Manual Information

Part No.:

Version: V1.0

This manual is applicable to Fussen Digital Intraoral Scanner System (S7000,S7000 Premium).

Statement

This manual is reference material for the operation, maintenance, and repair of the product. The user shall operate the product in strict accordance with the manual. Fussen takes no legal liability for any failure or accident caused due to failure to comply with this manual. Copyright in any part of this manual is owned by Fussen. Without our prior written approval, anyone shall not copy, reprint or translate it into any other language.

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Manufacturer's Liability

Fussen will be liable for safety, reliability, and performance of the product only on the condition that: assembly, operation, expansion, regulation, improvement, and repair and maintenance of the product are performed by persons approved by Fussen; the electrical environment in the room where the product is installed meets related national standards, and the instrument is operated under the instructions herein. Fussen will, on your request, provide a paid circuit diagram and other information to assist your technical staff in repairing parts of the instrument which are classified by Fussen as maintainable to users.

FOREWORD

This manual mainly describes the functions and operations of the Digital Intraoral Scanner System.

Target Readers

This manual is intended for clinic staff and other authorized users.

Legend and Designation

Any legend provided in this manual is used only for exampling and description.

Terminology

⚠ Warning

- **Indicates operation or circumstance which may cause personal injury or death.**

⚠ Caution

- **Indicates operation or circumstance which may cause equipment damage or data error or process failure.**

Note

- **Indicates any important information which you should understand.**

CE

Contents

Chapter 1 Safety Guide

This section presents important safety information on the operation of the product.

1.1 Intended Purpose

This product can be used in medical institutions to perform oral scanning, collect images of teeth and other tissues, and provide 3d digital model for CAD/CAM denture design and processing, which can be used for tooth restoration, orthodontics, and implant.

1.2 Contraindications

patients with oral mucosal disease, mental illness, severe respiratory disease, asthma, Parkinson's disease, ADHD.

This product should be used with caution in patients with moderately or severely limited mouth opening.

1.3 Construction

This product consists of a hand piece, tip, holder, battery, battery charging stand, adapter, and software processing system (release version: V1.0.0).

1.4 Model Difference

	S7000	S7000 Premium
Software output format	Support Dicom,obj, ply, stl	Support obj, ply, stl

1.5 Operating Conditions

Environment Conditions:

a) Environment temperature: 5℃ ～30℃.

b) Relative humidity: <80%RH.

c) Atmospheric pressure: 70kPa～110kPa.

The computer system (including the monitor) is a user-made accessory, and its configuration requirements are as follows:

Item	Recommended	Minimum
Computer Hardware	CPU:Intel i7-10750H 2.6G	CPU：Intel i7-7700HQ 2.8G
	RAM:32G DDR	RAM:16G DDR
	Hard Disk: 512 G high speed hard disk	Hard disk: 256 G high speed hard disk
	Monitor: 1920×1080 LCD	Monitor: 1440×900 LCD
	Video Card: NVIDIA GeForce GTX 3060	Video Card: NVIDIA GeForce GTX 1650Ti
Other Hardware	USB2.0, USB3.0 interface	
Operating System	Windows 10 Professional (64 bit)	

Table 1-1 Computer Configuration

1.6 Warning and Note

For safe and effective use of the system, and to avoid system failure, users should first be familiar with operations in the Windows system, read this manual carefully and be familiar with the software and its operations. Users need to pay special attention to the following warnings and cautions during operation.

Note

- **This system is not suitable for home use.**
- **The images and screenshots provided in this manual are for reference only.**
- **This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.**

1.6.1 Safety Warning

⚠ Warning

- **Indicates operation or circumstance which may cause personal injury or death.**
- **Failure to operate the instrument and system in accordance with the safety instructions may endanger the operator. The manufacturer will take no liability for any injury resulting from improper operation.**
- **The system shall be installed by a qualified service engineer.**
- **Before using this system, users should be trained professionally and read this manual carefully.**

- **This system shall not be used for treatment.**
- **This system shall not be used for any family purpose.**
- **Diagnosis and examination with this system should be combined with clinic research on patients, and the diagnostic result should be used only for physician's reference.**
- **Risk of explosion - this equipment shall not be used in any environment exposed to mixture of flammable anesthetic gases and air or oxygen or nitrous oxygen.**
- **This system is furnished with no waterproof device and therefore shall not be used at any location exposed to humidity or water.**
- **Do not splash any liquid on or into this equipment, or otherwise risk of electric shock may be caused.**
- **Do not spray any cleaning agent onto the product to avoid damage to electronic parts and internal components by organic solvent.**
- **In case of any failure, shut down the equipment immediately and contact us or our authorized representative.**
- **When more than one type of medical equipment is connected to the patient, the sum of the leakage current of all equipment should be considered. Please use it with care.**
- **Risk of electric shock - Do not handle the power supply component with wet hands. Be sure to touch the power cable with clean and dry hands.**
- **Do not touch the accessible parts of non-medical electrical equipment and the patient at the same time.**
- **Be sure to operate any non-medical device (e.g. external printer) at least 1.5m/6ft away from the patient.**
- **This system can be connected only to accessory supplied or recommended by the manufacturer.**
- **Pay attention to and prevent any ESD and EMI of any other instrument.**
- **Using this instrument near any strong EMI source, such as surgical electrical equipment or MRI, may cause negative effects.**
- **The battery should be replaced by the Trained personnel, incorrect replacement would result in an unacceptable RISK .**
- **Do not attempt to disassemble, repair, or modify the product. There are no user repairable parts in the product.**

- **Necessary repairs must be made by the manufacturer or its designated agent**
- **The device should not be used adjacent to or stacked with other equipment. If the devices need to be used adjacent to each other or stacked, observe the devices to verify their normal operation.**

1.6.2 Caution

⚠ Caution

- **Before using this product, users must inspect the main unit and any accessory for any damage which may endanger the operator or impair the performance of the instrument. It is recommended to inspect the equipment weekly or more frequently. In case of any obvious damage, replace the damaged part before using this product.**
- **In case that the power cable is missing, damaged, or unavailable, select an alternative power cable that meets the original specifications and your local codes.**
- **Any used device or accessory shall be disposed following local laws and regulations, or returned to the manufacturer or dealer for recycling or proper disposal.**
- **Select a power cable with proper rating to minimize risk.**
- **No part in the system is maintainable by user, so any maintenance operation must be performed by our service personnel.**
- **In the process of installation, maintenance and use, try to avoid the exposure of LED, do not look directly at the LED beam from the scanning window or aim the LED beam at others.**
- **FCC Caution:**

  Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

  This manual is intended for clinic staff and other authorized users, the guidelines are based on standards that were developed by independent

scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

Body and limbs operation; this device was tested for typical body and limbs operations kept 0mm for body contact. To maintain compliance with RF exposure requirements, use accessories that maintain a 0mm for body contact.

1.6.3 Note

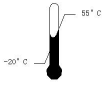
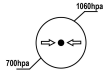
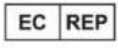
Note

To avoid damage to the system, do not use the product in the following environment:

- Exposed to direct sunlight;
- Exposed to sharp temperature variation;
- Exposed to thick dust;
- Exposed to heat source;
- Exposed to high humidity.

1.7 Symbol Description

Symbol	Name
	Note
	Refer to the operation manual.
	Recyclable
	Wireless Communication

	Serial number
	Date of production
	Manufacturer information
	This Side Up
	Fragile Article
	Protect from Rain
	Maximum Tiers of Stack
	Temperature Limits
	Relative humidity limit (no condensation)
	Atmospheric Pressure Limit
	Authorized representative in the European Community

CE	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
UDI	Unique device identifier
	Scan Tip of the device is a type BF applied part.

1.8 FCC Statement of Compliance

This product complies with Part 15 of the FCC Rules. The following two conditions should be met:

- This product does not cause harmful interference.
- This product must accept any interference received, including interference that may result in an undesired operation.

