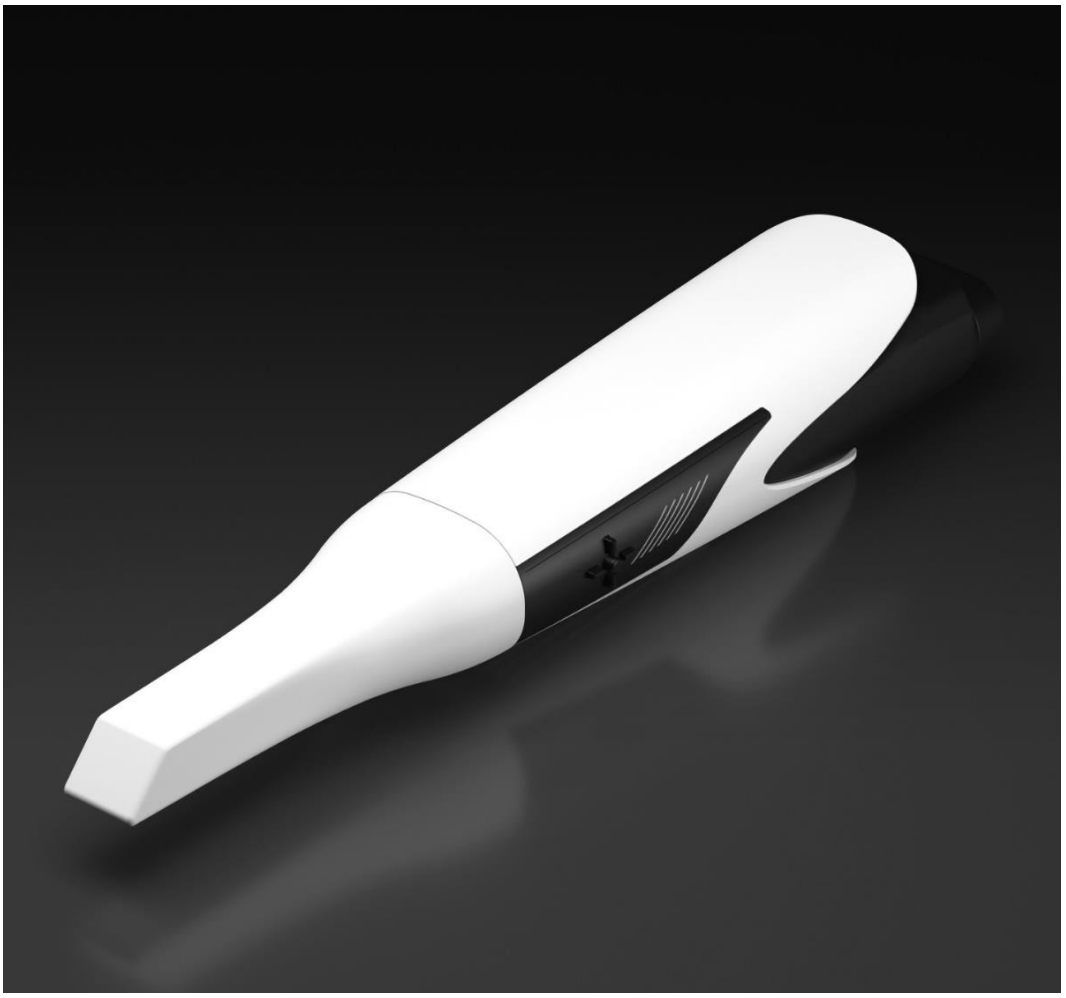
Doc. No: DOF-UM-ENG-001

User Manual

Intraoral Scanner “DSI-100“

FREEDOM i



DOF Inc.

Table of contents

0. About this guide

The user manual provides general descriptions and safety information about DSI-100 systems, its software SCANAPP i. Describes how to use the system, how to install the software, how to start and shut down the system, and how to clean and disinfect it. Before using the product, it is recommended that the safety is carried out in the user manual and that the system is operated according to the manual.

1. General

In this manual, the following special symbols are used to guide the user's safety and information emphasis, and to prepare for hazards that may occur from the equipment.

 Warning	Notifies users to follow safety instructions correctly to avoid serious injury to themselves or others
 Caution	Describe situations that may cause minor problems to users or dangerous situations such as system damage
 Hint	Provides additional information and helpful hints to the user while maintaining the optimal state of the system and using the equipment

1.1. Copyright and trademark

1.2. Symbol

Symbol	Description
	Manufacturer and address

	Date of manufacture and country of manufacture (Korea)
	European representative and address
	Serial Number
	Unique device identifier
	Medical Equipment
	Prescription symbol (USA only)
	Non-sterile
	Caution
	Warning
	Refer to user manual
	Consult instructions for use
	BF type mounting part
	Electrical Insulation Class II
	Temperature
	Humidity
	Atmospheric pressure

	Fragile
	WEEE product disposal symbol
	CE mark
	Federal Communications Commission (FCC)
	UL mark
	KC mark
	TELEC
	Alternating current
	Direct current
	Ethernet

2. System overview

2.1. Usage

DSI-100 is a device that captures video images of intraoral conditions using a camera and reproduces them in three-dimensional form.

2.2. Operating principle

This product is a digital optical scanning device used to record the surface characteristics of human tissues in the oral cavity, such as teeth and gums, and artificial structures in the oral

cavity, such as implant structures, in 3D. Structured light is projected onto the tooth surface with an LED optical projector, and a 2D image of the tooth surface where the structured light is projected is obtained with a CMOS camera to reconstruct a 3D shape on a PC. The 3D geometry data reconstructed through this product is used as basic data for making dental restorations or orthodontic devices such as artificial teeth.

This product consists of DSI-100 body, normal tip, lateral tip, wireless LAN card, PSM (Power & Signal Module), table holder, wall holder, rechargeable battery, battery charger, power adapter, cable (Ethernet communication/HDMI/power), software, etc.

2.3. User

- Users of the DSI-100 system must comply with the contents of the manual for handling and use.
- The DSI-100 system must be used by dental professionals or technicians only.
- In addition, the user is responsible for determining the suitability and reliability of the data acquired from this system, and judging whether it is applicable to patient treatment.
- The user cannot modify or change the DSI-100 system, and the user should contact the store where you purchased the product or DOF inc. for any question or information.
- This system may not be able to obtain normal 3D scan data when there are 4 or more consecutive missing teeth in the oral cavity of the patient.
- Users of this system must check the contents of the Safety Guide in Section 6, which contains detailed safety and precautions required before, during, and after use, before use.

2.4. Indication

- DSI-100 is an intraoral scanner system for dental professionals to record morphological characteristics of teeth, gingiva and/or palate or stone models.
  - ① Single crowns
  - ② Up to 5-unit bridge
  - ③ Inlays
  - ④ Onlays
  - ⑤ Veneers
  - ⑥ Implants (single abutments)

⑦ Orthodontics
⑧ Implant guide
⑨ Diagnosis models

2.5. contraindication scope

- 3D scans cannot be performed on parts of the oral cavity that are deformed, such as the tongue, cheeks, and lips.
- 3D scanning cannot be performed normally if there is excessive saliva or blood on or around the tooth surface.
- The internal structure of teeth and gums or the skeletal structure that supports them cannot be 3D scanned.
- A normal 3D scan cannot be performed on areas with continuously missing teeth or flat shapes.
- Excessively shiny metallic artificial teeth and structures in the oral cavity cannot be 3D scanned normally.

2.6. Environmental conditions

2.6.1. Computer system requirements

- It is recommended to use a computer and monitor certified by IEC 60950, IEC 55032,and IEC 55024.
- Note: You must ensure that your current system configuration meets the computer system requirements for DSI-100 software.

Item	Requirement
CPU	Intel® 9th Gen i7 or higher
OS	Windows 10 64 bit or higher
Memory	32 GB or more
Hard disk	1TB or more (SSD 256GB or more)
GPU Memory	NVIDIA 8GB or more
Wi-Fi	(AMD graphic card not supported)
Security	Using wireless Wi-Fi (frequency 5 GHz, IEEE 802.11ac)

2.6.2. Operating and storage requirements

Operating environment	
Operating temperature	18°C ~ 28°C
RF test Temperature	0°C ~ 40°C
Humidity	20-75% relative humidity (non-condensing)
Air pressure	800 hPa to 1100 hPa
This equipment should only be used indoors at an altitude of 2000M or less.	
Storage environment	
Temperature	-5°C to 45°C
Humidity	20-80% relative humidity (non-condensing)
Air pressure	800 hPa to 1100 hPa
Transportation environment	
Temperature	-5°C to 45°C
Humidity	20-80% relative humidity (non-condensing)
Air pressure	620 hPa ~ 1200 hPa

2.6.3. Max RF Output Power

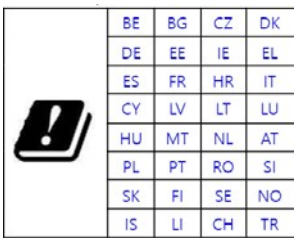
- 5GHz WLAN 802.11ac VHT40, VHT80 (5150~5250 MHz) : 16.84 dBm e.i.r.p
- 5.8GHz WLAN 802.11ac VHT40, VHT80 (5755~5795MHz) : 12.58 dBm e.i.r.p

2.7. Certifications and Regulations

2.7.1. CE mark

This product complies with the European Medical Devices Directive 2017/745, Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU and Waste Electrical and Electronic Equipment Directive 2012/19/EU, ISO 15223-1 Symbols Used on Medical Device Labels CE marked according to standard.

This device can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.



2.7.2. Electrical safety

The system is tested and used for electrical medical equipment attached to the patient, IEC 60601-1 Common standard for design of medical devices (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance), IEC 60601-1-1 2 (Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests), EN 301 489-1, 3, 17 Electromagnetic Compatibility Specification for Radio Devices (1 Part: Common technical requirements, Part 3: Specific conditions for SRDs between 9 kHz and 246 kHz; Harmonized standards covering the essential requirements of clause 3.1(b) of Directive 2014/53/EU, Part 17: Broadband data transmission systems specific conditions for), ETSI EN 301 893 5GHz wireless LAN; (harmonized standard covering the essential requirements of clause 3.2 of Directive 2014/53/EU), ETSI EN 300 440 Near-Range Devices (SRD) (radio equipment used between frequencies 1 GHz and 40 GHz; clause 3.2 of Directive 2014/53/EU harmonized standards covering essential requirements), EN 62209-2 human exposure to the radio frequency range of portable radiocommunication devices (Human Body Models, Devices and Procedures – Part 2: Specific Absorption Rate (SAR) of radiocommunication devices used in close proximity to the human body.) is confirmed to be in compliance with the standard.

2.7.3. Biosafety

Since this system comes into contact with the patient's oral cavity and mucous membrane, it has been confirmed to comply with the ISO 10993-1 medical device biological evaluation standard by conducting Cytotoxicity, Oral mucosa Irritation test, Sensitization, Acute systemic toxicity test, and pyrogenicity test.

2.7.4. FCC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with RF exposure requirement.

2.7.5. IC

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

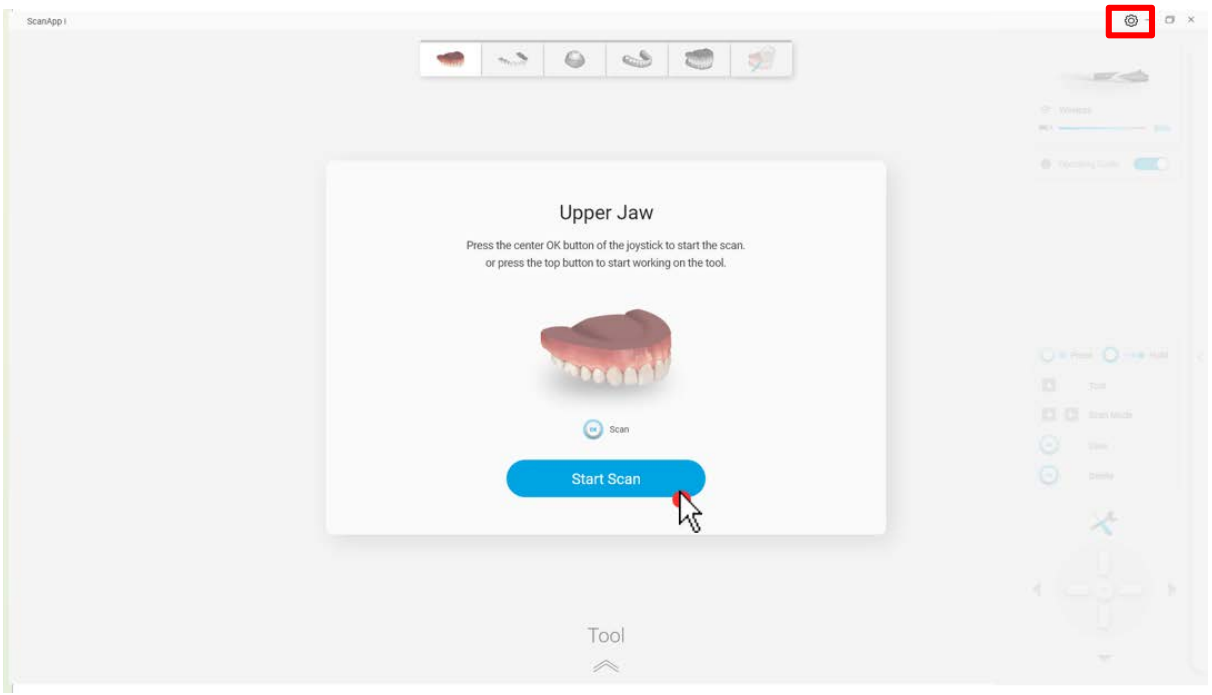
Cet appareil contient des émetteurs / récepteurs exempts de licence qui sont conformes aux RSS exempts de licence d'Innovation, Sciences et Développement économique Canada. Son fonctionnement est soumis aux deux conditions suivantes:(1) Cet appareil ne doit pas provoquer d'interférences.(2) Cet appareil doit accepter toute interférence, y

compris les interférences qui peuvent provoquer un fonctionnement indésirable de l'appareil.
This device complies with RF exposure requirement.
Cet appareil est conforme à l'exigence d'exposition RF.

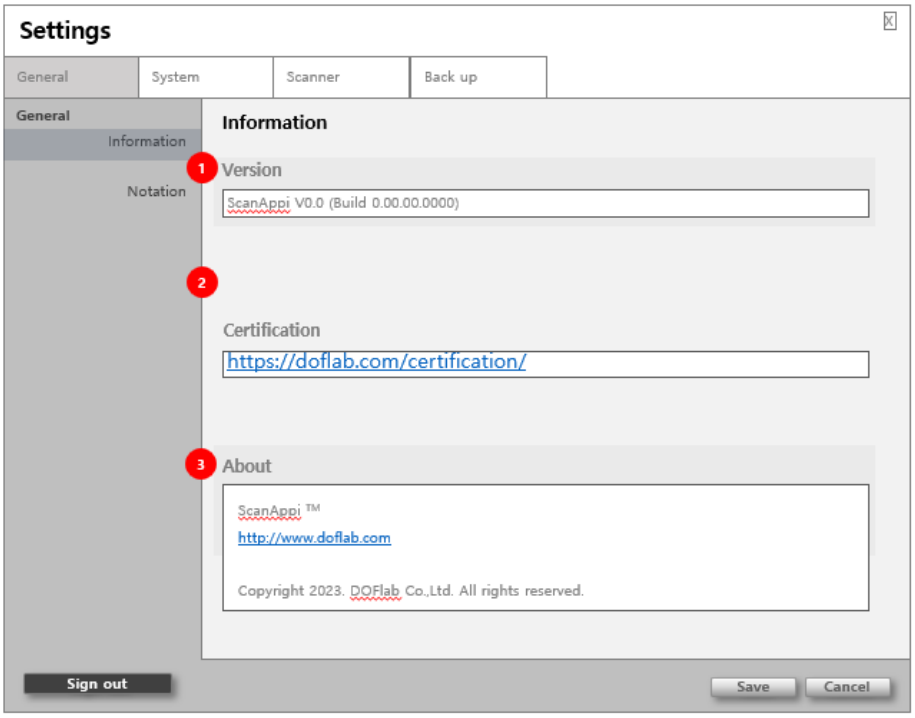
2.8. Description of E-Label

This device is applied E-label.

Step 1. Run scan app settings.



Step 2. Select the General information tab.



Step 3. Go to web site link number 2. (https://doflab.com/certification/)

There are no special access codes, accessories, or permissions beyond the normal security protection to unlock the screen, sign-in page, or overall product access. The E-Label will be easily accessible by the user and cannot be modifiable by the user
The E-Label will be clearly legible whithout the aid of magnification.

This device can only be operated via a dedicated software.
Regulatory information can be checked through the website linked to the dedicated software.
Regulatory information cannot be changed or deleted except manufacturer.

1. System configuration and functions

1.1. System specification

Item name		Optical Impression Acquisition Device
Product name		Certain low-power wireless devices(Wireless devices for wireless access systems including wireless LAN (5150~5350MHz, 5470~5850MHz frequency band)
Model name		DSI-100
Item approval number		written after approval
Camera resolution		1920 X 1200 pixels
Field of view		at least 12.8 X 10.5 mm
Depth		at least 15 mm
Remote control		Using the D-Pad of the intraoral scanner main body without using a mouse, it is possible to start and stop scanning, move before and after the scanning stage, and select tools.
Light source		LED (White, Blue)
Dimensions		296.63 x 59.96 x 50.31 mm (body + tip)
Weight		282g (body + tip)
Electrical rating	**Adapter**	·Input: AC 100-240V, 50-60Hz ·Output: DC 12 V, 3.4 A ·Manufacturer : BridgePower Corp ·Model Name : BM040S12N03
	Battery	Normal Voltage: 3.6V 3500mAh(12.6W) 1INR19/70(18650)
Power consumption		50W
Communication standard	**Wireless**	- CE/FCC/IC • 802.11 ac(VHT40) : 5 190 MHz ~ 5 230 MHz • 802.11 ac(VHT80) : 5 210 MHz • 802.11 ac(VHT40) : 5 755 MHz ~ 5 795 MHz • 802.11 ac(VHT80) : 5 775 MHz

		- Telec • 802.11 ac(VHT40) : 5 190 MHz ~ 5 230 MHz • 802.11 ac(VHT80) : 5 210 MHz
	Wired	Gigabit Ethernet (1000BASE-T, IEEE 802.3ab)
Electric shock protection type and degree		Class 2 equipment, BF type equipment

1.2. Product composition

1.2.1. Description and features

- DSI-100: Handheld wireless and wired intraoral scanner for scanning dental impressions and oral tissues.
- SCANAPP i: Software that controls DSI-100. It is connected to DSI-100 with a wired Ethernet cable or Wi-Fi and receives multiple 2D images from the device. It is a software/application application/user interface that digitizes the received 2D image in 3D and uses it for designing dental implants and prostheses.
- Normal tip: This is a reusable scanner tip that is attached to the DSI-100 intraoral scanner. The tip is the part that is inserted into the patient's mouth during intraoral scanning and must be cleaned and sterilized before and after use on the patient.
- Lateral tip: This is a reusable scanner tip attached to the DSI-100 intraoral scanner. It is a 90-degree bent tip for easier grip of the DSI-100
- PSM: Abbreviation for Power & Signal Module, this module receives power from the power adapter to operate the DSI-100 system wired, receives Ethernet signals from the PC, and sends power and signals to the DSI-100 through the DP cable .
- Wireless LAN card: To operate the DSI-100 intraoral scanner wirelessly, it is connected to the PC's USB port to transmit and receive wireless signals to the PC.
- The length of the Ethernet communication cable (LAN Cable) is 2M and is a Shield LAN Cable.

