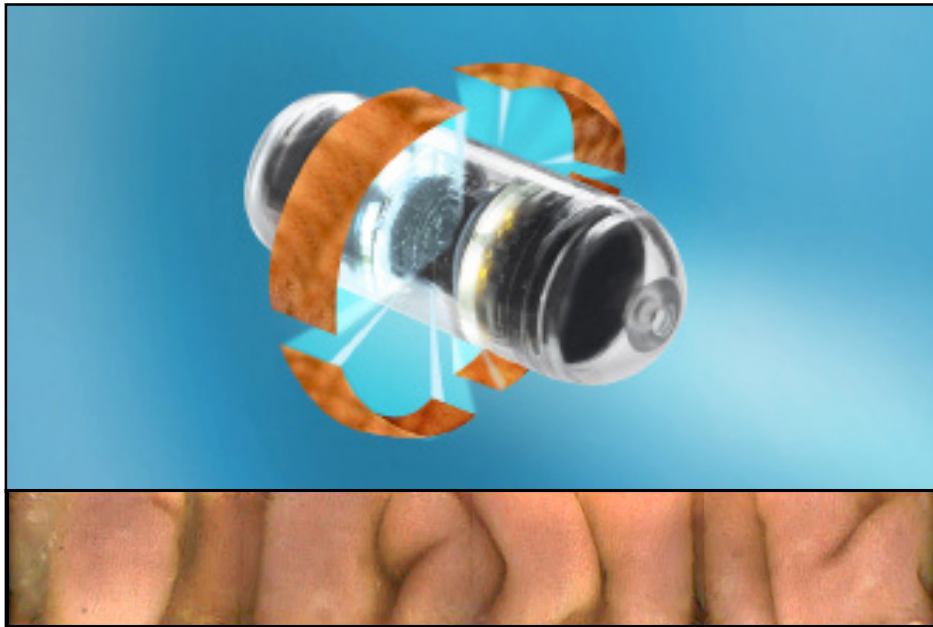


# INSTRUCTIONS FOR USE

## ALICAM™ Software



*Panoramic Image*

## Device Description

ALICAM™ Software is Infiniti Medical's proprietary software program used to download and view ALICAM™ images, and to generate detailed reports

## Indication for Use

ALICAM™ Software is intended to download the images from the ALICAM™ capsules, generate video files, review videos, annotate images, and generate reports

## Contraindications

ALICAM™ Software has no known contraindications

## Warnings

To prevent incorrect reports as result of improper use of the program, please read these operating instructions carefully before using the ALICAM™ Software program

## Intended Patient Population

This software is to be used by licensed veterinarians. It is not intended to be used directly by the animal owners. It is for animal use only and should not be used for human patients

## Intended Part of the Body or Type of Tissue Applied to or Interacted With

None

## Intended User Profile

Veterinarians





## Intended Conditions of Use

Veterinary hospitals, veterinary clinics, and veterinarian's offices

## Operating Principle

Displaying images and video for review and diagnosis on a personal computer (PC)

**Table of Symbols**

Symbol	Meaning	Symbol	Meaning
	Manufacturer's catalog designation or number		Item lot number (with accompanying number)
	Instructions are included and must be followed		Manufacturer
<b>Qty</b>	Quantity		

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# 1 Introduction

## 1.1 Infiniti Medical ALICAM™ System

The Infiniti Medical ALICAM™ system has three components:

- **ALICAM™ Capsule:** A single-use ingestible video capsule that acquires and stores images in on-board memory while moving through the patient's gastrointestinal tract propelled by natural peristalsis.
- **ALICAM™ Reader:** ALICAM™ Reader includes a Capsule Reader intended to allow trained medical personnel to download examination images from the retrieved ALICAM™ capsule after the procedure.
- **ALICAM™ Software:** The proprietary software for the management of ALICAM™ examination image data. ALICAM™ Software enables download, and easy and accurate review of the examination images and efficient report generation.

## 1.2 Intended Usage

After the patient's owner has retrieved and returned the ALICAM™ Capsule as directed by the veterinarian, trained personnel should perform the following steps to download and review the examination images and to generate a report:

1. Connect the **ALICAM™ Reader** to the workstation PC where **ALICAM™ Software** is installed.
2. Place the **ALICAM™ Capsule** in the **ALICAM™ Reader**. Please see the **ALICAM™ Reader** Instructions for Use (IFU) for the details of this step.
3. Use the **Download Images** function in **ALICAM™ Software** to download and save the examination images in a video file format.
4. Use the video playback functions in **ALICAM™ Software** to review the examination images.
5. Use the image annotation functions in **ALICAM™ Software** to annotate images of interest.
6. Use the **Generate Report** function in **ALICAM™ Software** to generate the report.

## 2 Installation

### 2.1 System Requirements

The ALICAM™ Software can be installed on a computer that meets the following requirements:

<b>CPU</b>	Intel Processor with the following specifications based on software usage: <ul style="list-style-type: none"><li>For video review, Intel i3 or above</li></ul> For download, Intel i5 or i7
<b>Memory</b>	Minimum 2 GB for 32-bit operating system Minimum 4 GB for 64-bit operating system
<b>Operating System</b>	Microsoft Windows 7 (with Service Pack 1) Microsoft Windows 8.1
<b>Display</b>	Minimum display resolution of 1680x1050. Display resolution of 1920x1080 is recommended
<b>Additional Software</b>	Software that is capable of displaying a PDF document on your computer

### 2.2 ALICAM™ Software CD

The ALICAM™ Software CD contains the following files and programs:

- ALICAM™ Software Installation Wizard program for installing ALICAM™ Software to your computer.
- ALICAM™ Software Instructions for Use (IFU) document.
- ALICAM™ Reader USB Driver Installation Wizard program for installing the USB driver for the ALICAM™ Reader to communicate with the computer.

### 2.3 ALICAM™ Software Download

Downloaded ALICAM™ software is packaged as a compressed (.zip) file. The compressed file contains the same programs and files as contained on the ALICAM™ software CD.

To unzip (extract) the downloaded software, follow the below steps:

#### For Windows 7

- 1 Locate the compressed folder that you want to extract files or folders from.
- 2 Right-click the folder, click Extract All, and then follow the instructions.

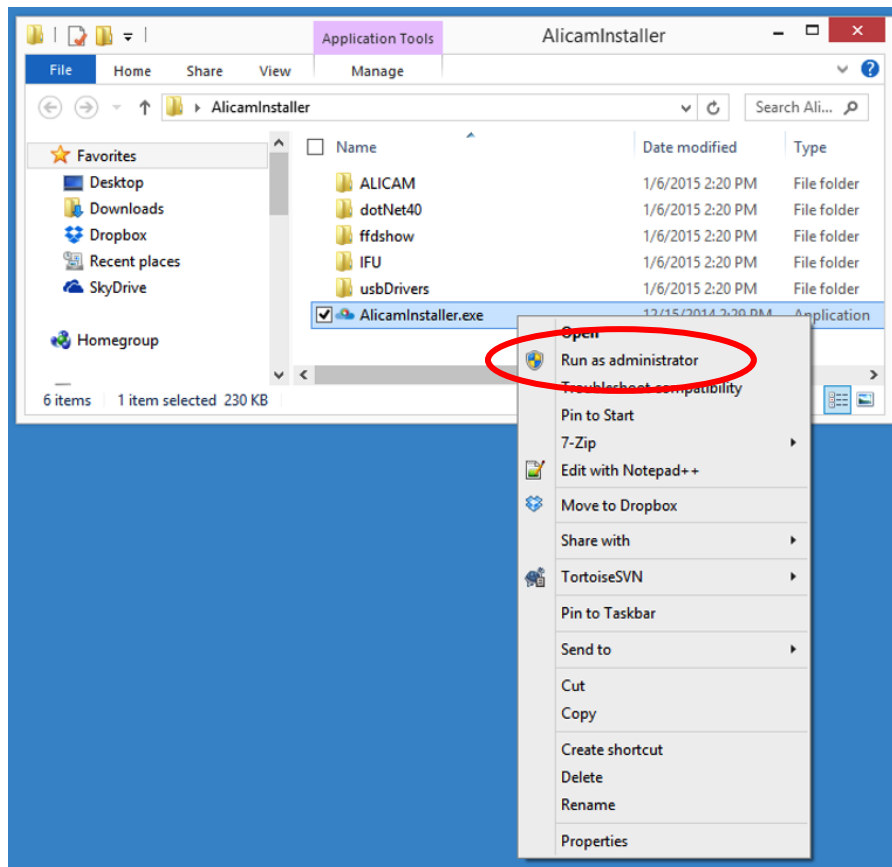
## For Windows 8.1

- 1 Open File Explorer by swiping in from the right edge of the screen, tapping Search (or if you're using a mouse, pointing to the upper-right corner of the screen, moving the mouse pointer down, and then clicking Search), entering File Explorer in the search box, and then tapping or clicking File Explorer.
- 2 Tap or click the Compressed Folder Tools tab, and then tap or click Extract all.

## 2.4 Installation of ALICAM™ Software

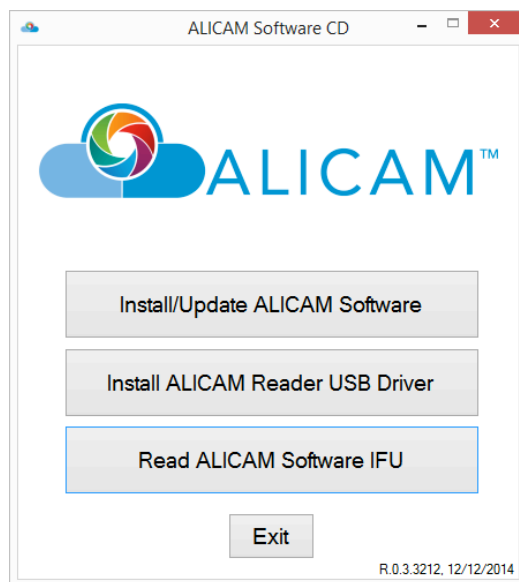
Follow these steps to install ALICAM™ Software to your computer:

- Step 1. Login to your computer as an administrator.
- Step 2. If installing from a CD, insert the **ALICAM™ Software CD** to the CD/DVD drive of your computer.
- Step 3. Use the **Windows File Explorer** to browse the content of the ALICAM™ Software CD/Folder, and then right-click **AlicamInstaller.exe**, then select **Run as Administrator**.



**Figure 1. ALICAM™ Software CD**

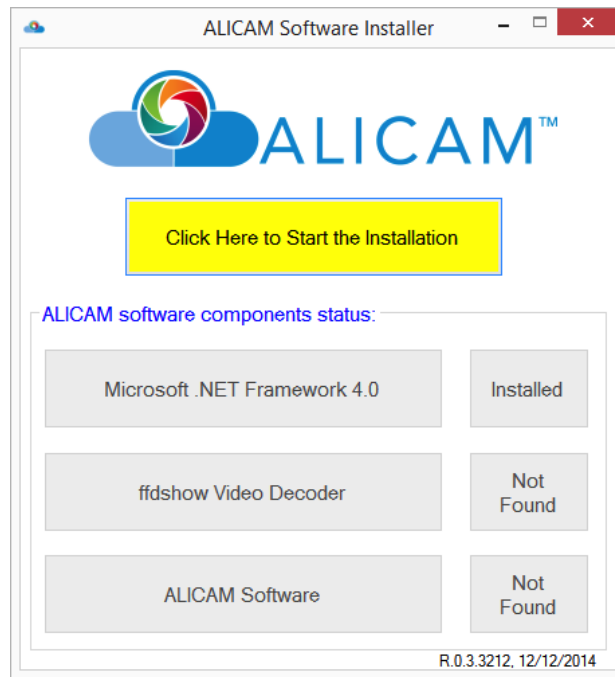
- Step 4. Click **Install/Update ALICAM Software** button when the ALICAM™ Software Installation Wizard program appears.



**Figure 2. ALICAM™ Software Installation Wizard Program**

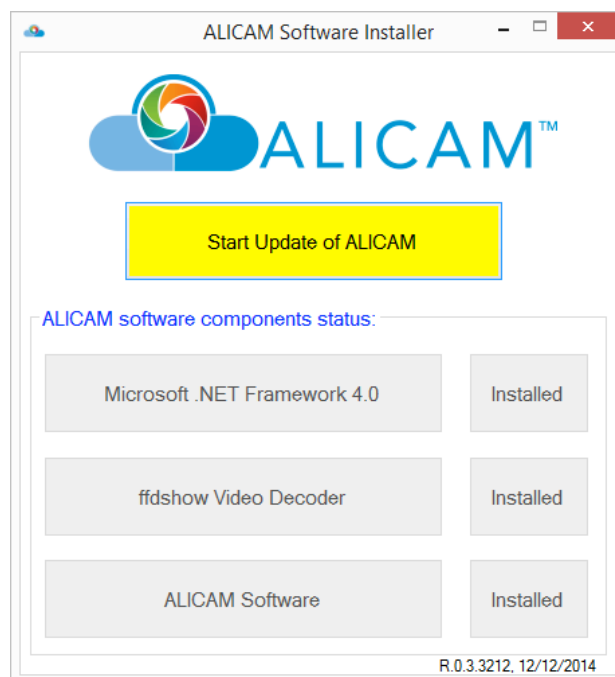
- Step 5. The ALICAM™ Software Installation Wizard will detect if the components of ALICAM™ Software have been installed on your computer, and then display the ALICAM™ Software Installer dialog box with their installation status.
- Step 6. Install ALICAM™ Software and its required components:
- If you are performing a fresh installation of ALICAM™ Software, press the **Click Here to Start the Installation** button, and then follow the on-screen instructions to complete the installation process. The ALICAM™ Software Installation Wizard will guide you through the installation of all required components.





