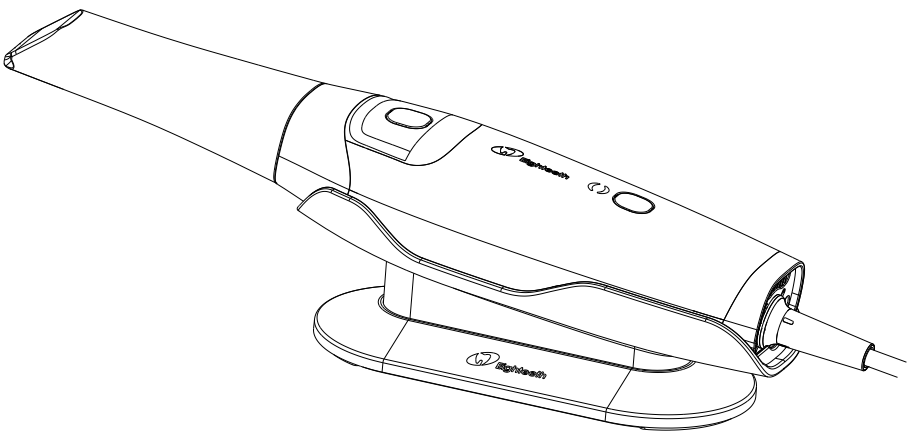
CE

Eighteeth



Helios 500

USER MANUAL

Changzhou Sifary Medical Technology Co., Ltd.

Part NO.: IFU-7635006
Version: 04
Issued: 2024.02.21
Size: 197mm x 140mm.

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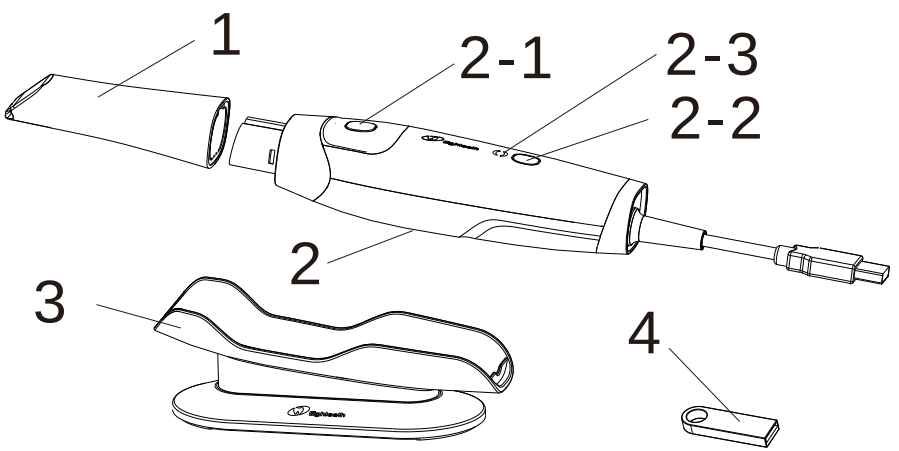
1.1 Parts Identification

1.Reusable tip

2.Scanner

3.Holder of scanner

4.USB flash driver



1.2 Button of scanner

2-1. Start / stop scan button

Press once to start scanning

Press again to stop scanning

2-2 Jaw/ Bite Switch button

2-3. Mode indicators

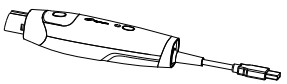
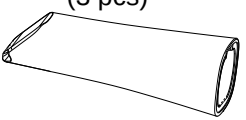
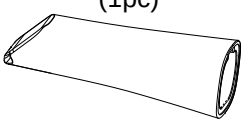
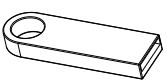
Upper jaw scan mode

Lower jaw scan mode

Bites mode

Note: Workstations are not included in this product

1.3 Packing list

Scanner (1pc) 	Holder of scanner (1pc) 	Reusable tip (Size L) (3 pcs) 
Reusable tip (Size S) (1pc) 	USB flash driver (1pc) 	

2 Symbols

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Authorized representative in the European Community
	Manufacturer
	Country of manufacture
	Washer-disinfector for thermal disinfection
	Type BF applied part
	Keep dry
	CE marking
	Dispose of in accordance with the WEEE directive
	Direct current
	Consult instructions for use
	Manufacturer’s LOGO
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit
	Humidity limit
	Atmospheric pressure limit

3 Introduction

3.1 Indications for Use

The Helios 500 is a digital optical scanning device used to record the topographic characteristics of teeth or dental impressions in 3D dimensions. The resulting topographic impressions are intended for use in the computer-aided design and manufacturing of dental restorative prosthetic devices, dental implant prosthetic devices, and orthodontic models.

The Helios 500 could be used for both adult and children in clinical practice.

The Helios 500 is designed to acquire 3D models in the followings

- Upper jaw
- Lower jaw
- Bites

3.2 Contraindications

Patients with oral mucosal disease, mental illness, severe respiratory disease, asthma, Parkinson's disease, hyperactivity disease are forbidden.

Patients with moderate or severe opening limitation should use it with caution.

3.3 Safety Instructions

Scanner

- You MUST read and understand this safety information before using the scanner.
- This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.
- This scanner shall only be used inside hospitals and other professional healthcare facilities and MUST NOT be used near high frequency surgical equipment and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.
- Before using the scanner, check the outer surfaces of the unit and any accessories to ensure there are no rough surfaces, sharp edges, or protrusions which may cause a safety hazard.
- DO NOT place objects within the field of operation of the unit.
- When the unit is not in use, ensure that the scanner is turned OFF.
- DO NOT use the scanner in conjunction with oxygen-rich environments. This unit is not intended for use with flammable anesthetics or flammable agents.
- DO NOT pull or twist the cable.
- DO NOT drop the scanner.
- DO NOT sterilize the scanner.
- DO NOT expose the scanner to water spray or submerge it in water or disinfectant.
- DO NOT expose the scanner to high vibrations.
- DO NOT expose the scanner to ultraviolet radiation for a long period.
- DO NOT stare at the LED emission window.

- DO NOT remove the cover of any scanner components. The scanner contains no user-serviceable parts. For any repairs, contact a qualified Eighteeth service technician.
- DO NOT replace the cables provided with the scanner with other cables. Doing so may damage the scanner and adversely affect the safety protection and EMC performance of the scanner.
- Any other equipment not complying with IEC 60601 shall be kept at least 1.5 meters away from the patient.
- If the equipment is faulty, turn it OFF, display an “Out of Service” notice, and contact a qualified Eighteeth service technician.
- Using components, cables and spare parts other than those specified or provided by the manufacturer of this equipment may impair the safety protection of the scanner and may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- No modification of this equipment is allowed.
- Additional multiple outlet strips or extension cords should not be connected to the system.
- When the device breaks down, stop using it immediately and pull out the USB plug from the workstation. When the device breaks down, the temperature of the applied part may reach to 43°C, but no higher than 48 °C.
- This equipment contains certain materials and chemical compounds incidental to the manufacture of electrical and electronic equipment, and improper “end-of-life” disposal of such equipment can result in environmental contamination. Therefore, this equipment should not be disposed of as ordinary household waste but should instead be delivered to a designated electrical and electronic waste disposal or recycling center. For further information on disposing of electrical and electronic waste, contact the cognizant authority within the jurisdiction.
- Do not use the device continuously for more than 10 minutes.

