NOVADAQ

PINPOINT

OPERATOR'S MANUAL

PINPOINT ENDOSCOPIC FLUORESCENCE IMAGING SYSTEM

PC9000

US
REV. M, 2015

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Chapter 1 Health and Safety Compliance

Important Information

WARNING: Read Before Use

This instruction manual contains essential information on using the PINPOINT Endoscopic Fluorescence Imaging System (PINPOINT) 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 NOVADAQ's Customer Service and Technical 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.

Indication for Use

PINPOINT is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. PINPOINT enables surgeons to perform routine visible light endoscopic procedures as well as further visually assess vessels, blood flow and related tissue perfusion with near infrared imaging during minimally invasive surgery.

WARNING: PINPOINT should be used according to its approved Indication for Use.

User Qualifications

WARNING: This manual does not explain or discuss clinical surgical procedures. Therefore, the healthcare professional using PINPOINT must be licensed physician or medical personnel under the supervision of a licensed physician and must have received sufficient training in clinical procedures and the use of PINPOINT.

Repair and Modification

WARNING: PINPOINT 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.

If an irregularity appears to be minor, refer to Appendix A - Troubleshooting. If irregularity cannot be resolved, contact NOVADAQ's Customer Service and Technical Support.

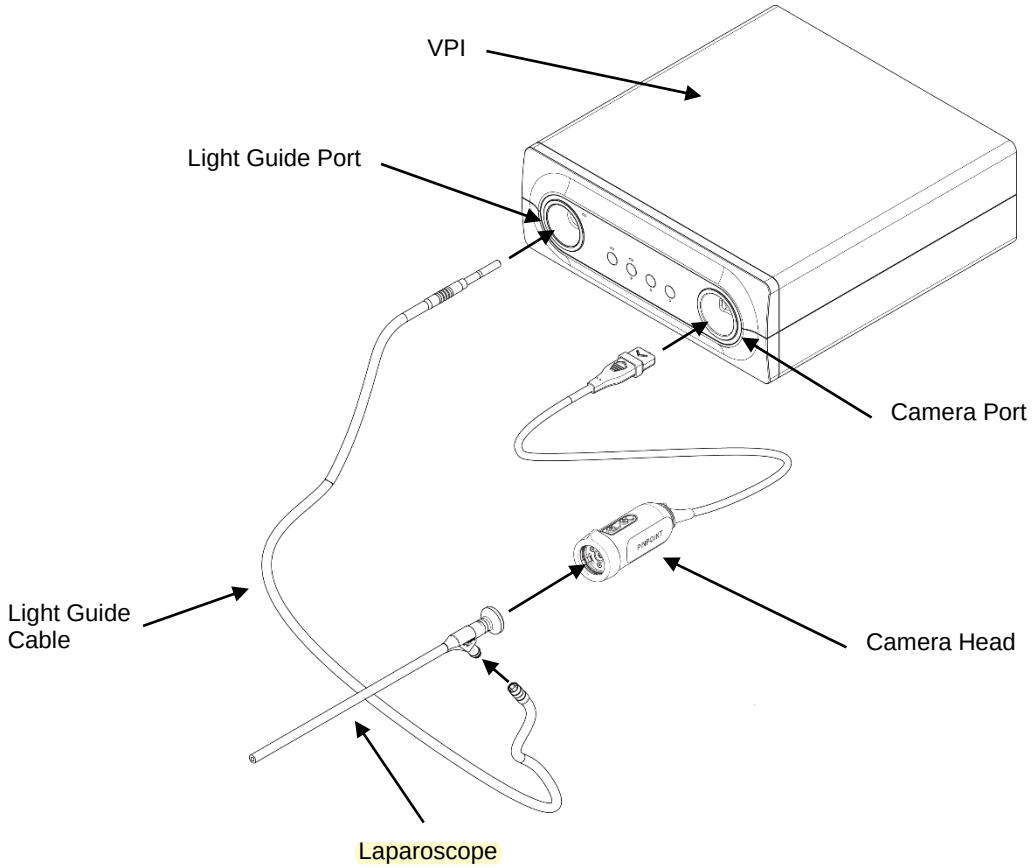
- Clean, disinfect and sterilize the camera, light guide cable and laparoscope thoroughly prior to returning for repair.
- Ideally, return the part in its original packaging. If this is not possible, package the part to secure it for transport.
- NOVADAQ is not liable for damage resulting from improper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

System Overview

Components

PINPOINT is an endoscopic fluorescence imaging system for high definition (HD) visible (VIS) light and near infrared (NIR) fluorescence imaging. PINPOINT consists of the components shown in Figure 1.

Figure 1 PINPOINT components



PINPOINT includes the following components:

- A surgical laparoscope optimized for VIS/NIR illumination and imaging, which is available in different diameters, lengths and directions of view. Alternatively, a surgical laparoscope optimized for visible light only is available.
- A camera head that is also optimized for VIS/NIR imaging and mounts to the laparoscope eyepiece
- A flexible light guide cable
- An endoscopic Video Processor / Illuminator (VPI) capable of providing VIS/NIR illumination to the surgical laparoscope via a flexible light guide cable, and the image processing required to generate simultaneous, real-time HD video color and NIR fluorescence images

PINPOINT is designed to be connected to a medical-grade HD color video monitor, such as those normally used in surgical endoscopy.

PINPOINT Accessories include:

- PINPOINT Cart
- HD Monitor
- Recorder
- Printer
- Sterilization trays for camera, light guide cable, and laparoscope

PINPOINT Paqs are available from NOVADAQ's Customer Service Department and include the following components:

- One (1) box of sterile indocyanine green for injection, USP (ICG) imaging agent that contains:
  - Six (6) single use 25 mg vials of ICG
  - Six (6) single use 10 ml ampules of sterile Aqueous Solvent
  - IC-GreenTM Package Insert
- Twelve (12) 3 ml syringes, sterile
- Twelve (12) 10 ml syringes, sterile
- Six (6) 3-way stopcocks, sterile
- Twelve (12) needles,18G, 1 inch, sterile
- Labels for syringes
- Procedure Coding Sheets

WARNING: Do not use the PINPOINT VPI and camera with laparoscopes or light guide cables that have not been clearly identified for use with the system.

Imaging Agent

- The ICG imaging agent is a sterile, water soluble tricarbocyananine 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 aqueous solvent provided with the ICG, pH of 5.5 – 6.5, is a prepared Sterile Water for Injection used to dissolve the ICG.
- Instructions for preparation, handling and administration of ICG imaging agent are provided in **Chapter 4 Handling, Preparation, and Administration of ICG**.

General System Safety

Electrical Safety – General

 **WARNING:**  To avoid the 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 PINPOINT VPI. If liquid enters the PINPOINT VPI, immediately turn system off and unplug it from the power outlet.**

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

Do not connect or disconnect the camera cable while PINPOINT 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 PINPOINT only to approved medical systems or to systems that are powered from approved isolation transformers.

The patient leakage currents from multiple, simultaneously used, energized endoscopic accessories may be additive. Use PINPOINT only with Type CF Applied Part energized endoscopic accessories that minimize leakage currents to the patient.

Avoid the use of Pinpoint with HF energized endotherapy devices in the event of explosive gas concentrations being present in the area of use.

Do not use PINPOINT 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.

Damaged or Malfunctioning Equipment

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

Light Safety

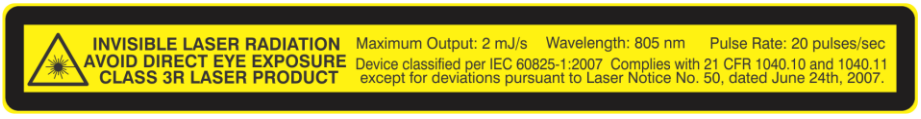
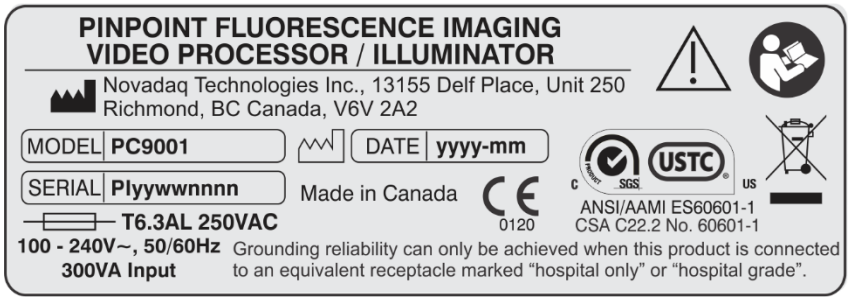
WARNING: Avoid looking at light emitted directly from the laparoscope or the light guide cable tip. Table 17 on page 71 contains specifications for NIR radiation emitted in fluorescence mode.

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

Always use standby mode by turning illumination off (see Turning Illumination On and Off, in Chapter 5) when connecting or disconnecting the light guide cable from the laparoscope, or prior to removing the laparoscope from the patient.

The PINPOINT VPI is labeled with the following warning labels in accordance with applicable standards:

Table 1 Warning Labels and their Locations

Label	Location
	Front panel, See Figure 7, page 23
	Rear panel, See Figure 8, page 23

Cleaning and Disinfecting

WARNING: Follow the instructions in Chapter 6 to clean, disinfect and/or sterilize the PINPOINT components and accessories.

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

WARNING: For storage, transport and processing, ensure that the laparoscope is not subjected to mechanical strain to prevent damage to the sensitive lens system.

The laparoscopes are delivered non-sterile as reusable products.

In general, users are responsible for validation of their re-processing processes.

Ensure that the processing, material and personnel are suitable for achieving the results necessary.

- Observe all local regulations for operator safety, protection and training in performance of manual cleaning and drying processes.
- Clean / disinfect and sterilize the laparoscope prior to initial use as well as each subsequent use of the laparoscope.
- Observe appropriate protective measures to prevent contaminating the environment.

WARNING: There is high-energy light at the distal end of the laparoscope. This can cause the temperature of the body tissue to rise to 41°C. Avoid direct contact of the distal end with body tissue or flammable materials as it can cause burns.

EMC and Environmental Safety

PINPOINT has been certified for compliance with international standards for electromagnetic compatibility (EMC). PINPOINT 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. If turning PINPOINT off and on shows that it does cause harmful interference to other electro-medical equipment, the user is encouraged to try to correct the interference by:

- Reorienting or relocating PINPOINT or the equipment receiving the interference
- Increasing the separation between PINPOINT and the equipment receiving the interference

- Connecting PINPOINT to an outlet on a different circuit from the one to which the other equipment is connected

For further information and guidance refer to “PINPOINT Guidance and Manufacturer’s Declaration – Electromagnetic Compatibility”.

If PINPOINT becomes unresponsive, and does not resume normal function after turning off and back on, stop using PINPOINT and contact NOVADAQ Customer Service and Technical Support.

Advice When Used with High Frequency Surgical Equipment

WARNING: NOVADAQ rigid laparoscopes are not designed to provide insulation against HF electrical currents. To prevent burns and unintended thermal injury of surrounding tissue, activate electrodes only when visible through the laparoscope and avoid contact between active electrodes and the laparoscope.

ICG Safety

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 normal biological 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.

PINPOINT 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 aqueous solvent are intended for use with only 1 patient and within 6 hours of reconstitution. Any prepared ICG solution remaining after each imaging procedure must be discarded.

