SHINING 3D®

Aoralscan 3

Manual

V1.1

CE MD

SHINING 3D®

Foreword

General

The manual (hereinafter referred to as "the Manual") introduces the functions, installation, usage and maintenance of the Aoralscan 3 (hereinafter referred to as "the Scanner"). MD indicates the item is a medical device.

Safety Instructions

Signal	Meaning
	Note：This symbol is used to inform you of the additional information of the product.
	Caution：This symbol is used to inform you of incorrect operations that may damage the device or result in data loss. Any damages resulting from misuse are not covered by the warranty.
	Warning：This symbol is used to inform you of the potential risks that may result in serious personal injury and other safety incidents.

Release Date

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About the Manual

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

Table of Contents

1. Read This First

The Manual provides important procedures and information on how to operate the scanner and configure the IntraoralScan software correctly and safely. Before attempting to operate the product, read the Manual and strictly observe all warnings and cautions. Pay extra attention to the information from Safety information in chapter 2.

1.1. Basic Information

I. Product name, model

Product name: Intraoral scanner

Model: Aoralscan 3

II. Name, residence, contact information and after-sales service of the manufacturer

Manufacturer name: Shining 3D Tech Co., Ltd.

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

III. Contact Information

Manufacturer

Shining 3D Tech Co., Ltd.

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

www.shining3ddental.com

Customer Support

Email: dental_support@shining3d.com

Shining 3D's Representative

Lotus NL B.V.

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

Telephone: +31644168999

Email: peter@lotusnl.com

IV. Product performance, main structural composition

Product performance

- Appearance and structure

The appearance should be: Smooth, no cracks, no stains, no obvious deformation. Flexible

and reliable for operation.

- Function control and display

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

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

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

- Software features

1. Wizard type scanning operation process with backward function.

2. Establishing demand information, which may include: jaw position information, tooth position information, and treatment modality information.

3. Scanning the teeth according to the demand information.

4. Editing function of the scanned result data, including: hole repair, data selection.

5. scanner with undercut, occlusion, texture and smoothing functions (optional).

6. scanner with orthodontic simulation function (optional).

7. scanner with model making (Accu Design) function (optional).

8. scanner with report examination function (optional).

- Performance

Dental scan imaging: The scanner scans the teeth and gingiva to form a 3D digital model.

Accuracy: Under normal conditions, the scanner is used to scan against 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 under working condition.

- Data interface

USB 3.0, data storage format shall include 3D digital model format .stl, .ply and .obj.

Main structural composition

The Scanner consists of Scanner body, scanner tip, USB 3.0 repeater, power adapter, cradle, USB cable, calibrator（optional）, software, and encryption module. The software carrier is USB

flash drive, and the software release version is 1.

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 efficiency.
- Do not insert wireless USB network card in the computer. USB wireless network card will cause USB bandwidth occupation, limiting camera performance.

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

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

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

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

4) special storage/transportation conditions, operating conditions ： For more details, see 9.2.

Note

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

VI. Production date and lifecycle

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

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

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

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

(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, because this 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 3 intraoral scanner should not be used in close proximity or stacked with other equipment, and if it must be used in close proximity or stacked, observe to verify proper operation in the configuration in which it is used.
- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- Interruptions during electrostatic testing can be recovered within 5s without affecting basic performance.

1.2. Intended Use

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

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, 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**

No known contraindications (or side effects).

1.4. **Warnings**

Before using the Aoralscan 3, 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 is accidentally dropped to the ground, check to make sure the lens is not loose before using it.
- If the scanner is inadvertently dropped on the ground or impacted, it must be calibrated before use. If there are still accuracy problems or scanning abnormalities after calibration, please consult technical support.
- Do not drop or apply shock/vibration to this scanner and its cradle. Strong impacts may damage the components inside.
- Do not cut, bend, modify, place heavy objects, or step on the cables. Otherwise, the external insulation may be damaged and result in short circuit or fire.
- To avoid electrical shock, use only supplied power adapter and connect it only to properly grounded wall outlets.
- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

1.5. Waste Electrical and Electronic Equipment

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

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

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 3. To ensure correct product performance and to obtain warranty service, contact technical support.

2. Safety Information

2.1. Precautions

Failure to observe the instructions or disregard the warnings may result in damages to the product, personal injury, or even death of the user or the patient.

- Do not use the hardware and software for any application until you have read, understood, and known all the safety information, safety procedures, and emergency procedures contained in the chapter. Operating the hardware and software without a proper awareness of safe use could lead to fatal damage to the hardware or permanent data loss.
- Ensure that the connection is performed correctly. See 5.1 Connect the Scanner.
- Use only medical grade devices with the scanner in the patient environment.
- The hardware and software should only be used in a medical facility under the supervision of trained personnel.
- Only authorized service labs should perform maintenance. It is expressly prohibited to open the scanner with tools.
- The hardware and software have been fully adjusted and tested prior to shipment from the factory. Unauthorized modifications will void your warranty.
- If the hardware or software is modified, appropriate inspection and testing must be conducted to ensure continued safe use.
- Check the scanner and components for sharp edges.
- Before 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. Consult technical support staff promptly.
- To ensure the performance and safety of the scanner, use only the original accessories provided with the scanner (or accessories specified by Shining 3D, consult technical support for details) and software.
- Use only supplied accessories and approved software with the scanner in order to achieve the designed performance.
- Do not use a power adapter other than the one supplied with the package.
- Connecting the scanner to an unknown power adapter is very dangerous and may lead

to fire or explosion.

- Using cables or accessories other than those specified for use with the scanner 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.
- There is a risk of explosion when the scanner is used around flammable anesthetics.
- Do not connect USB peripherals with an extended USB cable. Extended connection may cause unexpected usage fault.
- Always handle the scanner with care and avoid hitting or scratching the surfaces as it contains fragile components. Dropping the scanner on the floor may cause permanent damage. If you accidentally drop the scanner, you MUST dispose the scanner tip immediately and do not use the same tip again. The mirror in the tip might shatter into small pieces, and using it again poses the highest risk of causing serious injury to the user and patient.
- The scanner might heat up to above the normal body temperature, yet this short- term exposure and contact with small areas will not pose a health or safety hazard to the patient.
- The scanner may interfere with pacemakers and ICDs, and use of the scanner on patients with pacemakers and ICDs is prohibited.
- Never place any objects or load on the scanner and its cradle.
- Do not dispose the scanner as unsorted municipal waste. The scanner must be collected separately and disposed of in accordance with the local laws and regulations. For proper disposal of this scanner, contact your local representative of Shining3D Corporation.

