Aoralscan 2

IntraoralScan

SHINING 3D®

CATALOG

1. Read this First

The **Aoralscan 2** is an intraoral scanner that works with the supplied software programs. With **Aoralscan 2,** you can perform oral scanning and digitally acquire and save the 2D/3D color images of a patient's teeth for orthodontic, implant, and restoration use.

This User Manual provides important procedures and information on how to operate the scanner and configure the IntraoralScan software correctly and safely. Before attempting to operate the product, read this User Manual and strictly observe all warnings and cautions. We suggest that you have easy access to the User Manual whenever necessary. Pay extra attention to the information from Safety information on chapter 2.

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Updates to hardware and/or software components are made regularly; therefore, some of the instructions, illustrations, and specifications mentioned in this User Manual may differ slightly from your particular situation. To obtain the most updated and accurate information, visit en.shining3d.com for the latest version of this User Manual.

1.3. Intended Use

An optical impression system for computer assisted design and manufacturing (CAD/ CAM) is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer- assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software.

⚠ WARNINGS

● Do not use the scanner for purposes other than those intended and expressly stated above.

● This product is designed and intended for use by persons with professions of dentistry and dental laboratory technology. The product can not be operated by the patients themselves.

● Do not misuse the scanner, and do not use or operate the software programs incorrectly.

● The clinical environments where the scanner and the software programs can be used include dental clinics, dental hospitals, and dental laboratories.

● Only trained medical personnel may use the scanner and the supplied software programs.

● Installation, use, and operation of the scanner are subject to the law in the jurisdictions in which it is used. Install, use, and operate the scanner only in such ways that do not conflict with applicable laws or regulations, which have the force of law. Use of the scanner for purposes other than those

intended and expressly stated here, as well as incorrect use or operation, may relieve us or our agents from all or some responsibilities for resultant noncompliance, damage, or injury.

● The users of this scanner and software are responsible for image quality and diagnosis. They should ensure that the inspection data is being used for the analysis and diagnosis only, and furthermore the data is sufficient both spatially and temporally for the measurement approach being used.

● The images acquired by the scanner must be interpreted by a qualified medical professional. The software in no way interprets these images or provides a medical diagnosis of the patient being examined.

1.4. Warnings

Before using the **Aoralscan 2,**read these warnings and Safety information on chapter 2.

⚠ **WARNINGS**

● Do not attempt to disassemble, repair, or modify the scanner and software.

● There are no user serviceable parts inside the scanner. Necessary modifications must be made only by the manufacturer or its designated agents.

● Do not allow any liquid to get inside this scanner and its cradle. Water and moisture may cause short-circuit to the electronic components and lead to malfunctions.

● Do not drop or apply shock/vibration to this scanner and its cradle. Strong impacts may damage the components inside.

● Do not cut, bend, modify, place heavy objects, or step on the cables.

● Otherwise the external insulation may be damaged and result in short-circuit or fire.

● To avoid electrical shock, use only supplied power adapter and connect it only to properly grounded wall outlets.

● The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

1.5. WEEE

Disposal of Waste Electrical and Electronic Equipment and by users in private households in the European Union.

This symbol on the product or on the packaging indicates that this can not be disposed of as household waste. You must dispose of your waste equipment by handling it over to the applicable take-back scheme for the recycling of electrical and electronic equipment and/or battery. For more information about recycling of this equipment, please contact your city office, the shop where you purchased the equipment or your household waste disposal service. The recycling of materials will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and environment.

1.6. Disposal

⚠ **CAUTION**

The scanner must be reprocessed prior to disposal in order to prevent cross-contamination.

All electrical and electronic devices must be disposed of separately from your other household waste in order to promote reuse, recycling and other forms of recovery, to prevent any potential adverse effects of hazardous substances on the environment and human health, and also to reduce the amount of waste in landfill. This includes accessories such as power adapters, power cords, etc. Do safely dispose of the device and its accessories in accordance with applicable laws and regulations.

For specific information on disposal of your device and the packaging, contact your local distributor or service provider.

1.7. Typographics

Special notes, cautions, and warnings that appear throughout this User Manual are designed to ensure that you perform specific tasks properly, preventing unnecessary errors.

This icon marks NOTE(S); additional information for particular situation

This icon marks CAUTION(S); improper actions or conditions that may damage the product or injury, and consequently void your warranty orservice contract or lose the patient data or system data.

This icon marks WARNING(S); the safety instructions that you must precisely follow in order to avoid injury. Failure to observe can cause damages to your product, or result in personal injuries, or even death.

1.8. Warranty

The warranty is void if unauthorized personnel perform service or maintenance on the set of **Aoralscan 2**. To ensure correct product performance and to obtain warranty service, contact technical support. For more information, see the following.

1.9. Contact Information

Manufacturer

Shining 3D Tech Co.,Ltd

No.1398,Xiangbin Road,Wenyan,Xiaoshan,Hangzhou,Zhejiang,China

en.shining3d.com

Customer Support

Email：dental_support@shining3d.com

2. Safety Information

2.1. Precautions

⚠️ **WARNING**

Follow the procedures carefully and ensure that the power/electrical/environmental requirements are satisfied. Failure to observe the instructions or disregard the warnings may result in damages to the product, personal injury, or even death of the user or the patient.

Observe the following precautions carefully.

● Do not use the hardware and software for any application until you have read, understood, and known all the safety information, safety procedures, and emergency procedures contained in this chapter. Operating the hardware and software without a proper awareness of safe use could lead to fatal damage to the hardware or permanent data loss.

● Ensure that the connection is performed correctly by following the instructions given in Connecting the scanner on chapter 4.

● Use only medical grade devices with the scanner in the patient environment.

● The hardware and software should only be used in a medical facility under the supervision of trained personnel.

● Only authorized service labs should perform maintenance. It is expressly prohibited to open the scanner with tools.

● The hardware and software have been fully adjusted and tested prior to shipment from the factory. Unauthorized modifications will void your warranty.

● If the hardware or software is modified, appropriate inspection and testing must be conducted to ensure continued safe use.

● Use only supplied accessories and approved software with the scanner in order to achieve the designed performance.

● Do not use a power adapter other than the one supplied with the

package.

● Connecting the scanner to an unknown power adapter is very dangerous and may lead to fire or explosion.

● Using cables or accessories other than those specified for use with the scanner may result in increased emissions or decreased immunity of the device.

● The supplied medical grade power adapter should only be connected to a grounded power socket.

● Do not connect USB peripherals with an extended USB cable. Extended connection may cause unexpected usage fault.

● Always handle the scanner with care and avoid hitting or scratching the surfaces as it contains fragile components. Dropping the scanner on the floor may cause permanent damage. If you accidentally drop the scanner, you MUST dispose of the scanner tip immediately and do not use the same tip again. The mirror in the tip might shatter into small pieces, and using it again poses the highest risk of causing serious injury to the user and patient.

● The scanner might heat up to above the normal body temperature, yet this short- term exposure and contact with small areas will not pose a health or safety hazard to the patient.

● Never place any objects or load on the scanner and its cradle.

● Pay close attention to the hygiene guidelines given in Pre-cleaning, disinfection, and sterilization on chapter 9.

● Do not dispose of this scanner as unsorted municipal waste. The scanner must be collected separately and disposed of in accordance with the local laws and regulations. For proper disposal of this scanner, contact your local representative of Shining3D Corporation.

2.2. Legend of Labels and Symbols

The following symbols provide information on the product's labels and regulatory compliance.

2.2.1. On the Device

Specification of scanner serial number

Serial number AOS-AH001K13 represents the No.001 device produced on November 13. 2018.

● AOS…represents the type of scanner which is the abbreviation of Aoralscan2.

● AH…represents the productive year, the letter A to I in alphabetical order represent number 1 to 9 and the number 0 remains the same.

● 001…represents the production serial number, the No.001 device.

● K…represent the month, the letter A through L represent January through December.

● 13…represent date by the number 0 through 31.

Symbol	Explanation
⚠	General warning – caution.
🧍	Indicates that the device complies with requirements for the BF type applied part according to IEC 60601-1, providing protection against electric shock.

Table 2-1 Labels and symbols on the device

On the carry box/package

Symbol	Explanation
⚠	General warning – caution.
🧍	Indicates that the device complies with requirements for the BF type applied part according to IEC 60601-1, providing protection against electric shock.
🍷	Indicates that the contents of the transport package are fragile and therefore shall be handled with care.
☂	Indicates that the transport package shall be kept dry.

⬆⬆	Indicates correct upright position of the transport package.
♻	Indicates that the material shall be recycled.

Table 2-2 Labels and symbols on the carry box/package

2.3. Compliance

Anyone creating or changing a medical electrical system through a combination with other devices in accordance with standard EN 60601-1-1:2001 based on 60601-1-1:2000 (specification for the safety of medical electrical systems)/UL 60601-1 Part 1: first edition 2003 is responsible for ensuring that the requirements of these standards are met to the full extent in order to ensure the safety of patients, operators and the environment.

2.4. FCC Compliance Statement

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.

2.5. Electrical Safety

Only trained medical personnel should operate this scanner. The product complies with the following standards:

2.5.1. Electrical

- IEC 60601-1-2:2014
- IEC 60601-1:2015/A1:2012 (ed 3.1)
- IEC 60601-1-6: 2013.Con Ed 3.1 Rev. October 29. 2013.
- IEC 62366-1:2015

2.5.2. Classification

- Type of protection against electric shock: Class II
- The degree of protection against electric shock: Type BF

- The mode of operation: Continuous operation
- Pollution degree 2

For maximum safety, observe the following guidelines strictly:

⚠️ **WARNINGS**

- Shock hazards exist if the power adapter is damaged or is not properly grounded. Use only the supplied medical grade power adapter.

- To avoid the risk of electric shock, connect the scanner only to properly grounded wall outlets.

- Only authorized service labs can make internal replacements of the scanner and modify the software.

- Do not use the scanner if its tip or cable is damaged. Contact technical support for replacement of the damaged equipment (see Contact information on chapter 1).

- To avoid risk of electrical shock hazards, always inspect the scanner and cable connections before use.

- Check the cable housing before use. Do not use the scanner if the housing is damaged or the cable is abraded.

- All devices connected to the **Aoralscan 2** shall comply with IEC 60601-1 and IEC 60950.

2.5.3. EMC Notice

Electromagnetic Emissions

Medical electrical equipment such as the **Aoralscan 2** requires special precautions regarding electromagnetic compatibility, and must be installed and put into service according to the following electromagnetic tables.

The **Aoralscan 2** is intended for use in the electromagnetic environment specified below. The customer or user of the **Aoralscan 2** should assure that it is used in such an environment.

Emission measurement	Conformity	Electromagnetic environment - guidelines
RF emissions CISPR 11	Gr 1	The **Aoralscan 2** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **Aoralscan 2** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker according	Complies	

Table 2-3 Guidance and manufacturer's declaration – electromagnetic emissions

Interference immunity

The **Aoralscan 2** is intended for use in the electromagnetic environment specified below. The customer or user of the **Aoralscan 2** should assure that it is used in such an environment.

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment–guidance

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (100% dip in UT) for 0.5/1 cyclea 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25/30 cyclesa (for 0.5 sec) 0% UT (100% dip in UT) for 250/ 300 cyclesa (for 0.5 sec)	0% UT (100% dip in UT) for 0.5/1 cyclea 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25/30 cyclesa (for 0.5 sec) 0% UT (100% dip in UT) for 250/ 300 cyclesa (for 0.5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Aoralscan 2** requires continued operation during power mains interruptions, it is recommended that the **Aoralscan 2** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. If image distortion occurs, it may be necessary to position the **Aoralscan 2** further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			
a For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz.			

Table 2-4 Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
Conducted RF	3 Vrms 150 kHz to 80 MHz outside ISM bandsc	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **Aoralscan**, including cables, than the recommended separation distance calculated from the equation appliance to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\ \sqrt{P}$
IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 Vrms 150 kHz to 80 MHz in ISM bandsc 3 V/m 80 MHz to 2.7 GHz	6 Vrms 3 V/m	IEC 60601-1-2: 2007 $d = 1.2\ \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\ \sqrt{P}$ 800 MHz to 2.5 GHz IEC 60601-1-2: 2014 $d = 2.0\ \sqrt{P}$ 80 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol:

Table 2-4 Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Aoralscan 2** is used exceeds the applicable RF compliance level above, the **Aoralscan 2** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Aoralscan 2**. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. [c] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.			

Table 2-4 Guidance and manufacturer's declaration – electromagnetic immunity

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality or launch warning messages, it is necessary to position the **Aoralscan 2** further from sources of electromagnetic interference or install electromagnetic shielding to block unwanted interference. The customer or the user of the **Aoralscan 2** should operate the device under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

Separation distances

The **Aoralscan 2** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Aoralscan 2** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Aoralscan 2** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter				
	IEC 60601-1-2 : 2007			IEC 60601-1-2 : 2014	
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0 \sqrt{P}$
0.01	0.12	0.12	0.23	0.12	0.20
0.1	0.38	0.38	0.73	0.38	0.63
1	1.2	1.2	2.3	1.2	2.0
10	3.8	3.8	7.3	3.8	6.3
100	12	12	23	12	20

For transmitters rated a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 2-5 Recommended separation distances between portable and mobile RF communications equipment and the **Aoralscan 2**

The medical electrical equipment is suitable for the professional healthcare environment per 60601-1-2:2014. It is suitable for use in physician offices, clinics, hospitals, and other professional healthcare environments except near HF surgical equipment and the RF shielded room of an ME

system for magnetic resonance imaging or other environments where the intensity of electromagnetic disturbances is high.

The clinical environments where the device can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients except environments where the intensity of electromagnetic disturbances is high.

⚠ **WARNINGS**

● Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **Aoralscan 2**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

● If higher IMMUNITY TEST LEVELS than those specified in IEC60601-1-2

● Table 9 are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in IEC60601-1-2 Chapter 8.10.

3. Overview

3.1. Benefits of the Product

The **Aoralscan 2** is designed to provide powder-free intraoral color scanning, with higher speeds bringing greater accuracy and less time-lag for image acquisition. It can be used to scan a single tooth, multiple teeth, and whole dental arches. The captured 3D digital impressions of teeth and soft-tissue areas are designed to be used in conjunction with the supplied software programs.Dental Order System Module,which helps manage the patient information and scanned records, and Scan module,which assists you in acquiring digital impressions,and supports scan data export (in STL/OBJ format) to CAD/CAM systems for different purposes of dental care.

3.2. Carry box List

Check the carry box for the following items. If any item is missing or damaged, contact the distributor or service provider immediately.
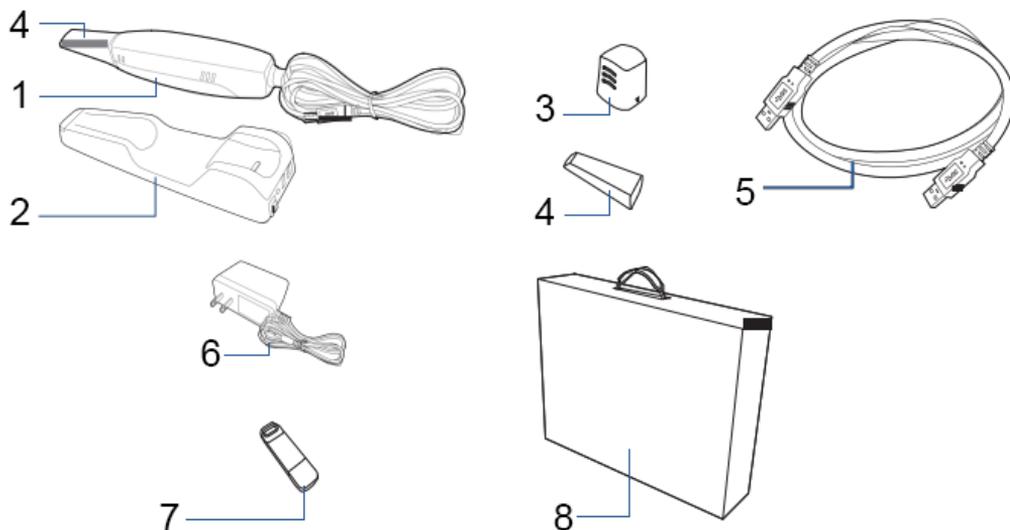
1. 1 x Intraoral Scanner with a USB 3.0 upstream cable (length:2 meters)
2. 1 x scanner cradle (12 Vdc, 1.67 A)
3. 1 x protection cap
4. 2 x scanner tip (1 is already attached to the intraoral scanner when

shipped)

    5.   1 x USB 3.0 cable (for the connection between the cradle and your computer; cable length: 1.5 meters)

    6.   1 x medical grade AC/DC power adapter (manufacturer: Adapter Technology Co., Ltd.; model name: ATM020-W120U; input: 100-240 V, 50-60 Hz, 0.45-0.27 A; output: 12 Vdc,1.67 A; cable length: 2 meters)

    7.   1 x 2-in-1 USB dongle (the license key for authorized access to the IntraoralScan software program for Windows)

    8.   1 x carry box

   Other accessories: the calibrator and USB cable

    ◆   1 x Calibrator

    ◆   1 x USB 3.0 cable (for the connection between the Calibrator and your computer; cable length: 1.5 meter)
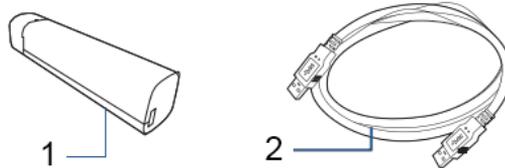
⚠ **WARNINGS**

● AC plug types vary by country/region.

● Using accessories, peripherals, or cables not supplied with the product or recommended by Shining3D Corporation can affect the device in the form of increased emissions or decreased immunity to external EMI/EMC occurrences. Non-specified peripherals, and cables in some cases, can also increase leakage current or compromise the safety of the grounding scheme.

● Using accessories or power supply units other than those specified may cause the warranty to void and result in increased emissions, decreased EMI immunity of the device, or even damages to the device and personal injuries.

● Use of other accessories results in non-compliance.

● Always store the 2-in-1 USB dongle in a safe place for later use

📑 NOTE

We recommend that you keep all the original packaging components in a safe place in case you need to transport or dispose of the scanner in the future. For details, see Storage for transport on chapter 9.

3.3. Scanner Overview

3.3.1. Tip and scanner body

No.	Component	Function
1.	Scanner tip	Use the tip to scan the upper jaw, lower jaw, or total jaw. The tip(s) can be autoclaved up to 20 times.
2.	Heater	The anti-condensation heater prevents fogging on the mirror to ensure successful scanning.
3.	Exhaust vents	Allows the heat produced by the operation of scanner to be dissipated from the case.
4.	Intake vent	Allows the ambient cool air to enter into the case to help cool down the heat produced by the operation of scanner. **NOTE** **When scanning, do not hold the scanner in the way that covers or blocks the intake and exhaust vents. Otherwise the scanner may become overheated.**
5.	LED ring light	Indicates the status of your scanner. ● Blinking green: the scanner is in preparation/warm-up mode. ● Solid green: the scanner is ready for use. ● Solid blue: the scanner is processing the alignment of scanned data. ● Solid amber: an error occurs and needs your attention.

Table 3-1 Introduction to the scanner tip and scanner body

No.	Component	Function
6.	Scanner body	Hold the scanner body on the sides and rotate the scanner body to obtain the best scan angle. The scanner body may get warm during scanning, yet the temperature won't cause harm to the user and the patient.

Table 3-1 Introduction to the scanner tip and scanner body

3.3.2. Scanner cradle
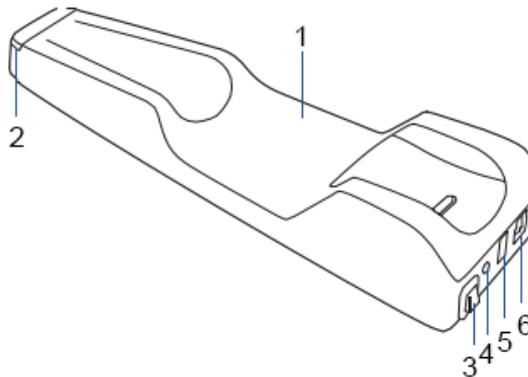
No.	Component	Function
1.	Cradle	Place the scanner in the cradle when you are not using it.
2.	LED indicator	Indicates the status of the cradle. ● Solid green: power on. ● LED off: power off.
3	Power switch	To receive power from the power outlet, turn it on; to stop receiving power from the power outlet, turn it off.
4	Power connector	Connect the power plug from the supplied power adapter to this power connector, and plug the power adapter to the power outlet.
5.	USB 3.0 downstream port	For connecting the scanner cradle and the USB port of your computer using the supplied USB cable.This port transfers data between the **Aoralscan 2** and your computer.
6.	USB 3.0 upstream port	Connect the scanner cable to this port. This port provides power supply and data communication between the scanner and cradle. For details, see Connecting the scanner on chapter 4.

Table 3-2 Introduction to the scanner cradle

SHNING 3D TECH Co.,Ltd - 24 -

📋 NOTES

● When the scanner is left idle for 10 minutes (including being placed on a desk), it will go into standby mode. After 1 minute of inactivity, it will automatically go into sleep mode, and the LED ring light on the end of the scanner body will also go off.

● To activate the scanner, place it in the cradle. The scanner will go into standby mode within 3 minutes. If the scanner is left idle for more than 1 minute, it will automatically go into sleep mode.

