stryker®

SPY PHI

OPERATOR'S MANUAL

SPY PORTABLE HANDHELD IMAGING SYSTEM

HH9000

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SPY COLOR-SEGMENTED FLUORESCENCE™ (SPY CSF™)

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Contents

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Chapter 1 Health and Safety Compliance

Important Information

WARNING: **Read before use.**

This Operator's Manual contains essential information on using the SPY Portable Handheld Imaging System (SPY-PHI System) safely and effectively. Before use, thoroughly review this manual and use the system as instructed.

Keep this manual in a safe, accessible location. Questions or comments about any information in this manual should be sent to Stryker Customer Support.

The words **WARNING**, **CAUTION**, and **Note** carry special meaning and the associated clauses should be carefully reviewed:

WARNING: Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.

CAUTION: Indicates risks to the equipment. Failure to follow cautions may result in product damage.

Note: Provides special information to clarify instructions or present additional useful information.

Intended Use

The SPY Portable Handheld Imaging System (SPY-PHI System) is an active device used to visualize circulation, including lymphatics and blood vessels, as well as related tissue perfusion with near infrared fluorescence imaging during a variety of surgical procedures.

The SPY Portable Handheld Imaging System is to be used by trained healthcare professionals and it does not provide diagnosis or prescribe therapy.

WARNING: **The imaging system should be used according to its approved Intended Use.**

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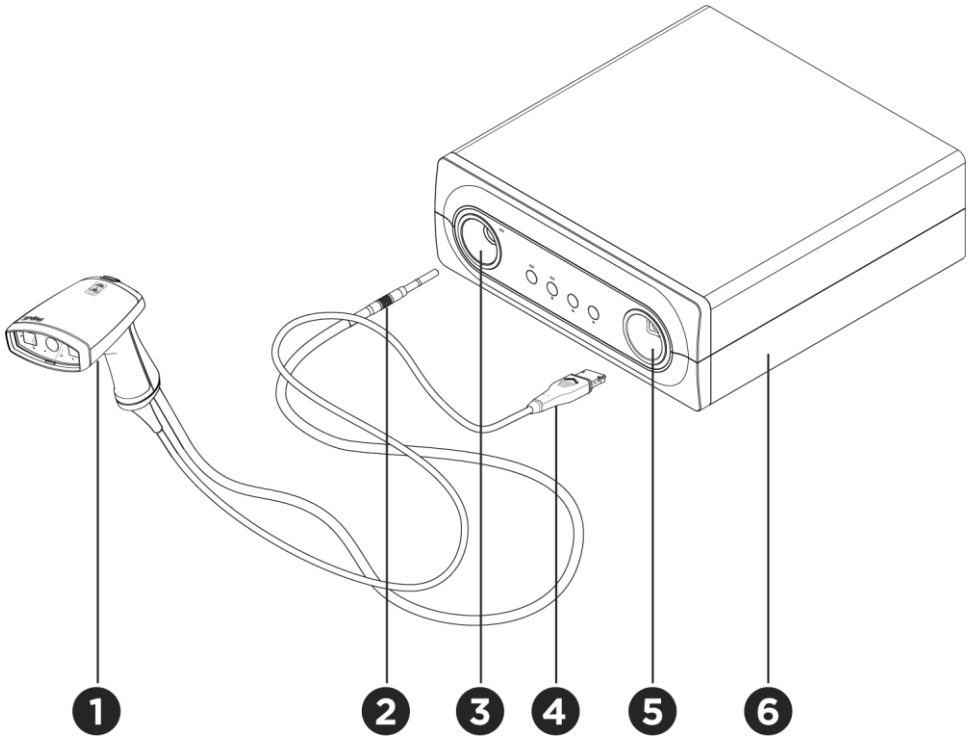
Overview of the SPY-PHI System

The SPY-PHI System is configured as shown in Figure 1 and includes the following components:

- SPY Portable Handheld Imager (HH9030) with integrated light guide and camera cables, optimized for VIS/NIR imaging
- Video Processor/Illuminator (PC9001) capable of providing VIS/NIR illumination to the SPY-PHI imager via its light guide cable and the image processing required to generate simultaneous, real-time HD-video color and NIR fluorescence images

Figure 1: SPY-PHI System components



1. SPY Portable Handheld Imager (SPY-PHI)
2. Light guide cable
3. Light guide port
4. Camera cable
5. Camera port
6. Video Processor/Illuminator (VPI)

The SPY-PHI System is used in conjunction with the following consumable products:

- sterile drape
- ICG imaging agent

Medical-grade accessories, which may be used to support the SPY-PHI System include:

- medical-grade video monitor
- medical-grade video recorder
- articulating arm
- medical cart

User Qualifications

WARNING: **This manual does not explain or discuss clinical procedures. Therefore, this imaging system must only be used by, or under the supervision of, a licensed physician. The operator must be trained in clinical procedures.**

General System Safety

Electrical Safety – General

WARNING: **To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.**

CAUTION: Do not use or store liquids around the VPI. If liquid enters the VPI, immediately turn system off and unplug it from the power outlet.

Do not insert objects into the ventilation holes of the VPI enclosure.

Do not connect or disconnect the SPY-PHI camera cable while the VPI is powered on.

Electrical Safety – Power

WARNING: **Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked 'hospital only' or 'hospital grade'.**

Connect the imaging system components only to approved medical systems or to systems that are powered from approved isolation transformers.

Do not use the imaging system if the power cord or plug is damaged or modified in any way.

Do not remove or override the ground connection on the power cords.

CAUTION: Unplug power cords by grasping the plug. Do not unplug power cords by pulling on the cable.

To isolate the equipment from supply mains, set the mains power switch on the rear panel of the VPI to off.

Light Safety- Illumination

WARNING: **Avoid looking at light emitted directly from the SPY-PHI imager. Table 13 in Appendix C contains specifications for the NIR radiation emitted in Fluorescence mode.**

Use of controls or performance of procedures other than those specified herein may result in hazardous radiation exposure.

A laser aperture label is located on the top surface of the imager as prescribed by applicable standards (see Figure 2).

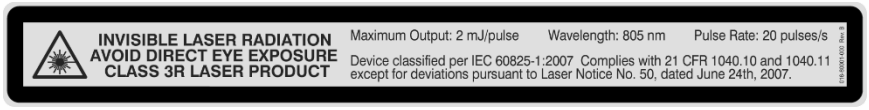
Figure 2: Laser aperture on the SPY-PHI imager

Note: The SPY-PHI System is a laser device. Always comply with local regulations and consult with a local laser safety officer for safe use of laser devices, particularly, when using the SPY-PHI System for imaging a patient's facial area.

Warning Labels on the SPY Portable Handheld Imaging System

The SPY-PHI imager and system VPI[1] are labeled with the following laser safety warning labels in accordance with applicable standards:

Table 1: Images and Locations of Laser Warning Labels

Label	Location
	Top of SPY-PHI imager, see Figure 2.
	VPI, front panel, see Figure 9.

[1]The Video Processor/Illuminator used with the SPY-PHI imager is a component that is shared with the PINPOINT Endoscopic Fluorescence Imaging System.

Electromagnetic Compatibility (EMC) and Environmental Safety

The user is expected to follow all precautions and warnings outlined in this manual, and adhere to the electromagnetic compatibility (EMC) limits set out in the electromagnetic compatibility guidance document. Failure to do so may compromise the system's ability to maintain basic safety under abnormal EMC conditions.

The imaging system has been certified for compliance with international standards for EMC and is suitable for use in professional healthcare environments. The imaging system generates radio frequency energy and should be installed and used in accordance with these instructions in order to minimize the possibility of interference with other electro-medical equipment. However, there is no guarantee that interference will not occur in any particular installation.

If in turning the imaging system off and on, the SPY Portable Handheld Imaging System is shown to cause harmful interference to other electro-medical equipment, the user is encouraged to try to correct the interference by:

- Reorienting or relocating the imaging system or the equipment receiving the interference
- Increasing the separation between the imaging system and the equipment receiving the interference
- Connecting the imaging system to an outlet on a different circuit from the one to which the other equipment is connected

WARNING: **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify normal operation.**

WARNING: **Use of accessories, transducers and cables other than those specified or provided by NOVADAQ could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**

Note: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). It is not intended for use in a residential environment (for which CISPR 11 Class B is required).

For further information and guidance refer to “Guidance and Manufacturer’s Declaration – Electromagnetic Compatibility” included with the SPY-PHI System.

If the imaging system becomes unresponsive and does not resume normal function after turning off and back on, stop using the imaging system, and contact Stryker Customer Support.

Damaged or Malfunctioning Equipment

WARNING: **Do not use the SPY-PHI imager if any part of the system is damaged or does not function properly. Failure to follow this warning may lead to injury.**

In the event of a drop or impact, inspect the SPY-PHI imager and do not use it:

- **If there is any visible damage to the imager**
- **If there is evidence of sharp edges or exposed pinch points**
- **If there is concern that the impact might have damaged the imager**

If any of the above events occur, please contact Stryker Customer Support.

Cleaning and Disinfecting

WARNING: **Follow the instructions in Chapter 8 to clean and disinfect the SPY-PHI System components and accessories.**

Keep the light guide cable connector clean at all times. Contaminants on the light guide cable connector may cause overheating.

Repair and Modification

WARNING: **The imaging system does not contain any user-serviceable parts and does not require any preventive inspection or maintenance. Do not disassemble, modify or attempt to repair it. Patient or user injury and/or instrument damage can result. Refer all servicing to a qualified NOVADAQ service representative.**

If an irregularity appears to be minor, refer to Appendix A -Troubleshooting. If the irregularity cannot be resolved, contact Stryker Customer Support.

In the case that any component of the SPY-PHI System needs to be returned to NOVADAQ please adhere to the following:

- **Clean and disinfect the component thoroughly prior to returning for repair.**
- **Ideally, return the component in its original packaging. If this is not possible, package the part sufficiently to secure it for transport. NOVADAQ is not liable for damage resulting from improper shipping.**

Disposal of SPY-PHI System Components

The SPY-PHI System components should be disposed of in compliance with local, regional, and national regulations, or returned to NOVADAQ for disposal.

Symbols and Indicator Lights

The following section describes symbols and indicators that appear on the SPY-PHI imager and VPI.

Table 2: Symbols on the SPY-PHI Imager

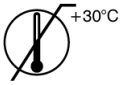
Symbol	Indicates	Location
	Turn laser on/off (green button)	Button pad
A	Display Mode (grey button)	Button pad
B	Tools menu button (grey button)	Button pad
	Focus (upper blue button)	Button pad
	Focus (lower blue button)	Button pad
	Laser Aperture indicator	Top of imager
	Manufactured by	Device ID label, bottom of imager
	Do not immerse in any liquid.	Device ID label, bottom of imager
	Maximum temperature: +30°C	Device ID label, bottom of imager
	Refer to instruction manual/booklet	Device ID label, bottom of imager
REF	Reference or Model name/number	Device ID label, bottom of imager
SN	Serial number	Device ID label, bottom of imager
CE 0197	CE Marking declaring EU Directive compliance	Device ID label, bottom of imager

Table 3: Symbols on the Video Processor / Illuminator (VPI) and on System Labeling

Symbol	Indicates	Location
	Power On	Rear panel, power switch
	Power Off	Rear panel, power switch
	Stand-by mode	Front panel
	Laser on	Front panel
	Type CF patient-applied part*	Front panel
	Illumination on/off	Front panel
	White balance	Front panel
	Menu	Front panel
	Down (part of menu feature)	Front panel
	Up (part of menu feature)	Front panel
	Right (part of menu feature)	Front panel
	Camera socket	Front panel
	Refer to instruction manual/booklet	Rear panel
	Caution	Rear panel

*applicable to PINPOINT camera and NOVADAQ laparoscope

Symbol	Indicates	Location
	General Warning	Accompanying Documentation
	Laser Warning	Front panel
	Manufacturer	Rear panel
	Date of manufacture	Rear panel
REF	Reference or Model name/number	Accessory Packaging
SN	Serial number	Accessory Packaging
LOT	Lot number/Date code	Accessory Packaging
Made in Germany	Made in Germany	Accessory Packaging
Made in Canada	Made in Canada	Accessory Packaging
Made in USA	Made in USA	Accessory Packaging
Made in Taiwan	Made in Taiwan	Accessory Packaging
	Do not reuse - single use only	Accessory Packaging
	Use-by Date	Accessory Packaging
	Fuse	Rear panel
	Do not dispose in general waste	Rear panel

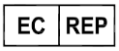
Symbol	Indicates	Location
	Equipotential symbol	Rear panel
	SGS Q-mark	Rear panel
	CE Marking declaring EU Directive compliance	Rear panel
	Authorized European (EC) Representative	Accompanying Documentation
	Medical Device	Accompanying Documentation

Table 4: Onscreen Symbols in the Software Interface

Symbol	Indicates	Description
	Standby mode	See Chapter 6
	White light mode	See Chapter 6
	Illumination failed error	Appendix A
	Overlay display mode	See Chapter 6
	SPY display mode	See Chapter 6
	CSF display mode	See Chapter 6
	White balance in progress	See Chapter 7

Symbol	Indicates	Description
	White balance completed	See Chapter 7
	White balance failed	See Chapter 7
	Video recording in progress	See Chapter 7
	Video recording paused	See Chapter 7
	Video recording in progress (TEAC UR-4MD recorder)	See Chapter 6
	Video recording paused (TEAC UR-4MD recorder)	See Chapter 6
	Video recording stopped (TEAC UR-4MD recorder)	See Chapter 6
	Display image currently rotated 180^0	See Chapter 7
	SPY-PHI imager error	See Appendix A
	Language setting	See Chapter 7
	Button action- Focus adjustment	See Chapter 6
	Button action- Focus limit reached	See Chapter 6

Symbol	Indicates	Description
	Button action- Screenshot captured	See Chapter 7
	Tools menu – Image flip	See Chapter 7
	Tools menu – Video recording	See Chapter 7
	Tools menu – Video recording device unavailable	See Chapter 7
	Tools menu – Screenshot	See Chapter 7
	Tools menu – Screenshot device unavailable	See Chapter 7
	Tools menu – White balance	See Chapter 7
	Tools menu – VPI Options menu	See Chapter 7

Indicator Lights on the Video Processor / Illuminator (VPI)

Table 5: Indicator Lights on the VPI

Indicator	Location	Color	Indicates
Laser indicator[1]	Top left side of front panel	Blue	Laser on
Power indicator	Above “Power” button	Amber	Off
		Green	On
Illumination indicator	Above “Illumination” button	White	Illumination on
	Below “Illumination” button	Green	Down

Indicator	Location	Color	Indicates
	(part of menu feature)	Green	Up
	Below “White Balance” button	Green	Select

[1] A laser-on indicator light is also located on the SPY-PHI imager.

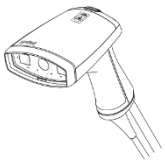
Chapter 2 Unpacking and Setting up the System

SPY-PHI System Parts

WARNING: **If any items are missing or damaged, do not use the SPY-PHI System and contact a Stryker service representative.**

Use Table 6 to identify and inspect all SPY-PHI System parts before setting up the system.

Table 6: List of SPY-PHI System Parts

Item	Illustration
Video Processor / Illuminator (VPI) Model PC9001*	
SPY Portable Handheld Imager (SPY-PHI) Model HH9030	
Power cord	
HD-SDI cable	
DVI cable	
SPY Portable Handheld Imaging System Operator's Manual	
Guidance & Manufacturer's Declaration – Electromagnetic Compatibility	

*The Video Processor/Illuminator used with the SPY-PHI System is a component that is shared with the PINPOINT Endoscopic Fluorescence Imaging System.

Setting Up the SPY-PHI System

WARNING: **The SPY-PHI System has been certified for compliance with international standards for electromagnetic compatibility (EMC).**

The imaging system generates radio frequency energy and should be installed and used in accordance with the instructions in order to minimize the possibility of interference with other electro-medical equipment. However, there is no guarantee that interference will not occur in any particular installation.

Please see Table 8 in Appendix A if the imaging system is suspected of causing interference with other electro-medical equipment, despite being installed according to the instructions.

Selecting an Appropriate System Installation Location

1. Select a location in which to use the imaging system that is within 3 m access of an appropriate power outlet.

WARNING: **Read and follow the information in "Electrical Safety – Power" in Chapter 1 and only connect the VPI to a "Hospital Only" or "Hospital Grade" power outlet.**

2. Place the VPI on a cart, on a shelf supported by a ceiling-mounted boom, or on a suitable table.
3. Select a location in which to use the imaging system that is within 3 m access of a medical-grade HD color video monitor.

CAUTION: Ensure that the selected location provides a minimum 5 cm (2 inch) gap around the VPI cooling vents to allow for required ventilation.

Do not place heavy objects directly on top of the VPI.

