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CHAPTER

Read this first

The **Intraoral Scanner** is an intraoral scanner that works with the supplied software programs. With **Intraoral Scanner**, you can perform oral scanning and digitally acquire and save the 2D/3D color images of a patient's teeth for orthodontic, implant, and restoration use.

This *User Manual* provides important procedures and information on how to operate the scanner and configure the **DentalManager** and **IntraOralScan** software correctly and safely. Before attempting to operate the product, read this *User Manual* and strictly observe all warnings and cautions. We suggest that you have easy access to the *User Manual* whenever necessary. Pay extra attention to the information from Safety information on page 5.

Copyright

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Updates to hardware and/or software components are made regularly; therefore, some of the instructions, illustrations, and specifications mentioned in this *User Manual* may differ slightly from your particular situation. To obtain the most updated and accurate information, visit en.shining3d.com for the latest version of this *User Manual*.

Intended use

An optical impression system for computer assisted design and manufacturing (CAD/CAM) is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer-assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software.



WARNINGS

- 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 can not be operated by the patients themselves.
- 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.
- 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.

Warnings

Before using the **Intraoral Scanner**, read these warnings and Safety information on page 5.



WARNINGS

- 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 any liquid to get inside this scanner and its cradle. Water and moisture may cause short-circuit to the electronic components and lead to malfunctions.
- Do not drop or apply shock/vibration to this scanner and its cradle. 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.

WEEE

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 can not be disposed of as household waste. You must dispose of your waste equipment by handling 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, please 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.



Disposal



CALITION

The scanner must be reprocessed prior to disposal in order to prevent crosscontamination. 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.

Typographics

Special notes, cautions, and warnings that appear throughout this *User Manual* are designed to ensure that you perform specific tasks properly, preventing unnecessary errors.



This icon marks NOTE(S); additional information for particular situation.



This icon marks CAUTION(S); improper actions or conditions that may

damage the product or injury, and consequently void your warranty or service contract or lose the patient data or system data.



This icon marks WARNING(S); the safety instructions that you must precisely follow in order to avoid injury. Failure to observe can cause damages to your product, or result in personal injuries, or even death.

Warranty

The warranty is void if unauthorized personnel perform service or maintenance on the set of **Intraoral Scanner**. To ensure correct product performance and to obtain warranty service, contact technical support. For more information, see Contact information on page 4.

Contact information

Manufacturer

Shining 3D Tech Co., Ltd. No.1398, Xiangbin Road, Wenyan, Xiaoshan, Hangzhou, Zhejiang, China

en.shining3d.com

Customer Support

Email: dental support@shining3d.com

CHAPTER 2

Safety information

Precautions



WARNING

Follow the procedures carefully and ensure that the power/electrical/environmental requirements are satisfied. 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.

Observe the following precautions carefully.

- 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 this 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 by following the instructions given in Connecting the scanner on page 25.
- 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 technicians 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.
- 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 may 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.
- 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. If you accidentally drop the scanner, you MUST dispose of
 the scanner tip immediately and do not use the same tip again. The mirror in the
 tip might shatter into small pieces, and using it again poses the highest risk of
 causing serious injury to the user and patient.
- The scanner might heat up to above the normal body temperature, yet this shortterm exposure and contact with small areas will not pose a health or safety hazard to the patient.
- Never place any objects or load on the scanner and its cradle.
- Pay close attention to the hygiene guidelines given in Pre-cleaning, disinfection, and sterilization on page 59.
- Do not dispose of this 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.

Legend of labels and symbols

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

On the device

Table 2-1 Labels and symbols on the device

Symbol	Explanation
Â	General warning – caution.
木	Indicates that the device complies with requirements for the BF type applied part according to IEC 60601-1, providing protection against electric shock.

On the carry box/package

Table 2-2 Labels and symbols on the carry box/package

Symbol	Explanation	
À	General warning – caution.	
木	Indicates that the device complies with requirements for the BF type applied part according to IEC 60601-1, providing protection against electric shock.	

Table 2-2 Labels and symbols on the carry box/package

₿	Indicates that the user should read the operating instructions for information on using this equipment.		
	Indicates that the final disposal of the device complies with Waste Electrical & Electronic Equipment and waste regulations. It can no longer be used for its intended purposes.		
Â	General warning – caution.		
Y	Indicates that the contents of the transport package are fragile and therefore shall be handled with care.		
T .	Indicates that the transport package shall be kept dry.		
Indicates correct upright position of the transport package.			
Indicates the stack limits. A maximum of 6 units of identification packages may be stacked.			
+60°C	Indicates temperature limits. The product must be stored in the original shipping package in environments between -25°C and 60°C.		
Indicates the humidity limits. The product must be store original shipping package in environments with 30% to relative humidity and noncondensing.			
Indicates the atmospheric pressure limits. The product m stored in the original shipping package in environments to 700 hPa and 1060 hPa air pressure.			
Indicates that the material shall be recycled.			

Compliance

Anyone creating or changing a medical electrical system through a combination with other devices in accordance with standard EN 60601-1-1:2001 based on 60601-1-1:2000 (specification for the safety of medical electrical systems)/UL 60601-1 Part 1: first edition 2003 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.

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

Electrical safety

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

Electrical

- IEC 60601-1-2:2014
- IEC 60601-1:2015/A1:2012 (ed 3.1)
- IEC 60601-1-6: 2013.Con Ed 3.1 Rev. October 29. 2013.
- IEC 62366-1:2015
- IEC 62304:2006/AMD1:2015

Classification

- Type of protection against electric shock: Class II
- · The degree of protection against electric shock: Type BF
- The mode of operation: Continuous operation
- Pollution degree 2

For maximum safety, observe the following guidelines strictly:



WARNINGS

- Shock hazards exist if the power adapter is damaged or is not properly grounded. Use only the supplied medical grade power adapter.
- To avoid the risk of electric shock, connect the scanner only to properly grounded wall outlets.
- Only authorized service technicians can make internal replacements of the scanner and modify the software.

- Do not use the scanner if its tip or cable is damaged. Contact technical support for replacement of the damaged equipment (see Contact information on page 4).
- 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 if the housing is damaged or the cable is abraded.
- All devices connected to the Intraoral Scanner shall comply with IEC 60601-1 and IEC 60950.

EMC notice

Electromagnetic emissions

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

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

Table 2-3 Guidance and manufacturer's declaration - electromagnetic emissions

Emission measurement	Conformity	Electromagnetic environment - guidelines
RF emissions CISPR 11	Group 1	The Intraoral 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 Intraoral Scanner is suitable for use in all establishments, including domestic establishments and those
Harmonic emissions IEC 61000-3-2	Class D	directly connected to the public low- voltage power supply network that supplies buildings used for domestic
Voltage fluctuations/ flicker according IEC 61000-3-3	Complies	purposes.

Interference immunity

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

Table 2-4 Guidance and manufacturer's declaration - electromagnetic immunity

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, a relative
IEC 61000-4-2	±15 kV air	±15 kV air	humidity of at least 30% is recommended.
Electrical fast transient/burst	±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.
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	
Surge	±1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	±2 kV line(s) to earth	±2 kV common mode	

Table 2-4 Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$0\% \ U_{T}$ $(100\% \ dip \ in \ U_{T}) \ for \ 0.5/1 \ cyclea$ $40\% \ U_{T}$ $(60\% \ dip \ in \ U_{T}) \ for \ 5 \ cycles$ $70\% \ U_{T} \ (30\% \ dip \ in \ U_{T}) \ for \ 25/30 \ cycles^a \ (for \ 0.5 \ sec)$ $0\% \ U_{T}$ $(100\% \ dip \ in \ U_{T}) \ for \ 250/300 \ cycles^a \ (for \ 0.5 \ sec)$	$0\% \ U_{T}$ $(100\% \ dip \ in \ U_{T}) \ for 0.5/1 \ cycle^{a}$ $40\% \ U_{T}$ $(60\% \ dip \ in \ U_{T}) \ for 5 \ cycles$ $70\% \ U_{T} \ (30\% \ dip \ in \ U_{T}) \ for 25/30 \ cycles^{a}$ $(for \ 0.5 \ sec)$ $0\% \ U_{T}$ $(100\% \ dip \ in \ U_{T}) \ for 250/300 \ cycles^{a}$ $(for \ 0.5 \ sec)$	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Intraoral Scanner requires continued operation during power mains interruptions, it is recommended that the Intraoral 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 Intraoral 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.

