



# SPY-QP Fluorescence Assessment Software

User Guide, North America

**REF** PC9200

**R<sub>x</sub> ONLY**

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# About SPY-QP Fluorescence Assessment Software

The SPY-QP Fluorescence Assessment Software is an upgrade to the SPY-PHI System that enables relative quantification of near-infrared (NIR) fluorescence. The software detects the onset and stability of the fluorescence signal within the field of view and displays fluorescence signal intensity as a color map and percentage value relative to a reference set by the user.

Information obtained through the use of SPY-QP should be used in combination with other clinically relevant information when planning or providing interventions.

Two workflows available when working with SPY-QP are:

- For users who need all SPY-QP information and tools, and start SPY-QP prior to injection of indocyanine green (ICG): This workflow displays all SPY-QP on-screen information when active, including the quantification box, state indicators, timer, and timestamps. See *Starting SPY-QP at the Beginning of an Imaging Sequence* (page 3).
- For users who desire SPY-QP information only when needed and start SPY-QP after injection of ICG: The system displays limited on-screen information, including the timer and stability timestamp (during confirmation only), without starting the software. SPY-QP runs in the background and detects onset and stability of fluorescence. SPY-QP can be started at any time to enable all of the information and tools. See *Starting SPY-QP during an Imaging Sequence* (page 8).

SPY-QP may be used as an additional intraoperative tool to assist trained healthcare practitioners in the assessment of fluorescence response in tissue during various surgical procedures. The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their clinical judgment and standard practices.

SPY-QP is an upgrade to the SPY-PHI System. SPY-QP is not stand-alone software and is intended for use with the SPY-PHI System.

For SPY-PHI System indications for use, refer to the SPY-PHI System Operator's Manual.

## Warning, Caution, and Note Definitions

Please read and follow these Instructions for Use carefully. The words warning, caution, and note carry special meaning and should be carefully reviewed:

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

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

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**Note** - Clarifies the instructions or presents additional useful information.

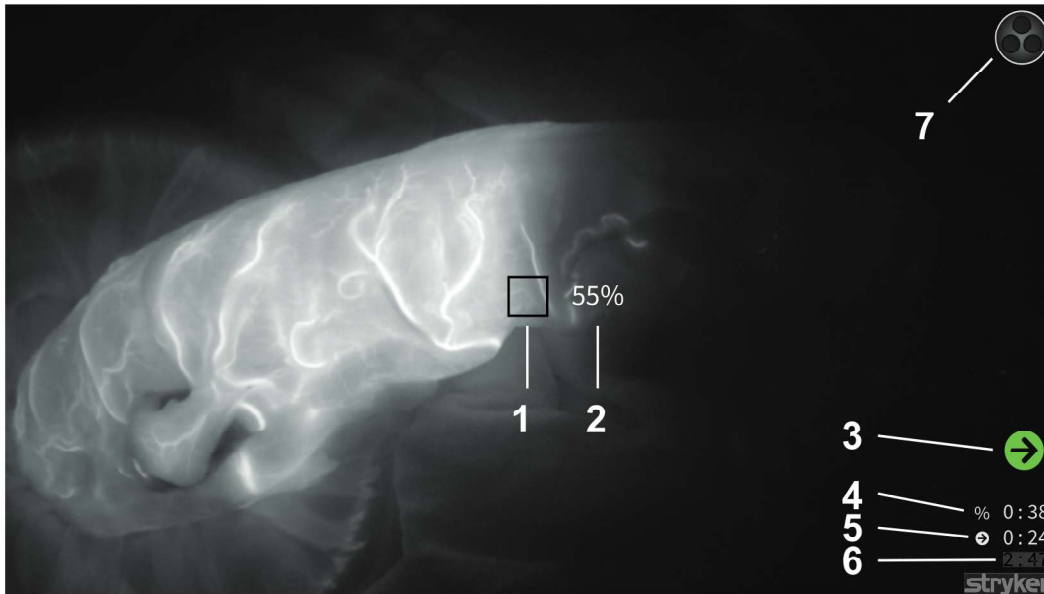
## Warnings and Cautions

Observe the following warnings.

- This manual does not explain or discuss clinical procedures. Therefore, the SPY-QP Fluorescence Assessment Software, as part of the SPY-PHI system, must only be used by, or under the supervision of, a licensed physician. The operator must be trained in clinical procedures.

