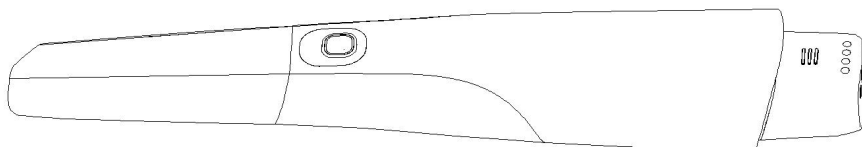




Digital Intraoral Scanner System

S10Wireless series

Instructions for Use



Manual Information

Part No.:

Version: V1.0

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This manual is applicable to Fussen Digital Intraoral Scanner System(S10P Wireless,S10L Wireless,S10E Wireless,S10D Wireless).

Statement

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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 dental clinic staff and other authorized users.

Legend and Designation

Any legend provided in this manual is used only for exemplifying 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.



Safety Guide

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

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 computer-assisted design and manufacturing (CAD/CAM) denture design and processing, which can be used for tooth restoration, orthodontics, and implant.

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.

3. Construction

This product consists of a hand piece, scan tips and software (release version: V1).

4. Model differences

Model \ Software Functions	Enhanced scan	Impression scan	Scanning mode	Sensory perception
S10P Wireless	Yes	Yes	High-performance mode/Conventional mode	Yes
S10L Wireless	No	Yes	Conventional mode	No

S10E Wireless	Yes	No	Conventional mode	No
S10D Wireless	Yes	No	High-performance mode	Yes

5. Operating Conditions

Environment Conditions:

- a) Environment temperature: 5°C ~40°C.**
- b) Relative humidity: <80%RH.**
- c) Atmospheric pressure: 70kPa~106kPa.**

Storage Conditions:

- a) Storage temperature: -20°C ~55°C.**
- b) Relative humidity: <80%RH.**
- c) Atmospheric pressure: 70kPa~106kPa.**

The computer system (including the monitor) have to meet its configuration requirements are as follows:

Item	Minimum configuration	Recommended configuration
CPU	Intel i7 -10750H 2.6GHz	Intel i7 -13800H 4.6GHz
RAM	16GB DDR high-speed memory	32GB DDR high-speed memory
Hard disk	512GB or higher high-speed hard drive	1TB or higher high-speed hard drive
Monitor	1920 × 1080 LCD	1920 × 1080 LCD
Video Card	NVIDIA GeForce RTX 1650 4G and above	NVIDIA GeForce RTX 4060 6G and above
Interface	USB3.2, Gen1, TypeC, 5V3A	
Computer operation system	Windows 10/11 64 bit	

Table 1-1 Computer Configuration

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.

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 nitro 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.
- 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.
- Connection of the PEMS (Programmable Electrical Medical System) to an IT NETWORK that includes other equipment could result in risks to patients, operators, or third parties. The responsible organization should identify, analyze, evaluate, and control these risks.
- Notification that changes to the IT-NETWORK could introduce new RISKS.Changes to the IT-NETWORK include:
 - changes in network configuration;
 - connection of additional items;
 - disconnection of items ;
 - update of equipment
- CAUTION - Failure to control, adjust, or perform steps in accordance with prescribed use may cause harmful radiation exposure.
- Switch off and unplug the LS equipment when not in use.
- Note: The light emitted by this equipment may be harmful to the eyes, do not look directly into the laser beam when using it, you can complete the active

protection response by moving your head or closing your eyes, and avoid continuous intentional beam inward.

- **Note:** The light emitted by this device may be harmful to the skin. When using it, please do not expose the skin to the light source for a long time. You can achieve active protection by moving the device away or avoiding the light source.
- Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- **Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.

- This device is designed for and classified as “Professional population/controlled Use”, 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.
- Head and extremity operation; this device was tested for typical head and extremity operations kept 0mm for head. To maintain compliance with RF exposure requirements, use accessories that maintain a 0mm for head.

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.

