

Runyes® 3DS

Intraoral Scanner

Operation Manual
Technical Manual



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Product Model:

Product Name:

Serial Number:

Date of Manufacture:

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Introduction

Thank you for your trust in us. We hope this product will satisfy you completely. It is recommended that you read this manual before installation and use, which is beneficial to eliminate and reduce the risk of harm to you and your patients due to improper operation.

◆ Components

Scanner handpiece, scanner tip, base, power adapter, USB control box, data cable, and U disk with software.

◆ Intended Use

Using optical scanning method to collect the 3D geometric data of the tooth in the patient's mouth and provide the 3D digital model for CAD/CAM denture design and processing.

◆ Intended User

The scanner should be operated by a healthcare professional educated and competent to perform dental intraoral image acquisition.

◆ Power

Power Adaptor
 Input: 100-240V~ |50-60Hz| 0.5A
 Output: 12V $\overline{\text{---}}$ 1.5A
 Intraoral scanner: 12V $\overline{\text{---}}$ 1.5A

◆ 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

Name	Scope of Reconstruction	Pixel
Oral Digital Impression Scanner	14 x 14 x 15 mm	1024 X 768 pixels

◆ Components Of Scanner

No.	Components	Quantity	
1	Scanner Handpiece	1	Without Scanner Tip
2	Scanner Tip	3	Size 1: 78.9mm×19.8mm×15.8mm
		1	Size 2: 79.2mm×16.2mm×12.8mm
3	Base	1	
4	Data Cable	1	
5	USB Control Box	1	USB 2.0/3.0
6	Power Adapter	1	INPUT:100-240V~ 50/60Hz 500mA
			OUTPUT: DC 12V , 1.5A
7	U disk with Software	1	
8	Operational Manual	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 scanner's 3D information is reconstructed from 2D images taken by the scanner. The scanner is mainly composed of optical and imaging systems, and the top of the handpiece has protective glass protection.



Scanner Tip:

Made of medical plastic and optical prism, it is installed into the head of the scanner for scanning. The scanner tip can be sterilized in accordance with the prescribed method. The scanner tip comes in two sizes, as shown in the following pictures:

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

Base:

Scanner handpiece base bracket, when the handpiece is placed on the base in the scanning state, it will enter the standby mode.



USB Control Box with Data Cable:

It is used to transmit the output signal from the scanner host to the computer, and connect the scanner host and the computer. It also connects to the adaptor and provide power for the scanner.



Data cable:

Used to transmit the output signal from the scanner handpiece to the USB control box.



U disk

It is used to transmit output signals from the base to the computer, connecting the base and the computer.

Power Adapter:

Medical certification power adapter.
INPUT: 100-240V~ 50/60Hz 500mA
OUTPUT: 12V= 1.5A



The Intraoral Scanner is integrated with the Power Adapter and cannot be replaced at will.

◆ 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.

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.

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 3.0or 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

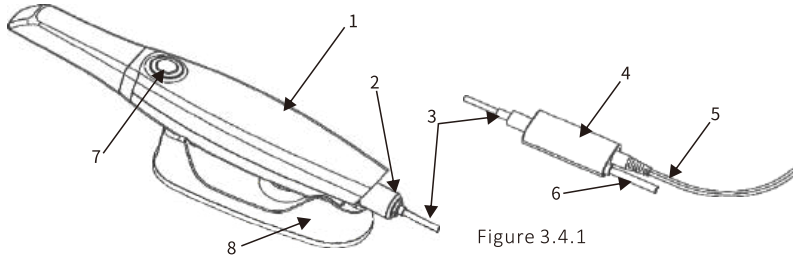


Figure 3.4.1

1. View Figure 3.4.1, connect the data cable 3 to the handpiece 1 of the oral digital impression machine, and tighten the cable lock shell 2.

Pay attention to insert the data cable 3 into the rear port of the host computer 1 first, and then tighten the cable lock shell 2, pay attention to the direction of the buckle in Figure 3.4.2.

