Manuals+

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SHINING 3D CRAEW 2AMG4 Aoralscan Elite Wireless

Product Information

- The Aoralscan Elite Wireless is a medical device designed for dental scanning purposes. This wireless scanner provides functions for accurate scanning, installation, and maintenance.

Product Usage Instructions

- Unbox the scanner and all accompanying accessories.
- Charge the scanner fully before initial use.
- Download and install any necessary software on your compatible device.
- Turn on the scanner and pair it with the software on your device.
- Ensure the scanner is fully charged.
- Position the scanner correctly for scanning purposes.
- Follow the software instructions for scanning procedures.
- Review the scanned data for accuracy before further processing

Foreword

General

This instruction for Use (hereinafter referred to as "the Instructions") introduces the functions, installation, usage, and maintenance of Aoralscan Elite Wireless (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 about 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 date

Release version	Release date	Language

V1.0.4	xxxx-xx	Original Instructions

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2. Please inspect and/or maintain the product before use. If the product is damaged, deforme, 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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8. All disputes between you and SHINING 3D that arise 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 the 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 use.

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.

Basic information

Product name, model and catalogue number

- Product name: Intraoral Scanner
- Model: Aoralscan Elite Wireless

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:
    - 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 of ISO 9687.
- Noise requirement: ≤ 50dB (A).
- The scanner is able to work normally 5 meters away from the cradle. The camera window can display the video normally without apparent stops.
- Morphological accuracy refers to the degree of consistency between the test result and the entire 3D surface of the test object. The standard deviation of the morphological accuracy of scanner tips shall meet the following requirements:

Measurement range	Standard deviation
Three teeth	≤ 0.02 mm

Full dental arch	≤ 0.05 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 requirements of the following table:

Measurement range	Detection index	Accuracy	Deviation (Δd)
Single tooth	The d, h of any conic table	≤ 0.02 mm	-0.02 mm ≤ Δd ≤ 0.02 mm
Full dental arch	Distance l1—l4	≤ 0.1 mm	-0.1 mm ≤ Δd ≤ 0.1 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

- The software guides the users to understand the operations. It has a backward function as well.
- Establishing demand information, which may include: jaw position information, tooth

position information, treatment modality information, and occlusal relationship information.

- Running the scanning teeth and/or occlusal relationship according to the demand information.
- The scanning data can be exported and saved in various formats, including STL, OBJ, and PLY.
- 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), report examination function (optional), tooth preparation monitoring function (optional).
- Scanner with auto calibration function (optional).

Internet security

- Data interface: Transmit the information and acquire the image by wireless module or USB cable.
- 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 the scanner tip, scanner body, calibrator, and its cable (optional), cradle (optional), rechargeable battery, charging case (optional), and the software. The software carrier is a USB flash drive, and the software release version is 3.

Note:

The scanner tips include 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's hard disk before installing the driver.
- Use NVIDIA graphics cards to get the best scan efficiency.
- Do not insert wireless USB network card into the computer. A USB wireless network card will cause USB bandwidth occupation, limiting camera performance.

Production date and lifetime

The production date is shown on the product label.

- Lifetime: 8 years.

Intended use

The scanner is intended to record the 2D/3D topographical images of teeth, gingiva, and oral mucosa for CAD/CAM fabrication of dental orthodontic treatment, implants, 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 $C\,\epsilon$ 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 or a 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 consequential damage, harm, and corresponding breaches of contract, no matter whether partially or totally.

Contraindications

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

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.

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 batteries.
- For more information about the 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 the 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.

Warranty

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

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, the package shall be handled with care.
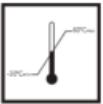
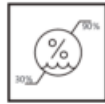- To indicate that the transport package shall be kept away from rain and in dry conditions.

- To indicate the 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, transported, or used.

- 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 indicate the date on which a product was manufactured.

- **SN** 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.

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

- **MD** To indicate the item is a medical device.

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

- To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.

- To indicate a carrier that contains Unique Device Identifier information.

- To indicate that 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.

