ENG

OCTiX IntraOral Scanner

LSO-100

USER MANUAL





IMPORTANT NOTICE

This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as, which affect this product, brought near the product. The information in this publication has been carefully checked and is believed to be entirely accurate at the time of publication. We assume no responsibility, however, for possible errors or omissions, or for any consequences resulting from the use of the information contained herein. We reserve the right to make changes in its products or product specifications at any time and without prior notice, and is not required to update this documentation to reflect such changes.

This document describes safety precautions and considerations related to your Intraoral Scanner. Please read and follow this instructions step by step regarding configuration and operation of your device. The instructions for re-use have been validated by Huvitz Co., Ltd as being capable of preparing the Intraoral Scanner. Reprocessing validation has been done for 150 cycles. It remains the responsibility of the user to ensure that the reprocessing procedure as actually performed with equipment, material and personnel in the dental or reprocessing facility achieves the desired result.
This requires validation and routine monitoring of the process. Likewise, any deviation by the user from the instructions provided is performed under the responsibility of the user. It should be properly evaluated for effectiveness and potential adverse consequences.

■ **Revision History**

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1

SAFETY PRECAUTIONS

1.1. Overview

Safety is everyone's responsibility. The safe use of this device is largely dependent upon the installers, users, operators, and managers. It is prerequisite to read and understand these specifications before installing, using, cleaning, fixing or revising. Fully understanding the whole instructions must be the first priority. For this reason, the following safety notices have been placed appropriately within the text of this manual to highlight safety related information or information requiring special emphasis. All users, operators, and maintainers must be familiar with and pay particular attention to all signs of Warnings and Cautions.

⚠ WARNING

"Warning" indicates the presence of a hazard that could result in severe personal injury, death or substantial property damage if ignored.

"Warning" indique la présence d'un danger qui pourrait entraîner des blessures graves, la mort ou des dommages matériels importants si ignoré.

⚠ CAUTION

"Caution" indicates the presence of a hazard that could result in minor injury, or property damaged if ignored.

"Caution" indique la présence d'un danger pouvant entraîner des blessures légères ou des dommages matériels en cas d'ignorance.

⚠ NOTE

This is used to emphasize essential information.

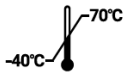
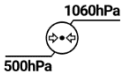
Be sure to read this information to avoid operating the device incorrectly.

Ceci est utilisé pour souligner les informations essentielles.
Assurez-vous de lire ces informations pour éviter de mal utiliser l'appareil.

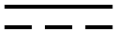
2

Symbol Information

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connection or warn of any potential hazards. The classifications and symbols are shown below.

Symbol	Indication
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual. (Ce symbole identifie une note de sécurité. Assurez-vous de comprendre la fonction de ce contrôle avant de l'utiliser. La fonction de contrôle est décrite dans le manuel d'utilisation ou d'entretien approprié.)
	This symbol means device is switched On or Stand-by.
	Temperature Limitation for transportation (Limitation de température)
	Atmospheric pressure limitation for transportation (Limitation de pression atmosphérique)
	Humidity limitation for transportation (Limite d'humidité)
	Stack direction (Direction de la pile)
	Keep DRY (Garder au sec)
	Fragile, handle with care (Fragile, manipuler avec soin)
	Keep away from sunlight (Tenir à l'écart de la lumière du soleil)
	Stack layer limit (Limiter la couche de pile)
	CE Mark (Marque CE)
	Use no hook (N'utilisez aucun crochet)

	WEEE Symbol – EU only Disposal of your old appliance When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2012/19/EU. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product. (Symbole WEEE- EU seulement Mise au rebut de votre ancien appareil Lorsque ce symbole de poubelle barrée est joint à un produit, cela signifie que le produit est couvert par la directive européenne 2012/19/EU. Tous les produits électriques et électroniques doivent être éliminés séparément du flux des déchets municipaux via des installations de collecte désignées par le gouvernement oules autorités locales. L'élimination correcte de votre ancient appareil aidera à prévenir les conséquences negatives potentielles sur l'environnement et la santé humaine. Pour plus d'informations sur l'élimination de votre ancient appareil, veuillez contacter votre mairie, le service d'élimination des déchets ou le magasin où vous avez acheté le produit.)
	Authorized representative in the European Community – EU ONLY (Représentant autorisé dans la Communauté européenne- EU seulement)
	Manufacturer (Fabricant)
	Date of manufacture (Il indique l'année de fabrication et le fabricant.)
	Refer to instruction manual/booklet (Se reporter au manuel d'instructions / brochure)
	Type B Isolated patient connection (Type B Connexion patient isolée.)
	Class I Laser product (Produit au laser de classe I)

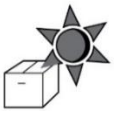
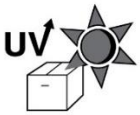
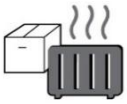
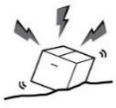
	QR code (QR code)
	Alternating Current (Courant alternative)
	DC current
	Class II equipment (Équipement de classe II)
	Consult instructions for use (Consulter les instructions d'utilisation)
CE RoHS	CE for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
MD	To indicate this product is Medical device (Pour indiquer que ce produit est un dispositif medical)
SN	SN Marking
Rx only	RX Only
UDI	UDI Symbol

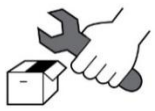
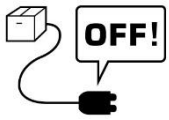
2.1. Usage Precautions

This device has been developed and tested in conformity with domestic & international safety standards and regulations, which guarantees the high stability of this product. This guarantees a very high degree of safety for this device. The legislator expects us to inform the user expressively about the safety aspects in dealing with the device. The correct handling of this equipment is imperative for its safe operation. Therefore, please read carefully all instructions before switching on this device. For more detailed information, please contact our Customer Service Department or one of our authorized representatives.

2.2. Environmental Consideration

Avoid the following environments for operation or storage**:**

	Where the device is exposed to water vapor. Don’t operate the device with wet hands Indoor use only.
	Where the device is exposed to direct sunlight.
	A place where the equipment can be exposed to direct ultraviolet.
	Where there are big changes in temperature.
	Where there is hot equipment nearby.
	Where the humidity is extremely high or there is a ventilation problem.
	Where the device is exposed to excessive shocks or vibrations.
	Where the device is exposed to chemical material or explosive gas.
	Be cautious so that things like dust and metal do not fall inside the device.

	Don’t disassemble or open the product. WE do not take responsibility for the possible problems
	Be careful not to block the fan of the device.
	Don’t plug the AC power cable into the outlet unless all parts of the device are completely connected. Otherwise, it will cause severe damage on the device.
	Pull out the power cable with holding the plug, not the cord. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

This device can withstand the following conditions:

1. Operation

- An ambient temperature range of 18℃ ~ 28℃ (64°F ~ 82°F)
- A relative humidity range of 20% ~ 75% (with non-condensing)
- An atmospheric pressure range of 800 ~ 1060hpa

2. Transportation

- An ambient temperature range of -40℃ ~ 70℃ (23°F ~ 113°F)
- A relative humidity range of 10% ~ 95%
- An atmosphere pressure range of 500 ~ 1060hpa

3. Storage

- An ambient temperature range of -10℃ ~ 55℃ (23°F ~ 113°F)
- A relative humidity range of 10% ~ 95% (with non-condensing)
- An atmosphere pressure range of 700 ~ 1060hpa

Avoid environments where the equipment is exposed to excessive shocks or vibrations.
Do not expose products or packing to environmental conditions outside of those specified above.
Do not expose products to rain or snow.

2.3. Safety Precautions

1. This is an electric medical device. Use is limited to doctors or persons qualified by the law of each country.

2. The mirror in the tip is a delicate optical component. Users should handle it with care and keep it clean and undamaged. Be careful not to scratch or smudge it before scanning a patient.

3. The scanner tip must be sterilized before disposal.

4. Dispose the scanner tip as you should other clinical waste.

5. This device must not be used in an area that is in danger of explosions and in the presence of flammable, explosive, or volatile solvent such as benzene or similar chemicals.

6. Do not place or store this device in humid area. Do not expose the device to water splashes, dripping water, or sprayed water. Do not place containers with fluids, liquids, or gases on top of this device.

7. The device must be operated by a trained and qualified person or und his or her supervision.

8. Repair of this device must be conducted by the service technicians or other authorized persons.

9. Maintenance by users must observe the User's Manual and Service Manual. Any additional maintenance may only be performed by the service technicians or other authorized persons.

10. Manufacturers are responsible for the safety, reliability, and performance of this device only when the following requirements are fulfilled.
    (1) When the device has been installed in a proper area, following the manual.
    (2) When the device has been operated and maintained according to the manual and service manual.

11. This device must be connected with the accessories supplied by manufacturer. If you are to use other accessories, their safety or usability must be checked and proved by their manufacturers.

12. Before you use, check the exterior of the device and its conditions. Ensure that all components provided are free from physical damage. Safety cannot be guaranteed if there is any physical damage on the unit.

13. Do not block any ventilation outlet necessary for proper heat dissipation.

14. If smoke, sparks or any abnormal noise or smell is noticed coming from the device, please switch the power off immediately and pull out the plug.

15. Install and use only approved programs to ensure proper functionality of the LSO-100 system.

16. To avoid the risk of electric shock, this device must only be connected to protective earth.

17. Do not place the device where it is difficult to operate the disconnecting device. (Disconnecting device: power cable)

18. You should only disconnect the LSO-100 system from the power adapter via its power cord

19. Before disconnecting the power cord, make sure to turn off the power on the device using the power switch on the Mainunit.

20. Only use the power adaptor supplied together with LSO-100. Using other power adaptors may result in damage to the system.

21. Avoid pulling on the communication cables, power cables used in LSO-100 system.

22. The device may be impaired if it is used in a manner not specified by the manufacturers or manual.

23. External equipment intended for connection to signal input, signal output or other connectors of this device, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC 60601-1 series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative. The operator should not touch the patient and accessible male parts of the SIP/SOP connectors simultaneously.

24. In the event of a serious incident involving the device, the user shall report it to the manufacturer and the competent authority of the Member State in which the user and/or patient are established.

25. When the device LSO-100 detecting cybersecurity treats, the user shall report it to the manufacturer and the competent authority of the Member State (Section 10. - Contact information)

2.4. Preface

1. This manual is valid for the L-Scan OCTiX software version 1.0.0 or higher.

2. Electronic instruction for use is published in PDF format. A PDF reader can be downloaded at www.adobe.com.
   Authorized people can download the manual anytime, anywhere.

3. Electonic instruction for use can be downloaded by an authorized person on the ATHENA website at http://svc.ossvis.com

4. Instruction for use can be requested on paper if required.

3

INTRODUCTION

3.1. Indication for Use

The LSO-100 device supports patients for Intraoral indications and can be used for patients who require dental treatments.

3.2. Intended Use

The Dental Intraoral Scanner(LSO-100) is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. LSO-100 produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.

3.3. Contraindications

The device is not intended to be used to create images of the internal structure of teeth or the supporting skeletal structure. It is not intended to be used for cases with more than four (4) subsequent edentulous tooth positions.

3.4. User Profile

This device must be operated only by trained and qualified person/s such as dentist or dental hygienist.

- Age: adult (> 21 years of age)
- Occupation: Dentist, Dental hygienist
- Level of training: Recommend completing training how to use it is.
- Education: Basic training is required for the use of equipment. (Obtains a certificate of qualification such as dental, medical school, etc., after completing a certain amount of education.)

3.5. Patient Profile

Patients who want 3D scanning for a topographical characteristic of teeth and surrounding tissues.

a. Age: not relevant
b. Weight / Height: not relevant
c. Health: not relevant
d. Nationality: multiple
e. Patient state: not relevant

3.6. Classification

• Classification of product: Class I device according to Annex VIII (Rule 13) of the Medical Device Regulation 2017/745.
• Protection class against electric: Type B
• Resistance against electric shock: Class II

3.7. Residual Risk

Residual risk evaluations are conducted with Intraoral Scanner ‘LSO-100’ and there is no residual risk.

3.8. Operating Principles

3.8.1 Operating Principle

This device LSO-100 that works with the supplied image acquisition software. Input Power Adapter receives 100 ~ 240VAC input and supplies stable 24V DC power to the handpiece of LSO-100. This device connects to the desktop or Laptop with two USB 3.0 cables and can be used in combination with installed image acquisition software. Intraoral scanner ‘LSO-100’ makes the pattern image through the inner projector and OCT image through the line camera with high-resolution and three-dimensional information. The margin of target tooth could be detected by combining the OCT image based on the 3D oral cavity information.

3.8.2 Image Acquisition Principle

Intraoral scanner (IOS) is powerful devices used for optical impressions and is able to collect information on the shape and size of the dental arches through the emission of a light beam. The major components of LSO-100 are the engine of Digital Light Processing(DLP) for 3D scans and coated lens (mirror), RGB LED.

3.9. Applied Standard List

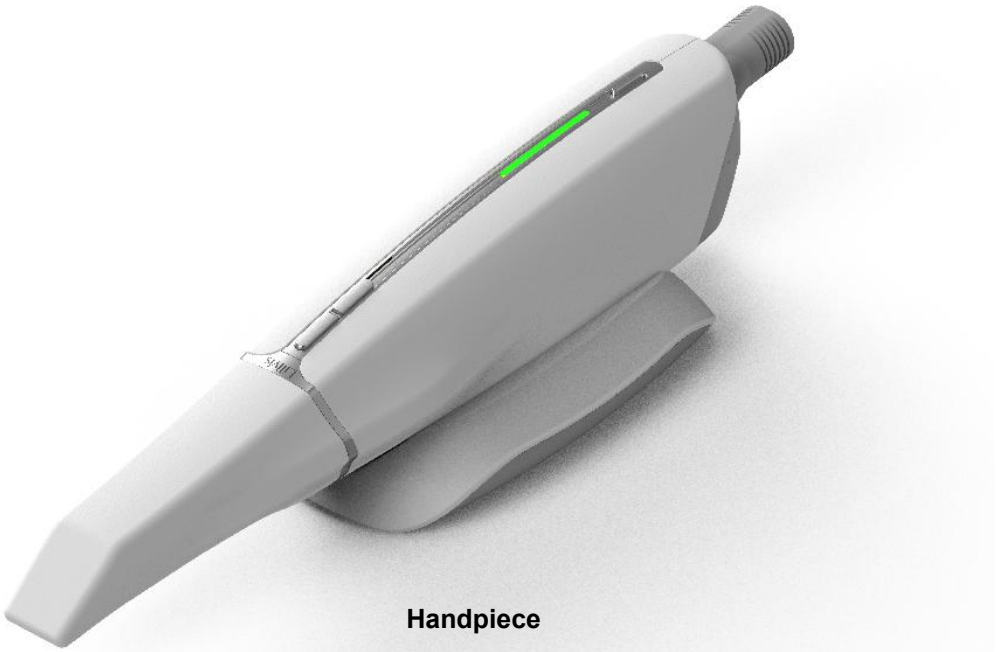
- IEC/EN 60601-1: MEDICAL ELECTRICAL EQUIPMENT
  - Part 1: General requirements for safety
- IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety
  - Collateral Standard: Electromagnetic Compatibility-Requirements and tests
- IEC 62304: Medical device software - Software life-cycle processes
- IEC 62366-1: Medical devices - Application of usability engineering to medical devices
- ISO 10993-1:2018 Biological evaluation of medical devices
- ISO 20896-1:2019 Dentistry — Digital impression devices — Part 1: Methods for assessing accuracy
- EN ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 17665-1:2006: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical device
- IEC 60825-1:2014: Safety of laser products – Part1: Equipment classification and requirements

4

Component Overview

4.1. Configuration

LSO-100 Components Overview



Handpiece



Main unit

5

Set-up Procedure

5.1. Basic Setting

1. Connect the cable



Camera

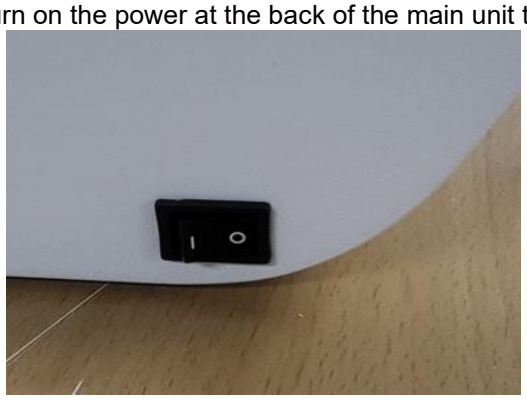
Data

Power





2. Turn on the power at the back of the main unit to apply power.



3. Press the soft switch to make it ready for use.



6

Software

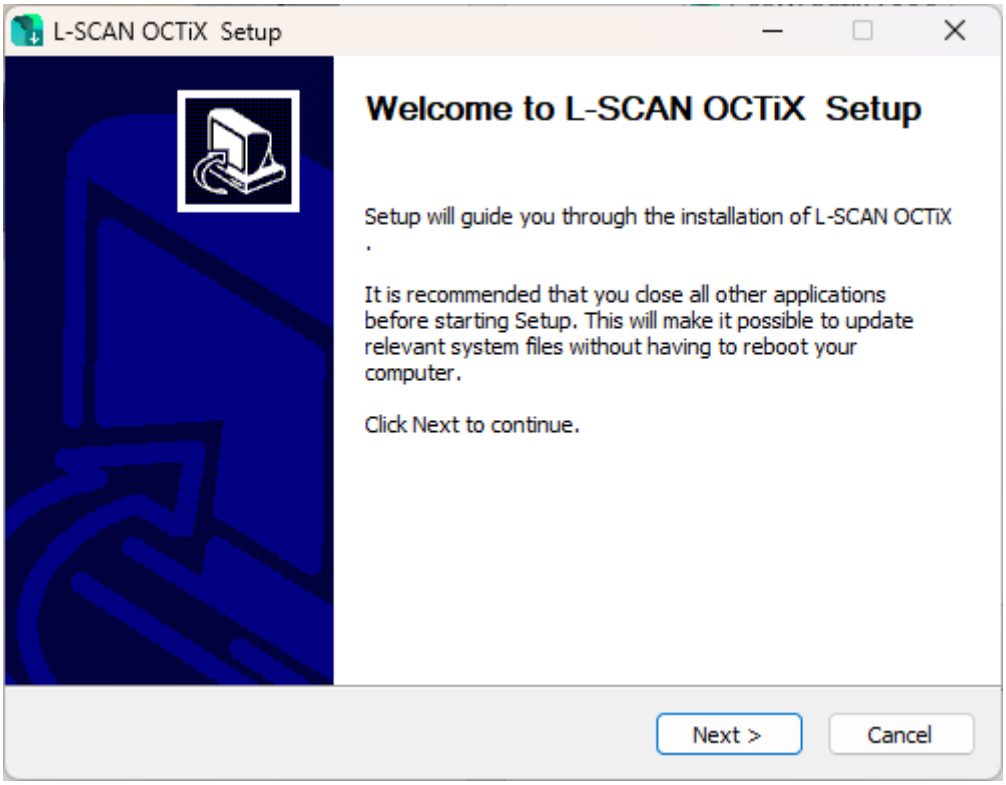
6.1. Overview

LSO-100 software is composed with L-Scan OCTiX for device control or scanning and Lilivis-Works(L-Works) software. The functions for User/Admin account and data storage of patient information (including acquisition images) management can be conducted with L-Works software.

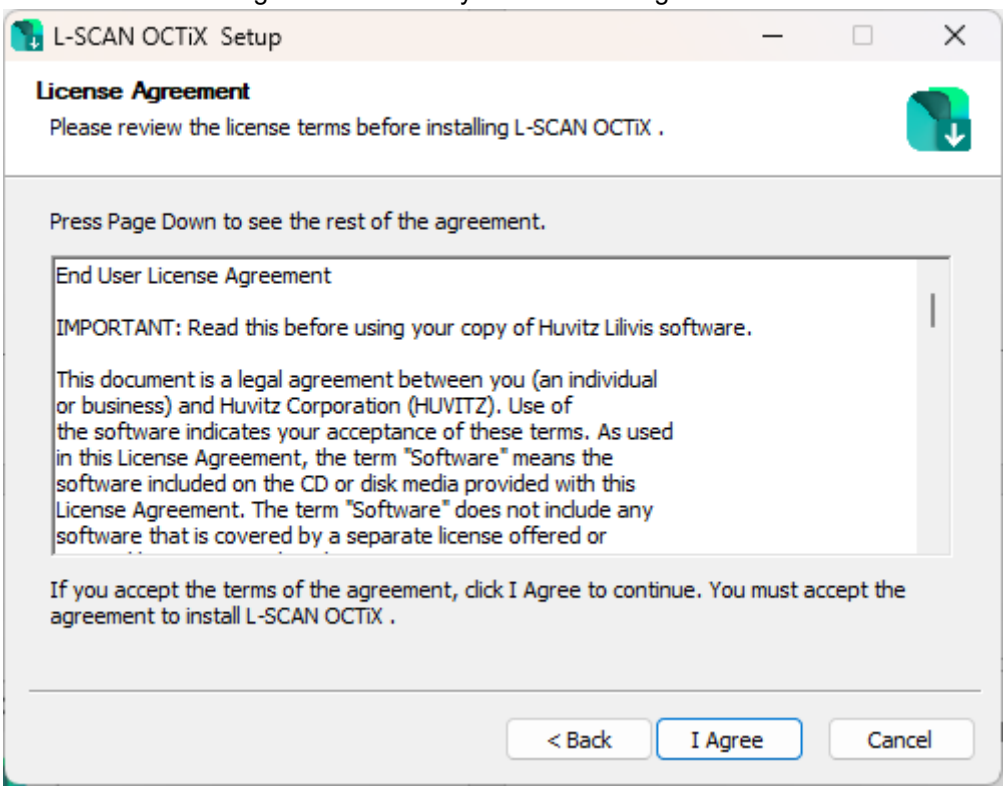
The image acquisition software (L-Scan OCTiX) provides a user-friendly working interface to digitally record topographical characteristics of teeth and surrounding tissues using Intraoral Scanner LSO-100.

