

Firefly Imaging

System User Manual

Addendum



Copyright

©2022 Intuitive Surgical Operations, Inc. All rights reserved.

Trademarks

Intuitive, *Intuitive Surgical*, *da Vinci*, and *Firefly* are trademarks or registered trademarks of Intuitive Surgical. Product and brand names/logos are trademarks or registered trademarks of Intuitive Surgical or their respective owner. See www.intuitive.com/trademarks.

Rx only

Table of Contents

| | |
|--|-----------|
| Introduction | 4 |
| Indications for Use | 4 |
| Safety Information for Indocyanine Green | 4 |
| System Overview | 6 |
| System Components | 7 |
| Indicators | 7 |
| Firefly Imaging Operation | 12 |
| Connecting the Endoscope to the Endoscope Controller | 12 |
| Select the Visualization Mode | 13 |
| Adjust Image | 18 |
| Sensitive Mode Operation | 23 |
| Select Sensitive Mode | 24 |
| Adjust Image in Sensitive Mode | 28 |
| Instrument Function During Sensitive Mode | 31 |
| Sensitive Mode Signal and Working Distance | 31 |
| Troubleshooting and Service | 32 |
| Troubleshooting | 32 |
| Firefly Laser Test Procedure | 34 |
| Customer Service | 34 |
| Safety and Symbols | 35 |
| Safe Use | 35 |
| Symbols and Icons | 36 |

Introduction

This addendum to the *da Vinci Xi System User Manual* and the *da Vinci X System User Manual* provides details specific to the Firefly Imaging System.

-
- Note:** Aspects of the da Vinci Firefly Imaging System not addressed in this document are the same as for the da Vinci Vision system. For details, refer to the applicable system user manual, including current addenda, if any.
 - Note:** All da Vinci instruments and accessories are compatible with both the da Vinci systems.
-

This addendum to the user manual presents representative images of the system, instruments, accessories, and user interface. The representative images provide instruction on the use of the product. In some cases, the aesthetics or dimensions of the device shown in the representative images may be different from the product in use.

Indications for Use

Upon intravenous administration and use of an ICG drug product consistent with its approved label, the da Vinci Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the da Vinci Firefly Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration and use of an ICG drug product consistent with its approved label, the da Vinci Firefly Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Safety Information for Indocyanine Green

The da Vinci Firefly Imaging System is restricted for use only with legally-marketed indocyanine green (ICG) imaging agent that has indications for use consistent with its approved label and indications for use with a fluorescence imaging device.

-
- Note:** For information on the imaging agent precautions, warnings, and contraindications, refer to the imaging agent labeling.
-

ICG Contraindications

Indocyanine green is contraindicated in patients with a history of hypersensitivity to indocyanine green. Reactions have included anaphylaxis.

ICG Warnings and Precautions

For information on imaging agent precautions, warnings, and contraindications, refer to the imaging agent labeling.

**WARNING:**

Hypersensitivity reactions including anaphylaxis, urticaria, and deaths due to anaphylaxis have been reported following intravenous administration of indocyanine green. Always have cardiopulmonary resuscitation personnel and equipment readily available and monitor all patients for hypersensitivity reactions.

Because indocyanine green contains iodine, the iodine-binding capacity of thyroid tissue may be reduced for at least one week following administration. Do not perform radioactive iodine uptake studies for at least a week following administration of indocyanine green.

System Overview

The Firefly Imaging System consists of a near-infrared laser located in the Endoscope Controller and an endoscope (0° or 30°). All da Vinci endoscopes and Endoscope Controllers are capable of visible light and Firefly imaging. The Firefly Imaging System uses near-infrared light in conjunction with the imaging agent Indocyanine Green (ICG), to create fluorescent images of tissue. ICG is administered to the patient and the system is switched to Firefly imaging. Two modes are available in Firefly imaging: Standard mode and Sensitive mode.

Only use ICG at indicated doses and concentrations as defined in the imaging agent labeling.

 **Note:** Firefly Sensitive mode is not available with all endoscopes. Contact your Intuitive representative for additional information.

In Standard mode, the system displays the resulting images as a fluorescent (green) overlay on a black and white background image. In Sensitive mode, the black-and-white background is no longer illuminated, resulting in increased sensitivity to fluorescent signal.

The surgeon can switch into Firefly imaging using the hand controls at the Surgeon Console, view fluorescence, and switch back to visible light (white light) mode and manipulate the tissue.

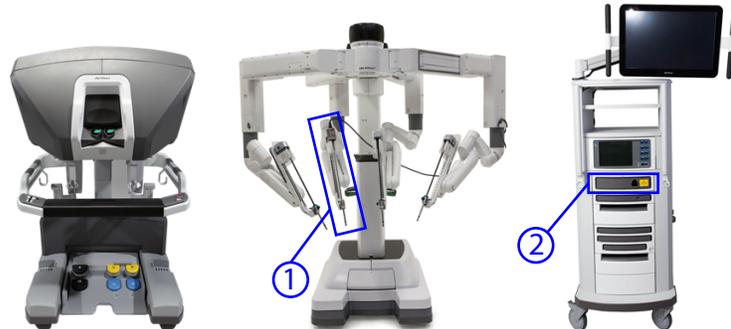
 **Note:** For information on preparation and administration of ICG, refer to the imaging agent labeling.

 **Note:** Spilled blood or other body fluids containing ICG in the surgical field can maintain their fluorescence for the duration of the procedure.

 **WARNING:** Factors such as dosing of the imaging agent, timing of the imaging agent administration, working distance, fluorescence visualization mode, fluorescence visualization settings, are variables that affect the quality of the image. Adjustments may be required to obtain a satisfactory image. Information obtained through the use of Firefly imaging should be used in combination with other clinically relevant information when planning or providing alternative or additional interventions. Failure to observe this warning may result in misidentification of critical anatomical structures or misinterpretation of tissue characteristics.

System Components

Figure 1 da Vinci system with Firefly imaging components (example)



1. 0 degree or 30 degree surgical endoscope
2. Endoscope Controller



Note: The Firefly Imaging System is a fully integrated part of the da Vinci Surgical System (da Vinci system). For information on topics not addressed in this document, refer to the applicable system user manual.



WARNING: Only use the system with a compatible endoscope. Do not connect the endoscope to a third-party device. Failure to observe this warning presents risk of exposure to laser energy that could result in injury to the operator or the patient, and could cause improper functioning.



WARNING: Use of Firefly fluorescence imaging depends on illumination coming only from da Vinci endoscopes; any external or additional light sources may lead to poor imaging quality, which can result in inaccurate interpretation of the image and subsequent tissue damage. The da Vinci Firefly Imaging System is a fully integrated part of the da Vinci surgical system, and is for use only with these systems. It is not intended for use with any other surgical imaging systems.

Indicators

Endoscope Controller

The front of the Endoscope Controller has the following three LED indicators:

- The Endoscope Controller LED indicates the power status of the Endoscope Controller.

Table 1 Endoscope Controller

| Endoscope Controller LED | Status |
|--------------------------|-------------------|
| Off | No Power |
| Red | Failure |
| Blue, Flashing | Powering up |
| Blue, Steady | Powered and ready |

- The Endoscope Cable Connection LED indicates when an endoscope is connected and ready for use.

