

2.1.2 Operating Personnel

The software is designed solely for use by trained professional users who are proficient in operating diagnostic software in compliance with applicable national regulations. Users must undergo instruction on proper handling, utilization, and operation, as well as on permitted connections with other medical devices, objects, and accessories.

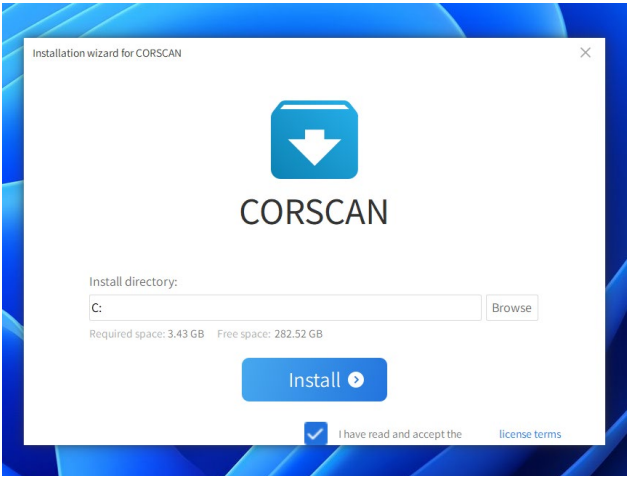
NOTE

Only trained and authorized personnel are allowed to work with the software.

3 Handling

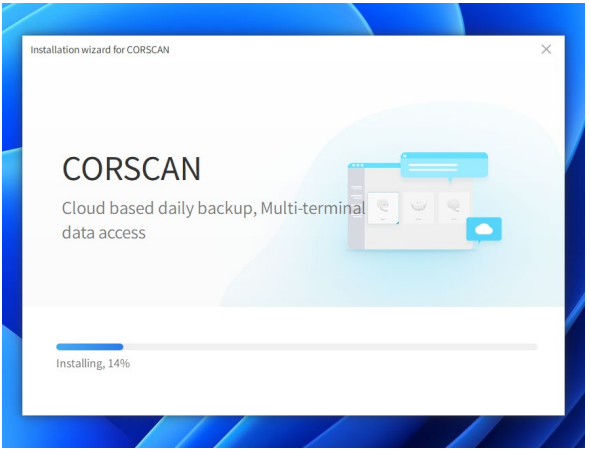
3.1 Installing DentalFlex and ScanFlex

The software DentalFlex and ScanFlex are compatible with Windows operating systems. To streamline installation, both applications are packaged within a single executable file tailored for the specified systems. Upon downloading the installation file (ScanFlex...-VX.X.X.X.exe) to your hard drive, simply execute the file and follow the prompts to initiate the installation process



Select the installation path. Typically, it is recommended to install the software in the default directory path.

Please thoroughly review the "License Terms" before confirming acceptance by checking the box "I have read and accept the license terms," then proceed by clicking "Install."



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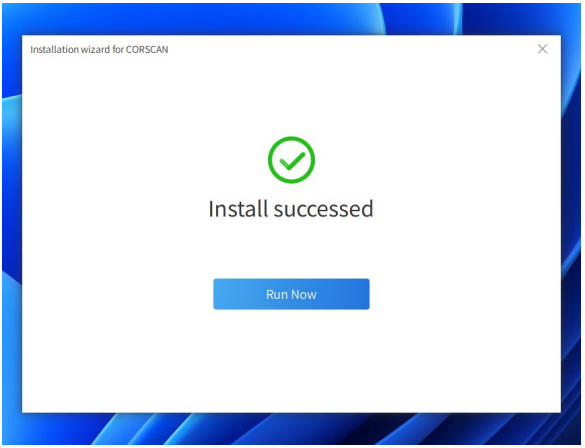


The installation process may take several minutes to complete. Please refrain from shutting down the PC until the installation has finished.

NOTE

Upon completion of the installation, both DentalFlex and ScanFlex are installed under separate paths. For uninstallation, both software applications must be uninstalled. For further details, please refer to Section 3.8 Uninstalling DentalFlex and ScanFlex.

3.2 User Registration

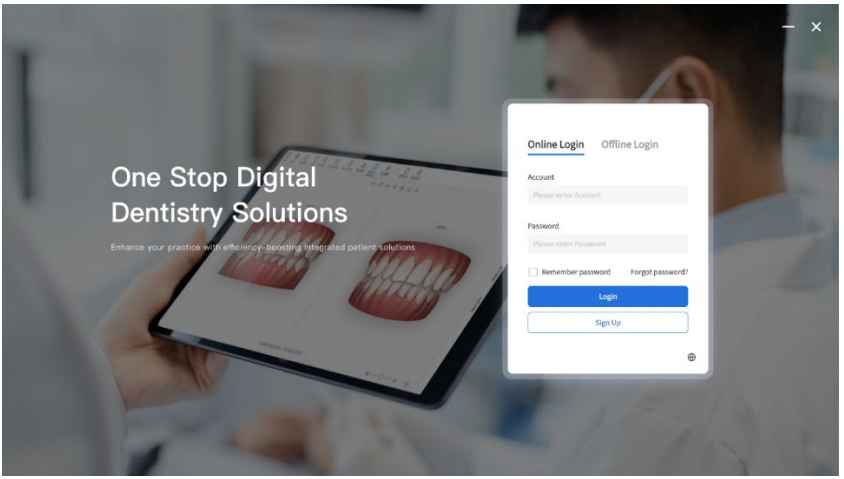
3.2.1 Login Page

Upon clicking "Run Now" or double-clicking the DentalFlex desktop icon  , the web-browser-based login page will be launched.

DentalFlex offers two login options: online login and offline login, as introduced in the following sections.

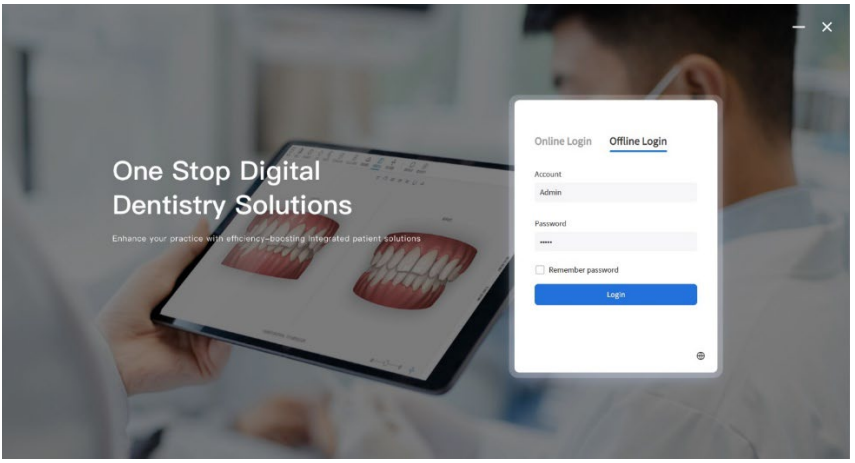
3.2.1.1 Online login

New users are required to register by clicking the "Sign Up" button. Registered users may then log in using their designated username and password.



3.2.1.2 Offline login

In addition to the "Online Mode" (online login), DentalFlex offers users the option to operate in "Offline Mode" when internet connectivity is unavailable or when users prefer to store data locally. The default account name is "Admin," and the default password is "admin." It is important to note that opting for "Offline Mode" restricts access to functions reliant on Cloud services, such as data synchronization, importing data from Cloud, placing orders with dental labs, checking order statuses, and installing third-party interfacing applications.



NOTE

Cloud service access is exclusively available to registered users under the online mode.

For logging in under Offline mode, the default account name is "Admin “and the default password is "admin."

3.2.2 Register

To operate the DentalFlex software in "Online Mode," users must create a user account for initial access. Prior to clicking the "Sign Up" button, users must determine whether to create a "Clinic" or a "Lab" account:

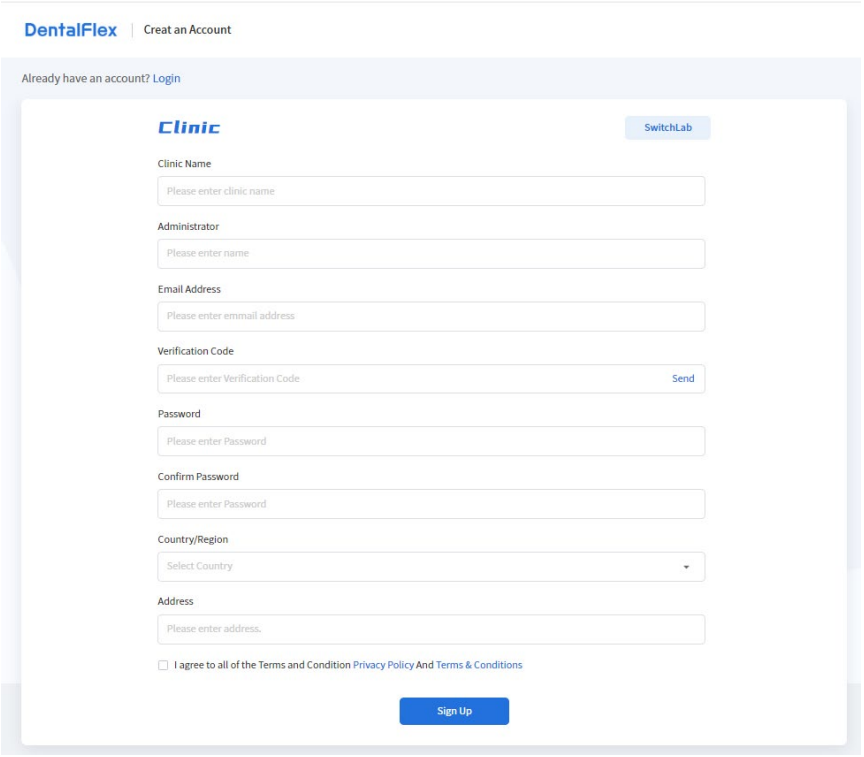
- Registering as a **“Clinic”** enables users to acquire intraoral scan images by operating the digital intraoral scanner system.

- Registering as a **"Lab"** does not grant users the ability to operate the digital intraoral scanner system for image acquisition, but they can receive digital image data and related digital order forms.

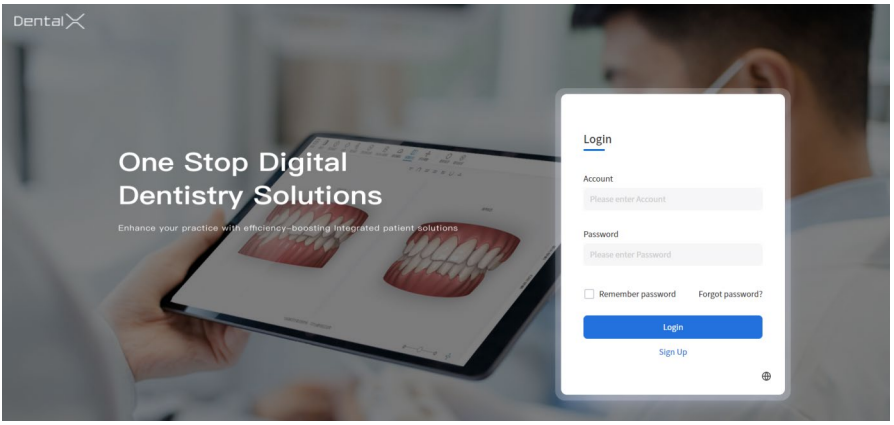
After determining the type of account to create, users may complete the registration form. Before proceeding with the sign-up process, an email address must be provided, and a verification code needs to be requested by clicking the "Send" button.

