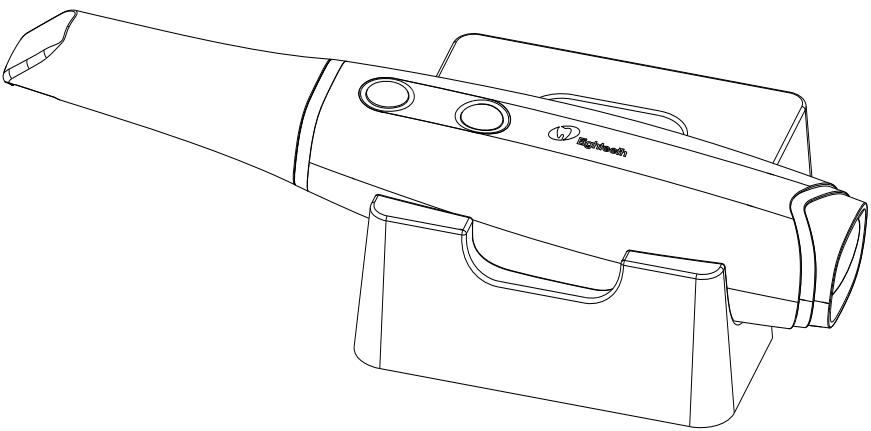
Eighteeth



Helios 700

USER MANUAL

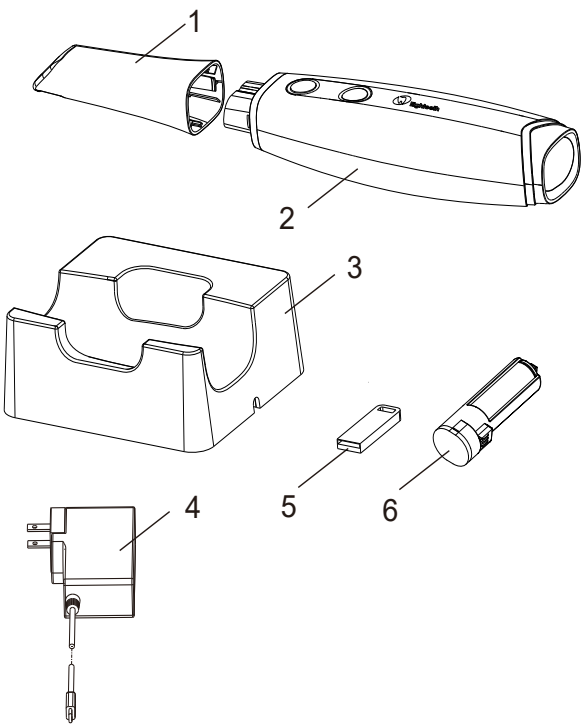
Changzhou Sifary Medical Technology Co., Ltd.

Table of Contents

1 Helios 700 Components

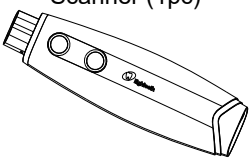
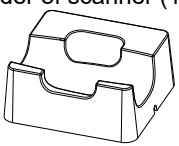
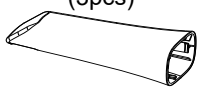
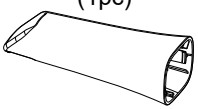
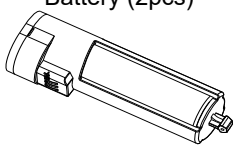
1.1 Parts Identification

1. Reusable tip
2. Scanner
3. Holder of scanner
4. Adapter
5. USB flash driver
6. Battery

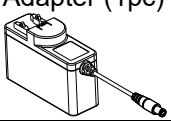
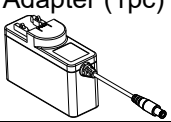
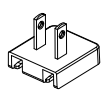
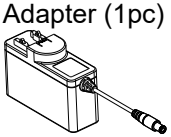
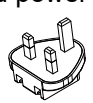
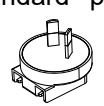
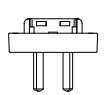


Note: The scanner connects to the software through a wireless connection. Before using the scanner, a compatible wireless adapter needs to be connected to the workstation running the software. The workstation and wireless adapter are not included in this product. The wireless adapter, serving as the network adapter for detecting the scanner's signal, must be purchased separately according to the recommended models. Recommended models include TP-Link TL-XDN9000 and UGREEN AC1300. Please select a wireless adapter that complies with local multimedia IT equipment certification.

1.2 Packing list

Scanner (1pc) 	Holder of scanner (1pc) 	Reusable tip (Size L) (3pcs) 
Reusable tip (Size S) (1pc) 	USB flash driver (1pc) 	Battery (2pcs) 

For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
European standard	Adapter (1pc) 	European standard power plug (1pc) 
American standard	Adapter (1pc) 	American standard power plug (1pc) 
Multi-standard	Adapter (1pc) 	British standard power plug (1pc) 
		Australian standard power plug (1pc) 
		Argentina standard power plug (1pc) 

2 Symbols

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Manufacturer
	Country of manufacture + Date of manufacture
	Washer-disinfector for thermal disinfection
	Type BF applied part
	Keep dry
	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 limitation
	Humidity limitation
	Atmospheric pressure limitation

3 Introduction

3.1 Indications for Use

The Helios 700 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.

This device should only be used in hospitals or clinics by trained and qualified professionals such as dentists.

The Helios 700 could be used for both adult and children in clinical practice.

The Helios 700 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 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 the distributor.

- 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 and remove the baterry, and contact the distributor.
- 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.
- 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.
- Do not position the device where it is difficult to disconnect the power.

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.

Battery

- Do not disassemble or crush the battery.
- Do not expose the battery to high-temperature environments; do not store the battery in direct sunlight.
- Prevent the battery from mechanical impact.
- Use only the original power adapter for charging.
- Do not use batteries other than those specified by the company.
- If the device is not used for a long period, do not keep it continuously charging. Remove the battery from the device.
- If the battery is not used for an extended period, multiple charge and discharge cycles may be required to achieve optimal performance.
- Keep the battery clean and dry.
- Only trained professionals should replace the battery. Using an incorrect battery or improper installation may damage the electronic components.

Wi-Fi

For Intraoral scanner:

- Please take attenion that changes or modifcation not expresly approved by the party responsible for complance could void the user's authorly to operate the

equipment.

