Ver. A / 1
May 22, 2023

USER MANUAL

Intraoral Scanner
Model: DL-300 Wireless

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Preface

Thank you for purchasing theIntraoral 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.**

⚠ **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.**

Packing List of Intraoral Scanner DL-300 Wireless:

Intraoral Camera	1 piece
Camera tip (standard)	2 pieces
Camera tip (mini)	1 piece
Recharge Li-ion battery	3 pieces
Camera adapter unit	1 piece
Power adapter	1 piece
Converter	1 piece
Battery charger	1 piece
Charger cable	1 piece
Dongle	1 piece
User Manual	1 piece
Certificate	1 piece

Chapter I Product Overview

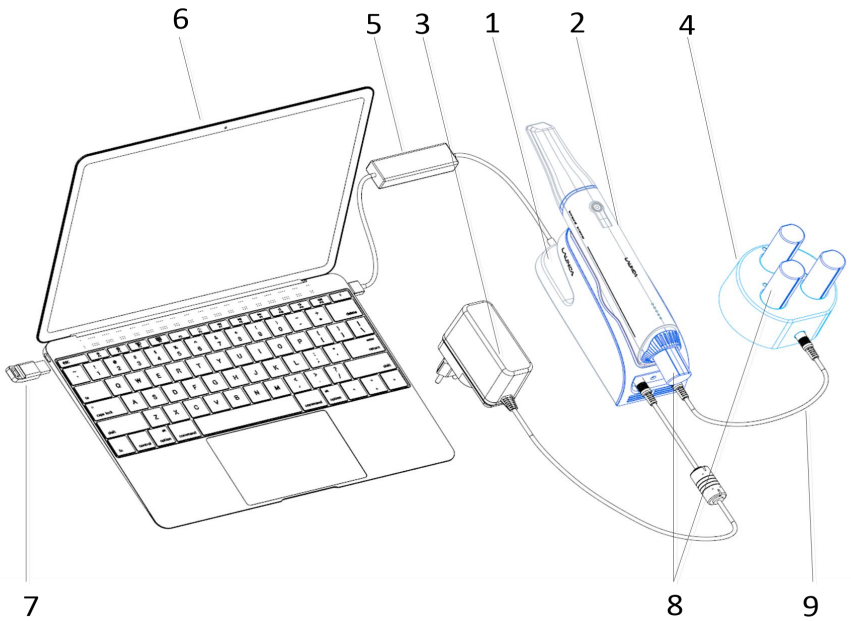
1 Intended Use

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

2 Structure

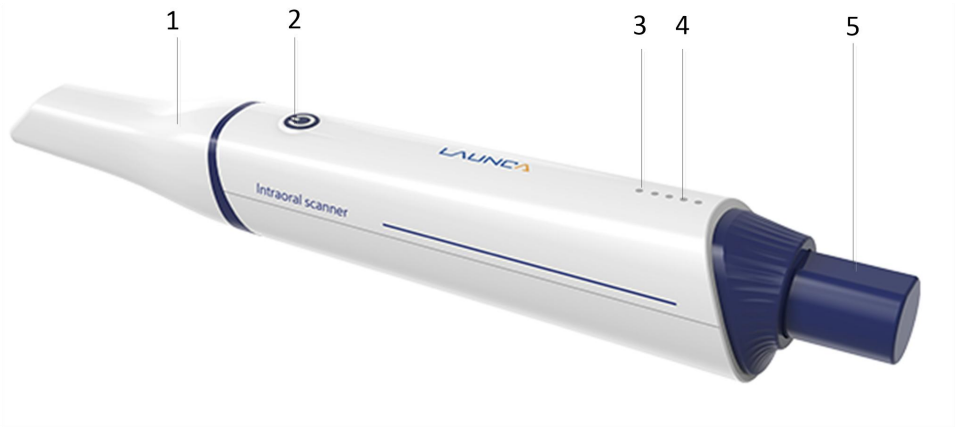
2.1 Appearance

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:



1- Camera adapter unit	2- Camera	3- Power adapter
4- Battery charger	5- Converter	6- Notebook
7- Dongle	8- Recharge Li-ion battery	9- Charger cable

Figure 1-1 Intraoral Scanner DL-300 Wireless



1-Camera tip 2-Start button and indicator 3- Charge indicator
4- Battery indicator 5-Recharge Li-ion battery

Fig. 1-2 Intraoral Camera (Camera of the Intraoral Scanner)

1-Reflective Mirror 2- battery unlock button
3-Camera charging contact point 4- Recharge Li-ion battery

Fig. 1-3 Intraoral Camera(Camera of the Intraoral Scanne)

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.

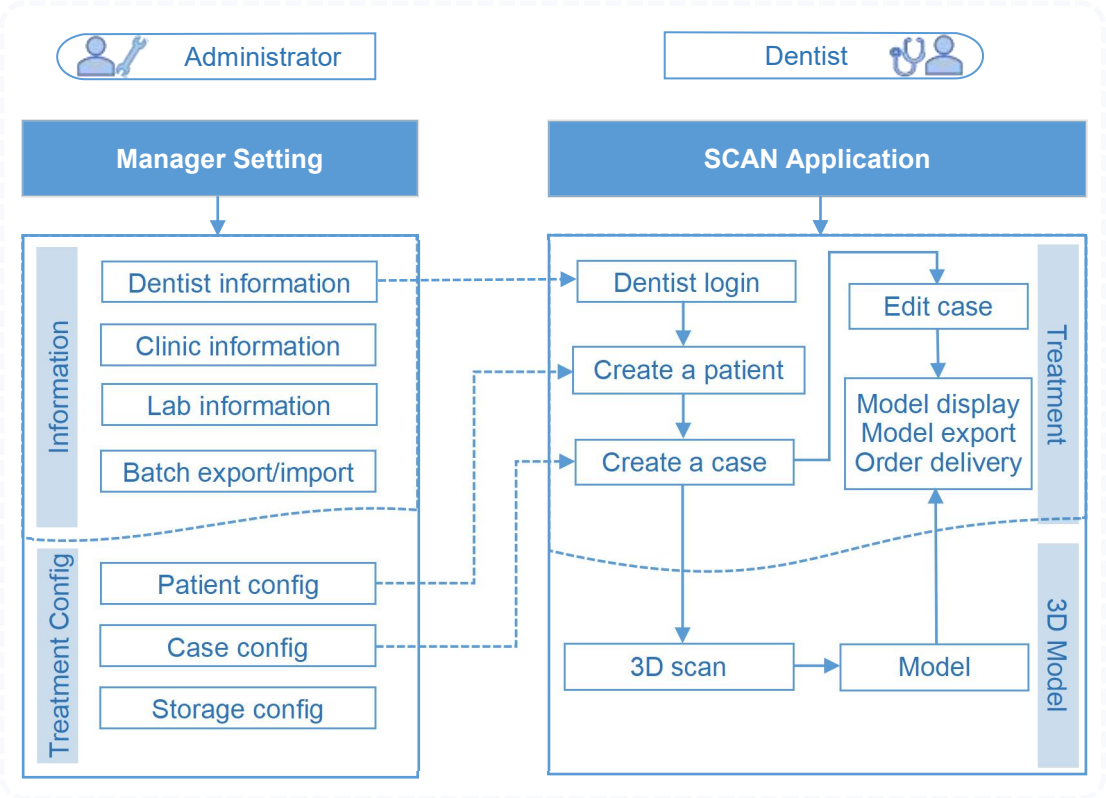


Fig. 1-4 The Workflow of the Intraoral Scanner Software System

2.3 Accessories

2.3.1 Standard Accessories

DL-300 Wireless

- Recharge Li-ion battery — 3 pieces
- Power Adapter
（Optional Plug :EU Plug、AU Plug、UK Plug、CN Plug、BR Plug、US Plug） — 1 piece
- Camera adapter unit — 1 piece
- Battery charger — 1 piece
- Charger cable — 1 piece
- Dongle — 1 piece
- Converter — 1 piece
- Camera tip (standard) — 2 pieces
- Camera tip (mini) — 1 piece

The Camera tip is a applied part.

2.3.2 Optional Accessories

- Notebook 1 set

2.4 System Connection

This section describes connections of the system components.

2.4.1 Connect to Power

When connecting the intraoral scanner to AC power, make sure that one end of the power adapter is properly connected to the power socket of the base, and the other end is plugged into an AC outlet.

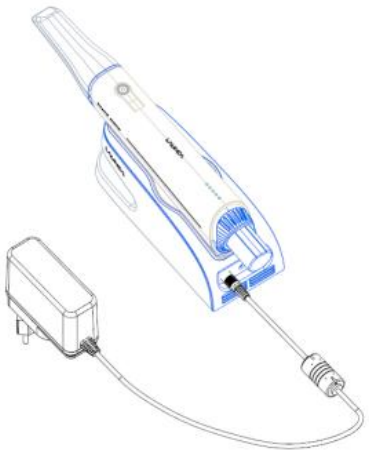


Fig. 1-6 Power Interface Diagram

2.4.2 Connect to a notebook by wireless

① Plug the RJ45 data cable on the camera adapter unit into the converter, and plug the USB data cable on the Converter into a Notebook. Then the camera adapter unit is contected to AC power as shown in Fig 1-6.

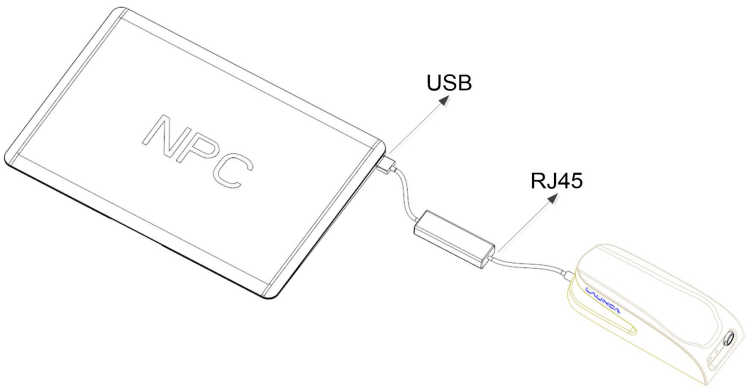


Fig. 1-7 Connection of USB data cable

②Press the bottom of the camera battery for 2 seconds as shown in Fig 1-8. Then, the start button indicator lights up yellow, indicating that the camera power is on and the camera fan is running.

Fig. 1-8 Start camera power

③About 30 seconds after the camera is powered on, the start button indicator changes from yellow to long green, indicating that the camera wifi function has been successfully contected,as shown in Fig 1-9.

Fig 1-9 Camera successfully connected

④When the camera wifi function is contected,it is ready for scanning after pressing the start button.

2.5 Lithium battery using and charging

2.5.1 Install lithium battery

As shown in the Fig 1-10, point the flat end (electrical extreme) of the lithium battery at the flat end of the camera battery entrance, and then gently push the lithium battery into.Until it will reach the electrode connection of the camera, push the battery slightly to connect the electrode of the lithium battery with the electrode of the camera completely, and feel that the camera has locked the battery, the battery can no longer be pulled.

Fig 1-10 Install lithium battery

2.5.2 Dismantle lithium battery

Before dismantling, check whether the camera is powered off. If not, the camera should be powered off firstly.

As shown in the Fig 1-11, press the battery unlock button at the bottom of the camera, and the lithium battery will pop up to unlock. At this time, hold the lithium battery and gently pull it out of the camera battery entrance.

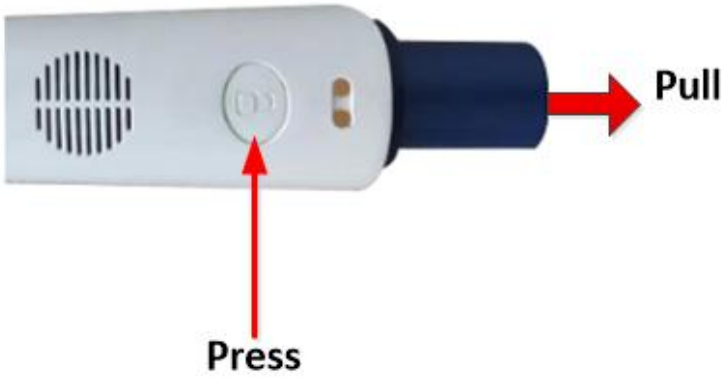


Fig 1-11 Dismantle lithium battery

⚠**Warning:** When the camera is working, do not press the battery unlock button and dismantle the lithium battery . Otherwise, it may damage the internal electronic circuit of the camera !