A verification code will be sent to the registered email address. Enter the verification code in the corresponding input field and ensure all required information is provided. Thoroughly review the "Privacy Policy" and "Terms & Conditions" and check the box "I agree to all of the Terms and Conditions" to proceed with the sign-up.

If the user needs to register as a dental lab, they should click the "Switch Lab" button and follow the same instructions as for clinic account registration.



After a successful registration, the user may login either by starting DentalFlex software or visiting DentalX Could login page under http://eur.dentalx.cloud.



NOTE

No additional account is required for ScanFlex. Upon logging in with the DentalFlex account, ScanFlex will be automatically launched when a scan task is initiated.

3.2.3 Miscellaneous

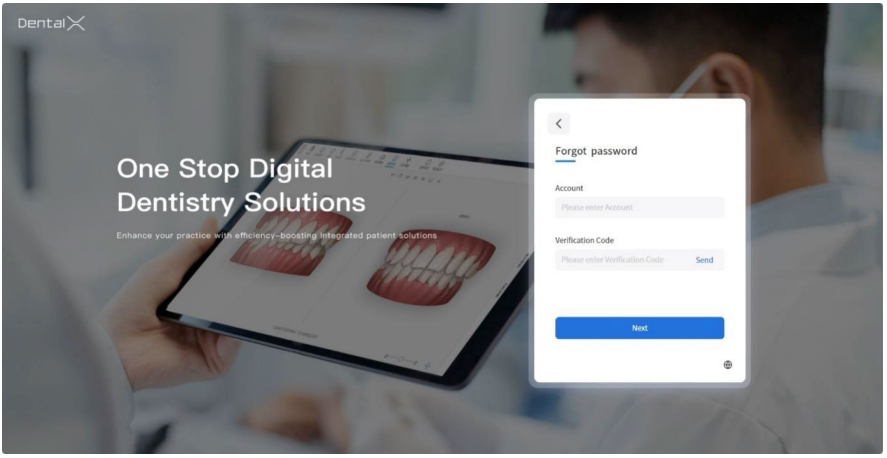
3.2.3.1 Remember Password

Tick the box to save the account and password for future logins.

3.2.3.2 Forget Password

Select the "Forgot password?" button to access the password resetting page on DentalX. Upon entering the email address associated with the account registration and clicking "Send," a

verification code for resetting the password will be dispatched to the provided email address.



NOTE

Password resetting is only available for the users who registered for "Online Mode". This feature is not available for the offline mode users with default account name and password.

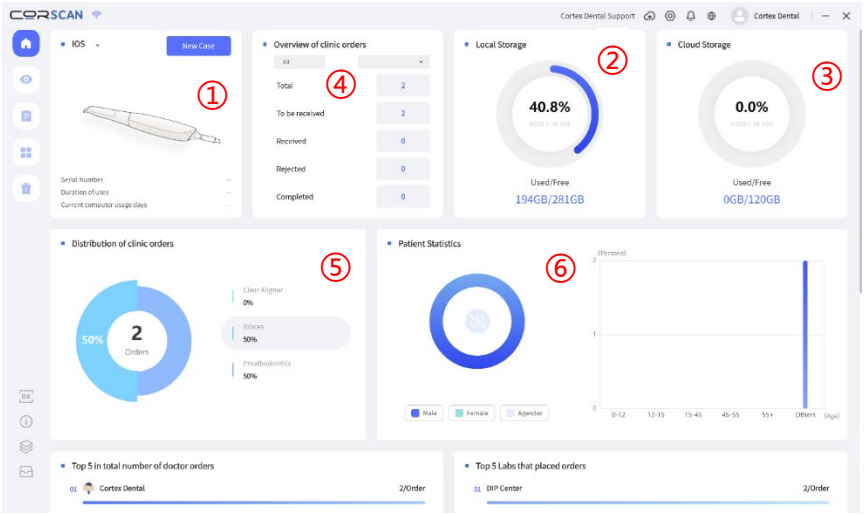
3.2.3.3 Switch Language

Click  on the login page to select other languages of the software.

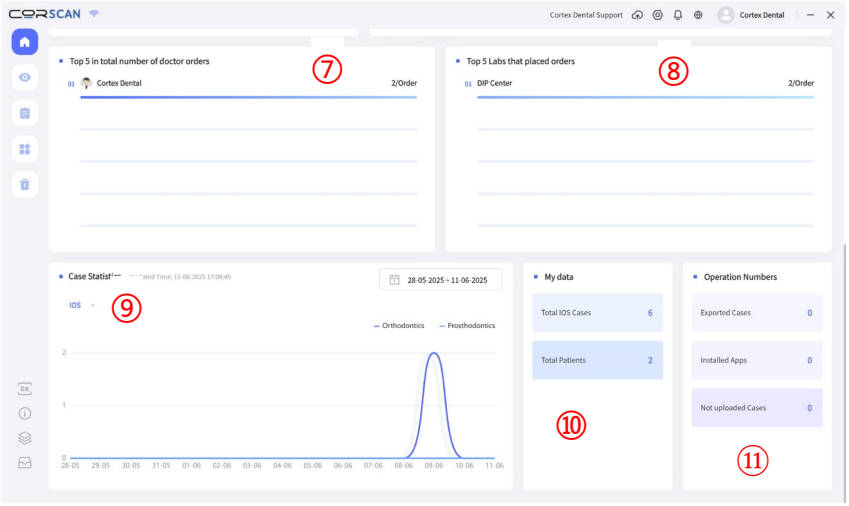
3.3 DentalFlex User interface

3.3.1 Dashboard area

The DentalFlex user interface features a dashboard comprising 11 distinct areas, each serving a specific purpose. To view all areas, simply scroll using the vertical scrollbar located on the right side of the window. The areas are depicted below in three consecutive screenshots, accompanied by an introduction to each area in the order indicated by annotated numbers in the screenshots:



①	-	**Device connectivity:** This area displays connected device, with the option to initiate a new scanning task by clicking the "New Case" button.
②	-	**Local storage usage:** Visualizes the total storage capacity and volume in use of the local PC where DentalFlex is installed.
③	-	**Cloud storage usage:** Visualizes the total storage capacity and volume in use of the user account's Cloud storage.
④	-	**Order statistics:** Provides statistics on orders placed by dental clinics to dental labs, including the total number of orders, orders awaiting acceptance by the lab, orders rejected, and orders completed.



Distribution of orders:

⑤ - Presents the distribution of orders across various indications using a pie chart.

Patient portraits:

⑥ - Illustrates the distribution of patients by gender and age groups in a pie chart.

Top 5 dentists by order count:

⑦ - Displays the top 5 dentists ranked by total order count.

Top 5 labs by placed order count:

⑧ - Display the top 5 lab partners who receive orders in numbers.

⑨ - **Cases statistics:**
Utilizes a linear diagram to display daily case data within the selected time range for analysis and management.

⑩ - **My data:**
Display the daily cases specific to the logged-in account.

⑪ **Operation statistics:**
Displays the numbers of different operation to the cases, as well as installed apps.

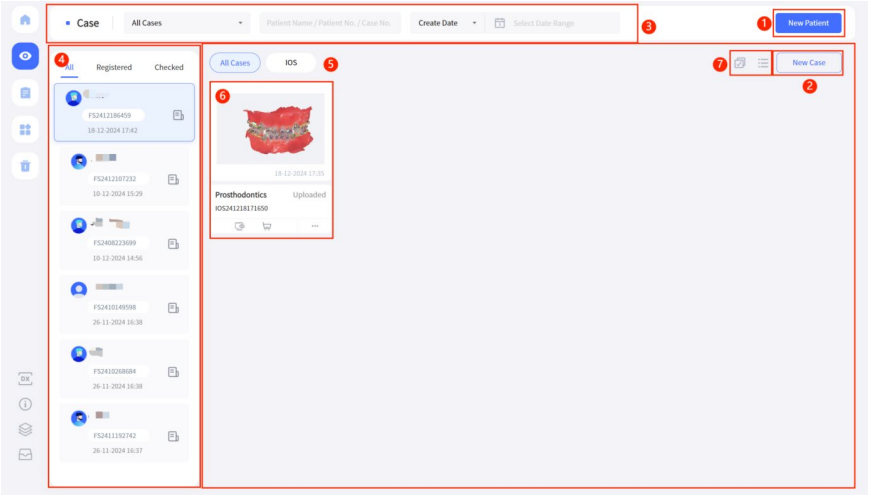
3.3.2 Working areas

DentalFlex comprises four primary working areas ("Case," "Order," "Apps," and "Bin").

3.3.2.1 Working area “Case”

This working area serves as the central hub for executing the scan workflow, facilitating the creation of new scan tasks (cases) under selected patients, and overseeing the image acquisition process. Further details on the comprehensive scan workflow can be found in section 3.5: Scan Workflow.

Within this subsection, the working area and its included features are described, encompassing the patient list, cases associated with the selected patient, and case information. Additionally, features supporting the scanning task within this working area are outlined below.



New patient:

① - Initiate the creation of a new case (scan task) for the selected patient.

New case:

② - Create a new case under the selected patient.

Filter:

③ - Allows filtering of cases by specifying patient name/number and setting a date range for scan conduct.

Patients list:

④ - Displays a comprehensive list of added patients, featuring patient names, IDs, and creation timestamps.

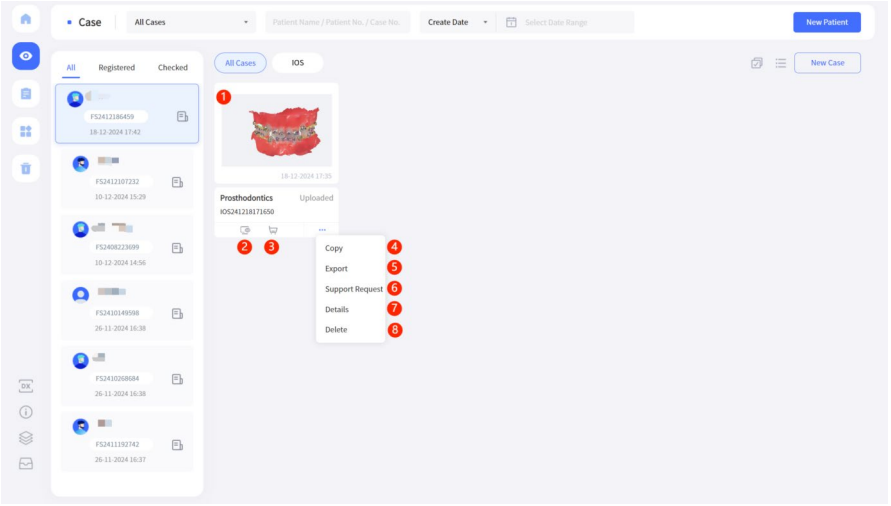
⑤ - **Case Info:**
Provides detailed patient information and a list of images associated with the selected patient.