- 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.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

For Holder of scanner:

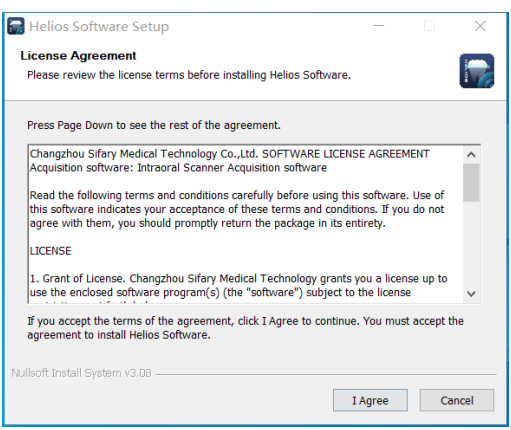
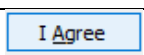
- Any modifications or adjustments not expressly approved by the compliance authority may result in the revocation of the user's authorization to operate this device.
- Please take attenion that changes or modifcation not expresly approved by the party responsible for complance could void the user's authorly to operate the equipment.
- 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.
- This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

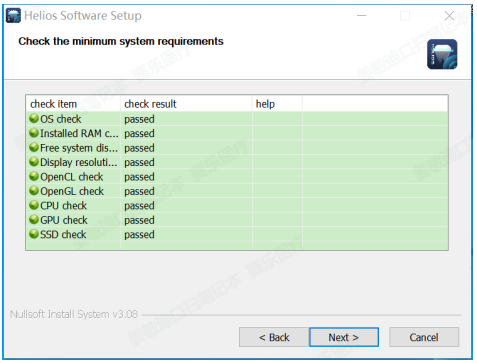
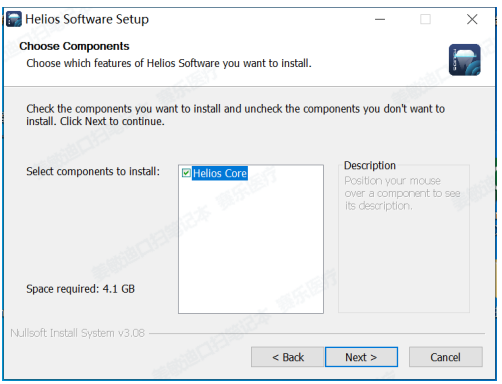
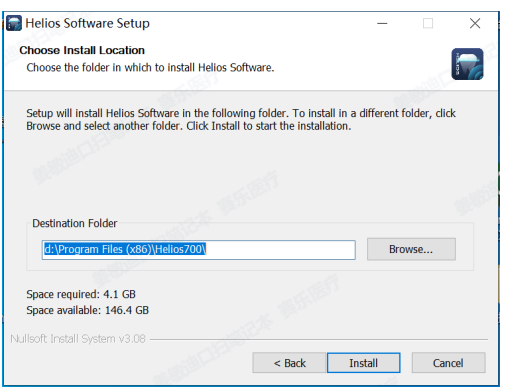
4 Product Installing

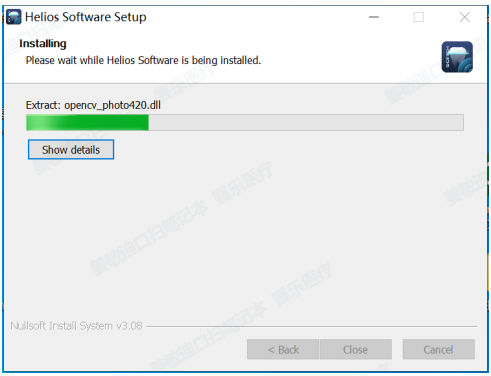
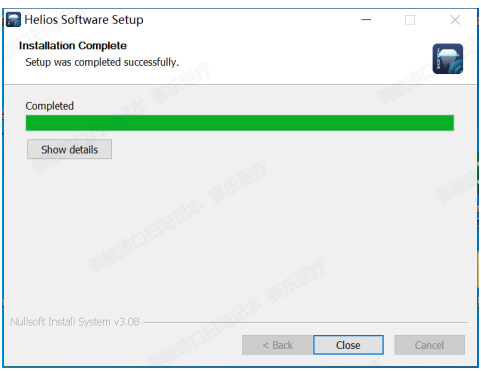
4.1 Installation Environment Requirements

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.

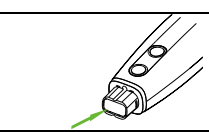
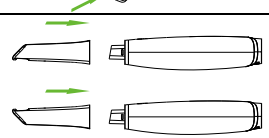
4.2 Software Installing

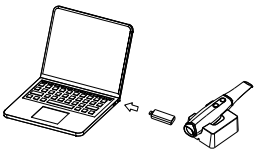
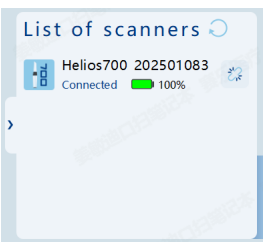
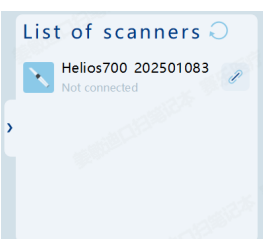
Step	Graphic Example	Description
1		The Helios image processing software is stored on the USB flash drive. Connect the USB flash driver to the workstation and open it. Double Click 
2		Click 

3		Click Next >
4		Click Next >
5		Select the installation location and click Install

6		Wait until the software installation complete
7		Software installation complete, click Close

4.3 Connecting the Helios 700 to the workstation

Step	Graphic Example	Description
1		Insert the battery into the scanner.
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 wireless adapter to any USB 3.0 port on the workstation. For details on how to establish the connection, please refer to the user manual of the purchased wireless adapter. ⚠ ● Make sure the wireless adapter is connected to the USB 3.0 port. ● If connected to a USB 2.0 port, the wireless adapter may not work properly.
5		After opening the scanning interface, select the scanner you need to connect from the list of scanners at the bottom right, and click the connection icon on the right to connect. Once connected, remove the scanner from the holder of scanner, and the scanner will turn on automatically. 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. Click the connection icon on the right again, and the scanner will disconnect.

⚠
- All IT components electrically connected to the Helios 700 must confirm to IEC 60950-1/ IEC 62368-1.

4.4 Software Update

If there is an update of Helios 700 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 Charging

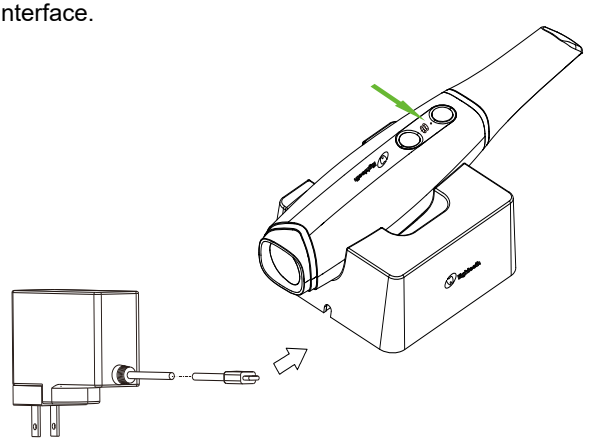
This product is equipped with two batteries: one as the internal battery in the scanner

main unit and one as a spare battery in the holder of scanner. When the scanner main unit's battery indicator light is solid red, it indicates that the battery is about to run out. Please charge it promptly or replace it with the spare battery.

The charging method is as follows:

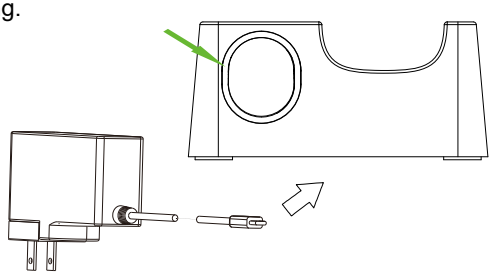
1. Scanner internal battery charging

Place the scanner on the holder of scanner, insert the Type-C plug of the power adapter into the charging port at the bottom of the holder of scanner, and connect the other end to the power supply. After standing idle for ten minutes, the charging indicator on the scanner's main unit interface will display the charging status. You can check the scanner's battery level by clicking on the scanner list in the workstation interface.



