

Firefly® Imaging System User Manual Addendum for da Vinci Xi® and da Vinci X® Systems



Copyright

© 2019 Intuitive Surgical, Inc. All rights reserved.

Trademarks

Intuitive, Intuitive Surgical, da Vinci, da Vinci Xi, da Vinci X, and Firefly are trademarks or registered trademarks of Intuitive Surgical, Inc. Other parties' trademarks are the property of their respective owners and should be treated as such.

Rx only

Contents

1	Introduction	5
1.1	Indications for Use	5
1.2	Compliance and Classification	5
	Compliance and Classification	5
2	System Overview	6
2.1	System Components	7
2.2	Indicators	8
	Endoscope Controller	8
	Endoscope Indicators	10
	Surgeon Console 3D Viewer and Vision Cart Touchscreen	11
3	Firefly Imaging Operation	12
3.1	Connecting the Endoscope to the Endoscope Controller	12
3.2	Select the Visualization Mode	13
	Firefly Settings Overview	13
	Activate Firefly at Surgeon Console	14
	Activate Firefly at Vision Cart	16
	Toggle Between Firefly and Visible Light Imaging	16
	Deactivate Firefly on the Endoscope	17
3.3	Adjust Image	18
	Image Adjustment on Surgeon Console	19
	Image Adjustment on Vision Cart Touchscreen	22
4	Sensitive Mode Operation	23
4.1	Select Sensitive Mode	24
	Activate Sensitive Mode at Surgeon Console	24
	Activate Sensitive Mode at Vision Cart	27
	Activate Sensitive Mode Using Hand Controls	27
4.2	Adjust Image in Sensitive Mode	28
	Image Adjustment on Surgeon Console	28
	Image Adjustment on Vision Cart Touchscreen	29
	Firefly Black Point	29
4.3	Instrument Function During Sensitive Mode	30
	Instrument Motion	30
	Pedal Functions	30
4.4	Sensitive Mode Signal and Working Distance	31

A	Appendix A: Troubleshooting and Service	32
	A.1 Troubleshooting	32
	A.2 Firefly Laser Test Procedure	34
	A.3 Customer Service	34
B	Appendix B: Safety and Symbols	35
	B.1 Safe Use	35
	Light Safety	35
	B.2 Symbols and Icons	36

1 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 System¹.

- i** **Note:** Aspects of the da Vinci Firefly Imaging System not addressed in this document are the same as for the da Vinci Xi and the da Vinci X vision system. For details, refer to the applicable system user manual, including current addenda, if any.
- i** **Note:** All da Vinci Xi instruments and accessories are compatible with both the da Vinci Xi and the da Vinci X systems.
- ⚠** **WARNING:** Read this entire document before using the da Vinci Firefly Imaging System. Failure to follow the instructions and warnings in this manual may result in unsafe operation of the system and/or injury to the patient or operator. Be sure to read and understand all caution and warning information found in this addendum and the da Vinci Xi System User Manual or the da Vinci X System User Manual before using this product.
- ⚠** **WARNING:** Personnel operating and cleaning the Firefly endoscope should receive training in all aspects of the operation and cleaning of the system.

1.1 Indications for Use

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.

1.2 Compliance and Classification

C E
0543

Compliance and Classification

The Intuitive Surgical da Vinci Xi Endoscopic Instrument Control System Model IS4000 (da Vinci Xi System) is in conformance with the Medical Device Directive, 93/42/EEC.

The Intuitive Surgical da Vinci X Endoscopic Instrument Control System Model IS4200 (da Vinci X System) is in conformance with the Medical Device Directive, 93/42/EEC.

End of section _____

¹ Not all technologies may have regulatory approval or may be commercially available in all geographies. **For availability in your country, please check with your local representative.**

2 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 Xi endoscopes and Endoscope Controllers are capable of visible light and Firefly imaging. The Firefly Imaging System uses near-infrared light in conjunction with an imaging agent to create fluorescent images of tissue. The imaging agent is intravenously administered to the patient and the system is switched to Firefly imaging. Two modes are available in Firefly imaging: Standard mode and Sensitive mode.

i Note: Firefly Sensitive mode is not available with all endoscopes. Contact your Intuitive Surgical 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.