Table 2 Endoscope Cable Connection

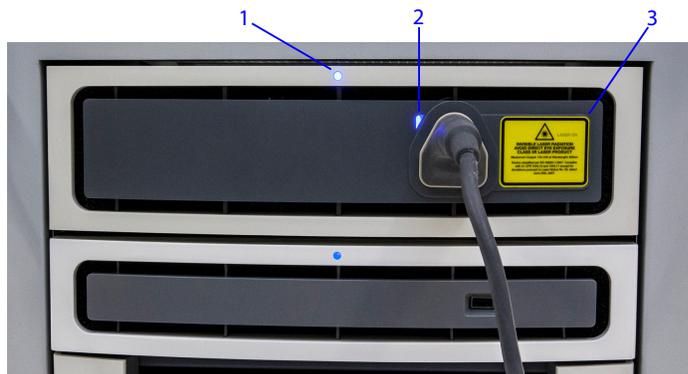
| Endoscope Cable Connection LED | Status |
|--------------------------------|---|
| Off | Endoscope is not connected, or Endoscope is attached to arm |
| Blue, Steady | Endoscope is connected and ready |

- The Laser Safety Label LED illuminates "LASER ON" when Firefly imaging is activated .

Table 3 Laser Safety Label

| Laser Safety Label LED | Status |
|------------------------------|----------------------------------|
| Off, Text is not illuminated | Firefly imaging is not activated |
| On, Text is illuminated | Firefly imaging is activated |

Figure 2 Endoscope Controller front panel



- Endoscope Controller LED
- Endoscope Cable Connection LED
- Label: Laser On indicator (example)

Figure 3 Laser safety label (example)

1. "LASER ON" illuminates when Firefly imaging is active

Endoscope Indicators

Endoscope Laser Aperture Label

The endoscope laser aperture label points in the direction that laser light is emitted.

Figure 4 Laser aperture label (example)

1. Laser Aperture label

Endoscope LED

The Endoscope LED indicates connection to the Endoscope Controller.

Figure 5 Endoscope LED (example)

1. Endoscope LED

**Table 4** Endoscope LED

| Endoscope LED | Status |
|-----------------|--|
| Off | Endoscope is not connected to the Endoscope Controller. |
| Green, Flashing | Endoscope is connected to the Endoscope Controller and the system is loading calibration data. |
| Green, Steady | Endoscope is connected to the Endoscope Controller and calibration data is fully loaded. |

Laser On LED

When Firefly imaging is active, the “LASER ON” LED indicator (Figure 6) on the back of the endoscope illuminates a solid green color. This indicates that the endoscope tip is emitting laser light. The illumination from the tip of the endoscope visually appears blue in color in Standard mode. There is no visible illumination from the tip in Sensitive mode.

⚠ WARNING: Avoid looking into the tip of the endoscope when the LASER ON indicator is lit green. Invisible near-infrared laser light is being emitted from the tip. Failure to observe this warning could result in eye injury.

Figure 6 LASER ON indicator

1. LASER ON indicator

**Table 5** Laser ON Indicator

| Laser Safety Label LED | Status |
|-----------------------------|----------------------------------|
| Off, LED is not illuminated | Firefly imaging is not activated |
| On, LED is illuminated | Firefly imaging is active |

Surgeon Console 3D Viewer and Vision Cart Touchscreen

On the Surgeon Console 3D viewer and the Vision Cart touchscreen, the “LASER ON” indicator is displayed when Firefly imaging is active.

Figure 7 User interface LASER ON indicator

Firefly Imaging Operation

WARNING: Ensure adequate illumination of the operative field while using fluorescence imaging modes. Failure to do so may lead to false positive interpretation of the image, which can result in ischemia, or false negative interpretation of the image that can result in unplanned removal of healthy tissue.

Connecting the Endoscope to the Endoscope Controller

The light guide and endoscope communication signals are integrated into a single cable that is permanently attached to the endoscope. The endoscope cable connects directly to the Endoscope Controller on the Vision Cart to provide communication and illumination to the endoscope.

1. If not already done, remove the cover from the connector.

Note: The part of the connector that is under the sterilization cover is not sterile. Sterile users should not handle the end of the connector once the sterilization cover has been removed.

2. Plug the endoscope connector into the Endoscope Controller.

Figure 8 Plug the connector into the Endoscope Controller



In Standard mode, the Endoscope Controller produces invisible (near-infrared) laser energy as well as a blue-tinted visible light. In Sensitive mode, the Endoscope Controller produces only invisible (near-infrared) laser energy. See [Sensitive Mode Operation](#) on page 23 for information about Sensitive mode.

Note: The endoscope must be sterilized before each use according to the Reprocessing Instructions and handled only by a person prepared to work in the sterile field. For more information about reprocessing, refer to the applicable reprocessing manual.

Note: The Endoscope Controller does not output light unless an endoscope is connected. It is not possible to verify illumination functionality without an endoscope connected to the Endoscope Controller.

 **Note:** Keep the light guide connector clean at all times. Contaminants on the light guide connector may cause overheating.

 **WARNING:** The Endoscope Controller receptacle has a spring-loaded shutter designed to prevent light from exiting the receptacle if no connector is installed. If you observe light coming from the receptacle while no light guide is installed, do not look directly into the receptacle. Avoid direct eye exposure as directed by the yellow warning label on the front of the Endoscope Controller, to prevent eye injury (see [Light Safety](#) on page 35).

Select the Visualization Mode

Users can change between visible light and Firefly (near-infrared) imaging at both the Surgeon Console touchpad and the Vision Cart touchscreen. Firefly imaging (Standard mode and Sensitive mode) is also deactivated automatically when the endoscope is detached from the arm; the system reverts to visible light imaging.

 **WARNING:** To prevent user confusion, follow instructions to enter and exit fluorescence mode.

 **WARNING:** To minimize exposure to laser energy that could result in eye injury to operator or patient, deactivate Firefly imaging when removing the endoscope from the patient.

 **CAUTION:** Use default settings if visualization is sufficiently reduced in an advanced imaging mode to prevent tissue damage.

 **CAUTION:** Follow the provided instructions for safe and effective use of advanced imaging features, including reverting the system to visible light imaging for sufficient surgical visualization to prevent tissue injury.

 **Note:** Before delivering the ICG into the patient, locate the target anatomy in visible light mode and then activate Firefly imaging.

Firefly Settings Overview

On the Surgeon Console touchpad Settings tab, the Firefly section enables the surgeon to activate Firefly and configure Firefly imaging controls:

- Restore Firefly to Factory Defaults
- Firefly Mode (OFF/ON)
- Firefly Fingerswitch
- Firefly Intensity
- Background Brightness
- Sensitive Mode

 **Note:** Sensitive mode is not available with all endoscopes. Contact your Intuitive representative for additional information.

 **Note:** See [Sensitive Mode Operation](#) on page 23 for specific instructions on activating and using Firefly imaging in Sensitive mode.

On the Surgeon Console touchpad Instrument tab, in the endoscope arm pod, the surgeon can activate Firefly and adjust background brightness.

