NaviCam Capsule Endoscope System with NaviCam Stomach Capsule User Manual

AnX Robotica Corp.

UM-NCES-ST-01, Revision 1

Warranty
AnX Robotica Corp. assures that all parts in the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule are well-designed, manufactured, packed and tested for prevention of defects, and assumes no responsibility for any accident, loss, damage or cost increase directly or indirectly resulting from use of the ESNavi platform. AnX Robotica Corp. will repair or replace parts within the warranty period, while customer is responsible for all other items including normal wear and team or anything that is out of the control of AnX Robotica Corp., including but not limited to operation, storage, cleaning, misuse, abuse, patient treatment or diagnosis. This warranty replaces any other warranties which may have been implied in verbal or documented form.

Modifications by User or Third Party
Any and all modifications to the product which are not expressly in writing approved AnX Robotica Corp. will void this warranty in its entirety.

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Caution:
US Federal law restricts this device to sale by or on the order of a physician.

Contents

CHAPTER 1: INTRODUCTION

1.1 Important Information

A thorough understanding of the technical principles, clinical applications and risks associated with the NaviCam Stomach Capsule is necessary before using this product. Read this entire manual before using the system for the first time.

Caution

Failure to follow this instruction may result in damage to the equipment or pollution to environment.

Warning

1. **Failure to follow instructions could result in injury or even death to operator, patient or other personnel.**
2. **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

1.2 About NaviCam Capsule Endoscope System with NaviCam Stomach Capsule

The User Manual introduces the use of NaviCam Capsule Endoscope System with NaviCham Stomach Capsule (Model: NC-I). The NaviCam Capsule Endoscope System with NaviCham Stomach Capsule is a Controllable Stomach Capsule System. This chapter introduces tip information involved in the quick guide and the User Manual.

NaviCam Capsule Endoscope System with NaviCham Stomach capsule enables the operator to control the capsule endoscope inside the stomach. The capsule endoscope can be moved in any direction during examination. The direction and angulation of the capsule camera head can be adjusted in real-time, hence realizing complete control of capsule endoscope movement and attitude during examination in the X left and right, Y forward and backward, Z up and down directions as well as rotation clockwise and counterclockwise.

The NaviCam Capsule Endoscope System with NaviCham Stomach capsule is comprised from the following components:

- NaviCam Controller（Model: NaviEC-1000)
- Data recorder (Model: AKR-1)
- Capsule (Model: AKEM-11SW)
- Locator (Model:AKS-1)
- NaviCam ESNavi Software

A description of each component is provided below.

1.2.1 NaviCam Controller

The NaviCam Controller consists of four parts:

Name	Length (mm)	Width (mm)	Height (mm)	Weight (kg）
Console	1190±20	840±20	790±20	65
Translational Rotation Platform	2140±20	1850±20	1930±20	510
Magnetic Head	420±20	320±20	520±20	40
Examination Bed	1750±20	650±20	630±20	45

The Translational Rotation Platform constitutes the main structure. The magnetic head is rigidly attached to the front cantilever of the platform and covered by an outer casing.

The examination bed is rigidly attached to the base of the platform and covered by the outer casing.
The Console is independently and firmly placed next to the platform and bed. It is connected to the platform with cables, which are set into an aluminum rail to prevent stepping on and damaging the cables.
Image transmission from capsule to recorder is through wireless transmission. Image transmission between the recorder and the NaviCam Controller is through USB cable.

1.2.1.1. Translational Rotation Platform, Examination Bed and Magnetic Head

The Translational Rotation Platform houses the magnetic head and electronic systems. The Platform includes a 5D motion system (3D linear motion and 2D rotation motion, achieving three-axis linear motion and two-axis rotation motion of the magnet during examination). Figure 1-1 demonstrate the Translational Rotation Platform, Examination Bed and Magnetic Head.

Figure 1-1 Translational Rotation Platform

Warning

The examining table has load-bearing capacity of 135 kg.

1.2.1.2. Console

The Console, presented in Figure 1-2, consists of an operator control panel, a computer which includes the ESNavi software and two monitors. The Console is used by the operator to control the motion of the Translational Rotation Platform which

controls the motion of the capsule endoscope inside patient's stomach. It also enables, related tasks such as image processing, patient information and reporting functions.

Figure 1-2 Console

Warning

The console can only be operated by well-trained operators.
Do not touch the display and the patient body simultaneously.

1.2.2 Data Recorder (AKR-1)

The Data Recorder (AKR-1), presented in Figure 1-3, is a portable data receiving unit with built-in rechargeable lithium battery placed inside the examination cloth worn by the patient during examination. It is used for receiving image data wirelessly transmitted from the capsule endoscope.
The Data Recorder is charged with an included charger when not in use.

Figure 1- 3 Data Recorder (AKR-1)

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference

to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

Warning

Never charge the Data Recorder when it is in use with a patient.

1.2.3 Capsule

The NaviCam Stomach Capsule (hereinafter referred to as "capsule"), presented in Figure 1-4, is a capsule endoscope capable of capturing images inside the human stomach. This capsule contains a built-in camera, wireless receiving and transmitting unit, LED lights, battery and a magnet. All components are sealed in a case made of biocompatible materials.

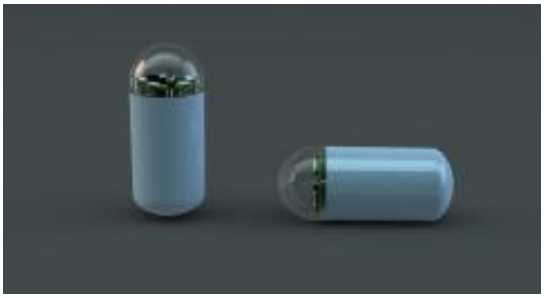


Figure 1-4 Capsule

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

1.2.4 Locator

The Locator, presented in Figure 1-5, is a portable magnetic scanning device with built-in rechargeable lithium battery. It can be used for detecting whether a capsule is inside the human body and probing its approximate position.
The Locator is charged with an included charger.

Figure 1- 5 Locator

Warning

Never charge the Locator when it is in use with patient.

1.2.5 NaviCam ESNavi Software

NaviCam ESNavi Software is installed in the Console computer and is used for operating the NaviCam System and Capsule. The ESNavi Software enables the following functions:

- Control X/Y/Z-axis translational motion of the magnetic head and rotation motion in horizontal/vertical direction which enables capsule movement.
- Capsule video monitoring.
- Enables multi-image browsing.
- Controls and adjusts browsing and playing speed.
- Controls image enhancement, rotation and zooming.
- Display's and controls system functions in real-time.
- Used to manage case database.
- Used for patient report editing, print preview and other functions.

CHAPTER 2: INDICATIONS, CONTRAINDICATIONS AND WARNINGS

2.1 Indications

The NaviCam Stomach Capsule is intended for visualization of the stomach. The system can be used in clinics and hospitals, including ER settings.

2.2 Contraindications

NaviCam Stomach Capsule is contraindicated in the following patients:

- Patient with known or suspected gastrointestinal obstruction, stenosis or fistula.
- Patient implanted with a cardiac pacemaker or other implantable electronic medical device.
- Patient implanted with an easily magnetized metal part.
- Patient with dysphagia.
- Pregnant women.

2.3 Adverse Events

Potential adverse events associated with the use of a capsule include injury to a patient caused by delayed excreting or not excreting of capsule, inhalation, and interference from strong magnetic field sources. It could be necessary to remove the capsule by intervention.

2.4 Warnings

Warning is used to suggest risks that may cause dange to patient or operator.

- Patient should fully understand the requirements for use of this product and instructed by the Physician.
- Patients should never use two capsules with the NaviCam System.
- Patients or practitioners implanted with an electronic device such as a pacemaker should remain at least 2 meters from the system
- The capsule can be swallowed and used only in the presence of authorized personnel.
- Before examination, make sure that all clothes with metal wire or metal parts and all other metal objects such as watch or coin are removed from the patient.
- If there is any concern about the integrity of the capsule, it should not be used until an authorized representative of AnX Robotica Corp. is consulted. The

capsule should be turned off and put back in the holder and then placed in the blister. A new capsule should be used.
- Do not use an expired capsule.
- The capsule can be swallowed and the system used for examination only after the physician has determined that the subject does not have any other camera capsules in their gastrointestinal tract that has not been excreted.
- Patient should avoid biting the capsule when swallowing.
- Do not approach any strong magnetic field source, such as the magnetic field generated by a magnetic resonance imaging device, after swallowing the capsule until it has been excreted or if it cannot be confirmed whether the capsule has been excreted.
- The capsule should be kept away from DC electromagnetic fields or static magnetic fields.
- If patient has any abdominal pain, nausea or vomiting after swallowing the capsule, contact the physician immediately.
- The capsule must be stored in a safe place and kept out of reach of children.
- If a child accidentally swallows any unused or used capsule, a physician must be consulted.
- A patient's dietary instructions must be followed as directed by the physician.
- Negative or normal results obtained from an imaging capsule cannot completely rule out the presence of a disease or injury and, if symptoms persist, further evaluation should be performed.
- The capsule is for single use only.
- If the patient is not sure whether the capsule has been expelled or not, the patient should immediately contact the physician.
- An MRI examination may cause serious injury to the intestine or abdominal cavity and should never be used on patient with an ingested capsule.
- When installing the system ensure that there is no strong magnetic field device such as MRI device within 5 meters of the installation room.
- Cover the inspection bed with new sheet before each patient to prevent contamination.
- To reduce influence from electromagnetic interference, keep a proper distance from other medical electronic devices when using the NC-I system.
- To reduce influence from electromagnetic interference, do not expose the equipment to or locate it closely to RF source (for example, a device working in 2.4GHz radio band).
- Even if other devices meet corresponding national emission standards, the system may still be interfered.

2.5 Emergency Stop Procedure

In the event of an emergency while using the system, press the emergency stop button. If appropriate, move the patient away from the area.

2.6 Disposal of the NaviCam Capsule Endoscope System

When the NaviCam Capsule Endoscope System with NaviCham Stomach Capsule is to be disposed, contact your local qualified solid waste disposal company to dispose the magnetic ball. Dispose of all other parts is done according to local regulations regarding electronics waste.

CHAPTER 3: WIRING AND CONTROL PANEL OF CONSOLE

3.1 Wiring of Console

The Console is connected to an external 120VAC 60Hz socket via a power cable. The Console is electrically connected to the Translational Rotation platform via a cable.

Interfaces for connecting the Translational Rotation platform and 120VAC 60Hz socket are visible on the lower left side of the console after the cover is removed. The potential equalization conductor is only be operated in medical facilities where supplementary equipotential bonding has been installed and tested according to country-specific regulations.

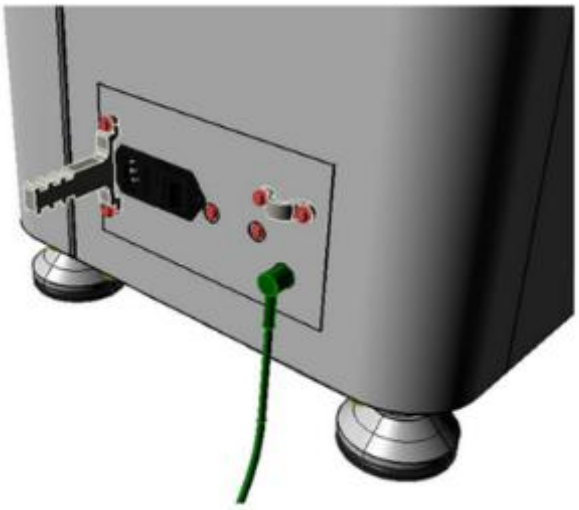


Figure 3- 1 Wiring Panel

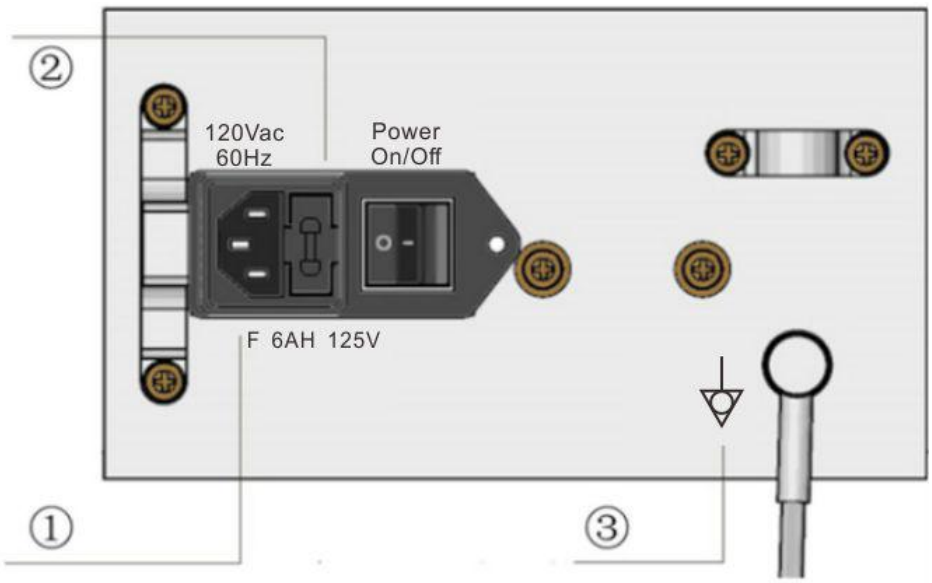


Figure 3- 2 Schematic Diagram of Wiring Panel

Wherein:
① 120Vac, 60Hz power interface.
② Fuse socket.
③ Potential equalization conductor

Warning

Do not step on the connection cable.
Unplug if not used for a long time to safely terminate the operation of the device.

3.2 Control Panel of Console

The control panel on the Console is provided with power switch and emergency stop switch as shown in the following figure:

Figure 3- 3 Equipment Panel

If the Console fails during operation, the NaviCam System can be immediately stopped by applying the brake and pressing down the emergency stop switch.

CHAPTER 4: OPERATION INSTRUCTION FOR ESNAVI SOFTWARE

4.1 Installing Software

1. Under the installation directory, double click the software installation icon ESNavi-Installer_... to access installation program.

Figure 4- 1 ESNavi Installation Welcome Interface

2. Click "Next" to access License Agreement Interface as shown in Figure 4-2.

Figure 4- 2 License Agreement Interface

3. Click "Next" to access installing interface as shown in Figure 4-3.

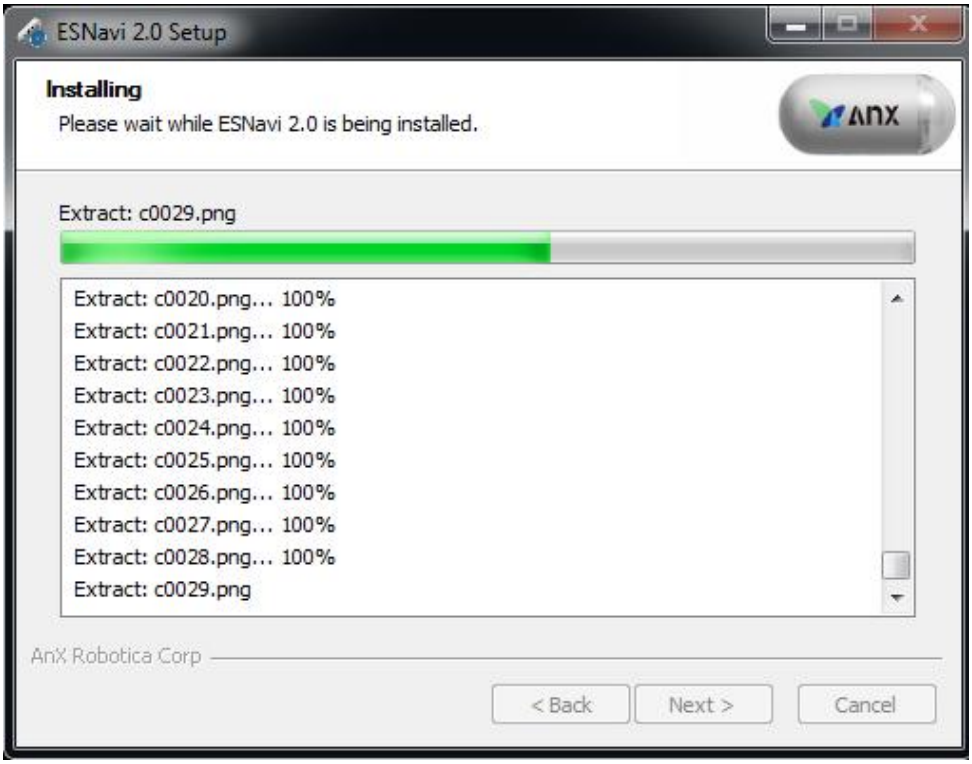


Figure 4- 3 Installation Interface

4. After installation finishes, access to Installation Successful interface as shown in Figure 4-4.

Figure 4- 4 Preparing for Installation Interface

5. Click "Finish" to finish ESNavi installation. After this, the shortcut of ESNavi main program will be generated on the desktop.

4.2 Uninstalling Software

1. From "Start"→"Programs", select "**ESNavi**" →"Uninstall ESNavi" to access software uninstalling interface as shown in Figure 4-5.

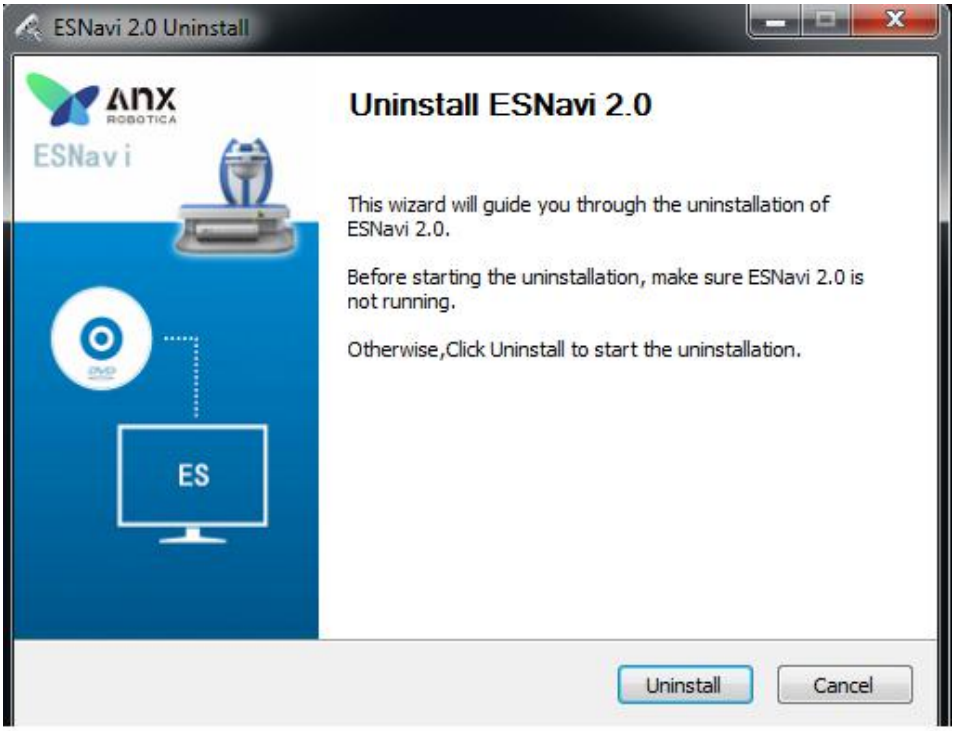


Figure 4- 5 Software Uninstalling Interface

2. Click "Next" to start uninstalling. After uninstalling finishes, you will access Uninstalling Successful interface as shown in Figure 4-6.

Figure 4- 6 Uninstalling Successful Interface

3. Click "Finish" to complete software uninstalling.

4.3 Basic Operation of Software

Basic flow of the software when performing a procedure:
Step one - enter basic and patient information.
Step two - save the information to the Data Recorder.
Step three - turn on the capsule endoscope.
Step four - observe and adjust capsule endoscope working status by viewing real-time display monitor.
Step five - examine the patient.
Step six - export image data captured by the capsule endoscope to computer by means of data export.
Step seven - view and annotate the image data.
Step eight - generate patient report. If there are several cases, the data of the cases can be managed on the case management interface. For details, refer to software use flowchart as shown in Figure 4- 9.

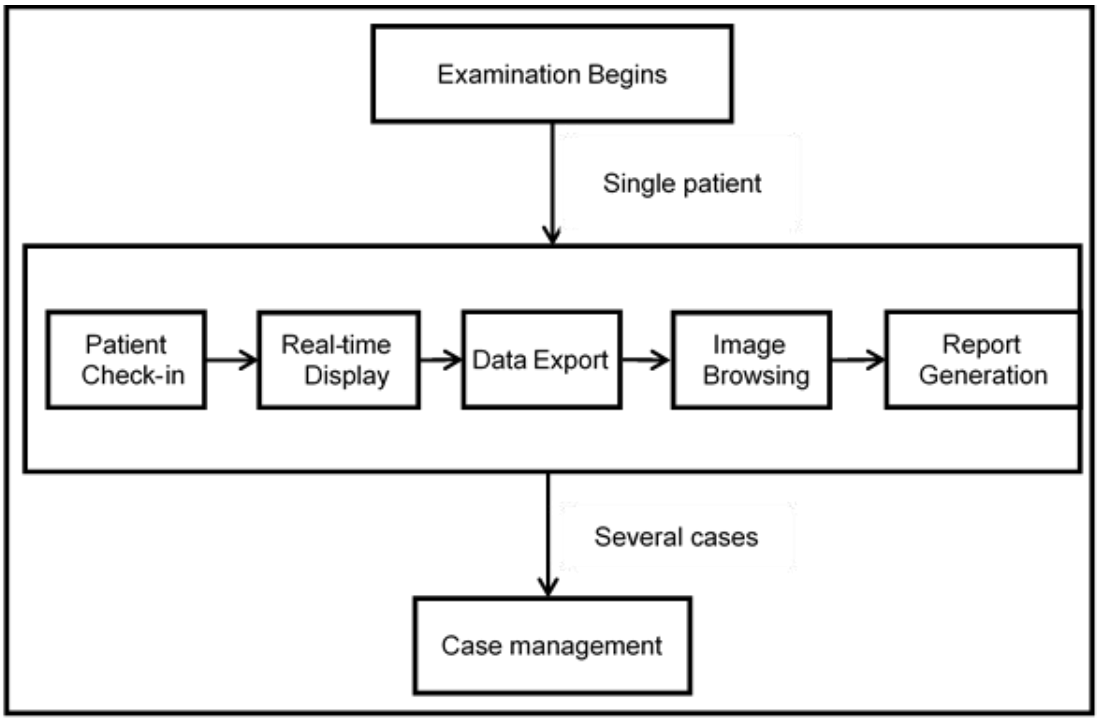


Figure 4- 9 Software Use Flowchart

4.3.1 Patient Check-In

1. Open the ESNavi software to access software registration interface as shown in Figure 4- 10. User feedback Serial No. and input the obtained registration license No. to register in the software. ESNavi software cannot be run if registration is not entered successfully.

Figure 4- 10 Software Registration Interface

2. After registration, run the ESNavi software. If your computer is not installed with Word 2003 or WPS or later version, ESNavi will prompt you with the prompt box indicating that Word format report is not supported, however, the use of ESNavi software will not be affected.

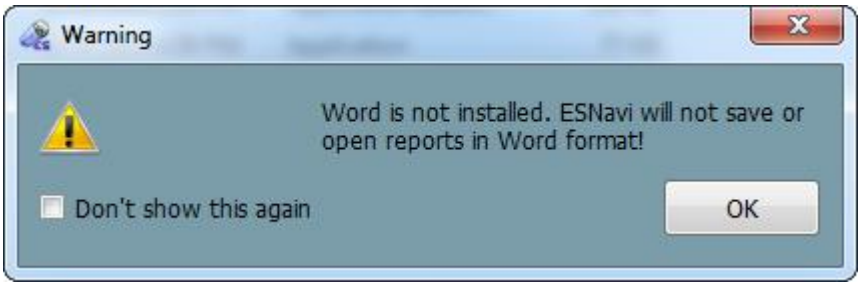


Figure 4- 11 Prompt Box Indicating that Word Format Report is Not Supported

3. Access the Image Browsing interface as shown in Figure 4- 12, where you can browse or annotate images. Access port is provided allows to open interfaces such as Patient Check-in, Real-time Browsing and Case Management.

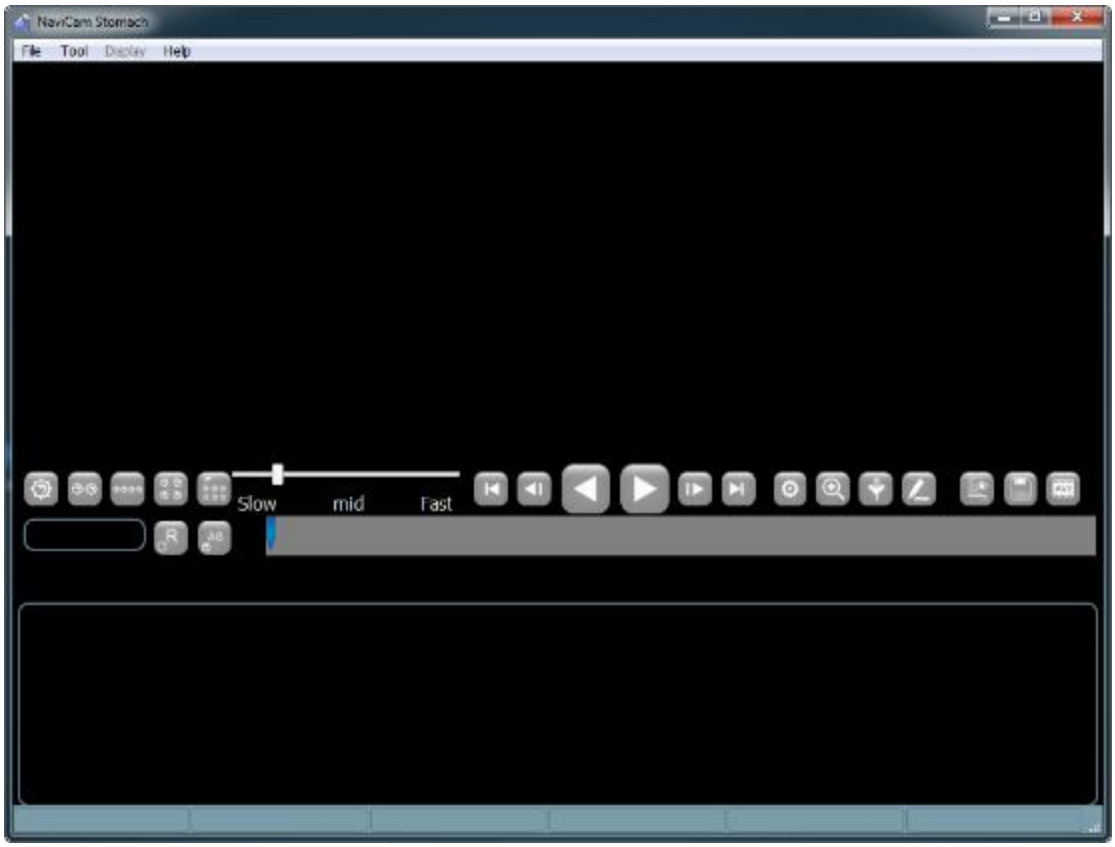


Figure 4- 12 Image Browsing Interface

4. Click "Tool" → "Patient Check-in" to access the Patient Check-in interface as shown in Figure 4-13, where patient information can be input and saved in the Data Recorder. The patient information will be exported to the computer along with image data via the Data Recorder. The Data Recorder should be connected to computer via USB before patient check-in.

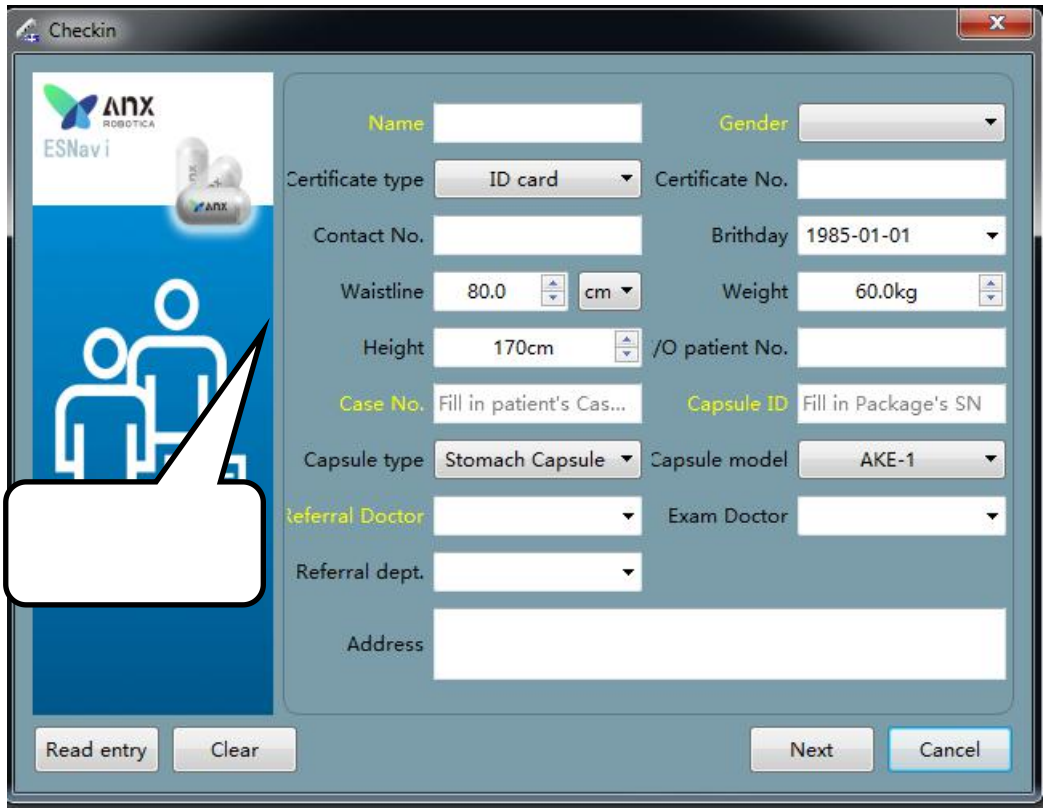


Figure 4- 13 Patient Check-in Interface

5. Only one patient information can be saved in the Data Recorder. Click "Read Check-in information" button to automatically read the saved patient information in the Data Recorder, which will then be displayed in the operator information input area. Click "Clear" button to clear patient information in the operator information input area; Click "OK" button to save patient information to the Data Recorder; Click "Cancel" button to exit from the Patient Check-in interface.

4.3.2 Real-time View

4.3.2.1. Access to Real-time View

1. On the Image Browsing interface as shown in Figure 4- 12, click "Tool" →"Rtdisply" to access "Rtdisply" interface as shown in Figure 4- 14.

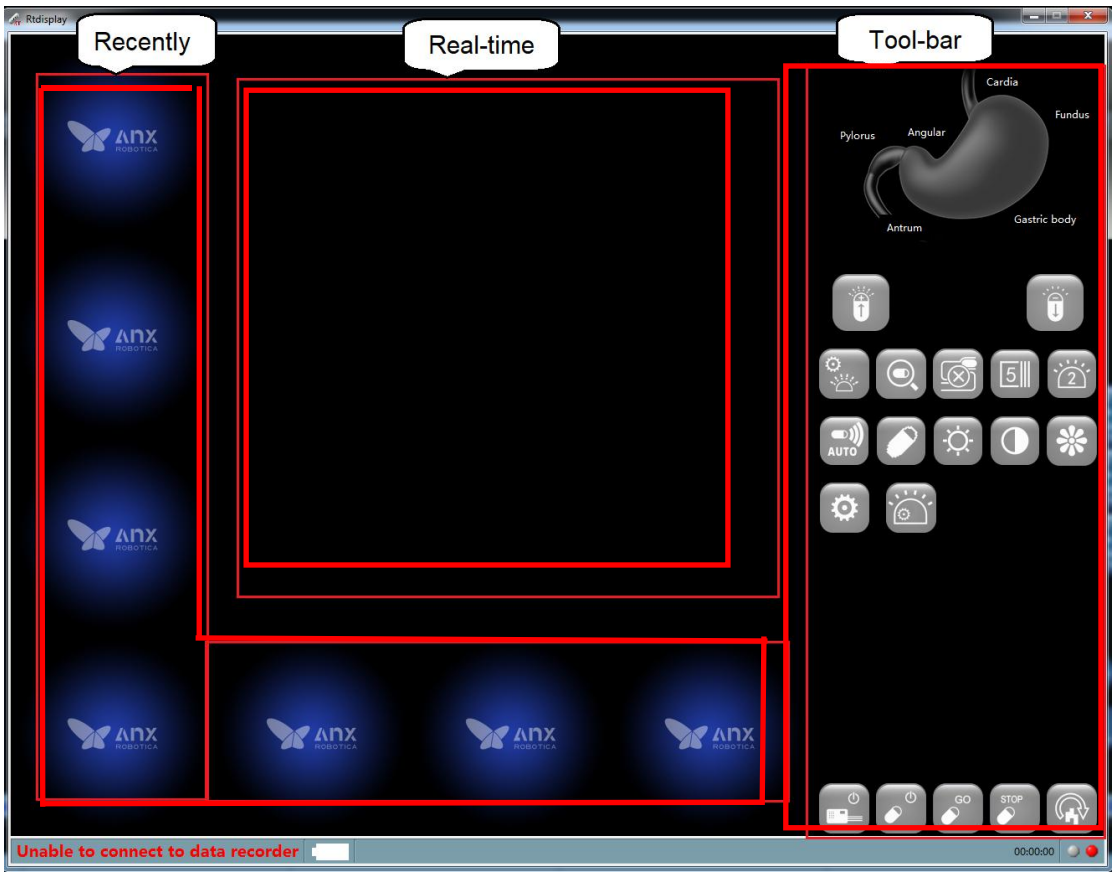


Figure 4- 14 Rtdisply Interface

2. Rtdisply interface is used to display images captured by the capsule endoscope inside the human digestive tract and adjust the capsule running status in real-time. The Data Recorder should be connected to the computer via USB for Rtdisply. If the Data Recorder is not properly connected, the connection status display area on the status bar on the Rtdisply interface as shown in Figure 4- 14 will display in red font "**Unable to connect to data recorder"**. In this case, images captured by the capsule cannot be displayed in real-time and buttons in the right toolbar are unavailable.

3. When the Data Recorder is connected to the computer via USB, buttons on the Rtdisply interface become available. The connection status display area in the status bar will display in black fond "**Connected to data recorder"**. In this case, capsule initiation is viewed in real-time, as shown in Figure 4- 15. Real-time images and captured images are automatically saved in the patient data export path, double click any real-time image or captured image to be directed to the related directory. The format of Rtdisply images in the patient data export path is **"Patient name (case No.)_Capsule ID_examination date_RTImage**s" folder, and captured images are saved in "Captured" folder in the Rtdisply image saving path.

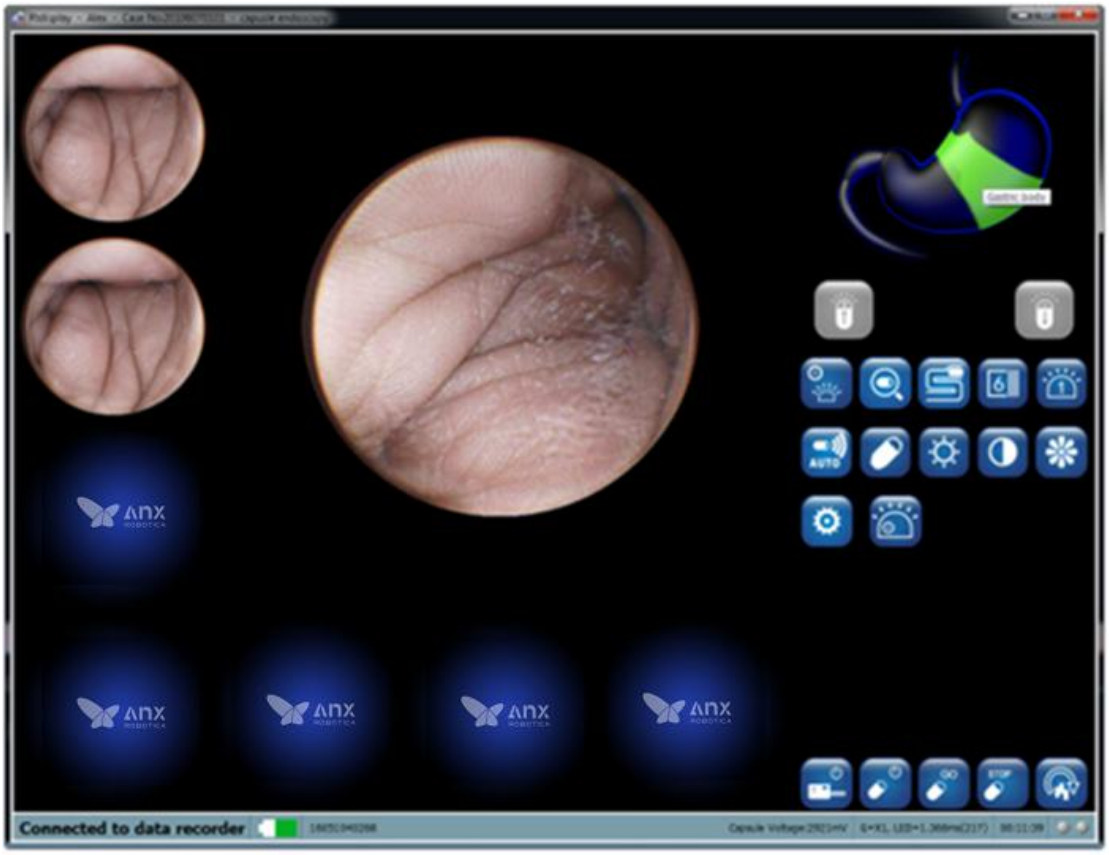


Figure 4- 15 Open Rtdisply

4.3.2.2. Functions of Buttons in the Toolbar

Table 4- 1 Real-time View Button Function

Icon	Function
	Capture and mark stomach image of different sites
	Increase exposure
	Reduce exposure
	Adjust image brightness
	Adjust image definition
	Switch auto/manual exposure
	Set frame rate of capsule endoscope
	Set wireless channel

	Set transmission rate
	Adjust image quality
	Search capsule endoscope
	Enter small bowel mode
	Close Data Recorder
	Close capsule endoscope
	Open capsule endoscope
	Stop capsule endoscope
	Restore default setting
	Set saturation
	Image enhancement
	Auto/manual frame rate control in small bowel mode

4.3.2.3. Rtdisply Image Zoom in and out

1. Image zoom in and out can be accomplished by mouse scrolling, then a scale as represented by x% will be displayed in the upper left corner of the image to represent current scaling factor as shown in Figure 4- 16.