2.2. Labels and Symbols

Labels and symbols on the scanner/carry box/package

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

	Type BF applied part. To identify a type BF applied part complying with IEC 60601-1.
	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.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
CE	Device fulfills the requirements of the European Regulation 2017/745 given on the EU Declaration of Conformity.
MD	Indicate the item is a medical device.
	Class II equipment.
	Class 1 laser product.
RoHs	Restriction of Hazardous Substances in Electrical and Electronic Equipment. Meets the requirements of Directive 2011/65/EU.
EC REP	Indicates the authorized representative in the European Community/ European Union.
	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.

Note：

The symbols meet the requirements of ISO 15223-1 2021"Medical devices - Symbols to be used with information to be supplied by the manufacturer Part1 General requirements".

2.3. Compliance

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

2.5. Electrical Safety

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

2.5.1. Electrical

- IEC 60601-1:2005+AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances–Requirements and tests
- IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-9:2007+AMD1:2013 Medical electrical equipment–Part 1-9: General

requirements for basic safety and essential performance–Collateral Standard: Requirements for environmentally conscious design

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

2.5.2. **Classification**

- Type of protection against electric shock: Class II
- The degree of protection against electric shock: Type BF applied part
- Enclosure protection: IPX0
- Degree of protection against incoming liquids: Common device.
- Level of safety when used with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non-AP/APG equipment.
- The mode of operation: Continuous operation
- Pollution degree 2

 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 3 shall comply with IEC 60601-1 and 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).

2.5.3. **EMC Notice**

 Caution

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

 Warning

- Aoralscan 3 should not be used in proximity to or on top of other devices. If it must be, observe to verify that it works properly in the configuration in which it is used.
- With the exception of cables sold by the manufacturer of Aoralscan 3 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 3.

Electromagnetic Emissions

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

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

Guidance and manufacturer’s declaration–electromagnetic emissions

Guidance and Manufacturer's Statement - Electromagnetic emission
Aoralscan 3 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3 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 3** is intended for use in the electromagnetic environment specified below. The customer or user of the **Aoralscan 3** should assure that it is used in such an environment.

Guidance and Manufacturer's Statement - Electromagnetic emission		
Aoralscan 3 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3 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.		

Guidance and manufacturer's declaration–electromagnetic immunity

Guidance and Manufacturer's Statement - Electromagnetic emission		
Aoralscan 3 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3 should ensure that it is used in this electromagnetic environment:		
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 Vrms 150 kHz to 80 MHz 6 Vrms ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz

Guidance and manufacturer’s declaration–electromagnetic immunity

Guidance and Manufacturer's Statement - Electromagnetic emission			
Aoralscan 3 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3 should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601 test levels**	**Compliance level**	**Electromagnetic environment – guidance**
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field 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 3** is used exceeds the applicable RF compliance level above, the **Aoralscan 3** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Aoralscan 3**. [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.			

Signal input/output parts 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

Test specificaions for enclosure port immunity to proximity magnetic fields

Test frequency	Modulation	Immunity test level
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 3** further from sources of electromagnetic interference or install electromagnetic shielding to block unwanted interference. The customer or the user of the **Aoralscan 3** should operate the device under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

Separation distances

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

Recommended separation distances between portable and mobile RF communications

equipment and the Aoralscan 3

Guidance and Manufacturer's Statement - Electromagnetic emission			
Aoralscan 3 is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan 3 should ensure that it is used in this electromagnetic environment:			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	IEC 60601-1-2: 2014		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

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


Warning

- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Aoralscan 3, including cables specified by the manufacturer. Otherwise, it could lead to degradation of the performance of this equipment.
- If immunity test level is higher than those specified in IEC60601-1-2, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in IEC60601-1-2 Chapter 8.10.

2.6. Biological Safety

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

2.7. 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.

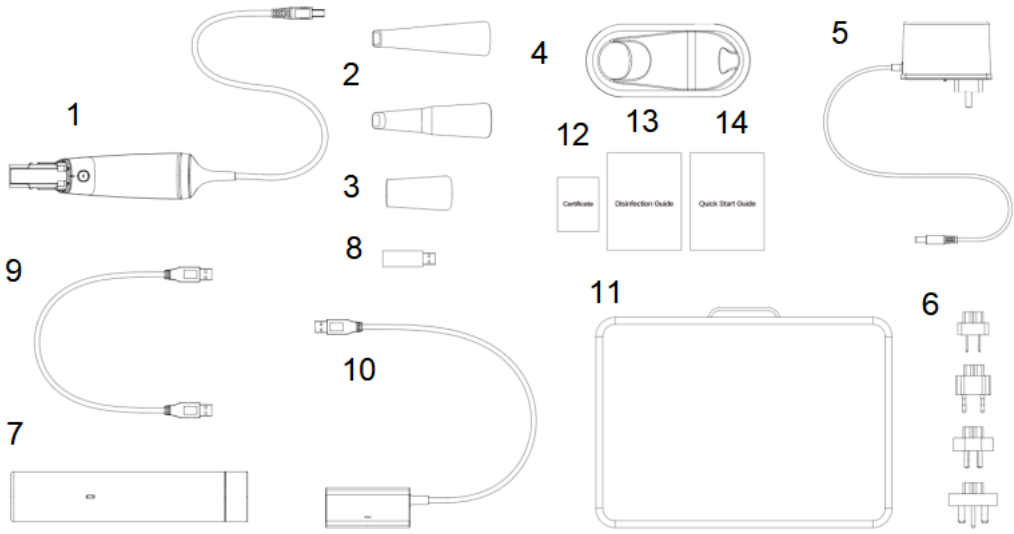
Users should be aware of optical radiation protection. Bright light is projected from the scanner tip during scanning. As with other light, there may be a temporary reduction in vision or visual residuals. Do not look directly into the light projected by the scanner tip or shine the light into the eyes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

3. 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.	Description	Quantity
1	Intraoral Scanner with a USB 3.0 cable (length: 2m)	1
2	Scanner tips (4 standard tips and 1 mini tip)	5
3	dust cap	1
4	cradle	1
5	Power adapter (input: 100-240 V, 50-60 Hz, 1.0 A; output: 12 V DC, 3 A; power cord length: 1.5 m)	1
6	power adapter plugs	5
7	calibrator	1
8	USB flash drive (the software carrier)	1

9	USB 3.0 cable. Use it together with the calibrator	1
10	USB 3.0 repeater	1
11	package box	1
12	Warranty &Quality certification	1
13	Disinfection guidelines	1
14	Quick start guide	1

 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 cause the warranty to void and result in increased emissions, decreased EMI immunity of the device, or even damages to the device and personal injuries.
- Use of other accessories results in non-compliance.
- 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.