## Overview of the SPY-QP User Interface

Following is an overview of the SPY-QP user interface.



1. Quantification box	5. Stability timestamp
2. Relative value	6. Timer
3. State indicator	7. Fluorescence imaging mode icon
4. Reference timestamp	

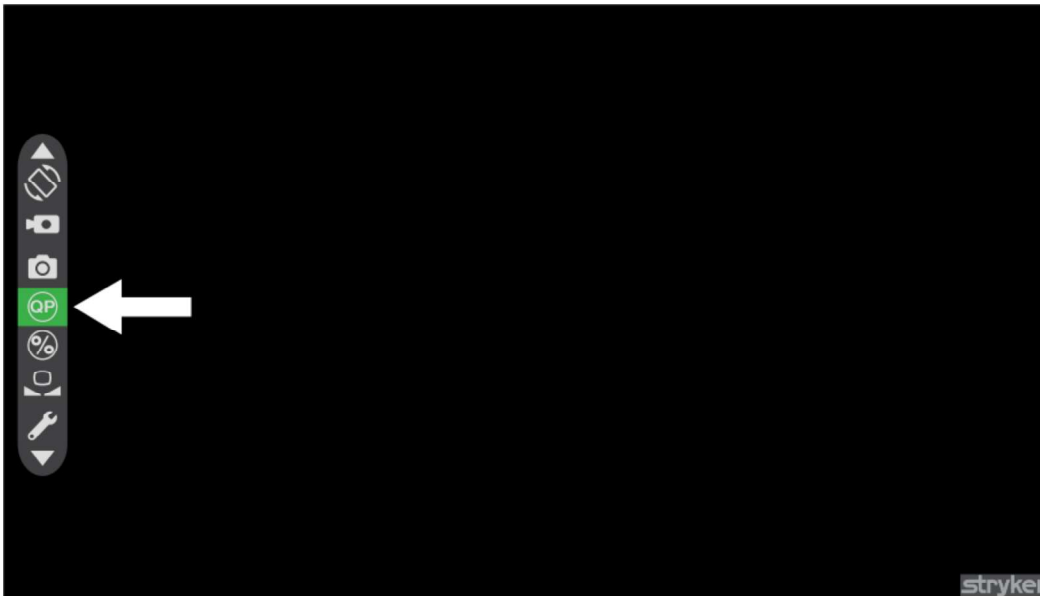
## Starting SPY-QP at the Beginning of an Imaging Sequence

The SPY-PHI System must be in fluorescence imaging mode before starting SPY-QP.

**Note** - To be ready to set a reference, start SPY-QP before injection of indocyanine green (ICG).

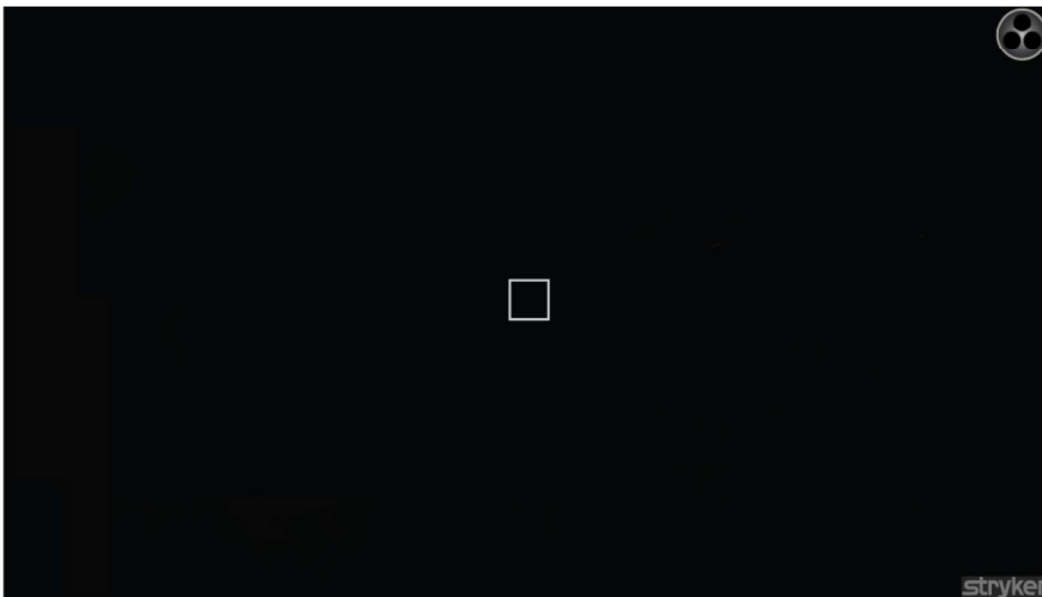
To start SPY-QP:

1. With the SPY-PHI System in fluorescence imaging mode, press the **B** button on the SPY-PHI imager to open the **Tools** menu.
2. In the **Tools** menu, select the **QP** icon.