**Figure 3. Install ALICAM™ Software**

- b. If you are updating the ALICAM™ Software to the latest version, click the **Start Update of ALICAM** button, and then follow the on-screen instruction to complete the update process. This installer program will remove the previous version of ALICAM™ Software and install the latest ALICAM™ Software version from the provided CD or file.



**Figure 4. Update ALICAM™ Software**

Follow these steps if you would like to uninstall ALICAM™ Software:

a. Windows 7 computers:

1. Click the Windows  button
2. Click **Control Panel**
3. Click **Uninstall a program**
4. Select **ALICAM Software**
5. Click **Uninstall**
6. Follow the on-screen instructions to complete the un-installation

b. Windows 8.1 computers:

1. Find **ALICAM Software** in **Start** screen
2. Right-click **ALICAM Software**
3. Click **Uninstall**
4. Follow the on-screen instructions to complete the un-installation

## **2.5 Installation of ALICAM™ Reader USB Driver**

You need to install the ALICAM™ Reader USB Driver only if you are going to use your computer to download examination images with the ALICAM™ Reader. Skip this part if you are only using the ALICAM™ Software to review and annotate the examination images and to generate reports.



Follow these steps to install (or update) the ALICAM™ Reader USB Driver on your computer:

- Step 1. Connect the **ALICAM™ Reader** to your computer with the USB cable that comes with ALICAM™ Reader.
- Step 2. Insert the **ALICAM™ Software CD** to the CD/DVD drive of your computer.
- Step 3. Use the **Windows File Explorer** to browse the content of the CD, right-click **AlicamInstaller.exe**, and then select **Run as Administrator**.
- Step 4. Click **Install ALICAM Reader USB Driver** button when the ALICAM™ Software Installation Wizard program appears.
- Step 5. The ALICAM™ Reader USB Driver Installation Wizard will detect the operating system of your computer, and then display the appropriate installer dialog box. Follow the on-screen instructions to complete the installation.

For further information about the use of ALICAM™ Reader, please refer to the ALICAM™ Reader Instructions for Use (IFU).

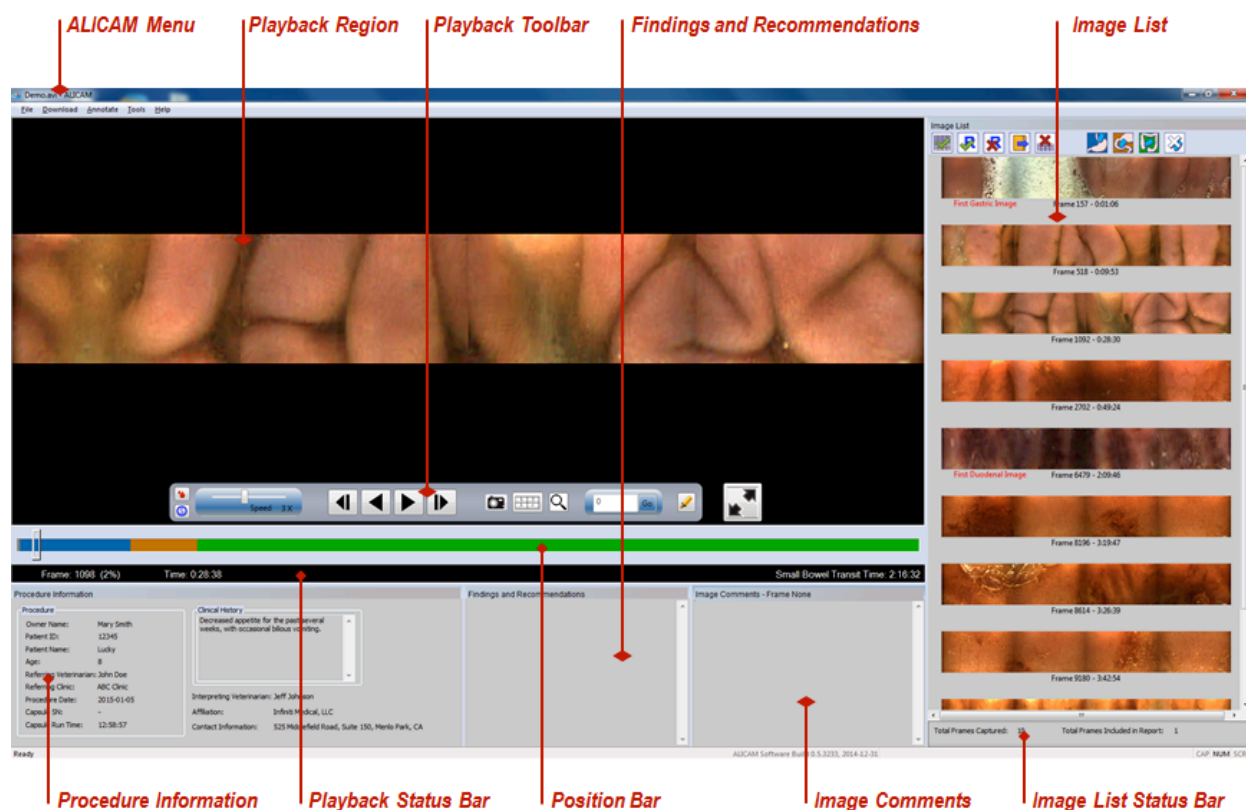
## 3 System Feature Overview

### 3.1 Starting ALICAM™ Software

Click the  icon on your desktop to start the ALICAM™ Software program. Alternatively, you can start it by clicking the  button, **All Programs, ALICAM Software** folder, and then **ALICAM Software**.

### 3.2 Main Screen

The following illustration shows the Main Screen of ALICAM™ Software.



**Figure 5. Main Screen in Standard Window Mode**

The Main Screen regions are briefly described here. More details on each of the regions are provided in later sections of this IFU:

- **ALICAM Menu** – Provides access to most ALICAM™ Software functions.
- **Procedure Information** – Displays the procedure and patient information and past clinical history for the ALICAM™ examination.

- **Playback Region** – Displays the examination video. This is also the region where graphical annotations are made while in Annotate Mode.
- **Playback Toolbar** – Contains buttons and other controls for the video playback.
- **Position Bar** – Displays the current playback position of the video, and color strips that represent anatomical gastrointestinal segments.
- **Playback Status Bar** – Shows the status information of the video playback.
- **Image List** – Displays the captured examination images from the video.
- **Image Comments** – Provides text annotation for a single image frame.
- **Findings and Recommendations** – Provides the region for the veterinarian to enter the findings and summary for the examination report and also the recommendations for future diagnosis and treatment.

### 3.3 ALICAM Menu

The ALICAM Menu provides access to the following system functions:

- **File**
  - **Open Video** – To open an examination video.
  - **Save Findings** – To save the annotations you have created/modified for the examination video.
  - **Save Video As** – To save the examination video in another file.

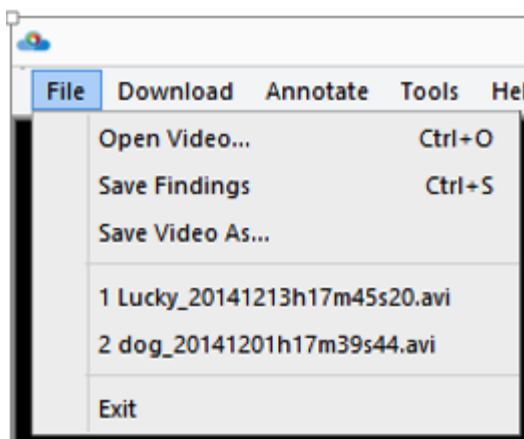


Figure 6. File Menu

- **Download**
  - **Download Images** – To download examination images.

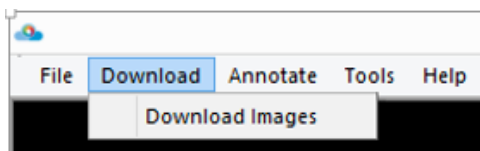
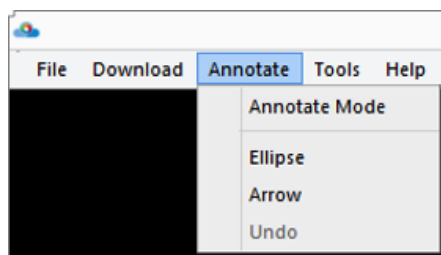


Figure 7. Download Menu

- **Annotate**

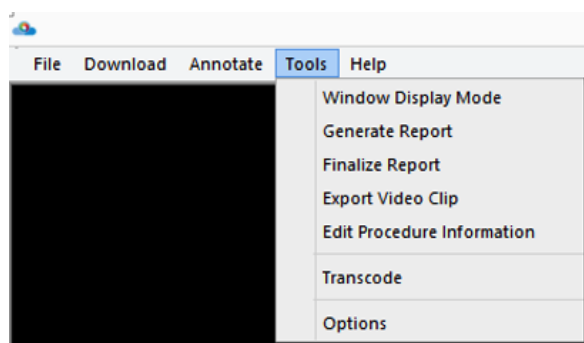
- **Annotate Mode** – To switch between examinations video Playback Mode and image Annotate Mode.
- **Ellipse** – To select ellipse annotation tool.
- **Arrow** – To select arrow annotation tool.
- **Undo** – To remove the previous graphical annotation created.



**Figure 8. Annotate Menu**

- **Tools**

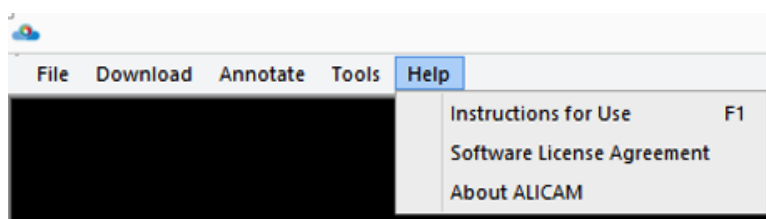
- **Window Display Mode** – To select either standard or full-screen display mode.
- **Generate Report** – To generate the report.
- **Finalize Report** – To mark a report as finalized.
- **Export Video Clip** – To export segment of the examination video to another video file.
- **Edit Procedure Information** – To make changes to the procedure information.
- **Transcode** – To re-generate the video file from the raw data (.bin) file.
- **Options** – To change ALICAM™ Software settings.



**Figure 9. Tools Menu**

- **Help**

- **Instructions for Use** – To display the IFU document.
- **End User License Agreement** – To review the ALICAM™ Software End User License Agreement (EULA).
- **About ALICAM** – To view the ALICAM™ Software version information.



**Figure 10. Help Menu**

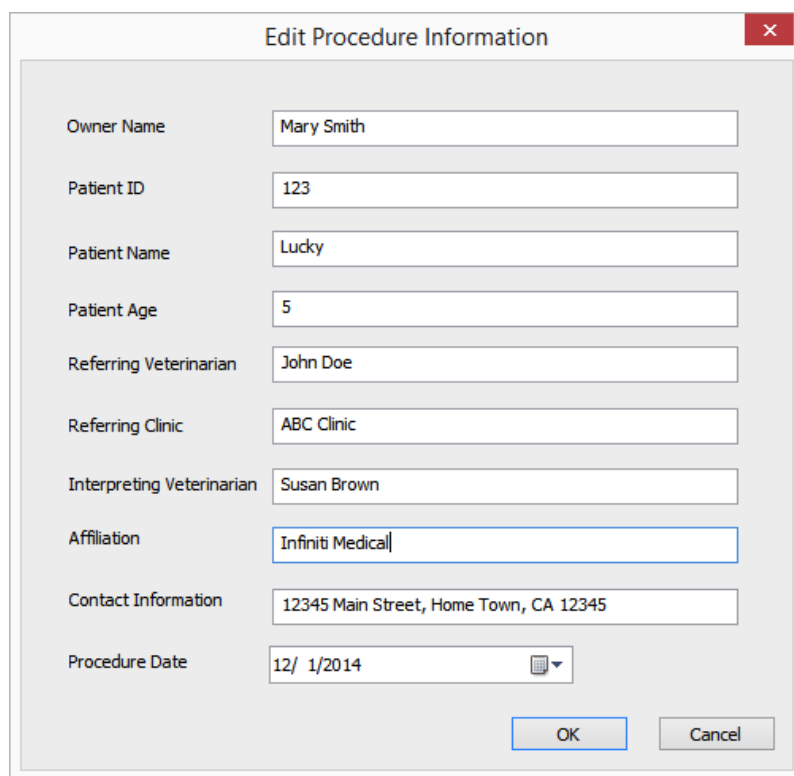
### 3.4 Procedure Information

Procedure Information	
<b>Procedure</b> Owner Name: Mary Smith Patient ID: 123 Patient Name: Lucky Age: 5 Referring Veterinarian: John Doe Referring Clinic: ABC Clinic Procedure Date: 2014-12-01 Capsule SN: J0595.0076 Capsule Run Time: 0:00:56	<b>Clinical History</b> <div>Eating disorder</div> Interpreting Veterinarian: Susan Brown Affiliation: Infiniti Medical Contact Information: 12345 Main Street, Home Town, CA 12345

**Figure 11. Procedure Information**

The **Procedure Information** displays the procedure and patient information, including the clinical history of the patient, entered during the **Download Images** process. This region also provides opportunity for cross-reference to ensure generation of report for correct patient. This section also provides a user interface to edit the **Clinical History**, which will be included in the final report.