2. Spare Battery Charging

Insert the battery into the holder of scanner, plug the Type-C connector of the power adapter into the charging port at the bottom of the holder of scanner, and connect the other end to the power supply. At this time, the battery charging indicator on the holder's user interface will flash blue, indicating that the spare battery is charging.



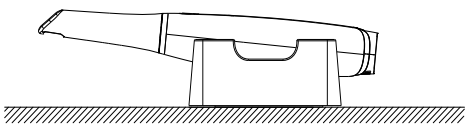
⚠

- Please use the original power adapter for charging. Using a non-original power adapter may damage the device.

- Ensure that the power adapter plug is correctly inserted into the charging port at the bottom of the holder.
- Please fully charge the new battery before use.
- Do not position the device where it is difficult to disconnect the power.

4.6 Scanner placement

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

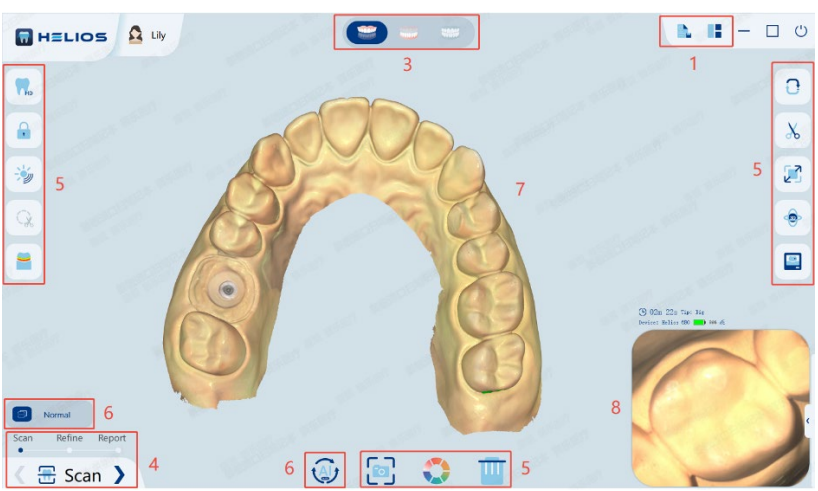
The holder can be used as a desktop mount holder. Place the scanner in the holder when you are not using it.	

5. Software Introduction

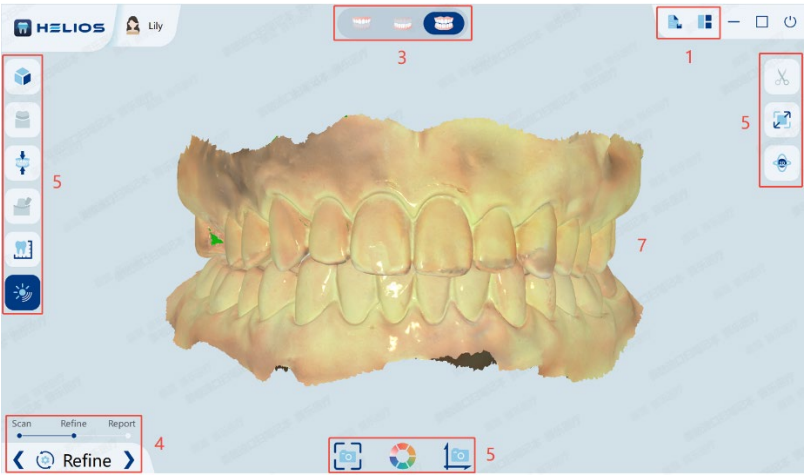
5.1 Interface

5.1.1 Login interface

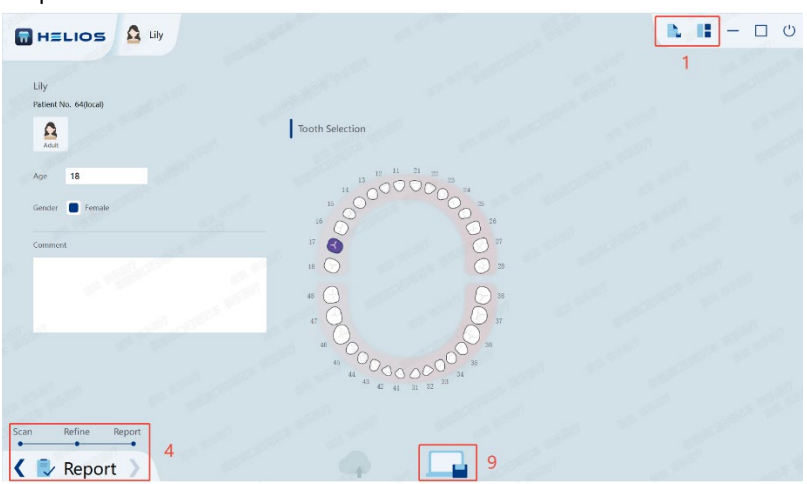
5.1.2 Scan interface.



5.1.3 Refine interface



5.1.4 Report interface



5.1.5 Requirement information list interface

No.	Menu Bar	Basic setup	Detailed content Explanation
1	Option Menu	Save scan history, user information and More options	See 5.2.1
2	Requirement information list	Order List and Patient List	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 toolbar	Refine 3D model	See 5.2.5
6	Scanning assistant	Benefite to obtain 3D model	See 5.2.6
7	3D model display area	Displays the 3D model created by the scanner	See 5.2.7
8	ScannerList and Video preview area	During scanning, the list of scanner automatically collapses and displays the live video of the scanned teeth. When not scanning, the list of scanner automatically opens. Click the collapse icon on the left side of the scanner list to view the scanner status.	See 5.2.8
9	Report saving	Save scan data locally in STL/PLY/OBJ format	See 5.2.9

5.2 Interface Overview

5.2.1 Option Menu

5.2.1.1 Save scan history

Click  , save the scan history.

5.2.1.2 User information

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

5.2.1.3 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 HZIP 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 HZIP format can be imported into the software.

5.2.1.2.2 Export scan data

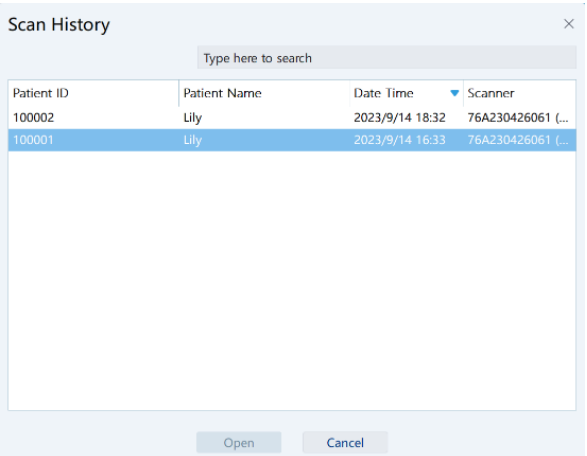
The Export scan data option allows users to save scan data locally in HZIP format for subsequent import to continue scanning or other operations.

⚠

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

5.2.1.2.3 Scan historys

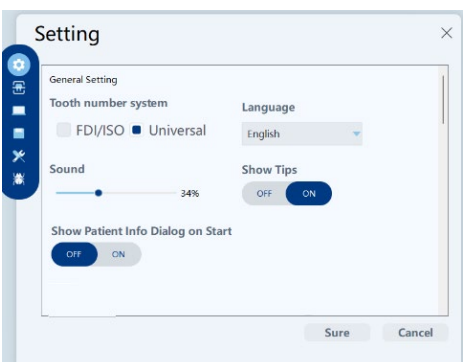
Scan records are saved in the scan historys, searching for patient information to open the previous scan data by the scan historys.



