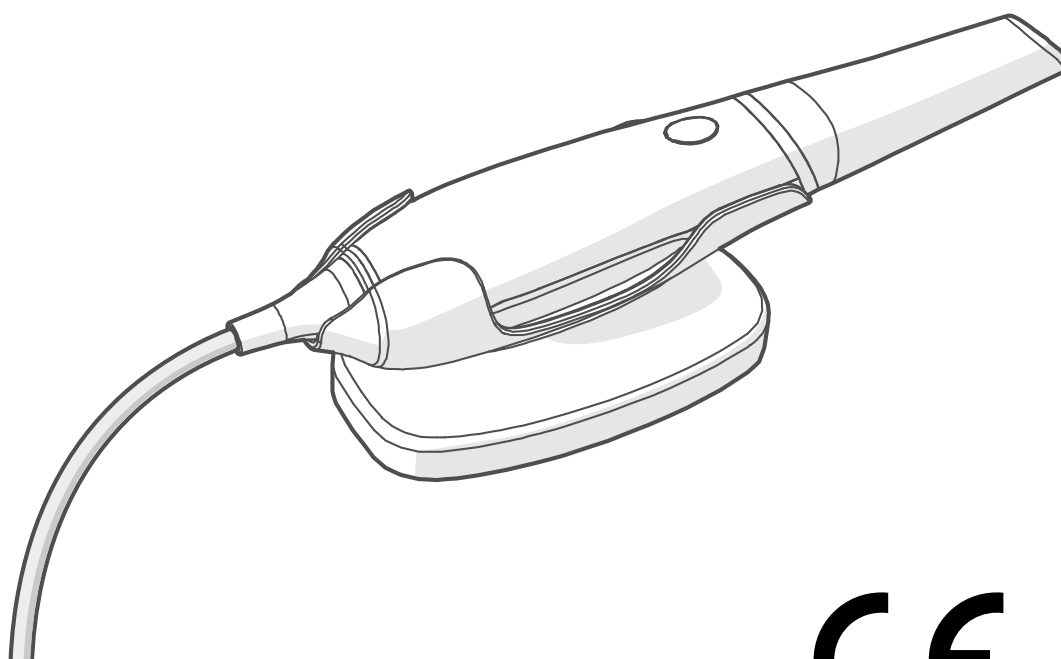


User Manual

RODIS-L

Intraoral Scanner



Version:A0

Doc No.: RS-YF-LBL-04-002

Date:15/6/2026

To Customers

Thank you for choosing the RODIS-L intraoral scanner from Foshan Roson Medical Instruments Co.,Ltd (hereinafter referred to as “Roson”) as your digital 3D imaging solution.

Carefully read this manual in its entirety before using the product and retain it for future reference.

Scope of this Manual

This user manual provides important procedures and information on how to operate the RODIS-L scanner and configure the iOralScan software correctly and safely. Before attempting to operate the product, Kindly take the time to read and observe all instructions and precautions in this manual to ensure safe operation and stable performance of the device.

Target Audience

This manual is intended for trained dental professionals and qualified personnel only.

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Disclaimer

- For the latest information, pay special attention to the revised information released by Roson or visit official Roson website (www.fsrosen.com).
- The illustrations in this manual are for explanatory and demonstration purposes only, the actual product shall prevail if there is any inconsistency.
- Roson shall not be held responsible for any consequences caused by violation of the storage, transportation, installation, and operation instructions specified in this document.
- In no event shall Roson be liable for any damage, loss, or injury arising from fire, earthquake, any action or accident by a third party, any intentional or negligent action by users, any trial usage, or other usages under abnormal conditions.
- Roson assumes no responsibility for any loss or injury resulting from unauthorized modifications to this product.
- In no event shall Roson be liable for malfunctions and damages resulting from use under environmental conditions outside the range specified for this device in this manual.
- Roson shall bear no legal responsibility for any damage or loss arising from the use of products or accessories not supplied or approved by Roson.
- The user and operator are responsible for maintaining the privacy of image data acquired from the product.
- The images acquired by the scanner must be interpreted by a qualified medical professional. The software in no way interprets these images or provides a medical diagnosis of the patient being examined.
- The users of this scanner and software are responsible for image quality and diagnosis.

Disposal



This symbol indicates that this product is not to be disposed of with your domestic or commercial waste. Disposal of this product in an unlawful manner may have a negative impact on health and the environment.

When disposing of the product, be sure to follow the procedure that conforms to the laws and regulations in your area. For country-specific information on disposal, contact your sales representative or local distributor.

Dispose of disposable tips and other medical waste following the normal dental office procedure for biomedical waste. Improper disposal of those can lead to the spread of illness and disease.

Symbols

The symbols used throughout this manual are classified as follows for better comprehension of their meanings:

 WARNING	Alerts a hazardous situation which, if not avoided, will or could result in severe personal injury, death, or substantial product damage.
 CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury, mechanical damage, performance degradation, or unexpected results.
 NOTE	Provides additional information to emphasize or supplement important points of the main text.

Abbreviations

Abbr.	Explanation	Abbr.	Explanation
AC	Alternating Current	OS	Operating System
CPU	Central Processing Unit	PC	Personal Computer
DC	Direct Current	RAM	Random Access Memory
EMC	Electro Magnetic Compatibility	SN	Serial Number
LED	Light Emitting Diode	UI	User Interface
ME	Medical Device		

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Chapter 1 Safety Information

1.1 Storage and Operation Environment

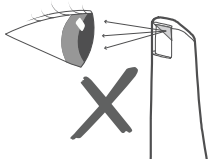
 WARNING	The scanner should be stored and operated in designated dental clinics, dental hospitals, or dental laboratories, and maintenance should be performed by qualified personnel under safe and operable conditions.
 WARNING	The product is not designed to be used in potentially explosive environments such as in close proximity to flammable liquids or gases or in oxygen-enriched atmospheres.
 WARNING	Do not install, use, or store the scanner in dusty and damp environments or areas of temperature extremes, or in direct sunlight.
 WARNING	After transporting or storing the system under extreme temperatures, it is recommended to wait 12 hours before putting the system into operation.
 CAUTION	Avoid holding the scanner in a way that blocks ventilation vents while scanning, as this may result in overheating.
 CAUTION	Do not allow any liquid to get inside this scanner. Water and moisture may cause short-circuit to the electronic components and lead to malfunctions.
 CAUTION	When the scanner is not scanned, it should be placed on the scanner holder to avoid falling damage caused by improper placement.
 CAUTION	When the scanner tip is detached from the scanner body, always place the protection cap on to safeguard the inner optical components.

1.2 Electrical Safety

 WARNING	No modification of this device is allowed. There are no user-serviceable parts inside the scanner. Necessary modifications must be made only by the manufacturer or its designated agents.
 WARNING	Do not modify the power adapter or extend its power cable.
 WARNING	To prevent shock, do not open the scanner housing. Only authorized and qualified service personnel may access the inside of any part of the system.

 WARNING	Use only the power adapter that is included with your scanner.
 WARNING	To ensure patient safety, the PC must be placed in the same room and outside the patient's environment (at least a radius of 1.5m surrounding the patient).
 WARNING	To avoid electrical shock, use only the supplied power adapter and connect it only to properly grounded wall outlets.
 WARNING	Before connecting the power supply, make sure that the surfaces of the scanner and the power hub are dry.
 WARNING	Securely plug the power plug into the AC outlet to avoid a contact failure.
 WARNING	Regularly inspect the power adapter and its cable for any visible signs of physical damage, such as cracks, dents, or loose parts. If it appears damaged, stop using it immediately.
 WARNING	Disconnect the cable by pulling on the connector or the plug, not the cable itself.
 WARNING	Do not insert any metal objects into your scanner.
 WARNING	The power outlet socket should be installed as near to the scanner as possible and should be easily accessible.