1.2.2. External parts

- **Photos of external parts**

No.	Category	Quantity	Photo

1	DSI-100 Main body (Including normal tip)	1ea	
2	Normal tip	2ea	
3	Lateral tip	2ea	
4	PSM	1ea	
5	Table holder	1ea	
6	Wall holder	1ea	
7	Power adapter	1ea	
8	Ethernet communication cable	1ea	

9	DP cable	1ea	
10	Power cable	1ea	
11	User Manual	1ea	

 # Separately purchased item

1	Wireless LAN Card	1ea	
2	Rechargeable battery	4ea	
3	Battery charger	1ea	

 # options

1	Thumb drive (Containing SCANAPP i software)	1ea	

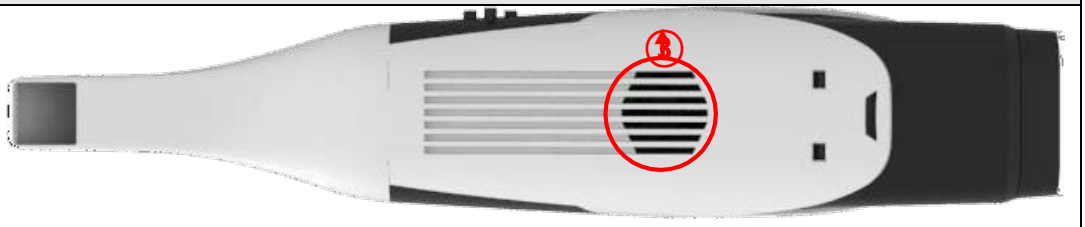
- **Description of external parts**

1) Main body (with basic tip)

Front view

Side view

Back view



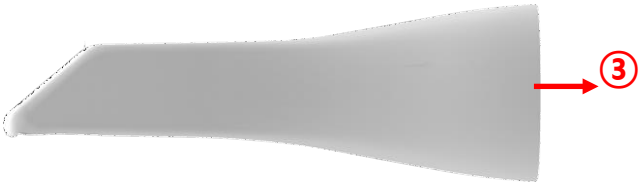
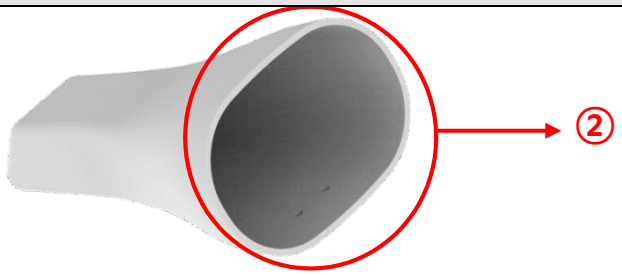
Rear view

No.	Category	Description
1	Main button	Power, Start/Stop Scanning, Scan Stepping and Tool Selection
2	LED status indicator	Power On/Off status, battery charge status display
3	Cooling air inlet	Cooling air intake
4	DP cable & connection port	DP cable connection for Ethernet communication and power supply

5	Battery replacement cap	Rotate the counterclockwise to remove the cap and replace the battery.

2) Normal tip

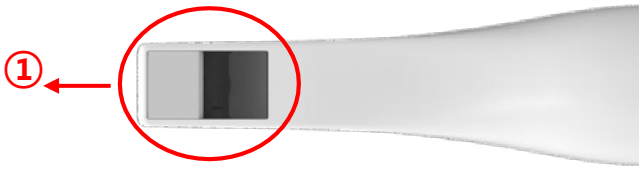
Front view

Side view

Rear view


No.	Category	Description
1	Mirror	Reflects the structured light projected from the mirror projector and the light entering the camera
2	Case	Tip case equipped with a mirror for intraoral scanning and used in combination with the main body
3	Joint	The joint for the main body

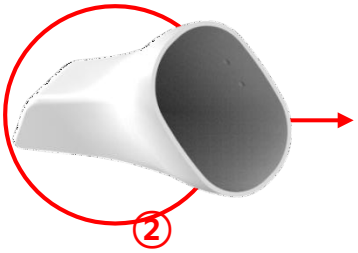
3) Lateral tip

Front view



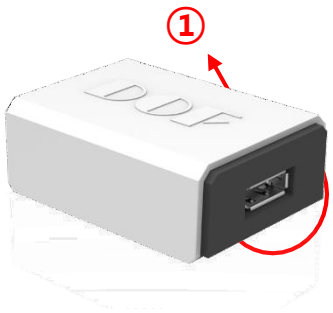
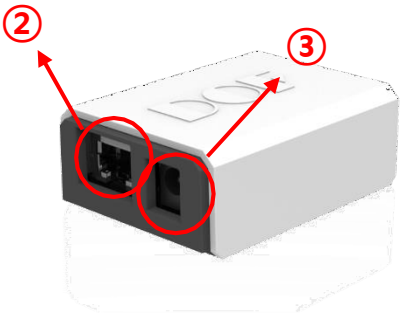
Side view

Rear view



No.	Category	Description
1	Mirror	Reflects the structured light projected from the mirror projector and the light entering the camera
2	Joint	The joint for the main body
3	Case	Tip case equipped with a mirror for intraoral scanning and used in combination with the main body

4) PSM

Photo	
	

No.	Category	Description
1	HDMI port	Port for Ethernet signal and power connection
2	Ethernet port	Port for Ethernet communication with PC
3	Power port	Power adapter and connection port

5) Table holder

Photo

Description
Used as a stand to place the DSI-100 on a table

6) Wall holder

Photo


Description
Used as a mount for fixing to a wall or cart

7) Power adapter

Photo

Description
As a power adapter, supplies power to DSI-100 via PSM

8) Ethernet communication cable

Photo


Description
The signal from the PC is transmitted to the PSM to send the signal to FREEDOM i, and the signal generated from DSI-100 is transmitted to the PC through the PSM . The length of the Ethernet communication cable (LAN Cable) is 2M and is a Shield LAN Cable.

9) DP cable

Photo

Description
PSM supplies power to DSI-100 and sends and receives Ethernet signals

10) Power cable

Photo

Description
Provides power to the power adapter

11) User manual

Photo

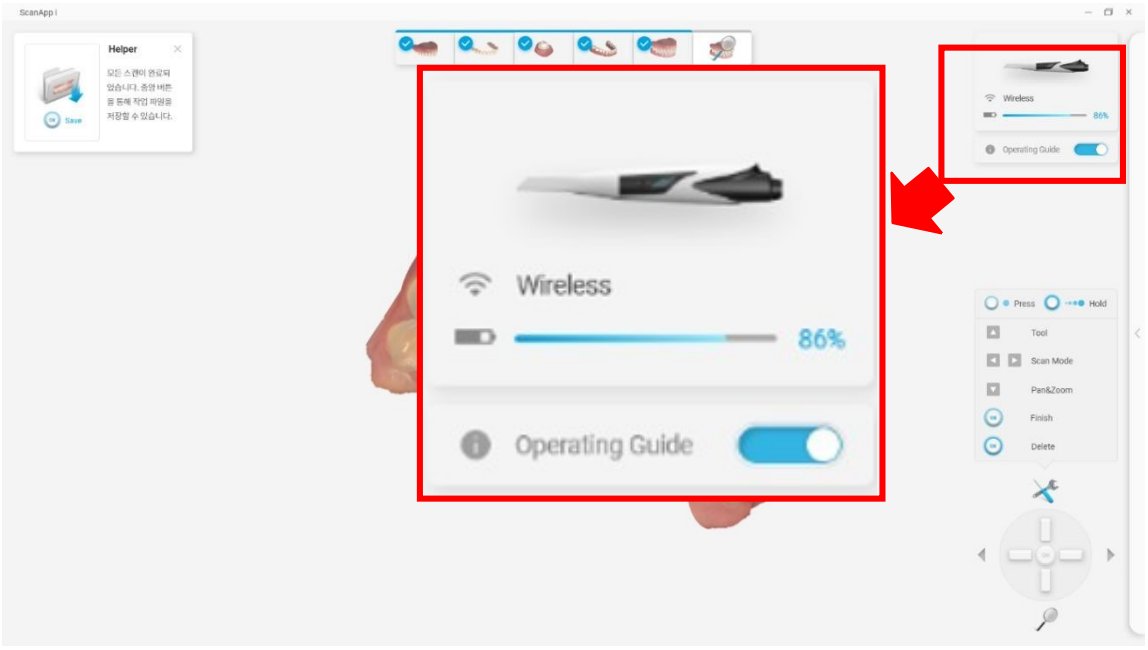
Description
This user manual describes the DSI-100 system overview, system configuration and functions, preparations before use, how to use the system, safety guide, maintenance, disposal, etc. for user safety and proper use.

1.3. Battery status indicator

The battery charge level is indicated by the color of the LED below.

LED Status	Description
Sky-blue	Battery is sufficiently charged
Blinking in sky-blue	Low on battery

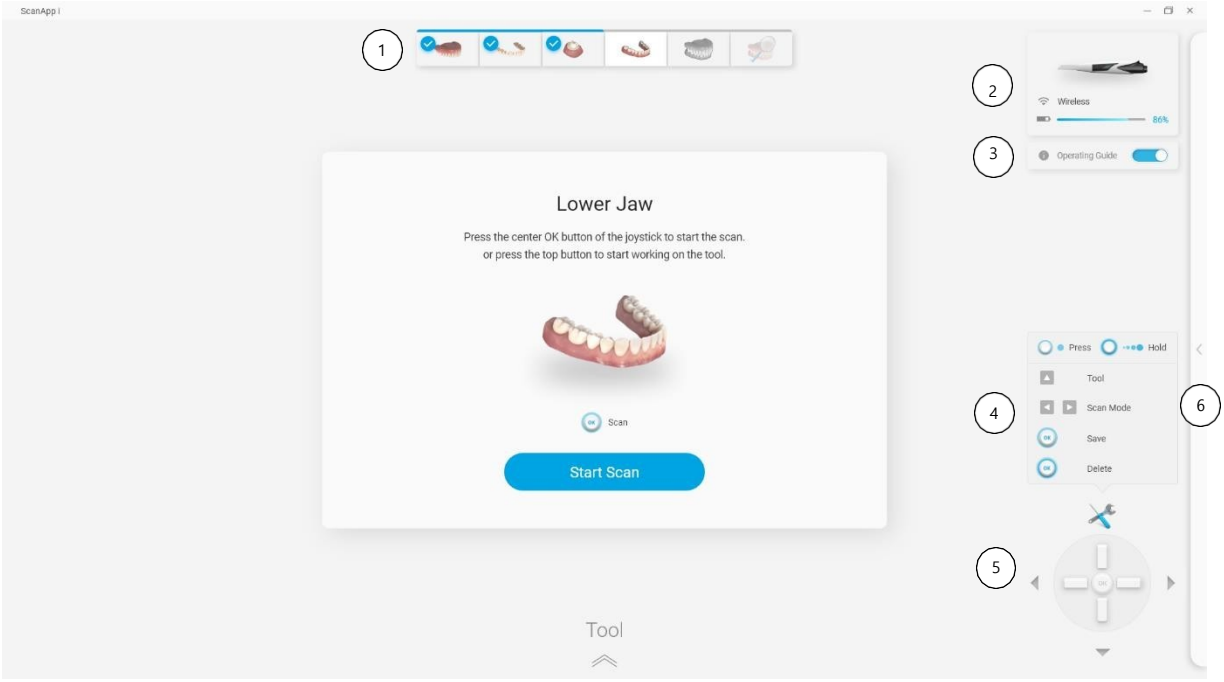
The battery charge level can also be checked in the software.



1.4. Software configuration and functions

1.4.1. Default screen

The default screen of SCANAPP i software consists of the following.

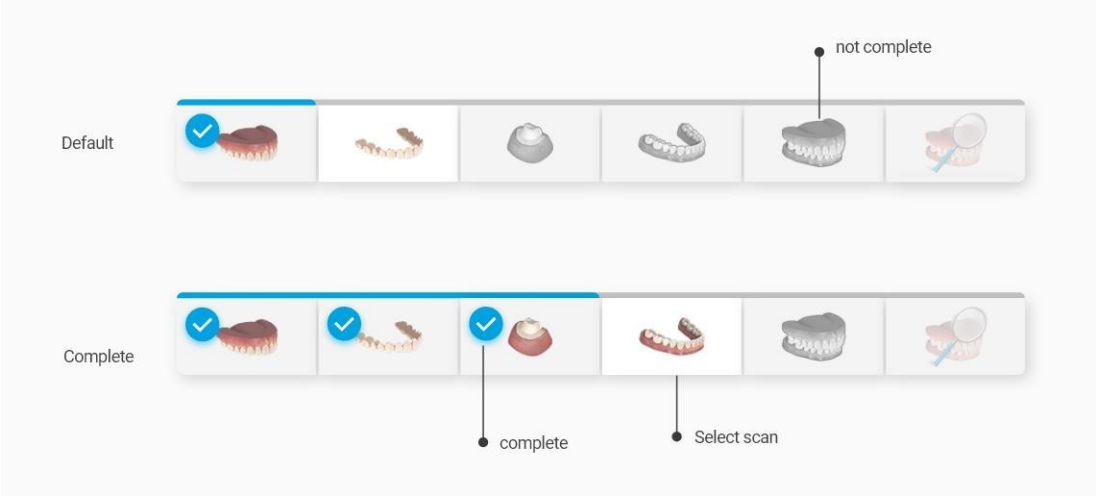


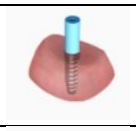
No.	Item

①	Scan step indicator
②	Scanner status indicator
③	User Guide ON/OFF
④	D-Pad Button Guide
⑤	D-Pad indicator
⑥	Open the settings window

1) Scan step indicator

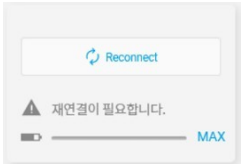
There are a total of 7 scanning steps as shown in the figure below. Steps that have already been scanned are marked with a blue checkmark, steps that are currently being scanned are marked with a white background, and steps that have not yet been scanned are marked with gray. The detailed explanation of each step is given below.



Display format	Format name	Description
	Maxillary pre-op scan	Scan the pre-prep condition of the maxillary teeth
	Mandibular pre-op scan	Scans the pre-prep condition of the mandibular teeth
	Maxillary scan	Scans the prepped teeth and their surrounding teeth
	Prep scan	Intensively scans the prepped teeth
	Scan body scan	Scan body scan
	Mandibular scan	Scans the prepped teeth and their surrounding teeth
	Occlusal scan	Scan the upper and lower jaw in the occlusion state from the side

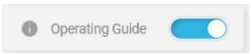
2) Scanner status indicator

Displays the connection status and battery level of connected scanners.

Display format	Format name	Description
	Wireless connection	Confirms that the scanner is connected wirelessly
	Wired connection	Confirms that the scanner is wired
	Not Connected	Appears when the scanner is not connected to the software.
	Full Battery	Displays blue when the battery is full.
	Low Battery	Displays red when the battery level is low

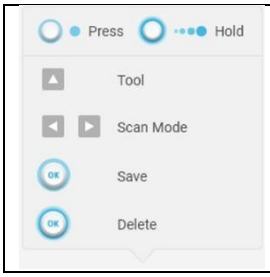
3) User Guide ON/OFF

You can show or hide the guide for inexperienced users.

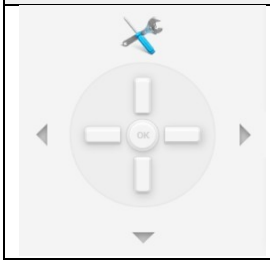
Display format	Format name	Description
	User Guide ON/OFF	User Guide ON/OFF

4) D-Pad Button Guide

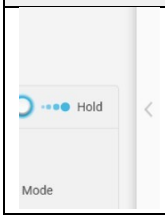
Display format	Format name	Description

	D-Pad Button User Guide	Description of the scanner's D-Pad button

5) D-Pad indicator

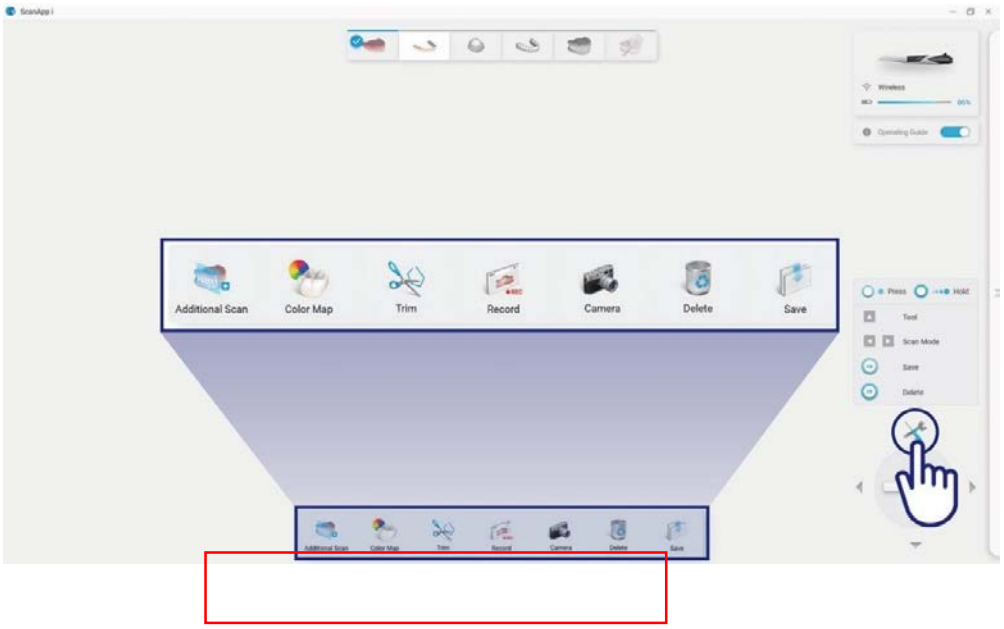
Display format	Format name	Description
	D-Pad indicator	Scanner's D-Pad operation is reproduced in real time on the monitor screen.

6) Open settings window

	Format name	Description
	Open settings window	Open various setting windows

1.4.2. Tool screen

Clicking the top button () of the D-Pad shows the tool menu at the bottom of the screen.



The detailed description of each tool is as follows.

Display format	Format name	Description
 Additional Scan	Additional Scan	Perform additional scans of unscanned areas in various scan steps. Accessible at all scan stages
 Color Map	Color Map	Select Real color or Mono rendering of 3D model
 Trim	Trim	Select and delete unnecessary parts of the scanned data
 Record	Record	Screen recording during intraoral scan
 Camera	Camera	Intraoral 2D photo and video recording
 Delete	Delete	Delete the scan data of the current step
 Save	Save	Save the project file up to the current stage

1) Additional Scan

- If the scan is insufficient or the data is noisy due to saliva, etc., additional

scans can be made to replace the existing scans.

- Clicking the Additional Scan icon shows the following menu at the bottom of the screen.

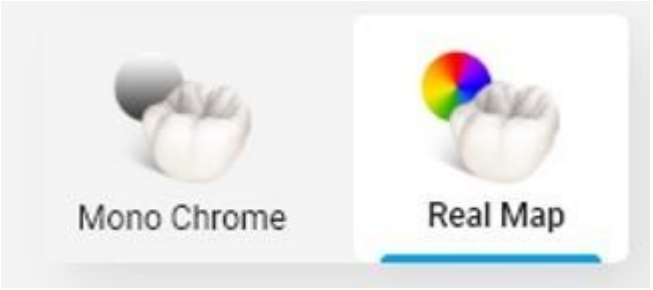
- Details of each tool are as follows.

Display format	Format name	Description
 Upper Teeth	Upper Teeth	Perform additional scan on the upper jaw
 Lower Teeth	Lower Teeth	Perform additional scan on the lower jaw
 Upper Pre-Op	Upper Pre-Op	Scan the upper jaw before tooth preparation
 Lower Pre-Op	Lower Pre-Op	Scan of the mandible before tooth preparation
 F Bite	F Bite Tray	Scan the intraoral scanner DSI-100 F bite

 Impression Tray	Impression Tray	Scan the impression tray (In case that the margin of the tooth is deep or in order to make a post)

2) Color Map

- Select whether to render the 3D data in actual color or monochrome.
- Click the Color Map icon to display the submenu below at the bottom of the screen.



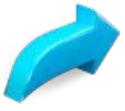
- Details of each tool are as follows.

Display format	Format name	Description
 Mono Chrome	Mono Chrome	express 3D data in monochrome
 Real Map	Real Map	express 3D data in real colors

3) Trim

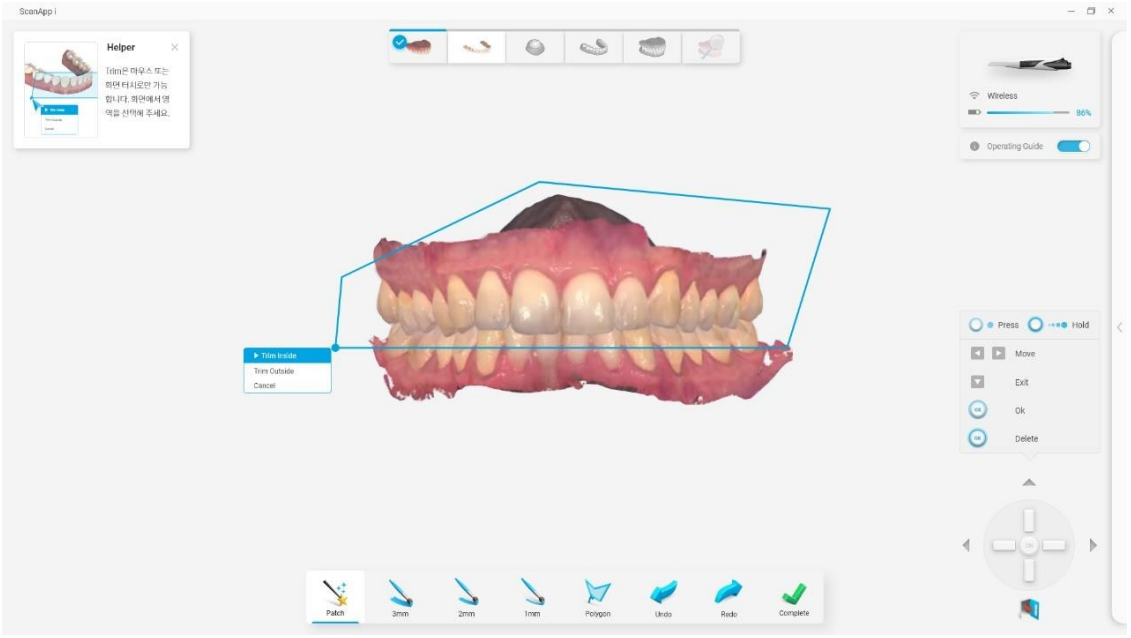
- Delete unnecessary parts of 3D data. Clicking the Trim icon shows the sub-tool menu at the bottom of the screen as shown below.

- Details of each tool are as follows.

Display format	Format name	Description
 Patch	Patch	Delete the island data using left click regardless of the patch size
 3mm	3mm	Delete selected data with 3mm brush
 2mm	2mm	Delete selected data with 2mm brush
 1mm	1mm	Delete selected data with 1mm brush
 Polygon	Polygon	Create a polygon by left-clicking or dragging the mouse and close the polygon by right-clicking to delete the 3D data inside the polygon.
 Undo	Undo	Recover deleted data (at most once)
 Redo	Redo	Cancel redo

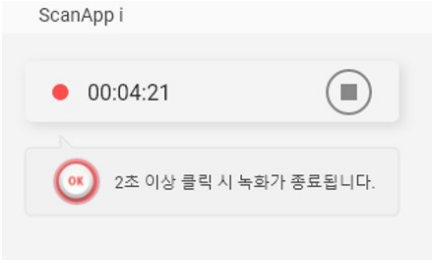
 Complete	Complete	Complete trim and exit trim mode

- When you select the Polygon tool and right-click to close the polygon, the following three menus appear.
  Trim Inside – Delete polygon interior data.
  Trim Outside – Delete polygon outside data.
  Cancel – cancel polygon selection.

