ENG

Intraoral Scanner

LS-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

Revision	Date	Approval	Description
A	2023.02.05	정 관 영	First issued
B	2024.02.05	정 관 영	Updated the information of accessories Added Lilivis Works user interface Added L-Scan user interface
C	2024.08.14	정 관 영	Added L-Scan updated smart scan functions, user interfaces
D	2025.11.05	정 관 영	Updated cleaning method for Handpiece & Cradle Updated the calibration tool as optional product Updated the description for setting with Instrument Table CIT-4100 Updated scanner tip model LS-100-TIP-3S Updated L-Scan user interface.
E	2026.06.23	정 관 영	Added Lilivis HUB cloud system

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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.

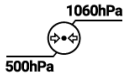
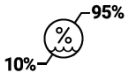
Be sure to read this information to avoid operating the device incorrectly.

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

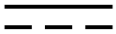
2

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.)

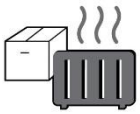
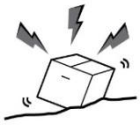
	QR code (QR code)
	Alternating Current (Courant alternative)
	DC current
	Protective earth
	Consult instructions for use (Consulter les instructions d'utilisation)
CE RoHS	CE for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
MD	To indicate this product is Medical device (Pour indiquer que ce produit est un dispositif medical)
CH REP	Authorized representative in Switzerland (Représentant autorisé dans la Suisse)
SN	SN Marking
Rx only	RX Only
UDI	UDI Symbol

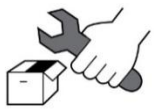
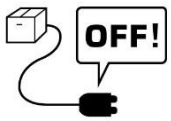
2.1. Usage Precautions

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 30% ~ 75% (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 LS-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 LS-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 handpiece.

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

21. Avoid pulling on the communication cables, power cables used in LS-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 LS-100 detecting cybersecurity treats, the user shall report it to the manufacturer and the competent authority of the Member State (Section 10. - Contact information)

Paper IFU shall be provided free of charge within 7 calendar days after receipt of the user's request, or at the time of device delivery if requested at the time of order.

2.4. Preface

1. This manual is valid for the L-Scan 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 LS-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(LS-100) is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. LS-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 I

3.7. Residual Risk

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

3.8. Operating Principles

3.8.1 Operating Principle

This device LS-100 that works with the supplied image acquisition software. Input Power Adapter receives 100 ~ 240VAC input and supplies stable 12V DC power to the handpiece of LS-100. This device connects to the desktop or Laptop with USB 3.1 cable and can be used in combination with installed image acquisition software. Intraoral scanner ‘LS-100’ makes the pattern image through the inner projector and camera with high-resolution and three-dimensional 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 LS-100 are the engine of Digital Light Processing(DLP) for 3D scans and coated lens (mirror), RGB LED. The LS-100 has the high resolution and accuracy about ≤ 70um.

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 10993-1:2025 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

4

Component Overview

4.1. Configuration

LS-100 Components Overview



5

Set-up Procedure

5.1. Basic Setting

1. Connect the USB cable (C to C) to the Handpiece



2. Connect the other end of the USB cable (C to C) to the PD hub



3. Connect the power cord to PD Hub.



4. Connect the USB-C cable (C to A) to the PD hub.

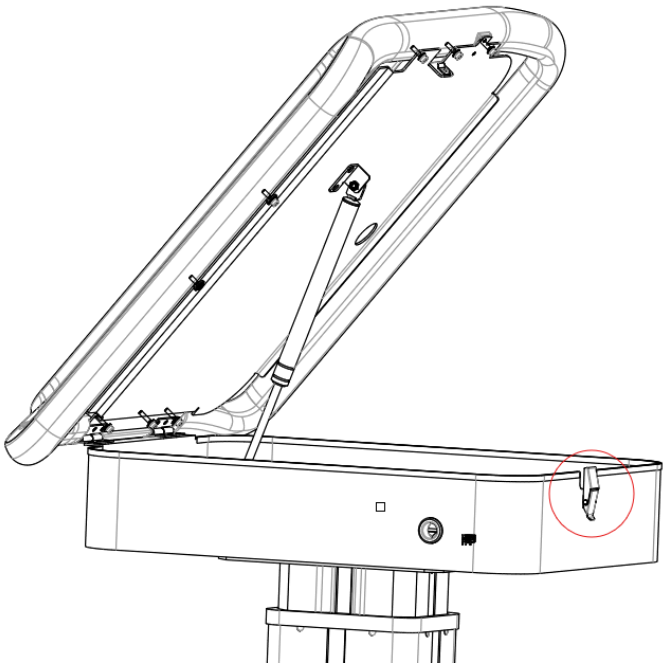


5. Connect the USB-A cable (C to A) to the PC.

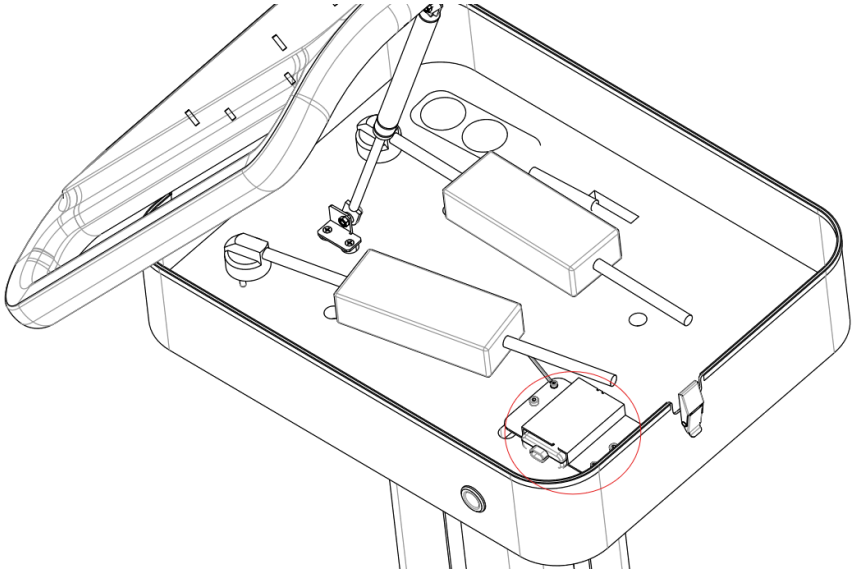


5.2. Setting with CIT-4100 Instrument Table

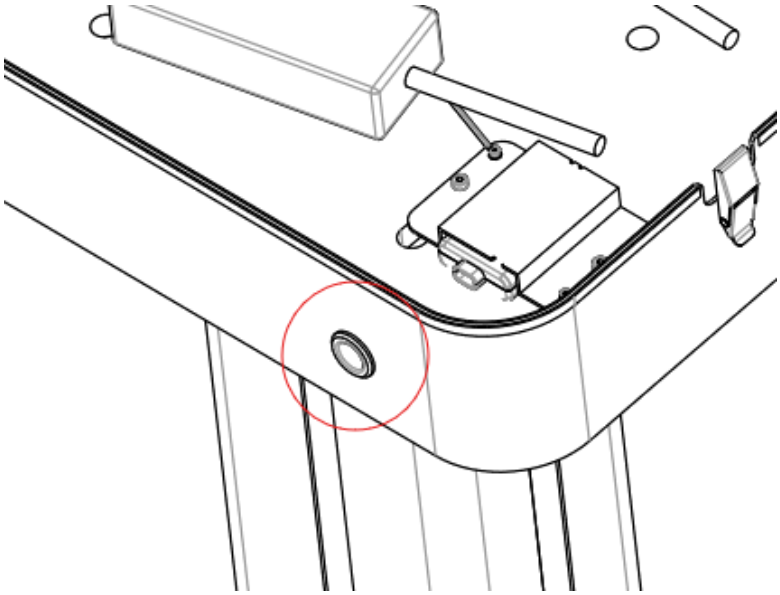
1. Release the latch and open the top panel.



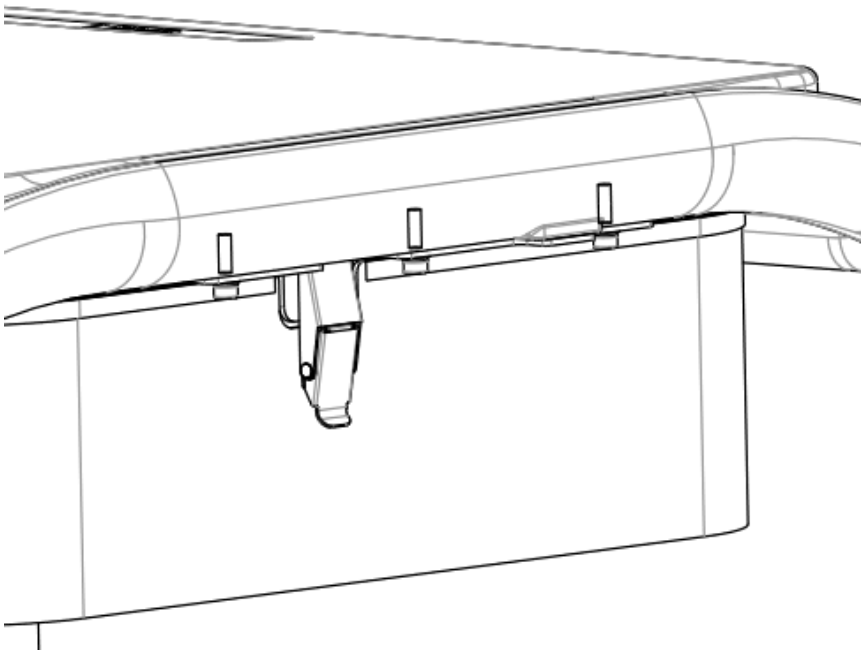
2. As shown in the picture, place the adapter and various cables in the space. At this time, place the PD HUB in the designated lacation.



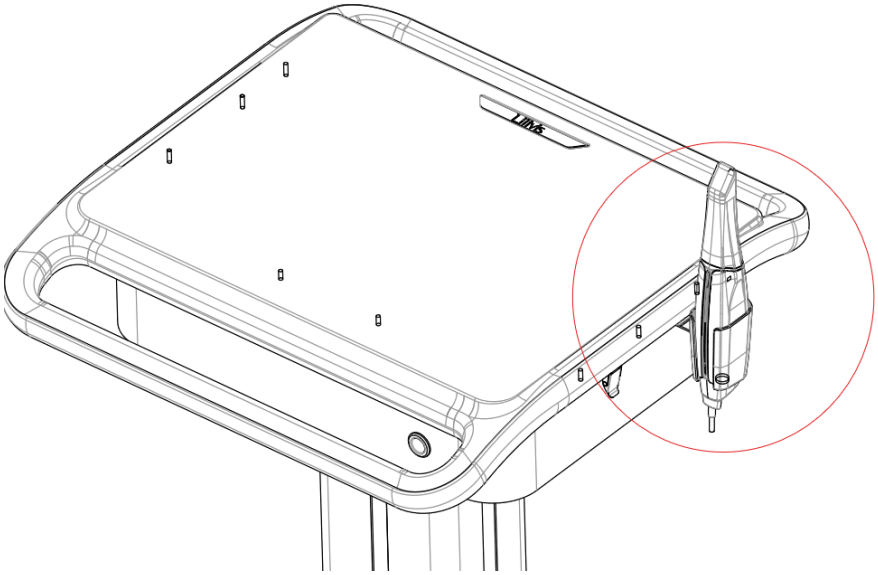
3. The c-c cable connected to the PD HUB come out through the hole in the front.



