



NaviCam Small Bowel Capsule Endoscopy System User Manual

ANKON Technologies Co., Ltd.

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CAUTION:

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

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CHAPTER 1: INTRODUCTION

1.1 Important Information

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



CAUTION

- **Failure to follow instructions could result in damage to the equipment or pollution to environment.**



WARNING

- **Failure to follow instructions could result in injury or even death to operator; patient, or other personnel.**
- **To avoid the risk of electric shock, this equipment must only be connected to a power supply that is properly grounded.**

1.2 About NaviCam Small Bowel Capsule Endoscopy System

The User Manual introduces the use of NaviCam Small Bowel Capsule Endoscopy System (Model: NS-I, hereinafter referred to as "NaviCam SB System"). The NaviCam SB System is a type of capsule endoscope system. This chapter introduces tip information involved in the quick guide and the User Manual.

NaviCam SB System is comprised from the following components:

- **Capsule (Model: AKES-11SW, AKES-SI)**
 - **Data Recorder (Model: AKR-1, AKRI-1)**
 - **Locator (Model: AKS-1)**
 - **ESView Software**

The NaviCam SB System contains two components, the Capsule and the Data Recorder, which work in different frequencies – 2.4GHz, 915MHz. These components are equally used in conjunction with the other components of the NaviCam SB System, namely, the Locator and the ESView software. The relationship between the models of the Capsules and the models of the Data Recorders with their corresponding frequencies is shown in Table1-1.



CAUTION

- **Mixing between the Capsule model and Data Recorder model will result**

in a failed examination and could damage the equipment.

Table1-1: Relationship between product models and associated frequencies

Frequency	Capsule Model	Data Recorder Model
2.4GHz	AKES-11SW	AKR-1
915MHz	AKES-11SI	AKRI-1

A description of each component is provided below.

1.2.1 Capsule(AKES-11SW/AKES-11SI)

The Capsule presented in Figure 1-1, is a capsule endoscope capable of capturing images inside the human digestive tract. 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 1-1: Capsule (2.4 GHz AKES-11SW, 915MHz AKES-11SI)



WARNING

- **Capsule is MR unsafe.**

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.

1.2.2 Data Recorder

1.2.2.1 Data Recorder (AKR-1)

The AKR-1 Data Recorder, presented in Figure 1-2, 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. The Data Recorder is charged with an included charger when not in use.



Figure 1-2: Data Recorder (2.4 GHz 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 by a patient.**

Note:

- **The Data Recorder is used in a hospital environment as well as in the home healthcare environment, and shall be used by trained personnel or professional personnel.**
- **The service life of the battery under the typical condition is 5 years.**
- **For the Data Recorder at low-temperature storage, which is beyond the operating temperature range, please place them for half an hour or more until warm to operating ambient temperature before using them. And also, for the Data Recorder at high temperature storage, which is beyond the operating temperature range, please place them for half an hour or more until cool to operating ambient temperature before using them.**

1.2.2.2 Data Recorder (AKRI-1)

The AKRI-1 Data Recorder works in the same way as Data Recorder (AKR-1). The AKRI-1 Data Recorder consists of the following three parts as shown in Figure 1- 3

- 1) Data Recorder Host.
- 2) Belt-examining cloth (including antenna) and data cable.
- 3) Charging base.



Figure 1- 3 Data Recorder (915MHz AKRI-1)

The Data Recorder is charged with an included charger when not in use.

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

- **Do not charge the Data Recorder when it is in use.**
- **The battery of the Data Recorder is non-removable and the users shall not replace the battery at discretion.**

Note:

- **The Data Recorder is used in a hospital environment, as well as in the home healthcare environment, and shall be used by trained personnel or professional personnel.**
- **The service life of the battery under the typical condition is 5 years.**
- **For the Data Recorder at low-temperature storage, which is beyond the operating temperature range, please place them for half an hour or more until warm to operating ambient temperature before using them. And also, for the Data Recorder at high temperature storage, which is beyond the operating temperature range, please place them for half an hour or more until cool to operating ambient temperature before using them.**

1.2.3 Locator

The Locator, presented in Figure 1-4, is a portable magnetic scanning device with built-in rechargeable lithium battery. It is used to turn the capsule on before it is swallowed by the patient and 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- 4: Locator**WARNING**

- **Never charge the Locator when it is in use by a patient.**
- **For patient who needs to undergo an MRI test before the expulsion of the capsule has been confirmed, Locator scan should not replace an X-Ray to confirm the absence of capsule in the body.**

1.2.4 ESView Software

ESView software is the image review software component of the NaviCam SB System . It can be installed on a dedicated image review computer at a hospital, clinic, or doctor's office for physicians to review capsule endoscope images.

The ESView enables the following functions:

- Patient check-in
- Data export
- Image browsing, processing, and editing, with or without the optional ProScan feature
- Report generation
- Case management
- Capsule endoscopy atlas

The minimum operating environment for running ESView software is as follows:

- CPU: Intel Core i3 2.0GHz or later
- GPU: rtx4000 or later
- Monitor: Resolution 1920*1080 or higher
- HDD: 250GB or above
- Memory: 8GB or above
- USB Port: 2 or more
- Operating System: Windows 7 or above

1.3 Summary of Clinical Performance

The NaviCam Small Bowel Capsule Endoscopy System was evaluated in two clinical studies: (1) a prospective study, comparing its performance to that of the FDA cleared PillCam SB3 Capsule Endoscopy System (hereafter referred to as "PillCam SB System"); and (2) a retrospective study to evaluate the performance of the optional ProScan feature of the ESView software. Summaries of both studies are provided below, and the full reports are attached to Section 20.

(1) "Performance Evaluation of the AKE-1(NaviCam SB) Capsule Endoscope System in Comparison to the PillCam SB3 Capsule System for the Diagnosis of Small Bowel Diseases"

This was a prospective, comparative study in 3 sites in China, aimed to evaluate the performance of the NaviCam SB System (trial capsule) when compared to the PillCam SB System (control

capsule or comparator) for the diagnosis of small bowel diseases.

Study primary endpoints included Per Findings analysis, where the recordings obtained with both capsules were independently evaluated and the agreement between findings of both capsules was evaluated; and, Per Subject analysis; where the diagnosis of subjects based on independent interpretation of images obtained with both capsules was evaluated (diagnosis of normal or abnormal per subject). A number of secondary endpoints were also assessed including ease of swallowing the capsule, intestinal transit time, capsule excretion time, diagnostic yield when compared to other standard mucosal imaging procedures, quality of small bowel images, image reading time, and agreement between two or more reviewers with respect to interpretation of the images obtained.

The study included adult subjects with symptoms of small bowel diseases or suspected gastrointestinal bleeding. After signing informed consent, subjects who met the study eligibility criteria completed gastrointestinal preparation in advance according to the examination schedule. Before swallowing the capsules, an antifoaming agent (10ml simethicone) with 120ml of water was administered to reduce air bubble formation in the small bowel. Each subject wore the two types of data recorders then swallowed the two types of small bowel capsules approximately 40 minutes apart in a randomized order. Subjects were allowed to drink water 2 hours after swallowing the capsules and eat a small amount of food 4 hours after swallowing the capsules. Upon confirming that the capsules have entered the small bowel, the subjects left the hospital and were instructed to continue wearing the data recorders for 8-10 hours until the power of the capsules were depleted, or the capsules were excreted.

The anonymized images acquired by both the trial capsule and comparator were read by two gastroenterologists independently for normal and abnormal interpretation and analysis of lesion type (edema, polyp, hemorrhage, etc.), capsule transit time, reading time and image quality; in cases of disagreement, a third gastroenterologist reviewed the video in question and provided his/her result.

A total of 97 subjects were enrolled in the study; 10 subjects were withdrawn or withdrew consent prior to the study procedure. As these subjects did not swallow the capsules, they were excluded from data analysis, therefore, the results from 87 subjects were included in both Per Protocol Set (PPS) analysis and Full Analysis Set (FAS).

Primary Efficacy Results:

Per Subject Analysis: Normal versus Abnormal

Abnormal rates (NaviCam 73/87 – PillCam 68/87)	83.91% – 78.16%,
Positive Percent Agreement (PPA) [95% CI]:	97.06% (89.90%, 99.19%)
Negative Percent Agreement (NPA) [95%CI]	63.16% (41.04%, 80.85%)
Overall Percent Agreement [95% CI]	89.66% (81.50%, 94.46%)
Overall percent agreement per Kappa analysis [95% CI]	0.6652 (0.4653, 0.8652)
Positive Predictive Value (PPV) [95% CI]	90.41% (81.50%, 95.28%)
Negative Predictive Value (NPV) [95% CI]	85.71% (60.06%, 95.99%)
McNemar Test Results	X ² =2.7778, p=0.0956

Per Finding Analysis:

There were no statistically significant differences between the 2 capsules in the detection of vascular lesions ($p=0.2087$), inflammatory lesions ($p=0.6831$), tumors/polyps/masses ($p=1.0000$), ulcers/ulcerations ($p=0.3938$), and other lesions ($p=0.4669$).

Safety Results:

One case of capsule retention occurred where both NaviCam and PillCam capsules were retained. The incidence of adverse events was 1.15%. No abdominal pain, abdominal distention, nausea, vomiting, headache, obstruction, or other adverse events occurred.

In conclusion, the NaviCam SB System and PillCam SB System had a diagnostic overall percent agreement rate of 89.66% (81.50%, 94.46%), and an overall percent agreement Kappa of 0.6652 (0.4653, 0.8652). The results of this comparative study indicate that NaviCam Small Bowel Capsule Endoscopy System performs similarly to the PillCam SB3 Capsule Endoscopy System and provides an effective non-invasive method for the detection of small bowel diseases.

(2) Retrospective Evaluation to Compare Small Bowel Video Reading by AKE-1 (NaviCam SB) Capsule Endoscopy System with ProScan Feature and PillCam SB3 Capsule System with SBI Feature”

The goal of this retrospective evaluation was to compare the performance of the NaviCam SB System ESView software with the ProScan feature to this of the PillCam SB System with the SBI feature. The recordings/images used in this study were previously obtained in the prospective study (study (1)) and were analyzed by two independent reviewers for visual comparison of the findings and analysis using ESView software with ProScan and Rapid software with SBI in comparison to the conventional reading previously performed for both systems.

Capsule endoscopy videos of 87 subjects were used and included in both the Full Analysis Set (FAS) and Per Protocol Set (PPS) analyses.

The primary endpoint of the study was to evaluate the performance of the NaviCam SB System with the ProScan software feature in comparison with the PillCam SB System SBI feature (per patient analysis). Secondary study endpoints included per findings analysis, image review time, and image review time of NaviCam reading with and without the ProScan feature on.

Per Subject Analysis: Normal versus Abnormal

Abnormal rates (NaviCam 84/87 – PillCam 81/87)	96.55% – 93.10%,
Positive Percent Agreement (PPA) [95% CI]:	100.00% (95.47%, 100.00%)
Negative Percent Agreement (NPA) [95%CI]	50.00% (18.76%, 81.24%)
Overall Percent Agreement [95% CI]	96.55% (90.35%, 98.82%)
Overall percent agreement per Kappa analysis [95% CI]	0.6506 (0.2866, 1.0000)
Positive Predictive Value (PPV) [95% CI]	96.43% (90.02%, 98.78%)
Negative Predictive Value (NPV) [95% CI]	100.00% (43.84%, 100.00%)
McNemar Test Results	X ² =3.0000, p=0.0833

These results demonstrate that the NaviCam SB System and PillCam SB System have good diagnostic consistency.

There were no statistically significant differences in the diagnosis of vascular lesions (p=0.4497), inflammatory lesions (p=0.3173), tumors/polyps/masses (p=0.2207), malabsorption (p=1.0000), ulcers/ulcerations (p=0.7963), and other lesions (p=0.0863) between the NaviCam SB and PillCam SB systems.

The video review time of the trial capsule was 1.63 min higher than that of the control capsule, and the difference was statistically significant. The difference between the mean reading time of the NaviCam SB with ProScan on and conventional reading (i.e., without ProScan feature on) was -36.63 min (-46.29 min, -26.72 min) (95% CI), the difference was statistically significant. The results of the analysis of the consistency of the interpretation of the images obtained by two or more reviewers (FAS/PPS) show that the differences between the two groups are not statistically significant.

The results of this study showed that the clinical performance of the NaviCam SB System with the ProScan feature and PillCam SB System (with SBI) were similar, and that the NaviCam SB System with ProScan feature on significantly reduced the physician's reading time compared to the reading time of the NaviCam SB System without the ProScan on (21.47±8.05 vs. 58.10±45.28, p<0.0001).

CHAPTER 2: INDICATIONS, CONTRAINDICATIONS AND WARNINGS

2.1 Indications

The NaviCam Small Bowel Capsule Endoscopy System is intended for visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.

2.2 Contraindications

The capsules are contraindicated for use under the following conditions:

- In patients with known or suspected gastrointestinal obstruction, strictures, or fistulas based on the clinical picture or pre-procedure testing and profile.
- In patients with cardiac pacemakers or other implantable electronic medical device.
- In patients with an easily magnetized metal part.
- In patients with dysphagia or other swallowing disorders.
- In pregnant women.

Note: The Capsule maybe deployed by using transendoscopic delivery in patients who are unable to ingest the capsule or are known to have prolonged gastric emptying time. Placement into the duodenum is recommended to prevent the patient from vomiting the capsule.

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, aspiration of the capsule, and interference from strong magnetic field sources. It could be necessary to remove the capsule by intervention.

2.4 Warnings

- △ A negative or normal result obtained by the capsule does not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.
- △ If intestinal fistulas, strictures, or stenosis are suspected, or the patient has had prior abdominal or pelvic surgery, the physician should consider performing an examination to ascertain patency for an object the size of the capsule.
- △ The safety of the capsule has not been established in children.
- △ The capsule should not be swallowed by patients where a concern for aspiration of the capsule exists (e.g., due to cognitive or neurological deficits or a history of aspiration). In these patients, it is recommended that a capsule endoscopic delivery system be used to

place the capsule directly in the duodenum. Placement of the capsule in the duodenum will decrease the risk of aspiration of the device [by vomiting] and gastric retention.