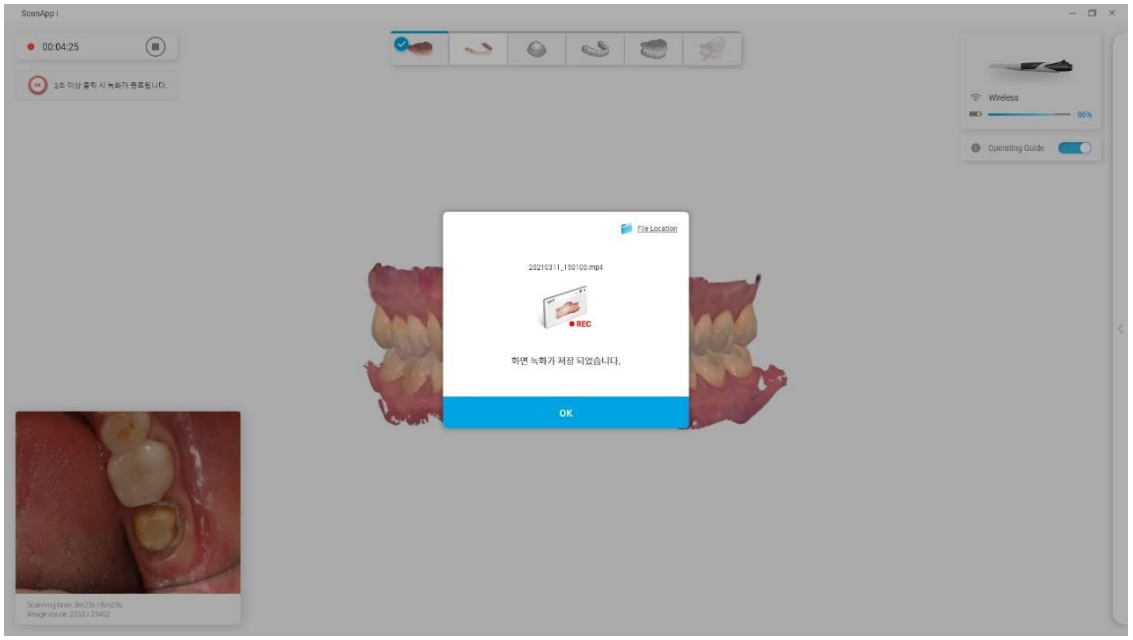


4) Record

- Clicking the Record icon shows the screen recording time at the top left of the screen as shown below.

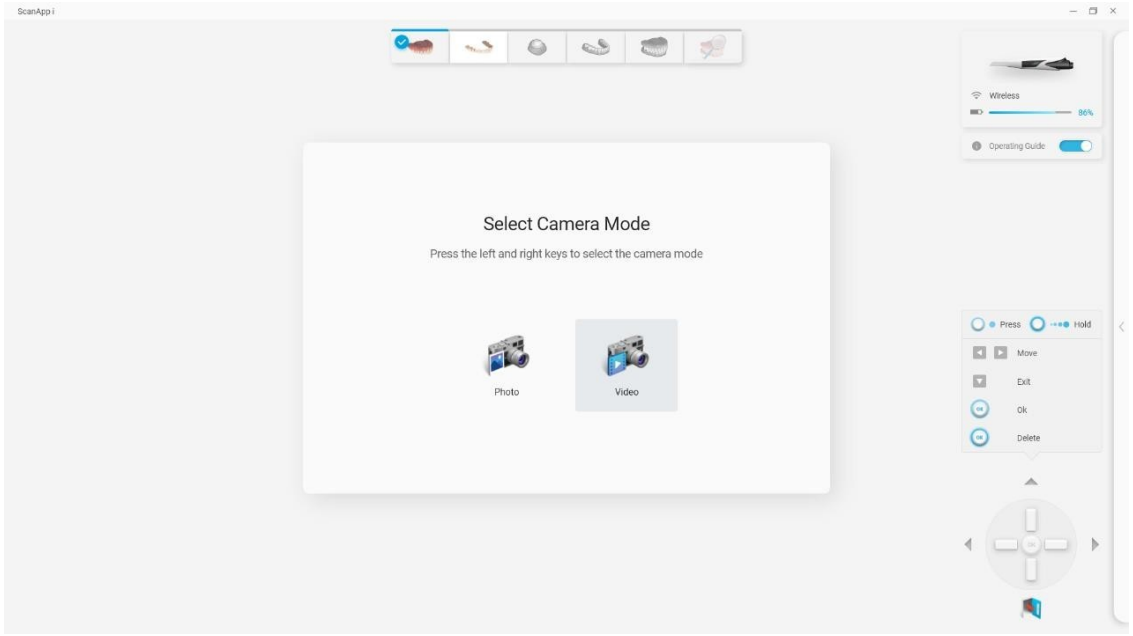


  - Press the center button of the D-Pad on DSI-100 for more than 2 seconds to end recording.

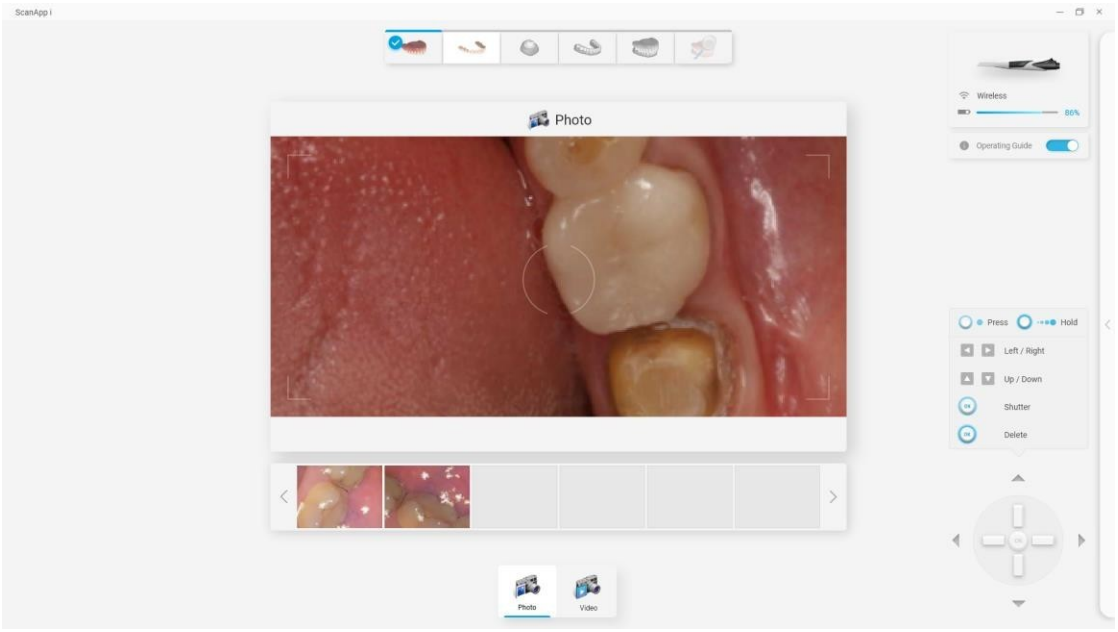


5) Camera

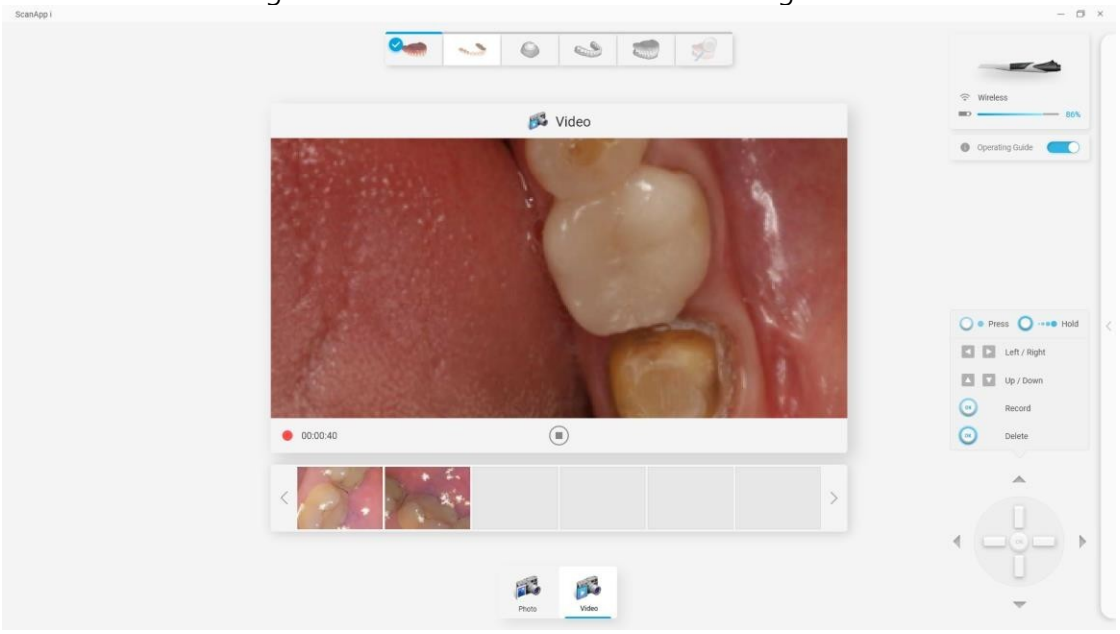
- The Camera tool is used to take pictures or videos of the oral cavity.
- If user clicks the Camera icon, the user can choose to take a photo or video as shown below.



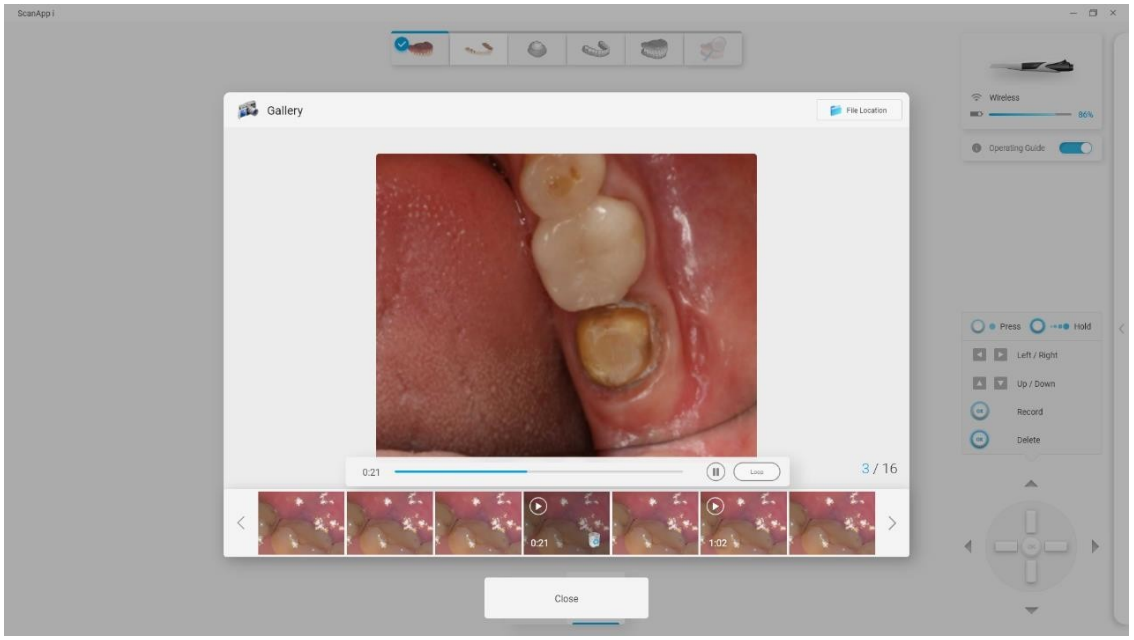
- Clicking the Photo icon shows the camera screen as shown below and press the center button of the D-Pad on FREEDOM to take a photo.



- Photos are saved in the gallery under the camera screen.
- Clicking the Video icon shows the video recording screen as shown below.



- Press the center button of the D-Pad on DSI-100 to start and stop recording. The recorded video is saved in the gallery under the camera screen.
- Photos are saved as jpg files and videos are saved as mp4 files. The files are saved in the patient's Project Files folder along with 3D data.
- In order to check the captured photos or videos, user can click the thumbnail and a gallery pop-up window will appear.



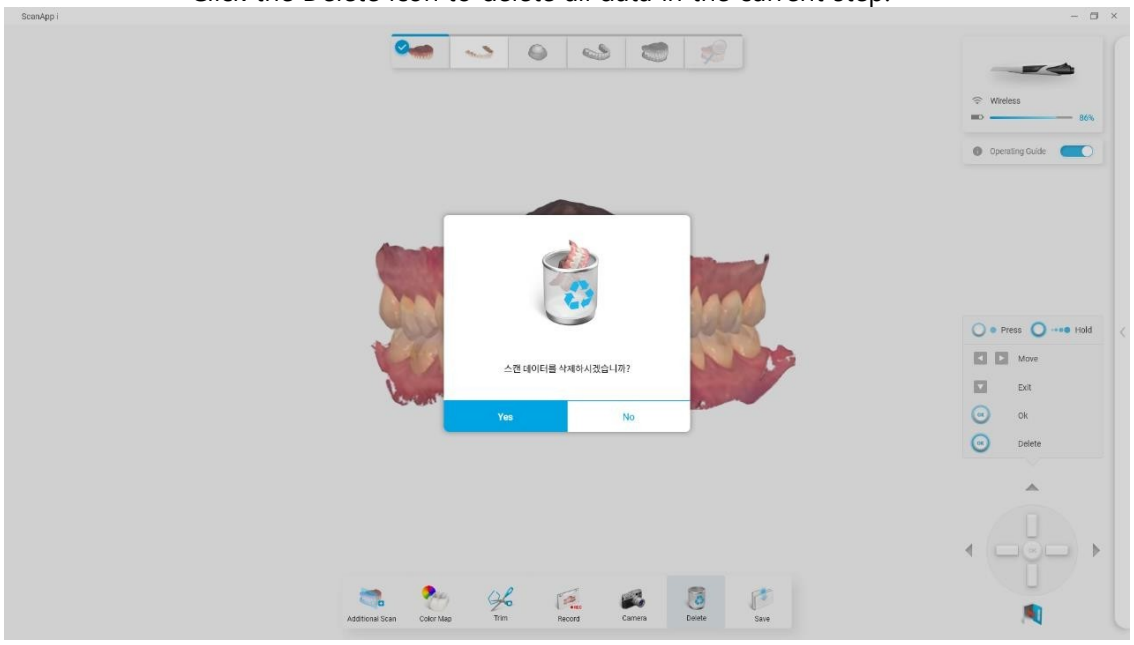
- Use the DSI-100 D-Pad button to view photos or videos.

D-Pad button	
	
Function	**Action**
Select	Press and hold button no.1
Start video playback	Short press button no.1
Stop video playback	Short press button no.1 during video playback

Move the thumbnail to the right	Short press button no.4
Move the thumbnail to the left	Short press button no.3

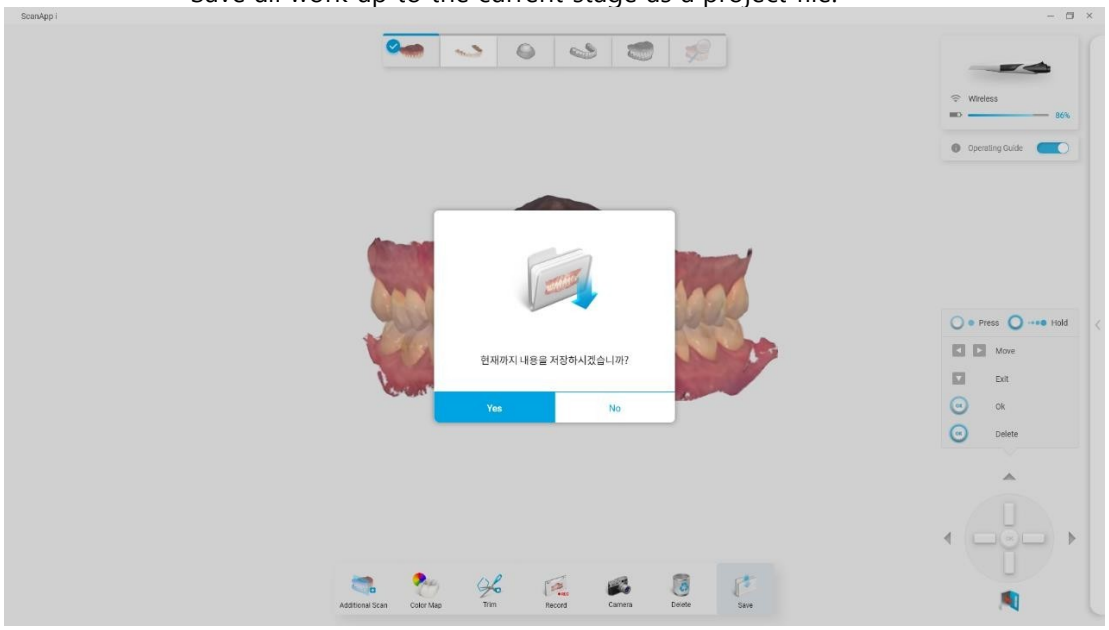
6) Delete

- Click the Delete icon to delete all data in the current step.



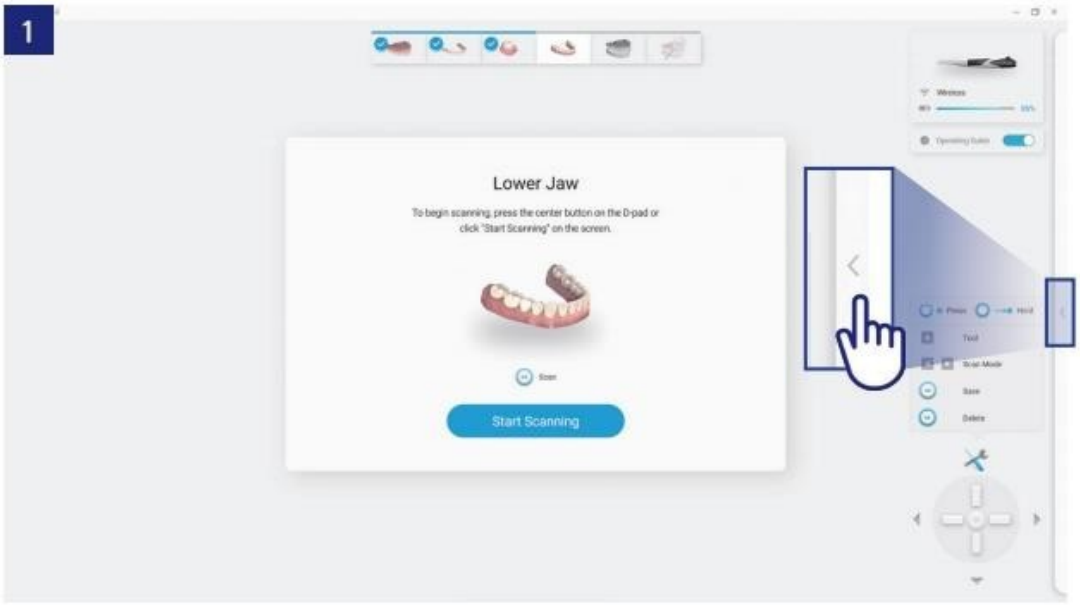
7) Save

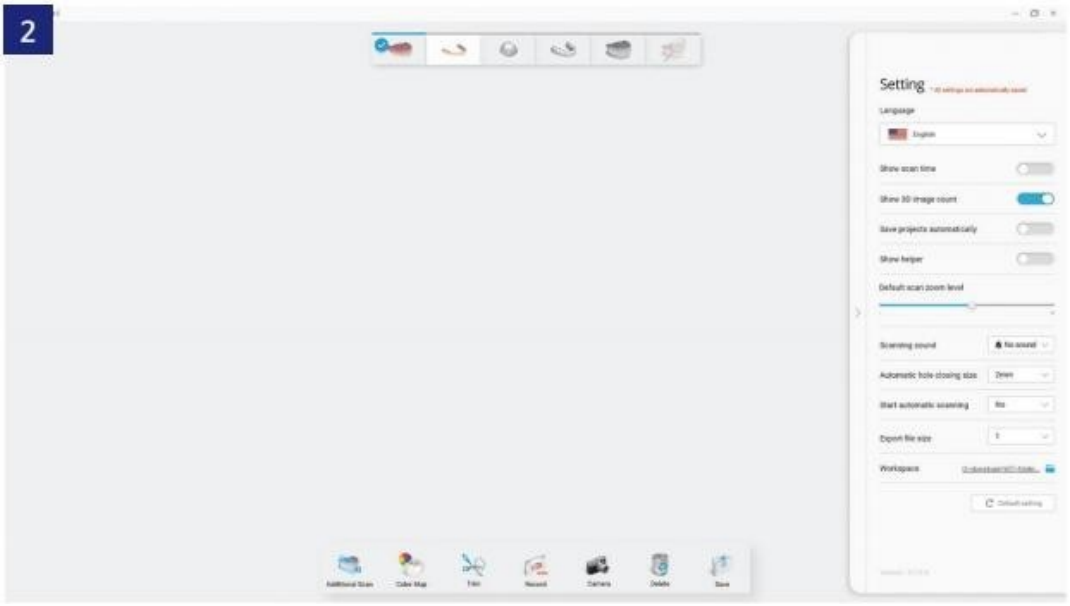
- Save all work up to the current stage as a project file.



3.4.3. Settings and status display

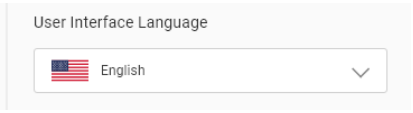
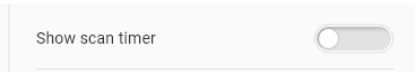
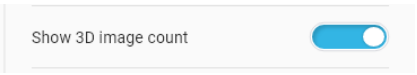
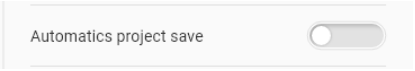
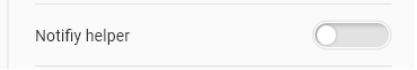
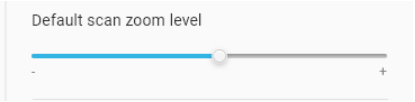
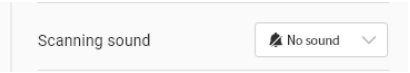
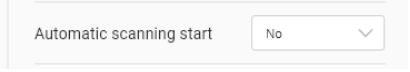
Clicking the right arrow on the screen shows the setting window.

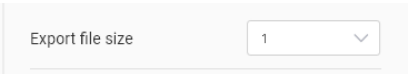
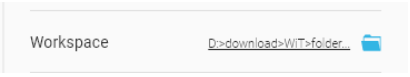
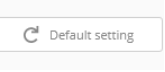




A detailed description of each item is shown in the table below.

