



SHINING 3D®



MetiSmile/Datascan

Instruction for Use V1.1






Foreword

General

The manual introduces the functions, installation, usage and maintenance of the MetiSmile System.

Safety Instructions

Signal	Meaning
	Note: This symbol is used to inform you of the additional information of the product.
	Caution : This symbol is used to inform you of incorrect operations that may damage the device or result in data loss. Any damages resulting from misuse are not covered by the warranty
	Caution: This symbol is used to inform you of the potential risks that may result in serious personal injury and other safety incidents.

Release Date

Release Date	Feb, 2023
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About the Manual

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- Updates to hardware and/or software components are made regularly; therefore, some of the instructions, illustrations, and specifications mentioned in the Manual may differ slightly from your particular situation.

Important Safeguards and Warnings

- Use in a dry room or similar environment with good ventilation, ambient temperature not exceeding 30°C and no flammable or corrosive gases in the air.
- Whether the weather is sunny or rainy, it is necessary to protect against the sun, rain, shock and other protective measure in advance.
- Take it lightly, put it lightly, put it horizontally, and do not squeeze the equipment.
- When the machine fails to work properly, it must be overhauled or instructed by professionals, and private disassembly and repair is strictly prohibited.
- The Scanner is prohibited for use by children.
- The Scanner should be handed over to the relevant qualified units for recycling, and should not be thrown into the household garbage.

Cautions

- The accuracy of the calibration will directly affect the scanning accuracy of the system and will need to be recalibrated in the following cases.
 - Scanners for the first time, or after a long period of time.
 - Scanners that have been severely shaken or vibrated during transport.
 - During the scanning process, a serious loss of accuracy was found, such as frequent splicing errors.
- Do not touch the markers on calibration plate and make sure it is clean and free of scratches to avoid damage to the front of the plate.
- Keep the calibration plate away from corrosive solutions, metals, and sharp objects to avoid corrosion and damage.
- Do not place heavy objects on the calibration plate.
- Do not wipe the front side of the calibration plate with chemical liquids or alcohol.
- After using the calibration plate, place it in a lint bag and put it away in time.
- Be sure to use an NVIDIA graphics card for maximum scanning efficiency.
- Download the corresponding installation package strictly according to the purchased equipment, each installation package has its corresponding calibration plate (each equipment is equipped with a calibration plate) to avoid the normal calibration.
- When the upper and lower jaw need to stick the markers , use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of markers.
- Do not start the program directly in the USB flash drive, you must copy the software from the USB flash drive to the computer's hard drive before use, and the user must have read and write access to the folder where the scanning software belongs.
- When the software prompts information of not recognized Scanner, close the scanner and the software, and re-plug the data cable from the USB port of the scanner and the computer.



Note

The pictures in this user manual are used for user's understanding, if they do not match with the actual product, the actual product shall prevail.

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1. Introduction

MetiSmile is a facial scanning device developed by Shining 3D Tech Co., Ltd. The facial scanner can be applied with the Aoralscan to align the scanned data in order to determine the follow-up treatment plan.

Intended Use

This is a face scanner that works with the supplied software programs. By performing facial scanning directly, the scanner could acquire and save the 3D images of the face and the mandibular movement trajectory digitally, which can be used for the facial or the oral Computer-aided design (CAD).



Warning

- Do not use the scanner for purposes other than those intended and expressly stated above.
- This product is designed and intended for use by persons with professions of dentistry and dental laboratory technology. The product cannot be operated by the patients themselves. The user is solely responsible for determining whether the scanner is appropriate for a particular patient case.
- Do not misuse the scanner, and do not use or operate the software programs incorrectly.
- The clinical environments where the scanner and the software programs can be used include dental clinics, dental hospitals, and dental laboratories.
- Installation, use, and operation of the scanner are subject to the law in the jurisdictions in which it is used. Install, use, and operate the scanner only in such ways that do not conflict with applicable laws or regulations, which have the force of law. Use of the scanner for purposes other than those intended and expressly stated here, as well as incorrect use or operation, may relieve us or our agents from all or some responsibilities for resultant noncompliance, damage, or injury.
- The users of this scanner and software are responsible for image quality and diagnosis. They should ensure that the inspection data is being used for the analysis and diagnosis only, and furthermore the data is sufficient both spatially and temporally for the measurement approach being used.
- The images acquired by the scanner must be interpreted by a qualified medical professional. The software in no way interprets these images or provides a medical diagnosis of the patient being examined.

2. Basic Information

1) Product name, model

Product name: 3D Face scanner

Model: MetiSmile

2) Name, residence, contact information and after-sales service of the manufacturer

Manufacturer name: Shining 3D Tech Co., Ltd.

Production Address: No. 1398, Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China, 311258

3) Contact Information

Manufacturer

Shining 3D Tech Co., Ltd.

No.1398, Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China

www.shining3ddental.com

Customer Support

Email: dental_support@shining3d.com

Shining 3D's Representative

Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Telephone: +31644168999

Email: peter@lotusnl.com

EU Importer

Shining3D Technology GmbH

Address: Breitwiesenstraße 28, 70565 Stuttgart Germany

Telephone: +49-711-28444089

4) Product performance

- Appearance and structure

The appearance should be: Smooth, no cracks, no stains, no obvious deformation. Flexible and reliable for operation.

- Function control and display

Scan: Scan faces contactlessly. The scanned data can be aligned with the intraoral data for smile design.

Calibration: Improves the scanning quality.

- Software features

1. Facial scanning: smiling face scanning and Openbite Face.

2. Jaw movement tracking (Optional).

- Performance

Facial scan imaging: The scanner scans the face and dentulous motion to form a 3D digital model.

Accuracy: Under normal conditions, the scanner is used to scan against a standard (e.g., a plaster standard known to be similar in size to face), obtain its three-dimensional stereoscopic data, and measure key dimensions to

obtain measured values.

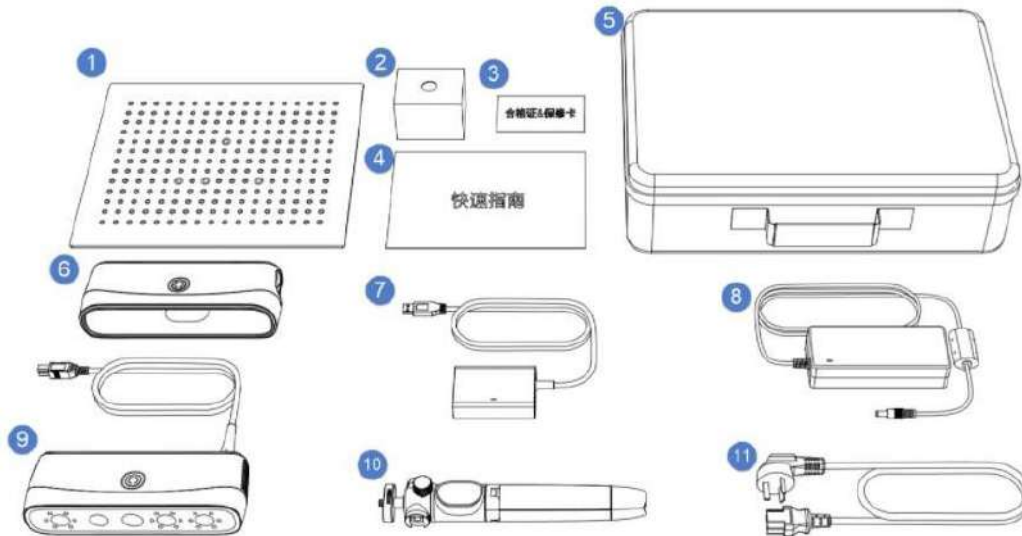
5) Product performance, main structural composition

Essential performance

During continuous scanning, the scanned image shall be accessible to it normally.

Main structural composition

Product consists of scanner body, calibration plate, USB 3.0 repeater, power adapter, tripod, markers and software, and the carrier of the software is USB flash drive, and the software release version is 1.



No.	Introduction
1	Calibration Plate
2	Markers
3	Certificate & Warranty
4	Quick Guide
5	Carrying Case
6	Protective shell
7	USB 3.0 Repeater
8	Power Adapter
9	Scanner body
10	Tripod
11	Cable

- Product maintenance and care methods, special storage/transportation conditions, operating conditions.
- Do not connect the scanner to power if not used, keep it in dry environment.



Note

- The temperature and humidity and atmospheric pressure conditions for storage/transportation are mentioned on the outer packaging.

- Production date and lifecycle
- The production date is shown on the product label. Lifecycle: 5 year.



Caution

- The scanner should not be used in close proximity or stacked with other equipment.
- Using cables or accessories other than those specified for use with the scanner tip might result in increased emissions or decreased immunity of the device.