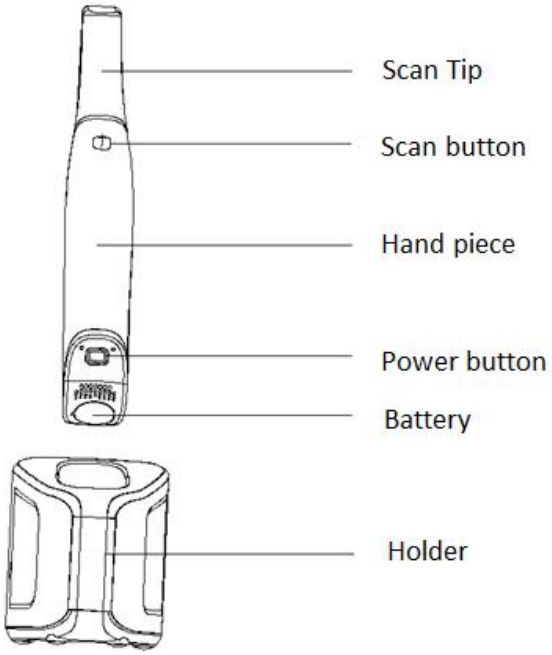
Chapter 2 Product Overview

The device is designed to acquire 3D still images in the following modes：

- Lower jaw
- Upper jaw
- Occlusion

2.1 Product Overview

The image below shows the device's main components.



- Scan Tip: It is reusable and needs to be cleaned and disinfected before use.
- Power button: Short press to power on,Long press to power on off.
- Scan button: Press to start/pause scan.
- Holder: Place it on a firm desktop. Place the device in the holder when it is not in use.
- Battery charging stand :Placed in horizontal table for the battery charing.

Chapter 3 Installation and Connection

Note：

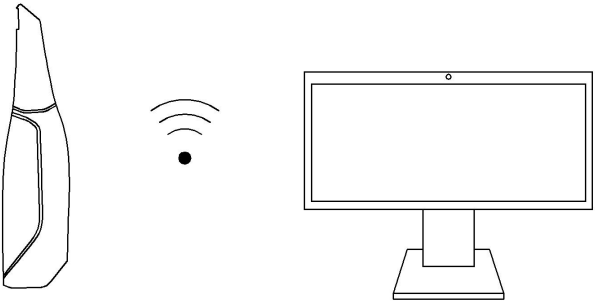
The device should be installed on a firm desktop. Loosely coil the cable to avoid damaging the device.

3.1 Installation of the Software

Install software on the computer. For details, please refer to the related software installation guide.

3.2 Installation of the Device

1. Insert the battery into the device's battery compartment, the power indicator turns green.
2. Press the power button to turn on the device, the power indicator turns white.
3. Place the computer in or near the operating area to ensure that the doctor can be within sight when sitting on a chair.
4. Turn on the wireless hotspot on the computer, click the scanner and connect, the WiFi connection indicator turns blue.



3.3 Computer

Place the computer in or near the operating area to ensure that the doctor can be within sight when sitting on a chair. Settling the patient within the visible range will facilitate communication between the dentist and the patient.

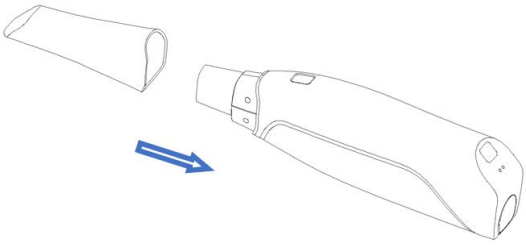
Chapter 4 Operation Guide of the Device

Note:

- To keep a clean environment and to protect the patient's safety, users should wear surgical gloves from starting to use the device until finishing the scan.
- Before scan, the tooth surface should be blow-dried and have moisture isolation treatment.
- When using the device, users should not stare at the scanner's light source for a long time or point the light at people's eyes, for strong light has a blinding effect.
- If the scanning quality decreases during scanning, replace the scan tip and try again.
- To avoid interruption from tongue, cheek and lips during scanning, use mouth mirror, swab, gloved fingers or mouth gag to assist in scanning.

4.1 Installing and Heating a Scan Tip

1. Connect a clean and disinfectant tip to the scanner before scanning.
2. Long press the power button to turn on the device and activate the heating system. Wait about 3mins to fully heat the scanner to prevent the scanner mirror from atomization during scanning.



4.2 Scan

1. Put the scan tip into the patient's mouth, and point to the tooth to be scanned.
2. Press the scan button on the device or click the scan icon on the computer to start scanning. Follow the corresponding scanning path of unilateral scanning and bilateral scanning during scanning.
3. An acquired 3D image will display on the computer screen as the scanning goes on. For detailed analysis and operation, please refer to Chapter 5.

Note:

- The optimum distance between the tip and tooth is 3-5mm. And try not to touch the tooth during the scan.
- Steadily and slowly moving the tip will help the splice of the image.
- Do not scan the lips, cheek, or tongue.

  a) Leave spaces among teeth, lips, and cheek by inserting fingers or a mouth mirror.

  b) Depart the lips and cheek by a lip buccal retractor.

  c) Do not scan fingers during scanning.

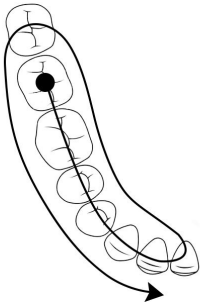
  d) If lips, cheeks, or tongue are scanned, please cut out their data.

4.2.1 Unilateral Scan

4.2.1.1 Lower Jaw Scan

1. Scan from the third molar's occlusal surface to the top of an incisor.
2. Turn to the lingual side, and scan back to the third molar. Try to splice with the obtained occlusal data during scanning.
3. Turn to the buccal side, and scan to the incisor.
4. Check if the scanned image is integrated and scan again for those disintegrated areas.

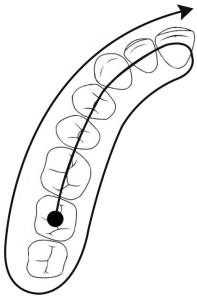
For the scan path, please see below the black lines with an arrow.



4.2.1.2 Upper Jaw Scan

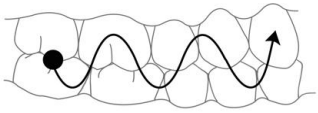
1. Scan from the third molar's occlusal surface to the top of an incisor.
2. Turn to the lingual side, and scan back to the third molar. Try to splice with the obtained occlusal data during the scan.
3. Turn to the buccal side, and scan to the incisor.
4. Check if the scanned image is integrated and scan again for those disintegrated areas.

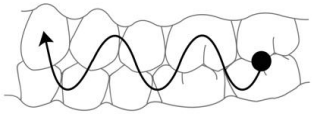
For the scan path, please see below the black lines with an arrow.



4.2.1.3 Occlusion Scan

Scan in S type from the buccal side of the third molar to an incisor.





Note

- During occlusion scanning, the patient should bite the upper and lower jaws tightly. Let the tip's mirror faces the teeth, and check if the occlusion is correct after scanning.

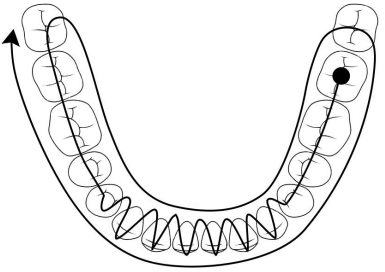
4.2.2 Bilateral Scan

4.2.2.1 Lower Jaw Scan

1. Scan from the third molar's occlusal surface of one side to the top of an incisor of the same side.
2. Scan the incisors from the tongue side in S type, and then scan from the canine to the third molar's occlusal surface of the other side.
3. Turn to the lingual side, scan from the third molar of this side to that of the other side.

4. Turn to the buccal side, scan from the third molar of this side to that of the other side.
5. Check if the scanned image is integrated and scan again for those disintegrated areas.

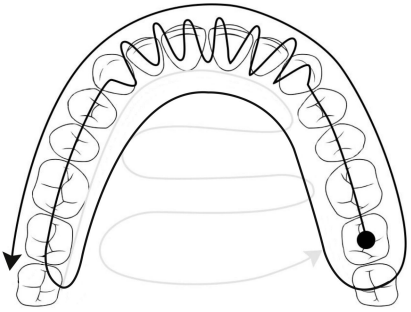
For the scan path, please see below the black line with an arrow.



4.2.2.2 Upper Jaw Scan

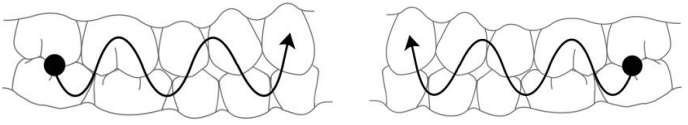
1. Scan from the third molar's occlusal surface of one side to the top of an incisor of the same side.
2. Scan the incisors from the tongue side in S type, and then scan from the canine to the third molar's occlusal surface of the other side.
3. Turn to the lingual side, scan from the third molar of this side to that of the other side.
4. Turn to the buccal side, scan from the third molar of this side to that of the other side.
5. Scan the palate. Scan from the third molar to an incisor from the lingual side, then scan from hard palate to soft palate in S type.
6. Check if the scanned image is integrated and scan again for those disintegrated areas.

