NanoScope™ Operative Arthroscopy System

V1.1.0 Software Operation Reference Guide

The NanoScope™ Software Operation Reference Guide provides an overview of how to navigate through the system's user interface.

Table of Contents

1. Introduction

This document is not intended to replace or supersede the directions for use (DFU) for the NanoScope™ operative arthroscopy system. Users must read the NanoScope DFU prior to using the device. The DFU provides the indications and contraindications for use, warnings, and the full list of product instructions. The document can be found on Arthrex.com as well as packaged with the Synergy Matrix™ system.

The touchscreen design of the user interface facilitates navigation through the different screens that will be defined in this reference guide along with their respective icons and their functionality.

2. NanoScope Software Operation

2.1. LOGIN SCREEN

The NanoScope **Login Screen** is divided into the following sections:

- **Menu Bar:** Settings, Facility Name, Peripherals, Battery Level Indicator, Date and Time
- **Center:** User Selection
- **Sleep Mode – Restart – Shutdown Buttons**
- **Add User Button**

Figure 1. Login Screen

2. NanoScope™ Software Operation (Cont.)

2.1.1. Menu Bar

The **Menu Bar** contains the following information:

- Admin Settings Button
- Facility Name
- Peripherals
- Battery Level Indicator
- Date and Time

Figure 2. Menu Bar

Icon/Button/Label/Event/Tab	Description
Settings (gear icon)	The Settings button provides access to the Administrator System Settings page, which allows the Administrator to modify settings as well as get general system status information.
Arthrex Surgery Center	Facility name.
Peripherals (USB, iPad, Ethernet, Camera head icons)	Provides status on peripherals: • USB drive • iPad • Ethernet connection • Camera head The icon will display as white when the peripheral is connected to the device.
90% (battery icon)	Battery status.
100% (battery charging icon)	Battery status: cable plugged in and charging.
May 30, 2019 10:17 AM	Current date and time.

2. NanoScope™ Software Operation (Cont.)

2.1.2. Types of Users

There are three types of users:

- Surgeon (center of the screen).
- Guest (center of the screen).
- Admin (top left corner)

Figure 3. Users

2.1.2.1. User: Surgeon

Surgeons can access their own list of procedures and cases along with their respective images and videos.
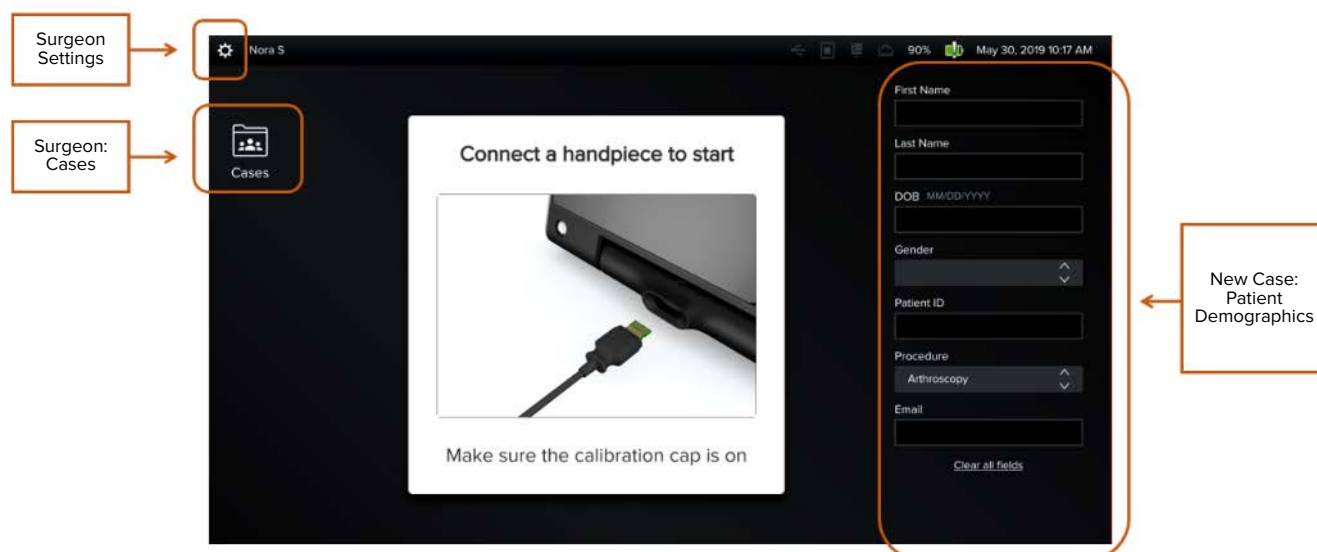
Log in as a Surgeon:

- Enter the surgeon's credentials, and then select **Log in.**

Figure 4. User: Surgeon (The following screen will then be displayed where the surgeon can view the list of cases, create a new case, and access the surgeon settings.)

Figure 5. Patient Demographics

Surgeon Settings

Surgeon: Cases

New Case: Patient Demographics

Emergency Login

Access will be restricted to performing procedures.

Note: After using the Emergency Login option to start a case, the surgeon will need to log in with their credentials to view the case later.

- To start a case without entering the surgeon's credentials, click on the Surgeon name from the Login screen.
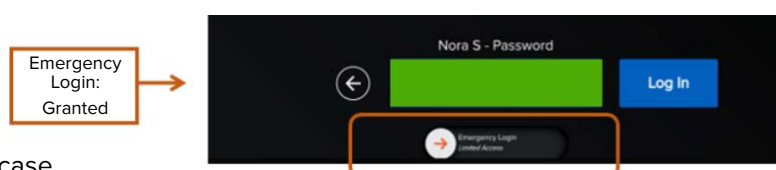
Figure 6. Emergency Login

Surgeon: Emergency Login

- Swipe to the right on the Emergency Login bar located below the Surgeon credentials field.

Figure 7. Emergency Login - Granted

Emergency Login: Granted

- The surgeon can now start a new case.

2.1.2.2. Demo User: Guest

The Guest user option allows a surgeon to start a case without logging in.

For Guest users, the following applies:

- Password not required
- No option to enter patient demographics prior to performing any procedure
- Option to export or access case media capture without patient demographics

Log in as a Guest

- As a Guest, user does not need to enter any type of credentials, the surgeon will be logged in automatically.
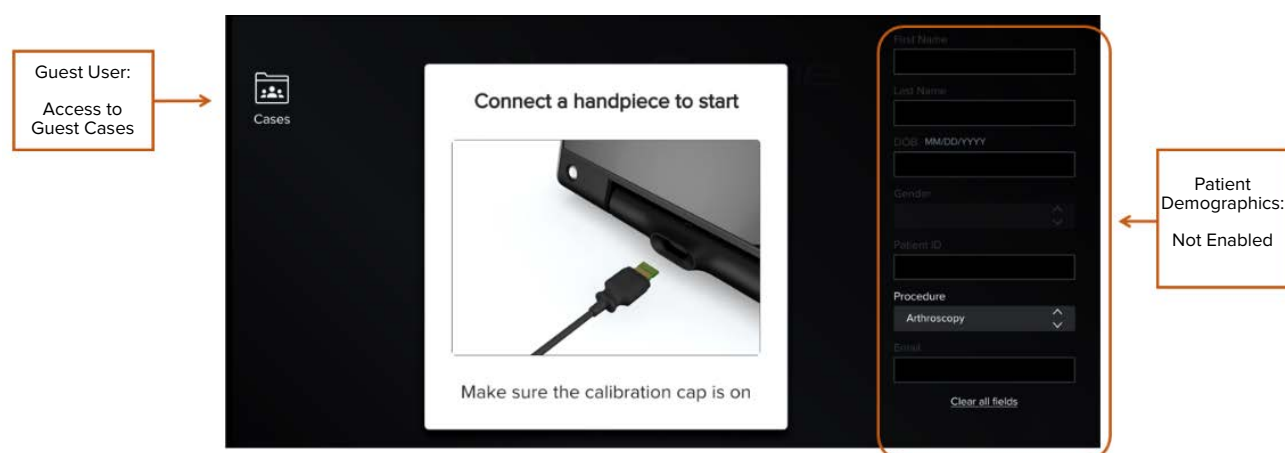
Figure 8. User: Guest

Guest User:

No Password Required

- Once logged in, the surgeon will be able to start a new case.

As seen in the figure below, as a Guest user, only type of Procedure is enabled as a field.

Figure 9. Home Page

Guest User:

Access to Guest Cases

Patient Demographics:

Not Enabled

2.1.2.3. User: Admin

The Administrator can perform the following actions:

- Create and manage the List of Procedures for the facility
- Manage users' accounts
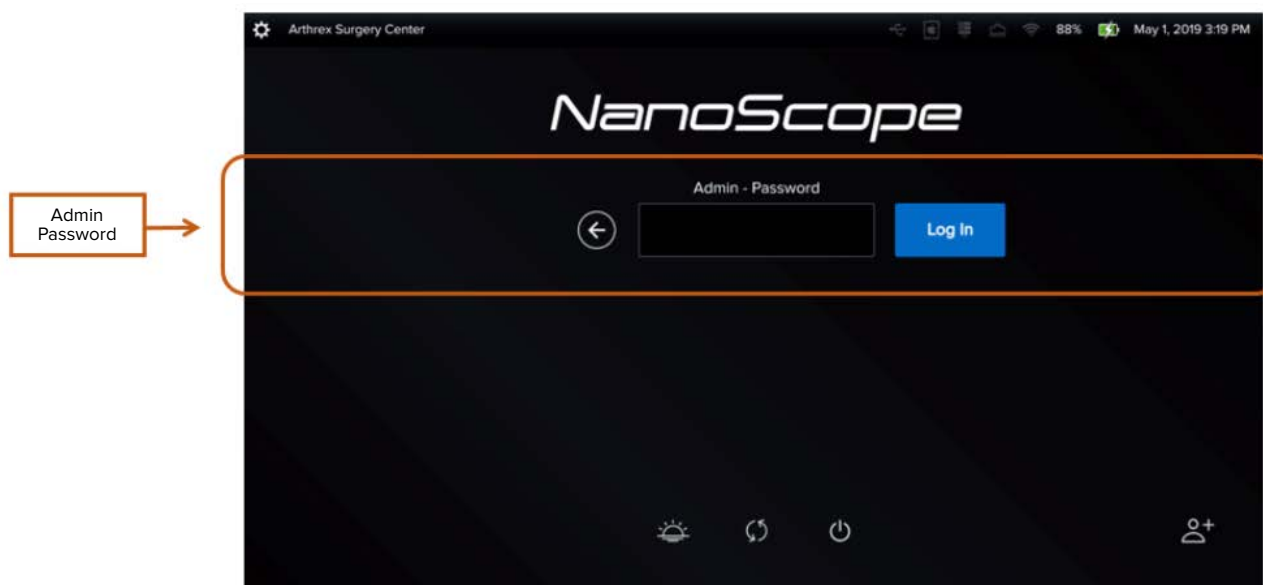- Manage data, connections, system updates, and logs

To log in as an Administrator, click on the gear icon at the top left corner of the Login page.

Figure 10. User: Admin

- The following screen will be displayed.

Figure 11. Admin Password

- Enter the Admin credentials.

Note: The default Admin password is Nanoscope!1. Once the administrator has logged in for the first time, it is recommended to change the default password.

2. NanoScope™ Software Operation (Cont.)

2.1.3. Add a New User
Anyone can add a new user.

- To add a new user, click on the **Add New User** button, located on the bottom right corner of the screen.

Figure 12. Add User: The email entered for the new user will be tied to the Surgeon Vault/iPad account.

**New User Field:** It should contain at least one capital letter, one number, and one special character.

2.2. SETTING UP THE CONSOLE
There are default settings that can be customized for each surgeon. To do so, log in as a Surgeon and access Surgeon Settings, which will display the following options: Handpiece, Export, and Procedure Settings.

Customizing Surgeon Settings on the console in advance allows for greater time efficiency.

