3DISC





Software Version 3.8

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The Scan&Tell communication-hub

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Introducing OVO

1.1 Introduction

Thank you for purchasing the OVO from 3DISC.

The OVO is designed and developed to produce high-quality digital intraoral scans or models, for dental restoration or analysis.

Designed with you as a dentist and your patient in mind, the OVO scanning device is lightweight, versatile and easy to use, enabling fast, accurate scans and enhanced patient experience.

Combined with the 3DiscClinic 3D Scanning and Case Management software, and the 3DiscCloud file-sharing platform for ordering and communicating with labs, the Heron IOS solution provides a comprehensive, intuitive and fully digital experience.

We hope you enjoy your new intraoral scanner solution.

1.2 3Disc Online Help

For your comfort, **3DISC Online Help** is now available at:

3DISC Online Help

Links to 3DISC Online Help are indicated by the following icon:



1.3 Indications supported

The software enables you to select the following indications* when filling out orders for restoration:

- Conventional crowns
- Anatomic crowns
- Copings
- Provisional crowns
- Anatomical pontics
- Reduced pontics
- Provisional pontics
- Inlays/Onlays
- Implant abutments

- Implant-based bridges
- Tooth-based bridges
- Orthodontic aligners
- Nightguards
- Splints
- Retainers
- Bleach trays
- Sleep appliances
- ...

^{*} Verify with your dental lab or service provider about their capabilities to produce different indications.

1.4 Certification and compliance

The system has been tested and conforms to the following standards:

- IEC 60601-1, Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- 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:
- IEC 62471, Photobiological safety of lamps and lamp systems

1.5 Regulatory

The OVO is manufactured and marketed in accordance with US FDA Regulations and EU Medical Device Regulation 2017/745.

1.6 Intended Use

The OVO is an optical impression system. It is used to record the topographical characteristics of teeth, dental impressions, or stone models for use in the computer-aided design (CAD) and computer-aided manufacturing (CAM) of dental restorative prosthetic devices.



WARNING: Unintended use of the system can result in physical injury to the patient and operator, and damage to the system.



CAUTION: Rx only - Federal law restricts this device to be sold by or on the order of a Dentist.

1.7 Classifications

The OVO system has the following classifications

- Protection against electrical shock: Type B Applied Part
- Protection against harmful ingress of water: Ordinary equipment (IPXO)
- Safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide: Equipment not suitable for use in

the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

1.8 3DISC Privacy Policy and GDPR Privacy Statement

Your privacy and the privacy of the patient data managed by you is important to 3DISC.

For information on 3DISC Privacy Policy, go to:

Privacy policy - 3DISC

To access 3DISC's GDPR Privacy Statement, go to:

GDPR Privacy statement - 3DISC

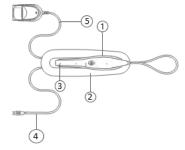
2. Components Overview

The OVO system is composed of hardware and software components.

2.1 Hardware Components

The Heron IOS system is composed of the following hardware components*:

- 1. Heron IOS Scanner
- 2. Heron IOS base
- 3. Removable autoclavable tips
- 4. USB 3.0 cable
- 5. AC/DC power adapter



Hardware Component	Part Number
OVO (Includes 3 Tips)	IOS-FP-71-001
USB 3.0 Cable	IOS-CP-00-043
AC/DC Power Adapter	IOS-CP-00-088

Save the Box: It is highly recommended that you store the packaging in a safe place and do not dispose of it. The original packaging box is optimal for any necessary transportation or shipment of the OVO.

*Note: Packaging details and contents may vary from those described in this guide.

2.2 Software Components

The OVO system comprises the following software components:

 $3DiscClinic^{TM}$: 3D Scanning and Case Management software.

3DiscCloud™: Dedicated cloud platform for ordering and communicating with

labs.

2.3 System Requirements and Specifications

Scanner Specifications

Scanner Type	Hand-held (chairside) scanner that creates optical impressions for dental restorations.
Design	Compact, lightweight, ergonomic – designed to be operated with little physical effort.
Dimensions Base	Size: L 306mm, W 98mm, H 72mm
Dimensions Scanner	Weight: 150 grams
	Size: L 256mm, W 43mm, H 43mm
	Cable length (scanner to base): 2m
Power Requirement	DC 5.0V / 4A (Power supply included)
Scanner Tip	Reusable up to 250 times, sterilize using steam autoclave
Heating Element	Ventilated. Prevents formation of fog on optics
Acquisition Method/Imaging technology	Hybrid technology: active stereo imaging and structured light
Sensor technology	CMOS
Color Scanning	24-bit (8-bit per channel)
Scanning frequency	25-30 FPS
Imaging field-of-view	12mm x 14mm
Light sources	High-power LEDs

Scanning Process

Tooth Preparation	No powder or spray required
Scanning Principle	Continuously scanning and accumulating (stitching) depth and color data
Distance Scanner - Tooth	-1mm – 19mm
Possible contact duration by operator	<10 min. Note : May vary with hardware configuration
Operator accessible part	Handpiece
Possible contact duration by patient	t ≤ 10 min

Patient accessible part (Type B Applied Part)	Tip (autoclavable)
Computer – Scanner Interface	USB 3.0

2.4 Software output and design software compatibility

Output File Format	STL, PLY, OBJ
Compatibility with CAD/CAM Systems	Open Architecture Output format STL, PLY, OBJ Compatible with most Dental CAD systems

2.5 Minimum Computer Requirements

The following requirements have been defined by 3DISC to ensure the 3DiscClinic software operates properly. The related configurations have been tested by 3DISC.