6.2. Installation Procedure

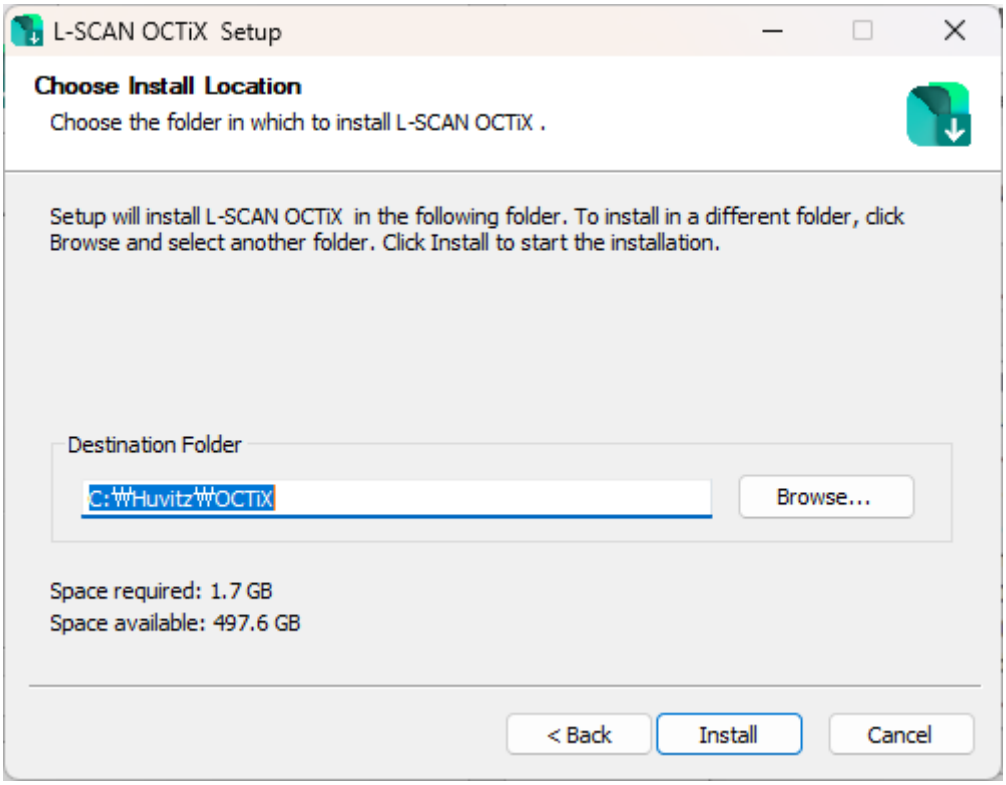
1. Run L-Scan OCTiX.exe
2. Click next button.



3. Read the license agreement carefully before checking then click Install

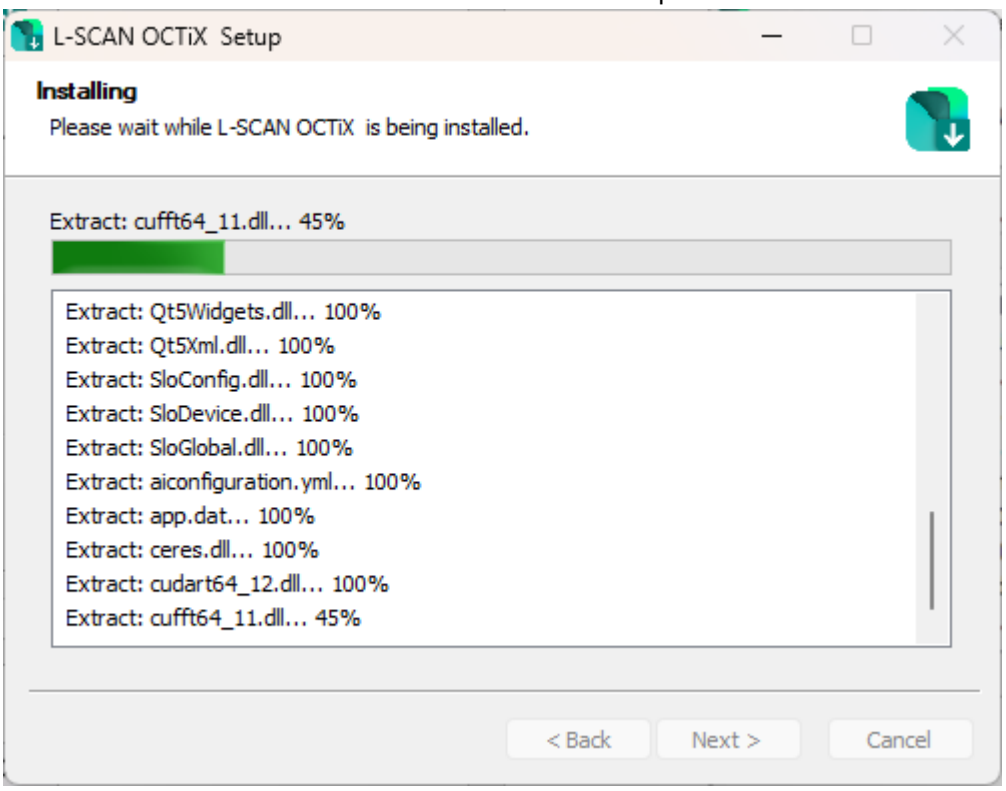


4. Select the installation Path

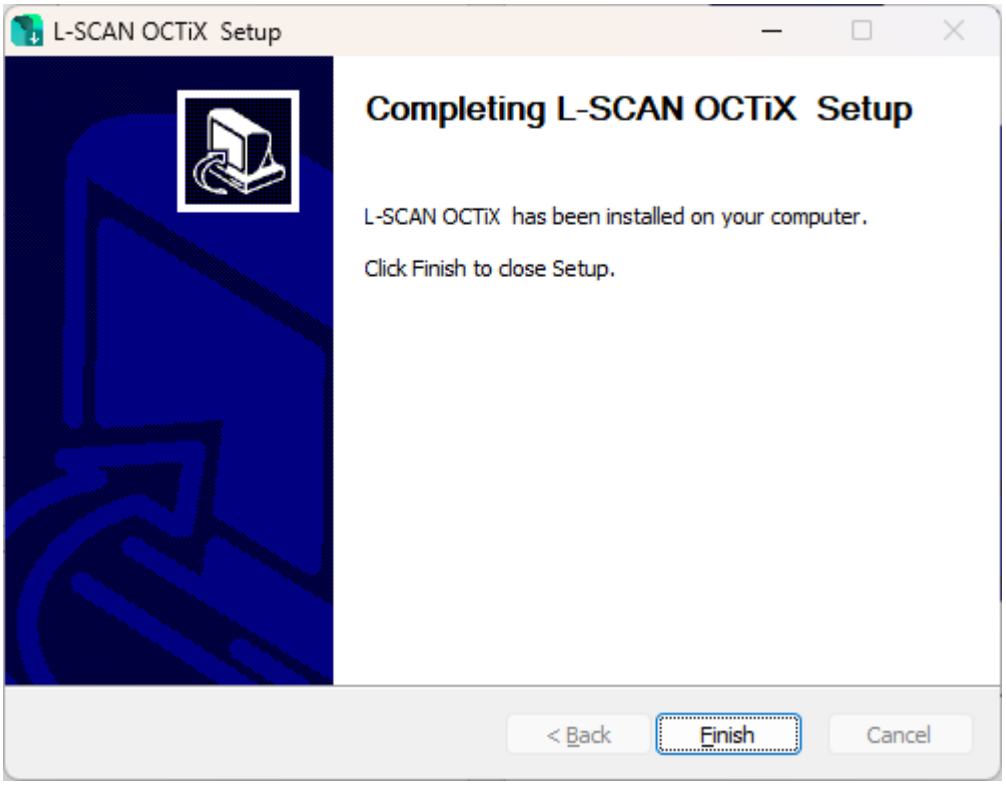


5. If the scanner is connected, please disconnect the scanner from the PC by removing USB cable.

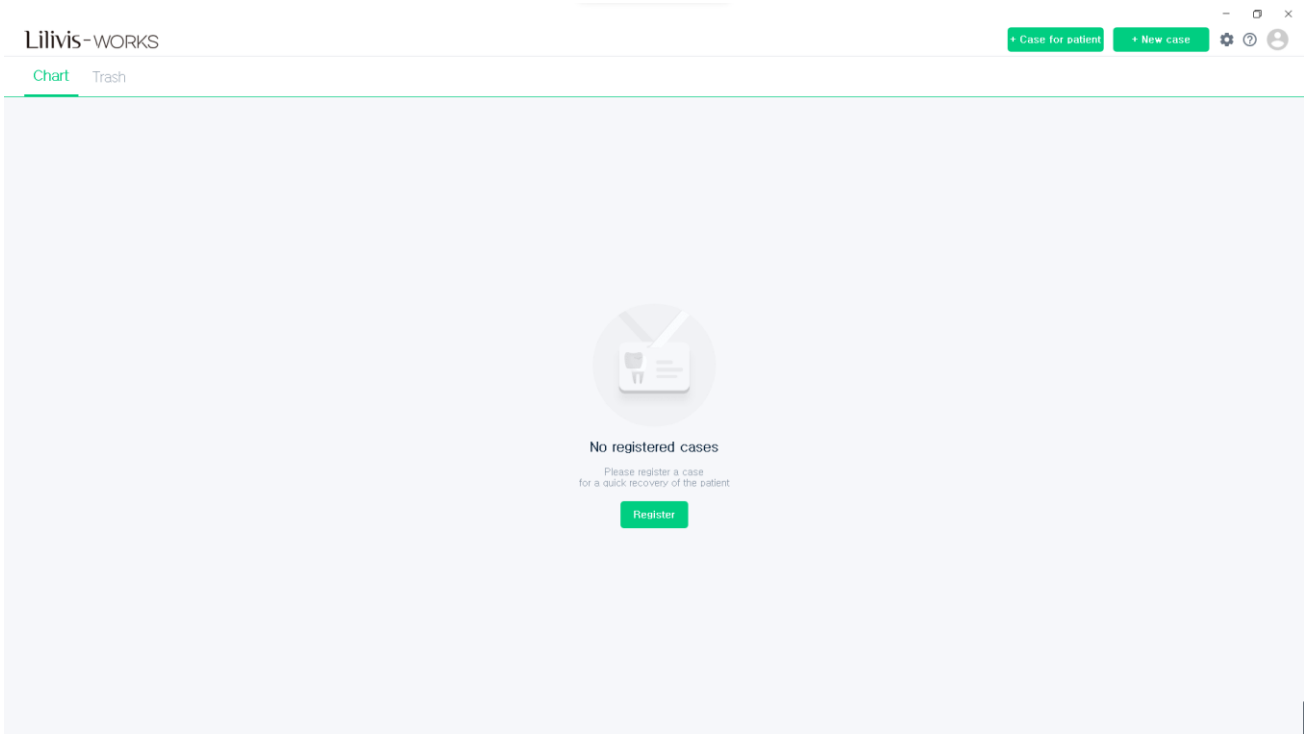
6. It may take up to several minutes to finish the recommended installation process.
   Please do not shut down the PC until installation is completed.



7. After installation is completed, we recommend restarting the PC to ensure optimal program operation.



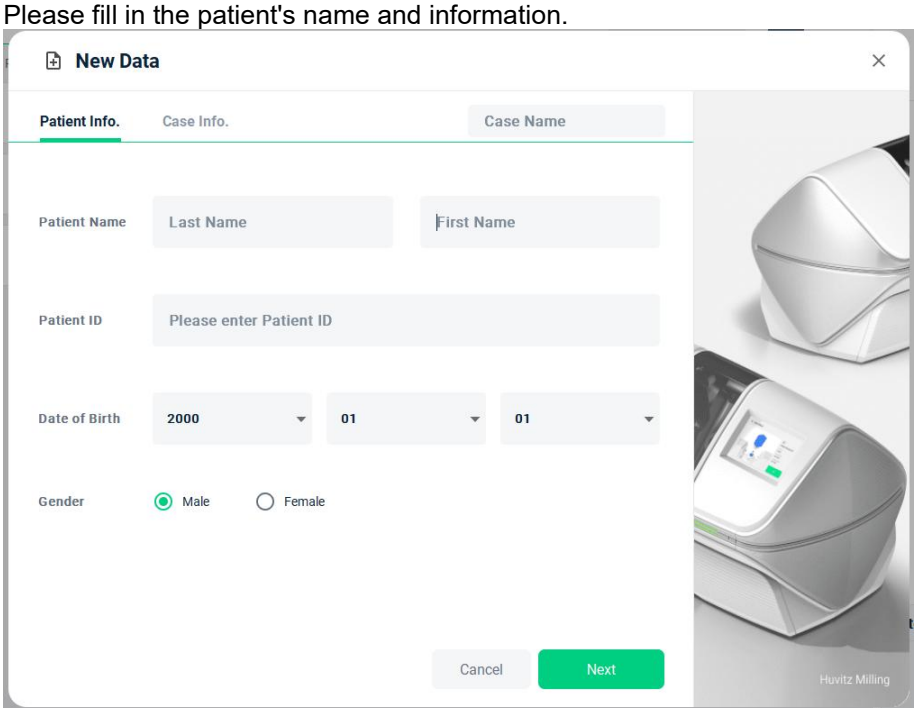
6.3. Lilivis-WORKS User Interface



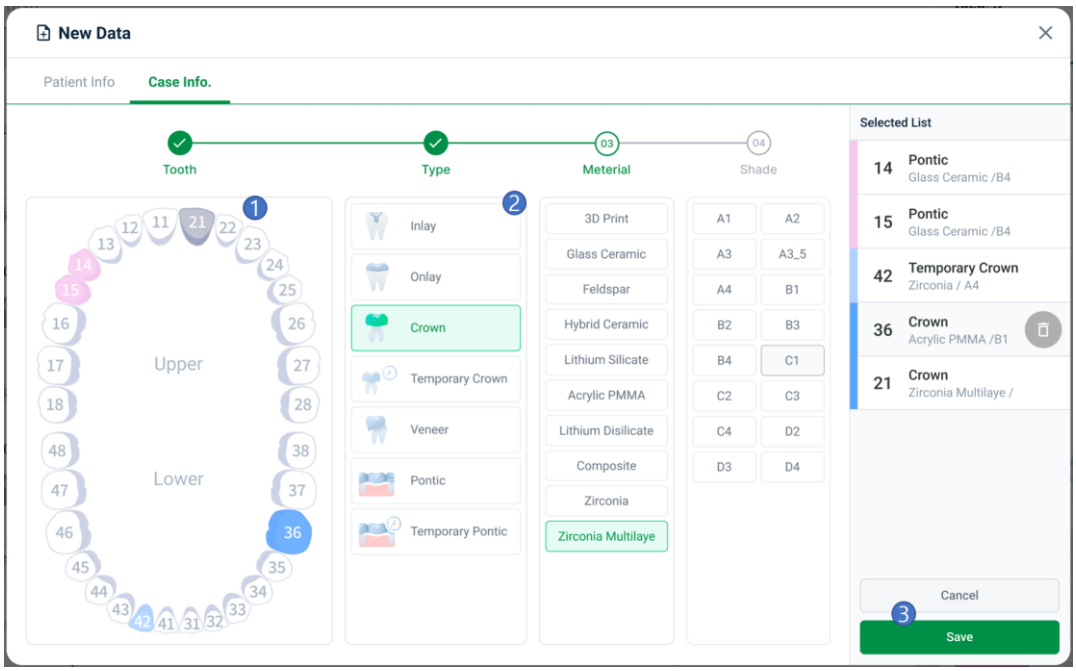
6.3.1 Create for patient and case

Click the “Case for patient” button or “Register” button to create a patient.

1. Please fill in the patient's name and information.



2. Click “Next” button.
3. Please fill in the case information.

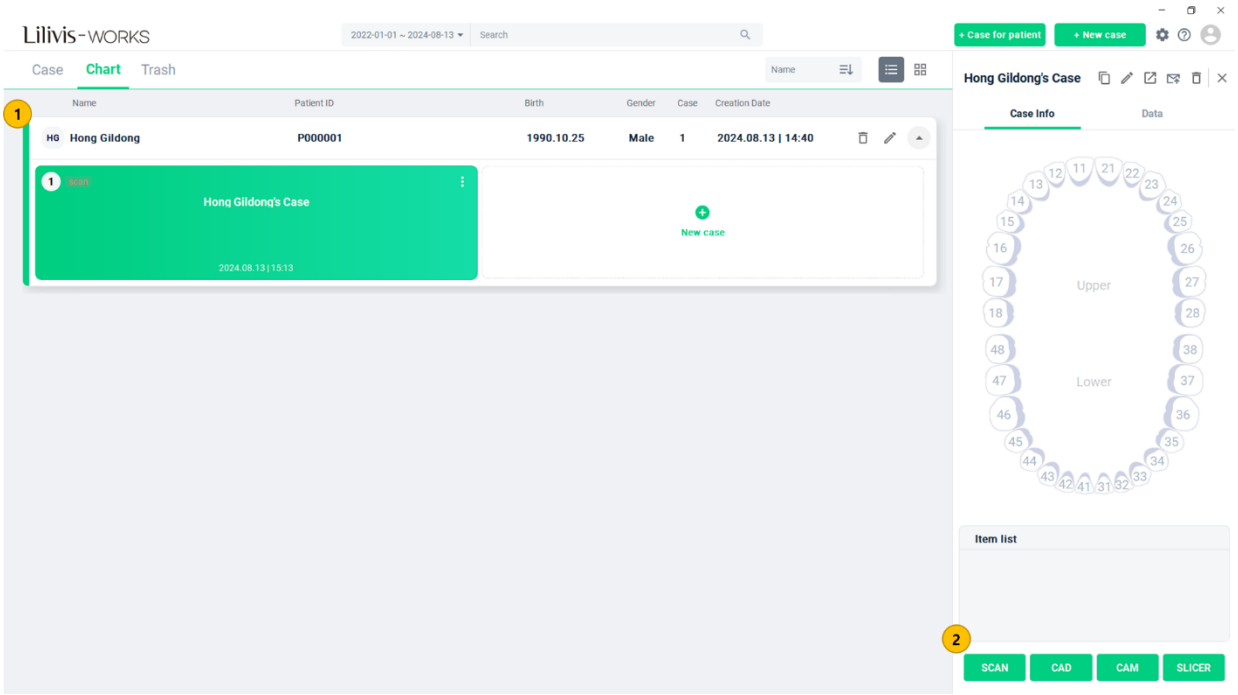


1. Select tooth to create item.
2. Select type, material, shade.
3. Click “Save” button.

*After selecting shade type, you can add multiple items in 1. or 2. iterations.

Edit item	1. Select item in the list. 2. Select type, material, shade.
Delete item	1. Select item in the list. 2. Hover over the item to be deleted and click the delete button.

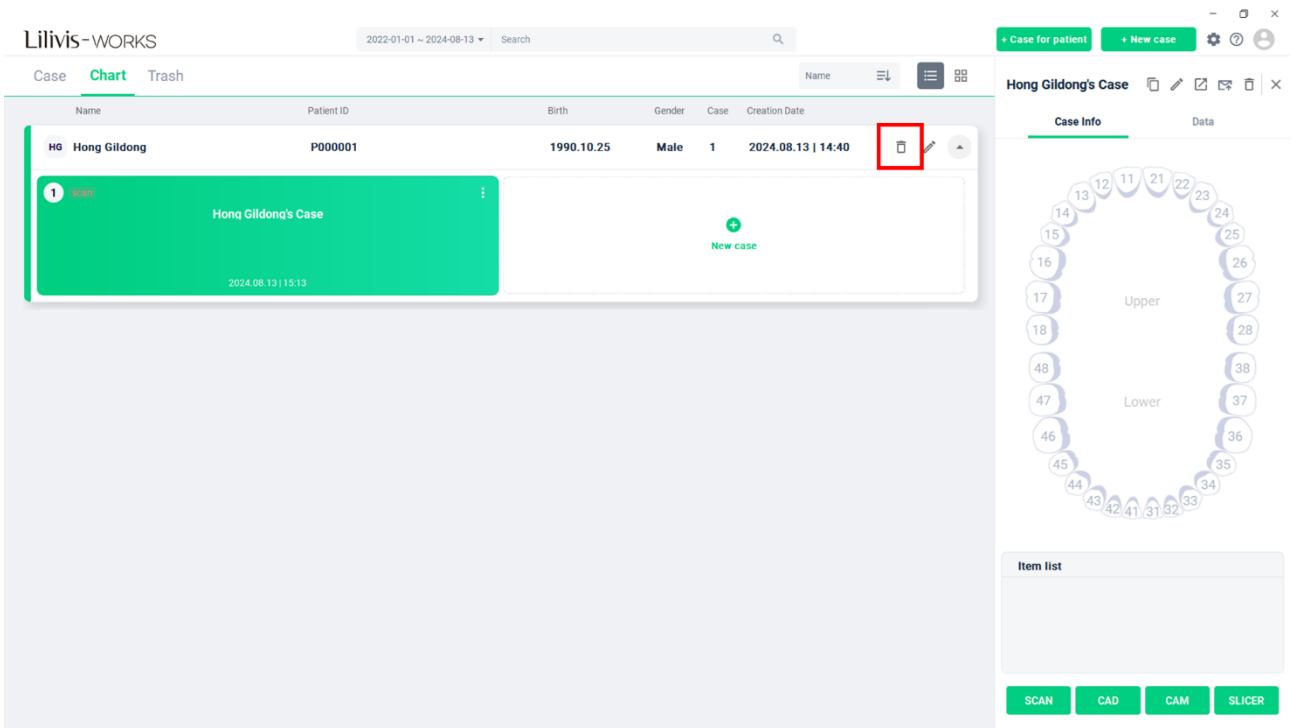
6.3.2 Run scan



1. Select patient, case to scan.
2. Click “SCAN” button.

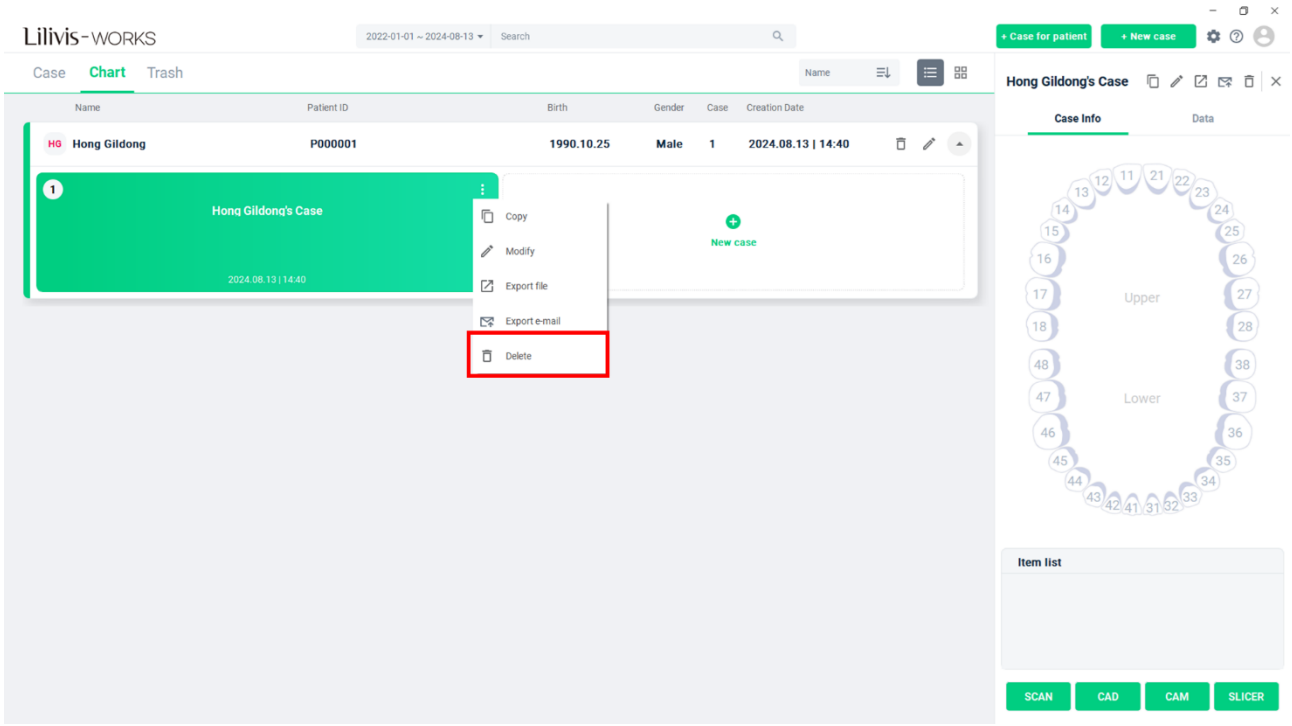
* Only L-Scan OCTiX can be run at a time.
  Close and run the program to change the case.

