VISIONSCOPE SYSTEM QUICK REFERENCE GUIDE



SYSTEM ORIENTATION

START UP

PATIENT REGISTRATION/RECORDS

ENDOSCOPE ASSEMBLY

IMAGE CAPTURE/MANAGEMENT

ENDOSCOPE DISASSEMBLY

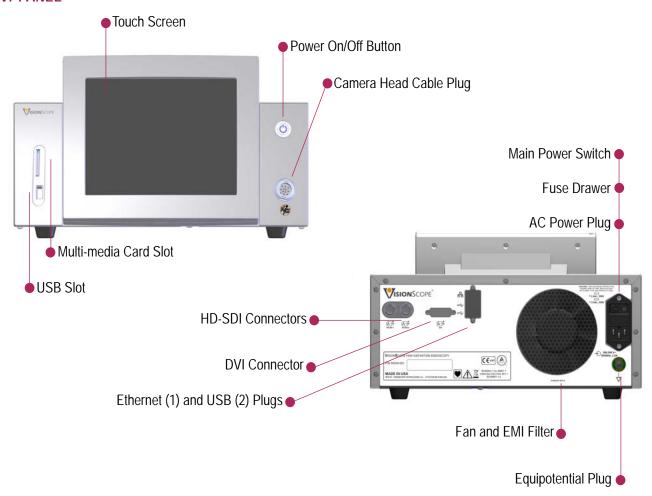
SHUT DOWN

TROUBLESHOOTING

SYSTEM ORIENTATION

CAMERA CONTROL UNIT

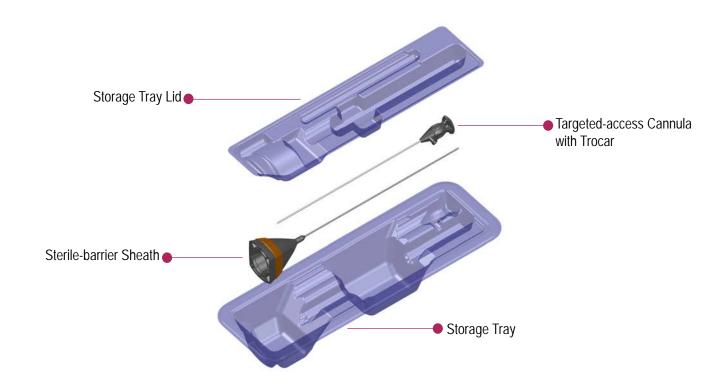
FRONT PANEL



BACK PANEL

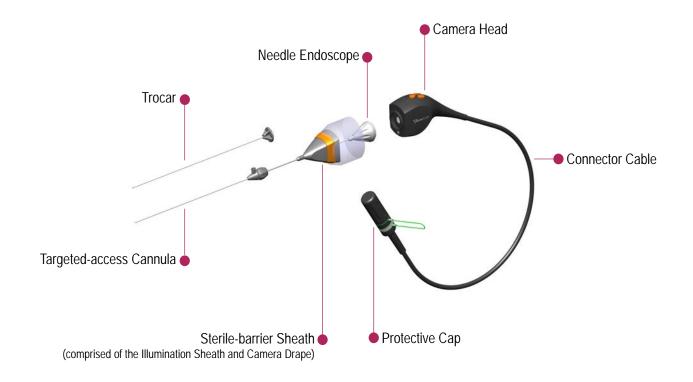


STERILE PROCEDURE KIT