4. After all the components are placed, lock the top plate with the latch.



5. After assembling the provided cradle as shown in the picture, mount the scanner.



6. For detailed table usage, please refer to the CIT-4100 manual.

5.3. Desk-Top Cradle



6

Software

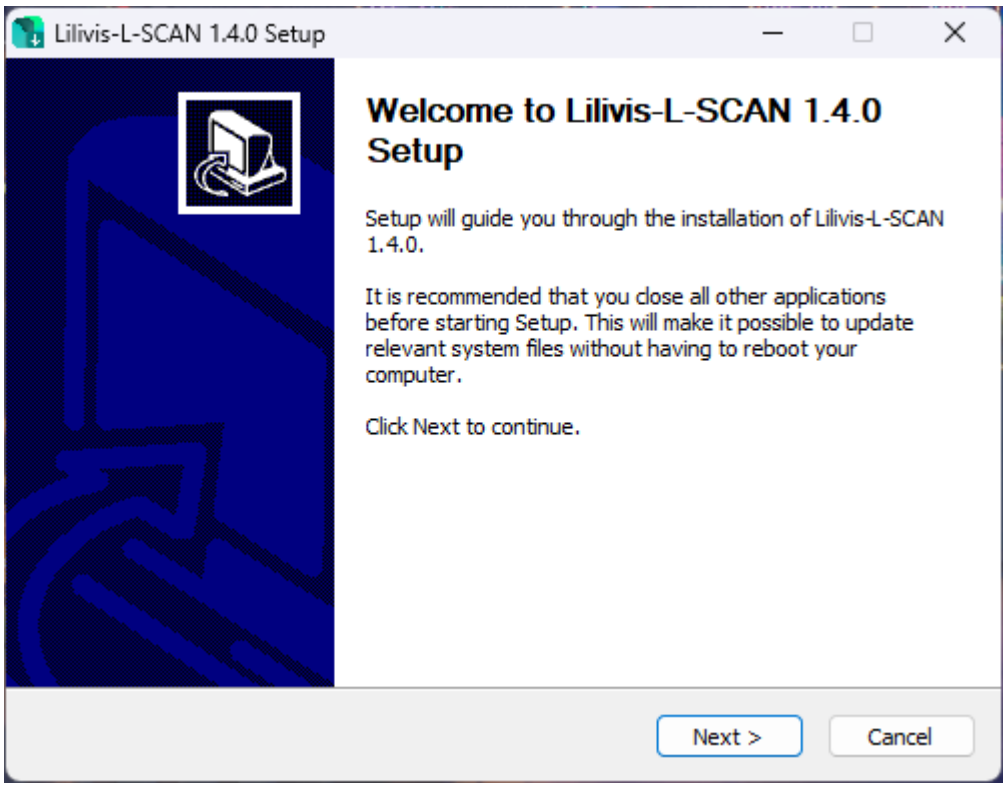
6.1. Overview

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

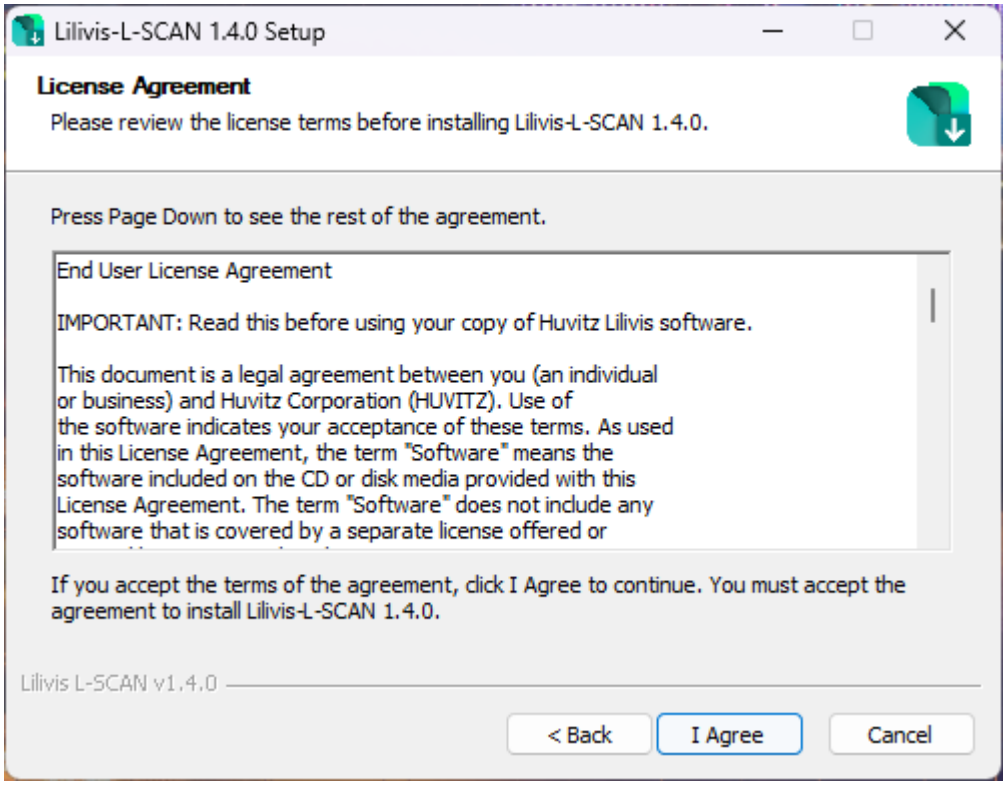
The image acquisition software (L-Scan) provides a user-friendly working interface to digitally record topographical characteristics of teeth and surrounding tissues using Intraoral scanner LS-100.

6.2. Installation Procedure

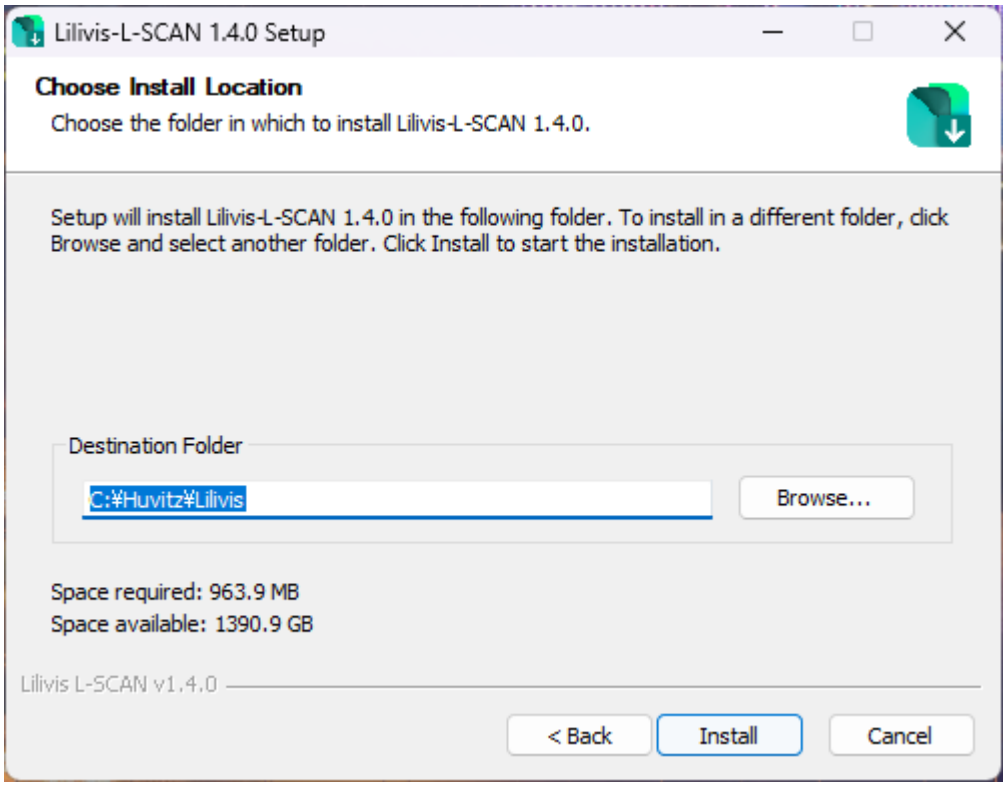
1. Run L-Scan.exe
2. Click next button.