Connecting to Ancillary Video Devices (Optional)

WARNING: **All electro-medical devices connected to the imaging system must be certified medical-grade and all interconnected configurations shall comply with the IEC 60601-1 system standard. Failure to comply with this standard may result in unsafe operation of the system and/or injury to the patient or operator.**

The VPI may be interconnected to other medical-grade video devices such as:

- Video recording or display systems
- Digital image-capture stations for hospital PAC systems
- Stand-alone image management systems

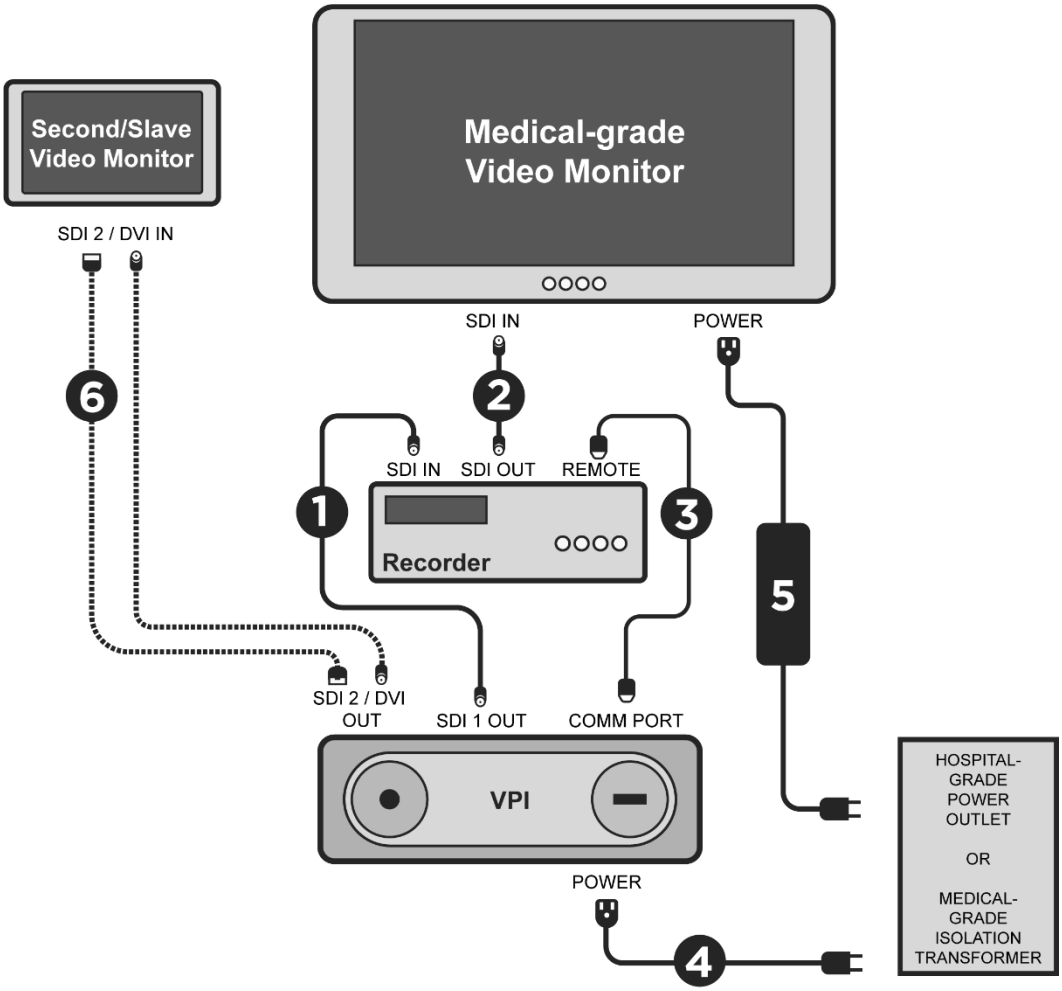
See **Table 10** in **Appendix C** for specifications of the video output signals and to ensure compatibility of the selected video devices.

Connect the Video Processor / Illuminator (VPI)

Connect the VPI cables and components as shown in Figure 3.

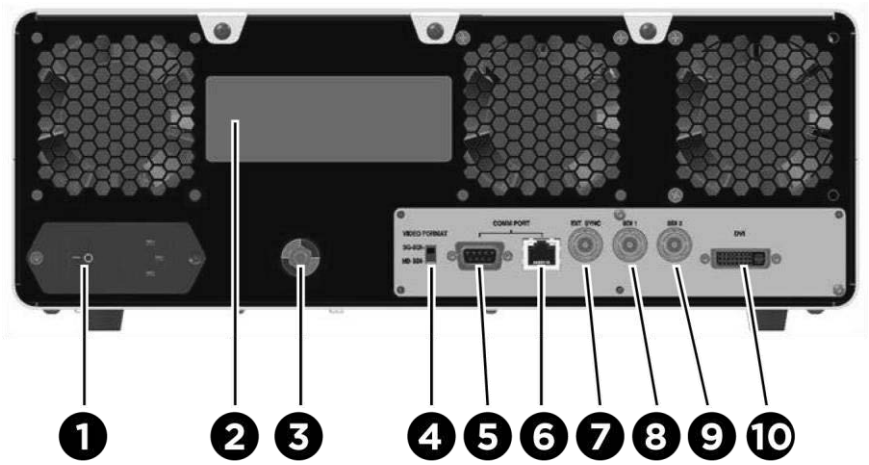
The connections on the rear VPI panel are described in Figure 4.

Figure 3: SPY-PHI system wiring diagram showing connection to video monitors and recorder



1. SDI co-axial cable
2. SDI co-axial cable
3. RS232 serial cable
4. VPI power cord
5. Medical video monitor power cord
6. OPTIONAL Second video monitor cable (SDI or DVI)

Figure 4: Video Processor / Illuminator rear panel showing connectors and ports



1.	Main power switch	6	RJ45 port (Communication port)
2.	Device identification label	7	Ext. sync
3.	Potential equalization conductor	8.	SDI 1 video out
4.	Video format switch	9.	SDI 2 video out
5.	RS232 port (Communication port)	10.	DVI video out

CAUTION: The communication ports on the rear panel are intended for use by NOVADAQ service representatives only.

Note: Normal use of the system does not require the user to connect to the potential equalization conductor. The potential equalization conductor can be used to equalize across multiple devices or to provide a redundant ground. The potential equalization conductor is only to be used by qualified personnel. (IEC 60601-1 Ed. 3.2 en:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance CONSOLIDATED EDITION, § 8.6.7)

Connecting to an Medical-grade Video Monitor

A medical-grade color video monitor can be connected via the SDI and DVI connectors on the rear panel of the VPI (Figure 4).

See **Table 10** in **Appendix C** for specifications of the video output signals to ensure compatibility of the selected video monitor. Consult the operator instructions provided by the manufacturer of the video monitor for details on operation and adjustment of the video monitor.

Connecting to a Medical Recorder

There are several NOVADAQ-certified recorders for use with the SPY Portable Handheld Imaging System. Availability varies depending on region.

Note: In order for the onscreen recorder controls and status to be visible to the operator during normal operation of the SPY-PHI System, the VPI SDI 1 video output must be connected to the SDI-IN connector on the recorder. The SDI-OUT connector on the recorder should be connected to the monitor. For more information, see Figure 3.

For more information about setting up the recorder, please refer to **Chapter 6**.

Connecting to Ancillary Video Devices (Optional)

WARNING: **All electro-medical devices connected to the imaging system must be certified medical-grade and all interconnected configurations shall comply with the IEC 60601-1 system standard. Failure to comply with this standard may result in unsafe operation of the system and/or injury to the patient or operator.**

The VPI may be interconnected to other medical-grade video devices such as:

- Video recording or display systems
- Digital image-capture stations for hospital PAC systems
- Stand-alone image management systems

See **Table 10** in **Appendix C** for specifications of the video output signals and to ensure compatibility of the selected video devices.

Selecting the Appropriate Video Output Format

Use the video-format switch on the rear panel of the VPI to select one of the following video output formats:

- HD-SDI 1080i 59.94
- 3G-SDI 1080p 59.94

Note: Ensure that the video-format switch on the VPI is in the correct position for the recorder that is being used.

The correct output formats are as follows:

- Stryker SDC3™ HD Information Management System: 3G-SDI
- SONY 1000MD recorder: HD-SDI
- SONY 3300MT recorder: 3G-SDI
- TEAC UR-4MD recorder: HD-SDI or 3G-SDI
- MediCapture USB300 recorder: HD-SDI or 3G-SDI

Connecting the SPY-PHI Imager to the VPI

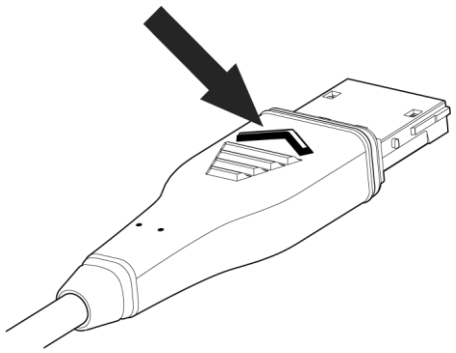
WARNING: **The following procedures must be performed using proper sterile technique if they are being performed in preparation for surgery.**

CAUTION: The SPY-PHI imager is a precision medical instrument; handle with great care.

To connect SPY-PHI to the VPI:

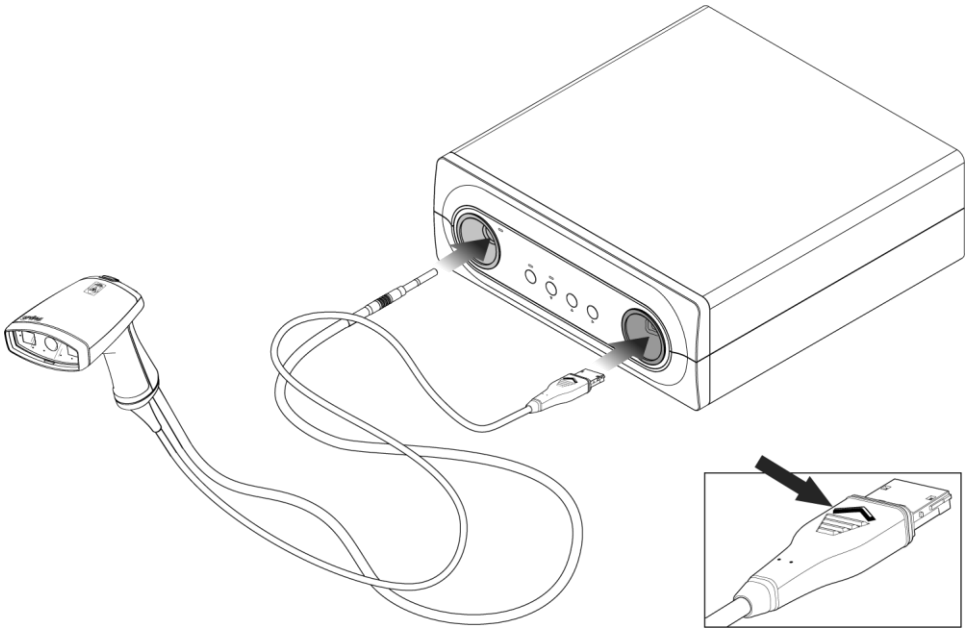
1. Remove the camera cable cap and orient the camera cable connector with the raised arrow facing up (see Figure 5).

Figure 5: Raised arrow on top of the connector facing up



2. Insert the camera cable into the camera port on the VPI (see Figure 6).

Figure 6: Connecting the SPY-PHI imager to the VPI



3. Fully insert the end of the SPY-PHI imager light guide cable into the light guide port on the VPI and confirm that it is fully engaged (see Figure 6).

WARNING: Avoid looking at light emitted directly from the SPY-PHI imager.

Chapter 3 Handling, Preparation, and Administration of ICG

About Indocyanine Green (ICG) Imaging Agent

ICG imaging agent is a sterile, water soluble tricarbocyanine dye with a peak spectral absorption at 800-810 nm in blood plasma or blood. ICG contains not more than 5.0% sodium iodide. ICG is to be administered intravenously.

The Sterile Water for Injection, pH of 5.0 to 7.0, provided with the ICG is used to reconstitute the ICG.

Instructions for preparation, handling and administration of ICG imaging agent are provided in this chapter.

Note: NOVADAQ does not distribute ICG – ICG imaging agent should be acquired through normal hospital channels.

Regulation of ICG varies by country. In certain countries, ICG is not registered for use as a pharmaceutical product. Contact your local distributor for more information on the availability of ICG at your location.

ICG Safety

WARNING: **Refer to the ICG Package Insert prior to use.**

Clinical Pharmacology

Following intravenous injection, ICG is rapidly bound to plasma proteins, primarily lipoproteins with a lesser and variable binding to albumin (2-30% of total). Simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebro-spinal uptake of the ICG. ICG is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. ICG does not undergo significant enterohepatic recirculation. ICG has a half-life of 2.5-3.0 minutes.

ICG Contraindications

ICG contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides or iodinated imaging agents due to a risk of anaphylaxis.

The Imaging System should not be used for NIR imaging during surgical procedures with patients who are known to be sensitive to iodides or iodinated imaging agents.

ICG Warnings

WARNING: **Anaphylactic deaths have been reported following ICG administration during cardiac catheterization.**

Each vial of ICG and accompanying Sterile Water for Injection are intended for use with only 1 patient and within 6 hours of reconstitution. Discard any unused reconstituted ICG after each surgery is completed or 6 hours have lapsed since reconstitution. If a precipitate is present upon reconstitution, do not use and discard the solution.

ICG powder may cling to the vial or lump together because it is freeze-dried in the vials. This is not due to the presence of water - the moisture content is carefully controlled. The ICG is suitable for use.

The outside packaging of needles, syringes, stopcock, ICG vials, and the Sterile Water for Injection are NOT sterile. The contents of the ICG vial are sterile and must be handled aseptically to maintain the sterile field during surgery.

Radioactive iodine uptake studies should not be performed for at least a week following the use of ICG for injection.

Pregnancy Category C: Animal Reproduction studies have not been conducted with ICG. It is not known whether ICG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ICG should be given to a pregnant woman only if clearly indicated.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ICG is administered to a nursing woman.

Only use ICG at indicated doses and concentrations as defined in the SPY Portable Handheld Imaging System Operator’s Manual.

Do not use needles, syringes, stopcocks, ICG vials and Sterile Water for Injection that appear to have packaging or seals that are compromised in any way.

ICG is generally injected through a shared intravenous line with no reported difficulties or unexpected results to date. However, drug / drug interactions have not been identified in the ICG Package Insert.

ICG Adverse Reactions

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides. If such reactions occur, immediate treatment with the appropriate agents, for example, epinephrine, antihistamines, and corticosteroids should be administered. Resuscitative measures may also be required.

General ICG Preparation Instructions

WARNING: **Do not use any ICG that has been reconstituted for more than 6 hours.**

Discard any unused reconstituted ICG after each surgery is completed.

The ICG imaging agent can be reconstituted and prepared for injection either at the beginning of, or during the surgery, depending on the preference of the surgical team. Prepare ICG for administration as follows:

1. Remove one (1) 25 mg vial of ICG and one (1) 10 ml vial of Sterile Water for Injection from the kit.
2. Draw up the 10 ml Sterile Water for Injection into a 10 ml syringe.
3. Remove the flip off cap on the ICG vial (25 mg) and inject the 10 ml of Sterile Water for Injection through the stopper into the ICG vial.
4. Shake the ICG vial gently to mix.

Note: This yields a 2.5 mg/ml solution of reconstituted ICG.

5. Mix the contents of the ICG vial thoroughly and inspect the reconstituted vial for precipitation. If precipitation is noted, continue to gently shake until all ICG is dissolved in solution.

WARNING: **If precipitation persists, do not use the mixture. Discard the reconstituted vial and prepare a new vial, as described above.**

WARNING: **The total dose of ICG injected should be kept below 2 mg/kg of patient body weight.**

ICG Administration via Central or Peripheral Venous Line

Supplies Required for each Imaging Sequence

- 10 ml reconstituted ICG solution
- Sterile normal saline for injection
- 3 ml syringe
- 10 ml syringe
- 3-way stopcock

Dosage

For recommended dosage per procedure, see Table 7.

Note: Dosing per procedure will vary based on the procedure and is determined at the discretion of the imaging surgeon.

Table 7: Recommended ICG Dosage for Perfusion Assessment per Procedure

Recommended dosage per procedure for indicated uses with ICG concentration of 2.5 mg/ml	
Procedure	Dosage
Plastic, Reconstructive, and Micro-surgery	For most imaging sequences: 5 mg (2 ml ICG solution) For acquiring images through the patient's skin: 10 mg (4 ml ICG solution)
Gastrointestinal surgery	5 mg (2 ml ICG solution)

Preparation for ICG Administration

1. Prior to the NIR imaging procedure, withdraw the desired dosage of ICG solution for each planned imaging sequence into separate single use 3 ml syringes.
2. With a single use 10 ml syringe, withdraw 10 ml of sterile saline.

ICG Administration

1. Switch to Fluorescence mode using the Illumination button on the SPY-PHI imager.
2. ICG administration is to be performed via a central or peripheral venous line. Use a three-way stopcock attached to an injection port on the infusion line. Attach one prepared 3 ml syringe of ICG solution and one prepared 10 ml syringe of saline solution.
3. Inject the prepared 2.5 mg/ml ICG solution into the line as a tight bolus.
4. Immediately switch access on the stopcock to the syringe containing saline and briskly flush the ICG bolus through the line with 10 ml of sterile saline.