- △ A thorough understanding of the technical principles, clinical applications and risks associated with the Capsule System is necessary before using this product. Read the entire manual before using the system for the first time.
- △ Make sure that only trained personnel or professional personnel, familiar with all operating procedures of the NaviCam SB System, use the system.
- △ To prevent the patient from being exposed to unforeseen risks during passage of any capsule, make sure the patient thoroughly understands the procedure, and provide the patient with a copy of the Patient Labeling.
- △ A patient with known or suspected delayed gastric emptying (whether disease related or drug induced) could be at increased risk for incomplete the NaviCam SB System.
- △ When swallowing the capsule there is a possibility of choking on the capsule. If the patient exhibits any symptoms and/or clinical signs of choking (labored breathing, wheezing, involuntary coughing, etc.), the recommended first-aid procedure should be followed.
- △ Keep the capsule away from implants such as pacemakers and other devices that could be affected by proximity to a DC magnetic field.
- △ If a child has accidentally swallowed any unused or spent capsule, seek medical attention.
- △ Instruct the patient not to sit on bare metal surfaces, such as chairs with metal seating area, during the procedure.
- △ Instruct the patient to contact the physician immediately if, after ingesting any capsule, there is any abdominal pain, nausea, or vomiting.
- △ Only one capsule should be ingested at a time and only after confirmation that no other capsules or ingestible diagnostic devices remain in the patient's body.
- △ If, contrary to instructions, a patient ingests more than one capsule, instruct the patient to immediately contact the physician.
- △ In patients with unsuspected strictures of the GI tract, any capsule can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery.
- △ The safety of this device in patients with significant gastrointestinal diverticular disease is unknown.
- △ Final diagnosis based on the capsule images should be made only by physicians who are trained in the interpretation of capsule endoscopy images.
- △ If there is reasonable doubt concerning the integrity of the capsule due to dropping, biting, or any other eventuality, the capsule should be deactivated by returning it to its box and it should not be used until consulting with an authorized ANKON Technologies representative.
- △ Store all capsules in a safe place, out of the reach of children and infants.
- △ Do not use any capsule after its expiration date.
- △ Instruct the patient to avoid biting the capsule prior to swallowing.
- △ Instruct the patient to wear the data recorder throughout the procedure.
- △ After ingesting the capsule and until it is excreted, the patient should not be near any source of powerful electromagnetic fields such as one created near an MRI device.

- △ Undergoing an MRI while the capsule is inside the patient's body may result in serious damage to his/her intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of any capsule from his/her body, he/she should contact the physician for evaluation with the Locator and possible abdominal X-ray before undergoing an MRI examination.
- △ A capsule should be ingested only in the presence of authorized medical personnel. The patient should be instructed not to let relatives, neighbors or acquaintances use any capsule without medical attention.
- △ If excretion of the capsule from the patient has not been positively verified, and the patient develops unexplained post-procedure abdominal pain, vomiting, or other symptoms of obstruction, he/she should contact the physician for evaluation with the Locator and possible abdominal X-ray examination.
- △ Use the system only with components purchased from ANKON Technologies. Use of other components may damage the system and void the warranty.
- △ In a small number of cases, the capsules may not image the entire small bowel due to variations in patient GI motility.
- △ After ingesting the capsule, the patient should abstain from eating or drinking for another 2 hours. After 2 hours, the patient may drink water. After 4 hours, the patient may have a light snack. After the examination is completed, the patient may return to a normal diet. These instructions related to eating apply unless physician instructs otherwise.
- △ The inspection will last for about 8 hours. The physician should instruct the patient when the examination is considered complete. During the examination, the patient should avoid any physical activity that involves sweating and to abstain from bending. The Data Recorder should be treated with utmost care and protection. Sudden movement and banging of the Data Recorder should be avoided. The patient should be instructed not to remove the Data Recorder during the examination.
- △ The patient may take his/her usual prescribed medication up until two hours before the examination and resume two hours after capsule ingestion, with water.
- △ If the patient is taking any medication that may delay gastric emptying, consider withholding the drug on the day of the test if this is medically acceptable.
- △ The capsule is for single use only.
- △ Even if other devices meet corresponding national emission standards, the system may still be interfered.
- △ The battery of the Data Recorder is not removable, and incorrect replacement will lead to unacceptable risks. Unauthorized personnel are prohibited to replace the lithium battery in the equipment.
- △ The users shall not disassembled/modified the Vest/Examination cloth as well as any connection cable by themselves

CHAPTER 3: ESVIEW SOFTWARE OPERATION INITIATION

3.1 Installation

1. Double click the ESView software installer to install ESView software. The welcome dialog box will pop up (Figure 3-1). Click “Next” to continue.



Figure 3-1: ESView Installation Welcome Dialog Box

2. The Software License Agreement dialog box (Figure 3-2) is displayed. Scroll down to view the agreement in its entirety. Click “I Agree” to accept.

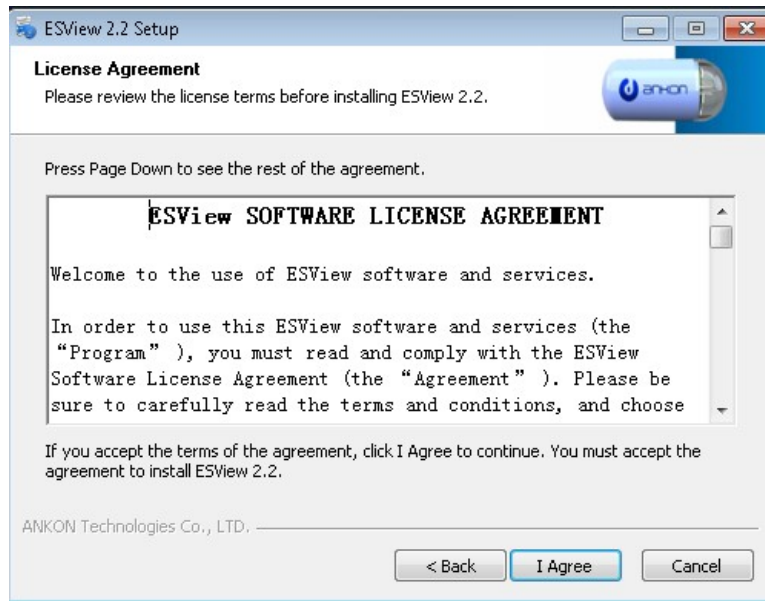


Figure 3-2: Software License Agreement Dialog Box

3. The dialog box for selecting the destination folder (Figure 3-3) is displayed. The default installation directory is C:\Program Files(x86)\ESView. Click “Browse” to change the directory. Click “Install” to continue installation in the selected directory.

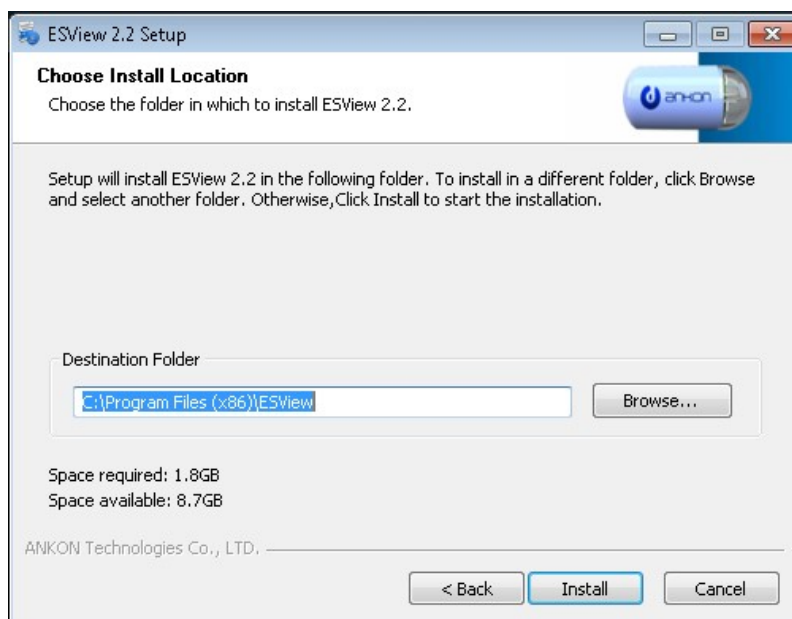


Figure 3-3: Selection of Installation Directory

4. The dialog box, showing the installation progress (Figure 3-4), is displayed.

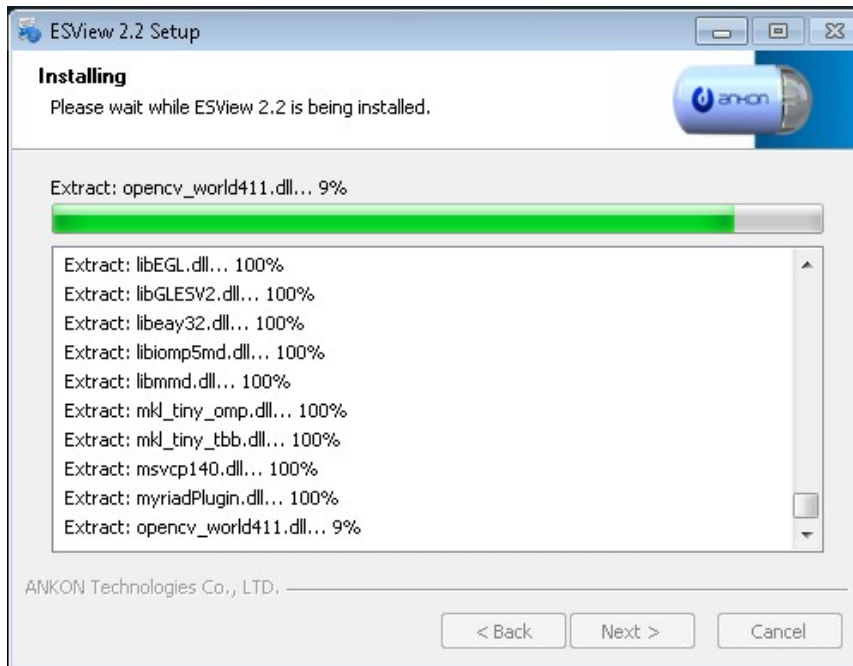


Figure 3-4: Installation Progress Dialog Box

5. After ESView software is successfully installed, the “Setup Completed!” dialog box (Figure 3-5) appears. Click “Finish” to complete installation. A shortcut to the ESView program is created on the desktop.

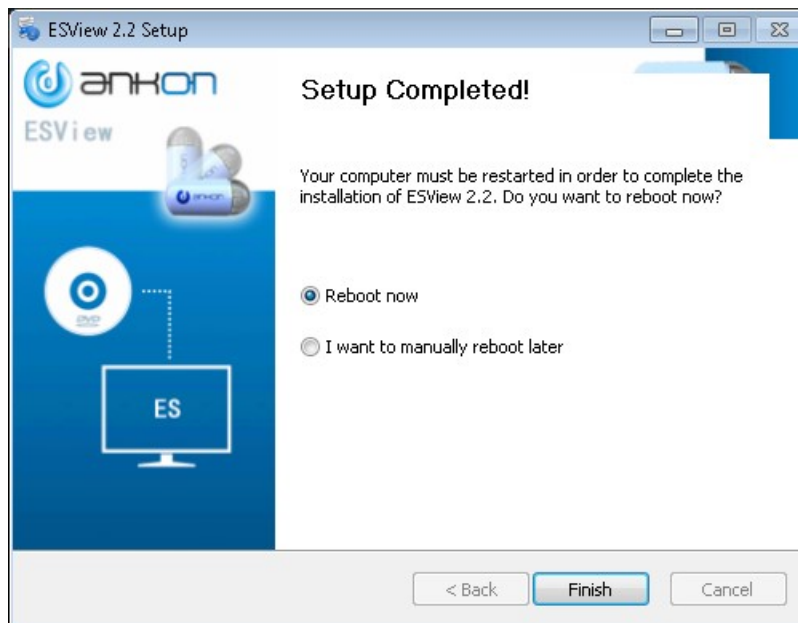


Figure 3-5: Successful Installation Dialog Box

3.2 Uninstallation

1. To uninstall the ESView software, from the Windows Start menu, select “Programs” → “ESView” → “Uninstall ESView”. The uninstallation dialog box (Figure 3-6) appears. Click “Uninstall” to begin the uninstallation.

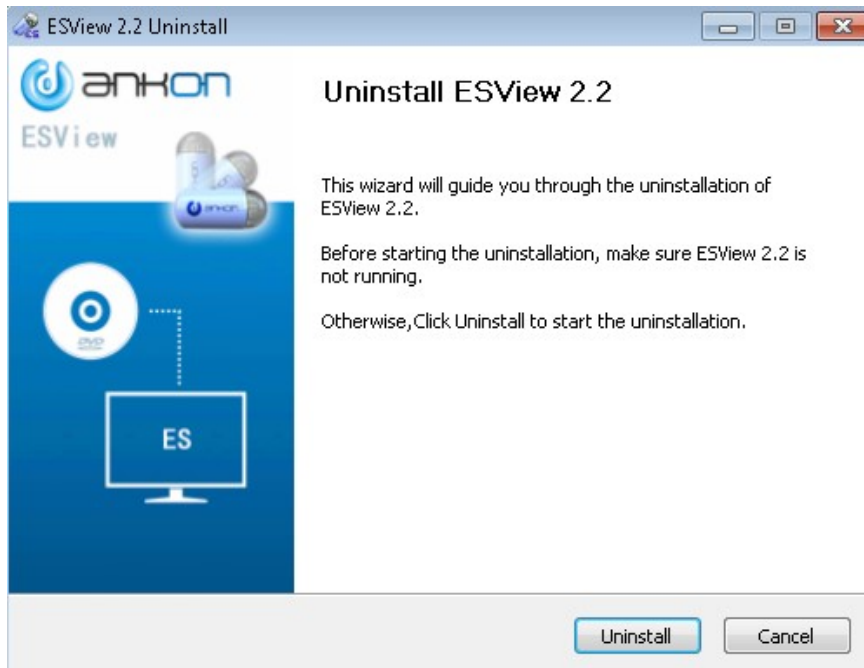


Figure 3-6: Uninstallation Dialog Box

2. After ESView software is successfully uninstalled, the “Uninstall Success!” dialog box (Figure 3-7) appears. Click “Finish” to complete uninstallation.