Intended Use

This is a face scanner that works with the supplied software programs. By performing facial scanning directly, the scanner could acquire and save the 3D images of the face and the mandibular movement trajectory digitally, which can be used for the facial or the oral Computer-aided design (CAD).

General Requirements:

Working environment: Use the scanner only in dental laboratories, dental clinics, and equivalent environment.



Warning

- Do not use the scanner for purposes other than those intended and expressly stated above.
- This product is designed and intended for use by persons with professions of dentistry and dental laboratory technology. The product cannot be operated by the patients themselves. The user is solely responsible for determining whether the scanner is appropriate for a particular patient case.
 - Do not misuse the scanner, and do not use or operate the software programs incorrectly.
 - The clinical environments where the scanner and the software programs can be used include dental clinics, dental hospitals, and dental laboratories.
 - Only trained medical personnel may use the scanner and the supplied software programs. When under an adverse event, inform the relevant notified authorities and competent authorities.
 - Installation, use, and operation of the scanner are subject to the law in the jurisdictions in which it is used. Install, use, and operate the scanner only in such ways that do not conflict with applicable laws or regulations, which have the force of law. Use of the scanner for purposes other than those intended and expressly stated here, as well as incorrect use or operation, may relieve us or our agents from all or some responsibilities for resultant noncompliance, damage, or injury.
 - The users of this scanner and software are responsible for image quality and diagnosis. They should ensure that the inspection data is being used for the analysis and diagnosis only, and furthermore the data is sufficient both spatially and temporally for the measurement approach being used.

- The images acquired by the scanner must be interpreted by a qualified medical professional. The software in no way interprets these images or provides a medical diagnosis of the patient being examined.

1) Contraindications

Contraindication: Disabled for epileptic patients.

2) Warnings

Before using the scanner, read warnings and Safety information.

- Do not attempt to disassemble, repair, or modify the scanner and software.
- There are no user serviceable parts inside the scanner. Necessary modifications must be made only by the manufacturer or its designated agents.
- Do not allow foreign objects (including all types of liquids) to enter the scanner. Water, moisture, etc. may cause a short circuit in the electronic components and lead to malfunction.
- If the scanner is inadvertently dropped on the ground or impacted, it must be calibrated before use. If there are still accuracy problems or scanning abnormalities after calibration, please consult technical support.
- Do not drop or apply shock/vibration to this scanner. Strong impacts may damage the components inside.
- Do not cut, bend, modify, place heavy objects, or step on the cables. Otherwise, the external insulation may be damaged and result in short-circuit or fire.
- To avoid electrical shock, use only supplied power adapter and connect it only to properly grounded wall outlets.
- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

3) Waste Electrical and Electronic Equipment

Disposal of Waste Electrical and Electronic Equipment and by users in private households in the European Union.

This symbol on the product or on the packaging indicates that this cannot be disposed of as household waste. You must dispose of your waste equipment by handing it over to the applicable take-back scheme for the recycling of electrical and electronic equipment and/or battery. For more information about recycling of this equipment, contact your city office, the shop where you purchased the equipment or your household waste disposal service. The recycling of materials will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and environment.



4) Disposal

The scanner must be reprocessed prior to disposal in order to prevent cross-contamination.

All electrical and electronic devices must be disposed of separately from your other household waste in order to promote reuse, recycling and other forms of recovery, to prevent any potential adverse effects of hazardous substances on the environment and human health, and also to reduce the amount of waste in landfill. This includes

accessories such as power adapters, power cords, etc. Do safely dispose of the device and its accessories in accordance with applicable laws and regulations.

For specific information on disposal of your device and the packaging, contact your local distributor or service provider.

5) Warranty

The warranty is void if unauthorized personnel perform service or maintenance on the set of the scanner. To ensure correct product performance and to obtain warranty service, contact technical support.

3. Safety Information

1) Precautions

Failure to observe the instructions or disregard the warnings may result in damages to the product, personal injury, or even death of the user or the patient.

- Do not use the hardware and software for any application until you have read, understood, and known all the safety information, safety procedures, and emergency procedures contained in the chapter. Operating the hardware and software without a proper awareness of safe use could lead to fatal damage to the hardware or permanent data loss.

- Ensure that the connection is performed correctly.

- Use only medical grade devices with the scanner in the patient environment.

- The hardware and software should only be used in a medical facility under the supervision of trained personnel.

- Only authorized service labs should perform maintenance. It is expressly prohibited to open the scanner with tools.

- The hardware and software have been fully adjusted and tested prior to shipment from the factory. Unauthorized modifications will void your warranty.

- If the hardware or software is modified, appropriate inspection and testing must be conducted to ensure continued safe use.

- Check the scanner and components for sharp edges.

- Before use, check the device for damage, loose parts, wear and tear, and other cosmetic problems. In case of such problems, please contact after-sales service.

- During use, always pay attention to abnormal conditions of the scanner and the patient. In case of abnormal conditions, you need to stop using it immediately. Consult technical support staff promptly.

- To ensure the performance and safety of the scanner, use only the original accessories provided with the scanner (or accessories specified by Shining 3D, consult technical support for details) and software.

- Use only supplied accessories and approved software with the scanner in order to achieve the designed performance.

- Do not use a power adapter other than the one supplied with the package.

- Connecting the scanner to an unknown power adapter is very dangerous and may lead to fire or explosion.

- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.

- The supplied medical grade power adapter should only be connected to a grounded power socket.

- Reasonably arrange communication cables, power lines and other types of cables to prevent users or patients from tripping over the wires. Do not forcibly pull or bend cables of any kind.

- The scanner is not intended for use in environments with high concentrations of flammable liquids, gases, or atmospheric oxygen.

- There is a risk of explosion when the scanner is used around flammable anesthetics.

- Do not connect USB peripherals with an extended USB cable. Extended connection may cause unexpected usage fault.














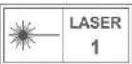
- Always handle the scanner with care and avoid hitting or scratching the surfaces as it contains fragile components. Dropping the scanner on the floor may cause permanent damage.


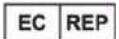



- Never place any objects or load on the scanner.
- Do not dispose the scanner as unsorted municipal waste. The scanner must be collected separately and disposed of in accordance with the local laws and regulations. For proper disposal of this scanner, contact your local representative of Shining3D Corporation.

2) Labels and Symbols

The following symbols provide information on the product's labels and regulatory compliance.

labels and symbols on the scanner/carry box/package

Symbol	Explanation
	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Indicate that the contents of the transport package are fragile and the package shall be handled with care.
	Indicate that the transport package shall be kept away from rain and in dry conditions.
	Indicate correct upright position of the transport package
	Indicate that the marked item or its material is part of a recovery or recycling process.
	Indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Indicate the acceptable upper and lower limits of atmospheric pressure
	Indicates the medical device manufacturer.
	Indicate the date on which a product was manufactured.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Device fulfills the requirements of the European Regulation 2017/745 given on the EU Declaration of Conformity.
	Indicate the item is a medical device.
	Class 1 laser product.

	Restriction of Hazardous Substances in Electrical and Electronic Equipment. Meets the requirements of Directive 2011/65/EU.
	Indicates the authorized representative in the European Community/ European Union.
	Signify that the instruction manual/booklet must be read.
	Indicate the unique device identifier information.
	Indicate the entity importing the medical device into the locale.



Note:

The symbols meet the requirements of ISO 15223-1 2021 "Medical devices - Symbols to be used with information to be supplied by the manufacturer Part1 General requirements".

3) Compliance

Anyone creating or changing a medical electrical system through a combination with other devices in accordance with standard IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance is responsible for ensuring that the requirements of these standards are met to the full extent in order to ensure the safety of patients, operators and the environment.

4) FCC Compliance Statement

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.
- (2) This device must accept any interference received, including interference that may cause undesired operation.

5) Electrical Safety

Only trained medical personnel should operate this scanner. The product complies with the following standards.

6) Electrical

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances– Requirements and tests
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 Medical electrical equipment–Part 1-9: General

requirements for basic safety and essential performance—Collateral Standard: Requirements for environmentally conscious design

- IEC 62366-1:2015+AMD1:2020 Medical devices—Part 1: Application of usability engineering to medical devices

7) Classification

- Type of protection against electric shock: Class I
- The degree of protection against electric shock: No applied apart
- Enclosure protection: IPX0
- Degree of protection against incoming liquids: Common device.
- Level of safety when used with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non-AP/APG equipment.
- The mode of operation: Continuous operation
- Pollution degree 2



Warning

- Shock hazards exist if the power adapter is damaged or is not properly grounded. Use only the supplied medical grade power adapter.
- To meet waterproof requirements, the sockets should not be placed on the ground.
- Do not use grounding type plugs for other purposes.
- Only authorized service labs can make internal replacements of the scanner and modify the software.
- Do not use the scanner if it is damaged. Contact technical support for replacement of the damaged equipment (see Contact information on chapter 1).
- To avoid risk of electrical shock hazards, always inspect the scanner and cable connections before use.
- Check the cable housing before use. Do not use the scanner if the housing is damaged or the cable is abraded.
- All devices connected to the scanner shall comply with IEC 60950.
- The radiation characteristics of the scanner is suitable for use in all locations, including domestic and direct connection to the residential public low-voltage supply grid for domestic use.(CISPR 11 Class B).

