FUSSEN S-6000 D-Oralscan

Manual Information

Part No.: 11.029.0050-00

Version: V1.2

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This manual is applicable only to Fussen Digital Intraoral Scanner System S6000.

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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Application of Manual

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. Any legend and designation provided as an example in this manual are virtual, and any similarity is a coincidence.

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.**

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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

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

1.3 Construction

This product consists of a handpiece, tip, holder, power adapter, and its software FIOS.

1.4 Operating Conditions

Environment Conditions:

a) Ambient temperature: 10℃ ～30℃.

b) Relative humidity: <80%. Atmospheric pressure: 70kPa～110kPa.

A computer system (including monitor) that meets requirements.

Item	Recommended	Minimum
CPU	Intel i7-7700HQ, Quad CPU, 2.8 GHz	Intel i7-4700QM, Quad CPU, 2.4 GHz
RAM	16 GB RAM	16 GB RAM
Monitor	Standard CRT/LCD monitor with screen resolution of 1920 x 1080	Standard CRT/LCD monitor with screen resolution of 1440 x 900
Operating system	Windows 10 Professional (64 bit)	Windows 10 Professional (64 bit)
Video card	NVIDIA GeForce GTX 1050 Ti	NVIDIA GeForce GTX 960M
USB port	USB 3.0 high-speed port	USB 3.0 high-speed port

Table 1-1 Computer Configuration

1.5 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 FIOS 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.**

1.5.1 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.
- 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.
- 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.**

1.5.2 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.**

1.5.3 Note

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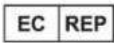
To avoid damage to the system, do not use the product in the following environment:

- Exposed to direct sunlight;

- Exposed to sharp temperature variation;

- Exposed to thick dust;

- Exposed to heat source;

- Exposed to high humidity.

1.6 Symbol Description

Symbol	Name
⚠	Note
👁	Refer to the operation manual.
♺	Recyclable
P/N	Part number
SN	Serial number
⚒	Date of production
⬛	Manufacturer information
↑↑	This Side Up
🍷	Fragile Article
☂	Protect from Rain

3	Maximum Tiers of Stack
	Temperature Limits
	Relative humidity limit (no condensation)
	Atmospheric Pressure Limit
EC REP	Authorized representative in the European Community

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 sterilized before use.

- Power button: 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.

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 Device

1. Plug the scanner's power adapter plug (part 1 in the figure below) into the socket.

2. Connect the scanner's USB connector (part 2 in the figure below) with the computer's USB interface (3.0).

3. Connect the other end of the power adapter (part 3 in the figure below) with the scanner's USB connector.
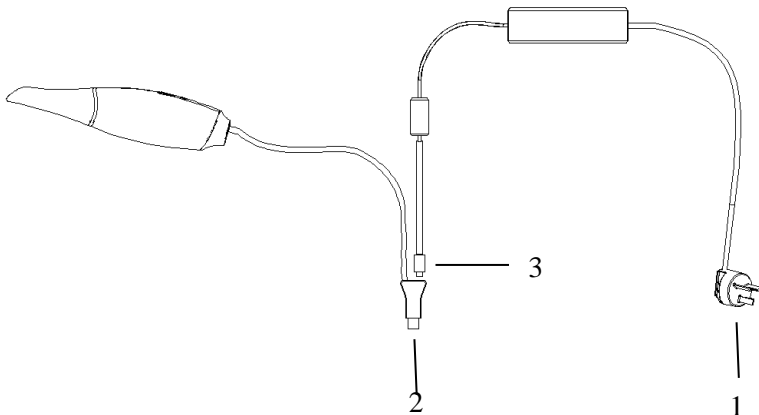
4. Long press the power button to turn on the device, and the power indicator will flash first and then turn to blue.

5.　Put the holder on a stable desktop, and put the handpiece on the holder.

3.2　Installation of the FIOS Software

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

3.3　Computer

Locate the computer and monitor near this device so that the dentist operates it easily 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 sterile 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.
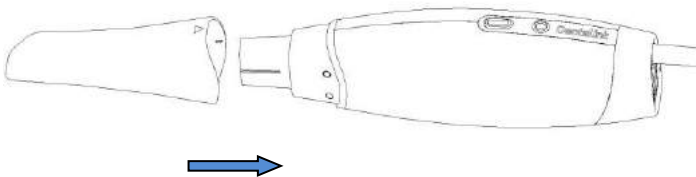
4.2 Scan

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.