On the Vision Cart touchscreen Display tab, the surgeon can activate Firefly and adjust the Firefly image:

- Firefly OFF/ON
- Firefly Intensity
- Background Brightness

Activate Firefly at Surgeon Console

The Firefly Imaging System can be activated on the Surgeon Console using the touchpad or the hand control (master) finger clutches (switches).

i Note: By default, the hand control finger clutches are not enabled to toggle between visible light and Firefly imaging while you press the endoscope control pedal. The ability to use the hand control finger clutches to toggle between visible light and Firefly imaging is set up at the Surgeon Console touchpad. For details on setting up and using the hand control finger clutches, see the section [Toggle Between Firefly and Visible Light Imaging](#) on page 16.

Surgeon Console Touchpad - Settings Tab

1. Touch the **Settings** tab.

Figure 9 Touch the Settings tab

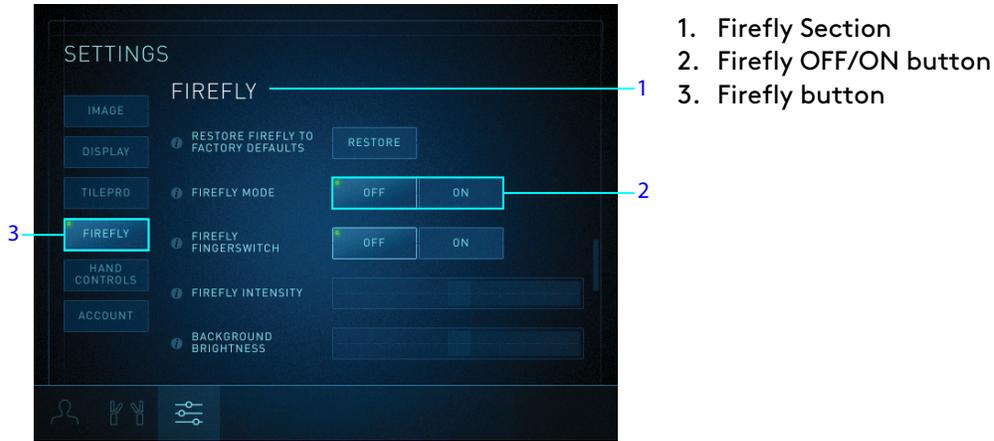


1. Settings Tab

2. Touch the **Firefly** button or scroll to view the Firefly section ([Figure 10](#)).

3. Touch the **Firefly Mode ON** button. If Firefly is already activated, touching the **OFF** button deactivates Firefly and the system reverts to visible light imaging.

Figure 10 Surgeon Console Firefly Mode OFF/ON button

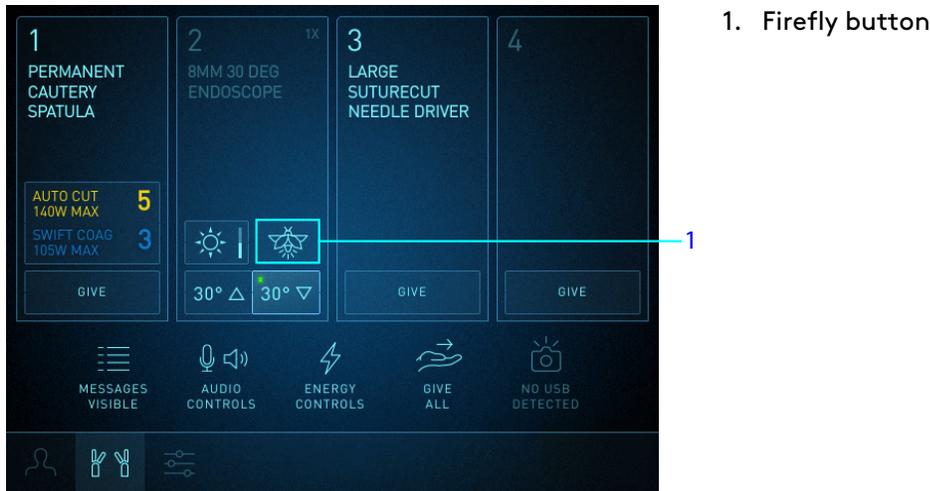


1. Firefly Section
2. Firefly OFF/ON button
3. Firefly button

Surgeon Console Touchpad - Endoscope Arm Pod

To activate or deactivate Firefly on the Instrument tab endoscope arm pod, touch the **Firefly** button.

Figure 11 Surgeon Console Firefly button on endoscope arm pod



1. Firefly button

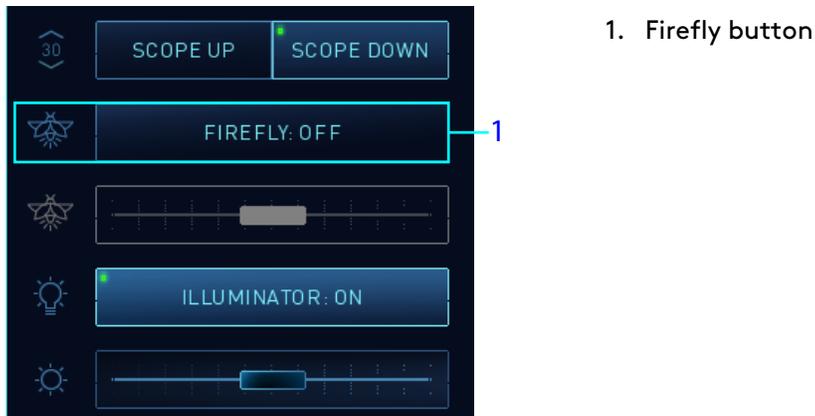
Activate Firefly at Vision Cart

1. Touch the **Display** tab on the Vision Cart touchscreen.



2. Touch the **Firefly OFF** button. If Firefly is already activated, touching the **ON** button deactivates Firefly.

Figure 12 Vision Cart Firefly OFF/ON button



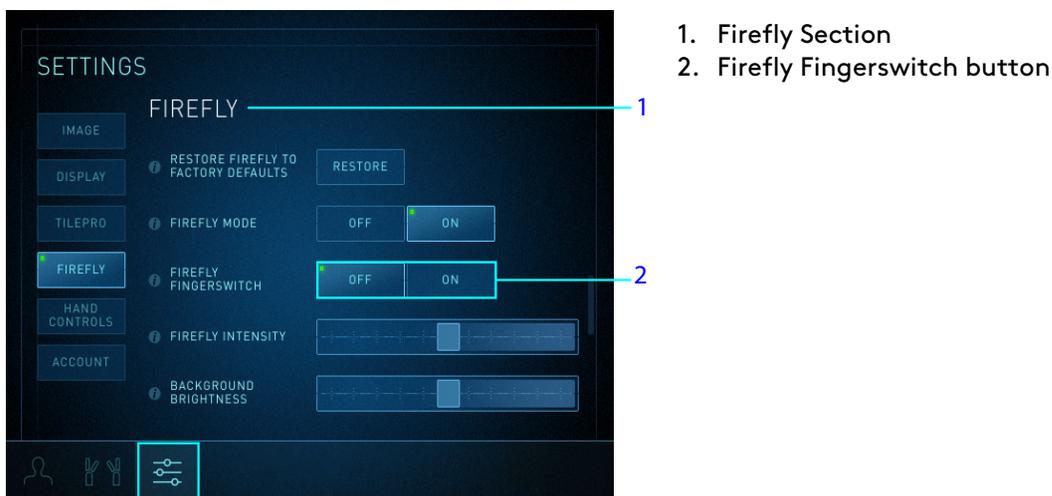
Toggle Between Firefly and Visible Light Imaging

Firefly Fingerswitch

The ability to use the hand control finger clutches to toggle between visible light and Firefly imaging is set at the Surgeon Console touchpad.

