SHINING 3D®

Aoralscan 3i Wireless Manual

CE MD

V1.1

Foreword

General

The Manual introduces the functions, installation, usage and maintenance of the Aoralscan 3i Wireless (hereinafter referred to as "the Scanner").

Safety Instructions

Signal	Meaning
	Additional information for particular situation.
	Improper actions or conditions that may damage the product or cause injury, and consequently void your warranty or service contract or lose the patient data or system data.
	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, or even death.

Release Date

Release Date	
Version	1.1.3

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Catalog

1. Read This First

Aoralscan 3i Wireless 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.

The intraoral scanner is also intended for aid in detection of interproximal carious lesions on the teeth by near infra-red imaging.

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 the information from Safety Information in chapter 2.

1.1. Basic Information

I. Product name and model

Product name: Intraoral Scanner

Model: Aoralscan 3i Wireless

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

III. Contact Information

Manufacturer

Shining 3D Tech Co., Ltd.

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

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Email: peter@lotusnl.com

Product performance

- Appearance and structure

The appearance should be smooth and has no cracks, no stains, and no obvious deformation. It must be flexible and reliable for operation.

- Function control and display

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

The scanner has the function of 3D image processing.

Scanning speed: It takes no more than 3 minutes to scan a single jaw model.

Calibrator: With its self-checking function, the calibrator can check whether its inner components work normally.

Battery charge: The user can charge the device.

Wireless connection: With its wireless transmission function, the user can connection the scanner and computer without wires.

-Software Function

The software provides guidance for the users to understand the operations. It has backward function as well.

The users can add requirements of jaw, tooth and treatment.

The software will scan teeth according to the requirements.

It allows users to edit the scanned data such as repairing holes and selecting data.

The functions include Tooth Preparation Monitoring (optional), checking undercut, bite areas and texture, and smoothing the model (optional), orthodontic simulation (optional), AccuDesign (optional), checking oral report (optional), automatic calibration(optional) and near-infrared imaging.

The software displays the battery status of the device in real time. When the battery is lower than 20%, the software will remind the user. Please replace the battery when it is lower than 10%.

The software displays the device status in real time.

The software displays the device temperature in real time. When the device is too hot, please stop using it and put it back to the cradle.

The camera window automatically adopts the scanner types.

-User Access Control

Normal user access control. Users can log in via their login name and password.

-Performance

Dental scan imaging: The scanner scans the teeth, gingiva or a teeth model to form a 3D digital model and the users can check the 2D and 3D imaging of the scanned object (such as teeth) on the display respectively.

Accuracy: Under normal conditions, the scanner is used to scan a standard (e.g., a plaster standard known to be similar in size to a tooth), obtain its three-dimensional stereoscopic data, and measure key dimensions to obtain measured values.

Heating of the entrance part of the scanner tip: Under normal working conditions, the intraoral scanner should have heating and anti-fogging function when entering the mouth.

Quick heating of the scanner tip: The scanner tip can be heated within 30s.

-Environment Requirements

- Data interface

Transmit the information and acquire the image by a wireless module or a USB cable.

Data storage format shall include 3D digital model format .stl, .ply and .obj.

Main Structural Composition

The Scanner consists of scanner body, scanner tip, power adapter, cradle, USB cable, calibrator (optional) , rechargeable batteries, charging case (optional) and software. The software carrier is USB flash drive, and the software release version is 3.

⚠ Caution

- 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 cards to get the best scanning effect.
- Do not insert a wireless USB network card in the computer. The USB wireless network card will cause USB bandwidth occupation and affect camera's performance.

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

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

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

3) After using the scanner tip, use alcohol to wipe it and then use an autoclave to sterilize it. (121°C, 102.9kPa for 30 minutes; 134°C, 205.8kPa for 4 minutes). Use alcohol to wipe the scanner body. Use dust-proof cloth to wipe the scanning window and keep it clean and dry.

4) special storage/transportation conditions and operating conditions: For more details, see 8.2.

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

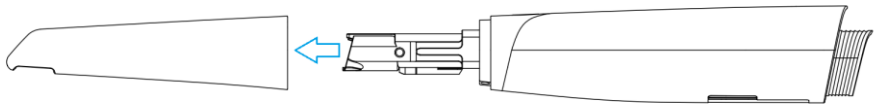
VI. Production date and life cycle

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

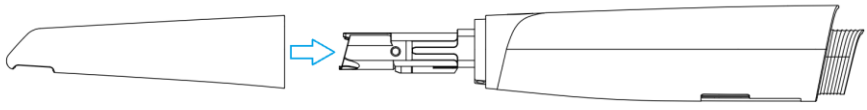
VII. The list of accessories, including accessories, wear and tear replacement cycle and instructions on how to replace.

Scanner tip as a consumable can be recycled up to 100 times, and then it needs to be replaced.

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



(2) Hold the scanner tip firmly with your thumb and index finger on both sides 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. Otherwise, it might cause damage to the lenses.

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

 Caution

- The Aoralscan 3i Wireless intraoral scanner should not be used when it is around or stacked with other equipment, and if need be, observe and ensure it works well with the configuration in use.
- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.

1.2. Intended Use

This is an scanner that works with the supplied software programs. By performing scanning directly and digitally acquiring and saving the 2D/3D color images of teeth, gingiva and oral mucosa, the Scanner is available for patients with needs of orthodontic, implant, and restoration. The intraoral scanner is also intended for aid in detection of interproximal carious lesions on the teeth by near infra-red imaging.

 **Note**

- 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, thus facilitating comfortable data capturing for patients, reducing stress for medical care, and improving efficiency for following processing.
- The scanner satisfies CE related requirements.

 **Warning**

- 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

Photosensitive epilepsy patients. There is a risk of epileptic shock from the flashing light of the scanner.

1.4. Warnings

Before using the Aoralscan 3i Wireless, read warnings and Safety Information on chapter 2.

- 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 accidentally drops to the ground, check to make sure the lens is not loose before using it.
- If the scanner accidentally drops to the ground or it is 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 on, 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 when it is around or stacked with other equipment, and if need be, observe and ensure it works well with the configuration in use .
- Do not repair or maintain the product components when scanning the patient.

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.

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 3i Wireless. 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 disregarding 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 4.1 Connect the Scanner.
- Use only medical grade devices with the scanner in the medical 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 dissemble the scanner privately.
- 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 inspections and tests must be conducted to ensure normal and safe use.
- Check the scanner and components for sharp edges.
- Before use, 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 use, always pay attention to abnormal conditions of the scanner and the patient. In case of abnormal conditions, you need to stop using it immediately and consult technical support staff promptly.
- To ensure the performance and safety of the scanner, use only the original accessories provided for the scanner (or accessories specified by Shining 3D, consult technical support for details) and software.
- 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 might

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.
- The scanner is intended for use in Professional healthcare facility environment and home healthcare environment.
- 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 of the scanner tip immediately and do not use the same tip again. The lens in the tip might shatter into small pieces, and using it again may causes serious injury to the user and patient.
- The scanner might heat up to above the normal body temperature, yet this short-term and small-scale contact will not pose a health or safety hazard to the patient.
- 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 of 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 Corporation.
- Do not put the equipment where it is difficult to disconnect the device.

2.2. Labels and Symbols

Table 2-1 Labels and symbols on the scanner/carry box/package

Symbol	Explanation

	Indicate that the contents of the transport package are fragile and the package shall be handled with care.
	Indicate that the transport package shall be kept away from rain and in dry conditions.
	Indicate correct upright position of the transport package.
	Indicate that the marked item or its material is part of a recovery or recycling process.
	Indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Indicate the acceptable upper and lower limits of atmospheric pressure
	Indicates the medical device manufacturer.
	Indicate the date on which a product was manufactured.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Device fulfills the requirements of the European Regulation 2017/745 given on the EU Declaration of Conformity.
	Indicate the item is a medical device.
	Class II equipment.
	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
	Class 1 laser product.

	Signify that the instruction manual/booklet must be read.
	Indicates the need for the user to consult the instructions for use.
UDI	Indicate the unique device identifier information.
	Indicate the entity importing the medical device into the locale.
RESET	Click ”Reset”, and the default parameters will be restored.
Rx only	US Federal Law restricts this device to sale by or on the order of a licensed Dentist or Dental Professional. The system serves as a prescription medical device and should be operated by qualified health-care providers only.
EC REP	Indicates the authorized representative in the European Community/ European Union.

2.3. Compliance

Anyone creating or changing a medical electrical system through a combination with other devices in accordance with standard 60601-1:2005+AMD1:2012+AMD2:2020 Medical 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

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

(1) This device may not cause harmful interference;

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

Note

- The guarantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  • Reorient or relocate the receiving antenna.
  • Increase the separation between the equipment and receiver.
  • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  • Consult the dealer or an experienced radio/TV technician for help.
- This device complies with FCC radiation exposure limits set forth for an uncontrolled rolled environment. Cradle should be installed and operated with a minimum distance of 20cm between the radiator and your body.
- This device for operation in the band 5150-5250 MHz is only for indoor use.

2.5. ISED Compliance

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

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est

susceptible d'en compromettre le fonctionnement.

2.6. Electrical Safety

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

2.6.1. Electrical

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 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+AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 Medical electrical equipment–Part 1-9: General requirements for basic safety and essential performance–Collateral Standard: Requirements for environmentally conscious design
- IEC 62366-1 2015+AMD1:2020 Medical devices–Part 1: Application of usability engineering to medical devices

2.6.2. Classification

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

 Warning

- 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 (see Contact Information on Chapter 1).
- To avoid risk of electrical shock hazards, always inspect the scanner and cable connections before use.
- Check the cable housing before use. Do not use the scanner if the housing is damaged or the cable is abraded.
- Scanning with the device in a 40℃ environment (for 1-10 minutes), the temperature of the scanning tip or the surface of the device may exceed 41°C but will be maintained below 48°C.
- All devices connected to the Aoralscan 3i Wireless shall comply with IEC 60950.
- The radiation characteristics of the scanner is suitable for use in all locations, including domestic and direct connection to the residential public low-voltage supply grid for domestic use.(CISPR 11 Class B).

2.6.3. EMC Notice

Caution

- Aoralscan 3i Wireless meets the EMC requirements.
- Users should install and use the product according to the EMC information provided in the attached file.
- Aoralscan 3i Wireless might affect the performance of a portable or mobile RF communication device. Avoid strong electromagnetic interference when using the scanner, such as when it is near a mobile phone or microwave oven.
- The guideline and manufacturer's statement are shown in the attached table.

Warning

- The Aoralscan 3i Wireless intraoral scanner should not be used when it is around or stacked with other equipment, and if need be, observe and ensure it works well with the configuration in use.

- With the exception of cables sold by the manufacturer of Aoralscan 3i Wireless 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 3i Wireless.

No.	Name	Length(m)
1	Power line of adapter	1.5
2	Power line of scanner	2.0
3	Cable of calibrator	1.5
4	Cable of cradle and computer	1.0

Essential Performance

The device does not have the essential performance. During the EMC testing, pass and fail criteria is: There should be normal communication and normal collect to images of the tooth model during continuous scanning.

Electromagnetic Emissions

Medical electrical equipment such as the Aoralscan 3i Wireless requires special precautions regarding electromagnetic compatibility, and must be installed and put into service according to the following electromagnetic tables.

The Aoralscan 3i Wireless is intended for use in the electromagnetic environment specified below. The customer or user of the Aoralscan 3i Wireless should assure that it is used in such an environment.

Table 2-2

Guideline and Manufacturer's Statement - Electromagnetic Emission	
Aoralscan 3i Wireless is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3i Wireless should ensure that it is used in this electromagnetic environment:	
Emission Measurement	**Conformity**
RF emissions CISPR 11	Group 1

RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker according to IEC 61000-3-3	Applicable

Interference immunity

The Aoralscan 3i Wireless is intended for use in the electromagnetic environment specified below. The customer or user of the Aoralscan 3i Wireless should assure that it is used in such an environment.