ENDOSCOPE COMPONENTS



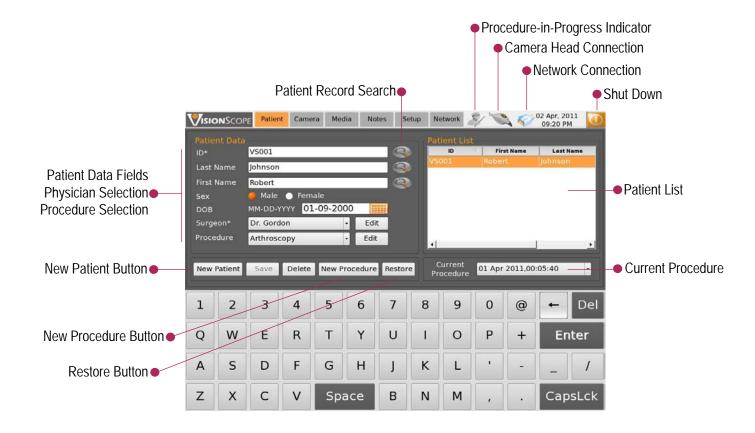


ASSEMBLED ENDOSCOPE



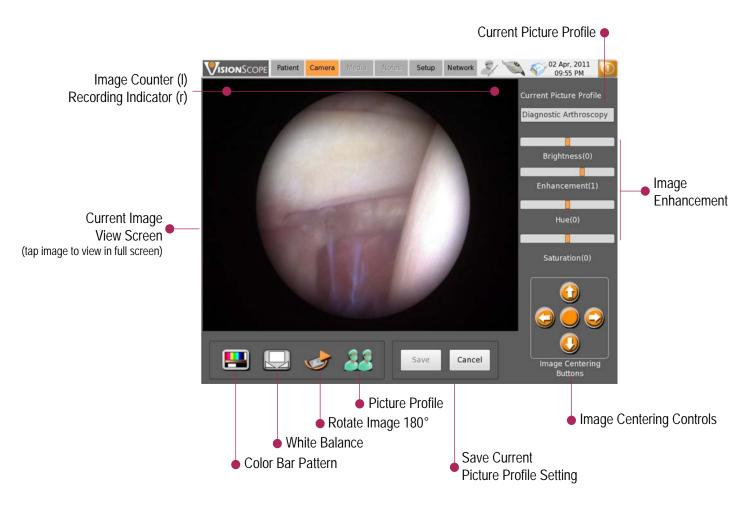


CCU SCREEN: PATIENT TAB



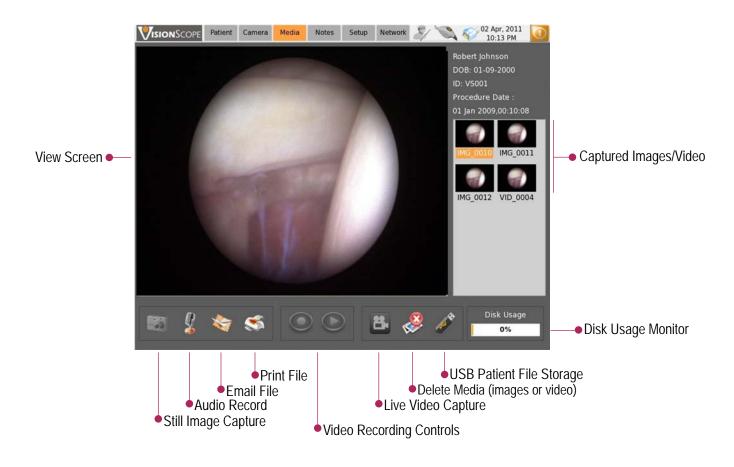


CCU SCREEN: CAMERA TAB





CCU SCREEN: MEDIA TAB



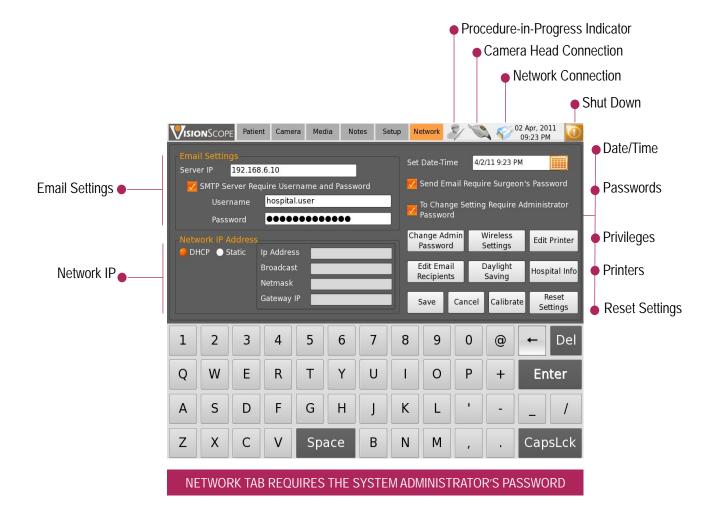


CCU SCREEN: SET-UP TAB





CCU SCREEN: NETWORK TAB





S T A R T U P

IN THIS SECTION

Camera Head Connection to the Camera Control Unit (CCU)

