Use and Maintenance Manual

TriScan
Intraoral scanner

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1 INTRODUCTION

Dear Customer
Thank you for having chosen the digital scanner, we feel confident that the performance of this system can meet your requirements and can be fully satisfactory.

You will find in this manual a detailed description of all operating instructions and procedures for a correct use of the system, as well as all specifications relating to digital image treatment.

We are in any case at your complete disposal for any additional information you may require, as well as for any suggestion aimed at an improvement in the device performance or in the service landed.

1.1 Icons and Symbols Used in this Manual

1.1.1 Icons

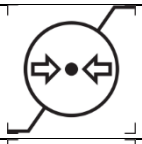
On this manual, the following icons are used:

	Shows a "**NOTE**". We recommend paying particular attention when reading the arguments identified by this icon, because is referred to an operative conditioning that can be dangerous for the unit if ignored.
	Shows a "**WARNING**"; the arguments identified by this icon refer to the patient and operator safety.
	Consult the accompanying documentation

1.1.2 Symbols

This manual and the equipment use the following symbols:

SYMBOL	DESCRIPTION
	Manufacturer address
	Manufacturing date
	Unit with applied parts of type B. IEC 60601-1 uses the term "applied part" to refer to the part of the Medical device which comes into physical contact with the patient in order to carry out its intended function.
	The product, at the end of its useful life, can not be thrown in the regular trash with other wastes and is subject to a separate collection.
	Product Reference

SYMBOL	DESCRIPTION
	Serial Number
	Laser source
	Humidity limitation
	Atmospheric pressure limitation
	Temperature limits
CE	Class 1 equipment, in compliance with requirements 93/42/EEC and subsequent amendments.

1.2 Purpose of this Manual

This manual is intended to provide a general overview of the system and its technical characteristics; also, it provides a description of the operations necessary for a correct installation and proper use, safe, efficient.

This manual is used as a guide. The photos, graphics and illustrations provided in the manual are for explanatory and illustrative purposes only and may differ from specific products. Due to product version upgrade or other needs, the company may update this manual.

	This manual is updated to the current condition of the product, ensuring an appropriate reference to use the unit properly and safely.
	Changes in the product without impact on operating procedures and on safe use may not be included in this manual.

	When using this product, please strictly follow the applicable law. If this product is used to infringe upon the rights of a third party or other improper use, the company will not bear any responsibility. If the contents of this manual conflict with the applicable law, the provisions of the law shall prevail.

1.3 User Obligations

	Read this manual to become familiar with the unit before putting it into service. Carefully follow the warnings and safety instructions.

	Always keep this manual handy, so that it can be consulted even after the first use.
	The unit must always be used in accordance with the procedures explained in the present manual, and shall never be used for purposes other than those it was designed for. Failure of the user to properly maintain the equipment may relieve Trident or its dealer, from responsibility for any injury, damage, or non-compliance, which may result.
	Report promptly to Trident or to its dealer any accident involving this unit or any alteration in features and/or performances which could cause death, injuries or health hazard to Patient and/or Operator.

1.4 General warnings

	Do not touch equipment and equipment plugs with hands or other objects with water.
	Please connect the equipment to a power supply with protective grounding.
	Please avoid pulling, knotting, trampling and other operations on the cable, so as not to damage the power cord.
	When there are problems in the process of use, do not disassemble the equipment privately, please contact us in time.
	After each use on the patient, the probe head must be disinfected and sterilized
	When using the equipment, please handle it gently, do not drop or smash the equipment, so as not to cause damage to the equipment.
	Do not block the heat sink under the equipment. Do not use this equipment in an overheated, wet or cold environment.
	Do not touch the reflector of the probe head with other objects, so as not to dirty and damage the reflector
	Do not touch the lens with your hands or other objects, so as to avoid getting dirty or damaging the lens.
	**PRECAUTIONS TO KEEP IN MIND WHEN USING THE SYTEM'S PROBE:** This product uses a visible laser light. Although the laser centering unit used with the scanner is classified in class 2 in accordance with IEC 60825-1 and attachments, it is recommended to follow this precautions: • Do not shine a laser directly on eyes of any people • Do not look inside the window of probe unit.

	• Do not look at the reflections of laser pointers. • Do not open the laser centering unit as this could modify the optics of the same.

1.5 Applicable standard

EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 62304:2006+A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2009/AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
EN 60601-1:2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility Requirements and tests
EN 60825-1:2014	Safety of laser products. Equipment classification and requirements
EN 62471:2008	Photo biological safety of lamps and lamp systems
93/42/EEC	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices purposes

1.6 Electromagnetic environment

This product i suitable for use in all facilities of domestic and direct public low-voltage power supply network for home use.

Medical devices manufactured by Trident comply with the EN60601-1-2: 2014 standard for both immunity and emissions.

- The electro medical equipment requires special precautions regarding EMC (Electromagnetic Compatibility) and must be installed and put into service in accordance with the EMC information contained below.
- This product belongs to the Group 1 Class B equipemt specified in IEC/CISPR11, non-permanent installation equipment, non-living support equipment and belongs to equipment that is expected to be directly connected to power public grid.
- Portable and mobile radio communication devices may affect the normal operation of the device and the high frequency surgical equipment that that this product is expected to use together. It should be ensured that the portable and mobile RF communication equipment and the high-frequency surgical equipment that this product is expected to use together meet a certain space distance.
- Cable information are as follow:

No.	Name	Cable length (m)	Shielded
1	Connection cable	1.9	Yes
2	DC power supply lines	1.5	No
3	Power supply line	1.5	No

- The use of accessories, transducers and cables other than those specified, with the exception of those sold by the manufacturer as spare parts can cause an increase in emissions and a decrease in immunity.
- The electro medical equipment has been tested and found to comply with the emission and immunity limits of electro medical equipment in accordance with the IEC60601-1-2: 2014 standard. These limits are designed to provide adequate protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If the electro-medical device, interacting with another device, causes or receives detectable interference, the user is invited to limit the interference by adopting one or more of the following measures:
  1. reorient or relocate the receiving device;
  2. increase the distance between the appliances;
  3. Connect the equipment into an outlet on a circuit different from the device or devices causing the interference;
  4. Contact the manufacturer or local technician for assistance.

Refer to the additional information below regarding the EMC environment in which the device is to be used.

1.6.1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device are intended for use in the electromagnetic environment specified below. The customer or the user of these devices should ensure that they are used in such an environment.

EMISSIONS	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF (radio frequency) emissions CISPR 11	Gruop I	This product uses radio frequency energy only for its internal function. As a result, its RF emissions are very low and unlikely to cause any interference in nearby electronic devices.
RF emissions CISPR 11	Class B	This product i suitable for use in all facilities of domestic and direct public low-voltage power supply network for home use.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

1.6.2 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below.
The customer or the user of this devices should ensure that they are used in such an environment

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ENVIRONMENT EMC - REGULATION
Electrostatic discharge (ESD) IEC 61000-4-2	contact ± 8kV	contact ± 8kV	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
	in air ± 15 kV	in air ± 15 kV	
Transients / sequence of rapid electrical pulses IEC 61000-4-4	± 2kV for the power lines	± 2kV for the power lines	Mains voltage quality should be that of a typical commercial or hospital environment.
	± 1 kV for the input / output lines	± 1 kV for the input / output lines	
Overvoltages IEC 61000-4-5	± 1kV between phases	± 1kV between phases	Mains voltage quality should be that of a typical commercial or hospital environment .
	± 2kV between phase (i) and earth	± 2kV between phase (i) and earth	
Voltage dips, short interruptions and	<5 % UT for 0.5 cycles	<5 % UT for 0.5 cycles	Mains voltage quality should be that of a

voltage variations on the power input lines IEC 61000-4-11	40 % UT for 5 cycle	40 % UT for 5 cycle	typical commercial or hospital environment. If the user of the equipment requires continued operation during mains voltage interruptions, it is recommended that the equipment be used with an uninterruptible power supply or batteries.
	70% UT for 25 cycles	70% UT for 25 cycles	
	0% UT for 5 s	0% UT for 5 s	
High frequency magnetic field (50 / 60Hz) EC 61000-4-8	3 A/m.	3A/M	Network frequency magnetic fields should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity Magnetic Field IEC 61000-4-39	30 KHz, CW, 8 A/m	30 KHz, CW, 8 A/m	If errors occurs during the work, it will be necessary to move the system away from frequency magnetic field or the magnetic shield must be mounted on the location. The expected site of installation should be measured in the frequency field to check if it is below the level of compliance with the requirements.
	134.2 KHz, PM, 65 A/m	134.2 KHz, PM, 65 A/m	
	13560 KHz, PM, 7.5 A/m	13560 KHz, PM, 7.5 A/m	
NOTE UT is the AC mains voltage. before applying the test level.			

1.6.3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below.
The customer or the user of this devices should ensure that they are used in such an environment.
Portable and mobile RF communications equipment should not be used within 30cm of any part of the device including cables.

IMMUNITY TEST	IEC 60601 TEST LEVEL		COMPLIANCE LEVEL	Recommended separation distance d:
RF conducted IEC 61000-4-6	3 V (RMS) from 150kHz to 80MHz 3V/M 80 mHz ÷ 2.5 GHz		3 V(RMS)	d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2.5 GHz d = 1,2 √P Where (P) is the maximum output
RF Irradiate IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz		3 V/m	
	TETRA 400	27 V/m	27 V/m	

Immunity to proximity fields from wireless RF communication devices IEC 61000-4-3	380 – 390 MHz			power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency rangeb
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	
Interference may occur in the vicinity of equipment marked with the symbol shown on the right				

1.6.4 Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and intra oral scanne

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3 \sqrt{P}$
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

NOTES

For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be determined 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.

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2 EQUIPMENT DESCRIPTION

2.1 Product use

This product uses the optical scanning method to obtain the three -dimensional geometric data of dentition directly, and provides the digital three –dimensional model of CAD / CAM denture design and processing, which can be used in the fields of dental repair, orthodontics and implant.

Compared with the traditional method of crown production, the Trident impression scanner has great advantages.

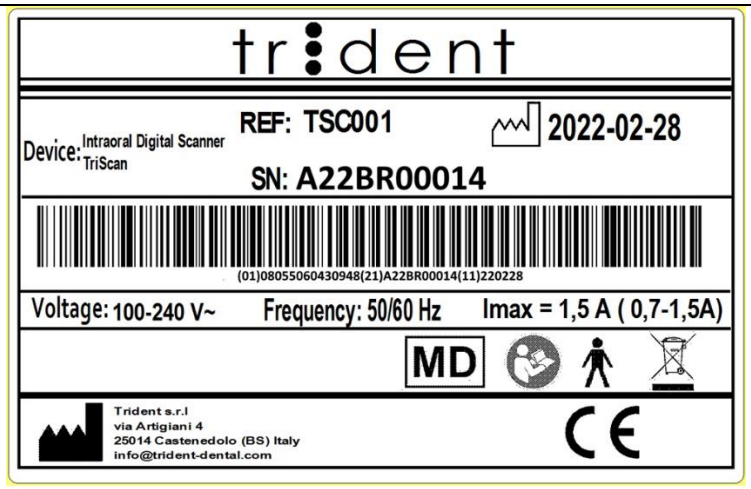
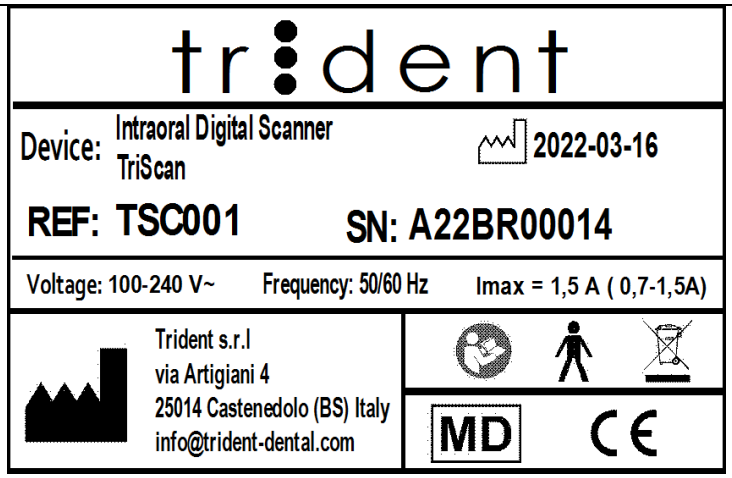
1. No powder: improve the comfort of patients.
2. Timely feedback: the corresponding 3D data can appear in the computer immediately, so that doctors and patients can understand the oral situation at the first time.
3. High precision: this product has ultra-high accuracy, the data can be directly sent to the processing factory for designing and processing.

2.2 Product description:

This product is composed by the parts described on the following oimage:

2.3 Device identification

The Intra oral scanner is identified by the following labels:

Label Type	Label	Position
Main label		This label is glued under the power supply module. This label hold the UDI.
Additional label		This label is glued on the power switch controller.
SN label		This label holds only the SN of the probe module. T's glued under the holder of the probe.

Intraoral digital Scanner TriScan is a Class I Medical Device according to 93/42/EEC

2.4 Technical characteristics

2.4.1 Dimensions

Length into the mouth	85 mm
Height of probe head assembly	15 mm
Total size	216 mm(L) x 40 mm (W) x 36 mm (H)

2.4.2 Specifications

Scanning depth	0 ÷ 15 mm
Scanning accuracy	≤ 15 µm
Repeatability precision	≤ 10 µm

2.4.3 Power requirements

Power Parameters	Requirements
Rated Voltage	AC100V-240V
Rated Current	30 VA
Rated Frequency	50/60 Hz

2.4.4 Computer requirements

Computer Parts	Requirements
CPU	i7-7700k (3.6GHz; quad-core; 8-thread) or above
RAM	DDR4 2400 16G or above
Hard Disk	SSD 240G or above
Graphics Card	GTX 1060 Memory 6G or above
Operating System	Windows 7* 64 bit, Windows10* 64 bit
Graphics Driver Version	NVIDIA* Driver 436.15 - WHQL Version or above

	These specifications refer to the PC currently provided by Trident (optional); you may receive a different PC depending on availability, but with equal or superior specifications.
	The PC and any other external device connected to the unit must meet the IEC 60950 standard (minimum requirements)
	The PC and any other external device must be connected in accordance with IEC 60601-1-1
	The PC and any other external device must not be connected to the same power supply as the unit.
	The unit shall be connected directly to the acquisition PC with an Ethernet cable. Connection through the LAN-network of the site is not allowed. Two network ports are needed in the PC in order to connect also to the site network.

2.4.5 Environmental Requirements

Parameter	Requirements
Working environment temperature	5 ℃ ÷ 40℃
Working environment relative humidity	≤ 80%

Parameter	Requirements
Working environment:	indoor, avoid any other strong light, away from strong electromagnetic interference source.
Atmospheric pressure	760 hPa ÷ 1060 hPa
Storage conditions	10℃ ÷ 50℃ , keep dry
Storage Humidity	≤ 93%

2.4.6 Laser specification

Parameter	Specification
Laser class	2 according to IEC/EN 60825-1:2014
Laser wavelength	450 – 520 nm
Laser output	≤ 0.4 mW
Beam divergence angle	33°
Laser pulse width	25 ms
Laser pulse frequency	30M hZ

2.5 Instrument disposal

After the instruments is used at the end of its life, the instrument should be disposed of in accordance of local law and regulations, or contact and manufacturer or local representative for recycling and centralized disposal in accordance with local law and regulation.

2.6 Equipment installation

- After removing the packaging, put the probe body 2 and the base4 on a safe and stable horizontal table. If the table is unstable or uneven, there will be a large sloshing in the operation of the equipment, which may cause deterioration of image data.
- Insert the probe body 2 into the probe head 1; the probe head can be replaced.
- The probe body 2 and the cable3 are integral and cannot be disassembled. If you pull out the cable or check the plug and unplug connection by yourself, the cable will be damaged.
- Plug the power cord into the power Jack 6 and turn on the power.
- Plug the USB interface 5 into the computer's USB 3.0 port (blue).
- Clean the scanner regularly to keep it clean

2.7 Imaging Software installation

Deep-View is the software for the management (acquisition, modification and storage) of digital images developed by Trident for TriScan intraoral digital scanner. Deep View comes in a portable USB marked with Trident logo.

The USB contains the following folders:

- DEEP-VIEW Installer
- DEEP-VIEW Manuals
- Utilities

Insert the DEEP-VIEW USB key in the USB port of the computer where the program is to be installed; wait a few seconds until the start-up window automatically appears. The installation process for this system entails:

- Installation of main program
- Installation of the protection key drivers
- Installation of sensor drivers

The complete software installation and using tips are fully explained in the Deep-View user's Manual

	Please carefully read and follow the instruction of the DEEP-VIEW software Manual before using your sensor for the first time .