⚠**Note:** When the battery is dismantled, be sure to press the battery unlock button first! If you do not press the unlock button, the lithium battery is locked. Do not pull the battery to remove it. Otherwise, it may damage the battery device inside the camera.

2.5.3 Check lithium battery level

The intraoral scanner provides user with two ways to check ：

① Check the battery indicator on the rear of the camera :

Battery Indicato	Battery level
4 blue lights	80%～100%
3 blue lights	60%～80%
2 blue lights	40%～60%
1 blue lights	20%～40%
1 blinking light	< 20% Please replace the battery now
No lights on	0% ， or no battery

②Also after connecting to a notebook , login the scanning software and view the battery level indicator function in the scanning software. The battery level displayed in the function is the battery level of the camera, as shown in the Fig 1-12.

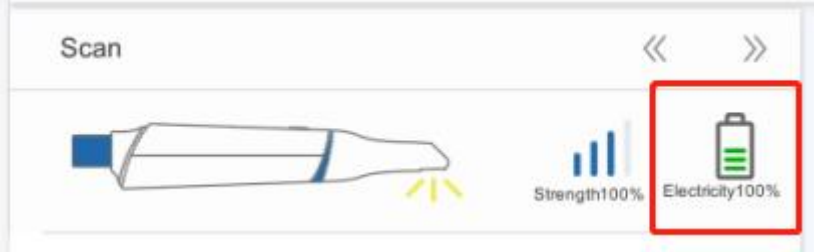


Fig 1-12 Battery level indicator function in the scanning software

2.5.4 How to Charge battery

The intraoral scanner provides user with two charging modes :

Online charge mode

After scanning, as shown in the Fig 1-13 , place the camera on top of the Camera adapter unit, then connect the power adapter to AC power, the charge indicator wil light , the camera is being charged now.

Fig 1-13 Online charge mode

External charging mode

Turn off the camera and dismantle the battery from the camera. As shown in the Fig 1-14, the battery is directly aligned with the position into any charging port of the charger base, then connect the power adapter to AC power . When the charge indicator lights red , the battery is being charged now.

A charger base allows three batteries to be charged simultaneously.

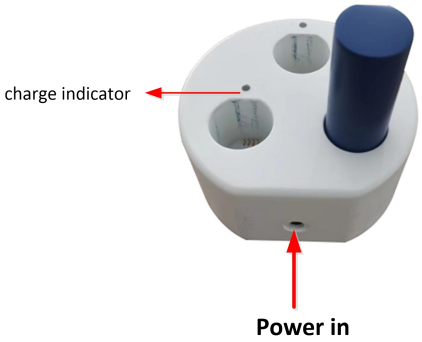


Fig 1-14 External charge mode

When the charge indicator lights red, the battery is being charged. When the charge indicator turns green, the battery is fully charged.

⚠**Note**: Both online charge mode and external charge mode are equipped with a overcharge protection function.

⚠**Note**: In the process of using the product or charging the battery, if you find any abnormal conditions such as overheating, damage or leakage of the battery, please stop using the battery immediately, shut it down and power it off, and call our company after-sales service number in time.

⚠**Note**: In case of battery fire and burning during use, please put down the device immediately, and then use the fire extinguisher to extinguish the fire. Finally, please contact the after-sales technicians to confirm the safety before the next use the device.

⚠**Note**: Do not discard lithium batteries at will. Discarding lithium batteries at will will pollute the environment.It should classify and recycle lithium batteries according to local environmental laws and regulations.

⚠**Note**: If you find the battery is difficult to install or ismantle, you should check the battery whether the battery is deformed.If the battery is deformed,you should no longer use this battery. Or if you can not identify ,you can ask our after-sales service.

⚠**Warning:These battery had specially approved by battery safety test for DL-300 Wireless. Please do not use any other brand battery that is not authorized by our company, otherwise, the product may be damaged, or even fire and other safety accidents may occur. Therefore, do not use any other lithium battery that is not authorized by our company. If the user uses other lithium batteries without the authorization of our company, we will not be responsible for any loss!**

Chapter II Safety Precautions

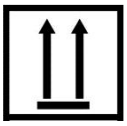
1 Safety Precautions

- **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

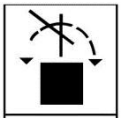
B-type Device



UPWARD

FRAGILE, HANDLE WITH CARE

KEEP DRY

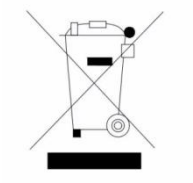


NO ROLLING

NO STACKING

IPX0 NO WATERPROOF

Lithium batteries are mounted in the device for transport



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: Make sure the power supply is a three-hole socket with a ground wire and the AC power supply is 100/240V, 50/60Hz.**

⚠**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.**

FC WARNING

⚠**Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to**

try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

*** RF warning for Portable device:**

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC ID: 2BBRU-DL300W

2 Environmental Requirements

2.1 Normal Working Conditions

- Ambient Temperature: 10℃ ~ 28 ℃
- Relative Humidity: 30% ~ 75%
- Atmospheric Pressure: 86kPa ~ 106kPa
- Camera Internal supply : Li-ion battery 3.6V d.c 3450 mAh 12.42Wh
- Camera adapter unit power : AC100/240V ± 10%, 50/60Hz ± 1Hz

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

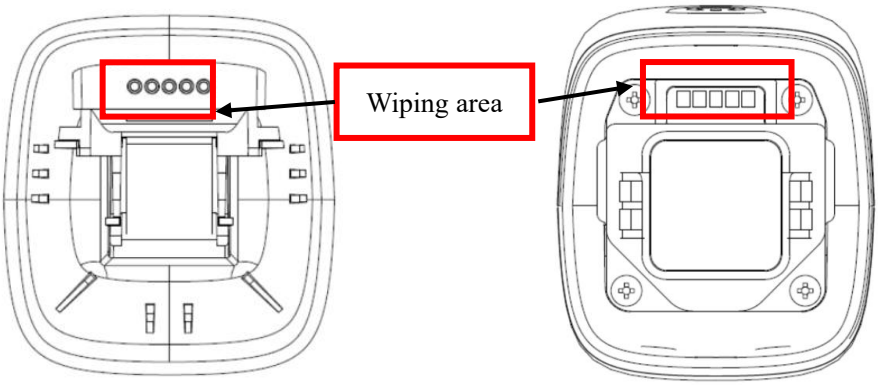
IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz	IEC 60601-1-2: 2014+A1: 2020 IEC 61000-4-39: 2017	PASS

Note: "N/A" means "not applicable".
The measurement uncertainty is not included in the test result.

Chapter III Scanner Settings

1 Before Scanning

It is recommended that the camera tip be sterilized by steam before use. Set the parameter to 134℃ for 5 minutes. Use a cotton swab with 75% alcohol, wipe back and forth on the thimble of the camera tip and the ejector seat of the camera lens for no less than 3 times:



⚠ **Note:**

- **Only the camera tip can be used for steam pressure disinfection. Do not sterilize the entire intraoral camera by steam pressure. The number of disinfection use shall not exceed 40 times.**
- **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.**
- **The method and process of disinfection should be carried out in accordance with the hospital disinfection technical specifications.**
- **Recommendation: Before scanning, warm up the intraoral camera for 5-10 minutes for a smoother scanning process.**

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”.**

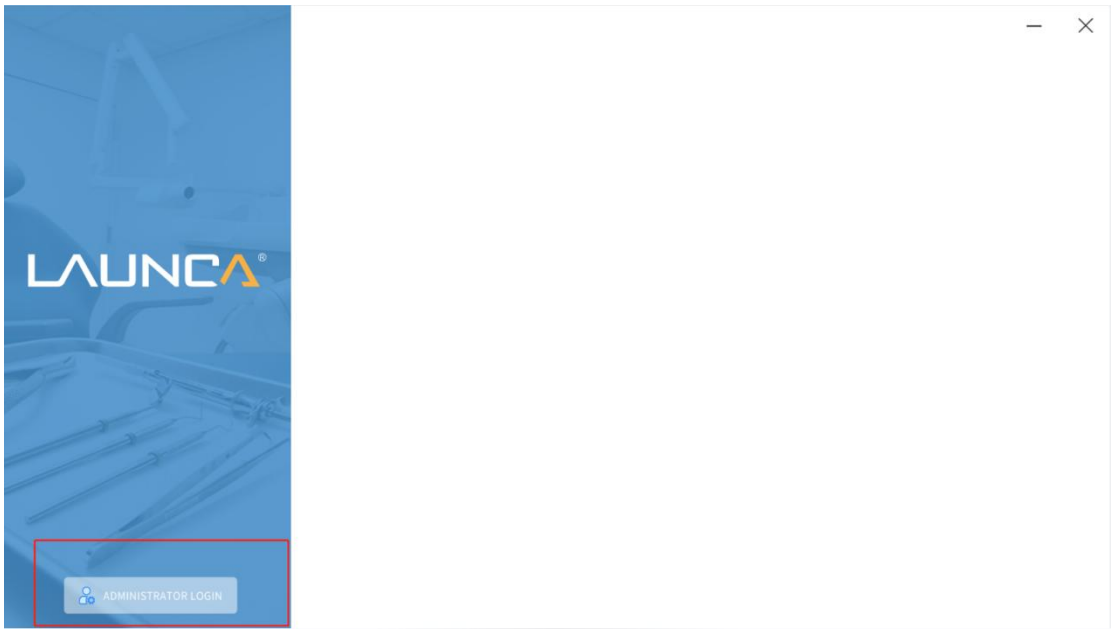


Fig. 3-1 Manager Setting

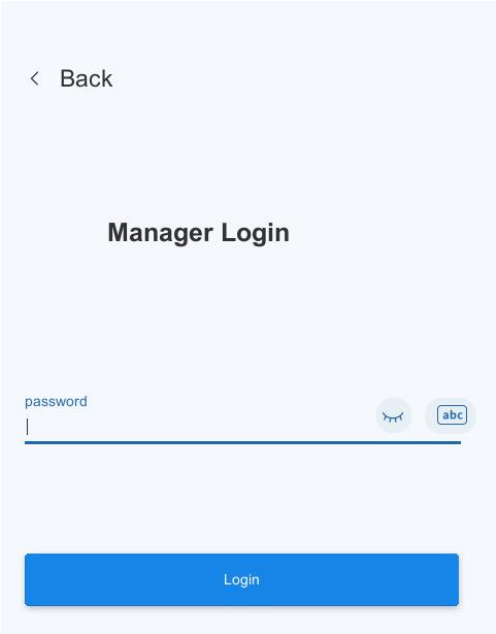


Fig. 3-2 Administrator Login Interface

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.

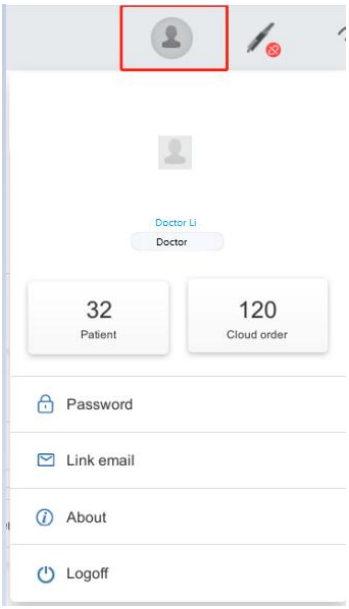


Fig. 3-3 Open Administrator's Password

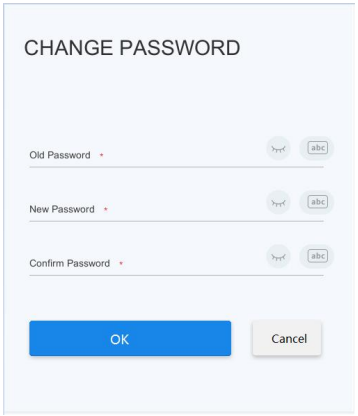


Fig. 3-4 Change Administrator's Password

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.