Figure 4- 16 Image Scaling Function

2. If you wish to restore the original size of the displayed image without any zoom in or out, double click the image display area.

4.3.2.4. Data Recorder Status Indicator

1. Rtdisply view of the two LED status indicators in the lower right corner are as shown in Figure 4-17. The left indicates the work status (Green), and the right indicates warning (red).

Figure 4- 17 Status Indicators

2. Meaning of the status indicators:
(1) Green LED flashes and red LED does not light indicate image data from capsule endoscope has been received.
(2) Green LED does not light and red LED lights indicate no signal from capsule endoscope has been received.
(3) Green LED does not light and red LED flashes indicate capsule endoscope signal has been received, but no image data has been received.

4.3.2.5. Search Capsule Endoscope

If the capsule endoscope has been turned on, and capsule current channel is unclear, then the search capsule endoscope function can be used by:
1. First turn on the capsule endoscope with Locator for more than 3 seconds.

2. Then click “search capsule endoscope” button on the interface, then searching capsule endoscope dialog box will be prompt out as shown in Figure 4- 19.

Figure 4- 18 Search Capsule Endoscope

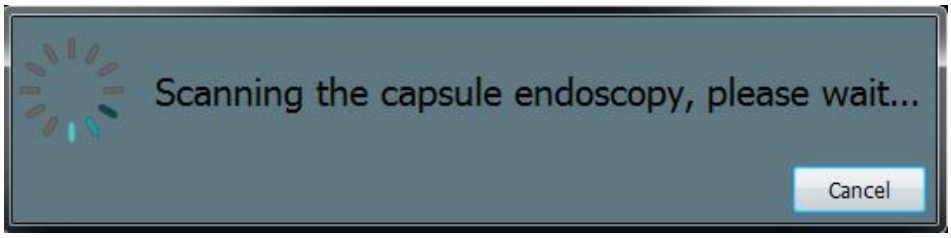


Figure 4- 19 Searching Capsule Endoscope Prompt Information

If the capsule endoscope is found, the dialog box disappears, image displays as normal, and the channel will be updated to the channel value found, as shown in Figure 4- 20. If no capsule endoscope is found, then “no capsule endoscope is found” will be displayed.

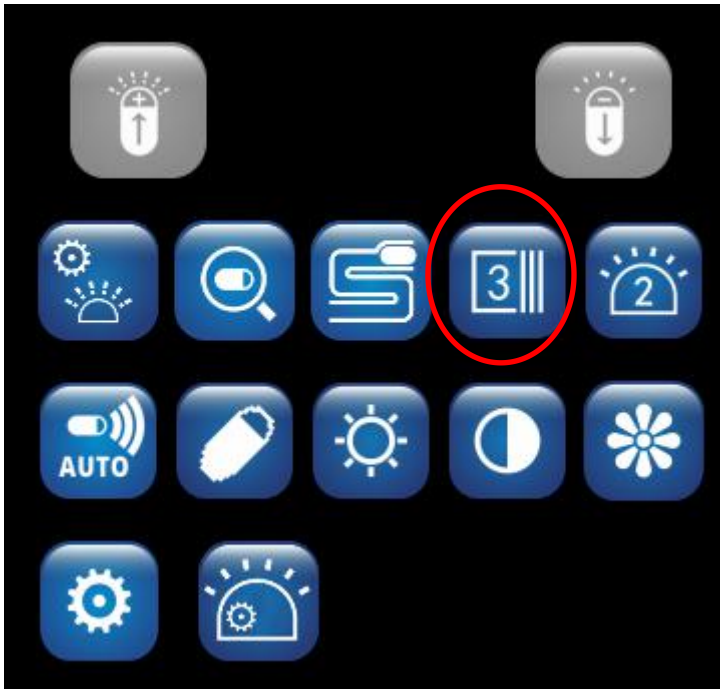


Figure 4- 20 Channel will be Updated to the Channel Value which is Found

4.3.2.6. Select Small Bowel Mode

After the controlled operation of the examination is finished, click small bowel mode button as shown in Figure 4- 21.

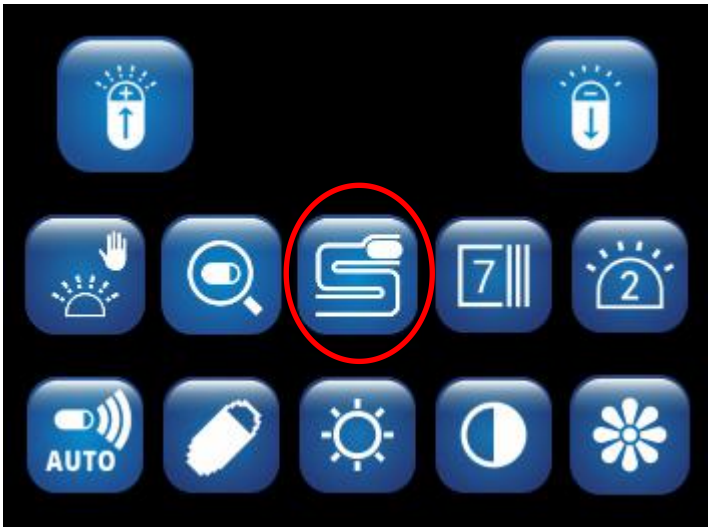


Figure 4- 21 Enter Small Bowel Mode

4.3.3 Real-time Control

If the capsule type in patient check-in is stomach capsule, the real-time control program will be automatically turned on. On the Image Browsing interface as shown in Figure 4- 12, click "Tool" →"ESCtrl(Real-time Control)" to access the capsule

control program interface, including capsule control main interface and Rtdisply interface.

The main interface is provided with four modules including stomach simulation, 3D schematic view, capsule position display, electronic examination bed display and control buttons, as shown in Figure 4- 22 capsule control program main interface. For Rtdisply, refer to 4.3.2.

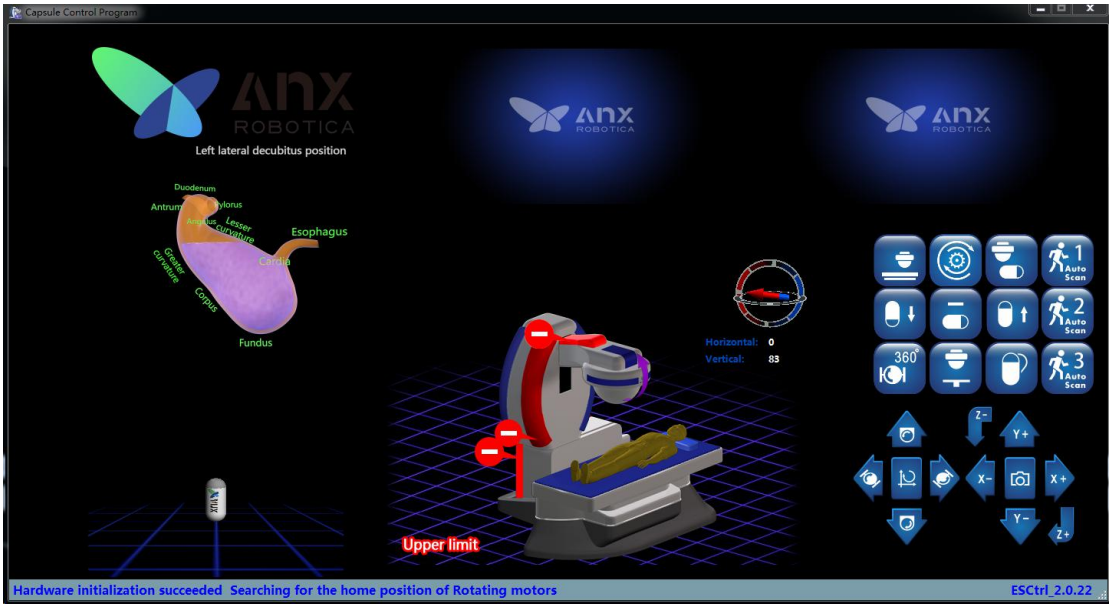


Figure 4- 22 Capsule Control Program Main Interface

Note: When the equipment is initialized to find the original position, ensure that no patient is on the examination bed before starting initialization. Please close the real-time control software before turning power off; ensure that XYZ-axis translational equipment and horizontal & vertical rotation equipment are in the original position before use.

1. Three-axis translational motion

After initialization succeeds, you can use the 3D joystick or use up, down, left, right, forward and backward motion controls to control horizontal motion of XYZ axis (one click on the icon represents 1mm movement in the corresponding direction, holding down the button represents keep moving in the direction until its limit).

Figure 4- 23 Move in negative direction along X Axis

Figure 4- 24 Move in positive direction along X Axis

Figure 4- 25 Move in Negative Direction along Y Axis

Figure 4- 26 Move in Positive Direction along Y Axis

Figure 4- 27 Move in Negative Direction along Z Axis

Figure 4- 28 Move in Positive Direction along Z Axis

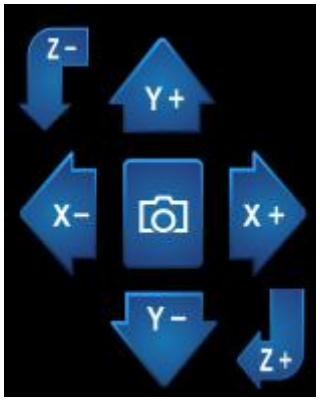


Figure 4- 29 Up, Down, Left, Right, Front and Back Motion and Capture Controls

2. 2D Rotation Motion

After initialization is completed, you can use the 2D joystick or rotation controls to control rotation of horizontal and vertical rotation of the system (counterclockwise push of the vertical rotation which causes the capsule to roll forward; clockwise push of the vertical rotation which causes, the capsule to roll backward).

Figure 4- 30 Horizontal and Clockwise Rotation

Figure 4- 31 Horizontal and Anticlockwise Rotation

Figure 4- 32 Vertical and Clockwise Rotation

Figure 4- 33 Vertical and Anticlockwise Rotation

Figure 4- 34 Rotation Equipment Motion and Capsule Coupled Movement Control

3. Capsule Coupled Movement

When capsule is directly under the magnetic head, capsule coupled movement can be accomplished by clicking the left joystick button or capsule coupled movement button on the interface screen. This causes a 360 degree rotation in the capsule head direction, and XY axis of the magnetic head moves at the same time to ensure capsule is still right under the capsule head after completing the rotation. When using the capsule coupled movement, first draw the equipment close to or away from patient in the up/down direction. When capsule location (front wall, posterior wall) cannot be clearly detected by the magnetic head, click the left joystick button, in the lower left corner of the interface “move the Z axis of the equipment to ensure capsule is at the front wall or posterior wall before using the capsule coupled movement function” will be displayed as shown in Figure 4- 35, then adjust the height of the magnetic head until capsule location can be detected.

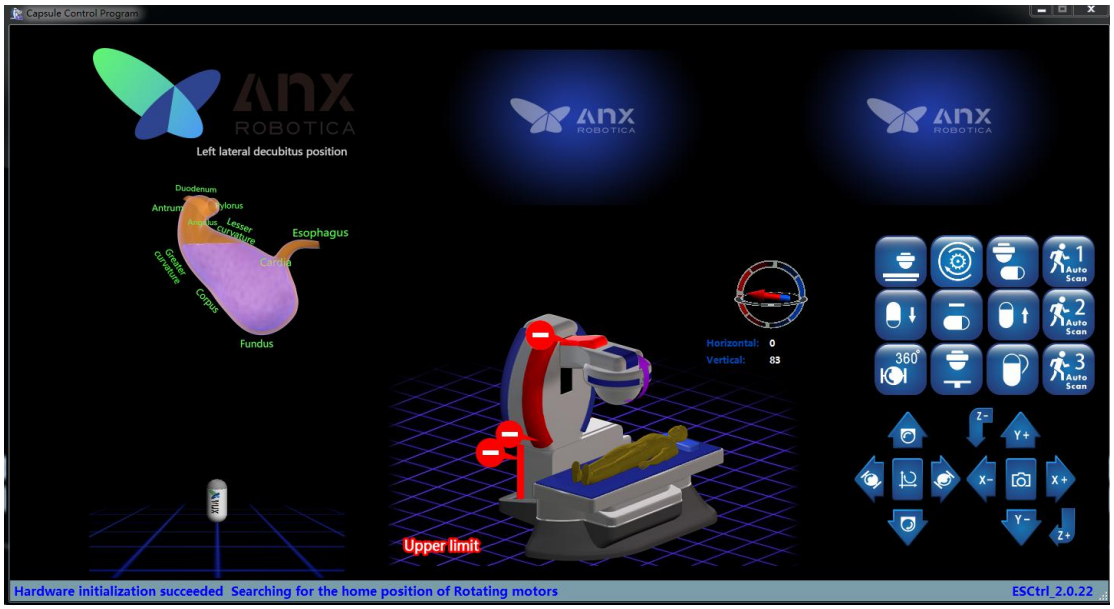


Figure 4- 35 Magnetic Ball Cannot Clearly Detect Capsule Location

4. Limit Action Display

When the system runs to the limit (the maximum position), the screen image will display a corresponding alarming message. You can eliminate the alarm simply by moving the system in the reverse direction.

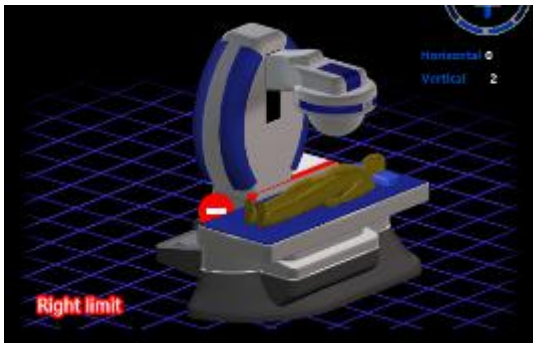


Figure 4- 36 Right Limit Alarm

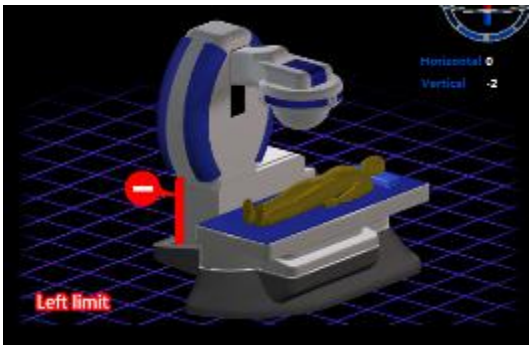


Figure 4- 37 Left Limit Alarm

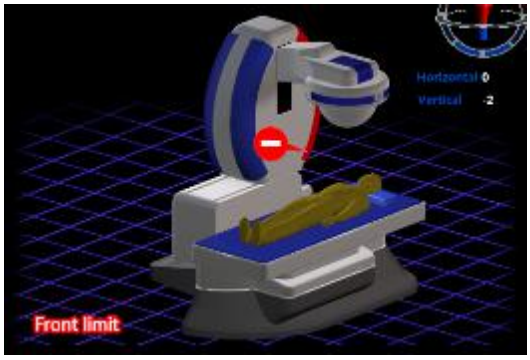


Figure 4- 38 Front Limit Alarm

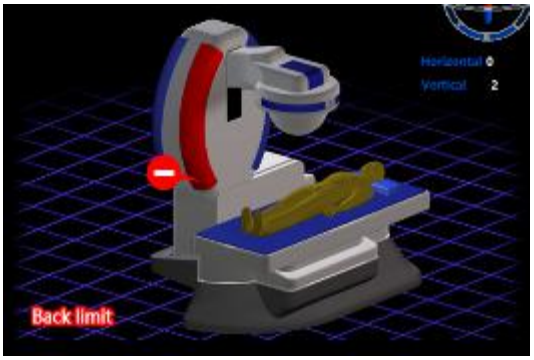


Figure 4- 39 Back Limit Alarm

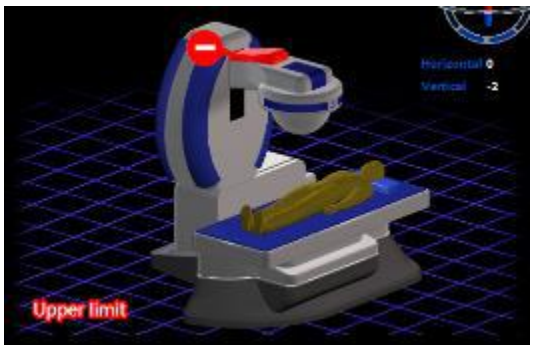


Figure 4- 40 Upper Limit Alarm

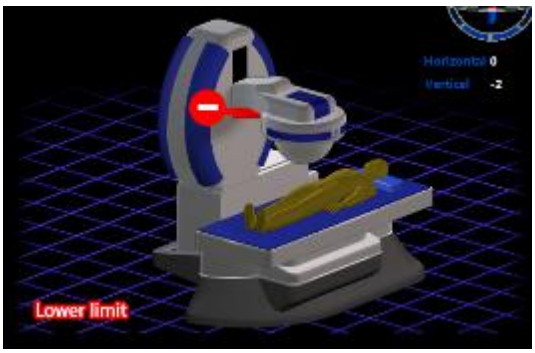


Figure 4- 41 Lower Limit Alarm

4. Table 4- 2 shows buttons on the Capsule Control Program interface.

Table 4- 2 Button Function of Capsule Control Program

Icon	Function	Description
	Getting on/down bed avoidance	Click the button, the system will move in the negative direction along the X axis, Y axis and positive direction of Z axis until it reaches its limit. (Neutral position)
	Three-axis equipment automatic search for original position	Click the button, the system begins to automatically locate the original position of the XYZ-axis and stop in the original position.

	Automatic search for capsule	Click the button, it begins a search for capsule location and stops right above capsule (capsule head upwards).
	Capsule head down	Click this button to head the capsule downward.
	Capsule lying flat	Click this button to lay the capsule flat.
	Capsule head up	Click this button to head the capsule upward.
	360 degree horizontal rotation	Click the button, 360 degree horizontal rotation icon turns into  , click again to 360 degree horizontal rotation.
	Set/cancel Z axis minimum safe limit	Click the button to set the current Z axis coordinate position as the minimum safe limit (therefore the Z axis minimum value >= this value), click again, the set value is canceled.
	45 degree capsule relative rotation	Click the button, moves the capsule 45 degrees
	Counter-clockwise vertical rotation of magnetic head	Hold down the left mouse button to increase the speed of counterclockwise, vertical rotation of the capsule. Left click the mouse one time to rotate the capsule 5 degrees. The rotation is equivalent to pushing the left joystick forward.
	Clockwise vertical rotation of magnetic head	Hold down the left mouse button to increase the speed of the clockwise, vertical rotation of the capsule. Left click the mouse one time to rotate 5 degrees. The rotation is equivalent to pushing the left joystick backward.
	Counter-clockwise horizontal rotation of magnetic head	Hold down the left mouse button to increase the counter-clockwise, horizontal rotation of the capsule. Left click the mouse button one time to rotate the capsule 5-degrees. The rotation is equivalent to pushing the left joystick to the right.

	Clockwise horizontal rotation of magnetic head	Hold down the left mouse button to increase the clockwise, horizontal rotation of the capsule. Left click the mouse button one time to rotate 5-degrees. The rotation is equivalent to pushing the left joystick to the left.
	Capsule coupled movement	Same effect by clicking left mouse button and pressing left joystick button.
	To move along X axis in the positive (right) direction	Click the left mouse button to move the capsule along the X axis 1 mm in the positive direction. Holding down the left mouse button keeps the capsule moving along the X axis in the positive direction. The movement is equivalent to pushing the right joystick to the right.
	To move along X axis in the negative direction(left)	Click the left mouse button to move the capsule along the X axis 1 mm in the negative direction. Holding down the left mouse button keeps the capsule moving along the X axis in the negative direction. The movement is equivalent to pushing the right joystick to the left.
	To move along Y axis in the positive direction (forward)	Click the left mouse button to move the capsule along the Y axis 1 mm in the positive direction. Holding down the left mouse button keeps the capsule moving along the Y axis in in the positive direction. The movement is equivalent to pushing the right joystick forward.
	To move along Y axis in the negative direction (backward)	Click the left mouse button to move the capsule along the Y axis 1 mm in the negative direction. Holding down the left mouse button keeps the capsule moving along the Y axis in the negative direction. The movement is equivalent to pushing right joystick backward.
	To move along Z axis in the positive direction (upward)	Click the left mouse button to move the capsule along the Z axis 1 mm in the positive direction. Holding down the left mouse button keeps the capsule moving along the Z axis in the positive direction. The movement is equivalent to turn right joystick clockwise.
	To move along Z axis in the negative direction	Click the left mouse button to move the capsule along the Z axis 1 mm in the negative direction. Holding down the left mouse button keeps the capsule moving along the Z axis in the negative direction. The movement is equivalent to turn right joystick counterclockwise.

	(downward)	
	Capsule captures image	Click the left mouse button to capture image. It is equivalent to clicking the button on the top of the right joystick.
	Macro command button	Click the button to load a new macro command. During execution of the macro command, click the button again to pause execution (click again to resume execution), meanwhile pushing left or right joystick would stop execution of the macro command. Related operation of the system is not possible during execution of the macro command, and "Auto Scan" in the lower corner of the macro command will turn to red. For safety always set the Z axis minimum safe limit to a desired position before executing macro command.

If motion of the system fails requiring emergency braking, press the emergency stop switch to stop motion of the XYZ axis as shown in Figure 4- 42. After pressing emergency stop switch, software exits automatically. Turn off the power switch and then turn it on before starting real-time control program again.

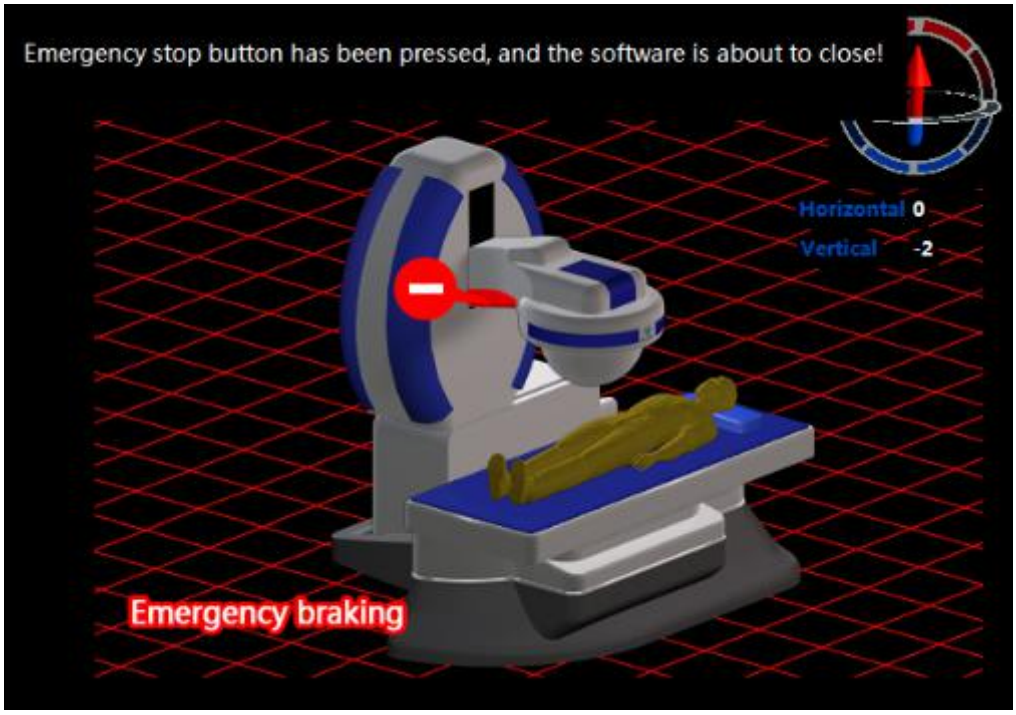


Figure 4- 42 Working Status When Emergency Stop Button is Pressed

5. Stomach simulation 3D schematic view: Double click the 3D schematic view in the left side of the ESCtrl interface. The 3D schematic area switches between four

postures (lying on back, lying face downward, lying left lateral position, and lying right lateral position), as shown from Figure 4-43 to Figure 4-46; place the cursor in the schematic diagram and hold down the left mouse button and drag upward or downward to adjust schematic viewing angles, as shown in Figure 4-47.

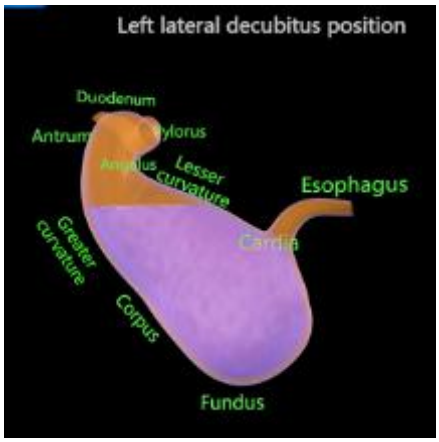


Figure 4- 43 Lying Left Lateral Position

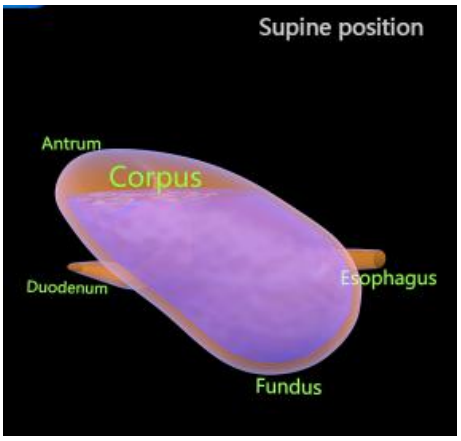


Figure 4- 44 Lying on Back

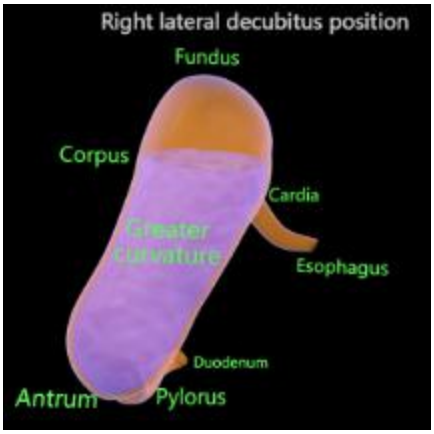


Figure 4- 45 Lying Right Lateral Position

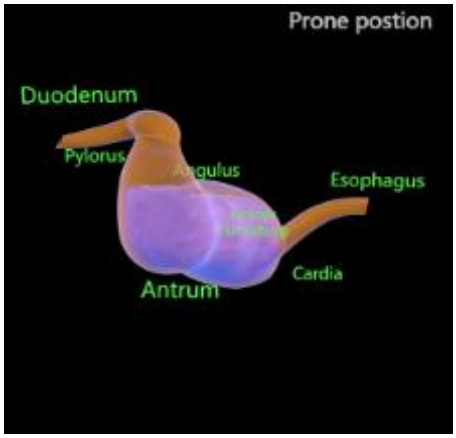


Figure 4- 46 Lying Face Downward

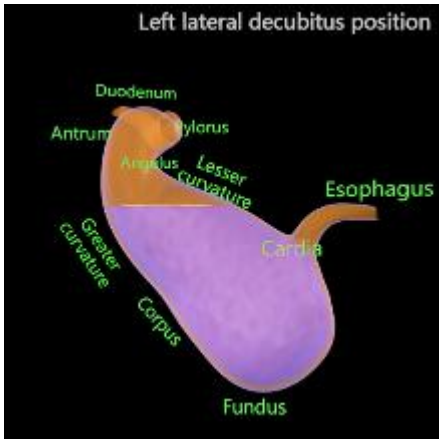


Figure 4- 47 Original Viewing Angle When Lying Left Lateral Position

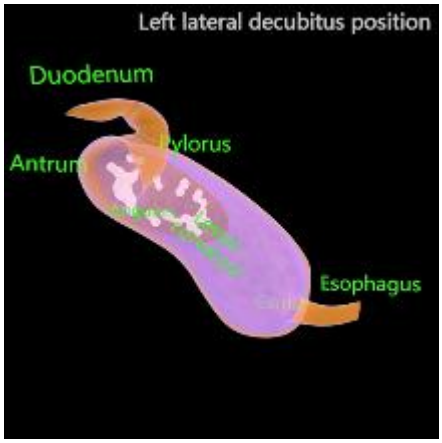


Figure 4- 48 Downward Drag Viewing Angle When Lying Left Lateral Position

4.3.4 Data Export

1. On the Image Browsing interface as shown in Figure 4- 12, click "Tool" →"Data Export" to access "Data Export" interface as shown in Figure 4- 49.

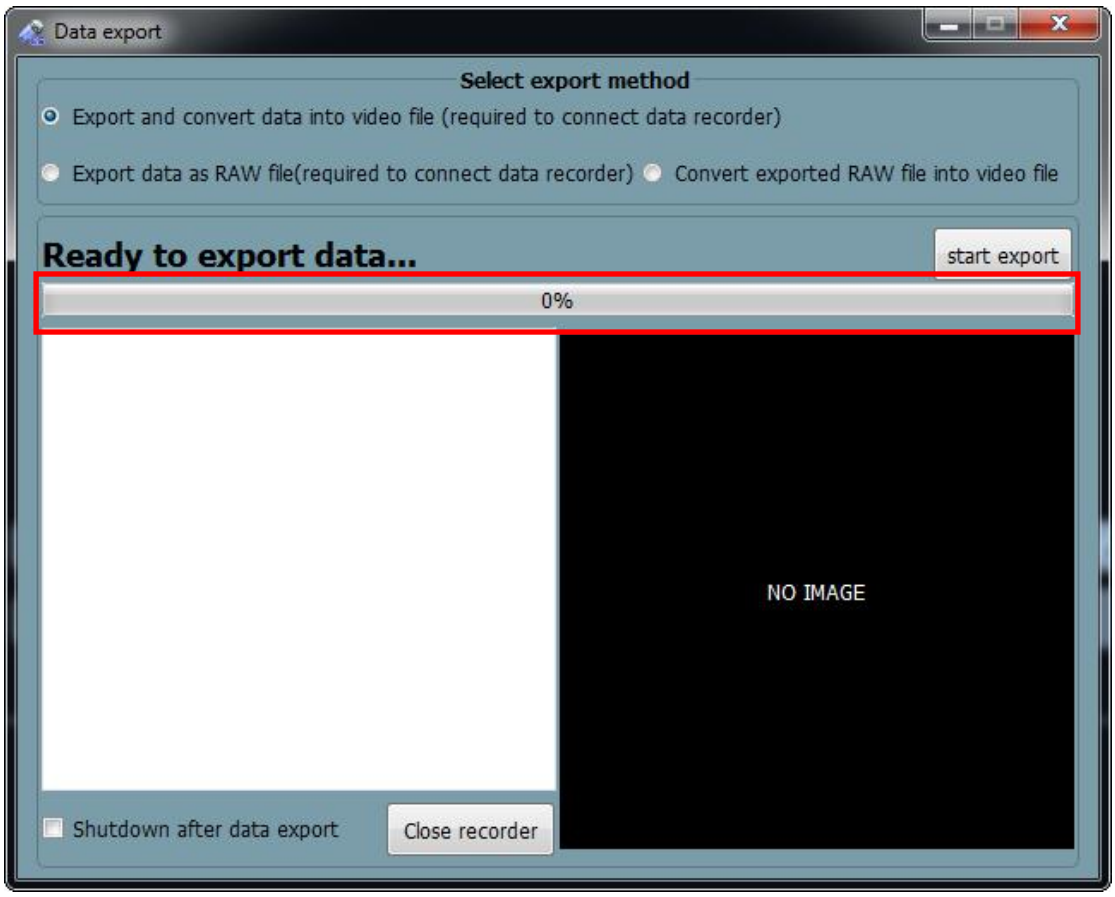


Figure 4- 49 Data Export Interface

2. Data export interface is mainly used to export image data captured by the capsule endoscope in specific data format supported by ESNavi to the computer. The interface supports two export modes: one is quick export, exporting data as raw data with suffix *.ankon, which is unable to be opened by ESNavi software before parsing, and is applicable to export image data quickly of the last patient, and preparing for the next capsule endoscope examination. The other is direct export, exporting and parsing data as video file that can be opened by ESNavi software.
3. Check "Export and convert data into video file" and click "start export" key, the image data is exported from Data Recorder as video file that can be directly opened by ESNavi software, check "Export data as RAW file " and click " start export ", the image data is exported from Data Recorder as raw data with suffix *.ankon; check "Convert exported RAW file into video file" and click " start export ", select RAW file on the RAW data file selection interface as shown in Figure 4- 50 and export as video file.

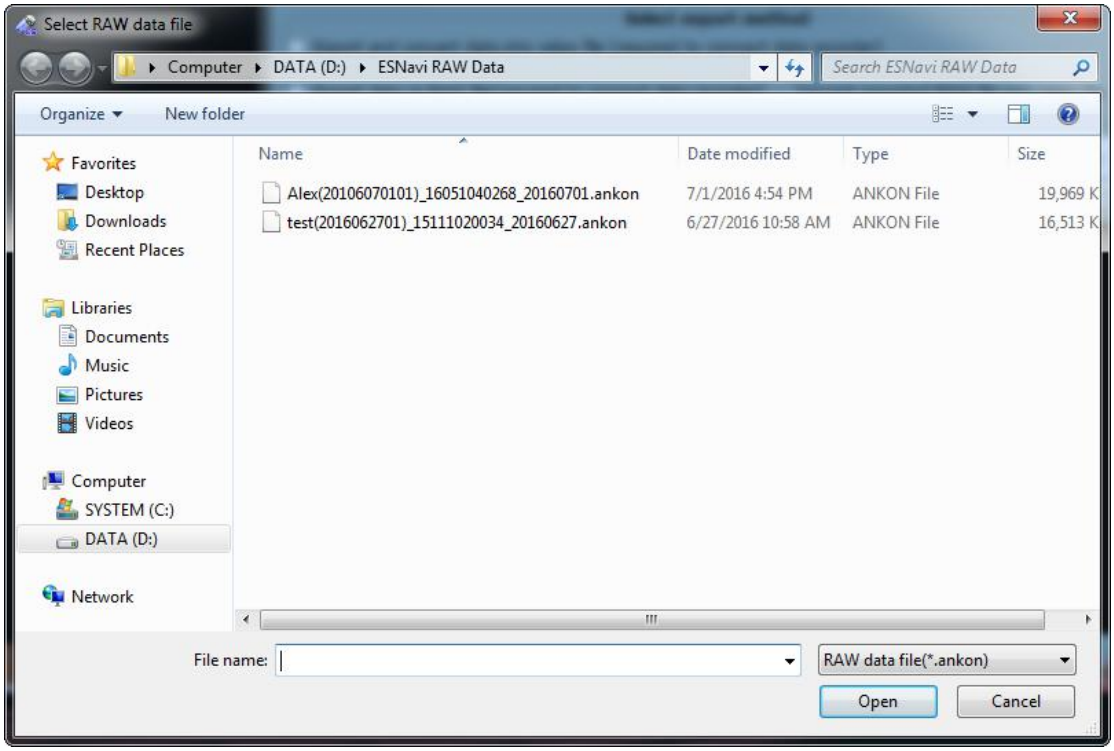


Figure 4- 50 RAW Data File Selection Interface

4. The Data Recorder should be connected to the computer via USB when data is exported by using "Export and convert data into video file" and "Quickly export data as RAW file" modes; otherwise, the Connecting Error interface as shown in Figure 4- 51 will prompt out when clicking "Start" button.

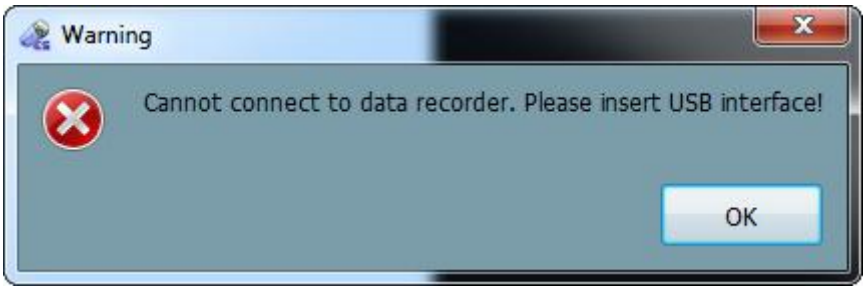


Figure 4- 51 Connecting Error Interface

5. If "Automatically shut down the computer after data export" is checked, the computer will automatically shut down after data export finishes.

4.3.5 Image Browsing

4.3.5.1. Open Video

1. On the Image Browsing interface as shown in Figure 4- 12, click "File"→"Open Video" to access to the Patient Data File selection interface as shown in Figure 4- 52. The default display path is data export path.

