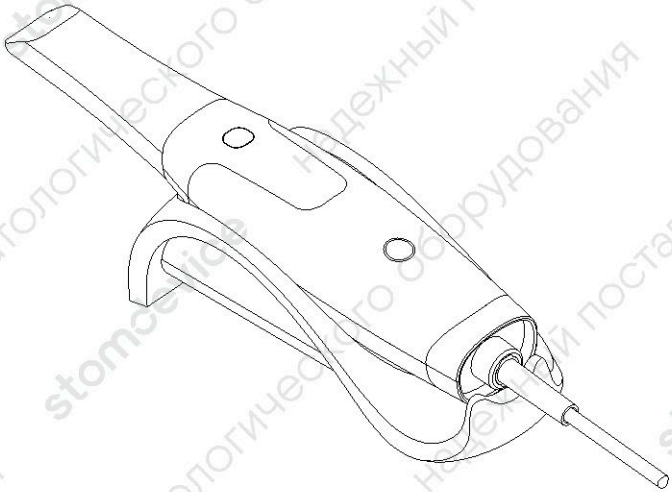
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Eighteeth



Helios 600

USER MANUAL

Changzhou Sifary Medical Technology Co., Ltd

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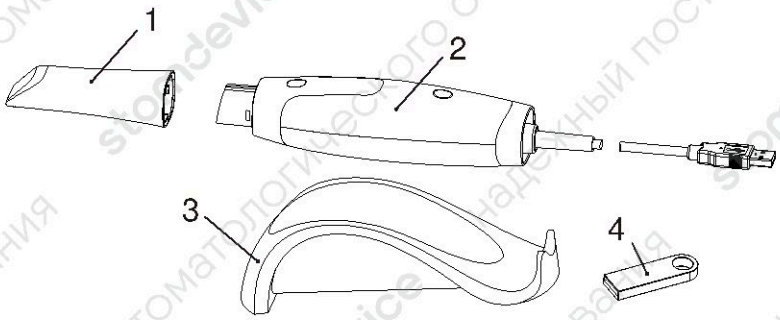
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1. Helios 600 Components

The Helios 600 consists of the following parts:

1.Reusable tip
2.Scanner
3.Hold of Scanner
4.USB Flash Driver



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2. Symbols

WARNING	If the instructions are not followed properly, the operation may lead to hazards for the product or the user/patient.
NOTE	Additional information, explanation of operation, and performance.
SN	Serial number
REF	Catalogue number
	Manufacturer
	Date of manufacture
LOT	Lot of manufacture
	Type BF applied part
	Dispose of in accordance with the WEEE directive
	Keep dry
-20°C 55°C	Temperature limitation
20% 80%	Humidity limitation
50kPa 106kPa	Atmospheric pressure limitation
Eighteeth	Manufacturer's LOGO
	Follow instructions for use
	Important: Remind you to a condition that might cause problems.
	Tip: Provides extra information and hints.
	Direct current.
134°C	Can be autoclaved up to a maximum temperature of 134° Celsius

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3. Introduction

3.1 Indications for Use

The HELIOS 600 is a digital optical scanning device used to record the topographic characteristics of teeth or dental impressions in three 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 600 could be used for both adult and children in clinical practice.
The HELIOS 600 is designed to acquire 3D models in the in the followings

- Upper jaw
- Lower jaw
- Buccal bite registration

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



WARNING

Scanner:

- You MUST read and understand this safety information before using the scanner.
- 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.
- You are responsible for the operation and maintenance of the scanner. You MUST have training to use the scanner.
- 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

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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, accessories, 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.
- The maximum temperature of the applied part may reach to 43 ° C; to avoid overheating, do not use it for extended periods.
- 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.

Computer

- DO NOT place the computer 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 computer that is at least IEC 60950 / IEC 62368, or equivalent standards certified. Connecting the scanner to other equipment may be hazardous.

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- See the installation guide for your computer for information about the data processing system, computer, and screen. Leave a sufficient amount of clear space around the computer 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.

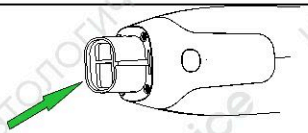
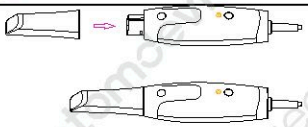
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4. Product Installing

4.1 Installation Environment Requirements

Since this product is not equipped with a computer, during the installation of this product, customers need to provide an additional laptop or desktop computer. The specific performance requirements of the computer see Technical Specification

4.2 Connecting the Helios 600 to the Computer Terinal.

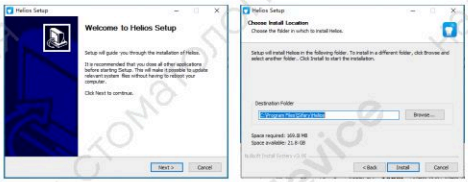
Step	Graphic Example	Description
1		Make sure the lens window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue.
2		Slide the tip onto the scanner as shown below.
3		Insert the USB connector of the scanner to any USB 3.0 port on the computerMake， ⚠Make sure the scanner is connected to the USB 3.0 port. If connected to a USB 2.0 port, the scanner may not work properly.
4		The scanner will automatically turn on, the status indicator flashes slowly, and then enters the sleep state, waiting for connection When the scanner is connected to the HELIOS software, the status indicator stays in solid blue.

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NOTE

All IT components electrically connected to the Helios must confirm to IEC 60950-1.

4.3 Software Installing

Step	Graphic Example	Description
1		Connect the USB flash driver to the computer and open it. Click open EXE format file
2		Choose a language from the drop-down list and click OK to install
3		Follow the instructions on the screen to complete the installation

4.5 Software Update

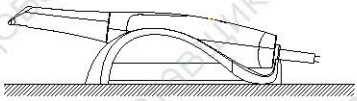
If there is an update of Helios 600 software, we(Sifary) will notify local distributors (agents) and provide free installation U disk, and the distributor(agents) will upgrade the software for everyone.

4.6 Helios 600 Mounting

It is recommended to use the Helios 600 mounting bracket to place the Helios 600.

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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.	

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5. Software Introduction

5.1 HELIOS Interface Overview

The HELIOS 600 scanner operates with HELIOS software. The HELIOS interface enables you to acquire 3D models in two ways:

Partial arch scan: Several teeth in the preparation area on both the upper and lower jaws, and buccal bite registration.