- Log in as a Surgeon, as outlined in the section Types of Users.
- Click on the **Surgeon Settings** icon, which is located on the top left corner of the Home Page.
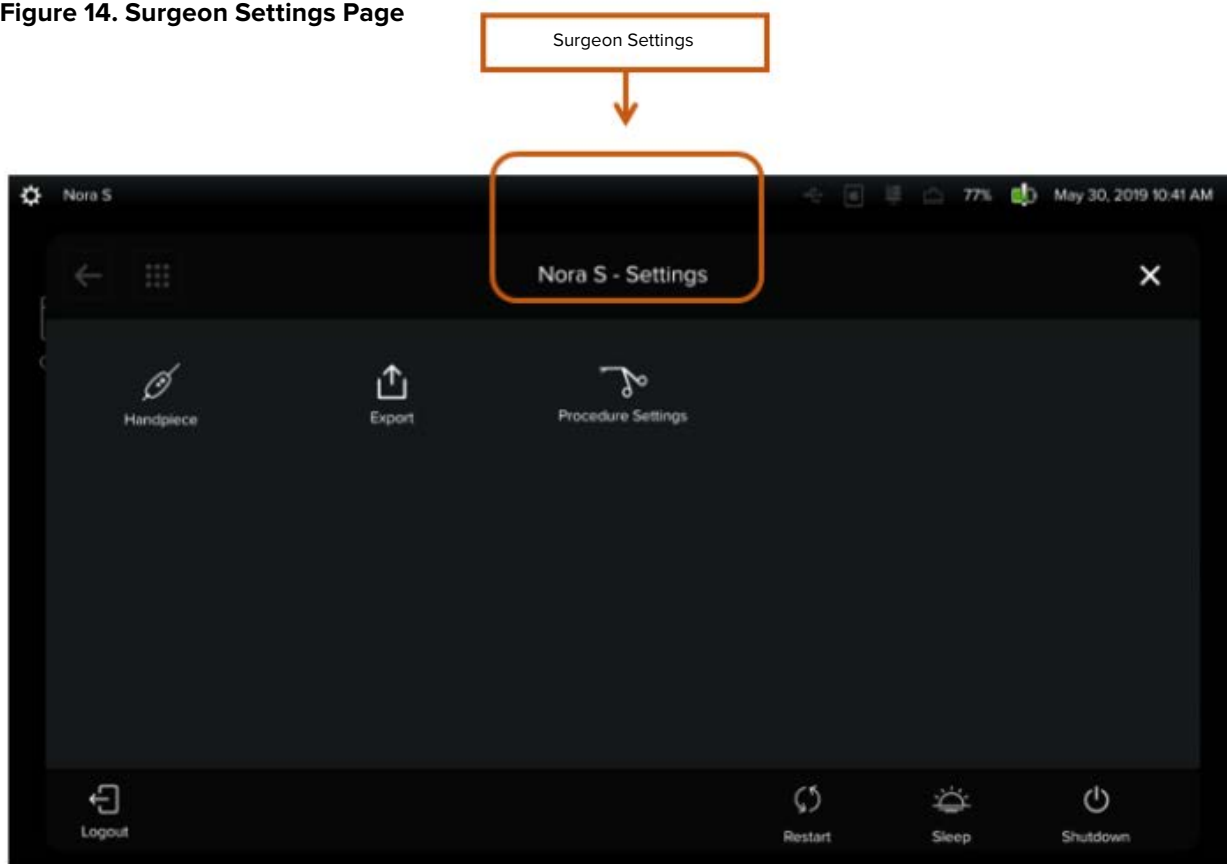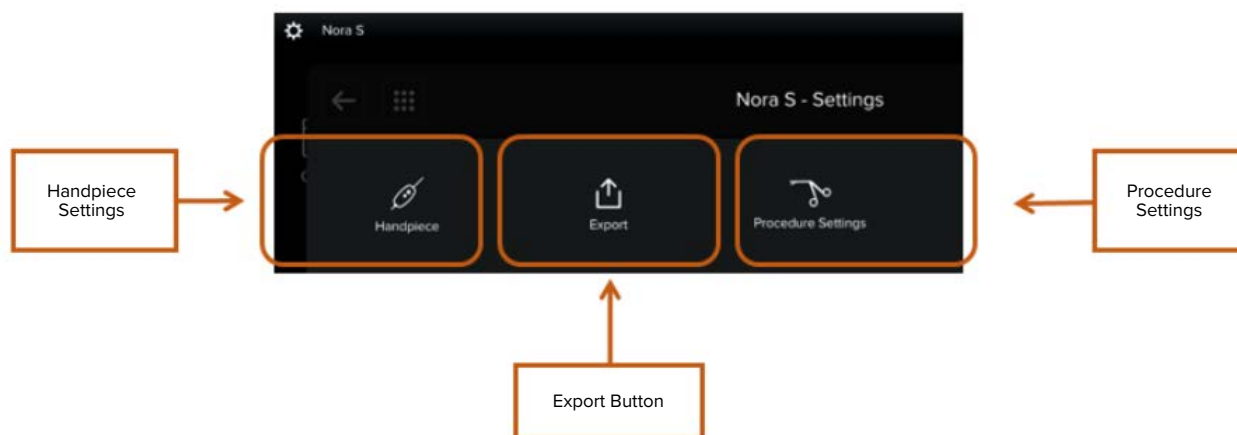
Figure 13. Surgeon Settings Icon
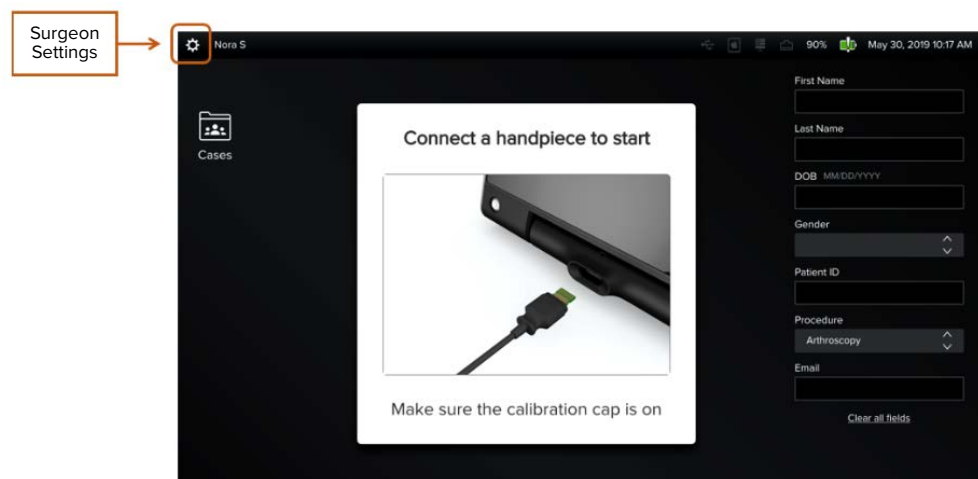
The following page will be displayed.

Figure 14. Surgeon Settings Page

As seen in the figure below, the surgeon can access the following settings.

Figure 15. Surgeon Settings

Icon/Button/Label/Event/Tab	Description
Handpiece	Adjust the handpiece front and rear buttons.
Export	Export media to a USB, iPad, or Network.
Procedure	Add procedures from the Master List of Procedures to the surgeon's profile.

2.2.1. Handpiece Settings

For each of the front and rear buttons, there is a short and long press and, in turn, for each press, there are four options available:

- Capture image
- Record video
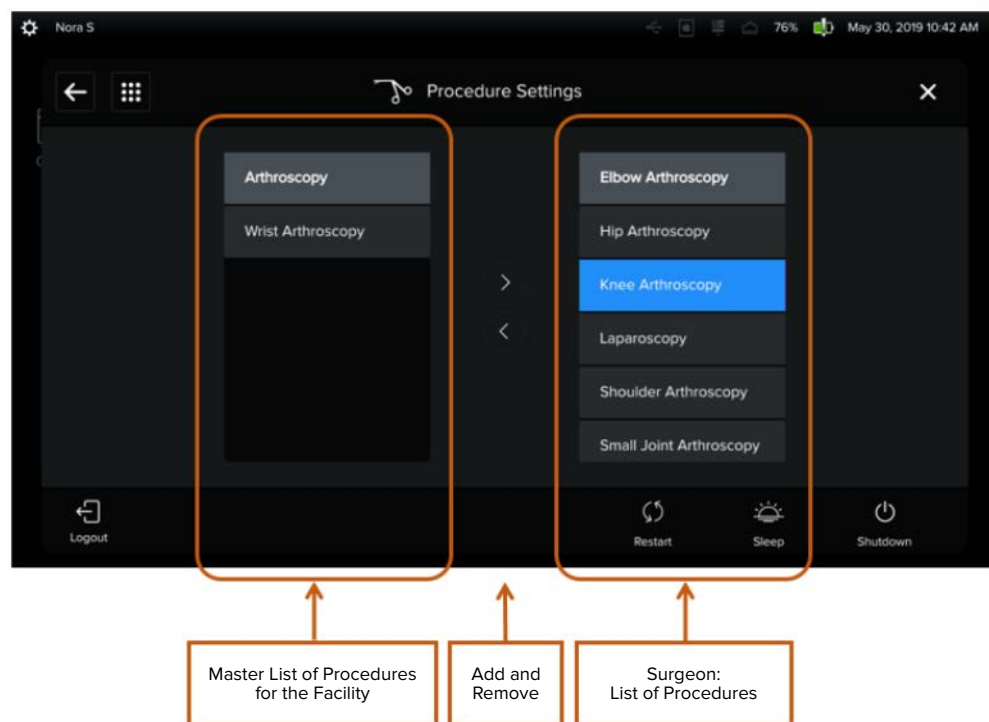- White balance
- None

Figure 16. Handpiece Settings
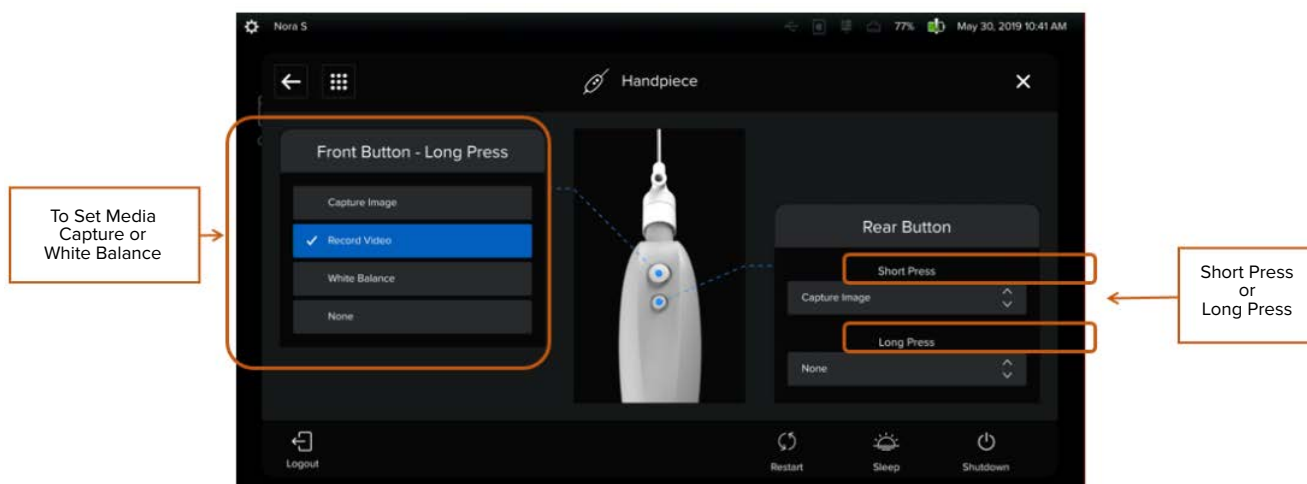
2.2.2. Procedure Settings

Each surgeon can create their own list of procedures from the Master List of Procedures.

- Click on **Procedure Settings** to display the following screen:

Figure 17. Surgeon: Procedure Settings - All procedures entered by the Admin are shown in the left column: Master List of Procedures.

Note: Refer to Section 2.4.11 Admin Settings, Procedure Settings for further details on how to create the Master List of Procedures for the facility.
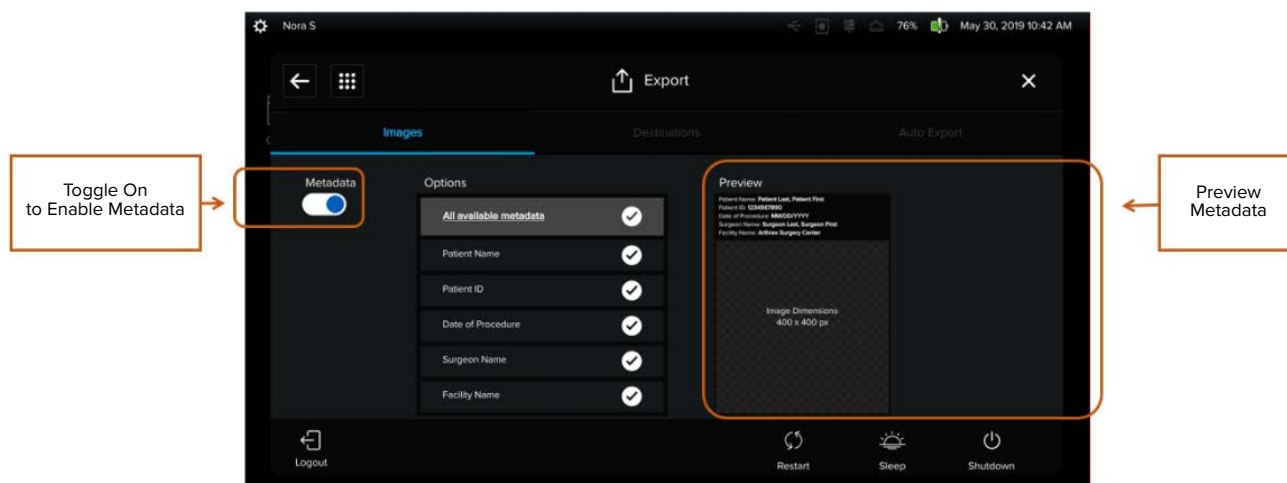
The surgeon can perform the following actions:

- Add procedures from the Master List to their own List of Procedures.
- Remove procedures from the Surgeon's list.

2.2.3. Export Settings

Export Settings gives the Surgeon the option to select which metadata, if any, is exported on the image.

Figure 18. Export Settings

Note: Destinations and Auto Export are not enabled for this software version.

Metadata

- Toggle On and Off to display and select specific pieces of metadata for the patient, procedure, surgeon, and facility.
- Once the metadata options have been selected, they are displayed in the Preview panel located on the right side of the screen.

Selected metadata are included in the file to be exported via USB, iPad, or PC.
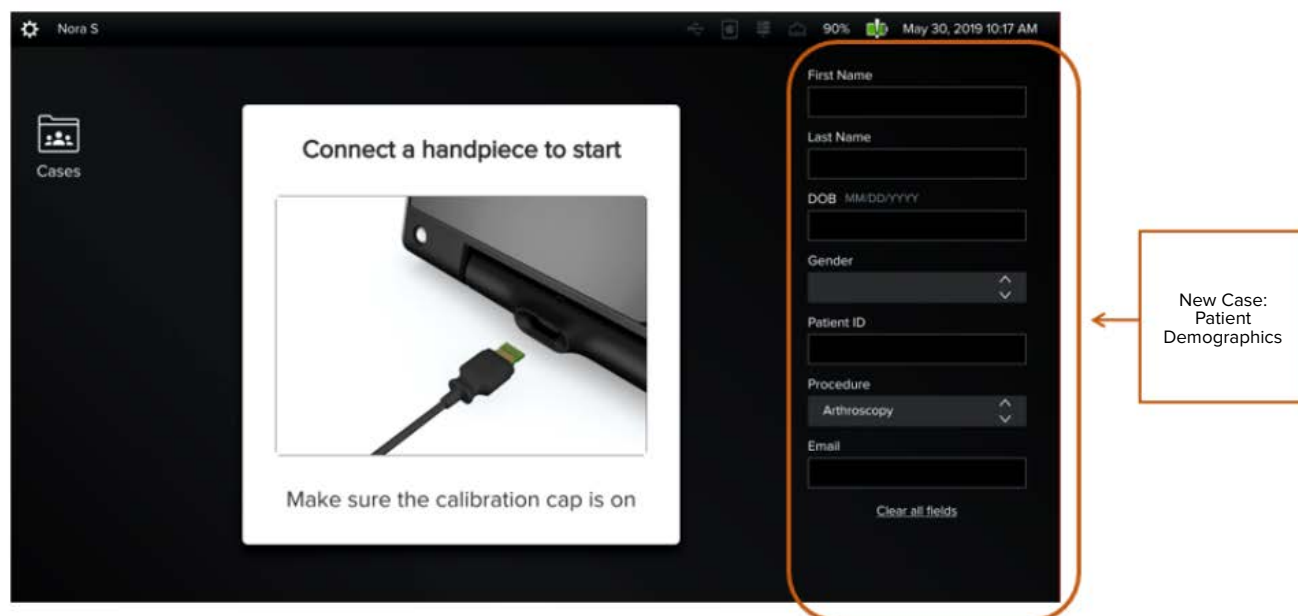
Note: Image dimensions: 400 pixels × 400 pixels.