1.3 Laser Safety

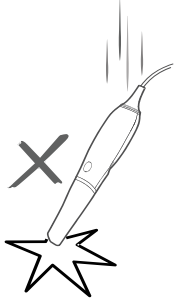
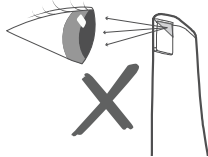
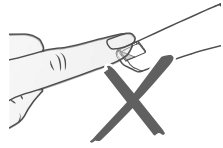
 WARNING	Never point a laser beam at anyone, nor look directly into the beam. 
 WARNING	During the inspection, ensure that there is no person in the direction of laser irradiation.
 CAUTION	The patient should wear goggles before starting scanning.
 CAUTION	Laser Wavelength : Blue 448nm, Green 517nm. Class 2 , Maximum Output Optical Power: 1mW

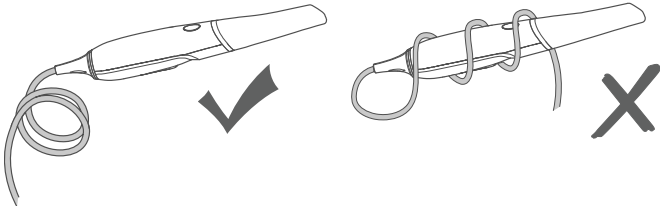
1.4 EMC Precautions

 WARNING	Using cables or accessories other than those specified for use with the scanner may result in increased emissions or decreased immunity of the device.
 WARNING	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 Intraoral Scanner, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
 WARNING	The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

1.5 Installation and Operation

 WARNING	This product is designed and intended for use by properly trained persons with professions in dentistry and dental laboratory technology. The product cannot be operated by the patients themselves.
 WARNING	- The user or operator must ensure that the scanner is installed correctly as described to ensure optimal use of the system. This includes, but is not limited to: - Verify the installation environment meets the requirements in this manual - Verify the PC meets the minimum specifications required by the scanner - Verify the 3D image captured is qualified after performing the test scanning of dental phantoms - Verify the scanner functions well when in operation
 WARNING	Use only supplied accessories and approved software with the scanner to achieve the designed performance. The parts that are not supplied by the manufacturer may reduce the accuracy and safety of the device.
 WARNING	Use only medical-grade devices with the scanner in the patient environment.
 WARNING	Do not use the scanner for purposes other than those intended.

 WARNING	• Exercise caution when handling the scanner. In case the scanner falls, proceed as follows: The scanner tip should be disposed of immediately, and must not be used on patients. There is a high risk that the mirror in the scanner tip has become dislodged and may fall out. The scanner should immediately be calibrated before further use. If calibration fails, please contact your distributor. 
 CAUTION	• The scanner is a very sensitive optical device and must therefore be handled with the utmost care. To maintain the life of the scanner, consider the following: 1) Do not handle the device with wet hands. 2) Keep the power hub clean and dry. 3) Do not insert the USB plug at an angle or with excessive force into the PC USB port. 4) Do not drag on the cable itself but hold the USB plug to disconnect the scanner. 5) Lay the cable (e.g. power cable, USB cable) in such a way that there is no risk of tripping. 6) Do not unnecessarily touch the USB plug pins, to avoid malfunctions due to electrostatic discharge. 7) Do not unplug the USB plug or disconnect the power supply during scanning. 8) Do not drop a scanner onto, or let it knock against a hard surface. 9) Never place any objects or loads on the scanner. 10) The scanner must not be used inside the patient's mouth without a scanner tip. 11) Store the scanner on the scanner holder when not in use.
 WARNING	• If you suspect device malfunction or encounter the following circumstances, discontinue using the scanner and contact Customer Support immediately. Do not attempt to make any repairs to the device. 1) When there is smoke, odd smell, or abnormal sound 2) When liquid has been spilled into the device or a metal object has entered the scanner air vents. 3) When the scanner has been dropped and is damaged 4) When the original power adapter is damaged
 CAUTION	• Never point a laser beam at anyone, nor look directly into the beam. 
 CAUTION	• The mirror is a delicate optical component that must be handled with care to ensure optimal scan quality. Avoid scratching or smudging it, as any damage or blemishes may impact the data collected. 

 CAUTION	To avoid damaging the USB cable from excessive bending or twisting, loosely coil it and steer clear of kinks or sharp bends. 
 CAUTION	Do not allow any liquid to get inside this scanner. Water and moisture may cause short-circuit to the electronic components and lead to malfunctions.
 CAUTION	- The reusable tip shall no longer be used in the following situations: - The tip has been autoclaved 100 times. - The surface of the scanner tip has obvious scratches, damage, or wear. - The tip mirror has cracks or severe stains that cannot be removed. - There is a noticeable decline in scan quality compared to other scanner tips. - The scanner has been dropped.
 NOTE	When the scanner is working, the body part will be slightly heated.

1.6 Handling of Device Failures and Serious Incidents

 WARNING	- If you suspect device malfunction or encounter the following circumstances, discontinue using the scanner and contact Customer Support immediately. Do not attempt to make any repairs to the device. - When there is smoke, odd smell, or abnormal sound - If liquid has been spilled into the scanner, or if it has been exposed to rain or water - When the scanner has been dropped, or its housing is damaged - If the scanner exhibits a distinct change in performance, indicating a need for service. - When the original power adapter is damaged, or the power cable or plug is damaged or frayed.
 WARNING	Immediately notify the manufacturer and the national competent authority of any serious incident that has occurred with the product.

1.7 Disinfection and Sterilization

 WARNING	Ensure the scanner is disconnected from the USB 3.0 port and power adapter before cleaning and disinfection to prevent electric shock or damage to the device.
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 WARNING	Use only cleaning and disinfecting agents that have been approved by Roson.
 WARNING	To prevent cross-infection, always replace another scanner tip after each patient examination. The used reusable scanner tips should be cleaned and disinfected, and the disposable tips shall be disposed of as per relevant local regulations for handling contaminated medical waste.
 WARNING	Do not use an autoclave or a UV oven to sterilize the scanner body and its cable. Autoclaving a scanner will cause permanent damage.
 CAUTION	Always wrap the tip before autoclaving. Autoclaving an exposed tip will result in stains on the mirror that are impossible to remove.
 CAUTION	Take special care during cleaning and disinfection not to allow liquids to reach the scanner's vents, as this can result in device failure. 
 CAUTION	Make sure the mirror and lens window at the base of the scanner are clean by wiping it with a moist, lint-free cloth or lens tissue.
 CAUTION	Make sure that used sleeves, disposable tips, and used wipes are properly disposed of as infected waste which is potentially biologically hazardous. Improper disposal of biomedical waste can lead to the spread of illness or disease.

1.8 Inspection and Maintenance

 WARNING	In the interest of the safety and health of patients, users, and other persons, inspections must be performed at scheduled intervals to ensure the operational reliability and functional safety of your product.
 CAUTION	Before each usage, always check the outer surfaces of the scanner and cable for any signs of damage or defect. Do not use the scanner if its housing has visible damage.
 CAUTION	Remove the dust attached to the USB plug periodically with a dry cloth.

Chapter 2 Overview

2.1 Intended Use

The RODIS-L system is an intraoral scanner that uses the optical scanning method to obtain the three-dimensional shape feature data of the surfaces of teeth, gums, and other tissues. It outputs the three-dimensional digital impression data.