If you need to make any corrections or edits to the procedure information that was entered during the **Download Images** process, select **Edit Procedure Information** under the **Tools** menu.



**Edit Procedure Information**

Owner Name: Mary Smith

Patient ID: 123

Patient Name: Lucky

Patient Age: 5

Referring Veterinarian: John Doe

Referring Clinic: ABC Clinic

Interpreting Veterinarian: Susan Brown

Affiliation: Infiniti Medical

Contact Information: 12345 Main Street, Home Town, CA 12345

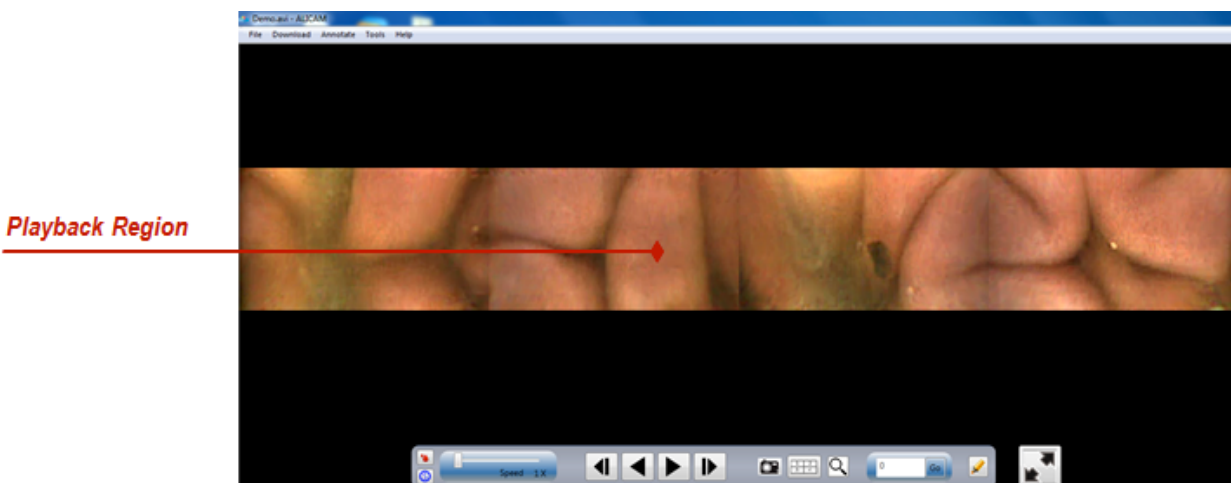
Procedure Date: 12/ 1/2014

OK Cancel

**Figure 12. Edit Procedure Information**

You can make any necessary changes to Owner Name, Patient ID, Patient Name, Patient Age, Referring Veterinarian, Referring Clinic, Interpreting Veterinarian, Affiliation, Contact Information and Procedure Date in this dialog box. To save these changes, enter the required information then click **OK**. ALICAM™ Software will display another dialog box asking you to confirm the changes.

### 3.5 Video Playback User Interfaces

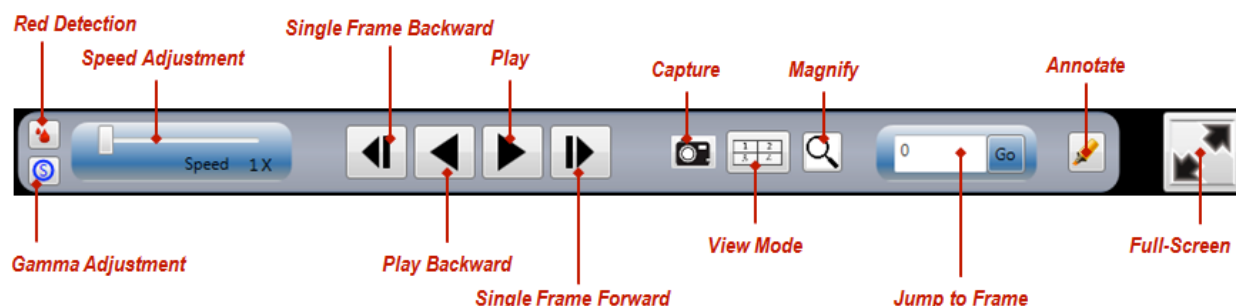


**Figure 13. Playback Region**

As the examination images are displayed in the **Playback Region**, ALICAM™ Software provides multiple user interfaces for you to control the video playback:

- **Playback Toolbar**
- **Position Bar**
- Mouse clicks in the **Playback Region**
- Keyboard

The **Playback Toolbar** (located at the bottom of the **Playback Region**) is depicted in the following figure:



**Figure 14. Playback Toolbar**

The functions for individual buttons and controls are listed below.

**Table 1. Playback Toolbar buttons**



#### **Play**

To play the video at a constant speed specified by the **Speed Adjustment** control. When the video is playing, the **Play** button will become the **Pause** button. Alternatively, you can also use left mouse click in the **Playback Region** to switch between playback and pause. Place the mouse pointer on the video and left-click once to play the video. To pause, left-click again.



#### **Play Backward**

To play the video backwards (in reverse) at a constant speed specified by the **Speed Adjustment** control. When the video is playing backward, the **Play Backward** button will become the **Pause** button. Alternatively, you can also use left mouse click in the **Playback Region** to switch between playback and pause. Place the mouse pointer on the video and left-click once to play the video backwards. To pause, left-click again.



#### **Pause**

To pause the video playback.



#### **Single Frame Backward**

To display the previous frame. Pressing the button repeatedly will cause the video to play backward one frame at a time. The scroll wheel of the mouse or the **LEFT ARROW** key can also be used to perform this function.





### Single Frame Forward

To display the next frame. Pressing the button repeatedly will cause the video to play forward one frame at a time. The scroll wheel of the mouse or the **RIGHT ARROW** key can also be used to perform this function.



### Capture

To save the current frame to the **Image List**.

It is recommended to pause the video prior to capturing an image.

Alternatively, the current frame can be captured by double-clicking when the mouse pointer is in the **Playback Region**, or by right-clicking when the mouse is on the video and then using the **Capture** menu.



### View Mode

To switch between **Normal View** (the mode to display a frame in one row, essentially 4x1) and **Stack View** (the mode to display a frame in two rows, essentially 2x2).

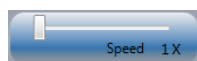


### Magnify

To display magnified view of 2 of the 4 sub-images.

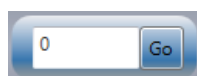
Pressing it when in normal mode will display a magnified view of sub-image 1 & 2.

Pressing it repeatedly will cycle through displaying sub-image 1 & 2, 2 & 3, 3 & 4, and then return to a normal view of all sub-images.



### Speed Adjustment

To adjust the playback speed. The playback speed can be set to desired speed by moving the slider. The playback speed can be set to from 1X (5 frames per second) to 8X (40 frames per second).



### Jump to Frame

To jump to a specific frame. Enter the desired frame number of the examination video into the text box and then click the **Go** button or press the **RETURN** key. The video is paused, and then the playback position will move to the frame number you entered.



### Red Detection

To identify frames which contain red areas in the examination video. When this button is pressed, a window opens displaying all the frames that have high concentration of red color, if there are any. Click on each frame to display the frame of the video in the **Playback Region**.

---

**Warning: Red detection is to be used as an aid to the reader. This feature should not be relied upon for diagnostic purposes.**

---



### Gamma Adjustment

To adjust the gamma parameter to change the image contrast. When this button is pressed, the Gamma Adjustment dialog box appears. The gamma setting can be made by moving the slider to choose the desired contrast.



### Annotate

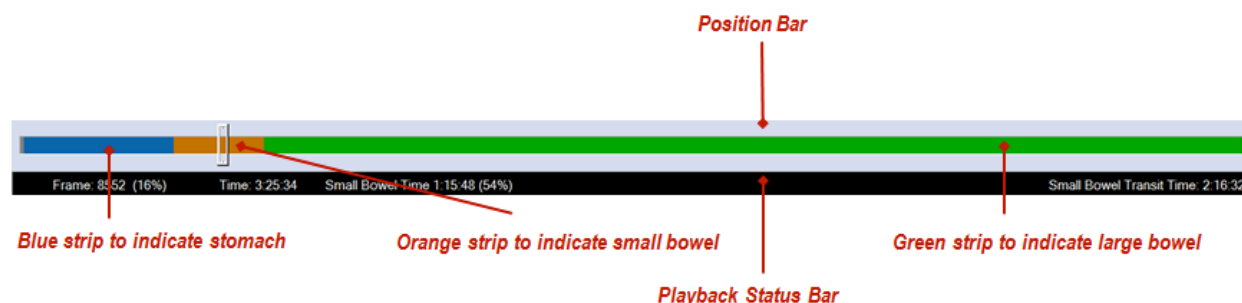
To switch from Playback Mode to Annotate Mode. This mode change can also be achieved by clicking the Annotate Mode in the ALICAM menu.



### Full-Screen

To switch from Standard Window mode to Full-Screen mode where only the Playback Region, Playback Toolbar, Position Bar, and Playback Status Bar are displayed.

The **Position Bar** and **Playback Status Bar** are depicted in the following figure:



**Figure 15. Position Bar and Playback Status Bar**

The **Playback Status Bar** provides information on the frame number and transit time.

The **Position Bar** is a slider that shows the current position in the video. However, it should be noted that the position displayed in the **Position Bar** corresponds linearly to the frame number and not necessarily to the transit time, because the frame-capture rate is not constant while the capsule travels in the gastrointestinal tract. For example, if the position is at the middle of the slider, the displayed frame number will be approximately half the number of the total frames, but this may not represent the midpoint of the total transit time. You can also click on the **Position Bar** to move the video to the position indicated by the location of the mouse. Once you are nearby the frame of interest, you should pause the video, and then use the **Single Frame Forward** and **Single Frame Backward** buttons (or scroll wheel of the mouse) to land on the exact frame of interest.

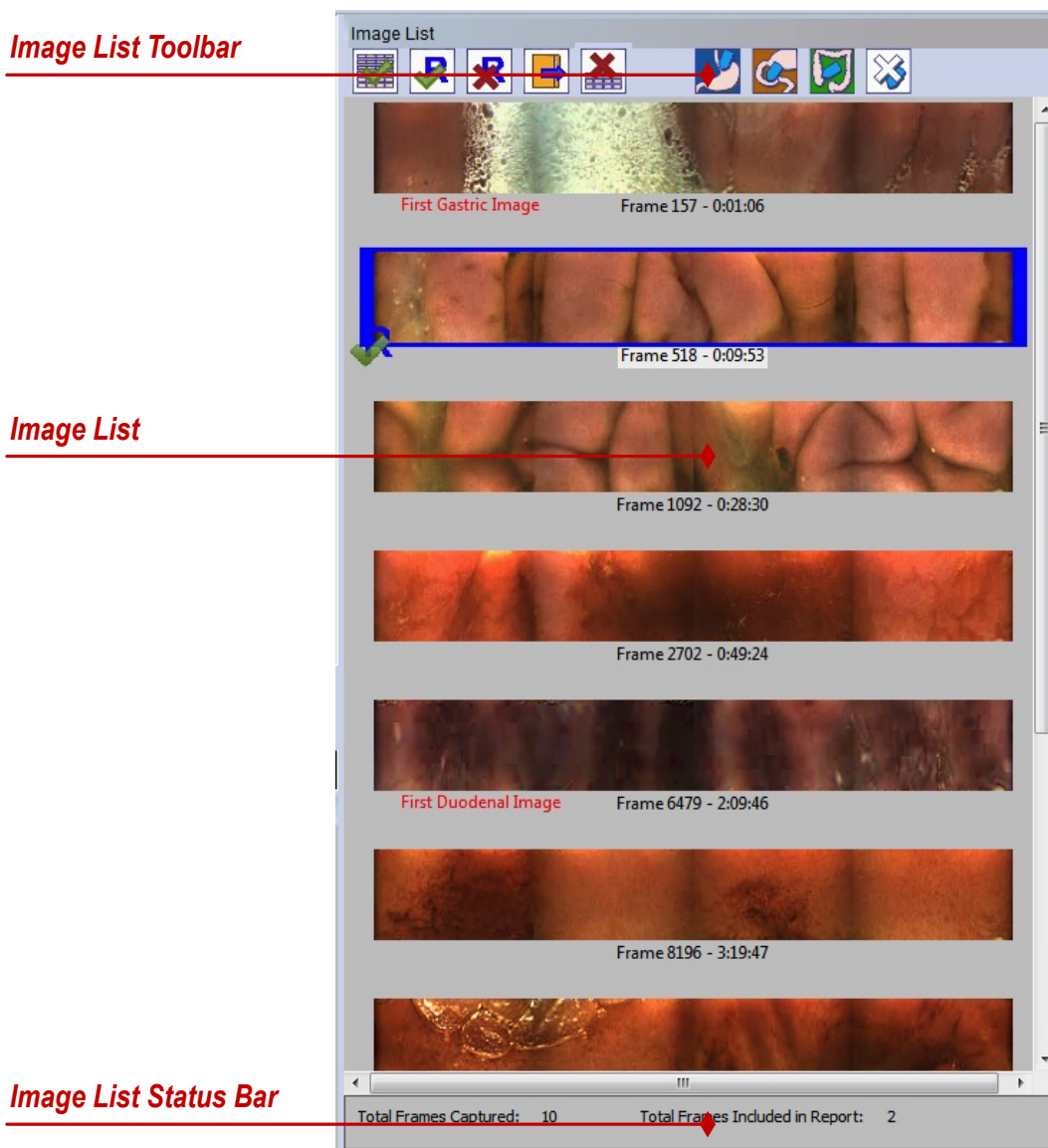
After you have placed the anatomical location for the first gastric image, first duodenal image and first cecal image (see 3.6 *Annotation User Interfaces*), the **Position Bar** would display color strips that represent different anatomical regions in the gastrointestinal tract – blue for stomach, orange for small bowel, and green for colon.

