



SHINING 3D

Aoralscan 3 Wireless Instructions for Use



V2.0

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1 Foreword

General

This Instructions for Use (hereinafter referred to as "the Instructions") introduces the functions, installation, usage and maintenance of Aoralscan 3 Wireless (hereinafter referred to as "the scanner").  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 date

Release version	Release date
2.0.0	May 2024

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2 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.

2.1 Basic information

I. Product name, model and catalogue number

Product name: Intraoral Scanner

Model: Aoralscan 3 Wireless

II. Manufacturer information and production address

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

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

III. Contact information

Manufacturer

Shining 3D Tech Co., Ltd.

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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.
- Scanning speed: The average time to scan a single jaw model is no more than 3 minutes.
- Calibrator: With its self-checking function, the calibrator can check whether its inner components work normally.
- Battery charge: The user can charge the device.
- Wireless connection: With its wireless transmission function, the user can connect the scanner and computer without wires.
- Heating and anti-fogging of the scanner tip: Under normal working conditions, the scanner tip should resist fog and be heated automatically.
- Quick heating of the scanner tip: The scanner tip can be heated within 30s.
- Software features
 - a. The software provides guidance for the users to understand the operations. It has backward function as well.
 - b. The users can add requirements of jaw, tooth and treatment.
 - c. The software will scan teeth according to the requirements.
 - d. It allows users to edit the scanned data such as repairing holes and selecting data.
 - e. The functions include checking undercut, bite areas and texture, smoothing the model (optional), orthodontic simulation (optional), AccuDesign (optional) and checking oral report (optional).
 - f. Able to monitor tooth preparations (optional).
 - g. Able to calibrate itself automatically (optional).
- Performance
 - Accuracy: Under normal conditions, the scanner is used to scan against a standard (e.g., a plaster standard known to be similar in size to a tooth), obtain its three-dimensional stereoscopic data, and measure key dimensions to obtain measured values.
- Function control and display
 - Function control: After pressing the scanning button, the front end of the scanner should flash normally.
 - Display: Under normal working conditions, when the scanner starts scanning, the two-dimensional and three-dimensional imaging of the scanned object (such as teeth) can be seen on the display respectively.
 - Dental scan imaging: The scanner scans the teeth and gingiva to generate a 3D digital model.

- Internet security
- Data interface: Transmit the information and acquire the image by USB 3.0.
- User Access Control: Normal user access control. Users can log in via their login name and password.

Main components

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

Caution:

- It is recommended that users copy the software from the USB flash drive to the computer hard disk before installing the driver.
- Use NVIDIA graphics cards to get the best 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.

2.2 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  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.

2.3 Contraindications

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

2.4 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.

2.5 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.

2.6 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.

2.7 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, 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.



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 indicate the device is a Class II equipment.



To indicate the device is a Class 1 laser product.



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 the entity importing the medical device into the locale.



Click "Reset", the default parameters will be restored.



To indicate lithium ion batteries contained in equipment or packed with equipment.

**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".

3 Product overview

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.

3.1 Hardware overview

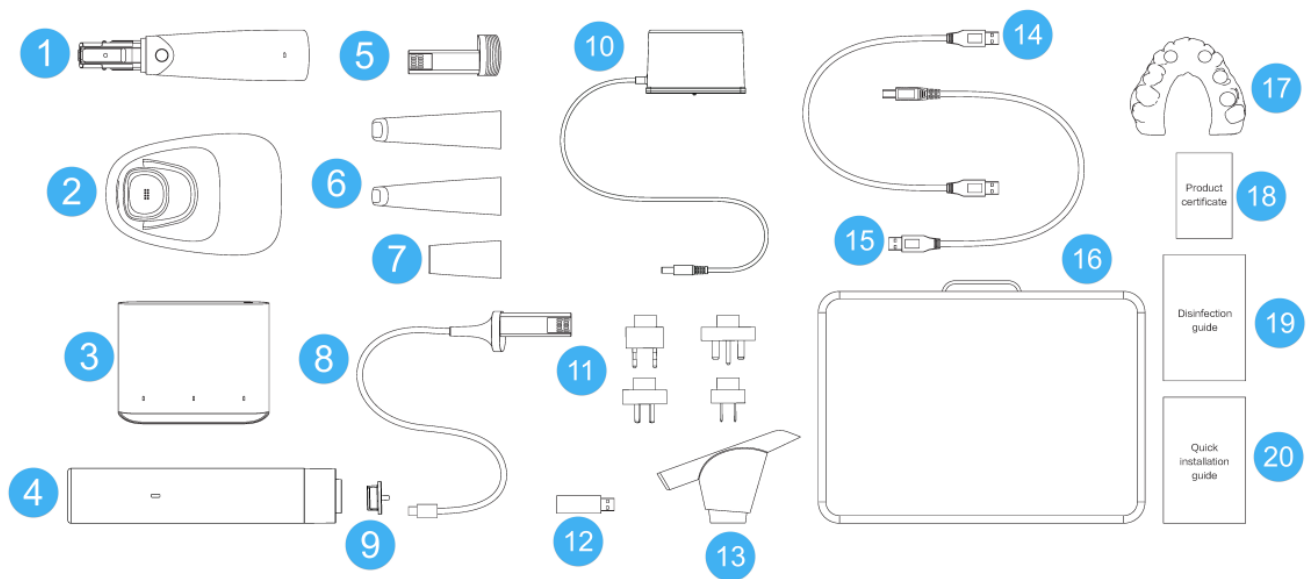
The following offers a hardware overview about the scanner, including the parts list and description.

3.1.1 Parts list

Check the carry box for the following items. If any item is missing or damaged, contact the distributor or service provider immediately. The color of the scanner tip can be gray or white; the color of the metal ring can be silver or red and the color of the cradle can be silver and white or red and white.