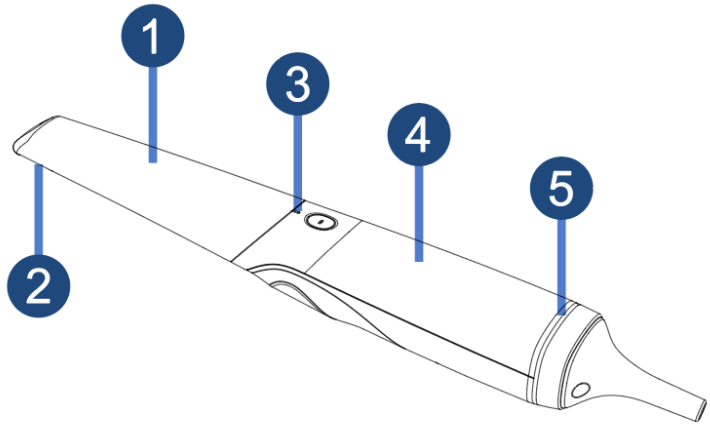
4. Scanner

4.1. Overview

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

4.2. Hardware Overview

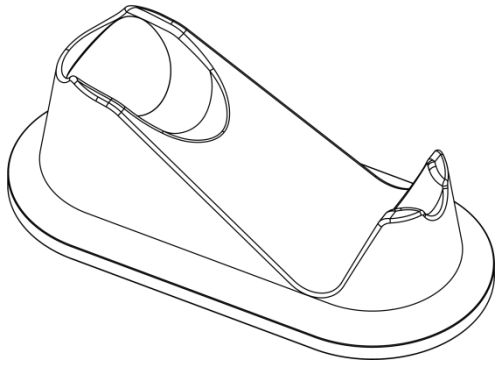
4.2.1. Scanner Tip and Scanner Body



No.	Item	Description
1	Scanner tip	Use the scanner tip to scan the upper, lower or full jaw. The scanner tip can be recycled up to 100 times.
2	Heating device	The heating device ensure successful scanning by preventing fogging on the lens.
3	Scan button	Single press to start scanning and pause scanning; long press to proceed 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	Indicator	Indicates the status of the scanner. ● Green: The scanner is in scanning, heating or standby status. ● Blue: The alignment unsuccessful when the scanner is scanning or aligning. ● Breathing green: The scanner is in sleep. Orange: Abnormal scanner status.

4.2.2. **Scanner Cradle**

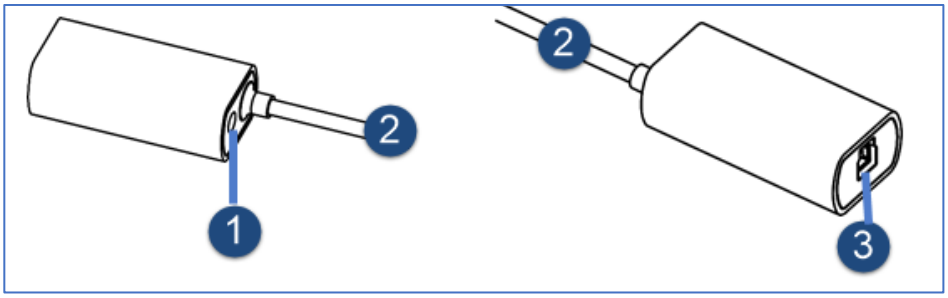


Item	Description
Scanner cradle	When the scanner is not in use, place it on the cradle.

Note

- If the scanner is idle for more than 1 minute, it will automatically enter the standby mode. When the scanner is idle for more than 3 minutes (such as on the cradle), it will enter the sleep mode, and the indicator on the scanner body will also be in the breathing light state.
- As long as there is power connected to scanner, the scanner tip will be heated even if the scanner is in standby or sleep mode.

4.2.3. **USB 3.0 Repeater**

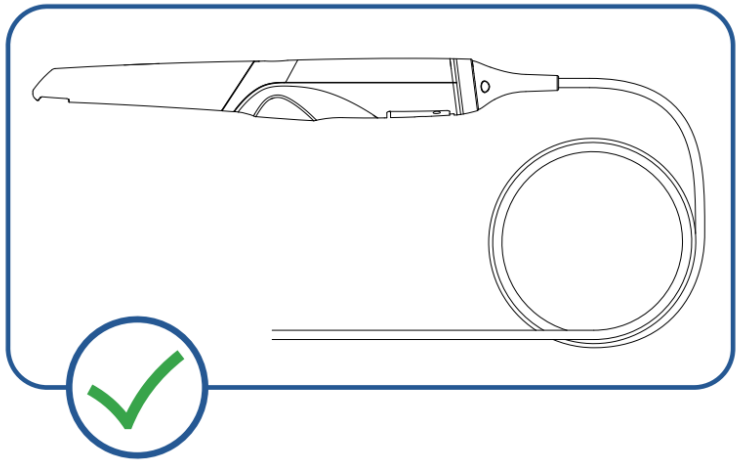


Item	Description
USB 3.0 repeater	Power port. USB 3.0 Data cable. Connect it to your PC USB3.0 port. Connect the port to the scanner.

