

S6500(BAISC version)

Digital Intraoral Scanner System

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1. Company Introduction

1.1 FUSSEN Technology Introduction

Founded in 2010, headquartered in Shenzhen, China, it is one of the leading R&D and manufacturer in the field of Intraoral scanner. We are committed to providing high quality digital dental medical equipment and solutions for dental clinical and dental laboratories to promote the development of digital dentistry.

Currently in Shenzhen, Chengdu, China, and Germany has research and development center, is a focus on dental digital application of high-tech enterprises, build the FUSSEN Image devices, FUSSEN Practice Management Software (SAAS) , FUSSEN dental online supply chain system, FUSSEN digital dental laboratory and FUSSEN digital cloud platform, is committed to dental clinics and institutions to provide more advanced digital technology, with higher efficiency to achieve high quality dental medical services.



Fig. 1. Software works and patent certificate

Adhering to the core values of "innovation, quality and service", FUSSEN Technology continues to promote technological innovation and product improvement to provide solutions that fully meet customer needs. FUSSEN are committed to the success and satisfaction of the customers, winning the trust and support of our customers with high quality products and excellent service.

Products are exported to domestic and overseas markets, established a global sales and service network. We have established close partnerships with dental clinics, dental laboratories, technical training centers and digital dental solution providers to continuously promote technological innovation and application development in the field of digital dentistry.

In addition, FUSSEN digital dental solutions, from the provision of equipment, solution design, the purchase of consumables, to the realization

of technical training services and value-added products, to create a complete set of digital dental solutions for dental clinical services. The scheme to the technology independent research and development of high-end imaging equipment (CBCT, Intraoral scanner, CR, Intraoral camera, sensor, etc.) as the foundation, combined with the dental practice management platform, through the image data acquisition, storage and to design processing, for dental institutions to provide a full range of digital services.

1.2 Basic information

- Company name: Shenzhen FUSSEN Technology Co., LTD
- Address: 901,1001, Building D1, Nanshan Zhiyuan, No.1001, Xueyuan Avenue, Changyuan Community, Taoyuan Street, Nanshan District, Shenzhen
- Phone number: 400-660-5770
- Official website: www.fussengroup.com
- Number of employees: 700+ employees, 10,000 square meters

1.3 Registration information

- Registered capital: RMB 11,583,304 million
- Economic nature: Limited liability company
- Business Registration License No: 440301104655596

2. Device introduction

2.1 Technical specifications and parameters of the S6500BASIC

S6500BASIC Technical specifications and parameters	
configuration:	
1	Frames: 20 FPS Size (L*W*H): 247×43×35mm Weight: 240g Tips size (L*W*H) : Standard: 95.3×22.5×16.6mm Pediatric: 94.0×17.9×13.2mm FOV: Standard: 16×12mm Pediatric:12×9mm
2	Ambient temperature: 5°C ~40°C; Relative humidity: <80%; Atmospheric pressure: 70 KPa ~ 110 KPa;
3	Measured accuracy: Single unit Accuracy: 10 μ m (± 1.1 μ m) 7 units Accuracy: 22 μ m (± 3.5 μ m) 14 units Accuracy: 32 μ m (± 11 μ m) * Accuracy according to the industry standard test method, through the industrial high-precision scanner data as the reference model
4	Scan depth of field: 0-18mm
5	Light source: LED: red, green and blue

6	Imaging technology: Dynamic 3D imaging
7	Image sensor: High frame rate CMOS
8	Scan time: The average duration of the total full arch scan is under 1 minute
9	Connection: Wired connection
10	Cable length: 2.0 m
11	File type: open system, .STL .PLY and .OBJ general 3D format files can be exported and also on the cloud
12	Scan texture: color, scan can obtain the color model in real time
13	Software Features:
	1. Gyroscope sensor: Remote control 2. Hall sensor: Auto Start / Pause Scan 3. 3D image editing tool: Move, rotate, zoom in and out 4. Scanning guideline 5. Functional tips 6. Multi-language choice 7. Default HD display 8. Scanning depth display 9. True color scanning mode 10. Personalize scan music configuration 11. Automatic hole filling and color selection 12. 3D model edit: -Trimming: Polyline trimming, Laser trimming, and Brush trimming -Locking: locking area, reverse locking 13. Mono/Real color switch

14. Auto deletion of redundant data
15. Data reliability map
16. HD photo capture
17. Working area selection
18. Occlusion analysis
19. Undercut analysis
20. 2D section and distance measurements
21. Straight line measurements
22. Angular measurements
23. Scan video recording
24. Rescan for unfinished case
25. Copy and rescan for finished case
26. Cloud platform: data viewing, data storage, data transmission, and AI-driven TOOLS
27. AI-driven Orthodontic simulation
28. AI-driven Oral health report
29. AI-driven 2D smile design simulation
30. Third-party application in Appbox

Packing List:

	Name	quantity
14	S6500 handpiece	1
	Holder	1
	Scan Tips	Standard: x3; Pediatric: x1
	Lens protector	1
	Instructions for use	1
	Certificate	1
	Warranty card	1
	U Disk	1

2.2 Technical overview and product characteristics

FUSSEN technology digital dental impression device adopts advanced scanning technology to realize the fast and high precision digitization of dental impression. The device uses the principle of optical scanning to scan the tooth and gum areas in the mouth with a high-resolution camera and convert it into a digital model. This digital model can be used in a variety of dental applications, such as orthodontics, prostheses and etc.