2.3. STARTING A NEW CASE

2.3.1. Enter Patient Demographics

1. Log in as a Surgeon.
2. Enter the patient's demographics.

Figure 19. Patient Demographics

Note: At this point, if needed, the surgeon can start a case by inserting a handpiece without entering any patient demographics.

Patient Demographics:

- Enter patient demographics on the Home Page either before calibration of the handpiece or after case end.
- Patient demographics can be completed or edited when reviewing the case.

2.3.2. Calibrate the Handpiece

Figure 20. Insert the Handpiece

1. Insert the handpiece as shown in Figure 20.
2. Press any camera button to calibrate the handpiece.

Note: Use only new, sterile handpieces. If a used handpiece is connected, the following message will be displayed:

Figure 21. Used Handpiece

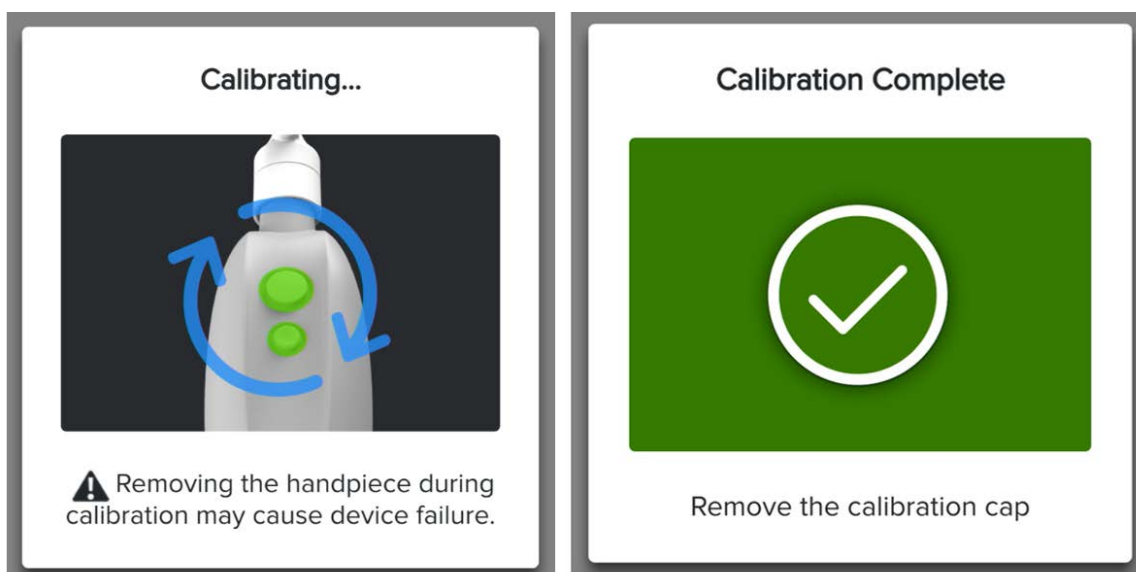To continue, remove the used handpiece and insert a new one**.**

3. Start handpiece calibration. Keep the calibration cap on during this process.

Once the handpiece has been connected to the console, the following messages will be shown, indicating the calibration process.

Figures 22 and 23. Handpiece Calibration

Figures 24 and 25. Handpiece Calibration

2.3.3. White Balance

Once calibration is complete, the surgeon can view the media capture screen as shown in the figure below. If, during a case, the media captured does not render colors correctly, perform one of the two options below to adjust the color balance.

1. Tap on the Settings icon, which is located on the top left corner of the screen.
2. Press the Camera button that has been previously set for white balance.

Figure 26. White Balance
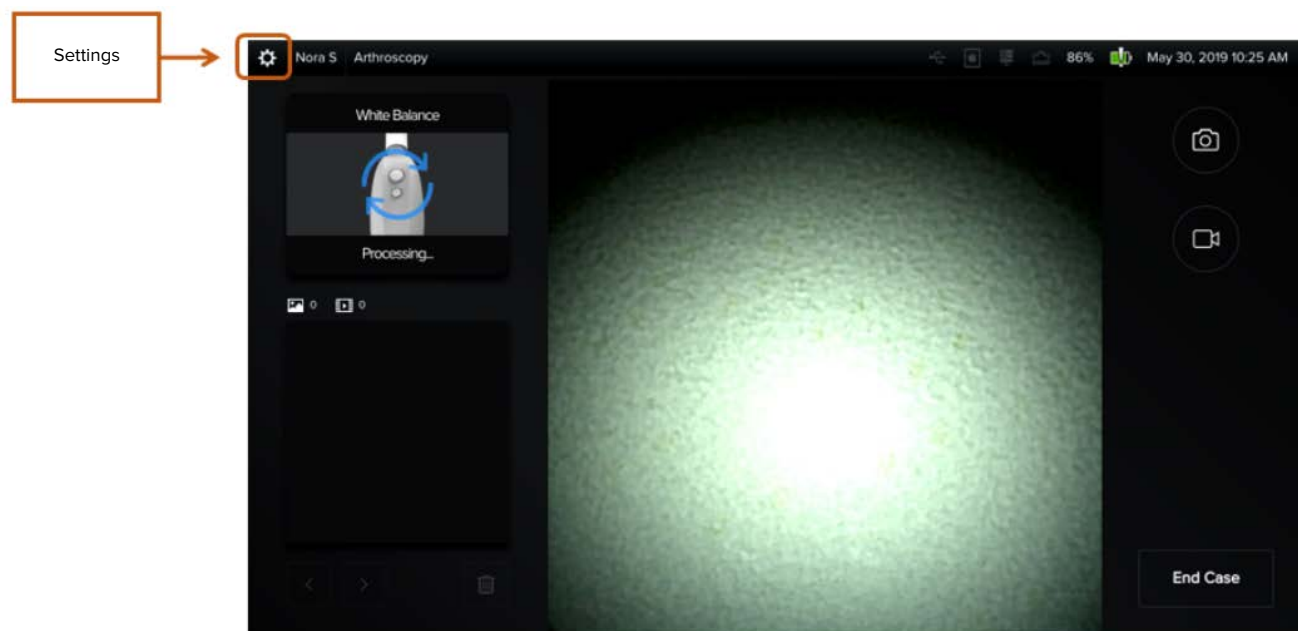
Note: The default handpiece configuration for this feature is the front button, long press.
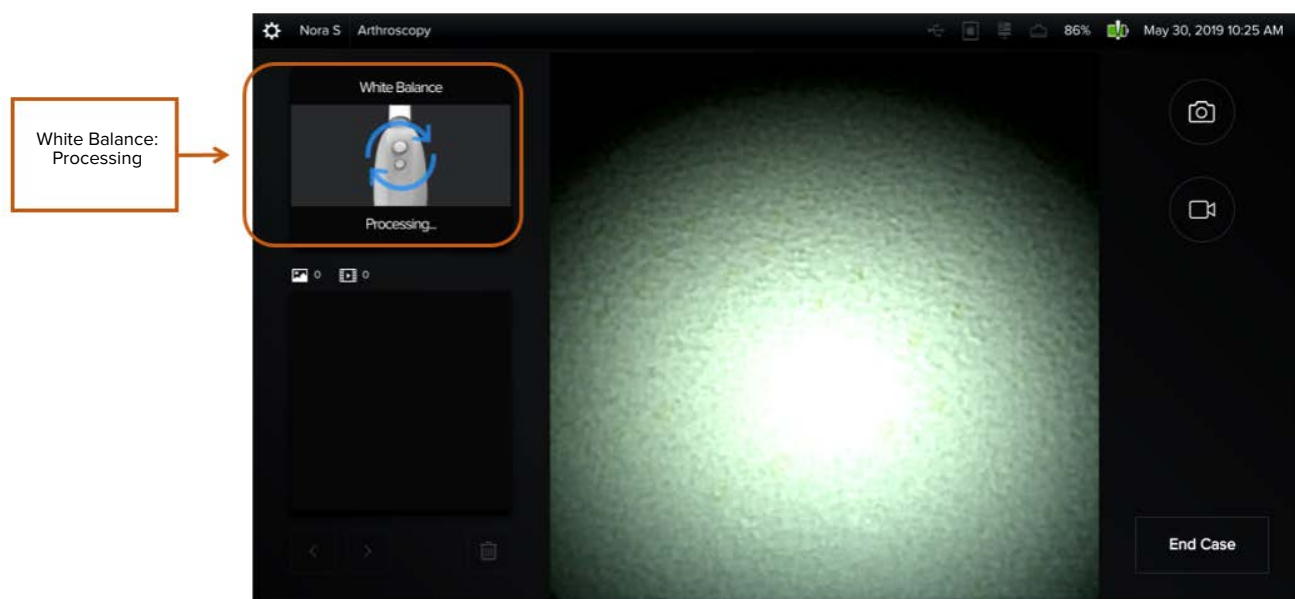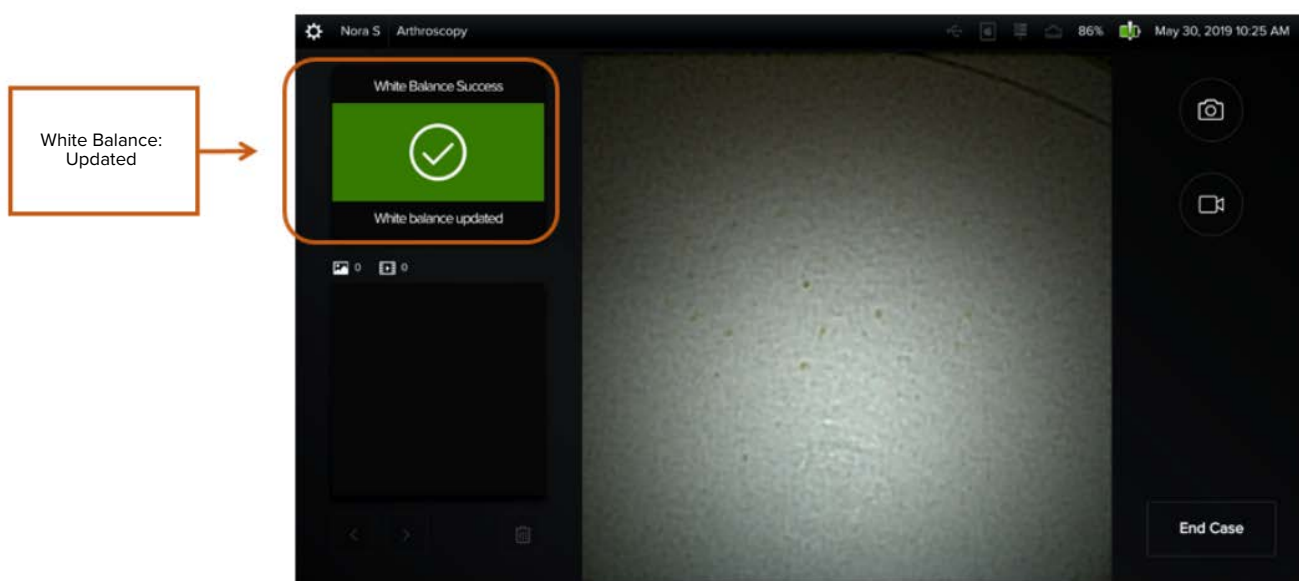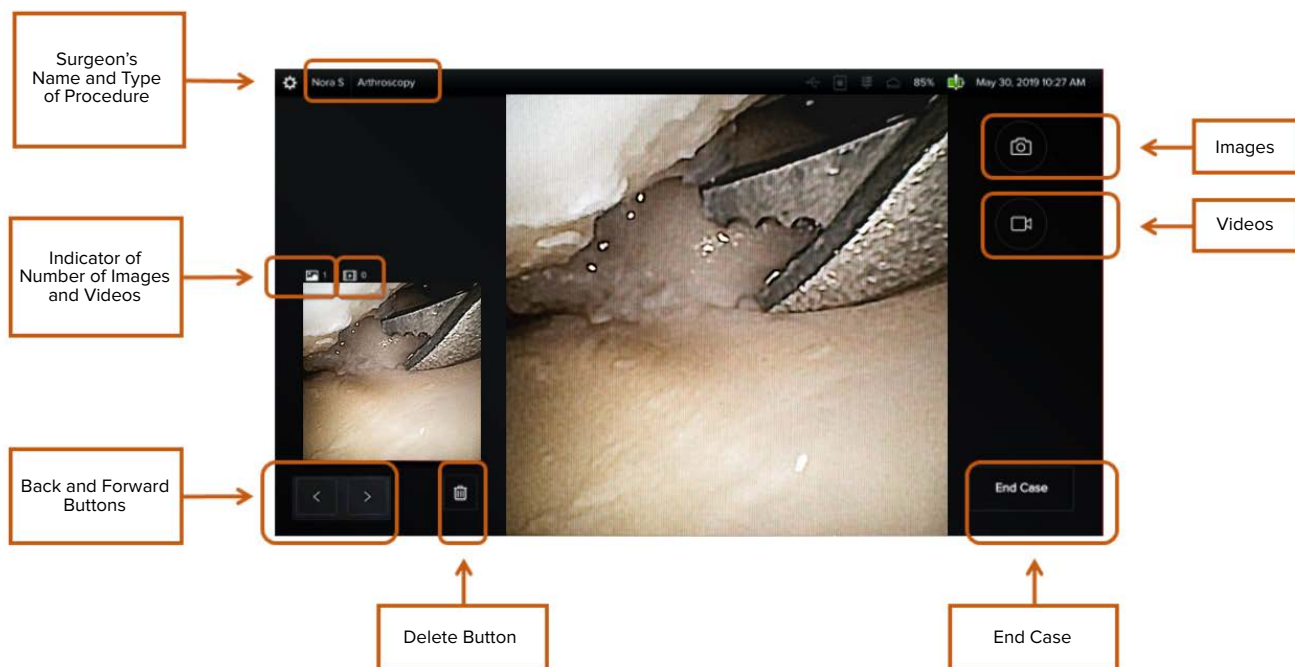
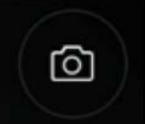**Figure 27. White Balance: Processing**

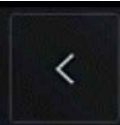
Figure 28. White Balance: Updated

2.3.4. Capture Images and Videos

Once the handpiece has been calibrated and the white balance adjusted, the surgeon can start the case and capture images and videos.