Timing of ICG Administration

A fluorescence response should be visible in blood vessels visualized with the SPY-PHI System within 5 to 15 seconds after the injection.

Disposal of Consumables and ICG

Consumables should be disposed of in compliance with local, regional, and national regulations.

Single-use or consumable components and accessories such as prepared or partially used ICG should be disposed of in compliance with regulations for the disposal of such items.

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Chapter 4 Draping the SPY-PHI Imager

WARNING: **Proper sterile technique must be used when preparing the SPY-PHI imager for surgical procedures. The following components are not sterile and should not be handled by a sterile operator:**

- **Video Processor / Illuminator (VPI)**
- **Undraped SPY-PHI imager and cables.**

WARNING: **Use only the approved drape model. Other drapes may result in poor imaging performance.**

WARNING: **The outside of the pouch containing the drape is NOT sterile.**

WARNING: **Do not use the drape if the seals on the pouch appear compromised.**

WARNING: **The drape is supplied sterile (sterilized using ethylene oxide) and must be handled aseptically to maintain sterility.**

WARNING: **The drape is supplied for single-patient use only. DO NOT RE-STERILIZE. DO NOT RE-USE.**

WARNING: **If the drape becomes compromised during application to the SPY-PHI imager or during the procedure, remove the imager from the sterile field, remove the compromised drape, and replace with a new drape as per the draping instructions provided in this Operator's Manual.**

CAUTION: The drape is not intended to contact the patient. Do not contact the patient with the draped SPY-PHI device**.**

Fitting the Drape

The following draping instructions must be followed:

1. **Non-sterile operator:** Open the package containing the sterile drape.

2. **Non-sterile operator:** Remove the wrapped drape from the pouch by grasping it between the folded paper insert. Do NOT touch the wrapping or the drape.

3. Sterile operator: Using proper sterile technique, take the wrapped drape from the non-sterile operator.

4. Sterile operator: Place the wrapped drape on a sterile surface.

5. Sterile operator: Unwrap the drape and place the sterile rubber bands to the side.

6. Sterile operator: Grasp the drape, locate the opening, and insert one hand.

7. Sterile operator: Using the hand inside the drape, grasp the lens by the edges and hold it firmly.

⚠ **CAUTION:** Do not hold the lens by the lens-tabs.

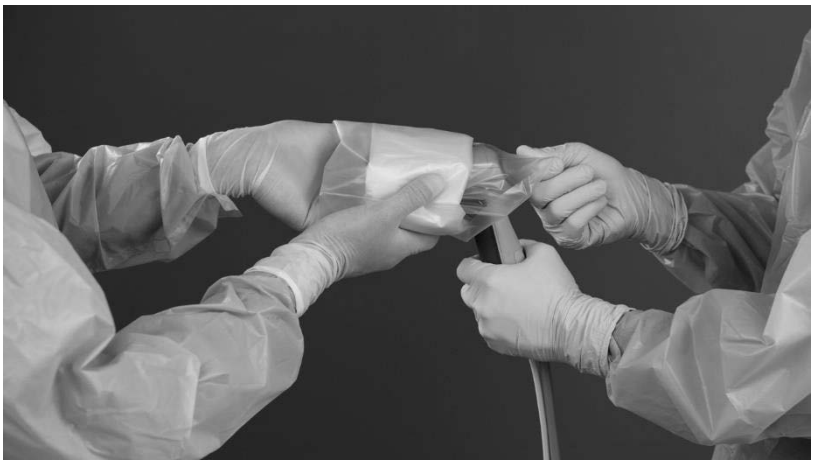
8. **Non-sterile operator:** Present the SPY-PHI imager to the sterile operator, nose first, such that the lens is inserted into the front nose-piece of the SPY-PHI.

9. **Sterile operator:** Use the hand inside the drape to press the lens firmly onto the front of the SPY-PHI imager.

10. **Sterile Operator:** With the clip engaged, push the drape over the SPY-PHI imager.

11. Non-sterile operator: Grasp the exposed end of the drape and pull the drape over the SPY-PHI imager.

CAUTION: Touch ONLY the end of the drape.



12. Non-sterile operator: Pull the drape over the entire length of the cables.

CAUTION: The sterile operator must be careful not to accidently touch the undraped cables while the drape is pulled over the SPY-PHI imager and cables.

13. Sterile operator: Wrap one sterile rubber band over the front of the imager and onto the handle to secure the drape.


14. Sterile operator: Pull the drape taut around the lens so that no part of it is obscuring the imaging field.

15. Sterile Operator: Wrap one sterile rubber band around the body of the imager.


Removing the Drape

To remove the drape:

1. Remove the sterile rubber bands.
2. Squeeze the two tabs on the drape lens together and pull the imager away from the drape lens.

3. When the clip has disengaged, carefully remove the SPY-PHI imager from the drape.

Disposal of Consumables

Consumables should be disposed of in compliance with local, regional, and national regulations.

Chapter 5 Overview of SPY-PHI Components

SPY-PHI Imager Controls, Indicators, and Labels

The SPY-PHI imager is designed for single-handed operation with ergonomic controls. The size and weight of the SPY-PHI imager have been optimized to ensure user comfort during imaging.

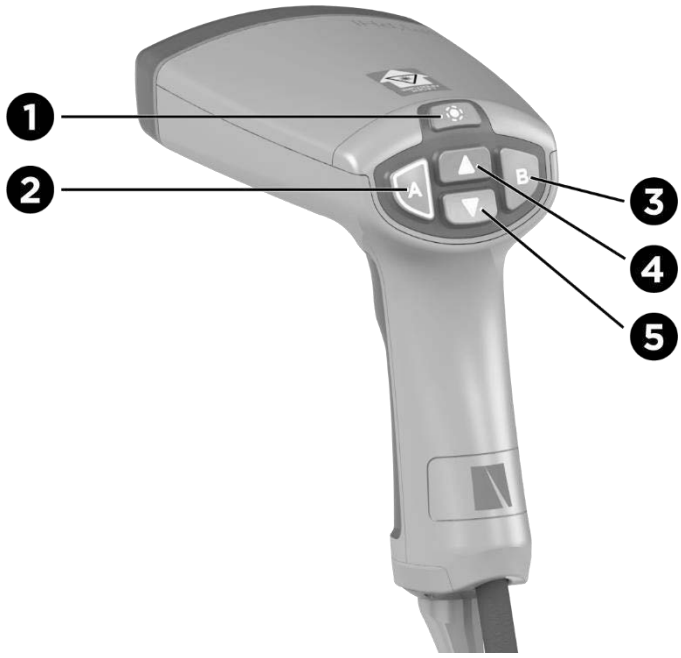
The buttons on the imager can be used to control all imaging functions, including:

- Turning illumination on and off
- Selecting display modes
- Starting and pausing video recording*
- Capturing screenshots*
- accessing the VPI Options menu

*These functions are available when a recorder is configured with the system.

The controls and indicators on the SPY-PHI imager are shown in Figure 7.

Figure 7: Overview of SPY-PHI imager controls and indicators



1. Illumination button / Laser-on indicator
2. Display mode / exit menu button
3. Menu / menu select button
4. Focus near (press and hold) / vertical menu navigation (up) button
5. Focus far (press and hold) / vertical menu navigation (down) button

The label locations on the SPY-PHI imager are shown in Figure 8.

Figure 8: Overview of label locations on the SPY-PHI imager

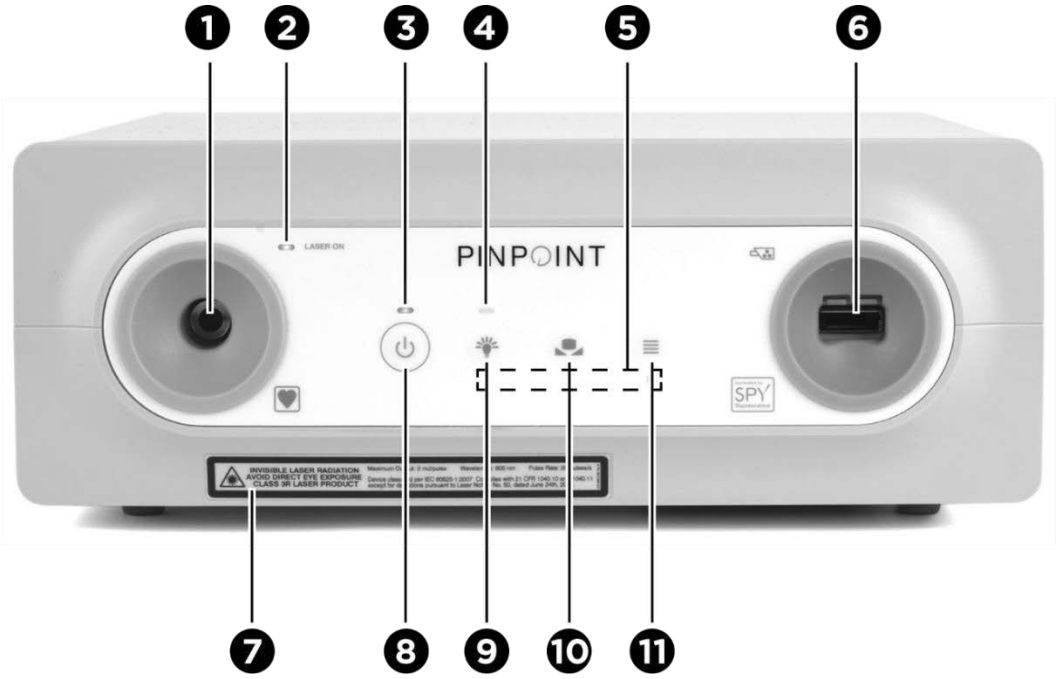
1. Laser aperture warning label
2. Device ID label
3. UDI

VPI Controls, Indicators, and Labels

The VPI provides NIR and white light illumination, video processing, user interface, and other control capabilities for the SPY-PHI system.

The front panel includes buttons for controlling the primary functions of the system, indicators for power and laser-on, and ports for the SPY-PHI light guide and camera cables (see Figure 9). The rear panel includes the imager identification labels and inferface and power connection ports (see Figure 4).

Figure 9: Overview of VPI front panel controls and indicators



1. Light guide port
2. Laser-on indicator
3. Power indicator
4. Illumination indicator
5. Menu control indicators
6. Camera port
7. Laser warning label
8. Power button
9. Illumination button
10. White balance button
11. Menu button

Chapter 6 Operating the SPY-PHI System

The primary functions of the SPY-PHI System include:

- Powering on the system into Standby mode
- Focusing the image
- Turning Fluorescence Illumination on
- Selecting fluorescence display modes
- Toggling between Fluorescence and White Light Illumination modes
- Returning to Standby mode and powering off the system

Powering on the System into Standby Mode

CAUTION: In order for it to initialize correctly, the SPY-PHI imager should be draped, and connected to the VPI, prior to powering on the system.

To power on the system:

1. Move the SPY-PHI System into an appropriate position for the clinical imaging procedure.
2. Plug the VPI power cord into an AC wall outlet or isolation transformer.

   After plugging in the power cable, the power indicator on the front of the VPI above the VPI power button should illuminate amber.

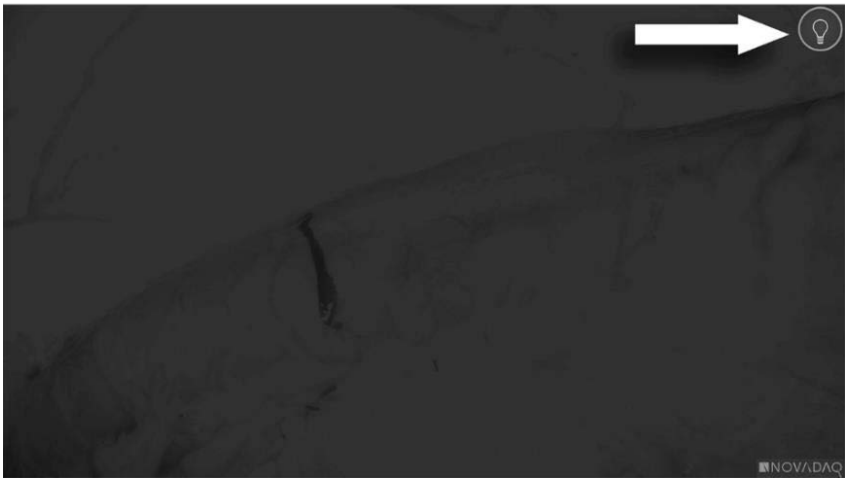
   - If the power indicator does not illuminate, check to confirm that the main power switch (on the rear panel of the VPI) is turned to the 'on' position.
   - If, after confirming that the main power switch is in the 'on' position, the indicator still does not illuminate, please consult Appendix A: Troubleshooting.
3. Connect the draped SPY-PHI imager to VPI by plugging the camera and light guide cables into the appropriate ports on the VPI front panel (see Figure 6).
4. Press the power button on the front panel of the VPI.

   The power indicator turns green and the system enters Standby mode.

   The SPY-PHI imager initializes and the Standby mode icon displays in the top-right corner of the video image (see Figure 10).

Note: In Standby mode, video display is enabled and ventilation fans are on. Illumination is not active and the video image on the display may be dark.

Figure 10: Onscreen Standby mode icon



 Standby Mode

Focusing the Image using the SPY-PHI Controls

To focus the video image during imaging:

1. Hold the SPY-PHI imager 10 to 40 cm (4 to 15 inches) from the surface or tissue to be imaged.
2. While viewing the image on the video monitor, press and hold one focus button at a time until a sharp and focused image is achieved (see Figure 11).

Figure 11: Focus adjustment buttons on the SPY-PHI imager

An animated focus adjustment icon  displays onscreen when either focus button is pressed (see Figure 12).

Figure 12: Animated onscreen focus adjustment icon

If the focus-stop icon  displays, the focus has reached the end of its adjustment range. Press the opposite focus button.

Turning On Fluorescence Imaging Mode

WARNING: **Avoid looking at light emitted directly from the SPY-PHI imager.**

In Fluorescence Imaging mode, the VPI provides near-infrared spectrum illumination through the SPY-PHI imager for viewing a fluorescence image on the system display.

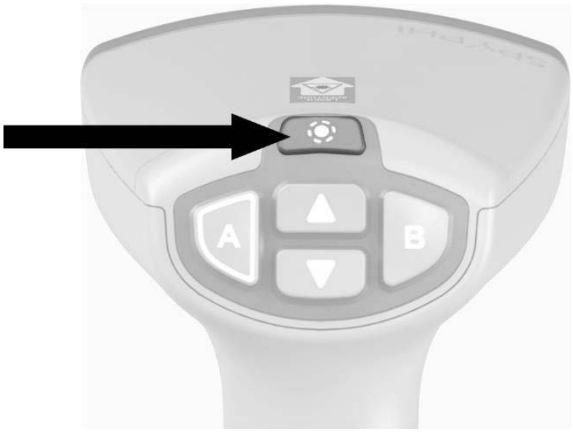
To turn on Fluorescence Imaging mode:

- Press the Illumination button  on the SPY-PHI imager (see Figure 13)

  OR

  Press the Illumination button  on the front panel of the VPI (see Figure 9).

Figure 13: Illumination button on the SPY-PHI imager



- The laser-on indicator (Illumination button) illuminates.
- On the VPI, the indicator above the Illumination button glows white and the laser-on indicator illuminates.
- The system displays the video image in the default display mode: Overlay mode.
- The Overlay mode icon  displays in the top-right corner of the video image (see Figure 14).

Figure 14: Overlay mode with displayed Fluorescence mode icon

Note: For best results, dim or turn away overhead and head-mounted surgical lights during fluorescence imaging.

Display Modes in Fluorescence Imaging Mode

In Fluorescence Imaging mode, three different display modes are available:

- Overlay mode – see Figure 15
- SPY Color-Segmented Fluorescence (CSF) mode – see Figure 16
- SPY mode – see Figure 17

Overlay Mode

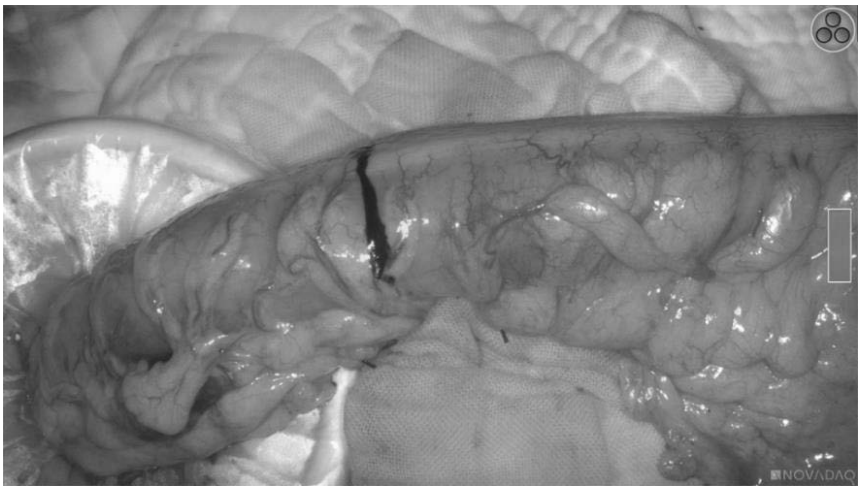
In Overlay mode, an NIR fluorescence image is superimposed in pseudo-color (green) on a white light image.