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

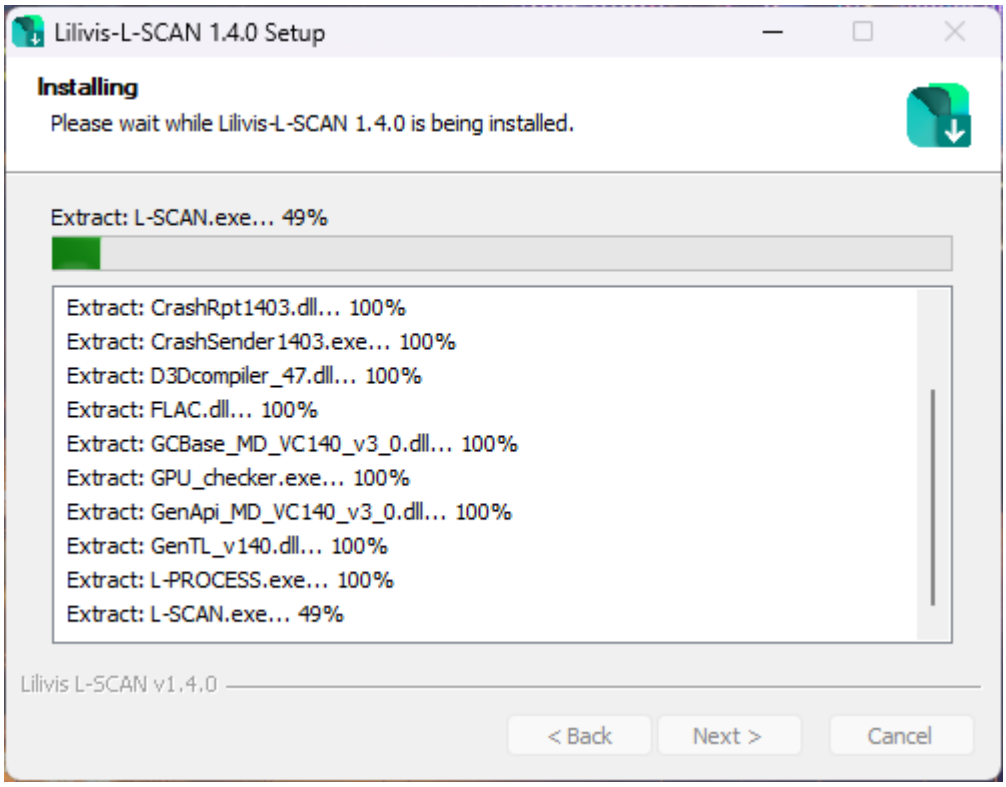


4. Select the installation Path

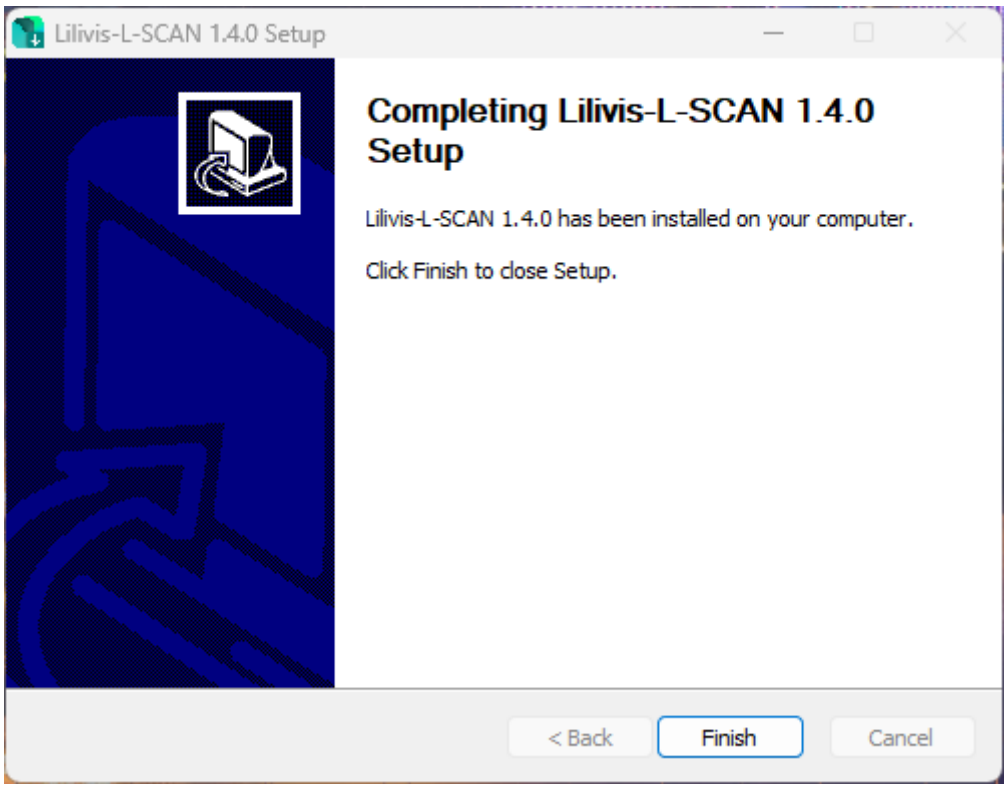


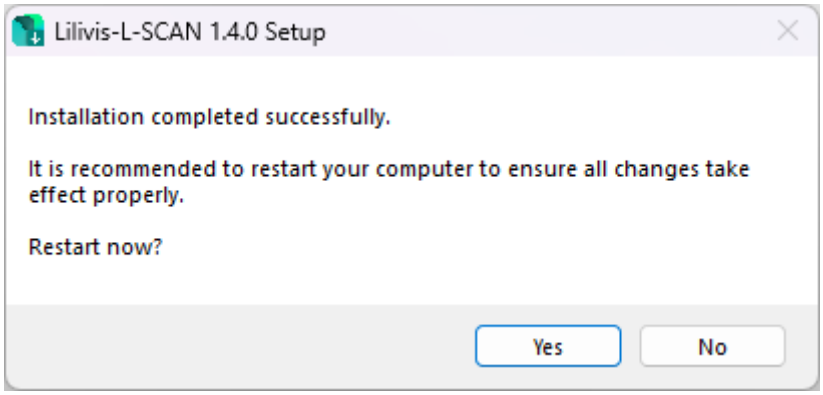
5. If the scanner is connected, please disconnect the scanner from the PC by removing USB cable.

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.

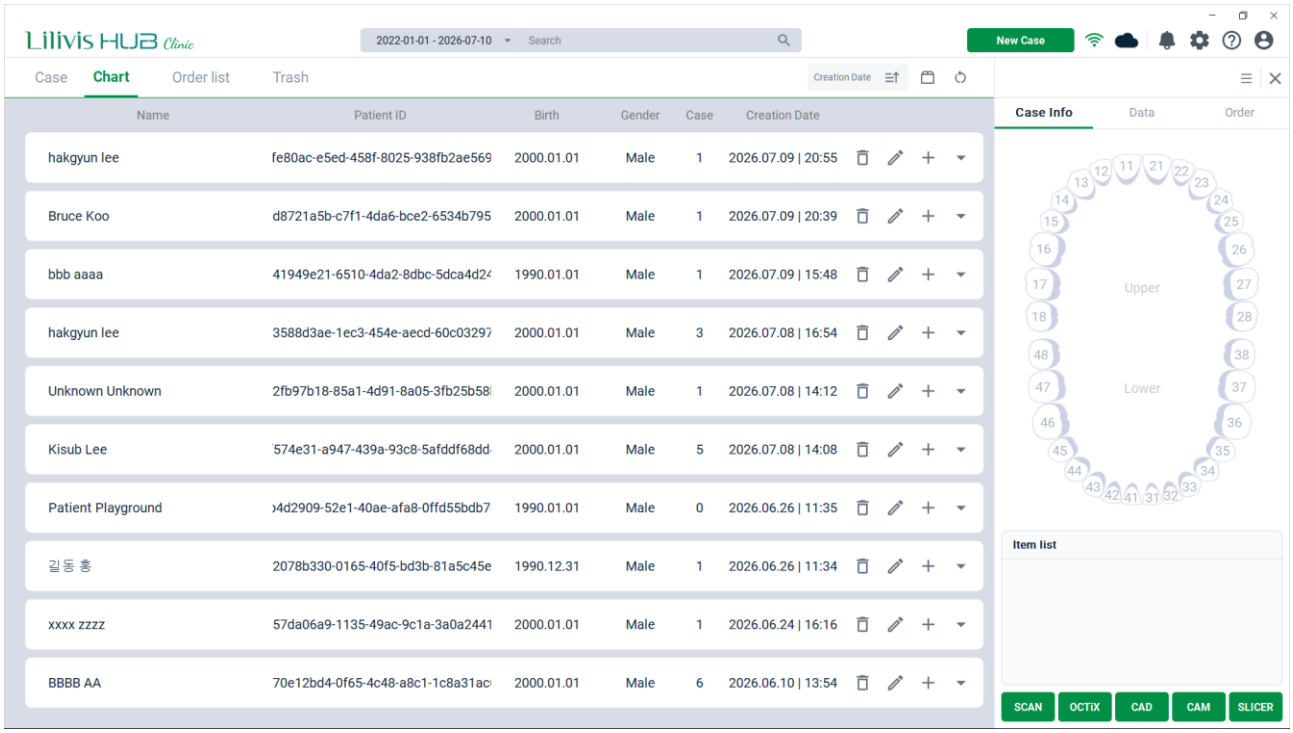


7. After installation is completed, we recommend restarting the PC to ensure optimal program operation.


Lilivis-L-SCAN 1.4.0 Setup
Completing Lilivis-L-SCAN 1.4.0 Setup
Lilivis-L-SCAN 1.4.0 has been installed on your computer.
Click Finish to close Setup.
< Back
Finish
Cancel


Lilivis-L-SCAN 1.4.0 Setup
Installation completed successfully.
It is recommended to restart your computer to ensure all changes take effect properly.
Restart now?
Yes
No

6.3. Lilivis HUB User Interface



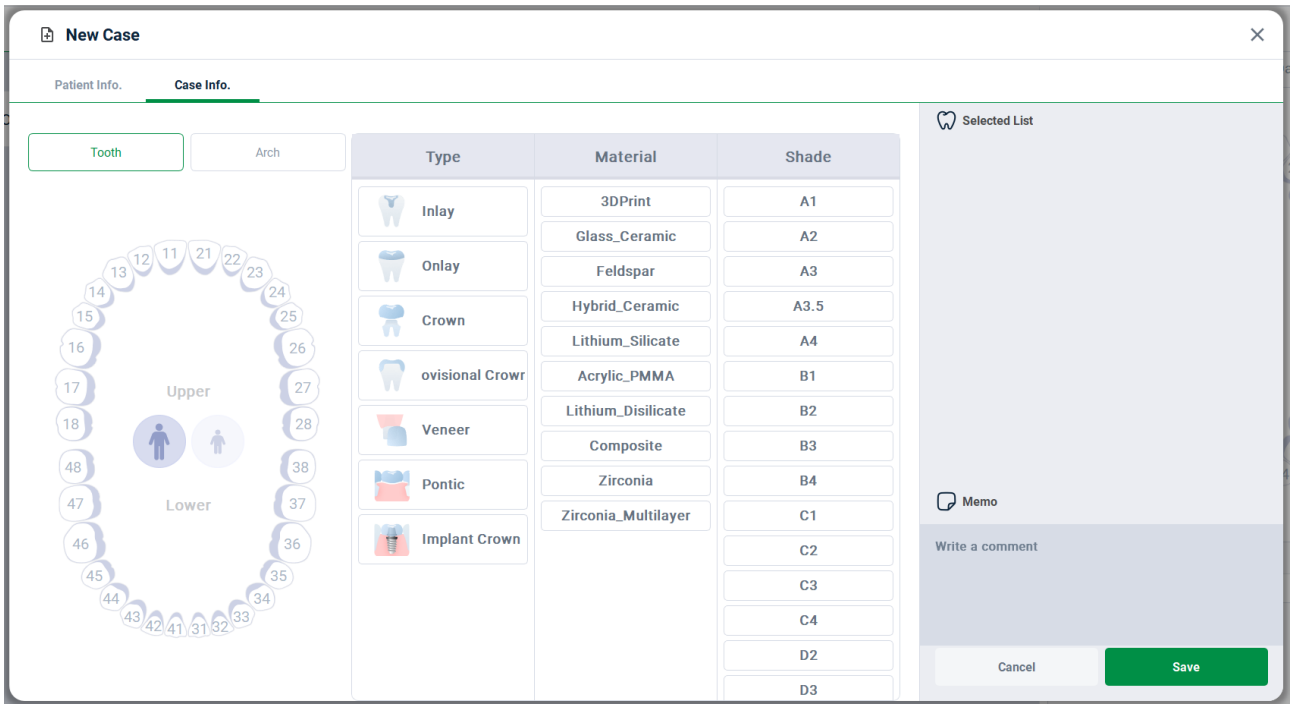
6.3.1 Create for patient and case

Click “New Case” button to create a patient. (Added patient and case information is synchronized with the cloud.)



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.

1) Crown

Crowns - Contains the available crown red-negative types, each linked to a material. for each material you want to use.

2) Veneer

Veneers - Contains the available veneer red-negative types, each linked to a material. You need at least one item for each material you want to use. Added - Stock new veneer items.

3) Inlay/Onlay

Inlays/Onlays - Contains the types of available inlays/onlays, each associated with a material. You need at least one item for each material you want to use.