2.7.1 Deep-View Software Characteristics

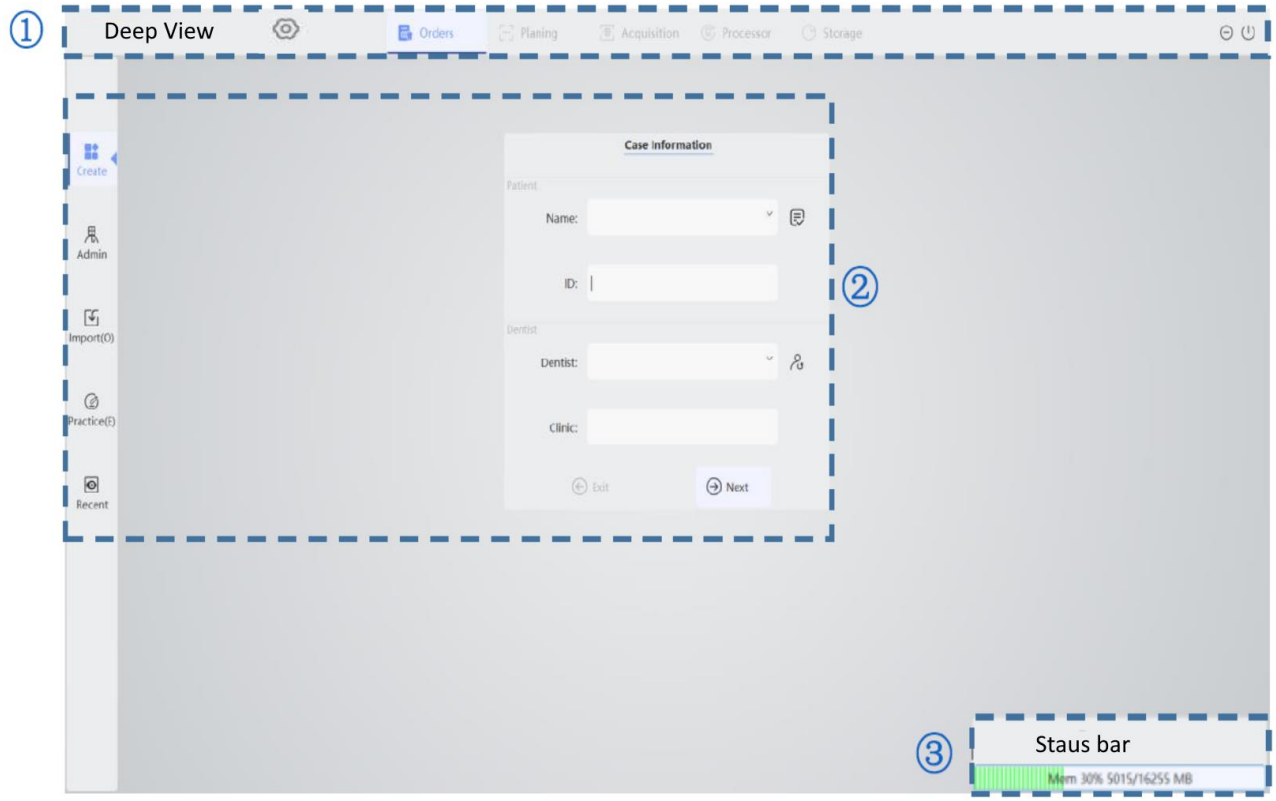
	TriScan intraoral scanner only works when connected to a PC on which you have previously installed the software Deep-View.

CHARACTERISTIC	VALUE
Manufacturer	Digital Imaging srl – Nichelino (TO)
Operating system	Windows ® 8.1 or 10
Main functions available	Full size and/or multi image visualization Images magnification with dynamic zoom and scroll Image reverse and rotation Brightness and contrast adjustment

	Special filters application: harmonizer to optimize the visualization to all density present on image Histograms and density profile visualization Linear and angular measurement with dedicated calibration Images printer with or without overlays Database

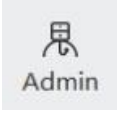
3 SYSTEM USE

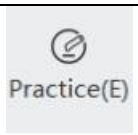
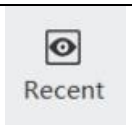
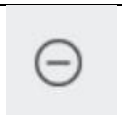
3.1 Software interface



① Main menu: consist of Orders, Planning, Acquisition, Processor, Storage and Parameter Setting, etc, each of which opens the corresponding page.
② Display area: show the contents of each page.
③ Status bar: show the feedback information of each move and hints in the process of operation.

3.1.1 Icons used on the software

Icon	Meaning
	**Settings button:** click Settings to open the settings interface, you can set the language, format, save path, etc
	**Create button:** click to enter the creation interface, you can create or modify doctor- patient-related information.
	**Administration button:** click to enter the administration interface, you can create /modify / view doctor or patient medical record information.
	**Import button:** click to load the medical record from the computer folder.

Icon	Meaning
	**Practice button:** you can directly enter the scan interface for exercise without creating doctor and patient information
	**Recent button:** click to open the recent case interface to view or open the selected case.
	**Minimize button**: click to minimize the current software interface to a button on the taskbar.
	**Close button:** click to close the software

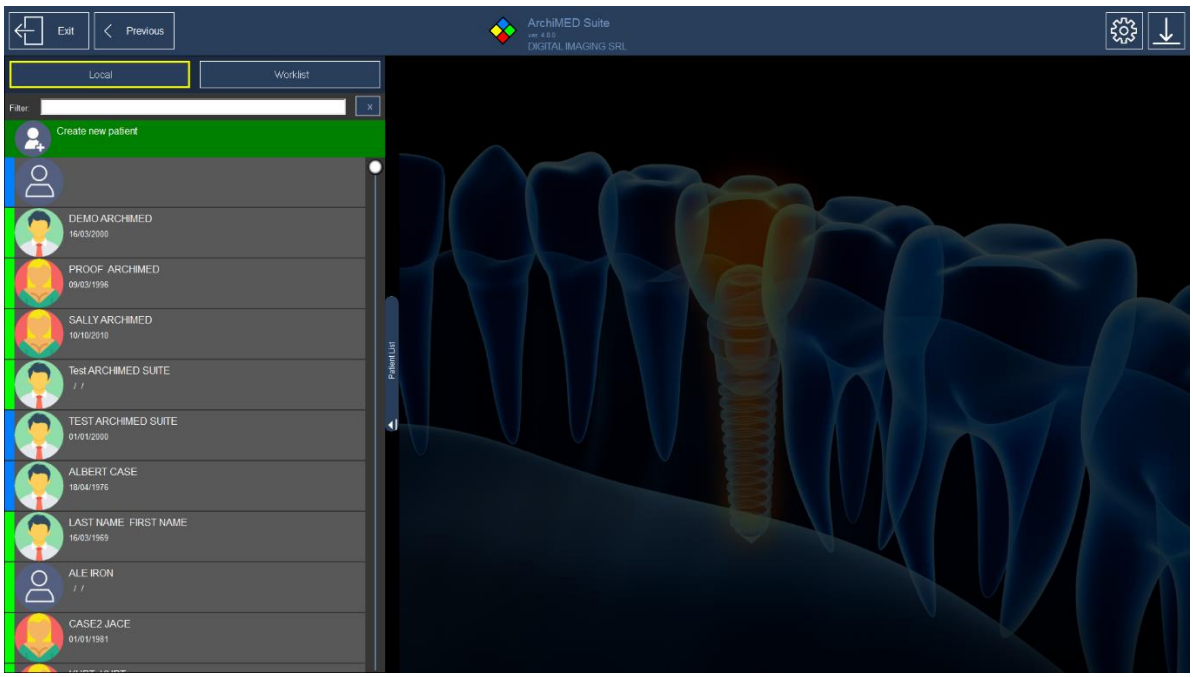
3.2 Input Patient data

To input patient data, please follows the next steps:

1) Run Deep-View entering your password
2) Select the device "Intraoral scanner"
3) It is now possible to select an already existing patient or create a new one.

3.2.1 Creating a new patient

In the main page of the program, on the left there is the patients list.



To create a new patient, click on  , then will appear this window:

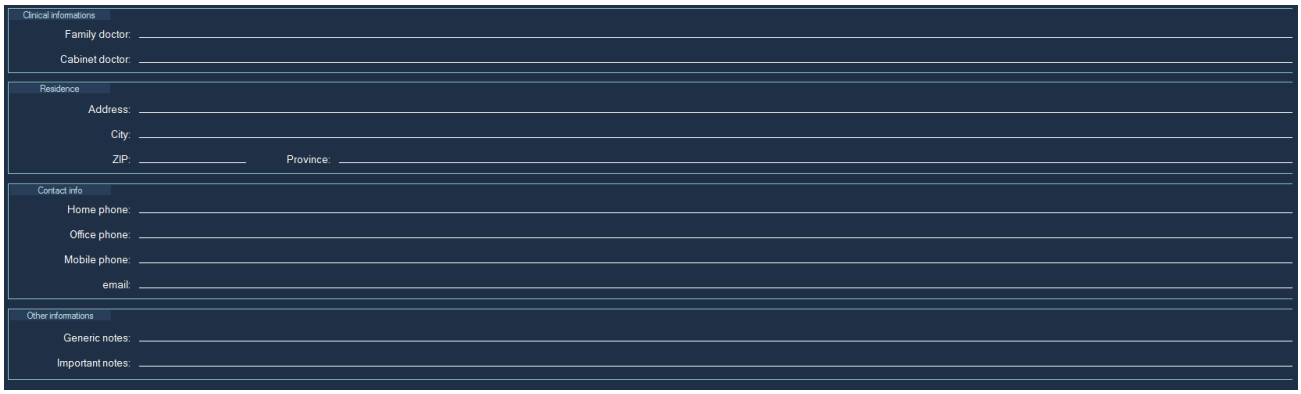
To create a new patient, you must enter some basic information (First Name, Last Name and Date of Birth).

Before save a new patient you have to select the destination database (only if you have more than one active database). Click on the destination database, then on 

.

3.3 Patient Information

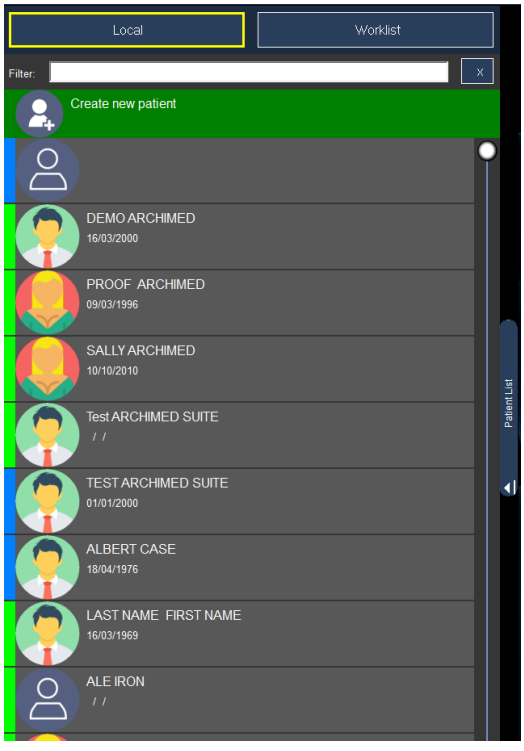
There are also some optional information that can be assign to each patient and shown in the following window



- Family doctor
- Address
- Home phone, mobile phone, e-mail
- Other generic and important notes

3.3.1 Select an already existing patient

To search for a patient, go back to the main page and enter the patient's surname or first name in the input box "Filter" (if only the first or last name is written, the program will automatically find all patients whose surname or first name contains the text entered)



By pressing  the program will connect with RIS database which contains exam scheduling and other patient's data. ArchiMED Suite® includes the list of local database with RIS patients list. To configure DICOM modality worklist, please refer to chapter "*DICOM Settings*".

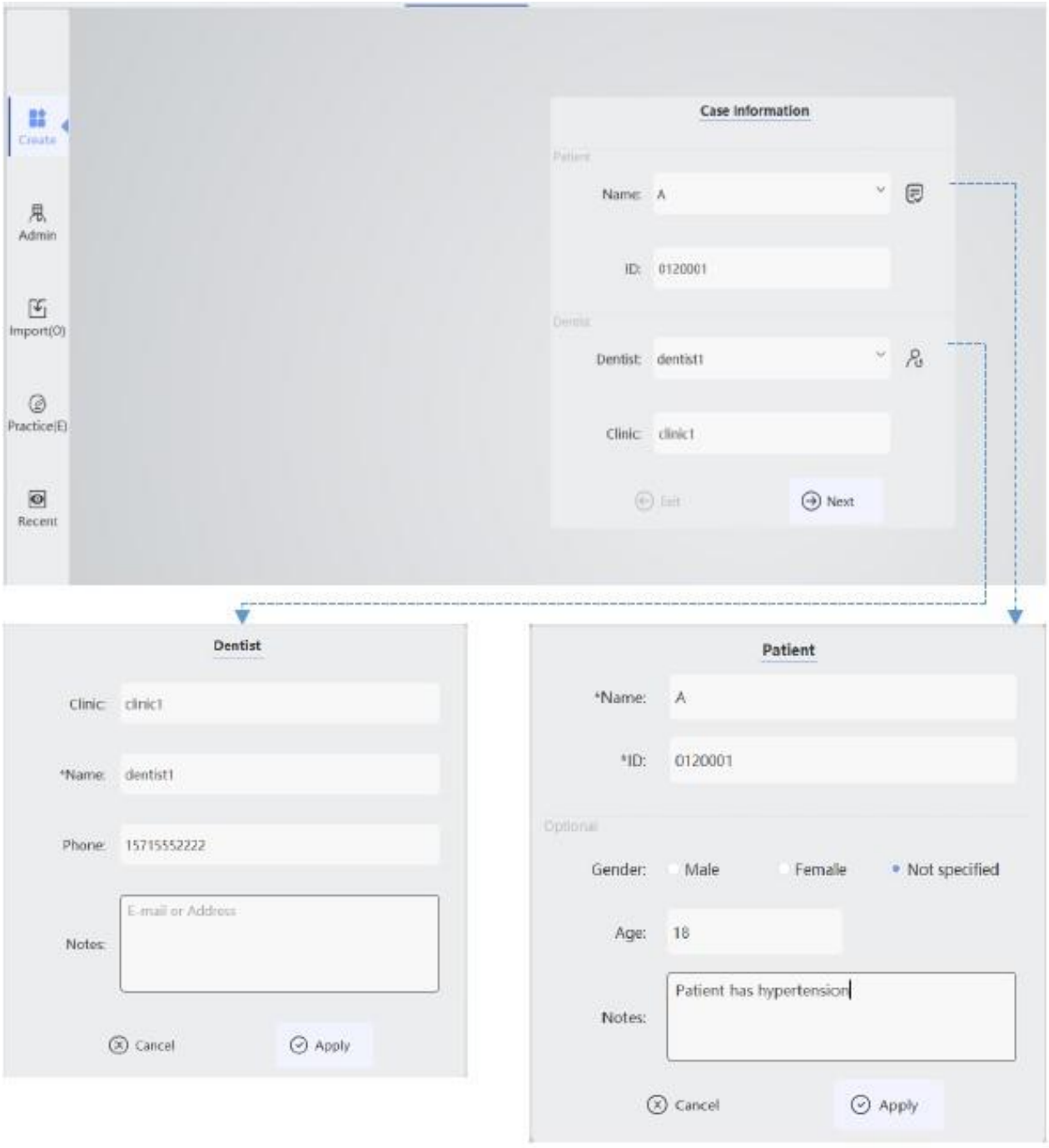
3.4 Management phase

- Method 1 for creating patients and their cases

3.4.1 Case

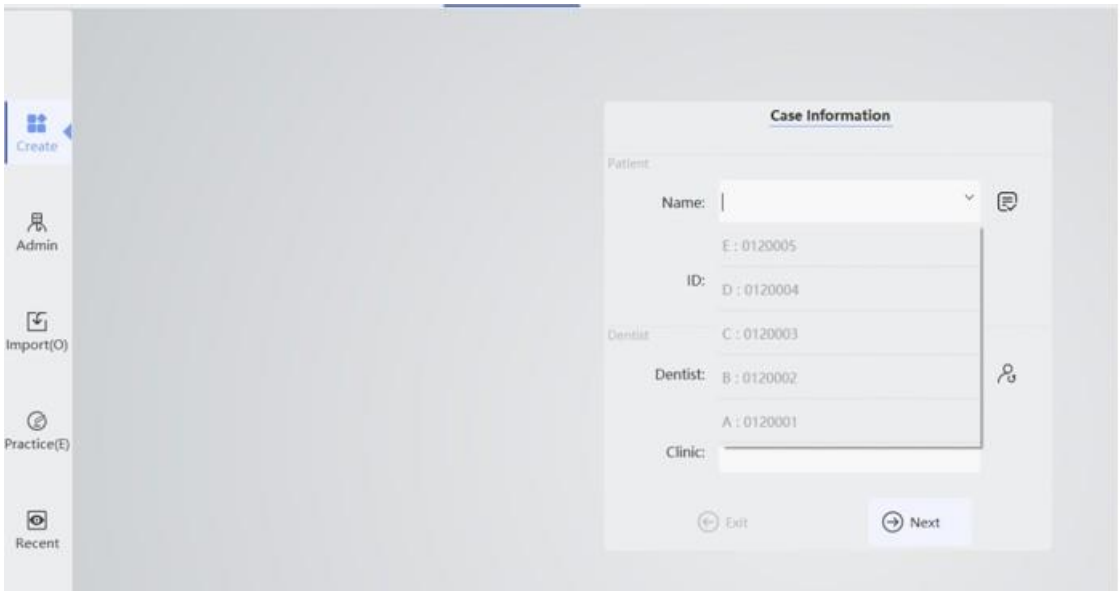
Method 1 for creating patients and their cases

Input doctor and patient's name and ID >> click / to complete data >> click OK >> next step create successfully



3.4.1.1 Create case of existing patient

Click button >> select a patient >> next step ———create new case of the patient successfully

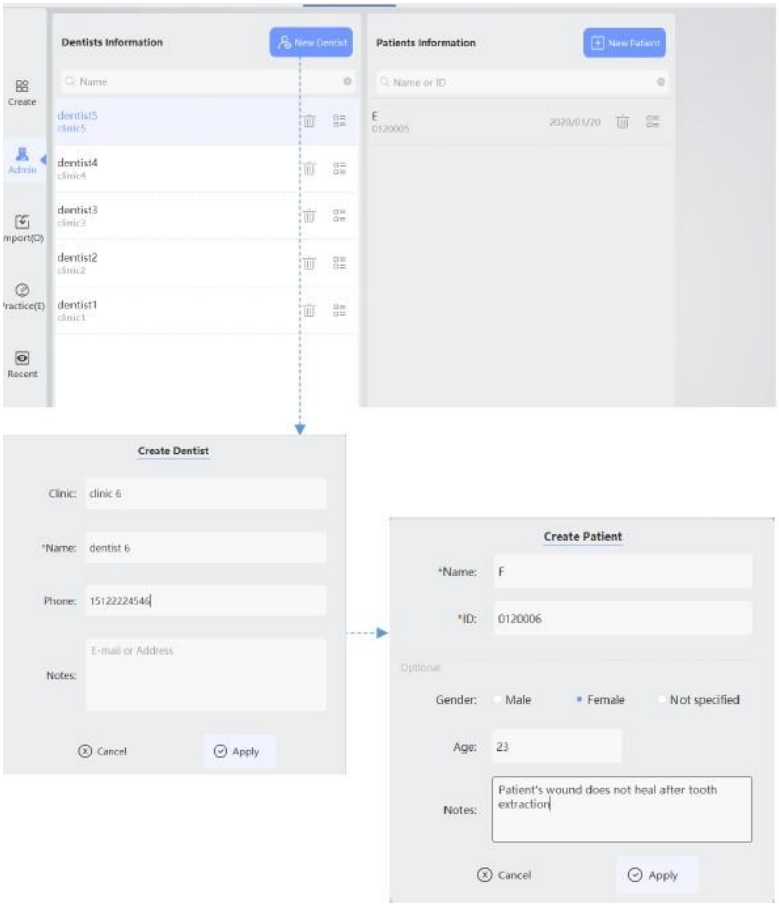


Drop-down button: display the name and ID of the patient of the last five cases.