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 outer box of PINPOINT Paq and the outside packaging of needles, syringes, stopcock, ICG vials, and the aqueous solvent ampules are NOT sterile. The contents of the ICG vial and aqueous solvent ampule 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.

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 *ICG Instructions for Use* or in **General ICG Preparation Instructions**.

Do not use needles, syringe, stopcock, ICG vial and aqueous solvent ampule 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 studied.

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.

Symbols and Indicator Lights

Table 2 Symbols on the PINPOINT Camera

Symbol	Indicates	Location
	Coupler rotation direction to lock	Camera
	Coupler rotation direction to unlock	Camera
	Focus buttons	Camera
	Button 1: PINPOINT Mode on/off	Camera
	Button 2: Display modes, white balance	Camera
	Laser Aperture indicator	Camera

Table 3 Symbols on the Video Processor / Illuminator (VPI)

Symbol	Indicates	Location
	Power	Front panel
	Laser on	Front panel
	Type CF patient-applied part	Front panel
	Illumination on/off	Front panel
	White balance	Front panel

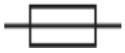
Symbol	Indicates	Location
	Menu	Front panel
	Down (part of menu feature)	Front panel
	Up (part of menu feature)	Front panel
	Right (part of menu feature)	Front panel
	Camera socket	Front panel
	Follow instructions for use	Rear panel
	Manufactured by	Rear panel
	Date of manufacture	Rear panel
	Caution	Rear panel
	Fuse	Rear panel
	Do not dispose in general waste	Rear panel
	Equipotential symbol	Rear panel

Table 4 Symbols in the Video Image

Symbol	Indicates	Description
	White light mode	See Chapter 5
	PINPOINT mode	See Chapter 5
	Standby mode	See Chapter 5
	Illumination Failed	See Chapter 5
	White light display	See Chapter 5
	SPY display	See Chapter 5
	PINPOINT display	See Chapter 5
	SPY CSF display	See Chapter 5
	White balance in progress	See Chapter 5

Symbol	Indicates	Description
	White balance completed	See Chapter 5
	White balance failed	See Chapter 5
	Focus Adjustment	See Chapter 5
	Camera Failed	See Chapter 5
	Language Setting	See Chapter 5

Table 5 Indicator Lights on the Video Processor / Illuminator (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
	Below **White Balance** button 	Green	Up
	Below **Menu** button 	Green	Select

[1] A laser-on indicator light is also located on the camera.

In Case of a Malfunction During Use

Loss of Imaging

If PINPOINT fails to produce continuous imaging, switch the main power (back panel) off for five seconds and then switch the power on again.

The camera head and light guide should remain connected during this time.

1. If PINPOINT imaging fails to resume, remove the camera head from the laparoscope and
2. Use direct visualization through the laparoscope eyepiece in conjunction with PINPOINT illumination to safely conclude the procedure.

Disposal

PINPOINT components and consumables should be disposed of in compliance with local, regional and national regulations. Specifically:

- 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.
- Other PINPOINT components should be returned to NOVADAQ for disposal.

Chapter 2 Unpacking and Setting Up

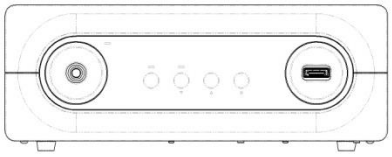
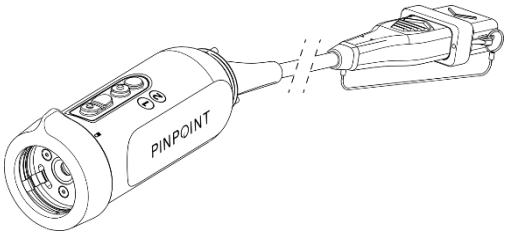
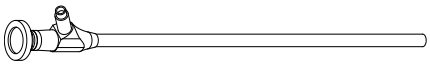
Unpacking the System

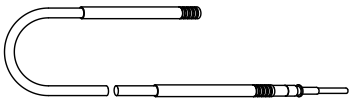
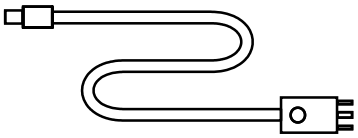
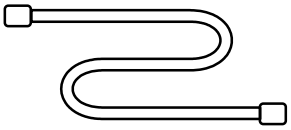
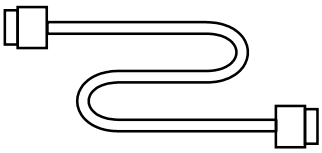
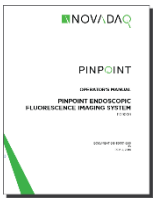
WARNING: Do not use PINPOINT and contact a NOVADAQ service representative if any items are missing or damaged.

Use the following table to identify and inspect all PINPOINT parts before proceeding with setting up the system.

Note: PINPOINT Paqs are purchased separately and shipped with individual Instructions for Use.

Table 6 System Components

Item	Illustration
Video Processor / Illuminator (VPI) Model PC9001	
Camera Head Model PC9002	
Fluorescence Imaging Laparoscope(s) (10 mm dia.) Model SC9100 (0° view, 42 cm) Model SC9130 (30° view, 42 cm) Model SC9104 (0° view, 32 cm) Model SC9134 (30° view, 32 cm) Model SC9144 (45° view, 32 cm)	

Item	Illustration
High-Definition White-Light Laparoscope(s) (10 mm dia.) Model SC9101 (0° view, 33 cm) Model SC9131 (30° view, 33 cm)	(***Not*** for Fluorescence Imaging) 
Light Guide Cable Model PC9004	
Power Cord (P/N: 940-01090-002)	
HD-SDI Cable (P/N: 940-01955-000)	
DVI Cable (P/N: 940-01226-000)	
PINPOINT Operator's Manual (P/N: 016-50001-000)	
PINPOINT Guidance & Manufacturer's Declaration – Electromagnetic Compatibility (P/N: 016-50003-000)	

Setting Up PINPOINT

Selecting a Location

WARNING: PINPOINT has been certified for compliance with international standards for electromagnetic compatibility (EMC). PINPOINT 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 10, starting on page 59, if PINPOINT is suspected of causing interference with other electro-medical equipment, despite being installed according to the instructions.

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

   WARNING: Observe the information in "Electrical Safety – Power" on page 5 and only connect the PINPOINT VPI to a "Hospital Only" or "Hospital Grade" power outlet.

2. Place the PINPOINT VPI on an endoscopy cart, on a shelf supported by a ceiling-mounted boom, or on a suitable table.

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

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

3. Select a location in which to use PINPOINT that is within 3 m access of a medical-grade HD color video monitor.

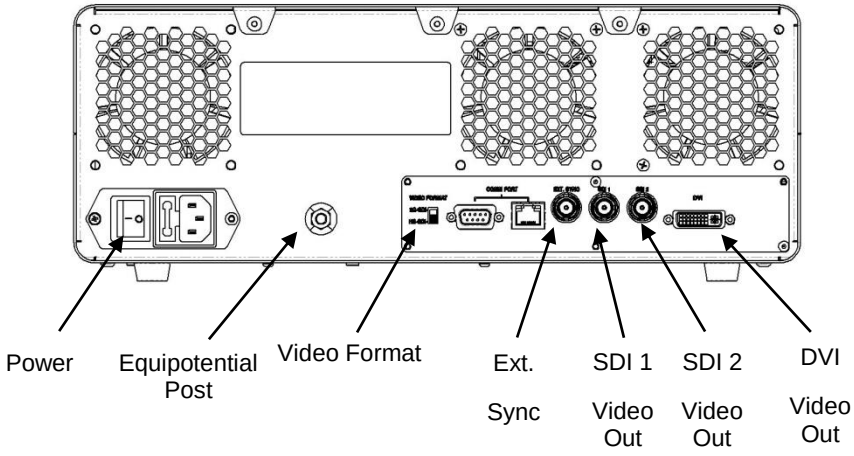
   Connection to such monitors and ancillary video equipment is described in the following sections.

Connect the Video Processor / Illuminator (VPI)

Connect the PINPOINT VPI cables and components as shown in **Figure 2**.

The Comm Ports on the rear panel are intended for use by NOVADAQ service representatives only.

Figure 2 Video Processor / Illuminator Rear Panel



Note: Normal use of the system does not require the user to connect to the potential equalization conductor. The potential equalization conductor is only to be used by qualified personnel.

Connecting to an HD Video Monitor

A medical-grade HD color video monitor can be connected to the appropriate video output on the rear panel of the VPI through a Coax SDI or DVI video cable.

See **Table 12** on page 67 for specifications of the video output signals and connectors 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.

Selecting a Video Monitor

PINPOINT provides output video in the following format:

- HD-SDI (1080i59.94)

Connecting to Ancillary Video Devices (Optional)

WARNING: All electro-medical devices connected to the PINPOINT 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.

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

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

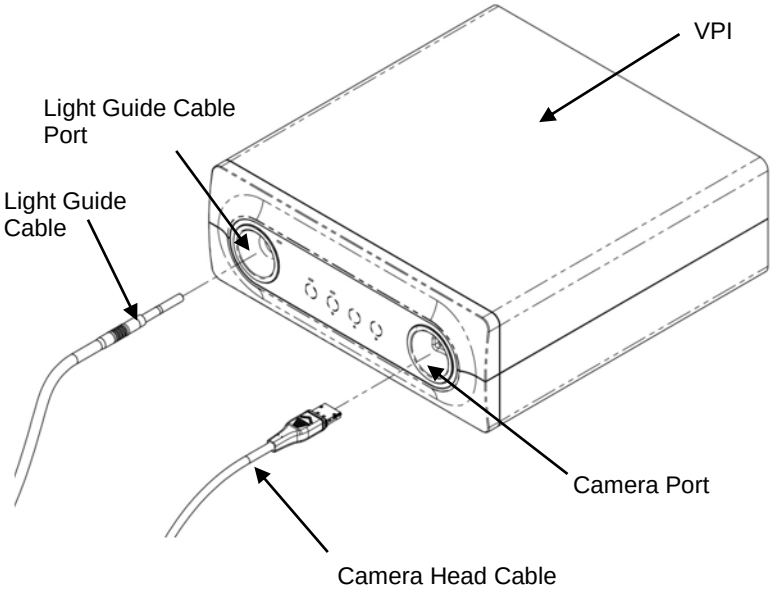
See **Table 12** on page 67 for specifications of the video output signals and connectors and to ensure compatibility of the selected video devices.

WARNING: If the video output is routed through a video recorder, operators must always be aware of whether they are viewing a live or recorded image. Wave your hand in front of the camera head to determine whether or not you are viewing a live image.

Connecting the Camera Head to the VPI

Insert the end of the camera head cable into the camera port on the VPI.