Workstation

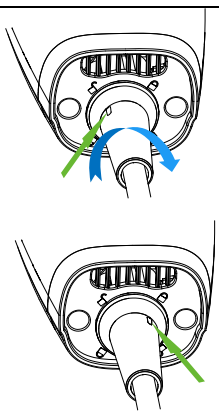
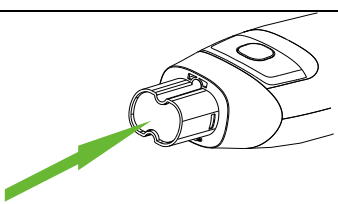
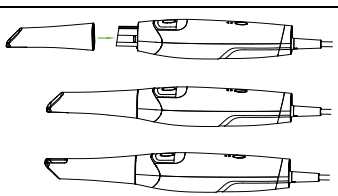
- DO NOT place the workstation and the peripheral equipment connected to it in the immediate vicinity of the patient. Leave at least 1.5 meters distance between the patient and the equipment.
- The scanner is only intended to be connected to a workstation that is at least IEC 60950-1 / IEC 62368-1, or equivalent standards certified. Connecting the scanner to other equipment may be hazardous.
- Leave a sufficient amount of clear space around the workstation to ensure that it is properly ventilated.
- Position the screen to avoid light reflections from internal or external lighting for maximum image quality and visual comfort.

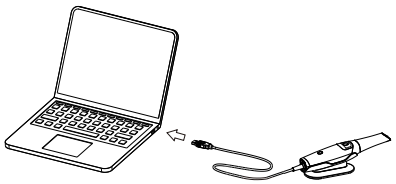
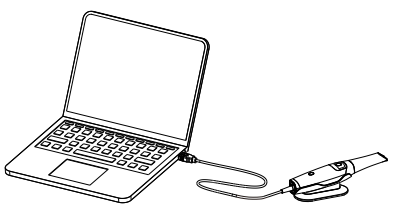
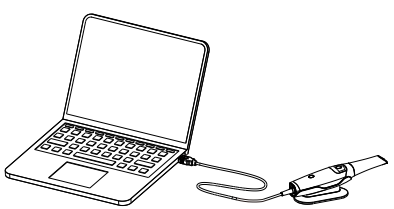
4 Product Installing

4.1 Installation Environment Requirements

Since this product is not equipped with a workstation, during the installation of this product, customers need to provide an additional laptop or desktop workstation.

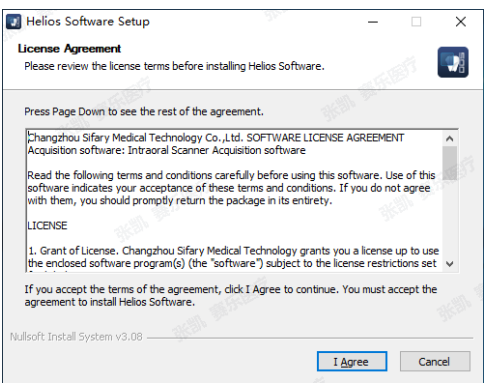
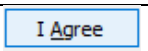
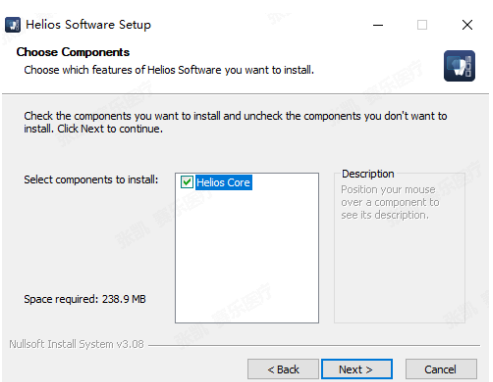
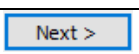
4.2 Connecting the Helios 500 to the workstation

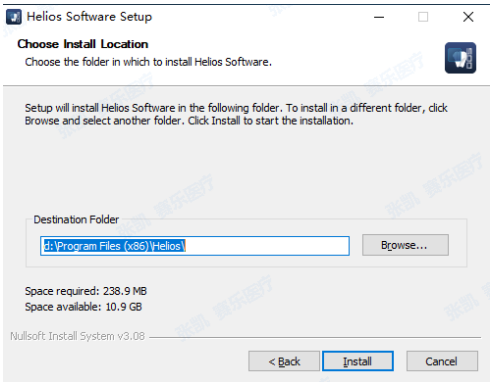
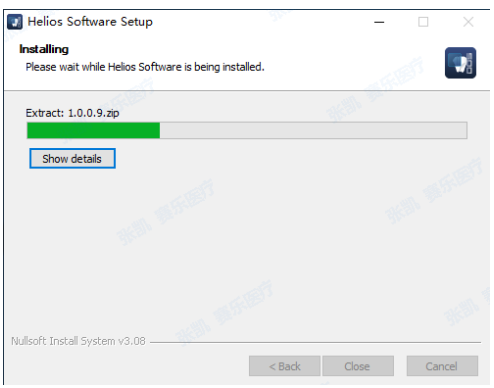
Step	Graphic Example	Description
1		If cables are not installed, perform the following steps: Align the latch indication with  , insert the type-c and latch into the scanner, and turn the latch clockwise so that the latch indication is aligned with  .
2		Make sure the lens window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue.
3		Slide the tip onto the scanner as shown, the tip can be mounted in both directions. ⚠ Please use the original reusable tips.

4		Insert the USB connector of the scanner to any USB 3.0 port on the workstation. ⚠ Make sure the scanner is connected to the USB 3.0 port. If connected to a USB 2.0 port, the scanner may not work properly. Do not position the device where it is difficult to disconnect the power.
5		The scanner will automatically turn on, place the scanner on the holder of scanner, and the device will enter the sleep state.
6		After the scan is complete, place the scanner on the holder of scanner, and the device will enter the sleep state. Pull out the USB plug to disconnect the scanner.

⚠
All IT components electrically connected to the Helios 500 must confirm to IEC 60950-1/ IEC 62368-1.