After selecting any existing patient in the drop -down list, if any information is modified in this interface, it is considered to create a new patient. (If it is modified in the right extension window, it is considered to modify the patient.)

3.4.1.2 Method 2 for creating patients and their cases

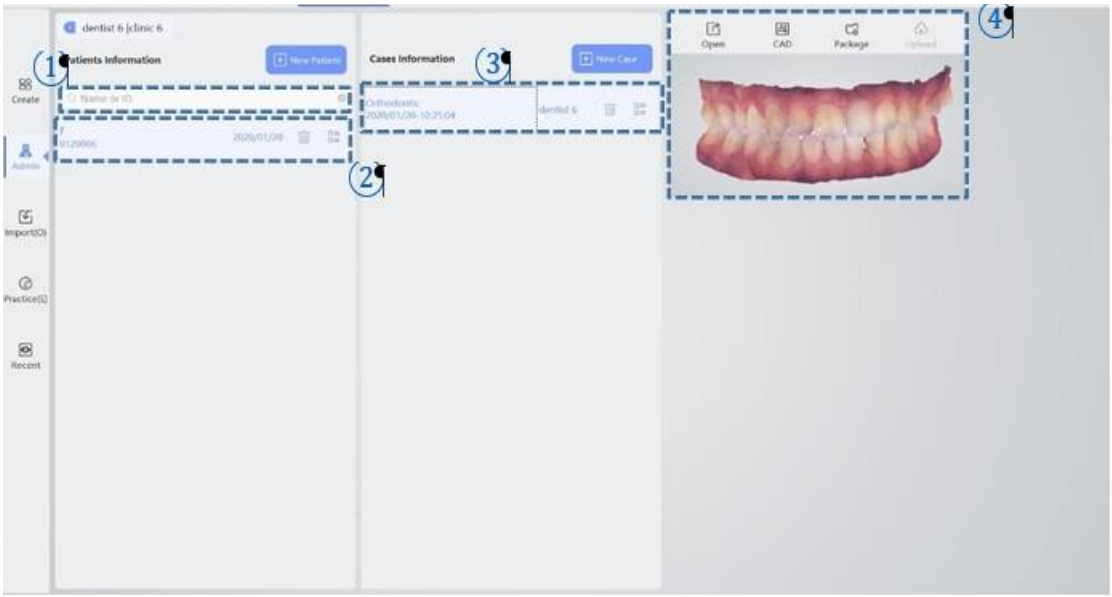
Click New Dentist >> fill in doctor information and apply >> fill in patient information and apply → create successfully



The "Tab" key is to switch the edit column.

3.4.1.2.1 Open the existing medical record information

Select a doctor >> click to view the patient >> click Open → Open successfully

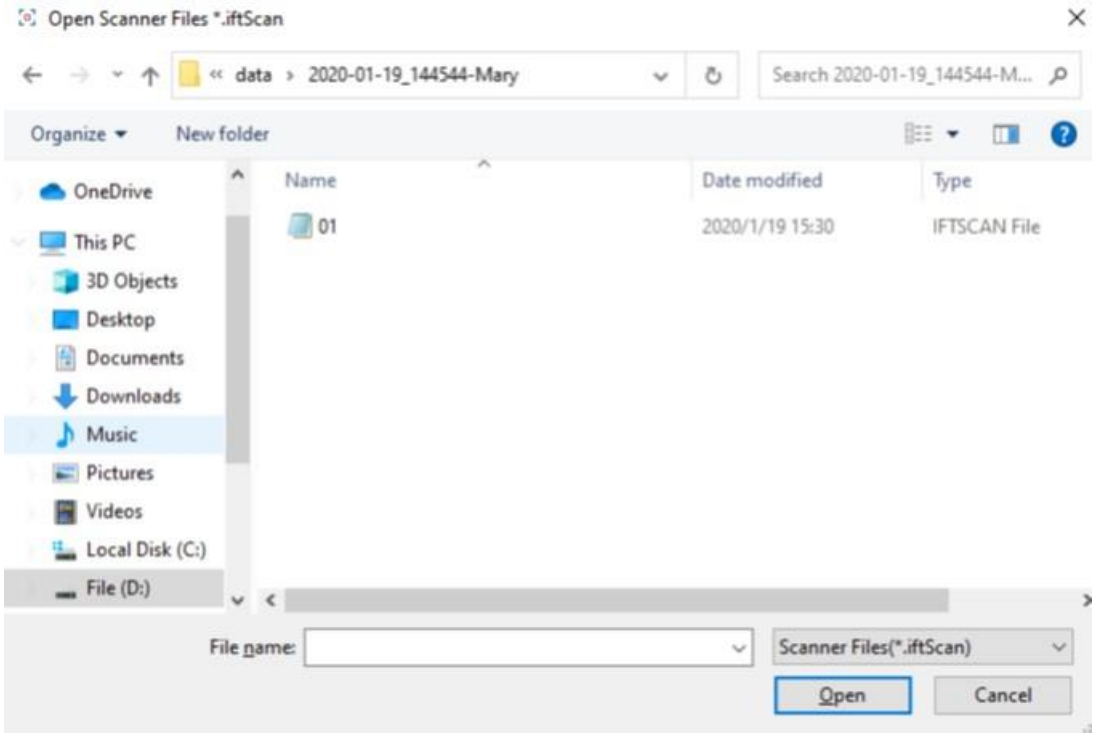


① Search: search the doctor / patient information through the keyword (Doctor name / number).
② Patient basic information: including patient name, ID and creation time.
③ Patient medical record: including patient scanning scheme, doctor and creation time of this diagnosis and treatment information.
④ Detailed function area: load the two-dimensional data in the patient medical record for viewing.

Icon	Meaning
	Delete button: click to delete the selected doctor / patient / medical record information.
	Expand button: click to view the details of the changed patient or doctor.
Open	**Open button:**click to enter the processing interface to view the existing 3D data.
CAD	**Design button:** view data and design in EXO CAD
Package	**Package button:** package the data and open the location of the folder where is located.
Upload	**Upload button:** upload the current data to the network. (This function is to be open)

Load

Import existing case information



3.5 Treatment page

3.5.1 Planning selection

Select tooth number >> select scanning type >> fill in information >> click next

Icon	Meaning
Empty	**Empty button:** click to empty all the selected teeth (click the selected tooth to cancel the selection).
Orthodontics	**Orthodontic mode:** just need to fill in the note.
Restoration	**Restoration mode:** fill material, color, remarks. You can choose the pre-preparation scan function
Implant	**Implant mode:** fill the implanting brand, material, color and remarks

Pre-preparation scan: after selection, the dentition before preparation and the abutment after preparation can be scanned. This procedure is only used in cases where the shape after repair is required to be consistent with that before repair.

3.5.2 Acquisition

PRECAUTIONS TO KEEP IN MIND WHEN USING THE SYTEM'S PROBE:

This product uses a visible laser light.

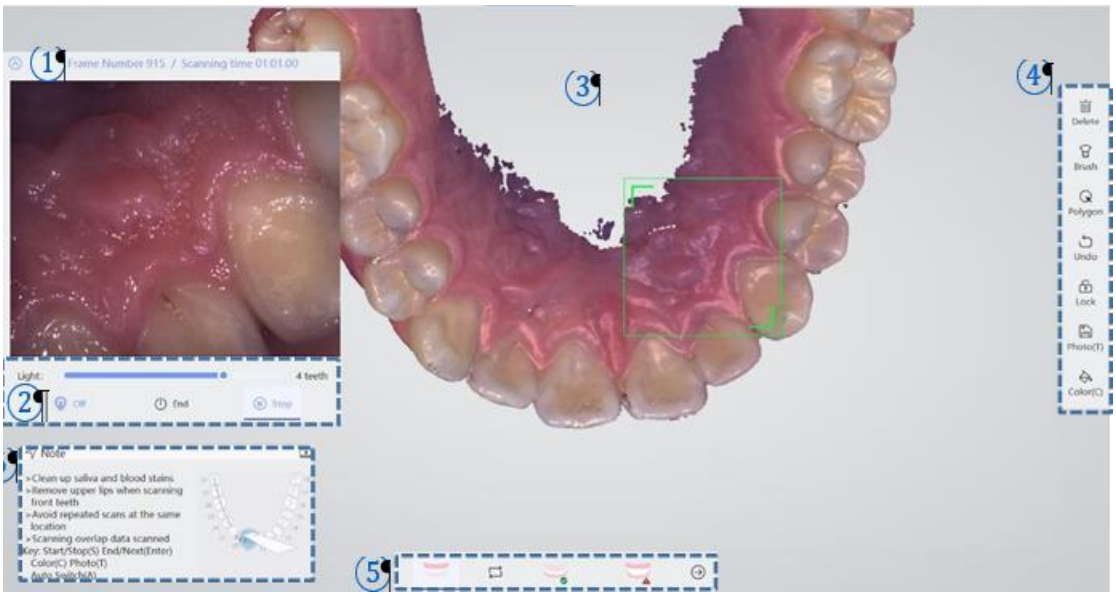
Although the laser centering unit used with the scanner is classified in class 2 in accordance with IEC 60825-1 and attachments, it is recommended to follow this precautions:

- Do not shine a laser directly on eyes of any people
- Do not look inside the window of probe unit.
- Do not look at the reflections of laser pointers.
- Do not open the laser centering unit as this could modify the optics of the same.

3.5.2.1 Acquisition Page

3.5.2.1.1 Scan the upper and lower jaw

Click open (S) to open light >> click start (S) to scan >> click end (Enter)-scan completed.



① 2D real-time display area: display real-time scanning in the mouth, prompting the number of scanning frames and scanning time.

- There is a hint of whether the "A" intelligent scanning function is enabled :
- Blue when scanning: indicates that "A" intelligent scanning is running. Only enabled in mode 4 or 5.
- Black when scanning: indicates that "A" smart scanning is not running. You can pause the scan, then click the keyboard "A" key to enable the A function,
- and then start the scan.
- Gray when scanning: indicates that it cannot be used. When it exists in mode 1 to 3, the mode has no "A" intelligent function.

② Scan control area: start, pause, and end of the scan

③ Scan display area: display the data of the scan in the mouth. The operations are as follows.

- Data control: After clicking the data, the left mouse button controls the data rotation, the mouse wheel controls the data zoom, and the right mouse button
- controls the data translation.
- Data Supplement Scan: when the data is missing, return to the scanning interface, click Start, and then scan the missing data location.

④ Auxiliary scanning tool area: provides auxiliary tools for data inspection and modification.

⑤ Dental jaw selection area: select the area to scan the position of the corresponding jaw.

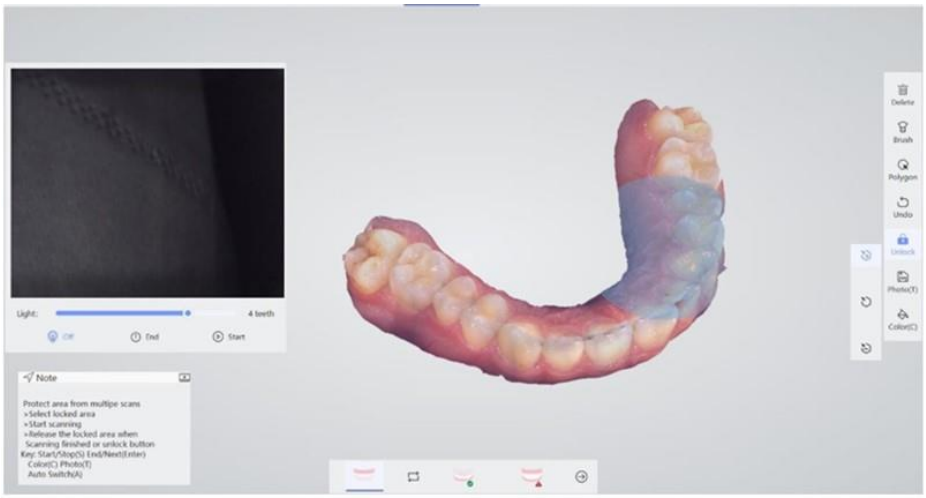
⑥ Prompt area: users can follow the prompts. If you want to close the interface, need to go to the settings interface to close it

Icon	Meaning
	**Delete button:** delete the whole data, which cannot be recovered again.
	**Brush button:** after clicking, the mouse becomes a brush. And delete excess data as a brush.
	**Polygon button :** after clicking, the mouse becomes a multilateral shape, and the closed area that is circled is deleted.
	**Lock button:** after clicking, you can circle a closed area, and the circled area will not be affected during the scan.
	**Undo button:** click once to restore the previous state of this operation, and click again to restore all.
	**Photo button:** saves the image of the current two-dimensional imaging frame.
	**Color button:** click to make the current 3D data switch between true color and gypsum color
	**Upper jaw button:** click to enter the Upper jaw-scanning interface for related operations.
	**Mandibular button:** click to enter the mandibular scanning interface for related operations.
	**Bite button:** click to enter the bite scanning interface for related operations.
	**Swap button:** click to swap the upper and lower jaw.
	**Next button**: complete the scan operation and enter the model processing

3.5.2.1.1.1 Lock Function

It is used to protect the area that you do not want to change during the scanning process. It's only used when scanning is paused.

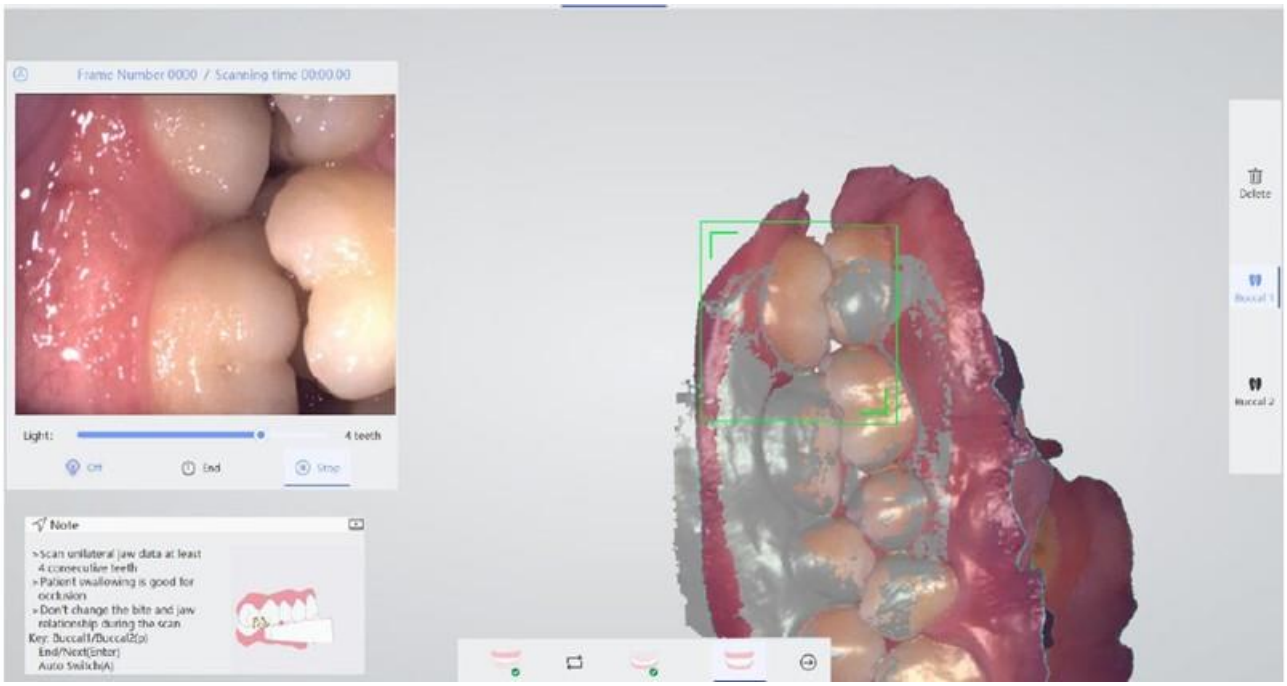
Start scan → >> scan pause >> click "Lock" → circle Target area → continue scan → >> end scan



Icon	Meaning
	Radio button: you can circle one area at a time, circle multiple times to save only the last selected area.
	Multiple selection button: select the area with circle where all selections are saved multiple times.
	Remove button: check the locked area to unlock the corresponding position Note: Function can only be used when the scanning is paused. –Select the locked area and start scanning. –The unlock button and the end button can release the locked area.