6.3.3 Delete patient



1. Change to view as patient list.
2. Select the patient to delete.
3. Click delete button.

6.3.4 Delete Case

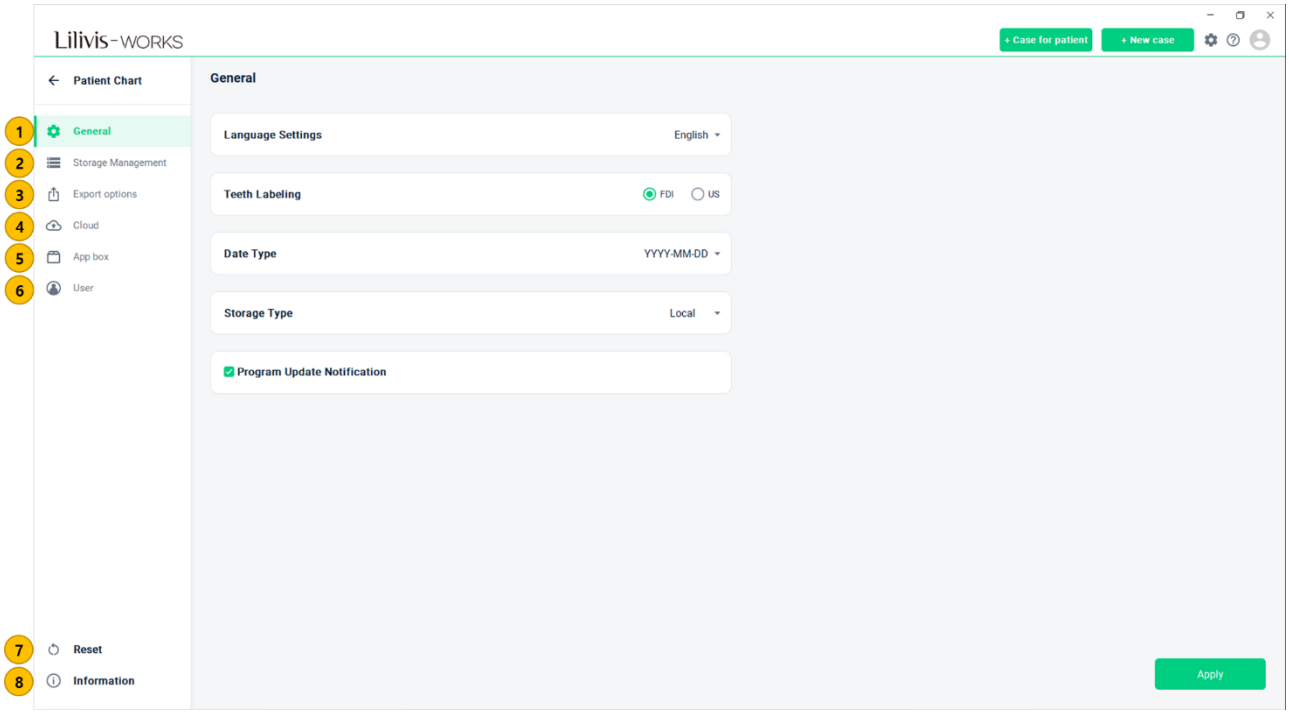


1. Select the patient and case to delete.
2. Click “Delete” menu.

6.3.4.1 Recover deleted case

1. Change “Trash” tab.
2. Click recover on the button to recover case item.

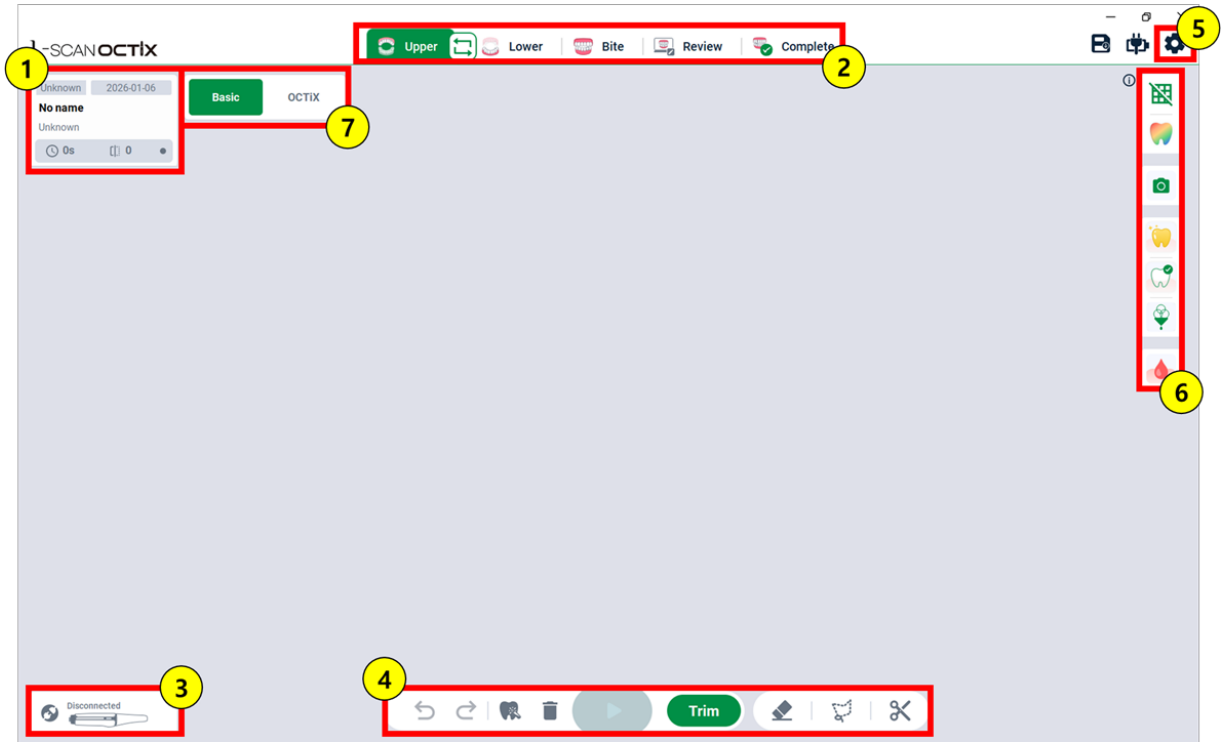
6.3.5 Setting



1	General	- Language - Teeth numbering system - Date type
2	Export options	- Mesh format - External program path - SMTP
3	Reset	- Reset to initial state

6.4. L-Scan OCTiX User Interface

1. Patient information Bar
2. Stage Bar
3. Device Status
4. Control Bar
5. Settings
6. Subfunction
7. Scan



6.4.1 Patient information Bars

Patient information is received from the L-Works.

Patient information	Shows information of the current patient.
Operation Time	Shows scan time.
The number of patches	Shows number of patches scanned.

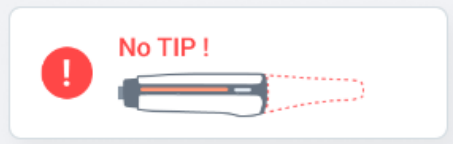
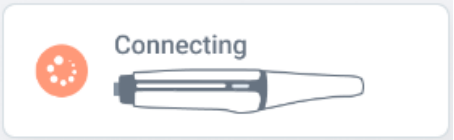
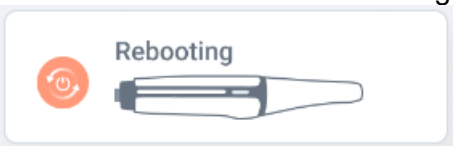
6.4.2 Stage Bar

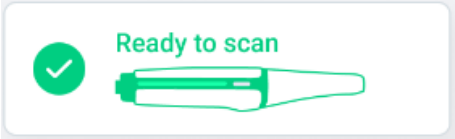
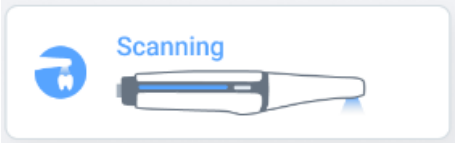
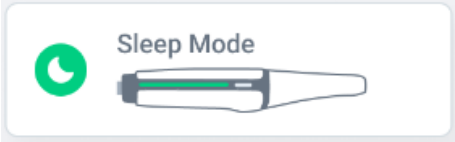
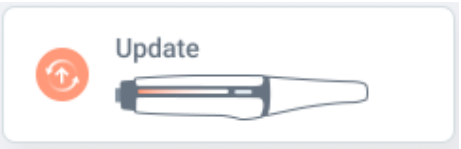
The stage bar indicates the current scanning step.

Scan Pre-Upper	Acquires the preoperational 3D image of the maxilla.
Scan Pre-Lower	Acquires the preoperational 3D image of the mandible.
Scan Upper	Acquires the 3D image of the maxilla.
Scan Lower	Acquires the 3D image of the mandible.
Bite (Occlusion)	Acquires the 3D images of the occlusion alignment
Review	Review OCT data and generates a digital die.
Complete	Completes the scanning process then generates the result data.

6.4.3 Device Status

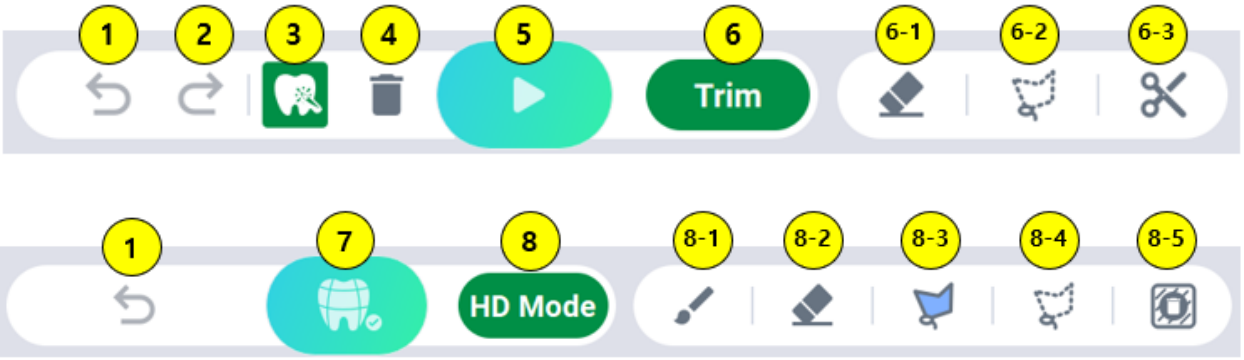
Display the current status of LSO-100 device

1	Not Connected	Indicates the LSO-100 is not connected. 
2	No Tip	Indicates the tip is not mounted. 
3	Connecting	Indicates the LSO-100 is trying to connect. 
4	Rebooting	Indicates the LSO-100 is rebooting. 

5	Ready to Scan	Indicates the LSO-100 is ready for use. (Heater of scanner tip is in proper temperature) 
6	Scanning	Indicates the LSO-100 is currently in the process of scanning. 
7	Sleep	Indicates the LSO-100 is in sleep mode. 
8	Overheating	Indicates the LSO-100 is overheated. 
9	Power Off	Indicates the LSO-100 is powered off. 
10	Air Mouse Mode	Indicates the LSO-100 is running in air mouse mode. 
11	Error	Indicates the LSO-100 has error. 
12	Update	Indicates the LSO-100 is updating firmware version. 

6.4.4 Control Bar

The Control Bar contains useful commands for editing and analyzing the 3D model.



Command Option Detail		
1	Undo	Undo previous action.
2	Redo	Redo previous action.
3	Optimize	Optimizes the alignment of scan data to improve scanning accuracy.
4	Clear all	Removes all 3D images of occlusion to start over
5	3D Scan mode	Toggle 3D scan mode.
6	Trimming Mode	Removes unnecessary data such as soft tissue and noise.
6-1	Brush Trimming	Removes all elements along the freely drawn path on the screen.
6-2	Polygon Trimming	Removes all elements within the polygon drawn on the screen.
6-3	Quick Trimming	Removes grouped data by selection.
7	Mesh Processing	Opens the dialog for mesh generation.
8	HD Mode	HD Mode.
8-1	Brush Selection	Selects the region to be converted to HD mode by freely drawing a path on the screen. Available only in the Complete step.
8-2	Brush Deselection	Deselects the region to be converted to HD mode by freely drawing a path on the screen. Available only in the Complete step.
8-3	Polygon Selection	Selects the region to be converted to HD mode within the polygon drawn on the scree. Available only in the Complete step.
8-4	Polygon Deselection	Deselects the region to be converted to HD mode within the polygon drawn on the scree. Available only in the Complete step.
8-5	Deselect All	Removes all selected HD regions. Available only in the Complete step.

6.4.4.1 Trimming Mode

Apply by deleting unnecessary parts from scan data.

6.4.4.1.1 How to trim the area

1. Click the trim menu.
2. Choose a selection tool.
3. Select the area you want to remove.

6.4.4.1.2 Selection Tools

Various selection methods are available in the surface data command.

1	Brush trimming	Removes all entities within a polyline shape drawn on the screen.
2	Polyline trimming	Removes all entities on a freehand-drawn path on the screen.
3	Quick trimming	Removes island data by picking.

6.4.4.2 HD Mode

Converts the selected region into high-density data. Available only in the Complete step.

6.4.4.2.1 How to trim the area

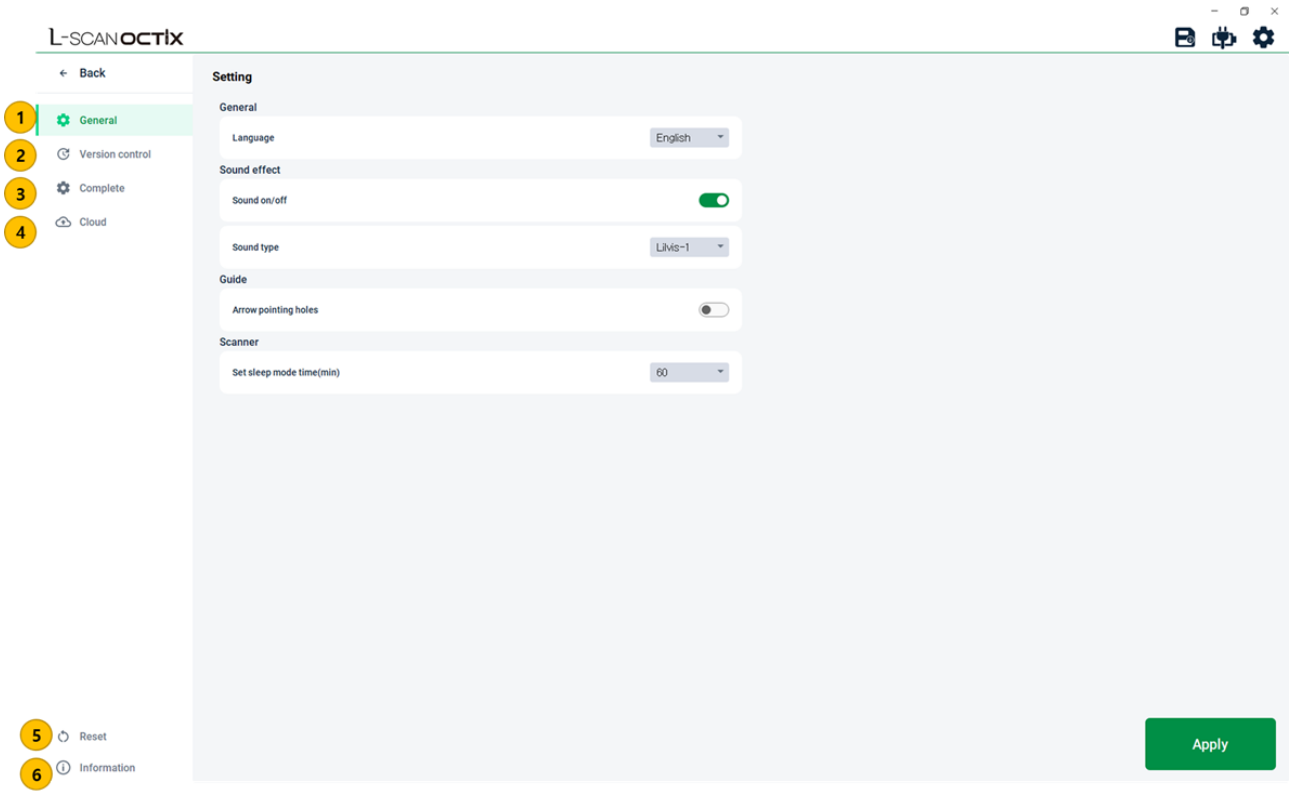
1. Move to Complete step.
2. Enables HD mode in the Mesh Processing dialog and generates the mesh.
3. Click the HD Mode menu.

6.4.4.2.2 Selection Tools

Various selection methods are available in the surface data command.

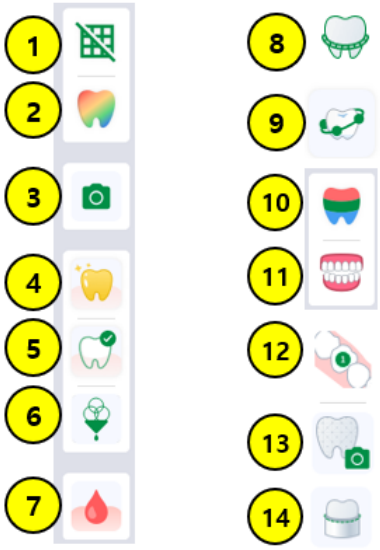
1	Brush Selection	Selects the region to be converted to HD mode by freely drawing a path on the screen.
2	Brush Deselection	Deselects the region to be converted to HD mode by freely drawing a path on the screen.
3	Polygon Selection	Selects the region to be converted to HD mode within the polygon drawn on the scree.
4	Polygon Deselection	Deselects the region to be converted to HD mode within the polygon drawn on the scree..
5	Deselect All	Removes all selected HD regions.

6.4.5 Set-up



1	General	- Language - Sound - Scan Guide
2	Scanner Version	- Manage scanner firmware
3	Finishing	- Default finishing options
4	Cloud	- Set cloud options
5	Reset	- Reset to initial state
6	Information	- Program version information

6.4.6 Sub-function shortcut



1	Grid option	Displays grid view off/above/below model
2	Render option	Changes render option of the model.
3	Mode for image capture	Capture and manage images
4	Mode of metal	Improve the accuracy of scanning metal material
5	Remove of soft tissue	Remove unnecessary soft tissue
6	Color for filtering	Remove the pre-set colors
7	Blood Scan Mode	Enable scanning of the blood surface
8	Margin Line Option	Set the margin line model render option.
9	Pre-margin Line Edit	Adjust the pre-margin line.
10	Occlusion analysis	Analyzes the interference between the maxilla and mandible and shows the result with color map. *This function is only available on bite step.
11	Manual registration	Align manually the maxilla/mandible during the occlusion phase
12	Tooth Number Option	Set the tooth number render option.
13	Texture Option	Renders using real textures.
14	Digital die	Generate a digital die.

6.4.6.1 Grid option

Displays a grid on the screen. The grid can be positioned in front of or behind the model.





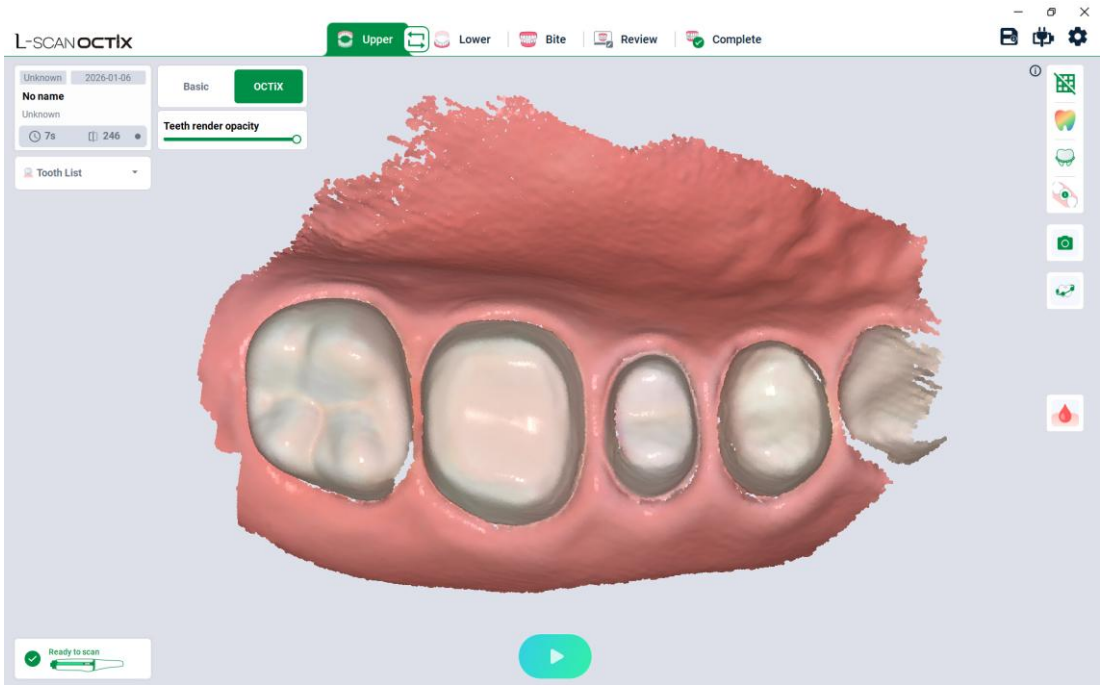


6.4.6.2 Render option

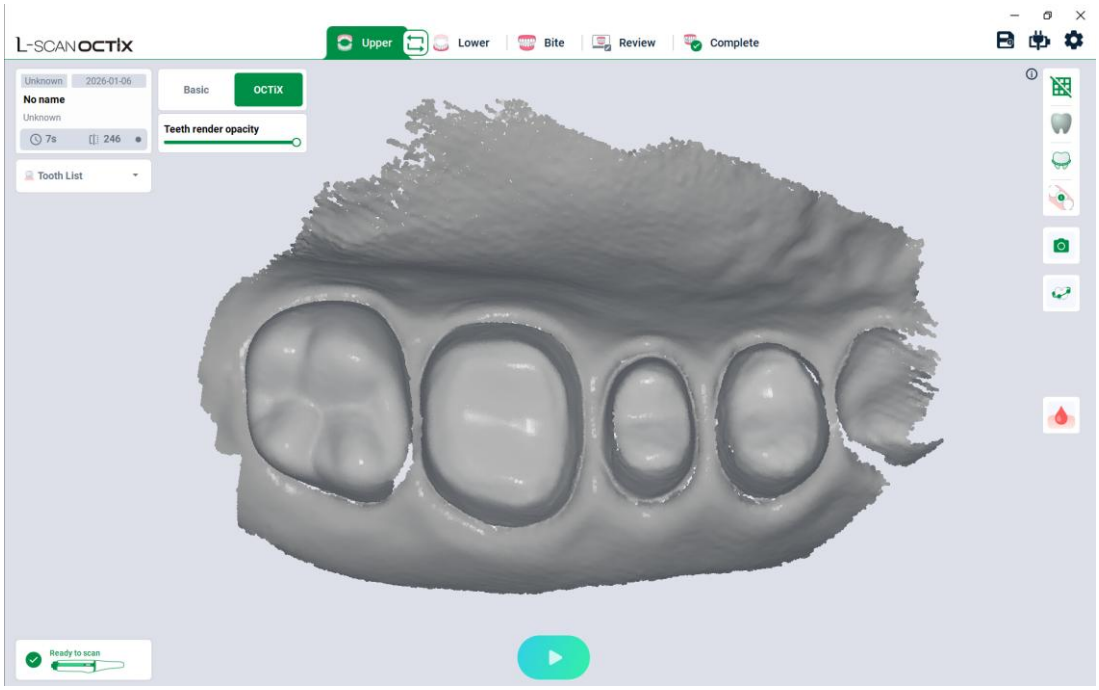
Rendering options can be configured. There are three selectable modes: Real, Gray, and Mono.