● To lower the temperature inside scanner body, the cooling fan still operates for about 30 minutes after the scanner goes into standby or sleep mode. Then it will stop spinning.

● The scanner tip is being heated whenever power is supplied, even if the scanner is in standby or sleep mode.

USB cable storage

To prevent the USB cable from getting damaged by excessive bending or twisting, you should loosely coil the cable and avoid making kinks or sharp bends.
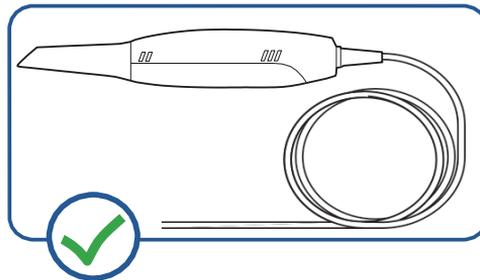
⚠ CAUTION

Do NOT roll the cable over the handle of the scanner or even bend the cable sharply. The illustration below demonstrates improper cable storage
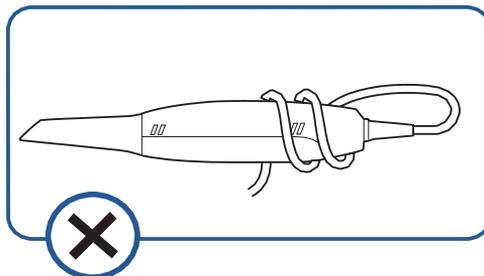
3.4. Software Overview

The **Aoralscan 2** is designed to operate with the software programs,which include two modules (supplied in the 2-in-1 USB dongle):

● Dental Order System Module

Designed to manage and store patient data, including cases, prescriptions, and restoration information,realizing functions such as order creation, editing, searching, scanning and deletion, as well as uploading, downloading, previewing and tracking of scanned order and data.

● Scan Module

The interface guides you through the entire scanning process of acquiring intraoral digital impressions via the scanner.

For information on how to use these software programs, see Using IntraoralScan on chapter 7.

3.4.1. System requirements

Before installing and running the supplied software programs, your computer shall meet the following requirements:

CPU	Intel Core i7-8700 or higher
Memory	16 GB or higher
Hard drive	1 TB SATA Hard Drive (7200 RPM, 6.0 Gb/s) or higher
Graphic card (GPU)	NVIDIA GTX 1070 6GB DDR3 or higher (supporting NVIDIA CUDA)
Operating system	Windows 10 Professional (64-bit) or later versions of Windows operating system
I/O ports	More than 3 Type-A USB 3.0 (or higher) ports

Table 3-3 System requirements

⚠️ **WARNING**

The computer or notebook you use shall meet the safety requirements of IEC 60601-1 and IEC 60950

3.4.2. Installing the software programs

The supplied 2-in-1 USB dongle contains the IntraoralScan software program.

⚠ CAUTIONS

● Install the software programs in accordance with the instructions given here.

● When the installation is completed, do not plug the power adapter to the wall outlet or turn on the scanner yet. See Setting up the scanner on chapter 4 for more necessary procedures to get started.

Follow the steps below to complete the installation of software programs:

(1) Insert the supplied 2-in-1 USB dongle into the USB port of your computer

(2) Find the file named IntraoralScanX.X.X.X.exe and run it as administrator.

(3) The IntraoralScan InstallShield Wizard window appears to start the installation.

(4) Specify a language from the drop-down list.

(5) Click OK.

(6) Follow the on-screen instructions to complete the installation.

When done, three shortcut icons, and ,will appear on your desktop for quick access.

4. Setting up the Scanner

4.1. Connecting the Scanner

⚠ **CAUTIONS**

● Ensure the supplied software programs are installed on your computer before the connection.

● Install the scanner in accordance with the instructions stated in this User Manual.

● Use the scanner only in dental laboratories, dental clinics, and equivalent environment.

● Do not install, place, and use the scanner in dusty and damp environment or in the areas of temperature extremes or in direct sunlight.

● Prepare a flat surface, e.g. your desk, for the scanner and the cradle. Do not place them on a slanted surface.

● Before the installation is completed, do not plug the power adapter into the wall outlet or turn on the scanner until you are instructed to do so.

● Always return the scanner to the cradle when it is not in use. Do not place the scanner in heated or wet surfaces as this can cause damage to the tip and scanner.

● It is normal that the scanner gets warm when in use.

⚠ **WARNING**

Ensure that you use only the supplied power adapter,power cable, and USB cable.

Follow the steps below to complete the connection:

(1) Make sure the scanner tip is firmly attached to the front end of the scanner; otherwise, gently and firmly slide the scanner tip onto the front-end of the scanner, as illustrated.

(2) Insert the power plug of the supplied power adapter into the power connector on the cradle, and plug the power adapter into a wall outlet.

(3) Connect the scanner cable to the USB 3.0 upstream port on the cradle.

(4) Connect the USB 3.0 downstream port on the cradle and your computer with the supplied USB 3.0 cable.

(5) Insert the supplied 2-in-1 USB dongle into the USB port of your computer.
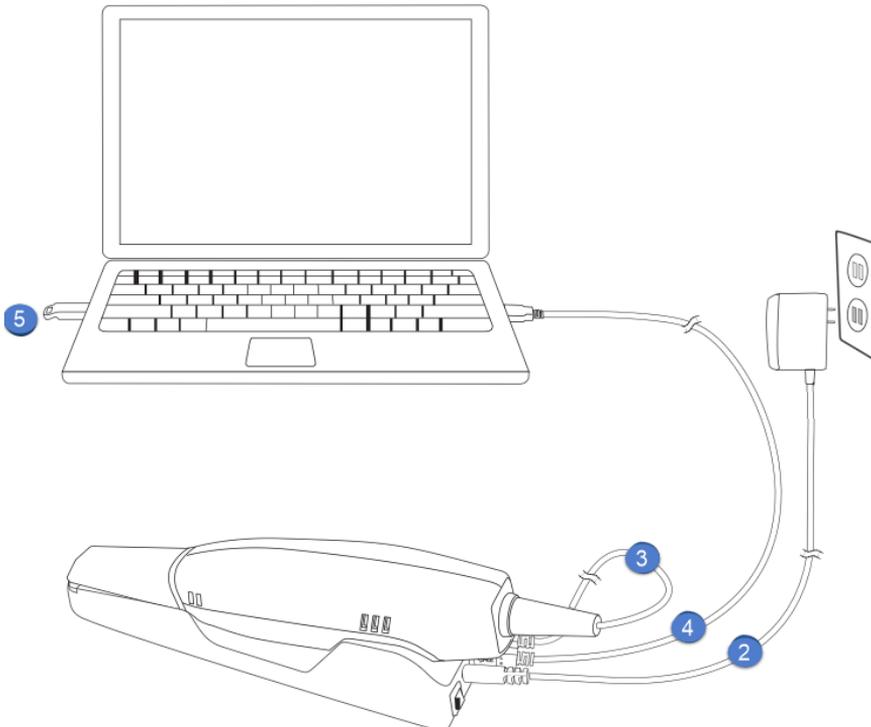
(6) Turn on the power switch on the cradle.

(7) Click the shortcut icon of IntraoralScan 🦷 on the desktop to launch the software

4.2. Disconnecting the Scanner

⚠ **CAUTION**

Do not attempt to directly disconnect the scanner by removing the power cable and USB cable.

Follow the steps below to safely disconnect the scanner:

(1)Quit the IntraoralScan scanning software.

(2)Turn off the power switch on the cradle.

(3)Disconnect the scanner cable from the cradle.

(4)Disconnect the USB 3.0 cable from the USB 3.0 downstream port on the cradle and your computer.

(5)Right-click the "Safely Remove Hardware" icon on Windows taskbar and select"Eject Flash Drive".

(6)Unplug the 2-in-1 USB dongle and keep it in a safe place for future use.

(7)Unplug the power adapter from the wall outlet and remove the power plug from the power connector on the cradle.

⚠ **CAUTION**

Do NOT roll the cable over the handle of the scanner or even create any sharp bends in the cable after you disconnect the scanner. See USB cable storage on chapter 3 for more details.

4.3. Calibrating the Scanner

Under these circumstances, we recommend that you shall execute the calibration for the scanner to ensure the accuracy of scanned data:

● The initial setup of the scanner is completed.

● The scanner has been used for a period of time (e.g. 2 weeks).

● The scanner is accidentally dropped.

Follow the steps below to perform the calibration:

(1) Insert the power plug of the supplied power adapter into the power connector on the cradle, and plug the power adapter into a wall outlet.

(2) Connect the scanner cable to the USB 3.0 upstream port on the cradle.

(3) Connect the USB 3.0 downstream port on the cradle and your computer with the supplied USB 3.0 cable.

(4) Turn on the power switch on the cradle.

The LED light ring on the end of the scanner body lights up green when the power connection is working properly.

(5) Insert the supplied 2-in-1 USB dongle into the USB port of your computer.
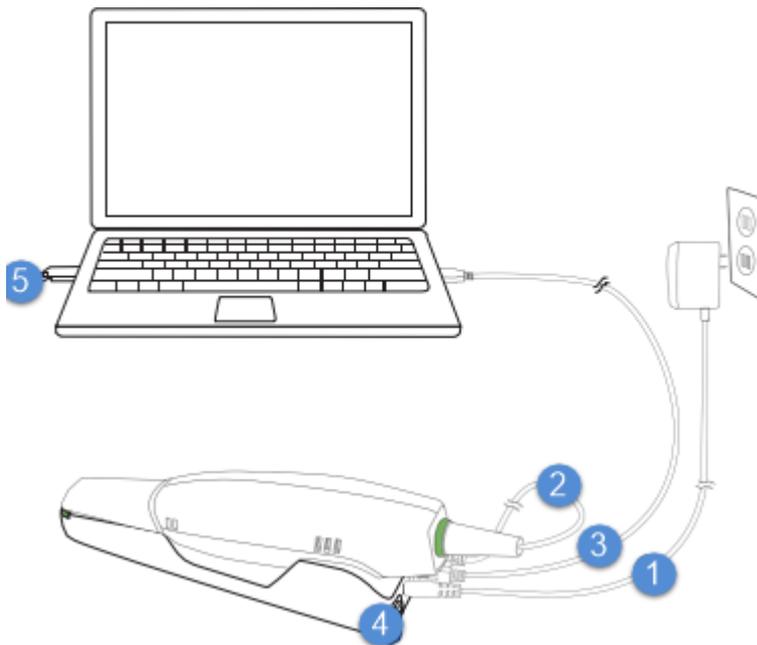
(6) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner, as illustrated.
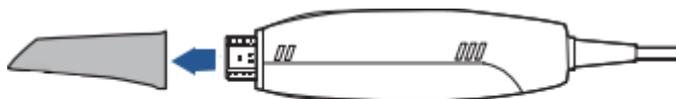
(📝) NOTES

● Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

● Store the detached tip in a safe place, e.g. a dental instrument tray, for future use.

(7) Connect the supplied Calibrator and your computer with the supplied USB 3.0 cable.

(8) Gently slide the Calibrator onto the front end of the scanner, as illustrated.
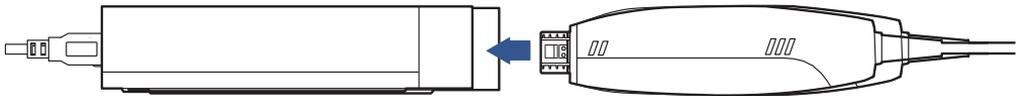
(9) Double-click the shortcut icon of IntraoralCalibration ,and the following interface is displayed.

(10) Click Calibration.If the Calibrator was not closely plugged onto the scanner, a warning message would be popped up. So, make sure the scanner be plugged into the calibration firmly before next operation.
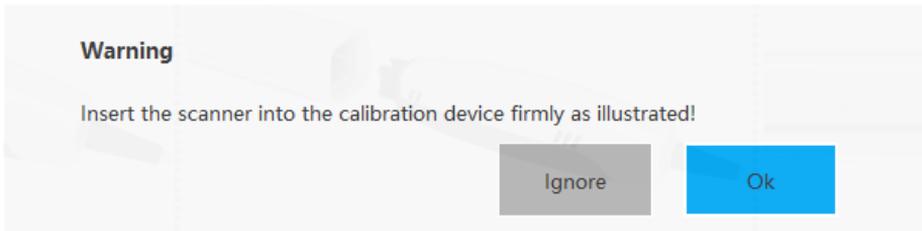
(11) Click Start. The status bar shows the percentage of completion.
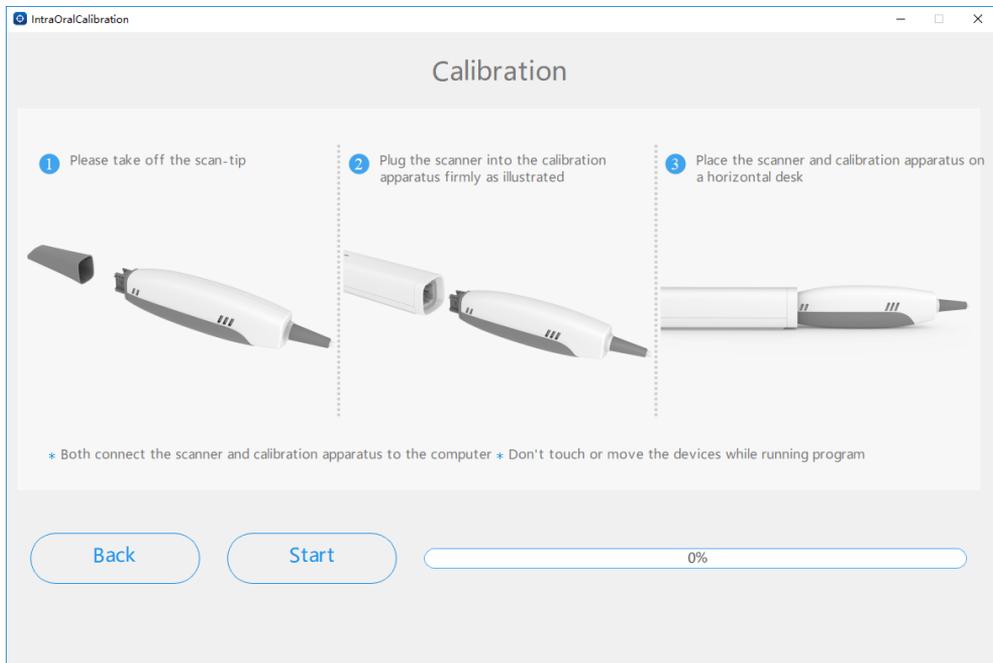
📝 **NOTE**

Normally the calibration takes approximately 5 minutes.

(12) The following message appears once the calibration is completed. Click OK to exit.

Information

Calibration succeed!

Ok

(13) Gently slide the Calibrator off the scanner.

⚠ CAUTION

Make sure that the Calibrator is removed from the scanner after the calibration is done. Otherwise, the Calibrator temperature may get very high.

(14) Re-attach the scanner tip to the scanner for later use or put the protection cap onto the scanner to prevent damage and dust.

5. Scanning Sreparation

5.1. Scanning Basics

Read and follow the guidelines and tips given in this chapter prior to acquiring quality images.

⚠️ **WARNING**

Concerning hand hygiene and personnel safety when performing a scan, you must wear clean surgical gloves through the whole process.

5.1.1. Tooth preparation

● Make sure there is no foreign body or blood in the mouth after gargling. Stop the bleeding if necessary.

● If necessary, ask the patient to keep the tongue still and move it to the other side of the mouth.

● Consider using a dental three way syringe to blow dry or a tampon to dry the tooth surface before starting the scan.

● Turn off the oral light on the dental chair and start scanning.

● Consider using aspirators and tampons to keep the surfaces dry during scanning.

● If necessary, consider using an oral mirror to help create space while working in the narrow area between the teeth.

5.1.2. Scanner preparation

● Ensure that the scanner tip, scanner body, and cradle are properly pre-cleaned, disinfected, or sterilized. See Pre- cleaning, disinfection, and sterilization on chapter 9.

● Ensure that the scanner tip has no scratches or is not damaged. Additionally, the tip is firmly attached to the front end of the scanner body.

● Ensure that the scanner connection is ready; it is correctly connected

to a power source and powered on, and IntraoralScan is launched and ready to work.

● To avoid condensation on the mirror of the tip when scanning, the scanner tip must have been warmed up. For details, see Heating the scanner tip on chapter 5.

● Calibrate the scanner and verify the accuracy of the acquisition regularly. For details, see Calibrating the scanner on chapter 4.

5.1.3. Scanning position and path

● Avoid direct light from any light source, e.g. dentist chair lamp, to shine on the area you are working on.

● Hold the scanner steady by resting it on the tooth surface and keep the scanner tip within 15 mm from the teeth.

● When scanning, slowly move the scanner and simultaneously check the scan results on the screen to ensure that the scanning is of good quality.

● When scanning, the scanner tip should be centered over the teeth, and each movement should align with the cross-hairs, following the lower and upper dental arch shapes.

● A complete scan data of a single area includes the surfaces of occlusal, lingual, buccal, interproximal contacts of the adjacent teeth, and 2-3 mm buccal gingiva.

● A complete scan data of a single case includes the lower jaw, upper jaw, and bite registration.

● When scanning, change the scanning angle to 35-55 degrees in order to create overlaps. It is important to achieve an overlap of at least 30% between each acquisition. If the overlap is small, it may cause the alignment to fail.

● To scan the occlusal surface of the teeth, hold the scanner at a 90-degree angle; to scan the buccal and lingual surfaces of the teeth, hold the scanner at a 45- degree angle.

● Inspect the scanned image in the 3D scan view window (IntraoralScan) and pay attention to warning messages.

5.1.4. Heating the Scanner Tip

In order to obtain optimal image quality, you should prevent condensation on the scanner mirror before each scan by heating the scanner tip.

Follow the steps below to warm up the scanner before starting an acquisition:

(1) Ensure that the scanner tip, scanner body, and cradle are clean and sterile. For details, see Pre-cleaning, disinfection, and sterilization on chapter 9.

(2) Gently and carefully attach the scanner tip to the scanner body, with the mirror facing downward.

(3) Connect the power supply to the **Aoralscan 2**. For details, see Connecting the scanner on chapter 4.

(4) Place the scanner in the cradle to secure it in place.

(5) When the LED ring light on the end of the scanner body lights up green, the heater automatically turns on and detects the temperature.
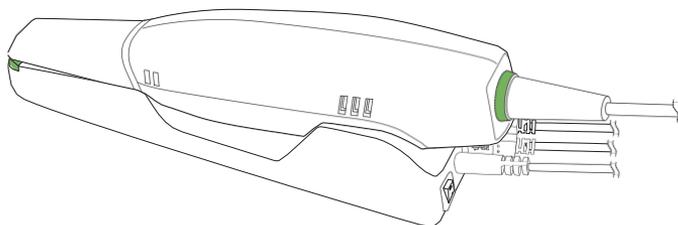
It the temperature of the scanner tip is lower than the set point for anti-fogging, a notification message of pre-heating and current temperature appears.

When the message disappears, the warm-up is done. The scanner is now ready for an acquisition.

📝 NOTES

● The heater maintains constant temperature on the scanner tip.

● The scanner tip is being heated whenever power is supplied, even if the scanner is in standby or sleep mode.

● If the heater does not reach the necessary temperature for preventing condensation during scanning, the message of "The scanner is pre- heating. Please wait" appears.

6. Clinical Case Quick Guide

6.1. Connection the Scanner

See Chapter 4 "Connecting the scanner"for details

6.2. Calibration

See Chapter 4 "Connecting the scanner" for details.In order to ensure the quality of the scanned data, it is necessary to perform calibration periodically (recommended every 15 days).

6.3. Create Order

Double-click desktop icon and the Dental Order System is opened .Click Project and select New to create a new order. Fill out the necessary order information, including the order number,names of dentist(s), patient, and lab(s). Or select Load to open an existing project.

Select the desired type of restoration and the tooth number (the restoration site), and then click Save.
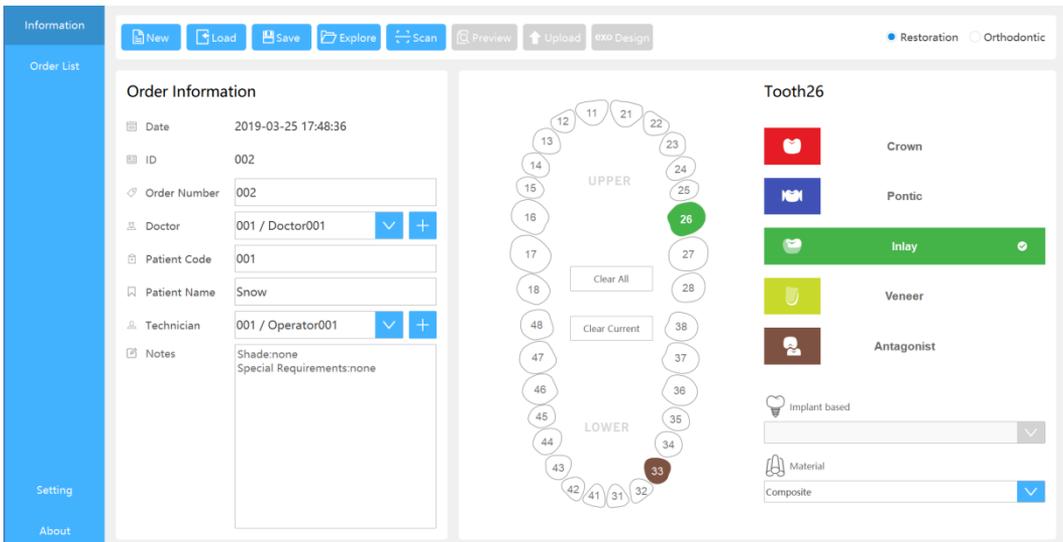
Click the "Scan" button, The Intraoral Scan interface will be automatically

displayed.