Note

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

Product Overview

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

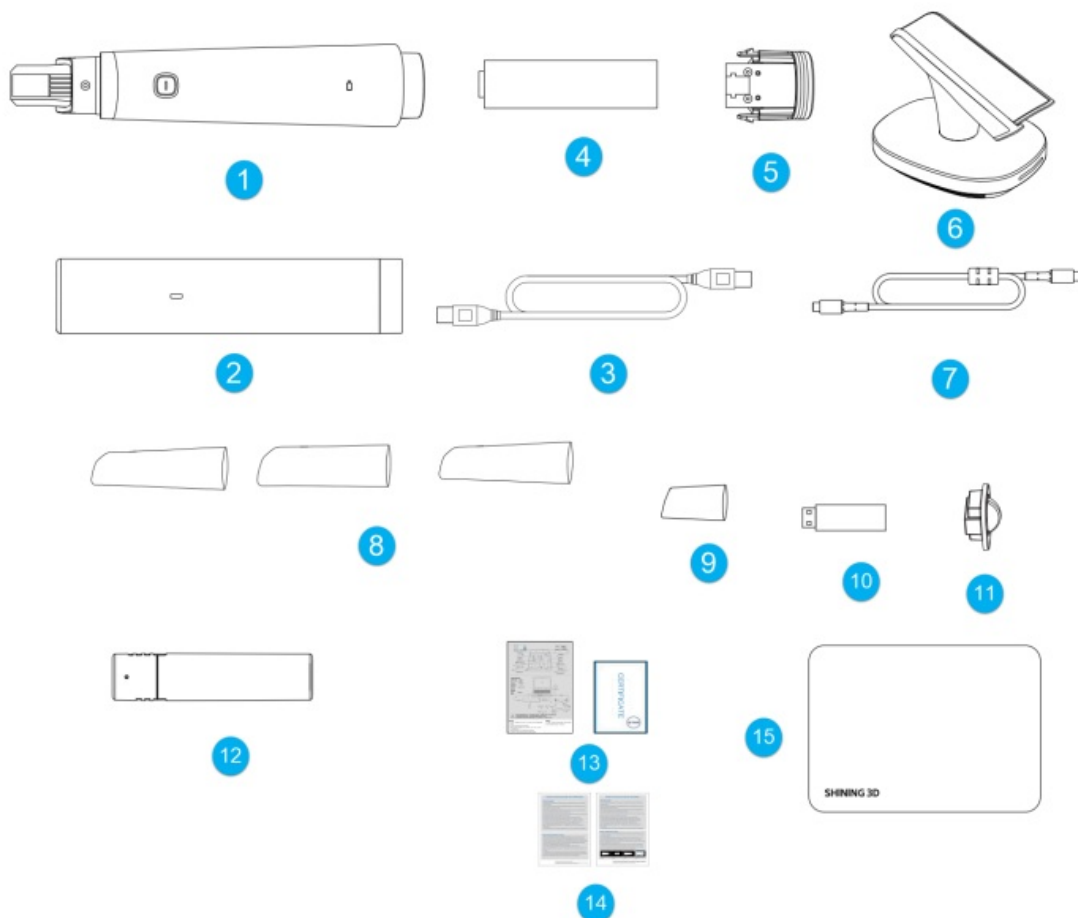the scanner or revise the software configuration privately.

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
3	USB 3.0 cable	4	Battery
5	Battery cover	6	Cradle
7	Type-C cable	8	Scanner tips(big tip, standard tips, and mini tip)
9	Dust cap	10	USB flash drive
11	Dust cover	12	Charging case
13	Quick guide and certificate	14	Disinfection guides