Table 2-3

Guideline and Manufacturer's Statement - Electromagnetic Immunity		
Aoralscan 3i Wireless is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3i Wireless should ensure that it is used in this electromagnetic environment:		
Immunity test	**IEC 60601 test levels**	**Compliance level**
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
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s)	±0.5, ±1kV line(s) to line(s)

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in UT) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T (100% dip in UT) for 1 cycle and 70% U_T (30% dip in U_T) for 25/30 cycles At 0° 0% U_T (100% dip in U_T) for 250/300 cycles	0% U_T (100% dip in UT) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T (100% dip in UT) for 1 cycle and 70% U_T (30% dip in U_T) for 25/30 cycles At 0° 0% U_T (100% dip in U_T) for 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

Table2-4

Guideline and Manufacturer's Statement - Electromagnetic Immunity		
Aoralscan 3i Wireless is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3i Wireless should ensure that it is used in this electromagnetic		
Immunity test	**IEC 60601 test levels**	**Compliance level**
Radiated RF EM fields IEC 61000-4-3	3V/m 10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3V/m 10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15MHz to 80 MHz 6 V in ISM bands between 0.15MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15MHz and 80 MHz 80% AM at 1 kHz

Table2-5 RF wireless communication equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460，FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900,TETRA 800,IDEN 820,CDMA 850,LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800;CDMA 1900;GSM 1900;DECT;LTE Band 1,3,4,25;UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic transmission is affected by absorption and reflection from structures, objects and people.
[a] 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 3i Wireless is used exceeds the applicable RF compliance level above, the Aoralscan 3i Wireless should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Aoralscan 3i Wireless. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. [c] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Table2-6SIP/SOP PORT

Phenomenon and standard	**IMMUNITY TEST LEVELS**	
	Professional healthcare facility environment	**Home healthcare environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2，±4，±8，±15 kV air	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15MHz to 80 MHz 6 V in ISM bands between 0.15MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15MHz and 80 MHz 80% AM at 1 kHz

Table2-7 Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL(A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation 2,1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7,5

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 3i Wireless farther from sources of electromagnetic interference or to install electromagnetic shielding to block unwanted interference. The customer or the user of the Aoralscan 3i Wireless should operate the device under EMI conditions that minimize power supply transience, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

Separation distances

The Aoralscan 3i Wireless is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aoralscan 3i Wireless can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aoralscan 3i Wireless as recommended below, according to the maximum output power of the communications equipment.

The medical electrical equipment is suitable for the professional healthcare environment and home healthcare environment per 60601-1-2. It is suitable for use in physician offices, clinics, hospitals, and other professional healthcare environments except where it is 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.

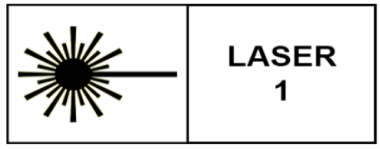
 Warning

- 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 3i Wireless, 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. The lower minimum separation distance shall be calculated using the equation specified in IEC60601-1-2 Chapter 8.10.

2.7. Biological Safety

Meets biological criteria: ISO10993-5: 2009 (Biological evaluation of medical devices — Part 5:Tests for in vitro cytotoxicity); ISO10993-10: 2021 (Biological evaluation of medical devices — Part 10: Tests for skin sensitization); ISO10993-23: 2021 (Biological evaluation of medical devices — Part 10: Tests for irritation)

2.8. Laser Protection



This product is a class 1 laser product and is only for maintenance, replacement and removal by professional personnel of the manufacturer or its designated agent (if necessary). If the device is not used, removed or replaced as required, the normal use of the device may be affected and laser radiation may occur. If a laser component is faulty, contact the manufacturer for help.

This product is a class 1 laser product according to "IEC 60825-1:2014 Safety of laser products-Part 1: Equipment classification and requirements", without harmful laser radiation. Users will not be exposed to laser radiation if they operate the equipment correctly according to the instructions.

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.

3. Scanner

3.1. Brief Introduction

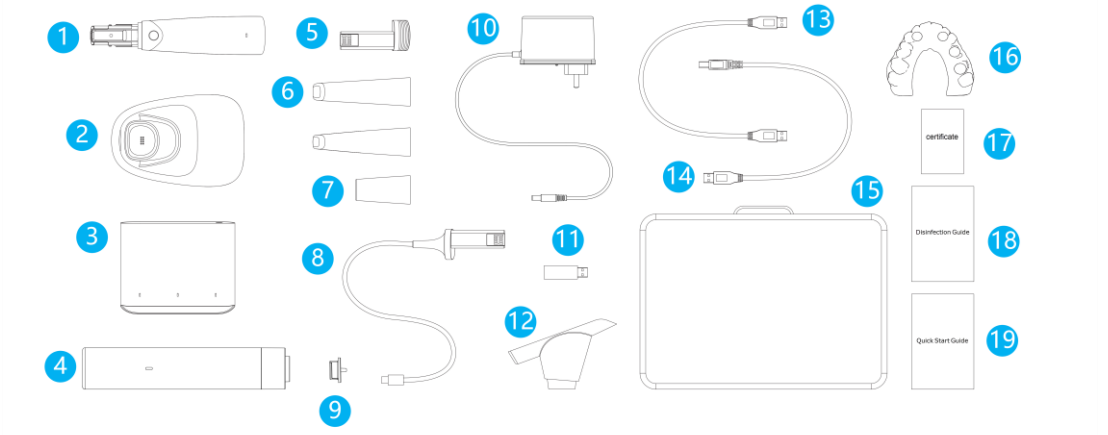
The Aoralscan 3i Wireless is designed to provide powder-free intraoral color scanning with higher speed of 20 FPS, thus bringing greater accuracy and less time-lag for image acquisition. It can be used to scan a single tooth, multiple teeth, and whole dental arches. Dental Order System Module helps manage the patient information and share data with others. Scan module assists you in acquiring 3D digital images of teeth and soft-tissue areas, and supports exporting scan data (in STL/OBJ/PLY format) to CAD/CAM systems for different purposes of dental care.

3.2. 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.

Note:

The following figures in the parts list are for reference only. The actual product shall prevail if there is any inconsistency.



No.	Name	Description
1	Scanner	Data collection.
2	Cradle	1.The scanner can be put on the cradle. 2.A wireless AP. 3.Charge the scanner when it is wired.
3	Charging case	Charge the battery.
4	Calibrator	Calibrate the scanner, including a dust cover.
5	Battery	Wireless power supply.
6	Scanner tip	4 standard tips and 1 mini tip
7	Dust cap	For the scanner
8	Spare cable	A detachable spare USB 2.0 cable for connecting scanner and cradle.
9	Dust cap	For the calibrator.
10	Power adapter	Charge the cradle and the charging case.
11	USB flash drive	The software package is contained.
12	Transfer Bracket	The scanner can be put on the bracket when it is wired.
13	USB cable	Connect the calibrator with the computer.
14	USB cable	Connect the cradle with the computer.
15	Package box	/
16	Practice model	/
16	Product certificate	/
17	Disinfection guide	/
18	Quick installation guide	/

 Warning

- 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 void the warranty 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.
- Place the USB flash drive in a safe place for later usage.

Note

We recommend that you keep all the original packaging components in a safe place in case you need to transport or dispose of the scanner in the future.

3.3. Hardware Overview

3.3.1. Scanner Tip and Scanner Body

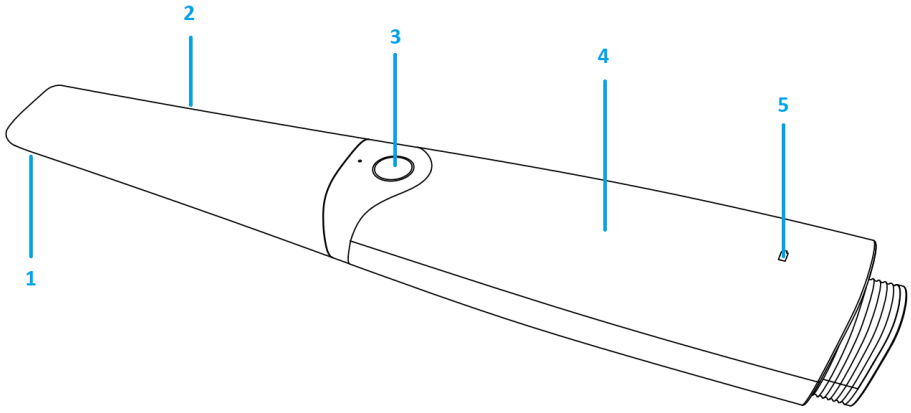


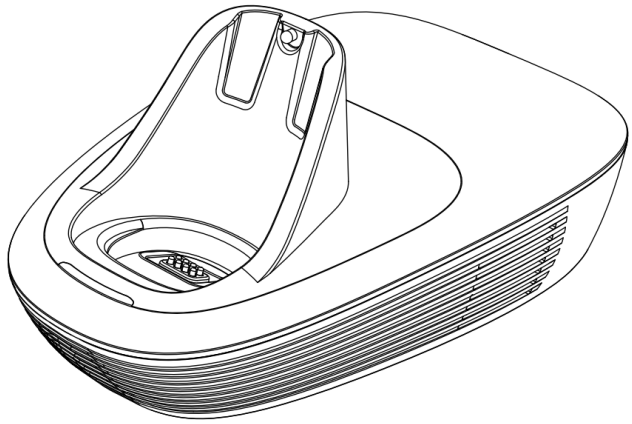
Table 3-1 Introduction of scanner tip and scanner body

No.	Item	Description
1	Heating component	The heating component ensures successful scanning by preventing fogging on the lens.
	Laser window	The laser window is on the tip of the scanner.

2	Scanner tip	Use the scanner tip to scan the upper, lower or full jaw. The scanner tip can be recycled up to 100 times. The scanner can identify tips with different sizes and adjust the breadth of the camera according to the tip size automatically.
3	Button	● When the scanner isn't connected: Press the button and scan the QR code on the cradle to match it with the scanner. ● When the scanner is connected: - If the scanner is in sleep state, press the button to wake it; - If the scanner is working, press the button to start scanning. Press it again to pause scanning. - Double press the button to enter the button interface. - Long press the button to go to the next step.
4	Scanner body	Rotate the scanner body during scanning to obtain the best scanning angle. During the scanning process, the scanner body may heat up, but the temperature will not cause harm to users and patients.

5	Battery indicator	When the green light is on: 1. The battery is inserted into the scanner. 2. The scanner is charged in the cradle. When the green light flashes: The battery power is less than 20%. When the green light goes out: 1. The scanner is in sleep mode. 2. The battery is not inserted into the scanner. 3. The scanner is not connected to the cable. Note: The battery indicator is extinguished in wired connection mode.
6	Status indicator	Indicates the status of the scanner. ● When the green light is on: The scanner is in scanning, heating or standby status. ● When the orange light is on: Abnormal status. For example, the scanner is not correctly connected; the scanner malfunctioned; the scanner tip is not inserted tightly or the scanner is not connected to the Wi-Fi. ● When the green light breathes: The scanner is in standby mode, low battery or unconnected. ● When the light goes out: The scanner is in sleep mode; the scanner has no power or the scanner is not connected.

3.3.2. Scanner Cradle



Cradle indicator:

Cradle indicator status description:

When the orange light is on: The device is initialized or it is abnormal.

When the green light is on: Scanner charging is completed or the cradle is in normal working condition.

When the green light flashes: The scanner is charging.

When the green light goes out: The scanner is not connected to power.

Note

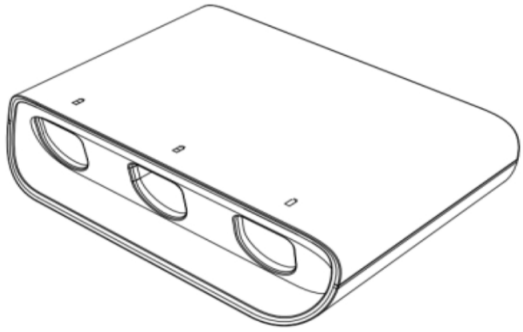
- If the scanner is idle, please put it on the cradle. Then the camera and projector will stop working and save the working log.
- When the cradle is connected to power supplies and the scanner is put on the cradle for 30 minutes, the scanner will automatically enter the sleep state.
- When the cradle is not connected to power supplies and the scanner is put on the cradle for 10 minutes, the scanner will automatically enter the sleep state.
- When the scanner is not put on the cradle and not moved for less than 3 minutes, the scanner will be still on working state. For more than 3 minutes, it will enter the standby state. After 10 minutes, it will enter sleep state and the indicator will go out.
- The scanner tip will be heated even if the scanner is on standby or sleep state.

cradle use.