- Click the icon of render option button

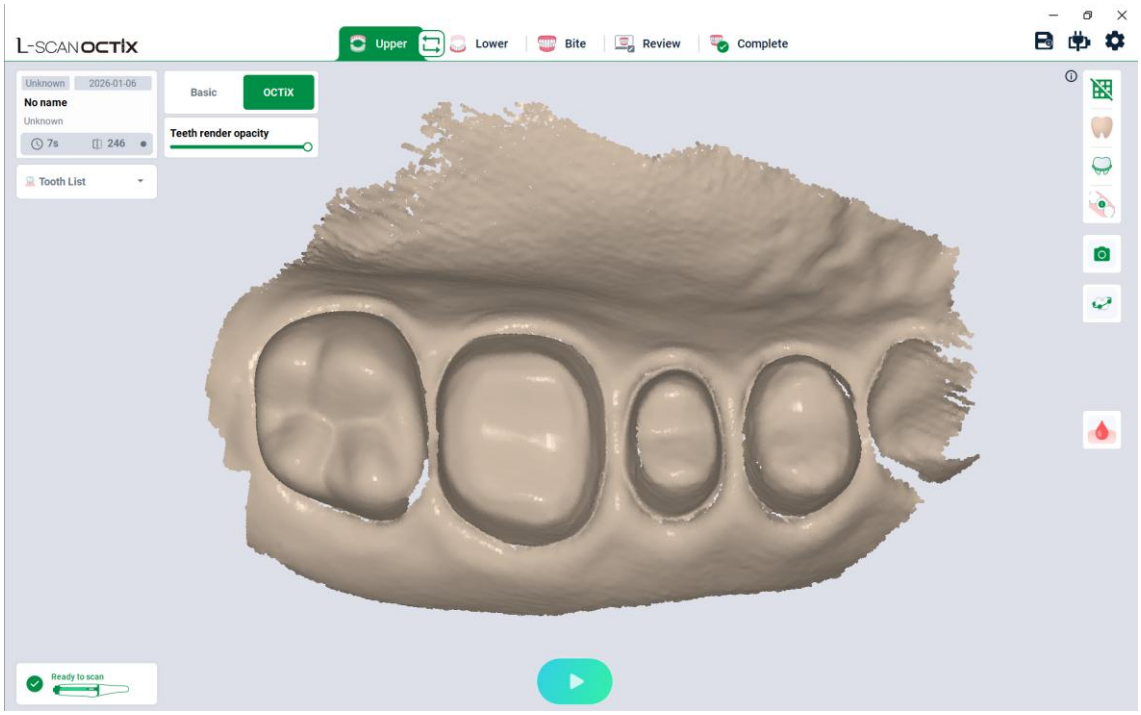




<Real>



<Gray>



<Mono>

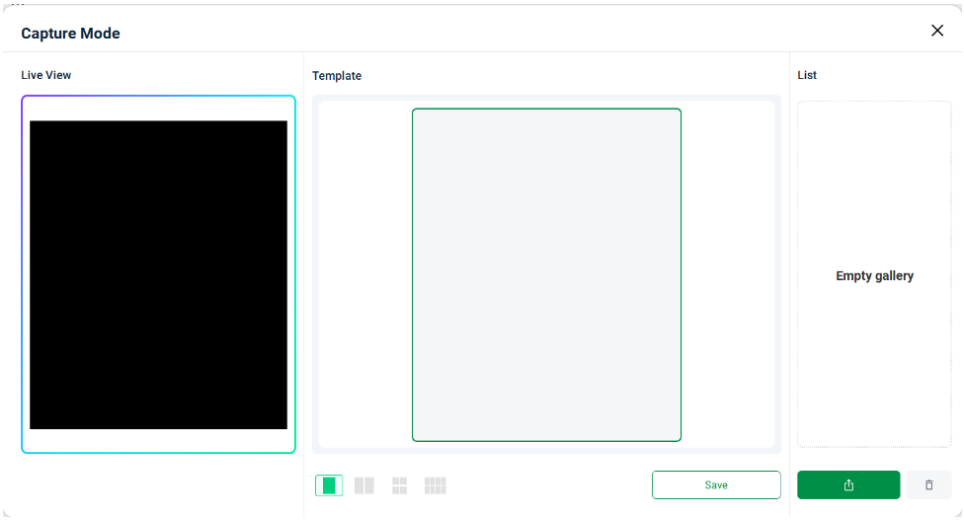
6.4.6.3 Mode for image capture

Start/Stop the capture process. Press the Start button on the control bar and press the Function button to capture the image. Alternatively, you can press the Function button on your handpiece to start the capture and hold the Function button to stop the capture process.

- Click the icon of Image Capture Mode.



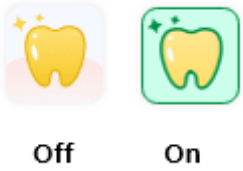
- Turn on the scanner
- Click the Start button on the control bar or press and hold the function button on the scanner to start.



6.4.6.4 Mode of Metal

Improves scanning accuracy of metal materials

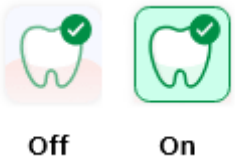
- Click the icon of metal mode button.



6.4.6.5 Remove of soft tissue

Remove unnecessary soft tissue effectively during the scanning process

- Click the icon of soft tissue removal (Activate/Deactivate)



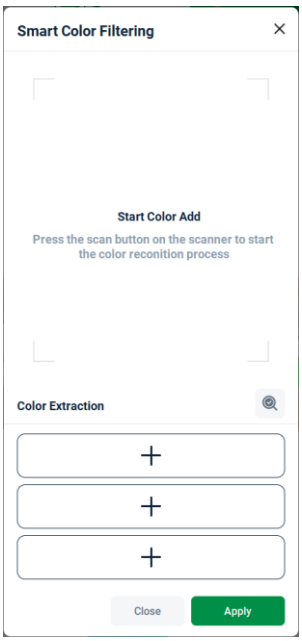
6.4.6.6 Color for filtering

Filtering specific colors during the scanning process

- Turn on the scanner
- Click the icon of color filtering



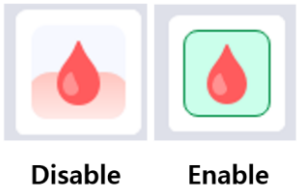
- Select the cell to apply the color from the three available cells.
- Fix the tip to the location of filtering and click the middle start button



6.4.6.7 Mode of blood

When Blood Mode is enabled, scanning is possible including the blood surface.

- Click the icon of mode of blood

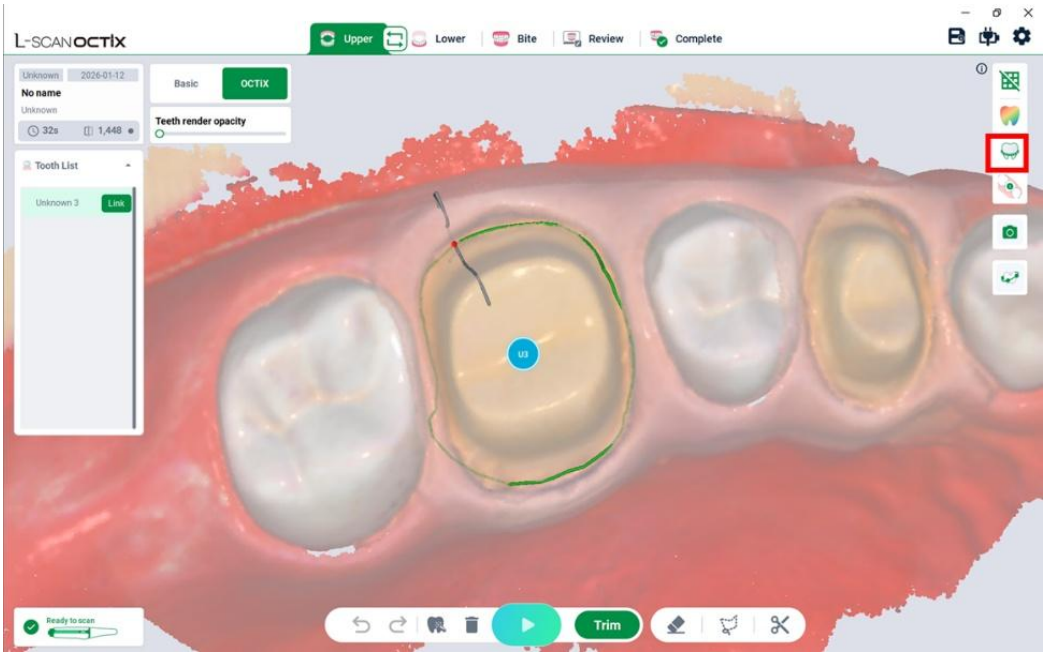


6.4.6.8 Margin Line Option

Set the margin line model render option.

- Click the icon of margin line render option.





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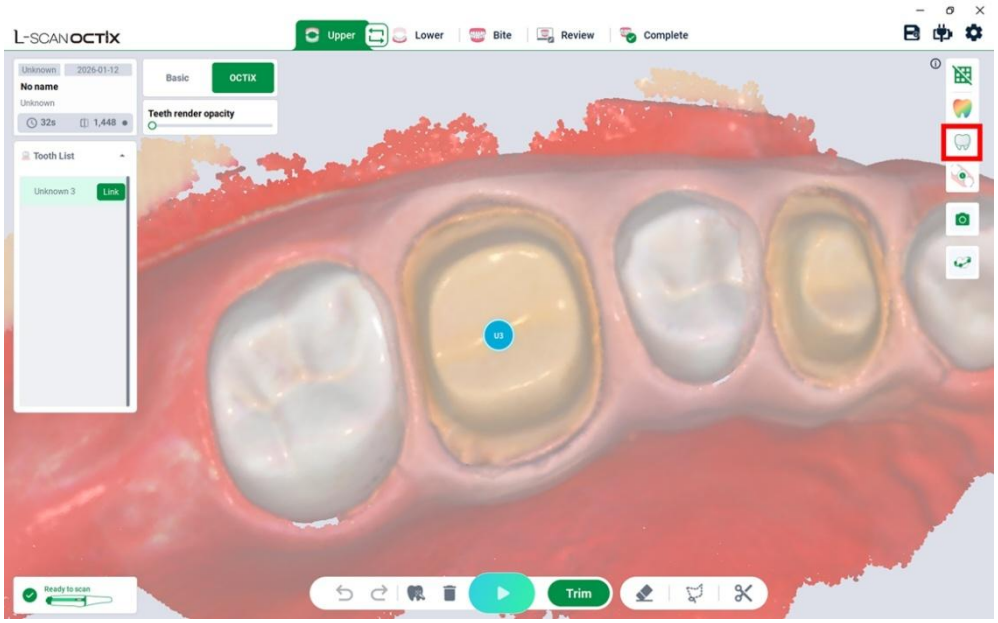


<Hide>

6.4.6.9 Pre-margin Line Edit

Set the margin line model render option.

- Click the icon of margin line edit option

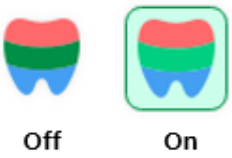


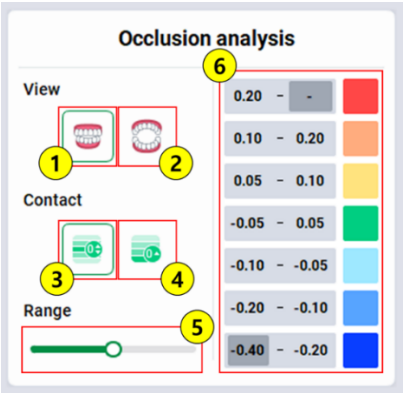
Disable Enable

- When the Pre-margin Line Edit button is activated, you can edit or add pre-margin lines.
- Left-click and drag and existing pre-margin point to edit it, and right-click a point to delete it.
- Left-click on and empty area to add a new margin line point. When a closed loop is formed, a new margin line created.

6.4.6.10 Occlusion Analysis

Analyzes the interference between the Upper(maxilla) and Lower(mandible) and shows the result with color map.





1	Fold View	Fold maxillar and mandibular data
2	Expand View	Expand maxillar and mandibular data
3	All Direction	Shows interference of positive and negative direction.
4	Positive Direction	Shows interference of positives.
5	Set Interference Range	Adjust the tolerance levels for occlusal contact.
6	Interference Legend	Display the color scale of occlusal pressure

***This function is only available on bite step.**

NOTE

Unfold the model to check the deviation values. When you move the mouse over the color areas of the 3D model, the system displays the deviation values.

6.4.6.10.1 How to use

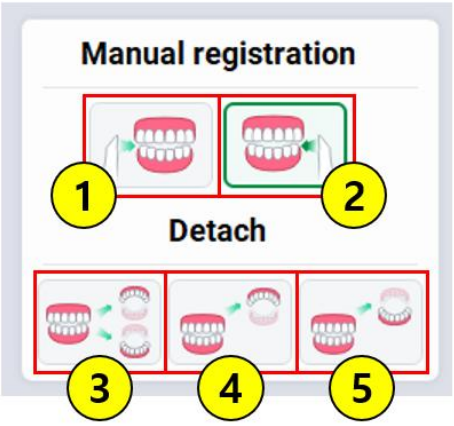
1. Click Occlusion Analysis
2. Change the view style between show all and contasct area by clicking on the button.
3. Change the segmentation of color range using the level slide bar.
4. It can adjust the maximum and minimum value.
5. If you hover your mouse over the colored part, the distance value will show.

s

6.4.6.11 Manual Registration

Use in case of automatic alignment failure.





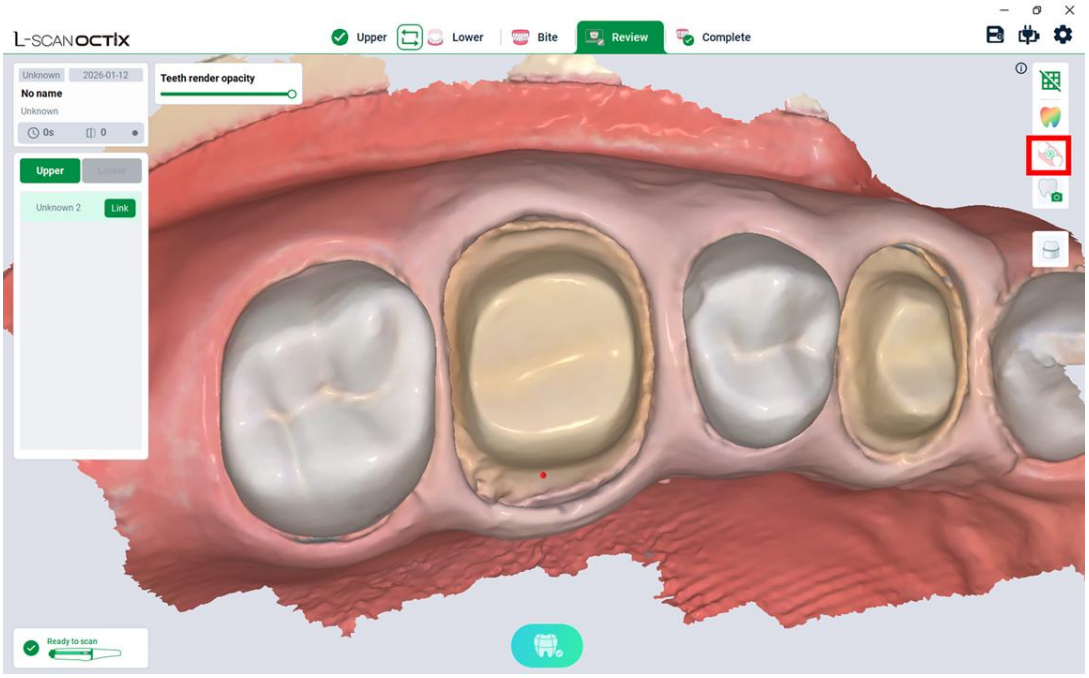
1	Set Left Bite Data	Selects the left bite scan data.
2	Set Right Bite Data	Selects the right bite scan data.
3	Detach Both	Detach the bite scan data from upper and lower scan data.
4	Detach From Upper	Detach the bite scan data from upper scan data.
5	Detach From Lower	Detach the bite scan data from lower scan data.

6.4.6.12 Tooth Number Option

■ Click the icon of tooth number option.

s





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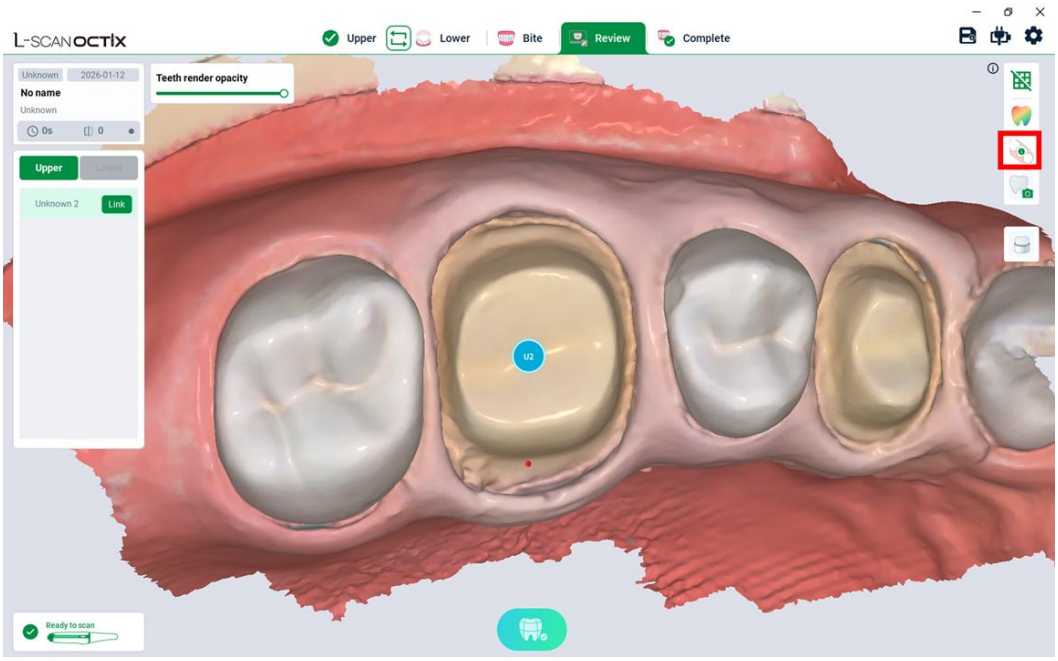
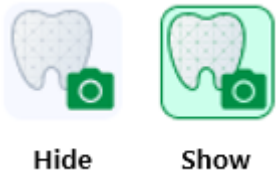
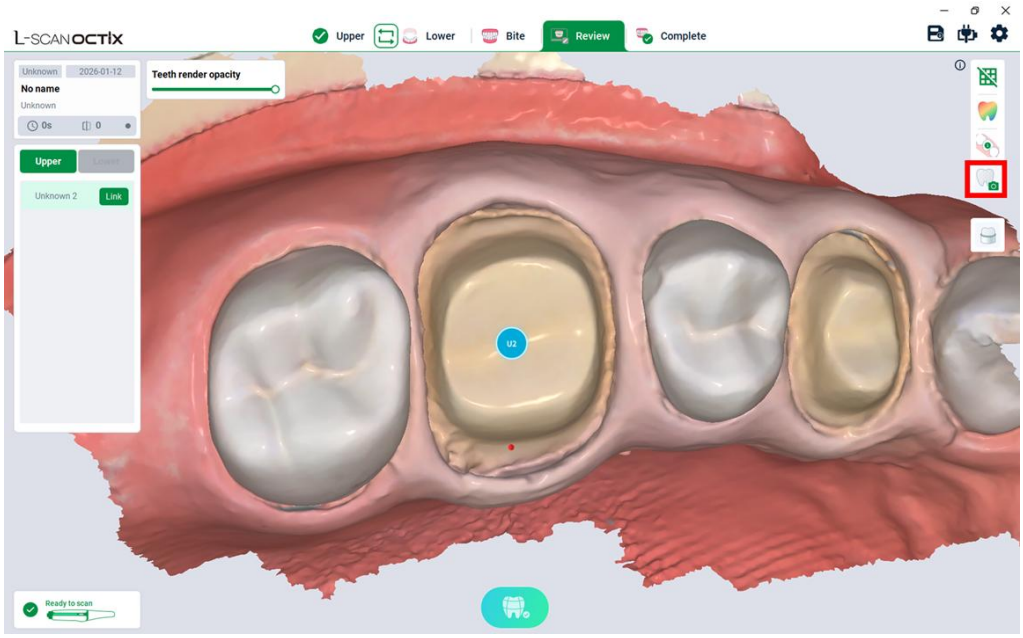


<Show>

6.4.6.13 Texture Option

- Click the icon of mesh texture option.





