



SHINING 3D

Aoralscan Elite Instructions for Use



V1.0






Foreword

General

The instructions for use (hereinafter referred to as "the Instructions") introduces the functions, installation, usage and maintenance of the Aoralscan Elite (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 Instructions

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Table of Content

Foreword.....	- 1 -
1. Read This First	- 6 -
1.1. Basic Information	- 6 -
1.2. Intended Use	- 10 -
1.3. Contraindications	- 12 -
1.4. Warnings	- 12 -
1.5. Waste Electrical and Electronic Equipment	- 12 -
1.6. Disposal	- 13 -
1.7. Warranty	- 13 -
2. Safety Information	- 14 -
2.1. Precautions.....	- 14 -
2.2. Labels and Symbols	- 15 -
2.3. Compliance.....	- 16 -
2.4. Electrical Safety	- 17 -
2.4.1. Electrical	- 17 -
2.4.2. Classification.....	- 17 -
2.4.3. EMC Notice.....	- 18 -
2.5. Biological Safety	- 23 -
2.6. Laser Protection	- 23 -
3. Unpack the Package	- 25 -
4. Scanner.....	- 27 -
4.1. Overview	- 27 -
4.2. Hardware Overview	- 27 -
4.2.1. Scanner Tip and Scanner Body	- 27 -
4.2.2. Scanner Cradle	- 28 -
4.2.3. Cable storage.....	- 29 -
4.3. Software Overview	- 30 -
4.3.1. System Requirements	- 30 -
4.3.2. Install the Software	- 31 -
5. Set the Scanner	- 32 -
5.1. Connect the Scanner	- 32 -

5.2.	Calibrate the Scanner	- 34 -
5.3.	Disconnect the Scanner.....	- 35 -
6.	Scanning Preparations.....	- 36 -
6.1.	Intraoral Environment.....	- 36 -
6.2.	Scanner Preparation.....	- 36 -
6.3.	Scanning Position and Path	- 36 -
6.4.	Heat the Scanner Tip	- 37 -
7.	Clinical Case Quick Guide	- 39 -
7.1.	Connect the Scanner	- 39 -
7.2.	Register Account	- 39 -
7.3.	Activate the Scanner	- 39 -
7.4.	Calibration (optional)	- 39 -
7.5.	Create Orders	- 39 -
7.6.	Scan Upper Jaw	- 40 -
7.7.	Scan Lower Jaw	- 41 -
7.8.	Scan Total Jaws.....	- 42 -
7.9.	Mark Scan Body Scanning	- 43 -
7.10.	View Result Data	- 43 -
7.10.1.	View Upper/Lower Jaw	- 43 -
7.10.2.	View Occlusal Effect	- 43 -
7.10.3.	Tooth preparation monitoring	- 43 -
7.11.	Pre-Design	- 44 -
7.11.1.	Texture and Smooth.....	- 44 -
7.11.2.	Occlusion Test	- 44 -
7.11.3.	Check Undercut.....	- 45 -
7.11.4.	AccuDesign	- 46 -
7.11.5.	Orthodontic Simulation.....	- 46 -
7.11.6.	Oral Report	- 46 -
7.11.7.	View Data Storage Path.....	- 47 -
7.11.8.	Upload Order.....	- 47 -
8.	Care and Maintenance	- 48 -
8.1.	Pre-cleaning, Disinfection, and Sterilization	- 48 -

8.2.	Scanner Body, Cradle and Calibrator Care	- 48 -
8.3.	Scanner tip maintenance	- 50 -
8.3.1.	Cleaning steps	- 50 -
8.3.2.	High-level disinfection steps	- 51 -
8.3.3.	High temperature autoclave sterilization steps	- 52 -
8.3.4.	Attach the Scanner Tip	- 52 -
8.4.	Scanner Storage	- 53 -
8.4.1.	Storage for Transport	- 53 -
8.4.2.	Daily and Long-term Storage	- 54 -
9.	Hardware Specification	- 55 -
9.1.	Specifications	- 55 -
9.2.	Environmental Requirements	- 56 -

1. Read This First

The Instructions 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 Instructions 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 and catalogue number

Product name: Intraoral Scanner

Model: Aoralscan Elite

Catalogue number: G, DG, GR, B, DB, BR and S.

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

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

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Shining3D Technology GmbH

Address: Breitwiesenstraße 28, 70565 Stuttgart Germany

Telephone: +49-711-28444089

IV. Product performance, main structural composition

Product performance Indicator

- Appearance and structure: The appearance should be smooth, crackless, stainless with no obvious deformation. The device should be flexible and reliable for operation.

- Requirements for operating and controlling:

The design and positioning for the operation and control of the Scanner should be able to prevent accidental starting.

The graphic symbols for operation and control of the Scanner should meet the requirements ISO 9687.

- Noise requirement ≤ 50 dB(A).
- Scanning speed: The average time to scan a single jaw model is no more than 3 minutes.
- Heating and anti-fogging of the scanner tip: Under normal working conditions, the scanner tip should resist fog and be heated automatically.

- Software features:

General Requirements:

It should be driven by software installed in the Scanner or by software specified by the manufacturer for digitizing and presenting the surface of the patient's teeth and adjacent soft tissues.

Software Features Requirements:

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

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

3. Running the scanning teeth and/or occlusal relationship according to the demand information.

4. The scanning data can be exported and saved in various formats, including STL, OBJ and PLY.

5. Editing function of the scanned result data, including: hole repair, data selection, data cropping, undercut, occlusion, texture and smoothing function (optional), orthodontic simulation function (optional), model making (AccuDesign) function (optional), report examination function (optional), tooth preparation monitoring function (optional).

6. Scanner with auto calibration function (optional).

- Performance
-

Morphological accuracy refers to the degree of consistency between the test result data and the 3D morphology of the whole surface of the tested object. The standard deviation of this morphological accuracy of the big scanner tip and the mini scanner tip shall meet the requirements:

Scanner tip specification	Measurement range	Standard deviation
Big/Mini Scanner Tip	Three teeth	$\leq 0.02\text{mm}$
	Full dental arch	$\leq 0.05\text{mm}$

Accuracy and deviation: Under normal conditions, the scanner is used to scan a standard model, obtain its three-dimensional stereoscopic data, and measure key dimensions to obtain measured values and the deviation and accuracy should meet the requirements of the following table:

Measurement range	Detection index	Accuracy	Deviation (Δd)
Single tooth	The d, h of any conic table	$\leq 0.02\text{mm}$	$-0.02\text{mm} \leq \Delta d \leq 0.02\text{mm}$
Full dental arch	Distance l1—I4	$\leq 0.1\text{mm}$	$-0.1\text{mm} \leq \Delta d \leq 0.1\text{mm}$

- Internet security

Data interface: Transmit the information and acquire the image by a USB cable.