4) Pontic

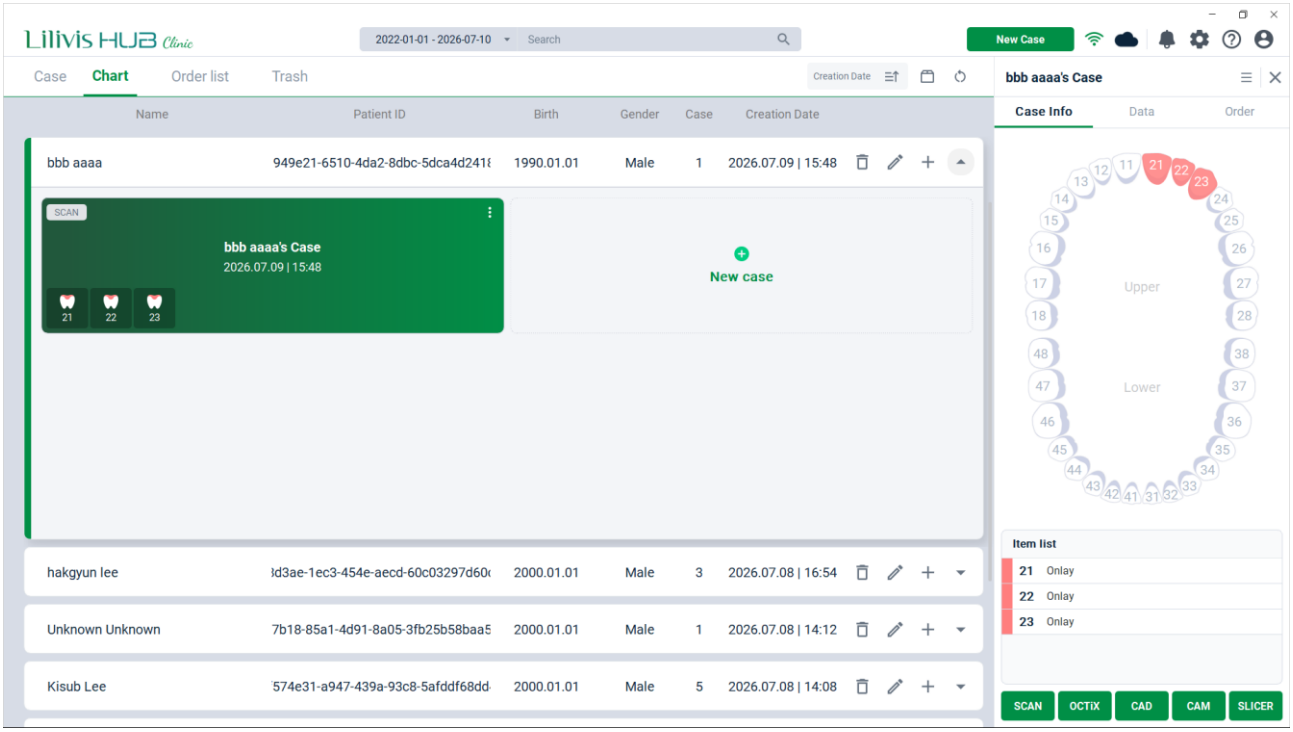
Pontic - Contains the types of available pontic, each associated with a material.

You need at least one item for each material you want to use.

NOTE

For efficiency, it is recommended to simultaneously select all teeth that require the same type of restoration and material.

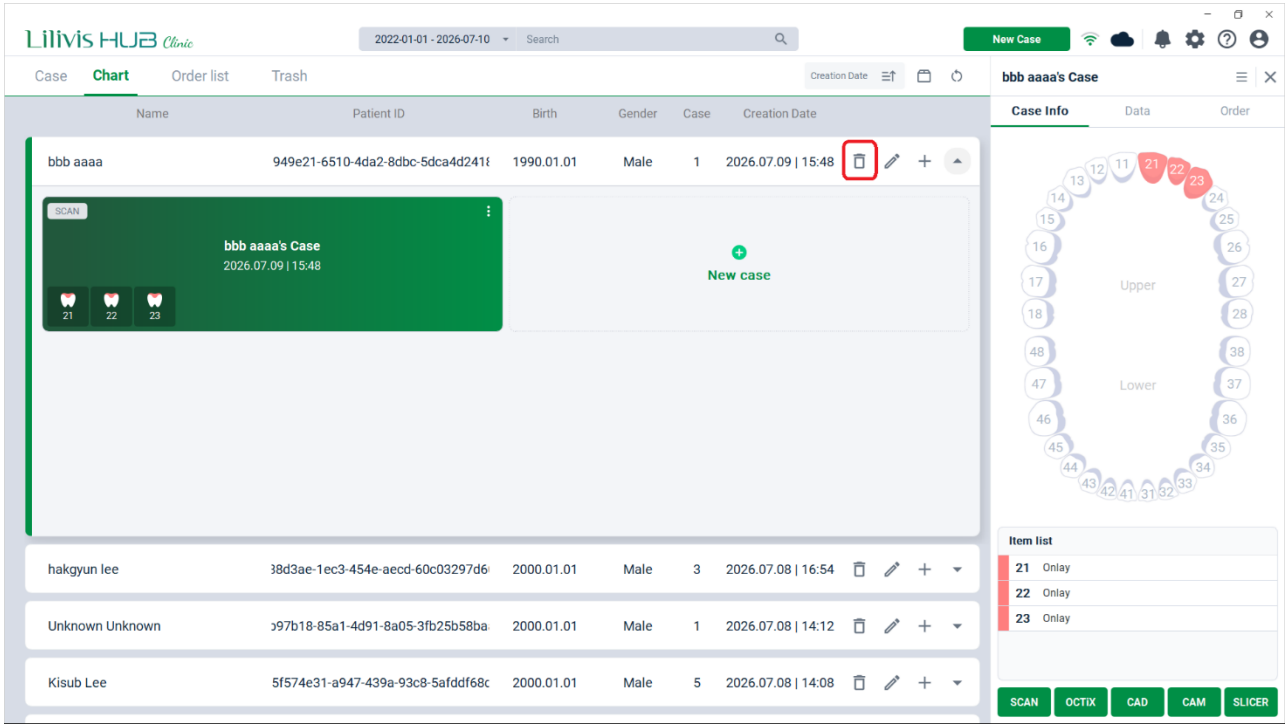
6.3.2 Run scan



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

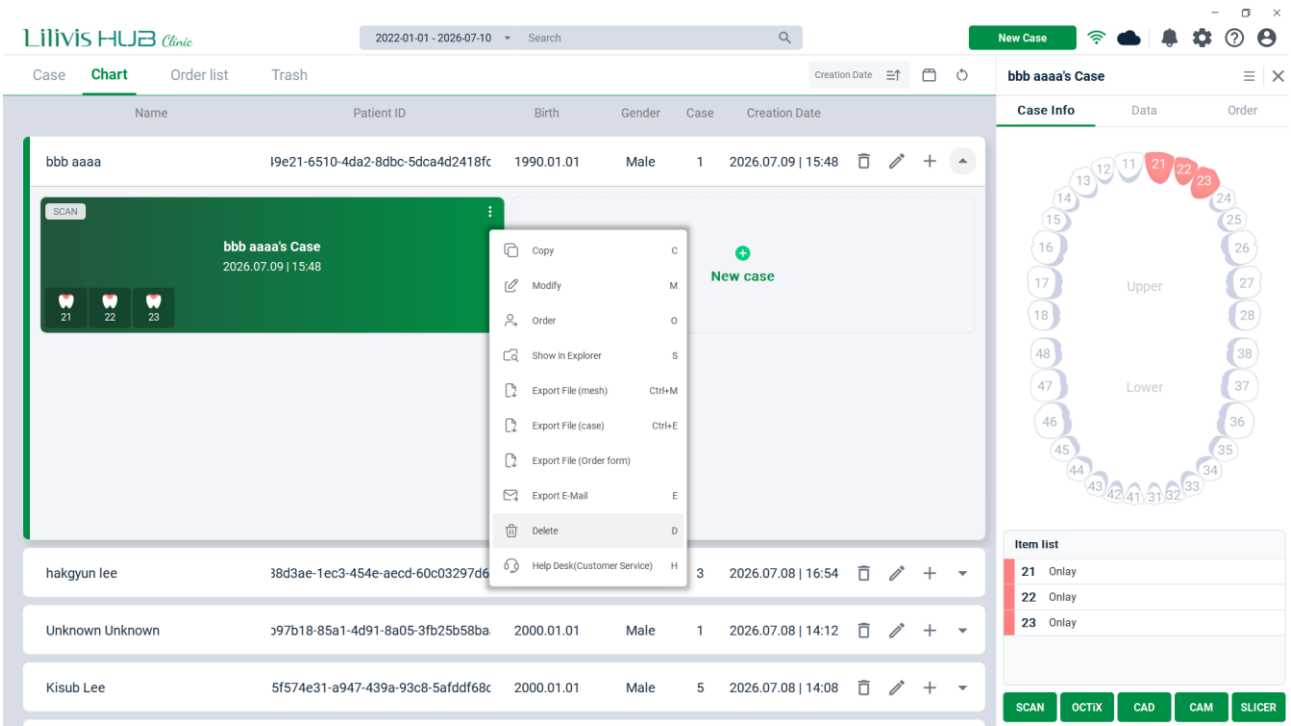
* Only L-Scan can be run at a time.
  Close and run the program to change the case.

