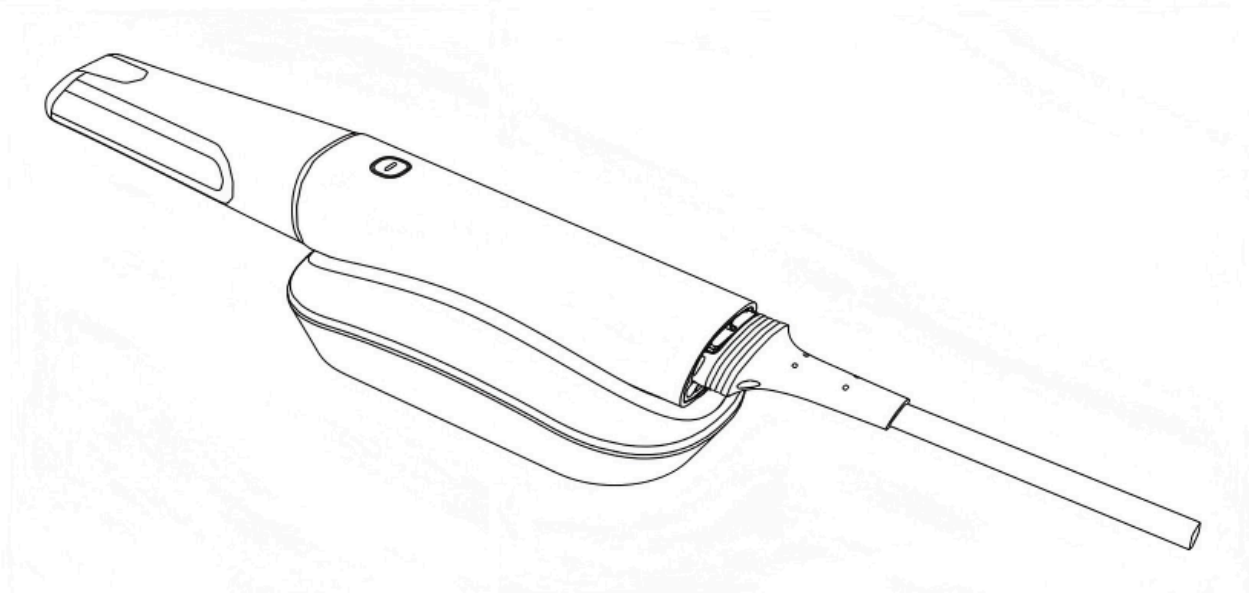
SHINING 3D

Aoralscan Elf
Instructions for Use



CE MD

Version: V1.0

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Foreword

General

This Instructions for Use (hereinafter referred to as "the Instructions") introduces the functions, installation, usage and maintenance of Aoralscan Elf (hereinafter referred to as "the scanner"). MD indicates that it is a medical device.

Symbol conventions

Symbol	Description
	**Note:** This symbol is used to inform you of additional information of the product.
	**Caution:** This symbol is used to inform you of the 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 information

Release version	Release date	Language version
V1.0	August 2025	English - Original Instructions

The Declaration of Intellectual Property and Disclaimer

Thank you for using the products of SHINING 3D TECH CO., LTD. (hereinafter referred to as the "SHINING 3D”). Before you use the products, please carefully read and understand this declaration. Once you use this product, it means that you fully accept this statement and promise to comply with the relevant regulations.

1. The contents of the Product Instruction and User Manual (hereinafter collectively referred to as the "Product Usage Documentation") are critical to your personal safety, legal rights, and liabilities. Before you use the products, please ensure that you have carefully read the Product Usage Documentation, and use the product correctly in accordance with the requirements of the Product Usage Documentation. We also recommend that the products be operated by trained professional technicians.

2. Please inspect and/or maintain the product before use. If the product is damaged, deformed or in any other abnormal condition, stop using it immediately and contact the after-sales service personnel for maintenance. SHINING 3D will not be responsible for any problems caused by your failure to inspect or maintain the product in a timely manner.
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6. SHINING 3D shall not be held responsible for any damages and/or losses caused by human factors, environmental factors, improper storage and use, or any other factors other than due to the quality of the product.SHINING 3D also shall not be held responsible for any indirect anticipated profit loss, loss of reputation and other indirect economic losses. Except as otherwise expressly provided by laws and regulations, the total liability assumed by SHINING 3D (regardless of cause) shall not exceed the purchase price of the products you paid to SHINING 3D.
7. Disputes arising from this Declaration and the Product Usage Documentation thereof shall be governed by the laws of the People’s Republic of China, excluding its conflict of law rules. In the event that certain provisions are in conflict with the applicable law, these provisions will be reinterpreted in full accordance with the law, while other valid provisions will remain in force.
8. All disputes between you and SHINING 3D that arise from, shall first be resolved amicably through negotiation. If a dispute cannot be resolved through friendly negotiation, any party may submit the dispute to the Court of Xiaoshan District, Hangzhou City, Zhejiang Province, People's Republic of China for litigation and settlement.
9. In the event of any questions about the contents of this Declaration and application of Product Usage Documentation, please contact us by the contact information provided in the User Manual. Thank you for your cooperation and support! We hope that our products can bring you a great experience of using.

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1. Read This First

Before using the product, please read the Instructions carefully and strictly observe all cautions and warnings. Not following the cautions and warnings may result in product damage, or even personal injury.

1.1 Basic information

I. Product name, model and catalogue number

Product name: Intraoral Scanner

Model: Aoralscan Elf

Catalogue number: R, CG, DB, P and TS.

II. Manufacturer information and production address

Manufacturer Name and Address

Shining 3D Tech Co., Ltd.

No. 1398 Xiangbin Road, Wenyan Street, Xiaoshan District, Hangzhou, Zhejiang, 311258, China

Manufacturing Location

No. 1398 Xiangbin Road, Wenyan Street, Xiaoshan District, Hangzhou, Zhejiang, 311258, China;

Building 3, No. 111 Yanshankong Road, Wenyan Street, Xiaoshan District, Hangzhou, Zhejiang, 311258, China

III. Contact information

Manufacturer

Shining 3D Tech Co., Ltd.

No. 1398 Xiangbin Road, Wenyan Street, Xiaoshan District, Hangzhou, Zhejiang, 311258, China

www.shining3ddental.com

Customer support

Email: dental_support@shining3d.com

SHINING 3D's EU representative

Lotus NL B.V.

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

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EU importer

Shining3D Technology GmbH

Address: Breitwiesenstraße 28, 70565 Stuttgart Germany

Telephone: +49-711-28444089

IV. Product performance and main components

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:
  a. The design and positioning for the operation and control of the Scanner should be able to prevent accidental starting.
  b. The graphic symbols for operation and control of the Scanner should meet the requirements ISO 9687.
- Noise requirement: ≤ 50 dB (A).
- 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 scanner tips shall meet the following requirements:

Scanner tip type	Measurement range	Standard deviation
Big/Standard scanner tip	Three teeth	≤ 0.020 mm
	Full dental arch	≤ 0.050 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. The accuracy and deviation should meet the following requirements:

Scanning range	Detection index	Accuracy	Deviation (Δd)
Full dental arch	The d, h of any conic table	≤ 0.020 mm	-0.020 mm ≤ Δd ≤ 0.020 mm
Full dental arch	Distance l_1—l_4	≤ 0.100 mm	-0.100 mm ≤ Δd ≤ 0.100 mm

- 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 functions
  a. The software provides guidance for the users to understand the operations. It has backward function as well.
  b. Establishing demand information, which may include: jaw position information, tooth position information, treatment modality information, and occlusal relationship information.
  c. Running the scanning teeth and/or occlusal relationship according to the demand information.
  d. The scanning data can be exported and saved in various formats, including STL, OBJ and PLY.
  e. 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 function (optional, for Windows); report examination function (optional); tooth preparation monitoring function (optional, for Windows).
  f. Scanner with auto calibration function (optional).
- Internet security
  a. Data interface: The transport protocols are TCP, USB and HTTPs.
  b. User access control: Normal user access control. Users can log in via their login name and password.
- Heating and anti-fogging of the scanner tip: Under normal working conditions, the scanner tip should resist fog and be heated automatically.
- Scanning speed: The average time to scan a single jaw model is no more than 3 minutes.
- Repeat treatment tolerance requirements: Repeat 100 times according to the method in *3.3 Scanner tip maintenance*, the appearance should be free of surface defects visible to the naked eye, and meet the requirements of accuracy and deviation.