This device is intended for use in medical institutions, providing 3D scanning for adult and pediatric patients undergoing dental treatments like restorations, orthodontics, and implants.

■ Intended Operators

The product may be operated only by trained dental professionals and qualified personnel.

■ Contraindications

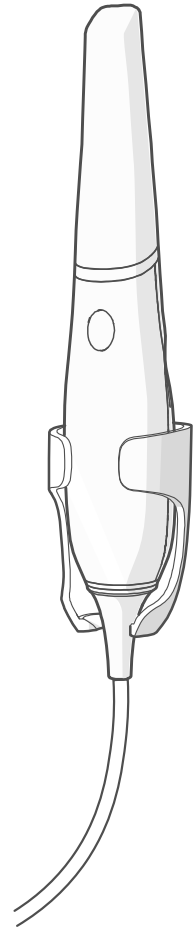
None known.

■ Essential Performance

During the continuous scanning process, communication should be normal, and it should be able to acquire images of the teeth and generate the 3D data normally.

■ Key Features

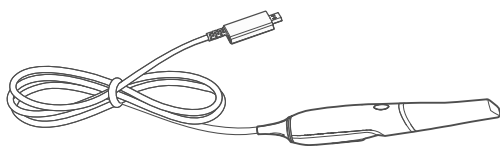
- | | |
|--|--|
| ✓ Lightweight and ergonomic design | ✓ Two scan tips for different angle scanning |
| ✓ Designed specifically for intraoral scanning | ✓ Fast and smooth intraoral scanning |
| ✓ High accuracy | ✓ User-friendly interface |



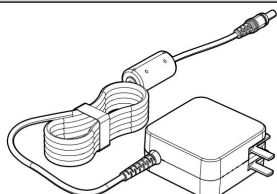
2.2 System Components

Upon receipt of the package, be sure to identify and locate each of the package items shown below:

Scanner Unit with a USB 3.0 cable (length:1.5 meters)*1



Power Adapter*1 (With AC plug*1 Different sales regions)



Desktop holder*1

Wall mount holder*1(M4x12
self-tapping screws *2)



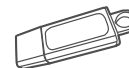
Tip*6

Protective tip *1

USB flash disk (preloaded
with image acquisition software)

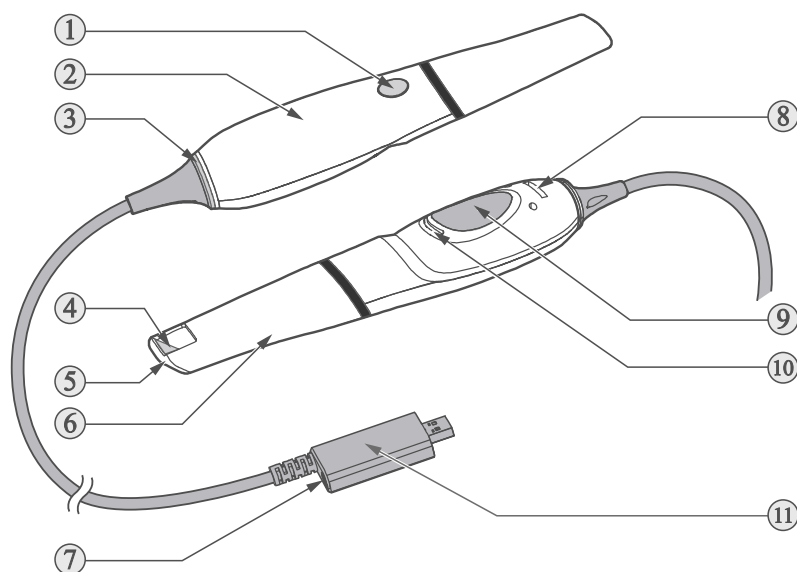


Small tip*1
Standard tip*5



 NOTE	The actual packing list for this product might differ due to your customization preferences or country-specific accessories.
 NOTE	Verify that all items listed on the Packing List are contained in your order. If any item appears to be missing, contact your local distributor.
 NOTE	AC plug types vary by country/region.
 NOTE	Note that items denoted with * are optional parts.

2.3 Part Name and Function



No.	Part name	Description
①	Scan button	Single press to start or pause the scan. Long press to proceed to the next step.
②	Scanner body	Grip the scanner body and rotate it for optimal scan angle.
③	LED indicator	Indicates the status of the scanner. - Off: no power applied - Solid green: the scanner is ready for use - Breathing green: standby
④	Scan window	Captures intraoral image data.
⑤	Heater	Ensure successful scanning by preventing fogging on the mirror.
⑥	Scanner tip	Scan the upper jaw, lower jaw, or full jaw.
⑦	Power interface	Supplies power to the scanner.
⑧	Air outlet	Helps to release heat generated by the scanner during operation, preventing overheating.
⑨	Anti-slip gasket	Prevent the equipment from sliding during use
⑩	Air intake	Allow the cold air from the environment to enter the casing
⑪	Power hub	Supplies power to the scanner and facilitates data transfer between PC and the scanner.

Chapter 3 Technical Specifications

3.1 Intraoral Scanner

Item	Specification
Model	RODIS-L
Light source	Laser
Scan field	Normal: 16 mm×12 mm Small: 12 mm×9 mm
Scan depth	20mm
Data output format	STL, PLY, OBJ
Data interface	USB 3.0
Power supply	DC 12V, 3A
Power consumption	≤36W
Cable length	1.5m
Tip size	Normal: 17.5 mm×17.5 mm Small: 13.5 mm×13.5mm
Dimension (tip included, cable excluded)	251 mm (W)×50.5 mm (L)×43 mm (H)
Weight (tip included, cable excluded)	≤220g

3.2 Recommended Environmental Conditions

The device must be transported, stored, and operated in permissible environmental conditions, as stated below:

Item	Operating Condition	Storage and Transport Condition
Ambient temperature	10~30°C	-20~60°C
Relative humidity	10%~85%RH (non-condensing)	10%~95%RH (non-condensing)
Atmospheric pressure	70~106kPa	60~106kPa
Altitude	Max. 3000m	/



Do not expose this scanner to environments beyond its specified limits. Doing this may cause the device to malfunction.

Item	Specification
Model	LXCP37-120
Input	AC 100~240V, 50Hz/60Hz, 0.9Amax
Output	12V, 3.0A

3.4 PC System Requirements

For optimal performance, we recommend your host PC meets the following requirements:

Item	Minimum
OS	Windows 10 (64-bit)
CPU	Intel Core i7-8700 and above
RAM	16GB and above
Video card	NVIDIA GeForce RTX 2060, 6GB
USB port	USB 3.0 high-speed port



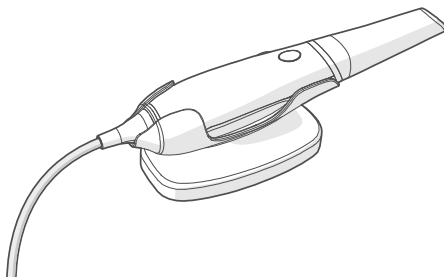
NOTE

The scanner can only be connected to a USB 3.0 port on a computer that is at least IEC 60950 /IEC 62368, or equivalent standards certified.

Chapter 4 Setting up the Scanner

4.1 Installing the Holder

■ Placing on the Desktop Holder



■ Placing on the Wall Mount Holder



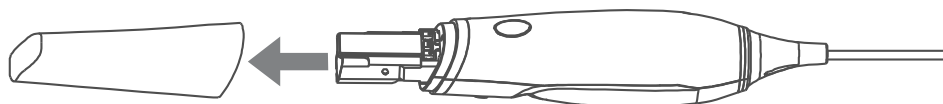
 CAUTION	Improper installation of the wall-mounted holder may cause the scanner to fall unexpectedly, potentially damaging the scanner. Roson is not responsible for accidents or damage involving the scanner falling due to improper installation.
 NOTE	Place the scanner in the holder, either the desktop holder or the wall mount holder, when it is not in use.