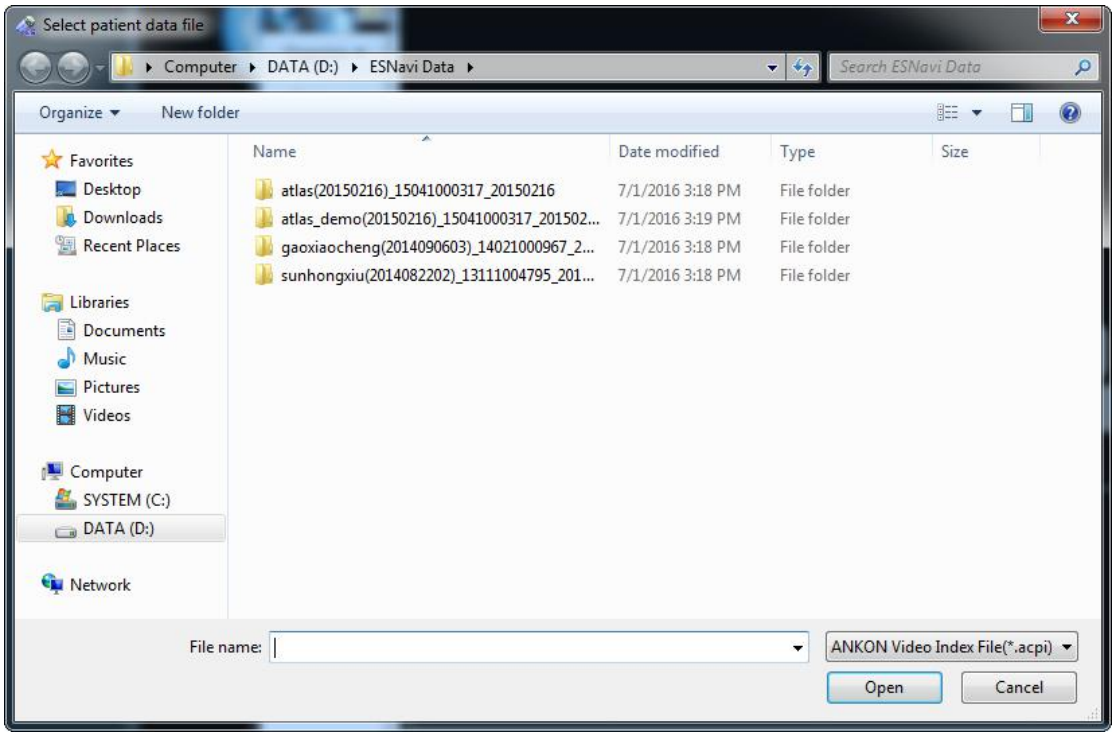


Figure 4- 52 Patient Data File Selection Interface

2. Open *.acpi type file, the software will automatically load image data in this folder, and access the Load Image Data interface as shown in Figure 4- 53.

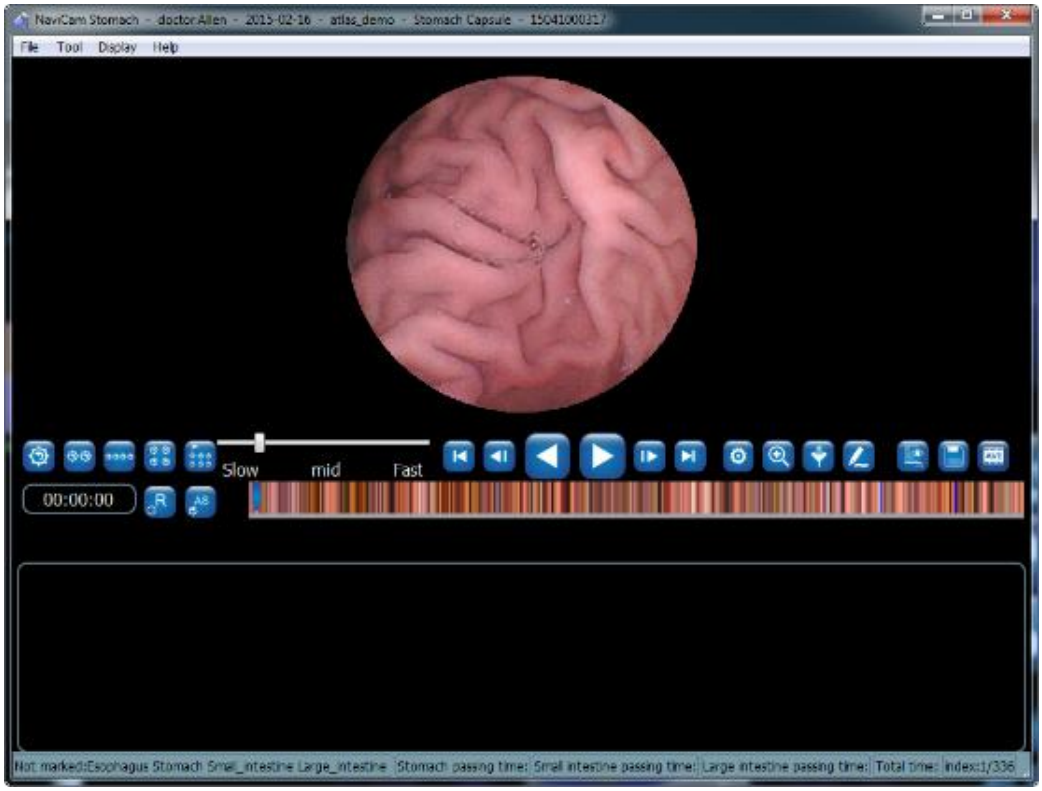


Figure 4- 53 Load Image Data Interface

3. If you wish to open recently opened videos, click “File” → “Recently Opened Video” →“Video Path”.
4. Access to image browsing interface as shown in Figure 4- 12, click “File” → “Open Video” to access video play interface as shown in Figure 4- 54, schematic view of capsule endoscope and translational rotation platform simulation will be displayed in the lower left part of the interface, the schematic view may display four human body postures (lying on back, lying face downward, lying left lateral position, lying right lateral position), as hown in Figure 4- 55,Figure 4- 56,Figure 4- 57,and Figure 4- 58, schematic view of capsule attitude changes with real-time capsule attitude, Figure 4- 59 and Figure 4- 60 displays specifically capsule up attitude (capsule captures image of magnetic ball when it is on examination bed) and capsule down attitude (capsule captures image of mattress when it is on examination bed), schematic view of translational rotation platform changes with up, down, left, right, front, and back movement of the translational rotation platform, right movement is shown in Figure 4- 61, left movement is shown in Figure 4- 62, back movement is shown in Figure 4- 63, front movement is shown in Figure 4- 64, up movement is shown in Figure 4- 65, and down movement is shown in Figure 4- 66.

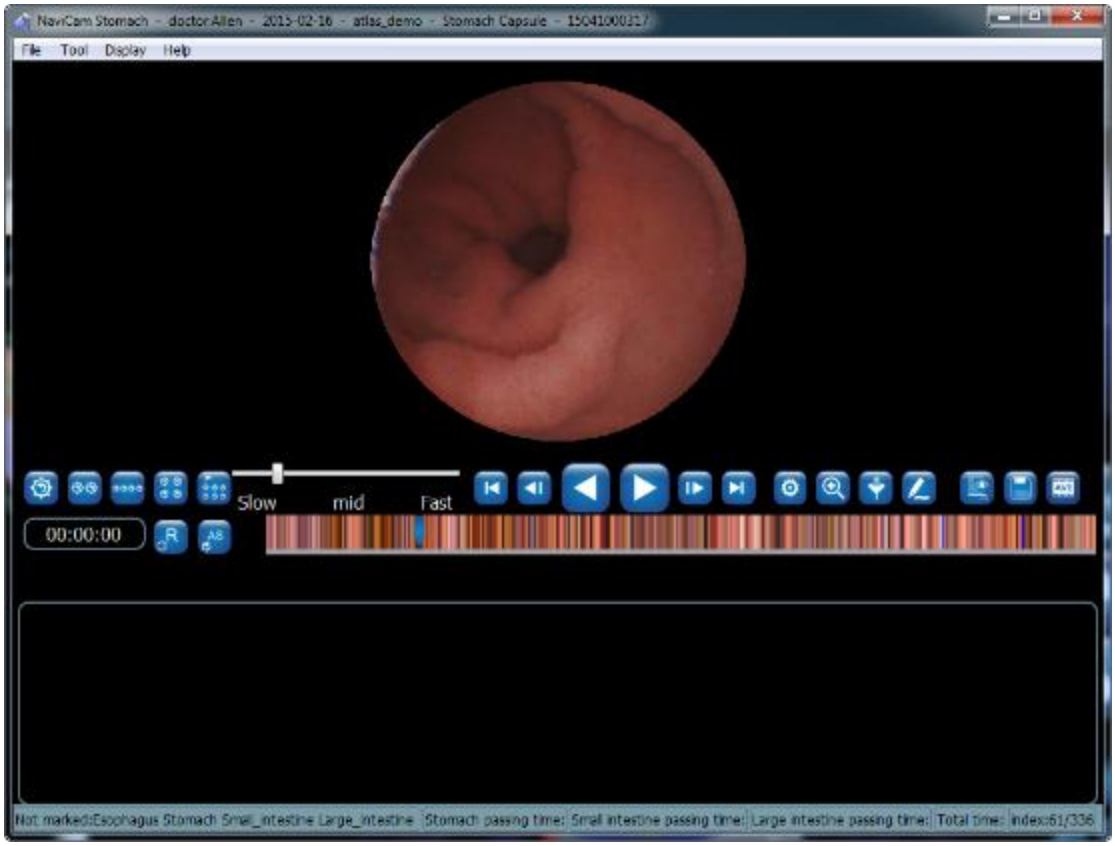


Figure 4- 54 Video Play Interface

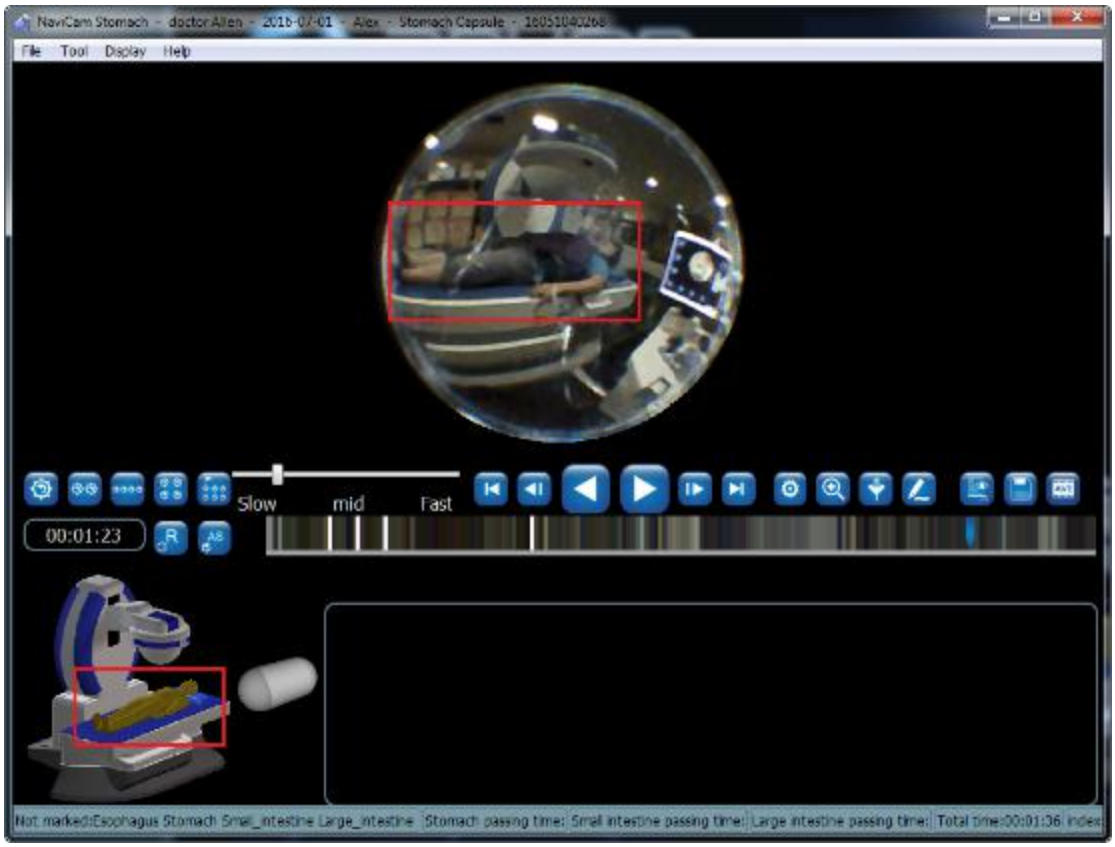


Figure 4- 55 Lying on Back

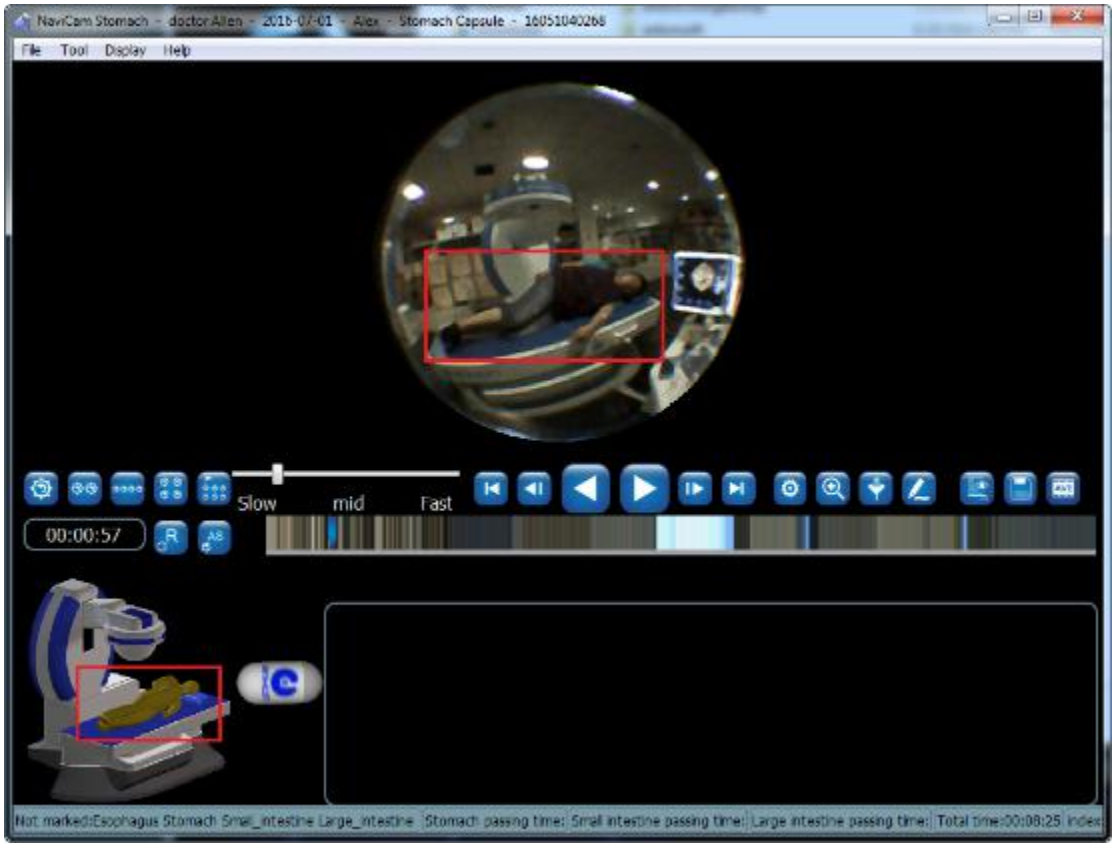


Figure 4- 56 Lying Left Lateral Position

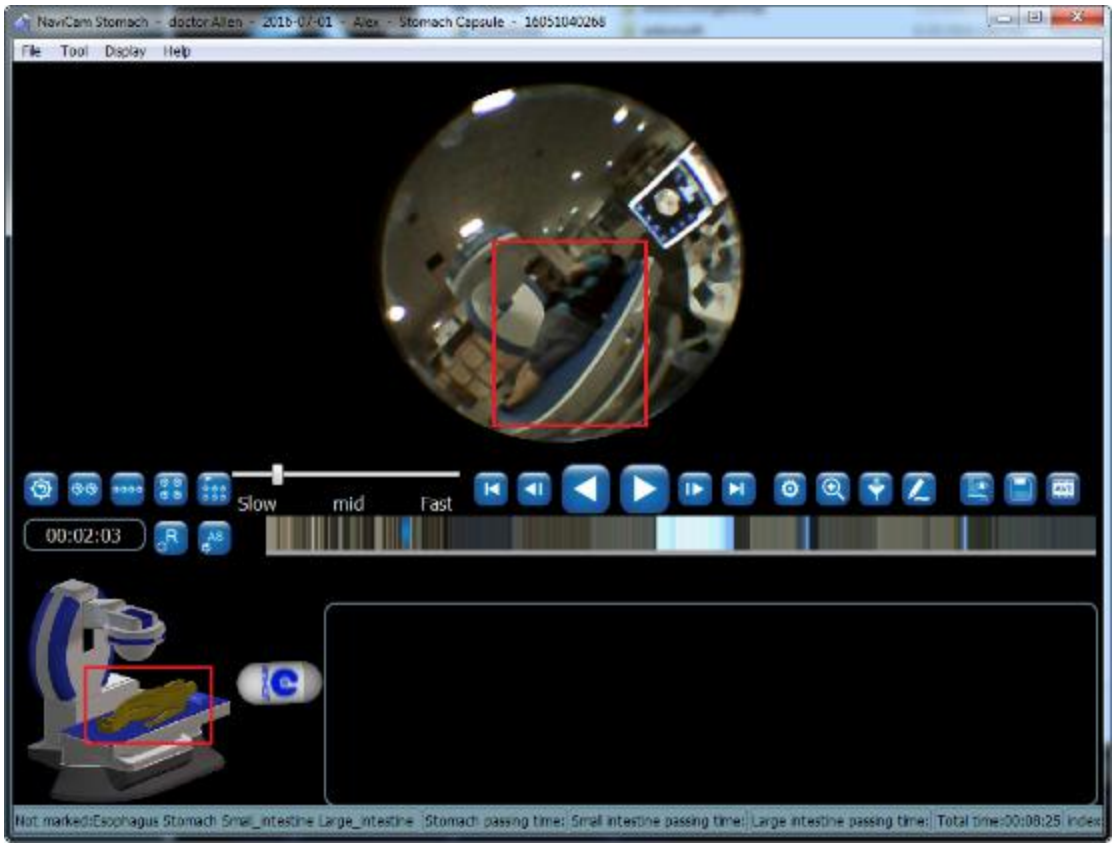


Figure 4- 57 Lying Right Lateral Position

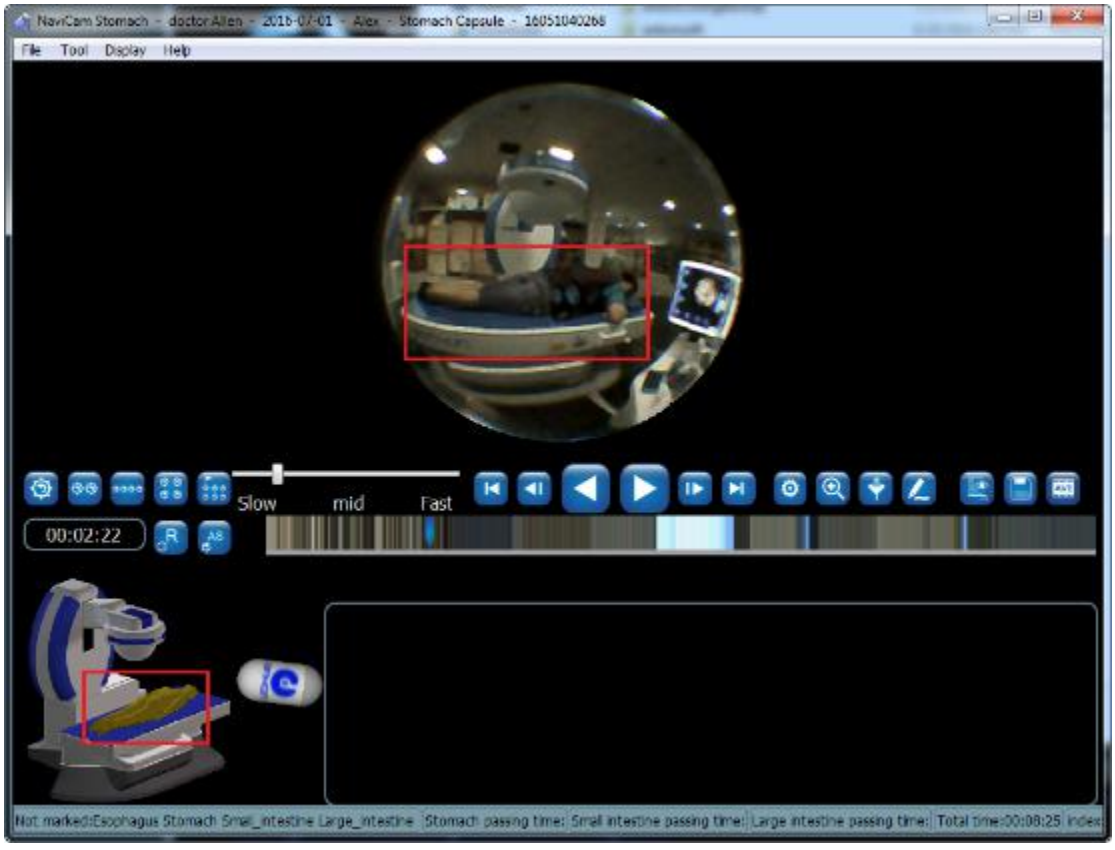


Figure 4- 58 Lying Face Downward

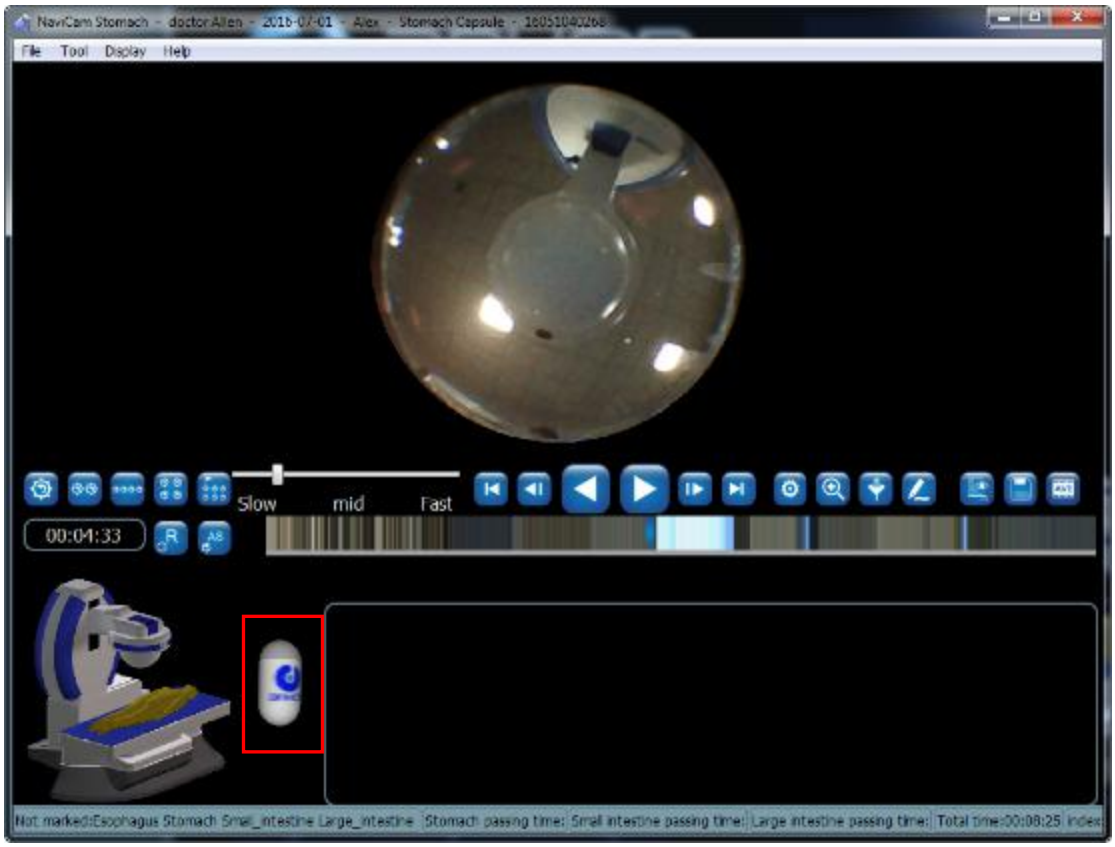


Figure 4- 59 Capsule Up Attitude

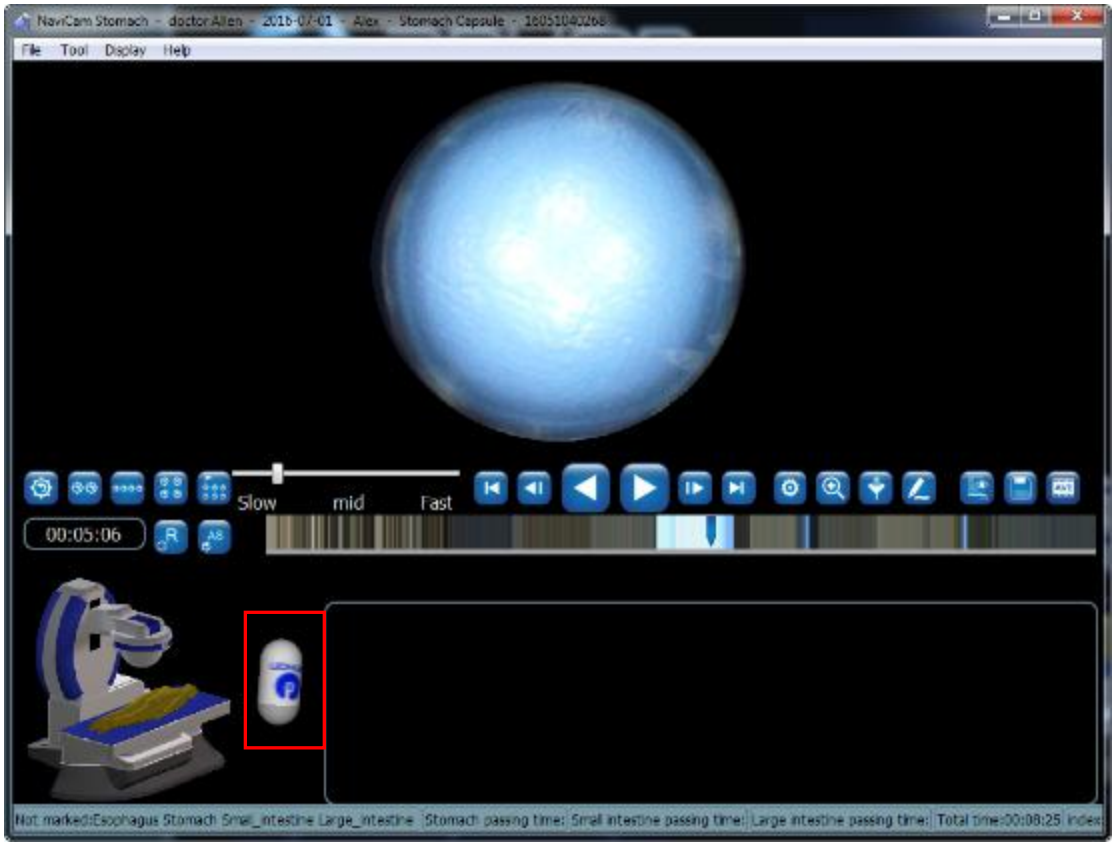


Figure 4- 60 Capsule Down Attitude

Figure 4- 61 Right Movement

Figure 4- 62 Left Movement

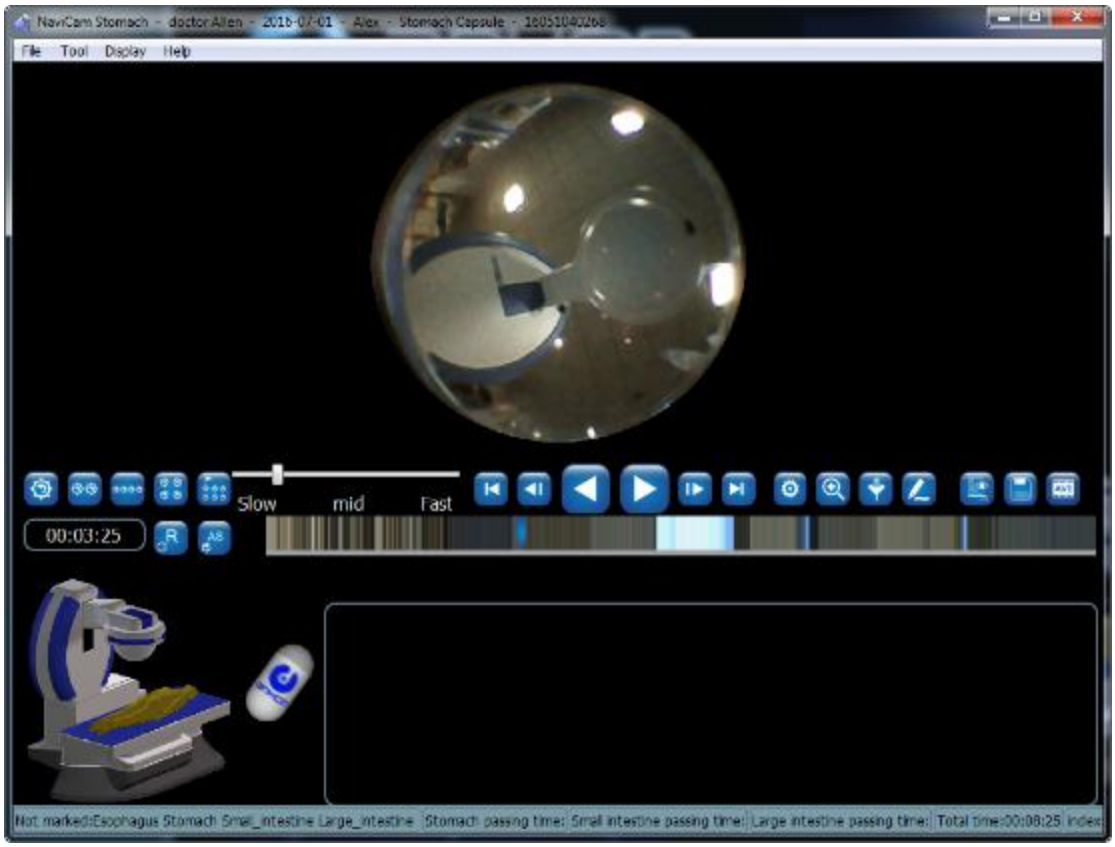


Figure 4- 63 Back Movement

Figure 4- 64 Front Movement

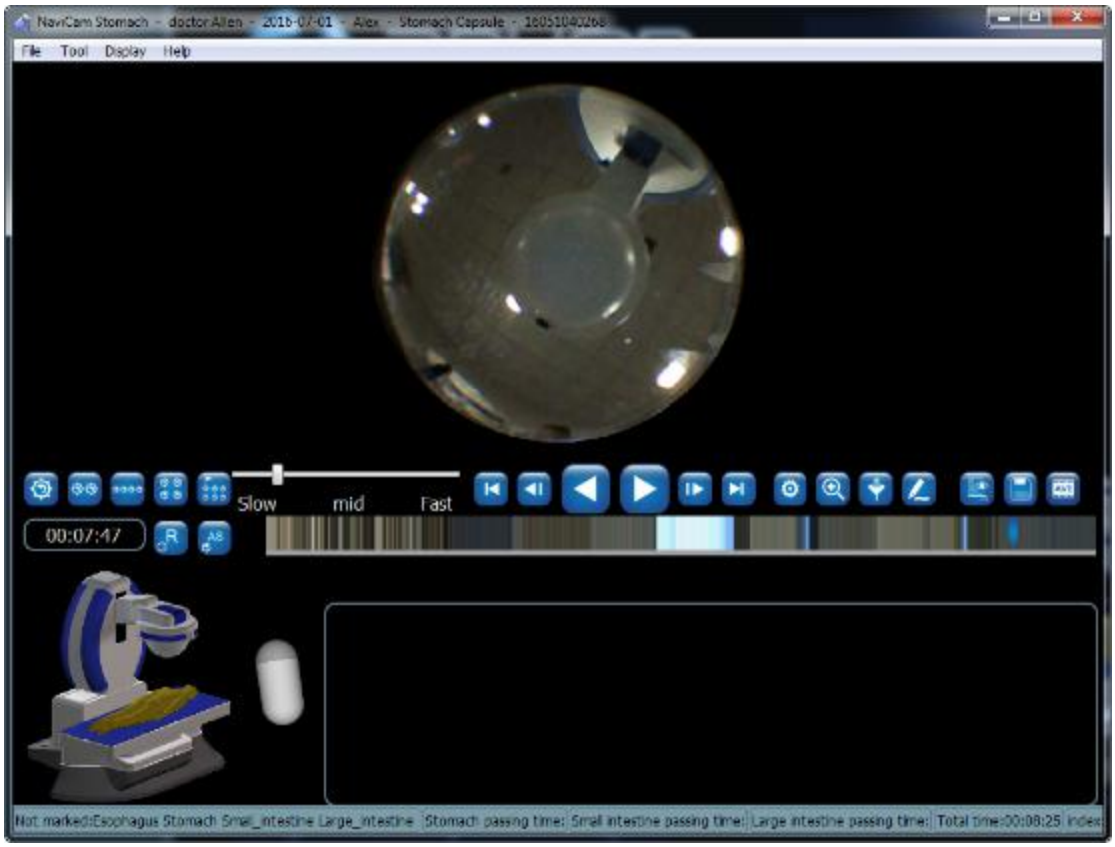


Figure 4- 65 Up Movement

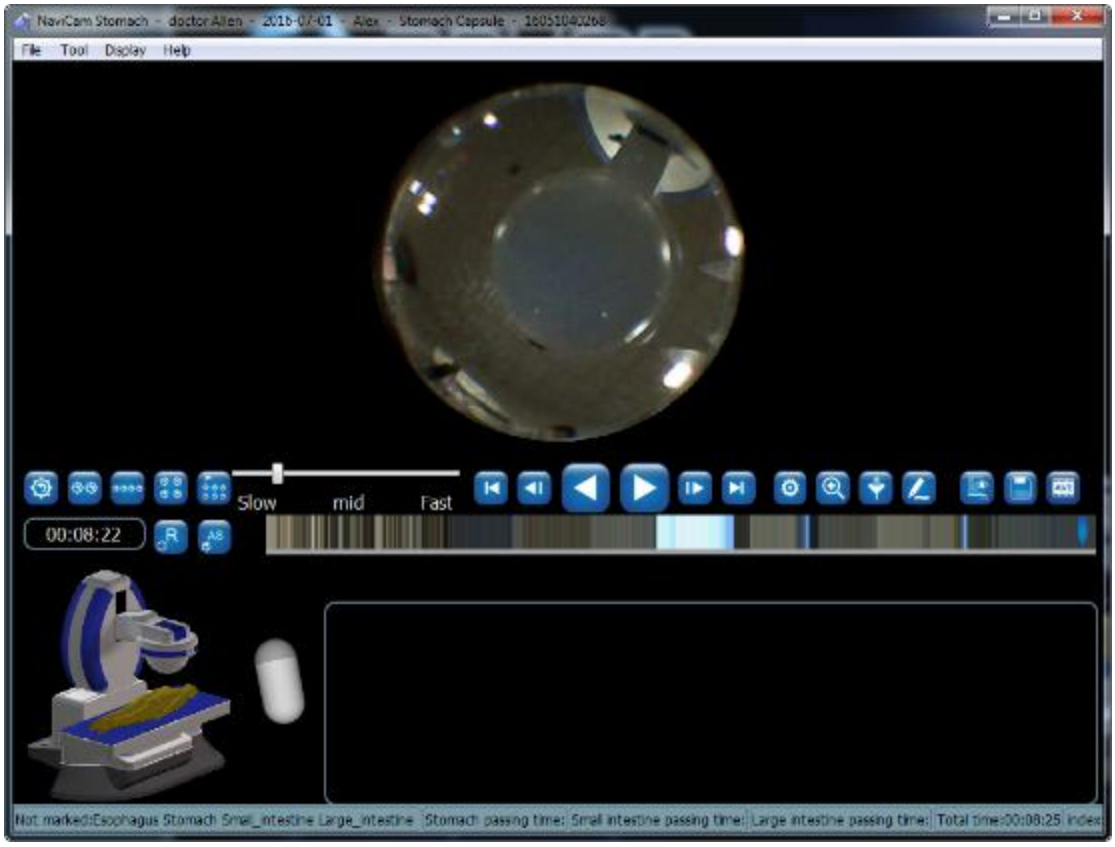


Figure 4- 66 Down Movement

4.3.5.2. Stop Video Playing

On the Image Browsing interface as shown in Figure 4- 12, click "File"→"Open Video" , click “Play” to start video playing as shown in Figure 4- 67.