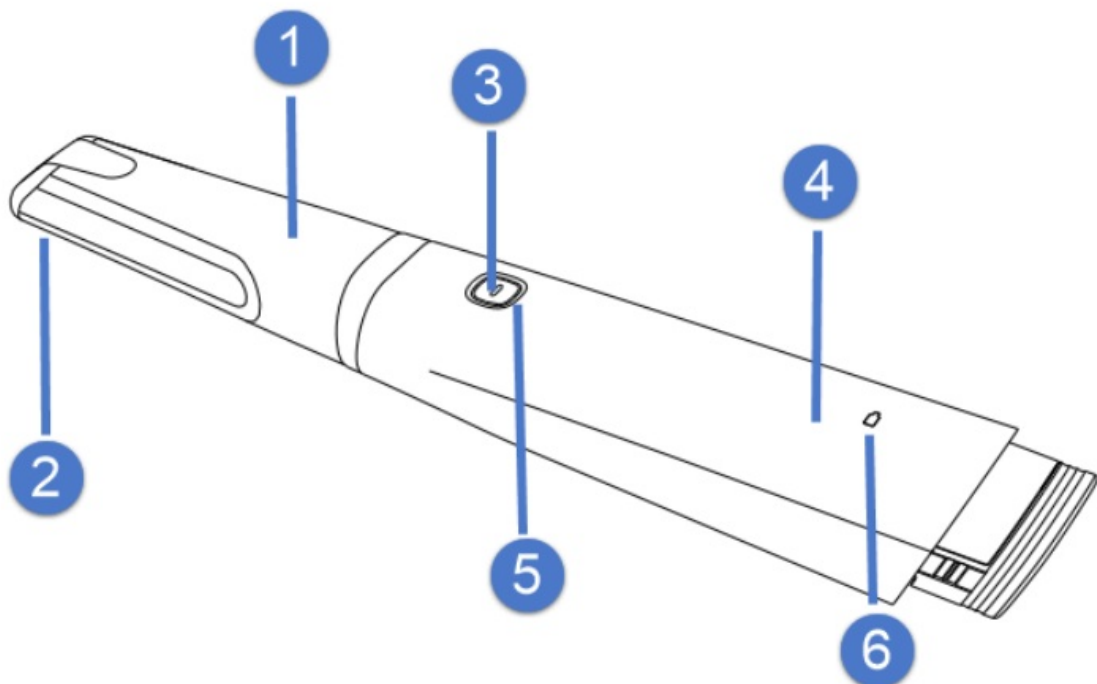| 15	Package		

Note:

The number of scanner tips is selectable.

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
    1. Applied part: Scanner tip.

2. Use the scanner tip to scan the upper, lower or full jaw. The scanner tip can be recycled up to 100 times.

2. Heating element
    1. The heating element heats the lens to prevent it from fogging, ensuring successful scanning.
3. Scan button
    1. Press to start scanning; press again to pause scanning. Double-press to enter the button interface.
    2. Press for about 2 seconds to go to the next step; press for about 5 seconds to power off the scanner.
4. Scanner body
    1. Rotate the scanner body during scanning to obtain the best scanning angle.
    2. During the scanning process, the scanner body may heat up, but the temperature will not cause harm to users and patients.
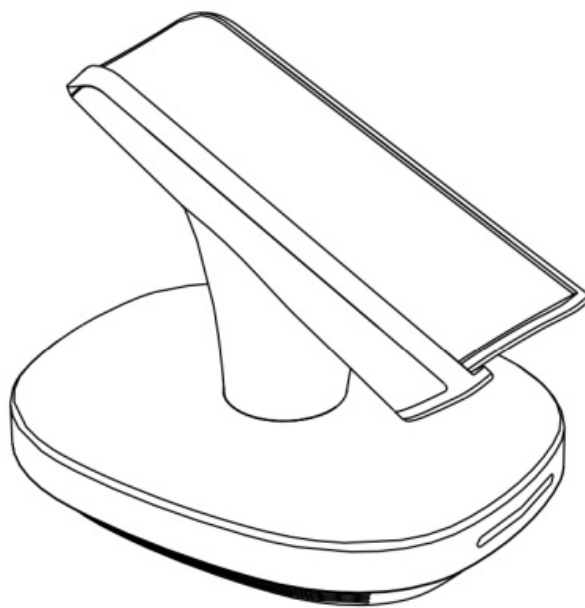5. Indicator

    Indicate the status of the scanner.
    1. Steady green: The scanner is working.
    2. Breathing green: The scanner is in standby mode.
    3. Flashing green: The scanner is paired with the cradle.
    4. Steady orange: The scanner is abnormal, such as a wrong connection, malfunction, loose plugging or disconnection to wifi.
    5. If the indicator goes out:
        1. The scanner is in sleeping mode.
        2. The battery is not inserted into the scanner. The scanner is shut down.
6. Battery indicator
    1. Steady green:
        1. The scanner is not in the cradle, and the battery power is above 20%. The scanner charging is completed in the cradle.
        2. Breathing green: The scanner is charging in the cradle.
        3. Slow flashing green: The battery power is less than 20%.
        4. Fast flashing green: The battery power is 0%.
        5. If the indicator goes out:
            1. The scanner is shut down.
            2. The battery is not inserted into the scanner.

