



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.

Note: Provide an operator with help information.



CAUTION

- **Failure to follow this instruction may 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 product components (Capsule, Data Recorder) which working in different frequencies (2.4GHz, 915MHz), which are used in conjunction with other components in the NaviCam SB System (AKS-1 Locator and ESView software).

When working normally, the equipment with the same frequency can be used together, and Capsules and the Data Recorder with different frequencies are not allowed to be mixed. The corresponding relationship between the associated product models and different frequencies is shown in the following Table1-1.

Table1-1 Relationship between associated product models and different frequencies

Frequency	Asscoiated Capsule Model	Asscoiated 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.

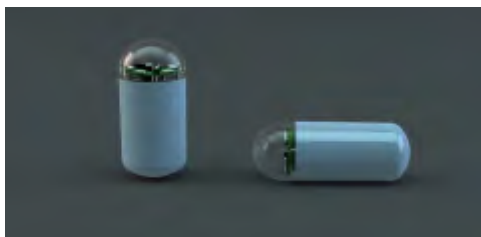


Figure 1-1: Capsule (2.4 GHz AKES-11SW, 915MHz AKES-11SI)



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.**

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 **Error! Reference source not found.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.**

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, Proscan mode (Optional)
- 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

1.3.1 Clinical Trial Report of NaviCam SB

Abstract and Summary of Results

Name of Sponsor: Ankon Technologies Co., Ltd	
Name of Investigational Device: AKE-1 (NaviCam SB) Capsule Endoscope System	
Title of Study	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

Investigator(s)	Hou Xiahou, MD, PhD, Lin Rong, MD, PhD	
Study Centre(s)	01: Union Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology, 02: Qilu Hospital of Shandong University, 03: First Affiliated Hospital of Naval Medical University (Shanghai Changhai Hospital)	
Publication	N/A	
Study Period	From: September 23rd, 2021 To: December 30th, 2021	Phase of development: NMPA approved product, V&V phase for US development
Objective and Evaluation Indicators	<p>Objective</p> <p>This study uses a comparative method to evaluate the performance of the AKE-1(NaviCam SB) capsule endoscope system in comparison to the PillCam SB3 capsule system for the diagnosis of small bowel diseases.</p> <p>Primary Indicator(s)</p> <ol style="list-style-type: none"> 1.Record the findings after independent image reading, and evaluate the agreement between the two SB capsule endoscope systems with respect to the findings. 2.Evaluate the diagnostic performance of AKE-1 capsule endoscopy system and PillCam SB3 capsule endoscopy system for small bowel diseases per Subject analysis, normal versus abnormal. <p>Secondary Indicator(s)</p> <ol style="list-style-type: none"> 1. Ease of swallowing the capsule; 2.Intestinal transit time (time between ingestion and excretion); 3.Capsule excretion time; 4.Diagnostic yield when compared to other standard mucosal imaging procedures (upper endoscopy, enteroscopy, colonoscopy, etc.); 5.Quality of small bowel images; 6. Image reading time; 	

	7. Agreement between two or more reviewers with respect to interpretation of the images obtained.
Methodology	A prospective, self-controlled clinical trial.
Number of Subjects	Planned: 100 Enrolled: 97 Analysed: 87
Inclusion Criteria	1) Adult Subjects (≥ 18 years old) who have symptoms of small bowel disease or suspected GI bleeding; 2) Those need capsule endoscopy because the recurring GI symptoms cannot be explained by other imaging methods; 3) Those can understand and accept this study protocol and voluntarily sign an informed consent.
Exclusion Criteria	1) Subject is expected to undergo MRI examination within 7 days after ingestion of the capsule; 2) Subject with known gastrointestinal motility disorders; 3) Subject with known or suspected gastrointestinal obstruction, stenosis or fistula; 4) Subject with known or suspected delayed gastric emptying; 5) Subject suffers from any condition, such as swallowing problems, which precludes compliance with study and/or device instructions; 6) Subject has any allergy or other known contraindication or intolerance to the medications used in the study; 7) Subject has any condition, which precludes compliance with study and/or device instructions; 8) Women who are either pregnant or nursing at the time of screening; 9) Concurrent participation in another clinical trial using any investigational drug or device; 10) Subject suffers from a life-threatening condition;

	<p>11) Subjects with history or clinical evidence of renal disease and/or previous clinically significant laboratory abnormalities of renal function parameters;</p> <p>12) Subjects with pace-maker or implantable cardioverter other implantable electronic medical device;</p> <p>13) Subject with an easily magnetized metal part;</p> <p>14) Subject requires endoscopic placement of the capsule;</p> <p>15) Others considered by the investigator not suitable for this study.</p>
Medical Devices Used in Trial	<p>Investigational Device: AKE-1 (NaviCam SB) System</p> <p>Model: AKE-1</p> <p>Source: ANKON Technologies Co., Ltd.</p> <p>Registration Certificate No.: National Device Registration Approval 20173220096</p> <p>Control device: PillCam Capsule Endoscopy System</p> <p>Model: PillCam SB3</p> <p>Source: Given Imaging, Inc.</p> <p>Registration Certificate No.: National Device Registration Import 20173062353</p>
Duration of Treatment for Subject	<p>14 days</p>
Statistical Methods	<p>SAS 9.4 software is used for analysis. The safety data set is used for analysis of the safety, and data of full analysis set and Per Protocol Set are used for analysis of efficacy.</p> <p>A two-sided test is used for all statistical tests, and P value less than or equal to 0.05 will be considered statistically significant. (unless otherwise specified).</p> <p>The description of quantitative indicators will calculate the mean, standard deviation, median, minimum, and maximum.</p> <p>Classification indicators are described by the number of cases and percentages of each category.</p>

Primary Efficacy Results:**Per Subject Analysis:** Normal versus Abnormal

AKE-1 (NaviCam SB) CE		PillCam SB3 CE		
		Normal	Abnormal	Total
	Normal	12	2	14
	Abnormal	7	66	73
	Total	19	68	87

PPA (95% CI): 97.06% (89.90%, 99.19%).

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).

Per Findings Analysis:

Diagnosis	AKE-1 (NaviCam SB) Capsule No. of findings	PillCam SB3 Capsule No. of findings
Vascular diseases (bleeding, blood clots, vasodilation and lymphatic dilation)	43	36
Inflammatory lesions (erythema, edema, erosion, aphthous ulcer)	58	56
Tumor /polyps /lump	10	10
Malabsorption (spue, abnormal villi)	2	0

Iatrogenic, including radiation enteritis	0	0
Ulcer/rupture	22	26
Other (including parasites and foreign bodies)	10	13

The diagnostic consistency (FAS/PPS) analysis results of different types of lesions show that there were no statistically significant differences in the diagnosis 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 ($p=0.4669$) between the trial capsule endoscopy and control capsule endoscopy. The number of cases diagnosed as malabsorption and nosocomial diseases by trial capsule endoscopy and control capsule endoscopy is 0. Analysis results of lesion detection (FAS/PPS) show that there is no significant difference in lesion detection between the trial capsule endoscopy and the control capsule endoscopy.

Secondary Efficacy:

The analysis results of swallowing difficulty (FAS /PPS) of the capsules show that there is no significant difference in swallowing difficulty between trial capsule endoscope and control capsule endoscope.

Analysis results of intestinal transit time (FAS /PPS) show that there is a significant difference between the trial capsule endoscope and the control capsule endoscope, and the trial device is significantly higher than the control device ($t=5.00$, $P < 0.01$). The mean value of difference of intestinal passage and 95% confidence interval is 116.3 (70.00,162.5) min.

Intestinal excretion time (FAS/PPS) analysis results show that there is no significant difference in intestinal excretion time between trial capsule endoscope and control capsule endoscope. Mean value of difference of intestinal passage and 95% confidence interval is -23.00 (-69.94,23,94) min.

Analysis results of comparison of diagnostic rates with other standard mucosal imaging tools (upper gastrointestinal endoscopy, enteroscopy, colonoscopy, etc.) (examination results within one week before or after enrollment) (FAS/PPS) show that the consistency of diagnostic rate between the trial capsule endoscope and other standard mucosal imaging diagnostic tools is 80.33%. The difference has no statistical significance. ($\chi^2=3.0000$, $p=0.8333$). The consistency of diagnostic rate between control capsule endoscope and other

standard mucosal imaging diagnostic tools is 75.41%. The difference has statistical significance. ($X^2=5.4000$, $p=0.0201$).

Analysis results of small bowel image quality (FAS/PPS) show that there is no significant difference in all indicators of small bowel image quality between trial capsule endoscope and control capsule endoscope.

Analysis results of Image viewing time (FAS/PPS) show that the image viewing time of trial capsule endoscope is 2.12min higher than that of control capsule endoscope, but there is no statistically significant difference between the two groups.

Consistency analysis results of image interpretation (FAS/PPS) by two or more viewers show that the consistency of image interpretation of trial capsule endoscope is lower than that of control group, and the difference between the two groups is statistically significant ($X^2=8.3104$, $P=0.0039$).

Safety Results:

Incidence Rate: 1.15%

Adverse Event (AE): Capsule retention occurred in 1 of 87 Subjects evaluated in trial.

Serious Adverse Event (SAE): 0%

Unanticipated Adverse Device effect (UADE): 0%

Conclusion of Clinical Trial: The AKE-1 (NaviCam SB) System (model: AKE-1) of ANKON Technologies Co., Ltd. in comparison with PillCam SB3 Capsule Endoscope System (model: SB3) of Given Imaging, Inc., has a diagnostic Overall Percent Agreement rate and 95% confidence interval of 89.66% (81.50%, 94.46%), and the overall percent agreement Kappa and 95% confidence interval is 0.6652 (0.4653, 0.8652).

Results from this study indicate that AKE-1 (NaviCam SB) and PillCam SB3 perform similarly in comparison and provide an effective non-invasive means for detecting small bowel diseases.

Date of the Report: 19-01-2022

1.3.2 Clinical Trial Report of Retrospective Evaluation

Abstract and Summary of Results

Name of Sponsor: Ankon Technologies Co., Ltd		
Name of Investigational Device: AKE-1 (Navicam SB) Capsule Endoscope System		
Title of Study	Retrospective Evaluation of the AKE-1 (Navicam SB) Capsule Endoscope System Conventional Reading in Comparison with ProScan and PillCam SB3 Capsule System SBI for the Diagnosis of Small Bowel Diseases	
Investigator(s)	Hou Xiahou, MD, PhD	
Study centre(s)	Union Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology	
Publication	N/A	
Study period	From: March 3rd, 2022 To: April 10th, 2022	Phase of development: NMPA approved product, V&V phase for US development
Objectives	<u>Primary study objective</u> 1. To evaluate the performance of the AKE-1 (Navicam SB) Capsule System ESView software with ProScan feature in comparison with the PillCam SB3 Capsule system SBI feature (per patient analysis). <u>Secondary study objective</u> 1.To evaluate the performance of the AKE-1 (Navicam SB) Capsule System ESView software with ProScan feature in comparison with the PillCam SB3 Capsule system SBI feature (per findings analysis). 2.Evaluating read time of AKE-1 (Navicam SB) with ProScan and PillCam SB3's Rapid with SBI. 3.Image review time of AKE-1 (Navicam SB) conventional reading versus ProScan assisted reading.	
Study design	Retrospectively evaluate visual images of the small bowel that were prospectively collected from patients. The video images will be obtained as previously anonymized, de-	

	identified, and reviewed 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 for each software system.
Number of Subjects	Enrolled: 87 Analysed: 87
Inclusion Criteria	Patients who participated in the study titled <i>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</i> (Ethics Approval No. [2021] (0635-01)) and were included in the FAS.
Exclusion Criteria	None.
Medical devices used in trial	Investigational Device: AKE-1 (Navicam SB) Capsule Endoscope System Model: AKE-1 Source: ANKON Technologies Co., Ltd. Control device: PillCam Capsule Endoscopy System Model: PillCam SB3 Source: Given Imaging, Inc. Registration Certificate No.: National Device Registration Import 20173062353
Duration of treatment for Subject	NA
Statistical methods	SAS 9.4 software is used for analysis. The safety data set is used for analysis of the safety, and data of full analysis set and Per Protocol Set are used for analysis of efficacy. A two-sided test is used for all statistical tests, and P value less than or equal to 0.05 will be considered statistically significant. (unless otherwise specified).

	<p>The description of quantitative indicators will calculate the mean, standard deviation, median, minimum, and maximum.</p> <p>Classification indicators are described by the number of cases and percentages of each category.</p>
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Primary Efficacy Results:**Per Subject Analysis: Normal versus Abnormal**

AKE-1 (Navicam SB) CE	PillCam SB3 CE		Total
	Normal	Abnormal	
Normal	3	0	3
Abnormal	3	81	84
Total	6	81	87

Overall Percent Agreement (95% CI): 96.55% (90.35%, 98.82%)

PPA and 95% confidence interval is 100.00% (95.47%, 100.00%)

NPA and 95% confidence interval is 50.00% (18.76%, 81.24%)

Overall percent agreement Kappa and 95% confidence interval is 0.6506 (0.2866, 1.0000)

PPV and 95% confidence interval is 96.43% (90.02%, 98.78%)

NPV and 95% confidence interval is 100.00% (43.84%, 100.00%)

McNemar test results $X^2=3.0000$, $p=0.0833$

Secondary Efficacy Results:**Per Findings Analysis:**

Diagnosis	AKE-1 (Navicam SB) Capsule No. of findings	PillCam SB3 Capsule No. of findings

Vascular diseases (bleeding, blood clots, vasodilation and lymphatic dilation)	67	63
Inflammatory lesions (erythema, edema, erosion, aphthous ulcer)	72	68
Tumor /polyps /lump	18	12
Malabsorption (spue, abnormal villi)	4	4
Iatrogenic, including radiation enteritis	0	0
Ulcer/ulceration	29	28
Other (including parasites and foreign bodies)	31	21

Table 16.2.2.1 to Table 16.2.2.8 are the diagnostic consistency (FAS/PPS) analysis results of different types of lesions. 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 trial capsule endoscopy and control capsule endoscopy. The number of cases diagnosed as nosocomial diseases by trial capsule endoscopy and control capsule endoscopy is 0.

Table 16.2.3 shows the results of the comparative analysis of the reading time of the trial capsule endoscope and the control capsule endoscope (FAS/PPS), the Image review time of trial capsule endoscope is 1.63min higher than that of control capsule endoscope, and the difference was statistically significant. Table 16.2.4 shows the results of the mean reading time comparison between the trial device assisted reading and conventional reading (FAS/PPS), the difference between the mean reading time of assisted reading and conventional reading with 95% confidence interval was -36.63 (-46.29, -26.72) min, the difference was statistically significant.

Conclusion of clinical trial:

The AKE-1 (Navicam SB) Capsule Endoscope System (model: AKE-1) of ANKON Technologies Co., Ltd. in comparison with PillCam SB3 Capsule Endoscope System (model: SB3) of Given Imaging, Inc., has a diagnostic

Overall Percent Agreement rate and 95% confidence interval of 96.55% (90.35%, 98.82%) , and the overall percent agreement Kappa and 95% confidence interval is 0.6506 (0.2866, 1.0000). The results of this study showed that the clinical performance of the AKE-1 (Navicam SB) and PillCam SB3 reading systems was similar, and the AKE-1 (Navicam SB) assisted reading system significantly reduced the physician's reading time compared to conventional reading (21.47 ± 8.05 vs. 58.10 ± 45.28 , $p < 0.0001$).

Date of the Report: 2022-04-12

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, 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.

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.

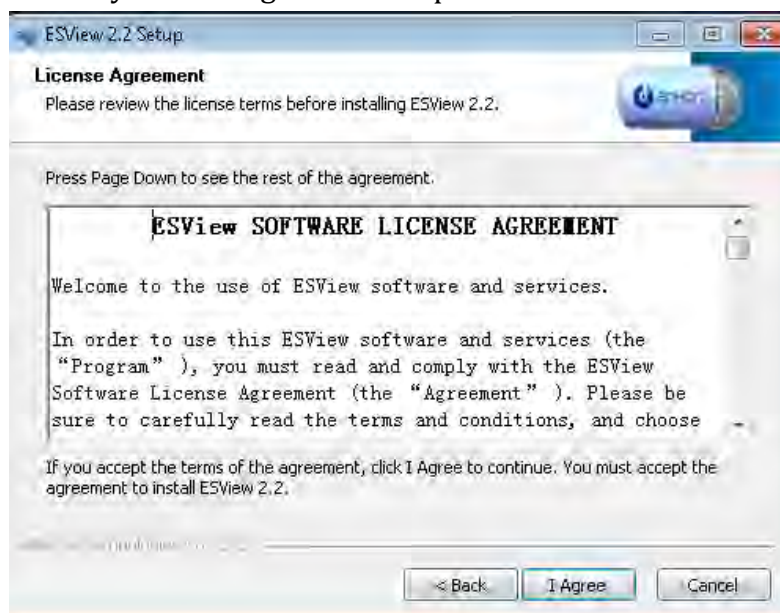


Figure 3-2: Software License Agreement Dialog Box

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.

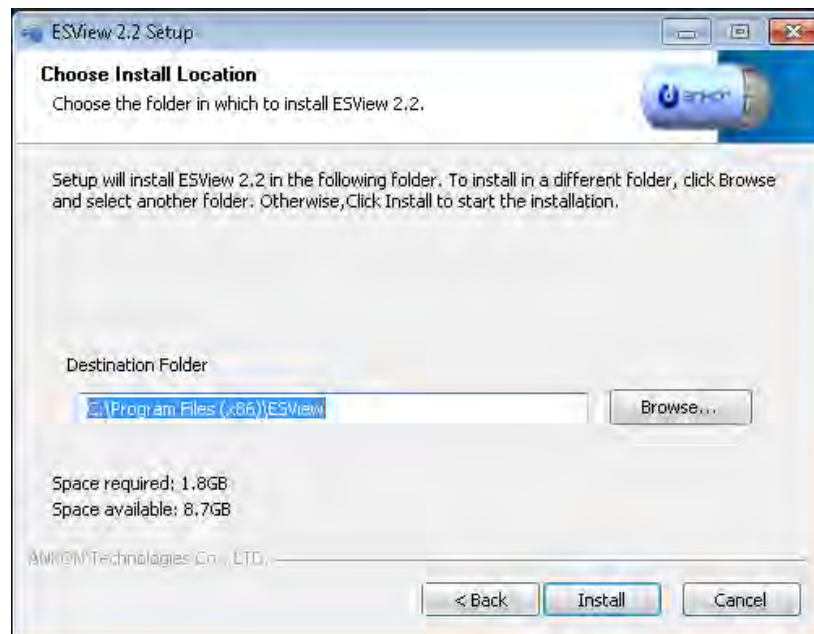


Figure 3-3: Selection of Installation Directory

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

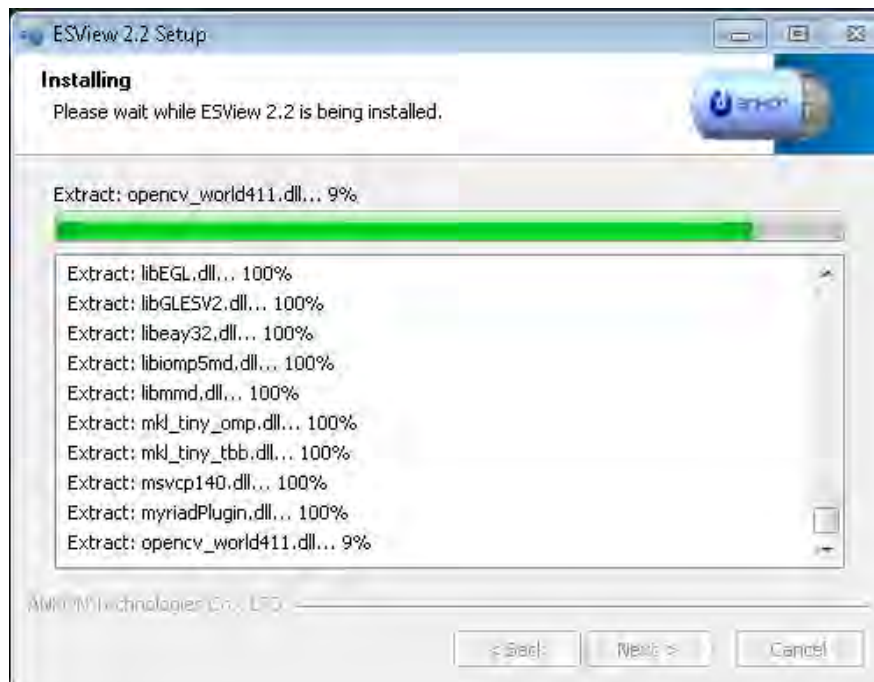


Figure 3-4: Installation Progress Dialog Box

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.