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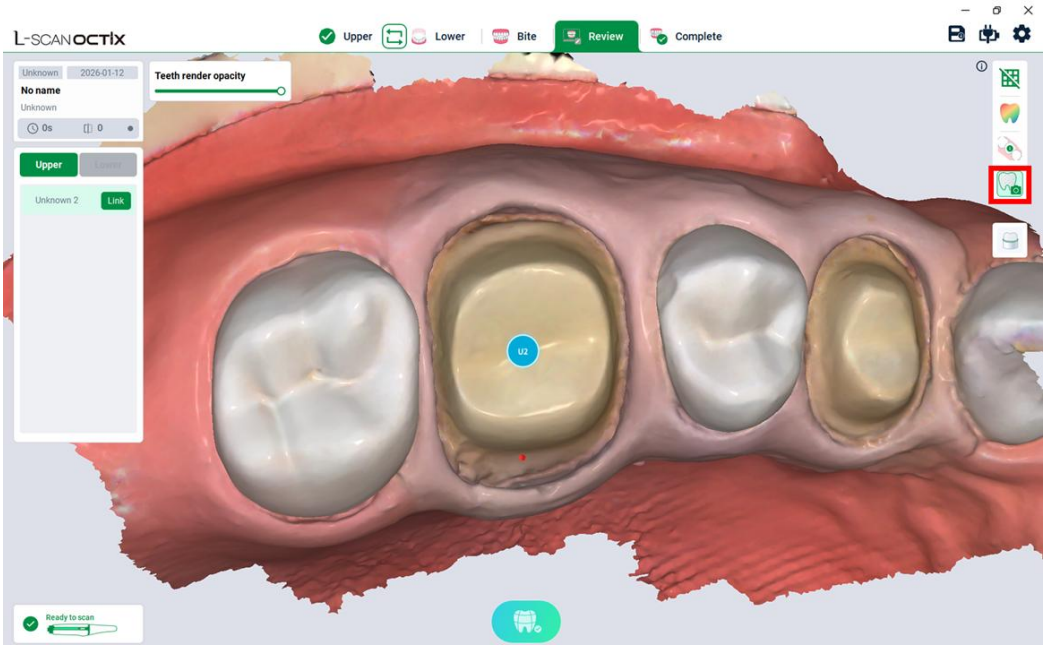
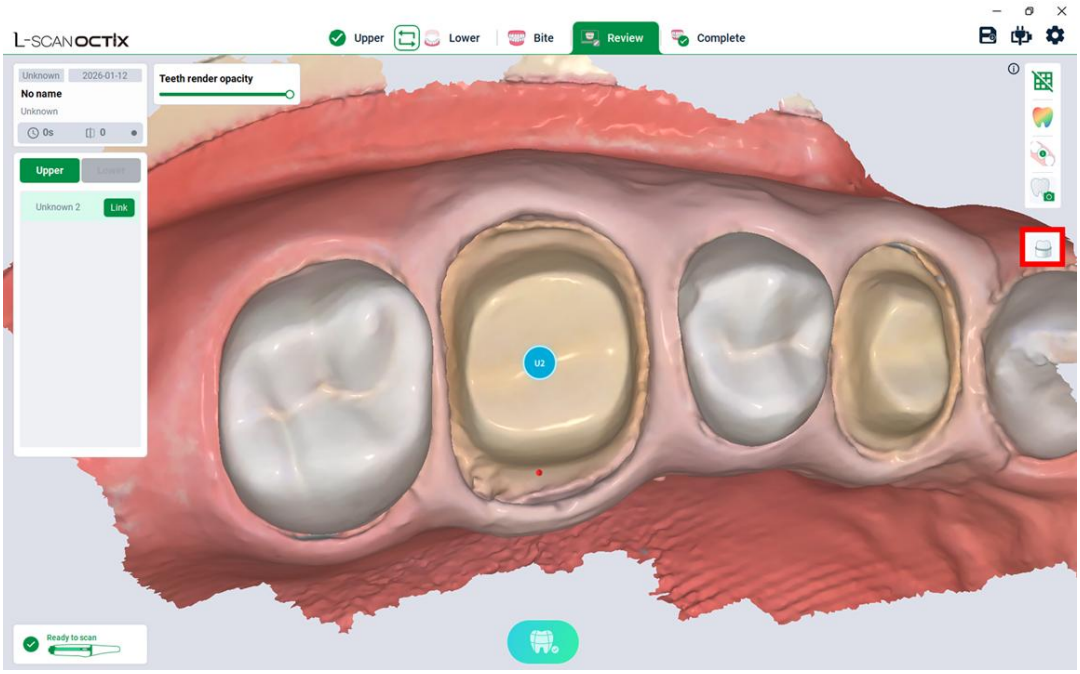


<Show>

6.4.6.14 Digital Die





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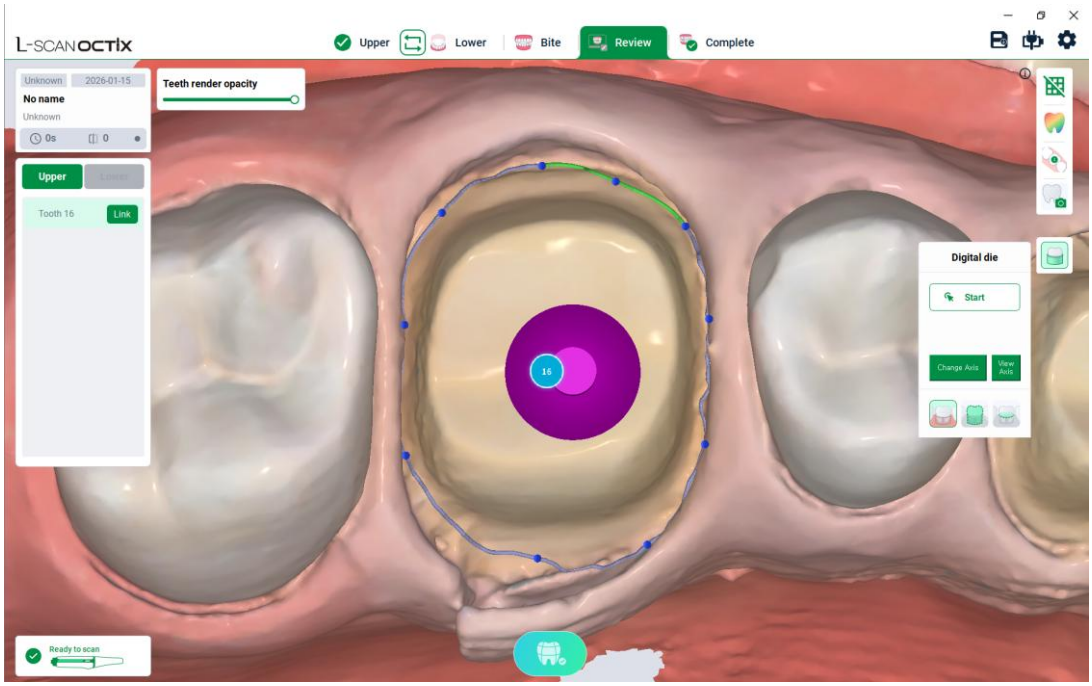
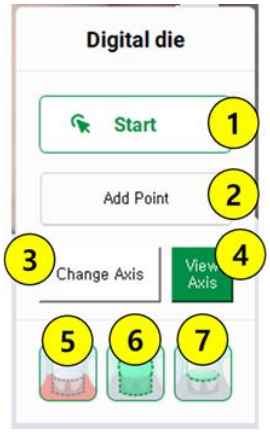


<Show>

6.4.6.14.1 How to use

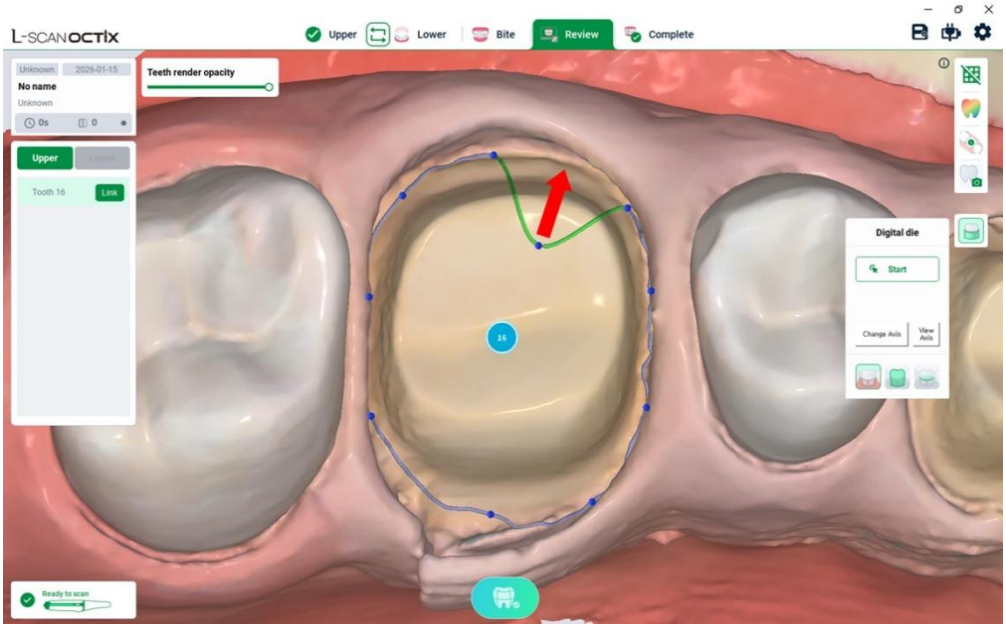
The following screen is the Digital Die dialog, where users can generate a digital die, add cutting line points, change the digital die axis, and control rendering options.

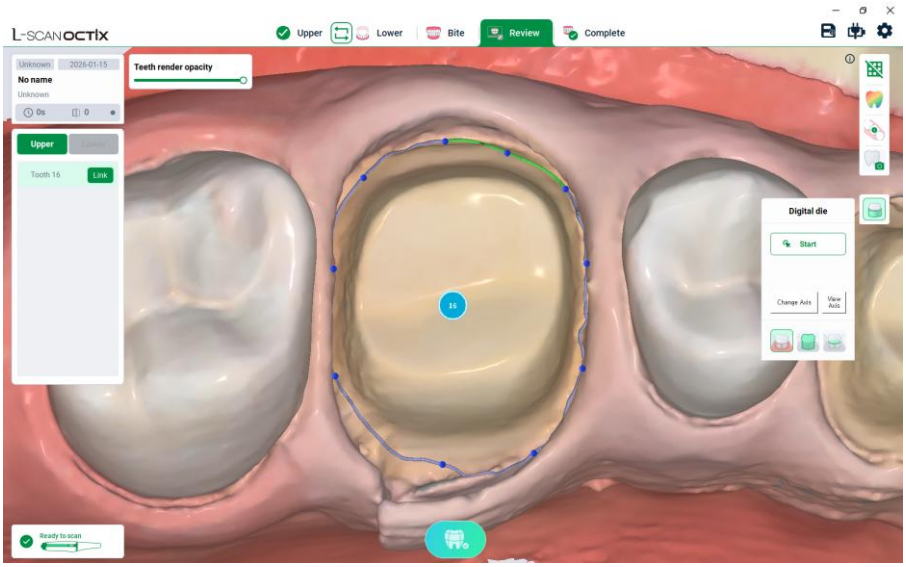


Review UI		
1	Start	Start digital die generation.
2	Add Point	Append new point to cutting line.
3	Change Axis	Change base axis of digital die.
4	View axis	Toggle show/hide of arrow instance of digital die reference axis.
5	Mesh visibility	Toggle show/hide of oct mesh.
6	Digital die visibility	Toggle show/hide of digital die.
7	Margin line visibility	Toggle show/hide of margin line of tooth.

The following explains how to use the Digital Die options.

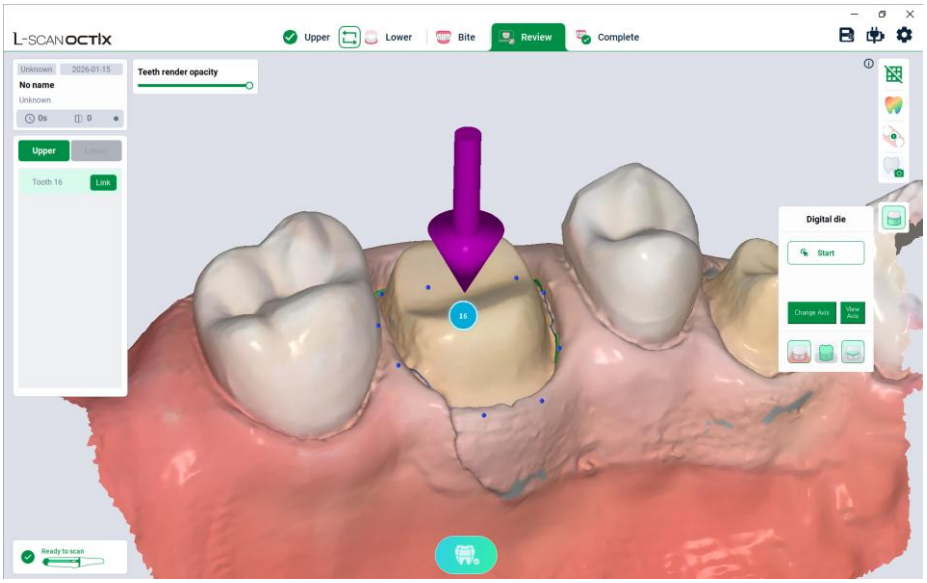
1. Adjust the cutting line position for the Digital Die appropriately.
    - Change the position by dragging and dropping the blue points on the screen.



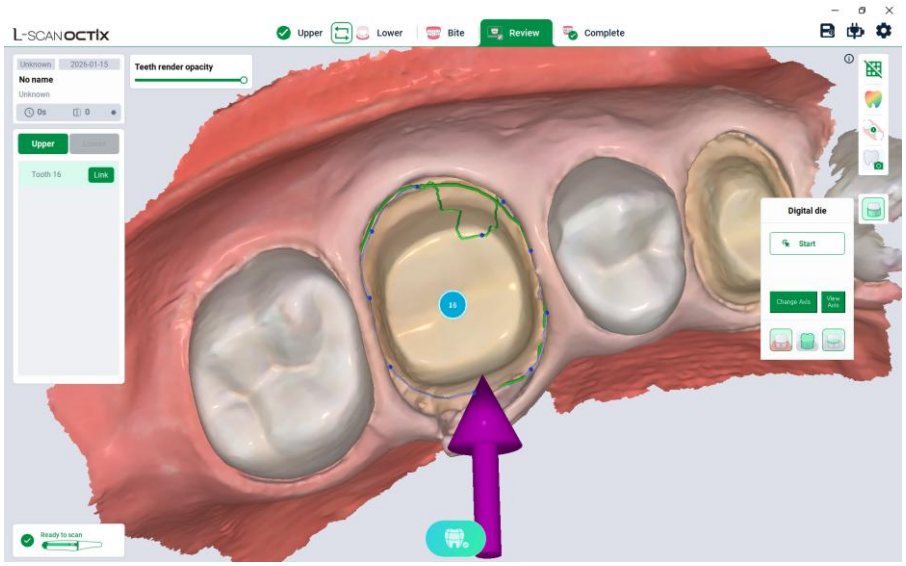


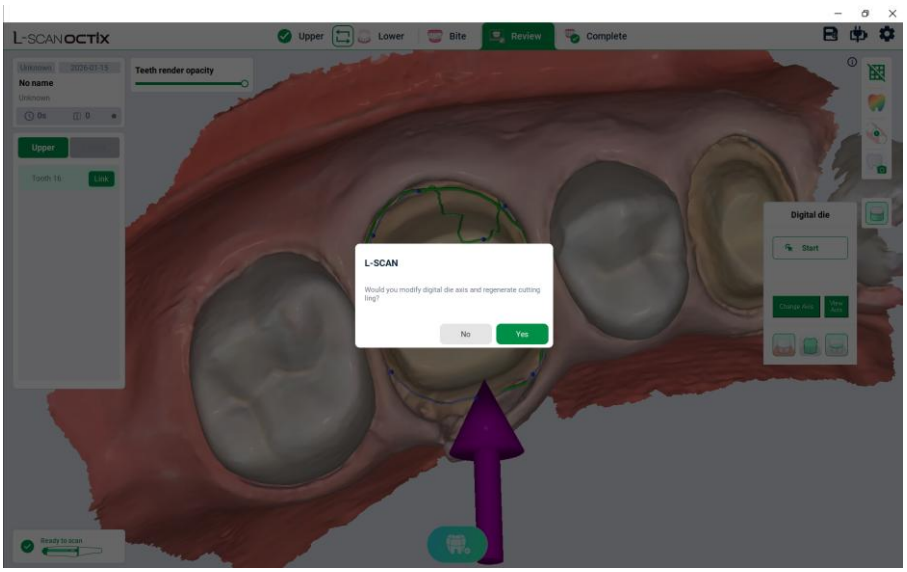
- If necessary, additional blue points can be added using the Add Point button.
- After activating the Add Point button, place the mouse cursor on the blue line and left-click to create a new points.

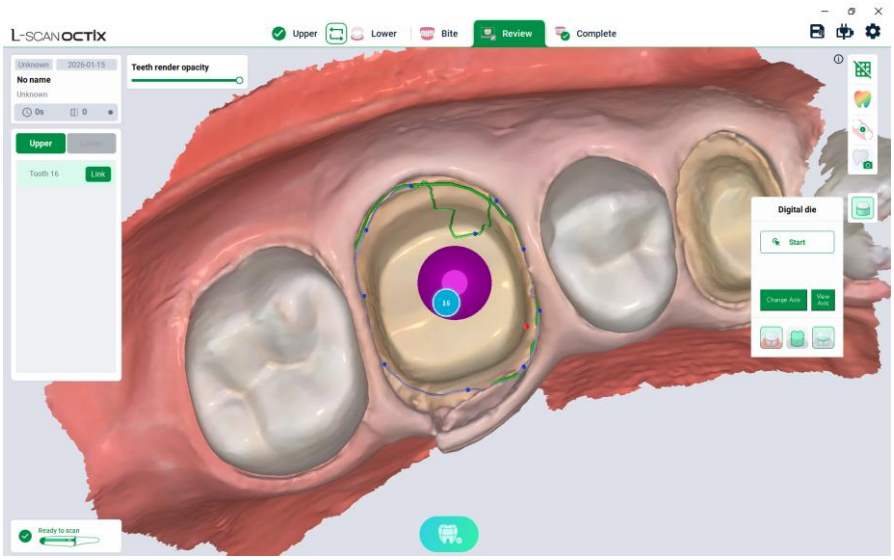
2. Adjust axis of digital die.
   - Change the arrow so that it points in the vertical direction of the tooth.



   - If the axis is not correct, rotate the view so that the tooth is viewed vertically, activate the Change Axis button, and then click the tooth on the screen.

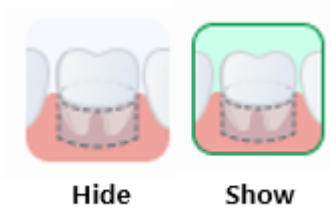






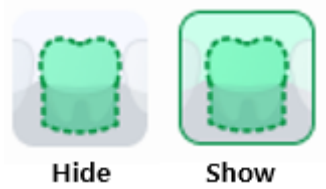
3. Click the Start button to generate the Digital Die.
4. Use the rendering options appropriately to review the result.
    - Toggle the visibility of the OCT mesh.

Toggle the visibility of the mesh.



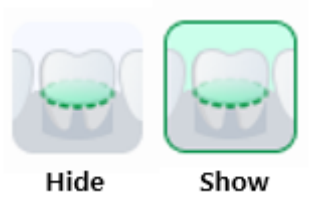
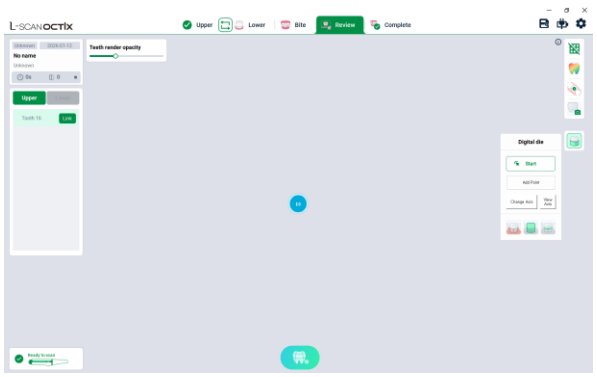
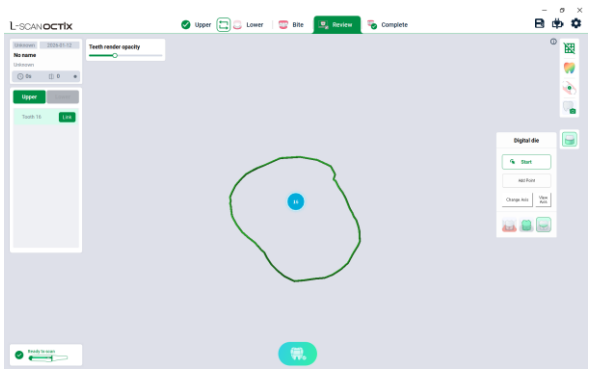
<Hide>	<Show>

Toggle the visibility of the digital die.