Camera Control Unit Start Up



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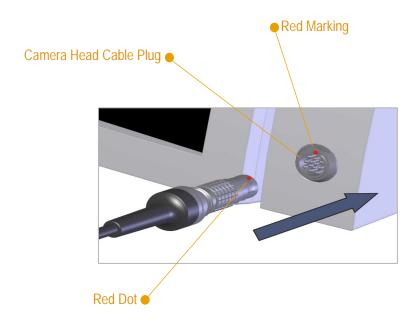
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CONNECTING THE CAMERA HEAD TO THE CCU

- 1. Unscrew the protective cap from the connecting end of the camera head cable.
- 2. Align the red dot on the camera head connector with the red marking on the CCU cable plug.
- 3. Push in tightly until an audible 'click' in heard.



• NOT CONNECTING THE CAMERA NOW? While easier, it's not required that the camera head cable be connected at this time. You can connect it at any point before starting a new procedure. Additional steps may be required. (See page 14)



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STARTING THE CAMERA CONTROL UNIT (CCU)

- 1. Press the power button on the front panel of the CCU. The button will illuminate green indicating the system is starting up.
- 2. Wait a moment while the system initializes and the screen becomes active.
- 3. When system initialization is complete, the patient record screen will appear.
- 4. The camera head icon (in the screen's tool bar) will confirm the connection status.

 If the connection is unsuccessful, disconnect the camera head and follow the connection instructions on page 14.







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CONNECTING THE CAMERA HEAD AFTER THE SYSTEM HAS BEEN TURNED ON

The camera head can be connected to the CCU any time prior to the initiation of a patient procedure.

- 1. Unscrew protective cap from the connecting end of the camera head cable.
- 2. Align the red dot on the camera head connector with the red marking on the CCU cable plug.
- **3. Push in tightly.** There will be an audible 'click' when securely in place. The camera head icon on the tool bar will indicate an **unsuccessful connection**.

Unsuccessful connection

- **4. Tap the camera tab**. Then **tap the continue button**. The screen will signal it's detecting the camera head.
- 5. Tap the patient tab to return to patient registration. The camera head icon will signal a successful connection.



1 UNSUCCESSFUL CAMERA HEAD CONNECTION? Disconnect the camera head cable and reconnect following the above steps, beginning with #2.



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PATIENT RECORDS

IN THIS SECTION

New Patient Registration

Existing Patient Record Retrieval

A Note about White Balance







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PATIENT REGISTRY

NEW PATIENTS

Before performing a procedure, a patient must be registered. Refer to page 17 for instructions on registering a new patient

RETURNING PATIENTS

To perform a procedure on a returning patient, you do not need to re-register, but simply recall their record from the database and initiate a new procedure (page 18).





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REGISTERTING A NEW PATIENT

Before conducting a procedure, a new patient must be registered.

- 1. Tap the new patient button.
- 2. Enter patient ID number (required).
- 3. Enter name, sex, date of birth (optional).
- 4. Select attending physician from drop-down menu (required).
- 5. Select procedure type (optional).
- 6. Tap the save button.
- 7. Review and confirm data, then tap the save button.





• THE BEST TIME TO WHITE BALANCE

Once data has been saved, the screen will prompt to white balance. Page 19 details more about white balancing.

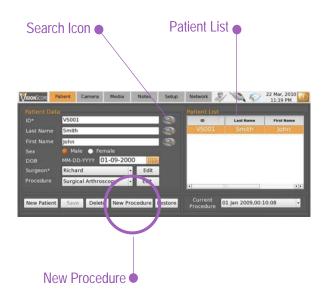


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OPENING AN EXISTING PATIENT RECORD

To capture new images and video on a previously-registered patient, a new procedure must be initiated.