The distance between the scanner body and the cradle is recommended to keep within 5

meters, where the signal is better.

3.3.3. Charging Case



Charging case indicator status description.

When the green light flashes: charging in progress

When the green light is always on: charging is complete

When the green light goes out: battery not inserted or not inserted in place (not charging)

3.3.4. Calibrator

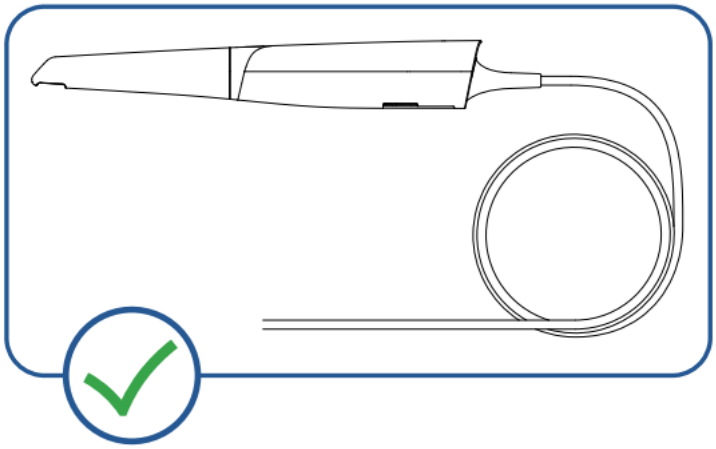
Description of the calibrator indicator:

Orange: .It is initialized or abnormal.

Green: It is working normally.

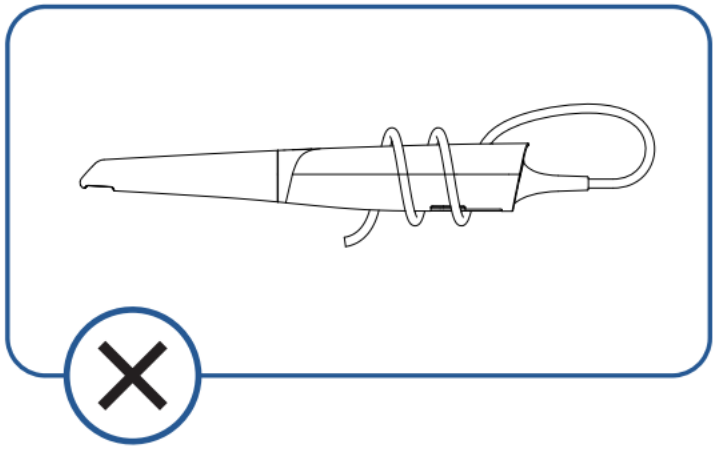
3.3.5. USB Storage

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



Caution

Do not roll the cable over the handle of the scanner or even bend the cable sharply. The illustration below demonstrates improper cable storage.



3.4. Software Overview

The Aoralscan 3i Wireless is designed to operate with the software programs (on the USB), which include four modules:

- 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 the convenience of users to use in the design software. Use the feature to adjust coordinates, mark tooth position, extract margin lines and so on.

3.4.1. System Requirements

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

Name	Description
CPU	Intel Core i7-8700 or higher
Memory	16 GB or higher
Hard Disk Drive	256 GB SSD or higher
Graphics Card (GPU)	NVIDIA RTX 2060 6GB or higher
Operating System	Windows 10 Professional (64-bit) or later versions of Windows operating system
Display Resolution	1920 × 1080, 60Hz or higher
I/O Ports	More than 2 type-A USB 3.0 (or higher) ports

MacBook Recommended Configuration

Name	Description
CPU	Apple M2
Memory	16 GB or higher， mini: 8GB
Hard Disk Drive	512GB or higher， mini: 256GB
Operating System	macOS

Note

Your PC shall meet the safety requirements of IEC 60950.

3.4.2. Install the Software

The USB flash drive contains the software program.

 Caution

- Install the software programs in accordance with the instructions given here.
- When the installation is completed, do not plug the power adapter into the wall outlet or turn on the scanner yet.

(1) Insert the supplied USB flash drive into the USB port of your PC.

(2) Find the file and run it as administrator.

(3) The 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, a shortcut icon will be displayed on your desktop for quick access.

4. Set the Scanner

4.1. Connect the Scanner

The scanner can be connected in wired mode or wireless mode.

 Caution

- 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, please 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 extreme temperature 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.

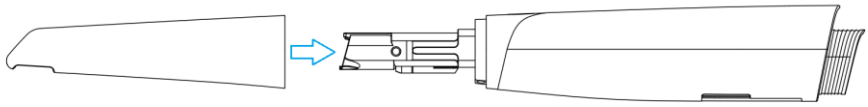
- Before the installation is completed, do not plug the power adapter into the wall outlet or turn on the scanner until you are instructed to do so.
- Always hold the scanner firmly when lifting from the cradle or when using the scanner. Do not shake the scanner.
- Always return the scanner to the cradle when it is not in use. Do not place the scanner in heated or wet surfaces as this can cause damage to the 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, it will stop working.

 Warning

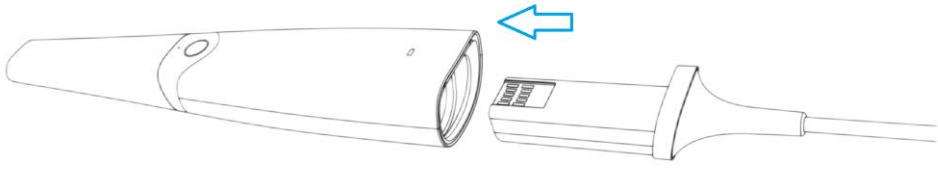
Ensure that you use only the supplied power adapter, power cable, and USB cable.

Follow the steps to connect the scanner in the wired mode:

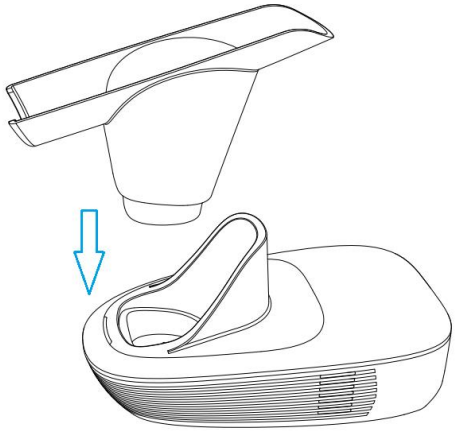
(1) Push the scanner tip hard to the scanner main body to ensure firm attachment.



(2) Push the spare cable hard to the scanner and ensure the firm attachment.



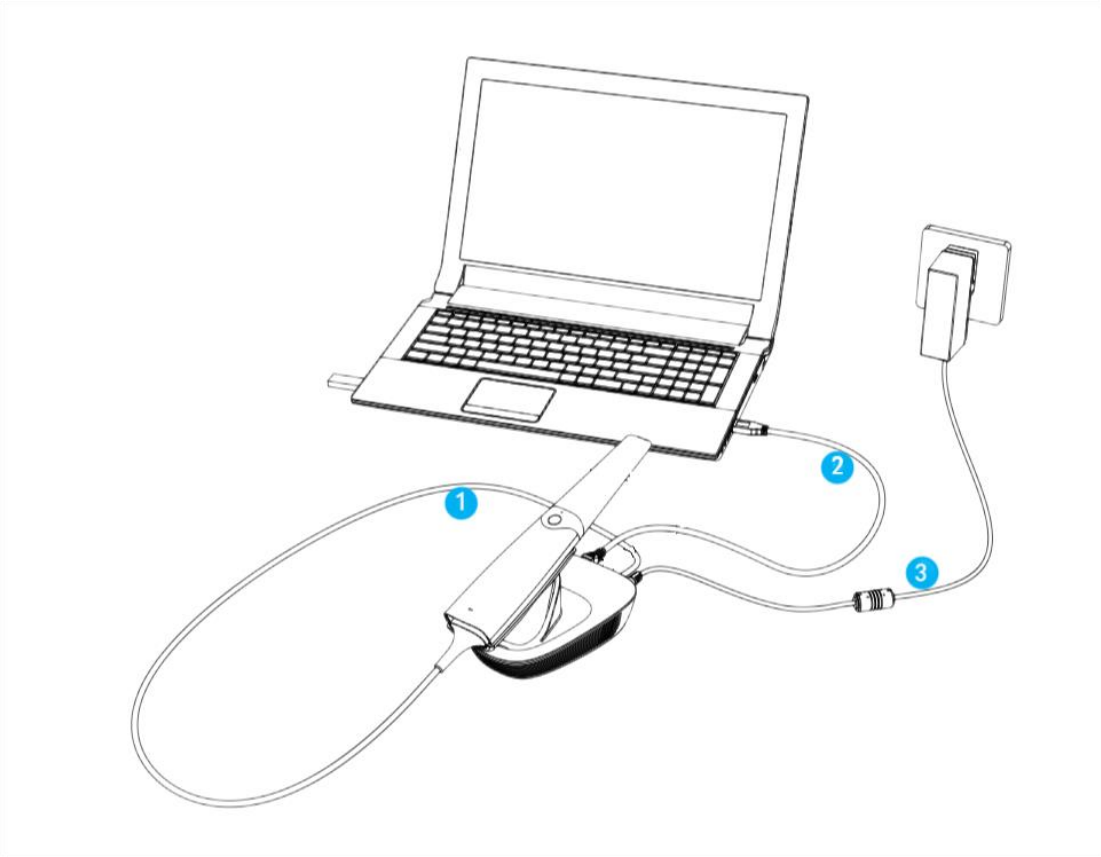
(3) Insert the transfer bracket downward into the cradle.



(4) Connect the USB cable line of the scanner to the USB 3.0 port on the cradle as ① shows.

(5) Connect one end of the USB 3.0 cable line to the cradle and the other to the USB 3.0 port on the computer as ② shows.

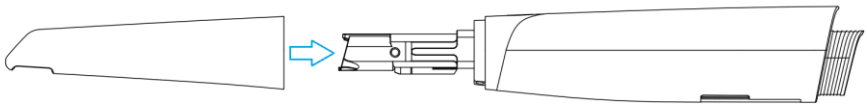
(6) Plug the round splice of the power adapter into the power port on the cradle and connect it to the power supplies as ③ shows.



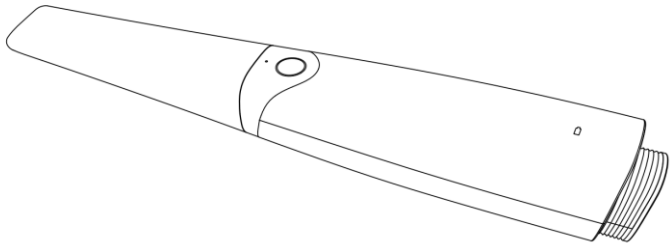
(7) Double-click the shortcut icon on the desktop to launch the software.

Follow the steps to connect the scanner in the wireless mode:

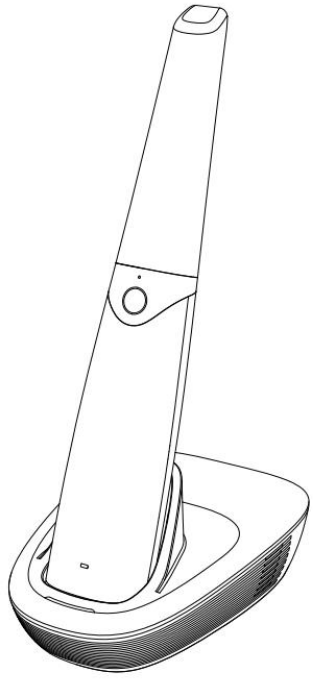
(1) Push the scanner tip hard to the scanner main body to ensure firm attachment.