User Access Control: Normal user access control. Users can log in via their login name and password.

- Repeat treatment tolerance requirements:

Repeat 100 times according to the method in "8.3 Scanning tip maintenance", the appearance should be free of surface defects visible to the naked eye, and meet the requirements of accuracy and deviation.

Main structural composition

The Scanner consists of scanner body, scanner tip, calibrator and its cable (optional), cradle (optional), and the software. The software carrier is a USB flash drive, and the software release version is 3.



Note:

The number of scanner tips is selectable.



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, clean first 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.



Caution

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

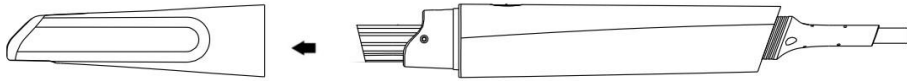
VI. Production date and life cycle

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

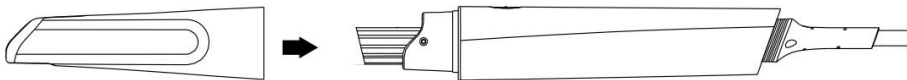
VII. The list of accessories, including accessories, wear and tear replacement cycle and instructions on how to replace.

Scanner tip as a 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 Elite 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.

1.2. Intended Use

This is an intraoral 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.



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 user should be responsible for image quality and diagnosis and ensure that the inspection data is only used for analysis and diagnosis.
 - 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
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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 Elite, 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.
- 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

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. 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 Elite. 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 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 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.









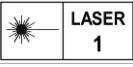
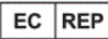





- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.

- Do not put matched plugs and USB ports in a place where it is difficult to disconnect the device.
- Reasonably arrange all 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 peripherals with an extended 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
	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.
	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 1 laser product.
RoHs	Restriction of Hazardous Substances in Electrical and Electronic Equipment. Meets the requirements of Directive 2011/65/EU.
	Indicates the authorized representative in the European Community/ European Union.
	Signify that the instructions for use/booklet must be read.
	Indicates the need for the user to consult the instructions for use.
	Indicate the unique device identifier information.
	Indicates high temperature.
	Indicate the entity importing the medical device into the locale.

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+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 to ensure the safety of patients, operators and the environment.

2.4. Electrical Safety

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

2.4.1. 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

2.4.2. Classification

- Type of protection against electric shock: depended on end product
- 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

- 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.

2.4.3. EMC Notice



Caution

- Aoralscan Elite meets the EMC requirements.
- Users should install and use the EMC information provided in the accompanying document.
- The performance of Aoralscan Elite might be affected by 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.
- The scanner is intended for use in Professional healthcare facility environment and home healthcare environment.



Warning

- Aoralscan Elite 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 Elite 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 Elite.
- 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).

List of cables:

No.	Name	Length
1	Scanner cable	2.0m
2	Connection cable (calibrator)	1.5m

Essential performance: No.

Electromagnetic Emissions

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

The **Aoralscan Elite** is intended for use in the electromagnetic environment specified below. The customer or user of the **Aoralscan Elite** 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 Elite is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan Elite 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
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Interference immunity

The **Aoralscan Elite** is intended for use in the electromagnetic environment specified below.

The customer or user of the **Aoralscan Elite** should assure that it is used in such an environment.

Guidance and Manufacturer's Statement - Electromagnetic emission		
Aoralscan Elite is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan Elite 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) ± 0.5kV, ± 1 kV, ± 2 kV line(s) to ground	±0.5, ±1kV line(s) to line(s) ± 0.5kV, ± 1 kV, ± 2 kV line(s) to ground
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T (100% dip in U_T) 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 U_T) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T (100% dip in U_T) 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 Elite is intended to be used in the following electromagnetic environment. The purchaser or user of Aoralscan Elite 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	10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	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 and amateur radio 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

RF wireless communication equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation(W)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	1,8	27
450	430 - 470	GMRS 460, FRS 460	2	28
710	704 - 787	LTE Band 13, 17	0,2	9
745				
780				
810	800 - 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	2	28
870				
930				
1720	1700 -1990	GSM 1800; CDMA 1900; GSM 1900;	2	28
1845				
1970				

		DECT; LTE Band 1,3,4,25; UMTS		
2450	2400 -2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	2	28
5240	5100 -5800	WLAN 802.11 a/n	0,2	9
5500				
5785				

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

equipment.

The medical electrical equipment is suitable for the professional healthcare environment per IEC 60601-1-2. 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.



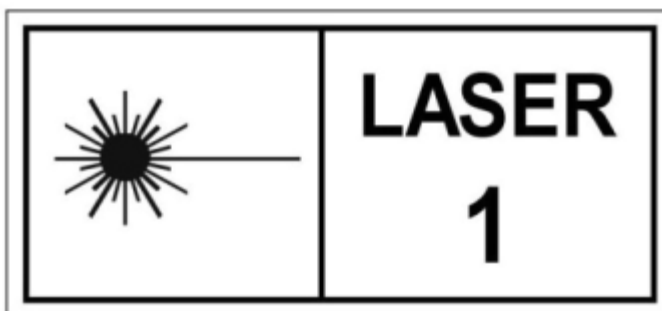
Warning

- 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 Elite, 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.

2.5. 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)

2.6. 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.

Wavelength: $450\text{nm} \pm 10\text{nm}$, pulse width: 5ms(max.), maximum average power: $179.3\mu\text{W}$. 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.