USB cable storage

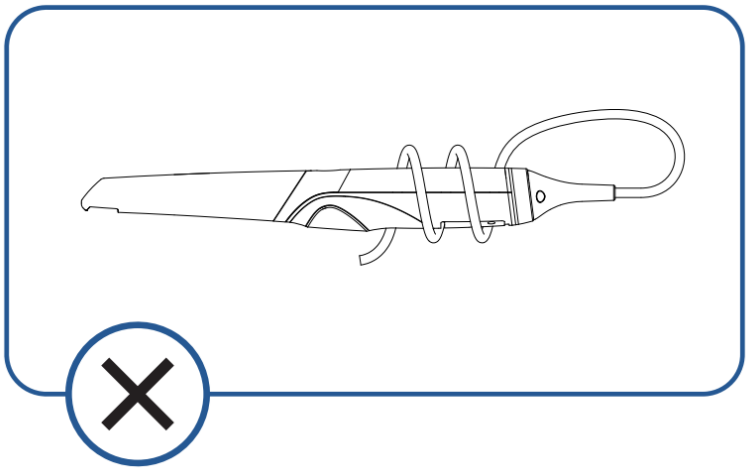
To prevent the USB cable from getting damaged by excessive bending or twisting, you should loosely coil the cable and avoid making kinks or sharp bends.

Up to 30,000 uses of the scanner tail cable.



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.



4.2.4. Main Cables

See the table for main cables.

No.	Name	Length (m)
1	Power adapter cable	1.5
2	USB 3.0 repeater data cable	1.0
3	Scanner connection cable	2.0
4	Calibrator connection cable	1.5

4.3. Software Overview

The Aoralscan 3 is designed to operate with the software programs, 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 users to be more convenient to use in the design software. Use the feature to adjust coordinates, mark tooth position, extract margin lines.

4.3.1. System Requirements

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

CPU	Intel Core i7-8700 or higher
Memory	16 GB or higher
Hard disk drive	256 GB SSD or above
Graphic 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

 Note

Your PC shall meet the safety requirements of IEC 60950.

4.3.2. Install the Software

The USB flash drive contains the IntraoralScan 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 to the wall outlet or turn on the scanner yet.

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

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

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

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

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

(5) Click OK.

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

When done, an icon named after DentalLauncher will be displayed on your desktop for quick

access.

5. Set the Scanner

5.1. Connect the Scanner

Caution

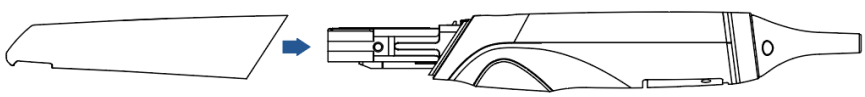
- Ensure the supplied software programs are installed on your computer before the connection.
- If the accuracy of the equipment decreases or if the equipment does not work properly, please consult technical support promptly.
- Install the scanner in accordance with the instructions stated in the Manual.
- 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 temperature extremes or in direct sunlight.
- Prepare a flat surface, e.g. your desk, for the scanner and the cradle. Do not place them on a slanted surface.
- Before the installation is completed, do not plug the power adapter into the wall outlet or turn on the scanner until you are instructed to do so.
- Always hold the scanner firmly when lifting from the stand or when using the scanner. Do not shake the scanner.
- Always return the scanner to the cradle when it is not in use. Do not place the scanner in heated or wet surfaces as this can cause damage to the scanner.
- It is normal that the scanner gets warm when in use. Do not block the ventilation holes on the bottom of the scanner. If the scanner overheats, the scanner will stop working.

Warning

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

Follow the steps below to complete the connection:

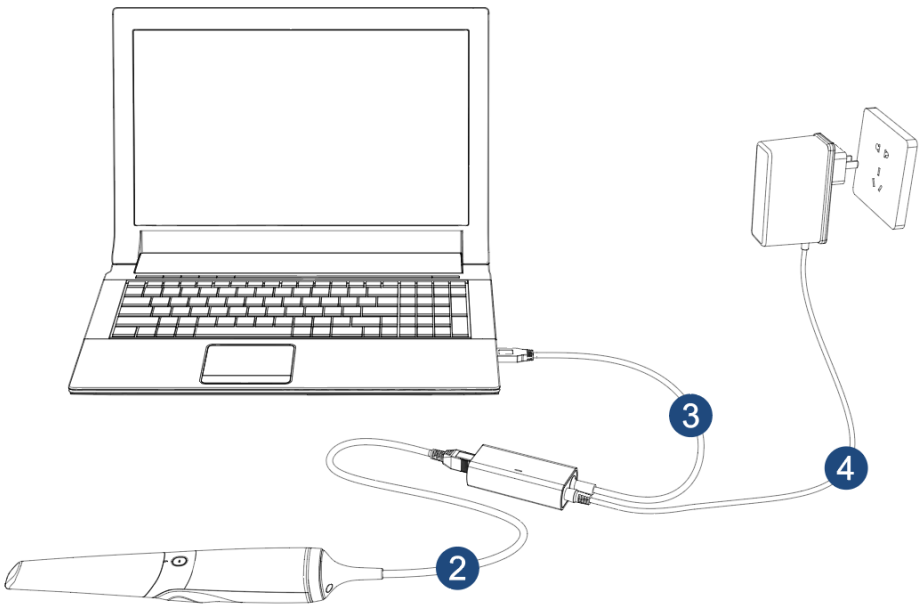
(1) Push the scanner tip hard to the scanner main body to ensure firm attachment.



(2) Connect the scanner cable to the USB 3.0 repeater.

(3) Connect the USB 3.0 repeater to the USB 3.0 port on your PC.

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



(5) Click the shortcut icon of IntraoralScan on the desktop to launch the software.

5.2. Calibrate the Scanner

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

- The initial setup of the scanner is completed.
- The scanner has been used for a period of time (e.g. 2 weeks).
- The scanner is accidentally dropped.
- Scanner brightness adjustment is recommended once every 3 months.

Follow the steps below to perform the calibration:

Step 1 The LED light of the scanner body turns green when the power connection is working properly.

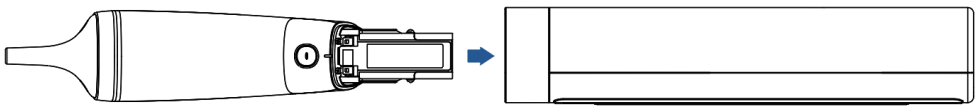
Step 2 Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner.