Scanner cradle

Cradle using

When the distance between the scanner body and the cradle keeps within 5 meters, the signal is better.

Cradle indicator

- Steady green: The cradle is powered up or the scanner is not on the cradle.
- Flashing green: The scanner is placed on the cradle.
- Steady orange: The cradle is in abnormal status, like a wrong connection, abnormal temperature, or malfunction.
- Extinguished: The cradle is not powered up.

Caution:

- When the scanner is not in use, place it on the cradle.
- When placing the scanner on the cradle to charge it, please ensure that the groove at the end of the scanner is stuck on the convex part of the cradle.
- When the scanner is charging on the cradle, the battery indicator on the scanner body is breathing green. When the scanner is placed on the cradle:
- If the cradle is powered up, the scanner will enter the standby mode immediately and the indicator on the scanner body will be breathing green. After 3 minutes, the

scanner will enter the sleeping mode and the indicator will be extinguished.

- If the cradle is not powered up, the scanner will enter the standby mode after 30 seconds and the indicator on the scanner body will be breathing green. After another 3 minutes, the scanner will enter the sleeping mode and the indicator will be extinguished.
- When the scanner is not placed on the cradle for 30 seconds, it will enter the standby mode. After another 3 minutes, the scanner will enter the sleeping mode.
- When the scanner is placed and enters sleeping mode on the cradle which is powered up, the scanner tip will be heated up for 10 minutes.
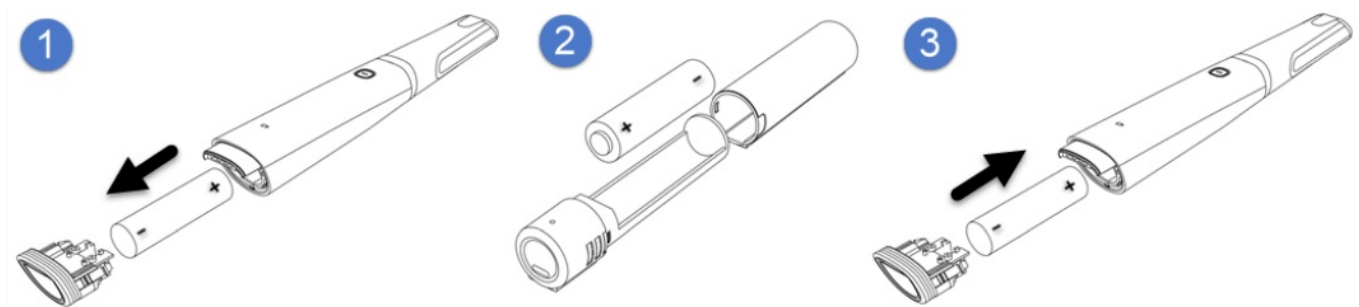
Calibrator

Calibrator indicator

- Orange light: During initialization or calibration instrument abnormal
- Green light: Normal operation in progress

Charging case

When the scanner's battery is low, please replace it in time and put it in the charging case.

Caution:

When open the battery cover, please take out the battery carefully to prevent it from slipping out and dropping down.

Charging case indicator

Note:

- Steady green: The power is connected or the charging is completed.
- Flashing green: The case is charging the battery.
- Extinguished: The power is not connected.

Warning:

- Do not immerse the battery in water or allow it to get wet.
- If the scanner is not in use for a long time, take out the battery.
- Do not strike, throw or subject the battery to sever physical shock.
- Do not pierce the battery casing with a nail or other sharp objects, break it open with a hammer, or step on it.
- If the battery leaks and electrolyte gets in your eyes, do not rub them. Instead, rinse them with clean running water and immediately seek medical attention.
- If left as it is, electrolyte can cause eye injury.

