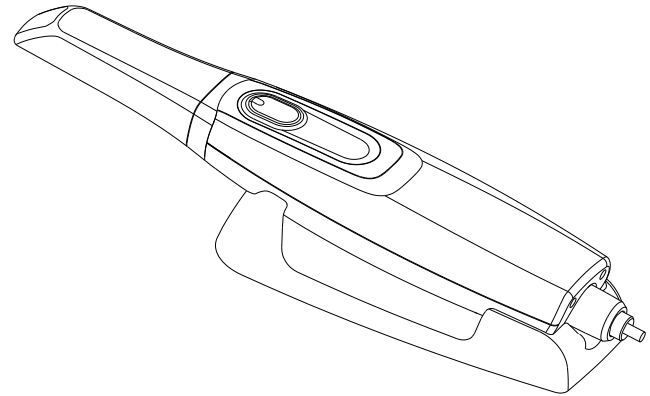


Intraoral Scanner

Operation Manual

Technical Manual



Product Model:

Product Name:

Serial Number:

Date of Manufacture:

A large dashed rectangular box, likely a placeholder for a QR code or a form for entering product information.

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Chapter 1 Introduction

Thank you for choosing our product. We hope that it is entirely to your satisfaction.
Please read the manual carefully before installation and use it to reduce the risk of harm to you or your patients due to improper operation.

◆ Components

Consists of a scanner handpiece, scanner tip, and base, along with three-dimensional acquisition software.

◆ Intended Use

The 3D geometric data of the tooth in the patient's mouth is collected using an optical scanning method to provide a 3D digital model for CAD/CAM denture design and processing.

◆ Intended User

An educated and competent healthcare professional should operate the scanner to perform dental intraoral image acquisition.

The intraoral scanner features the following characteristics:

Excellent image quality based on advanced CMOS technology

More convenient three-dimensional acquisition process

Smaller, more comfortable, and durable scanner tip, detachable and suitable for high-temperature and immersion disinfection

Easy-to-use Type-C/USB 3.0 interface

◆ Power

DC 5V

◆ Product Life

12 years

◆ Contraindication

No

◆ Classification

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements and Tests

EN ISO 780 Packaging - Distribution packaging - graphical symbols for handling and storage of packages

Safety classification: type B medical device equipment.

Applied parts: scanner head.

Not belong to the category AP or APG device.

Operation mode: Continuous.

Degree of protection against harmful ingress of water: IPX0.

◆ Specification

According to the oral cavity digital printer area different classification

Model	Scope of Reconstruction	Pixel
SCAN33	14 x 14 x 15 mm	1024 X 768 pixels

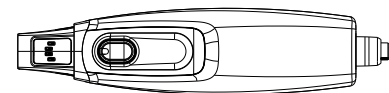
◆ Components of Scanner

No.	Components	Quantity
1	Scanner Handpiece	1
2	Scanner Tip	3
3	Scanner Tip (Mini)	1
3	Base	1
4	Data Cable (Type-C port)	1
5	Protective Tip	1
6	U Disk with Software	1
7	USB to Type-C Adapter	1
8	Operational Manual	1
9	Certificate of Conformity, Warranty Card	1
10	Packaging Box	1
11	Calibration Tip (Optional)	1

Please check the following table to see if the parts are complete before the installation of the Intraoral Scanner. If the individual content does not match and you cannot install the system, please contact the local distributor or agent for support.

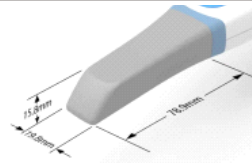
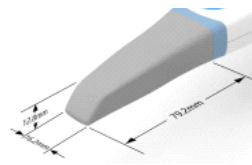
Scanner Handpiece:

The 3D information captured by the scanner is reconstructed from 2D images. The scanner consists mainly of optical and imaging systems, with protective glass on top of the handpiece.



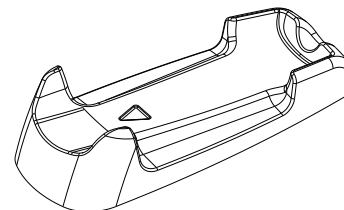
Scanner Tip:

The scanner tip, made of medical plastic and optical prism, is installed into the head of the scanner for scanning purposes. It comes in two sizes, as shown in the following pictures, and can be sterilized according to the prescribed method:

Size 1	78.9mm×19.8mm×15.8mm	
Size 2	79.2mm×16.2mm×12.8mm	

Base:

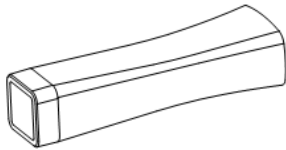
The scanner handpiece enters standby mode when it is placed on the base in scanning mode.



Protective Tip:

Protects the head of the oral digital impression device from dust and accidental damage to the head components.

Note: Remove the protective tip and replace it with the scanner tip when the device is in operation. When the scanner tip needs to be removed (e.g., for sterilization) or when the device is no longer in use, please replace it with the protective tip. (The protective tip can only be wiped with alcohol on the surface and cannot be subjected to high-temperature sterilization.)



Data Cable (Type-C Port) :

Used to transfer the output signal from the impression device host to the computer. Please make sure to use the accompanying data cable.

