NanoScope[™] Operative Arthroscopy System

V1.2.0 Software Operation Reference Guide



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

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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 system 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 system **Login Screen** is divided into the following sections:

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

Figure 1. Login Screen



2.1.1. Menu Bar

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

- Admin Settings Button
- Facility Name
- Live Remote Support
- · Peripherals
- Battery Level Indicator
- Date and Time

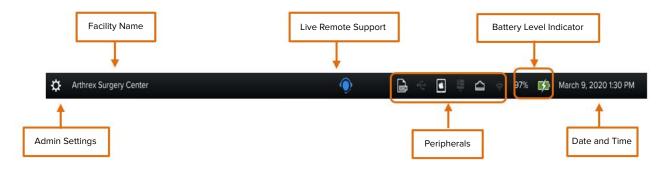
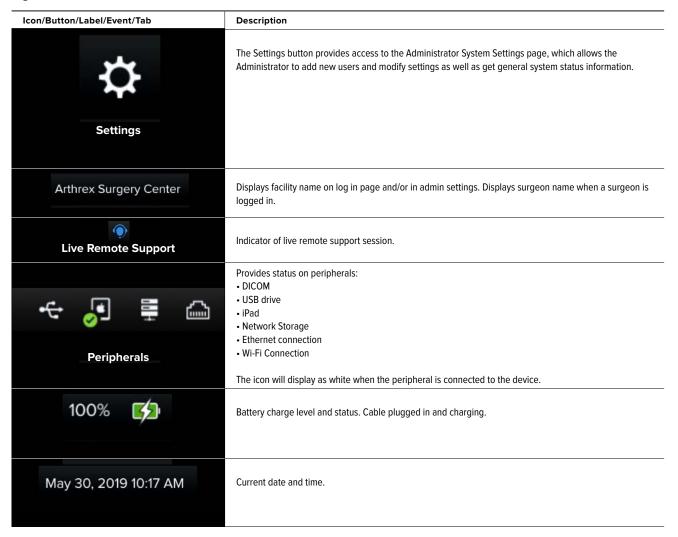


Figure 2. Menu Bar



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)

Note: Refer to Section 2.4.2.1 to add a New User

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:

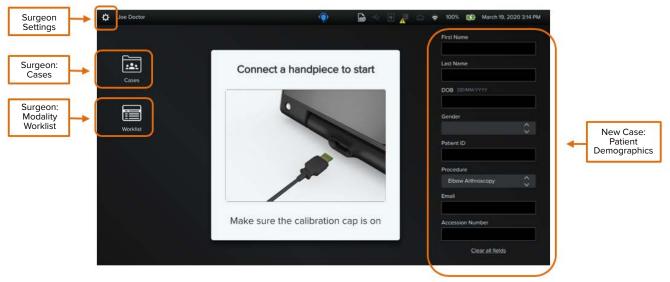
• Enter the surgeon's credentials, and then select Log in.

Note: All new users must be added via the user management page in the password protected Admin settings.

Figure 4. User: Surgeon



Figure 5. Patient Demographics (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.)



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



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

Figure 7. Emergency Login - Granted

• The surgeon can now start a new case.



2.1.2.2. 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.

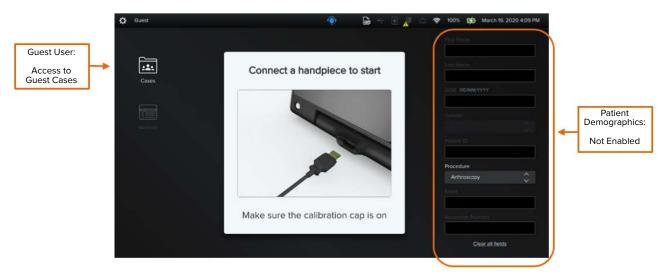
Figure 8. User: Guest



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

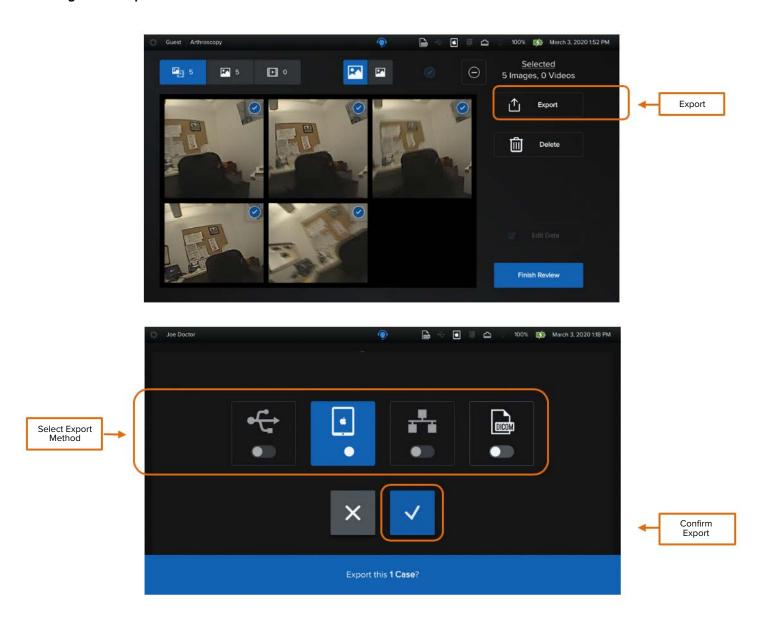
As seen in the figure below, as a Guest user, only type of Procedure is enabled as a field.

Figure 9. Home Page



• At the end of the procedure, the case review page provides an export option. Cases will be exported without patient demographics.

Figure 10. Export From Case Review



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

Figure 11. Admin Login

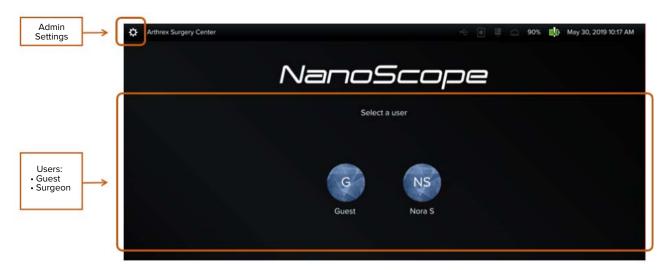
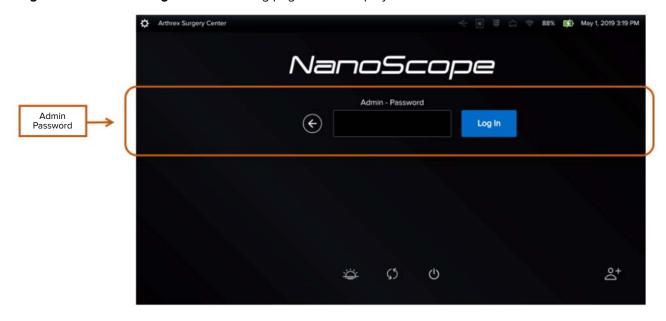


Figure 12. Admin Settings – The following page if then displayed:



• Enter the Admin credentials.

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, Procedure Settings, and Recordings.

