

# Aoralscan 2 User Manual









# Foreword

#### General

The Manual introduces functions, installation, usage and maintenance of the Aoralscan 2

Scanner (hereinafter referred to as "the Scanner"). **MD** indicates the item is a medical device.

# Safety Instructions

Signal	Meaning
	Additional information for particular situation.
$\triangle$	Improper actions or conditions that may damage the product or injury, and consequently void your warranty or service contract or lose the patient data or system data.
$\wedge$	The safety instructions that you must precisely follow to avoid injury. Failure to observe can cause damages to your product, or result in personal injuries.

#### **Revision History**

No.	Version	Revision Content	Release Date
1	V1.0.0.0	Initial release version.	Nov., 2019
2	V1.0.0.30 (10)	Added safety guidelines for operation.	Aug., 2021
3	V1.0.0.30 (20)	Added chapters of orthodontic simulation process and generating examination reports.	Oct., 2021
4	V1.0.0.30 (30)	Added conventions according to relevant laws and regulations.	Nov., 2021
5	V1.0.0.30 (40)	Added new parameters, by which the filled holes are displayed in grey color.	Dec., 2021
6	V1.0.0.30 (50)	Added the 13 <sup>th</sup> digit to original 12-digit serial number, which enables identifying customized products.	Mar.,2022
7	V1.0.0.30 (60)	Added Audit Report.	Apr.,2022
8	V1.0.0.310	Added new patients' profiles when creating orders and case types. Added dynamic bite scanning. Added orthodontics simulation, dynamic bite, and oral report in pre-design process.	Jul., 2022
9	V1.0.0.3104	Added edentulous jaw scanning mode.	Jul., 2022



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- Updates to hardware and/or software components are made regularly; therefore, some of the instructions, illustrations, and specifications mentioned in the Manual may differ slightly for your particular situation.



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# 1. Read This First

The 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 the Manual and strictly observe all warnings and cautions. Pay extra attention to safety information in chapter 2.

# 1.1. Basic Information

I. Product name, model Product name: Intraoral Scanner Model: Aoralscan 2

II. Name, residence, contact information and after-sales service of the manufacturer Manufacturer name: Shining 3D Tech Co., Ltd.

Production address: No. 1398, Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China, 311258

III. Contact Information

#### Manufacturer

Shining 3D Tech Co., Ltd.

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

www.shining3ddental.com

#### **Customer Support**

Email: dental\_support@shining3d.com

#### Shining 3D's Representative

Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Telephone: +31644168999

Email: peter@lotusnl.com

IV. Product performance, composition, and application



XL/QER-RD-404

#### **Product performance**

• Appearance and structure

The appearance should be: Smooth, no cracks, no stains, no obvious deformation. Flexible and reliable for operation.

• Function control and image display

Function control: After pressing the scanning button, determine whether the front end of the scanner flashes normally.

Display: Under normal working conditions, when the scanner is opened for scanning, the two-dimensional and three-dimensional imaging of the scanned object (such as teeth) can be seen on the display respectively.

3D image processing: After the 3D image is generated, the 3D image can be cropped as needed by using the relevant buttons on the top, bottom and right side.

Irradiance: Under normal use of the intraoral scanner, the irradiance is not greater than 1mW/cm<sup>2</sup> (Refer to IEC 62471:2006 Photo-biological safety of lamps and lamp systems.).

User access control

An authorized USB dongle shall be used to access the software of the product.

• Cradle function

After powering on, make sure the cradle and scanner are powered on, and the cradle indicator should be green when powered on.

• Data interface

USB3.0, data storage format shall include 3D digital model format .stl, .ply and .obj.

#### Main structural composition

The Scanner kit consists of scanner body, scanner tip, cradle, power adapter, USB dongle, USB 3.0 cable, calibrator, and software (V1.0). The software carrier is USB flash drive, and the software release version is V1.0.



- It is recommended that users copy the software from the USB flash drive to the computer hard disk before installing the driver.
- Use Nvidia graphics card to get the best scanning efficiency.
- Do not insert wireless USB network card in the computer. USB wireless network card will cause USB bandwidth occupation, limiting camera performance.



V. Product maintenance and care methods, special storage/transportation conditions, operating conditions

1) Do not connect the scanner to power if not used, keep it in dry environment.

2) Use the dust cap when you leave the scanner unworking.

3) After using scanner tip, use alcohol to wipe and then use autoclave to sterilize it. (121°C,

102.9kPa for 30 minutes; 134°C, 205.8kPa for 4 minutes). Use alcohol to wipe the scanner cover.

Use dust-proof cloth to wipe the scanning window to ensure the window keeps dry.

4) Operating temperature: 10°C to 40°C, relative humidity: 30%–75%.

5) Storage/transport temperature: -25°C to 60°C, relative humidity: 30%–75%.

6) Air pressure: 86 kPa-106 kPa.



The temperature and humidity and atmospheric pressure conditions for storage/transportation are reflected on the outer packaging.

VI. Production date and lifecycle

The production date is shown on the product label. Lifecycle: 8 years.

VII. The list of accessories, including accessories, wear and tear replacement cycle and instructions on how to replace.

Scanner tip as a wear and tear products can be autoclaved up to 100 times, after which it needs to be replaced.

(1) Disconnect the scanner power, hold the scanner tip firmly with thumb and index finger on both sides, and then gently slide the scanner tip out of the scanner as shown in the figure.

Figure 1-1



(2) Hold the scanner tip firmly with your thumb and index finger on either side and gently attach the scanner tip to the scanner with the tip facing down.





# Caution

Do not place your fingers on the lens of the scanner tip when removing and attaching the scanner tip, as this may cause damage to the lens.

(3) Try to gently shake the scanner tip to ensure that it locks into place and is stable.



- The Scanner should not be used in close proximity or stacked with other equipment, and if it must be used in close proximity or stacked, observe to verify proper operation in the configuration in which it is used.
- Class A equipment is intended for use in industrial environments where it may be potentially difficult to ensure electromagnetic compatibility in other environments due to conducted and radiated disturbances from the Aoralscan 2 intraoral scanner.
- The use of accessories and cables other than those specified may result in increased emissions or reduced immunity of the Aoralscan 2 intraoral scanner, except for cables sold by the manufacturer of the Aoralscan 2 intraoral scanner as spare parts for internal components.
- Interruptions during electrostatic testing can be recovered within 5s without affecting basic performance.

# 1.2. Intended Use

This is an intraoral scanner that works with the supplied software programs. By performing intraoral scanning directly and digitally acquiring and saving the 2D/3D color images of teeth and gingiva, the Scanner is available for patients with needs of orthodontic, implant, and restoration.



• Benefits to be achieved: As a device that applies a probing optical scanner tip, this



scanner can directly scan inside the patient's mouth to obtain three-dimensional morphology and color texture information of soft and hard tissue surfaces such as teeth, gums, and mucous membranes in the oral cavity, facilitating comfortable mold taking for patients, reducing stress for medical care, and improving efficiency for back-end processing.

● The scanner satisfies C€ related requirements.

Marning

• 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 cannot be operated by the patients themselves. The user is solely responsible for determining whether the scanner is appropriate for a particular patient case.

 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. When under an adverse event, inform the relevant notified authorities and competent authorities.

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.

# 1.3. Contraindications

No known contraindications (or side effects).

# 1.4. 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 foreign objects (including all types of liquids) to enter the scanner and its cradle. Water, moisture, etc. may cause a short circuit in the electronic components and lead to malfunction.

• If the scanner tip is accidentally dropped to the ground, check to make sure the lens is not loose before using it.

• If the scanner is inadvertently dropped on the ground or impacted, it must be calibrated before use. If there are still accuracy problems or scanning abnormalities after calibration, please consult technical support.

• 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. Waste Electrical and Electronic Equipment

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 cannot 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, 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.

Figure 1-3



# 1.6. Disposal

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. 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.



# 2. Safety Information

# 2.1. Precautions

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.

• 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 the 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. See 5.1 Connect the Scanner.

• 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.

• Check the scanner and components for sharp edges.

• Before usage, check the device for damage, loose parts, wear and tear, and other cosmetic problems. In case of such problems, please contact after-sales service.

• During usage, always pay attention to abnormal conditions of the scanner and the patient. In case of abnormal conditions, you need to stop using it immediately. Consult technical support staff promptly.

• To ensure the performance and safety of the scanner, use only the original accessories provided with the scanner (or accessories specified by Shining 3D, consult technical support for details) and software.

• Use only supplied accessories and approved software with the scanner 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.

• Reasonably arrange communication cables, power lines and other types of cables to prevent users or patients from tripping over the wires. Do not forcibly pull or bend cables of any kind.

• The scanner is not intended for use in environments with high concentrations of flammable liquids, gases, or atmospheric oxygen.

• There is a risk of explosion when the scanner is used around flammable anesthetics.

• 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 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.

• Users should be aware of optical radiation protection. Bright light is projected from the scanner tip during scanning. As with other light, there may be a temporary reduction in vision or visual residuals. Do not look directly into the light projected by the scanner tip or shine the light into the eyes of others.

• The scanner may interfere with pacemakers and ICDs, and use of the scanner on patients with pacemakers and ICDs is prohibited.

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

• Do not dispose the 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. Labels and Symbols

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

#### 2.2.1. On the Scanner

#### Specification for scanner serial number

Serial number AOS-AH001L13 represents the 001 product manufactured on November 13, 2018.

- AOS.....Stands for scanner model, abbreviation for Aoralscan 2.
- AH.....Represents the year of production, A J in alphabetical order stands for 1:
   9 (Since letter I and number 1 are easily confused, ignore I), and 0 is represented by the letter X.
- 001.....On behalf of the production flow number, unit 1.
- L.....On behalf of the month, by letter A-M for 1-12 (Since letter I and number 1 are easily confused, ignore I).
- 13.....Represents the date, expressed in 01 31.

#### Specification for serial number of calibrator

Serial number iCII-AH001M05 represents the 001 product produced on December 05, 2018.

- iCII.....Represents the model of the calibrator.
- AH.....Represents the year of production, A to J in alphabetical order stands for 1: 9 (Since letter I and number 1 are easily confused, ignore I), and 0 is represented by the letter X.
- 001.....On behalf of the offline water number.
- M.....On behalf of the month, by letter A-M for 1-12 (Since letter I and number 1 are easily confused, ignore I).
- 05.....Represents the date, expressed in 01 31.

#### 2.2.2. Symbols

#### Table 2-1 Symbols

Symbol	Explanation
Â	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.



Ϋ́	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
Y	Indicates a medical device that can be broken or damaged if not handled carefully.
<b>Ţ</b> .	Indicates a medical device that needs to be protected from moisture.
ÎÎ	Indicates correct upright position of the transport package.
	Indicates that the material shall be recycled.
***	Indicates the medical device manufacturer.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
CE	Device fulfills the requirements of the European directives given on the EU Declaration of Conformity.
	Class II equipment.
Class 1 Laser Product)	Class 1 laser product.
RoHs	Restriction of Hazardous Substances in Electrical and Electronic Equipment. Meets the requirements of Directive 2011/65/EU.
EC REP	Indicates the authorized representative in the European Community/ European Union.
i	Indicates the need for the user to consult the instructions for use.