Full arch scan: Upper jaw, lower jaw, and buccal bite registration



1.	Acquisition Step: Displays the current step in the acquisition process.
2.	Implant/ Restoration /Orthodontics Switch: Enables you to select the Implant model, Restoration model, or Orthodontics Switch model.
3.	Image Toolbar: Enables you to select and manage 3D images.
4.	Jaw/Bite Switch: Enables you to select the upper jaw, lower jaw, or buccal bite registration.
5	3D Model Display Screen: Displays the 3D model created from the scan.
6	Video Preview Screen: Displays live video when scanning, or the scanner status when not scanning.
7.	Display Toolbar: Enables you to change how the 3D model is displayed.

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8.	Option Menu: Access the system configuration and version information.
9.	Login Menu: Enables you to log in, log out and switch users.

5.2 Toolbar Overview

Acquisition Step Toolbar	
	**Scan** button: Enables you to scan the upper and lower arch, and the buccal bite registration.
	**Refine** button: Refines the acquired 3D model, and enables you to use various tools to check the refined results..
	**Finish** button: complete the case information and save the scan results.
Jaw/Bite Switch Toolbar	
	**Upper Jaw** button: Acquires a 3D model of the upper jaw.
	**Lower Jaw** button: Acquires a 3D image of the lower jaw
	**Buccal Bite Registration** button: Acquires a 3D image of the bite.
	**Switch Upper/Lower Jaw** button: Changes the acquisition mode from upper to lower or vice versa, if you accidentally scan teeth on the wrong jaw.
Image Toolbar	
	**Scan body** button: enter the scan body scan workflow.
	**Cut** button: draw a curve to delete unnecessary data.
	Undo the last cut operation
	**Lock** button: Enables you to select and lock an area on the model to prevent it from being updated by additional scanning.
	Unlock the last Locked area
	**Mark tooth** button: Mark one or more preparation areas.
	Unmark one or more marked preparation area
	Return to the up-level toolbar
	Delete button: Delete all models from the current case.

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	Quadrant Snapshot button: Displays a preview of five 2D images showing different views of the model.
	Transparency button: Set the transparency of the scanned model.
	Return to the up-level toolbar
Display Toolbar	
	True Color button: When selected, displays the 3D model in the actual color of the patient's hard and soft tissues. When deselected, displays the 3D model in monochrome.
	Zoom fit button: Scales the 3D model to the best size to fit the display region.
	Views orientation button: Displays a list of views.
	Front view
	Back view
	Left view
	Right view
	Top view
	Bottom view
	Return to the up-level toolbar
	Snapshot button: Takes a snapshot of the 3D model as it appears on your screen.
	Intraoral camera button: Enables you to select 2D intraoral images.
Option Menu	
	Show more options button: Enables you to access Import/Export scan data, Scan history, Preference and About dialogs.
Scanner Status Icons	
	Scanner is not connected
	Scanner is connecting
	Scanner is in sleep mode

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	Scanner is in the holder
	Scanner tip is not detected

5.3 Option Menu Overview

5.3.1 Import/Export Scan Data Overview

The import/export scan data menus allow users to export the current scan data to a specified folder, and import it later to continue scanning or perform 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.

5.3.2 Scan History Dialog Overview

The Scan History dialog allows users to import automatically saved scan history data. Based on different user settings, the scan history data is retained for up to 30 days. In the scan history dialog, you can search data by ID or name. To import or manage the selected record, right-click the entry, and then select "Import", "Lock/Unlock" or "Delete".

Import: Import the selected scan history data.

Lock/Unlock: Lock or unlock the selected scan history. The locked scan history records will not be cleared after the storage period expires.

Delete: Delete the selected scan history data.

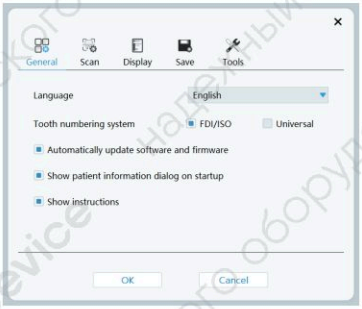
If you need to continue scanning after importing the previously saved scan data, you must ensure that the scan data is acquired by the same scanner currently connected, otherwise you will not be able to perform subsequent scans on the imported data.

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6.Preference Dialog Overview

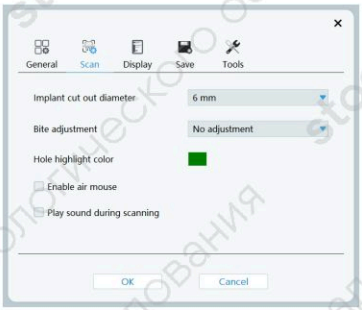
The Preferences dialog enables you to select the Acquisition interface and scanner settings

6.1 General



6.1.1 Language: Select the user interface language.
6.1.2 Tooth numbering system: Select the FDI/ISO or Universal as the tooth numbering system.
6.1.3 Automatically update software and firmware: When selected, Automatically update software version and firmware when connected to the network.
6.1.4 Show patient information dialog on startup: When selected, the patient information dialog will pop up when HELIOS opens.
6.1.5 show instructions: When selected, the screen displays an indication of the correct scanning method When scanning 3D image of the bite

6.2 Scan



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6.2.1 Implant cut out diameter: Set the diameter of the automatic cut out areas in implant mode, it is recommended to choose a value slightly larger than the diameter of the scan body used.
6.2.2 Bite adjustment:When selected, the software will automatically correct over-bite after refinement.
6.2.3 Hole highlight color: When selected, the software will fill holes in the model after refinement.
6.2.4 Enable air mouse: When selected, the scanned 3D model can be rotated by rotating the scanner while not scanning.
6.2.5 Play sound during scanning: When selected, a sound will be continuously played when you are successfully scanning (if your computer does not have speakers, this option will not take effect).

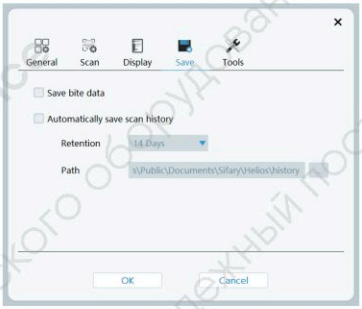
6.3Display



6.3.1 Color scheme: Select the color scheme of the user interface.
6.3.2UI element size: Select the size of interface icons to adapt to different screen resolutions.
6.3.3 Monochrome color: Select the color when displaying the 3D model in monochrome.