For the scan path, please see below the black line with an arrow.



4.2.2.3 Occlusion Scan

Occlusion scanning on bilateral needs two steps. Scan in S type from the buccal side of the third molar to an incisor on one side. Do the same operation on the other side to complete the scanning.



Chapter 5 Operation Guide of the Software

5.1 Overview

The software (Scanflex) is the software of Fussen Digital Intraoral Scanner System. It includes three modules, order, scan, and model check, which can be applied to the collection of intraoral scan data for oral treatment projects.

5.1.1 System Functions

The software consists of three modules with every module has its specific functions.

- Order module: Add patients, dentists and indications. It mainly focuses on patient information management.
- Scan module: Activate the camera to collect intraoral data such as the upper jaw, lower jaw, and occlusion.
- Model check module: Edit and modify the scanned image, convert the data into STL, PLY, OBJ and/or DICOM format for storage or sending, and export videos.

5.1.2 Operation Condition

Please refer to Table1-1 for details.

5.2 Basic Examination Operations

This section mainly explains how to examine a patient through the software of the device. Make sure the device is well connected with the computer before basic examinations.

5.2.1 Logging in to the System

Booting and logging into the system is mainly completed by the following steps:

a) Turn on the console host

b) Log in to the console software

5.2.1.1 Turn on the console host

Note: Before turning on the computer, please make sure the device is on and well connected with the computer.

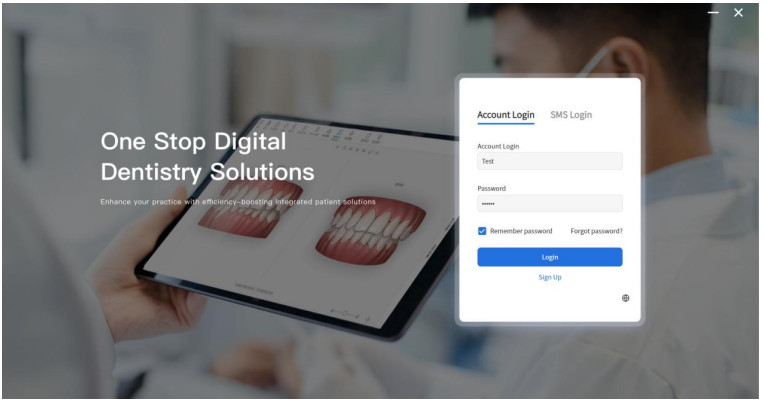
1) Press the computer's power button to display the boot information on the monitor. Several minutes later, the computer turns on.
2) When the computer turns on, the login wiPress the computer's power button to display the boot information on the monitor. Several minutes later, the computer turns on.
3) ndow displays. Enter a correct user name and password for login. (For different system settings, it may not need a password for login.)

5.3 Software Operation

- **Login Page**

Users can register an account through this software or log in to the software with the existing accounts.

Login mode is email address and password for login.



➢ **Register**

Click 'Register now' on the page, jump to the browser web page (the browser should be Google Chrome or Microsoft Edge), and register your Dental X account.

➢ **Login**

Account Login: enter the account (account is registered email address), enter the password and click log in

➢ **Forget the password**

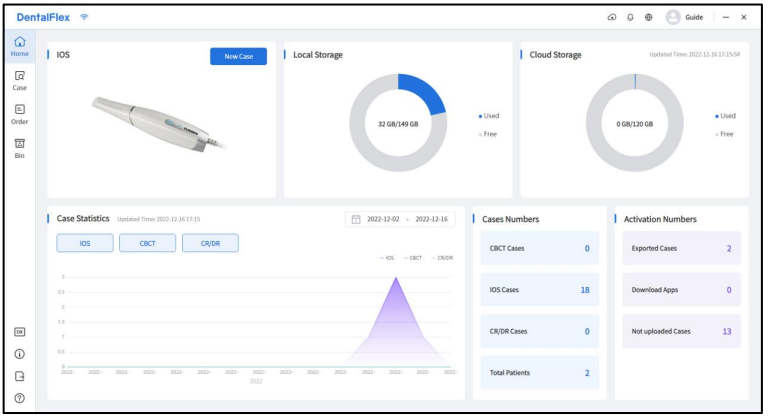
If you forget your password, click "Forgot password" and reset the password by verify from your email address.

➢ **Switch language**

Click ' ' to select another language.

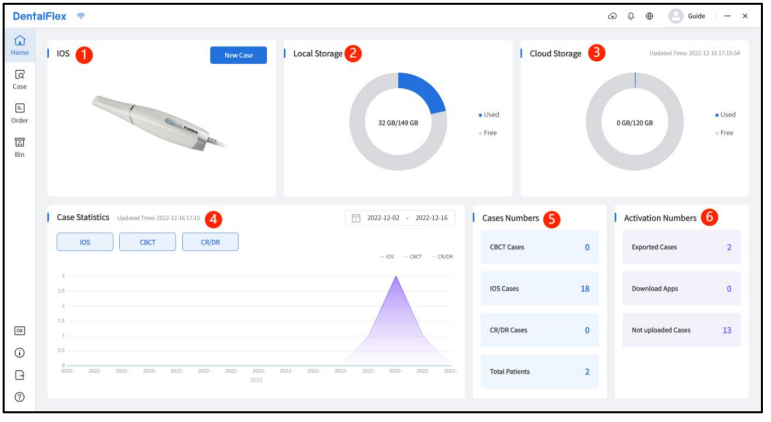
5.3.1 Data management Module

The Data management module is mainly divided into four modules: home page, case, order, and bin, also common function buttons.



5.3.1.1 Home

The home page module contains different windows, device details, local storage capacity, cloud storage capacity, statistics, case information, and analysis information.



1) Device details: Displays the connected equipment model and serial number. You can click on the 'New Case' at this window to add new patient and scanning case.

2) Local storage capacity: displays the total amount of storage and used storage from software installation path.

3) Cloud storage capacity: displays the total amount of storage and used storage of the cloud data of the current account.

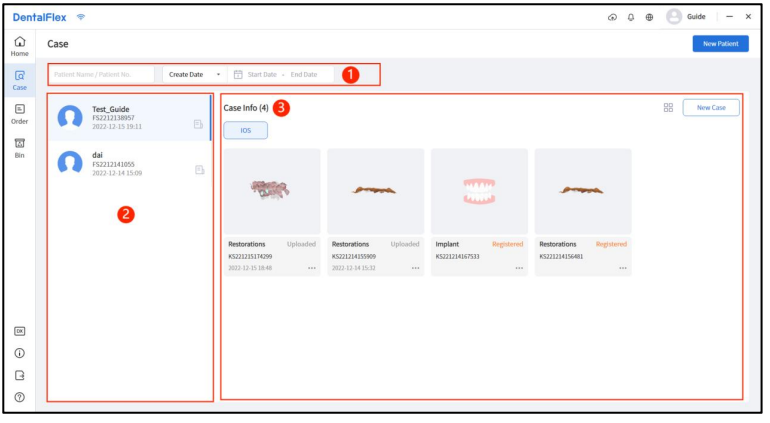
4) Cases statistics: display the daily cases within the selected time range through the linear diagram to do analysis and management.

5) Cases information: Count the cases number from different types of device.

6) analysis information: Count the order number from different types of device.

5.3.1.2 Case

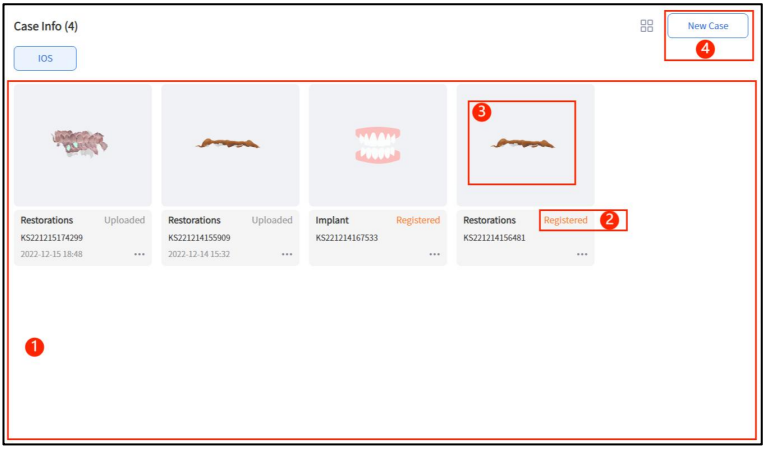
The case module has the query line, patient list and patient information list.