Figure 3 Connecting the camera head to the VPI



Connecting the Light Guide Cable to the Laparoscope

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

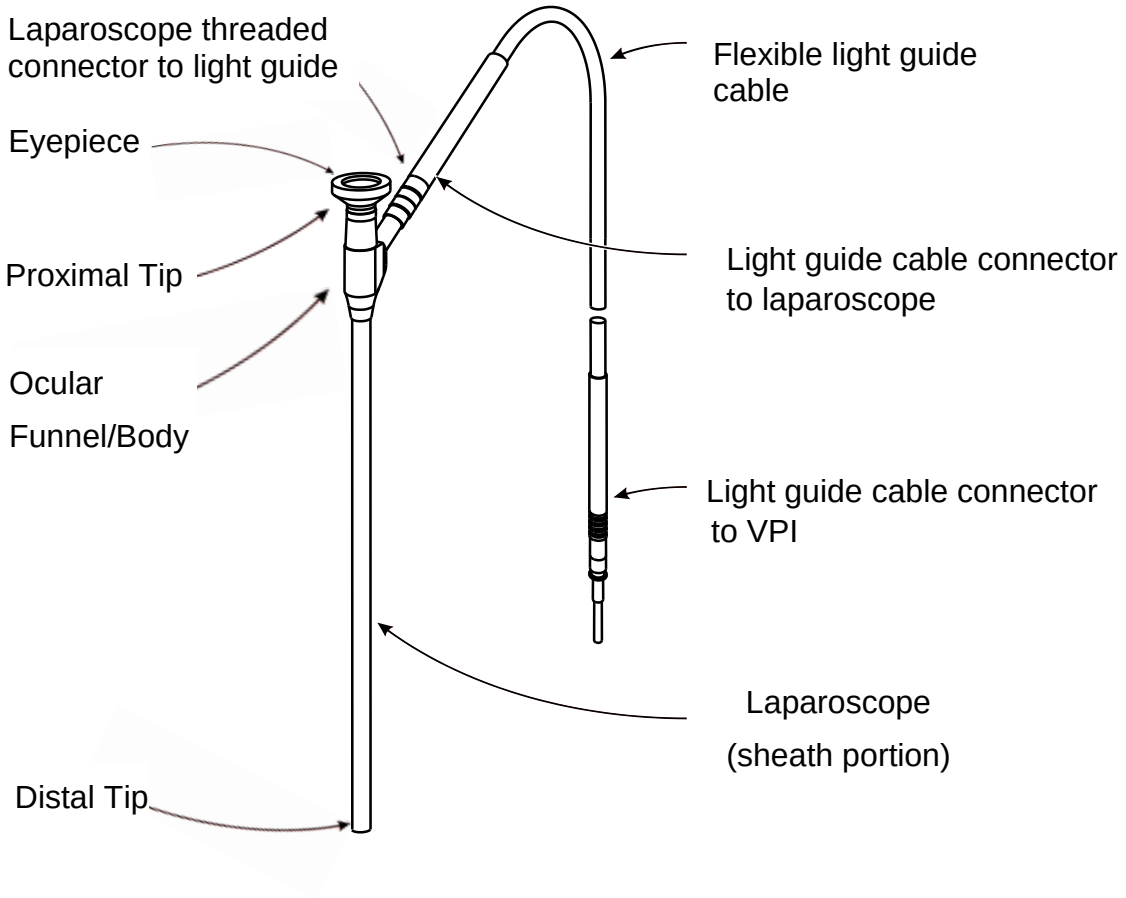
CAUTION: The Camera and Laparoscope are precision medical instruments; handle with great care.

- Inspect the laparoscope for damage before and after use. If the laparoscope is damaged, discontinue use and contact the manufacturer.
- Do not subject to impact. Put the laparoscope down carefully.
- Hold laparoscope only by the ocular funnel or body and not by the sheath. Do not bend the sheath.
- Store laparoscopes safely in a tray or similar container.

To connect the light guide cable to the laparoscope and VPI:

1. Connect the light guide cable to the laparoscope via its threaded connector.
2. Plug the other end of the light guide cable firmly into the light guide cable port of the VPI (not shown) and confirm that it is fully engaged.

Figure 4 Laparoscope and Light Guide Cable connections



WARNING: Both ends of light guide cable and distal end of laparoscope can become hot and may cause patient/operator burns or thermal damage to surgical equipment (e.g. surgical drapes, plastic material, etc). Do not touch the glass tip of light guide cable or distal end of laparoscope. Do not allow the glass tip of light guide cable or distal end of laparoscope to contact the patient, surgical drape, or any other flammable material.

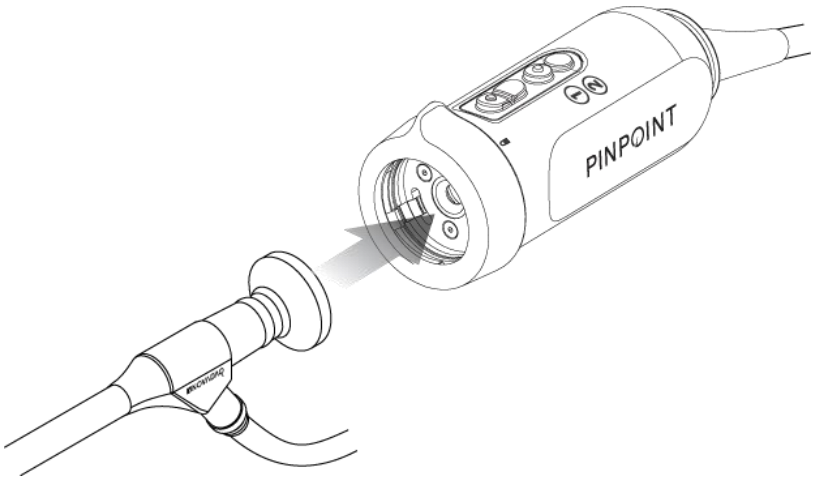
WARNING: Avoid looking at light emitted directly from the ends of light guide cable and laparoscope.

Connecting and Disconnecting the Laparoscope to the PINPOINT Camera

To connect the laparoscope to the camera head:

- Insert the laparoscope eyepiece firmly into the camera head until the coupler rotates to the locked position 🔒 (shown next).

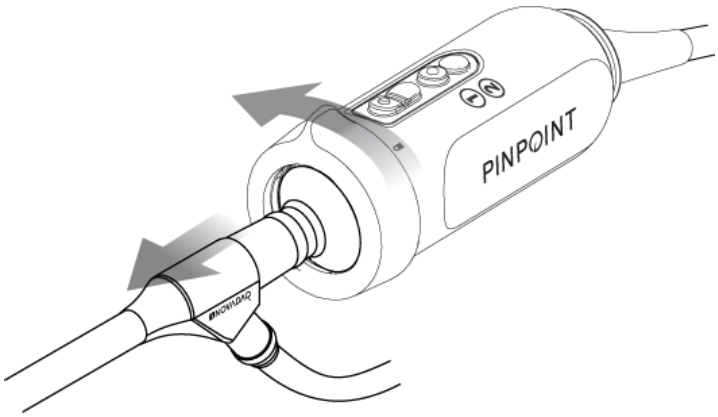
Figure 5 Connecting the laparoscope to the camera head



To disconnect the laparoscope from the camera head:

1. Hold both the camera and laparoscope and rotate the coupler toward the unlock symbol 🔓 on the camera until it clicks (shown next).
2. Pull the laparoscope straight out.

Figure 6 Disconnecting the laparoscope from the camera head



Safe Storage and Transport of Laparoscope

If possible, reprocess laparoscopes immediately after use.

Always store laparoscope securely and transport it to reprocessing in a closed container to prevent damage to the laparoscope and contamination of the environment.

Decontaminated and cleaned, unsterile laparoscopes must be stored in a clean, dry environment. The storage time of unsterile units is not limited; the units are made of a non-degradable material which maintains its stability when stored under the recommended conditions.

- Avoid direct sunlight.
- Store laparoscope securely either in the original packaging or in a tray or container.
- Observe the respective valid national provisions when storing in a sterile condition.
- See **Table 14** on page 69 for the storage conditions

Chapter 3 Controls and Indicators

Video Processor / Illuminator (VPI)

Figure 7 VPI Front Panel controls and indicators

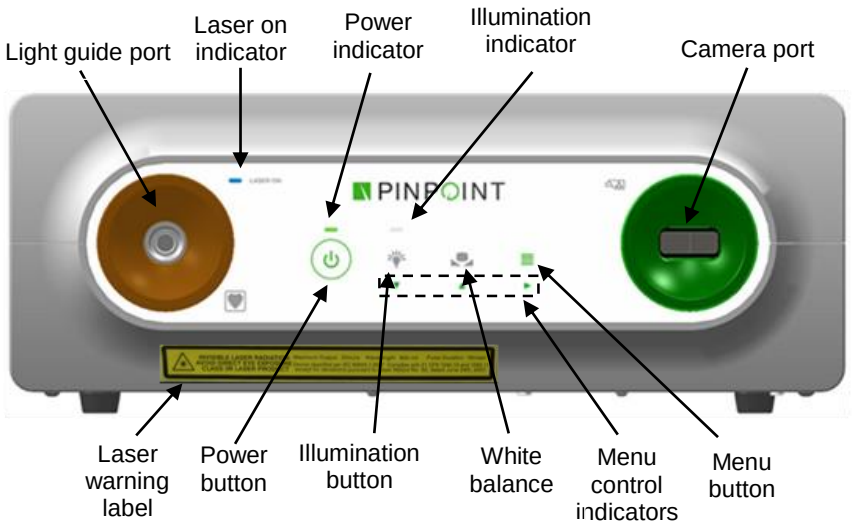
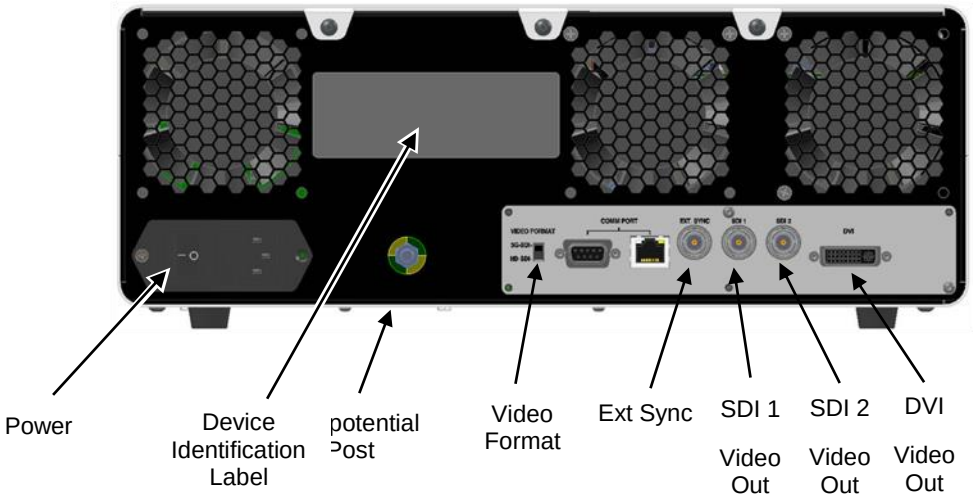
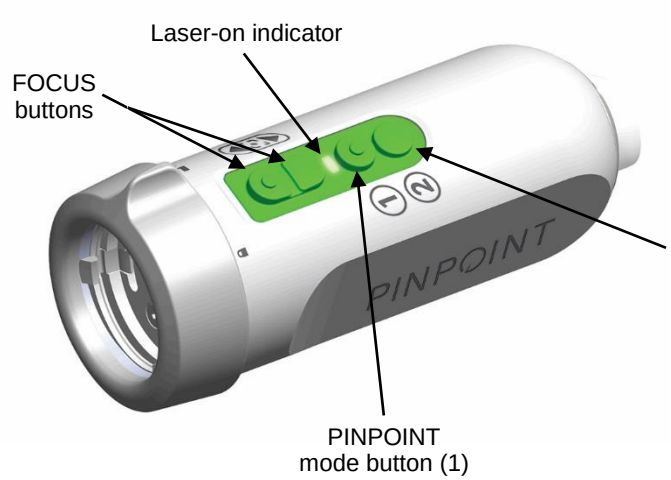


Figure 8 VPI Rear Panel controls and connections



Camera Head

Figure 9 Camera Head controls and indicators



Chapter 4 Handling, Preparation, and Administration of ICG

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 or 6 hours have lapsed since reconstitution.