# 2.3. Compliance

Anyone creating or changing a medical electrical system through a combination with other devices in accordance with standard IEC 60601-1:2005+AMD1:2012Medical electrical equipment – Part 1: General requirements for basic safety and essential performance 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

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



- The device may not cause harmful interference.
- The 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 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

• IEC 60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances– Requirements and tests

• IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

• IEC 60601-1-9:2007+AMD1:2013 Medical electrical equipment–Part 1-9: General requirements for basic safety and essential performance–Collateral Standard: Requirements for environmentally conscious design

• IEC 62366 2007+AMD1:2014 Medical devices–Part 1: Application of usability engineering to medical devices

#### 2.5.2. Classification

- Type of protection against electric shock: Class II
- The degree of protection against electric shock: Type BF
- Enclosure protection: IPX0
- Degree of protection against incoming liquids: Common device.

• Level of safety when used with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non-AP/APG equipment.

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



Shock hazards exist if the power adapter is damaged or is not properly grounded. Use



only the supplied medical grade power adapter.

- To meet waterproof requirements, the sockets should not be placed on the ground.
- Do not use grounding type plugs for other purposes.

 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.

• To avoid risk of electrical shock hazards, always check the scanner and cable connections before using it.

• 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.

• The radiation characteristics of the scanner are suitable for industrial and hospital use.

(CISPR 11 Class A). If the Aoralscan 2 system is used in a residential environment (CISPR 11 Class B), it may not adequately protect RF communications.

#### 2.5.3. EMC Notice

Caution

- Aoralscan 2 meets the EMC requirements.
- Users should install and use the EMC information provided in the random file.
- Aoralscan 2 might affect the performance of a portable or mobile RF communication device. Avoid strong ELECTROMAGNETIC interference when using a scanner, such as near a mobile phone or microwave oven.
- The guidance and manufacturer's statement are shown in the attached table.



- Aoralscan 2 should not be used in proximity to or on top of other devices. If it must be, observe to verify that it works properly in the configuration in which it is used.
- This device is not intended for use in residential environments, which may not provide adequate protection for radio reception.
- With the exception of cables sold by the manufacturer of Aoralscan 2 as spare parts for internal components, the use of accessories and cables other than those specified



may result in an increase in transmission power or a decrease in immunity of Aoralscan 2.

#### **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.

Guidance and manufacturer's declaration–electromagnetic emissions

#### Guidance and Manufacturer's Statement - Electromagnetic Emission

Aoralscan 2 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 2 should ensure that it is used in this electromagnetic environment:

Emission Measurement	Conformity	Electromagnetic Environment - Guidelines	
RF emissions CISPR 11	Group 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 A	The Aoralscan 2 is suitable for use in all locations other	
Harmonic emissions IEC 61000-3-2	Not applicable	than those allocated in residential enviornments and those directly connected to a low vlotage power	
Voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	supply network which supplies buildings used for domestic purposes.	

#### **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.

#### Guidance and Manufacturer's Statement - Electromagnetic Emission

Aoralscan 2 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 2 should ensure that it is used in this electromagnetic environment:



Immunity Test	IEC 60601 Test Levels	Compliance Level	Electromagnetic Environment–Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2,±4,±8,±15 kV air	±8 kV contact ±2,±4,±8,±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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s)	±0.5, ±1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and	0% U <sub>T</sub> (100% dip in UT) for 0.5/1 cycle 70% U <sub>T</sub> (30% dip in	0% U⊤ (100% dip in U⊤) for 0.5/1 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Aoralscan 2 requires
voltage variations on power supply input lines	$U_T$ ) for 25/30 cycles	70% U⊤ (30% dip in U⊤) for 25/30 cycles	continued operation during power mains interruptions, it is recommended that the
IEC 61000-4-11	0% U⊤ (100% dip in U⊤) for 250/300 cycles	0% U $_{\rm T}$ (100% dip in U $_{\rm T}$ ) for 250/300 cycles	Aoraiscan 2 be powered from an uninterruptible power supply or a battery.



			Power frequency magnetic fields should be at levels characteristic of a typical location in a typical
			commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	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.

# Guidance and manufacturer's declaration-electromagnetic immunity

Guidance and Manufacturer's Statement - Electromagnetic Emission					
Aoralscan 2 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 2 should ensure that it is used in this electromagnetic environment:					
Immunity Test IEC 60601 Test Levels Compliance Level Guidance					



Conducted RF	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 V (effective value)	Portable and mobile RF communications equipment should be used no closer to any part of the Aoralscan 2, including cables, than the recommended separation distance calculated from the equation appliance to the frequency of the transmitter. Recommended separation distance: d = 1.2 VP
			IEC 60601-1-2: 2014 d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz IEC 60601-1-2: 2014
	6 Vrms ISM bands between 150 kHz and 80 MHz	6 V (effective value) ISM bands between 150 kHz and 80 MHz	Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).
EC 61000-4-6 Radiated RF			Field strengths from fixed RF transmitters, as determined by
	3V/m 80 MHz to 2.5 GHz	3 V/m	an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each
			frequency range <sup>b</sup> . Interference may occur in the vicinity
			of equipment marked with following
			symbol:
			((·••))

#### Guidance and manufacturer's declaration-electromagnetic immunity

#### Guidance and Manufacturer's Statement - Electromagnetic Emission

Aoralscan 2 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 2 should ensure that it is used in this electromagnetic environment:



**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.

<sup>a</sup> Field strength 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.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

<sup>c</sup> 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.

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.

Recommended separation distances between portable and mobile RF communications equipment and the Aoralscan 2

Guidance and Manufacturer's Statement - Electromagnetic Emission



Aoralscan 2 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 2 should ensure that it is used in this electromagnetic environment:

	Separation distance according to frequency of transmitter (m)			
Rated maximum output power of transmitter (W)	IEC 60601-1-2: 2014			
	150 kHz to 80 MHz d = 1.2 VP	80 MHz to 800 MHz d = 1.2 VP	800 MHz to 2.5 GHz <i>d</i> = 2.3 <i>VP</i>	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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.

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.



Warning

- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- 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, it could lead to degradation of the performance of this equipment.

 If immunity test level is higher than those specified in IEC60601-1-2, 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.

# 2.6. Biological Safety

Meets biological criteria: ISO10993-5: 2009 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity); ISO10993-10: 2010 (Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization).



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# 3. Unpack the Package

Check the carry box for the following items. If any item is missing or damaged, contact the distributor or service provider immediately.



Figure 3-1

- 1.  $1 \times$  Scanner with a USB 3.0 cable
- 2. 1 × Scanner cradle
- 3.  $1 \times dust cap$
- 4. 2 × Scanner tip

5.  $1 \times \text{USB}$  3.0 cable (for the connection between the cradle and your computer; cable length: 1.5 meters)

6.  $1 \times$  medical grade AC/DC power adapter (input: 100-240 V, 50-60 Hz, 0.45-0.27 A; output: 12 V DC,1.67 A)

7.  $1 \times 2$ -in-1 USB dongle (the license key for authorized access to the IntraoralScan software program for Windows and the software carrier)

8.  $1 \times carry box$ 

#### Additional accessories

- 1 × calibrator
- 1 × USB 3.0 cable (for the connection between the calibrator and your computer;





Figure 3-2





• 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 usage.



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.



# 4. Scanner

# 4.1. Overview

Aoralscan 2 is designed to provide powder-free intraoral color scanning with higher speed, 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 images 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 images, and supports scan data export (in STL/OBJ format) to CAD/CAM systems for different purposes of dental care.

## 4.2. Scanner

#### 4.2.1. Scanner Tip and Body





Table 4-1 Component description

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 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.
		<ul> <li>Blinking green: The scanner is in preparation/warm-up mode.</li> </ul>
		<ul> <li>Solid green: The scanner is ready for use.</li> </ul>
		• Solid blue: The scanner is processing the alignment of scanned data.
		<ul> <li>Solid amber: An error occurs and needs your attention.</li> </ul>
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.

4.2.2. Cradle





No.	Component	Function
1	Cradle	Place the scanner in the cradle when you are not using it.
2	LED indicator	<ul> <li>Indicates cradle status.</li> <li>Solid green: Power on.</li> <li>LED off: Power off.</li> </ul>
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 p 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. The port transfers data between the Aoralscan 2 and your computer.
6	USB 3.0 upstream port	Connect the scanner cable to the port. The port provides power supply and data communication between the scanner and cradle. See 5.1 Connect the Scanner.



• When the scanner is left idle for 1 minute (including being placed on a desk), it will go into standby mode. After 3 minutes 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 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.
- 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. Do not roll the cable over the handle of the scanner or even bend the cable sharply.











#### 4.2.3. Cables

See the table for main cables.

Table 4-3

No.	Name	Length (m)	
1	Scanner connection cable	2.0	
2	Power adapter cable	2.0	
3	Data cable for USB 3.0	1.5	

# 4.3. Software

The **Aoralscan 2** is designed to operate with the software programs, which include 4 modules (supplied in the 2-in-1 USB dongle):

• Calibration module

Calibrate the scanner.

• 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 images with the scanner.

• Pre-design module

Mainly for users to be more convenient to use in the design software. Use the feature to adjust coordinates, mark tooth position, and extract margin lines.

## 4.3.1. System Requirements

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



the following requirements.

Table 4-4

Component	Description
CPU	Intel Core i7-8700 or higher
Memory	16 GB or higher
Hard drive	256 GB SSD and above
Graphic card (GPU)	NVIDIA RTX 2060 6GB or higher
Operating system	Windows 10 Professional (64-bit)
Display Resolution	1920 × 1080, 60Hz or higher
I/O ports	More than 3 Type-A USB 3.0 (or higher) ports



Your PC shall meet the safety requirements of IEC 60601-1 and IEC 60950.

#### 4.3.2. Install Software

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

- (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 Installation 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, an icon named after DentalLauncher will be displayed on your desktop for quick access.



# 5. Set the Scanner

# 5.1. Connect the Scanner



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

• If the accuracy of the equipment decreases or if the equipment does not work properly, consult technical support promptly.

Install the scanner in accordance with the instructions stated in the 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 hold the scanner firmly when lifting from the stand or when using the scanner. Do not shake the scanner.

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. Do not block the ventilation holes on the bottom of the scanner. If the scanner overheats, the scanner will stop working.



Warning

Ensure that you use only the supplied power adapter, power cable, and USB cable. Power supplies are supplied with connectors designed for this scanner. Do not connect any device other than this scanner.

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.



Figure 5-2

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

(7) Click the IntraoralScan shortcut icon (Named "Dental Launcher") on the desktop to launch the software.



# 5.2. Calibrate 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.
- Scanner brightness adjustment is recommended once every 3 months.
- The calibration plate inside the calibrator is a high-precision component, and the

surface of the plate must be kept clean. If the calibration does not proceed smoothly, check the condition of the calibration plate surface. If you find a dirty surface, consult the manufacturer or the authorized distributor.

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.



Figure 5-3


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



⚠ Caution

• 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.



Figure 5-6



(10) Ensure the scanner is plugged into the calibrator firmly. Click Start. Calibration begins.