6.3. Note

Note

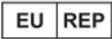
To avoid damage to the system, do not use the product in the following environment:

- **Exposed to direct sunlight;**

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

7. Symbol Description

Symbol	Name
	Note
	Refer to the operation manual.
	Recyclable
	Serial number
	Date of production
	Manufacturer information
	This Side Up
	Fragile Article
	Protect from Rain
	Maximum Tiers of Stack
	Temperature Limits

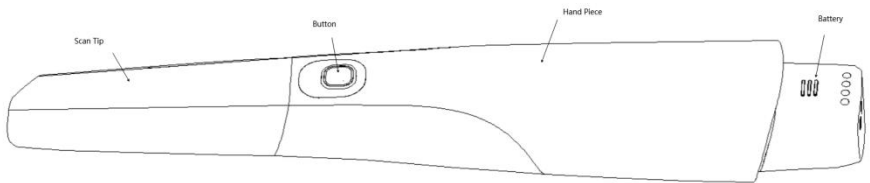
	Relative humidity limit (no condensation)
	Atmospheric Pressure Limit
	Authorized representative in the European Community
	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
	Unique device identifier
	Scan Tip of the device is a type BF applied part.
	Medical device
	Importer
	Warning label-Hazard symbol

Chapter 1 Product Overview

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

- **Lower jaw**
- **Upper jaw**
- **Occlusion**

1.1 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.
- **Scan Button:**
 - Short press: Start/Pause;
 - Long press: Switch workflow such as upper jaw/lower jaw;
 - Double click: Enter G-motion mode.
- **Hand Piece:** The main part of the device.
- **Battery:** The power supply for the wireless intraoral scanner.

1.2 Charging Dock

The following diagram depicts the exterior structure of the main components of the charging dock for the S10 Wireless Intraoral Digital Impression Scanner.

- **Base:** Supports vertical charging placement. When the backrest is detached, it enables horizontal placement.

- Detachable Backrest: When assembled, it supports vertical charging; when detached, it allows horizontal device placement.
- Charging Indicator: Illuminates a steady blue light when powered.

1.3 Charging Case

The following diagram depicts the exterior structure of the main components of the charging case for the S10Wireless Intraoral Digital Impression Scanner.

- Charging Case Body: Supports charging for up to three inserted batteries.
- Charging Indicator: Illuminates a steady blue light when powered.
- Fast/Standard Charging Mode Switching: Allows toggling between fast and standard charging modes.
- Battery: The power supply for the wireless intraoral scanner.
- Battery Level Indicator: Four segments, each representing 25% capacity, Segments flash during charging, All four illuminate steadily when fully charged.

Chapter 2 Installation and Connection

Note:

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

2.1 Installation of the Software

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

2.2 Installation of the Device

1. Power on the device: Inserting the battery powers on the device instantly.
2. After the device is powered on, if there are no abnormalities, the device status light is blue and the breathing light is breathing.
3. If there is any abnormality, the white breathing light of the device status light will flash.
4. Start working, the equipment status light is blue and the breathing light is constantly on.

2.3 Computer

Place the computer in or near the operating area to ensure that the operator can observe the monitor while scanning. And the monitor should be visible will facilitate communication between the the operator and the patient.

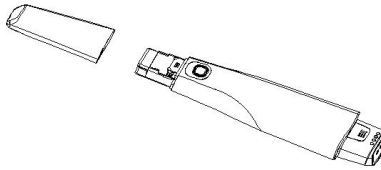
Chapter 3 Operation Guide of the Device

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.

3.1 Installing and Heating a Scan Tip

1. Connect a clean and sterilized tip to the handpiece before scanning, Scanner tip indicator turns blue flash while the scanner tip is inserted.
2. After preheating, the scanner tip indicator turns to blue light up.



3.2 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.

3.2.1 Lateral Scan

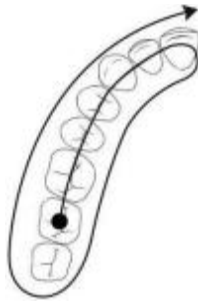
3.2.1.1 Lower Jaw Scan

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.