For an online version, visit: Minimum Computer Requirements



IMPORTANT NOTICE: The use of any other hardware units and/or other base software modules to run the 3DiscClinic software is not recommended and is not supported by 3DISC.

Minimum Software Requirements

Operating System	Windows 10 (Excluding Windows 10 S, now defunct) Administrative rights required.
Disk Space	100 GB or greater of free disk space
Ports	At least 1 x USB 3.0 port (SuperSpeed)
Nvidia Driver	Nvidia Studio driver version 516.94 is currently required. Nvidia gamer-ready driver should not be used with the HeronClinic software.
NVIDIA GPU operation mode	The PC must be able to ensure that the Nvidia GPU is the only GPU activated on the PC and that <u>any Intelintegrated GPU is disabled</u> . (This is usually achieved using high level configuration tools or BIOS commands).
	Warning : Certain models of computer of the following brands - Acer, MSI, HP, provide no option to only have the Nvidia GPU active. This may affect performance: low FPS or freeze during scan.

Screen resolution	Full HD (1920 x 1080) with DPI 100%
	NOTE: The use of 4K (3840 x 2160 pixels) or Ultra- Wide (3440 x 1440 pixels) resolutions is also possible,
	however the impact on performance has not been quantified by 3DISC at this stage.

Software Configuration Recommendations

Windows automatic updates	3DISC recommends deactivating all Windows automatic updates (except for security updates).
Nvidia driver automatic updates	Nvidia driver automatic updates <u>should be disabled</u> .
Windows Battery Settings	On laptops, the battery setting in Windows should be configured to high performance mode only , with <u>no battery saving option</u> .

Minimum Hardware Requirements

СРИ Туре	Intel 10, 11 and 12 generation. Intel i7 or i9 – 4 Cores give best performance.	
CPU Clock	2.8 GHz clock or greater "Turbo" and "boost" speeds cannot be considered.	
Memory	32 GB of RAM or greater (DDR4 or better)	
Graphics Card Memory	6GB of RAM minimum on the graphics card are needed. Below this, the software will not launch: an error message will inform you that the minimum requirement is not reached.	
GPU	 Quadro RTX3000, RTX4000 and above for laptop and desktop RTX2070 for laptop and desktop RTX2080 for laptop and desktop RTX2080TI for desktop RTX3070 for laptop and desktop RTX3080 for laptop and desktop RTX3090 for desktop 	

These PC requirements may be revised without notice by 3DISC to take into account observations made on the field or additional test results performed by our teams.



IMPORTANT: Compatibility of AMD GPUs is not guaranteed with the Heron $^{\text{TM}}$ IOS.

Not meeting minimum hardware requirements will affect the performance of the scanner.

2.6 Environment Conditions

Operating Temperature	10°C to 30°C	
Operating Temperature		
Operating Relative Humidity	10% to 80% (non-condensing)	
Storage Temperature	- 20°C to 60°C	
Storage Relative Humidity	10% to 80% (non-condensing) Indoor use only	
Installation Category	1	
Pollution Degree	2	
Ingress of Liquids	IPXO	
Protective Class	Class IIIb	
Overvoltage category	II per IEC 60664-1	
Max. working condition	Continuous cycles with image capture and transmission from/to Notebook or non-medical grade PC.	
Other possible accessories (IEC60601-1 3rd, Cl. 16)	Notebook with AC/DC Adapter.	
Equipment Maintenance	No user maintenance is required, and no user service is allowed. Please contact technical support in case of problem.	
Cleaning	Do not try to clean the inside of the device. Refer to section 9: Cleaning the Handpiece for cleaning	
	and sterilization.	

2.7 Power Input

The power adapter input is 5V DC, 100-240V AC, 50-60Hz.

2.8 Reusable Tips

Scanner tip is autoclavable up to 250 times in a steam autoclave when used with min cycle:

- 132°C (270°F) at 4 minutes, or
- 134°C (273°F) at 4 minutes, or
- 121°C (250°F) at 45 minutes.

See below: section 9.2 Cleaning and Sterilizing Tips.

2.9 Scanner Base and Handpiece

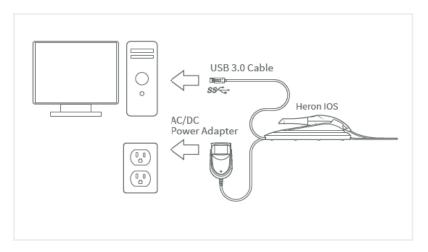
The scanner body consists of the Docking Base and Handpiece, which are connected by a flexible, non-detachable cable.

2.10 Calibration

The OVO™ is factory calibrated. In the case of calibration issues due to transport, please contact your reseller or 3Disc support technician.

3. Installing and connecting the OVO

3.1 Connecting the OVO



For an online version, visit: Getting Started with OVO



To install and connect the OVO Scanner:

- **Step 1.** Place the docking base on a flat, stable surface and place the OVO handpiece securely on the base.
- **Step 2.** Connect the AC/DC power adapter cable to the docking base (the connector socket is located underneath the base of the scanner).



WARNING: Make sure you use the 5.0V 4A power adapter provided. Failure to do so may result in damage to the scanning device.

Step 3. Connect the provided USB 3.0 cable to the docking base (the connector socket is located



WARNING: Using a USB cable other than the one provided may result in system malfunction or reduced performance.

underneath the base of the scanner).

Step 4. Connect the other end of the USB 3.0 cable to the computer.