Normally the calibration takes approximately 5 minutes.

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

(12) Gently slide the calibrator off the scanner.



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

(13) Reattach the scanner tip to the scanner for later use or put the dust cap onto the scanner to prevent damage and dust.



## 5.3. Disconnect the Scanner



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.



# 6. Scanning Preparations



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

## 6.1. Intraoral Environment

• 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 scanning.

• 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.

## 6.2. Scanner

• Ensure that the scanner tip, scanner body, and cradle are properly pre-cleaned, disinfected, or sterilized.

• 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.

## 6.3. 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.

# 🍪 SHINING 3D°

• Hold the scanner steady by resting it on the tooth surface and keep the scan tip window in the range of -1 mm to 16 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° angle; to scan the buccal and lingual surfaces of the teeth, hold the scanner at a 45° angle.

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

## 6.4. Heat 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.

(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.
- (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.



(6) If 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.



• The heater helps keep the scanner tip temperature in a normal range.

• 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.



# 7. Use IntraoralScan

## 7.1. Introduction to IntraoralScan

IntraoralScan includes four modules: Calibration module, dental order system, scan module and pre-design module.

- Calibration module is mainly used to calibrate the accuracy of scanner and ensure the quality of scan data. It contains two functions which are brightness adjustment and calibration.
- Dental order system is a module for dental order management, realizing management functions such as order creation, editing, searching and deletion, as well as uploading, downloading, previewing and tracking of orders.
- The scan module collects oral digital images, and exports 3D data (STL/OBJ/BEB (format by Shining 3D)/PLY).
- The pre-design module is mainly for the user to be more convenient to use in the design software. Use the feature to adjust coordinates, mark the tooth position, and extract margin lines.



To run software, ensure the connection between the scanner and your computer is ready. See "5.1 Connect the Scanner."

# 7.2. Register User and Cooperator Info

Register user and your cooperator information.

## 7.2.1. Register Account and Log in

If the customer has Shining 3D accounts, he can directly enter the account and password for login. Selecting an institution before logging in (if there is only one institution here, log in directly without selection).

If there are no Shining 3D accounts, click **New User? Click here to register** to enter the registration interface:



I'm the hospital/clinic	<ul><li>() ↓ +86 中国</li></ul>	
	After registered, this cannot be changed	
	Hospital/Clinic's name	
	Contact	
	Image captcha 👸 🕥 🖡 🕅	
a second second	Email or phone	
	captcha Send	
	Password 😽	
	confirm password	
	Read and agree with it Privacy policy	

(1) Registration information: Fill in the real application information according to the content (Connections and order status notification will be sent to your registered mobile phone number or Email).

(2) Click **Privacy policy** and read it. When you agree, select the check box.

3 Click **Register**.

(4) Click **Back** to return to the login interface, and enter the registered account and password to login.

### 7.2.2. Log in by Password

Double-click with to enter the login interface of the software. If you have registered an account, you can use a password to log in.

Step 1 Enter the username: E-mail address, or mobile phone number.

Step 2 Enter your password.

Step 3 Select Remember password as needed to help log in quickly next time.

Step 4 Select Privacy policy.

Step 5 Click Sign in.





#### Log in by Verification Code 7.2.3.

Double-click 💹 to enter the login interface of the software. If you have registered an account, you can use a verification code to log in.

Step 1 Enter the username: E-mail address, or mobile phone number.

Step 2 Enter the numbers or letters in the image.

Step 3 Click send to send verification code to your E-mail or phone.

Step 4 Type the verification code.

Step 5 Select Privacy policy.

Step 6 Click Sign in.

#### 7.2.4. Profile



Click I in the upper right corner of the software to open the profile information.

👤 Profile		Х	Connections	×
8 Contact	Nick			
合 Hospital/Clinic	-			
🖒 Lab	-			
Phone	-			
🖾 Email	224			
	U Sign Out			



The user information lists the contact, hospital/clinic, lab, phone and E-mail filled in when registering the account.

Click **Sign Out** to exit the login of the current user.

#### 7.2.5. Connections

Click I in the upper right corner of the software to display the **Connections** interface.

	<b>P</b> rofile			<b>X</b> 0	onnections	×
Contact		Target lab		Status	Action	
Nick			~		~ ×	

+ New

All relevant contacts are listed.

Acceptance awaited: Indicates that the relationship needs to be confirmed by the target lab and data cannot be uploaded to the target lab.

Accepted: Indicates that the relationship can be used normally and data can be uploaded to the target lab.

Rejected: Indicates that the relationship is rejected by the target lab and data cannot be uploaded to the target lab.

Manage your connections:

Delete relationships: Click the delete button in the action bar of a relationship list.

New relationship: Click New to add a new relationship in the first row of the list.

Nick	~	✓ ×

Enter the name of the target lab in the edit box (fuzzy search available). Click check to confirm the relationship and click cross to cancel.

## 7.3. Activate the Scanner

To make sure the device is authorized, you need to activate it. You need to activate your



device for full permission.

When the scanner is used for first time, it must be connected to the internet and activated successfully. Double-click IntraoralScan icon on the desktop. The activation prompt interface is displayed.

Ensure the computer has been connected to the Internet, click **Yes** to open the authorization tool and click **Activate**. A message will be displayed indicating that the activation is successful. Otherwise, contact technical staff.

Both Online Activation and Offline Activation are available for downloading the permission file.

	Auth	norization Tools		×
	Online Activation	Offl	ine Activation	
Device Number Activation Date Days Left	-	Name Phone Number Email Institute Name Country Industry	- 1 中国	
Copy Devic	<u>e Information</u>	Activate		

### 7.3.1. Online Activation

Select **Online Activation**, the activation will be processed after clicking **Activate** if the computer with installed software has been networked.

You will enter the homepage after registering.

### 7.3.2. Offline Activation

Please select **Offline Activation** and perform the following operations when the computer with installed software is not connected to the Internet.





Please plus a USB disk or a portable hard disk (hereinafter referred to as "the Disk") into the computer before offline activation.

Step

1. Export C2V file:

Click Export and save C2V file to the Disk or the USB.

2. Upload C2V file:

(1) Plug the Disk into a networked computer. Enter <a href="http://passport.shining3d.com/">http://passport.shining3d.com/</a>, log in or register a new account.

- (2) Click OffLine Activation after logging in successfully.
- (3) Upload the downloaded .C2V file.
- (4) Export .V2C file bound to your device and account.
- (5) Down .V2C file corresponding to you account to your Disk or USB.

3. Import V2C file:

- (1) Plug the Disk into the computer with installed software.
- (2) Click Import on the offline activation pop-up and import .V2C file.
- (3) Activate successfully.

## 7.4. Upgrade Software

Open "About" of scanning software and click "Check for Updates". If there is updated installation package on the network, then you can download.

If "Download updates automatically" is checked, the software will automatically download the update package when the network is connected. When the download is completed, an information box indicating whether to update immediately will pop up:





If there is no updated installation package, it will pop up the information box of "The current version is already the latest version!"





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## 7.5. Calibrate

After the installation of calibrator is completed, connect it to the scanner and power on, click on the upper right corner of the software, then you can proceed the next operation include brightness control and calibration.

### 7.5.1. Brightness Adjustment

Brightness adjustment is to correct the brightness of scanner and improve the color fidelity of scan data. It is recommended to proceed the brightness adjustment every 3 months.



Connect the scanner and calibrator correctly as shown, click **Start** to proceed the brightness adjustment.

## 7.5.2. Calibration

Calibration is to calibrate the accuracy of the scanner and ensure the quality of scan data.





Connect scanner and calibrator correctly as shown, and click **Start** to start calibrating.

## 7.6. Order System

#### **Order Settings** 7.6.1.

Click to set order parameters. To restore parameters on **Order Settings** interface to

# the default, click $^{\mathbb{C}}$ . General

## General C

Language	English
Default Dentistry Type	Restoration ~
Dental Notation	FDI World Dental Federation notation 🗸
Order Save Path	D:/DentalOrder
Exocad DentalCAD Path	//DentalCADApp/bin/DentalCADApp.exe

Parameter	Description
	Users can set the software interface language: Chinese
Language	(Simplified), English and other languages. The default language
	is the language selected during software installation.
Default Dentistry Type	Select a default dentistry type from Restoration and
Default Defitistry Type	Orthodontics.
Dontal Notation	FDI World Dental Federation notation and Universal numbering
	system. The default is FDI World Dental Federation notation.
	Set the order saving path. The default is to save the DentalOrder
Order Save Bath	file in the installation package disk. If the installation package is
	stored in the C disk, the software installation path is
	C:\DentalOrder.
Everad DentalCAD Dath	To combine EXO software to IntraoralScan, enter EXO software
	location.

## Naming Rules



#### Order File Naming Rule C

	Order ID	Order Number
	Doctor Code	Doctor Name
	Patient Code	Patient Name
	Operator Code	Operator Name
	Create date	
Nam Exar	ning Rule: "Order ID_Create date_Doctor Code" nple: "001_2022-07-07_001"	

Default naming rule is "Create date\_Doctor Code\_Order ID". Still, you can define your own naming rule. Select wanted naming rules (order ID is a must) one after another and the final naming will be displayed in earlier selected rule→later selected rule sequence. Saved Format

Parameter	Description
	The exocad order *.dentalProject is saved while saving the order.
Save EXO order	You can import the order into the EXO design software for design.
	The default is on.
	Save third-party software order when an order is finished. A
	third-party software order is saved while saving the order. The folder
	named "original order name_thirdParty" is generated under the
Save 3rd party order	order path, and the *.xml file and the scanning result data *.stl/*.ply
	(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 on.

After you set order parameters and exit the interface, the software informs you that "Settings change, do you want to save". Click Yes and it will save the changes. Click No the changes will not be saved.

### 7.6.2. Create an Order

When creating an order, enter information of patients and doctors. Then select **Dentistry Type** and teeth to be scanned.