4.2 Attaching and Detaching the Scanner Tip

■ Attaching the Scanner Tip

Follow the steps below to complete the attachment:

1. Grasp the scanner body with one hand, hold the scanner tip firmly with the other, and then gently attach the tip facing downward to the scanner.



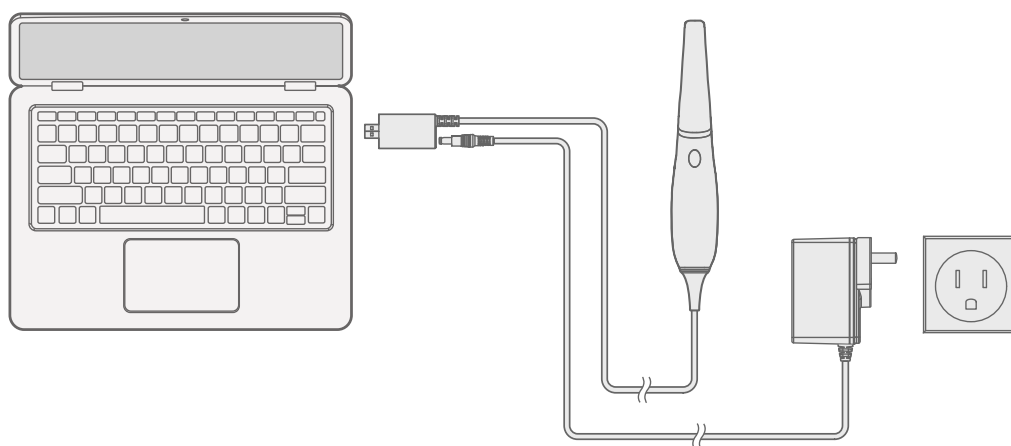
2. Gently wiggle the scanner tip to check for any gaps between it and the scanner body to ensure it's securely installed.
3. Protect the front end of the scanner body with the supplied protection cap.
4. Position the scanner in the cradle, and it will be ready for use.

 NOTE	The reusable tip can be re-sterilized up to 100 times and must be disposed of afterward.
 NOTE	Once used, disposable tips must be disposed of according to biomedical waste disposal procedures.
 NOTE	The mirror found in the tip is a delicate optical component that should be handled with care to ensure optimal scan quality.
 NOTE	The scanner tip is the part that is inserted into the patient's mouth during scanning. It must be thoroughly cleaned and sterilized before and after each patient's use to prevent cross-contamination.

4.3 Connecting the Scanner

Follow the steps below to complete the connection:

1. Gently and firmly slide the scanner tip onto the front end of the scanner, ensuring it is securely attached.
2. Connect the USB plug on the scanner hub to the USB 3.0 port on your computer.
3. Attach the AC plug to the power adapter.
4. Connect one end of the medical adapter to the power interface on the hub and the other to a wall outlet.



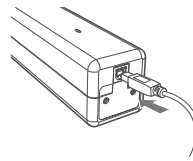
 NOTE	The RODIS-L will automatically power on when the power is supplied and will power off instantly if the power is lost.
 NOTE	Verify that the scanner is connected to a USB 3.0 port. It may not function properly if connected to a USB 2.0 port.

4.4 Calibrating the Scanner

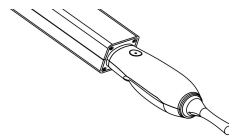
4.4.1 Optical Calibration

➔ Calibrate the scanner by following the steps below:

1. Connect the calibration device to the workstation host using the provided USB3.0 cable. After connection, confirm that the indicator light on the calibration device shows a steady green light, indicating a normal connection;



2. Carefully remove the scanning head from the scanner body and place it properly;
3. Connect the scanner to the power adapter, and insert the hub into the workstation;
4. Remove the dust cover from the calibration device, and smoothly and accurately insert the front end of the scanner into the calibration device.

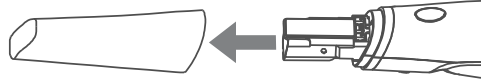


5. Open the **iOralScan** software and enter the general settings interface. In this interface, locate and click the [**Optical Calibration**] button, which will promptly pop up the optical calibration window.
6. Within the optical calibration window, click the [**Start**] button to initiate the calibration process. Please wait patiently for approximately 5 minutes at this time, and refrain from performing other operations on the equipment during this period;
7. Once the "**Calibration Complete**" prompt message appears, click the [**Finish**] button to end the calibration process;
8. After calibration is completed, hold the scanner and gently remove it horizontally from the calibration device. Immediately after removal, cover the calibration device with its dust cover to prevent dust entry;
9. Reinstall the previously removed scanning head back onto the scanner. If the scanner is not for immediate use, you can install a dust cover on its front end.

4.4.2 White Balance Calibration

➔ Follow the steps below to calibrate the color balance of the scanner:

1. Remove the scanning head from the scanner and place it properly.



2. Remove the dust cover from the calibration device, and align the front end of the scanner with the calibration device;
3. Open the **iOralScan** software and enter the General Settings interface. In this interface, locate and click the [**White Balance Calibration**] button, which will promptly pop up the white balance calibration window.
4. The white balance calibration window will pop up; click [**Start**].
5. Wait for a period of time until the "White Balance Calibration Complete" prompt message appears, then click [**Finish**].
6. After the white balance calibration is completed, reattach the dust cover to the calibration device.

Reinstall the previously removed scanning head back onto the scanner. If the scanner will not be used immediately, you can install a dust cover on its front end.

4.5 Cleaning, Disinfection, and Sterilization

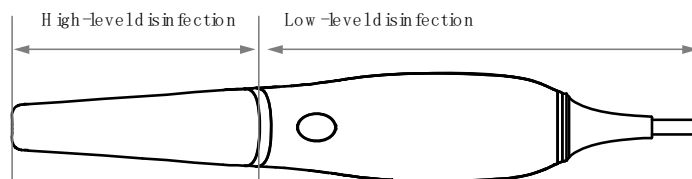
 WARNING	Before each scan, make sure that both the scanner's main body and the scanning tip have been cleaned and disinfected/sterilized as specified in the manual.
 WARNING	When installing or removing the scanning tip, do not place your fingers on the scanning tip lens to prevent it from getting dirty or broken.
 CAUTION	It is essential to strictly follow the recommended disinfectants and disinfection/sterilization procedures to avoid damaging the equipment.

Cleaning and Disinfecting the Scanner Body, Desktop Holder and Wall Mount Holder

Below you will find the recommended steps for cleaning and disinfection:

- 1) Wear single-use PPE gloves.

- 2) Unplug the scanner from the PC USB port and disconnect the power plug from the hub.
- 3) Pull the scanning tip out horizontally from the scanner body and put on the dust cover.



NOTE

When disassembling the scanning tip, be sure to avoid touching the mirror of the scanning tip with your fingers to prevent leaving fingerprints, stains or causing scratches.

- 4) Place the separated scanning tip in the designated position and store it properly.
- 5) Use a non-woven cloth slightly dampened with 70% - 75% ethanol solution, and wipe the surface of the device uniformly and meticulously. During the wiping process, pay attention to moderate force to ensure that all parts of the device can be effectively cleaned. After cleaning, place the device in a clean, safe and dry place and wait for it to air dry naturally to avoid bacteria growth or secondary contamination on the device in a damp state. After disinfection, dispose of all used wipes, gloves, disposable scanner tip (if used), and other potentially infectious in the medical waste bin.
- 6) Clean, disinfect and dry the bracket in the same way.