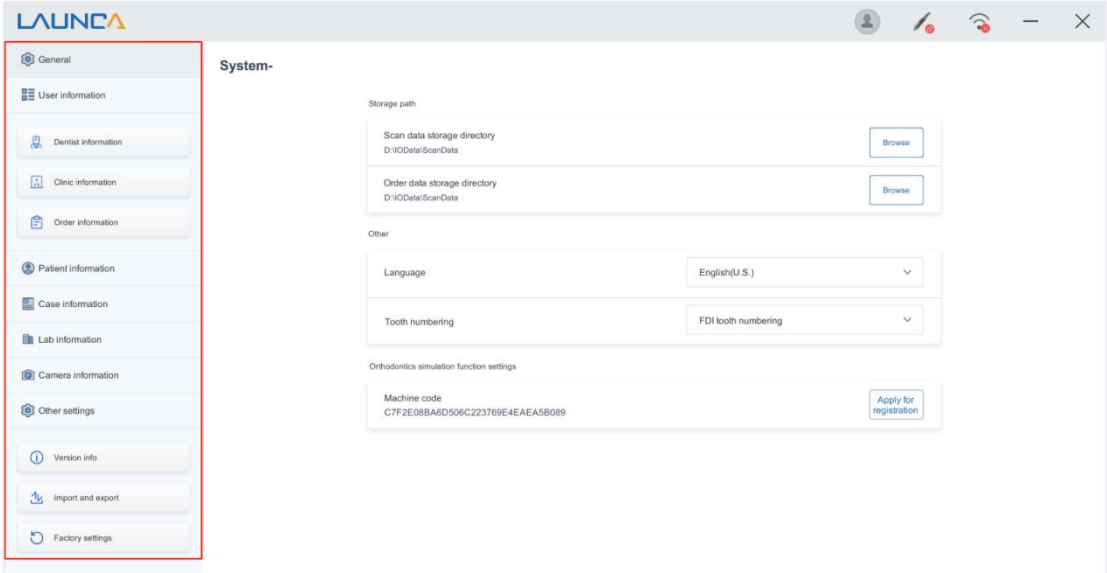


Fig. 3-5 Menu Bar

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.

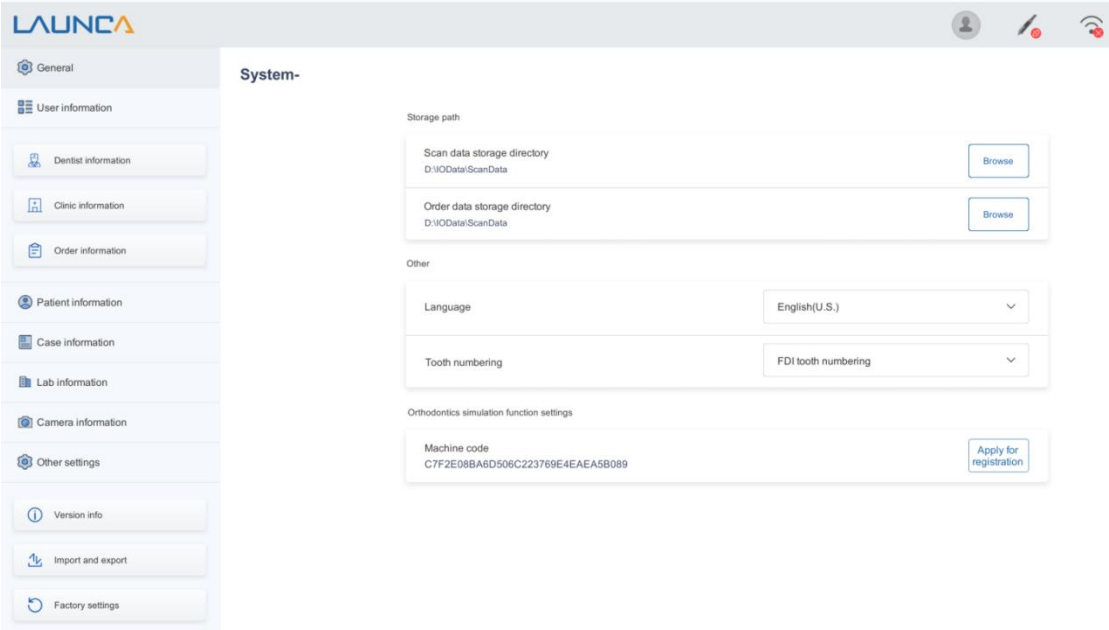


Fig. 3-6 General Settings Interface

- **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.
- **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.
- **Machine code:** It shows the machine code of this product.

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.

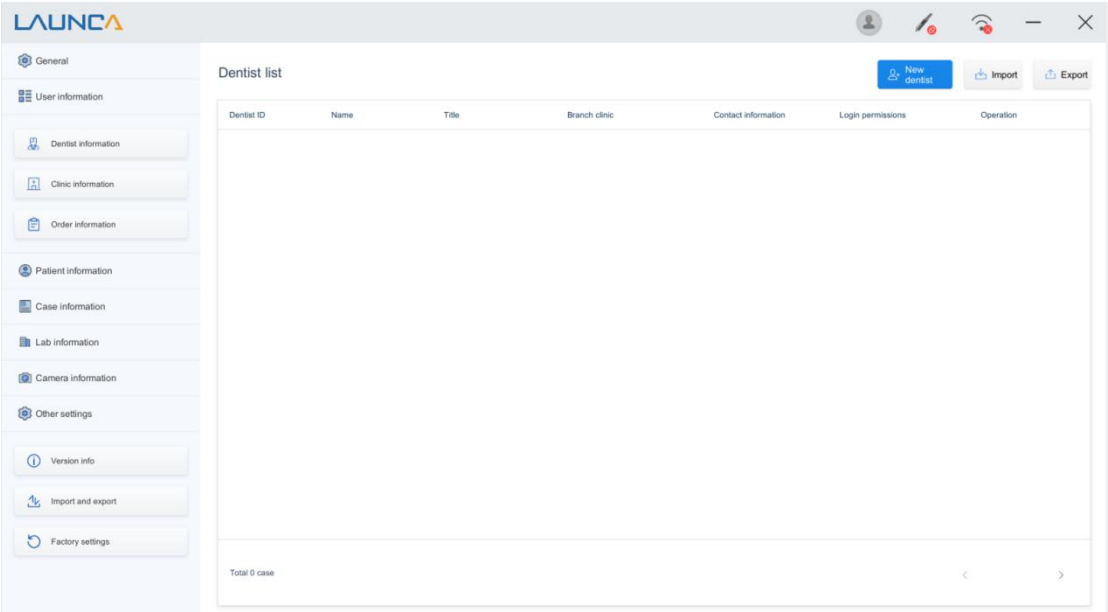


Fig. 3-7 User - Dentist Information

- **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.
- **Current password:** Set the doctor account password when setting up doctor information for the first time
- **Confirm password:** Confirm the doctor account password when setting up doctor information for the first time.
- **Clinic:** The name of the main clinic can be changed in "Clinic Information", without filling in the information for each dentist.
- **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.

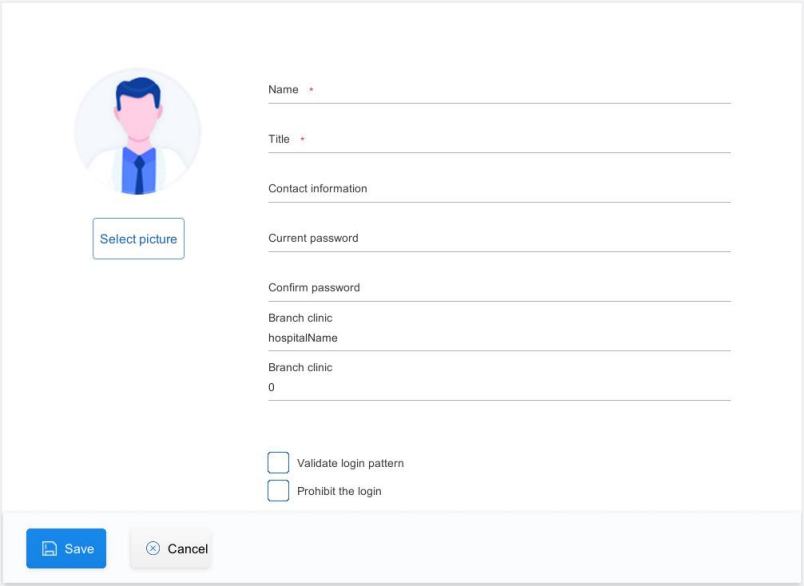


Fig. 3-8 Dentist Information Input

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.

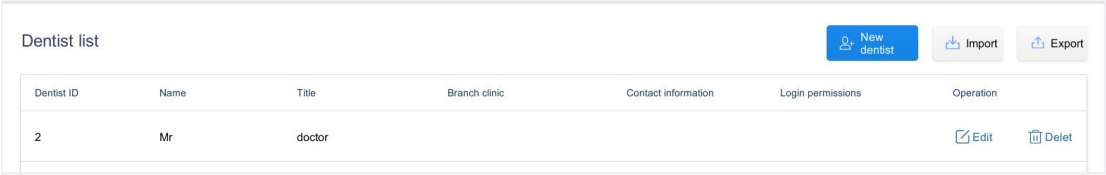


Fig. 3-9 Dentist List

2.3.3 Clinic Information

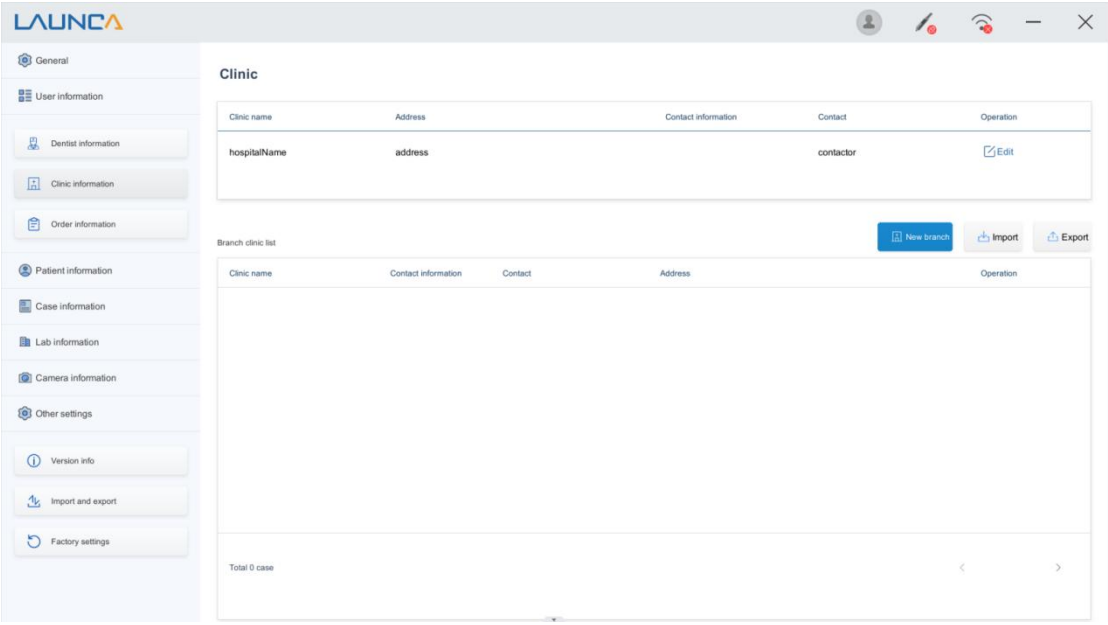


Fig. 3-10 Clinic Information

- **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.