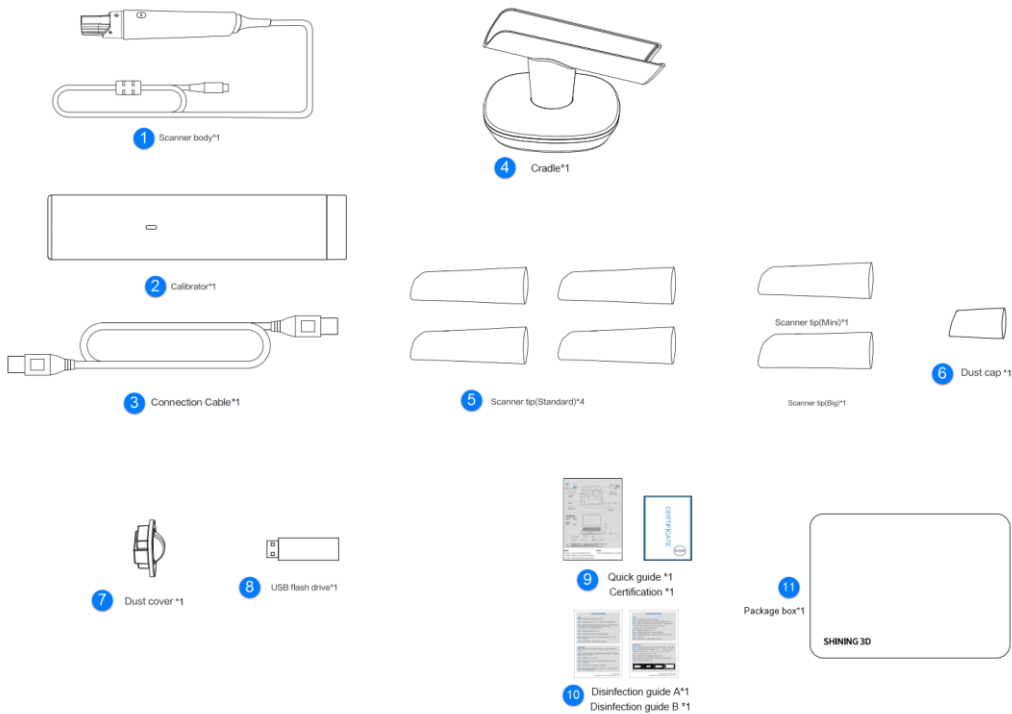
3. Unpack the Package

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
1	Scanner body
2	Calibrator (optional)
3	Connection cable
4	Cradle (optional)
5	Scanner tips (4 standard tips, 1 big tip [optional], and 1 mini tip [optional]) Note: 1. The number of scanner tips is selectable.

	2. The mini tip is intended to be used for patients who can not fully open their mouth, or for scanning narrow areas in the mouth (such as the back teeth area, etc.). Please do not use the mini tip for other purposes.
6	Dust cap for the scanner body
7	Dust cover for the calibrator
8	USB flash disk
9	Quick guide and Certification
10	Disinfection guide A and Disinfection guide B
11	Package box



Warning

- 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.

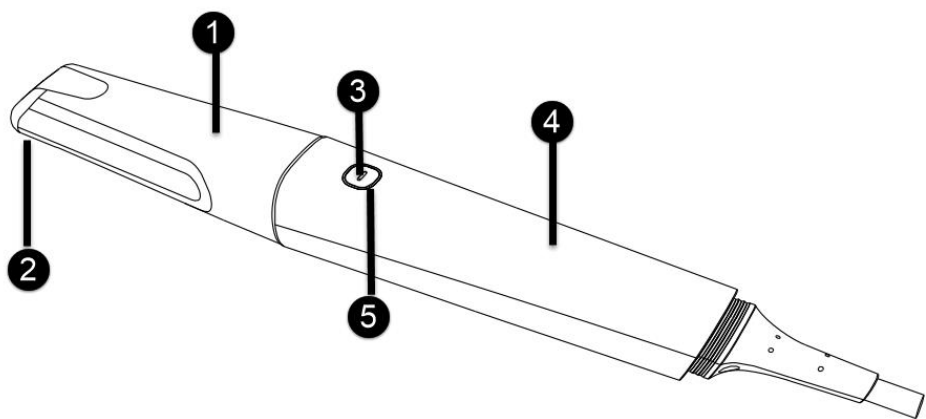
4. Scanner

4.1. Overview

The **Aoralscan Elite** 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

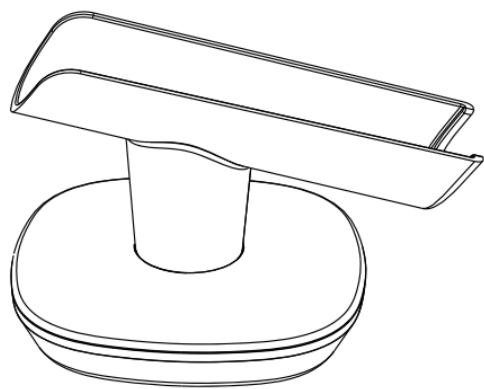
4.2.1. Scanner Tip and Scanner Body



No.	Item	Description
1	Scanner tip	The scanner tip is the applied part. 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 for about 3 seconds to enter the next step, long press for about 7 seconds to enter the shutdown state;

		Double press to enter the button interface.
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. The status indicator on the scanner: Green: The scanner is in scanning, heating or standby status. Breathing green: The scanner is in standby mode, low battery or unconnected. Orange: Abnormal status. The scanner is not correctly connected or malfunctioned. The scanner tip is not inserted tightly or the scanner is not correctly connected. Extinguished: 1. The scanner is in the sleep mode. 2. There is no power supply. 3. The scanner is shut down.

4.2.2. Scanner Cradle



Note

- When the scanner is not in use, please place it on the cradle. The scanner will immediately enter standby mode and the indicator on the scanner body will also be in the breathing light state. After 10 minutes, it will enter sleep mode and the indicator light will

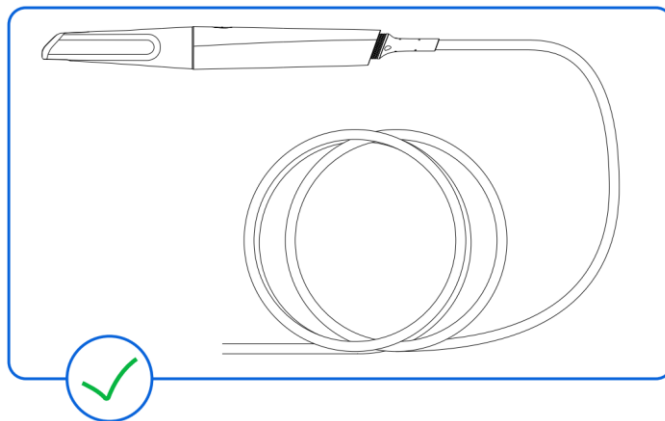
go out.

- If the scanner is not placed on the cradle and is idle for more than 3 minutes, it will automatically enter standby mode. After another 10 minutes, it will enter sleep mode.
- The scanner tip is still heated when the scanner is in standby mode.