◆ 1.1. Icons

	Descrição
	Caution: please refer to the instructions in the user manual.
	Express important instructions. Failure or damage system or other property if not observed.
	Represents useful information and how to use our software.
	Represents warnings and safety instructions. Failure to comply may pose a serious threat of injury to both the patient and the operator
	Refer to instruction manual/booklet for safety instructions.
	Type B applied part
	Stand-by
	Serial Number
	Medical device
	Compliance to European Community Requirements
	Date of manufactureManufacturer
	Manufacture's name and address
	Unique Device Identifier
	Fragile Contents of the transport package are fragile therefore it shall be handled with care
	This way up
	Keep away from rain Transport package shall be kept away from rain
	Package symbol, stacking limit by number, it shows the maximum number of identical transport package which may be stacked on the bottom one, where “n” is the limiting number.
	Do not dispose this product into the ordinary municipal waste or garbage system

◆ Expected User Profile

Staffs who are engaged in the diagnosis and treatment of dental diseases in dental hospitals and clinics, and have been trained in the operation of this product.

Operators should be familiar with the use of personal computers and related programs to make it easy to use features on a personal computer.

Chapter 2 Safety

◆ 2.1 General Warning

Read the instructions to familiarize yourself with the device before putting it into service.

Read the warnings and the safety instructions carefully.

No modification of this equipment is allowed.

The equipment can only be sent back to our company for repair.

◆ 2.2 General Safety

The user is responsible for the obligations associated with the installation and operation of the equipment.

Only qualified technicians can use and maintain this equipment.

Turn off the machine and unplug the power cord before cleaning and disinfecting.

Use only original accessories and accessories supplied or recommended by the manufacturer.

Do not connect to devices that are not compatible with the system.

Chapter 3 Hardware Installation

◆ 3.1 What to Do Before Use

Remove the Intraoral Scanner from the original packaging and check that the device received matches your reservation. All accessories are intact and undamaged.

You need to install the driver in the PC which to identify the Intraoral Scanner.

◆ 3.2 Installation Notes

1. When installing, please handle with care and minimize the distortion and pull of the wires. Do not tread or roll the wires.

2. Place the base on a flat and stable surface to prevent falling.

3. Do not drop the handle and base on the ground in order to avoid irreparable damage.

4. To prevent the occurrence of disruptive images, refrain from allowing the system to approach strong magnetic fields and avoid sources of static emissions.

5. While the electromagnetic interference of this product is low, it does not guarantee that its operation won't affect surrounding equipment. If interference occurs, please keep the product away from the interfering device.

6. Power adapter plug is intended to be used as the isolation means from supply mains, do not position the Intraoral Scanner so that it is difficult to operate the disconnection device.

◆ 3.3 PC Specification

 We cannot guarantee the work of the Intraoral Scanner and the pirated Microsoft Windows. So please use the legitimate version of Microsoft Windows 10/11.

Basic & Recommended Computer Specification Microsoft Windows 10/11, 64bit or above			
CPU	Desktop: Intel i7-9700 quad-core or above; (Recommended: Intel Core i7-11700) Laptop: Intel i7-9700H quad-core or above; (Recommended: Intel Core i7-11700H)	System	Windows 10/11 Pro/Corporate Edition
Graphics Card	NVIDIA GeForce 1660GTX or above, more than 6G (Recommended: NVIDIA GeForce 3060 or above graphics card with 6G or more memory) Note: AMD graphics cards are not supported	Monitor Resolution	1920 * 1080
Memory	More than 16 GB	Port	USB 3.0 or above
Hard Disk	More than 256GB SSD or 128GB+1TB mechanical hard disk	Power Consumption	25 V/A

 Additional equipment connected to the Intraoral Scanner must comply with the current IEC or ISO standards (e.g. IEC60950-1 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see clause 16 of IEC60601-1). Anybody connecting additional equipment to the Intraoral Scanner configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements.

When more than one device is connected to use, the accumulation of leakage current may cause the danger of security. If in doubt, consult your local representative or the technical service department.

 Before installing the software and the server, you must close the Windows system's firewall and the anti-virus software with firewall function to make sure the software can be installed and run properly.

 If you need to install additional software on your computer, only install internationally recognized programs.

◆ 3.4 Installation Steps

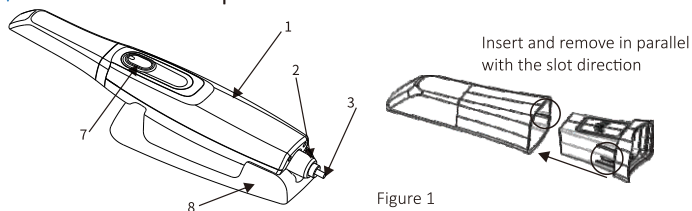


Figure 1

1. Connect data cable 3 to the oral digital impression device host 1 and tighten the cable lock shell 2.

2. Connect the other end of data cable 3 to the computer's Type-C port.

Note: If the computer does not have a Type-C port, use the supplied adapter to connect to the computer's USB port. Do not use other adapters instead.

Note: This product can be directly connected to a computer without the need for an external power adapter. You only need an oral digital impression device and a data cable (Type-C port). However, compatibility depends on the available Type-C and USB types on the computer. First, check the symbols on the Type-C and USB ports on the computer. Type-C and USB ports available for plug-and-scan must be powered ports.

Requirements for computer ports are as follows:

a. It is not recommended to connect to Type-C (USB) 1.0, 2.0 ports, as this may cause the product to not work or connect unstably (specific icons as shown below).



Connect to Type-C (USB) 3.0, 3.1, 3.2, 4, Thunderbolt ports (specific icons as shown below).



b. When using a desktop computer, it is recommended to plug the scanner cable into the rear ports of the host instead of the front ports. This can avoid potential issues with insufficient power supply from the front ports leading to the device not working or connecting unstably.