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

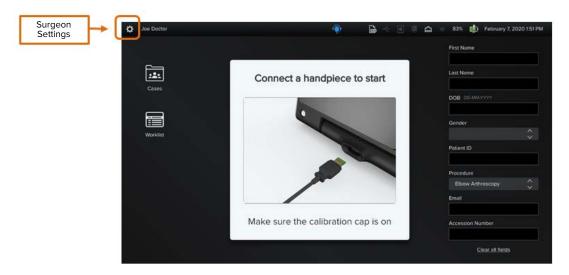
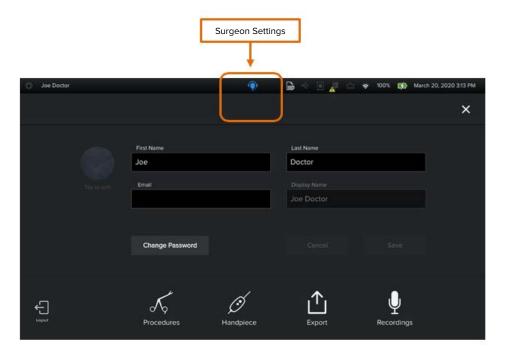


Figure 14. Surgeon Settings Page

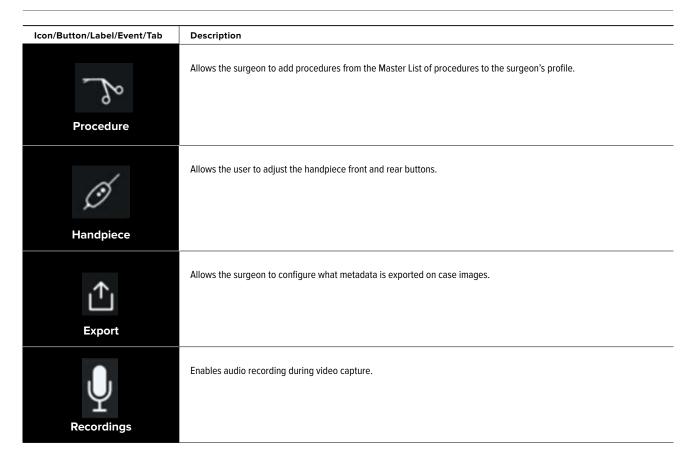


As seen in the figure below, the surgeon will have access to the following settings.

Figure 15. Surgeon Settings



2. NanoScope™ Software Operation (Cont.)

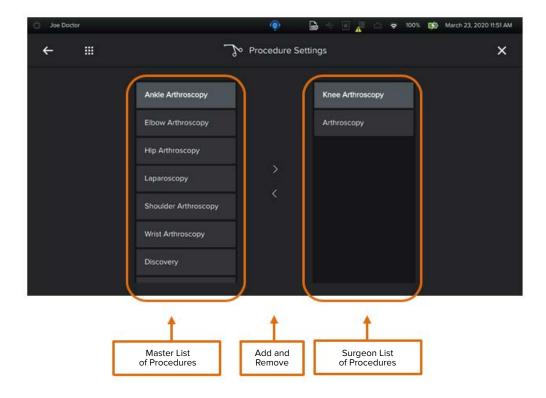


2.2.1. Procedures Settings

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 16. Procedures Settings - All procedures entered by the Admin are shown in the left column: Master List of Procedures.



Note: Refer to Section 2.4.4 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:

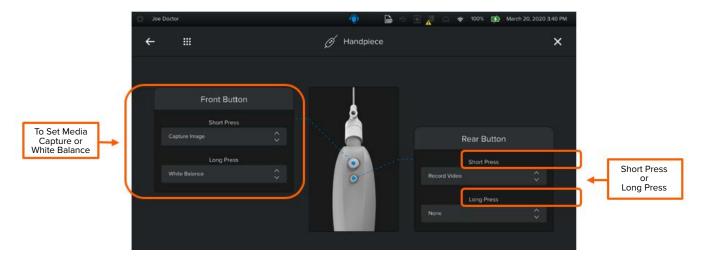
- Add procedures from the Master List to their own List of Procedures.
- Remove procedures from the Surgeon's list.

2.2.2. Handpiece Settings

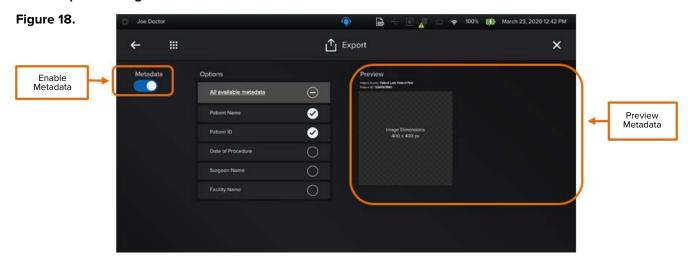
For each of the front and rear button, there is a short and long press, and for each press, there are 4 options available.

- · Capture image
- Record video
- · White balance
- None

Figure 17. Handpiece Settings



2.2.3. Export Settings



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

Metadata

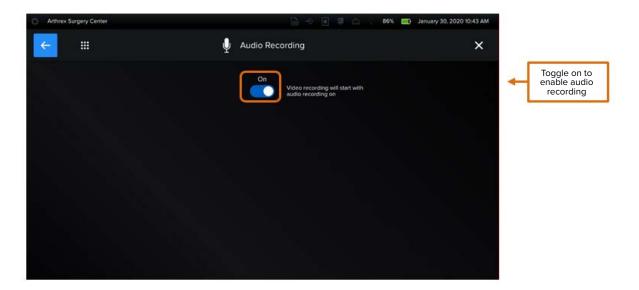
- Toggle On and Off to display and select specific pieces of metadata for the patient, procedure, surgeon, and facility (as seen in Figure 18).
- Once the metadata options have been selected, they are displayed in the Preview panel located on the right side of the screen.

Selected metadata would be included in the file to be exported via USB, iPad, Network Storage, or DICOM.

Note: Image dimensions: 400 pixels × 400 pixels.

2.2.4. Recording Setting

This is a default setting to have audio enabled when video recording starts.

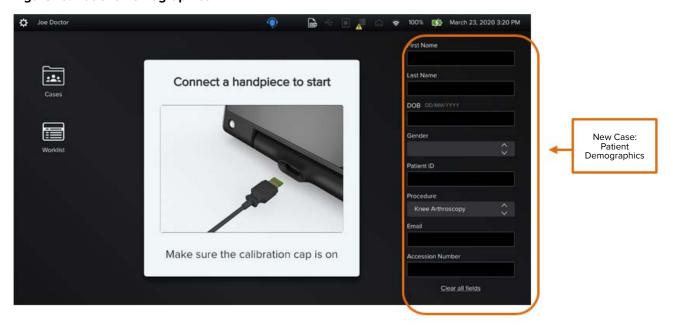


2.3. Starting a New Case

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:

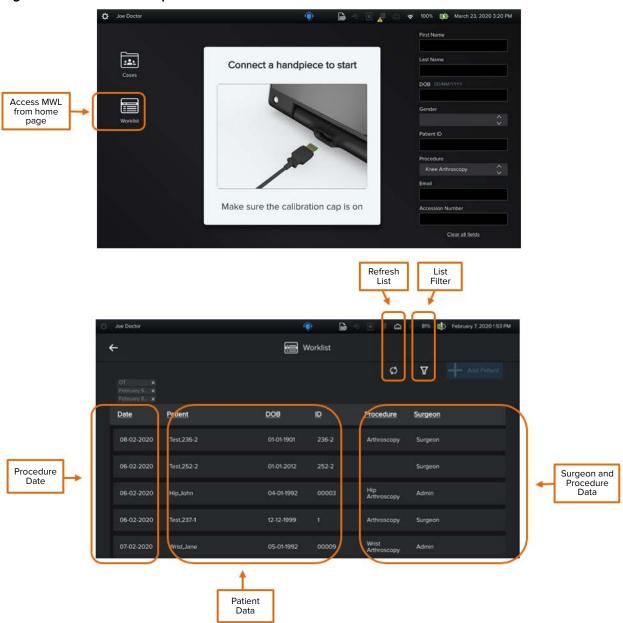
- Enter patient demographics on the Home Page either before calibration of the handpiece or after case end.
- Patient demographics can be completed or edited when reviewing the case.

2.3.2. Modality Worklist

The Modality Worklist, also referred to as MWL, is a DICOM service that allows users to:

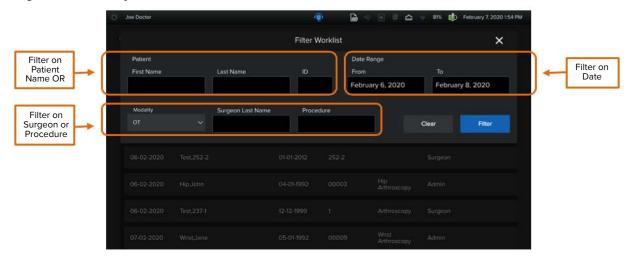
- Facilitate populating patient demographic information, eliminating dual data entry and providing data integrity
- Filter worklist for find patient
- · Add patient to worklist

Figure 20. Insert the Handpiece



- Select patient from list OR
- Filter list to find patient

Figure 21. Modality Worklist: Filter



· After selecting patient from worklist, the patient demographics will be populated on the home page.