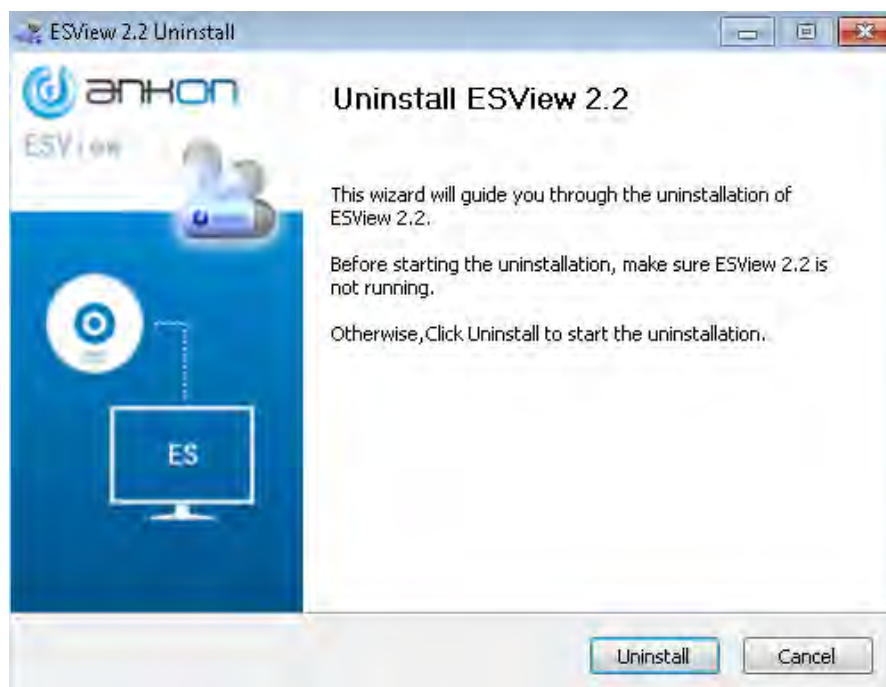


Figure 3-6: Uninstallation Dialog Box

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

3.3.1 Operation Steps

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.

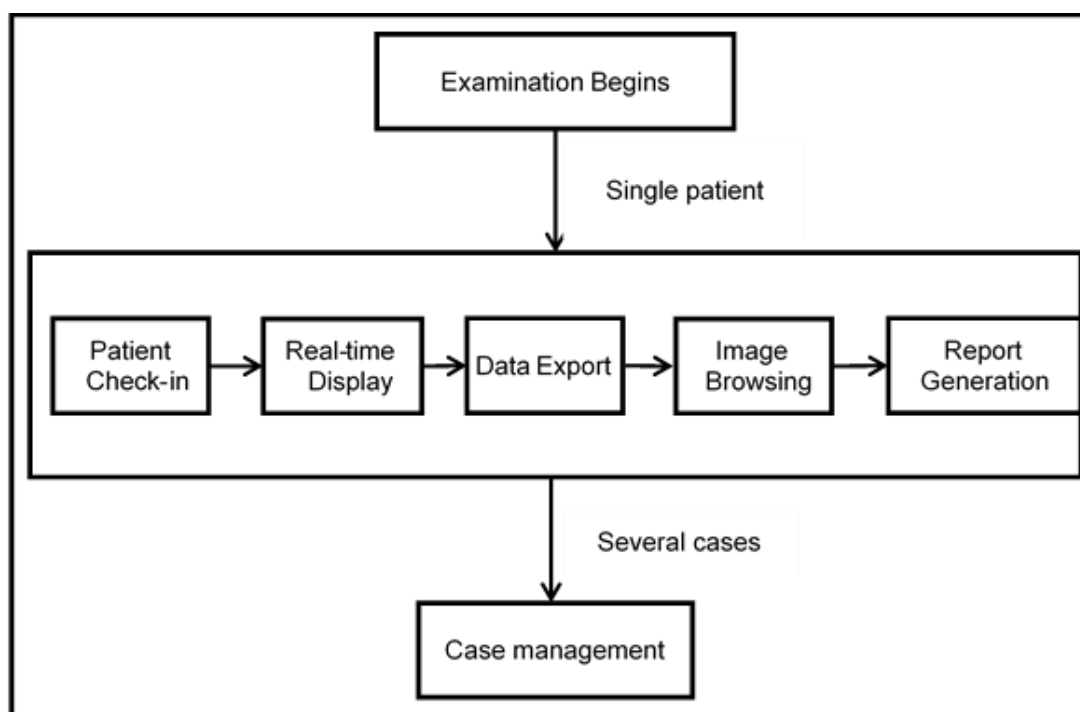


Figure 3-8: NaviCam SB System Workflow

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.

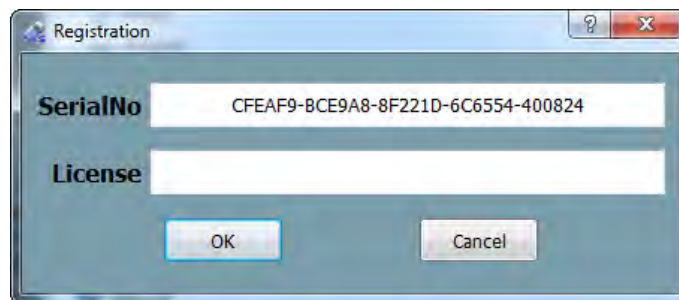


Figure 3-10: Registration Interface

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).

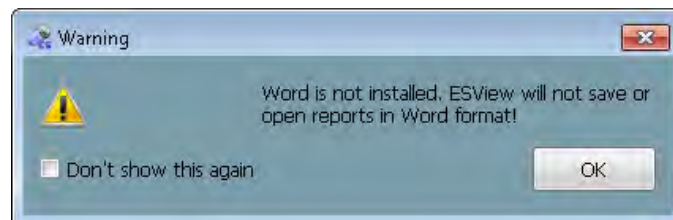


Figure 3-12: Dialog Box Alerting that Word Format Report Is Not Supported

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.

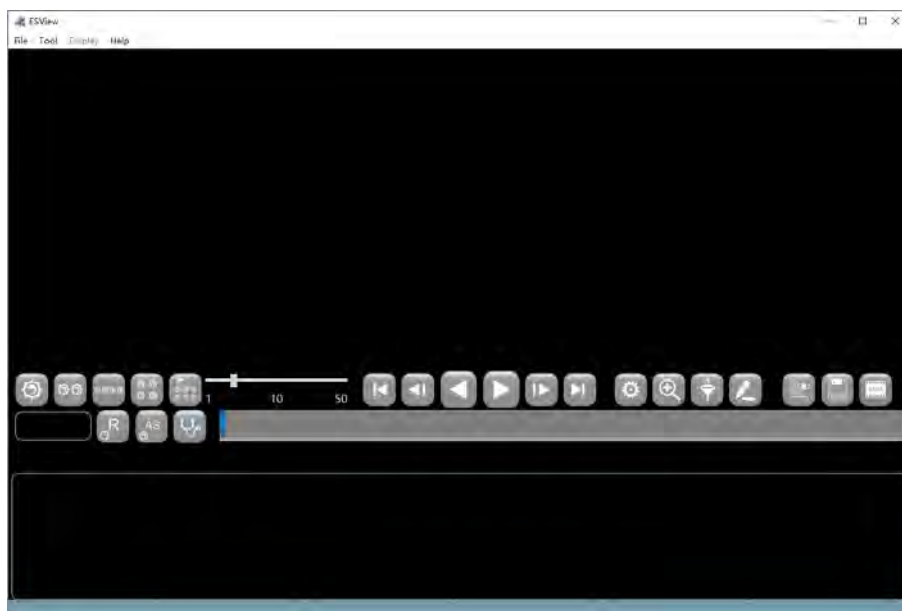


Figure 4-1: Main ESView Software Interface

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.

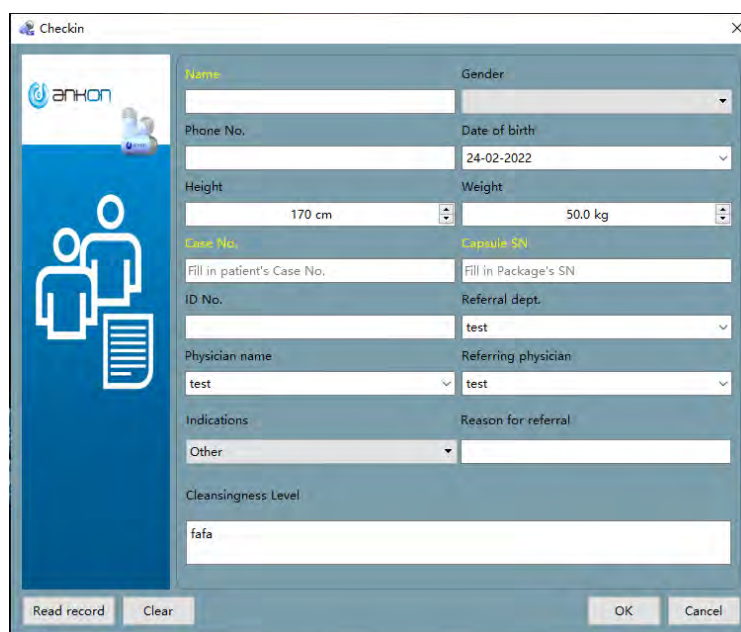


Figure 4-2: Patient Check-in Interface

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.

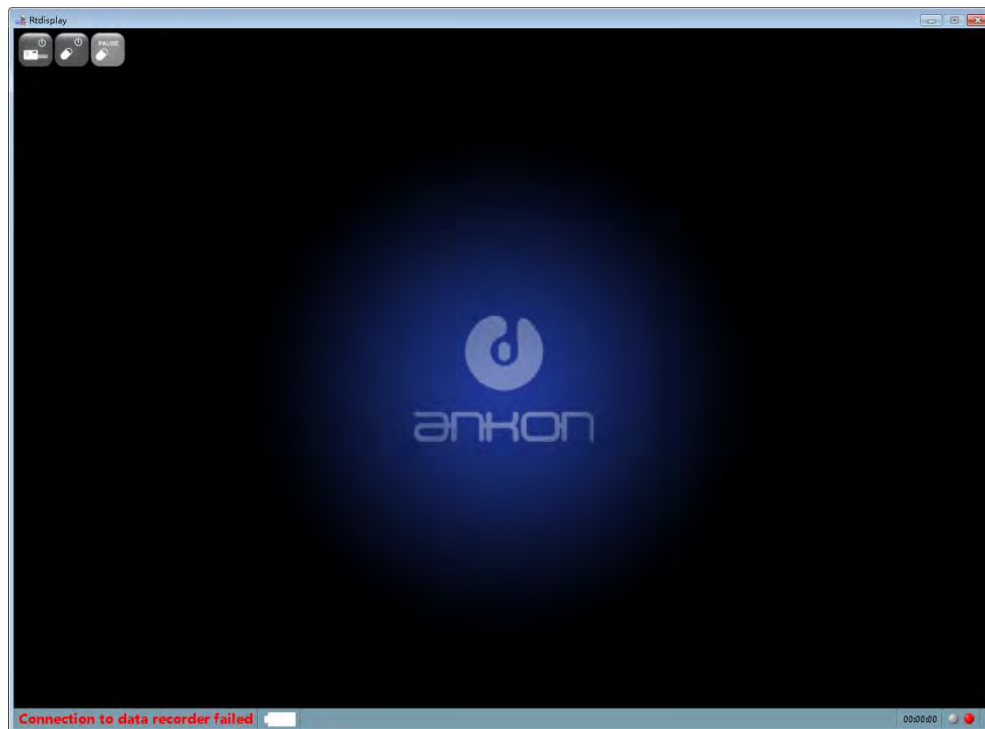





Figure 4-3: Rtdisplay Interface

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.

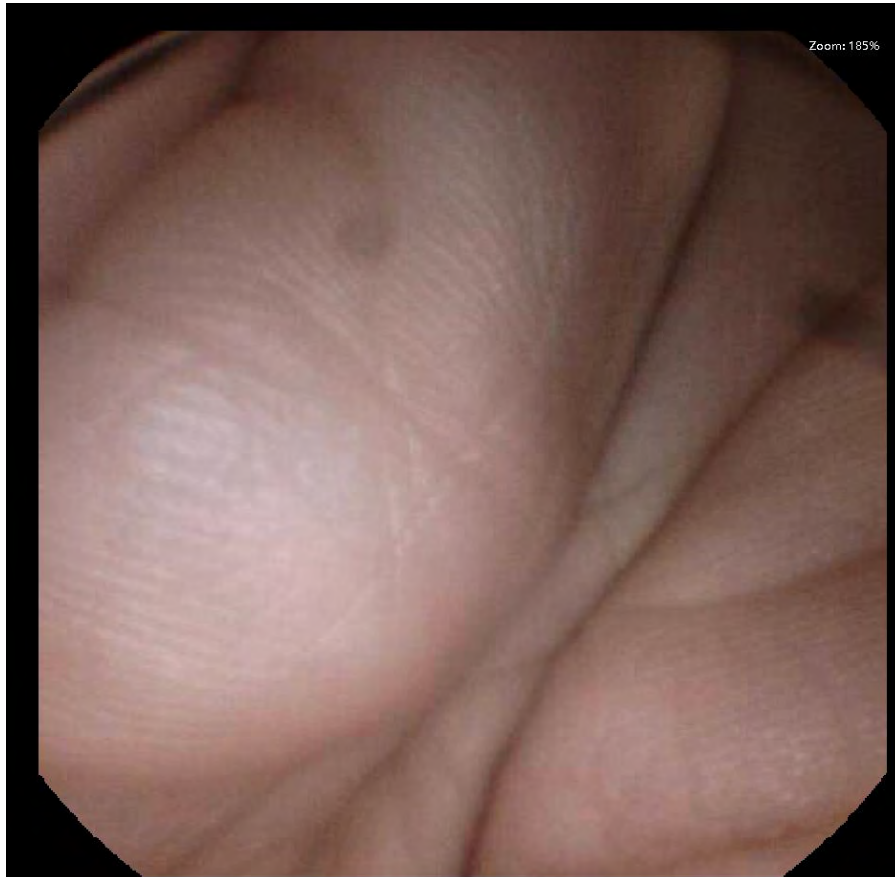




Figure 4-4: Zoom Function

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)

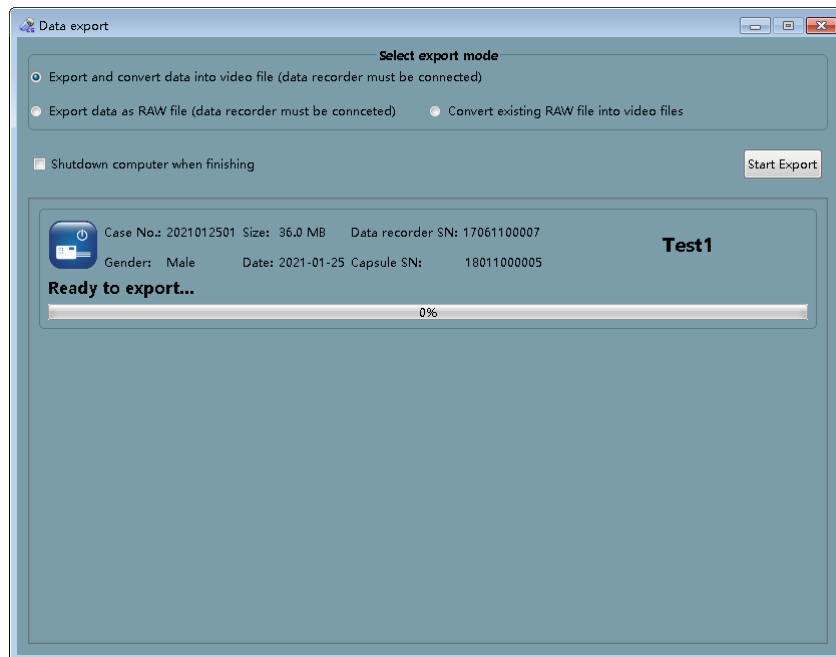


Figure 4-5: Data Export Interface

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.

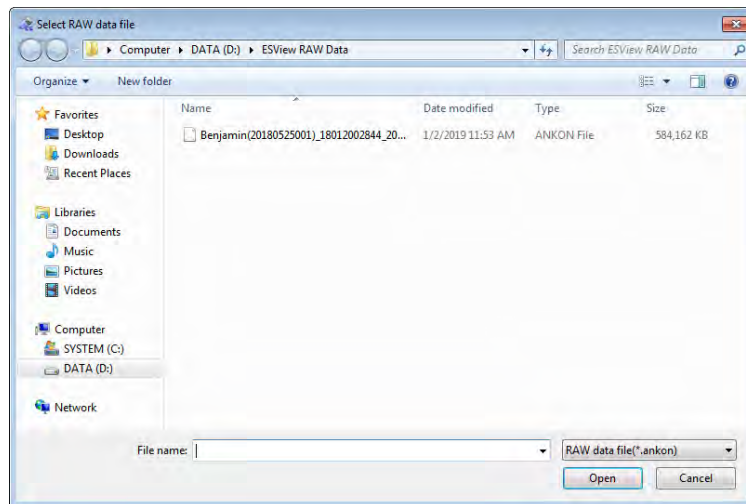


Figure 4-6: RAW Data File Selection Interface

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).

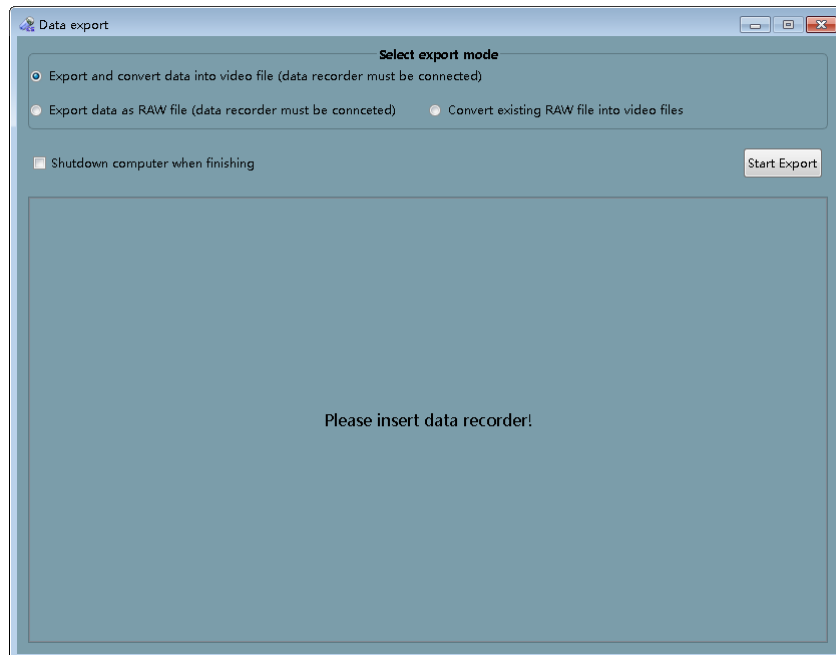


Figure 4-7: Data Recorder Not Connected Alert

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.