Figure 15: Overlay mode

SPY Color-Segmented Fluorescence (CSF) Mode

In SPY Color-Segmented Fluorescence (CSF) mode, a white light image is displayed in grayscale with NIR fluorescence overlaid in a color scale. Increasing fluorescence levels transition from blue to yellow to red. A color legend is provided on the right side of the screen.

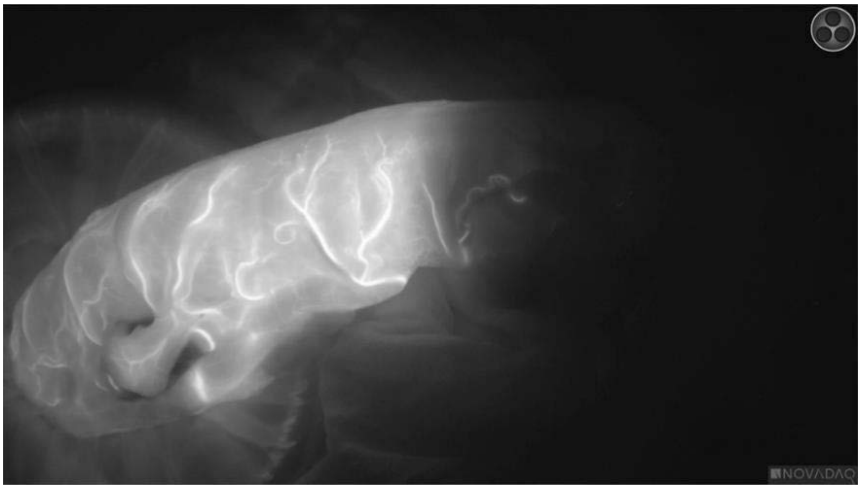
Figure 16: SPY CSF mode



SPY Mode

In SPY mode, an NIR fluorescence image is displayed in grayscale.

Figure 17: SPY mode



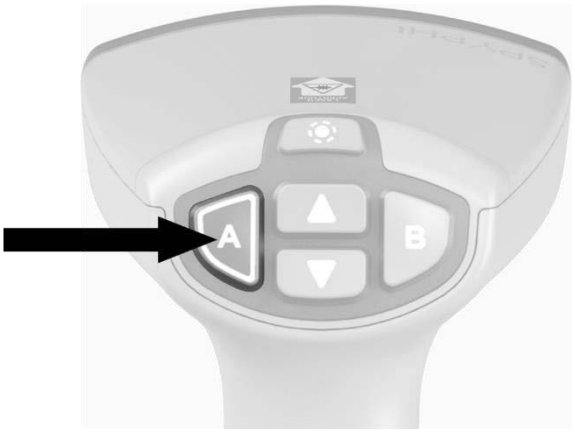
Selecting Fluorescence Display Modes

To select fluorescence display modes:

- Press the **A** button  on the SPY-PHI imager (see Figure 18).

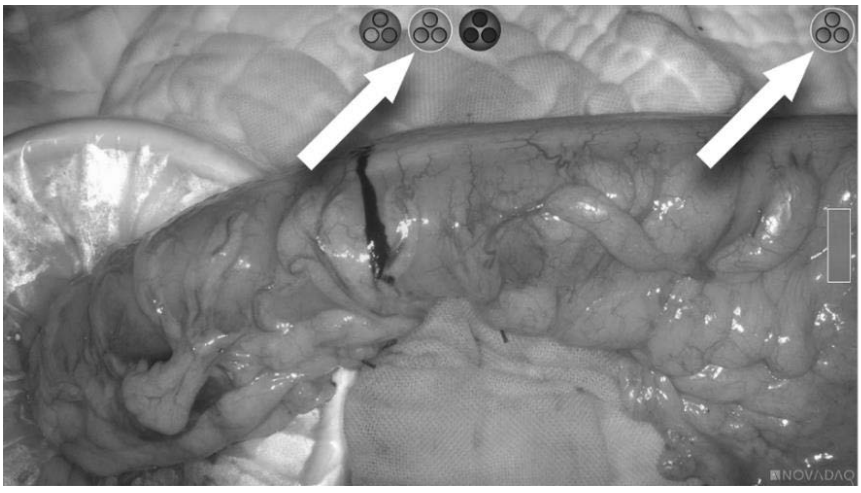
  The fluorescence display mode changes each time the button is pressed.

Figure 18: Display mode button



The mode selections are indicated by the icons at the top of the screen (see Figure 19). The selected mode is always indicated by an icon in the upper right corner.

Figure 19: CSF mode with icons showing selected display mode



Note: The list of available fluorescence display options can be configured in the VPI Options Menu (see **Appendix B**, Display options).

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Toggling between Fluorescence and White-light Imaging

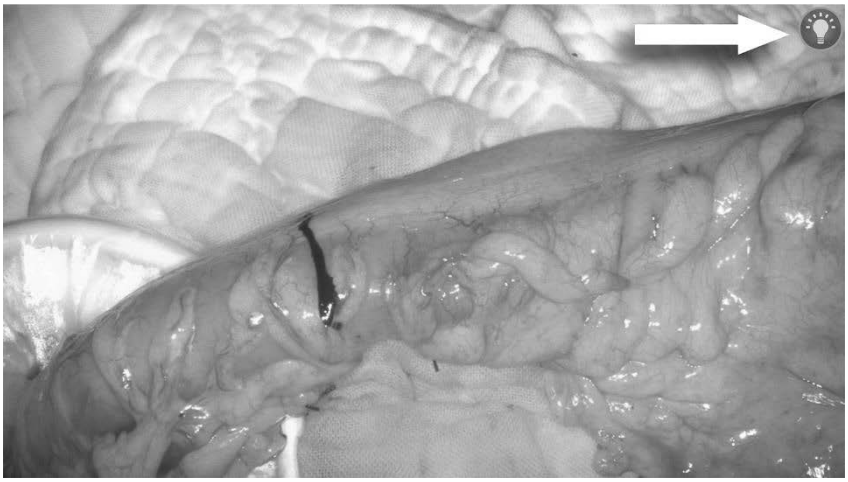
The SPY Portable Handheld Imaging System enables the user to toggle between fluorescence imaging and white-light imaging at any time during a procedure.

To toggle between Fluorescence mode and white-light mode:

- On the SPY-PHI imager, press the Illumination button  .

  The White Light mode activated icon displays in the top right corner of the screen for two seconds (see Figure 20).

Figure 20: White Light Illumination mode icon



 White-light mode

Returning to Standby Mode and Shutting down the System

To shut down the SPY-PHI system at the end of a procedure:

1. Return to Standby mode by turning off the system illumination:

- Press and hold the Illumination button on the SPY-PHI imager 

  OR

- Press the Illumination button on the front panel of the VPI  .

2. If using the Sony video recorder (PC9026), press the Stop button on the recorder to close the video case.

3. Press the power button  on the front panel of the VPI. The system shuts down and the power indicator glows amber.

 **Note:** Once the SPY-PHI System has been installed and used for the first time, the VPI can be powered off using the power button on the front panel. It is not necessary to power off the system using the main power switch on the back of the VPI.

Loss of Imaging During Use

If the SPY-PHI System fails to produce continuous imaging, switch the main power off(on the VPI rear panel) for five seconds and then switch the power on again.

The SPY-PHI imager cables should remain connected to the VPI during this time.

If the fault persists after cycling the power on and off as described, please contact Stryker Customer Support.

Chapter 7 Operating the SPY-PHI System: Secondary Functions

Secondary functions of the SPY-PHI System include:

- Flipping the display image 180˚
- Starting and pausing video recording
- Capturing screenshots
- Performing a white balance
- Accessing the VPI Options menu

Using the SPY-PHI Tools Menu

The Tools menu provides access to additional functions at any time during imaging. When accessed, the tools menu displays on the left side of the video image.

Figure 21: Overview of the Tools menu

Flip display image

Start and pause video recording

Capture screenshot

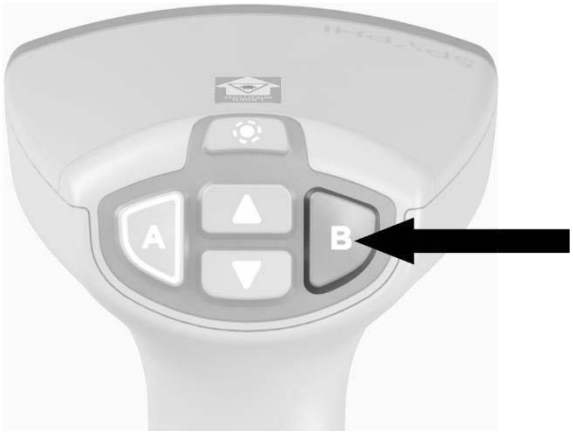
Perform white balance

Access VPI Options menu. For more information see Error! Reference source not found..

To access the Tools menu:

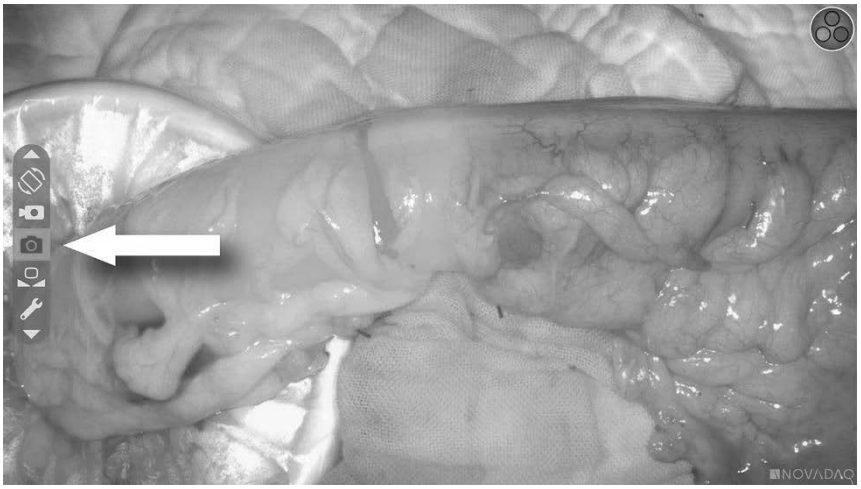
1. Press the **B** button  (see Figure 22).

Figure 22: Tools menu button



The Tools menu displays on the left side of the screen (see Figure 23).

Figure 23: Tools menu



2. Navigate the menu by pressing the focus/arrow buttons,  (up) and  (down).

3. Press  to activate the selected icon in the menu.

4. To exit the **Tools** menu and return to a live image at any time, press the A button  .

Flipping the Display Image 180°

If required, the display image can be flipped 180°. This is useful when the SPY-PHI imager is mounted on a table-mounted medical arm and reorientation of the image is desired.

To flip the image:

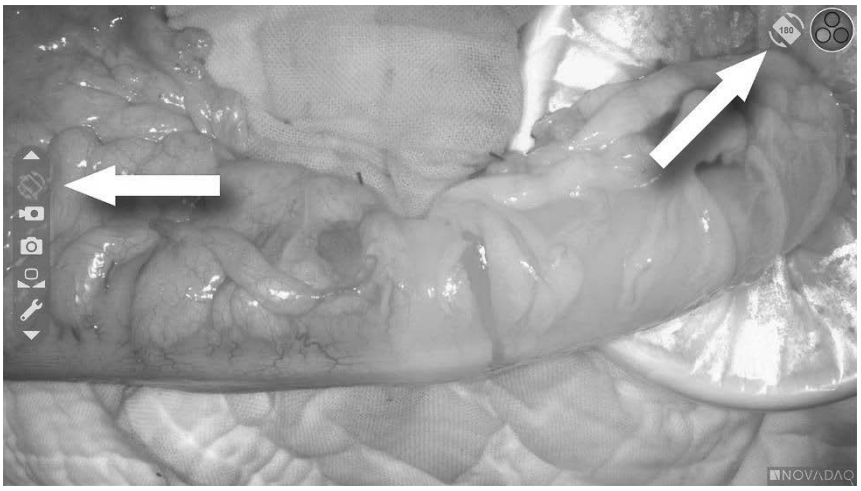
1. Open the **Tools** menu by pressing the **B** button  .

2. Select the **Flip Display Image** icon by navigating to it using the arrow buttons and pressing the **B** button  to activate (see Figure 24).

Figure 24: Flip Display Image icon in the Tools menu

The image inverts 180°. The image inverts each time the icon is toggled. An image flipped icon displays in the top-right corner of the screen as long as image flip is active (see Figure 25).

Figure 25: Onscreen image flipped icon



Recording Video

Video recording can be started and paused from the Tools menu.

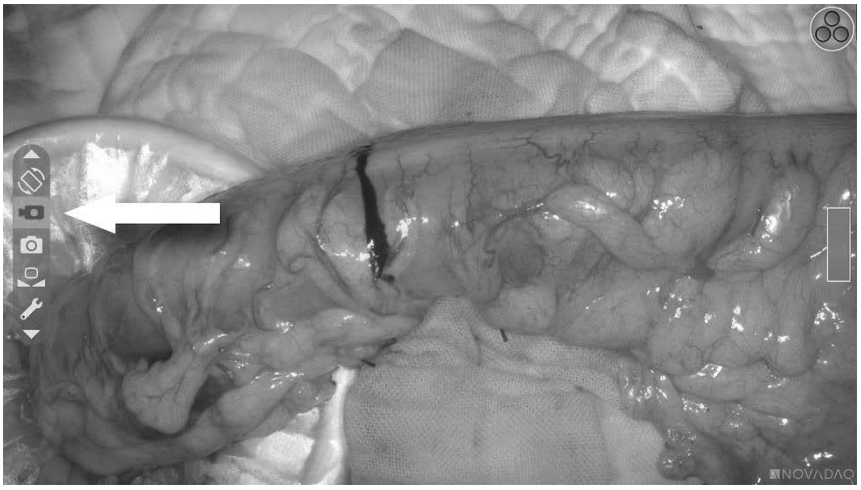
Note: When using a MediCapture recorder, control from the Tools menu is not available.

Recording Video on the Stryker SDC3™ HD Information Management System

To start and pause video recording:

1. Open the **Tools** menu by pressing the **B** button .
2. In the **Tools** menu, select the **Record** icon (see Figure 26).

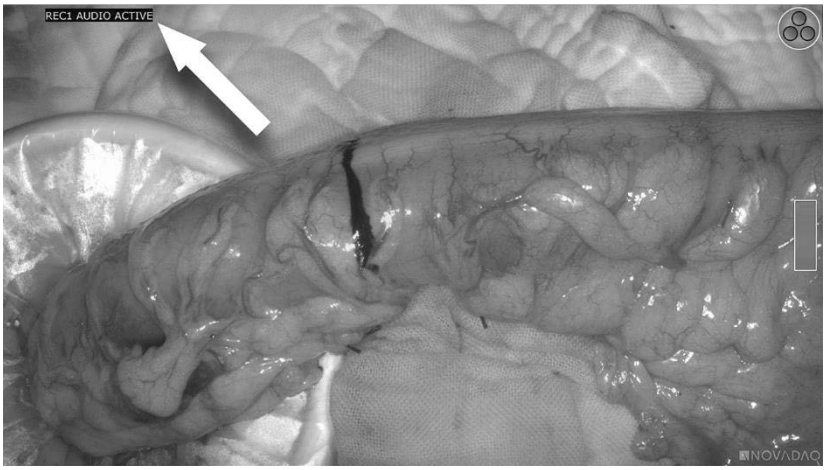
Figure 26: Recording icon in the Tools Menu



3. Press the **B** button to start and pause recording.

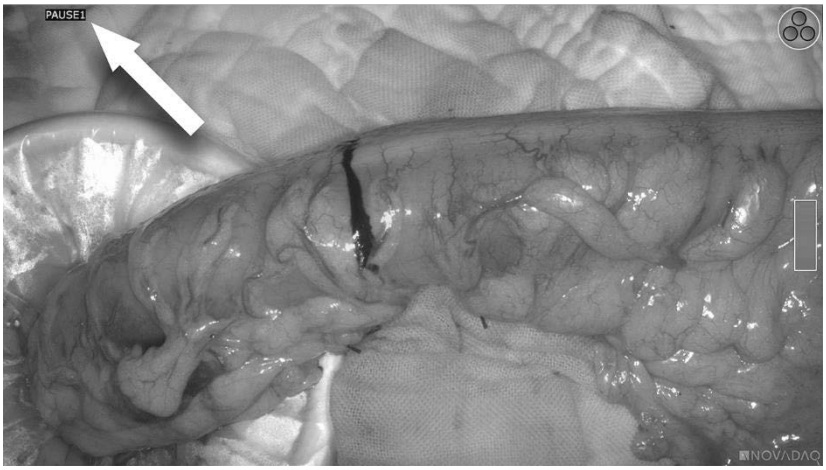
   A recording-active message displays in the top left corner of the screen during recording (see Figure 27).

Figure 27: Recording-active message



A recording-paused message displays in the top left corner of the screen when recording is paused (see Figure 28).