## 3.6 Annotation User Interfaces

ALICAM™ Software provides several user interfaces to annotate the examination video:

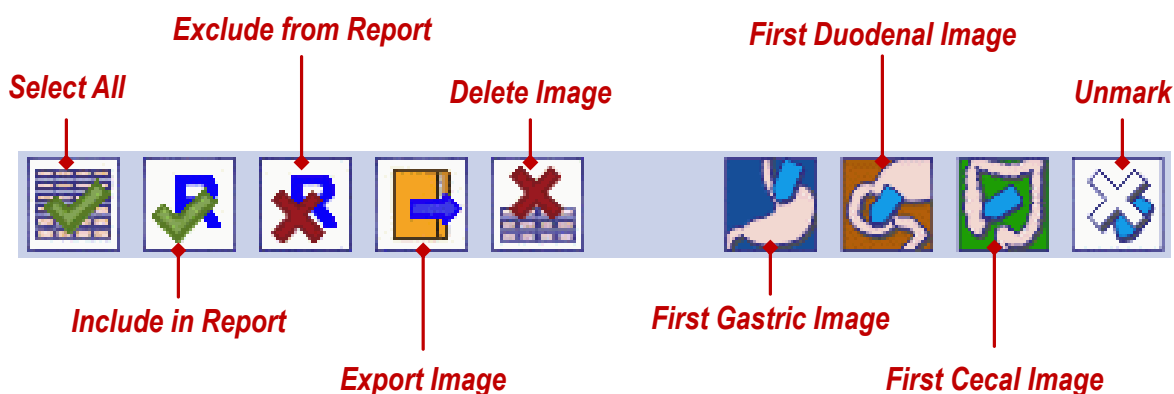
- **Image List** and **Image List Toolbar** for managing the images to be annotated.
- **Findings and Recommendations** and **Image Comments** for text annotation.
- **Annotate Toolbar** for graphical annotation.

Before annotating any image, you have to capture the image of interest. The captured images are displayed in the **Image List** as depicted in the following figure.



**Figure 16. Image List**










The **Image List Status Bar** displays a summary of the image list at the bottom.



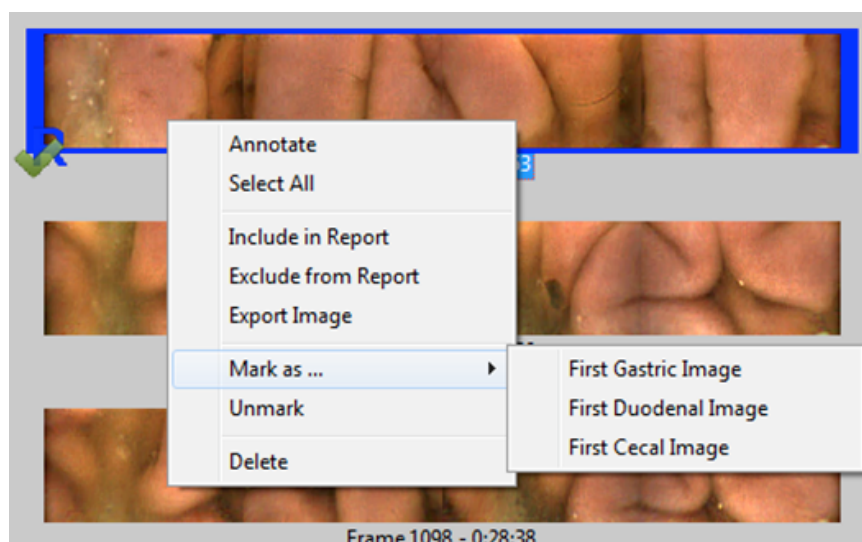
**Figure 17. Image List Toolbar**

The **Image List Toolbar** includes the following buttons to manage the images in the **Image List**.

**Table 2. Image List Toolbar Buttons**

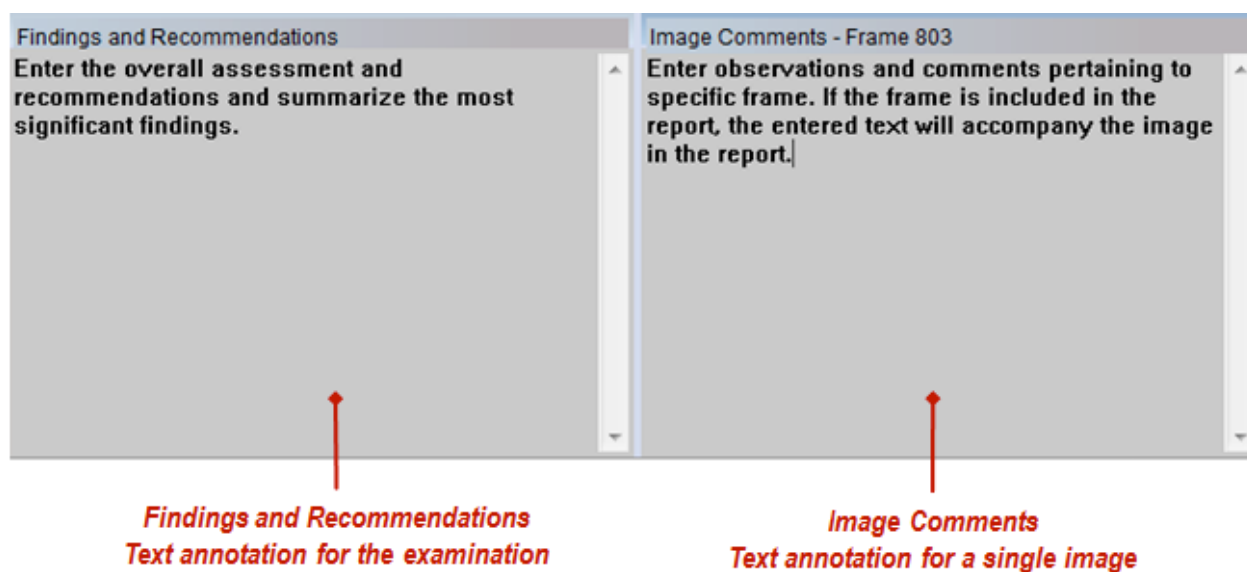
	<b>Select All</b> To select all images in the Image List.		<b>Delete Image</b> To delete an image from the Image List.
	<b>Include in Report</b> To indicate that image will be included in the report.		<b>Mark as First Gastric Image</b> To mark an image as the first gastric image.
	<b>Exclude from Report</b> To exclude from the report a previously included image.		<b>Mark as First Duodenal Image</b> To mark an image as the first duodenal image.
	<b>Export Image</b> To save an image in a separate PNG or JPG image file.		<b>Mark as First Cecal Image</b> To mark an image as the first cecal image.
	<b>Unmark Image</b> To remove the anatomical location tag from an image.		

Alternatively, you can also access the same functions by right-clicking an image in the **Image List**, as shown in the following figure.



**Figure 18. Image List Functions**

ALICAM™ Software provides two distinct text annotation regions: **Findings and Recommendations** region is to record the finding summary and recommendations for the entire examination; **Image Comments** region is to record the text annotation for a single image in the **Image List**.



**Figure 19. Text Annotation Regions**





The **Annotate Toolbar** provides the graphical annotation for an image. **Annotate Mode** must be enabled in order to use the graphical annotation functions. Annotate mode can be initiated using the **ALICAM Menu** or by clicking the **Annotate** button in the **Playback Toolbar**.



**Figure 20. Annotate Toolbar**

The **Annotate Toolbar** is located below the image to be annotated in the **Playback Region**.

**Table 3. Annotate Toolbar Buttons**

	<b>Ellipse</b> To draw an ellipse.
	<b>Arrow</b> To draw an arrow pointing to an area of interest.
	<b>Undo</b> To remove a graphical annotation.
	<b>Exit</b> To exit Annotate Mode and switch back to the Playback Mode.

## 4 Download Images and Generate Examination Video

### 4.1 Download Images

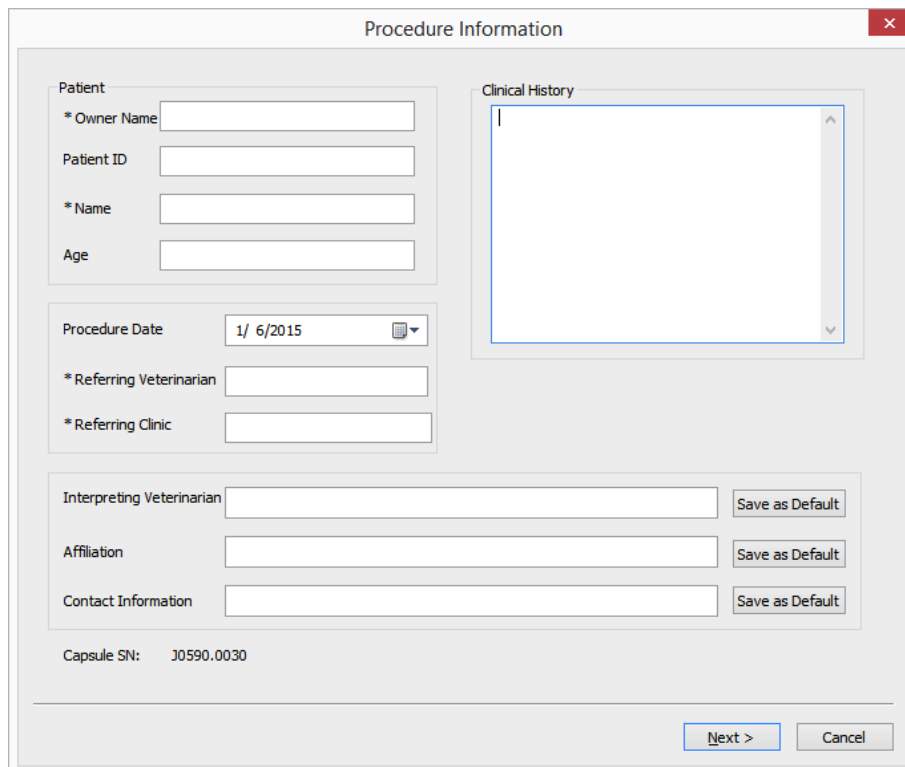
#### Step 1 – Insert the ALICAM™ Capsule into the ALICAM™ Reader

- Inspect the inside of the **ALICAM™ Reader** receptacle and remove any obstructions.
- Turn ON the **ALICAM™ Reader** power switch. The light on the system should illuminate.
- Place the capsule into the **ALICAM™ Reader** system, battery-end up.
- Close the lid of **the ALICAM™ Reader** system.

Refer to the ALICAM™ Reader Instructions for Use (IFU) for more information.

#### Step 2 – Initiate Download

On the **Download** menu, click **Download Images** to start this process. **Download Images** is not enabled unless ALICAM™ Software detects a properly connected ALICAM™ Reader. For troubleshooting, refer to the **ALICAM™ Reader Instructions for Use**. After a few seconds, the following **Procedure Information** dialog box appears.



The dialog box is titled "Procedure Information" and contains the following fields and controls:

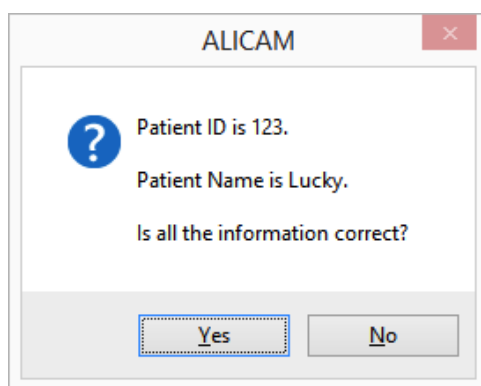
- Patient Section:**
  - \* Owner Name: [Text Field]
  - Patient ID: [Text Field]
  - \* Name: [Text Field]
  - Age: [Text Field]
- Clinical History:** [Large Text Area]
- Procedure Date:** [Date Picker] (1/ 6/2015)
- \* Referring Veterinarian: [Text Field]
- \* Referring Clinic: [Text Field]
- Interpreting Veterinarian:** [Text Field] [Save as Default]
- Affiliation:** [Text Field] [Save as Default]
- Contact Information:** [Text Field] [Save as Default]
- Capsule SN:** J0590.0030
- Navigation:** [Next >] [Cancel]

**Figure 21. Procedure Information Dialog Box**

Each ALICAM™ Capsule has a unique serial number (SN) that is programmed and stored inside the capsule during the manufacturing process. The serial number is also printed on the ALICAM™ Capsule package. The user should record the capsule serial number printed on the package into the patient chart when giving the capsule to the animal. When you place the capsule in the **ALICAM™ Reader** and start the download process, ALICAM™ Software reads the serial number from the ALICAM™ Capsule and displays it in the **Capsule SN** field. It is recommended to confirm the serial number displayed in the **Procedure Information** dialog box matches that recorded in the patient chart.