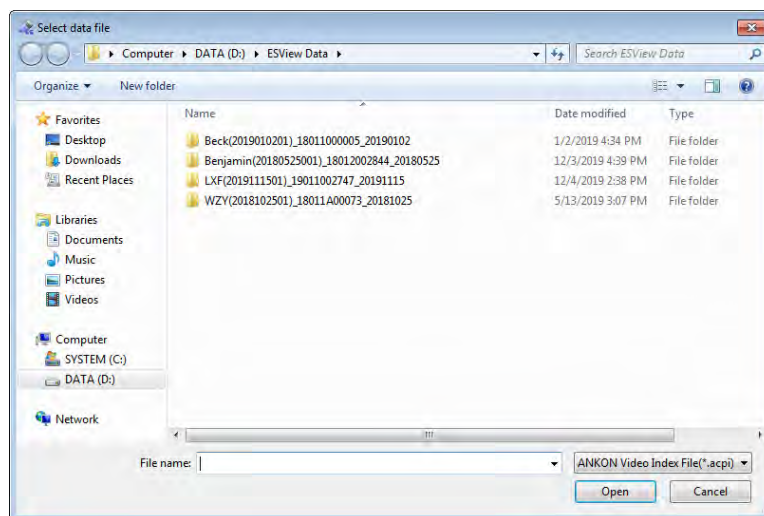


Figure 4-8: Patient Data File Selection Interface

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).

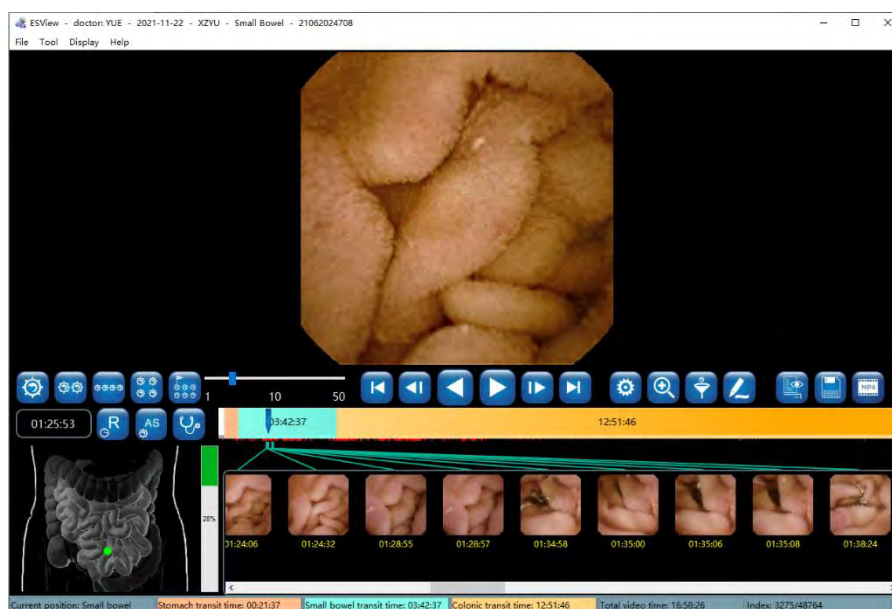


Figure 4-9: Main Software Interface After Opening Image Data

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.

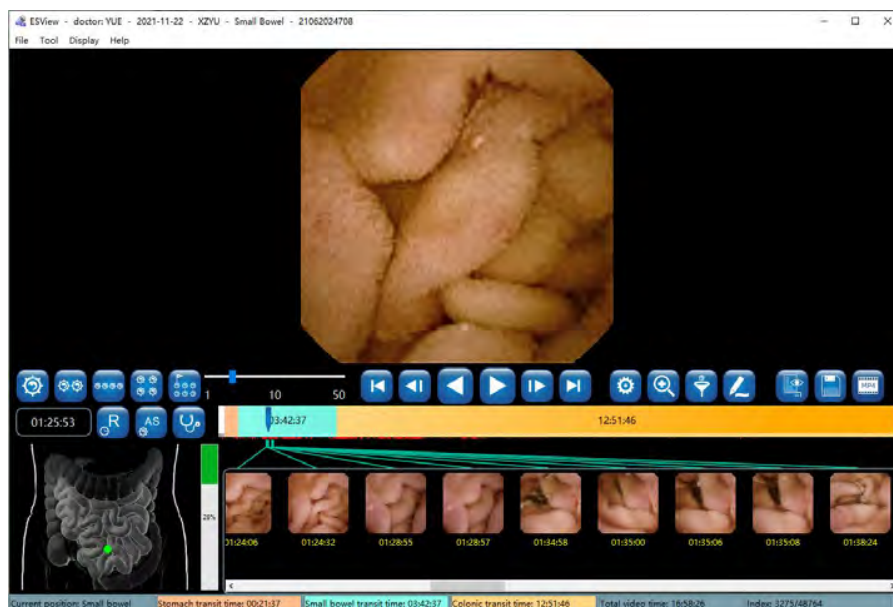


Figure 4-10: Video Playback Buttons

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

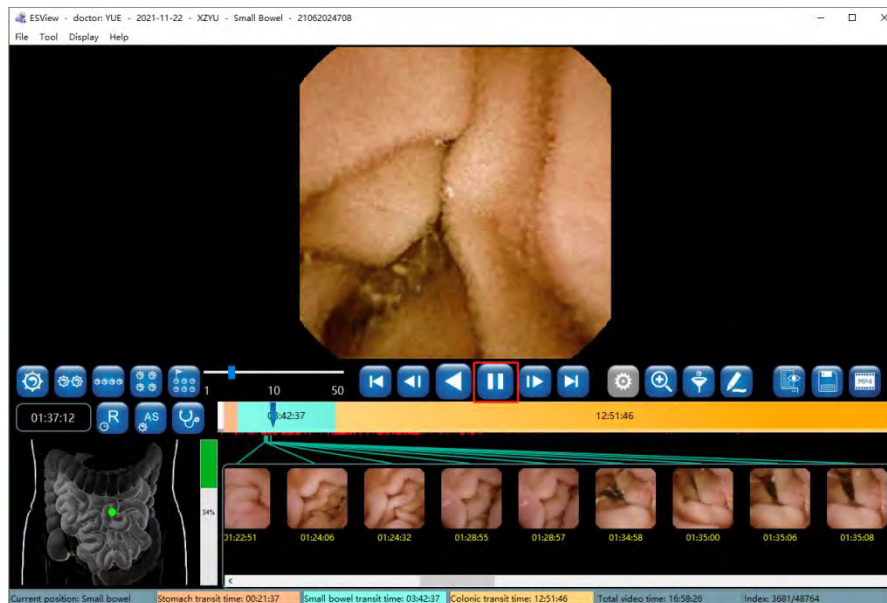






Figure 4-11: Pause Playback Button

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.

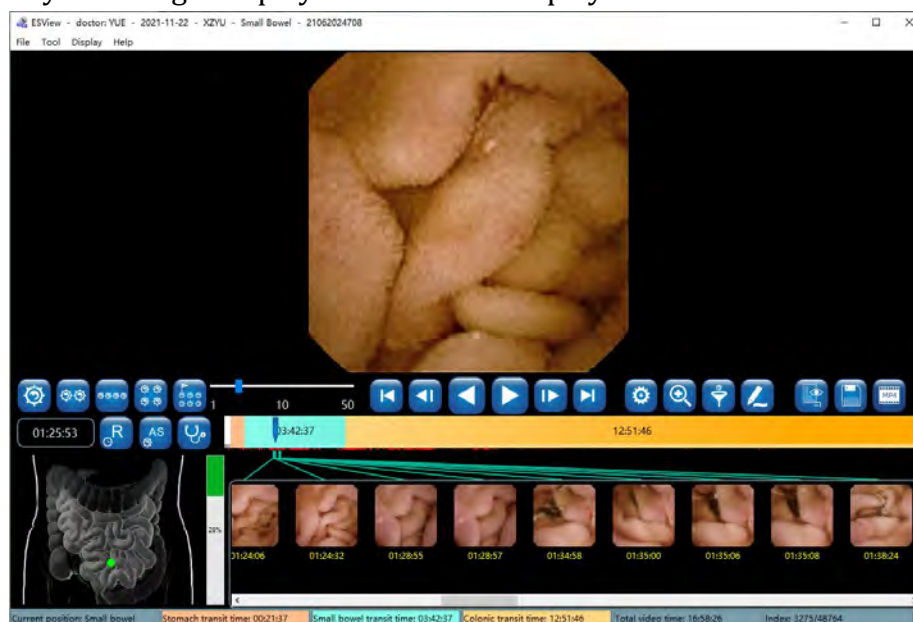


Figure 4-12: Single-Image Display Mode

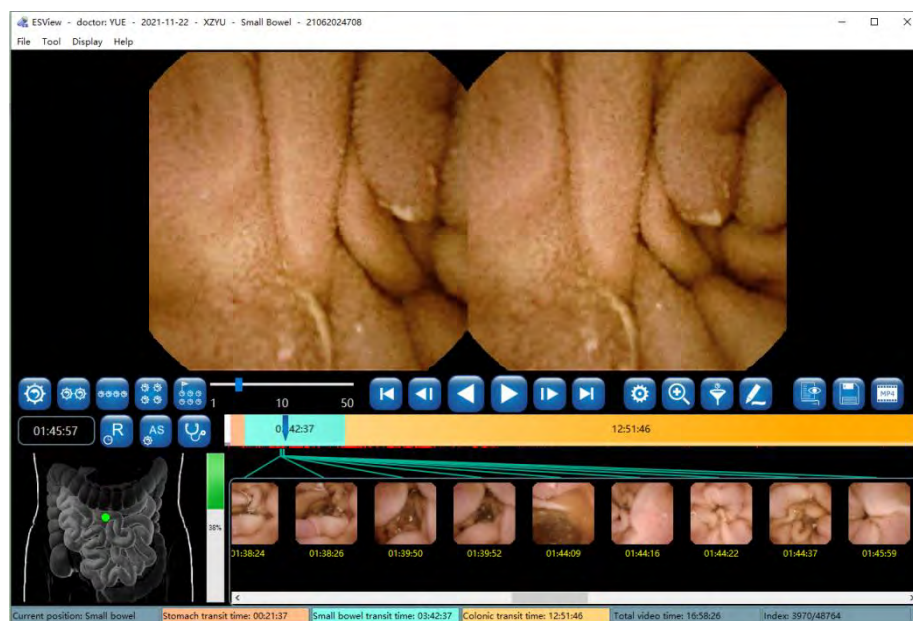


Figure 4-13: Two-Image Display Mode

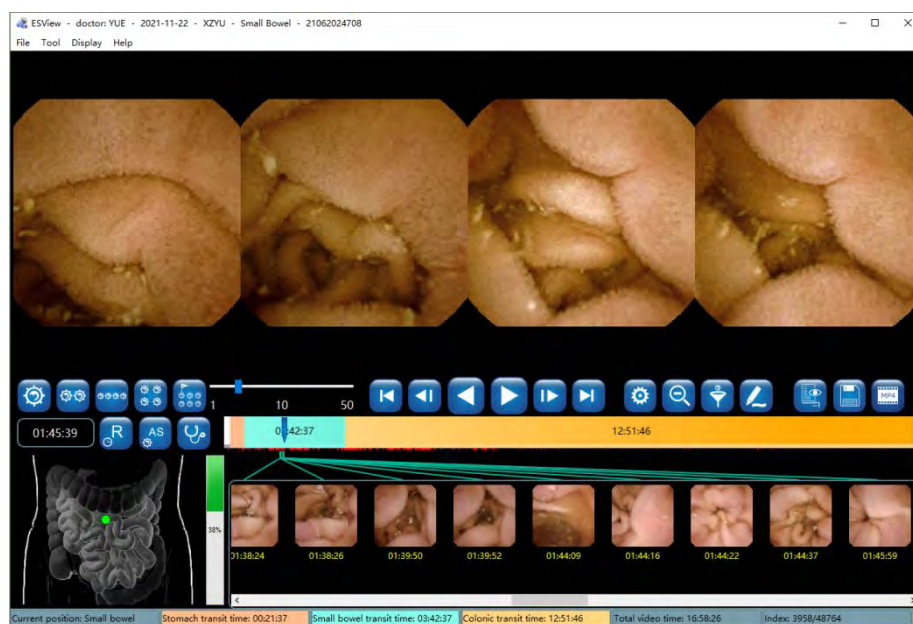


Figure 4-14: Transverse Four-Image Display Mode

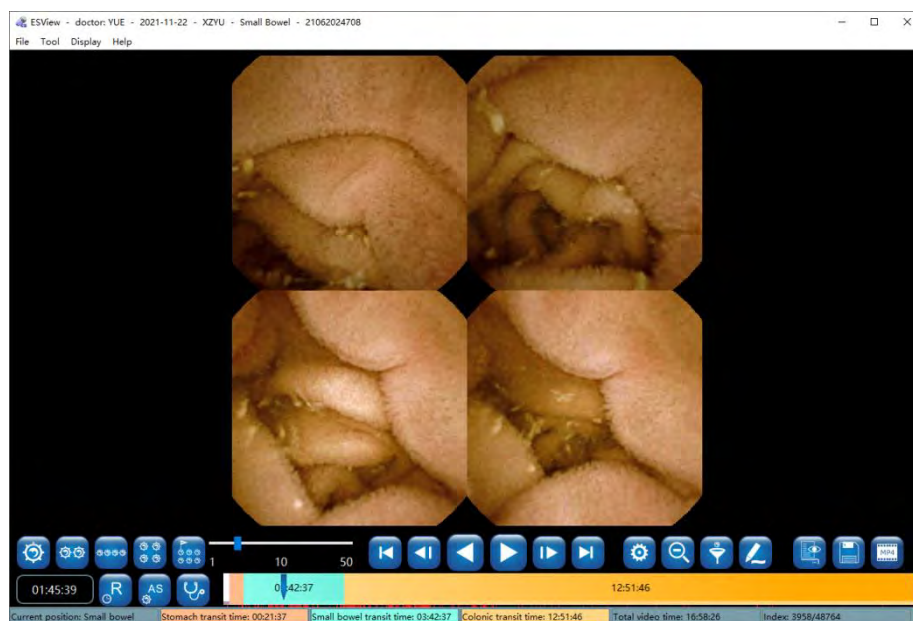


Figure 4-15: Array Four-Image Display Mode

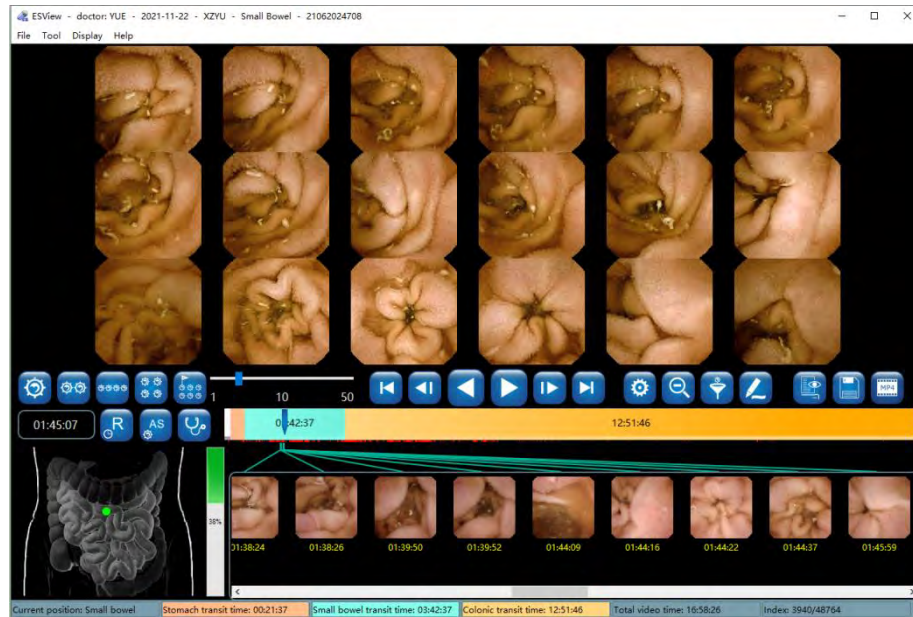






Figure 4-16: Multi-Image Display Mode


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.

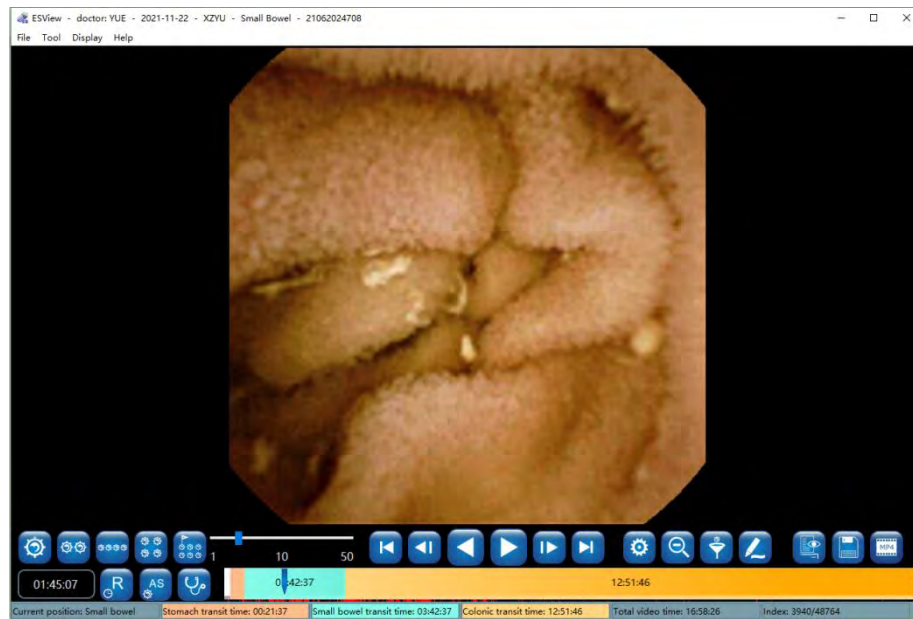




Figure 4-17: Single-Image Enlargement Mode



Figure 4-18: Two-Image Enlargement Mode

- 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. processed by the corresponding algorithm.

Click  to undo all the image processing.