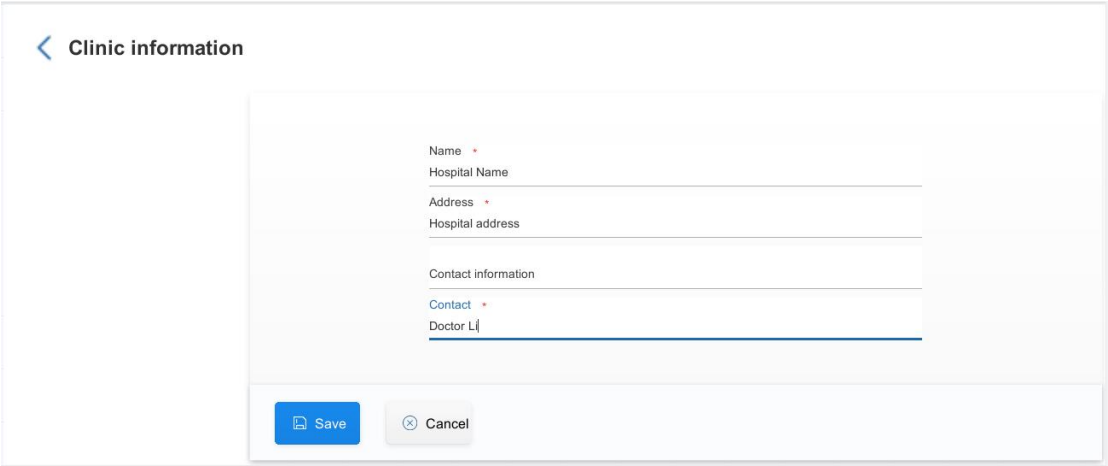


Fig. 3-11 Clinic Information Input

- **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

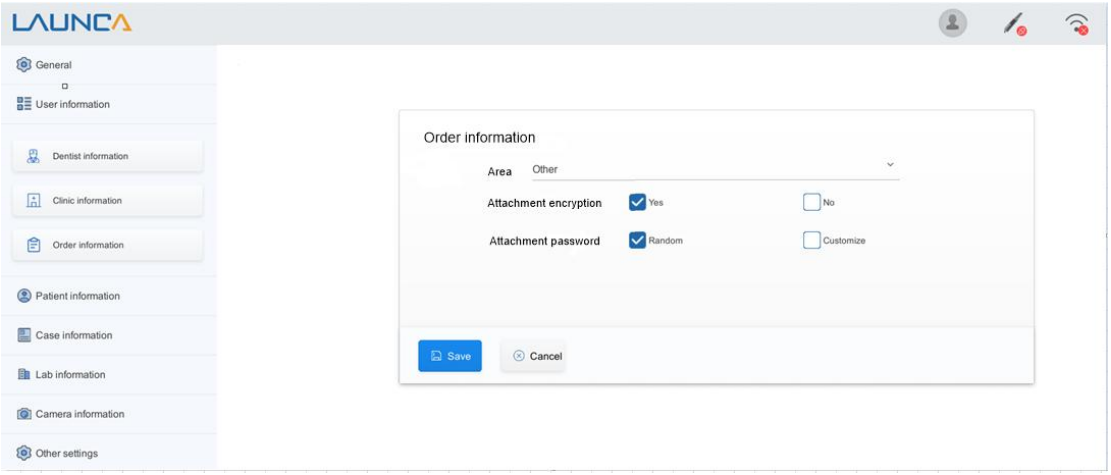


Fig. 3-12 Order Information

- **Area:** The area where the order wil be sent.
- **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.

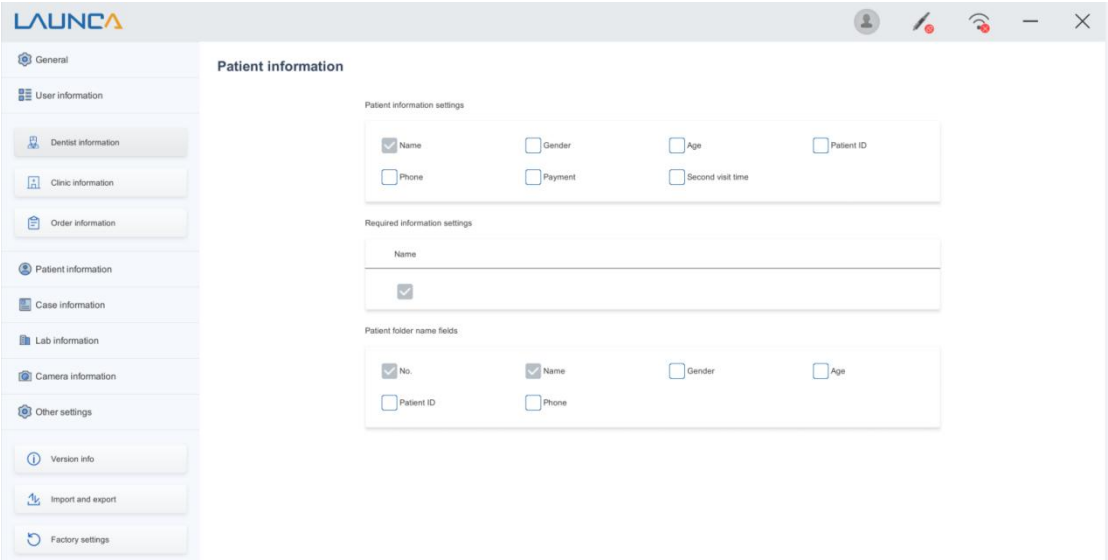


Fig. 3-13 Patient Information Settings

- **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.

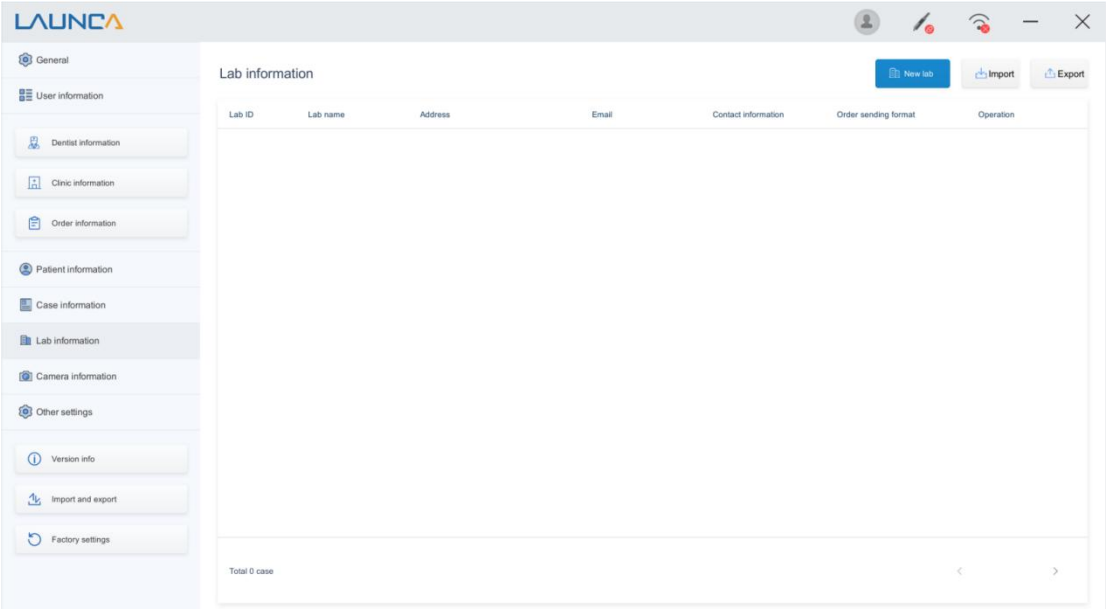


Fig. 3-14 Lab Information Settings

- **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

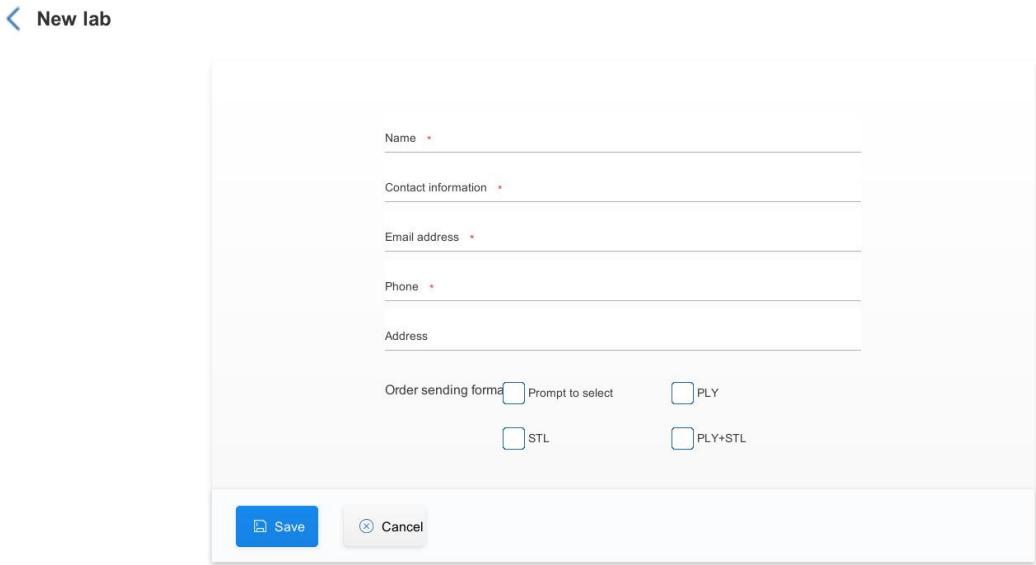


Fig. 3-15 Lab Information Settings

- **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.

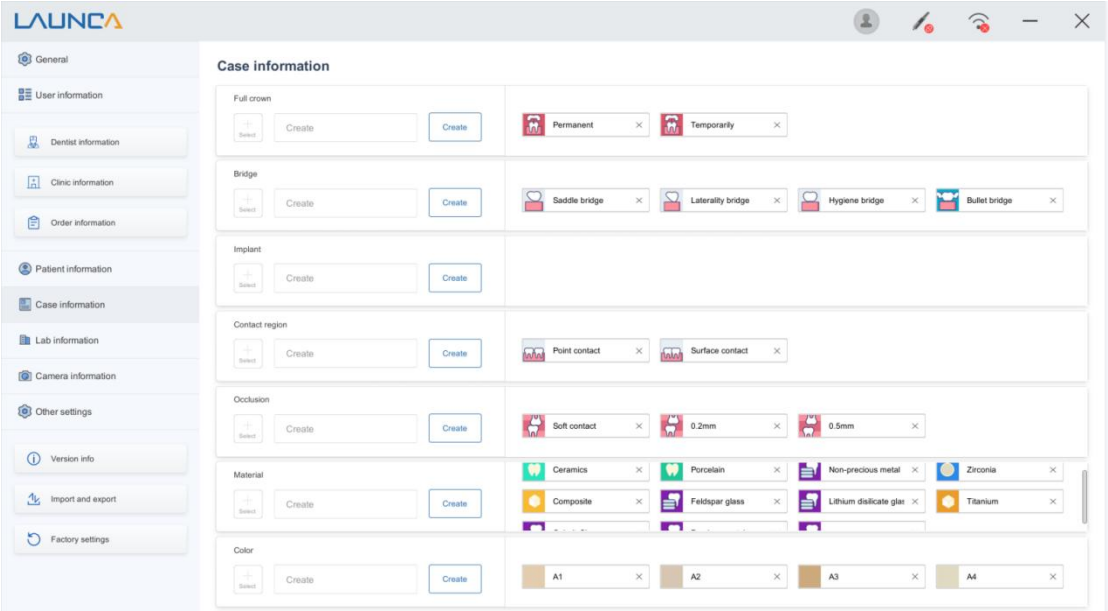


Fig. 3-16 Case Information Settings

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 Camera Information

You can check the number and eeprom of the Intraoral Camera here, as shown in Fig. 3-17.

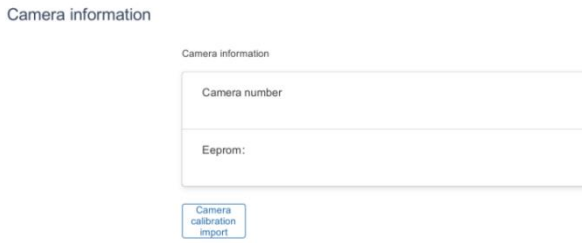


Fig. 3-17 Camera Information

2.8 Other settings

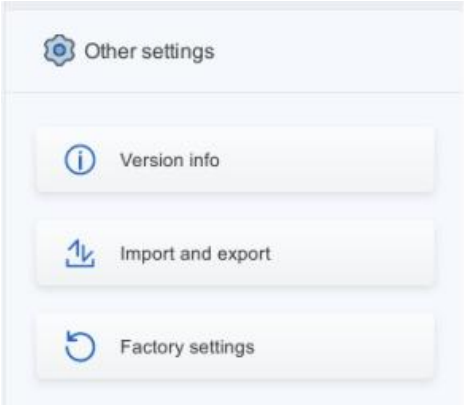


Fig. 3-18 Tool Menu Bar

Version info: The current software version is displayed.