Figure 22. Modality Worklist: Patient Demographics

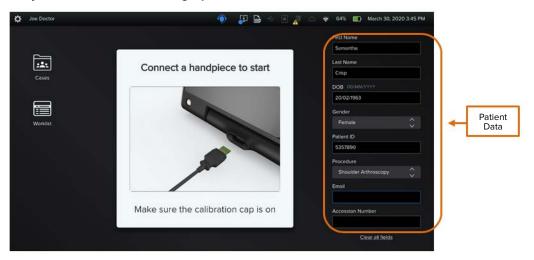
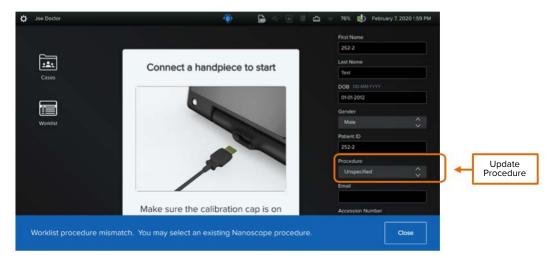


Figure 23. Modality Worklist: Procedure Mismatch



- If a procedure from DICOM does not match the NanoScope™ system master list of procedures, a procedure mismatch may occur.
- To correct, select procedure from NanoScope system procedure menu.

2.3.3. Calibrate the Handpiece

Figure 24. 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.

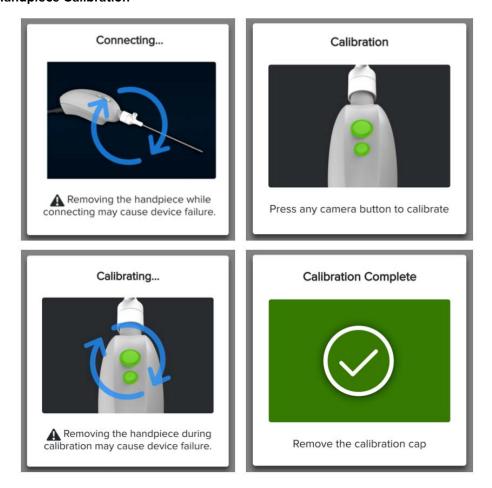


Figure 21. Used HandpieceTo continue, remove the used handpiece and insert a new one.

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.

Figure 25. Handpiece Calibration

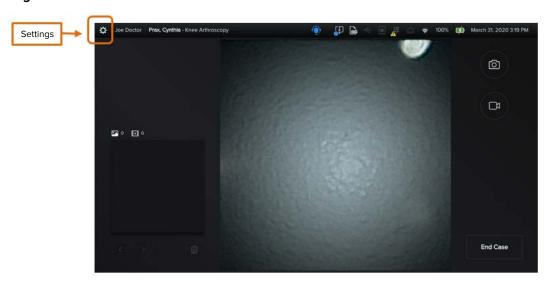


2.3.4. White Balance

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.

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

Figure 26. White Balance

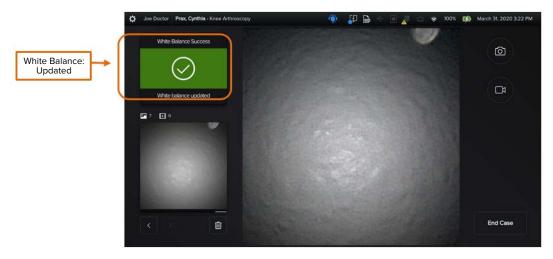


Note: The default handpiece configuration for this feature is the front button, long press.

Figure 27. White Balance: Processing



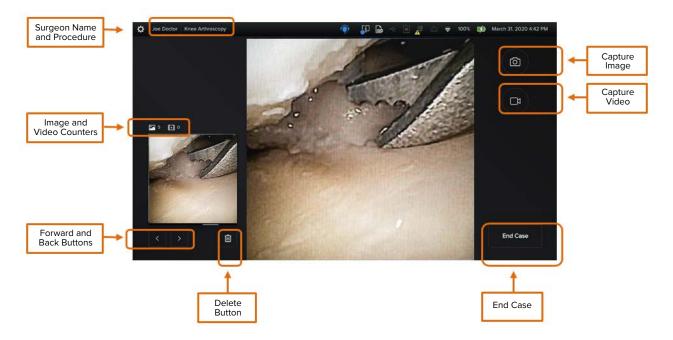
Figure 28. White Balance: Updated



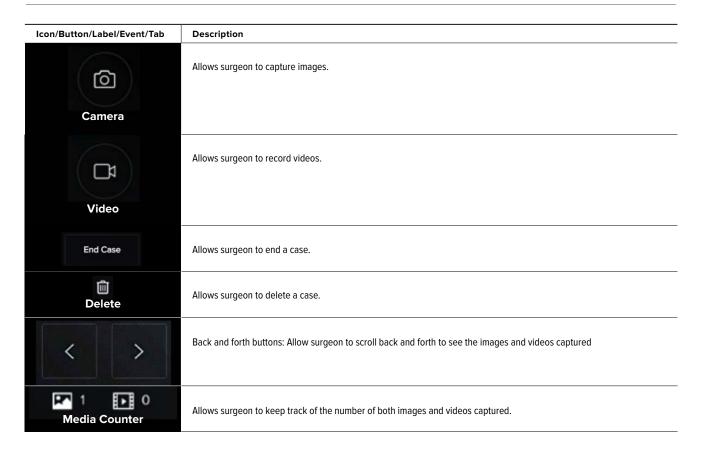
2.3.5. Capture Images and Videos

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.)



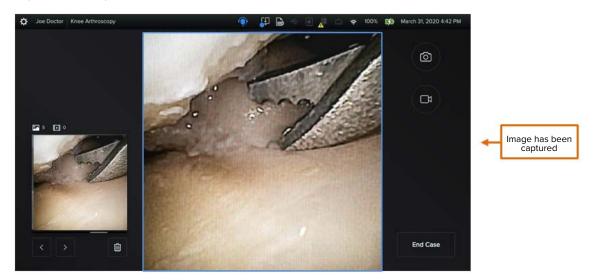
There are two ways to capture images and videos:

- Handpiece buttons
- Camera and Video buttons on the screen (should only be used by an assistant who does not need to remain sterile)

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 will display around the captured image on the screen.

Figure 30. Image Capture

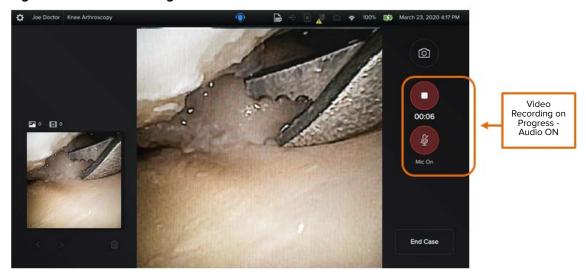


- A thumbnail of the captured image is displayed on the left side of the screen.
- Use the **Back** and **Forward** buttons to navigate through the media.
- To discard a captured image, click the **Delete** button.
- Click on **End Case** when procedure is complete.

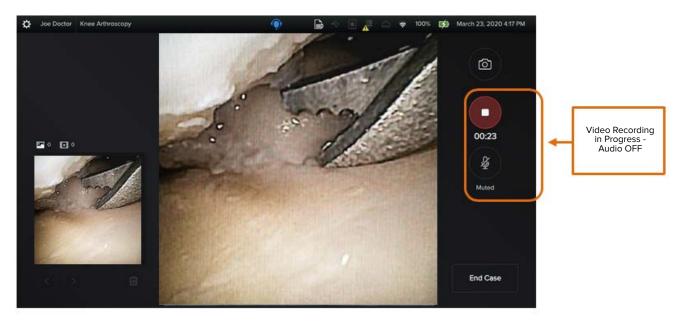
Video Capture

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 31. Video Recording



- Use the back and forth buttons to navigate through the media captured.
- If any of the videos captured are to be discarded, click on the **Delete** button.
- Click on **End Case** when procedure is complete.