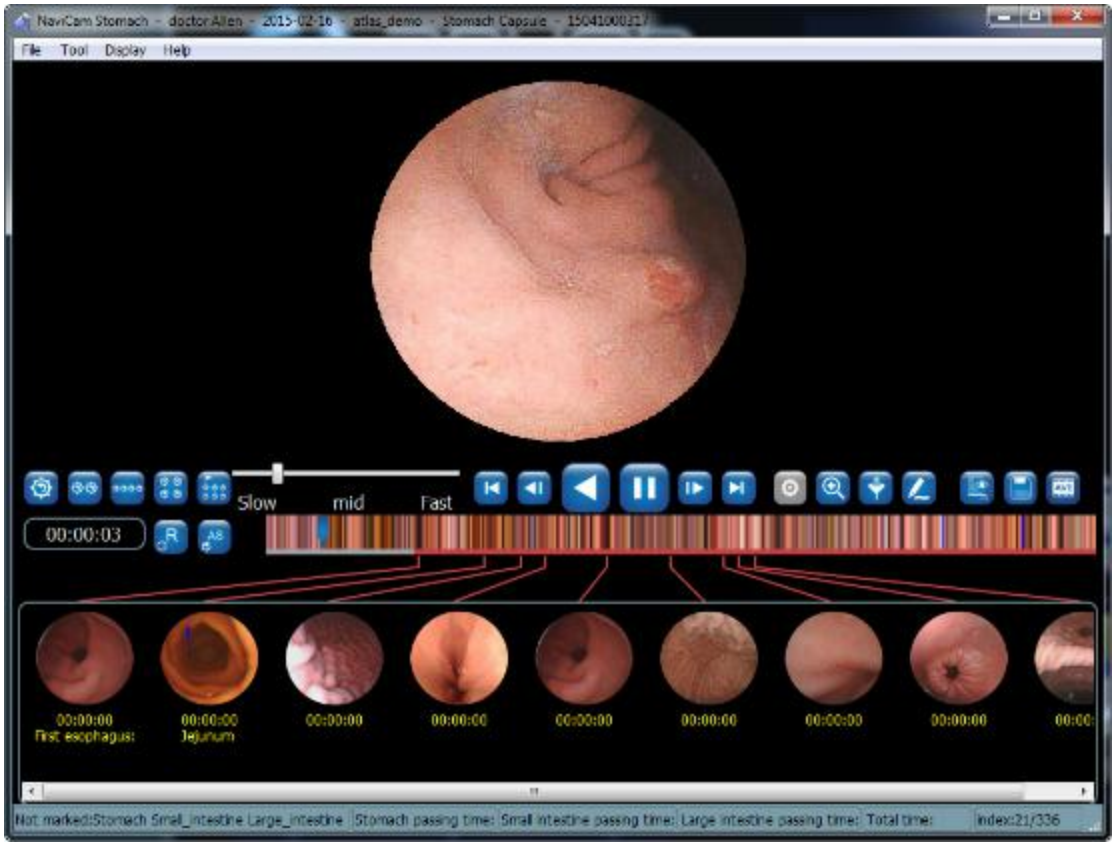


Figure 4- 67 Image Browsing

The interface when video is playing is as shown in Figure 4- 68, the playing function can be stopped once the black area is clicked with the mouse.

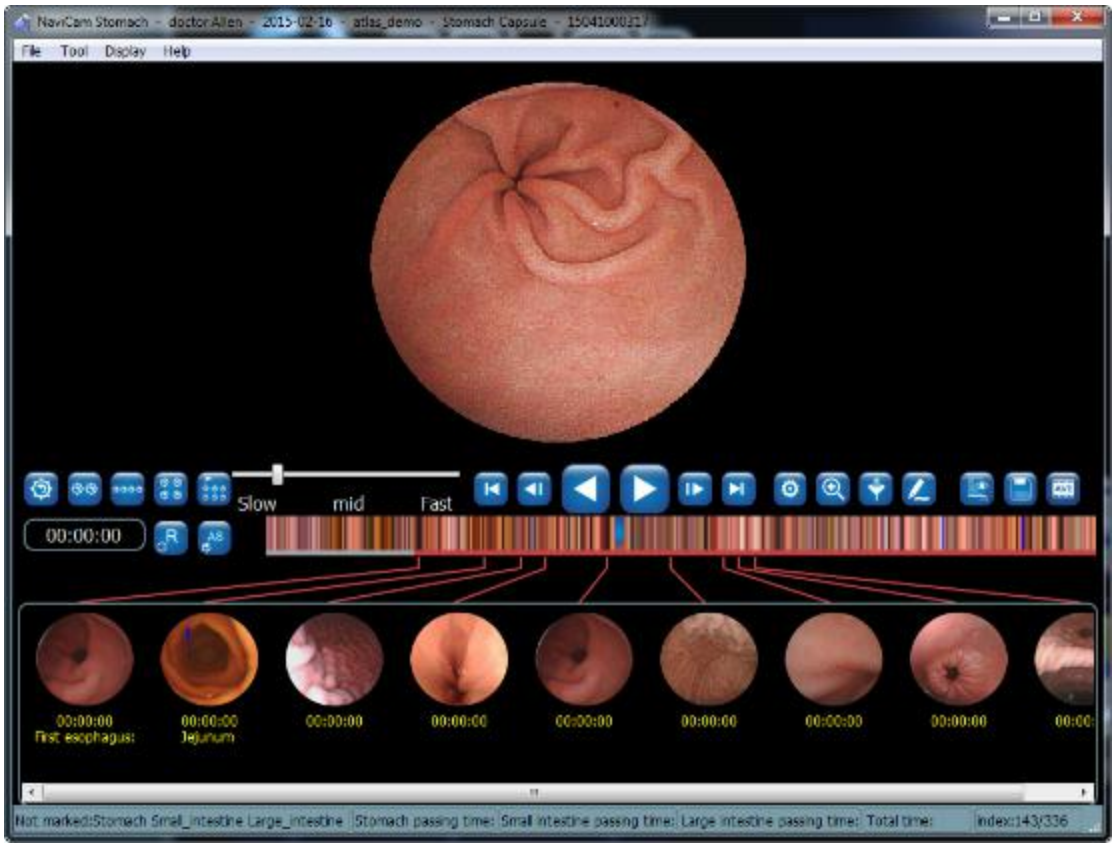


Figure 4- 68 Click the Black Area When Playing Video

4.3.5.3. Image Browsing

1. Click , , , and to access single-image display mode, two-image display mode, transverse four-image display mode, array four-image display mode, multi-image display mode respectively, as shown from Figure 4- 69 to Figure 4- 73. You can also switch display mode by clicking a display mode in "Display" menu.

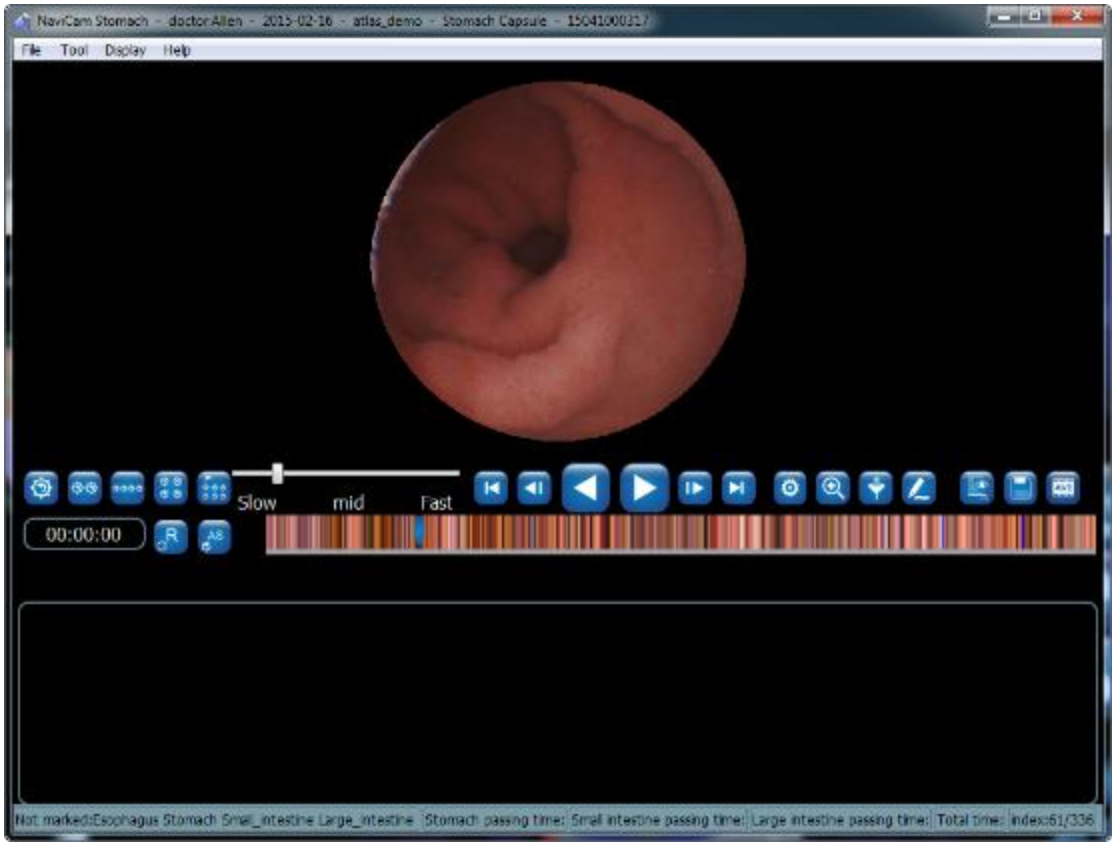


Figure 4- 69 Single-image Display Mode

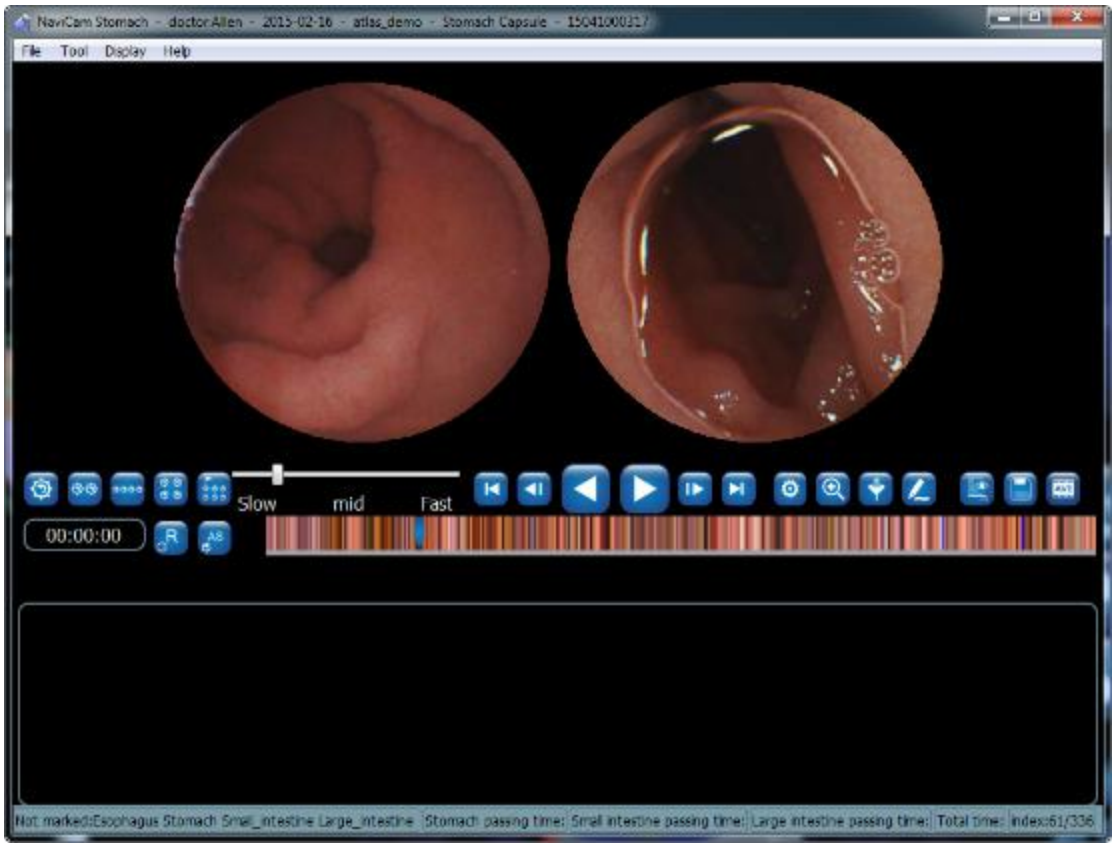


Figure 4- 70 Two-image Display Mode

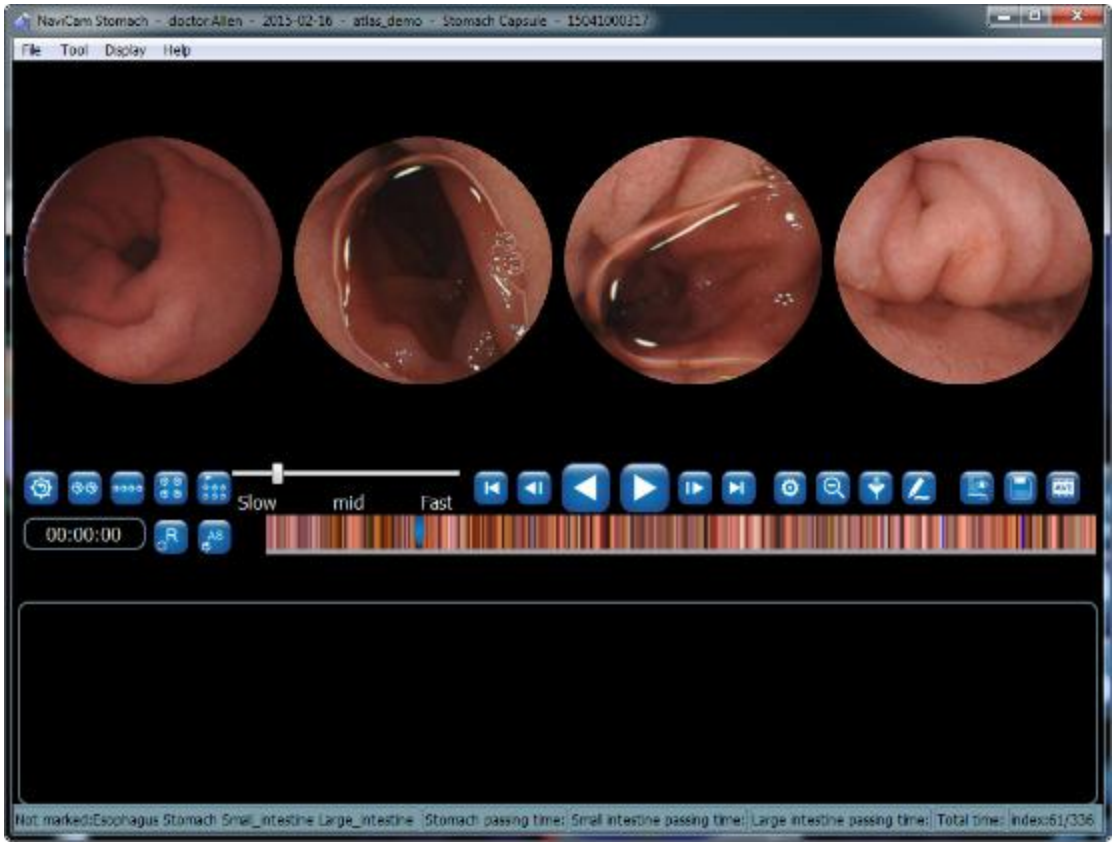


Figure 4- 71 Transverse Four-image Display Mode

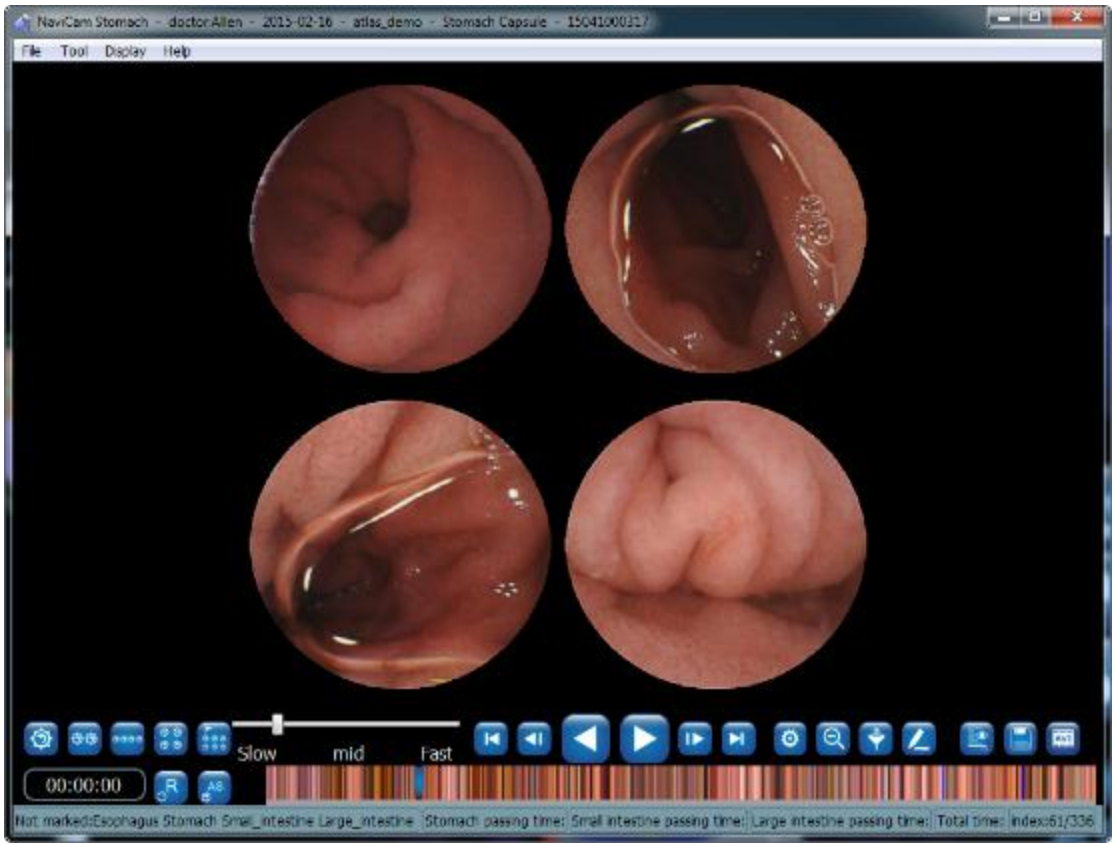


Figure 4- 72 Array Four-image Display Mode

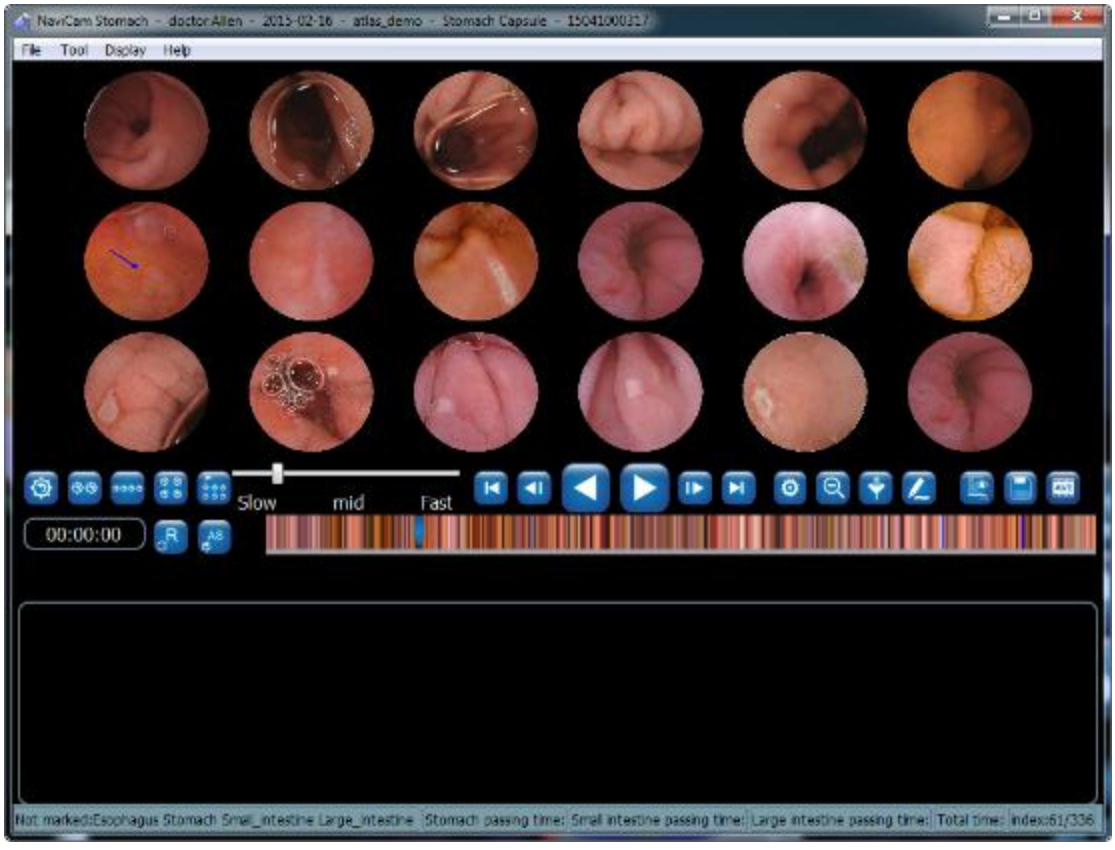


Figure 4- 73 Multi-image Display Mode

2. Drag 

(Slow Mid Fast) to adjust the play speed, and click  to play images. Click  to play back images. Click  to select the next image. Click  to select the previous image. Click  to select the last image. Click  to select the first image.

3. In single-image display mode and two-image display mode, click  to zoom an image in, and click  to zoom it out. In other display modes, zooming-in is unavailable. In this case, the button icon is  . Click the icon to switch to the single-image display mode. Figure 4- 74 shows the single-image amplification mode and Figure 4- 75 shows two-image amplification mode.

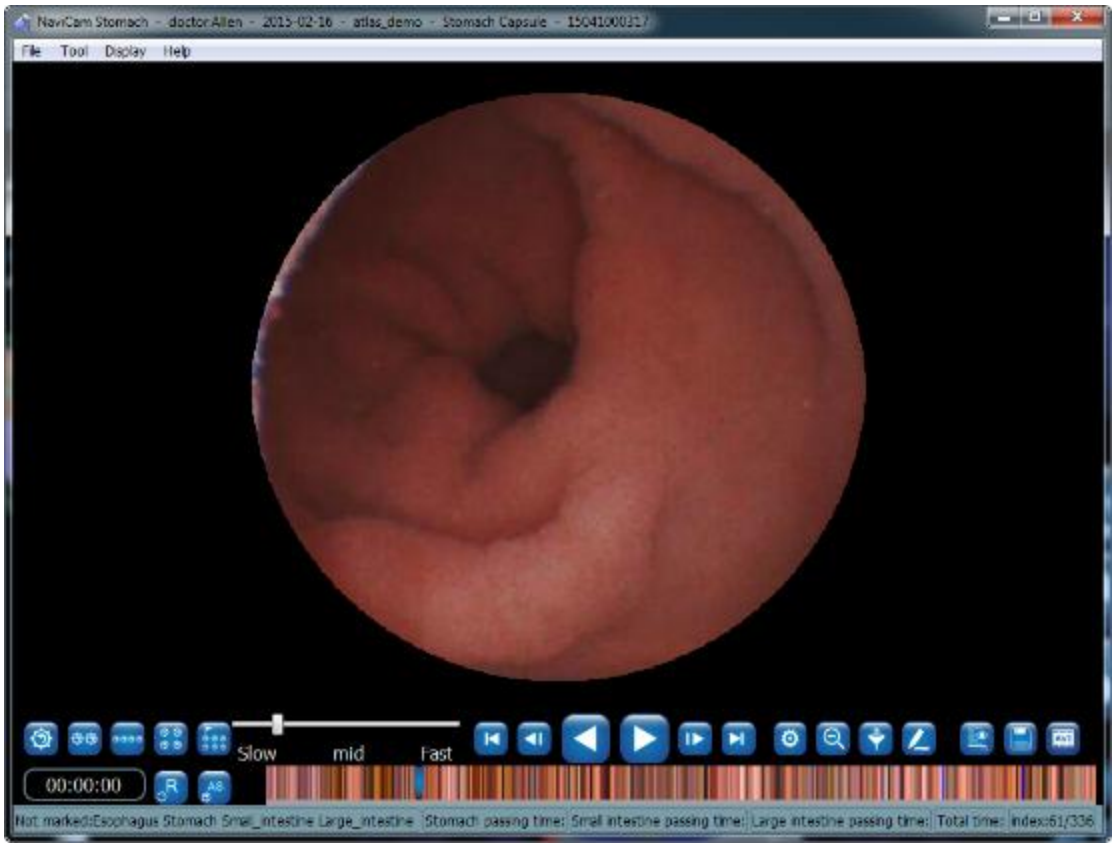


Figure 4- 74 Single-Image Amplification Mode

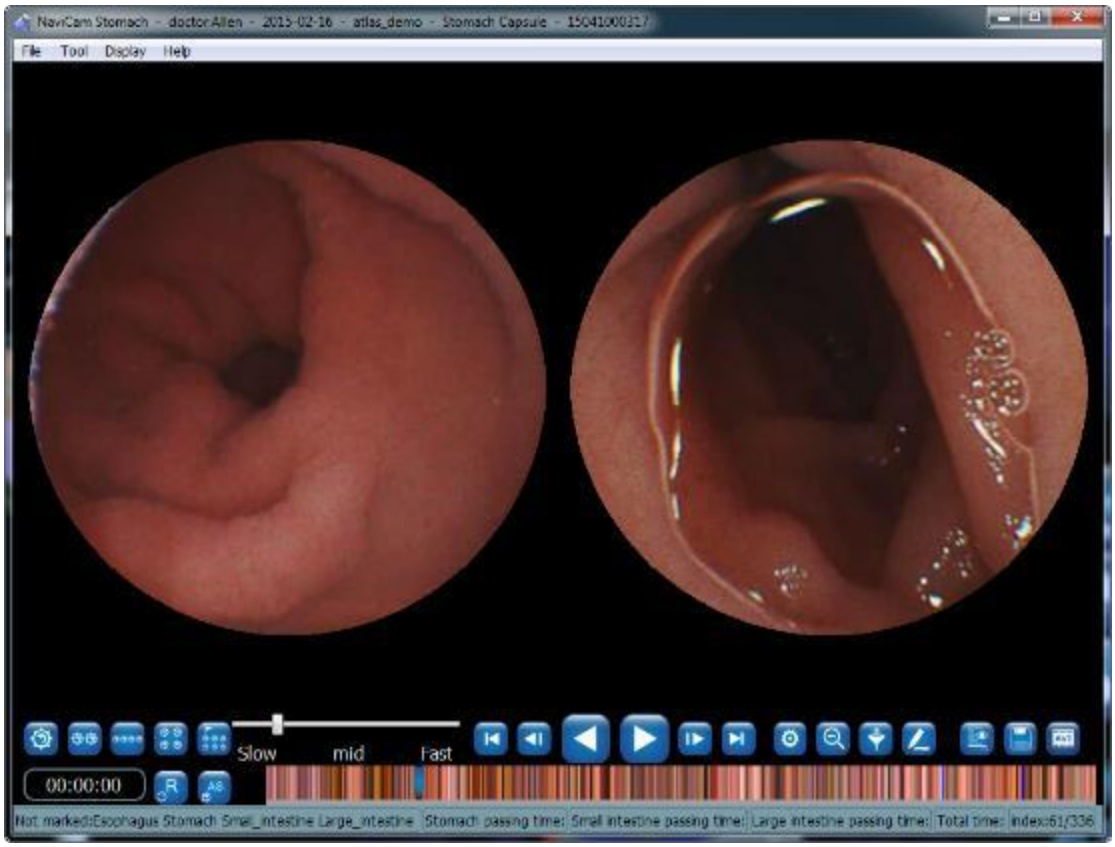


Figure 4- 75 Two-image Amplification Mode

4. By clicking  and when the button icon changes to  , time bar displays and the thumbnail displays image absolute time, by clicking  and when the button icon changes to  , time bar displays and the thumbnail displays image relative time. The absolute time is the time when the image is captured by the capsule endoscope, the relative time is the time difference between the time when the image is captured and the capture time of the first image.

4.3.5.4. Image Marking

1. Move the mouse over the image to be marked and right click on the image. On the pop-up right-click menu, you are able to select "Mark the first esophagus image", "Mark the first stomach image", "Mark the first small bowel image", and "Mark the first large bowel image", as shown in Figure 4- 76. By marking the images of the digestive tract enables, the information in the status bar to change automatically with the image position being marked. Marked image will appear in the lower thumbnail area.

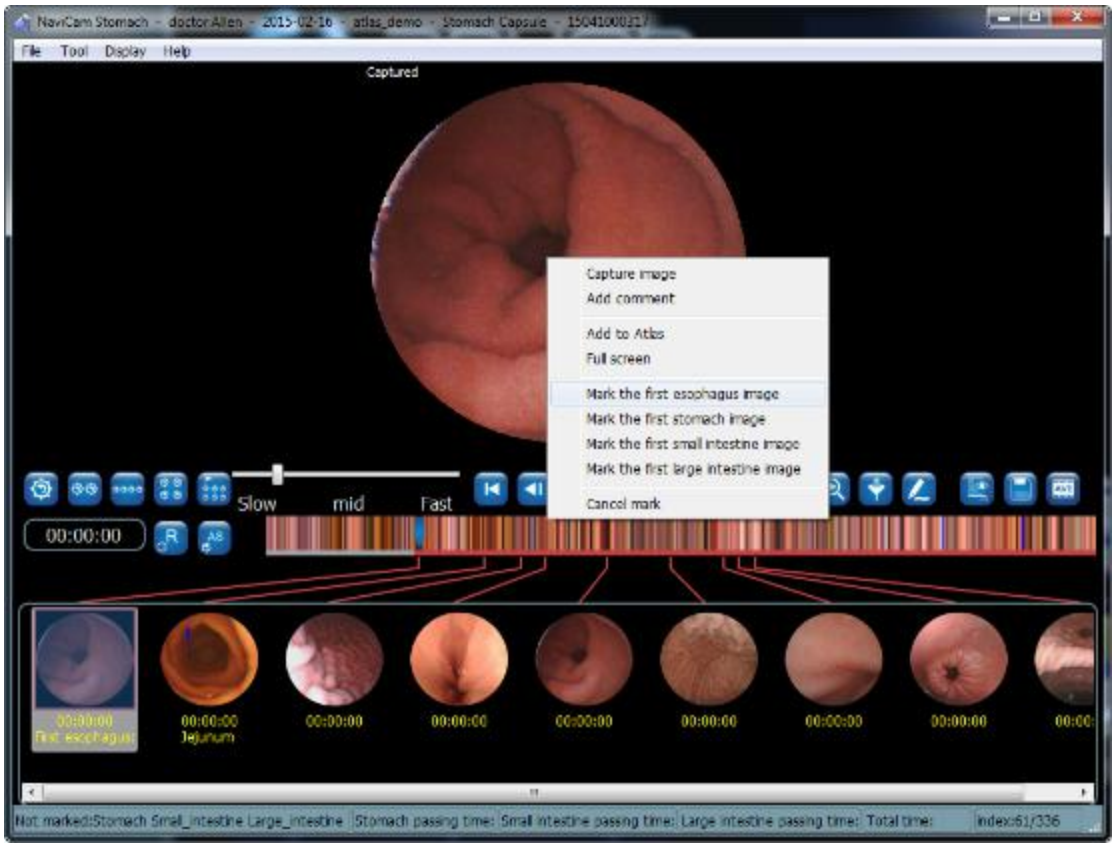


Figure 4- 76 Marking Image

2. In addition to marking an image, you can also capture an image. Move your mouse over the image to be captured, and right click on the image, on the pop-up right-click menu, you can click to capture the image, as shown in Figure 4- 77, you can also double click on the image to capture it. The captured image will appear in the lower thumbnail area.

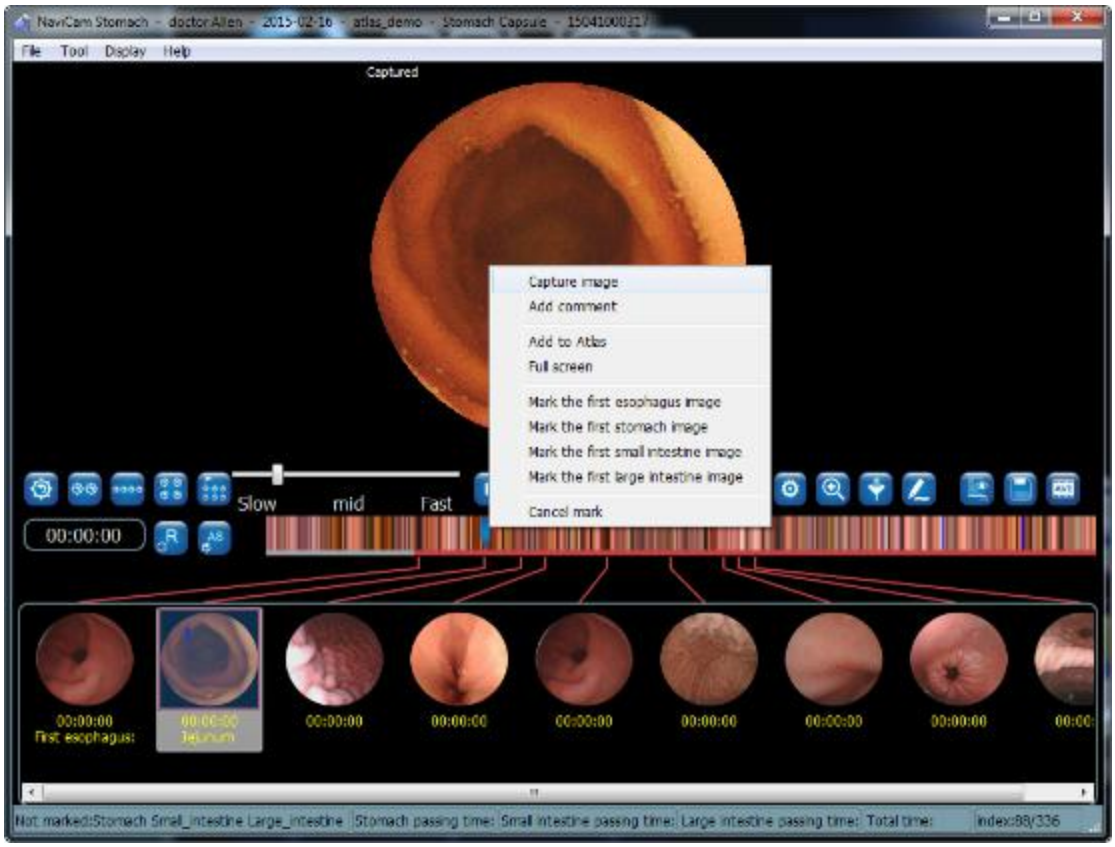


Figure 4- 77 Capture Image

3. Move your mouse over the image to cancel mark and right click on the image, on the pop-up right-click menu, you can select "Cancel Mark", as shown in Figure 4- 78, and then delete this image in the thumbnail.

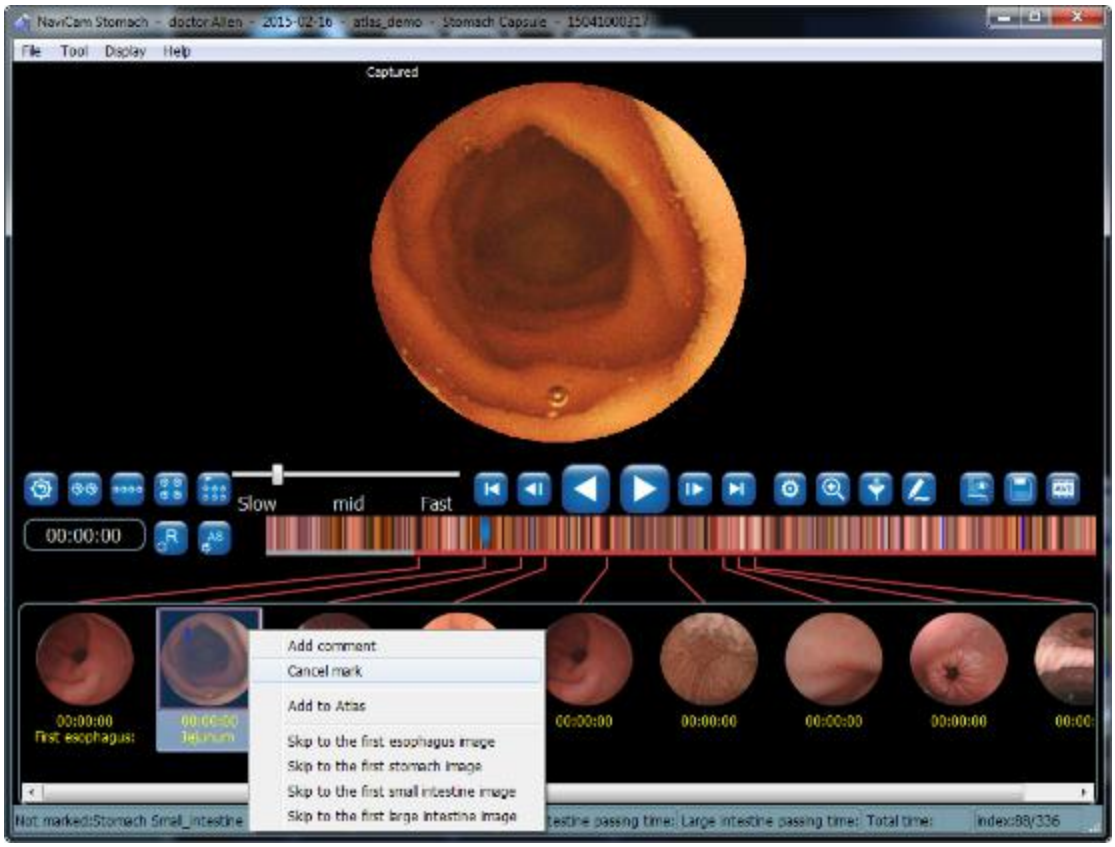


Figure 4- 78 Cancel Mark

4.3.5.5. Image Comment

1. Move your mouse over the image to add comments, and right click on the image, on the pop-up right-click menu, you can select "Add Comment" as shown in Figure 4- 79, or click  to access the Add Comment interface as shown in Figure 4- 80.