1) Query line: it can be checked by patient name / patient number or time period.

2) Patient list: List of added patients, click  to view patient details.

3) Case information:



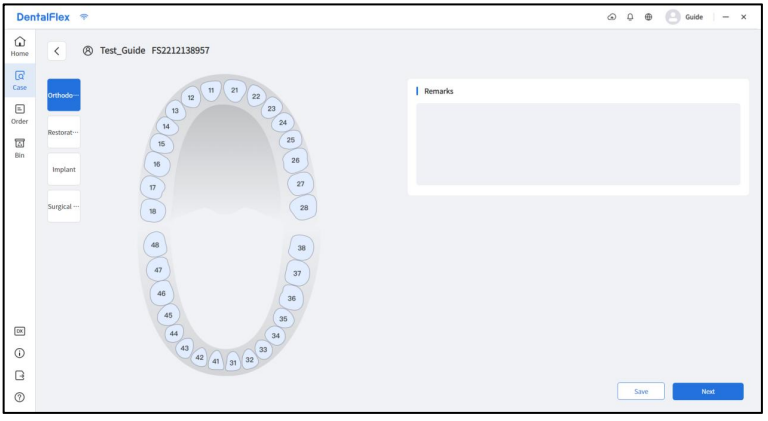
a. List the various cases of the selected patients;

b. A case information has four states: to be checked / not uploaded / uploading / uploaded / ordered.

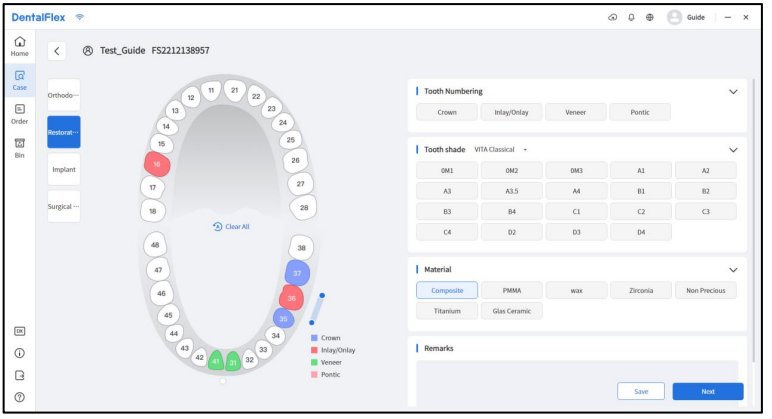
c. To be checked / Not uploaded / Uploading / Uploaded / Ordered, click the scanning data display column to enter the model viewing interface.

d. A New case order creation have orthodontic, restoration, implant and Surgical guide to select.

a) Orthodontic: Create orthodontic case which will select full arch by default, and add comments at right side.



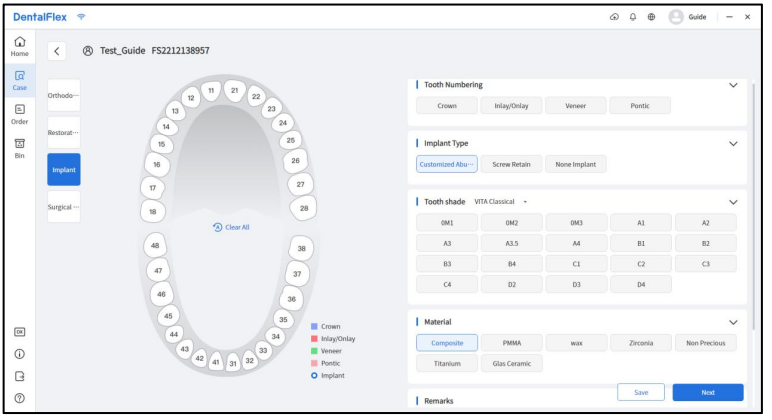
b) Restoration: Create a restoration case, select the tooth position, then choose proper configuration, tooth color, material and comments according to the patient's condition.



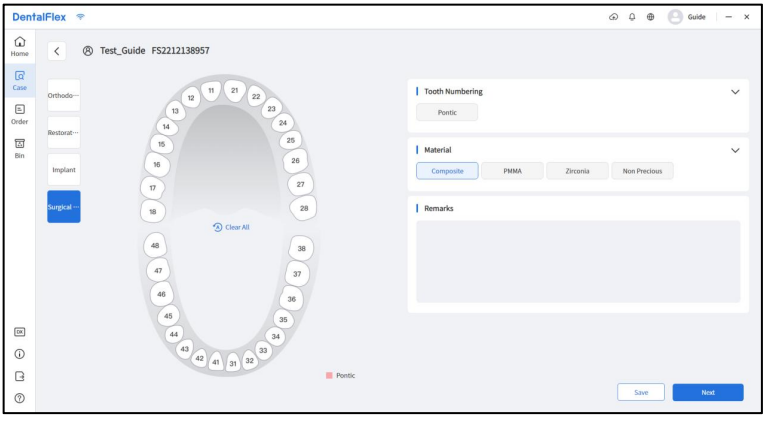
Selection steps: first select the tooth position, then select the configuration. If it is a bridge case, select the point next to the selected tooth position.

- Double-click the position to do deselection
- Press ‘Ctrl’ to select a single and multiple tooth position, and press ‘Shif’t to select the tooth position in batch (keyboard mode).

c) Implant: Create implant case, select the tooth position, then choose proper configuration, implant type, tooth color, material and comments according to the patient's condition.



d) Surgical Guide: Create Surgicla Guide case select the tooth position, then choose proper configuration according to the patient's condition,



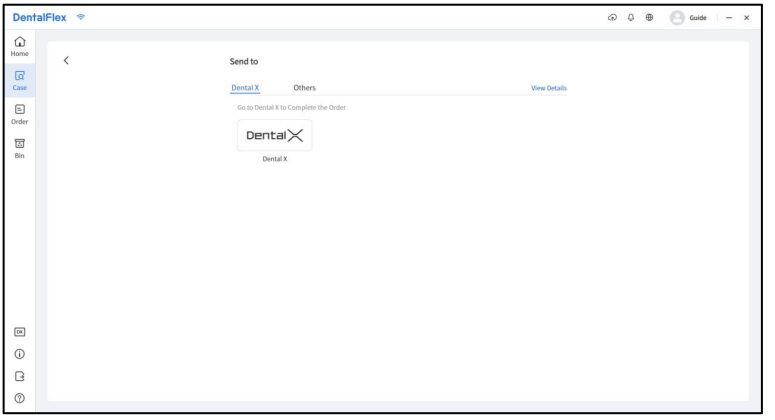
4) For the cases, click '  ' to find more functions of operation;

a. Continue scan: Continue to scan currently unfinished case.

b. Delete: Delete all locally stored information, which can be found at the recycle bin.

c. Copy: Copy the data within the current case data and scan it again.

d. Order: In the uploaded state, the order can be send to certain manufacturer via Dental X platform or other platforms.

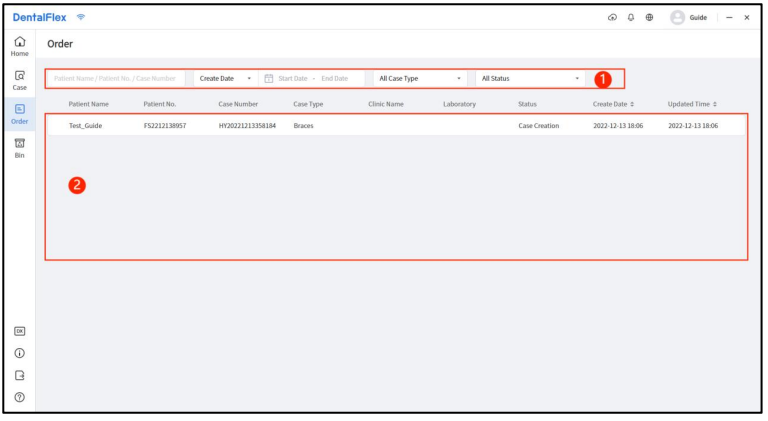


e. Export: Exports all the data and information of the current case.

f. Delete： Delete all information of the item stored locally, which can be found in the recycle bin.

5.3.1.3 Order

The order module has a query line, an order list.