Figure 28: Recording-paused message



If the recorder-unavailable icon  displays, see Video Recording and Screenshot Errors on page 82.

Note: For more information about using the Stryker SDC3™ HD Information Management System, see the device operating instructions.

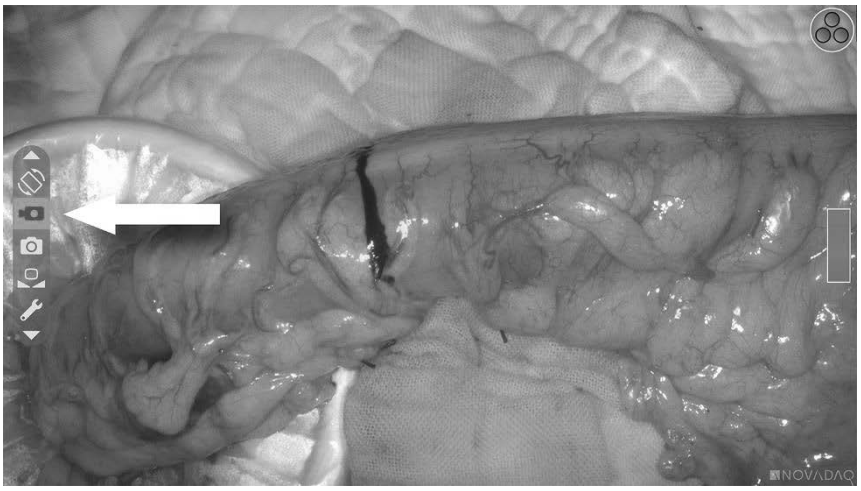
Recording Video on Sony 1000MD and Sony 3300MT Recorders

To start and pause video recording:

1. Open the **Tools** menu by pressing the **B** button 

.
2. In the **Tools** menu, select the **Record** icon (see Figure 29).

Figure 29: Recording icon in the Tools menu

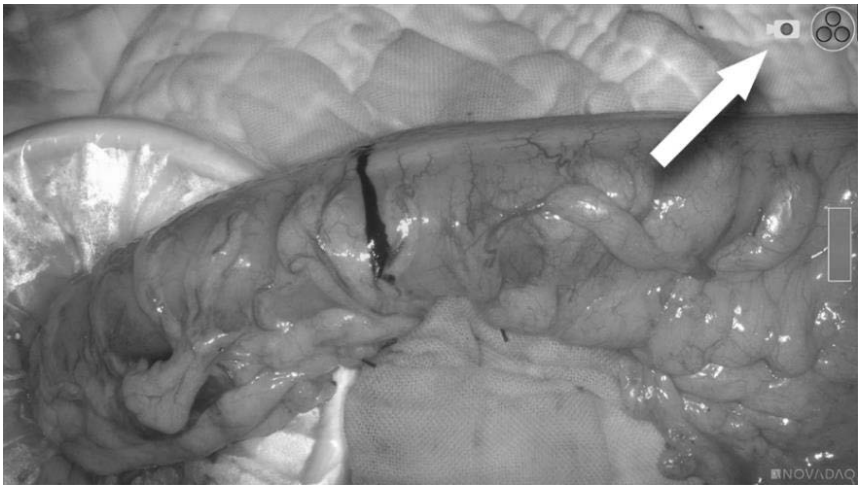


3. Press the **B** button 

to start and pause recording.

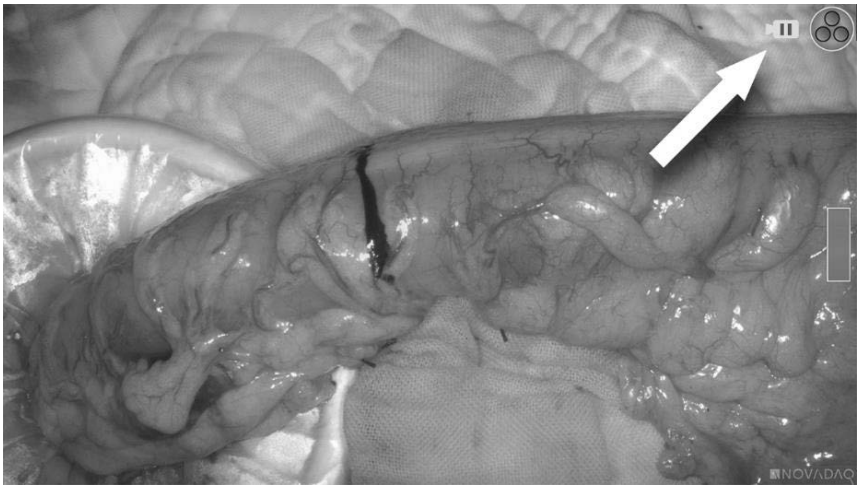
   A recording icon  displays in the top right corner of the screen during recording (see Figure 30).

Figure 30: Onscreen recording icon



   A recording-paused icon  displays in the top right corner of the screen when recording is paused (see Figure 31).

Figure 31: Onscreen recording-paused icon



Note: When using the Sony recorder (PC9026), press the stop button on the recorder to stop recording and close the video case.

If the recorder-unavailable icon displays, see Video Recording and Screenshot Errors on page 82.

For more information about using Sony recorders, see the device operating instructions.

Recording Video on TEAC UR-4MD Recorders

To start and stop video recording from the Tools menu:

1. Open the **Tools** menu by pressing the **B** button .
2. In the **Tools** menu, select the **Record** icon (see Figure 29).
3. Press the the **B** button to start and stop recording.

   A recording icon displays in the top right corner of the screen during recording (see Figure 31).

   A recording-stopped icon displays in the top right corner of the screen when recording is stopped.

4. To pause video recording, press the VIDEO/PAUSE button on the front panel  of the recorder. A recording-paused icon  displays on the screen. To resume recording, press the VIDEO/PAUSE button again.
5. To enable playback, press the CLOSE button on the front panel of the recorder.

If the record icon  displays briefly and then disappears, the TEAC recorder may not be selected in the VPI Service menu. See Recorder Setup on page 76.

For more information about using the TEAC UR-4MD recorder, see the device operating instructions.

Capturing Screenshots

Screenshots can be captured from the Tools menu.

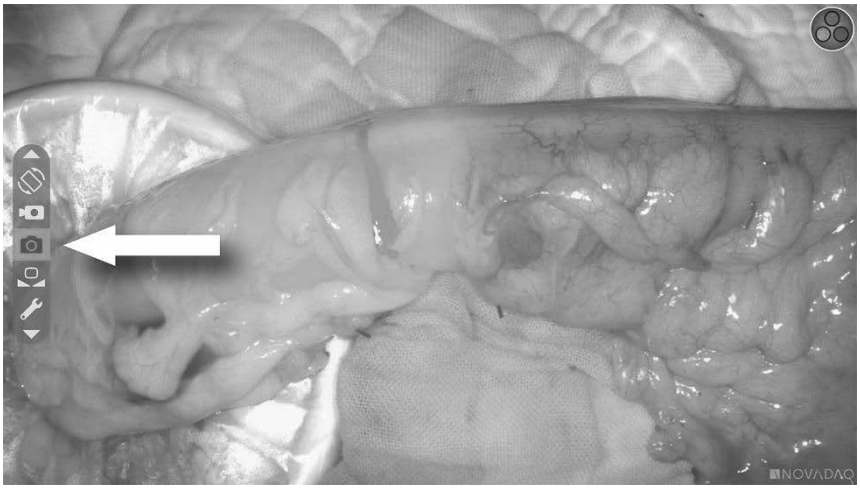
 **Note:** When using a MediCapture recorder, control from the Tools menu is not available.

Capturing Screenshots on the Stryker SDC3™ HD Information Management System

To capture a screenshot:

1. Open the **Tools** menu by pressing the **B** button  .
2. In the **Tools** menu, select the **Screenshot** icon (see Figure 32).

Figure 32: Screenshot icon in the Tools menu

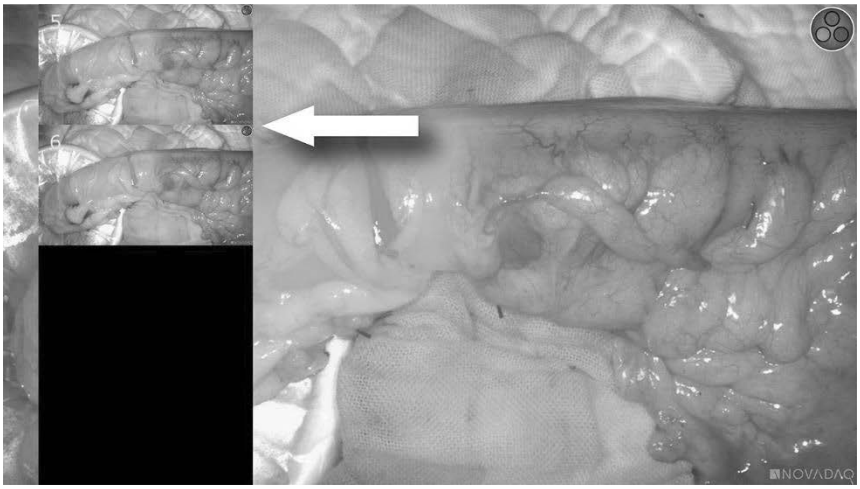


3. Press the **B** button  to capture the screenshot.

   The screenshot thumbnails momentarily display on the screen with the image number in a picture-in-picture window bar (see Figure 33).

   The screenshot will be automatically saved to the system.

Figure 33: Capturing screenshots on the Stryker SDC3 system



If the recorder-unavailable icon  displays, see Video Recording and Screenshot Errors on page 82.

Note: For more information about using the Stryker SDC3™ HD Information Management System, see the device operating instructions.

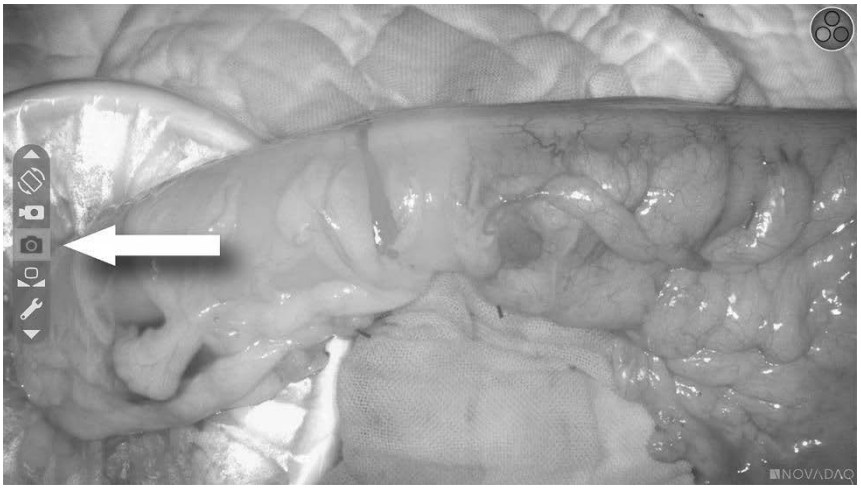
Capturing Screenshots on Sony 1000MD and Sony 3300MT Recorders

To capture a screenshot:

1. Open the **Tools** menu by pressing the **B** button 

.
2. In the **Tools** menu, select the **Screenshot** icon (see Figure 34).

Figure 34: Screenshot icon in the Tools menu



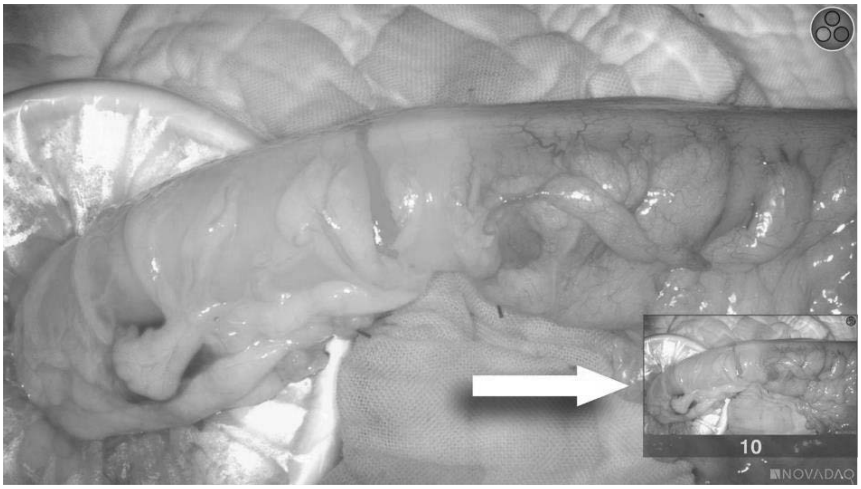
3. Press the **B** button 

to capture the screenshot.

   The screenshot icon momentarily displays in the top right corner of the screen and the captured screenshot appears briefly in a picture-in-picture window in the lower-right corner of the screen, followed by the image number (see Figure 35).

   The screenshot will be automatically saved to the system video recorder.

Figure 35: Onscreen screenshot display



If the recorder-unavailable icon displays, see Video Recording and Screenshot Errors on page 82.

Note: For more information about using Sony recorders, see the device operating instructions.

Capturing Screenshots on TEAC UR-4MD Recorders

To capture a screenshot:

1. Open the **Tools** menu by pressing the **B** button .
2. In the **Tools** menu, select the **Screenshot** icon (see Figure 34).
3. Press the **B** button to capture the screenshot.

   The screenshot-active icon momentarily displays in the top right corner of the screen and the screenshot will be automatically saved to the system video recorder.

Note: For more information about using the TEAC UR-4MD recorder, see the device operating instructions.

Performing a White Balance

The color fidelity of the color image may be affected by external sources of white light, such as surgical lights, overhead lighting, or daylight. Performing a white balance optimizes the image so that white objects appear white. Perform a white balance if the image color fidelity appears inaccurate.

A white balance can be performed using the controls on the front panel of the VPI, or using the buttons on the SPY-PHI imager.

To perform a white balance from the VPI:

1. With illumination on, hold the SPY-PHI imager approximately 10 cm (4 inches) from a matte white surface, such as gauze or white cloth.
2. Press the white balance button  on the front panel of the VPI. An icon will appear in the center of the video image for several seconds to indicate that the white balance is in progress and the result of the adjustment (see Figure 36).
3.  indicates that white balance has successfully completed. Proceed to use the SPY-PHI imager.
4.  indicates that the system has been unable to complete the white balance. Repeat the white balance procedure.

   If the white balance procedure fails a second time, turn off the system power and contact a qualified NOVADAQ service representative.

 **Note:** Illumination must be turned on to perform a white balance.

Figure 36: Onscreen white balance icons

White balance is active

White balance completed

White balance failed

To perform a white balance from the SPY-PHI imager:

1. With Illumination on, hold the SPY-PHI imager approximately 10 cm (4 inches) from a matte white surface, such as gauze or white cloth.
2. Press the **B** button  to open the Tools menu.
3. Press the bottom focus button  to navigate to white balance in the list (see Figure 37).

Figure 37: White balance in the Tools menu

4. Press the **B** button  again to execute the white balance.

Note: Illumination must be turned on to perform a white balance.

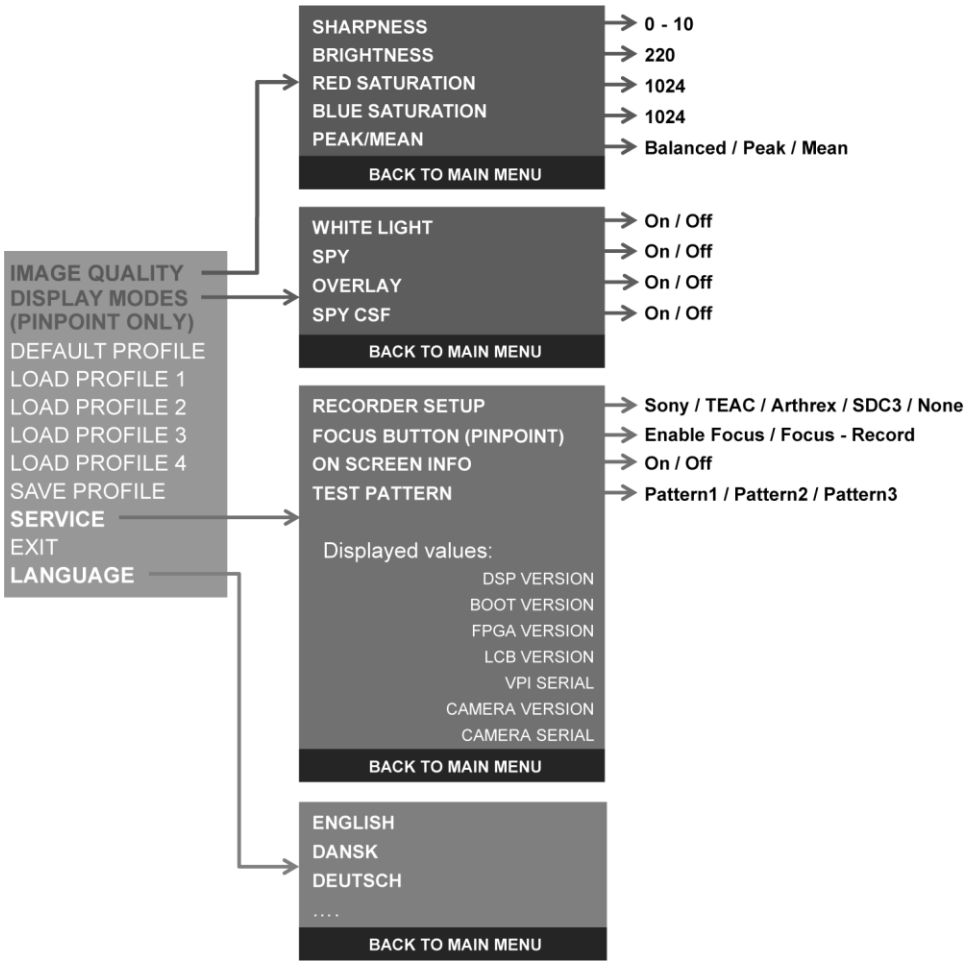
Using the VPI Options Menu

The following settings and options can be configured from the menu (see Figure 38):

- Image Quality
- Display Options (PINPOINT Camera)
- Default Profile
- Load Profile (1-4)
- Save Profile
- Service
- Exit
- Language

For more information about the VPI Options menu, refer to **Appendix B**.