- In Settings option, you can set the Auto save scan history, Save date, Save path.
- Click on any record in the "Scan History" list, then click the "Open" icon to restore the historical data of the selected record.

5.2.1.2.4 Settings

1) General Setting



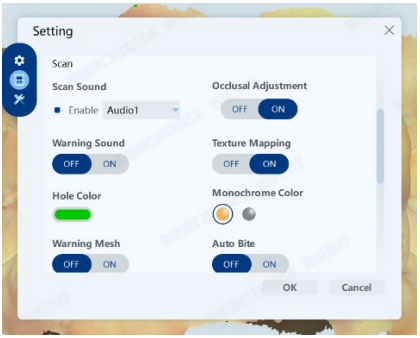
Tooth number system: Select the FDI/ISO or Universal as the tooth numbering system.

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

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).

Texture Mapping: When enabled, the scanned 3D model appears more realistic.

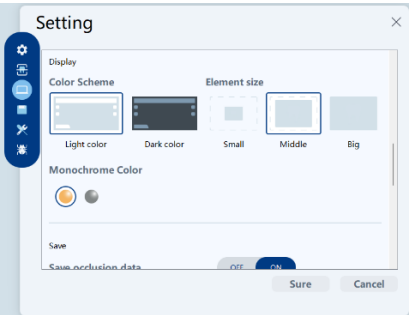
Hole Color: After optimization, the software fills the holes in the model with the specified color.

Monochrome Color: Select the color for displaying the 3D model in monochrome mode.

Warning Mesh: When enabled, low-quality scan areas are automatically highlighted.

Auto Bite: When enabled, scanning stops automatically upon completion of the occlusion scan; otherwise, it must be stopped manually.

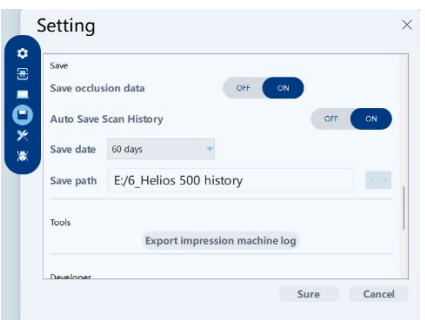
3) Display



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

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

4) Save



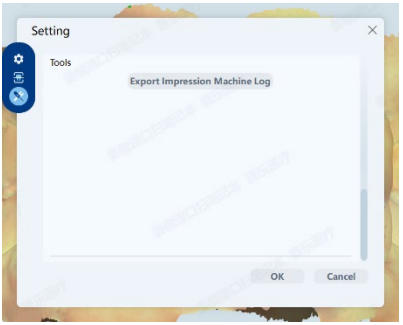
Save occlusal data: When selected, the occlusal registration relationship is saved

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

5.2.1.2.5 About

Information about the software version is displayed.

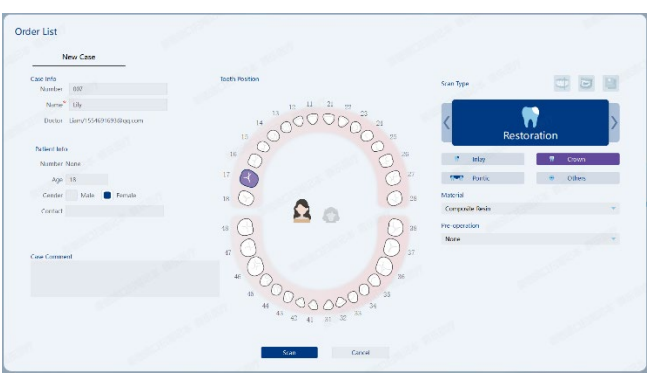
5.2.2 Requirement information list

5.2.2.1 Order List

1. Order List: The case list includes three case statuses: All States, Wait Scan, and Complete Scan, Selecting a different status will display the corresponding cases in the list.

2. Search box: You can enter the case ID or patient name in the search box to find the corresponding case.

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



Case information: Number, Name

Patient information: Age, Gender, Contact, and Case Comment

Tooth position: Adult and child tooth position information

Scan type: Restoration, implant and othodontics

Material: Materials are selected according to patient

Pre-operation: None, Upper jaw, Lower jaw, Upper/Lower jaw

5.2.2.2 Patient List

1. Search box: You can enter the patient name in the search box to find the corresponding case.

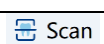
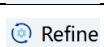
2. Click  , Create a case for this patient, enter the case list, and edit the information.

3. Click  , Select patients can be deleted.

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 the implant
	Upper jaw-Pre-operation: Acquires a 3D model of the upper jaw
	Lower jaw-Pre-operation: Acquires a 3D model of the lower jaw

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 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

 	Select an area to lock: Lock an area on the model to prevent it from being updated by additional scanning
	Undo: Return to previous step
	Vivid display mode: After the color mode is selected, select the Vivid display mode, the model color is more realistic
 	Circle add: add a cirle for implant analog area
	Circle delete: delete a cirle for implant analog area
	Circle cut: confirmation of cuts
	Undo: Return to previous step
 	Circle add: add a cirle for implant analog area
	Circle delete: delete a cirle for implant analog area
	Circle cut: confirmation of cuts
	Undo: Return to previous step
 	Set insertion direction: Set insertion direction of undercut check
	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
	Delete: Delete all models from the current case
	Quadrant snapshot: Displays preview of five 2D image showing different views of the model
 	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
 	Margin line insertion direction: Set insertion direction
	Margin line edit: Edit the inserted margin line
	Reset: Reset a new margin line
 	Clipping mode: Selecet a clipping mode
	Reset: Reset a new section
	Bite refine snapshot: Preview the optimized occlusion
	Delete marker: Delete the selected marker
	Detach maxillary: Separate the upper jaw from the occlusion
	Detach mandible: Separate the lower jaw from the occlusion

		Detach all: Separate both the upper and lower jaws from the occlusion simultaneously
		Zoom fit: Scales the 3D model to the best size to fit the display region
		Undo: Undo the last executed action
		Redo: Redo the last undone action.
		Save & Exit: Save the current data and exit this case

5.2.6 Scanning assistant

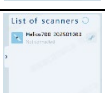
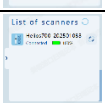
Normal	Non-highlight surface scanning
Shinning	Highlight surface scanning
AI	AI: When turned on, soft tissue is removed during the scanning automatically

5.2.7 3D model display area

Displays the 3D model created by the scanner

5.2.8 Scanner List and Video preview area

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

List of scanners		Scanner is not recognized
		Scanner is not connected, scanner model and serial number will be displayed
		Scanner is connected, scanner model, serial number and remaining power will be displayed
Scanner status		Scanner is in the holder
		Reusable tip is not connected

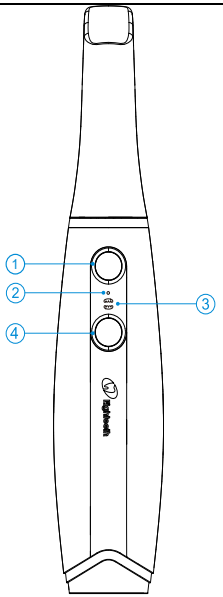
5.2.9 Report saving

Click , Save scan data locally in STL/PLY/OBJ form.