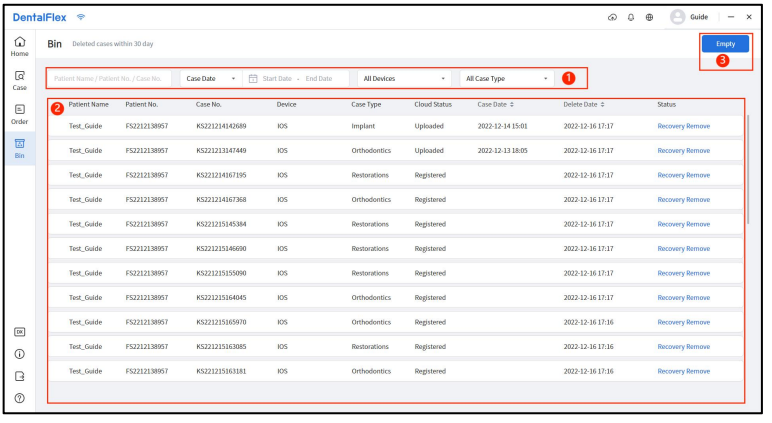


1) Query line: query the order through the patient.

2) Order list: display the ordered cases s, click the order line to jump to the Dental X platform to browse the order details.

5.3.1.4 Recycle Bin

Recycle bin module has query line, order list and empty recycle bin.

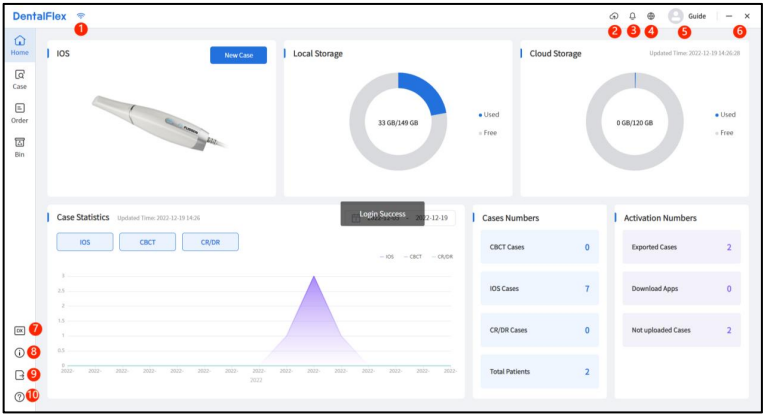


1) Query line: query the order through various patient information.

2) Order list: Displays deleted orders, ‘recovery’ and ‘delete’ can be function at the right side use click.

3) Empty recycle bin: Click to delete all the orders in the bin permanently.

5.3.1.5 Other Functions



1) Network status display: displays the current network status.

2) Cloud synchronization: local and cloud data communication, upload and import.

3) Notification: the related information and message push of the updated version of the official notification.

4) Language: Change the software display language.

5) Account info: management of login account information and logout.

6) Minimize and close software: minimize software and close this software.

7) DX platform: enter to Dental X website.

8) Version information: display the current version, version details and update of the software.

9) Export list: Enter the exported check item list.

10) Help center: contains the software operation manual.

5.3.2 Interface Overview

5.3.2.1 Interface introduction

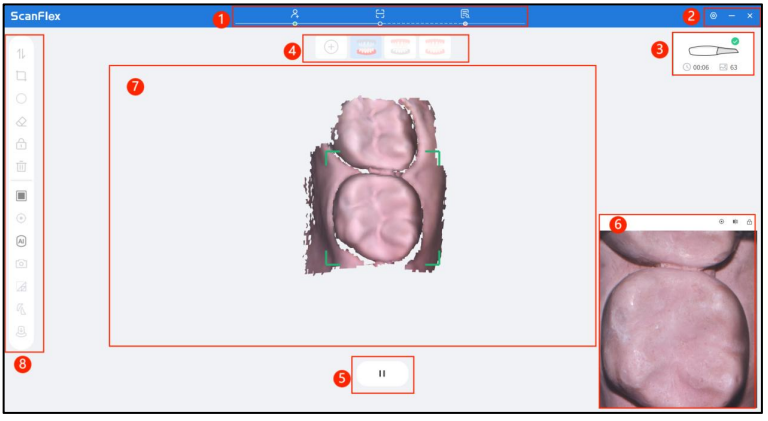


Table 2.1

Serial	Explanation
1	Title bar shows overall workflow include Order Create, Scan and Model Check.
2	Title bar with Setting, Minimize and Close.
3	Device status with Device connection status, Scan time and Scan frames.
4	Scanning workflow under different clinical indications.
5	Start/Pause button and Secondary tool bar
6	Live view window
7	3D model view area
8	Tool bar

5.3.2.2 Tools & Functions

1) Main Tools

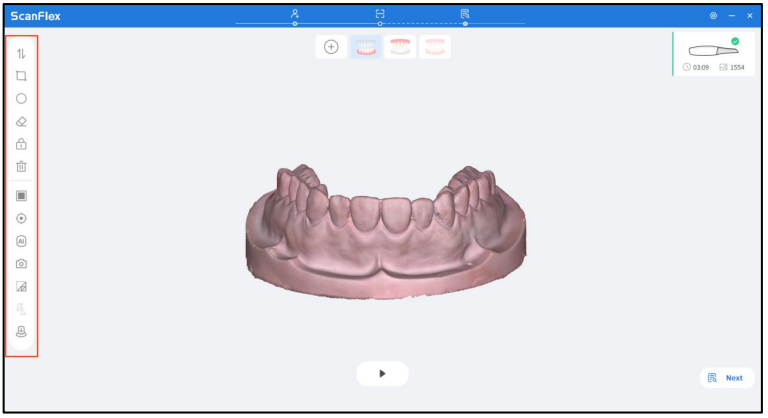


Table 2.2.1

Icon	Function	Explanation
	Trimming	Removes all entities within a poly-line/circled shape drawn on the screen.
	Trimming Brush	Removes all entities on a freehand-drawn path on the screen. The brush comes in 2 different sizes.
	Swap maxilla and mandible	While scanned the wrong jaw, swap maxilla and mandible scan data.
	Lock area	Lock a specific area using the selection tools, further scanning cannot affect the shapes of locked area, but the color. The function can be applied on locking prep area to re-scan margin, or locking margin area to

		re-scan prep.
	Circle Trimming	Select implant position and trim off the gingival area data.
	Delete	Delete 3D model data/Reset 3D model data to original data under post-prep or implant scanbody workflow.
	Reset	Reset 3D model data to original data under post-prep or implant scanbody workflow.
	Texture on/off	Displays the model with texture colors/Displays the model without texture color.
	Centre	Reset the 3D model into the original position.
	AI Denoising	Block unnecessary data if turn on the function, such as tongue, gloves etc.
	HD camera	Takes 2D intraoral pictures, which can share with laboratory.
	Working area	Increase model density and details after selection
	Occlusion Analysis	Analyzes occlusion areas and space based on the scanned bite.
	Undercut Analysis	Analyzes undercut areas and depth based on insertion direction.

2) Secondary Tools

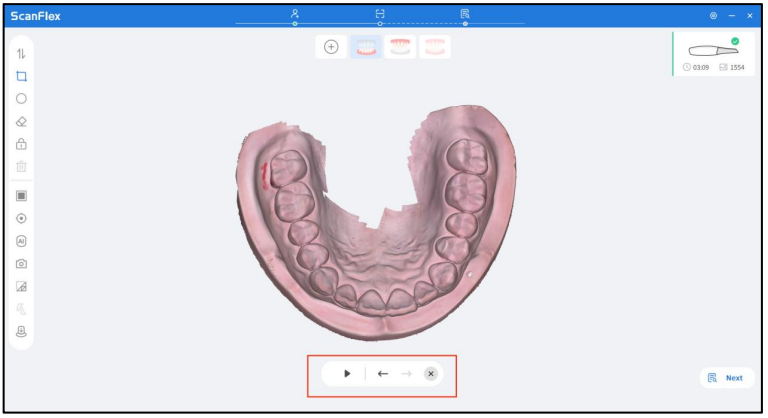


Table 3

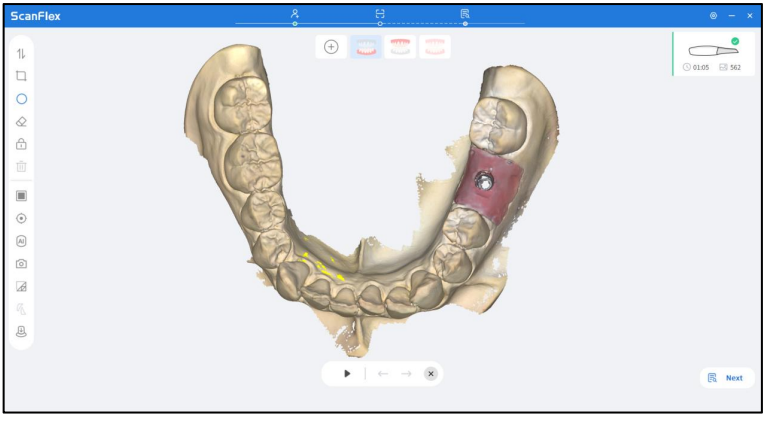
Icon	Function	Explanation
	Start/Pause	Start/Pause scan
	Redo	Redo last step
	Undo	Undo last step
	Undo All	Undo all the steps
	Exit	Exit secondary tools