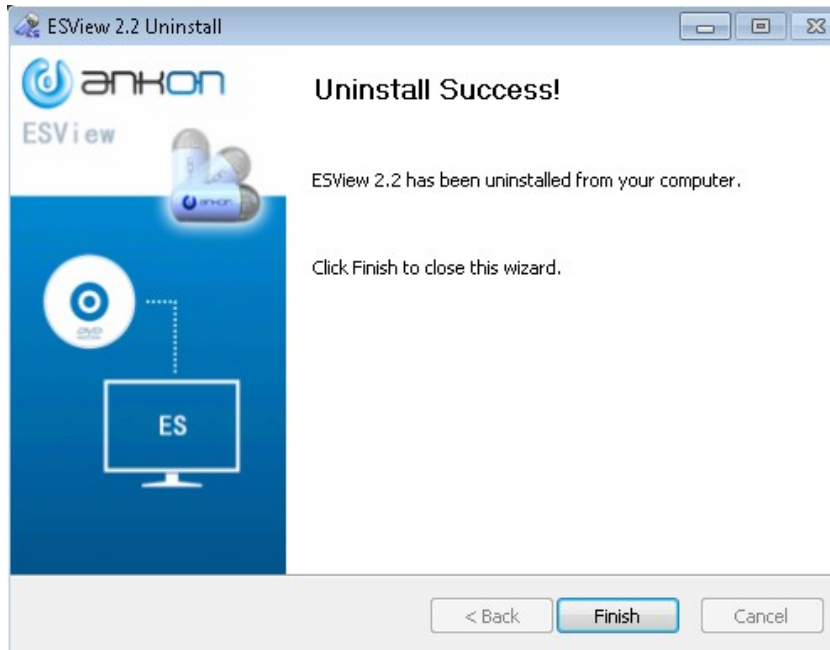


Figure 3-7: Successful Uninstallation Dialog Box

3.3 Basic Software Operation

1. Connect the data recorder to the PC installed with the ESView software, open the ESView and create a new case, and enter and save the basic information of the patient in the data recorder.
2. After confirming the patient information, turn on the capsule, and the images the capsule is capturing and displayed on the Rtdisplay interface. Check if the capsule image display is normal and if the capsule voltage meets the examination requirements. After confirmation, operate according to the examination manual, and help the patient swallow the capsule.
3. After the examination is complete, connect the data recorder to ESView software and export the image data from the recorder and generate a report after viewing the images.

The chart below (Figure 3-8) shows the workflow of the system.

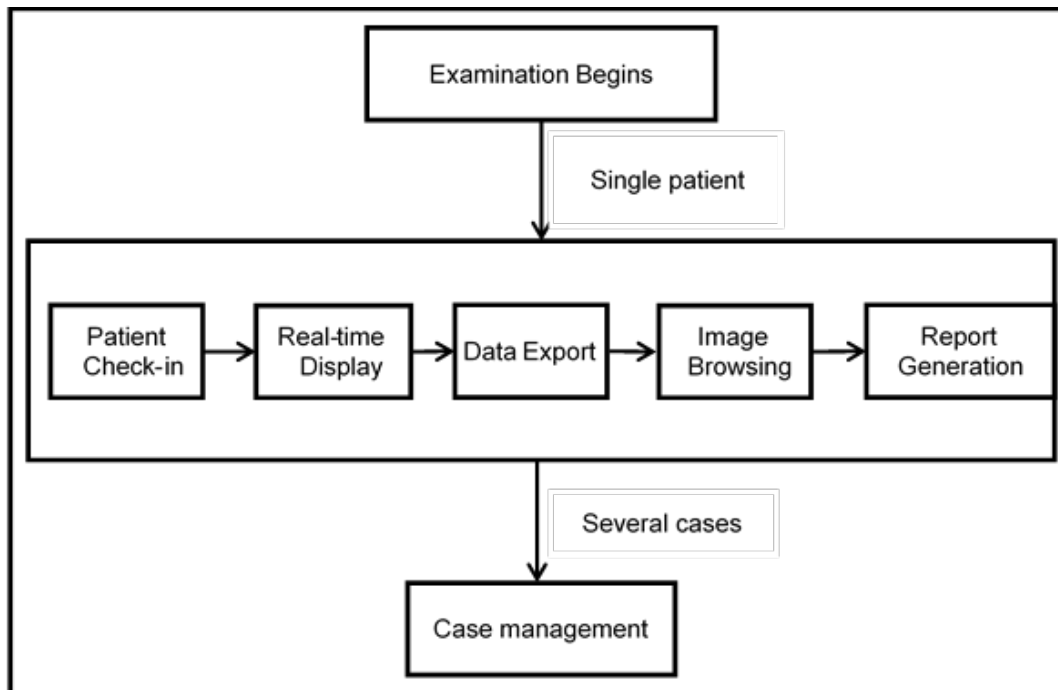


Figure 3-8: NaviCam SB System Workflow

3.4 Software Startup

ESView software can be launched by double clicking the ESView shortcut icon on the desktop. The ESView software launch screen (Figure 3-9) will appear.



Figure 3-9: ESView Software Launch Screen

3.4.1 First-time Startup

When ESView software is launched for the first time on the computer it is installed on, the user

needs to complete a registration step, using the unique license code received from ANKON, and set up a software password.

1. At first-time launch of ESView software, the registration interface (Figure 3-10) is displayed. The serial number in the top box automatically appears and the user has to enter the license code received from ANKON into the blank box to register the software.

Note: ESView software will not function until registration is completed.

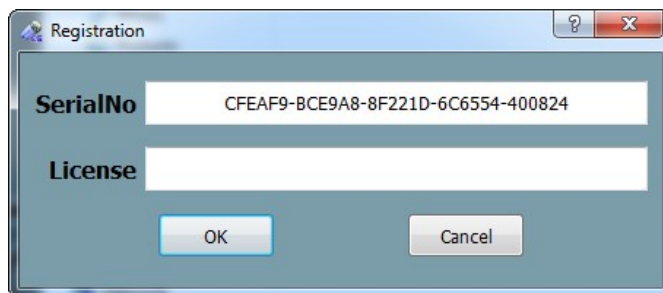


Figure 3-10: Registration Interface

2. After registration, the user is presented with an UI to set up a login password for ESView software. The user can choose to require the password to be manually entered every time ESView software is launched or have the software automatically fill in the password, i.e., auto login.

Note: After logging into the main software interface, the user can select “Tools” → “Accounts” in the menu to add/delete accounts and change passwords.

3. The user can then proceed to use ESView software.

3.4.2 Regular Startup

1. Use your login credentials to enter into ESView. Figure 3-11



Figure 3-11: Login

2. If Microsoft Word 2003 or later version is not installed on the computer, ESView will display a dialog box to alert the user that report generation in Word format will not be supported (Figure 3-12).

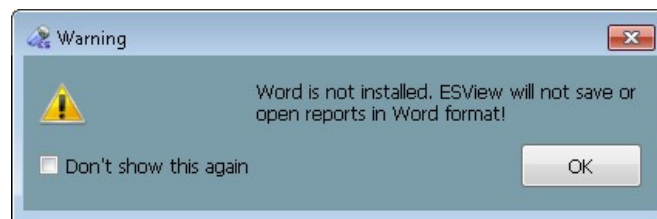


Figure 3-12: Dialog Box Alerting that Word Format Report Is Not Supported

Note: All other functions of ESView software will not be affected.

CHAPTER 4: ESVIEW SOFTWARE OPERATION INSTRUCTIONS

The main ESView software interface, where the user can browse and annotate images, is shown in Figure 4-1. The user can also use the menu or buttons to access interfaces for patient check-in, data export, medical record management, and report generation, etc.

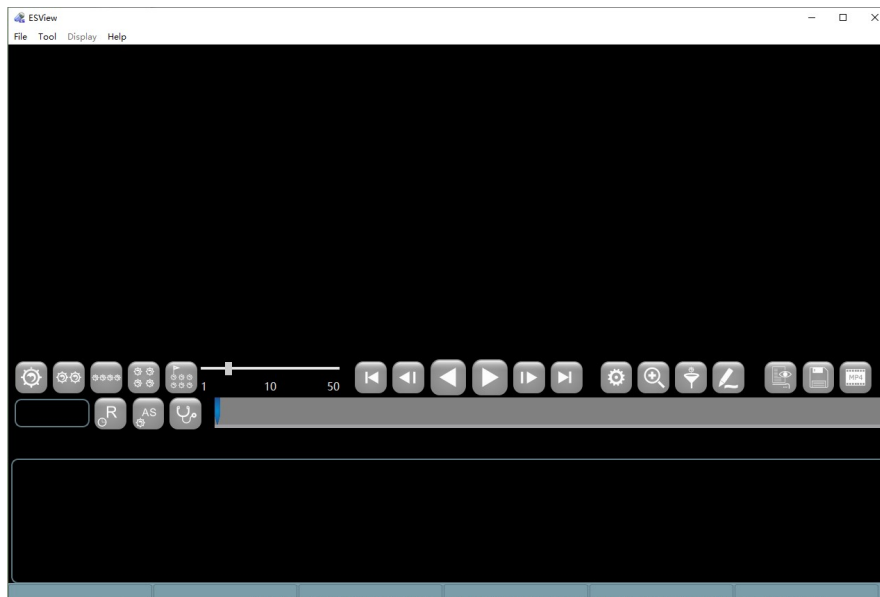


Figure 4-1: Main ESView Software Interface

4.1 Patient Check-in

In the main software interface, select “Tool” → “Check-in” in the menu to launch the patient check-in interface (Figure 4-2), where the user can enter patient information and save it to the data recorder. Eventually the patient information will be exported together with the patient image data from the data recorder to the computer. The data recorder should be connected to the computer via USB before patient check-in. Only one patient information can be saved in the data recorder at a time.

Name	Gender
Phone No.	Date of birth
Height	Weight
Case No.	Capsule SN
ID No.	Referral dept.
Physician name	Referring physician
Indications	Reason for referral
Cleansingness Level	

Figure 4-2: Patient Check-in Interface

The patient information already stored in the data recorder can be retrieved and displayed in the information entry area by clicking the “Read record” button. The “Clear” button can be used to clear patient information in the entry area. After entering the patient information, click “OK” button to save the patient information to the data recorder, or click “Cancel” button to exit the patient check-in interface without saving.

4.2 Real Time Viewing in Rtdisplay Interface

4.2.1 Access Rtdisplay

1. In the main software interface, select “Tool”→“Rtdisplay” in the menu to launch the real-time display interface as shown in Figure 4-3.

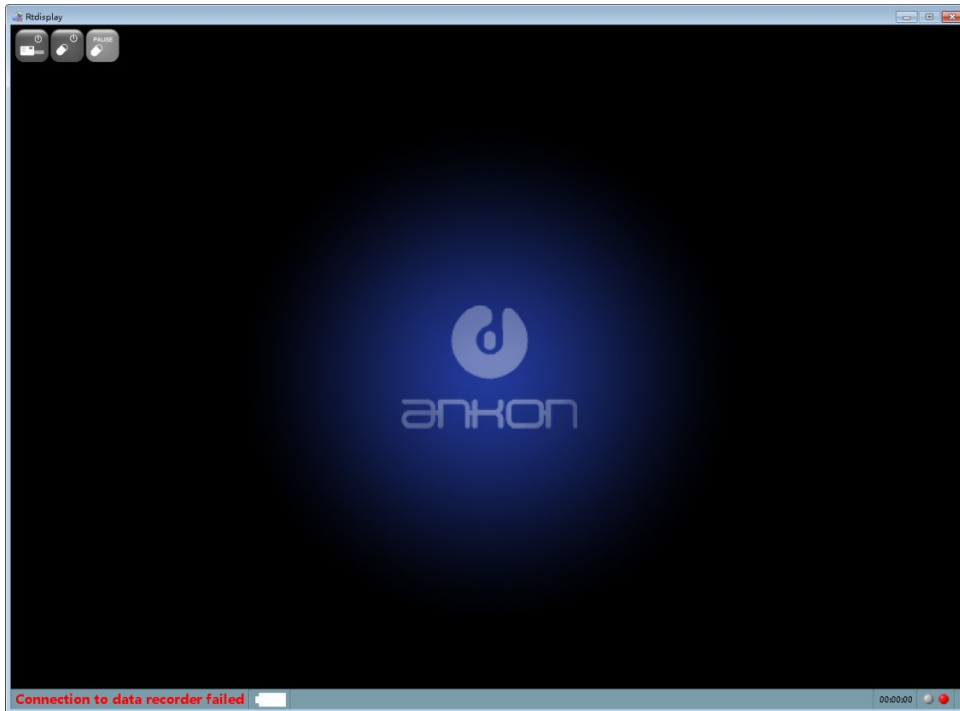


Figure 4-3: Rtdisplay Interface

2. In the Rtdisplay interface, images captured by the capsule endoscope inside the digestive tract can be real-time displayed and its running status can be adjusted. The Data Recorder should be connected to your computer via USB for Rtdisplay. If the Data Recorder is not properly connected, buttons on the toolbar area are disabled, and "Connection to data recorder failed" in red will be shown at the connection status display area on the status bar.
3. If the Data Recorder is correctly connected, buttons on the toolbar are available, and "Connected to data recorder " in black will be shown at the connection status display area on the status bar.