IMPORTANT: Make sure to use a USB port that is compatible with USB 3.0 (SuperSpeed), usually indicated by this symbol: not doing so may result system malfunction or reduced performance.



IMPORTANT: When using a desktop computer, it is strongly recommended to plug the USB cable to a USB port located at the back of the computer; not doing so may result in system malfunction or reduced performance.

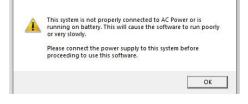
DO NOT plug the USB cable into an intermediate hub.

Step 5. Connect the adapter block provided to a power outlet.

IMPORTANT: Connect to Power Supply before Scanning!

If your laptop computer is not properly connected to a power outlet, the following message will appear:

In this case, please connect your laptop to the power supply **before proceeding** to use to scanner.



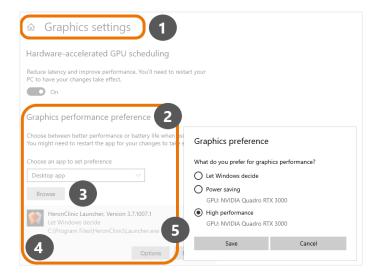


IMPORTANT: If using a laptop computer, make sure the power supply is connected to a power outlet and not running on battery power. Failure to do so will mean that the scanner will not have sufficient power to produce images.

3.2 Configuring Windows High Performance Graphics Mode

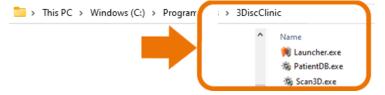
On laptop computers, battery settings in Windows should be configured to high performance mode only, with no battery saving option (Settings/System/Battery).





To select High Performance mode for the HeronClinic application:

- In Windows Graphic settings: click to activate Hardware-accelerated GPU scheduling
- 2. In Graphics performance preference: select Desktop app
- 3. Click **Browse** and select the **3DiscClinic** app as shown (**Launcher.exe**):



- 4. In Options, select High performance, and click Save.
- Repeat this for the HeronClinic PatientDB.exe and Scan3D.exe executable files.
- 6. Restart your PC to apply changes.



IMPORTANT: On laptop computers, battery settings in Windows should be configured to high performance mode only, with no battery saving option (Settings/System/Battery).

WARNING: Unsuitable installation sites



WARNING: Unsuitable installation sites:

- Locations with excessive humidity or dust
- Locations subject to high temperature
- Locations subject to shaking or vibration
- Locations exposed to considerable electrical or magnetic noise, or other forms of electromagnetic energy

4. Getting Started With 3DiscClinic

For an online version, visit: Getting Started with OVO



4.1 Launching 3DiscClinic

Once you have connected the OVO scanner, you are ready to launch the 3DiscClinic software installed on your computer.

Step 1. Click on the **3DiscClinic** desktop icon to launch the 3DiscClinic software.



Registration & Activation

On first launch, you will be invited to register and activate the 3DiscClinic software on your computer.



First Name		* Country	United States	V
ast Name		Address		
Insail Address		Address (continued)		
Scanner S/W	104246	* City		
restallation Date	5/23/2022	State/Zip Code		
		• Phone	-1	
			, you agree to the storage and proces	

In the Device Registration dialog box:

- **Step 2.** Enter your registration details (required information is indicated by *)
- **Step 3.** Tick the **consent** checkbox, to consent to the collection and processing of data.



Step 4. Click SUBMIT.



IMPORTANT: It will not be possible to perform new scans or export existing scans if the device has not been registered on the PC.

Data collected is used in accordance with the **General Data Protection Regulation** (GDPR) and is not shared with third parties. For information, see:

- section 1.8 3DISC Privacy Policy and GDPR Privacy Statement
- https://gdpr-info.eu/

Accessing the Admin User Account

The 3DiscClinic Start Screen will display the default 3DiscClinic Admin User Account (**HC**) in the left-hand menu.

To access the Admin user account:

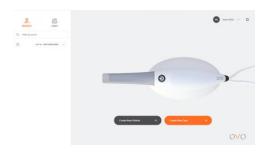
Step 1. Click on the Admin User Account (HC) icon in the lefthand menu.



The HeronClinic Sign In page invites you to **sign in** or **create a new account**.

Step 2. Enter your password and click **Sign In**.

The Admin User Start Screen displays as shown:





4.2 Setting Up A 3DiscClinic User Account

Customizing the Admin User Account

To customize the **3DiscClinic** Admin User Account (**HC**):

Step 3. Click the System icon located in the top right-hand corner of the User Start Screen, to access the **Settings** interface.





Step 4. Select Users in the left-hand Settings menu, and click on Add and Edit Users.



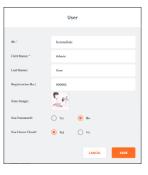
Step 5. Select the **default "3Disc Clinic" User profile**, and click on the **Edit** icon to customize the default Admin User account.

Note: The default admin ID "**3DisClinic**" cannot be modified.

Step 6. In the User Image field, you can click to open the Picture dialog box, to add or take a User Photo.



Step 7. To apply changes, <u>restart</u> the **3DiscClinic** application.



4.3 Adding a New User Account

Only the **3DiscClinic** Admin User profile (HC) can add new User Accounts.



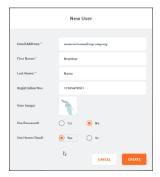
To add a new User account:

Step 1. In Settings/Users, click ADD NEW USER:

This opens the New User dialog box.



Step 2. Enter User information: email, first name, last name, registration no. (optional), photo (optional).