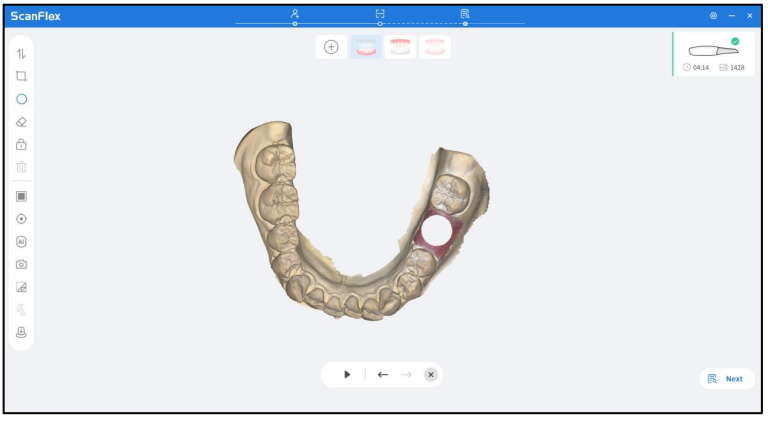
5.3.2.3 Workflow customization

	custom	Customize scan workflow by using to add or delete.

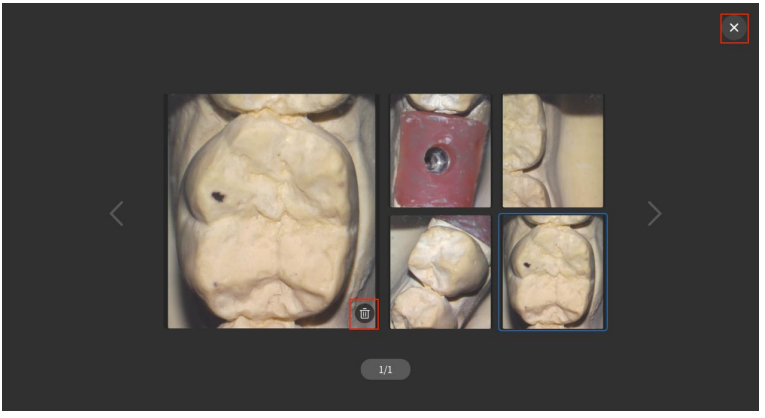
5.3.2.4 Circle Trimming

Can only apply under implant scanbody workflow.



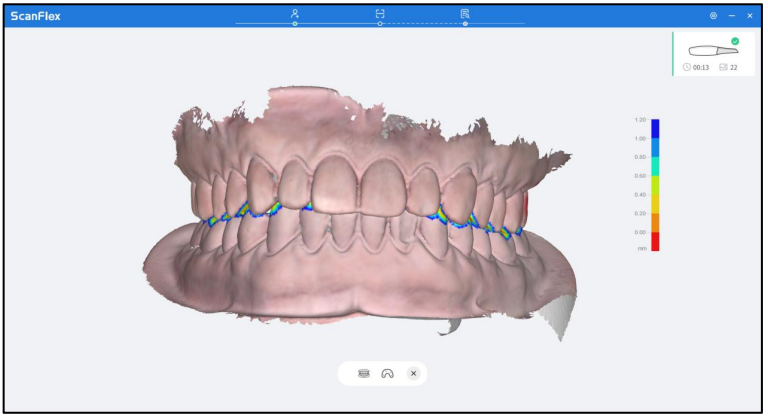


5.3.2.5 HD camera



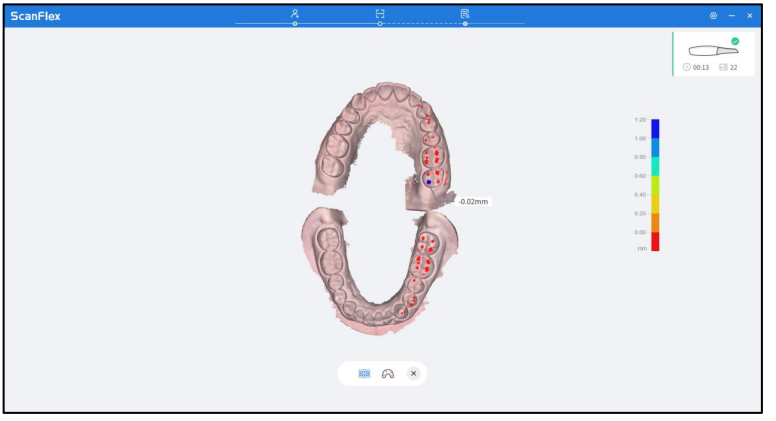
	Delete	Delete current photo
	Exit	Exit photo viewer

5.3.2.6 Occlusion Analysis

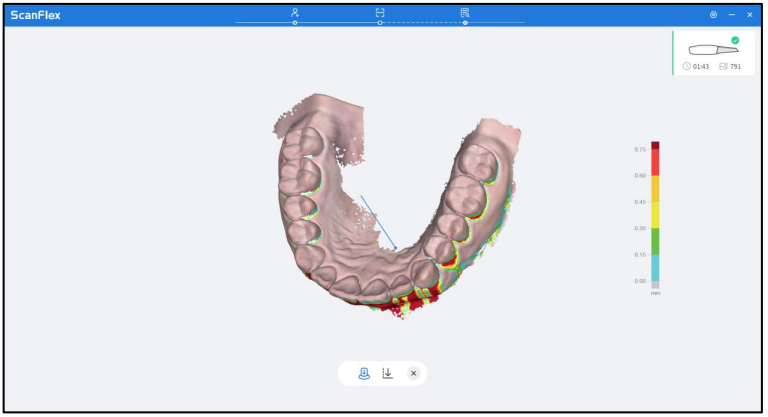


	Open	Open Bite
	Close	Close Bite
	Contact points	Show contact points only


ScanFlex
00:13
22
1.20
1.00
0.80
0.60
0.40
0.20
0.00
mm


ScanFlex
00:13
22
1.20
1.00
0.80
0.60
0.40
0.20
0.00
mm
0.02mm

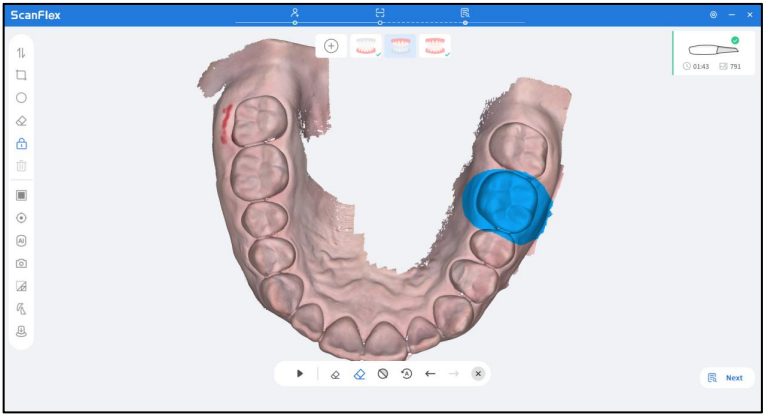
5.3.2.7 Undercut Analysis



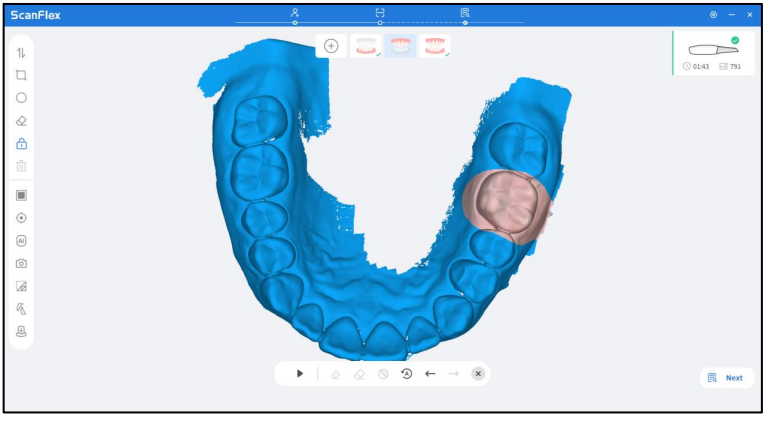
	Insertion direction	Setup insertion direction
	Reset	Reset to original insertion direction

5.3.2.8 Lock & Reverse Lock

Use Brush to select the area, there are 2 different size of brush. The locked area data is not going to change by further scanning.