Order Information	Tooth Selection	
ID Create time		
026 7/7/22 8:40 PM	(12) (11) (21) (22)	Full Crown Pontic
Order Number Type	(13) (23)	
026 FirstVisit 🗸	(14) (24)	🕅 Inlay 🛛 🖤 Veneer
	15 linner law (25)	
Patient Name*	opper jun	Antagonist
P+		
	(17) (27)	
Doctor	$\mathbf{\times}$	
001 Doctor001 ~ 🗹		
	( X Clear All )	
Operator		
001 Technician001 🗸 🗹	40	Implant-Based
Dentistry Type	(47) (37)	
	(46) (36)	
Restoration      Implant      Orthodontics	Lower Jaw (35)	Material
Notes		×
Shade: None.		
Additional comment: None.		Scan a pre-op model
	41 31	Yes
	Full Crown     Pontic     Inlay	
Cancel )	Veneer U Antagonist	( 🕅 Explore ) ( 🗎 Save ) ( 🔪

No.	Feature	Description
		1.Choose the types of patients. FirstVisit or Follow-Up. 2.Click to enter required information of the patient such as name and age.
		• Select a doctor/Operator: Click to select a doctor and Operator
		from the drop-down list. If not found in the list, add a doctor/Operator:
1	Order Information	1. Click Main and the <b>Doctor/Operator</b> interface is displayed.
		2. Enter the name of a doctor/Operator in the Doctor/Operator name
		box.
		3. Click + to add the doctor/Operator information to the list.
		• Select a dentistry type:
		Based on patient's treatment type, select from Restoration,
		Orthodontic, implant and other.
		Restoration: Replace or restore your missing parts of your tooth
		structure. The treatment types include Full Crown, Pontic, Inlay, Veneer and
		Antagonist, and the dentist will choose the proper types according to the



		situation.
		Implant: Replace damaged or missing teeth with artificial teeth. Implant
		treatment types include Full Crown, Bridge, Upper, Lower and Full, and the
		dentist will choose the proper types according to the situation.
		Orthodontics: Deal with irregularities of the teeth and their correction.
		Treatment types include Fixed Ortho, Mobile Ortho and Invisible Ortho.
		Other: Receive other dental examinations and treatments including Oral
		Exam, Caries Filling, Oral RCT and Period DontTm.
		Note:
		When you choose <b>Other</b> , you can change the order type from other into
		restoration, implant and orthodontics later.
		Select teeth:
		1. Based on the teeth to be treated, select the teeth directly on the teeth
		map.
		2 Select restoration type from Full Crown Pontic Inlay Veneer and
		Autocovict
		(E) Note:
		• When selecting Full Crown, you can select the <b>Implant-Based</b> type.
		• When two or more teeth are selected as <b>Restoration</b> type (full crown or
		• When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic) gray spots will appear between the two teeth. When the spots
		• When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots
	Tooth	• When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.
2	Tooth	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> </ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as Restoration type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> <li>Image: Comparison of the spot of th</li></ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> <li>Image: Comparison of the spot of</li></ul>
2	Tooth selection	<ul> <li>When two or more teeth are selected as <b>Restoration</b> type (full crown or pontic), gray spots will appear between the two teeth. When the spots turn blue, the bridge is shown.</li> <li>Image: Comparison of the spot of</li></ul>



	Implant-Based, Material and Scan a pre-op model.
	4. Click Save.
	<b>Explore</b> : Open the folder where the order has been saved.
	Scan: Enter the scanning interface.
	Left-click: Select a tooth.
	Right-click: Cancel settings of a tooth.
	Click Clear All: Clear all defined restoration types.
Short-cut	Ctrl+ left-click: Copy the last defined dental restoration type to the currently
key	selected dental position.
	Shift + left-click: Copy the restoration type defined by the previous tooth
	position to all teeth between the selected tooth position and the previous
	tooth position.

## 7.6.3. Import Orders

Click **Import order** and select \*.inProject or \*.dentalProject file. Supports importing orders saved by IntraoralScan software and ExoCAD orders.

When importing scanned orders and clicking **Go to scan**. The following prompt interface is displayed:

To load the last scanned data, click Yes. To close the dialog box, click No.

### 7.6.4. View Order

View created or imported orders in card or table mode on the software main interface.

Click 🖽 or 🖽 to switch the order display mode. Order information includes patient information, order status, and creation time.

Double-click an order to enter the order information interface.



6/24/23	6/24/21	6/24/21
Walting to send	Waiting to be accepted	Walting to be accepted
No. 001 👗 sunny	No. 041	No. 040 👗 040
6/24/21	6/24/21	6/24/21
Waiting to be accepted	Waiting to be accepted	Waiting to be accepted
No. 014	No. 009	No. 031 👗 031

اڭ 🕄

Under the table mode, settings before closing the software are saved.

Q No., Patient Name	T I				
Order Number	Patient Name	Dentistry Type	Order State	Create time	Operation
386	386	Restoration	Waiting to be accepted	6/25/21 4:42 PM	±
362	362	Restoration	Waiting to send	6/24/21 10:42 AM	<b>4</b> 🖻 🖻
001	001	Orthodontics	Waiting to be accepted	6/24/21 8:43 AM	ŧ
006	006	Restoration	Waiting to send	6/25/21 10:13 AM	<b>4 G Ú</b>
005	005	Restoration	Waiting to scan	6/25/21 10:11 AM	G Ó
045	kk	Orthodontics	Waiting to be accepted	6/25/21 8:56 AM	±
044	044	Restoration	Waiting to be accepted	6/25/21 8:43 AM	±
004	004	Restoration	Waiting to send	6/24/21 6:04 PM	<b>4 G Ú</b>
003	003	Restoration	Waiting to send	6/24/21 5:47 PM	<b>4</b> 🖻 🟛

- Search an order: Enter the number or patient name in the search box to list the orders that meet the conditions.
- Filter orders: Click it expand the filtering criteria, which supports status, source and time filtering.



Cancelled, PreOrder.



- Waiting to scan: Orders that have not been scanned.
- Waiting to send: Orders that have been scanned and not uploaded to the dental cloud platform.
- Waiting to be accepted: Orders that have been uploaded to the dental cloud platform and are waiting to be accepted by the operator.
- Accepted: The order has been accepted by the operator's office.
- Cancelled: The doctor cancels the order data that has been uploaded to the dental cloud platform. The doctor can cancel the order until the order is received by the target operator.
- Source: IntraoralScan and exocad.
- Multi-selection mode: Click and turn on the multi-select switch to support selecting multiple orders.
- Operate orders: Under the table mode, operate orders as follows:

## Icon Description

- Download the order data from the cloud platform to the local area.
- Copy the currently selected order file and the scanned data to a new order.
  - Delete the currently selected order from the order list, and the user can choose whether to delete the stored order files and scanned data.
- Upload the currently selected order file and scan data to the Dental Cloud Platform.
  - Cancel an order that has been sent but not received, the action must be performed on the order details page.
- Check the Audit Report.

### 7.6.5. View Order Data

• Cloud Platform Orders.

Cloud platform orders are orders with (under card mode), or orders with only download operations in order list in table mode.

Cloud platform order data can be downloaded to local and can be browsed and edited.

- Local order data.
  - \*.dentalProject: exoCAD order project document

## 没 SHINING 3D°

- ◆ \*.inProject: Shining 3D intraoral scanning order project document
- \*.stl: Untextured 3D data (binary)
- \*.obj: Textured 3D data, used it with \*.mtl/\*.jpg
- \*.beb: Shining 3D's own format 3D data
- \*-margin.xyz: Extractive margin line data.
- Project: Scan project data document, store the temporary project document.

## 7.7. Scan

After creating and saving an order in the Dental Order System, then you can scan target teeth. If no scanner is connected, an error message appears to remind you to check and reconnect the scanner.



## 7.7.1. Interface Introduction

No. Name

### Description

Home, New Order, Scan, Pre-design, and Send. The executed steps can be

1 Navigation bar

switched by clicking on the navigation bar.

- User: Display the logged-in user information and relationship network.
- 2 Other operation
- Screenshot: Record the screen, take a screenshot and check the

screenshots.

SHINING 3D<sup>®</sup>

- Calibration: Open the calibration interface.
- Settings: Open Order Settings, Scan Settings and About (displays software version, copyright information, check for updates, device serial number, dongle serial number and days left to license).
- Help: Open the software's user manual.
- Minimize: Click to minimize the window.
- Close: Click to exit the software.

View the camera video image.

Move the mouse within the image window to display four icons:

Endoscope: Click to enlarge the image window, and click again to restore it to the default size.

Screenshot: Take a screenshot of the current image in the image window, and save the image in the "EndoscopeImg" folder under the current order directory.

Brightness: Brightness switch, when it is turned on, a brightness slider will appear under the image window, the user can slide this slider only when the "Settings->Scan Settings" interface is set without the "Auto Brightness Adjustment" checkbox. Manually adjust the brightness, dental model scanning is recommended [0,2]; intraoral scanning is recommended [8,12].

Mask: Scanning indication switch. Disabled by default. When turned on, the camera window displays the current unscanned data area in purple when scanning.

- Provides scanning operation demonstration and related prompt 4 Scanning prompt information.
- 5 Back to orders Return to the order interface to view order information or edit.
- Hold the scanner, pause for 1 second and swing it up and down twice to
   IMU operations
   display the motion menu.
- 7 Flow Contains order system, maxillary (maxillary implant), mandibular

Live image

window



(mandibular implant), full jaw, pre-design, and upload order.

- Device status Displays device status during non-scanning processes.
- Scan frames and 9 Records the number of scanned frames; scan and data processing time. time

8

11

Displays the 3d data model collected by scanning.

Scan effect viewHold down the left/right mouse button to rotate the 3D data model; Hold<br/>down the left/right mouse button and move the cursor to move the 3D<br/>data model.

Edit scanned data, implement refined scanning and optimize data.

- Edit: When this button is clicked, it enters the edit interface to select the data to be deleted.
- Remove isolated data: Click to delete the smaller independent model data that are not connected to the main model data. Help delete unrelated model data quickly.
- Refined area: Select refined area, which reflects more partial details in a higher resolution during post-processing. This feature is best used in conjunction with the Tooth Color function to ensure that the quality of the tooth color is true in the refined area. Select
   Operation bar
   Refined Scan in the Settings > Scanning Settings to automatically enter the process of refined area selection when the maxillary/mandibular scan is completed.
  - Part lock: When the scan is paused, click to set the scanning lock area, and the data in the locked area will not change in subsequent scans.
  - Undercut: The scan is paused and, when clicked, this button allows you to view the dental undercut.
  - Switch Upper and Lower Jaw: Swaps the data from the upper and lower jaws after the scan is completed or post-processing is completed. For cases where the upper and lower jaw flow is reversed during scanning.



- Texture: Texture switch. Set whether the model data shows texture or not. It's checked by default to display textures.
- Tooth color: Tooth color switch. Turn on the tooth color display. If the gray color is displayed when scanning, it means the data quality in these areas is not high enough, and more scans should be performed in this area, and when the corresponding gray color becomes true color display, it means the data quality has reached better post-processing requirements.
- Al Optimize: Apply to intraoral scanning. After clicking this button, the intraoral scan automatically deletes miscellaneous data, such as buccal and lingual data, soft tissue, etc. When you use the software for the first time and enter the scanning interface, this button is grayed out and you need to wait for 1–2 minutes for Al initialization, after the initialization is completed, the button can be clicked.
- View lock: When you click the button, the scanning is done with a fixed perspective and the automatic perspective tracking function is not enabled. Not enabled by default.
- Metal tooth scan: When scanning metal teeth, click this button so that it can improve the scanning speed and sweep the whole situation.

Scan menu: Start/pause scanning (shortcut key: Space key), reset (rescan) and finish.

- Scan: Click 🕑 or press the Scanner button to start scanning
  - ( turns to ) and click ( to pause scanning. When

finishing scanning, click V or press the Scanner button to add scanning.

- Reset: Click 💟 to delete the scanned model.
- Reset all: When selecting whole jaw scanning, you can select all

12



reset to delete all maxillary and mandibular data.

- Finish: Click or press the Scanner button longer than 3 seconds.
- Intraoral scan Enabled by default, applicable to intraoral scanning. It is mode recommended to leave it off when scanning dental models.