8) EMC Notice



Caution

- Scanner meets the EMC requirements.
- Users should install and use the EMC information provided in the random file.
- Scanner might affect the performance of a portable or mobile RF communication device. Avoid strong ELECTROMAGNETIC interference when using a scanner, such as near a mobile phone or microwave oven.
- The guidance and manufacturer's statement are shown in the attached table.



Warning

- Scanner should not be used in proximity to or on top of other devices. If it must be, observe to verify that it works properly in the configuration in which it is used.
- With the exception of cables sold by the manufacturer of scanner as spare parts for internal components, the use of accessories and cables other than those specified may result in an increase in transmission

power or a decrease in immunity of scanner.

Electromagnetic Emissions

Medical electrical equipment such as the scanner requires special precautions regarding electromagnetic compatibility, and must be installed and put into service according to the following electromagnetic tables.

The **scanner** is intended for use in the electromagnetic environment specified below. The customer or user of the **scanner** should assure that it is used in such an environment.

Guidance and manufacturer’s declaration–electromagnetic emissions

Guidance and Manufacturer's Statement - Electromagnetic emission		
scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:		
Emission Measurement	Conformity	Electromagnetic Environment - Guidelines
RF emissions CISPR 11	Group 1	The scanner uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The scanner is suitable for use in all locations, including domestic and direct connection to the residential public low-voltage supply grid for domestic use.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Applicable	

Interference immunity


The **scanner** is intended for use in the electromagnetic environment specified below. The customer or user of the **scanner** should assure that it is used in such an environment.

Guidance and Manufacturer's Statement - Electromagnetic emission			
scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s)	±0.5, ±1kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles	0% U_T (100% dip in U_T) for 0.5/1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in	Mains power quality should be that of a typical commercial or hospital environment. If the user of the scanner requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. If image distortion occurs, it may be necessary to position the scanner further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer’s declaration–electromagnetic immunity

Guidance and Manufacturer's Statement - Electromagnetic emission			
scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance

<p>Conducted RF</p>	<p>3 Vrms 150 kHz to 80 MHz outside ISM bands</p>	<p>3 V (effective value)</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the scanner, including cables, than the recommended separation distance calculated from the equation appliance to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$</p>
<p>EC 61000-4-6 Radiated RF</p>	<p>6 V ISM bands between 150 kHz and 80 MHz 3V/m 80 MHz to 2.5 GHz</p>	<p>6 V (effective value) ISM bands between 150 kHz and 80 MHz 3 V/m</p>	<p>IEC 60601-1-2: 2014 $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz IEC 60601-1-2: 2014 Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with following symbol: </p>

Guidance and manufacturer's declaration–electromagnetic immunity

<p>Guidance and Manufacturer's Statement - Electromagnetic emission</p>			
<p>scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:</p>			
<p>Immunity test</p>	<p>IEC 60601 test levels</p>	<p>Compliance level</p>	<p>Electromagnetic environment – guidance</p>

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strength from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **scanner** is used exceeds the applicable RF compliance level above, the **scanner** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **scanner**.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

^c The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality or launch warning messages, it is necessary to position the **scanner** further from sources of electromagnetic interference or install electromagnetic shielding to block unwanted interference. The customer or the user of the **scanner** should operate the device under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

Separation distances

The **scanner** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **scanner** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **scanner** as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the scanner

Guidance and Manufacturer's Statement - Electromagnetic emission			
scanner is intended to be used in the following electromagnetic environment. The purchaser or user of scanner should ensure that it is used in this electromagnetic environment:			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	IEC 60601-1-2: 2014+AMD1:2020		
	150 kHz to 80 MHz <i>d = 1.2 √P</i>	80 MHz to 800 MHz <i>d = 1.2 √P</i>	800 MHz to 2.5 GHz <i>d = 2.3 √P</i>
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
<p>For transmitters rated a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p>			
<p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

The medical electrical equipment is suitable for the professional healthcare environment per 60601-1-2:2014+AMD1:2020. It is suitable for use in physician offices, clinics, hospitals, and other professional healthcare environments except near HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging or other environments where the intensity of electromagnetic disturbances is high.

The clinical environments where the device can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients except environments where the intensity of electromagnetic disturbances is high.



Warning

- Using cables or accessories other than those specified for use with the scanner might result in increased emissions or decreased immunity of the device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the scanner, including cables specified by the manufacturer. Otherwise, it could lead to degradation of the performance of this equipment.
- If immunity test level is higher than those specified in IEC60601-1-2, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in IEC60601-1-2 Chapter 8.10.

9) Biological Safety

Markers will contact with teeth and oral mucosa for a short time

Meets biological criteria: ISO10993-5: 2009 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity); ISO10993-10: 2021 (Biological evaluation of medical devices — Part 10: Tests for skin sensitization); ISO10993-23: 2021 (Biological evaluation of medical devices — Part 10: Tests for irritation)

10) Laser Protection

This product is a class 1 laser product and is only for maintenance, replacement and removal by professional personnel of the manufacturer or its designated agent (if necessary). If the device is not used, removed or replaced as required, the normal use of the device may be affected and laser radiation may occur. If a laser component is faulty, contact the manufacturer for help.

This product is a class 1 laser product according to "IEC 60825-1:2014 Safety of laser products-Part 1: Equipment classification and requirements", without harmful laser radiation. Users will not be exposed to laser radiation if they operate the equipment correctly according to the instructions.



4. Care and Maintenance

The scanner requires proper care, cleaning, and handling. As individual part may be processed differently, read and follow the information and instructions given to help you effectively and thoroughly reprocess the set.

Clean the scanner : Wipe the scanner with a piece of alcohol gauze or CaviWipes (Alcohol gauze or CaviWipes should liquid in 75% alcohol concentration).



Warning

- All parts are shipped non-sterilized. Follow the instructions prior to initial use.
- Ensure that you have completely disconnected the power supply and all connections from the scanner.
- Using detergent, disinfection solutions or wipes, sterilization procedures other than those specified in the Manual may damage the product and void your warranty.
- To prevent cross-contamination, disinfection must be correctly performed after each use.

5. Scanner Storage

In case you need to transport the device, we strongly recommend that you keep the original packaging after unpacking the Scanner. Shipping the device without its original packaging material may cause possible product damage and result in additional service fees.

If the original packaging is no longer available or damaged, carefully package each part of the scanner with bubble wrap to protect against any possible damage during transportation.

1) Storage for Transport

- Make sure that the scanner is clean before placing it in the original carry box/package to avoid any possible contamination.

- Place each part of the product, e.g. scanner body, tripod, power adapter, in the original package carefully and prevent kinks of the cable.

- Make sure that each cable is rolled up and tangle-free before placing it in the original carry box.

- Before closing the lid, make sure no part of the product is protruding from the package.

2) Daily and Long-term Storage

Before storing the scanner, make sure the scanner is thoroughly dry.

6. Specifications

Parameter	Description
Resolution	Black and White: 1280 × 1080 Texture: 2448 × 2048
Accuracy	≤ 50μm
FOV	Black and White: 41.3° Texture: 49.3°
Output Format	PLY, OBJ, STL
White LED color temperature	5500K
Dimension	215mm × 50mm × 75mm
Weight	800g
Power Supply	Input: AC100 — 220V; FR 50Hz or 60Hz; 1.5A Output: DC 12V/7.0A

7. Overview



No.	Name	Description
1	Depth Camera	Collect depth data.
2	Texture Camera	Collect data with color.
3	Projector	Project the light source to adjust the ambient brightness.
4	Scanning Button	Press the button to start scanning; press again to pause scanning Press and hold for more than 3 seconds to complete the scan and save the scanned data.
5	USB 3.0 cable	Used for power supply and data transmission.
6	Light Bar	Provide enough light for optimal scan quality.