4.2.3. Cable storage

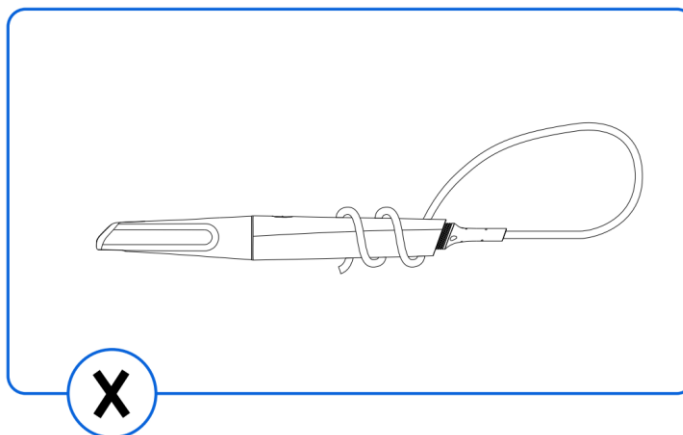
To prevent the cable from getting damaged by excessive bending or twisting, you should loosely coil the cable and avoid making kinks or sharp bends.

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.



4.3. Software Overview

The Aoralscan Elite 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 compatible versions of Windows operating system
Display Resolution	1920 × 1080, 60Hz or higher
I/O ports	At least 1 USB Type-C port 1 type-A USB 3.0 (or higher) ports



Note

Your PC shall meet the safety requirements of IEC 60950-1, IEC 62368-1/GB 4943.1.

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 named IntraoralscanVXXXX.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.
- (7) When done, an icon named after DentalLauncher will be displayed on your desktop for quick access.



Note

- Purpose of connecting to the IT-network: For communication and data transmission.
 - Network Conditions: Ethernet network with a bandwidth higher than 1MBps.
 - Network Configuration: The computer is required to access to the public network, and it is configured according to environment. Typically, the computer will automatically retrieve an IP address.
 - Technical Specifications: From device end to cloud server: HTTPS protocol, port 443; from cloud server to device end: MQTT protocol, port 8083.
 - Expected Information Flow and Routing: Patient information, scan order data, and other information are exchanged via local gateways or through the company's cloud platform.
 - Network Failure: If the network connection fails when the product is offline used, data is stored in local path. When the product have access to the network, data transmission will resume. If network connection fails during transmission, any data that has been
-

transmitted will be invalidated without causing impact.

- **Network access:**

(1) After accessing the network, the software will automatically connect to the cloud platform and obtain information about the software-connected devices, while users can upload patients and order data information on the cloud platform by registering and logging into their accounts through the software.

(2) Network anomalies caused by changes in network configurations, updates to network-connected devices, additions or deletions of network devices, or interruptions in network connections do not create a hazardous situation for this system.

(3) Failure to access our cloud platform may result in risks identified by patients, operators, and third parties, and it is appropriate for the party responsible for the controlled local area of the dental clinic or technician's office to identify, analyze, evaluate, and control these risks.

(4) The party responsible for the controlled local area of the dental clinic or technician's office shall perform additional analysis to identify, analyze evaluate and control the risks that may be introduced before making changes to the network and shall operate in accordance with the relevant cybersecurity regulations.

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.
 - 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.

- 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.

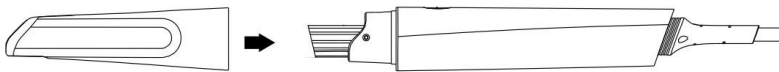


Warning

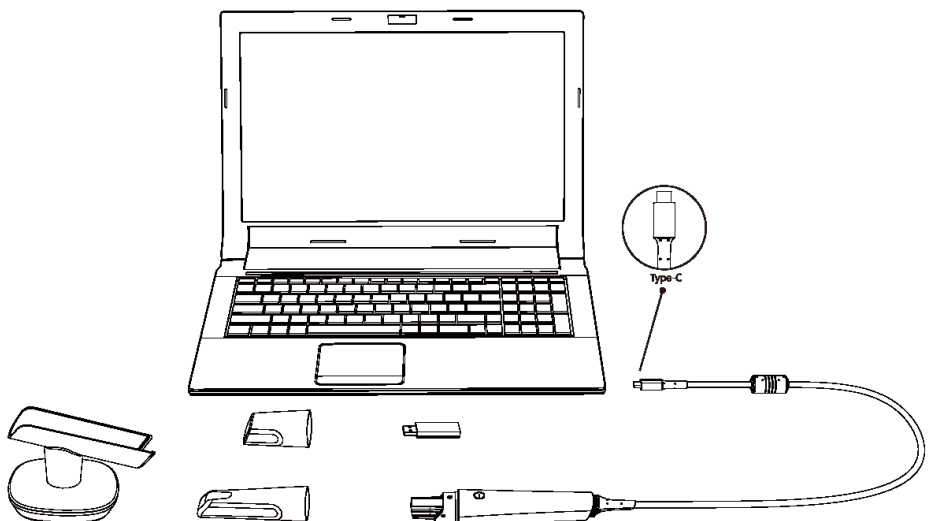
Ensure that you use only the supplied cables.

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 Type-C port of the computer.



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

5.2. Calibrate the Scanner

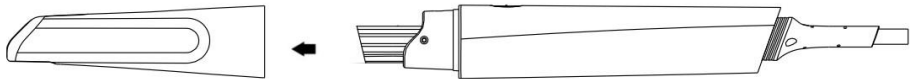
Under these circumstances, we recommend that you shall execute the calibration for the scanner to ensure the accuracy of scanned data:

- 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.

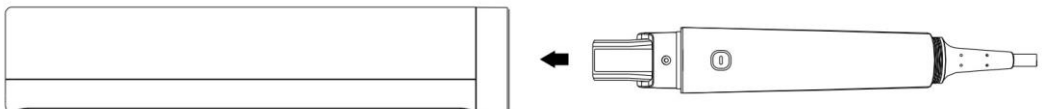
Step 3 Connect the supplied calibrator and your computer with the supplied USB 3.0 cable.