3. Press the **B** button on the SPY-PHI imager to start SPY-QP.

The quantification box displays in the middle of the screen.



4. Press the **A** button on the SPY-PHI imager to select the desired fluorescence imaging mode.

**Note** - If desired, toggle between fluorescence imaging mode and white-light mode by pressing the **Illumination** button on the SPY-PHI imager.

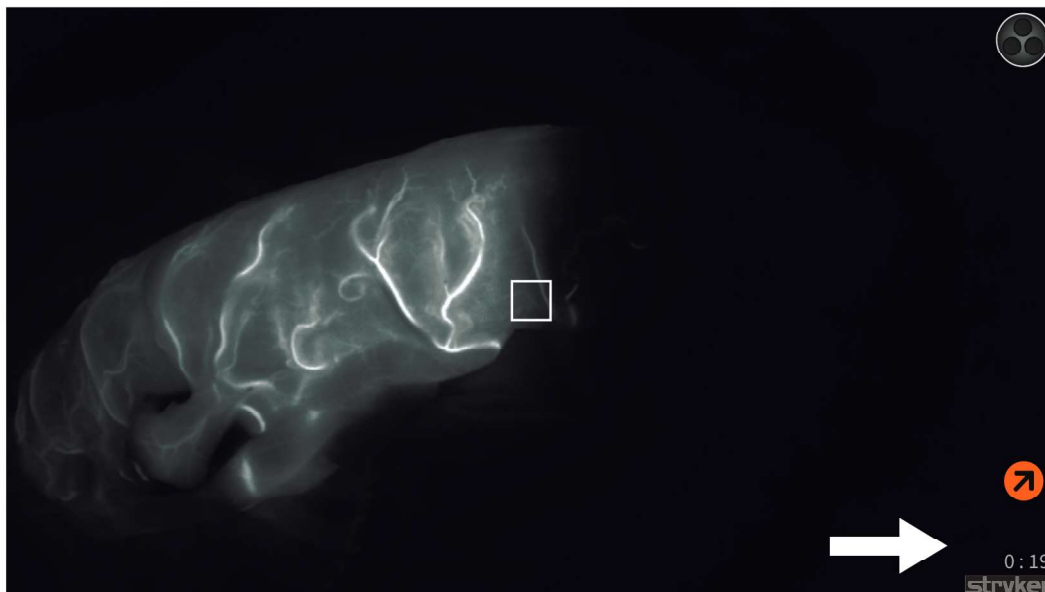
## Onset of Fluorescence and Fluorescence Stability

### Note

- The SPY-PHI system must be in fluorescence imaging mode to detect the onset and stability of fluorescence.
  - For best results, the SPY-PHI imager should be aimed at the region of interest and held steady from the onset of fluorescence until confirmation of fluorescence stability.
1. Aim the SPY-PHI imager to position the region of interest in the field of view.
  2. Hold the SPY-PHI imager steady until the onset of fluorescence has been confirmed. Excessive movement may prevent the detection of the onset and stability of fluorescence.