Indicators on the right side of the screen:

- The video capture feature displays a **Stop button** and **Microphone button** in the right panel.
- Red indicates a video is being recorded.
- **Red** indicates audio is being recorded.
- Audio will be on or off based on default setting 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

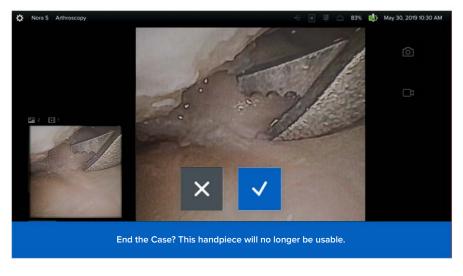


Figure 33. Case Complete

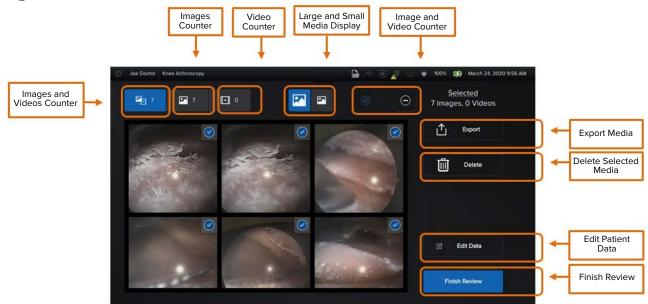
- The case is now complete.
- Remove the handpiece.



2.3.6. Review a Case

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

Figure 34. Case Review



While on this screen, the surgeon can perform the following actions:

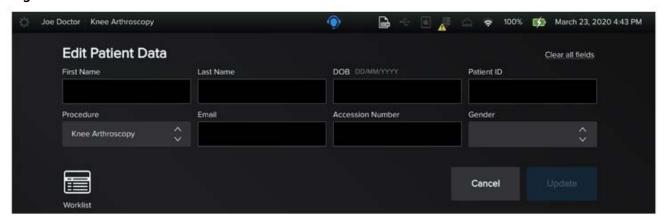
- Review the images and videos captured
- · Select media
- · Delete media
- Export media
- Edit data

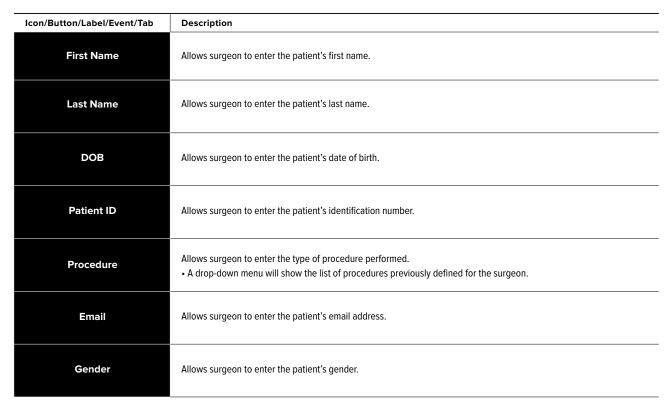
2.3.7. Edit Data

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 34).

The following screen will then be presented.

Figure 35. Edit Data





• 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.

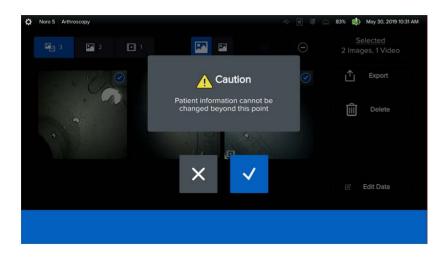
The user will be prompted to confirm that action.

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

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

Note: This action helps protect patient's data.

Figure 36. Finish Review



2.3.8. Export Media

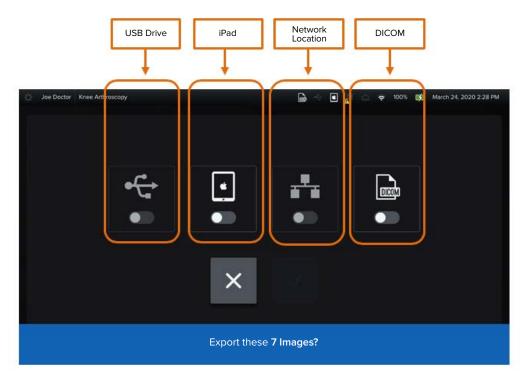
Once a case has been reviewed, the surgeon can opt to export its metadata along with the media captured.

Four options are presented:

- USB
- iPad
- Network capabilities
- DICOM

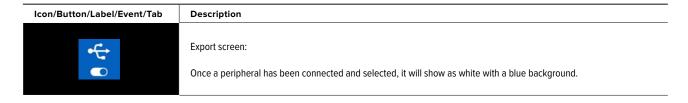
Note: DICOM requires additional licensing for purchase.

Figure 37. Export Case



Note: White indicates that option is available (peripheral is plugged in). In the figure shown above, the iPad and DICOM options are connected.

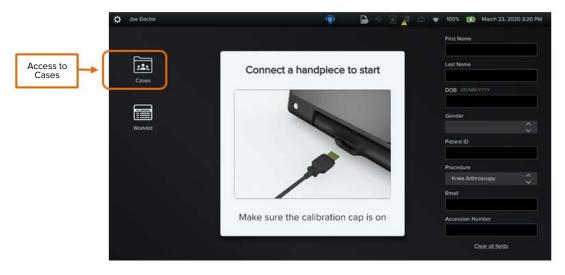
Figure 38. Peripherals



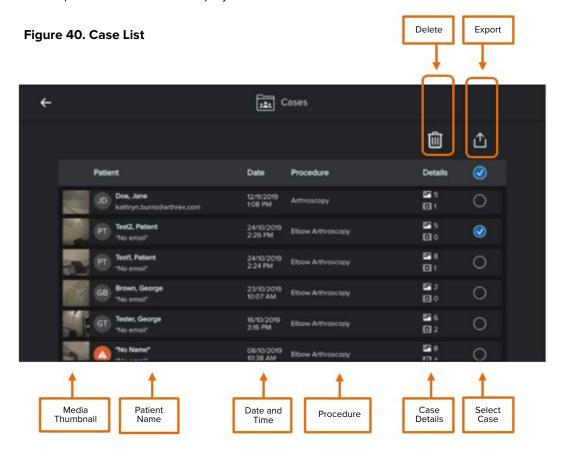
2.3.9. View the Case List

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

Figure 39. Access to Cases



Saved patient cases will be displayed.



2. NanoScope™ Software Operation (Cont.)

Case List

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

2.3.10. Export Cases

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

Figure 41. Export Cases



2.3.11. Log Out From Surgeon Profile

Figure 42. Surgeon Settings (top left corner).

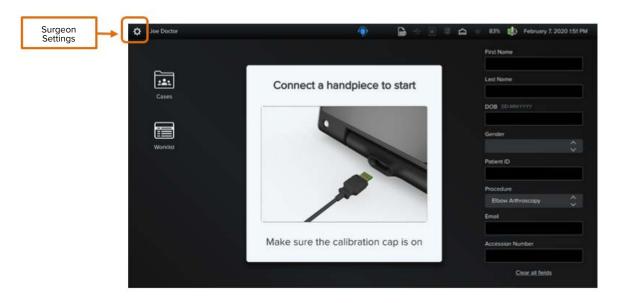
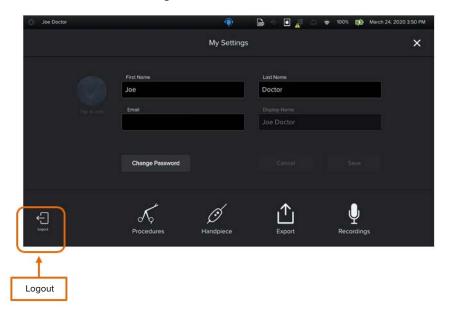


Figure 43. Logout

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



2.4. ADMIN SETTING

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

Figure 44. User: Admin



The following screen will be then displayed

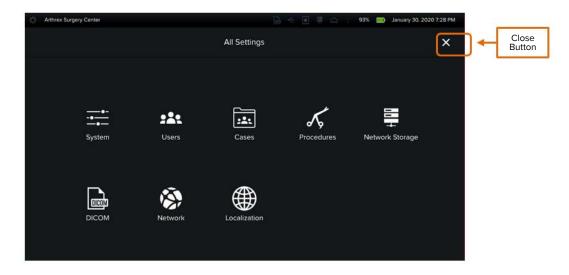


• Enter the Admin password.