When identifying the alveolar ridge for those who lose multiple teeth or the edentulous patient, enter edentulous jaw scan mode for promoting integrity and smoothness of the acquired gum data. As this mode enables the scanner to capture a small number of buccal-lingual area data specially, to maintain the scanning accuracy, please don't pull surrounding flesh so as to avoid changing the original shape of gum data.

• IMU menu: IMU refers to motion sensing. Hold the scanner by hand, pause for 1 second, and swing it up and down 2 times to display the motion sensing menu.



Swing the scanner up/down and left/right. Blue color indicates its in the selected state. When the blue color fills up the whole button, the function will be triggered.



Description



Exit the IMU menu.

Pause scanning and scanning in progress.





ノ Note

- If the scanner is not connected, a prompt is displayed to remind you to check and reconnect the scanner.
- If the scanner is connected and error prompts still appear, power off the base and then power on again; If the software still does not detect the scanner, turn off the



software, wait a few seconds, and then restart the software.

• If the scanner is not used for half an hour, it will enter the dormant state.

### 7.7.2. Scanning Settings

Click

and then click the Scan Settings tab to view or set scanning

#### parameters.

0	rder Settings	🔅 Scan Setting	s 🕞 Pre-Design S	ettings	(j) About
Ger	neral C				
	<ul> <li>Intraoral</li> <li>Auto-bright</li> </ul>	ness	V IMU menu		
	Supports al	ternate day scanning			
Car	Supports ali	ternate day scanning			
Car	Supports ali mera C (unit:pixel) Margin-left	ternate day scanning	Margin-right	0 +	
Car	Supports ali mera C (unit:pixel) Margin-left Margin-top	ternate day scanning	Margin-right — Margin-bottom	0 +	

### General

- IMU menu: Motion sensing function. Enabled by default.
- Auto-brightness: Adjust the brightness of the camera when scanning to capture clear images. Default is automatic adjustment. If this check box is unchecked, you can drag the slider or enter the value to set the brightness manually. [0,2] is recommended for dental model scanning; [8,12] is recommended for intraoral scanning.
- Refined scan: Unchecked by default. Suitable for refining the area by selecting the prepared tooth area, post-processing data are processed more finely to enhance data details.
- Supports alternate day scanning: Enabled by default. Scanned orders support unlimited add-scan.
- Filled holes will be displayed in grey: Check the feature to make the holes of teeth will be displayed in grey, refer to the following picture. The feature is unchecked by



default, that make the holes of teeth will be displayed in colour.



## Camera

Camera top, bottom, left, and right margins' values, they are acquired from the camera by default; you can also manually set the cropping parameters for the top, bottom, left, and right margins of the camera window, adjustable in the range of [8,160].

C : Restores the margin values in the camera.

## **Music Settings**

Click the button of music and upload music documents by clicking  $\ \ \Box^2$  .

The computer connected to the scanner will play music when finishing different operations.

### 7.7.3. Scan Upper/Lower Jaw

After creating or importing an order, click **Go to scan** to enter the scanning process.

Step 1 To enter the jaws scanning process, first check whether the image display in the image window is normal or not.

Step 2 After confirming the image, click D or press the Space key to start scanning.



The maximum number of frames for upper/lower jaw scanning is 3,000, and



the scan will be paused automatically for you to decide whether to stop scanning at

2,500 frames, and you can continue scanning for another 500 frames.





to enable tooth color. It will guide the

user to judge the reliability of the data quality in this area.



If there is too much gray, scan the gray area again until it shows a normal tooth color.

## Display the tooth color (gray)



Step 4 Based on needs, click on the image window to enable scanning guidance. It guides you to scan this area from multiple angles to obtain high quality data.



The purple area in the camera window indicates that no data are scanned.

Mask



Step 5

XL/QER-RD-404



Based on the needs, click

button on the right, which will

then become to start the AI optimization function, thus miscellaneous data such as buccal and lingual soft tissue data will be automatically eliminated during intraoral scanning. See the following figure (With and without AI Optimization).







XL/QER-RD-404



When the scanner tip leaves the object or the scanning is paused, the green area means this area is not scanned. User can rescan the corresponding area accordingly.

## Scan paused (hole areas are in green)



Step 7 If the scan data is not satisfactory, you can rescan it. Click  $\bigcirc$ , and the following prompt message box is displayed.

Click Yes to delete the previous data and restart the scan.





Step 8 After the scanning or post-processing is completed, do not exit the scanning interface and click scan button to add scanning.



Step 9 After confirming that the scan is completed, click the finish button or long press the space bar to save the data. The green tick in the lower right corner of the icon as shown below indicates that the scanning process is finished.

Scan completed





#### 7.7.4. **Unlock Features**

## 7.7.4.1. Part Lock

Pause scanning of pre-operative upper and lower jaw or normal upper and

lower jaw, and then the part lock icon **final** on the right side of the software can be clicked.

Click to open the part lock interface and set the scanning lock area,

thus the data of the locked area will not change in subsequent scanning.





### XL/QER-RD-404

		Hold the left/right mouse button to rotate the 3D
\$	Rotate	data model; hold the left/right mouse button and
		move the cursor to move the 3D data model.
/		Scroll the mouse wheel to scale the data to adjust the
		brush radius. Hold left mouse key and brush the data,
	Brush	brushed area will be displayed in blue. Release the
		mouse key, then all the brushed areas become the
		locked area.
۲	Frasor	This button cannot be clicked until the lock area is set.
	LIUSCI	Click this button to erase the editing lock area.
8.	Select	Select areas other than the previously selected area as
	reversely	the lock area.
<b>İ</b>	Clear	Clear all the set areas.
*	Withdraw	Withdraw the last operation.
1	Redo	Resume the last cancellation operation.
×	Cancel	Cancel the set locked area and exit.
	Confirm	Confirm the lock area where the settings are saved
$\checkmark$	Commi	and exit.

### 7.7.4.2. Edit Data

Data can be edited when upper/lower jaw scanning is paused, or after the data processing of upper/lower jaw or upper/lower implant jaw is completed.

Click months on the right bar of the software interface, and the edit interface is displayed. The default selection button is brush.



Icon Name Description



Rotate		Hold the left/right mouse button to rotate the 3D data
	Rotate	model; hold the left/right mouse button and move the
		cursor to move the 3D data model.
		Scroll the mouse wheel to scale the data to adjust the
1	Druch	brush radius. Hold left mouse key and brush the data,
<u>s</u>	DIUSII	brushed area will be displayed in blue. Release the mouse
		key, then all the brushed areas become the locked area.
	Free	Press and hold the left mouse button to draw a closed
	Selection	curve, and the selected area is shown in red. Then release
		the mouse and the selected areas will be deleted.
•	Withdraw	Withdraw the last operation.
1	Redo	Resume the last cancellation operation.
×	Cancel	Cancel the set locked area and exit.
	Confirm	Confirm the lock area where the settings are saved and
$\checkmark$		exit.

## 7.7.4.3. Undercut

Undercut is used to calculate and view the undercut area of the marked (corresponding part in the order) teeth.

When scanning the upper and lower jaw, pause the scanning to operate the undercut feature on the right-side feature bar. Use the brush to select the undercut range, and the undercut area is automatically calculated after the range selection is completed.

The following figure shows the effect of the undercut display in a certain visual direction:

- The blue arrow indicates the visual direction.
- The light green is the undercut range.
- The green indicates the visible area.


• The red indicates the invisible area.





lcon	Name	Description
1	Brush	Set the range of undercut generation.
*=	Calculate the undercut	Display the undercut effect.
$\checkmark$	Exit	Exit the process of undercut.
	7744 Scan Meta	l Teeth

# 7.7.4.4. Scan Metal Teeth

To get better scanning performance for metal teeth, click 🚿 to enable the

feature.





## 7.8. Clinical Scanning Sample

#### 7.8.1. Pre-operative Scanning

Create pre-operative scanning orders in the order system. As shown below, there are pre-operative scanning orders for both the upper and lower jaws. Save the orders.

Order Information	Tooth Selection	
ID         Create time           026         7/7/22 8:40 PM	12 11 22 22	Full Crown
026 Type	(13) (14) (23) (24)	Minlay Veneer
Patient Name*	15 Upper Jaw 25 16 26	Antagonist
Doctor		
001 Doctor001 ~		
Operator	X Clear All	
001 Technician001 🗸 🗹	48 38	Implant-Based
Dentistry Type	47 37	No implant 🗸
Restoration Implant Orthodontics	Other (46) (36) (36) (35)	Material
Notes	(44) (34)	~
Additional comment: None.	43 33	Scan a pre-op model
	41 31 31	Yes 🗸
	Full Crown O Pontic O Inlay	
	Veneer Antagonist	

Click **Scan** to open the scanning interface. The scanning process is: Pre-operative upper jaw, upper jaw, pre-operative lower jaw, lower jaw and total jaw.



The default scanning sequence: Pre-operative upper jaw -> pre-operative lower Jaw -> total jaw (scanning occlusion data) -> upper jaw > lower jaw -> total jaw (automatic alignment).

The scanning process of upper jaw/lower jaw (post-operative data) is similar to that of implant jaw: Loading pre-operative data, digging hole, and scanning post-operative data.

Scan pre-operative upper jaw with the sterilized scanner.



## 7.8.2. Scan Jaw Implant

## 7.8.2.1. Scan Single Implant Tooth

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

scanning is added in the scanning process.

Order Information	Tooth Selection	
ID Create time		
026 7/7/22 8:40 PM	11 21 21	🛛 🕅 Full Crown 🔵 🕻 🏙 Bridge 🌖
Order Number Type	(13) (23)	
026 FirstVisit V	(14) (24)	Upper Upper Lower
	(15) Unper Jaw (25)	
Patient Name*		Full
P+		
	(17) (27)	
Doctor		
001 Doctor001 ~		
Operator	X Clear All	
	(48) (38)	
		Implant-Based
Dentistry Type	(47) (37)	Custom Abutment 🗸
<ul> <li>Restoration</li> <li>Implant</li> <li>Orthodontic</li> </ul>	s Other (46) (36)	
Notos	45 Lower Jaw 35	Material
Chada: Nono	(44) (34)	Glass Ceramic 🗸 🗸
Additional comment: None.	43 33	
	42 41 31 32	Scan a pre-op model
		No

Scan the lower jaw first (without intraoral scan body). After the lower jaw scan is complete, the lower jaw implant scanning interface is displayed. Select the implant area and delete it.



#### Select the implant area

Dig a hole





Click volume to enter scanning implant process (the scan body must be inserted in the implant position before scanning).



Lock the lower jaw's data (deep green), the unlock areas can be edited

Scan scan body





## Post-processed implant data



## 7.8.2.2. Scan Multiple Implant Teeth

When scanning multiple implant teeth, scanning by group is supported. The guidance will show how to avoid scanning two adjacent scan bodies, scan the first group of non-adjacent scan bodies and then another group of non-adjacent scan bodies.





On the interface of hole digging for implant jaw, users need to select the gingiva data of all implant teeth and delete it. Then insert the first group of scan bodies to scan. After the first group scanning is completed, click Pause, then click

to add another set of implant jaw scan.



