COXO®

Ver. A / 1
Mar.6, 2026

USER MANUAL

Intraoral Scanner
Model: Breezyscan

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Table of Contents

Preface

Thank you for purchasing the Intraoral Scanner manufactured by Guangdong Launca Medical Device Technology Co., Ltd.

Based on our proprietary technology, Guangdong Launca Medical Device Technology Co., Ltd. focuses on developing an intraoral 3D optical impression system, which is designed to make digital impression to provide accurate 3D teeth model for dental treatments.

The 3D scanning technology enables doctors to conveniently create high-accuracy digital impressions. The scanned digital data of the teeth is then transmitted through the internet to a chairside milling unit or a dental laboratory.

Compared to the traditional impression, digital impression by using the intraoral scanner has the following advantages:

- Avoids repeated impression and greatly reduces labor and material cost.
- Improves patient comfort in the impression process.
- Improves restorative quality: intraoral scanner acquires more accurate data than the traditional impression, consequently leading to better restorative quality.
- Speeds up the restorative process.

⚠Note: Operators who use this product must be professionals with appropriate qualifications in product operation. Before use, please read all contents of this manual.

⚠Note: This product can only be used for its intended purpose.

⚠Note: This user manual includes the contents of both the Instructions for Use and the Technical Description.

⚠ Warning: Since the Intraoral Scanner is a precision device, we do not recommend or allow users or other non-authorized personnel to disassemble this device. If any failure occurs, contact an authorized Launca distributor for technical support.

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Packing List of Intraoral Scanner Breezyscan:

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Intraoral Camera	1 piece
Camera Tip（Standard）	3 pieces
Camera Tip（Mini）	1 piece
Desktop Cradle	1 piece
Connection Cable	1 piece
User Manual	1 piece
Certificate	1 piece

Chapter I Product Overview

1 Intended Use

The intraoral scanner is a medical device designed to capture the topographical features of human teeth. It provides 3D digital models for CAD/CAM restoration and implantation.

2 Structure

2.1 Appearance

The intraoral scanner consists of camera, display unit and image processing system.

Each component of the intraoral scanner is specifically shown in Figures 1-1 to Fig. 1-3:

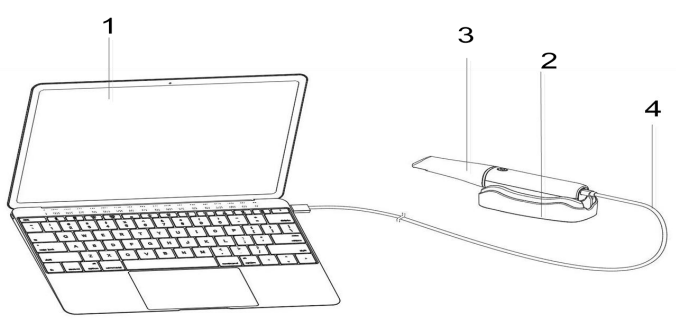
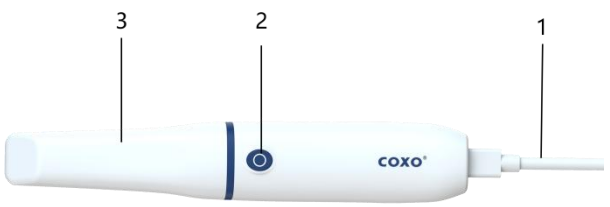


Fig 1-1 Intraoral Scanner Breezyscan

1- Notebook 2- Desktop Cradle 3- Intraoral Camera

4- Connection Cable



1 Connection Cable

2 Start Button

3 Camera Tip

Fig. 1-2 Intraoral Camera

1 Reflective Mirror

Fig. 1-3 Intraoral Camera

2.2 Software Overview

The workflow of the entire software system is as shown in Fig. 1-4.

2.2.1 SCAN Application

The SCAN application has three main functions:

- Manager Setting ；
- Managing treatment information: it includes adding, modifying and deleting patient/case/order information;
- Scanning teeth and editing models.

With this application, dentists can create files of patients and cases, scan the teeth, and send out the final orders.

2.2.2 Manager Setting

The Manager Setting is into the SCAN application .it has two main functions:

- Managing clinic related information: it includes adding, modifying and deleting clinic/dentist/ laboratory information;
- Managing treatment configuration: it includes patients, cases and data configuration.

With this setting, the intraoral scanner administrator can easily configure the scanner device and the scanner application.

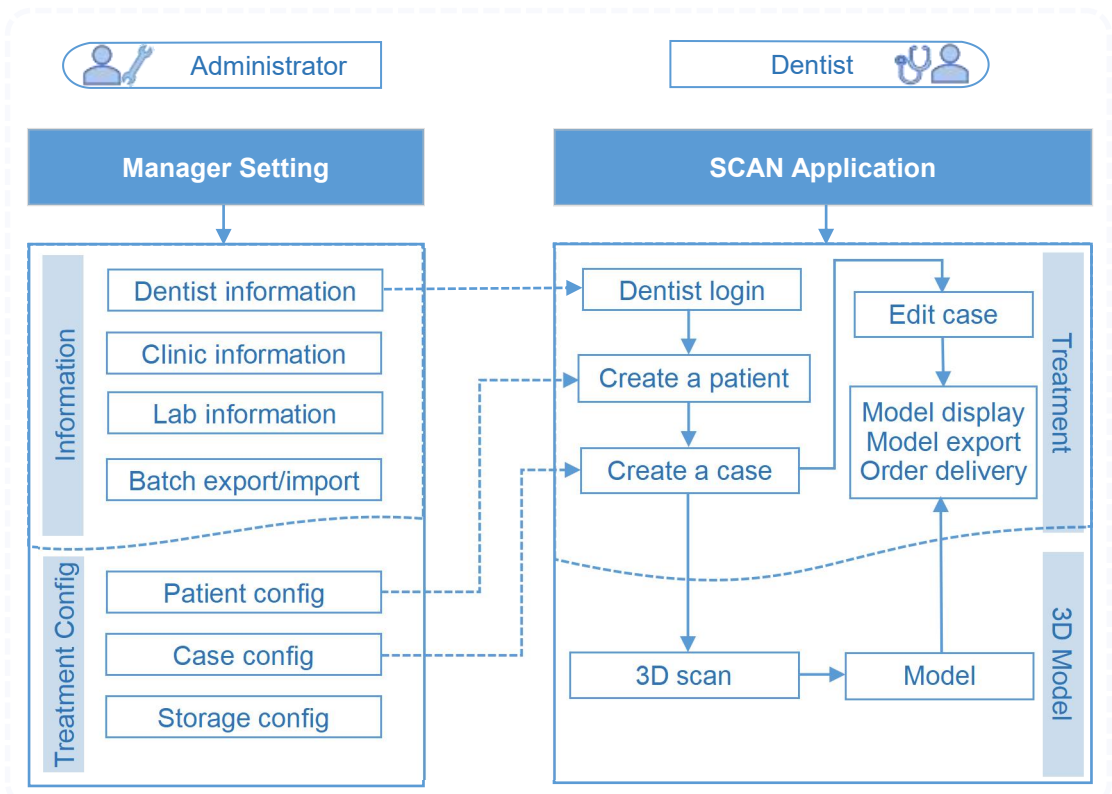


Fig. 1-4 The Workflow of the Intraoral Scanner Software System

2.3 Accessories

2.3.1 Standard Accessories

Breezyscan

- Desktop Cradle 1 piece
- Connection Cable 1 piece
- Camera tip (Standard) 2 pieces
- Camera tip (Mini) 1 piece

The camera tip is a applied part.

2.3.2 Optional Accessories

Optional Accessories	unit
● Notebook	1 set

2.4 System Connection

This section describes connections of the system components.

Take the Breezyscan intraoral camera out of the box, and connect one end of the cable to the Type-C port of the intraoral camera.And then insert the other end of the cable into a

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notebook.

⚠ Note: Make sure your notebook supports the Type-C USB3.0 port.

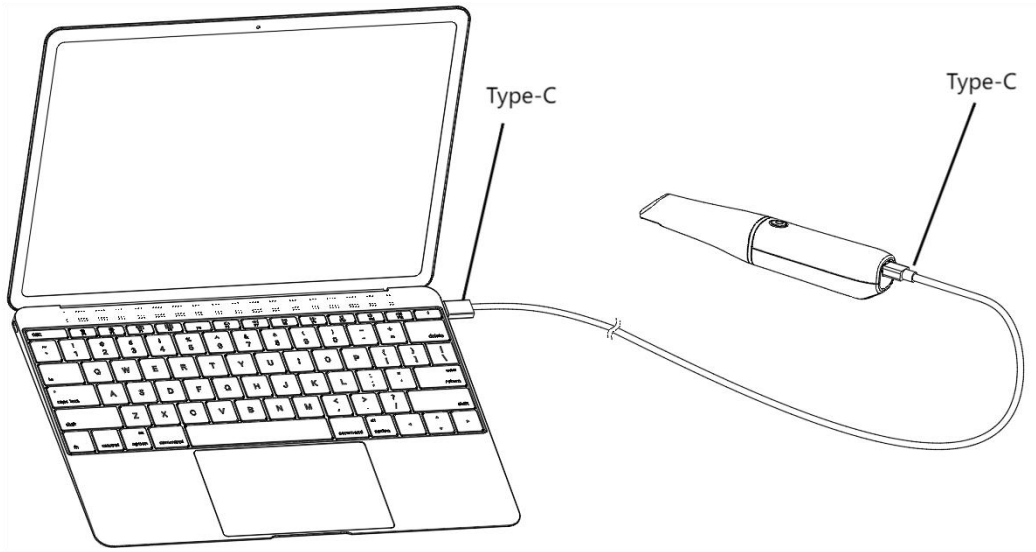
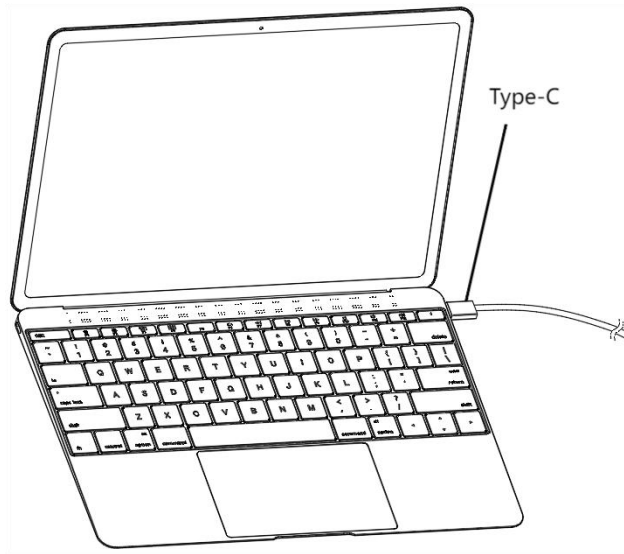


Fig. 1-4 Connection of Cable



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Chapter II Safety Precautions

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1 Safety Precautions

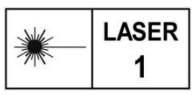
- **Warning signs and illustrations in the manual are intended to enable users to use the product safely and correctly and to avoid harm to users and other people or loss of property.**
- **Warning signs, illustrations and their meanings are as follows:**

Note, refer to the attached document

Refer to the user manual

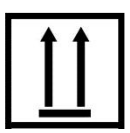
B-type Device

Double-insulated Class II appliances



Class I laser

IPX0 NO WATERPROOF

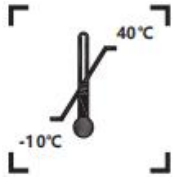


UPWARD

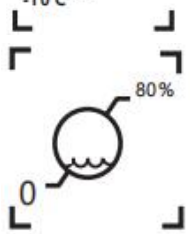
FRAGILE, HANDLE WITH CARE

KEEP DRY

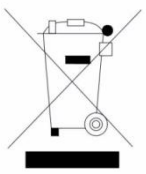
STACKING LIMIT IS 5



STORAGE AMBIENT TEMPERATURE



STORAGE AMBIENT HUMIDITY



Don't throw it away

⚠**Note: Do not hit or drop this unit or the intraoral camera of the scanner.**

⚠**Note: Do not open the intraoral camera when not scanning.**

⚠**Note: Do not pull hard on or bend the cable connecting the intraoral camera and the unit.**

⚠**Note: Check all power supplies and connecting cables to ensure that there are no abnormalities (such as scratches, breaks, etc.).**

⚠**Note: Check the intraoral camera and its connecting parts to ensure that there are no abnormalities (such as scratches, pieces falling off, looseness, etc.).**

⚠**Note: If the product needs to be disposed at the end of its service life, please follow the relevant regulatory requirements for such products.**

⚠**Note: The production and use of this product does not produce substances harmful to the human body or the environment.**

⚠ **Note: Do not position the product to make it difficult to operate the disconnection device.**

⚠**Note: Operators who use this product must be professionals with appropriate qualifications in product operation. Before use, you should read all contents of this manual.**

⚠**Note: This product can only be used for its intended use.**

⚠**Warning: Since the Intraoral Scanner is a delicate optical device, we do not recommend users or other non-authorized personnel to dismantle this device. If any failure occurs, contact an authorized Launca distributor for technical support.**

⚠**Warning: The product contains a Class 1 laser, do not look directly at the light output window.**

2 Environmental Requirements

2.1 Normal Working Conditions

- Ambient Temperature: 10℃ ~ 35℃
- Relative Humidity: 30% ~ 75%
- Atmospheric Pressure: 86kPa ~ 106kPa
- Power : Input 5V DC/3A

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2.2 Storage

The packaged scanner should be stored at an ambient temperature of -10℃ ~ +40℃, relative humidity of less than 80%, in a well-ventilated room without corrosive gases.

3 Electromagnetic Compatibility Information

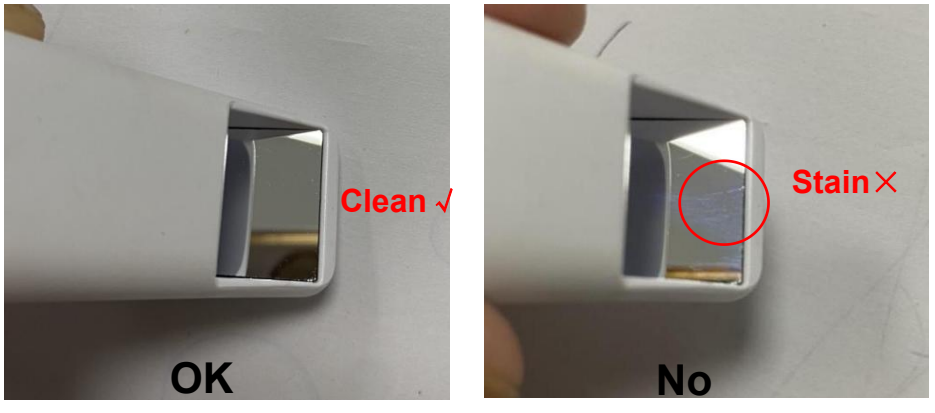
Emission Measurement		
Radiated Emission	IEC 60601-1-2:2014+A1:2020 CISPR 11:2015+A1:2016+A2:2019	PASS
Conducted Disturbance (0.15～30MHz)	IEC 60601-1-2:2014+A1:2020 CISPR 11:2015+A1:2016+A2:2019	PASS
Harmonic Current	IEC 60601-1-2:2014+A1:2020 IEC 61000-3-2:2018+A1:2020	PASS
Voltage Fluctuation and Flicker	IEC 60601-1-2:2014+A1:2020 IEC 61000-3-3:2013	PASS
Immunity Measurement		
Electrostatic Discharge	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-2:2008	PASS
RF Field Strength Susceptibility (80～2700MHz)	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-3:2006+A1:2007+A2:2010	PASS
IMMUNITY to proximity fields from RF wireless communications equipment	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-5:2006+A1:2007+A2:2010	PASS
Electrical Fast Transient/Burst Test	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-4:2012	PASS
Surge Test	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-5:2014+A1:2017	PASS
Conducted Susceptibility Test	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-6:2013	PASS
Power Frequency Magnetic Field Susceptibility Test	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-8:2009	PASS
Voltage Dips and Interruptions Test	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-11:2004	PASS
IMMUNITY to proximity magnetic Fields in the frequency range 9 kHz to 13.56 MHz	IEC 60601-1-2:2014+A1:2020 IEC 61000-4-39 :2017	PASS

Chapter III Scanner Settings

1 Before Scanning

● Check whether the camera tip has been cleaned and disinfected. If not, you can refer to Chapter Ⅴ for instructions on how to clean and disinfect it

● Ensure that there are no stains on the reflective mirror of the camera tip, as any stains can affect the scanning results.