The Administrator will be able to 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 access the Admin Settings, click on the **Admin Settings button** located on the top left corner of the Home Page.
- Enter the Admin credentials.

Figure 45. All Settings - The following screen will then be displayed.



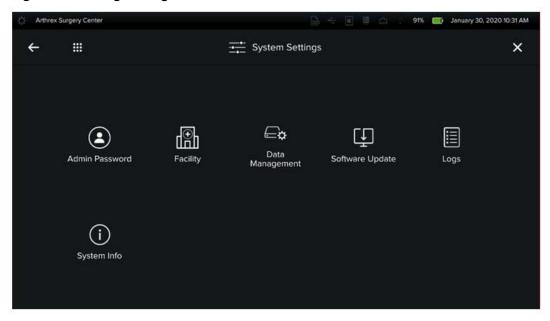
2.4.1. System Settings

Manage settings for the console operating system.

Admin has the ability to perform the following actions:

- Change Admin Password
- Change Facility Name
- Data Management import/export configurations and data cleanse
- Software Updates
- Audit and Support Logs
- System Information

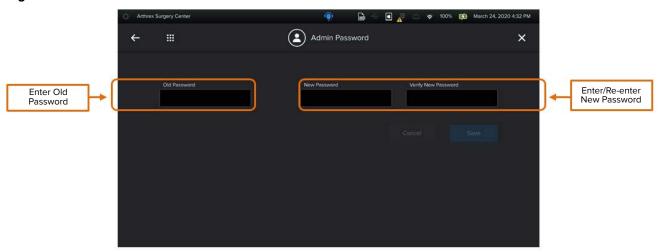
Figure 46. Setting Settings



2.4.1.1. Admin Password

Once the administrator has logged in for the first time, it is recommended to change the default password.

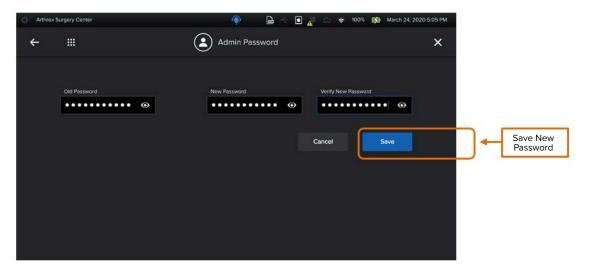
Figure 47. Admin Password



Note: Password requirements: All passwords in the NanoScope™ system must contain all of the following:

- 8 characters or more
- At least 1 upper case
- At least 1 lower case
- At least 1 number
- At least 1 special character

Figure 48. Admin Password



2.4.1.2. Facility Name

Set facility name and enable audio recording settings for the facility.

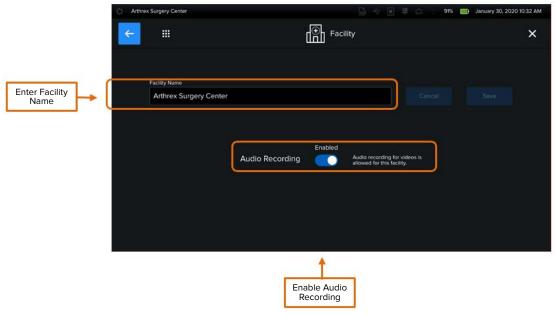


Figure 49. System Settings: Facility Name

Note: Enabling audio recording allows recording of audio during video capture for the facility. Having it enabled allows surgeons to enable audio recording within their settings.

2.4.1.3. Data Management

Data management allows admin to:

- Import device configuration and user profiles to a USB drive
- Export device configuration and user profiles to a USB drive
- Data cleanse remove all user profiles, case data, and device configuration

Figure 50. Data Management

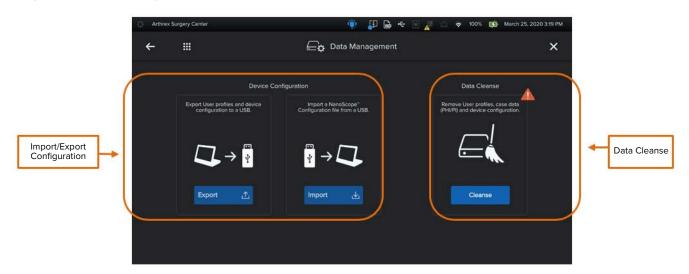
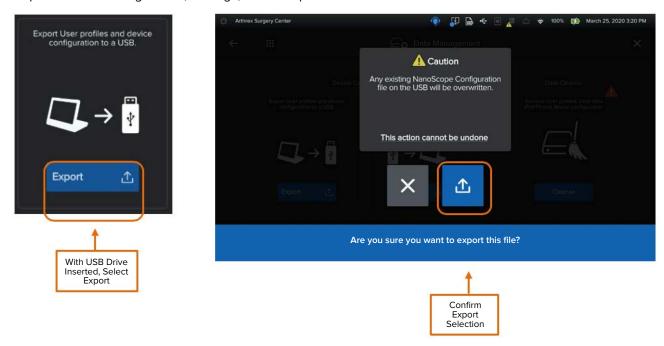


Figure 51. Data Configuration: Export

Exports device configuration, settings, and user profiles.



Note: Any NanoScope[™] system configurations on the USB drive will be overwritten when device files are exported. It is recommended these be moved to another drive if the facility wishes to retain them.

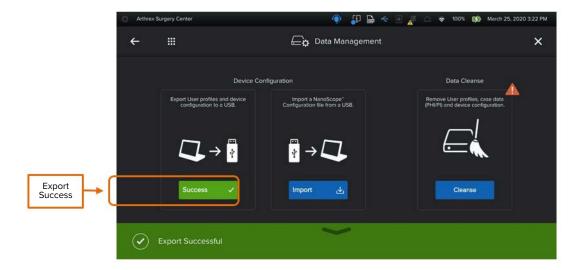
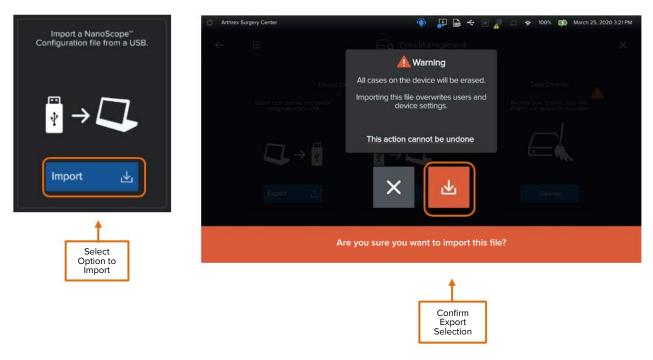


Figure 52. Data Configuration: Import

Imports device configuration, settings and, user profiles.



Note: All device settings and user profiles will be overwritten and cannot be undone. Device will reboot when file imported successfully.