3.5.2.1.1.2 Scan byte

Click start (S) to scan → scan bite point 1 (→ scan bite point 2) → bite success → -scan scan finished



Icon	Meaning
	**Delete button:** click to delete the current data
	**Bite point 1:** click to switch to scan bite point 1.
	**Bite point 2:** click to switch to scan bite point 2.

3.5.2.1.1.3 Scanning Method

Upper and lower jaw scanning

- Recommended grip: pen-style
- Scanning distance: 2mm-5mm
- Initial scanning position: scan from the occlusal plane, parallel to the occlusal plane, and scan along the arc of the dental arch;

	When you start scanning, the probe head is facing the occlusal surface. Do not scan the probe at an angle

- Scan path: occlusal surface → tongue tip / lingual surface → cheek tip / lip surface

Scanning steps

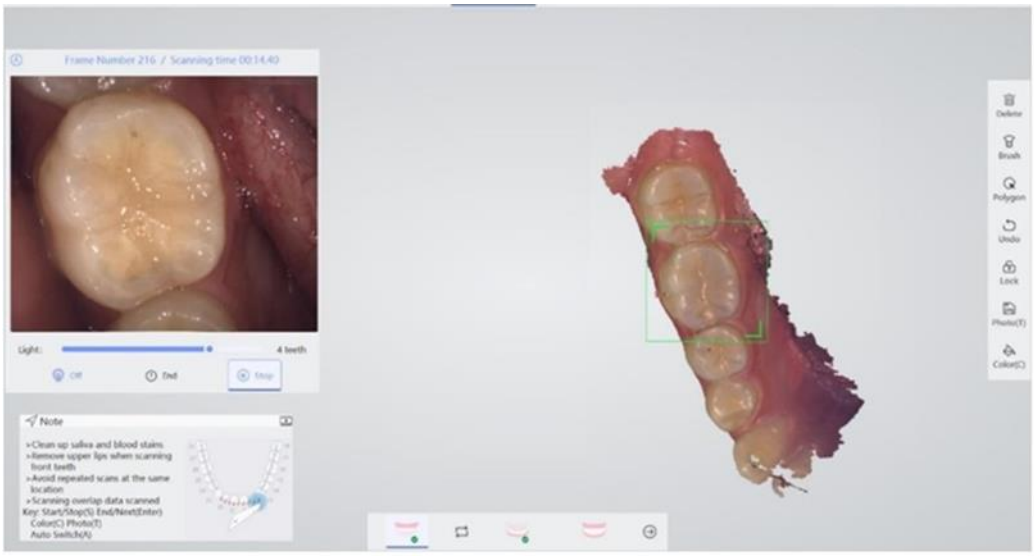
① Place the scanning probe head directly on the posterior occlusal surface and start scanning.

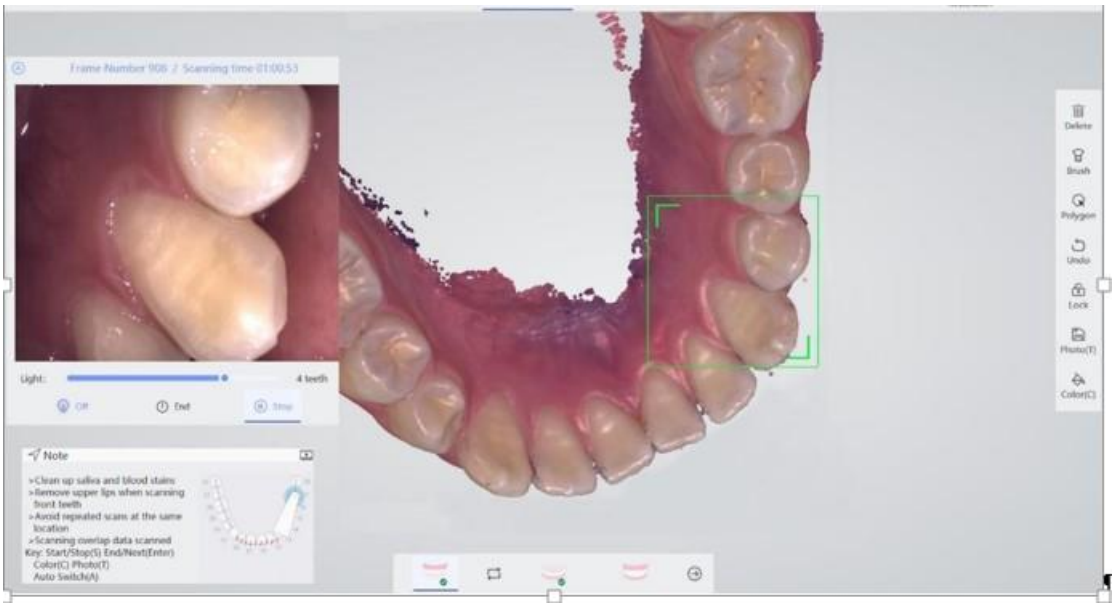
② When reaching the position of tooth No. 3, the probe head is tilted toward the buccal side and scans the anterior lip data and incisor data at the same time.

③ After crossing the midline, the probe head slowly turns to the palatal side, scans the lingual / palatal side, turns from the palatal side to the opposite side, and scans the contralateral buccal data to the posterior teeth.

④ Turn to the lingual /palatal side to scan data.

⑤ Turn to the buccal side and scan. After reaching the midline, remove the scanning probe head from the mouth and place it on the opposite contralateral posterior occlusal surface. After repositioning, slowly turn to the buccal side to scan the buccal data.





	• −The saliva and blood stains should be cleaned before scanning. • −The lips should be removed when scanning the anterior teeth of the upper and lower jaw. • −When scanning the buccal and lingual side, the data of the incisal teeth should be covered to avoid repeated scanning in the same position.

Bite scanning: when scanning the bite, it is necessary to scan 1 to 2 buccal points to determine the bite relationship. If scanning the full mouth, scan the two points on the left and right buccal sides; if it is half mouth, scan one point on the left or right buccal side.

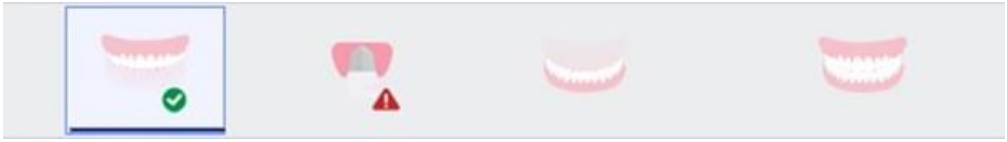
① **Clamp the patient's upper and lower jaw (swallow),keep still.**

② Place the probe head on the patient's buccal side, and slowly move forward with the "S" path between the upper and lower jaw. Take 4 teeth and match the upper and lower jaw. Then click the "S" key to pause and switch to the buccal point 2,

move slowly between the upper and lower jaw in an "S" shaped path, take 4 teeth and match the upper and lower jaw, click Enter.

Point switching: after scanning one bite relation, pause the scan and switch the buccal point 2 to scan. Switching the buccal point can be achieved through the shortcut key "P".

Implant scanning: when the treatment planning is implant, the jaw selection area will appear in two types as is shown in the following figures: jaw scan and body scan.



- Implant working jaw: first remove the healing cap and scan the working jaw where the cuff is located.
- Implant scan body: put on the scan body, and then only need to scan the data of the scan body completely, without scanning other data.

After the scan is completed, a small green check mark will appear in the lower right corner of the icon; when not scanning, the icon remains unchanged. When data are missed, a red exclamation mark will appear in the lower right corner of the icon.

☞	• The bite relationship of the patient must remain the same during the buccal scan, and the swallowing action is good for the bite relationship. • Before processing model, please use editing tool to remove extra data.

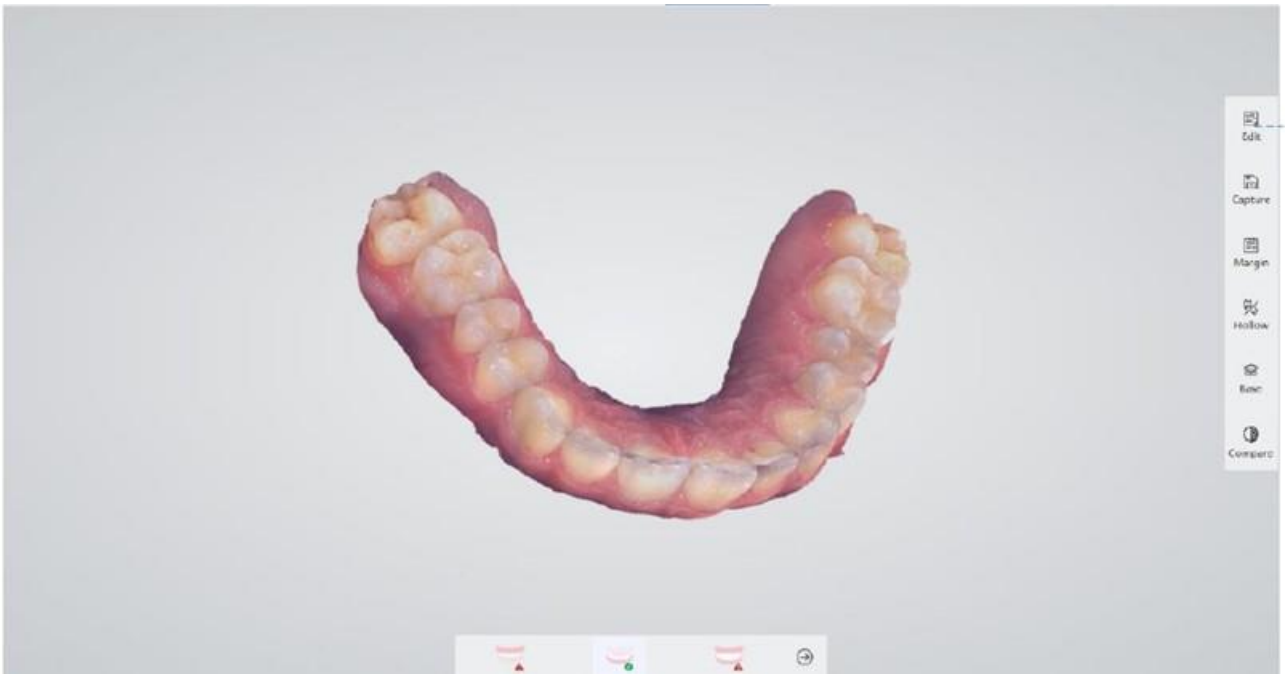
3.6 Processor

After the scan is completed, click button  or the "Enter" to enter the model processing interface, and the scanned model will be processed.

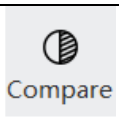
3.6.1 Processor page

3.6.1.1 Upper/lower jaw interface

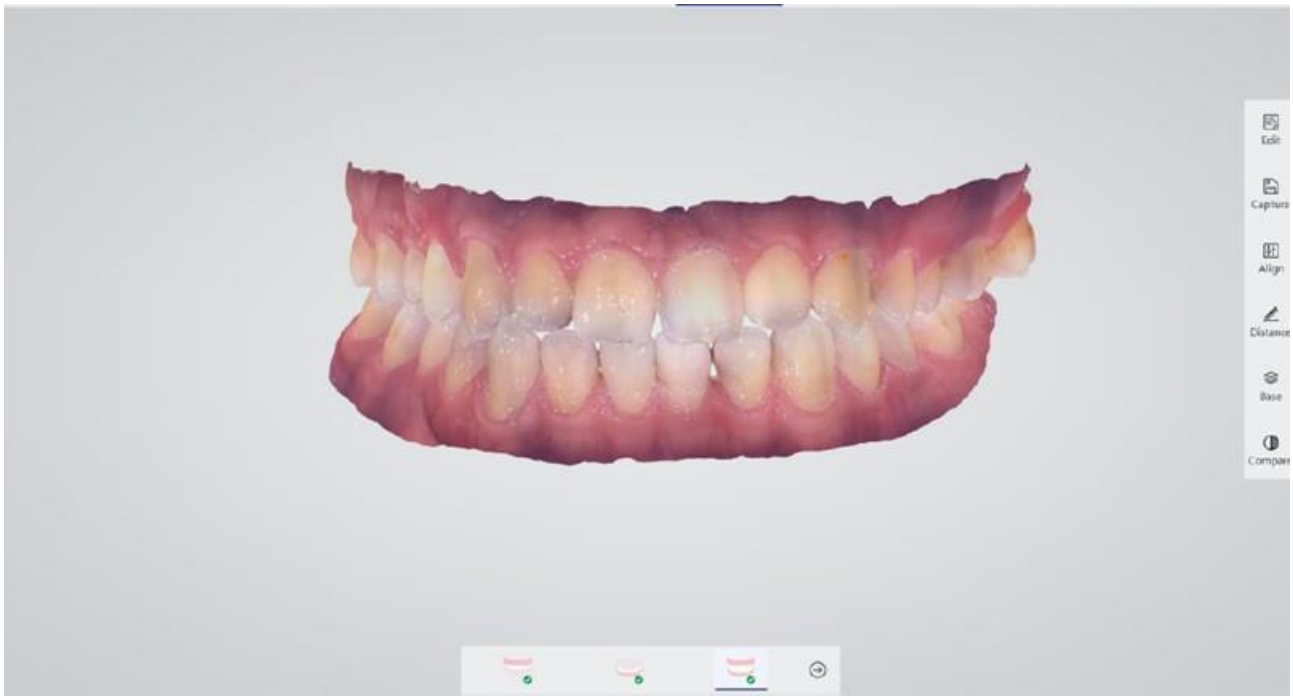
Click the maxillofacial selection button below the interface to switch the maxillofacial surface.



Icon	Meaning
Edit	**Edit button:** click to enter the editing function area, including circle selection, restore, flip, return and other functions.
Polygon	**Polygon button:** after clicking, the mouse will become polygonal, and the circled closed area will be deleted.
Reback	**Reback button:**click once to restore the previous state of this operation, and click again to restore all.
Flip	**Flip button:** convert impression data into normal 3D data.
return	**Return button:** exit the current editing ribbon.
Capture	**Capture button:** capture the three-dimensional dataof the current interface and save.
Margin	**Margin button:** click to mark the cervical margin of the selected tooth position
Hollow	**Hollow button:** click to check the concave situation from various directions.
Base	**Base button:** add the base for the data model; click the button again, cancel the base.

Icon	Meaning
	**Compare button:** you can select the target data to compare with the current model data and calculate the error.

3.6.1.2 Bite interface

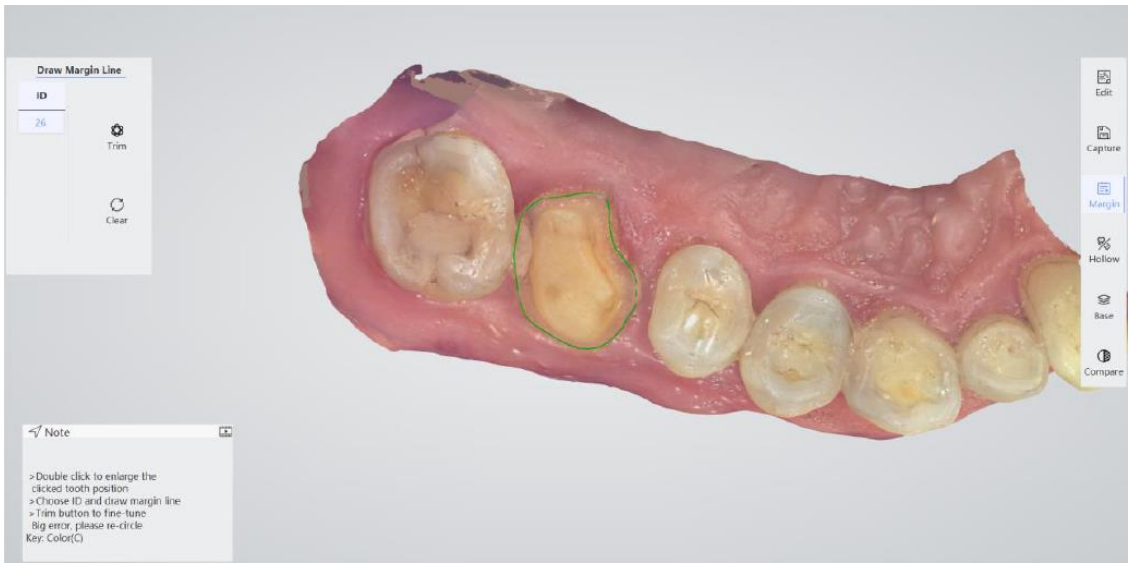


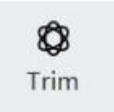
Icon	Meaning
	**Registration button:** manually register the bite relationship..
	**Distance button:** check the occlusal distance of the current model data.