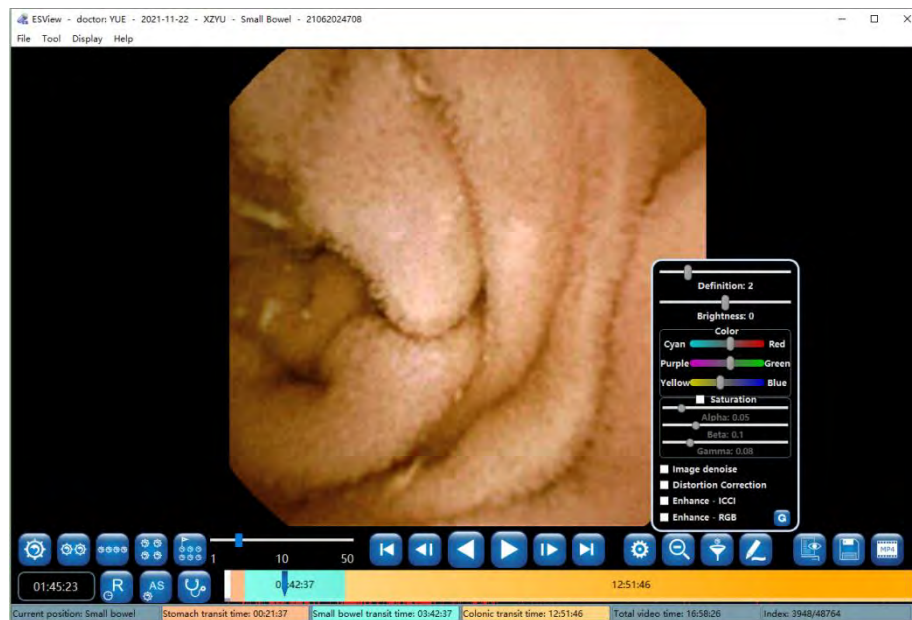







Figure 4-19: Image Processing Control Panel

- 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

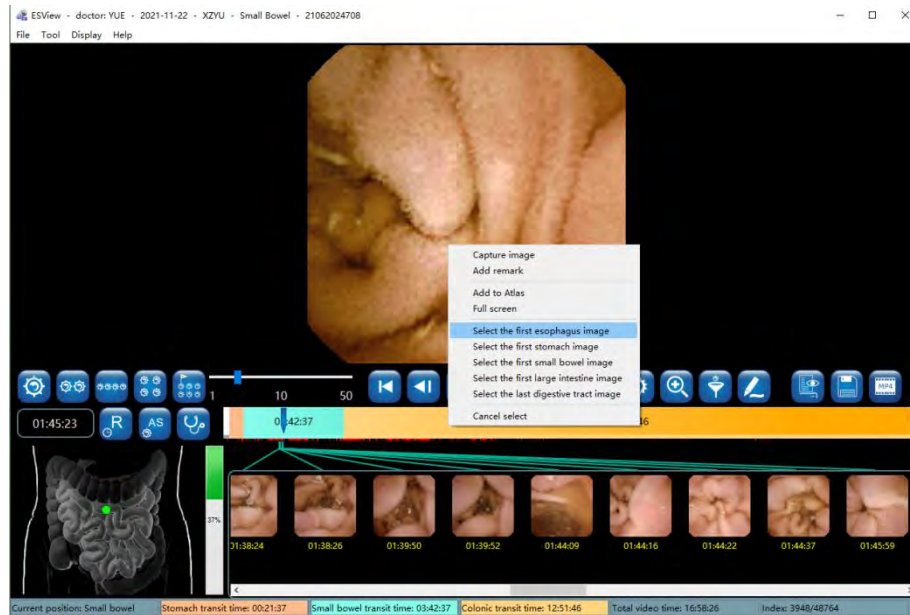


Figure 4-20: Image Tagging

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.

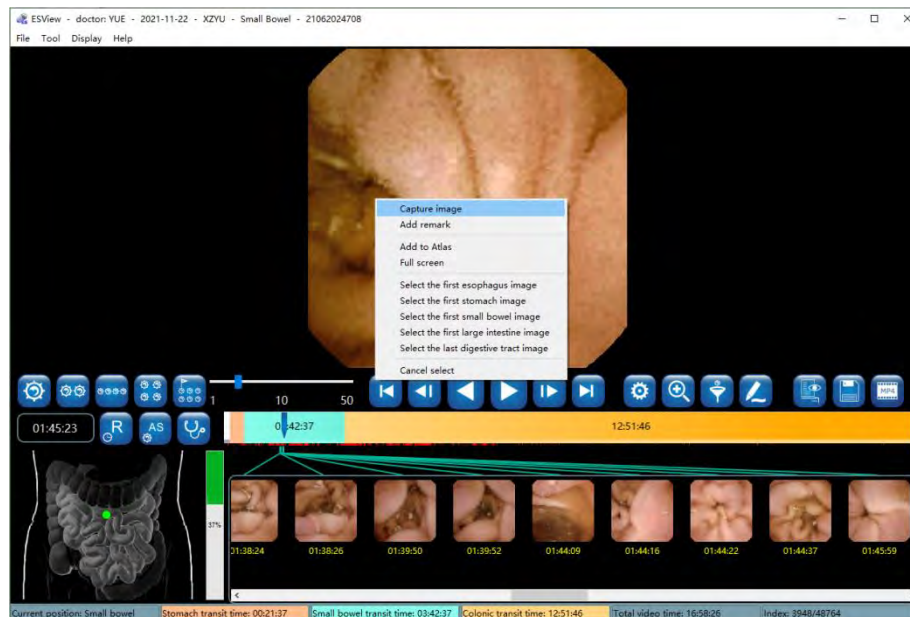


Figure 4-21: Image Capture

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.

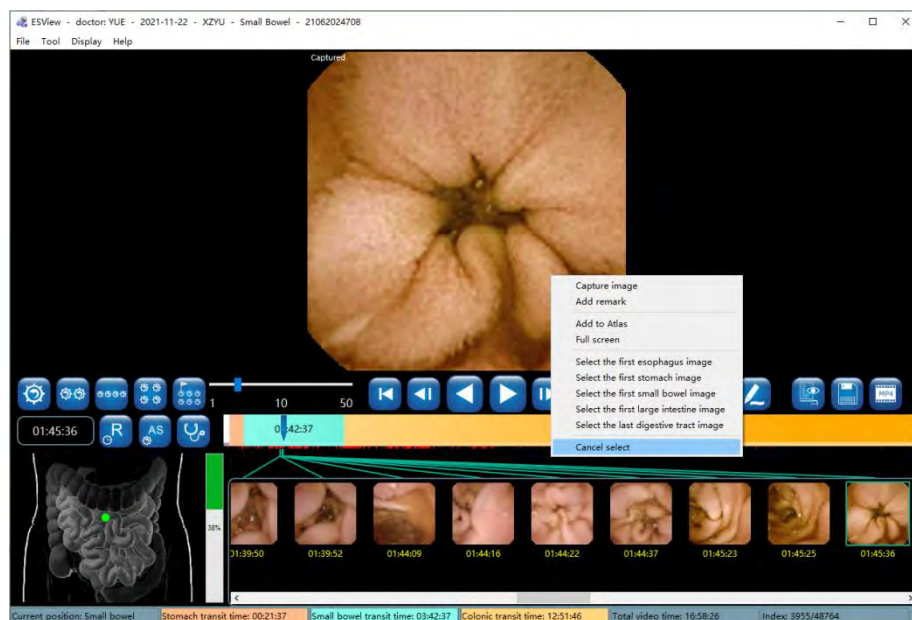



Figure 4-22: Cancel Image Tagging or Capture

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).

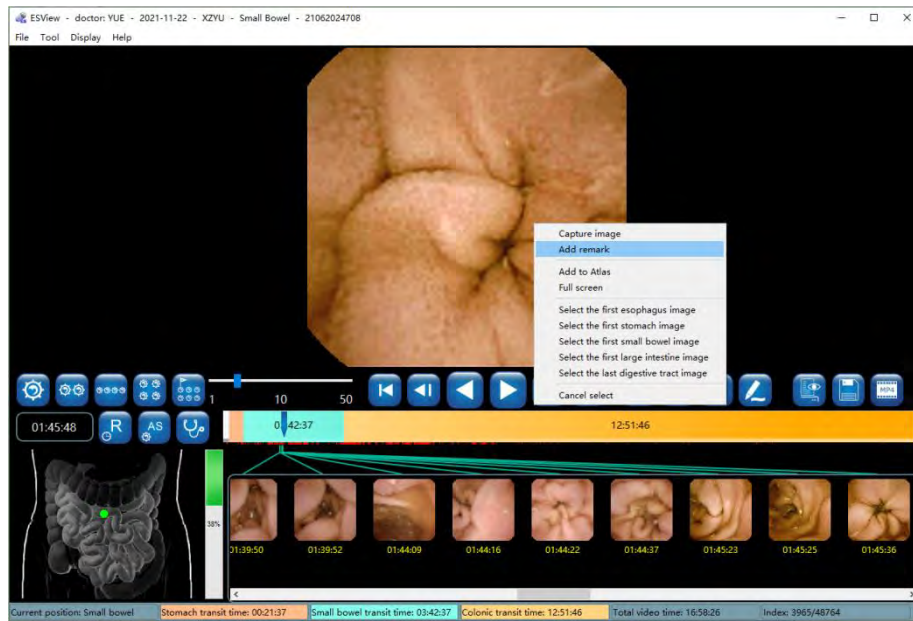


Figure 4-23: Add Remark Through Pop-Up Menu

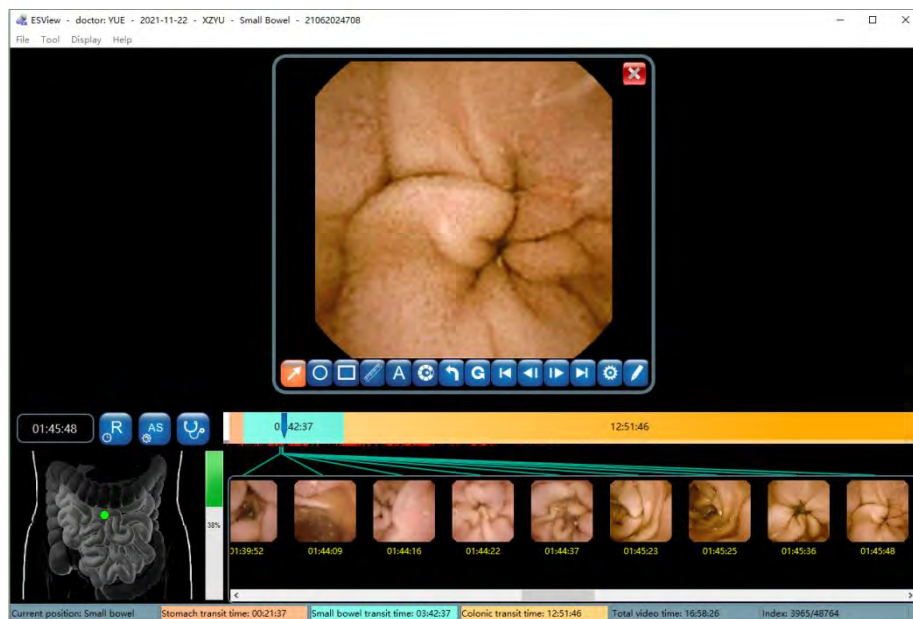








Figure 4-24: Add Remark Interface

- 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.

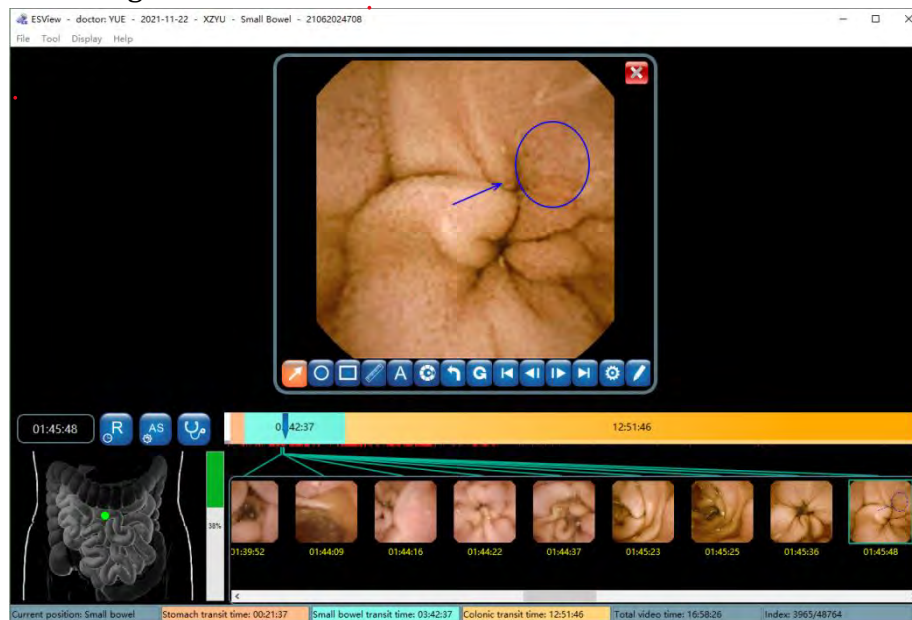


Figure 4-25: Add Markings




















- 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

	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 ESView 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.

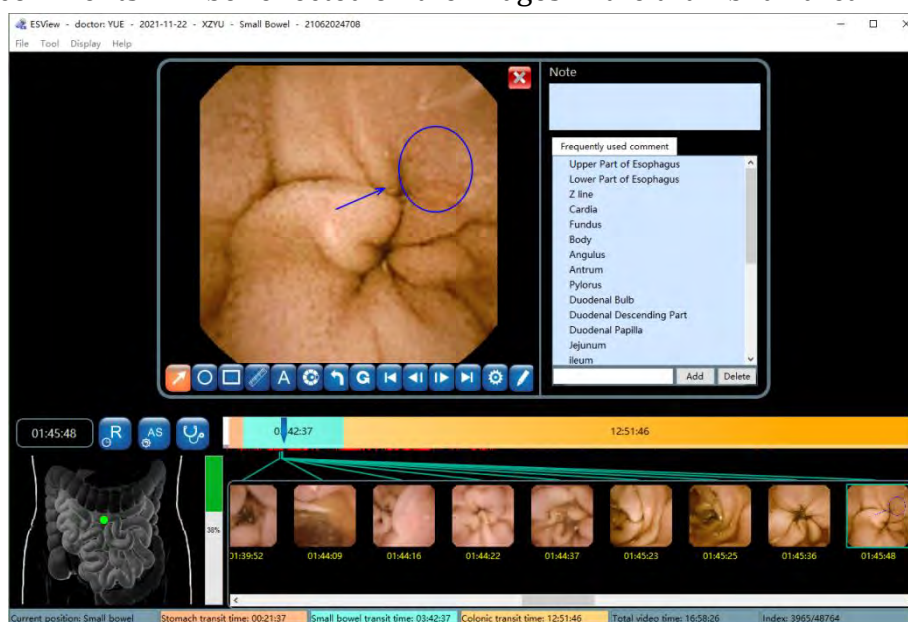



Figure 4-26: Add Remark Interface

- 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.

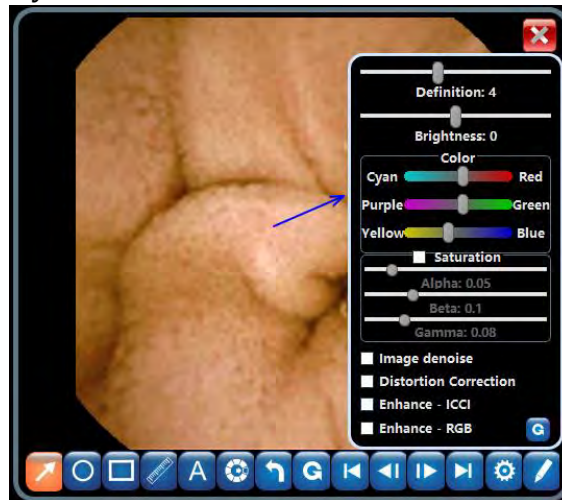



Figure 4-27: Image Processing Control Panel

- 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.

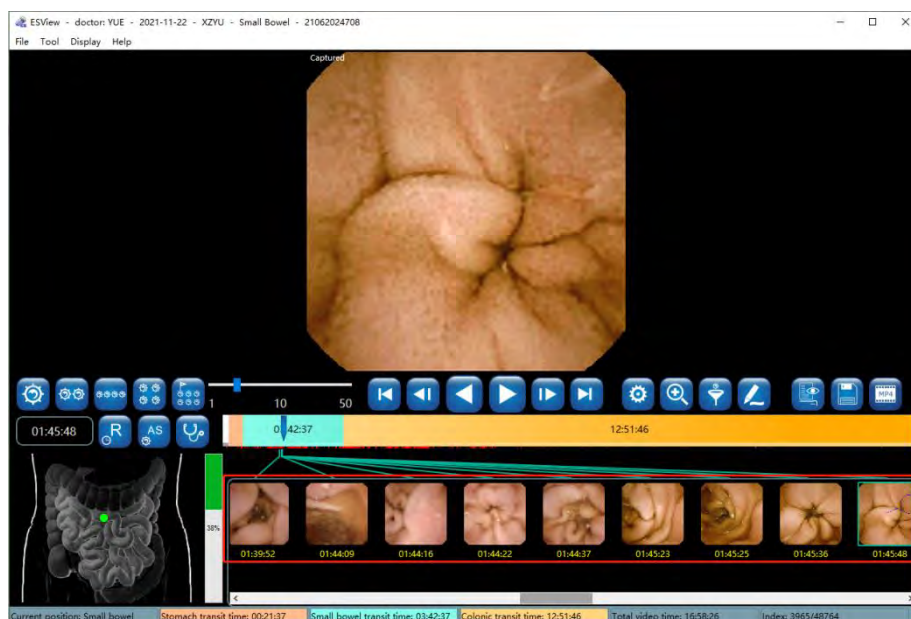


Figure 4-28: Thumbnail Display Area

- 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.

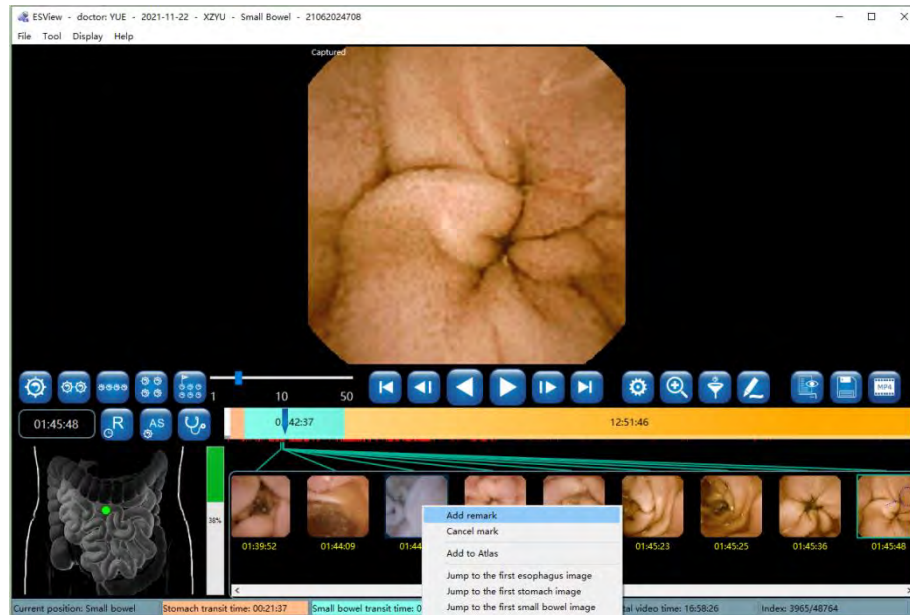


Figure 4-29: Add Remark to Thumbnail

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.