4.2.2 Functions of Buttons in the Toolbar

The functions of the toolbar buttons are detailed in Table 4-1 below.

Table 4-1: Rtdisplay View Button Function

Icon	Function
	Shut down Data Recorder
	Shut down capsule endoscope
	Pause capsule endoscope

4.2.3 Rtdisplay Image Zoom-in and Out

1. Image zoom-in and out can be realized by mouse scrolling, then scaled to x% will be displayed in upper right corner of the image to represent current scaling factor, as shown in Figure 4-4.

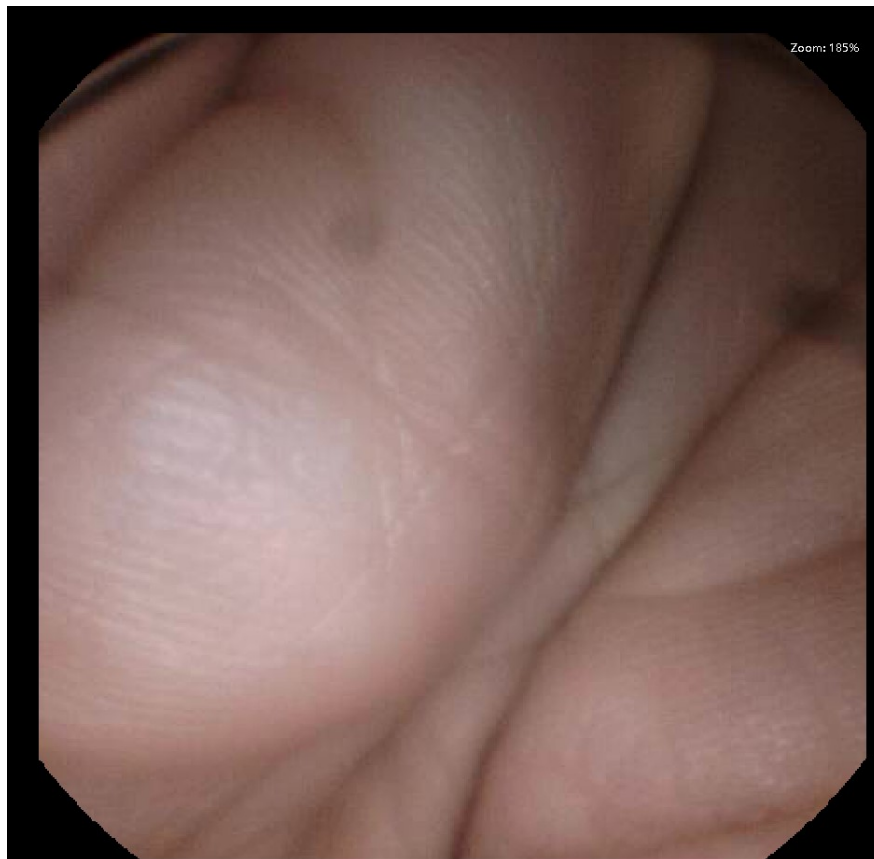

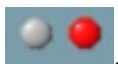


Figure 4-4: Zoom Function

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

4.2.4 Data Recorder Status Indicator

1. Two LED status indicators are located in the lower right bottom of the Data Recorder. The left one indicates work status (Green)  , and the right one indicates warning (red)



2. Meaning of status indicators:

a) Green LED flashes, red LED does not light – indicates image data from capsule

endoscope has been received.

b) Green LED does not light, red LED lights – indicates no signal from capsule endoscope has been received.

c) Green LED does not light, red LED flashes – indicates capsule endoscope signal has been received, but no image data has been received.

4.3 Data Export

1. In the main software interface, select “Tool” → “Data export” in the menu to access the data export interface (Figure 4-5)

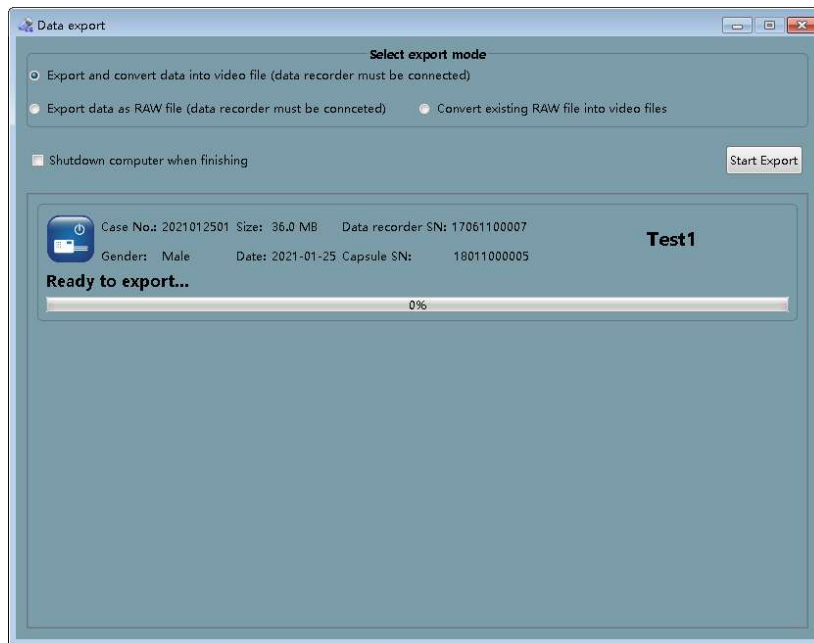


Figure 4-5: Data Export Interface

2. The data export interface is mainly used to export image data captured by the capsule endoscope to the computer. This interface supports two export modes. One is quick export, which exports the data as a raw data file with suffix *.ankon. *.ankon files cannot be opened by ESView until being parsed to video files. The quick export mode is applicable when it is needed to export image data of the last patient quickly and prepare the data recorder for the next examination. The other export mode is direct export, which exports and parses the data as a video file that can be opened by ESView software.
3. To use the direct export mode, select “Export and convert data into video file” and click “Start export”. The image data will be exported from the data recorder as a video file that can be directly opened by ESView.
4. To use the quick export mode, select “Export data as RAW file” and click “Start export”. The image data will be exported from the data recorder as a raw data file with suffix *.ankon. To convert raw data file to video file, select “Convert existing RAW file into video files” and click

“Start export”, then select a RAW file in the raw data file selection interface (Figure 4-6) and generate the video file.

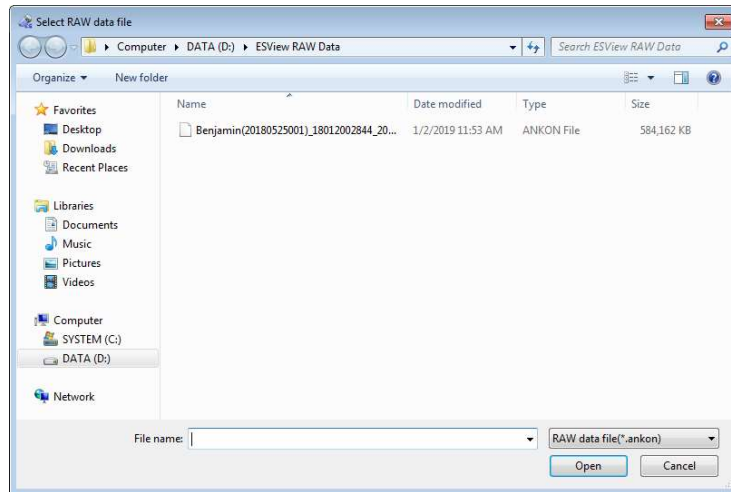


Figure 4-6: RAW Data File Selection Interface

5. The data recorder should be connected to the computer via USB when exporting data, otherwise, an alert will appear on the data export interface to remind the user to connect the data recorder to the computer (Figure 4-7).

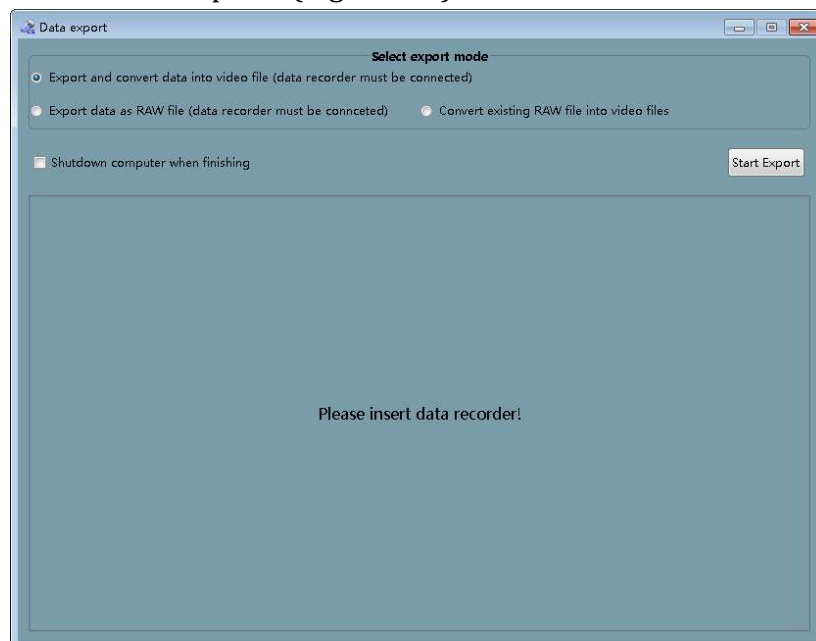


Figure 4-7: Data Recorder Not Connected Alert

6. If “Shutdown computer when finishing” is checked, the computer will automatically shut down after data export finishes.

4.4 Image Browsing, Processing, and Editing, ProScan mode

4.4.1 Open Video

1. In the main software interface, select “File”→“Open video” to access the patient data file selection interface (Figure 4-8). The default path is the data export path.

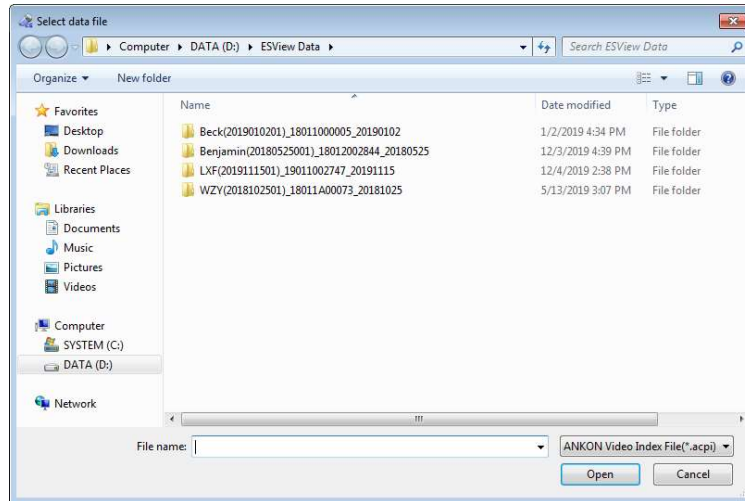


Figure 4-8: Patient Data File Selection Interface

2. Select a patient folder and open the *.acpi file under the folder. The software will automatically load image data in this folder, and the image data will be displayed in the main software interface (Figure 4-9).

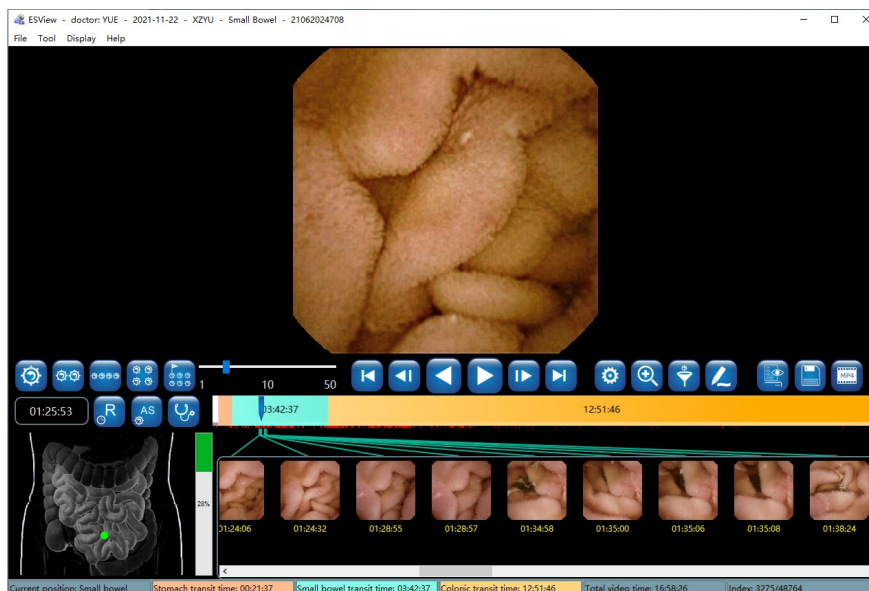


Figure 4-9: Main Software Interface After Opening Image Data

3. To open recently opened videos, select “File”→ “Recent video”→ “select video path” in the menu.

4.4.2 Video Playback Function

1. In the main software interface, click the forward or backward playback button (Figure 4-10) to play the loaded video in forward or backward direction.