Password Protecting a User Account

To password protect a User profile (recommended):

- **Step 3.** Select **Yes** in the **Use Password** field.
- **Step 4. Enter and confirm** the password to apply to this user account.
- Step 5. Click CREATE.
- **Step 6.** To apply changes, **close and restart** the application.



IMPORTANT: To protect the privacy of patient data processed by you, it is important to password protect all user accounts.

4.4 Linking a User Account to the 3DiscCloud

You can link your **3DiscClinic** User account(s) to the **OVO** solution's dedicated **3DiscCloud** platform. The **3DiscCloud** enables users to easily and efficiently setup and manage file transfers and connections with labs.



Note: The Heron IOS **3DiscCloud** platform is designed to facilitate file sharing and manage connections with laboratories. **It is not a cloud storage service.**

To link the **3DiscClinic** User profile to a **3DiscCloud** account:

- **Step 1.** Using the Admin account, In Add and Edit Users, click **ADD NEW USER** to create a User account.
- Step 2. Enter account details, and in the Use HeronCloud field, Select Yes.
- **Step 3.** Click Create, to add the new User account.
- Step 4. Click OK.



The **3DiscCloud Login** window will open automatically, inviting you to **Login** or to **Create a New 3DiscCloud Account**.

For more information, see below:

Chapter 0 -

Communicating With Labs:

- Error! Reference source not found. Error! Reference so urce not found.
- Error! Reference source not found. Error! Reference so urce not found.

4.5 Accessing the 3DiscClinic Start Screen



User accounts are displayed in the left-hand menu of the 3DiscClinic Home Page.



To access the User Start Screen:

Step 1. Click on your User profile in the left-hand menu of the 3DiscClinic Home page.



The **3DiscClinic Login** window will open automatically, inviting you to **Login** or to **Create** a **New Account**.

Step 2. Enter your password and click SIGN IN.

4.6 Overview of the 3DiscClinic Start Screen

When you login to your **3DiscClinic** User account, the Start Screen is displayed as shown:



A. Patients/Cases View

You can toggle between **Patients** and **Cases** views, and Filter or search desired Patients/Cases.

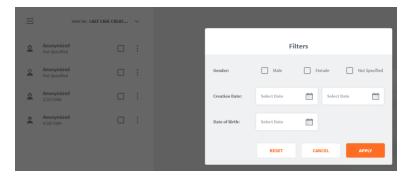


Filter/Search

Search by term or Click on the Filter icon to open the **Filters** dialog box.

You can display a list of Patients by:

- Gender
- Case Creation Date (or range of dates)
- Date of Birth



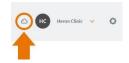
Select A User Start Page Default View To select a preferred Default View for the User Start Page:



- **Step 1.** Click **Settings** (E).
- Step 2. In the left-hand Settings menu select General.
- Step 3. Click Preferred Start Page, and
- **Step 4.** In the drop-down menu, select **Recent Patients** or **Recent Cases**.

Access directly your 3DiscCloud account

You can access the 3DiscCloud dashboard linked to your account by clicking on the Cloud icon opposite your username.



Enabling Direct Scan

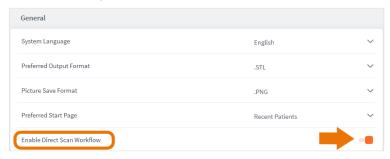


It is possible to directly access the scanning module without first selecting a patient profile or adding a case.

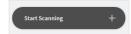
To enable Direct Scan:

- Step 1. Click Settings (E) to access System Settings.
- Step 1. In the Settings Menu, select General.

Step 2. In General settings, Select **Enable Direct Scan Workflow**. (Note: this option is disabled by default).



The **Start Scanning** bar is displayed in the User Start Screen.



Next Steps

For information on configuring 3DiscClinic Settings, see:

• Chapter 5 - Configuring Settings & Preferences

For information on managing patient cases in **3DiscClinic** see:

• Chapter 0 -

Managing Patients & Cases

For information on scanning with **3DiscClinic** see:

• Chapter 7 -

Scanning with HeronTM IOS

5. Configuring Settings & Preferences

For an online version, visit: HeronClinic Settings



5.1 Configuring Case Setup Settings

For an online version, visit: Case Setup Settings



5.2 Configuring Lab Sheet Settings

Lab Sheet settings enable users to customize Order forms for use by their organization, by adding the name, address and corporate logo to their Lab Sheets, and selecting a page format (A4/US Letter).



Order Forms are published in PDF format, and created automatically based on the **Case Setup Options** and **Lab Sheet** settings selected by you.

5.3 Configuring 3D Settings

For an online version, visit: Configuring 3D Settings



6. Managing Patients & Cases

For an online version, visit: Managing Patients & Cases



6.1 Managing Patient Profiles

For an online version, visit: Managing Patients



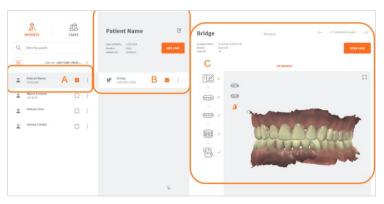
6.2 Managing Patient Cases

Previewing a Patient Case

The **Case Finalization page** provides detailed case information at-a-glance: creation date, case ID, restoration types, status, and any 3D models and 2D images associated with the case...

To preview a patient case:

- **Step 1.** Select a patient in the left-hand menu.
- **Step 2.** Select a case in the list of cases associated with the patient profile (4).



The **Case Preview** is displayed as shown.