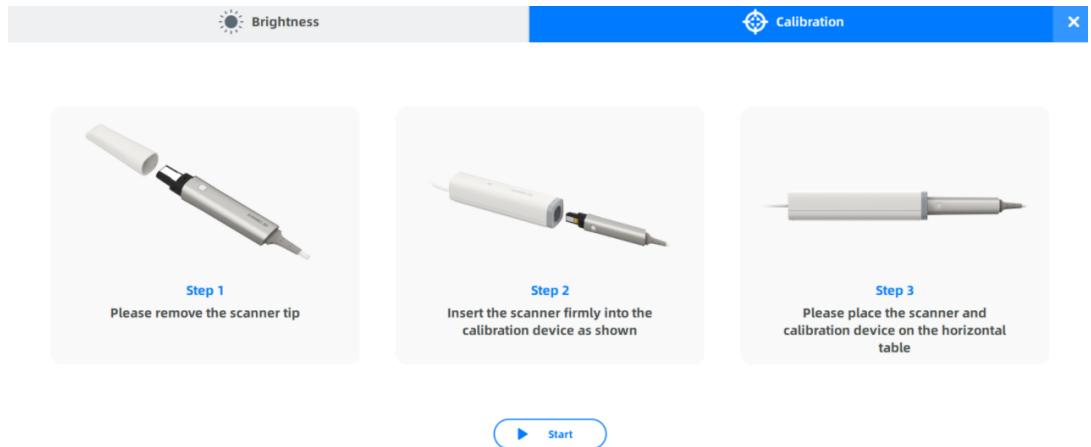
Note

Aoralscan Elite can be connected with an all-in-one machine or an external touch screen.

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 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 cable from the computer.

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 8.
- 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.
-

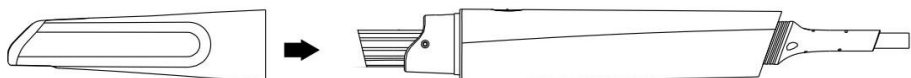
- Hold the scanner steady by resting it on the tooth surface and keep the scan tip window in the range of -1 mm to 16 mm from the teeth.
- When scanning, slowly move the scanner and simultaneously check the scan results on the screen to ensure that the scanning is of good quality.
- When scanning, the 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.

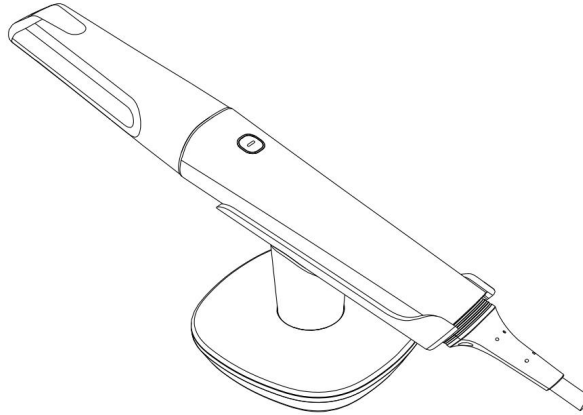
Follow the steps below to warm up the scanner before starting an acquisition:

- (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 Elite. 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.



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

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



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. 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**.

7.3. 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.

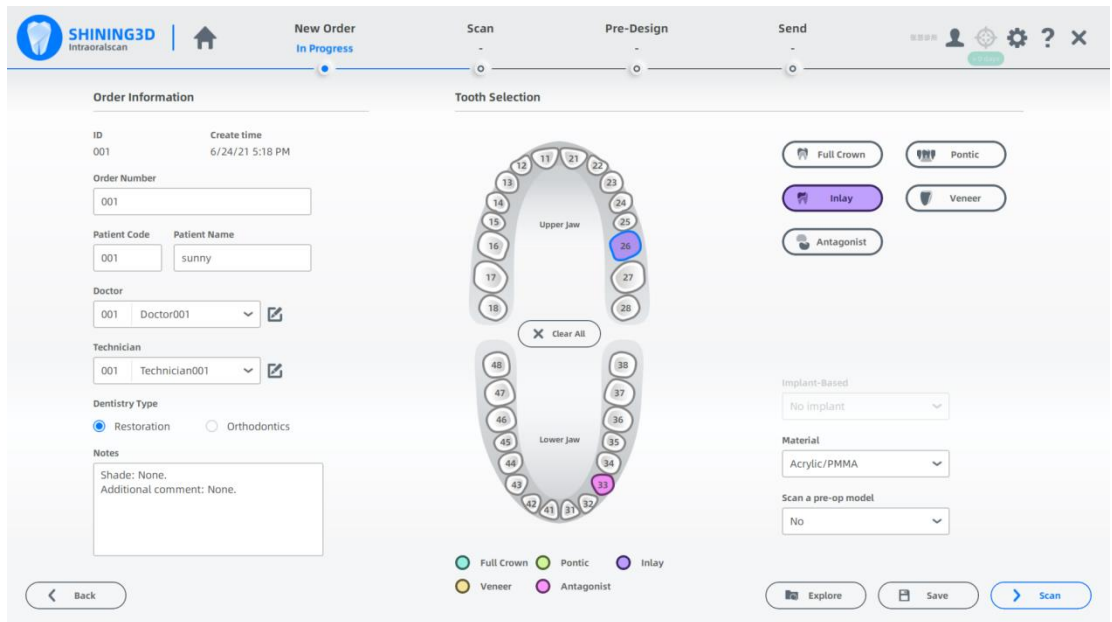
7.4. Calibration (optional)

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).

7.5. 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**.




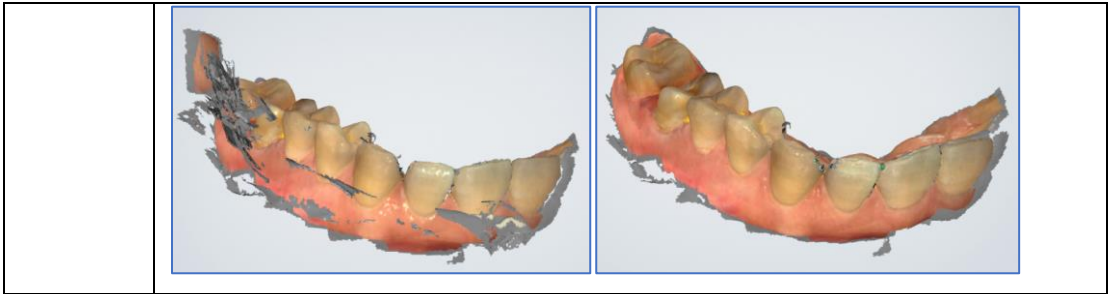
Click **Scan**. Scanning begins.