The **Procedure Information** dialog box provides entry for pertinent patient information. At minimum, **Patient Name, Owner Name, Referring Veterinarian, and Referring Clinic** must be entered in order to proceed to the next step. In order to select default values to auto-populate in the **Interpreting Veterinarian, Affiliation** and **Contact Information** fields, enter the desired names in the boxes provided and click **Save as Default**. The default settings will be effective the next time you use **Download Images** function.

Click **Next** button after verification of the capsule serial number and all procedure and patient information has been entered. ALICAM™ Software will then display a dialog box (as shown in the following figure) to confirm the patient information. Click **Yes** to continue to the next step. Otherwise, click **No** to go back to the **Procedure Information** dialog box to correct the information.

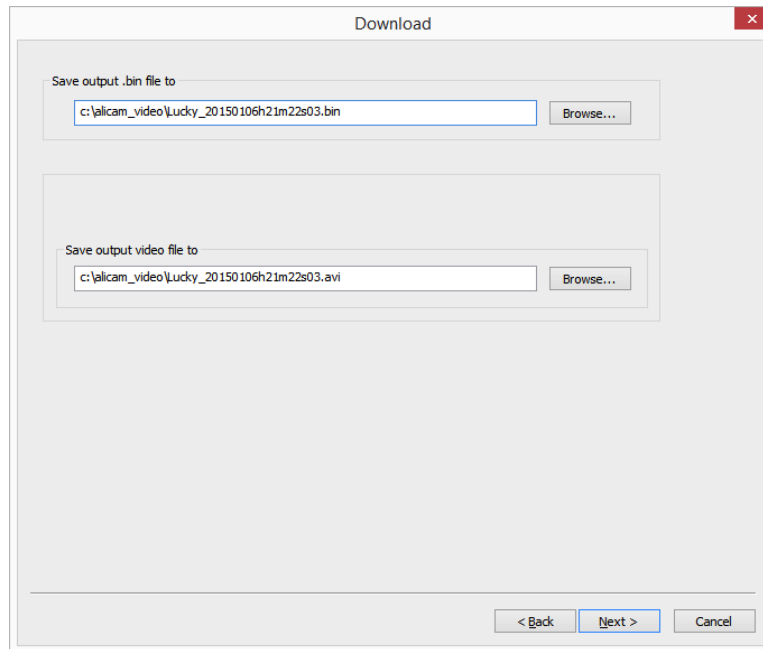


**Figure 22. Patient Information Confirmation Dialog Box**

### **Step 3 – Specify where to save the files**

After confirming patient information, the following **Download** dialog box appears.



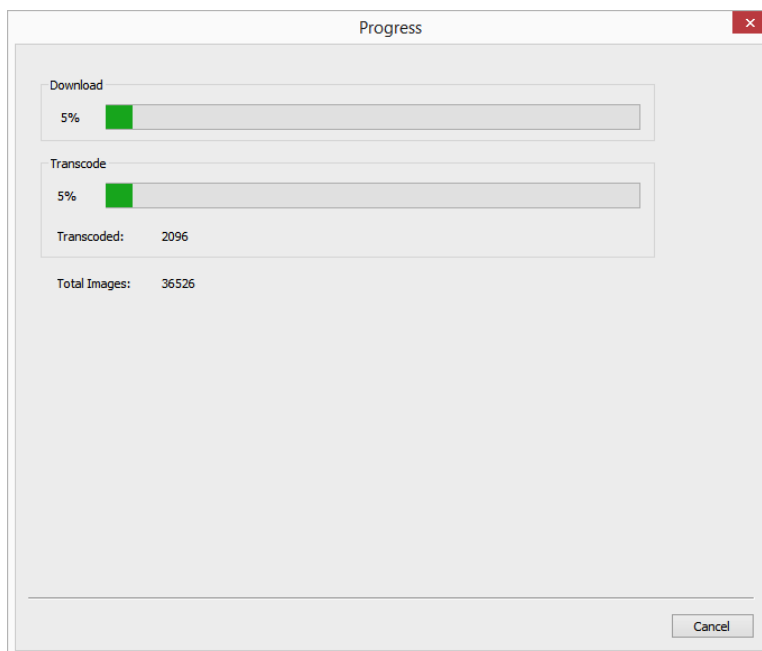


**Figure 23. Download File Dialog Box**

Using the system settings and the entered information, ALICAM™ Software will automatically assign the file names for the download. The **Download File** dialog box can be used to change the file names. The default directory for saving files is **C:\alicam\_video**, which can be changed using the **Tools** menu. Click **Next** to go to the next step.

#### **Step 4 – Download in progress**

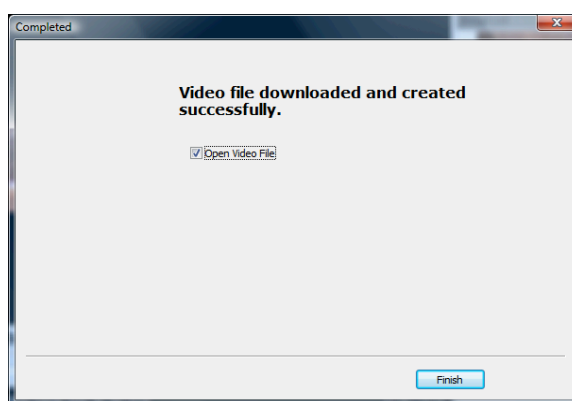
After confirming the file names, ALICAM™ Software will perform the calibration, and then display the following **Progress** dialog to show the progress of the download and the transcode function.



**Figure 24. Download Progress Dialog Box**

### Step 5 – Complete the download

After the download is complete, the following dialog box appears. Click **Finish** to dismiss this dialog box. If you check **Open Video File**, ALICAM™ Software will open this examination video once **Finish** is clicked.



**Figure 25. Download Completed Dialog Box**

Download may be terminated by clicking the **Cancel** button anytime in Step 2, 3 or 4.

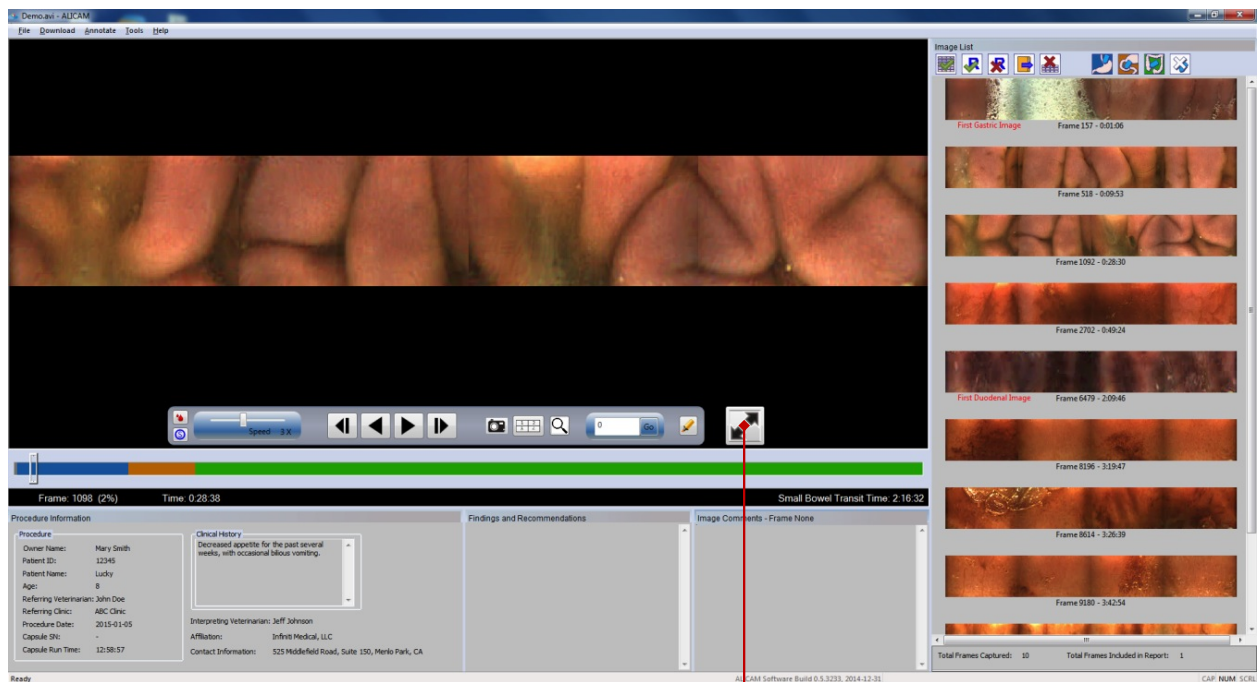
## 5 Review Examination Video

### 5.1 Display Modes

#### 5.1.1 Standard Window and Full-Screen Modes

When ALICAM™ Software is started, the **Main Screen in Standard Window** is displayed, as illustrated in Figure 5. This view provides full access to system functions. ALICAM™ Software also provides an alternative Full-Screen mode. In this mode, the Image List, Procedure Information, Finding Summary and Image Comment regions are hidden in order to view the Playback Region with minimal

distraction. After opening a video, click the **Full-Screen** button  from the **Playback Toolbar** to get into this mode.



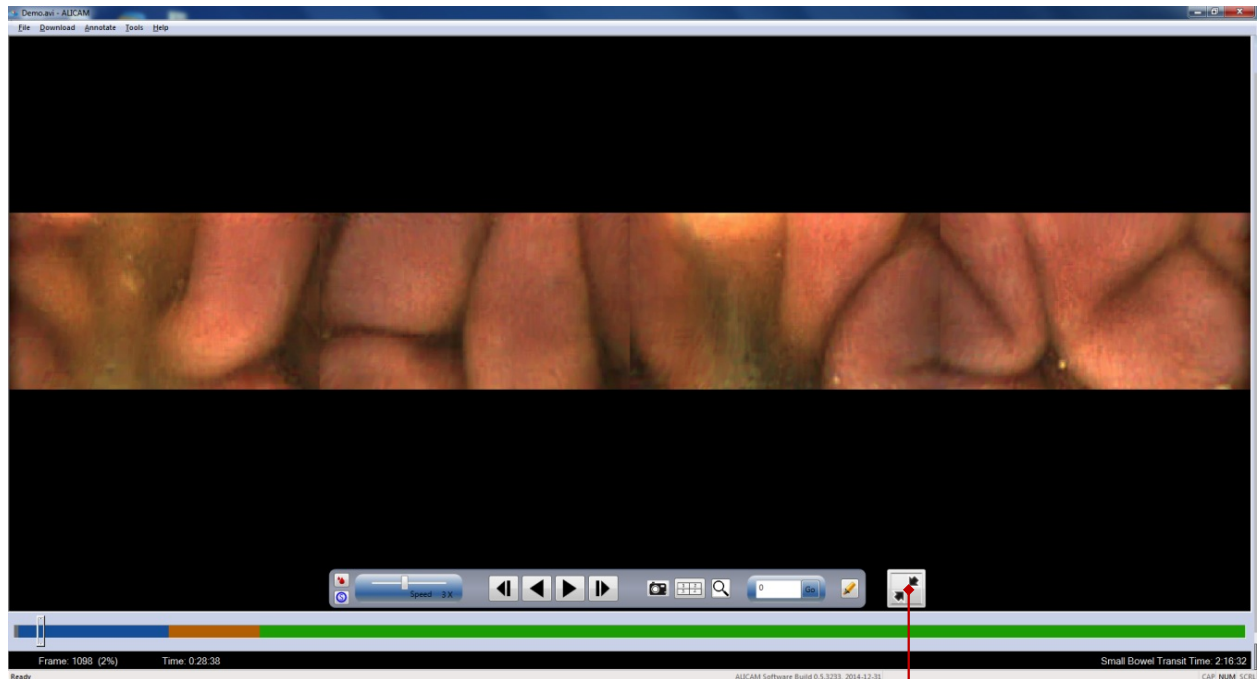
*Switch to Full-Screen mode*

**Figure 26. Full-Screen Mode Button**

When you are in Full-Screen mode, the **Full-Screen** button becomes the **Standard Window** button



, as illustrated in the following figure.