Recommended PC Configuration

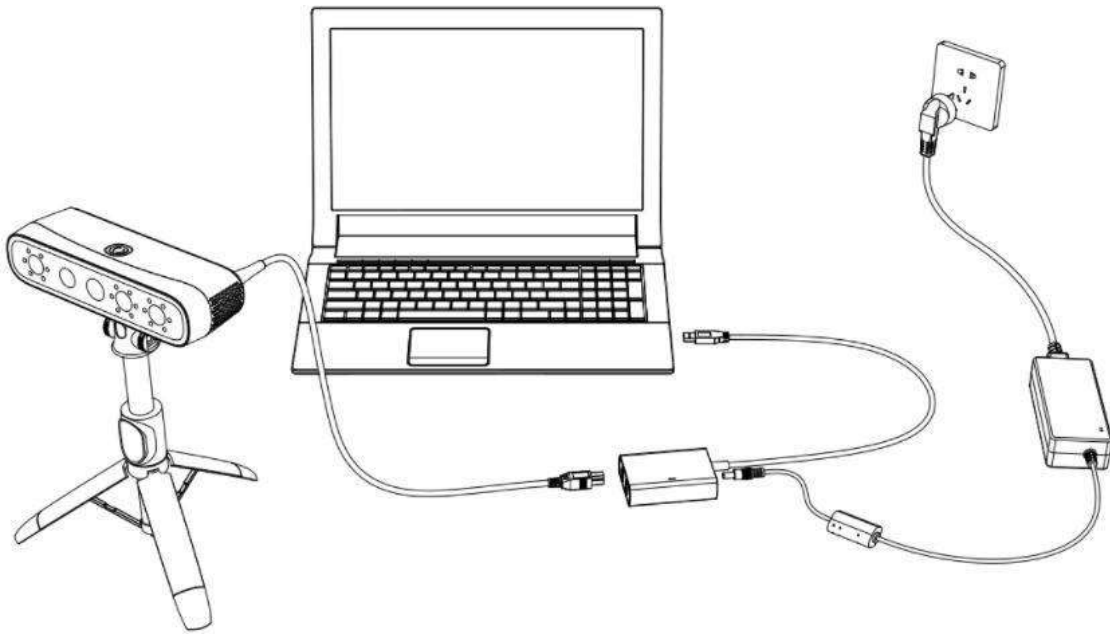
Before installing and running the software, your computer shall meet the following requirements:

Module	Recommendation
CPU	Intel® Core™ i7-8700 or above
Memory	Minimum: 16GB RAM Recommend: 32GB RAM
Hard Disk Drive	Minimum: 256GB Recommend: 2TB
GPU	NVIDIA RTX 2060 or above
OS	Windows 10/11 Professional (64-bit)
Ports	More than 2 type-A USB 3.0 (or higher) ports

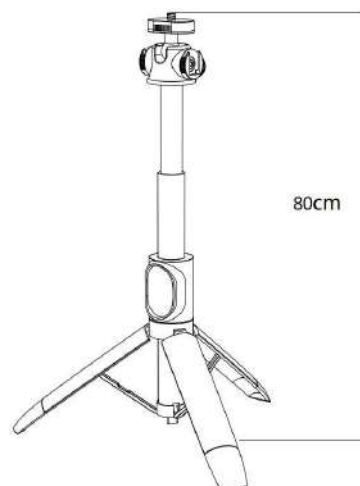
8. Connect the Scanner

Connect the scanner according to the illustrations.

One interface of repeater USB3.0 is connected to the scanner, and the other interface connects to other scanner.



The tripod can be raised to 80cm, and it is recommended to raise the tripod to about 45cm, which is more stable.



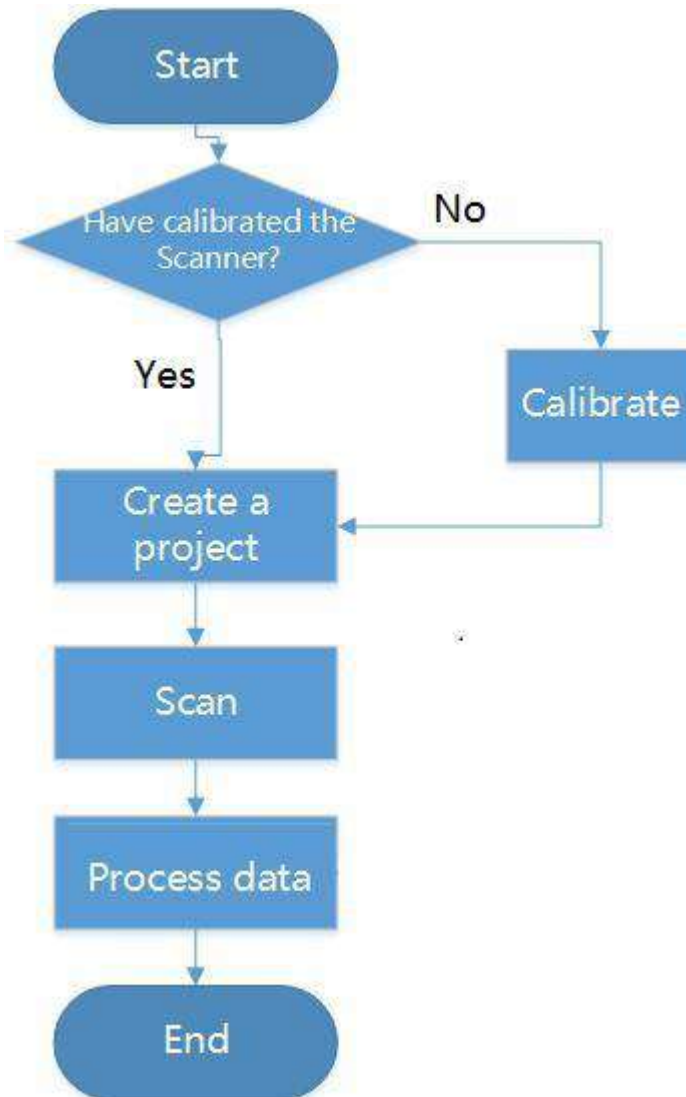
9. Operation

This chapter mainly introduces how to operate the software.
Double-click the software icon to run the software.

9.1. Workflow

To operate the software for the first time, please refer to the following steps.

9.2. Calibration



Workflow

Please read the following instructions carefully before calibration.

Under these circumstances, we recommend that you shall execute the calibration for the scanner to ensure the accuracy of scanned data:

- The initial setup of the scanner is completed.
- The scanner has been used for a period of time (e.g. 2 weeks).

- The scanner is accidentally dropped.




Note:

The LED light of the scanner body turns green when the power connection is working properly.

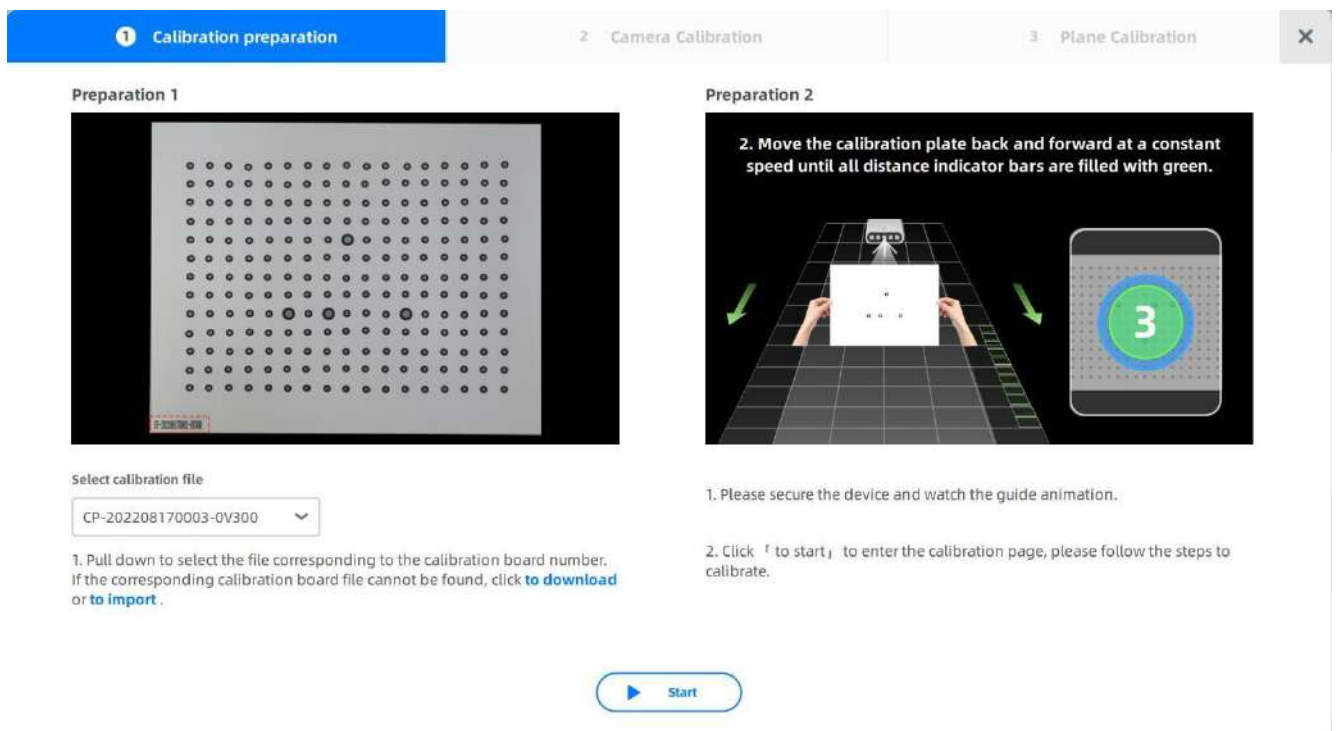
9.2.1. Camera Calibration

Through calibration, it can not only ensure precision of the equipment, but also improve the alignment of the scanned data.