Opening a Patient Case

To open an existing patient case:

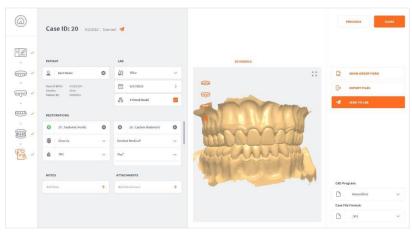
Step 3. Click **Open Case** in the **Case Preview** window.

OPEN CASE

This will open the **Finalization** page.

To directly access any step of the Case Workflow:

Step 4. Click on the relevant icon in the left-hand



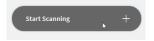
menu.

For information on using the **Finalization** page, see below:

• Chapter 41 - Finalizing a Patient Case

6.3 Using Direct Scan

It is possible to skip the **Case Setup** step and directly access the Heron[™] IOS Scanning module. To do so, select the **Start Scanning** click bar in the 3DiscClinic Start Screen.



In the case of a Direct Scan, the scan data is not associated with an existing patient profile, and is attributed an automatically generated patient ID.

Note: The Direct Scan feature is not activated by default. To activate click **Enable Direct Scan Workflow** in System Settings.



6.4 Merging a Direct Scan with a Patient Profile

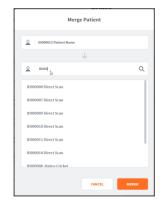
It may be useful to merge a direct scan you have carried out with an existing patient profile. You do this by merging the automatically generated DirectScan profile with an existing profile.

To merge patient profiles:

- **Step 1.** Select the profile to be merged and click the icon to the right of the patient folder (see above).
- Step 2. Select merge in the expanded list.

In the Merge Patient window:

- **Step 3.** Search and select a patient ID.
- **Step 4.** Click **Merge** and **Confirm**.

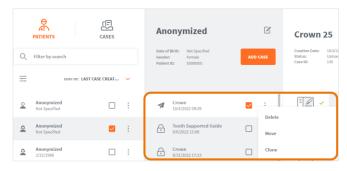


Cloning a Case

It is possible to duplicate an existing case and all associated data, including order form, scan data, intraoral photos, and attachments.

To clone a case:

Step 1. Click on the 3-point icon to the right of the selected case as shown



Step 2. Click Clone in the drop-down list.

Note: You cannot clone a case for which scan data has already been deleted.

Moving a Case

If a case has been associated with an incorrect patient profile, you can move a case from one patient profile to another.

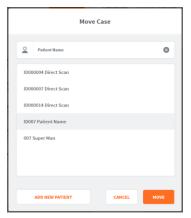
To move a case:

- **Step 1.** Click on the 3-point icon to the right of the selected case.
- **Step 2.** Click **Move** in the expanded list.

In the Move Case dialog box:

- Step 3. Select or create a patient profile (ADD NEW PATIENT).
- Step 4. click MOVE.

The case is associated with the selected patient profile.



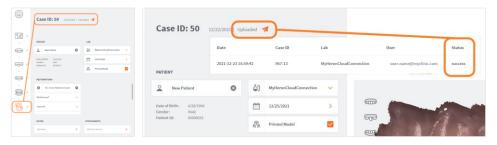
6.5 Viewing Case Status

To access Case status details in the Finalization page:



Step 1. Click on the status icon as shown above.

The expanded list provides information on the User, Case ID, Lab, Date the case was last modified, and the send status.



Case Status Icons

	Case Status	Description
4	Created	Case is created and currently in progress.
Nº	Scanned	Case is scanned and finalized.
1	Uploaded	Case is uploaded to lab via 3DiscCloud.
7	Closed	Case is closed. When the Auto Clean Raw Scan Data option is enabled in Data Settings , cases for which raw scan data is deleted are automatically closed.

6.6 Setting Up a Case in 3DiscClinic

The following workflow briefly describes the typical steps and options available to set up a patient case in 3DiscClinic.

For an online version, visit: Creating a Patient Case



For an online version, visit: Case Setup Settings



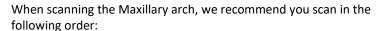
7. Scanning with Heron™ IOS

For an online version, visit: Scanning with Heron IOS



Scanning the Maxillary Arch

For an online version, visit: Scanning the Maxillary Arch





7.1 Using Scan Tools

At each step of the scan workflow, you can use the features available in the right-hand **Scan Tools** menu.

For an online version, visit: Using Scan Tools



7.2 Using the Quality Map ¶

The Quality Map tool enables you to assess in real-time if enough data has been collected in the area of interest of the scan.



For an online version, visit: Using the Quality Map[©]



7.3 Taking Live View Screenshots

To obtain Live View Screenshots during the scan:

 Press the C key on your keyboard or click on the icon in the scan tools menu.



2D Live View Screenshots are displayed in thumbnail format in the bottom left-hand corner of the screen.





- 2. Click on a thumbnail image to inspect the 2D images in fullscreen format.
- 3. Click on the Delete icon to delete as necessary.
- Click on the *Close* icon in the top right-hand corner to close the fullscreen view.

Live View Screenshots taken during the scan can be viewed in the **Finalization** page.

7.4 Using Auto-Realignment ¶

The **Auto-Realignment** tool carries out realignment of the scans, optimizing the scan data based on **Artificial Intelligence** (AI). To simplify, the scan data is cleaned by discarding frames that are calculated to be misaligned with respect to the totality of the available data.



You are advised to use the **Auto-Realignment** tool <u>before</u> proceeding to the **Bite Alignment** step, as optimization may modify the occlusal position of the realigned arches.