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 25 mg vial of ICG and one 10 ml aqueous solvent from the ICG box.
2. Draw up the 10 ml into a 10 ml syringe.
3. Remove the flip off cap on the ICG vial (25 mg) and inject the 10 ml of aqueous solvent through the stopper into the ICG vial.

   Note: This yields a 2.5 mg/ml solution of reconstituted ICG.
4. Shake the ICG vial gently to mix.
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.

   CAUTION: 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

Table 7 ICG Dosage

Patient's Body Weight	Recommended Dose of ICG per Injection		Maximum Total Dose of ICG Injected per ICG Package Insert
	mg ICG	ml of 2.5 mg/ml ICG	
≤90 kg	1.25	0.5	2 mg/kg body weight
>90 kg	2.5-3.75	1-1.5	

Increase in dose may be required in those patients exhibiting heavy deposits of fat on the area of interest being imaged.

Dosing is determined at the discretion of the imaging surgeon.

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 3 ml syringes.
2. With an individual 10 ml syringe, withdraw 10 ml of normal saline.

ICG Administration

1. Switch to PINPOINT mode using buttons on camera head.
2. ICG administration is to be performed via a central or peripheral venous line. Using a three-way stopcock attached to an injection port on the infusion line, inject the prepared 2.5 mg/ml ICG solution into the line as a tight bolus. 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 within the PINPOINT field of view within 5-15 seconds after the injection.

Chapter 5 Operation

Preparing the Camera Head and Laparoscope

WARNING: Proper sterile technique must be used when preparing the camera and laparoscope for surgical endoscopy. The following components are not sterile and should not be handled by a sterile operator:

- **Video Processor / Illuminator (VPI)**
- **Camera Head Connector**

Do not remove the cap of connector while it is in a sterile field.

Inspect Laparoscope prior to attaching it to the camera head:

- Ensure that no parts are missing or loose.
- Ensure that the proximal end is dry to prevent the laparoscope from fogging during examination / procedure.
- Ensure that there are no residual cleaning agents or disinfectants on the laparoscope.
- Inspect the entire laparoscope, particularly the sheath, for contaminants and damage of any type, such as dents, scratches, cracks, bending or sharp edges.
- Inspect distal end, proximal end and irradiation surface of the illumination fibers for contamination and scratches. Make contaminants and scratches visible using light reflections. Hold the connection of the optical fibers against the light and inspect whether the optical fibers illuminate evenly at the distal end. Contaminants on the irradiation surface of the illumination fibers can damage fibers, which impacts image quality.

Connect the desired laparoscope to the camera following the instructions in **Chapter 2**. Note that High-Definition Imaging Laparoscopes are optimized for imaging with visible light and will not perform ICG fluorescence imaging. To perform ICG fluorescence imaging, use an ICG Fluorescence Imaging Laparoscope.

PINPOINT Camera Button Functions

The PINPOINT camera's primary functions can be controlled using the buttons on the camera head.

Figure 10: PINPOINT camera button functions

Powering on PINPOINT

To power on PINPOINT:

1. Press the main power switch on the back panel of the VPI unit.

   The system is in the *off* state and the power indicator above the front panel power button shows amber.

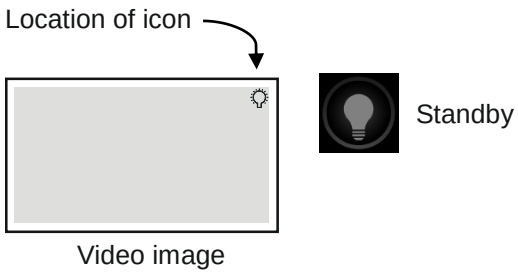
2. Press the power button on the front panel of the VPI .

   The power indicator turns green and the system enters Standby mode. The Standby icon displays in the top-right corner of the video image (shown in **Figure 11**).

   During standby mode, video display is enabled and ventilation fans are on.

3. Press the power button on the front panel of the VPI at any time during operation top turn off illumination and return PINPOINT to standby mode.

Figure 11 Standby mode



If PINPOINT detects a failure in camera communication, the camera failed icon displays.

Power off the VPI, reconnect the camera and power on to clear the error. If the camera fails a second time, switch PINPOINT power off and contact a qualified NOVADAQ service representative.

Turning Illumination On and Off

The illumination button controls the light output from the VPI. To turn white-light illumination on or off:

1. Press the illumination button on the front panel of the VPI  .

   The indicator above the illumination button glows white and the illumination icon appears in the top-right corner of the video image (shown in **Figure 12**).

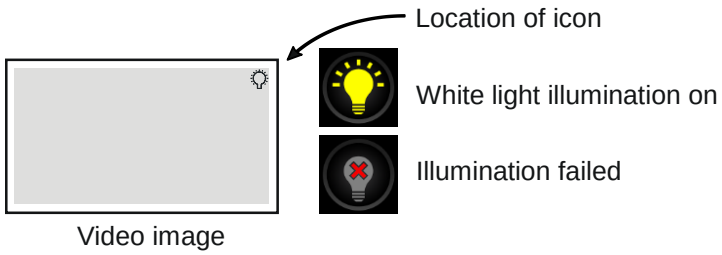
2. Press the illumination button a second time to turn off illumination and return the VPI to standby mode.

   The light guide cable can now be safely disconnected from the laparoscope, or the laparoscope can be safely removed from the patient (without powering off the VPI).

If PINPOINT detects a failure in illumination components, the illumination failed icon displays. Press the illumination button twice to clear the error. If the illumination fails a second time, switch PINPOINT power off and contact a qualified NOVADAQ service representative.

WARNING: Do not disconnect the light guide cable from the laparoscope once PINPOINT is powered on without turning the illumination off.

Figure 12 Illumination icons



Performing a White Balance

Perform a white balance prior to each clinical procedure by executing the following steps:

1. Hold the laparoscope tip approximately 5 cm (2 inches) from a matte white surface, such as gauze or white cloth.
2. Press and release the white balance button on the front panel of the illuminator/video processor

   OR

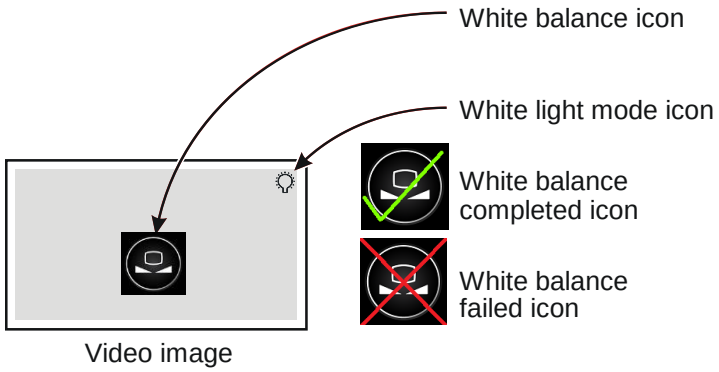
   Press and hold the ② button on the PINPOINT camera head.

   The White Balance icon (shown in **Figure 13)** displays in the center of the video image for several seconds.
3.  indicates that white balance has successfully completed. Proceed to use the PINPOINT system.
4.  indicates that the PINPOINT system has been unable to complete the white balance. Repeat the white balance procedure.

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

   Note: If illumination is not turned on, white balance cannot be performed.

Figure 13 White balance icons



Note: White balance should be performed if the laparoscope is changed during a procedure.

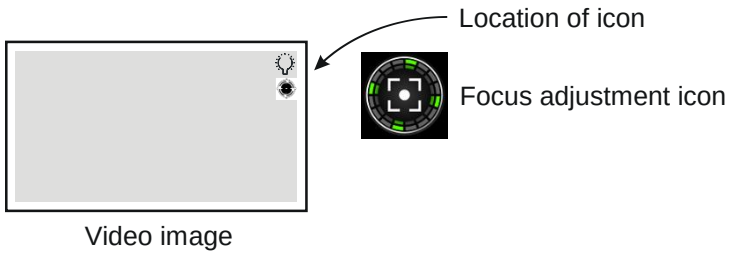
Focusing the Image

With PINPOINT powered on and the white light mode icon displayed (illumination turned on), use the following steps to focus the video image:

1. Hold the laparoscope tip approximately 5 cm (2 inches) from a suitable surface.
2. While viewing the image on the video monitor, press the FOCUS buttons on the camera head to achieve a sharp and focused image. A focus adjustment icon displays when either FOCUS button is pressed (shown in **Figure 15**).

Figure 14 Focus adjustment

Figure 15 Focus adjustment icon



Selecting an Operating Mode

Note: Attempting to use PINPOINT mode with a High-Definition Imaging Laparoscope will produce an image in which the video screen is flooded with fluorescence signal obscuring the white-light image. For ICG fluorescence imaging using PINPOINT mode, ensure a Fluorescence Imaging Laparoscope is used.

With the VPI powered on, use the following steps to switch between white light and PINPOINT operating modes.

1. Press the PINPOINT mode button on the camera head (shown in **Figure 16**).
    - The LED indicator on the camera head and the Laser-on indicator on the front panel of VPI illuminate to indicate that the NIR laser is switched on (**Figure 17)**.
    - The PINPOINT mode icon displays in the top-right corner of the video image (**Figure 18**).

Figure 16 PINPOINT mode button

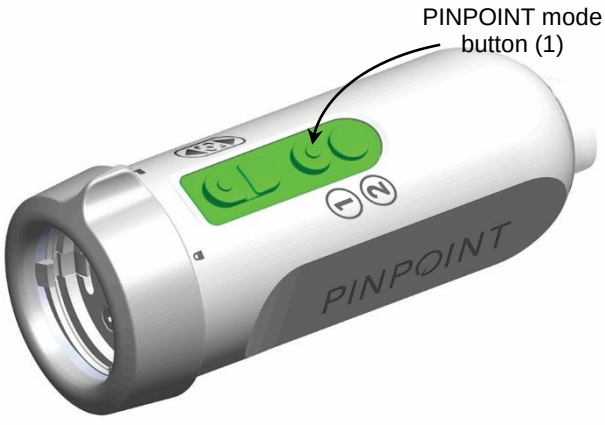
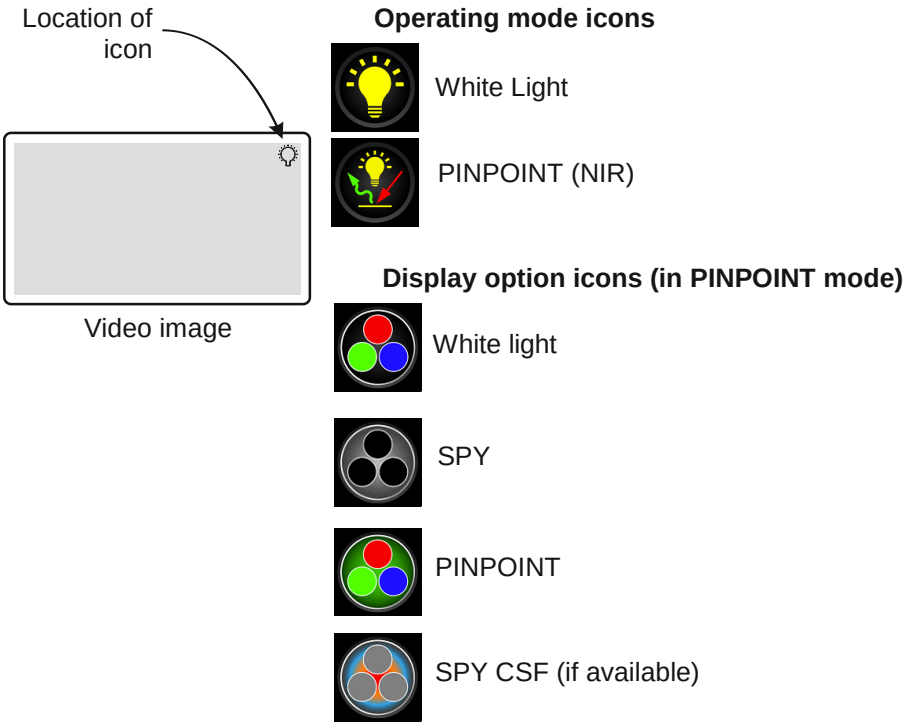