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

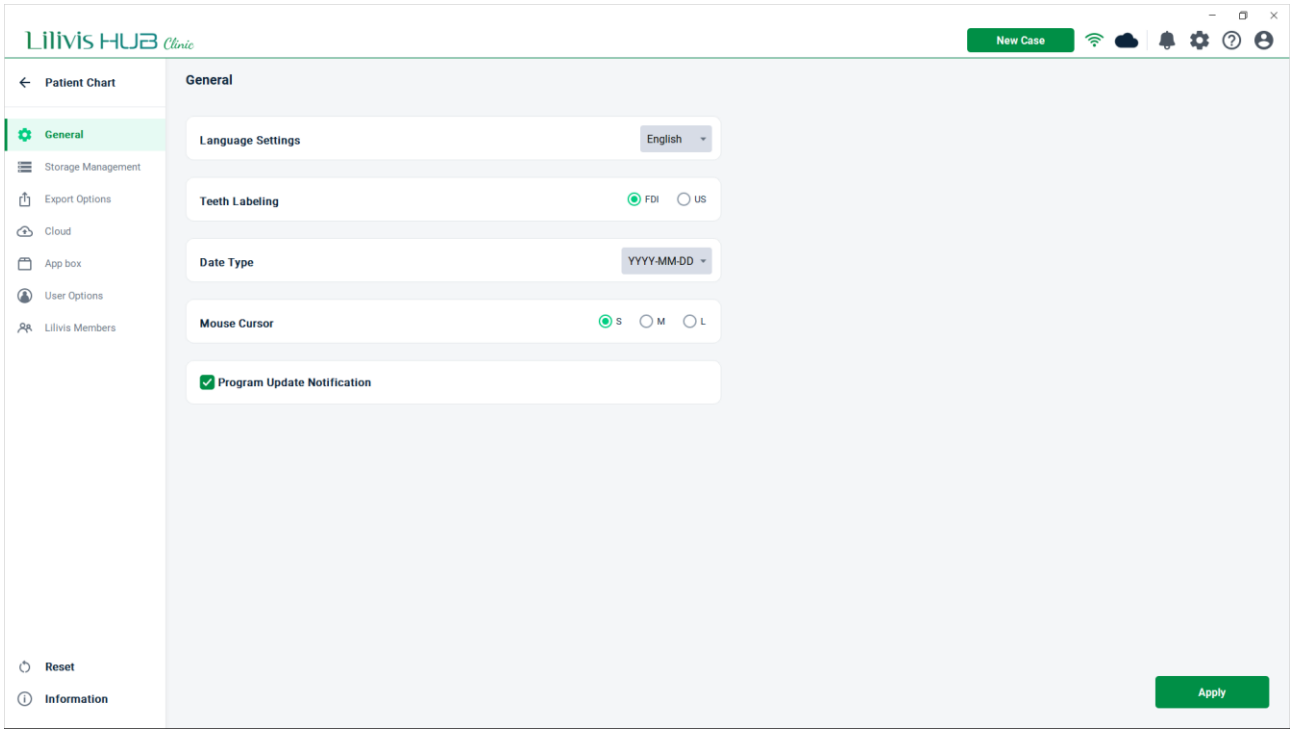


1. Select the patient and case to delete.
2. Click “Delete” menu.

6.3.4.1 Recover deleted case

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

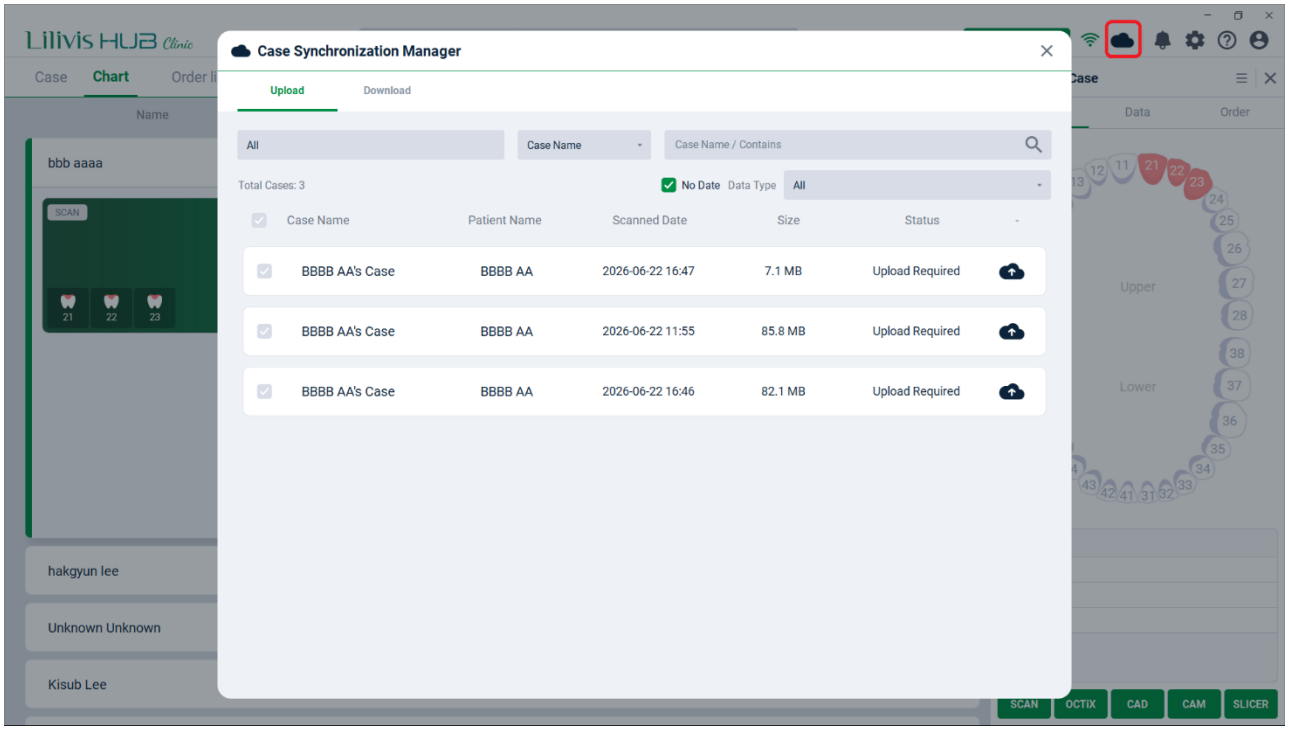
6.3.5 Setting



1	General	- Language - Teeth numbering system - Date type
2	Storage Management	- Management for storage capacity
3	Export options	- Mesh format - External program path - SMTP
4	Cloud	- Setting for cloud account setting
5	App Box	- Management of program update
6	User Options	- Management of user accounts
7	Lilivis Members	- Access the Lilivis Members website.
8	Reset	- Reset to initial state
9	Information	- Information of the program version

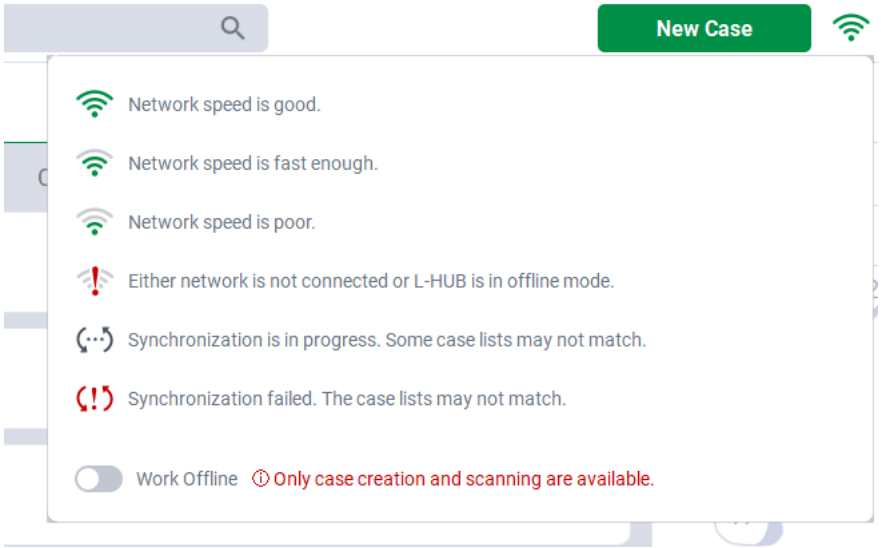
6.3.6 Cloud

6.3.6.1 Sync



1. You can upload or download data to and from the cloud.
2. You can synchronize data during upload and download. (In case of a conflict, the user can choose an option.)

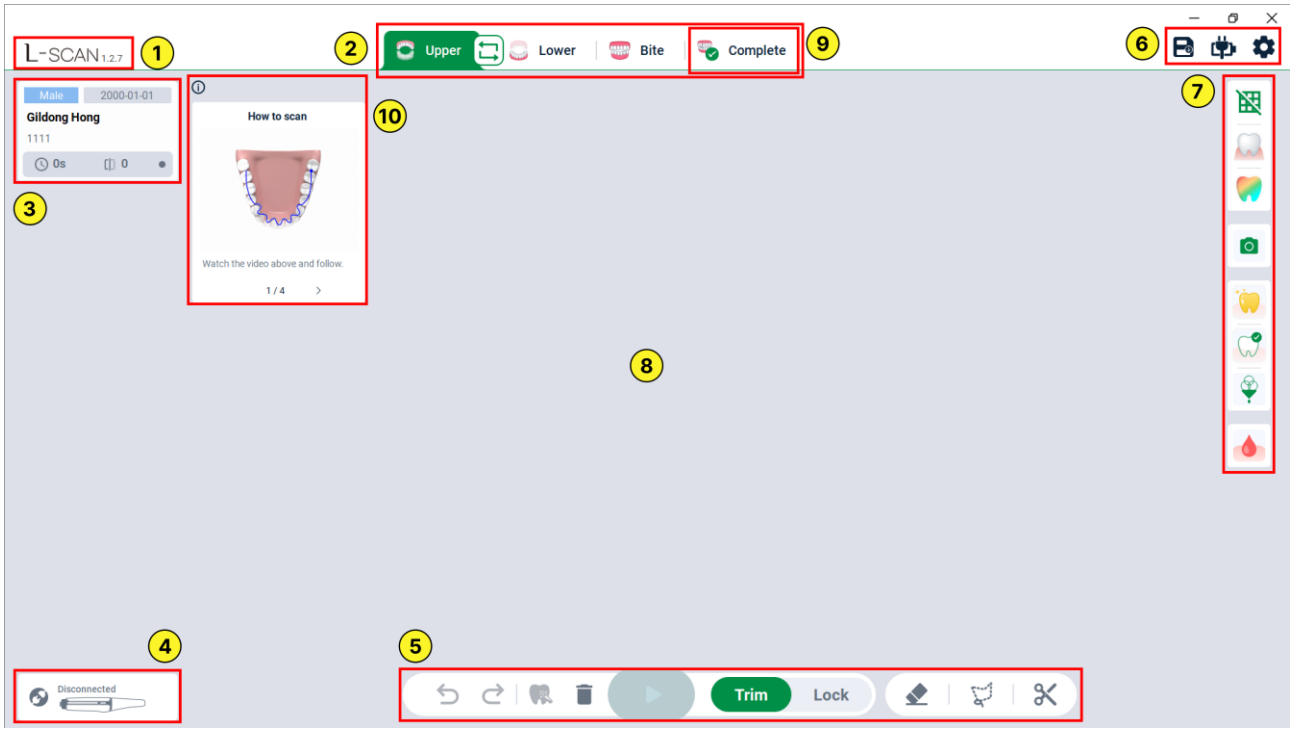
6.3.6.2 Connection Status



1. Information about the internet connection status, speed, online/offline status, and synchronization status is displayed.

6.4. L-Scan User Interface General Overview

1 Program version
2. Stage Bar
3. Information Bar
4. Device Status
5. Control Bar
6. Settings
7. Subfunction
8. Scan process
9. Complete
10. Help



6.4.1 Version Information

You can check the version information of the L-SCAN program.

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.
Swap	Swaps the data of the maxilla and 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
Upper Scanbody	Acquires the 3D image of the upper scanbody.
Lower Scanbody	Acquires the 3D image of the lower scanbody.
Complete	Completes the scanning process then generates the result data.

* To use the Preoperative Model, enable the Settings → Scan Settings → Pre Operation-Upper / Pre Operation-Lower toggle.

* The Scanbody step is automatically created when a tooth is selected in Lilivis HUB and its type is set to Implant.