Note:

If users move to scan the second group, the previous group data doesn't support further add-scan.

When you move to scan the second group, first group data is locked (in dark green). During the process of scanning the second group, the data of first group won't be changed even when the scanner scan the locked area. If there are more groups than two, do as what you do with first & second group.

Click the complete button 🧭 and finish the implant jaw scanning case.

If the implant jaw scan is completed, you can add scan to the upper/lower jaw. The implant jaw data can be imported with the following prompt window popping up.



7.8.3. Scan Total Jaws

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



Click

or press the space bar to start scanning. After scanning some data,

the software automatically performs dynamic bite alignment.



Before alignment

After alignment





After the upper and lower jaws' data are aligned successfully with the bite, click





Click the finish button or long press the space bar to post-process the data.

For the bite scan, you do not need to scan the entire jaws; you can just scan the bite of anterior teeth in 1 step, or you can scan the bites of both left and right posterior teeth in 2 steps (recommended), or you can scan bites for frontal anterior and left and right posterior teeth in 3 steps. You can stop the scanning once the jaws are aligned.

The maximum number of frames per step is 500 for the bite, and the software will be forced to stop scanning when it reaches 500 frames.

## 7.8.4. Occlusion Preposition

Occlusion preposition is supported during scanning, i.e., the total jaw can be scanned first.

Step 1 The total jaw scanning is completed. The total jaw icon is marked with an exclamation mark, indicating there is already data for the total jaw but alignment



unfinished.



Step 2 Automatically skip to upper jaw. Scanning upper jaw is checked and completed.



Step 3 Automatically skip to lower jaw. Scanning lower jaw is checked and completed.





Step 4 Automatically align the total jaw (align successfully). Rescan the total jaw if the auto total jaw alignment fails (marked with a red exclamation mark).





# 

• To collect data of dynamic bite, you need to collect data of static bite first.



- The areas of dynamic bite and static bite should be overlapped.
- The scanner tip should be at the center of upper and lower jaw when scanning.



• Make sure there are contacting points when biting.



Steps:



- 1. Click and enter the interface of Dynamic Bite.
- 2. Click and start scanning
- 3. Open mouth and scan the bite motion on the left and right.
- 4. Scanning completed, the video of dynamic bite is played automatically.



You can move the cursor and rotate the model to view the bite condition from different perspectives.

5. Click and save data of dynamic bite.

After saving, you will enter the pre-design interface of dynamic bite.



# 7.9. Pre-design Module

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

There are nine different functions in this module.



- View edit: Browse and edit data.
- Adjust coordinate: Manually adjust the reference coordinate system of the dental jaws, and adjust the dental jaws' data to the unified standard reference coordinate system (compatible with the exocad coordinate system); the middle of the upper and lower incisors' bite is the coordinate center, X axis points outward (pointing to the observer), Y axis points to the right (observer's perspective), upward direction is positive on the Z axis, forming the right-handed coordinate system.
- Mark teeth: Used to manually mark the corresponding position of the teeth specified in the scan order in the scanned model for subsequent extraction of the margin line and detecting of the undercut.
- Occlusion check: Adjust and view the occlusal gap between the upper and lower jaws.
- Extract margin line: Extract and save the margin line of the marked (corresponding) teeth.
- Check undercut: Calculate and view the area of undercut of the marked (corresponding to the order) teeth.
- AccuDesign: AccuDesign software implement operations such as "hollow", "solid", adding drain hole and adding text labels to the model data obtained by Shining 3D company.
- Orthodontic simulation: simulate orthodontic treatment solution, and view the expected effect according to different treatment solutions.



• Dynamic Bite: Bite movement is displayed by videos.

## 7.9.1. Preview and Edit

Preview every ja	w and click to edit.	
	0000	
Model List	🚺 🍽 👘 👘 👘	5
✓ ────○		
· · · · · · · · · · · · · · · · · · ·		
· · · · · · · · · · · · · · · · · · ·	and the second sec	Ē
· · · · · · · · · · · · · · · · · · ·		*®
M H V A M M		99
		0
		9C
		•
Back to scan		Go to send

lcon	Name	Description
10572		When this button is clicked, it enters the edit interface to select
	Luit	the data to be deleted.
		Click to delete the smaller independent model data that are not
(X.47)	Remove isolated data	connected to the main model data. Help delete unrelated
		model data quickly.
		Use the feature to make the model complete. Enable the
99	Fill holes	feature to adjust the circumference of hole filling, and all holes
		within the circumference will be filled.
<b>M</b>	Texture	Obtain surface color of scanned objects.
٠	Smooth	Smoothing is denoising data to make grid data smoother.
	Fit view	Adjust the scanned data to the appropriate display size.



## 7.9.2. Adjust Coordinate

Click under the "pre-design" process to enter the interface. Position the model in each of the three views with reference to the dental arch diagram and the coordinate axes.



Instruction	Short-cut Key
Potato model	Press and hold the left (or right) mouse button, and
Rotate model	meanwhile move the cursor.
Movo modol	Press and hold the left and right mouse button, and
Novembder	meanwhile move the cursor.

Auto-align: Auto-align the model, suitable for full-mouth models.

Reset: Cancel the current model position and reset it to the original model position.

After adjusting the coordinates, click **Go to send** to upload data or implement other operations.



## 7.9.3. Mark Teeth

Click 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.

Select the tooth number in the tooth map and locate the corresponding tooth on the scanned model by double-clicking.



7.9.4. Check Occlusion



Click under the "Pre-design" process to enter the occlusion detection interface.

- The green color indicates there is a distance between the two jaws.
  - The red color indicates the touching area between the two jaws.
  - The blue color indicates the bite-through area between the two jaws.

Double-click on the point of the model to detect the occlusal gap at that point.







• Undo adjustment : Undo the bite adjustment operation.

## 7.9.5. Extract Margin Line

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

B Note

If you have ground the teeth, click (IM) to automatically extract the margin line. The interface will automatically divide and extract the margin line of the spare tooth.



Margin line not extracted

Margin line extracted

- Step 1 On the teeth position marking list, select a tooth.
- Step 2 Under tooth map, click to select margin line extraction method.

 Sectional view : The curvature of the profile along the tooth surface normal to the occlusion plane is displayed, and the effect is as follows.



- Drawing line extraction : Long press the left mouse key to draw a line, and release the mouse to extract part of the margin line, each drawn line is automatically connected with the previous one, and finally a closed margin line is extracted.
- Segment extraction :: Left click the mouse to generate a control point, move the mouse along the margin of the tooth, a line segment will be automatically generated between previous control point and current mouse position, left click to generate another control point; repeat the above steps before you set the final control point to overlap with the first one to form a closed margin line by double clicking.

# <u>ال</u> الم

Line segment extraction is a complementary tool for magnetic extraction, suitable for teeth with no clear margins.

• Magnetic switcher :: Used to control the magnetic suction function switch of the line segment extraction method. After the magnetic suction function is turned on, the line between the current position of the mouse and the previous control point will be automatically attached to the margin (large curvature), the attaching effect is related to the current mouse position; when you left click to add a new control point, the attached line segment between the first two control points will not change again, repeat the above steps before you set the final control point to overlap with the first one to form a closed margin line by double clicking. When the magnetic suction function is off, a straight line will be created between the current mouse position and the previous control point (i.e. line segment extraction). Magnetic suction extraction is suitable for teeth with clear margins.



Step 3 Edit margin lines to make them closer to tooth edges.

- Segment extraction mode : Move the mouse to the extracted margin line, the red point indicates the location of the control point, if you left click the mouse key, a new control point will be added; select a control point, the control point color changes from green to red, you can move or delete the control point.
- Draw line extraction mode : The newly drawn line replaces part of originally extracted margin line.



- Delete: Delete the currently extracted partial or complete margin line of the tooth.
  - Undo: Undo the last operation.



Redo: Restore the operation that has been undone.

## 7.9.6. Check Undercut



Click on the right side of the software to open the undercut interface.

You can rotate the model to the appropriate view, double-click the view or click



to recalculate undercut area.



#### 7.9.7. AccuDesign

On the pre-design interface, click **m** to enter the AccuDesign interface. AccuDesign is a model generation software. Use it to generate solid or hollow model out of the scanned data by 3D scanner. You can add attachments to the model, such as text, frame, and drain hole in a convenient way. And then export file for 3D printing.



#### 7.9.8. Orthodontic Simulation

When creating a new order, select the Dentistry Type as Orthodontics to enable

the orthodontic simulation function. On the pre-design interface, click to enter the orthodontic simulation interface.

Orthodontic simulation can be divided into pre-processing, tooth segmentation, and tooth setup.

## 읍 Note

When creating a new order, select the Dentistry Type as Orthodontics to enable the orthodontic simulation function.

## Pre-processing

Edit the model data to make preparation for tooth segmentation and setup.

lcon	Name	Description
<b>&gt;</b> -	Adjust Coordinate	<ul> <li>Check the center position from 3 perspectives.</li> <li>Press left mouse button and move to adjust the center position of the model.</li> <li>C: Reset the coordinates of upper and lower jaw to original position.</li> </ul>
	Trim Model	<ul> <li>Delete unnecessary scanning data of the model.</li> <li>Change the brush size by dragging the slide.</li> <li>Press left mouse button and move the cursor to delete model data.</li> <li>Scroll up and down the wheel to zoom in and out of the model.</li> <li>Press right mouse button and move the cursor to adjust the perspective of the model.</li> </ul>



•	Edit Surface	Remove image noise on the model and make the model
B		surface smoother. Improve the quality of data.
		Click Smooth, the surface will be smoother.
		Click Add, the surface will bulge.
		Click Decrease, the surface will sag.
		Minimum: The aperture can be zoomed in and out by
		dragging the slider.
<b>1</b>	Perspective	Check the model from different perspectives.
C * *	Control Panel	

## The tooth segmentation interface.



## No. Description

2

The upper and lower jaw number. The marked teeth is with white background labels; If the tooth position is not identified or has no teeth, it is with blue background label.

Displays the number of marked tooth positions. And distinguish each tooth by different colors.

Click the number on the tooth to delete, modify the number, edit the tooth area



and adjust the frame.

Icon	Name	Description
	Modify Area	If the tooth is not fully colored or too much color is
		painted, the tooth cannot be correctly identified.
		You need to manually adjust and edit the tooth
		area. Click Area to recolor the tooth.
	Adjust FrameAdjust	Professionals are required to readjust each tooth
¢.	Frame	direction. By three-dimensional coordinate system
		on each tooth, you can adjust the teeth
		orthodontics direction.
		<ul> <li>Press the grey origin and move the 3D</li> </ul>
		coordinate system.
		• Press left mouse button and move the cursor to
		adjust the direction of the coordinate.
	Change Tooth	Click the number on the tooth to change it.
ŝ	Number	
	Remove Teeth	1 Select the tooth needed to be deleted.
		2 Click to delete its mark.
		3 Click 💙 to confirm deletion.
-0	Add Tooth	Fill the teeth as needed.
		Click a missing tooth and add a tooth.
		You can set the tooth number and radius.
	Object Control	Choose to display tooth number, texture, frame
	Panel	and area or not.