The Scanning Tip

Personal Standard Tip

- 1) Rinse the Personal Standard Tip with purified water for at least 1 minute to remove contaminants.
- 2) Prepare an effective cleaning solution using purified water in an appropriate container, according to the specifications of the cleaning solution manufacturer (e.g., Neodisher® MediZym). During use, the temperature of the cleaning solution must not exceed 45°C (113°F).
- 3) Use a soft brush dipped in the enzyme cleaning solution to scrub all surfaces of the Personal Standard Tip for at least 1 minute.
- 4) Rinse all surfaces of the Personal Standard Tip under flowing purified water for at least 1 minute.
- 5) Visually inspect the Personal Standard Tip; if it is not clean, repeat the cleaning process.
- 6) Use lens paper or lint-free cloth to remove any dust from the tip lens surface.
- 7) Place the Personal Standard Tip into disinfectant (0.55% Cidex® OPA) at least 5min and disinfectant temperature is 20°C (68°F).

- 8) Rinse all surfaces of the Personal Standard Tip under flowing purified water for at least 1 minute.
- 9) Manual drying can be performed through lint free towel. Insufflate cavities of Personal Standard Tip by using sterile compressed air.

The Standard Tip and The Small Tip

- 1) Rinse the Standard Tip with purified water for at least 1 minute to remove contaminants.
- 2) Prepare an effective cleaning solution using purified water in an appropriate container, according to the specifications of the cleaning solution manufacturer. During use, the temperature of the cleaning solution must not exceed 45°C (113°F).
- 3) Use a soft brush dipped in the enzyme cleaning solution to scrub all surfaces of the Standard Tip for at least 1 minute.
- 4) Rinse all surfaces of the Standard Tip under flowing purified water for at least 1 minute.
- 5) Visually inspect the Standard Tip; if it is not clean, repeat the cleaning process.
- 6) Use lens paper or lint-free cloth to remove any dust from the tip lens surface.
- 7) Place the cleaned Standard Tip into a double-layer sterilization pouch and seal the pouch.

Parameter	IFU Parameter-1	IFU Parameter-2	IFU Parameter-3
Type of cycles	Pressure steam sterilization (Pre-vacuum)		
Sterilization time	5 min	4 min	4 min
Sterilization temperature	134°C	134°C	132°C
Drying time	20min	20min	20min

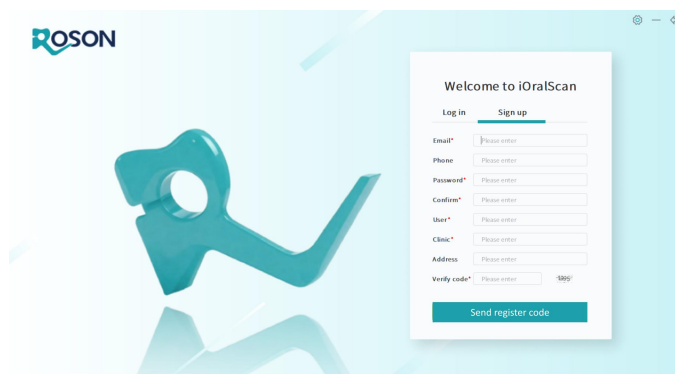
Chapter 5 User Interface

 NOTE	Before you proceed with the software installation, check your computer system configuration is compatible with the computer system requirements for the RODIS-L software.
 NOTE	Install only the approved software to maintain the system's runtime stability.

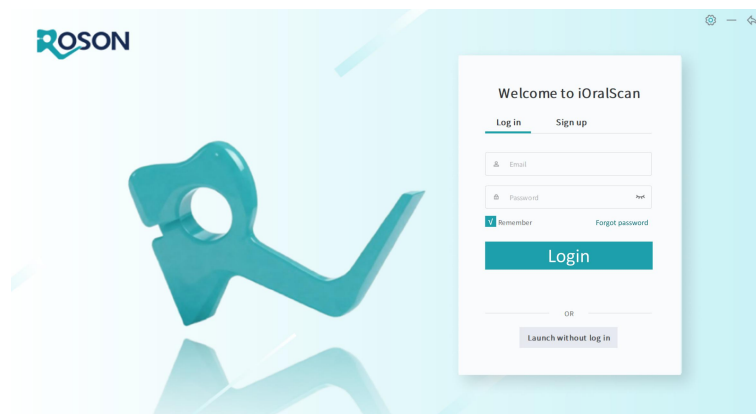
5.1 Software Installation

1. Connect the USB flash driver to the computer.
2. Locate and click to open the **iOralScan.exe** file.
3. Choose a language from the drop-down list and click **OK** to install.
4. Select the installation path.
5. It may take up to several minutes to finish the recommended installation process. Please do not shut down the PC until installation is completed.
6. Follow the instructions on the screen to complete the installation.
7. After installation, you will see a shortcut icon  on the desktop. Double-click to open the software.

5.2 Log in Interface



 NOTE	For the first time, click on [Sign up] to enter the registration interface. Fill in the required information to register a new iOralScan account. The password should consist of a combination of letters and numbers, be eight characters long, and must include both uppercase and lowercase letters. Please note: The items marked with a red asterisk (*) are required. After completing the registration, you can log in using the newly created account and password.
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NOTE

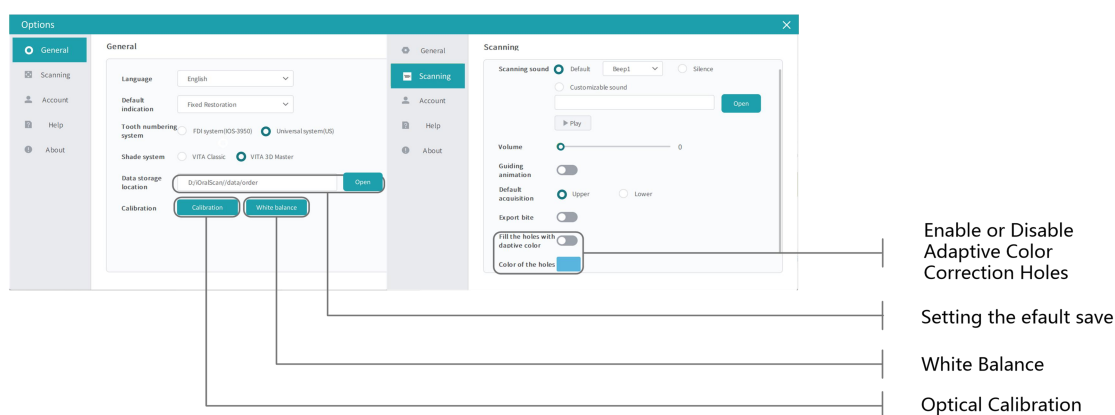
After completing the registration, you can log in using the newly created account and password. If you need to use it offline, click the **【Launch without log in】** to directly access the software.



NOTE

You can check the option "Remember" as needed, so that the system will automatically fill in the password during subsequent logins.