<Hide>	<Show>

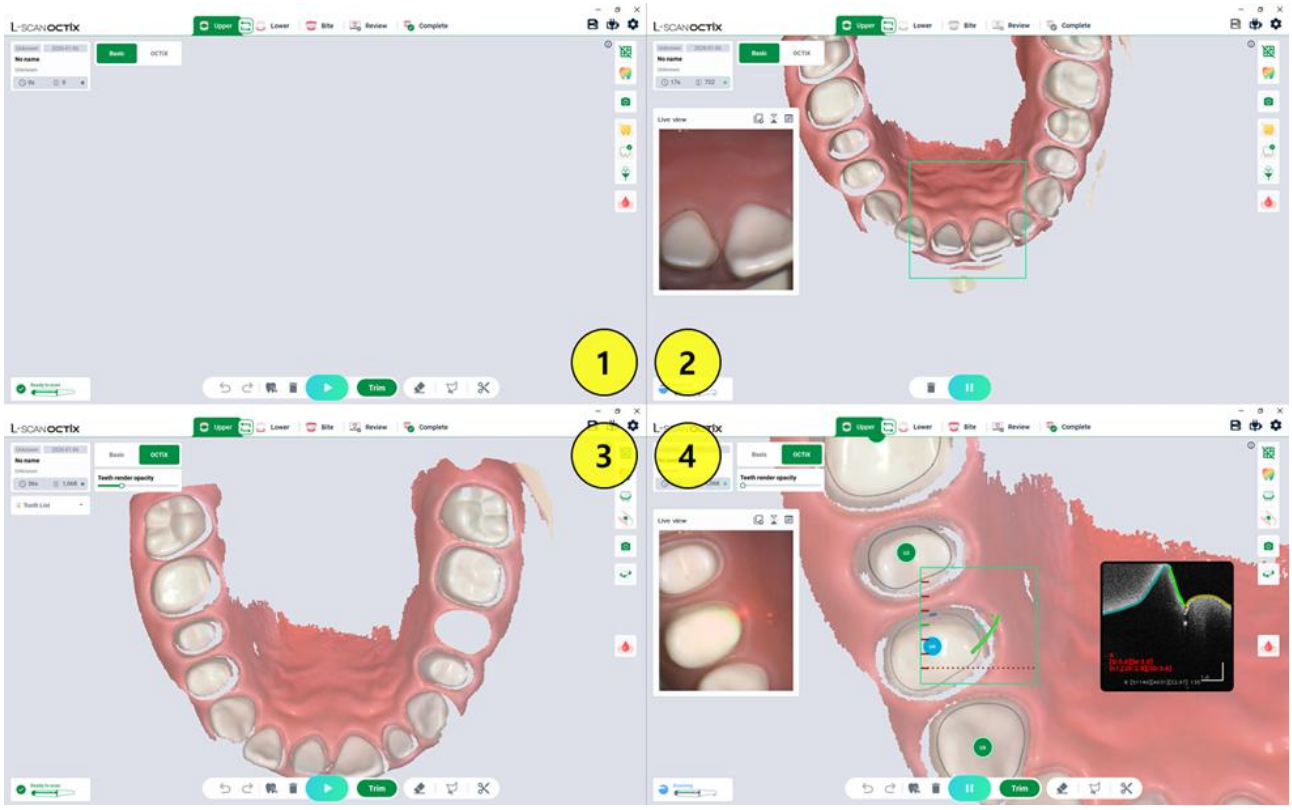
Toggle the visibility of the OCT margin line.

<table>
<tr><td colspan="2">
</td></tr>
<tr><td></td><td></td></tr>
<tr><td><Hide></td><td><Show></td></tr>
</table>

6.4.7 Scans

Acquires the 3D images of the pre-operation upper(maxilla), pre-operation (lower)mandible, upper, lower and bite, and also acquires OCT data.

The scan process is divided into four stages in total: IOS(Intra Oral Scan) Mode, IOS Scan Mode, OCT(Optical Coherence Tomography) Mode, and OCT Scan Mode.



Scan Mode		
1	Basic Mode	Basic Mode is the initial screen. It is the stage shown before starting the 3D scan and also the stage in which 3D data manipulation is performed.
2	Basic Scan Mode	Acquire 3D image pre-operation upper(maxilla), pre-operation (lower)mandible, upper
3	OCTiX Mode	It is the stage in which OCT scanning can be initiated or scanned OCT data can be manipulated.
4	OCTiX Scan Mode	OCT data are acquired.

6.4.7.1 Scan process

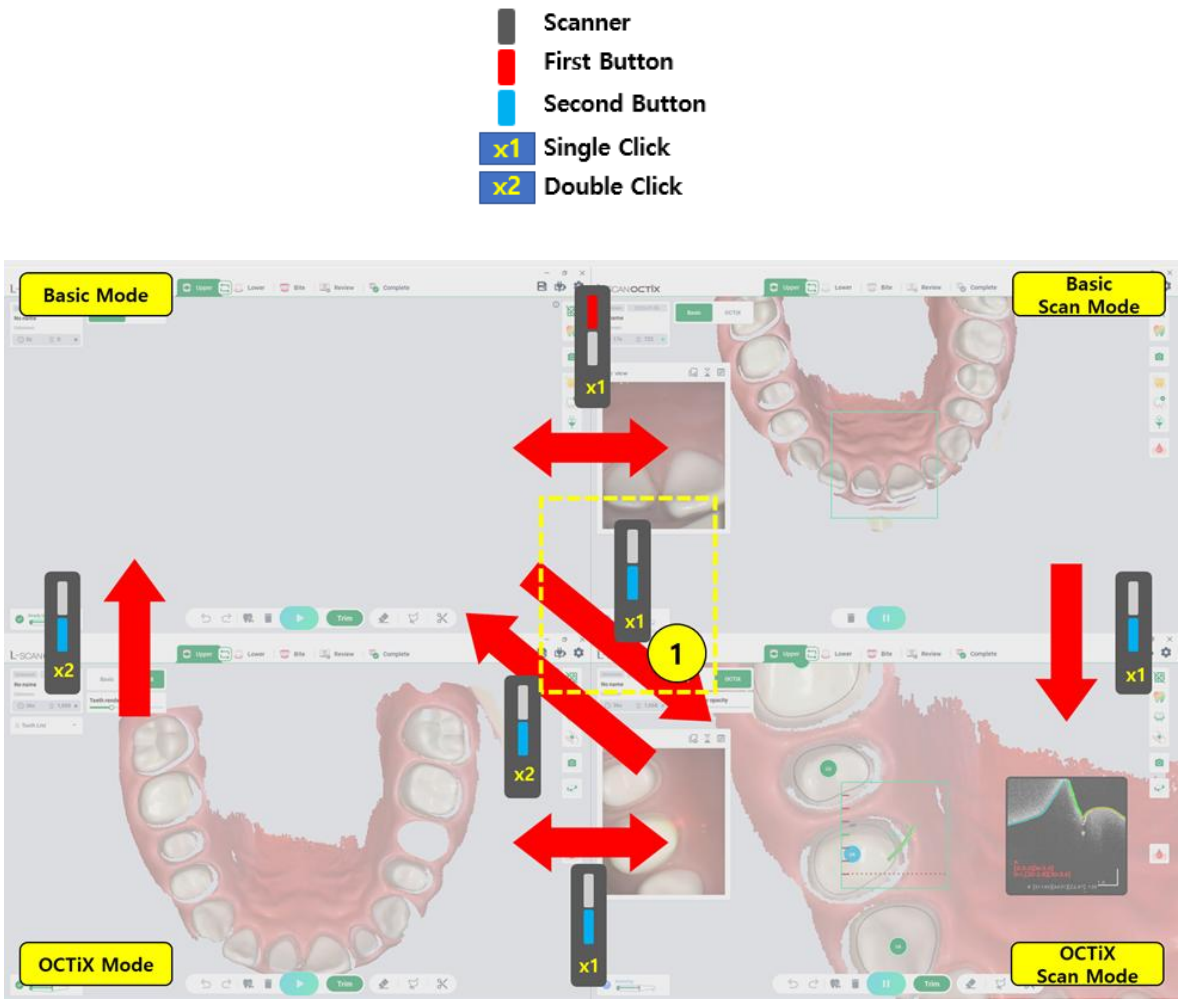
The most common scan process is as follows.

From IOS Mode, the system enters IOS Scan Mode. After acquiring intraoral 3D data, it proceeds to OCT Scan Mode. Once OCT imaging is completed, the system enters OCT Mode to review the scanned data.

The methods for changing modes to proceed with the process are as follows.

6.4.7.1.1 Mode change using scanner

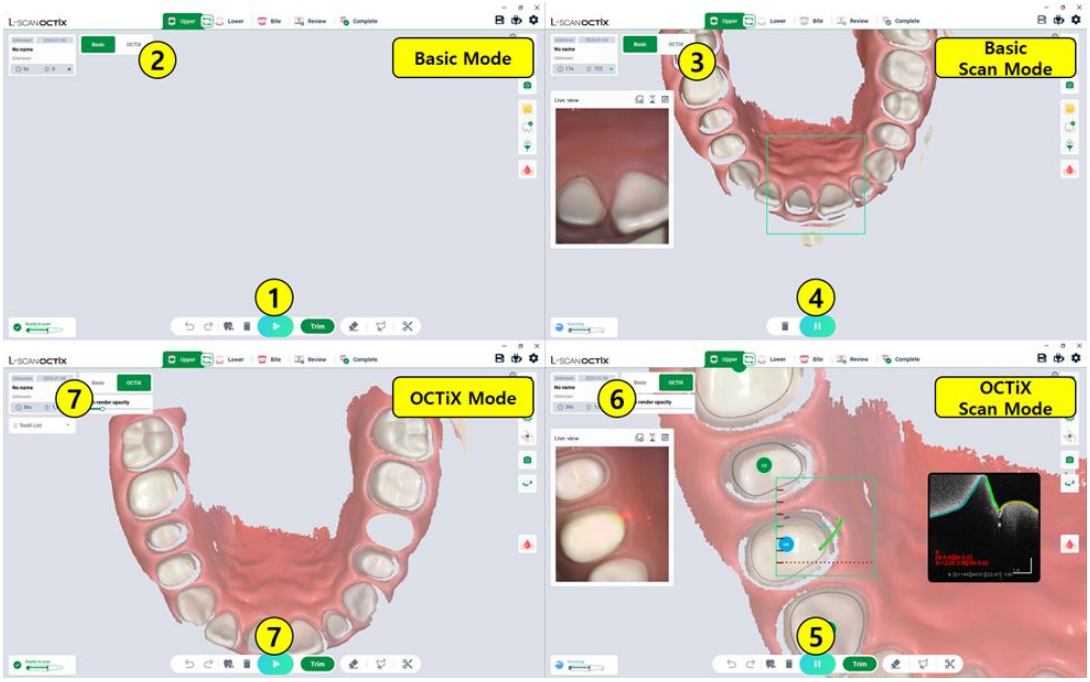
Explains how to change modes using the scanner button.



Additional explains		
1	Basic Mode to OCT Scan mode	This feature is only available when IOS scan data is provided.

6.4.7.1.2 Mode change using UI

Explains how to change modes using the UI button.



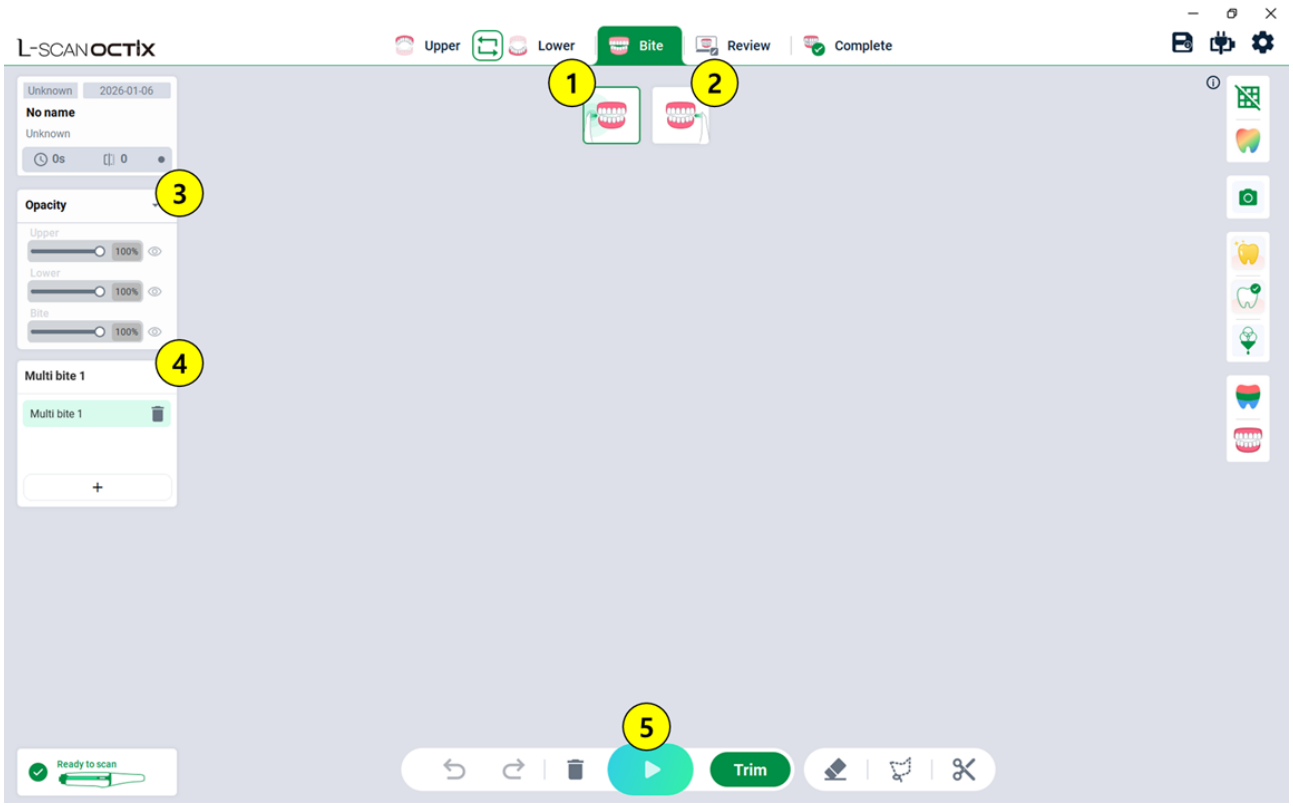
Scan Mode using UI Button		
1	Scan Start	Basic Scan Start
2	OCTiX Mode(1)	Change mode from Basic mode to OCTiX scan mode. 3D scan data is required.
3	OCTiX Mode(2)	Change mode from Basic scan mode to OCTiX scan mode.
4	Scan Stop	Basic Scan Stop
5	OCTiX Scan Stop	Stop the scanning process of OCTiX.
6	Basic Mode(1)	Change mode from OCTiX scan mode to Basic mode.
7	OCT Scan start	Start the scanning process of OCTiX.
8	Basic Mode(2)	Change mode from OCTiX mode to Basic mode.

6.4.7.1.3 Model Control in View Screen using Mouse

1	Left	Click	Starts selection or deletion of entities in view screen when using the polyline selection or polyline trimming tool.
		Double click	Double click model: Zoom in to the clicked point. Double click outside: Reset camera position.
		Drag	Selects or deletes entities in view screen when using the Brush selection or Brush trimming tool.
2	Wheel	Drag	Moves model in view screen.
		Scroll	Zooms in/out the model in view screen

3	Right	Click	Completes selection or deletion of entities in view screen when using the polyline selection or polyline trimming tool.
		Double click	Double click model: Zoom in to the clicked point. Double click outside: Reset camera position with rotation.
		Drag	Rotates model in view screen.

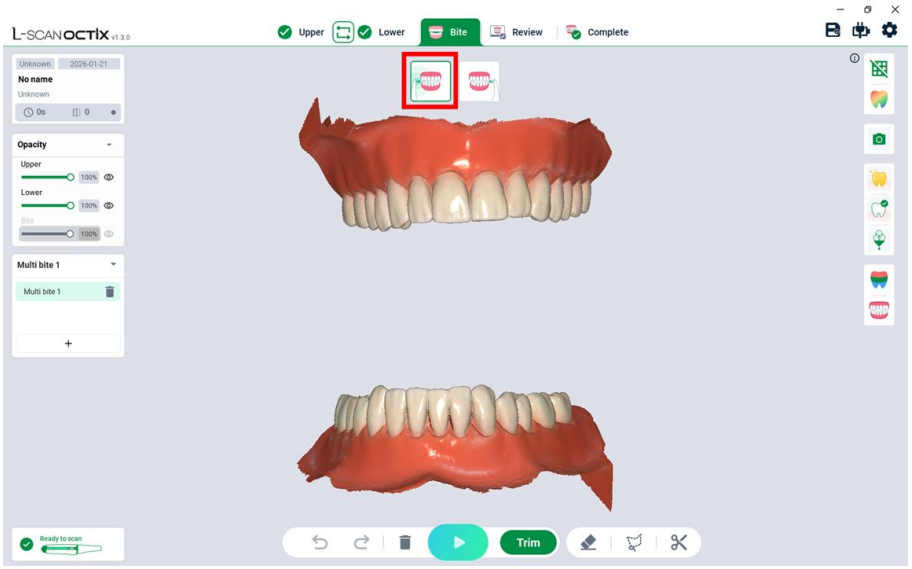
6.4.7.2 Bite

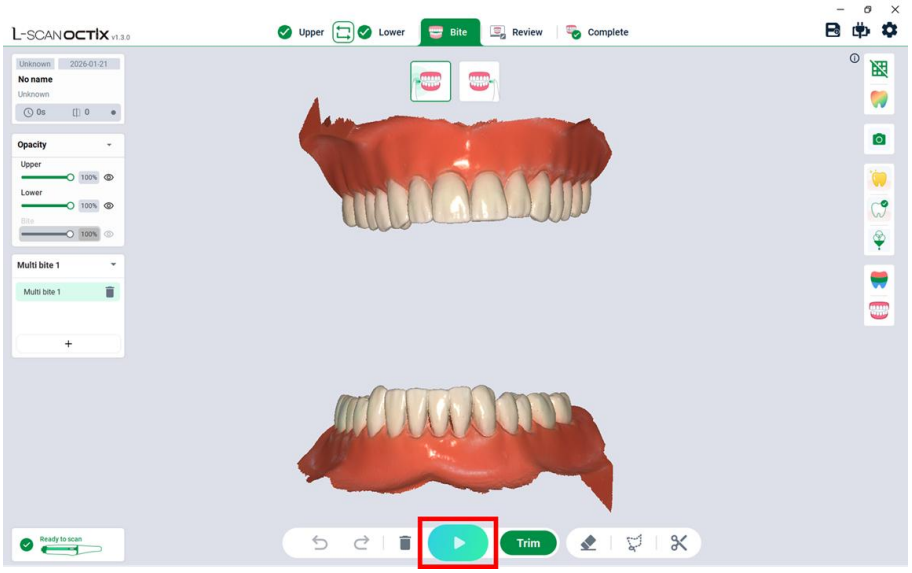


Scan Mode using UI Button		
1	Right bite	Start scanning from right
2	Left bite	Start scanning from left
3	Opacity dialog	Adjust the visibility and opacity of scan data.
4	Multi bite list	Manage multi bite data.
5	Start/Stop scan	Starts or stops the scanning process of bite.

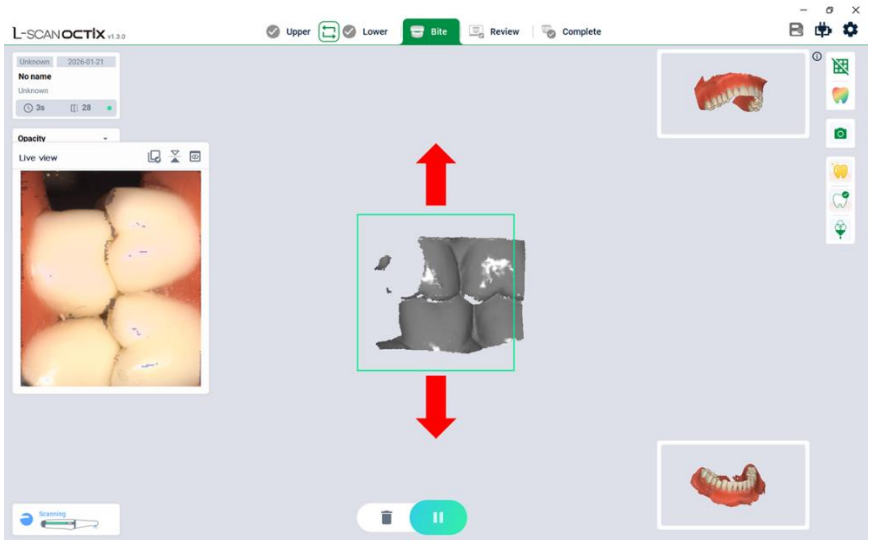
6.4.7.2.1 How to use

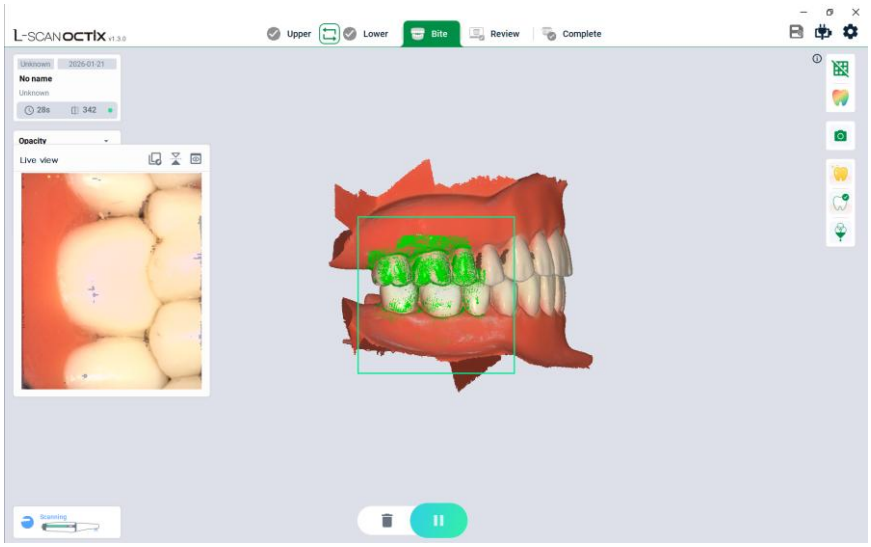
1. Taking scan data of the maxilla(upper) and mandible(lower).
2. Select the left bite scan and start scanning.



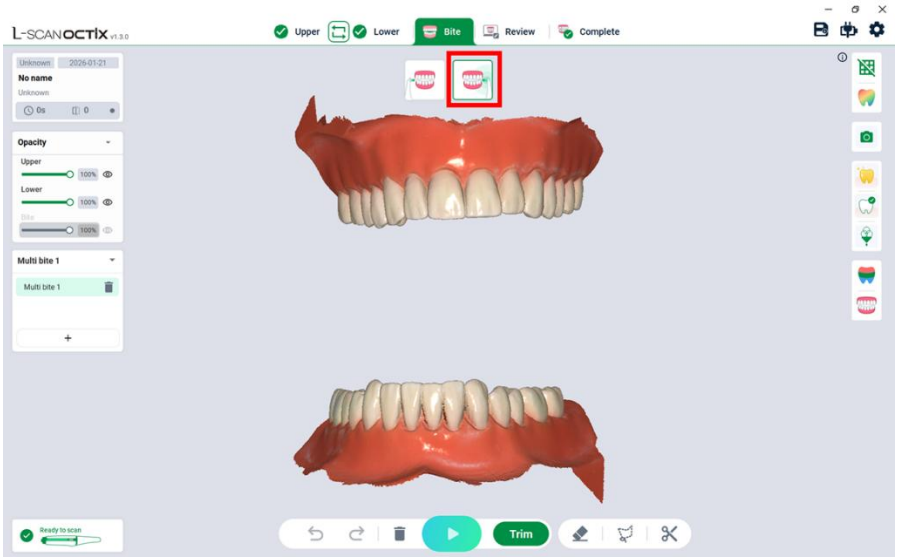


3. Scanning the left bite
    - Chrome(grey) color: If data appears in monochrome, it indicates that the bite data has not yet aligned with the upper and lower arch data. In this case, continue scanning by moving the scanner vertically to include more gingival tissue.
    - Green color: The green color signifies that the bite data has benn successfully aligned with the upper and lower arches. Once both arches are fully rendered, you may stop the scan.