7.5 Using 3DiscClinic Live Scan Tools ¶

During the **3DiscClinic Scan Workflow**, **Live Scan Tools** are displayed below the digital 3D Model.

For an online version, visit: Using 3DiscClinic Live Scan Tools



For an online version, click: <u>Automatic Bite Alignment</u>

7.6 Carrying out a Manual Bite Alignment

For an online version, click: Manual Bite Alignment



8. Finalizing a Patient Case



For an online version, click: Finalizing a Case in HeronClinic_



8.1 Using Case Finalization Tools

For an online version, click: Using Case Finalization Tools



9. Communicating With Labs

For an online version, visit: Communicating with Labs



10. Maintenance

9.1 Cleaning the Handpiece

The entire body, cord and base of the scanner must be wiped down using a **Federal Environmental Protection Agency (EPA)** approved disinfectant that is labeled and specified for tuberculocidal/ mycobactericidal activity. Do not use disinfectant on the nozzle.



IMPORTANT: All components of the scanner (excluding the tips) must be **wiped down** and <u>not sprayed</u>. Avoid getting any moisture, alcohol or disinfectant inside the open scanner chamber.

Recommended and approved surface disinfectants:

- Birex Wipes: TB Claim= 10 minutes- 'Phenolic (Dual) Water-Based'
- Prospray Wipes: TB Claim=10 minutes- 'Phenolic (Dual) Water-Based'
- Cavicide Wipes: TB Claim=3 minutes- 'Phenolics (Dual) Alcohol-Based'
- DisCide ULTRA Wipes: TB Claim-1 minute- 'Phenolics (Dual) Alcohol-Based'
- Maxiwipe Germicidal Cloth: TB Claim=5 minutes- 'Phenolics (Dual) Alcohol-Based'
- Ster 1 Plus: TB Claim=5 minutes- 'Quaternary ammonium and Alcohol-Based'

9.2 Cleaning and Sterilizing Tips



IMPORTANT: The included tips must be autoclaved prior to use as they do not come pre-sterilized.



IMPORTANT: Ensure that the surface of the mirror does not show residues, smudges, scratches, or any damage, as this would affect the performance of the device.

Step-by-Step Procedure

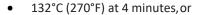
Step 1. Clean the tip with soapy water, ensuring that the mirror is clean and free of smudges, stains, or any residue. Avoid using abrasive cloth materials as this will scratch the mirror.



Step 2. After drying the tip exterior, carefully dry the interior and mirror with lint free wipes ensuring you do not scratch the sur-face. The mirror should be free of any noticeable debris or water spots.



- **Step 3.** Insert and seal the tip into a sterilization pouch. Make sure the seal is airtight. Each tip should be packaged individually.
- **Step 4.** Sterilize the wrapped tip in a steam autoclave at the following parameters:



- 134°C (273°F) at 4 minutes, or
- 121°C (250°F) at 45 minutes



Step 5. Ensure the dry cycle is complete prior to removing the tip from the autoclave. If the pouch is damp with moisture, proper sterilization cannot be guaranteed



WARNING: Always autoclave the tip wrapped in a sealed sterilization pouch; failure to do so will result in permanent stains on the mirror.



NOTE: Tips should not be placed in an ultrasonic cleaner or any cold sterile solutions. The sterilant solutions will leave a sticky residue or film on the mirror when drying



WARNING: Do not autoclave the handpiece of the device.



WARNING: Do not remove the pouch before the sterilizer completes its full dry cycle. If the pouch is wet or has any signs of moisture, this can potentially leave water spots on the mirror which can affect image quality during scanning.

9.3 Disposal

The Heron is an electrical device with electronical components inside and should be disposed of in accordance with local environmental laws and regulations.

9.4 Calibration

The OVO is calibrated in the factory and therefore does not require calibration when installed.



WARNING: General prohibition indication. The functionality of the system can be destroyed in the case of incorrect use. If unauthorized changes have been made to the delivered system and accessories, the warranty by 3DISC becomes void. 3DISC will not accept any responsibility or liability for the improper functioning of the product in such a case.



WARNING: Use extreme caution when cleaning the mirror as it is very delicate and is prone to scratching.

If the **OVO** begins to have problems scanning and recognizing teeth models, contact your dealer or **3DISC Support** technician.

If the scanner cannot be recalibrated remotely, this may result in the system being returned for repair/ calibration.

For more information, see below:

• Chapter 12 - Support, Warranty and Repair Service.

11. Safety Guidelines and Warnings

11.1 Warnings and Symbols



NOTE: Notes represent information that is important to know but which do not affect the functionality of the system.



WARNING: The functionality of the system will be limited in the case of incorrect use.

11.2 General Guidelines

- Do not spill liquids on the body of the device
- Never operate the device in a wet environment.
- Keep the device away from radiators and heat sources.
- Use the device only with the accessories supplied.
- Do not alter the device or open enclosures.



WARNING: General prohibition indication. The functionality of the system can be destroyed in the case of incorrect use. If unauthorized changes have been made to the delivered system and accessories, the warranty by 3DISC becomes void. 3DISC will not accept any responsibility or liability for the improper functioning of the product in such a case.

If any of the following conditions occur, unplug the device from the electrical outlet and contact authorized service personnel:

- The power cord or power adapter is damaged.
- The device has been exposed to water.
- The device has been damaged.
- The device does not operate correctly when the operating instructions are followed.

11.3 General Warnings

System Modification



WARNING: Modifying the system may result in physical injury to the patient and operator, and damage to the system.