- 1. Open an existing record by selecting a patient from the patient list.
- 2. Or enter any known data and tap the search icon to initiate the database search.
- 3. Tap the new procedure button.



• NEED TO EDIT DATA ON EXISTNG RECORD?

Some patient data can be edited on an existing record. Once the record has been loaded, edit as necessary, then tap the save button. You will be asked to confirm data, save and then white balance the camera head.



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A NOTE ABOUT WHITE BALANCING

BEST PRACTICE:

White balance the system once the endoscope and sterile-barrier sheath are fully assembled on the camera head.

WHEN THERE IS SCREEN DIRECTION TO WHITE BALANCE THE CAMERA HEAD PRIOR TO COMPLETE ENDOSCOPE ASSEMBLY:

- 1. Tap on the screen, taking you to the camera tab.
- 2. The camera head icon (in the tool bar) will confirm the connection status.
- 3. Successfully connected camera head: Assemble the endoscope and sterile barrier sheath.
- 4. Fully assembled endoscope: Initiate the white balancing process.



UNSUCCESSFUL CAMERA HEAD CONNECTION? Disconnect the camera head and reconnect by following the instructions on page 14.



ENDOSCOPE ASSEMBLY

IN THIS SECTION

System Components Overview

Needle Endoscope Connection

Sterile-Barrier Sheath Assembly

- Illumination Sheath
- Camera Drape

Endoscope White Balance



COMPONENTS OVERVIEW: STERILE VS NON-STERILE

Camera Control Unit (CCU)
Camera Head
Needle Endoscope

These components are durable and re-useable.

DO NOT HANDLE THESE COMPONENTS WITH GLOVES THAT WILL BE USED FOR STERILE PROCEDURES.

NON-STERILE



Sterile-barrier Sheath (illumination sheath/camera drape)

Cannula with Trocar

These components are disposable and should be discarded immediately after use or if the sterile packaging as been violated.

DO NOT HANDLE THESE COMPONENTS WITH GLOVES THAT HAVE,

OR MAY, COME IN CONTACT WITH NON-STERILE COMPONENTS.



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CONNECTING THE ENDOSCOPE TO THE CAMERA HEAD

The camera head and needle endoscope are non-sterile. Gloves are not required for this step.

1. Select/confirm the correct anatomy-specific endoscope for the procedure. Endoscope working lengths have color-coded packaging for easy identification.



- 2. Ensure all components are clean, dry and undamaged.
 Disinfect the endoscope and camera head before each procedure by wiping them down with a 70% isopropyl alcohol-soaked gauze pad.
- 3. Thread the endoscope, clockwise, into the C-mount on the camera head. Hand-tighten, compressing the O-ring.

 Do not use hand tools to tighten the endoscope.

 Camera Hea



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ASSEMBLING STERILE COMPONENTS

Double Glove

Put two sterile surgical gloves on your non-dominant hand (e.g. your left hand if you are right handed).

As long as both gloves remain on this hand, it will be considered your NON-STERILE hand.

NON-STERILE



STERILE

Single Glove

Put a single sterile surgical glove on your dominant hand (e.g. your right hand if you are right handed). This hand, with the sterile glove, will be always be considered your STERILE hand.



ATTACHING THE ILLUMINATION SHEATH

1. Confirm that the selected sterile procedure kit is the same working length as the selected endoscope. Procedure kits have color-coded packaging for easy identification.



2. Confirm proper sterile vs. non-sterile glove protocol.



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ATTACHING THE ILLUMINATION SHEATH

- 3. Have an assistant open the procedure kit.
- 4. With your sterile hand, remove the storage tray lid.

 Leave the cannula/trocar in the sterile tray until needed.
- 5. With your sterile, dominant hand, remove the sterile-barrier sheath from the tray and hold it at the illumination sheath base.

To avoid damage or breakage, do not hold by the semi-flexible needle channel.