**Note:**

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



No.	Name	Description
1	Scanner body	Data collection.
2	Cradle	1.The scanner can be put on the cradle. 2.A wireless AP. 3.Charge the scanner when connected with a wire.
3	Charging case	Charge the battery.
4	Calibrator	Calibrate the scanner.
5	Battery	Wireless power supply.
6	Scanner tip	4 standard tips and 1 mini tip.
7	Dust cap	Protect the scanner from dust.
8	Spare cable	A detachable spare USB 2.0 cable for connecting scanner and cradle.
9	Dust cap	Protect the calibrator from dust.

No.	Name	Description
10	Power adapter(include one plug)	Charge the cradle and the charging case.
11	Power Adapter Plugs	/
12	USB flash drive	The software package is contained.
13	Transfer bracket	The scanner can be put on the bracket when wired connected.
14	Calibrator cable	Connect the calibrator with the computer. Length: 1.5m
15	Cradle cable	Connect the cradle with the computer.
16	Package box	Contain all parts.
17	Practice model	For scanning presentations and practice.
18	Warranty & Quality certification	/
19	Disinfection guidelines	/
20	Quick start guide	/

 Warning:

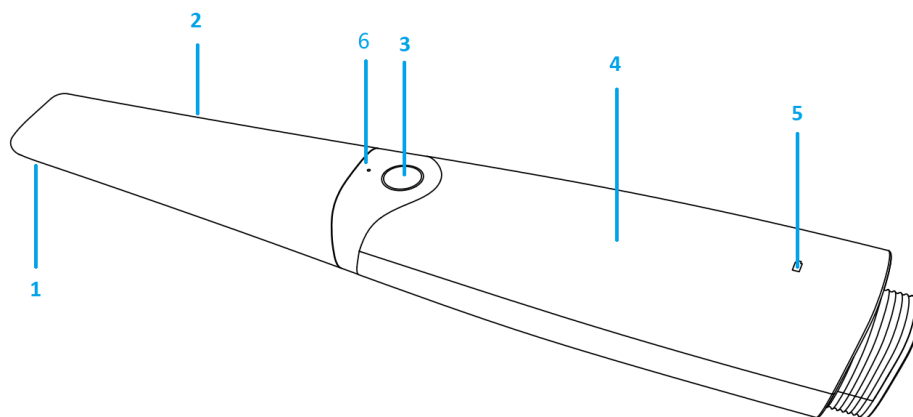
Please do not use accessories, peripherals, or cables not provided with the product or recommended by SHINING 3D Tech Co., Ltd. Otherwise, it may void the warranty, lead to electrical leakage, threaten the safety of the grounding scheme, and decrease the scanner's resistance to external EMI/EMC interference.

 Note:

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.

3.1.2 Hardware description

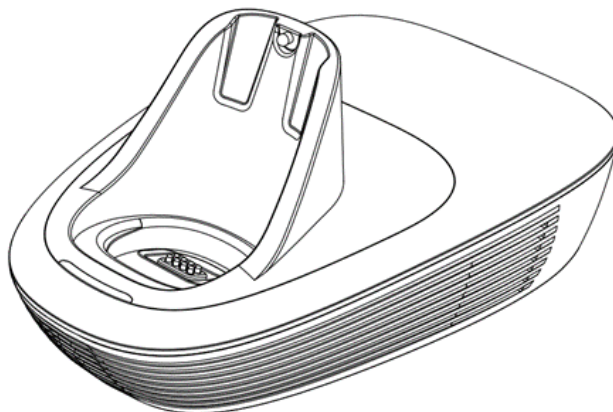
Scanner tip and scanner body



No.	Item	Description
1	Heating component	The heating component ensures successful scanning by preventing fogging on the lens.
2	Scanner tip	- Use the scanner tip to scan the upper, lower or full jaw. The scanner tip can be recycled up to 100 times. - The scanner can identify tips with different sizes and adjust the breadth of the camera according to the tip size automatically.
3	Button	When the scanner isn't connected with the computer: - Press the button to connect the scanner and the computer via Wi-Fi. When the scanner is connected with the computer: - If the scanner is in sleeping mode, press the button to awake it; - If the scanner is on the working mode, press the button to start scanning. Press again to pause scanning. - Double press to enter the button interface. - Long press to enter the next step.
4	Scanner body	- Rotate the scanner body during scanning to obtain the best scanning angle. - During the scanning process, the scanner body may heat up, but the temperature will not cause harm to users and patients.

No.	Item	Description
5	Battery indicator	Green: • The battery is inserted into the scanner. • The scanner is charged above 20% in the cradle. Flashing green: • The battery power is less than 20%. Extinguished: • The scanner is in sleeping mode. • The battery is not inserted into the scanner. • The Scanner is not connected. Note:The battery indicator is extinguished in wired connection mode.
6	Status indicator	Indicates the status of the scanner. • Green: The scanner is in scanning, heating or standby status. • Orange: Abnormal status. The scanner is not correctly connected or malfunctioned. The scanner tip is not inserted tightly or the scanner is not connected to the Wi-Fi. • Breathing green: The scanner is in standby mode, low battery or unconnected. • Extinguished: The scanner is in sleeping mode.

Scanner cradle



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

Cradle indicator:

- Orange light: Pay attention to the device initialization or device abnormality. Such as connection abnormality, device failure.
- Steady green: Scanner charging is completed or the cradle is in normal working condition.
- Flashing green: The scanner is charging.
- Extinguished: Not connected to power.