⑥ - **Case image:**
Displays a reduced-size image of the captured images, including indications, case ID, and creation timestamps.

⑦ - **Multi selection:**
Enables batch operations such as exporting or ordering multiple cases.

Once the scan is completed and the image data is uploaded to the DentalX Cloud database under the logged-in account, the case will appear in the case area for the selected patient.

Clicking the button ••• will reveal additional operation items in a drop-down menu, allowing users to select the desired operations as needed.



Preview:

① Upon completion of image acquisition, clicking on the image itself enables users to navigate to the model viewer to inspect the colored 3D model. And other features are available in preview window.

Model Viewer:

② - Upon completion of image acquisition, clicking on the image itself enables users to navigate to the model viewer to inspect the colored 3D model.

Order:

③ Once the case has been uploaded, it can be forwarded to a dental lab via the DentalX Cloud platform or alternative platforms.

④ - **Copy:**
Duplicates the current scan file.

⑤ - **Export:**
The image data in STL, PLY, or OBJ format, along with videos recorded during scanning operations and HD photos within the selected case folder, can be exported either in their entirety or selectively, either as a compressed file or in a standard folder format.

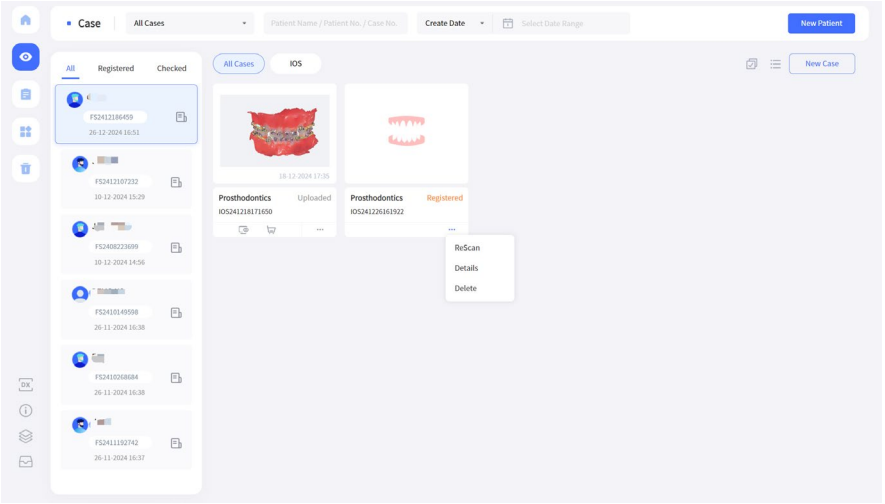
⑥ - **Support Request:**
Users have the option to provide feedback on encountered issues, including issue type, description, improvement suggestions to the manufacturer. Attachments relevant to the feedback can also be uploaded.

⑦ - **Details:**
Displays comprehensive case details, including information on previous orders.

⑧ - **Delete:**
Erases all locally stored information associated with the item, retrievable from the recycle bin.

In the event of an incomplete case, denoted as a "registered" case, the term "registered" will be displayed on the case symbol. Clicking the button at the bottom right of the case

symbol will reveal additional operation items in a drop-down menu, including options for rescan, details, and deletion. Users can select the desired operation as needed.

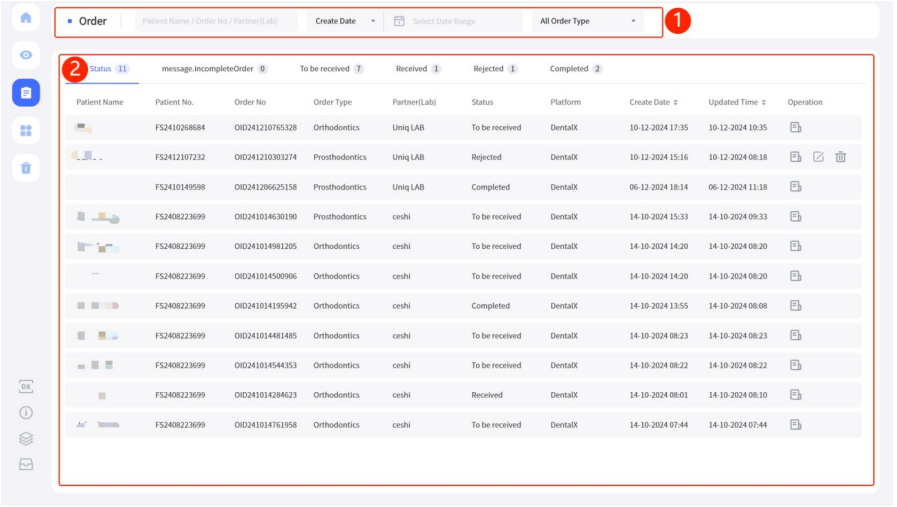


Rescan:

By clicking to continue the uncompleted scan tasks.

3.3.2.2 Working area "Order"

This working area serves to view the status of each placed orders, encompassing patient filtering and an order list for each case. Once an order is initiated, its status can be tracked on this working area.

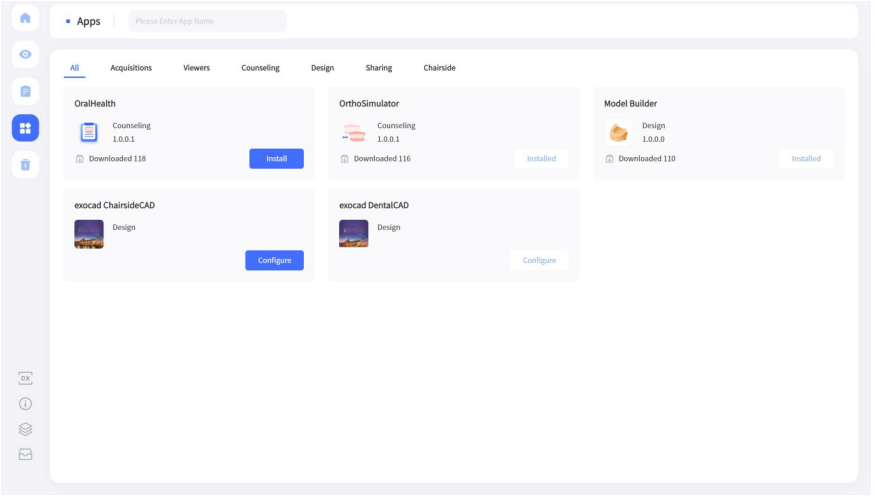


① - **Filter:**
Allows for the filtering of cases by specifying patient name/number and setting a date range for scan conduct.

② - **Order List:**
Displays orders that have been placed, including case details and order status.

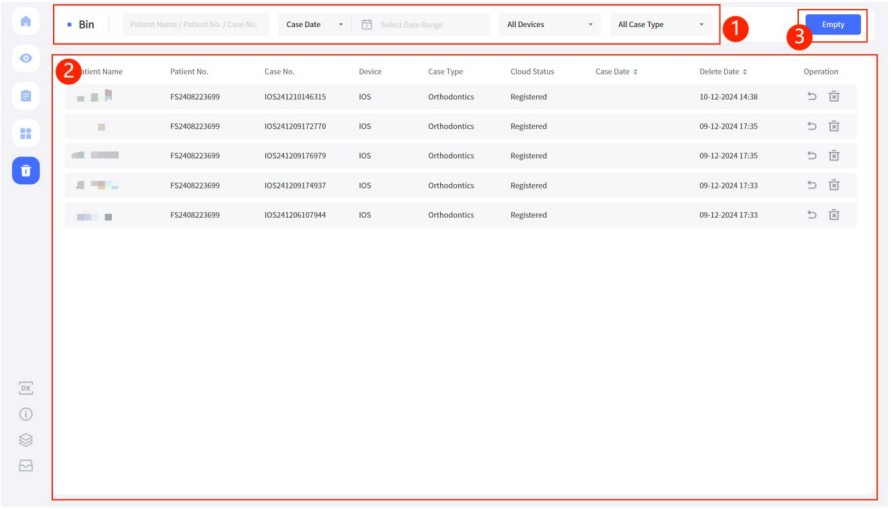
3.3.2.3 Working area "Apps"

This working area functions as a container providing a range of apps or functionalities for users to install according to their specific requirements. Users have the flexibility to add apps to this area as per their needs.



3.3.2.4 Working area “Bin”

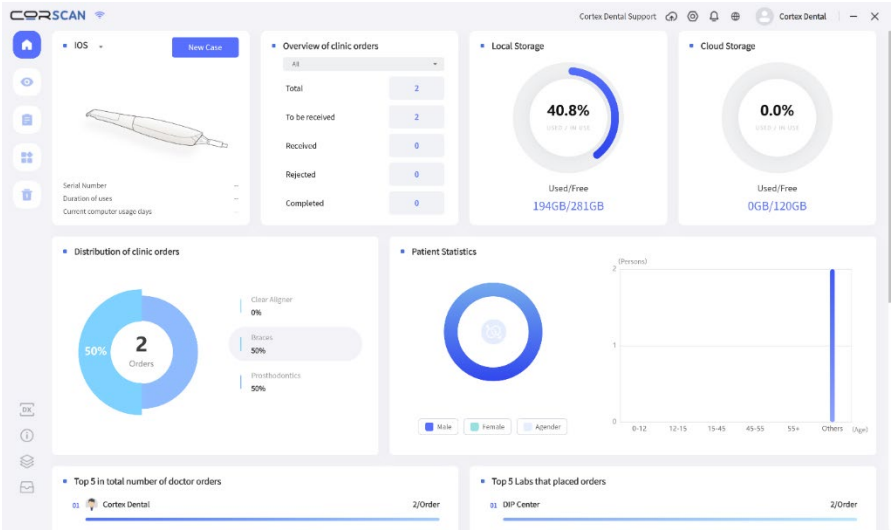
The Recycle Bin temporarily stores deleted cases, enabling users to recover files that were deleted from the DentalFlex software.



①	-	**Filter:** Allows for the filtering of cases by specifying patient name/number and setting a date range for scan conduct.
②	-	**Deleted case list:** Displays orders that have been deleted. Deleted orders can be recovered or permanently deleted.
③	-	**Empty:** Permanently deletes all orders in the recycle bin.

3.3.3 Other Features

Several frequently used features are accessible in the navigation area, including network status, cloud synchronization, notifications, language switch, account information, access to the DentalX platform (designated as "DX"), version information, export list, and the help center.



- **Network status:**
  Indicates the current network connectivity status.

- **Cloud sync:**
  Facilitates communication between local and cloud-based data, along with data upload and import functionalities.

- **Settings:**
  Allows users to customize or configure various options based on their preferences or requirements.

- **Notification:**
  Displays official notifications from CORTEX related to software updates and other pertinent information.

- **Language switch:**
  Enables users to change the displayed language of the software.

- **Account info:**
  Manages logged-in account information and allows for logout operations.

- **DentalX platform:**
  Upon clicking "DX," the DentalX Cloud platform will be loaded in the default web browser.

- **Version info:**
  Displays current version details and provides updates.