Figure 4- 79 Add Comment to Image

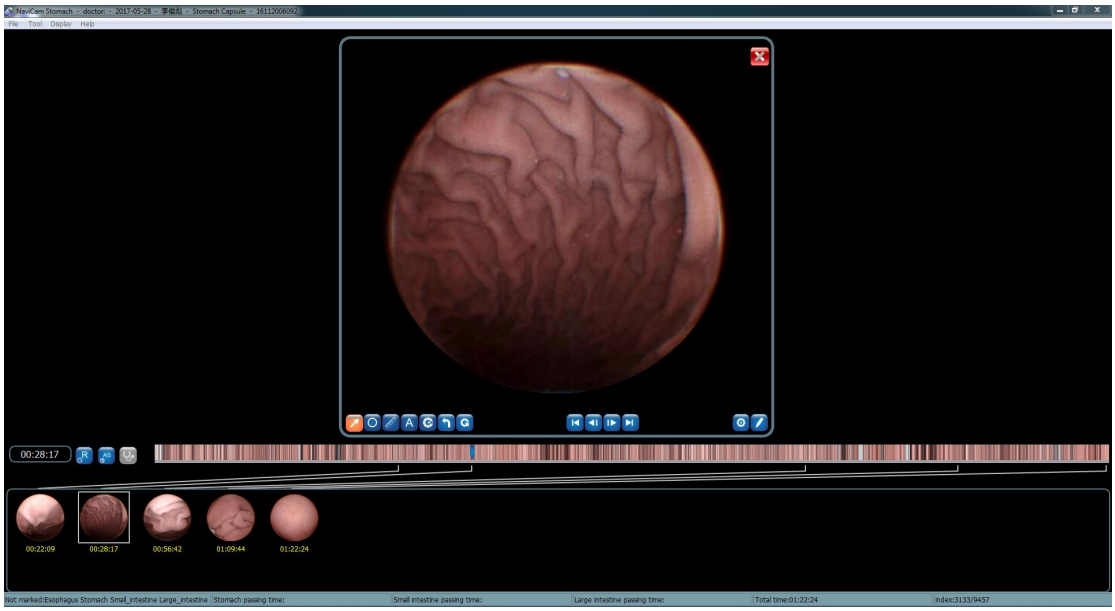


Figure 4- 80 Add Comment Interface

2. On the Add Comment interface, by clicking  and when the button icon changes to  , you can add an arrow mark on the image by moving your mouse over the image, and then clicking and holding down left mouse button to drag your mouse. By clicking  and when the button icon changes to  , you can

add a circular mark on the image by moving your mouse over the image, and clicking and holding down left mouse button to drag your mouse, as shown in Figure 4-81. Click  to undo the previous mark and click  to undo all marks. Marks will be reflected on images in the thumbnail.

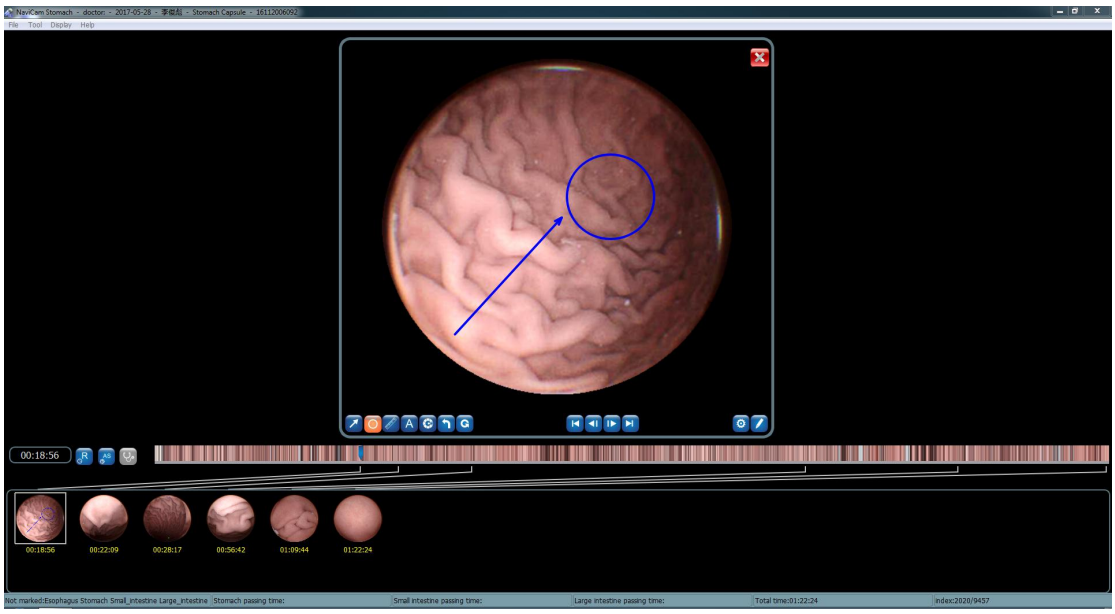


Figure 4-81 Add Mark

3. Click  to select the first marked or captured image, click  to select the previous marked or captured image, click  to select the next marked or captured image, and click  to select the last marked or captured image. Alternatively, you can move your mouse over an image to scroll over images to select the desired image.
4. Click  to access the Add Comment interface as shown in Figure 4-82. You can enter textual descriptions to corresponding images into the comment text box by two input sources: one is manual input and the other is to double click useful expressions in the useful expression list. After the software is installed, the useful expression list populates automatically. Users can add or delete a useful expression as required. The comments added will be reflected on images in the thumbnail.

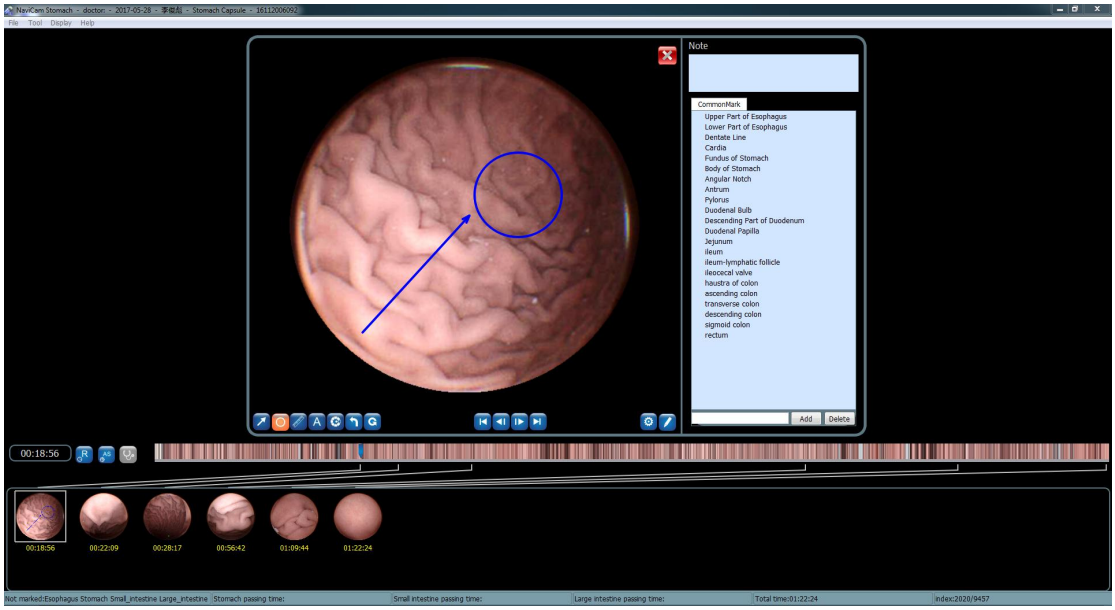


Figure 4- 82 Add Comment Interface

5. Click  to exit the Add Comment interface.

4.3.5.6. Thumbnail

1. The images with marks and comments will be reflected in the thumbnail. Figure 4- 83 shows the thumbnail display interface.

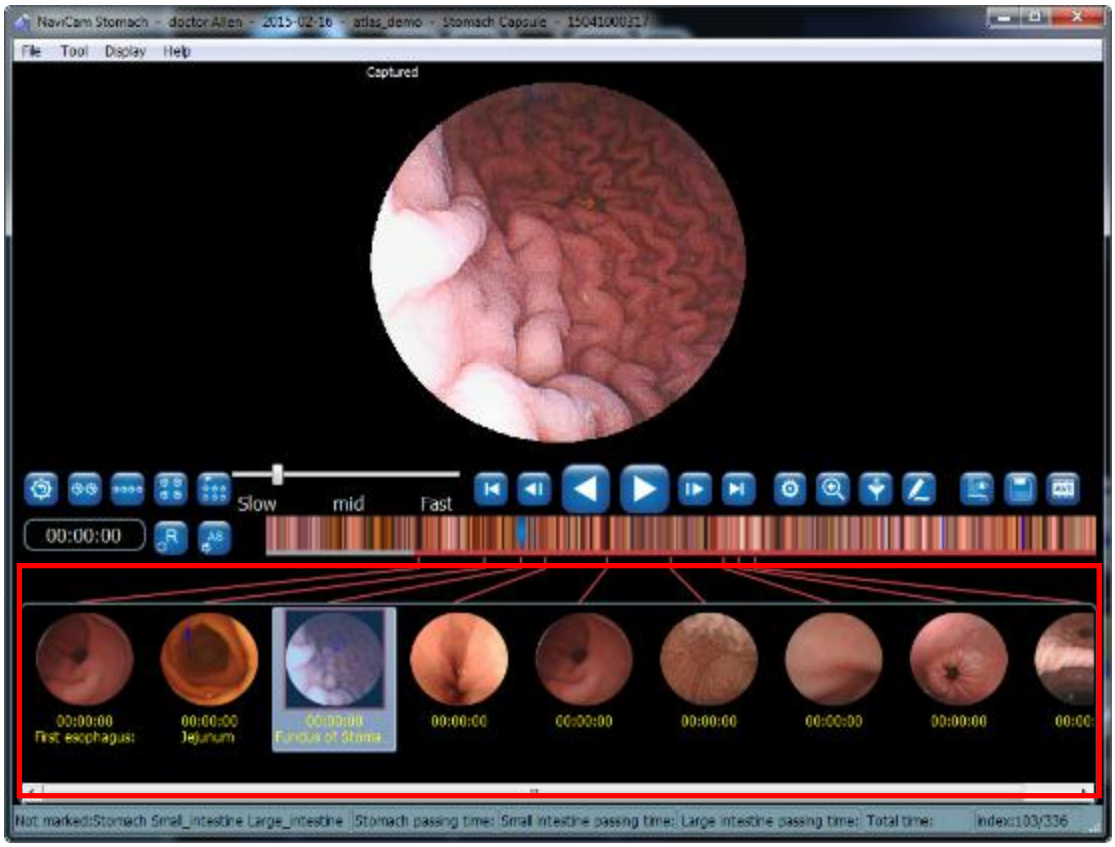


Figure 4- 83 Thumbnail Display Interface

2. In the thumbnail display area, move your mouse over the image to add comments, and right click on the image, on the pop-up right-click menu, select "Add Comment" as shown in Figure 4- 84 to add comments to the thumbnail. After operation, you will access the add comment interface as shown in Figure 4- 82.

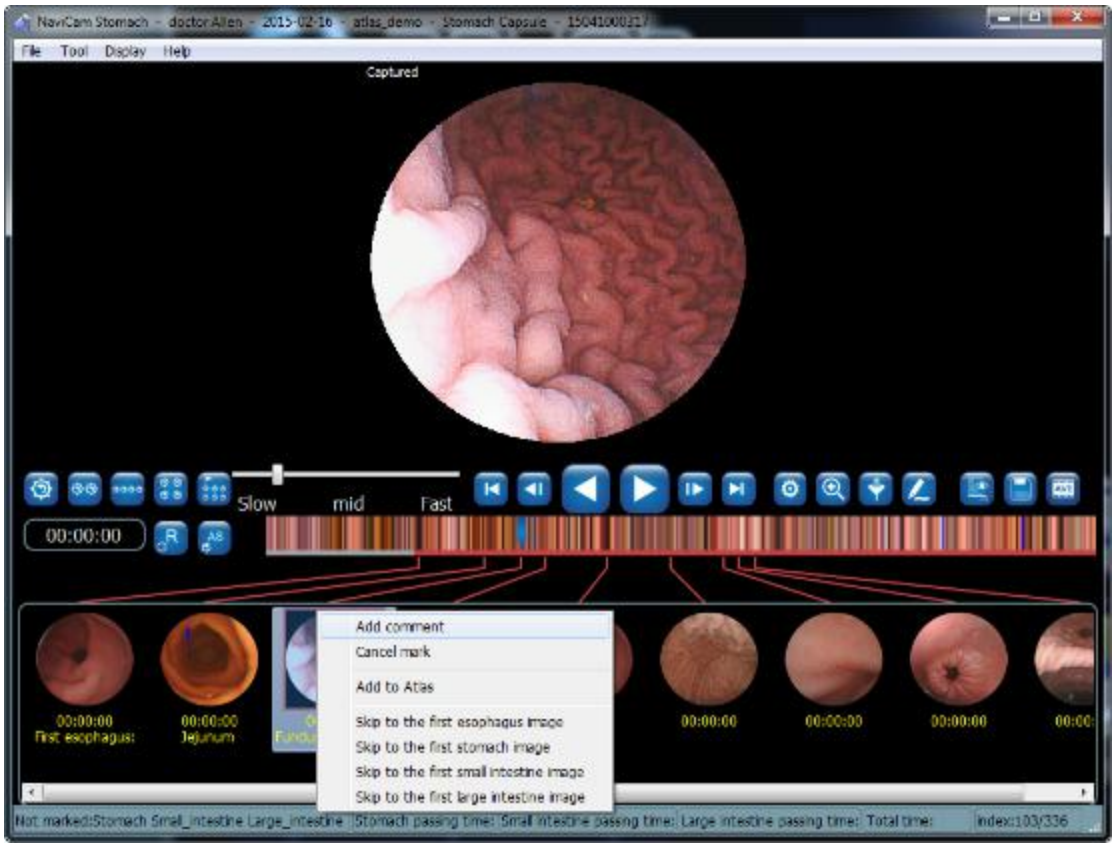


Figure 4- 84 Add Comment to Thumbnail

3. In the thumbnail display area, move your mouse over the image to cancel mark, and right click on the image. On the pop-up right-click menu, select "Cancel Mark" to delete the image from the thumbnail as shown in Figure 4- 85. You can delete multiple images at a time by left clicking images to be deleted while holding down Ctrl key, or keep holding down the left mouse button and dragging your mouse to select multiple images, and then right clicking to select "Cancel Mark" from the pop-up right-click menu to delete multiple images from the thumbnail area.

Figure 4- 85 Cancel Mark

4. In the thumbnail display area, right click on the image, the manu above will be the pop-up. You can also move your mouse over the thumbnail to be displayed, and then double click left mouse button to display this thumbnail in the image display area.

4.3.5.7. Image Processing

1. Click  , image processing control will be prompted on the interface as shown in Figure 4- 86. Adjust image definition and brightness by dragging the slider, and adjust image color by dragging color sliders.

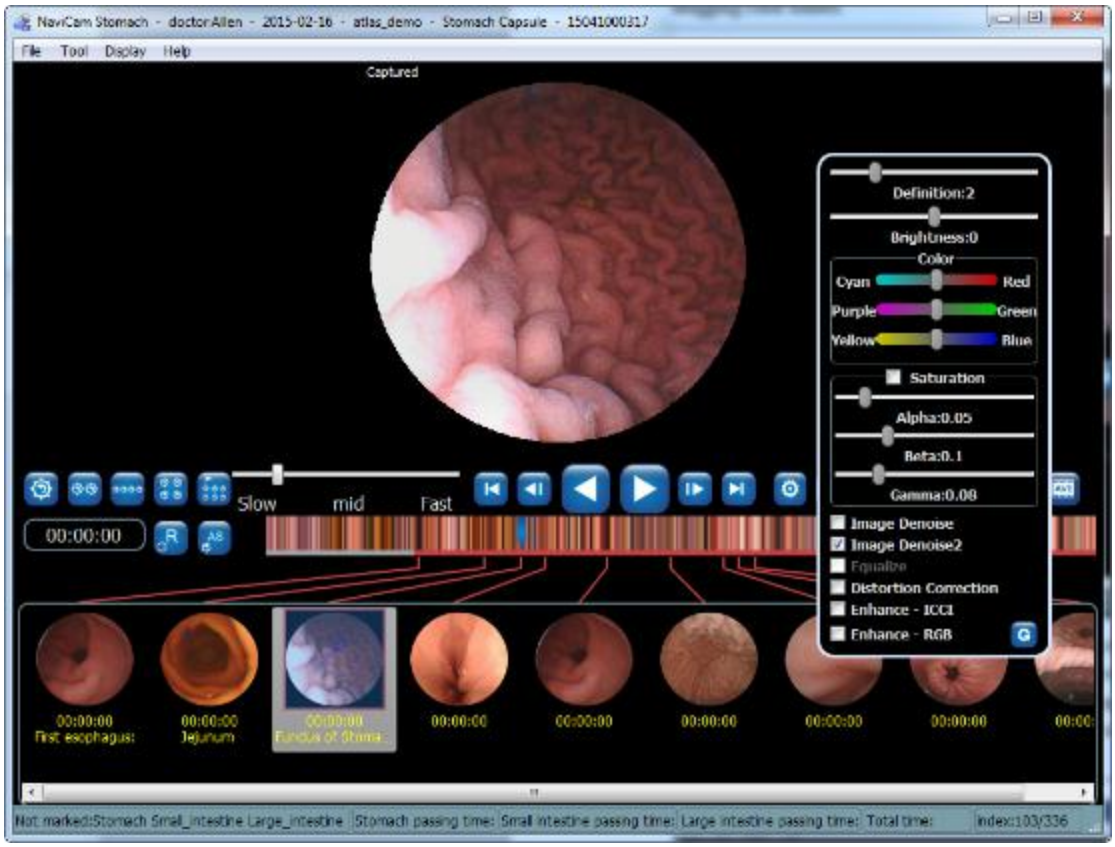


Figure 4- 86 Image Processing Control

2. The software is equipped with two image noise removal algorithms, by default "Removing image noise 2" algorithm will be used, the effect of image noise removal is shown in Figure 4- 87, and the effect of image when image noise is not removed is shown in Figure 4- 88.

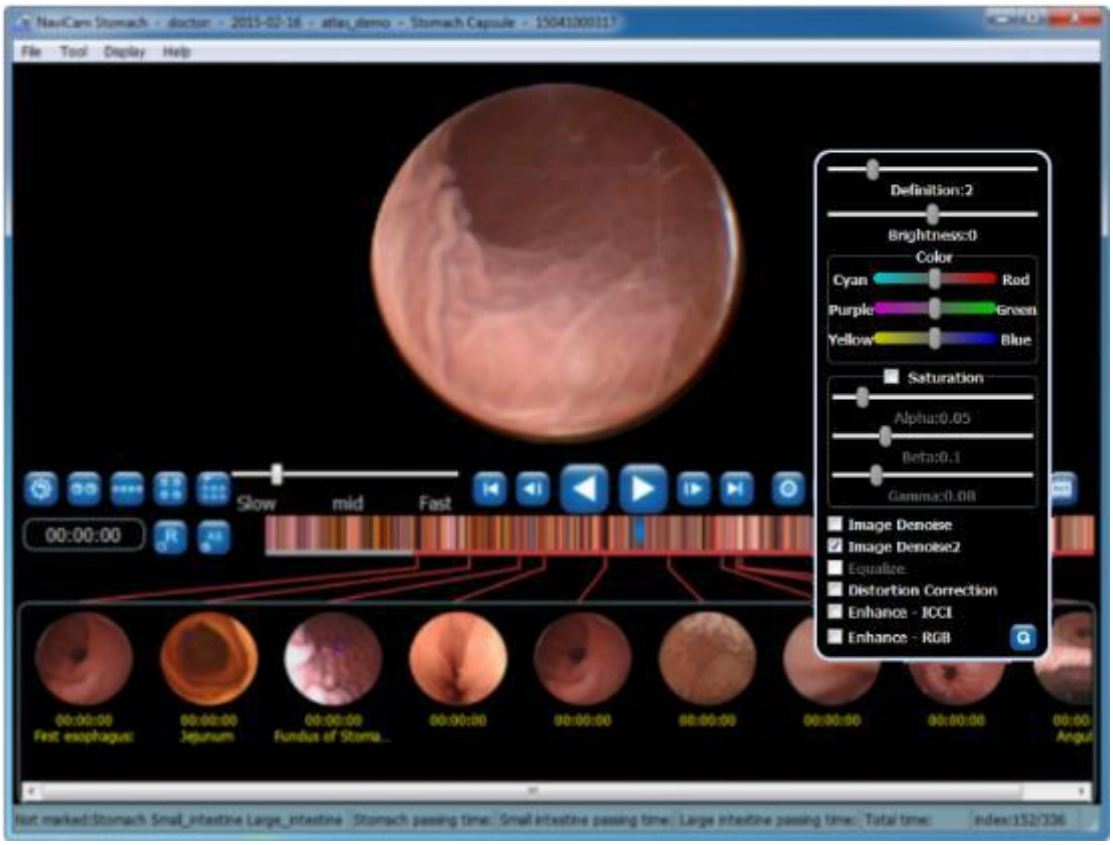


Figure 4- 87 Removing Image Noise

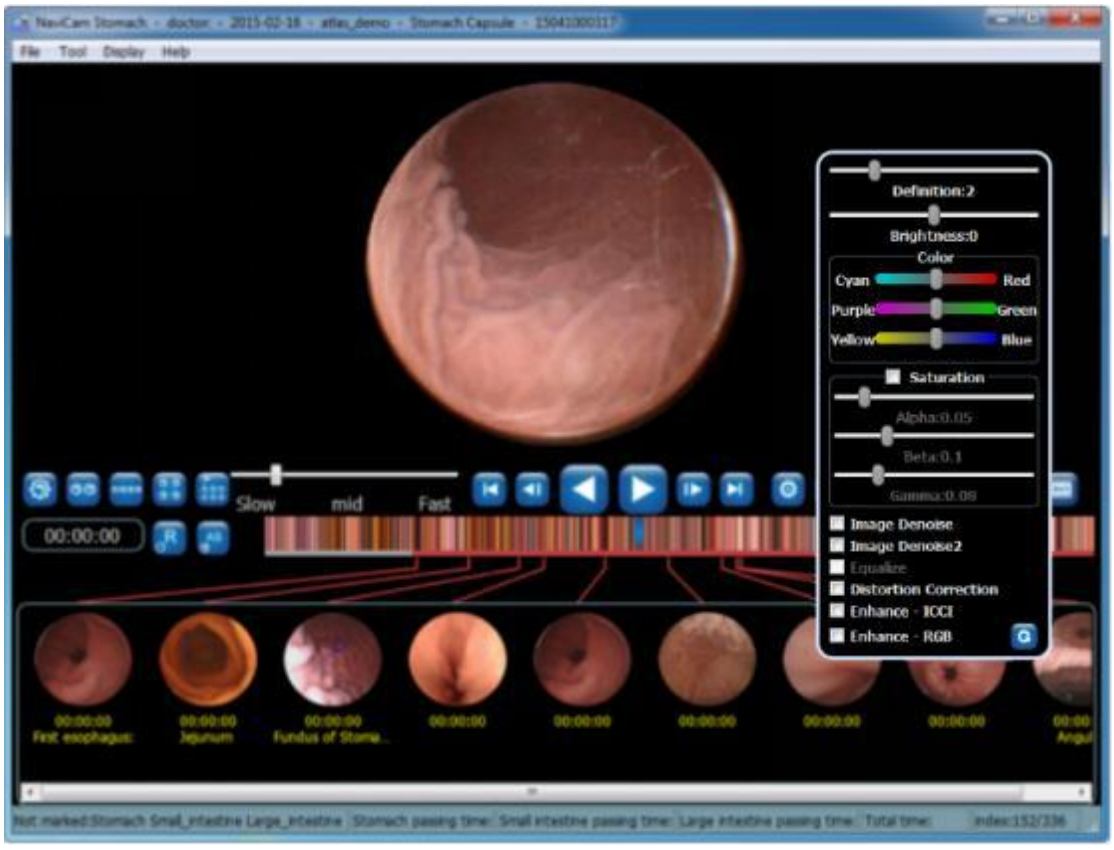


Figure 4- 88 Image Noise is not Removed

3. Select “Distortion Correction” to have image effect as shown in Figure 4- 89:

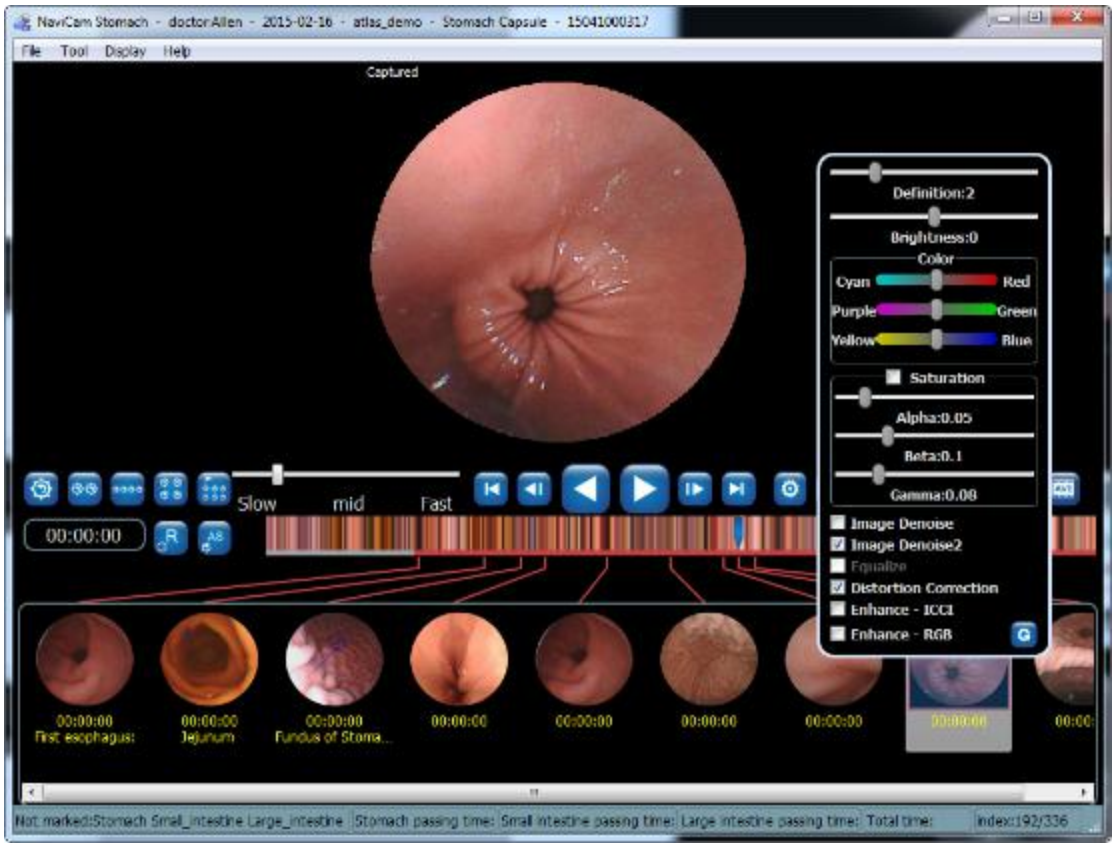


Figure 4- 89 Distortion Correction

4. Select “Enhance-ICCI” to have image effect as shown in Figure 4- 90:

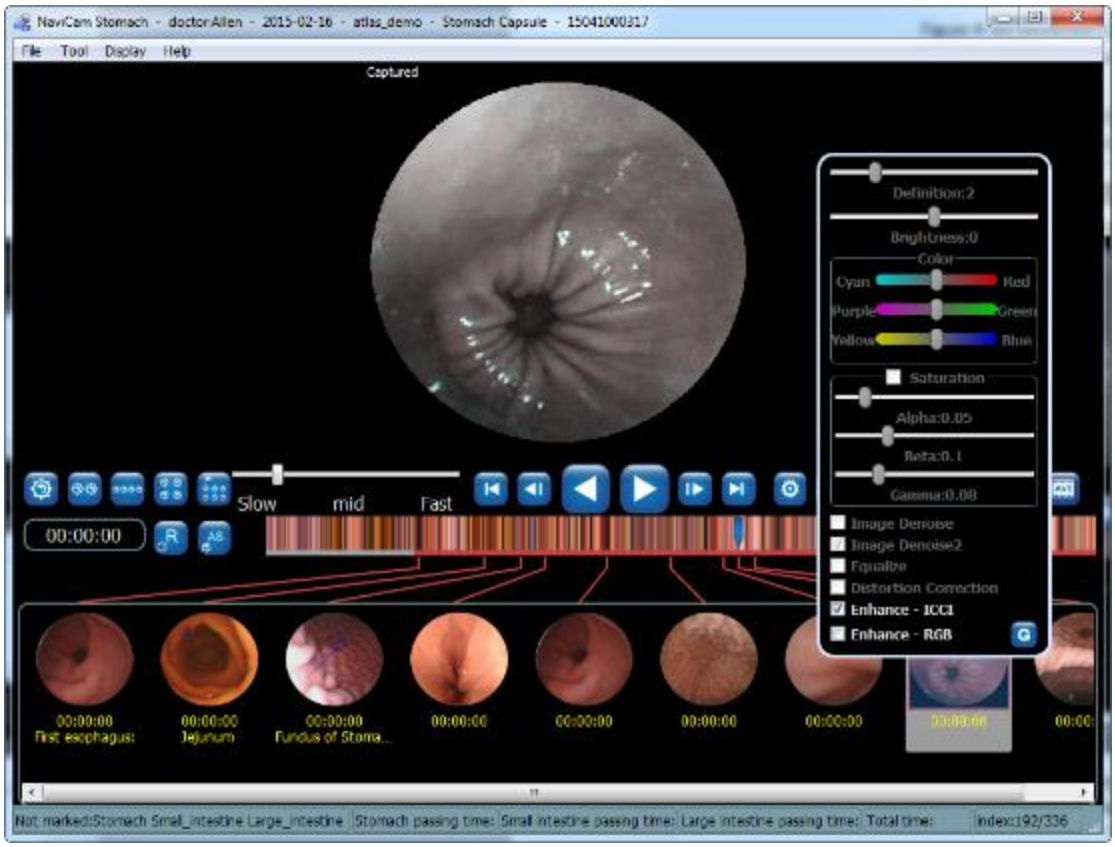


Figure 4- 90 Enhance-ICCI

5. Select “Enhance-RGB” to have image effect as shown in Figure 4- 91:

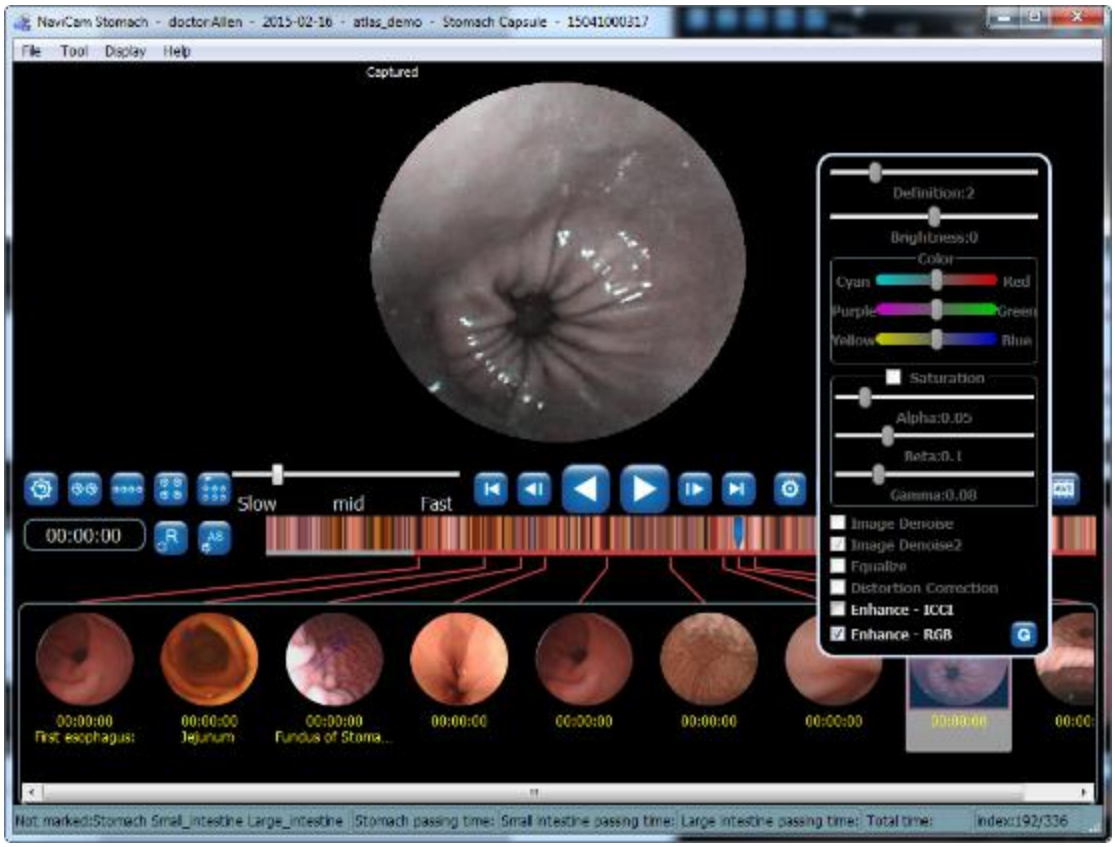


Figure 4- 91 Enhance-RGB

6. Drag saturation adjustment slider to have image effect as shown in Figure 4- 92:

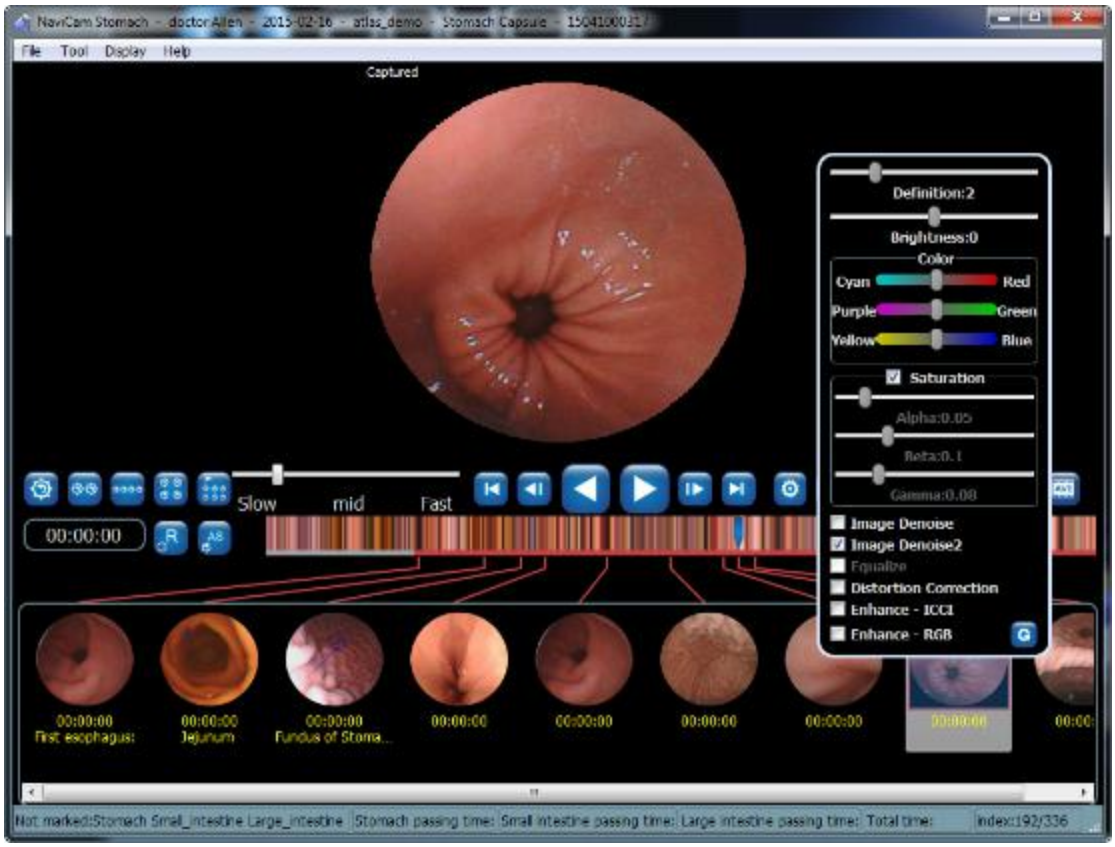


Figure 4- 92 Saturation Adjustment Control

7. Click  on the add comment interface as shown in Figure 4- 82 to access image processing interface as shown in Figure 4- 93. Adjust image definition and brightness by dragging definition and brightness sliders; adjust image color by dragging color sliders, and set image enhancement effects by selecting image enhancement check box.