Figure 29. Media Capture

2. NanoScope™ Software Operation (Cont.)

Icon/Button/Label/Event/Tab	Description
Camera	Capture images.
Video	Record videos.
	End the case.
Delete	Delete the case.
‹ ›	Scroll back and forth between the images and videos captured.
1 0 **Media Counter**	Track the number of images and videos captured.

**There are two ways to capture images and videos:**
- Handpiece buttons
- Camera and Video buttons on the screen (should only be used by an assistant that does not need to remain sterile)

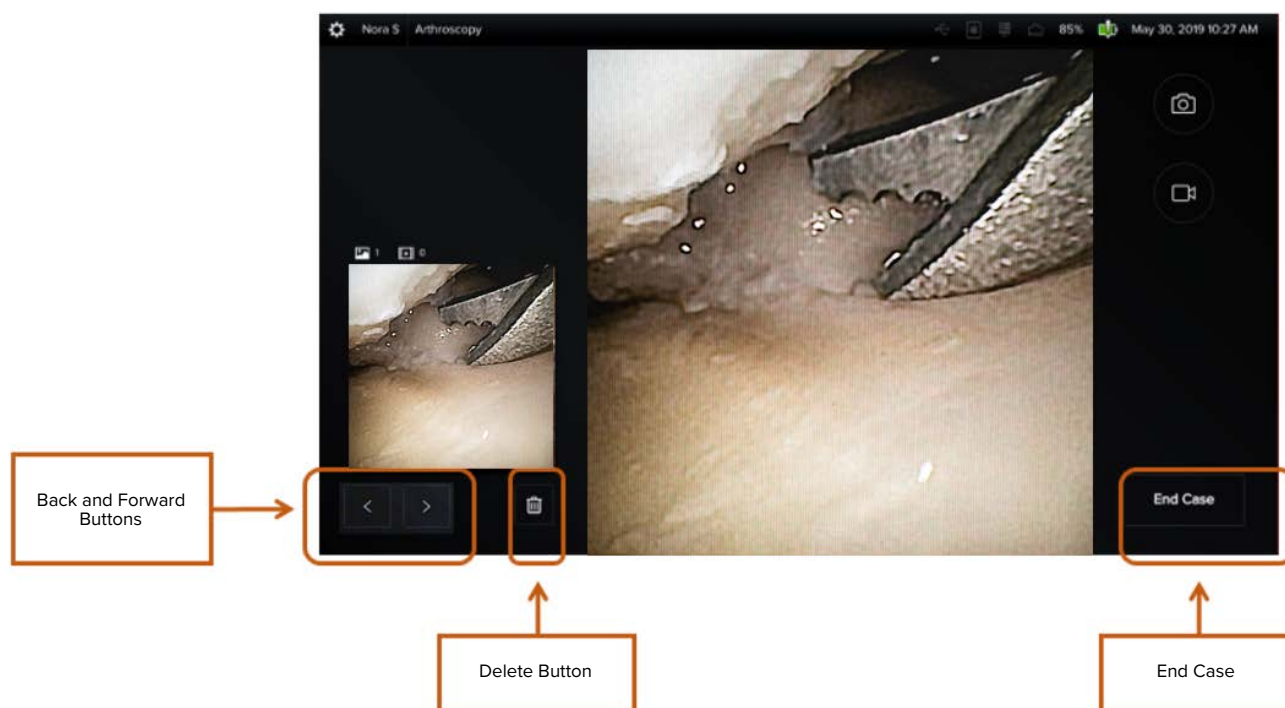# 2. NanoScope™ Software Operation (Cont.)

Image Capture

The Handpiece or the Camera button on the screen allows the surgeon to capture an image during a live case. Each time an image is captured, a blue frame is displayed around the captured image on the screen.

Figure 30. Image Capture
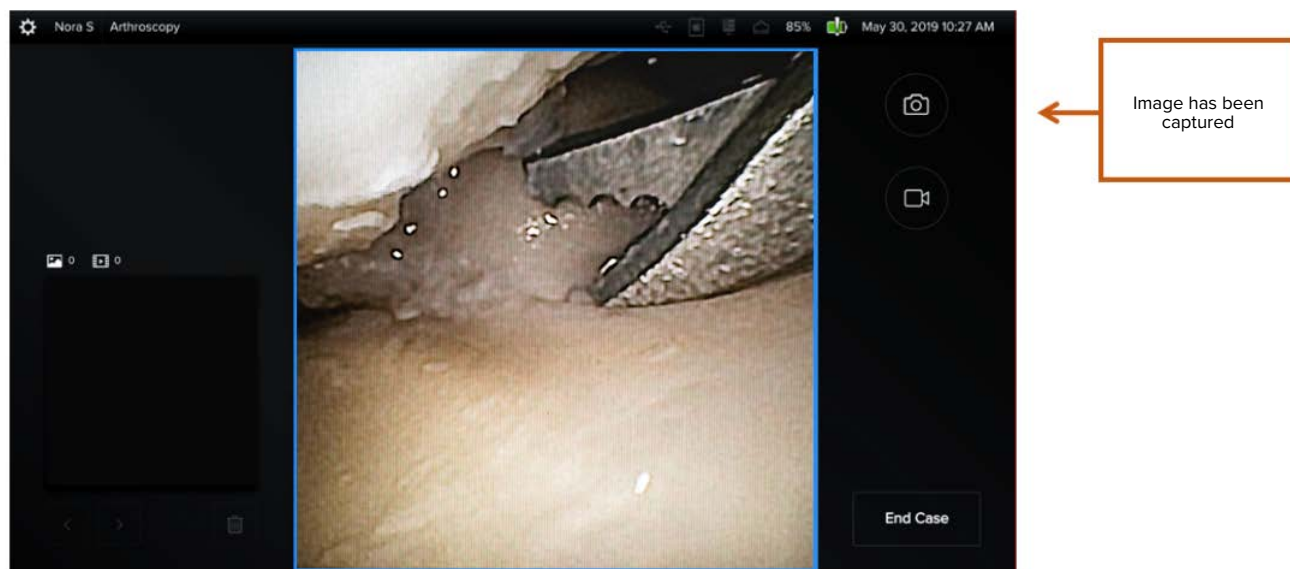
- A thumbnail of the captured image is displayed on the left side of the screen.
- Use the **Back** and **Forward** buttons to navigate through the media captured.
- To discard a captured image, click the **Delete** button.
- Click on **End Case** to stop reviewing captured images.
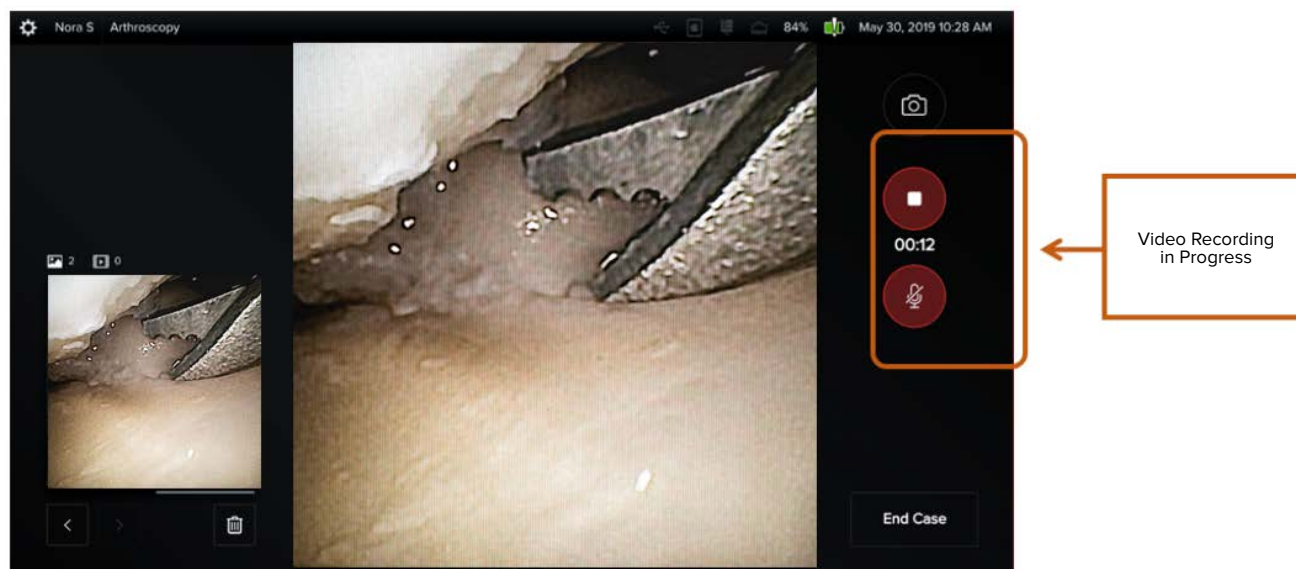
Figure 31. Image Capture

2. NanoScope™ Software Operation (Cont.)

Video Capture

The Handpiece or the Camera button on the screen allows the surgeon to capture video during a live case. Each time a video is captured, its thumbnail is displayed on the left side of the screen.

Figure 32. Video Recording

- Use the **Back** and **Forward** buttons to navigate through the media captured.
- To discard a captured image, click the **Delete** button.
- Click on **End Case** to stop reviewing captured images.

Indicators on the right side of the screen:

- The video capture feature displays a **Stop** button and **Microphone** button.
- **Red** indicates a video is being recorded.
- Audio is set to mute by default in the surgeon profile.
- If using the handpiece to capture videos, tap the programmed button to start or stop recording a video.
- Once the procedure is complete, click on **End Case** (bottom right corner of the screen).
- After clicking on the End Case button, a notification that the handpiece will no longer be usable appears.

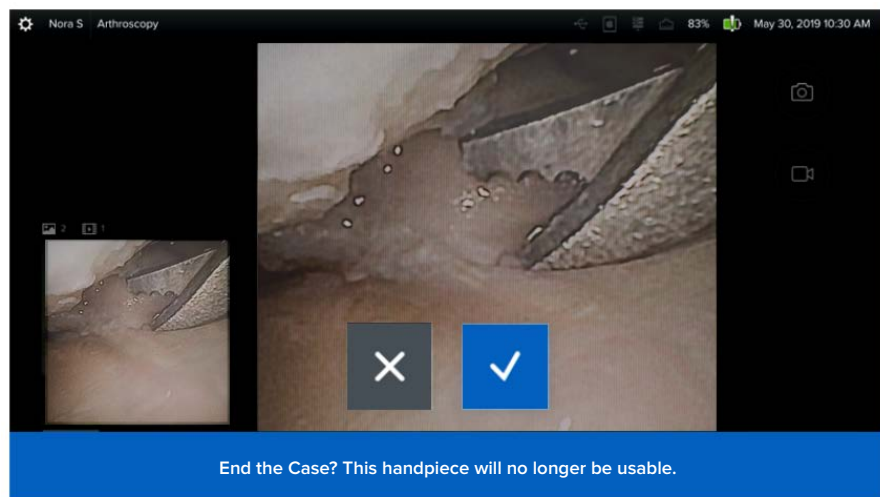**Figure 32. Handpiece No Longer Usable**
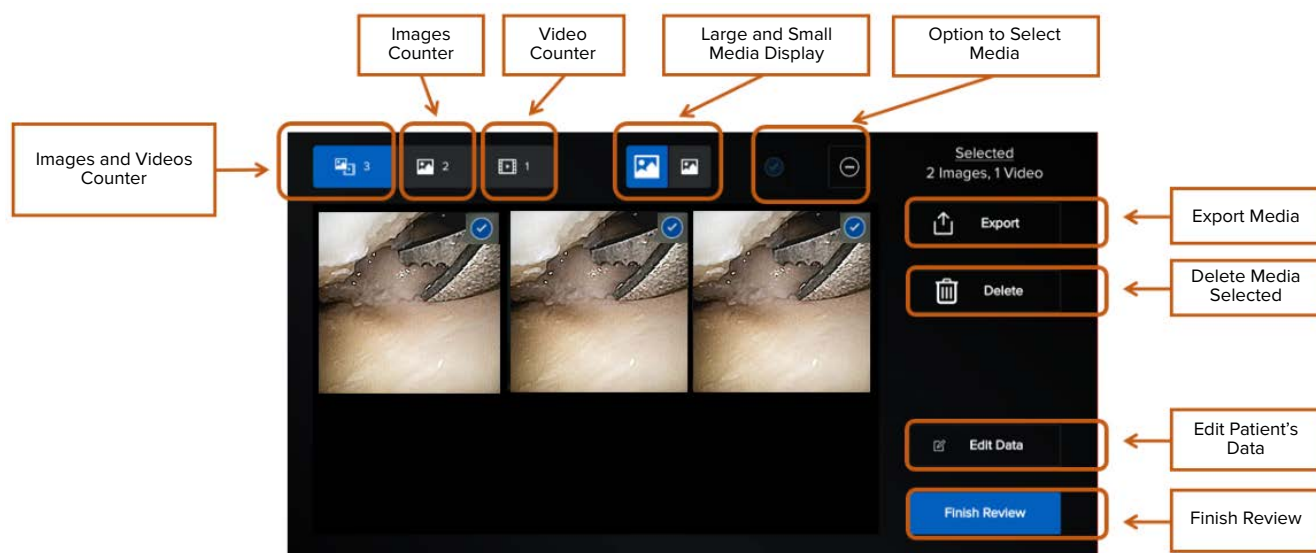
Figure 34. Case Complete
- The case is now complete.
- Remove the handpiece.

2.3.5. Review a Case

Once the handpiece has been removed, the surgeon can access the Case Review screen.