Main components

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:

- According to the size, the scanner tips includes the standard scanner tip, mini scanner tip (optional) and big scanner tip (optional).

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 scan efficiency.

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

V. Production date and life time

The production date is shown on the product label.

Life time: 8 years.

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.
- The user should be responsible for deciding whether the scanner is suitable for a specific patient.
- This product is designed and intended for dental professionals, lab technicians and well-trained medical practitioners. Patients can't use it privately.
- The user should be responsible for image quality and diagnosis and ensure that the inspection data is only used for analysis and diagnosis. Images acquired by the scanner should be interpreted by eligible medical professionals. The software doesn't offer any interpretation of images and medical diagnosis of the inspected patient.
- Installation, use, and operation of the scanner are subject to the law in the jurisdictions in which it is used. Ways to install and use the scanner should not conflict with applicable laws or regulations that have legal effects. If the user applies the scanner in an unspecified scope or with an unspecified purpose, or uses the

scanner incorrectly, the Company should not be responsible for consequent damage, harm and corresponding breaches of contract, no matter partially or totally.

1.3 Contraindications

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

1.4 Precautions and warnings

- Do not use the scanner on patients using the cardiac pacemaker or ICD in order to avoid possible interference.
- Do not attempt to disassemble, repair, or modify the scanner. If necessary, please contact the manufacturer or its designated distributor.
- If the scanner is accidentally dropped to the ground, check the scanner tip to make sure its lens is not loose and there is no damage to the scanner before using it.
- If the scanner is inadvertently dropped on the ground or impacted, calibrate it before use. If there are still accuracy problems or scanning abnormalities after calibration, please consult technical support.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which you are established.

1.5 Waste disposal

This symbol on the product or on the packaging indicates that the product cannot be disposed of as household waste. The users must dispose of the waste equipment by handling it over to the applicable take-back scheme for the recycling of electrical and electronic equipment and/or battery.

For more information about recycling of this equipment, please contact your city office, the shop where you purchased the equipment or your household waste disposal service. The recycling of materials will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and environment.



Given possible cross-contamination and potential negative influences of hazardous material on the environment and human health, all electrical and electronic devices must be disposed of separately from other household waste in order to promote reuse and recycling, and also to reduce the amount of waste in landfill.

Please safely dispose of the device and its accessories in accordance with applicable laws and regulations.

1.6 Warranty

Do not disassemble or repair the scanner privately, or the warranty may get void. If there is any problem covered by the warranty, feel free to contact the technical support.

1.7 Labels and symbols



To identify a type BF applied part complying with IEC 60601-1.



To indicate that the contents of the transport package are fragile and the package shall be handled with care.



To indicate that the transport package shall be kept away from rain and in dry conditions.



To indicate correct upright position of the transport package.



To indicate that the marked item or its material is part of a recovery or recycling process.



To indicate the maximum and minimum temperature limits at which the item shall be stored or transported.



To indicate the acceptable upper and lower limits of relative humidity for transport and storage.



To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.



To indicate the medical device manufacturer.



To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.



To indicate conformity with local laws and regulations within the European Economic Area.



To indicate the item is a medical device.



To signify that the Instructions for Use/booklet must be read.



To indicate the need for the users to consult the instructions for use.



To indicate a carrier that contains Unique Device Identifier information.



To indicate the device is a Class 1 laser product.

RoHS

To indicate the device conforms to Restriction of Hazardous Substances in Electrical and Electronic Equipment.



To indicate the authorized representative in the European Community/European Union.



To indicate the entity importing the medical device into the locale.



To indicate that the marked item can be hot and should not be touched without taking care.

Note:

The symbols meet the requirements of ISO 15223-1:2021/Amd 1:2025 "Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements".

2. Product Overview

2.1 Introduction

The scanner offers a colorful intraoral scan without powder spraying. A high scanning speed up to 20 frames per second improves the accuracy of image acquisition and reduces the time lapse. It can be used to scan one tooth, several teeth and the whole dental arch.

The order system is mainly designed to manage patient information and share data. The scan module can acquire a 3D digital image of the tooth and soft tissues. Besides, it can export scanned data to CAD/CAM system, in STL/OBJ/PLY format, to provide dental care.

⚠ **Caution**:

The hardware and the software have been adjusted and tested. Do not reassemble the scanner or revise the software configuration privately.

2.2 Hardware overview

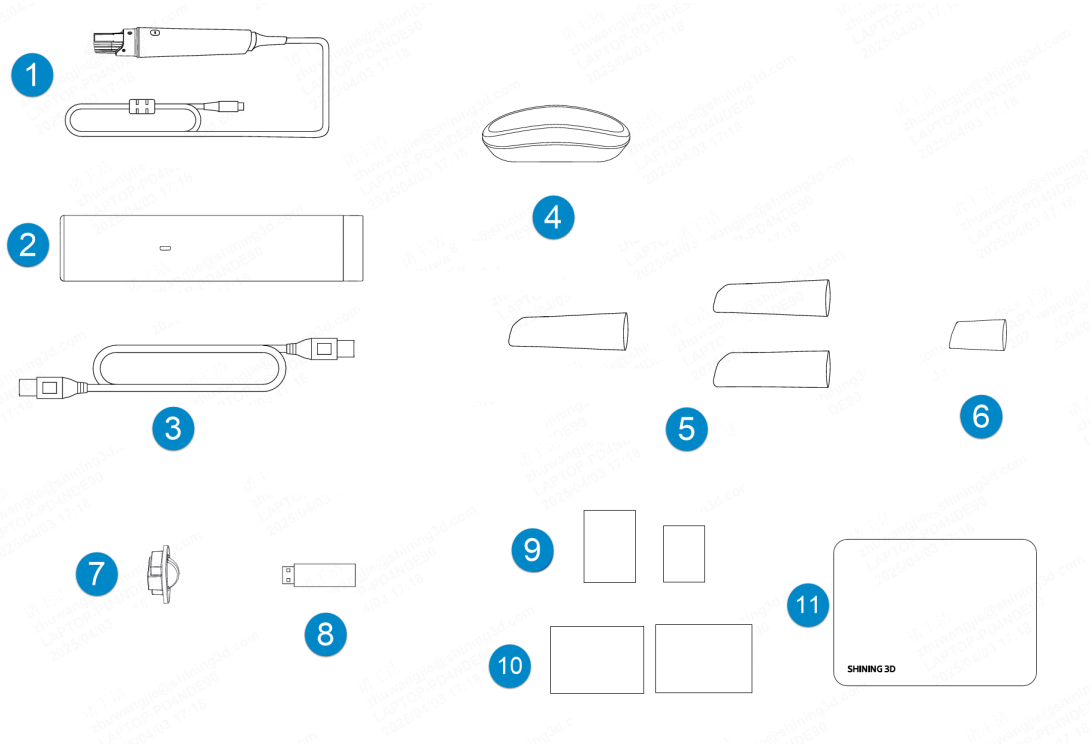
The following offers a hardware overview about the scanner, including the parts list and description.