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.
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

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:

1. Insert the supplied USB flash drive into the USB port of your PC.
2. Copy the software installation package from th USB flash drive to the computer hard disk.
3. Find the file named 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.

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.
- 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:
    - 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.
    - 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.

Care and Maintenance

Pre-cleaning, disinfection, and sterilization

The whole set of scanner, including scanner tip, scanner body, cradle, calibrator and charging case, 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.
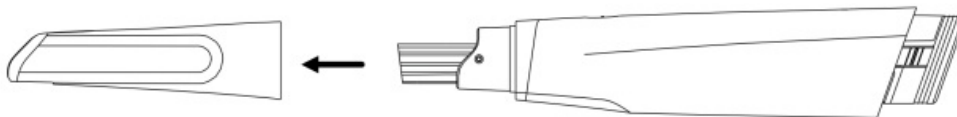
Scanner body, cradle and calibrator maintenance

Scanner body, 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. Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of the scanner body.
5. When done, store the scanner body in a clean and safe place.
6. Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of the cradle and the calibrator.
7. 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.

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 tip must be thoroughly cleaned and sterilized before and after it touches a patient.

Caution:

- When immersing the scanner tip into the disinfectant solution, please follow the Instructions of the disinfectant solution.
- 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, please wear clean surgical gloves and goggles. There are two effective and approved methods:

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

Cleaning steps

1. Disconnect the power of the scanner, and pull the scanner tip off the scanner body. See more details in Detach the scanner tip.
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.

1. 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.
2. 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.

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

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

Battery and charging case maintenance

- If the battery has not been used for a long time, the capacity may decreases, thus affecting the lifetime and the rechargeability.
- We recommend that you charge the battery every 3 months and keep its capacity at 30%~50% of the standard capacity when it comes to long-term storage.
- Do not wait to recharge the battery until it is almost running on empty (the battery indicator is flashing green), as this can damage the battery life.
- The charging case requires an intermediate-level disinfection. Please remove the battery from the charging case and disconnect the power, then wipe the surface of the charging case with new cotton gauze moistened with 70%-75% solution of ethanol.
- Check if there are black stains out of friction on both ends of the battery regularly. If so, swab the stains with alcohol.

Caution:

- Put the battery and the charging case where children can't reach.
- Avoid a fall from height and an accidental hit to prevent the charging case from being damaged.
- Avoid splashing water into the charging case to protect it.
- Despite a careful maintenance and a normal usage, the lithium-ion battery's capacity still decreases with its aging. It has nothing to do with the quality of the product.
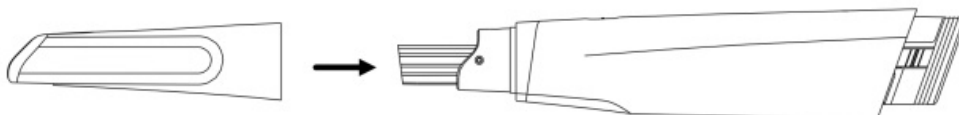
Scanner Settings

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.

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.
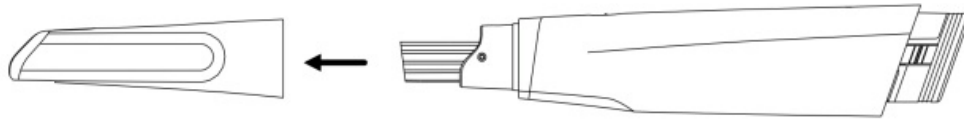

Caution:

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.

Detach the scanner tip

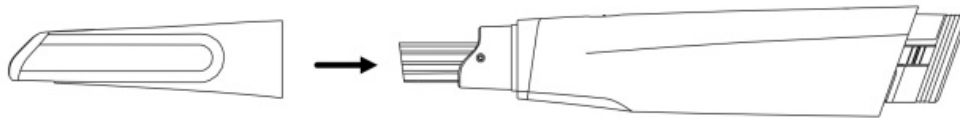Disconnect the power of the scanner, and pull the scanner tip off the scanner body.