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6.4 Save



6.4.1 Save bite data: When selected, the bite registration relationship is saved as additional file along with the maxilla and mandibular files.

6.4.2 Automatically 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.

6.5 Tools



6.5.1 Create support file：After-sales related documents

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7. Getting Started

7.1 Accessing the HELIOS User Interface

To access the HELIOS user interface, follow these steps:

7.1.1. Double-click the icon from your desktop

7.1.2. In the HELIOS window, Automatic display of the login window



7.1.3 Type your Eighteeth DataHub account information in the username and password fields, and click Login.

7.1.4. If the scanner is not activated, the device activation dialog will be displayed. Follow the instructions on the screen to complete device activation.

7.1.5. The HELIOS scan window will be displayed and the Patient Information dialog box will pop up.



7.1.6. Do one of the following:

- Enter patient information and tooth number information, and click OK.
- Click Skip and continue without patient information.

7.1.7. Click and select Preferences

- Click General to set the general prefe rences.
- Click Scan to set the scan preferences.
- Click Display to set display preferences.
- Click Save to set save preferences

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7.2 start acquiring 3D models.

7.2.1 Audio Prompts

When the Play sound during scanning option is enabled, your computer will play a continuous sound when you are successfully scanning. If the sound stops, it means the scan has stopped. If you need to continue, please return to the previous scanning area until the scanner resumes scanning and your computer plays a continuous sound. When a bite registration relationship is successfully scanned, your computer will also play a short sound. If the cumulative scan time of the current case exceeds the recommended threshold and your computer may not be able to keep peak scan performance, your computer will also play a short warning tone.

To enable the audio prompts, your computer must have speakers

7.3Preparing the Teeth

7.3.1 If there is a preparation area, retract the gingiva by gingival restriction cords. And extract the cords just before scanning the pre€paration.

7.3.2 Before starting the scan, dry the teeth thoroughly.

7.3.3 During the scan, re-dry the teeth moderately

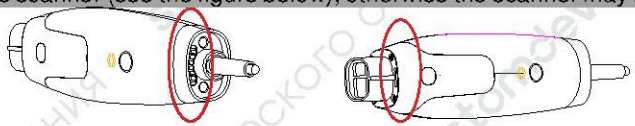
7.4 reparing the Scanner

The reusable tip attached to the scanner provides sanitary shield for patients. Always disinfect the body of the scanner and perform high-level disinfection or sterilization on the reusable tip after each use.

Scanner tips received from the manufacturer are NOT sterilized. You must sterilize the tips before the first use.

For detailed information on cleaning, disin[ii]fection and sterilization, please refer to the HELIOS 600 User Manual: Safety, Regulatory and Technical Specifications.

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.



7.4 Starting Scanning

To start scanning, place the tip of the scanner on the surface of the tooth to stabilize the scanner and press the Start Scan button. 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.

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During the scanning process, adjust the surgical light to keep the light away from the patient's mouth to avoid interference with the scanner.

7.5Scanning Approach

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.

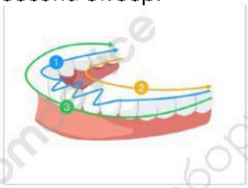


7.6 Scanning Protocol

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 occlusal 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.



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8 Acquiring a 3D Model for Orthodontics

The common scan workflow allows you to scan either a partial or full arch. For either type of scan, you should scan upper jaw, lower jaw, and buccal bite registration. Once this basic information has been scanned, other scan types (such as scan body scanning) can be used to acquire other information.

To use the common scan workflow to obtain a 3D model for orthodontic use, you should acquire images of the upper jaw, lower jaw, and the buccal bite registration, as well as several millimeters of gingival tissue in

the lingual and buccal scans. You can also use the Quadrant Snapshot tool to automatically extract five 2D images from the scanned data.

In some cases, you can acquire images of a single arch (partial or full) and not obtain a buccal bite registration (for example, if there are no teeth in the opposing arch), but it is recommended that you acquire both arches and a buccal bite registration when possible.

8.1 To acquire a 3D model, follow these steps:

8.1.1 Scan the upper and lower jaw.

8.1.2 Scan the buccal bite registration.

8.1.3 Refine and check the 3D model.

8.1.4 Complete and save the 3D model.

8.2 Scanning the Upper and Lower Jaw

To scan a 3D model of the upper and lower jaw, follow these steps:

8.2.1 Dry the teeth thoroughly before starting an acquisition.

8.2.2. On the HELIOS interface, select the Upper Jaw acquisition mode

OR

Press the mode button on the scanner to select the upper jaw scan mode

8.2.3. Place the tip of the scanner on the surface of the tooth to stabilize the scanner and press the Start
Scan button. 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. The image will be automatically scanned and displayed in the 3D model display area.

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8.2.4. Slowly move the tip of the scanner along the occlusal surface to scan the remaining teeth in the arch.

If Fill tooth holes with color is enabled, the holes will be displayed in the specified color. It is recommended to scan these areas until the holes disappear.

8.2.5.When the occlusal surface scan is complete, scan the lingual or buccal surface of the teeth in the arch.

8.2.6. When the lingual or buccal scan is completed, scan the opposite side of the arch.

Re-dry the teeth as appropriate throughout the acquisition process.

If you need to remove soft-tissue artifacts, mismatches, or unwanted views during the acquisition, click the Cut tool, then draw a curve that covers the region to be removed on the 3D model. If necessary, rescan the area to fill the holes.



8.2.7. After scanning the upper jaw, you can continue scanning the lower jaw. On the HELIOS interface,

select the Lower Jaw acquisition mode

OR

Press the mode button on the scanner to select the lower jaw scan mode

8.2.8. Repeat steps 8.2.3 to 8.2. 6 until the lower jaw scan is completed.

8.2.9. Check whether there are obvious holes in the 3D model and rescan if necessary.

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8.2.10. When you confirm that the 3D model of the upper and lower jaw is complete, continue with the buccal bite registration acquisition.