1. Touch the **Settings** tab, then touch the **Firefly** button or scroll to view the **Firefly** section.
2. Touch the **Firefly Fingerswitch** button **OFF** or **ON**.

Figure 13 Firefly Fingerswitch control

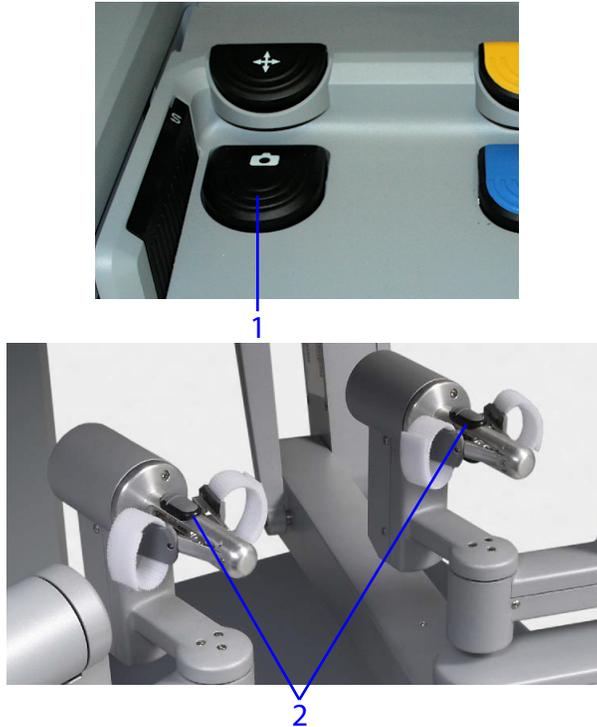


When the **Firefly Fingerswitch** button is ON, the surgeon can toggle between visible light imaging and Firefly imaging by using the endoscope control pedal and the hand control finger clutches.

Hand Control Finger Clutches

While pressing and holding the endoscope control pedal, use the finger clutches on either of the hand controls to toggle between visible light imaging and Firefly imaging.

Figure 14 Switching modes at Surgeon Console



1. Press endoscope control pedal
2. Use hand control finger clutches to toggle between visible light and Firefly imaging

Deactivate Firefly on the Endoscope

Illumination On/Off Button

Pressing and holding the illumination button on the endoscope (Figure 15) turns off all illumination. The system only responds to a long press (that is, longer than one second) of the button and ignores momentary presses.

The illumination button only functions when the endoscope is detached from a system arm. If Firefly imaging is active, and the endoscope is not on the arm, pressing and holding this button turns off all illumination. Pressing the button again activates visible light imaging.

The illumination button cannot be used to activate Firefly imaging. In order to activate Firefly imaging, use the **Firefly OFF/ON** button on either the Surgeon Console touchpad or the Vision Cart touchscreen.

Table 6 Illumination Button

| Illumination State | Press and Hold Button |
|----------------------|--|
| Visible light is ON | Visible light turns OFF |
| Firefly ON | Visible light and near-infrared light turn OFF |
| Visible light is OFF | Visible light turns ON |

Figure 15 Illumination On/Off button (example)



1. Illumination On/Off

Adjust Image

The brightness and intensity (contrast) of the Firefly image can be adjusted on both the Surgeon Console touchpad and the Vision Cart touchscreen.

To improve the image from a weak signal, increase intensity and decrease background brightness.

i Note: Although the same brightness slider is used for both visible light and Firefly imaging, the system remembers separate settings for each mode. When Firefly imaging is activated and deactivated, the brightness slider remains in the position that it was in when it was last adjusted.

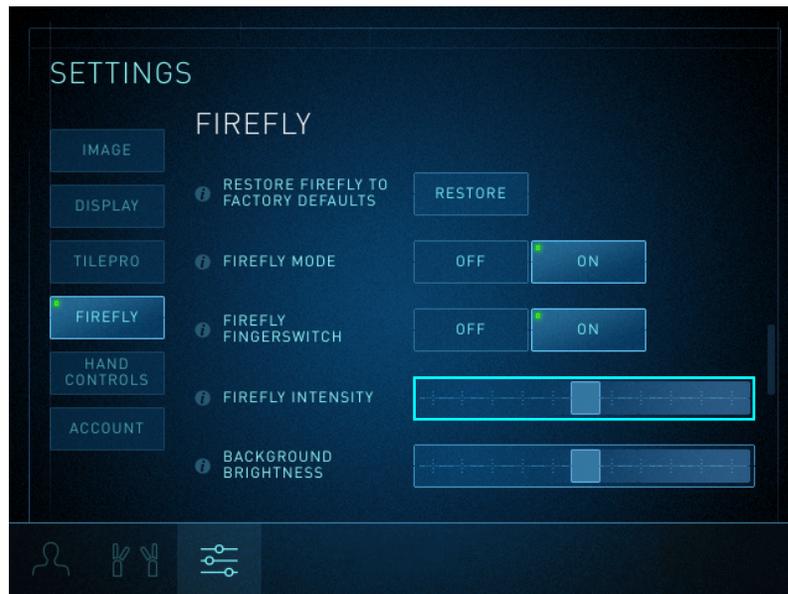
Image Adjustment on Surgeon Console

Firefly Intensity Slider

The Firefly Intensity slider adjusts the visibility of the green fluorescing image relative to the non-fluorescing image (black and white). This slider is enabled in Firefly imaging and disabled when the system is in visible light mode (when Firefly is deactivated).

1. Touch the **Settings** tab, then touch the **Firefly** button or scroll to view the **Firefly** section.
2. Drag the **Firefly Intensity** slider to adjust the intensity of the green fluorescence. Moving it to the right increases the intensity of the fluorescence (appears more saturated).

Figure 16 Surgeon Console Firefly Intensity slider



Background Brightness Slider

To adjust image background brightness when Firefly is activated, use the Background Brightness slider on the Instrument tab endoscope arm pod or the Background Brightness slider in the Firefly section of the Settings tab.