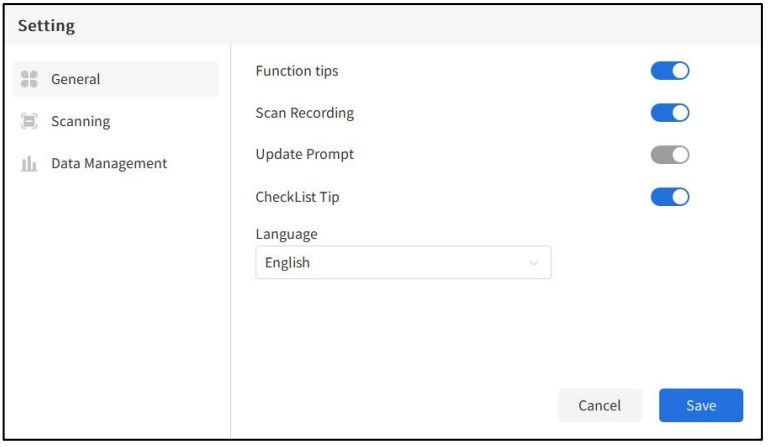


	Reverse lock	By click Reverse lock function will lock the non-selected area.



5.3.2.9 Setting

1) General



a. Function Tips: Turn on/off functions hover tip.

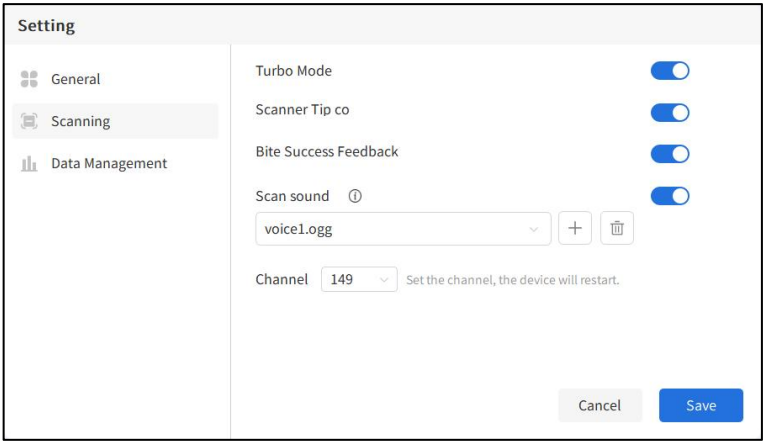
b. Scan Recording:Turn on/off scanning video record.

c. Automatic Update notification: To check and notify if there are any patch can be updated.

d. Check list: pop-up a window shows checklist before model optimization

e. Language: Select different languages.

2) Scaning



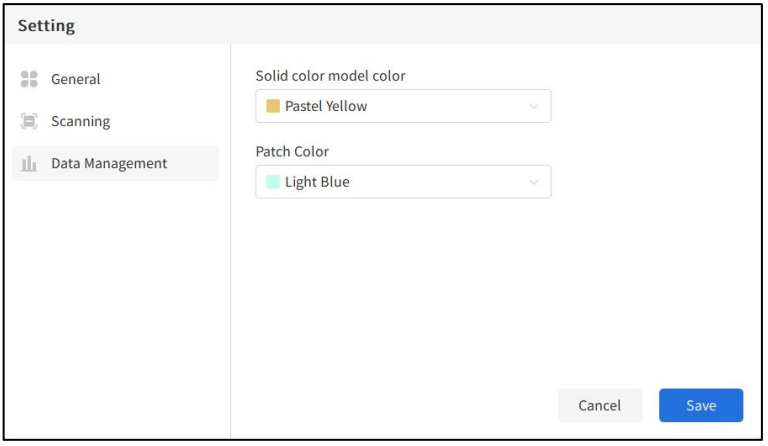
a. Turbo mode: default on, increase scanning fluency by using more computer performance.

b. Scanner tip connection: Automatically recognizes whether the scan tip is connected firmly, close window by clicking Start button.

c. Bite stitching feedback: A sound indicate that the bite is been stitched succeed.

d. Scan sound: Select or add different sound during scanning.

3) Data Management



a. Model mono-color: Select different displayed stone color.

b. Hole-Patch color: Select different hole- patch color on model.

5.3.3 Model Check

This module is used for final model data check before complete the scanning.

5.3.3.1 Real-Time 3D view.

5.3.3.2 3D model view: It shows all scanned single model, use √ it shows model individually, also can adjust transparency of the model.

5.3.3.3 Multi-view: it can switch to front, left, right, top, and bottom, by just click the button.

5.3.3.4 Texture on/off: Displays the model with texture colors/Displays the model without texture color.

5.3.3.5 Centre: Reset the 3D model into the original position.

Chapter 6 Cleaning

⚠ Warning

1. Please obey applicable safety protection provisions.
2. Please carefully read the material safety data list of each detergent.
3. Please carefully read the operation and maintenance instructions of all disinfectant equipment.
4. Prevent liquid from splashing on the device during cleaning.

Notes:

1. Clean the equipment according to demands before being used for the first time. See cleaning methods in this chapter.
2. To prevent equipment damage, refer to data provided by the manufacturer in case of any question about detergent.
3. Do not use organic, halogenated, or petroleum-based solvent, glass cleaner, acetone, or other irrational detergents.
4. Do not use abrasive detergent (e.g. steel wool, silver polish, or detergent).
5. Keep liquid away from electronic members.
6. Prevent liquid from permeating into the equipment shell.
7. The pH value of the detergent shall be within 7.0-10.5.
8. Turn off the power before cleaning.
9. Wear gloves to clean and disinfect the device.

6.1 Clean the Device

1. Keep the device clean.
2. Clean the device's surface with a wet soft cloth, if necessary, clean with 75% medical alcohol.

6.2 Change and Disinfecting Scan Tips

1. A disinfected scan tip should be installed before a new scan.
2. Hold the main part of the device to pull out the scan tip.
3. Install a disinfected scan tip on the device.

Warning

- A scan tip must be disinfected before use.
- A scan tip could be disinfected through high temperature up to 20 times. After 20 times, the scan tip is recommended to be discarded if there is a sign of deterioration.
- Please discard scan tips according to relevant local regulations or hospital's (or clinic's) waste treatment rules.

6.2.1 Disinfectant Methods of Scan Tip

It is recommended to disinfect scan tips through high temperature or with o-benzaldehyde disinfectant (o-benzaldehyde content is 0.5%-0.6%).

1）High temperature disinfectant.

a. Clean a scan tip with clean water or soapy water. Check the scan mirror and make sure it has no stain. Dry the scan tip with an air gun.

b. Put the scan tip into a sterilizing bag, and then seal the sterilizing bag.

c. Put the wrapped scan tips into the sterilizer, select the 121 sterilization process to disinfect at 121° C for at least 45 minutes.

d. After disinfecting, take the scan tips out from the sterilizer for storage.

2）O-benzaldehyde disinfectant

a. Clean a scan tip with clean water or soapy water. Check its scan mirror and make sure it has no stain or milky mist. Dry the mirror with clean tissues.

b. Use o-benzaldehyde disinfectant to disinfect the scan tip for at least 20 minutes. For details, please refer to the o-benzaldehyde disinfectant's user manual.

c. Take out the scan tip from the o-benzaldehyde disinfectant and clean it with clean water. For details, please refer to the o-benzaldehyde disinfectant's user manual.

d. Dry the scan tip. Use a sterile and non-abrasive cloth or tissues to dry the scan tip.

6.3 Maintenance

Before using this system, users shall read this manual carefully and become familiar with all operations on the system.

Only simple maintenance is required in the operation of this equipment, while only proper operations on it can ensure its long-term stable operation. Therefore, you must fully comply with the manufacturer's instructions and recommendations.

6.3.1 Maintenance of the Device

The main unit and monitor shall be placed at a dry location with good ventilation and not exposed to thick dust or humidity. The air duct cooling system shall be kept well-ventilated.

6.3.2 Computer Data Protection

The database must be backed up to any reusable high-capacity storage medium, such as magnetic tape, ZIP disk, DAT digital audiotape.

Store any copy of data at a safe location under the computer supplier's recommendation.