Package list

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	No.	Description
1	Scanner body	2	Calibrator (optional)
3	Connection cable	4	Cradle (optional)
5	Scanner tips (standard tip, big tip [optional], and mini tip [optional])	6	Dust cap for the scanner body
7	Dust cover for the calibrator	8	USB flash drive
9	Quick guide and certification	10	Maintenance guide A and Maintenance guide B
11	Package box		

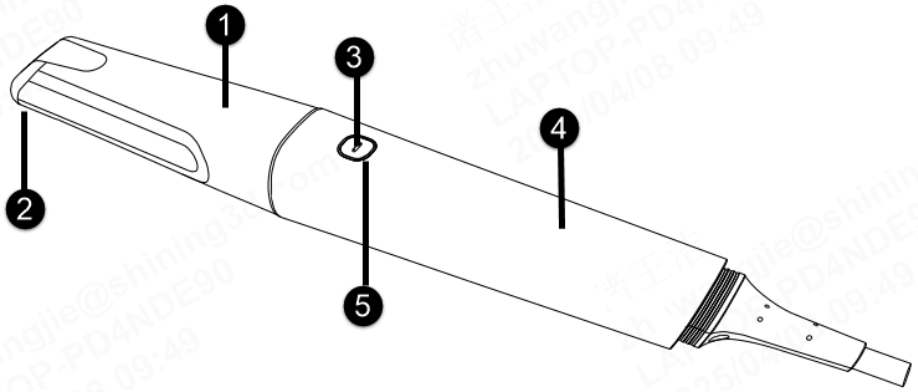
Note:

- The number of scanner tips is selectable.
- 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.
- It is recommended that the users should keep all the original packaging components in a safe place for future transportation or disposal of the scanner.

⚠ **Warning**:

Please do not use accessories, peripherals, or cables not provided with the product or recommended by SHINING 3D Tech Co., Ltd. Otherwise, it may void the warranty, lead to electrical leakage, threaten the safety of the grounding scheme, and decrease the scanner's resistance to external EMI/EMC interference.

Scanner Tip and Scanner Body



① Scanner Tip

- Applied part: Scanner tip.
- Use the scanner tip to scan the upper, lower or full jaw.
- The scanner tip can be recycled up to 100 times.
- The scanner can identify tips with different types.

② Heating element

The heating element heats the lens to prevent it from fogging, ensuring successful scanning.

③ Scan button

- Long press for about 3 seconds to enter the next step.
- Long press for about 7 seconds to enter the shutdown state.
- Press to start scanning; press again to pause scanning.
- Double-press to enter the button interface.

④ Scanner Body

- Rotate the scanner body during scanning to obtain the best scanning angle.

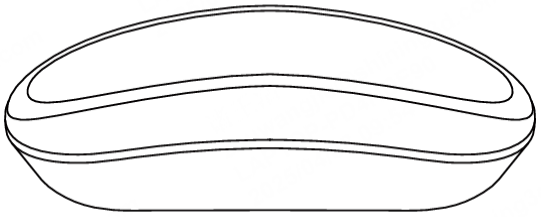
- During the scanning process, the scanner body may heat up, but the temperature will not cause harm to users and patients.

⑤ Indicator

Indicate the status of the scanner.

1. Steady green: The scanner is working.
2. Breathing green: The scanner is in standby mode.
3. Steady orange: The scanner is abnormal, such as a wrong connection or malfunction.
4. If the indicator goes out:
   - The scanner is in sleeping mode.
   - There is no power supply.
   - The scanner is shut down.

Cradle



- When the scanner is not in use, place it on the cradle.
- When the scanner is idle for 20 seconds, it will enter standby mode; after 30 minutes, it will enter sleeping mode.
- The scanner tip is still heated when the scanner is in standby mode.

Calibrator

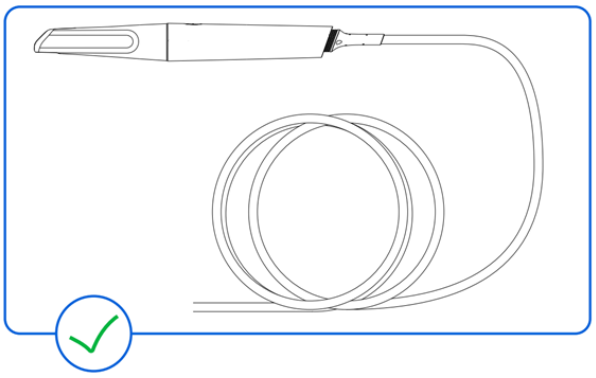


Calibrator indicator	Description
Orange light	During initialization or calibration instrument abnormal.
Green light	Normal operation in progress.

Cable using and storage

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

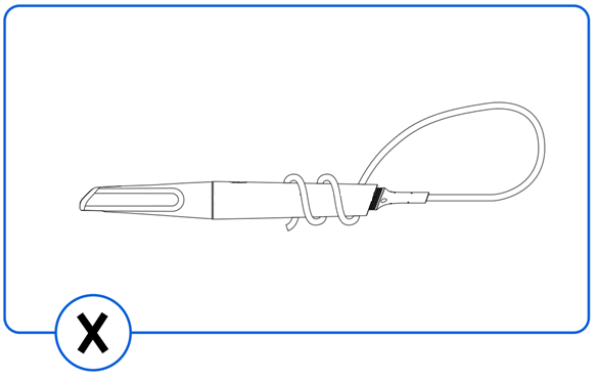
The scanner tail cable can be used up to 30,000 times.



Right cable storage

⚠ **Caution**:

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



Wrong cable storage

2.3 Software overview

The software is designed to operate with the scanner, which include the following modules:

1. **Calibration module**: Calibrate the scanner.
2. **Dental order system module**: Manage and store patient data, and the device end will send data to the receiver through a third-party tool selected by the users.
3. **Scan module**: Acquire intraoral digital images with the scanner.
4. **Pre-design module**: Edit the model by adjusting coordinates, marking tooth position, or extracting margin lines, and so on.

System requirements

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

Windows recommended configuration

Components	Configuration
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 6 GB 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) port

macOS recommended configuration

Components	Configuration
Chip	Apple M2 or higher
Memory	16 GB or higher
Storage	256 GB or higher
Operating system	macOS 13.0 or compatible versions

Note:

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

Software installation

The USB flash drive contains the IntraoralScan software program.

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

Installation on Windows

1. Insert the supplied USB flash drive into the USB port of your PC.
2. Copy the software installation package from the USB flash drive to the computer hard disk and unzip it.
3. Find the file named QuickInstaller_IntraoralScanXXXX.exe and run it as administrator.
4. The IntraoralScan Installation Wizard window appears to start the installation.
5. Specify a language from the drop-down list.
6. Click OK.
7. Follow the on-screen instructions to complete the installation.

   After that, a shortcut named DentalLauncher will appear on your desktop.

Installation on macOS

1. Insert the supplied USB flash drive into the USB port of your computer.
2. Copy the software installation package from the USB flash drive to the computer and unzip it.
3. Find the file named IntraoralScan_macOS_XXXX.pkg and run it as administrator.
4. Follow the on-screen instructions to complete the installation.

   After that, a shortcut named DentalLauncher will appear.

Note:

- Purpose of connecting to the IT-network: For data transmission.
- Network Conditions: Ethernet network with a bandwidth higher than 1 MBp/s.
- 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: The device end will send data to the receiver through a third-party tool selected by the users (the port will be determined by the third-party tool).
- Expected Information Flow and Routing: Scanning order data and other information are exchanged or transmitted via the third-party tool.
- Network Failure: If the network connection fails when the product is offline used, data is stored in local path. Once the product is reconnected to the IT network, the local data will not be lost, but it needs to be retransmitted.
- Network Access:

    a. Upgrading devices when changing the network configuration and connection, or changing numbers of devices, or network interruptions will lead to network anomalies. However, these anomalies will not pose any danger to this system.

    b. If the product is connected to public IT-networks, it may lead to unidentified risks for patients, operators, and third parties. It is suggested that controlled local entities in dental clinics or dental laboratories should identify, analyze, evaluate, and control these risks.

    c. Before making changes to the network, controlled local entities in dental clinics or dental laboratories should identify, analyze, evaluate, and control potential risks, and operate in accordance with relevant network security regulations.