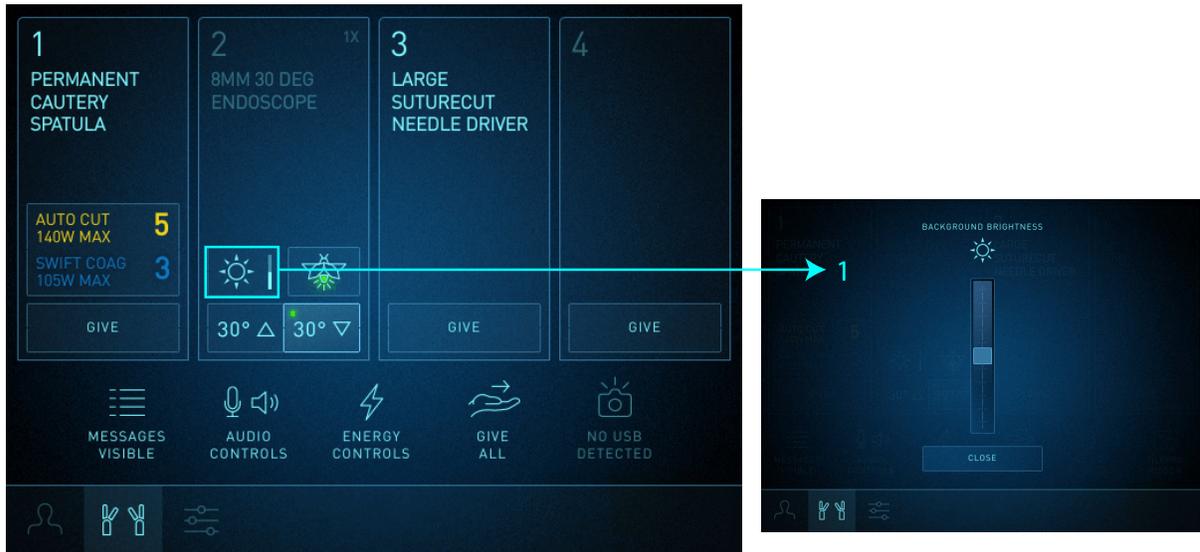
On the Instrument tab, the Background Brightness slider is used to adjust background brightness in Firefly imaging. For information about adjusting image brightness in visible light mode, refer to the applicable system user manual.

On the Instrument tab, with Firefly activated (the tip of the Firefly button icon is lit green):

1. Touch the **Brightness** button on the endoscope arm pod (Figure 17).
The Brightness screen opens.
2. Drag the **Background Brightness** slider to adjust brightness of the image. Moving it up increases brightness.

3. Touch **Close** to exit the Brightness screen.

Figure 17 Instrument Tab Brightness slider

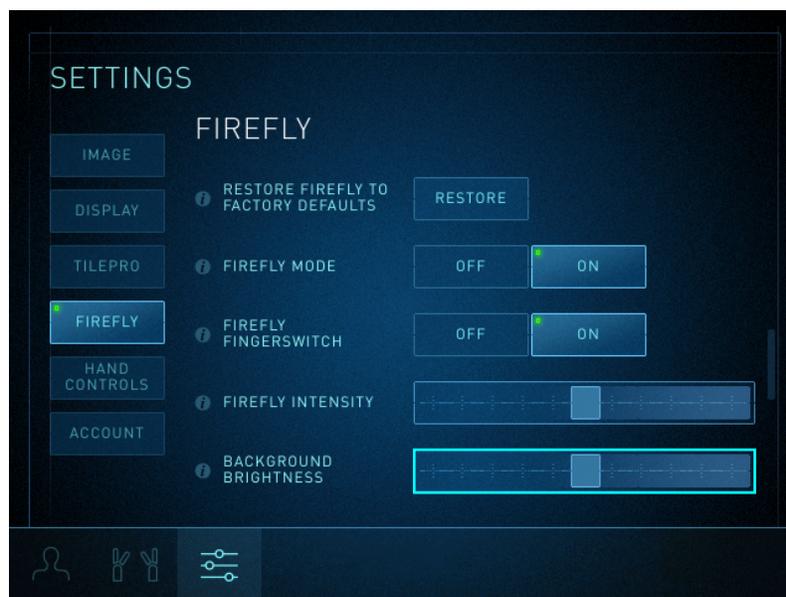


1. Background Brightness screen

In the Firefly section of the **Settings** tab when Firefly is activated:

1. Touch the **Settings** tab, then touch the **Firefly** button or scroll to view the Firefly section.
2. Drag the **Background Brightness** slider to adjust the brightness of the image. Moving it to the right increases brightness.

Figure 18 Firefly Background Brightness slider



Restore Settings to Factory Defaults

The following Firefly settings can be reset to factory default values.

- Brightness: 50% (of full slider value)
- Firefly Intensity: 50% (of full slider value)
- Firefly Background Brightness: 50% (of full slider value)

In the Firefly section of the Settings tab when Firefly is activated:

1. Touch the **Settings** tab, then touch the **Firefly** button or scroll to view the Firefly section (Figure 19).
2. Touch **Restore**.

For information about all of the system settings that can be reset to factory values, refer to the applicable system user manual.

Figure 19 Restore Firefly to factory defaults button



Image Adjustment on Vision Cart Touchscreen

Firefly Intensity Slider



Touch the **Display** tab and move the **Firefly Intensity** slider to change the contrast between the fluorescing image and non-fluorescing image. This slider is disabled in visible light mode.

Figure 20 Vision Cart Firefly Intensity slider

1. Firefly Intensity slider

Brightness Slider



On the **Display** tab, move the Brightness slider to change the background brightness when Firefly is activated. This slider also adjusts image brightness in visible light mode (when Firefly is deactivated).

Figure 21 Vision Cart Brightness slider

1. Brightness slider

Sensitive Mode Operation

 **Note:** Sensitive mode is not available with all endoscopes. Contact your Intuitive representative for additional information.

Sensitive mode increases the fluorescent sensitivity of the Firefly Imaging System, which enables visual detection of lower concentrations of fluorescent imaging agents. Sensitive mode increases the sensitivity by turning off the illumination used to create the gray scale (black and white) background images observed in Standard mode. In addition to removing the black-and-white background, the gain applied to the fluorescent image can be increased, resulting in a more vibrant, green fluorescent image (Figure 22).

 **WARNING:** Use of Firefly fluorescence imaging depends on illumination coming only from da Vinci endoscopes; any external or additional light sources may lead to poor imaging quality. The da Vinci Firefly Imaging System is a fully integrated part of the da Vinci surgical system, and is for use only with these da Vinci systems. It is not intended for use with any other surgical imaging systems.

 **WARNING:** Follow all instructions and warnings to safely and effectively use the system lasers for targeting and Firefly, to prevent eye injury.

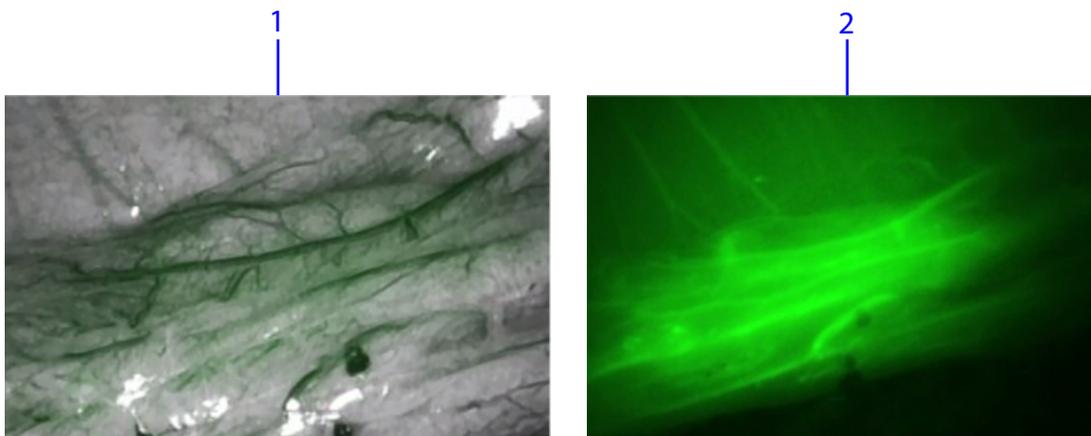
 **CAUTION:** To prevent patient tissue damage or patient harm, do not use da Vinci Firefly and Sensitive Firefly with external surgical imaging systems.