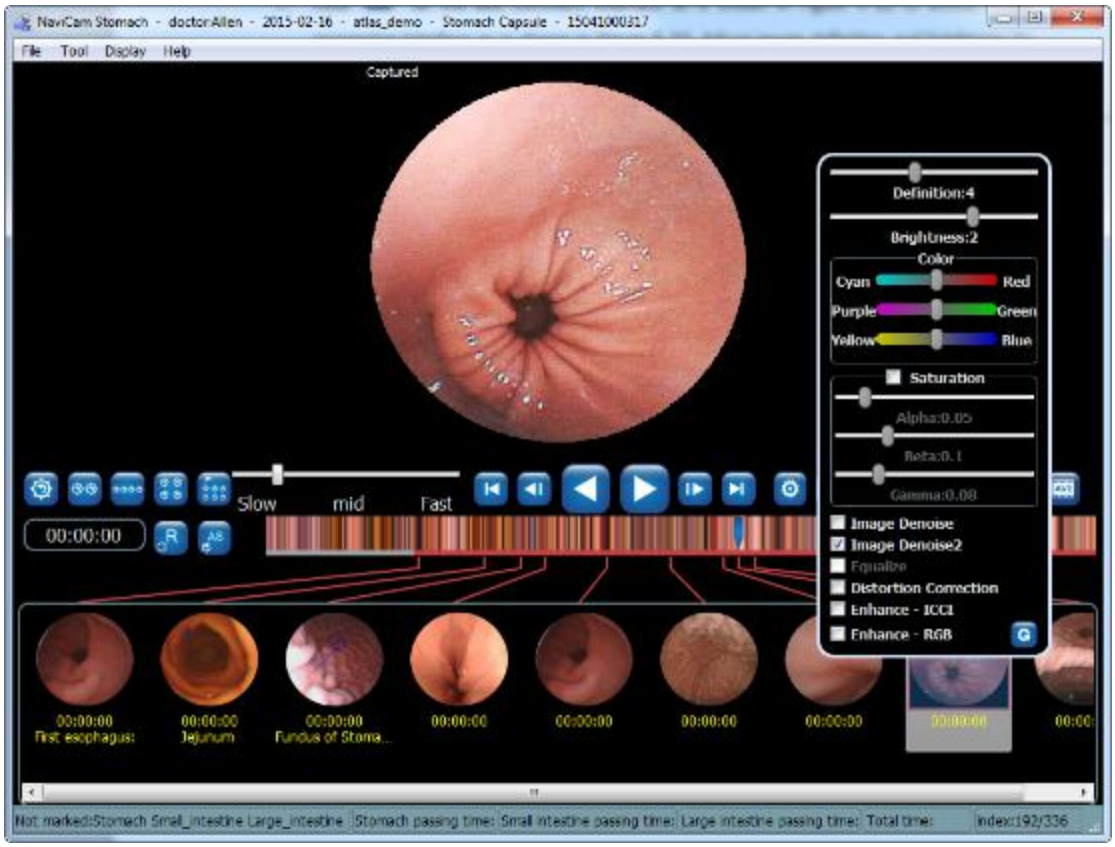


Figure 4- 93 Brightness, Definition Set

4.3.5.8. Browsing Mode

1. **By clicking**  **and when the button icon changes to**  **, you will access the Similarity** Browsing Mode as shown in Figure 4- 94. In this mode, the software displays only one image for similar images, thus reducing quantity of images to be browsed. Experiments show that quantity of images is cut about 50%.

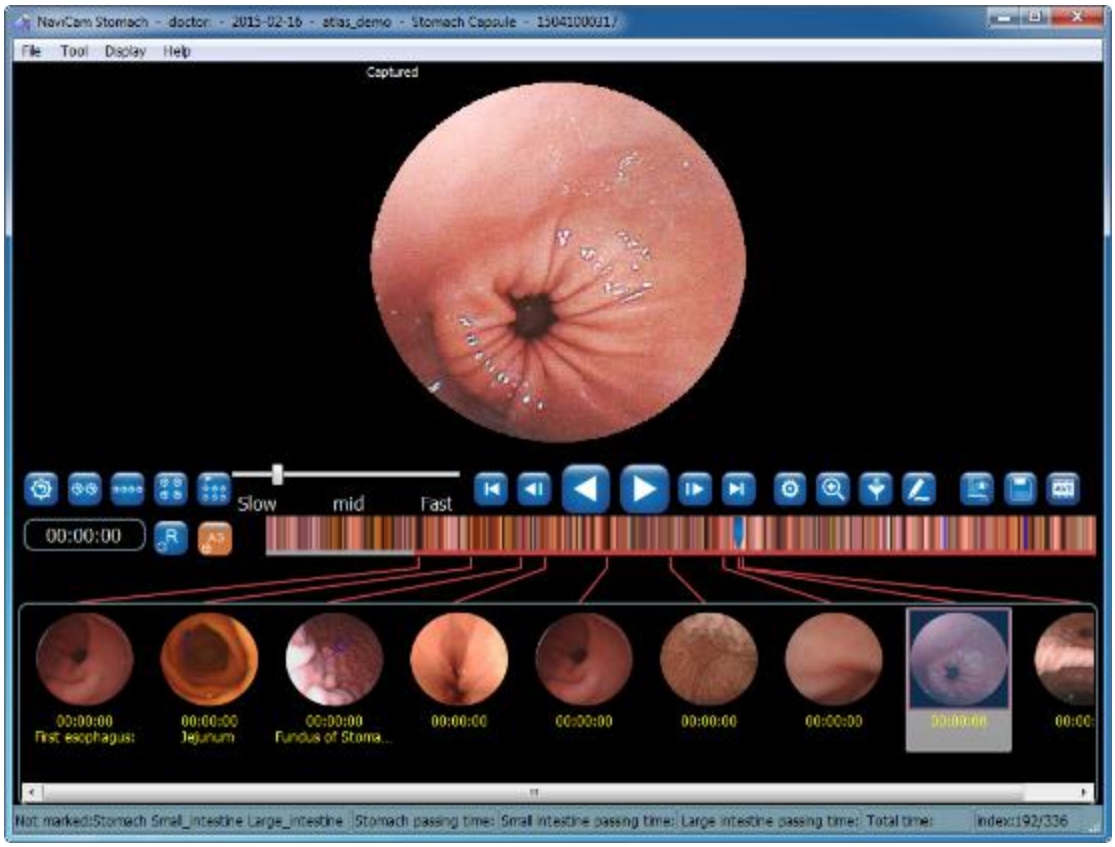


Figure 4- 94 Similarity Browsing Mode

2. By clicking  and when the button icon changes to  , you will access Filter Browsing Mode as shown in Figure 4- 95. In this mode, the software displays only marked or captured images for further screening.

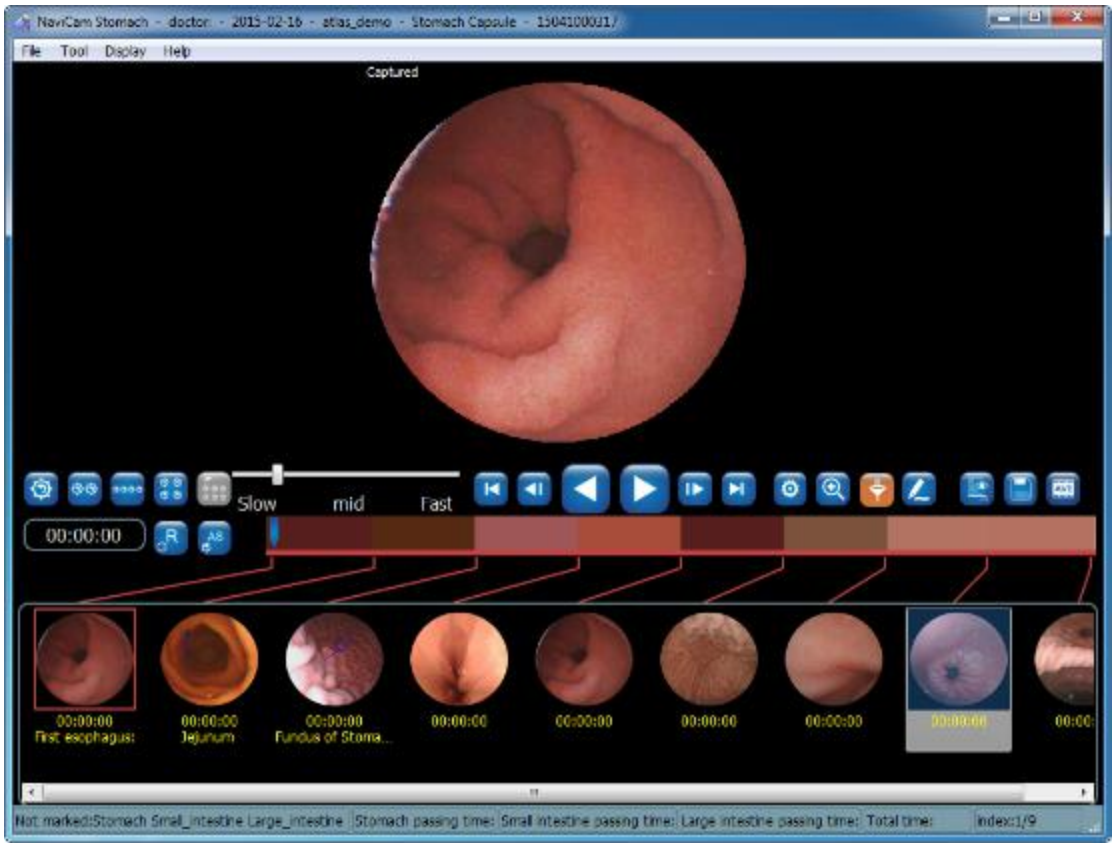


Figure 4- 95 Filter Browsing Mode

4.3.5.9. Option Setting

1. On the Image Browsing interface as shown in Figure 4- 12, click "Tool" →"Option" to access "Option" interface as shown in Figure 4- 96.

Figure 4- 96 Options Interface

2. In "Department" column, fill in department information, which will appear in the case report.
3. In "Export Path" column, set a data export path. If the "Delete RAW files after video is exported" is checked, and data is exported in form of "Export and parse data into video file" as specified in Figure 4- 49 Data Export Interface, then after export, related RAW files in its export path will be automatically deleted.
4. In “Others” column:
   If "Add patient information when saving an image" is checked, then on Image Browsing Interface as shown in Figure 4- 12, left click  to save images with mark or comment. After saving, right click  to open the folder where these images are located. Double click a saved image, and patient information will appear in the left upper, right upper or left lower corner, as shown in Figure 4- 97 Saved Image Displaying Patient Information.
   If "Open the finding file when opening the video" is checked, then on the Image Browsing interface as shown in Figure 4- 12, you can open the last saved finding file when opening the patient video.
   If "Display image preview when mouse hovers over the time progress bar" is

checked, then the image preview where mouse hovers over will appear as shown in Figure 4- 98 Image Preview Interface when mouse hovers over the time progress bar and stops about 1 second on Image Browsing Interface as shown in Figure 4- 12.

If “Allow to upload to cloud server (Effective after reboot)” is checked, after software reboot, local data can then be uploaded to internet server, appointment code input column appears in patient check-in interface. “Upload data” button appears on case management interface.

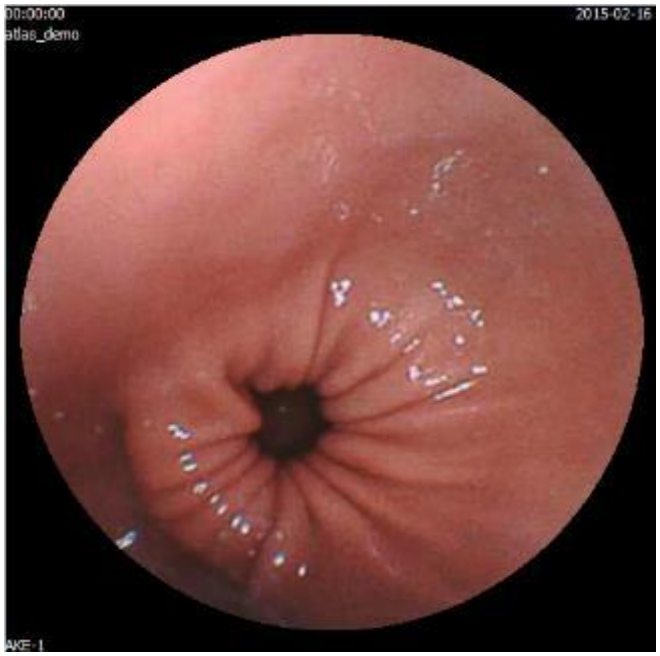


Figure 4- 97 Saved Image Displaying Patient Information

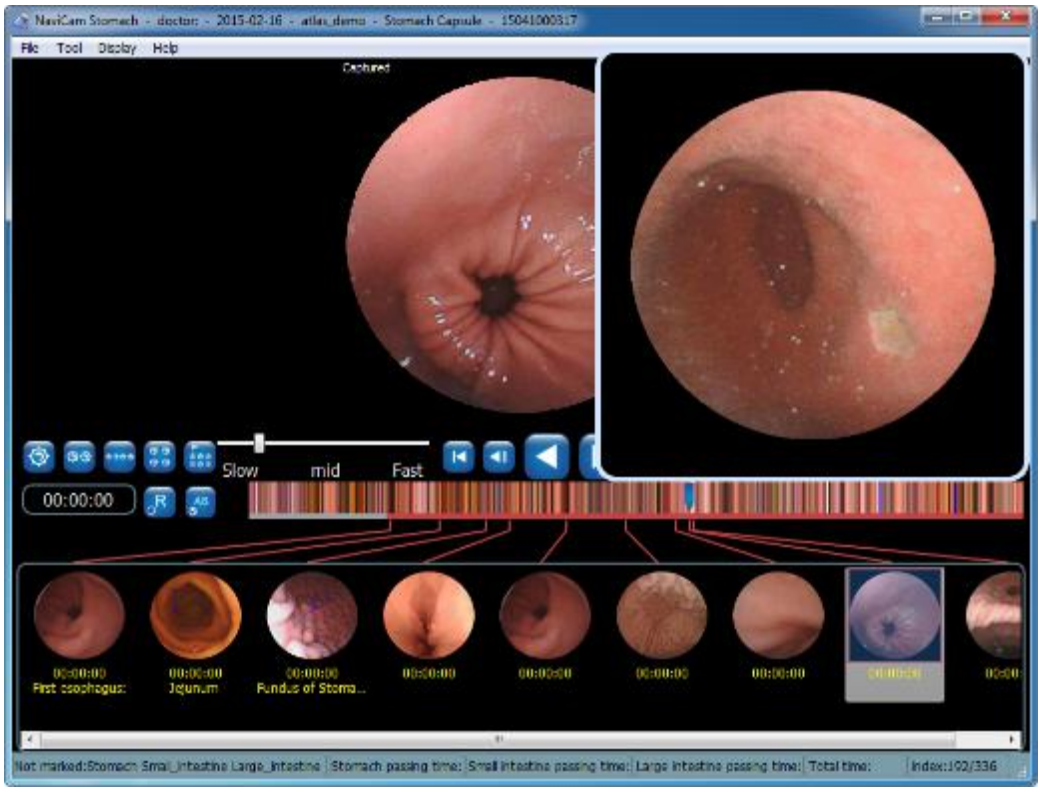


Figure 4- 98 Image Preview Interface

4.3.5.10. Add to Atlas

1. Move the mouse over the image to be added to atlas, right click the mouse, on the pop-up right-click menu, select “Add to atlas” as shown in Figure 4- 99.

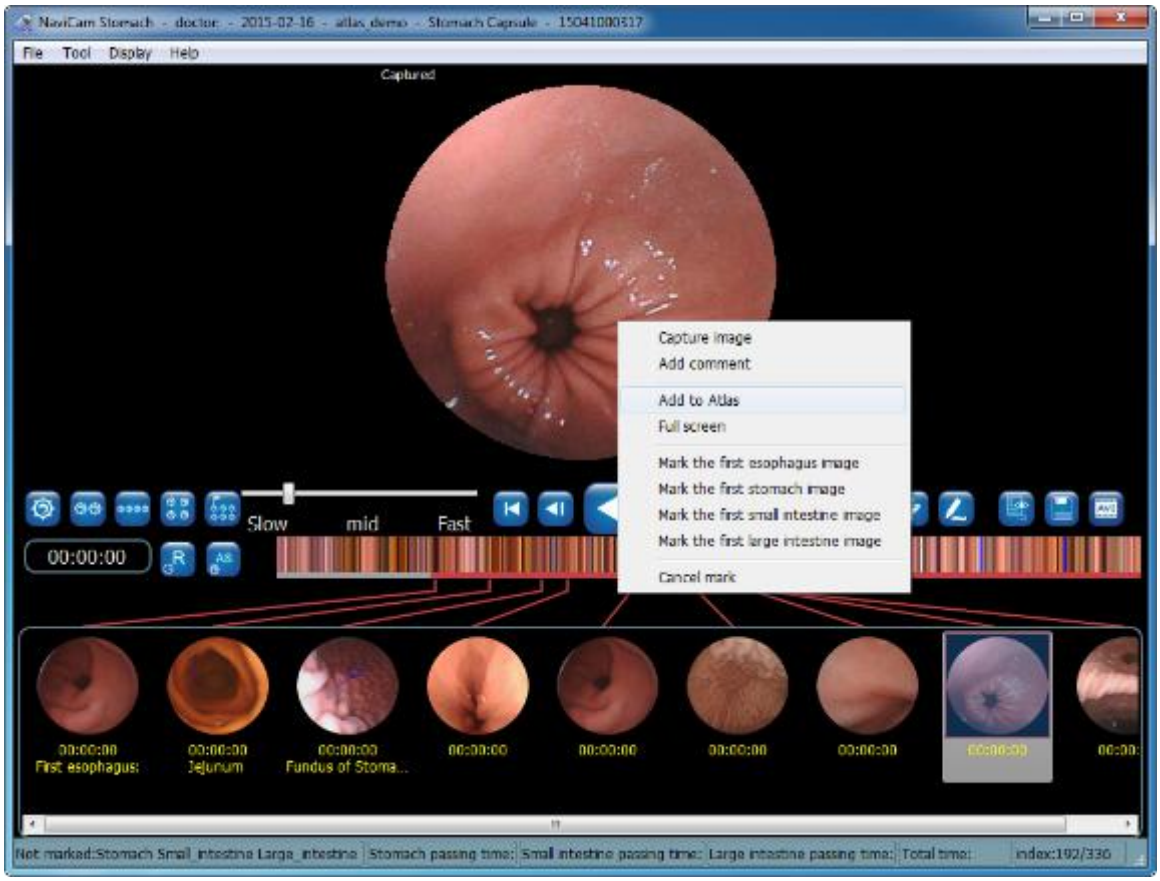


Figure 4- 99 Add to Atlas

2. In the “Add to atlas” dialog box, select atlas type in the left column, fill in name in the right bottom column as shown in Figure 4- 100, and click “Confirm” after filled in.

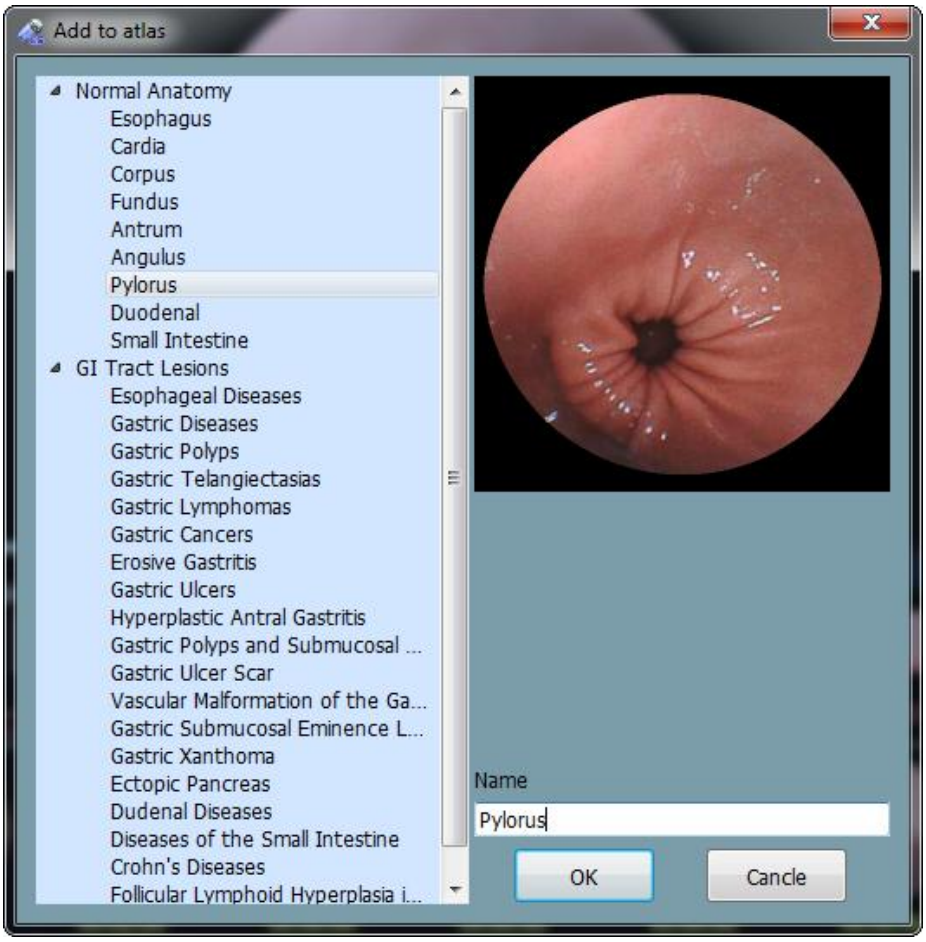


Figure 4- 100 Add to Atlas

3. Access to Image Browsing interface as shown in Figure 4- 12, click “Tool” → “Capsule endoscope atlas” to access capsule endoscope atlas interface, click 【Pylorus】 in the left column, the “Pylorus” image added in step 1-2 can be seen as shown in Figure 4- 101.

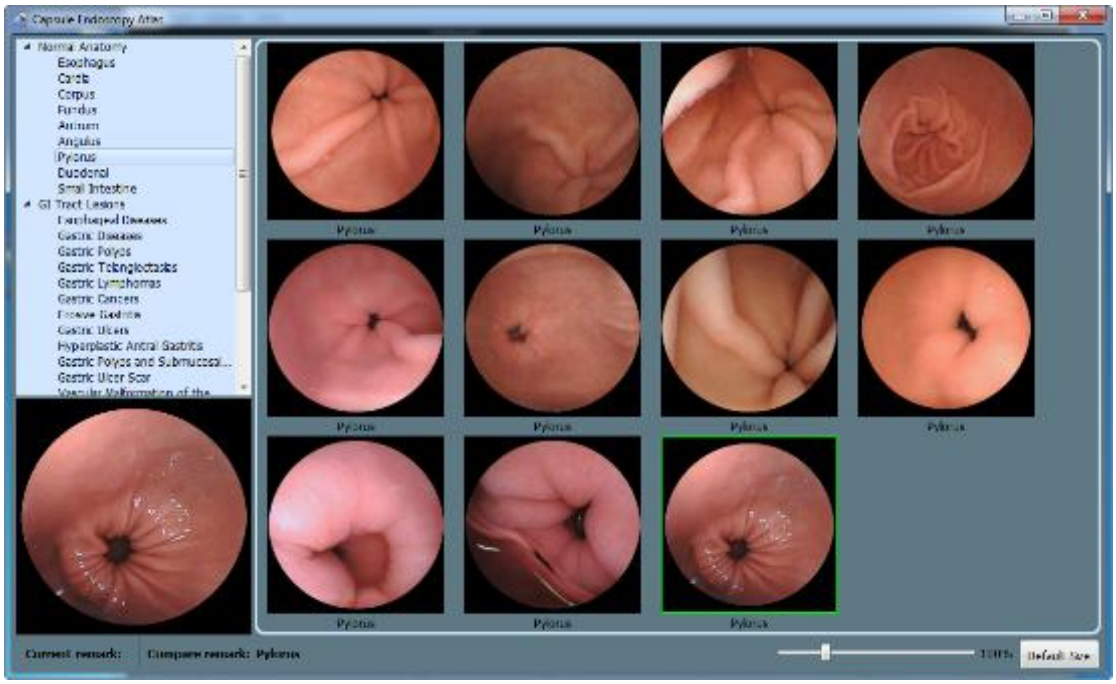


Figure 4- 101 Added Image in the Atlas

4.3.6 Report generation

1. On the Image Browsing interface as shown in Figure 4- 12, click  to access the Report Generation interface as shown in Figure 4- 102.

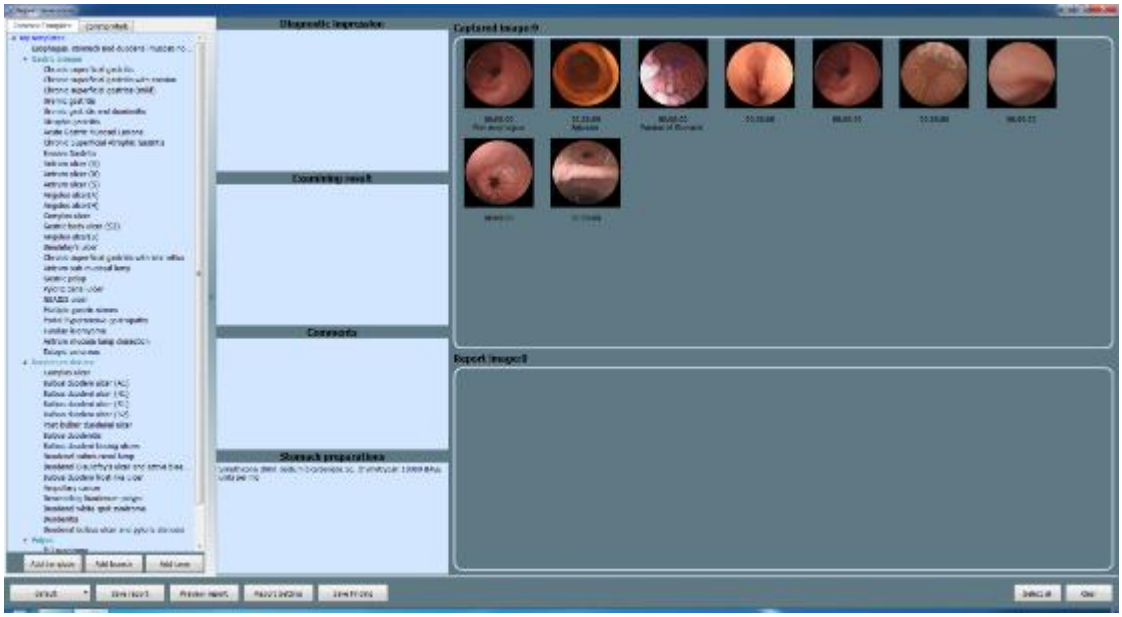


Figure 4- 102 Report Generation Interface

2. Move your mouse over a “captured image” and left click to select the image, which will then be switched to display in “report image” column, and will then be added to the printed report; click the image in “report image” to deselect it. You

can also click "Select All" or "Clear" buttons to select all or select invert, as shown in Figure 4- 103 Selected Report Image.

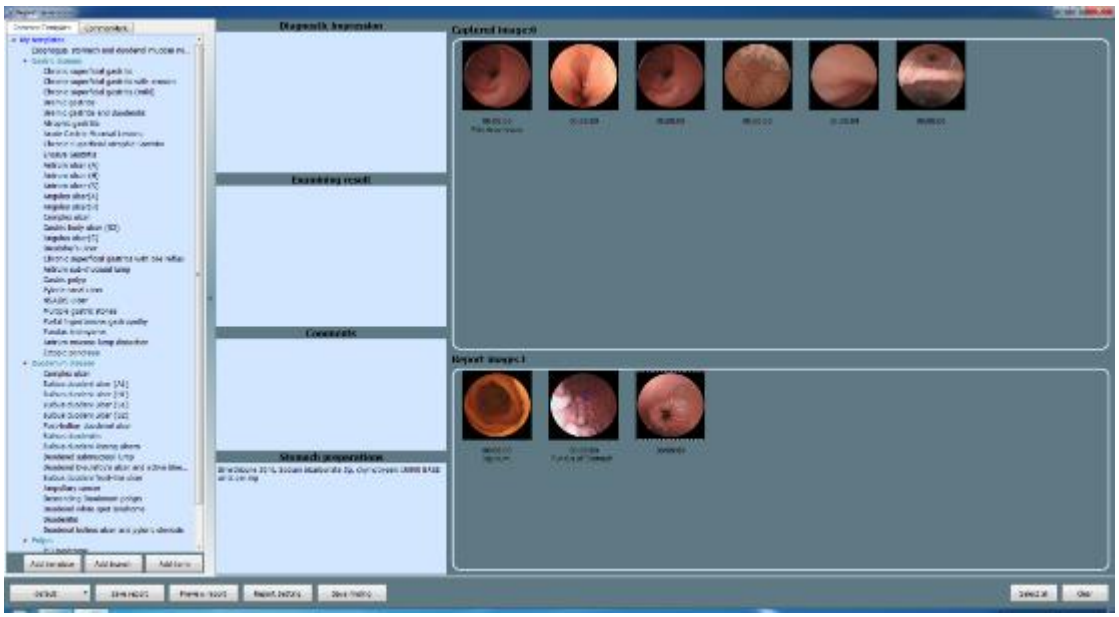


Figure 4- 103 Report Image Selection

3. Move your mouse over an image, and double click the left mouse button. You can edit image comment in the pop-up text box, as shown in Figure 4- 104 Edit Report Image Comment.

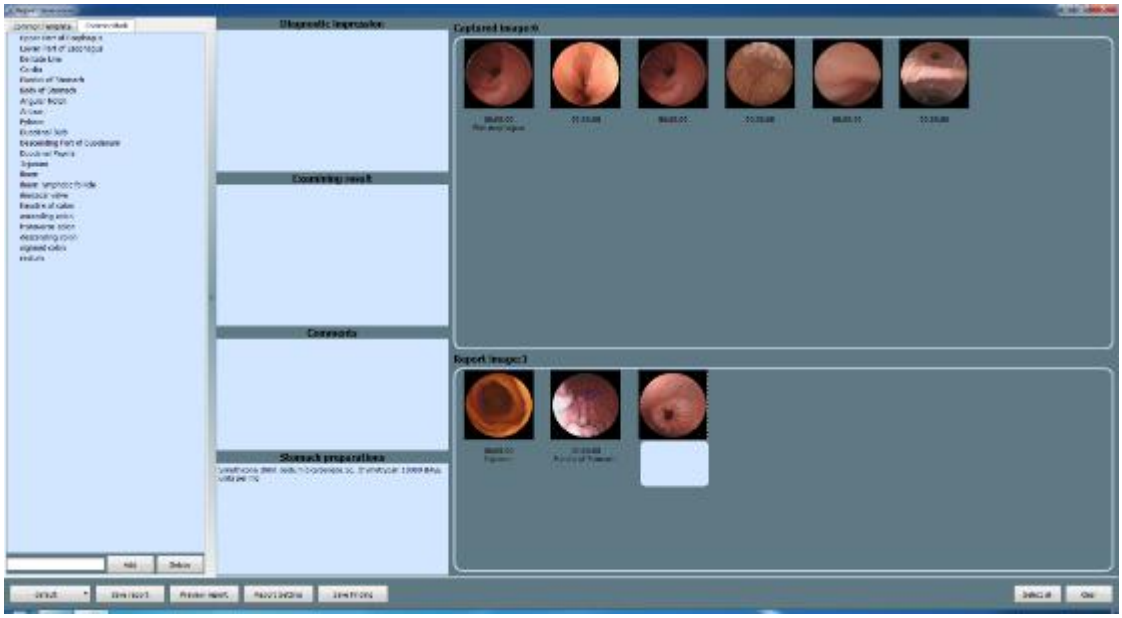


Figure 4- 104 Edit Report Image Comment

4. On the “captured image” column and “report image” column, right click the mouse button, image edit menu will be prompt out, click to access image edit interface, you can edit image like in the report browsing interface, as shown in

Figures 4- 105and Figure 4- 106.

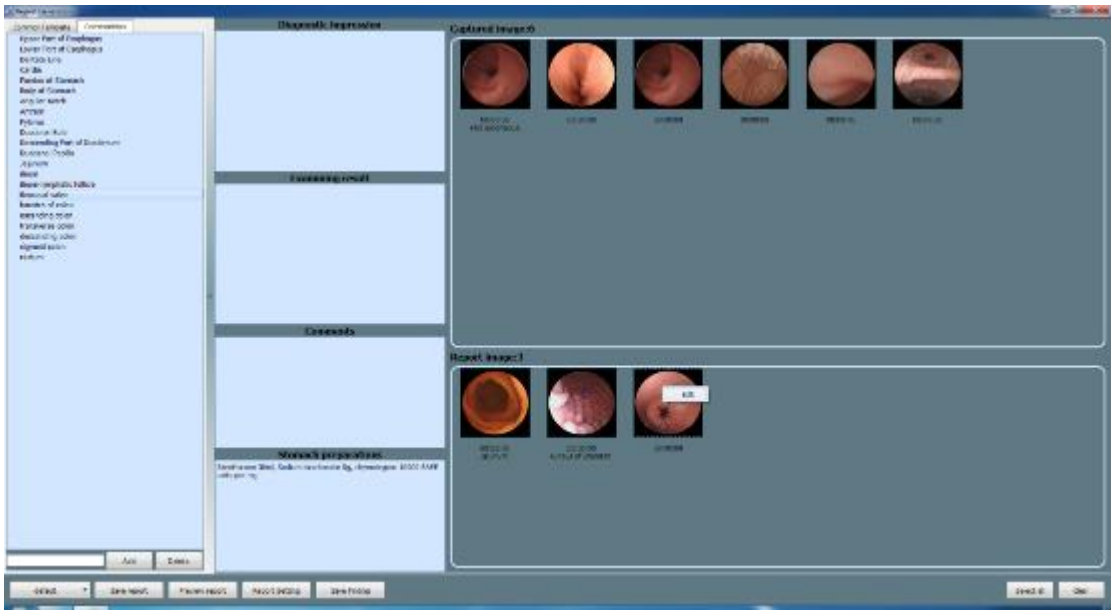


Figure 4- 105 Edit Image in the Report Interface

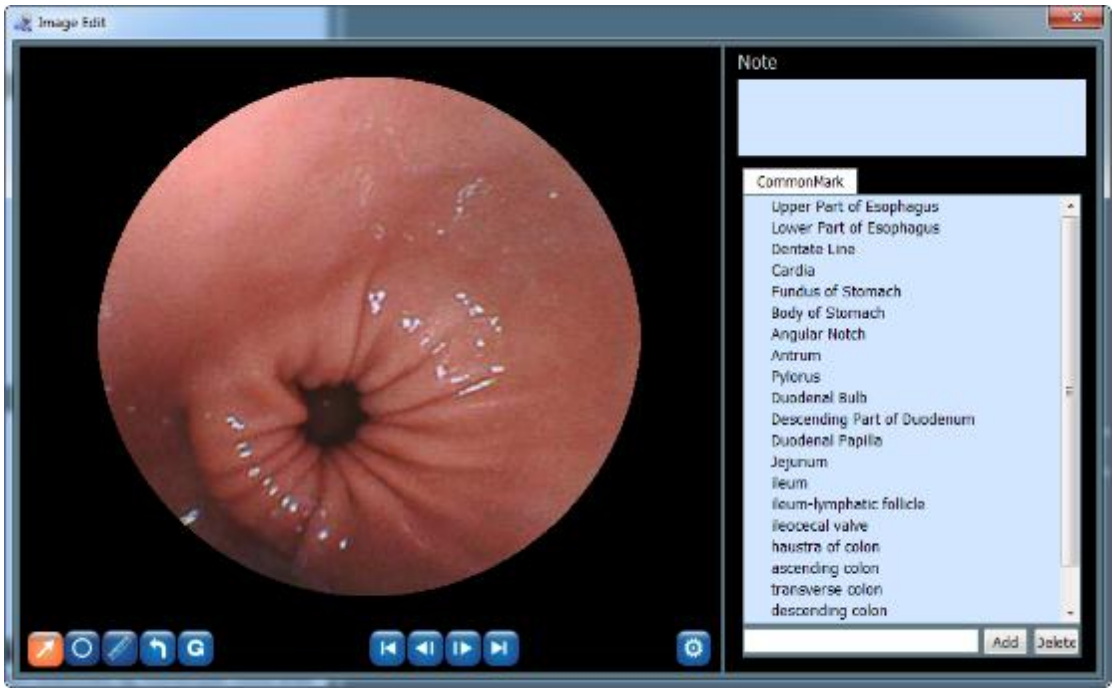
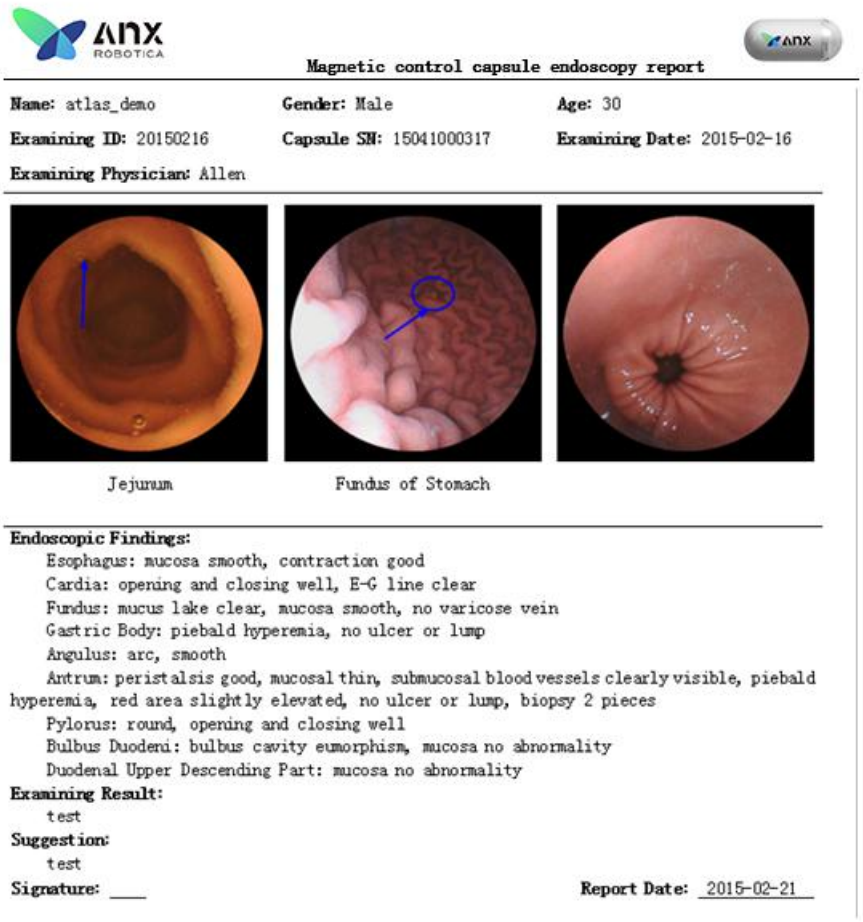


Figure 4- 106 Edit Image Interface

5. In the text box right to the Report Generation interface as shown in Figure 4- 12, input diagnosis information that will be displayed in the case report. Similar to Add Comment Interface as shown in Figure 4- 82, you can manually input or use useful expressions or comments to add diagnosis information.
6. Click input columns for diagnosis information, right click to use cancel edit, restore edit, cut, copy, paste, clear and selection all in the right-click menu for corresponding functions as shown in Figure 4- 107.