 Caution:

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

Charging case indicator:

- Flashing green: Charging in progress
- Steady green: Charging is complete
- Green off: Battery not inserted or not inserted in place (not charging)

Calibrator indicator:

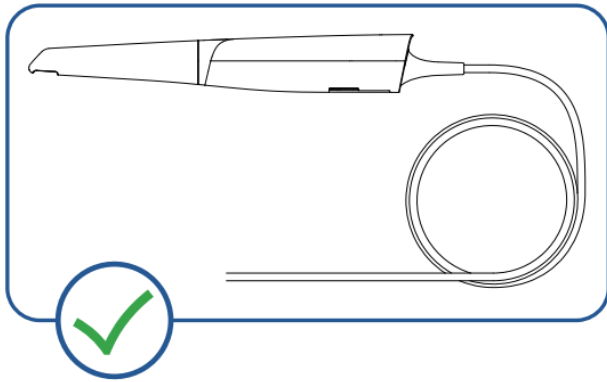
- Orange light: During initialization or calibration instrument abnormal
- Green light: Normal operation in progress

USB cable storage

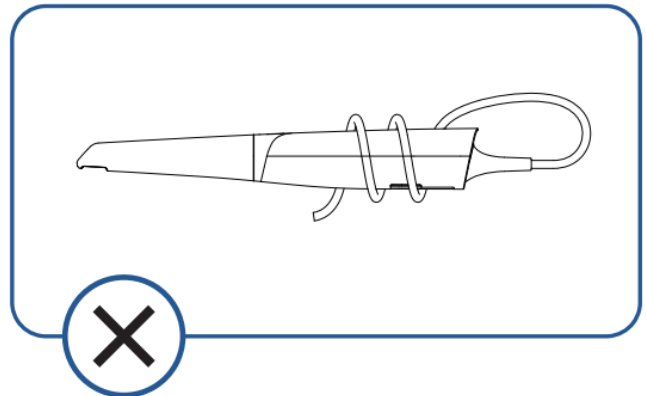
To prevent the USB cable from getting damaged by excessive bending or twisting, you should loosely coil the cable and avoid making kinks or sharp bends.

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

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



Right cable storage



Wrong cable storage

3.2 Software overview

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

1. **Calibration module:** Calibrate the scanner.
2. **Dental order system module:** Manage and store patient data, and upload it to Dental Cloud for sharing.
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.

3.2.1 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		More than 2 type-A USB 3.0 (or higher) ports

MacBook recommended configuration

Components	Configuration
CPU	Apple M2
Memory	16 GB or higher, mini: 8 GB
Hard disk drive	512 GB or above, mini: 256 GB
Operating system	macOS

iPad recommended configuration

Components	Configuration
CPU	Apple M2
Memory	16 GB above
Hard disk drive	1 TB or above
Operating system	iPadOS 16



Note:

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

3.2.2 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. Find the file named IntraoralscanVXXXX.exe and run it as administrator.
3. The IntraoralScan Installation Wizard window appears to start the installation.
4. Specify a language from the drop-down list.
5. Click OK.
6. Follow the on-screen instructions to complete the installation.

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 or through the company's cloud platform.
- Network Failure: If the network connection fails when the product is offline used, data is stored in local path. When the product have access to the network, data transmission will resume. If network connection fails during transmission, any data that has been transmitted will be invalidated without causing impact.
- Network Access:
 - a. After the computer has access to the network, the software will be automatically linked to the cloud platform and retrieve information about the device connected to the software. Users can register, log in and upload patient and order data to the cloud platform as well.
 - b. 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.
 - c. Failure to link to our company's cloud platform may lead to identification 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.
 - d. 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.

 Caution:

1. The computer should be dedicated for IntraoralScan. Please do not install unrelated software. Ensure that the system disk (usually the C drive) and the disk where the orders are saved have enough space.
2. Install copyright and legitimate firewall and antivirus software. Please do not visit insecure websites to prevent computer viruses, personal information theft, or data corruption.
3. Set an administrator password for the dedicated computer and keep it properly to prevent unauthorized access or data theft.
4. For important data, we recommend you to regularly back up and upload them to the personal cloud.
5. Please do not manually delete or rename the path where the orders are saved to prevent accidental data loss.

4 Care and maintenance

4.1 Pre-cleaning, disinfection, and sterilization

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

4.2 Scanner body, cradle and calibrator maintenance

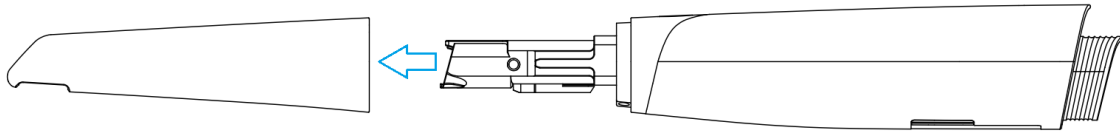
The scanner body, cradle and calibrator require an intermediate-level disinfection.

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.

4.3 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 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 [Disattach 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.
 - When cleaning the inside of the tip, insert the sponge brush into the tip from both the front and rear ends, and move the brush lightly in tiny circles.
 - When cleaning the outside of the tip, brush the surface back and forth lightly.
4. Rinse the tip thoroughly with distilled water for at least 3 minutes.
5. If there is any stain or fingerprint on the lens, repeat step 3 and 4.

Caution:

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

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

Warning:

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

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

High temperature autoclave sterilization steps

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

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

 Warning:

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

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

5 Scanner settings

5.1 Connection and disconnection

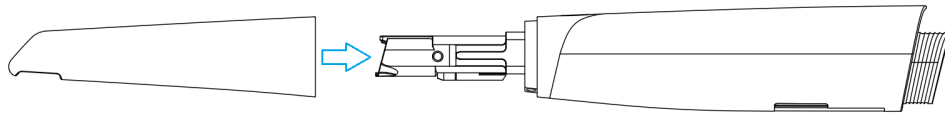
 Caution:

- 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.

5.1.1 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.



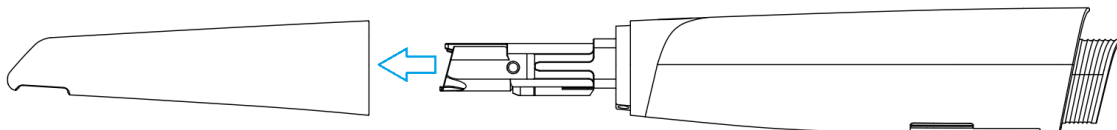
⚠ Caution:

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.

5.1.2 Disattach the scanner tip

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



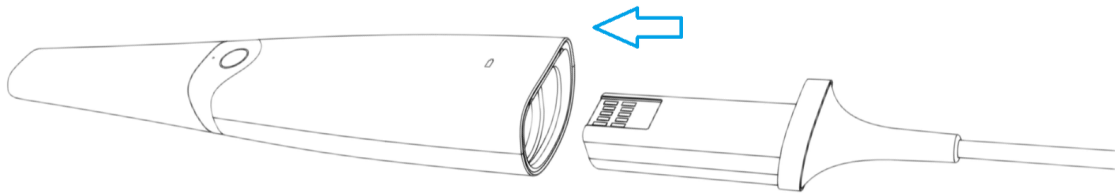
⚠ Caution:

- 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.