3. Care and Maintenance

3.1 Pre-cleaning, disinfection and sterilization

The whole set of scanner, including scanner tip (with the dust cap), scanner body, cradle and calibrator, requires proper care, cleaning, and handling.

As individual part may be processed differently, please read and follow the given Instructions to help you effectively.

⚠ **Caution**:

- All parts are provided non-sterilized. Please follow the Instructions before the first use.
- Follow the Instructions to pre-clean, disinfect, and sterilize each part of the scanner. Using other methods not approved by the Instructions may damage your scanner and void your warranty.
- Only disinfect or sterilize the specified part(s). Do not attempt to disinfect or sterilize all parts of the product. The Company is not liable for any damages due to improper disinfection and sterilization.
- To ensure safety and effectiveness, it is recommended to use equipment, materials, and disinfectants that have been approved by local regulatory authorities for sterilization and disinfection.

⚠ **Warning**:

- Before pre-cleaning, disinfection and sterilization, please wear a pair of clean medical gloves.
- 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, proper pre-cleaning, disinfection and sterilization of the scanner after each use is necessary.
- 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.

3.2 Scanner Body (with the dust cap), Cradle and Calibrator maintenance

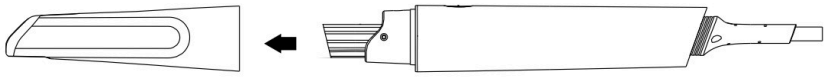
Scanner body (with the dust cap), cradle and calibrator require an intermediate-level disinfection.

⚠ **Caution**:

Before disinfecting the scanner body, please ensure that the scanner tip is detached from the scanner body, and the scanner body is covered by the dust cap.

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 and then gently take the tip off from the scanner.



3. Store the detached tip in a safe place, e.g. a dental instrument tray.
4. Cover the scanner body with the dust cap.
5. Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of the scanner body (with the dust cap).
6. When done, store the scanner body (with the dust cap) in a clean and safe place.
7. Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of the cradle and the calibrator.
8. When done, store the cradle and the calibrator in a clean and safe place.

⚠ **Caution**:

- When detaching the scanner tip, do not put your fingers on the lens of the scanner tip. Otherwise, the lens may be damaged.
- Put the scanner into a dust-proof bag when it's not in use to avoid collision or accidental drop.
- Avoid using any kind of detergent as some detergents or surfactants might penetrate the surface of the scanner body and then damage the device.
- Please do not clean the outer units and inner optical components on the front end of the scanner with any sharp objects, which may cause scratches and damage to the scanner.

3.3 Scanner Tip maintenance

The scanner tip is the most essential part of the scanner as it is inserted into the patient's mouth during scanning. Therefore, in order to prevent cross-contamination, the scanner tip must be thoroughly cleaned and disinfected/sterilized after it touches a patient; before using, please make sure that the scanner tip has been cleaned and disinfected/sterilized, and is sterile.

⚠ **Warning**:

- The scanner tip can be sterilized under high temperature up to 100 times and must be disposed of afterwards.
- **High-level disinfection and high temperature autoclave sterilization must NOT be combined**.
- Before cleaning and disinfection/sterilization, please wear clean surgical gloves and goggles.

There are serval effective and approved methods:

- Method 1: Cleaning, auto-disinfection (optional) and high-level disinfection.
- Method 2: Cleaning, auto-disinfection (optional) and high temperature autoclave sterilization.

For cleaning steps, you can choose manual cleaning or auto-cleaning.

Manual cleaning steps

1. Disconnect the power of the scanner, and pull the scanner tip off the scanner body. Please transport the scanner tip to the point where cleaning is to be performed as soon as practical.

   ⚠ **Caution**:

   - Do not place your finger (s) on the lens of the tip when detaching the tip to prevent damages 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.
   - Please do not mix the uncovered scanner tip with other devices to prevent from damages.
2. Pre-clean the scanner tip with purified water at a temperature of less than 30℃ for 3 minutes to remove stains, such as saliva or blood.
3. Brush the inside and the outside of the scanner tip with a neutral enzyme surfactant for 2 ~ 10 minutes. Repeat the step for at least 2 times. 3M fast and efficient multi enzyme cleaning agent is recommended with a suggested ratio of 5 mL ~ 10 mL of cleaner to 1 L of water at a temperature of 25℃ ~ 40℃ (if the cleaning solution used is not the recommended one, please follow its instructions).
   - When cleaning the inside of the scanner tip, insert a sponge brush or a common brush into the scanner tip from both the front and rear ends, and move the brush lightly in tiny circles.
   - When cleaning the outside of the scanner tip, brush the surface back and forth lightly.
4. Rinse the scanner tip thoroughly with purified 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 scanner tip with purified 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 scanner tip to make sure it is clean and free of damage.

⚠ **Warning**:

If the lens of the scanner tip has cracks or scratches on it, contact your local distributor or service provider after cleaning and disinfection/sterilization.

Auto-cleaning steps

1. Disconnect the power of the scanner, and pull the scanner tip off the scanner body. Please transport the scanner tip to the point where cleaning is to be performed as soon as practical.

   ⚠ **Caution**:

   - Do not place your finger (s) on the lens of the tip when detaching the tip to prevent damages 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.
   - Please do not mix the uncovered scanner tip with other devices to prevent from damages.

2. Pre-cleaning: Pre-clean the scanner tip with purified water at a temperature of less than 30℃ and a sponge brush or a common brush for 2 minutes.
   - When cleaning the inside of the scanner tip, insert a sponge brush or a common brush into the scanner tip from both the front and rear ends, and move the brush lightly in tiny circles.
   - When cleaning the outside of the scanner tip, brush the surface back and forth lightly.
3. Auto-cleaning: After pre-cleaning, please place the scanner tip into a washing machine. Set the procedure as follows:
   a. **Cleaning**: Clean the scanner tip with a neutral enzyme surfactant for 2 ~ 10 minutes. 3M fast and efficient multi enzyme cleaning agent is recommended with a suggested ratio of 2.5 mL ~ 5 mL of cleaner to 1 L of water at a temperature of 40℃ ~ 60℃ (if the cleaning solution used is not the recommended one, please follow its instructions).
   b. **Washing (rinsing)**: Wash (rinse) the scanner tip with purified water for 3 minutes at the temperature of 40℃.
   c. **Terminal rinsing**: Rinse the scanner tip with purified water for 5 minutes at the temperature of 40℃.
   d. **Drying**: Dry the scanner tip for 25 minutes at a temperature of 110℃.
4. Take out the scanner tip after drying. Inspect the lens of the scanner tip to make sure it is clean and free of damage.

   ⚠ **Warning**:

   - After drying, cool the scanner tip to room temperature to avoid a scald.
   - If the lens of the scanner tip has cracks or scratches on it, contact your local distributor or service provider after cleaning and disinfection/sterilization.

   Note:

   If auto-disinfection is supported by the washing machine, it can be directly carried out after auto-cleaning is complete.

Auto-disinfection

Auto-disinfection can be carried out after cleaning. Set the procedure as follows:

1. **Disinfection**: Disinfect the scanner tip with purified water for 5 minutes at the temperature of 90℃.

2. **Drying**: Dry the scanner tip for 25 minutes at a temperature of 110℃.
3. Take out the scanner tip after drying. Inspect the lens of the scanner tip to make sure it is clean and free of damage.

   ⚠ **Warning**:

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

High-level disinfection steps

1. Carefully fill the container with phthalaldehyde at a concentration of 5.5 g/L, and fully immerse the scanner tip in the disinfectant for at least 5 minutes at a temperature of 20℃ ~ 25℃.

   ⚠ **Caution**:

   - When immersing the scanner tip into the disinfectant solution, please follow the instructions of the disinfectant solution.
   - It has been verified that the scanner tip can be disinfected in 5 minutes. It is not recommended to immerse the scanner tip in the disinfectant for more than 14 minutes.
2. Take out the scanner tip from the disinfectant, and rinse it with purified water 3 times and 1 minute for each to remove disinfectant residues.