Note

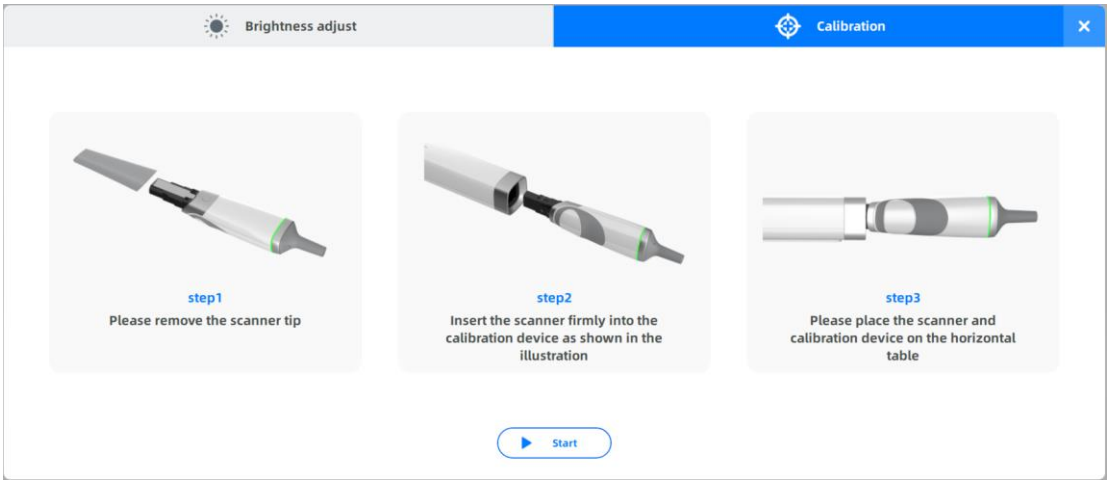
- Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.
- Store the detached tip in a safe place, e.g. a dental instrument tray, for future use.

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

Step 4 Gently slide the calibrator onto the front end of the scanner.



Step 5 Click  on the main interface to display the calibration interface.



Step 6 Ensure the scanner is plugged into the calibrator firmly. Click **Start**. Calibration begins.

Note

Normally the calibration takes approximately 7 minutes.

Step 7 The message prompting successful calibration appears once the calibration is

completed. Click OK to exit.

Step 8 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.

Step 9 Reattach the scanner tip to the scanner for later use or put the dust cap onto the scanner to prevent damage and dust.

5.3. Disconnect the Scanner

 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 IntraoralScan scanning software.

(2) Disconnect the scanner USB 3.0 cable from the USB 3.0 repeater.

(3) Disconnect the other port of the USB 3.0 repeater from the computer.

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

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

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

6. Scanning Preparations

 Warning

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

6.1. Intraoral Environment

- Make sure there is no foreign body or blood in the mouth after gargling. Stop the bleeding if necessary.
- If necessary, ask the patient to keep the tongue still and move it to the other side of the mouth.
- Consider using a dental three-way syringe to blow dry or a tampon to dry the tooth surface before starting the scan.
- Turn off the oral light on the dental chair and start scanning.
- Consider using aspirators and tampons to keep the surfaces dry during scanning.
- If necessary, consider using an oral mirror to help create space while working in the narrow area between the teeth.

6.2. 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 10.
- Ensure that the scanner tip has no scratches or is not damaged. Additionally, the tip is firmly attached to the front end of the scanner body.
- Ensure that the scanner connection is ready; it is correctly connected to a power source and powered on, and IntraoralScan is launched and ready to work.
- To avoid condensation on the mirror of the tip when scanning, the scanner tip must have been warmed up. See 6.4 Heat the Scanner Tip.
- Calibrate the scanner and verify the accuracy of the acquisition regularly. See 5.2 Calibrate the Scanner.

6.3. Scanning Position and Path

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

6.4. Heat the Scanner Tip

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

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

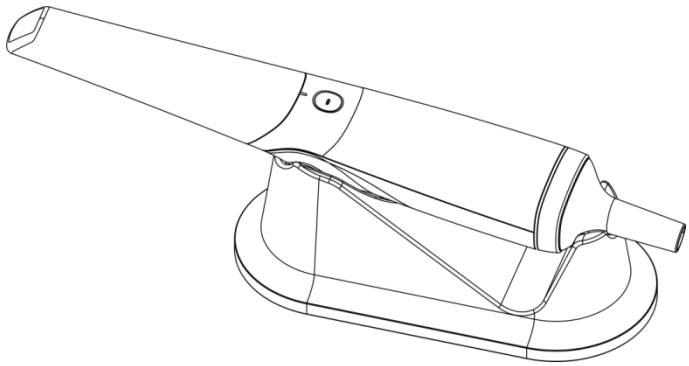
(1) Ensure that the scanner tip, scanner body, and cradle are clean.

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

(3) Connect the power supply to the Aoralscan 3. See Connecting the scanner in chapter 4.

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

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



It the temperature of the scanner tip is lower than the set point for anti-fogging, a notification message of pre-heating and current temperature appears.

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

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.

7. Clinical Case Quick Guide

Note

The chapter takes clinical case as example to show software related operations. For more software related operations, see User Manual.

7.1. Connect the Scanner

See 5.1 Connect the Scanner.

7.2. Activate the Scanner

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

Ensure the computer has been connected to the Internet, click “Yes” to activate the device, proceed to the next step after successfully activated. Otherwise, contact technical staff.

7.3. Calibration

See 5.2 Calibrate the Scanner. To ensure the quality of the scanned data, it is necessary to perform calibration periodically (every 15 days recommended).