1. Click  on the main interface to display the calibration interface.
2. Select the calibration file.

The calibration file name is matched with the number on the calibration plate back.

If there is no matching file, you can click “Download” or “Import the calibration file” to get the file that matches the calibration plate.

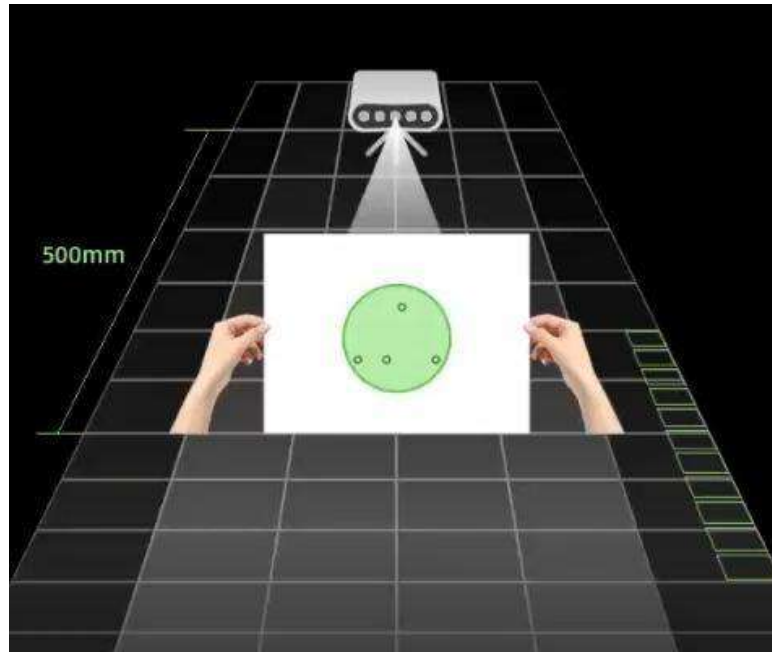


The screenshot displays a software interface for camera calibration. At the top, there are three tabs: '1 Calibration preparation' (active), '2 Camera Calibration', and '3 Plane Calibration'. Below the tabs, the interface is divided into two main sections: 'Preparation 1' and 'Preparation 2'.

Preparation 1: Shows a grid of small circles representing a calibration board. Below the grid, there is a dropdown menu labeled 'Select calibration file' with the value 'CP-202208170003-0V300'. Below the dropdown, there is a note: '1. Pull down to select the file corresponding to the calibration board number. If the corresponding calibration board file cannot be found, click to [download](#) or to [import](#).' At the bottom of this section is a blue 'Start' button.

Preparation 2: Shows a 3D perspective view of a scanner on a grid. A person is holding a white calibration plate. Text above the view says: '2. Move the calibration plate back and forward at a constant speed until all distance indicator bars are filled with green.' To the right, there is a circular icon with the number '3'. Below this view, there are two instructions: '1. Please secure the device and watch the guide animation.' and '2. Click ' to start, to enter the calibration page, please follow the steps to calibrate.'

3. Place and secure the scanner.
4. Position the calibration plates as directed by the guide.



5. Click "Start calibration" .

Adjust the calibration panel approximately 500 mm from the camera and ensure that the circle at the center of the calibration panel is green.

6. Remain the calibration panel stable, 3 seconds later, enter the calibration operation interface.
7. Hold the calibration panel and move it forward and backward at a constant speed until all the distance bars is fully filled with green.
8. Rotate the calibration panel 90° clockwise, move calibration panel forward and backward at a constantspeed until all the green distance bars is fully filled with green.

 **Note:**

- Do not move the scanner during the calibration process.
- Click "Recalibrate" if calibration fails.

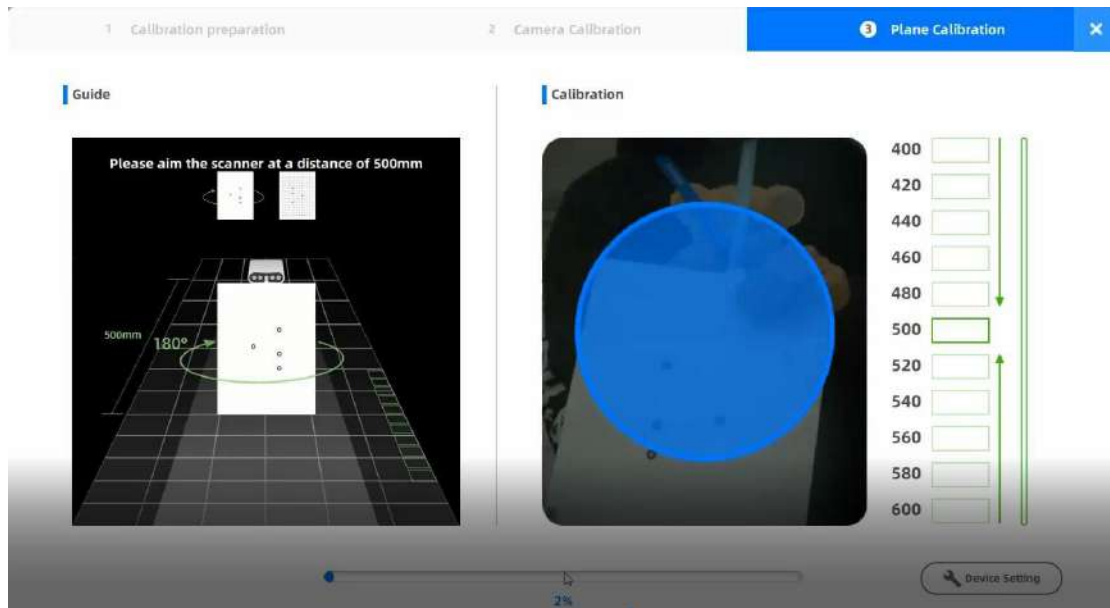
9.2.2. Plane Calibration

Plane calibration is a correction tool for white balance. In order to prevent the color deviation of the scanned object, it is necessary to perform a white balance calibration to ensure that the color temperature of the camera is consistent with the color temperature of the environment.

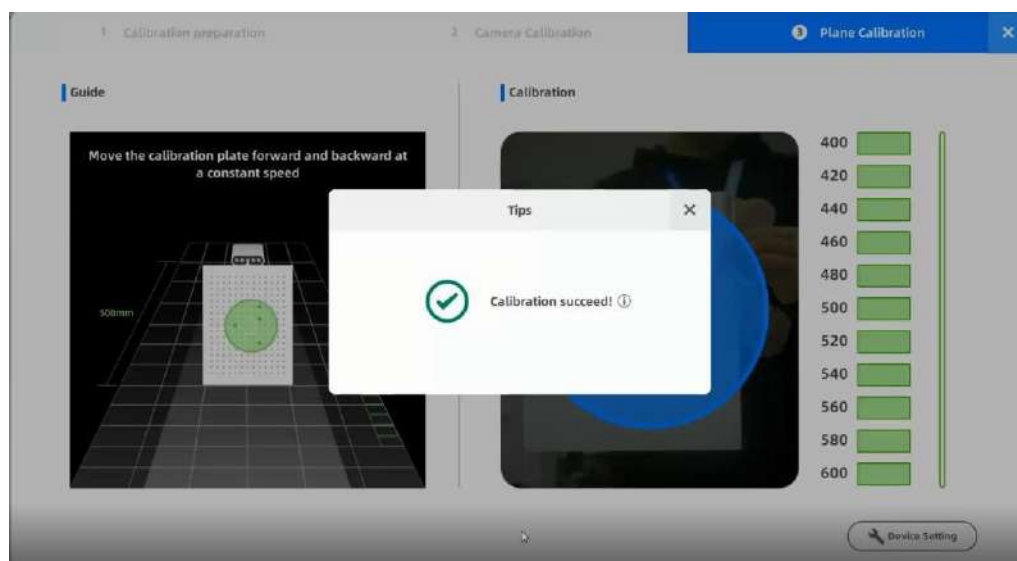
 **Note:**

After a successful calibration, it will automatically enter the plane calibration.