Figure 17: PINPOINT mode active (laser on)

2. Press the PINPOINT mode button again to return the system to white light mode.

Figure 18 Operating mode icons



Selecting Display Options in PINPOINT Mode

While in PINPOINT mode, the screen uses Parallel Display to display multiple images simultaneously. Use the Display Button to cycle through the display options to be shown on the main display. In the User Options menu, choose which of the following display options to include in the cycle:

- **PINPOINT image** – NIR fluorescence is superimposed in pseudo-color (green) on a white light image

- **SPY image** – a NIR fluorescence image is displayed in grayscale
- **SPY CSF image** (if available) – In SPY Color Segmented Fluorescence (CSF) mode, a high-definition white-light image is displayed in grayscale with NIR fluorescence overlaid in on a color scale. Increasing fluorescence levels transition smoothly from blue through yellow to red.
- **White light image** – White light imaged is displayed in full color.

For more information about the display options, see **Appendix B**.

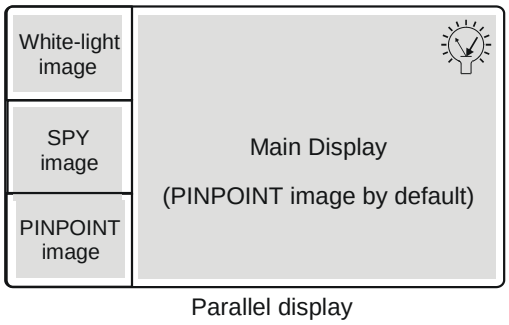
To select the display option:

1. Turn PINPOINT mode on.
2. Press and release the DISPLAY button on the camera head (**Figure 19**).

   The display on the main window cycles to the next display mode each time the button is pressed. The selected mode is indicated by an icon in the upper right corner of the video image (shown in **Figure 20**).

Figure 19 DISPLAY button

Figure 20 Parallel Display in PINPOINT mode



Parallel display

Options Menu

Note: The user options menu is not intended to be used during a clinical procedure, as the menu will obstruct the image.

The following user settings can be configured:

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

To access the User Menu and configure settings:

1. Press the Menu button on the front panel of the VPI. The three arrow indicators illuminate.

   If no selection is made within approximately 15 seconds, the menu will automatically exit.

2. Press the illuminated Down arrow (Illumination button), Up arrow (White Balance button) and Right arrow (Menu button) to navigate the menu (shown next).

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.

For more information about the User Menu, see **Appendix B**.

Image Quality Menu

To adjust an image quality setting:

1. Press the Menu button on the front panel.
2. 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.
5. Press the Up or Down arrow button to adjust the setting. The setting takes effect immediately and is visible in the video image.
6. Press the Right arrow button to deselect when done.

Table 8 lists the user-configurable image quality settings. For more information about Image Quality settings, see **Appendix B**.

Table 8 User-configurable Image Quality Settings

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 end of the laparoscope. 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.

Display Options

To select the display options that are available when cycling through using the Display Button:

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

Default Profile

To restore the Image Quality settings and Display Modes selections to the default settings:

1. Press the Menu button on the front panel.
2. Highlight **Default Profile** and press the Right arrow 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:

1. Press the Menu button on the front panel.
2. Highlight **Load Profile "#"** and press the Right arrow 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:

1. Press the Menu button on the front panel.
2. Highlight **Save Profile** and press the Right arrow 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 to select the profile.

Service (Intended for Service Personnel Only)

Select **Service** in the menu to display information about the device.

To view the VPI properties:

1. Press the Menu button on the front panel.
2. Highlight **Service** and press the Right arrow 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:

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

Test Pattern

To display a test pattern on the screen:

1. Press the Menu button on the front panel.
2. Highlight **Service** and press the Right arrow button to select.
3. Highlight **Test Patterns** and press the Right arrow button to select.
4. Press the Up or Down arrow button to choose the desired test pattern.
5. Press the Right arrow button to display the test pattern.
6. Press the Right arrow button to exit the test pattern when done.

Language Setting

To change the language setting:

1. Press the Menu button on the front panel.
2. Highlight  and press the Right arrow button to select.
3. Highlight the desired language and then press the Right arrow button to select.

Shutting Down PINPOINT

To shut down PINPOINT:

1. Immediately after use, unplug the camera-head connector from the VPI and secure the cap over the connector.
2. Turn off the VPI by pressing the power (standby) button  on the front panel.

Chapter 6 Cleaning, Disinfection, and Sterilization

Cleaning and Disinfecting Non-sterile Components

Preparation

It is recommended that PINPOINT components be cleaned immediately after each use to prevent surface drying of the contaminants. Prepare components for cleaning after surgery using the following procedure:

1. Turn off the power to the VPI.
2. Disconnect the laparoscope from the camera head and clean as described below.

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

Failure to properly clean the components listed below prior to sterilization could lead to inadequate sterilization.

Cleaning Non-sterile Components

The VPI and related cables are considered non-sterile and are subject to the following cleaning procedure:

- 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.

CAUTION: Do not use caustic or abrasive cleaners that could damage the PINPOINT components.

Disinfecting Non-sterile Components

Non-sterile PINPOINT 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.

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.

Cleaning, Disinfecting, and Sterilizing the Laparoscope

Laparoscopes are classified as “critical” under the Spaulding classification. These components must be thoroughly cleaned and sterilized before each use.

There are four stages in re-processing the laparoscope:

- preparation
- cleaning and disinfection
- inspection
- sterilization

CAUTION: Dropping of instruments may cause damage to the laparoscope optics. Always handle with care.

Do not use ultrasonic bath for cleaning or disinfection.

Use only approved cleaning agents. Do not use alcohol or other corrosive cleaning agents.

Preparation for Cleaning Laparoscopes

The laparoscope may contact human tissue and fluids during clinical use. To avoid drying of blood, protein and other substances on these instruments, they should be prepared for cleaning immediately after use (within 2 hours).

WARNING: Remove any adapters attached to the light guide cable and laparoscope prior to cleaning and sterilization. Failure to do so could result in inadequate cleaning and sterilization of the light guide cable.

1. Disassemble the laparoscope and light guide cable from PINPOINT.

2. Wipe the laparoscope with aldehyde-free detergent-soaked, soft, lint-free cloth to remove gross debris as soon as possible after surgical use.
3. Remove the light post adapter from the laparoscope (shown in **Figure 21**).
4. Remove any remaining residue using a soft brush or clean, soft cloth under running water or while the devices/components are immersed in an aldehyde-free detergent solution until all visible contaminants have been removed.

Figure 21 PINPOINT Laparoscope (detached from system)

Cleaning and Disinfection of Laparoscope

General

The pre-cleaning steps described in **Preparation for Cleaning Laparoscopes** should always be performed prior to cleaning and disinfection of the laparoscope.

An automated washer-disinfector should be used wherever possible. Washer-disinfector units must have been validated for efficacy in accordance with applicable standards (e.g. DGHM, FDA or DIN EN ISO 15883). Similarly, validated thermal disinfection programs must be used.

Use freshly prepared solutions only. Use sterile or low-bacteria (up to 10 bacteria/ml) and low-endotoxin (maximum 0.25 EU/ml) water (e.g. purified or highly purified water) and filtered air for drying.

A variety of agents are appropriate for cleaning and disinfecting the PINPOINT laparoscopes. When choosing the appropriate available cleaning agent and disinfectant, ensure the following conditions are met:

- They are suitable for use on optic fiber cables and on instruments made of metal and plastic.
- The cleaning agent has been approved and is non-foaming, if applicable.
- The disinfectant has demonstrated efficacy (i.e. VAH/DGHM, FDA approval, CE Mark approval) and is compatible with the cleaning agent.
- The cleaning and disinfectant solutions are prepared and used per the manufacturer's recommendation.

  Do not use the following substances as cleaning agents or disinfectants:

  - Organic, mineral or oxidizing acids (minimum acceptable pH 5.5)
  - Strong alkalis (maximum acceptable pH 11; neutral/enzymatic or slightly alkaline detergent recommended)
  - Organic solvents (e.g. alcohols, ethers, ketones, benzenes)
  - Oxidizing agents (e.g. hydrogen peroxide)
  - Halogens (e.g. chlorine, iodine, bromine)

- Aromatic/halogenated hydrocarbons
- Oils

Do not use fixating cleaning agents or hot water (greater than 40 °C) as these can result in residues and contaminants that jeopardize successful cleaning.

Do not scratch contaminants off with hard objects as this can cause damage to the optical end surfaces. Strictly adhere to the instructions provided by the cleaning agent/disinfectant manufacturer to determine concentration and exposure time.

Automated Cleaning and Disinfection

WARNING: Use only approved automated washer-disinfector that has been validated for efficacy in accordance with applicable standards.

1. Place the disassembled laparoscopes in the washer-disinfector. Ensure that the instruments are not touching to prevent damage during cleaning.
2. **Start the cleaning process:** follow the parameters specified by the cleaning-disinfection unit and the detergent manufacturers.

   To clean the laparoscope, complete the following steps:

   a. Pre-rinse with cold water for 1 minute. Drain.
   b. Pre-rinse with cold water for 3 minutes. Drain.
   c. Clean with 0.5% alkaline cleaning agent for 5 minutes at 55 °C or with 0.5% enzymatic cleaning agent at 45 °C. Drain.
   d. Neutralize for 3 minutes with warm tap water (less than 40 °C) and neutralizer. Drain.
   e. Intermediate rinse for 2 minutes with warm tap water (less than 40 °C). Drain.

3. **Start the thermal disinfection process:** carry out thermal disinfection considering national requirements regarding the A0 value per DIN EN ISO 15883.
4. Remove instruments after the disinfection process. Ensure the exteriors of the instruments are dry: if necessary, dry with a soft cloth.
5. Perform INSPECTION procedures described in the next section prior to sterilization.

The above procedure has been validated as effective to clean and disinfect the laparoscopes, when used with the following agents and parameters:

Laparoscope Models SC9100, SC9130

- Cleaning / Disinfection Unit: G 7836 CD (Miele Cie. GmbH)
- Detergent: Neodisher Mediclean Forte (Dr. Weigert GmbH & Co.)

Laparoscope Models SC9101, SC9131, SC9104, SC9134, SC9144

- Cleaning / Disinfection Unit: G 7736 CD (Miele Cie. GmbH)
- Detergent: Alkaline – Neodisher FA (Dr. Weigert GmbH & Co.)