2. The other end of the data cable 3 is connected to the USB control box 4.

3. Connect the USB cable interface 6 on the USB control box 4 to the computer USB port.

4. The adapter is connected to the power supply, and the adapter cable 5 is connected to the USB control box 4. The indicator light of the USB control box 4 is on and the whole machine is powered on.

5. Pick up the main unit 1 of the oral digital impression machine, press the button 7, the button indicator light is on, indicating that it can be scanned.

Pay attention to install the scanner tip before use, and insert and unplug it in parallel with the direction of the card slot as shown in Figure 3.4.3, do not tilt it, and the protection head is inserted and unplugged in the same way.

Button indicator:

Green light: self-test/scanning

Blue-ray: standby

Blue light: flashing USB connection failed

USB connection failed

6. When the scanning is over, put the main unit 1 of the oral digital impression machine into the base 8, and the main unit will enter the standby mode and stop the scanning process.

7. cut off the connection between the adapter and the power supply or disconnect the connection between the adapter line 5 and the USB control box 4, and the whole machine is powered off.

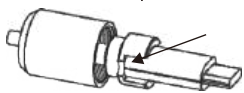


Figure 3.4.2

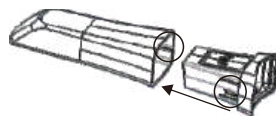


Figure 3.4.3

◆ Cable Connection

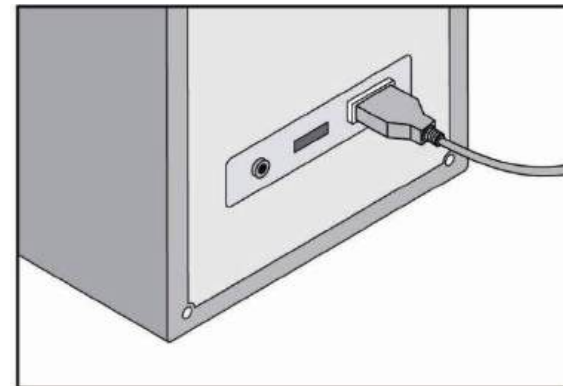
1. Connect the handpiece to connector;



2. Connect the data cable to the USB control box



3. Plug USB control box to PC's USB port



4.Connect the power adapter to USB control box.




Software Installation

◆ Install Software

Step 1:

Insert U disc to the computer, manually operate installation

The file currently contained on the disc

 setup_x64_2.1.23.0328_runyes_plus_globa...

Step 2:

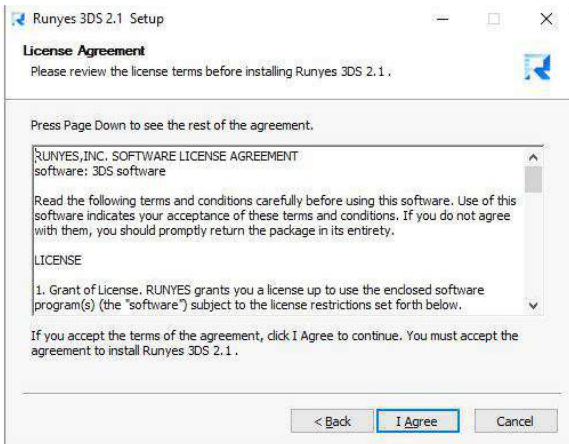
please select a language



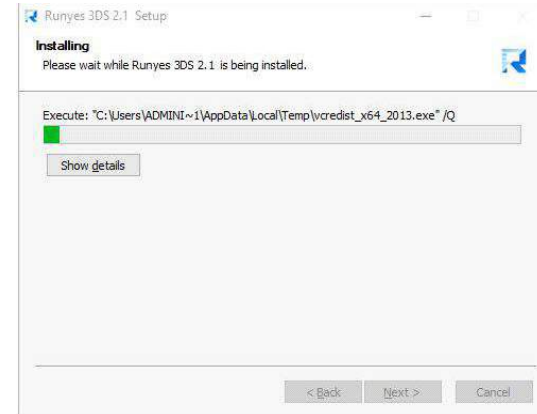
Step 3:
Enter the installation wizard, click "Next".