7.6. Scan Upper Jaw

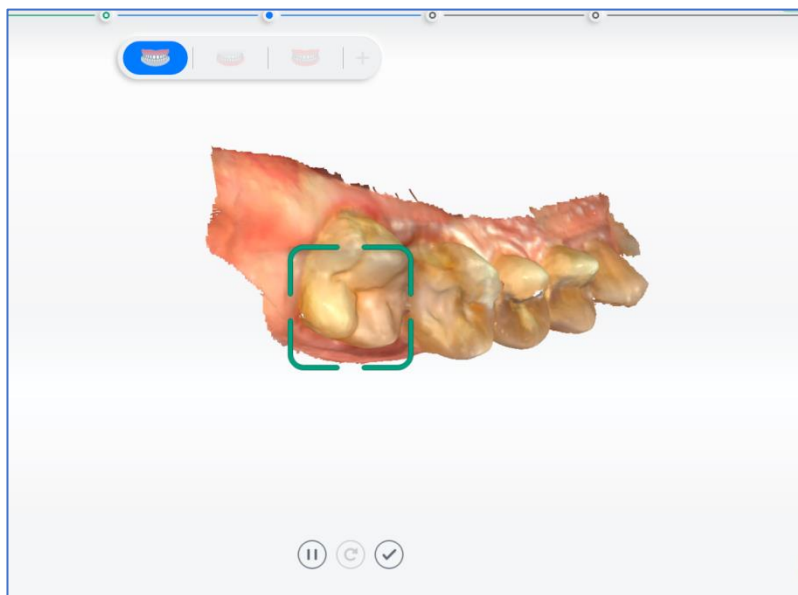
Confirm that the image of the camera window in the upper right corner of the software is

displayed normally. Click  or press the Space key or press the scanner body button to start scanning.


Auxiliary Function	Note
	<ul style="list-style-type: none"> For intraoral scanning. When it is turned on, the miscellaneous data are automatically eliminated during intraoral scanning, i.e., no buccolingual data, soft tissue and other miscellaneous data. When you use the software for the first time and enter the scanning interface, you need to wait for 1~2 minutes for initialization, and only after the initialization is completed can you turn on the function. Below are the before and after pictures, the left picture is the unopened state, the right picture is the opened state.



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.

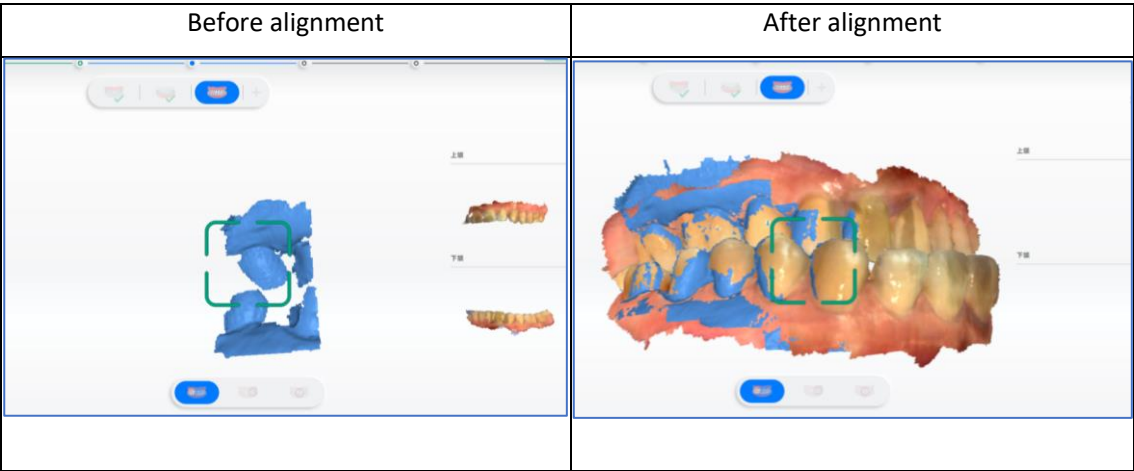
7.7. Scan Lower Jaw

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.



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.



Click the Finish button  or press the Space key for more than 3 seconds to post-process the data.

7.9. Coded Scanbody Scanning

Coded scanbody scanning is supported. After scanning the jaws and coded scanbody, the software will align the mark scan body to the jaws.

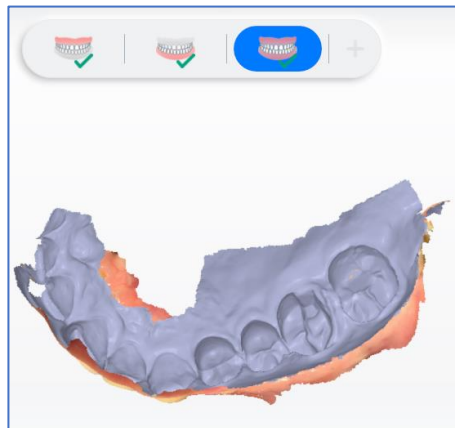
7.10. View Result Data

View result data in IntraoralScan.

7.10.1.View Upper/Lower Jaw




7.10.2.View Occlusal Effect



7.10.3.Tooth preparation monitoring


Tooth preparation is only supported for pre-op orders. By monitoring the prepared tooth, data will be saved during the grinding. It's convenient to compare multiple sets of tooth preparation data to standard model.

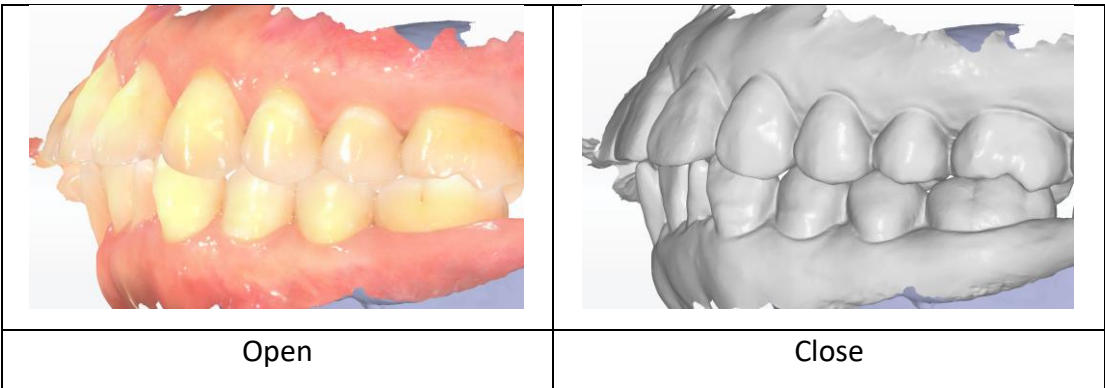
After creating a pre-op order and scanning the models, click  on the right side of the


interface and make comparison. Click on the compared models to check the results.

7.11. Pre-Design

7.11.1.Texture and Smooth


Texture: Click  to view the texture of the model.



Smooth: Click  to clean the noise and improve the quality of the model.