Display format	Description

	Choose UI language
	The scan time is displayed at the bottom left of the main screen
	The number of scanned 3D data is displayed at the bottom left of the main screen
	Automatically save project file after each scanning step
	Activate software guide
	Set the default size of 3D data displayed on the screen
	Select scan sound
	Select automatic hole fill size
	Automatically begin scanning at the start of each scan step

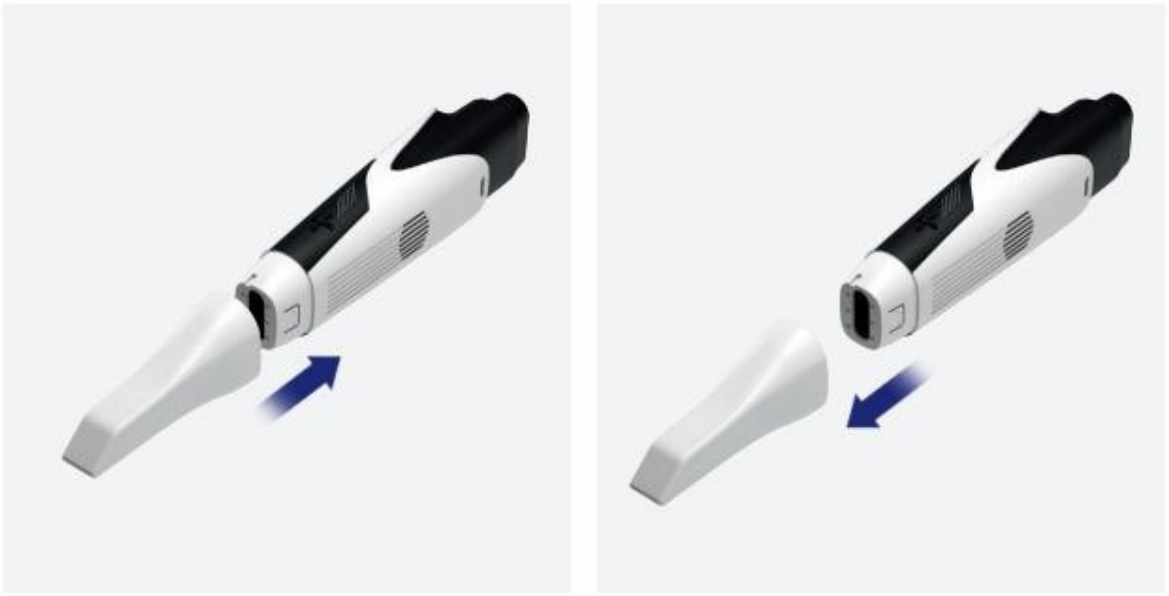
	Select the export file size of 3D data
	Set the storage location for photos and videos. The default location is the same as the project file location of the current case.
	Restore to default settings
	Software version

2. Preparation before use

2.1. Body assembly

Step.1: Rotate the battery cap on the rear counterclockwise to remove the battery replacement cap. After installing the battery, rotate the cover clockwise to close the battery cap.

Step.2: Install the sterilization relief tip to the body. At this time, after wearing the surgical protective gear, you can remove it in the direction of the arrow.



2.2. Cleaning and sterilizing

2.2.1. Tip

- The manufacturer provides unsterilized scanner tips. Therefore, tips must be cleaned and sterilized before first use.
- In the case of cleaning, use soapy water and a brush to clean it thoroughly, and if foreign substances or stains are found on the mirror inside the tip, clean it again in a repetitive manner.
- When cleaning is complete, wipe the tip mirror lightly with a clean cloth to remove moisture. The cloth should be a dry, lint-free cloth.
- Wiping with strong force may cause scratches on the mirror, which may affect the quality of the scanned data.
- If foreign substances or stains on the mirror are not removed by cleaning, or if the mirror of the scanner tip is dirty, scan data may not be acquired normally, or the quality of the acquired scan data may deteriorate. Observe the following instructions.
    1) After removing the tip from the scanner, clean it with a clean cloth or cotton swab dipped in an enzyme cleaner until it is clean.

       [Recommended product specifications]

       Ethyl alcohol or ethanol (60-70% Alc/Vol)
    2) After wiping the mirror with a dry, lint-free cloth, check to see if any dust or fibers remain on the mirror, and repeat until they are gone.
    3) If the stain persists through the above procedure, replace the tip.
- Place the cleaned and dried tips into a sterile bag (or pouch) and seal tightly.
- Place the tip in the autoclave while still sealed.
- Perform sterilization under the following conditions. After sterilization, allow the tip to dry completely before removing the product from the sterilizer.

  [Steam (high pressure steam) sterilization conditions]

  121 ℃, heating for 30 minutes / drying for 15 minutes
- Autoclaving the tip in a sterile bag (or pouch) that is not completely sealed can leave stains on the mirror that cannot be cleaned. For details, refer to the operating instructions of the autoclave.
- Visually inspect the scanner tip for signs of degradation before use.

- Use of damaged tips may cause unintentional injury to the patient. Discard the tip upon finding any damage.

2.2.2. Body

- Clean and disinfect the intraoral scanner body after scanning is finished and the

machine is turned off.

- For general cleaning, use a soft cloth and disinfectant solution. For the disinfectant solution, the following products are recommended to prevent damage to the product.

  [Recommended product specifications]
  Ethyl alcohol or ethanol (60-70% Alc/Vol)
- For the front optical lens of the body, as with the mirror in the tip, care must be taken to avoid foreign matter and smudges.
- If you wash with the power applied, you must be careful as the cleaning solution permeates into the product and may cause a malfunction. After washing, the body should be completely dried before use.
- Read and follow the warnings and personal protection instructions provided in the safety data sheet (SDS) regarding the disinfectant used to handle the scanner for reuse.
- Gloves must be worn when cleaning and disinfecting the scanner.
- Do not place the scanner in a sterilizer or immerse it in water or disinfectant solutions.
- Excessive liquid may damage the scanner.
- When disinfecting the scanner, do not use cotton products, clothing or tissues soaked in disinfectant.
- If the scanner is contaminated with blood or bodily fluids, it must be cleaned prior to disinfection.
- The scanner must be thoroughly disinfected after each patient visit.

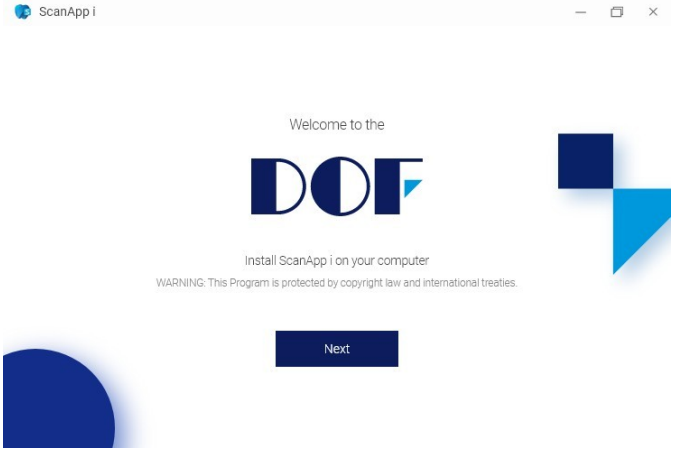
2.2.3. External parts

- Surfaces should be wiped with a soft, non-abrasive, lint-free cloth moistened with a non-drip disinfectant solution.
- Use after the surface is completely dry.

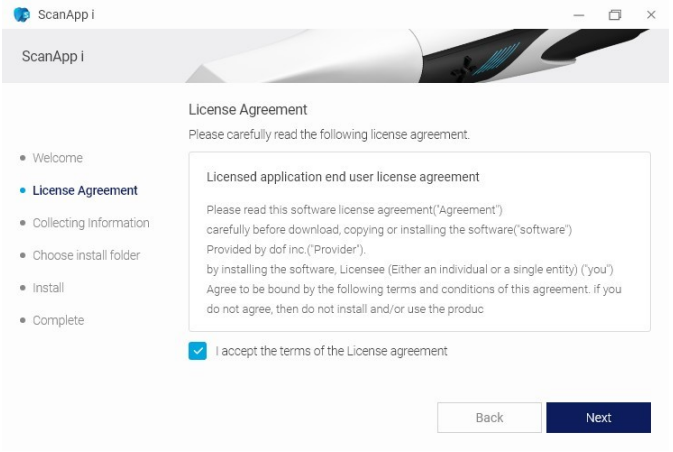
2.3. Software installation

- You must install and use only approved software for normal use of your DSI-100 system.
- We recommend Windows Update before installation. If the installation does not work normally, contact the supplier.
- The installation file of SCANAPP i software to run DSI-100 is included in the thumb drive included with the product.

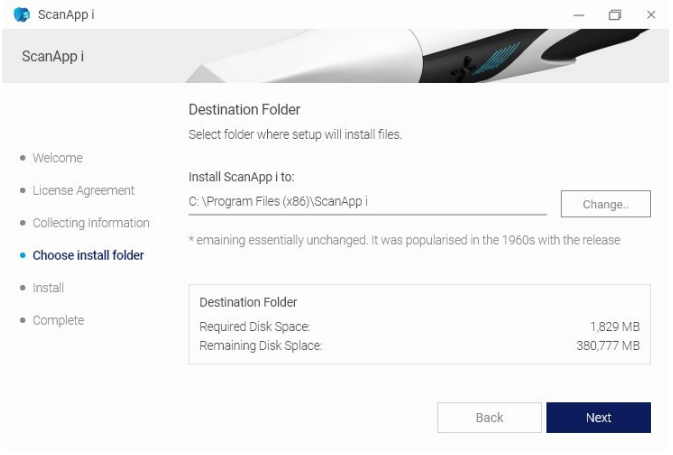
- The icon of the installation file is shown on the right.
- Proceed through the installation wizard.



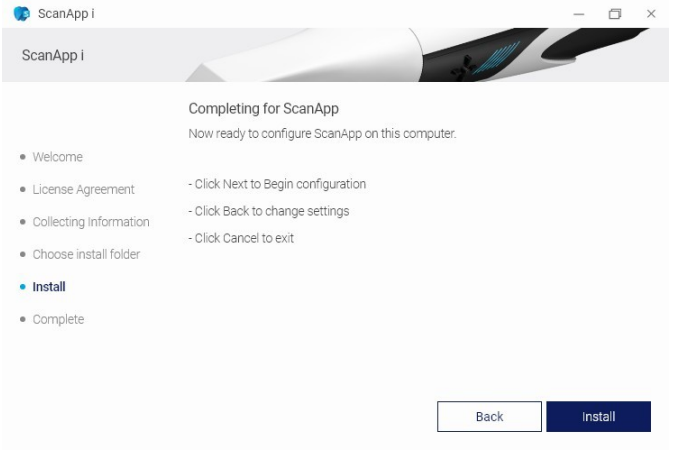
- Read the License Agreement carefully and check the Agree button.



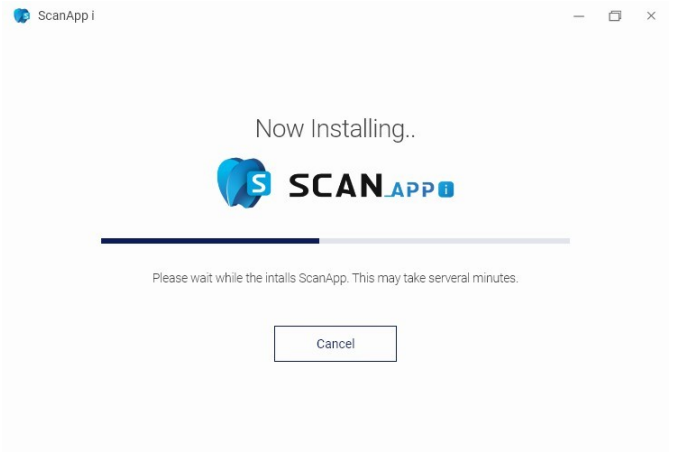
- Select the location to install the SCANAPP I software.



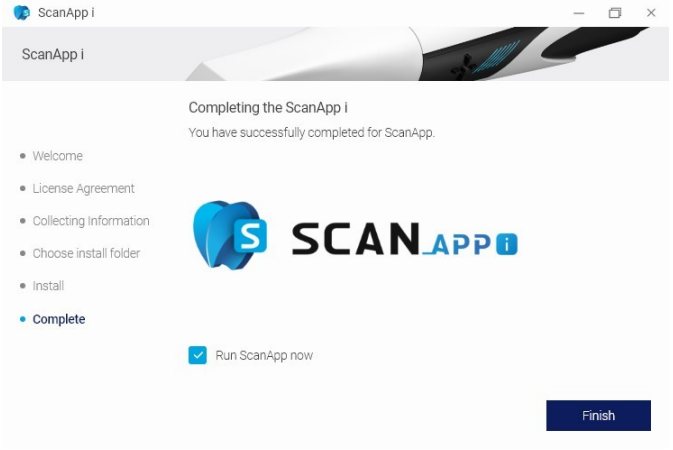
- Click the Install button to proceed with the installation.



- Installation may take several minutes. Do not power off your PC during installation.



- Installation is complete. Click the Finish button.



- Reboot the PC after installation is complete.

3. System operation

3.1. Turning on and off

3.1.1. Turning on the DSI-100 main system

Step 1: Insert a charged battery for a wireless connection. Connect the cable if using a wired connection.

Step 2: Press the center button of the D-Pad on the main unit for 3 seconds.

Step 3: When the power is turned on, the LED lights up and the body vibrates. In case of wireless connection, connect by selecting the corresponding serial number in SCANPP i.

3.1.2. Turning off DSI-100 main system

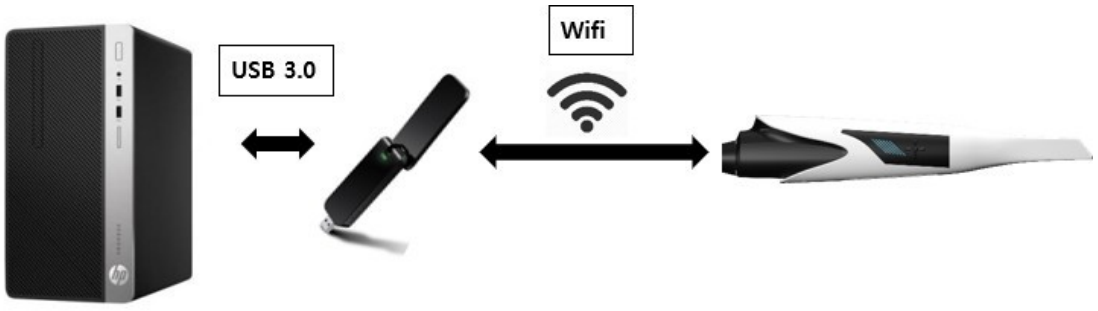
Method 1: Press the center button of the D-Pad on the main unit for 3 seconds.

Method 2: Click the Power Off button in the SCANAPP i software.

Method 3: After exiting the SCANAPP i software, wait for more than 1 minute without any operation.

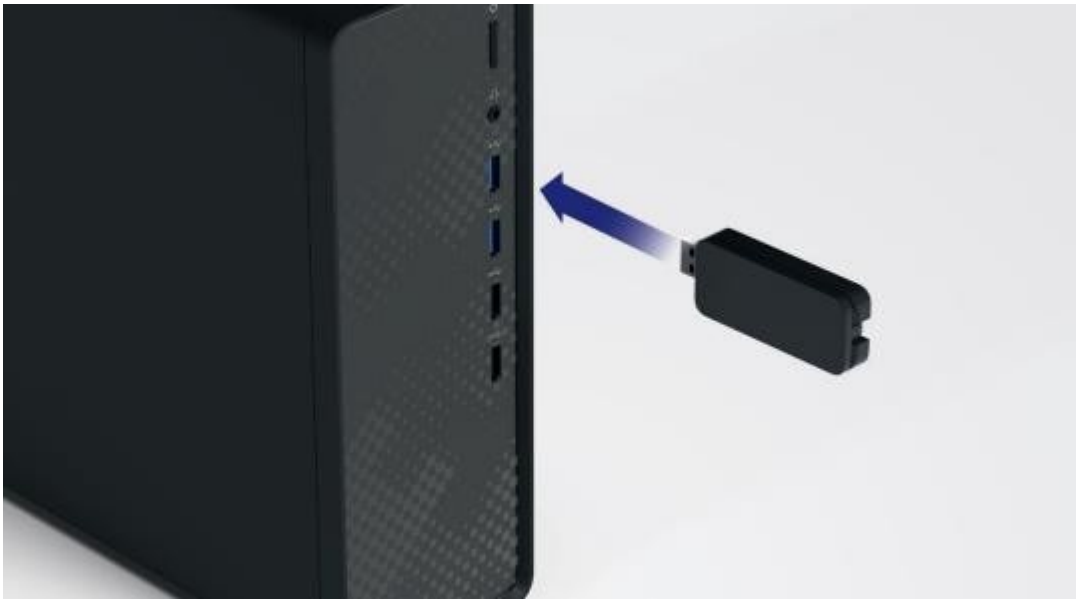
3.2. Wireless and wired connection

3.2.1. Wireless connection



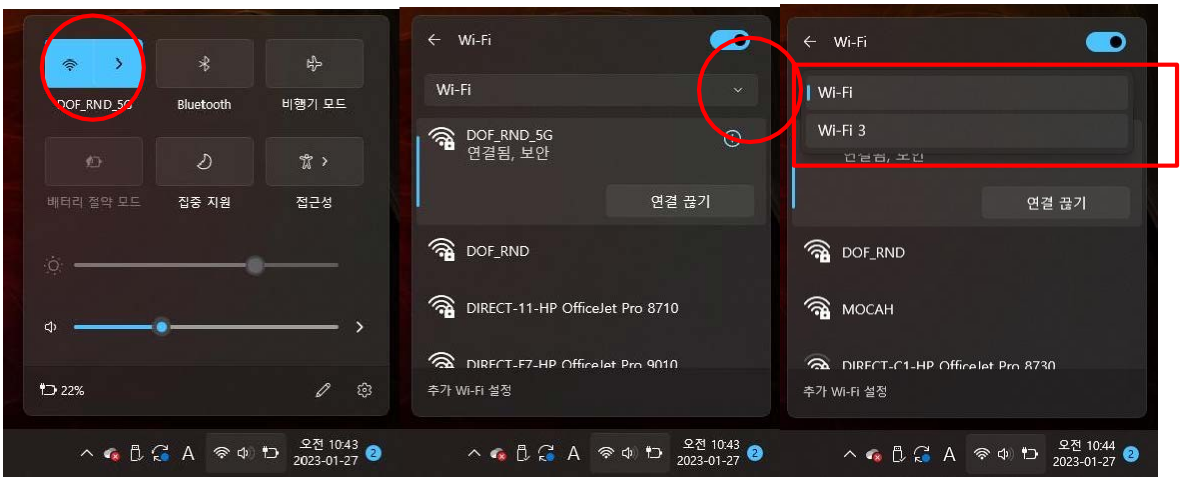
[Wireless connection flow diagram]

Step 1: Connect the wireless LAN card to the computer's USB 3.0 port.



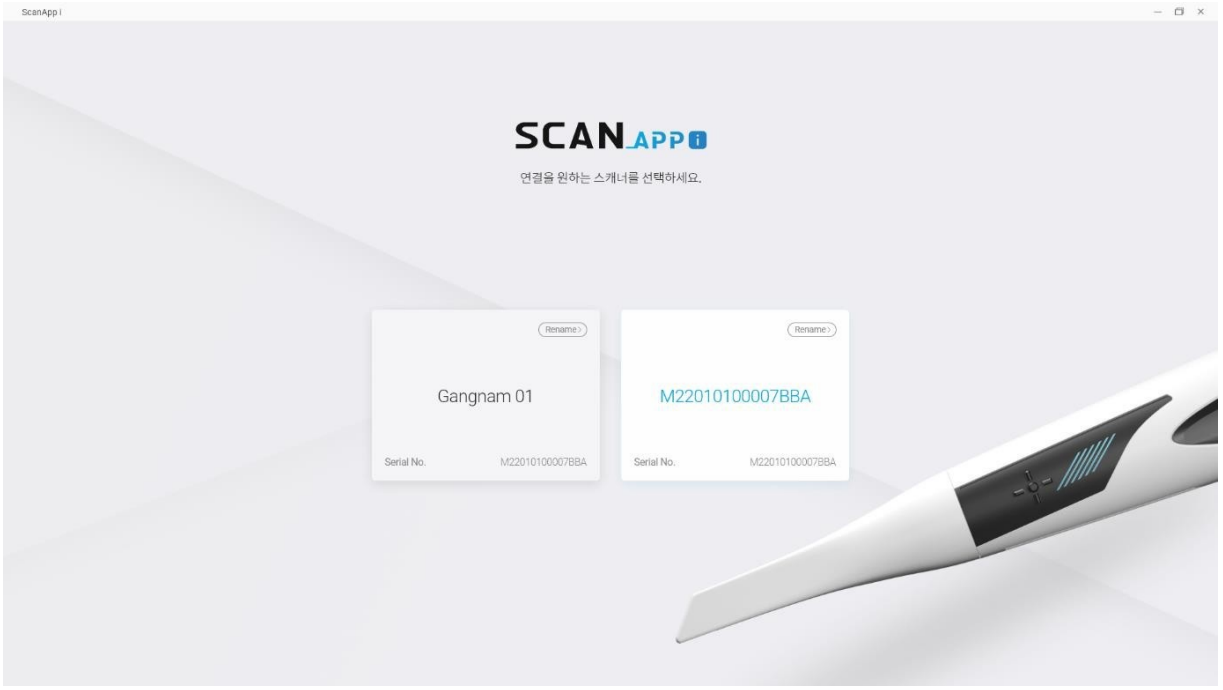
Step 2: Click the Wi-Fi button at the bottom right of the PC monitor to check if the USB wireless LAN card is connected.

Step 3: As shown in the picture below, if additional Wi-Fi devices are displayed in addition to the PC's built-in Wi-Fi, the wireless LAN card is connected normally.



Step 4: Turn on the DSI-100 main body and run the SCANAPP i software after 3 seconds when the LED lights on the main body and vibration is felt.

Step 5: Select the serial number of the DSI-100 you want to use on the software screen and connect.