   ⚠ **Caution**:

   Discard the used purified water. Do not reuse the water for rinsing or any other purpose.
3. Flush the scanner tip with purified water for at least 3 minutes.
4. Dry the scanner 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 scanner tip to make sure it is clean and free of damage.
6. If using the scanner tip immediately is required, reconnect it; if not, store it with other dental instruments.

   ⚠ **Caution**:

   Before using or storing the scanner tip, please ensure that it is completely dry. Or it may cause damage to the scanner or affect scanning performance.

High temperature autoclave sterilization steps

1. Fill the scanner tip with medical gauze and seal it in an autoclave bag.
2. Place the wrapped scanner tip into a sterilizer and set the sterilization parameters according to the sterilizer type as the following table.

Sterilizer type	Sterilization parameters
Dynamic-air-removal sterilizer	Sterilize for 4 minutes at 134°C; dry for 30 minutes.
Gravity-displacement sterilizer	Sterilize for 30 minutes at 121°C; dry for 30 minutes.

⚠ **Warning**:

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

3. Inspect the lens of the scanner tip to make sure it is clean and free of damage.
4. If using the scanner tip immediately is required, reconnect it; if not, store it with other dental instruments.

⚠ **Caution**:

Before using or storing the scanner tip, please ensure that it is completely dry. Or it may cause damage to the scanner or affect scanning performance.

4. Scanner Settings

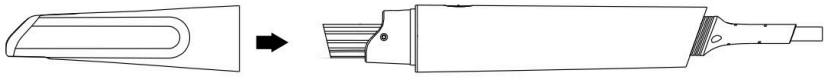
4.1 Notes of connection and disconnection

- If the accuracy of the scanner decreases or the scanner does not work properly, please consult technical support promptly.
- 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 it from the cradle or when using the scanner. Do not shake the scanner.
- Install the scanner in accordance with the Instructions.
- Please put the scanner back to the cradle when it is not in use.
- Use the scanner only in dental laboratories, dental clinics, and equivalent environment.
- Do not place the scanner in heated or wet surfaces to prevent damages to the scanner.
- Do not install, place, and use the scanner where it is dusty, damp, or in a place with extreme temperature or under direct sunlight.
- It is normal that the scanner gets warm when in use. Do not block the ventilation holes on the bottom of the scanner. The scanner will stop working when it overheats.
- Wear clean surgical gloves before you start.
- Ensure that the scanner cradle, scanner body, and scanner tip are pre-cleaned and disinfected/sterilized.

4.2 Attach the Scanner Tip

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**:

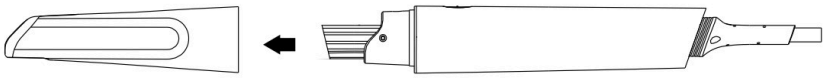
Do not place your finger(s) on the mirror of the tip when attaching as this may result in damage to the mirror.

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.

4.3 Detach the Scanner Tip

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



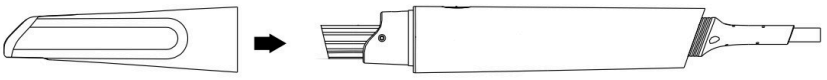
⚠ **Caution**:

- Do not place your finger (s) on the lens of the tip when detaching the tip to prevent damages 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.

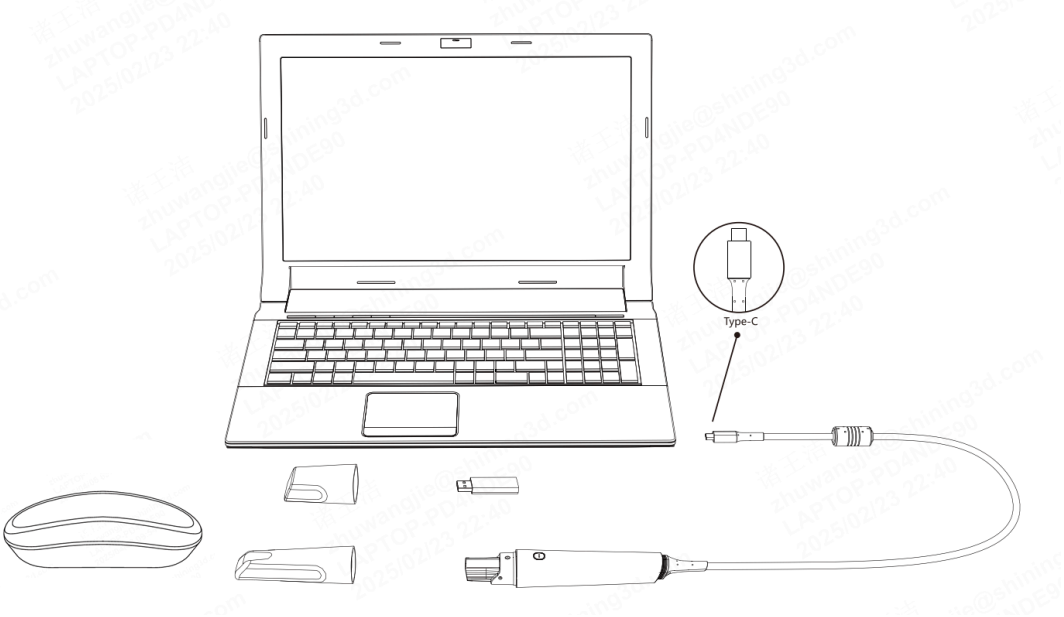
4.4 Connect the Scanner

Follow the steps below to complete the connection:

1. Cap the scanner with the scanner tip and ensure it's firmly attached.



2. Connect the scanner cable to the Type-C port of the computer.



3. Launch the software.

⚠ **Caution**:

- Before using the scanner, make sure the supplied software is installed on your computer.
- Before using the scanner, put the scanner and the cradle on a flat surface without any inference on cable connection.
- Do not put the supplied plugs and USB Type-C port where it is difficult to disconnect the device.
- For stable operation of the scanner, please ensure that no other devices (a HUB, an adapter, .etc.) are connected to the computer during the scanning process on macOS.

4.5 Disconnect the Scanner

Follow the steps below to safely disconnect the scanner:

1. Quit the IntraoralScan scanning software.
2. Disconnect the scanner with the computer.

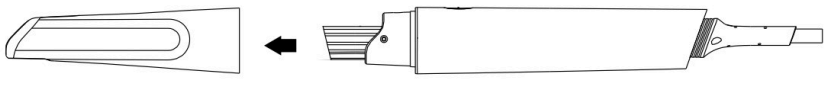
4.6 Calibration

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 is accidentally dropped.
- The scanner has been used for a period of time (e.g. 2 weeks).

Follow the steps below to perform the calibration:

1. The LED light of the scanner body turns green when the power connection is working properly.
2. Hold the scanner tip firmly and then gently take the tip off from the scanner.

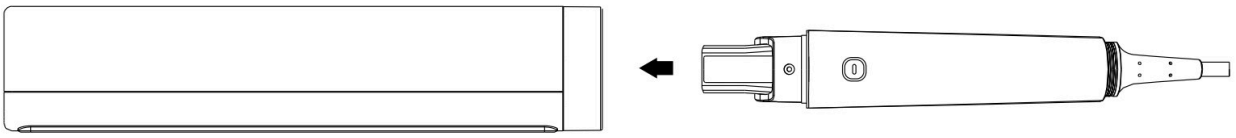


⚠ **Caution**:

- Do not place your finger(s) on the lens of the tip when detaching the tip to prevent damages to the lens.
- Store the detached tip in a safe place, e.g. a dental tray, for future use.

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

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



5. Click on the main interface to enter the calibration.
6. Click Start.
7. When the calibration (including the brightness adjustment) is completed, the software will prompt a tip.
8. Click on the upper right to close the calibration.
9. Gently take the calibrator off the scanner. Reconnect the scanner tip to the scanner for future use, or cap the scanner with the dust cap to avoid damage.
10. Disconnect the calibrator from the computer and cap the calibrator with its dust cover for future use.