⚠ **Note:**

- **Recommendation: Before scanning, warm up the intraoral camera for 5-10 minutes to ensure a smoother scanning process.**
- **If any fissures or damages are found on the reflective mirror or the window of the tip, it must be immediately taken out of use.**

2 Operating Instructions for Manager Setting

You can configure the settings using the Manager Setting as needed. Dentists/clinics/labs information, patient/case configuration, scanned data storage paths, etc. can be configured in this setting.

⚠ **Note:**

- **The Manager Setting should only be used by authorized intraoral scanner administrators.**

2.1 Management User Login

Start the SCAN application, then click the “ADMINISTRATION” as shown in Fig. 3-1. When loading is completed, the application enters the administrator login interface, as shown in Fig.3-2. Input the administrator password and click "Login" to enter the Manager Setting.

⚠ **Note:**

- **The default password is “admin”.**

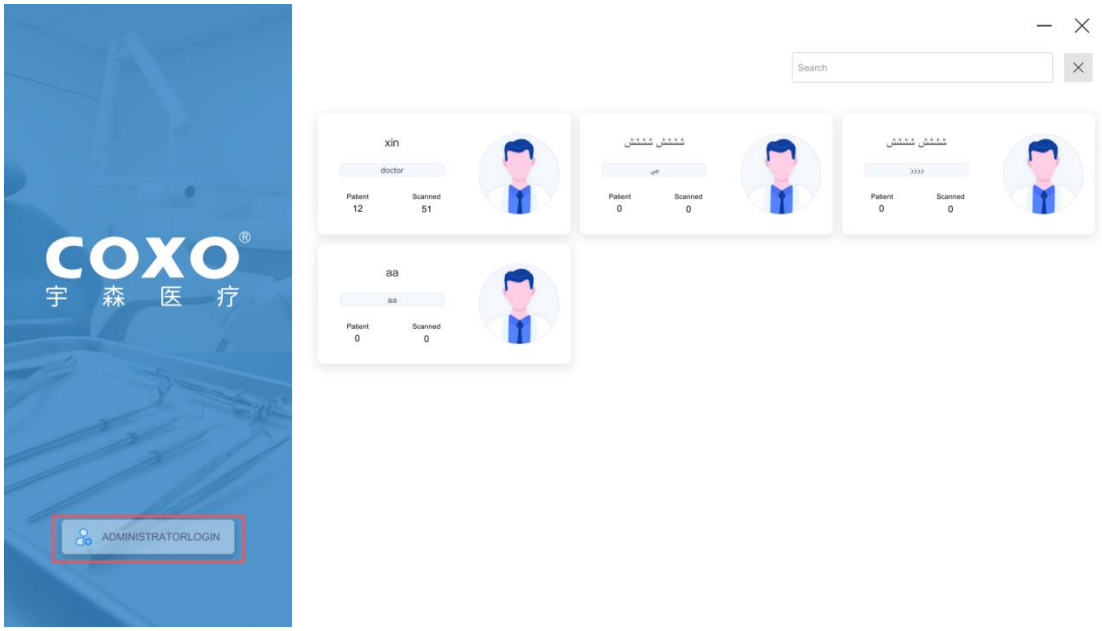


Fig. 3-1 Manager Setting

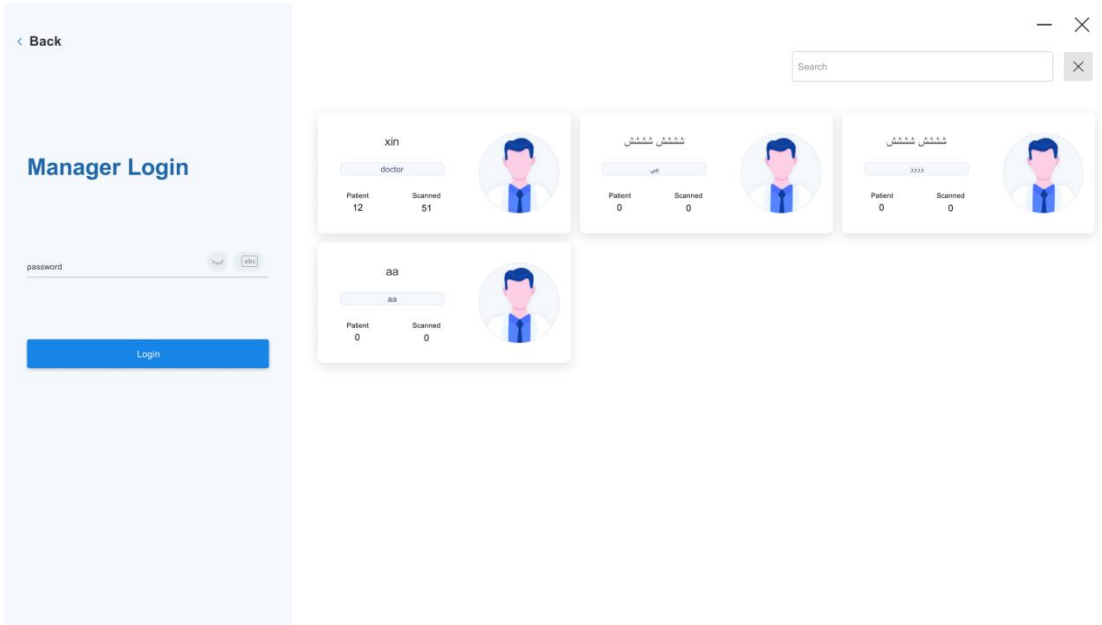


Fig. 3-2 Administrator Login Interface

After logging in, you can modify the administrator password as needed. Click the "  " on the upper right corner and a drop-down menu will pop up, as shown in Fig. 3-3. Click on “Password" to change administrator's password. Then, click "OK" and the new settings will be applied immediately,as shown in Fig. 3-4.

Fig. 3-3 Open Administrator’s Password

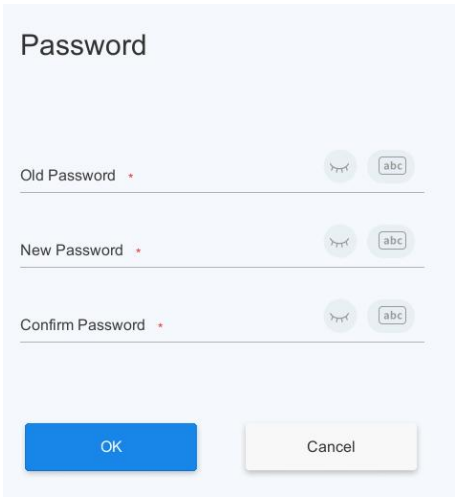


Fig. 3-4 Change Administrator’s Password

After logging in, a menu bar will appear on the left side of the interface, as shown in Fig. 3-5. You can create/amend the settings of user, patient, lab, case, camera and other.

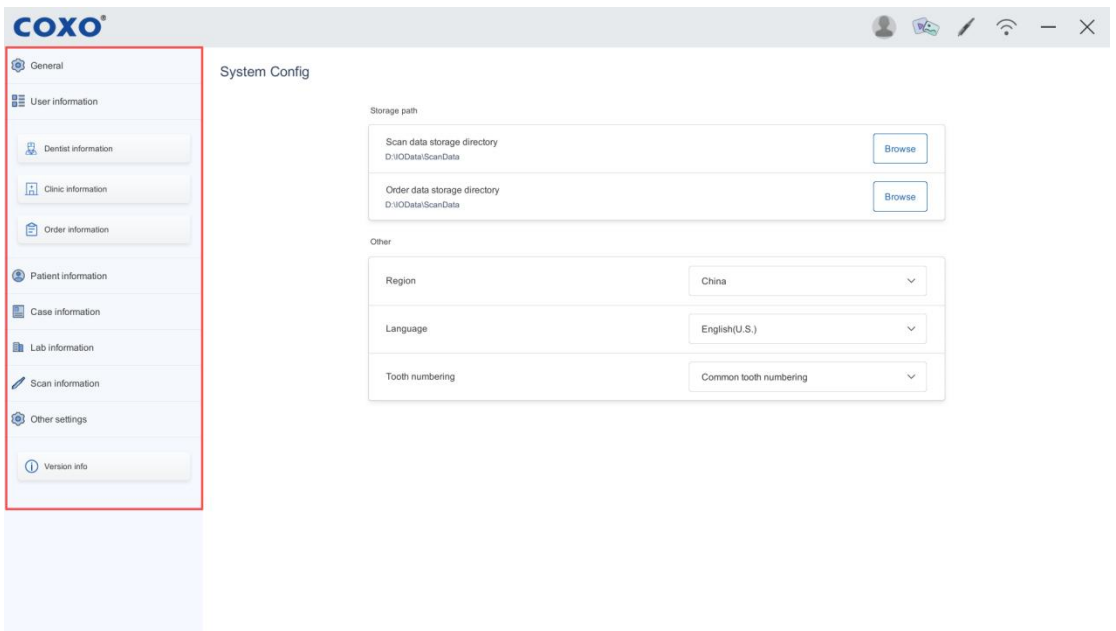


Fig. 3-5 Menu Bar

2.2 General Settings

Click "General" in the menu bar to enter the general settings interface of the Manager Setting, as shown in Fig. 3-6.

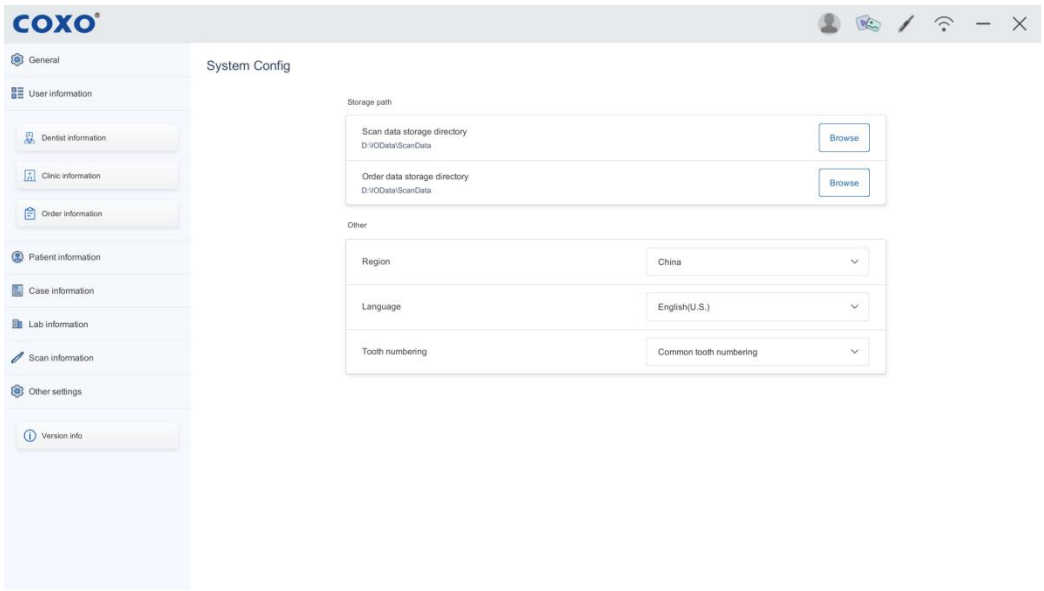


Fig. 3-6 General Settings Interface

- **Scan data storage directory:** You can set the scanned data storage directory for the Scanner application.
- **Order data storage directory:** You can set the order data storage directory for the Scanner application.
- **Region:** You may select according to your location. Currently there are two regions available: China and Other Countries.
- **Language:** You can set the language preference for the user interface. Currently 6 languages are supported, including Simplified Chinese, Traditional Chinese, English, French, Spanish and Russian.
- **Tooth Numbering:** You can choose the tooth numbering method of the dental arch diagram in the Scanner application. Currently the FDI numbering system and the Common tooth numbering system are supported.

Note:

➢ **After changing the language, restart the SCAN application to save the change.**

2.3 User Information Settings

Click "User information", from the drop-down menu bar, you can find edit the "Dentist Information" and "Clinic Information", as shown in Fig. 3-7.

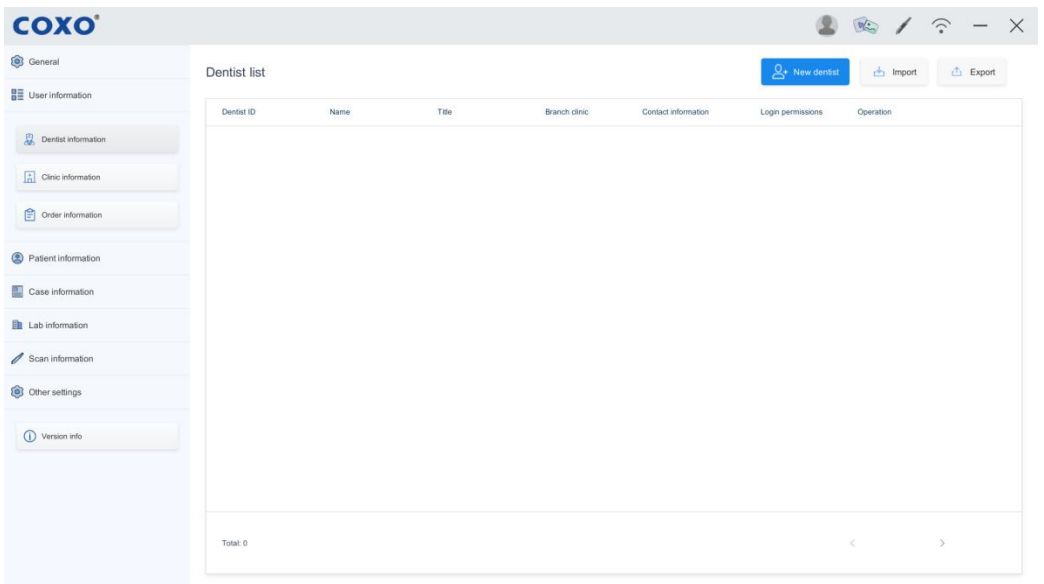


Fig. 3-7 User - Dentist Information

- **Dentist Information:** Add, delete or modify dentist's account for the scanning application. The dentist's account is used to login at the scanner application. After logging in, the dentist will be able to manage the patients at the scanner application.
- **Import:** Import bulk dentist accounts from an XML file.
- **Export:** Export part or all of existing dentist accounts to an XML file.

2.3.1 Add Dentist

To add a dentist account, click "New dentist" on the upper right corner of the interface to enter the dentist information, as shown in Fig. 3-7. After filling in the required information as in Fig. 3-8, click “Save” to exit. A "Dentist" account created for the first time is not activated, so the password input box will not be displayed. When you log in at the scanner application for the first time, the application will prompt the “Dentist” user to set a new password. After setting the password, the "Dentist" account will be activated.

- **Name:** The account name of the "Dentist".
- **Title:** Enter the dentist's title, such as "DDS", "MD" and “DR”.
- **Contact Information:** When an order is sent to a lab, the dentist's contact information will be displayed in the email.
- **Password login:** If this option is not selected, password setup is not required.If selected, you can choose to log in using a gesture pattern or a password.
- **Set Branch Clinic:** For large clinics, their branch clinic information can be added in the clinic information section. Branch information is shown in the branch list.
- **Prohibit login:** Once selected, this doctor will not be displayed on the login interface.

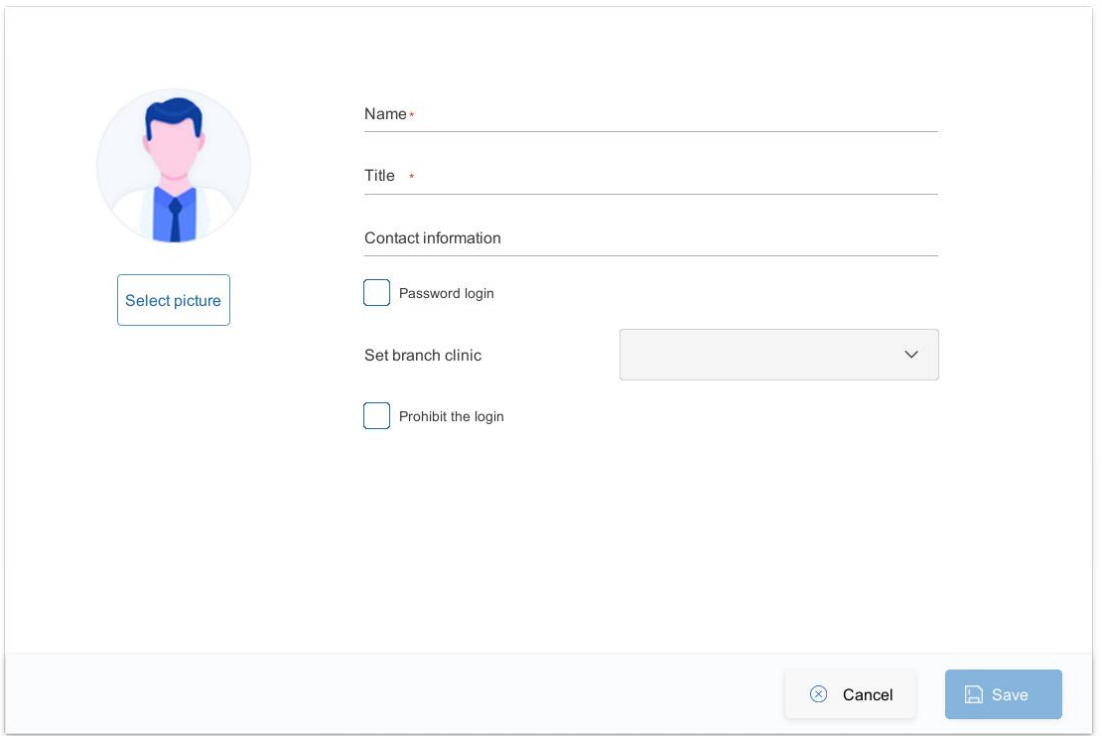


Fig. 3-8 Dentist Information Input

After inputting, click the "Save" button to add the "Dentist" information which can be viewed in the "Dentist List".