5.3 Setting Interface



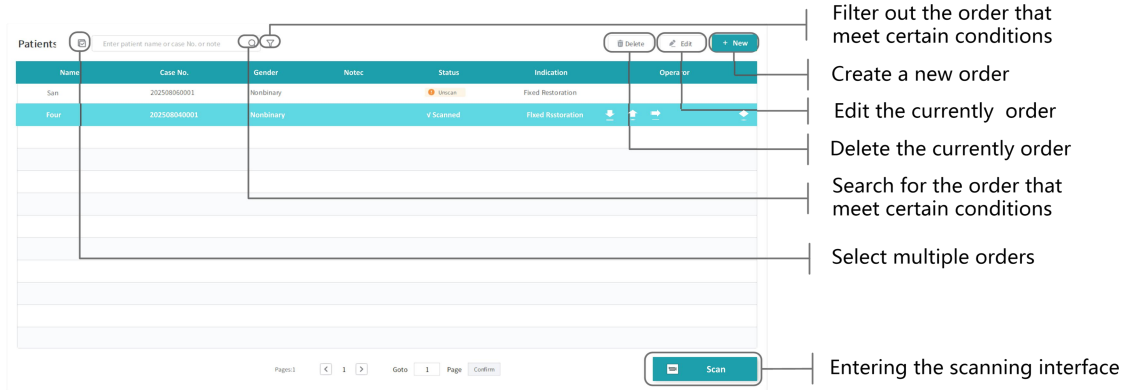
Enable or Disable
Adaptive Color
Correction Holes

Setting the default save

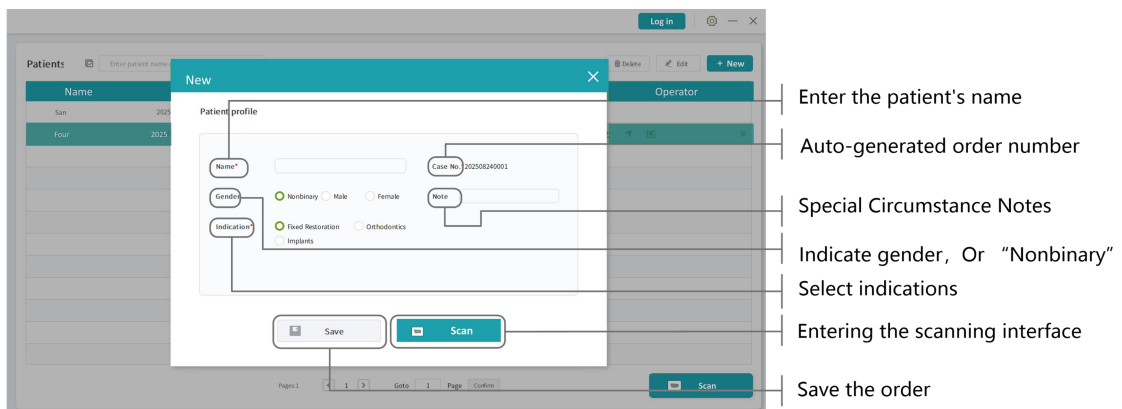
White Balance

Optical Calibration

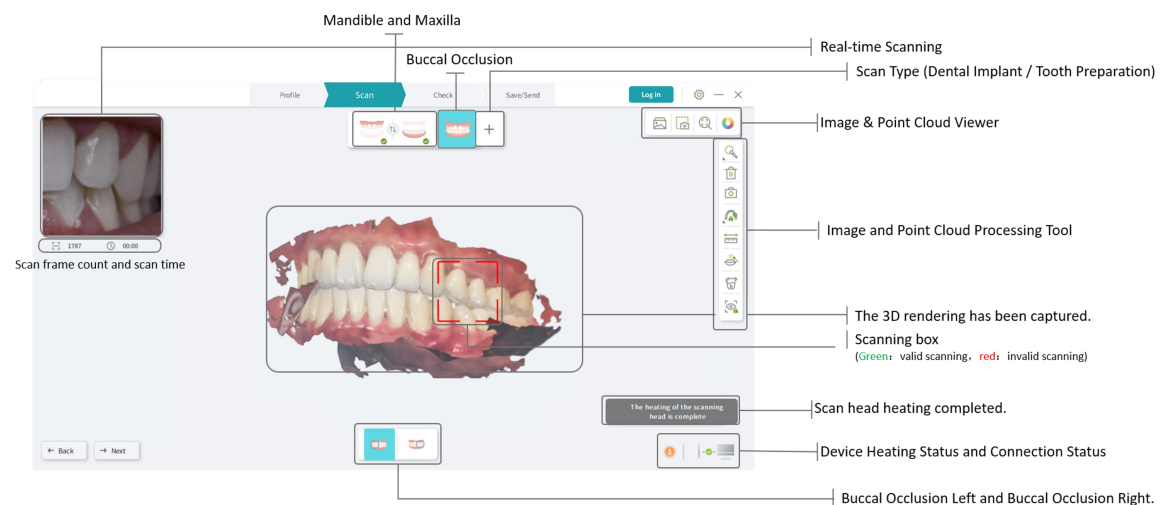
5.4 Order Management Interface



5.5 Order Creation Interface



5.6 Scanning Interface



Scanner Operating Status

	Device disconnected: The software failed to detect that a scanner was connected.
	Device overheating
	Device connection in progress
	Device failure
	No Tip detected.

Function icon description

	Gallery: View the 2D images generated internally by the software
	Screenshot: Capture the current 3D model image
	Pose Reset: Restore the 3D model that has been translated, enlarged or rotated to its original position.
	Display the texture and Coloring of the 3D model
	Disable the 3D model texture coloring. The model will display in gray by default.
	Trimming the 3D model
	Brush Cropping: Cursor in circular ROI brush mode, right-click to select the area within the ROI on the model as the user cropping area, and Ctrl + mouse scroll wheel to adjust the radius of the circular ROI.
	Select and Crop, by right-clicking and dragging, the cursor movement path obtained forms a closed polygonal area which serves as the user-selected cropping area.
	Revoke the previous selection area
	Revoke all electoral districts

	Delete the current 3D model data
	Intraoral camera, once activated, displays the images captured by the scanner in real time. Click the device button to capture the current frame and save it to the gallery.
	Freeze the model. The data of the selected area during the scanning process will be fixed.
	Selection, Right-click selection, Select the area as the model freezing area, Ctrl + mouse scroll to adjust the radius of the circular ROI
	Reverse selection, right-click selection, the unselected area serves as the model freezing area, and Ctrl + mouse scroll wheel is used to adjust the radius of the circular ROI.
	Distance measurement: Right-click on two points on the model to form a line segment, and calculate the spatial distance between them.
	Remove the oral mucosa: After opening, perform anti-interference processing on the oral mucosa in the scanned images within the oral cavity.
	Metal tooth scanning mode
	The fixed viewing angle: Once activated, it will maintain the current scanning angle.
	Erosion calculation: Double-click with the right mouse button to calculate the erosion result within the circular ROI area under the current perspective. Press Ctrl and scroll the mouse wheel to adjust the radius of the circular ROI.
	Check the occlusal stress
	Adjustment of the six-view 3D model, allowing for quick viewing of the model from the front/back/right/left/top/bottom perspectives.
	Obtain 3D model six-view snapshots, which can be viewed in the gallery.
	View the oral survey report
	Local high definition