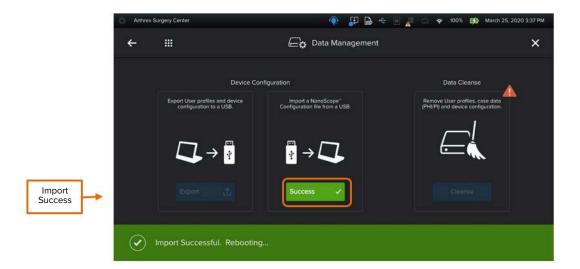
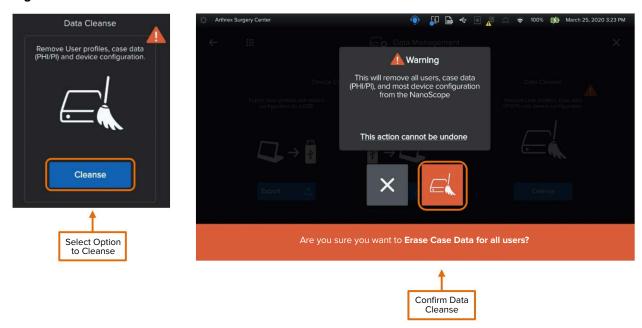


Figure 53. Data Cleanse



Note: This feature will clear all users, case data, and most device configuration and cannot be undone.

This may be used if a device needs to be returned to Arthrex for service or repair.

2.4.1.4. Software Update

Software updates can be performed via USB drive or via internet connection via remote support.

Figure 54. Software Update: Update Available

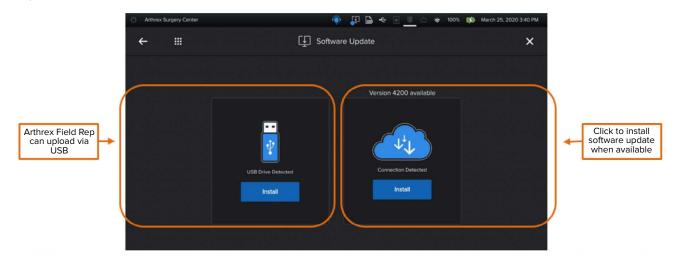
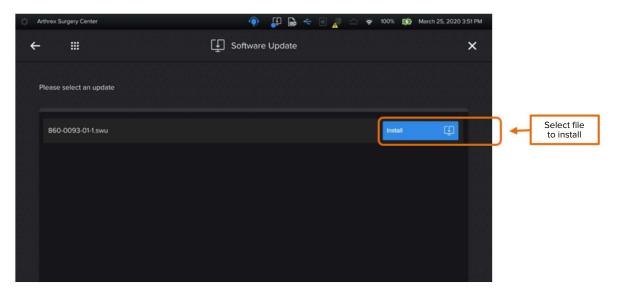


Figure 55. Software Update: USB Process

With USB drive inserted, select the option to install.



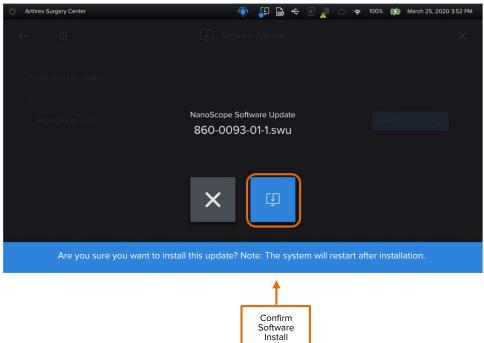


Figure 56. Software Update: Remote Update

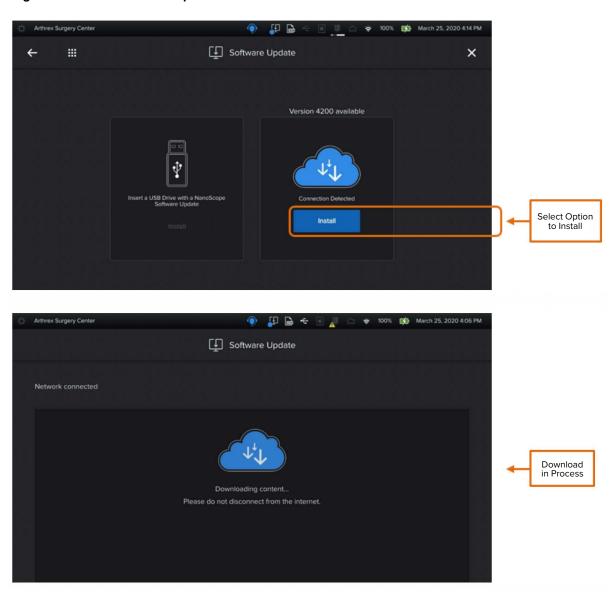
Software Update via Remote Support

- Contact Arthrex Service to request a software update
- Make sure the NanoScope™ system has an active internet connection
- Arthrex Service will push most recent software update to the device



Note: If a software update is pushed while device is offline, you will receive a notification the next time the NanoScope™ system is online. Notification will remain persistent until dismissed. The menu bar notification (blue dot) is persistent until software update is installed.

Figure 57. Cloud Software Update



^{*} Devices must be provisioned to perform software updates via the internet. Refer to section 2.4.1.6 of this manual for additional information.

2.4.1.5. Logs

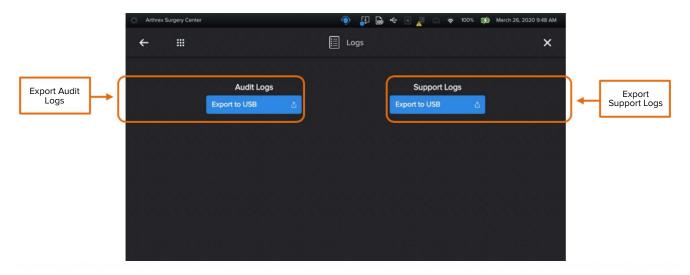
There are two types of logs that can be retrieved from the NanoScope $^{\scriptscriptstyle{\text{\tiny{M}}}}$. Those are as follows:

- Audit Logs
- Support Logs

Logs can be obtained by:

- Export logs to a USB Drive
- Remote Support Log Capture contact Arthrex Service

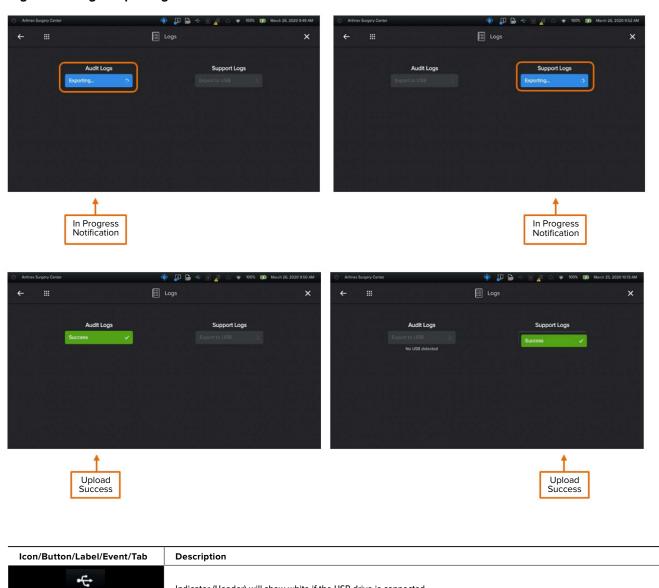
Figure 58. System Logs: USB



- With USB drive inserted select logs to be downloaded.
- Audit Logs system logs that track user access to the system and updating of data.
- Support Logs system logs that track device functions, warnings, and errors and are used to evaluate issues.

Figure 59. Logs: Exporting

USB Drive



Indicator (Header) will show white if the USB drive is connected.