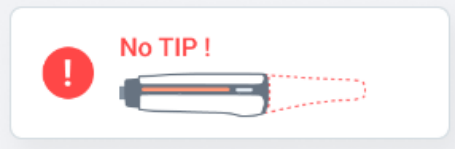
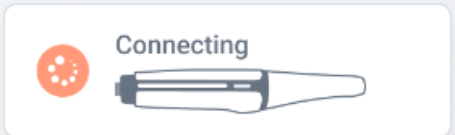
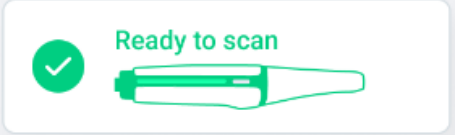
6.4.3 Information Bar

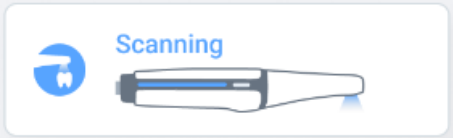
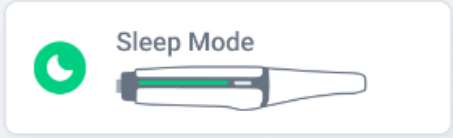
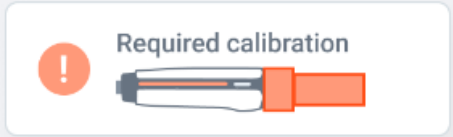
Patient information is received from the Lilivis HUB

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

6.4.4 Device Status

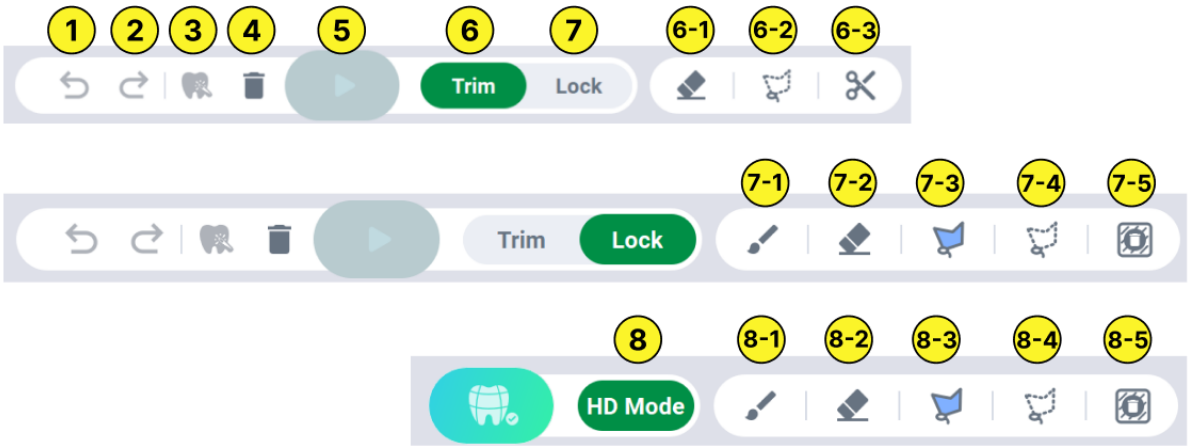
Display the current status of LS-100 device

1	Not Connected	Indicates the LS-100 is not connected. 
2	No Tip	Indicates the tip is not mounted. 
3	Connecting	Indicates the LS-100 is trying to connect. 
4	Rebooting	Indicates the LS-100 is rebooting. 
5	Ready to Scan	Indicates the LS-100 is ready for use. (Heater of scanner tip is in proper temperature) 

6	Scanning	Indicates the LS-100 is currently in the process of scanning. 
7	Sleep	Indicates the LS-100 is in sleep mode. 
8	Overheating	Indicates the LS-100 is overheated. 
9	Required calibration	Indicates the LS-100 is needed calibration. 
10	Power Off	Indicates the LS-100 is powered off. 
11	Air Mouse Mode	Indicates the LS-100 is running in air mouse mode. 
12	Error	Indicates the LS-100 has error. 
13	Update	Indicates the LS-100 is updating firmware version. 

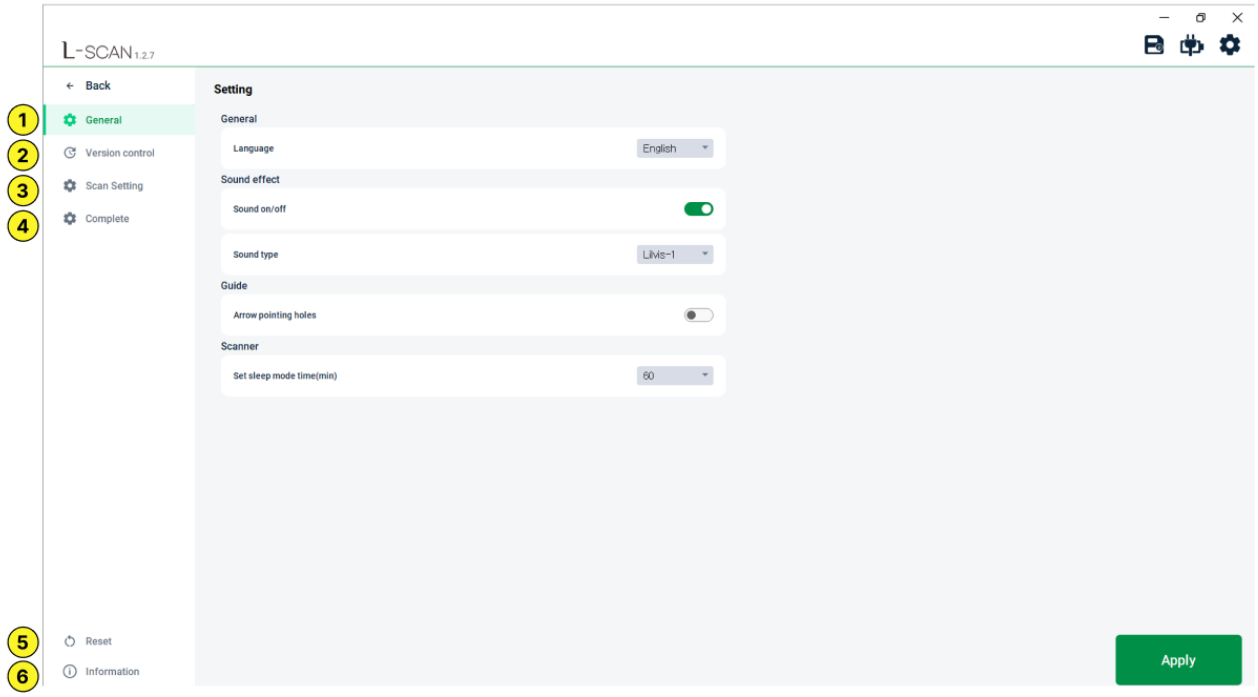
6.4.5 Control Bar

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



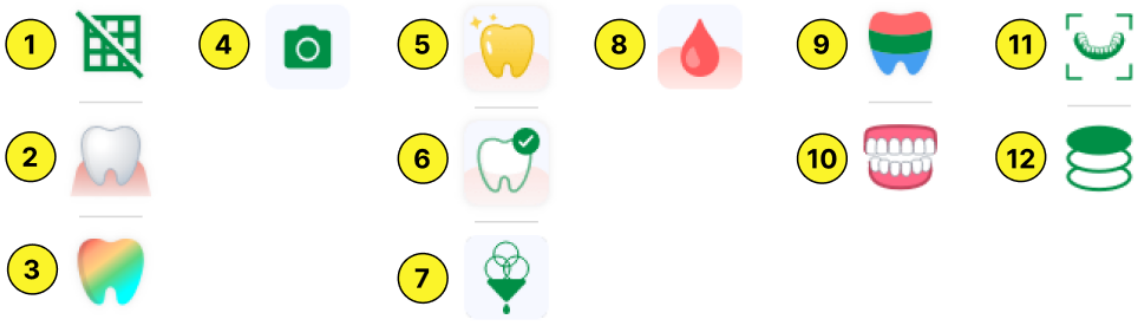
Command Option Detail		
1	Undo	Undo previous action.
2	Redo	Redo previous action.
3	Pose optimization	Automatically realigns misaligned scan data to create a smooth connection.
4	Clear all	Removes all 3D images of occlusion to start over
5	Start/Stop scan	*3D scan mode Starts/stops the scanning process. You can also start the scanning process using the function button on the device. *Image capture mode Starts/stops the capture process. You can also start the capturing process using the function button on the device. And you can also stop the capturing process using the function button by long-press action on the device.
6	Trim mode	Removes unnecessary data, such as soft tissues and noise.
6-1	Polyline trimming	Removes all entities within a polyline shape drawn on the screen.
6-2	Brush trimming	Removes all entities on a freehand-drawn path on the screen.
6-3	Quick trimming	Removes island data by picking.
7	Area lock mode	Locks the selected scan area to prevent additional scanning or data modification.
7-1	Brush Lock Area	Locks all scan points along the freely drawn brush path on the screen.
7-2	Unlock Brush Area	Unlocks all locked scan points along the freely drawn brush path on the screen.
7-3	Polygon Lock Area	Locks all scan points within the polygon drawn on the screen.
7-4	Unlock Polygon Area	Unlocks all locked scan points within the polygon drawn on the screen.
7-5	Unlock All Areas	Unlocks all locked areas.
8	HD Mode	Generates result data in high resolution during the Complete step and highlights high-resolution areas with color.
8-1	Select Brush HD Area	Selects scan points along the freely drawn path on the screen as an HD area.
8-2	Deselect Brush HD Area	Clears the HD selection of scan points along the freely drawn path on the screen.
8-3	Select Polygon HD Area	Selects scan points within the polygon drawn on the screen as an HD area.
8-4	Deselect Polygon HD Area	Clears the HD selection of scan points within the polygon drawn on the screen.
8-5	Deselect All HD Areas	Clears all selected HD areas.

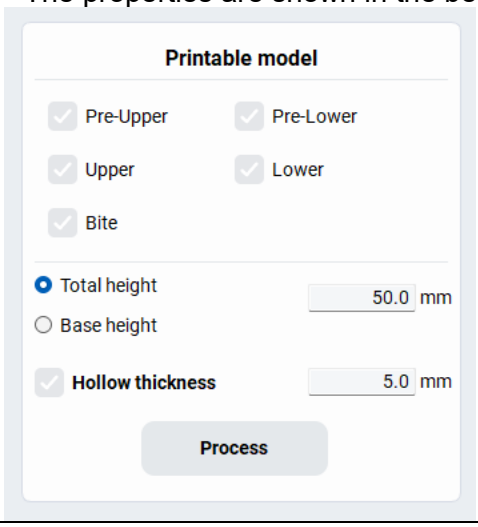
6.4.6 Setting



General	Language Sound Scan Guide Sleep Mode
Version	Management of firmware information
Scan setting	Configure preoperative model usage Set scan direction and light intensity Configure gingiva options Configure the scanner button long-press function
Finish	Setting the default option for finishing
Reset	Reset to initial state
Information	Program version information

6.4.7 Sub-function shortcut



1	Grid option	Displays grid view off/above/below model
2	Render option	Changes render option of the model.
3	Reliability map	Displays the reliability of the scanned data as a color overlay.
4	Mode for image capture	Capture and manage images
5	Mode of metal	Improve the accuracy of scanning metal material
6	Remove of soft tissue	Remove unnecessary soft tissue
7	Color for filtering	Remove the pre-set colors
8	Bleeding scan mode	Enables stable scanning even when blood is present on the target surface.
9	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.
10	Manual align	Align manually the maxilla/mandible during the occlusion phase
11	Mode of final	Display the completed result data
12	Mode of printable	Create a 3D printable model. Select the data to be printed and set the property values * The properties are shown in the below figure. 

6.4.7.1 Grid option

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



6.4.7.2 Render mode

Rendering options can be configured. Available modes are Real, Gray, and Mono.



6.4.7.3 Reliability Map

Displays vertices with a color overlay based on the reliability score of the scanned data.
Visually highlights areas that require additional scanning, helping users perform a complete and accurate scan.