4.3 Software Installing

Step	Graphic Example	Description
1		Connect the USB flash driver to the workstation and open it. Double Click 
2		Click 
3		Click 

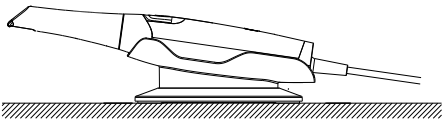
4		Select the installation location and click 
5		Wait until the software installation complete

4.4 Software Update

If there is an update of Helios 500 software, we(Sifary) will notify local distributors (agents) and provide free installation USB Flash Driver, and the distributor(agents) will upgrade the software for everyone.

4.5 Scanner placement

It is recommended to place the scanner in the holder of scanner. The installation method is as follows:

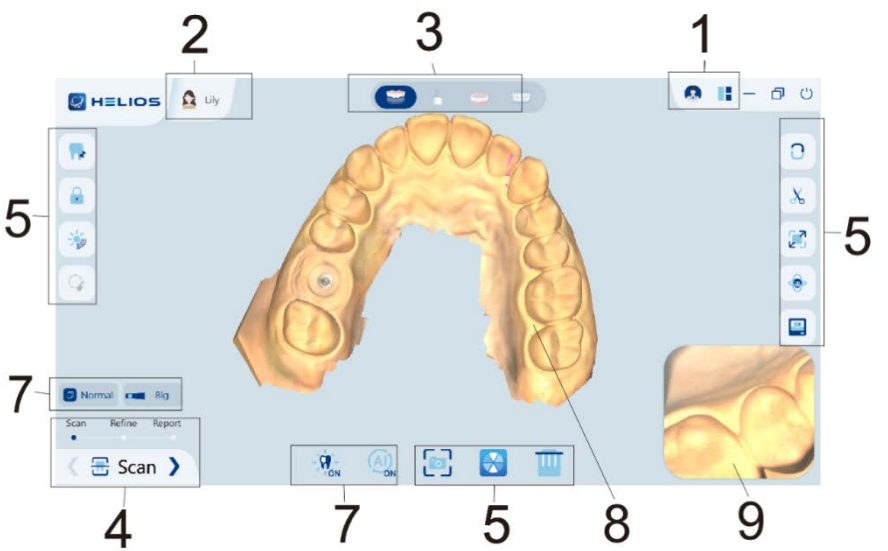
The holder can be used as a desktop mount holder. Place the scanner in the holder when you are not using it.	

5. Software Introduction

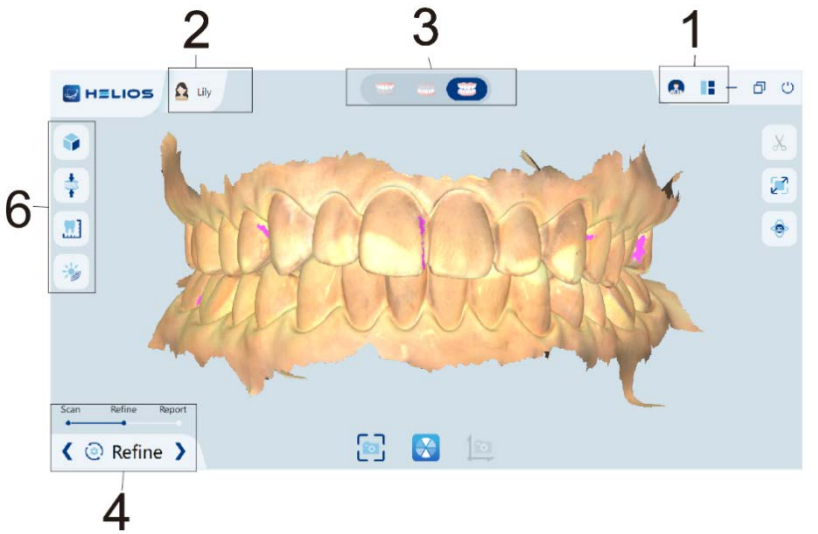
5.1 Interface

5.1.1 Login interface

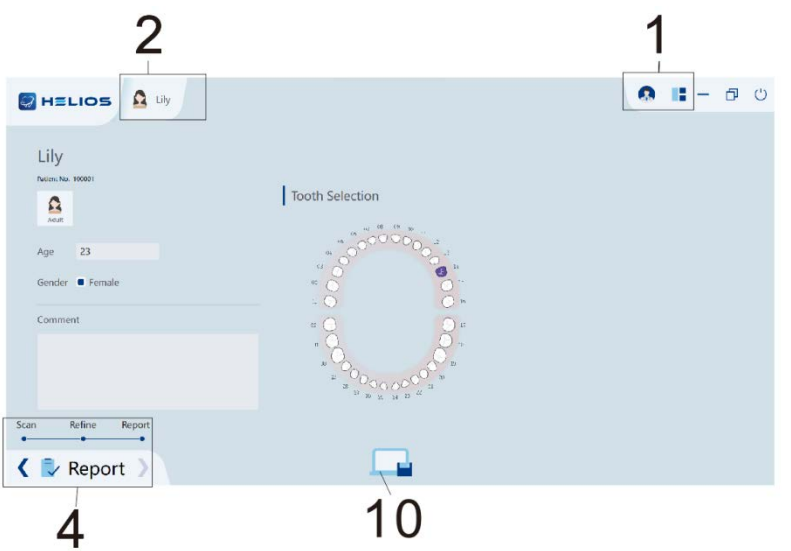
5.1.2 Scan interface.



5.1.3 Refine interface



5.1.4 Report interface



1	Option Menu	User information and More options	See 5.2.1
2	New patient	New patient information	See 5.2.2
3	Jaw/ bite Switch	Select the upper jaw, lower jaw, or bites	See 5.2.3
4	Process guide	Displays the current step in the process	See 5.2.4
5	Data editing toolbar	Select and manage 3D model	See 5.2.5
6	Data refining toolbar	Refine 3D model	See 5.2.6
7	Scanning assistant	Benefite to obtain 3D model	See 5.2.7
8	3D model display area	Displays the 3D model created by the scanner	See 5.2.8
9	Video preview area	Displays live video when scanning, or the scanner status when not scanning	See 5.2.9
10	Report saving	Save scan data locally in STL/PLY format	See 5.2.10

5.2 Interface Overview

5.2.1 Option Menu

5.2.1.1 User information

Click  , User information page is displayed, you can view user information, switch and exit the current user

5.2.1.2 More options

Click  , More options is displayed, enables you to access Import scan data, Export scan data, Scan historys, Settings and About dialogs

5.2.1.2.1 Import scan data

The Import scan Data option allows users to import local scan data in HIZP format into the software for further scanning or other operations.