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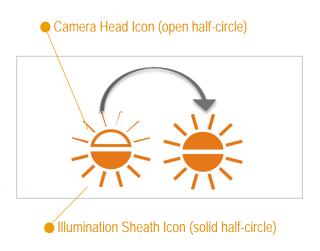


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ATTACHING THE ILLUMINATION SHEATH

- 6. Hold the camera head in your non-sterile, non-dominant hand.

 Carefully insert the endoscope into the funnel of the illumination sheath.
- 7. Align the solid half-circle sunbeam icon on the illumination sheath base with the open half-circle icon on the camera head.
- 8. Lock the sheath to the camera head by rotating the base of the sheath a ¼ turn clockwise until it firmly snaps into place and the two half-circle solid sunbeam icons align.



■ NO ILLUMINATION BEAM?

Confirm: 1) the endoscope and sterile-barrier sheath are the same working length, 2) the sunbeam icons are properly aligned, and 3) the light source is on by tapping the Set-up tab and flipping the light control switch to the ON/NORMAL position.



DEPLOYING THE CAMERA DRAPE

- Continue to hold the camera head in your non-sterile, non-dominant hand.
 With your sterile hand gently begin to feed the camera drape over the camera head until it is nearly covered.
- 2. Switch and hold the assembled endoscope in your sterile, dominant hand near the sheath base area.
- 3. Using your non-sterile, non-dominant hand carefully pull the deployment cord of the camera drape over the camera head and down the length of the camera head cable. Only the deployment cord should be touched with a non-sterile glove.
- 4. Carefully remove the outer glove from your double-gloved hand. BOTH HANDS ARE NOW STERILE. Do not touch any non-sterile components.
- 5. Inspect the camera drape for complete coverage and any damage.

 If there is damage, the sterile-barrier sheath **must** be removed and replaced with a new one.



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WHITE BALANCING THE ENDOSCOPE

With the system fully assembled:

- 1. Point the assembled endoscope at a piece of white gauze (easy-to-see fibers) or another white object from a short distance.
- 2. Short press the middle button on the camera head.
- 3. An on-screen message will signal white balance process has been initiated. Another message will indicate the white balance process is complete.
- 4. Upon completion of white balance, take a still image of a textured white object (gauze pad) from a distance of 8-10mm, to ensure illumination level is bright, color is correct, focus is sharp and that there are no foreign objects in the field of view.

 White Balance (short press)

• NO ILLUMINATION BEAM OR DARK IMAGE?

Confirm: 1) the endoscope and sterile-barrier sheath are the same working length, 2) the sunbeam icons are properly aligned, and 3) the light source is on by tapping the set-up tab and flipping the light control switch to the ON/NORMAL position.



I M A G E C A P T U R E

IN THIS SECTION

Assembled Endoscope Operation

Image Capture: Camera Tab

Image Management: Media Tab



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OPERATING THE ASSEMBLED ENDOSCOPE

The three buttons on the camera head control:

1. TOP CENTER

- Camera settings (picture brightness scale)
- White balance (when prompted by system)

2. LEFT BUTTON

- Short press: still image capture
- Long press (5 sec): last captured still image

3. RIGHT BUTTON

- Short press: video recording
- Long press (5 sec): picture enhancement scale



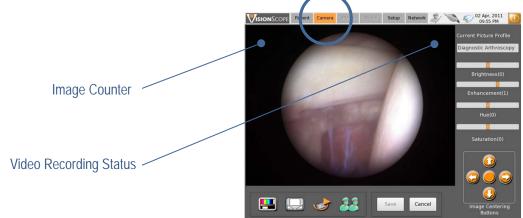
1 CUSTOMIZING THE PICTURE PROFILE

Custom picture enhancement profiles can be created or edited to match operating or image enhancement preferences. Tap the surgeon icon in the camera tab and follow the instructions.



- 1. Tap the camera tab on the CCU screen. The camera tab includes controls for image adjustment.
- 2. Before performing a patient procedure, take a still image of a textured white object (gauze pad) from a distance of 8-10mm, to ensure illumination level is bright, color is correct, focus is sharp and that there are no foreign objects in the field of view.
- 3. Press the left button (short press) on the camera head to take a still image. An image counter appears in the upper-left corner of the screen.
- 4. Press the right button (short press) on the camera head to record video. Push the right button again to stop recording. A recording indicator appears in the upper right hand corner of the screen when recording.