Figure 4- 107 Text Edit Functions in Mouse Right Click Button

7. Click "Print Preview" button to access the Report Preview interface as shown in Figure 4- 108, where you can preview or print a report.



Magnetic control capsule endoscopy report

Name: atlas_demo **Gender:** Male **Age:** 30

Examining ID: 20150216 **Capsule SN:** 15041000317 **Examining Date:** 2015-02-16

Examining Physician: Allen

Jejunum Fundus of Stomach

Endoscopic Findings:

Esophagus: mucosa smooth, contraction good
Cardia: opening and closing well, E-G line clear
Fundus: mucus lake clear, mucosa smooth, no varicose vein
Gastric Body: piebald hyperemia, no ulcer or lump
Angulus: arc, smooth
Antrum: peristalsis good, mucosal thin, submucosal blood vessels clearly visible, piebald hyperemia, red area slightly elevated, no ulcer or lump, biopsy 2 pieces
Pylorus: round, opening and closing well
Bulbus Duodeni: bulbus cavity eumorphism, mucosa no abnormality
Duodenal Upper Descending Part: mucosa no abnormality

Examining Result:

test

Suggestion:

test

Signature: ____ **Report Date:** 2015-02-21

Figure 4- 108 Report Preview Interface

8. In the Report Generation interface as shown in Figure 4-102, click "Save Report" to access the Save Report interface as shown in Figure 4-109. The software saves a report in *.pdf format by default, you may also choose to save in *.doc format, click “Save” to save the report. After saving, you will be directed to Save Successfully interface as shown in Figure 4-110. Click "OK" to complete report saving. Click "Open" to open the report.

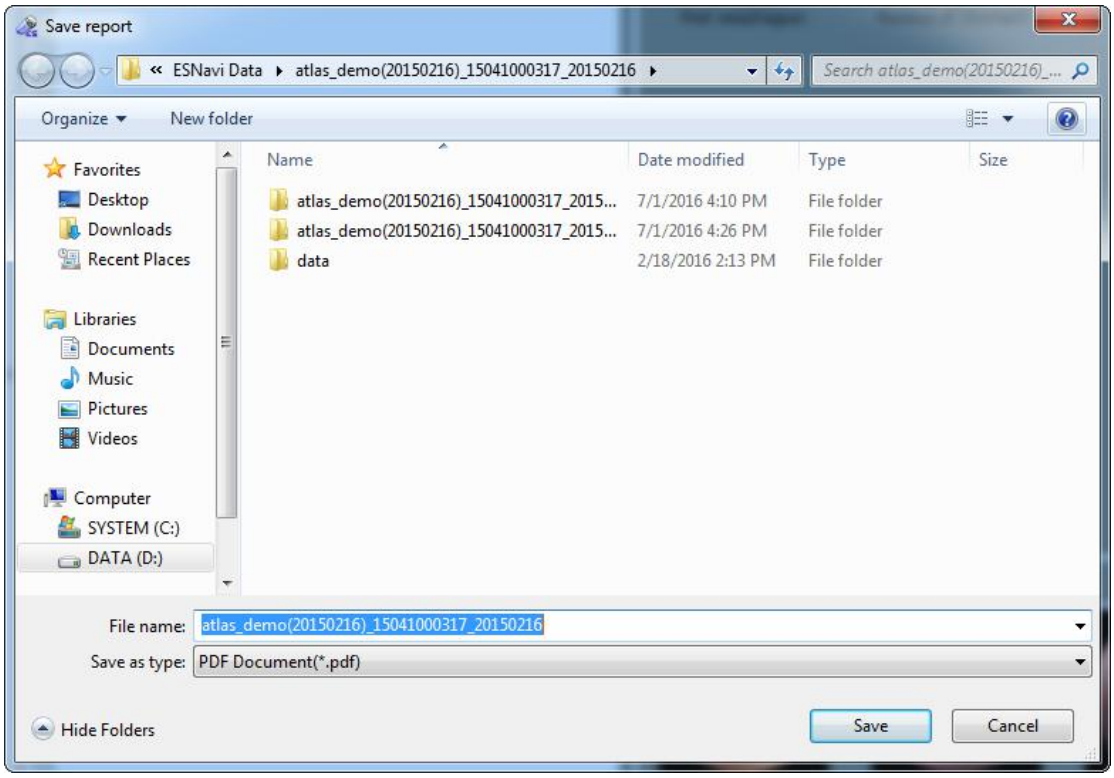


Figure 4-109 Save Report Interface

Figure 4-110 Save Successfully Interface

9. In the Image Browsing interface as shown in Figure 4-12, click "File" →"Save finding" to access the Save finding interface as shown in Figure 4-111. The discovery file saves following information: commented image mark and textual information; whether to add the commented image to a report; diagnosis information in the report. Next time you open the video, you can click "File"→"Open Finding" to load it again.

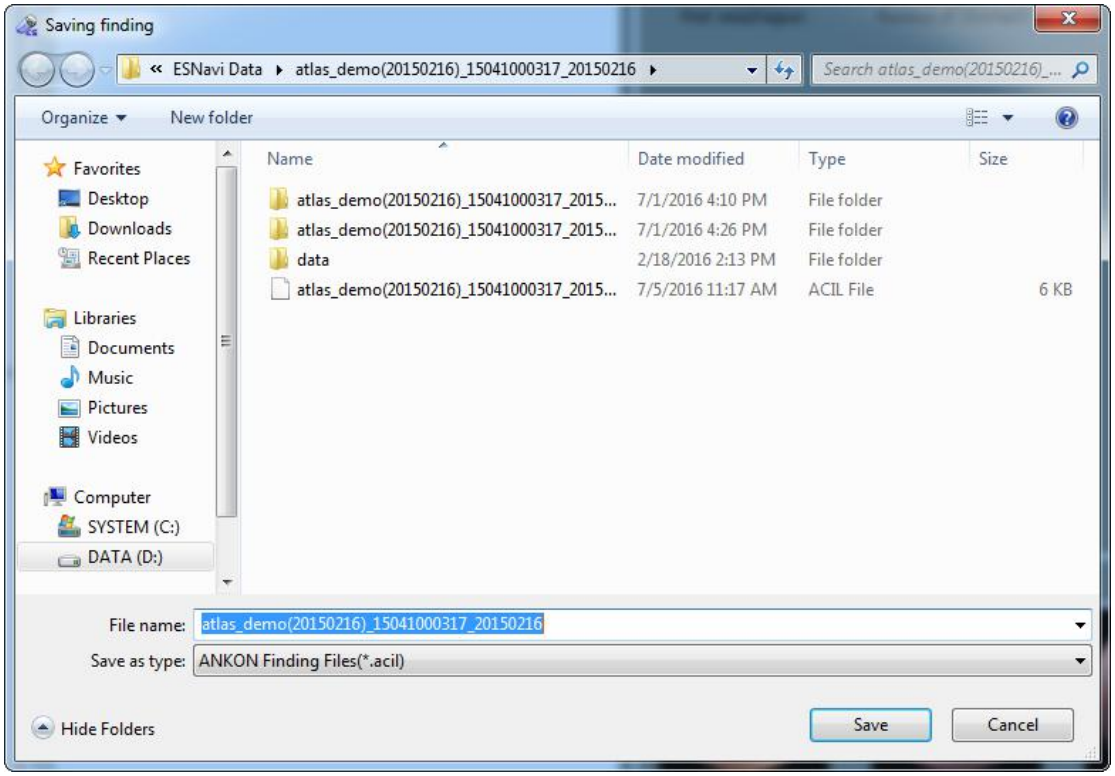


Figure 4- 111 Save Finding Interface

10. In the Report Generation interface as shown in Figure 4- 102, click “Report Setting” button to access Report Setting interface as shown in Figure 4- 112. In the Report Setting interface, you can set image zoom scale in the report, image quantity to be displayed in each row, image sort order (to be sorted by image comments and add “Sequence No #” in front of the image, for example: 1#Gastric body), font size of the image comments, whether to print image background and to add patient information in the image. Click “OK” to finish and save report setting, click “Cancel” to cancel the modifications.

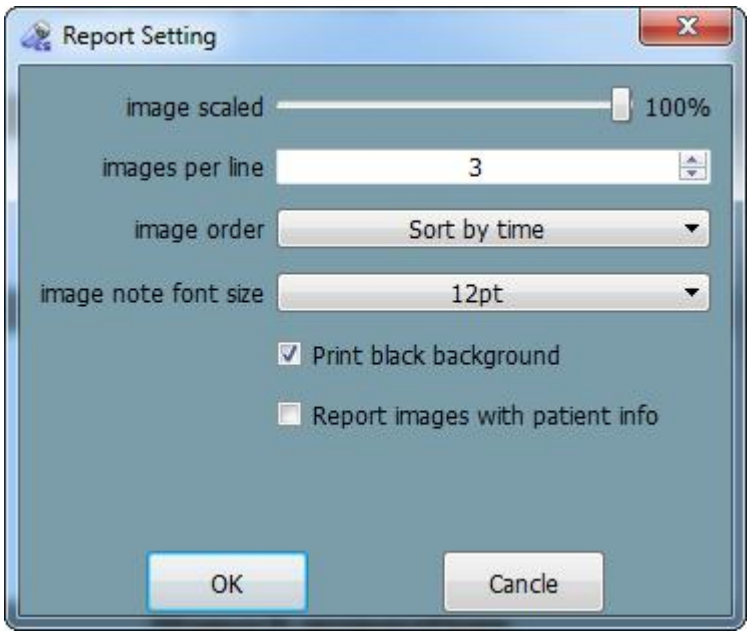


Figure 4- 112 Report Setting interface

11. In the Report Generation interface as shown in Figure 4- 102, click “Common Template” tab, double click the template in the Common Template tab, the template information can be displayed in the input box, users can also add their own template as needed, click “Add template” button to access template name input interface as shown in Figure 4- 113. Users can also add template names as needed. After clicking “Add template” button, click “Add branch” button to access Branch Name Input interface as shown in Figure 4- 114. Users can also add branch name as needed. After inputting visualization results corresponding to the template in the visualization result input box, click “Add node” button to access Node Input interface as shown in Figure 4- 115. Users can add term names as needed, click “OK” to add the node name and the corresponding visualization result to the template.

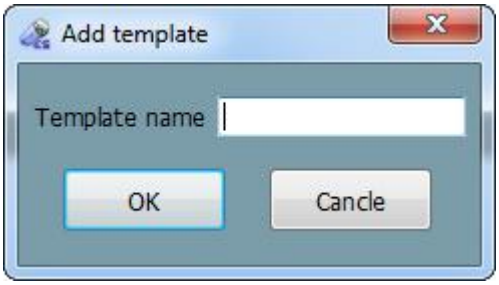


Figure 4- 113 Template Name Input interface

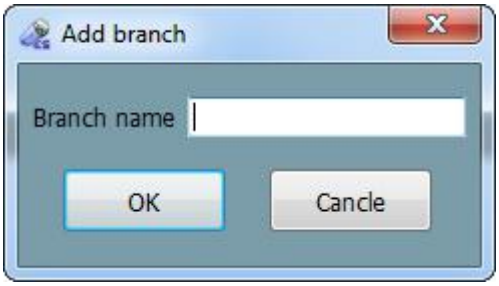


Figure 4- 114 Branch Name Input interface

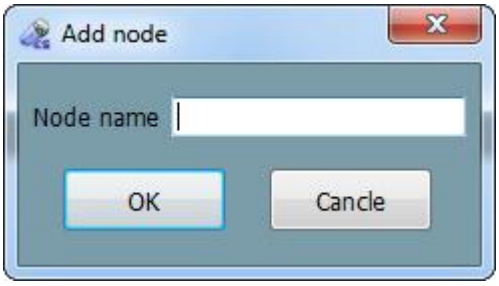


Figure 4- 115 Node Name Input interface

12. In the Report Generation interface as shown in Figure 4- 102, click “Common Mark” tab to open Frequently-used Comment interface, double click on the frequently used comments to insert the said comments at the position of the mouse cursor, after inputting comments in the input box below, click “Add” button to add frequently-used comments. Click to select a frequently-used comment and click "Delete" button to delete it.

4.3.7 Case management

1. In the Image Browsing interface as shown in Figure 4- 12, click "Tool" →"Case Management" to access Case Management interface as shown in Figure 4- 116.

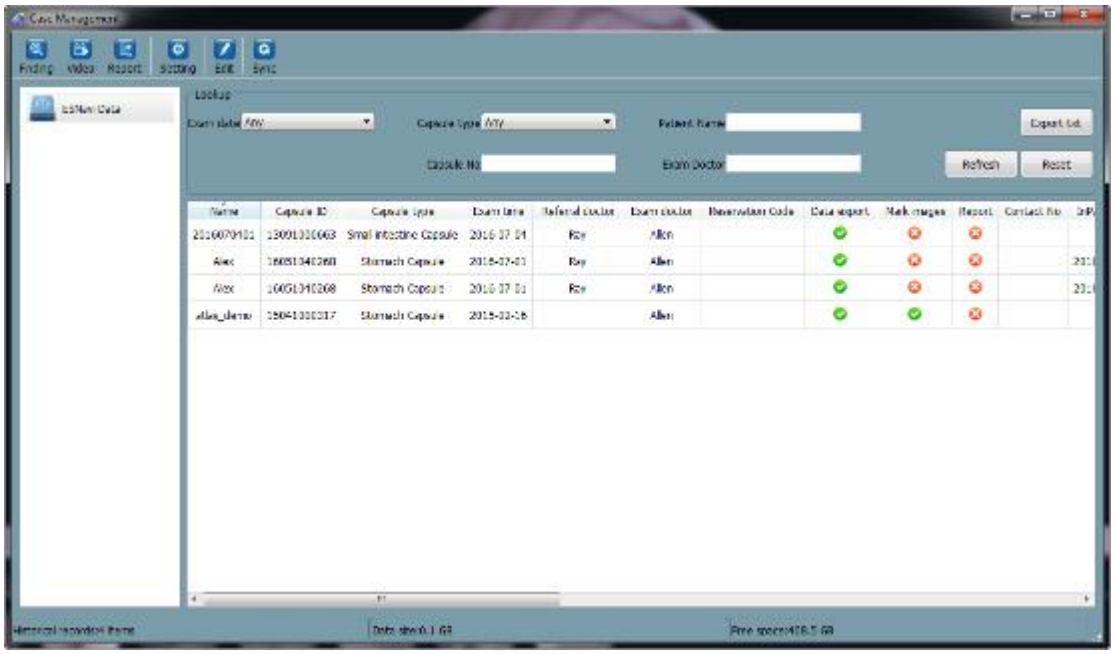


Figure 4- 116 Case Management Interface

2. The program will automatically add the data export path when access the Case path Management interface as shown in Figure 4- 116 for the first time. Click  to access the Add Case Data Storage Path interface as shown in Figure 4- 117. You can click "Add", "Delete" or "Rename" button to add, delete or rename the case data storage path. The software can automatically add mobile hard-disc or CD/DVD root directory path. Following this operation, click "Save" button to save settings, or click "Cancel" to cancel settings.

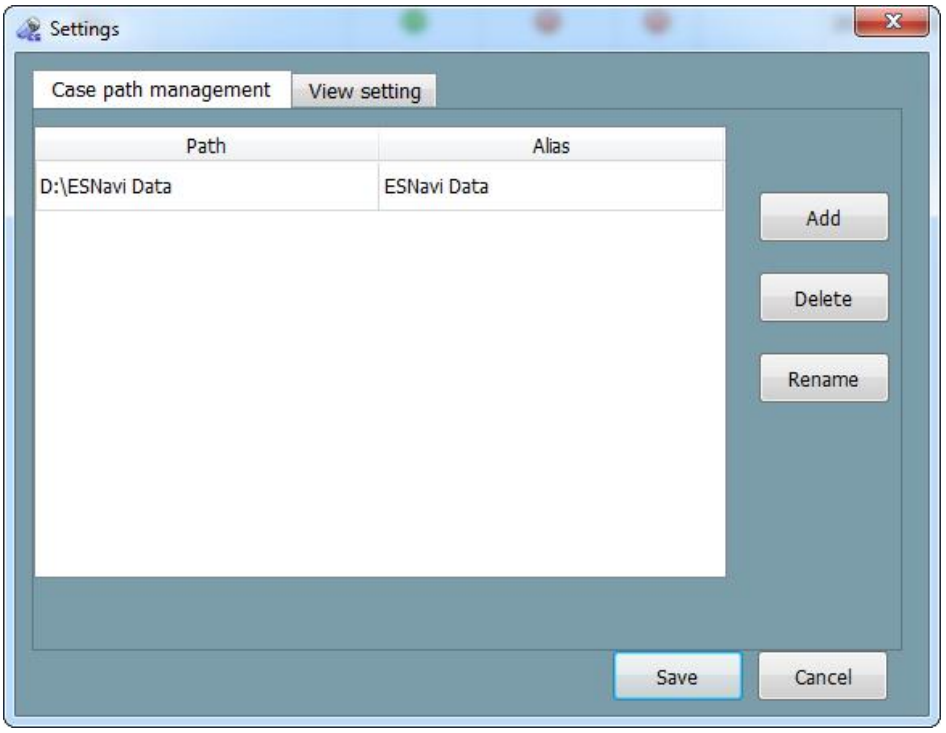


Figure 4- 117 Add Case Data Storage Path Interface

3. The software will automatically search two levels of directory under the case data storage path, and display the finding patient information in the case list. In the Add Case Data Storage Path interface as shown in Figure 4- 117, click "View Setting" to access View Setting interface as shown in Figure 4- 118. You can drag your mouse or click "Move to Left" or "Move to Right" button to display case data in Available Column or Used Column, among which the Available Column will not display case data, while the Used Column displays case data in a sorted order.

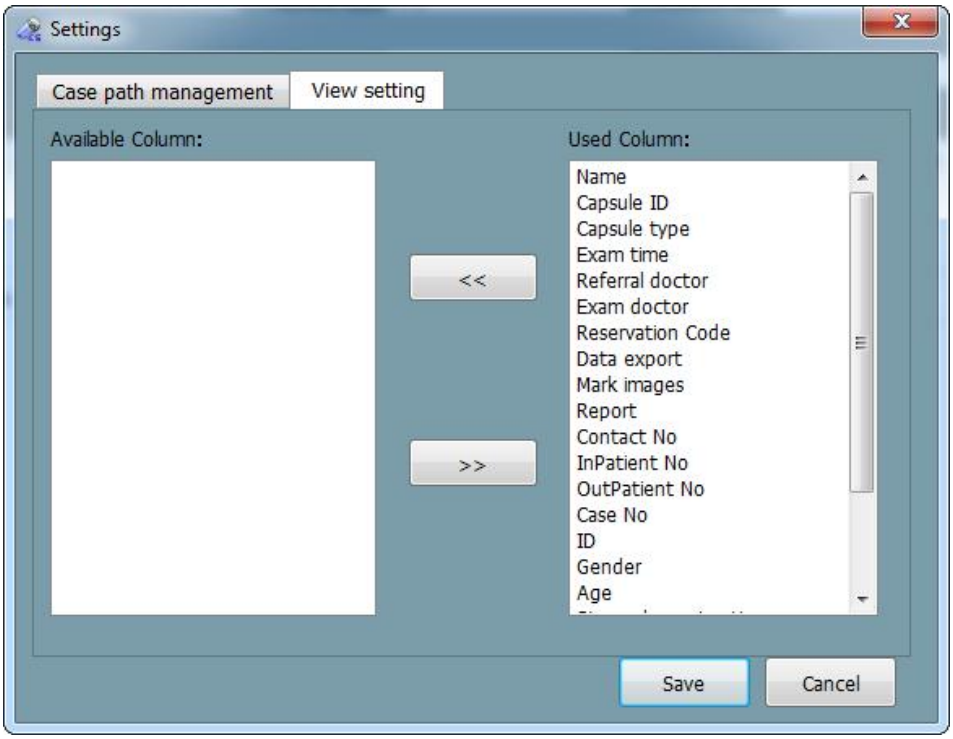


Figure 4- 118 View Setting Interface

4. In the Case Management interface as shown in Figure 4- 116, select a case and click to open the case video and load the finding file; Click to open the case video; click to open the recently saved report; click to access the Patient Information Editing interface as shown in Figure 4- 119, where you can change case data. In the Image Browsing interface as shown in Figure 4- 12, open the video file and click "File" → "Edit Patient Information" to access the Case Editing interface.

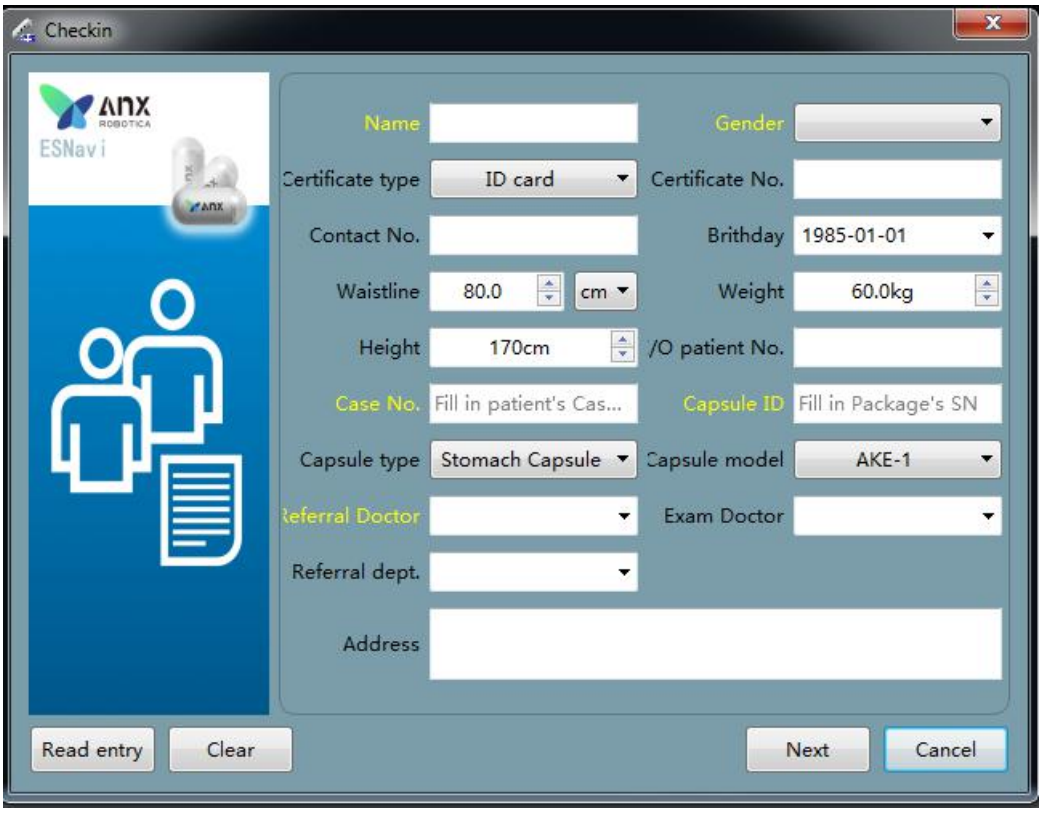


Figure 4- 119 Patient Information Editing Interface

5. From the "Query" toolbar, users can filter cases by 5 conditions like Examination Date, Capsule Type, Capsule No., Patient Name and Referral Physician. Click "Refresh" button to refresh cases; click "Reset" button to reset filter conditions and refresh cases.
6. Click “Export as .txt” button, the software will prompt out dialog box to select save path and file name as shown in Figure 4- 120:

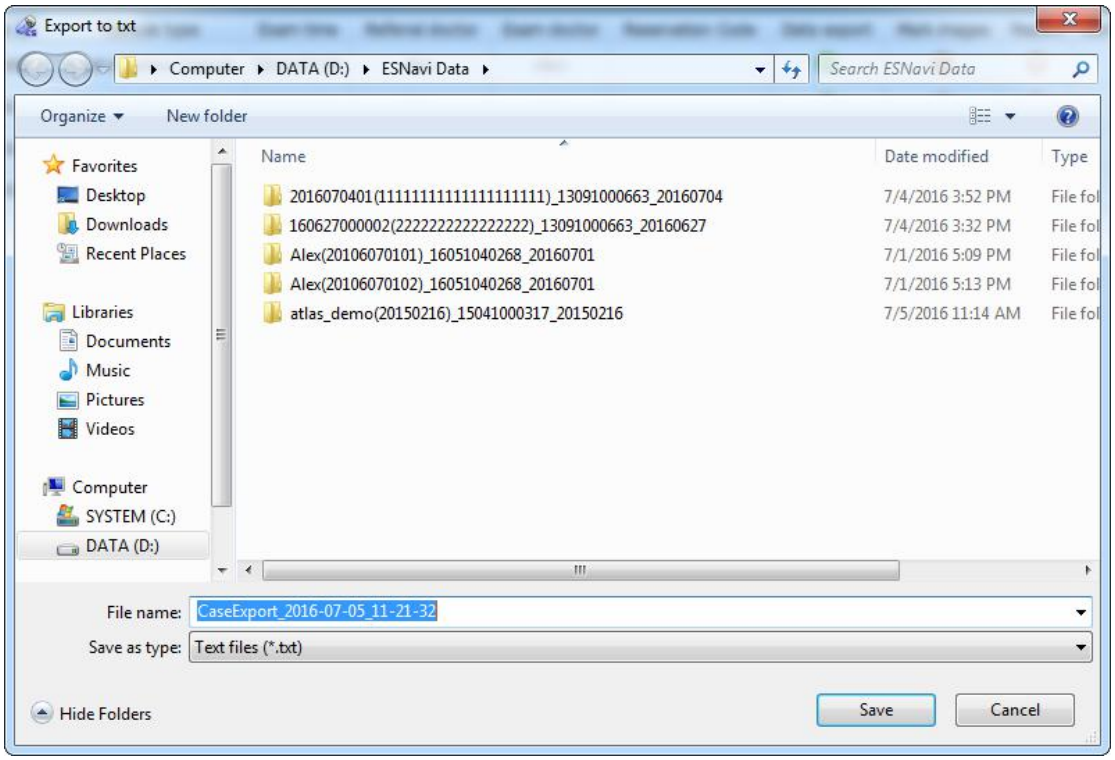


Figure 4- 120 select save path

After selecting saving path and filling in file name, click “Save” button to export all the reports in current report list as .txt file.

4.3.8 Capsule Endoscope Atlas

1. In the Image Browsing interface as shown in Figure 4- 12, open the video file, double click 1 image in the thumbnail area, click “Tool”→ “Capsule Endoscope Atlas” to access Capsule Endoscope Atlas Interface as shown in Figure 4- 121.

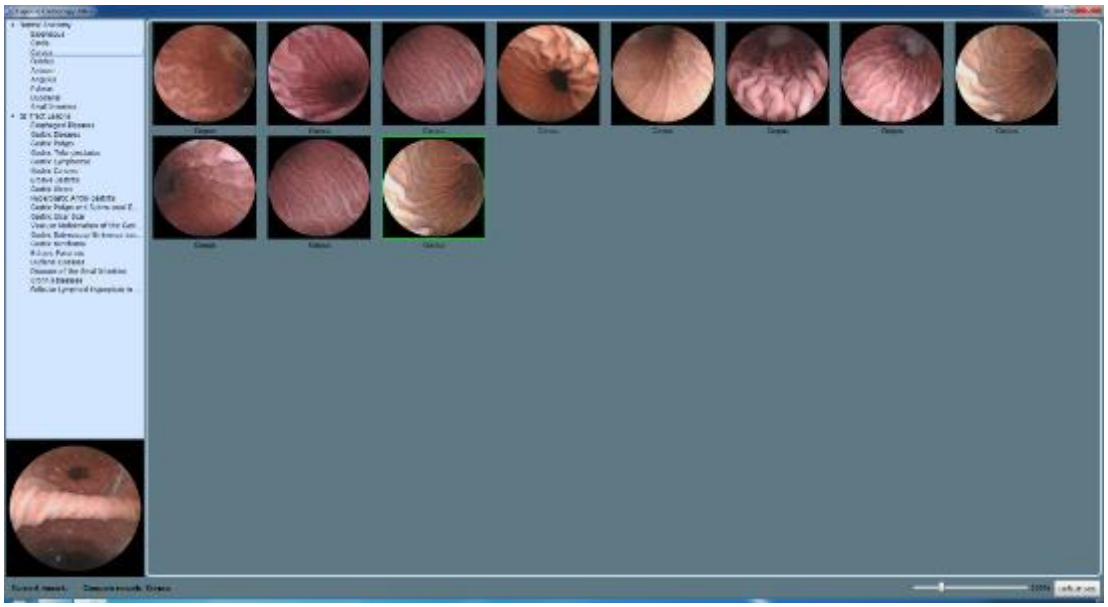


Figure 4- 121 Capsule Endoscope Atlas Interface

2. Click normal anatomy image or original images of typical lesions in stomach, duodenum, and small bowel, click stomach landmarks and lesion name to be compared, you can see corresponding normal anatomy image or lesion images as shown in Figure 4- 122.

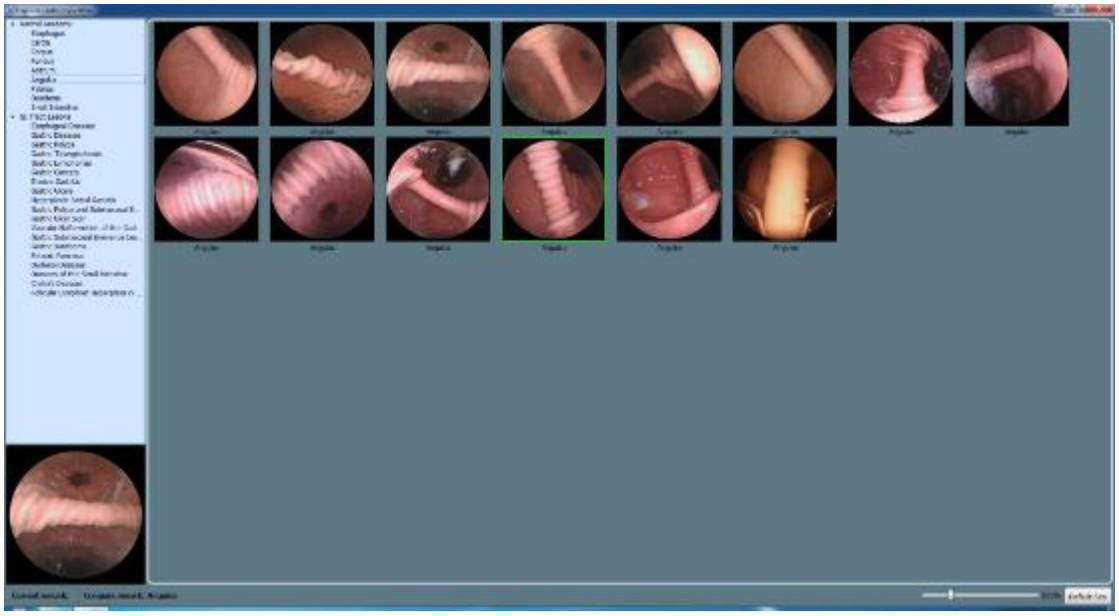


Figure 4- 122 Normal Anatomy Images of Angulus

3. In the atlas image to be compared, right click and select comparison menu to open Comparison Interface and compare the selected visualization image with atlas image as shown in Figure 4- 123 and Figure 4- 124. The image size can be scaled by scrolling the mouse in the Comparison Interface.

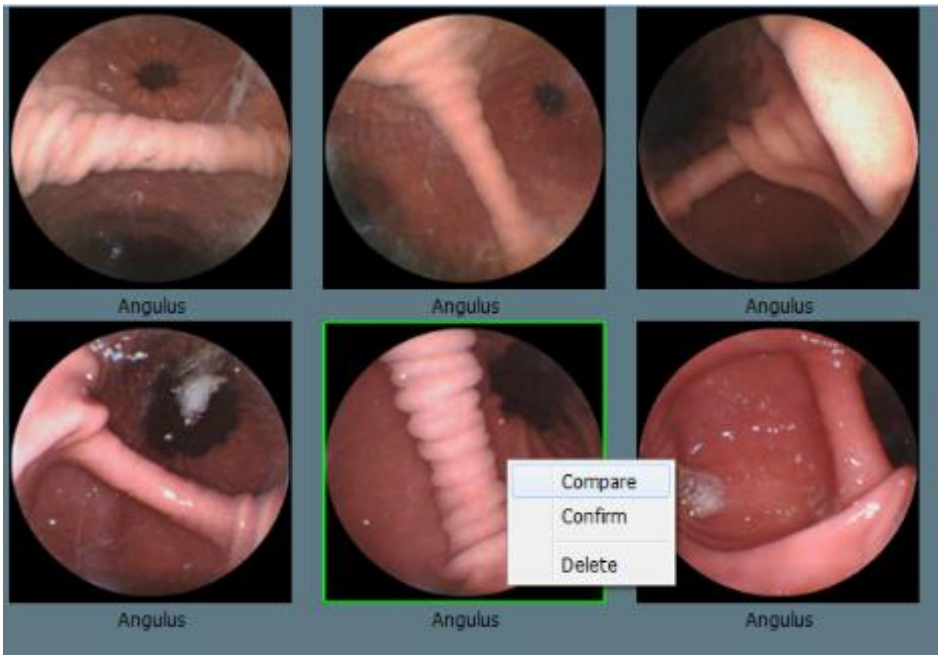


Figure 4- 123 Compare the Visualization Image with Atlas Image

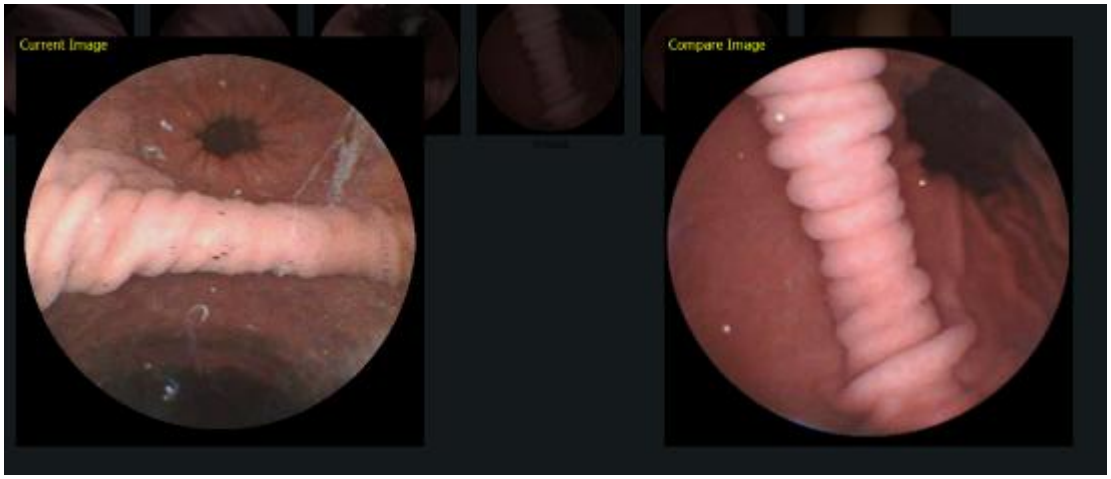


Figure 4- 124 Comparison Interface

4. After comparison, if the location or lesion of the visualization image is confirmed consistent with the compared atlas image, click the green tick in the upper right corner of the Comparison Interface, or right click “Confirm” button in the said atlas image to close it, the software will automatically close the atlas image, and the name of the said atlas image will be added as comments of the visualization image as shown in Figures 4- 125 and Figure 4- 126.

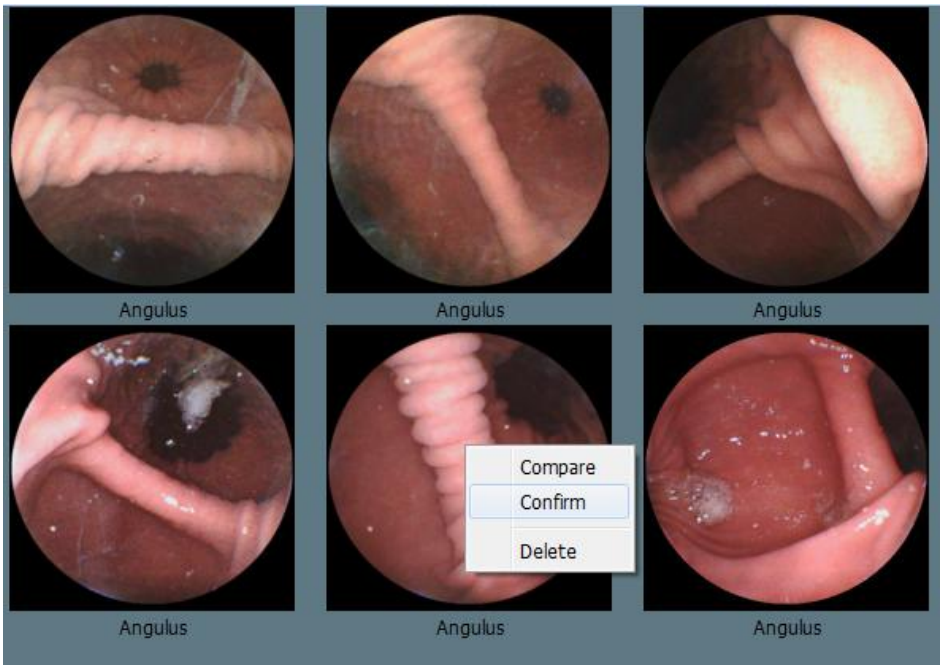


Figure 4- 125 Confirm the Comparison Result

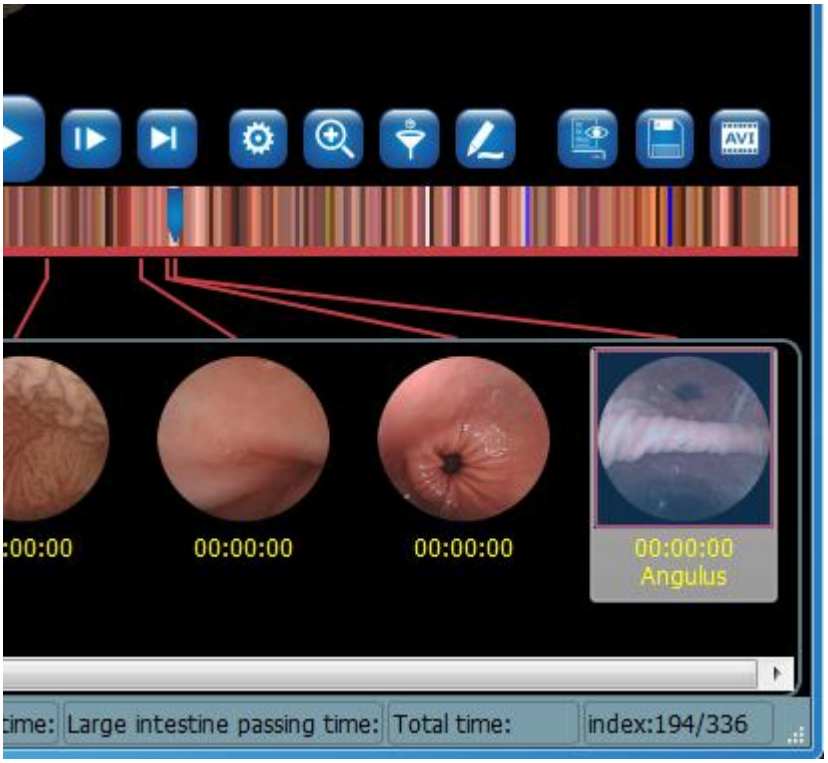


Figure 4- 126 The Name of the Atlas Image added as Comments of the Visualization Image

4.3.9 Help

1. In the Image Browsing interface as shown in Figure 4- 12, click "Help"→"About" to access the Software Information interface as shown in Figure 4- 127. The interface describes full name, abbreviation, version No. and ownership of the software.