Import and Export: The administrator can export the selected data to an XML file,as shown in Fig. 3-19. Under "Select Data", check the general information you want to export and click "Export Data" on the upper right corner. If you want to import data, click the "Import Data" button to select an XML files to import.

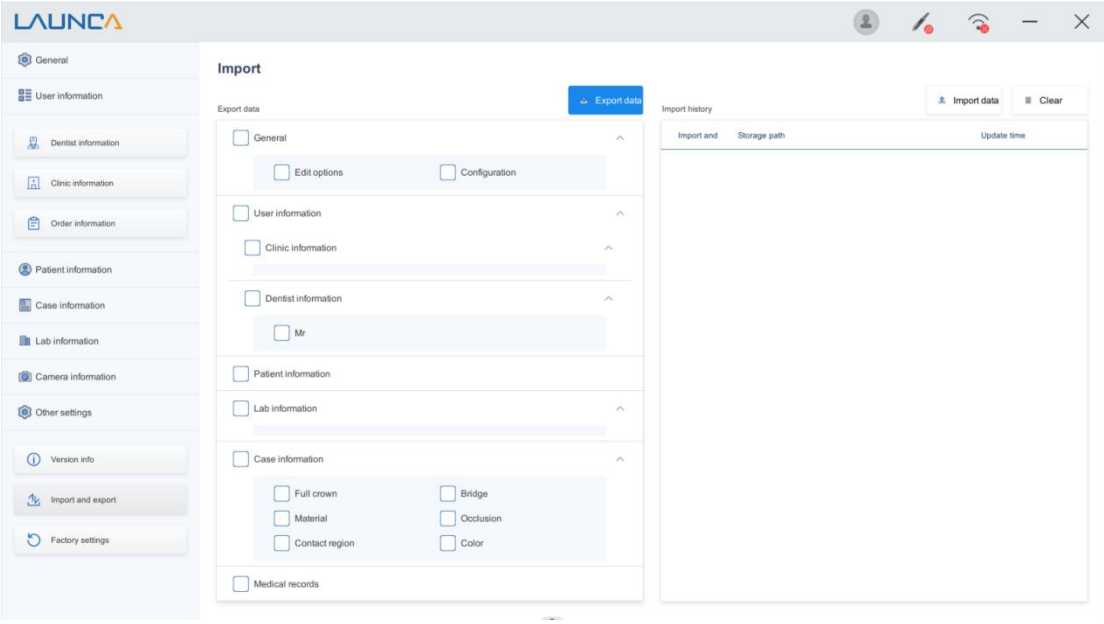


Fig. 3-19 Data Import/Export

Factory settings: This is factory reset, this operation wil completely delete database data,as shown in Fig. 3-20.

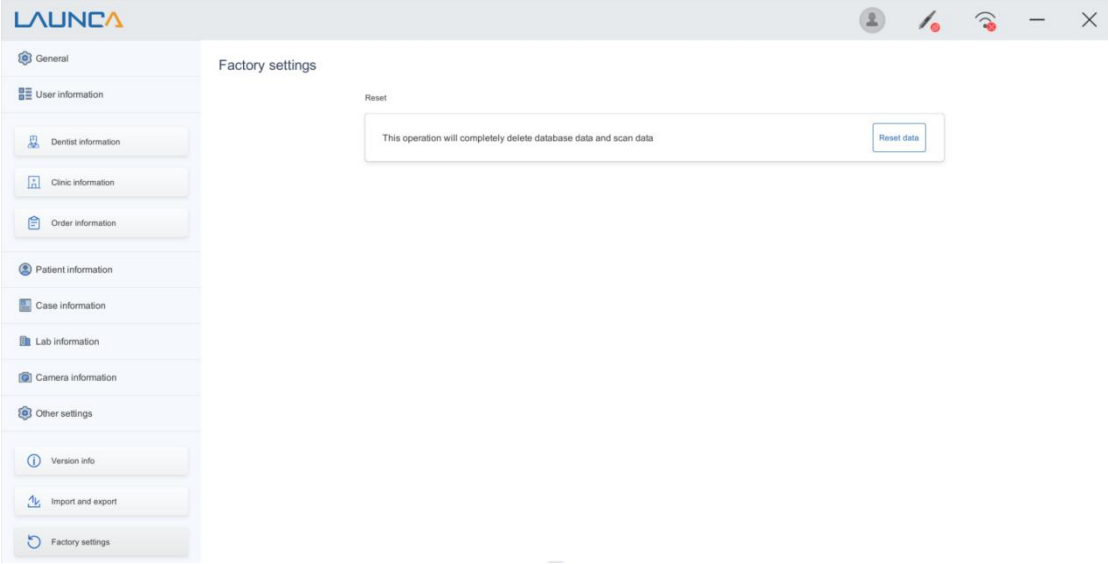


Fig. 3-20

Chapter IV Scanning Operation

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.

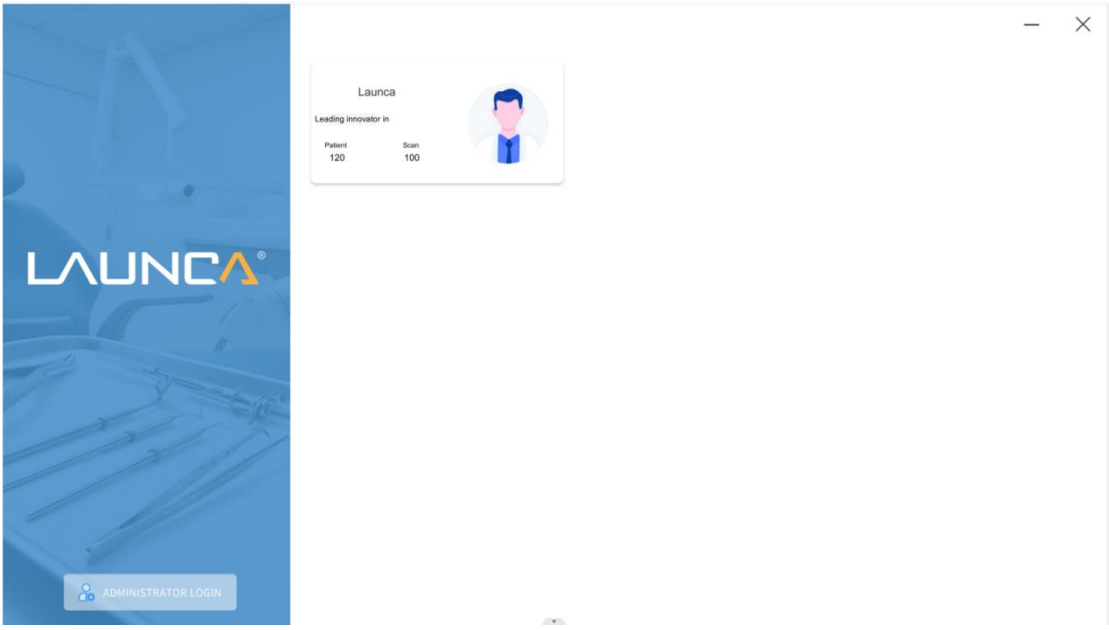


Fig. 4-1 SCAN Application Login Interface

Click on the "Dentist" icon as shown in Fig. 4-1, enter the password which was set in "Chapter III 2.3.1 Add Dentist " to login as shown in Fig. 4-2.

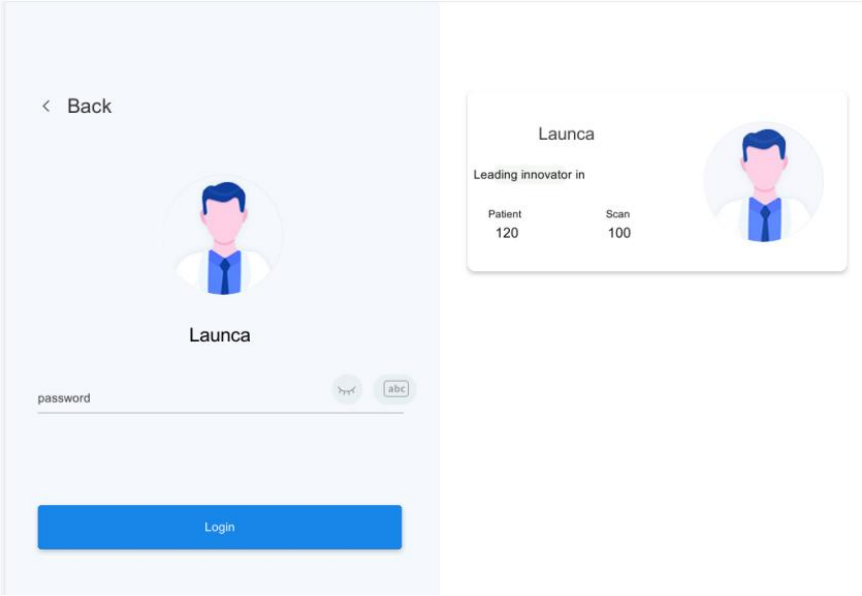


Fig. 4-2 Enter password to login

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

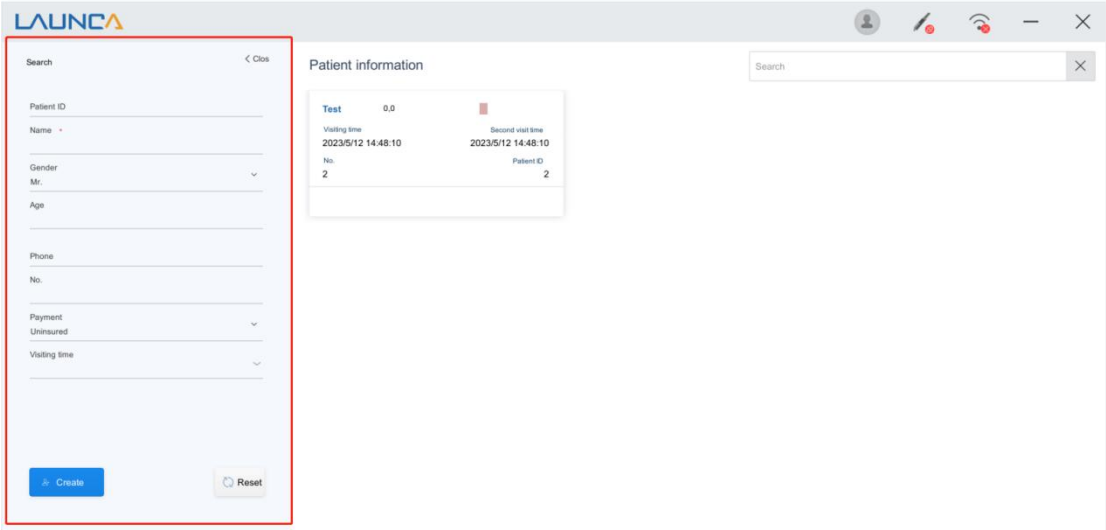


Fig. 4-3 Create a New Patient

After login, you will enter the patient information interface. Input the patient information in the interface as shown in Fig. 4-3 and click "Create" to add a new patient.