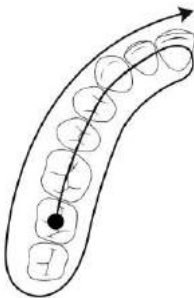4.   Check if the scanned image is integrated and scan again for those disintegrated areas.

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.
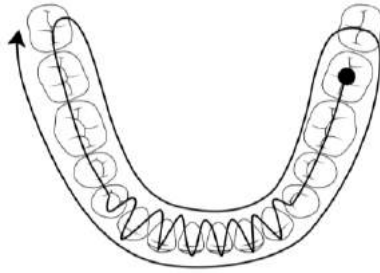
4.2.2.2 Upper Jaw Scan

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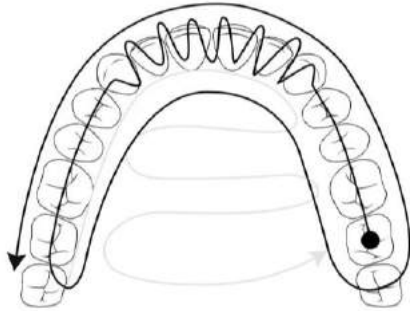
4.2.2.3 Occlusion Scan
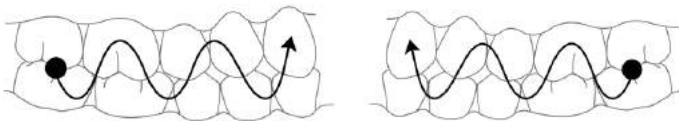
Occlusion scanning on bilateral needs two steps. Scan in S type from the buccal side of the third molar to an incisor on one side. Do the same operation on the other side to complete the scanning.

Chapter 5 Operation Guide of the FIOS Software

5.1 Overview

The FIOS software is the software of Fussen Digital Intraoral Scanner System. It contains three modules, including order, scan, and model check. It helps to acquire intraoral scanning data in restoration, implant, and orthodontics.

5.1.1 System Functions

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

- Order module: Add patients, dentists, indications, and processing scheme. 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 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 describes how to examine a patient with FIOS. Make sure the device is well connected with the computer and adaptor before basic examinations.

5.2.1 Logging in to the System

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 window displays. Enter a correct user name and password for login. (For different system settings, it may not need a password for login.)

5.2.2 Logging in to the FIOS Software

1. Double click shortcut icons of FIOS on the computer desktop to open it and access the login screen, as shown below:
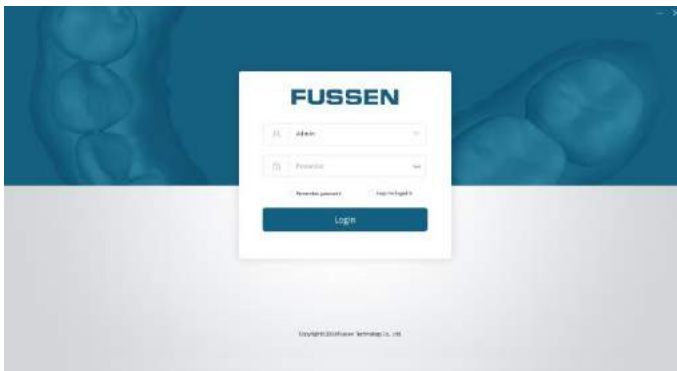
2. Choose an account to enter the home screen of the software.

5.2.3 Management Options

5.2.3.1 User Management

1.Put in a password on the login screen to log in to the home screen.

2. Click **Admin > Management** on the right upper corner of the screen to pop up system configuration dialog, such as below.