⚠ Note:

- **The dentist's contact information will be displayed in the order email when an order is sent to a lab. Therefore, it is recommended to complete this section properly.**
- **If a dentist needs to send orders through the Launca cloud platform, a valid email address binding to the dentist's account is required. Ensure the computer is connected to internet when adding the dentist's email. An email with a verification code will be sent from the Launca cloud to the dentist's mailbox. The administrator needs to enter the verification code to complete the binding.**

2.3.2 Edit and Delete Dentist

After adding a dentist account, it can be viewed, edited or deleted in the "Dentist List" interface. As shown in Fig. 3-9, you can find “Edit” and “Delete” button within the Operation section.

- **Edit:** If the current dentist information is incorrect, it can be modified in the “Edit” interface. In addition, the dentist can change the account and password in this interface.
- **Delete:** If the dentist no longer has permission to use this device, the administrator can delete the dentist's information.

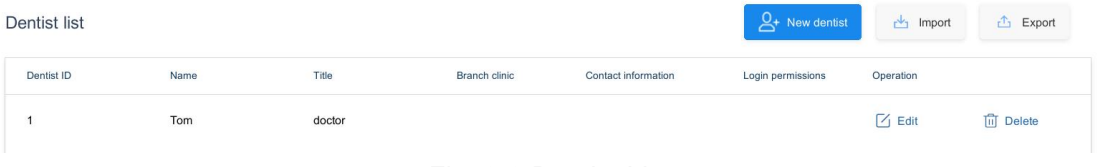


Fig. 3-9 Dentist List

2.3.3 Clinic Information

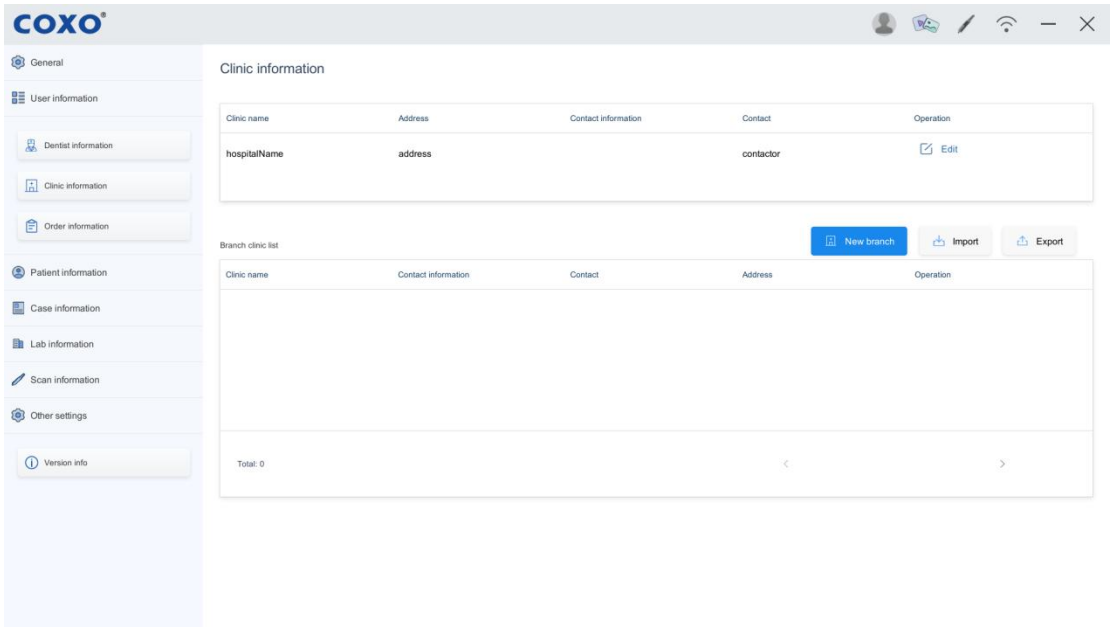


Fig. 3-10 Clinic Information

- **New Branch:** A branch clinic can be added. If a dentist is set as a branch member, the branch mailbox is set as the default for sending orders.
- **Import:** Import bulk branch clinic data from an XML file.
- **Export:** Export part or all of existing branch clinic data to an XML file.

In the clinic information, you can input clinic information. Click "Edit" to modify the main clinic settings; click "New Branch" to add a new branch.

The default clinic information is Launca Medical, as shown in Fig. 3-11.

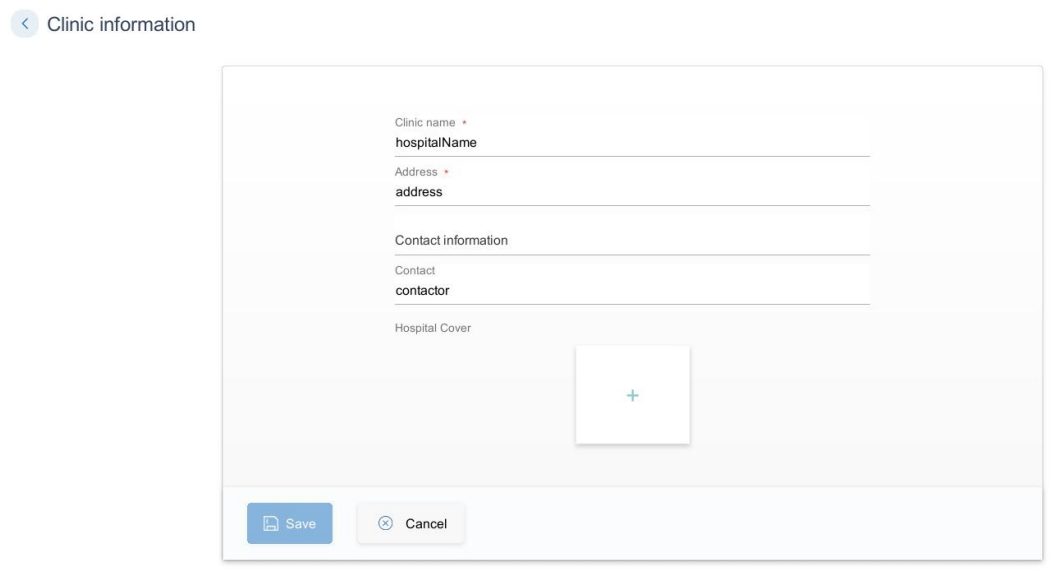


Fig. 3-11 Clinic Information Input

- **Name:** Input the name of the main clinic.
- **Address:** Input the address of the main or branch clinic.

- **Contact Information:** Input the telephone number of the main or branch clinic.
- **Contact:**Input the contact of the main clinic.

2.3.4 Order Information

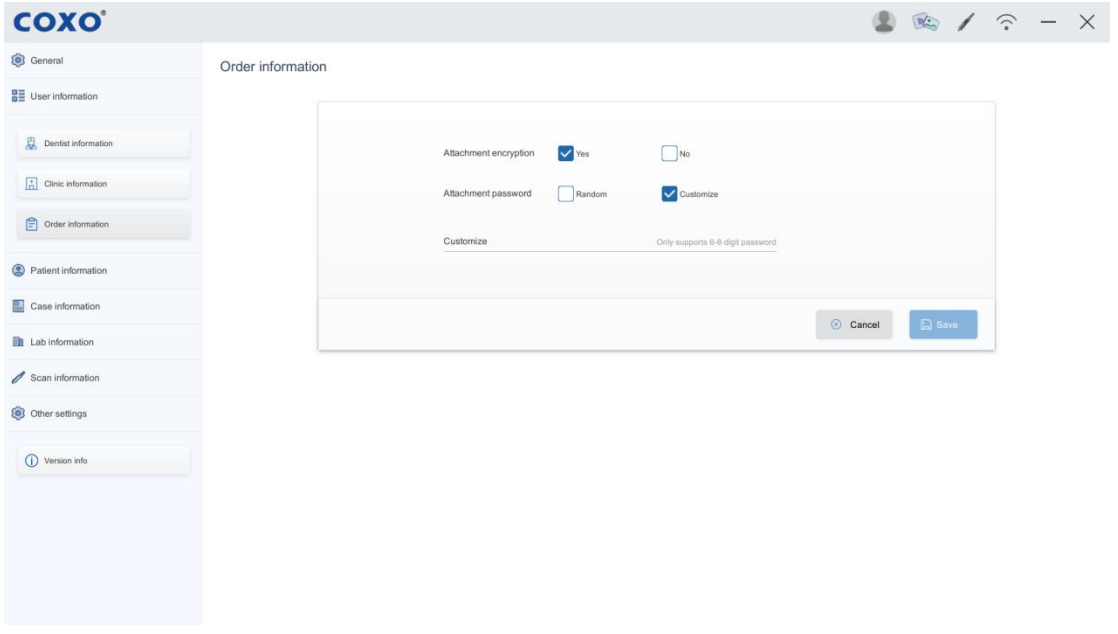


Fig. 3-12 Order Information

- **Attachment encryption:** Select whether to encrypt the order attachment.
- **Attachment password:** Select the encryption method for the order attachment.

2.4 Patient Information Settings

In "Patient Information", you can select optional and required patient information in a clinical case. For details please see Fig. 3-13.

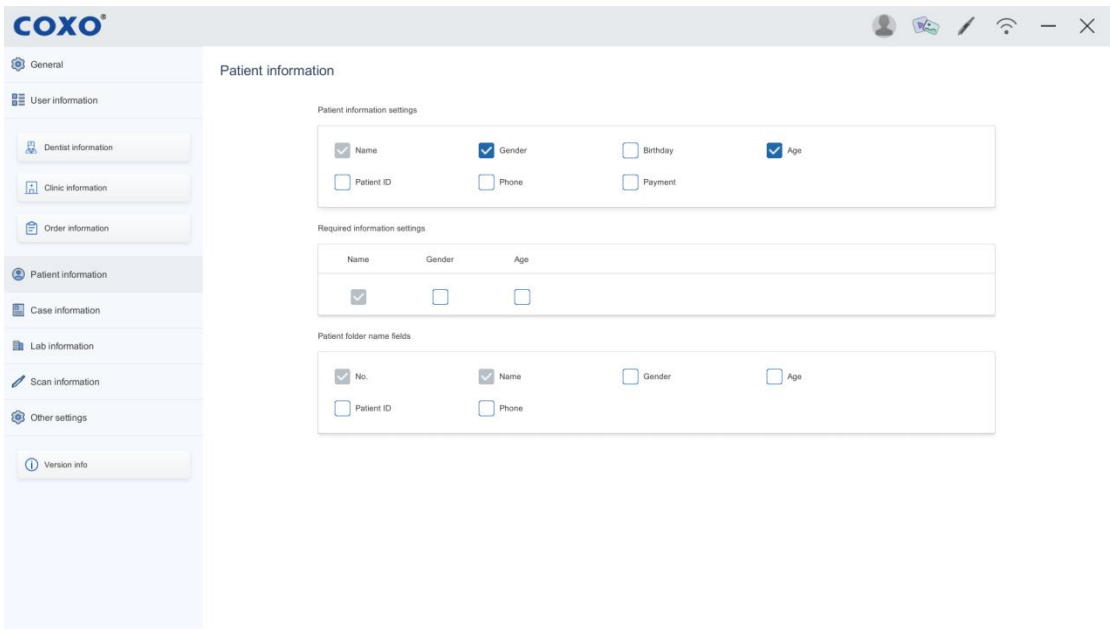


Fig. 3-13 Patient Information Settings

- **Patient Information Settings:** The SCAN application will show toggled information in the Patient Information interface.
- **Required Information Settings:** In the SCAN application, dentists must fill in required information in order to create a new patient.
- **Patient folder name fields:** The SCAN application will automatically create a folder on disk for each patient, the folder name is generated based on selected fields. For example, if “Patient ID”, “Name” and “Age” fields are toggled, a patient folder might be named as “id-1-name-ZhangSan-age-18”.

2.5 Lab Information Settings

The laboratory information can be edited here, as shown in Fig. 3-14.

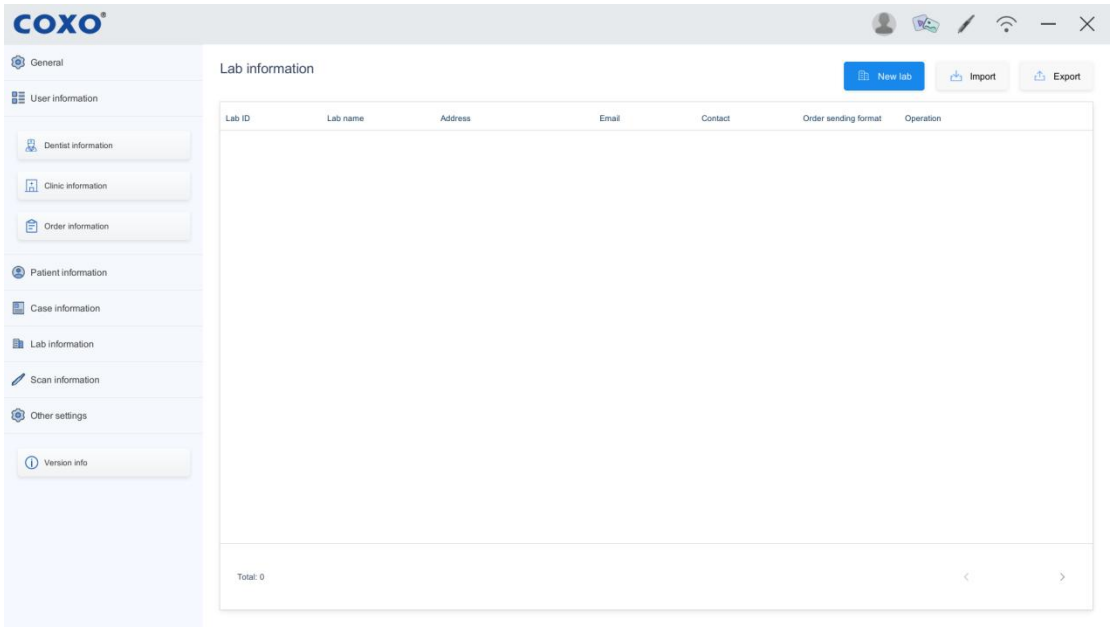


Fig. 3-14 Lab Information Settings

- **New lab:** Click “New Lab” to add dental laboratory information. The name of the lab, contact information, email address, etc. must be filled in the lab information input interface. **Orders will be sent to this email address via the SCAN application.**
- **Import:** Import bulk lab data from an XML file.
- **Export:** Export part or all of existing lab data to an XML file

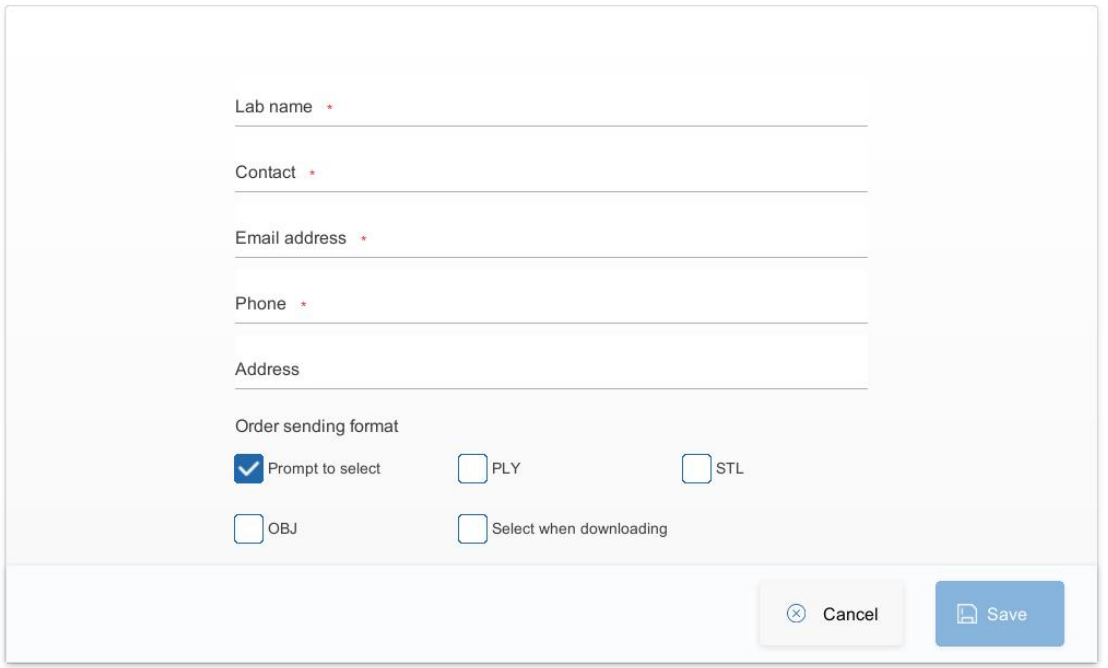


Fig. 3-15 Lab Information Settings

- **Lab Name:** Input the name of the Lab.
- **Contact Information:** Input the contact of the Lab.
- **Phone:** Input the telephone number of the Lab.
- **E-mail address:**Input the E-mail address of the Lab.
- **Address:** Input the contact of the Lab.
- **Order sending format:** You can select the data format of the orders sent to the lab.