5. Full screen mode: have an assistant tap on the screen to enlarge the image and hide icons. Tap again to unhide icons.





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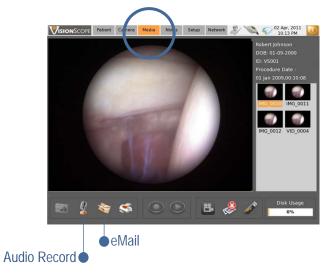
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MANAGING IMAGES: MEDIA TAB

Following a procedure, when you are able to touch non-sterile components (or with the aid of an assistant during a procedure), you can review captured images/video.

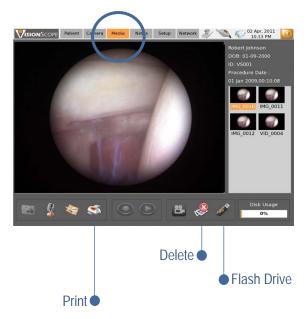
- 1. Tap the media tab on the CCU screen. The media tab includes controls for reviewing and managing images and audio/video recordings.
- 2. The microphone icon allows you to add audio notes to the patient's procedure record.
- 3. If an institution allows, and this system has been set up accordingly, patient files can be emailed to the attending physician for inclusion in the patient's electronic record by tapping the envelope icon. Upon entering the physician's password, the patient file will be sent.



SYSTEM SET UP FOR EMAIL TRANSMISSION? Contact your network administrator for assistance.



- 4. To print all or a selection of images, tap on the printer icon.
- 5. To delete unwanted images/video, tap on a selected image and tap the delete icon.
- 6. Patient Images can be stored on a flash drive. This function is password protected. Put the flash drive in one of the three available USB ports. Tap the flash drive icon. Enter the physician's password. Continue as directed.



• FORGOT YOUR PASSWORD? System administrator help may be required.



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ENDOSCOPE DISASSEMBLY

IN THIS SECTION

Endoscope Disassembly

Re-Use Preparation



DISASSEMBLING THE SYSTEM

- 1. Holding the assembled endoscope, turn the illumination sheath base ¼ turn counter-clockwise to disengage the sheath from the camera head C-mount.
- 2. Gently retract the sterile-barrier sheath from the camera head/endoscope. Keep pulling until the camera drape is completely separated from the camera head/endoscope.
- 3. Set the camera head with endoscope down on a clean work surface.
- 4. Dispose of the sterile-barrier sheath (as well as the cannula and trocar if not already done so) in a bio-hazard waste bin per the hazard waste disposal policy of your facility.
- 5. Disconnect the needle endoscope from the camera head and store it in its original, padded, color-coded packaging. This will ensure easy identification and protect it against damage.





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PREPARING SYSTEM FOR RE-USE

If the proper procedure is followed during assembly and disassembly, the camera head and endoscope should be uncontaminated at the end of a patient procedure and ready for immediate re-use with a sterile wipe down.

- 1. If the same anatomy-specific procedure follows, the endoscope does not need to be changed. Only wiped down. Then, at the right time, attach a new sterile-barrier sheath as directed.
- 2. If a procedure on a different anatomy follows, gently unscrew the endoscope from the camera head, wipe it down and store properly.
- 3. Select a new anatomy-specific endoscope and repeat assembly process as directed in this guide.

DISINFECTION

Wipe down with a 70% isopropyl alcohol-soaked gauze pad before and after each procedure.



S H U T T I N G D O W N

IN THIS SECTION

Camera Control Unit (CCU) Shut Down
Camera Head Disconnection



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SHUTTING DOWN THE CAMERA CONTROL UNIT

Patient images and video are automatically saved as part of the patient file on the CCU hard drive. The save tab is deactivated on the patient tab signaling it is not necessary to save data after each procedure.