3. Click **Account management** on the system configuration screen.

4. Click **Add Account**, enter needed account information, and click **Save** to add a
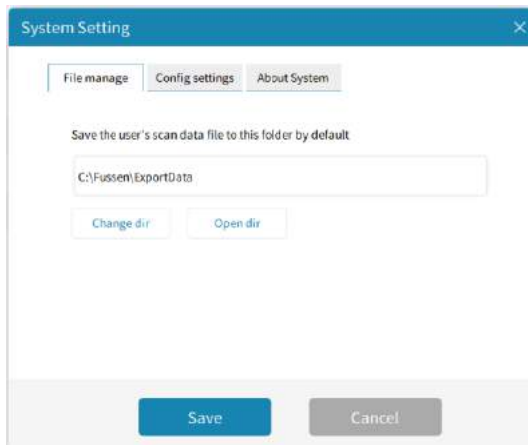
new account.

5. Select an account that needs to delete from the user list, click **Delete Account** to delete it.

5.2.3.2   System Settings

1. Put in a password on the login screen to log in to the home screen.

2.Click **Admin > Settings** on the right upper corner of the home screen to pop up system settings dialog, such as below.

3. Click **Configuration setting**, select an item that needs to change, such as **Scan audio** and **Record video**, and change it.
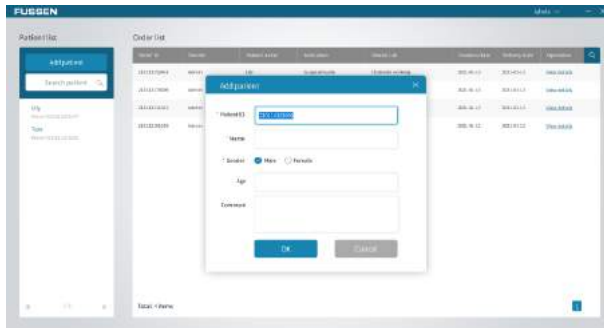
4. Click **About system** to display system information.

Notice

When **Scan audio** turns on, the device beeps each time it starts or stops scan.

5.2.4 Adding Patient Information

1. Select **Add patient** on the home screen to pop up a window as below.

2. Add **Name**, **Gender**, **Age,** and **Comment** in the window and click **OK** to add a new patient.

Note: **Name** and **Gender** are required information.

3. The patient's name will display on the patient list.

4. Click ✏️ on the right side of the patient's name to re-edit the patient's information and click **OK** to confirm the information, or click 🗑️ > **OK** to delete the patient.

5. Click 🔍 on the right upper corner of the screen to enter keywords to search in the patient list.

6. Click a patient name in the patient list to enter the patient screen, such as below.

5.2.5 Adding New Cases

Click **Add** to enter **Order** screen, such as below.

1	Indication list	4	Special demand
2	Navigation bar	5	Back/Next
3	Min/Close		

5.2.6 Selecting Indications

1. Select desired examination items from the indication list for the patient.

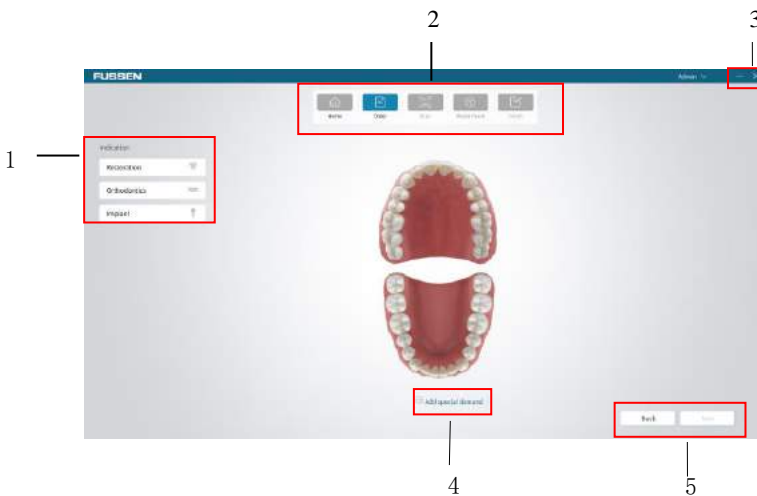| Indications	Examination items
Restoration	Crown, veneer, inlay/onlay, missing teeth
Orthodontics	Clear Aligner, retainer, splint
Implant	Surgical Guide, scan body

5.2.7 Scan and Model check

Scan and model check are the most important steps, please refer to 5.3, 5.4, and 5.5 for details.