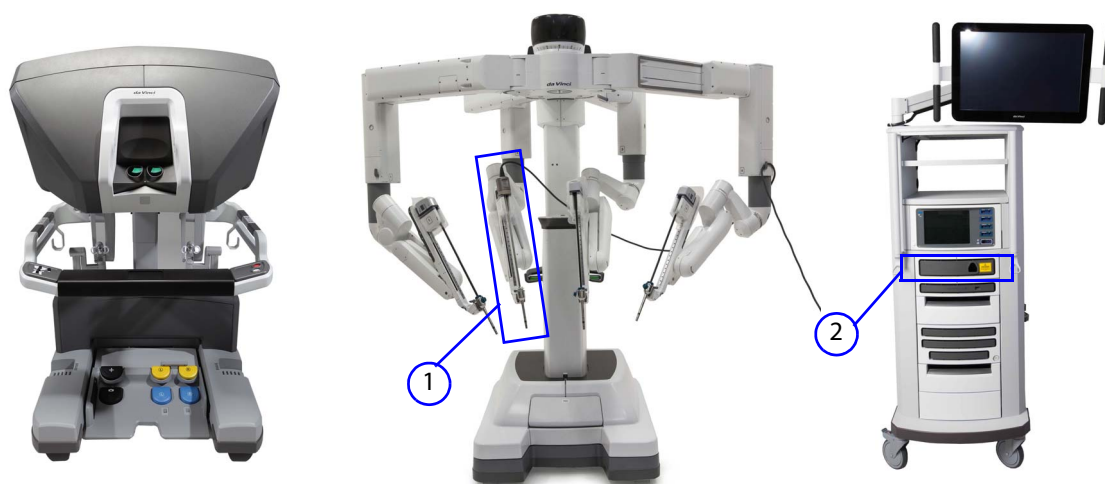
i Note: For information on preparation and administration of the imaging agent, follow the imaging agent manufacturer's Instructions for Use.

i Note: Viewing NIR fluorescence images in Firefly mode requires use of an imaging agent that fluoresces with an excitation wavelength of 805 nm \pm 4 nm, emits light at approximately 830 nm, and has sufficient quantum yield in order to be detected by the camera.

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

⚠ CAUTION: Factors such as dosing of the imaging agent, timing of imaging agent administration, working distance, fluorescence visualization mode, fluorescence visualization settings, etc. 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.

2.1 System Components



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

Figure 2.1 da Vinci Xi System with Firefly imaging components (example)

- i** Note: The Firefly Imaging System is a fully integrated part of the da Vinci Xi Surgical System (da Vinci Xi System) and the da Vinci X Surgical System (da Vinci X System). For information on topics not addressed in this document, refer to the applicable system user manual.
- ⚠** WARNING: Only use components supplied by Intuitive Surgical for Firefly imaging with the da Vinci Xi System or da Vinci X System. Do not use any third-party components in conjunction with the da Vinci Xi or da Vinci X vision system. 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 of the da Vinci Xi System or da Vinci X System.
- ⚠** CAUTION: Use of Firefly fluorescence imaging depends on illumination coming only from da Vinci Xi 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 Xi Surgical System and the da Vinci X Surgical System, and is for use only with these da Vinci systems. It is not intended for use with any other surgical imaging systems.

2.2 Indicators

Endoscope Controller

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

Endoscope Controller LED

- The Endoscope Controller LED ([Figure 2.2](#)) indicates the power status of the Endoscope Controller.

Table 2-1 Endoscope Controller

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

Endoscope Cable Connection LED

- The Endoscope Cable Connection LED ([Figure 2.2](#)) indicates when an endoscope is connected and ready for use.

Table 2-2 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

Laser Safety Label LED

- The Laser Safety Label LED ([Figure 2.2](#)) illuminates "LASER ON" when Firefly imaging is activated ([Figure 2.3](#)).