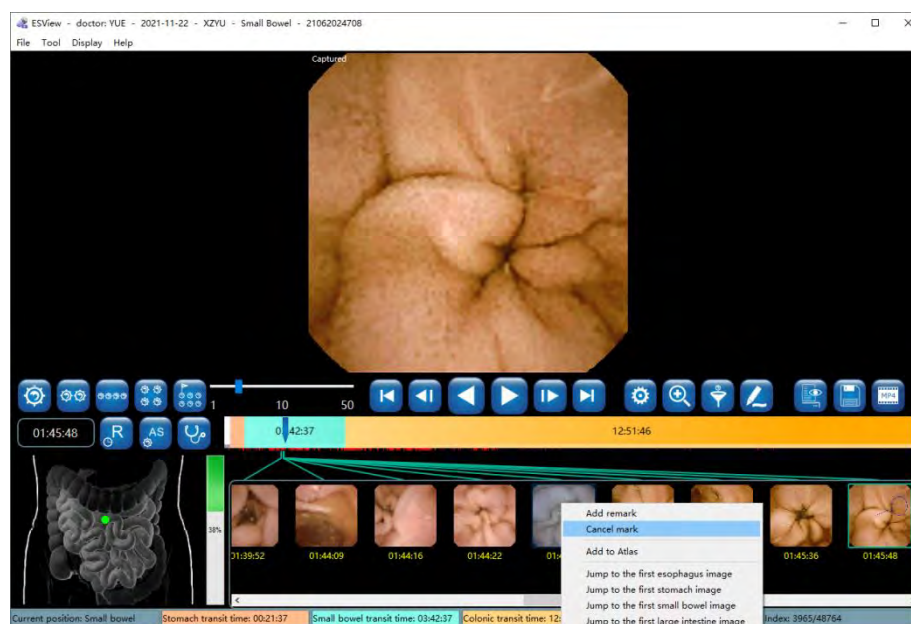



Figure 4-30: Thumbnail “Cancel Mark”

- 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

- 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.

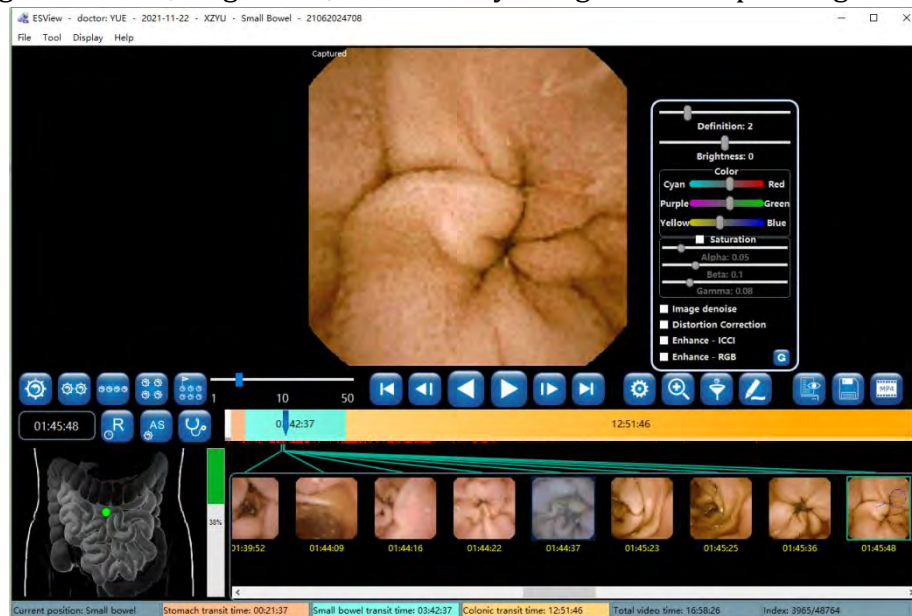


Figure 4-31: Image Processing Control Panel

- 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.

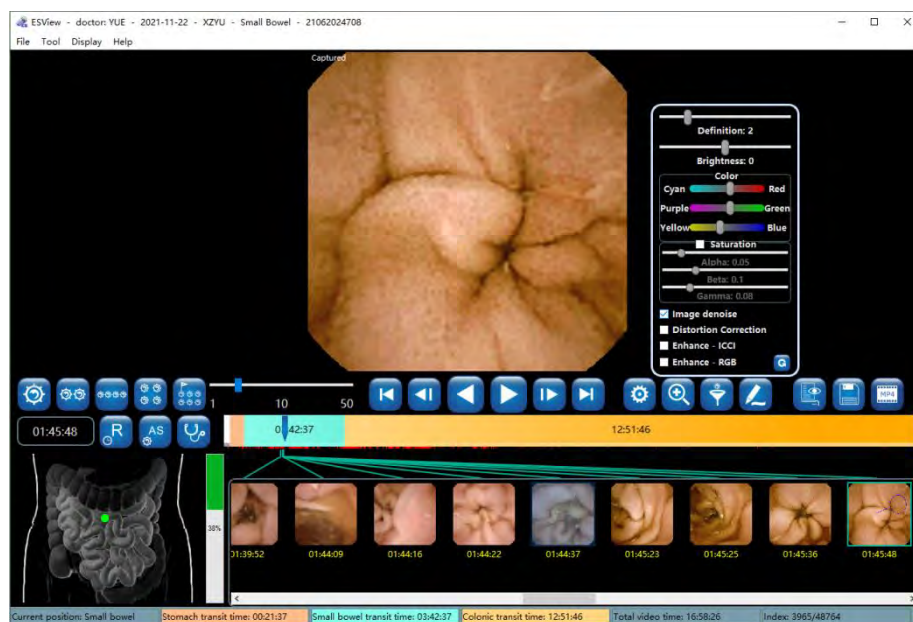


Figure 4-32: Image Denoise

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

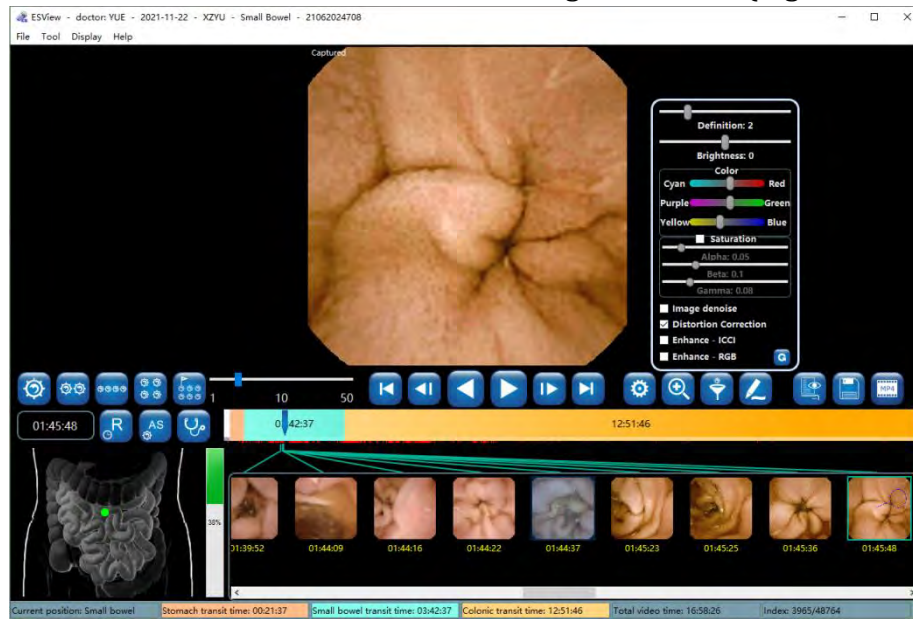


Figure 4-33: Distortion Correction

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

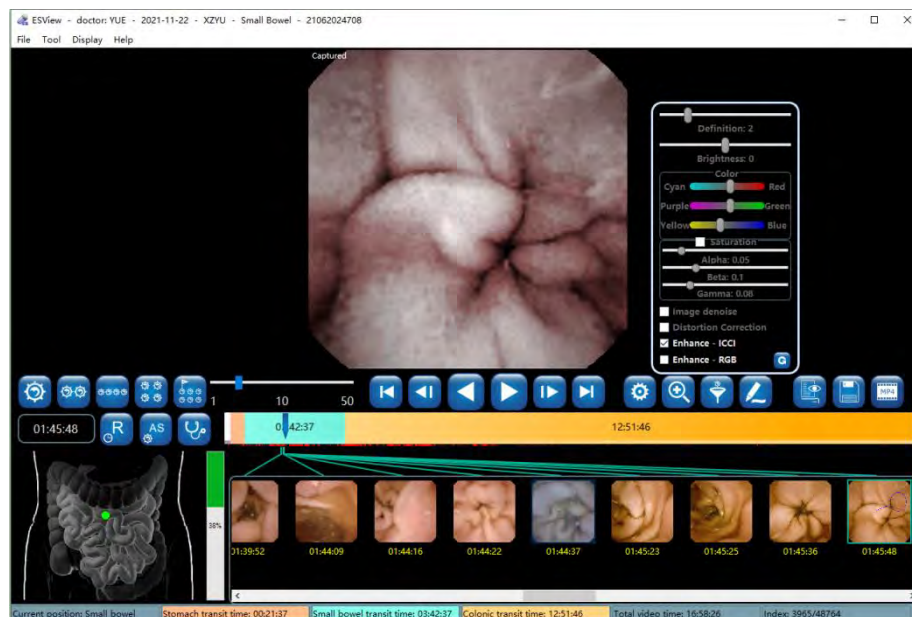


Figure 4-34: Image Enhancement - ICCI

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

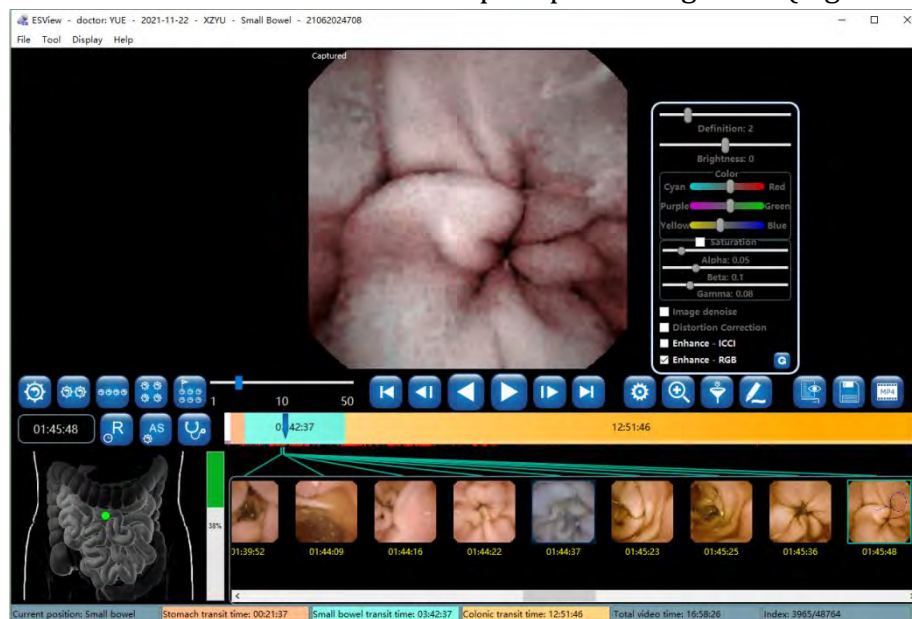


Figure 4-35: Image Enhancement - RGB

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

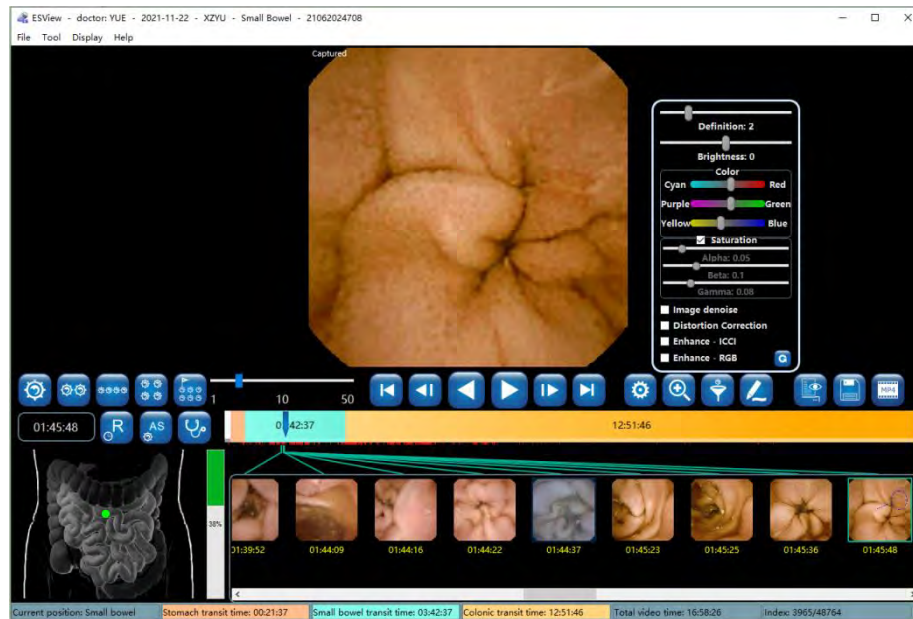


Figure 4-36: Image Saturation Adjustment

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

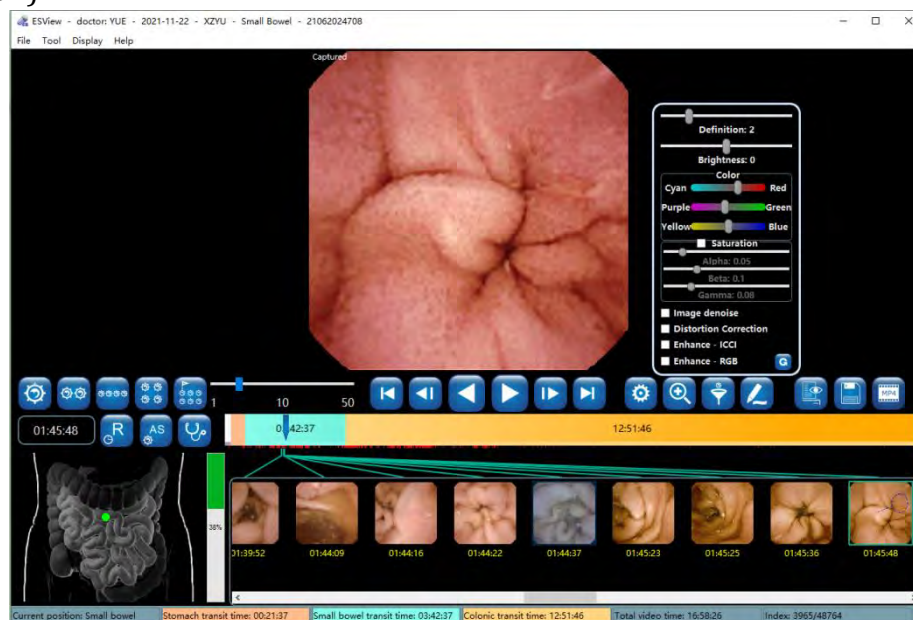




Figure 4-37: Definition and Brightness Adjustment

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%.

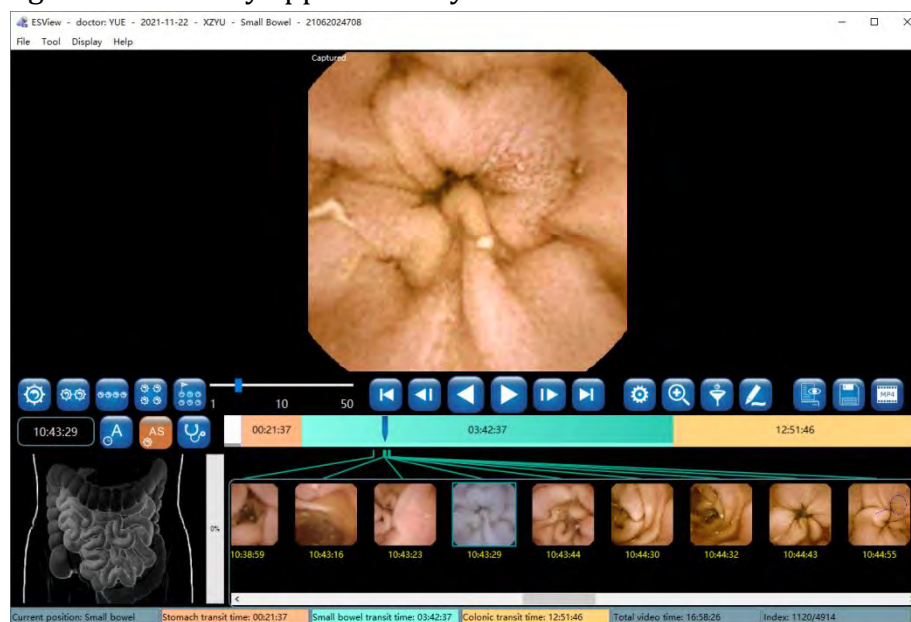




Figure 4-38: Similarity Browsing Mode

- Click , when the button icon changes to , the filter browsing mode will be activated (Figure 4-39). In this mode, the software displays only tagged or captured images for further screening.

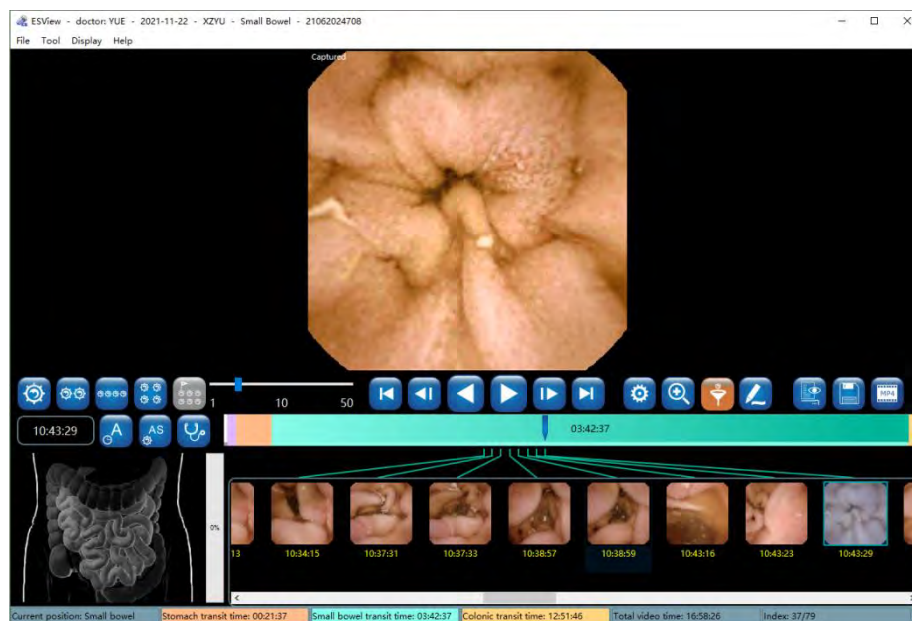


Figure 4-39: Filter Browsing Mode

4.4.9 Option Setting

- In the main software interface, select “Tool” → “Option” to access the option setting interface

(Figure 4-40).

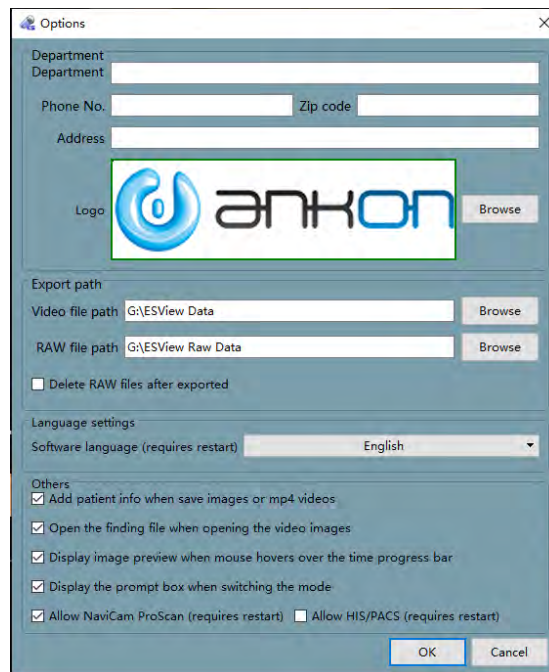


Figure 4-40: Option Setting Interface

2. In the “Department” area, fill in the department information, which will appear in the case report.
3. In the “Export path” area, choose the paths for exported video files and raw data. If the “Delete RAW files after exported” option is checked and the data is exported to video file using the direct export mode, then after export, the related RAW files in the RAW file path will be automatically deleted to save space.
4. In the “Others” area, if the “Display image preview when mouse hovers over the time progress bar” option is checked, as the mouse moves over the progress bar, the preview of the image corresponding to the mouse location will be displayed in a floating window if the mouse stops for about 1 second, as shown in Figure 4-41.