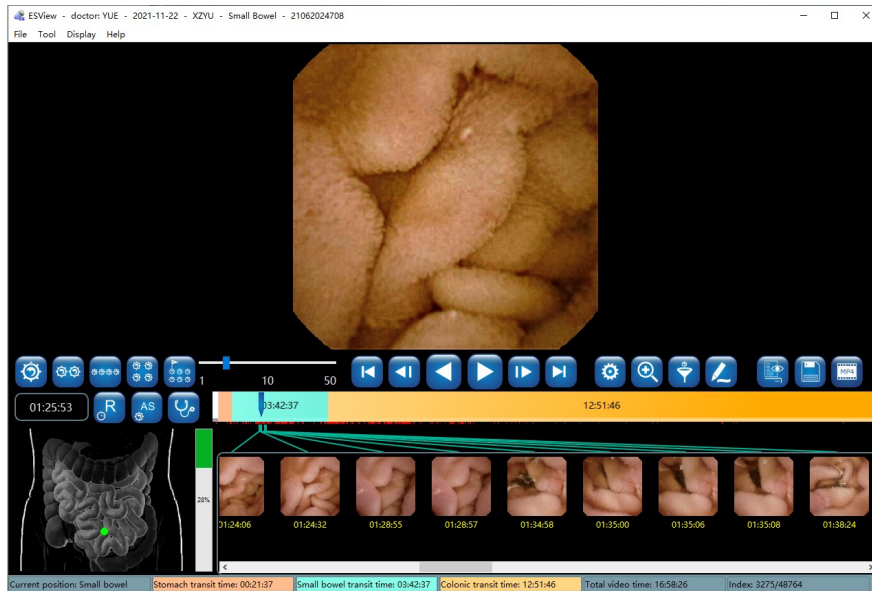


Figure 4-10: Video Playback Buttons

2. To stop video playback, click the pause button (Figure 4-11).

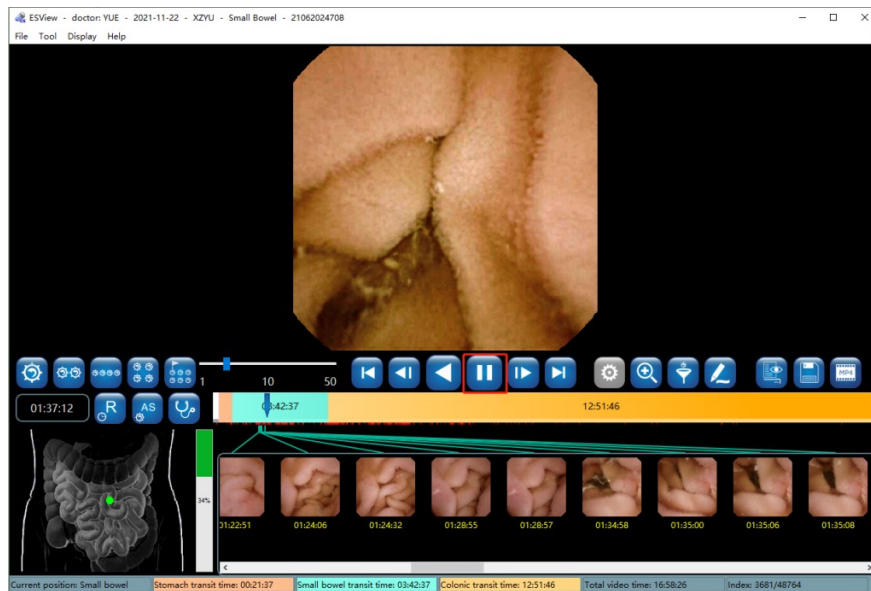






Figure 4-11: Pause Playback Button

4.4.3 Image Browsing

1. Click the , , , and  buttons to access single-image display mode, two-image

display mode, transverse four-image display mode, array four-image display mode, and multi-image display mode, respectively, as shown in Figures 4-12 to 4-16. The display mode can also be switched by selecting a display mode in the “Display” menu.

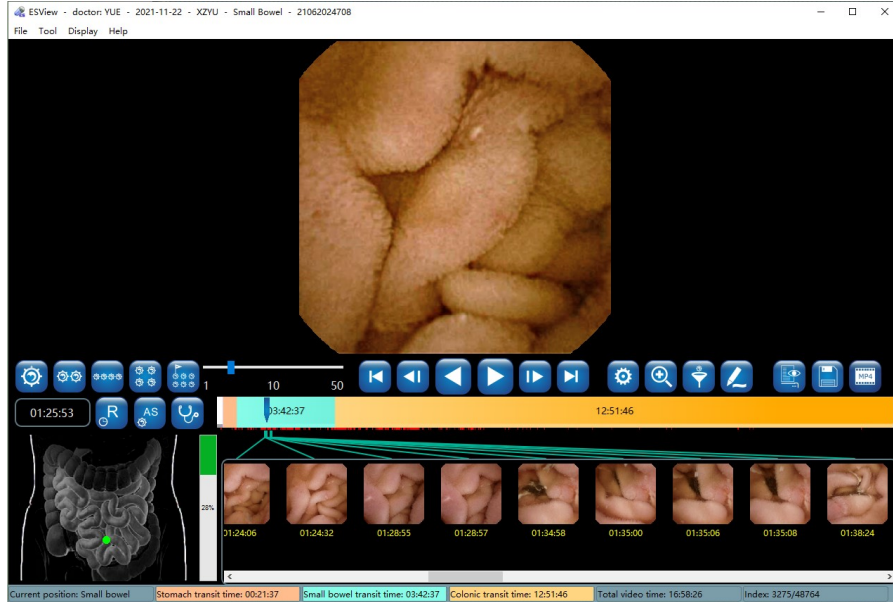


Figure 4-12: Single-Image Display Mode

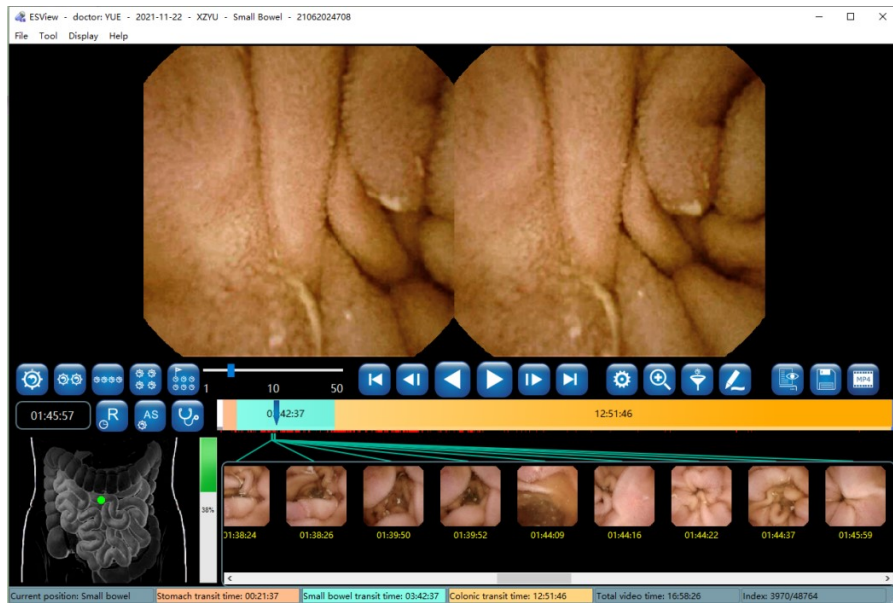


Figure 4-13: Two-Image Display Mode

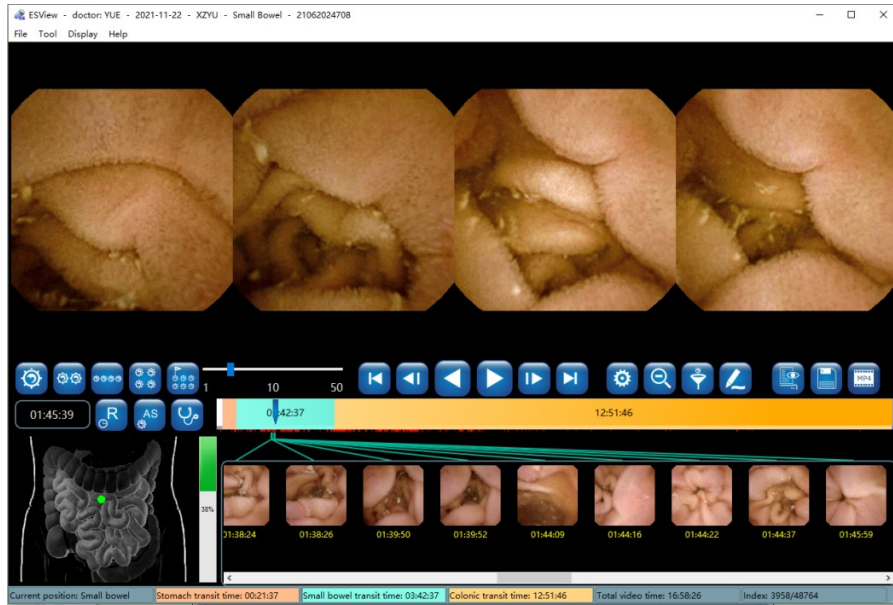


Figure 4-14: Transverse Four-Image Display Mode

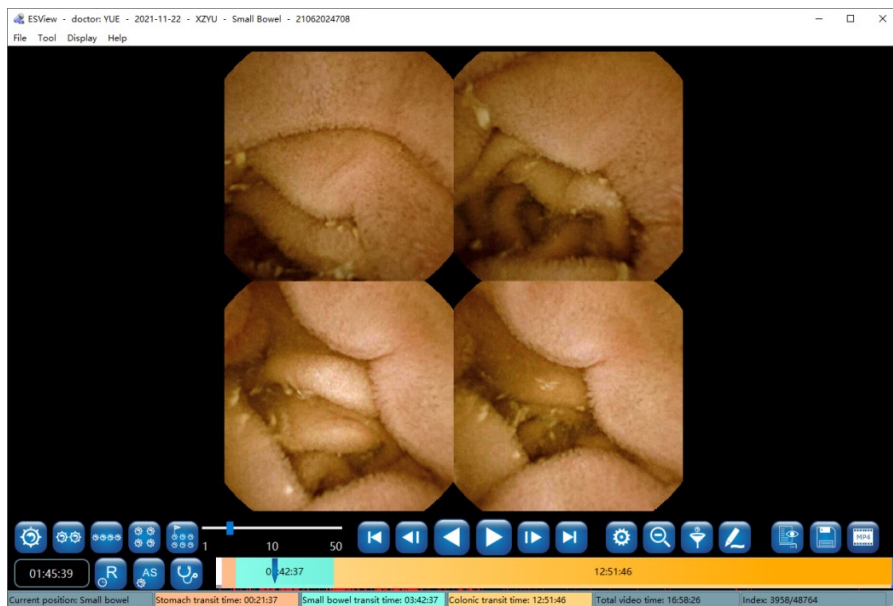


Figure 4-15: Array Four-Image Display Mode

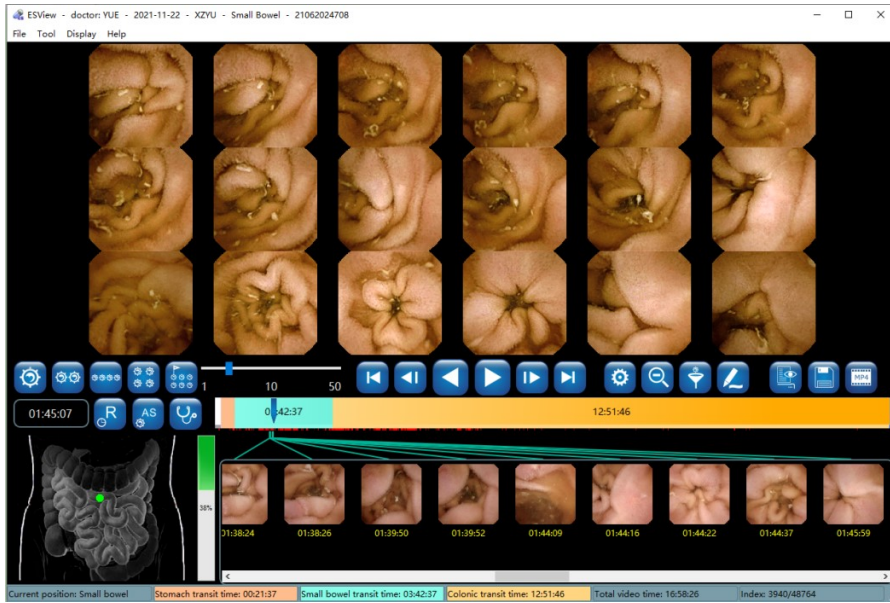
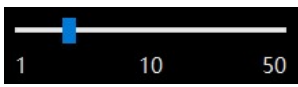











Figure 4-16: Multi-Image Display Mode

2. Use the playback speed slider  to adjust the video playback speed.
 Click  to play video in forward direction. Click  to play video in backward direction.
 Click  to display the next image frame. Click  to display the previous image frame.
 Click  to display the last image frame. Click  to display the first image frame.
3. In single-image and two-image display mode, click  to enlarge image display, and click  to shrink the image display. In other display modes, the enlargement function is unavailable. In such case, click  to switch to the single-image display mode. Figure 4-17 shows the single-image enlargement mode and Figure 4-18 shows two-image enlargement mode.