2.6 Case Information Settings

You can set case information here, as shown in Fig. 3-16.

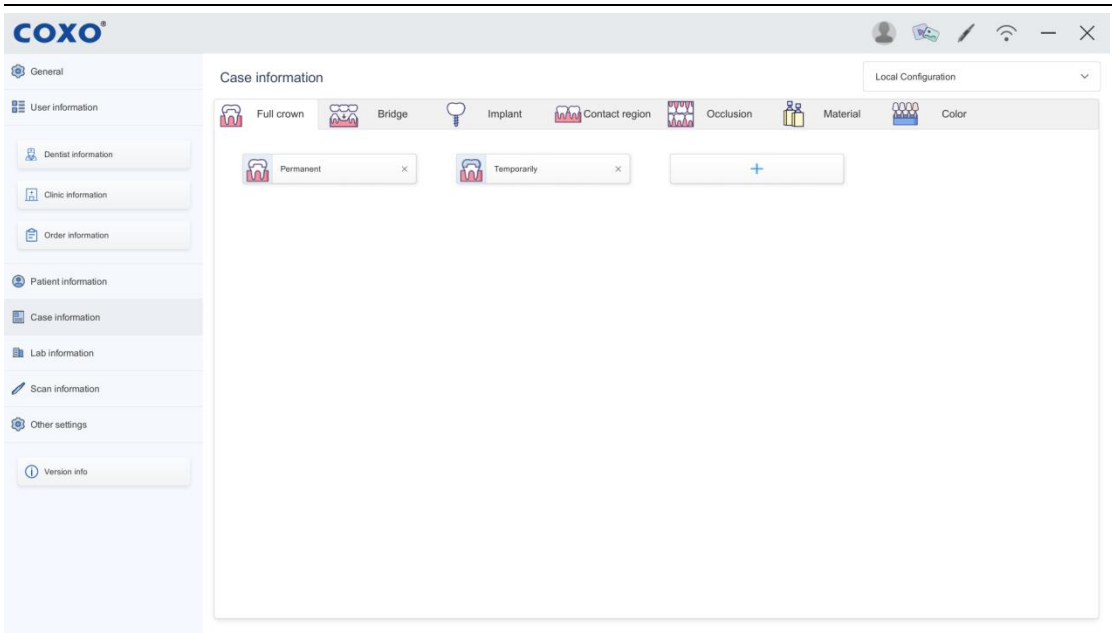


Fig. 3-16 Case Information Settings

Contact region, buccal, material, color and other options can be edited as needed. Input the name of the item in the dialog box and then click "Add" button to add a new item to the option's item list.

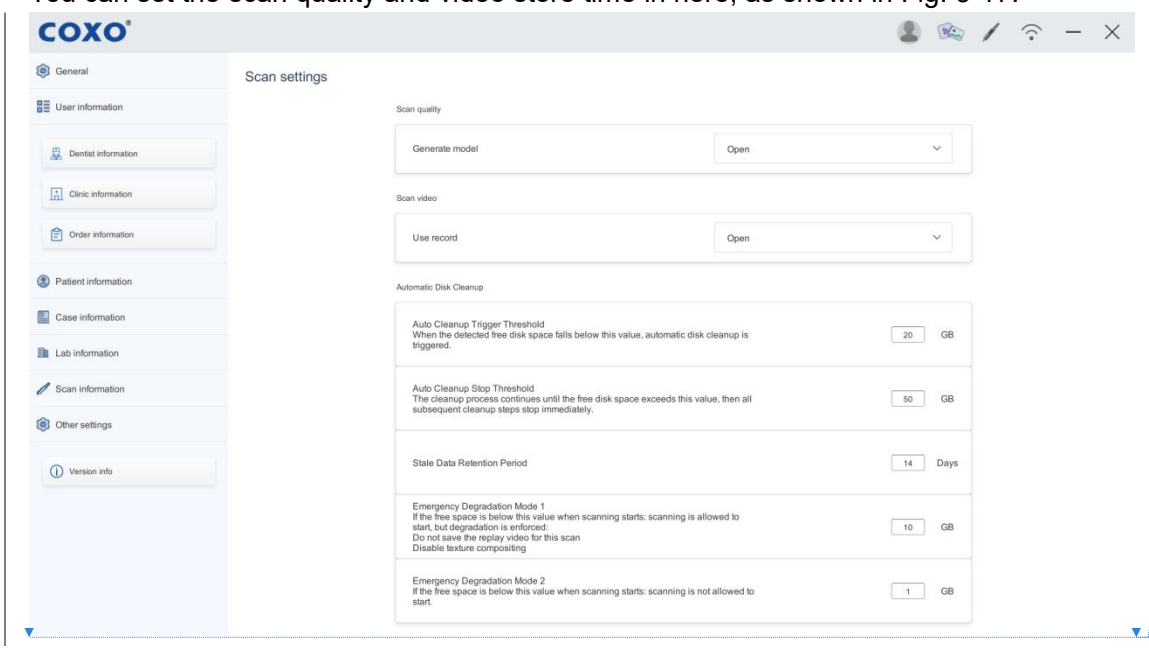
The administrator can choose default options for the SCAN application's case menu.

⚠ Note:

- **Default options cannot be edited or deleted.**

2.7 Scan Information

You can set the scan quality and video store time in here, as shown in Fig. 3-17.



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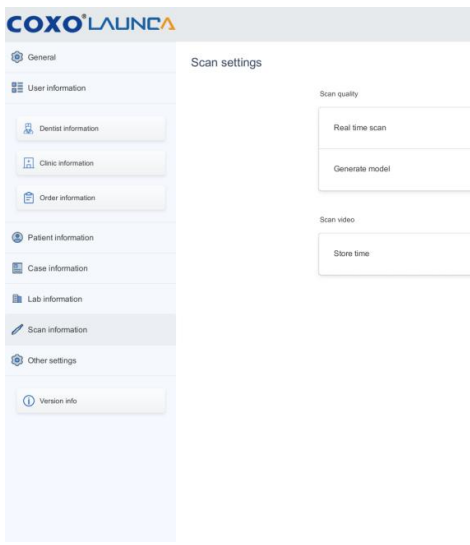

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Fig. 3-17 Scan Information

2.8 Other settings

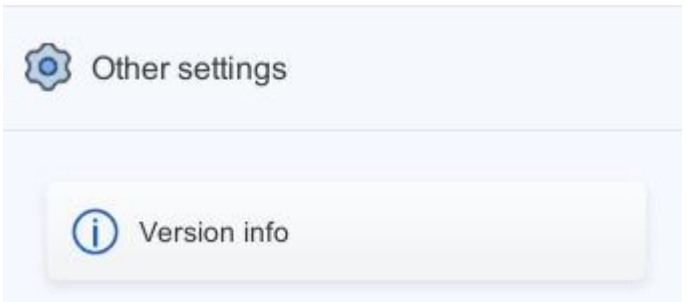

Fig. 3-18 Tool Menu Bar

Version info: The current software version is displayed.

Chapter IV Scanning Operation

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1 SCAN Application Login

After login to the SCAN application, dentists can set up patient and case information, scan the teeth and send order to a laboratory.

Before using the SCAN application for the first time, please configure the intraoral scanner settings and add at least one dentist account in the “Manager Setting”. Refer to "Chapter III Scanner Settings" for details.

The dentist login interface is shown in Fig. 4-1.

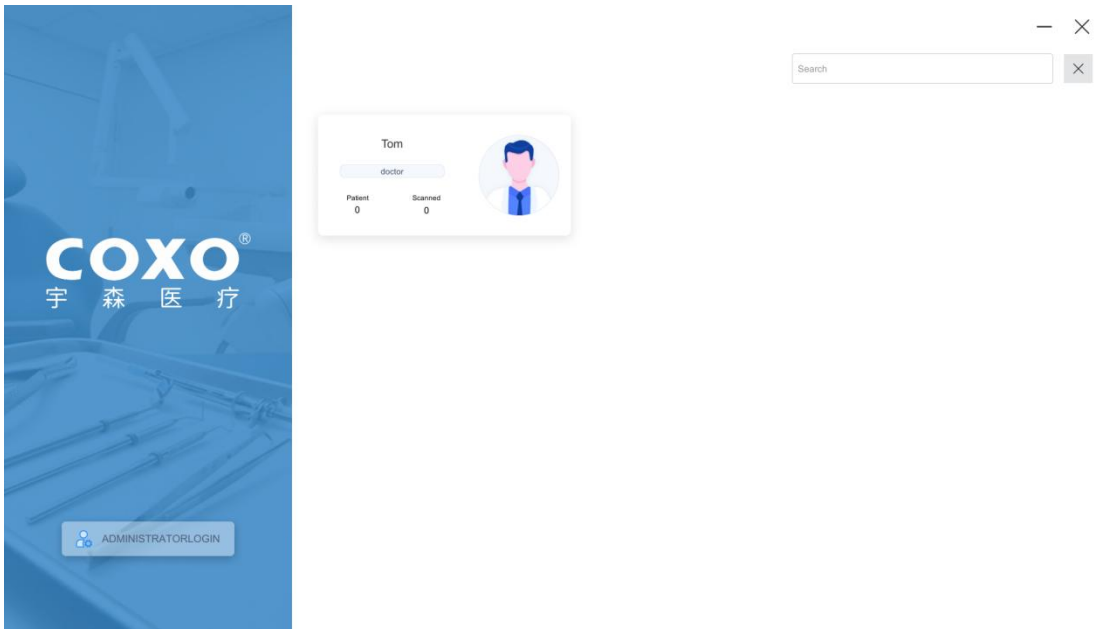

Fig. 4-1 SCAN Application Login Interface

Click on the "Dentist" icon as shown in Fig. 4-1.If password login is selected,enter the password which was set in "Chapter III 2.3.1.A gesture password needs to be set during the first login, as shown in Fig. 4-2.

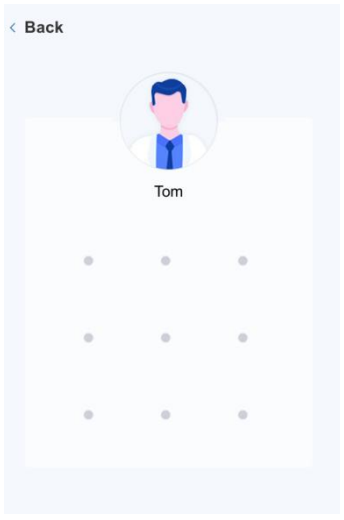

Fig. 4-2 Enter password to login

⚠ Note:

- **If you forget the login password , ask your system administrator to find it in**

the manager setting.

2 Setting Before Scanning

2.1 Add Patient

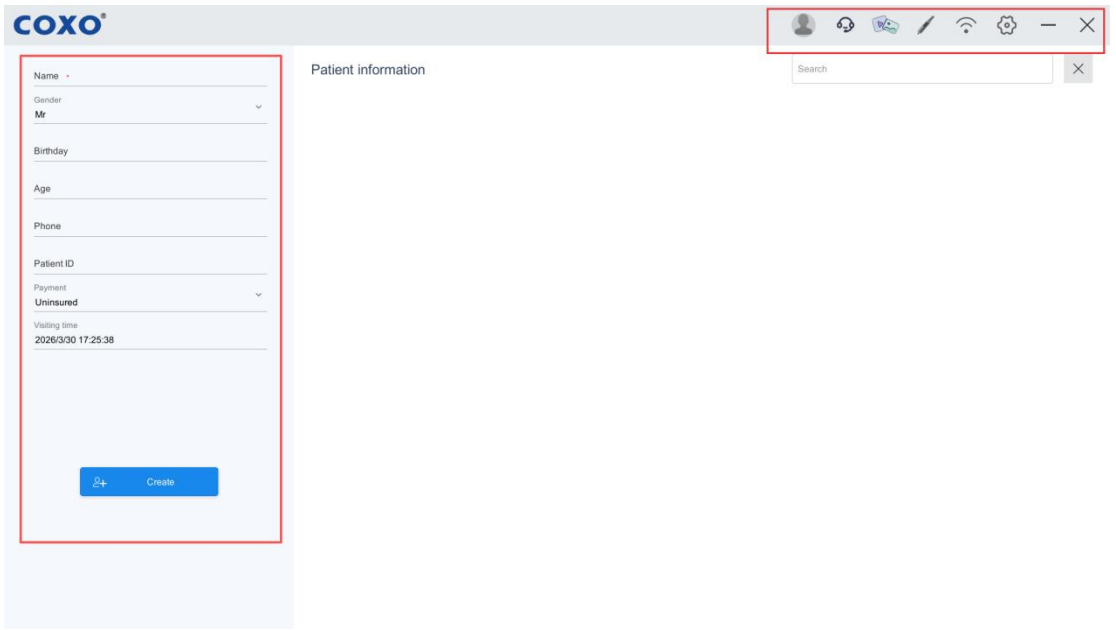

Fig. 4-3-1 Create a New Patient

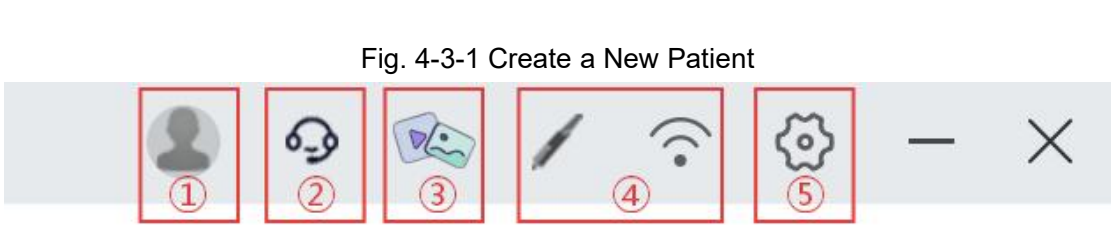

Fig. 4-3-2 Top Navigation Bar

After login, you will enter the patient information interface.

From left to right, the top navigation bar consists of: doctor-related information, feedback, screen recording/screenshot, camera connection status, network connection status, and management settings.

No.	Description
1 Doctor-related Information	● Cloud Orders: View historical sent orders as well as their sending and receiving statuses. ● Email: Orders sent after binding will be synchronized to the cloud platform of this email. ● Change Login Password: Click to modify the login password. ● About: View version information. ● Logout: Sign out of the current doctor account.
2 Feedback	Enter the problematic case, click “Feedback” icon, enter relevant information such as feedback description and personal email, then click Send.Without closing the software, open the network connection icon in item (4) and wait until the case feedback is completed.
3 Screen Recording /	● Browse Folder: Opens the folder for the current date when clicked. ● Video Settings: Configures video frame rate, and sets audio to software sound, device sound, or mute during recording.

Screenshot	● Record Video: Records the software screen. ● Area Screenshot: Allows manual selection of the area to capture. ● Screenshot: Captures the entire software interface.
4 Camera and Network Connection Status	When the camera icon is displayed  , it means the camera is not connected; if the red icon does not appear, the connection is successful. After opening the network icon, you can view the progress of the sent orders.
5 Management Settings	After clicking this icon, part of the management console settings will pop up, which can be customized according to the doctor's preferences, including language, tooth position, patient information, case information, and laboratory information.

Input the patient information in the interface as shown in Fig. 4-3-1 and click "Create" to add a new patient.

- **Name:** Enter the patient’s name.
- **Gender:** Select the patient's gender.
- **Age:** Input the patient's age.
- **Phone:** input the patient’s contact telephone number.
- **Patient ID:** The patient’s ID is generated automatically by the system when a new patient is set up. It is used for inquiry purposes.
- **Payment:** Click "▼" to select the method of payment from the drop-down menu.
- **Visit Time:** This will be inputted automatically by the system. You do not have to fill it in.