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.
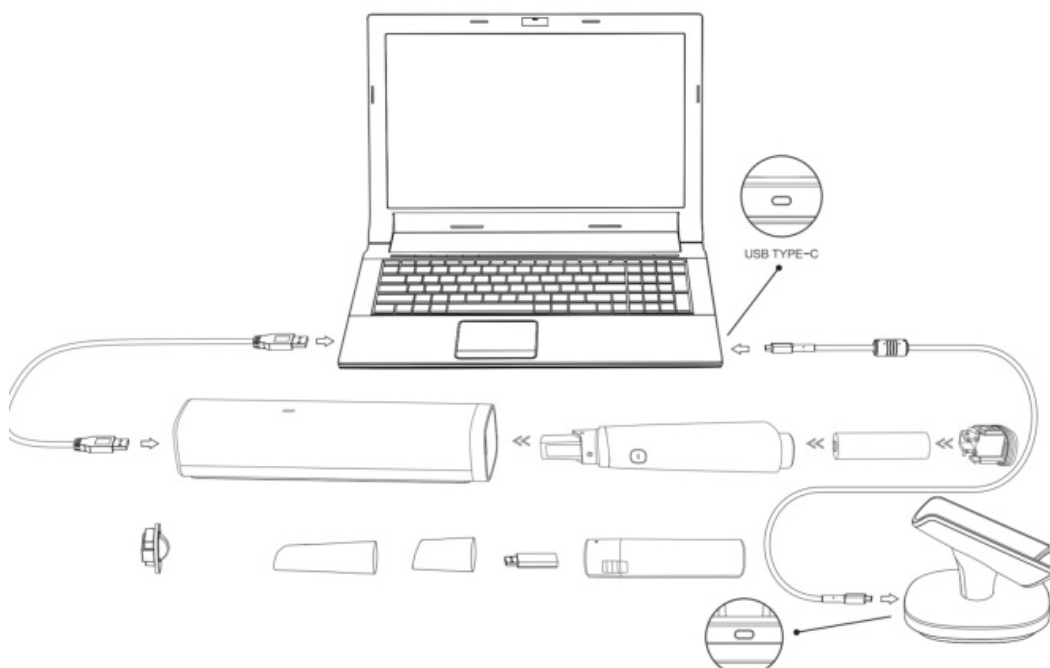
Connect the scanner

Follow the steps below to complete the connection:

1. Insert the battery into the scanner and cover it with the battery cover.
2. Cap the scanner with the scanner tip and ensure it's firmly attached.

3. Connect the cradle with the cable and plug it into a Type-C port on the computer.

USB TYPE-C

4. 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.

Disconnect the scanner

Follow the steps below to safely disconnect the scanner:

1. Quit the IntraoralScan scanning software.
2. Long press the scan button on the scanner body to power off the scanner.
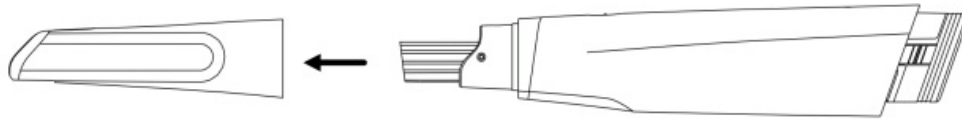3. Disconnect the cable of the cradle with the computer.

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 has been used for a period of time (e.g. 2 weeks).
- The scanner is accidentally dropped.
- Scanner brightness has not been adjusted for a long time (e.g.3 months).

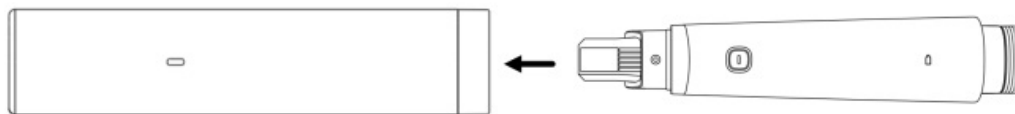**Follow the steps below to perform the calibration:**