[Screen for selecting the serial number of the scanner to use]

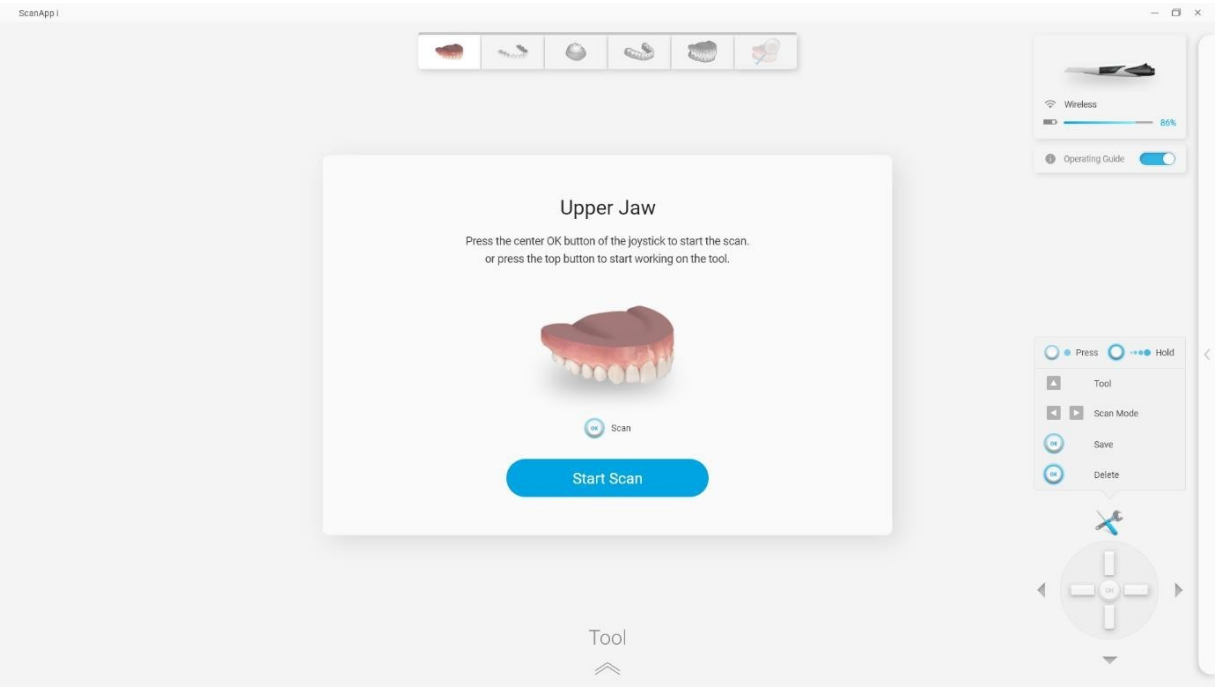
Step 6: Once the connection is complete, you can launch the SCANAPP i software to perform a scan.

[Wireless Connection Conditions]

- Actual frequencies depend on local regulations.
- The actual usage distance is up to 5m, and the available distance may vary depending on the usage environment.

- CE/FCC/IC
  - 802.11 ac(VHT40) : 5 190 MHz ~ 5 230 MHz
  - 802.11 ac(VHT80) : 5 210 MHz
  - 802.11 ac(VHT40) : 5 755 MHz ~ 5 795 MHz
  - 802.11 ac(VHT80) : 5 775 MHz

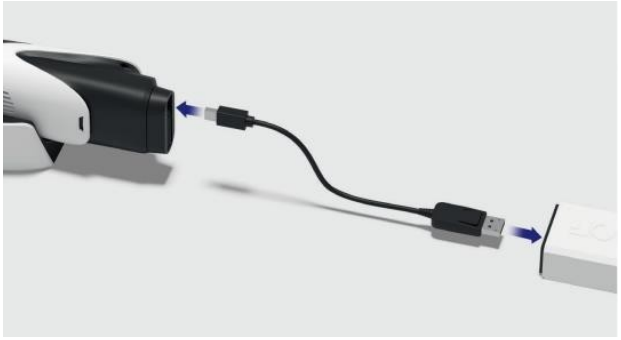
- Telec
  - 802.11 ac(VHT40) : 5 190 MHz ~ 5 230 MHz
  - 802.11 ac(VHT80) : 5 210 MHz



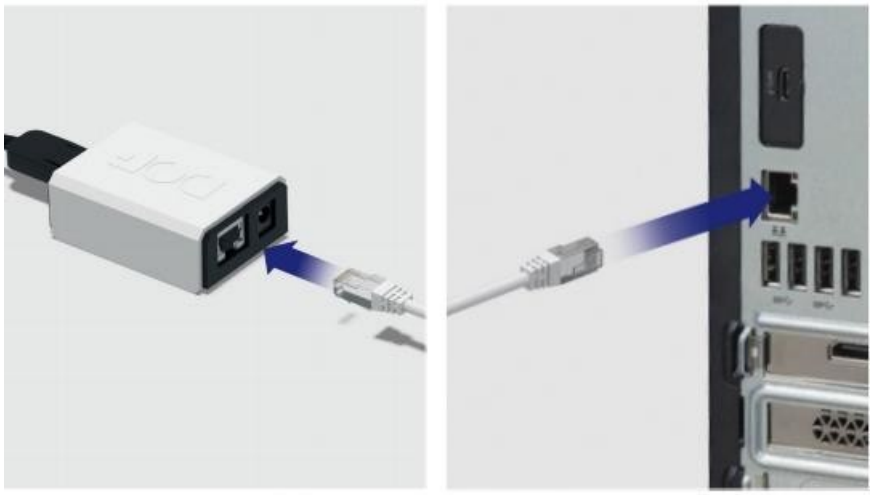
[Screen when the scanner is successfully connected]

3.2.2. Wired connection

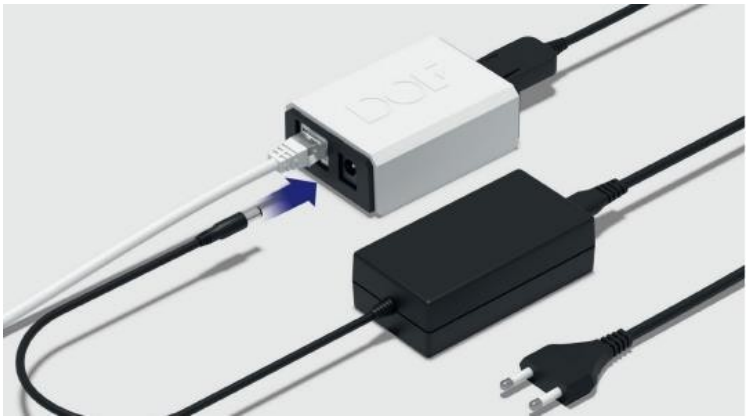
Step 1: Connect the intraoral scanner and PSM with an DP cable.



Step 2: Connect PSM and PC with LAN cable.



Step 3: Connect adapter power to PSM.



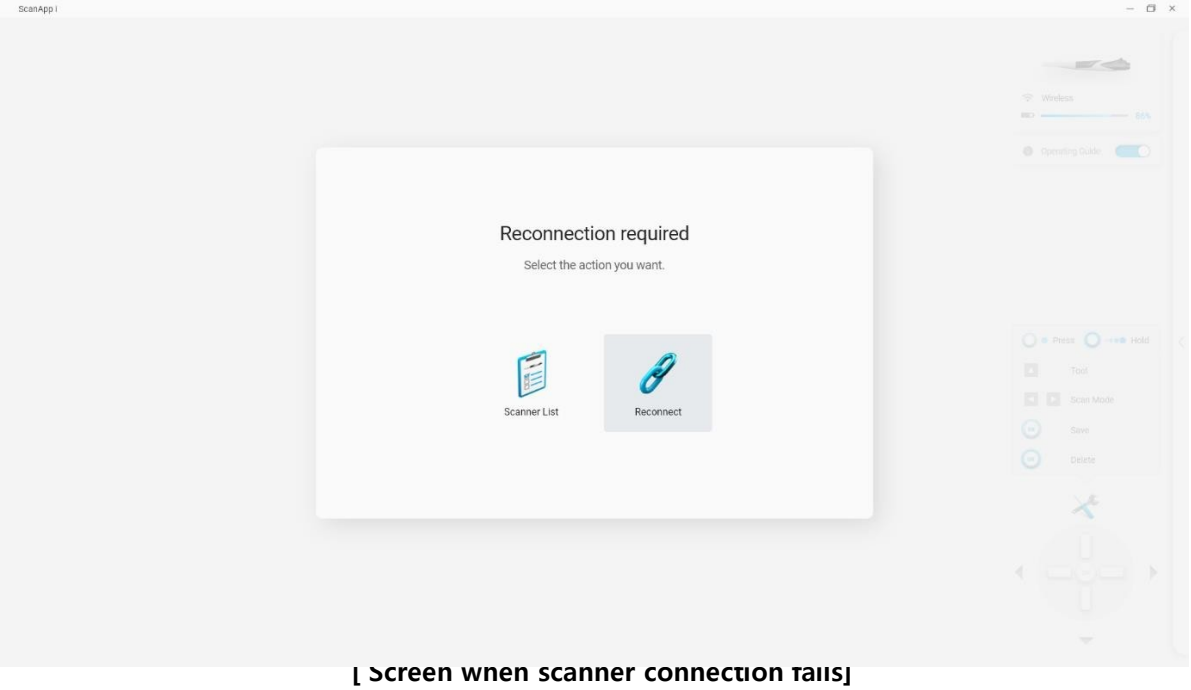
Step 4: Press and hold the center button (No. 1) of the D-Pad on the intraoral scanner with your hand for 1 second to turn on the DSI-100 main body and run the SCANAPP i software when the main body vibrates after 3 seconds.

When power is normally supplied, the display part of the intraoral scanner body lights up

in blue.

3.2.3. Scanner connection failure

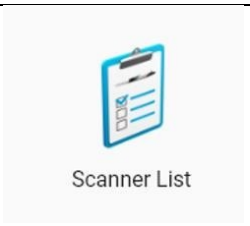
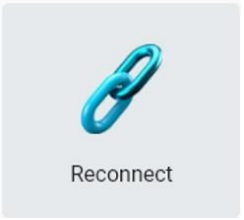
- If the connection to the scanner fails, the screen below appears.



[Screen when scanner connection fails]

- The description of each button is as follows.

Display format	Format name	Description

	Scanner List	Go to scanner list screen
	Reconnect	Try reconnecting with the same scanner

Step 1: If the scanner connection fails, click the Reconnect button to try again, or click the Scanner List button to go to the scanner serial number selection screen and try to connect again from the beginning.

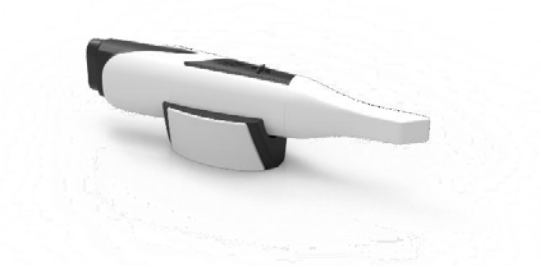
Step 2: If the connection is in progress, the LED on the top of the main unit blinks, and when the connection is complete, the LED on the top of the main unit turns on.

Step 3: Once the connection is complete, you can launch the SCANAPP i software to perform a scan.

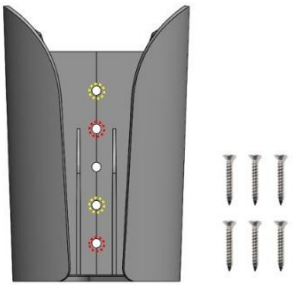
3.3. How to use the cradles

3.3.1. Table holder

The horizontal holder is placed on a flat table and holds DSI-100.



3.3.2. Wall holder



① Place the wall mount horizontally against the wall and mark the screw holes.

(at least 2 locations depending on the surrounding environment)

② Use the 6mm bit of a drill to drill a 30mm deep hole and insert the knife block into the hole. (Depending on the installation environment, the knife block may not be used)

③ Secure the wall mount to the wall using the included screws.

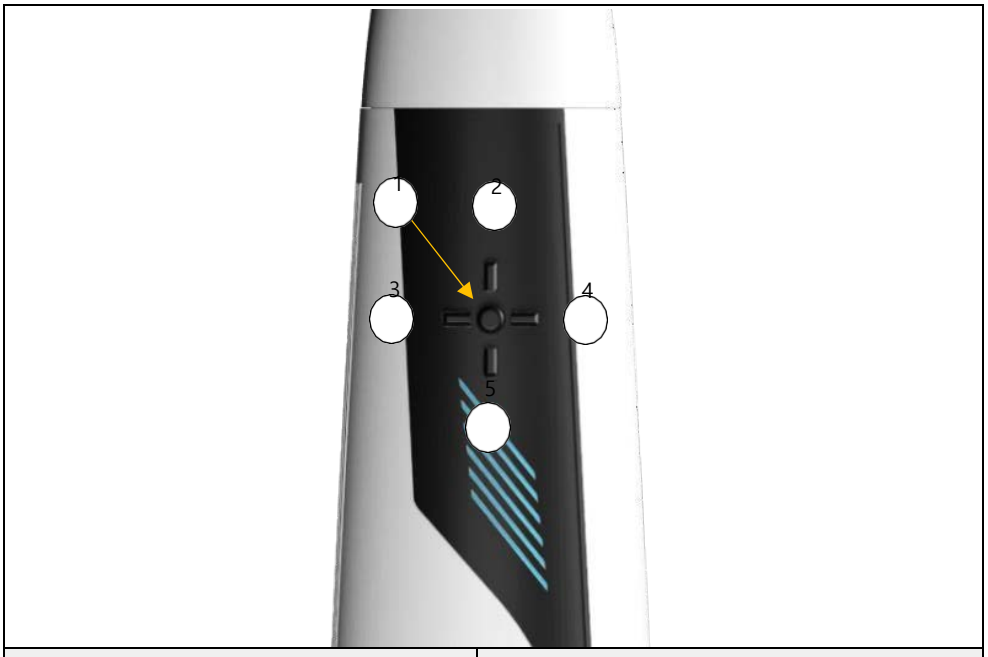
(Six M3 30mm countersunk head screws provided)

3.4. Mouse interaction

Mouse button	Button name	Description
	**Left click**	Click icon to use associated functions. Select the "trim" area of 3D data.
	**Right click**	Rotate 3D data. Terminate "trim" operation of 3D data.
	**Scroll**	Zoom in or out of 3D data.

3.5. Functional button interaction

D-Pad button

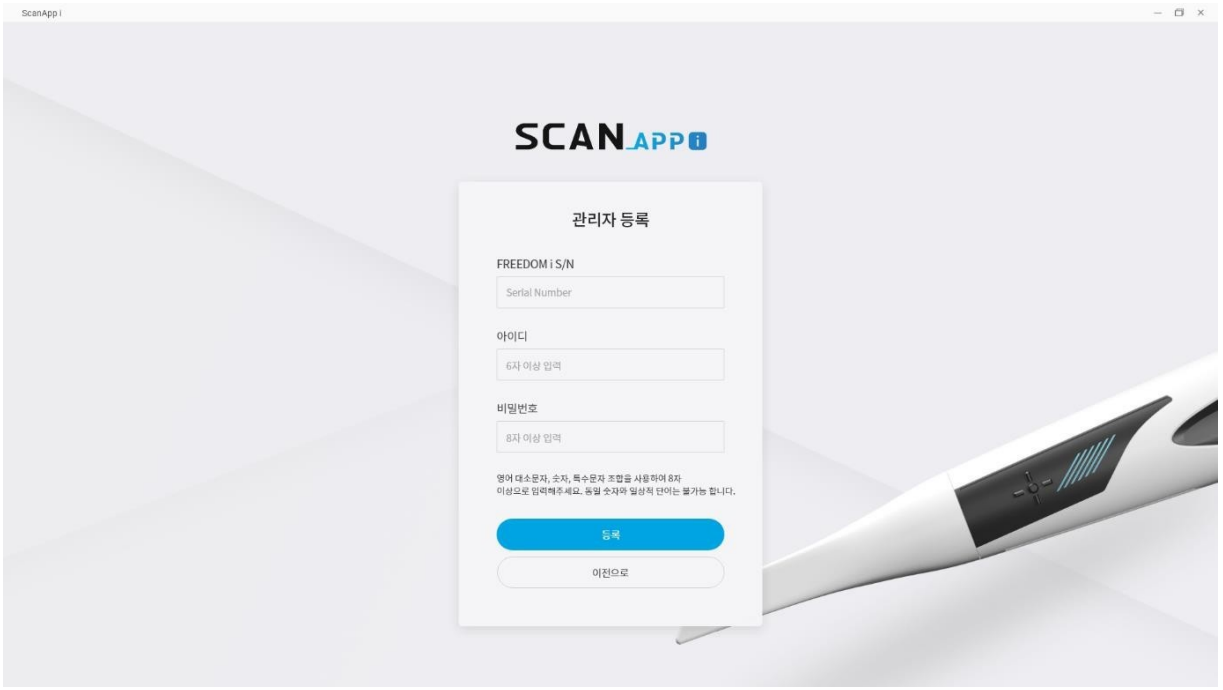


Operation	Action
Power on	Press and hold button no.1
Start scanning	Short press button no.1
Stop scanning	Short press button no.1 in scan mode
Go to the next step	Short press button no.4
Go to the previous step	Short press button no.3
Enter the tool menu	Short press button no.2
Select tool icon on the right	Short press button no.4
Select tool icon on the left	Short press button no.3
View mode	Short press button no.5
Click the selected icon	Short press button no.1
Exit the tool menu	Short press button no.5
Power off	Press and hold button no.1

3.6. Login

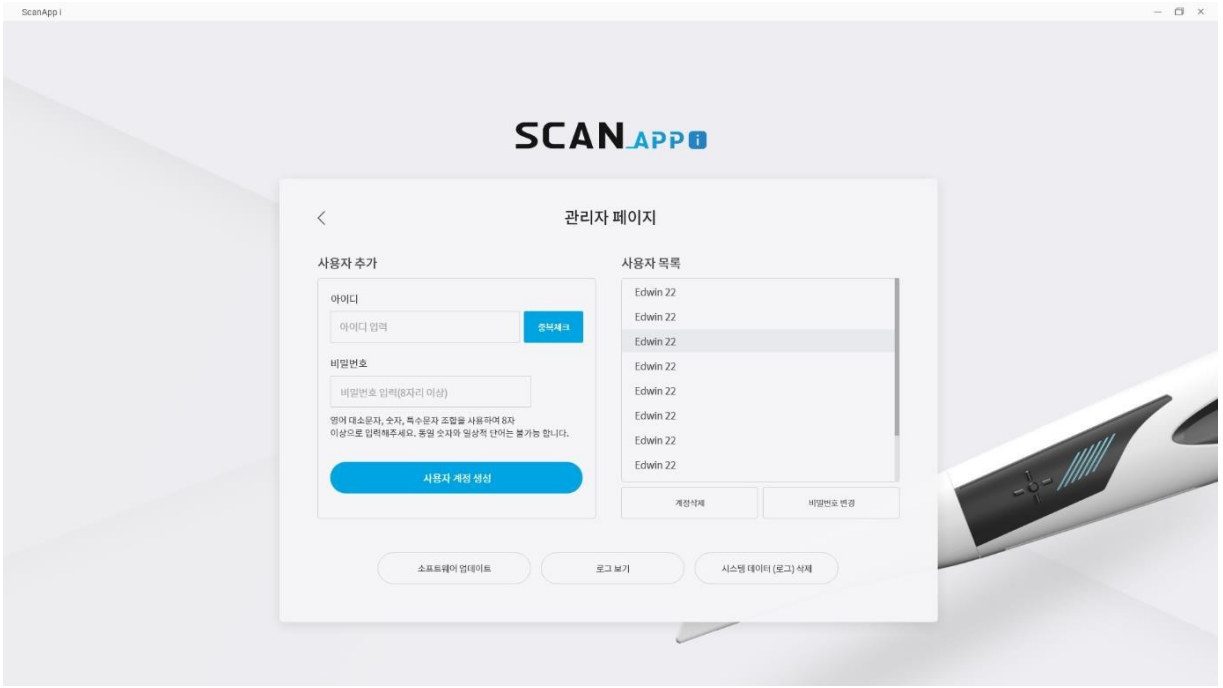
3.6.1. Registering administrator

Click the "Register administrator" button to register the admin for the first time. Enter the DSI-100 serial number and register your ID and password. Only one administrator ID can be registered per device.



3.6.2. Registering user

- If a user registers an administrator and log in as an administrator, the administrator page appears.



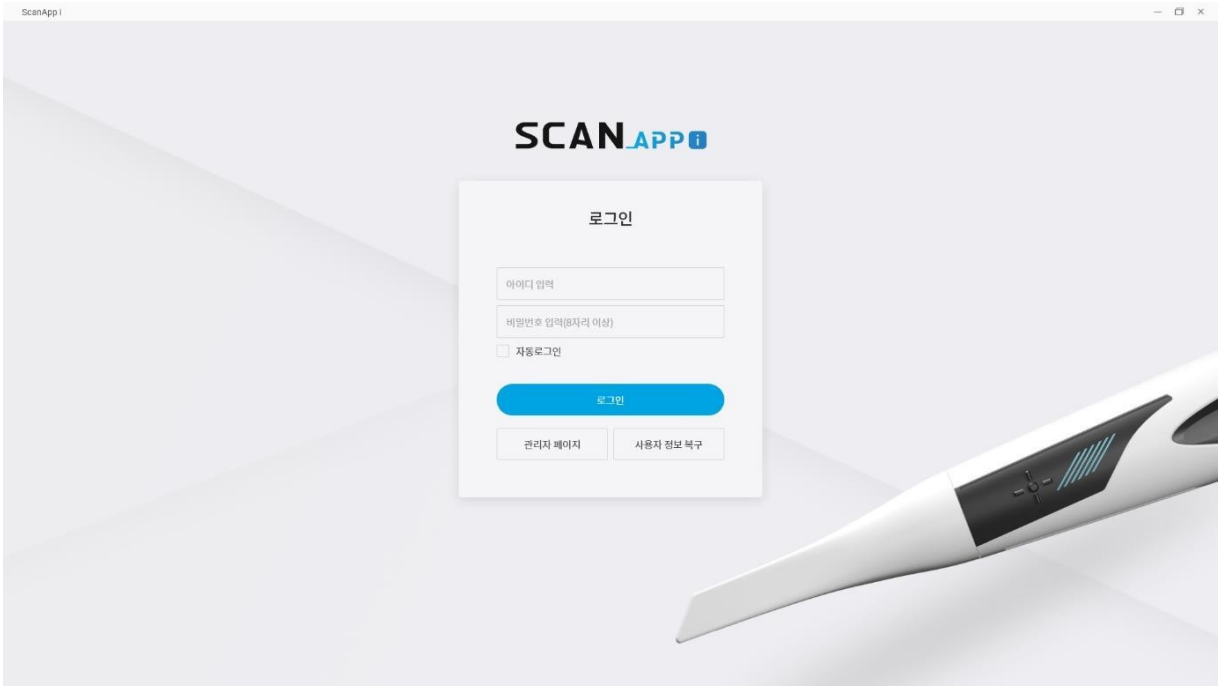
- General users can be registered from the administrator page.
- Administrator can select and delete a user from the right user list or change the password. If a general user has lost their ID or password, they should contact the

administrator for confirmation.