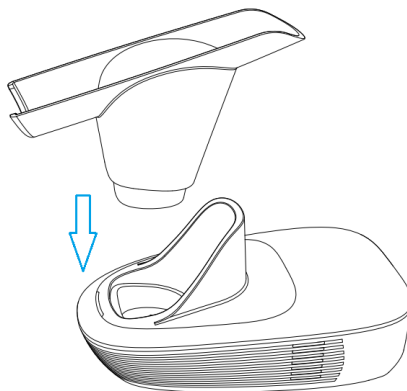
5.1.3 Connect the scanner

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

1. Attach the scanner tip first. See more details in [Attach the scanner tip](#).
2. Push the spare cable hard to the scanner and ensure the firm attachment.



3. Insert the adapter of the cradle downward into the cradle.

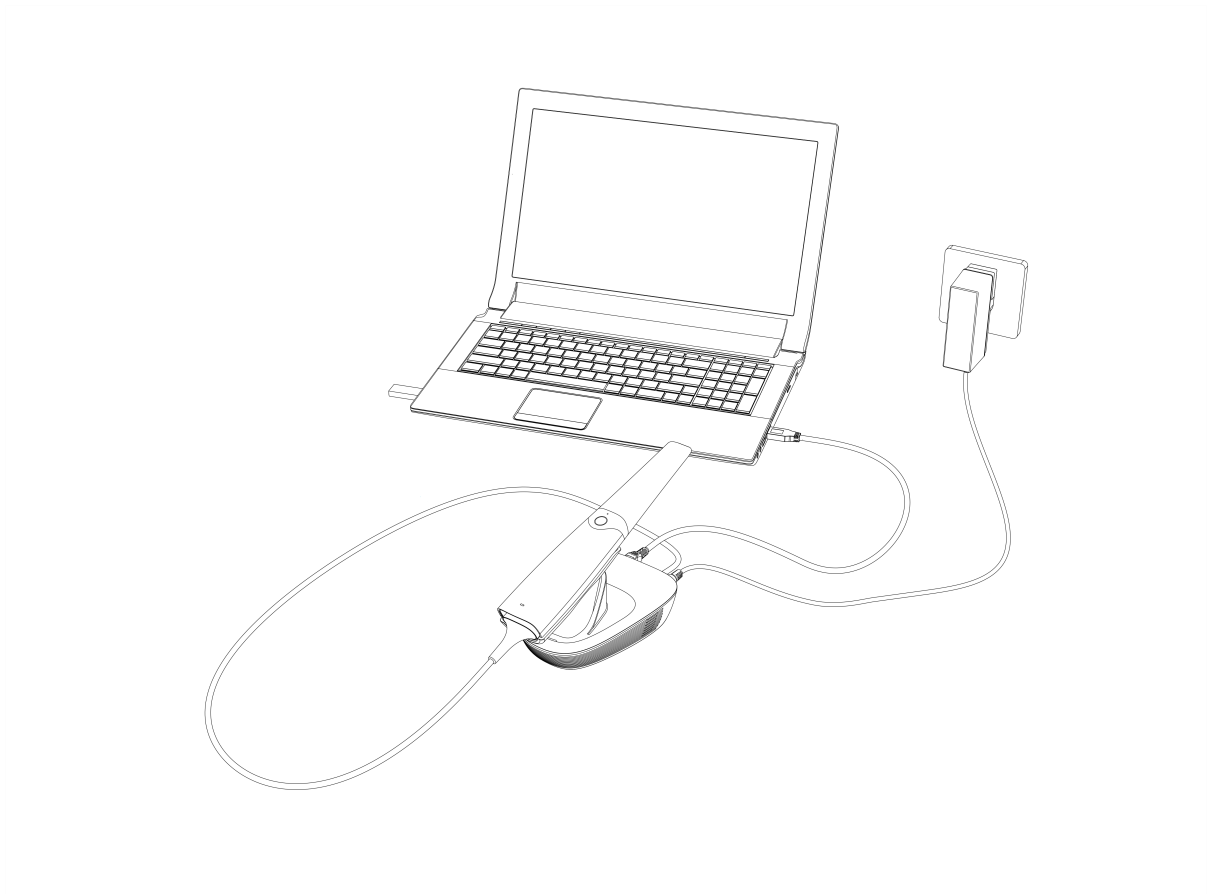


4. Connect the USB cable line of the scanner to the USB 3.0 port on the cradle as ① shows.

5. Connect the calibrator and cradle via spare wire as ② shows.

6. Connect one end of the USB 3.0 cable line to the cradle and the other to the USB 3.0 port on the computer as ③ shows.

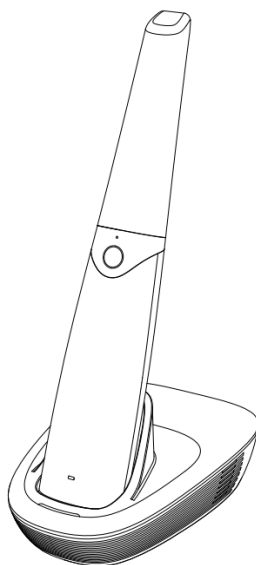
7. Plug the round splice of the power adapter into the power port on the cradle and connect it to the power supplies as ④ shows.



8. Double-click the shortcut icon on the desktop to launch the software.

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

1. Attach the scanner tip first. See more details in [Attach the scanner tip](#).
2. Push the scanner hard and ensure the whole device is firmly attached.
3. Insert the scanner into the cradle.



4. Click the shortcut icon on the desktop to launch the software.
5. Enter the interface of device connection and connect it via wireless AP binding.

 Note:

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

 Note:

Aoralscan 3 Wireless can be connected with an All-in-One machine or an extended touch screen. It is also supported to be connected with Cart V3. More details about connection and operations can be found in the Instructions of Cart V3.