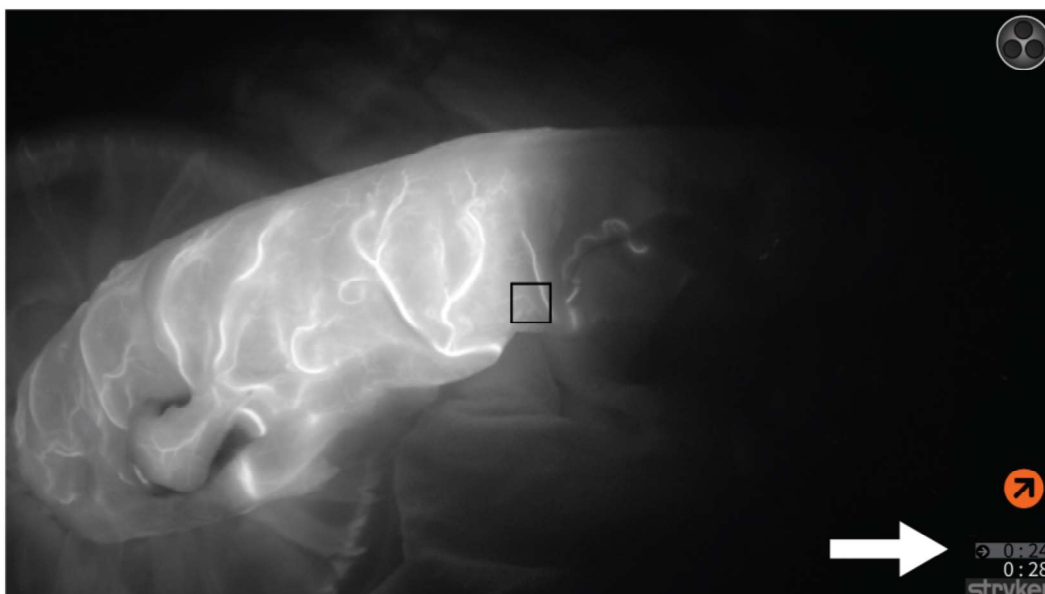
The on-screen timer displays when the system detects the onset of fluorescence. The timer appears dimmed while the system confirms onset. When onset of fluorescence is confirmed, the timer displays at full brightness and the onset state indicator displays above the timer.

**Note** - The timer will disappear if the onset of fluorescence is not confirmed and will reappear when the system detects onset again. The system may attempt to confirm the onset of fluorescence multiple times.

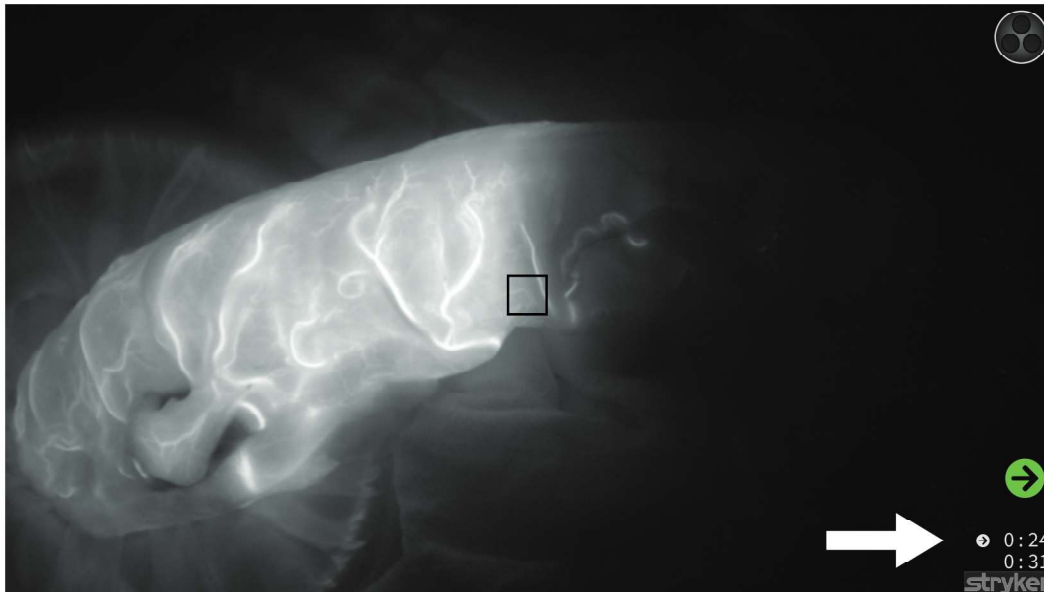


A stability timestamp displays when the system detects fluorescence stability. The timestamp appears dimmed while the system confirms stability.

**Note** - The stability timestamp will disappear if fluorescence stability is not confirmed, and will reappear when the system detects stability again. The system may attempt to confirm fluorescence stability multiple times.



When fluorescence stability is confirmed, the timestamp displays at full brightness and the state indicator changes to a green arrow icon.