Chapter 7 Accessories

⚠ Warning

Only the accessories provided by the manufacturer can be used, otherwise the equipment performance may not be ensured.

The company will not be responsible for any serious consequences caused by the use of accessories not approved by the manufacture.

Accessory	Type	Quantity
Power adapter	LXCP61-012600	1
Handpiece	S7000-10	1
Scan Tip	S7000-20	3
Holder	S7000-30	1
Battery charging stand	S7000-40	1
Battery	S7000-50	4
U disk	S7000-60	1

Table 7- 1 List of Standard Accessories

Digital Intraoral Scanner System and its accessories can be purchased from the manufacturer or your local dealer.

Chapter 8 Trouble Shooting

This section lists some basic troubleshooting steps you can use to resolve common issues with the device.

1. The scan speed is slow.

   Update computer configuration to the recommended requirement.

2. Margin line is not clear.

   Adjust the tip position to get a clear view of the margin line, then reacquire.

3. The mesh is not smooth and there are spikes on some areas.

   Delete the acquired data and reacquire.

4. Some mesh is in stripes.

   Wipe the tip's mirror and reacquire.

5. There is fog on the mirror inside the tip.

   Delete the acquired data, reopen the device, wait for 2-3 minutes and reacquire.

Note: For more information, please contact Fussen.

Chapter 9 Specifications and Parameters

Product Specifications：

Component	Parameter
Sensor	1/2"　CMOS
Illumination	LED：Red，Green，Blued
Anti-fogging technology	Actively heated tip
Dimensions of the tip' front part	20mm*20mm/21mm*17mm/16mm*15mm
Nominal voltage	100-240V～50/60Hz 1.5A MAX
Input current	12V⎓6A
Software version	V1.0

Environment Conditions：

Operating Temperature	+5 – 30℃
Operating Relative Humidity	< 80%RH
Operating Atmosphere Pressure	70Kpa-110Kpa
Transportation and Storage Temperature	-20 – 55℃
Transportation and Storage Relative Humidity	< 95%RH
Transportation and Storage Atmospheric Pressure	60Kpa-110Kpa

Chapter 10 After-sales Service

Fussen guarantees that all products supplied meet the specifications as labeled on them, and contain no defect in the material or workmanship within the warranty period. The warranty period refers to 2 years after the products arrive at the dealer.

The warranty will become invalid in any of the following cases:

a) damage caused in shipping;

b) damage caused by improper use or maintenance;

c) damage caused by change or repair of any person other than authorized by Fussen:

d) accidental damage;

e) the label indicating the serial number or manufacturer is replaced or removed.

Contact Information

For any question on or problem in maintenance, technical specification, or equipment failure, contact your dealer or our after-sales service department.

E-mail: info@fussencgroup.com

Manufacturer Address: 3F, Building #B, Minlida Industrial Building, Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue, Pingshan Community, Taoyuan Street, Nanshan District, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Postal Code: 518055

EC REP

Share Info GmbH

Heerdter Lohweg 83, 40549 Düsseldorf

Tel： +49 1795 6665 08 Fax： +49 1795 6665 08

Appendix 1 Manufacturer information

Manufacturer: Fussen Technology Co., Ltd

Product Name: Digital Intraoral Scanner System

Product Models: (S7000,S7000 Premium)

Manufacturer Address: 3F, Building #B, Minlida Industrial Building,
Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue,
Pingshan Community, Taoyuan Street, Nanshan District, Shenzhen,China

Production Date: See the label for details

Product Life Cycle: 5 years

Prepared on: Feb.2023

FCC information:

FCC Applicant Name: Fussen Technology Co., Ltd
Address: 3F,Minlida Bld #B, Honghualing Industrial Zone 4,Nanshan ,518055
Shenzhen,Guangdong,CHINA

Appendix 2 EMC Declaration

<table>
<tr><td colspan="3">Guidelines and manufacturer's declaration–EMI</td></tr>
<tr><td colspan="3">Fussen digital intraoral scanner is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment。</td></tr>
<tr><td>EMI TEST</td><td>compliance</td><td>electromagnetic environment–Guidelines</td></tr>
<tr><td>IEC 60601-1-2:2014
RF emission</td><td>Type B</td><td rowspan="2">Fussen digital intraoral scanner’s Radio frequency energy is used only for its internal function. Therefore, its radio frequency emission is very low, and the possibility of causing interference to nearby electronic equipment is very small.</td></tr>
<tr><td>IEC 60601-1-2:2014
Conducted disturbance</td><td>Type B</td></tr>
<tr><td>IEC/EN 61000-3-2:2014
Harmonic current</td><td>Type B</td><td rowspan="2">Fussen digital intraoral scanner is suitable for use in all facilities, including households and residential public low-voltage power supply networks directly connected to households.</td></tr>
<tr><td>IEC/EN 61000-3-3:2013
Voltage fluctation and flicker</td><td>compliant</td></tr>
</table>

Guidelines and manufacturer's declaration–EMS			
Fussen digital intraoral scanner is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment。：			
EMS TEST	IEC60601 TEST VOLTAGE	**COMPLIANCE VOLTAGE**	electromagnetic environment**–Guidelines**
ESD IEC 60601-1-2:2014	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%。
Electrical fast transient **IEC 60601-1-2:2014**	±2kV to power line ±1kV to in/out signal line	±2kV to power line ±1kV to in/out signal line	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge **IEC 60601-1-2:2014**	±1 kV power line to line ±2 kV power line to earth	±1 kV power line to line ±2 kV power line to earth	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dips and interruptions	<5 % U_T,Duration 0.5 Period （%U_T>95% dip	<5 % U_T,Duration 0.5 Period （%U_T>95% dip	The network power supply should have the quality used in a typical

IEC 60601-1-2:2014	and short interruptions） <5 % U_T,Duration 1 period （%U_T >95% dip and short interruptions） 70 % U_T，25/30 period （%U_T 30% dip and short interruption） <5 % U_T,250/300 （%U_T >95% dip and short interruption）	and short interruptions） <5 % U_T,Duration 1 period （%U_T >95% dip and short interruptions） 70 % U_T，25/30 period （%U_T 30% dip and short interruption） <5 % U_T,250/300 （%U_T >95% dip and short interruption）	commercial or hospital environment. If users of Fussen Digital intraoral scanner need continuous operation during power interruption, it is recommended that Fussen Digital intraoral scanner use uninterrupted power supply or battery power supply.
Magnetic Field Immunity（50/60Hz） **IEC 60601-1-2:2014**	3A/m	3A/m/50Hz	The power frequency magnetic field should have the level characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment。
Note: UT refers to the AC network voltage before the test voltage is applied			

Guidelines and manufacturer's declaration–EMS			
Fussen digital intraoral scanner is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
EMS test	**IEC60601 test voltage**	**Compliant voltage**	electromagnetic environment**–Guidelines**
RF conduction **IEC 60601-1-2: 2014** RF emission **IEC 60601-1-2: 2014**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communication equipment should not be used closer to any part of the Fussen Digital Dental Impression System than the recommended isolation distance, including cables. The distance should be calculated by the formula corresponding to the transmitter frequency. **Recommanded isolation distance** d = $1.2\sqrt{P}$ d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.5 GHz Above, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W), and d is the recommended isolation distance, in meters (m). The field strength of the fixed RF transmitter is determined by surveying the

			electromagnetic field a, and in each frequency range b should be lower than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbols. 

note1：At 80MHz and 800MHz, the higher frequency band formula is used.

note2：These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.

a Strong fixed transmitting airports, such as: base stations of wireless (cellular/cordless) telephones and ground mobile radios, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasting and TV broadcasting, etc., the field strength is not theoretically accurate Foreknowledge. In order to assess the electromagnetic environment of a fixed RF transmitter, a survey of electromagnetic fields should be considered. If the measured field strength of the Fussen digital dental impression machine is higher than the RF compliance level of the above application, the Fussen digital dental impression machine should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of the Fussen digital dental intraoral scanner.b In the entire frequency range of 150KHz～80MHz, the field strength should be lower than 3 V/m.

Recommended isolation distance between portable and mobile radio frequency communication equipment and Fussen digital intraoral scanner

Fussen digital intraoral scanner is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the Fussen digital dental impression machine as recommended below.

Maximum rated output power of the transmitter (W)	**Corresponding to the isolation distance of the transmitter at different frequencies /m**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the emission provided by the transmitter manufacturer The maximum rated output power of the machine, in watts (W).

note1：At 80MHz and 800MHz, the higher frequency band formula is used.

note2：These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and humans.