8.3 Scanning the Buccal Bite Registration

To acquire a buccal bite registration, follow these steps:

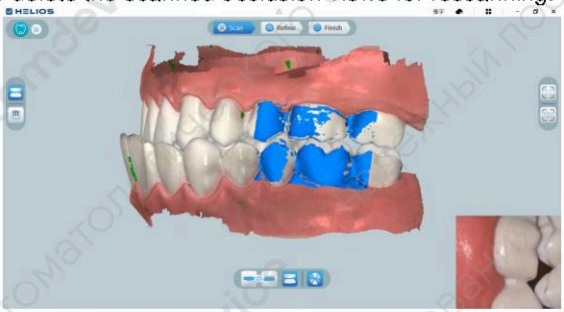
8.3.1. On the HELIOS interface, select the **Buccal Bite Registration** acquisition mode

OR

Press the mode button on the scanner to select the buccal bite registration mode

8.3.2. 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.

8.3.3. Press the Star Scan button, slowly move the scanner tip in mesial direction with equal coverage of upper and lower teeth. The example below shows a buccal bite registration. You can use the toolbar on the under side to switch between the scanned occlusion views, or delete the scanned occlusion views for rescanning.



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

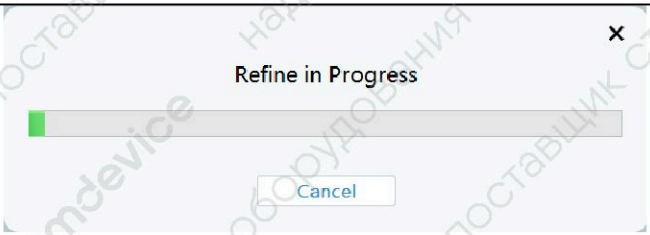
8.3.4. After scanning the buccal bite registrations, rotate the model and zoom the view to ensure that the bite is accurate and that there are no areas where the bite is mismatched. If necessary, you can delete the scanned occlusion and rescan.

8.4Refining and Checking the 3D Model

Refining the 3D model allows you to obtain higher accuracy data for further processing. To refine the 3D model, follow these steps:

8.4.1. Click the Refine button, the refining progress bar will be displayed. Depending on your computer configuration, the refining process may take several minutes.

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8.4.2. After the refining is complete, manipulate the refined 3D model using the following methods:

- Right-click and hold on the 3D model to move it in the window.
- Click and hold on the 3D model to rotate it.
- Use the wheel of the mouse to zoom in or zoom out on the 3D model.
- Click the **True color** button to view the color or monochrome 3D model.
- Click the **Zoom fit** button to scale the model to its best view.
- Click the **Six Views** button to see six views of the 3D model.
- Click the **Snapshot** button to take a snapshot of the 3D model.
- Click **Upper Jaw** button or **Lower Jaw** button to hide or display the jaws.
- Click the **Transparency** button to display the transparency slider, click and drag the slider to adjust the transparency of the 3D model.
- Click **Cut** button to select and delete unwanted data.
- Click **Intraoral Image** button to pick up intraoral images from the scanned data.
- Click the **Quadrant Snapshot** button to open the Quadrant Snapshot window, which displays multiple views of the model.

8.4.3. If you find obvious holes when checking the 3D model, click the **Scan** button and rescan the areas to fill the holes.

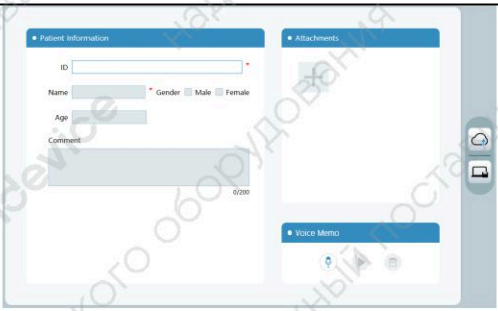
8.4.4. Repeat steps 1 through 3 until you are satisfied with the 3D model.

8.5Completing and Saving the 3D Model

To complete the scan and save the 3D model, follow these steps:

8.5.1. Click the **Finish** button and the following page will be displayed. If you entered patient information in the previous step, it will be displayed on this page.

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

8.5.3. Click the **save (** **or** **)** button to save the case.

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9.Acquiring a 3D Model for Restoration

To use the common scan workflow to obtain a 3D model for restoration use, you should acquire images of the upper jaw, lower jaw, and the buccal bite registration.

In some cases, you can acquire images of a single arch (partial or full) and not obtain a buccal bite registration (for example, if there are no teeth in the opposing arch), but it is recommended that you acquire both arches and a buccal bite registration when possible.

To acquire a 3D model, follow these steps:

- Scan the upper and lower jaw.
- Scan the buccal bite registration.
- Mark the preparation areas
- Refine and check the 3D model.
- Complete and save the 3D model.

9.1 Scanning the Upper and Lower Jaw

If you use gingival restriction cords to retract the gingiva around the preparation, you should scan the preparation immediately after removing the gingival restriction cords so that the gingival area can be scanned before gum collapses.

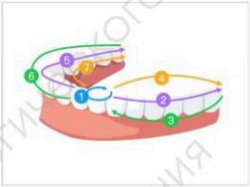
To scan the 3D model of the preparation, follow these steps:

9.1.1. Dry the teeth thoroughly before starting an acquisition.

9.1.2. On the HELIOS interface, select the jaw (or) with preparation OR Press the mode button on the scanner to select the jaw with preparation.

9.1.3. Place the tip of the scanner on the surface of the tooth to stabilize the scanner and press the Start Scan button. Wait until a 3D image appears in the 3D model display screen.

9.1.4. Move the tip of the scanner slowly around the preparation at 0-5mm from the teeth. The image will be automatically scanned and displayed in the 3D model display area.



9.1.5. Turn to the lingual and buccal side of the preparation for scanning.

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9.1.6. Go to the adjacent side of the preparation (including the distal and mesial points) to scan the 3D model of the adjacent side and the contact point of the preparation.

After scanning the preparation, you can use the **Lock** tool to lock the scanned area to prevent it from being updated by additional scanning.

9.1.7. Take the preparation as a starting point, slowly move the tip of the scanner to both sides of the preparation along the occlusal surface to scan the remaining teeth in the arch.



If **Fill tooth holes with color** is enabled, the holes will be displayed in the specified color. It is recommended to scan these areas until the holes disappear.

9.1.8. When the occlusal surface scan is complete, scan the lingual or buccal surface of the teeth in the arch.

9.1.9. When the lingual or buccal scan is completed, scan the opposite side of the arch.

Re-dry the teeth as appropriate throughout the acquisition process.