 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 3.0 port where it is difficult to disconnect the device.

5.1.4 Disconnect the scanner

Follow the steps below to safely disconnect the scanner:

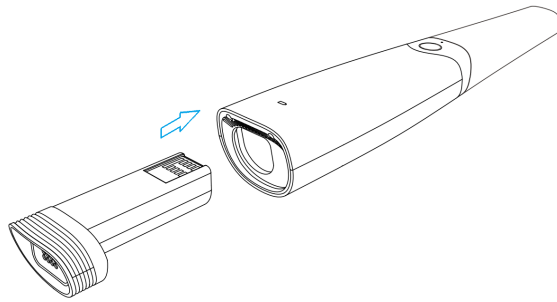
1. Quit the IntraoralScan scanning software.
2. Disconnect the USB data cable from the cradle and scanner.
3. Right-click the "Safely Remove Hardware" icon on Windows taskbar and select "Eject Flash Drive".
4. Unplug the USB flash drive and keep it in a safe place for future use.
5. Unplug the power adapter from the wall outlet and remove the power plug from the power port on the cradle.

 Caution:

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

5.2 Replace 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.



5.2.1 Battery use

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

- When replacing the battery, make sure the scanner is turned off.
- Do not remove the battery or install/replace an unsuitable battery.
- Do not charge the battery 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.

5.2.2 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.

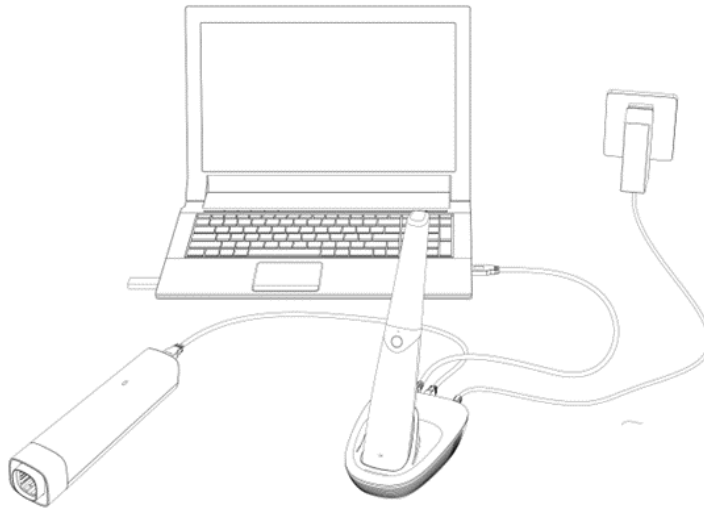
5.3 Calibration

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).

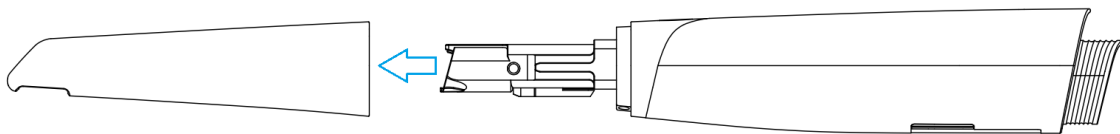
Follow the steps below to perform the calibration:

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



Calibration in Wireless Connection Mode

2. Hold the scanner tip firmly and then gently take the tip off from the scanner.

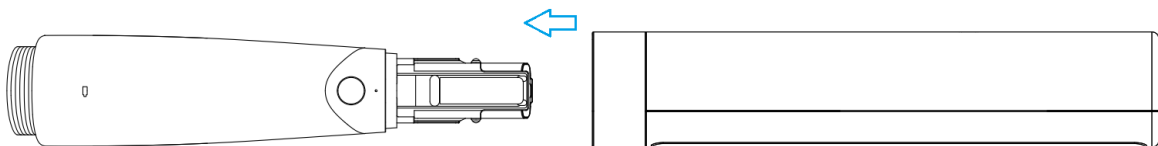


⚠ Caution:

- 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.

6 Preparations and use of scanner

 Warning:

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

6.1 Preparations

6.1.1 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.

6.1.2 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.

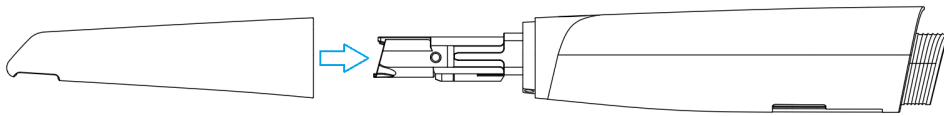
 Note:

- 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.
- The scanner tip will still be heated when the scanner is in standby or sleeping mode.

6.1.3 Heat the scanner tip

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

- Gently and carefully attach the scanner tip to the scanner body, with the mirror facing downward.



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

 Note:

- If the temperature of the scanner tip is lower than the set value for anti-fogging, a notification message of pre-heating and current temperature appears.
- When the notification message disappears, the pre-heating is done. The scanner is now ready for scanning.
- The heater helps keep the scanner tip temperature in a normal range.
- The scanner tip is being heated whenever power is supplied, even if the scanner is in standby or sleeping mode.
- If the heater does not reach the necessary temperature for preventing condensation during scanning, the message of "The scanner is pre-heating. Please wait" appears.

6.2 Use of scanner

6.2.1 Connection

See more details in [Connection and disconnection](#).

6.2.2 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.

6.2.3 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.