Table 2-3 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

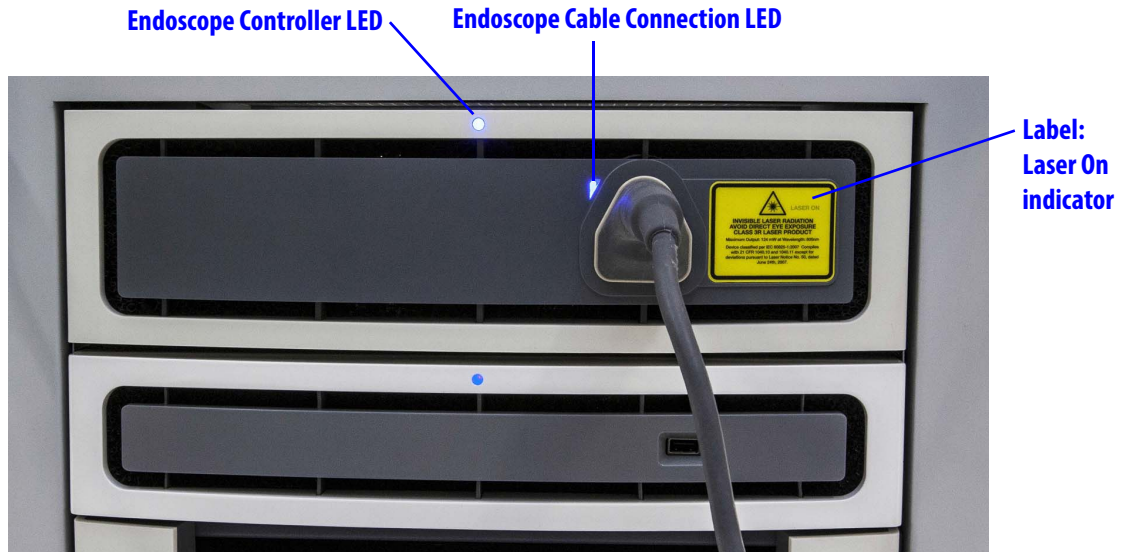


Figure 2.2 Endoscope Controller front panel

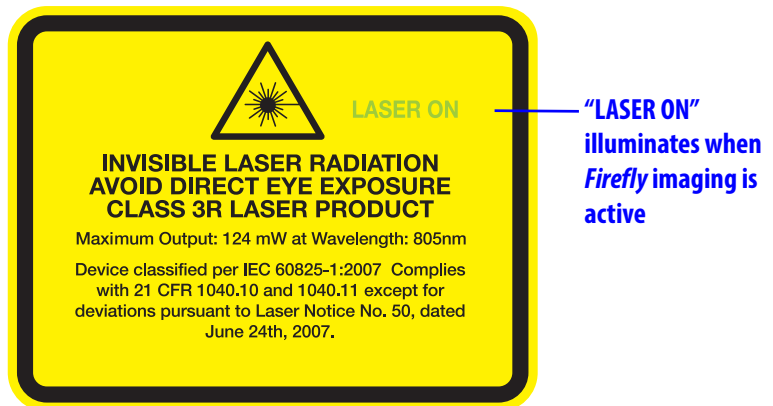


Figure 2.3 Laser safety label

Endoscope Indicators

Endoscope Laser Aperture Label

The endoscope laser aperture label (Figure 2.4) points in the direction that laser light is emitted.



Figure 2.4 Laser aperture label (example)

Endoscope LED

The Endoscope LED (Figure 2.5) indicates connection to the Endoscope Controller.



Figure 2.5 Endoscope LED (example)

Table 2-4 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 2.6) 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.

- i Note:** 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.



Figure 2.6 LASER ON indicator

Table 2-5 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 2.7).



Figure 2.7 User interface LASER ON indicator

End of section

3 Firefly Imaging Operation

⚠ WARNING: Proper sterile technique must be used when preparing the endoscope for surgical endoscopy. The endoscope and its cable are sterilized and may only be handled by a sterile operator.

3.1 Connecting the Endoscope to the Endoscope Controller

The light guide and endoscope communication signals are integrated into a single cable which 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.

i 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 3.1](#)).



Figure 3.1 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 [Chapter 4 Sensitive Mode Operation](#) for information about Sensitive mode.

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

⚠ CAUTION: 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 (see [Table B-1 Warning Label](#), page 35).

3.2 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 minimize exposure to laser energy that could result in injury to operator or patient, deactivate Firefly imaging when removing the endoscope from the patient.

i Note: Before delivering the imaging agent 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

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

i Note: See [Chapter 4 Sensitive Mode Operation](#) 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).

- 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 3.2).



Settings Tab

Figure 3.2 Touch the Settings tab

2. Touch the **Firefly** button or scroll to view the **Firefly** section (Figure 3.3).
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 3.3 Surgeon Console Firefly Mode OFF/ON button

Surgeon Console Touchpad - Endoscope Arm Pod

To activate or deactivate Firefly on the Instrument tab endoscope arm pod, touch the **Firefly** button (Figure 3.4).



Figure 3.4 Surgeon Console Firefly button on endoscope arm pod

Activate Firefly at Vision Cart



1. Touch the **Display** tab on the Vision Cart touchscreen.
2. Touch the **Firefly OFF** button (Figure 3.5). If Firefly is already activated, touching the **ON** button deactivates Firefly.



Figure 3.5 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 3.6).