Figure 38: Options and settings that are available from the VPI Options menu



Accessing the VPI Options Menu from the SPY-PHI imager

To access the VPI Options menu from the SPY-PHI imager:

1. Press the **B** button  to open the Tools menu.
2. Press the bottom focus controls  to navigate to the wrench icon  in the list and press the **B** button again to open the VPI Options menu (see Figure 39).

Figure 39: Accessing the VPI Options menu in the Tools menu

3. Press the **B** button  again to open the VPI Options menu (see Figure 40).
4. To exit the VPI Options menu and return to a live image at any time press the **A** button  .

Figure 40: Display screen showing the VPI Options menu overlying the video image

Navigating the VPI Options Menu

When the VPI Options menu is displayed on the monitor, it can be navigated using the buttons on the SPY-PHI imager.

To navigate the VPI Options menu using the SPY-PHI imager:

1. With the VPI Options menu open, navigate by pressing the focus buttons,  (up) and  (down).

2. Press **B** button  to select the highlighted options in the menu.

   The control indicators on the front panel of VPI also illuminate to reveal a down arrow (Illumination button), up arrow (White Balance button) and right arrow (Menu button). The buttons in the VPI front panel can also be used to navigate the Options menu directly from the VPI.

3. Press the **A** button  on the camera to exit the VPI Options menu.

 **Note:** If no menu selection is made within approximately 15 seconds, the VPI Options menu will automatically exit. Button **A** on the camera will also exit the menu.

Accessing and Navigating the VPI Options Menu from the VPI

To access the VPI Options menu from the VPI front panel:

1. Press the Menu button  on the VPI front panel.
2. Press the illuminated Down arrow (Illumination button), Up arrow (White Balance button) and Right arrow (Menu button) to navigate the menu (see Figure 41).
3. To return to a higher level of the menu, select the back item on the monitor, indicated by "  ", and press the Right arrow button to select.

Figure 41: Menu controls on the VPI front panel

For more information about the VPI Options menu, see **Appendix B**.

Image Quality Settings

The following image quality settings are user-configurable. For a more complete description of these settings refer to **Appendix B**.

Setting	Value	Effect
Sharpening	From 0 to 10	Larger values increase image sharpening
Brightness	From 0 to 255	Larger values increase image brightness
Red Saturation	From 0 to 1024	Larger values increase red saturation—red objects look more deeply red
Blue Saturation	From 0 to 1024	Larger values increase blue saturation—blue objects look more deeply blue
Peak / Mean	Peak Mean Balanced	Select **Peak** to set the brightness for viewing small, foreground objects that are closer to the front of the SPY-PHI imager. Select **Mean** to set the brightness by weighting the adjustment more by the mean brightness of the scene and less by the brightest points. Select **Balanced** to set the brightness by balancing the Peak and Mean settings.

To adjust an image quality setting, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. On the menu, select Image Quality.
3. Press the Up or Down arrow button to highlight the desired image setting.
4. Press the Right arrow button to select or the 

button to select.
5. Press the Up or Down arrow button to adjust the setting. The setting takes effect immediately and is visible in the image.
6. Press the Right arrow button or the 

button to deselect when done.

Display Options Settings

To select which fluorescence display modes shall be available to the user when using the system, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Display Options** and press the Right arrow button or the  button to select.
3. Press the Up or Down arrow button to choose the desired display options.
4. Press the Right arrow button or the  button to select or deselect.

User Profiles

Default Profile

To restore the Image Quality settings and Display Modes selections to the default settings, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Default Profile** and press the Right arrow button or the  button to select.

Load Profile 1-4

Load User Profiles allows the user to retrieve a previously saved set of configurable settings:

- Display Modes
- Image Quality
- On-screen Info

Up to 4 profiles are available.

To load a profile, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Load Profile "#"** and press the Right arrow button or the  button to select.

Save Profile

Save Profile allows the user to save a set of configurable settings for future use. These settings include:

- Display Modes
- Image Quality
- On-screen Info

Up to 4 profiles are available.

To save a profile, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Save Profile** and press the Right arrow button or the  button to select.
3. Press the Up or Down arrow button to choose the profile number to save to.
4. Press the Right arrow button or the  button to select the profile.

Service

Selecting **Service** in the menu will display device specific information about the device.

To view the VPI properties, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Service** and press the Right arrow button or the  button to select.

Recorder Setup

To select the recorder used with the system and enable recorder control from the Tools menu:

1. Press the Menu button on the front panel of the VPI or select the VPI Options menu in the Tools menu  .
2. Highlight **Service** and press the Right arrow button or the  button to select**.**
3. Highlight **Recorder Setup** and press the Right arrow button or the  button to select.
4. Press the Up or Down arrow button to choose a recorder from the list.
5. Press the Right arrow button or the  button to select.

On-screen Info

To turn on or turn off the image information that appears on the bottom-left corner of the screen, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Service** and press the Right arrow button or the  button to select**.**
3. Highlight **On-Screen Info** and press the Right arrow button or the  button to select.
4. Press the Up or Down arrow button to choose **On** or **Off**.
5. Press the Right arrow button or the  button to select.

Test Pattern

To display a test pattern on the screen, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .
2. Highlight **Service** and press the Right arrow button or  button to select.
3. Highlight **Test Patterns** and press the Right arrow button or the  button to select.

4. Press the Up or Down arrow button to choose the desired test pattern.

5. Press the Right arrow button or the  button to display the test pattern.

6. Press the Right arrow button or the  button to exit the test pattern when done.

Language Setting

To change the language setting, complete the following steps:

1. Press the Menu button on the front panel or select the VPI Options menu in the Tools menu  .

2. Highlight  and press the Right arrow button or the  button to select.

3. Highlight the desired language and then press the Right arrow button or the  button to select.

Chapter 8 Cleaning the SPY PHI Imager

Preparation

It is recommended that the imaging system components be cleaned after each use. Prepare components for cleaning using the following procedure:

1. Turn off the power to the VPI.
2. Remove and discard the drape (if applicable).

WARNING: **Failure to power off the VPI before starting to clean may expose personnel to unsafe conditions and result in damage to the system.**

Cleaning SPY-PHI Components

The SPY-PHI components are considered non-sterile. Recommended cleaning procedures are as follows:

- Clean all exterior surfaces of these components with a soft cloth moistened with a mild detergent solution. Remove all residual cleaner from the component surfaces.
- If the front glass of the SPY-PHI imager requires cleaning, use a small amount of glass cleaner and a soft cloth or gauze. Do not use abrasive cleaners or strong solvents.

CAUTION: Do not use caustic or abrasive cleaners that could damage the SPY-PHI components.

Do not immerse the SPY-PHI imager in liquid.

Disinfecting SPY-PHI Components

The imaging system components are classified as “non-critical” under the Spaulding classification for recommended level of disinfection. Therefore, low-level disinfection will be sufficient in normal use conditions. Recommended disinfection procedures are as follows.

1. Disinfect the exterior surfaces of these components with one of the following:
    - 70% ethyl or isopropyl alcohol
    - A mild, inorganic, chlorine solution that is tuberculocidal. For example, 1:50 dilution of bleach containing 5.25% sodium hypochlorite. Refer to the information provided by the disinfectant manufacturer to ensure proper selection and preparation of the solution.
2. Dry all component surfaces.

Inspecting SPY-PHI Components

After cleaning and/or disinfection, inspect all components for corrosion, damaged surface, chips or contamination. Components found to be contaminated must be cleaned and low-level disinfected again following the procedures described above.

Visually inspect the SPY-PHI imager, including its cables, for the following:

- Damage
- Sharp edges
- Loose or missing parts
- Rough surfaces
- Residue from cleaners and disinfectants (residues must be removed)
- Text and labels which are required for the safe and intended use must be legible

WARNING: **Observe caution with a damaged and incomplete product (injury to the patient, operator, or third parties is possible).**

Perform a check before and after each use. Do not continue to use a product that is damaged and/or incomplete or has loose parts. Contact Stryker Customer Support to send in the damaged product with loose parts to be repaired. Do not attempt to carry out any repairs on your own.

Storage

After cleaning and/or disinfection, store the product in sterile goods packaging as follows:

- Protected from humidity and temperature fluctuations
- Protected from direct sunlight
- Protected from dust

Appendix A: Troubleshooting

WARNING: **Do not use the SPY-PHI imager if any part of the system is damaged or does not function properly. Failure to follow this warning may lead to injury.**

The SPY-PHI System contains no user-serviceable parts. Do not attempt to open imaging system components. Refer all servicing to a qualified NOVADAQ service representative.

Clearing SPY-PHI Imager, Illumination, and Recorder Errors

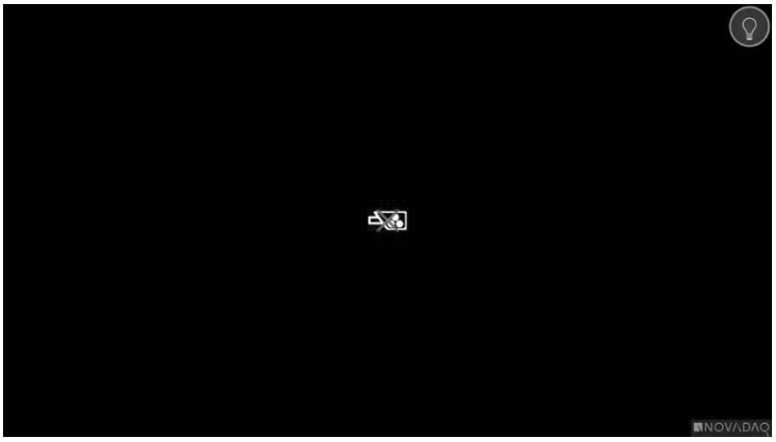
SPY-PHI Imager Communication Error

As the system enters Standby mode, the connected imager initializes. If a communication error is detected , the camera-failed error icon will display and there will be no illumination (see Figure 42).

If this error occurs:

1. Power off the VPI.
2. Disconnect and reconnect the SPY-PHI imager, and then power on the VPI again to clear the error.
3. If the SPY-PHI imager fails a second time, turn the VPI power off and contact a qualified NOVADAQ service representative.

Figure 42: Camera-failed icon



Illumination Error

If the system detects an illumination failure, the illumination-failed icon displays (see Figure 43).

If an Illumination-failed error occurs:

1. Press the Illumination button on the VPI twice to clear the error.
2. If the illumination fails a second time, turn off the system power off and contact a qualified NOVADAQ service representative.

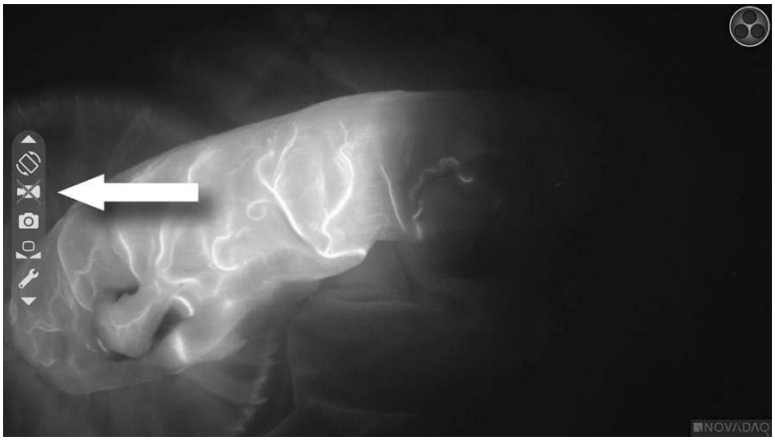
Figure 43: Onscreen Illumination-failed icon

Video Recording and Screenshot Errors

If the VPI is not configured for recording and Video Recording or Screen Capture is selected, the icons in Figure 44 display in the Tools menu.

If the VPI is configured for recording but not properly connected to the recorder, or the recorder is unresponsive and Video Recording or Screen Capture is selected, the screen may momentarily pause (<0.5s) before returning to normal without providing confirmation of the recording occurring.

Figure 44: Recorder unavailable icon in Tools menu



Recorder unavailable when video record selected

Recorder unavailable when screenshot selected

To select the recorder in the VPI Options menu, see Recorder Setup on page 76.

For more information about configuring Sony recorders, see Setting up the Sony 1000MD Recorder for Control from the VPI on page 83 or Setting up the Sony 3300MT Recorder for Control from the VPI on page 87.

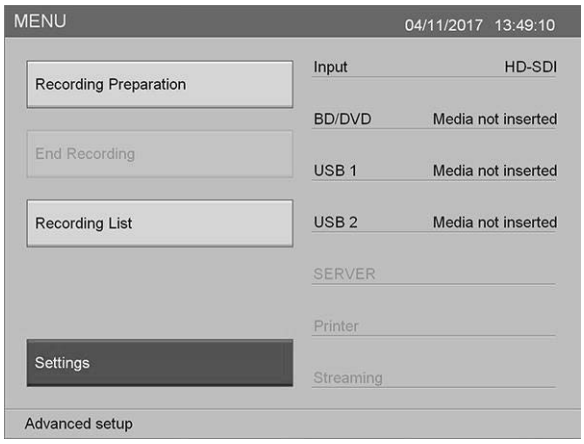
Setting up the Sony 1000MD Recorder for Control from the VPI

If the Sony recorder is being installed for the first time, or if the Sony recorder has reverted to its factory default settings, it will be necessary to reconfigure the recorder settings to enable direct control from the SPY-PHI imager.

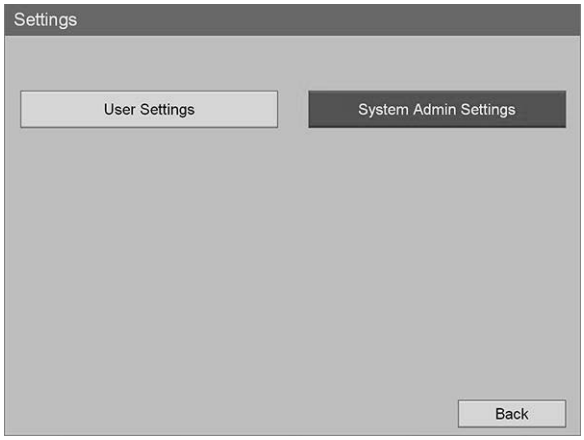
To configure the SONY 1000MD recorder:

1. Press the MENU button on the front panel of the recorder. The main recorder menu opens on the display.

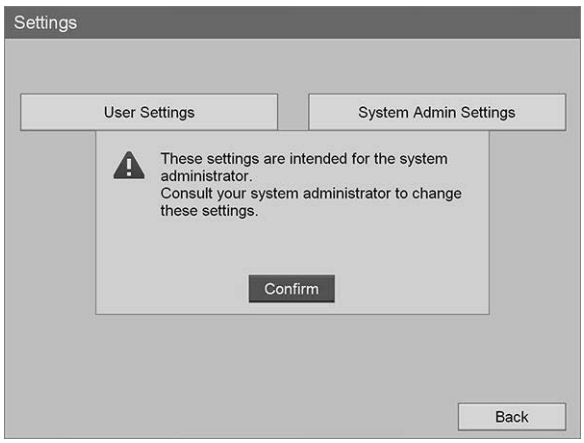
2. Using the arrow buttons on the front panel, navigate to **Settings** and press the ENTER button.



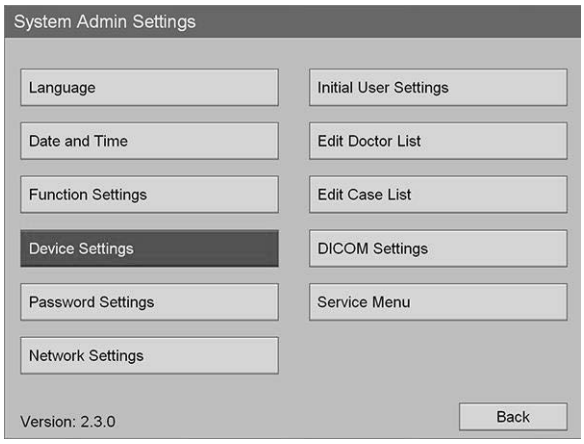
3. In the **Settings** menu, select **System Admin Settings** and press the ENTER button.