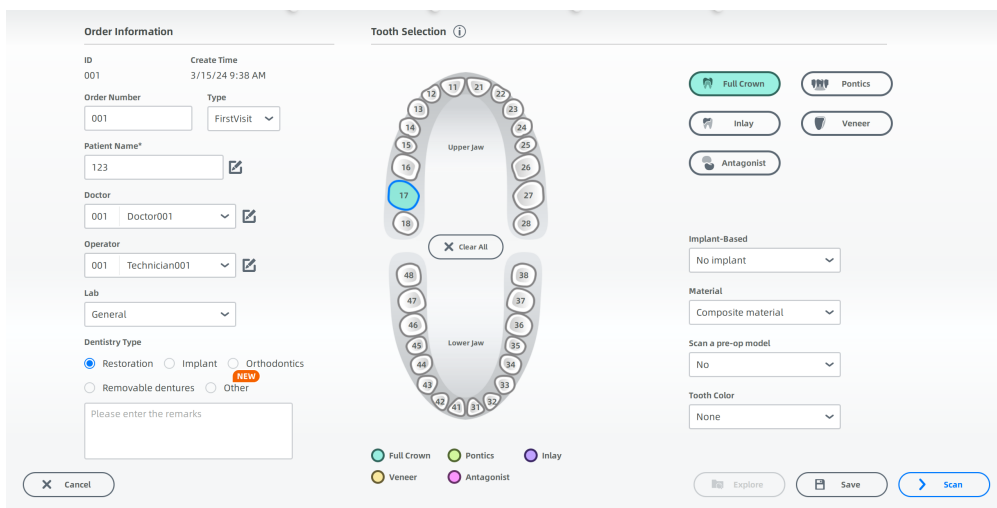
6.2.4 Calibration

See more details in [Calibration](#).

6.2.5 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.



The screenshot displays the 'Order Information' and 'Tooth Selection' interface. On the left, the 'Order Information' section includes fields for ID (001), Create Time (3/15/24 9:38 AM), Order Number (001), Type (FirstVisit), Patient Name* (123), Doctor (001 Doctor001), Operator (001 Technician001), Lab (General), and Dentistry Type (Restoration, Implant, Orthodontics, Removable dentures, Other). A 'Please enter the remarks' text area is at the bottom. The 'Tooth Selection' section shows a diagram of the upper and lower dental arches with numbered teeth. Tooth 17 in the upper arch is highlighted in blue. A 'Clear All' button is located below the diagram. To the right of the diagram are buttons for 'Full Crown', 'Pontics', 'Inlay', 'Veneer', and 'Antagonist'. Below these are dropdown menus for 'Implant-Based' (No implant), 'Material' (Composite material), 'Scan a pre-op model' (No), and 'Tooth Color' (None). At the bottom right are 'Explore', 'Save', and 'Scan' buttons. A legend at the bottom center identifies the colors for Full Crown (green), Pontics (yellow), Inlay (purple), Veneer (orange), and Antagonist (pink).

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.

6.2.6 Scanning

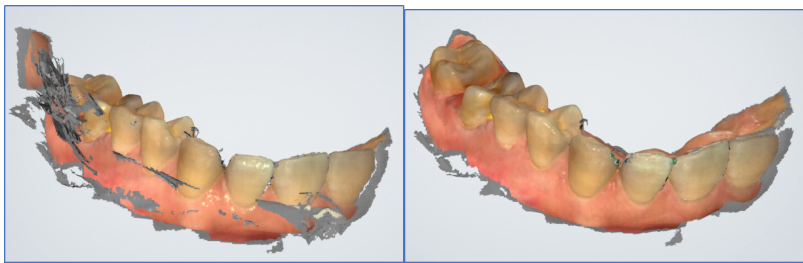
Note:

- 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.
- Scanning with the device in a 40°C environment (for 1-10 minutes), the temperature of the scanning tip or the surface of the device may exceed 41°C but will be maintained below 48°C.
- 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:

- 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

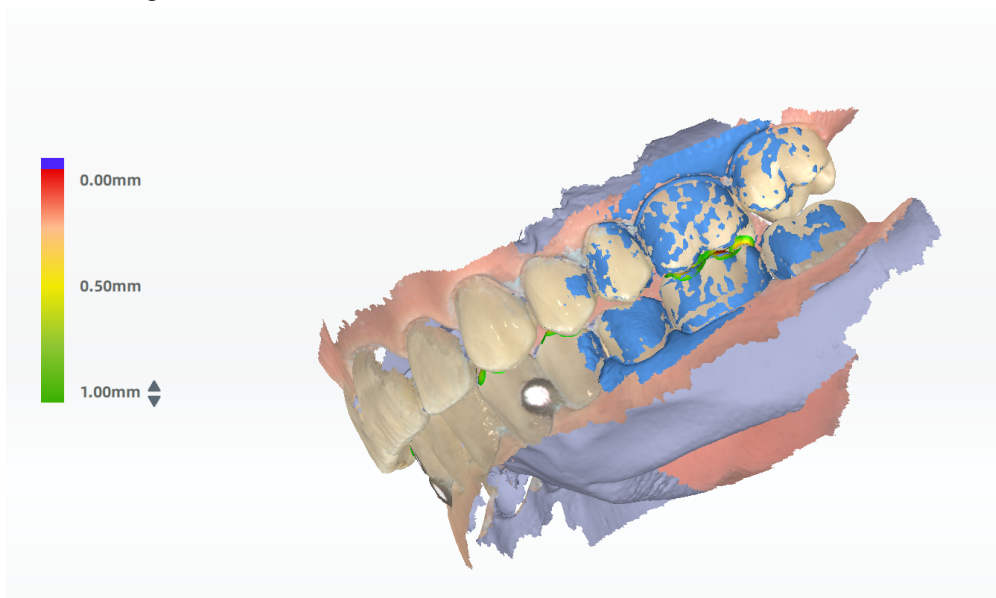
After the upper jaw scanning and the data processing are completed, the lower jaw scanning interface is automatically displayed. The procedure is the same as scanning the upper jaw.

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.



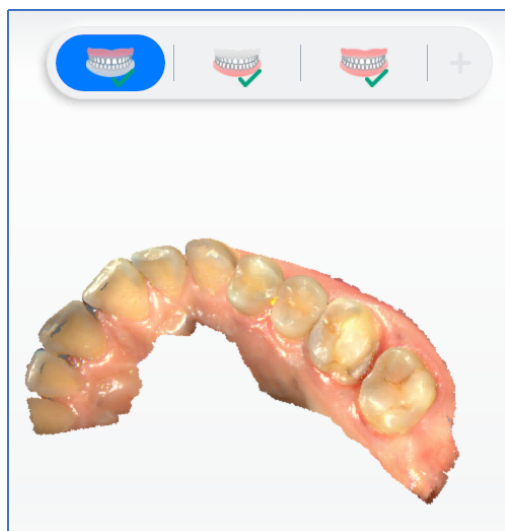
Click ✓ or long press the Space key or the scanner body button for about 3 seconds to post-process the data.