(2) Push the scanner hard and ensure the whole device is firmly attached.



(3) Insert the scanner into the cradle.



(4) Click the shortcut icon on the desktop to launch the software.

(5) Enter the interface of device connection and connect it via wireless AP binding.

Note

- Once connected, the software will search the bound device for re-connection next time.
- The software will re-connect the device via WiFi when an unexpected power outage starts during scanning.

4.2. Calibrate the Scanner

The Mac and iPad both support calibration by wireless Bluetooth.

Note:

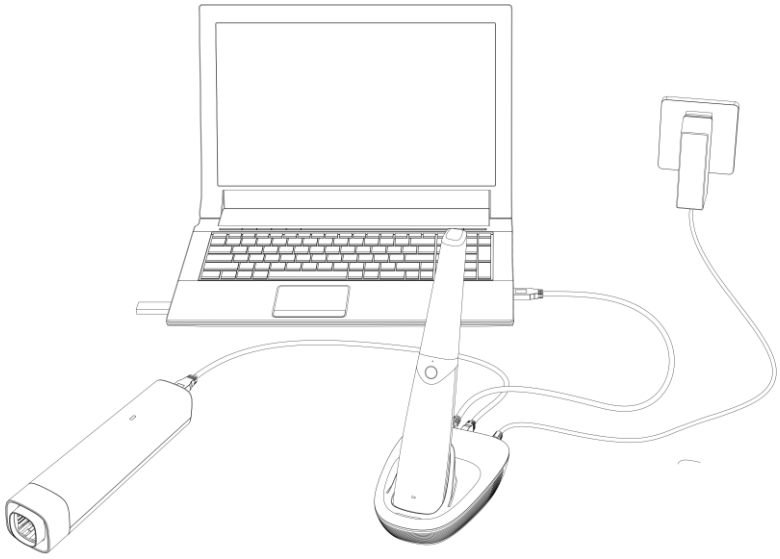
Calibration by the wireless Bluetooth, please turn on the Bluetooth of the Mac and the iPad first.

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.

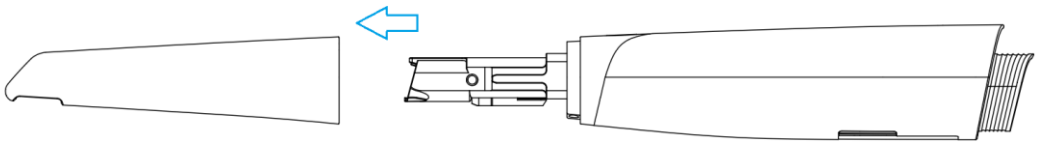
Follow the steps below to perform the calibration:

(1) The indicator of the scanner body turns green when the power connection is working properly.



Calibration in Wireless Connection Mode

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



Note

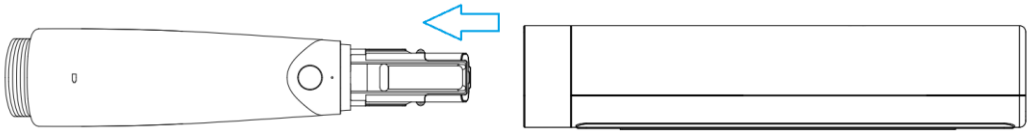
- Do not place your finger(s) on the lens of the tip when detaching the tip as this may result in damage to the lens.
- Store the detached tip in a safe place, e.g. a dental instrument tray, for future use.

(3) Connect the calibrator and your computer with the supplied USB 3.0 cable.

Note

The scanner can be connected with an all-in-one machineor external touch screen.

(4) Gently slide the calibrator onto the front end of the scanner.



(5) Click the calibration icon on the main interface to display the calibration interface.

(6) Ensure the scanner is plugged into the calibrator firmly. Click **Start** and start the calibration.

(7) The message prompting successful calibration appears once the calibration is completed. Click OK to exit.

Note

Normally the calibration takes approximately 7 minutes.

(8) Click “x” on the top right corner to exit the calibration interface.

(9) Gently slide the Calibrator off the scanner.

 Caution

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

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

4.3. Disconnect the Scanner

 Caution

- Do not attempt to directly disconnect the scanner by removing the power cable and USB cable.
- Do not roll the cable over the handle of the scanner or even create any sharp bends in the cable after you disconnect the scanner.

Follow the steps below to safely disconnect the scanner:

(1) Quit the scanning software.

(2) Disconnect the USB data line from the cradle and scanner.

(3) Right-click the “Safely Remove Hardware” icon on Windows taskbar and select “Eject Flash Drive”.

(4) Unplug the USB flash drive and keep it in a safe place for future use.

(5) Unplug the power adapter from the wall outlet and remove the power plug from the power port on the cradle.

5. Scanning Preparations

Warning

You must wear clean medical gloves during scanning for your hand hygiene and safety.

5.1. Intraoral Environment

- Make sure there is no foreign body or blood in patient's mouth after he/she gargles. 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 or a medical sponge to dry the tooth surface before starting the scan.
- Turn off the oral light on the dental chair and start scanning.
- Consider using a saliva ejector and a medical sponge to keep the surfaces dry during scanning.
- If necessary, consider use an oral mirror to help create space while working in the narrow area between the teeth.

5.2. Scanner Preparation

- Ensure that the scanner tip, scanner body, and cradle are properly pre-cleaned, disinfected, or sterilized. See Pre- cleaning, Disinfection, and Sterilization on chapter 7.
- 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 lens of the tip when scanning, the scanner tip must have been warmed up. See 5.4 Heat the Scanner Tip.
- Calibrate the scanner and verify the accuracy of the acquisition regularly. See 4.2 Calibrate the Scanner.

5.3. Scanning Position and Path

- Avoid direct light from any light source, e.g. dentist chair lamp, to shine on the area

you are working on.

- Hold the scanner steady by resting it on the tooth surface and keep the 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 to create overlaps. It is important to achieve an overlap of at least 30% between each acquisition. If the overlap is small, it may cause the alignment to fail.
- To scan the occlusal surface of the teeth, hold the scanner at a 90-degree angle; to scan the buccal and lingual surfaces of the teeth, hold the scanner at a 45-degree angle.
- Inspect the scanned image in the 3D scan view window (IntraoralScan) and pay attention to warning messages.

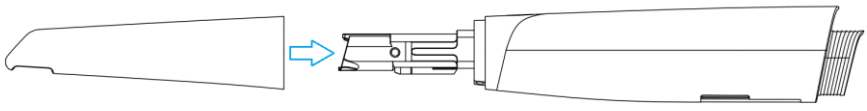
5.4. Heat the Scanner Tip

To ensure optimal image quality, you should prevent condensation on the scanner lens before each scan by heating the scanner tip.

Please follow the steps to heat the scanner tip before starting an acquisition:

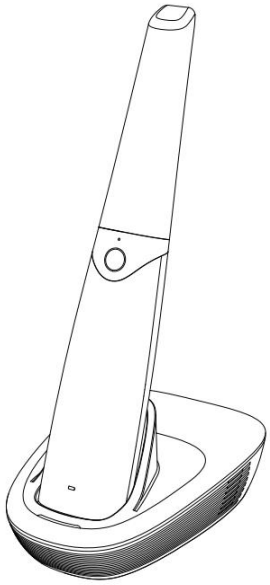
(1) Ensure that the scanner tip, scanner body, and cradle are clean.

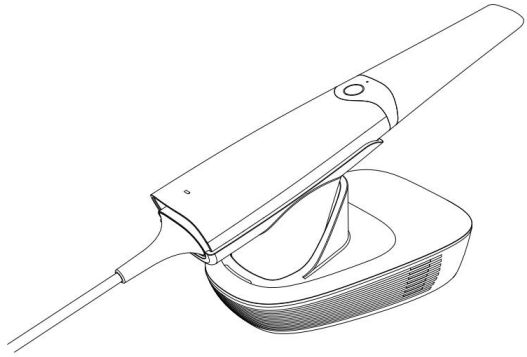
(2) Gently and carefully attach the scanner tip to the scanner body, with the lens facing downward.



(3) Connect the power supply to the Aoralscan 3i Wireless. See Connecting the Scanner in Chapter 4.

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





(5) When the indicator on the scanner body lights up green, the heater automatically turns on and detects the temperature.

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 pre-heating is over. The scanner is now ready for an acquisition.

Note

- 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.

6. Clinical Case Quick Guide

6.1. Connection

For more details, see Chapter 4.

6.2. Register and Log in

If the customer has a Shining 3D account, he/she can directly enter the account and password for login. If not, please register an account. click **New User? Click here to register** to enter the registration interface.

6.3. Activate

When the scanner is used for the first time, the user should online activate the device first.

You need to confirm activation—click **Yes** to open the authorization tool, enter the organization name, name, mobile phone, and email, and click **Activate**. Please make sure that your computer has been connected to the Network. If you can't activate the device, please contact with us.

6.4. Calibrate

For more details, please see Chapter 4.2 Calibrate the Scanner. In order to ensure the scanning quality, regular calibration is required which is recommended every 15 days.

6.5. Create an Order

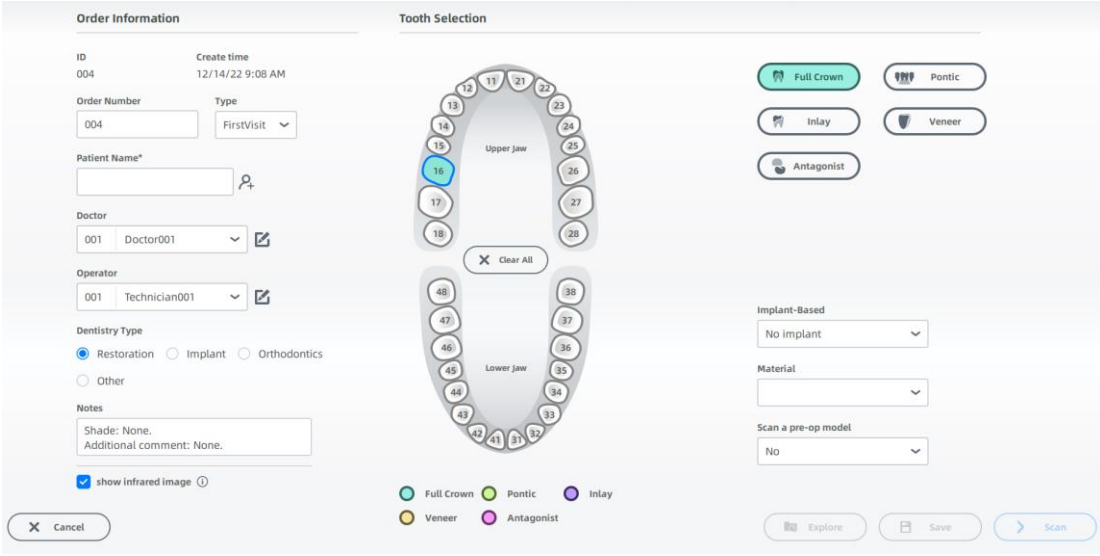
After logging in and entering the interface of the software, the user can create a new order or import orders.

Click "New Order" and enter information including the order number, the doctor, the patient and the technician. Then select Dentistry Type and the teeth to be scanned. Click "Save" to save the order.

Check "show intrared image". NIR (Near-infrared) imaging technology allows the user to check the infrared images of the model. This function is used to help doctors detect and monitor caries on adjacent approximal tooth surfaces. During intraoral scanning, the real-time texture images and NIR images collected by the scanner are displayed on the software. By comparing

texture images and NIR images, the doctors can better identify and locate caries. The user can record and take screen shots when scanning, and save these images in the order file.

Check this function and the user can check texture images and NIR images of the certain model on the pre-design interface.