2.4.1.6. System Info

The System Info screen displays the following information:

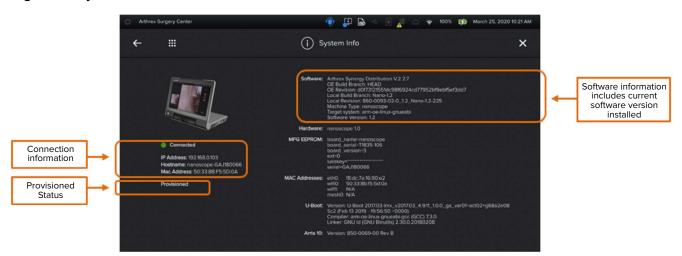
Left side of page:

- · Connection Status
- IP Address
- Host Name
- MAC Address
- Provisioned Status (allows for remote support connection)

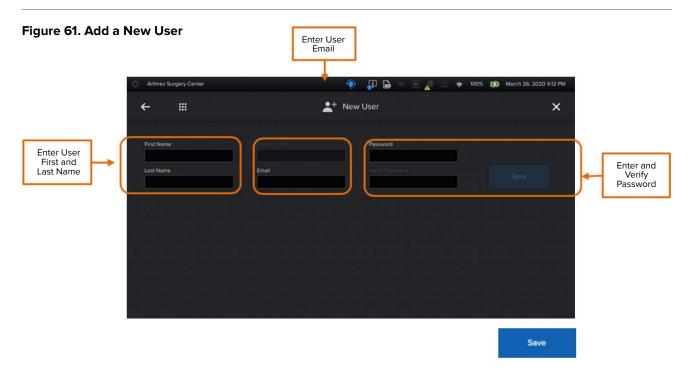
Right side of page:

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

Figure 60. System Info



Note: If your device does not display active provisioned status, as above, please contact Arthrex Service. Device provisioning is required for remote support, remote software upgrades, and remote license activation.

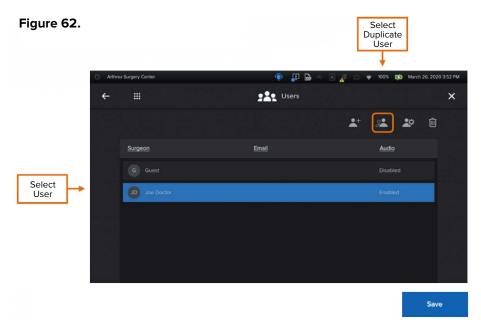


• Save button will be active when all required information is completed.

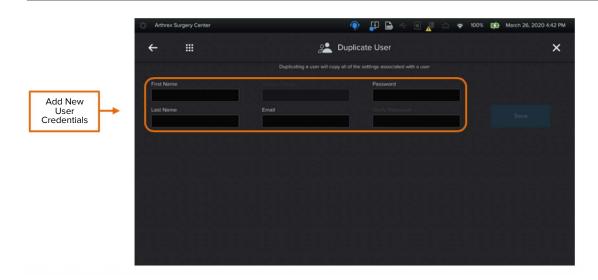
2.4.2. User Management: Duplicate User

To simplify adding multiple user profiles, the admin can duplicate a specific user's settings when adding a new user. The following settings will be duplicated:

- Procedures
- Handpiece
- Export
- · Recordings



• The save button will be activated when all required information is completed. Click Save to retain changes.



2.4.2.2. User Management: Edit User

Edit user credentials and access user settings.

• From the User Management page, select the edit user icon.



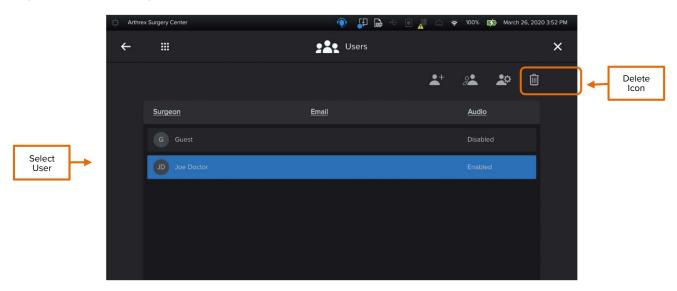
Figure 63. User Management: Edit User



2.4.2.4. Delete User

Select and delete users.

Figure 64. User Management: Delete User

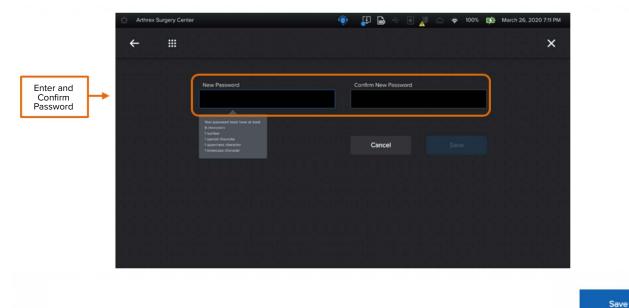


Note: Once a user is deleted, that action cannot be undone, and all cases associated with that user will be permanently deleted.

2.4.2.5. Change User Password

Admin can change password for the user.

Figure 65. User Management: Change Password

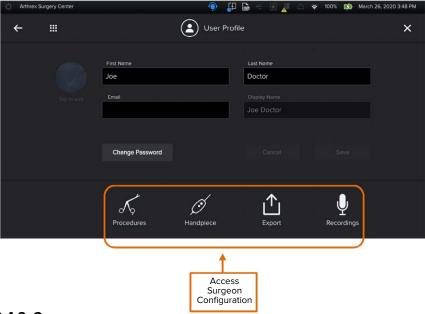


• The save button will be activated when all required information is completed. Click Save to retain changes.

2.4.2.6. Configure User Settings

Admin can configure Surgeon preferences as described in Section 2.2. These settings are included when duplicating user configuration.

Figure 66. Configure Surgeon Settings

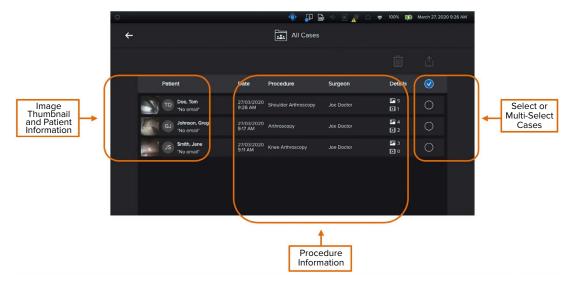


2.4.3. Cases

Admin has access to all cases performed in the NanoScope™ system. Case Management allows admin to:

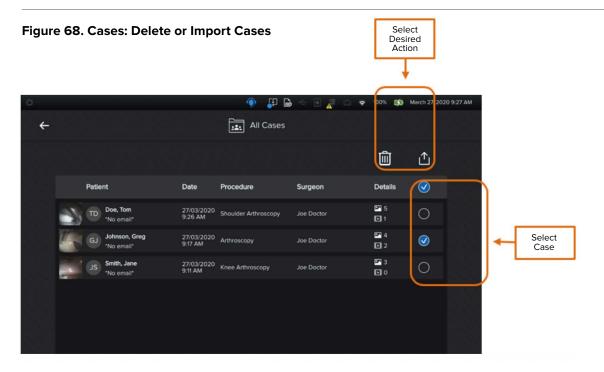
- View case media
- · Import individual or multiple cases
- Delete individual or multiple cases

Figure 67. Cases: Case List



- To view case media, tap anywhere on the desired case row, and the case will automatically open to the Case Review page.
- Delete or import options become active once a case is selected.

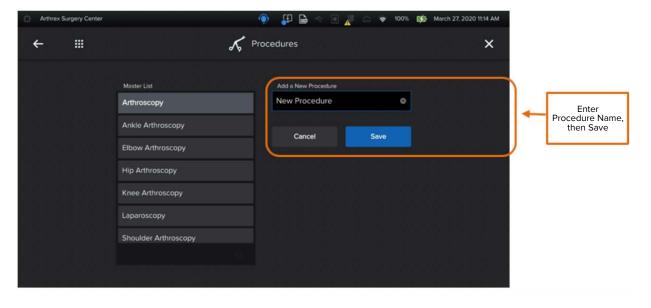
Note: Once a case is deleted, that action cannot be undone and will be permanently deleted.



2.4.4. Procedures

Allows admin to add new procedures to the master list.

Figure 69. Procedures

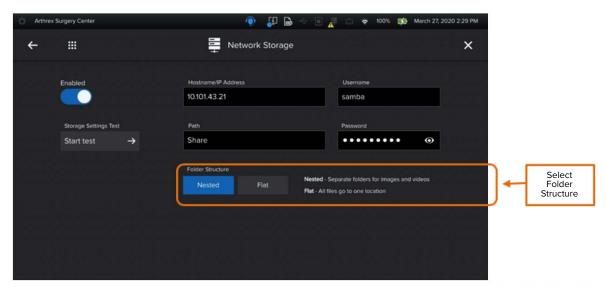


2.4.5. Network Storage

Toggle On to enable network storage.