^a For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz.

Table 2-4 Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment – guidance
Conducted RF	3 Vrms 150 kHz to 80 MHz outside ISM bands ^c	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Aoralscan , including cables, than the recommended separation distance calculated from the equation appliance to the frequency of the transmitter. Recommended separation distance: d = 1.2 √P
IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz in ISM bands ^c	6 Vrms	IEC 60601-1-2: 2007 $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	IEC 60601-1-2: 2014 d = 2.0 √P 80 MHz to 2.7 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey³, should be less than the compliance level in each frequency range¹. Interference may occur in the vicinity of equipment marked with following symbol:

Table 2-4 Guidance and manufacturer's declaration - electromagnetic immunity

Immunity test	IEC 60601	Compliance	Electromagnetic
	test levels	level	environment – guidance

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 strengths 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 **Intraoral Scanner** is used exceeds the applicable RF compliance level above, the **Intraoral Scanner** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **Intraoral 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 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality or launch warning messages, it is necessary to position the **Intraoral Scanner** further from sources of electromagnetic interference or install electromagnetic shielding to block unwanted interference. The customer or the user of the **Intraoral 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 **Intraoral Scanner** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Intraoral Scanner** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Intraoral Scanner** as recommended below, according to the maximum output power of the communications equipment.

Table 2-5 Recommended separation distances between portable and mobile RF communications equipment and the Intraoral Scanner

Rated maximum	Separation distance according to frequency of transmitter (m)					
output power of transmitter (W)	IEC 60601-1-2 : 2007			IEC 60601-1-2 : 2014		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √P	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0 \sqrt{P}$	
0.01	0.12	0.12	0.23	0.12	0.20	
0.1	0.38	0.38	0.73	0.38	0.63	
1	1.2	1.2	2.3	1.2	2.0	
10	3.8	3.8	7.3	3.8	6.3	
100	12	12	23	12	20	

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.

- **NOTE 1:** At 80 MHz and 800 MHz, the separation distance for 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.

The medical electrical equipment is suitable for the professional healthcare environment per 60601-1-2:2014. 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.



WARNINGS

- 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 Intraoral Scanner, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- If higher IMMUNITY TEST LEVELS than those specified in IEC60601-1-2
 Table 9 are used, 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.

CHAPTER 3

Overview

Benefits of the product

The Intraoral Scanner is designed to provide powder-free intraoral color scanning, with higher speeds resulting in greater accuracy and less time-lag for image acquisition. It can be used to scan a single tooth, multiple teeth, and whole dental arches. The captured 3D digital impressions of teeth and soft-tissue areas are designed to be used in conjunction with the supplied software programs -- DentalManager, which helps manage the patient information and scanned records, and IntraOralScan, which assists you in acquiring digital impressions and is capable of exporting the scan data (in STL/OBJ format) to CAD/CAM systems for different purposes of dental care.

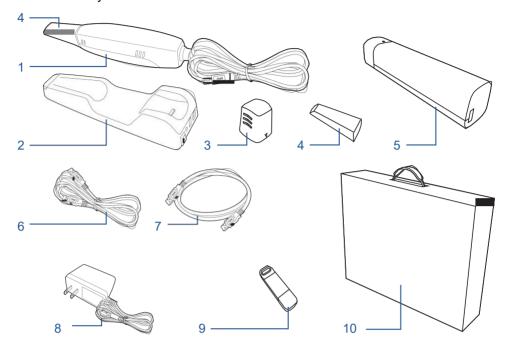
Carry box list

Check the carry box for the following items. If any item is missing or damaged, contact your place of purchase immediately.

- **1.** 1 x Intraoral Scannerwith a USB 3.0 upstream cable (length: 2 meters)
- **2.** 1 x scanner cradle (12 Vdc, 1.67 A)
- 3. 1 x protection cap
- **4.** 2 x scanner tip (1 is already attached to the intraoral scanner when shipped)
- 5. 1 x Calibrator
- **6.** 1 x USB 3.0 cable (for the connection between the cradle and your computer; cable length: 1.5 meters)
- **7.** 1 x USB 3.0 cable (for the connection between the Calibrator and your computer; cable length: 1 meter)
- **8.** 1 x medical grade AC/DC power adapter (manufacturer: Adapter Technology Co., Ltd.; model name: ATM020-W120U; input: 100-240 V, 50-60 Hz, 0.45-0.27 A; output: 12 Vdc, 1.67 A; cable length: 2 meters)

9. 1 x 2-in-1 USB dongle (the license key for authorized access; containing the software programs for patient data management (**DentalManager**) and scanning software (**IntraOralScan**) for Windows)

10. 1 x carry box





WARNINGS

- AC plug types vary by country/region.
- Using accessories, peripherals, or cables not supplied with the product or recommended by Shining3DCorporation can affect the device in the form of increased emissions or decreased immunity to external EMI/EMC occurrences. Non-specified peripherals, and cables in some cases, can also increase leakage current or compromise the safety of the grounding scheme.
- Using accessories or power supply units other than those specified may cause the warranty to void and result in increased emissions, decreased EMI immunity of the device, or even damages to the device and personal injuries.
- Use of other accessories results in non-compliance.
- Always store the 2-in-1 USB dongle in a safe place for later use.



NOTE

We recommend that you keep all the original packaging components in a safe place in case you need to transport or dispose of the scanner in the future. For details, see Storage for transport on page 68.

Scanner overview

Tip and scanner body

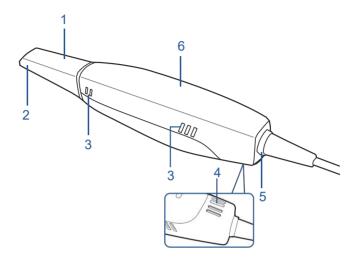


Table 3-1 Introduction to the scanner tip and scanner body

No.	Component	Function
1.	Scanner tip	Use the tip to scan the upper jaw, lower jaw, or full jaw. The tip(s) can be autoclaved up to 20 times.
2.	Heater	The anti-condensation heater prevents fogging on the mirror to ensure successful scanning.
3.	Exhaust vents Allows the heat produced by the operation of scale be dissipated from the case.	
4.	Intake vent	Allows the ambient cool air to enter into the case to help cool down the heat produced by the operation of scanner. NOTE When scanning, do not hold the scanner in the way that covers or blocks the intake and exhaust vents. Otherwise the scanner may become overheated.
5.	LED ring light	 Indicates the status of your scanner. Blinking green: the scanner is in preparation/warm-up mode. Solid green: the scanner is ready for use. Solid blue: the scanner is processing the alignment of scanned data. Solid amber: an error occurs and needs your attention.

Table 3-1 Introduction to the scanner tip and scanner body

No.	Component	Function
6.	Scanner body	Hold the scanner body on the sides and rotate the scanner body to obtain the best scan angle. The scanner body may get warm during scanning, yet the temperature won't cause harm to the user and the patient.