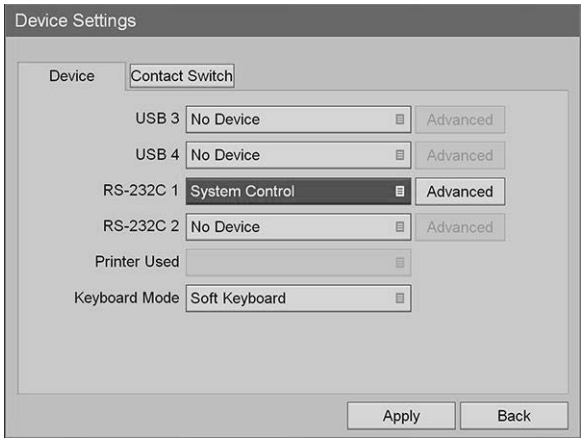
4. In the warning dialog box, select **Confirm** and press the ENTER button.



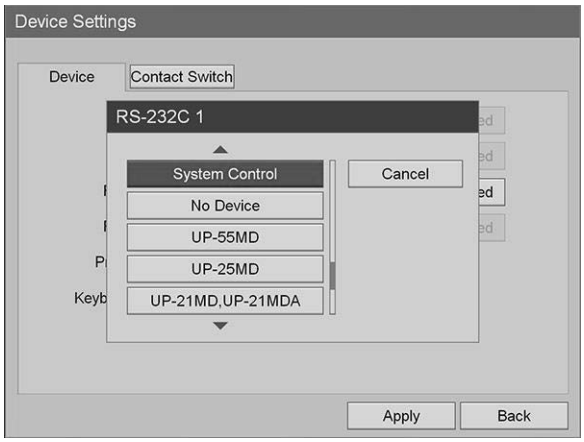
5. In the **System Admin Settings** menu, select **Device Settings** and press the ENTER button.



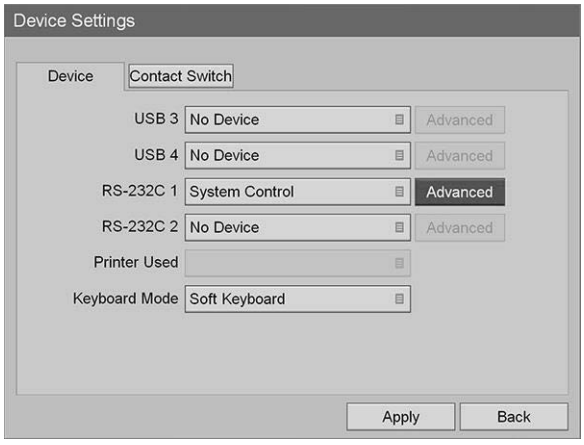
6. In the **Device Settings** menu, navigate to the **RS-232C 1** field, press the ENTER button.



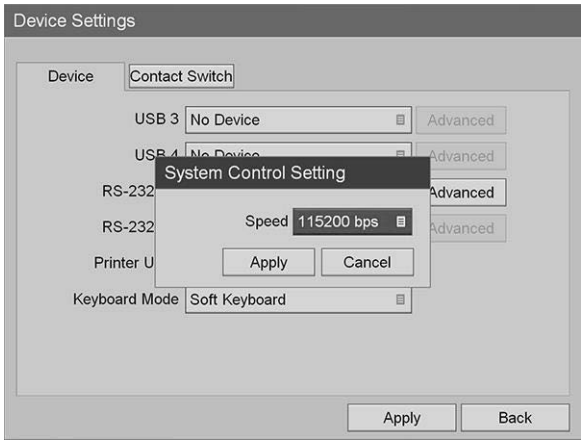
7. Select **System Control** from the list and press the ENTER button.



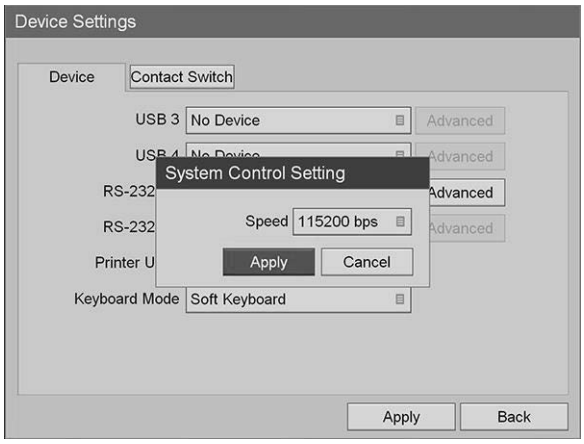
8. Select **Advanced** and press the ENTER button.



9. In the **System Control Setting** dialog box, in the **Speed** field, select **115200 bps** from the list.



10. Select **Apply** and press the ENTER button.



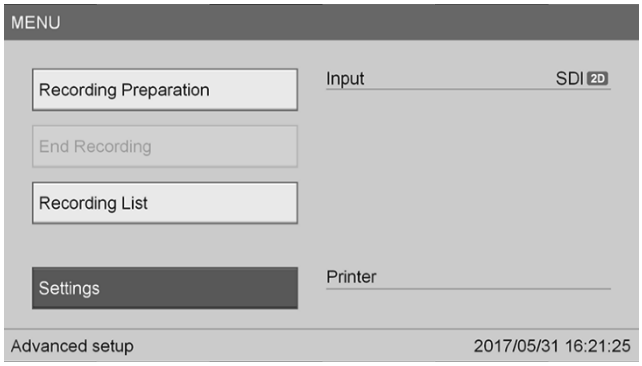
11. In the **Device Settings** menu, select **Apply** and press the ENTER button.

12. Press the MENU button to exit.

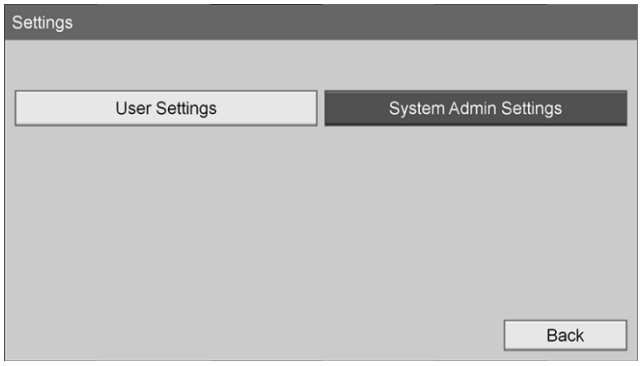
Setting up the Sony 3300MT Recorder for Control from the VPI

To configure the Sony 3300MT recorder:

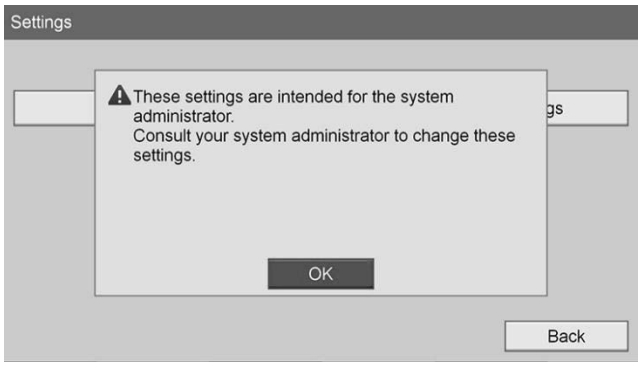
1. Press the MENU button on the front panel of the recorder. The main recorder menu opens on the display.
2. Using the arrow buttons on the front panel, navigate to **Settings** and press the ENTER button.



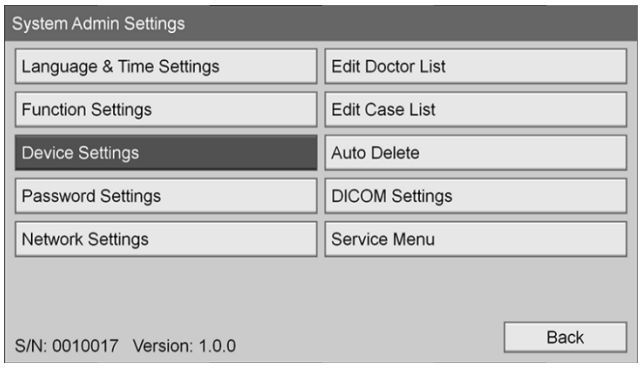
3. In the **Settings** menu, select **System Admin Settings** and press the ENTER button.



4. In the warning dialog box, select **OK** and press the ENTER button.

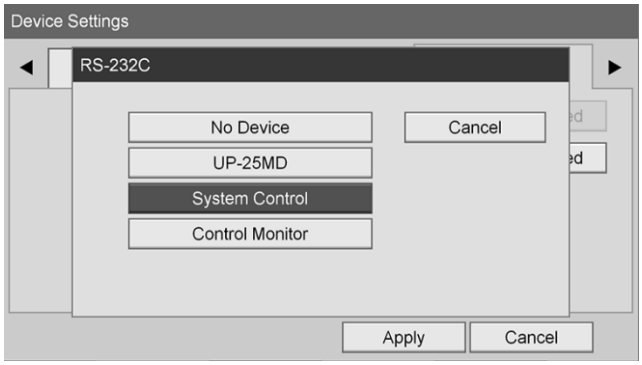


5. In the **System Admin Settings** menu, select **Device Settings** and press the ENTER button.

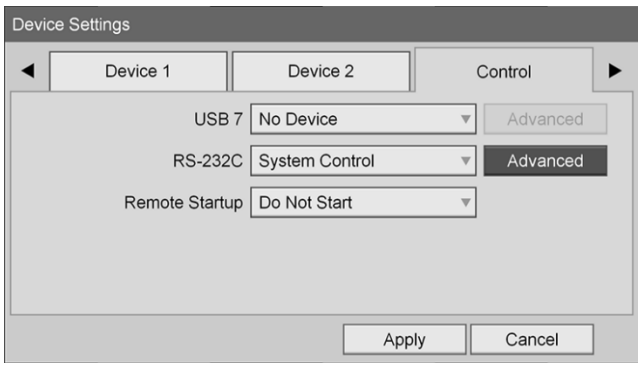


6. Select the **Control** tab.

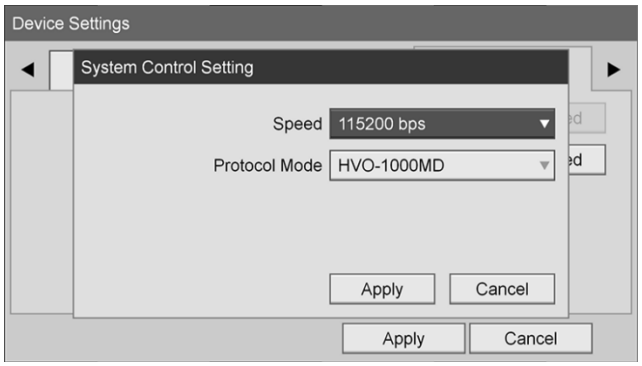
7. In the **RS-232C** field, select System **Control** from the list.

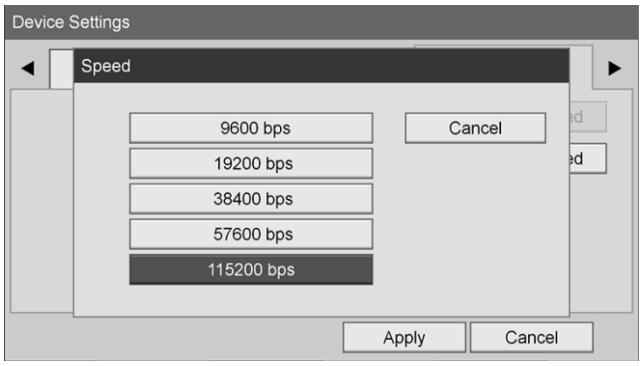


8. Next to the RS-232C field, select **Advanced** and press the ENTER button.

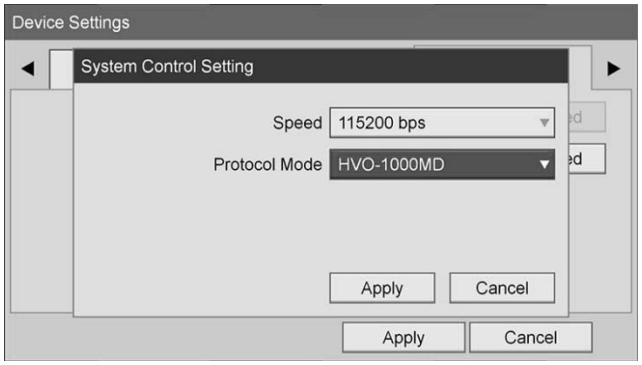


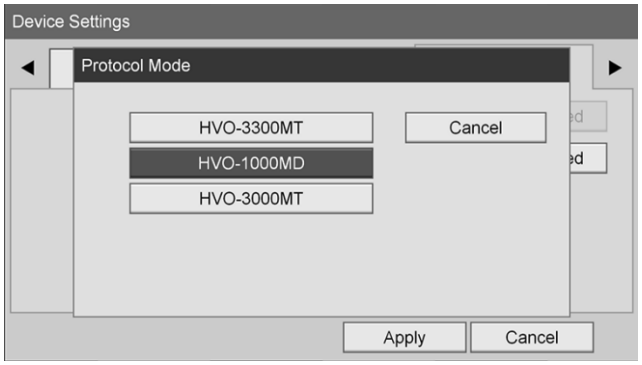
9. In the **Speed** field, select **115200 bps**.





10. In the **Protocol Mode** field, select **HVO-1000MD**.





11. In the **System Control Setting** dialog, click **Apply**.

12. In the **Device Settings** dialog, click **Apply** and then press the MENU button to exit.

General Troubleshooting

For a general troubleshooting guide, see Table 8.

Table 8: General Troubleshooting Guide

Symptom	Cause	Action
Video image is dark, Illumination button does not change the Fluorescence mode when pressed. Camera failed icon displays after SPY-PHI imager is connected and VPI is powered on. An operating mode icon is displayed but no video image is displayed	The VPI is not able to communicate with the SPY-PHI imager.	⚠ **CAUTION:** The SPY-PHI imager may be damaged if it is connected to or disconnected from the VPI while it is powered on. **1.** Power off the VPI. **2.** Check that the SPY-PHI imager camera cable is properly connected to the VPI. **3.** Power on the VPI. **4.** If no video image is being displayed on the video monitor, contact a qualified NOVADAQ service representative.
White balance failed icon displays after attempting to white balance the SPY-PHI imager	The system was unable to adjust the color response of the SPY-PHI imager.	**1.** Check that the SPY-PHI imager is properly connected to the VPI. **2.** Check that Illumination is turned on. **3.** Ensure that the front of the SPY-PHI imager is 10 cm from a matte, white surface such as gauze or white cloth when the white balance is executed. **4.** Retry the white balance. **5.** If the white balance fails a second time, contact a qualified NOVADAQ service representative.
The video image is out of focus.	The focus adjustment on the SPY-PHI imager has not been set to the correct position.	▪ Move the SPY-PHI imager closer or farther from the subject, or ▪ press the focus buttons on the SPY-PHI imager until a sharp, focused image is achieved.
	The front of the SPY-PHI device is obstructed by foreign material	▪ Clean the front glass element of the SPY-PHI device.
The video image appears grainy or noisy.	The Sharpening value is set too high.	**1.** In the VPI Options menu, check the Image Quality value for Sharpening. **2.** If the value is 5 or greater, reduce the value.
The video image appears too bright.	The Brightness value is set too high.	**1.** In the VPI Options menu, check the Image Quality value for Brightness. **2.** If the value is greater than 192, reduce the value.

Symptom	Cause	Action
The video image appears too dark.	The Brightness value is set too low.	**1.** In the VPI Options menu, check the Image Quality value for Brightness. **2.** If the value is less than 175, increase the value.
The video image appears too red or blue.	The Red or Blue Saturation value is set too high.	**1.** In the Options menu, check the Image Quality value for the Red or Blue Saturation. **2.** If the Red value is greater than 768 or the Blue value is greater than 1024, decrease the value.
Image quality is poor due to poor color or brightness.	Image quality settings have been altered significantly.	▪ Reset the Image Quality settings by selecting the Default Profile from the user options menu.
Other equipment near the SPY-PHI imager and/or PINPOINT Endoscopic Fluorescence Imaging System seems to malfunction when the system is powered on, but works normally when the system is powered off.	Radio frequency interference may be occurring between the imaging system and the malfunctioning equipment.	**1.** Check to see if any of the following resolve the problem: ▪ Reorient or relocate the imaging system or the equipment receiving the interference. ▪ Increase the separation between the imaging system and the equipment receiving the interference. ▪ Connect the imaging system to a power outlet on a different circuit from that to which the other equipment is connected. **2.** If the imaging system becomes unresponsive, and does not resume normal function after turning off and back on, stop using the system and contact a qualified NOVADAQ service representative.