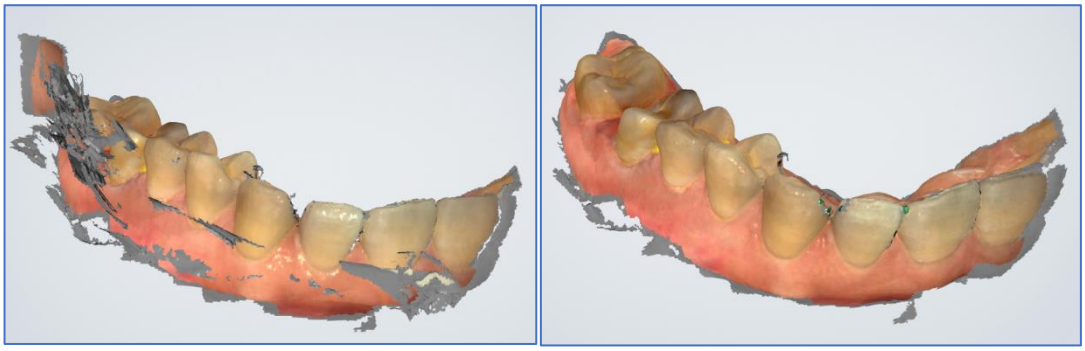


Click “Scan” and enter the scanning interface.

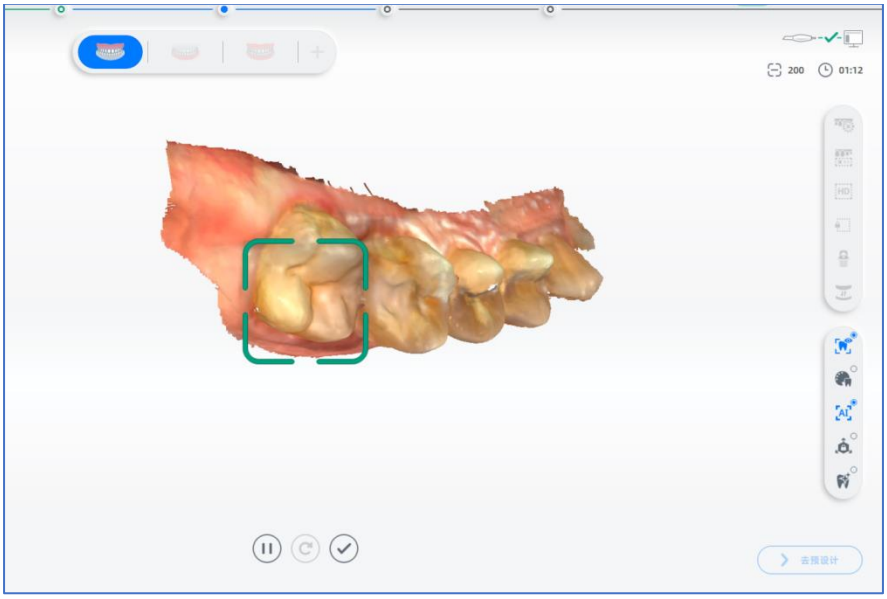
6.6. Scan Upper Jaw

Please check whether the image on the camera window on the top right corner displays normally. Then click  , or press space bar or press the button on the scanner to start scanning.

Before scanning, click  on the right panel to open AI optimization, and this icon will turn into  . Then the software will automatically delete unrelated data such as data of buccal and lingual soft tissues during intraoral scanning. See the following figure (with and without AI Optimization)



The green box shows the current scanning data. If the box turns into red, it indicates that the user is scanning the wrong place and needs to move the scanner tip to the place the red box shows.



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.

After confirming that the scan is completed, click  or long press the space bar or long press the button on the scanner for over 3 seconds 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.

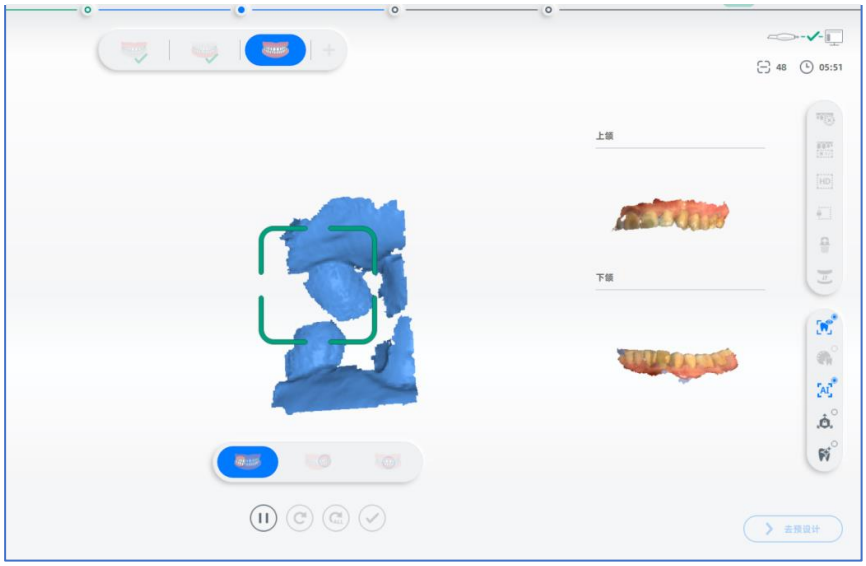
6.7. Scan Lower Jaw

The steps of scanning lower jaw are the same as that of upper jaw. When finishing scanning upper jaw, the software will enter the process of scanning lower jaw automatically.

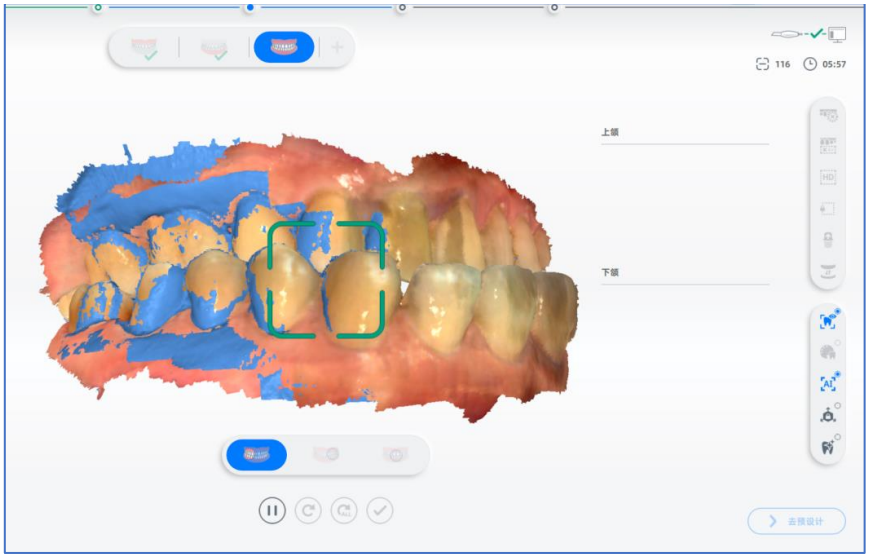
6.8. Scan Whole Jaw

When finishing scanning upper jaw and lower jaw, the software will automatically enter the process of scanning whole jaw.

The user can click  , or press space bar or the button on the scanner to start scanning. The software will automatically align the model when it has obtained some data.

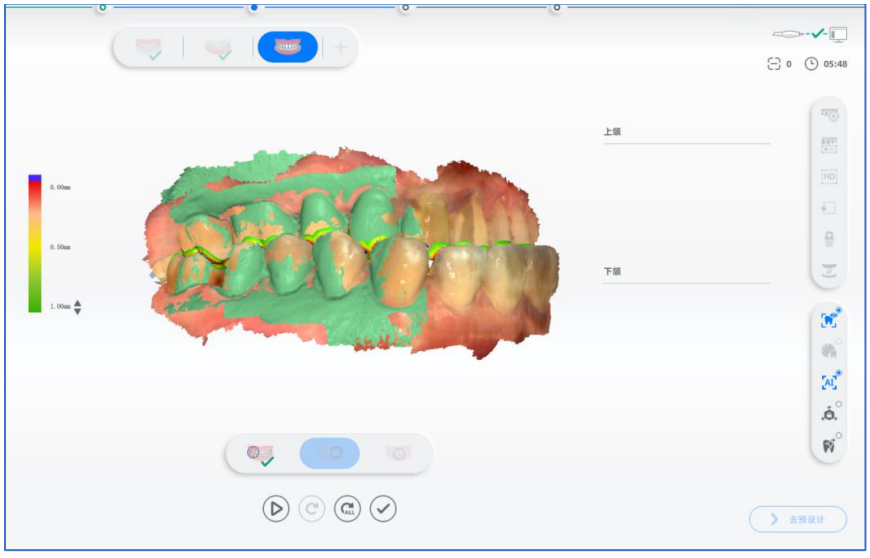


Before alignment



After alignment

When you finish the scanning and the alignment, click  , press space bar or the button on the scanner to pause scanning and check the effect.



Click  , or long press space bar or the button on the scanner for over 3 seconds to edit data.

6.9. NIR Imaging

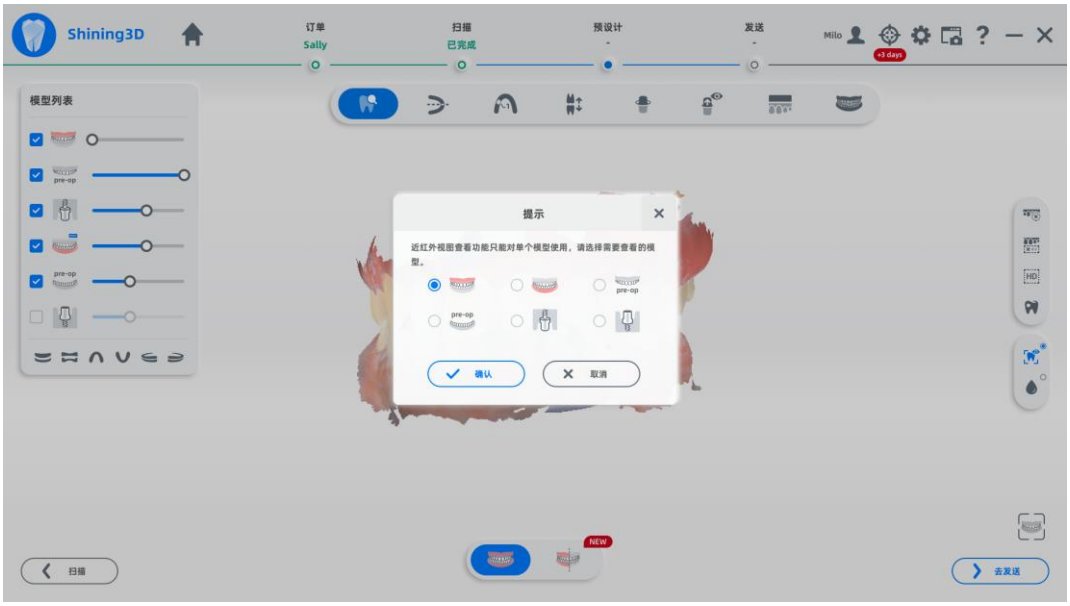
NIR (Near-infrared) imaging technology allows the user to check the infrared images

of the model. This function is used to help doctors detect and monitor interproximal carious lesions on the teeth. During intraoral scanning, the real-time texture images and NIR images collected by the scanner are displayed on the software. By comparing texture images and NIR images, the doctors can better identify and locate caries. The user can record and take screen shots when scanning, and save these images in the order file.