4. Move to the right bite step. And repeat the process 3 for the right bite scan.

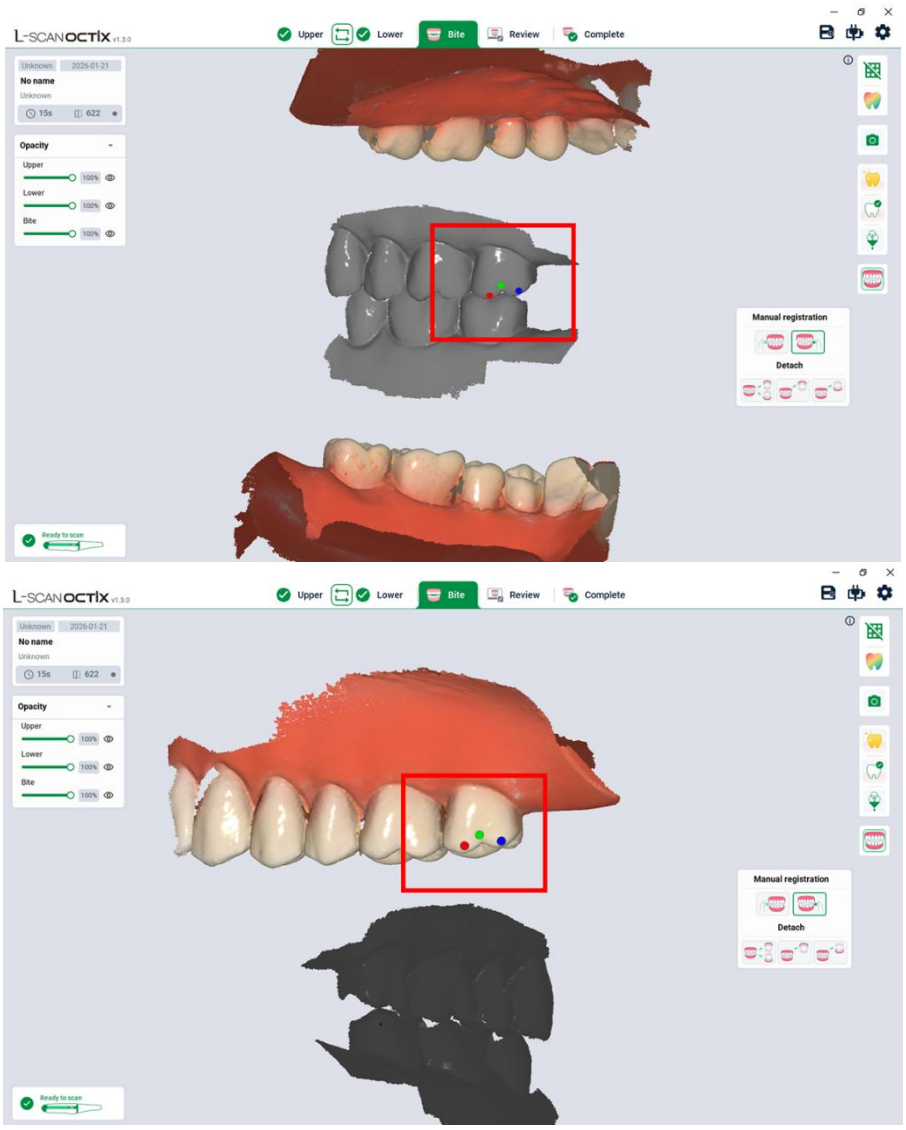


6.4.7.2.2 How to use manual registration

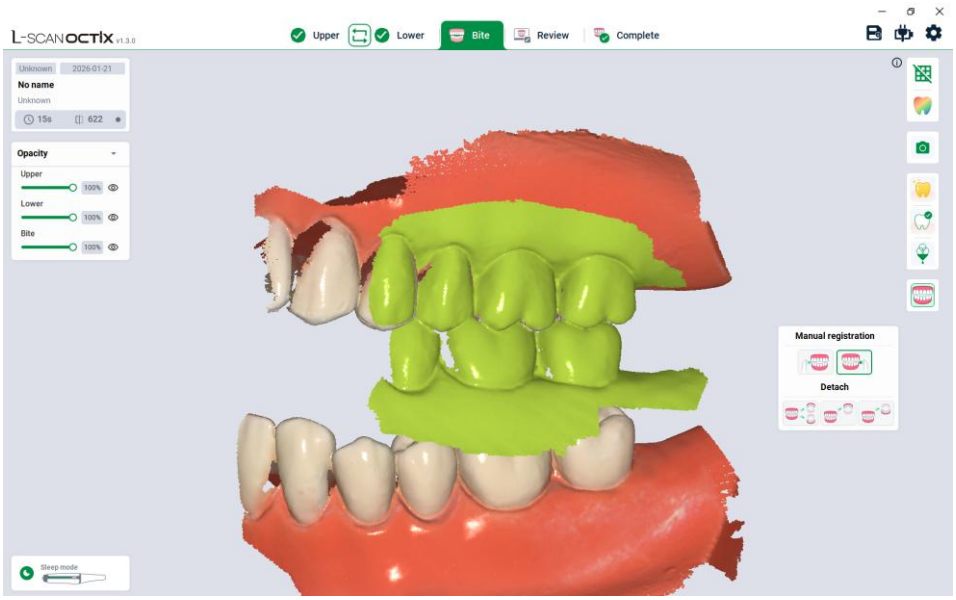
1. Click the manual registration button.
2. Click the detach button.
    - The bite scan data will be detached from upper and lower scan data.



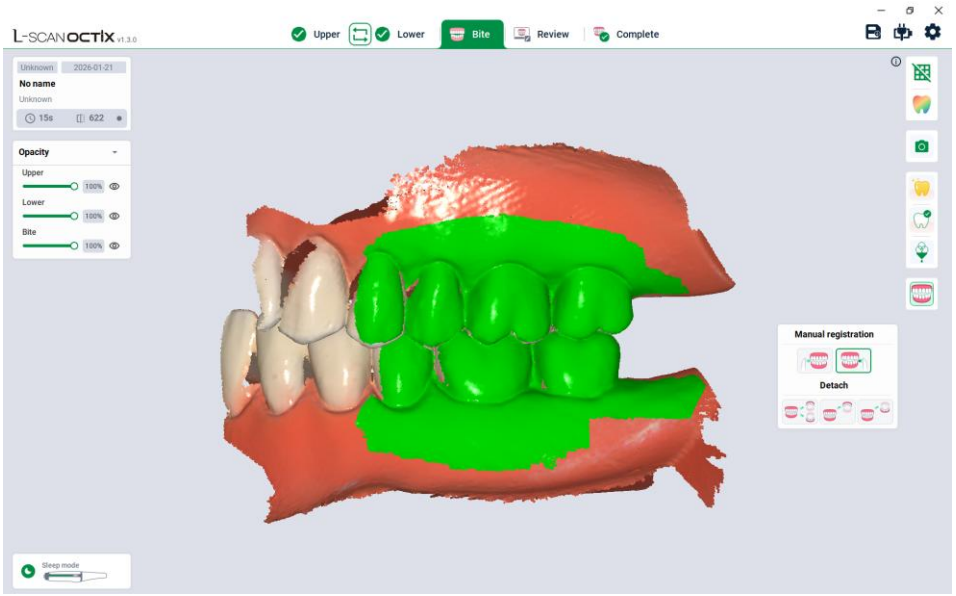
3. Select the locations for manual alignment between the upper/lower arch and the bite scan data.
    - Click to place up to three alignment points. The points will be generated in the following color roder; Red, Green, and Blue.
    - Click an existing point to delete it.



- The data sets will be aligned after the same number of points have been selected on each side.

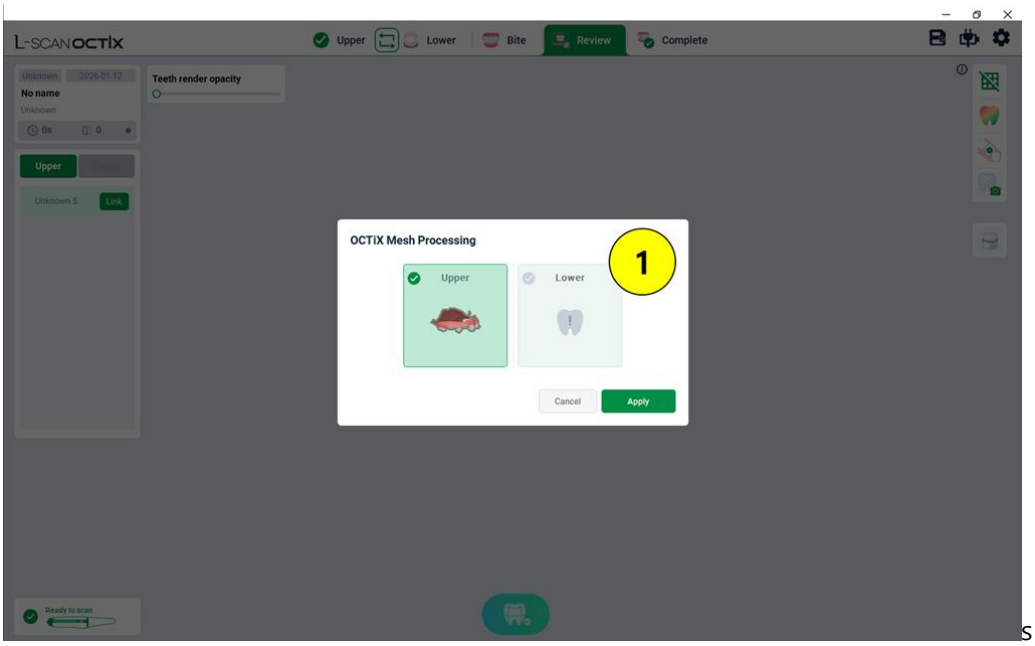


- Follow the same procedure to align the opposite.

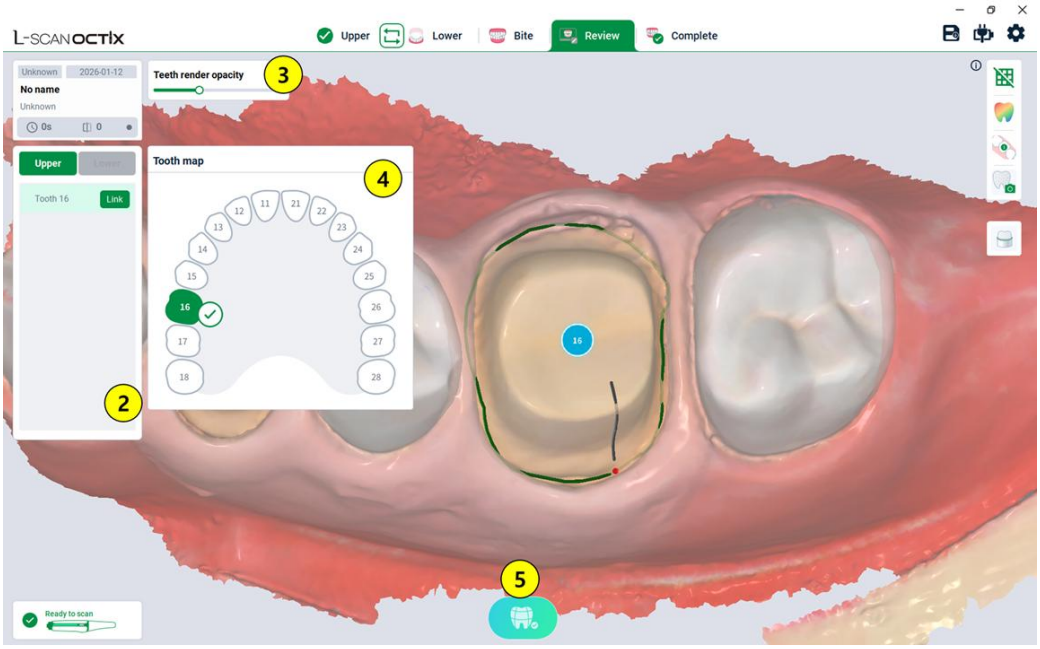


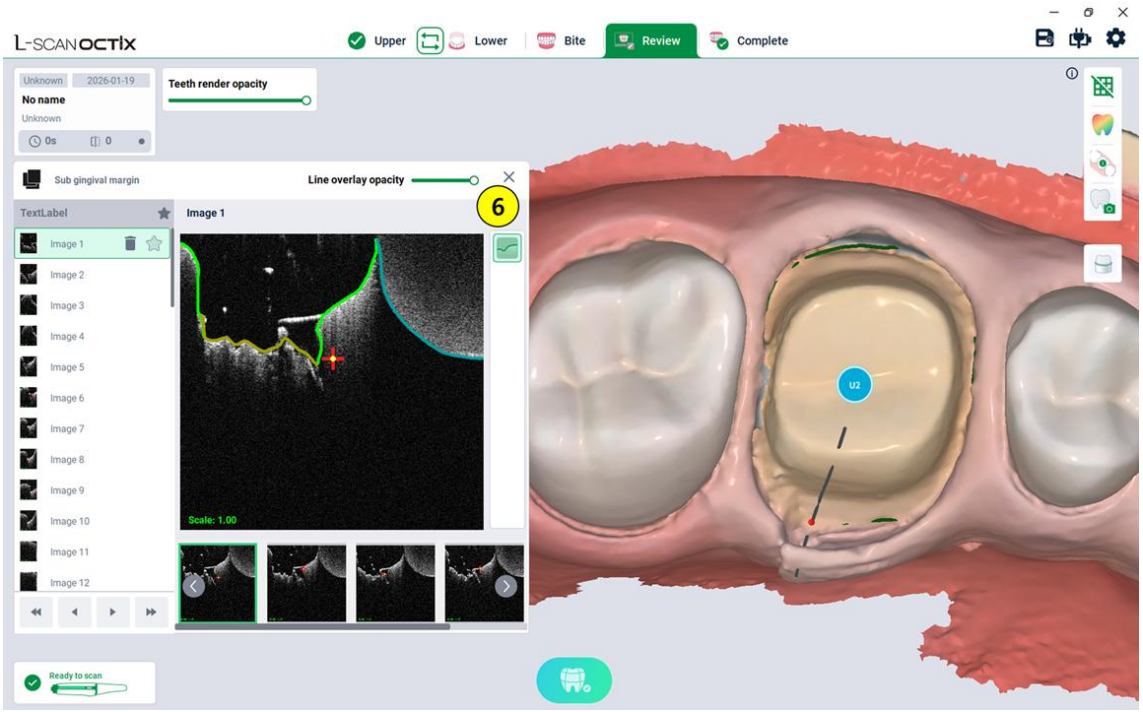
6.4.7.3 Review

In the review stage, high-precision meshes are generated using the 3D data acquired during the scan stage, and digital dies are created using margin points obtained from the OCT data.


L-SCANOCTIX
Upper
Lower
Bite
Review
Complete
Teeth render opacity
OCTiX Mesh Processing
Upper
Lower
1
Cancel
Apply
Ready to scan

S

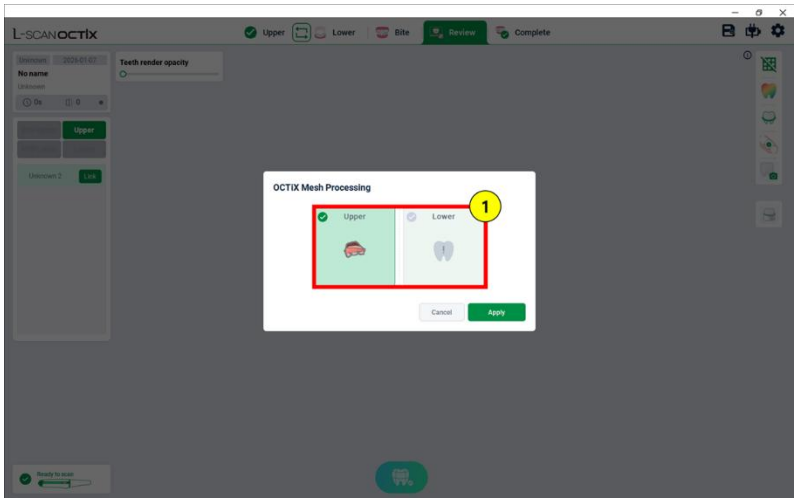

L-SCANOCTIX
Upper
Lower
Bite
Review
Complete
Teeth render opacity
3
Tooth map
4
Tooth 16
Link
2
5
Ready to scan



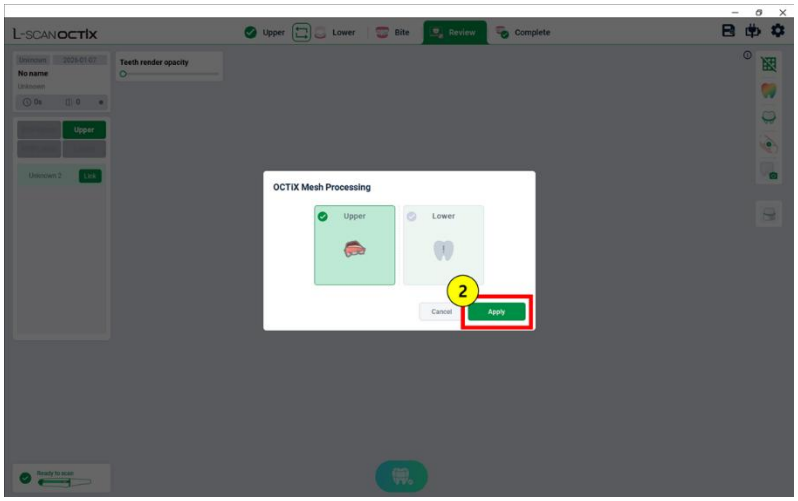
Review UI		
1	Mesh dialog	Select data to create a mesh.
2	Tooth list	Select the maxilla or mandible. Check the list of teeth for which OCT data has been acquired. Enter the tooth number.
3	Opacity dialog	Adjust the opacity of the teeth.
4	Tooth map	Link the acquired OCT data to a tooth number.
5	Mesh dialog button	Button to open the mesh dialog.
6	OCT image viewer	Review and edit the acquired OCT data.

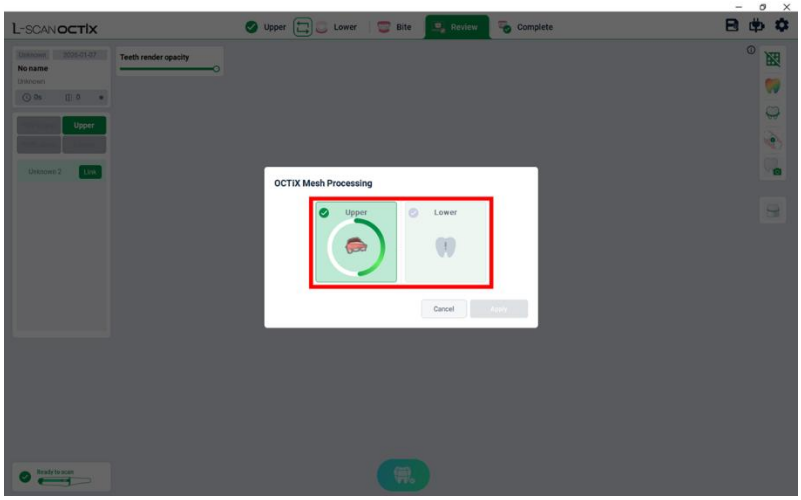
6.4.7.3.1 How to use

4. Select the target data to be created as mesh.



5. Click the apply button to generate the mesh.

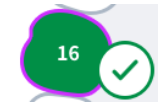




6. Click the LINK button from the list of tooth.

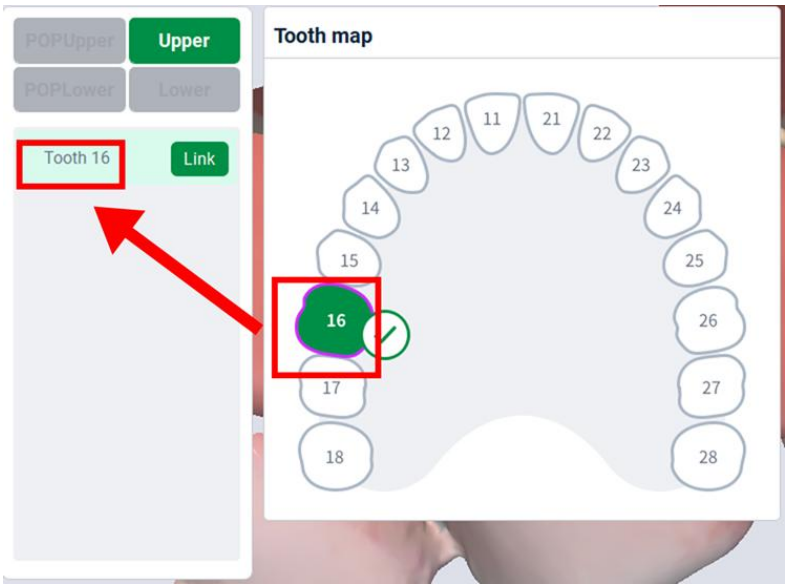


- 

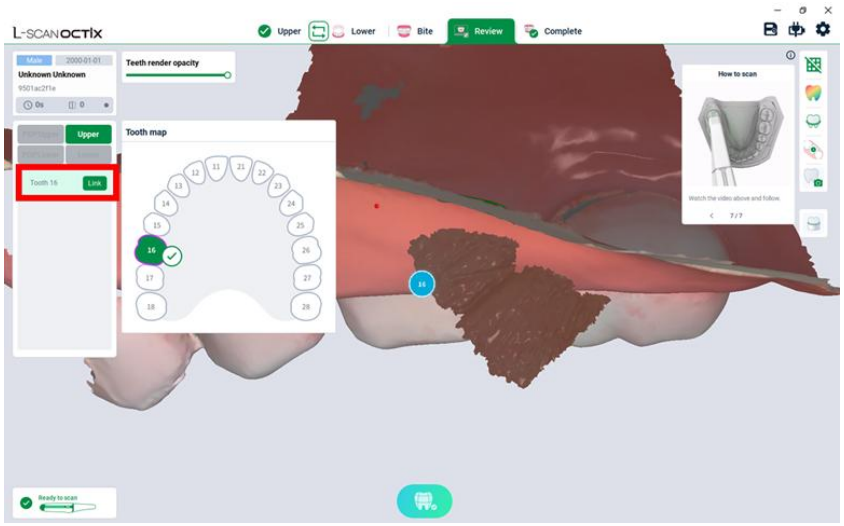
, This is the tooth selected in L-WORKS.
- 

, This indicates a tooth that has already been selected.
- 
, Click this button to reset the currently linked tooth number to an unknown state.