⚠

- If you need to continue scanning after importing the previously saved scan data, you must ensure that the scan data is acquired by the same scanner currently connected, otherwise you will not be able to perform subsequent scans on the imported data.
- Only scan data in local HIZP format can be imported into the software

5.2.1.2.2 Export scan data

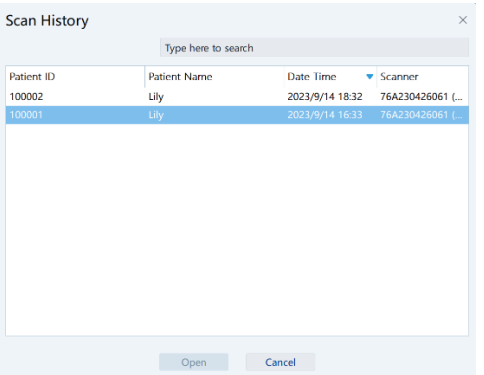
The Export scan data option allows users to save scan data locally in HIZP format for subsequent import to continue scanning or other operations

⚠

The scan data is saved locally in HIZP format by the Export scan data option.

5.2.1.2.3 Scan historys

Scan records are saved in the scan historys, searching for patient information to open the previous scan data by the scan historys.

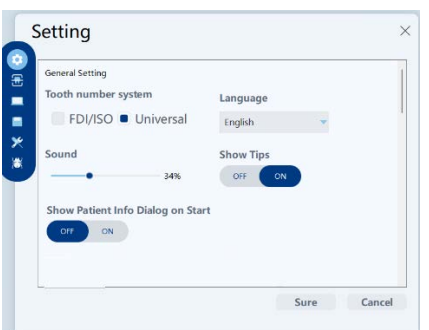


⚠

In Settings option, you can set the Auto save scan history, Save date, Save path

5.2.1.2.4 Settings

1) General Seting



Tooth number system: Select the FDI/ISO or Universal as the tooth numbering system.

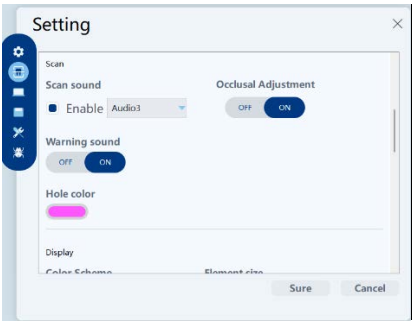
Language: Select the user interface language.

Sound: Adjust the volume

Show tips: When selected, the screen displays an indication of the correct scanning method When scanning 3D image of the occlusal

Display patient information dialog on start: When selected, the patient information dialog will pop up when Helios opens.

2) Scan

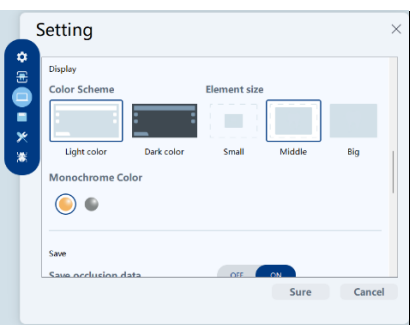


Scan sound: When selected, a sound will be continuously played when you are scanning (if your workstation does not have speakers, this option will not take effect).

Occlusal adjustment:When selected, the software will automatically correct over- occlusal after refinement.

Warning sound: When selected, a warning sound will be played if the scanning duration exceeds the recommended thresholds, a strong light is detected, or the scanning performance is declined (if your workstation does not have speakers, this option will not take effect).

3) Display

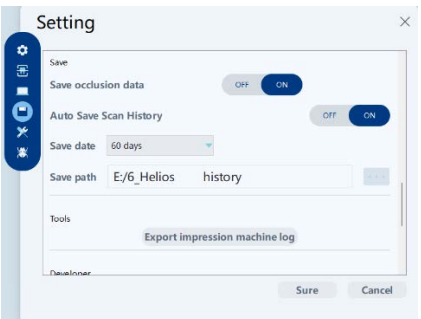


Color scheme: Select the color scheme of the user interface.

Element size: Select the size of interface icons to adapt to different screen resolutions.

Mode color: Select the color when displaying the 3D model in monochrome.

4) Save



Save occlusal data: When selected, the occlusal registration relationship is saved

Auto save scan history: When selected, scan history files are automatically saved when the scan is completed. When this option is enabled, users can customize the number of days and path for saving the scan history.

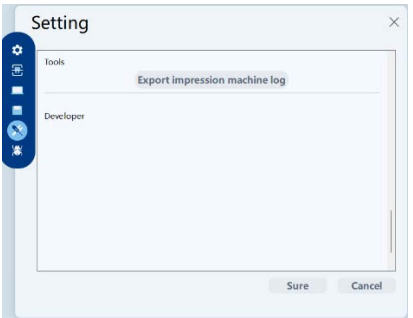
Save date: After auto save scan history is enabled, you can define the number of days for auto save scan history

Save path: After auto save scan history is enabled, you can define the path for auto save scan history

5) Tools

Export impression machine log: You can export scan logs

6) Developer

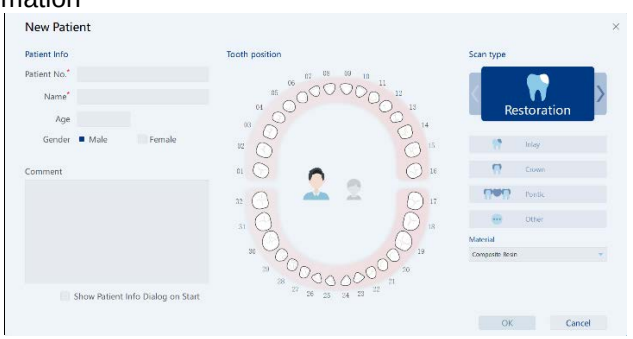


5.2.1.2.5 About

Information about the software version is displayed.

5.2.2 New patient

Click , New patient page is displayed, you can create, modify or view patient information



Patient information: Patient NO., name, age, gender and comment

Tooth position: Adult and child tooth position information

Scan type: Restoration, implant and othodontics

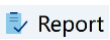
Material: Materials are selected according to patient

5.2.3 Jaw/ bite Switch

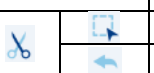
	Upper jaw: Acquires a 3D model of the upper jaw
	Lower jaw: Acquires a 3D model of the lower jaw
	Bites: Acquires a 3D model of the bite

	Implant: Acquires a 3D model of scanning rod

5.2.4 Process guide

	Scan: Enables you to scan the upper and lower jaw, and the bites
	Refine: Refines the acquired 3D model, and enables you to use various tools to check the refined results
	Report: Complete the case information and save the scan results
	Next step: Proceed to the next step
	Previous step: Proceed to previous step

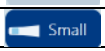
5.2.5 Data editing toolbar

	Swap upper and lower jaws: Changes the acquisition mode from upper to lower or vice versa, if you accidentally scan teeth on the wrong jaw.
	Free cut: draw a curve to delete unnecessary data.
	Undo: Return to previous step
	Zoom fit: Scales the 3D model to the best size to fit the display region.
	Show 3D center：Show 3D model center
	Io camera: Enables you to select intraoral images
	Add tooth mark: Mark one or more preparation areas
	Delete tooth mark: Delete marked preparation area
	Lock area: Lock an area on the model to prevent it from being updated by additional scanning
	Take snapshot: Take a snapshot of the 3D model displayed on the screen
	Color mode: When selected, displays the 3D model in the actual color. When deselected, displays the 3D model in monochrome
	Vivid display mode: After the color mode is selected, select the Vivid display mode, the model color is more realistic
	Circle cut: draw a circle to delete unnecessary data.
	Undo: Return to previous step
	Delete: Delete all models from the current case.