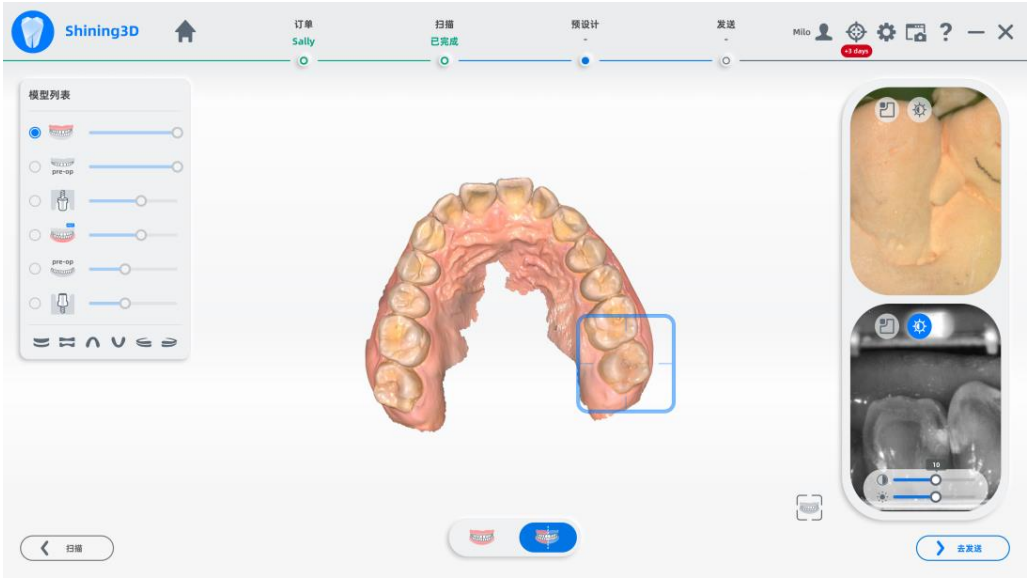
Open this function and the user can check texture images and NIR images of a certain model on the pre-design interface.

Step:

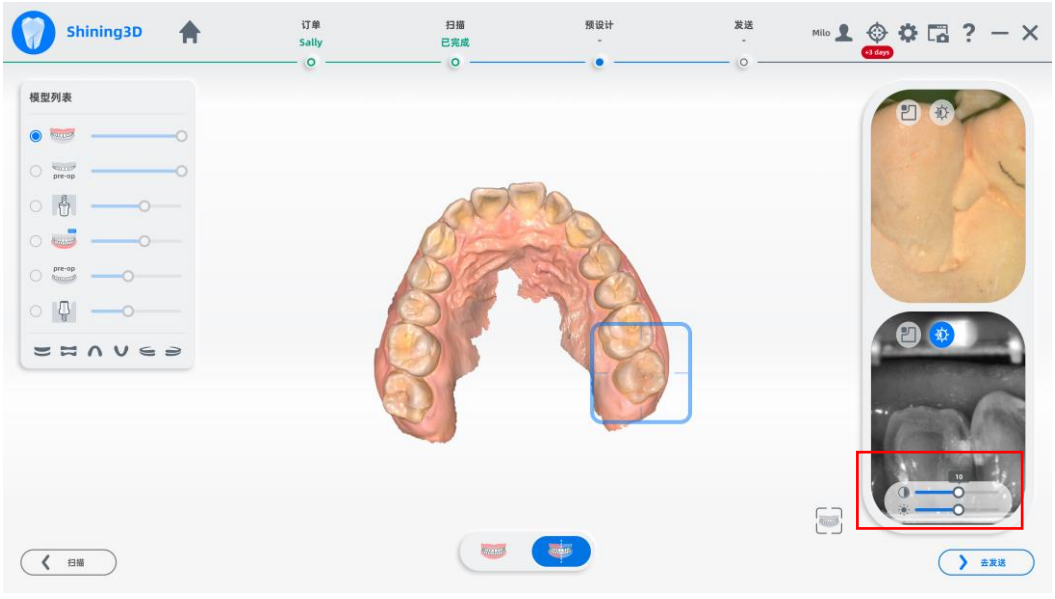
1. Select one model and click "**Confirm**".



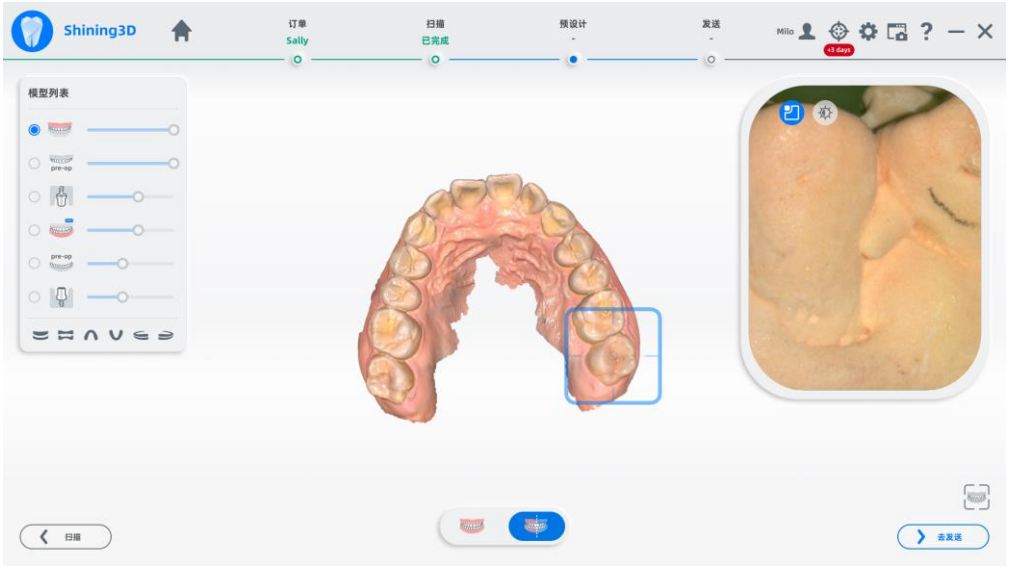
2. Move the cursor on the model. The texture image and NIR image of this position are displayed on the right.



3. Click  on the NIR image window to adjust its brightness and contrast. Click this icon again to close the adjustment window.



4. Click  and check the enlarged texture image of a certain position.



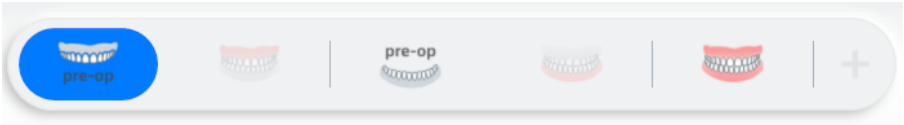
6.10. Tooth Preparation Monitoring

By monitoring the prepared tooth, data will be saved during the grinding. So it's convenient to compare multiple sets of tooth preparation data to standard model. Only pre-op scanning order can switch into tooth preparation monitoring order.

Note

- A prompt of "Functionality is limited" is popped up when the device is not authorized.
- Before scanning the prepared teeth, you can enable “Save the data of the **tooth** preparation monitoring and scanning process” in the > Scan Settings. The tooth preparation data after each scanning will be saved and you can check and compare multiple sets of tooth preparation data in the Pre-Design.

The default scanning process of a pre-op order: Pre-operative Upper Jaw > Pre-operative Lower Jaw > Bite > Upper Jaw > Lower Jaw > Bite(automatic alignment)



Note

The scanning steps of the upper jaw or the lower jaw (post-op) is similar to implant jaw: After loading pre-op data, you need to dig a hole on the tooth, then starts scanning post-op teeth.

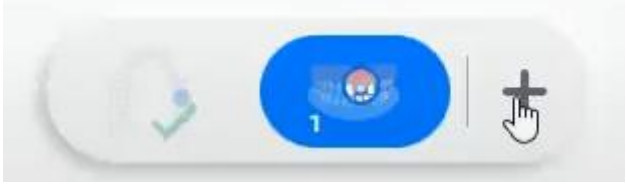
Scan the jaw in order:

1. Scan pre-op upper jaw with a disinfected scanner.

2. Dig a hole on the treated tooth to avoid alignment failure resulting from the inconsistent scanning data of pre-op and post-op.

3. Scan the post-op teeth.

4. Click + to add a tooth preparation group for multiple prepared tooth scanning.



5. Click  and then click  to import the standard models.

6. Compare the data of the prepared tooth with that of standard prepared tooth. Click different position of the prepared tooth to check the value. (Blue indicates the tooth is not prepared, green indicates the tooth is well-prepared, and red indicates the prepared tooth needs grinding.)

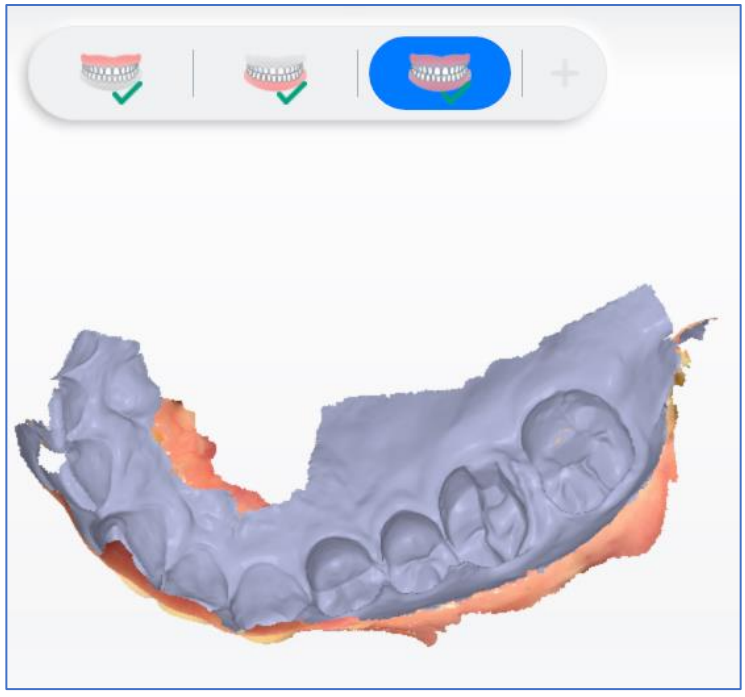
Icon	Function	Description
	Contrast	Compare a set of model with an imported standard model.
	Screenshot	Capture the picture of comparison between two prepared teeth.
	Show report	The report will be generated when you take a screenshot.
	Delete report	Delete the generated report.
	Confirm	Apply it.

6.11. Check Scanning Results

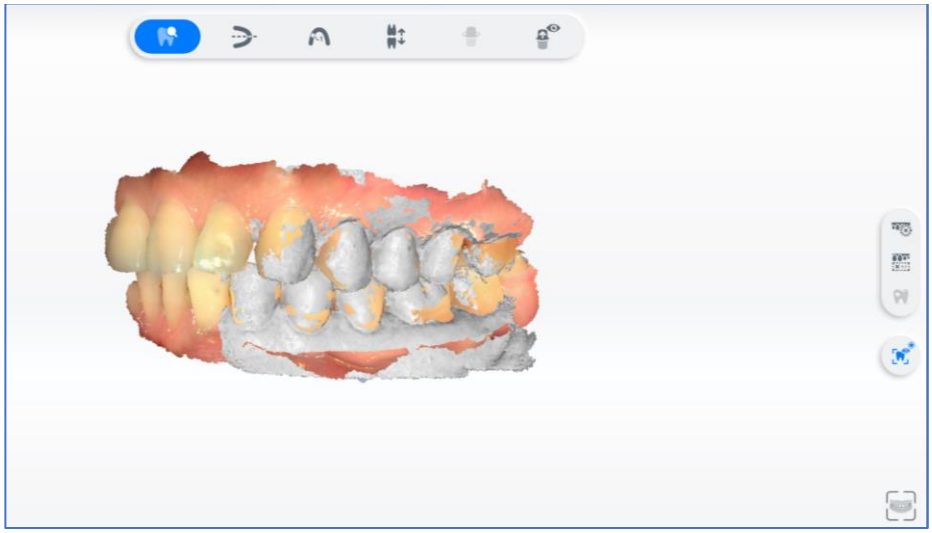
Check the model data.