⚠ **Caution**:

- Detach the calibrator from the scanner in time after calibration to avoid overheating of the calibrator.
- Do not place the calibrator vertically or aslant.

5. Preparations and Use

5.1 Preparations

Warning:

Please wear a pair of clean medical gloves during scanning for your hand hygiene and safety.

Intraoral Environment

- Make sure no dental plaque or materia alba on the patient's teeth.
- Arrange all types of cables carefully to prevent the user or the patient from being tripped.
- Avoid direct exposure of the scanned area to light sources, like a chairside light or the sunlight.
- Make sure there is no foreign body or blood in the mouth after gargling. Stop the bleeding, if any.
- Consider using a dental three-way syringe to blow dry or a cotton ball to dry the tooth surface before starting the scan.
- Consider using saliva ejectors and cotton rolls to keep the surfaces dry during scanning.
- If necessary, consider using an oral lens to help create space while working in the narrow area between the teeth.

Scanner Preparations

- Ensure the scanner or other parts have no sharp edges.
- Ensure that there are no other objects on the scanner and the cradle.
- Ensure that the scanner tip, scanner body, and cradle are properly pre-cleaned, disinfected, or sterilized.
- Ensure that the scanner tip has no scratches or is not damaged. Additionally, the tip is firmly attached to the front end of the scanner body.
- Ensure that the scanner is correctly connected to the computer and a power source, and the scanner has been powered on. Ensure that IntraoralScan is launched and ready to work.
- Ensure the calibration is completed to guarantee the accuracy of scanned data.
- Ensure the scanner is free of problems like broken parts, loose connection or abrasion. If so, contact the after-sales service.
- To avoid condensation on the lens of the tip when scanning, the scanner tip must have been heated up.

Note:

- After the scanner is connected correctly and capped with the scanner tip, the scanner tip will automatically be heated up when the indicator turns green.

5.2 Start using

Connection

See more details in *Connection and disconnection*.

Registration and login

If you already have an account, enter your username and password or use verification code to log in. If not, you need to register first.

Activation

Activation is to ensure that the scanner is officially authorized. You have to activate the scanner to make it work properly.

When you use the scanner for the first time, you need to activate it. See more details of activation in the User Manual.

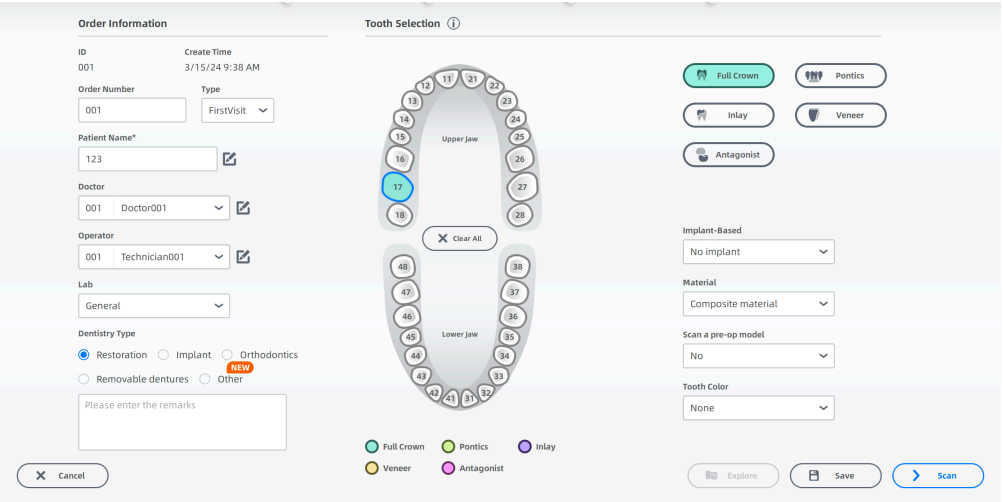
Calibration

See more details in *Calibration*.

Order creation

After a successful login, you can create a new order or import an order.

Click on the left to create a new order. You can also select a patient in the patient list and click to create a new order.



Please fill in related information of the patient and the dentist, select dentistry type and tooth. Then the user can save the order for future use or start scanning.

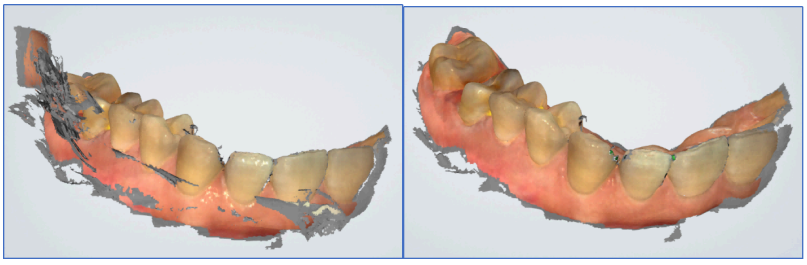
5.3 Scanning

Note:

- Pay attention to the guidance and notes in the software interface.
- If necessary, ask the patient to keep the tongue still and move it to the other side, so as to avoid unnecessary influences.
- Hold the scanner steady on the tooth surface and keep the scan tip window 15 mm away from the teeth.
- When scanning, slowly move the scanner along with the dental arches and simultaneously check the scan results on the screen to ensure high-quality scanning.
- To scan the occlusal surface of the teeth, hold the scanner parallel to it; to scan the buccal and lingual surfaces of the teeth, hold the scanner at a 45-degree angle.
- Please pay attention to the device and the patient's status. If there are abnormalities or warning messages, please stop scanning immediately and consult the technical support.
- 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, the jaws may fail to align.
- 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 bites.

Scan upper jaw

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

Function	Description
	Enabled during intraoral scanning. When it is enabled, miscellaneous data, including buccolingual data and soft tissues data, will be deleted automatically. When you use the software for the first time, it takes 1~2 minutes to initialize this function. Left image: Function disabled. Right image: Function enabled. **Note**: If the data is not scanned smoothly or does not meet the requirement when this function is enabled, please disable it and scan. 

Note:

- The green box in the middle of the software interface indicates the data range of the current scanning. If the green box turns into red, the scanned position is incorrect. Please move the scanner tip to the position where displayed in the red frame.
- When the scanning is paused or finished, areas which are not been scanned on the model will turn into green. Users can rescan the corresponding areas according to the demand.

2. When the scanning is paused, you can click to edit data.
3. Once enough data has been scanned, click or long press the Space key or press the scanner body button to process and save the data.

   When it is completed, the upper jaw icon is green and ticked with a , indicating that the scanning process is finished.

Scan lower jaw

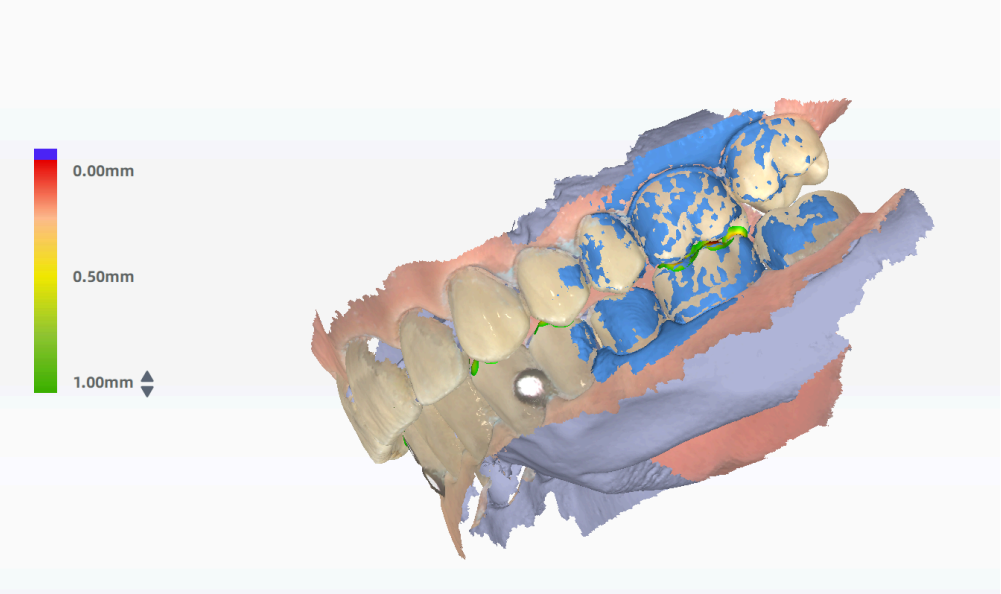
After the upper jaw scanning and the data processing are completed, the lower jaw scanning interface is automatically displayed. The procedure is the same as scanning the upper jaw.