⚠ Note:

➢ **The information input box supports a fuzzy inquiry function. Input relevant information in the input box to inquire. If you cannot find the relevant user, you can add a new patient according to the above procedure.**

2.2 View Patient Information

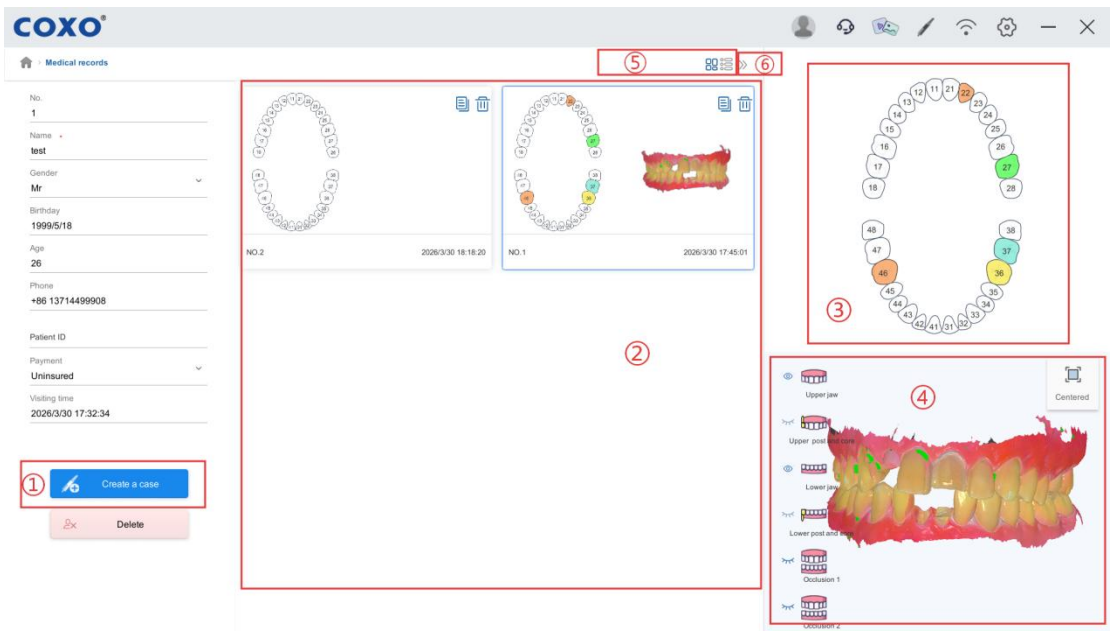

Fig. 4-4-1 View Patient Information and Case Records(Card Mode)

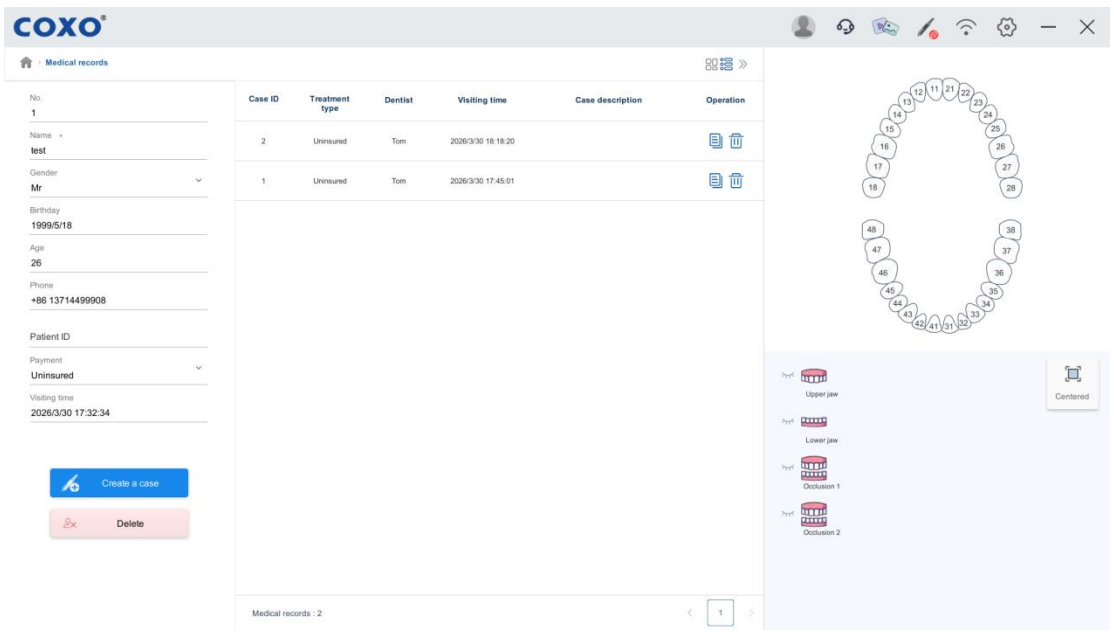

Fig.4-4-2 View Patient Information and Case Records(List Mode)

No.	Description
1	Create a case
2	Edit, view and delet a single case record
3	Corresponding to the dental arch information of the selected case record
4	Click the eye icon to view the scanned model corresponding to the selected diagnosis and treatment information
5	Switch the case records in item 2 to display in Card Mode / List Mode
6	Collapse the detailed display window on the right side

⚠ **Note:**

- **Clicking the "Delete patient" button will delete all the patient's case records, including scanned data and order records. This operation can NOT be undone. Therefore, please operate carefully.**

2.3 Case Information

Click the 

icon in the existing case records (as shown in Fig. 4-4) to enter the case information interface as shown in Fig. 4-5. The case can be set up following the below steps:

1) The teeth in the dental arch diagram (area ② in Fig. 4-5) will be selected and edited one by one. The position number of the selected tooth will turn red. The Dentist can edit the selected tooth with the **Case Menu** in the area ① shown in Fig. 4-5. The area ③ in Fig. 4-5 is the information area for the selected tooth.
2) If there is other necessary information in addition to the case options you can enter them in the “Case remarks” area ④ in Fig. 4-5.
3) After all the information is completed, click "Next" start the scanning window.

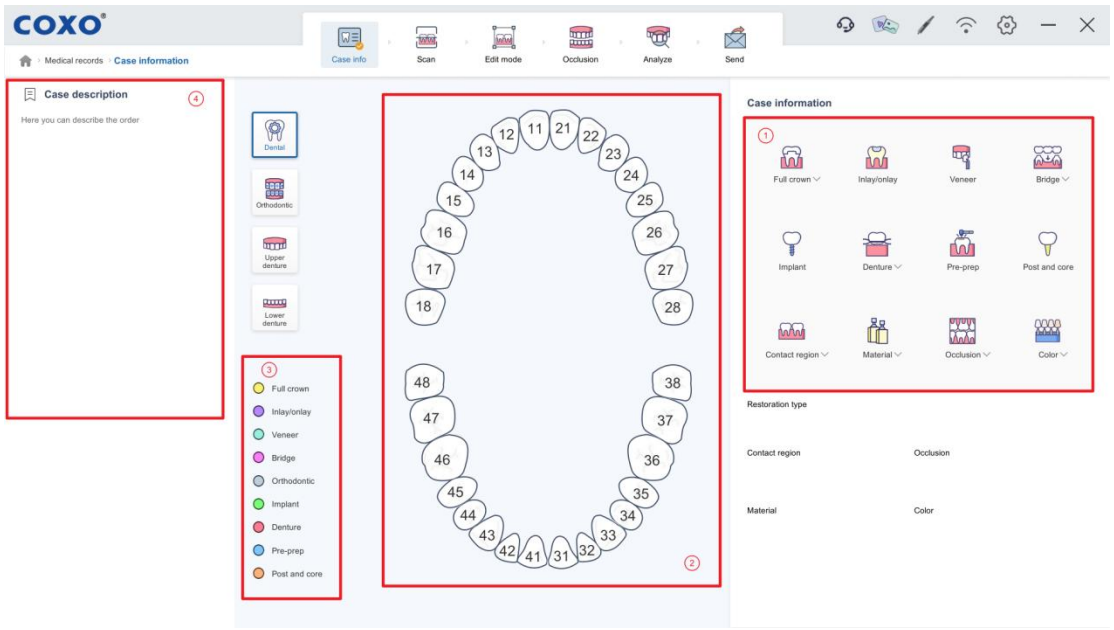

Fig. 4-5 Case Information

No.	Description
1	Case option menu.
2	Dental arch diagram and tooth numbering (currently both FDI notation and general tooth position recording methods are supported).
3	Selected treatment/material/colour for the tooth.
4	Case description or other necessary content.

The menu bar of case item and the dental arch diagram (including tooth numbering) can be set or modified in "Case Information" in the management application. For details, refer to "Chapter III 2.2 General Settings" and "Chapter III 2.6 Case Information Settings".

Scanning workflow and status are displayed as shown in Fig. 4-6. If the scan is completed, a yellow status prompt "✓" will appear on its icon. During the whole workflow, the green status prompt "✓" appears only when "Scan" or "Edit Mode" or "Occlusion" is completed. This status prompt does not appear for the "Case information"、"Analyze"and "Send" icons.

Fig. 4-6

⚠ Note:

- **Information of areas No. 2, No. 3, and No. 4 in Fig. 4-5 will appear in the order information. Therefore, please confirm the contents before sending an order.**
- **Some of the options in the case menu will make the scanner enter different scanning modes, such as implant mode. Please select the case properly to enter the correct scanning mode.**

3 Scanning

After confirming the case information, click "Scan" in the Scanning workflow to start the scan window. Fig. 4-7 shows that the scan window is loading. After the scan window starts, it will switch to the interface as shown in Fig. 4-8-1.

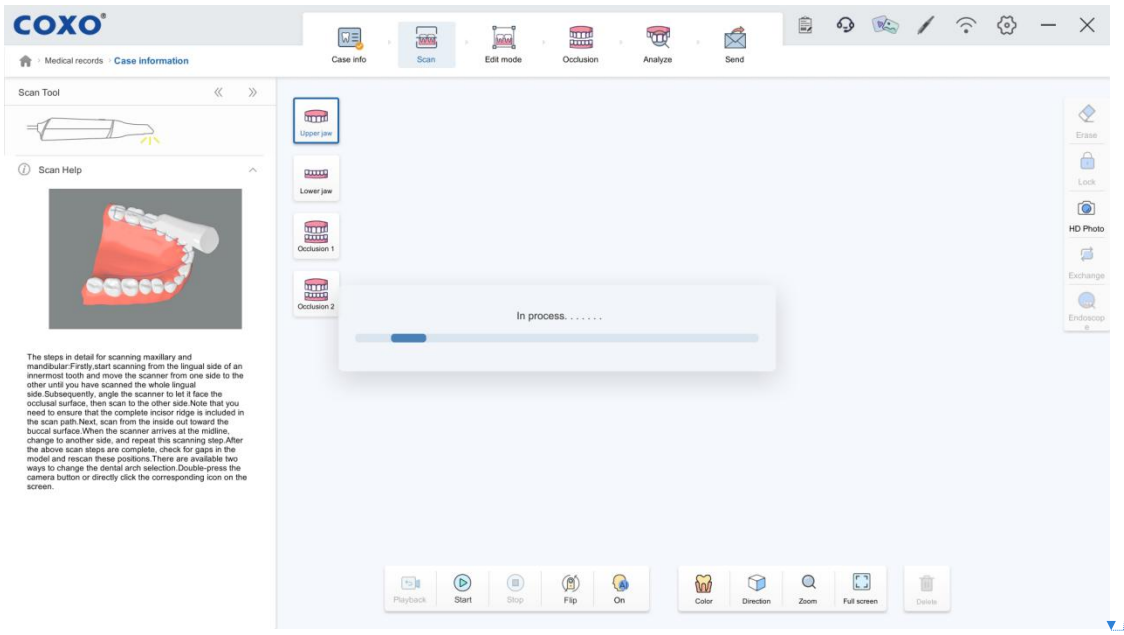

Fig. 4-7 The Scan window is Loading

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3.1 Scan window Interface Description

3.1.1 General Scanning Mode

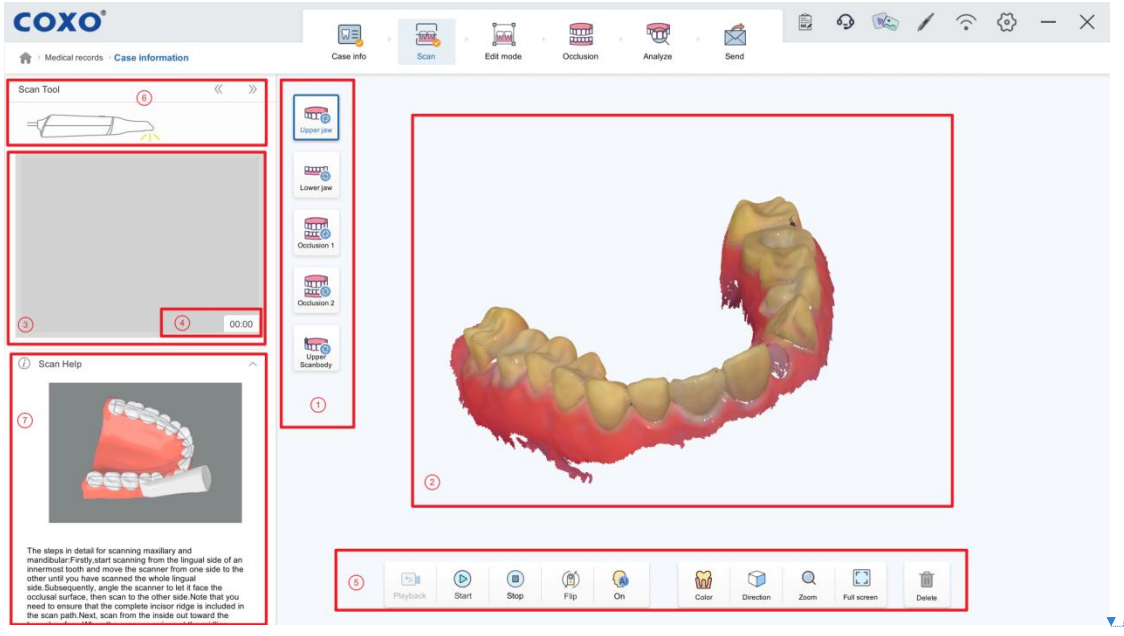
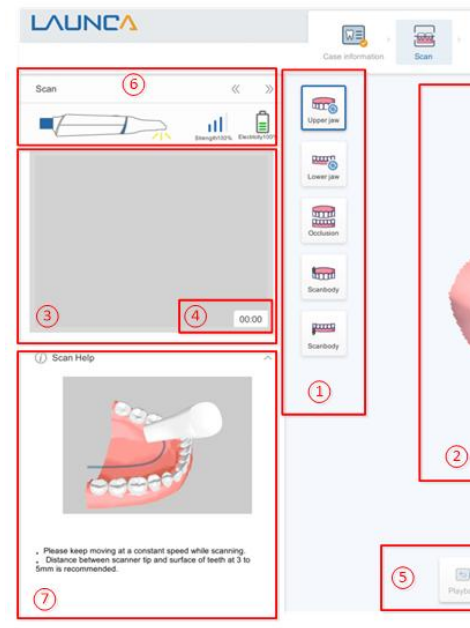


Fig. 4-8-1



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3.1.2 Function Area Description

No.	Description
1	Scanning Target Bar: Upper jaw, lower jaw, buccal, upper scanbody, lower scanbody • **Upper Jaw:** Click “Upper Jaw” to enter the upper jaw scanning mode. After scanning, the scanned data is saved as upper jaw data, and the

	icon will show on the upper jaw icon. • **Lower Jaw:** Click “Lower Jaw” to enter the lower jaw scanning mode. After scanning, the scanned data is saved as lower jaw data, and the icon will show on the lower jaw icon. • **Scanbody Upper** : Click “Scanbody Upper” to enter the upper jaw scanbody scanning mode. After scanning, the scanned data is saved as upper jaw scanbody data, and the icon will show on the upper jaw scanbody icon. • **Scanbody Lower** : Click “Scanbody Lower” to enter the lower jaw scanbody scanning mode. After scanning, the scanned data is saved as lower jaw scanbody data, and the icon will show on the lower jaw scanbody icon. • **Occlusion :** Click “Occlusion” to enter the occlusion scanning mode. In this mode,you don't need scan the whole model,you can scan one side,and then scan another side. After finishing scanning,it will show two side scaning data in the 3D Model display,and the icon will show on the occlusion icon, as show in Fig. 4-8-2.They will be automatically ransformed into a whole occlusion data in the next workflow.
2	3D Model Display Area: Real-time intermediate models or post-processed models are displayed in this area.
3	2D Image Window: This window is displayed in real time during scanning. When scanning does not start, the window is in grey rectangular shown in the area ③ in Fig. 4-8-1.
4	Timer: Counts the effective time of the current scanning.
5	Scanning Control Bar: Start, pause, stop, color, flip, delete. • **Playback :** Playback the scanning process . • **Start:** The camera starts scanning. To start scanning, you can either click the “Start” button on the screen or press the start button on the handpiece. • **Stop:** To stop scanning, you can either click the “Stop” button on the screen or press the “start” button on the handpiece to stop scanning; You cannot resume scanning after clicking “Stop”. Post-processing will automatically start when scanning stops; • **Flip:** Flip a 2D image horizontally. This function only affects real-time 2D images in the endoscopy window. This function does not affect 3D models. • **AI On/Off:** When “AI On” appear, the software automatically identifies the soft tissues of the mouth and the teeth , and only retains 3D data of the teeth and part of the gingiva in the area② in Fig. 4-9-1.When “AI Off” appear , this function is off. • **Color:** Indicates that the default 3D model is in color mode. Both "Color" and "Grayscale" modes are supported. • **Direction :** You can select a viewing angle of the 3D Model. It provides top, front, back,left,right and bottom fot selecting. • **Zoom :** Zoom in/out the 3D Model display • **Delete:** Delete a final 3D model that has been post-processed.