- Only the administrator can update the software on the administrator page and delete system data before disposing of the product. We may also back up your information and store it in a third location.
- Even if the PC is changed or formatted, you can log in with the same ID and password as before by loading the user information backed up on the login screen.

3.6.3. Login screen

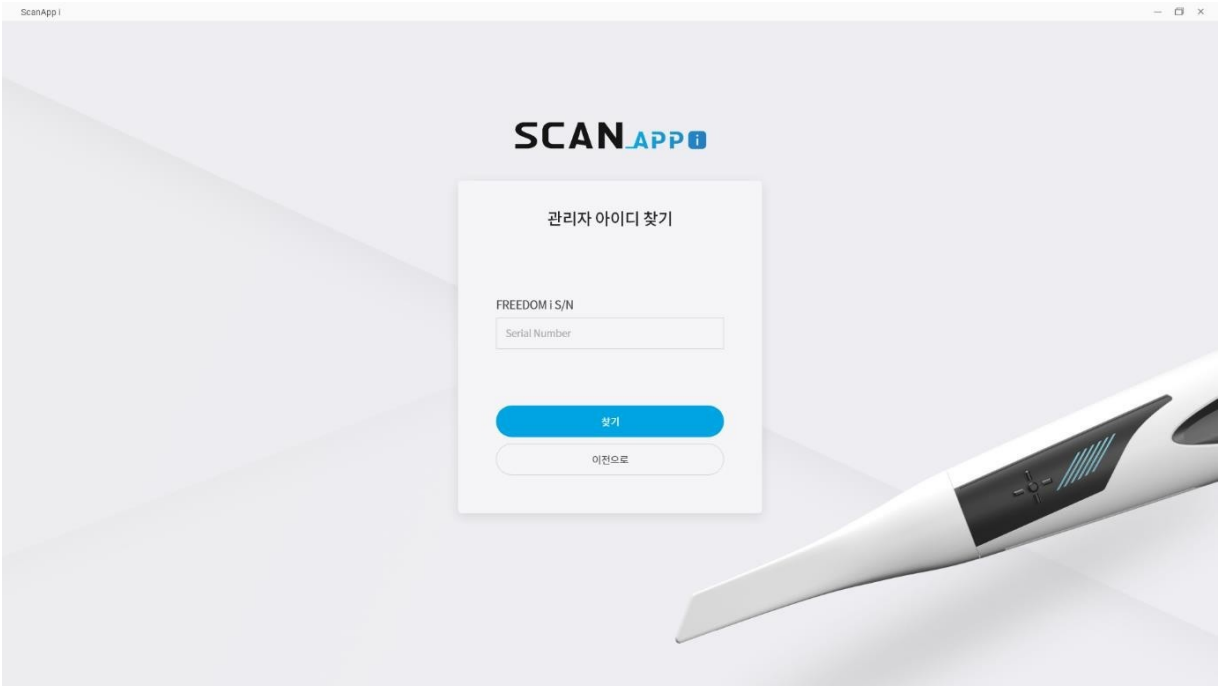
- Upon running SCANAPP i, the login screen appears. Enter your ID and password and log in. If a user fails to log in more than 5 times, the user cannot make a login attempt for 30 minutes.



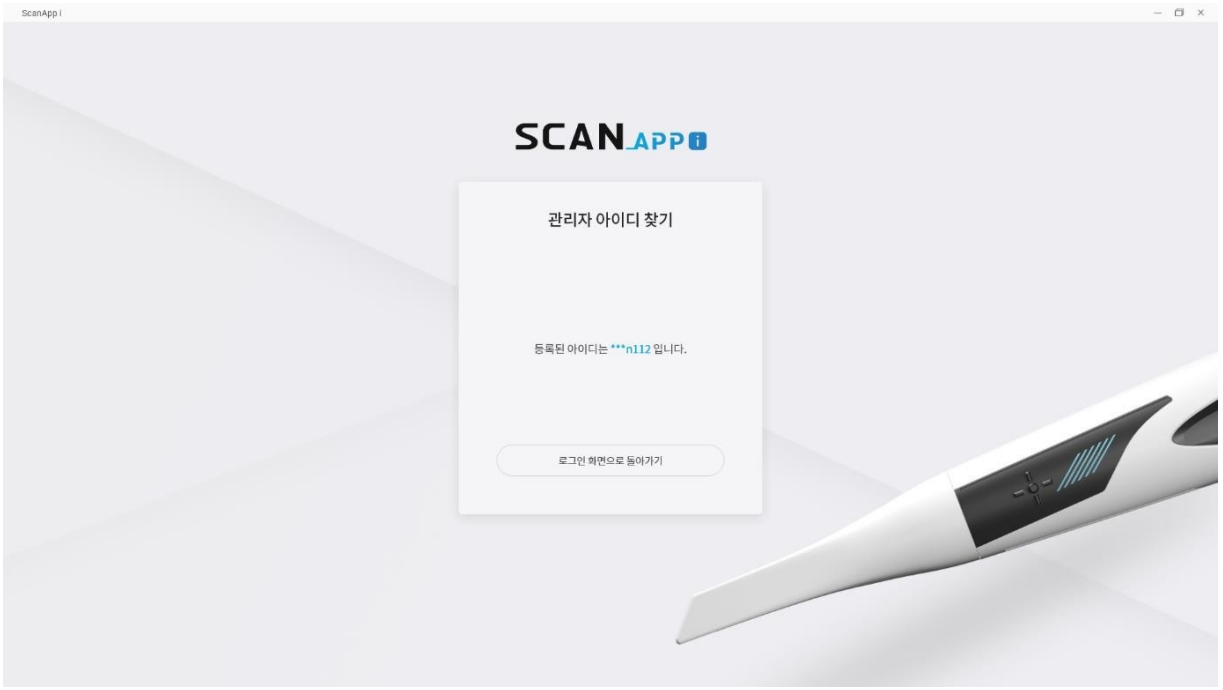
- To login as the administrator, click the "administrator page" at the bottom of the login button and log in after administrator login screen appears.

3.6.4. Find administrator ID

- If the administrator has lost his/her ID, click the Find ID button on the administrator login screen.

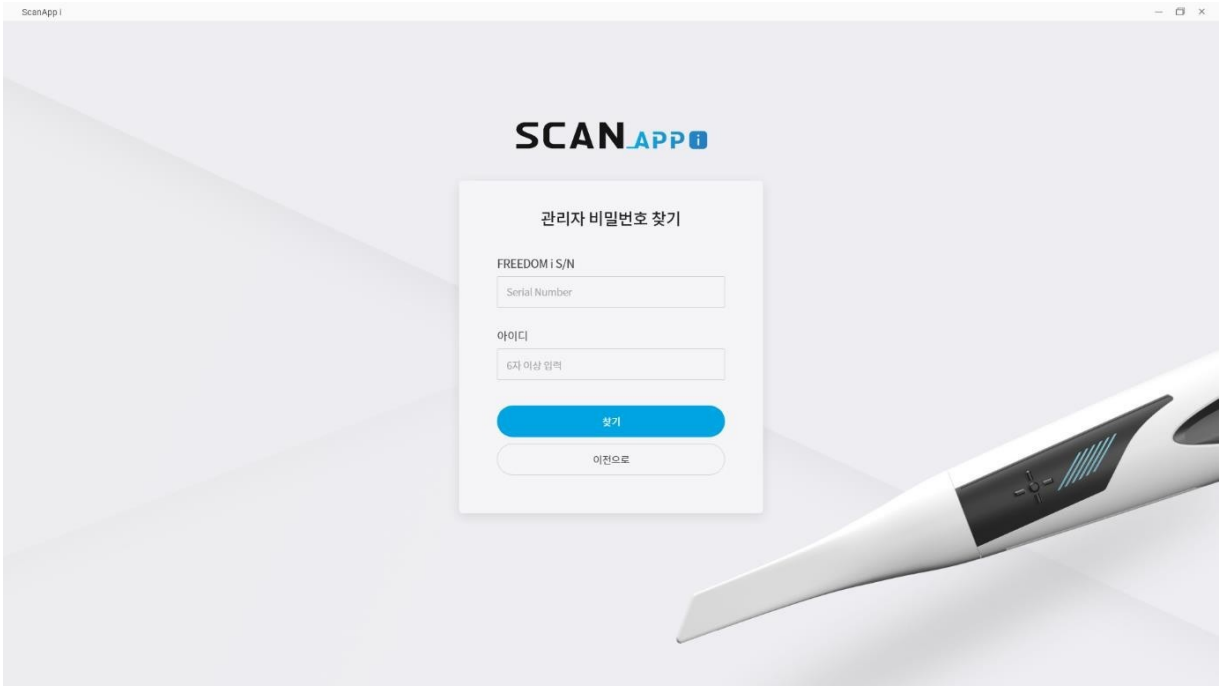


- If the administrator enters the DSI-100 serial number, a part of the administrator ID will be displayed as shown below.



3.6.5. Find administrator password

- The administrator can find the password by entering the DSI-100 serial number and ID.



3.6.6. In case that both the password and the ID of administrator are lost

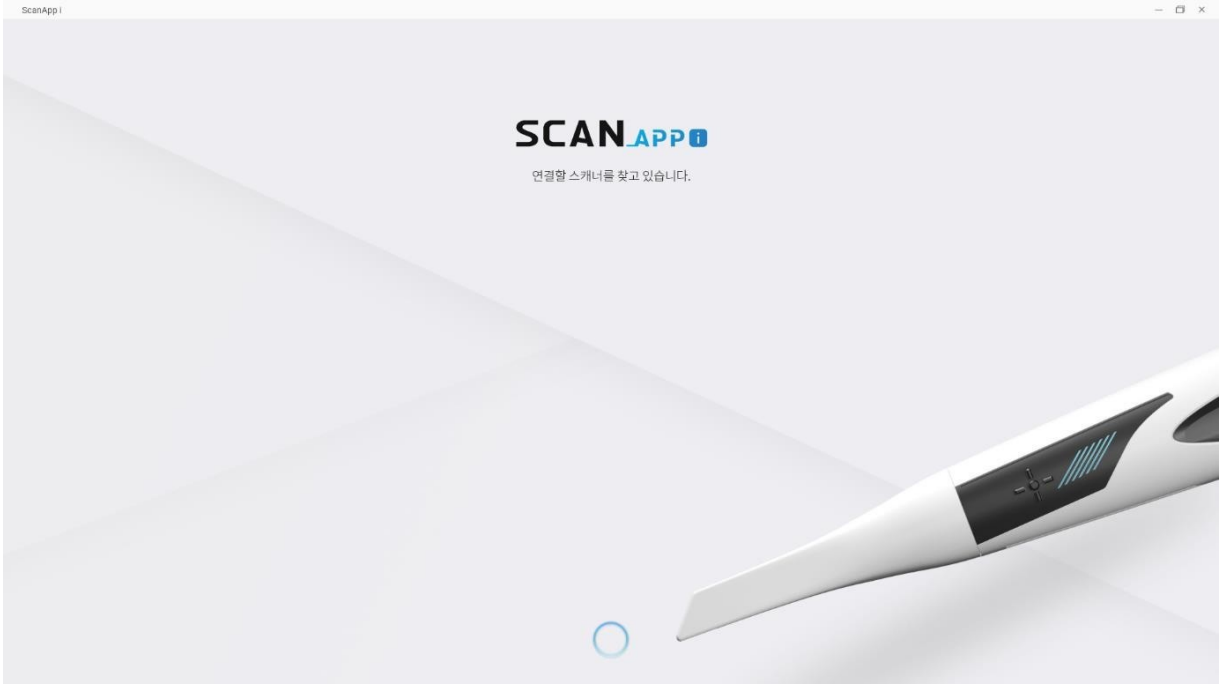
- Reset user information by requesting support from the place of purchase. After

resetting, register a new administrator and proceed with user registration.

3.7. Scan

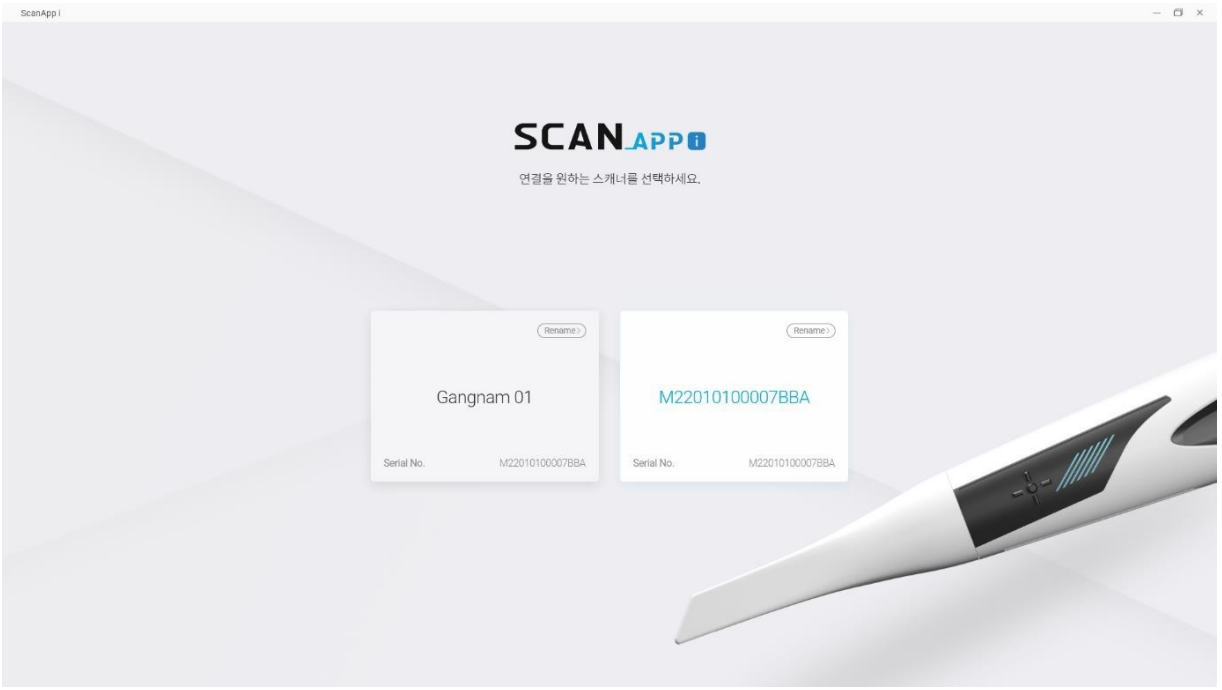
3.7.1. Intro screen

- Upon running SCANAPP i, it automatically searches for nearby scanners that can be connected.

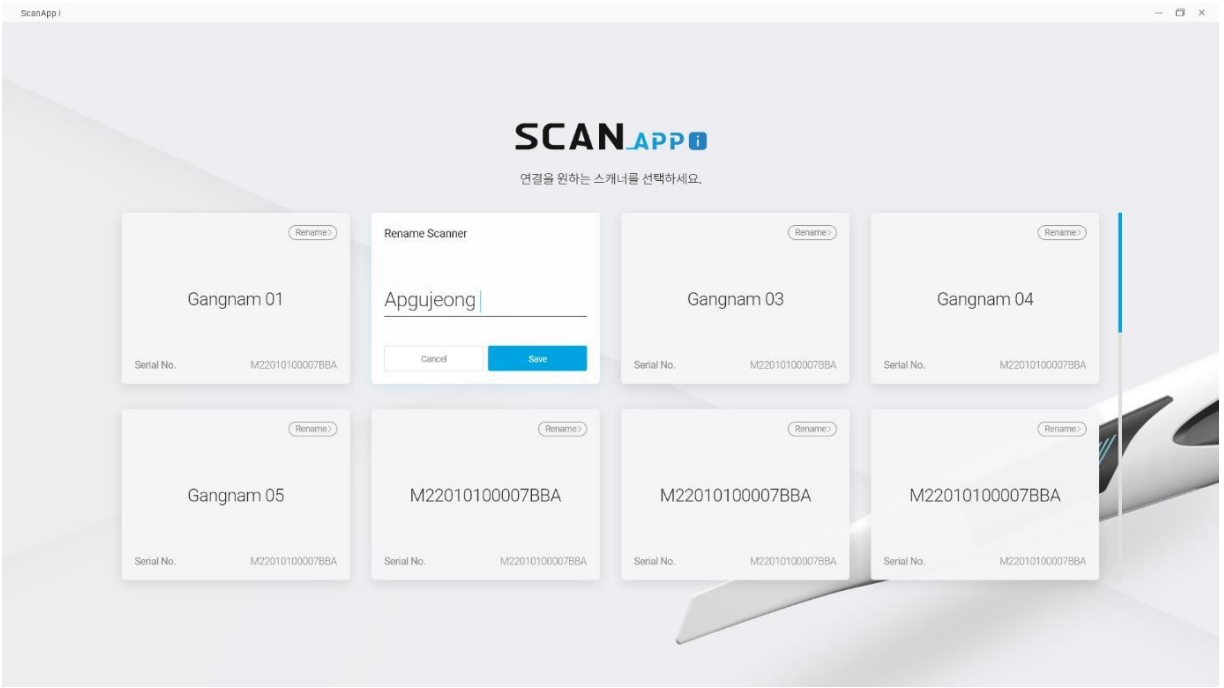


3.7.2. Scanner selection screen

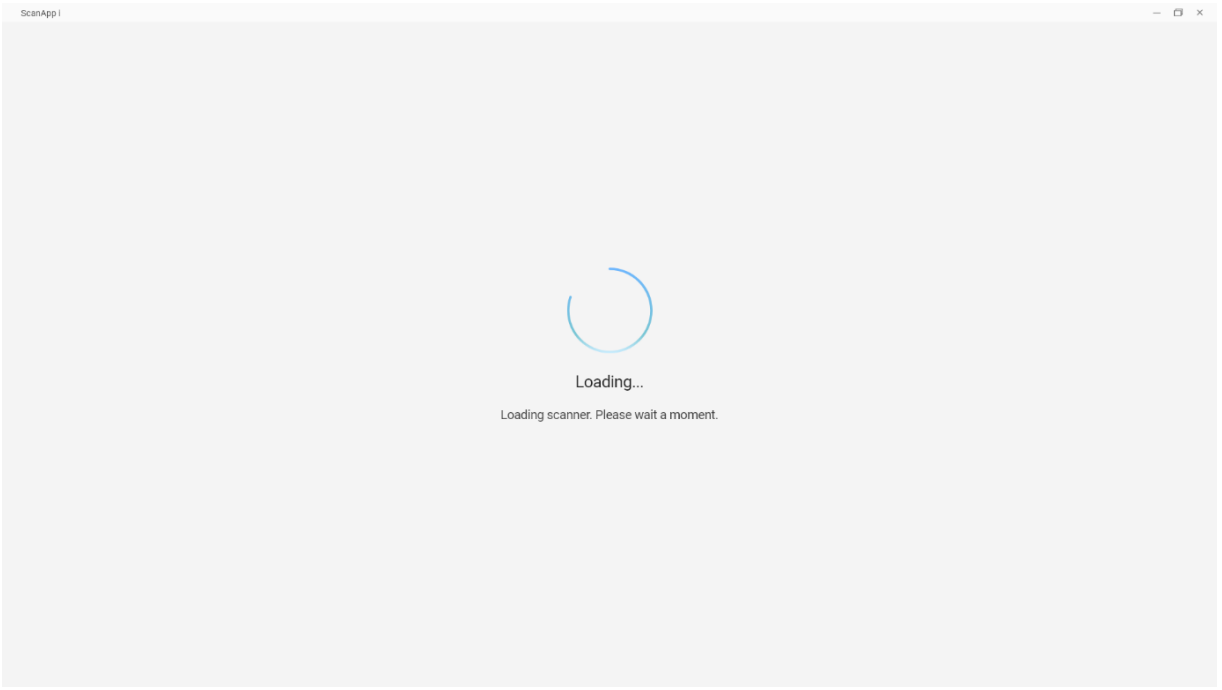
- The serial number of registered scanners that can be connected will appear on the screen. Select the scanner to use after checking its serial number.



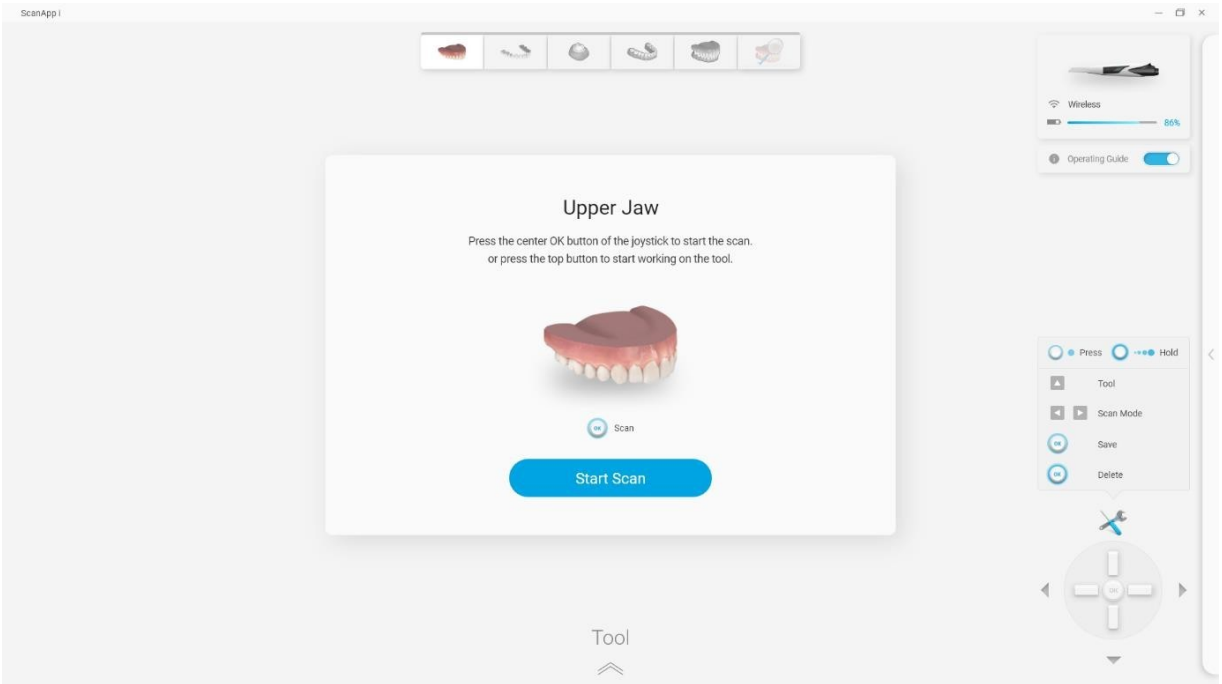
- Using the "Rename" function, you can designate the device with a desired name instead of a serial number.