Figure 35. Case Review

While on this screen, the surgeon can perform the following actions:
- Review the images and videos captured
- Select media
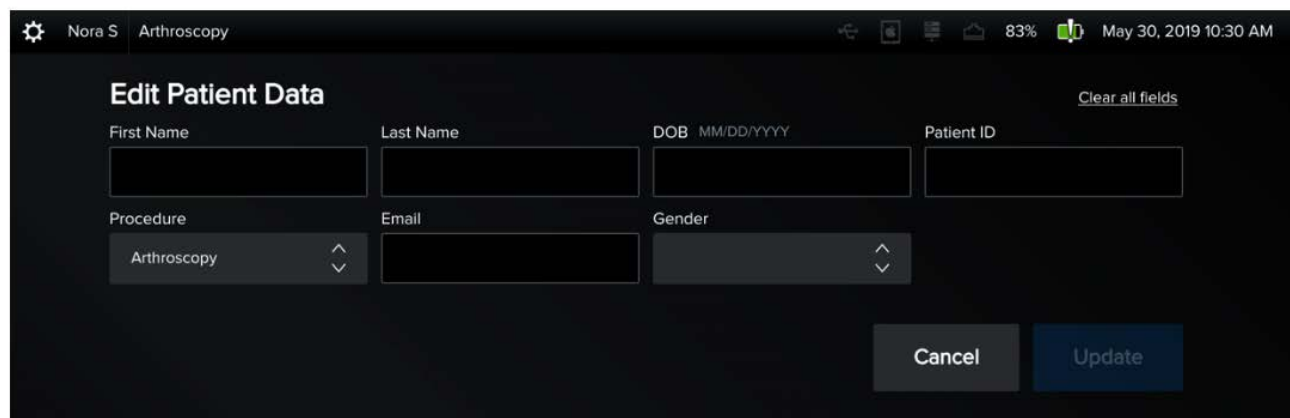- Delete media
- Export media
- Edit data

2.3.6. Edit Data

After reviewing a case, the surgeon can edit patient demographics by clicking on the **Edit Data** button located on the bottom right corner of the screen (see Figure 36).

The following screen will then be presented.

Figure 36. Edit Data

Icon/Button/Label/Event/Tab	Description
First Name	Enter the patient's first name.
Last Name	Enter the patient's last name.
DOB	Enter the patient's date of birth.
Patient ID	Enter the patient's identification number.
Procedure	Enter the type of procedure performed. • A drop-down menu will show the list of procedures previously defined for the surgeon.
Email	Enter the patient's email address.
Gender	Enter the patient's gender.

• Once all data have been entered, click **Update.**

This action will take the user back to the previous screen where the case review can be completed.

• Click on **Finish Review.**

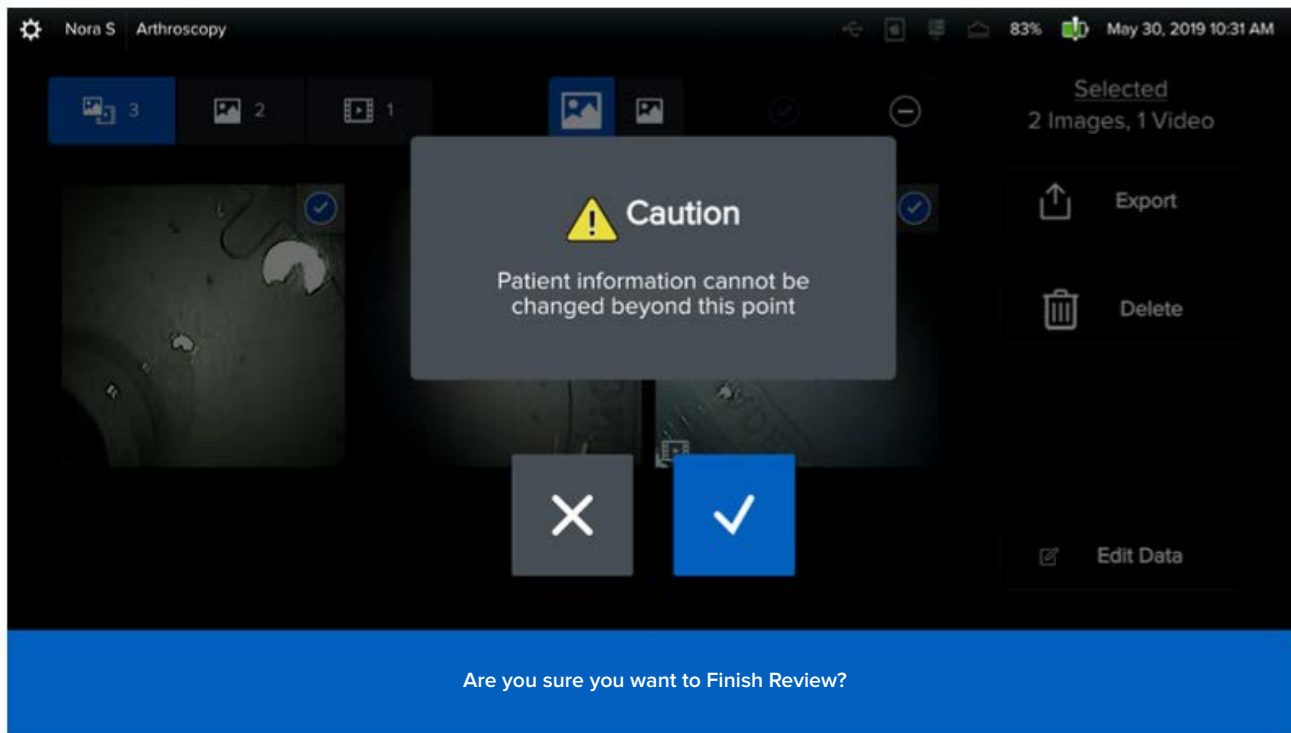The user will be prompted to confirm that action.

Note: Neither media nor patient demographics can be changed after finishing a case review.

Figure 37. Finish Review

Once the action is confirmed, the surgeon will be returned to the Login screen.

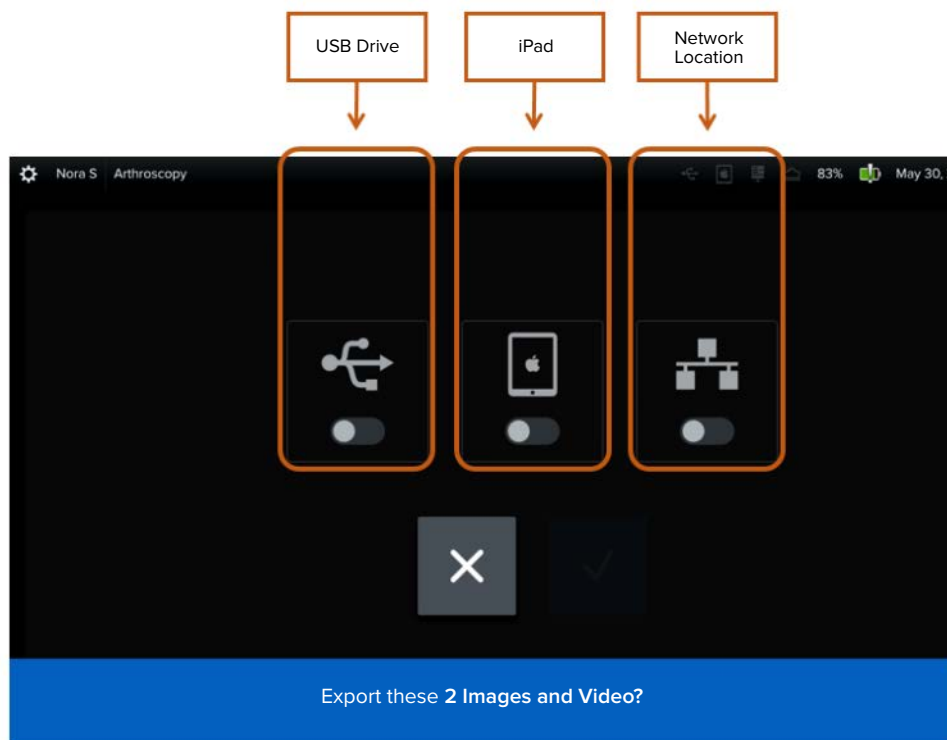**Note:** This action helps protect patient's data.

2.3.7. Export Media

Once a case has been reviewed, the surgeon can opt to export its metadata along with the media captured.

Three options are presented:

- USB
- iPad
- Network capabilities

Figure 38. Export Case

Note: White indicates the option is available (peripheral is plugged in). In the figure shown above, none of the options presented is connected.

Figure 39. Peripherals

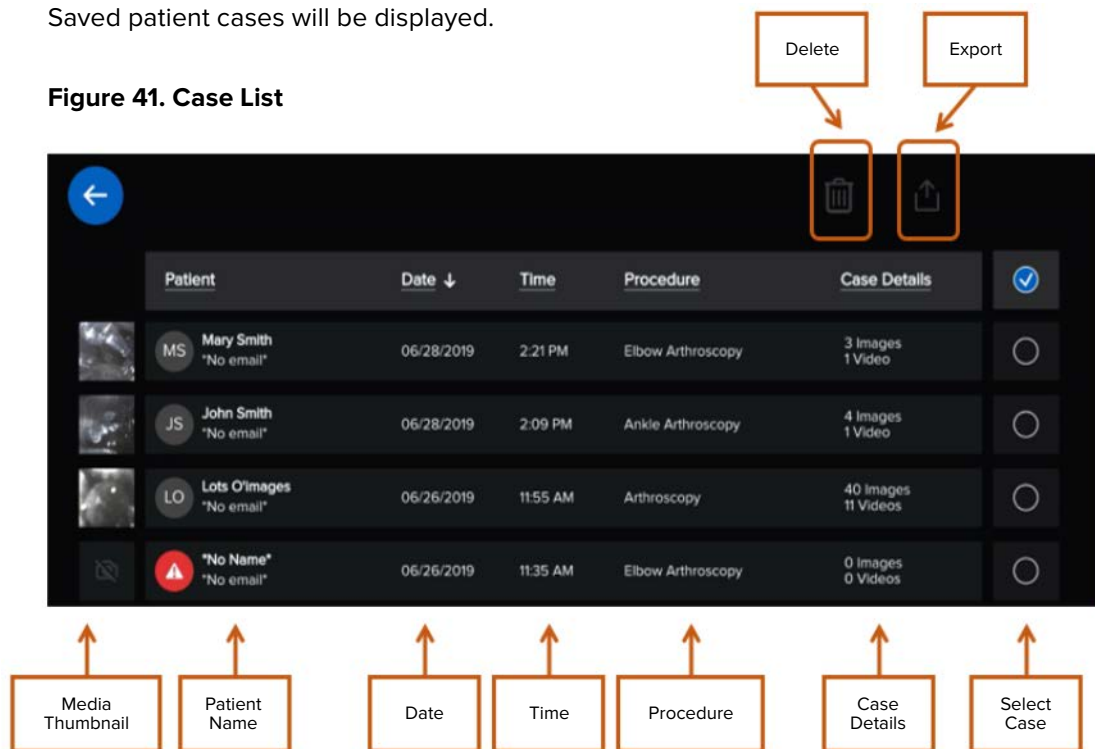| Icon/Button/Label/Event/Tab	Description
	Export screen: Once a peripheral has been connected and selected, it will show as white with a blue background.

2.3.8. View the Case List

- To see the Case List, log in as a **Surgeon.**
- Click on the **Cases** icon (top left corner of the screen).

Figure 40. Access to Cases
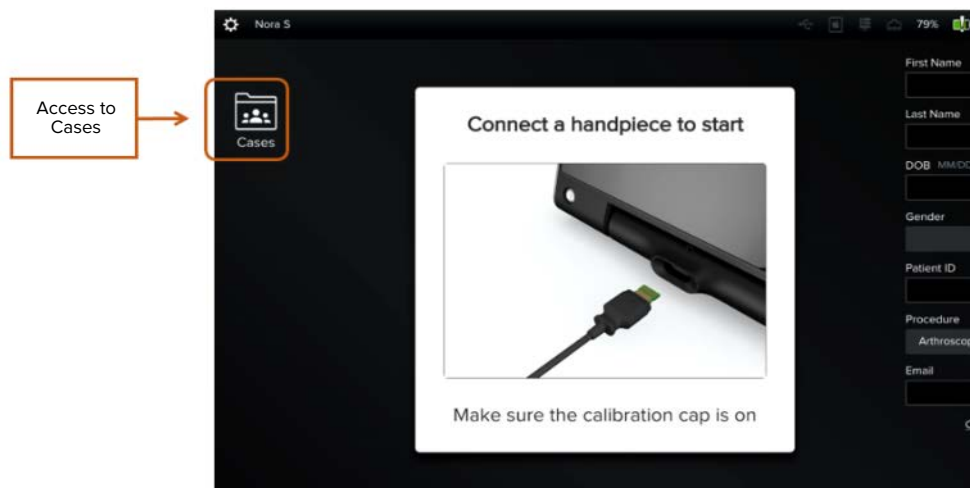
Saved patient cases will be displayed.

**Figure 41. Case List**

2. NanoScope™ Software Operation (Cont.)

Figure 42. Case List

Icon/Button/Label/Event/Tab	Description
Media Thumbnail	Allows surgeon to quickly see whether cases contain media.
Patient Name	Patient's full name and initials.
Date	Date on which the procedure was performed.
Time	Time when the procedure was performed.
Procedure	Type of procedure performed.
Case Details	Displays image and video counters.
Select Case	Allows surgeon to select cases to be deleted or exported. • Blue: Indicates a case has been selected.
Delete	Delete cases. • **Note:** Once the selected cases are deleted, that data cannot be retrieved.
Export	Export cases.

2.3.9. Export Cases

- From the case list view, click the **Export** button.
- The Export screen has three available options: USB, iPad, and Network Location.