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View wifi strength and camera battery power when wireless is connected

(Applicable to Breezyscan)

设置格式[叶梓茵]: 正文, 段落间距段前: 0 磅, 段后: 0.2 行, 行距: 最小值 0 磅, 边框: 顶端: (无框线), 左侧: (无框线), 右侧: (无框线), 孤行控制, 与下段不同页, 段中分页, 不取消行号

6	If you are not familiar with using the device, you can scan by referring to the camera scanning demonstration video

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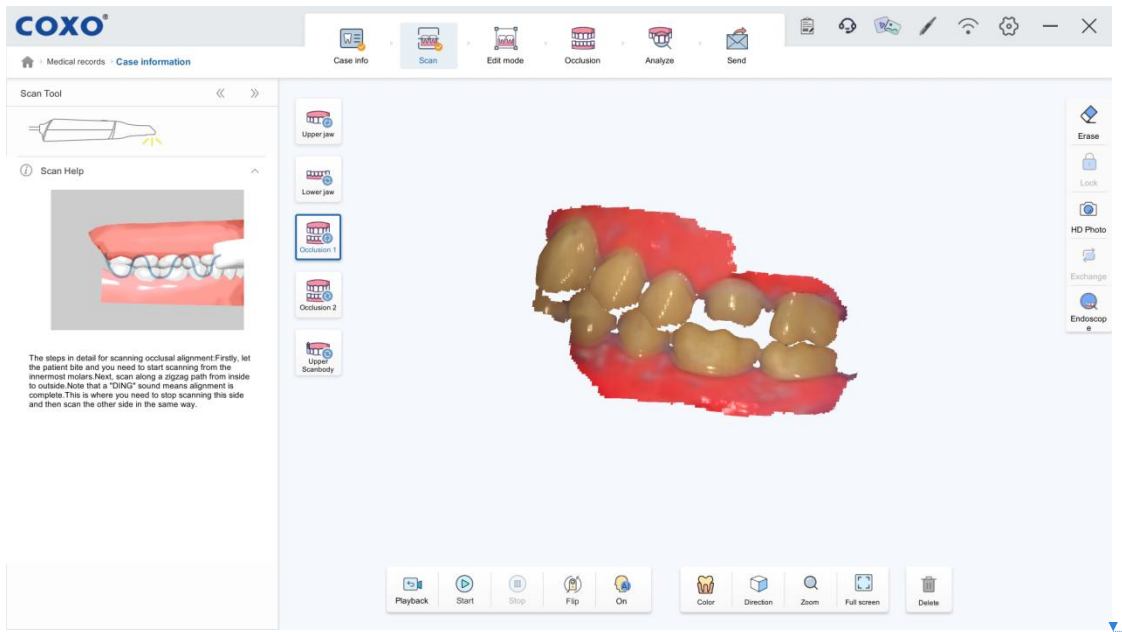

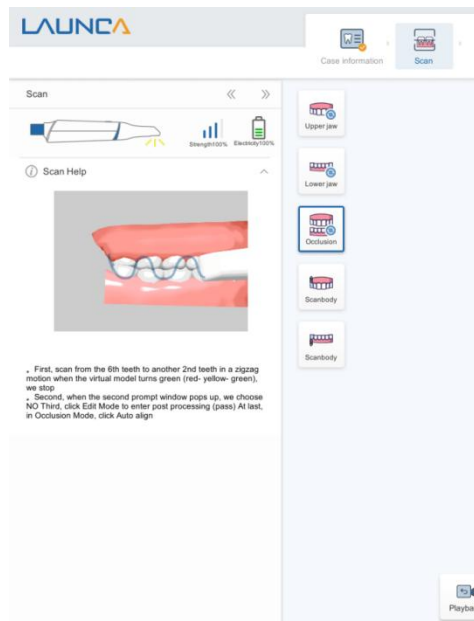

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Fig. 4-8-2

3.1.3 Model Operation Instructions

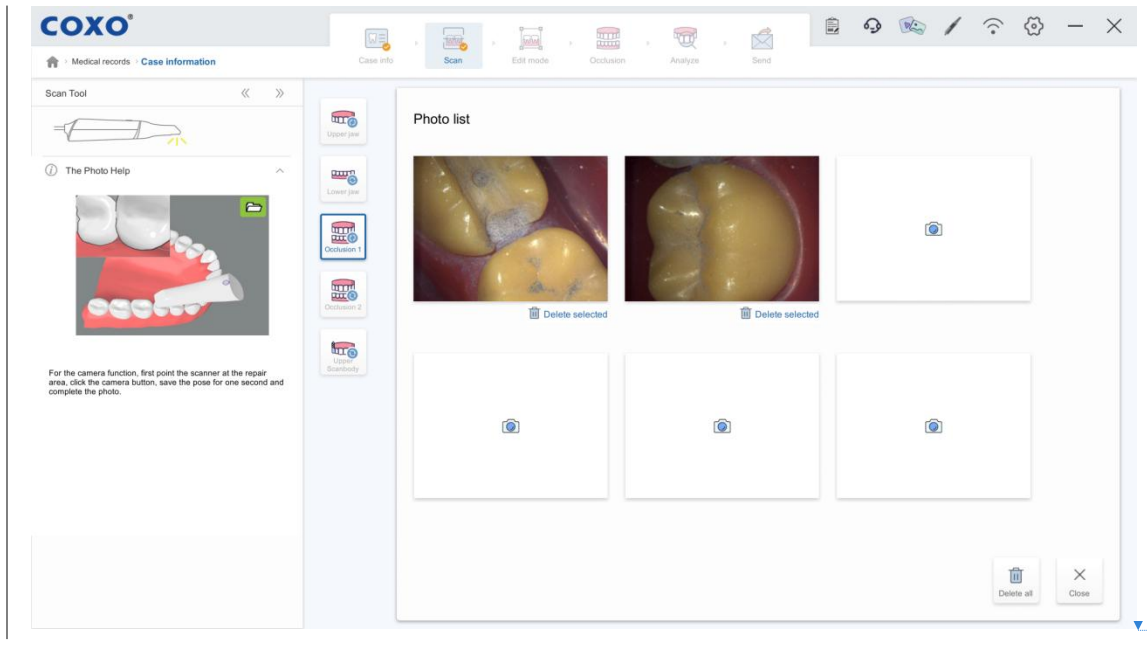
Operation	Description
Multi-touch Gesture Control	• **Move:** Hold and drag the model with two fingers. • **Rotate:** Hold and rotate the model with two fingers. Buccal parts in the Edit mode interface can only be rotated by one finger. • **Zoom:** Hold two points on the model with two fingers and move near or far to zoom in or out. Edit mode interface does not support the zoom function.
Mouse Control	• **Move:** Hold down the right mouse button and drag. • **Rotate:** Hold down the left mouse button and drag. • **Zoom:** Scroll the mouse wheel up or down to zoom in or zoom out. Zoom function cannot be used under Edit mode interface.

⚠ **Note:**

- **You must select a scan target properly from upper jaw, lower jaw, buccal, upper scanbody (implant mode), or lower scanbody (implant mode) before scanning. Otherwise, the models may not be correctly aligned in "Edit mode".**
- **The delete function is used to completely delete a 3D model, and can NOT be restored. Therefore, please operate with cautions to avoid scan data loss.**

3.1.4 HD Photo Capture

Click the "HD Photo" icon in the right navigation bar to capture real-time photos during the scanning process.



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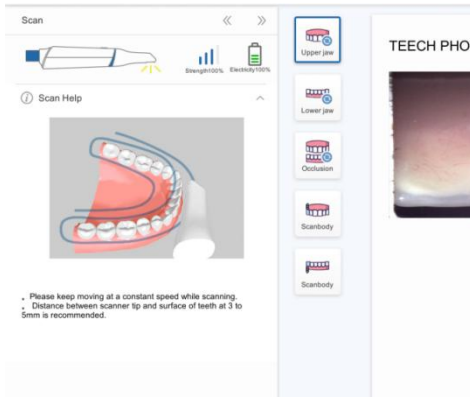

Fig. 4-8-3

3.1.5 Lock

You can pause during scanning and use the lock function. Click the “Lock” icon, select the area to be locked on the model, and this area will not be modified when scanning is resumed.

3.1.6 Exchange

After scanning is completed, click the “Exchange” icon to exchange the maxillary and mandibular models or the maxillary and mandibular scanbody models.

3.1.7 Endoscope

After scanning, click the “Endoscope” icon and click the desired position on the model to display the 2D scan image at that position, as shown in Fig. 4-8-4.

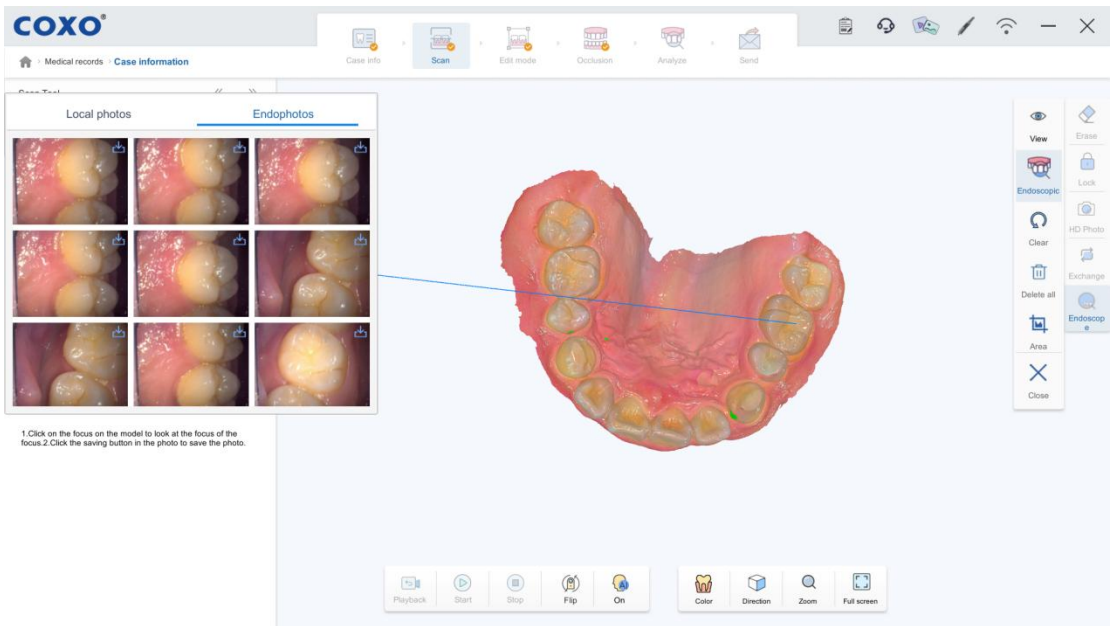

Fig. 4-8-4

3.2 Intraoral Camera Scanning Operation

3.2.1 Precautions of Intraoral Camera Operation

1) Make sure that the intraoral camera is properly connected to the Camera Adapter Bracket.
2) After pressing the start button on the handpiece for a few seconds, the intraoral camera indicator will light or flash. You can use the camera. It is not recommended if it is not lit.
3) **Do NOT** allow the laryngoscope, tongue or other objects to obstruct the scanning window during an intraoral scan.
4) **Do NOT** wipe the surface with a cotton pad or cotton stick when the scanning window of the intraoral camera appears misty. Any cotton product may pollute the front of the camera, dramatically decrease the quality of scan image.

3.2.2 Recommended Scanning Order

1) General Mode

Upper Jaw → Lower Jaw → Occlusion, or

Lower Jaw → Upper Jaw → Occlusion

2) Single Upper Implant Mode

Upper Jaw → Upper Scanbody → Lower Jaw → Occlusion, or

Lower Jaw → Upper Jaw → Upper Scanbody -> Occlusion

3) Single Lower Implant Mode

Lower Jaw → Lower Scanbody → Upper Jaw → Occlusion, or

Upper Jaw → Lower Jaw → Lower Scanbody → Occlusion

4) Upper and Lower Implant Mode

Upper Jaw → Upper Scanbody → Lower Jaw → Lower Scanbody → Occlusion, or

Lower Jaw → Lower Scanbody → Upper Jaw → Upper Scanbody → Occlusion.

3.2.3 Operation of Intraoral Camera

The intraoral camera features a simple one-button operation. You can perform all operations with only one button: Each time you press the start button of the intraoral camera, the scan window will switch as shown in Fig. 4-9.

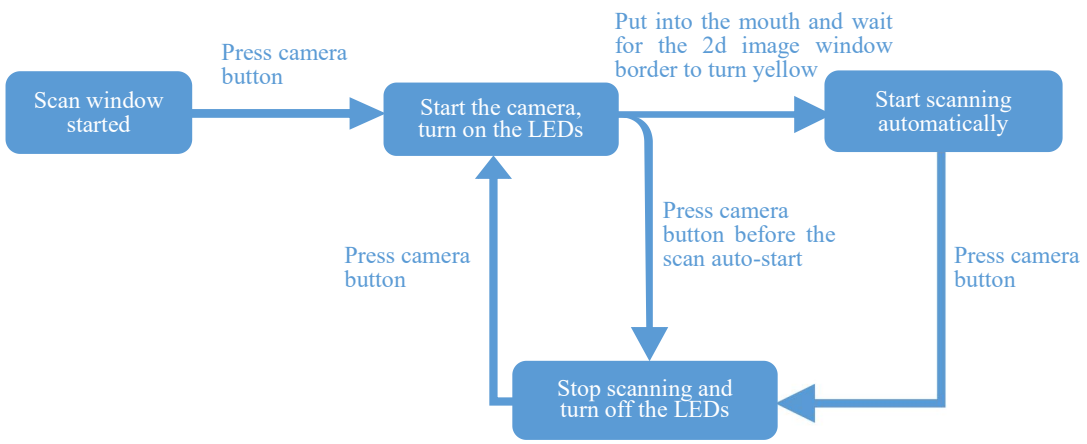

Fig. 4-9

1) Take out the intraoral camera, select one part to scan from the scanning target bar (upper jaw, upper scanbody, lower jaw, lower scanbody, buccal). Press the "Start"

button on the handpiece, the LED lights at the front of the camera will begin to flash. Place the camera into the patient's mouth. You can observe the mouth in real time from the 2D image window of the area ③ in Fig. 4-8-1.

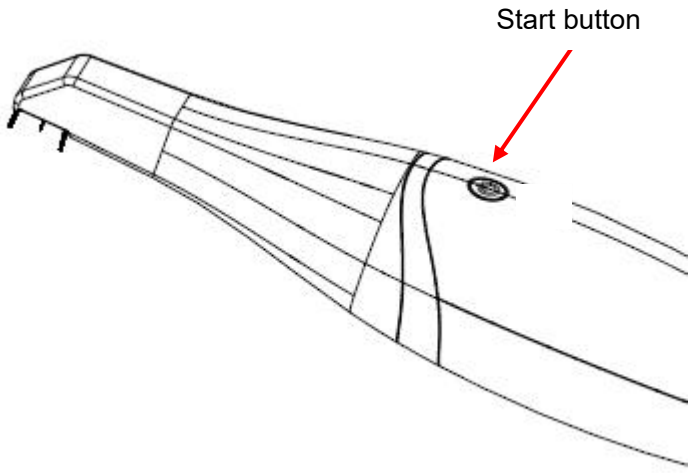

Fig. 4-10

2) Point the scanning window to the teeth to be scanned, and observe the teeth in the 2D image window in the area ③ of Fig. 4-8-1. Wait for the window border to turn yellow and keep the camera stable for two seconds, the scanning will start automatically, as shown in Fig. 4-11.