The system can be left running and turned off at the end of each day. It is recommended that the light source be turned off if the system will be inactive for a period of time.

To turn the light source ON/NORMAL and OFF/STANDBY:

- 1. Tap the set-up tab.
- 2. With the stylus, flip the light source switch to the ON/NORMAL or OFF/STANDBY position







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SHUTTING DOWN THE CCU

To shut down the CCU:

- 1. Tap the patient tab.
- 2. Tap the close icon in the upper right corner of the screen.
- 3. Tap the shutdown icon on the screen.
- 4. When the screen message signals it's safe to turn off the machine, push the power button.
- 5. System will shut down.





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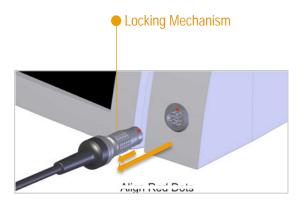
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It is not necessary for the camera head to be disconnected from the CCU after each procedure or after the CCU has been shut down.

If you would like to remove the camera head from the CCU:

- 1. Using one hand, pull back slightly on the retractable sleeve.
- 2. Once pulled back, and holding it in that position, use your other hand to pull the camera connector out of the CCU plug – holding the connector as close to the CCU plug as possible.
- 3. Store the camera head in a safe, clean location.





TROUBLE SHOOTING

IMAGE NOT VISIBLE

The illumination sheath may not be securely attached to the camera head.

- Align the half-circle solid sunbeam on the illumination sheath with the open half-circle icon on the camera head
- Rotate the base of the sheath a ¼ turn clockwise until it firmly clicks into place and the two half-circle solid sunbeam icons align

The camera head cable may not be connected to the CCU properly.

- Remove camera head cable from the CCU cable plug
- Align the red dot on the camera head connector with the red marking on the CCU cable plug
- Push in tightly until an audible 'click' is heard



IMAGE DISCOLORED

The camera head /endoscope may need to be properly white balanced.

- Point the camera head and endoscope at a white object (cotton gauze)
- Press the middle button on the camera head for 1-2 seconds
- Touch screen display will signal that the white balance has been activated and also it's completed



IMAGE BLURRY OR OBSTRUCTED

The illumination sheath may not be securely attached to the camera head.

- Align the half-circle solid sunbeam on the illumination sheath with the open half-circle icon on the camera head
- Rotate the base of the sheath a ¼ turn clockwise until it firmly clicks into place and the two half-circle solid sunbeam icons align

The endoscope may not be securely seated in the cannula collar.

- Re-insert the assembled endoscope into the funnel of the cannula
- With a gentle, firm push continue until the entire length of the endoscope has been inserted into the cannula
- A final, firm push securely positions the endoscope in the cannula collar

The endoscope, illumination sheath or camera head may be dirty.

- With a sterile surgical cotton gauze, clean and dry:
 - Illumination sheath exterior window
 - Endoscope distal tip window
 - Endoscope proximal end window
 - Camera head window



IMAGE DARK OR BRIGHT

The illumination sheath may not be securely attached to the camera head.

- Align the half-circle solid sunbeam on the illumination sheath with the open half-circle icon on the camera head
- Rotate the base of the sheath a ¼ turn clockwise until it firmly clicks into place and the two half-circle solid sunbeam icons align

The endoscope may not be securely seated in the cannula collar.

- Re-insert the assembled endoscope into the funnel of the cannula. With a gentle, firm push continue until the entire length of the endoscope has been inserted into the cannula
- A final, firm push securely positions the endoscope in the cannula collar

The light source may be turned off.

• Tap the Set-up tab and with the stylus flip the light switch to turn the light source on and off



IMAGE DARK OR BRIGHT

The camera head cable may not be connected properly.

- Remove camera head cable from the CCU cable plug
- Align the red dot on the camera head connector with the red marking on the CCU cable plug
- Push in tightly until an audible 'click' is heard

The CCU power may not be on.

- Make sure the power switch on the back panel is turned on
- Confirm the power button on the front panel is on and illuminating green

The brightness setting may be too low.

- Tap the camera tab and check the brightness setting
- Adjust if necessary
- If using an external monitor, check the brightness and contrast settings

The light source may have blown.