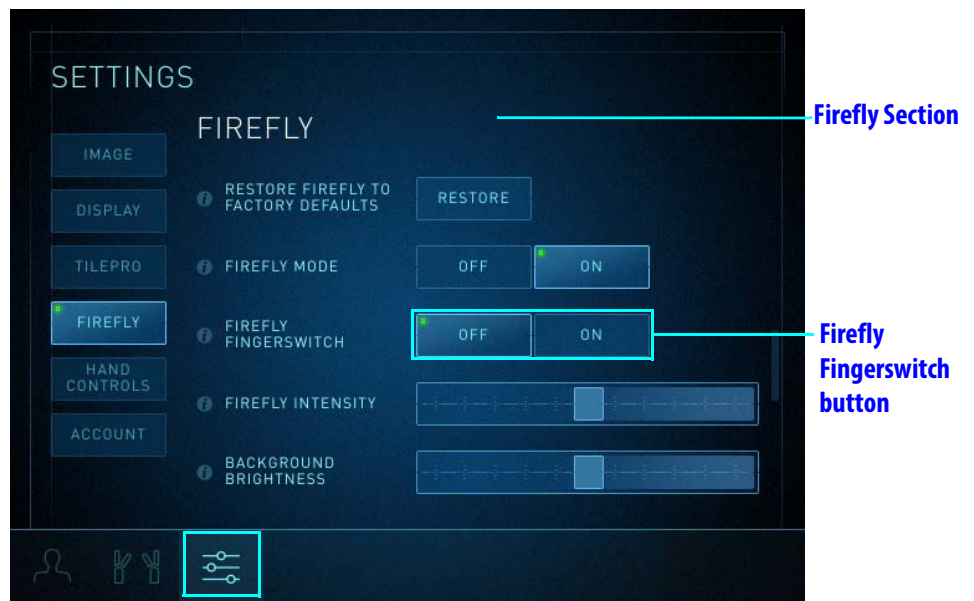


Figure 3.6 Firefly Fingerswitch control

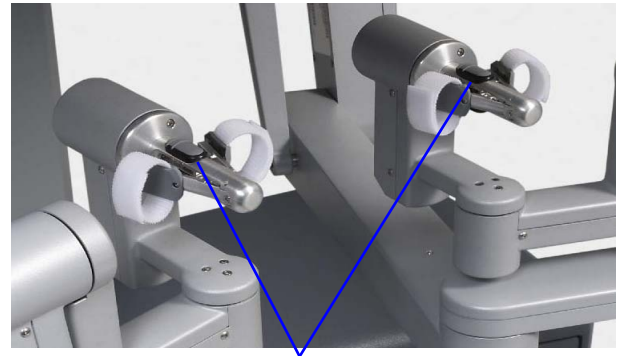
When the **Firefly Fingerswitch** button is ON, the surgeon can toggle between visible light imaging and Firefly imaging by using the endoscope control pedal and the hand control finger clutches.

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 3.7).



Press endoscope control pedal



Use hand control finger clutches to toggle between visible light and Firefly imaging

Figure 3.7 Switching modes at Surgeon Console

Deactivate Firefly on the Endoscope

Illumination On/Off Button

Pressing and holding the illumination button on the endoscope (Figure 3.8) turns off all illumination. The system only responds to a long press (for example, 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 3-1 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 3.8 Illumination On/Off button (example)

3.3 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 (Figure 3.9). Moving it to the right increases the intensity of the fluorescence (appears more saturated).



Figure 3.9 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 3.10).
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.

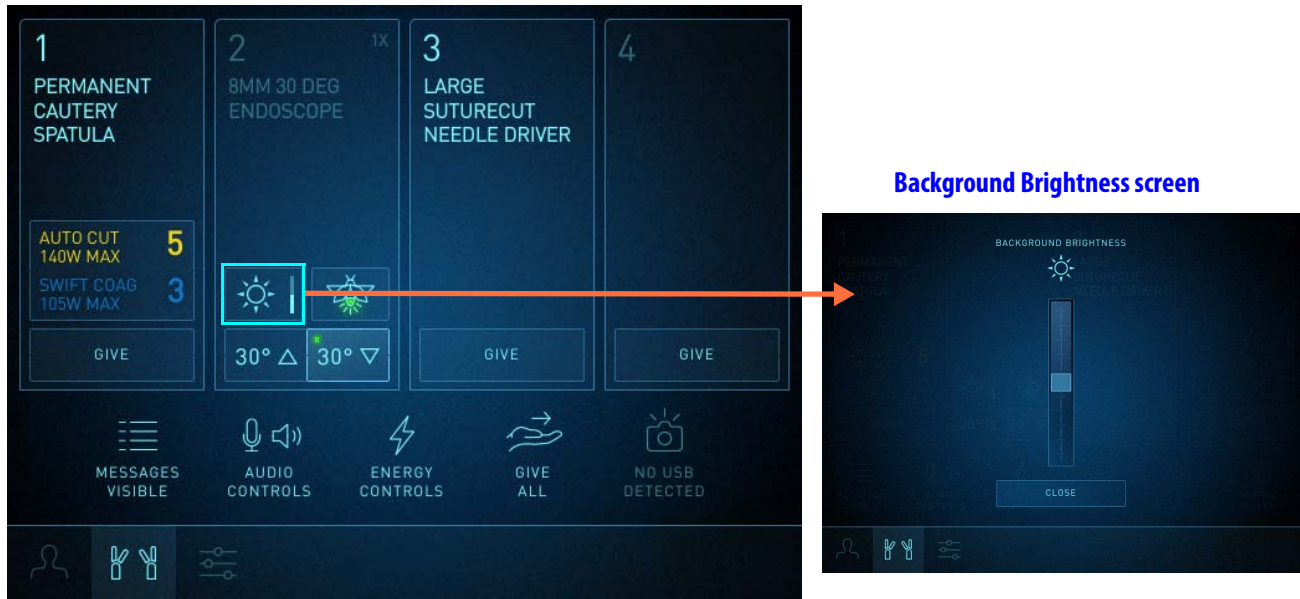


Figure 3.10 Instrument Tab Brightness slider

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 (Figure 3.11).
Moving it to the right increases brightness.