  Enzymatic – Endozime (Ruhof)
- Neutralizer: Neodisher Z (Dr. Weigert GmbH & Co.)
- Loading Rack: Loading Rack – E 327-06

Manual Cleaning and Disinfection

WARNING: Combined cleaning/disinfecting agents should not be used, or used only in cases of very low contamination (no visible impurities).

Strictly adhere to the instructions provided by the cleaning agent/disinfectant manufacturer to determine concentration and exposure time.

Cleaning

1. Fully immerse the disassembled instruments in the cleaning bath per the detergent manufacturer's directions. Using a soft-bristled brush, thoroughly brush the instruments ensuring that special attention is paid to areas where soil may accumulate.
2. Brush the adaptor threads on both ends of the light guide cable.
3. Remove the instruments from the cleaning bath and rinse thoroughly at least 3 times with reverse osmosis/de-ionized (RO/DI) water.
4. Perform INSPECTION procedures described in the Inspection Section that follows prior to disinfection.

Disinfection

1. Place the disassembled, cleaned and inspected instruments and components in the disinfectant according to the instructions and for the amount of time indicated by the disinfectant manufacturer. Ensure the entire laparoscope and all components are covered with disinfectant solution. Ensure laparoscope and components are not touching.
2. Remove the instruments from the disinfectant bath and rinse them thoroughly at least five times with RO/DI water.
3. Dry instruments with filtered compressed air.
4. Perform INSPECTION procedures described in the Inspection Section prior to sterilization.
5. Pack instruments per Chapter 2, Safe Storage and Transport of Laparoscope.

The above procedure has been validated as effective in cleaning and disinfecting both the Fluorescence Imaging Laparoscope and the High-Definition Imaging Laparoscope when used with the following agents:

Cleaning Detergent: Cidezyme (Johnson & Johnson Medical Limited)

Disinfectant: Cidex OPA (Johnson & Johnson Medical Limited)

Inspection of Laparoscope

WARNING: If stubborn deposits are not removed by cleaning, the laparoscope should be returned to the manufacturer for repair.

Laparoscopes with damaged glass surface (e.g. chips), with impaired image quality or with any deformation (e.g. unintended rough surfaces, sharp edges or protrusions) may no longer be used and should be discarded or returned to the manufacturer for repair.

1. **After disinfection** inspect all instruments for corrosion, damaged surface, chips or contamination. Soil may accumulate on the glass surface of mechanics and optics. Instruments found to be contaminated must be cleaned and disinfected again following the procedures described above.
2. **Laparoscopes surfaces** must be undamaged and in particular should be free of sharp edges. Check for dents, bends, cracks or any signs of mechanical or thermal damage.
3. **Examine the fiber optic.** Hold one end pointing toward a light source (e.g. lighted window or a lamp). Check the other end for dark spots. These dark spots indicate broken optical fibers. Should the dark spots cover more than 20 – 25% of the light output surface, discard the instrument.
4. **The surfaces of the light entry and exit** should be smooth and clean. If the surfaces show deposits, insufficient lighting might result. With further use, it may result in progressive damage to the laparoscope.
5. **Verification of the proximal and distal areas of glass.** The glass surfaces must be clean and free of debris. Any dirt deposits should be removed using appropriate cleaning pastes or alcohol-soaked cotton swabs.

Sterilization of Laparoscope

 **Note:** See **Table 9** on page 57 for a summary of compatible sterilization methods.

Packing for Sterilization

Use sterilization trays/containers and packaging materials (wraps/pouch) that meet the following requirements:

- Approved by FDA or CE Marked and has demonstrated effectiveness in allowing sterilization and maintaining sterility of the enclosed instruments.
- Suitable for steam sterilization (stable up to 141 °C and has sufficient vapor permeability)
- Provides adequate protection of instruments against mechanical damage
- Sterilization trays/containers should be regularly maintained per manufacturer's directions

1. Assemble the laparoscopes by connecting the adaptors and light guide cable. Place them in sterilization tray or container. Wrap the container/tray or place them in a disposable sterilization packaging material.
2. The packaging must be sufficiently marked with identification such as nature and date of sterilization, batch number and expiration date.

Sterilization: Fractional Pre-Vacuum Method

CAUTION: Only laparoscopes which are marked “autoclaveable” or “autoclave” are intended for autoclaving.

Ensure that thermal optical lenses are not in contact with hot metal surfaces, as these thermal bridges may cause damage and can cause leakage to the entire system.

Do not use flash sterilization or hot air sterilization.

Thermal optical lenses must be cleaned with pure alcohol.

Other sterilization parameters/autoclave settings may not be compatible with the laparoscope and light guide cable.

Validated maximum load configuration of the sterilizer should not be exceeded as it may cause condensation resulting in rust damage.

Dryness of optics must be achieved after cooling to room temperature. The drying time must be at least 10 minutes.

Follow sterilizer manufacturer’s instructions. Relevant national legal regulations must be observed.

1. The sterilization temperature shall not exceed 138 °C (280 °F). Autoclave the laparoscope at a minimum temperature of 134 °C (273 °F) for a minimum of 5 minutes.
2. When the sterilization process has ended, allow the laparoscopes to cool gradually to room temperature.

Sterilization: Gravity Method (Models SC9104, SC9134, SC9144, SC9101, SC9131 Only)

The laparoscopes have material compatibility for a hold time of 15 minutes.

Sterilization: French Cycle (Models SC9104, SC9134, SC9144, SC9101, SC9131 Only)

Autoclave the laparoscope at a minimum temperature of 134 °C (273 °F) for 18 minutes.

Sterilization: Hydrogen Peroxide Gas Plasma (STERRAD® and STERIS®)

1. Place the laparoscope in a tray compatible with STERRAD® or STERIS® Systems. Please see ‘Warning’ Statement below.
2. Sterilize the laparoscope using one of the following methods:
    - STERRAD® NX® Standard Cycle
    - STERRAD® NX® Advanced Cycle
    - STERRAD® 100NX® Standard Cycle
    - STERRAD® 100S Short Cycle
    - STERIS® V-PRO® 1

- STERIS® V-PRO® 1 Plus
- STERIS® V-PRO® maX

WARNING: Not all sterilization trays are compatible with STERRAD® or STERIS® systems. Using an incompatible tray may result in incomplete device sterilization. Consult the instructions that came with your sterilization tray to determine which sterilization method is compatible with your tray and devices. If a compatible tray is not available, the laparoscope can be placed in a single STERRAD® ASP pouch prior to using the STERRAD® system or in a single STERIS® pouch prior to using the STERIS systems.

Special Precautions: Pathogens of Transmissible Spongiform Encephalopathy

A comprehensive explanation of the necessary preventative measures with regard to agents of Transmissible Spongiform Encephalopathy (TSE) would go beyond the scope of this document.

It is assumed that pathogens of the Creutzfeldt-Jakob disease cannot be killed using normal disinfection and sterilization processes. Therefore, the standard methods for decontamination and sterilization are not sufficient if there is a risk of transferring Creutzfeldt-Jakob disease.

In general, only tissue with a low potential of TSE infection comes into contact with surgical instruments. In spite of this, special preventative measures must be taken for instruments which are used to treat patients with a known or suspected infection of TSE, as well as for patients at risk.

Cleaning, Disinfecting, and Sterilizing the Light Guide Cable

The light guide cable is classified as “critical” under the Spaulding classification. These components must be thoroughly cleaned and sterilized before each use. There are four stages in re-processing the light guide cable:

- preparation
- cleaning and disinfection
- inspection
- sterilization

CAUTION: Always handle with care.

Do not use Ultrasonic cleaning, flash autoclaving or hot air sterilization for cleaning or disinfection.

Damage to the protective outer cover causes damage to fiber optic light cable. Protect the light guide cable from sharp bending which may damage the inner fiber bundle.

It is very important to prevent bumping, especially of the fused light entry, as this can lead to the destruction of the fusing.

Preparation for Cleaning the Light Guide Cable

Frequent preparation has little impact on these products. The end of the product's life is normally caused by wear and damage from use.

It is recommended to store the product in containers which are suitable for the transport. The transport into the preparation rooms can take place wet as well as dry.

For a dry disposal, make sure that no residuals dry on the surface. Close the container. The cleaning should take place within three hours.

For a wet disposal, the cleaning must take place within one hour, and the recommended combined cleaner and disinfectant (see manual cleaning) must be used.

WARNING: Remove any adapters attached to the light guide cable and laparoscope prior to cleaning and sterilization. Failure to do so could result in inadequate cleaning and sterilization of the light guide.

1. Disassemble the light guide cable from the VPI and laparoscope.
2. Remove the adapters from the product, as a separate, manual cleaning and disinfection of the individual parts will take place.

   Properly put away the individual parts in order to prevent damages.

3. Wipe off surface contamination with a non-shedding single-use towel.
4. Properly put away the product in order to prevent damages.

Cleaning and Disinfection of the Light Guide Cable

General

The pre-cleaning steps described above should always be performed prior to cleaning and disinfection of the laparoscope and light guide cable.

An automated washer-disinfector should be used wherever possible. Washer-disinfector units must have been validated for efficacy in accordance with applicable standards (e.g. DGHM, FDA or DIN EN ISO 15883). Similarly, validated thermal disinfection programs must be used. The 'Vario TD programme' for the machine cleaning and disinfection procedure is recommended.

Use freshly prepared solutions only. Use sterile or low-bacteria (up to 10 bacteria/ml) and low-endotoxin (maximum 0.25 EU/ml) water (e.g. purified or highly purified water) and filtered air for drying.

A variety of agents are appropriate for cleaning and disinfecting the PINPOINT laparoscopes and light guide cable. When choosing the appropriate available cleaning agent and disinfectant, ensure the following conditions are met:

- They are suitable for use on optic fiber cables and on instruments made of metal and plastic.
- The cleaning agent has been approved and is non-foaming, if applicable.
- The disinfectant has demonstrated efficacy (i.e. VAH/DGHM, FDA approval, CE Mark approval) and is compatible with the cleaning agent.
- The cleaning and disinfectant solutions are prepared and used per the manufacturer’s recommendation.

CAUTION: Excessive concentrations of disinfectant solution or excessive soaking time can permanently damage the light guide cable.

Do not use the following substances as cleaning agents or disinfectants:

- Organic, mineral or oxidizing acids (minimum acceptable pH 5.5)
- Strong alkalis (maximum acceptable pH 11; neutral/enzymatic or slightly alkaline detergent recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzenes)
- Oxidizing agents (e.g. hydrogen peroxide)
- Halogens (e.g. chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Oils

Do not use fixating cleaning agents or hot water (greater than 40 °C) as these can result in residues and contaminants that jeopardize successful cleaning.

Do not scratch contaminants off with hard objects as this can cause damage to the optical end surfaces.

Strictly adhere to the instructions provided by the cleaning agent/disinfectant manufacturer to determine concentration and exposure time.

Automated Cleaning and Disinfection

WARNING: Use only approved automated washer-disinfector that has been validated for efficacy in accordance with applicable standards.

1. Place the disassembled light guide cable in the washer-disinfector. Ensure that the instruments are not touching to prevent damage during cleaning.
2. **Start the cleaning process:** follow the parameters specified by the cleaning-disinfection unit and the detergent manufacturers.