Scanner cradle

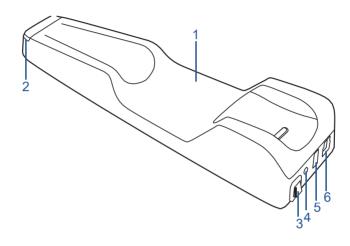


Table 3-2 Introduction to the scanner cradle

No.	Component	Function		
1.	Cradle	Place the scanner in the cradle when you are not using it.		
2.	LED indicator	Indicates the status of the cradle. • Solid green: power on. • LED off: power off.		
3.	Power switch	To receive power from the power outlet, turn it on; to stop receiving power from the power outlet, turn it off.		
4.	Power connector	Connect the power plug from the supplied power adapter to this power connector, and plug the power adapter to the power outlet.		
5.	USB 3.0 downstream port	For connecting the scanner cradle and the USB port of your computer using the supplied USB cable. This port transfers data between the Aoralscan 2 and your computer.		
6.	USB 3.0 upstream port	Connect the scanner cable to this port. This port provides power supply and data communication between the scanner and cradle. For details, see Connecting the scanner on page 25.		

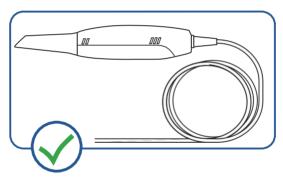


NOTES

- When the scanner is left idle for 10 minutes (including being placed on a desk), it will go into standby mode. After 1 minute of inactivity, it will automatically go into sleep mode, and the LED ring light on the end of the scanner body will also go off.
- To activate the scanner, place it in the cradle. The scanner will go into standby mode within 3 minutes. If the scanner is left idle for more than 1 minute, it will automatically go into sleep mode.
- To lower the temperature inside scanner body, the cooling fan still operates for about 30 minutes after the scanner goes into standby or sleep mode. Then it will stop spinning.
- The scanner tip is being heated whenever power is supplied, even if the scanner is in standby or sleep mode.

USB cable storage

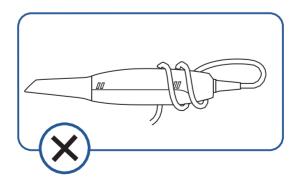
To prevent the USB cable from getting damaged by excessive bending or twisting, you should loosely coil the cable and avoid making kinks or sharp bends.





CAUTION

Do NOT roll the cable over the handle of the scanner or even bend the cable sharply. The illustration below demonstrates improper cable storage.



Software overview

The **Intraoral Scanner** is designed to operate with the following software programs (supplied in the 2-in-1 USB dongle):

- Dental database software -- DentalManager
 Designed to manage and store patient data, including cases, prescriptions, and restoration information.
- Image acquisition software -- IntraOralScan
 The interface guides you through the entire scanning process of acquiring intraoral digital impressions via the scanner.

For information on how to use these software programs, see:

- Using DentalManager on page 35
- · Using IntraOralScan on page 41

System requirements

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

Table 3-3 System requirements

СРИ	Intel Core i7-7700 or higher	
Memory	16 GB or higher	
Hard drive	1 TB SATA Hard Drive (7200 RPM, 6.0 Gb/s) or higher	
Graphic card (GPU)	NVIDIA GTX 1060 6GB DDR3 or higher (supporting NVIDIA CUDA)	
Operating system	Windows 10 Professional (64-bit) or later versions of Windows operating system	
I/O ports	More than 3 Type-A USB 3.0 (or higher) ports	



WARNING

The computer or notebook you use shall meet the safety requirements of IEC 60601-1 and IEC 60950.

Installing the software programs

The supplied 2-in-1 USB dongle contains these software programs: DentalManager and IntraOralScan.

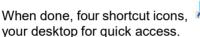


CAUTIONS

- Install the software programs in accordance with the instructions given
- When the installation is completed, do not plug the power adapter to the wall outlet or turn on the scanner yet. See Setting up the scanner on page 25 for more necessary procedures to get started.

Follow the steps below to complete the installation of software programs:

- 1. Insert the supplied 2-in-1 USB dongle into the USB port of your computer.
- 2. Find the driver named IntraOralScanVX.X.X.exe and double-click it.
- 3. The IntraOralScan InstallShield Wizard window appears to start the installation.
- 4. Specify a language from the drop-down list.
- 5. Click OK.
- **6.** Follow the on-screen instructions to complete the installation.









and , will appear on

CHAPTER

4

Setting up the scanner

Connecting the scanner



CAUTIONS

- Ensure the supplied software programs are installed on your computer before the connection.
- Install the scanner in accordance with the instructions stated in this User Manual.
- Use the scanner only in dental laboratories, dental clinics, and equivalent environment.
- Do not install, place, and use the scanner in dusty and damp environment or in the areas of temperature extremes or in direct sunlight.
- Prepare a flat surface, e.g. your desk, for the scanner and the cradle. Do not place them on a slanted surface.
- Before the installation is completed, do not plug the power adapter into the wall outlet or turn on the scanner until you are instructed to do so.
- Always return the scanner to the cradle when it is not in use. Do not place the scanner in heated or wet surfaces as this can cause damage to the tip and scanner.
- It is normal that the scanner gets warm when in use.

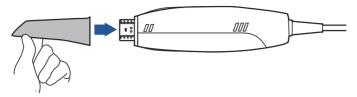


WARNING

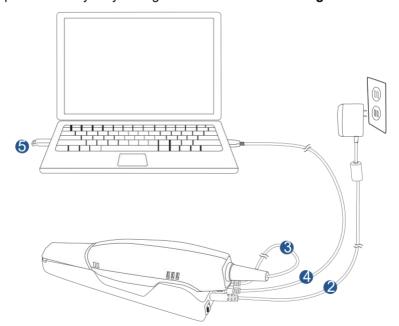
Ensure that you use only the supplied power adapter, power cable, and USB cable.

Follow the steps below to complete the connection:

 Make sure the scanner tip is firmly attached to the front end of the scanner; otherwise, gently and firmly slide the scanner tip onto the front-end of the scanner, as illustrated.



- 2. Insert the power plug of the supplied power adapter into the power connector on the cradle, and plug the power adapter into a wall outlet.
- 3. Connect the scanner cable to the USB 3.0 upstream port on the cradle.
- **4.** Connect the USB 3.0 downstream port on the cradle and your computer with the supplied USB 3.0 cable.
- **5.** Insert the supplied 2-in-1 USB dongle into the USB port of your computer. This step is necessary for you to gain access to **DentalManager**.



- 6. Turn on the power switch on the cradle.
- 7. Click the shortcut icon of **DentalManager** on the desktop to launch the software.

Disconnecting the scanner



/ CAUTION

Do not attempt to directly disconnect the scanner by removing the power cable and USB cable.

Follow the steps below to safely disconnect the scanner:

- 1. Quit the IntraOralScan scanning software.
- 2. Turn off the power switch on the cradle.
- 3. Disconnect the scanner cable from the cradle.
- 4. Disconnect the USB 3.0 cable from the USB 3.0 downstream port on the cradle and your computer.
- 5. Right-click the "Safely Remove Hardware" icon on Windows taskbar and select "Eiect Flash Drive".
- 6. Unplug the 2-in-1 USB dongle and keep it in a safe place for future use.
- 7. Unplug the power adapter from the wall outlet and remove the power plug from the power connector on the cradle.



CAUTION

Do NOT roll the cable over the handle of the scanner or even create any sharp bends in the cable after you disconnect the scanner. See USB cable storage on page 21 for more details.