7.4. Register Account

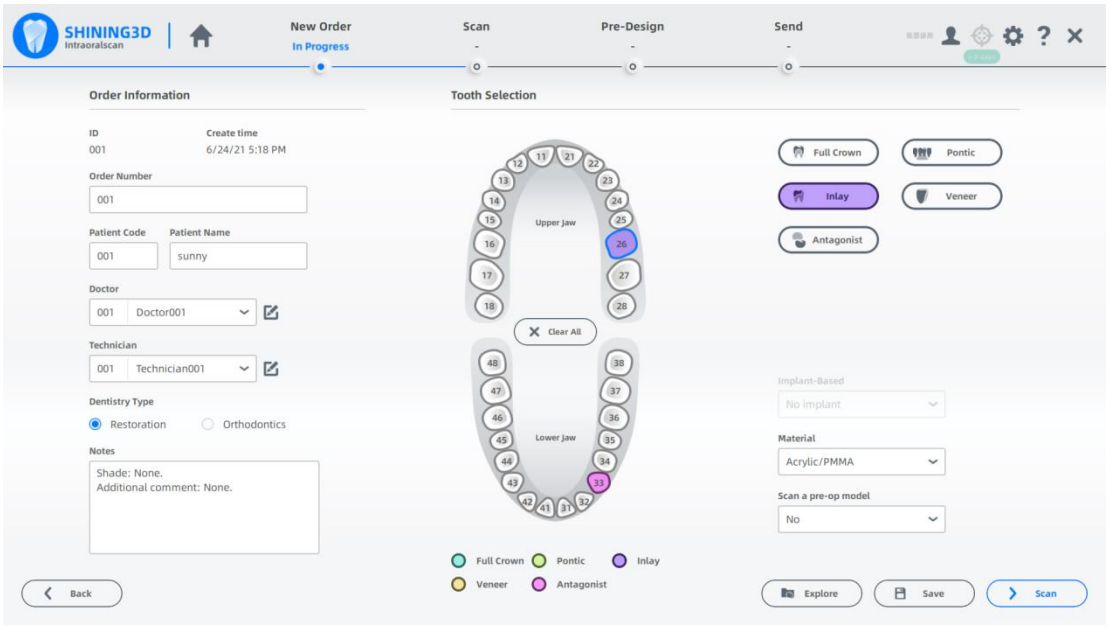
For users without other Shining 3D account, register account first. Click **New User? Click here to register**. The register interface is displayed. Select **Forget Password** or enter user info. Mind that you need to select **Read and agree with it**.

7.5. Create Orders

On the New Order interface, create a new order or import a saved order.

Click **Create New Order**. Fill out the necessary order information, including the order number, names of dentist(s), patient, and lab(s).

Select the desired type of restoration and the tooth number (the restoration site), and then click **Save**.



Click **Scan**. Scanning begins.

7.6. Scan Upper Jaw

Confirm that the image of the camera window in the upper right corner of the software is displayed normally. Click  or press the Space key or press the scanner body button to start scanning.

Before scanning, click  in the right side and then it will turn to  . The software will automatically remove the buccal and tongue side data during intraoral scanning. (Images of disabled and enabled AI optimization)

The green frame in the middle of the software interface indicates the data range of the current scanning. If the green frame changes to a red frame, as shown in the figure below, the scan position is incorrect. You need to move the scanner tip to scan the data displayed in the red

frame.

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 according to the demand.

Confirm that the model scan is complete. Click  or long press the Space key or press the scanner body button to process and save the data. After the completion, the upper jaw icon is green and ticked, indicating that the scanning process is finished.

7.7. Scan Lower Jaw

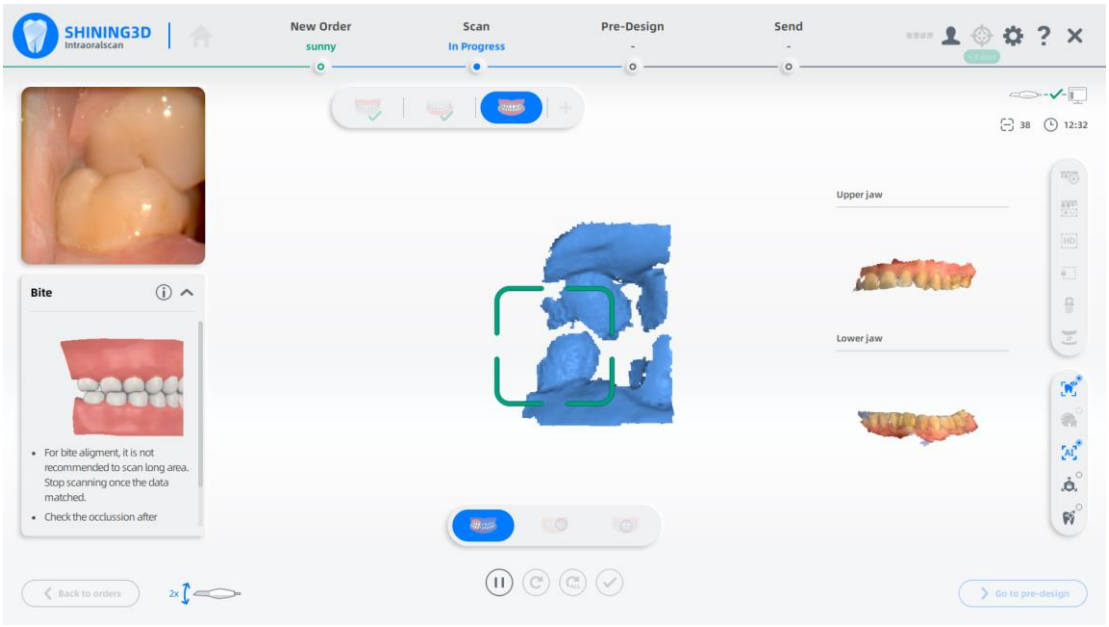
After the upper jaw scanning and the data processing are completed, the lower jaw scanning interface is automatically displayed. The procedure is the same as scanning the upper jaw.

7.8. Scan Total Jaws

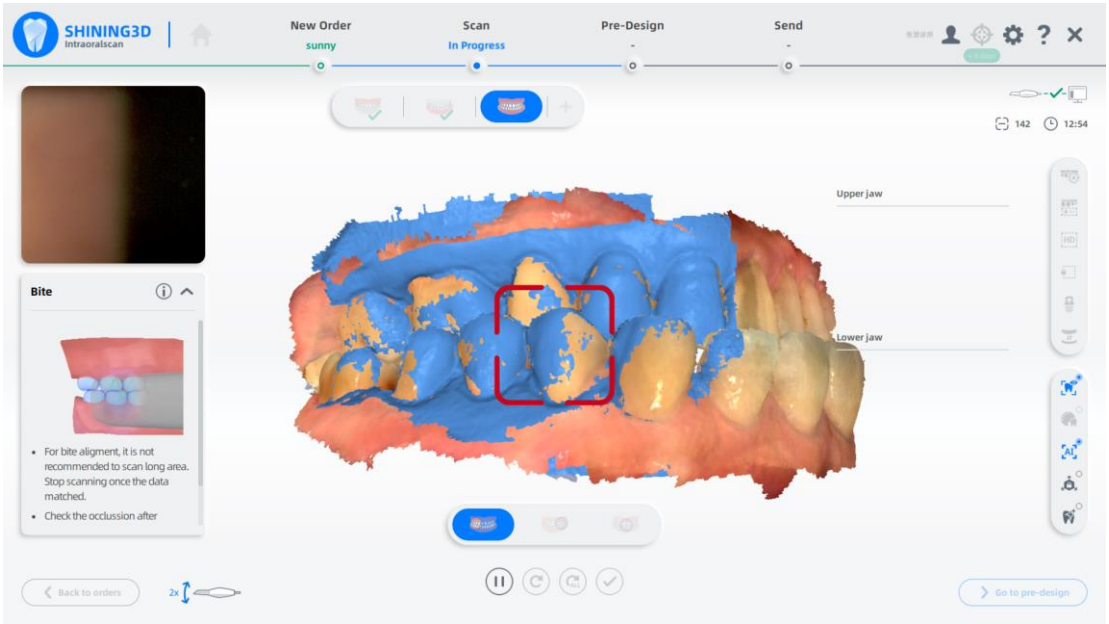
After the lower jaw scanning and the data processing are finished, the total jaw scanning interface is automatically displayed.