   To clean and disinfect the light guide cable, complete the following steps:

   a. Pre-rinse intensively with cold water. Drain.
   b. Clean for 5 minutes at 55 °C. Drain.
   c. Conclude the process with thermal disinfection with >90°C with a 5-minute hold time.
   d. Final rinse with DI water (preferably for optimal care of the instrument) and without rinsing agents.

   CAUTION: The light guide cable should be stored in a suitable container (sterilization tray / basket) in the machine, in order prevent damages of the product.

   Corrosion on the product can occur from using chloride-containing water; this is why the final rinse procedure should take place with fully demineralised water.

   The operating instructions and loading instructions of the manufacturer must be precisely adhered to during the cleaning and the following thermal disinfection.

   The cleaning agents used must be exactly dispensed according to the prescription of the manufacturer.

   The disinfection temperature must not exceed 93°C.

   e. Put the cleaned and disinfected individual parts back together.
   f. Dry the product by means of the non-shedding towel and/or the compressed air.
   g. Properly put away the parts in order to prevent damages.

3. Perform INSPECTION procedures described in the next section prior to sterilization.

Manual Cleaning and Disinfection

WARNING: Combined cleaning/disinfecting agents should not be used, or used only in cases of very low contamination (no visible impurities).

Strictly adhere to the instructions provided by the cleaning agent/disinfectant manufacturer to determine concentration and exposure time.

Cleaning:

1. Thoroughly rinse off the individual parts with tap water (max.45°C).
2. Place the individual parts into the sterilization tray and then transfer them into an immersion bath with the self-acting disinfecting cleaning solution of Sekusept 4%.
3. Brush the adaptor threads on both ends of the light guide cable.
4. After the recommended soaking time according to the manufacturer specifications of the cleaning solution:
   a. Rinse each light guide cable for 5 minutes with DI water.
   b. Dry the exterior with a non-shedding single use towel or swab.
   c. Clean the mechanical parts and optical surfaces (light entry and light exit) with a soft towel or soaked cotton ball and the 70% alcohol solution, provided that a disinfection does not take place after the cleaning.
5. Properly put away the individual parts in order to prevent damages.

CAUTION: Do not use any metal brushes or cotton wool applicators made from metal for the manual cleaning.

Do not use any other instruments for cleaning the optical surfaces. After the manual cleaning, inspect all the individual parts for damages

Disinfection:

1. Place the individual parts into the sterilization tray and then transfer them into an immersion bath with disinfection solution. Refer to the specifications of the chemical manufacturer for the concentration and soaking time of the deployed disinfectant.
2. Thoroughly rinse the light guide cable for 5 minutes with DI water.
3. Dry the exterior with a non-shedding single use towel or swab.
4. Clean the mechanical parts and optical surfaces (light entry and light exit) with a soft towel or soaked cotton ball and the 70% alcohol solution.
5. Properly put away the individual parts in order to prevent damages.

CAUTION: Disinfectants which contain acetic acid or chlorine compounds may not be used.

After the manual disinfection, inspect all the individual parts for damages. Observe the manufacturer's specifications for the disinfectant regarding the:

- Disinfectant effectiveness
- Concentration
- Soaking time
- Product Life

Storage

After **disinfection**, store the product according to the following conditions:

- Completely dry
- Protected from dust
- In a closed container
- In a germ-free environment

WARNING: If the product has been stored for several days, it must be disinfected again before the sterilization.

Inspection of the Light Guide Cable

After disinfection, inspect all instruments for corrosion, damaged surface, chips or contamination. Soil may accumulate on the glass surface of mechanics and optics. Instruments found to be contaminated must be cleaned and disinfected again following the procedures described above.

1. Visually inspect the light guide cable 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 of 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. Send in the damaged product with loose parts to be repaired. Do not attempt to carry out any repairs on your own.

2. After the initial visual inspection, inspect the light guide cable optical surfaces for the following:
    - Light output

- Broken fibres: Hold one end pointing toward a light source (e.g. lighted window or a lamp). Check the other end for dark spots.
  - broken fibres appear as black dots on the cold light connection
  - Should the dark spots cover more than 20-25% of the light output surface, discard the instrument.
- The surfaces of the light entry and exit should be smooth and clean. Deposits on the surfaces can diminish light transmission.
  - clean the glass surfaces (see Manual Cleaning and Disinfection)

CAUTION: Do not attempt to carry out any repairs on your own if the coatings cannot be removed with the recommended cleaners and disinfectants (see **Automated Cleaning and Disinfection** or **Manual Cleaning and Disinfection**).

Regular cleaning with a 70% alcohol solution after each preparation prevents coatings.

Sterilization of Light Guide Cable

Note: See **Table 9** on page 57 for a summary of compatible sterilization methods.

CAUTION: Other sterilization parameters/autoclave settings may not be compatible with the laparoscope and light guide cable.

The cleaned and disinfected individual parts must be put back together before sterilization.

The product must be sufficiently clean and dry.

Follow sterilizer manufacturer's instructions. Relevant national legal regulations must be observed.

Brand-new light guide cables must be sterilized before their first use.

Packing for Sterilization

Use sterilization trays/containers and packaging materials (wrap/pouch) that meet the following requirements:

- Approved by FDA or CE Marked and has demonstrated effectiveness in allowing sterilization and maintaining sterility of the enclosed instruments.
- Suitable for steam sterilization (stable up to 141 °C and has sufficient vapor permeability)
- Provides adequate protection of instruments against mechanical damage
- Sterilization trays/containers should be regularly maintained per manufacturer's directions

1. Assemble the cleaned and disinfected adaptors to the light guide cable. Place them in the sterilization tray or container. Wrap the container/tray or place them in a disposable sterilization packaging material.
2. The packaging must be sufficiently marked with identification such as nature and date of sterilization, batch number and expiration date.

Sterilization: Fractional Pre-Vacuum Method

1. The sterilization temperature shall not exceed 138 °C (280 °F). Autoclave the laparoscope and light guide cable at a minimum temperature of 134 °C (273 °F) for a minimum of 5 minutes.
2. When the sterilization process has ended, allow the light guide cable to cool gradually to room temperature.

Storage

After **sterilization**, store the product in sterile goods packaging as follows:

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

WARNING: Improper storage can lead to loss of sterilization—the manufacturer assumes no liability in this case.

Special Precautions: Pathogens of Transmissible Spongiform Encephalopathy

A comprehensive explanation of the necessary preventative measures with regard to agents of Transmissible Spongiform Encephalopathy (TSE) would go beyond the scope of this document.

It is assumed that pathogens of the Creutzfeldt-Jakob disease cannot be killed using normal disinfection and sterilization processes. Therefore, the standard methods for decontamination and sterilization are not sufficient if there is a risk of transferring Creutzfeldt-Jakob disease.

In general, only tissue with a low potential of TSE infection comes into contact with surgical instruments. In spite of this, special preventative measures must be taken for instruments which are used to treat patients with a known or suspected infection of TSE, as well as for patients at risk.

Reusability

If handled with the necessary care and remaining undamaged and unsoiled, the light guide cable can be reused up to 100 times. Using it beyond this limit or using damaged and/or soiled instruments is the responsibility of the user.

Cleaning, Disinfection and Sterilization of the PINPOINT Camera

The camera is classified as "**critical**" under the Spaulding classification. It **MUST** be used aseptically, using one of the following methods:

- Clean, disinfect and sterilize camera using NOVADAQ approved cleaning and sterilization cycles. This component must be thoroughly cleaned, disinfected and sterilized before each use; or
- Clean and disinfect camera. Cover unsterile camera with the sterile mini-Novadrape® and use in accordance with its Instructions for Use.

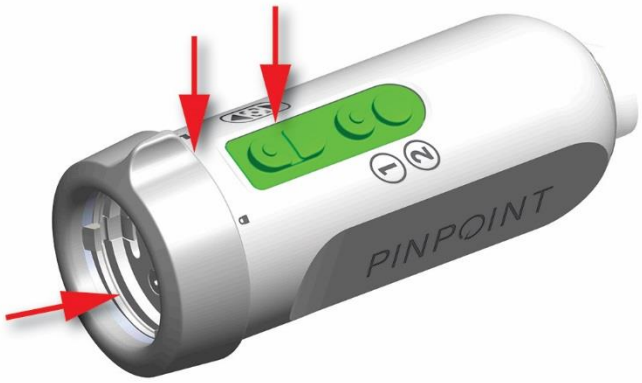
Preparation for Cleaning the Camera

WARNING: The camera must be cleaned and sterilized prior to the first use and after every subsequent use.

Note: If the camera-head connector or cap are contaminated with debris, clean using 70% ethyl or isopropyl alcohol.

1. Immediately after use, unplug the camera-head connector from the VPI and protect it using the cap. Place the cap over the connector ensuring that it is secure.
2. Rinse in running water (35 – 40 °C) to remove debris from the camera as soon as possible after surgical use.
3. Prepare an enzymatic detergent per manufacturer's recommendations using tap water at 35 – 40 °C.
4. Fully immerse the device in the prepared detergent and allow it to soak for a minimum of 15 minutes. During the 15-minute soak, use a syringe to flush the 3 areas indicated in **Figure 22**. Each area should be flushed a minimum of 5 times using a minimum of 50 ml of the prepared detergent per flush.

Figure 22 Cleaning of PINPOINT camera head



Cleaning the Camera

1. **Brush**

    a. Prepare a fresh batch of enzymatic detergent per manufacturer's directions using tap water at 35 – 40 °C.
    b. Fully immerse the camera in the fresh batch of prepared detergent and, using a soft-bristled brush, thoroughly scrub the camera. Pay special attention to areas where soil may accumulate.
    c. Using a syringe, flush the 3 areas indicated in **Figure 22**. Each area should be flushed a minimum of 5 times using a minimum of 50 ml of the prepared detergent per flush.
    d. Using soft-bristled brush, thoroughly scrub the 3 areas of the camera indicated in **Figure 22**. Each area should be thoroughly brushed 5 times.

2. **Rinse**

    a. Rinse the device with reverse osmosis/de-ionized (RO/DI) water at ambient temperature until all detergent residues are removed.
    b. Using a syringe, flush the areas indicated in **Figure 22**. Each area should be flushed a minimum of 5 times using a minimum of 50 ml of RO/DI water at ambient temperature.
    c. Drain excess water from the device and dry it using a clean cloth or pressurized air.
    d. Visually inspect the device for cleanliness, paying close attention to the 3 areas indicated in **Figure 22**. If visible soil remains, repeat steps 1 and 2.

3. **Soak**

    a. Prepare a pH-neutral non-enzymatic detergent per manufacturer's directions using tap water at 35 – 40 °C.
    b. Fully immerse the device in the prepared detergent and allow it to soak for a minimum of 15 minutes. During the 15-minute soak, use a syringe to flush the 3 areas indicated in **Figure 22**. Each area should be flushed a minimum of 5 times using a minimum of 50 ml of the prepared detergent per flush.

4. **Brush**

    a. Thoroughly brush the exterior of the device using a soft-bristled brush.
    b. Use a syringe to flush the 3 areas indicated in **Figure 22**. Each area should be flushed a minimum of 5 times using a minimum of 50 ml of the prepared detergent per flush.

5. **Rinse**

    a. Thoroughly rinse the device with RO/DI water until all detergent residues are removed.
    b. Use a syringe to flush the 3 areas indicated in **Figure 22**. Each area should be flushed a minimum of 5 times using a minimum of 50 ml RO/DI water at ambient temperature.
    c. Once all detergent residues are removed, continue to rinse for a minimum of 30 seconds.
    d. Drain the excess water from the device and dry it using a clean cloth or pressurized air.