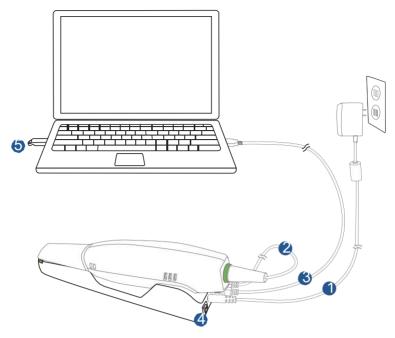
Calibrating the scanner

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

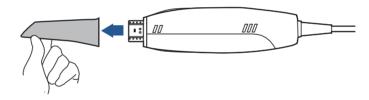
- The initial setup of the scanner is completed.
- The scanner has been used for a period of time (e.g. 2 weeks).
- The scanner is accidentally dropped.

Follow the steps below to perform the calibration:

- 1. Insert the power plug of the supplied power adapter into the power connector on the cradle, and plug the power adapter into a wall outlet.
- 2. Connect the scanner cable to the USB 3.0 upstream port on the cradle.
- 3. Connect the USB 3.0 downstream port on the cradle and your computer with the supplied USB 3.0 cable.
- **4.** Turn on the power switch on the cradle.
 - The LED light ring on the end of the scanner body lights up green when the power connection is working properly.
- 5. Insert the supplied 2-in-1 USB dongle into the USB port of your computer.



6. Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner, as illustrated.





NOTES

- Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.
- Store the detached tip in a safe place, e.g. a dental instrument tray, for future use.
 - **7.** Connect the on the supplied Calibrator and your computer with the supplied USB 3.0 cable.
 - **8.** Gently slide the Calibrator onto the front end of the scanner, as illustrated.



9. Double-click the shortcut icon of IntraOralCalibration . Display th following screen.



10. Click Calibration.



11. Click Start. The status bar shows the percentage of completion.



NOTE

It is normal that the calibration takes approximately 5 minutes.

12. The following message appears once the calibration is completed. Click **OK** to exit.



13. Gently slide the Calibrator off the scanner.



CAUTION

Make sure that the Calibrator is removed from the scanner after the calibration is done. Otherwise, the Calibrator may get very warm.

14. Re-attach the scanner tip to the scanner for later use or put the protection cap onto the scanner to prevent damage and dust.

CHAPTER 5

Scanning preparation

Scanning basics

Read and follow the guidelines and tips given in this chapter prior to acquiring quality images.



WARNING

Concerning hand hygiene and personnel safety when performing a scan, you must wear clean surgical gloves through the whole process.

Tooth preparation

- Ensure that saliva is not blocking the vision of the working area for the scanner user. Dry the working area (lips, tongue, and tissues) whenever needed.
- If necessary, ask the patient to hold the tongue still and move it to the opposite side of the mouth.
- Dry the teeth thoroughly before starting a scan.
- When scanning, consider using the saliva ejector and tampons to keep the surfaces of teeth dry.
- If necessary, consider using the retractors to avoid excessive tissue from being scanned.
- If necessary, consider using tampons to help create space while working on narrow regions between teeth.

Scanner preparation

- Ensure that the scanner tip, scanner body, and cradle are properly pre-cleaned, disinfected, or sterilized. See Precleaning, disinfection, and sterilization on page 59.
- Ensure that the scanner tip has no scratches or is not damaged. Additionally, the tip is firmly attached to the front end of the scanner body.

- Ensure that the scanner connection is ready; it is correctly connected to a power source and powered on, and **DentalManager** and **IntraOralScan** are launched and ready to work.
- To avoid condensation on the mirror of the tip when scanning, the scanner tip must have been warmed up. For details, see Heating the scanner tip on page 33.
- Calibrate the scanner and verify the accuracy of the acquisition regularly. For details, see Calibrating the scanner on page 27.

Scanning position and path

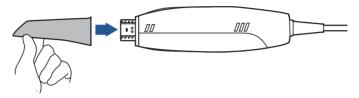
- Avoid direct light from any light source, e.g. dentist chair lamp, to shine on the area you are working on.
- Hold the scanner steady by resting it on the tooth surface and keep the scanner tip within 15 mm from the teeth.
- When scanning, slowly move the scanner and simultaneously check the scan results on the screen to ensure the scanning is of good quality.
- When scanning, the scanner tip should be centered over the teeth, and each movement should align with the cross-hairs, following the lower and upper dental arch shapes.
- A complete scan data of a single area includes the surfaces of occlusal, lingual, buccal, interproximal contacts of the adjacent teeth, and 2-3 mm buccal gingiva.
- A complete scan data of a single case includes the lower jaw, upper jaw, and bite registration.
- When scanning, change the scanning angle to 35-55 degrees in order to create overlaps. It is important to achieve an overlap of at least 30% between each acquisition. If the overlap is small, it may cause the alignment to fail.
- To scan the occlusal surface of the teeth, hold the scanner at a 90-degree angle; to scan the buccal and lingual surfaces of the teeth, hold the scanner at a 45degree angle.
- Inspect the scanned image in the 3D scan view window (IntraOralScan) and pay attention to warning messages.

Heating the scanner tip

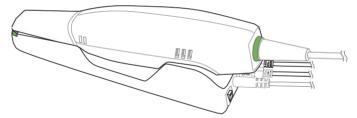
In order to obtain optimal image quality, you should prevent condensation on the scanner mirror before each scan by heating the scanner tip.

Follow the steps below to warm up the scanner before starting an acquisition:

- 1. Ensure that the scanner tip, scanner body, and cradle are clean and sterile. For details, see Pre-cleaning, disinfection, and sterilization on page 59.
- 2. Gently and carefully attach the scanner tip to the scanner body, with the mirror facing downward.



- **3.** Connect the power supply to the **Aoralscan 2**. For details, see Connecting the scanner on page 25.
- **4.** Place the scanner in the cradle to secure it in place.
- **5.** When the LED ring light on the end of the scanner body lights up green, the heater automatically turns on and detects the temperature.



It the temperature of the scanner tip is lower than the set point for anti-fogging, a notification message of pre-heating and current temperature appears.

When the message disappears, the warm-up is done. The scanner is now ready for an acquisition.



NOTES

- The heater maintains constant temperature on the scanner tip.
- The scanner tip is being heated whenever power is supplied, even if the scanner is in standby or sleep mode.
- If the heater does not reach the necessary temperature for preventing condensation during scanning, the message of "The scanner is preheating. Please wait" appears.

CHAPTER 6

Using DentalManager

Introduction to DentalManager

DentalManager is designed to work with the scanner to manage patient data and treatment reports, which are automatically saved by the supplied scanning software -- **IntraOralScan**. It also exchanges data between the dental laboratories/technicians and the dentists.

Navigating DentalManager interface

To run **DentalManager**, the following requirements must be met:

- The supplied 2-in-1 USB dongle is plugged into the USB port of your computer.
- The connection between the scanner and your computer is ready. For details, see Connecting the scanner on page 25.

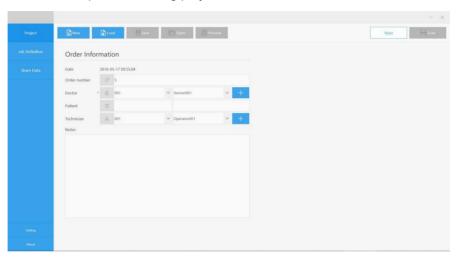
Double-click the shortcut icon of **DentalManager** on your desktop.

Work flow

Creating a project

Click **Project** and select **New** to create a new order. Fill out the necessary order information, including the names of dentist(s), patient, and technician(s). Then click **Next** to proceed.

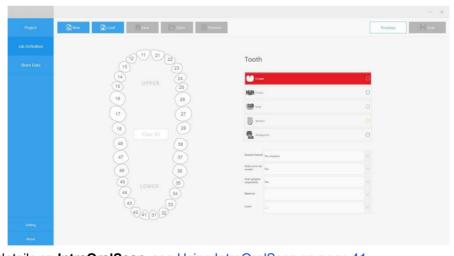
Or select Load to open an existing project.