Note: Depending on the manufacturer of the computer, there may be cases where the ports do not meet the requirements, causing this device to not function properly. If this happens, try changing the port or connect it to an externally powered USB hub.

3. Pick up the oral digital impression device host 1. When the indicator light 4 is green, it indicates that scanning can begin.

Note: Before use, install the scanner tip and insert and remove it parallel to the slot direction as shown in the diagram. Do not tilt. The method of inserting and removing the

protective tip is the same.

Indicator light:

Green light: Self-check/scanning in progress

Blue light: Standby

Flashing blue light: Connection unsuccessful (refer to the troubleshooting section for details)

4. After scanning is complete, place the oral digital impression device host 1 into the base 5.

The host enters standby mode and stops scanning.

5. Disconnect data cable 3 from the computer and turn off the entire device.

Chapter 4 Software Installation

◆ Install Software

Step 1:

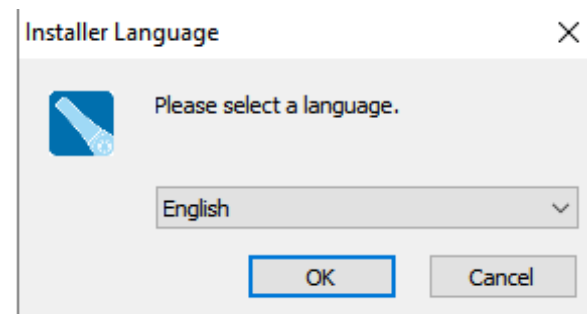
Insert U disc to the computer, manually operate installation

The file currently contained on the disc



Step 2:

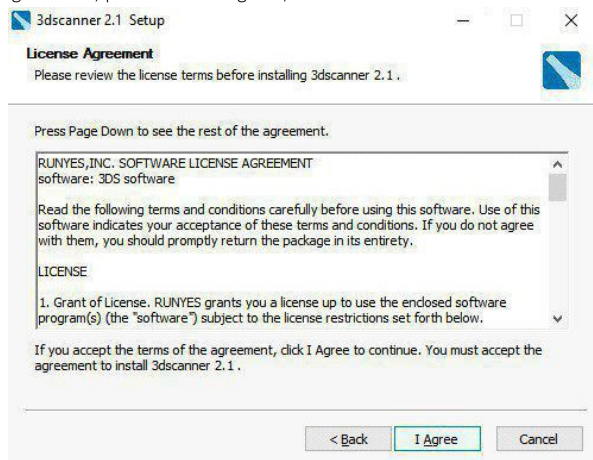
please select a language



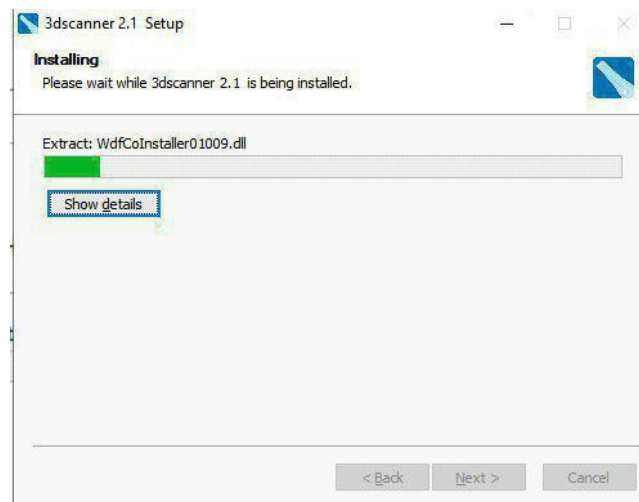
Step 3:
Enter the installation wizard, click "Next".



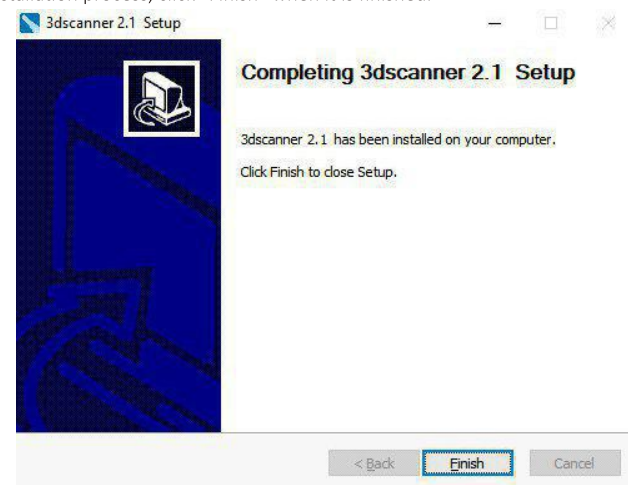
Step 4:
Read carefully the license terms before installation, if you agree with the agreement, please click "I Agree", if not click "Cancel"



Step 5:
When "Dental Viewer"'s installshield pops up, click "Next"



Step 6:
Installation process, click "Finish" when it is finished.



The image acquisition process of intraoral scanner



Warning: Surface High Temperature

The Intraoral Scanner base has a preheating device for preheating the scanner tip to reduce fogging of the scanner tip lens during scanning. The temperature of the heating sheet can reach about 60 degrees. Please do not touch it with your hands to prevent burns.



Description: Image Brightness.

The image is automatically adjusted to the image brightness, always with the best brightness. The ambient lighting should be as dark as possible. Avoid any external light source entering. Turn off the oral lights.



Important: Do Not Use Hemostatic Cotton in Impression Meter.