5.2.8 Closing the Software

1. Click **Admin > Log off** on the right upper corner of the home screen.

2. Click **OK** to log out of the current account.

3. Click ⊠ > **OK** to close the software.

5.3 Restoration Module

5.3.1 Creating an Restoration Order

1. Select a restoration item on the **Order** screen, then select the teeth that need restoration on the dentition. The teeth information will appear on the right of the screen.
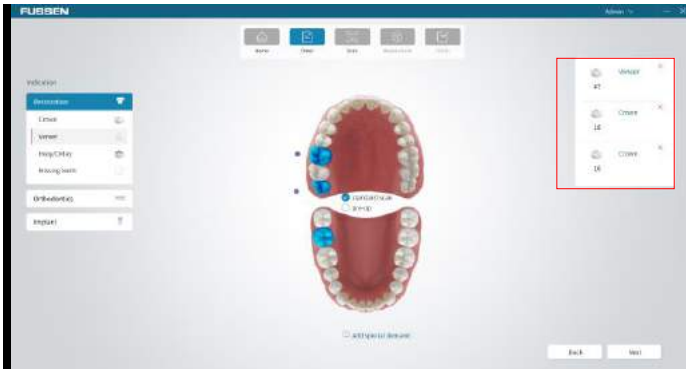
Note: Standard scan is selected by default on the screen, and pre-op scan can be selected manually.

2. Click **Add special demand** at the bottom of the screen, enter the demand, and click **OK** on the popup dialog. The request will display at the bottom.
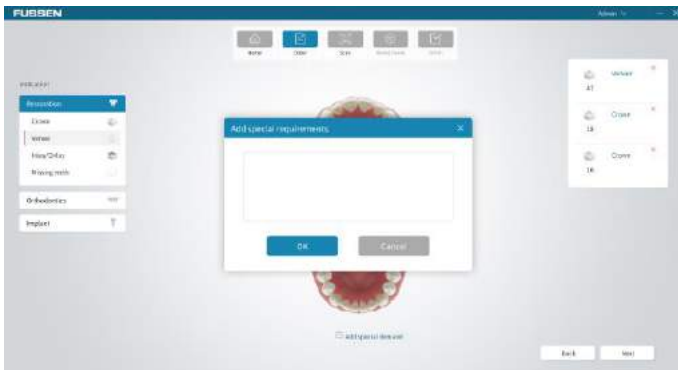
3. Click **Next** to access the scan screen.

5.3.2 Restoration Scan

5.3.2.1 Scan Screen
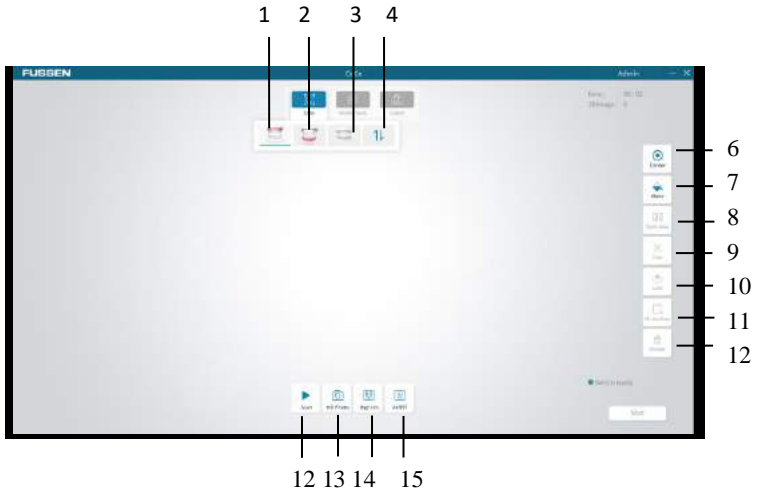
No	Name	Description
1	Upper jaw scan	Scan the patient's teeth on the upper jaw.
2	Lower jaw scan	Scan the patient's teeth on the lower jaw.
3	Occlusion scan	Scan the patient's teeth for occlusion.
4	Exchange	Exchange the scanned models between the upper jaw and lower jaw.
5	Centre	The image return to the centre of the screen.
6	Mono	Change the model between color and mono.