 **CAUTION:** Follow safe and effective use of Sensitive Firefly and its imaging adjustments, which could result in unplanned removal of healthy tissue. Improper use of Sensitive Firefly imaging adjustments may result in:

- insufficient surgical visualization
- reduced visibility of tissues or surgical tools
- reduced visibility of small volumes of dye and "False Negatives"
- inability to differentiate true fluorescent signal from background autofluorescence or sensor noise

 **CAUTION:** Follow the provided instructions for safe and effective use of advanced imaging features, including reverting the system to visible light imaging for sufficient surgical visualization to prevent tissue injury.

Figure 22 Image in Firefly Standard mode and in Sensitive mode (example)



1. Standard mode
2. Sensitive mode

Select Sensitive Mode

When the appropriate endoscope is installed, the Sensitive Mode option is available at the bottom of the Firefly section of the Settings tab.

- i** **Note:** The Show Controls button on the Surgeon Console must be enabled in order to activate Sensitive mode at either the Surgeon Console or the Vision Cart. After Show Controls is enabled, the setting is saved to the user profile.

Activate Sensitive Mode at Surgeon Console

Surgeon Console Touchpad - Settings Tab

1. In the Firefly section of the Settings tab, scroll down and touch the **Show Controls** button in the Sensitive Mode option (Figure 23).

The Show Controls button changes to Hide Controls, and the Sensitive mode options are displayed (Figure 24):

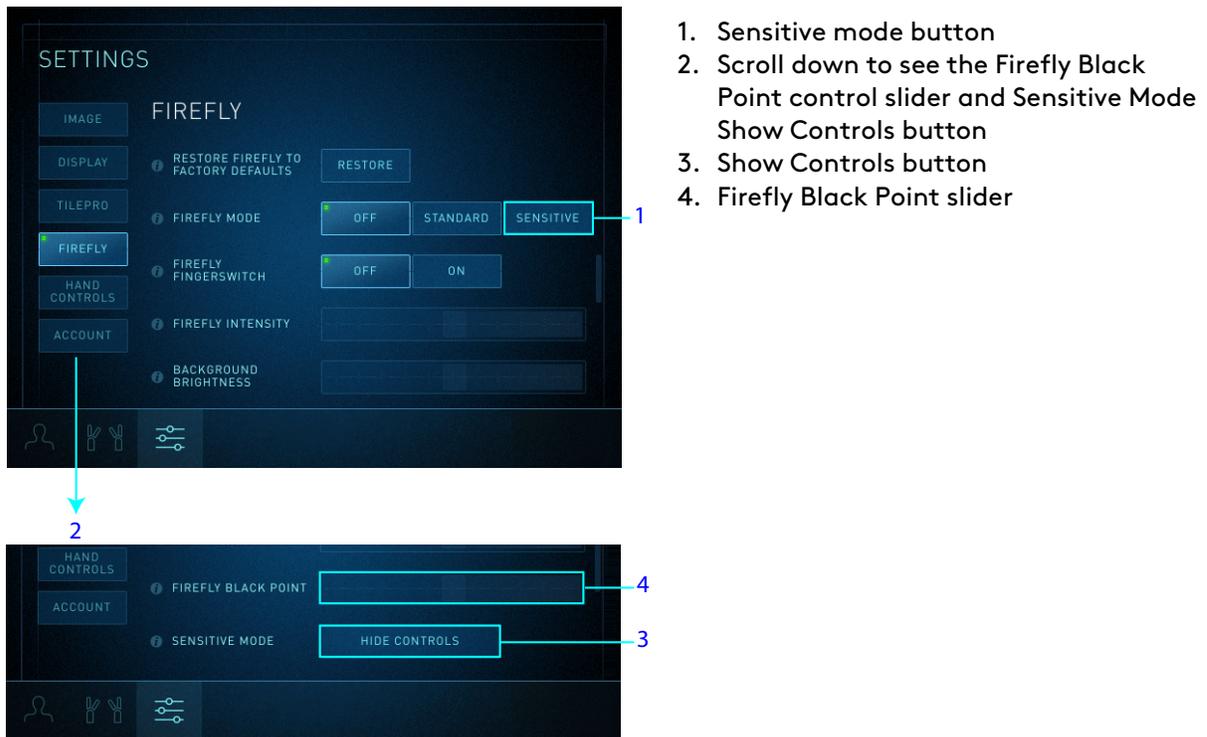
- Firefly Mode: Cycles among OFF (turn off Firefly), Standard mode, and Sensitive mode. Turning off Firefly reverts to visible light imaging.
- Firefly Black Point control slider: Adjusts the minimum level of the green fluorescent signal that is displayed to enhance the appearance of weak fluorescent signals. Available only in Sensitive mode.

Figure 23 Touch the Show Controls button



1. Show Controls button

Figure 24 Sensitive mode options

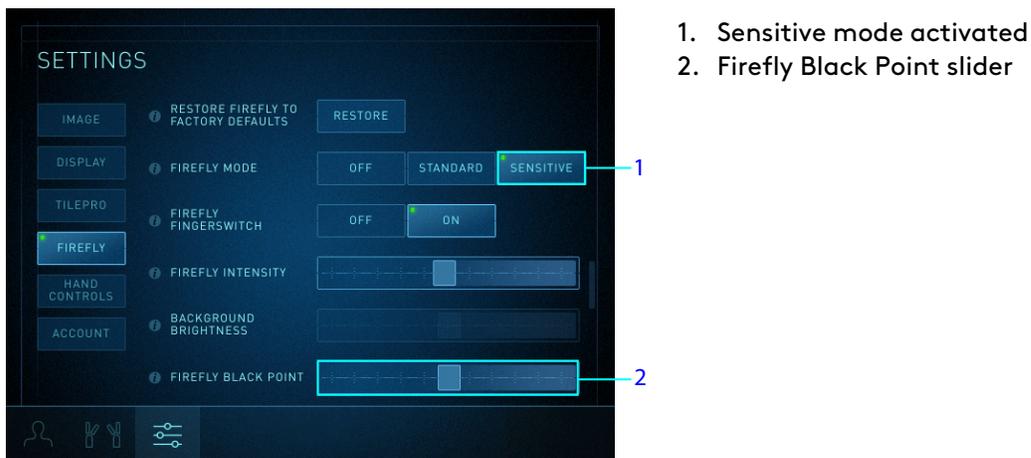


Note: Touching Hide Controls while in Sensitive mode reverts Firefly imaging to Standard mode.

2. Touch the **Sensitive** button to activate Sensitive mode (Figure 25).

Firefly Intensity and Firefly Black Point controls are enabled. Background Brightness is not applicable in Sensitive mode, so the slider is disabled.