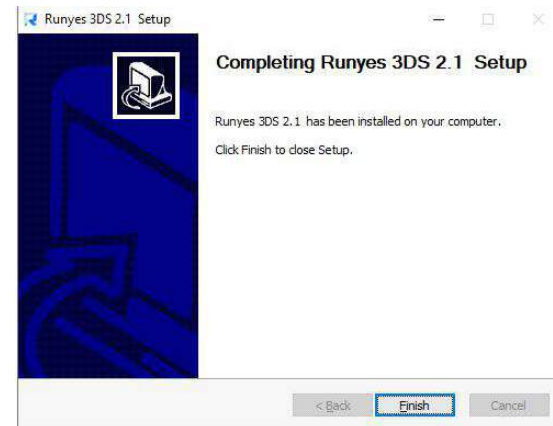
Step 4:
Read carefully the license terms before installation, if you agree with the agreement, please click "I Agree", if not click "Cancel"




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:

- a)Make sure all the connections be ready;
- b)Create the patient archive, enter the scanning interface, and select the dental arch to be scanned;
- c)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.

- 1.Turn the scanning tip to the buccal side from 45 degrees to 90 degrees.(max degree)
- 2.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.

- 3.Rotate the scanner tip from 90 degrees on the buccal to the side of the lingual 45 degrees to the maximum 90 degrees.
- 4.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 Runyes 3DS Scanner

Intraoral scanning software operation process:

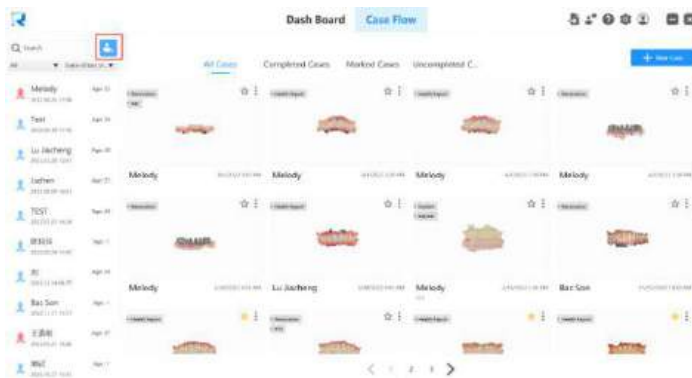
Step 1

Open the shortcut of "Runyes 3DS" on the desktop to enter the software interface



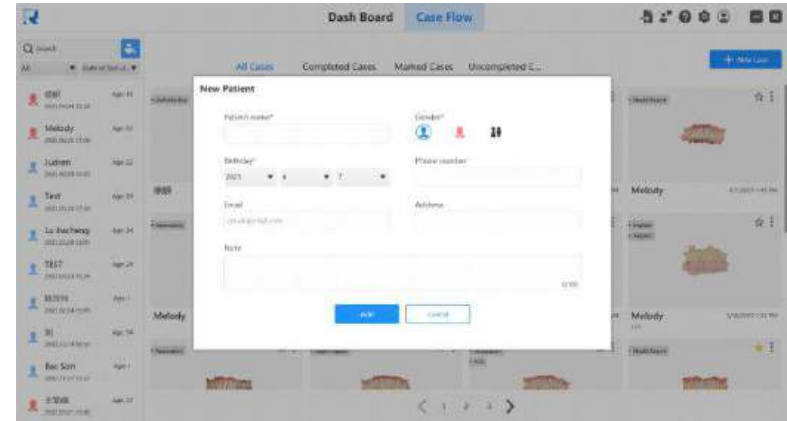
Step 2

Click the "New Patient" icon in the red box



Step 3

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



Step 4

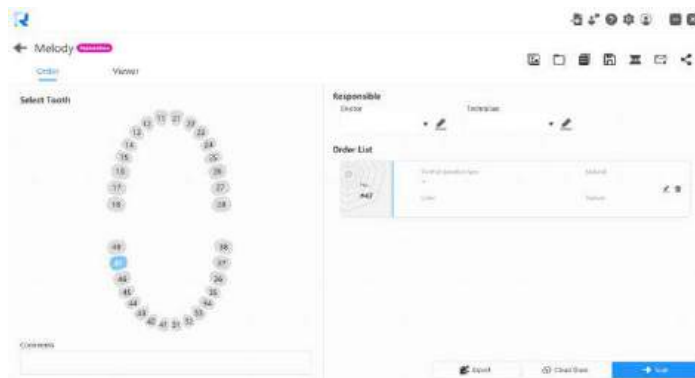
Click the "New Case" icon in the red box



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.



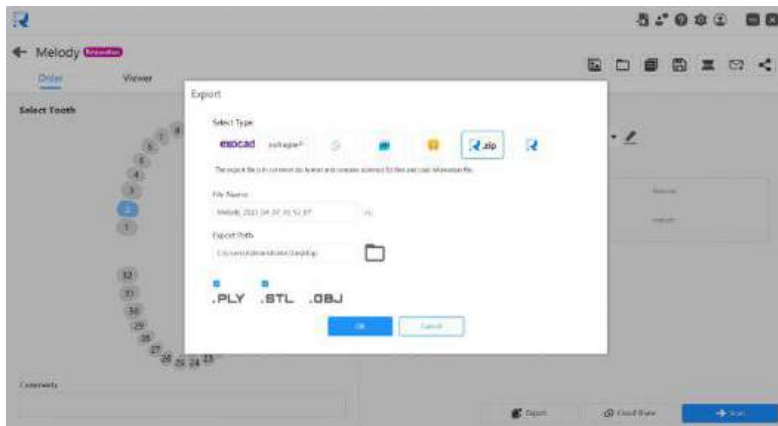
Step 11:

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.



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 :

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

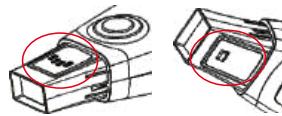
2.1 Cleaning and Disinfection of Scanner Handpiece

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.

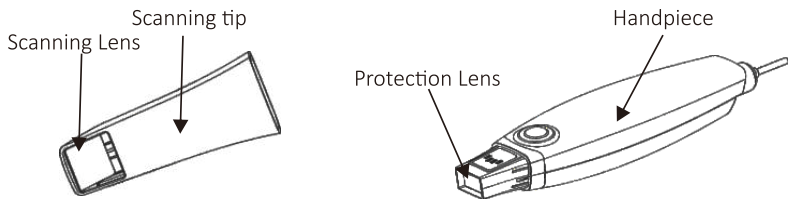
CAUTION Attention: Do not use cleaning materials that can damage the surface of the casing for wiping. Do not allow liquid to enter the interior of the equipment, causing mechanical damage. Pay special attention to the areas shown in the below picture.



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.

CAUTION 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:** 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

Common Problems And Solutions

1. After Pressing the Power Button, the Device Cannot be Turned On.
 1. Check whether the adapter is in good contact and the power indicator is normal.
 2. The equipment power indicator light, the computer cannot identify the equipment.
 3. Check whether USB and the platform are plugged in properly.
 4. Check whether the platform and computer USB plug is good.

2. The Computer Has Identified the Device, but the Application Has No Image.
 1. The device has a sleep function. Check whether the device is in sleep state and pick up the device to wake it up.
 2. Restart the application and reconnect with the device.
 3. Turn off the device power and restart the device.

3. During the Use of the Device, the Scan is Interrupted and Does Not Work.
 1. The device has the function of thermal protection, and after the protection function, please turn off the device. After 5-10 minutes, the ambient temperature should be re-opened. During the use of the equipment, the camera fog. The device is equipped with a thermal protection function. After the protection activates, please turn off the device. Wait for 5-10 minutes before restarting in order to allow the ambient temperature to stabilize. In some instances, fogging may occur on the camera during equipment use.
 2. Use after removing the fog, or put in the base to heat the lens and continue to use.
 3. This electronic equipment waterproof grade is IPX0, do not spray directly, immerse in various liquids.