- **Export list:**
  Shows a list of exported cases. Clicking "Export list" allows users to view the 3D model of the selected case in the Model Viewer Module.

- **Help center:**
  Accesses the digital version of the software user manual.

3.4 ScanFlex User interface

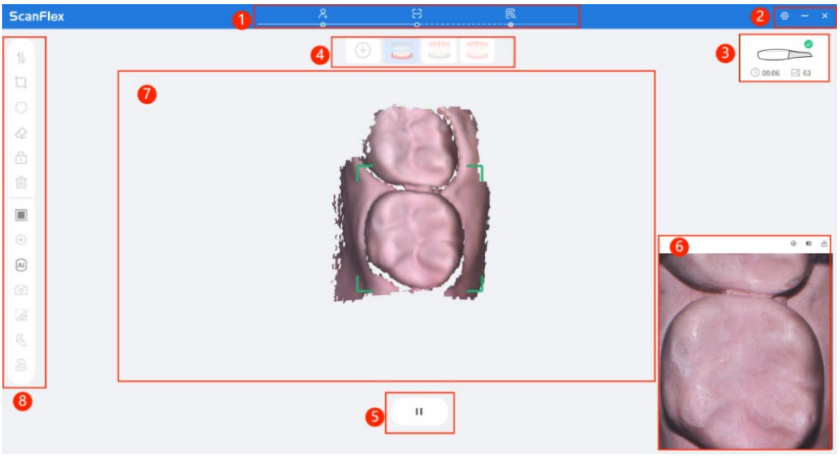
This section introduces the scanning interface (for image acquisition) and the model viewer interface (for 3D image viewing). The primary working area of the scanning interface

enables users to define the specifications of a new scan task (i.e., a new case).

3.4.1 Scanning operation area

3.4.1.1 Scanning operation area introduction

The primary working area of the scanning interface enables users to specify the parameters of a new scan task, also known as a new case.



Title bar:

① - Displays the overall workflow, encompassing Order Creation, Scan, and Model Check.

Menu bar icons:

② - Includes settings, window minimize, and close functions.

③ - **Device status:**
Provides information on device connection

status, scanning duration, and the number of scanned images.

Workflows:

④ - Offers various scan workflows tailored to different clinical indications.

⑤ - **Scanning toolbar:**
Features a Start/Pause button and secondary toolbar.

⑥ - **Live view window:**
Offers a real-time scan viewing window.

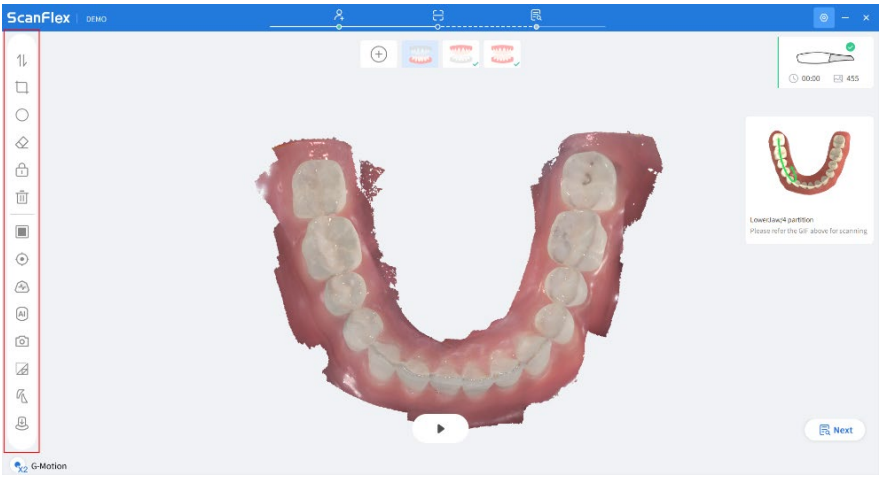
⑦ - **3D view:**
Provides an area for viewing the 3D model.

⑧ - **Editing toolbar:**
Facilitates the creation of a new case under the selected patient.

3.4.1.2 Scanning tools and features

Upon completion of a scan task, ScanFlex provides users with a variety of tools and features to edit the images.

3.4.1.2.1 Main tools



- **Trimming:**
  Removes all entities within a polyline or circled shape drawn on the screen.

- **Trimming brush:**
  Eliminates all entities along a freehand-drawn path on the screen, available in two different brush sizes.

- **Swap maxilla and mandible:**
  Allows for the interchange of upper and lower jaw scan data if the jaw position is mistakenly scanned.

- **Lock area:**
  Secures a specific area using selection tools, preventing further scanning from altering the shape (though color changes are still possible). This function is useful for locking prep areas for margin rescanning or locking margin areas for prep rescanning.

- **Laser trimming:**
  Erases all entities along a freehand-drawn path on the image, with two different brush sizes available.

- **Delete:**
  Removes 3D model data or resets it to its original state under post-prep or implant scan body workflows.

- **Reset:**
  Returns 3D model data to its original state under post-prep or implant scan body workflows.

- **Texture on/off:**
  Displays the model with or without texture colors.

- **Center:**
  Resets the 3D model to its original position.

- **AI denoising:**
  Intelligent-based masking unwanted soft tissue

or other irrelevant data during the scanning process.

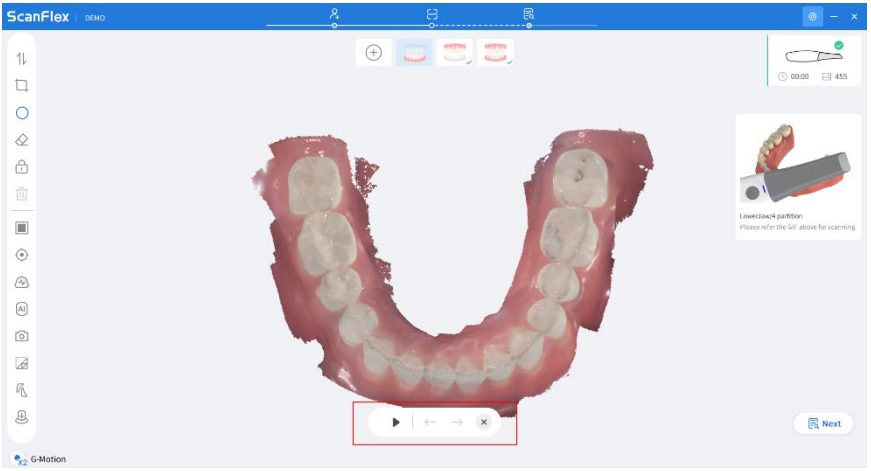
- **HD camera:**
  Captures 2D intraoral pictures for sharing with dental labs.

- **Working area:**
  Enhances model density and details after selection.

- **Occlusion analysis:**
  Analyzes occlusion areas and space based on the scanned bite.

- **Undercut analysis:**
  Evaluates undercut areas and depth based on the insertion direction.

3.4.1.2.2 Secondary tools



Start/Pause:

Initiates or pauses the scanning process.

- **Redo:**

Repeats the last step.

- **Undo:**

Reverts the last action.

- **Undo all:**

Reverses all previous actions.

- **Exit:**

Closes the secondary tools.

- **Island delete:**

Delete unnecessary data out of model by one click.

- **Scanbody group:**

  While in scanbody workflow stage, it indicate that the current group of the scanbody

Add Scanbody group:

While in scanbody workflow stage, add another scanbody group, maximum 6 groups.

Delete current Scanbody group:

While in scanbody workflow stage, delete the current scanbody group, must have one scanbody group left.

Display current scanbody group/all scanboday group:

While in scanbody workflow stage, this button can be used for show all scanbody group or only current scanbody group

Show/Hide Gingival Model

While in scanbody workflow stage, this button can be used for show/hide gingival model (blue colored).

3.4.1.2.3 Workflow customization tools

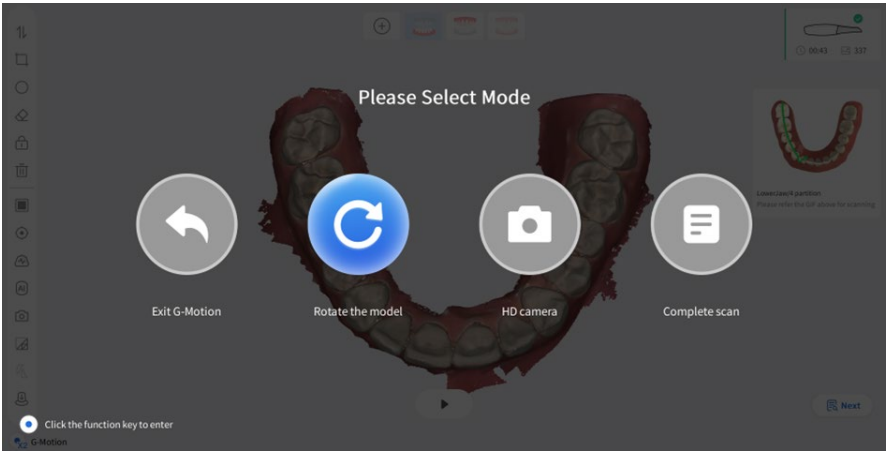
- **Add:**
  Enables the addition of new workflow content.

3.4.1.2.4 G-motion

The G-motion, also referred to as an accelerometer, In the context of the intraoral scanner system, a gravity sensor holds potential for multiple applications, primarily focused on model inspection without requiring direct interaction with a laptop or touchscreen.

To activate G-motion, simply double-click the functional button, initiating access to the feature selection interface.

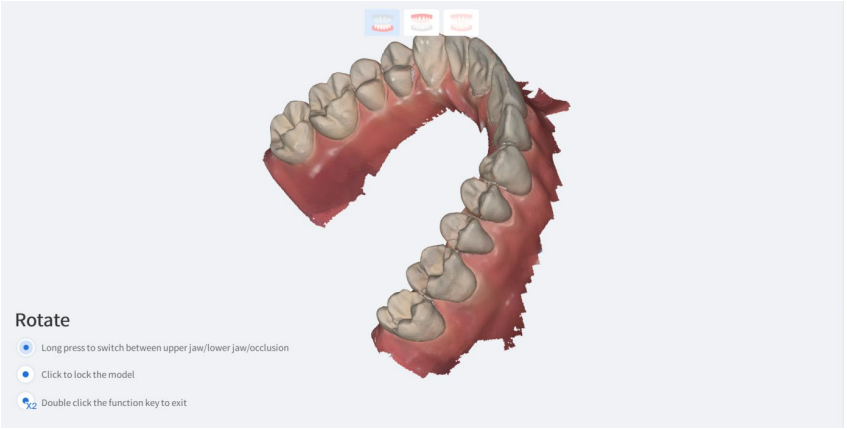
G-motion selection interface



To navigate through the G-motion interface, tilt the device left or right to access various features, such as exiting G-motion, rotating the model, activating the HD camera, and completing the scan.

To exit the G-motion mode, simply double-click the functional button. Users can rotate the model by physically rotating the

device itself. Additionally, long press enables switching between different jaws, while a single click locks the model in place. To exit G-motion, double-click the functional button once again.