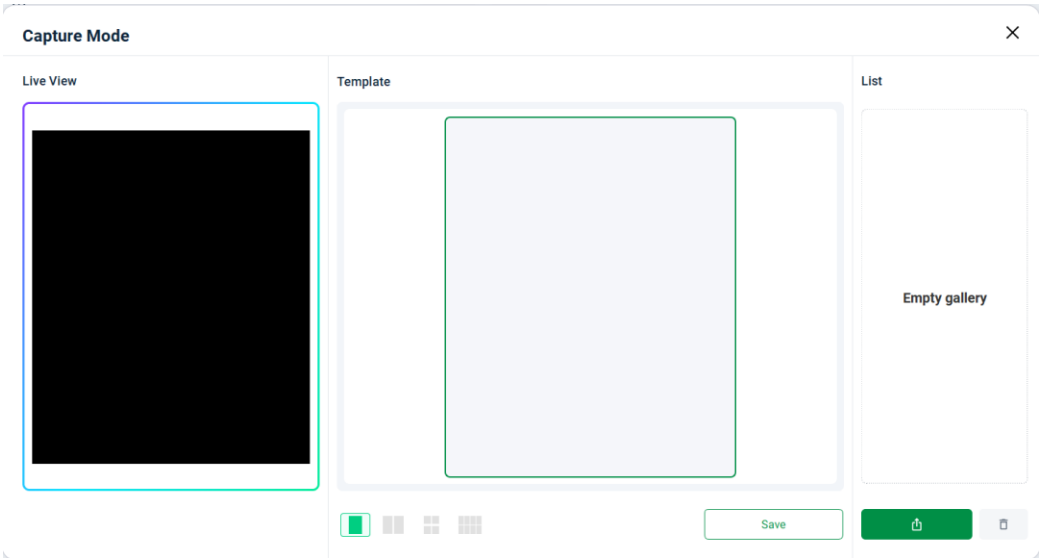


6.4.7.4 Mode for image capture

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

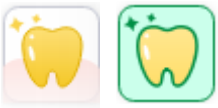
- Click the Start button on the control bar or press and hold the function button on the scanner to start.



6.4.7.5 Mode of Metal

Improves scanning accuracy of metal materials

- Click the icon of color filtering



6.4.7.6 Remove of soft tissue

Remove unnecessary soft tissue effectively during the scanning process

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



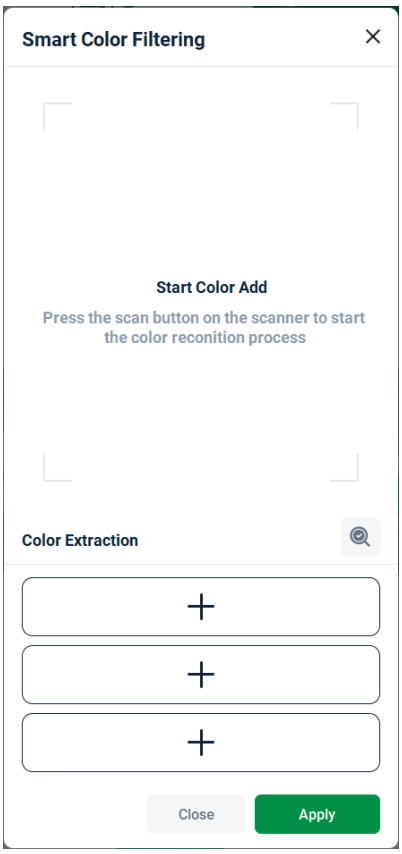
6.4.7.7 Color for filtering

Filtering specific colors during the scanning process

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



- Fix the tip to the location of filtering and click the middle start button



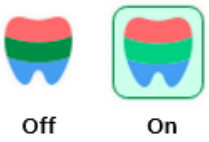
6.4.7.8 Bleeding scan mode

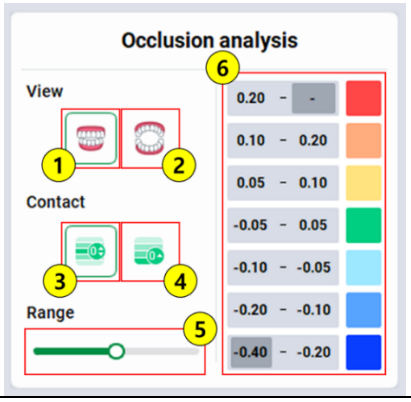
When this option is enabled, stable scanning can be maintained even if blood is present on the target surface.



6.4.7.9 Occlusion Analysis

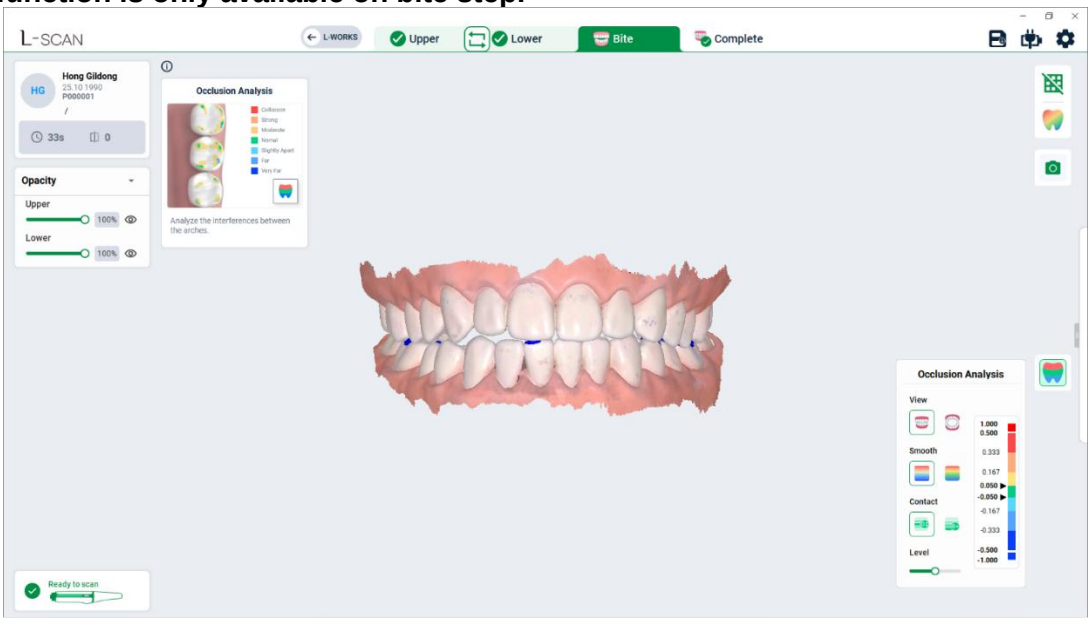
Analyzes the interference between the Upper(maxilla) and Lower(mandible) and shows the result with color map.





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.**

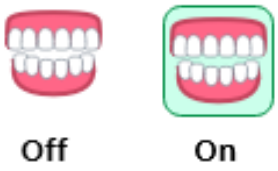


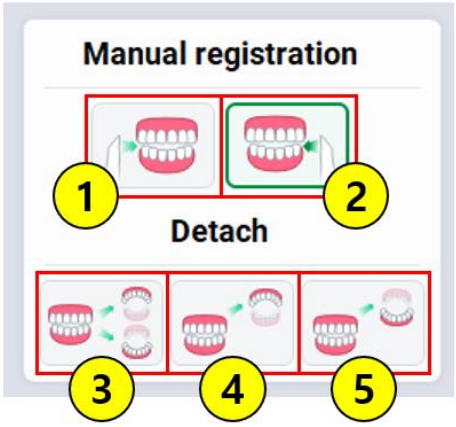
6.4.7.9.1 How to use

1. Click Occlusion Analysis
2. Change the view style between show all and contact 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.

6.4.7.10 Manual Registration

If automatic occlusion fails, the manual occlusion function can be used to align the occlusal surfaces.

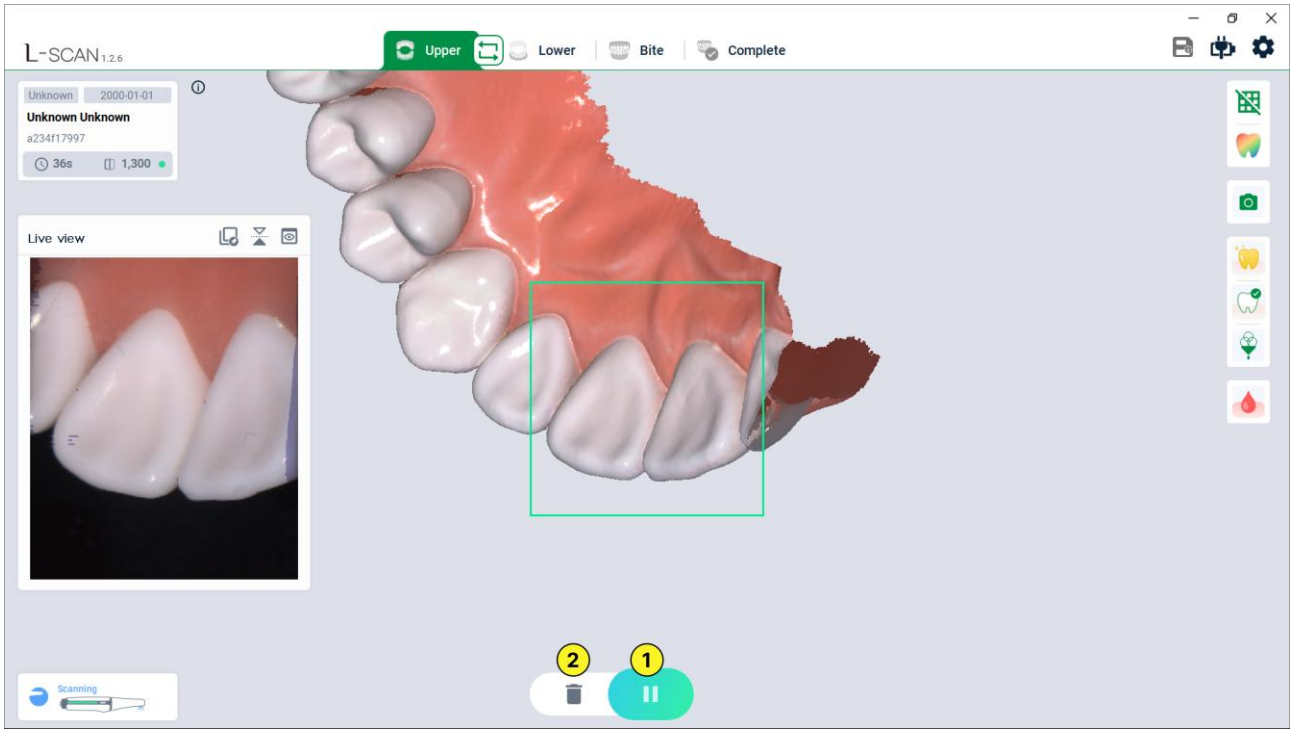




1	Set Left Bite Data	Selects the left bite scan data.
2	Set Right Bite Data	Selects the right bite scan data.
3	Detach Both	Detach the bite scan data from upper and lower scan data.
4	Detach From Upper	Detach the bite scan data from upper scan data.
5	Detach From Lower	Detach the bite scan data from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

6.4.8 Scan process

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

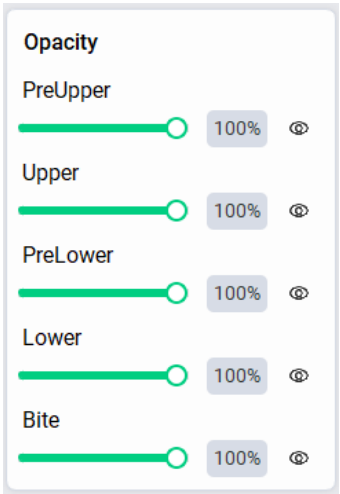


6.4.8.1 Command Option Detail

Command Option Detail		
1	Start/Stop scan	Starts or stops the scanning process. You can also start or stop the scanning process using the function button on the device.
2	Clear all	Removes 3D image of step to start over.