7	Split view	Display the scanned models of pre-op and preset at the same time.
8	Trim	Adjust the 3D image and delete the extra parts.
9	Lock	Lock an area, and scan it again, the data in the area will not change.
10	Hi-res Area	Mark hi-res areas after scan and the area will be in high resolution after reconstruction.
11	Delete	Delete the current image.
12	Scan	Click to start scan.
13	HD photo	Click to take oral photos.
14	High res	Turn on to acquire a clearer model.
15	AI RST	Turn on to distinguish and remove the soft tissue such as the tongue during scanning.

5.3.2.2　Upper Jaw and Lower Jaw Scan

Note

- Since the saliva on the tooth surface will reflect light and affect scan accuracy, the teeth should be blow-dried and be with moisture isolation treatment before scan.

- Check if the tooth edge is exposed. If not, use a gingival retraction cord to move the gums backward before scan.

- The scan tip needs to be heated before scan. Refer to Chapter 4 for detail.

1. Click 🖼 or 🖼 on the scan screen.

Note: The image acquisition screen will display icons of the upper jaw, lower jaw,

and occlusion scan by default. Icons of upper jaw preset and lower jaw preset will display at the image acquisition screen only when **Pre-op** is ticked at the newly added indication screen.

2. Press the scan button on the device or click on the screen to start scan. A real-time dynamic window will appear on the right bottom of the screen.

3. Let the scan tip's scan mirror faces the teeth that need to be scanned. When the scan begins, the acquired image will display on the screen, such as below.

Note

- The area under scanning will display with a green frame.

- When the scan begins, the scan icon on the screen changes to . Click to pause the scan. If the image is incomplete, click to continue this scan.

- You can also press the scan icon on the device to pause the scan, or long press the scan icon to stop the scan.

4. If the image is well-formed, click **Next** and select **Ok** in the pop-up dialog box for model optimization to generate a 3D image, such as below.

Note: If both upper jaw scan and lower jaw scan are needed, select **Cancel** in the pop-up dialog box for model optimization. And select **OK** in the pop-up dialog box when all scans complete.

5. When the 3D image is generated, hold the right mouse button and drag the image to rotate it with the mouse; or hold the right and left mouse buttons at the same time to drag it, or scroll the mouse wheel up and down to zoom it accordingly.

5.3.2.3 Occlusion Scan

1. Click on the scan screen.

2. Press the scan button on the device or click on the screen to start scanning.

3. Let the scan tip's scan mirror faces the occlusal teeth that need to be scanned. Move the scan tip up and down to scan. Click **Pause** when an occlusal point is successfully collected, and the icon will appear at the bottom of the screen.

Note:

- After an occlusal point is collected, click **Pause**, and click **Scan** again to start the scanning of the next occlusal point.

- If the acquisition of the occlusal point is unsuccessful, the next occlusal point icon will not appear.

- The more occlusal points collected, the more accurate the occlusal scan. If 7 teeth are scanned, at least 2 occlusal points need to be collected. At least 4 occlusal points need to be collected for 14 teeth. Up to six occlusion points can be collected.

4. Click **Next** and select **Ok** in the pop-up dialog box for model optimization to generate 3D images. The occlusion model will display. And the occlusion scan completes.

Note:

- When upper jaw, lower jaw, and occlusal scans complete, click to export the image file to a folder, which can save the collected image for future use.

- Select **Scan** or **Import** in the scan interface during preset scanning. If click **Scan**, the steps are the same as the standard scan. If click **Import**, the imported image files could be accessed, and the images saved before could be imported.

5.3.2.4 Locking an area

When the scan pauses, select some area on the acquired image with the **Lock** button, the image in the area will no longer change with the scanning lens.