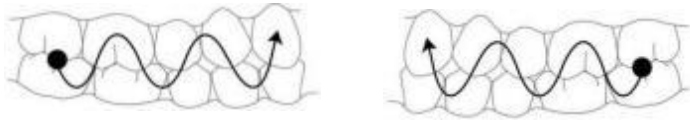
3.2.1.2 Upper Jaw Scan

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.



3.2.1.3 Occlusion Scan

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



Note

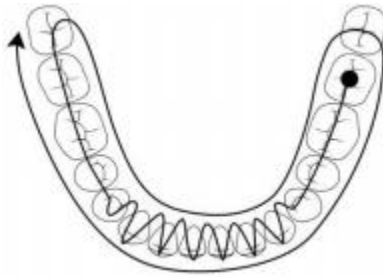
- During occlusion scanning, the patient should bite the upper and lower jaws tightly. Let the tip's mirror faces the teeth, and check if the occlusion is correct after scanning.

3.2.2 Full arch Scan

3.2.2.1 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.

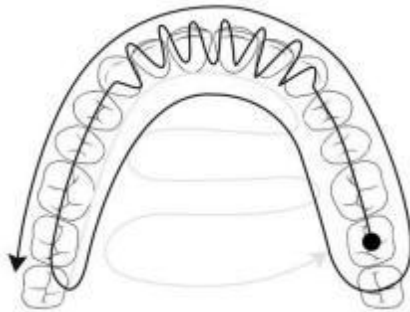
4. Turn to the buccal side, scan from the third molar of this side to that of the other side.
5. Check if the scanned image is integrated and scan again for those disintegrated areas. For the scan path, please see below the black line with an arrow.



3.2.2.2 Upper Jaw Scan

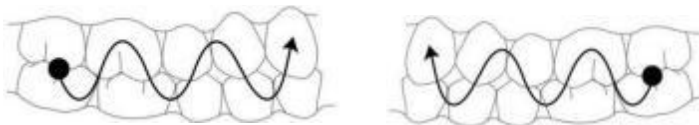
1. Scan from the third molar's occlusal surface of one side to the top of an incisor of the same side.
2. Scan the incisors from the tongue side in S type, and then scan from the canine to the third molar's occlusal surface of the other side.

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.



3.2.2.3 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 4 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.

4.1 Handpiece disinfection method

1. Use disposable covers or sleeves to prevent cross-contamination.
2. Clean the device's surface with a wet soft cloth, if necessary, clean

with 75% medical alcohol.

4.2 Scan tip disinfection Methods

4.2.1 Replace of 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 asterilized 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 200 times. After 200 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.

4.2.2 Autoclave 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 soap 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 autoclave machine, select the 121°C sterilization process. Alternatively, select 134°C and sterilize for at least 5 minutes at this temperature.
- 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.

4.3 Cleaning Charging Dock, Charging Case, and Battery

1. Put on gloves, apply gentle disinfectant, and gently wipe the surface of the charging dock.
2. Put on gloves, apply gentle disinfectant, and gently wipe the surface of the charging case.
3. Put on gloves, apply gentle disinfectant, and gently wipe the surface of the battery.

4.4 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.

4.4.1 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.

1. Clean the scanner regularly: Use a soft, non-abrasive cloth or disposable wipes to clean the scanner after each use. Avoid using harsh chemicals or excessive moisture to prevent damage.

2. Check cables and connections: Regularly inspect the scanner's cables and connections for any signs of wear or damage. If any issues are found, contact the manufacturer for assistance or to arrange repairs.

3. Store properly: When the scanner is not in use, store it in a clean, dry location at room temperature. Protect it from excessive heat, direct sunlight, and humidity.

4. Handle with care: Avoid dropping or mishandling the scanner, as this may cause internal damage. When transporting the scanner, use a protective case or packaging recommended by the manufacturer.

5. Protect the scanner from contamination: Use disposable covers or sleeves to prevent cross-contamination between patients. These covers should be changed regularly.