If you need to remove soft-tissue artifacts, mismatches, or unwanted views during the acquisition, click the **Cut** tool, then draw a curve that covers the region to be removed on the 3D model. If necessary, rescan the area to fill the holes



9.1.10. After scanning the jaw with preparation, you can continue scanning the

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opposite side referring to steps 7 to 9.

9.1.11. Check whether there are obvious holes in the 3D model and rescan if necessary. If there is a hole in the preparation area, rescan the area until the hole is filled.

9.1.12. When you confirm that the 3D model of the upper and lower jaw is complete, continue with the buccal bite registration acquisition.

9.2 Scanning the Buccal Bite Registration

To acquire a buccal bite registration, follow these steps:

9.2.1. On the HELIOS interface, select the **Buccal Bite Registration** acquisition mode OR

Press the mode button on the scanner to select the buccal bite registration mode .

9.2.2. 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.

9.2.3. Press the Star Scan button, slowly move the scanner tip in mesial direction with equal coverage of upper and lower teeth.

The example below shows a buccal bite registration. You can use the toolbar on the left side to switch between the scanned occlusion views, or delete the scanned occlusion views for rescanning.

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



9.2.4. After scanning the buccal bite registrations, 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.

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9.3 Marking the Preparation Areas

After the scan is complete, you can mark the preparation areas for further processing. To mark one or more preparation areas, follow these steps:

9.3.1. On the HELIOS interface, select the jaw (or) with preparation to activate the 3D model.

9.3.2. Click the Mark tooth button, and then click in the center of the occlusal surface of the preparation tooth. A 3D ball will display on the occlusal surface indicating a preparation area.



9.3.3. Rotate the 3D model if necessary, and mark all the preparation areas.

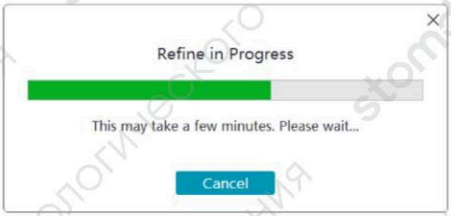
You can click and hold the middle mouse button to rotate the 3D model when using tools such as **Cut** , **Lock** and **Mark tooth** .

9.3.4 Click the **Return** button to quit Mark tooth tool.

9.4 Refining and Checking the 3D Model

Refining the 3D model allows you to obtain higher accuracy data for further processing. To refine the 3D model, follow these steps:

9.4.1. Click the **Refine** button, the refining progress bar will be displayed. Depending on your computer configuration, the refining process may take several minutes.



9.4.2. After the refining is complete, manipulate the refined 3D model using the following methods:

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- Right-click and hold on the 3D model to move it in the window.
- Click and hold on the 3D model to rotate it.
- Use the wheel of the mouse to zoom in or zoom out on the 3D model.
- Click the True color button to view the color or monochrome 3D model.
- Click the Zoom fit button to scale the model to its best view.
- Click the Six Views button to see six views of the 3D model.
- Click the Snapshot button to take a snapshot of the 3D model.
- Click Upper Jaw button or Lower Jaw button to hide or display the jaws.
- Click the Transparency button to display the transparency slider, click and drag the slider to adjust the transparency of the 3D model.
- Click Cut button to select and delete unwanted data.
- Click Intraoral Image button to pick up intraoral images from the scanned data.
- Click the Quadrant Snapshot button to open the Quadrant Snapshot window, which displays multiple views of the model.

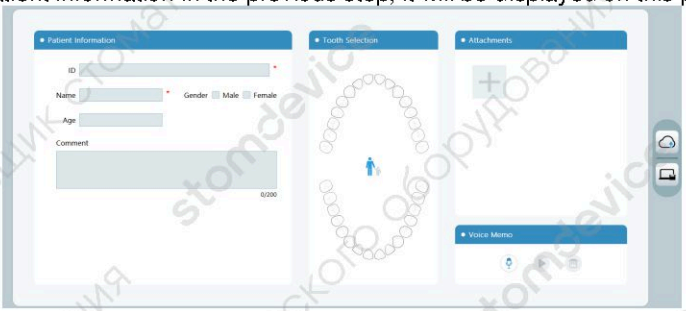
9.4.3. If you find obvious holes when checking the 3D model, click the **Scan** button and rescan the areas to fill the holes.

9.4.4. Repeat steps 1 through 3 until you are satisfied with the 3D model.

9.5 Completing and Saving the 3D Model

To complete the scan and save the 3D model, follow these steps:

9.5.1. Click the **Finish** button and the following page will be displayed. If you entered patient information in the previous step, it will be displayed on this page.



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

9.5.3. Click the **save** (or) button to save the case.

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10.Acquiring a 3D Model for Implant

To use the common scan workflow to obtain a 3D model for implant use, you should first acquire images of the upper jaw, lower jaw, and the buccal bite registration. After that you should rescan the jaw with the scan body in place.

In some cases, you can acquire images of a single arch (partial or full) and not obtain a buccal bite registration (for example, if there are no teeth in the opposing arch), but it is recommended that you acquire both arches and a buccal bite registration when possible.

10.1 To acquire a 3D model, follow these steps:

- Scan the upper and lower jaw.
- Scan the buccal bite registration.
- Mark the implant areas
- Install and scan the scan body
- Refine and check the 3D model.
- Complete and save the 3D model.

10.2 Scanning the Upper and Lower Jaw

To scan a 3D model of the upper and lower jaw, follow these steps:

10.2.1. Dry the teeth thoroughly before starting an acquisition.

10.2.2. On the HELIOS interface, select the **Upper Jaw** acquisition mode OR Press the mode button on the scanner to select the upper jaw scan mode .

10.2.3. Place the tip of the scanner on the surface of the tooth to stabilize the scanner and press the Start Scan button. 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. The image will be automatically scanned and displayed in the 3D model display area.



10.2.4. Slowly move the tip of the scanner along the occlusal surface to scan the

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remaining teeth in the arch.

If **Fill tooth holes with color** is enabled, the holes will be displayed in the specified color. It is recommended to scan these areas until the holes disappear.

10.2.5. When the occlusal surface scan is complete, scan the lingual or buccal surface of the teeth in the arch.

10.2.6. When the lingual or buccal scan is completed, scan the opposite side of the arch.

Re-dry the teeth as appropriate throughout the acquisition process.

If you need to remove soft-tissue artifacts, mismatches, or unwanted views during the acquisition, click the **Cut** tool, then draw a curve that covers the region to be removed on the 3D model. If necessary, rescan the area to fill the holes.