6.4. Activate the scanner

When the scanner is first used, it must be connected to the internet and

activated successfully. Double-click the intraoralScan icon on the

desktop, open the order system. The interface will pop up as below
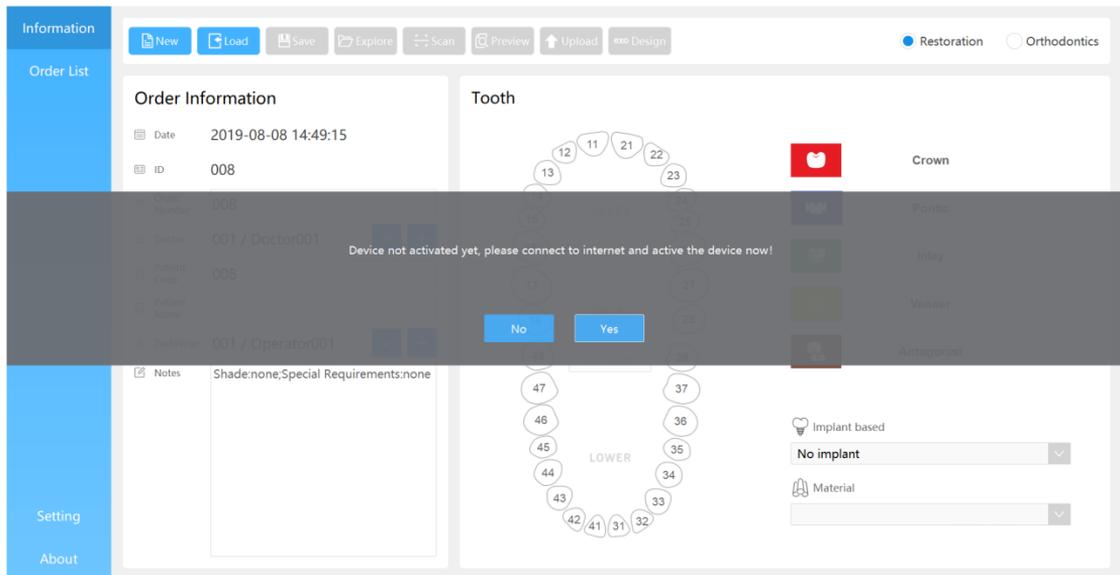
Please make sure the computer has been connected to the Internet, click "Yes" to activate the device, proceed to the next step after successfully activated. Otherwise, please contact the technical staff.

6.5. Scan UpperJaw

Confirm that the image of the camera window in the upper right corner of

the software is displayed normally. Click the scan button or press the

space bar to start scanning.

The green frame in the middle of the software interface indicates the data range of the current scanning. If the green frame changes to a red frame, as

shown in the figure below, the scan position is incorrect. You need to move the scan tip to scan the data displayed in the red frame.

Click the " " button in the right side and then it will turn to " ", during the scanning, the model will display the tooth color (gray), it will guide the user to judge the reliability of the data quality in this area.

If there is more buccal tongue side data during the scanning process, it is recommended to press the pause button to automatically delete these data, as shown below (images before and after pause)
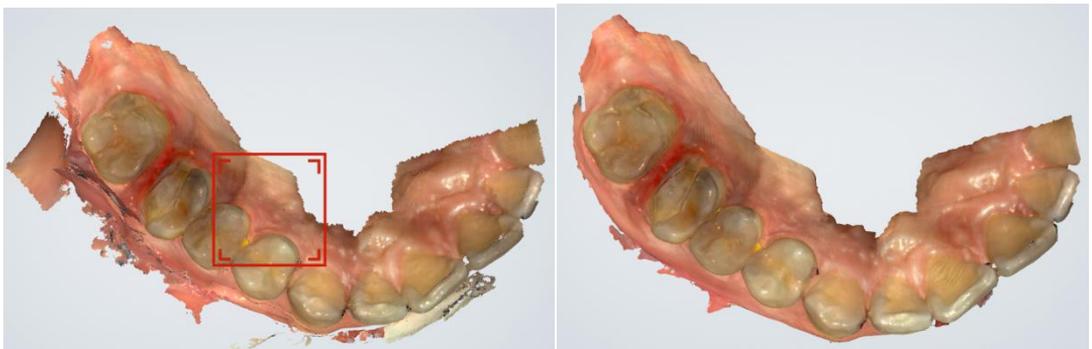
When the scanning head leave the object or the scanning is paused, the green area means this area is not scanned. User can re-scan the corresponding area according to the demand.

Confirm that the model scan is complete.Click the finish button ✓ or long press the space bar to process and save the data. After the completion, the upper jaw icon is green and ticked, indicating that the scanning process is finished.

6.6. Scan LowerJaw

After the upper jaw scanning and the data processing are completed, the lower jaw scanning interface is automatically displayed. The procedure is the same as scanning the upper jaw.

6.7. Scan TotalJaw

After the lower jaw scanning and the data processing are finished, the total jaw scanning interface is automatically displayed.

Click the scan button ▶ or press the space bar to start scanning. After scanning some data, the software automatically performs dynamic bite stitching alignment, as shown below.

Before the stitching
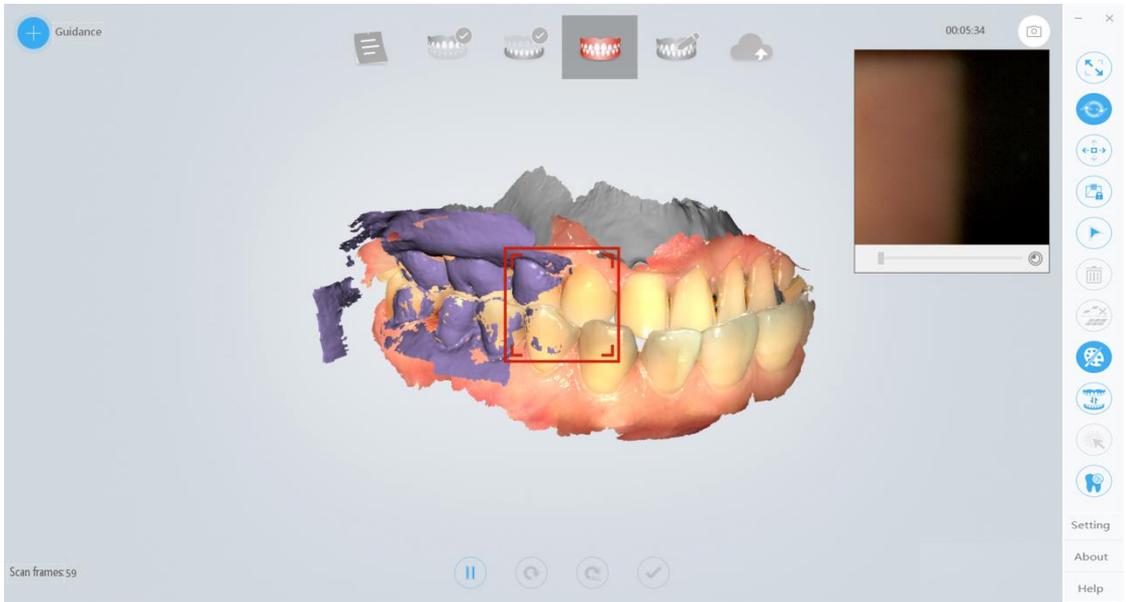
After the stitching

After the upper and lower jaws' data are stitched successfully as well as

the whole jaw, click "⏸" or press the space bar to pause the scanning,

check the occlusion and collision results.

Confirm that the bite effect is appropriate. Click the finish button ✓ or

long press the space bar to post-process the data.

6.8. View Result Data

View result data in IntraoralScan

6.8.1. View upperjaw/ lowerjaw

6.8.2. View the occlusal effect

6.9. Pre-Design
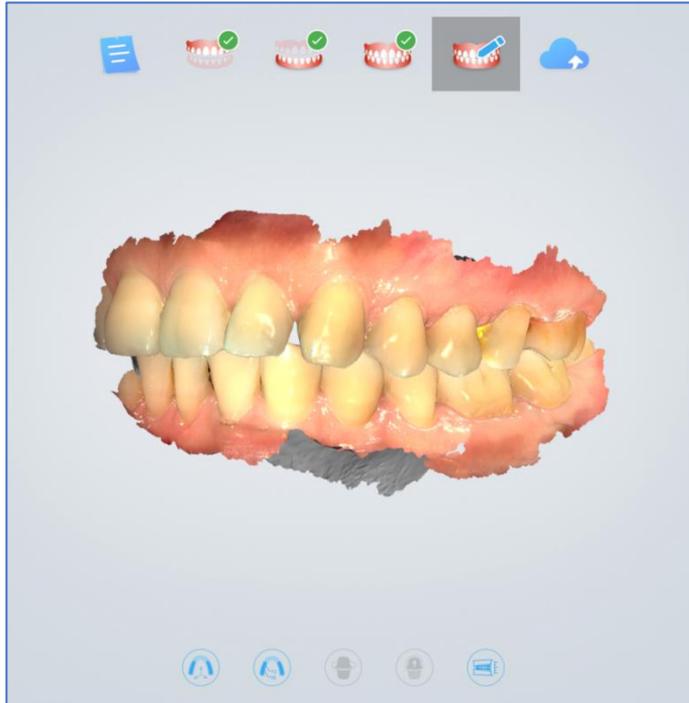
See Chapter 7 "Pre-Design" for details on pre-design functions.

6.10. View Data Storage Path

Click the button [icon] to return to the order interface and click [Explore] to open the folder path of the current order storage.

6.11. Upload Order

Click [icon] icon to upload the scanned order. If you have not logged in, the software will prompt "No login to the account, go to the setup interface to log in?", select "Yes" to open the "Configure Account" interface. Register the account on the webpage of the dental cloud, add the lab, refer to Chapter 8 "Registering Account" and "Building Relationship Network". Then return to the Dental Order System to login and upload the order.

Upload order

Time	2019-03-25 17:48:36
ID	002
Doctor	Doctor001
Patient	Snow
Dentistry Type	Restoration
Notes	Shade:none Special Requirements:none

UPPER

LOWER

Tooth Number	Reconstruction Type	Implant Based	Material
26	Inlay	No implant	Composite
33	Antagonist	No implant	Zirconium

Choose lab sunnyLab ⌄   ✓ Review design data?

Cancel   Confirm and Upload

7. Using IntraoralScan

7.1. Introduction to IntraoralScan

IntraoralScan includes three modules: calibration module,dental order system and scan module.

- Calibration module is mainly used to calibrate the accuracy of scanner and ensure the quality of scan data, it contains three functions which are accuracy measurement, intensity control and calibration.

- Dental order system is a module for dental order management, realizing management functions such as order creation, editing, searching, scanning and deletion, as well as uploading, downloading, previewing and tracking of scanned order and data.

- The scan module collects oral digital images, processes rendering data and exports 3D data (STL/OBJ).

NOTE

To run software, the following requirements must be met:

- The supplied 2-in-1 USB dongle is plugged into the USB port of your computer.

- The connection between the scanner and your computer is ready. For details, see chapter 4 "Connecting the scanner".

7.2. Introduction to Calibration module

After the installation of calibrator is completed, connect it to the scanner and power on, open "IntraoralCalibration.exe", then you can proceed the next operation include accuracy measurement, intensity control and calibration.
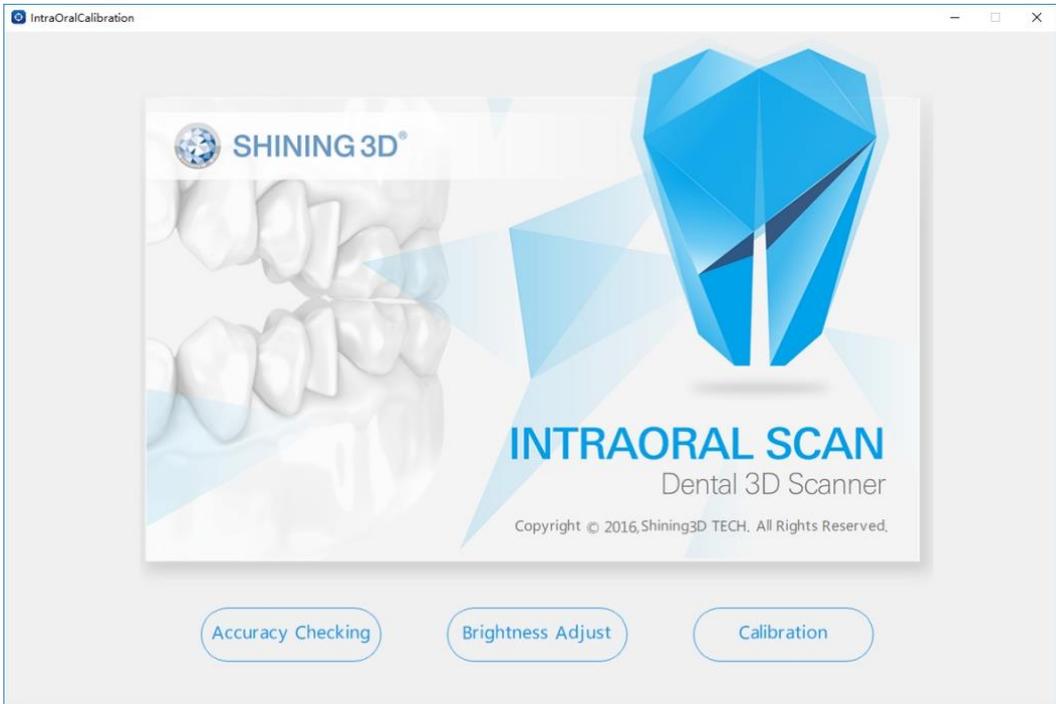
7.2.1. Accuracy Checking

Accuracy checking is used to check the accuracy validity of existing calibration result of the scanner.
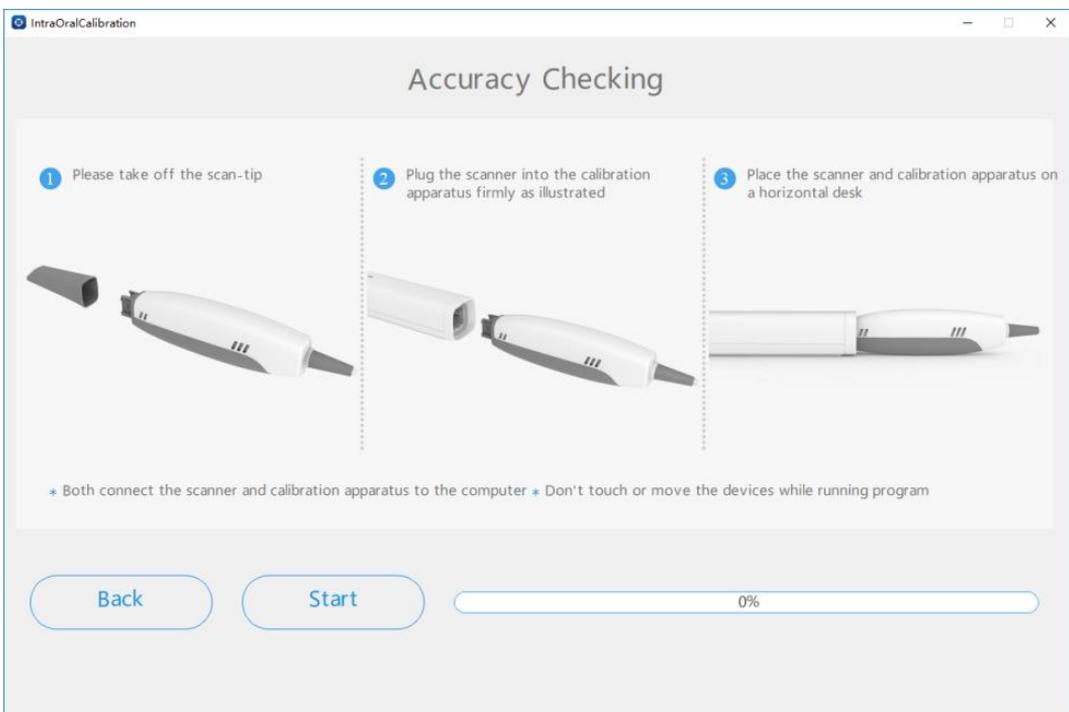
Connect the scanner and calibrator correctly as shown, click "Start" button

to proceed the accuracy measurement, continue the next step according to the testing result.

7.2.2. Brightness Adjust

Brightness adjust is to correct the brightness of scanner and improve the color fidelity of scan data. It is recommended to proceed the intensity control every 3 months.
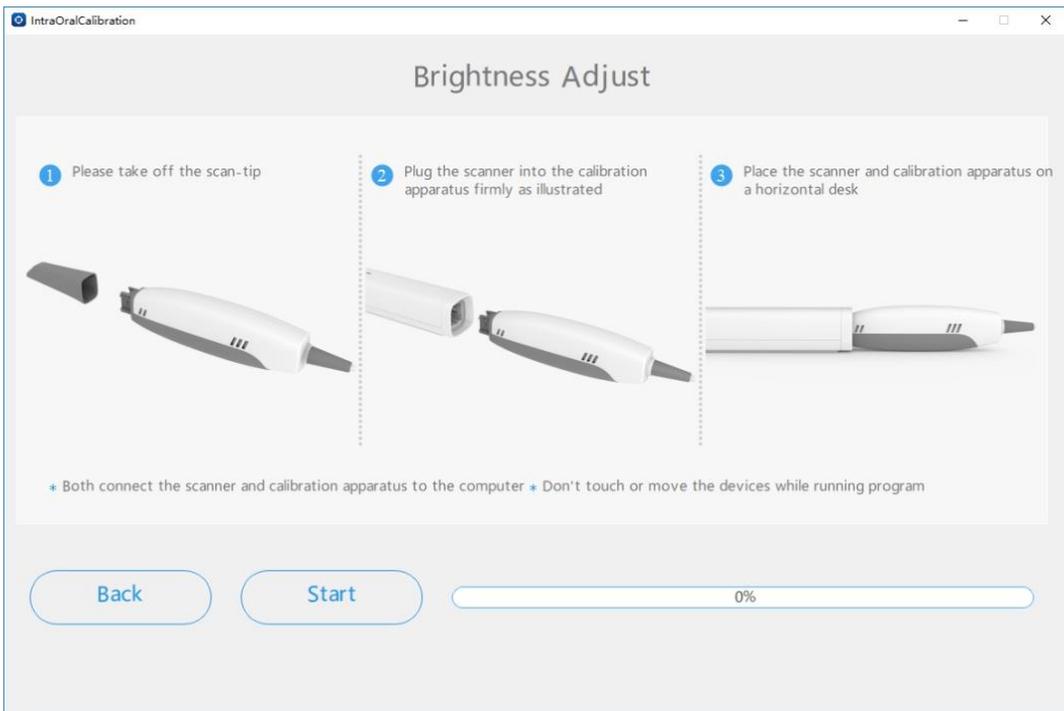
Connect the scanner and calibrator correctly as shown, click "Start" button to proceed the intensity control.

7.2.3. Calibration

The goal of calibration is to calibrate the accuracy of the scanner, insure the quality of scan data. The regular calibration is required which is recommended every 15 days.
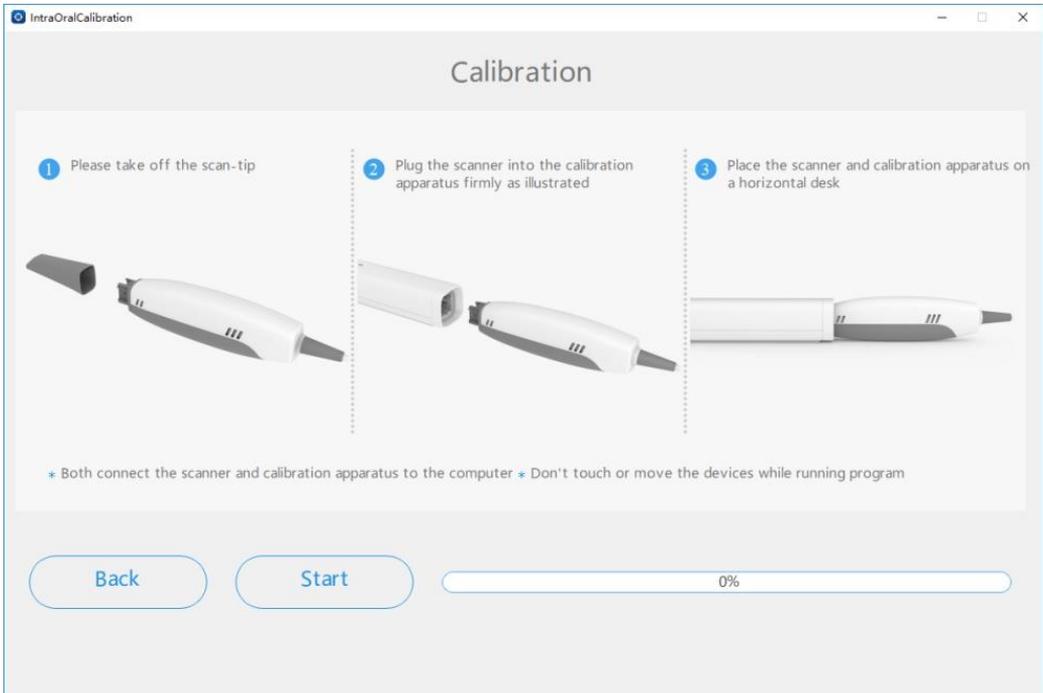
Connect scanner and calibrator correctly as shown, click "Start" button to proceed the calibration.