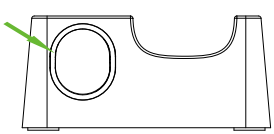
5.3 Buttons and indicator lights

5.3.1 Scanner main unit buttons and indicator lights

	① **Start/ stop scan button** While powered on, press once to start

<table>
<tr>
<td rowspan="4"> 
</td>
<td>scanning, and press again to stop scanning</td>
</tr>
<tr>
<td>② Charging indicator light of scanner
Solid Red: Scanner battery is about to run out
Flashing Blue: Scanner is charging
Solid Blue: Scanner battery is fully charged</td>
</tr>
<tr>
<td>③ Scan mode indicators
Upper jaw scan mode
Lower jaw scan mode
Bites mode</td>
</tr>
<tr>
<td>④ Jaw/ Bite Switch button
During scanning, click to switch the scanning mode</td>
</tr>
</table>

5.3.2 Holder indicator lights

<table>
<tr>
<td>  </td>
<td>Battery charging indicator light
Flashing Blue: Battery is charging
Solid Blue: The proportion of the ring light that remains steadily lit approximately corresponds to the battery level.</td>
</tr>
</table>

6. Clinical Guide

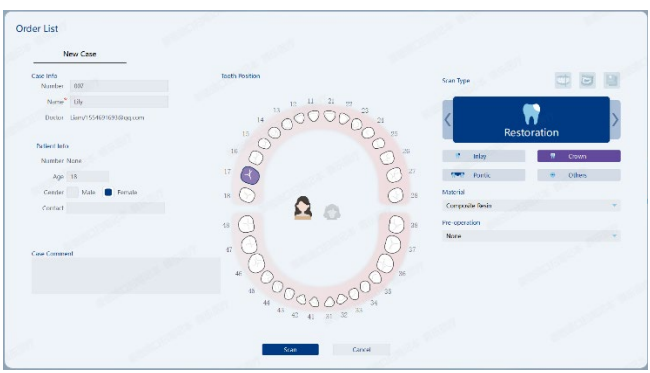
6.1 Restoration process

6.1.1 User login

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

6.1.2 Establish requirement information

Click to open the new order process, Click to copy the case, Click to edit the case: fill in the information such as Name, Age, Gender, Contact and Case Comment, select Tooth Position, Scan Type, Restoration(Inlay, Crown, Pontic, Other), Material and Pre-operation, and click Scan or to enter the scan process.



- Wireless card inserted into workstation, if the scanner is not recognized, click List of scanners.

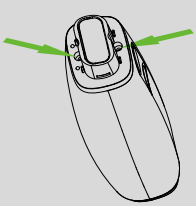
6.1.3 Upper Jaw/ Lower Jaw scan

1) If the Pre-operation select Upper jaw, Lower jaw, or Upper/Lower jaw when establishing the requirement information, you can select the / , or press the Jaw/ Bite Switch button on the scanner to select the upper jaw mode / lower jaw mode . After the procedure, scanning can be performed by selecting the / .

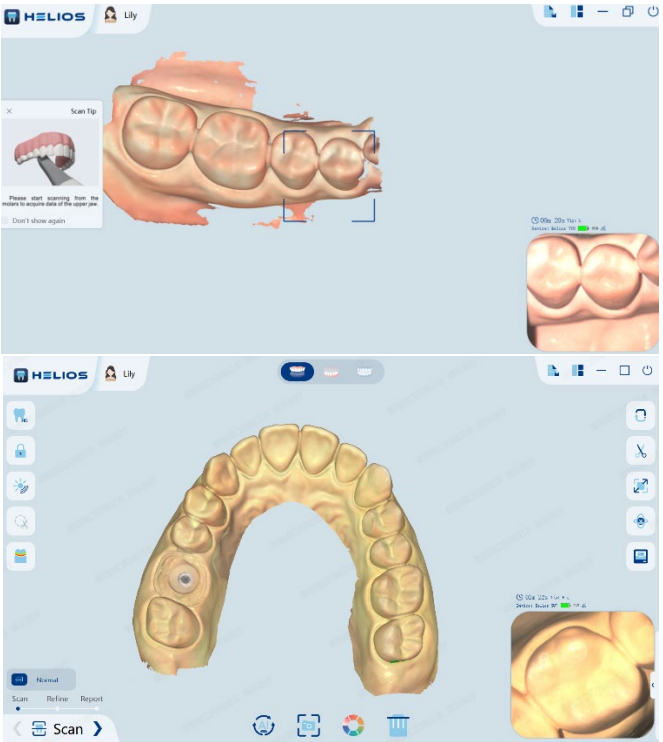
2) If the Pre-operation select None when establishing the requirement information, you can select the / , or press the Jaw/ Bite Switch button on the scanner to select the upper jaw mode / lower jaw mode .

- 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.
- If condensation appears on the mirror, it can be removed within 5 seconds after powering on the scanner.

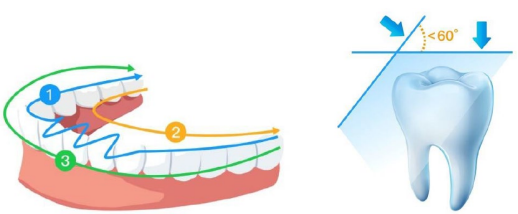
- Reusable tips received from the manufacturer are NOT sterilized. You must sterilize them before the first use.
- For detailed information on cleaning, disinfection and sterilization, please refer to the Helios 700 User Manual: cleaning, disinfection and sterilization.
- Avoid any liquid from leaking 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 start / stop scan 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.

- Holes in the scanned image will be displayed in the system-specified color. It is recommended to scan these areas until the holes disappear.
- During scanning, periodically dry the teeth as needed.
- When the scanning sound is enabled, the workstation will emit a continuous prompt sound during normal scanning. If the sound is interrupted, it indicates that the scan has stopped due to unsuccessful image matching. To continue scanning, return to the previous scanned area until the scanner resumes scanning and the workstation emits a continuous prompt sound again.

6.1.4 Data editing

After pressing the start / stop scan 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

Select  to scale the 3D model to the best view

Select  show 3D center

Select  in  to choose one or multiple areas on the 3D model. The selected areas will not be updated in subsequent scans.

Select  in  to undo the last selected area.

Select  in  and click on the desired area with the mouse to mark it. Select  in  and click on an already marked area to remove the mark.

Adjust the model's orientation, Select  in  to generate undercut detection results. The undercut direction is set to be perpendicular to the screen by default. Rotate the model to view the results.

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 display five 2D images from different perspectives of the 3D model

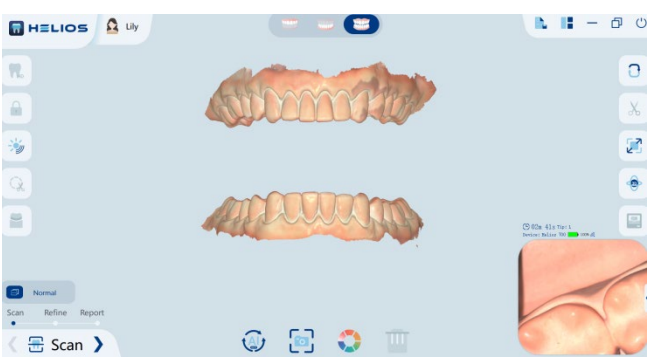
Click to delete the model

6.1.5 Scanning the bites

1) Select the , or press the Jaw/ Bite Switch 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 start / stop scan button on the scanner, slowly move the scanner tip in mesial direction with equal coverage of upper and lower teeth. The example below shows a bites.