5.2.6 Data refining toolbar

		Front view
		Back view
		Right view
		Left view
		Top view
		Bottom view
		Show occlusion analysis: Check the bite surface penetration results
		Switch view: Unfold the bite surface penetration results
		Clipping mode：Selecet a clipping mode
		Reset：Reset a new section

5.2.7 Scanning assistant

	Non-highlight surface scanning
	Highlight surface scanning
	Selecet it when connecting reusable tip size L
	Selecet it when connecting reusable tip size S
	Auto exposure: When turned on, the scanner adjusts the scanner light intensity according to the ambient light automatically
	AI: When turned on, soft tissue is removed during the scanning automatically

5.2.8 3D model display area

Displays the 3D model created by the scanner

5.2.9 Video preview area

Displays live video when scanning, or the scanner status when not scanning.

	Scanner is not connected
	Scanner is connectting
	Scanner is in the holder

5.2.10 Report saving

Click  , Save scan data locally in STL/PLY format

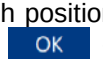
6. Clinical Guide

6.1 Restoration process

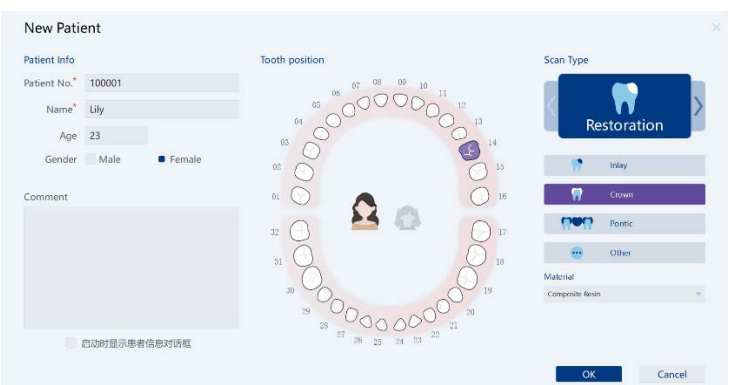
6.1.1 User login

Startup software  ，fill in Username, Password and verification code，and click 

6.1.2 New patient

Click  to open the new order process: fill in the information such as Patient NO., name, age, gender and comment, select tooth position and scan type, Restoration(Inlay, Crown, Pontic, Other), and click 

to enter the scan process.



⚠

- Scanner USB inserted into workstation, If the scanner not connect, click 

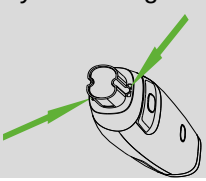
6.1.3 Upper Jaw/ Lower Jaw scan

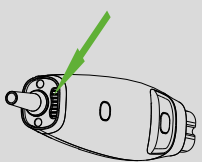
1) Select  /  according to the Reusable tip，select the  /  ，OR press the button  on the scanner to select the upper jaw mode  / lower jaw mode 

⚠

- If there is a preparation area, retract the gingiva by gingival restriction cords. And extract the cords just before scanning the preparation.
- Before starting the scan, dry the teeth thoroughly.
- During the scanning process, adjust the surgical light to keep the light away from the patient's mouth to avoid interference with the scanner.
- It is recommended to activate during scanning to automatically remove soft tissue.
- It is recommended to activate during scanning, the scanner automatically adjusts the scanning light intensity, which is conducive to the scanning accuracy.

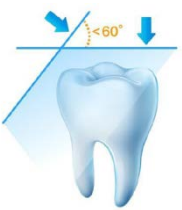
- Reusable tips received from the manufacturer are NOT sterilized. You must sterilize them before the first use.
- For detailed information on cleaning, disinfection and sterilization, please refer to the Helios 500 User Manual: cleaning, disinfection and sterilization.
- Avoid any liquid from leaking into the air outlet near the tip mount or the air inlet at the rear of the scanner (see the figure below), otherwise the scanner may be damaged.



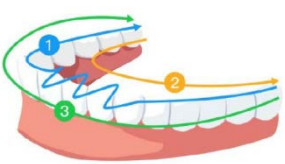


2) To start scanning, place the tip of the scanner on the surface of the tooth to stabilize the scanner and press the button on the scaner. Wait until a 3D image appears in the 3D model display screen, and then slowly move it along the arch at 0-5mm from the teeth.

3) The recommended scanning method is to start with a molar, since it has greater details for easier identification. Change the scanning angle to less than 60 degrees during scanning to allow the surfaces to overlap, if the overlap is too small, the alignment may be lost.



4) The recommended scanning protocol consisting of 3 sweeps: occlusal, lingual and buccal to ensure good data coverage of all surfaces. It is recommended to start the first sweep from the bite surface. If there is a preparation, start with preparation so that the gingival area can be scanned before gum collapses; if there is no preparation (for example, in orthodontic cases), you should start with the first molar. The second sweep can scan both the lingual and buccal sides, and the third scan covers the opposite side of the second sweep.



6.1.4 Data editing

After pressing the button  on the scanner to stop scanning, the software

will automatically repair the holes in the model and mark the color, you can do the following during or after the scanning

Hold down the middle mouse button to zoom in and out of the model

Hold down the left mouse button and drag the mouse to rotate the model

Click  to exchange the upper jaw and lower jaw

Click  in  draw a curve on the 3D model to delete unnecessary data.

Click  in  to undo the previous step

Click  to scale the 3D model to the best view

Click  Show 3D center

Select  , displays the 3D model in the actual color. When deselected, displays the 3D model in monochrome

Select  , then select  , the model color is more realistic

Adjust model perspective, click  , capture the model image

Click  to take a snapshot of the 3D model displayed on the screen

Click  to delete the model

- The holes will be displayed in green. It is recommended to scan these areas until the holes disappear.
- Re-dry the teeth as appropriate throughout the acquisition process.