The successful (or failed) calibration will pop up the corresponding information dialog.

7.3. Introduction to Dental Order System

Double-click the desktop icon to open the software to dental order system. The dental order system is displayed as follows:
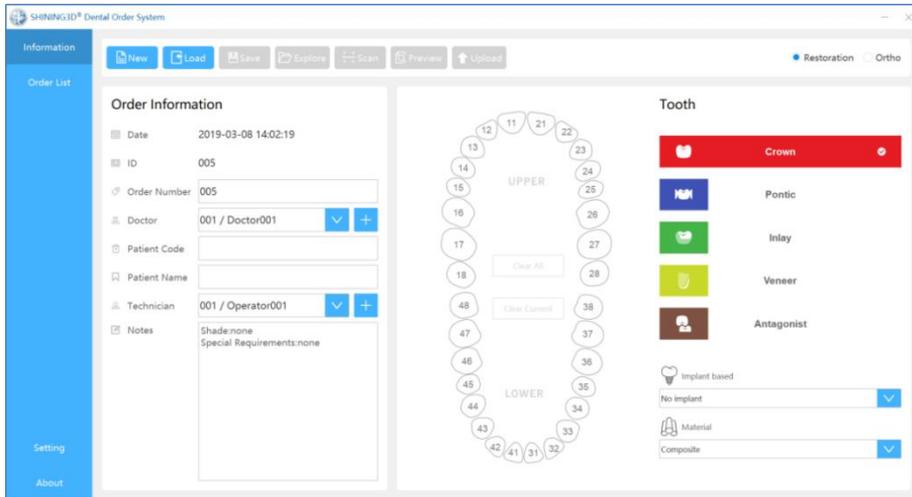
The dental order system is mainly composed of three parts:order information, order   list and setting.

7.3.1. Information
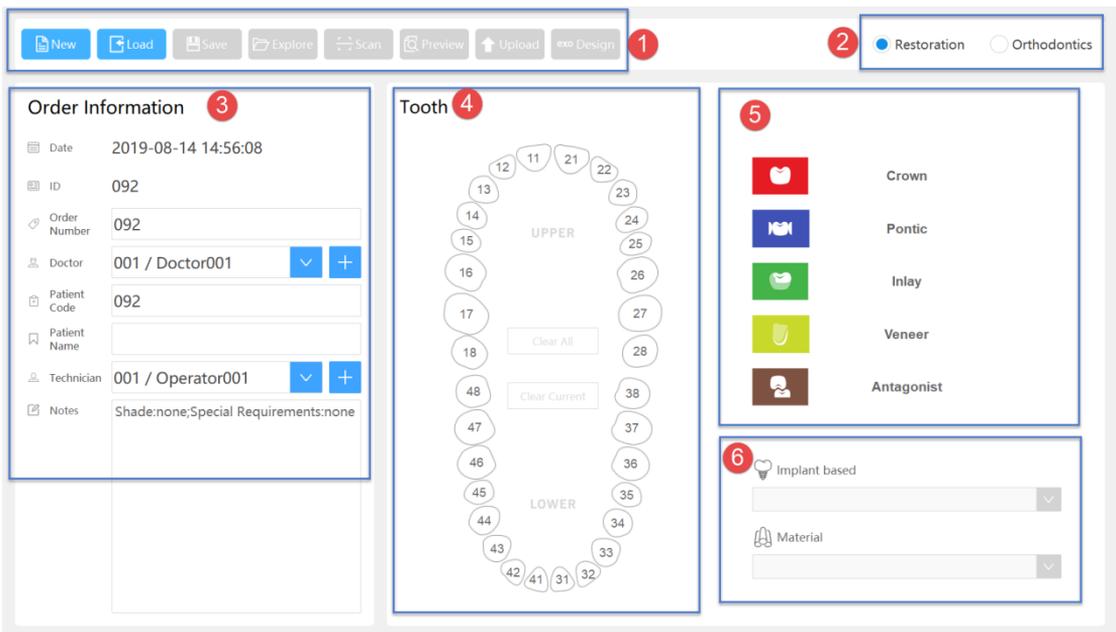
 (1) Button column

✧ New: Create a new order.

✧ Load: Load a saved order.

✧ Save: Save the new order with the completed order information.

✧ Explore: Open the folder where the saved order is located.

✧ Scan: Start scanning.

✧ Preview: After the order scan is completed, the scanned data is viewed through the DentalViewer.

✧ Upload: After the order scan is completed, the current order data is uploaded to the dental cloud.

✓ Choose lab: choose a lab in the drop-down list

✓ Review design data: Does the design data of the lab need a doctor to review it. The default is yes.

✓ Cancel: Cancel the upload.

✓ Confirm and Upload: Confirm the upload of order data to the dental cloud.

✧ exo Design: After the order scan is completed, open the EXOCAD design software directly for design. The first time you click this button, you need to set the path of the EXOCAD design software first.

(2) Order Type: Restoration and Ortho.

(3) Order Information: Set the order number, doctor, patient, lab and notes information.

(4) teeth map

✧ Left click button to select the tooth position.

✧ Right click button to cancel the defined repair type.

✧ Ctrl+left click to button, copy the repair type defined by the previous tooth position to the currently selected tooth position.

✧ Shift+left click to button, copy the type of repair defined by the previous tooth to all the teeth between the tooth position of the same jaw and the last tooth position.

✧ Clear current: Clear the defined repair type of the currently selected tooth position.

✧ Clear all: Clear the defined repair types of all the teeth position.

(5) Types of dental restoration: crown, pontic, inlays/onlays, veneers and antagonist. The crown is selected by default.

(6) Implant based and Material: Set the implant type and materials. The type of implant cannot be set if the type of dental restoration is not "Crown".

7.3.2. Order list

The order list lists the order status of all orders under the dental order path.

(1) Refresh: Refresh the order list

(2) Import order: Import orders that are not stored in the order path. If the import is successful, it will be displayed in the first line of the list. If an order with the same name already exists in the order path, the imported order is automatically renamed to "source order name +_import_*".

(3) Search: Search by order date or by entering a doctor/patient/lab name.

(4) Order Status: Lists the status of all orders, which can be filtered by

order status.

 ✧ Need Scan: orders that have not been scanned. The right-click menu or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete.

 ✧ Need Upload: Orders that have been scanned but have not been uploaded order data to the dental cloud. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete/Upload.

 ✧ Waiting Accept: The order data has been uploaded to the dental cloud, waiting to be received by the lab. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Cancel Order/Delete/Re-upload.

 ✧ Accepted: The lab has received the order,which is awaiting a design plan. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete/Cancel Order.

 ✧ Need Confirm Design: The lab has uploaded the design plan and the doctor has not reviewed the approved order. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete/Download Design/Confirm Design/Request Re-design.

 ✧ Making: The design plan has been approved by the doctor, and the order of the lab is making. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete/Download Design/Request Re-design.

 ✧ Delivering: The lab has shipped the goods, and the doctor has not received the order for the goods. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete/Download Design/Delivery Information/Confirm Received/Request Re-delivery.

 ✧ Finished: Orders for which the doctor has received the goods.The right-click menu or operate icons for such orders is: Load/Open in Explore/Duplicate/Delete.

 ✧ Rejected: The order data has been uploaded to the dental cloud, and the lab refused to accept the order. The lab can refuse to accept orders

before uploading the design. The right-click menus or operate icons for such orders are: Load/Open in Explore/Duplicate/Delete/Re-Upload.

✧ Canceled: Order data has been uploaded to the dental cloud, and the doctor has cancelled the order. Doctors can refuse to take orders before the labs uploads the design. The right-click menu or operate icons for such orders is: Load/Open in Explore/Duplicate/Delete.

(5) The descriptions for orders operation icons.

Icon Example	Description
	Load the currently selected order.
	Open the folder where the currently selected order is located.
	Duplicate the currently selected order and save it as a new order.
	Delete the currently selected order form the order list,you can choose whether to delete stored order files and scanned data.
	Upload the currently selected order to the dental cloud .
	Order data has been uploaded to the dental cloud, and the doctor has cancelled the currently selected order.
	Download Design.
	Confirm Design.
	Request Re-design.
	Delivery Information.

	Request Re-delivery.
	Confirm Received.

7.3.3. Setting

Users can view or set specific information through the setting button

Setting on the software interface.
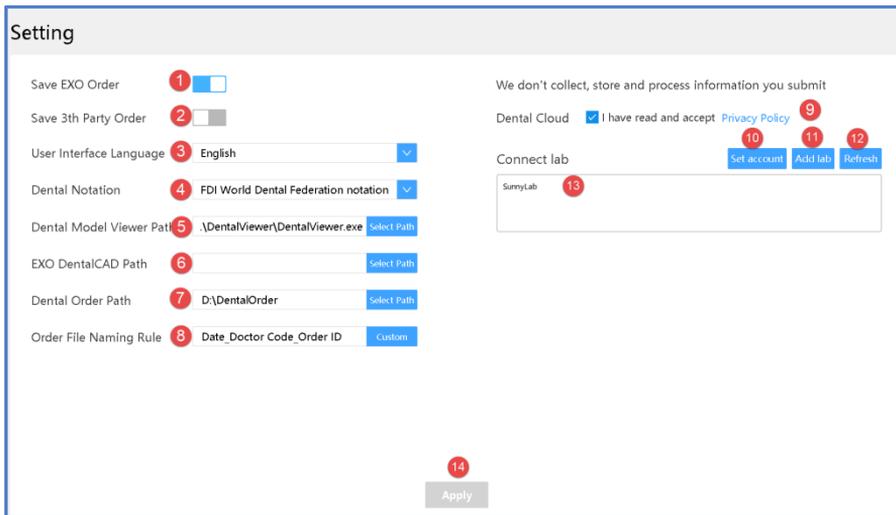
(1) Save EXO order: The exocad order *.dentalProject is saved while saving the order. You can import the order into the EXO design software for design. The default is on.

(2) Save 3th Party Order: A third-party software order is saved while saving the order. The folder named "original order name_thirdParty" is generated under the order path, and the *.xml file and the scanning result data *.stl (the coordinate system is consistent with the third-party design software)are stored. You can create an order into a third-party design software and import the data to design. The default is off.

(3) User Interface Language: Users can set the software interface language: Chinese (Simplified) and English. The default language is the language selected during software installation.

(4) Dental Notation: FDI World Dental Federation notation and Universal numbering system.The default is FDI World Dental Federation notation.

(5) Dental Model Viewer Path:Set the path of the DentalViewer program.After the order scan is completed, the scanned data is viewed through DentalViewer.

(6) EXO DentalACD Path: Set the path of the EXOCAD program so that you can launch the EXOCAD software instantly when you click the "Information" ->"exo Design" button.

(7) Dental Order Path: Set the order saving path. The default is C:\DentalOrder.

(8) Order File Naming Rule:Set the order file name.
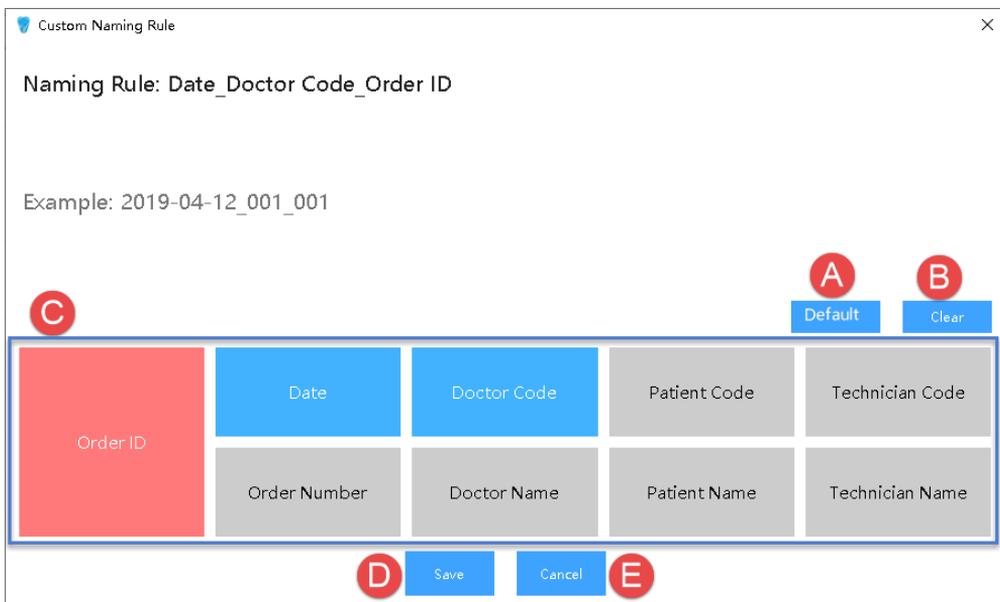
(A) Default:Restore to the default order name: "Date_Doctor Code_Order ID".

(B) Clear:Clear all the selected items except "Order ID".

(C) Naming Rule items:Order ID/Date/Doctor Code/Patient Code/lab Code/Order Number/Doctor Name/Patient Name/lab Name. Order ID is required.

(D) Save:Save the current setting.

(E) Cancel:Cancel and discard the current setting.

📋 NOTE

After modifying the setting "User Interface Language" / "Dental Notation" / "EXO DentalACD Path"/"Dental Order Path" /"Order File Naming Rule", click "Apply" button, and the message "New setting will take effect after restart, do you want to restart application now?" is displayed. Then click "Restart Now" button, and the software will be automatically restarted and the setting will take effect.

(9) Privacy Policy: Unchecked by default. Users must check the "I have read and agree to the Privacy Policy" to activate the configuration information related to the dental cloud.

(10) Set Account: Register or log in to the dental cloud account.
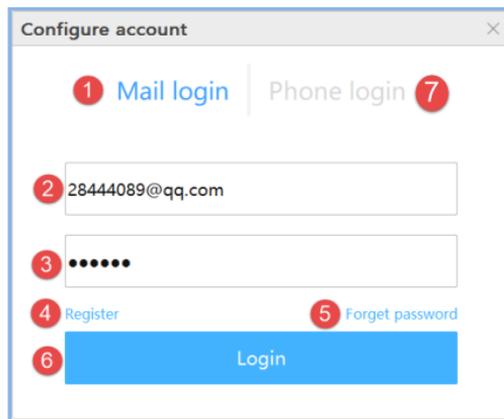
①Login type: email login and mobile number login. You should log in with a doctor or hospital/clinic account here, and you cannot log in with a lab's account.

②For mail login, enter the email account.

③Enter the login password.

④Register: Unregistered users can click this link to register on the dental cloud website.

⑤Forget password: Users who forgot the password can click this link to retrieve the password on the Dental Cloud website.

---

⑥Login: Fill in the account and corresponding password. The contact information filled in during registration is displayed in the upper left corner of the software.

⑦Phone login:First select the area, then enter the mobile number. The default area is China.

(11) Add Lab: If you have not added a lab, you can click this button to add a network on the Dental Cloud website to establish a cooperative relationship with the lab.

(12) Refresh: Refresh the list of dental labs.

(13) Connected lab: The accepted labs are listed.

7.3.4. Data storage

Introduction to order data:

❖ *.dentalProject: exoCAD Order project document

❖ *.inProject: Shining 3D intraoral scanning order project document

❖ *.stl: Untextured 3D data (binary)

❖ *.obj: Textured 3D data, used it with *.mtl/*.jpg

❖ *.beb: Shining's own format 3D data

❖ *-margin.xyz: Extractive edge line data.

❖ Project: Scan project data document, store the temporary project document.

The data is saved in the directory as set before, and the default path is C:\DentalOrder. The file is named by date as shown below.

2018-11-20_001_1
2019-02-22_001_001
2019-02-22_001_002
2019-02-22_001_003
2019-02-22_001_004
2019-02-22_001_005
2019-02-22_001_008
2019-02-22_001_009
2019-02-22_001_012
2019-02-22_001_013
2019-03-08_001_001
2019-03-08_001_002
2019-03-08_001_003
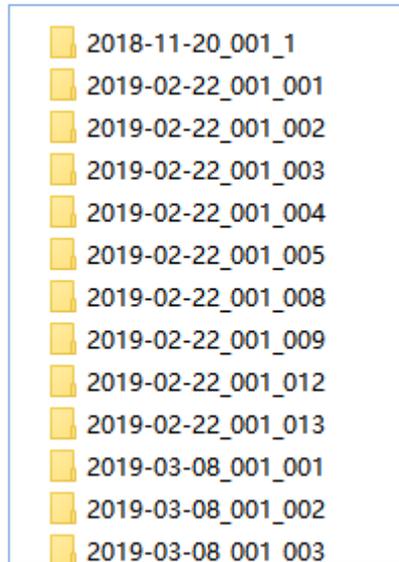
7.4. Navigating IntraoralScan Interface

After creating and saving an order in the Dental Order System, the scanning interface is displayed. If no scanner is connected, an error message appears to remind you to check and reconnect the scanner, as shown below.
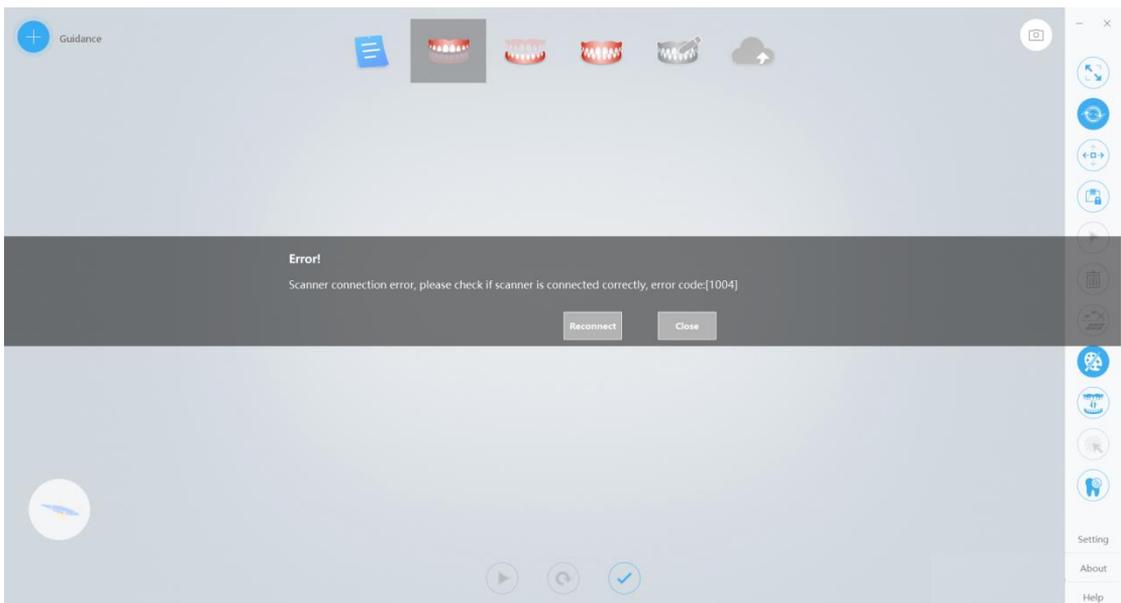
NOTE

If the scanner is connected yet the error message remains, cut the base power supply and supply the power again, then reconnect the scanner. If IntraoralScan still cannot detect the scanner, quit IntraoralScan. Wait for a few

seconds, and relaunch IntraoralScan again.

   If the scanner is detected, the workspace is shown as below.
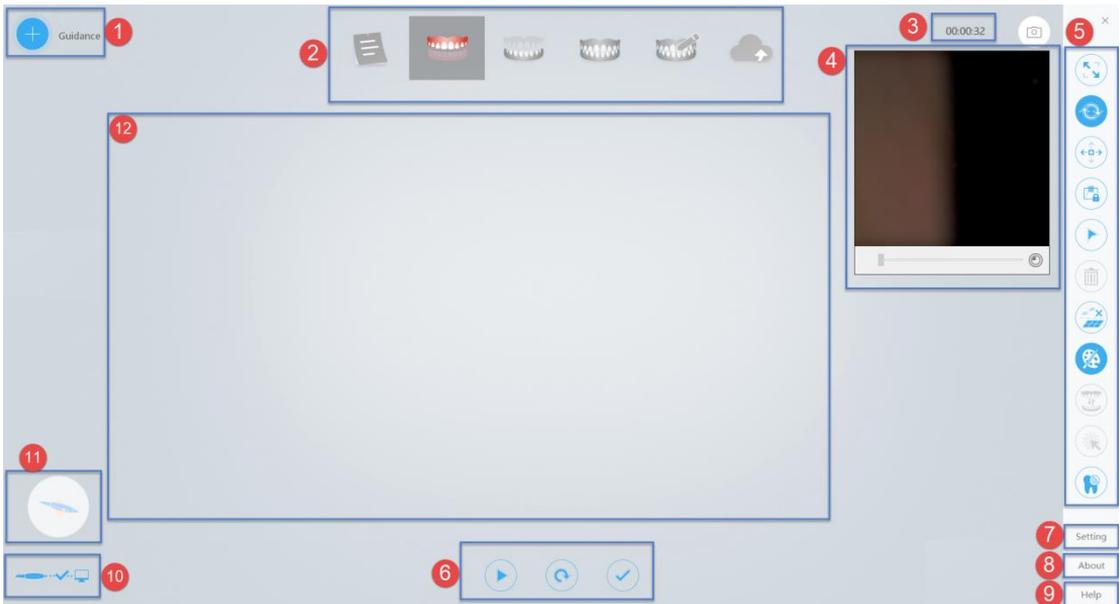
（1）   Guidance: Scan wizard description, prompt information, etc.