6.11.1. Check Upper/lower Jaw

6.11.2. Check Occlusion



6.12. Pre-design

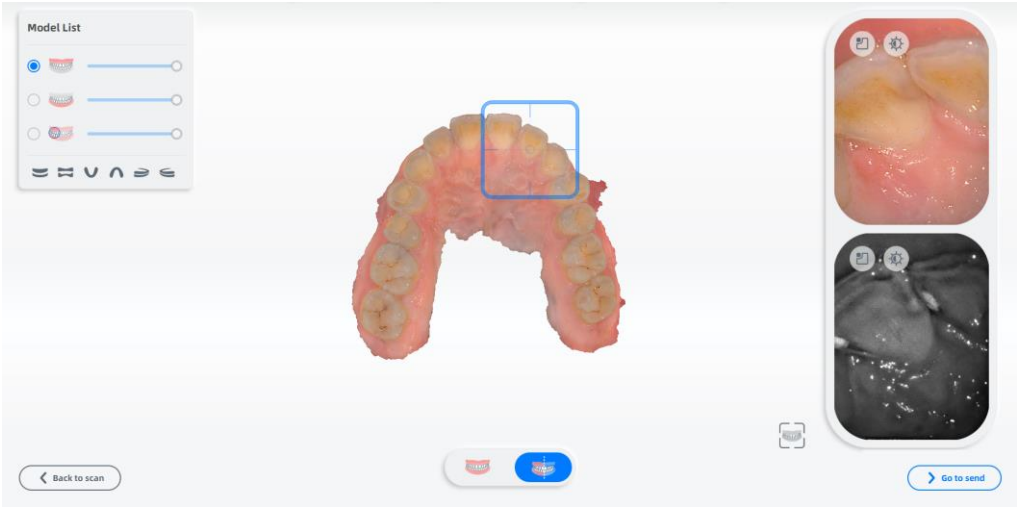


For more details of pre-design, please check the Manual.

6.12.1. Model list

IR view：Click on a location of the model to view upper/lower jaw images.

When creating the order, check **show infrared image** to preview IR view.

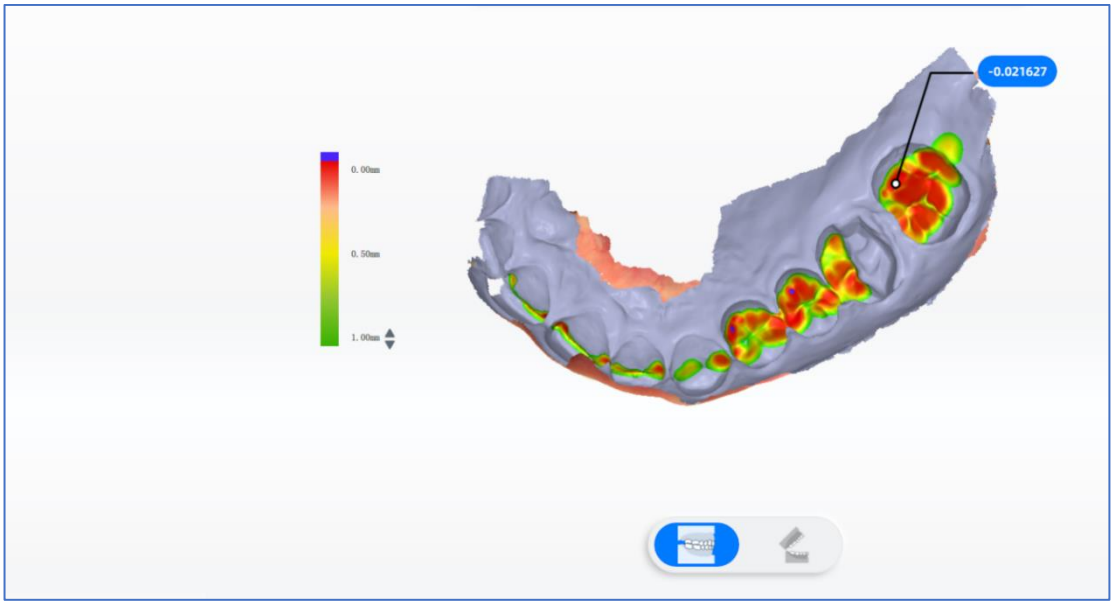


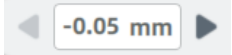
6.12.2. Occlusion Test

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 a point of the model to detect the occlusal gap at that point.



- Switch upper and lower jaws: Switch by clicking the upper jaw icon  and the lower jaw icon  on the upper left corner.
- Close/open jaw: Switch between the Close button  and then Open button  to see the occlusal result.
- Occlusion adjustment  : Click this icon to open the occlusion adjustment parameters.
  - ✧ Occlusion parameter values  :Three values, namely

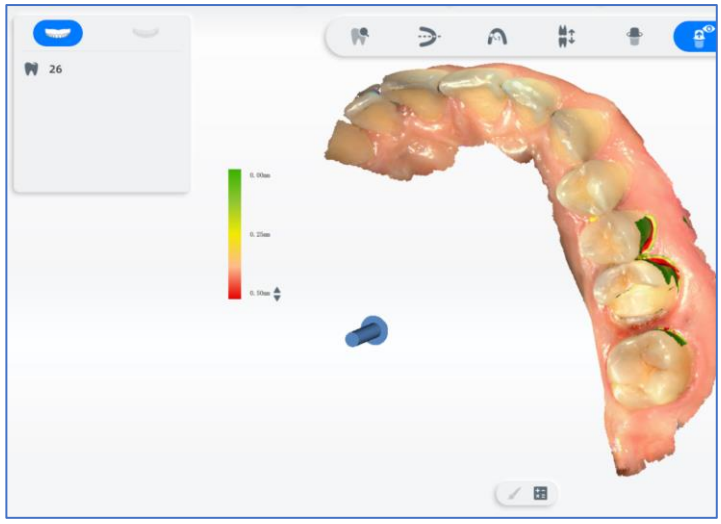
-0.05mm, -0.10mm, and -0.15mm, are available, and the default is -0.05 mm.

- ✧ Cancel  : Cancel the adjusted occlusion parameters and exit.
- ✧ Confirm  : Save the adjusted occlusion parameters and exit.

- Undo adjustment  : Undo the occlusion adjustment.

6.12.3. Check Undercut

Click  on the right side of the software to open the undercut interface. You can rotate the model to an appropriate view, double-click the view or click  to recalculate undercut area.



6.12.4. AccuDesign

On the pre-design interface, click  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. For more details, please check the AccuDesign User Manual.

6.12.5. Orthodontic Simulation

Simulate orthodontic treatment, and view the expected effect according to different treatments. Click  on the pre-design interface to enter the orthodontic simulation interface. Orthodontic simulation can be divided into pre-processing, tooth segmentation, and tooth setup.

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 preparations for tooth segmentation.

Icon	Name	Description
	Adjust Coordinate	Check the center position from 3 perspectives. Press left mouse button and move to adjust the center position of the model.  : Reset the coordinates of upper and lower jaw to the original position.
	Trim Model	Delete unnecessary scanning data of the model. Change the brush size by dragging the slide. • Press left mouse button and move the cursor to delete model data. • Scroll up and down the wheel to zoom in and out of the model. • Press right mouse button and move the cursor to adjust the perspective of the model.
	Edit Surface	Remove image noise on the model and make the model surface smoother. Improve the quality of data.
	Perspective Control Panel	Check the model from different perspectives.

Tooth Segmentation

Tooth segmentation will mark the position of each tooth and distinguish them with different colors. You can edit, delete and add information to the tooth position. It is easy for you to check the expected effect of each tooth after orthodontics.

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 Frame	Professionals are required to readjust each tooth direction. By three-dimensional coordinate system on each tooth, you can adjust the teeth orthodontics direction. • Press the grey origin and move the 3D coordinate system. • Press left mouse button and move the cursor to adjust the direction of the coordinate.
	Change Tooth Number	Click the number on the tooth to change it.
	Remove Teeth	1 Select the tooth needed to be deleted. 2 Click  to delete its mark. 3 Click  to confirm deletion.
	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 Panel	Choose to display tooth number, texture, frame, area and features or not.

Tooth Setup

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

- 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.

 Note

You can click Setup to enter setup interface if the segmentation is completed.

 Create a Plan

Icon	Name	Description
	Fit views	Press Ctrl and select multiple plans. The treatment effect of plans is displayed by fit views.
	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.
	Rename	Rename the treatment plan.
	Upload	Export or upload your plan to Dental Cloud.
	Delete	Delete the plan.

 Animation

Play the whole process of orthodontic treatment and preview the effect of different treatments.

 Manual Setup

You can set up the tooth manually.

Icon	Name	Description
	Move	Move the tooth.
	Rotate	Rotate the tooth with tooth root as the origin.
	Twist	Twist the tooth from side to side with the root as the origin.

6.12.6. Oral Report

When creating a new order, the doctor can select the case as “Check” to generate a report in the pre-design interface. Doctors can know patient-related information with the report.

6.13. Check the Save Path

Click  in “New Order” on the panel to return to the order interface. Then click  to open the folder of the current order.

6.14. Upload Order

Click  to upload finished orders to the dental cloud where you can transmit the orders to others.

7. Care and Maintenance

7.1. Pre-cleaning, Disinfection, and Sterilization

The whole set of Aoralscan 3i Wireless, including scanner tip, scanner body, and scanner cradle, calibrator and charging case, requires proper care, cleaning, and handling. As individual parts 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 3i Wireless in the following order:

(1) Scanner body, cradle, calibrator and charging case care

(2) Scanner tip care

 Warning

- 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, and 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 and responsible for any damages due to improper sterilization.
- After the 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.

7.2. Scanner Body, Cradle, Calibrator and Charging Case Care

Both the scanner body, cradle, calibrator and charging case require an intermediate-level disinfection.

 Warning

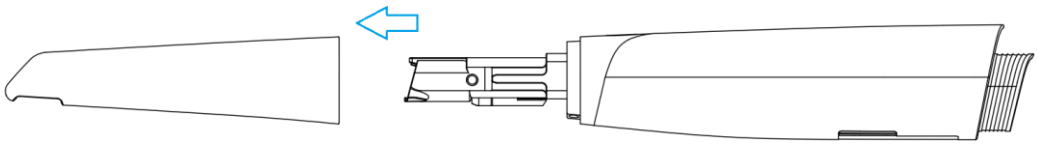
- Considering hand hygiene and personnel safety when performing pre- cleaning and disinfection/sterilization, you must wear clean medical gloves before you start.
- Always ensure that you have pre-cleaned and disinfected/sterilized the scanner bodyand scanner tip before each scan.
- The caring methods for the 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 of the Aoralscan 3i Wireless (see Disconnecting the scanner on chapter 4).

(2) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then

gently slide the tip off from the scanner.



Note

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

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

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.

(4) Hold the scanner body with your hand.

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

Caution

- Avoid using detergent of any kind as some detergents or surfactants might penetrate the surface of the scanner body, cradle, calibrator or charging case.
- Do not clean the intake and exhaust vents with any sharp objects or other such tools.

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

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

surface of cradle, calibrator and charging case.

(8) When it is done, store the cradle, calibrator and charging case in a clean and safe place.

(9) Proceed to the cleaning, disinfection or sterilization of the scanner tip.

7.3. Scanner Tip Care

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

 Warning

- Considering hand hygiene and personnel safety when performing cleaning and disinfection/sterilization, you must wear clean surgical gloves and goggles before you start.
- Cleaning the scanner tip is an essential step before effective disinfection or sterilization.
- When inserting the scanner tip into the disinfectant solution, make 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 100 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 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:

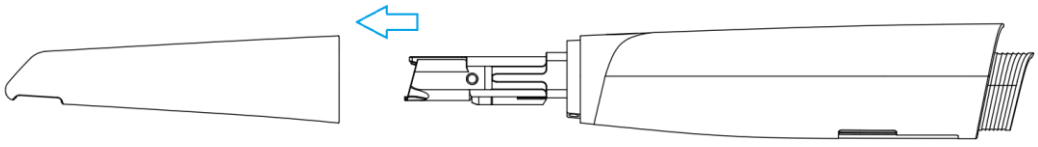
- Cleaning and High-level Disinfection
- Cleaning and Steam Sterilization

7.3.1. Cleaning and High-level Disinfection

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

(1) Disconnect the power of the Aoralscan 3i Wireless (see Disconnecting the Scanner on Chapter 4).

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



Caution

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

(3) Pay particular attention to inspecting the lens of the tip to ensure that the lens is not cracked or broken and there is no scratch on it.

Caution

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

(4) 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.

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

(6) Rinse the tip thoroughly with sterile water.