3.6.1.3 Button function introduction

3.6.1.3.1 Margin button

The cervical margin confirms the position of the shoulder edge by drawing the margin line, which provides a guidance basis for subsequent data processing, as is shown in the figure:





Adjustment button: c lick to adjust, the cervical margin line is displayed in the form of small dots, drag the small dot to change the cervical margin line

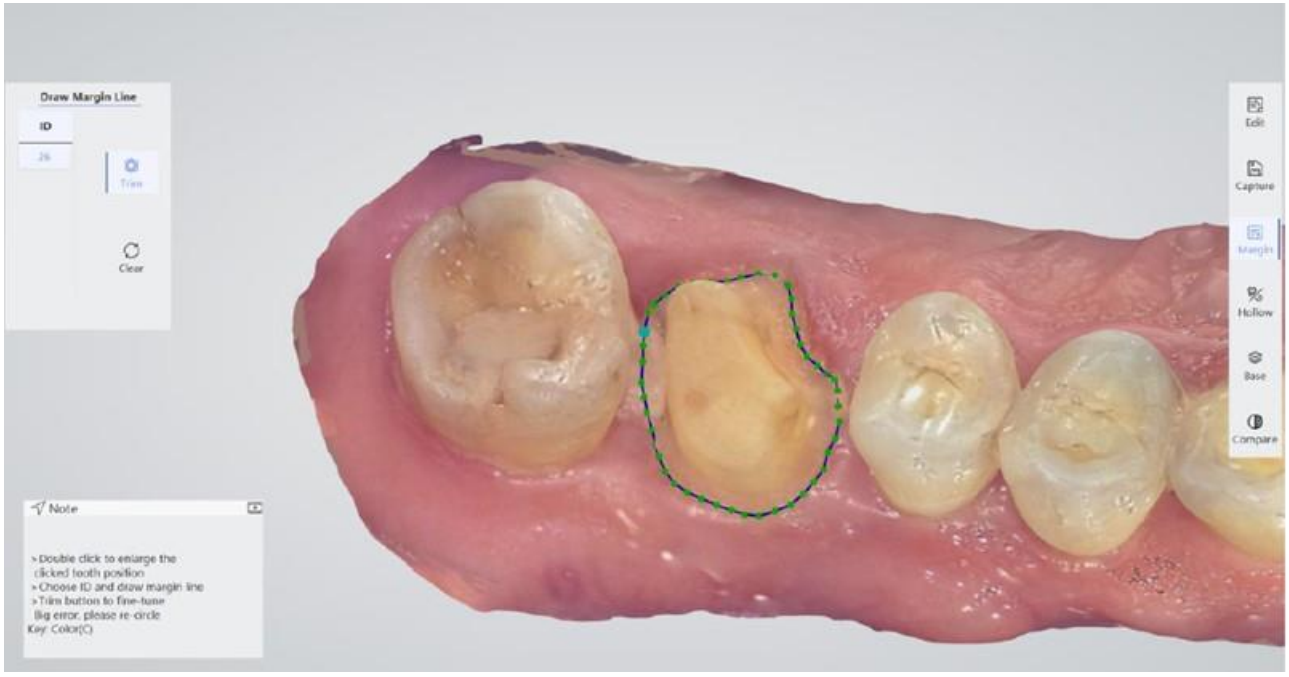
Clear button: click to clear, remove the cervical margin mark of the selected tooth position

Step 1

Hold down the left mouse button to draw the neck edge line in the abutment shoulder position.

Step 2

Click the "Trim" button, the mark line appears a lot of points, the left mouse button to select the need t o adjust the position of the point, you can fine tune the position of the mark line.



- Click the "clear" button to clear the currently marked neck line.

- When multiple teeth are restored, directly click the tooth number ID to switch the teeth position.

The data is saved and the corresponding neck line data file is generated in the default save path. When the data is designed, the marked neck line can be displayed after the file and the scan data are imported into the dental CAD software at the same time.

	• Tip: double click the model data to enlarge the position clicked. • Only by selecting teeth in restoration mode can you use the neck margin function. • Click the shortcut key C to switch to plaster colour to help the neck margin mark.

3.6.1.3.2 Hollow

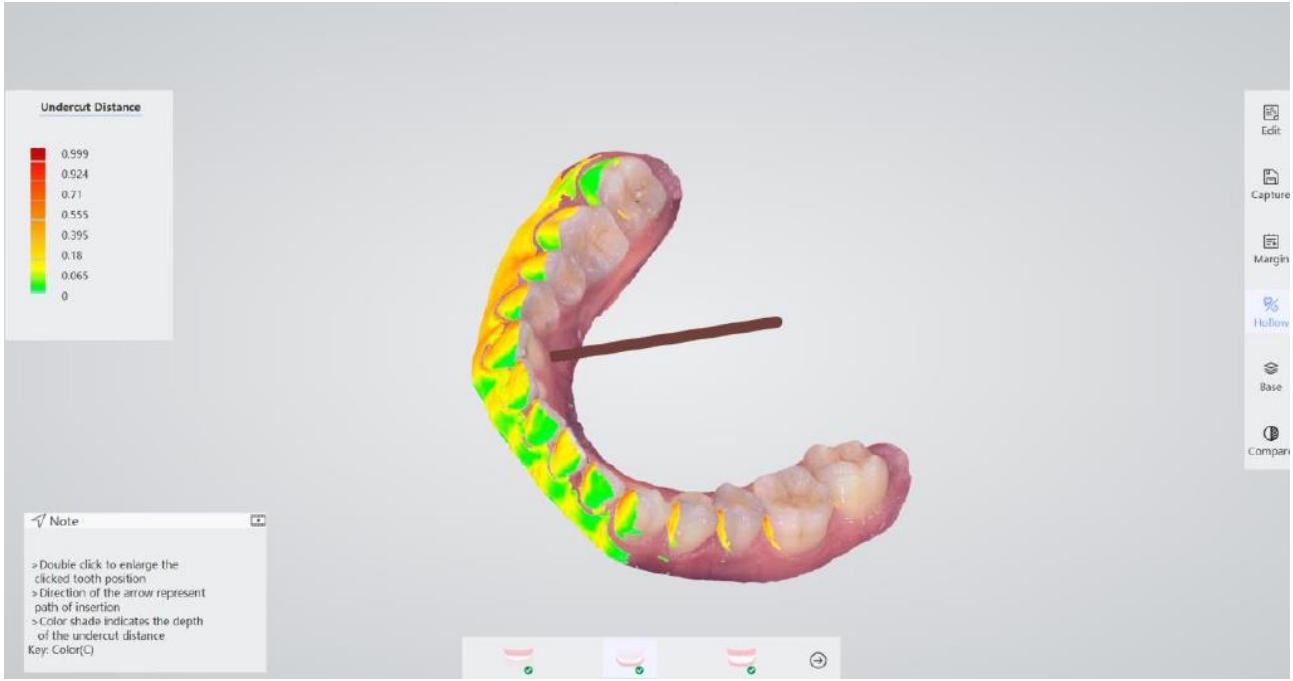
Click the " to check the undercut at different perspectives. The undercut area will be marked with gradient colour.

Step 1

Adjust the data model to the point of view that needs to be observed.

Step 2

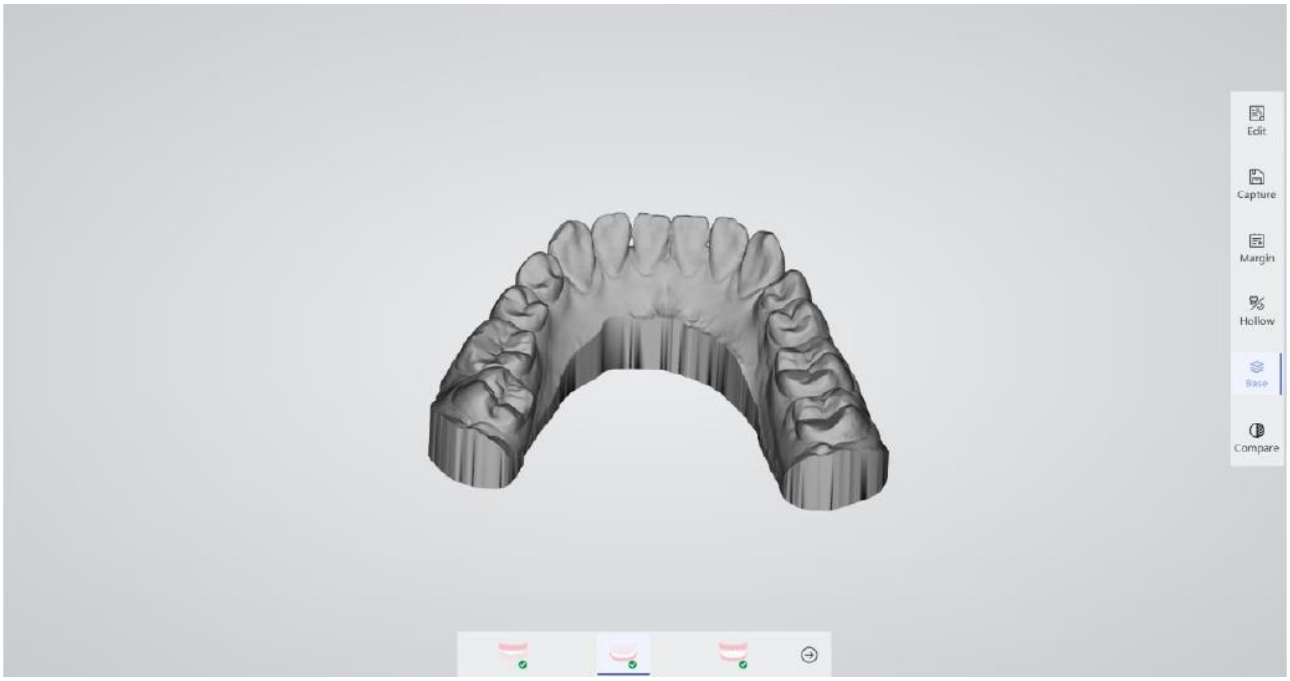
Click the "Hollow" button to view the concave condition. Hold down the left mouse button to rotate the model data. Release the mouse and click the left button again to turn the data model to adjust the observation direction. Double click to zoom in on the tooth. The direction of the arrow represents the current observation direction.



3.6.1.3.3 Base

Preview function to add a base to the data model, as is shown in the figure. Clicking again to

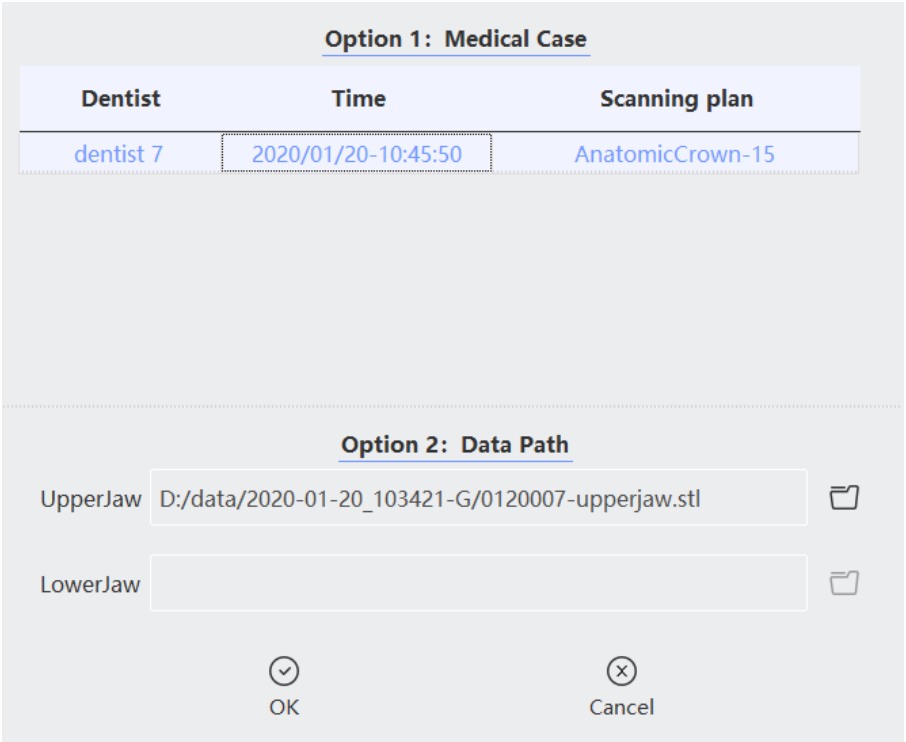
cancel the base. When the data center module is saved, the model data saved after adding the base is selected, which is consistent with the base style of the current preview.



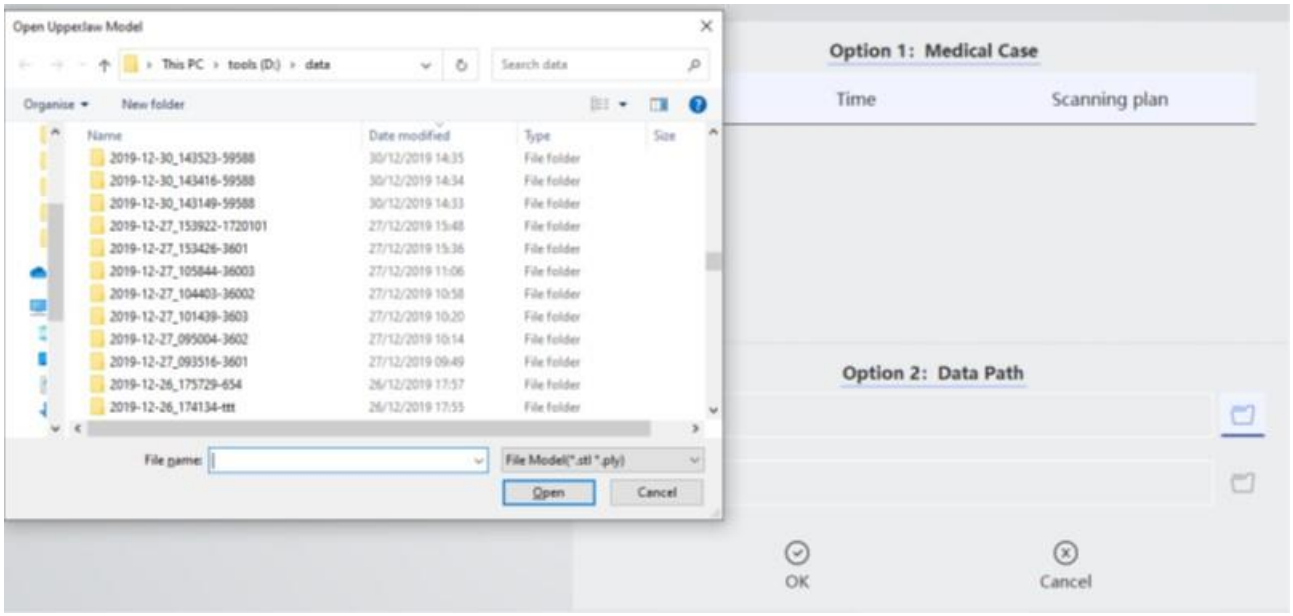
3.6.1.3.4 Compare

There are two ways for selecting the models to be compared.

- The first way is select ing the current historical case of the patients to get the data to compare.
  Double click the treatment history in Medical Case and click the "OK" button to make a comparison.

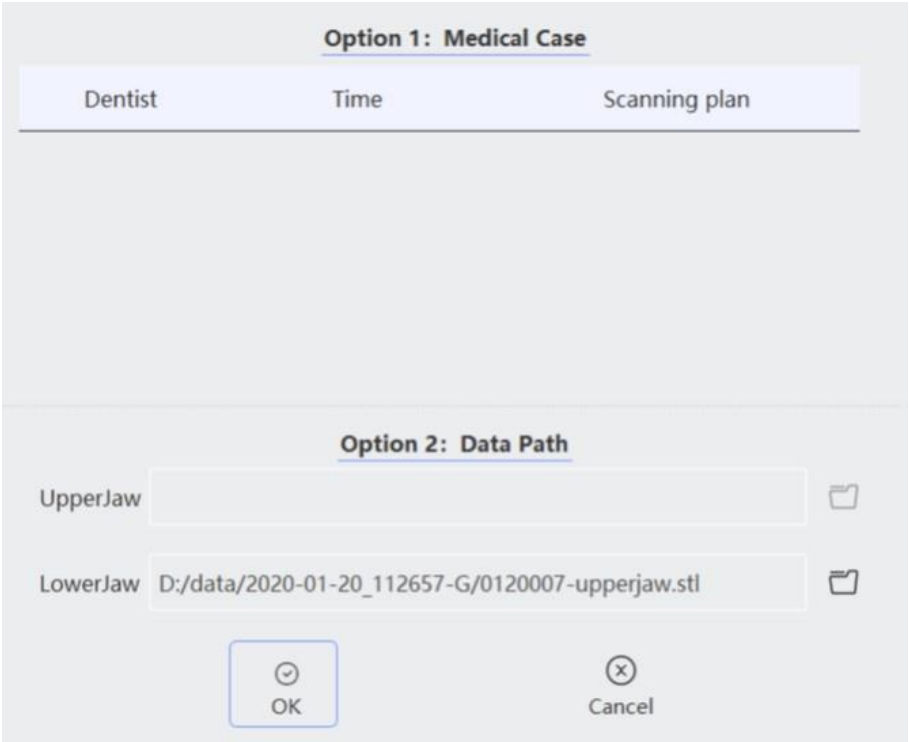


The second way is directly selecting the data from the storage path, and click Confirm after selecting.



Step 1

Click compare, select the object to be compared (patient related medical records or upper and lower jaw storage path), and click Confirm "". As is shown below.



Step 2

Enter the model alignment interface, using direct automatic alignment or three Point alignment, and click " OK". As is shown below.