1. Face the whiteboard with the camera.



2. Adjust the calibration panel approximately 500 mm from the camera and ensure that the circle at the center of the calibration panel is green.
3. Remain the calibration panel stable, 3 seconds later, enter the calibration operation interface.
4. Hold the calibration panel and move it forward and backward at a constant speed until all the distance bars is fully filled with green.
5. After data collection is completed, the interface prompts information of successful calibration.



9.3. Create a Project

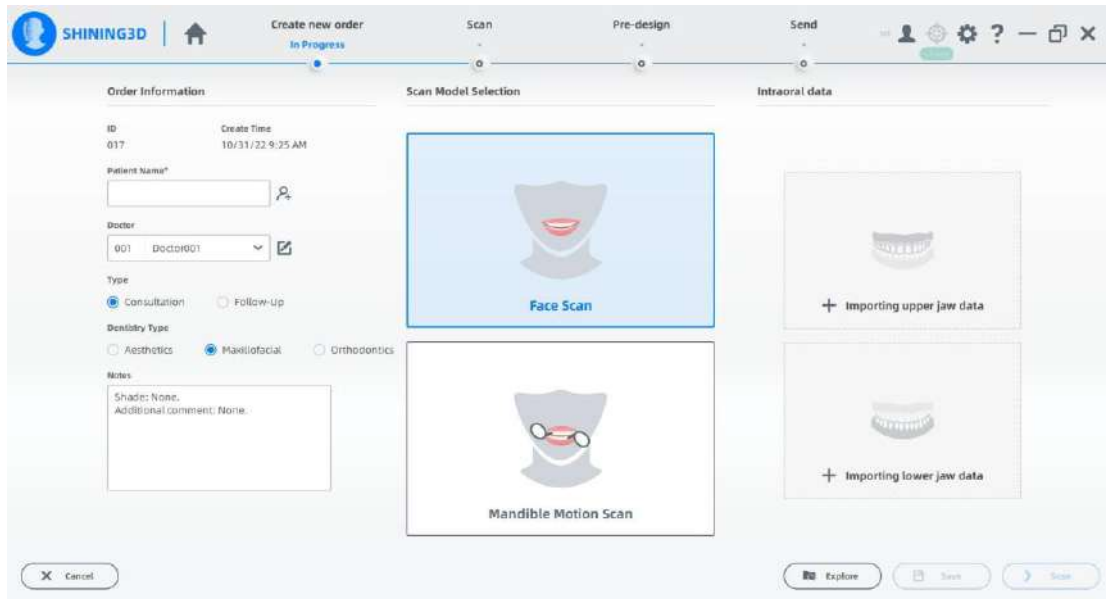
Before scanning objects, please create a new order.

 **Note:**

Please calibrate before creating an order.

Step

1. Click "Create New Order" on the main interface.
2. Enter relevant information.



Note:

Face scan is mandatory. Others are optional.

3. Click "Scan" to enter the scanning interface.

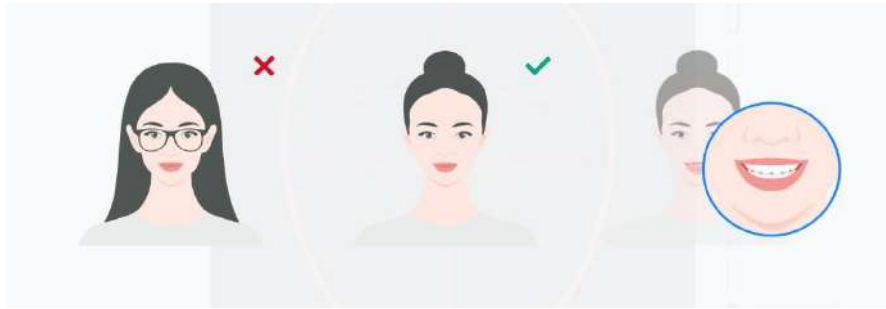
9.4. Face Scan

There are no more than 5 steps to collect facial data. The default step is the smile face scan step. Open face scanning step and custom face scanning step can be added if needed.

- smiling and showing teeth under the smiling face scan mode.
- When the alignment of face scan data and intraoral scan data is not optimal, add the open face scanning step. Users are required to clench their teeth or to be scanned with a mouth dilator at the open face scanning step, so that the dental data can be scanned more completely and clearly.
- Custom face scanned data could be used for doctor's diagnosis or other purposes. The scanned data needs to be aligned with the face scanned data.

Scanning methods include handheld and fixed modes.

Preparation before scanning: Before collecting data, take off your glasses, tie up your hair, and keep your mouth open and smile.

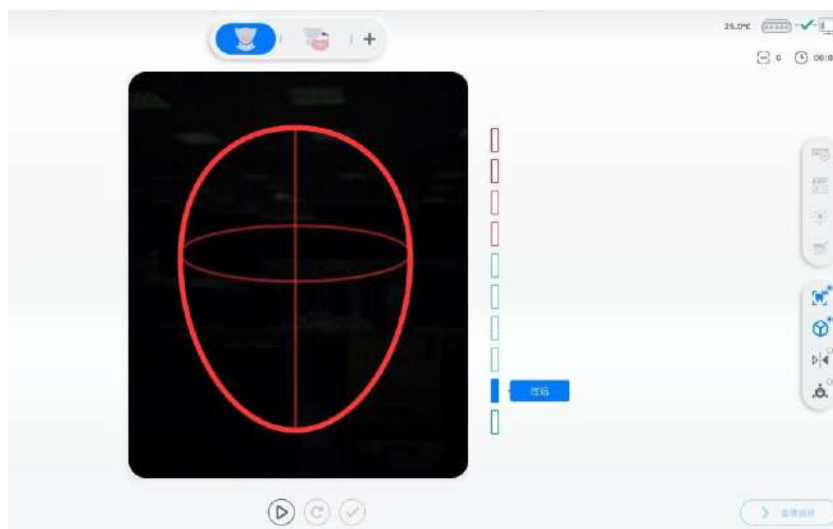


Handheld Mode

Step

1. Adjust the distance from the face to the camera. When the distance bar on the right is green, it means the distance is suitable; when it is red, it means too close; when it is blue, it means too far.
2. Click the button of the scanner or "Start Scan" on the interface.

Scan the facial data at a constant speed.



3. Click the button of the scanner or "Start Scan" on the interface.
4. Scan the facial data at a constant speed.

In order to better collect facial information, you need to wear mouth prop for collect more scan data.





Note:

If the intraoral model has been imported, align automatically the intraoral model and facial model. If there is no intraoral model, click "Import Intraoral Model" to upload the upper jaw data or lower jaw data.



Note:

If the oral data has been imported, the oral data and facial data will be aligned automatically; if there is no oral data, click "Import" and select the corresponding oral data.

- Click "Auto" to align the intraoral scanned data and scanned face data automatically.



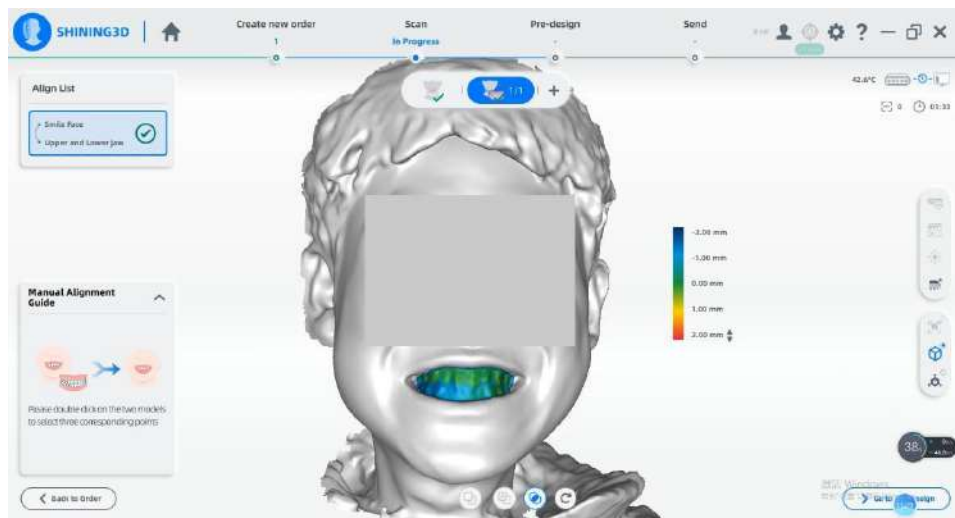
Note:

If the result of automatic alignment is not optimal, align the data manually. Double-click to add points (max.3 points on each model) on the model. The points should not be on one straight line.