Click  or press the Space key or press the scanner body button to start scanning. After scanning some data, the software automatically performs dynamic bite alignment, as shown below.

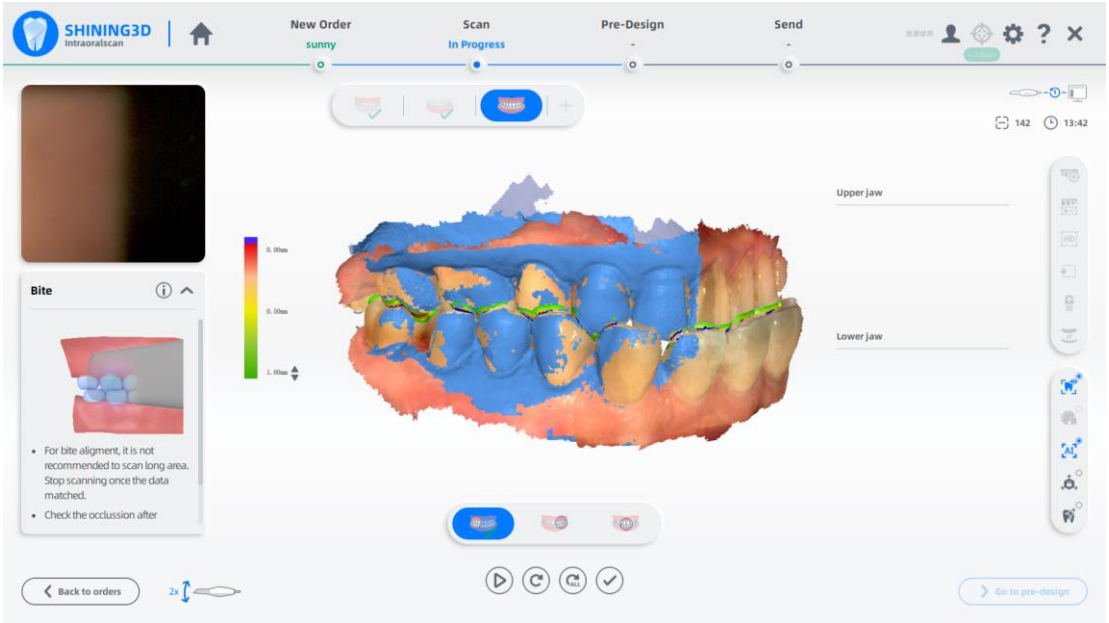
Before alignment



After alignment



After the upper and lower jaws' data are aligned successfully as well as the whole jaw, click  or press the Space key to pause the scanning, check the occlusion.

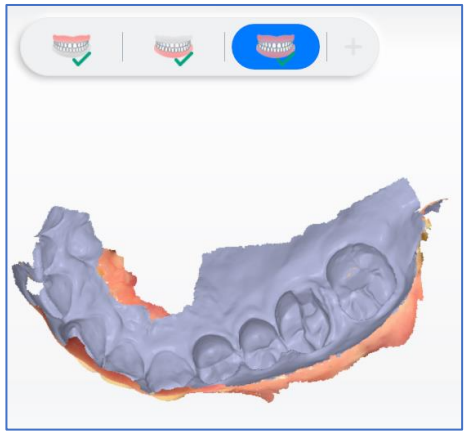


7.9. View Result Data

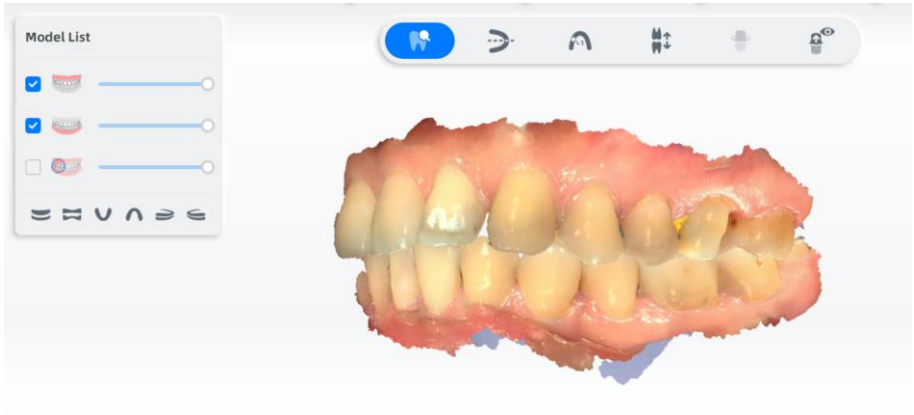
View result data in IntraoralScan.

7.9.1. View Upper/Lower Jaw

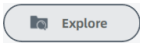
7.9.2. View Occlusal Effect



7.10. Pre-Design

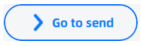


7.11. View Data Storage Path

Click  under **New Order** to return to the order interface and click 

to open the folder path of the current order storage.

7.12. Upload Order

Click 

to upload the scanned order.

8. Care and Maintenance

8.1. Pre-cleaning, Disinfection, and Sterilization

The whole set of Aoralscan 3, including scanner tip, scanner body, and scanner cradle, requires proper care, cleaning, and handling. As individual part may be processed differently, read and follow the information and instructions given to help you effectively and thoroughly reprocess the set.