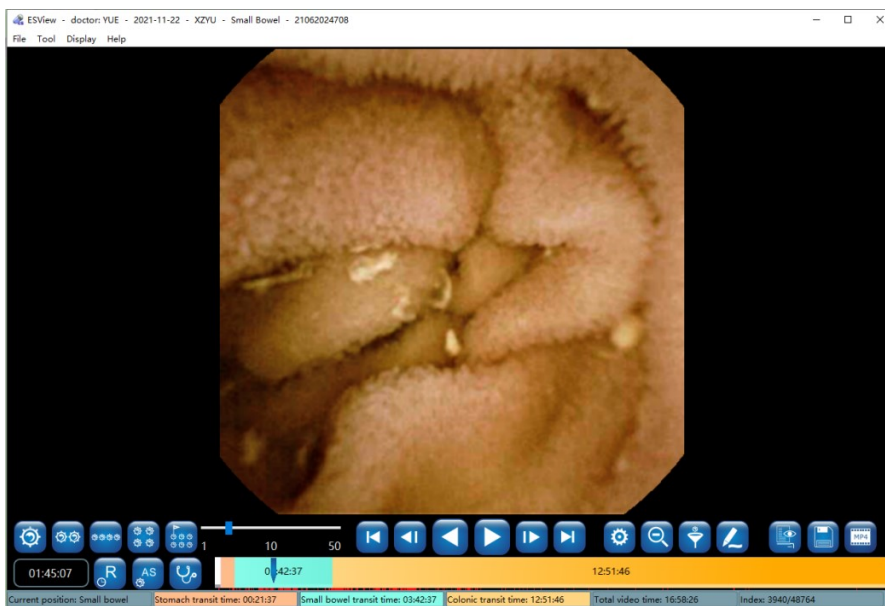




Figure 4-17: Single-Image Enlargement Mode



Figure 4-18: Two-Image Enlargement Mode

4. Click  to access the image processing control panel, as shown in Figure 4-19. Drag the corresponding sliders to adjust definition, brightness, and color. Checking the “Saturation” box and then drag the sliders below to adjust saturation. The image can also be processed using the software’s built-in algorithms, including denoise, distortion correction, and image enhancement. It is important to note that if any one of the four options (Image denoise, Distortion correction, Enhance-ICCI, Enhance-RGB) at the bottom is selected, the adjustment of definition, brightness, and color will be disabled, and the image is automatically

processed by the corresponding algorithm.

Click  to undo all the image processing.

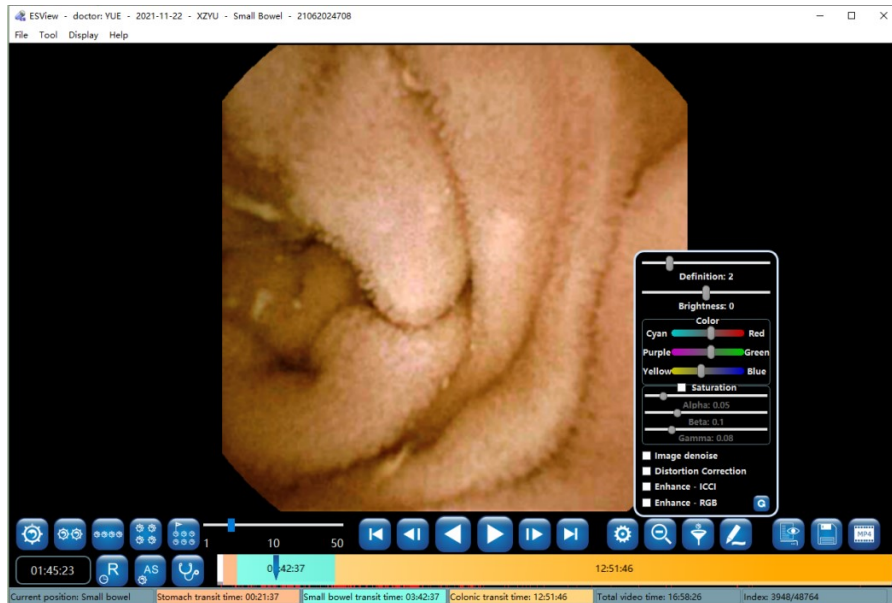







Figure 4-19: Image Processing Control Panel

- When the icon of the button next to the time window shows as , the time window and the thumbnail time display show image absolute time. Click , the button icon will change to , and the time window and the thumbnail time display will show image relative time. Click , and the button icon will change back to . The absolute time is the wall clock time when the image is captured by the capsule endoscope, the relative time is the time difference between the image and the first captured image.

4.4.4 Image Tagging

- Move the mouse over the image to be tagged and right click on the image. In the pop-up menu (Figure 4-20), select “Select the first esophagus image”, “Select the first stomach image”, “Select the first small intestine image”, “Select the first large intestine image”, or “Select the last digestive tract image” to tag the image as a landmark of the digestive tract. When an image is tagged, the colors in the progress bar will change automatically according to the position of the tagged image, separating the images by different sites of the digestive tract. The information in the status bar also changes automatically. The tagged images will appear in the bottom thumbnail area

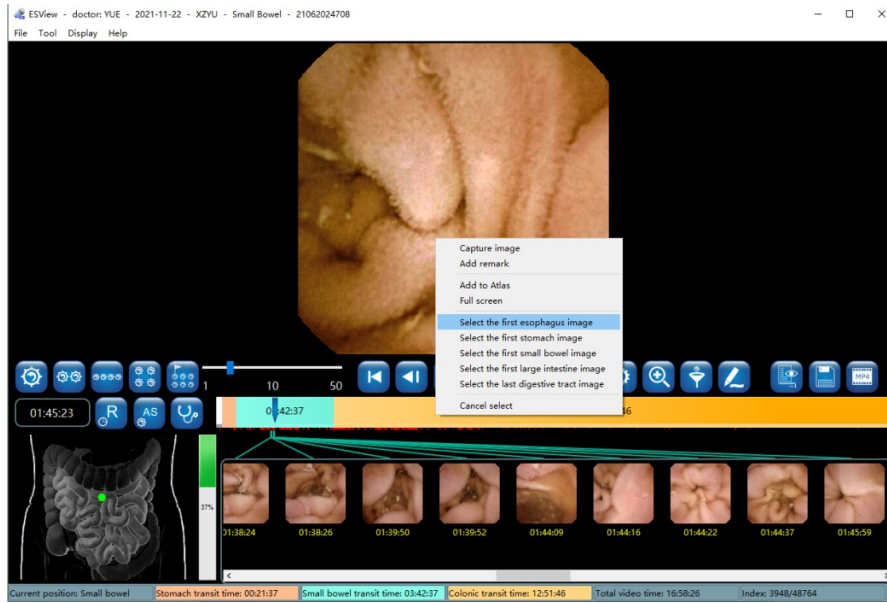


Figure 4-20: Image Tagging

2. In addition to tagging an image, the user can also capture an image. Move the mouse over the image to be captured and right click on the image, then select “Capture image” in the pop-up menu to capture the image (Figure 4-21). An alternative way to capture an image is to double click on the image. The captured image will also appear in the bottom thumbnail area. If the current image is already tagged, such as first esophagus image, the image capture function is disabled.

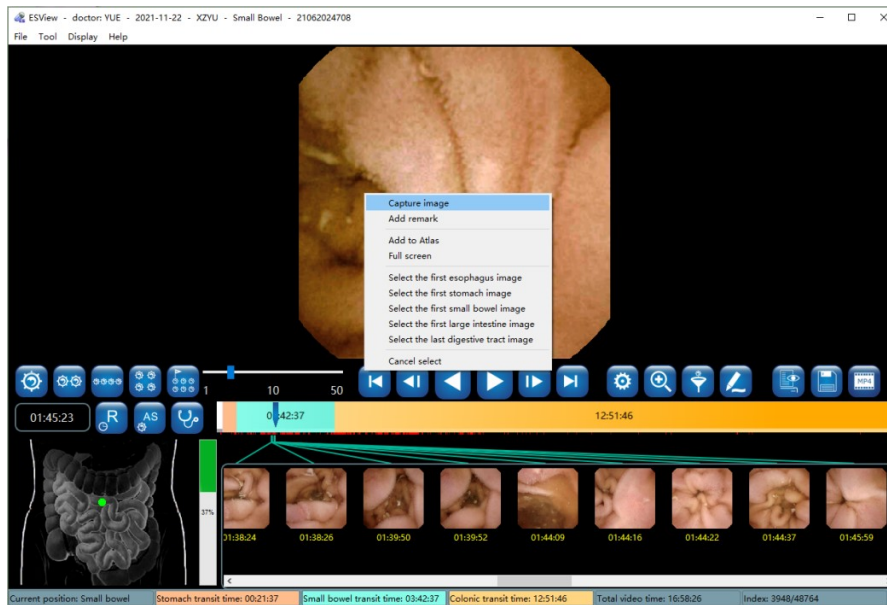


Figure 4-21: Image Capture

3. To cancel image tagging or remove an image from the captured image set, click on the image thumbnail in the thumbnail area to select the image, move the mouse over the image and

right click on the image then select "Cancel select" in the pop-up menu (Figure 4-22). The image will be removed from the thumbnail area and the colors in the progress bar will be updated accordingly.

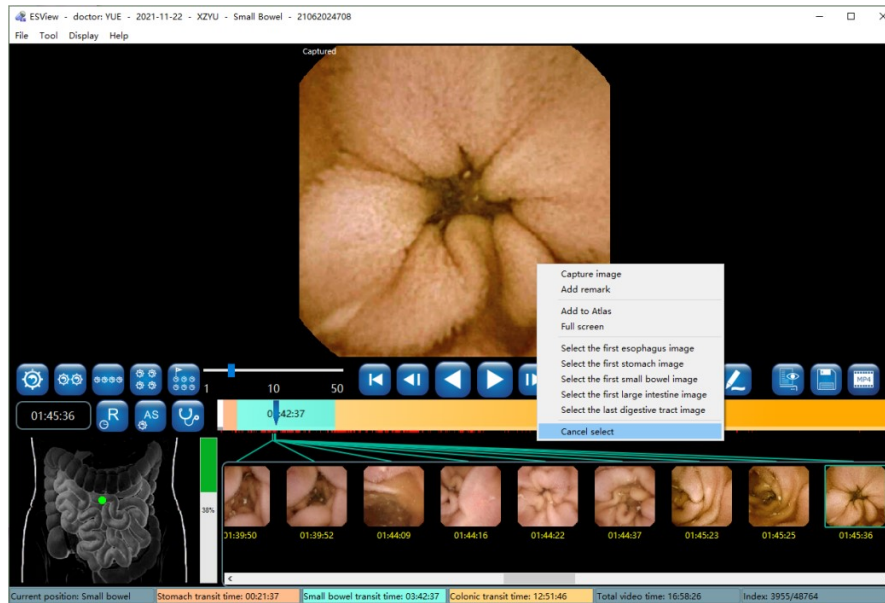



Figure 4-22: Cancel Image Tagging or Capture

4.4.5 Image Remark

1. Move the mouse over the image you want to add a remark to and right click on the image.

Select "Add remark" in the pop-up menu (Figure 4-23) or click  to access the add remark interface (Figure 4-24).

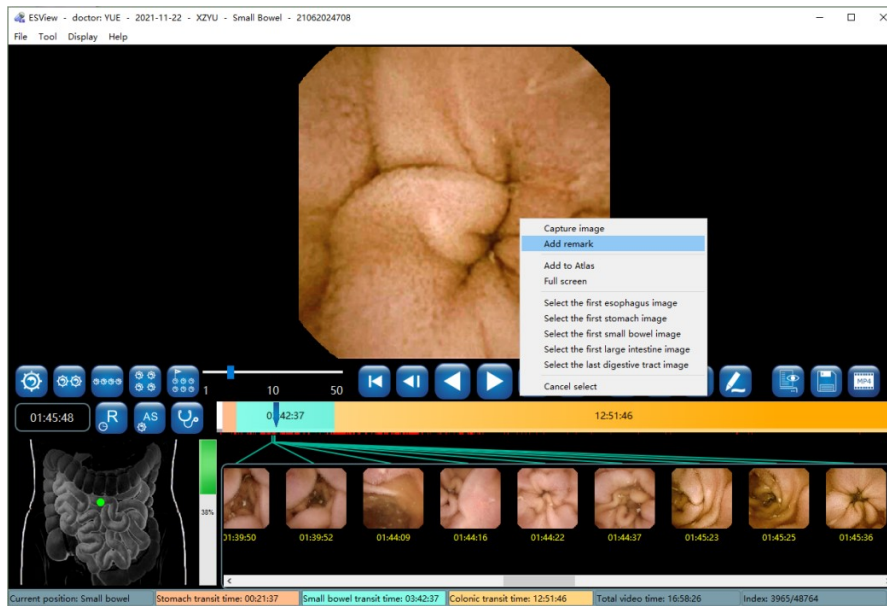


Figure 4-23: Add Remark Through Pop-Up Menu

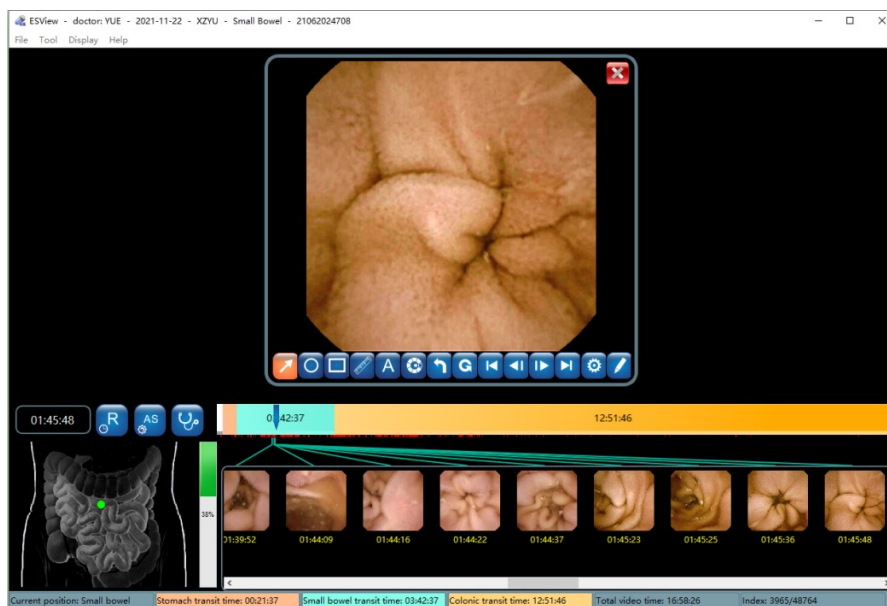








Figure 4-24: Add Remark Interface

- In the add remark interface, click  to add arrow markings. When the icon changes to , the user can add an arrow on the image by left clicking to set the start point and holding the left mouse button and dragging to set the endpoint. Click  to add circular markings. When the icon changes to , the user can add a circle on the image by left clicking to set

the center and holding the left mouse button and dragging to change its size (Figure 4-25). Click  to undo the previous marking and click  to undo all markings. The markings will be reflected on the images in the thumbnail area.