- Select the scanner to use and the software will attempt to establish a connection with the scanner.



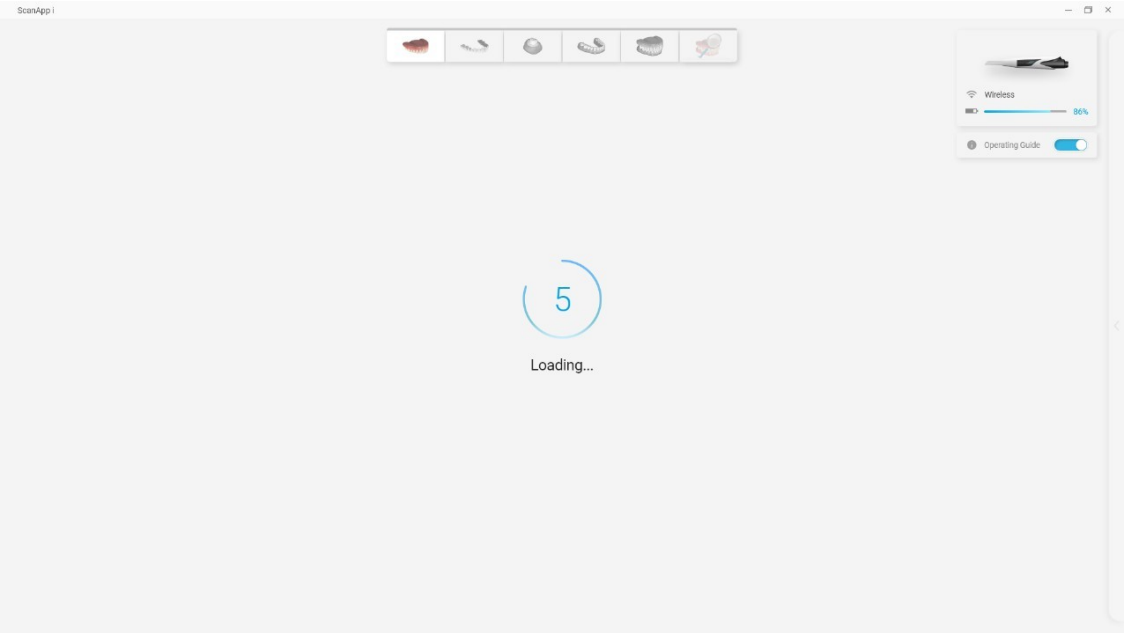
- If the connection with the software is successful, the "scan screen" will appear as shown below.



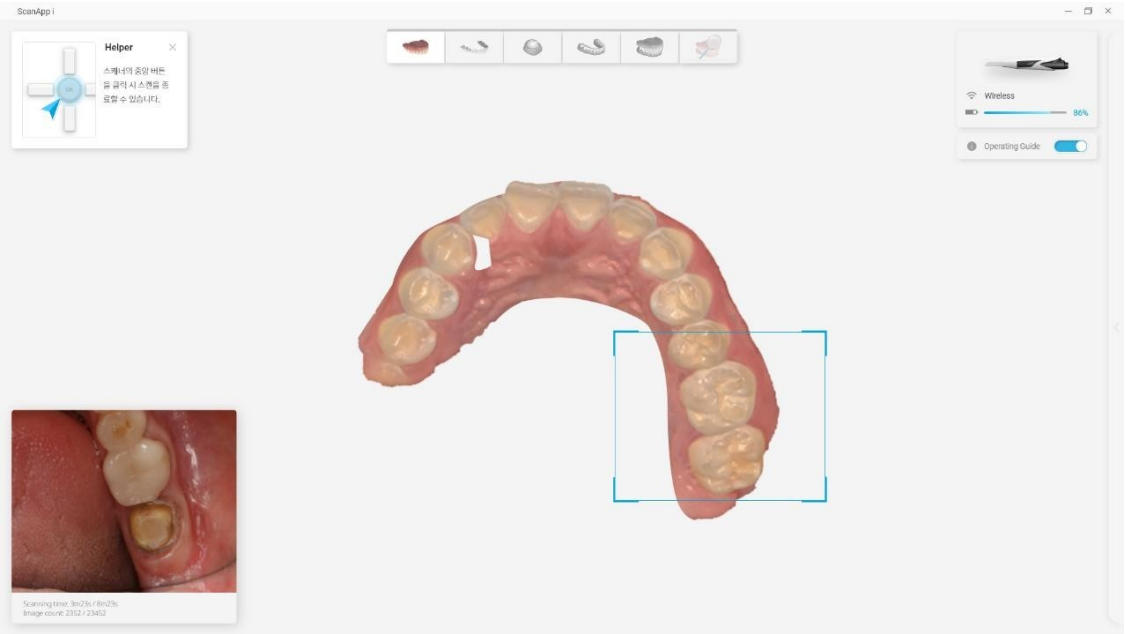
3.7.3. Scan screen

- The following screen is the main "scan screen" that users will most frequently encounter. Pressing the center button of D-Pad on DSI-100 starts the countdown to

start scanning. Scanning will start in 5 seconds, so position the scanner tip in the desired location within 5 seconds.



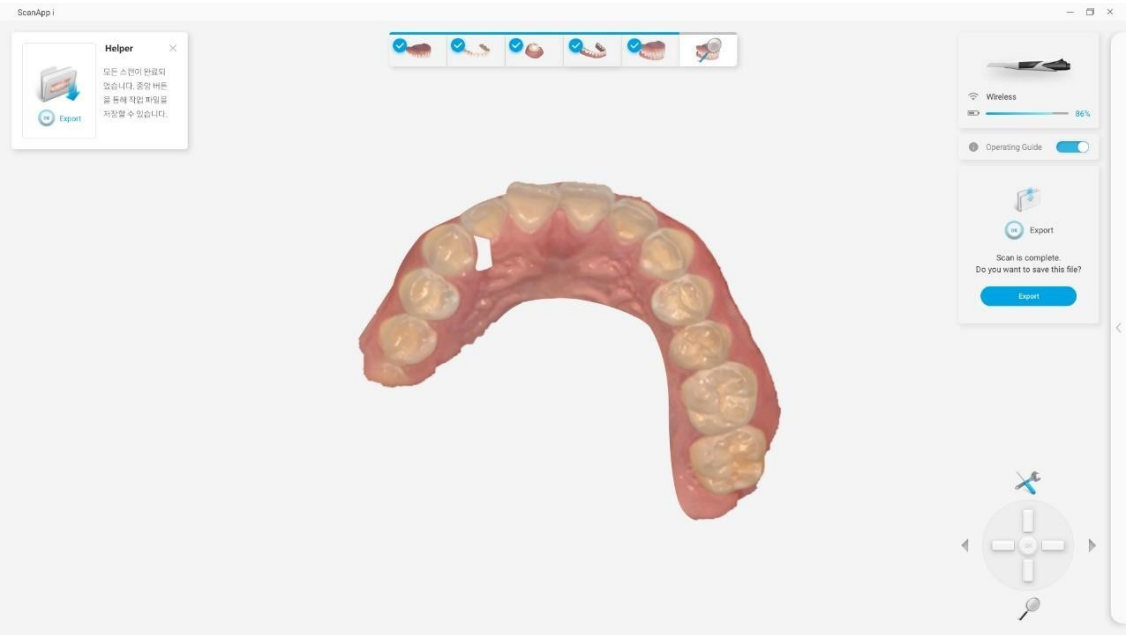
- When scanning starts, the camera's live image will be updated in real time at the bottom left of the screen and the scanned 3D data is displayed in the center.



- If scanning is successful, a blue square border is displayed on the recently scanned portion of the 3D data and a regular sound effect for scanning is played.
- If scanning is not performed normally, a red square border is displayed on the recently scanned area and a "scan error" sound effect is played.
- If scanning is interrupted, positioning the scanner tip in the last scanned position

automatically matches the previous data to continue scanning.

- When you have finished scanning the required part, press the center button of the D-Pad to stop scanning. If there are still incomplete areas after stopping the scan, you can perform additional scanning by pressing the scan button again.
- When scanning is complete, press the right button of the D-Pad to move on to the next scanning step.
- When all scans are completed, click the export button, or click the center button of the D-Pad to save all scanned 3D data.



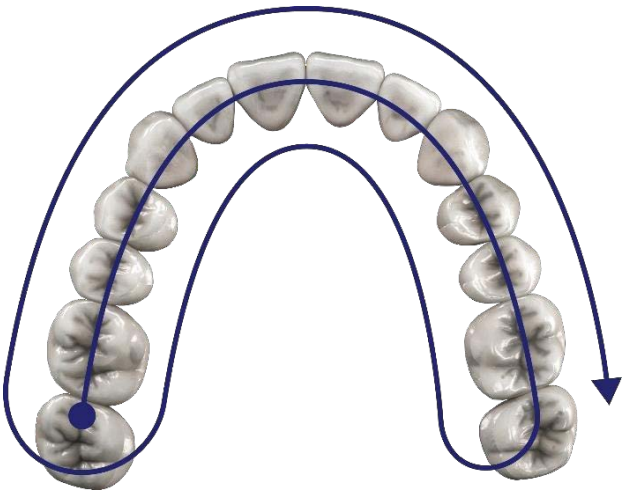
- The file type of the exported 3D data is either STL or OBJ. The location where the file is saved is the case's project folder.

3.7.4. Upper and lower full arch scan method

Move the scanner in the order below to scan the oral cavity more accurately and quickly.

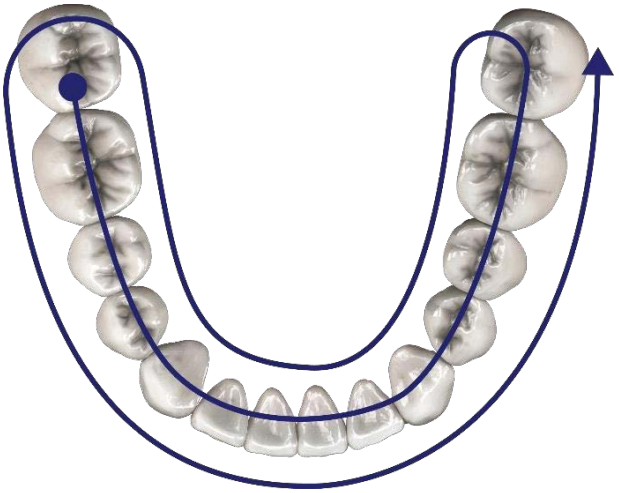
1) Maxillary full arch scan method

Scan by moving the scanner in the direction of the arrow in the figure below.



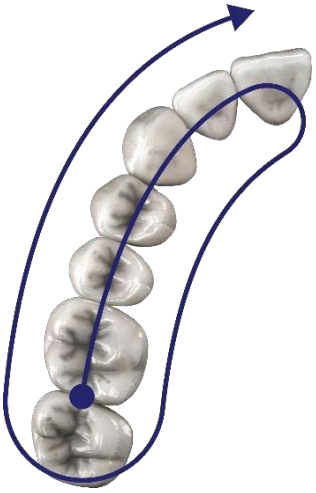
2) Mandibular full arch scan method

Move the scanner in the direction of the arrow in the figure below to scan.



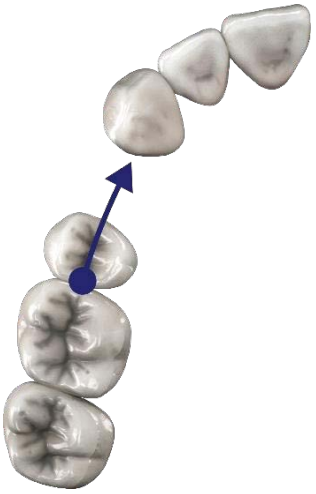
3.7.5. One-sided scan method

Move the scanner in the direction of the arrow in the figure below to scan.



3.7.6. Additional scan methods

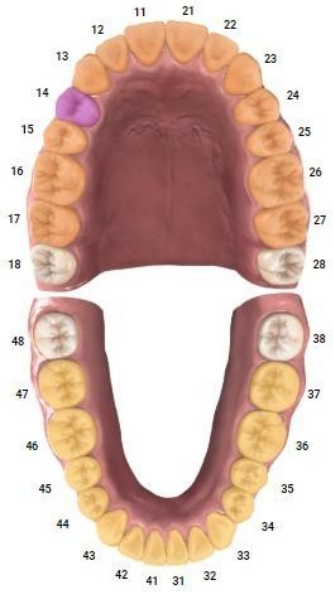
As shown in the figure below, when scanning the unscanned area, scan starts from the occlusal surface of the adjacent tooth and fills in the empty space.



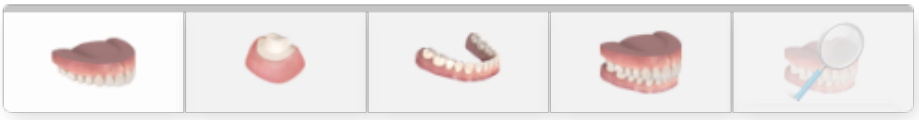
3.8. Scan methods by major cases

Here's how to scan for each major case:

3.8.1. Maxillary abutment case



For the case shown in the figure above, the software creates the following scan steps.



Scan the entire maxilla, and scan only the abutment teeth after stop the bleeding in the abutment area.

Step 1: Scan overall the maxilla.

Step 2: Stop bleeding in the abutment area and rescan the abutment only. Depending on the circumstances, this step can be omitted.

Step 3: Scan the entire mandible.

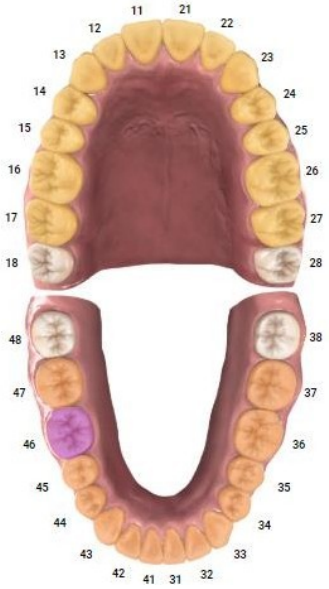
Step 4: Scan the buccal surfaces of the teeth by interlocking the upper and lower jaws.

- Scanning the buccal surface of the teeth automatically matches the upper and lower jaws.
- If an accurate occlusion relationship cannot be obtained with only one side, scan the buccal data of the opposite tooth to match the upper and lower jaws.
- If the upper and lower jaw data are not automatically matched with the side scan data, match them manually. In manual matching, select three matching points to match.

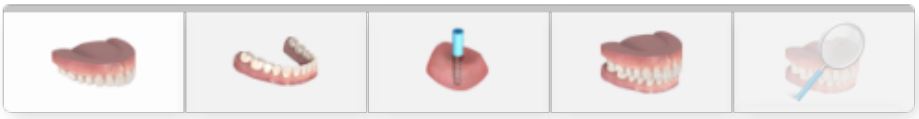
Step 5: If there is no problem with occlusion matching, save and close the project.

3.8.2. Mandibular implant case

The next case is the mandibular No. 46 implant case.



In this case, the mandibular scan body step is created as shown below. First, scan the antagonist. Then scan the entire mandible and the scan body.



Step 1: Scan the maxillary teeth.

Step 2: After removing the healing cap, scan the entire mandible.

Step 3: Insert the scan body and scan the scan body and surrounding teeth in detail.

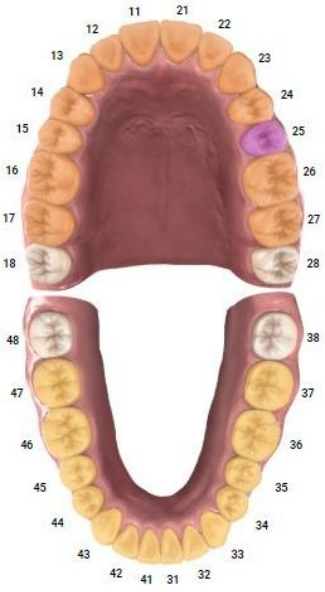
Step 4: Scan the buccal surface of the teeth by interlocking the upper and lower jaws.

Step 5: The software uses the buccal data to automatically match the upper and lower jaws.

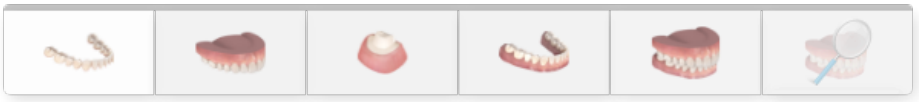
Step 6: If the matching is determined to be incomplete, the opposite side is additionally scanned and matched to increase the accuracy of occlusion. If there is no problem with the occlusion alignment, save and exit the project.

3.8.3. Preop scan added to the maxillary abutment

The following case is a case where a pre-op was added to the maxillary #25 abutment case.



In this case, the maxillary pre-op scan step is created as shown below.



Step 1: First, scan the condition before tooth preparation.

Step 2: Save the project file and close the software while the tooth is being prepared. Meanwhile, it is okay to proceed with other patient cases.

Step 3: After the preparation, start additional scan by calling the same case project.

Step 4: When the entire upper jaw is scanned, the scan data before deletion is automatically matched.

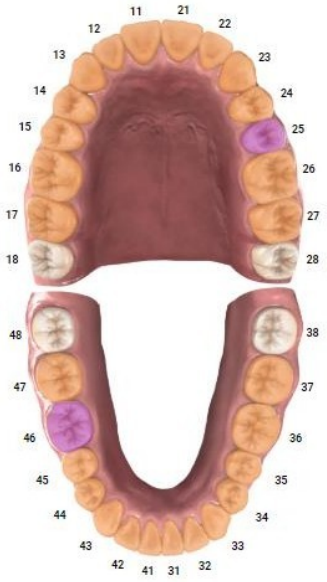
Step 5: After stopping the bleeding in the abutment tooth, focus on scanning only the abutment tooth.

Step 6: Scan overall the antagonist of the mandible.

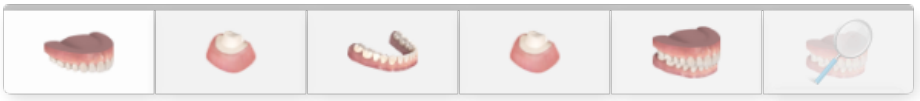
Step 7: Interlock the upper and lower jaw and scan the buccal surface to automatically match the upper and lower jaw. If there is no problem with the occlusion, save and close the project.

3.8.4. If both the maxilla and mandible have abutment teeth

he following case is when both the maxillary and mandibular abutments are present.



In this case, the scan stage is created as shown below.



Step 1: Scan the entire maxilla.

Step 2: Stop the bleeding from the maxillary abutment and intensively scan the abutment.

Step 3: Scan the entire mandible.

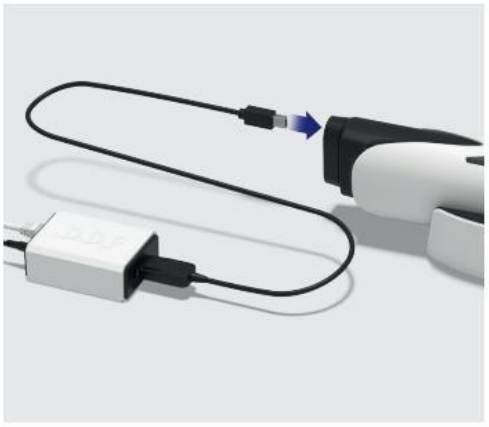
Step 4: Stop the bleeding from the mandibular abutment and intensively scan the abutment.

Step 5: After bringing the upper and lower jaws into contact, scan the buccal surface to match the upper and lower jaws. If there is no problem with the occlusion, save and close the project.

3.9. Charging method

3.9.1. Charging directly with main system

After connecting the adapter power to the PSM, connect the main body to the DP cable. When charging starts, the LED light turns on.



3.9.2. Charging battery separately

After removing the battery from the main body, insert it into the battery charger in the same direction as the charging terminal. If user connects the adapter port to the battery charger power port, it will charge after confirming that the power is applied.

4. Safety Guide

4.1. System Basic Safety

4.1.1. General precautions

- Before using the DSI-100 system, users must read and understand the following safety information.
- Failure to follow the instructions in the Safety Guide may result in injury to the user, patient, or damage to equipment.
- DSI-100 system users are responsible for the operation and maintenance of their scanners.
- You must complete training on how to use the scanner, use it only by trained dental professionals or technicians, and understand and be familiar with all contents of the user manual.
- If the DSI-100 system is used for purposes other than those specified in Section 2, it may cause damage or defects to the equipment, and use it in accordance with the safety guideline to prevent injury to patients during use.
- Negligence in handling or improper use of this system may cause problems other than system malfunction, and this is not covered under warranty.

- If you connect to a wired or wireless network that has devices other than the one you want to connect connected, there may be a security risk. Therefore, when connecting to a network with peripheral devices, be careful not to connect the product to an unsecured network. Also, if you want to change your network, additional analysis may be required.
- Risky situations in wired/wireless networks can occur due to the following reasons.
  1) Data loss
  2) Improper data exchange
  3) Corrupted data
  4) Improper timing of data
  5) Receiving unexpected data
  6) Unauthorized access to data
- Consider the following situations that may lead to risky situations involving wired and wireless networks.
  1) Remote service (external access to the network)
  2) Operating system (operating system compatibility)
  3) Software modification/upgrade (operating system, application, etc.)
  4) Interface compatibility (data conflict, data format)
     - Connections (hardware modifications, network connectors)
     - Network interface board (compatibility)
     - Network protocol (DICOM, HL7, etc.)
  5) PACKET address structure/timing
  6) Normal network load/bandwidth
  7) Maximum network load
  8) Data medium (longevity and searchability)
  9) Security (viruses, worms, unauthorized software updates or upgrades)
  10) Maximum allowable response time
  11) Network availability (planned and unplanned maintenance)
  12) Fidelity loss during information transmission due to interface/format mismatch
  13) Heterogeneous network topologies.)