6. Train and educate users: Provide proper training to all users on the correct operation and handling of the intraoral scanner. This will

help prevent accidental damage and ensure consistent and accurate results.

7. Keep the scanner protected during travel: If you need to transport the scanner, use a secure and padded carrying case designed specifically for the device. This will help protect it from any accidental bumps or impact.

4.4.2Data 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.

1. Stay updated: Keep the scanner's software and firmware up to date by installing any updates provided by the manufacturer. This helps ensure optimal performance and compatibility with other devices or software.

2. Document usage and maintenance: Keep a record of the frequency of use, maintenance activities performed, and any issues encountered with the scanner. This documentation can be helpful for future reference, troubleshooting, or warranty claims

Chapter 5 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.

Component	Configuration	Quantity
Handpiece	Standard	1
Standard scan tip	Standard	3
Small scan tip	Standard	1
scan tip protector	Standard	1
Charging Case	Optional	1
Charging Dock	Standard	1
Battery	Standard	1
Manual	Standard	1
U disk	Standard	1

Table 5- 1 List of Standard Accessories

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

Chapter 6 Troubleshooting

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

1. **Power Source:** Ensure that the scanner is properly connected to a power outlet or that the battery is charged to ensure it has enough power to function.
2. **Calibration:** Calibrating the scanner according to the manufacturer's instructions can help improve the accuracy of the images produced.
3. **USB Connection:** Verify that the USB connection between the scanner and the computer is secure. If there are connectivity issues, try using a different USB cable or port to establish a stable connection.
4. **Obstructions:** Check for any physical obstructions that could impede the movement of the scanner's components. Inspect cables, wires, and connectors for damage or blockages that may affect the scanner's functionality.
5. **Ambient Lighting:** Pay attention to the lighting conditions in the scanning area. Excessive ambient light or shadows may affect the scanner's ability to capture accurate images. Ensure proper lighting for optimal scanning results.
6. **Driver Installation:** Install the necessary drivers for the scanner as

instructed by the manufacturer. Outdated or incompatible drivers can cause connectivity or functionality problems.

7. Software Updates: Keeping the scanner's software up to date is essential for optimal performance. Check the manufacturer's website regularly for any available software updates or patches.

8. Check System Requirements: Ensure that your computer meets the minimum system requirements specified by the scanner's manufacturer. Inadequate system specifications may lead to performance issues or compatibility problems.

9. Scanner Firmware Updates: Check for firmware updates specific to your scanner model. Firmware updates can address known issues, improve performance, or introduce new features. Follow the manufacturer's instructions to update the scanner's firmware if applicable.

10. Storage Space: Verify that there is enough available storage space on both the scanner and the computer. Insufficient storage can impact the scanner's ability to save or transfer scans.

11. Cleaning and Maintenance: Regularly clean the scanning tip of the intraoral scanner and follow the manufacturer's guidelines for disinfection if necessary. Proper maintenance and cleanliness help

ensure accurate and hygienic scans.

12. Error Messages: If the scanner displays any error messages, consult the user manual or contact the manufacturer's support for specific troubleshooting instructions and solutions related to the error message received.

13. Reboot: When facing temporary software or connectivity issues, try restarting both the scanner and the connected computer. This simple step can often resolve minor glitches and restore normal functioning.

14. User Permissions: Ensure that you have the necessary user permissions to access and operate the scanner software. If you're using the scanner in a professional setting, consult with your IT department to ensure that there are no restrictions or limitations in place.

15. Network Security: If you're using a network-connected scanner, check your network security settings to ensure that they are not blocking the scanner's communication. Firewalls, antivirus software, or other security measures may interfere with the scanner's functionality.

16. Scan Technique: Review the proper scanning technique recommended by the scanner's manufacturer. Ensure that you are positioning the scanner correctly and following the suggested scanning

motions or patterns. Incorrect scanning technique can result in distorted or inaccurate scans.