- Shut down the system remove the needle endoscope if necessary
- Turn the system back on and wait for the system to initialize
- Tap the set-up tab and flip the light source switch on and off with the stylus
- When on, a light beam should shine from the camera head
- DO NOT LOOK DIRECTLY INTO THE LIGHT
- If there is no light, contact VisionScope Technical Support



IMAGES/VIDEO: UNABLE TO SAVE

The hard drive may be full.

- Check the data storage indicator in the lower right-hand corner of the media tab screen
- If full, remove unneeded, archived images and video to make room for new procedure media

Images cannot be saved to a closed procedure.

• Open a new procedure to save new images or video



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IMAGES: UNABLE TO PRINT

A printer has not been selected.

Select a printer

The selected printer may not be configured properly.

• Re-install the current printer or select a different printer



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IMAGE CORRUPTED

The camera control unit (CCU) may need to be re-started

- Shut down the CCU
- Restart the CCU



ENDOSCOPE: BENT OR BUCKLED

A bent or buckled endoscope must not be used. It needs to be replaced prior to initiating a patient procedure.



STERILE-BARRIER SHEATH: BENT OR DAMAGED

The sterile-barrier sheath must be replaced.

To ensure patient safety and proper endoscope insertion/connection, the illumination sheath must be completely undamaged.

- Inspect the sterile-barrier sheath for damage prior to assembly
- If the sterile-barrier sheath becomes damaged during the assembly process, gently remove it, discard properly and open a new, sterile procedure kit



FLUID LEAKAGE FROM CANNULA

The cannula collar may not be tightened around the endoscope.

- Hand-tighten the cannula collar (clockwise) to compress the O-ring and prevent fluid leakage
- Do not use hand tools to tighten the cannula collar or any part of the VisionScope system



ENDOSCOPE STUCK IN CANNULA

The cannula collar may need to be loosened.

• Before removing the endoscope from the cannula, post procedure, loosen the cannula collar (counter clockwise) to relax the O-ring and allow for smooth movement within the cannula channel



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ENDOSCOPE & ILLUMINATION SHEATH LENGTHS DON'T MATCH

The needle endoscope and the illumination sheath must have matching lengths in order to operate correctly and ensure patient safety.

If the non-sterile endoscope is longer than the illumination sheath:

• It can break through the window of the illumination sheath tip and be exposed within the patient cavity

If the endoscope is shorter than the illumination sheath:

• It can not be fully inserted to where the tip of the endoscope unites with the tip of the illumination sheath.

Only in this secure position can diagnostic-quality images and video be generated



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NEW PROCEDURE WON'T START

The hard drive may be full.

- Check the data storage indicator in the lower right-hand corner of the media tab screen
- If full, remove unneeded, archived images and video to make room for new procedures

The file system may be corrupted.

• Contact VisionScope Technical Support



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PASSWORD HAD FAILED

The password may have been entered incorrectly.

- Verify password and re-enter
- Confirm correct field of entry (physician or administrator)
- Contact the system administrator to reset the password



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SYSTEM DATE IS INCORRECT

The daylight savings settings may have been changed.Contact the system administrator for further assistance

The date (and time) may need to be adjusted.

• Contact the system administrator for further assistance



EMAIL WON'T SEND

Connection to the mail server may have failed.

- Check the mail server settings and host name configuration
- Contact your institution's technical support team for assistance

The network cable or wireless transmitter may not be attached.

• Check the back panel to ensure there is a connection



UNABLE TO CONNECT TO THE NETWORK

The network cable may be disconnected.

- Plug in the network cable
- If problem persists, contact your institution's technical support team

The wireless device may be disconnected.

- Plug in the wireless device
- Check the wireless access point configuration
- If problem persists, contact your institution's technical support team



UNABLE TO ACCESS THE HARD DRIVE

The hard drive may be full.

- Check the data storage indicator in the lower right-hand corner of the media tab screen
- If full, remove unneeded, archived images and video to make room for new procedures

The file system may be corrupted.

• Contact VisionScope Technical Support





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