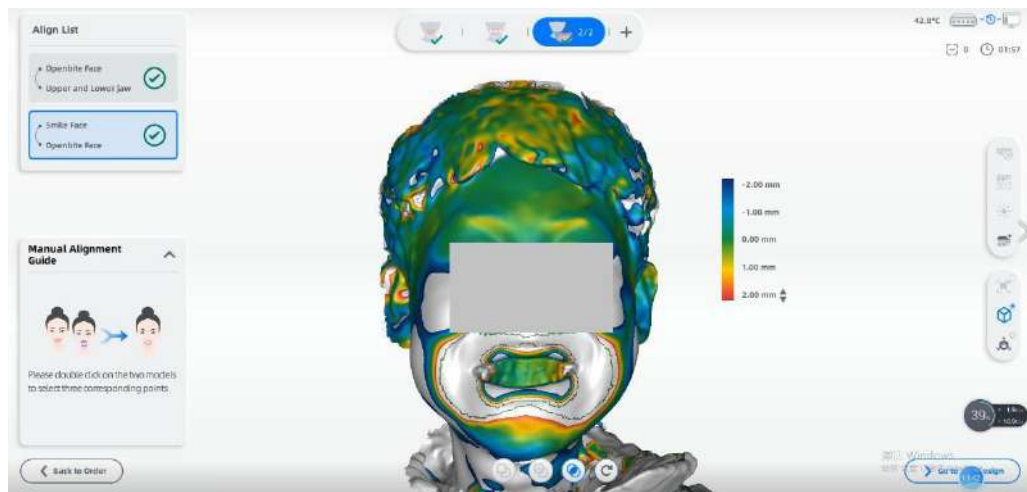


- Click "Confirm" to save the edit and return to the scanning interface.

Calculate and view the alignment effect by the colour bar. When picture of teeth is shown more in green, it indicates that the alignment effect is better.



If the mouth dilator is worn , need to alignment the smile face scan data and smile face with mouth dilator scan data.



Fixed Mode

Step

1. Adjust the face position until you can preview all face images in the green frame.
2. Start scanning when hearing the voice "3-2-1". Complete the facial data collection according to the instruction such as turning the head and returning the head.
3. Turn the head at a constant speed and a voice prompt will remind that the collection has been completed.



Note:

If the oral data has been imported, the oral data and facial data will be aligned automatically; if there is no oral data, click "Import" and select the corresponding oral data.

- Click "Auto" to align the intraoral scanned data and scanned face data automatically.

 **Note:**

If the result of automatic alignment is not optimal, align the data manually. Double-click to add points (max.3 points on each model) on the model. The points should not be on one straight line.



- Click "Confirm" to save the edit and return to the scanning interface.

9.5. Dentulous Motion Scan

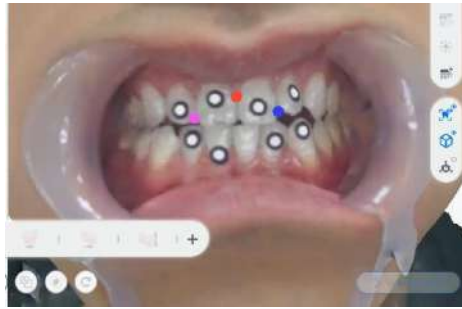
Collect dentulous motion to know whether the mandibular movement before and after treatment is normal. According to the result, it can help to determine the further treatment plan. When creating an order, select the dentulous motion scan mode to start.

 **Note:**

This function is an optional feature.

Preparations

- If you have long hair, please tie your hair first; if you wear glasses, please take off first.
- Wear a sterilized mouth dilator.
- Wipe the markers with a cotton pad soaked in 97% alcohol.
- Paste the markers on the teeth (the number of markers ≥ 3), and ensure that the markers are arranged irregularly.
- Do not arrange a straight line or approximate a straight line (such as obtuse angle $>150^\circ$)
- Do not arrange in an isosceles triangle.



Collection of Markers

1. Markers pasted on the teeth are collected and recorded for aligning with static facial data, thereby realizing the combination of dentulous motion and the entire facial data.
2. Paste the markers on the teeth of the upper and lower jaws.
3. Fill in the number of markers to be pasted on the teeth of the upper and lower jaws.

Marker point input

Upper Jaw

Lower Jaw

please input the number between 3 to 15

✓ Confirm

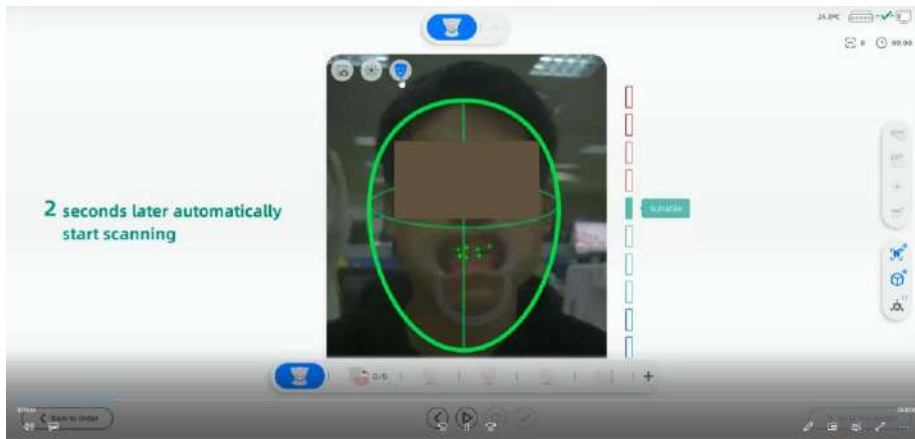
4. Identify the markers and save it.
5. Keep the head fixed first. Then keep the distance between the head and the camera lens at 500mm according to the interface guide.
6. The camera automatically identifies the number of markers.
7. When the upper and the lower jaws are occluded, if the number of markers identified by the camera is the same as the number of markers input, the coordinates of markers will be automatically saved.
8. If the number of recognized targets is inconsistent with the input, adjust the face position or re-paste the markers.
9. Distinguish the number of markers pasted on the teeth of the upper and lower jaws. Slightly open the upper and lower jaws, and the camera automatically recognizes the number of markers on the teeth of the upper and lower jaws.
10. After completing the collection of markers, the interface will pop up a message for the completion of collection.



I Static Facial Scan

Static face scanning is mainly used for target data in the scanning mouth, and for matching face and target data.






1. Keep the head fixed first. Then keep the distance between the head and the camera lens at 500mm according to the interface guide.
2. According to the interface wizard prompts, display the countdown of 3 seconds into the static face scan.




3. The head moves slowly from left to right, and the whole set lasts for 10 to 15 seconds.

Operation bar

Icon	Name	Description
	Edit	When this button is clicked, it enters the edit interface to select the data to be deleted.
	Remove isolated data	Click to delete the smaller independent model data that are not connected to the main model data. Help delete unrelated model data quickly.

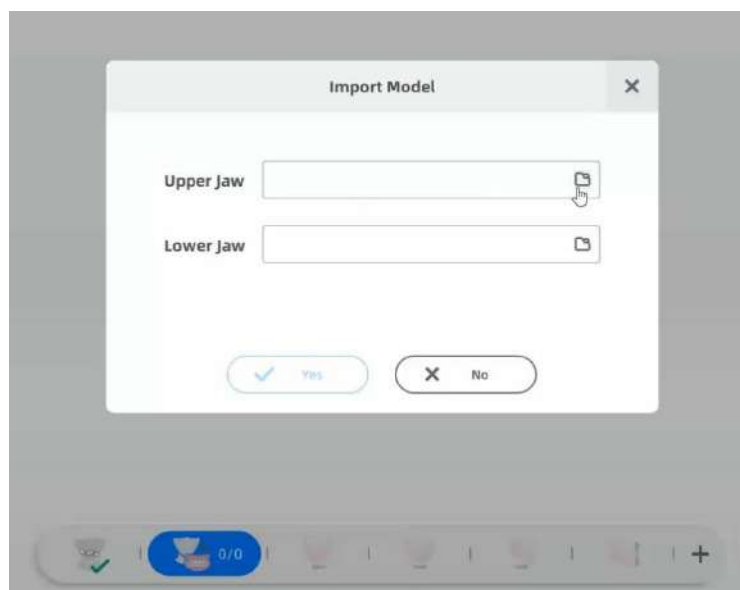
	Brightness		Adjust the camera brightness while scanning to capture a clear image.
	Import Model	Intraoral	Import the intraoral data of total jaw.
	Texture		Obtain surface color of scanned objects.
	Inversion		When it is turned on, the left and right faces are opposite.
	View Lock		When you click the button, the scanning is done with a fixed perspective and the automatic perspective tracking function is not enabled. Not enabled by default.