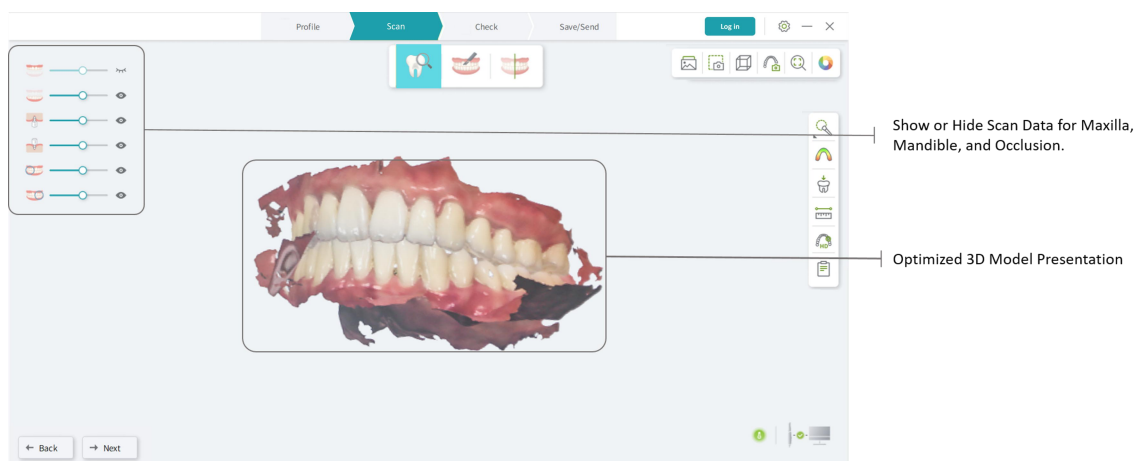


Confirm to carry out local high-definition processing



Reset the local high-definition result

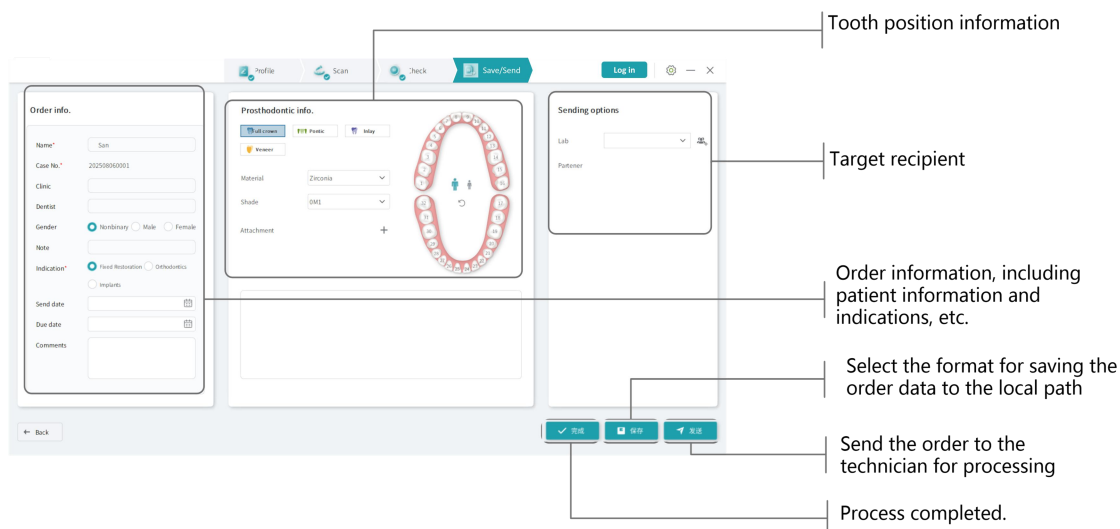
5.7 Image Browsing Interface



NOTE

Enter the image browsing interface, check the image quality. If you find any scanning issues (such as missed scanning, data distortion, scanning artifacts, geometric distortion, superimposition errors, non-aligned occlusal surfaces on the cheek side, etc.), or if you are not satisfied with the image quality, you can click "Back" to return to the scanning interface.

5.8 Order Sending Interface



5.9 Software Upgrade



NOTE

Do not unplug the scanner while the firmware is being updated.

Chapter 6 Getting Started

1. Access the iOralScan.exe

Double-click the iOralScan.exe icon from your desktop, and log in with your account and password.

2. Connect your Scanner

- Remove the scanner protection cap and install the disinfected reusable tip or disposable tip.
- Plug the scanner USB plug into your computer's 3.0 USB port.
- Connect one end of the power adapter to the scanner's hub and the other to the wall outlet.

NOTE	Make sure the scanner is plugged into a USB 3.0 port, as it may not function correctly on a USB 2.0 port.
NOTE	The reusable tips are shipped non-sterilized. New tips need to be cleaned and disinfected prior to initial use.
NOTE	Always ensure that you have pre-cleaned and disinfected the scanner body, scanner tip and holder before each scan.
NOTE	Before proceeding with the scan, ensure the tip casing is free of scratches or damage, the scanning mirror is intact, and that the tip is properly installed.

3. Preparing the teeth

- Adjust the dental chair to the appropriate height and angle to ensure the patient is comfortable during the scanning process.
- Dry the teeth thoroughly.

NOTE	Prior to the scan, check that the patient's mouth is free of debris and blood and the teeth are dried thoroughly.
NOTE	Remind the patient to use nasal breathing to avoid fogging on the scanner mirror which can hinder imaging precision.
NOTE	Adjust the surgical light position to ensure it is directed away from the patient's mouth to prevent interference with the scanner.

4. Create an Order

On the order page, click :

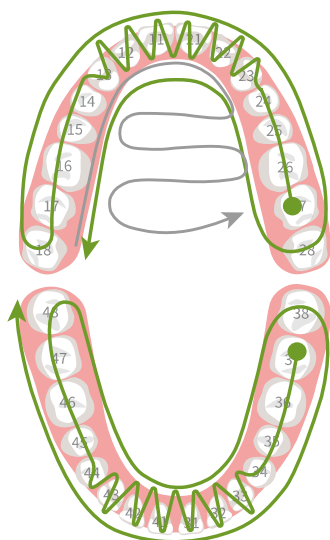
- Enter the patient's information (name, gender, indications).
- Add any remarks.

5. Start scanning

- Ensure the scanner heating is complete , with the status in the bottom right corner showing "Ready" before initiating the intraoral scan.

 NOTE	The device will automatically start heating for roughly 30 seconds after being powered on. The heating status can be found on the scan screen.
 NOTE	The device will automatically enter standby mode if it is idle for more than 30 minutes. To resume use, unplug and replug the device or click the icon  in the lower right corner of the iOralScan.exe.

- Hold the scanner body in the same way as a pen and carefully place the scanner tip onto the patient's tooth to stabilize the scanner and then press the scan button. When a 3D image appears on the upper-left display screen, and then steadily and slowly move it along the arch at 0~5mm from the teeth while watching the screen for real-time feedback to ensure optimal image quality. After the scan is complete, press the scan button again to end the scan.



 NOTE	To ensure thorough coverage of all surfaces, implement the suggested scanning path: <u>occlusal</u>→<u>lingual</u>→<u>buccal</u>. You can interrupt the scan path at any time, for example, to dry the tooth surface to obtain an optimal result, and pick up where you stopped.
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- Upon completion of the upper jaw scan, tap the lower jaw icon  or long-press the scan button on the scanner to enter lower jaw scan mode, and proceed to scan the lower jaw using the same strategy as the upper jaw.
- When you confirm that the 3D model of the upper- and lower jaw is complete, continue with the buccal bite registration by clicking the  icon. Instruct the patient to align and firmly securely bite down with their upper and lower jaws. Follow the on-screen instructions to capture the occlusal force data for both the left and right sides. After scanning a portion of the data, the software will automatically stitch the occlusion. Once both sides have been collected successfully, rotate the model and zoom the view to ensure that the bite is accurate and that there are no areas where the bite is mismatched.



 NOTE	 indicates that the buccal bite registration on this side is done.
 NOTE	Throughout the scan process, re-dry the teeth moderately.

 NOTE	Maintain the scanner tip at a distance of 0 to 5 mm from the teeth. Try not to touch the teeth during the scan, or . Occasional contact with the teeth is acceptable.
 NOTE	While the scanner body can heat up during use, it remains at a safe temperature for users and patients.
 NOTE	The holes in the 3D model will be highlighted in the color specified by the user. It is recommended to scan these regions until they are no longer present.
 NOTE	The area being scanned will be highlighted with either a green or red frame. A green frame with a continuous beep signals normal scanning, while a red frame indicates an error and requires re-scanning.