Specifying job definition

Select the desired type of restoration and the tooth number (the restoration site), and then click **Save**.

When the **Scan** button is active, click it to launch **IntraOralScan** and start the scan.



For details on IntraOralScan, see Using IntraOralScan on page 41.

Sharing data

Creating an account

- 1. Double-click SnFtpAccountMgr.exe.
- **2.** In the window that appears, enter the FTP host, port, user name, and password.



3. Click **Create** to add a new FTP account with encryption (in .prcdat file format), by which you may login to **DentalManager**.



NOTE

The user name and password for accessing the host server must have been specified when you set up the FTP server.

Using private cloud

Importing DentalManager login accounts

To import an account file:

- 1. In the **DentalManager** window, click **Setting**.
- 2. Click Private Cloud under Data Cloud.
- 3. Click Apply.
- 4. Re-launch DentalManager.
- 5. In the **DentalManager** window, click **Share Data**.
- 6. Click Account Manager in the top-right corner of the window.
- 7. In the window that appears, select the account file (in .prcdat format, generated by **SnFtpAccountMgr.exe**) you intend to import.

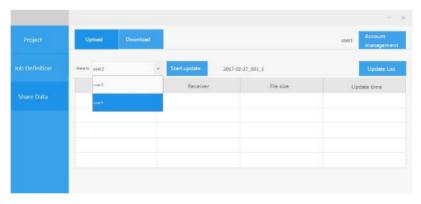
To log in to the account:

- 1. Select the imported account file from the drop-down menu.
- 2. When the **Login** button is highlighted in blue, click the button.
- 3. When you have successfully logged in, click ★ to close the window.

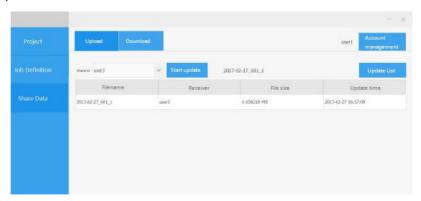


Uploading the data

- 1. After importing or saving an order, or completing the scan, specify a receiver.
- 2. Click Start Update.



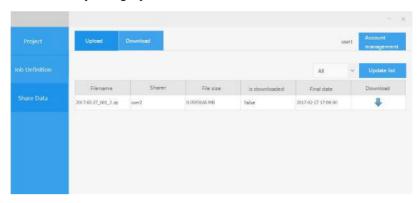
3. After finishing uploading, click **Update List** to display the information on the uploaded files.



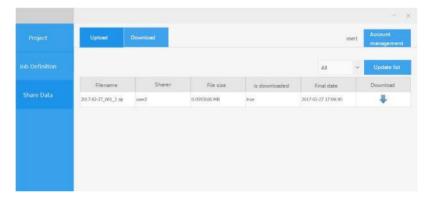
A copy of the data uploaded to the cloud will automatically be compressed and saved on the local computer in the following location: C:\DentalOrder\FtpUp-Load\.

Downloading the data

1. Click **Download** to display the information on the downloaded files. You may view the files by category: **All**, **Downloaded**, and **Data Not Downloaded**.



2. After finishing downloading, the download list is updated.



The downloaded data will automatically be extracted and saved in the folder with the name exactly the same as the UserName on the local computer in the following location: C:\DentalOrder\Ftp-DownLoad\.

CHAPTER

Using IntraOralScan

Introduction to IntraOralScan

IntraOralScan is designed with a graphical user interface (GUI), so you will be guided step-by-step through the process of each task. Before performing a scan, understand and learn the features of the software.

Navigating IntraOralScan interface

Double-click the shortcut icon of **IntraOralScan** on your desktop , then one of the following main screens appears.

a. If no scanner is connected, an error message appears to remind you to check and reconnect the scanner.

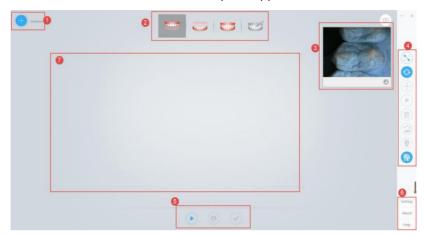




NOTE

If the scanner is connected yet the error message appears, remove then reconnect the scanner. If IntraOralScan still cannot detect the scanner, quit IntraOralScan. Wait for a few seconds, and relaunch IntraOralScan again.

b. If the scanner is detected, the workspace appears as below.





NOTE

If IntraOralScan is already open, you cannot launch another instance of this program.

The following table provides a general overview of **IntraOralScan**:

Table 6-1 Functions of IntraOralScan

No.	Function	Description
1.	Guidance	The Guidance walks you through to learn the basic scanning hints to perform a successful scan.
	2. Scanning work flow bar	These icons provide a step-by-step guide to start the scan from the upper jaw, the lower jaw, and finally the full jaw of the 3D model.
2.		When sufficient scan data is obtained, the Design tool automatically provides an accurate alignment of the teeth and bite and measures the cervical line of tooth crowns.
3.	2D view window	Displays the 2D real-time preview in color when scanning.

Table 6-1 Functions of IntraOralScan

No.	Function	Description
		Fit View
		Select to restore the image of the scanned model to its original size.
		Rotate
		Select and place the mouse pointer over the image of the scanned model, then you can left click and drag the mouse pointer to rotate the image to the desired orientation.
		Move
		Select and place the mouse pointer over the image of the scanned model, then you can left click and drag the mouse pointer to move the image to the desired position.
		Select
4.	Edit tools	Left click and drag the mouse pointer to draw margin lines on the tooth in order to specify the area of the model you wish to delete.
		Delete
		After defining the area, select this button to delete the specified data.
		Remove redundant 3D proliferation
		The function is only available when you select Delete . To remove all redundant proliferation from the scanned 3D data, select this tool.
		Undercuts
		Select to check for the undercuts.
		Texture
		Select to display the 3D real-time preview or finished scan results in color or monochrome. The default setting is on.

Table 6-1 Functions of IntraOralScan

No.	Function	Description
	Scan menu	Start/Pause To activate or pause scanning, select this button to start/pause/resume.
		Reset Delete the whole scanned data to start over.
5.		Stop To save the scanned data, select this button to complete the scan task.
		NOTE If you proceed to the next phase, you will not be able to redo the previous acquisition.
		Setting Configure the camera settings.
6.	6. Menu	About View the version number of IntraOralScan.
		Help Select to open the Help file.
7.	3D view window	Displays the 3D real-time preview or finished scan results. NOTE
		When you are in the Guidance mode, the window displays the scanning hints.

Guidance

When the installation of the **Intraoral Scanner** is ready, double-click the shortcut icon IntraOralScan on your desktop . The initial screen appears as below:

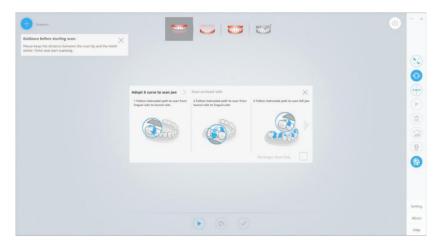


Table 6-2 Overview of Guidance

Displays	Description
Guidance	The initial status of the Guidance icon.
Guidance Guidance before starting scan: Please keep the distance between the scan-tip and the teeth within 15mm and start scanning.	When you select the "+ Guidance " button, the "+" icon changes to "-".
Adopt S curve to scan jaw Scan occlusal side 1 Follow instructed path to scan from lingual side to buccal side 2 Follow instructed path to scan from buccal side to buccal side to fingual side to buccal side to fingual side to find the scan form buccal side to find the scan fo	Select ">>" to proceed to the next step - Scan occlusal side.
No longer show Help	2. Check "No longer show Help" to stop displaying Guidance next time you launch IntraOralScan. 3. Select "X" to exit.