1. Click on the right side of the screen and circle the area to be locked.

2.	Double click the left mouse button and the selected area will turn blue.

3.	Repeat steps 1 and 2 could add more locked areas.

4.	Click to cancel the selected area in the previous step; Or click to cancel all the locked areas.

5.3.2.5   Trimming Images

Select on the bottom of the screen to modify the image.

1.	Select in an non-scan state.

2. Select ![Polyline icon] Polyline or ![Lasso icon] Lasso and draw the area that needs to be deleted, then double click at the terminal to delete the area. Click ![Undo icon] Undo to restore the deleted area.

3. Click **Done** or **Trim** to confirm the deletion.

5.3.2.6 Deleting Images

If the acquired image is not needed, select ![Delete icon] Delete on the bottom of the screen to delete it.

5.3.2.7 Taking HD Photos

1. Click ![Stop icon] Stop to complete the scan and acquire a 3D image on the scan screen.

2. Click ![HDPhoto icon] HDPhoto on the bottom of the screen to access the photo screen.

3. Put the scan tip on the aimed teeth. The scanned teeth will display on the centre live window. Users could adjust the brightness of the scanned image by adjusting the scroll bar on the window. Once the brightness is set, the device will keep it in later scanning.
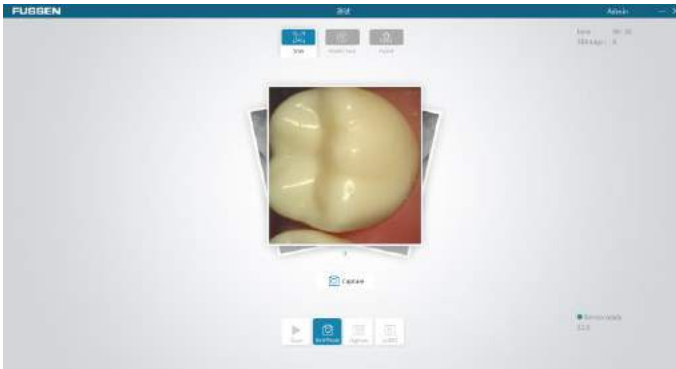
4. Press the scan button on the device or click on the screen to take photos.

4.Click the photo on the center to access the photo list screen to view photos.
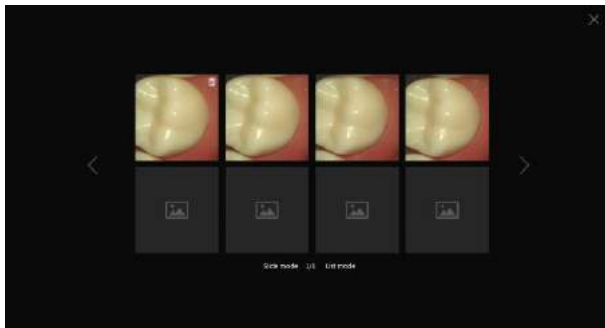
5. There are two modes of photo preview, slide mode and list mode, which could be switched by clicking the corresponding mode.

6. Click on the right-upper corner of a photo to delete an extra photo.

5.3.3 Model Check

When 3D images are acquired, click **Next** on the right bottom of the screen to access the model check screen, such as below.

5.3.3.1 Viewing Occlusion

1. Select ____, then click **Occlusion** on the bottom of the screen to view the occlusion state, such as below.

2.Click **Open jaw/Close jaw** to view its images.
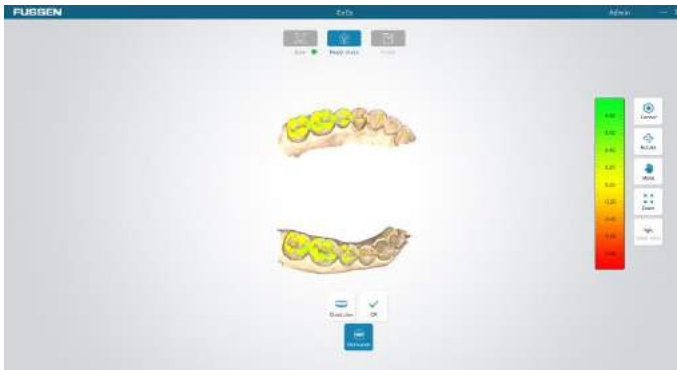
3. Click **OK** to retreat from the view.