6. Refine and check the 3D Model

If the acquired models are well-formed, click **Next** to enter the submission screen. If not, click **Back** to return and re-scan the area.

7. Save or submit the order

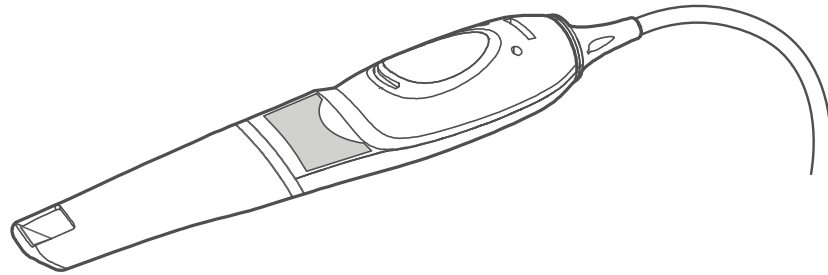
You can opt to save the 3D model file locally or send the order to the designated cloud platform.

 NOTE	You must log in to your account before you can send orders to the designated cloud platform.
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Chapter 7 Regulatory Information

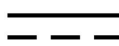
7.1 Symbols on System Labels

The markings on the RODIS-L system and its packaging box indicate the following details:



Take special care not to damage or remove the labels attached to the device and its accessories, as this may affect the warranty service.

Symbol	Explanation
	This side up
	Fragile, handle with care
	Keep dry
	Stacking limit by number
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from direct sunlight
	Serial number
	Caution! Consult accompanying documents
	Roson trademark

Symbol	Explanation
	Manufacturer
	Follow instructions for use
	This symbol indicates that this device must be sent to separate collection facilities for recovery and recycling at the end of its service life
	Unique Device Identifier
	CE mark
	Warning label – Laser hazard symbol
	Medical device
	Type BF Applied Part
	Caution, hot surface
	Authorized representative in the European Community/European Union
	Non-sterile
	Alternating current
	Direct current
	CLASS II equipment
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
 20XX-XX-XX	Date of manufacture

7.2 Safety Standards for Medical Device

7.2.1 Medical Device Classification

Item	Classification
Type of protection against electrical shock	External power supply II ME equipment
Degree of protection against electrical shock	Type BF applied part (Tip)
Degree of protection against ingress of water	IPX0
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide. Not suitable for use in an oxygen-rich environment

7.2.2 Safety Standards Reference

The scanner complies with the following standards:

Standard	Description
IEC 60601-1:2005/AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1:2006 + A1:2013 + A2:2020	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
EN60601-1-2:2015 + A1:2020	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 + A1:2013 + A2:2020/EN 60601-1-6:2010 + A1:2013 + A2:2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
ANSI/AAMI ES60601-1:2005 + A1:2012 + Amendment 2:2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
CSA CAN/CSA-C22.2 NO. 60601-1:14-2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

7.3 Guidance and Manufacturer's Declaration for EMC

7.3.1 Important Information Regarding Electromagnetic Compatibility (EMC)

RODIS-L needs special precautions regarding EMC and needs to be installed only by Roson or authorization engineers and put into service according to the EMC information provided in the user manual.

RODIS-L is intended for use in both professional healthcare facility environment and home healthcare environment.

- **WARNING: Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the RODIS-L system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

7.3.2 Guidance and manufacture's declaration – electromagnetic emissions

RODIS-L is suitable for use in both professional healthcare facility environment and home healthcare environment and it has meets the following standard's emission requirements.

Phenomenon	Home healthcare environment
Conducted and radiated RF emissions	CISPR 11, Group 1, Class B
Harmonic distortion	IEC 61000-3-2, Class A
Voltage fluctuations and flicker	IEC 61000-3-3

7.3.3 Guidance and manufacture's declaration – electromagnetic immunity

RODIS-L is suitable for use in both professional healthcare facility environment and home healthcare environment and it has meets the following immunity test levels. Higher immunity levels may cause the RODIS-L's essential performance lost or degraded.

Phenomenon	Basic EMC standard or test method	Home healthcare environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80%AM at 1kHz

Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances".
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50 Hz or 60Hz
Electric fast transients bursts	IEC 61000-4-4	±2kV 100kHz repetition frequency
Surges	IEC 61000-4-5	Line to line: ±0.5kV, ±1kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V in 0.15 MHz - 80 MHz 6 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T : 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% U_T : 1 cycle and 70% U_T : 25/30 cycles sine phase at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T : 250/300 cycle
U_T : rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz		

7.3.4 Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. RODIS-L has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014+A1. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and RODIS-L as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						

1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Chapter 8 Troubleshooting

No.	Failure	Possible solutions
1	Connection failed	Check power supply: Ensure the scanner is properly powered on and connected to a power source.
		Check USB port: Verify that the scanner USB plug is properly connected to a PC USB 3.0 port.
		Inspect cables: Examine all cables for any signs of damage or loose connections.
		Update software: Ensure that the scanner’s software and drivers are up to date.
		Restart devices: Restart the PC, and then replug the scanner.
2	Poor3D model quality	Test on another device: If possible, connect the scanner to another computer to see if the issue persists.
		Calibration issues: Ensure the scanner is properly calibrated. Follow the manufacturer’s instructions for calibration procedures.
		Surface preparation: Ensure the teeth and gums are clean and dry. Residual saliva, blood, or debris on the teeth can interfere with the scanner’s ability to capture accurate details.
		Patient positioning: Ensure the patient is comfortably positioned to minimize movement during scanning.
		Scanning technique: Improper scanning techniques can affect the scan quality. Use consistent, smooth movements while scanning. Avoid rushing or moving too quickly.
		Environmental factors: Ensure that the surgical light does not shine directly into the patient’s mouth.
		Check the mirror: Inspect the scanner tip for any signs of damage or wear. Clean the scanner tip thoroughly to remove any debris, saliva, or residue that may affect scanning quality. Replace it if necessary.
		Rescan problematic areas: If certain areas are not well captured, re-scan those sections carefully.
 WARNING		If the aforementioned troubleshooting steps prove ineffective, discontinue any further attempts and promptly reach out to your local distributor or Roson Customer Service Center for assistance. Do not attempt to perform any unauthorized repairs.

Chapter 9 Service Information

9.1 Service Life

Under normal operating conditions, the expected service life of the RODIS-L is 8 years.



For the specific production date, please refer to the product label.

9.2 Daily Inspection

The RODIS-L doesn't require any special maintenance other than daily inspection, cleaning, and disinfection.

Item	Check
Scanner	Visual inspection for any physical damage and wear (e.g. scratches, discoloration, corrosion) to the scanner housing or cable.
Scanner tip	Check the scanning tip mirror to ensure it is securely fixed and free from any dirt, damage, or scratches.
	Check the surface of the scanning tip to ensure it is free from rough areas, sharp edges, or protrusions.
Labels	Check that all visible labels are clear and intact.
Calibration	Check that the scanner is calibrated when needed as per the manufacturer's instructions

9.3 Repair

In the event of product failure that cannot be removed, please contact the sales representative or dealer, and provide the following information as per the product label:

- Product model: RODIS-L
- SN: Serial number on the product label
- Symptoms: Describe the device failure as detailed as possible



Foshan ROSON Medical Instruments Co.,Ltd

File Number: RS-YF-LBL-04-002

Version: A0

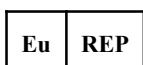


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