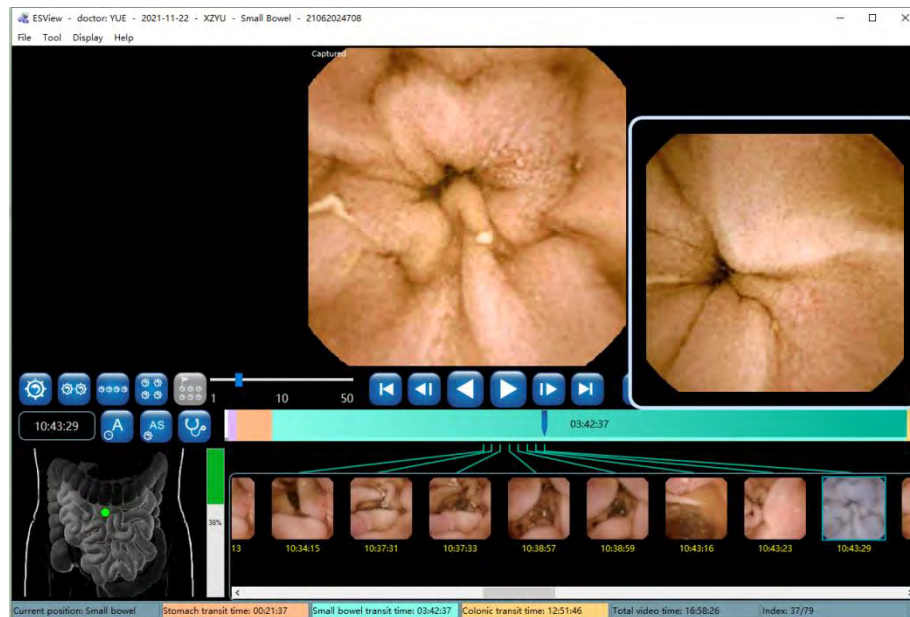


Figure 4-41: Image Preview



5. If the “Add patient info when save images or mp4 videos” option is checked, the patient information will be added to the upper left, upper right, and lower left corners of the save image, as shown in Figure 4-42. Left click  to save the current image. Right click  to open the folder where the saved images are located. If the “Open the finding file when opening the video images” option is checked, then the user can open the last saved finding file when opening the patient video.



Figure 4-42: Saved Image Showing Patient Information

4.4.10 NaviCam ProScan

NaviCam ProScan mainly contains two functions:

--Images of suspected positive lesions (including four kinds: *lymphangiectasia* , *Inflammation/erosion/bleeding/ulcer* , *polyp/bulging* or *lymphoid follicular hyperplasia* and *diverticulum*) are automatically marked, and the image position is marked in red on the image

ribbon.

--The esophagus, stomach, and small intestine are automatically segmented for the digestive tract image, and different digestive tract segments are marked with different colors on the image ribbon. This NaviCam ProScan feature can only be used when the following 3 conditions are met:

1) Check the "Allow NaviCam ProScan (requires restart)" option, and restart the ESView software to take effect, as shown in Figure 4-43.



Figure 4-43: ProScan Mode Option

2) Use "Export and convert data into video file" or "Convert existing RAW file into video files" to export data. After exporting, check "Recognize Progress" as 100% and "Recognize Status" as "Recognition success" in the Case Management case list, as shown in Figure 4-44.

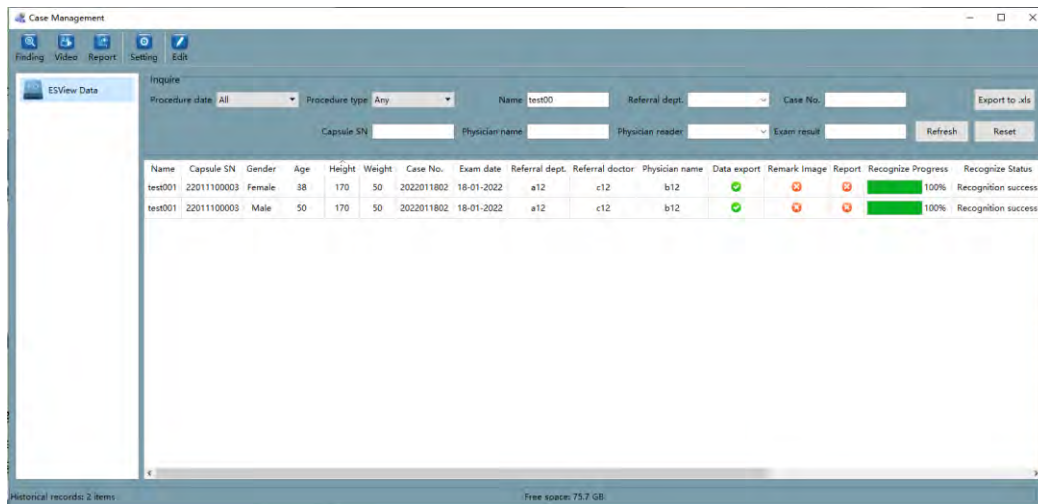


Figure 4-44: Recognize Progress

3) If suspected positive lesions are found.

1. If the NaviCam ProScan function is not enabled, there will be no ProScan icon displayed on the main interface of ESView. If the NaviCam ProScan function is enabled but the data has not been automatically identified and processed by ProScan, the ProScan icon displayed by "File" -> "Open Video" to open the data will be displayed. It is gray, as shown in Figure 4-45. Only after the above three conditions are met, the ProScan icon displayed by opening the data will turn blue;

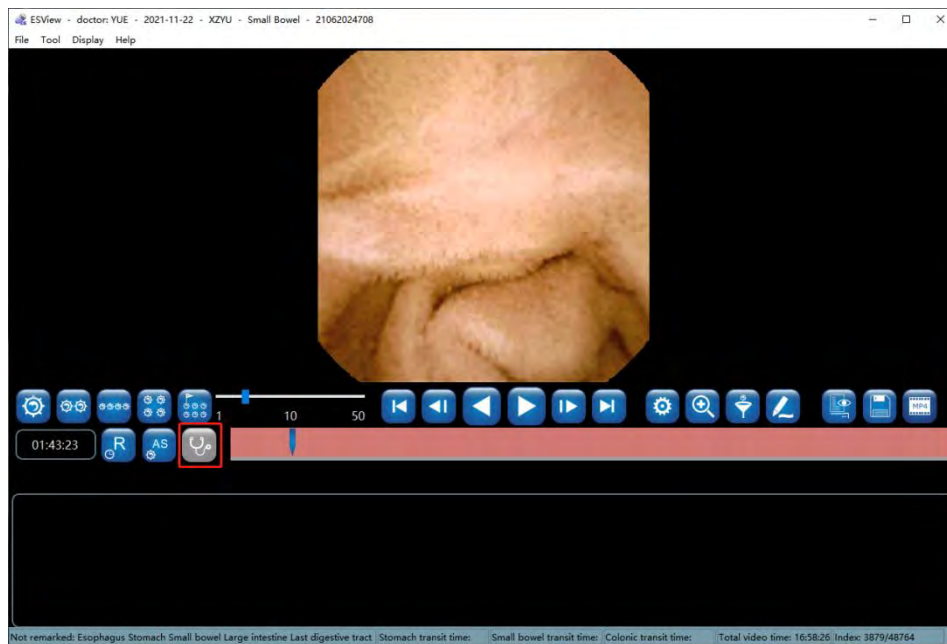


Figure 4-45: NaviCam ProScan function is enabled

2. When the NaviCam ProScan icon is blue, the images of suspected positive lesions are marked with red on the image color band, and the "First esophagus image", "First stomach image" and "First small bowel image" images are displayed in the image capture area, and are displayed in the

image capture area. Mark position and segment color on the image ribbon, as shown in Figure 4-46;

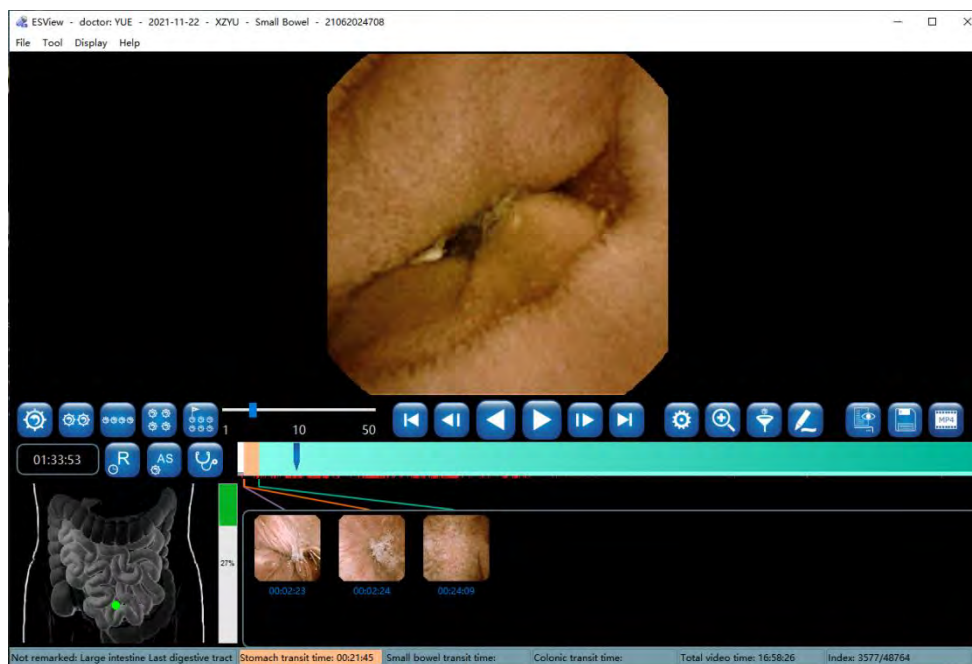





Figure 4-46: NaviCam ProScan Total Images Mode

3. When the NaviCam ProScan icon is blue, the default is Total Images Mode, click  to switch to NaviCam ProScan Mode, the button color changes to orange, click  to switch to Normal Images Mode, the color changes to green, as shown in Figure 4-47 and Figure 4 -48, click  to switch back to Total Images Mode.

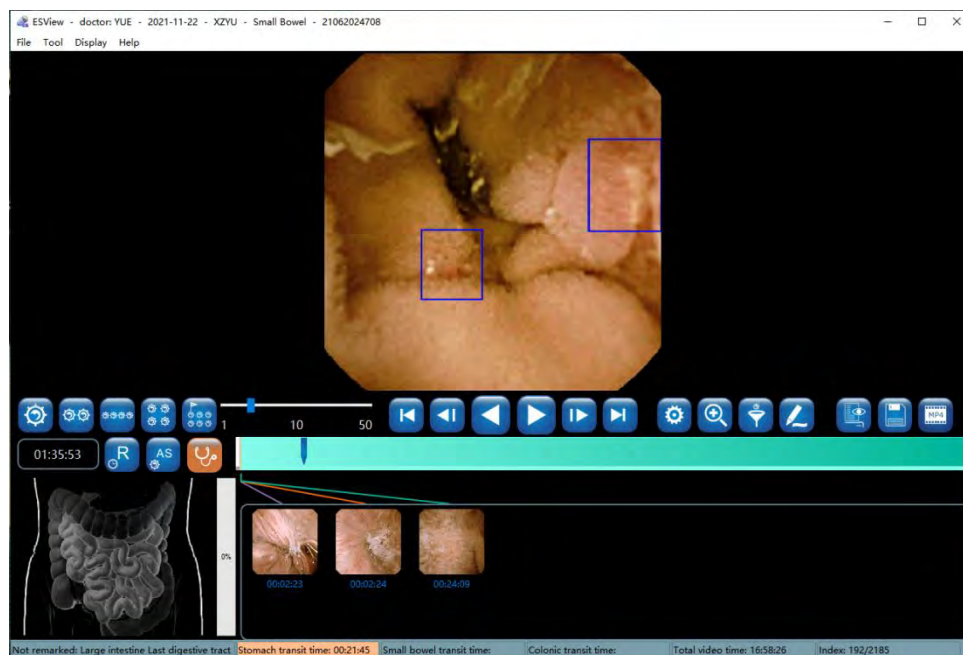


Figure 4-47: NaviCam ProScan Mode



Figure 4-48: NaviCam ProScan Normal Images Mode

4.4.11 Add to Atlas

1. Move the mouse over the image, right click the mouse and select "Add to Atlas" in the pop-up menu (Figure 4-49 to access the add to atlas interface).

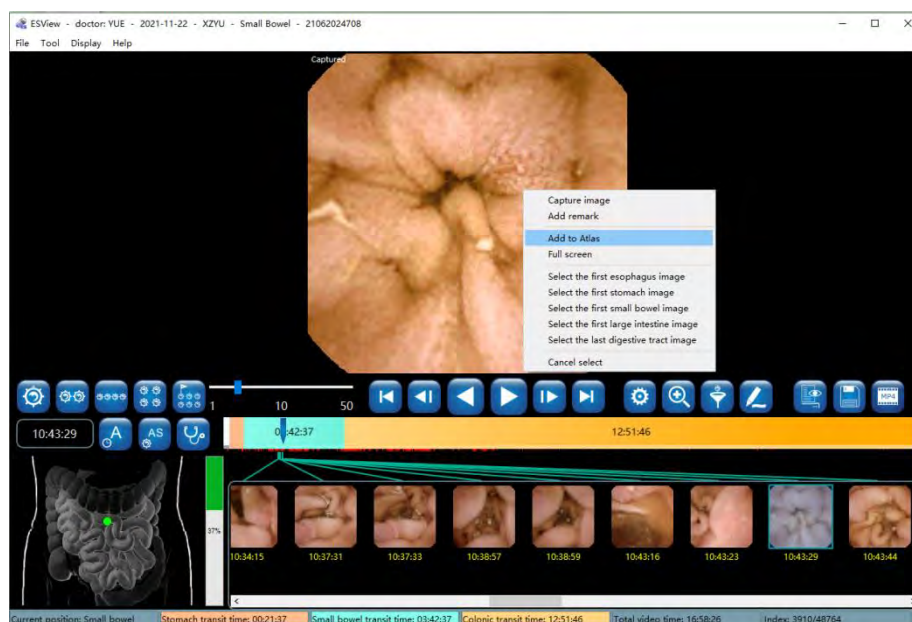


Figure 4-49: Add to Atlas

2. In the add to atlas interface, select an atlas type in the list on the left and fill in the name in the text box on the right, as shown in Figure 4-50. Click “OK” to confirm.

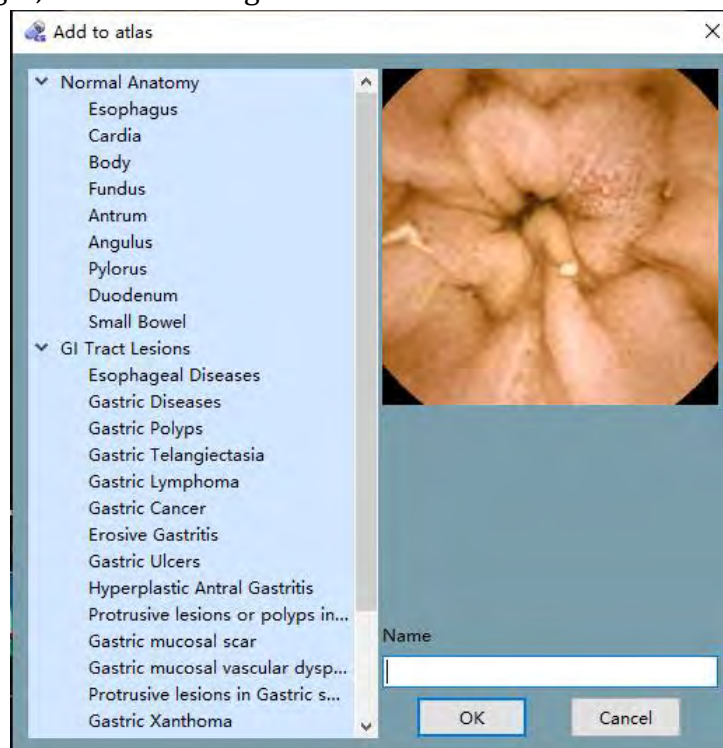


Figure 4-50: Add to Atlas Interface

3. In the main software interface, select “Tool”☐“Capsule endoscopy atlas” to access the capsule endoscopy atlas interface. Select a landmark of the digestive tract, for instance “Esophagus” in the left column, the images added in steps 1-2 will be displayed, as shown in Figure 4-51.

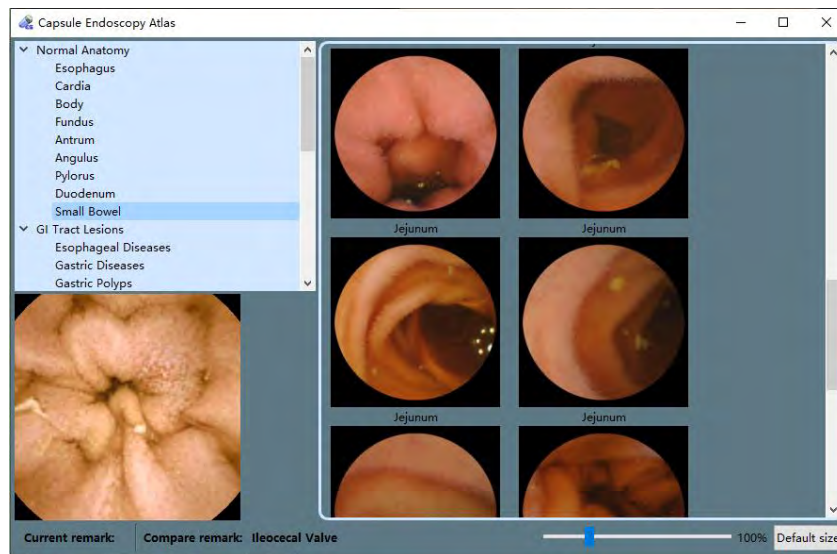



Figure 4-51: Capsule Endoscopy Atlas Interface

4.5 Report Generation

1. In the main software interface, click  to access the report generation interface (Figure 4-52).

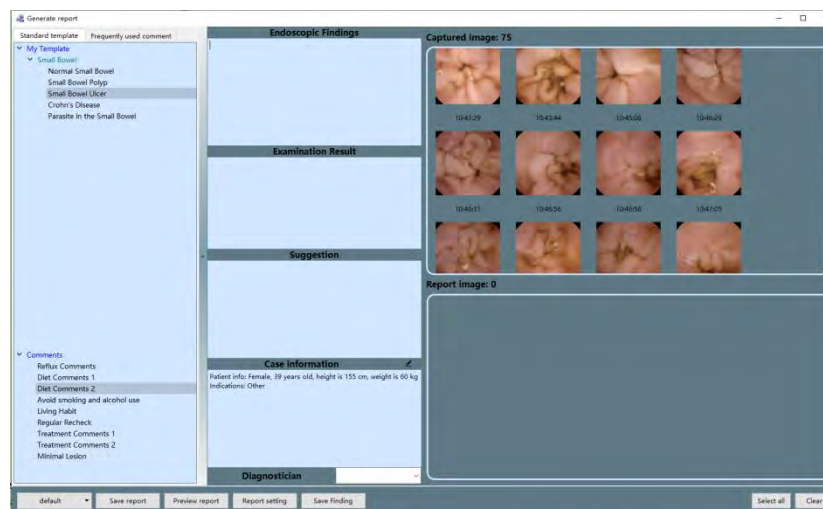


Figure 4-52: Report Generation Interface

2. Move the mouse over the captured image area and double click to select images. The selected images will then be added to the report image area. Double click on images in report image area to remove them. The "Select all" or "Clear" buttons can be used to select all captured images for report or remove all images from report (Figure 4-53).