Approved Software

The OVO device is designed to operate with the 3DiscClinic software.



WARNING: The Heron[™] IOS scanner should only be used with approved, compatible software.

Equipment Failure



WARNING: In case of **system** malfunction or failure, you should:

- Prevent any contact between the system and the patient.
- Unplug the system from the power outlet and the computer.
- Store the system away so it cannot be used by someone else.
- Contact service personnel.

11.4 Mechanical Hazards

Moving Parts



NOTE: All moving parts are inside handheld scanner so do not open the unit.

Dropped Equipment



WARNING: If the scanner tip is dropped, ensure that the mirror is not damaged and that it is not detached; if the tip is damaged it should be disposed of immediately. If the scanner handpiece is dropped or bumped, ensure that no part of the system is damaged as it could affect performance.

Base



NOTE: When not in use, always rest the handpiece on the Base. The Base may be mounted on the wall per provided instructions. Do not place the Base on a slanted surface. Place the cables (power cable and USB cable) where people cannot accidentally get caught in them and potentially damage the system.

11.5 Electrical Safety

Electrical Shock



WARNING: There is a risk of electrical shock when opening or attempting to open any part of the system; only qualified service personal should open parts of the system.

Stress on Cables



WARNING: Care should be taken not to apply unnecessary stress on the cables of the system, whether it is the power cable, the USB cable or the cable between the handpiece and the Base.



WARNING: Only use the power adapter supplied as a part of the system.

11.6 Eye Safety



WARNING: During operation, the system emits a bright, flashing light from its tip. Although the system complies with standard IEC 62471 (Photobiological safety of lamps and lamp systems), prolonged exposure to flashing light may result in discomfort, seizure or eye irritation.

11.7 Hygiene



WARNING: In order to maintain safety for the patient, wear surgical gloves when handling any parts of the system. Always ensure that the tip is mounted on the handpiece before inserting it into the mouth of the patient. Before using the system with a new patient, ensure that the system is disinfected, and the tip is sterilized.

11.8 Precautions During Systems Operation



WARNING: The Heron™ IOS system contains delicate optical and mechanical elements and therefore should be handled carefully. Do not drop, bump, or shake the handpiece or the tip. Always place the handpiece on the Base when not in use. Do not put stress on the cable connecting the handpiece to the Base. Do not submerge the handpiece or the Base in any liquid. Do not place the handpiece or the Base on wet or heated surfaces. Hold the handpiece with a firm grip when handling it.



WARNING: Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the Heron™ IOS, including cables specified by the MANUFACTURER. Otherwise, performance degradation of this equipment may occur.



NOTE: During operation of the system, the handpiece and the tip may get slightly warm; this is normal.



WARNING: In order to prevent over-heating of the system, the ventilation opening at the bottom of the handpiece should never be obstructed.



WARNING: Use of this equipment adjacent to or on other equipment must be avoided as it may result in improper operation. If this use is necessary, it is advisable that this and the other equipment be observed to verify that they are operating normally.

OVO Performance

Under normal use, the OVO should transmit images to the laptop/workstation with the installed image manipulation software and the video stream is visible in the bottom left corner of the screen. If not used properly, there may be loss of transmission of image information or slow transmission temporarily.

11.9 Accessories



WARNING: Only use 3DISC approved accessories. Not using 3DISC approved accessories may result in deterioration of performance.

Accessory	3DISC Part Number
USB 3.0 Cable	IOS-CP-00-043
AC/DC Power Adapter	IOS-CP-00-088

OVO is intended for use in a professional healthcare setting with electromagnetic environment specified below.

11.10 EMC Guidance and Declaration

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1, Class A	OVO 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000- 3-3	Complies	OVO is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Immunity	Test Level	Compliance	Electromagnetic Environment
Test		Level	Guidance

	1	ı	T
Electrostatic	± 8 kV	± 8 kV	Surface should be wood,
discharge	/Contact	/Contact	concrete, or ceramic tile. If floors
(ESD) IEC	± 2 kV, ± 4	± 2 kV, ± 4	are covered
61000-4-2	kV, ± 8 kV,	kV, ± 8 kV, ±	with synthetic material, the
	± 15 kV /air	15 kV /air	relative humidity should be at
			least 30%.
Electrical fast	± 2 kV for	± 2 kV for	Mains power quality should be
transient/	power	power	that of a typical professional
burst IEC	supply lines	supply lines	healthcare facility environment.
61000-4-4	± 1 kV for	± 1 kV for	
	input/outpu	input/outpu	
	t lines	t lines	
Surge IEC	± 0.5 kV, ± 1	± 0.5 kV, ± 1	Mains power quality should be
61000-	kV line(s) to	kV line(s) to	that of a typical professional
4-5	line(s)	line(s)	healthcare facility environment.
	± 0.5 kV, ± 1	± 0.5 kV, ± 1	
	kV, ± 2 kV	kV, ± 2 kV	
	line(s) to	line(s) to	
	earth	earth	
Voltage dips,	<5% UT	<5% UT	Mains power quality should be
short	(>95% dip in	(>95% dip in	that of a typical professional
interruptions	UT) for	UT) for	healthcare facility environment.
and	0,5 cycle	0,5 cycle	
voltage	40% UT	40% UT	
variations on	(60% dip in	(60% dip in	
power supply	UT) for 5	UT) for 5	
input	cycles 70 %	cycles 70 %	
lines IEC	UT (30% dip	UT (30% dip	
61000-4-11	in UT) for	in UT) for	
	25 cycles	25 cycles	
	<5% UT	<5% UT	
	(>95% dip in	(>95% dip in	
	UT) for 5 s	UT) for 5 s	
Power	30 A/m	30 A/m	Power frequency magnetic fields
frequency			should be at levels characteristic
(50/60 Hz)			of a location in a typical
magnetic			professional healthcare facility
field IEC			environment.
61000-4-8			
Radiated RF	Table 9 in	Table 9 in	Portable and mobile RF
IEC 61000-4-3	IEC-60601-	IEC-60601-	communications equipment
	1-2 2014	1-2 2014	should be used no closer to any
Conducted RF	3V 0.15-	3V 0.15-	part of the OVO system, including
IEC 61000-4-6	80MHz	80MHz	cables, than the recommended