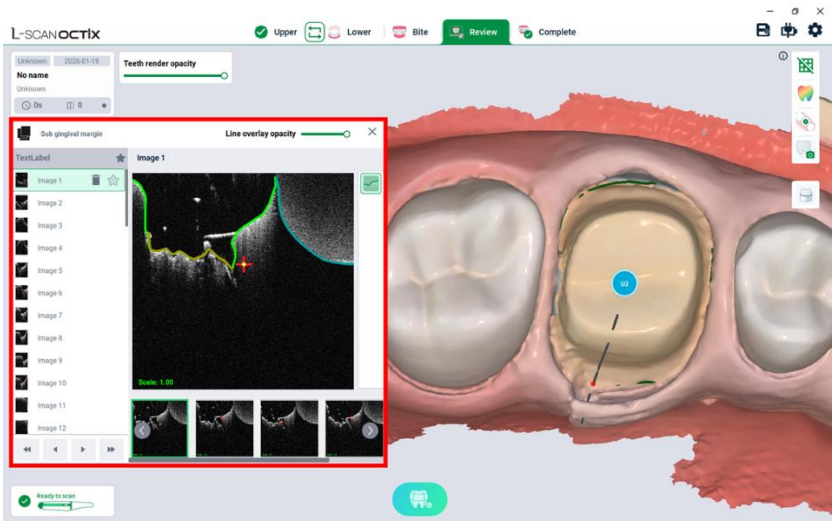
7. Select the appropriate tooth number to link it to the data.
   - Select tooth number.



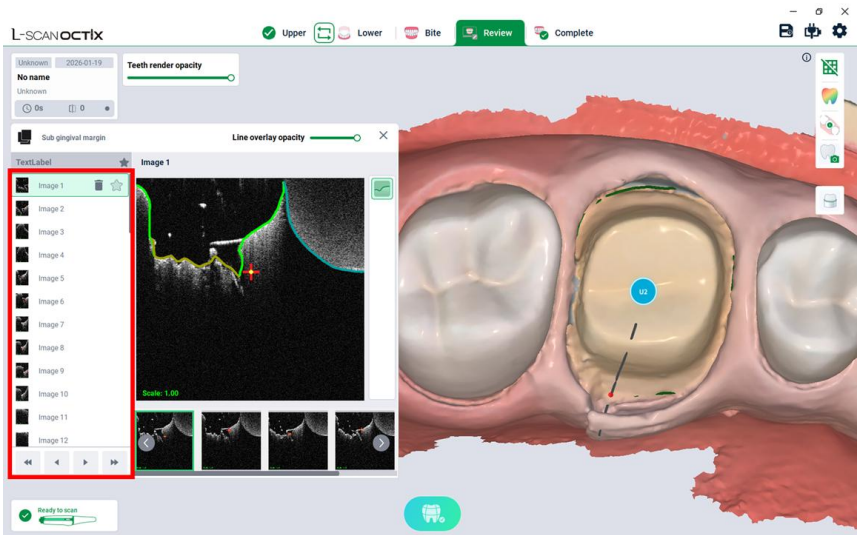
8. Select a tooth from the tooth list and edit the data.
    - Click the tooth to view the data.



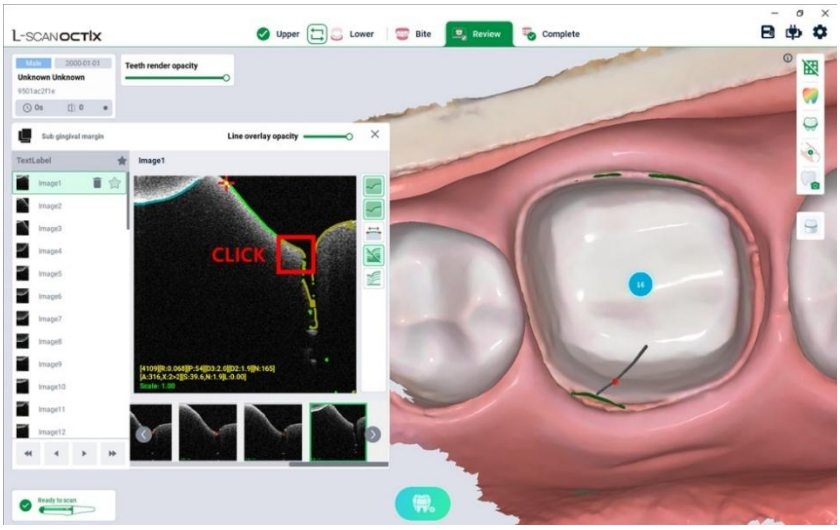
    - Then, the image viewer opens.



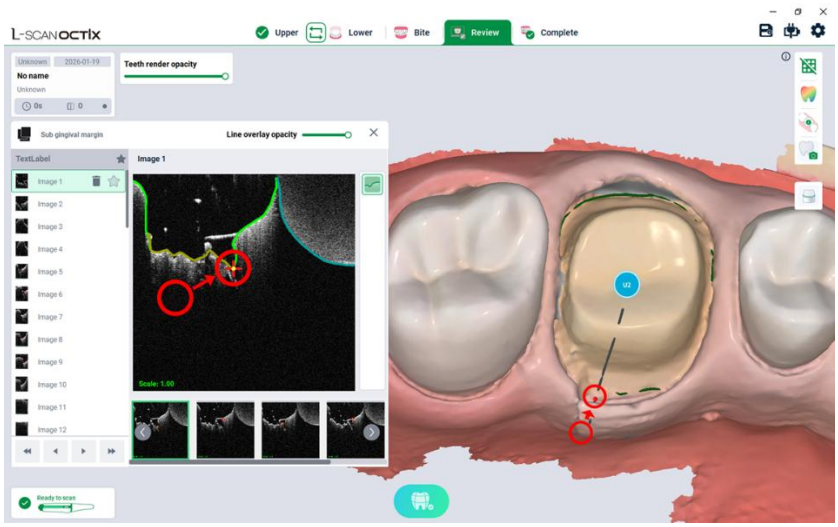
9. Edit margin line from image viewer.
    - Select the image set you want to edit.



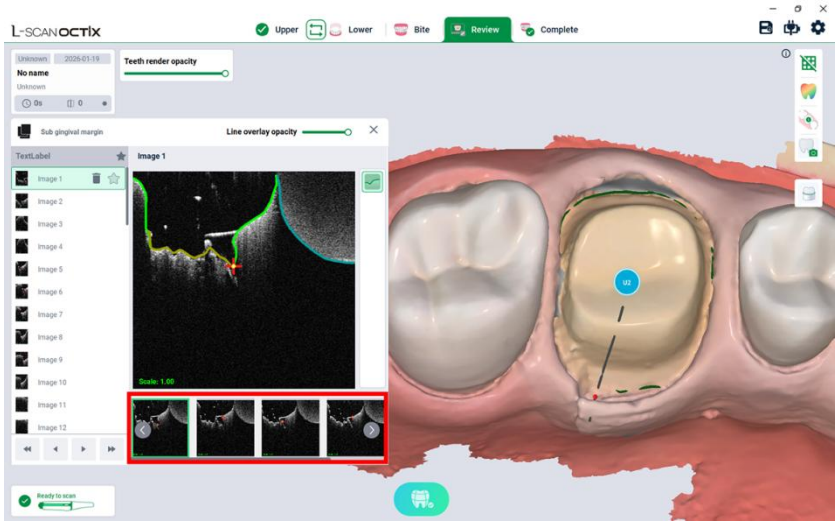
- Edit margin point in the OCT image.



- Then, the 2D and 3D margin points are recalculated and displayed on the image.

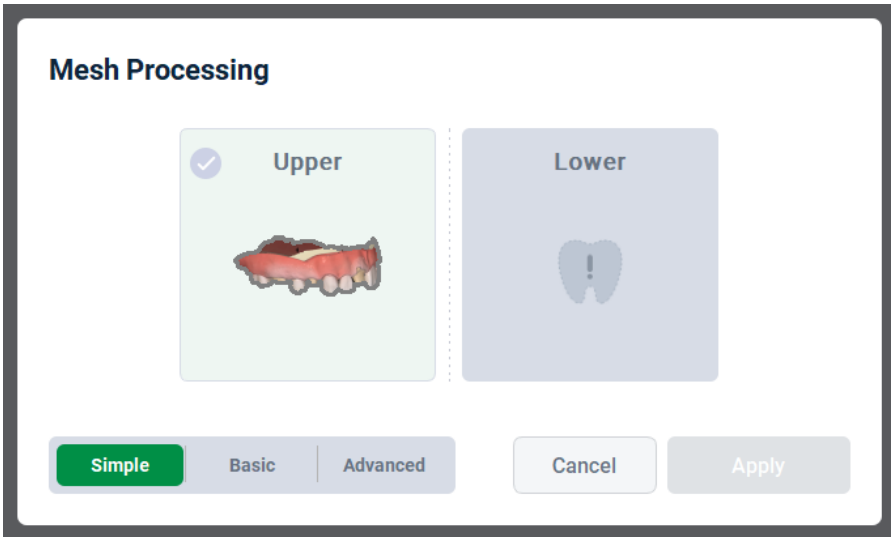


- Change the representative image used to generate the margin line in the image set.



6.4.7.4 Complete

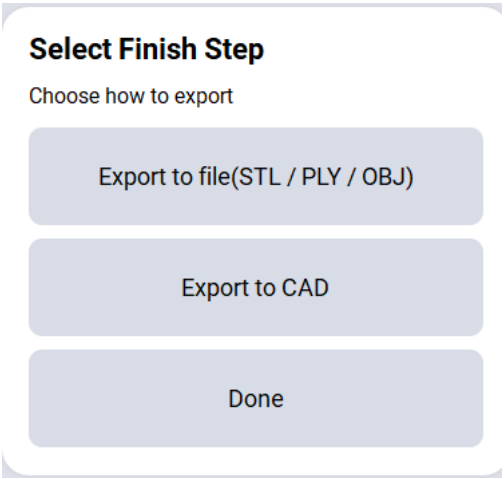
Completes the scanning process then generates the result data.



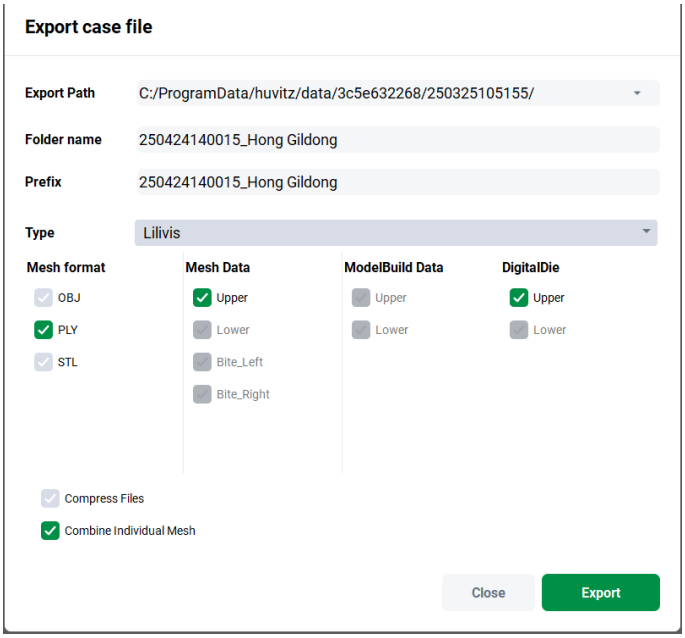
6.4.7.4.1 How to use

1. Select the scan data to be created as result data.
   - If scan data exists, it is automatically selected.
   - If result data exists, it is automatically released. Select to regenerate result data.
2. Choose the target reduction of result.
3. Select the option of filling in the blank space
4. Select the result of quality
5. Select the HD mode to use or not
6. Select the photo surface to view a photorealistic result
   - This option only increases the resolution of the visible image, not affect the actual data
7. Click “Apply” button.

6.4.7.5 Finish



6.5.7.5.1 Export to file



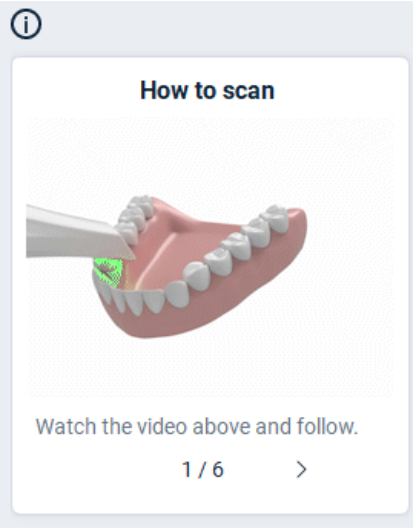
When a digital die is generated, the Digital Die item is activated in the Export window. The data for the step where the digital die exists will be enabled, and all digital die files present in the selected step will be generated.

6.5.7.5.2 Export to CAD

When you generate a digital die and select Export to CAD, the arch model, digital die model, and margin line data are sent to CAD.

6.4.7.6 Help

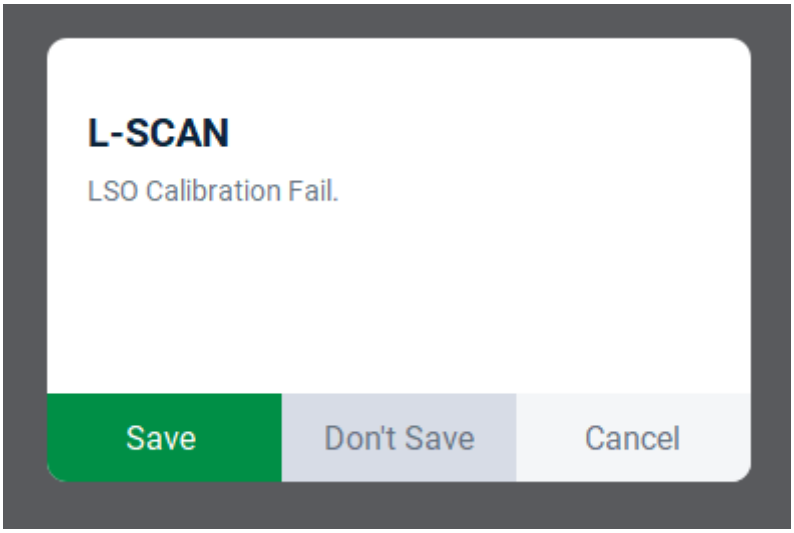
Provides help for efficient work tailored to each step or function operation. You can show/hide it by clicking the icon at the top.



6.4.7.7 Application Alarms

6.5.7.7.1 Calibration Fail

If the device calibration file is missing, the corresponding alarm occurs.



7. Maintenance

7.1 Sleeve Tip

The LSO-100 reusable tip is the part of the scanner that is inserted into the patient's mouth during scanning. The tip can be reused for a limited number of times, but it must be cleaned, disinfected and sterilized between patients to avoid cross-contamination. User must wear clean surgical gloves before start the cleaning and disinfection procedure.

7.1.1 Cleaning, Disinfection, and Sterilization

[Step 1]

- Dis-apart the scanner tip from the handpiece.
- Attach the handpiece cover to the front of the scanner.

[Step 2]

- Clean the tip manually using IPA (typically 70% Alc/Vol) tissues for 4 minutes.
- Clean the tip manually using soft cloth for 1 minutes thoroughly.
- Inspect the mirror and tip after cleaning.
- Repeat this procedure of step 2 at least two times

[Step 3]

- Dry the scanner tip thoroughly during 10 minutes including the mirror.
- If the mirror appears stained, smudged or has a milky haze, return to the step 2 process.

⚠ CAUTION

- The method of cleaning and disinfection must be manual as described in 7.1.1 not including automated cleaning/disinfection methods (e.g. automatic washer, ultrasonic cleaners, High-level disinfection).

7.1.2 Sterilization procedure

- User must proceed the cleaning and disinfection procedure before start this sterilization procedure.
- Prepare the scanner tip the cleaning and disinfection procedure completed.
- Put the tip in a paper sterilization pouch and seal it, making sure that it is airtight by using a self-adhesive pouch.

■



■ Sterilize the wrapped tip in an autoclave with the following conditions:

- Pre-vacuum cycle conditions

At 134℃ for a minimum of 4 minutes, Dry the sterilized tip for 20 minutes.
Use an autoclave program that dries the wrapped tip before opening the autoclave.

■ A number of wrapped and sterilized tips can be kept at a suitable place ready for use at your convenience. (Storage for sterilized scanner tip)

⚠ CAUTION

- Use the class B autoclave according to EN 13060 that utilizes a vacuum pump to completely remove air from the chamber, which enables steam to better penetrate the load. See the autoclave manual for more information such as specific sterilization pressure. (206kPa at 134℃ is recommended)
- User don't need to consider other information mentioned in this manual.
- The endotoxin limit of our device is less than 20 EU/Device according to USP<161> test for bacterial endotoxins.
- The mirror in the tip is a delicate optical component. It should be handled with care as its clean and undamaged surface is critical for scan quality. Be careful not to scratch or smudge it before scanning a patient.
- Never autoclave a tip that is not wrapped as this will leave stains on the mirror which cannot be removed.
- New tips must be cleaned and disinfected, sterilized according to manufacturer instructions.
- The scanner tip can be re-sterilized up to 150 times and must be disposed afterwards as described in the next section on Disposal.

7.1.3 Disposal

Please contact the manufacturer or distributor, if there is country-specific information on disposal.

⚠ CAUTION

- The scanner tip must be cleaned and disinfected, sterilized before disposal. Sterilize the tip as described in 7.1.2.
- Dispose the scanner tip as you would other clinical waste

7.2 In case of Device Failure

The LSO-100 reusable tip is the part of the scanner that is inserted into the patient's mouth during
If your LSO-100 system is not working properly, or if you suspect that there is a problem with the equipment:

- Remove the device from the patient and discontinue use immediately.
- Disconnect the device from the PC and check for errors.
- Contact the manufacturer or distributor.
- LSO-100 system should not be dismantled arbitrarily.
- Damage due to careless handling This product is a precision optical device. Damage or malfunction caused by user negligence, such as dropping or external shock, is not covered by the warranty. In such cases, repair or replacement will be processed as a paid service.

⚠ CAUTION

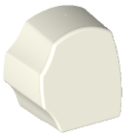
If the laser emission is not operated properly (Eg. Not intended condition), this error is displayed on the software.

'SLD is not operating in pulse mode, needs to be checked.'

8

Specifications and Accessories

8.1. Standard Accessories

No.	Item	Qty	Description
1	LSO-100 Handpiece	1EA	
2	LSO-100 Main Unit	1EA	
3	Handpiece Cover	1EA	
4	Wall Mount Holder	1EA	
5	USB 3.0 Cable (Micro B to A)	1EA	
6	USB 3.0 Cable (B to A)	1EA	

7	Medical Adapter	1EA	
8	Power Cord	1EA	

8.2. Optional products

1	Calibration Tool	1EA	
2	LSO-100-TIP-NORMAL	3EA	
3	LSO-100-TIP-SMALL	3EA	

8.3. Specifications

Device specifications	
Type	Intraoral optical scanning system
Model name	LSO-100
Rating	24Vdc, 3.75A, 90W
Performance	
Field of View (LSO-100-TIP-NORMAL)	Min 15mm x 17mm
Field of View (LSO-100-TIP-SMALL)	Min 14mm x 11mm
Depth of Field	Max 22mm
DC Adapter	
Model name	MDS-090AAS24 B
Input Voltage	100-240Vac
Output	24 Vdc
Rated output current	3.75A
Case dimension	60 x 150 x 35 [mm] (W x D x H)
Handpiece	
Dimension	275 x 42 x 58 [mm] (W x D x H)
Weight	310g
Applied part	Type B
Imaging	
HD Video	3D in motion video
Real Color	3D full color streaming
Scanner Tip (LSO-100-TIP-NORMAL)	
Tip Size	35 x 44 x 102 [mm] (W x D x H)
Scanning window Size	18 x 21 [mm]
Autoclavable times	150 times per tip
Scanner Tip (LSO-100-TIP-SMALL)	
Tip Size	35 x 44 x 102 [mm] (W x D x H)
Scanning window Size	18 x 15 [mm]
Autoclavable times	150 times per tip
Control BOX	
Dimension	490 x 363 x 100 mm
Weight	10 Kg

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EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

  LSO-100 should be used in the below mentioned electromagnetic wave environment. LSO-100 purchaser or user needs to confirm whether LSO-100 is used in this type of environment.

Trouble test	Question of appropriateness
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker IEC 61000-3-3	Complies

- **Electromagnetic waves tolerance**

  LSO-100 is to be used in the below designated electromagnetic wave environment. LSO-100 customer and user need to guarantee that the LSO-100 will be used in this type of environment.

Tolerance test	IEC 60601 test level	Appropriateness level
Electrostatic discharge(ESD) IEC 61000－4－2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 15 kV air
Electric rapid transients/bust IEC 61000－4－4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency
Surge IEC 61000－4－5	±0.5 kV, ±1 kV	±1 kV
Voltage dip, instantaneous interruption, voltage fluctuation at the power input line IEC 61000－4－11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Power frequency magnetic field (50/60 Hz) IEC 61000－4－8	30 A/m	30 A/m
Other UT is the a.c. power voltage for before approving the test level.		

- **Electromagnetic waves tolerance**

  LSO-100 is to be used in the below mentioned electromagnetic wave environment. LSO-100 purchaser or user needs to confirm whether LSO-100 is sued at this environment.

Tolerance test	IEC 60601 test conditions	Appropriateness level
Conductivity RF electromagnetic field IEC 61000 – 4 – 6	3 V 0,15 MHz–80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz–80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radioactivity RF electromagnetic field tolerance IEC 61000 – 4 – 3	3V/m 80Mhz-2.7 GHz 80% AM at 1 kHz	3V/m 80Mhz-2.8 GHz 80% AM at 1 kHz

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SERVICE INFORMATION

Repair: If the problem is not solved in spite of the settlement according to the contents of chapter 7, please contact to the agent with the information on the following items.

1.1 Name of device Type: LSO-100
1.2 Typical No.of Device : Typical number consisted of 8 digits and characters written on its name plate.
1.3 Explanation on its symptom: Description in detail.

Supply of parts required for repair:

1.4 The preservation period of parts required for repair of this machine is by seven(7) years after stopping to produce the product.

Parts to be repaired by qualified service manpower:

1.5 Parts below are consumable in their characteristics, or the quality of them shall degraded after the long time use. User should not replace them by him or herself. Please contact to agent for the replacement if these parts are consumed enough or degraded by the longtime use.