Table 6-2 Overview of Guidance

	Description
Adopt S curve to scan jaw 1 Follow instructed path to scan from lingual side to buccal side 2 Follow instructed path to scan from buccal side to lingual side No longer show Help	 Select ">>" to proceed to the next step - Scan occlusal side. Select "<<" to return to the previous step - Adopt S curve to scan jaw.
Adopt 5 curve to scan jaw > Scan occlusal side 1 Follow instructed path to scan lingual side of jaw side of jaw	Select "<<" to return to the previous step - Adopt S curve to scan jaw.
No longer show Help	 Check "No longer show Help" to stop displaying Guidance next time you launch IntraOralScan. Select "X" to exit.

Scanning work flow and tools

After closing the window of Guidance, the following screen appears:



By default, the entire scanning work flow starts with the upper jaw, then the lower jaw, and finally the full jaw.

Alternatively, you may define the scanning work flow as first the lower jaw, then the upper jaw, and finally the full jaw.

Table 6-3 Scanning work flow and tools

Work flow icon	Tool icon	Description
		The Scan button. The current working area is shown inside the square with green outline in the 3D view window.
Upper Jaw		
		Algred frame; 31 (b) (c) (c)
		If you re-click Scan , the button will change to indicating a pause.

Table 6-3 Scanning work flow and tools

Work flow icon	Tool icon	Description
		The Pause button. When the button is selected, it changes to During the pause, you may examine the scanned data in the 3D view window and check if any areas need to be re-scanned. To resume scanning, select the button again.
	•	The Reset button. This button is only available when scanning is paused. To clear the scanned data, select this button. The following message appears: Delete scanned data? Scanned data will be deleted if you chose Yes!
		To clear all the scanned data, select Yes ; to cancel the operation, select No .
		The Stop button. When you finish scanning, select this button to perform the post-processing tasks and proceed to the next phase of the work flow.

Table 6-3 Scanning work flow and tools

Work flow icon	Tool icon	Description
		When the scan of the upper jaw is done, IntraOralScan automatically guides you to the next task - scanning the lower jaw.
		If you wish to re-scan the upper jaw, select the icon of the upper jaw, and then select the Scan button. When the " Rescan? " message appears, select " Yes " to delete the scanned data and restart to scan.
		Miles 7 Sunsed are of our by savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have by the savet of the savet 9 years have been savet 10 years have been savet 10 years have 10 years ha
		Almot High
Lower Jaw		Scanning the lower jaw. Read the work flow of Upper Jaw on page 47 to learn the use of tools.
		When the scan of the lower jaw is done, IntraOralScan automatically guides you to the next task - scanning the full jaw.
		If you wish to re-scan the lower jaw, select the icon of the lower jaw, and then select the Scan button. When the " Rescan? " message appears, select " Yes " to delete the scanned data and restart.

Table 6-3 Scanning work flow and tools

Work flow icon	Tool icon	Description
		The Scan button.
	0	The Pause button. During the pause, IntraOralScan automatically aligns the acquired data of upper jaw, lower jaw, and full jaw.
		The Reset button. The button is only available when you select Pause .
TARREST .		To delete the scanned data, select this button, then the following message appears:
Full Jaw	•	Delete scanned data ? Scanned data will be deleted if you chose Yes! No Yes
		To clear all scanned data, select Yes ; to cancel the operation, select No .
		The Stop button. When you finish scanning, select this button to optimize the acquired data of the model, including the upper jaw, lower jaw, and full jaw, and then IntraOralScan will perform the post-processing tasks.
		When 3D data optimization and post-processing tasks are done, the 3D view window displays the 3D data in STL/OBJ format.
		You may select the icons of upper jaw or lower jaw to view the data respectively.

Table 6-3 Scanning work flow and tools

Work flow icon	Tool icon	Description
Others		
Scanning Timer	The Scannin window:	g Timer is at the upper right corner of the 3D view
		00:01:09
	The timer sho	
		tal scanning time for the upper and lower jaws.
		al time for scanning the full jaw, data optimization s, and post-processing tasks.
Alignment Frames	corner of the	of the acquired 2D frames is displayed at the lower left 3D view window. The default maximum number is 2500. mber reaches 2499, IntraOralScan will stop scanning.
		Aligned frames: 291

2D view window

Table 6-4 Tools for 2D view window

Tool icon	Description
	The 2D view window button. After activating IntraOralScan , the 2D view window appears by default. To close the window, select this button.
	0
	The 2D view window displays the real-time image of the model during scanning.
	When the scanner pauses or stops scanning, the 2D view window
	appears as below:

Table 6-4 Tools for 2D view window

Tool icon	Description
	The Zoom button. Use the button to enlarge the 2D view window to see more details or resume it to the default size. The default 2D view window:
	© California (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)
•	Algred frame: 95 Aloof Peop
	The enlarged 2D view window:
	Algred frame: 159
	n.,
[6]	The Capture button. Select to save the current captured image as a bitmap (bmp) file. When you select the button, the following message appears to notify that the current 2D image has been saved to the specified location.
	Information Path:C:\Shining3D\IntraOralScan\Bin\EndoscopeImg \20180426_11_24_29_641.bmp

Edit tools

Table 6-5 Icon status

Tool icon	Status
(+ + + + + + + + + + + + + + + + + + + +	If the function is available, the button is highlighted in white.
(- 	If the function is in use, the button is highlighted in blue.
(† ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ; ;	If the function is disabled, the button is gray.

Table 6-6 Tools for editing

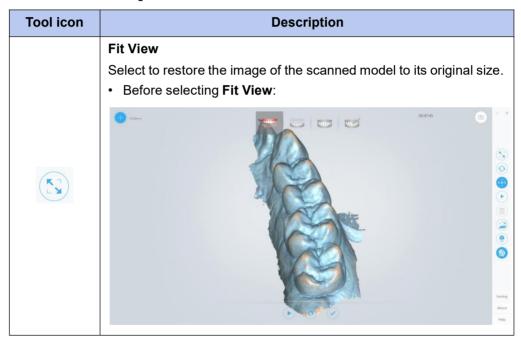


Table 6-6 Tools for editing

Tool icon	Description
	After selecting Fit View:
	① COMESSO ① - X
	Serting Serting Management
0	Rotate Left click and drag the mouse pointer to rotate the image to the desired orientation.
(+ -	Move Left click and drag the mouse pointer to move the image to the desired position.
	Select Left click and drag the mouse pointer to draw margin lines on the tooth you select. The area with margin lines is displayed in red.
	COSSISS COS
	To remove the margin lines, select the button (highlighted).

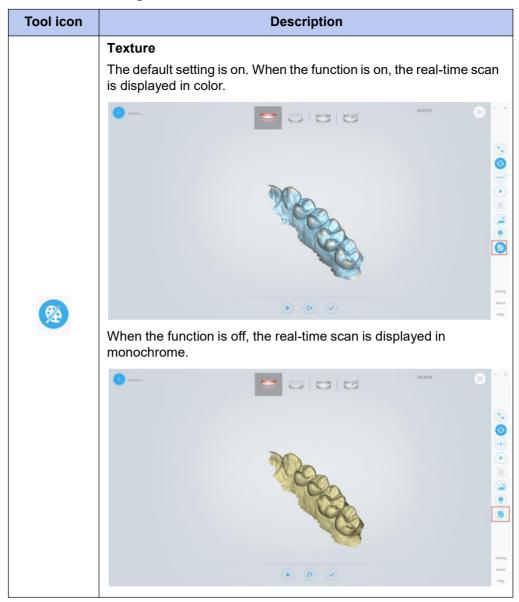
Table 6-6 Tools for editing

Tool icon	Description
	Delete Select to delete the specified area (the area in red). The button is only available when you have selected an area.
- X	Remove redundant 3D proliferation Select to automatically remove the redundant or unnecessary data from the scanned image. • Before selecting Remove redundant 3D proliferation
	So Co
	After selecting Remove redundant 3D proliferation
	© Calebra 00:527 (2) - X
	Senting About Help

Table 6-6 Tools for editing

Tool icon	Description
	The Undercut button. Select to automatically detect and measure the undercut area of the tooth. During the pause, you may select this button to view the effects of blocking the undercuts of the tooth, as shown below:
	Aloca Maga
	The green arrow indicates the insertion axis. The blue shade indicates an undercut area. To cancel the effects, select the Undercut button again.