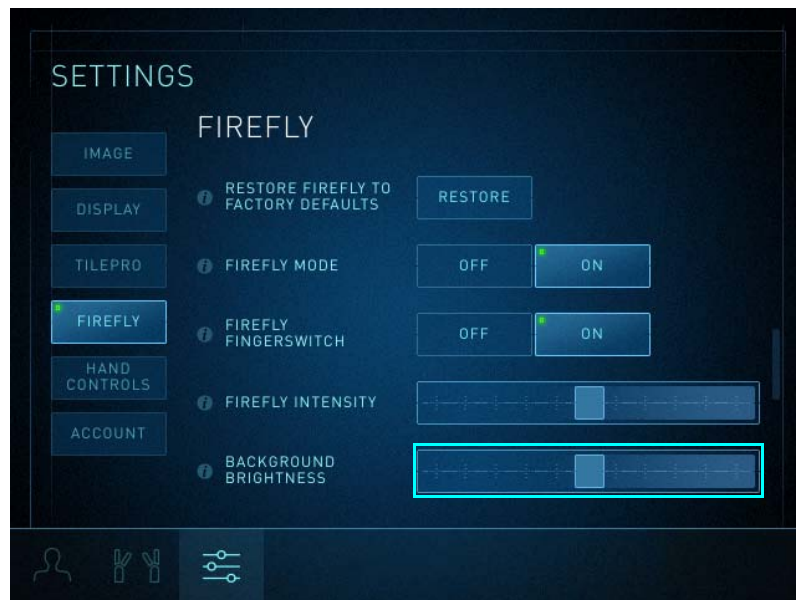


Figure 3.11 Firefly Background Brightness slider

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 3.12).
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.

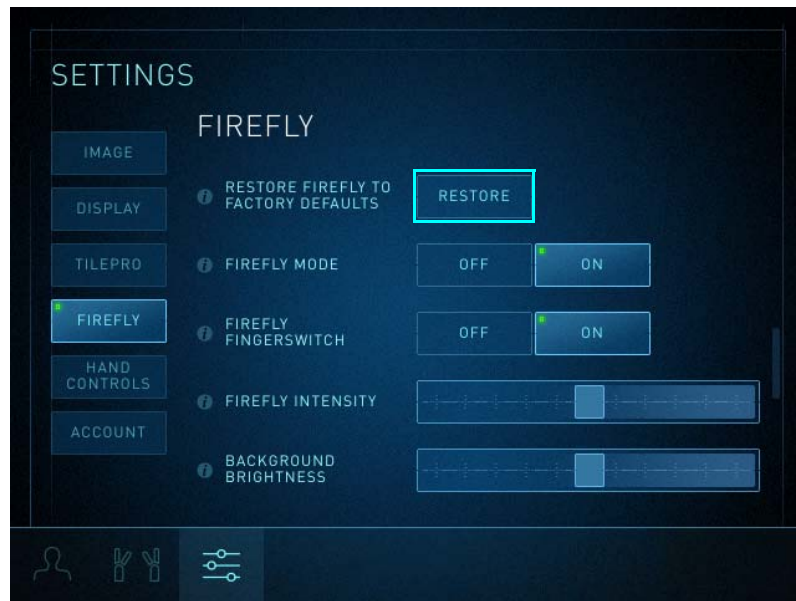


Figure 3.12 Restore Firefly to factory defaults button

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 (Figure 3.13). This slider is disabled in visible light mode.

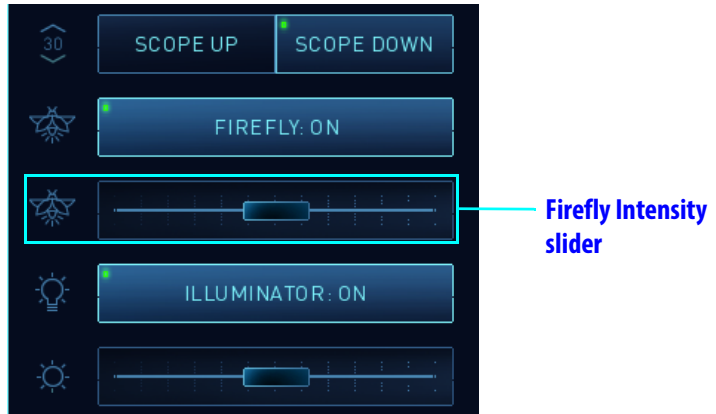


Figure 3.13 Vision Cart Firefly Intensity slider

Brightness Slider



On the **Display** tab, move the Brightness slider to change the background brightness when Firefly is activated (Figure 3.14). This slider also adjusts image brightness in visible light mode (when Firefly is deactivated).



Figure 3.14 Vision Cart Brightness slider

End of section

4 Sensitive Mode Operation

i **Note:** Sensitive mode is not available with all endoscopes. Contact your Intuitive Surgical 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 4.1).

⚠ CAUTION: Use of Firefly fluorescence imaging depends on illumination coming only from da Vinci Xi 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 Xi Surgical System and the da Vinci X Surgical System, and is for use only with these da Vinci systems. It is not intended for use with any other surgical imaging systems.