Figure 43. Export Cases
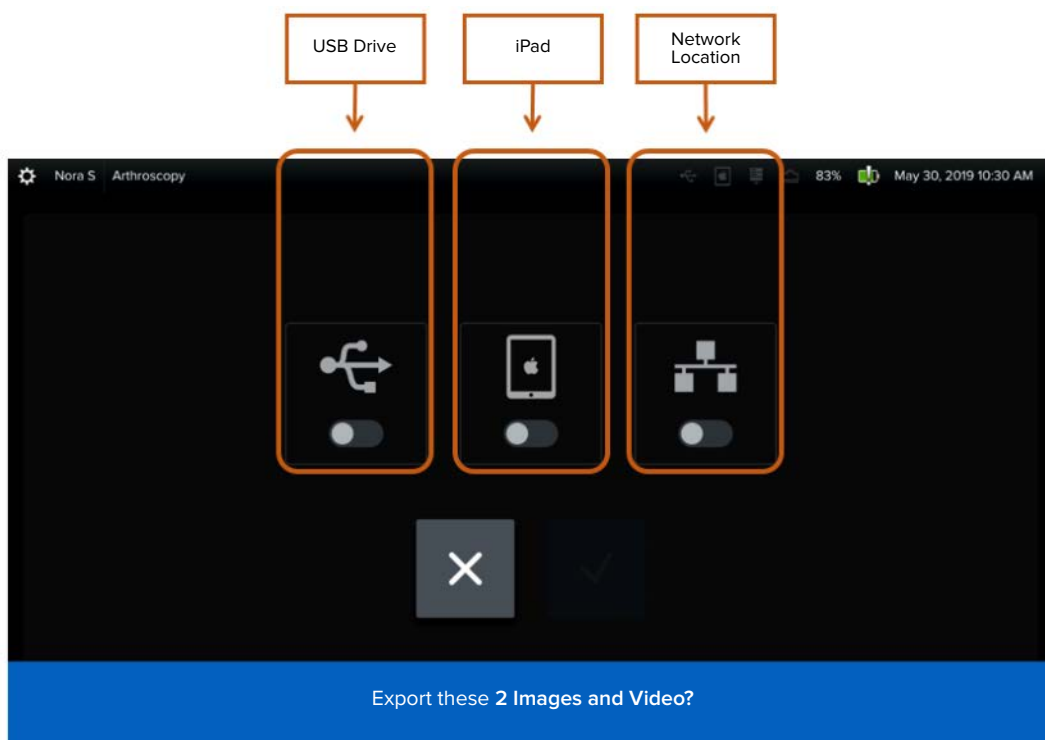
2.3.10. Log Out From Surgeon Profile

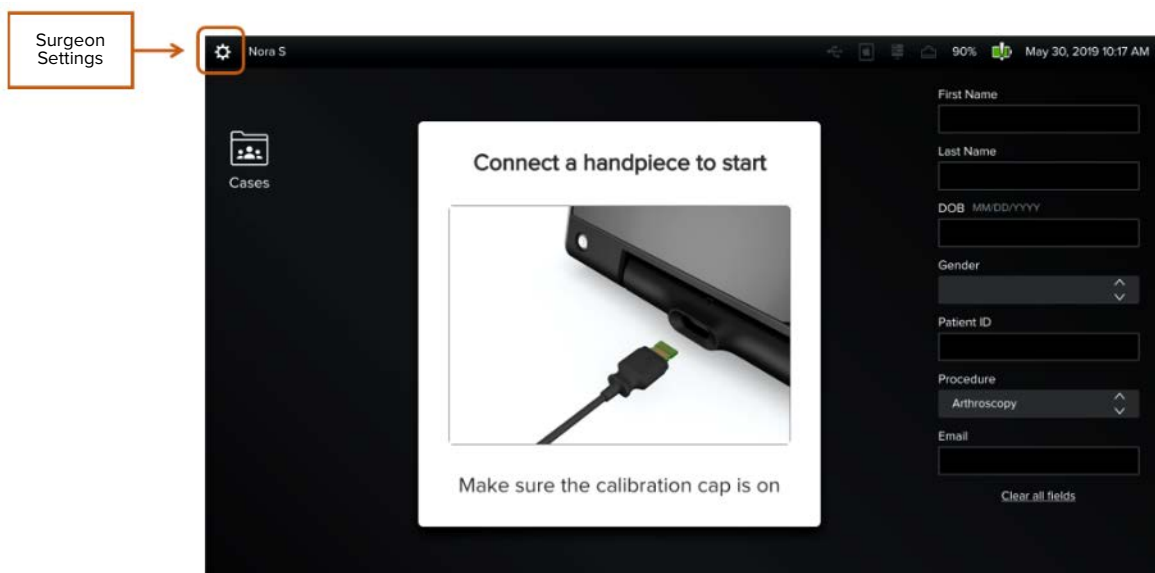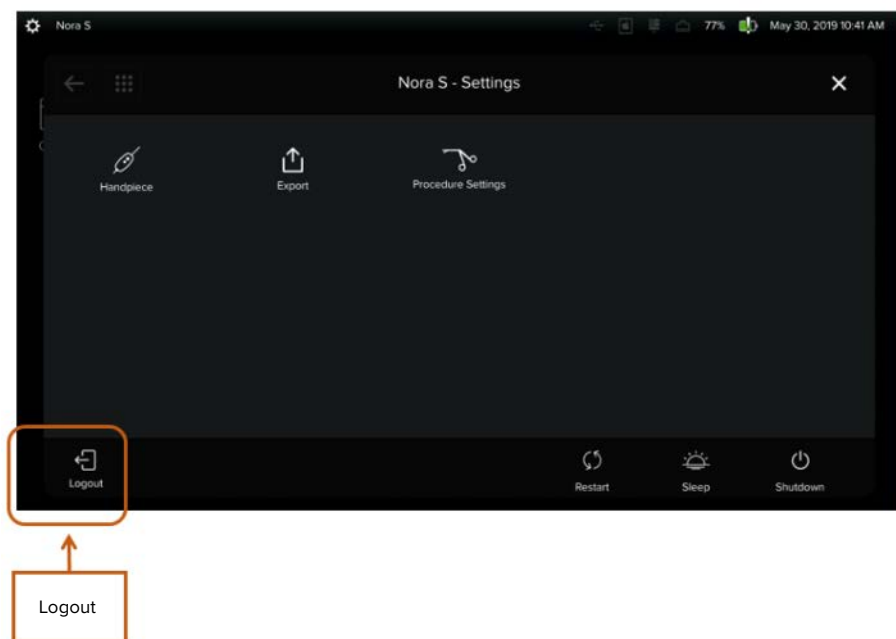**Figure 44. Surgeon Settings** (top left corner).
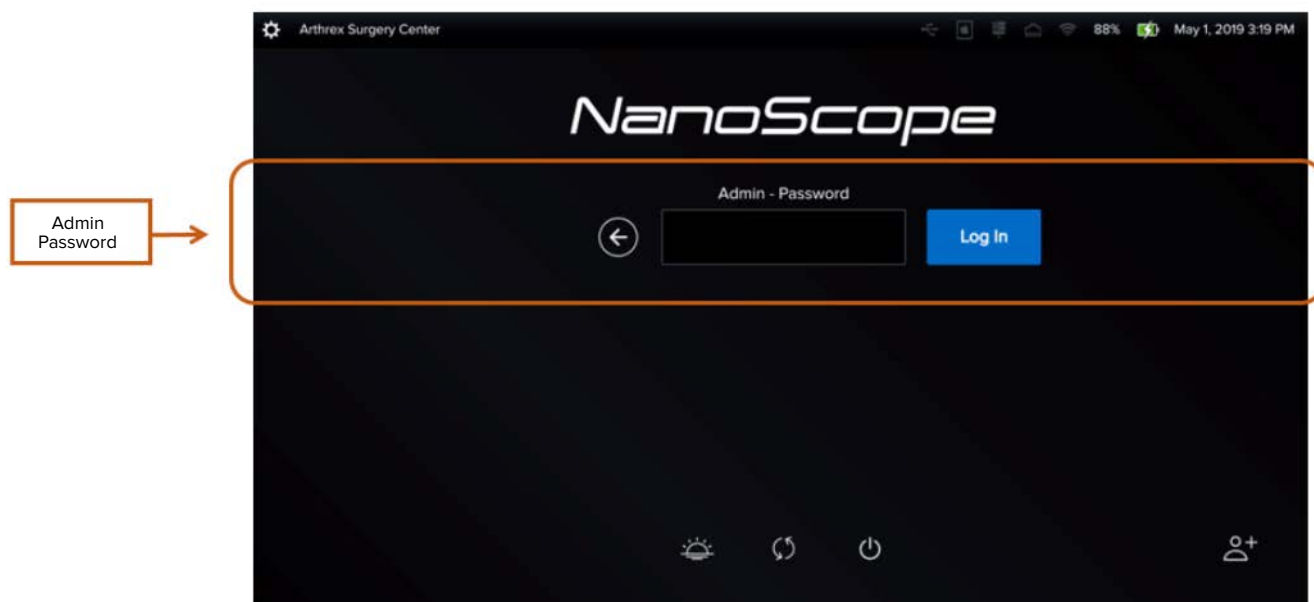
Figure 45. Logout

- Click on the **Logout** button, which is located on the bottom left corner of the screen.

Logout

2.4. ADMIN SETTING

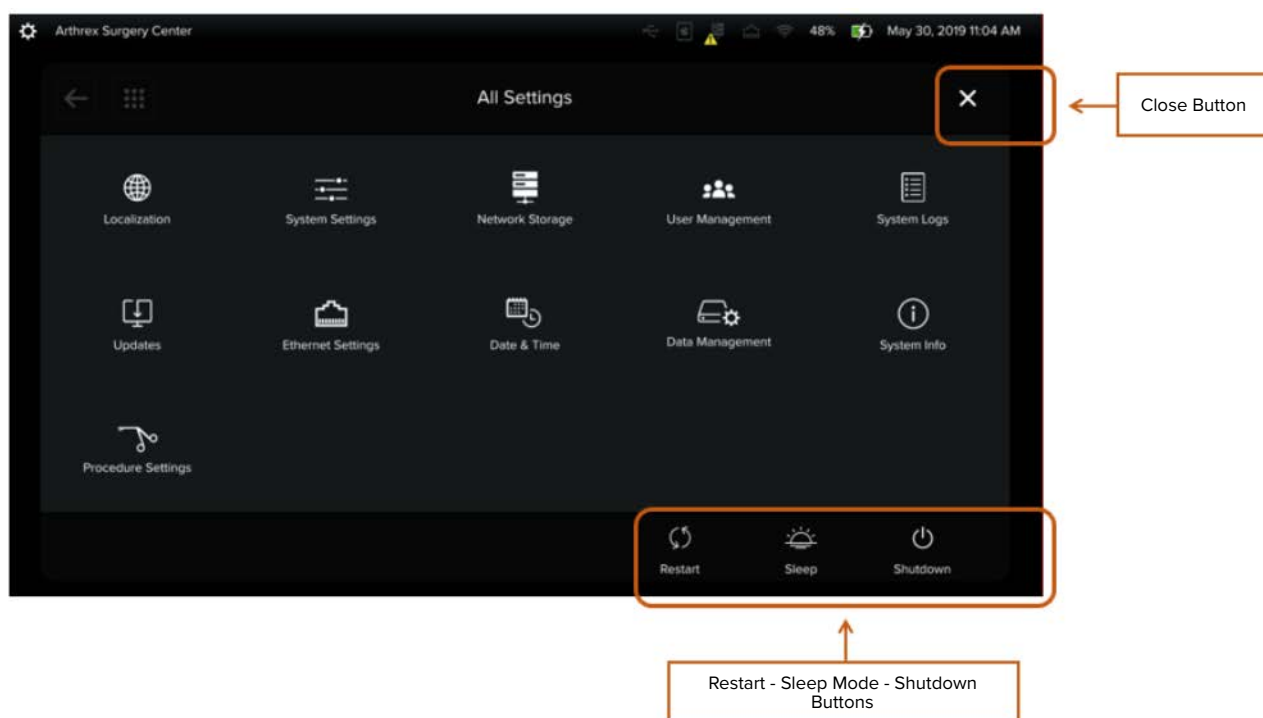To access the Admin Settings, click on the **Admin Settings** button located on the top left corner of the Home Page.

Figure 46. Admin Settings - The following page is then displayed:

Admin
Password

- Enter the Admin password.

Figure 47. All Settings - The following screen is displayed

All Settings Page:

- Top left corner: Back button and All Settings button
- Top right corner: Close button