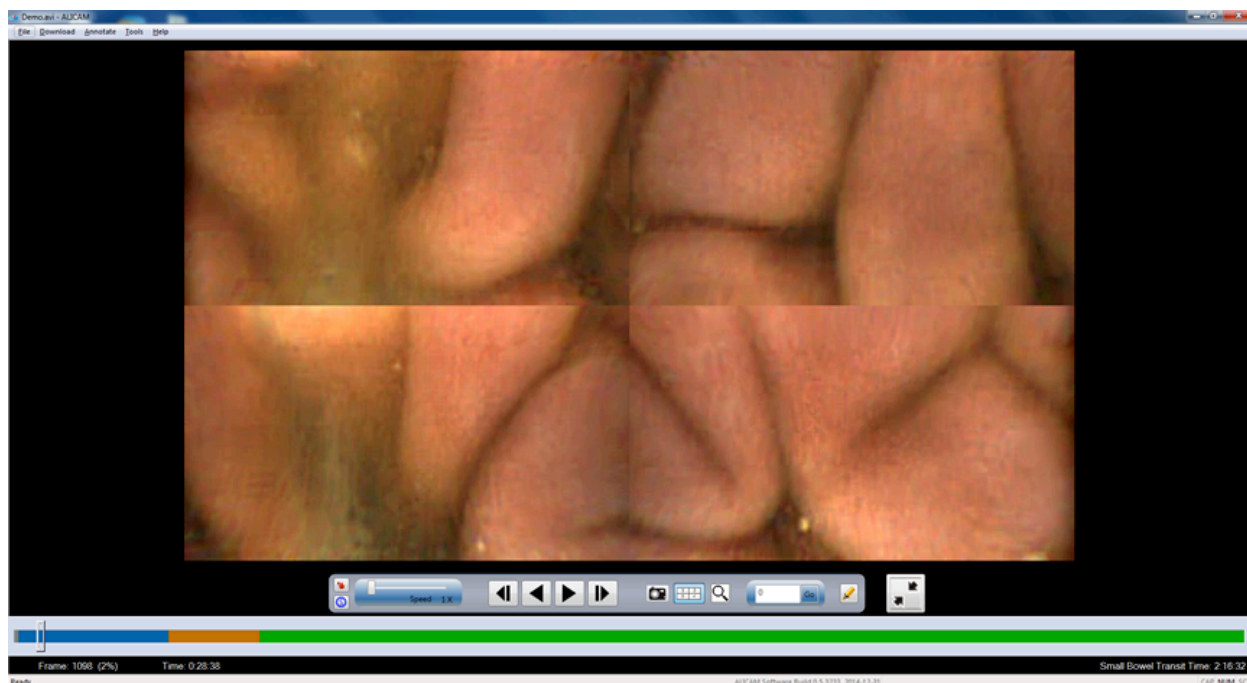
*Switch to Standard Window mode*

**Figure 27. Full-Screen Mode**

### 5.1.2 Normal View and Stack View Modes

There are four (4) cameras in the ALICAM™ Capsule that provide a 360° panoramic view of the gastrointestinal tract. The four images from these four (4) cameras comprise circumference of the gastrointestinal tract. By default, these four images are displayed in a single row. This is called the **Normal View** mode.

The images from the four (4) cameras can also be displayed in two rows, with the left two images (images 1 and 2) in the top row and the right two images (images 3 and 4) in the bottom row, as shown in the following figure. This display mode, called **Stack View** mode, provides a narrower display width/height aspect ratio.



**Figure 28. Stack View Mode**

Click the **View Mode** button  on the **Playback Toolbar** to switch between these two modes.

## 5.2 Playback Status

Both **Position Bar** and **Playback Status Bar** (Figure 15) provide status information for the current playback. The **Position Bar** displays the current position in the video graphically. Once frames are marked as the **First Gastric Image**, **First Duodenal Image**, and **First Cecal Image**, color strips will be displayed at the bottom of the **Position Bar** to indicate different segments in the gastrointestinal tract: blue for stomach, orange for small bowel, and green for colon.

**Playback Status Bar** displays information in text, including frame number, transit time and small bowel time.

**Frame number** - Indicates the frame number and percentage of frames viewed at the current position on the examination video.

**Transit time** - Indicates the time travelled by the capsule from the time it was activated until the current position.

If the current position is within small bowel region (between the first duodenal image and the first cecal image), the small bowel time and percentage will also be displayed.

### 5.3 Controlling the Video Playback

After opening a video in ALICAM™ Software, start playing the video by clicking the **Play** button in the **Playback Toolbar**. Once the video starts playing, the **Play** button will become the **Pause** button allowing for pause during playback. Alternatively, video pause or play can be achieved by clicking anywhere in the **Playback Region**.

The **Play Backward** button can be used to return to an earlier portion of the video by playing the video in reverse direction. Similar to the **Play** button, this button will become the **Pause** button once playing the video backward. Alternatively, video pause or play can be achieved by clicking within the **Playback Region**.

The playing direction (forward or backward) can only be changed through the **Play** button and **Play Backward** button.

**Single Frame Forward** and **Single Frame Backward** buttons can be used to review the examination video frame-by-frame. Pressing the **RIGHT ARROW** key will have the same effect as clicking the **Single Frame Forward** button while pressing the **LEFT ARROW** key will have the same effect as clicking the **Single Frame Backward** button. Alternatively, scrolling the mouse scroll wheel provides the same function. When the video is paused, scroll the mouse wheel down one click to forward the video one frame and scroll the wheel up one click to step the video back one frame.

The default setting of playback speed is 1X (5 frames per second), which is the lowest playback speed. The playback speed can be increased or decreased by moving the **Speed Adjustment** slider.

In addition to going through the images sequentially (either forward or backward), ALICAM™ Software also provides two features to move to a different position in the video. Click on **Position Bar** to move the video to the position indicated by the location of the mouse. Alternatively, the **Jump to Frame** allows the user to enter a specific frame number and then click **Go** button to move to that position in the video.

Use the **Gamma Adjustment** on the **Playback Toolbar** to change the image illumination as necessary. The default value for gamma is 1.0 and can be adjusted to fit the user needs in viewing any particular frames.

## 6 Annotate Images

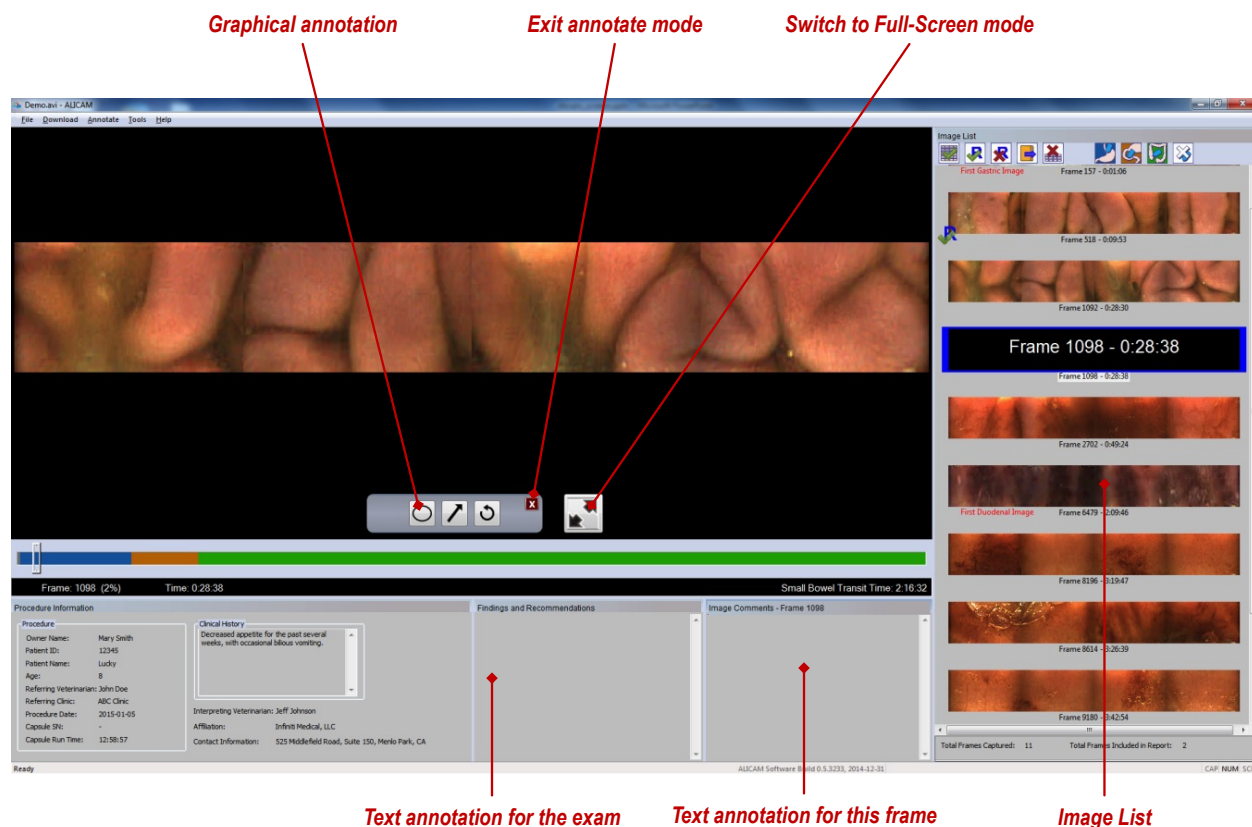



Figure 29. Annotation in Standard Window Mode

### 6.1 Capture Image


Before images can be annotated, the video must be paused and the image captured and saved into the **Image List**.

There are two ways to capture an image: (1) click the **Capture** button  in the **Playback Toolbar**; (2) double-click in the **Playback Region**. With the mouse pointer in the **Playback Region**, a single-click will pause the video if it is playing, or to start playing again if it is paused. Double-click to capture the current frame and save it to the **Image List** when the mouse pointer is in the **Playback Region**.


Even though you can capture images while the video is playing, it is recommended that you pause the video before capturing the image. Otherwise, the image captured may not be the one intended.

### 6.2 Image List

All captured images are saved in the Image list displayed at the right-hand side of the Main Screen in Standard Window mode as illustrated in Figure 29. The thumbnails of these images are displayed in the order of the transit time in this list. The frame number, transit time, and text annotation are

displayed beneath the thumbnails. If an image is selected to be included in the report, a  symbol will display at the lower-left corner of the thumbnail. If an image is marked as the **First Gastric Image**, **First Duodenal Image**, or the **First Cecal Image**, it will also be displayed here.

The **Image List Toolbar**, located at the top of the list (Figure 17) can be used to manage the image list. The buttons in this toolbar are discussed in Table 2.

Use the last button  to unmark the previously marked image. Alternatively, another image may be chosen and marked with the anatomical location. The only restriction for marking an image with an anatomical location tag is that the first duodenal image must be in between the first gastric image and the first cecal image.

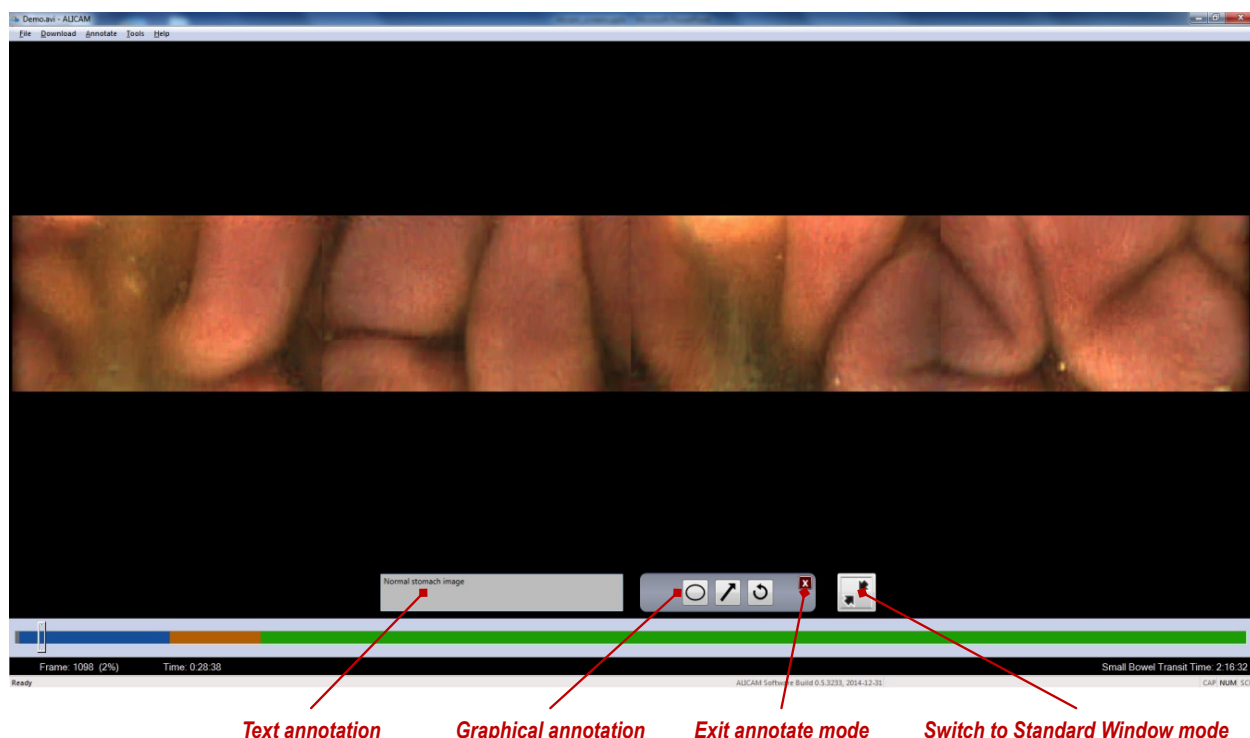
The alternative way to access these **Image List Toolbar** functions is to right-click an image in the list, the functions will appear as illustrated in Figure 18.