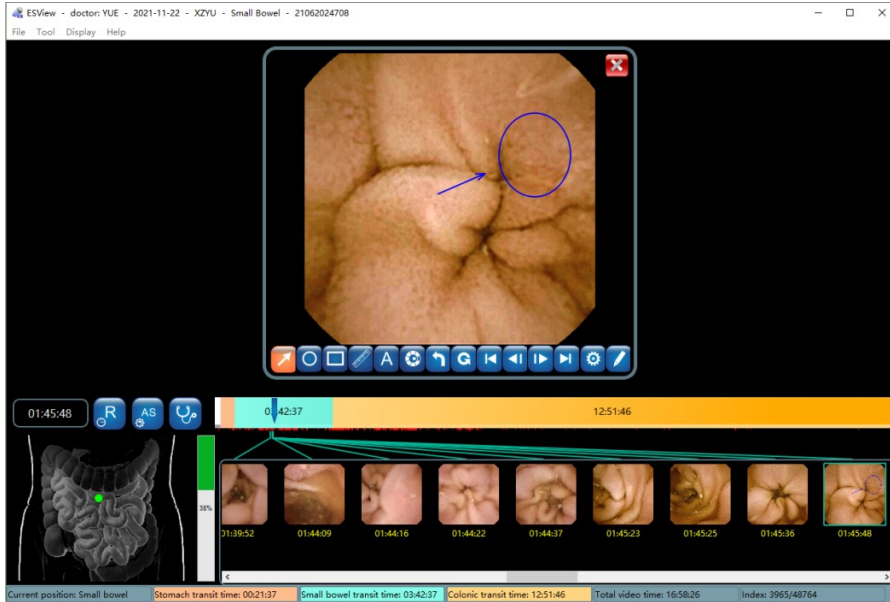


Figure 4-25: Add Markings




















- Click  to select the first tagged or captured image, click  to select the previous tagged or captured image, click  to select the next tagged or captured image, and click  to select the last tagged or captured image. Alternatively, the user can move the mouse over an image and scroll over images to select the desired image.

Table 4- 2 Description of buttons in the Add Remark Interface

Button	Function Description
	Add arrow remark
	Add circle remark
	Add rectangle remark
	Measure lesion length
	Add text remark

Button	Function Description
	Set remark color
	Remove the previous remark
	Remove all remarks
	Display the first selected image
	Display the previous selected image
	Display the next selected image
	Display the last selected image
	Image Setting
	Add text notes

4. Click  to access the add comment interface (Figure 4-26). The user can enter textual descriptions to the image into the comment text box in two ways:
- Input manually; or
 - Double click one of the expressions in the “Frequently used comment” list, a built-in list in EView software. The user can also add or remove entries in the list.
- The added comments will be reflected on the images in the thumbnail area.

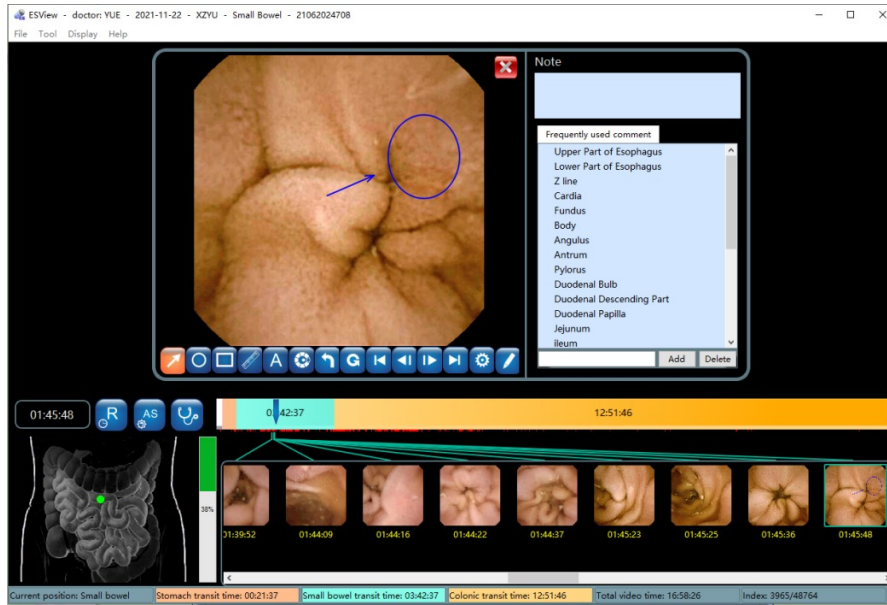



Figure 4-26: Add Remark Interface

- As previously described, clicking  brings up the image processing control panel (Figure 4-27). The sliders and checkboxes function the same as those in the image processing control panel described previously.

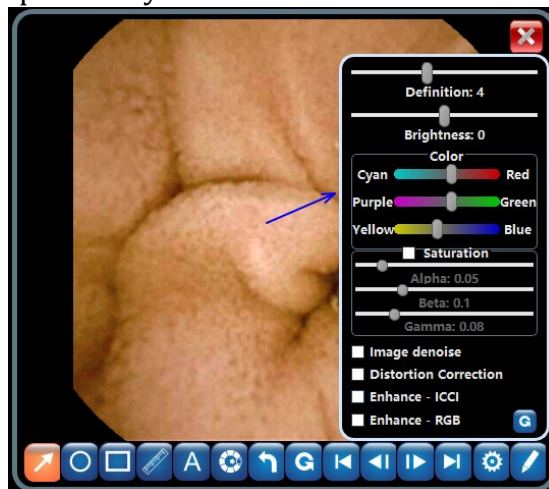



Figure 4-27: Image Processing Control Panel

- Click  to exit the add remark interface.

4.4.6 Thumbnails

- Thumbnails of the tagged and captured images are displayed in the thumbnail area, as shown in Figure 4-28.

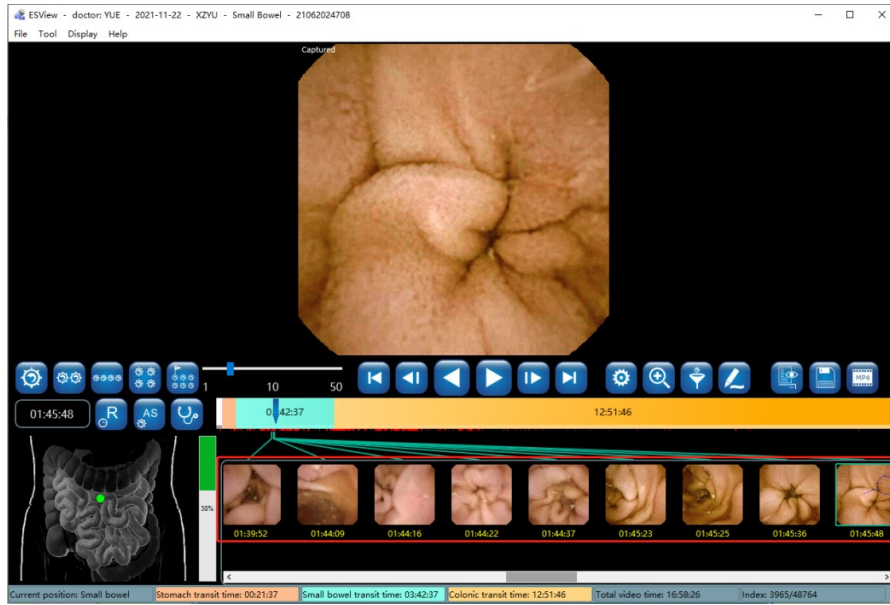


Figure 4-28: Thumbnail Display Area

2. In the thumbnail display area, move the mouse over the image to add remark to and right click on the image, then select “Add remark” in the pop-up menu (Figure 4-29) to add remark to the corresponding image using the add remark interface shown in Figure 4-26.

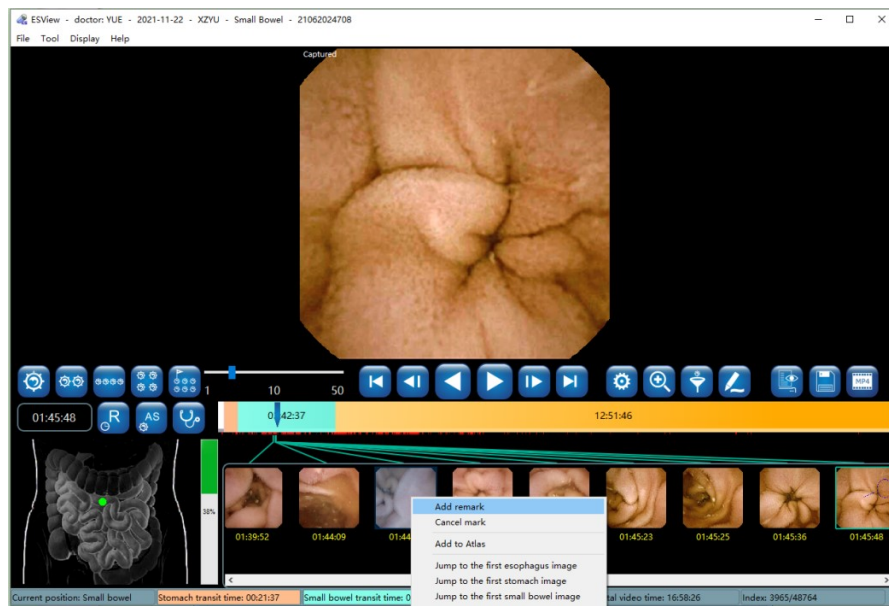


Figure 4-29: Add Remark to Thumbnail

3. In the thumbnail display area, right click on a thumbnail, then select “Cancel mark” in the pop-up menu to remove the thumbnail from the thumbnail area, as shown in Figure 4-30. Multiple thumbnails can be removed together by left clicking the thumbnails to be deleted while holding down the Ctrl key or by holding down the left mouse button and dragging the mouse to select multiple thumbnails, and then right clicking to select “Cancel mark” from the

pop-up menu.

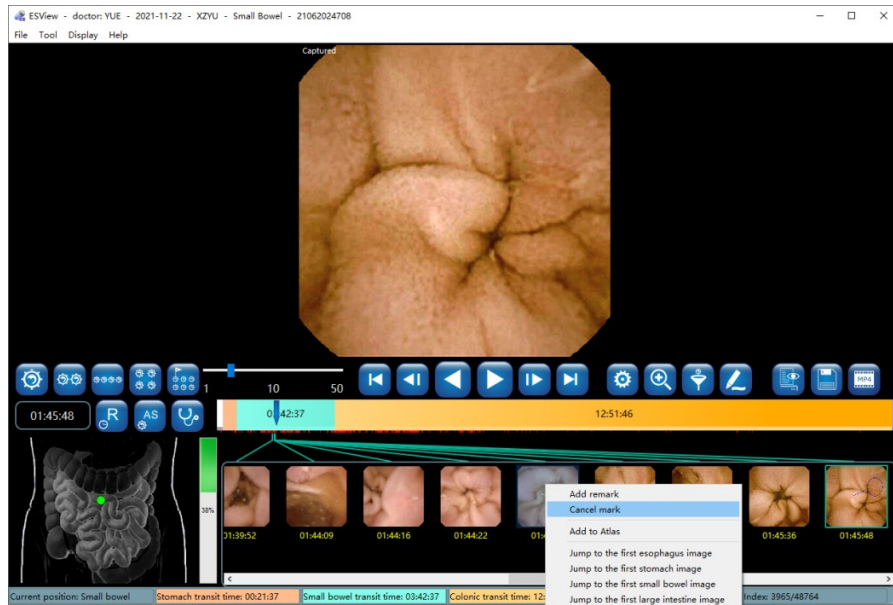



Figure 4-30: Thumbnail “Cancel Mark”

4. To go to a specific landmark and display the image in the main display area, in the thumbnail display area right click on a thumbnail and select “Jump to the first esophagus image”, “Jump to the first stomach image”, “Jump to the first small intestine image”, “Jump to the first large intestine image”, or “Jump to the last digestive tract image” in the pop-up menu. Alternatively, move the mouse over a thumbnail and then double click the left mouse button to display the corresponding image in the main display area.

4.4.7 Image Processing

1. Clicking  will bring up the image processing control panel (Figure 4-31). The user can adjust image definition, brightness, and color by using the corresponding sliders.

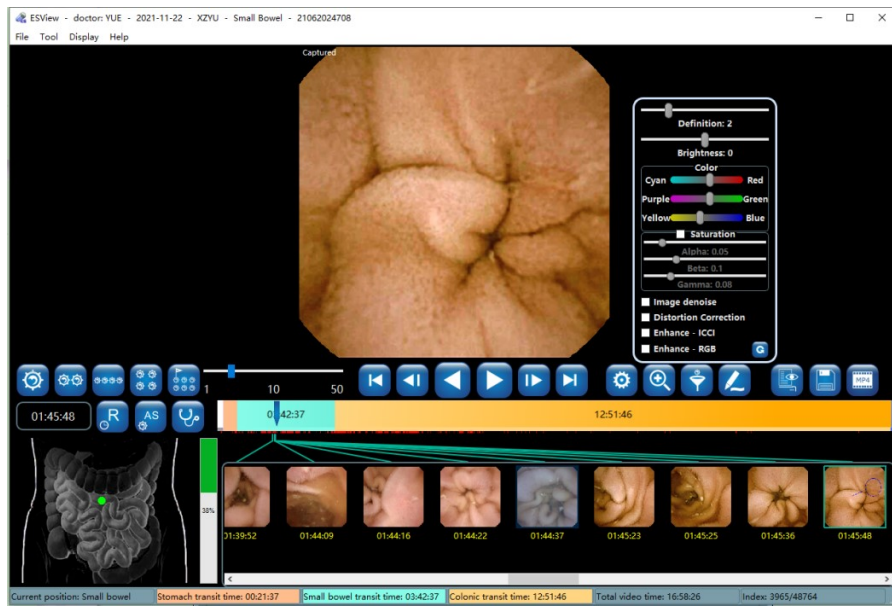


Figure 4-31: Image Processing Control Panel

- ESView software is equipped with image denoise algorithm. Check the “Image denoise” box and the effect as shown in Figure 4-32. To undo the denoising, uncheck the “Image denoise” box.