Do not use hemostatic cotton or other objects that may affect the image in the scanning area, otherwise it will result in an error.

Ready to Start Scanning:

- Make sure all the connections be ready;
- Create the patient archive, enter the scanning interface, and select the dental arch to be scanned;
- Take the scanner handpiece the base, press the button, when the light becomes green means it is ready to start scanning.

Scanner Tip:



Important: The camera should be cleaned and disinfected after each use. Please follow the instructions of cleaning and disinfection to avoid cross-infection between patients.

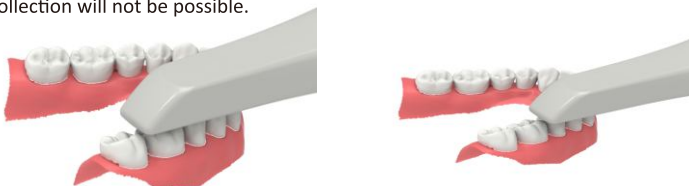
There are four consecutive steps of images capturing:

- Occlusal Surface
- Buccal Side
- Lingual Side
- Mesial Surface

Occlusal Surface Scanning



Important: It is necessary to measure the distance between the radiating window of the impression meter and the surface to be measured. This distance should be maintained between 0 and 15mm, with the optimal distance being 5mm. Ensure that the camera is not positioned directly on the teeth or gums. If the distance is too long, data collection will not be possible.

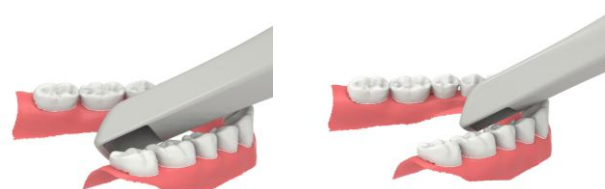


Buccal Side Scanning



The scanning tip is located near the adjacent tooth of the prepared tooth.

- Turn the scanning tip to the buccal side from 45 degrees to 90 degrees.(max degree)
- Move the scanning tip over the surface of the tooth, through the entire buccal side.



Lingual Side Scanning

The scanning tip is located near the adjacent tooth of the prepared tooth.

- Rotate the scanner tip from 90 degrees on the buccal to the side of the lingual 45 degrees to the maximum 90 degrees.
- Move the scanning tip over the surface of the teeth, through the entire lingual side.

Mesial Side Scanning

Move the scanner tip towards the direction of Mesial side by tilting the scanner tip, in order to take the good image of adjacent teeth.

Reminder:

Please remove the soft tissue.

Remove the tooth saliva from the activity, and make the tooth silver distance between 1 and 2mm.

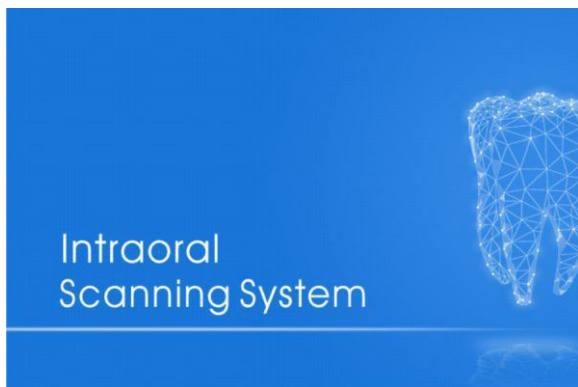
The next button is completed, and the calculation stage is optimized. After the optimization calculation, the final generated 3d image will be displayed. Please check the correct output. If part of the image is missing, click "scan" and continue scanning.

◆ Running Scanner

Intraoral scanning software operation process:

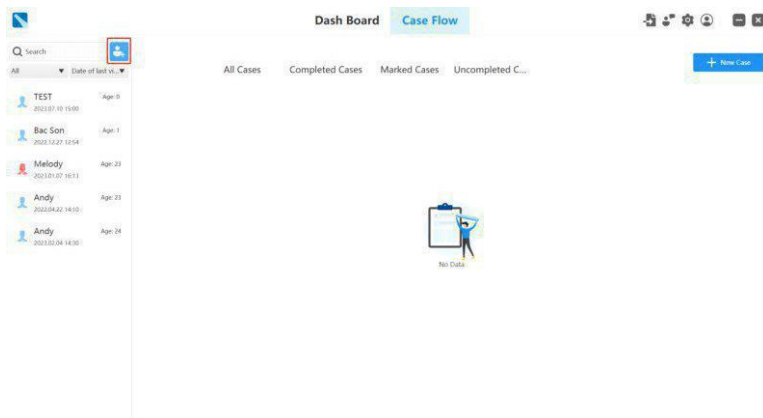
Step 1

Open the shortcut of on the desktop to enter the software interface



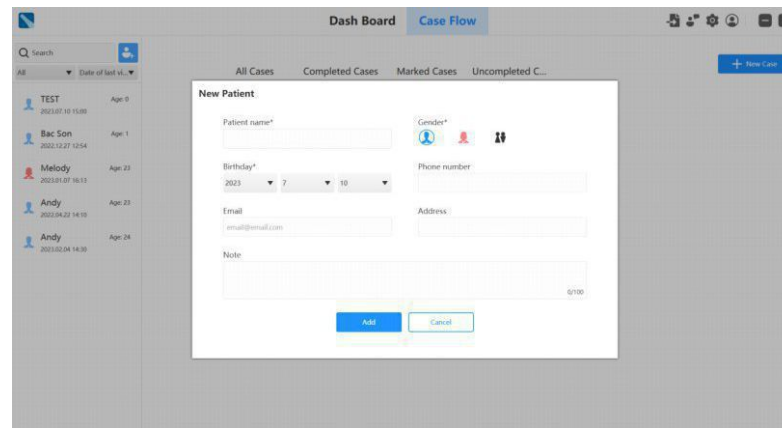
Step 2

Click the "New Patient" icon in the red box



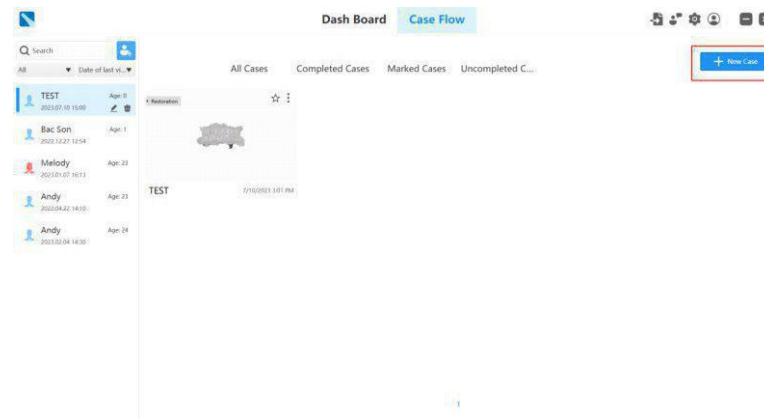
Step 3

Enter the "patient name" and other relevant information, click "Add"



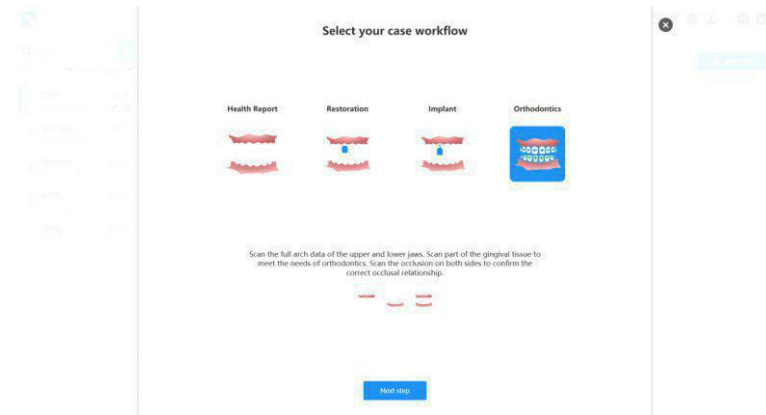
Step 4

Click the "New Case" icon in the red box



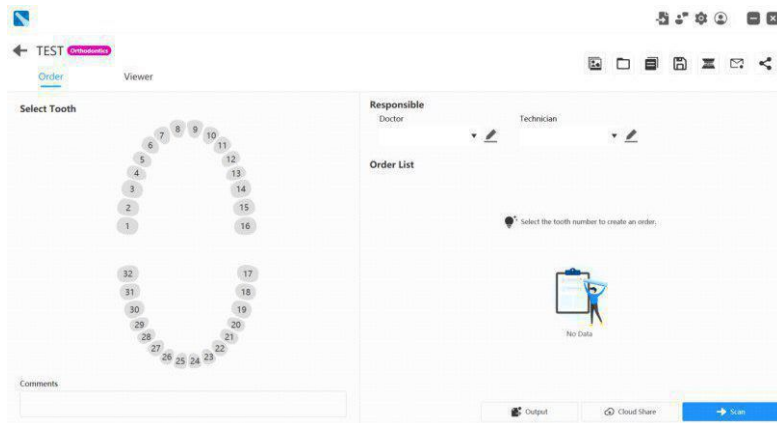
Step 5

Click the "Next step"



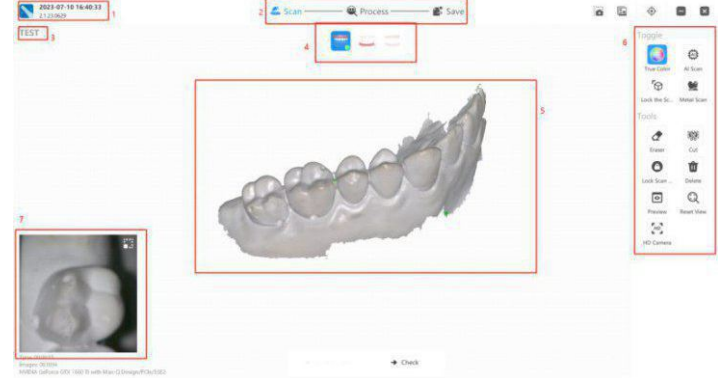
Step 6

Click "Scan" in the lower right corner



Step 7

The main function of the main interface



1. System time and software version information
2. Process steps
3. Patient name
4. Scan object switching
5. 3D scan results show
6. Function key area: including "True Color", "Lock the Scanning View", "AI Scan", "Metal Scan", "Eraser", "Cut", "Lock Scan Area", "Delete", "Preview", "Reset View", "HD Camera", "Swap Jaws"
7. Scanner Status/Video

Step 8:

Select the scan object to "upper jaw" and scan to obtain a 3D model of the patient's upper jaw.