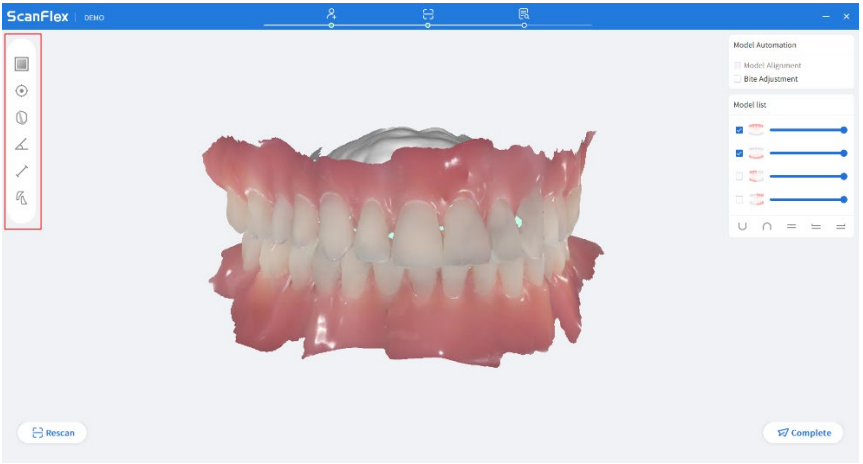
Open HD camera feature: Switch to HD Camera feature by not touching laptop.

Complete Scan: Go to “Next" to model optimization and “ModelViewer”.

3.4.2 Model viewing area - ModelViewer

This working area primarily serves viewing intraoral scanning data in a 3D image mode. It allows for separate viewing of maxillary, mandibular, and occlusal image data. Additionally, it includes functions such as multi-views, color mode switching, and reset.

3.4.2.1 Model viewing tools and features



- **Texture on/off:**
  Displays the model with or without texture colors.

- **Center:**
  Resets the 3D model to its original position.

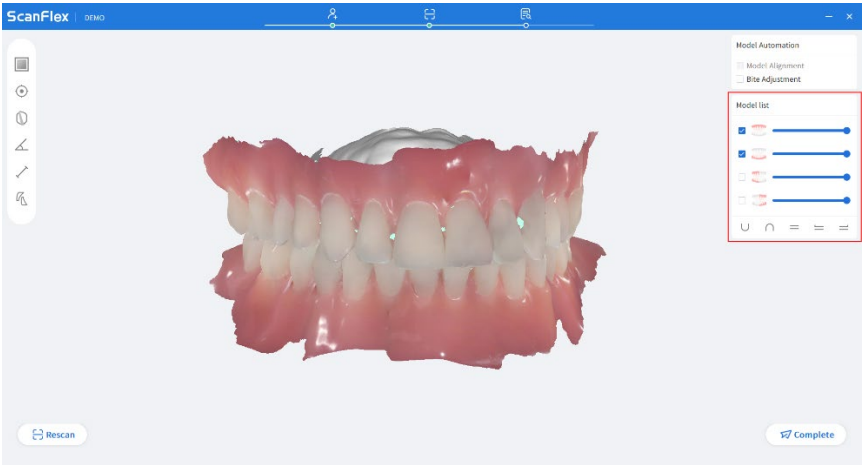
- **2D section measurement:**
  Measures the distance between selected points under the 2D section mode.

- **Angle measurement:**
  Calculates the angle value between three selected points.

- **Straight measurement:**
  Determines the distance between two selected points.

- **Occlusion analysis:**
  Analyzes occlusion areas and space based on the scanned bite.

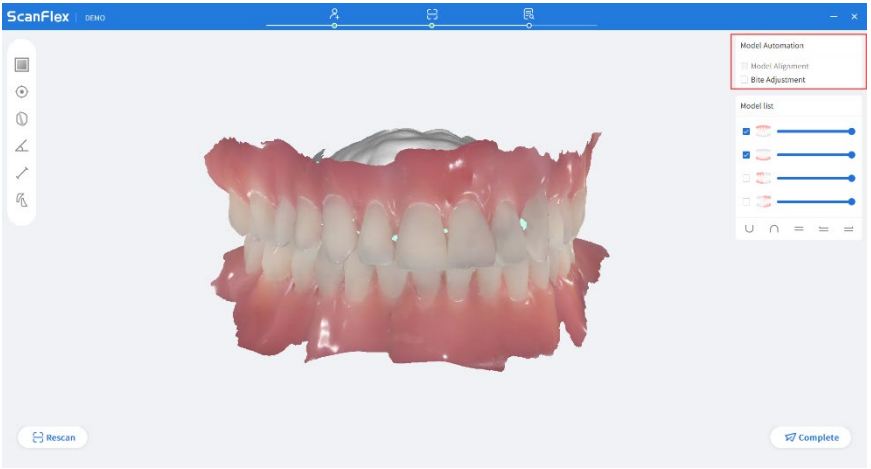
3.4.2.2 3D model view



In this area, users can switch the 3D model view mode of the scanning by selecting the icon located on the right-hand side of the screen, highlighted within a red frame.

Additionally, users have the option to display separate 3D images of the upper jaw, lower jaw, upper and lower jaw on the left side, and upper and lower jaw on the right side by selecting the corresponding icons.

3.4.2.3 Model annotation



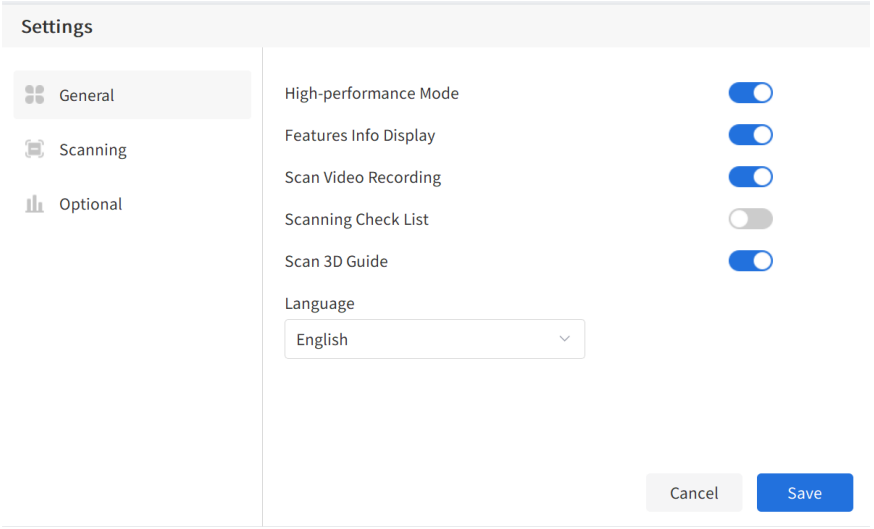
① - **Model alignment:**
Allows users to realign (calibrate) the alignment in cases of post-preparation arch or implant arch occurrence.

② - **Bite adjustment:**
Enables correction when penetration occurs during the final bite registration.

3.4.3 Settings areas

In this section, users can configure general settings, scanning settings, and optional settings.

3.4.3.1 General settings



High-performance Mode:

It can be enabled under high performance computer, to boost scanning speed.

Features Info Display:

Enables or disables hover tips for functions when the mouse is placed on the icon.

G-Motion:

Rotates the digital model by moving the device itself.

Scan Video Recording:

Activates or deactivates video recording during scanning.

Scanning Checklist:

Displays a checklist pop-up window before model generation.

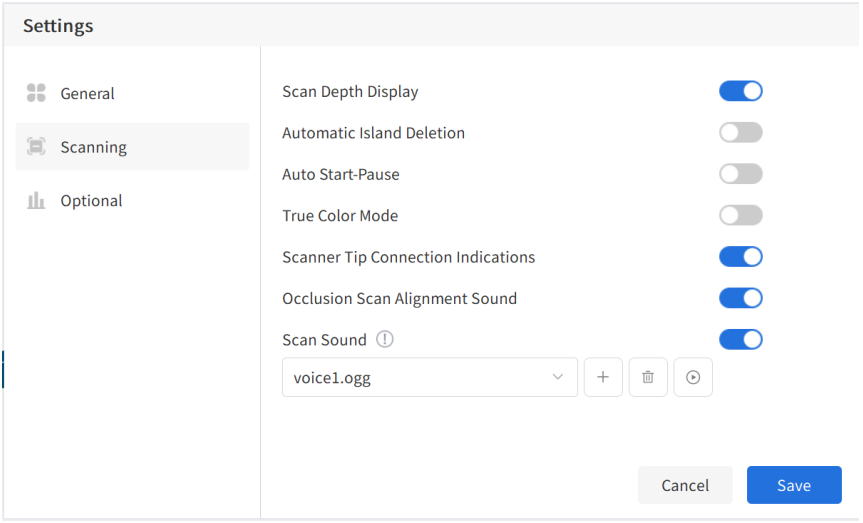
Scan 3D Guide:

Shows or hides the scanning path instructions on the right side of the main window.

Language:

Allows selection of the display language from the available options.

3.4.3.2 Scanning settings



Scan Depth Display:

Displays the depth or distance of objects in the scanning process if this option is turned on.

Automatic Island Deletion:

While scanning the unnecessary data out of model will be autocratically deleted after pause scanning; when it is turned off, manual ‘Island delete' can be applied.

Auto Start-Pause:

Automatically starts or pauses the device when placed on the holder.

True color mode:

Displays a wide range of colors on the model.

Scanner tip connection warning:

Provides an audible sound indication when occlusion is successfully matched.

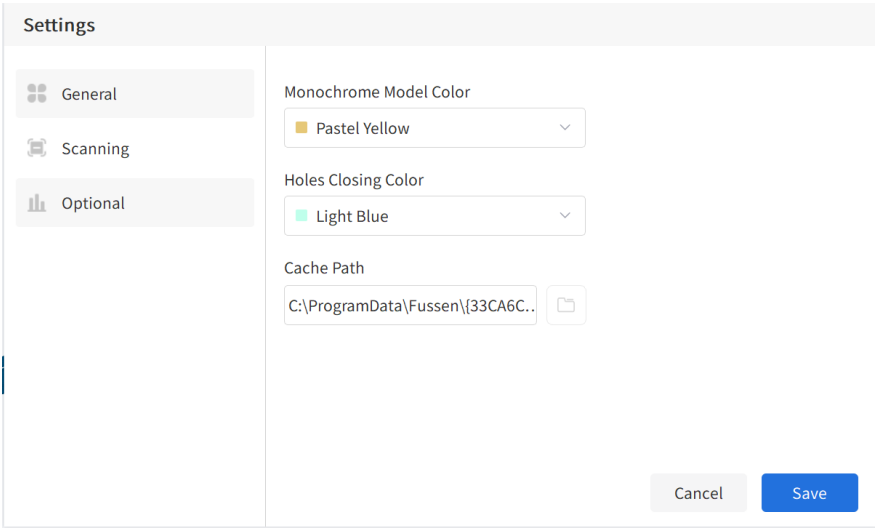
Occlusion Scan Alignment Sound:

Provides real-time feedback in the scan viewing window.

Scan sound:

Enables users to decide whether to have sound during scanning and allows selection or addition of preferred sound options within the provided range.

3.4.3.3 Optional settings



Monochrome model color:

Allows selection of different solid colors for the model.