Click  to edit scanning data :

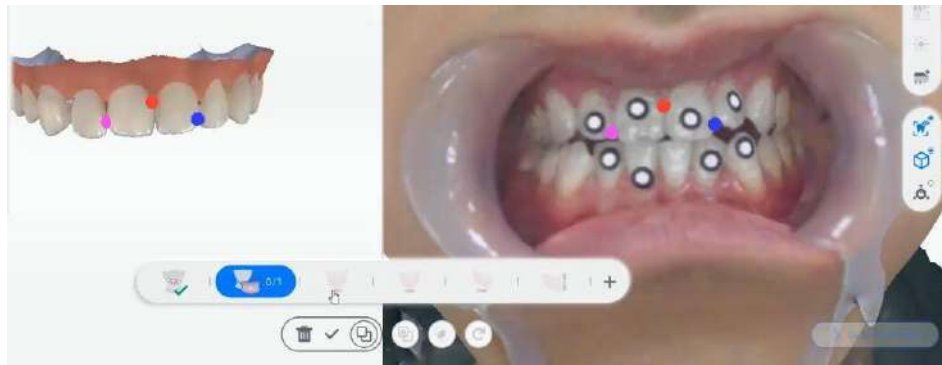


Alignment

Alignment mode supports automatic and manual mode. If the alignment effect is not satisfactory, you can choose manual . When creating an order, upload intra-oral scanning data to align with facial scanning data.



Double click on the two models to select three corresponding points to align.



III Collect dentulous motion scan data

Ensure that the complete dentulous motion scan data is collected.

1. Select the intra-oral scanning data and align to the static facial data. 2.

According to the interface wizard, collect the movement of dentulous data.



IV Preview dentulous motion

After completing the dentulous motion scanning, will preview the dentulous motion.

Through the collected the dentulous motion scan data, the doctor can preview the open and closed jaw movement of the patient, so as to communicate with the patient about the specific motor dysfunction, facilitate the follow-up of the subsequent treatment plan, and compare with the post-treatment effect.

9.6. Pre-design

9.6.1. View Edit

Support preview the different angles of the model and optimized scan data. In the right operation bar, you can edit the scanned data.

- Edit: When this button is clicked, it enters the edit interface to select the data to be deleted.
- Remove isolated data: Click to delete the smaller independent model data that are not connected to the main model data. Help delete unrelated model data quickly.
- Texture: Obtain surface color of scanned objects.
- Smooth: Smoothing is denoising data to make grid data smoother.
- Ortho/Perspective :
 - Orthographic projection: the edge of the object is big when near and small when far.
 - Perspective projection: The distance to each edge of the object is equal.
- Fit View: Adjust the scanned data to the appropriate display size.




9.6.2. Lip Line Extraction

Lip line extraction function is convenient for the user to follow-up smile design and orthodontic treatment. By extracting the lip line and re-cutting the application, the expected treatment plan is better presented to the user. You can preview the treatment effects.



Note:


When creating a order, select scan mode as “Face Scan” to enable the extraction lip line function.

Picture	Feature	Description
	Automatic extraction of lip line	After clicking, will auto extraction of lip line.
	Manual adjustment of lip line	If auto extraction is not ideal, you can select adjusted manually.
	slicing	Click to remove the internal dental image.

9.6.3. Orthodontic Simulation

Simulate orthodontic treatment solution, and view the expected effect according to different treatment solutions.



Click  on the pre-design interface to enter the orthodontic simulation interface. Orthodontic simulation can be divided into tooth segmentation, modeling and tooth setup.



Note:

When creating a new order, select the Dentistry Type as Orthodontics to enable the orthodontic simulation function.

Pre-processing

Edit the model data to make preparation for tooth segmentation.

Tooth Segmentation

Tooth segmentation will mark position of each tooth and distinguish them with different colors. You can edit, delete and add information to the tooth position. It is easy for you to check the expected effect of each tooth after orthodontics.

Tooth Setup

Tooth setup shows and visualize the effect of orthodontics. Features are following:

- You can create your own plans (Maximum is 3) and preview the effect.
- The process of orthodontics is displayed by animation.
- You can setup the teeth manually.

Note

You can click Setup to enter setup interface if the segmentation is completed.

9.7. Send Order

When data processing is completed, click "Send" directly, or select "Target" to upload to the cloud platform.



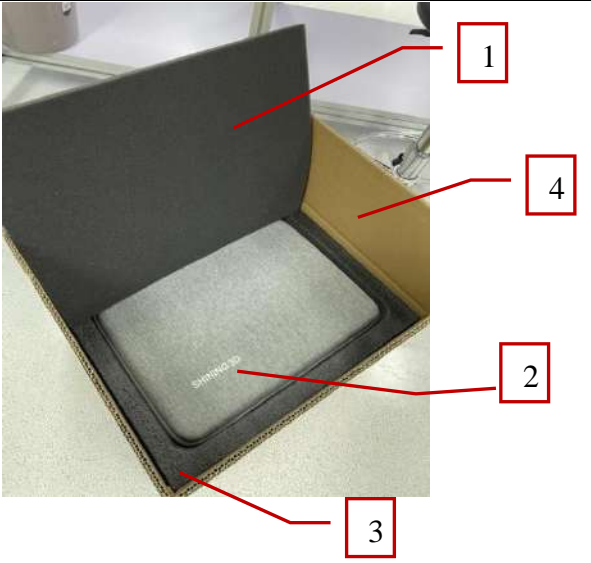

10. Product storage/transportation conditions, operating conditions.

Operating and storage requirements	Description
------------------------------------	-------------

Operating temperature	10°C – 40°C
Storage/Transport temperature	-30°C – 60°C
Storage/Transport/Relative humidity	30%RH – 90%RH
Air pressure	70 kPa – 106 kPa

3D Face Scanner MetiSmile/Datascan Packaging Description

1. 3D Face Scanner Packaging Description

Item	No.	Name	Material	Size	Photo
Outer packing	1	Upper pad	PU	510mm × 390mm × 15mm	
	2	Logo	---	90mm × 12mm × 0.5mm	
	3	Inner pad	EPE	510mm × 390mm × 145mm	
	4	Carton box	Corrugated Cardboard	522mm × 402mm × 175mm	
Inner packing	6	Package box	EVA + Fabric	445mm × 325mm × 125mm	
	7	Upper pad	EVA	416mm × 214mm × 18mm	
	8	Inner pad	EVA	420mm × 300mm × 90mm	
	9	Scanner and accessories	---	---	
	10	Envelope	Coated Paper	290mm × 233mm	

2. Package

A. Exterior appearance



Front



Side

B. Internal planning



3. Labers position

On scanner



Bottom side of scanner

On carton box



Front side of carton box

4. Documents in the package (Envelope)



A: Scanner Outer Kit Packing List (2 pieces)

B: Disinfection Guide for Scanner Tips (2 pieces)

C: Product Certification (1 piece)

D: Quick guide

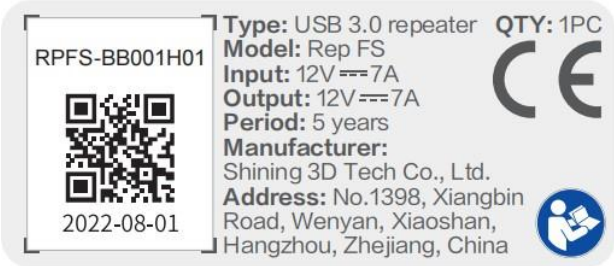
Metismile/Datascan 3D Face Scanner Physician Labels List

*Note: The QR codes mentioned in the document are for illustrative purposes only. The manufacture date of product symbol will be on the QR code like the first figure shows.

1. Label on Scanner



2. Label on repeater

<p>Metismile/Datascan</p>	 <p>The label on the repeater contains the following information:</p> <ul style="list-style-type: none"> RPFS-BB001H01 QR code 2022-08-01 Type: USB 3.0 repeater Model: Rep FS Input: 12V ---7A Output: 12V ---7A Period: 5 years Manufacturer: Shining 3D Tech Co., Ltd. Address: No.1398, Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China QTY: 1PC CE mark Recycling symbol
---------------------------	---

3. Label on Package

<p>Metismile/Datascan</p>	 <p>The label on the package contains the following information:</p> <ul style="list-style-type: none"> SHINING 3D QTY: 1PC Type: 3D Face Scanner Model: MetiSmile Input: 12V --- 7A Period: 5 years Manufacturer: Shining 3D Tech Co., Ltd. Address: No.1398, Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China Manufacturing date: The figure is shown below the QR code. For more details, please refer to the user manual Warning symbol QR code 2022-02-10 Recycling symbol Information symbol CE mark
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