Main Content Area: All Settings icons

- Bottom right corner: Restart, Sleep Mode, and Shutdown buttons

2.4.1. Localization

- **Language:** Allows selection of the language for the user interface
- **Time Zone:** Allows selection of the time zone
- **Date Format:** Choose preferred date format
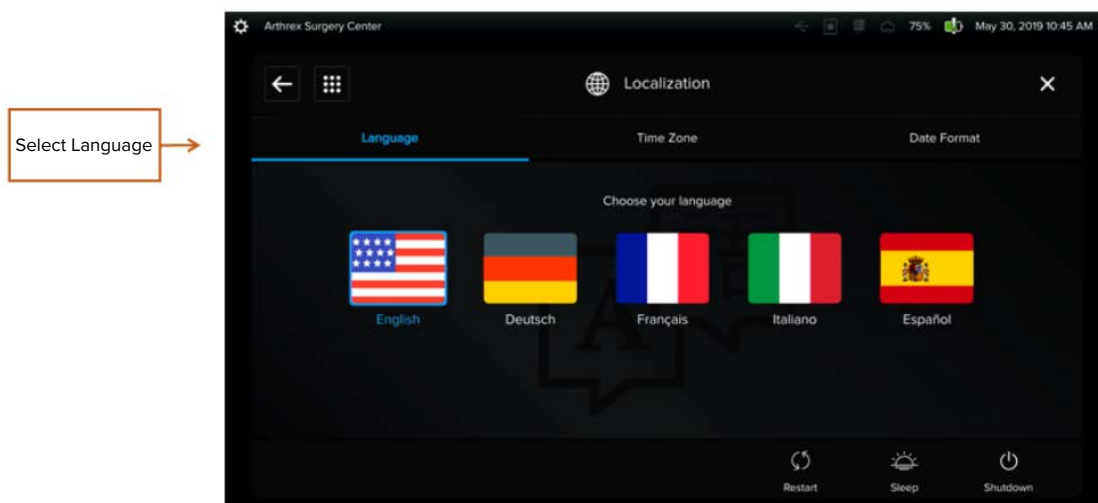
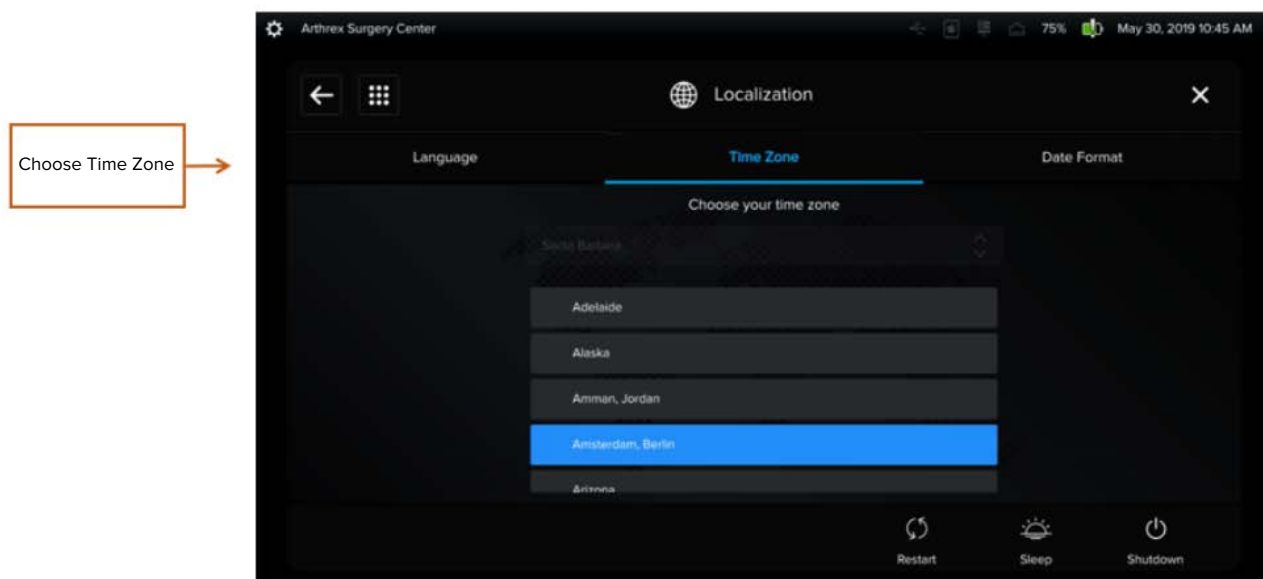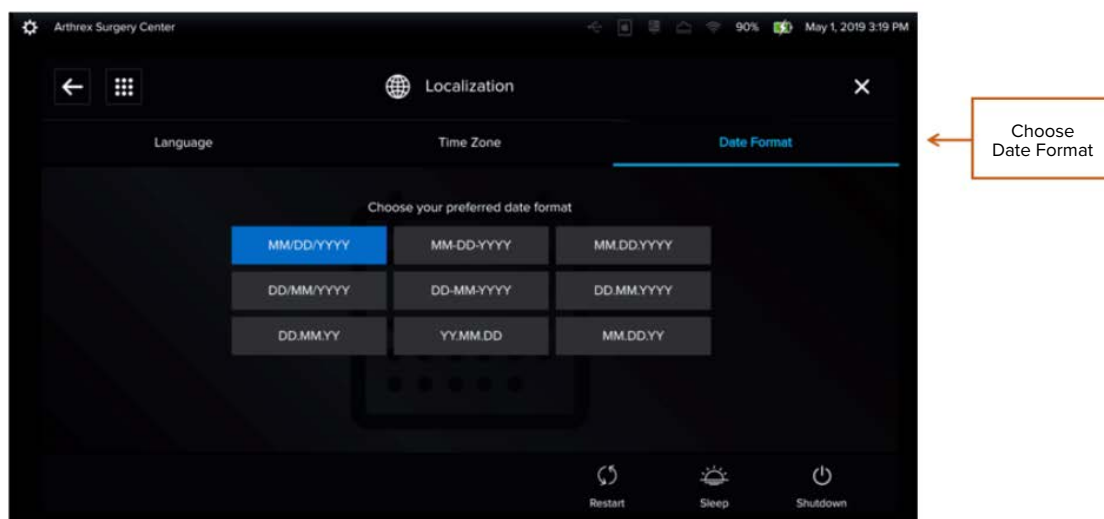**Figure 48. Settings: Language**
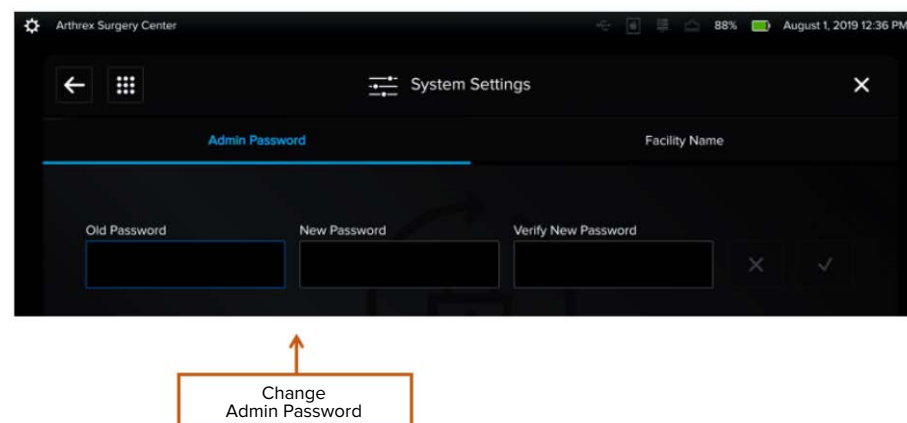
Figure 49. Settings: Time Zone

Choose Time Zone →

Figure 50. Settings: Date Format

Choose
Date Format ←

2.4.2. System Settings

Provides the ability to perform the following actions:

Figure 51. System Settings: Admin Password

Change
Admin Password

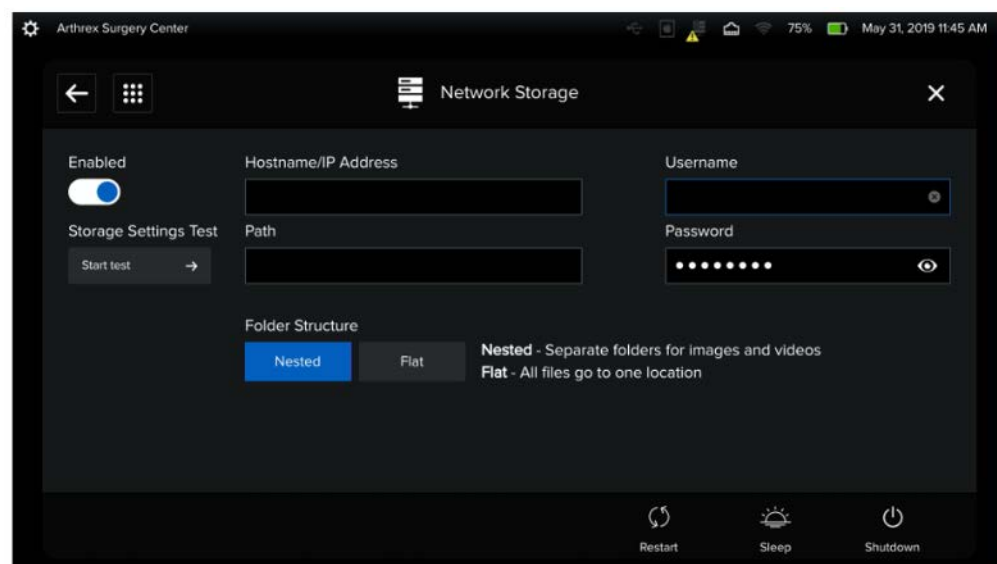**Figure 52. System Settings: Facility Name**
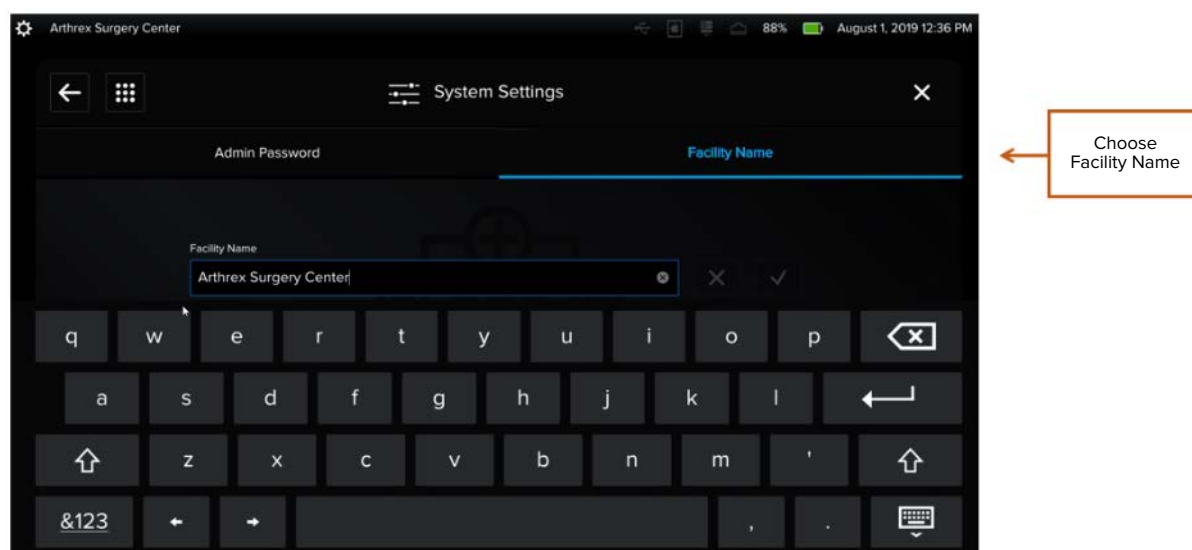
2.4.3. Network Storage

- Toggle On to enable network storage.

Note: All data in this section should be provided by the facility IT representative.
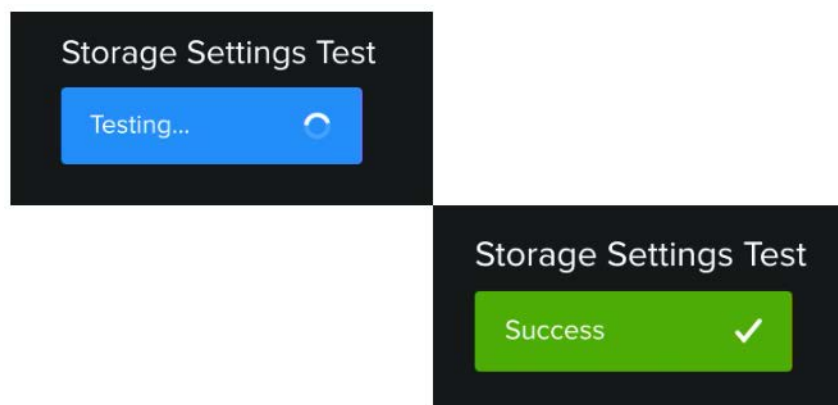
Figure 53. Settings: Network Storage

Folder Structure: Select the folder structure for all files to be exported.

- Nested: Separate folders for images and videos.
- Flat: All files go to one location.
- Once all fields have been populated, select **Start Test** to test network storage settings.

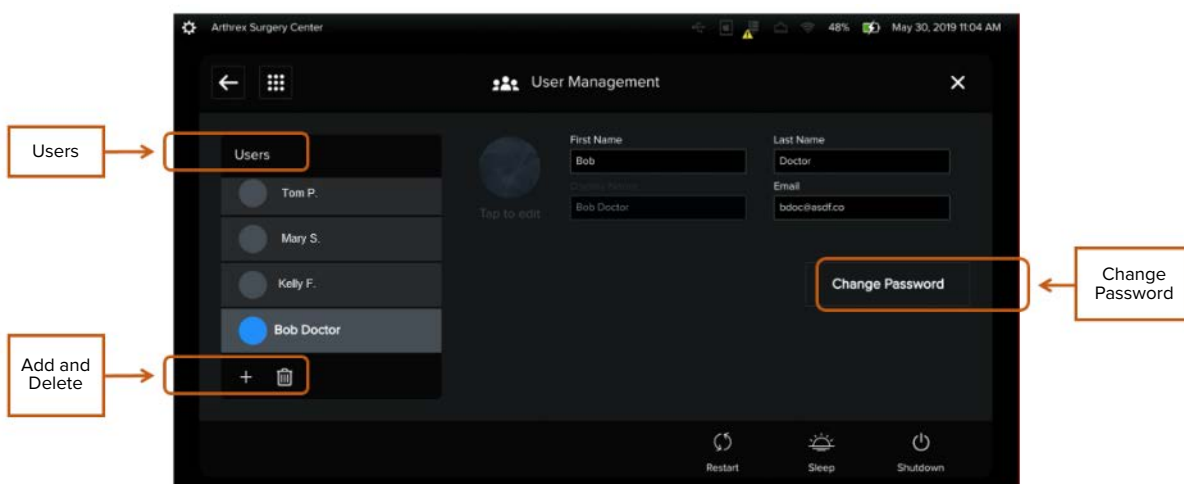**Figure 54. Storage Testing - Phases**

2.4.4. User Management

Actions that can be performed:

- Add a New User
  - There are two types of users: Guest and Surgeon
- Edit User credentials
- Change a User's password
- Delete a User

Note: Once a user is deleted, that action cannot be undone and all cases associated with that user will be permanently lost.
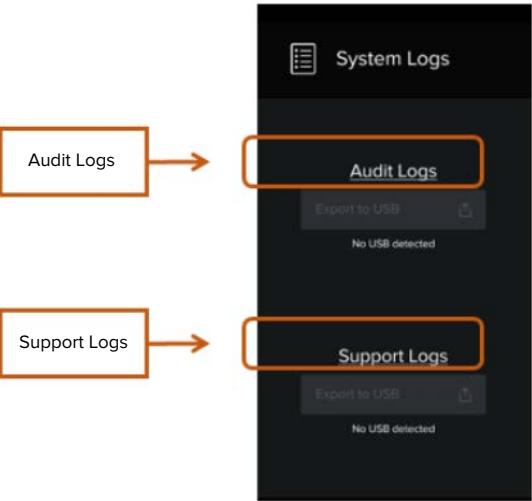
Figure 55. User Management

2.4.5. System Logs

There are two types of logs that can be retrieved from the NanoScope console. Those are as follows:

- Audit Logs
- Support Logs

Action that can be performed: Export logs to a USB drive.
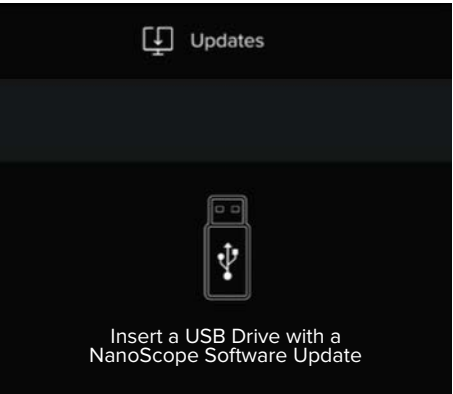
Figure 56. System Logs

Icon/Button/Label/Event/Tab	Description
USB Drive	Indicator (Header) will show white if the USB drive is connected.

2.4.6. Updates

To update the console, insert a USB drive with a NanoScope software update.