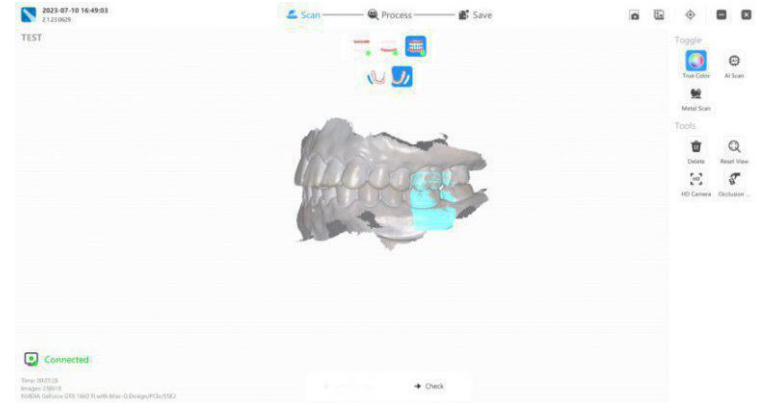
Step 9:

Switch the scan object to "lower jaw" and scan to obtain a 3D model of the patient's lower jaw.



Step 10:

Switch the scan object to "occlusion", and ask the patient to bite up and down in a normal state. Scan the teeth and move the scanner tip up and down to scan part of the upper and lower teeth, and then the software will automatically occlude the upper and lower teeth.



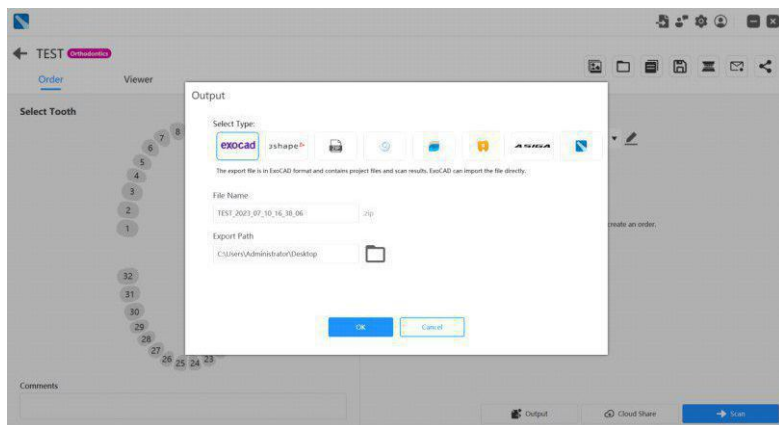
Step 11:

Click "Check" to check whether there is any problem in the final 3D model and whether it meets the design requirements, etc.



Step 12:

Click "Output", select the required file type, then click "OK", you can find the file under the corresponding path.



Chapter 5 Maintenance

When used by patients, do not maintain or disinfect the scanner inside the mouth. There are no user repairable or replaceable components in the intraoral scanner. You must return to the original factory to open and repair the scanner inside the entrance.

◆ Visual Inspection

Check the surface of the machine (including power adapter).
If there is any stain or smudge, it should be cleaned in time.
If there is damaged/distorted enclosure, do not use.
Visually check the connectivity of all cables. Reconnect the cable that has been loosened or disconnected.
Please clean the plug of power adapter at least once a year. Too much dust on plug may cause the fire.

◆ Cleaning, Sterilization and Disinfection

1. Scanner Tip

a) Cleaning: Separate the scanner head and scanner handpiece. First, clean the scanner handpiece and lens with clean water (running water) and alcohol (75% concentration medical alcohol). Pay attention to removing dirt, oil stains, spots and other marks on the lens, and dry the scanner tip and lens with a soft cloth (non-woven fabric) and dust-free cotton swab, and do a good job of drying.

b) Sterilization and Disinfection:

A. Pressure Steam sterilization

Place the scanner tip into a specialized sterilization bag and seal it. Use a pressure steam sterilizer to sterilize it in the following two ways:

Select a sterilization time of over 3.5 minutes at 134°C;

After sterilization, it is necessary to store according to the sensing requirements. Before use, it is necessary to check whether the scanning head and scanning head lenses are intact. If it needs to be used immediately after sterilization, it should be taken out and left to stand for more than 30 minutes to cool to room temperature before installation and operation.

Attention: The scanner tip is a consumable item that can be sterilized 100 times in a high-temperature sterilization environment. When the scanner tip shell ruptures, the contact spring falls off, the scanner tip lens cracks, severe spots, and dirt cannot be cleaned, it needs to be disposed of.

B. Soaking Disinfection

Soak the scanner tip completely in CIDEXOPA solution (0.55% Phthalaldehyde) for more than 5 minutes. After completion, dry the scanning head and scanner tip lenses with a soft cloth (non-woven fabric) and a dust-free cotton swab, and use immediately to prevent secondary contamination of the scanner tip. Before use, check whether the scanner tip and scanner tip lenses are intact.



Attention: When soaking and disinfecting, the scanner tip needs to be vertically placed in the solution, and it must be dried when taken out.



Attention: The scanner tip needs to be sterilized and disinfected for the first use, and it also needs to be sterilized and disinfected for different patients in the future.

2. Scanner Handpiece

2.1 Cleaning and Disinfection of Scanner Handpiece

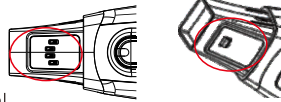
Wipe and clean the product shell with a small amount of soapy water dipped in a regular cotton cloth. After cleaning, soap and water should be removed, leaving no residue on the surface, and wiped dry with a clean, dry cotton cloth.

Dip a small amount of 75% medical alcohol onto a soft cloth (non-woven fabric) to wipe the surface of the scanner handpiece. After a certain period of time, air dry it naturally or use another clean and dry soft cloth (non-woven fabric) to dry the residual alcohol.