Holes Closing color:

Allows selection of different colors for hole-patching displayed on the model.

Cache Path:

Change. project data (raw data for rescan) saving path direction.

3.5 Scan Workflow

The digital intraoral scanner system S6500 enables the scanning of an entire dental arch to generate a 3D model. This model can be viewed in the ModelViewer interface, where users can measure and annotate necessary values.

Users have the flexibility to select different workflows to accommodate various medical needs. Depending on the indications, scanning can be performed for:

- Standard Scan Workflow: Orthodontic & Restoration Scan
- Implant Scan Body Scan Workflow

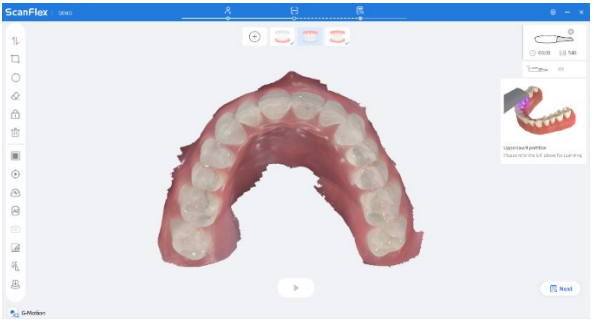
3.5.1 Orthodontic & Restoration Scan – Standard scan workflow

To acquire a 3D model for orthodontic use, follow these steps:

- Scan the upper and lower jaw.
- Scan the buccal bite registration.
- Refine the image.
- Complete the preparation check and export the image.

It's important to note that the standard restoration acquisition workflow is also applicable when scanning a complete or partial dental arch containing abutment(s).

Below is an example showcasing a 3D model of the upper jaw, featuring fully scanned occlusal, lingual, and buccal surfaces, as well as the palate.



Scan the upper and lower jaw.

Scan the buccal bite registration.

An icon  is displayed at the bottom of the window to indicate the capture was successful. A successful bite image includes both the upper and lower arch.

3.5.2 Implant scan

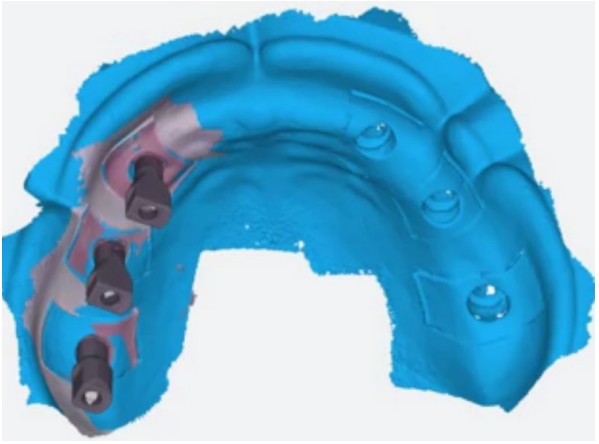
For scanning a complete or partial dental arch containing implants, a Scan Body implant acquisition workflow must be selected.

In the Scan Body implant acquisition workflow, the area of the implant in the image obtained from the initial scan operation will be removed. Subsequently, after installing the implant scan body, a re-scan operation must be conducted. This process results in the generation of two 3D models: one with the scan body and the other without. Based on these two models, dental labs can fabricate customized abutments.

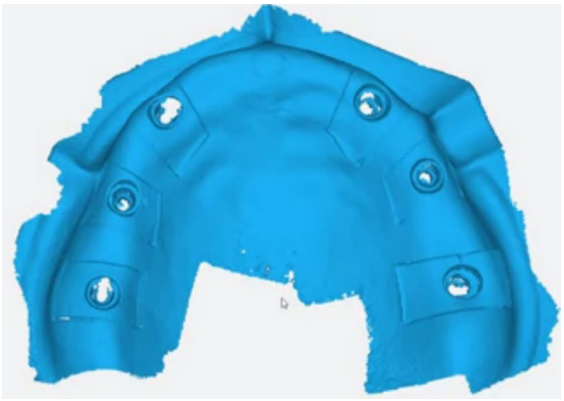
In summary, the steps to generate a 3D model for an implant are as follows:

- Scan the upper and lower jaw.
- Perform the buccal bite registration.
- Utilize the 'Implant Group' tools located at the bottom of the window to scan the 1st group of the implant
- Install the scan body and re-scan the jaw with the scan body.
- Refine the image.
- Complete the preparation check and export the images.

Below is an example depicting a 3D model of the lower jaw with an implant.



If the scan body is intended for implantation on the Upper Jaw, select "Upper Scan Body" to display the scanned model. The 'Implant group' is activated by default, it can start scan body scanning directly.



During the clinical operation, install the scan body, and proceed to rescan the scan body area to finalize the model. Repeat the operation for following implant group.

3.6 3D Model analysis

Through the utilization of 3D data registration technology, 3D models are generated and among with additional data (such as CBCT) aid in digital treatment plan designs for diagnoses, implantations, restorations, maxillofacial surgeries, orthodontics, and more. With ScanFlex, functionalities such as occlusion and undercut analysis, intraoral camera usage, 2D section measurements, as well as angle and length measurements of teeth, can be realized.

WARNING!

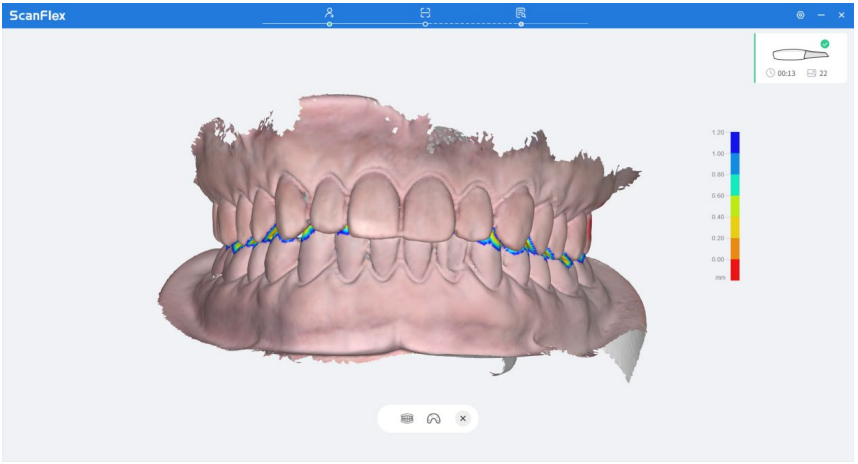
3D model data alone cannot be the diagnosis base for implant / surgical treatment planning. At least additional CBCT scan data should be used combined with surgeon knowledge

3.6.1 3D Model inspection

3.6.1.1 Occlusion analysis

Click the 'Occlusion Analysis' button  to visualize the occlusion of maxillary and mandibular teeth. Following occlusion, the static relationship between the occlusal surfaces of the maxillary and mandibular teeth is depicted using different colors. Red signifies the shortest distance between the occlusal surfaces, while blue represents the maximum distance. The units of the values in the figure are in millimeters.

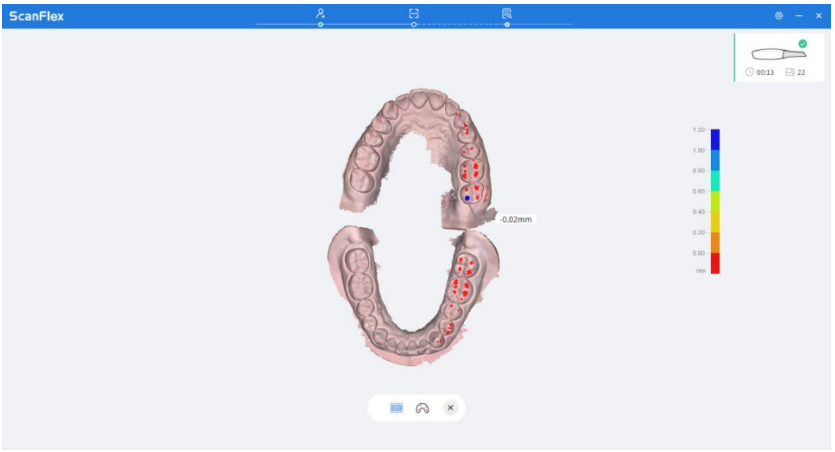
Users can directly check the values in the scanning interface or in the ModelViewer interface.



- **Occlusal surface relationship display - on:** Illustrates the static relationship between the occlusal surfaces of the maxillary and mandibular teeth using various color representations.

- **Occlusal surface relationship display - off:** The static relationship between the occlusal surfaces of the maxillary and mandibular teeth will not be showed.

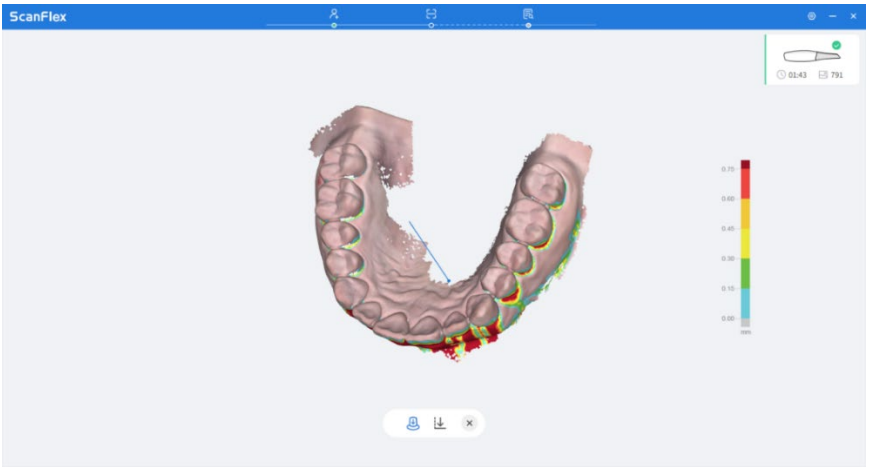
- **Showing occlusal contact point only:** Only the contact points are displayed.



Hover over a specific area to view detailed values.

3.6.1.2 Undercut analysis

Click icon to view information regarding the undercut. The depth of the undercut is depicted through a color range on the mesh. Users can directly view the value in the scanning interface or ModelViewer interface. Rotate the model to the desired position and hover over the specific area to display detailed values.

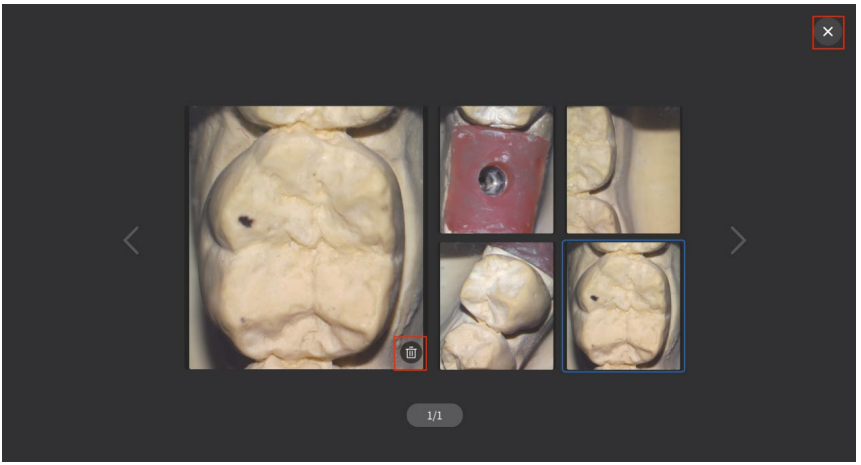


- **Undercut Depth Display:**
  Click this icon to visualize the depth of the undercut, represented by a color range on the 3D model.