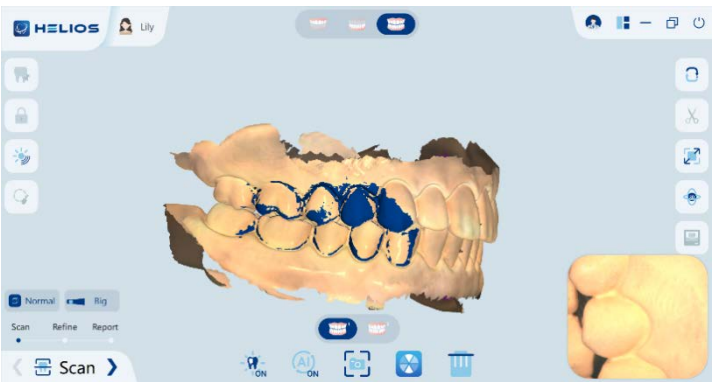
6.1.5 Scanning the bites

1) select the  , OR press the button  on the scanner to select the bites mode 

2) Place the tip of the scanner into the buccal side in the patient's mouth, then rotate the tip to align with the teeth, close the patient's mouth and confirm that

the bite position is correct.

3) Press the button  the scanner, slowly move the scanner tip in mesial direction with equal coverage of upper and lower teeth. The example below shows a bites.

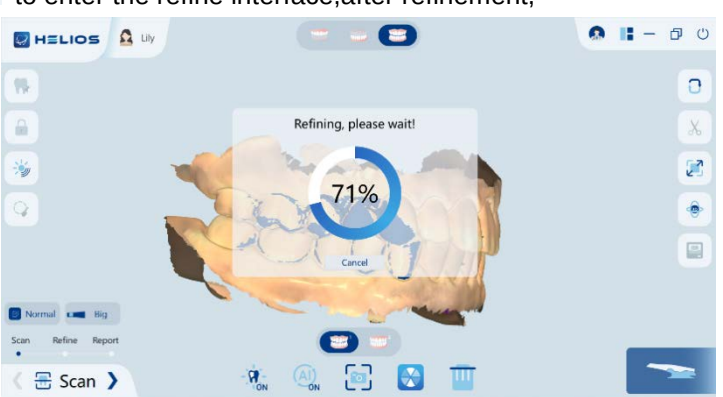


- You can scan one or two bites. It is recommended to scan one on the left side and one on the right side of the patient's mouth

4) After scanning the bites, rotate the model and zoom the view to ensure that the bite is accurate and that there are no areas where the bite is mismatched. If necessary, you can delete the scanned occlusion and rescan.

6.1.6 Refine the 3D Model

Click  to enter the refine interface,after refinement,



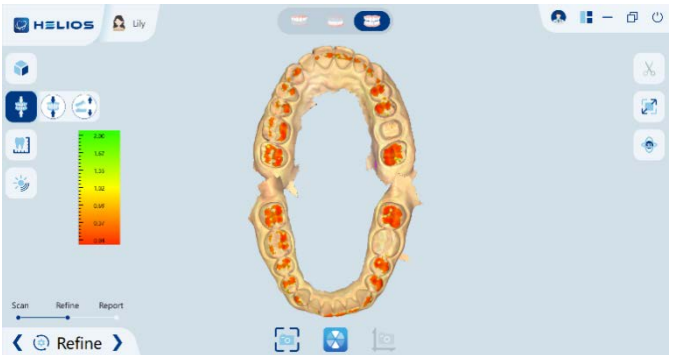
6.1.6.1 View orientation

Click , Select a perspective to view the model

6.1.6.2 Occlusion analysis

Click to check the bite surface penetration results

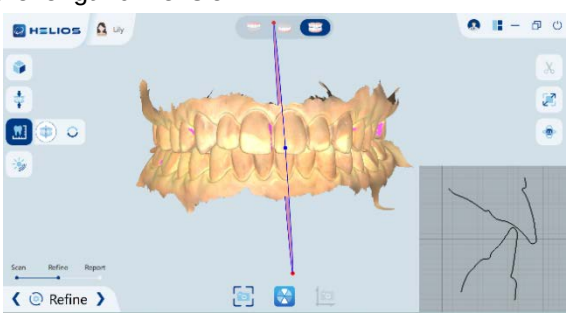
Click to check the bite surface penetration results from the front



6.1.6.3 Measurement

Click , then create a section, the section outline is displayed on the right. Click display different clipping mode. Click to reseat a new section;

The left button of mouse selects the two points to be measured and generates the length dimension.

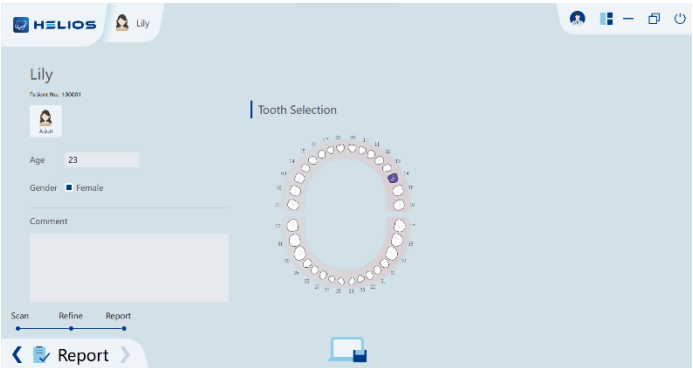


6.1.7 Completing and Saving the case

Click to enter the report interface

Complete the patient information, if necessary, you can add some more information to the case.

Click to save the case to the workstation, the storage format is STL and PLY.

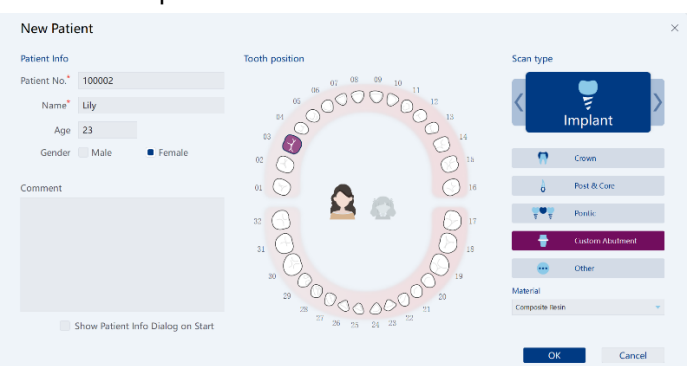


6.2 Implant process

6.2.1 User login

6.2.2 New patient

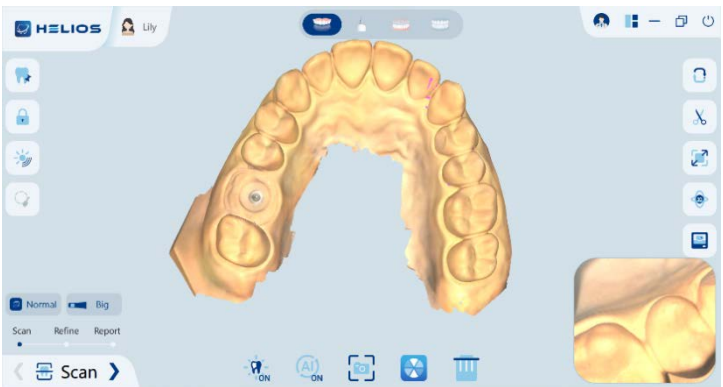
Click to open the new order process: fill in the information such as Patient NO., name, age, gender and comment, select tooth position and scan type, Implant(Crown, Post & Core, Pontic, Custom Abutment, Other), and click OK to enter the scan process.