Figure 57. Updates
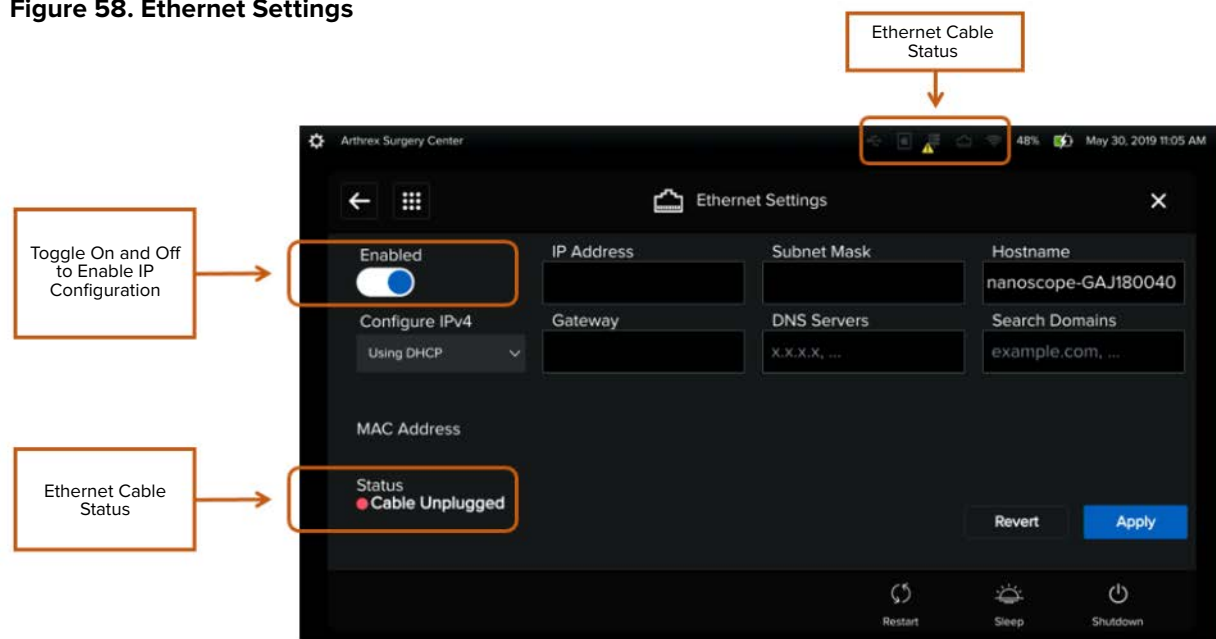
2.4.7. Ethernet Settings

Data is to be provided by the IT representative at the facility.

Toggle On and Off to enable IP configuration. When enabled, two options are presented:

- Using DHCP
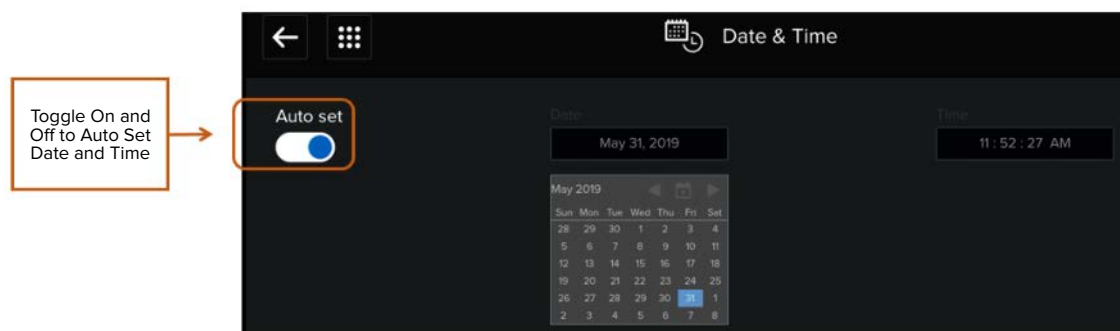- Support Logs

Note: Ensure the Ethernet cable is unplugged.

Figure 58. Ethernet Settings

2.4.8. Date and Time

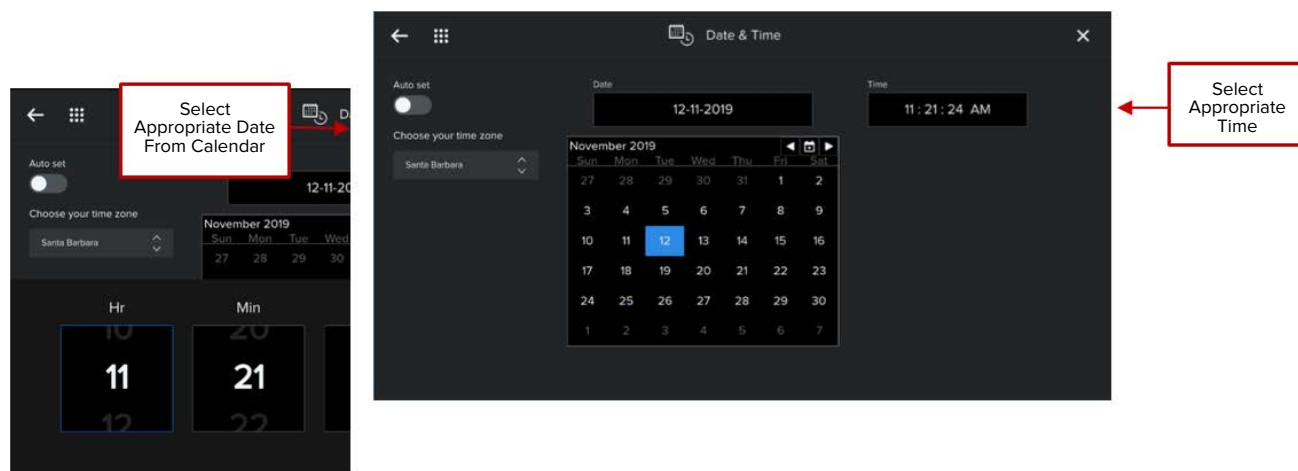If the Auto Set is enabled, and the console is connected to a network, date and time will be automatically set.

Figure 59. Date and Time Auto Set

If the Auto Set option is not selected, the date and time can be configured using the calendar and time settings feature, as seen below.

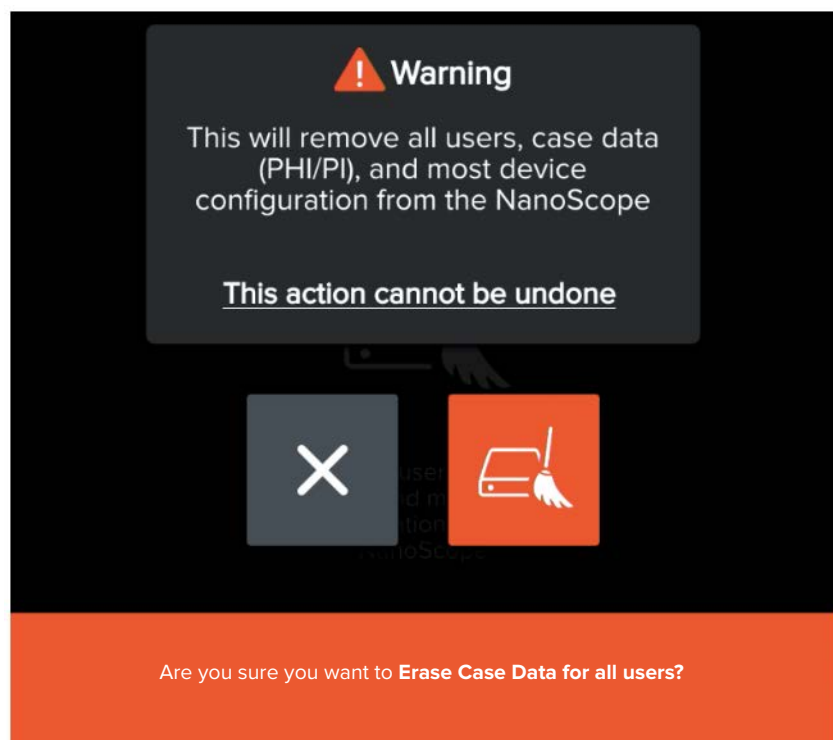**Figure 60. Date and Time Manual Set**

2.4.9. Data Management

Performing a **Data Cleanse** will erase all data for all users.

Figure 61. Data Cleanse
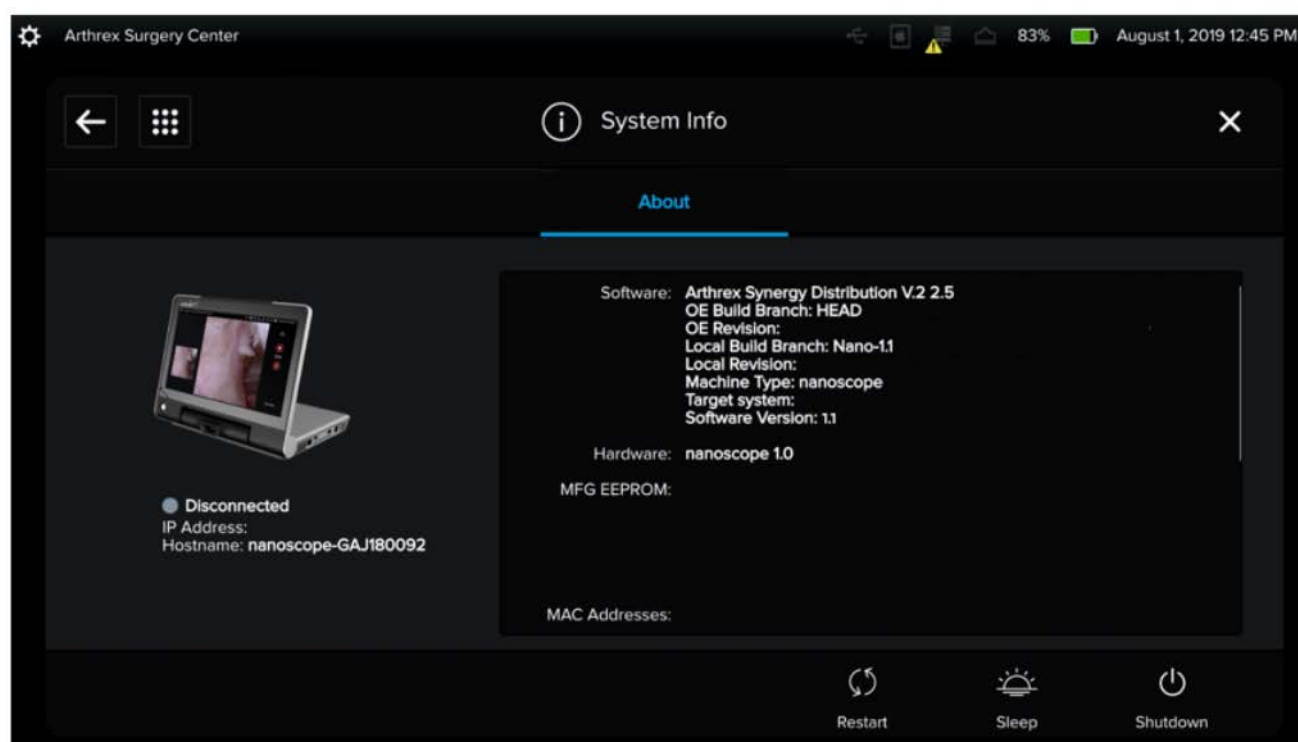
Figure 62. Data Cleanse

2.4.10. System Info

The System Info screen displays the following information:

About Tab
- Software
- Hardware
- MFG EEPROM
- MAC Addresses
- U-Boot
- Arria 10
- Max 10
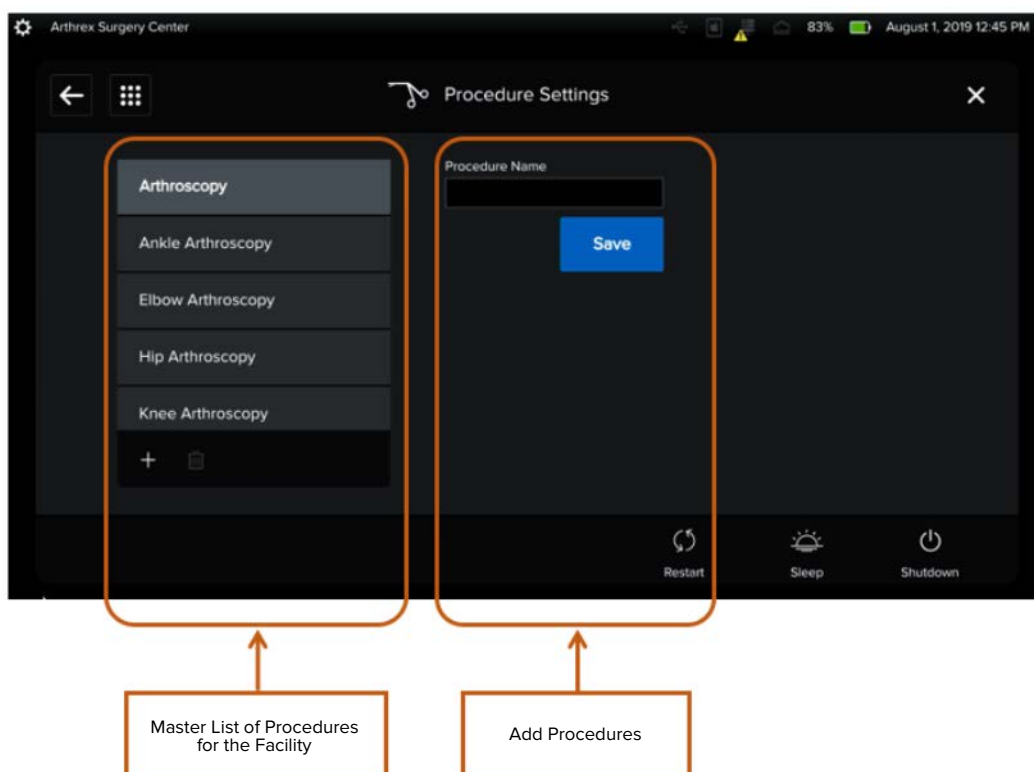- Crosslink

Figure 63. System Info

2.4.11. Procedure Settings

Actions that can be performed:
- Add new procedures to the Master List of Procedures for the facility.
- Delete procedures that are no longer applicable to the facility.

Figure 64. Procedure Settings

This is not a warranty document. For all warranty information, including disclaimers, exclusions, terms, conditions, and related provisions, refer to the "Arthrex U.S. Product Warranty" section of the Arthrex, Inc. website, found at www.arthrex.com, whose provisions are incorporated herein by reference.

Arthrex®