- **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.
- **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.
- **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

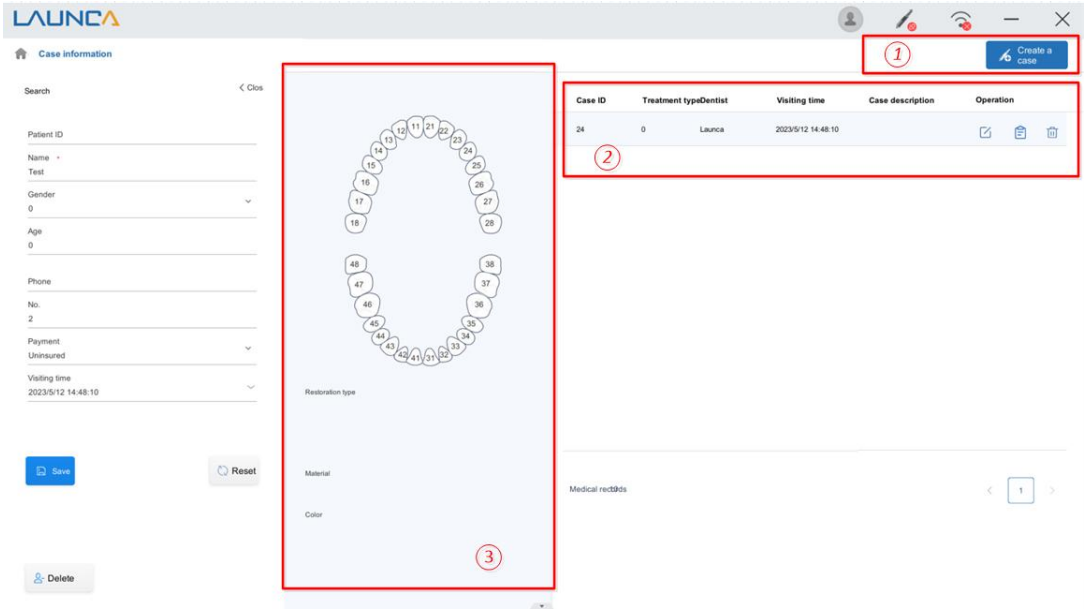


Fig. 4-4 View Patient Information and Case Records

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.

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 Create a case 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.

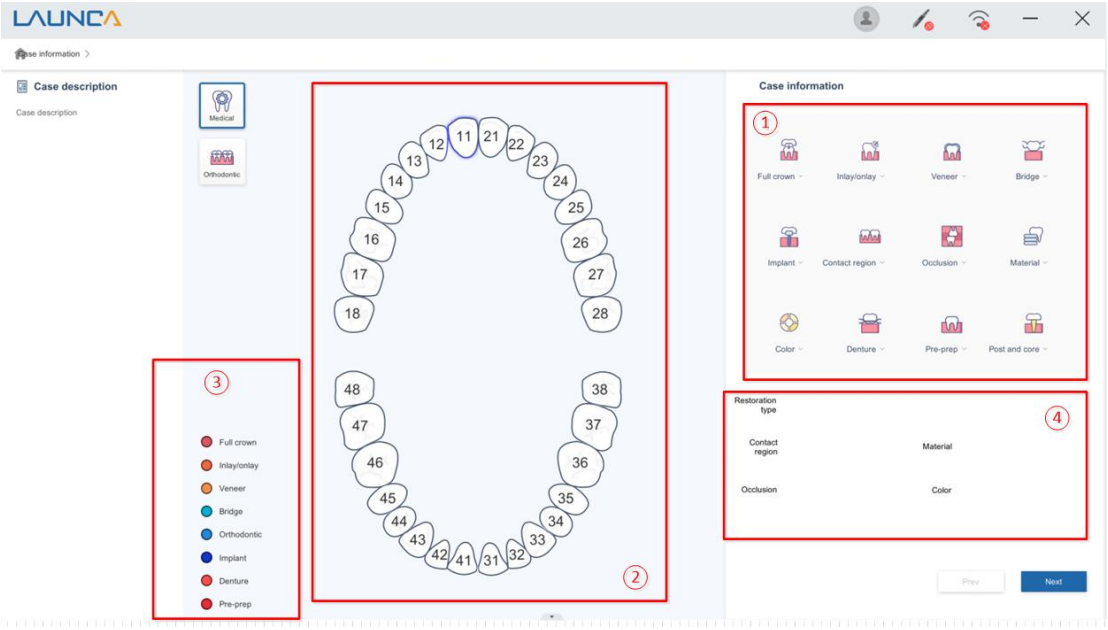


Fig. 4-5 Case Information

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"、"Send" and "Feedback" icons.

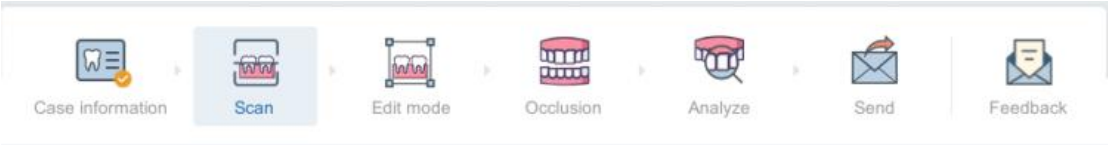


Fig. 4-6

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.

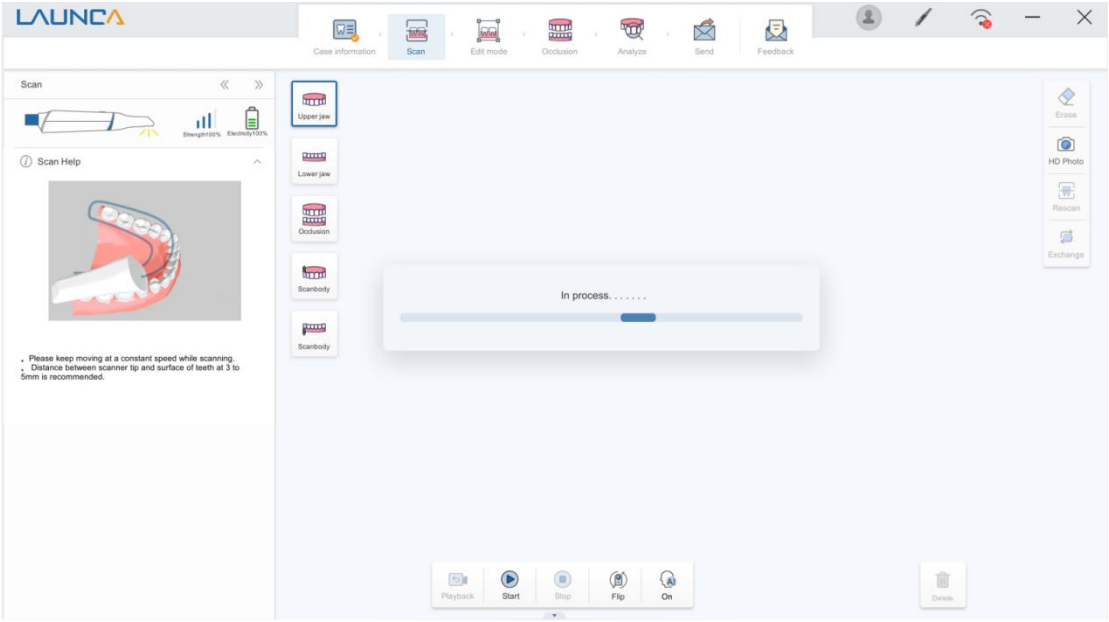


Fig. 4-7 The Scan window is Loading

3.1 Scan window Interface Description

3.1.1 General Scanning Mode

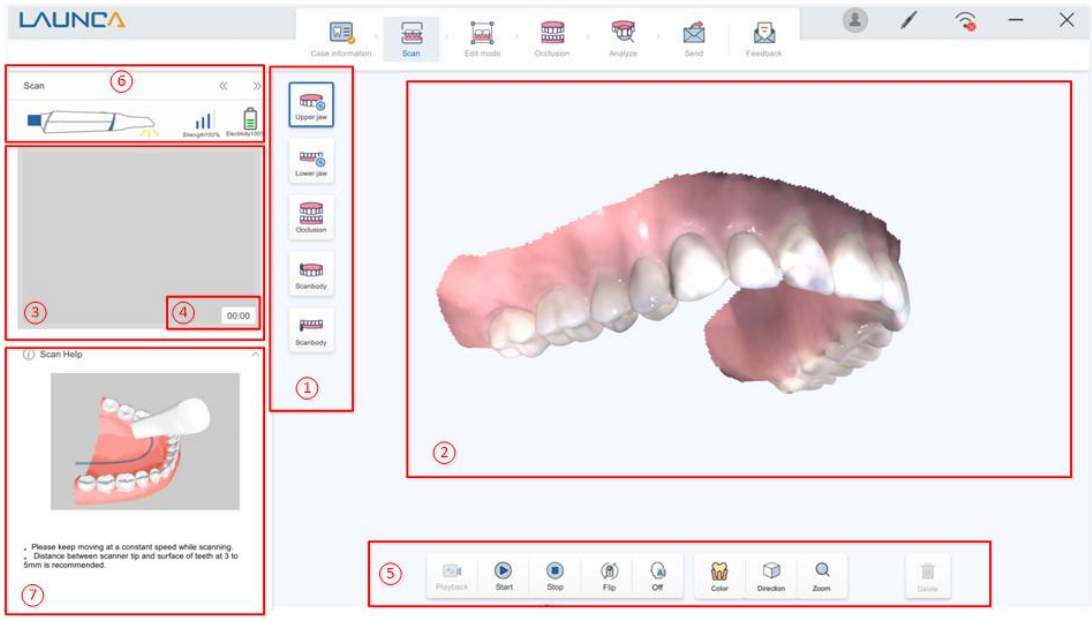


Fig. 4-8-1

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.

6	View wifi strength and camera battery power while wireless is connected (Apply to DL-300 Wireless)
7	If you are not familiar with using the device, you can scan by referring to the camera scanning demonstration video

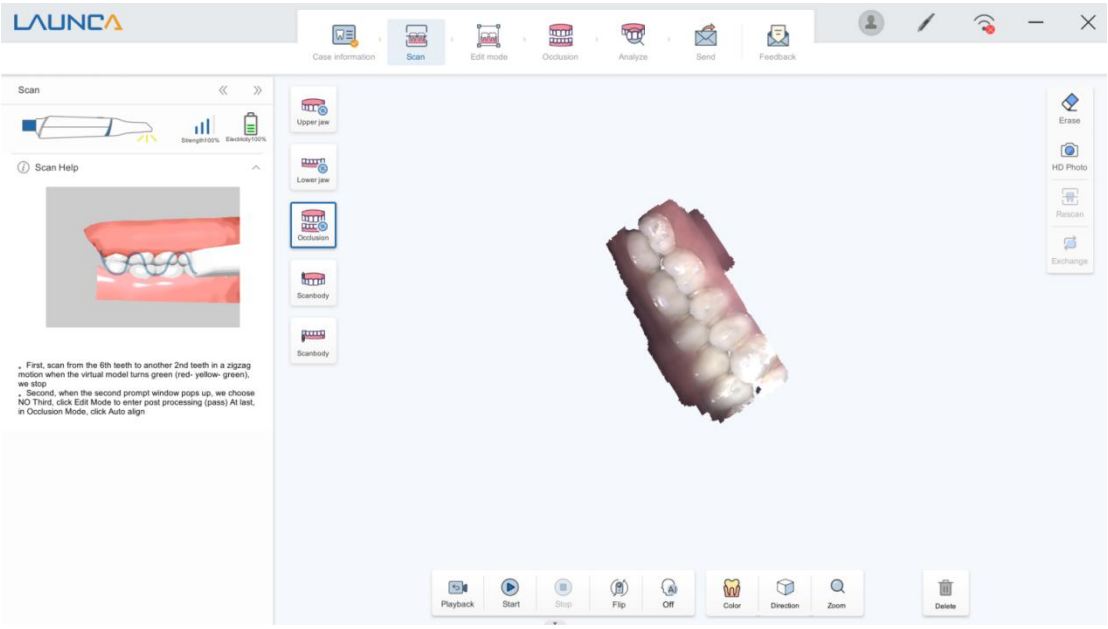


Fig. 4-8-2

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.