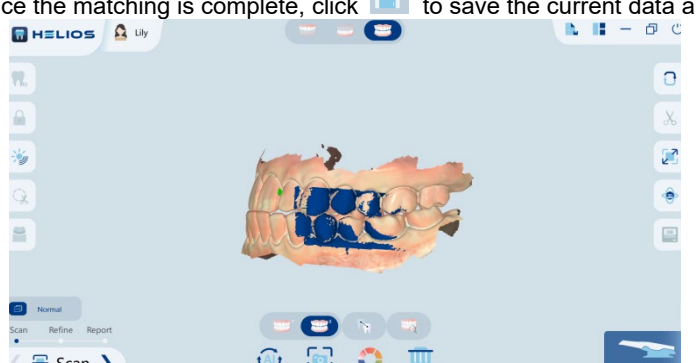


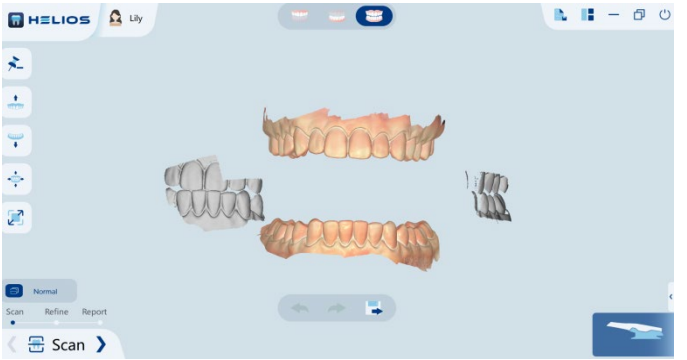
⚠

- 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. When scanning two or more occlusal relationships, click  to preview the optimized occlusion.

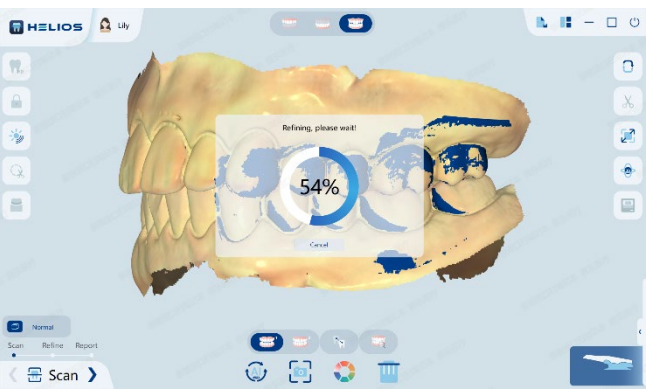
If the bites needs adjustment, click  to enter the bites adjustment interface. Manually select the scanned upper and lower jaws and match the corresponding teeth positions on the model for bites adjustment. Click  ,  , or  to re-match the bites. Click  to revert the last action. Click  to restore the last undone action. Once the matching is complete, click  to save the current data and exit.





6.1.6 Refine the 3D Model

Click ❯ to enter the refine interface

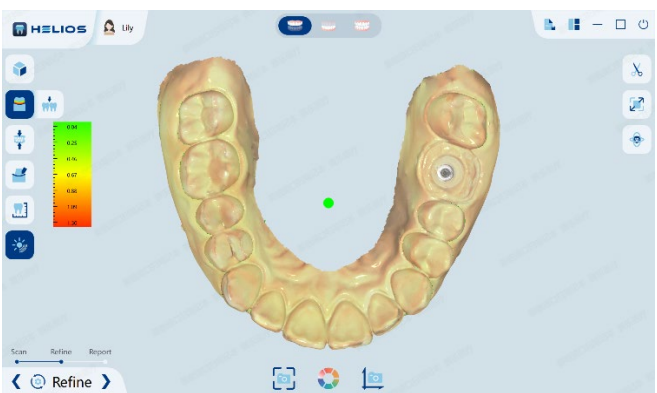


6.1.6.1 View orientation

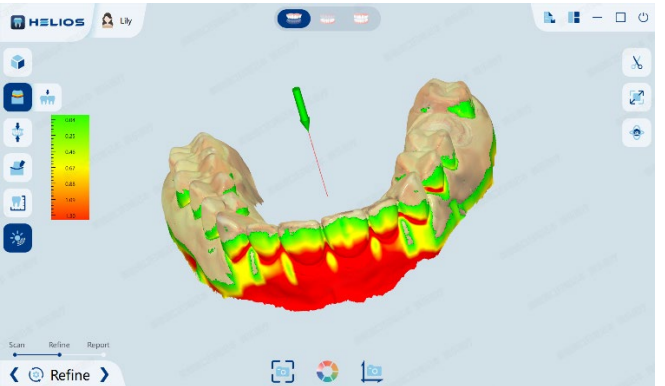
Click , select a perspective to view the model

6.1.6.2 Undercut check

Adjust the orientation of the model, click  in  , set the insertion direction, the direction defaults to vertical screen

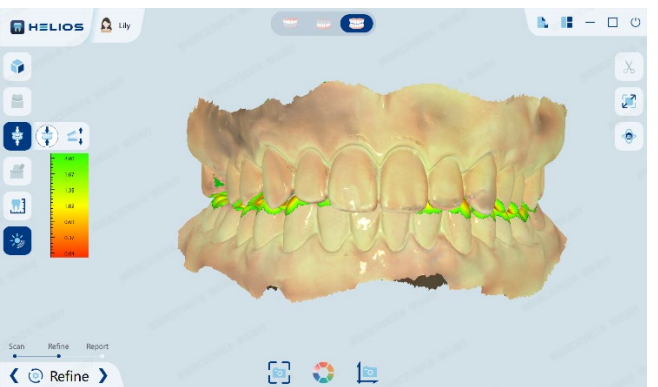


Rotate the model, You can see the results of the Undercut check



6.1.6.3 Occlusion analysis

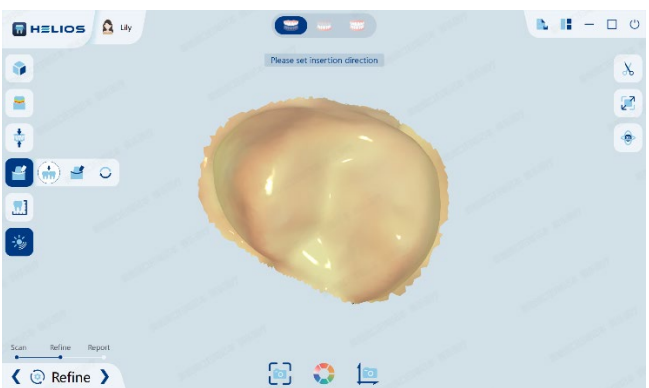
Click  to check the bite surface penetration results