6V in ISM	6V in ISM	separation distance calculated
bands	bands	from the
between	between	equation applicable to the
0.15 MHz	0.15 MHz	frequency of the transmitter.
and 80 MHz	and 80 MHz	Recommended separation
80% AM at	80% AM at	distance:
1KHz	1KHz	2.5
		$d = [\frac{3.5}{V1}]\sqrt{P}$ 150 kHz to 80 MHz
		$d = \left[\frac{3.5}{E1}\right] \sqrt{P}$ 80 MHz to 800 MHz
		. ,
		$d = \left[\frac{7}{E1}\right] \sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$
		where P is the maximum output
		power rating of the transmitter in
		watts (W) according to the
		transmitter manufacturer and d
		is the recommended separation
		·
		distance in metres (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:
		((1±))
		-1
 	<u> </u>	

NOTE: UT is the A.C. mains voltage prior to application of the test level.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the OVO System that is not Life-Supporting

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

Rated maximum	Separation distance according to frequency of transmitter m			
output power of transmitter W	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$	
0,01	0.12	0.12	0.23	
0,01	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11.11 Symbols on the Heron IOS and Transport Case

Symbol	Description
	Manufacturer's trade name and address (ISO 15223-1)
	Date of manufacture (ISO 15223-1)
(h)	Equipment Power On/Off (push/push)
ss⇔	USB 3.0 plug
<u>(1</u>	Warning, Consult Accompanying Documents
(!)	General mandatory action manual
\bigcirc	General prohibition indication
(2)	User Manual Reference
A	Directive on Waste Electrical and Electronic Equipment
EC REP	Authorized Representative in the European Community
Note Crossy 2 Control of Section (Section Section Sec	Warning label for LED
((•))	Non-ionizing electromagnetic radiation
	Direct Current
*	Type(B) Level of protection against electric shock
[]i	Consult operating instruction for use.
CE	European Conformity mark
R	Prescription symbol
NON STERILE	Non-sterile (Scanner-Tips) (IOS-FPL-71-001)
	User manuals are available electronically at the link provided (3disc.com/support-resources/heron-ios-user-manuals/)

Segurança CC DASTRO SE COD	INMETRO Certification Mark
(Ukraine Conformity Mark

12. Support, Warranty and Repair Service

12.1 Support

If you have questions about the software, please consult the manual and Help menu in the software. If you are experiencing issues with your software, please check the list of common issues provided below prior to contacting a dealer. It could be simply a question of a minor issue that can be fixed quickly. However, if you're still experiencing problems after following the recommendations in this section, then please contact the dealer where you bought the equipment.

Operating Issues Checklist

Issue	Recommendation
There's a memory full error message that pops up when the software is open.	Clear some space on the C Drive
The status in the Live view window is "Disconnected".	Check that you have external power to the Heron and that the USB cable is connected to a USB 3 Port.
Scanning is very slow.	Check that the Laptop is connected to an external power source.
The corners are cut in the live view window.	Check that the Tip is correctly mounted and when rotating it is locking in place with a click.
There is a red square in the scan window	Go back to a tooth that is scanned and start from there again
No images appear when scanned but everything else (e.g. live window image, sounds, FPS) works fine.	The scanner might need to be recalibrated. Please contact your local dealer for support.
There are spots on the Live view window.	Check and clean the mirror of the tip.
Where can I get the OVO software and manuals?	Software and manuals can be downloaded in the Support section of the 3DISC website.

12.2 Standard Warranty

3DISC warrants its non-consumable hardware products to be free from defects in materials and workmanship. The warranty covers the cost of parts and labor to repair the product.

Please keep the shipping container for future use. Products returned to the factory for

repair should be properly packaged. To obtain warranty service, follow the procedure described in the Repair Service section. Failure to do so will cause delays and additional expense to the customer.

The warranty is valid when the product is used for its intended purpose and does not cover products which have been modified without written permission from 3D Imaging and Simulation Corp. Americas, or which have been damaged by abuse, accident or connection to incompatible equipment.

This warranty is in lieu of all other warranties, expressed or implied.

12.3 Repair Service

The OVO cannot be serviced locally. In the event of a hardware malfunction, contact your dealer to arrange for a swap unit (same model or newer) so your unit can be replaced, and work can continue. Some testing might be needed in order to verify the Hardware/Software error or malfunction.

The company reserves the right to cease providing repair, maintenance, parts and technical support for its non-consumable hardware products five years after a product is discontinued.

12.4 Out of Warranty Repair Service

Out of warranty repair service is available in selected geographical locations. Contact the supplier for current terms and rates.

We hope this User Manual was helpful to you. For additional material and user information go to:

3disc.com/support-resources/

OVO User Manuals OVO How-to Videos OVO Training Videos

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