Figure 25 Firefly intensity and Firefly Black Point are enabled

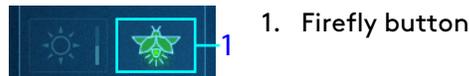


Surgeon Console Touchpad - Endoscope Arm Pod

1. In the Firefly section of the Settings tab, scroll down and touch the **Show Controls** button in the Sensitive Mode option.
2. On the Instrument tab endoscope arm pod, touch the **Firefly** button to cycle among OFF (turn off Firefly and revert to visible light imaging), Standard mode, and Sensitive mode.

In Sensitive mode, the Firefly button icon is completely lit green (Figure 26), and the Brightness button is disabled. The following example shows the Surgeon Console Firefly button while in Sensitive mode (on endoscope arm pod).

Figure 26 Firefly button — completely lit green in Sensitive mode



1. Firefly button

Activate Sensitive Mode at Vision Cart

1. On the Surgeon Console touchpad, in the Firefly section of the Settings tab, scroll down and touch the **Show Controls** button in the Sensitive Mode option.
2. Touch the **Display** tab on the Vision Cart touchscreen.



3. Touch the **Firefly** button to cycle among OFF (turn off Firefly and revert to visible light imaging), Standard mode, and Sensitive mode. In Sensitive mode, the Brightness slider is disabled.

Figure 27 Vision Cart Firefly button, in Sensitive mode (example)



1. Firefly button

Activate Sensitive Mode Using Hand Controls

Firefly Fingerswitch

The ability to use the hand control finger clutches to cycle between visible light and the Firefly modes is set at the Surgeon Console touchpad.

Touch the **Firefly Fingerswitch** button to ON. When this button is ON, the surgeon can cycle among OFF (turn off Firefly and revert to visible light imaging), Standard mode, and Sensitive mode by using the endoscope control pedal and the hand control finger clutches.

Figure 28 Firefly Fingerswitch control, in Sensitive mode (example)



1. Firefly Fingerswitch button

Hand Control Finger Clutches

While pressing and holding the endoscope control pedal, use the finger clutches on either of the hand controls to cycle among OFF (turn off Firefly and revert to visible light imaging), Standard mode, and Sensitive mode. See [Hand Control Finger Clutches](#) on page 17.

Adjust Image in Sensitive Mode

In Sensitive mode, the Firefly Intensity slider adjusts the visibility of the green fluorescent image relative to the non-fluorescing image (black background). It also increases or decreases the overall brightness of the Sensitive mode image. This slider is disabled in visible light mode.

The Firefly Black Point control slider adjusts the minimum level of the green fluorescent signal that is displayed.



CAUTION: Sensitive Firefly image adjustment selections (Firefly Intensity slider and Firefly Black Point slider) may reduce the visibility of tissue and surgical tools, which could result in unplanned removal of healthy tissue. Instrument motion or the Standard Firefly image adjustment selection increases the brightness of the surgical image during fluorescence imaging.



Note: Background Brightness adjustment is not available in Sensitive mode.

Image Adjustment on Surgeon Console

Firefly Intensity Slider

Drag the **Firefly Intensity** slider to adjust the intensity of the green fluorescent signal. Moving it to the right progressively increases the intensity of the fluorescent signal (appears more saturated).

Figure 29 Surgeon Console Firefly Intensity slider, in Sensitive mode (example)



1. Firefly Intensity slider

See [Firefly Imaging Operation](#) on page 12 and [Image Adjustment on Surgeon Console](#) on page 19 for general instructions on using the Firefly Intensity slider on the Surgeon Console touchpad.

Image Adjustment on Vision Cart Touchscreen

Firefly Intensity Slider



Touch the **Display** tab and move the **Firefly Intensity** slider to adjust the intensity of the green fluorescing image and change the contrast between the fluorescing image and non-fluorescing image. This slider is disabled in visible light mode.

Figure 30 Vision Cart Firefly Intensity slider, in Sensitive mode (example)



1. Firefly Intensity slider

See [Firefly Imaging Operation](#) on page 12, and [Image Adjustment on Vision Cart Touchscreen](#) on page 21 for general instructions on using the Firefly Intensity slider on the Vision Cart touchscreen.

Firefly Black Point

Note: Firefly Black Point control is available only in Sensitive mode.

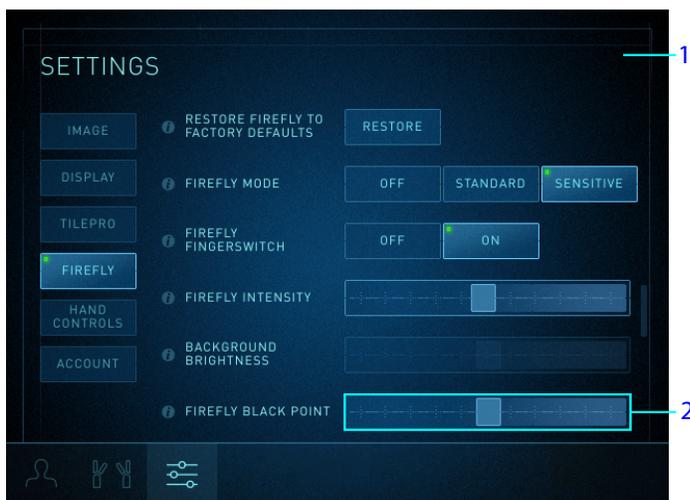
The Firefly Black Point slider adjusts the minimum level (threshold) of the green fluorescent signal that is displayed. It can improve the signal-to-noise ratio when observing features with low fluorescent signals.

Use of the Firefly Black Point slider at higher settings may reduce visibility of low fluorescent signals in order to improve signal-to-noise ratios, which could result in unplanned removal of healthy tissue. To make sure you have a sufficient view of low fluorescent signals, adjust the Firefly Black Point slider across a broad range of settings before you select a specific setting.

Scroll down within the Firefly section of the Settings screen until the Firefly Black Point slider is visible ([Figure 31](#)). Moving the slider to the right increases the threshold, hiding low fluorescent signals. Moving the slider to the left shows more fluorescent signals.

- When the Firefly Black Point slider is set to 0%, all fluorescent signals are displayed (more green, less black background).
- When the Firefly Black Point slider is set to 100%, weak fluorescent signals are filtered out (less green, more black background) to reduce background noise and unwanted reflection of near-infrared illumination.

Figure 31 Firefly Black Point slider



1. Scroll down to view Firefly Black Point slider
2. Firefly Black Point slider

Instrument Function During Sensitive Mode

Instrument Motion

Most anatomy is not visible in Sensitive mode. If instruments are in motion while Sensitive mode is selected, the system automatically switches to Standard mode, the black-and-white background displays, and the intensity of the Sensitive mode fluorescent signal decreases. This will happen, for example, if:

- One or more instruments are actively controlled from either console
- Instrument clutch or port clutch is activated on one or more instrument arms
- Integrated table motion is enabled

See [Select Sensitive Mode](#) on page 24 for instructions on how to return to Sensitive mode.

Pedal Functions



CAUTION: Electrocautery, suction irrigation, and advanced instrument functions are disabled when Sensitive mode is active, to prevent patient tissue damage. Disabled functions include:

- Firing energy instruments, including monopolar and bipolar cautery, and vessel sealers
- Firing or clamping of staplers
- Activation of suction irrigators

Sensitive Mode Signal and Working Distance

In Standard mode, the signal intensity varies depending on the working distance from the endoscope to the tissue. The closer the endoscope is to the tissue, the stronger (more intense green) the signal appears.