The above suggestion is to clean and disinfect once a day.



Attention: Do not use cleaning materials that can damage the surface of the casing for wiping. Do not allow liquid to enter the interior of the equipment, causing mechanical damage. Pay special attention to the areas shown in the below picture.

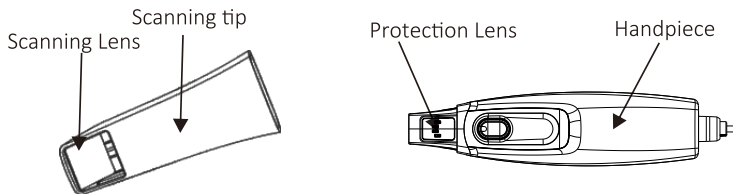


2.2 Cleaning and Disinfection of the Front Protection Window of the Scanner Host

Gently wipe the surface of the protective window with a small amount of 75% medical alcohol dipped in a dust-free cotton swab to remove dirt, oil stains, spots, and other marks on the lens. Then use another clean and dry dust-free cotton swab to dry the surface of the protective window.



Attention: The protective window is a precision optical component that must be carefully cleaned and disinfected, and be careful not to allow excess liquid to flow into other locations when wiping.



Note1: The scanner tip has a reflector made of glass material. Pay attention to the scanning angle and force to prevent damage caused by glass breakage;



Note2: The scanner tip should not make contact with the protection window while being inserted into the scanner handpiece. Ensure that the insertion is straight without tilting. Gently guide the scanner tip until the slot is securely in place.



Note3: If the detection is different from normal, please go to the local distributor to further explain the product problem.



Note that the scanner tip is placed vertically into the disinfectant solvent, and do not allow the solvent to enter the scanner tip.

Necessary maintenance and precautions:

Operation	Cycle	Responsible person
Visual Inspection	Daily	Operators
Visual Inspection	A year	Operators
Maintain Scanner	Daily	Operators
Cleaning and Disinfection	Daily	Operators
Cleaning and Disinfection	After each use	Operators

Chapter 6 Common Problems and Solutions

*Device cannot power on despite power supply being connected:

- 1.Ensure that the computer is powered on.
- 2.Check if the devices are correctly connected as required.
- 3.Verify if the computer configuration meets the software's operational requirements.

*Device power indicator is on, but the computer cannot recognize the device (main indicator light flashing blue):

- 1.Check if the connections between the devices are secure.
- 2.Ensure that the Type-C and USB interfaces meet the requirements (refer to hardware installation instructions).
- 3.Avoid using USB to Type-C adapters other than those provided.

*The computer has recognized the device, but the application software displays no image:

- 1.The device has a sleep function. Check if the device is in sleep mode and wake it up by shaking.
- 2.Restart the application software and reconnect it to the device.
- 3.Reinsert the connections between the devices.

*Device experiences interruptions during use and cannot resume operation:

- 1.The device has a thermal protection function. After the protection function activates, please turn off the device. Wait 5 to 10 minutes depending on the environmental temperature before restarting.
- 2.Check if the Type-C and USB interfaces meet the requirements (refer to hardware installation instructions).

*Lens fogs up during use:

- 1.Defog the lens before use or heat the lens by placing it on a platform and then continue using it.
- 2.This electronic device has an IPX0 waterproof rating. Do not directly spray or immerse

in any liquids.

*Device experiences image stuttering, slowing down, or disconnection during use:

- 1.Check if the connections between the devices are secure.
- 2.Determine if the device has been used for an extended period resulting in high internal temperatures.
- 3.If these issues persist frequently, it may be due to internal data cable damage. Please contact customer service for assistance.

*Device produces significant image noise or color distortion during use:

- 1.Handle the device with care as it is a precision instrument. Heavy impacts may cause unpredictable internal hardware issues.
 - 2.Internal software calibration issues with this device.
- If the above issues persist despite following the instructions, please contact customer service for further assistance.

Chapter 7 Product Application Precautions

1.The product is precision optical instrument equipment, need careful operation and maintenance; Accidental collision, falling may cause optical component damage and deviation, and ultimately affect the scan result. If any of the above occurs, please contact the customer service staff in time.

2.Use and maintenance of the scanner, it is necessary to pay attention to protect the leakage optical components, such as scanning prism, scanner ontology protection glass, etc., to avoid erosion corrosive liquid or sharp objects scratching the lens surface, if you have the above case, please contact customer service.

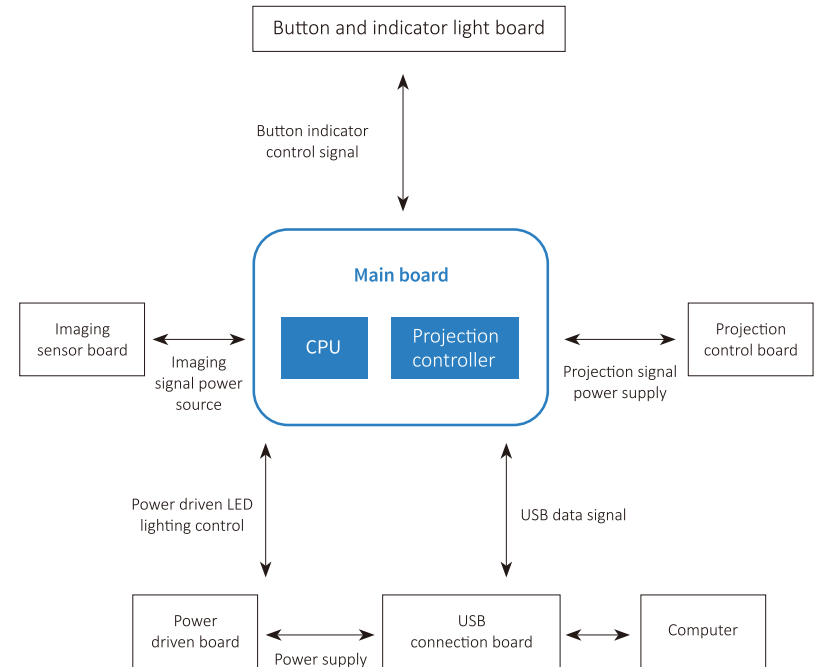
3.When sterilization/sterilization the scanner tip, it is necessary to avoid the infiltration of liquid from the back end of the scanner head. If there is infiltration and contamination of the inner surface of the lens, it is necessary to clean and blow dry with pure (99.9%) alcohol.