Sterilizing the Camera

The camera is sterilized using the STERRAD® and STERIS® Sterilization System (hydrogen peroxide sterilization).

Note: See **Table 9** on page 57 for a summary of compatible sterilization methods.

1. Clean and prepare the camera as recommended in the “Preparation for the Cleaning of Camera” and “Cleaning the Camera” sections. Ensure that the cap is securely installed over the camera head connector.
2. Prior to sterilization, place the camera in a tray compatible with STERRAD® or STERIS® Systems. Please see ‘Warning’ Statement below.
3. Sterilize the camera using one of the following methods:
    - STERRAD® NX® Standard Cycle
    - STERRAD® NX® Advanced Cycle
    - STERRAD® 100NX® Standard Cycle
    - STERRAD® 100S Short Cycle
    - STERIS® V-PRO® 1
    - STERIS® V-PRO® 1 Plus
    - STERIS® V-PRO® maX

WARNING: Not all sterilization trays are compatible with STERRAD® or STERIS® systems. Using an incompatible tray may result in incomplete device sterilization. Consult the instructions that came with your sterilization tray to determine which sterilization method is compatible with your tray and devices. If a compatible tray is not available, the camera can be placed in a single STERRAD® ASP pouch prior to using the STERRAD® system or in a single STERIS® pouch prior to using the STERIS systems.

Sterilization Compatibility Summary

The following table shows the sterilization compatibility for laparoscopes, light guide cables, and PINPOINT camera. Compatible sterilization methods are indicated by ●.

Table 9: Sterilization Compatibility

Laparoscope	Gravity	Pre-vacuum	French Cycle	STERRAD® NX® Advanced Cycle	STERRAD® NX® Standard Cycle	STERRAD® 100NX® Standard Cycle	STERRAD® 100S Short Cycle	STERIS® V-PRO® Series*
SC9100		●		●	●	●	●	●
SC9130		●		●	●	●	●	●
SC9101	●	●	●	●	●	●	●	●
SC9131	●	●	●	●	●	●	●	●
SC9104	●	●	●	●	●	●	●	●
SC9134	●	●	●	●	●	●	●	●
SC9144	●	●	●	●	●	●	●	●
Light Guide Cable		●						
PINPOINT Camera				●	●	●	●	●

*includes STERIS® V-PRO® 1, STERIS® V-PRO® 1 Plus, STERIS® V-PRO® maX

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Appendix A: Troubleshooting

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

PINPOINT contains no user serviceable parts. Do not attempt to open PINPOINT components. Refer all servicing to a qualified NOVADAQ service representative.

For immediate assistance and to order parts, call NOVADAQ Customer Service and Technical Support at:

Email: customerservice@NOVADAQ.com
Phone: 1-800-844-NOVADAQ (1-844-668-2327)
Fax: 1-800-886-2419

Table 10 Troubleshooting

Symptom	Reason	Action
Operating mode does not change when PINPOINT mode button is pressed and released.	PINPOINT is in standby (illumination off) mode.	If PINPOINT is in standby (illumination off) mode: **1** Press the illumination button on the front panel of the VPI. **2** Press PINPOINT mode button on the camera head to change operating mode.
Display option does not change when display button is pressed and released.	PINPOINT is not in PINPOINT mode.	If PINPOINT is in white light operating mode: **1** Press the illumination button on the front panel of the VPI. **2** Press PINPOINT mode button on the camera head to change operating mode. If PINPOINT is in standby (illumination off) mode, see previous troubleshooting item.

Symptom	Reason	Action
"White balance failed" icon is displayed after attempting to white balance PINPOINT camera head.	PINPOINT was unable to adjust the color response of the camera head.	**1** Check that: **a.** Camera head and laparoscope are connected to the VPI. **b.** PINPOINT is in white light operating mode. **c.** The tip of the laparoscope is clean. **d.** The tip of the laparoscope is being held approximately 5 cm (2 inch) from a matte white surface such as gauze or white cloth when the white balance switch is pressed. **2** Retry the white balance. **3** If the white balance fails a second time, contact a qualified NOVADAQ service
An operating mode icon is displayed on the video monitor, but no video is displayed.	The VPI is not able to communicate with the camera head.	**1** Power off the VPI. ⚠ **CAUTION:** The camera head may be damaged if it is connected to or disconnected from the VPI while it is powered on. **2** Check that the camera cable is properly connected to the camera head and 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.
The video image is out of focus.	The focus adjustment on the camera head has not been set to the correct position.	Press the focusing buttons on the camera head until a clear image is achieved.
	The tip of the laparoscope is obstructed by foreign material	Clean the tip of the laparoscope.
Upon selecting the PINPOINT operating mode, the entire image appears to show a strong fluorescence signal.	A High-Definition laparoscope, not a Fluorescence Imaging laparoscope, is in use.	**1** Check the laparoscope in the camera. **2** If the laparoscope is not intended to provide ICG fluorescence imaging, exchange the laparoscope for a one capable of ICG fluorescence imaging.
The video image appears grainy or noisy.	The Sharpening value is too large.	**1** Check the Image Quality value for Sharpening using the option menu. **2** If the value is 5 or greater, reduce the value.

Symptom	Reason	Action
The video image appears too bright.	The Brightness value is too large	**1** Check the Image Quality value for Brightness using the option menu. **2** If the value is greater than 192, reduce the value.
The video image appears too dark.	The Brightness value is too small	**1** Check the Image Quality value for Brightness using the option menu. **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 too large	**1** Check the Image Quality value for the Red or Blue Saturation using the option menu. **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 in the vicinity of PINPOINT seems to malfunction when PINPOINT is powered on, but works normally when PINPOINT is powered off.	Radio frequency interference may be occurring between PINPOINT and the malfunctioning equipment.	**1** Check to see if any of the following resolve the problem: • Reorient or relocate PINPOINT or the equipment receiving the interference. • Increase the separation between PINPOINT and the equipment receiving the interference. • Connect PINPOINT to a power outlet on a different circuit from that to which the other equipment is connected. **2** If PINPOINT becomes unresponsive, and does not resume normal function after turning off and back on, stop using PINPOINT and contact a qualified NOVADAQ service representative.

Fuse Replacement Procedure

1. Unplug the power cord to the VPI.
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: Options Settings and Display Options

Image Quality Settings

The Image Quality settings available through the menu refer to adjustments to the displayed video to suit the user's needs or preferences.

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 camera.

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 Pinpoint imaging device 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 PINPOINT uses to set the scene brightness for viewing objects at different distances from the tip of the laparoscope. 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 end of the laparoscope. Background objects farther from the end of the laparoscope 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 end of the laparoscope. 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 end of the laparoscope. Balanced is the default setting and is suitable for most scenarios.

Default Profile

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

Table 11 Default Profile

Menu Item	Default
Display Options	White Light
	SPY
	PINPOINT
	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

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

- DSP version
- Boot version
- FPGA version

- LCB version
- VPI serial number
- Camera version
- Camera serial number

Display Options

During fluorescence imaging, PINPOINT offers up to four different video display options.

White-light Image

The White-Light display shows the visible light image with no display of the NIR fluorescence. NIR fluorescence is displayed in all other modes.

SPY Image

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

PINPOINT Image

The PINPOINT image display combines the white light image and the NIR fluorescence 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 fluorescence 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 fluorescence image at different imaging distances.

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Appendix C: Specifications and Standards

Table 12 VPI Specifications

Feature		Specification	
Light Sources	Spectrum	Visible (VIS)	Near infrared (NIR)
	Type	Light-emitting diode array	NIR laser diode
Inputs/Outputs	Video input signals	HD-SDI, DVI	
	HD Format	1080i 59.94	
	Picture elements	1920x1080	
	Service port I/O	RS-232 (via D-subminiature 9-pin connector)	
Operator Controls	Power On/Off	Back panel switch	
	Standby	Front panel button	
	White balance	Front panel button	
	White light/PINPOINT mode	Camera Head	
	Video display option	Camera Head	
Operating Environment	Operating temperature	+10 to +30°C	
	Relative humidity	10 to 85%RH	
Storage and Transport Environment	Humidity range (storage)	10 to 85%RH	
	Temperature range (storage)	-10 to +55°C	
	Humidity range (transport)	5 to 95%RH	
Physical	Dimensions	W 400 mm x H 200 mm x D 465 mm	
	Weight	13 kg	
Electrical Power	Voltage	100 – 240 V~	
	Power frequency	50/60 Hz	
	Power consumption	300 VA	

Table 13 Camera Specifications

Feature		Specification
Optical	Image sensors	CMOS HD sensor assembly
	HD format	1080p
	Aspect ratio	16:9
Physical	Dimensions	Diameter – 47 mm, Length – 115 mm
	Weight	240 g (without cable)
	Cable length	3 m
Environment	Operating temperature	+10 to +30°C
	Relative humidity	10 to 85%RH
	Storage temperature	-10 to +55°C
	Sterilization	STERRAD® NX® Standard Cycle STERRAD® NX® Advanced Cycle STERRAD® 100NX® Standard Cycle STERRAD® 100S Short Cycle STERIS® V-PRO® 1 STERIS® V-PRO® 1 Plus STERIS® V-PRO® maX

Table 14 10mm Laparoscope Specifications

Feature		Specification
Optical	Viewing angle	0° (Models SC9100, SC9101, SC9104) 30° (Models SC9130, SC9131, SC9134) 45° (Model SC9144)
	Field of view	70° (Models SC9100, SC9130) 75° (Models SC9101, SC9131, SC9104, SC9134, SC9144)
	Resolution	HD compatible
	Transmission spectrum	VIS (Models SC9101, SC9131) VIS + NIR (Models SC9100, SC9130, SC9104, SC9134, SC9144)
Physical	Outer diameter	10 mm
	Working length	320 mm (Models SC9104, SC9134) 323 mm (Models SC9144) 330 mm (Models SC9101, SC9131) 423 mm (Models SC9100, SC9130)
	Total length	410 mm (Models SC9104, SC9134) 413 mm (Models SC9144) 400 mm (Models SC9101, SC9131) 490 mm (Models SC9100, SC9130)
Environment	Operating temperature	+10 to +40°C
	Storage temperature	-40 to +70°C
	Sterilization	Autoclave (all models) STERRAD® & STERIS® (Models SC9101, SC9131, SC9104, SC9134, SC9144)

Table 15 Light Guide Cable Specifications

Feature		Specification
Optical	Transmission spectrum	Visible + NIR
Physical	Fiber diameter	4.9 mm
	Length	3 m
	Weight/length	125 g/m
Environment	Operating temperature	+10 to +40°C
	Storage temperature	-40 to +70°C
	Sterilization	Autoclave

Table 16 Equipment Classification

Feature	Specification	
Type of protection against electric shock	Class I	as per IEC 60601-1
Degree of protection against electric shocks	CF-type	
Degree of protection against moisture	Ordinary	
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 17 NIR Radiation and Source Characteristics

Feature		Specification
Apertures for NIR radiation emission		Laparoscope tip & light guide cable tip
Accessible NIR radiation (at the tip of the laparoscope)	Wavelength	805 nm
	Repetition rate	20 pulses/sec
	Energy output (maximum)	2 mJ/sec
	Beam divergence	75°± 5°
Embedded laser source	Classification	Class 4, invisible


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