### 6.3 Text Annotation

After you have captured an image, text can be entered as text into the **Image Comments** region (Figure 19). This can be edited immediately after capturing the image or by selecting the image in the **Image List**. **Annotate Mode** is not necessary to use this function. The title at the top of this region indicates the frame for which the description is being entered. Also, the thumbnail of that image will be highlighted in the **Image List** to indicate that it is selected for text annotation.

When in **Annotate Mode** in Full-Screen display mode, the **Image Comments** region will appear as a small text box at the left-hand side of the **Annotate Toolbar** as illustrated in the following figure.








**Figure 30. Annotation in Full-Screen Mode**

After reviewing the video and entering annotation for the images, use the **Findings and Recommendations** region (Figure 19) to summarize findings and issue recommendations. After which the report can be generated.

## 6.4 Graphical Annotation

In addition to text annotation, graphical annotations on the images can be made. After capturing an image or selecting an image in the **Image List**, click the **Annotate** button on the **Playback Toolbar** to enter the Annotate Mode. Alternatively, on the **Annotate** menu, click **Annotate Mode**.

In Annotate Mode, instead of the **Playback Toolbar**, the **Annotate Toolbar** will appear in order to draw ellipses or arrows on the image.

To draw an arrow on an image, select the arrow drawing tool by clicking the **Arrow** button  in the **Annotate Toolbar**. Move the mouse pointer to the location in the image where one end of the arrow will be, press the left button of the mouse, move the mouse (without releasing the left button) toward the desired resting place of the arrow head and then release the mouse button. The arrow will now be drawn on the image. Similarly, an ellipse can be drawn in the same way by selecting the **Ellipse** button  first. To erase the previously created graphical annotation, click the **Undo** button  on the **Annotate Toolbar**.

These annotate functions are also available on the **Annotate** menu.

## **6.5 Saving Annotation**

When you click the **Save Findings** menu item, ALICAM™ Software will save all annotation data (captured images with graphical and text annotation, finding summary and recommendations) in a file with the same name as the video, but with CVA file extension. This file is saved in the same folder as the video file.

It is important that both the video file and the CVA annotation file are saved with the same name in the same file location.

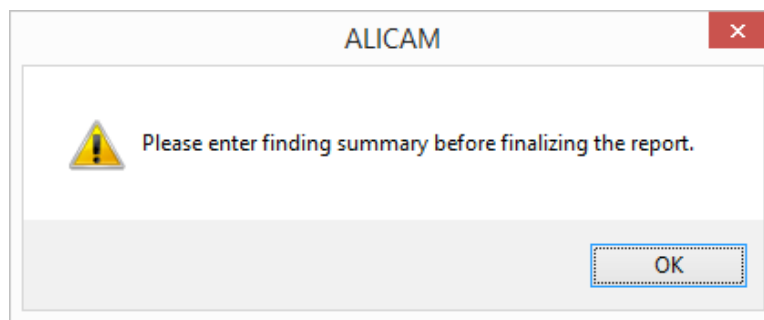
When you click the **Open Video** menu item, ALICAM™ Software will look for this annotation file and display the annotation. If you have accidentally renamed the annotation file, but still keep it in the same folder and still keep the CVA file extension, ALICAM™ Software can still find it and display the annotation. However, if you have deleted it or moved it to another folder, ALICAM™ Software will display the video without any annotation.

## 7 Generate Reports

ALICAM™ Software allows users to generate two types of reports: a draft report and a finalized report. The draft report allows users to preview a report, while a finalized report will mark the video as read-only, preventing further changes.

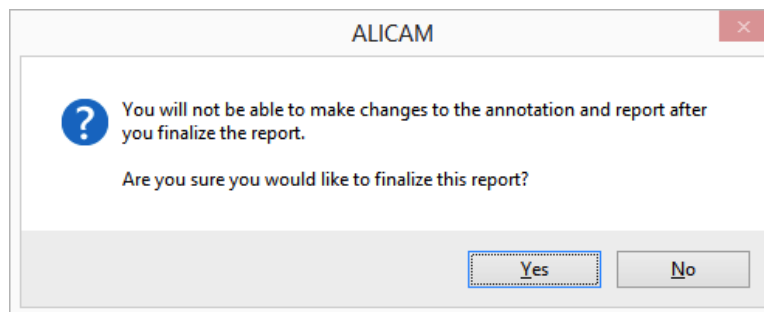
### 7.1 Finalize Report

When you are sure that you have correctly entered all information for the exam, you can mark the report as finalized so that you can generate the finalized report and prevent it from further editing. On the **Tools** menu, click **Finalize Report** to mark a report as finalized. If you have not entered minimum required data, an error message, similar to the one shown in Figure 31, will appear.



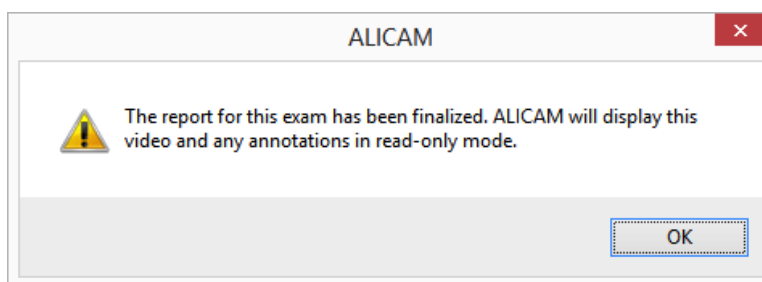
**Figure 31. Error Checking Before Finalize Report**

If you have entered minimum required data, the following dialog will appear to ask you to confirm.



**Figure 32. Confirmation for Finalizing Report**

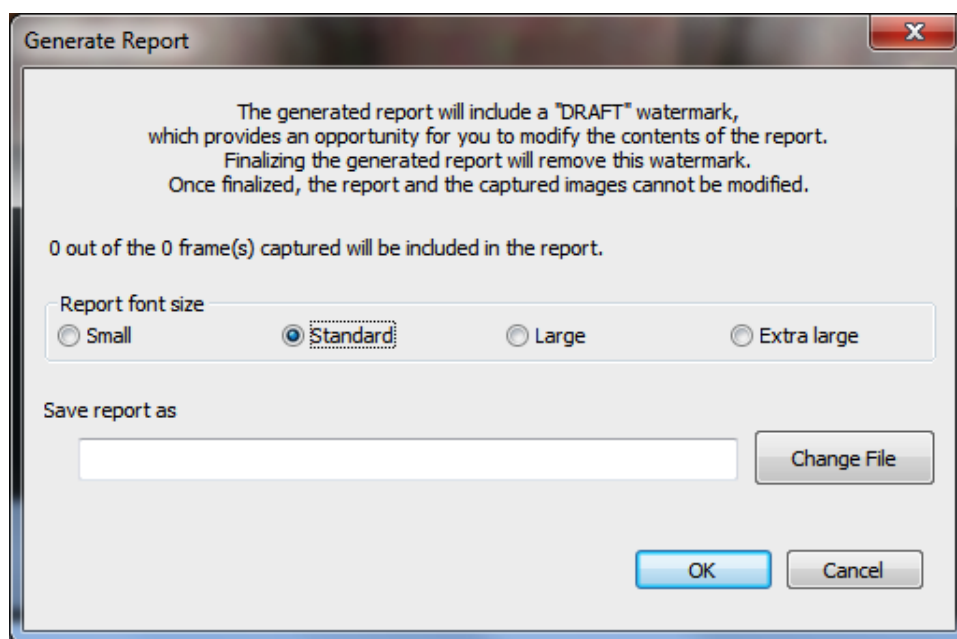
After you confirm the decision to finalize the report, ALICAM™ Software will switch to read-only mode, then display the following warning message. Whenever you try to open a video with finalized report, ALICAM™ Software will display the same message to remind you that you are viewing this video in read-only mode.



**Figure 33. Warning Message in Opening a Finalized Exam**

## 7.2 Generate Report

On the **Tools** menu, click **Generate Report** to create a PDF report using the annotated images selected to be included in the report. The following dialog box will appear.



**Figure 34. Report Generation Dialog Box**

Font size can be changed using the **Report Font Size** box.


Assign the saved report location by using **Change File** to start the **Windows File Explorer** to navigate to the desired folder. Enter the desired name of the file in this location.


Clicking the **OK** button will generate the report.

ALICAM™ Software will generate the report and display it in PDF Reader. If the report is still in draft status, a "DRAFT" watermark will appear in the report as shown in Figure 35. If the report has been marked as finalized, the report footer will include the date and time when the report was finalized by the veterinarian, as shown in Figure 36.

Draft.pdf - Adobe Reader

File Edit View Window Help


1 / 1
64.4%
Tools Sign Comment

## ALICAM Ambulatory Light-based Imaging Report

Patient Name:	Lucky
Patient Age:	8
Patient ID:	12345
Owner Name:	Mary Smith
Interpreting Veterinarian:	Jeff Johnson
Affiliation:	Infiniti Medical, LLC
Referring Veterinarian:	John Doe
Referring Clinic:	ABC Clinic
Procedure Date:	Monday, January 05, 2015
Capsule SN:	-

First Gastric Image:	Time: 0:01:06, Frame: 157
First Duodenal Image:	Time: 2:09:46, Frame: 6479
First Cecal Image:	Time: 4:26:18, Frame: 10295
Gastric Transit Time:	2:08:40
Small Bowel Transit Time:	2:16:32

Clinical History:  
Decreased appetite for the past several weeks, with occasional bilious vomiting.

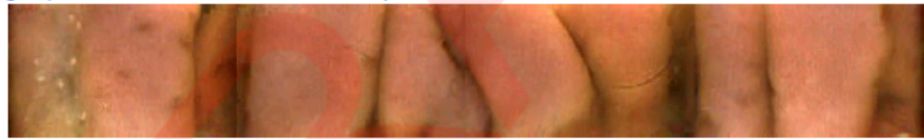
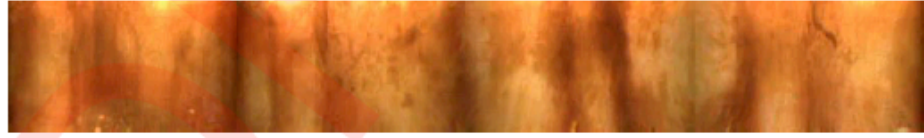
Findings:  
Image 1 (Frame Number: 518, Transit Time: 0:09:53)  


Image 2 (Frame Number: 10287, Transit Time: 4:24:05 ( Small Bowel Time 2:14:19 (99%) ))  


Finding Summary and Recommendations:  
Angiodysplasia. To be treated by prescription.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Contact Information: 525 Middlefield Road, Suite 150, Menlo Park, CA 94025


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Created at Wednesday, January 07, 2015, 11:49 AM

**Figure 35. Example Draft Report**

Final.pdf - Adobe Reader

File Edit View Window Help


1 / 1
64.4%
Tools Sign Comment

## ALICAM Ambulatory Light-based Imaging Report

Patient Name:	Lucky
Patient Age:	8
Patient ID:	12345
Owner Name:	Mary Smith
Interpreting Veterinarian:	Jeff Johnson
Affiliation:	Infiniti Medical, LLC
Referring Veterinarian:	John Doe
Referring Clinic:	ABC Clinic
Procedure Date:	Monday, January 05, 2015
Capsule SN:	-

First Gastric Image:	Time: 0:01:06, Frame: 157
First Duodenal Image:	Time: 2:09:46, Frame: 6479
First Cecal Image:	Time: 4:26:18, Frame: 10295
Gastric Transit Time:	2:08:40
Small Bowel Transit Time:	2:16:32

Clinical History:

Decreased appetite for the past several weeks, with occasional bilious vomiting.