10.2.7. After scanning the upper jaw, you can continue scanning the lower jaw. On the HELIOS interface, select the **Lower Jaw** acquisition mode OR Press the mode button on the scanner to select the lower jaw scan mode .

10.2.8. Repeat steps 3 to 6 until the lower jaw scan is completed.

10.2.9. Check whether there are obvious holes in the 3D model and rescan if necessary.

10.2.10. When you confirm that the 3D model of the upper and lower jaw is complete, continue with the buccal bite registration acquisition.

10.3 Scanning the Buccal Bite Registration

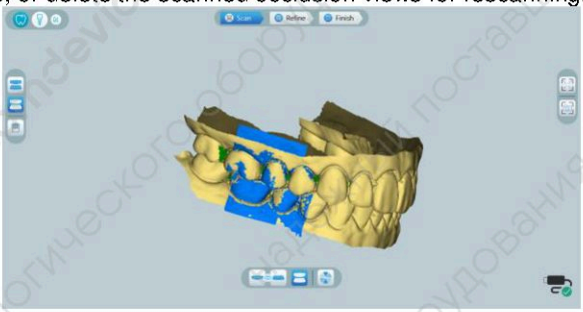
To acquire a buccal bite registration, follow these steps:

10.3.1. On the HELIOS interface, select the **Buccal Bite Registration** acquisition mode OR Press the mode button on the scanner to select the buccal bite registration mode .

10.3.2. 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.

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10.3.3. Press the Star Scan button, slowly move the scanner tip in mesial direction with equal coverage of upper and lower teeth. The example below shows a buccal bite registration. You can use the toolbar on the left side to switch between the scanned occlusion views, or delete the scanned occlusion views for rescanning.



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

10.3.4. After scanning the buccal bite registrations, 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.

10.4Marking the Implant Areas

After the scan is complete, you can mark the implant area so that you can rescan the area after installing the scan body. To mark one or more implant areas, follow these steps:

10.4.1. On the HELIOS interface, select the jaw (or) with implant to activate the 3D model.

10.4.2. Click the **Mark tooth** button, and then click in the center of the implant. A 3D ball will display on the occlusal surface indicating an implant.



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10.4.3. Rotate the 3D model if necessary, and mark all the implant areas.

You can click and hold the middle mouse button to rotate the 3D model when using tools such as **Cut** , **Lock** and **Mark tooth** .

10.4.4. Click the **Return** button to quit Mark tooth tool.

10.5 Installing and Scanning the Scan Body

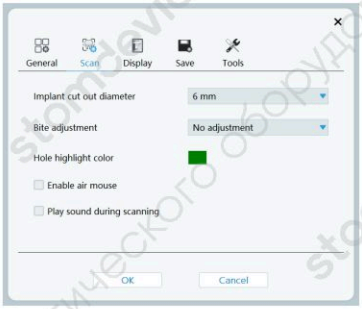
After installing the scan body, follow these steps to scan the scan body:

10.5.1. Click the **Scan body** button to enter the scan body scan.

10.5.2. Wait for the copy scan data process to complete.

10.5.3. Check whether the region automatically cut out by the software is big enough to surround the emergence profile and the scan body used. If the region is not big enough, you can click the **Scan body** button again to quit scan body scan, and re-mark the implant areas or adjust the **"Implant cut out diameter"** to fit the scan body used. After finishing the adjustment, enter the scan body scan again.





10.5.4. Rescan these implant areas in order to obtain 3D models of the scan body.

Start the scan body scanning from the surface 1-2 teeth away from the scan body, so that the system can recognize the 3D structure.

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If there are more than one adjacent scan bodies that cause mismatch, you can click the scan body placeholder at the bottom of the interface to specify the area for matching. The activated matching area is highlighted in a column. Click on an activated scan body placeholder again to restore the global match.

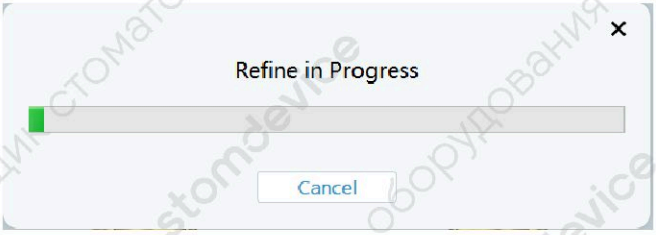


10.5.5. When you have completed the scan body scanning, proceed to the Refining and Checking the 3D Model step.

10.6 Refining and Checking the 3D Model

Refining the 3D model allows you to obtain higher accuracy data for further processing. To refine the 3D model, follow these steps:

10.6.1 Click the Refine button, the refining progress bar will be displayed. Depending on your computer configuration, the refining process may take several minutes.



10.6.2. After the refining is complete, manipulate the refined 3D model using the following methods:

- Right-click and hold on the 3D model to move it in the window.
- Click and hold on the 3D model to rotate it.
- Use the wheel of the mouse to zoom in or zoom out on the 3D model.
- Click the Scan body button to switch between different 3D models
- Model with scan body
- Model without scan body

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- Click the True color button to view the color or monochrome 3D model.
- Click the Zoom fit button to scale the model to its best view.
- Click the Six Views button to see six views of the 3D model.
- Click the Snapshot button to take a snapshot of the 3D model.
- Click Upper Jaw button or Lower Jaw button to hide or display the jaws.
- Click the Transparency button to display the transparency slider, click and drag the slider to adjust the transparency of the 3D model.
- Click Cut button to select and delete unwanted data.
- Click Intraoral Image button to pick up intraoral images from the scanned data.
- Click the Snapshot button to open the Quadrant Snapshot window, which displays multiple views of the model.

10.6.3. If you find obvious holes when checking the 3D model, click the Scan button and rescan the areas to fill the holes.

10.6.4. Repeat steps 1 through 3 until you are satisfied with the 3D model.

10.7 Completing and Saving the 3D Model

To complete the scan and save the 3D model, follow these steps:

10.7.1. Click the Finish button and the following page will be displayed. If you entered patient information in the previous step, it will be displayed on this page.



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

10.7.3. Click the save (or) button to save the case.

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11Cleaning, Disinfecting, and Sterilizing

You must clean, disinfect, and sterilize the scanner and accessories regularly.