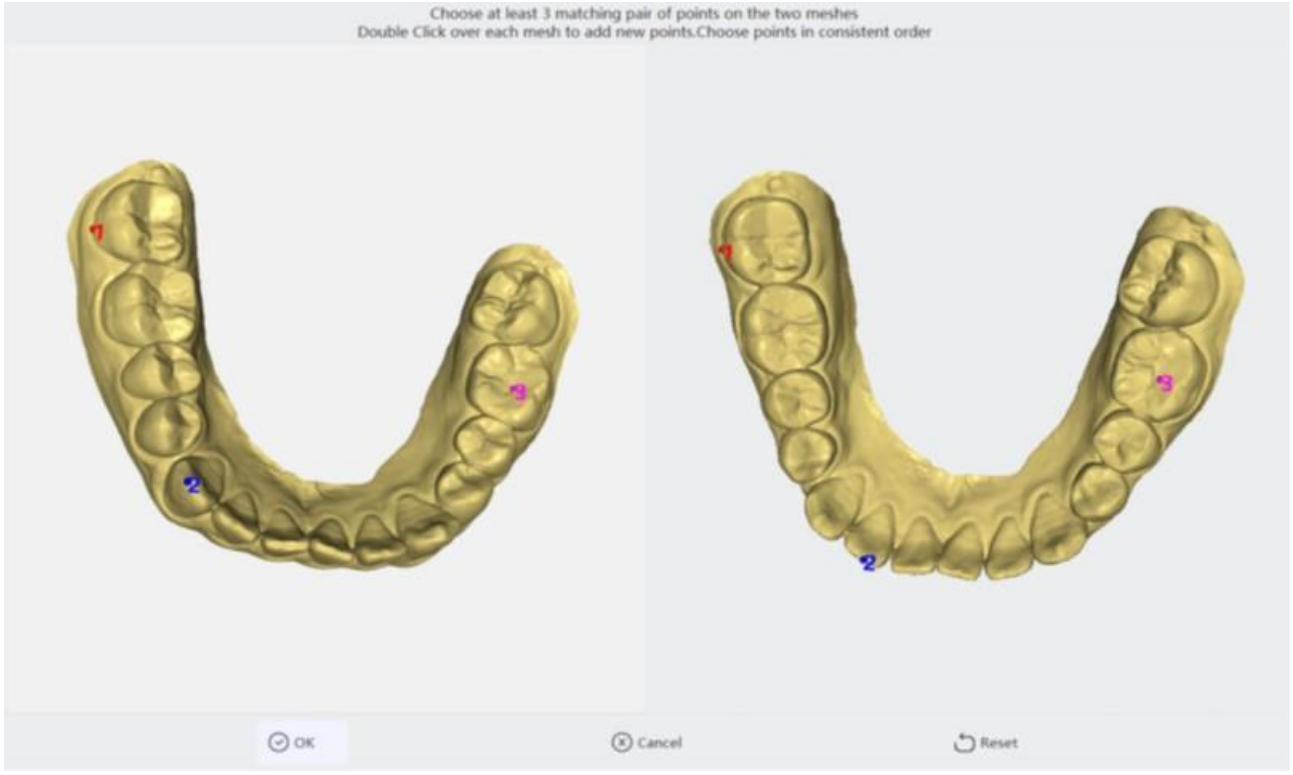
Direct alignment t he alignment interface is determined directly, and the software automatically carries out.

Three points alignment

Select 3 distinctive points in corresponding places in the current and the standard data. And click "OK" to start.

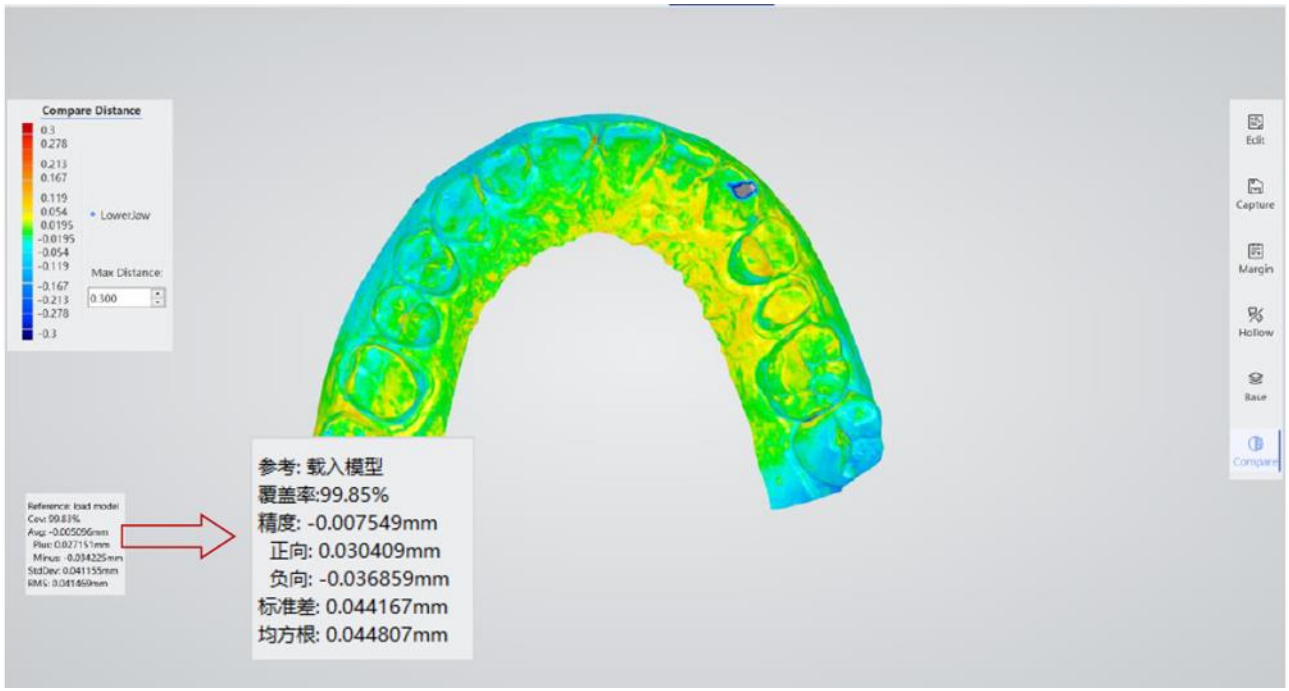
Unselect points

For unselecting some selected point, double click while pressing "Ctrl". For unselecting all the selected point, click "Reset" to clear all the points.



Step 3

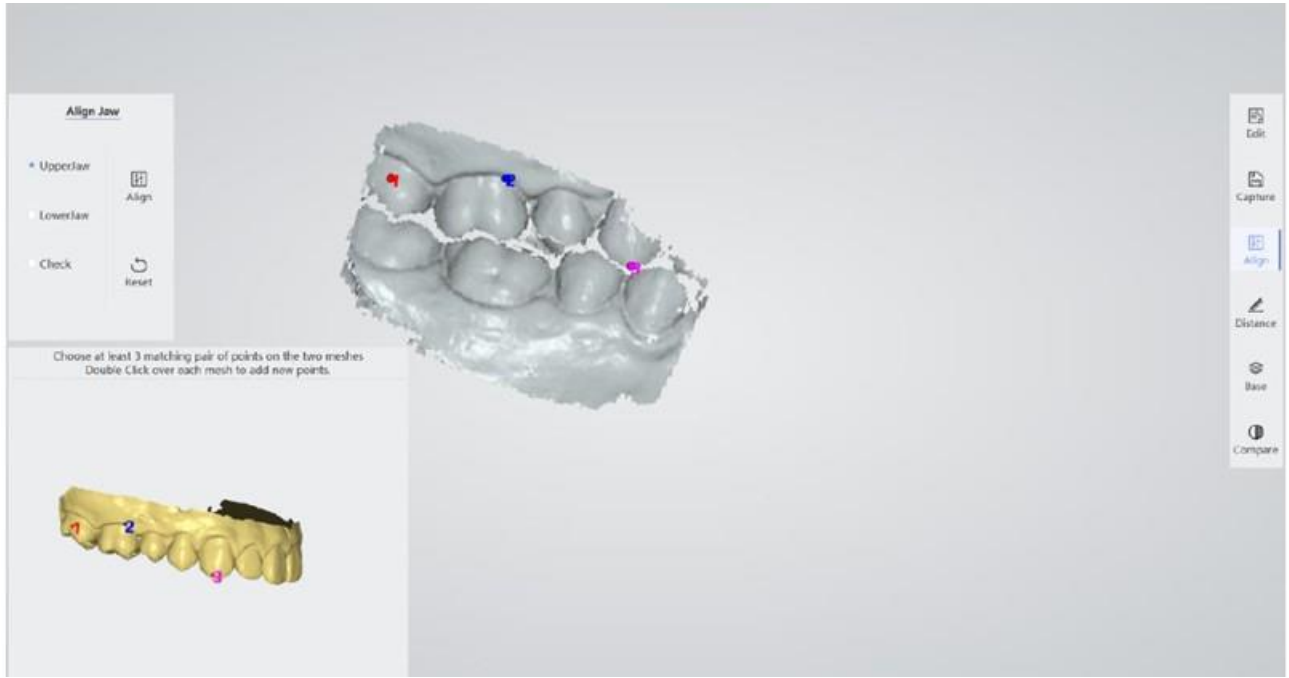
After selecting, users can check the comparison results, as is shown below. The middle is the result of the alignment between the current model and the selected standard model. The left side is the maximum distance setting area. The different distances within the maximum distance are displayed in different colours. The lower left corner of the page is the calculated coverage and the accuracy.

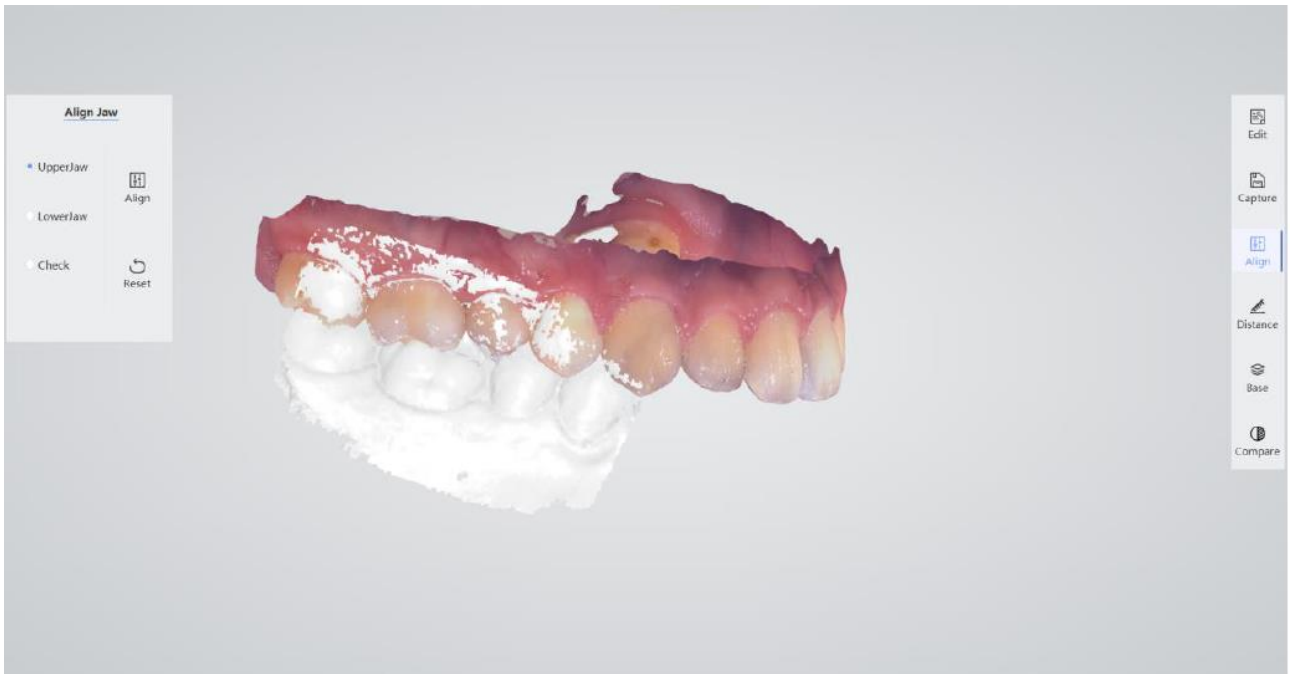


Align

Recalculate the current occlusion relationship.

As is shown below, after the selection is completed, the middle zone is the bite registration data display area. The left side is the selection of u p per lower jaw, and the currently selected upper/lower jaw model data in the lower left corner.





Step 1
Click the "Align" button to enter the alignment interface.

Step 2
After selecting "Upper jaw ", use the three point alignment method or click "Align" directly.

Step 3
After selecting "lower jaw", use the three point alignment method or click "Align" directly.

Step 4
Click the "check" button, and the display area will display the bite data after alignment.

☞	• Direct alignment: select the " button on the right side of the upper and lower jaw for automatic alignment. • Three point alignment: select three points with obvious features in the corresponding place between the current data and the standard data, click the " button for alignment. The "Reset" button can clear the selected points.

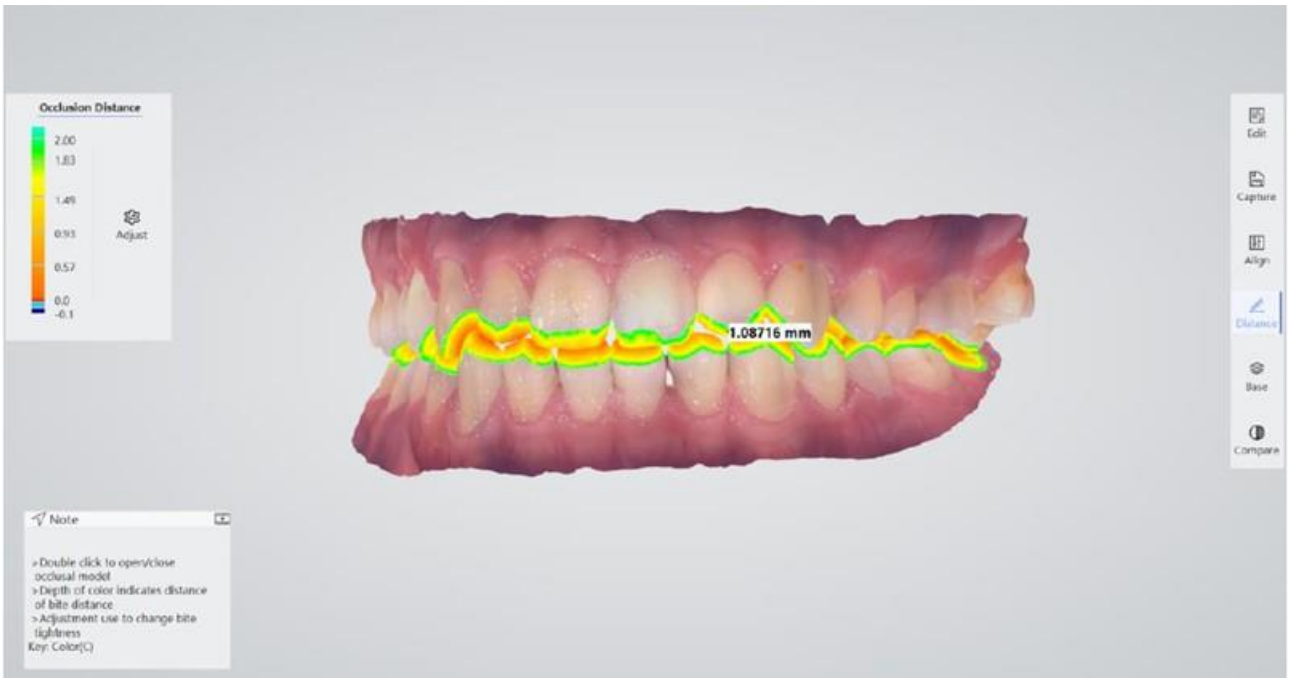
3.6.1.3.5 Distance

After the alignment, click "Distance" to calculate the occlusal distance and show the result. As is shown below, the left side is the rainbow diagram for distance reference, and the middle zone is the calculated results of the two jaws.

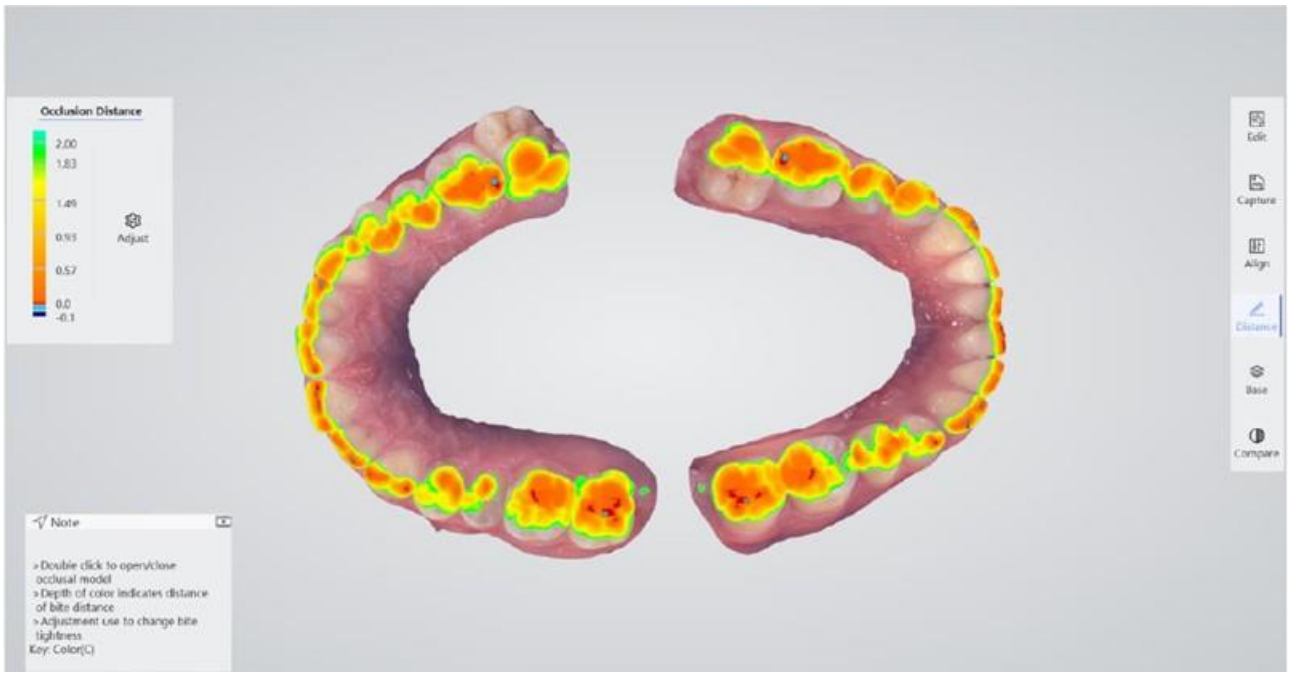
The darker the occlusal area is, the smaller the occlusal distance is. The lighter the occlusal area is, the larger th e occlusal distance is. When the occlusal area is dark blue, it indicates that the distance is negative. When there is no rainbow picture distribution in the occlusal

face, it indicates that the occlusal distance between the upper and lower jaw in this area is greater than that of 2mm.