Principle of optical imaging

Intraoral scanners often use multiple optical sensors to obtain a three-dimensional image of the oral interior.

- Principle of structured light: By casting structured light and observing its reflection, the scanner can capture the shape and texture of the object surface;

Data acquisition, processing, and export methods

- Data collection: The intraoral scanner uses sensors to collect images and geometric data inside the oral cavity;
- Data processing: The collected data is processed by algorithm and computer to generate 3D models;
- Data export: After completing the data processing, the algorithm of the scanner software can save the model into common file formats, such as STL, PLY, and OBJ.

Comparison of the intraoral scanner with the traditional impression

- **Truness and Precision:** the intraoral scanner has higher accuracy and precision, and can capture more accurate oral cavity structure;
 - **Speed and efficiency:** Compared with traditional impressions, intraoral scanners can quickly obtain data and generate models, save time and manpower;
 - **Patient comfort:** The intraoral scanner is more comfortable than traditional impressions, avoiding discomfort and vomiting;
- Digital storage and sharing:** The data generated by the scanner is convenient for storage, sharing and subsequent use, and improves the efficiency of team collaboration.

Technological superiority

We use the latest digital scanning technology to ensure accurate digital impression results. At the same time, our device has the ability of high-speed scanning and fast data processing, greatly improving the efficiency.

- **Convenient operation:**

The digital impression instrument design is simple and easy to operate. Equipped with intuitive touch screen interface and easy to understand operation menu, enable you to quickly start and easily complete the scanning tasks.

- **Multi-functional applications:**

FUSSEN technology digital dental impression device can be widely used in a variety of dental digital fields, It provides a variety of scanning modes and scan range selected indications, to meet the needs of different types of

impressions.

High quality and reliability: We are always committed to providing our customers with high quality and reliable products. FUSSEN technology digital dental impression device has undergoes strict quality control and testing to ensure stable working performance and long service life.

3.Comparison of competing products

	FUSSEN S6500	Medit i700	3Shape Trios 3	CS3600
scanning technique	Structural light	Structural light	confocal	Structural light
Scan speed (min)	< 2	< 2	< 2	< 2
Imaging speed (fps)	20	70	20	10
depth of field (mm)	0-18	0-21 Adjustable	0-18	-2-16
FOV	16*13/12*9	15*13	20*20	16*14/13*7
Anti-fogging (Sec)	< 30	<30	< 60	< 120
weight (g)	240	328	325	295
Handpeice size (mm)	247*43*35	313*44*47	273*42*45	220*38*58
Scanner Tip specification	Autoclave 100 Times	Autoclave 150 Times	Autoclave 20 Times	Autoclave 20 Times

4. After-sale service

4.1 Service Purpose

Complete after-sales service system, the establishment of the maintenance network, is to give users a backup guarantee;

Global after-sales network service system

- Regular equipment maintenance, online technical customer service answers and remote service, and achieve repair response within 30 minutes, 8 hours of city maintenance; 48 hours of national maintenance;
- There are many maintenance stations and many maintenance engineers in China, forming a national maintenance service network

Parts supply system

The establishment of parts spare station to ensure the timely supply of parts;

Equipment warranty period

- FUSSEN guarantees that the products produced meet the label specifications on the products and that there are no defects in materials and processes during the warranty period;
- Within two years after the product installation and acceptance inspection, if the quality problem of the product itself occurs, our company is responsible for free maintenance. If the product exceeds our warranty period, we will also provide you with the corresponding paid services within a reasonable range.

Maintenance arrangement

- Regular maintenance services shall be conducted during working hours and at the equipment location. The specific time shall be determined by both parties through negotiation
- The maintenance services include equipment inspection, performance testing, and necessary equipment or electrical adjustment

Service commitment

- The equipment provided by our company is of excellent quality, new and unused, and has passed the factory quality inspection, with good packaging, and is suitable for long-distance transportation.
- After the equipment arrives at the buyer's user, our company receives the notice that the site has met the installation conditions ", send the engineering and technical personnel to the site within 7 days, open the box and check the goods in the presence of the buyer's technical personnel, and organize the installation and debugging.

Training arrangement

After the equipment installation and debugging are completed, our engineers will train the customers free of charge in China mainland.

4.2 After-sales service work content

- During the warranty period, the whole equipment can be repaired and replaced with spare parts free of charge
- Equipment damage caused by human factors does not belong to our free maintenance category

- The latest information and application of the equipment, include free upgrade service (free software upgrade)

4.3 Contact information

For any questions regarding maintenance, technical specifications or instrument failure, contact the dealer or the FUSSEN after-sales Services.

- Email: [info @ fussengroup.com](mailto:info@fussengroup.com)
- Production and after-sales service Address: 2nd floor, Building B, Homag Furniture Industrial Factory, Kengzi Street, Pingshan District, Shenzhen City, Guangdong Province
- Registered address: 901,1001, Building D1, Nanshan Zhiyuan, No.1001, Xueyuan Avenue, Changyuan Community, Taoyuan Street, Nanshan District, Shenzhen
- Tel: 400-660-5770
- Zip code: 518055

5. Other related

Annex 1: Business License of Enterprise Legal Person

Attachment 2: Medical Device Production License

Attachment 3: Medical Device Registration Certificate and Registration Form

Attachment 4: ISO13485-2003 Quality certification