（2）   Process: Includes Dental Order System, upper jaw (upper jaw implant), lower jaw (lower jaw implant), total jaw, pre-design, upload order.

（3）   Scan time: record the time of scanning and data processing.

（4）   Image window: View the video image of the camera.

（5）   Edit menu: from top to bottom respectively are:

✧ Fit View button: Click this button to restore the default size of the model;

✧ Rotate button: After clicking the button, press and hold the left mouse button to rotate the model;

✧ Move button: After clicking the button, press and hold the left mouse button to pan the model;

✧ View Lock button: When this button is clicked, the automatic view tracking function is unabled during scanning;

✧ Select button: After clicking this button, hold down the left mouse button and select the area to be deleted on the model;

✧ Delete button: Click the select button to select the specified area, click the delete button to delete the data;

✧ Remove disconnected data button: Click this button to automatically delete a number of large pieces of isolated data.

✧ Texture button: Whether the model data shows texture, the default is highlighted, indicating that the texture is displayed.

✧ Swap jaws button: After the scan is completed or after the post-processing is completed, the data of the upper and lower jaws are exchanged. It is applied for the cases where the upper and lower jaws are reversed during scanning.

✧ Refined area button: Select the refined area and perform refinement processing after post processing.

（6） Scan menu: Scan start/pause (shortcut: space bar), reset and complete

✧ Scan:Click the button to start scanning; after starting the scan, the icon changes to ,indicating that the scan is in progress; if the scan is completed, click the scan button again to add scanning.

✧ Pause:Click the button to pause the scan; after the pause, the icon changes to , indicating the scanning is paused.

✧ Reset:Click to delete the scanned model.

✧ Complete:Click to save the data after optimization.

（7） Setting: Set scan parameters, and camera window crop parameters.
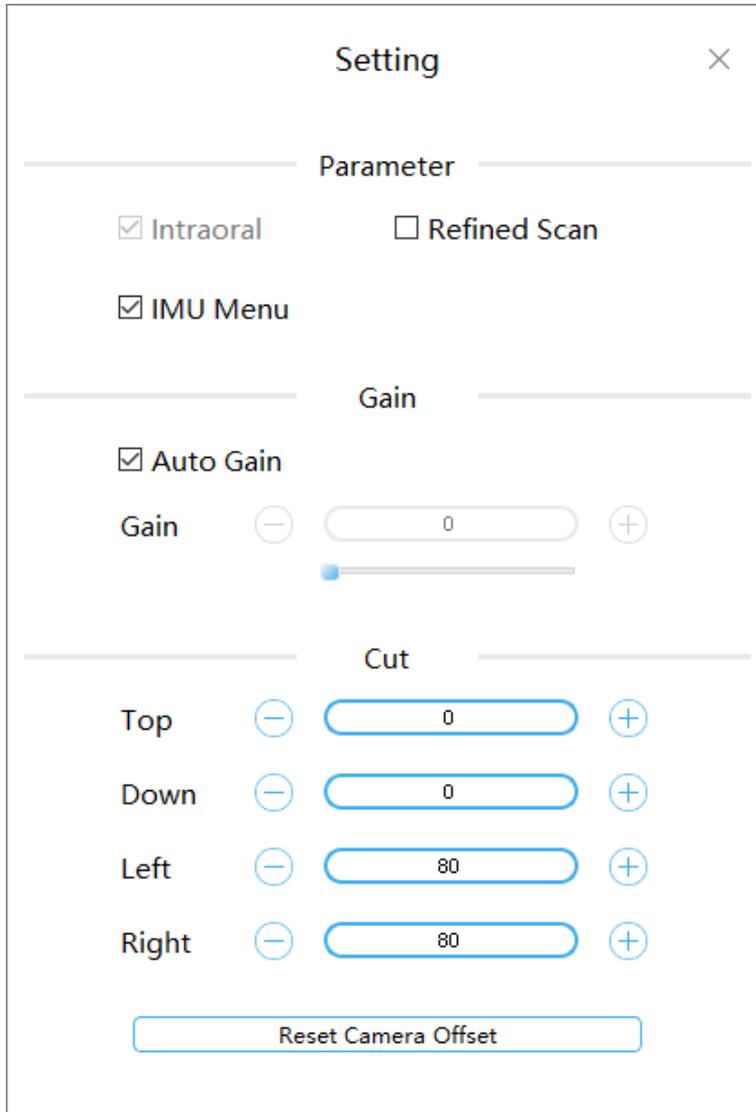
♦ Intraoral: Checked by default. It is for intraoral scan. It is recommended not to tick this when scanning the dental model.

♦ Refined Scan: Unchecked by default. It can be applied for selecting teeth in refined areas, and the post-processing data is more elaborate and refined.

♦ IMU Menu: IMU switch. The IMU function is turned on by default

♦ Auto Gain: The default is to adjust the gain automatically. If the "Auto Gain" check box is not checked, you can manually set the gain by dragging the slider or entering a value.
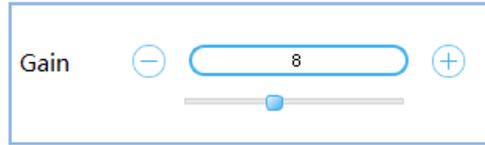
Recommended value for manual setting of the dental scan gain: [0, 2];

Intraoral Scan gain is recommended to be 8.

✦ Cut: By default, it is read from the camera. You can also manually set the cropping parameters of the top, bottom, left, and right sides of the camera window.

✦ Reset Camera Offset: Restores the cropping parameter values read in the camera.

（8） About: View the version number, the software dongle serial number, the number of days remaining for authorization and the scanner serial number.

（9） Help: Open the user manual of the software.

（10） Display device status icons during non-scanning:

Icon Example	Description
	Connecting
	Connected
	Not connected
	Connection error
	Standby
	Overheat
	Sleeping mode

During the scanning process, the number of scanning frames is displayed

here Aligned frames: 291 。

（11） IMU Icon: click the icon or hold the scanner, pause 1 second, shake 2 times, both can call out the IMU menu.
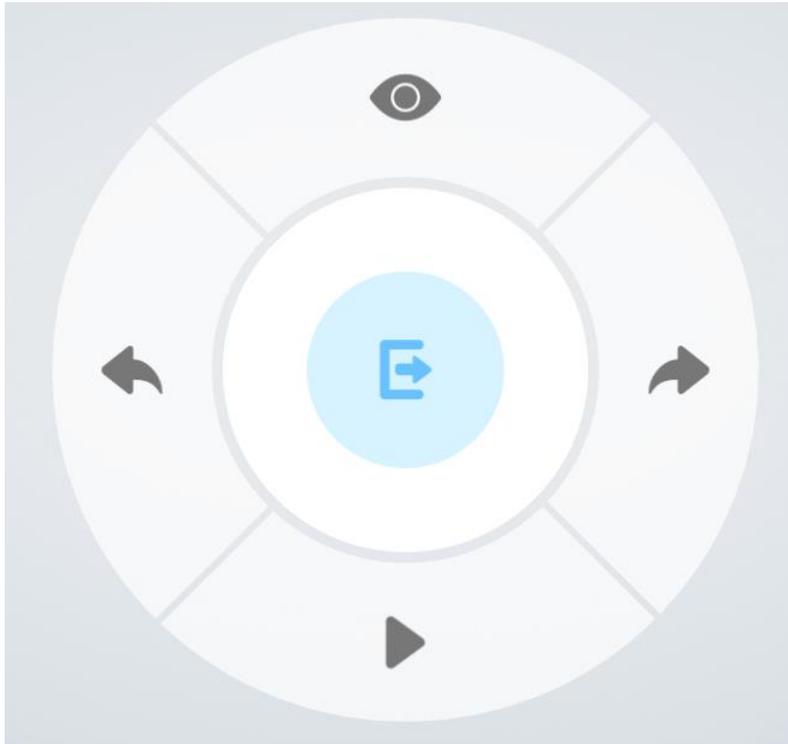
Move the scanner to select different functions, white means the selected state, wait for the blue area expanded to the corresponding menu area and the function will be triggered.

✧ : Exit the IMU menu.

✧ :Scan. The icon will become pause during the scanning state.

✧ :Last step. The icon will become reset after scanning

part of the data.

✦   :Next step. The icon will become "finish"   during the scanning.

✦   :Rotate the view data.

（12）3D View: Displays the 3D model data acquired by the scan. Support the left mouse button to rotate the 3D model, and the right mouse button to translate the 3D model data.

7.5. Introduction to IntraoralScan Functions

7.5.1. Scan technique

The scanning technique of the software has certain requirements. During the scanning process, the speed cannot be too fast, and the next part can be scanned only after the previous part has been scanned. During the scanning process, when scanning the previous area, the next area, the back side, and the front side, there must be a certain overlap area, otherwise the scanned model may have accumulated errors.

Users are advised to adopt S-type scanning, and the following figure a is taken as an example. The left distal tooth is used as the scanning starting tooth position (1 in the figure) and the S-shaped scanning is performed in the direction of the dotted arrow.

Figure a-scanning

The S-scan process is: face (1) -> lip side to tongue side (2) -> tongue side to lip side (3) -> face (4). In Figure a, steps 1, 2, and 3 are performed as shown in Figure b below for a single S-scan:

b-1

b-2

b-3

b-4

Figure b-S-type scanning

7.5.2. Loading project

Load the unscanned order (that is, the post-processing is not completed), open IntraoralScan and the following message is displayed:

Unfinished scanning is detected, do you want to continue the scaning?
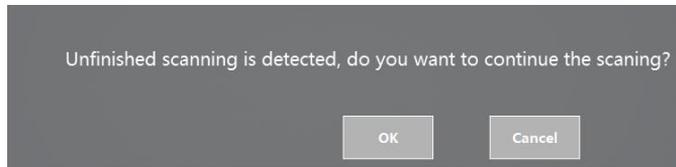
OK   Cancel

Click "OK" to continue the last scan and the total jaw data must be rescanned or click Cancel to restart scanning. After loading and processing the completed order, open IntraoralScan and the following message is displayed:

Click "OK" to load the data that was last processed or click Cancel to restart scanning.

Scanned data is detected, do you want to load it?

OK   Cancel
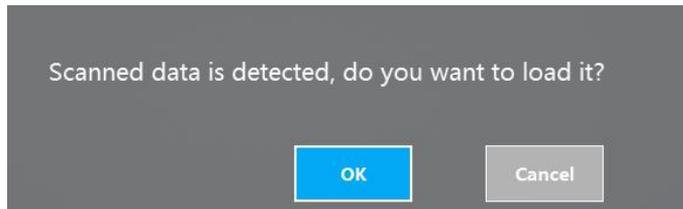
7.5.3. Dental Order System

Click the icon   to return to the dental order system and view/create/edit the order

7.5.4. Scan Upper/Lower Jaw

Scan

To enter the jaws scanning process, first check whether the image display in the image window is normal. After confirming the image, click the button

   or press the space bar to start scanning.

Click the " " button in the right side and then it will turn to " ", during the scanning, the model will display the tooth color (gray), it will guide the user to judge the reliability of the data quality in this area.
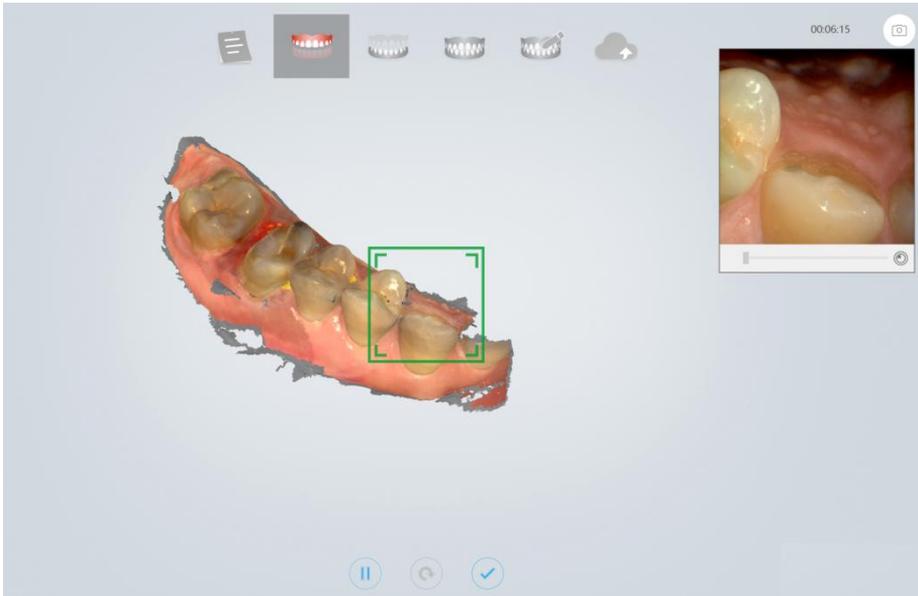
Figure 1 - display the tooth color (gray)

Pause

During the scanning process, you can click the or press space bar to pause the scanning, and delete the buccal and lingual data in the mouth during the pause to facilitate the user to check the tooth scanning effect, as shown below (images before and after pause)
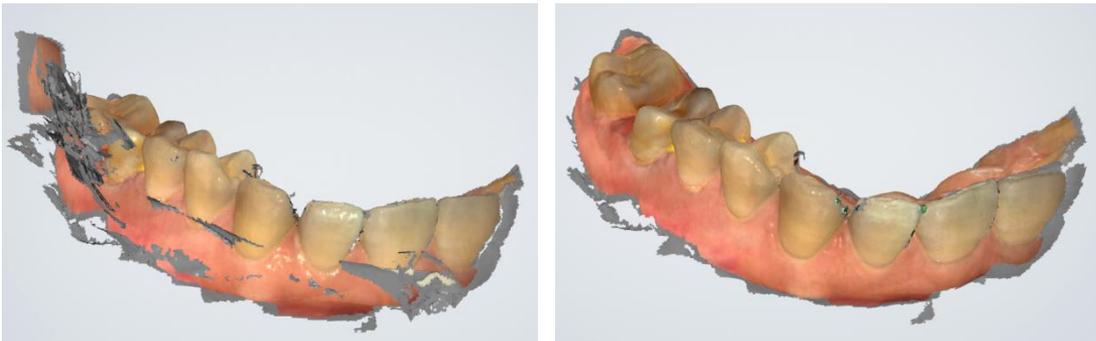
When the scanning head leave the object or the scanning is paused, the

green area means this area is not scanned. User can re-scan the corresponding area according to the demand.
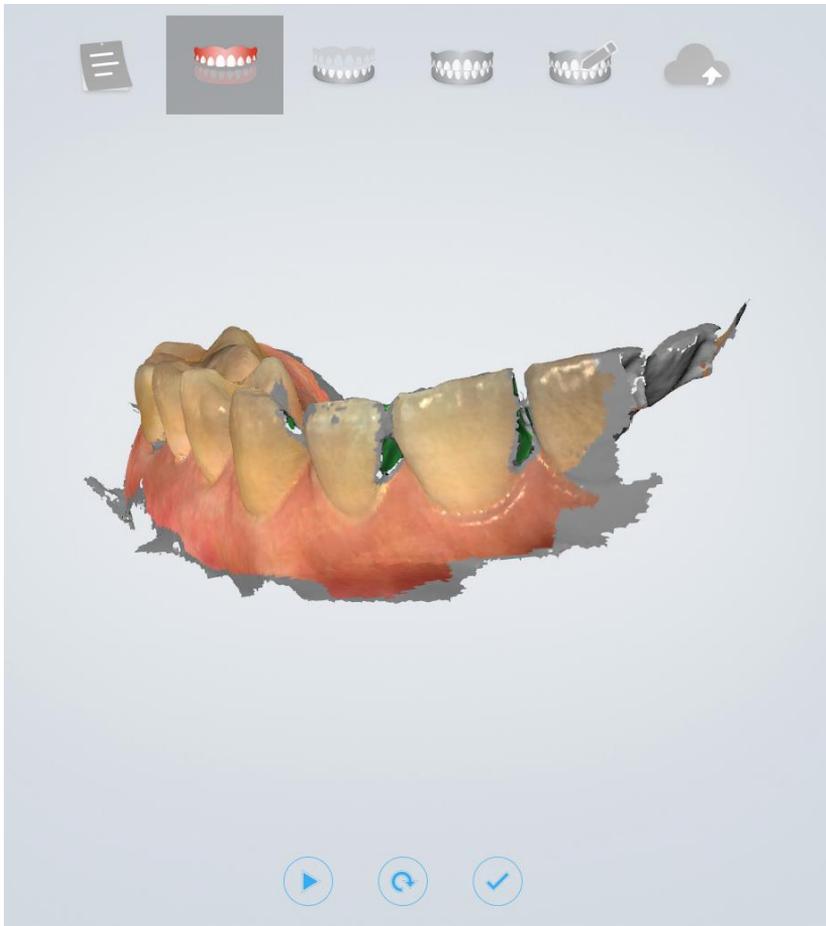
Figure 2 -Scan is paused, hole areas are in green

Click the " "button again to continue the scanning

Rescan

If the scan data is not satisfactory, you can re-scan it. Click the button

 , and the following prompt message box is displayed.
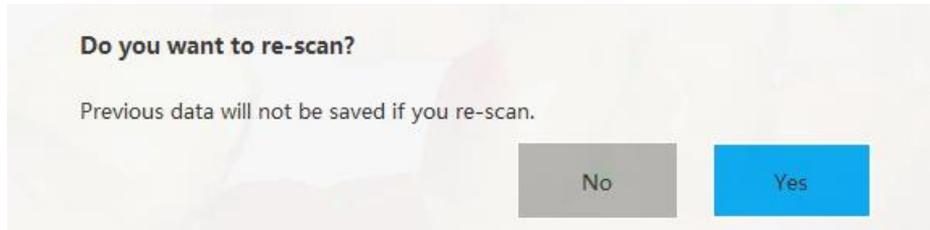
Click "Yes" to delete the previous data and restart the scan.

Add Scanning

After the scan or post-processing is completed, do not exit scan software interface and click scan button to re-scan the data.
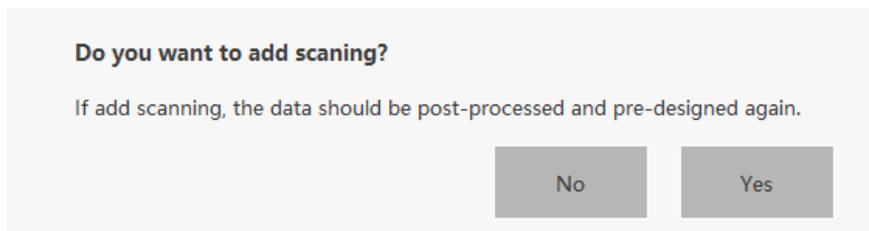
Scanning Completed

After confirming that the model scan is completed, click the finish button

 or long press the space bar to save the data. The green tick in the upper right corner of the icon as shown below indicates that the scanning process is finished.

Figure 3 - Scan completed

If the scan is completed and you return to the dental order system or upload the order, the prompt box "Do you confirm to complete scanning?" is displayed.
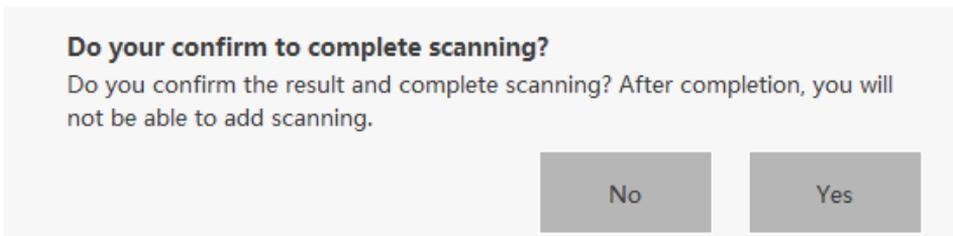
If you select "Yes", in this order you can no longer add scanning.

Note: The maximum number of frames for the upper/lower jaw scan is 3,000 frames. When scanning to 2,500 frames, it will prompt a message asking whether to stop scanning or continue to scan 500 frames.