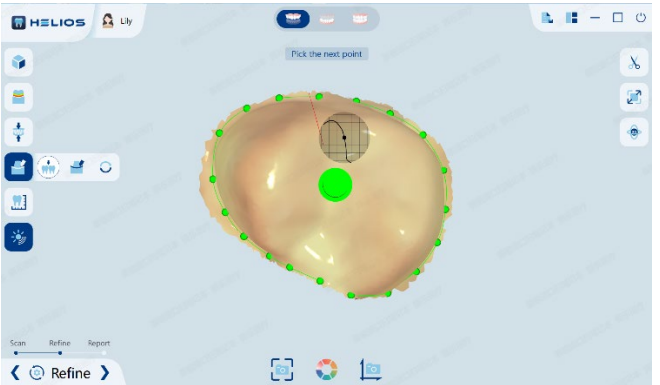
Click  to check the bite surface penetration results from the front

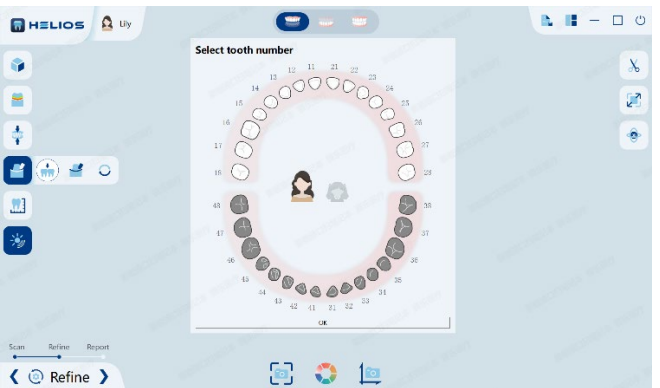
6.1.6.4 Margin line

Click , draw the area of the margin line, click , you can redraw the area of margin line,

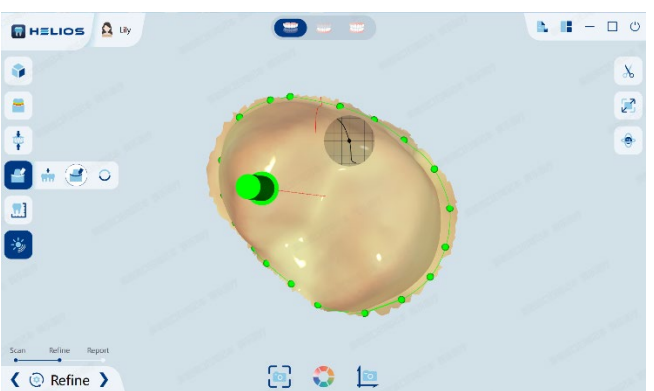


Rotate the model set the insertion direction, the direction defaults to vertical screen, select the point to draw the closed ring, and save the marhin line





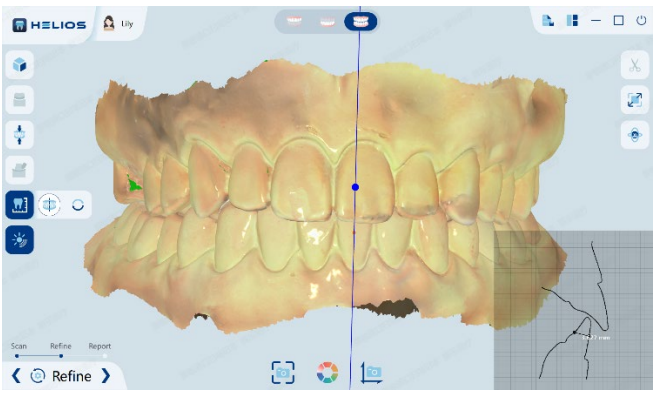
Click  to edit the drawn margin line



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.



6.1.6.4 Other operations

Click in to freely draw and remove selected parts of the 3D model.

Click in to undo the last trimming operation.

Select to scale the 3D model to the optimal view.

Select to display the model center.

Select to display the 3D model in its actual colors; when unselected, the model is shown in monochrome.

When is selected, then selecting makes the model colors appear more realistic.

Adjust the desired model view and click to capture intraoral image data.

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

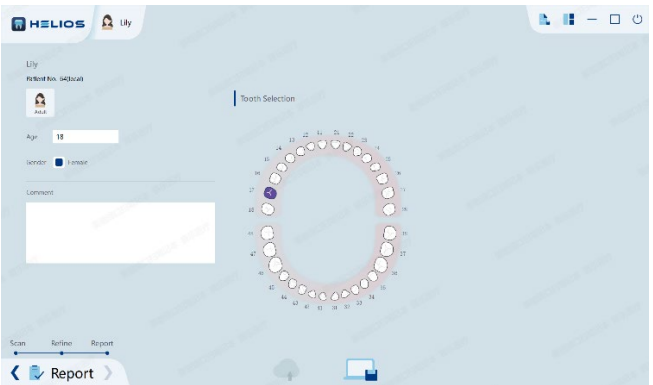
Click to display five 2D images from different perspectives of the 3D model.

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, PLY and OBJ.



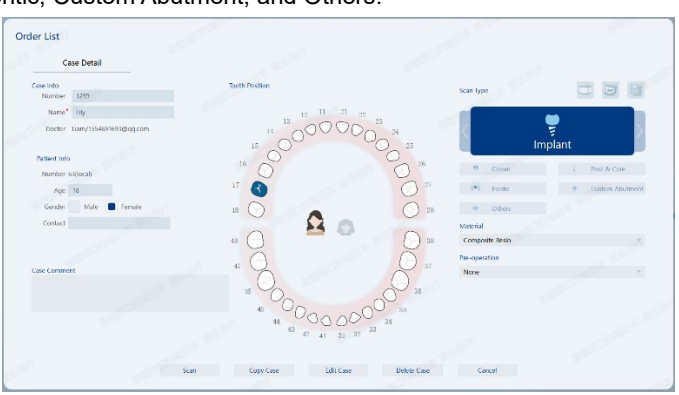
6.2 Implant process

6.2.1 User login

Log in using the method described in Section 6.1.1.

6.2.2 New Case

Establish the requirement information using the method described in Section 6.1.2. Select Implant as the scan type. The implant workflow scan types include Crown, Post & Core, Pontic, Custom Abutment, and Others.



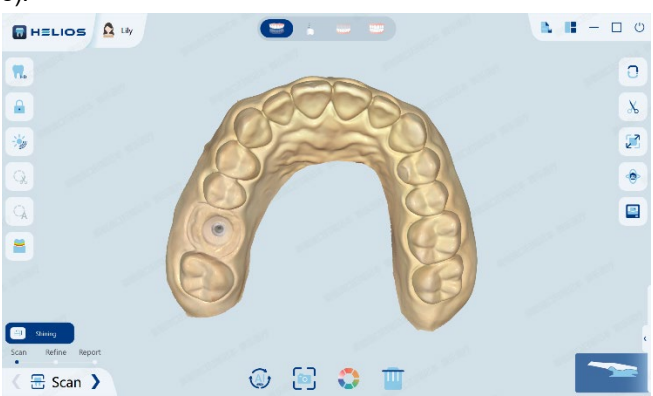
- Wireless card inserted into workstation, If the scanner not connect, click List of scanners .

6.2.3 Upper Jaw/ Lower Jaw scan

1) If the Pre-operation select Upper jaw, Lower jaw, or Upper/Lower jaw when establishing the requirement information, you can select the / / / , or press the Jaw/ Bite Switch button on the scanner to select the upper jaw mode / lower jaw mode .