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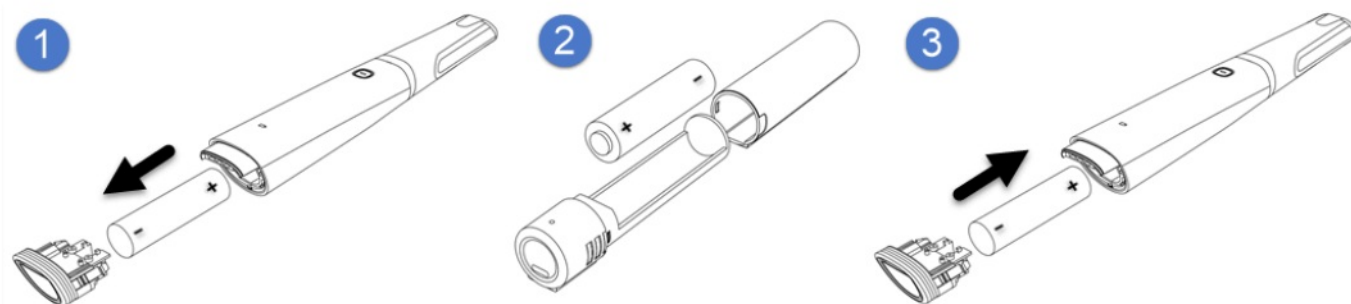4. Gently slide the calibrator onto the front end of the scanner.

5. Click ⊕ on the main interface to enter the calibration.
6. Click Start.
7. When the calibration is completed, the software will prompt a tip. The whole calibration lasts about 7 minutes.
8. Click ✕ on the upper right to close the calibration.
9. Gently take the calibrator off the scanner.
10. Reconnect the scanner tip to the scanner for future use, or cap the scanner with the dust cap to avoid damage.

Caution

Detach the calibrator from the scanner in time after calibration to avoid overheating of the calibrator.

Replace and Charge the Battery

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

Caution:

When open the battery cover, please take out the battery carefully to prevent it from slipping out and dropping down.

Battery Use

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

- When replacing the battery, make sure the scanner is turned off.
- Do not remove the battery or install/replace an unsuitable battery.
- Do not charge the battery for an extended period of time. If the battery casing is scarred, please replace it in time to avoid causing problems such as liquid leakage and fire.
- Leaving the battery idle for a long time without charging may cause the battery capacity to decrease and affect its service life and rechargeability.
- It is recommended that for long-term storage, please charge the battery once every 3 months and try to keep the battery capacity at 30%~50% of the standard capacity.

Charging Case Using Safety

- Place the charging case away from sparks, dust and other corrosive occasions.
- Please place it in a safe place where children cannot touch it.
- Store in an environment free of dust, liquid, metal debris, etc. Please store in a clean and dry environment.

Preparations and Use

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

- The scanner battery is full.
- 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.

CONTACT

- **Manufacturer information and production address**
- Manufacturer name: SHINING 3D Tech Co., Ltd.
- Production Address: No. 1398 Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China

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FAQ

- **Q:** What should I do if the scanner is damaged?
- **A:** If the scanner is damaged, deformed, or shows any abnormality, stop using it immediately and contact the after-sales service personnel for maintenance.
- **Q**: Can I copy or publish the Product Usage Documentation?
- **A**: No, without the written consent of SHINING 3D, it is not allowed to copy, transmit,

publish, adapt, compile, or translate any contents of the Product Usage Documentation in any form for any purpose.

Documents / Resources

SHINING 3D Aoralscan Elite Wireless Instructions for Use	[SHINING 3D CRAEW 2AMG4 Aoralscan Elite Wireless](#) [[pdf](#)] Instructions CRAEW 2AMG4, CRAEW 2AMG4CRAEW, CRAEW 2AMG4 Aoralscan Elite Wireless, CRAEW 2AMG4, Aoralscan Elite Wireless, Elite Wireless, Wireless

References

- 🌐 [Dental Scanners, CAD Software & Dental 3D Printers SHINING 3D Dental](#)
- [User Manual](#)

📁 SHINING 3D

🏷 Aoralscan Elite Wireless, CRAEW 2AMG4, CRAEW 2AMG4 Aoralscan Elite Wireless, CRAEW 2AMG4CRAEW, Elite Wireless, SHINING 3D, Wireless

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