Fill the teeth as needed. Double-click a missing tooth to automatically add a tooth. You can set the tooth number and radius.

## Click Tooth setup to enter the Tooth setup interface.

Tooth setup shows and visualize the effect of orthodontics. Features are following:

- You can create your own plans (Maximum is 3) and preview the effect.
- The process of orthodontics is displayed by animation.
- You can setup the teeth manually.



If you have set the teeth, you can switch to the **Tooth setup** interface by the navigation bar.



# Create a plan

lcon	Name	Description
	Fit views	Press Ctrl and select multiple plans. The treatment effect of
		plans is displayed by fit views.
Ħ	Measurement	Bolton Analysis: Refers to the proportion relation between the
		sum of crown widths of upper and lower anterior teeth and
		the sum of crown widths of all upper and lower dental arches.
		The proportion relation is divided into anterior ratio and
		whole ratio. Use the Bolton index to diagnose the
		incompatibility of tooth width between upper and lower
		dental arch. The Bolton index analysis assists in the diagnosis
		and analysis of the formation mechanism of malformation,
		and plays as a reference factor for treatment planning.
		Movement Overview: The amount of movement of each



		tooth after segmentation will be displayed.
	Rename	Rename the treatment plan.
ዋ	Upload	Export or upload your plan to Dental Cloud.
Ŵ	Delete	Delete the plan.



Play the whole process of orthodontic treatment. Preview the effect of different treatment plans.

# Manual Setup

You can set up the tooth manually.

lcon	Name	Description
÷	Move	Move the tooth.
Þ	Rotate	Rotate the tooth with tooth root as the origin.
0	Twist	Twist the tooth from side to side with the root as the origin.

lcon	Name	Description
•	Object Control Panel	Choose to display Arch Wire, Occlusion, Superimposed, Number, Frame, Jaw Plane, Adjacent Contact and Grids or not.





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#### 7.9.9. Dynamic Bite

Dynamic bite refers to the bite relationship between upper jaw and lower jaw in occlusion. Normally, other dental scanners collect data of static bite, which may pay less attention on occlusal problems with the impact of muscle stretching, joint motion and fissures.

Bite movement is displayed by videos.



Dynamic Bite is a additional function, please consult after-sales service.



and enter dynamic

After completing the dynamic bite scanning, click bite interface to preview the bite movement.

lcon	Name	Description
₩¢	Occlusion Detect	Check the occlusion situation.
Carls	Open Jaw	Choose contacting points in upper jaw and lower jaw
		for malocclusion cases.

## 7.9.10. Oral Report

Order report is convenient for doctors to understand patient treatment information.

Step 1 On the pre-design interface, click III. The Settings Of Examination Report interface is displayed.

Step 2 Select a hospital and a target.



## Step 3 Click **OK**.

Step 4 Record treatment details.

lcon	Name	Description
*	Data Screenshot	Take a screenshot of the scanning data.
		Click the button of screenshot and a black
		screenshot box is displayed on the right.
		Pressing left mouse button and move the
		cursor to adjust the screenshot area.
		Double click to confirm and enter
		description on the right box.
		Click Edit and select the treated tooth and
		problems if needed.
		Click to take more screenshots.
<b>P</b> 7	Endoscope Screenshot	Take a screenshot of the model.
		Click and the enlarged image window is
		displayed on the left.
		Scan teeth.
		Click Scanning or and take a
		screenshot of the picture displayed in the
		image window.
		Click Edit and select the treated tooth and
		problems if needed.
		Click vto take more screenshots.
23	CT Mode	Add an image and edit it. Treatment plan
		and other information of the treated teeth







		Mode. Share: Create a QR code, which when scanned with the phone will view the report. Export: The report will be exported in PDF.
AI beta	AI Recognition	Al recognition will automatically detect teeth problems and take screenshots of certain teeth. Only the target is adult the "Al Recognition" can be enable.



- The maximum number of screenshots taken in a report is 12.
- If the order hasn't been bound with lads, it can export to ExoCAD, DentalWings and 3<sup>rd</sup> Paryt.

## 7.9.11. Audit Report

Before accepting the order, the target lab could check it and feed back the audit report. When the lab accepts/refuses the order, there is a red dot prompt for the order in the software interface. The red dot disappears after viewing the report. If the order is refused, doctors could check it in time and send a new order after revising.



	3/22				
Re	efused	- Ander		100000 0000000000000000000000000000000	
Order Number	Patient Name	Dentistry Type	Order State	Create time	Operation
Order Number 008	Patient Name 008 007	Dentistry Type Check Restoration	Order State Waiting to send Waiting to send	Create time 4/13/22 3:48 PM 4/13/22 3:34 PM	Operation
Order Number 008 007 006	Patient Name 008 007 006	Dentistry Type Check Restoration Restoration	Order State Waiting to send Waiting to send Refused	Create time 4/13/22 3:48 PM 4/13/22 3:34 PM 4/13/22 2:17 PM	Operation
Order Number           008           007           006           005	Patient Name 008 007 006 005	Dentistry Type Check Restoration Restoration	Order State Waiting to send Waiting to send Refused Waiting to scan	Create time 4/13/22 3:48 PM 4/13/22 3:34 PM 4/13/22 2:17 PM 4/13/22 11:34 AM	Operation

Check the result of the order on the main interface.

If the order is rejected, copy the order to revise and send it.



Click to check the audit report on the main interface. After closing the audit report, you can review the audit report again by clicking on the right side of the Pre-Design interface.



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Click the QR code icon in the upper right corner of the audit report and scan the QR code on your mobile phone to view the report.



# 8. Use Tool Sets

# 8.1. Use DentalViewer

On the start menu select "DentalLauncher->DentalViewer" to open DentalViewer as follows. Select .stl, \*.obj, \*.beb, \*.ply (the latter two data are specific data generated by IntraoralScan) files and drag them to the DentalViewer interface to open the data.





1 Data list: Click to display/hide data.

2 View list: Front view, back view, left view, right view, top view, bottom view and fit view.

③ Software operation list: Texture, Smooth, Free Select, Box Select, Brush Select, Reverse Select, Cancel Selection, Delete, Undo, Redo and Save.

## 8.2. Use ScanBinder

On the start menu select "DentalLauncher -> ScanBinder" to open the scan binder.

Support binding of exocad and dentalwings design software.

● Exo	O dental wings	
Please select E	xo executable file DentalDB.exe	
		Select
	Dind	



Select the path of DentalDB (supporting Chairside 2.1, exocad 2018, 2019 and 3.0), and click **Bind**, and when **Bind Scanner Succeed** pops up, it is indicated that the binding is successful.

Start the DentalDB program, create an order, save and scan.



Start the scanning software for scanning and data processing. After the data processing is complete, click **Go to Send** to open the send interface, and select the target lab to send.

# 8.3. Use Dongle Authorization Tools

Insert Dongle into the computer, select the start menu "DentalLauncher-> SentinelUpdate" and open the Dongle authorization tool, as shown below.



1 Proxy: Network proxy parameter setting. If the client network uses



a network proxy, select the corresponding Type: http/socks5 and fill in other parameters. If no network proxy is used, use the default none.

2 Key: Enter the serial number of the Dongle.

③ Register: Complete the input and select this button, and wait for a few seconds for authorization update. The Dongle authorization update is successful when the update successful prompt is shown.



# 9. Use Dental Cloud

## 9.1. Introduction to Dental Cloud

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

Visit the website at: http://www.dental3dcloud.com.

## 9.2. Case Workflow

1. Labs register as a lab account on the website and log in.

2. Doctors register as a doctor account on the website and send a request to the labs to establish a network. And then the status of the connection is **Order Taking Awaited**.

3. Labs accept the request, then the status of the connection is "Active".

4. Doctors open the IntraoralScan software, go to **Setting->Set account** in dental order system, enter the account name and password to log in. After the scan data processing is completed, the doctor can upload the data.

5. Labs can download the data on website.

# 9.3. Register an Account

It is recommended to open the dental cloud website using browsers such as Chrome, Firefox, and Safari.

Password		Ø
7 Pamambar P	aceword	
	Sign up   Forgot	password

Click "Sign up" in the homepage.





"Create new account", select the registration type.

♦ I am a lab: Register as a dental laboratory.

♦ I am a hospital/clinic: Register as a hospital/clinic.

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

Fill in the 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 specified in the application form).




After the registration is successful, it will get back to homepage. Enter the mailbox or mobile phone number and password to log in to cloud platform. The hospital, clinic and doctor's account can establish a network connection with a lab.

## 9.4. Account Management

After logging in to your account, click the Account on the upper right corner. Then select **Account Setting** from the drop-down list.



#### Account Setting

#### My Profile

YOU CAN MAINTAIN YOUR PROFILE FROM HERE

Contact	Nick
Email	22- Change or bind email
Mobile	Change or bind mobile number
Password	Change Password
Country	· · · · · · · · · · · · · · · · · · ·
anguage	English Language Setting
nform Setting	Inform Setting
Default setting for order taking Marketing and	Confirm to take order once downloaded
Promotion Agreement	Read and agree our Marketing and Promotion Agreement(Optional) Receive useful product updates, software news and other relevant information
ign Up On	2021-08-23T06:13:44.369266Z
ast Login On	2021-08-23T06:14:04.947497Z
ast Login IP	60.191.66.42

On the "Account Setting" page, you will find:

- 1 Contact: You can edit the contact name.
- 2 Email: You can choose to change or bind email.
- 3 Mobil: You can change or bind mobile number.
- 4 Password: You can change the password.
- 5 Language: You can set the language to Simplified Chinese, English, Japanese.

## 9.5. Establish a Relationship Network

The network establishing request can be created by any account and then the lab can accept or reject the connection request. The account that created



relationship can only upload the order data to the laboratories that accept the connection request.

After logging in, select **Connections** in the upper right corner of the interface to create a new connection.



Hospital: Select the hospital.

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

After submitting the request, you will find that relationship status of the newly created relationship is "to be confirmed". You need to wait for the lab to accept the confirmation. Once accepted by the lab, the relationship status turns to "active". Only after the relationship is confirmed by the lab can dentists send scan data to the lab.

## 9.6. Manage Institutions

Only the account that is authorized can have the access to manage institutions member and information.

#### 9.6.1. Institution Member Management

On the Members interface, you will find:

Members	unt name, email, r	nobile phone numb	er, or the name of	2 Search Re	set					0	New
Belongs	Name	Mobile	Email	Is admin	Sign Up On	Status	Action		4	6	
suunylab				n	2020-09-15 02:11:33	Active	🖪 Devices Setting	Ocnnections	ය Set as admin	Delete	
suunylab		18:		У	2020-09-15 01:45:05	Active	🖪 Devices Setting	Ocnnections			
001		183		У	2020-09-15 01:45:05	Active	<b>B</b> Devices Setting	Connections			
Total: 3											

1 New: Click it to add a new member.





suunylab		+
Select the insitutio insitutions or choo administrator	n to join for the member wher se the institution to set the m	n there are multiple ember as its
い +86 中国(	China	~
Email or phone		
Please input your i the correct country exists, the account but the password doesn't exist, acco	nobile phone or email address code above. If the mobile ph t will be automatically added t and other information will not unt will be created automatics	a. Please pay attention to one or email already o the selected institution, be changed. If the user ally and default password

50

• Institution name: Enter/select the name of institution that you want to

add. You can also click



- Account member: Enter the phone number of E-mail of the new member.
- Set as admin: You can set the new member as admin. This option is not ticked by default. After submitting it, if the member account is a new account, the account will be registered with a default password of 888888. And the newly added members to the institution are all in "to be confirmed" status. Only after the member is logged in and confirm the request can the status turn into "Confirmed" and the institution sources can be used.
- 2 Search: Enter the account name, email address, mobile phone number or the name of lab/clinic, then click "Search" to get required member list.
- ③ Reset: Click it to clear all filter requirements and then all members are shown in the list.
- ④ Set as admin: If the member is not assigned as "admin" when you add the member, you can click "Set as admin" for this member. If the member is "admin" when you add the member, you can click to set the member as non-admin member.