The removable scanner tips can be high-level disinfected for up to 50 cycles. After 50 cycles, discard the tip.

The removable scanner tips can be autoclaved for up to 20 cycles. After 20 cycles, discard the tip.

Perform the following maintenance activities on your scanner and accessories regularly.

To ensure maximum hygienic safety for the patient, carefully follow the instructions to prepare the scanner for use.

To minimize the risk for cross-contamination, after each patient:

Clean and disinfect the scanner. See “Cleaning and Disinfecting the Scanner”).

And then, the operator can reprocess tips by one of following ways:

- Clean the tip, and then perform high level disinfection (See “Cleaning and High-Level Disinfecting Tips”),
- Clean the tip, and then perform Sterilization (See “Cleaning and Sterilizing Tips”).

WARNING Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the disinfectant used to process the scanner.

You must wear gloves while cleaning and disinfecting the scanner.

The scanner must be disinfected with a recommended intermediate-level disinfectant solution with tuberculocidal activity between patients.

DO NOT use a disinfectant containing phenolics or iodophors; doing so will damage the surface coating of the scanner.

Never put the scanner in an autoclave device or immerse it in water or the disinfectant solution. Excessive fluids can damage the scanner.

Do not use cotton, cloth, or tissues soaked with disinfectant to disinfect the scanner.

11.1 Cleaning the Scanner

11.1.1 If the scanner is visibly contaminated with blood and/or body fluids, you must clean it before disinfecting it.

11.1.2 To clean the scanner, follow these steps:

- Dampen (do not soak) a lint-free cloth with lukewarm water.
- Remove the blood and/or body fluids with the dampened lint-free cloth.

11.2 Disinfecting the Scanner

11.2.1 After each patient, the scanner must be thoroughly disinfected.

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11.2.2 To adequately disinfect the scanner, follow the disinfectant manufacturer's instructions for the appropriate contact time.

Important: If the scanner is visibly soiled, it must be thoroughly cleaned prior to disinfecting. See "Cleaning the Scanner".

11.2.3 To disinfect the scanner, follow these steps:

- Remove the reusable tip.
- Remove all visible soil (see "Cleaning the Scanner").
- Use a commercially prepared intermediate level disinfectant wipe. Follow the manufacturer's instructions for contact time.

  Recommended disinfectant wipes: CaviWipes

WARNING Using a disinfectant that has not been approved may cause damage to the scanne

- Thoroughly wipe all surfaces of the scanner.

WARNING : Do not rinse.

- Allow to air dry.
- After the scanner has dried, use a clean, lint-free cloth dampened with water to remove residual disinfectant from the surface of the scanner.

11.3 Visually Inspecting the Scanner for Damage

Visually inspect the scanner for signs of deterioration, especially around the buttons and the cable. If damage is noted, do not use the scanner and contact your representative.

11.4 Cleaning and High-Level Disinfecting Tips

Scanner tips received from the manufacturer are NOT disinfected. You must disinfect or sterilize the tips before the first use.

The tip can be disinfected by High Level Disinfectant up to 50 cycles.

WARNING

- Wear gloves when handling a contaminated scanner tip.
- Read and follow the warnings and personal protection instructions provided in the manufacturer's SDS for the detergent used to clean or disinfect the scanner tip.
- Do not soak the scanner tips in disinfectant for a long period.
- Dry the scanner tips thoroughly before mounting onto the scanner. Do not use an ultrasonic cleaning machine to clean the scanner tips.

11.4.1 The Operator can clean HELIOS 600 Tips by one of following two way

- Manually cleaning HELIOS 600 Tips
- Cleaning the HELIOS 600 Tips in an Automatic Washer

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11.5 Manually cleaning HELIOS 600 Tips

To manually cleaning the HELIOS 600 tips, follow these steps:

11.5.1 Rinse excess soil from the HELIOS 600 tip.

11.5.2 Using a soft brush, apply enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces (2 minutes).

11.5.3 Rinse under clean, running water (2 minutes).

11.5.4 Inspect HELIOS 600 tip. If the tip is not clean, repeat the steps11.5. 1-11.5.3.

11.5.5 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

11.6 Cleaning the HELIOS 600 Tips in an Automatic Washer

To clean the HELIOS 600 tips in an automatic washer or disinfector, follow these steps:

11.6.1 Rinse excess soil from the HELIOS 600 tip (2 minutes).

11.6.2 Using a soft brush, apply enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.

11.6.3 Load the HELIOS 600 tip in to washer equipment.

11.6.4 Run the cycle per the equipment manufacturer's instructions (about 5 minutes). If the machine does not have an automatic rinse cycle, rinse thoroughly to remove detergent residues by immersing in clean water.

11.6.5 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

11.6.6 After cleaning, the operator can high-level disinfect tips:

11.7High-Level Disinfection for HELIOS 600 Tips

11.7.1 After cleaning the tip, check tip mirror to make sure the surface is free of stains or fog. Dry the mirror with a lens tissue or lint-free cloth.

11.7.2 Immerse HELIOS 600 tips in to Johnson & Johnson® Cidex OPA disinfector for 5 minutes.Detailed disinfection method could be referred to instruction of Cidex OPA.

11.7.3 After immersing, clean the tips according to instruction of disinfector.

11.7.4 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

11.8 Cleaning and Sterilizing Tips

Scanner tips received from the manufacturer are NOT sterilized. You must sterilize the tips before the first use.

The removable scanner tips are autoclavable up to 20 cycles. After 20 cycles, discard the tip.

WARNING

- Wear gloves when handling a contaminated scanner tip.

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- Read and follow the warnings and personal protection instructions provided in the manufacturer's SDS for the detergent used to clean or disinfect the scanner tip.
- Do not soak the scanner tips in disinfectant for a long period.
- Dry the scanner tips thoroughly before mounting onto the scanner.
- Do not use an ultrasonic cleaning machine to clean the scanner tips.