⚠ Note:

- **To ensure the best quality of 3D scanning, it is recommended that the scanning window of the intraoral camera and the teeth to be scanned are kept at a constant distance of 5~15mm during scanning.**

After starting the camera, the sensing status of the 2D image window is as shown in Fig. 4-11.

Fig. 4-11

- Yellow: Camera sensing succeeds. The camera will automatically start scanning when the yellow status remains stable for two seconds. Do not press the camera button again. If you press the camera button, scanning will stop.
- Green: Scanning is in progress.
- Red: Indicates interruption of scanning due to losing track of camera position. Possible reasons include: ◦No camera calibration file. Abrupt change in position of intraoral camera (i.e., the intraoral camera moves too quickly).

⚠ **Note:**

- **If the camera loses its position, point the camera's scanning window at any previously scanned area. The camera will automatically recover the track of position and resume scanning.**
- **The model displayed in the 3D model preview area indicates positions that have been scanned. You can refer to the preview model to quickly recover the camera position.**

3) When scanning, the prepared tooth and its adjacent teeth should be scanned completely so that a restoration can be properly designed based on the 3D model. Users can click the “Pause” button on the user interface to pause the scanning, then rotate the preview model to check the scanning quality.
4) Make sure that the clinically required 3D model has been completely acquired before the scan stops. There are two ways to stop scanning:
   - Click the "Stop" button on the user interface (in the area ⑤ of Fig. 4-8-1) to finish the scanning.
   - Press the button on the intraoral camera to finish scanning.

After post-processing is finished, a blue "✓" will appear on the corresponding scanning target icon, as shown in Fig. 4-12.

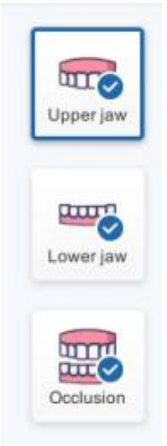

Fig. 4-12

5) Check whether the 3D model is complete. After post-processing is finished, a complete 3D model will be displayed in the model preview area. Check the 3D model carefully by rotating, moving, or zooming in/out on the mouse or touch screen. If the 3D model does not meet the clinical requirements, you can click the "Delete" button to delete the model, and re-scan following the steps 2) -5).
6) Select another scan target for the next scanning. The steps are the same as in steps 2) - 6). Repeat steps from 2) to 6) and ensure the items in the scanning target bar are all toggled in green, as shown in area ① of Fig. 4-8-1. This indicates that the data of all parts has been scanned and post processed. Thus, the scanning process has been completed.

3.3 Edit mode

After scanning, click “Edit mode” in the Fig.4-6 can enter the edit page, in which page the user can use "Erase"、"Fill" and "Invert" function to adjust the model,as shown in Fig. 4-13.

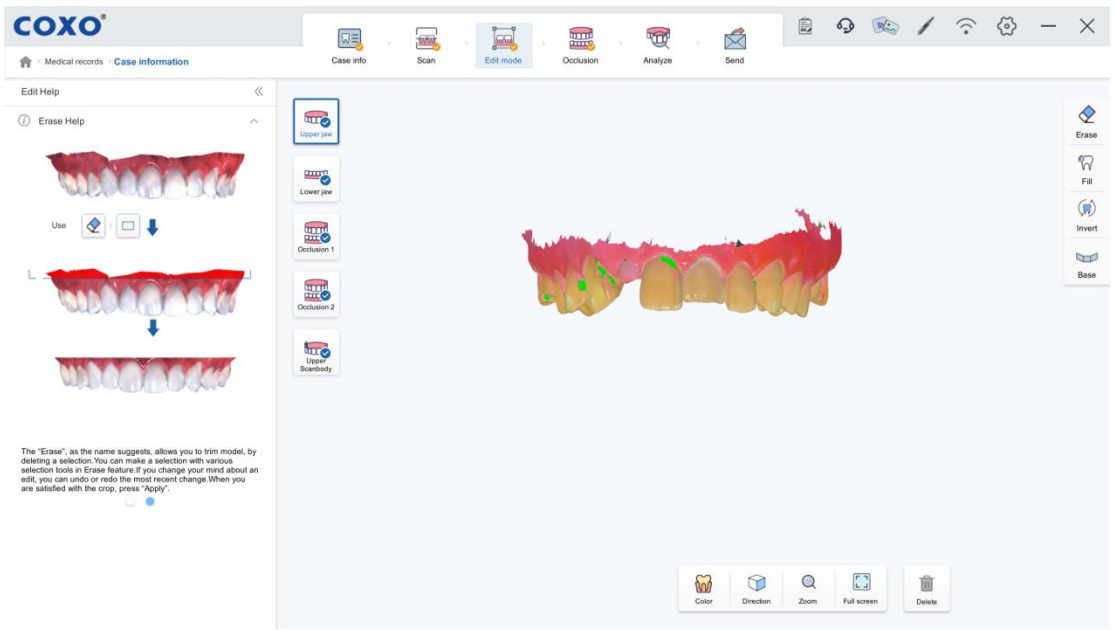

Fig. 4-13

- **Erase :**Trim unnecessary part of the model
- **Fill:** Fill the hole in the model automatically
- **Invert:** Invert the model direction automatically
- **Base：** Generate a base for model printing

4 Model Analyze

4.1 Occlusion analyze

Click "Occlusion" icon on the navigation bar to get the occlusion model which can be marked with different colors,as shown in Fig.4-14.

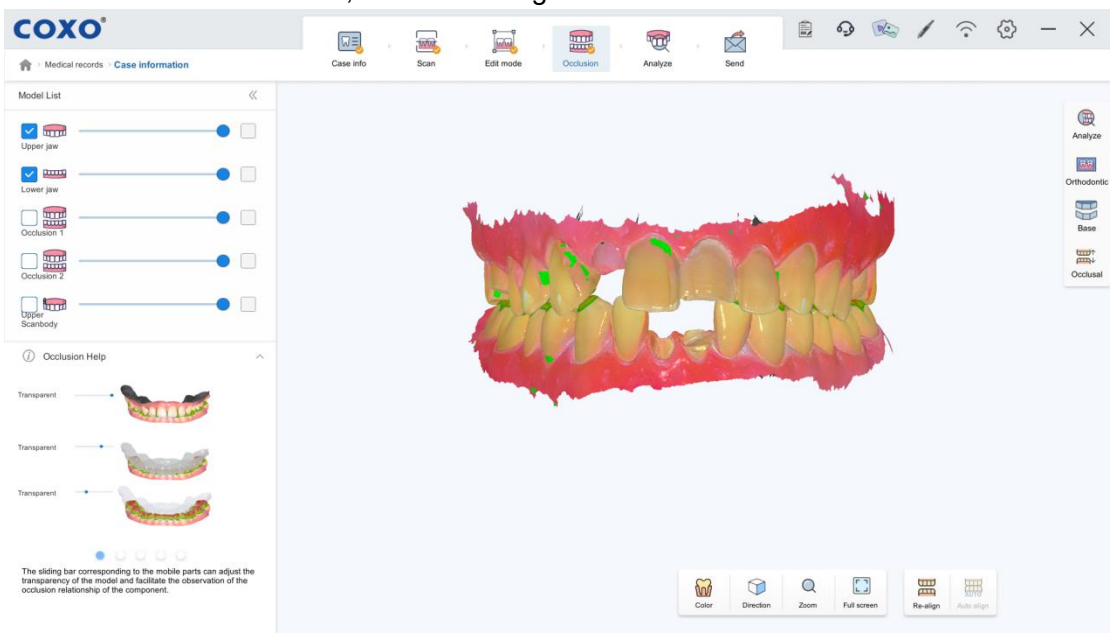

Fig. 4-14

Then click the "Analyze" icon in the right navigation bar of the "Occlusion" page to check the occlusion relationship of the model. User can analyze the distance between maxillary

teeth and mandibular teeth, as shown in Fig. 4-15.

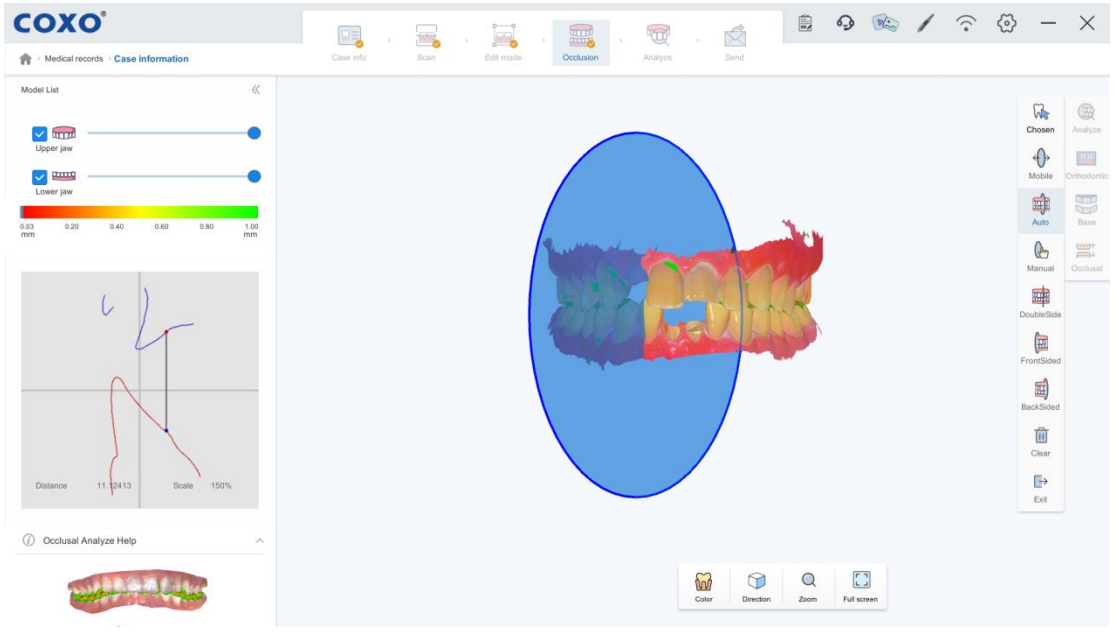

Fig. 4-15

4.2 Orthodontic Comparison

Click the Orthodontic Comparison icon, select extraction or space retention as required, then click Start Simulation to preview the approximate effect of orthodontic treatment on the current model，as shown in Fig. 4-16.

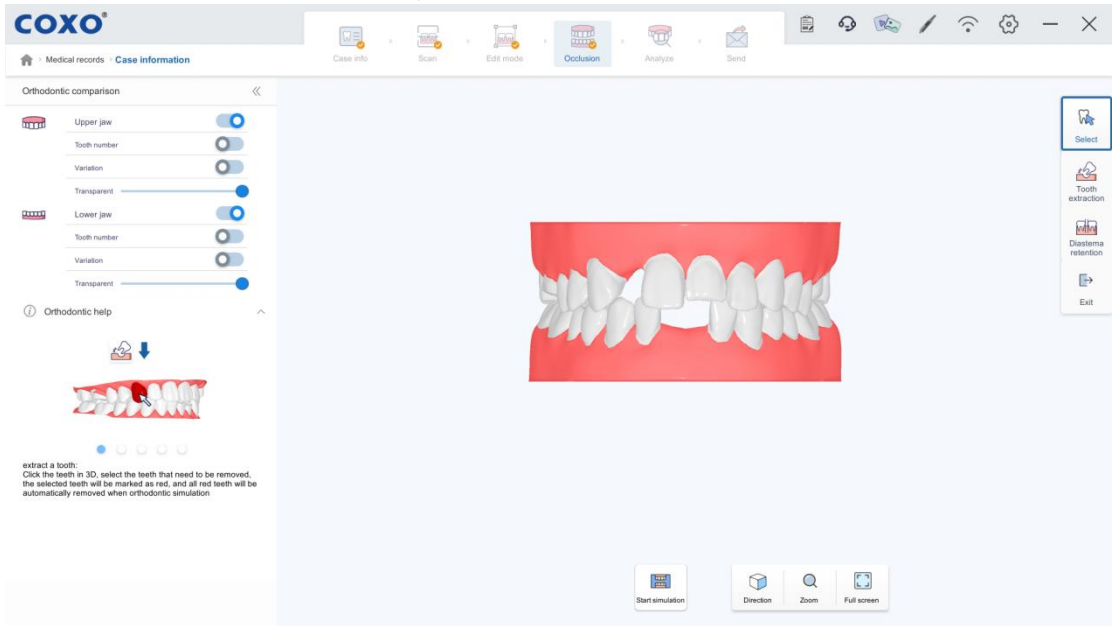

Fig. 4-16

4.3 Occlusal

Click the Occlusal icon to enter the expansion interface. You can drag the progress bar or click the play button to display the occlusion expansion animation,as shown in Fig. 4-17.

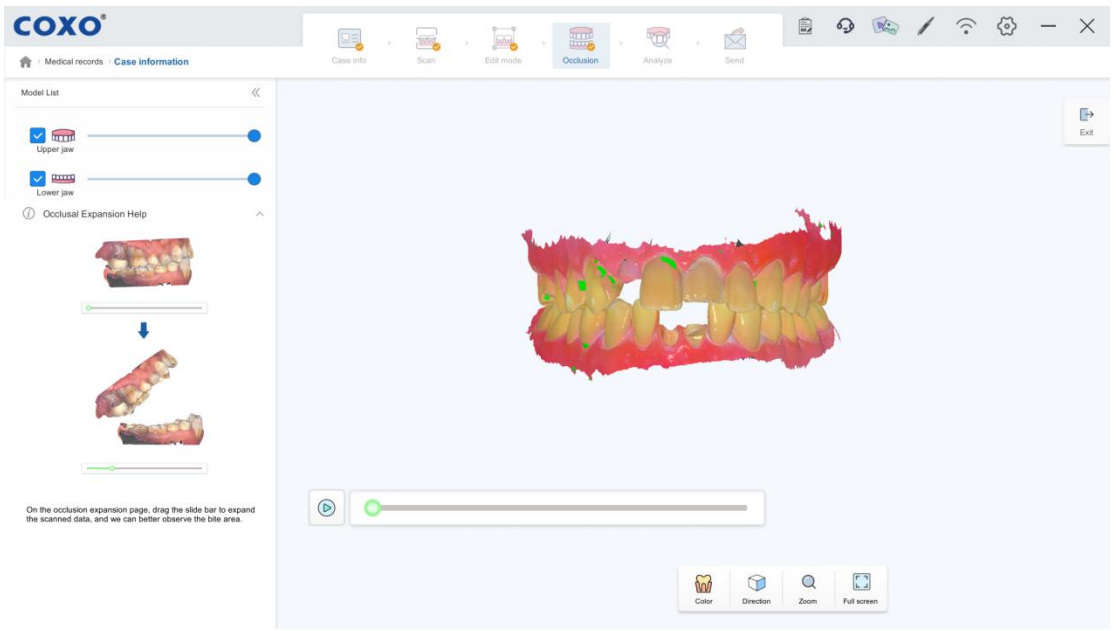

Fig. 4-17

4.4 Undercut, Margin line and Measurement

Click the "Analyze" icon on the top navigation bar to enter the analyze page, in which page the user can check the undercut of the model and draw margin lines and measure distances on the model, as shown in Fig. 4-18-1,Fig.4-18-2 and Fig. 4-18-3.