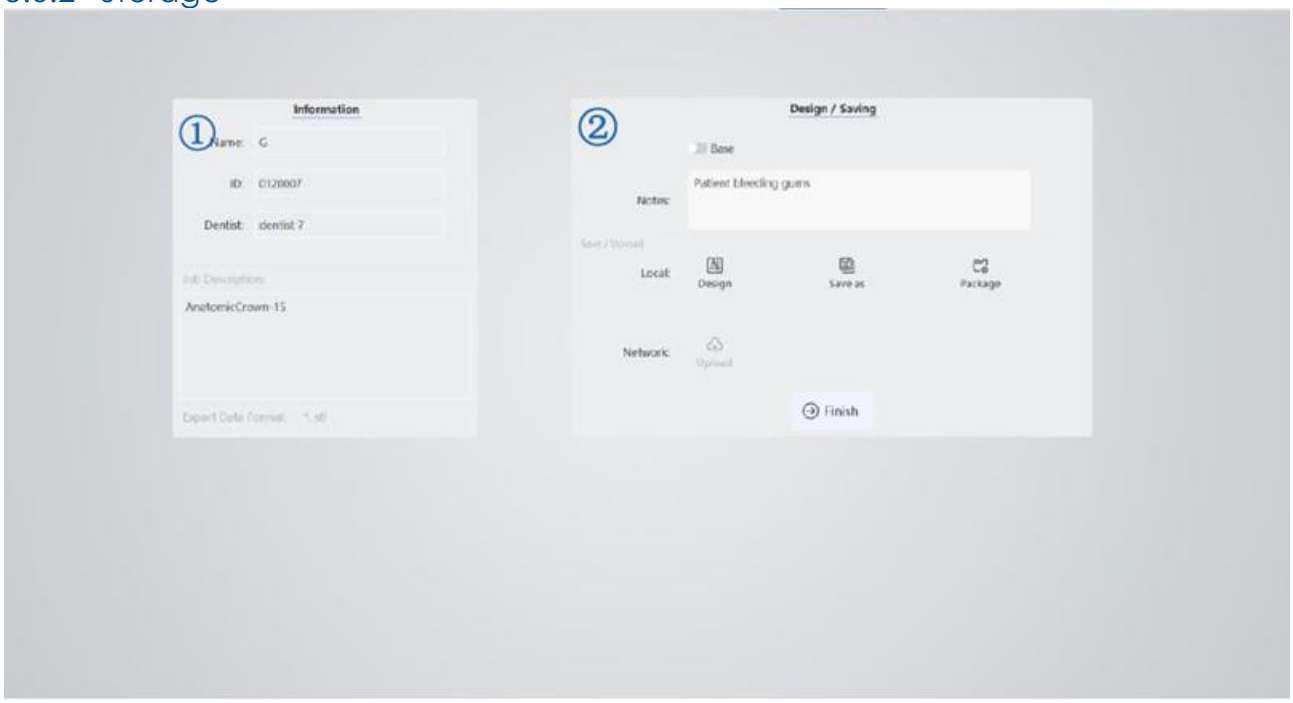
When it is found that the occlusion relationship of the scanned data is significantly different from the actual occlusion state, you can use the "Adjust" button to automatically optimize the occlusal jaw.



Double click to separate the upper and lower jaw to see the distance, as is shown below, double click again to restore the occlusal state.



3.6.2 Storage



① Information display area: displays the relevant information of the current case, including the patient's name, number, treatment doctor, treatment plan description and tips for the current data preservation format.

② Design / save area: including choosing whether to add a base to the saved data, editing and displaying the remarks bar, and CAD software to open the da ta, save the data, package the data, upload the data on the network (this function is to be opened) and other ways to save the data.

Add the base of the model: save after selection, and the stored data has a base, which is consistent with the preview of the base in the processor page.

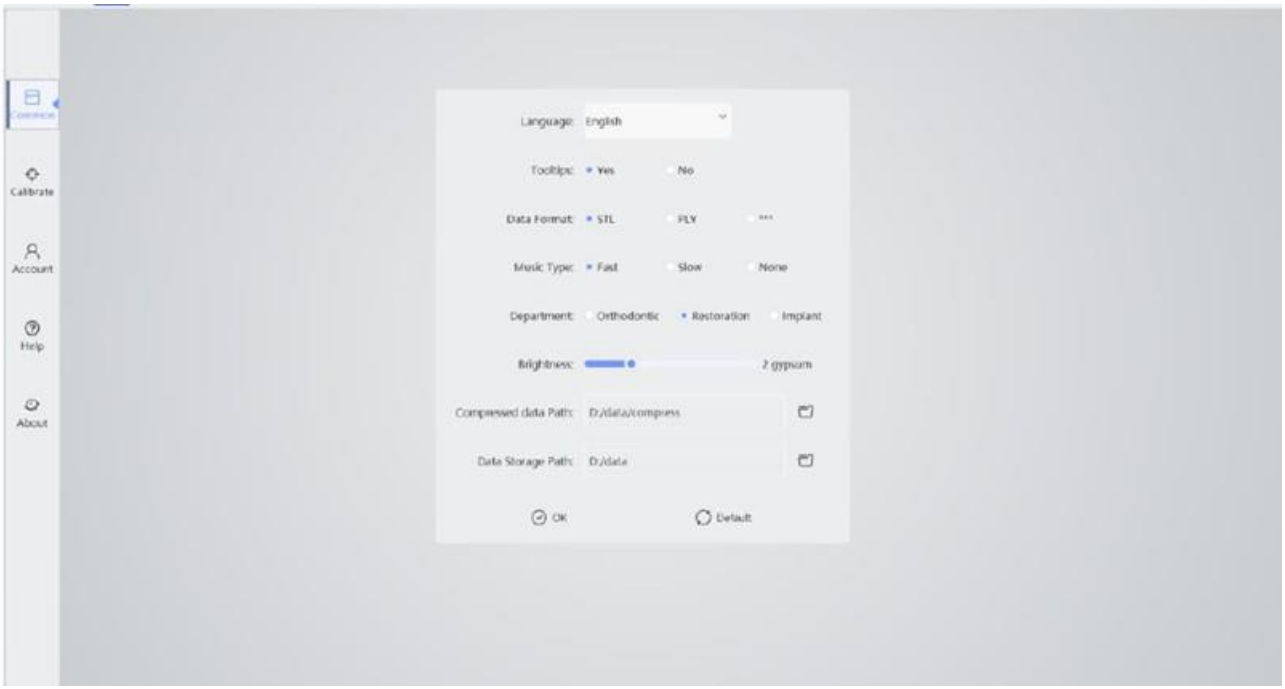
Design button: o pen the related dental CAD software directly, then create the project to process the scanned 3D data and design,

Save as : save the current case to the specified path.

Package: compress and package the scanned data and open the folder.

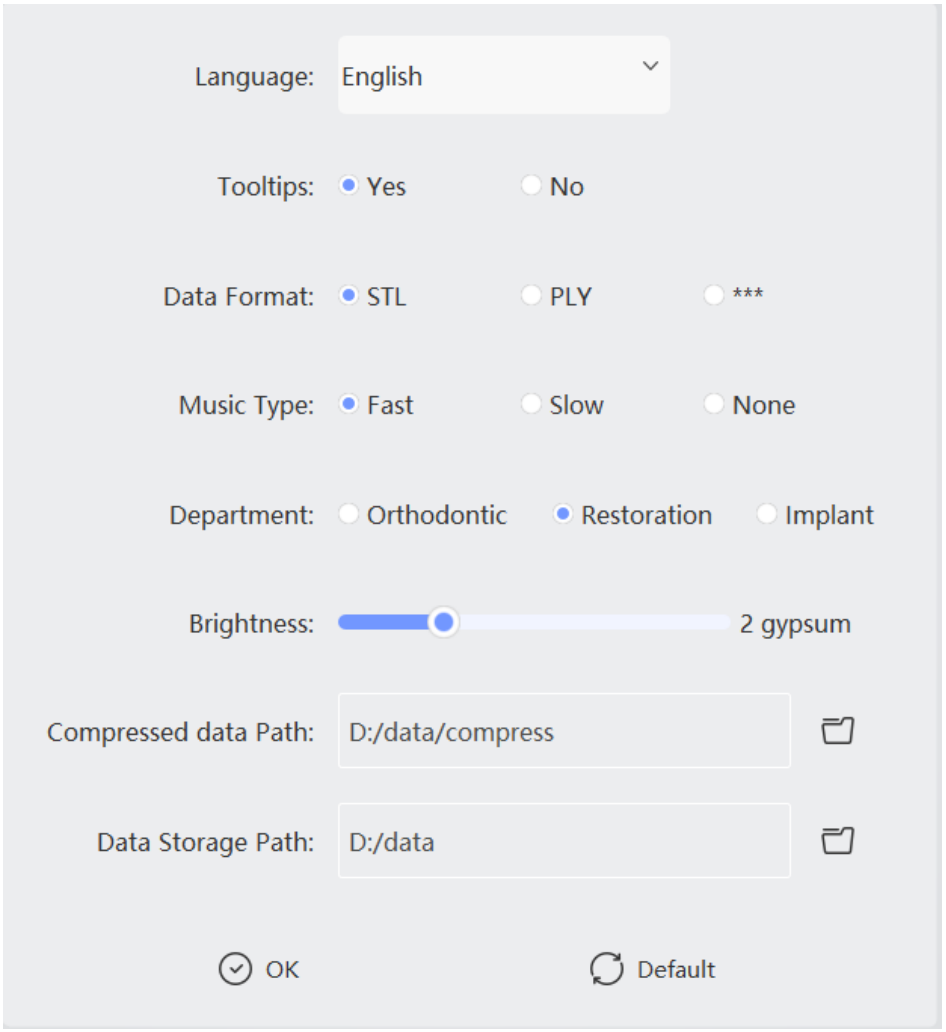
3.6.3 Setting

Software settings include system, network, registration and calibration. Click on the upper left corner  to open the settings interface, as is shown in the following figure:



3.6.4 Common

Set some default options when scanning, including language, prompt, data format, etc.



Language: Select different languages as you needed only English and Chinese are supported now.

Tip: select whether to display the prompt box. "Yes": a prompt box is displayed in the lower left corner during scanning. "No": there is no prompt box during scanning.

Mode:

- Grade 1 or 2 is for scanning white plaster models.
- Grade 3 is suitable for resin molds, and grade 2 or 3 is suitable for scanning colored plaster models.
- Grade 4 is for scanning re sin artificial teeth.
- Grade 4 or 5 are for scanning real teeth.

Data format: supported formats of the output data are STL, PLY and PTY (*).

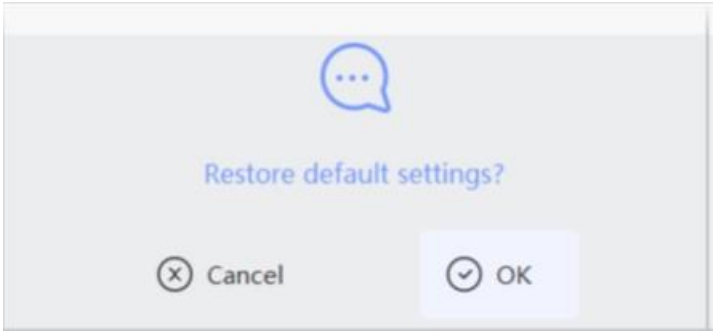
Music type: s elect the type of music when scanning. Turn off the music.

Department:

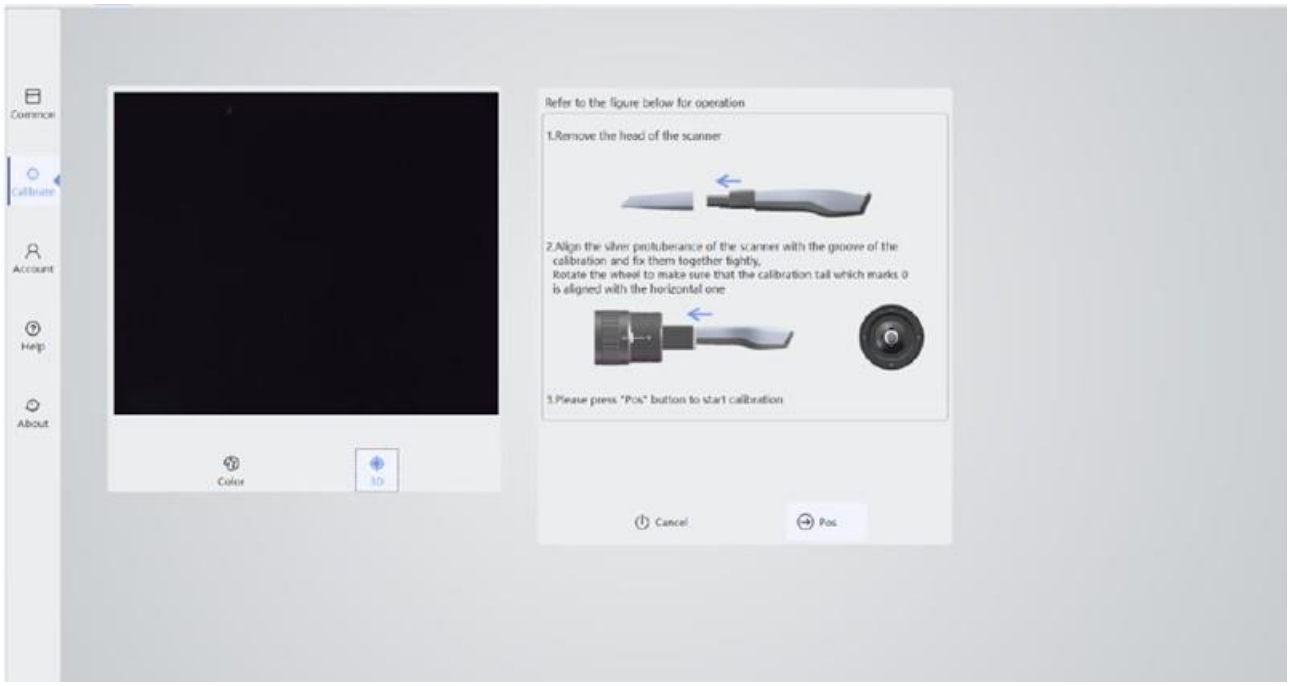
- - Orthodontics: n o need of t reatment setting.
- - Restoration: n eeds Treatment setting.
- - Implant: n eeds Treatment setting.

Package path: the path to save the current compressed packaged project for the convenient transmission of the data. The default path: "D: /data/compress".

Project path: the path to save the project data. The default path: "D: /data".
If users need to restore the system default settings, click " to pop up and the confirmation box will pop up as is shown in the following figure.