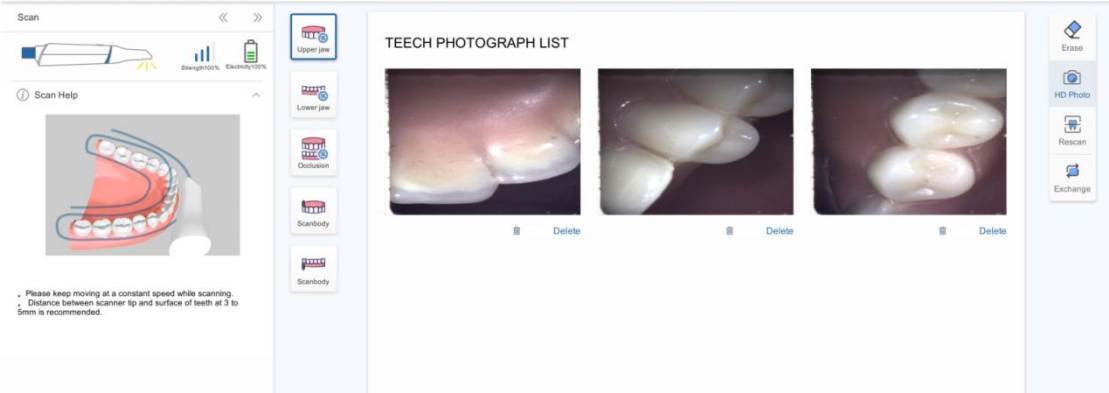


Fig. 4-8-3

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.

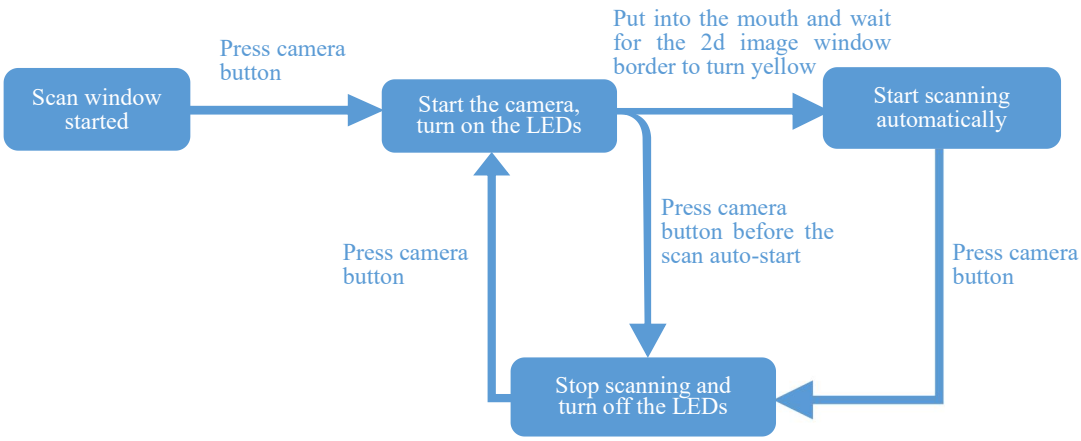


Fig. 4-9

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.

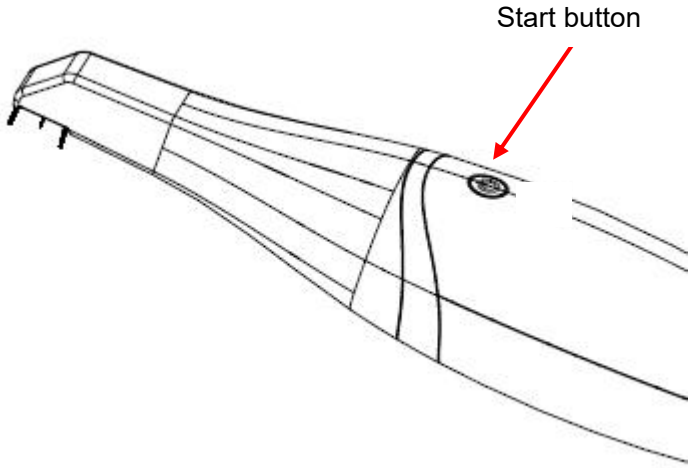


Fig. 4-10

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: ①No 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.

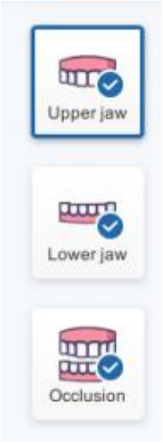


Fig. 4-12

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 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.

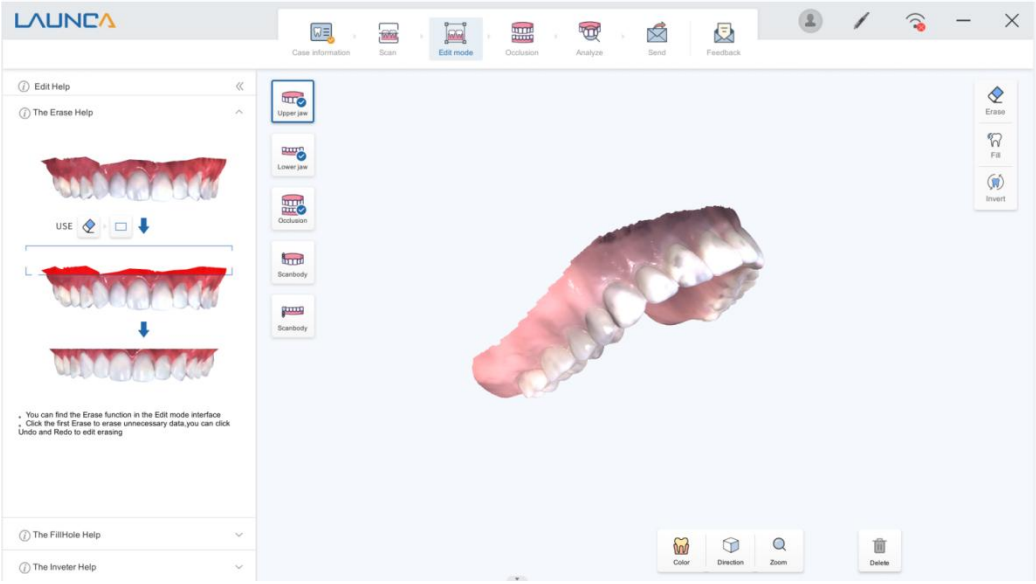


Fig. 4-13

- **Erase :**Trim unnecessary part of the model
- **Fill:** Fill the hole in the model automatically
- **Invert:** Invert the model direction automatically

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.

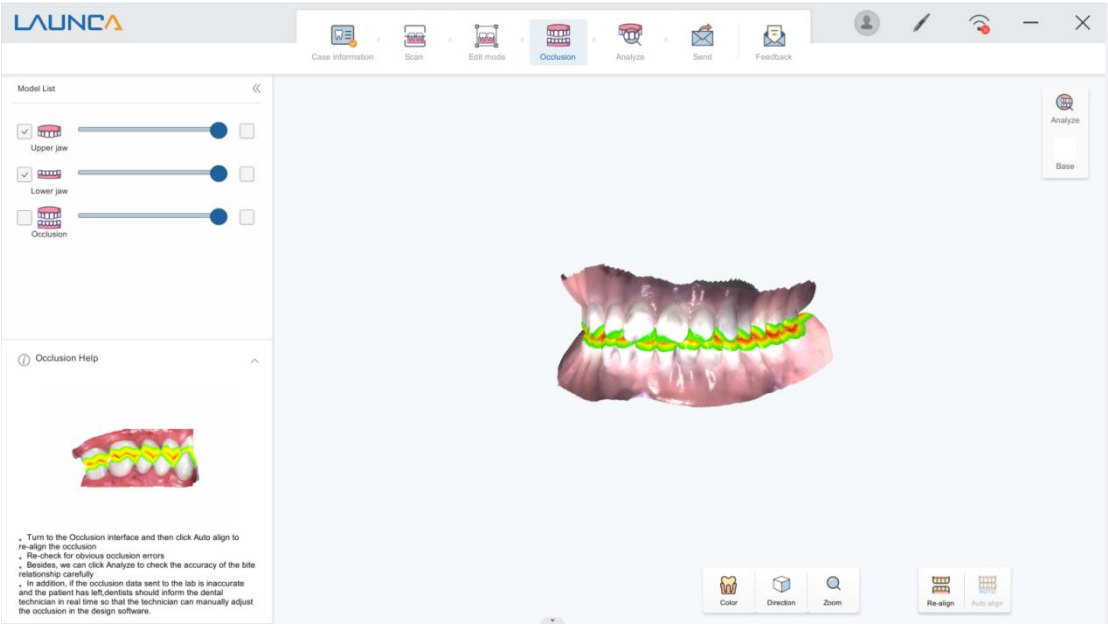


Fig. 4-14

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

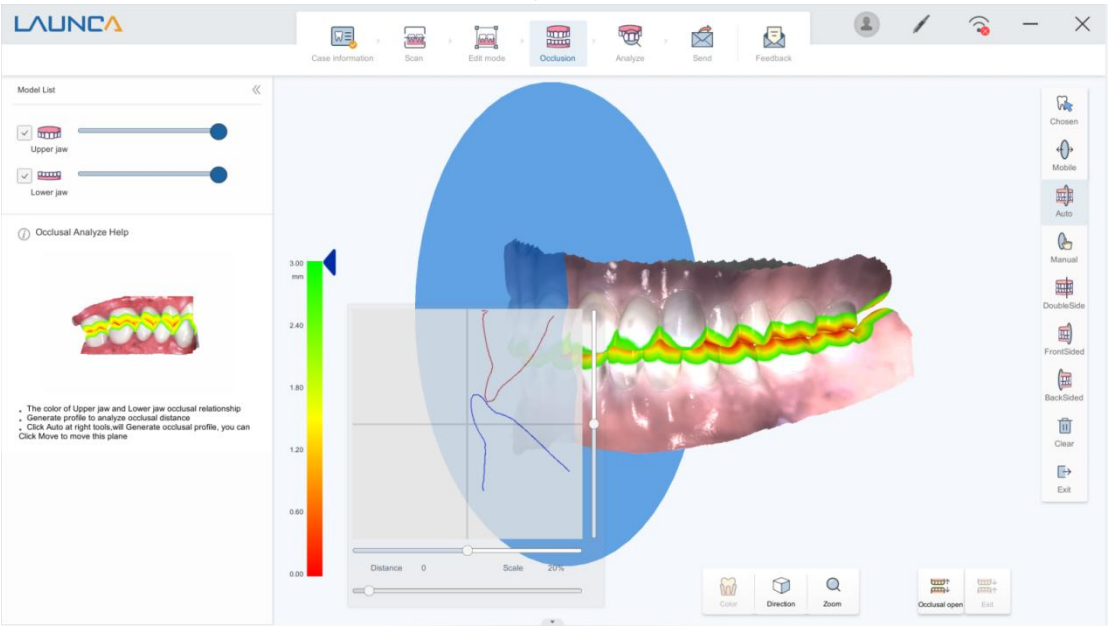


Fig. 4-15

4.2 Undercut and Margin line

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，as shown in Fig. 4-16-1 and Fig. 4-16-2.