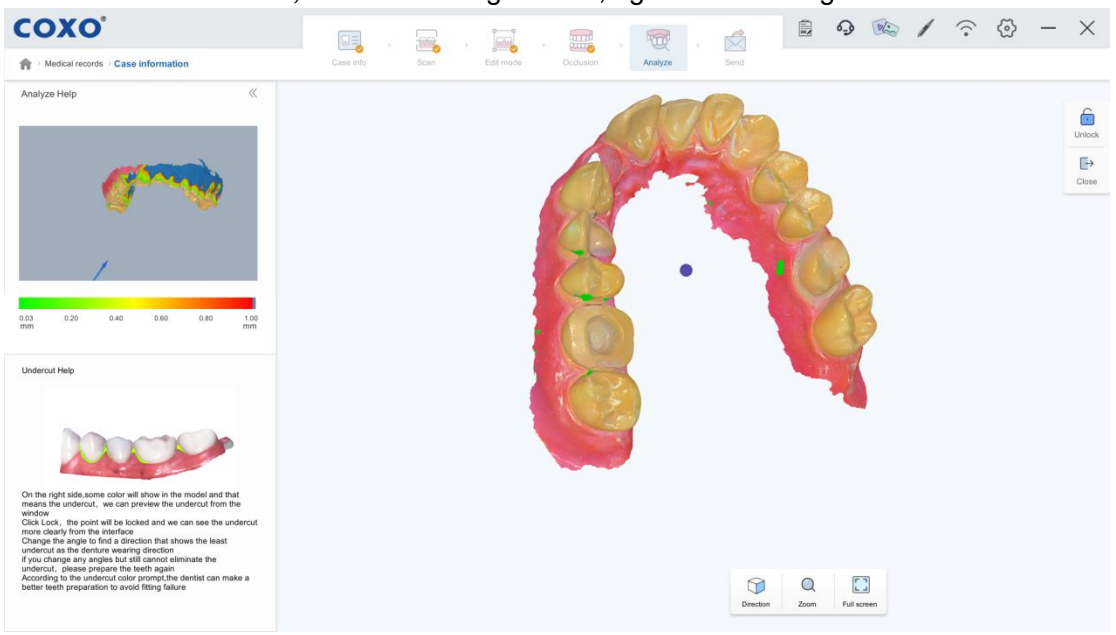

Fig. 4-18-1 Check the undercut

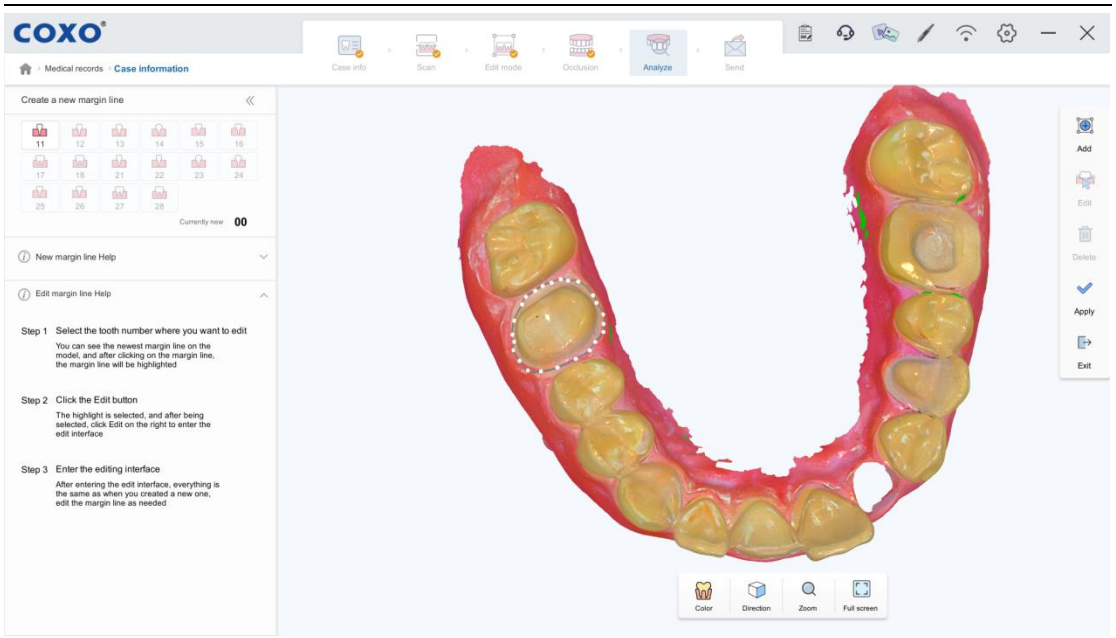

Fig. 4-18-2 Draw margin lines

Fig. 4-18-3 Measurement Interface

⚠ Note:

- **After scanning and post-processing are completed, click the “Report” icon as shown in Fig.4-18-3 item ① to generate a Intraoral scanner AI report.The doctor can fill in medical comments and revise the auto-generated content.Finally, the report can be saved, exported, attached to an order, or directly delivered to the patient.**

5 Order Sending and Management

When the model scanning, editing and other processes are completed, click the "Send" button on the top toolbar to enter the order sending interface, as shown in Fig. 4-19.

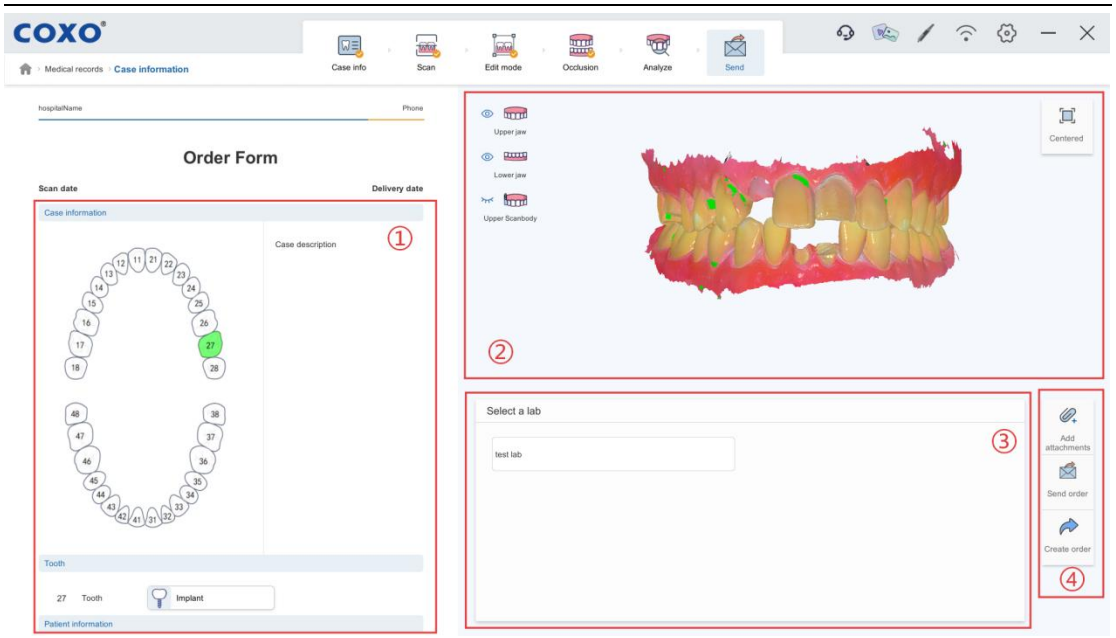

Fig. 4-19

No.	Description
1	Case Information Area: 1) Scroll down to view the complete case information. Before the order is sent out, you can double check it and confirm the case information. 2) You can select "Print" to print the order description file as needed, then select a printer for printing.
2	Scanned Model Browsing Area: You can browse the scanned 3D data model here. If you filled in holes for the model, the filled in parts are displayed in light yellow in the sending interface.
3	Select an appropriate lab and click the "Send Order" button to send an order.
4	Order Processing Area: • **Add attachments:** Add attachment files for this case. • **Create Order:** Create an order file for this case. • **Send Order:** Send the order file of this case. Different sending options (mail or cloud) and sending formats (PLY or STL) are provided. In the sending mode selection dialog, it will prompt that the format depends on the sending configuration in the management application. For details, please refer to "Chapter III 2.5 Lab Information Setting".

Chapter V

1 Repair

⚠ **Warning: For repair or replacement of scanner parts, please contact an authorized Launca distributor. Unauthorized personnel are not allowed to repair the product.**

2 Cleaning and disinfection

2.1 Camera tip cleaning and disinfection

The reflective mirror of the camera tip is a delicate optical element. Any stains on the reflective mirror will affect the quality of the scan data. To ensure the proper use of this product, please follow these steps to clean and disinfect the camera tip:

Step 1: Pull out the tip from the camera and rinse the reflective mirror under cold water. After rinsing, thoroughly dry it with a clean, nonfat gauze or dust-free cloth.

Step 2: Take a dust-free cloth and dip it in a small amount of 75% alcohol (anhydrous alcohol works better). Gently wipe the reflective mirror of the camera tip, ensuring there are no stains. If any stains are present, repeat this step.

⚠ **Note: Don't touch the mirror directly with your hands to avoid leaving stains.**

⚠ **Note: Carefully check the reflective mirror after cleaning. This step is crucial!**

Step 3: Place a non-woven sponge (the same size as the scan window) on the mirror position of the dried camera tip, ensuring that the non-woven sponge completely covers the window.

Step 4: Place the tip in a sterilization pouch and ensure that the pouch is sealed air-tight. Then put it into an autoclave sterilizer set at 134℃ for 5 minutes for sterilization, followed by an 8-minute drying cycle.

2.2 Device Cleaning

Before proceeding, make sure to turn off the power to the device.

Please wipe the device with wet gauze and then wipe it again with dry gauze. If the equipment is dirty, you can clean it with 75% alcohol and then wipe it with a dry cloth. Do not let disinfectant liquid to come into contact with the connections or inside the device.

⚠ **Note & Warning:**

- **Never immerse the intraoral camera in any liquid.**
- **Only the camera tip can be autoclavable. Do not sterilize the entire intraoral camera using steam pressure. The number of times the camera tip is disinfected should not exceed 100 times.**
- **Cleaning and disinfection before sterilization should be carried out in strict accordance with the hospital's cleaning and disinfection procedures.**
- **The scanning window at the front of the intraoral camera is made of optical-grade glass. Avoid bumping or scratching it with hard objects. The scanning window of the intraoral camera does not need to be cleaned when it is free of dirt. Please minimize the frequency of wiping the scanning window.**
- **Disinfection by higher temperature and pressure, irradiation and ethylene oxide or other means of disinfection may damage the precision parts, resulting in malfunction of the intraoral camera. Please note that this damage is not under the warranty.**

3 Technical Data

Function Items	Parameters and Configuration
Scanning Features	Continuous collections with high-definition video
Application Range	Prosthetics and orthodontics
Recommended Operating Distance	-1mm~21 mm
Scanning Accuracy	Single tooth ≤ 20 μm Bridge teeth ≤ 45 μm Full jaw ≤ 60 μm
Camera Size	195mm(L)*34mm(W)*35mm(H)
Camera Weight	130g(without cable)
Camera Tip	Standard:90mm(L)*33mm(w)*32mm(H) Scan Field:19mm*15mm ;
	Mini:90mm(L)*33mm(w)*32mm(H) Scan Field:14mm*12mm ;
3D Video Scanning	Real-time 3D scanning
Laser parameter	Classification : Class 1 Wavelength: Purple :405nm Laser-power : ＜ 5mW ; Beam divergence：20.3°

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Quick positioning for continuous scanning	Supported
Model optimization and hole filling	Supported
Automatic aligning	Supported
Contact analysis	Supported
Multi-touch screen operation	Not supported
Output Format	STL, PLY, OBJ
Package Dimensions	370mm (L) × 310 mm (W) × 135 mm (H)
Package Weight	1.5kg

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Chapter VI Product Service Information

1 Production and Regulatory Information

Manufacturer: Guangdong Launca Medical Device Technology Co., Ltd.

Address: Room 901-908 and 914-916, Building 5, No.1 Yanfa Road,Songshan Lake Park,Dongguan,Guangdong,523808,China

Phone: 86-400-823-7966

2 Authorised Representative In The European Community

Company Name: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

3 Warranty

Do not disassemble the machine. **Warranty starts from the date of purchase.** The scope of warranty does not cover the following aspects:

1. Any damage or breaks caused by incorrect operation or use (any application beyond the use scope of the instrument).
2. Any damage or breaks due to the failure to comply with the provisions of the power supply, installation and operation.
3. Any damage or breaks due to installation, modification, inspection or maintenance by non-authorized service engineers.
4. Any damage or breaks due to natural disasters such as fire, earthquakes or lightning.

If the machine stops working, please contact your supplier promptly for repair.

4 Certification

CE

This product bears the CE mark in accordance with the provisions of the Regulation (EU) 2017/745 on medical devices.

The version number is: A/1

Guangdong Launca Medical Device Technology Co., Ltd. has the final interpretation of this manual.

Chapter Ⅶ EMC Information

⚠Note：

1. The **Breezyscan Intraoral Scanner** is suitable for use in dental clinics and hospitals.It should be kept away from the area near the RF shielding room of the hospital's active high-frequency electrosurgical equipment or magnetic resonance imaging system

2. When the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES， the OPERATOR can not use scanning function, or the scanning function is affected .

3. Portable and mobile RF communication equipment may affect the performance of this equipment, avoid strong electromagnetic interference when using, such as close to mobile phones, microwave ovens, etc.

4. The guidance and manufacturer´s declaration see Appendix C ;

⚠**WARNING：**

1. 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.

2. 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 **Breezyscan Intraoral Scanner**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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3. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the **Breezyscan Intraoral Scanner** could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation..

The following table lists the cable information :

The name of the cable	**Length**	**Shield**
Connection Cable	2.0 M	Yes

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Appendix A: Troubleshooting

Problem	Solution
Email server connectivity test failed	1) The network status of some clinics may cause the failure of the mailbox connectivity test. Please check your network environment. 2) Please check whether the "Mailbox SMTP Settings" in the management application is correct. Incorrect settings may also cause failure of mailbox connectivity testing.
Fail to send an order	1) Please check whether the network environment of the device is normal. 2) Please check whether the "Mailbox SMTP Settings" in the management application is correct. Incorrect settings may also cause failure of order sending. 3) Check whether the order file size is too large. Since the size of sending or receiving files is limited by some mailboxes, it may also cause the failure of order sending if the order file is too large. In this case, please select "Export Order" in the "Send" interface at the scanner application and send it by other means.
Chinese Input Method	The scanner application and management application use the Google input methods. Do not uninstall it without permission. If you want to use Chinese input method, press "Ctrl + space" on the soft keyboard. ⚠ **Note: Since other Chinese input methods may not be compatible with the Scanner application, Do NOT install other input methods without permission to avoid system compatibility problems.**
Fail to align models	1) Try to select auto align first. Select manual aligning only when the automatic aligning fails several times. 2) Before manual aligning, you need to check and confirm that the orientations of the upper jaw, lower jaw and buccal model to be aligned are similar. If the orientations are too far, you need to adjust the 3D model of the upper jaw or lower jaw orientations to be similar with the buccal model. 3) If the model of the upper jaw/lower jaw cannot align with the buccal model for several times, you may need to re-scan the models.
Improper intraoral camera connection	Improper connection of the intraoral camera may cause failure to start the camera or failure to scan. In this case, refer to "Chapter I 3.4.3 Connection of Intraoral Camera", re-connect the intraoral camera and restart the scanner application.

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⚠ **Note:**

- **If you cannot solve the scanner problems with the above tips, contact an authorized Launca distributor for technical support.**
- **Do not disassemble the device. Any failure caused by unauthorized disassembly of the device is not covered by the warranty.**

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Appendix B: Name and Content Table of Toxic and Hazardous Substances or Elements

Pollution Control Labeling for Electronic Information Product: The numbers in the figure indicate the environment-friendly use period. They only refer to the period of time before any of the toxic and hazardous substances or elements are likely to leak out or mutate, causing pollution to the environment or serious damage to health and properties.

Name and Content Description Labeling of Toxic and Hazardous Substances or Elements:

Part Name	Toxic and Hazardous Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr6+)	Polybrominated biphenyl (PBB)	Polybrominated diphenyl ethers (PBDE)
LED Driver Board	○	○	○	○	○	○
FPC Board	○	○	○	○	○	○
Control Board	○	○	○	○	○	○
Camera Module	×	○	○	○	○	○
Connection Cable	×	○	○	○	○	○
Camera Tip	×	○	○	○	○	○

○: This sign indicates that the content of this toxic and hazardous substance in all homogeneous materials of this part is below the limit value specified in the SJ/T 11363-2006 standard.

×: This sign indicates that the content of the toxic and hazardous substance in at least one homogeneous material of the part exceeds the limit value specified in the SJ/T 11363-2006 standard.

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Appendix C: Guidance and manufacturer´s declaration – electromagnetic emission- for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission		
The **Breezyscan Intraoral Scanner** is intended for use in the electromagnetic environment specified below. The customer or the user of **Breezyscan Intraoral Scanner** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **Breezyscan Intraoral Scanner** uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **Breezyscan Intraoral Scanner** 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 emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

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Guidance and manufacturer´s declaration – electromagnetic immunity

The **Breezyscan Intraoral Scanner** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Breezyscan Intraoral Scanner** should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 %.
Electrostatic 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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of atypical commercial or hospital environment. If the user of the **Breezyscan Intraoral Scanner** requires continued operation during power mains interruptions, it is recommended that the **Breezyscan Intraoral Scanner** be powered from an uninterruptible power supply or a battery.
Power frequency	30 A/m		Power frequency magnetic fields should

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(50/60 Hz) magnetic field IEC 61000-4-8		30 A/m	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.			

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Guidance and manufacturer´s declaration – electromagnetic immunity			
The **Breezyscan Intraoral Scanner** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Breezyscan Intraoral Scanner** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Breezyscan Intraoral Scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W)

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			according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b 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 is affected by absorption and reflection from structures, objects and people.

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b. 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 transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Breezyscan Intraoral Scanner is used exceeds the applicable RF compliance level above, the Breezyscan Intraoral Scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating theBreezyscan Intraoral Scanner.

c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS

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

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

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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.

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