*** This function is only available on bite, scanbody, complete step.**

1. You can adjust transparent of model by using the Opacity slide bar.
2. You can set visibility of model by eye button.

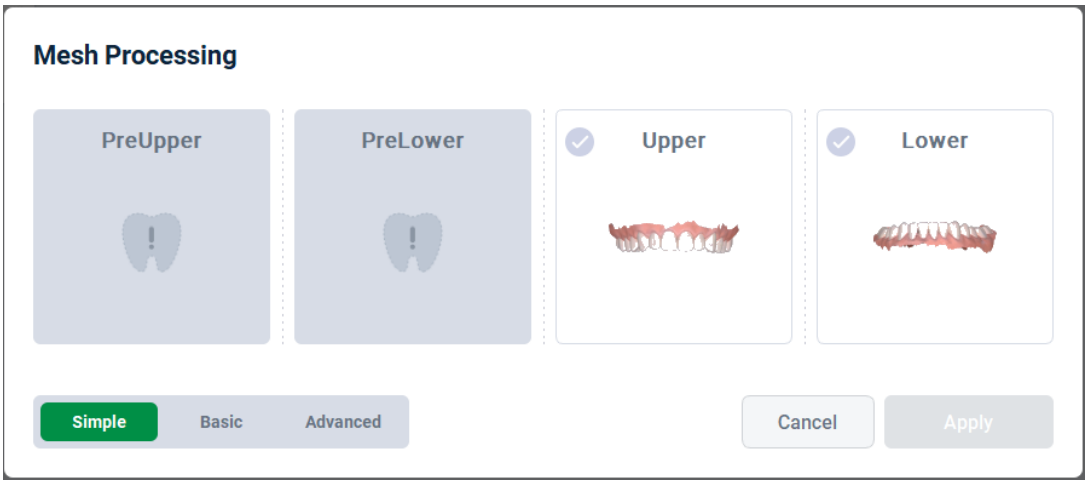


6.4.8.2 Model Control in View Screen using Mouse

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.

6.4.9 Complete

Completes the scanning process then generates the result data.

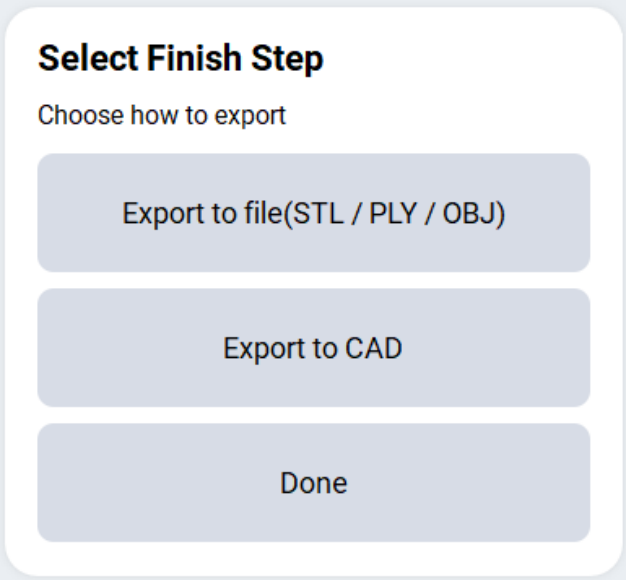


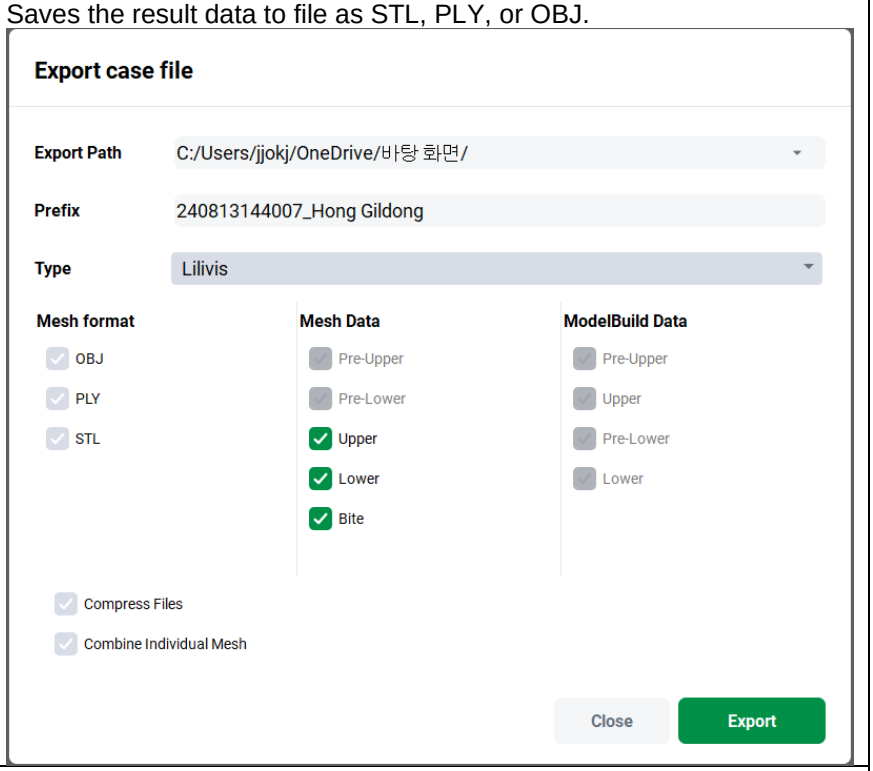
6.4.9.1 How to use

1. Select the scan data to be created as result data.
   A. If scan data exists, it is automatically selected.
   B. 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.

6.4.9.2 Finish

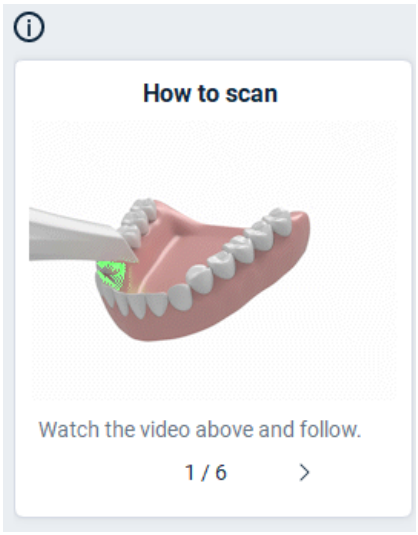
After generating the result data, click the “Finish” button to select finish step.



Export (STL, PLY, OBJ)	Saves the result data to file as STL, PLY, or OBJ. 
Export CAD	Exports result data to CAD.

6.4.10 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.



7. Maintenance

7.1 Calibration

The Intraoral Scanner LS-100 provide the factory calibration with very precise condition as default. The person who is qualified as maintenance needs to perform periodic calibration when the quality of the 3D model is not reliable or accurate compared to previous results or when environmental conditions changed such as temperature or air- pressure. If you meet this situation, the maintenance person can use calibration tools provided from manufacturer and calibrate your device for optimal image acquisition.

7.1.1 Calibration procedure

- Press the power button until the product turns on.
- Execute Calibration software.
- Insert the LS-100 into the calibration device with the sleeve removed.

Camera calibration

- Place the upper dial to 1 and lower dial to 0.
- Turn the upper dial repeatedly from 2 to 8.

DLP calibration

- Place the upper dial to 1 and lower dial to -12.
- Turn the lower dial repeatedly from -11 to 12.

7.2 Cleaning, Disinfection and Sterilization

7.2.1 Sleeve Tip

The LS-100 reusable Scanner Tip is the part of the scanner that is inserted into the patient's mouth during scanning. The Scanner 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.

1) Cleaning and disinfection procedure

[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 Isopropyl Alcohol Wipes (70%) for 4 minutes.
- Clean the tip manually using sterilized 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 7.2.1 not including automated cleaning/disinfection methods (e.g. automatic washer, ultrasonic cleaners, High-level disinfection).

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.

7.2.2 Handpiece

Cleaning the surfaces of the handpiece except for the scanner front and the end (Optical part and Vent hole). Follow the steps below to complete the cleaning :

[Step 1]

- Dis-connect the power of the handpiece. (Unplug all the cables from the PD-Hub)
- Attach the handpiece cover to the front of the scanner.

[Step 2]

- Pour the Isopropyl Alcohol (70%) on a sterilized cloth and wipe the surface.
- Dry the surface thoroughly with clean, dry cloth
- Store the handpiece in a clean and safe place

7.2.3 Other Components

- Pour the Isopropyl Alcohol (70%) on a sterilized cloth and wipe the surface.
- Dry the surface thoroughly with clean, dry cloth

7.2.4 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 7.2.1.
- Dispose the scanner tip as you would other clinical waste

7.2.4 In case of Device Failure

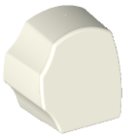
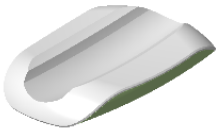
If your LS-100 system is not working properly, or if you suspect that there is a problem with the equipment:

- 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.
- LS-100 system should not be dismantled arbitrarily.

8

Specifications and Accessories

8.1. Standard Accessories

No.	Item	Qty	Description
1	LS-100 Handpiece	1EA	
2	PD Hub	1EA	
3	Handpiece Cover	1EA	
4	Wall Mount Holder	1EA	
5	Desk-Top Cradle	1EA	
6	USB 3.1 Cable (C to C type)	1EA	
7	USB 3.1 Cable (C to A type)	1EA	

8	Medical Adapter	1EA	
9	Power Cord	1EA	
10	Wrist strap	1EA	

8.2. Optional products

1	Calibration Tool	1EA	
2	Instrument Table (CIT-4100)	1EA	
3	Scanner Tip (LS-100-TIP-3R)	3EA	
4	Scanner Tip (LS-100-TIP-3S)	3EA	

8.3. Specifications

Device specifications	
Type	Intraoral optical scanning system
Model name	LS-100
Rating	12Vdc, 3A, 30W
Performance	
Field of View (LS-100-TIP-3R)	Min 15mm x 18mm
Field of View (LS-100-TIP-3S)	Min 14mm x 11mm
Depth of Field	Max 22mm
DC Adapter	
Model name	MEA-065A12C
Input Voltage	100-240Vac
Output	12 Vdc
Rated output current	3A
Case dimension	50 x 115 x 29 [mm] (W x D x H)
Handpiece	
Dimension	254 x 40 x 52 [mm] (W x D x H)
Weight	230g
Applied part	Type B
Imaging	
HD Video	3D in motion video
Real Color	3D full color streaming
Scanner Tip (LS-100-TIP-3R)	
Tip Size	37 x 37 x 110 [mm] (W x D x H)
Autoclavable times	150 times per tip
Scanner Tip (LS-100-TIP-3S)	
Tip Size	37 x 37 x 109 [mm] (W x D x H)
Autoclavable times	150 times per tip
PD Hub	
Dimension	66 x 46 x 17 mm
Weight	30.5g

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EMC INFORMATION

Manufacturer announcement – electromagnetic waves trouble

- **Electromagnetic waves trouble**

  LS-100 should be used in the below mentioned electromagnetic wave environment. LS-100 purchaser or user needs to confirm whether LS-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**

  LS-100 is to be used in the below designated electromagnetic wave environment. LS-100 customer and user need to guarantee that the LS-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**

  LS-100 is to be used in the below mentioned electromagnetic wave environment. LS-100 purchaser or user needs to confirm whether LS-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: LS-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.

■ How to Contact Huvitz Co., Ltd.

■ Huvitz Co., Ltd.

38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

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