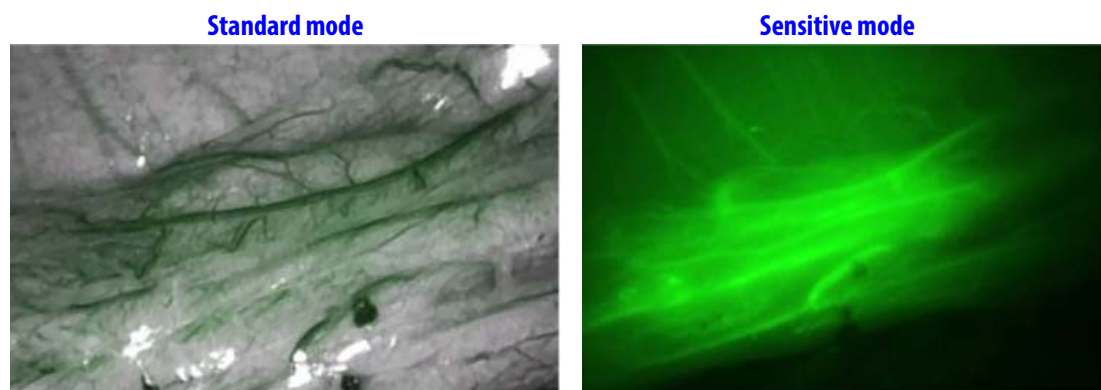


Figure 4.1 Image in Firefly Standard mode and in Sensitive mode (example)

4.1 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 4.2).

The **Show Controls** button changes to **Hide Controls**, and the Sensitive mode options are displayed (Figure 4.3):

- 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 4.2 Touch the Show Controls button



Scroll down to see the Firefly Black Point control slider and Sensitive Mode Show Controls button

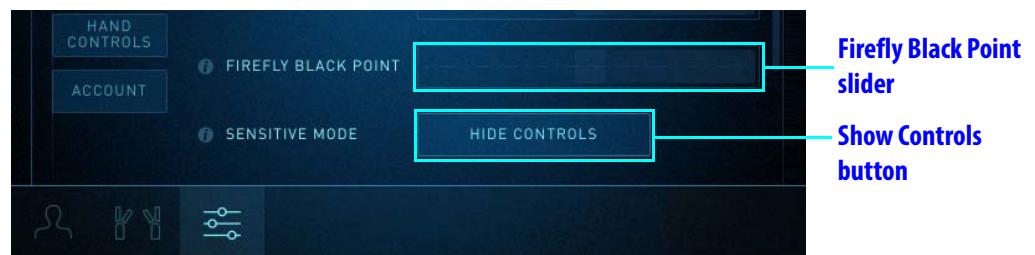


Figure 4.3 Sensitive mode options

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

2. Touch the **Sensitive** button to activate Sensitive mode (Figure 4.4).

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

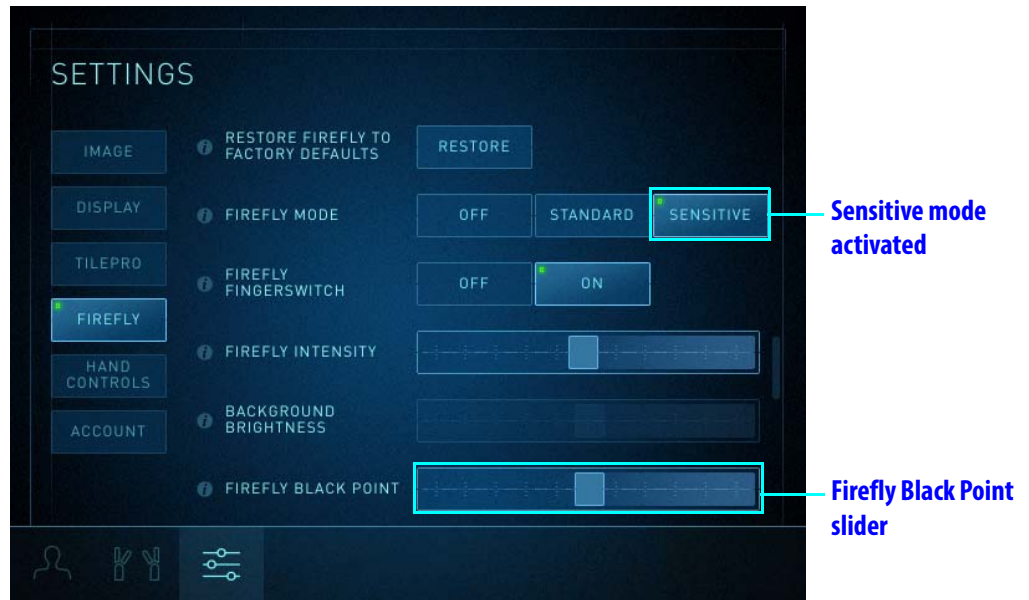


Figure 4.4 Firefly intensity and Firefly Black Point are enabled

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 4.5), and the Brightness button is disabled.



Figure 4.5 Surgeon Console Firefly button on endoscope arm pod, icon is completely lit green in Sensitive mode

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 (Figure 4.6). In Sensitive mode, the Brightness slider is disabled.



Figure 4.6 Vision Cart Firefly button, in Sensitive mode (example)

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 (Figure 4.7). 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.