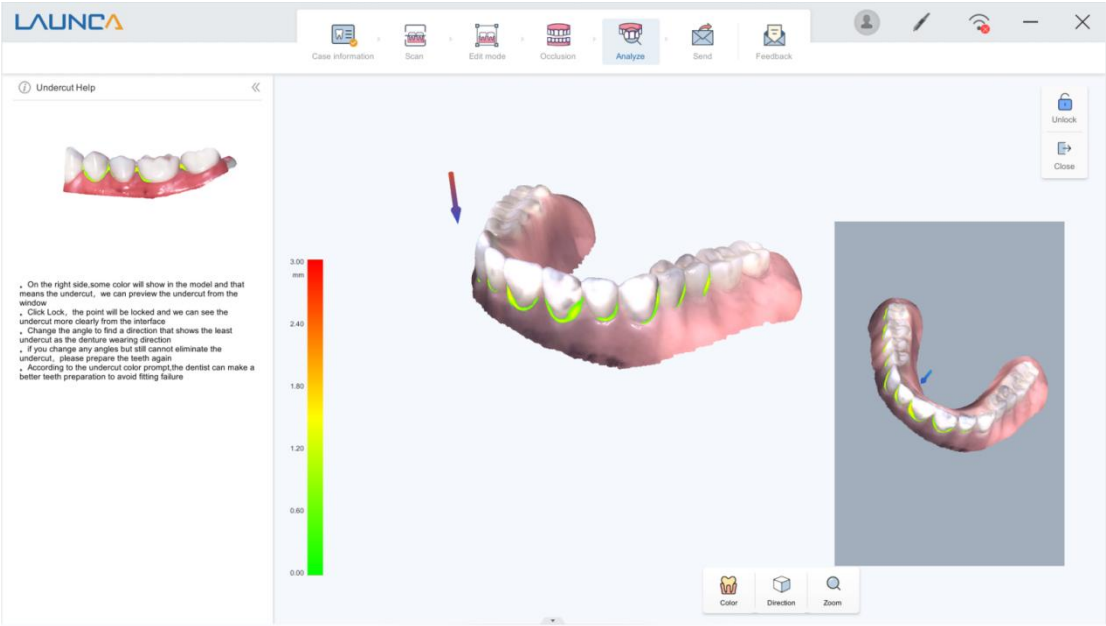


Fig. 4-16-1 Check the undercut

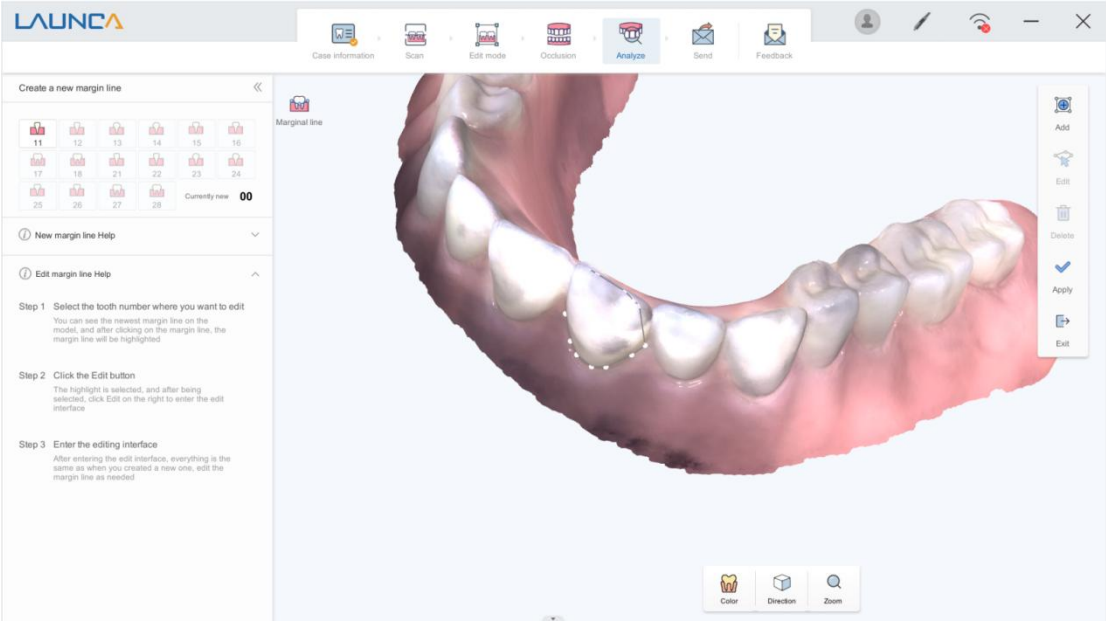


Fig. 4-16-2 Draw margin lines

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.

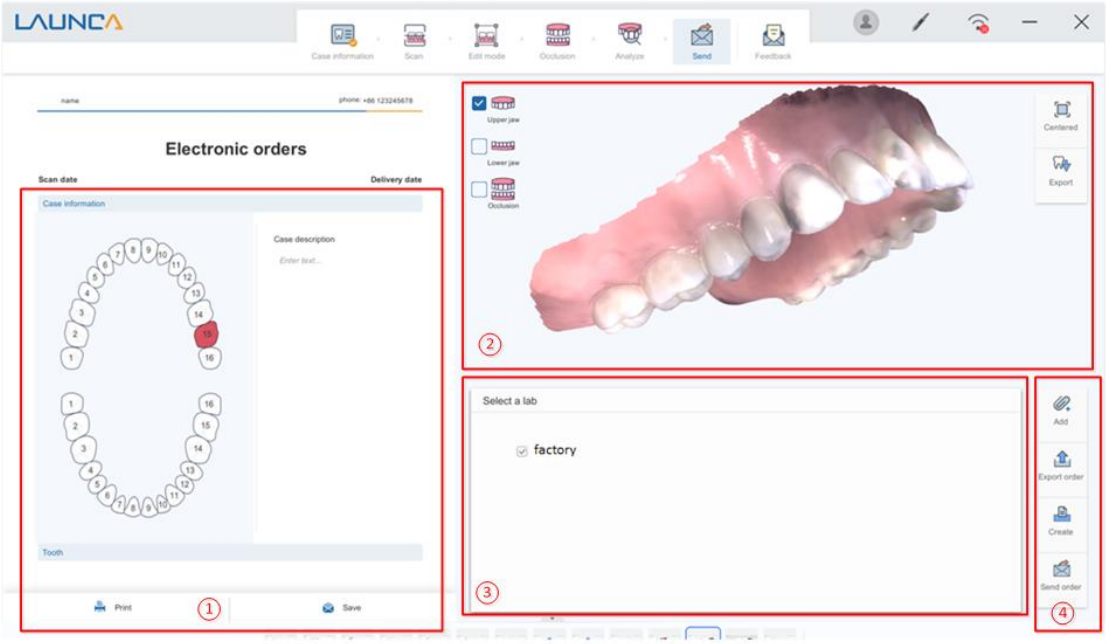


Fig. 4-17

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. • **Export Order:** The order is exported in ZIP format, which includes a PDF order description file and several model files (STL, PLY format supported, select as needed when exported). • **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 Repair and Maintenance

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

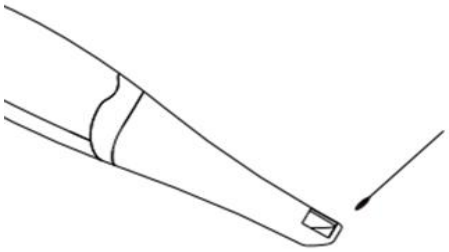
⚠ **Danger: Turn off the power before cleaning the machine, otherwise it may cause electric shock or damage the device.**

⚠ **Warning: Never allow any liquid into the device. This may cause electric shock or damage the device.**

2.1 Camera Adapter Unit Cleaning

Please gently wipe the unit with a damp soft cloth. Then wipe it again with a dry soft cloth. If the bracket is particularly dirty, you can clean it with alcohol, and wipe it again with a dry cloth. Never allow liquid to be put onto the interface and or inside the unit.

2.2 Intraoral Camera Cleaning



Gently wet a clean Cotton swab with 75% alcohol and gently wipe the reflective lens of the camera inside the mouth until no visible dust or water can be seen on the mirror. Be careful when cleaning the cable of the oral endoscope, ensure that it's not been pulled during cleaning process. ince the connecting parts are not waterproof, do not immerse them in any liquid. Wipe the cable with a soft and dry cloth and store it after drying.

Fig. 5-1 Clean the Intraoral Camera

2.3 Camera tip disinfection

The camera tip is hydrothermally sterilized under the ISO 17664-2017 international standard. The Camera tip should be placed in a high-pressure steam cooker at a set temperature of 134˚C, 0.2 MPa, and a sterilization time of 5 minutes.

⚠ **Warning:**

- **Never immerse the intraoral camera in any liquid.**
- **Since the high temperature and high humidity environment will cause irreversible damage to the rear end portion of the camera in the oral cavity, do not disinfect at**

high temperatures.

- **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. Do not bump it or scratch it with hard objects. The scanning window of the intraoral camera does not need to be cleaned when there is no dirt on it. Please minimize the times of wiping the scanning window.**
- **There are some delicate components in the intraoral camera. Please use it carefully! If the intraoral camera drops on the floor, even if there are no cracks or breaks, it may also lead to poor performance or other irreversible damages. In this case, you need to contact an authorized Launca distributor for recalibration or replacement.**

3 Technical Data

Function Items	Parameters and Configuration
Scanning Features	Continuous collections with high-definition video
Application Range	Prosthetics and orthodontics
Recommended Operating Distance	0mm~15 mm
Scanning Accuracy	Single tooth ≤ 20 μm Bridge teech ≤ 45 μm Full jaw teech ≤ 60 μm
Camera Size (including a battery)	250mm(L)*44mm(W)*40mm(H)
Camera Weight (including a battery)	400g
Camera Tip	Standard model: 90mm(L)*33mm(w)*33mm(H)，window:16mm*16mm ; Mini model: 90mm(L)*33mm(w)*33mm(H)，window:13mm*13mm ;
3D Video Scanning	Real-time 3D scanning
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

Recharge Li-ion battery	Model: DL-LiB300 Rated capacity: 3450 mAh 12.42Wh Rated voltage: 3.6V Limited charge voltage:4.2V Battery life: Continuous scan operation ≦ 60min ; Standby mode (power not turned off) ≦ 120min ; Battery cycle charging and discharging times: 500 times (Note: one battery charging and discharging cycle refers to the battery discharging to less than 10% and then charging to full battery) ; This battery complys with IEC62133 and UN38.3.
Wireless	Supports IEEE 802.11.ax communication protocol； Frequency Band ：5.15～5.25GHz 、5.725～5.825GHz Wireless connection working distance ≦ 5m ; This device complies with (RED) 2014/53/EU ; This device complies with part 15 of the FCC Rules. FCC ID No.:
Package Dimensions	640 mm (L) × 520 mm (W) × 1175 mm (H)
Package Weight	2.5kg

Chapter VI Product Service Information

1 Production and Regulatory Information

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

Production and Registration 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: Wellkang Ltd

Registered Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK

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.

No individual or team may reproduce, copy or transmit the contents of this manual in whole or in part without the formal written authorization of Guangdong Launca Medical Device Technology Co., Ltd.

Chapter Ⅶ EMC Information

⚠**Note:**

1. The **DL-300 Wireless 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 scaning 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 **DL-300 Wireless Intraoral Scanner**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

3. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the **DL-300 Wireless 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**
Power Adapter Cable	1.5 M	No
Camera adapter unit Cable	0.2 M	No
Charger Cable	1 M	No

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.
Loose dongle	When the dongle that comes with the scanner becomes loose, and therefore the scan window cannot be started normally, a "Not Found Key" prompt dialog box will pop up. In this case, contact an authorized Launca distributor for technical support.

⚠ **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.**

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	○	○	○	○	○	○
LED Board	○	○	○	○	○	○
Control Board	○	○	○	○	○	○
Camera Module	×	○	○	○	○	○
PCBA of Camera adapter unit	○	○	○	○	○	○
Power Adapter	×	○	○	○	○	○
Wireless Module	×	○	○	○	○	○
Camera tip	×	○	○	○	○	○
Recharge Li-ion battery	×	○	○	○	○	○
Charger base	○	○	○	○	○	○
Charger cable	○	○	○	○	○	○

○: 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.

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

<table>
<tr><td colspan="3">Guidance and manufacturer´s declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">The DL-300 Wireless Intraoral Scanner is intended for use in the electromagnetic environment specified below. The customer or the user of DL-300 Wireless Intraoral Scanner should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The DL-300 Wireless 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.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The DL-300 Wireless 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.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer´s declaration – electromagnetic immunity

The **DL-300 Wireless Intraoral Scanner** is intended for use in the electromagnetic environment specified below. The customer or the user of the **DL-300 Wireless 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 **DL-300 Wireless Intraoral Scanner** requires continued operation during power mains interruptions, it is recommended that the **DL-300 Wireless Intraoral Scanner** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer´s declaration – electromagnetic immunity

The **DL-300 Wireless Intraoral Scanner** is intended for use in the electromagnetic environment specified below. The customer or the user of the **DL-300 Wireless Intraoral Scanner** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the DL-300 Wireless Intraoral Scanner, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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	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) 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 theDL-300 Wireless Intraoral Scanner is used exceeds the applicable RF compliance level above, the DL-300 Wireless Intraoral Scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating theDL-300 Wireless Intraoral Scanner. c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

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 DL-300 Wireless Intraoral Scanner

The **DL-300 Wireless Intraoral Scanner** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **DL-300 Wireless Intraoral Scanner** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **DL-300 Wireless 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.