2) If the Pre-operation select None when establishing the requirement information, you can select the / , or press the Jaw/ Bite Switch button on the scanner to select the upper jaw mode / lower jaw mode .

3) Remove the healing abutment, adjust the scanning jaw position to the jaw position from which the healing abutment was removed, press the Start / stop scan button on the scanner to activate the scanner, and scan the gum section immediately (before gum collapse).



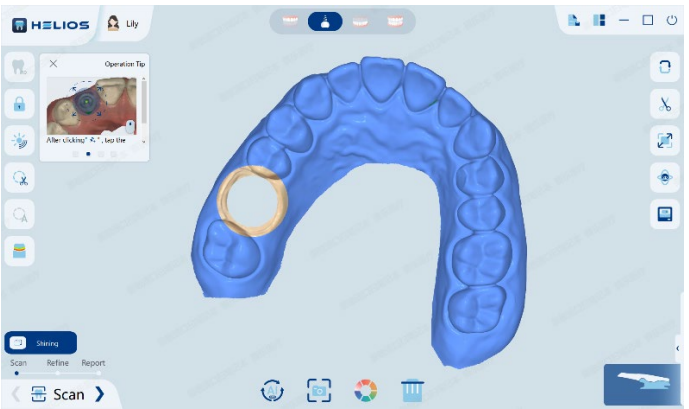
6.2.4 Scanning of the implant analog

1) Click , Switch to implant;

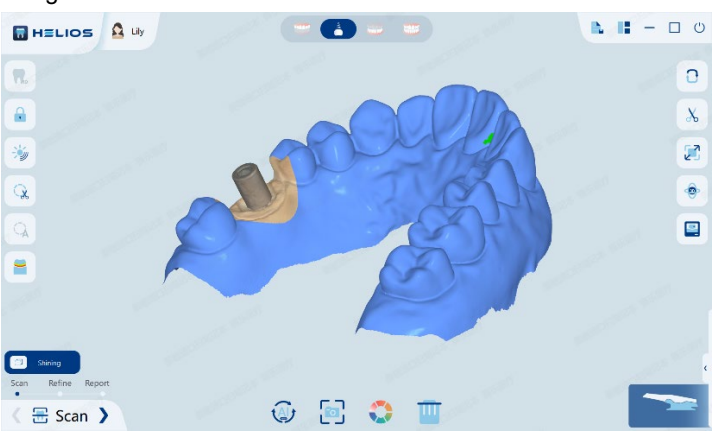
2) According to the dynamic guided scanning prompts on the left side of the screen, adjust the model so that the area to be trimmed faces directly upward.. Click in , add the cutting area, hold down the left mouse button to drag the cirle position, slide the middle mouse button to adjust the analog area, Click in , delete the cutting area, Click in , confirmation of cuts, the remaining part would be locked. This ensures that the locked area will not be affected by soft tissue collapse during further scanning.

3) Alternatively, click to automatically identify the hole area. Click to remove

the default selected area. Click  to add areas to be trimmed. You can drag the selected area by left-clicking the mouse, and adjust the size by scrolling the mouse wheel. Click  to delete the selected area.



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



⚠

- 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

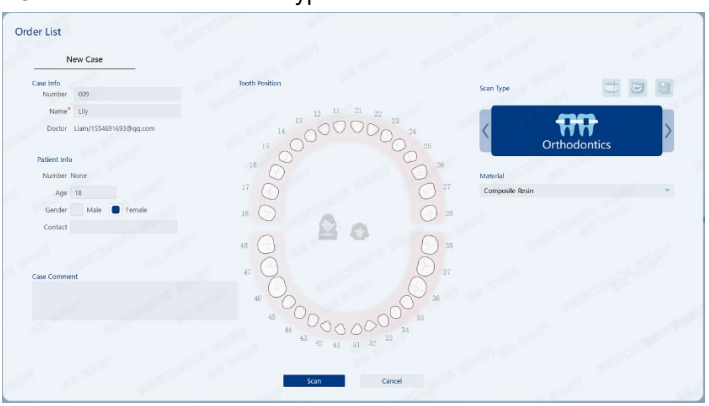
6.3 Orthodontics process

6.3.1 User login

Log in using the method described in Section 6.1.1.

6.3.2 New Case

Establish the requirement information using the method described in Section 6.1.2 and select Orthodontics as the scan type.



- Wireless card inserted into workstation, If the scanner not connect, click List of scanners.
- The default target group for the orthodontic workflow mode is adults.

6.3.3 Upper Jaw/ Lower Jaw scan

Click / , or press the Jaw/ Bite Switch button on the scanner to select the upper jaw mode / lower jaw mode .

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

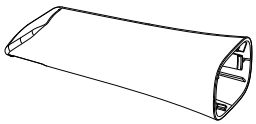
Reference to 6.1.6

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 100 cycles，After 100 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 700. 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 the surfaces with a soft bristol brush.</td></tr>
</table>

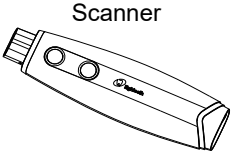
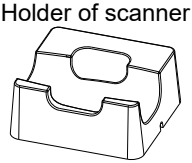
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Carefully 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.

7.3 Maintenance

The scanner main unit, reusable tip, holder of scanner and adapter need to be maintained by the operator.

The operator should maintain according to the following:

a. Routine examination

-- Check whether there are obvious abnormalities in the appearance of each component

-- Check whether the parts can be used normally

b. Check monthly

-- Check whether all parts are normal

-- Check whether the parts are complete

- The machine should not be maintained when used by patients.

- All technical service and maintenance (annually) of this product shall be performed by Changzhou Sifary Medical Technology Co., LTD. or Changzhou Sifary Medical Technology Co., LTD. authorized partners.

8 Troubleshooting

Helios 700 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 700, 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
Adapter cable	2.0	No	/

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:
	6Vrms in ISM bands between 0,15 MHz and 80 MHz	(E1)= 6Vrms in ISM bands	D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
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). 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 60601-1-2:2020. 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	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

10 Technical Specification

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	Helios 700
Dimensions	48cm x 40cm x 21cm ± 2cm(package)
Gross Weight	3Kg±10%
Color	3D full color
Connectivity	USB 3.0
Power supply	Lithium ion battery: DC 3.6V, 3300mAh, ±10%
Charger power supply	AC 100- 240V , ±10%
Charger power output	6V ⎓ 3A
Frequency	50/60Hz, ±1 Hz
Charger power input	0.5A
Field of view	Reusable tip(Size L)：16mm x 14mm Reusable tip(Size S)：12mm x 12mm
Connect with the workstation	Wi-Fi 5.0（IEEE 802.11a/b/g/n/ac）
Wireless transmission distance	No more than 5m
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(minimum requirement)	Processor: Intel® CoreTM i7 12TH Generation, base frequency 2.3 GHz Memory: 16 GB DDR4, frequency 2666MHz Disk: 512G SSD Display: FHD1920 x 1080 Others: USB 3.0 port Graphics card: NVIDIA® GeForce® GTX 1650

It is MANDATORY to check that your system configuration is compatible with the workstation system requirements for the Helios 700 software.

11 Statement

Service Life

The service life of Helios 700 series products is 5 years.

Warranty Period

The scanner of Helios 700 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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