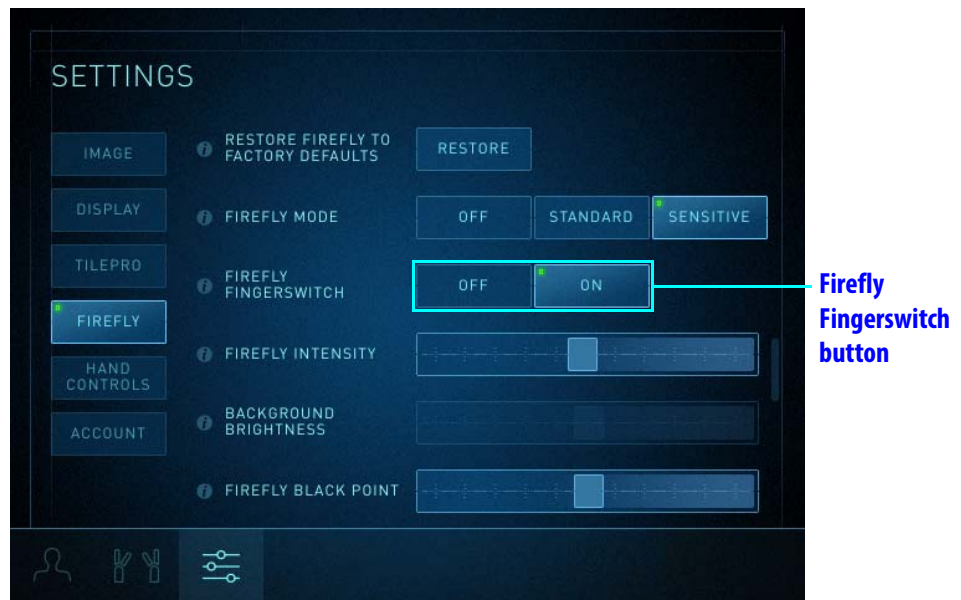


Figure 4.7 Firefly Fingerswitch control, in Sensitive mode (example)

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 [Figure 3.7](#).

4.2 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.

⚠ WARNING: Sensitive Firefly image adjustment selections (Firefly Intensity slider and Firefly Black Point slider) may reduce the visibility of tissues and surgical tools. Instrument motion or the Standard Firefly image adjustment selection increases the brightness of the surgical image during fluorescence imaging.

i 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 ([Figure 4.8](#)). Moving it to the right progressively increases the intensity of the fluorescent signal (appears more saturated).

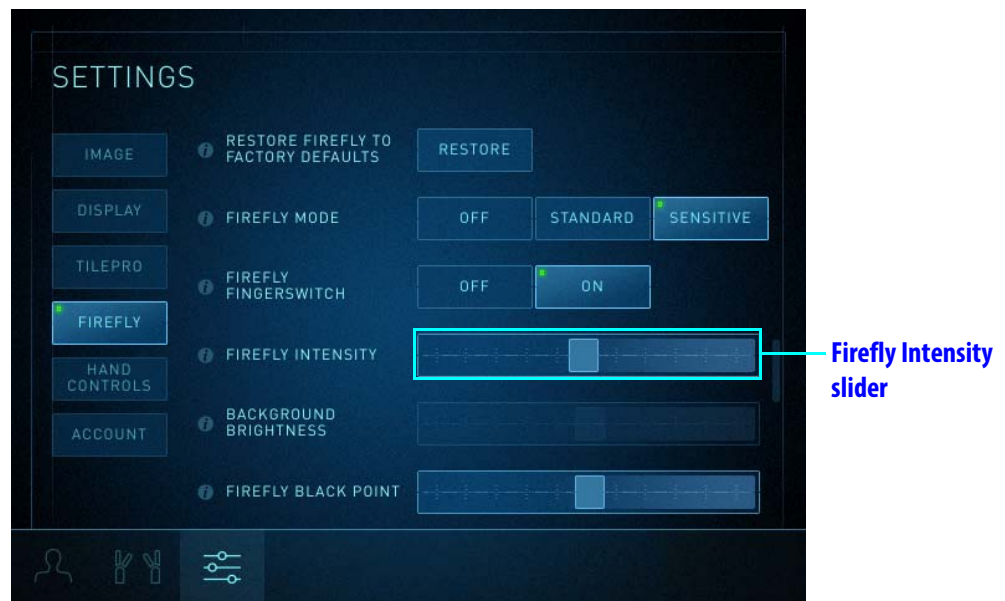


Figure 4.8 Surgeon Console Firefly Intensity slider, in Sensitive mode (example)

See [Chapter 3 Firefly Imaging Operation, Image Adjustment on Surgeon Console](#) 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 (Figure 4.9). This slider is disabled in visible light mode.

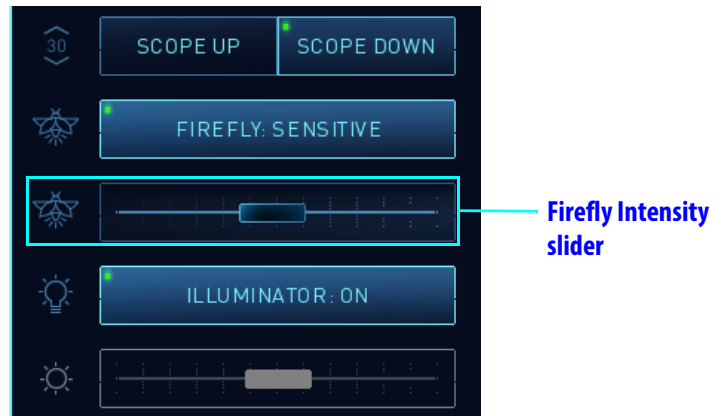


Figure 4.9 Vision Cart Firefly Intensity slider, in Sensitive mode (example)

See Chapter 3 [Firefly Imaging Operation, Image Adjustment on Vision Cart Touchscreen](#) 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.