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

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

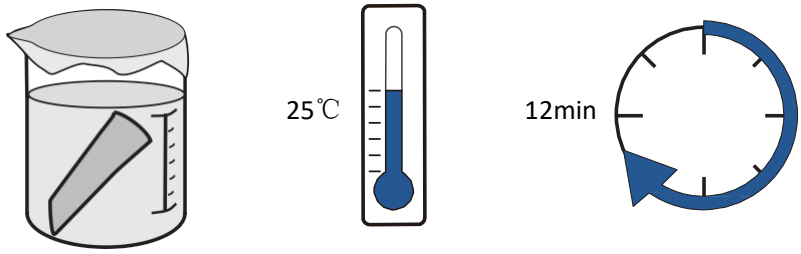
(9) Pay particular attention to inspecting the lens surface of the tip again to make sure that the cleaning is done properly and the lens is not damaged during the cleaning process.

(10) Carefully fill the container with a disinfectant solution, such as phthaldialdehyde at a concentration of 5.5g/L (depending on the brand of disinfectant used). In the event of a leak,

follow the disinfectant manufacturer's instructions for handling.

(11) Immerse the cleaned tip into the disinfectant and leave it for at least 12 minutes at 25°C.

The disinfection proves to be achieved in 12 minutes. Do not immerse it for more than 14 minutes in order to prevent a long-time soak.



(12) Prepare a large container with sterile water, e.g. 2 L.

(13) Take out the tip from the disinfectant.

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

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

Caution

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

(16) Repeat the rinsing process (step 12 to 15) for at least two times to remove the residue of disinfection solution.

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

(18) Pay particular attention to inspecting the lens surface of the scanner tip again to make sure that the disinfection is done properly and the lens is not damaged during the disinfection.

(19) Re-attach the scanner tip (see 7.3.3 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.

7.3.2. Cleaning and Steam Sterilization

Follow the steps below to perform cleaning and steam sterilization:

(1) Disconnect the power of the Aoralscan 3i Wireless (see Chapter 4).

(2) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then

gently slide the scanner tip off from the scanner.

 Caution

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

(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.

 Caution

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

(4) 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.

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

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

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

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

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

(10) Fill the scanner tip lens with medical gauze.

(11) 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).

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

(13) Reattach the scanner tip.

7.3.3. Attach the Scanner Tip

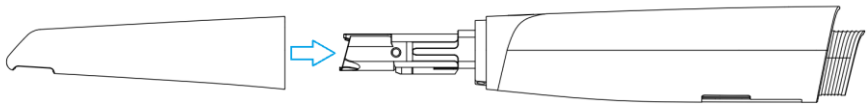
There is a risk of damaging the lens of tip if any improper actions are taken when you attach the tip to the scanner.

Warning

- Wear clean medical gloves before you start.
- Ensure that the scanner cradle, scanner body, and scanner tip are pre-cleaned and disinfected/sterilized (see Scanner Body Care on Chapter 7 and Scanner Storage on Chapter 7).

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.

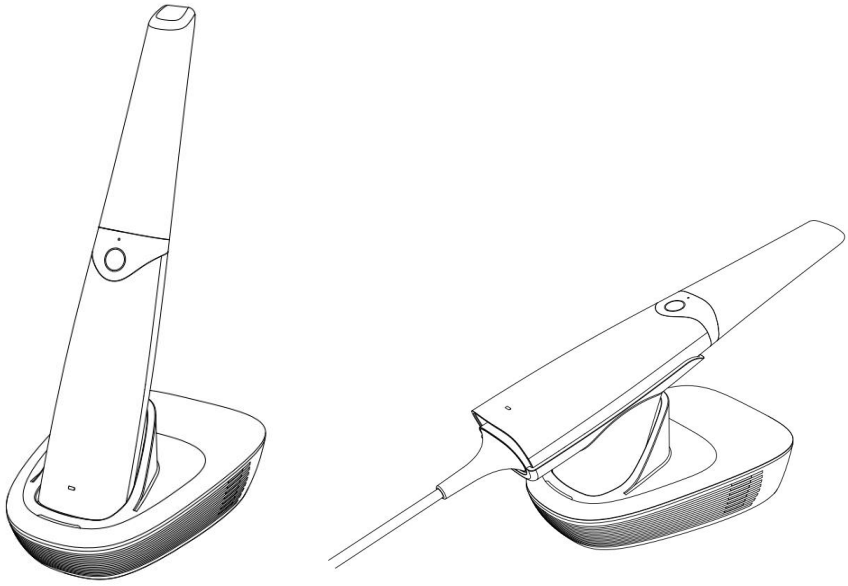


Caution

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

(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.



7.4. Scanner 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 it from any possible damage during transportation.

7.4.1. Storage for Transport

- 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 placed in the original carry box.
- Before closing the lid, make sure no part of the product is protruding from the package.

7.4.2. Daily and Long-term Storage

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

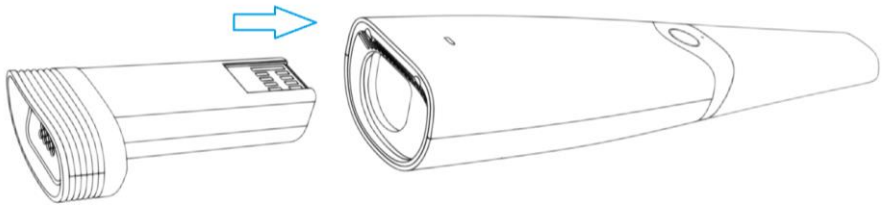
- When the scanner tip is detached from the scanner body, always protect the subtle units and the inner optical components on the front end of the scanner by putting on the supplied dust cap.
- Ensure the scanner is clean before long-term storage.
- Avoid storing the scanner and accessories in areas of extreme temperatures or under direct sunlight.
- Before storing the scanner, make sure the scanner tip, scanner body and cradle are thoroughly dry.

7.5. Replace Battery

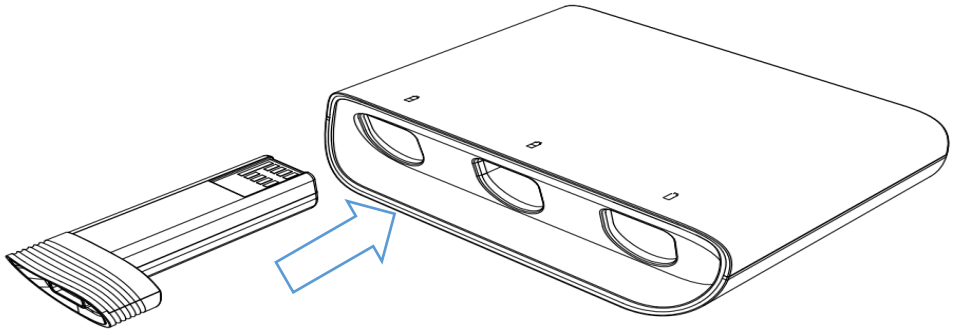
The software displays the connection status and battery usage of the device in real time. Please replace the battery when the device's battery is running low.

Replace the battery in following steps:

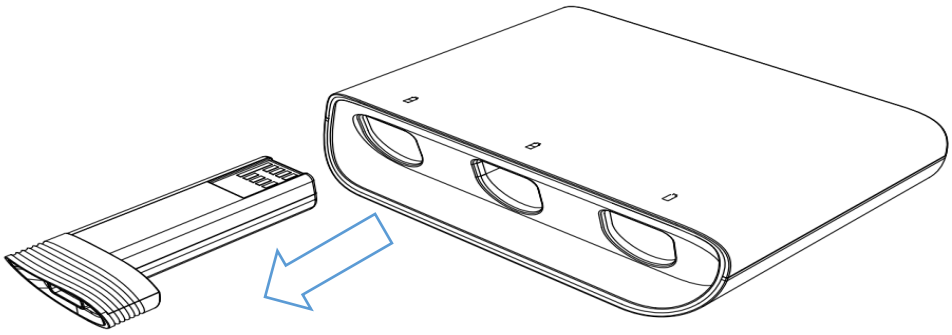
Step1: Pull the battery from the scanner body.



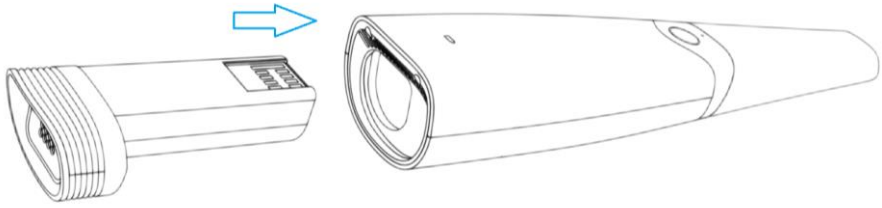
Step2: Insert the battery into the charging case.



Step3: Pull the battery out when there is a permanent green light.



Step4: Insert the battery into the Scanner body.



7.5.1. Battery Use

Under proper maintenance and normal use, the battery life is approximately 3 years, but as the lithium-ion battery ages, the capacity of the battery will decrease.

- When replacing the battery, make sure the scanner is turned off.
- Do not remove the battery or install/replace an unsuitable battery.
- Do not charge the battery too long. If the battery casing is scarred, please replace it in time to avoid problems such as liquid leakage and fire.
- Not using the battery for a long time may cause the battery capacity to decrease and affect the service life and rechargeability. For long-term storage, please charge the battery once every 3 months and try to keep the battery capacity at 30%~50% of the standard capacity .
- Do not charge the battery when it has low power (when the orange light flashes) in order not to affect its life.
- It is recommended that check if there are black stains resulting from friction on the tip and bottom connectors of the battery at regular intervals. Wipe it with a alcohol swab in time if

so.

- Put the battery at a place where children can not reach.
- Remove the battery if the product has not been in use for a long time.

7.5.2. Battery storage

The ideal temperature to store the lithium-ion battery is between 0~25°C. Please put the device at a cool and dry place to keep it away from high temperature and humidity..

When storing the battery, please keep it away from flammable and explosive items such as fire source.

7.6. Safety Use of the Charging Case

Place the charging case away from sparks, dust and other corrosives.

Please place it in a safe place where children cannot touch it.

Store it in an environment free of dust, liquid, metal debris, etc. Please store it in a clean and dry environment.

 Caution

- When you charge the case with the power adapter, the indicator on the cradle flashes. A permanent green light is on if the charging process is over.
- Avoid a long-time connection with the adapter. Cut the power in time for fear of safety hazards.
- Please use the specified charging case. Do not replace it at will.
- Do not detach the charging case at will.
- Do not place any objects on it when you charge the scanner or the case.
- Keep good ventilation and heat dissipation when using the charging case.
- Avoid a fall or a bump for fear of damage to the charging case.
- Do not let water splash onto the charging case for fear of function failure.

7.7. Safety Use of the Calibrator

- Connect it to the calibrator cable when you use the calibrator.

- Put the calibrator back into the bag when it is not in use.
- Avoid a fall or a bump for fear of damage to the calibrator.
- Do not let water or other liquids splash onto the calibrator.

8. Hardware Specifications

8.1. Specifications

Parameter	Description
Type Name	Intraoral Scanner
Model Name	Aoralscan 3i Wireless
Scanner	
Scan Field	Standard tip: 16 mm × 12 mm Mini tip: 12 mm × 9 mm
Connection	Wireless Connection (powered by battery) or Wired connection
Scanner tip types	Standard tip and mini tip
Scanner tip maintenance	Sterilized and disinfected by users (Maximum: 100 times)
Scanner tip connection	Pluggable
Light source	LED and laser
wave length	Green laser: 520nm Blue laser: 448nm White LED: 400nm-780nm NIR LED: 850nm
Output	STL、OBJ、PLY
Power	12V DC/3.0 A
Scanning tip dimensions	117mm × 34.5mm × 30mm
Battery	

type	Rechargeable battery
Dimension （L×W×H）	85mm× 37mm× 28mm
Weight	67± 5g
Nominal voltage	3.635V
Capacity	3500maH
Device Lifecycle	8 years

8.2. Environmental Requirements

Operating and storage requirements

- Operating temperature: 10°C – 30°C (recommended 20°C~30°C)
- Operating Relative humidity: 30%RH~80%RH
- Scanner (without battery) Storage/transport temperature: -30°C~60°C
- Scanner (without battery) Storage/transport relative humidity:30%–90%
- Air pressure: 70 kPa~106 kPa