Note: All data in this section should be provided by the facility IT representative.

Figure 70. Settings: Network Storage

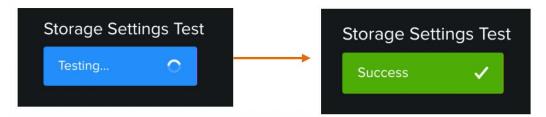


Folder Structure: Select the folder structure for all files to be exported.

- · 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 71. Network Storage Testing



2.4.6. DICOM

DICOM integration provides customers with the ability to automate the procedure and patient data entry process as well as export surgical imaging to a PACS or VNA for long-term retention. This feature requires an additional license for activation.

DICOM Features:

- Modality Worklist also referred to as MWL, facilitates procedure and patient demographic.
- Export this DICOM service allows images to be exported to a PACS or VNA.

Note: All configuration in this section should be provided by the facility IT Representative. See DICOM Set Up and Use Instructions (950-0043-00) for further instruction.

Figure 72. DICOM



Figure 73. DICOM: Modality Worklist Settings

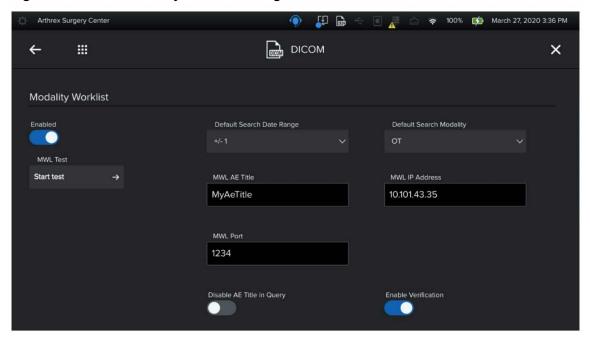
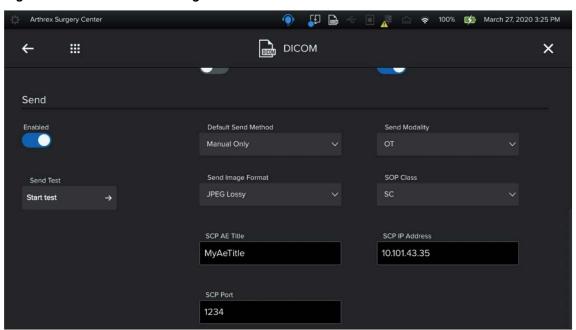


Figure 74. DICOM: Store Setting



2.4.7. Network

Network allows admin to:

- Configure Ethernet Settings
- Configure Wi-Fi Settings

Figure 75. Network

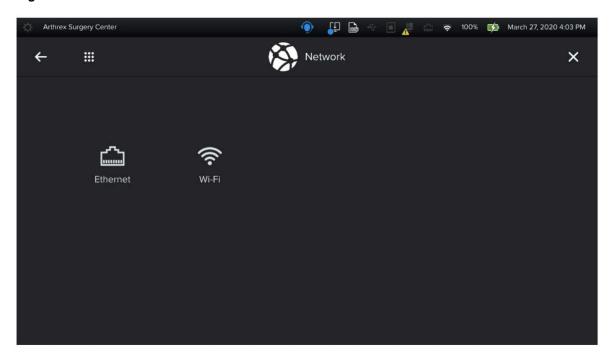
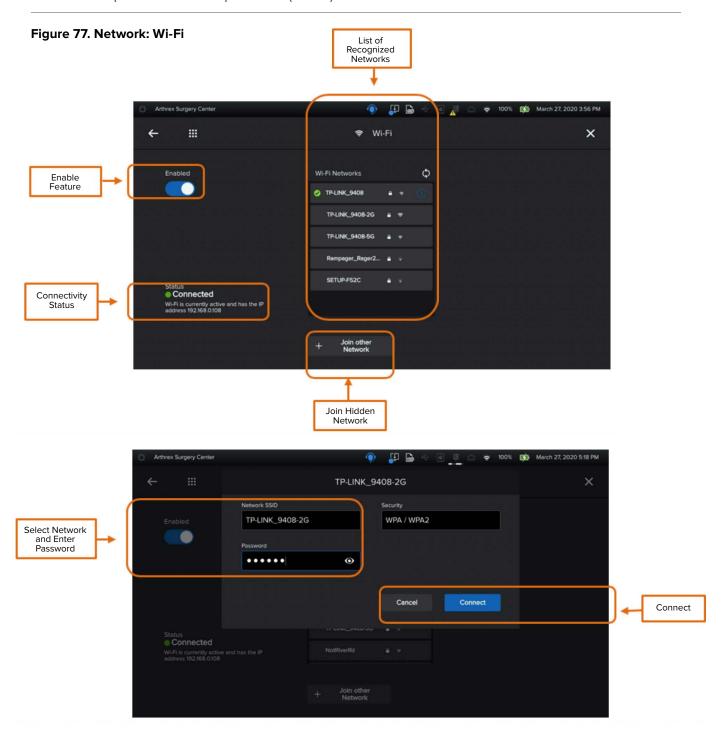


Figure 76. Network: Ethernet



Note: All configuration in this section should be provided by the facility IT representative.

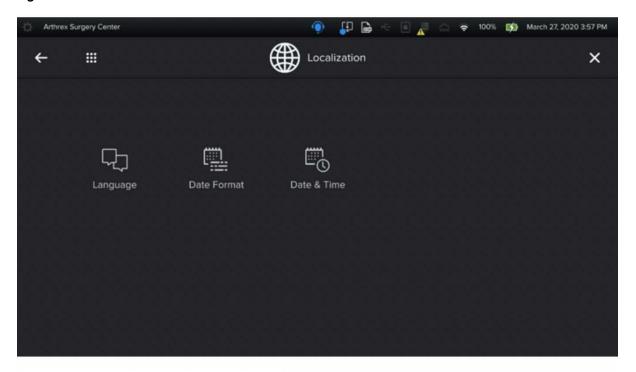


2.4.8. Localization

Localization allows admin to:

- Set Language
- Set Date Format
- · Set Time, Date, and Time

Figure 78. Localization



2.4.8.1. Localization: Language

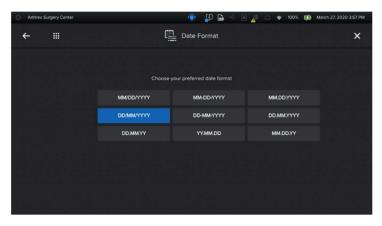
Figure 79. Language



2.4.8.2. Localization: Date Format

Date format will appear as selected on all cases and across screens on the NanoScope™ console.

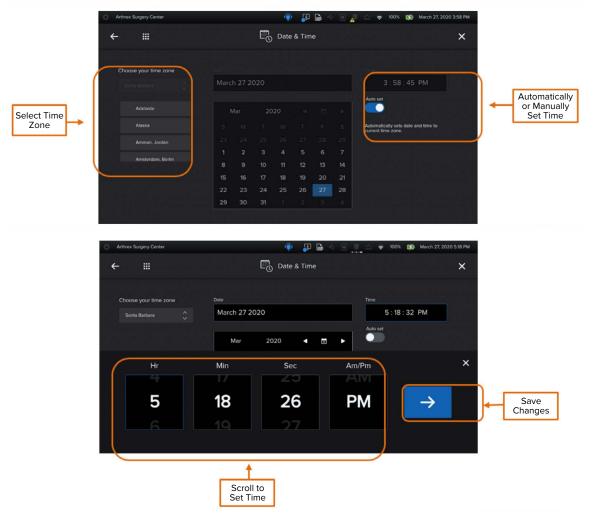
Figure 80. Localization: Date Format



2.4.8.3. Localization: Date and Time

- If the Auto Set is enabled and the console is connected to a network, date, and time will be automatically 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 81. Localization: Date and Time



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