5.3.4   Submitting an Order

When model check finished, click **Next** to access order confirmation screen, such as below.

Click **Submit** on the bottom of the screen, then click **OK** on the popup confirmation dialog. All the scanned images in the database will store and could be viewed on the home screen's order list by clicking **View details**.

5.4 Orthodontics Module

5.4.1 Creating an Orthodontics Order

1. Select an orthodontics item on the **Order** screen, then choose an item suitable for patients' needs: clear aligner, retainer, or splint. All the teeth will be automatically selected and the teeth information will appear on the right of the screen.
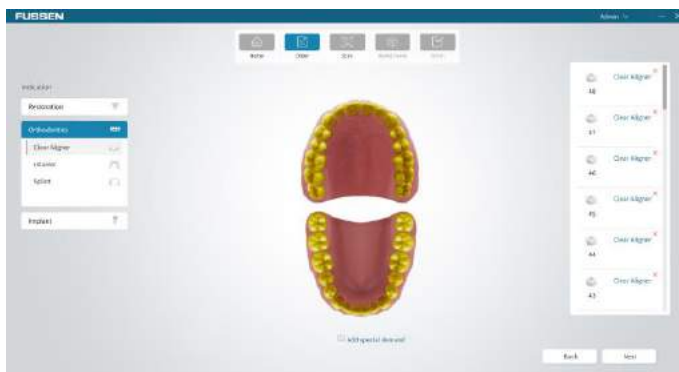
2. Click **Add special demand**, enter the demand, and click **OK** on the popup dialog. The request will display at the bottom.
3. Click **Next** to access the scan screen.

5.4.2 Orthodontics Scan

1. Please refer to 5.3.2.2 to scan the upper jaw and lower jaw.
2. Please refer to 5.3.2.3 to scan occlusion.

Note: For all orthodontics items, upper jaw scan, lower jaw scan, and occlusion scan should be performed successively.

5.4.3 Model Check

Please refer to 5.3.3 to do a model check. If the acquired models are well-formed, click **Next** to enter the submission screen.

5.4.4 Submitting an Order

Click **Submit** on the bottom of the screen, then click **OK** on the popup dialog. All the scanned images in the database will store and could be viewed on the home screen's order list by clicking **View details**.

5.5 Implant Module

5.5.1 Creating an Implant Order

1. Select an implant item on the **Order** screen, then choose an item suitable for patients' needs: surgical guide, or scan body.
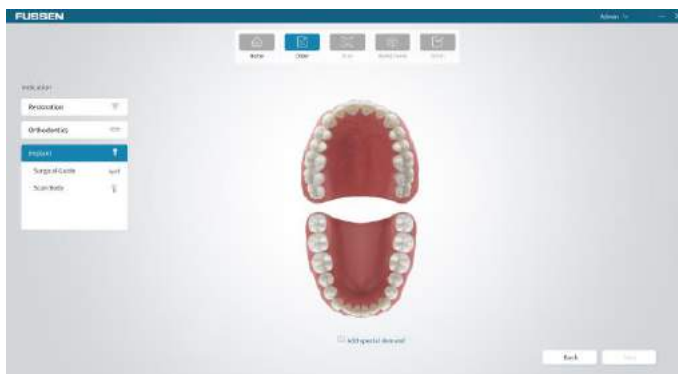
2. Click **Add special demand**, enter the demand, and click **OK** on the popup dialog. The request will display at the bottom.
3. Click **Next** to access the scan screen.

5.5.2 Implant Scan

5.5.2.1 Surgical Guide

1. Please refer to 5.3.2.2 to scan the upper jaw and lower jaw.

2. Please refer to 5.3.2.3 to scan occlusion.

Note: For all implant items, upper jaw scan, lower jaw scan, and occlusion scan should be performed successively.