Fuse Replacement Procedure

1. Disconnect the VPI power cord from the wall receptacle.
2. Carefully remove the fuse cover with the fuse located next to the three-prong power connector on the rear panel of the VPI.
3. Replace the fuse (Littelfuse, 021806.3HXP, 5x20mm, T6.3A L 250VAC) with the same model or a listed fuse with the same ratings.
4. Re-install the fuse cover.
5. If the VPI fails to operate properly again, contact a qualified NOVADAQ service representative for repair.

Appendix B: VPI Menu Options and Settings

Image Quality Menu Settings

Users can adjust displayed video image settings in the Image Quality menu.

Sharpening (0-10)

Increasing the sharpening value increases the degree to which the displayed video is sharpened. Video sharpening is an image processing feature and does not affect the focus of the SPY-PHI imager.

The Sharpening setting can be set to any value between 0 and 10.

Brightness (0-255)

The Brightness setting controls the overall image brightness displayed on the video monitor. The system maintains the displayed video brightness at a constant value regardless of the distance between the distal tip of the laparoscope and the tissue.

The Brightness setting can be set to any value between 0 and 255. Increasing this value, increases the brightness of the video displayed on the monitor.

Red Saturation (0-1024)

Increase the Red Saturation value to increase the overall redness of the video displayed on the monitor.

The Red Saturation can be set to any value between 0 and 1024.

Blue Saturation (0-1024)

Increase the Blue Saturation value to increase the overall blueness of the video displayed on the monitor.

The Blue Saturation can be set to any value between 0 and 1024.

Peak/Mean

The Peak/Mean menu enables control of the method that the imaging system uses to set the scene brightness for viewing objects at different distances from the front of the SPY-PHI imager. There are three modes in the Peak/Mean menu: **Peak**, **Mean**, and **Balanced**.

Peak

Select Peak to set the brightness for viewing small, foreground objects that are closer to the front of the front of the SPY-PHI imager. Background objects farther from the SPY-PHI imager may fall into darkness.

Mean

Select Mean to set the brightness by weighting the adjustment more by the mean brightness of the scene and less by the brightest points.

For example, use the Mean setting to set the brightness for viewing objects that are farther from the front of the SPY-PHI imager. Foreground objects may appear too bright to see detail.

Balanced

Select Balanced to set the brightness by balancing the Peak and Mean settings.

For example, use the Balanced setting when viewing objects both near to *and* farther away from the front of the SPY-PHI imager. Balanced is the default setting and is suitable for most scenarios.

Default Profile Menu

Default Profile allows the user to return to the settings as originally installed on the imaging system. The following are the default settings:

Table 9 Default Profile

Menu Item	Default
Display Options	SPY
	Overlay
	SPY CSF (if available)
Image Quality	Sharpening: 4
	Brightness: 192
	Red Color Saturation: 768
	Blue Color Saturation: 1024
	Peak/Mean: Balanced
On-screen Info	Off

Service Menu

Entering the Properties / Service menu displays device-specific information. The information shown includes:

- DSP version
- Boot version
- FPGA version
- LCB version
- VPI serial number
- SPY-PHI imager version
- SPY-PHI imager serial number

Display Options Menu

During fluorescence imaging, the imaging system offers up to three different video display options.

SPY Image

The SPY image display shows only the NIR fluorescence on the monitor in gray scale. No white-light image is displayed.

Overlay Image

The Overlay image display combines the white light image and the NIR fluorescent image. In this mode, the NIR fluorescence appears green on top of a high-definition white-light image.

SPY Color Segmented Fluorescence (CSF) Image

In this imaging display, the white-light image is shown as a gray scale image. The NIR fluorescent image is color-scaled, with red representing most fluorescence and blue representing least fluorescence, and displayed on top of the white-light image. In addition, the color scale of fluorescence is shown such that as the distance between the tip of the laparoscope and the tissue changes, the colors remain approximately the same. This allows assessment of the fluorescent image at different imaging distances.

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Appendix C: Specifications and Standards

Table 10: VPI Specifications

Feature		Specification	
Light sources	Spectrum	Visible (VIS)	Near Infrared (NIR)
	Type	Light-emitting diode array	NIR laser diode
Inputs/Outputs	Video output signals	HD-SDI, 3G-SDI, DVI	
	HD formats	HD-SDI 1080i 59.94, 3G-SDI 1080p 59.94	
	Resolution (pixels)	1920x1080	
	Service port I/O	RS-232 (D-subminiature 9-pin connector)	
Operator Controls	Power on/off	Back panel switch	
	Standby	Front panel button	
	White light/Fluorescence mode	SPY-PHI imager	
	Fluorescence display modes	SPY-PHI imager	
Operating Environment	Operating temperature	+10 to +30°C	
	Relative humidity	10 to 85%RH	
	Atmospheric pressure	70 kPa to 103 kPa	
Storage and Transport Environment	Temperature range (storage)	-10 to +55°C	
	Humidity range (storage)	10 to 85%RH	
	Humidity range (transport)	5 to 95%RH	
	Atmospheric pressure (storage/ transport)	70 kPa to 103 kPa	
Physical	Dimensions	Width: 382 mm, Height: 145 mm, Depth 409 mm	
	Weight	14.5 kg	
Electrical Power	Voltage	100 – 240 V~	
	Power frequency	50/60 Hz	
	Power consumption	300 VA	

Table 11: SPY-PHI imager Specifications

Feature		Specification
Optical	Image sensors	CMOS HD sensor assembly
	HD format	1080p
	Aspect ratio	16:9
Physical	Dimensions	Height 136 mm, Width 88 mm, Length 122 mm
	Weight	495 g not including cables
	Cable length	3 m
Environment	Operating temperature	+10 to +30°C
	Relative humidity (storage/transport)	10 to 85%RH
	Temperature (storage/transport)	-10 to +55°C
	Atmospheric pressure (storage/transport)	70 kPa to 103 kPa

Table 12: Equipment Classification

Feature		Specification
Type of protection against electric shock	Class 1 Continuous Operation	As per IEC 60601-1
Degree of protection against moisture	IPXX	
Laser class	Class 3R	As per IEC 60825-1
	Complies with 21CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.	
Radio frequency emissions	Group 1, Class A	As per CISPR 11
Harmonic emissions	Class A	As per IEC 61000-3-2

Table 13: NIR Radiation and Source Characteristics

Feature		Specification
Aperture for NIR radiation		SPY-PHI imager
Accessible NIR radiation	Wavelength	805 nm
	Repetition rate	Overlay mode: 20 pulses/s SPY mode: 40 pulses/s
	Power output (maximum)	2 mJ/pulse as per IEC 60825-1
	Pulse duration	Overlay mode: 8.33 ms SPY mode: 10 ms
	Beam divergence	50°± 5°
Embedded laser source	Classification	Class 4, invisible

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Appendix D: Software License Agreement

NOVADAQ® PINPOINT ENDOSCOPIC FLUROESCENCE IMAGING SYSTEM (PINPOINT) SOFTWARE LICENSE AGREEMENT

This Software End User License Agreement ("**Agreement**") is between you the end user ("**You**" or "**Your**" as appropriate) and **Novadaq Technologies ULC** ("**Novadaq**").

IMPORTANT – READ CAREFULLY

THE PINPOINT SYSTEM INCLUDES PINPOINT SYSTEM SOFTWARE WHICH NOVADAQ IS PREPARED TO LICENSE YOU TO USE AS PART OF YOUR USE OF THE PINPOINT SYSTEM BUT ONLY ON THE TERMS AND CONDITIONS SET OUT IN THIS AGREEMENT. BY CLICKING "I Accept" ON THE SCREEN, OR BY USING THE PINPOINT SYSTEM SOFTWARE IN ANY WAY, YOU CONFIRM YOUR AGREEMENT TO BE BOUND BY THE TERMS AND CONDITIONS OF THIS AGREEMENT. IF YOU DO NOT AGREE, YOU MUST CEASE ALL USE OF THE PINPOINT SYSTEM SOFTWARE AND RETURN IT TO THE DISTRIBUTOR OR VENDOR FOR REFUND OR CREDIT WHERE APPLICABLE.

1. DEFINITIONS

1.1 "**Documentation**" means the operator guides, manuals and other instructions for use of the Program that Novadaq makes generally available.

1.2 "**Program**" means Novadaq's PINPOINT System Software for operating and using the PINPOINT System (in object code form only) and any updates released by Novadaq, together with associated Documentation and media (if any) provided to You.

1.3 "**PINPOINT System**" means the fluorescent imaging system designed and manufactured by Novadaq having the following components: a surgical laparoscope, a camera head ("PINPOINT Camera"), a SPY-PHI handheld camera head, a flexible light guide cable, an endoscopic video processor, PINPOINT cart, HD monitor, recorder, printer and sterilization trays.

2. PROGRAM LICENSE

2.1 **Limited License**. Subject to Your compliance with the terms of this Agreement, Novadaq hereby grants to You, during the term of this Agreement, a limited, non-exclusive, non-transferable license:

(a) to use a single copy of the Program solely for Your own internal business operations solely on the PINPOINT System on which the Program was first installed, consistent with the Documentation;

(b) to use the Documentation provided with the Program in support of Your authorized use of the Program; and

(c) to copy the Program for archival or backup purposes.

2.2 **Restrictions**. You will not copy or use the Program except as expressly permitted by this Agreement. You will not relicense, sublicense, rent or lease the Program or use the Program for third-party training, commercial time-sharing or service bureau use. You will not, and will not permit any third party to, (a) copy, modify, translate, reverse engineer, disassemble or decompile any Program, or otherwise determine or attempt to determine source code of the Program, or (b) create any derivative work based upon the Program embedded in the PINPOINT System, except to the extent expressly permitted by applicable law. You will not use the Program on multiple processors without the prior written consent of Novadaq. Novadaq may, at its own expense and upon reasonable advance notice to You, conduct an audit of Your use of the Program to verify Your compliance with this Agreement.

2.3 **Ownership**. Novadaq will retain all right, title and interest in and to patent, copyright, trademark, trade secret and any other intellectual property rights in the Program and any derivative works thereof, subject only to the limited licenses set forth in this Agreement. You do not acquire any other rights, express or implied, in the Program or the Documentation other than those rights expressly granted under this Agreement.

3. WARRANTY AND REMEDIES

3.1 **Limited Warranty**. Novadaq warrants that the Program will perform the functions described in the Documentation under normal use for a period of twelve (12) months from the date the Program is shipped to You in the PINPOINT System by Novadaq.

3.2 Disclaimer. THE WARRANTY IN THIS SECTION 3 IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, ACCURACY, AND ANY WARRANTIES THAT MAY ARISE OUT OF COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE. Novadaq does not warrant that the Program will operate in combination with any hardware, software, systems, data, imaging agent, or other components or parts other than PINPOINT System operated with an imaging agent provided or approved by Novadaq or a supplier authorized by Novadaq, except as expressly specified in the Documentation. Novadaq does not warrant that the operation of the Program will be uninterrupted or error-free.

3.3 Exclusive Remedies. You must report to Novadaq or a supplier authorized by Novadaq, pursuant to the notice provision of this Agreement, any breach of the warranty specified in Section 3.1 during the relevant warranty period. Your sole and exclusive remedies, and Novadaq's entire liability, for such a reported breach will be for Novadaq or a supplier authorized by Novadaq to correct or provide a reasonable workaround for Program errors that caused the breach of warranty. If there is a material, bona fide claim of infringement, misappropriation, or violation of any third party intellectual property right in connection with the Program, Novadaq shall promptly (i) procure for You the right to continue using the Program, or (ii) replace or modify the Program to make it non-infringing.

3.4 Limitations. NOVADAQ WILL HAVE NO OBLIGATION OR LIABILITY WHATSOEVER UNDER THIS AGREEMENT (INCLUDING SECTION 3.3) OR OTHERWISE FOR ANY BREACH OF WARRANTY OR ADVERSE EVENT DUE TO ABUSE, MISUSE, ALTERATION, NEGLECT OR ACCIDENTAL DAMAGE OF THE PROGRAM OR THE PINPOINT SYSTEM; THE UNAUTHORIZED REPAIR, MODIFICATION OR INSTALLATION OF THE PROGRAM OR PINPOINT SYSTEM; OR THE USE OR ATTEMPTED USE OF ANY SOFTWARE, HARDWARE, SYSTEMS, DATA, IMAGING AGENT OR OTHER COMPONENTS OR PARTS NOT PROVIDED OR APPROVED BY NOVADAQ OR A SUPPLIER AUTHORIZED BY NOVADAQ IN CONNECTION WITH THE PROGRAM OR THE PINPOINT SYSTEM. Replacement or repair of a Program does not extend its warranty period beyond the original warranty expiration date.

3.5 No Support. Novadaq is not obligated to offer any maintenance or support services to You in relation to the Program other than as specified in Section 3.3. Novadaq or its authorized supplier may voluntarily and at its sole discretion offer such support to You.

4. TERMINATION

This Agreement is effective until terminated. Novadaq may terminate this Agreement upon Your breach of any of the provisions hereof by giving sixty (60) days' written notice identifying a breach of the terms of the Agreement by You and giving You the opportunity to cure within the sixty (60) day period. Either party may immediately terminate the Agreement upon the other's dissolution, insolvency, receivership, assignment for the benefit of creditors, or bankruptcy. Upon termination of this Agreement, You will (a) cease all use of the Program, (b) return the Program to Novadaq, or destroy the Program and all related materials in Your possession, and (c) so certify to Novadaq. Except for the license granted herein and as expressly provided herein, the terms of this Agreement will survive termination.

5. GENERAL TERMS

5.1 Governing Law. This Agreement and all matters arising out of or relating to this Agreement will be governed by the internal laws of the State of New York without giving effect to any choice of law rule. This Agreement will not be governed by the United Nations Convention on Contracts for the International Sales of Goods, the application of which is expressly excluded.

5.2 Confidentiality. You will treat and hold the Program and the terms of this Agreement in strict confidence and shall restrict access to the Program to Your employees only.

5.3 Limitation of Liability. In no event will either party be liable for any indirect, incidental, special, consequential or punitive damages, or damages, whether direct or indirect, for loss of profits, revenue, business, savings, data, use or cost of substitute procurement, incurred by either party or any third party, whether in an action in contract or tort, even if the other party has been advised of the possibility of such damages or if such damages are foreseeable. In no event will Novadaq's liability for damages hereunder exceed the amounts actually paid by You to Novadaq or its distributor for the PINPOINT System. The parties acknowledge that the limitations of liability in this Section 5.3 and in the other provisions of this Agreement and the allocation of risk herein are an essential element of the bargain between the parties without which Novadaq would not have entered into this Agreement. Notwithstanding the foregoing, nothing herein shall limit Novadaq's liability for death or personal injury caused by Novadaq's negligent or willful acts or for any other acts or losses for which liability cannot be excluded by mandatory provisions of applicable law.

5.4 Indemnification. Each party shall indemnify, defend and hold harmless the other party, its successors and assigns and their respective directors, officers, employees and agents from and against any and all liabilities, damages, losses, settlements, penalties, fines, costs and expenses, including, without limitation, reasonable attorneys' fees of whatever kind or nature (but not including taxes), to the extent arising from any third−party claim, action, suit or proceeding based upon: (a) the indemnifying party's negligence or misconduct in the performance of its obligations or exercise of its rights under the Agreement, and (b) the indemnifying party's breach of the Agreement; provided, however, that in each of (a) and (b), the indemnifying party shall not be obligated to indemnify, defend or hold harmless any other party to the extent that such other party would be obligated to indemnify, defend and hold harmless the indemnifying party pursuant to this Section.

5.5 Severability and Waiver. If any provision of this Agreement is held to be illegal, invalid or otherwise unenforceable, such provision will be enforced to the extent possible consistent with the stated intention of the parties, or, if incapable of such enforcement, will be deemed to be severed and deleted from this Agreement, while the remainder of this Agreement will continue in full force and effect. The waiver by either party of any default or breach of this Agreement will not constitute a waiver of any other or subsequent default or breach.

5.6 Assignment. You may transfer this Agreement and the license granted hereunder to the purchaser of the PINPOINT System with which the Program is used, however you may not otherwise assign, sell, transfer, delegate or dispose of, whether voluntarily or involuntarily, by operation of law or otherwise, this Agreement or any rights or obligations under this Agreement without the prior written consent of Novadaq. Any purported assignment, transfer or delegation by You in contravention of the foregoing will be null and void. Novadaq is free to assign, sell and transfer its rights and obligations hereunder without restriction or limitation. Subject to the foregoing, this Agreement will be binding upon and will inure to the benefit of the parties and their respective successors and assigns.

5.7 Delegation. You acknowledge that at Novadaq's sole discretion, the obligations of Novadaq under this Agreement may be delegated to, or performed by, Novadaq's designated distributor or authorized agent.

5.8 Compliance with Law. Each party shall comply with all applicable laws, governmental statutes, ordinances and regulations relating to license or use of the Program.

5.9 Export Administration. You will not, and You will require Your representatives not to, export, direct or transfer the Program, or any direct product thereof, to any destination, person or entity restricted or prohibited by applicable export control regulations in the jurisdiction in which the product was supplied to You.

5.10 Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior or contemporaneous agreements or representations, written or oral, concerning the subject matter of this Agreement. This Agreement may not be modified or amended except in a writing signed by a duly authorized representative of each party. It is expressly agreed that the terms of this Agreement will supersede the terms in any of Your purchase orders or other ordering documents.

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