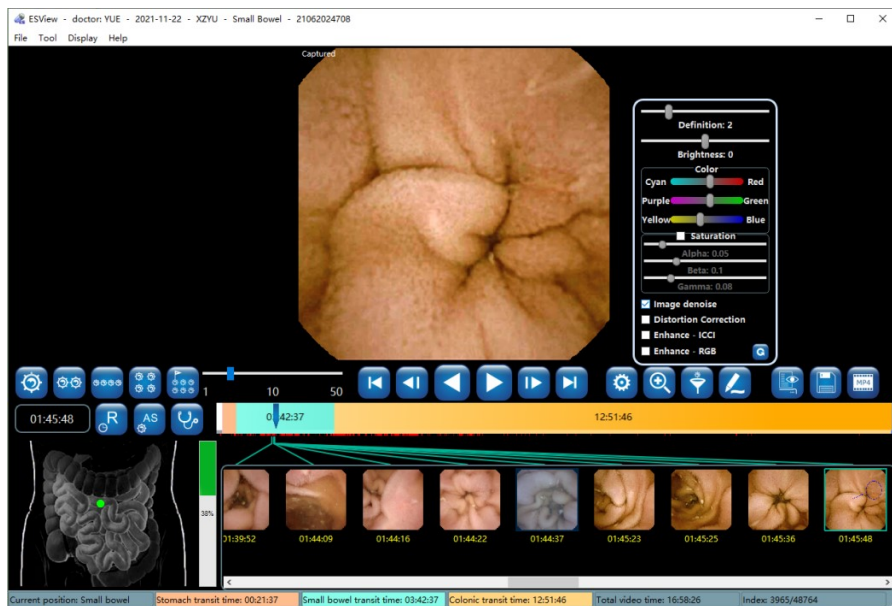


Figure 4-32: Image Denoise

- Check the “Distortion Correction” box to correct image distortion (Figure 4-33).

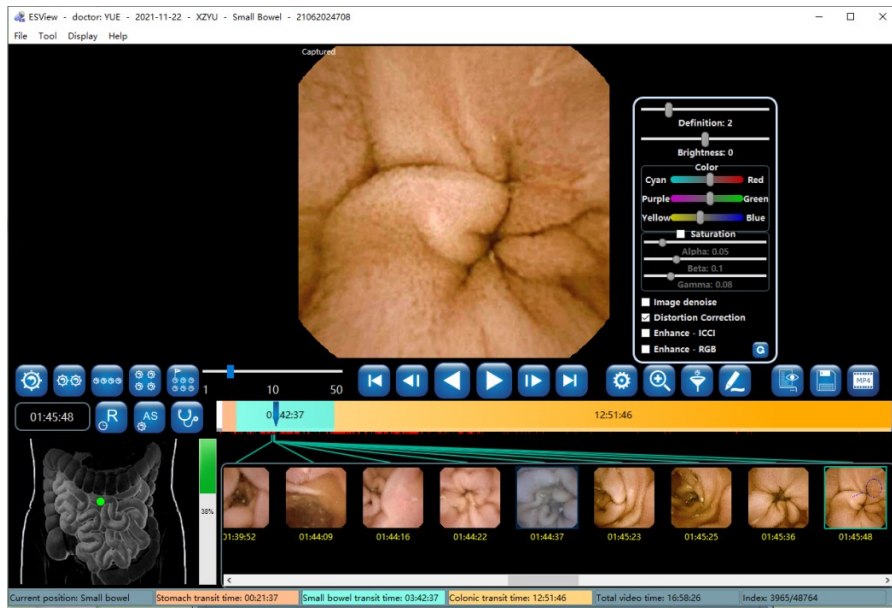


Figure 4-33: Distortion Correction

4. Check the “Enhance - ICCI” box to achieve the post-processing effect (Figure 4-34).

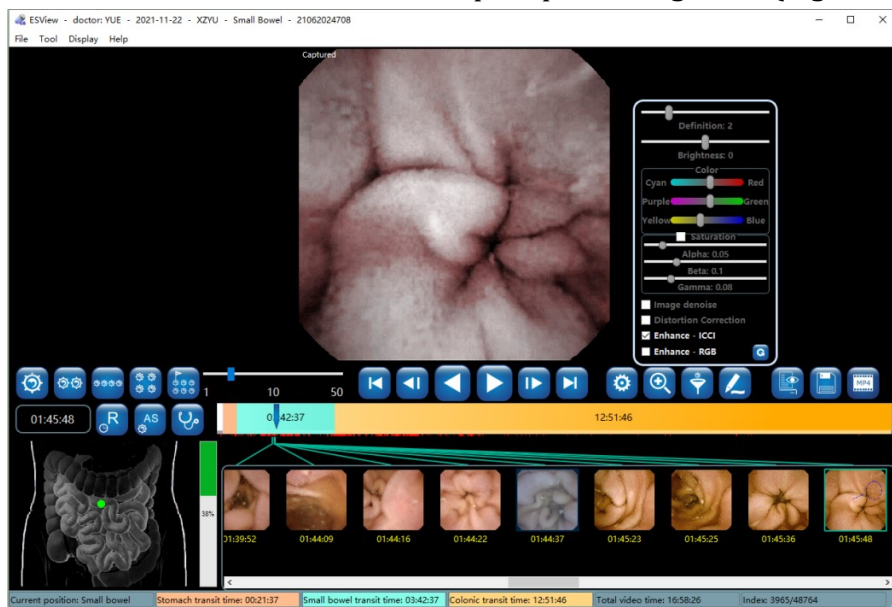


Figure 4-34: Image Enhancement - ICCI

5. Check the “Enhance - RGB” box to achieve the post-processing effect (Figure 4-35).

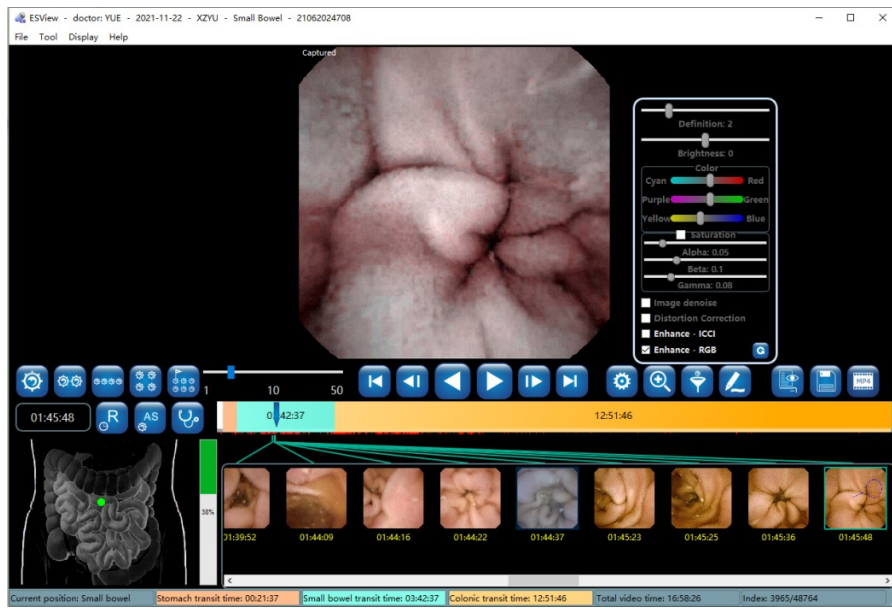


Figure 4-35: Image Enhancement - RGB

- Use the saturation adjustment sliders to adjust image saturation (Figure 4-36).

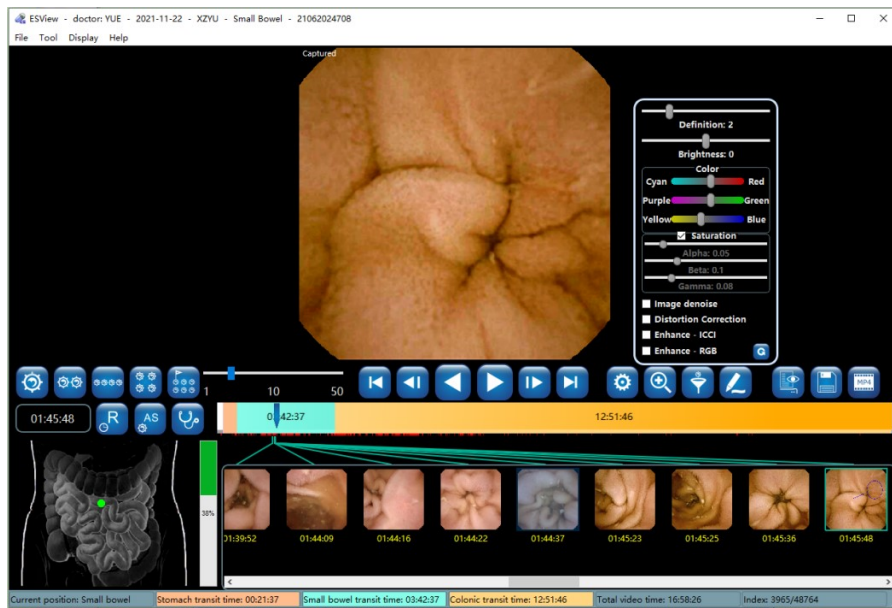


Figure 4-36: Image Saturation Adjustment

- Use the definition and brightness sliders to adjust the definition and brightness of the image (Figure 4-37).

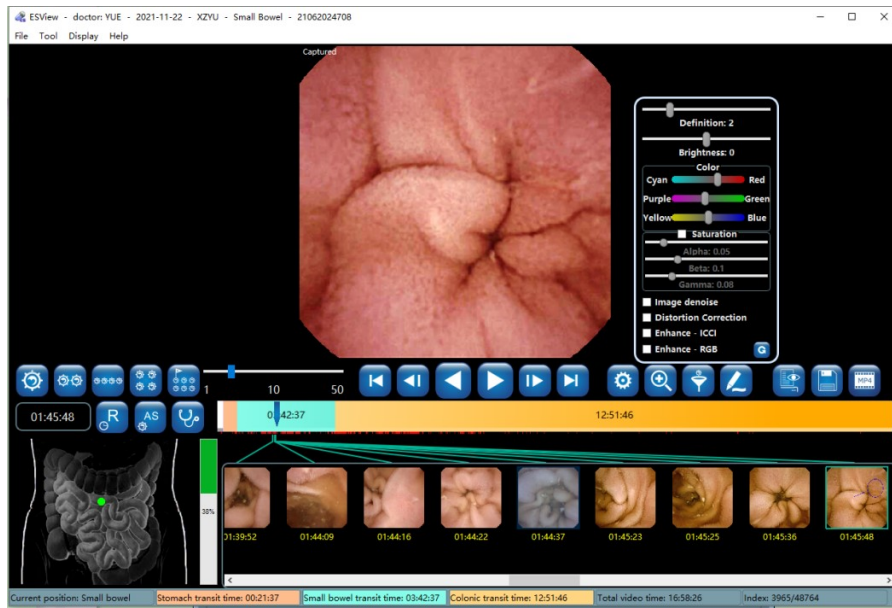




Figure 4-37: Definition and Brightness Adjustment

4.4.8 Browsing Mode

1. Click , when the button icon changes to , the similarity browsing mode will be activated (Figure 4-38). In this mode, the software displays only one image for all the adjacent similar images, reducing number of images to be browsed. Experiments show that the number of images is reduced by approximately 50%.

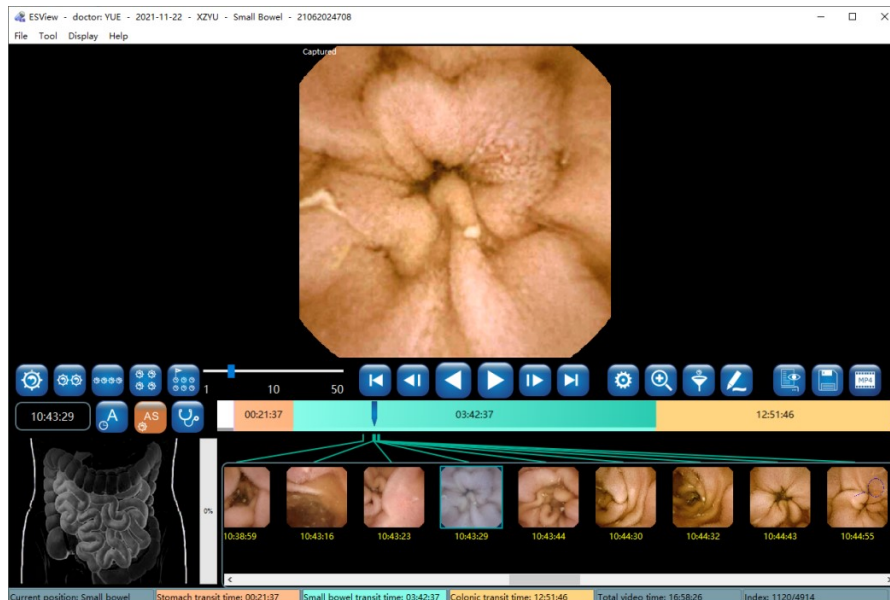


Figure 4-38: Similarity Browsing Mode