- Scanner USB inserted into workstation, If the scanner not connect, click

6.2.3 Upper Jaw/ Lower Jaw scan

Remove the healing abutment, adjust the scanning jaw position to the jaw position from which the healing abutment was removed, press the button on the scanner to activate the scanner, and scan the gum section immediately (before gum collapse), then refer to 6.1.3 to complete the scanning of the healing abutment jaw and the opposite jaw



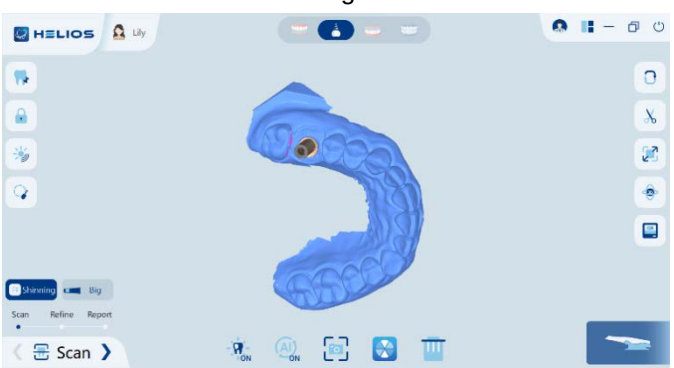
6.2.4 Scanning of the scanning rod

1) Click , Switch to implant;

2) Click , Circle the portion of the implant, and the circled area is automatically removed, If you are not satisfied with the removed part, you can continue to remove it or click to undo the removal of the previous step.

Fold , the circled area would be extended outward for a certain distance, the remaining part would be locked, Select the area around the gum portion that needs to be locked to lock so that the locked area is not affected by soft tissue collapse when further scans are performed

3) Attach the scanning rod to the implant and scan from 1-2 teeth near the scanning rod so that the system can identify the 3D model until completing scanning and then remove the scanning rod.



⚠

- Selecting Shinning to help scan accuracy when scanning high-light surfaces such as implants, scanning rod.

6.2.5 Data editing

Reference to 6.1.4 Data editing

6.2.6 Scanning the bites

Reference to 6.1.5

6.2.7 Refine the 3D Model

Reference to 6.1.6

6.2.8 Completing and Saving the case

Reference to 6.1.7

6.3 Othodontics process

6.3.1 User login

6.3.2 New patient

Click  to open the new order process: fill in the information such as Patient NO., name, age, gender and comment, select tooth position and scan type, Othodontics, and click OK to enter the scan process.

- Scanner USB inserted into workstation, If the scanner not connect, click 

6.3.3 Upper Jaw/ Lower Jaw scan

Reference to 6.1.3

6.3.4 Data editing

Reference to 6.1.4

6.3.5 Scanning the bites

Reference to 6.1.5

6.3.6 Refine the 3D Model

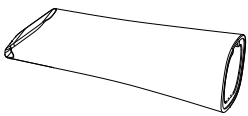
Reference to 6.1.6

6.3.7 Completing and Saving the case

Reference to 6.1.7

7 Cleaning disinfection and sterilization

7.1 Cleaning disinfection and sterilization of the reusable tip

<table>
<tr><td colspan="2">Autoclavable Components</td></tr>
<tr><td>Reusable tip</td><td>  </td></tr>
<tr><td colspan="2">⚠
● Only the component above can be autoclaved.
● Before first use and after each use, clean disinfect and sterilize the above component.
● Sterilization should be no more than 60 cycles，After 60 cycles, discard it.</td></tr>
<tr><td colspan="2">Reprocessing Instructions</td></tr>
<tr><td>Preparation at the Point of Use:</td><td>Before cleaning, disconnect the component from the Helios 500. Remove gross contaminations from the components with cold water (<40°C) immediately after use. Don’t use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Store the components in a humid surrounding.
⚠
Do not submerge the components or wipe them with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the components.</td></tr>
<tr><td>Transportation:</td><td>Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.</td></tr>
<tr><td>Preparation for Decontamination:</td><td>The devices must be reprocessed in a disassembled state.
⚠
Observe suitable personal protective measures.</td></tr>
<tr><td>Pre-Cleaning:</td><td>Do a manual pre-cleaning, until the components are visually clean. Submerge the components in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean</td></tr>
</table>

	the surfaces with a soft bristol brush.
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program: • 4 min pre-washing with cold water (<40°C); • Emptying; • 5 min washing with a mild alkaline cleaner at 55°C; • Emptying; • 3 min neutralising with warm water (>40°C); • Emptying; • 5 min intermediate rinsing with warm water (>40°C); • Emptying; The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note Acc. to EN ISO 17664-1 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.  ● Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Follow instructions and observe concentrations given by the manufacturer (see general recommendations).
Disinfection:	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN ISO 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000. After automated cleaning, the components should be automatedly disinfected immediately. A manual disinfection is not recommended.
Drying:	Automated Drying: Dry the outside of the components through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of the components

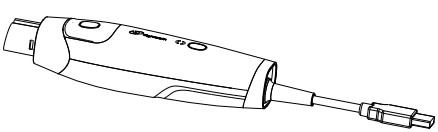
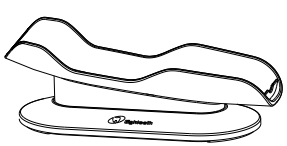
	by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspect the cleanliness of the components and reassemble them. Conduct functional testing according to instructions of use. If necessary, perform reprocessing process again until the components are visibly clean. Before packaging and autoclaving, make sure that the components have been maintained according to the manufacturer's instruction.
Packaging:	Pack the components in an appropriate packaging material for sterilization.  ● Check the validity period of pouch given by the manufacturer to determine the shelf life. ● Use pouches which resist to a temperature up to 141℃ and in accordance with EN ISO 11607.
Sterilization:	Sterilize the components by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134 °C (in EU: 5 min at 134 °C). Maximum sterilization temperature: 137°C. Drying time: at least 8min. Flash sterilization is not allowed on lumen instruments!  ● Use only approved autoclave devices according to EN 13060 or EN 285. ● Use a validated sterilization procedure according to EN ISO 17665. ● Respect the maintenance procedure of the autoclave device given by the manufacturer. ● Use only this recommended sterilization procedure. ● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters). ● The sterilization procedure must comply with EN ISO 17665. ● Waiting for cooling before touching.
Storage:	Store the sterilized components in a dry, clean and dust free environment at modest temperatures, refer to labels and instructions for use.