- **Restoring default position:**
  Click this icon to revert to the default position.

3.6.2 Intraoral camera

Click icon to enter the intraoral camera mode for capturing specific areas as a reference for further inspection or restoration.

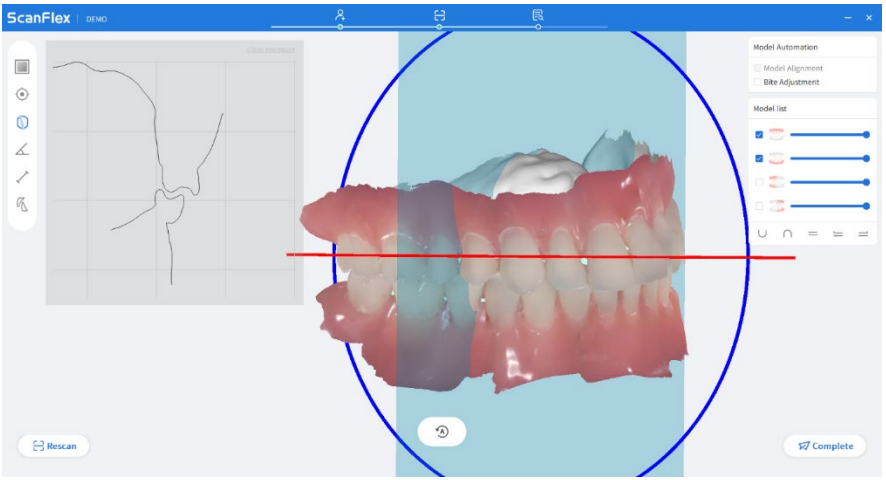


- **Delete:**
  Deletes the current photo.

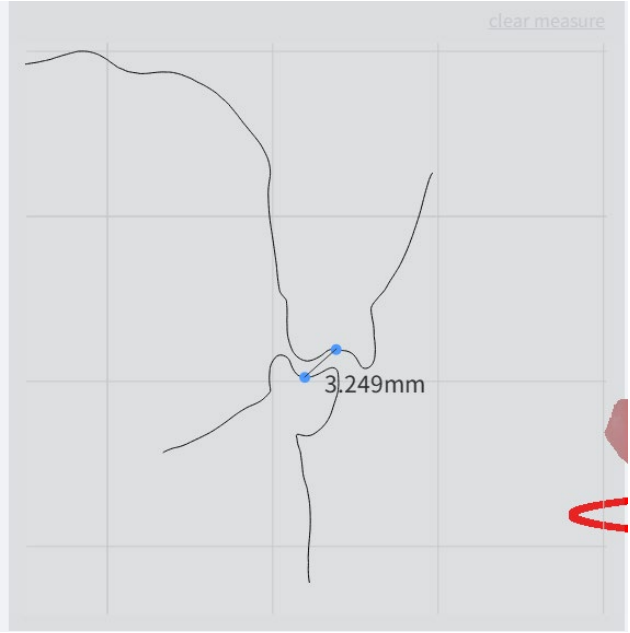
- **Exit:**
  Exits camera mode.

3.6.3 2D section measurement

Click to take measurements between selected points on digital model.



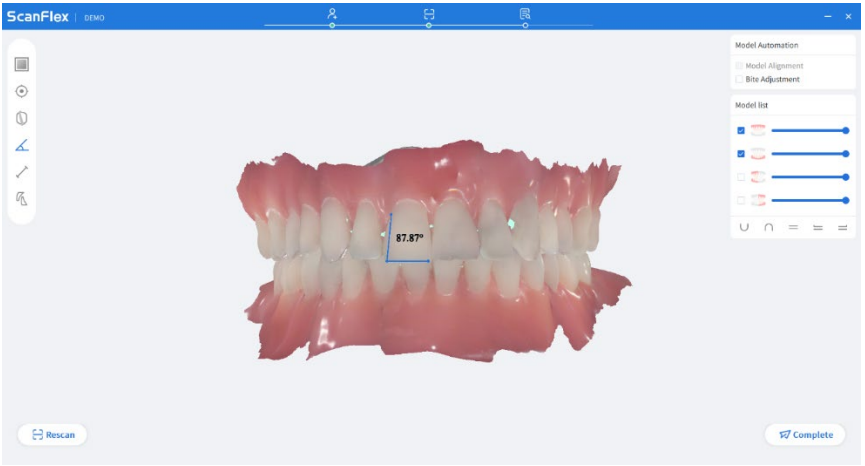
Click on the top of a tooth and move the horizontal slider to rotate the cutting plane. Move the vertical slider to translate the cutting plane.



The distance between the surfaces of selected maxillary tooth and the mandibular tooth can be measured and the detail value is displayed.

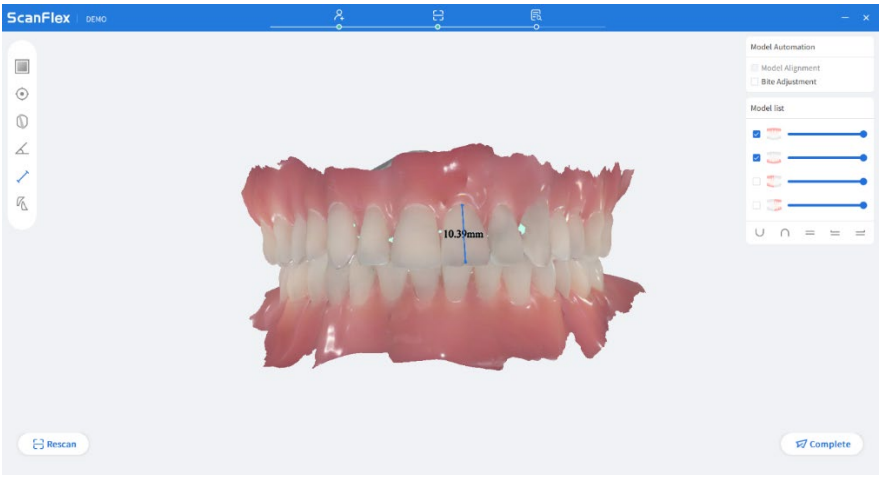
3.6.4 Angle measurement

Click  to measure the angle between selected points on the digital model.



3.6.5 Length measurement

Click  to take measurement between selected points on digital model.

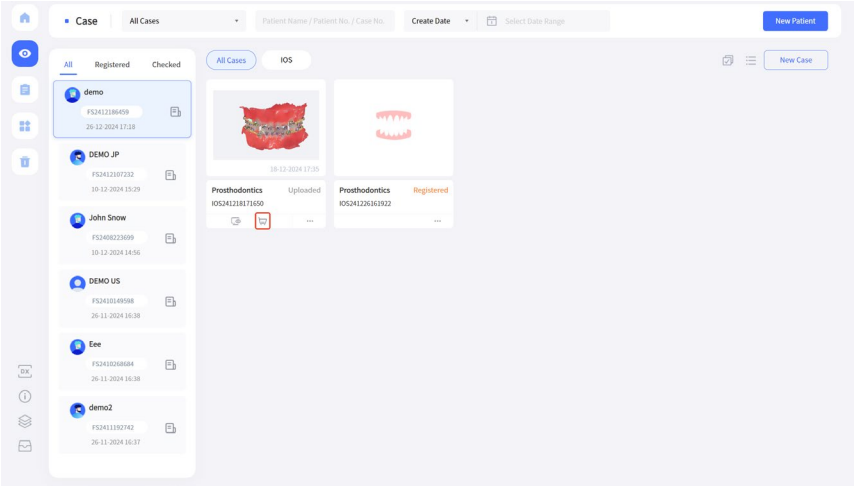


3.7 Order placement

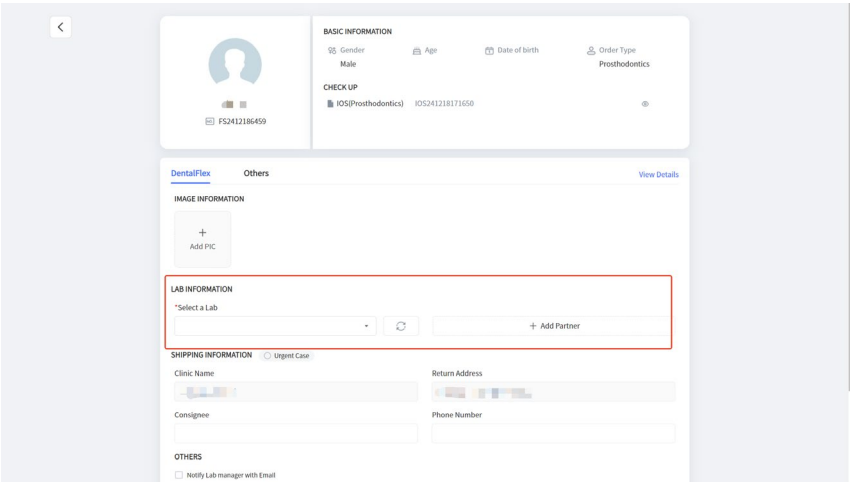
This section outlines the process of placing an order, including order form creation, order placement, data transfer, and order status checks, all of which are facilitated within the DentalFlex user interface.

3.7.1 When you registered as a clinic

After image acquisition is completed, go to ‘Case’ page DentalFlex user interface. Select the case that has been uploaded. Click ••• to show a drop-down menu includes „ Order” . Click order.



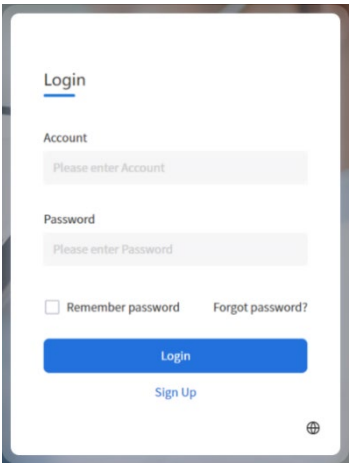
Select one of a dental lab from “Select a Lab”.



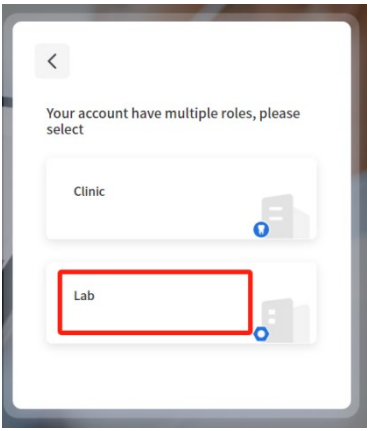
Select “Notify lab manager with Email”, the system will send a notification E-mail to the responsible person of the selected dental laboratory.