4.1.2. Precautions before use

• Modification of the DSI-100 system may affect the safety of users, patients or thirdparties and is therefore prohibited by law.

- Be sure to install and use only approved programs for normal use of the system.
- Before using the scanner, inspect the external surfaces of the scanner and all accessories to ensure that there are no rough surfaces, sharp edges or protrusions that could pose a safety hazard.
- If you find any problems with the appearance or parts, do not use the product and contact the manufacturer or the person in charge of the place of purchase.
- Do not place objects within the operating range of the device.

4.1.3. Precautions during use

- Use this product indoors only.
- Do not use the scanner in an oxygen rich environment.
- This device cannot be used with flammable anesthetics or flammable substances.
- Be careful not to drop the scanner.
- Always hold the DSI-100 body firmly when lifting it from the cradle or when holding it while scanning. If dropped, follow the measures in Section 7.7 to prepare for problems other than deterioration in scan quality during use.
- If the equipment does not operate normally, such as problems with precision during use, do not use the product and contact the manufacturer or the person in charge of the place of purchase.
- If the DSI-100 system does not operate properly or if the equipment is suspected of malfunctioning, take the following actions.
    - Remove equipment from patient and discontinue use immediately.
    - Disconnect the device from the PC and check/confirm any abnormalities.
    - Contact the manufacturer or point of purchase representative.

4.1.4. Precautions after use

- When not using the scanner, turn it off and place it in a cradle or storage box.
- Do not expose the scanner to a vibrating environment.
- Do not expose the scanner to an environment that emits ultraviolet rays for a long time.
- In the event of a serious incident occurring in connection with this system, it must be reported to the competent authority of the Member State where the user and/or patient is located.

4.2. Eye safety

- Do not stare into the optical window on the front of the scanner or shine it into the eyes of others, including patients.

- When scanning with the DSI-100 system, the bright light is reflected by the mirror surface of the tip end.
- If you look at the reflected light or shine it directly into the eyes of another person, such as a patient, glare may temporarily decrease your eyesight and leave an afterimage, which may increase the risk of dangerous situations and accidents.

4.3. Electrical safety

- If you use the cable while it is pulled or twisted, there is a very high possibility of causing danger factors such as internal disconnection or short-circuiting of the cable or making scanning impossible.
- Do not remove any scanner components. When disassembling the body, serious hazards to the safety of users and patients other than the risk of electric shock and abnormal operation during use may occur.
- The scanner does not contain user-serviceable parts, and if repairs are required, contact the person in charge of the place of purchase or the manufacturer.
- Do not replace the power adapter supplied with the scanner with another power adapter. Any replacement may not provide the required level of protection against electric shock.
- Do not connect multiple multi-tap or multi-tap cords to the system and use a single power cord. When operating with the same power cord as other equipment, malfunctions may occur during equipment operation or scanning may not work properly due to occurrence of electronic interference such as noise between equipment.
- For the communication cable connected between the equipment and the system, the cable provided at the time of purchase must be used. The device may not operate normally if third-party and commercial cables are used.
- If an equipment error occurs during use, turn off the equipment and attach a warning sign such as "Do not use" before contacting the person in charge of the place of purchase or the manufacturer.
- The use of accessories and spare parts purchased on the market other than those provided by the manufacturer may lower the security level and scan quality and may be dangerous.
- If it has been stored in a low temperature environment during the winter, use it after at least 2 hours have elapsed at the temperature of the usage environment. If used right away, the electronic parts inside the equipment may be damaged due to internal dew condensation.

4.4. Managing peripheral devices

- Do not place computers and peripherals connected to the unit in the immediate vicinity of the patient.
- The scanner should only be connected to a computer that conforms to at least IEC 60950 or an equivalent validated standard. (Compliance with Section 2.6.1. Computer System Requirements)
- If the scanner is connected to other equipment, it may not work, or the scanning quality may be unsatisfactory.
- Leave enough open space around the computer to allow for adequate ventilation.
- Do not connect the outlet to which the power plug is connected in a place that is difficult to access.

4.5. Caution on electromagnetic compatibility

- The radiation characteristics of the DSI-100 system make it suitable for use in industry and hospitals. Non-residential environment (CISPR 11 class A) Systems may not provide adequate protection to radio frequency communications when used in a residential environment (CISPR 11 class B).
- This product complies with Part 15 of the FCC Rules. During operation, the following conditions must be taken into account:
- This product generates, uses, and can radiate radio frequency energy. Therefore, if this equipment is not installed and used in accordance with the instruction manual, it may cause harmful interference to radio communications.
- Operation of this equipment in a domestic environment is likely to cause harmful interference in which case the user will be required to repair it at his own cost.
- This product uses RF energy only for its internal operation. Its RF emissions are very low and in most cases are not likely to cause any interference in nearby electronic equipment.

Status	Classification
Type of protection against electric shock	Class II Equipment
Degree of protection against electric shock	BF type mounting part
Degree of protection	class IPX0

against harmful ingress	**NOTE:** After the tip is properly seated, the device's tip position is IPX1.
Mode of operation	Continuous operation
Flammable anesthetics	Not recommended for use in the presence of flammable anesthetics or flammable anesthetic mixtures containing air, oxygen or nitrous oxide.

- Information on cable lengths supplied with the unit can be found in the table below.

Part photo	Part name	Cable length(m)
	Ethernet communication cable	2m
	DP cable	1m
	Power cable	1.5m

- Except for items sold by equipment manufacturers as replacement parts for internal components, use of cables or accessories other than those specified may reduce immunity or increase emissions of the medical equipment.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must not be used within 30 cm (12 inches) of any part of the DSI-100 device, including cables specified by the manufacturer. Otherwise, the performance of this device may deteriorate.

4.6. Subjects on which the use is prohibited

- Do not use the DSI-100 system on patients with pacemakers and ICD devices.
- Use of the DSI-100 system in patients with pacemakers is prohibited due to the risk of interference.

4.7. Preventing scanner from overheating

- Do not block the air vents on both sides of the DSI-100 main body.
- If the ventilation hole is artificially blocked, heat circulation is not possible during use, which increases the risk of equipment damage or fire.
- The DSI-100 system automatically stops operating if the equipment is overheated (internal temperature of 55 ℃ or higher) during use.
- It can be reused after cooling the equipment, but if automatic stop occurs repeatedly due to overheating, stop using it and contact the manufacturer or the place of purchase.
- To prevent overheating, do not exceed 10 minutes per scan job.

4.8. Avoiding scanner hazards

- If a tip is dropped on the floor, it must be discarded and never used again. There is a risk that the mirror attached to the end of the tip will fall and become separated.
- If the DSI-100 body is dropped on the floor or an impact is applied to the body, be sure to check for any abnormality before use. If there is any abnormality in precision or scanning during use, contact the manufacturer or the person in charge of the place of purchase.
- Always place the DSI-100 body on the cradle when not in use.
- Do not install the horizontal cradle on an inclined surface.
- Carefully route all cables so that you or the patient do not get caught on them. If the cable is pulled excessively, it may damage the body.

5. Maintenance

- Maintenance of DSI-100 system equipment can only be performed by DOF Inc. or personnel certified by DOF Inc.
- Normally, the user is not required to perform any equipment maintenance other than software updates, cleaning, disinfection, sterilization, and battery charging and replacement, and preventive inspections and regular maintenance are not required.

5.1. Caring battery

- Remove and store the battery if the system will not be used for a long period of time.
- After use, connect the cable dedicated for DSI-100 to automatically charge the battery.
- LED color indication of battery charge level is as follows.

LED color	Battery charge level	Action required	Number of scan available
Sky blue	Sufficient	None	At least 3 times
Blinking sky blue	Imminent discharge	Stop scanning and charge the battery	Less than 3 times

- Replace the battery when the battery run time is less than 30% of the usual.
- Batteries are commercially available.
- The battery must be a product that has received national safety certification and must be purchased and used with the specifications shown below. If the system does not operate smoothly or is inoperable after the specified battery replacement or replacement, contact the person in charge of the place of purchase or the manufacturer.

[Battery specifications]

- Series: 18650
- Type: Li-ion Battery
- Output voltage: Max.4.2V
- Recommended capacity: 3500 mAh or more.
- Normal Voltage: 3.6V 3500mAh(12.6W)
- 1INR19/70(18650)

5.2. Calibration

- This product is shipped after being calibrated during manufacturing.
- In the following cases, calibration is performed through the place of purchase or the manufacturer.

■ When to perform calibration

① If the wireless connection speed is delayed by more than 30 seconds.

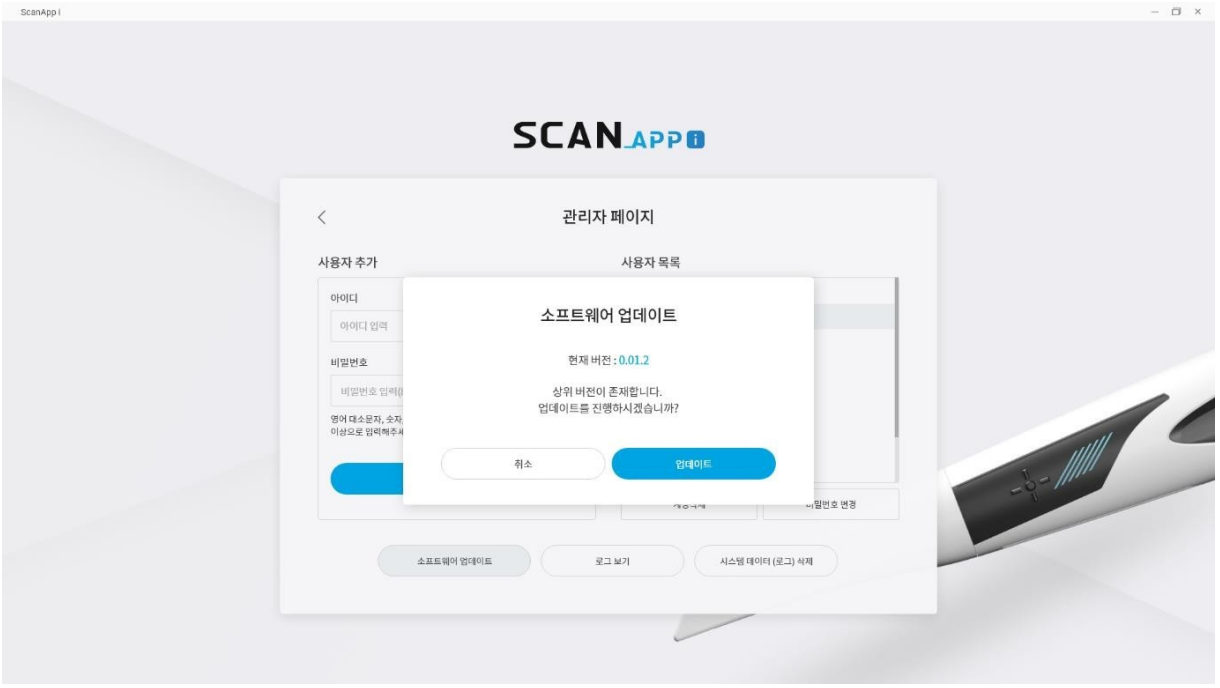
② When the quality of scan data deteriorates compared to before

- For precise scanning of this product, it is recommended to receive periodic calibration from the place of purchase or manufacturer.

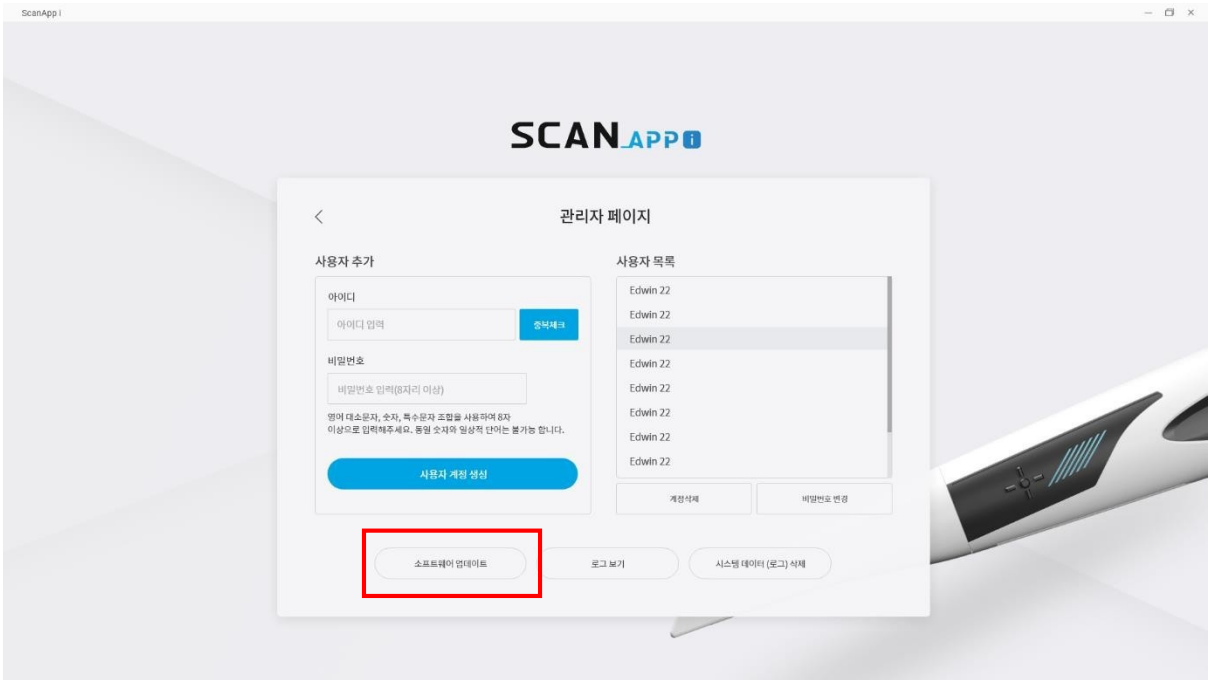
- **Contact us**
  - **Email: info@doflab.com**
  - **Phone: 070-7566-0070**
  - **FAX: 0303-3440-1827**

5.3. Software update

- If the PC is connected to the Internet and the user runs the DSI-100 software, the software communicates with the server to determine if it is the latest software. If the software is not up-to-date, an update notification will appear.



- The administrator enters the administrator screen after entering the ID and password and updates the latest version of SCANAPP i software.
- For the latest software update, click the "Software Update" button on the administrator screen as shown in the screen below.



- Click the button to automatically download the latest software after entering the serial number of the scanner. After downloading to the desired location, install the latest version in the same way as the initial installation method.

5.4. Cybersecurity related

- For safe use of your DSI-100 system, you must use a firewall and install antivirus

software and keep it up to date.

- If the user detects a cyber security incident, he or she must immediately stop using the DSI-100 device and block the external network. After that, report it to the manager and take the necessary action.
- The administrator account must not be accessed through a public network and must be accessed only through a secure network.

5.5. Maintaining scanner hygiene

- For a clean work environment and patient safety, wear clean surgical gloves
  - o when changing tips
  - o when scanning the oral cavity of a patient
  - o when touching the DSI-100 system
- The DSI-100 body and its lens unit should always be kept clean.
- Be sure to observe the following before applying the DSI-100 system to a patient.
- The DSI-100 system must be disinfected.
- Sterile tips must be used.

5.5.1. Tip

- Since the provided tip is used in contact with the patient's oral cavity during scanning, cleaning and sterilization must be performed before first use and reuse to prevent cross infection.
- The removable scanner tip can be autoclaved up to 20 times and must be discarded after 20 uses. Scanner tips can be repurchased through the manufacturer or the place of purchase.
- In the case of cleaning, use soapy water and a brush to clean it thoroughly, and if foreign substances or stains are found on the mirror inside the tip, clean it again in the same way.
- When cleaning is complete, wipe the tip mirror lightly with a clean cloth to remove moisture. The cloth should be a dry, lint-free cloth.
- Wiping with strong force may cause scratches on the mirror, which may affect the quality of the scanned data.
- If foreign substances or stains on the mirror are not removed by cleaning or if the mirror of the scanner tip is dirty, scan data may not be acquired normally, or the quality of the acquired scan data may be degraded. Observe the followings.
  1) After removing the tip from the scanner, wipe the mirror with a clean cloth or cotton swab dipped in an enzyme cleaneruntil it is clean.

[Recommended product specifications]

Ethyl alcohol or ethanol (60-70% Alc/Vol)

2) After wiping the mirror with a dry, lint-free cloth, check to see if any dust or fibers remain on the mirror, and repeat until they are gone.

3) If the stain persists through the above procedure, replace the tip.

- Place the cleaned and dried tips into a sterile bag (or pouch) and seal tightly.
- Place the tip in the autoclave while still sealed.
- Perform sterilization under the following conditions. After sterilization, allow the tip to dry completely before removing the product from the sterilizer.

  [Steam (high pressure steam) sterilization conditions]

  121 ℃, heating for 30 minutes / drying for 15 minutes

- Depending on the condition of the mirror surface within the tip, the scan data quality is greatly affected.

- Be sure to check the condition of the mirror before using the tip.
- If there are any foreign substances or stains on the mirror inside the tip, clean it before use. If there are scratches or stains on the mirror, discard the tip.
- Autoclaving the tip in a sterile bag (or pouch) that is not completely sealed can leave stains on the mirror that cannot be cleaned. For details, refer to the operating instructions of the autoclave.

- Visually inspect the scanner tip for signs of degradation. Discard if damaged.
- Use of damaged tips may cause unintentional injury to the patient.

5.5.2. Main body

- Clean and disinfect the intraoral scanner body after scanning is finished and the machine is turned off.
- For general cleaning, use a soft cloth and disinfectant solution. For the disinfectant solution, the following products are recommended to prevent damage to the product.

  [Recommended product specifications]

  Ethyl alcohol or ethanol (60-70% Alc/Vol)

- For the front optical lens of the body, as with the mirror in the tip, care must be taken to avoid foreign matter and smudges.
- If you wash with the power applied, you must be careful as the cleaning solution permeates into the product and may cause a malfunction. After washing, the body should be completely dried before use.
- Read and follow the warnings and personal protection instructions provided in the

safety data sheet (SDS) regarding the disinfectant used to handle the scanner for reuse.

- Gloves must be worn when cleaning and disinfecting the scanner.
- Do not place the scanner in a sterilizer or immerse it in water or disinfectant solutions.
- Excessive liquid may damage the scanner.
- When disinfecting the scanner, do not use cotton products, clothing or tissues soaked in disinfectant.
- If the scanner is contaminated with blood or bodily fluids, it must be cleaned prior to disinfection.
- The scanner must be thoroughly disinfected after each patient visit.

5.6. Safely storing for a long time without using

- Be sure to separate the battery from the scanner body when not using the device for a certain period of time or for a long period of time.
- After washing the scanner body and tip according to 7.5.1. above, put them in a designated storage box to prevent loss or loss of components during storage.

5.7. Troubleshoot

Symptom	Cause	Solution
The margins are not scanned clearly	If there is too much saliva or blood around the margins	Clean the margins and scan again.
Real-time matching is not possible because the scanner is lost during scanning.	If matching failed because the scanner moved too fast	Place the scanner at the lost position and start scanning again. Scan around until you find a match.
If the upper and lower jaws are reversed	If the lower jaw was scanned during upper jaw scanning stage, and the upper jaw was scanned during the lower jaw scanning stage	deletes the existing data, and scans again from the upper jaw.
If automatic matching of the upper and lower jaw fails	1. If insufficient matching information due to insufficient lateral scan	Return to the Occlusion scan stage and scan the lateral side additionally.

	2. If the patient's tooth shape is not suitable for automatic matching.	Click the Manual Matching button to manually match 1 point.
If the scan data does not come out well between the teeth	The area between the teeth may not be scanned well when scanning the side of the arch.	The angled tip could be used to scan well between the teeth.
If the occlusion is mismatched	Scanning only one side of the interlocked upper and lower jaw could result in misalignment in matching operation.	Scan the other side to obtain the complete scan data. Using the complete scan data will give a correct match.
the connection between the scanner and PC is lost	The scanner cannot connect to the PC via Wi-Fi, or the PC is connected to another scanner's Wi-Fi signal.	Check the wireless network of the PC and click "Reconnect" according to the software prompt.
The device is not working	The power switch does not work.	Check the power connection and supply status. (Battery, external power supply)
	The connection does not work.	Check the network configuration of your PC.
		In the case of wired connection, check the cable.
		In the case of wireless communication, please check the entered Wi-Fi password.
		In the case of wireless communication, reboot the device if the SSID of the Wi-Fi network is not visible.
	The LED indicator does not work.	Check if the power is on.
	The sound FAN cannot be heard during the operation of the scanner.	Please wait 60 seconds.
	The functional button does not work.	Check if the device and the PC are connected and rerun the software.

The software is not working.	The device is operating, but the program does not run.	Check the software installation status and reinstall it.
	The device is operating, but the program is not connected to the device.	Check the Ethernet connection status on the PC side.
	When you run the program, a message appears telling you that certain files cannot be loaded.	Uninstall and reinstall the software
	Scan is frequently interrupted while the program is running.	Check the Ethernet connection status on the PC side.
	During program operation, the operation speed of the program itself is very slow.	Shut down all programs on your PC and reboot your PC
	An unresolved error message appears while the program is running.	Please exit the software and run it again
	It terminates unintentionally while the program is running.	Please run the software again
	It shuts down repeatedly while the program is running.	Shut down all programs on your PC and reboot your PC

6. Disposal

6.1. Tip disposal

- Tips must be sterilized before disposal. (See Section 7.5.1. Tips above)
- Tips must be disposed of in accordance with standard operating procedures or national regulations for the disposal of contaminated medical waste.

6.2. Main body disposal

- DSI-100 body contains certain materials and compounds used in the manufacture of electrical and electronic equipment that can pollute the environment if improperly disposed of at the "end of life" of the equipment.
- Therefore, this product cannot be disposed of in the same way as normal household waste but must be disposed of in accordance with applicable national waste electrical and electronic waste regulations and directives, and must be disposed of as special disposal within the EU.

7. Contact information

7.1. Manufacturer's address

DOF Inc

B204, 601, 602, 77, Seongsuil-ro, Seongdong-gu, Seoul, Republic of Korea

Product usage and support inquiries

Email: info@doflab.com

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7.2.1. US branch

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KC Certification Number: R-C-dof-DSI-100

■ Revision History

No.	Rev. No	Revised Date	Description of changes	Remark
1	0	2023-02-01	Initial release	