	⚠ ● Sterility cannot be guaranteed if packaging is open, damaged or wet. ● Check the packaging before using it (packaging integrity, no humidity and validity period).

⚠

- Before sterilization, please remove the reusable tip.
- The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

7.2 Cleaning disinfection of the scanner and holder of scanner

Disinfection components	
Scanner 	Holder of scanner 
Preparation before processing:	Before cleaning and disinfecting, make sure the power is off.
Cleaning:	Wipe all the exterior surfaces of the components thoroughly with a cloth lightly moistened with Ethanol (Ethanol 70 to 80 vol%) at least 3 min, repeat for 5 times.
Disinfection:	Wipe all the exterior surfaces of the components thoroughly with a cloth lightly moistened with Ethanol (Ethanol 70 to 80 vol%) at least 3 min, repeat for 5 times.

Drying:	Use a lint free cloth to wipe the surfaces.
Inspection and maintenance:	Visual inspection for cleanliness of the components. Functional testing according to the user manual. If necessary, perform reprocessing process again until the components are visibly clean. Before packaging, make sure that the components have been maintained according to the manufacturer's instruction.
Storage:	Storage of the processed device in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

- Before first use and after each use, clean and disinfect the above components.
- Do not use anything except Ethanol for Disinfection (Ethanol 70 to 80 vol%).
- Do not use too much ethanol as it's going into machine and damage the components inside.
- Do not allow any moisture to get into the device.

8 Troubleshooting

Helios 500 Troubleshooting Instructions

Problem Description	Action
There is mismatching and overlap in the 3D image.	Remove mismatched data and excessive tissue using the Cut tool and rescan.
After bites, there is a gap or intersection between the upper jaw and the lower jaw.	Delete the incorrect bite view, and rescan. Enable bite optimization option.
Precision degradation is observed, or images are not well-stitched during acquisition.	Ensure that the lens window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue. Use a lens tissue or lint-free cloth to remove any dust or water stains. Make sure the tip is firmly installed and there are no dark edges on the live video.
Reconstruction of metallic preparations is sometimes difficult.	Adjust the scanner position (for example: distance or angle) and scan more of the area. Move the surgical light away from the patient to decrease light scatter. Turn on Shining Surface
The tip is installed but not detected. No live video is displayed, and the Scanner tip is not detected icon is displayed at the bottom-right of the interface.	Reinstall the tip, and make sure the tip is in firm contact with the scanner.
Fogging appears on the inner surface of the lens window at the base of the scanner.	Mount a completely dry tip on the scanner, and place the scanner in the holder or set it on the desk, and wait until the fogging fades. If the fogging does not disappear completely after 24 hours, contact your local service provider for assistance. Ensure that the tip is thoroughly dry before mounting on the scanner, and do not use a cloth soaked in disinfectant to clean the scanner.

9 Electromagnetic Compatibility Precautions

- This equipment conforms to IEC 60601-1-2: 2014 + AMD1: 2020 EMC requirements and tests, Medical Electrical Equipment including CSIPR11:2009+A1:2010 Group 1, Class B
- The equipment should be installed and used according to the EMC information provided in the attachment
- Guidance and manufacturer's declaration refer to the attachment

- Portable and mobile 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 Helios 500, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify normal operation.
- The use of cables or accessories other than those specified, with the exception of those sold by the manufacturer of the equipment, as replacement parts for internal components may result in increased emissions or decreased immunity of the medical equipment.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Power cable	1.8	YES	/

Attachment

Guidance and manufacturer's declaration – electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1 Class B	The equipment 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.

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/-8 kV contact +/-15kV air	+/-2, 4, 6 & 8kV contact +/-2, 4, 8, & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	3 & 30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The equipment is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the equipment by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
	6Vrms in ISM bands between 0,15 MHz and 80 MHz	(E1)= 6Vrms in ISM bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	(E1)=3V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter. 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).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The equipment is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			

1. 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 Model 005 is used exceeds the applicable RF compliance level above, the Model 005 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 005.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.
3. The ISM (industrial, scientific and medical) bands between 0.15 MHz 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. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Recommended minimum separation distances
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity

to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The equipment has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the equipment as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,	Pulse modulation 217Hz	2	0.3	28

		4, 25; UMTS				
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 **5500** **5785**	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

10 Technical Specification

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	Helios 500
Dimensions	48cm x 40cm x 21cm ± 2cm(package)
Gross Weight	3Kg±10%
Color	3D full color
Connectivity	USB 3.0
Power source	USB 3.0 5V, 900mA
Field of view	Reusable tip(Size L)：16mm x 14mm Reusable tip(Size S)：12mm x 12mm
Depth of view	16mm
Applied part	BF（Reusable tip）
Operating System	Windows 10/11(x64)
Operating Conditions	Ambient temperature: 15 °C~30 °C Relative humidity: 10% ~ 65 % Atmospheric pressure: 70kPa~106kPa
Transport and storage conditions	Ambient temperature: -10 °C~60 °C Relative humidity: 10% ~ 95 % Atmospheric pressure: 60kPa~106kPa
Configuration Requirement of Workstation(Standard edition)	Processor: Intel® CoreTM i5 12^{TH} Generation, base frequency 2.4 GHz Memory: 16 GB DDR4, frequency 2666MHz Disk: 256G SSD Display: FHD1920 x 1080 or more Others: USB 3.0 port Graphics card: NVIDIA® GeForce® GTX 1650 or more

Configuration Requirement of Workstation(Performance edition)	Processor: Intel® CoreTM i7 12TH Generation, base frequency 2.6 GHz Memory: 16 GB DDR4, frequency 2666MHz Disk: 512G SSD Display: FHD1920 x 1080 or more Others: USB 3.0 port Graphics card: NVIDIA® GeForce® GTX 1650 or more
⚠ It is MANDATORY to check that your system configuration is compatible with the workstation system requirements for the Helios 500 software.	

11 Statement

Service Life

The service life of Helios 500 series products is 5 years.

Warranty Period

The scanner of Helios 500 has a 12-month warranty period starting from the date of delivery to the customer. If the damage is proved to be caused by the user's use error, warranty is voided.

Maintenance

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, operation instructions to assist to SERVICE PERSONNEL in parts repair.

Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

Rights

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