7.11.2.Occlusion Test

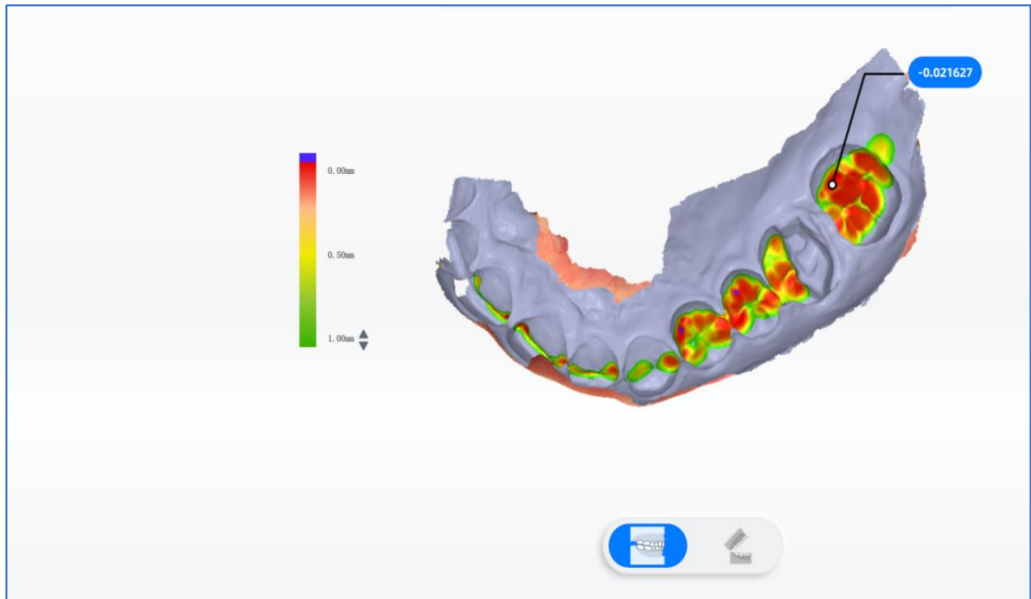
Click  under the "Pre-design" process to enter the occlusion detection interface.



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.

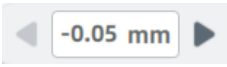



Double-click on the point of the model to detect the occlusal gap at that point.





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.

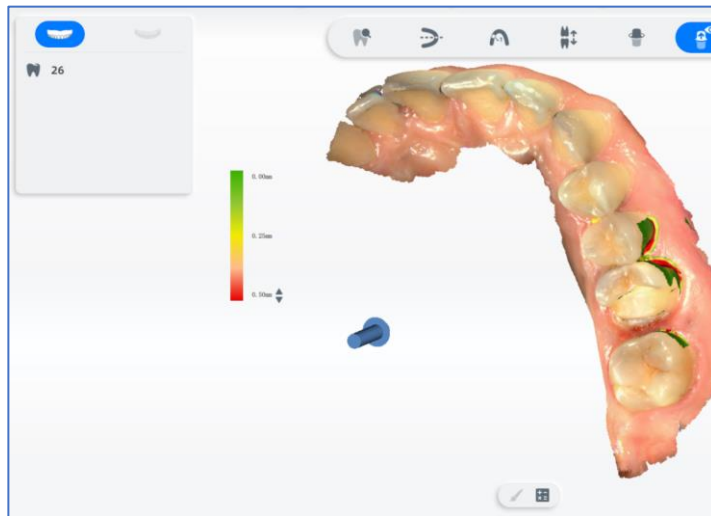
Occlusion adjustment  : Click this icon to open the occlusion adjustment parameters.

- ✧ Occlusion parameter values  : -0.05 mm, -0.10 mm, -0.15 mm. Three values are available to choose, and the default is -0.05 mm.
- ✧ Cancel  : Cancel the adjusted bite parameters and exit.
- ✧ Confirm  : Save the adjusted occlusion parameters and exit.
- ✧ Undo adjustment  : Undo the bite adjustment operation.


7.11.3. Check Undercut

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


area.



7.11.4.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.


7.11.5.Orthodontic Simulation

When creating a new program, select Orthodontics as the dentistry type to enable the orthodontic simulation function. Click  on the pre-design interface to enter the orthodontic simulation interface. Orthodontic simulation function can quickly realize orthodontic simulation by creating orthodontic simulation program and comparing orthodontic simulation effects in multiple windows. It can also carry out personalized customization of single tooth and overall adjustment of dental arch according to requirements by manual setup and adding brackets. For more details, please check the User Manual.


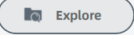
7.11.6.Oral Report

With the assist mode, Consul Report can help the dentist in recognizing oral symptoms. Tools such as the symptom labels, communication model and the observation glass help the dentist and the patient check the accurate position of the symptom. The oral report includes

detailed information of the symptoms and relevant solutions, which can be used for patient management and organisational diversion.

Click  on the pre-design interface to enter the oral report settings interface, which provides access to the oral report function. For more details, please check the User Manual.

7.11.7.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.

7.11.8.Upload Order

Click  to upload the scanned order.

8. Care and Maintenance

8.1. Pre-cleaning, Disinfection, and Sterilization

The whole set of Aoralscan Elite, including scanner tip, scanner body, scanner cradle and the calibrator, 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.



Caution

- All parts are shipped non-sterilized. Follow the instructions before the first use.
- Follow the instructions given in the Instructions to pre-clean, disinfect, and sterilize each part of the scanner. Using other methods not approved by the Instructions will damage your scanner and void your warranty.
- Only sterilize the specified part(s). Do not attempt to disinfect all parts of the product. The Company is not liable for any damages due to improper sterilization.



Warning

- Before pre-cleaning, disinfection and sterilization, wear a clean medical glove.
- Ensure that you have completely cut off the power supply and all connections from the scanner.
- After sterilization, cool the scanner tip for a period of time to prevent possible heat injuries to the user and the patient.
- To prevent cross-contamination, pre-clean, disinfect and sterilize the scanner after using it.
- 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, Cradle and Calibrator Care

The scanner body, cradle and calibrator require an intermediate-level disinfection.

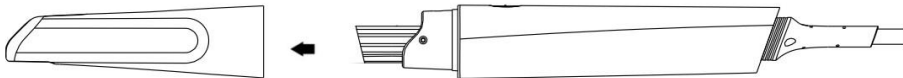


Caution

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 scanner (see more details in Connection and disconnection).
2. Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner.



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



Caution

- When detaching the scanner, do not put your fingers on the lens of the scanner tip in order to prevent it from being damaged.
 - Put the scanner into the flannel bag when it's not in use or after using it to avoid collision or accidental drop.
 - Avoid using detergent of any kind as some detergents or surfactants might penetrate the surface of the scanner body and damage the device.
 - 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
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damage to the scanner.