7.5.5. Scan Upper Jaw/Lower Jaw Implant

Create an order to define the type of dental restoration as implant. The

implant scanning is added in the scanning process.
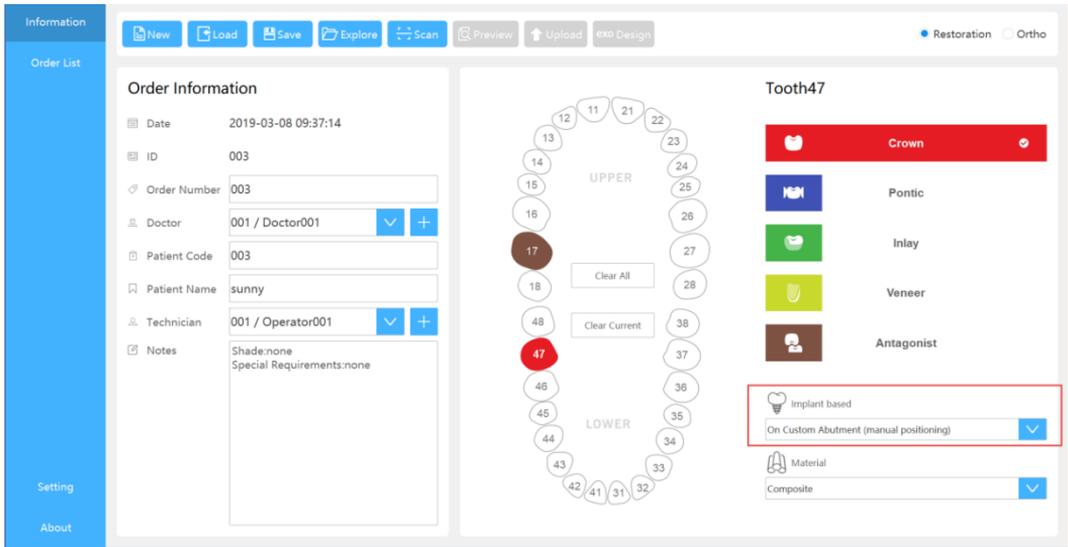
Scan the lower jaw first (without intraoral scan bar). After the lower jaw scan is complete, the lower jaw implant scanning interface is displayed. Select the implant area and delete it.
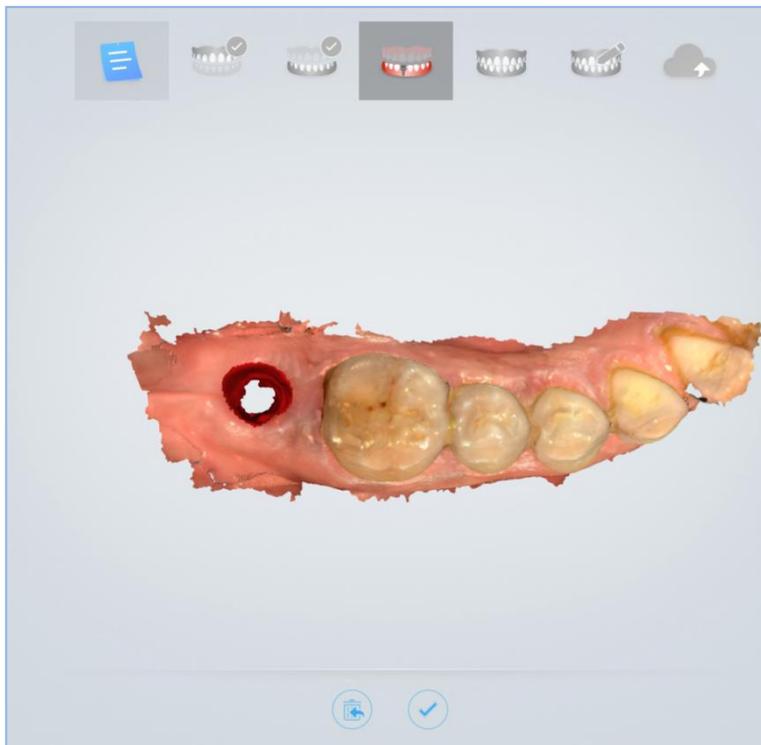
Figure 1 - Select the implant area

Figure 2 - Delete the selected area

Click the button [✓] to enter to the scanning implant process (the implant bar must be located in the model before scanning).
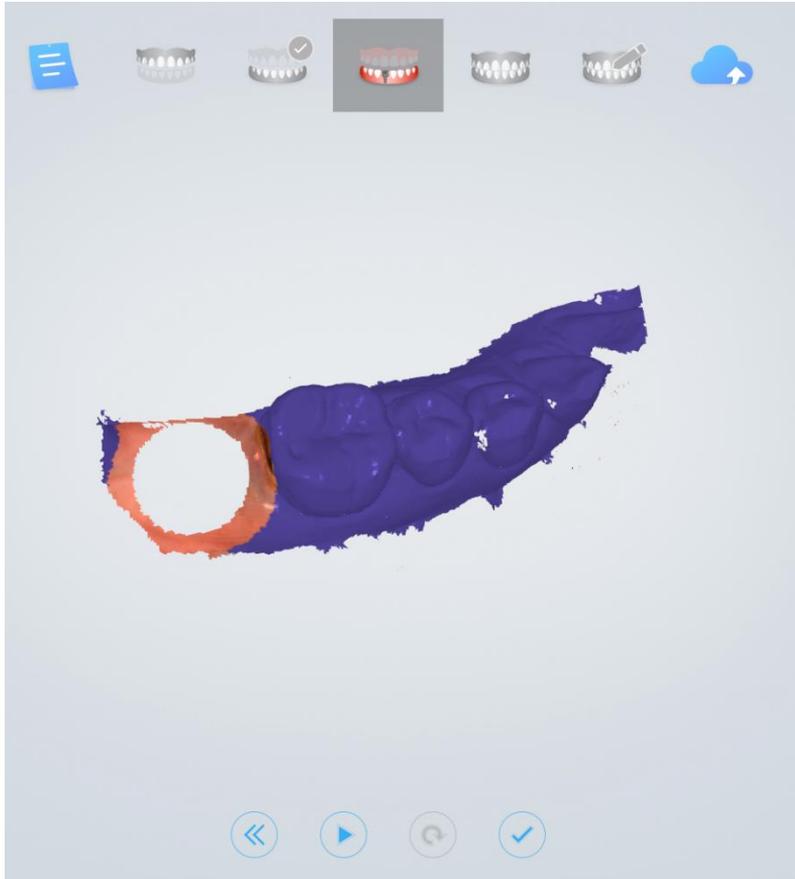
Figure 3-lock the lower jaw's data(deep blue), the unlock areas can be edited
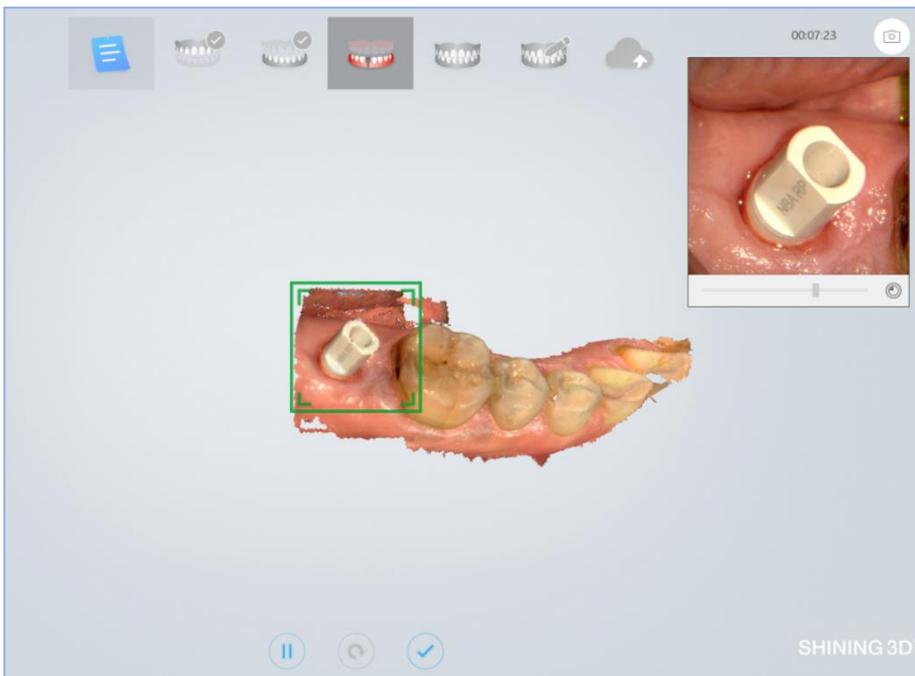
Figure 4- Scan implant bar
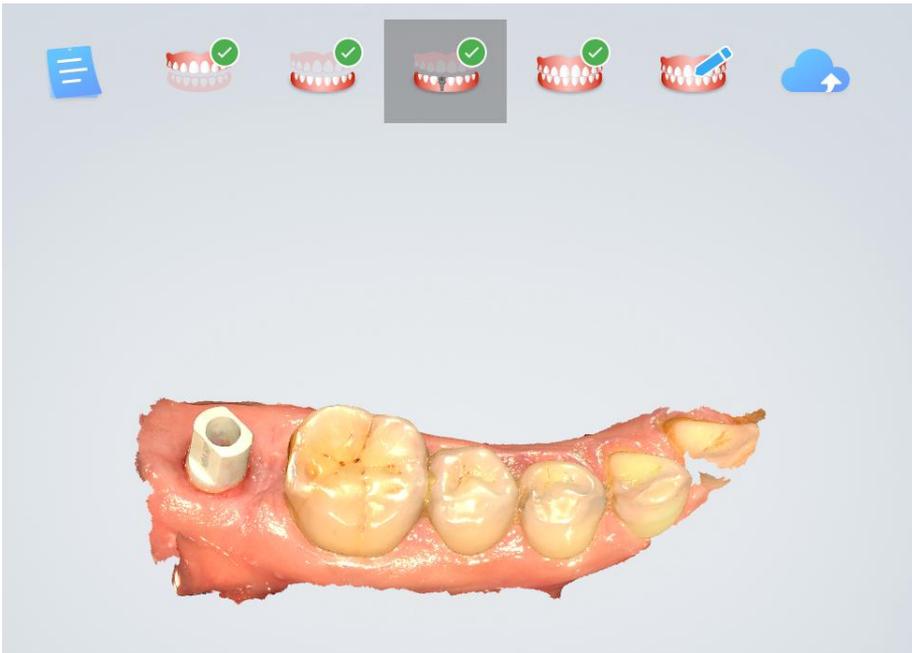
Figure 5 - Post-processed implant data

7.5.6. Scan Metal Tooth

Select " " during the scanning, the metal teeth can be scanned, the result is showed as below

7.5.7. Scan Total Jaw

After the lower jaw scanning and the data processing are finished, the total jaw scanning interface is automatically displayed.

Click the scan button ![button] or press the space bar to start scanning. After scanning some data, the software automatically performs dynamic bite stitching alignment, as shown below.

Before the stitching
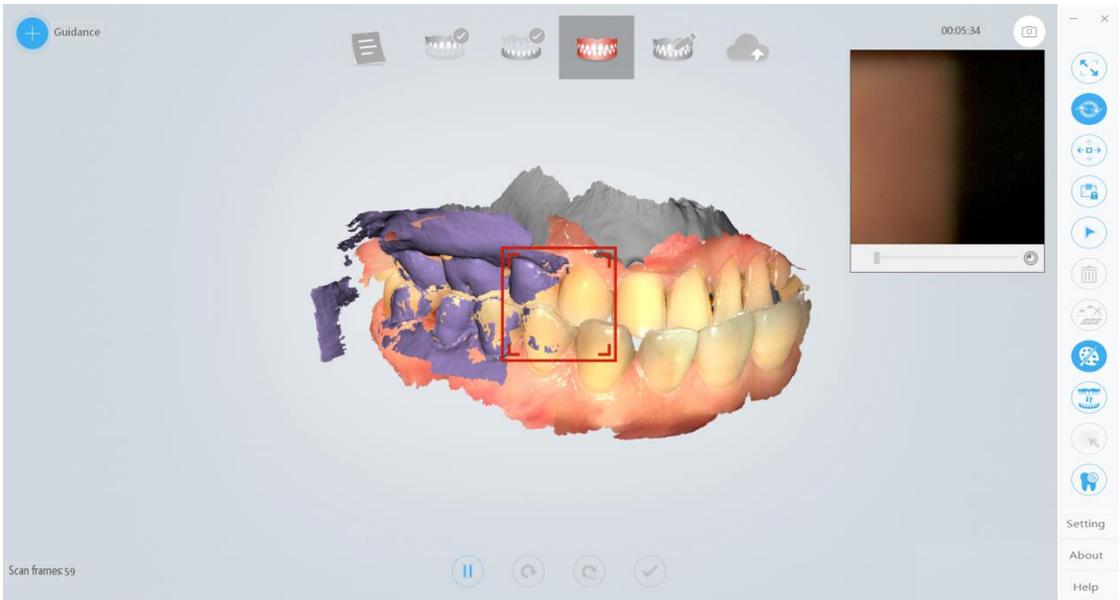
After the stitching

After the upper and lower jaws' data are stitched successfully as well as

the whole jaw, click " " or press the space bar to pause the scanning,

check the occlusion and collision results.

Confirm that the bite effect is appropriate. Click the finish button or

long press the space bar to post-process the data.

For the whole jaw scanning it does not need to scan the entire model, and you can just scan some part such as the whole jaw of the anterior portion, two total jaws on the left and right sides (recommended), three total jaws on the left and right sides and the anterior portion, so that the upper and lower jaw models of the scan are aligned. You can stop scanning after alignment. The maximum number of frames in the whole jaw is 800 frames. When scanning to 300 frames it will prompt a message asking whether to stop scanning or continue to scan 500 frames.

An example of scanning a total jaw: the purple is the data of the total jaw, and the tan is the alignment result of the upper and lower jaws.
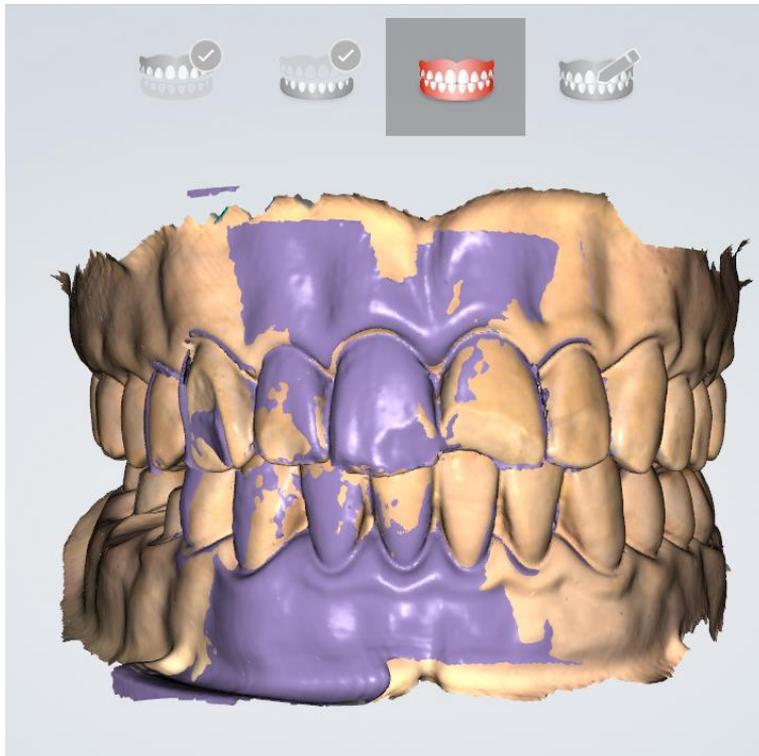
Scan a two-piece total jaw example (scan->pause, one piece of total jaw data is shown with scanning for once): the left image shows the total jaw data of the left side of the scan, and the right image shows the total jaw data of the left and right sides.
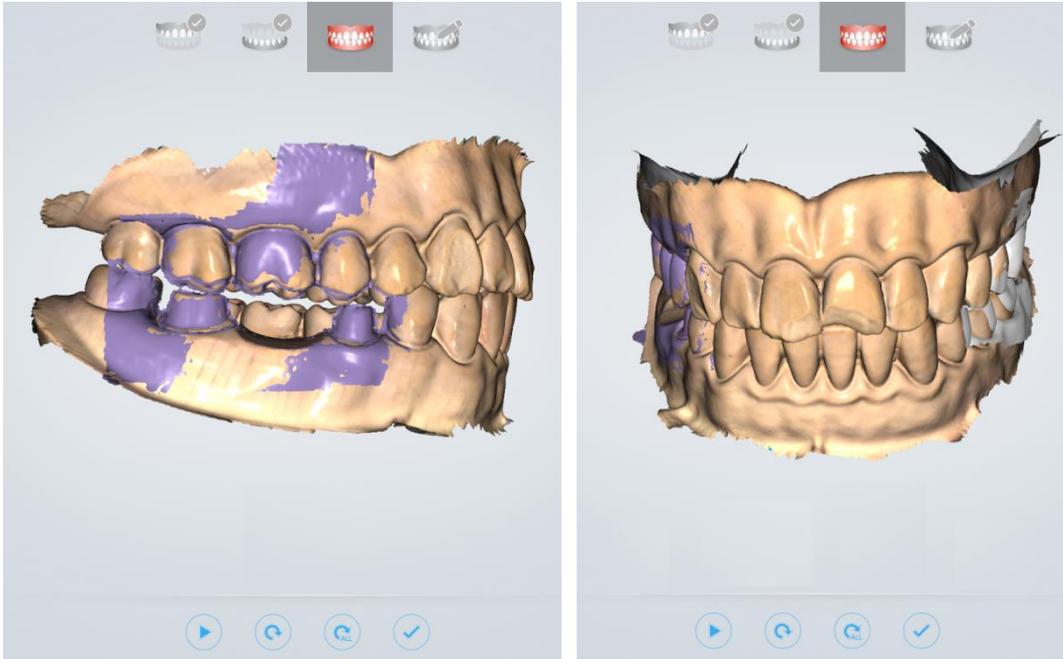
Scan a three-piece total jaw example:
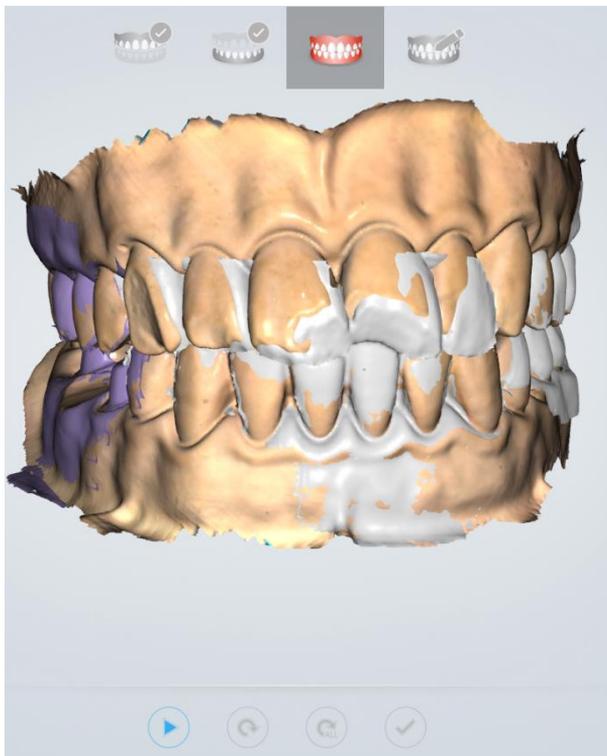
7.5.8. Pre-design

Pre-design function is added for users to easily apply the scanning data in the design software. Users can skip this process and upload orders directly.

This module provides five functions:
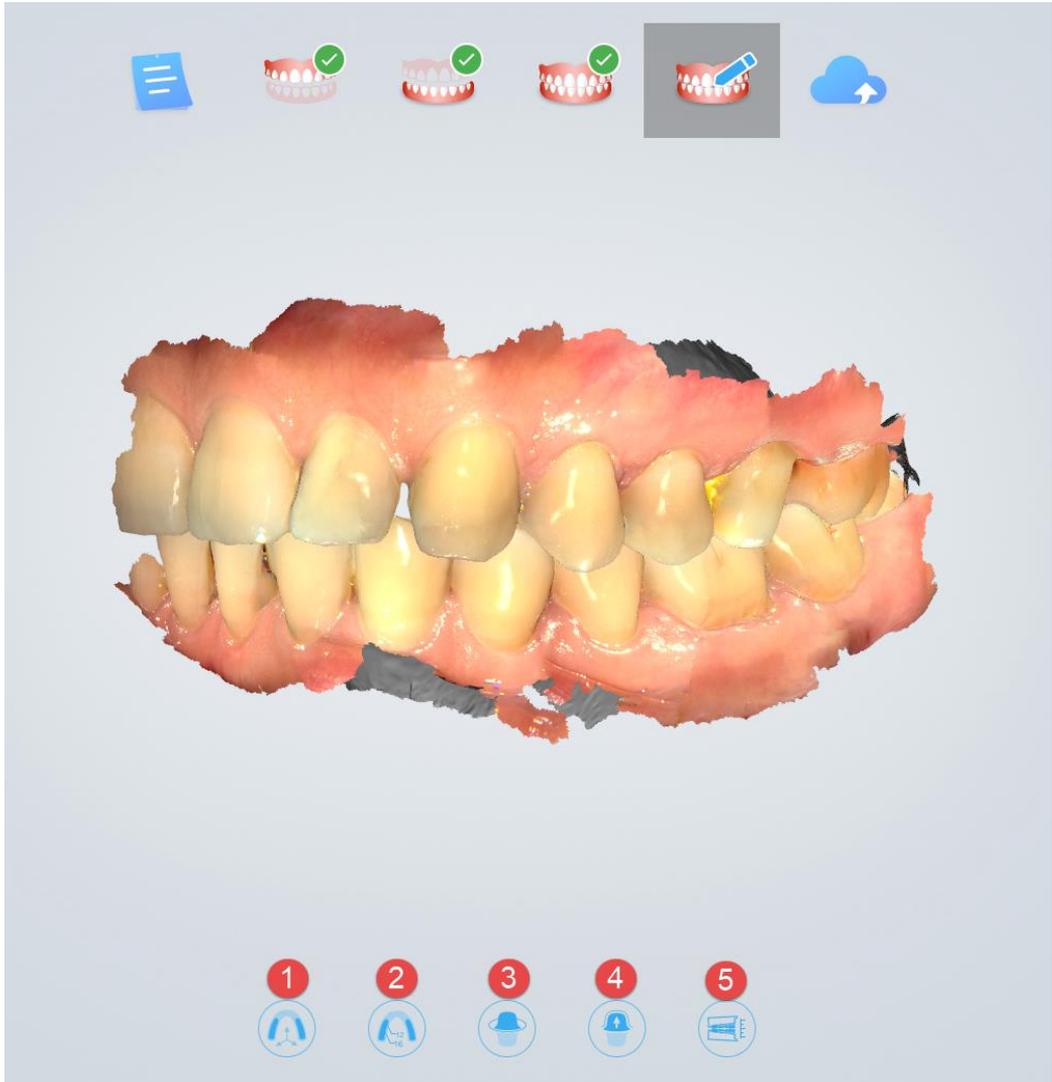
① Adjust Coordinate: used to (manually) adjust the reference coordinate system of the dental jaw, and adjust the dental jaw data to the unified standard reference coordinate system (supports the ExoCAD coordinate system) (the middle of the upper and lower incisors is the coordinate center, X outward (pointing to the observer), Y to the right (observer's perspective), upward direction is positive on the Z-axis, forming the right-handed coordinate system);

② Mark Teeth: used to manually mark the corresponding position of the tooth specified in the order in the scanning model for subsequent extraction of

the margin line and for viewing the undercut;

③ Extract Margin Line: used to extract and save the margin line of the marked (corresponding) teeth;

④ Check Undercut: Used to calculate and view the undercut area of the marked (corresponding to the order) teeth.