WARNING: 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. 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 4.10). 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.

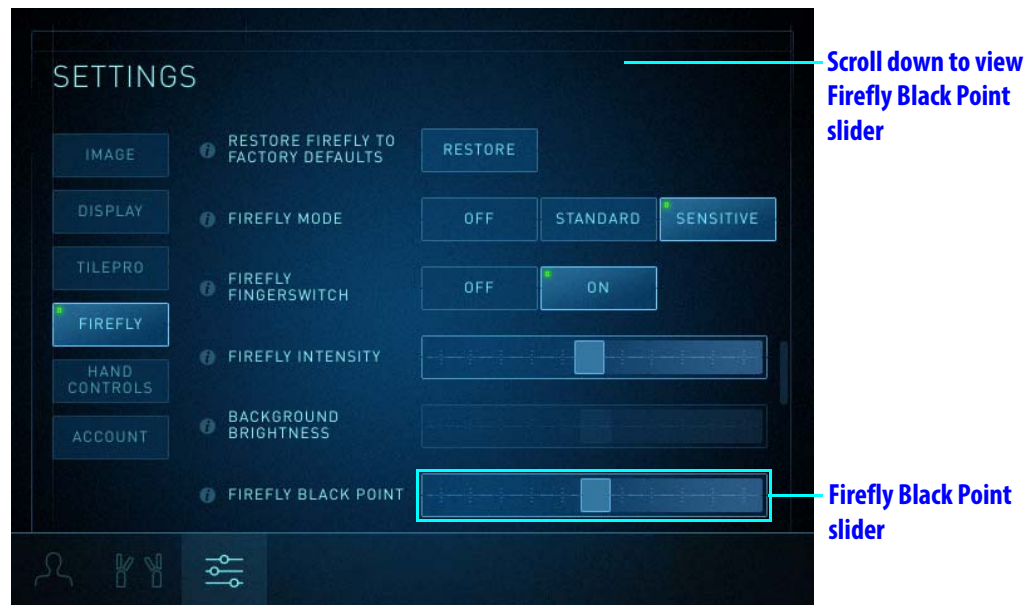


Figure 4.10 Firefly Black Point slider

4.3 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 [4.1 Select Sensitive Mode](#) for instructions on how to return to Sensitive mode.

Pedal Functions

Electrocautery, suction irrigation, and advanced instrument functions are disabled when Sensitive mode is active. Disabled functions include:

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

4.4 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, this behavior differs from the behavior in Standard mode. 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.

End of section

A Appendix A: Troubleshooting and Service

A.1 Troubleshooting

⚠ WARNING: Do not use endoscopes if any part of the system is damaged or does not function properly. Do not attempt to remove the cover from the Endoscope Controller. Refer all servicing to a qualified Intuitive Surgical service representative. Failure to follow this warning may lead to injury to operator or patient.

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. In Europe, call +41.21.821.2020.

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 3.2 Select the Visualization Mode). If the problem persists, contact Intuitive Surgical 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 Surgical Customer Service.
Fluorescence image does not appear or appears weakly in the expected time frame after imaging agent 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 Surgical 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 Surgical Customer Service.



Figure A.1 Illumination button on endoscope (example)

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 4.3 Instrument Function During Sensitive Mode . The user can choose to remain in Standard mode or return to Sensitive mode. See 4.1 Select Sensitive Mode 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.
	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 a different endoscope for Sensitive mode.

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
Email: customerservice@IntuitiveSurgical.com
Toll free: 1.800.876.1310
Fax: 1.408.523.2377 or 1.408.523.1390
Website: www.intuitivesurgical.com

Intuitive Surgical Sàrl
Chemin des Mûriers 1
1170 Aubonne, Switzerland
Toll free: +800.0821.2020
Direct: +41.21.821.2020
Fax: +41.21.821.2021

End of section

B 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, which could cause eye injury. [Table B-1](#) on page 35 contains specifications for near-infrared (NIR) radiation emitted in Firefly imaging.
- ⚠ CAUTION:** Do not examine optical fiber ports or optical fibers that are connected to a light source with optical instruments (for example, a magnifying glass).
- ⚠ CAUTION:** Use of controls, or adjustments, or performance of tasks other than those specified herein may result in hazardous radiation exposure. Refer to the applicable system user manual for a list of tasks.
- i Note:** 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.

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

Table B-1 Warning Label




Label	Location
<div style="text-align: center;">  <p>Label text reads:</p> <p>INVISIBLE LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCT</p> <p>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> </div>	<p>Front of Endoscope Controller to the right</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.
	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 _____