Table 6-6 Tools for editing



Menu tools

Table 6-7 Menu tools

Functions	Description	
About	View the version number of IntraOralScan , the serial number of the supplied license dongle, and the remaining time left.	
Help	Select to open the Help file.	

CHAPTER 8

Care and maintenance

Pre-cleaning, disinfection, and sterilization

The whole set of **Intraoral Scanner**, including scanner tip, scanner body, and scanner cradle, 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.

We suggest that you reprocess the **Intraoral Scanner** in the following order:

- 1. Scanner cradle care
- 2. Scanner body care
- 3. Scanner tip care



WARNINGS

- All parts are shipped non-sterilized. Follow the instructions prior to initial use.
- Ensure you have completely disconnected the power supply and all connections from the scanner.
- Follow the instructions given in this User Manual to pre-clean, disinfect, and sterilize each part of the scanner. Using other methods not approved by Shining3DCorporation will damage your scanner and void your warranty.
- Using detergent, disinfection solutions or wipes, sterilization procedures other than those specified in this *User Manual* may damage the product and void your warranty.
- Only sterilize the part(s) for which a sterilization method is specified. Do not attempt to sterilize all parts of the product. Shining3DCorporation is not liable for any damages due to improper sterilization.

- After sterilization, wait until each of the parts is at room temperature to prevent possible heat injuries to the user and the patient.
- To prevent cross-contamination, pre-cleaning, disinfection, and sterilization must be correctly performed after EACH use.
- When the scanner tip is detached from the scanner, always protect the subtle units and the inner optical components on the front end of the scanner body by putting on the supplied protection cap.



Scanner cradle care

The scanner cradle requires an intermediate-level disinfection.

Disinfection



WARNINGS

- Concerning hand hygiene and personnel safety when performing precleaning and disinfection/sterilization, you must wear clean surgical gloves before you start.
- Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.
- The caring methods for the scanner cradle, scanner body, and scanner tip
 are different and must be executed separately. After disinfecting the
 scanner cradle, you may proceed with the scanner body and finally the
 scanner tip. See Scanner body care on page 61 and Scanner tip care on page
 63 for details.
- Ensure that the scanner body is not placed in the cradle prior to disinfecting the scanner cradle.

Follow the steps below to complete the disinfection:

- Disconnect the power of the Intraoral Scanner (see Disconnecting the scanner on page 27).
- 2. Hold the cradle firmly with your hand.
- **3.** Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of cradle.



CAUTION

Avoid using detergent of any kind as some detergents or surfactants might penetrate into the surface of the cradle.

- **4.** When done, store the cradle in a clean and safe place.
- **5.** Proceed to the disinfection of the scanner body (see Scanner body care on page 61).

Scanner body care

The scanner body requires an intermediate-level disinfection.

Disinfection

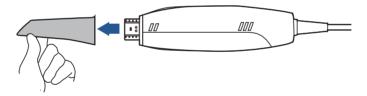


WARNINGS

- Concerning hand hygiene and personnel safety when performing precleaning and disinfection/sterilization, you must wear clean surgical gloves before you start.
- Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.
- The caring methods for the scanner cradle, scanner body, and scanner tip are different and must be executed separately. Before disinfecting the scanner body, you shall start with the cradle first. See Scanner cradle care on page 60) for details.
- Ensure that the scanner tip is detached from the scanner, and the protection cap is put on the scanner when disinfecting the scanner body.

Follow the steps below to complete the disinfection:

- 1. Disconnect the power of the **Intraoral Scanner** (see Disconnecting the scanner on page27).
- 2. Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner, as illustrated.

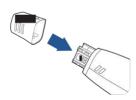




NOTE

Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

- **3.** Store the detached tip in a safe place, e.g. a dental instrument tray, prior to disinfecting the scanner body.
- **4.** Hold the supplied protection cap with the triangle mark facing upward. Then, align the protection cap blocks to the matching slots on the front end of the scanner body.



5. Slide the protection cap onto the scanner to prevent damage and dust.





CAUTIONS

 When the scanner tip is detached, always protect the subtle units and the inner optical components on the front end of the scanner by putting on the supplied protection cap.



 Do not attempt to clean the outer units and inner optical components on the front end of the scanner with any sharp objects or other such tools, which may result in scratches and damage to the scanner.

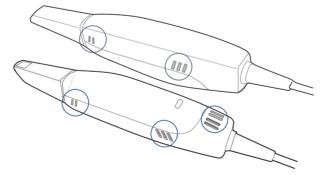


- **6.** Hold the scanner body with your hand.
- **7.** Use new cotton gauze moistened with 70%-75% solution of ethanol to wipe the surface of scanner body.



CAUTIONS

- Avoid using detergent of any kind as some detergents or surfactants might penetrate into the surface of the scanner body.
- Do not clean the intake and exhaust vents with any sharp objects or other such tools.



- 8. When done, store the scanner body in a clean and safe place.
- **9.** Proceed to the cleaning, disinfection or sterilization of the scanner tip (see Scanner tip care on page 63).

Scanner tip care

The scanner tip is the most essential part of the scanner as it is inserted into your patient's mouth during scanning. Therefore, the tip must be thoroughly cleaned and sterilized before and after each patient contact in order to prevent cross-contamination in your operation.



WARNINGS

- Concerning hand hygiene and personnel safety when performing cleaning and disinfection/sterilization, you must wear clean surgical gloves and goggles before you start.
- Always ensure that you have pre-cleaned and disinfected/sterilized the scanner body, scanner cradle, and scanner tip before each scan.
- The caring methods for the scanner cradle, scanner body, and scanner tip are different and must be executed separately.
- Cleaning the scanner tip is an essential step before effective disinfection or sterilization.
- When inserting the scanner tip into the disinfectant solution, be sure to follow the instructions on the disinfectant label and limit the time and depth that the tip is soaked within the minimum time recommended.
- The scanner tip can be sterilized up to 20 times and must be disposed of afterwards. For more information on disposal, see Disposal on page 3.
- High-level disinfection and steam sterilization must NOT be combined.
 Apply only either of these methods to ensure the safe and effective reprocessing of the scanner tip, and thus to prevent damage of reusable tip.

Two effective and approved methods of cleaning and disinfection/sterilization are recommended and described as below.

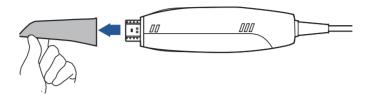
Either should be used to reprocess the scanner tip between each patient contact:

- Cleaning and high-level disinfection on page 64
- Cleaning and steam sterilization on page 66

Cleaning and high-level disinfection

Follow the steps below to perform cleaning and high-level disinfection:

- 1. Disconnect the power of the Intraoral Scanner (see Disconnecting the scanner on page 27).
- 2. Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the tip off from the scanner body, as illustrated.

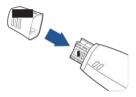




CAUTION

Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

3. Hold the supplied protection cap with the triangle mark facing upward. Then, align the protection cap blocks to the matching slots on the front end of the scanner body.