11.8.1 The Operator can clean HELIOS 600 Tips by one of following two ways:

- Manually cleaning HELIOS 600 Tips
- Cleaning the HELIOS 600 Tips in an Automatic Washer

11.9 Manually cleaning HELIOS 600 Tips

To manually cleaning the HELIOS 600 tips, follow these steps:

11.9.1 Rinse excess soil from the HELIOS 600 tip.

11.9.2 Using a soft brush, apply enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces (2 minutes).

11.9.3 Rinse under clean, running water (2 minutes).

11.9.4 Inspect HELIOS 600 tip. If the tip is not clean, repeat the steps 1-3.

11.9.5 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

11.10Cleaning the HELIOS 600 Tips in an Automatic Washer

To clean the HELIOS 600 tips in an automatic washer or disinfector, follow these steps:

11.10.1 Rinse excess soil from the HELIOS 600 tip (2 minutes).

11.10.2 Using a soft brush, apply enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.

11.10.3 Load the HELIOS 600 tip in to washer equipment.

11.10.4 Run the cycle per the equipment manufacturer's instructions (about 5 minutes). If the machine does not have an automatic rinse cycle, rinse thoroughly to remove detergent residues by immersing in clean water.

11.10.5 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

11.11 Sterilization for HELIOS 600 Tips

After cleaning, the operator can sterilize tips in a steam autoclave:

11.11.1 Clean the tip with soap and brush. After cleaning, check tip mirror to make sure the surface is free of stains or fog. Dry the mirror with a clean paper towel.

11.11.2 Put the tip into a sealed steam sterilization pouch.

11.11.3 Place the tips in a steam autoclave for the following condition: 121°C and

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exposure time for 20 minutes.

Important: Temperature should not exceed 121°C.

Important: Exposure time should not exceed 20 minutes.

11.12 Visually Inspecting the Mirror in the Scanner Tip

Before scanning, verify that the mirror inside the end of the tip does not have any smudges or scratches on it. This can affect image quality. Replace the tip as necessary.

11.13 Visually Inspecting the Scanner Tips for Damage

Visually inspect the scanner tips for signs of deterioration. Discard if any damage is noted.

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12 Troubleshooting

HELIOS 600 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 bite registration, there is a gap or intersection between the upper jaw and the lower	Delete the incorrect bite view, and rescan. Enable bite optimization option.
The margin line of the preparation is unclear.	Adjust the scanner position to see the margin line with good focus, then rescan.
The scan body is missing after refinement.	Mark the implant areas correctly before scanning the scan body. Set proper Implant cut out diameter.
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.

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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	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.

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13 Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in this documentation.

Other equipment can interfere with communications with the HELIOS 600, even if the equipment complies with CISPR emissions requirements.

WARNING 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 600, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

13.1 Guidance and Manufacturer's Declarations

13.1.1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The HELIOS 600 is intended for use in the electromagnetic environment specified below. The customer or user of the HELIOS 600 should assure that it is used in such an environment.

13.1.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity for 13.2

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1 Class B	The HELIOS 600 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.

13.2 Equipment and Systems

13.2.1 The HELIOS 600 is intended for use in the electromagnetic environment specified below. The customer or the user of the HELIOS 600 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance

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Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80MHz – 2.7GHz	3 V/m 80MHz – 2.7GHz	Environment of a professional healthcare facility. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HELIOS 600 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

13.2.2 For the immunity to proximity fields from RF wireless communications equipment, the HELIOS 600 is compliant with the test levels specified below, according to IEC 60601-1-2 standard. The customer or user of the HELIOS 600 should assure that it is used in such an environment.

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels
385	380 – 390	Pulse modulation 18Hz, 27V/m
450	430 – 470	FM, ±5 kHz deviation, 1 kHz sine, 28V/m
710	704 – 787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800 – 960	Pulse modulation 18Hz, 28V/m

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870		
930		
1720	1700 – 1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400 – 2570	Pulse modulation 217Hz, 28V/m
5240	5100 – 5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

13.3 EMC Standards for the HELIOS 600

IEC 60601-1-2: 2014 EMC requirements and tests, Medical Electrical Equipment including CSIPR11:2009+A1:2010 Group 1, Class B.

13.4 Accessories

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.

13.5 Other Equipment

⚠ WARNING 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.

13.6 Regulatory Information

The HELIOS 600 complies with the following regulations:

- (EU) 2017/745 Medical Device Regulation (MDR), Cass I following the Rule 5.
- FDA Center for Devices & Radiological Health CDRH - Title 21 CFR 872.3661 (USA). Medical Devices Regulations (Canada).
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

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14 Compliance with European and International Standards

- EN 60601-1 / IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
- ANSI/AAMI ES 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performanceCAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2 / IEC 60601-1-2: Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- EN 80601-2-60 / IEC 80601-2-60: Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- EN 62471 / IEC 62471: Photobiological safety of lamps and lamp systems: Equipment classification, requirements, and User's Guide
- EN ISO 17664: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- EN ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN 60601-1-6 / IEC 60601-1-6: Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- EN 62366 / IEC 62366: Medical devices - Application of usability engineering to medical devices EN 62304 / IEC 62304: Medical device software - Software life cycle Processes
- EN ISO 10993: Biological evaluation of medical devices
- EN ISO 14971: Medical devices - Application of risk management to medical devices
- EN ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- EN 1041: Information supplied by the manufacturer of medical devices ISO 9687: Dentistry - Graphical symbols for dental equipment
- AAMI TIR 12: Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR 30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

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15 Technical Specification

15.1 Model

Helios 600

15.2 HELIOS 600 Technical Specifications

Components	Technical Specifications
Weight	Scanner (cable included) without tip: 260g Tip: 12.5g
Color	3D full color
Connectivity	USB 3.0
Power source	USB 3.0 5V, 900mA
Field of view	16mm x 14mm
Depth of view	15mm
Operating System	Windows 10
Configuration Requirement of Workstation	Processor: Intel® CoreTM i7 9th Generation, base frequency 2.6 GHz (or better) Memory: 16 GB (or more) DDR4, frequency 2666 MHz (or better) Disk: 512G (or more) SSD Graphics card: NVIDIA® GeForce® GTX 1650 (or better) Display: 15.6" FHD (1920 x 1080) (or more) Others: USB 3.0 port Operating system: Windows 10 Pro Optional: Touch screen

Important: It is MANDATORY to check that your system configuration is compatible with the computer system requirements for the AS 100 software.

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16.Helios 600 Environmental Requirements

Components	Environmental Requirements
Operating Temperature	15°C ~ 30°C
Transport and Storage Temperature	-10°C ~ 60°C
Operating Relative Humidity	10% ~ 65% RH
Transportation and Storage Relative Humidity	10% ~ 95% RH
Operating Atmospheric Pressure	70 ~ 106 KPa
Transportation and Storage Atmospheric Pressure	60 ~ 106 KPa

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