⑤ Check Bite: used to adjust and view the occlusal space of the upper and lower jaws;

Adjust Coordinate

Click the button under the "pre-design" process to enter the interface on which you can adjust the adjustment data, as shown below:

Rotate the 3D model with the left mouse button and right-click the data to adjust the position of the jaw.

Click the button to confirm and save the current adjustment result.

Click the button to cancel and discard the current adjustment result, and exit the adjustment coordinate process.

Mark Teeth

Click on the button under the "Pre-design" process to enter interface on which you can mark the teeth, and the tooth map on the left side shows the teeth defined by the order.

Mark teeth operation: Select the tooth to be marked in the tooth map, and then double-click the corresponding tooth on the right to mark the tooth position information.

Click the button to confirm and save the current tag.

Click the button to cancel and discard the current marker, and exit mark   tooth process.

Extract Margin line

Click the button under the "Pre-design" process to enter the extract margin line interface.

Double-click to select four points on a margin line of a tooth, the system automatically draws the margin line of the tooth.

Margin line editing operation: double-click to add a point; select a point, the point color turns from green to yellow, and you can move or delete

(double-click with right mouse or press Del key or click 🗑) this point.

Click the ⟫ button to extract the margin line of the next tooth. Finally

click ✓ to complete the extraction of all margin lines, and generate a "45-margin.xyz" Margin line file in the order directory.

Description of several operation buttons:

⟪ : Previous Tooth (switch to the last marked tooth and its margin line).

⟫ : Next Tooth (switch to the next marked tooth and its margin line).

🗑 : Delete (delete a selected point on the margin line. If no point is selected, the margin line of the current tooth is deleted)

✕ : Cancel (abandon the extracted margin line and exit the process of extracting the margin line)

⬚ : Finish (confirm and save the extracted margin line and exit the extract margin line process).

Check Undercut

Click the button ⬚ under the "Pre-design" process to enter the check undercut interface. The following figure shows the effect of the undercut display in different visual directions: the blue arrow indicates the visual direction, and the blue surface of the tooth indicates the undercut area.
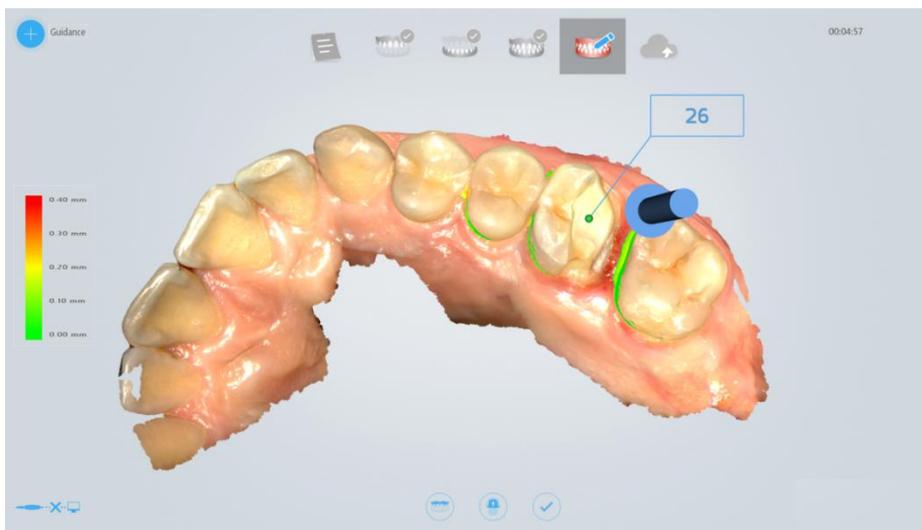
Undercut operation: Double click or click ⬚ button to adjust the undercut angle.

Description of several operation buttons:

⬚ or ⬚ : Switch between the upper and lower jaw.

⬚ : Generate Undercut (shows the undercut effect).

⬚ : Finish Undercut (exit the undercut process).

Check Bite

Click the button ⬚ under the "Pre-design" process to enter the check

bite interface. Green indicates that the teeth on the two jaws are distant while red indicates the contact area of the two jaw teeth, and blue indicates the bite overlap of the two jaw teeth.
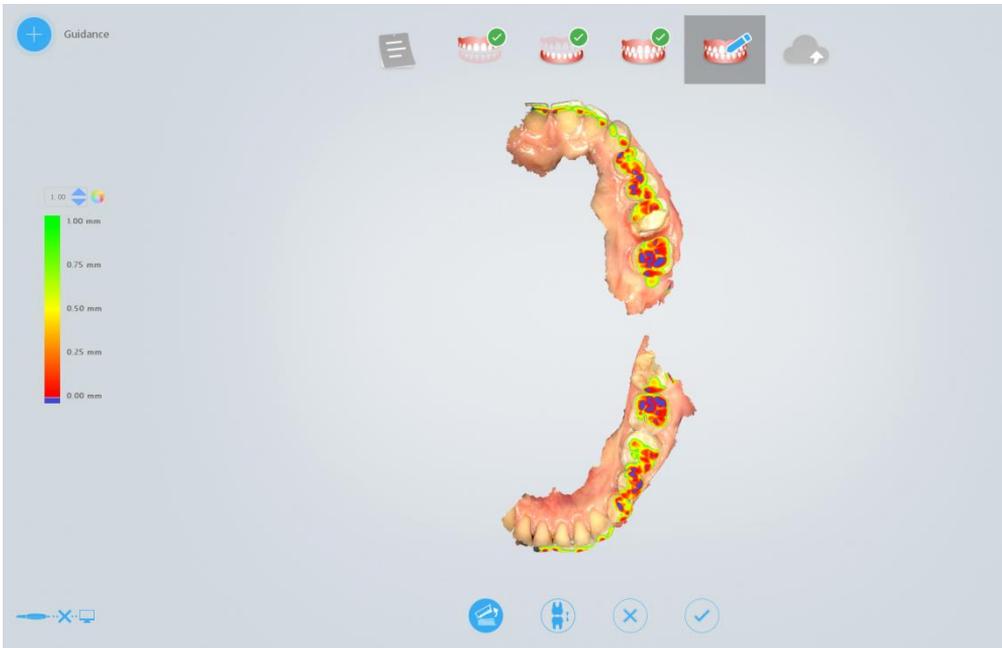
Figure 1 - Two jaw tile effect

Figure 2 - Two jaw bite effect

Click the button " " to adjust the occlusion parameters

" ". Click on a point to detect the occlusion clearance in this point.
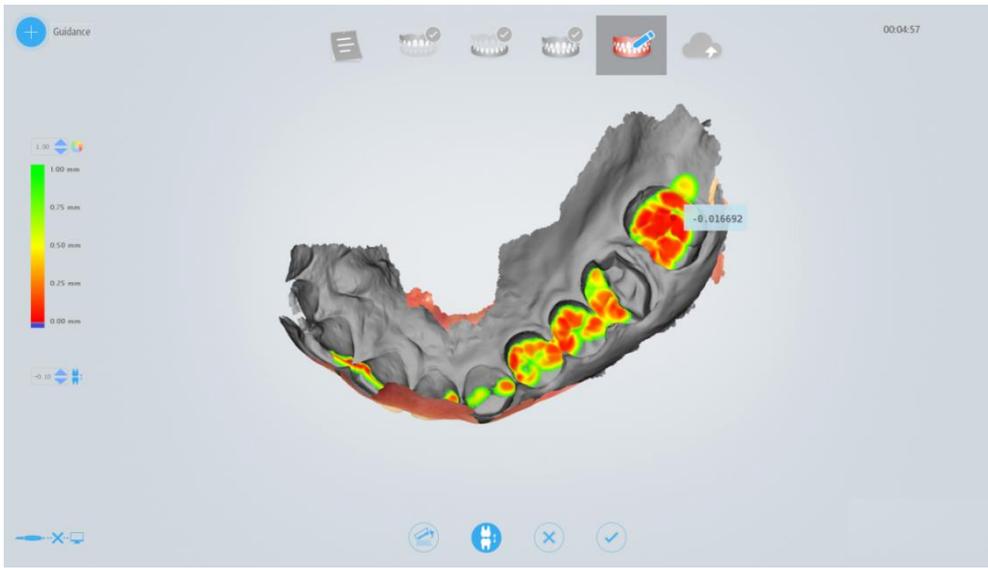
Description of several operation buttons:

:Open/Close Jaws (switche between the tile effect and bite effect of two jaws).

:Occlusal Adjust (adjust the bite).

:Cancel And Exit (give up the adjusted bite relationship and exit the check bite process).

:Finish And Save (save the adjusted bite effect and exit the check bite process).

7.5.9. Upload Order

When uploading the order for the first time in Intraoral Scan, it will prompt

"You have not logged in to the account. Whether to direct to the setting interface to log in?", select "Yes" to open the "Configure Account" interface. See chapter 6 "Upload Order" for the dental order system for details.

8. Using Dental Cloud

8.1. Introduction to Dental Cloud

Dental Cloud is a platform for connecting clinical and technical workers. In this platform, you can establish relationships between labs and doctors/clinics; you can manage order; manage organizations and maintain account information.

Visit the website: http://dental.shining3d.com

8.2. Register Account

To register for the dental cloud account, click the "Register" link to go to the dental cloud website. It is recommended to open the dental cloud website using browsers such as Chrome, Firefox, and Safari.
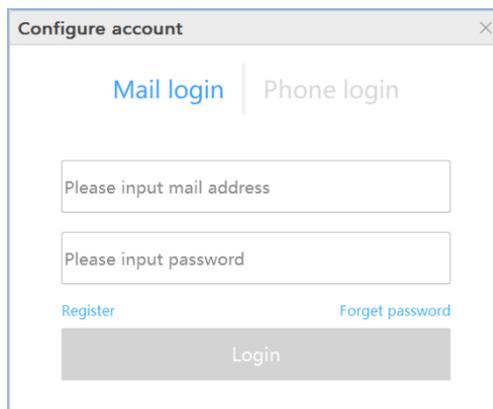
Click "Login" in the top right corner of the homepage to open the login page.
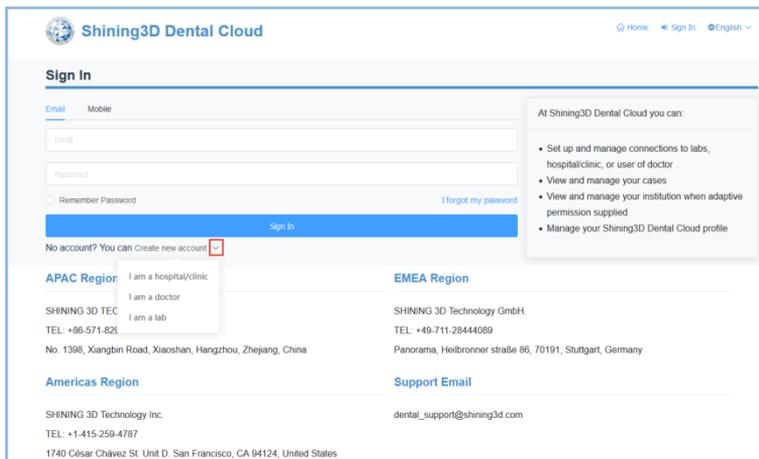
"Create new account", select the registration type.

✧   I am a hospital/clinic: register as a hospital/clinic institution and administrator. After registration is successful, you need to wait for the system administrator to review before you can log in.

✧   I am a doctor: register as an individual user. You can log in directly after registration.

✧   I am a lab: register as a dental laboratory and administrators. After registration is successful, you need to wait for the system administrator to review before you can log in. Note that this type of account can only be used on the web side and cannot be used on the desktop client.

Fill in the real application information as required (the notification of information such as the relationship network and order status will be sent to the mobile phone number and email address filled in the application)

After the registration is successful, the page automatically jumps to the login interface, enter the mailbox or mobile phone number and password, you can tick "Remember Password" for subsequent quick login.
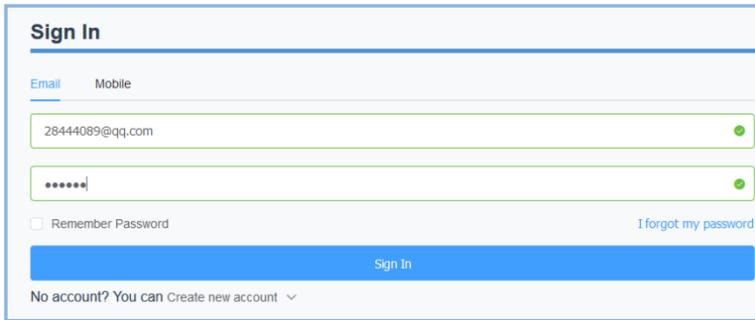
After the login is successful, the hospital, clinic or doctor's account can establish a network connection with the partner technical institution (i.e. add a lab)

8.3. Establish a Relationship Network

The network can only be created by a doctor/hospital/clinic account and then the lab can accept or reject the connection. The doctor can only upload the order data to the laboratories that accept the connection. After logging in as a hospital, clinic or doctor account, select "Relational Network" in the upper right corner of the interface to create a new network.
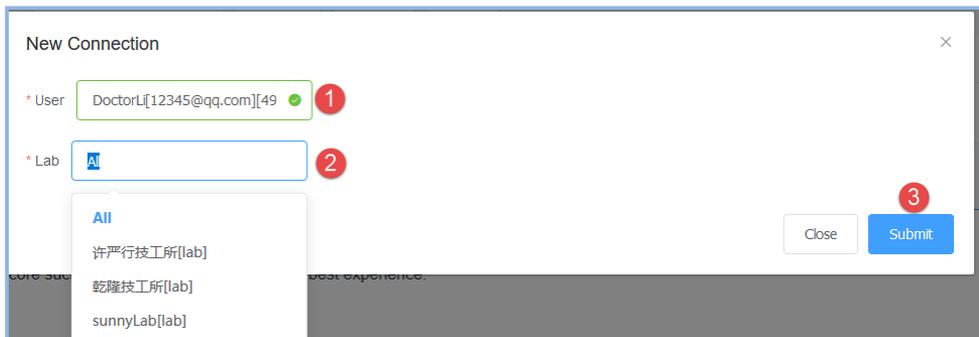
①　User: Select the user

②　Lab: Select a partner lab from the drop-down list

③　Submit: Submit the newly created network

The submission is successful and is displayed in the page list. The relationship status of the newly created relationship is "to be confirmed". You need to wait for the lab to accept the confirmation (the relationship status is "active"), and only after the relationship is confirmed by the lab can clinicians the data.

8.4. Management Institution

An institution administrator can add/remove members for this institution.

8.4.1. Add Member

After login, select "Admins" ->"Members", and create a new administrator and ordinary members for the institution.
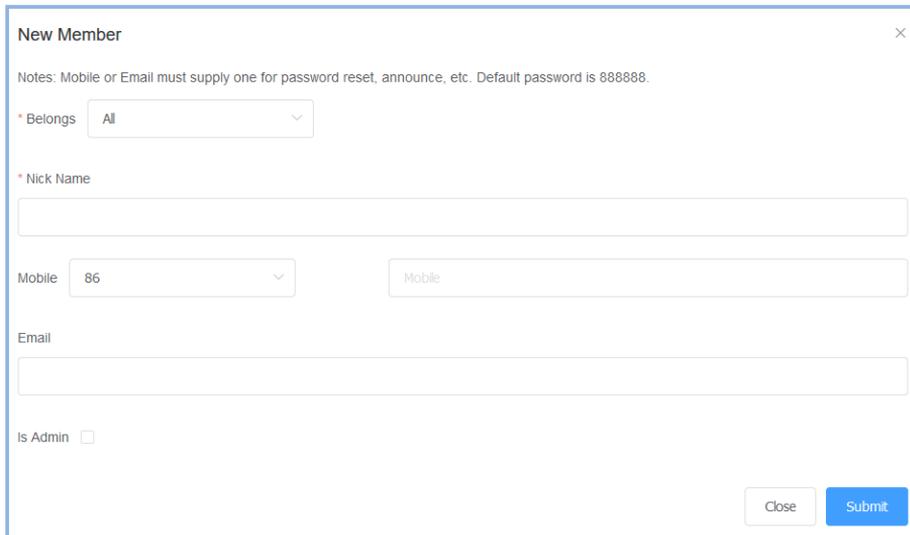
① Belongs: Select the name of the institution.

② Nick Name: Member nickname.

③ Mobile: The mobile number of this member. It is also the account of the mobile phone user. The default password for login is 888888. You can either fill in the mobile phone or mailbox.

④ E-mail: This member's e-mail. It is also the account of the e-mail user. The default password for login is 888888.

⑤ Is Admin: Set the member as an administrator. The default is No.

⑥ Submit: Fill in the information and the member is added successfully.
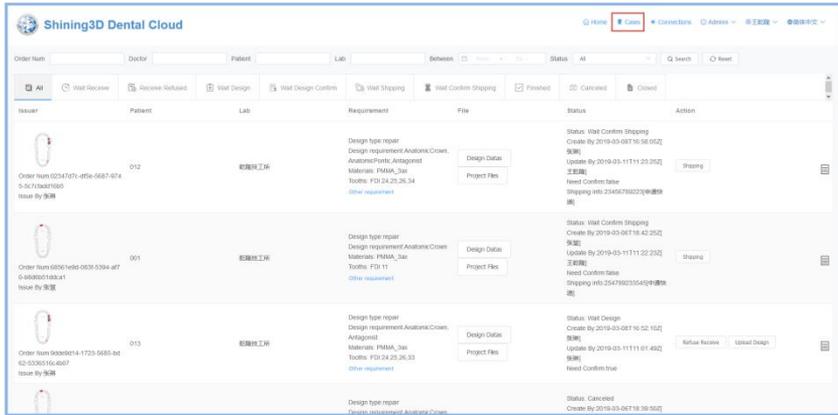
8.4.2. Delete Member

Select the member you want to delete and click the "Delete" button to confirm the deletion.
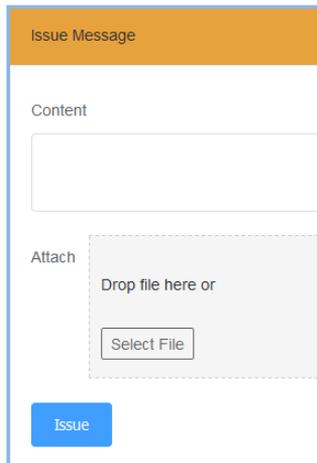
8.4.3. Case Management

The account is successfully logged in. Select "Case" in the upper right

corner of the page to see all the cases managed by this user

Doctor and lab can instantly communicate on each order on the webpage.

After clicking , they can send messages or documents in the prompted communication box.


8.5. Order Workflow

The order is transferred between the hospital (clinic/doctor) and the laboratories, and the two parties cooperate to advance the entire process from visit to completion of treatment. The doctor operates in the client Dental Manager Pro, and the lab operates on the web page side. The most common workflow for uploaded order is as follows:
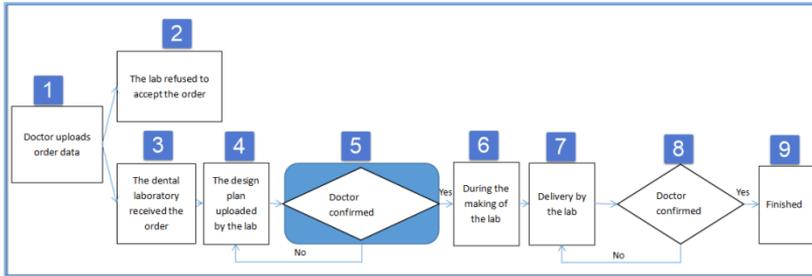
Brief introduction to the workflow:

(1) Doctor uploads order data: see the previous section for details.