## Setting a Reference Value and Quantification

The reference value is the value of fluorescence intensity to which the real-time fluorescence intensity within the quantification box is compared. For example, if the reference value is set on the fluorescence signal in healthy tissue, quantification of the fluorescence signal in the region of interest is displayed as a percentage of the reference fluorescence signal in the healthy tissue.

A reference value can be set at any time but the suggested time for setting a reference value is after fluorescence stability has been confirmed.

To set the reference value:

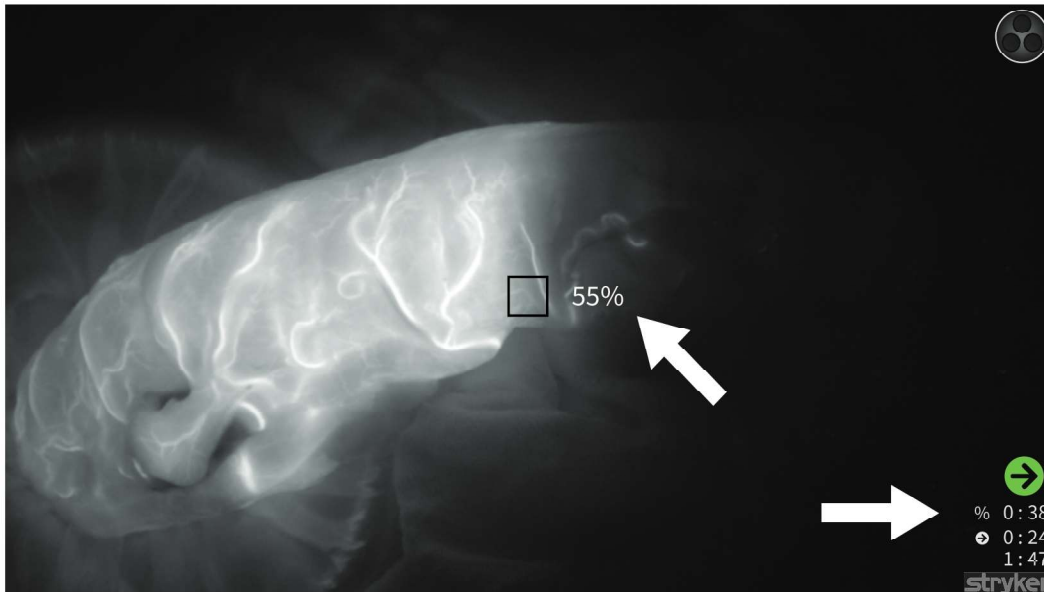
1. Aim the SPY-PHI imager with the quantification box centered on the desired reference tissue.
2. Press and hold the **B** button on the SPY-PHI imager for 1 second to set the reference value.

A timestamp indicating when the reference was set displays below the state indicator in the lower right corner of the screen.

3. Aim the SPY-PHI imager with the quantification box centered on the desired region of interest.

The relative value displays next to the quantification box as a percentage of the set reference value.