Scan bite

After the lower jaw scanning and the data processing are finished, the bite 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.

After the upper jaw and the lower jaw are successfully aligned to the bite, click or press the Space key to pause the scanning and check the occlusion.



Click or long press the Space key or the scanner body button for about 3 seconds to post-process the data.

See more details in User Manual.

Coded scanbody scanning (Optional)

Coded scanbody scanning is supported. After scanning the jaws and coded scanbody in Intraoral Photogrammetry (IPG), the software will align the coded scanbody to the jaws.

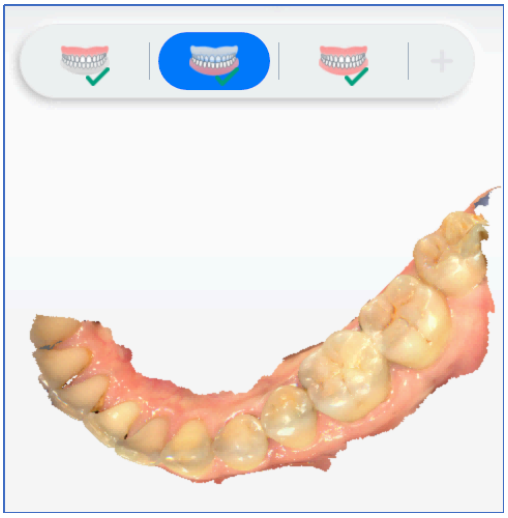
5.4 Scanned data view

View scanned data in IntraoralScan.

Check jaws



Upper jaw



Lower jaw

Check the bite



Tooth preparation dynamic depth 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.

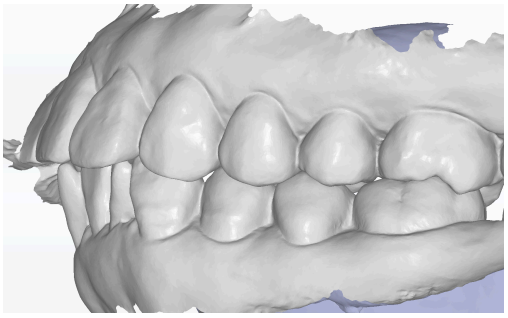
5.5 Pre-design

Texture

View the texture of the model.



Enabled



Disabled

Smooth

Clean the noise and improve the quality of the model.



Enabled



Disabled

Bite detection

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.

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 choose to recalculate undercut area.

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.

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.

Oral health report

ConsulReport can help the dentist and the patient check the accurate position of the symptom with the assist mode and multiple tools. The oral report includes detailed information of the symptoms and relevant solutions, which can be used for managing and attracting patients.

See more details in User Manual.

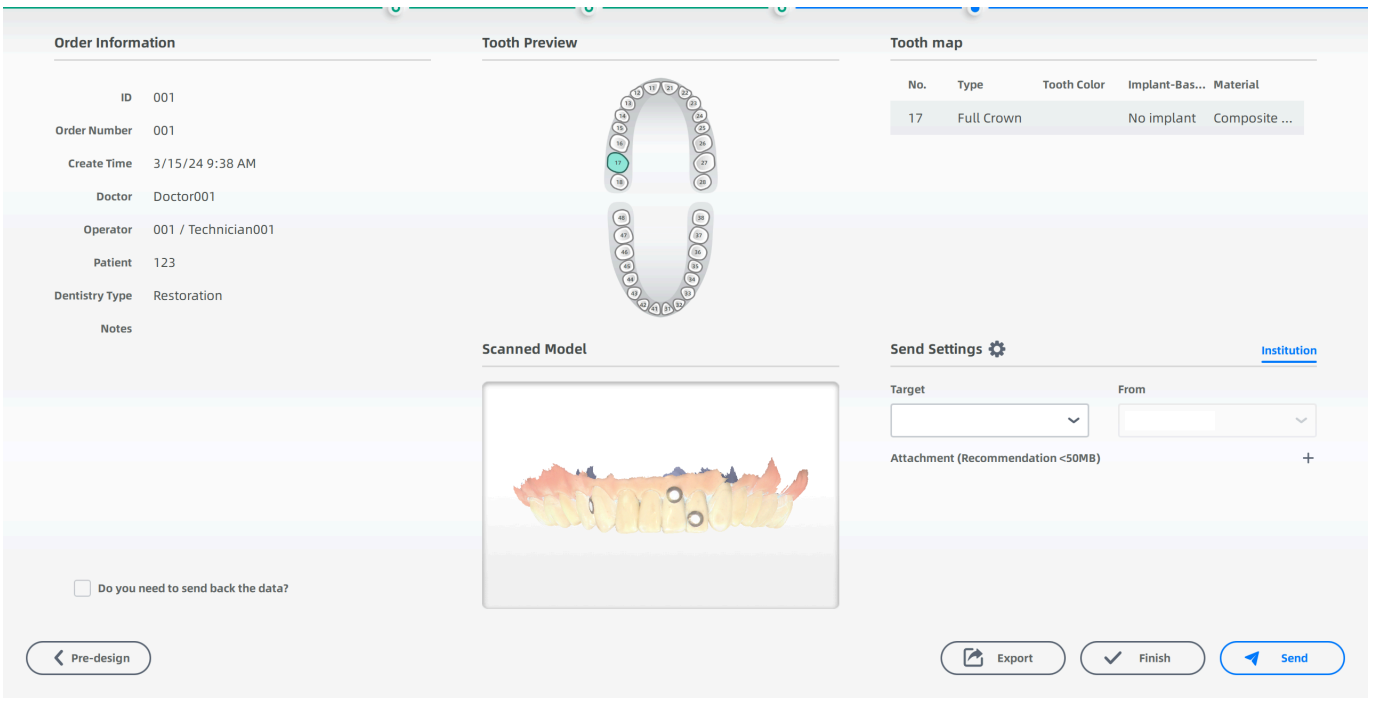
5.6 Order storage and exporting

After scanning, you can check the current storage path of the order.

Click **Export** to export and store the order information to the local. Click **Send** and the device end will send data to its server through a third-party tool selected by the users.

Note:

To send data, the computer connected with the scanner should be networked. Scanning is supported whether the computer is networked or not.


Order Information
ID 001
Order Number 001
Create Time 3/15/24 9:38 AM
Doctor Doctor001
Operator 001 / Technician001
Patient 123
Dentistry Type Restoration
Notes
Tooth Preview
Tooth map
No. Type Tooth Color Implant-Bas... Material
17 Full Crown No implant Composite ...
Scanned Model
Send Settings
Institution
Target
From
Attachment (Recommendation <50MB)
Do you need to send back the data?
Pre-design
Export
Finish
Send

6. Storage and Transport

6.1 Requirements for daily and long-term storage

- Please store the scanner in a place free of water and moisture.
- Ensure the scanner is disinfected or sterilized and is completely dry before long-term storage.
- Do not store the scanner and accessories in areas of extreme temperatures or under direct sunlight.
- As for the temperature, humidity, and air pressure required during daily and long-term storage, please check the labels on the package.