8.3. Scanner tip maintenance

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.



Caution

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



Warning

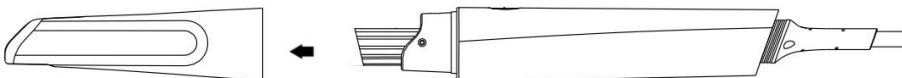
Before cleaning and disinfection/sterilization, wear clean surgical gloves and goggles.

The following are two effective and approved methods:

- Cleaning and high-level disinfection.
- Cleaning and high temperature autoclave sterilization.

8.3.1. Cleaning steps

1. Disconnect the power of the scanner, and pull the scanner tip off the scanner body.



Caution

- Do not place your finger (s) on the lens of the tip when detaching as this may result in damage to the lens.
 - 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.
2. Pre-clean the scanner tip with distilled water for 3 minutes to remove stains like the saliva or blood.
 3. Brush the inside and the outside of the tip with enzyme surfactant for 3 minutes. Repeat the step for at least 2 times.
 - When cleaning the inside of the tip, insert the sponge brush into the tip from both the front and rear ends, and move the brush lightly in tiny circles.
 - When cleaning the outside of the tip, brush the surface back and forth lightly.
 4. Rinse the tip thoroughly with distilled water for at least 3 minutes.
 5. If there is any stain or fingerprint on the lens, repeat step 3 and 4.



Caution

Rinse the tip with distilled water every time and discard the used water. Do not reuse the water for rinsing or any other purpose.

6. Dry the scanner tip with a soft lint-free cloth, and put it in a well-ventilated place to ensure it's totally dry, or put it in a dryer for 10 minutes.
7. Inspect the lens of the tip to make sure it is clean and free of damage.



Warning

If the lens of the tip has cracks or scratches on it, contact your local distributor or service provider.

8.3.2. High-level disinfection steps

1. Carefully fill the container with phthalaldehyde at a concentration of 5.5g/L, and immerse the scanner tip in the disinfectant for 12 minutes.
2. Take out the scanner tip from the disinfectant, and rinse it with distilled water 3 times and 1 minute for each to remove disinfectant residues.



Caution

Discard the used distilled water. Do not reuse the water for rinsing or any other purpose.

3. Flush the tip with distilled water for at least 3 minutes.

4. Dry the tip with a soft, lint-free cloth and put it in a well-ventilated place to make sure it is totally dry, or put it in a dryer for 30 minutes.

5. Inspect the lens of the tip to make sure it is clean and free of damage.

6. If the scanner tip needs using immediately, reconnect it; if not, store it with other dental instruments, and make sure it is totally dry.

8.3.3. High temperature autoclave sterilization steps

1. Fill the scanner tip with medical gauze and seal it in the autoclave bag.

2. Put the wrapped scanner tip into a sterilizer for 30 minutes at 121°C under a relative pressure of 102.9kPa (or 4 minutes at 134°C under a relative pressure of 205.8kPa), and then dry it for 30 minutes.



Warning

After drying, cool the scanner tip to room temperature to avoid a scald.

3. Inspect the lens of the tip to make sure it is clean and free of damage.

4. If immediate use of the scanner tip is required, reconnect it; if not, store it with other dental instruments, and make sure it is totally dry.

8.3.4. 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.

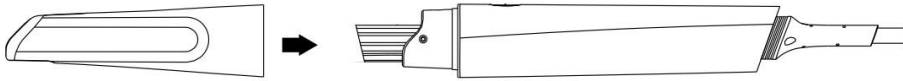


Warning

- 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:

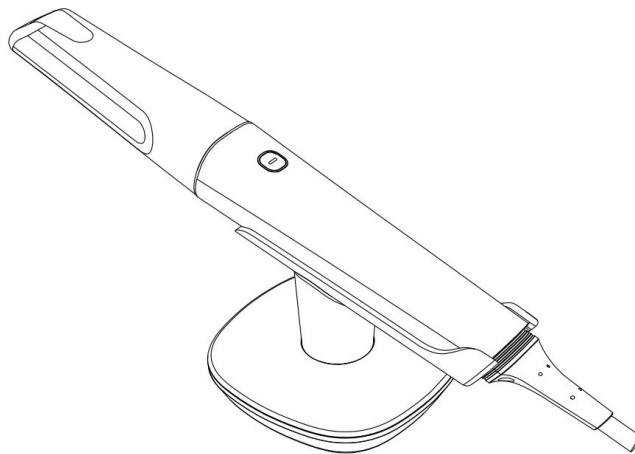
- (1) Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently attach the tip facing downward to the scanner.



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, 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 Elite
Scanner	
Scanner tip types	Big Scanner Tip, Standard Scanner Tip and Mini Scanner Tip
Scan field (L×W)	Big Scanner Tip: 19 mm × 14 mm Standard Scanner Tip: 16 mm × 12 mm Mini Scanner Tip: 12 mm × 9 mm
Scanner tip dimensions (L×W×H)	Big Scanner Tip: 95±2 mm × 30±1 mm × 26±1 mm Standard Scanner Tip: 93±2 mm × 30±1 mm × 26±1 mm Mini Scanner Tip: 92±2 mm × 30±1 mm × 26±1 mm
Scanning depth	22 mm (-2 mm ~ 20 mm away from the window of the scanner tip)
Scanner size (L×W×H)	245±4 mm × 30±1 mm × 26±1 mm
Scanner weight	124±20 g (with a standard scanner tip and without cable)
Scanner tip maintenance	Sterilized and disinfected by users (Maximum: 100 times)
Scanner tip connection	Pluggable
Light source	LED and laser
Wave length	Blue laser: 450±10 nm White LED: 400-780 nm
Output	STL、OBJ、PLY
Power	Input: 5V DC/3 A
Cradle	

Cradle size (L×W×H)	103±3 mm × 80±2 mm × 67±2 mm
Cradle weight	242±20 g
Device lifecycle	8 years
Calibrator	
Calibrator size (L×W×H)	236±3 mm × 50±2 mm × 50±2 mm
Calibrator weight	431±30 g
Calibrator cable length	1.5 m

9.2. Environmental Requirements

Operating and storage requirements

- Operating temperature: 10°C–30°C (Recommended: 20°C–30°C)
 - Operating Relative humidity: 30%RH~80%RH
 - Storage/Transport temperature: -30°C–60°C
 - Storage/Transport/Relative humidity: 30%RH–90%RH
 - Air pressure: 70kPa–106 kPa
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