We suggest that you reprocess the Aoralscan 3 in the following order:

(1) Scanner cradle care

(2) Scanner body care

(3) 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, sterilization procedures other than those specified in the Manual may damage the product and void your warranty.
- Only sterilize the part(s) for which a sterilization method is specified. Do not attempt to sterilize all parts of the product. Shining3D Corporation is not liable for any damages due to improper sterilization.
- After sterilization, wait until each of the parts is at room temperature to prevent possible heat injuries to the user and the patient.
- To prevent cross-contamination, pre-cleaning, disinfection, and sterilization must be correctly performed after each use.
- When the scanner tip is detached from the scanner, always protect the subtle units and the inner optical components on the front end of the scanner body by putting on the supplied dust cap.

8.2. Scanner Body and Cradle Care

Both the scanner body and cradle require an intermediate-level disinfection.

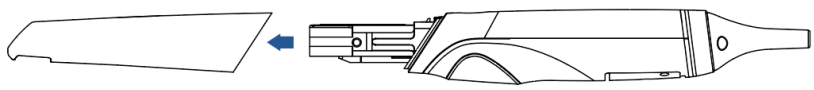
Warning

- Concerning hand hygiene and personnel safety when performing pre- cleaning and disinfection/sterilization, you must wear clean surgical gloves before you start.
- Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.
- The caring methods for the scanner cradle, scanner body, and scanner tip are different and must be executed separately. Before disinfecting the scanner body, you shall start with the cradle first.
- Ensure that the scanner tip is detached from the scanner, and the dust cap is put on the scanner when disinfecting the scanner body.

Follow the steps below to complete the disinfection:

(1) Disconnect the power of the Aoralscan 3 (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 mirror of the tip when detaching as this may result in damage to the mirror.

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

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

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

Caution

- When the scanner tip is detached, always protect the subtle units and the inner optical components on the front end of the scanner by putting on the supplied dust cap.
- Do not attempt to clean the outer units and inner optical components on the front end of the scanner with any sharp objects or other such tools, which may result in scratches and damage to the scanner.

(6) Hold the scanner body with your hand.

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

 Caution

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

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

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

8.3. Scanner Tip

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

 Warning

- Concerning 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, be sure to follow the instructions on the disinfectant label and limit the time and depth that the tip is soaked within the minimum time recommended.
- The scanner tip can be sterilized under high temperature up to 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 only either of these methods to ensure the safe and effective reprocessing of the scanner tip, and thus to prevent damage of reusable tip.

Two effective and approved methods of cleaning and disinfection/ sterilization are recommended and described as below.

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

8.3.1. Cleaning and High-level Disinfection

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

(1) Disconnect the power of the Aoralscan 3 (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 mirror of the tip when detaching as this may result in damage to the mirror.

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

 Caution

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

(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.

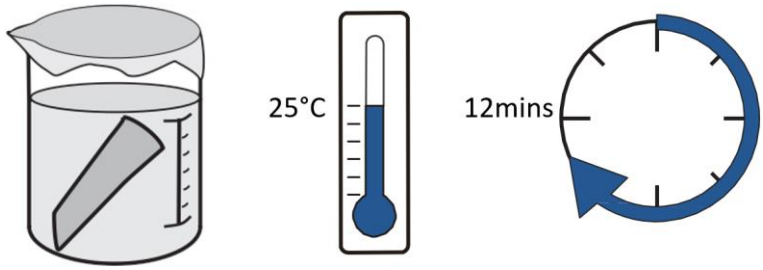
(7) If you notice stains, fingerprints, or smears on the mirror surface, repeat the previous step.

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

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

(10) Carefully fill the container with a disinfectant solution, such as phthalaldehyde 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.



(12) Prepare a large container of 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 volumes of 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 for removing the residue of disinfection solution.

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

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

(19) Re-attach the scanner tip (see 8.3.3 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.

8.3.2. Cleaning and Steam Sterilization

Follow the steps below to perform cleaning and steam sterilization:

(1) Disconnect the power of the Aoralscan 3 (see 5.3 Disconnect the Scanner).

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

Caution

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

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

Caution

If the mirror 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 mirror 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 inspect the mirror surface of the scanner tip again to make sure that the cleaning is done properly and the mirror is not damaged during the cleaning process.

(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.

8.3.3. Attach the Scanner Tip

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

the tip to the scanner.

Warning

- Wear clean surgical gloves before you start.
- Ensure that the scanner cradle, scanner body, and scanner tip are pre-cleaned and disinfected/sterilized (see Scanner body care on chapter 10 and Scanner storage on chapter 10).

Follow the steps below to complete the attachment:

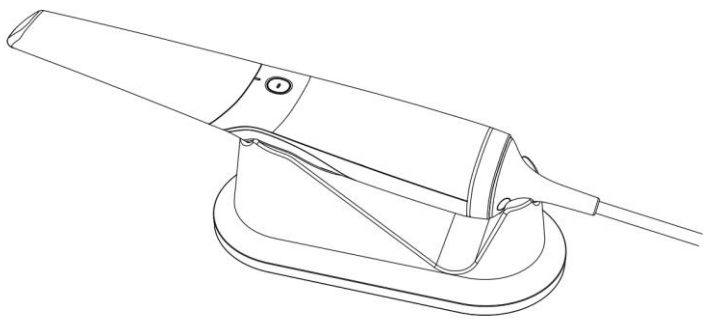
(1) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently attach the tip facing downward to the scanner.

Caution

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

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

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



8.4. 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 against any possible damage during transportation.

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

8.4.2. 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.

9. Hardware Specification

9.1. Specifications

Parameter	Description
Type Name	Intraoral Scanner
Model Name	Aoralscan 3
Scanner	
Connection	Wired connection
Scan Field	Standard tip: 16 mm × 12 mm Mini tip: 12 mm × 9 mm
Scanning tip dimensions	120 mm × 34.5 mm × 27 mm
Scanner tip types	Standatd tip and mini tip
Scanner tip maintenance	Sterilized 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
Connector	USB 3.0
Output	STL、OBJ、PLY
Power	12V DC/3.0 A
Device Lifecycle	8 years

9.2. Environmental Requirements

Operating and storage requirements

- Operating temperature: 10°C–40°C
- Operating Relative humidity: 30%RH~80%RH
- Storage/Transport temperature: -30°C–60°C
- Storage/Transport/Relative humidity: 30%RH–90%RH
- Air pressure: 70kPa–106 kPa