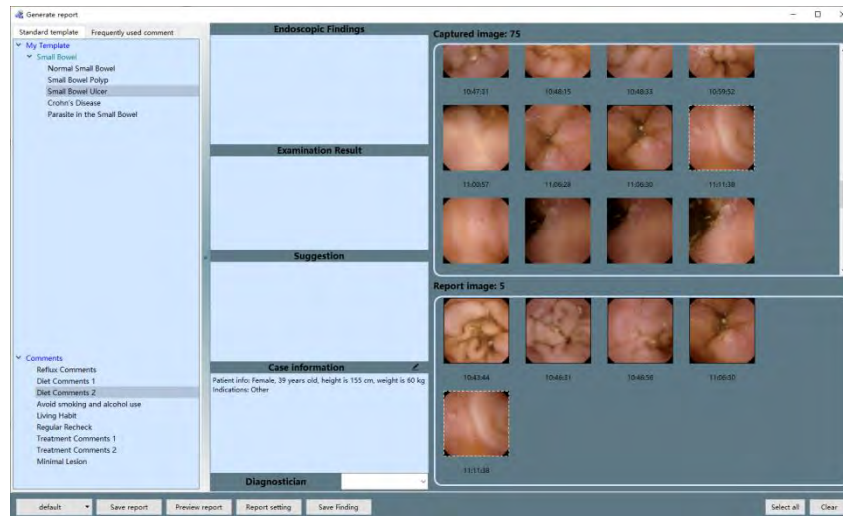


Figure 4-53: Select Images for Report

3. Move the mouse over the timestamp of an image and double click the left mouse button to edit image comment in the text box below the image (Figure 4-54).

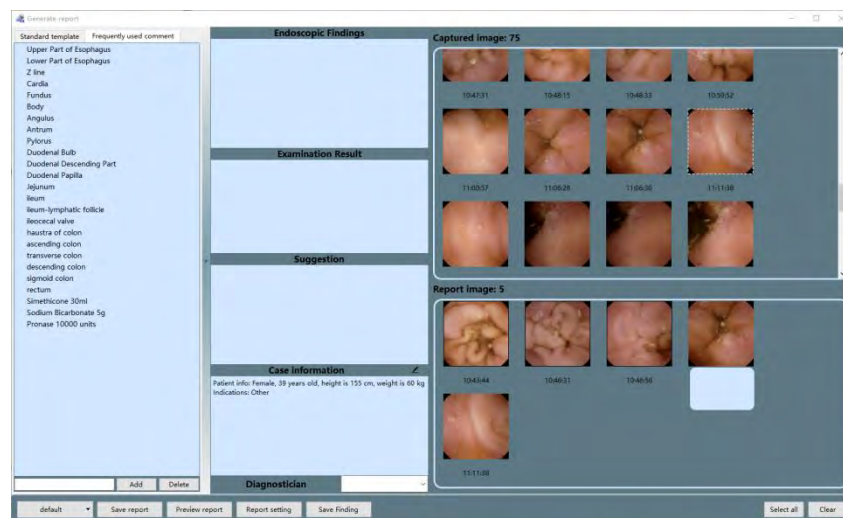


Figure 4-54: Edit Report Image Comment

4. In the captured image area and report image area, right clicking the mouse button will bring out the edit menu. Click "edit" to add annotation and comments.
5. The text boxes in the report generation interface can be used to input information that will be displayed in the case report. Similar to the add comment interface, the user can manually input or use useful expressions to add information.
6. If Microsoft Word is installed, click "Preview report" button to open Microsoft Word and access the report preview, as shown in Figure 4-55.

ANKON Capsule Endoscopy Systems Report

Name: XZYU Gender: Female Date of Birth: 22-11-1982
Case No.: 02018XZYU Capsule SN: 21062024708 Examining Date: 22-11-2021
Examining Physician: YUE

Reason for referral:
Indications: Other

Cleansingness Level: Esophagus transit time: 00:00:03, stomach transit time: 00:21:37, small bowel transit time: 03:42:37

Endoscopic Findings
The total duration of capsule endoscopy 16hr58mins26sec, the capsule enters into the esophagus at 2mins23sec, into the stomach at 2mins26sec, into the small bowel at 0hr24mins3sec, and into the large intestine at 4hr6mins40sec. At the end of the examination, the capsule is located at ""

Esophagus: Smooth mucosa with excellent contraction force.
Cardia: Regular opening and closing.
Fundus: Clear mucin pool, smooth mucosa, no varicose veins.
Gastric Body: Smooth mucosa, no significant congestive edema, no visible ulcerative mass.
Angulus Incisure: Curved appearance and smooth.
Gastric Antrum: Excellent motility, Smooth mucosa, no visible and significant erosion, ulcer or mass over the mucosa.
Pylorus: Round shape, with regular opening and closing.
Duodenum: Normal bulbar shape, no abnormal findings over the mucosa, and no erosion, ulcer or mass is found over the rest of the mucosa.
Jejunum and Ileum: Unobstructed intestine, integrated mucosa, no abnormal findings over the mucosa, no erosion, ulcer or mass.

Examination Result
Example

Suggestion
Maintain mental health, ensure the quality of sleep, keep warm and avoid colds and flu.

Signature: Report Date: 08-03-2022

TEL: ADDR: 1 / 1

Figure 4-55: Report Preview

7. In the report generation interface, click "Save report", choose a directory and click "Save" to save the case report (Figure 4-56). The software saves reports in *.pdf format by default. The user may also choose to save reports in *.doc format (Figure 4-57). After saving, a dialog box will appear to indicate saving success (Figure 4-58). Click "OK" to complete report saving or click "Open" to open the saved report.

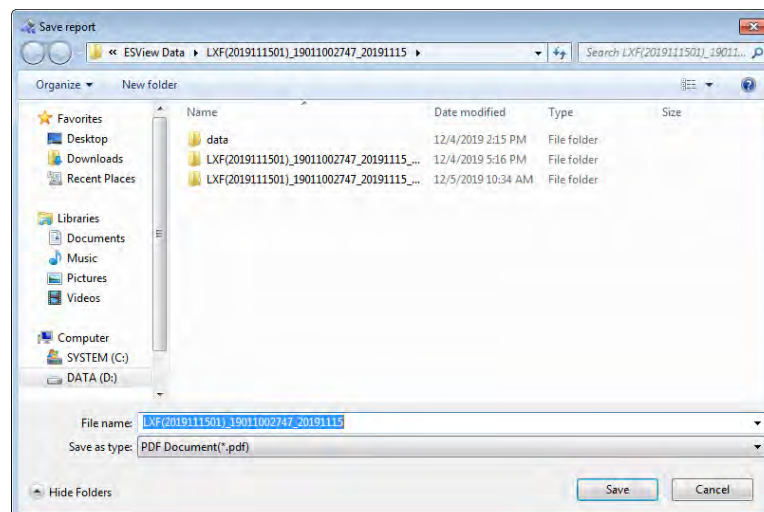


Figure 4-56: Save Report in .pdf Format

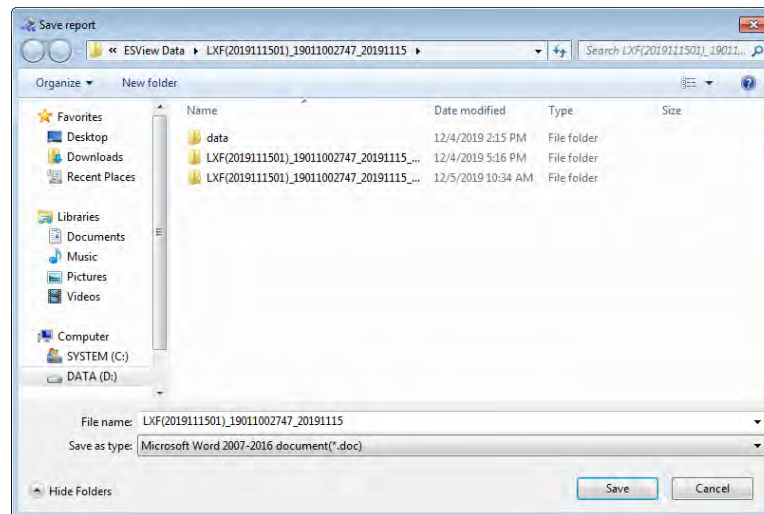


Figure 4-57: Save Report in .doc Format

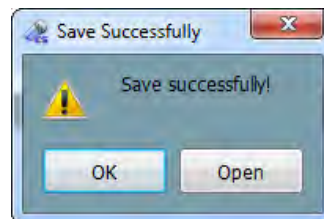


Figure 4-58: Saving Success Dialog Box

8. In the main software interface, select “File” → “Saving finding” to access the save finding interface (Figure 4-59). The finding file saves image markings, comments, and other textual information. Subsequently, the user can select “File” → “Open finding” in the menu to load video with all the findings again.

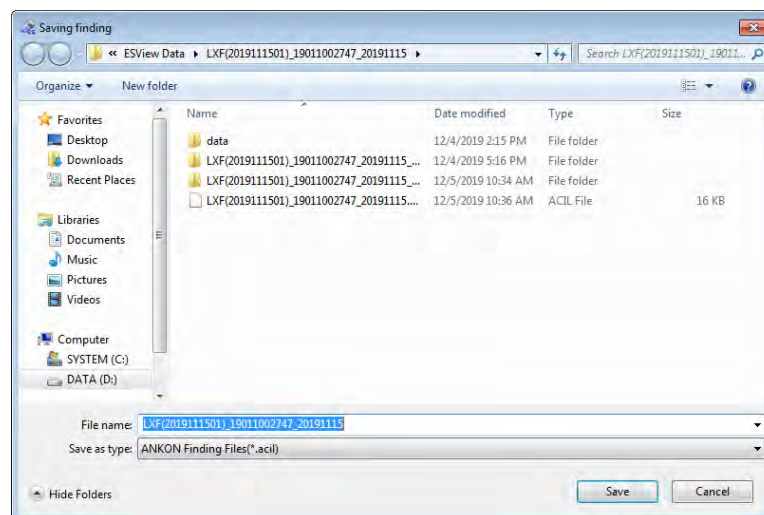


Figure 4-59: Save Finding Interface

9. In the report generation interface, click the “Report setting” button to access the report

setting interface. The user can set image zoom scale in the report, image quantity, font size of the comments, whether to print image background, and whether to add patient information in the image. Click “OK” to save report setting changes. Click “Cancel” to exit the interface without saving changes.

4.6 Case Management

1. In the main software interface, select “Tool” ? “Case management” to access the case management interface (Figure 4-60). The software will automatically add the data export path to the case data storage path.

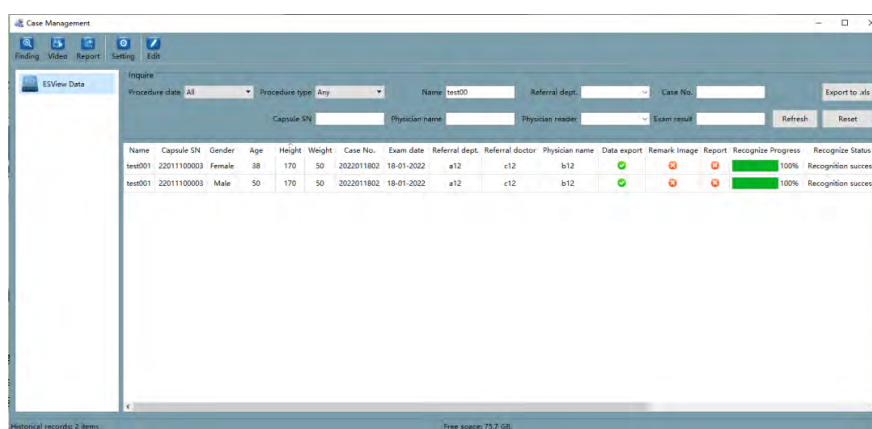



Figure 4-60: Case Management Interface

2. Click  to access the add case data storage path interface (Figure 4-61). Click “Add”, “Delete”, or “Rename” button to add, delete, or rename the case data storage path. Click “Save” to save changes in settings or click “Cancel” to cancel changes.

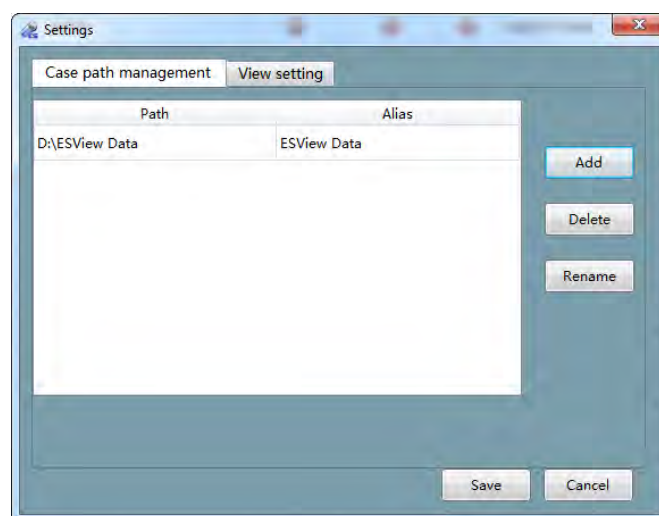


Figure 4-61: Add Case Data Storage Path Interface

3. The software automatically searches two levels of directory under the case data storage path and displays the patient information found in the case list. In the add case data storage path interface (Figure 4-61) click "View setting" to access the view setting interface (Figure 4-62). Drag the mouse or click the "<<" or ">>" buttons to select the data fields to be displayed. The data fields in the "Available Column" box will not be shown in the case management interface, while the data fields in the "Used Column" box will be displayed.

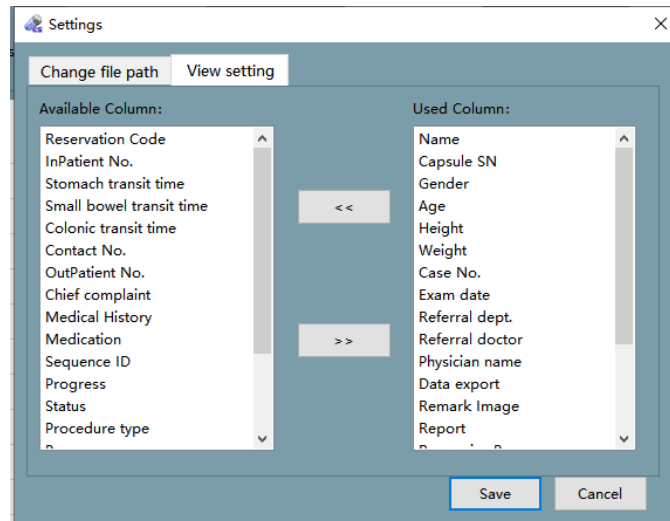




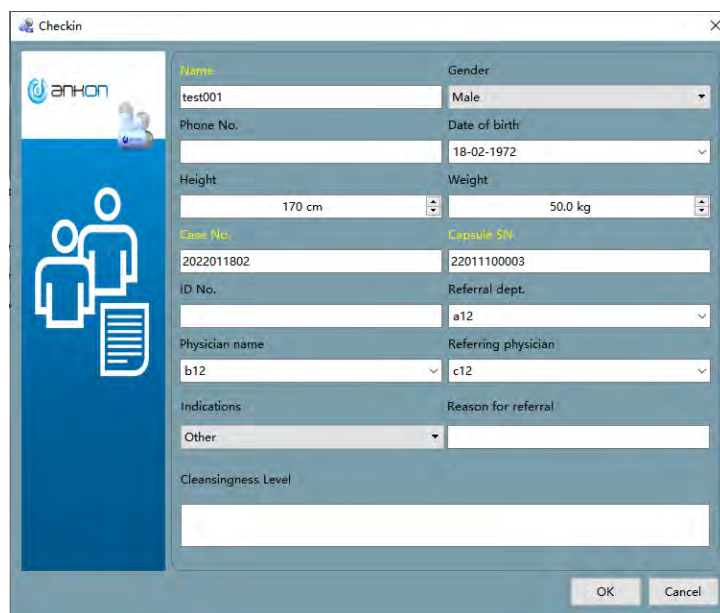


Figure 4-62: View Setting Interface

4. In the case management interface (shown in Figure 4-60), 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 (Figure 4-63), where you can change patient data. Alternatively, in the main software interface, open a video file and select "File" → "Edit patient info" to access the patient information editing interface.



The 'Checkin' dialog box is a software interface for editing patient information. It features a blue sidebar on the left with the ANKON logo and a stylized icon of two people. The main area contains various input fields and dropdown menus. The fields are organized into two columns. The left column includes fields for Name (test001), Phone No., Height (170 cm), Case No. (2022011802), ID No., Physician name (b12), Indications (Other), and Cleansingness Level. The right column includes fields for Gender (Male), Date of birth (18-02-1972), Weight (50.0 kg), Capsule SN (22011100003), Referral dept. (a12), Referring physician (c12), and Reason for referral. At the bottom right, there are 'OK' and 'Cancel' buttons.

Field	Value
Name	test001
Gender	Male
Phone No.	
Date of birth	18-02-1972
Height	170 cm
Weight	50.0 kg
Case No.	2022011802
Capsule SN	22011100003
ID No.	
Referral dept.	a12
Physician name	b12
Referring physician	c12
Indications	Other
Reason for referral	
Cleansingness Level	

Figure 4-63: Patient Information Editing Interface

5. Using the tools from the “Inquire” area, the user can filter cases by procedure date, procedure type, capsule SN, patient name, physician name, and exam result. Click the “Refresh” button to update cases. Click the “Reset” button to reset filters and update cases.

4.7 Capsule Endoscopy Atlas

1. In the main software interface with an opened video, double click one image in the thumbnail area and select “Tool”☐ “Capsule endoscopy atlas” to access the capsule endoscope atlas interface (Figure 4-64).

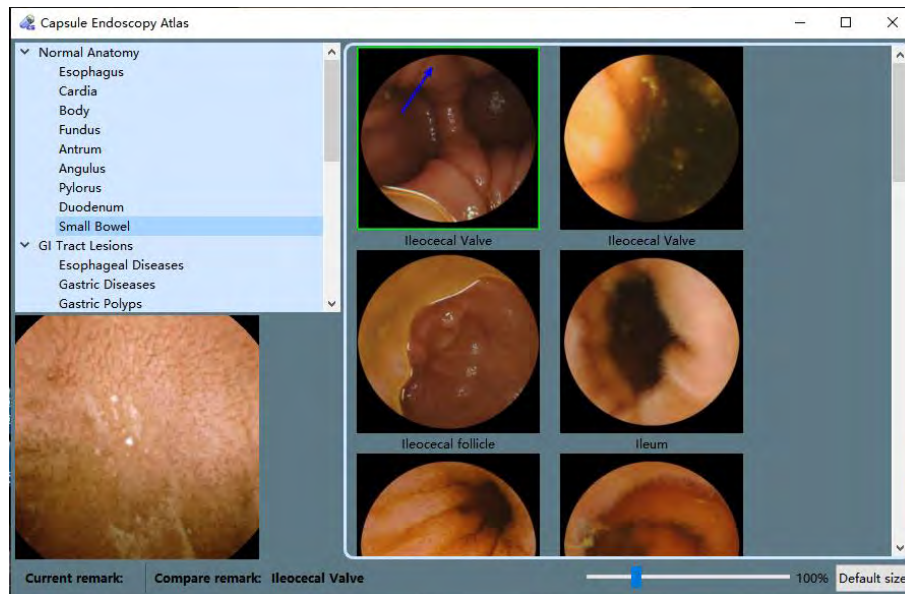


Figure 4-64: Capsule Endoscopy Atlas Interface

- Click on the normal anatomy images or typical GI tract lesions in stomach, duodenum, and small intestine. Select the stomach area or lesion type to be compared and view the corresponding normal anatomy images or lesion images, as shown in Figure 4-65.