Figure 4- 127 Software Information Interface

2. In the Image Browsing interface as shown in Figure 4- 12, click "Help" → "Instruction" to access the Instruction interface.

4.3.10 Software Configuration File Backup and Restore

1. The software is equipped with configuration file backup and restore function, you can automatically or manually backup configuration files, backup files are capsule.ini, ESCtrlCofig.xml, ESCtrlConfig1.xml, remarks.xml, words.xml and report templates, and backup path is D:\ankonConfigBackup\yyyymmdd_hhmmss. You can manually restore the backup configuration files.
2. During boot up, the software will check whether there are backup configuration files of the day, if none is found, it will automatically backup once.
3. Click "Help" → "Backup Configuration Files" to manually backup the configuration file, if backup is successful, the backup successful Prompt-box will pop up as shown in Figures 4- 128 and Figure 4- 129:

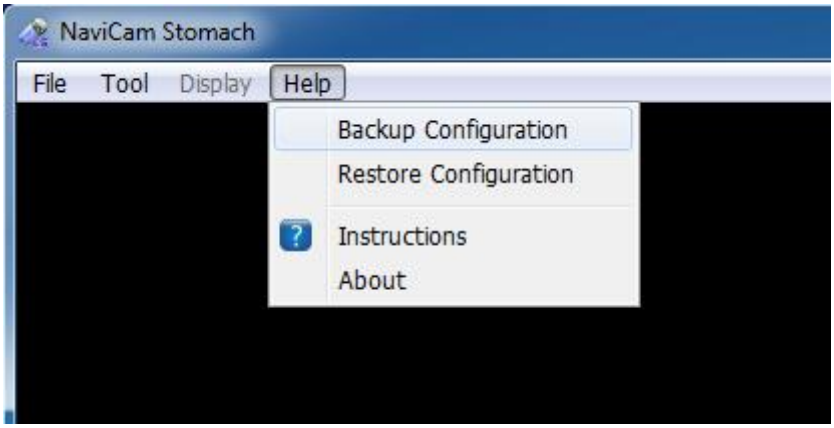


Figure 4- 128 Manual Backup Configuration Files

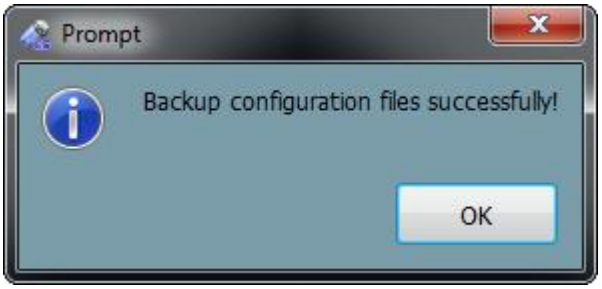


Figure 4- 129 Manual Backup Configuration Files Successfully

4. Click "Help" → "Restore Configuration Files" to open restore configuration files selection box, select the file folders where the configuration files to be restored are located, click “Confirm”, in the pop up restore confirmation box click “Confirm” to restore the said backup configuration files, after successful restoration, the restore successful Prompt-box will pop up as shown in Figure 4- 130, Figure 4- 131, Figure 4- 132 and Figure 4- 133.

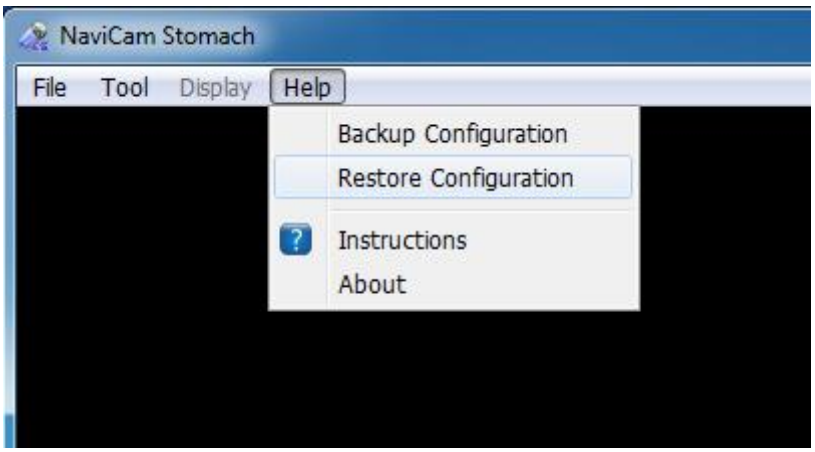


Figure 4- 130 Manually Restore Configuration Files

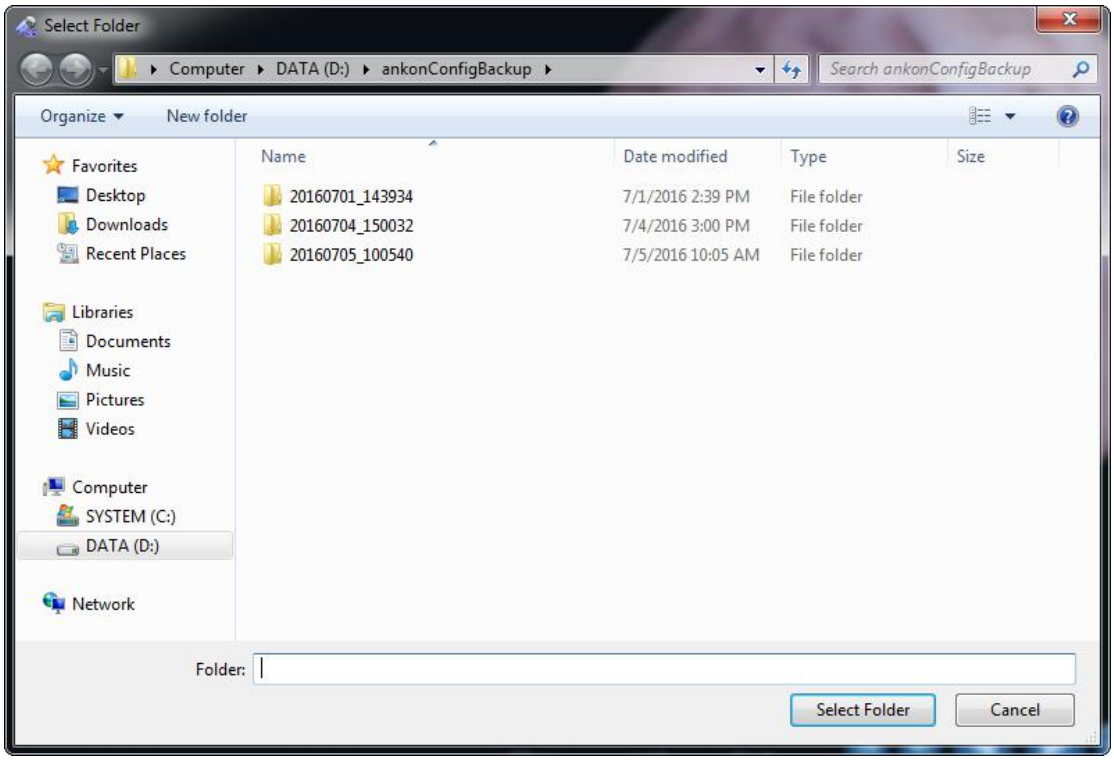


Figure 4- 131 Select Configuration Files to be restored

Figure 4- 132 Confirm to Restore Configuration Files

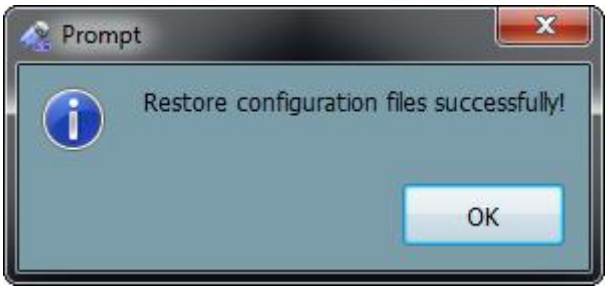


Figure 4- 133 Restore Configuration Files Successfully

4.3.11 Software Exit

1. In the Image Browsing interface as shown in Figure 4- 12, click "File" →"Exit" or click the  button on the upper right corner of the interface, and on the

pop-up Exit interface as shown in Figure 4- 134, click "Yes" to exit or click "No" to cancel exit operation.

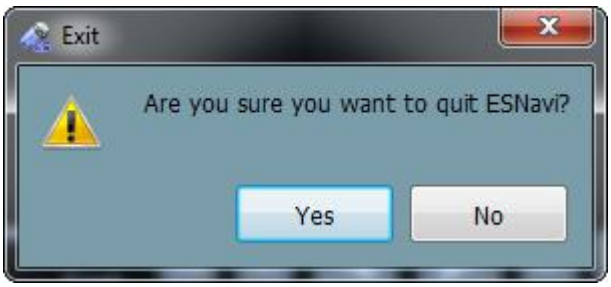


Figure 4- 134 Exit Interface

2. If a case report is changed before exit, you will be prompted with the Save Findings interface as shown in Figure 4- 135, where you can click "Yes" to save findings or click "No" to exit without saving findings; Click "Cancel" to cancel exit operation.

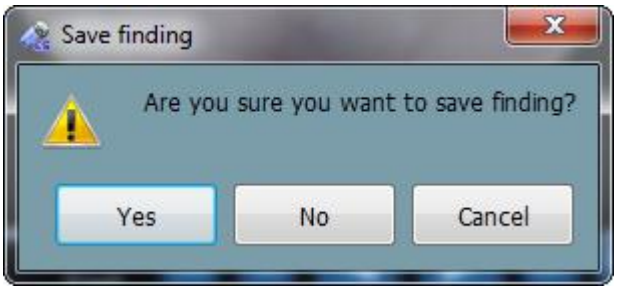


Figure 4- 135 Save Findings Interface

CHAPTER 5: USAGE OF CAPSULE

The capsule is packed in a sealed package. You can directly take the capsule out and activate it as shown in the following figures. The protective cover is used as a fixture and protects the capsule, facilitating its storage and handling before operation.

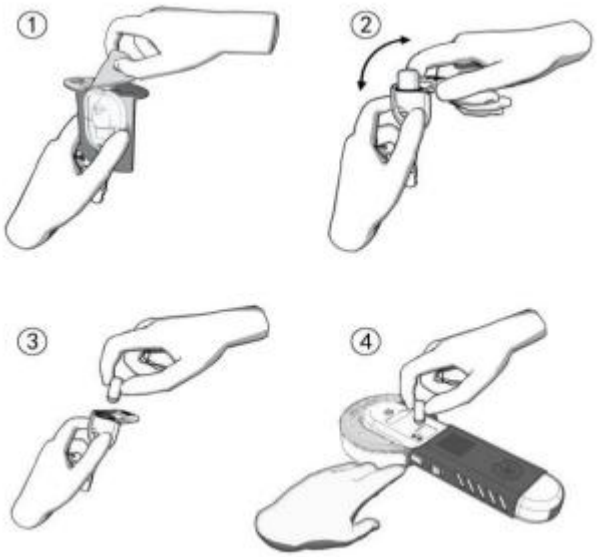


Figure 5- 1 Schematic Diagram of Capsule Activation for Using

1. Tear off the paper cover of the package box.
2. Remove the capsule with fixture from the cup and remove the upper part.
3. Remove the capsule.
4. Activate the capsule with light irradiated from the Locator.

Warning

The capsule must be removed and activated before ingestion and operation.
The capsule should only be stored in the original package before ingestion.
Do not use a capsule if package is damaged.

CHAPTER 6: USAGE OF DATA RECORDER

6.1 AKR-1 Data Recorder

6.1.1 Installation and Usage

The Data Recorder is equipped with 14 sensor arrays, as presented in Figure 6- 1.

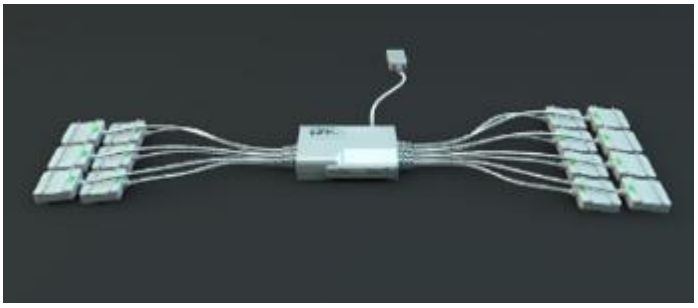


Figure 6- 1 Data Recorder (AKR-1)

When in use, the Data Recorder and sensor arrays are embedded into the corresponding examination cloth as shown in Figure 6- 2. As tested, the working temperature of the data recorder can reach 42℃ tested under 40℃ ambient temperature. Since the data recorder does not contact patient skin directly, the temperature will not cause burn or other hazard to patients and operators, and the contact duration can be longer than 10 minutes.

Figure 6- 2 Placement of Sensors

6.1.2 Operation Instruction

Related marks and position of power switch, USB interface, LED, keys on the Data Recorder are shown in Figure 6-3.

Figure 6-3 Data Recorder Operation Manual

①: Alarm indicator, yellow;
②: Run indicator, green;
③④⑤: Battery capacity indicators;
⑥: Charge indicator, white;
⑦: Power switch;
⑧: USB interface to connect computer;
⑨: Charging port.

Hold down the power switch without releasing until all the five LEDs (marked as ①②③④⑤ in Figure 6-3) are lit up to power on the Data Recorder normally. Click the related button in the ESNavi to power the Data Recorder off. If the Data Recorder is not connected to the computer via USB, and therefore no capsule information is detected for a consecutive 15 minutes, it will automatically power off to save energy. If the yellow LED alarm indicator (marked as ① in Figure 6-3 with word "alarm" under it) is always on, it indicates that no capsule is detected. If on/off continues flashing, it indicates that the capsule is present, however the upper-level software has not yet issued a command to let the capsule capture images. The green LED run indicator (marked as ② in Figure 6-3 with word "run" under it) will be lit up once it receives the image information from the capsule and off again quickly; it will light up again once it receives the next image information and then off again. The received image information captured by the capsule will also be marked accordingly.
The green LED battery capacity indicators (marked as ③④⑤ in Figure 6-3, with battery capacity icon under it, three lattices, two lattices and one lattice specifically)

indicate current battery capacity. It is 90% when ③④⑤LEDs are all lit up, more than 70% when ④⑤ LEDs are lit up, and 40% when ⑤ LED is lit up. If only ⑤ LED is on/off flashing, the remaining battery capacity is very limited. If the Data Recorder is powered on and being charged, these three LEDs will be on and off flashing in a cycle manner. If the white LED charge indicator (marked as in ⑥ in Figure 6- 3) keeps lighting up, it indicates that it is under charging (it will be lit up once it is charged regardless whether the Data Recorder is powered on). The white LED will automatically turn off when fully charged.

Warning

The Data Recorder should be charged only with provided charger.
Charging can only be performed by the physician/operator. Patients shall not have access to the adaptor.
The USB interface should only be connected to the PC of console.

6.2 Usage of Locator

6.2.1 Operation Panel

Figure 7-1 shows functional keys and indicators of the Locator.

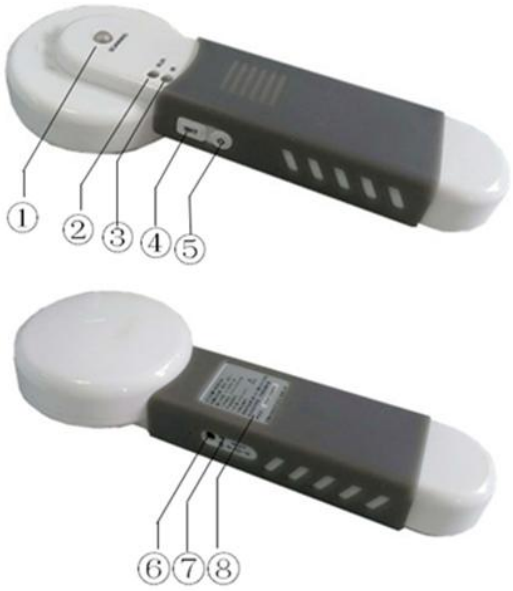


Figure 7-1 Operation Panel

①: Scanning indicator, Yellow;
②: Working indicator, Green;
③: Infrared light source to activate capsule;
④: Keys;
⑤: Power Switch;
⑥: Charging port;
⑦: Power switch indicator, white;
⑧: Label plate.

6.3 Usage

6.3.1 Turn-on the Capsule

Before starting the Capsule, press the "Power Switch" to activate the Locator. Once the Locator is on, the working indicator will flash. Place the Capsule front case opposite the start infrared light source of the Capsule. Press and hold the "INIT Button" to align the open position of the Capsule. The Capsule LED will start blinking after the Capsule is opened normally. The Capsule is activated as shown in Figure 7-2.

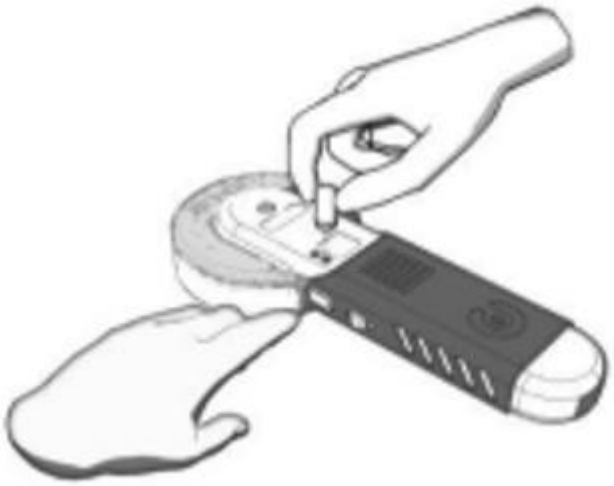


Figure 7-2 Schematic Diagram of turning-on the Capsule

6.3.2 Locate the Capsule

To detect the location of the capsule in a patient using the Locator, perform the following steps:

1. Turn on: Hold the Locator upright, start the Locator by pressing "Power Switch" in the open space without metal objects nearby. Once the Locator has started, the working indicator will flash at a frequency of once per second, and the scanning indicator will be off.
2. Locating: Use the Locator to move gently in the detection area. Once the Locator is near the capsule, the scanning indicator will light up. When the scanning indicator stays on, it indicates that the capsule is right below the scanning

indicator.

6.3.3 Turn-off the Locator

Press and hold the “Power Switch” for more than 5 seconds and the Locator will shut down. All the indicators will be off after the shutdown. The Locator will be automatically shuts down after 10 minutes without any operation.

6.3.4 Charge

The Locator uses a battery to supply power. When the battery voltage is low, the flashing frequency of the working indicator will get lower. When the flashing changes to one time per three seconds, The Locator needs to charge through the power port. During the charging process, the charging indicator is always on, and is automatically turned off after being fully charged.

Warning

The Locator can only be charged using a charger that comes with the unit. Charging can only be performed by the physician/operator. Patients shall not have access to the adaptor.

CHAPTER 7: INSTALLATION AND TRAINING

7.1 Requirements

The System requires the following space, power and environment conditions before installation.

Warning

Installation, handling and adjustment of the System should be completed by a technician assigned and well-trained.

7.1.1 Space Requirements

Ensure required space for maintenance and servicing. Take into account heat dissipation of the System. The installation requirements are:

- Area coverage: 3 m × 4 m
- Floor height: 2.5m or above
- Flat solid ground
- Determine the spatial line in accordance with the requirements of Figure 8- 1. It is advised to put warning tape at the spatial line but refer to your facility specific requirements.

Please refer to the following schematic diagram:

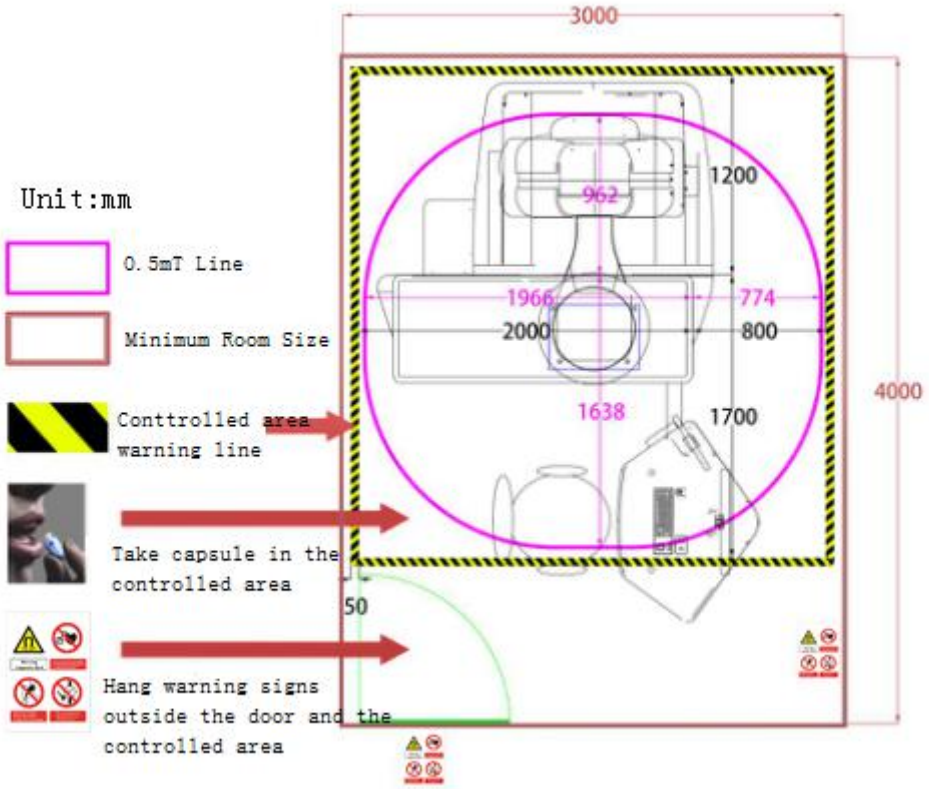


Figure 8- 1 Equipment Installation Schematic Diagram

Warning

Irrelevant personnel should not enter the spatial line
Do not position the device so that it is difficult to operate the disconnection device.

7.1.2 Power Requirements for the controller (model: NaviEC-1000)

	Voltage	Frequency	Input power	Fuse
Equipment	a.c. 120VAC	60 Hz	550 VA	F 6A 125VAC

Warning

The equipment must be properly grounded
The maintenance personnel should only use specified fuse
Make sure that the input voltage meets the equipment requirements

7.1.3 Working Condition Requirements

- Ambient temperature: 5 degrees Celsius~40 degrees Celsius

- Relative humidity: ≤80%
- Air pressure: 86 kPa~106 kPa
- The environment should be free of dust, with no mechanical vibration, no significant noise nearby and be free of power interference.
- Within 5m area coverage of the installed equipment, there should be no magnetic resonance imaging equipment or strong electromagnetic interference

7.2 Installation and Adjustment Instruction

Installation, movement or modification of the location of the System should be completed by a qualified maintenance technician or by AnX Robotica Corp personnel.

Warning

Do not move the equipment without authorization. If necessary, contact AnX Robotica Corp.

7.3 Training

7.3.1 Equipment Operation Training

The equipment operator should be trained by AnX Robotica Corp. personnel before start using the system. Your facility may designate a trainer to train additional personnel, as applicable.

7.3.2 Clinic Use Training

It is strongly recommended by AnX Robotica that the equipment be used only by well-trained physician or health professional with clinical operational experience with this System.

Warning

The equipment operator should be well trained before performing clinical operations with patients.

CHAPTER 8: MAINTENANCE

Maintenance of the equipment should be completed by qualified personnel at least once a year.AnX Robotica Corp. will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair the device. Do not attempt to make any modifications to the device. Any modification during the actual service life require re-evaluation of safety and EMC.
The following routine inspection and cleaning is required:

Power Inspection
Regularly check power supply of the System for damage, cracking or wear. Do not use the equipment when power voltage is out of specified range for the equipment 120VAC, 60Hz.

8.1 Replacement of Fuse

There are two fuses with fast-acting and high breaking capacity features. Each specified as 125VAC 6A, and the dimension is Φ5mm in diameter, 20mm in length. The two fuses are located near the power input terminal of the equipment (see Figure 9-1). Please use a fuse removal tool to remove the fuse caps and replace the related fuse. AnX Robotica recommends that the fuses by replaced annually.

Figure 9- 1: Schematic Diagram of fuse replacement

Warning

Replacing of the fuse can only be done by qualified personnel.

Improper replacement of the fuse can induce harm to both the personnel and the device.
Please follow the fuse replacing instruction to safely replace the fuse.

8.2 Inspection of Magnet strength

The service life of the Controller's magnetic ball is 6 years.
Check that the maximum magnetic field value at the lowest 30 mm. of the magnetic head is 189.8 55.0 mT. If it does not meet this value, the magnet of the Controller may need to be replaced or serviced.

8.3 System Cleaning

Your facility should provide a bed cover that meet medical standards. To avoid cross contamination between patients, please replace with a new cover for each patient.

Once a month wipe the examination bed surface with cleaning cloth lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes.

Once a month, in power off condition, wipe the instrument surface with cleaning cloth lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes. If cleaning of internal parts of the equipment is required, only qualified personnel may clean the inside panels. ALWAYS make sure it is powered off. Outer casing may be cleaned by air blower to remove dust.
Preventive inspection and maintenance of the examination bed surface, frame and electric equipment should be conducted at least once yearly by a professional technician. Check for loose fasteners or other factors that may cause injury to patients or operators.

8.4 Screw Lubrication

Lubricate the ball screws every three months, then start up the equipment and operate the equipment for 2-3 trips in XYZ directions.

Note

Reinstall the dust cover after lubrication, close the equipment back cover and lock it.

8.5 Cleaning of Data Recorder and Locator

The Data Recorder and Locator should be regularly and manually cleaned by wiping the equipment surface gently with a cotton ball lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes.

8.6 Treatment method after package damage of Capsule

The capsule endoscope is provided in a clean package and should not be used if its package is open, torn or damaged.
Disposal of the capsule endoscopes should be done in accordance with local regulations regarding the disposal of electronic products.

CHAPTER 9: WARNINGS, CAUTIONS AND TROUBLESHOOTING

9.1 ESNavi Error Messages

Message	Solution
9.1.1.1.1. Check if camera is connected firmly	Please connect the camera properly, exit the capsule control program and restart it.
9.1.1.1.2. Equipment initialization error	Check if power switch is turned on. If not, turn the power switch on, exit the capsule control program and restart it.
9.1.1.1.3. Port "COM7" does not exist	Check that 2D joystick is connected properly. After the equipment is turned on, exit the capsule control program and restart it.
9.1.1.1.4. Video monitoring connection fails	Connect the camera properly, exit the capsule control program and restart it.
9.1.1.1.5. Port "COM8" does not exist	Check that 3D joystick is connected properly. After the equipment is turned on, exit the capsule control program and restart it.
9.1.1.1.6. Serial port initialization error	Check that the three-axis equipment is connected properly. After the equipment is turned on, exit the capsule control program and restart it.
9.1.1.1.7. Port "COM4" does not exist	Check that the Z-axis 24V board is connected properly. After the equipment is turned on, exit the capsule control program and restart it.
9.1.1.1.8. Cannot connect to Data Recorder	Check if the Data Recorder is connected properly. Unplug and then plug USB interface from the Data Recorder
9.1.1.1.9. Password error	Log in again and reenter your password
Cannot delete physician information	Retry to delete current login physician information if not succeed
Failed to add physician	Retry inserting physician information if not succeed

Message	Solution
information	
9.1.1.1.10. "Print error" prompt box	Check printer power; check printer settings

Warning

If the solutions provided above do not address the problem, contact AnX Robotica Corp. for assistance.

9.2 Problems with Translational Rotation Platform

Problem	Cause	Action
The power switch is on but the system is not powered	Power cord is loosened	Check if the power cord is properly connected
	Fuse is burnt	Check and replace the fuse, if necessary
	Equipment failure	Contact technical support personnel
The video monitoring camera is lost, no image found	USB connection cable is loosened	Check the USB connection cable of the camera
	USB extension cable is damaged	Replace USB extension cable or contact technical support personnel
	Equipment failure	Contact technical support personnel
The linear motion of three axes is accompanied with noise or jamming	Equipment is overloaded	Reset the related equipment driver
	Equipment failure	Contact technical support personnel
Equipment emergency stop of three-axis linear motion	Equipment error	Reset the related equipment driver
	Equipment failure	Contact technical support personnel
Large difference of three-axis motion positions	Equipment error	Reset the related equipment driver
	Equipment failure	Contact technical support personnel
Over-speed of three-axis	Equipment error	Reset the related equipment

Problem	Cause	Action
linear motion		driver
	Equipment failure	Contact technical support personnel
Driver inhibition error	Equipment error	Reset the related equipment driver
	Equipment failure	Contact technical support personnel

9.3 Problems with Capsule

Problem	Cause	Action
When activating capsule, LED light does not lit up	Battery has no power or capsule damaged	Replace the capsule **Warning:** replacement of the battery is prohibited.
	Capsule is not activated	Activate the capsule again with infrared light
	Equipment failure	Contact technical support personnel
Real-time image is not transmitted to computer	Capsule is not in working state (all twelve cycles on the monitor are hollow rather than solid)	Issue operation commands through computer
	Problems with Data Recorder	See below actions

9.4 Problems with Data Recorder

Problem	Cause	Action
The power switch is on but LED and monitor do not lit up	The battery has no power	Recharge the recorder for 8 hours and use another recorder for the procedure. **Warning:** replacement of the battery is prohibited.
	Equipment failure	Contact technical support personnel
Real-time image is not transmitted to computer	Capsule is not activated (the circle in the upper left corner of the monitor is hollow rather than solid)	Activate the capsule with infrared light
	Capsule is not in working state (all twelve cycles on the monitor are hollow rather	Issue related operation commands through the computer

Problem	Cause	Action
	than solid)	
	Signal transceiver of the Data Recorder failure	Contact technical support personnel

9.5 Problems with Locator

Problem	Cause	Action
The power switch is on but LED and monitor do not lit up	The battery has no power	Recharge the locator again for 8 hours and use another locator for the procedure **Warning:** replacement of the battery is prohibited.
	Equipment failure	Contact technical support personnel
Cannot operate the capsule	Capsule failure	Contact technical support personnel
	Equipment failure	Contact technical support personnel

Warning

If the actions provided above do not address the problem, contact AnX Robotica Corp. for assistance.

CHAPTER 10: TECHNICAL SPECIFICATIONS

10.1 Controller

Physical characteristics:

Size (±20mm) Translational Rotation platform: 2140×1850×1930 mm
Console: 1190×840×790 mm
Material: 45#、304、ABS

Mechanical characteristics:

Range of Rotation angle of the magnet: 0~360°
X-axis (parallel to examination bed) movement range: 400±20mm
Y-axis (vertical to examination bed) movement range: 540±20mm
Z-axis movement range: 300±20mm
Examination bed bearing capacity: 135kg
Relative distance of mattress support platform above ground: 630 mm ±10mm
Noise: <65dB(A)

Magnetic field characteristic:

Magnetic induction intensity: 0~300mm

Operating performance:

Grade of waterproof: IPX0
Safety type: Class I Type B continuous running equipment
Ambient temperature: 5~40℃
Relative humidity: ≤80%
Air pressure: 86kPa~106kPa
Power supply: AC 120 VAC，60Hz

Note: Detachable power supply cord is used to supply or isolate its circuits electrically from the supply mains.

Controllable capsule: Positioning capsule endoscope system

Storage environment:

Storage temperature: 0~50℃
Relative humidity: ≤80％

Transport environment:

Transport temperature: -20~55℃
Transport Requirement:

- Vehicle is sealed and rain

proof

- Do not transport with flammable, explosive and corrosive objects
- Do not unload during transport

10.2 Data Recorder

Operating performance:

Recording time:	8 hours (2fps)
Storage capacity:	≥ 4 GB
Battery type:	Lithium battery,3.7-4.2VDC,≥2500mAh
Ambient temperature:	5~40℃
Storage temperature:	0~40℃
Safety type:	Built-in power supply type BF continuous running equipment
Grade of waterproof:	IPX0

The information of the adaptor:

Part no.	UE110725GWGQ01-P
Input:	110-240 Vac~50/60Hz, 500mA
Output:	5.2V⎓2A
Protection class:	class II, continuous duty

FCC ID: 2ATXZ-AKR-1

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

10.3 Capsule

Physical performance:

Length:	27 ± 1.0 mm
Diameter:	11.8 ± 0.5mm
Weight:	5.0 ± 0.5 g
Material:	Biocompatible materials

Optical performance:

Illumination: LED
LED flash frequency: 0.5~6 Hz adjustable
Camera: 1 piece
FOV: 100°±15%
DOF: 0mm~30mm
Resolving power: ≥6 lp/mm

Image performance:
Frame rate: 0.5~2 fps adjustable
Image resolution: 480*480 adjustable

Magnetic field performance:
Surface magnetic field strength: ≤2000 Gs
Capsule's non-optic bottom magnetic induction intensity: 96 Gs~360 Gs

Operating performance:
Operating time: ≥2 hours
Battery type: Silver oxide cell≥35mAh
Rated voltage 3V DC
Safety type: Built-in power supply type BF continuous running equipment
Grade of waterproof:
Chemical safety: Resistance to dissolve when pH ranges from 0.5-9
Operating temperature: 20~40℃
Storage temperature: 0~40℃
RH: ≤80%
Grade of waterproof: IPX8

FCC ID: 2ATXZ-AKEM11SW
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

10.4 Locator

Locating performance:
Probing distance: ≤150 mm
Operating performance:

Battery type: Lithium battery, 3.7-4.2V DC,2600mAh

The information of the adaptor:

Part no.	UE110725GWGQ01-P
Input:	110-240 Vac~50/60Hz, 500mA
Output:	5.2V⎓ 2A
Protection class:	class II, continuous duty
Ambient temperature:	5~40℃
Storage temperature:	0~40℃

Safety type: Built-in power supply type BF continuous running equipment

Grade of waterproof: IPX 0

10.5 Software

Running requirements:

CPU:	dual-core 2.0 GHz or above
Monitor:	double monitor, resolution 1024*768 or above
Hard disk:	250 GB or above
RAM:	2 GB or above
USB interface:	8 or more
Ethernet interface:	2

CHAPTER 11: SYSTEM LABELING

Followings are labels on system components:

Label	Description
	Manufacturer
	Date of Manufacture
	Serial Number
	Type B Applied Part
	Type BF Applied Part
	Potential Equalization Conductor
	Do not re-use
	IP Code(10m,2h)
	Batch Code
	Use-by date
	Non-ionizing electromagnetic radiation
	Do not use if package is damaged

Emergency stop

Refer to instruction manual/booklet

General warning sign

Warning, crushing hazard: hand

Warning, magnetic field

Warning, non-ionizing radiation

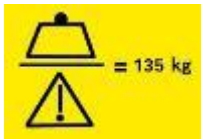
No stepping on surface

No access for people with active implanted cardiac devices

No metallic articles or watches

Do not touch

No access for persons with metallic implants



Safe working load: 135 kg

The way a patient lies during examination

Caution

Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice.”

Keep Clean

Warning Mechanical injury

Warning Mind your head 1

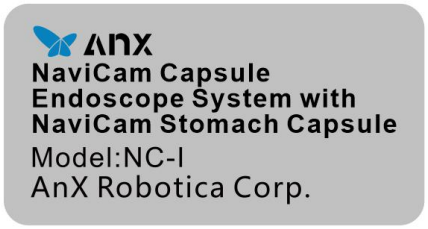
Warning Mind your head 2

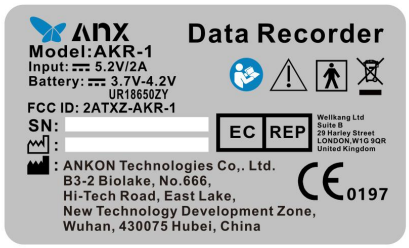
Blue logo

White logo

Product name identification

Nameplate of the Controller





Nameplate of the Data Recorder

Nameplate of the Locator