(2) The lab refused to accept the order: the technician of the lab refused to accept the order.

(3) The lab received the order: the technician of the lab confirmed the order.
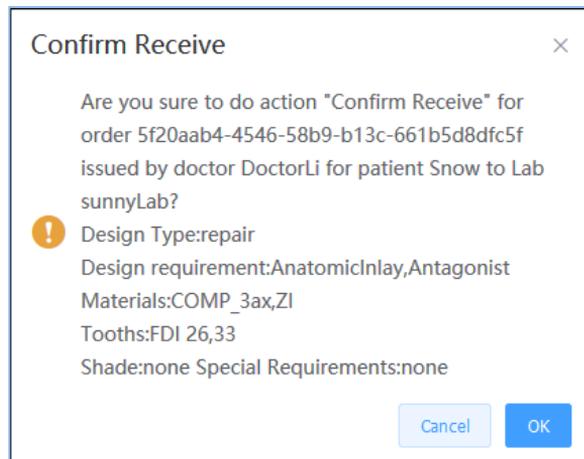
(4) The design plan uploaded by the lab: the technician of the lab uploads the design plan, including the documents and data.

Select the file to be uploaded. After the file is uploaded successfully, click Submit.

(5) Doctor confirmed plan: After the technician uploads the design plan, the order status is "Need Confirm Design", and the doctor can download the design plan in the client Dental Order System.

The design data is saved by default in the DesignData folder of the order catalog.The doctor can approve the design plan by clicking "Confirm Design" and the order status will become "Making"; if not approved, the doctor can click "Request Re-design"and make clear the design requirements, and the order status will become "Accepcted", which requires the lab to redesign and upload the plan.Then the doctor can check the plan again.
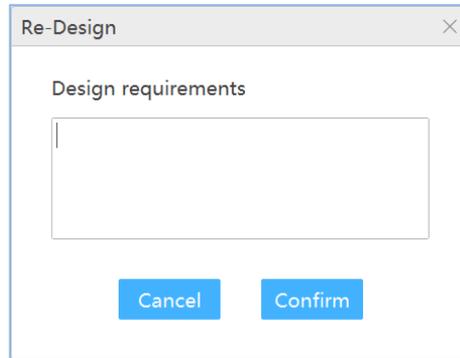
the doctor chooses not to review the design when uploading data, skip this process.

(6) During the making of the lab: After the doctor confirms the design plan, the order status is "Making", indicating the processing data of the lab.
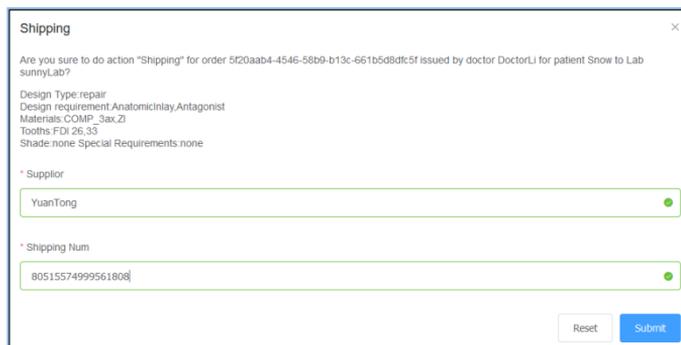
(7) Delivery by the lab: The data processing is completed in the lab, and the logistics information is submitted and the goods is delivered. The order status is "Delivering".

(8) Doctor confirmed the receipt: After the lab delivers the goods, the doctor can view the logistics information, and confirm the receipt after receiving the goods. The order status is "Finished". If the doctor does not receive the goods or the goods have problems, the doctor can request a re-delivery, and the order status is "Wait Shipping". In this circumstance, the lab needs to re-deliver the goods, and the doctor can confirm the receipt after receiving the goods.

(9) Finished: This order is completed.

9. Care and Maintenance

9.1. Pre-cleaning,Disinfection, and Sterilization

The whole set of **Aoralscan 2** , including scanner tip, scanner body, and scanner cradle, requires proper care, cleaning, and handling. As individual part may be processed differently, read and follow the information and instructions given to help you effectively and thoroughly reprocess the set.

We suggest that you reprocess the **Aoralscan 2** in the following order:

(1) Scanner cradle care

(2) Scanner body care

(3) Scanner tip care

⚠ WARNINGS

● All parts are shipped non-sterilized. Follow the instructions prior to initial use.

● Ensure that   you have completely disconnected the power supply and all connections from the scanner.

● Follow the instructions given in this User Manual to pre-clean, disinfect, and sterilize each part of the scanner. Using other methods not approved by Shining3D Corporation will damage your scanner and void your warranty.

● Using detergent, disinfection solutions or wipes, sterilization procedures other than those specified in this User Manual may damage the product and void your warranty.

● Only sterilize the part(s) for which a sterilization method is specified. Do not attempt to sterilize all parts of the product. Shining3D Corporation is not liable for any damages due to improper sterilization.

● After sterilization, wait until each of the parts is at room temperature to prevent possible heat injuries to the user and the patient.

● To prevent cross-contamination, pre-cleaning, disinfection, and sterilization must be correctly performed after EACH use.

● When the scanner tip is detached from the scanner, always protect the subtle units and the inner optical components on the front end of the scanner body by putting on the supplied protection cap.
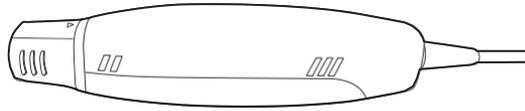
9.2. Scanner Cradle Care

The scanner cradle requires an intermediate-level disinfection.

Disinfection

⚠️ **WARNINGS**

● Concerning hand hygiene and personnel safety when performing pre-cleaning and disinfection/sterilization, you must wear clean surgical gloves before you start.

● Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.

● The caring methods for the scanner cradle, scanner body, and scanner tip are different and must be executed separately. After disinfecting the scanner cradle, you may proceed with the scanner body and finally the

● Scanner tip. See Scanner body care on chapter 9 and Scanner tip care on chapter 9 for details.

● Ensure that the scanner body is not placed in the cradle prior to disinfecting the scanner cradle.

Follow the steps below to complete the disinfection:

(1) Disconnect the power of the **Aoralscan 2** (see Disconnecting the scanner on chapter 4).

(2) Hold the cradle firmly with your hand.

(3) Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of cradle.

⚠️ **CAUTION**

Avoid using detergent of any kind as some detergents or surfactants might penetrate into the surface of the cradle.

(4) When done, store the cradle in a clean and safe place.

(5) Proceed to the disinfection of the scanner body (see Scanner body care on chapter 9).

9.3. Scanner Body Care

The scanner body requires an intermediate-level disinfection.
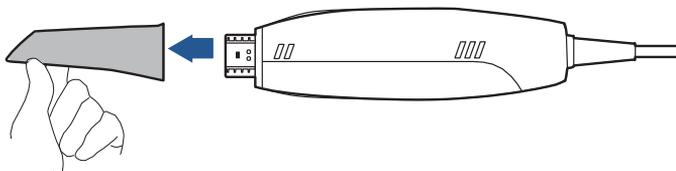
Disinfection

⚠️ **WARNINGS**

● Concerning hand hygiene and personnel safety when performing pre-cleaning and disinfection/sterilization, you must wear clean surgical gloves before you start.

● Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.

● The caring methods for the scanner cradle, scanner body, and scanner tip are different and must be executed separately. Before disinfecting the scanner body, you shall start with the cradle first. See Scanner cradle care on chapter 9) for details.

● Ensure that the scanner tip is detached from the scanner, and the protection cap is put on the scanner when disinfecting the scanner body.

Follow the steps below to complete the disinfection:

(1) Disconnect the power of the **Aoralscan 2** (see Disconnecting the scanner on chapter 4).

(2)Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner, as illustrated.

NOTE

Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

(3) Store the detached tip in a safe place, e.g. a dental instrument tray, prior to disinfecting the scanner body.

(4) Hold the supplied protection cap with the triangle mark facing upward. Then, align the protection cap blocks to the matching slots on the front end of the scanner body.
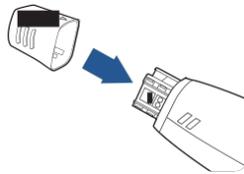
(5) Slide the protection cap onto the scanner to prevent damage and dust.
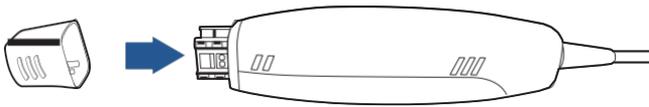
⚠ **CAUTIONS**

● When the scanner tip is detached, always protect the subtle units and the inner optical components on the front end of the scanner by putting on the supplied protection cap.

● Do not attempt to clean the outer units and inner optical components on the front end of the scanner with any sharp objects or other such tools, which may result in scratches and damage to the scanner.
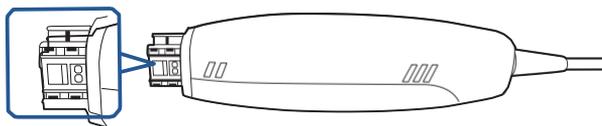
(6) Hold the scanner body with your hand.

(7) Use new cotton gauze moistened with 70%-75% solution of ethanol to

wipe the surface of scanner body.

⚠CAUTIONS

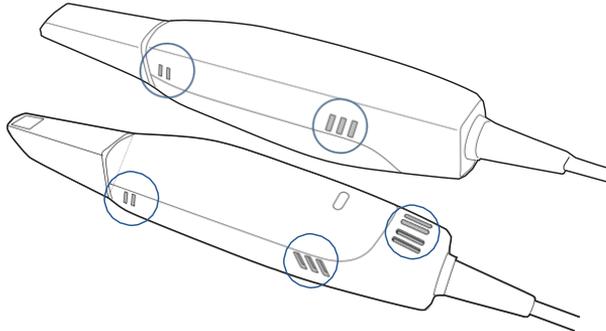● Avoid using detergent of any kind as some detergents or surfactants might penetrate into the surface of the scanner body.

● Do not clean the intake and exhaust vents with any sharp objects or other such tools.

(8) When done, store the scanner body in a clean and safe place.

(9) Proceed to the cleaning, disinfection or sterilization of the scanner tip (see Scanner tip care on chapter 9).

9.4. Scanner Tip Care

The scanner tip is the most essential part of the scanner as it is inserted into your patient's mouth during scanning. Therefore, the tip must be thoroughly cleaned and sterilized before and after each patient contact in order to prevent cross- contamination in your operation.

⚠ WARNINGS

● Concerning hand hygiene and personnel safety when performing cleaning and disinfection/sterilization, you must wear clean surgical gloves and goggles before you start.

● Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.

● The caring methods for the scanner cradle, scanner body, and scanner tip are different and must be executed separately.

● Cleaning the scanner tip is an essential step before effective disinfection or sterilization.

● When inserting the scanner tip into the disinfectant solution, be sure to follow the instructions on the disinfectant label and limit the time and depth that the tip is soaked within the minimum time recommended.

● The scanner tip can be sterilized up to 20 times and must be disposed of afterwards. For more information on disposal, see Disposal on chapter 1.

● High-level disinfection and steam sterilization must NOT be combined.

● Apply only either of these methods to ensure the safe and effective reprocessing of the scanner tip, and thus to prevent damage of reusable tip.
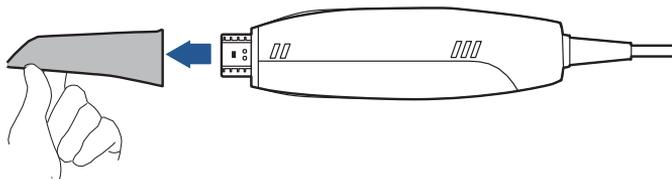
Two effective and approved methods of cleaning and disinfection/ sterilization are recommended and described as below.

Either should be used to reprocess the scanner tip between each patient contact:

9.4.1. Cleaning and high-level disinfection

Follow the steps below to perform cleaning and high-level disinfection:
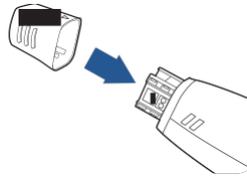
(1) Disconnect the power of the **Aoralscan 2** (see Disconnecting the scanner on chapter 4).

(2) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner body, as illustrated.
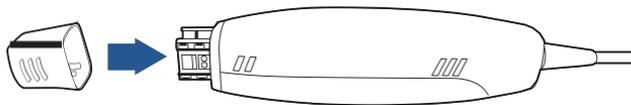

⚠ CAUTION

Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

(3) Hold the supplied protection cap with the triangle mark facing upward. Then, align the protection cap blocks to the matching slots on the front end of the scanner body.

(4) Slide the protection cap onto the scanner to prevent damage and dust.

(5) Pay particular attention to inspect the mirror of the tip to ensure that the mirror is not cracked or broken and there is no scratch on it.

⚠ **CAUTION**

If the mirror of the tip has cracks or scratches, stop the cleaning process and contact your local distributor or service provider.

(6) Gently clean the inner and outer sides of the tip using mild pH-neutral soap water and a soft brush for 3 minutes.

● When cleaning the inner surface of the tip, insert the soft brush into the tip from both the front and rear ends, and move the brush lightly in tiny circles.

● When cleaning the outer surface of the tip, move the brush lightly back and forth, and repeat for each side.

(7) Repeat the previous step for at least two times.

(8) Rinse the tip thoroughly with sterile water for at least 3 minutes.

(9) If you notice stains, fingerprints, or smears on the mirror surface, repeat the previous step.

(10) Dry the tip carefully with a clean soft lens tissue or lint-free cloth.

(11) Pay particular attention to inspect the mirror surface of the tip again

to make sure that the cleaning is done properly and the mirror is not damaged during the cleaning process.

(12) Cautiously fill a container with the FDA-approved disinfectant solution, e.g. CIDEX OPA® Solution. Do not spill any of it.

📋 **NOTE**

Read the CIDEX OPA® manufacturer's instructions and warnings thoroughly before use.

⚠️ **CAUTIONS**

● To avoid possible damage, use the disinfection solution verified by Shining3D Corporation and specified here only.

● Once a spill occurs, follow disinfectant manufacturer's handling instructions.

(13) Immerse the cleaned tip into the disinfectant and leave it for at least 12 minutes at 25° C.
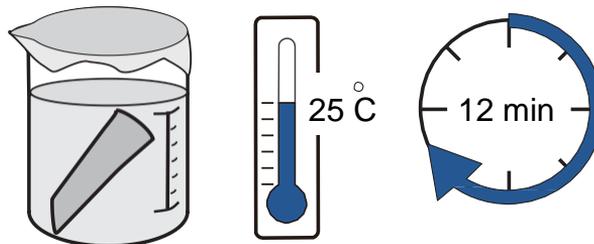
(14) Prepare a large container of sterile water, e.g. 2 L.

(15) Take out the tip from the disinfectant.

(16) Immerse the tip into the container of sterile water for at least 5 minutes.

(17) Take out the tip and manually flush it with at least 500 ml of sterile water.

CAUTION

Discard the rinse water. Always use fresh volumes of sterile water for each rinse. Do not reuse the water for rinsing or any other purpose.

(18) Repeat the rinsing process (step 14 to 17) for at least two times for removing the residue of disinfection solution.

(19) Use a soft lint-free cloth to dry the tip.

(20) Pay particular attention to inspect the mirror surface of the scanner tip again to make sure that the disinfection is done properly and the mirror is not damaged during the disinfection process.

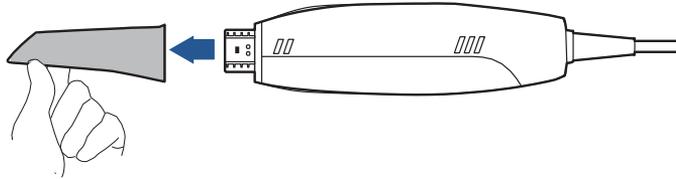(21) Re-attach the scanner tip (see Attaching the scanner tip on chapter 9).Or if you attempt to store the scanner tip with other dental instruments, e.g. a dental instrument tray, ensure that it is thoroughly dry.

9.4.2. Cleaning and steam sterilization

Follow the steps below to perform cleaning and steam sterilization:

(1) Disconnect the power of the **Aoralscan 2** (see Disconnecting the scanner on chapter 4).
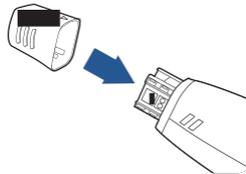
(2) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the scanner tip off from the scanner, as illustrated.

⚠ CAUTION

Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

(3) Hold the supplied protection cap with the triangle mark facing upward. Then, align the protection cap blocks to the matching slots on the front end of the scanner body.

(4) Slide the protection cap onto the scanner to prevent damage and dust.

(5) Pay particular attention to inspect the mirror of the tip to ensure that the mirror is not cracked or broken and there is no scratch on it.

⚠ CAUTION

If the mirror of the tip has cracks or scratches, stop the cleaning process and contact your local distributor or service provider.

(6) Gently clean the inner and outer sides of the tip using mild pH-neutral soap water and a soft brush for 3 minutes.

● When cleaning the inner surface of the tip, insert the soft brush into the tip from both the front and rear ends, and move the brush lightly in tiny circles.

● When cleaning the outer surface of the tip, move the brush lightly back and forth, and repeat for each side.

(7) Repeat the previous step for at least two times.

(8) Rinse the tip thoroughly with sterile water for at least 3 minutes.

(9) If you notice stains, fingerprints, or smears on the mirror surface, repeat the previous step.

(10) Dry the tip carefully with a clean soft lens tissue or lint-free cloth.

(11) Pay particular attention to inspect the mirror surface of the scanner tip again to make sure that the cleaning is done properly and the mirror is not damaged during the cleaning process.

(12) Wrap the cleaned tip with a cloth cautiously.

(13) Place the wrapped tip in the autoclave and sterilize it at 121°C and with 1.5 atm pressure for at least 30 minutes.

(14) Dry the sterilized tip for 30 minutes with the autoclave program before opening the autoclave.

(15) Re-attach the scanner tip (see Attaching the scanner tip on chapter 9).

9.4.3. Attaching the scanner tip

There is a risk of damaging the mirror of tip if any improper actions are taken when attaching the tip to the scanner.

⚠ **WARNINGS**

● Wear clean surgical gloves before you start.

● Ensure that the scanner cradle, scanner body, and scanner tip are pre- cleaned and disinfected/sterilized (see Scanner body care on chapter 9 and Scanner storage on chapter 9).

Follow the steps below to complete the attachment:

(1) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently attach the tip facing downward to the scanner.
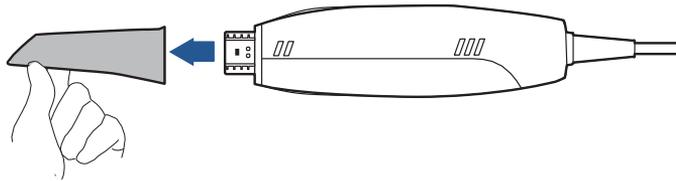
⚠ CAUTION

Do not place your finger(s) on the mirror of the tip when attaching as this may result in damage to the mirror.

(2) Try swiveling the scanner tip around to ensure it is locked into position and stable.

(3) Place the scanner in the cradle, and the set is ready for use.

9.5. Scanner Storage

In case you need to transport the device, we strongly recommend that you keep the original packaging after unpacking your **Aoralscan 2**. Shipping the device without its original packaging material may cause possible product damage and result in additional service fees.

For information on temperature and humidity requirements, see "Environmental requirements on chapter 10".

If the original packaging is no longer available or damaged, carefully package each part of the scanner with bubble wrap to protect against any possible damage during transportation

9.5.1. Storage for transport

● Make sure that the scanner is clean and sterile before placing it in the original carry box/package to avoid any possible contamination.

● Place each part of the product, e.g. the tip, scanner body, cradle, power adapter, in the original package carefully and prevent kinks of the cable.

● Make sure that each cable is rolled up and tangle-free before placing it in the original carry box.

● Before closing the lid, make sure no part of the product is protruding

from the package.

9.5.2. Daily and long-term storage

● Always place the scanner in the cradle when it is not in use.

● When the scanner tip is detached from the scanner body, always protect the subtle units and the inner optical components on the front end of the scanner by putting on the supplied protection cap.

● Ensure the scanner is clean and sterile before long-term storage.

● Avoid storing the scanner and accessories in areas of extreme temperatures or under direct sunlight

● Before storing the scanner, make sure the scanner tip, scanner body, and cradle are thoroughly dry.

10. Hardware Specification

10.1. Specifications

Type name	Intraoral Scanner
Model name	**Aoralscan 2**
Scanner	
Scan field	11 mm x 11 mm
Scan principle	Non-contact scanner with the (DLP) structured light
Dimension	Length: < 280 mm
	Width: < 40 mm
	Height: < 55 mm
Weight	≤ 325 g (without cable)
Output	STL, OBJ
Connector	USB 3.0
Power	Input: 5 Vdc/2 A
Cradle	
Dimension	Length: < 265 mm
	Width: < 82 mm
	Height: < 55 mm
Weight	900 ± 100 g
Power	Input: 12 Vdc/1.67 A
Product life	3 years

Table 10-1

10.2. Environmental Requirements

Operating and storage requirements

- Operating temperature: 10~40° C

- Storage/Transport temperature: -25° C~60° C

- Operating altitude: < 3000 M

- Storage/Transport/Relative humidity: 30%~75%

- MTBF: 14,600 hrs (except DMD/LED)

- Air pressure: 700 hPa~1060 hPa