17. Wireless Scanners: If using a wireless scanner, ensure that it is connected to a stable and secure wireless network. Unstable network connections can lead to data loss or scanning interruptions.

18. Consult Peers or Online Communities: Reach out to colleagues or online communities for assistance. They may have encountered similar issues and can provide insights or solutions based on their own experiences.

19. Manufacturer Support: If the issue persists or if you encounter more complex problems, it is advisable to contact the manufacturer's support team. Provide them with detailed information about the problem, any error messages received, and the troubleshooting steps you have already taken. They can offer further assistance and guidance to resolve the issue.

Note: For more information, please contact the manufacturer.

Chapter 7 Specifications and Parameters

Product Specifications:

component	parameter
Handheld size	270*38*33 ± 2 mm
Weight of handheld components	230 ± 15g (excluding wire)
Installation method of the scanning head	Plug-and-play
Maintenance method	High temperature and high pressure, soaking
Field of View (FOV)	Standard tip: 16 x 12mm, Std. ± 1mm Small tip: 13x 10mm, Std. ± 1mm
High temperature sterilization tolerance times	200 times
The type of light source used by the scanner	LD(Semiconductor laser)+White LED
Center wavelength of light source	Green light LD: 520 ± 10nmnm; Blue LD: 447nm ± 10nm; White LED: 380-780nm, broadband
Output illuminance (LED)	<900Lux
Max output of laser radiation	<0.3mW
Battery capacity	3200 mAh
Scanner connection method	Wireless connection
Wireless protocol	Wi-Fi transmission protocol 802.1
Imaging color	True colors
Recovery accuracy requirements	1) The accuracy of single crowns is less than 20 μm; the accuracy of three-unit fixed bridges and inlays is less than 30 μm; 2) The precision of single crowns and inlays is less than 20 μm; the precision of three-unit fixed bridges is less than 30 μm.
Orthodontic precision requirements	Accuracy of the entire dentition is less than 50 μm, and precision of the entire dentition is less than 60 μm.
Laser Classification	Class 1
data format	.stl、.ply、.obj

Chapter 8 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 will become invalid in any of the following cases;

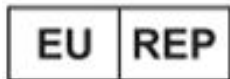
- Damage caused in shipping;
- Damage caused by improper use or maintenance;
- Damage caused by change or repair of any person other than authorized by Fussen;
- Accidental damage;
- The label indicating the serial number or manufacturer is replaced or removed.

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: international.support@fussengroup.com

Manufacturer Address: 902, Building #D1, Nanshan Zhiyuan, 1001 Xueyuan Avenue, Changyuan Community, Taoyuan Street, Nanshan District, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Postal Code: 518055



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Appendix 2 Manufacturer information

Manufacturer :Fussen Imaging Co.,Ltd.

Product Name:Digital Intraoral Scanner System

Model:S10P Wireless,S10L Wireless,S10E Wireless,S10D Wireless

Manufacturer Address:902,Building #D1, Nanshan Zhiyuan, 1001 Xueyuan Avenue, Changyuan Community, Taoyuan Street, Nanshan District, 518055 Shenzhen, Guangdong,PEOPLE'S REPUBLIC OF CHINA

Production Date:See the label for details

Product Life Cycle:12 years

FCC information:

FCC Applicant Name:Fussen Imaging Co.,Ltd.

Address:902,Building #D1, Nanshan Zhiyuan, 1001 Xueyuan Avenue, Changyuan Community, Taoyuan Street, Nanshan District, 518055 Shenzhen, Guangdong,PEOPLE'S REPUBLIC OF CHINA

Appendix 1 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 intraoralscanner 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 fluctuation 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 IEC 60601-1-2:2014	<5 % U_T , Duration 0.5 Period (% U_T >95% dip 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)	<5 % U_T , Duration 0.5 Period (% U_T >95% dip 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)	The network power supply should have the quality used in a typical 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 atypical 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. Recommended 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 radiofrequency 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 $d = [\frac{3,5}{f_1}] \sqrt{P}$	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.

FUSSEN

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