5 Delete: Click to delete the member from the institution. After deletion, the member account is still valid.

#### 9.6.2. Institution Information Management

Click "institution setting" on the left panel, then the institution setting interface is displayed if the admin account has only one institution. If the admin account has more than one institution, then the **Choose institution to set up** interface is displayed.



Select the institution and click Confirm.

9.6.2.1. Basic Information

Basic information	Custom order	
Name	suunylab	
Туре	Lab	
Address.		
Contact		
Contact information		
Setting on new order notification	ply(vertex color) x	1
format Note: If you choose th	e 3shape format, you need to inform the doctor to save the third-party settings in the software, otherwise your settings will prevent you from downloading the target data in this format.	
Save Reset		

- 1 Address: You can type in the address in the text box.
- 2 Contact: You can type in the contact name in the text box.
- ③ Contact information: You can type in the contact info in the text box.

### 9.6.2.2. Custom Order

If you have an OEM cloud platform, you can customize the web page contents.

You can select "Institution setting > OEM setting" to set the info on the left panel.

Basic information	Custom order			
		repair Orthodontics	Engli 🖕	release



## 9.7. Case Management

#### 9.7.1. Preview and Download Case

After logging in to the account, the **Cases** interface is displayed by default.

Cases											
🔍 Filter	according to doctor's na	me, account n	umber, hospital,	Ch	loose type	•	Upload b	etween	Fail to con	vert Search R	leset
All	Order Taking Awaited	Draft	Design includ	led Lo	gistics included	Messages inc	luded E-form	included C	anceled		
Created On	Doctor	Hospital/Clinic	Lab	Patient	Туре	Action	0	0			
2021-08-18 15:20:25	11 Doctor001		suunylab	003	Restoration	Download	Messages	Details		≜ Upload Design	🛱 Ship
2021-08-18 15:19:16	11 Doctor001		suunylab	005	Restoration	🛆 Download 🛱 Ship	🗩 Messages	🚯 Details	Confirm Received	🕵 Withdraw Order	≜ Upload Design
2021-08-18 13:37:08	11 Doctor001		suunylab	001	Restoration	🛆 Download	● Messages	Details	Confirm Received	Withdraw Order	≜ <u>≢</u> Upload Design

 Download: Labs/dentists can download the data that is uploaded to the cloud platform. The data format including ply, stl, obj and beb (original encrypted data format).

			🙊 Send MSG Now	× Close
Download	Project Files			
Messages	Origin: 2021-08-18_001_003(2).zip C ➡ Other format	$\overline{\mathbf{A}}$		
Screenshot	obj(for Maestro3D): 2021-08-18_001_003(2)_color1_obj.zip	$\star$		
Preview	stl: 2021-08-18_001_003(2)_stl.zip	$\overline{\mathbf{A}}$		
	ply(vertex color): 2021-08-18_001_003(2)_color_ply.zip	$\overline{\mathbf{A}}$		
	stl(for 3Shape): 2021-08-18_001_003(2)_3shape_stl.zip	$\overline{\mathbf{v}}$		

② Messages: For each order, dentist and lab can have chats on the webpage. You can click it to send messages as below picture shows. You can send texts and files.

	🙊 Send MSG Now 🛛 X Close
Download	
Messages	Content
Details	
Screenshot	
Preview	
	Add attachments Drop files here or C c click upload
	Send

③ Details: Click "Details" on the "Cases" page or select "Download->Details". The following page is displayed. You can check the details of the order



including: Order number, date on which the order is created, updated date, hospital/clinic/lab name, etc.



④ Screenshot: You can click "Download->Screenshot" to check the screenshot of all the data from this order. You can check the data from two views.



(5) Preview: Click "Download" on the "Cases" interface, click "Preview" and the following interface is displayed. You will find all the scan data from this order. You can click right button of the mouse to rotate the scan data. You can check different scan data on the left panel.



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### 9.7.2. Check Order Status

You can check the order status in the order list.

Cases 🔍 Filter acco 📋 Upload betweer Reset 1 All r Taking Awaited Draft esian included aistics included Messages i Created On Dector Lab Type 2021-08-18 003 Restoration ● Messages Details 🐼 Withdraw Order ▲ Upload Design E Ship Download Doctor001 suunylab 15:20:25 Details Confirm Received 🐼 Withdraw Order At Upload Design Messages 2021-08-18 11 suunylab Restoration Doctor001 15:19:16 🖬 Ship C Download Messages Details Oconfirm Received 🛇 Withdraw Order At Upload Design 2021-08-18 suunvlab 001 Restoration Doctor001 13:37:08 Ship

- 1) All: You can find all the orders' status.
- ② Order Taking Awaited: You can find all the orders that are not taken by labs.
- ③ Draft: View draft info.
- ④ Design included: You can check the orders whose design has been uploaded by labs.
- (5) Logistics included: You can check the orders whose logistics info has been uploaded by labs.
- 6 Message included: You can check the orders for which the messages have been sent by doctor/lab.
- (7) E-form included: View E-form data.
- (8) Canceled: If the lab does not confirm the order sent by the doctor, the doctor can cancel it. Then the order status will turn to "Canceled" and labs will not see the order upload record. The order canceled will be displayed in the "Canceled" list here.



#### 9.7.3. Check and Reset Order

Cases	0			2			3					
R Filter accord	ding to doctor's name	e, account number, hosp	pital, Ch	oose type	Ŧ	Upload betv	veen	Fail	to convert Search	Reset		
All Order	Taking Awaited	Draft Design in	icluded Lo	gistics included	Messages in	cluded E-form in	cluded Cance	led				
Created On	Doctor	Hospital/Clinic	Lab	Patient	Туре	Action						
2021-08-18 15:20:25	11 Doctor001		suunylab	003	Restoration	Download	🗭 Messages	🚯 Details		∧± Upload Design	🛱 Ship	
2021-08-18 15:19:16	11 Doctor001		suunylab	005	Restoration	▲ Download	🗭 Messages	1 Details	Confirm Received		∧± Upload Design	🔁 Ship
2021-08-18 13:37:08	11		suunvlab	001	Restoration	Download	Messages	Details	Onfirm Received	C Withdraw Order	At Upload Design	5 Ship

Search: You can type in doctor name, account, hospital name, lab name, patient info in (1), and select the restoration type from the drop- down list (2), and select the upload date in (3), then click **Search** to check the required order list.

Reset: You can click **Reset** to clear all filter requirements and then a list of all orders is displayed.



## 10. Care and Maintenance

## 10.1. 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



• 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 the 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 the 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 dust cap.



## 10.2. Scanner Cradle

The scanner cradle requires an intermediate-level disinfection.



• 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 scanning.

• 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 then the scanner tip.

• 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.

(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.

## 10.3. Scanner Body

The scanner body requires an intermediate-level disinfection.



• 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.

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

Follow the steps below to complete the disinfection.

(1) Disconnect the power.

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





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 dust cap with the triangle mark facing upward. Then, align the dust cap blocks to the matching slots on the front end of the scanner body.



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



Caution



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 dust 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.



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.

Figure 8-6



- (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.

## 10.4. Scanner Tip

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.



• 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 under high temperature 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:

- Cleaning and high-level disinfection
- Cleaning and steam sterilization

### 10.4.1. Cleaning and High-level Disinfection

Follow the steps below to perform cleaning and high-level disinfection:

(1) Disconnect the power.

(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.







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 dust cap with the triangle mark facing upward. Then, align the dust cap blocks to the matching slots on the front end of the scanner body.



(4) Slide the dust 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.

# ⚠ <sub>Caution</sub>

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<sup>®</sup> Solution. Do not spill any of it.



Read the CIDEX OPA<sup>®</sup> manufacturer's instructions and warnings thoroughly before usage.

Caution

• 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 (no longer than 30 mins recommended) 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 scanner tip (inside and outside).

(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. 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.

#### 10.4.2. Cleaning and Steam Sterilization

Follow the steps below to perform cleaning and steam sterilization:

(1) Disconnect the power of the Aoralscan 2.

(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.

# 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 dust cap with the triangle mark facing upward. Then, align the dust cap blocks to the matching slots on the front end of the scanner body.

(4) Slide the dust 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 scanner tip (inside and outside) 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) Fill the scanner tip lens with medical gauze.

(13) Put the wrapped scanner tip into an autoclave and sterilize it for 30 minutes at 121°C (or 4 minutes at 134°C). For the specific sterilization pressure, refer to the instructions of the autoclave (102.9kpa at 121°C is recommended; Or 205.8kPa at 134°C).

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

(15) Reattach the scanner tip.

#### 10.4.3. Attach 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.



- Wear clean surgical gloves before you start.
- Ensure that the scanner cradle, scanner body, and scanner tip are pre-cleaned and disinfected/sterilized.

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.

## 10.5. Storage

In case you need to transport the device, we strongly recommend that you keep the original



packaging after unpacking the Scanner. Shipping the device without its original packaging material may cause possible product damage and result in additional service fees.

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.

#### 10.5.1. Transportation Storage

• Make sure that the scanner is clean 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.

#### 10.5.2. 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 dust cap.

• Ensure the scanner is clean 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.



## 11. Hardware Specification

## 11.1. Specifications

Parameter	Description					
Model	Aoralscan 2					
Scanner						
Scan range	11 mm × 11 mm					
Scan theory	Non-contact scanning with the structured light					
Dimension (L $\times$ W $\times$ H)	nension (L $\times$ W $\times$ H) 280 mm $\times$ 40 mm $\times$ 55 mm					
Weight	< 325 g (without cable)					
Output format	STL, OBJ, PLY					
Connector	USB 3.0					
	Input: 100V-240V/0.45A-0.27A					
Power	Output: 12 V DC/1.67 A					
Lifecycle 8 years						
Cradle						
Dimension (L $\times$ W $\times$ H)	265 mm × 82 mm × 55 mm					
Weight	800 g <u>+</u> 50 g					

## **11.2. Environmental Requirements**

#### **Operating and storage requirements**

- Operating temperature: 10°C to 40°C
- Storage/Transport temperature: -25°C to 60°C
- Operating altitude: < 3000 m
- Storage/Transport/Relative humidity: 30%–75%
- MTBF: 10,000 hours (except light sources)
- Air pressure: 86 kPa–106 kPa