3.7.2 When you registered as a lab

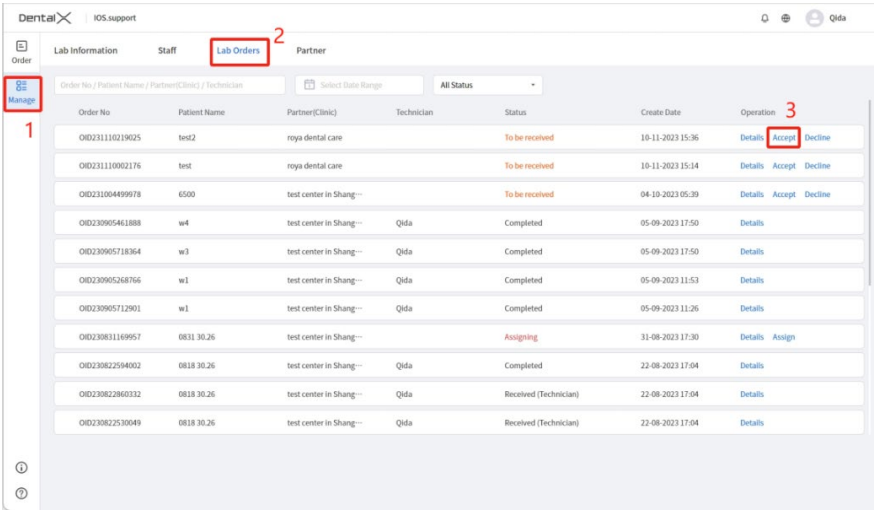
When you have registered as a dental laboratory, you can login to the DentalX by visiting: http://eur.dentalx.cloud. You can login with your username and password.



When you register both as a clinic and a dental lab, please choose the login path as needed.



Go to “Manager” tab and select “Lab Orders” page click “accept”.



Order management:

① - Click this icon to access the order management page.

Lab orders:

② - Click this icon to view the lab orders sent by dental clinics.

Options:

③ - Labs have the ability to accept or decline orders. Click on "Details" for further information regarding the order.

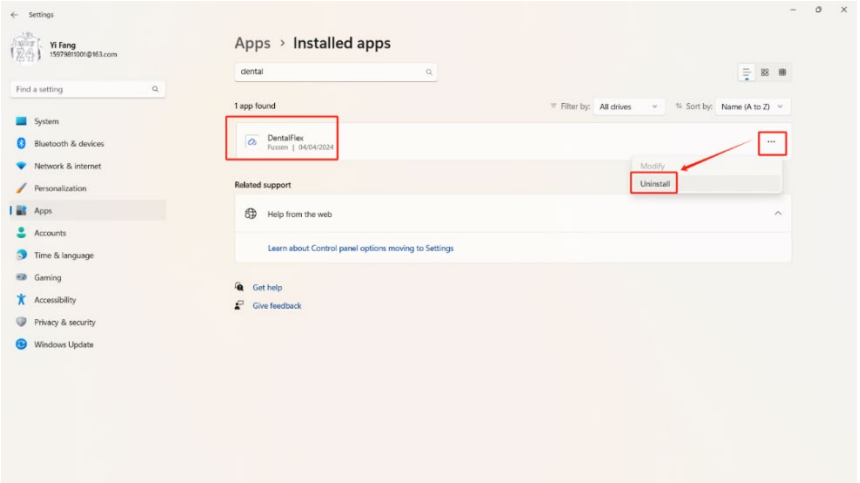
3.8 Uninstalling DentalFlex and ScanFlex

For uninstalling the software DentalFlex and ScanFlex, select the uninstall.exe file in the 'uninstall or remove apps and programs' to run uninstall. Please note that both software needs to be uninstalled.

NOTE

Both DentalFlex and ScanFlex need to be uninstalled.

Illustration of uninstalling DentalFlex:



Click "Confirm" to proceed the uninstall of DentalFlex software on the popped-up window.

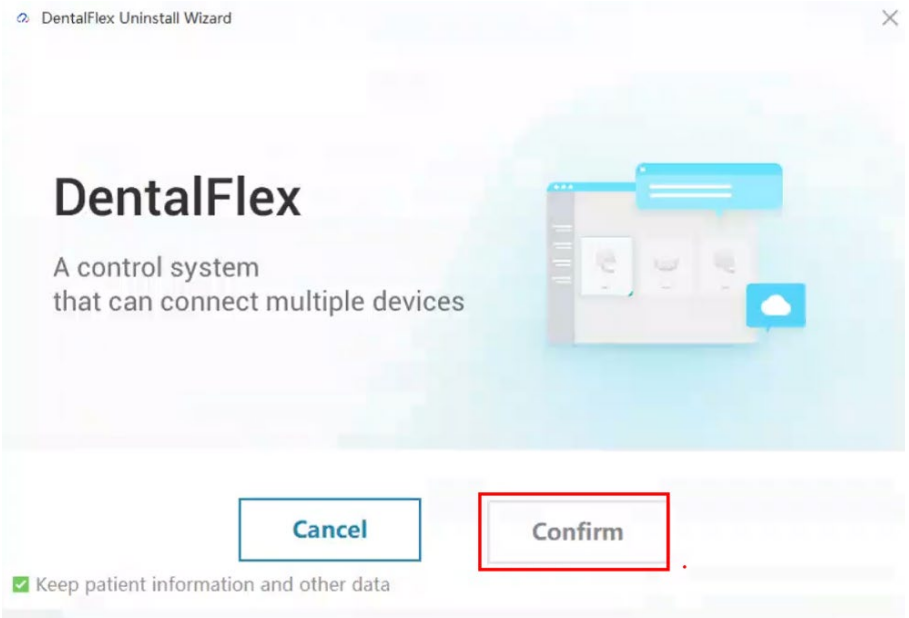
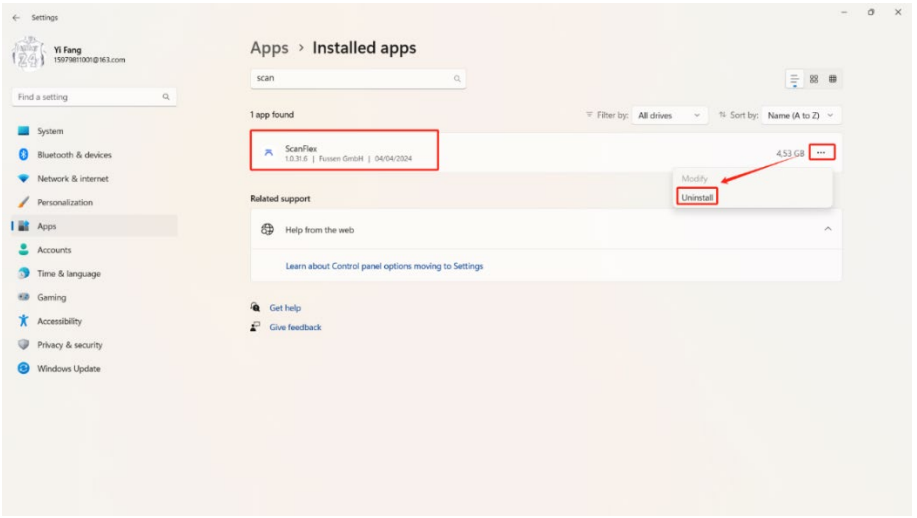
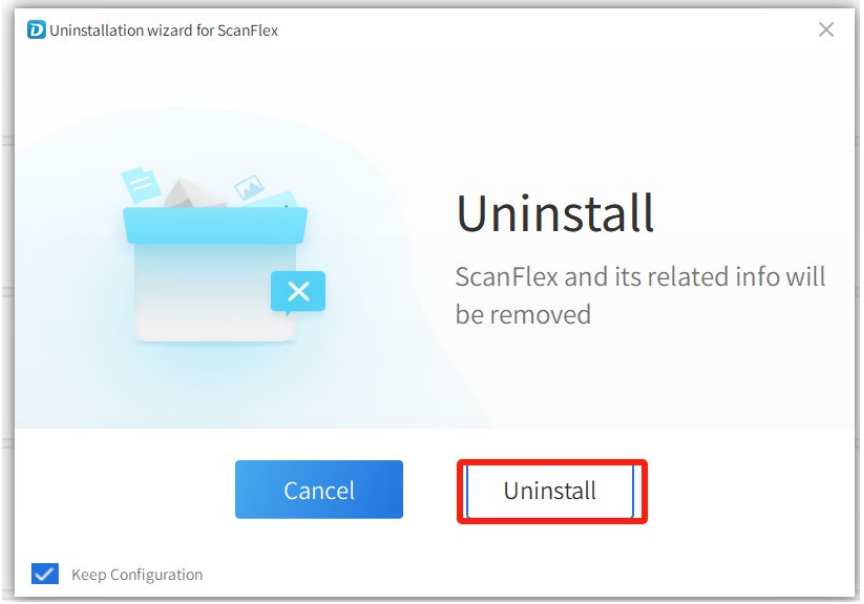


Illustration of uninstalling ScanFlex:



Click “Uninstall” to proceed the uninstall of ScanFlex software on the popped-up window.



4 Safety and Maintenance

4.1 Introduction

In this chapter you will find information about safety and maintenance that are necessary to ensure the correct and reliable function of the software after installation.

4.2 Inspection and maintenance

WARNING!

No maintenance or repair work may be performed while the software DentalFlex is being used with a patient!

All maintenance and repair work may only be performed by personnel trained or authorized by CORTEX.

4.2.1 Daily Monitoring Before and During the Examination Operation

When starting the software DentalFlex, make sure that the software starts without an error message. In general, the warning and error messages that the software reports must be observed.

4.2.2 Maintenance

The required maintenance as soon as a software update is available must be carried out by CORTEX service department or a service company authorized by them to ensure the safe and reliable functionality of the software.

In the event that the planned maintenance is not carried out, CORTEX assumes no liability whatsoever for damage to the user and third parties if damage results from inadequate or not carried out maintenance.

Prior to the scan operation, the user must satisfy himself that all appliances listed in the operating instructions and serving safety are in working order and that the software is ready for operation.

4.2.3 Warranty

NOTE

You will find the current warranty conditions in your order documents or in the price list valid at the time of purchase.

Repairs and spare parts in the event of improper use are also excluded.

Warranty work may only be carried out by trained specialists.

4.2.4 Product Service Life

The service life ends with the discontinuation of product support. After reaching the product lifetime, further use is at your own risk.

5 Description of Symbols, Labels and Abbreviations

5.1 Symbols

	Attention, observe accompanying documents
	Refer to Instructions for use
	Consult electronic Instructions for Use
	CE marking
	Manufacturer
	Order reference
	Serial number
	Unique Device Identification
	Production date

5.2 Abbreviations

mm	Millimeters
CE	CE marking
HD	High Definition
AI	Artificial Intelligent
3D	Three-dimensional
STL file	A Binary (or ASCII) file used to represent 3D objects for 3D printing and 3D modeling
PLY file	Known as Stanford Triangle Format, which is a simple 3D geometry format that stores triangular meshes and texture coordinates
OBJ file	A 3D model file format that contains the topology of 3D models

This manual is applicable only to CORSCAN Digital Intraoral Scanner System

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Website: https://www.cortex-dental.com/

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