4. Slide the protection cap onto the scanner to prevent damage and dust.



5. Pay particular attention to inspect the mirror of the tip to ensure that the mirror is not cracked or broken and there is no scratch on it.



/!\ CAUTION

If the mirror of the tip has cracks or scratches, stop the cleaning process and contact your local distributor or service provider.

- **6.** Gently clean the inner and outer sides of the tip using mild pH-neutral soap water and a soft brush for 3 minutes.
 - When cleaning the inner surface of the tip, insert the soft brush into the tip from both the front and rear ends, and move the brush lightly in tiny circles.
 - · When cleaning the outer surface of the tip, move the brush lightly back and forth, and repeat for each side.

- 7. Repeat the previous step at least two more times.
- **8.** Rinse the tip thoroughly with sterile water for at least 3 minutes.
- **9.** If you notice stains, fingerprints, or smears on the mirror surface, repeat the previous step.
- **10.** Dry the tip carefully with a clean soft lens tissue or lint-free cloth.
- **11.** Pay particular attention to inspect the mirror surface of the tip again to make sure that the cleaning is done properly and the mirror is not damaged during the cleaning process.
- **12.** Cautiously fill a container with the FDA-approved disinfectant solution, e.g. CIDEX OPA[®] Solution. Do not spill any of it.



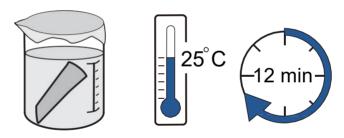
NOTE

Read the CIDEX OPA[®] manufacturer's instructions and warnings thoroughly before use.



CAUTIONS

- To avoid possible damage, use the disinfection solution verified by Shining3D Corporation and specified here only.
- Once a spill occurs, follow disinfectant manufacturer's handling instructions.
- **13.** Immerse the cleaned tip into the disinfectant and leave it for at least 12 minutes at 25°C.



- **14.** Prepare a large container of sterile water, e.g. 2 gallons.
- **15.** Take out the tip from the disinfectant.
- **16.** Immerse the tip into the container of sterile water for at least 5 minutes.
- 17. Take out the tip and manually flush it with at least 500 ml of sterile water.



CAUTION

Discard the rinse water. Always use fresh volumes of sterile water for each rinse. Do not reuse the water for rinsing or any other purpose.

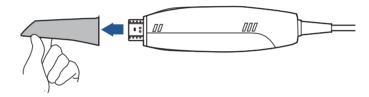
- **18.** Repeat the rinsing process (step 14 to 17) at least two more times for removing the residue of disinfection solution.
- 19. Use a soft lint-free cloth to dry the tip.

- **20.** Pay particular attention to inspect the mirror surface of the scanner tip again to make sure that the disinfection is done properly and the mirror is not damaged during the disinfection process.
- **21.** Re-attach the scanner tip (see Attaching the scanner tip on page 67). Or if you attempt to store the scanner tip with other dental instruments, e.g. a dental instrument tray, ensure that it is thoroughly dry.

Cleaning and steam sterilization

Follow the steps below to perform cleaning and steam sterilization:

- Disconnect the power of the Intraoral Scanner (see Disconnecting the scanner on page 27).
- **2.** Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently slide the scanner tip off from the scanner, as illustrated.

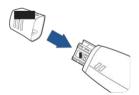




CAUTION

Do not place your finger(s) on the mirror of the tip when detaching as this may result in damage to the mirror.

3. Hold the supplied protection cap with the triangle mark facing upward. Then, align the protection cap blocks to the matching slots on the front end of the scanner body.



4. Slide the protection cap onto the scanner to prevent damage and dust.



5. Pay particular attention to inspect the mirror of the tip to ensure that the mirror is not cracked or broken and there is no scratch on it.



CAUTION

If the mirror of the tip has cracks or scratches, stop the cleaning process and contact your local distributor or service provider.

- **6.** Gently clean the inner and outer sides of the tip using mild pH-neutral soap water and a soft brush for 3 minutes.
 - When cleaning the inner surface of the tip, insert the soft brush into the tip from both the front and rear ends, and move the brush lightly in tiny circles.
 - When cleaning the outer surface of the tip, move the brush lightly back and forth, and repeat for each side.
- 7. Repeat the previous step at least two more times.
- **8.** Rinse the tip thoroughly with sterile water for at least 3 minutes.
- **9.** If you notice stains, fingerprints, or smears on the mirror surface, repeat the previous step.
- **10.** Dry the tip carefully with a clean soft lens tissue or lint-free cloth.
- **11.** Pay particular attention to inspect the mirror surface of the scanner tip again to make sure that the cleaning is done properly and the mirror is not damaged during the cleaning process.
- 12. Wrap the cleaned tip with a cloth cautiously.
- **13.** Place the wrapped tip in the autoclave and sterilize it at 121°C and with 1.5 atm pressure for at least 30 minutes.
- **14.** Dry the sterilized tip for 30 minutes with the autoclave program before opening the autoclave.
- **15.** Re-attach the scanner tip (see Attaching the scanner tip on page 67).

Attaching the scanner tip

There is a risk of damaging the mirror of tip if any improper actions are taken when attaching the tip to the scanner.

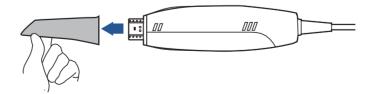


WARNINGS

- · Wear clean surgical gloves before you start.
- Ensure that the scanner cradle, scanner body, and scanner tip are precleaned and disinfected/sterilized (see Scanner body care on page 61 and Scanner storage on page 68).

Follow the steps below to complete the attachment:

1. Hold the scanner tip firmly with your thumb and forefinger on both sides, and then gently attach the tip facing downward to the scanner.





CAUTION

Do not place your finger(s) on the mirror of the tip when attaching as this may result in damage to the mirror.

- Try swiveling the scanner tip around to ensure it is locked into position and stable.
- 3. Place the scanner in the cradle, and the set is ready for use.

Scanner storage

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

For information on temperature and humidity requirements, see "Environmental requirements on page 70".

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.

Storage for transport

- Make sure that the scanner is clean and sterile before placing it in the original carry box/package to avoid any possible contamination.
- Place each part of the product, e.g. the tip, scanner body, cradle, 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.

Daily and long-term storage

- Always place the scanner in the cradle when it is not in use.
- When the scanner tip is detached from the scanner body, always protect the subtle units and the inner optical components on the front end of the scanner by putting on the supplied protection cap.
- Ensure the scanner is clean and sterile before long-term storage.
- Avoid storing the scanner and accessories in areas of extreme temperatures or under direct sunlight
- Before storing the scanner, make sure the scanner tip, scanner body, and cradle are thoroughly dry.

CHAPTER 9

Hardware specification

Specifications

Table 9-1

Type name	Intraoral Scanner	
Model name	Aoralscan 2	
Scanner		
Scan field	11 mm x 11 mm	
Scan principle	Non-contact scanner with the (DLP) structured light	
Dimension	Length: < 280 mm	
	Width: < 40 mm	
	Height: < 55 mm	
Weight	≤ 325 g (without cable)	
Output	STL, OBJ	
Connector	USB 3.0	
Power	Input: 5 Vdc/2 A	
	Cradle	
Dimension	Length: < 265 mm	
	Width: < 82 mm	
	Height: < 55 mm	
Weight	900 ± 100 g	
Power	Input: 12 Vdc/1.67 A	
Product life	3 years	

Environmental requirements

Operating and storage requirements

• Operating temperature: 10~40°C

• Storage/Transport temperature: -25°C~60°C

• Operating altitude: ≤ 3000 M

• Storage/Transport/Relative humidity: 30%~75%

• MTBF: 14,600 hrs (except DMD/LED)

• Air pressure: 700 hPa~1060 hPa