5.5.2.2 Scan Body

1. Please refer to 5.3.2.2 to prefer upper jaw scan and lower jaw scan.

2. Please refer to 5.3.2.3 to prefer occlusion scan.

3. Trim images

   - If the scan body will implant on the upper jaw, click , the scanned model appears. Click **Trim** to trim the implant area which should be larger than the cuff area.

   - If the scan body will implant on the lower jaw, click , the scanned model appears. Click **Trim** to trim the implant area which should be larger than the cuff area.

Note: If the cropped image is not satisfied, click to restore the image and repeat the trim process.

4. Click on the right side of the screen and circle the area to be locked.

Note:

- The lock function in the implant module is reverse locking. The model data in the circle will update when scanning again, while the model data outside the circle will be locked.

- Only one implant area can be locked at a time.

5. Install a scan body on the implant position and scan it.

6.   Click **Next** to reconstruct model data.

7.   Click **Next** to access the model check screen.

5.5.3 Model Check

Please refer to 5.3.3 to do a model check. If the acquired models are well-formed, click **Next** to enter the submission screen.

5.5.4 Submitting an Order

Click **Submit** on the bottom of the screen, then click **OK** on the popup dialog. All the scanned images in the database will store and could be viewed on the home screen's order list by clicking **View details**.

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 sterilization 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 sterilize 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 Sterilizing Scan Tips

1. A sterilized 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 sterilized scan tip on the device.

Warning

- A scan tip must be sterilized before use.

- A scan tip could be sterilized 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 Sterilization Methods of Scan Tip

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

1）High temperature sterilization

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 sterilize at 121°C for at least 45 minutes.

d. After sterilizing, 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 sterilize 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	HPU63A-105	1
Handpiece	FS-S6000-10	1
Tip	FS-S6000-20	5
Holder	FS-S6000-30	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	1/3.6" CMOS
Illumination	LED：Red，Green，Blued
Scan mode	No powder spraying
Anti-fogging technology	Actively heated tip
Cable length	2m
Digital connection	USB3.0
Dimensions of the tip' front part	20mm*20mm*19.2mm
Nominal voltage	100-240VAC
Input current	1.62A-0.72A
Software version	V1.0.29

Environment Conditions：

Environment temperature	+5 - 40°C
Relative humidity	< 80%RH
Atmosphere pressure	70Kpa-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@fussenct.com

Manufacturer Address: 3F, Building #B, Minlida Industrial Building, Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue, Pingshan Community, Taoyuan Street, Nanshan District, Shenzhen，Guangdong,China,518055

Production Address: 2F,Building #B,HAO MAI Furniture Industry Zone ,Kengzi Street ,Pingshan District,Shenzhen,Guangdong,China,518118

Telephone: 400 660 5770   Postal Code: 518055

EC	REP	Share Info GmbH

Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf

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

Appendix 1 Manufacturer information

Manufacturer: Shenzhen Fussen Technology Co., Ltd

Product Name: Digital Intraoral Scanner System

Product Models: S6000

Manufacturer Address: 3F, Building #B, Minlida Industrial Building, Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue, Pingshan Community, Taoyuan Street, Nanshan District, Shenzhen，Guangdong,China,518055

Production Address: 2F,Building #B,HAO MAI Furniture Industry Zone ,Kengzi Street ,Pingshan District,Shenzhen,Guangdong,China,5181

Production Date: See the label for details

Product Life Cycle: 5 years

Prepared on: Jan 2021

Appendix 2 EMC Declaration

Guidelines and manufacturer's declaration–EMI		
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。		
EMI TEST	**compliance**	electromagnetic environment–**Guidelines**
IEC 60601-1-2:2014 RF emission	Type B	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.
IEC 60601-1-2:2014 Conducted disturbance	Type B	
IEC/EN 61000-3-2:2014 Harmonic current	Type B	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.
IEC/EN 61000-3-3:2013 Voltage fluctation and flicker	compliant	

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** $d = 1.2\sqrt{P}$ P|N $d = $ 〔SN〕 80 MHz to 800 MHz $d = $ ⋀⋀ 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 $d = [\frac{3,5}{E_1}]\sqrt{P}$	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.