6.2 Requirements for transportation

- Make sure that the scanner is clean before placing it back to the original carry box/package to avoid any possible contamination.
- Place each part of the product, e.g. the tip, scanner body, and cradle, in the original package carefully.
- Make sure that each cable is rolled up and tangle-free before placing it in the original carry box.
- Before sealing the package box, please make sure that no part of the product is sticking out of the package box.
- As for the temperature, humidity, and air pressure required during the transportation, check the labels on the package.

⚠ **Caution**:

- If transportation of the scanner is required, it is recommended that the users can retain the original package.
- If the original package is no longer accessible, please wrap all parts of the scanner with bubble wrap to prevent damage during transportation.

7. Safety Information

7.1 Electrical safety

Only trained medical personnel should operate this scanner. According to the standard *IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, anyone who creates or adjusts a medical electrical system by combining with other devices, is responsible for meeting the following requirements to ensure the safety of patients, operators and the environment, and the product complies with the following standards.

- 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

Main safety features of the product

- 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
- Rated voltage and frequency:
  Rated voltage: DC 5 V
  Input current: 3.0 A
- Pollution degree: 2

⚠ **Caution**:

The product supplier can provide the circuit diagram, components list, illustrations, details of correction, or other materials that is necessary to help repair the component specified by the manufacturer.

⚠ **Warning**:

- To meet waterproof requirements, the sockets should not be placed on the ground.
- The supplied medical power adapter can only be used to connect the grounded outlet.
- To avoid risk of electrical shock hazards, always inspect the scanner and cable connections before use.
- Do not use the scanner when it is around or stacked with other equipment. If it is necessary, please make sure the scanner is working properly.
- Do not use the scanner in an environment with a high concentration of inflammable liquid and gas or oxygen.
- Only authorized technicians can replace internal parts of the scanner and modify the software configuration.
- If the scanner tip or cable is damaged, stop using it immediately and contact technical support to replace it.
- Do not cut, bend, reassemble or squeeze all types of cables in order to prevent the outside insulating material from being damaged, thus leading to a short circuit or even a fire accident.
- To prevent liquid and moisture from infiltrating into the device and lead to a short circuit, do not allow foreign objects (including all types of liquid) to enter the scanner and its cradle.

7.2 EMC notice

⚠ **Caution**:

- The scanner meets the EMC requirements.
- Users should install and use the product according to the EMC information provided in the attached file.
- A portable or mobile RF communication device might affect the performance of the scanner. When using the scanner, please keep the scanner away from strong ELECTROMAGNETIC interference, such as 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**:

- With the exception of cables sold by the manufacturer of the scanner 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 scanner.
- 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).
- The scanner 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.
- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

List of cables

No.	Name	Length
1	Scanner cable	2.5 m
2	Connection cable (For the calibrator)	1.5 m

Essential performance

None.

Electromagnetic emissions

Medical electrical equipment, such as the scanner, requires special precautions for electromagnetic compatibility. It must be installed and put into service according to the following electromagnetic tables.
The scanner is intended for use in specified electromagnetic environment. Customers or users of the scanner should assure that it is used in this environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emission	
The scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:	
Emission measurement	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Interference Immunity

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
The scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:		
Immunity test	**IEC 60601-1-2 Test level**	**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 kV, ± 1 kV, ± 2 kV line(s) to earth	±0.5, ±1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycle 0% U_T; 250/300 cycles	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycle 0% U_T; 250/300 cycles
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conducted RF IEC 61000-4-6	3 V r.m.s 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz	3 V r.m.s 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

RF wireless communication equipment				
Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (MHz)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTD Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28

RF wireless communication equipment				
Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (MHz)
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

Guidance and Manufacturer's Declaration - IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity level (A/m)**
30 kHz	CW	8
134.2 kHz	*Pulse modulation 2.1 kHz	**65
13.56 MHz	*Pulse modulation 50 kHz	**7.5
Note*: The carrier shall be modulated using a 50% duty cycle square wave signal. Note**: r.m.s., before modulation is applied.		

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality or launch warning messages, it is necessary to position the scanner further from sources of electromagnetic interference or install electromagnetic shielding to block unwanted interference.

Customers or the users of the scanner should operate the device under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

Separation distances

The scanner is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. Based on the maximum output power of the communications equipment, the customers or the users of the scanner can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the scanner.

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**:

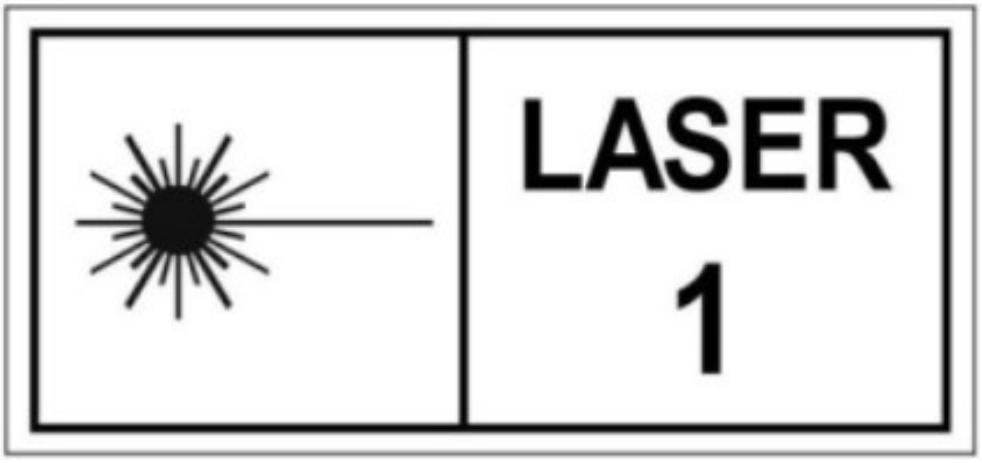
- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- If immunity test level is higher than those specified in IEC60601-1-2, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in IEC60601-1-2 Chapter 8.10.

7.3 Biological safety

The scanner meets the following biological standard:

1. ISO10993-5: 2009 (Biological evaluation of medical devices — Part 5:Tests for in vitro cytotoxicity)
2. ISO10993-10: 2021 (Biological evaluation of medical devices — Part 10: Tests for skin sensitization)
3. ISO10993-23: 2021 (Biological evaluation of medical devices — Part 23: Tests for irritation)

7.4 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, please disassemble the scanner or replace components as required. Otherwise, the scanner may not work properly and laser radiation may occur. If a laser component is faulty, please contact the manufacturer for help.

Wavelength: 450 nm ± 10 nm, maximum output power: 2.4 mW, pulse width: 0.05 ~ 4.8 ms.

This product is a class 1 laser product according to "IEC 60825-1:2014 Safety of laser products-Part 1: Equipment classification and requirements". This product doesn't have harmful laser radiation. Users will not be exposed to laser radiation if they operate this product correctly according to the Instructions.

The scanner will not cast light when the scanner tip is unplugged.

⚠ **Warning**:

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 to prevent eyes or skin from being burned by the light.

8. Specifications

8.1 Specifications of the scanner

Parameter	Description
Type name	Intraoral scanner
Model name	Aoralscan Elf

Scanner	
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 (with a standard tip)
Scanner weight	124±20 g (with a standard tip and without cable)
Scanner tip connection	Pluggable
Light source	LED and laser
Wave length	Blue laser: 450±10 nm White LED: 400 nm-780 nm
Output	STL, OBJ, PLY
Power	Input: 5 V DC/3 A
Device lifetime	8 years

Scanner tip	
Scanner tip types	According to size: 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
Scanner tip maintenance	Sterilized and disinfected by users (Maximum: 100 times)

Calibrator	
Model	iCalib-LF

8.2 Environmental requirements

Operating and storage requirements

	Requirement
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	70 kPa ~ 106 kPa

Appendix

FCC compliance statement

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

1. This device may not cause harmful interference;
2. This device must accept any interference received, including interference that may cause undesired operation.

Note:

- The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user’s authority to operate the equipment.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the Instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio / TV technician for help.

Technical Support

Register at *https://support.shining3ddental.com/en/support/home* to submit a support ticket and track your tickets status.

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