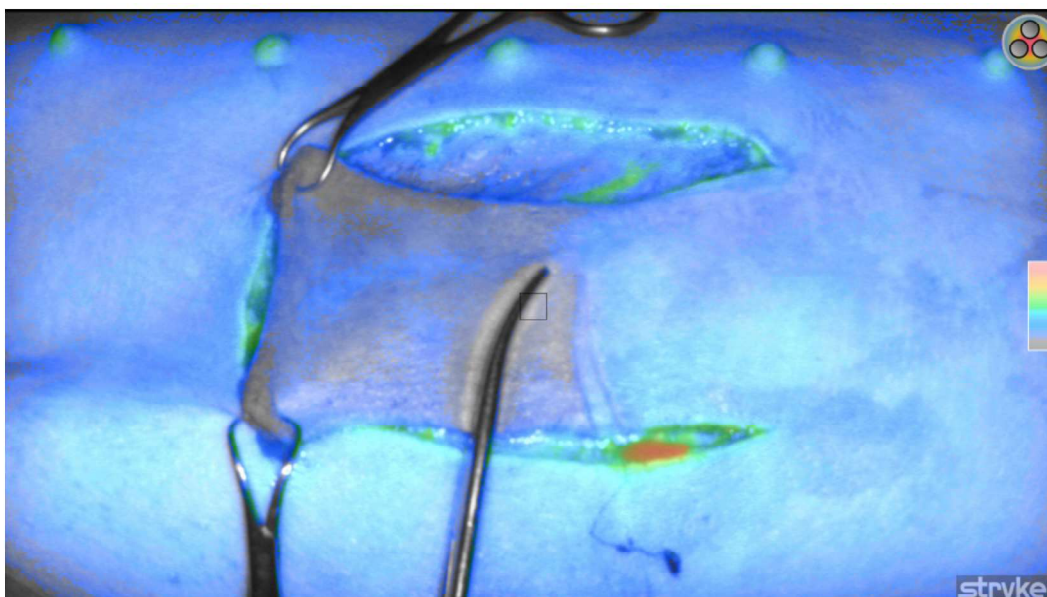
## Using the SPY-QP Color Map

When active, SPY-QP replaces the Color Segmented Fluorescence (CSF) display mode with a new Color Map. The SPY-QP Color Map displays a visual representation of the fluorescence signal. There is a legend on the right side of the screen when viewing the Color Map display mode.

To activate the Color Map:

1. Start SPY-QP.
2. On the SPY-PHI imager, press the **A** button to cycle through the display modes until the SPY-QP Color Map displays.

The Color Map displays a color scale based on raw data until a reference is set.



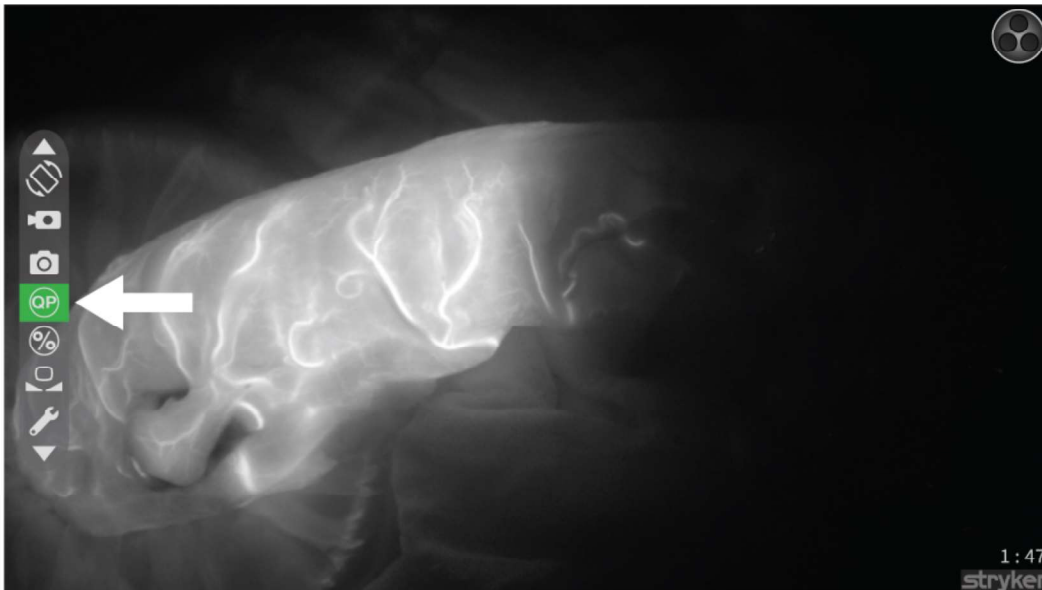
After the reference is set, the Color Map adjusts the scale to be relative to the reference.