4.The scanner should be used with attention to the joint; applying excessive force may render the connection unstable or result in disconnection. Additionally, please take care not to bend the wire to prevent damage.

5.When the scanner is not in use, please remove the scanner head, cover it with the protective sleeve, and turn off the base power. If the scanner will not be used for an extended period, disconnect the power adapter.

6.The scanner emits visible light when scanning. Please do not illuminate the eyes with scanning light, otherwise it will cause short-term discomfort.

Chapter 8 Circuit Connection Chart



Chapter 9 Technical Specification

9.1 Scanner Technical Specification

Scope of reconstruction: 14 × 14 × 15 mm

Camera resolution: 1.3MP CMOS

Pixel size: 4.8 μ m

Oral scanning light source: LED (without laser radiation)

Export development data format: OBJ/STL/PLY

Light radiant intensity: ≤ 100Mw/cm²

Size of scanner handpiece: 200 × 58 × 36mm

Scanner weight: 210g

Data cable of Scanner : 2.0m

Connection method: Type-C, USB 3.0

9.2 Equipment Operating Environment:

a) Environment temperature: 10 °C- 40°C

b) Relative humidity: ≤ 85%;

c) Atmospheric pressure: 86KPa~106KPa;

9.3 Equipment Storage, Transportation Environment:

a) Environment temperature: -20°C to 55°C

b) Relative humidity: ≤ 85%

c) Atmospheric pressure: 70KPa~106KPa;

9.4 Power

Input voltage: 5V

Operating current: 750mA

Chapter 10 Waste Disposal

In order to reduce the burden on the environment, recyclable parts should be sent to the recycling center after removing the hazardous materials. Disposing of obsolete products is the responsibility of the recycler.

All components and elements containing hazardous substances shall be disposed of in accordance with law and environmental provisions. When dealing with waste products, they must be protected from harm.

△Recyclable

▲Unrecyclable

Part	Main material	Recyclable material	Disposal center	Separation of harmful substances
Cover	ABS	△		
Metal	Aluminum	△		△
Circuit board		▲		
Wire	Copper	△		
Packing	Paper	△		
Other			△	

Chapter 11 Electromagnetic Compatibility

For this device, special precautions regarding Electromagnetic Compatibility (EMC) must be taken, and installation and use must be in accordance with the electromagnetic compatibility information specified in this manual. Portable and mobile radio frequency (RF) communication devices may affect this device.

Except when used as internal components of spare parts for sale, the cable (transducer) should only be used with the specified attachment. Utilizing other devices or placing them in close proximity may result in increased interference with equipment/system launches or reduced immunity. The equipment or system should not be used in conjunction with other devices or placed in close proximity. If proximity or stacking is unavoidable, validation should be conducted under normal operating conditions.

The following cables must be used to meet the requirements of electromagnetic emission and anti-interference:

Number	Name	Cable Length (m)	Whether to Block	Note
1	Type-C Cable	2.0 m	Yes	EUT

The fundamental nature can be used for image acquisition.

Name	Description
Image acquisition	When you turn on the power, start the software and move the handle, the image display box on the software can display the image normally.

Guidance and manufacture's declaration - electromagnetic emissions		
The Intraoral Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Intraoral Scanner should assure that it is used in such an electromagnetic environment:		
Emission Test	Compliance	Electromagnetic environment- guide
RF emission CISPR 11	Group 1	The Intraoral Scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Intraoral Scanner is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emission IEC 61000-3-3	Applied	

Guidance & Manufacturer's Declaration-Electromagnetic Immunity			
The Intraoral Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Intraoral Scanner should assure that it is used in such an electromagnetic environment:			
Immunity Test	IEC60601 Test Level	Compliance level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential mode ±2 kV common mode	±1 kV Differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (95% dip in UT) for 5 sec	<5 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Intraoral Scanner requires continued operation during power mains interruption, it is recommended that the Intraoral Scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the a.c. mains voltage prior to application of the test level.

Guidance & Manufacturer's Declaration-Electromagnetic Immunity			
The Intraoral Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of the Intraoral Scanner should assure that it is used in such an electromagnetic environment:			
Immunity test	IEC 60601 The test level	Compliance level	Electromagnetic environment - guide
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Intraoral Scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 23\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Intraoral Scanner is used exceeds the applicable RF compliance level above, the Intraoral Scanner should be observed to verify normal operation. If abnormal performance observed, additional measures may be necessary, such as reorienting or relocating the Intraoral Scanner.

Recommended separation distances between portable and mobile RF communications equipment and the Intraoral Scanner

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

Rated maximum output power of transmitter /W	Separation distance according to frequency of transmitter /m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d meters(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