In Sensitive mode, the system attempts to automatically adjust the signal intensity and brightness to be consistent over various working distances. The signal intensity appears the same, whether the endoscope is moved closer or farther away from the tissue.

Appendix A Troubleshooting and Service

A.1 Troubleshooting

If the system requires maintenance or service, call our Customer Service line. In the U.S., call 1.800.876.1310, where phones are staffed 24 hours a day, seven days a week.

Table A.1 Firefly Standard Mode Troubleshooting

| Symptom | Reason | Action |
|---|--|---|
| Visualization mode does not change when surgeon presses the endoscope control pedal and simultaneously presses and releases a hand control finger clutch. | Use of hand control finger clutches to toggle visualization mode is disabled. | On the Surgeon Console touchpad, touch the Settings tab and navigate to the Firefly section to verify that the Firefly Fingerswitch setting is set to On (see Select the Visualization Mode on page 13). If the problem persists, contact Intuitive Customer Service. |
| Visualization mode becomes locked in Firefly (near-infrared) mode, and the Endoscope is off the arm. | Communication or component failure. | <ol style="list-style-type: none"> 1. Press and hold the illumination button (see Figure A.1) on the endoscope to turn off the light source. 2. If pressing the illumination button does not turn off the source, restart the system when safe to do so. 3. If the problem persists, contact Intuitive Customer Service. |
| Fluorescence image does not appear or appears weakly in the expected time frame after ICG injection. | <ul style="list-style-type: none"> • Firefly laser may not be operating • Clinical factors related to dosage and administration • Firefly background brightness or intensity needs adjustment | On the Surgeon Console touchpad, touch the Settings tab and navigate to the Firefly section. Adjust the Background Brightness and Firefly Intensity slider controls as needed. If the problem persists, contact Intuitive Customer Service. |
| Light is emitting from the Endoscope Controller when the endoscope is removed from the Endoscope Controller. | On the Endoscope Controller, the shutter for the endoscope receptacle is stuck in the open position. | <ul style="list-style-type: none"> • Install and remove an endoscope from the Endoscope Controller. • If the problem persists, restart the system when safe to do so. • If the problem persists, contact Intuitive Customer Service. |

Figure A.1 Illumination button on endoscope (example)



1. Illumination button

Table A.2 Firefly Sensitive Mode Troubleshooting

| Symptom | Reason | Action |
|---|---|--|
| Cannot save Sensitive mode settings | If a user account is not used, Surgeon Console settings, including Sensitive mode settings are not saved. | Make sure you are logged into a Surgeon Console user account when pressing Show Controls . |
| Surgical image appears dark | Administration of fluorescent agent is inadequate or is not completed correctly. | Confirm that administration of the fluorescent imaging agent is completed correctly. |
| | Sensitive mode image adjustment selections produce a dark image. | Check the Sensitive mode image adjustment settings. Adjust the selections to ensure proper visualization of fluorescent signals. |
| Surgical image appears black and white | A Sensitive mode image adjustment selection displays the Standard mode black-and-white background image. | When the user moves instruments while in Sensitive mode, the system reverts to Standard mode. See Instrument Function During Sensitive Mode on page 31. The user can choose to remain in Standard mode or return to Sensitive mode. See Select Sensitive Mode on page 24 for instructions on how to return to Sensitive mode. |
| Surgical image has too many image artifacts | Fluorescent imaging agent is emitting a signal that is too low. | Check the Sensitive mode image adjustment settings. Decrease the Intensity and increase the Black Point settings to ensure proper visualization of fluorescent signals. |

(continues on next page)

Table A.2 Firefly Sensitive Mode Troubleshooting (continued)

| Symptom | Reason | Action |
|---------|--|--|
| | Administration of fluorescent agent is inadequate or is not completed correctly. | Confirm that administration of the fluorescent imaging agent is completed correctly. |
| | Endoscope limitations. | Use another Intuitive endoscope with Sensitive mode capability. |

A.2 Firefly Laser Test Procedure

If the Firefly laser is not operating, follow these steps to test it:

1. Ensure that the endoscope connector is fully inserted in the Endoscope Controller receptacle.
2. Hold the endoscope and point it at the test target on the Firefly Imaging Quick Reference Guide.
3. Switch to Firefly imaging. If the laser is working and you are aiming the endoscope at the test target, the target should appear lit green on the stereo viewer and touchscreen.

A.3 Customer Service

Intuitive Surgical, Inc.
 1266 Kifer Road
 Sunnyvale, CA 94086 USA
 Toll free: 1.800.876.1310
 Fax: 1.408.523.2377 or 1.408.523.1390
 Website: www.intuitive.com

Appendix B Safety and Symbols

B.1 Safe Use

Light Safety

-  **WARNING:** Avoid looking at light emitted directly from the endoscope or the light guide, to prevent eye injury. The warning label contains specifications for near-infrared (NIR) radiation emitted in Firefly imaging.

-  **WARNING:** Do not examine optical fiber ports or optical fibers that are connected to a light source with optical instruments (for example, a magnifying glass), to prevent eye injury.

-  **WARNING:** Use of controls, or adjustments, or performance of tasks other than those specified herein may result in hazardous radiation exposure. Use of these controls to perform these tasks correctly is to prevent eye injury. Refer to the applicable system user manual for a list of tasks.

-  **WARNING:** Follow the provided instructions to properly use the Firefly class 3R laser and avoid possible hazardous laser radiation exposure.

-  **WARNING:** Avoid looking into the tip of the endoscope when the LASER ON indicator is lit green. Invisible near-infrared laser light is being emitted from the tip. Failure to observe this warning could result in eye injury.

-  **CAUTION:** Use of controls, adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.

The Endoscope Controller is labeled with the following warning label in accordance with applicable standards:

Table B.1 Warning Label (example)

| Label | Location |
|--|---|
|  <p>Label text reads:</p> | <p>Front of Endoscope Controller to the right</p> |

(continues on next page)

Table B.1 Warning Label (example) (continued)

| Label | Location |
|---|----------|
| <p style="text-align: center;">INVISIBLE LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCT</p> <p style="text-align: center;">Maximum Output: 124 mW at Wavelength: 805 nm Device classified per IEC 60825-1:2007 Complies with 21 CFR 1041.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24th, 2007.</p> | |

B.2 Symbols and Icons

Table B.2 Symbols and Icons

| Symbol | Indicates | Location |
|-------------------------|---|--|
| LASER ON | Near-infrared laser light is being generated by the Endoscope Controller and emitting from the tip of the endoscope | Back of endoscope housing and within yellow laser safety label on Endoscope Controller |
| ◁ LASER APERTURE | Points in the direction where laser light is emitted | Side of endoscope housing |

Table B.3 Symbols Used in This Manual

| Symbol | Meaning |
|---|--|
|  | Note: Highlights important information. |
|  | Caution: Alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse. |

(continues on next page)

Table B.3 Symbols Used in This Manual (continued)

| Symbol | Meaning |
|---|--|
|  | Warning: Alerts the reader about a situation which, if not avoided, could result in death or serious injury. |
| Rx only | Federal (U.S.) law restricts this device for sale, distribution, and use by or on the order of a physician. |

End