## Starting SPY-QP during an Imaging Sequence

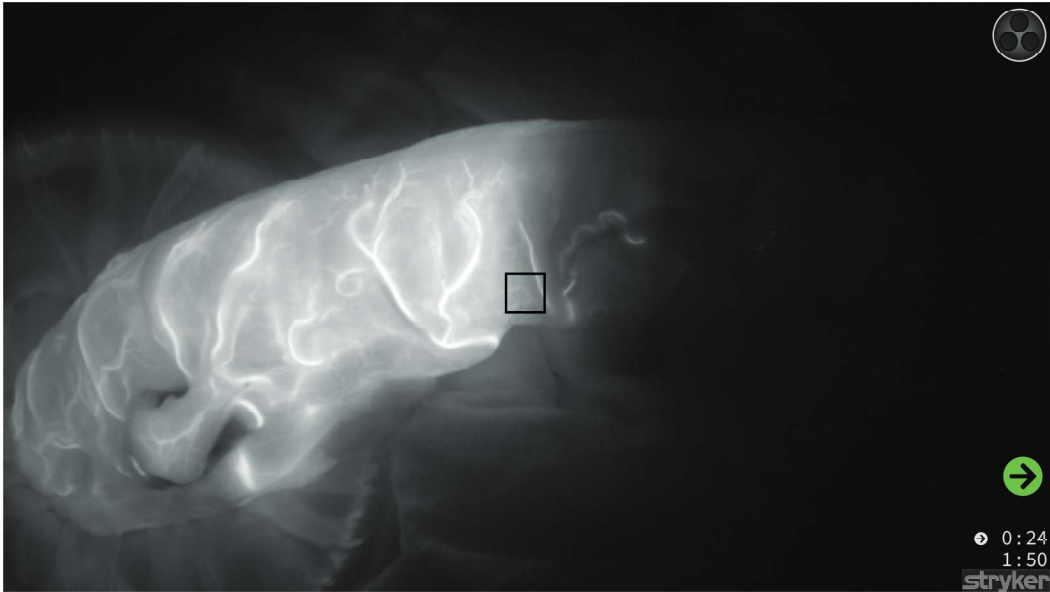
SPY-QP can be started at any time after injection of ICG.

1. With the SPY-PHI system in fluorescence imaging mode, press the **B** button on the SPY-PHI imager to open the **Tools** menu.
2. In the **Tools** menu, select the **QP** icon.



3. Press the **B** button on the SPY-PHI imager to start SPY-QP.

The stability state indicator and timestamp display if the system has confirmed fluorescence stability. The quantification box displays in the middle of the screen and a reference value can be set. The SPY-QP Color Map replaces the CSF display mode.



For information about setting a reference, see *Setting a Reference Value and Quantification* (page 6).

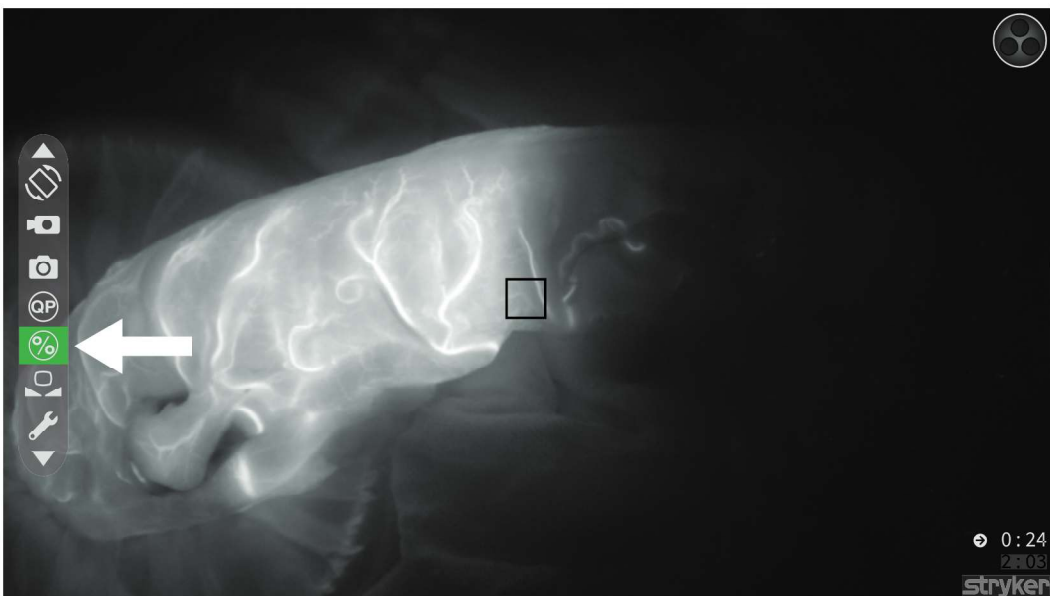
For information about using the SPY-QP Color Map, see *Using the SPY-QP Color Map* (page 7).

## Resetting the Reference Value

The reference value can be reset manually at any time after it has been set.

To reset the reference value:

1. On the SPY-PHI imager, press the **B** button to open the menu.
2. In the menu, select %.



3. Press the **B** button to reset the reference.

The reference can then be set. See *Setting a Reference Value and Quantification* (page 6) for information about setting the reference.

**Note** - The reference value is also reset if SPY-QP is exited and restarted from the menu.