Findings:

Image 1 (Frame Number: 518, Transit Time: 0:09:53)

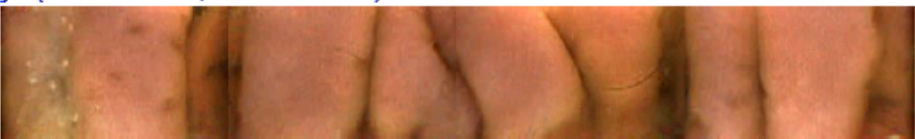
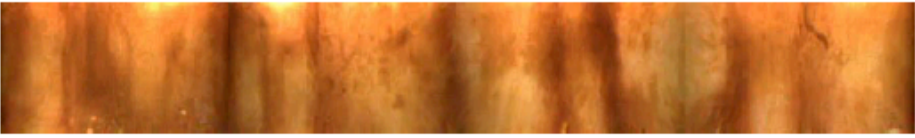


Image 2 (Frame Number: 10287, Transit Time: 4:24:05 ( Small Bowel Time 2:14:19 (99%) ))



Finding Summary and Recommendations:

Angiodysplasia. To be treated by prescription.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Contact Information: 525 Middlefield Road, Suite 150, Menlo Park, CA 94025

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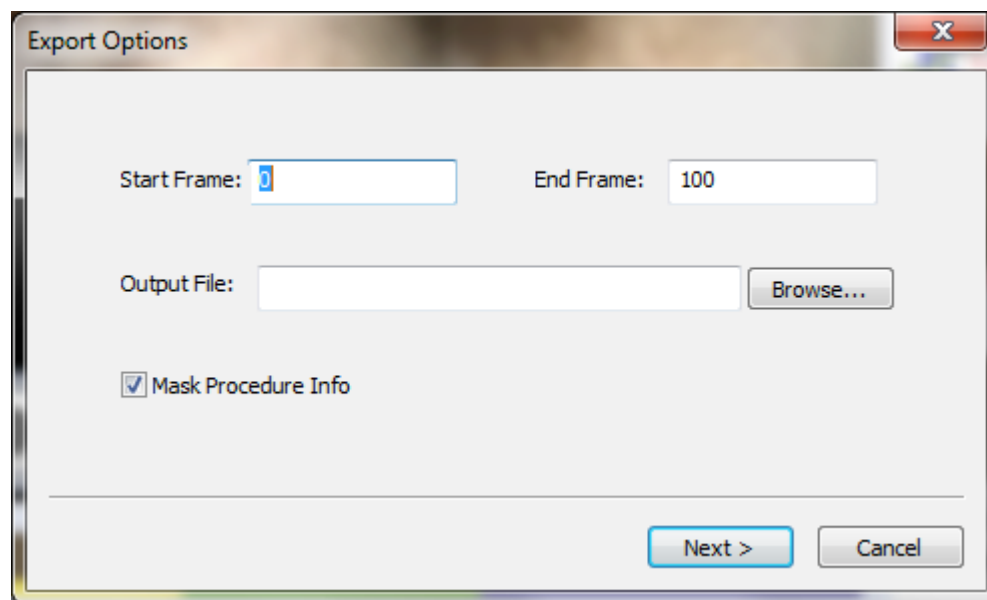
Report Finalized at Wednesday, January 07, 2015, 11:50 AM

**Figure 36. Example Finalized Report**

## 8 Export Video Clips and Images

### 8.1 Export Video Clips


On the **Tools** menu, click **Export Video Clip** to export and save a segment of the examination video to another file. The following dialog appears. Enter the start frame, end frame, output file name, and whether to mask the procedure info. Click the **Next** button to generate the video.

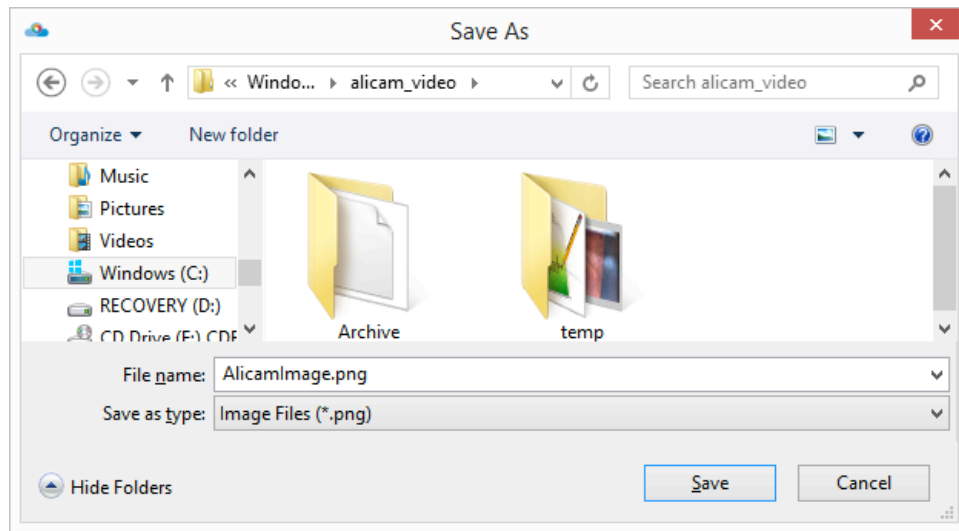


**Figure 37. Export Video Clip**

The numbers in **Start Frame** and **End Frame** indicate the video segment to be included in this video clip. Click the **Browse** button to start the **Windows File Explorer** to select the folder and file name to save the video. The default, **Mask Procedure Info** is checked to indicate that the procedure and patient information will not be included in the video clip to protect patient privacy. Uncheck this box to include that in the video clip. The finding summary and recommendation and image annotations will not be included in the exported video clip; only the original images for the selected video segment will be included.

### 8.2 Export Images

An image can be exported and saved to a separate PNG or JPG file by clicking the **Export Image** button (  in the **Image List Toolbar**) after selecting an image in the **Image List**. The following dialog box will appear to input the location to save the file. As the default, the file will be saved in PNG format, which has a better quality. Click **Save As Type** to change it to save the image in JPG format, which is compatible with most computer programs.



**Figure 38. Export Image Dialog box**

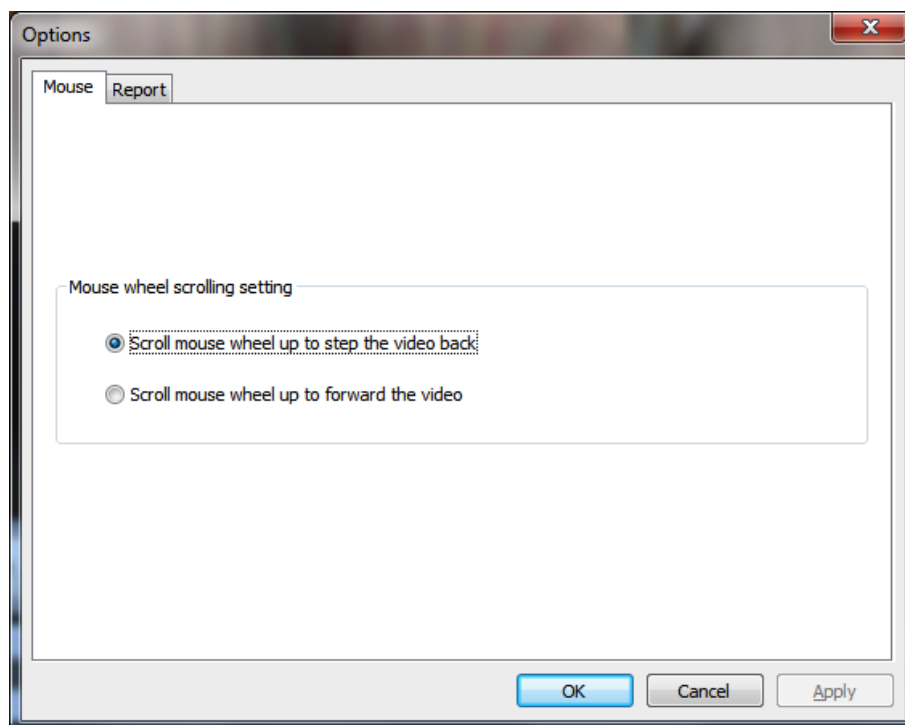


## 9 Change System Settings

There are several system settings in ALICAM™ Software that you can change to fit the operating environment and user preference. On the **Tools** menu, click **Options** to display the dialog box for changing the system settings. This dialog box includes two tabs that are described in the following sections.

### 9.1 Mouse

Instead of playing the video at a constant speed or using the **Single Step Backward** and **Single Frame Forward** buttons on the **Playback Toolbar**, the scroll wheel on the mouse may be utilized to control the video playback. With the default setting, after pausing the video, scrolling up the wheel has the same effect as pressing the **Single Step Back** button. Similarly, scrolling down the wheel has the same effect as pressing the **Single Frame Forward** button. The direction setting can be changed using the dialog box illustrated in the following figure.

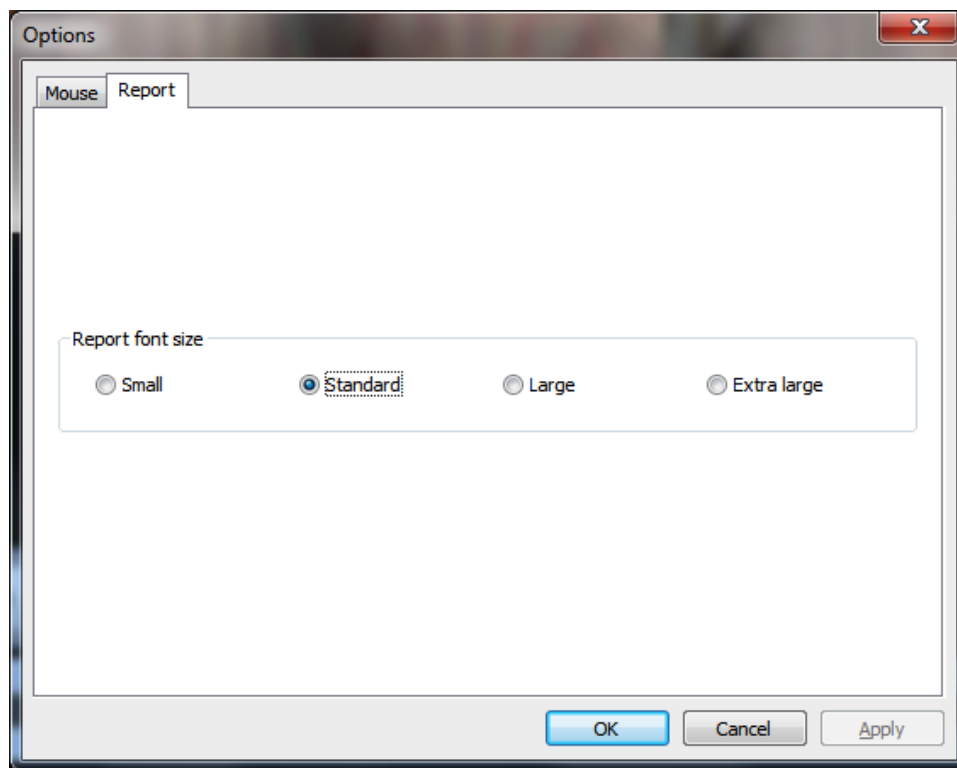


**Figure 39. Change Mouse Setting**

Simply choose the desired setting, and then click **OK** to save the change. The change is effective immediately after you saved it.

### 9.2 Report Generation

Even though the font size can be changed every time you want to generate a report, default values can be set via the dialog box illustrated in the following figure.



**Figure 40. Change Default Report Setting**

To change the default font size, simply select the desired size. After you make the changes, click **OK** to save the changes. The changes are effective immediately.

## 10 Training

Users can contact Infiniti Medical or its Authorized Representatives for training on how to use the ALICAM™ Software application. Contact information is listed at the end of this document.

## 11 Getting Help and Troubleshooting

This document is available in the ALICAM™ Software program in the **Help** menu, or by pressing the **F1** key. Other language versions are available on the **ALICAM™ Software CD**.

Please refer to **ALICAM™ Reader Instructions for Use** (provided with the ALICAM™ Reader System) for connecting the ALICAM™ Reader to your computer and for download images.

The following table provides common issues and their resolution:

Issue	Resolution
Some screens have been cut off	<ul style="list-style-type: none"> <li>Make sure that your computer screen resolution is 1680 x 1050 or higher</li> </ul>
Captured image is not the one that you intended to capture	<ul style="list-style-type: none"> <li>Pause the video before capturing an image</li> </ul>
Download Images menu is disabled	<ul style="list-style-type: none"> <li>Make sure that the ALICAM™ Reader USB Driver is installed on this computer</li> <li>Make sure the ALICAM™ Reader is turned on and is connected to the computer using the provided USB cable</li> <li>Make sure the ALICAM™ Capsule in the ALICAM™ Reader is properly aligned</li> <li>Try to turn off and then turn on the ALICAM™ Reader</li> </ul>
Error message appears during download	<ul style="list-style-type: none"> <li>Make sure the ALICAM™ Reader is properly connected to the computer using the provided USB cable</li> <li>Turn off the ALICAM™ Reader and then turn it back on. Re-align the ALICAM™ Capsule and then retry the download.</li> </ul>
Problem in installing ffdshow	<ul style="list-style-type: none"> <li>Make sure you use “Run as administrator” option in using the installer program</li> </ul>
Problem in installing ALICAM™ Reader USB driver	<ul style="list-style-type: none"> <li>Make sure you use “Run as administrator” option in using the installer program</li> <li>Check Infiniti Medical website to ensure you are using the latest version of the ALICAM™ Software to install the most current driver</li> </ul>

Please refer to Infiniti Medical web site for additional help and trouble shooting for using ALICAM™ Software.

Please include the following information if you are reporting a problem or requesting assistance from Infiniti Medical or its Authorized Representatives:

- Computer hardware specification.
- Version of the operating system on the computer.
- ALICAM™ Software version.
- Description of error situation, including screen shots when appropriate.
- Steps taken leading up to the error.

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**Warnings**

To prevent incorrect reports as result of improper use of the program, please read these operating instructions carefully before using the ALICAM™ Software program.

**Storage**

The ALICAM™ Software is stored on a CD. The CD should be kept in a cool dry location under normal environment conditions.

**Warranty**

Refer to the Warranty section in the End User License Agreement, which is available under the Help menu in ALICAM™ Software program.

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