See more details in User Manual.

6.2.7 Scanned data view

View scanned data in IntraoralScan.

Check jaws



Upper jaw



Lower jaw

Check the bite



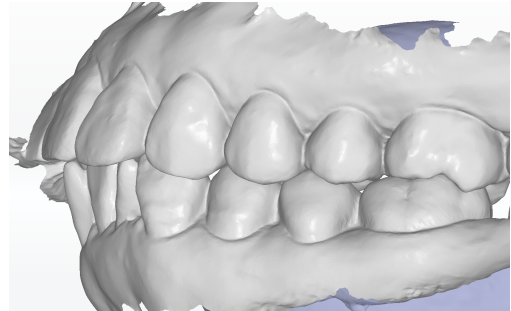
Name	Description
 Tooth preparation dynamic depth monitoring	Tooth preparation is only supported for pre-op orders. By monitoring the prepared tooth, data will be saved during the grinding. It's convenient to compare multiple sets of tooth preparation data to standard model. After creating a pre-op order and scanning the models, click on the right side of the interface and make comparison. Click on the compared models to check the results.

6.2.8 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

ConsulOS is an orthodontic simulation software specially used in face scan and intraoral scan. The software boasts many features:

- Simulates the face shape and dentition before and after the orthodontic tooth arrangement according to facial and intraoral scanned data.
- Supports a flexible switch between the face model and the tooth model to view different details.
- Improves the texture of teeth to simulate the patient's real intraoral conditions.
- Supports uploading multiple sets of plan and export multiple reports at once.

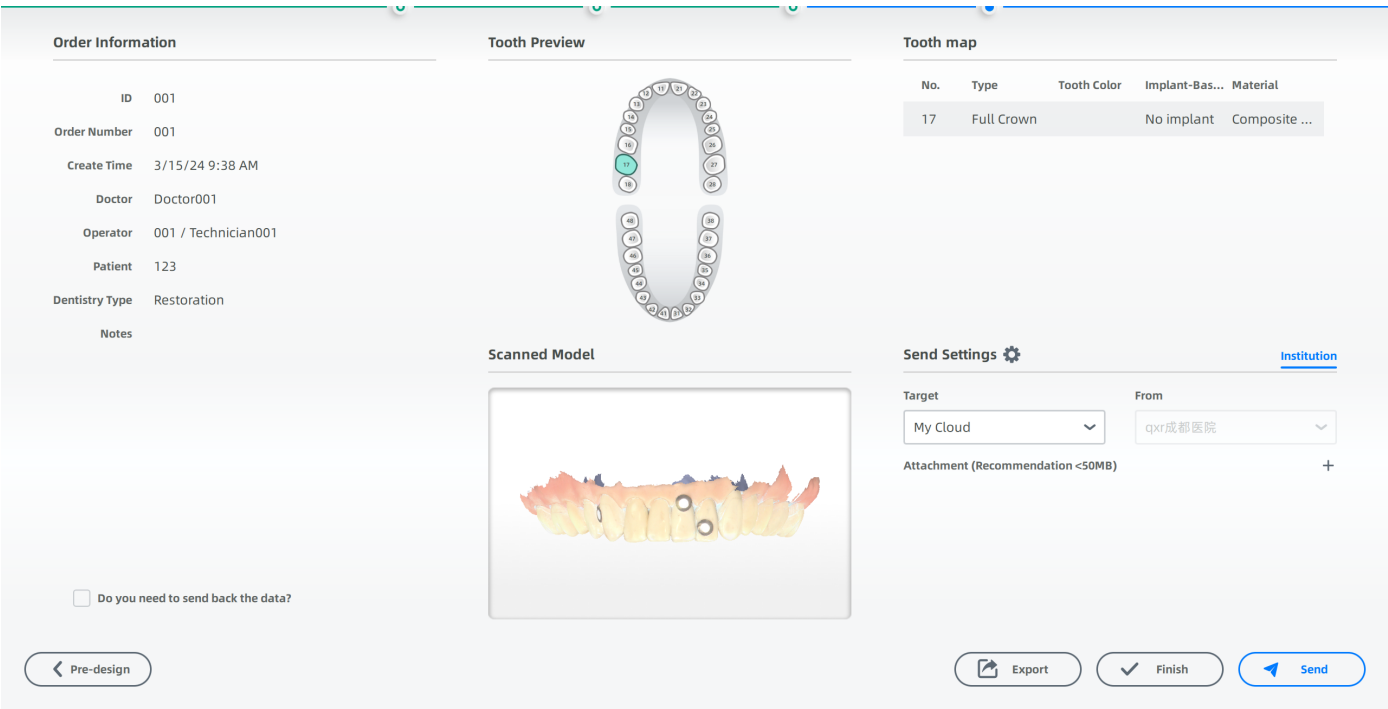
Oral health report

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

See more details in User Manual.

6.2.9 Order storage and uploading

After scanning, you can check the current storage of the order and upload it to Dental Cloud or third-party platforms.



7 Storage and transport

The requirements for the daily storage and transportation of the scanner are as follows.

7.1 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.

7.2 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, cradle, power adapter, 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.

8 Safety information

8.1 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: Class II
- The degree of protection against electric shock: Type BF applied part
- Degree of protection against incoming liquids:
 - Scanner body: IPX0
 - Charging case: IP20
- 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
- Nominal voltage:
Power adapter input/output: 12V, 3.0A;
Incoming current of the device: 1.0A;
- RF frequency range: 5150-5850MHz
- Bandwidth: ≤80MHz
- 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.
- 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).

8.2 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.

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 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.
- This device is not intended for use in residential environments and may not provide adequate protection for radio reception in such environments.

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

Essential performance

During the continuous scanning process, the scanned image should be acquired normally.