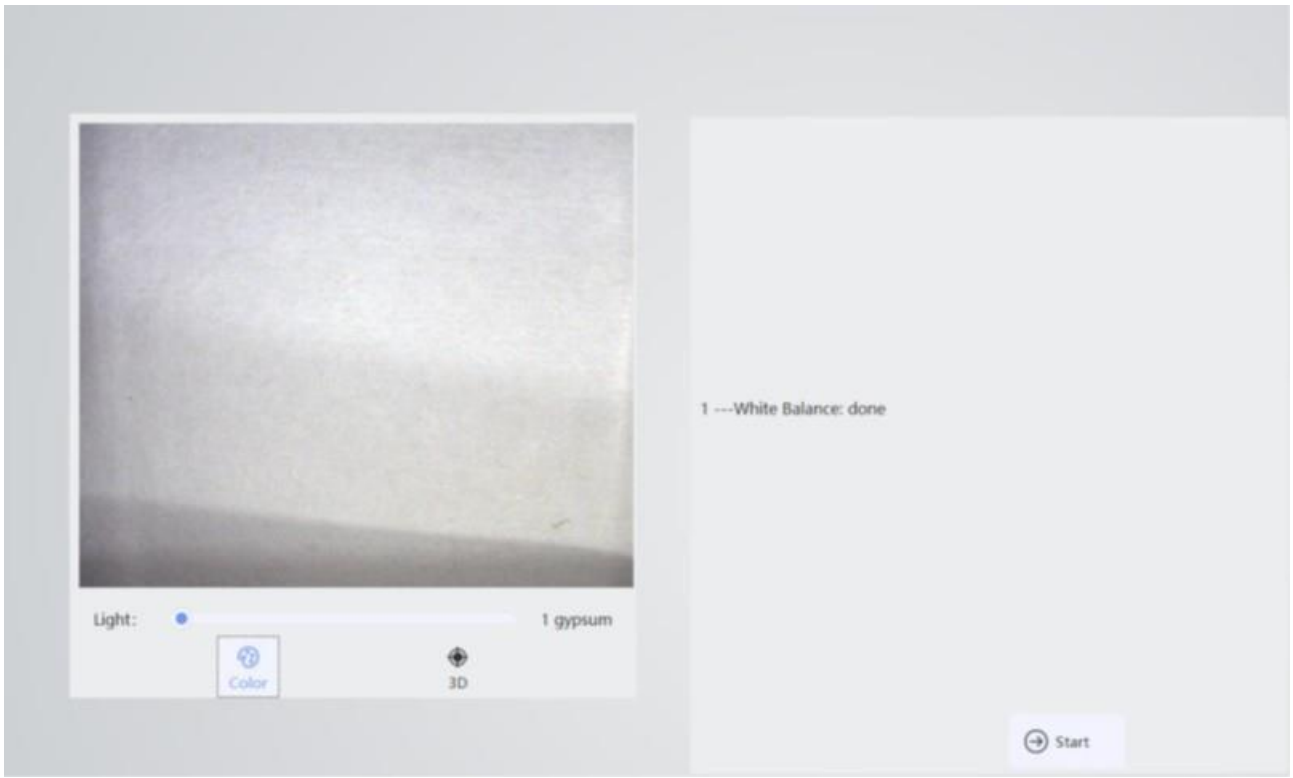


3.6.5 Calibrate



Color

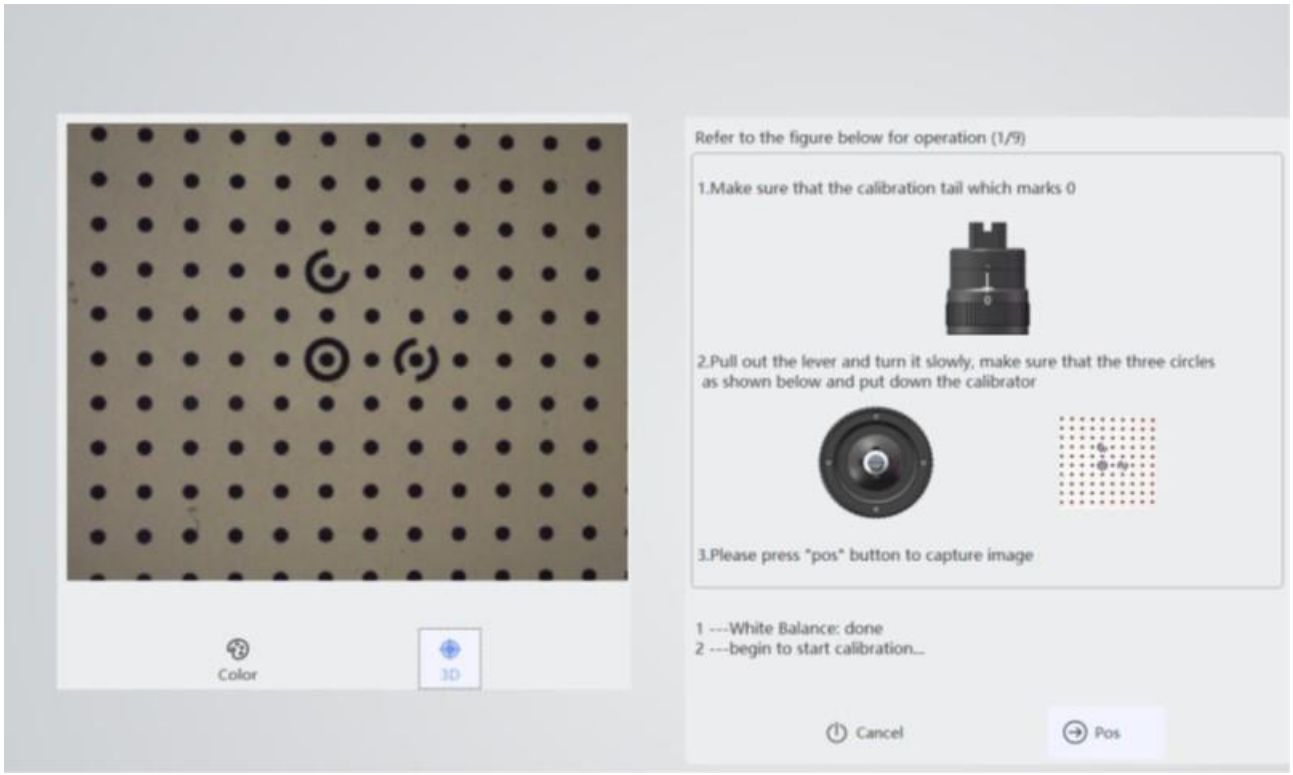
Color function is used to calibrate the color of the data. As is shown in the following picture click "White Balance" to turn it on. Set the correct grade, put the scanner close to the white paper, and adjust the brightness to gear 1. Then click Start. After the pr ogress, the information feedback area will display the information of the success or failure**. In general, do not change it.**



3D

When the scanner has undergone strong impact, severe temperature change or long transport, it should be calibrated immediately . Calibration should be taken regularly every 5 7 days for maintaining the accuracy of the scanner.

After turning on the scanner, connect the calibrator, click Calibration Mode icon and start calibration mode. And the user can follow the prompts in the information feedback area. As is shown below.



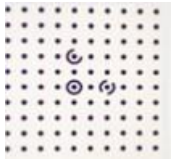
Calibration operation flow

(1) Align the silver protuberance of the scanner with me groove of the calibration and fix them together tightly.

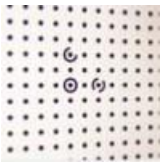
(2)Rotate the wheel to make sure that the calibration tail which marks 0 is aligned with the horizontal one. Please press "Pos" button to start calibration.

(3) Pull out the lever, make sure that the three circles as is shown below and put down the calibrator.

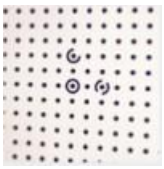
Please press " button to capture image and display "Add Position: Number 1".



(4) Move the lever to the top, ma ke sure that the calibration tail which marks "0". Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press "Pos" button to capture image and display "Add position: Number 2"

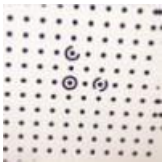


（5） Move the lever to the downwards, make sure that the calibration tail which marks "0". Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press “Pos” button to capture image, and display "Add position: Number 3".

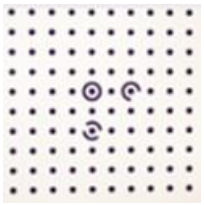


(6) Move the lever to the left, m ake sure that the calibration tail which marks "0". Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press “Pos“ button to capture image and display "Add position: Number 4"

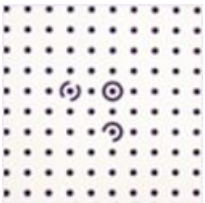
(7) Move the lever to the right, m ake sure that the calibration tail which marks "0". Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press “Pos” button to capture image and display "Add position: Number 5”



(8) Move the lever back to the center. Rotate the wheel clockwise once to align with the Number 1. Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press “Pos” button to capture image and display "Add posit ion: Number 6".

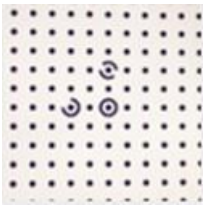


(9) Keep the lever in the center. Rotate the wheel clockwise once to align with the Number "2". Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press “Pos” button to capture image and display "Add Position: Number 7".

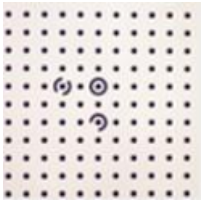


(10) Keep the lever in the center. Rotate the wheel anti clockwise three times to align with the Number "3". Pull out the lever, make sure that the three circles as is shown below and

put down the calibrator Please press “Pos” button to capture image and display "Add position: Number 8".

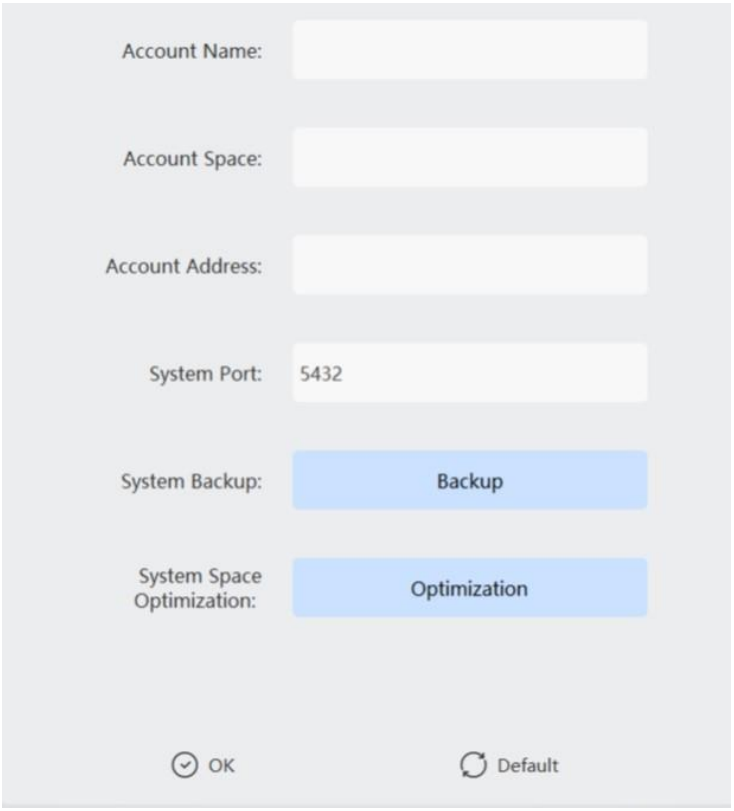


(11) Keep the lever in the center. Rotate the wheel anti clockwise three times to align with the Number "2". Pull out the lever, make sure that the three circles as is shown below and put down the calibrator. Please press “ button to capture image and display "Calibration: complete".



3.6.6 Account

This module displays the currently logged on network disk space account information. Includes account name, account space address, system port, and system backup and system space automatic optimization functions. As is shown below.



3.6.7 Help

As is shown below. If you need to feedback the experience of using the software or upload Bug, you can send E-mail to “info@trident-dental.com”.

3.6.8 About

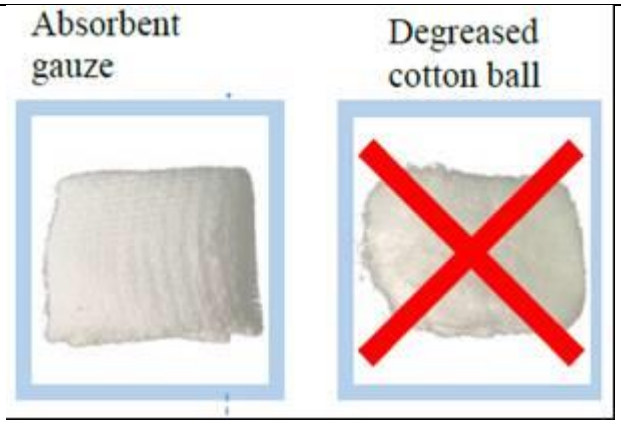
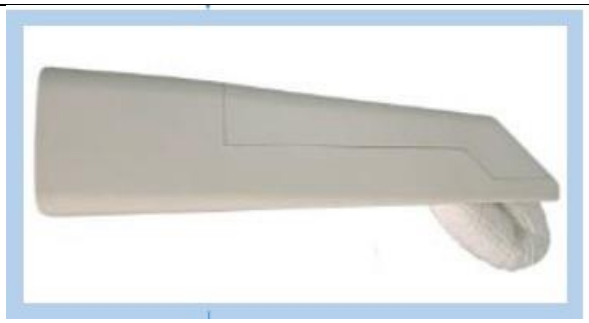
This software must be licensed before it can be used. As is shown below. If the software does not have an authorization number and expiration date, it can be considered as expired or pirated software, please stop using it and contact us.

This software will be updated and maintained from time to time. Please pay attention to the software version number for details. You can get the latest version of the software by following the version number.

4 EQUIPMENT STERILIZATION AND ROUTINE MAINTENANCE

4.1 Probe head sterilization

As the contamination of the probe head mirror will seriously affect the scanning effect, in order to ensure the normal use of the scanner, please strictly follow the high temperature and high pressure disinfection steps below.

Step 1 Clean the optical probe with soapy water. Rinse the probe head with water and wipe it dry with absorbent gauze in time. Do not wash the equipment body with water. Use absolute alcohol after drying, clean the probe head mirror carefully after soaking the absorbent gauze, keep the lens surface free of dirt.	
Step 2 Then fold the clean absorbent gauze to the long strips which is similar to lens size, please wear gloves or finger cots to prevent contamination of gauze.	
Step 3 Then cover the surface of the probe head mirror with absorbent gauze. Please take good care of contact and coverage. Put the head of the probe covered with gauze into the sterilization bag. Do not shift or drop the gauze during placing processes	
Step 4 For final disinfection, place the probe head window face down into a 90x260 self-sealing sterilization pouch and seal it. Suggest to sterilize with high temperature steam for a few minutes, such as134 °C for at least 6 minutes or 121 °C for at least 15 minutes The bag with probe head must be maintained vacuum during sterilization.	

	The absorbent gauze used in each step of the operation cannot be reused.
	Do not use absorbent cotton instead of absorbent gauze. The former is prone to residual cotton wool and difficult to clean.
	Use absolute alcohol when wiping the mirror. Do not use medical alcohol.
	The head of the probe, especially the lens, must be wiped dry after cleaning in the first step. Be careful not to scratch the mirror surface.
	When the disinfection is repeated for many times, which causes the mirror surface to be stained and affect the scanning effect, please replace the probe with a new one in time.

4.2 Routine Maintenance

Lens use:

It is prohibited to blow the inside of the probe with a three purpose air gun to prevent dust from being blown into the photoelectric system inside the device.

Equipment placement:

The base is placed on a stable table, and the handle is placed in the groove of the base after use.

Pay attention to protection to avoid unnecessary vibration or bumps.

Accuracy calibration:

Under normal circumstances, the calibration is performed once a week. If the scan is easily interrupted, the calibration should be performed immediately.

5 SOFTWARE AND HARDWARE COMMON PROBLEMS AND SOLUTIONS

5.1 Software startup issues

The software cannot be opened normally

- Check if the USB KEY is connected normally and within the validity period.
- If prompted "Workflow initial error" or "Unable to open file directory", please reinstall the software.

Software starts too slowly

- -Check if the computer power is connected normally.
- Confirm that the scanning software is running in "Administrator Mode" of Windows operating system.
- Check if the Windows operating system is being updated. If it is being updated, please complete the update before using the software
- Check if other software of the computer can start normally.

Software icon on the desktop turns white

- Check if there's any anti-virus software, if so, either put the software into the white list or uninstall the anti-virus software.
- Right click the icon and select "Open the file location " to see if the software icon is in the folder turns white. If the software can be opened normally and the icon in the folder is normal, delete the icon on the desktop and send the icon in the folder to the desktop. If the icon in the folder turns white, contact the customer service for help
- The icon turns white. If you cannot run the program by double clicking, please reinstall the scanning software.

5.2 Problems connecting devices

Camera connection failed

- Check whether the device power is on normally, whether the computer power is tightly connected, and whether the USB interface is correctly connected to the computer's USB3.0 interface.
- Replace interface or connect Hub, etc.
- If possible, replace the computer or device and try again.

5.3 Image display problems

No image display in 2D image area

- Make sure the device's USB interface is properly connected to the computer's USB 3.0 interface.
- Restart the software and scanning device to check if the image can be displayed normally.

2D image flicker

- Check if the modulator is connected properly.

- Replace the USB port of the device with the computer.
- Connect your computer to the Internet.

5.4 Scanning issues

Scans are easily interrupted and not smooth

- Inappropriate scan brightness. For plaster model scanning, choose 1/2, for resin model scanning, choose 3, for the intraoral scanning, choose 4, 5 is suitable for patients with darker teeth in the mouth.
- During scanning, confirm that A above the image area is blue. If it is black, use the keyboard A key to switch.
- Standardize scanning methods. Ensure coverage of scanned data with existing data.

Out sync of data between 2D and 3D

- Confirm whether the computer configuration meets the requirements (higher than or equal to our recommended configuration).
- Delays caused by too many scans (single jaw scans should be completed within 3 minutes).
- Uninstall antivirus software or add scanning software to the whitelist of antivirus software.
- Check the status of windows update. If the update is in progress or has failed, please restart the computer after the update is completed before using the scanning software.

Difficulty for scan relocation

- Ensure that the scanning direction is consistent with the previous scanning when repositioning
- Avoid long scans.

No 3D data when scanning

- - Recalibration.

5.5 Abnormal interrupt during scanning

- Check the status of windows update. If the update is in progress or has failed, please restart the computer after the update is completed before using the scanning software.
- Check whether the remaining storage space of drive C is sufficient.
- Turn off or uninstall anti virus software.

5.6 Problems with calibration

Failed to add position or calibration failed.

- If there are obvious stains or debris on the calibration plate in the 2D image display area of the software, plea se invert the calibrator first to make the debris out.
- Do not blow the inside of the calibrator directly with your mouth.

5.7 Other problems

Computer restarts repeatedly

- Reinstall NVIDIA graphics driver.
- If you still have problems, please replace your computer.

The device cannot be powered on normally

- Check if the adapter indicator is on and the adapter is powered on normally.
- Check if the current socket is powered.
- Replace the adapter and power cord.

6 CARE AND MAINTENANCE METHODS

The maintenance personnel must take laser protective measures during the inspection process, such as wearing goggles. During the inspection, ensure that there is no person in the direction of laser irradiation.

	Keep the outside of the probe clean.
	If the probe head glass smudging, can dipping a small amount of anhydrous alcohol with skimmed cotton, from the centre to gently wipe the rotation, If the glass is scratched, it need to be replaced.
	It is suggested to calibrate the product regularly with calibrator.
	The maintenance personnel must take laser protective measures during the inspection process, such as wearing goggles. During the inspection, ensure that there is no person in the direction of laser irradiation.
	Use only original equipment parts.
	Replacement equipment parts can be obtained from manufacturer or manufacturer approved dealer, otherwise it may reduce the accuracy and safety of the equipment.

7 DOCUMENT STATUS

VERSION	DATE	PARTS/PAGES MODIFIED
0	January, 25,2021	First release
1	September 9, 2021	Added Standard Applcable list