4. During the Use of the Device, the USB Image is Slowed Down or Disconnected.
 1. Check the USB cable connection see if it is good.
 2. Check Whether the equipment is used for a long time leads to higher internal temperature.
 3. If the above issue occurs frequently, it may be that the USB internal data cable is broken. Please contact the local after-sales service staff.

5. During the Use of the Equipment, the Image Noise is Large or the Image Color is Distorted.

1. This equipment belongs to the precision instrument, should be handled gently. Heavier shocks can cause unpredictable damage to internal hardware.
2. Internal software calibration of the equipment.
3. If the above issue occurs, please contact the local after-sales service staff.

6. During the Use of the Equipment, the Scanner Tip Lens Produces Fog, It Cannot be Scanned Normally.
Check if the heater chip on the base fails or is unheated.

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.

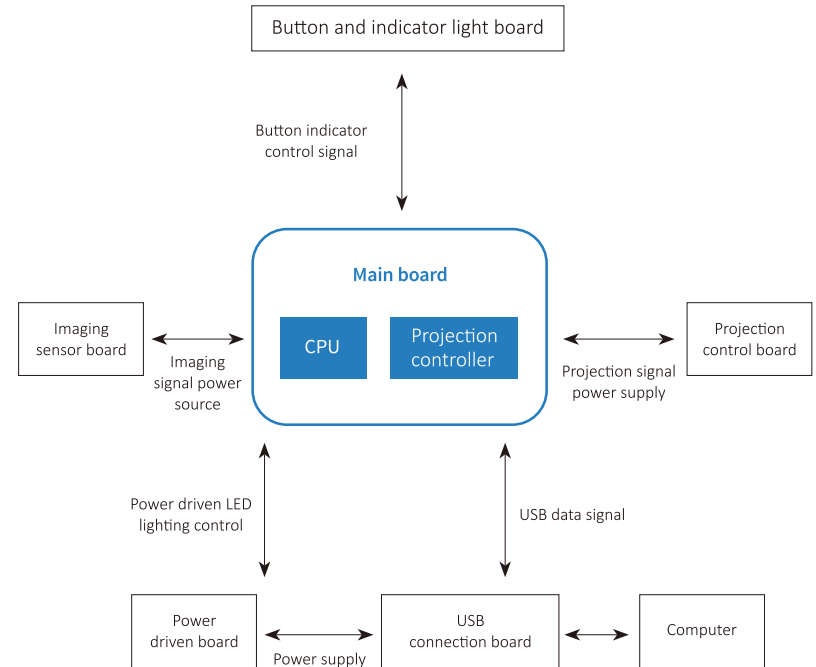
3. When sterilization/sterilization the scanner tip, it is necessary to avoid the infiltration of liquid from the back end of the scanner head. If there is infiltration and contamination of the inner surface of the lens, it is necessary to clean and blow dry with pure (99.9%) alcohol.

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.

◆ Circuit Connection Chart



◆ Technical Specification

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 (connecting USB control box to Scanner Handpiece): 2.0m

USB control box cable (USB control box to computer connection): 0.9m

USB Connection: USB 3.0 or above

2.Equipment Operating Environment :

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

b) Relative humidity: ≤ 85%;

c) Atmospheric pressure: 86KPa~106KPa;

3.Equipment Storage, Transportation Environment:

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

b) Relative humidity: 10%~93%;

c) Atmospheric pressure: 86KPa~106KPa;

4.Power

Power adaptor

Input power: 100-240V~ 50/60Hz 500mA

Out put power: 18VA

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			△	

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:

Name of cable	Length
Power Cable	1.5m
Data cable of Scanner (connecting USB control box to Scanner Handpiece)	2.0m
USB control box cable (connecting USB control box to computer connection)	0.9m

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.

Accessories

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 mans 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 $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 23\sqrt{P}$ 800 MHz to 2.5 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.