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 statement - 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	Conformity
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker according to IEC 61000-3-3	Applicable

Interference immunity

The 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 statement - 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:

Immunity test	IEC 60601 test levels	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s)	±0.5, ±1 kV line(s) to line(s)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U _T (100% dip in U _T) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _T (100% dip in U _T) for 1 cycle and 70% U _T (30% dip in U _T) for 25/30 cycles At 0° 0% U _T (100% dip in U _T) for 250/300 cycles	0% U _T (100% dip in U _T) for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _T (100% dip in U _T) for 1 cycle and 70% U _T (30% dip in U _T) for 25/30 cycles At 0° 0% U _T (100% dip in U _T) for 250/300 cycles

Guidance and manufacturer's statement - Electromagnetic emission

Immunity test	IEC 60601 test levels	Compliance level
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's statement - 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:		
Immunity test	IEC 60601 test levels	Compliance level
Radiated RF EM fields IEC 61000-4-3	3V/m 10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3V/m 10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15MHz to 80 MHz 6 V in ISM bands between 0.15MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15MHz and 80 MHz 80% AM at 1 kHz

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				

Signal input/output parts PORT

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

Test specifications for enclosure port immunity to proximity magnetic fields

Test frequency	Modulation	Immunity test level
30kHz	CW	8
134,2KHz	Pulse modulation 2.1kHz	65
13,56MHz	Pulse modulation 50kHz	7.5

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality or launch warning messages, it is necessary to position the 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, as recommended below.

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

Warning:

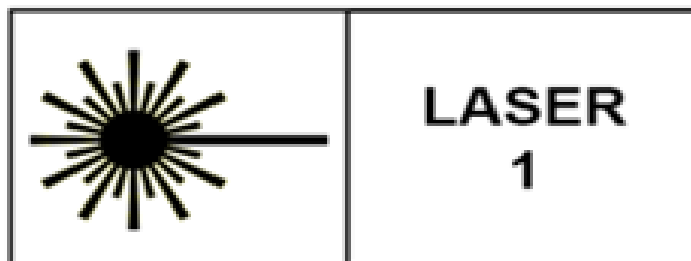
- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12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

8.3 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)

8.4 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.

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.

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.

8.5 Explosion prevention

- Do not charge the battery for a long time.
- Do not reverse the positive (+) and negative (-) terminals.
- Do not directly solder the battery terminals.
- Do not disassemble the battery and the charging case at will.
- Do not put the battery into a fire or apply direct heat to it.
- Do not place the battery in a microwave oven or pressurized container.
- Do not use or store the battery near sources of heat such as a fire or heater.
- Do not short-circuit the battery by connecting wires or other metal objects to the positive (+) and negative (-) terminals.
- Do not connect the battery directly to wall outlets or car cigarette-lighter sockets.
- Use the battery and the charging case supplied with the device. Do not change them at will.
- Replace the battery shell if it's damaged to prevent leak or fire accident.
- Do not put any objects on the charging case when it's charging the battery, in order to keep good ventilation and heat dissipation.
- Do not connect the charging case with power for a long time. Cut off the power after using the charging case to avoid safety hazards.
- Store the battery and the charging case in an environment that is clean, dry, and free of inflammable materials like powder, liquid, and metal scraps.
- Do not use the battery if it gives off an odor, generates heat, becomes discolored or deformed, or appears abnormal in any way. If the battery is in use or being recharged, remove it from the device or charger immediately and discontinue use.

9 Hardware specification

9.1 Specifications

Parameter	Description
Type name	Intraoral scanner
Model name	Aoralscan 3 Wireless

Scanner	
Scanner tip types	Standard tip and mini tip
Scan field(L×W)	Standard tip: 16 mm × 12 mm Mini tip: 12 mm × 9 mm
Scanning tip dimensions(L×W×H)	117±1 mm × 34.5±1 mm× 30.5±1 mm
Scanning depth	22 mm (-2 mm ~ 20 mm away from the window of the scanner tip)
Scanner size with scanner tip and battery(L×W×H)	275±3 mm × 46±3 mm × 40±3 mm
Scanner weight with scanner tip and battery	330±20 g (without the cable)
Scanner tip maintenance	Sterilized and disinfected by users (Maximum: 100 times)
Scanner tip connection	Pluggable
Light source	LED and laser
Wave length	Green laser: 520±10 nm Blue laser: 445±10 nm White LED: 400 nm-780 nm
Output	STL、OBJ、PLY
Device Lifetime	8 years

Cradle	
Cradle size (L×W×H)	160±3 mm × 110±3 mm × 77±3 mm
Cradle weight	560±20 g

Battery	
Battery type	Rechargeable battery
Dimension (L×W×H)	85 mm× 37 mm× 28 mm
Weight	67±5 g
Nominal voltage	3.635 V
Capacity	3500 mAh

9.2 Environmental requirements

Operating and storage requirements

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

Battery storage requirements

Storage time	Storage temperature
Short-term(less than 1 month)	0°C ~ 45°C
Middle-term(1 month to 3 months)	-20°C ~ 35°C
Long-term(3 months to 12 months)	-10°C ~ 25°C

- Relative humidity: 30%RH-75%RH

10 Wireless Compliance Notification

Symbol	Explanation
	Japan Ministry of Internal Affairs and Communications Certificate (MIC)
	Taiwan China National Communications Commission Certificate (NCC)
	Korea Certification (KC)

10.1 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.
 - 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.
 - This device complies with FCC radiation exposure limits set forth for an uncontrolled rolled environment. Cradle should be installed and operated with a minimum distance of 20cm between the radiator and your body.

- This device for operation in the band 5150-5250 MHz is only for indoor use.

10.2 ISED

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

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

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

L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement."

10.3 NCC

無線操作特殊警示說明：

- 取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前述合法通信，指依電信管理法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。應避免影響附近雷達系統之操作。

10.4 MIC

本機器は電波法に基づく工事設計認証を取得しています(技適マークが付いています) 5GHz帯:W52/W53屋内使用限定（ただし登録局に接続される場合は除く）