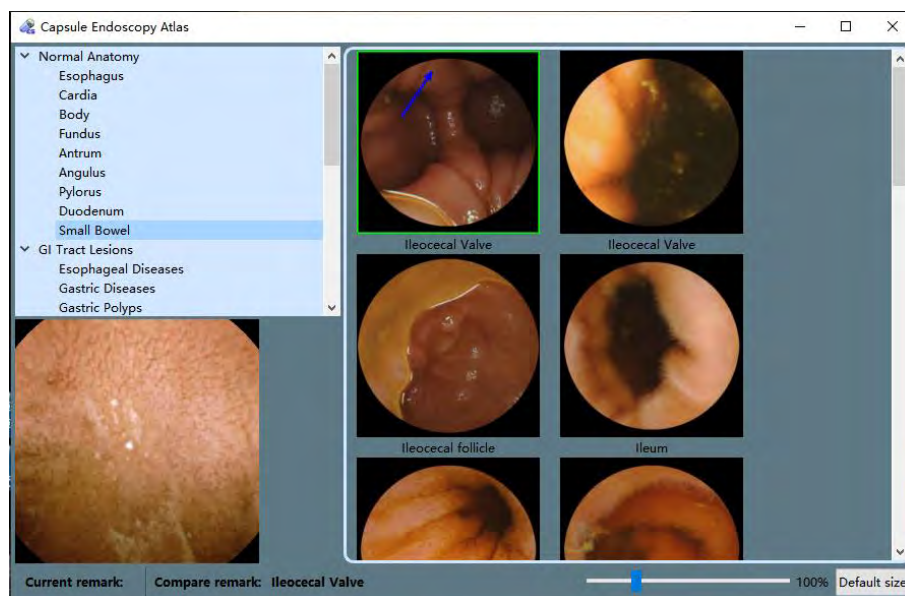


Figure 4-65: Normal Anatomy Images of Small Bowel

- On the atlas image to be compared, right click and select “Compare” in the pop-up menu to open the image comparison interface and compare the selected exam image with the atlas image, as shown in Figures 4-66 and 4-67. The image scaling factor can be changed by dragging the slider or scrolling the mouse.

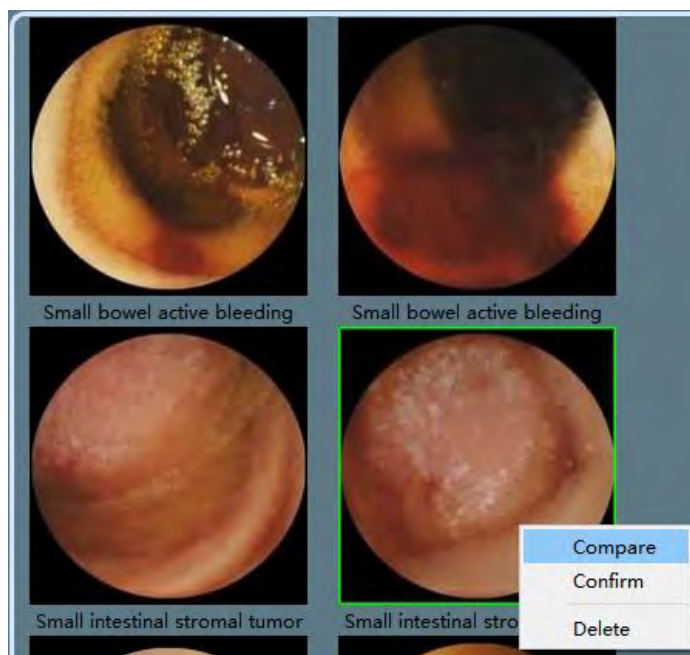


Figure 4-66: Comparison Between Exam Image and Atlas Image

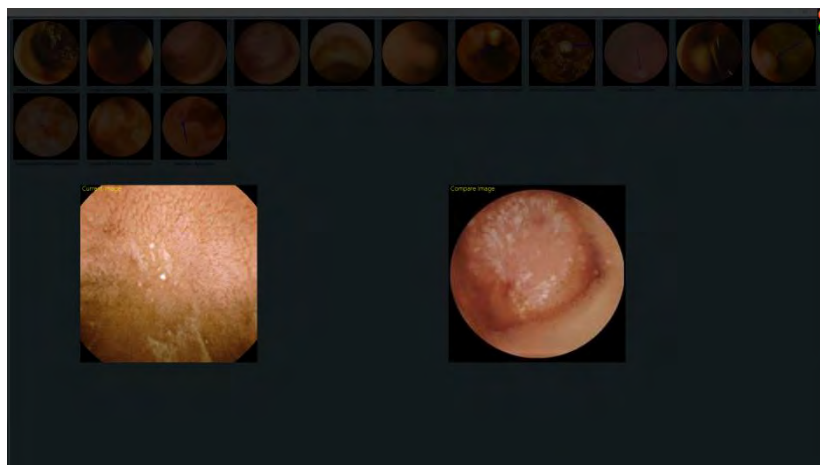


Figure 4-67: Image Comparison Interface

4. After comparison, if the location or lesion of the exam image is confirmed, click the green checkmark in the upper right corner of the image comparison interface to close it. The software will automatically add the name of the atlas image as a comment to the exam image (Figures 4-68 and 4-69).

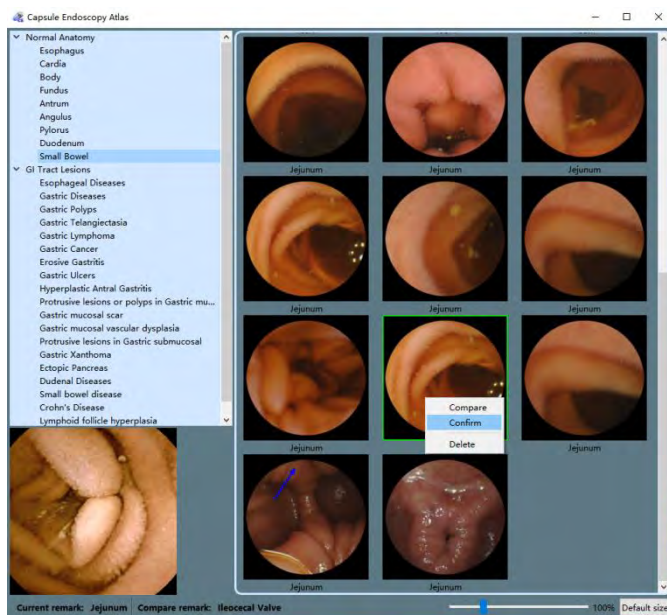


Figure 4-68: Confirm Comparison Result

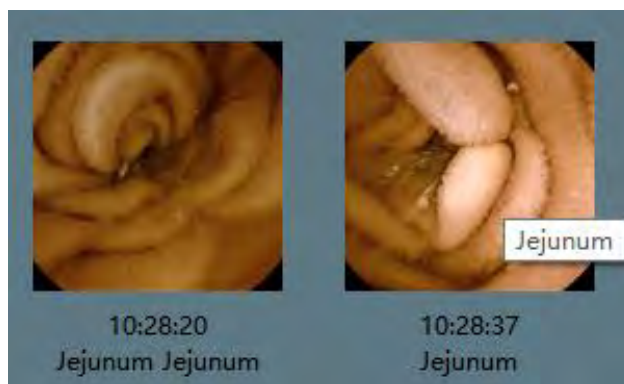


Figure 4-69: Name of Atlas Image Added as a Comment to the Exam Image

4.8 Software Help

1. In the main software interface, select “Help”→“About” to access the software information interface (Figure 4-70). The interface shows the full name, version number, and the manufacturer of the software.



Figure 4-70: Software Information Interface

2. In the main software interface, select “Help” ▾ “Instruction” in the menu to access the user manual.

4.9 Software Configuration Backup/Restore

1. The software supports configuration file backup and restore. The user can automatically or manually backup the configuration files of the software. The default backup path is D:\ankonConfigBackup\yyyymmdd_hhmmss. The user can manually restore the backup configuration files.
2. During initialization, the software will check if there are backup configuration files for the day. If not, it will automatically backup one.
3. Select “Help” ▾ “Backup configuration files” in the menu to manually backup the configuration files once. If the backup is successful, a dialog box confirming successful backup will appear (Figures 4-71 and 4-72).

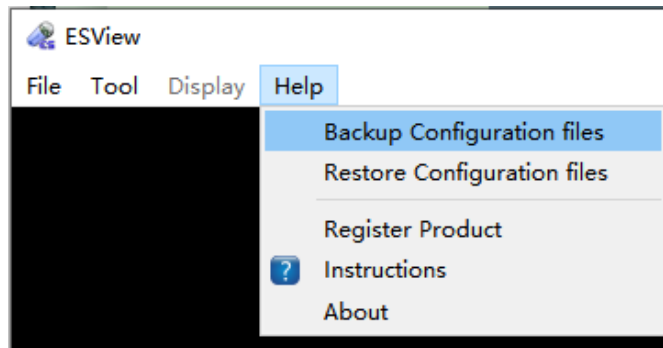


Figure 4-71: Backup Configuration File

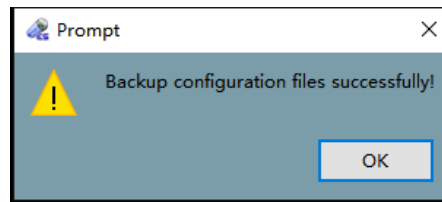


Figure 4-72: Dialog Box to Confirm Successful Backup of the Configuration Files

4. Select "Help" → "Restore configuration files" to open the restore configuration file selection interface, select the folder where the configuration files to be restored are located and click "Select Folder", then click "Confirm" in the pop-up dialog box to confirm configuration file restore. A dialog box will pop up to confirm the successful restore, as shown in Figures 4-73 to 4-76.

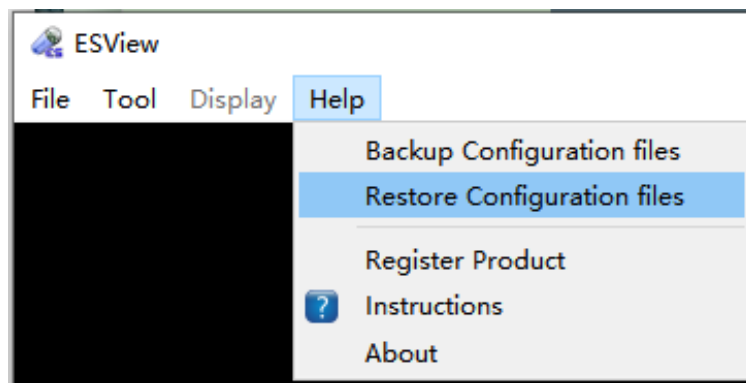


Figure 4-73: Restore Configuration File Manually

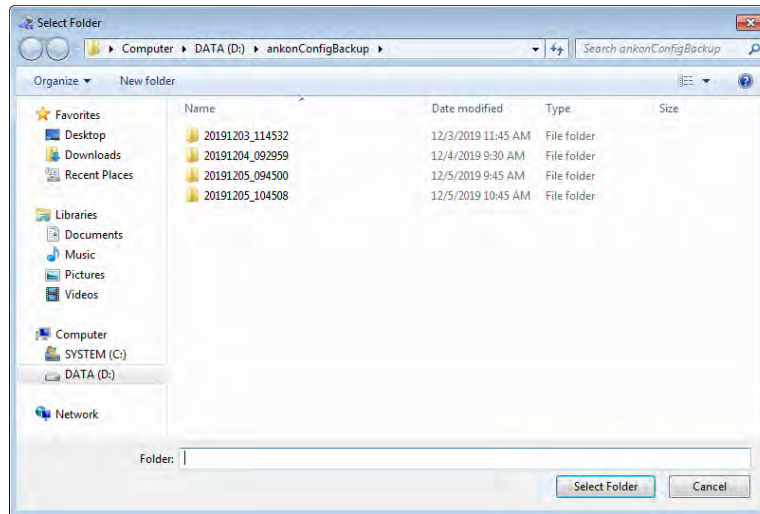


Figure 4-74: Restore Configuration File Selection Interface

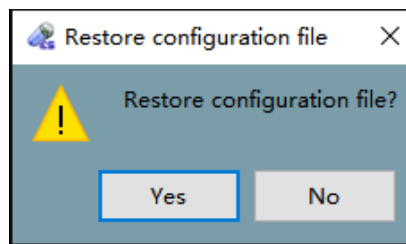


Figure 4-75: Dialog Box to Confirm Configuration File Restore

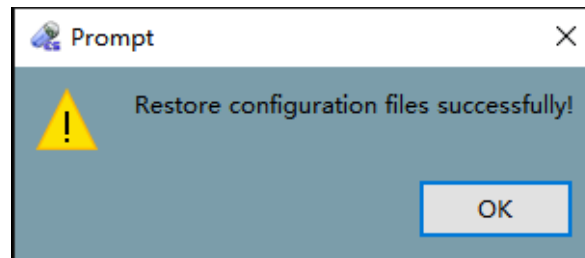



Figure 4-76: Dialog Box to Confirm Successful Restore

4.10 Software Exit

1. In the main software interface, select “File” → “Exit” in the menu or click the  button on the upper right corner, then on the pop-up dialog box (Figure 4-77) click “Yes” to exit or “No” to cancel.

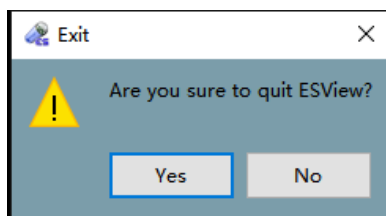


Figure 4-77: Exit Dialog Box

2. If a case report is changed, the user will be presented with the save finding dialog box (Figure 4-78) upon exit, where the user can click "Yes" to save findings, "No" to exit without saving findings, or "Cancel" to cancel exit.

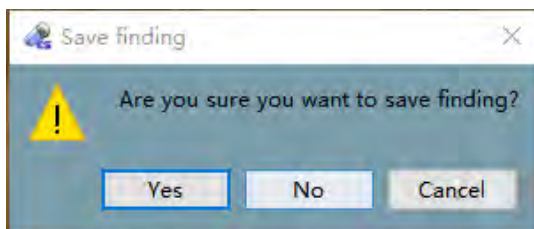


Figure 4-78: Save Finding Dialog Box

Chapter 5: USING THE 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.

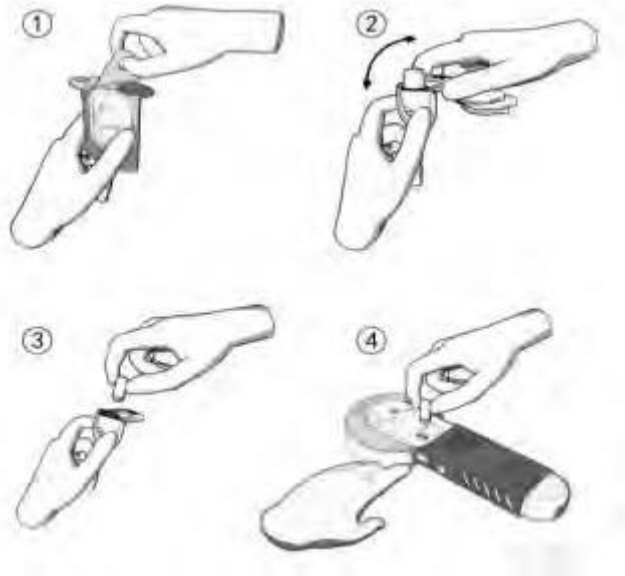


Figure 5-1: Schematic Diagram of Capsule Activation for Use

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: USING THE DATA RECORDER

6.1 Data Recorder(AKR-1)

6.1.1 Installation and Use

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 vest as shown in Figure 6-2. As tested, the working temperature of the data recorder can reach 42°C tested under 40°C 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.

Please pay attention to the matching relationship with the model and frequency of the Capsule when using the Data Recorder . See Table 1-1 for details.



Figure 6-2: AKR-1 Data Recorder Vest

6.1.2 Operation Instructions

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

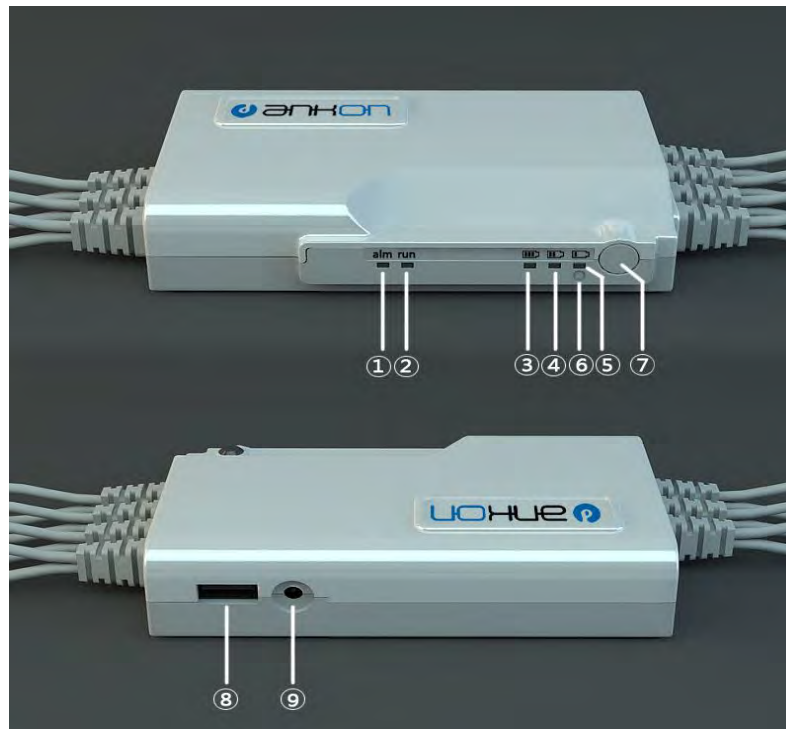


Figure 6-3 AKR-1 Data Recorder Operation Manual

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

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 ESView 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 ③④⑤ LEDs 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.

6.2 Data Recorder (AKRI-1)

6.2.1 Installation and Usage

The (AKRI-1) Data Recorder is composed of Host, Belt-examining cloth and Charging Base. The appearance are shown in Figure 6-4, Figure 6-5 and Figure 6-6 respectively.

Please pay attention to the matching relationship with the model and frequency of the Capsule when using the Data Recorder. See table 1-1 for details.



Figure 6-4 AKRI-1 Data Recorder Host



Figure 6-5 AKRI-1 Belt-examining cloth



Figure 6-6 AKRI-1 Charging Base

During the period of use, it is better to put on the cloth covers the belly button, and make it can be moved upward to obtain the best signal transmission effect during the examination of esophagus.

The port in the small pocket of the Belt-examining cloth is inserted into the right port of the AKRI-1 Data Recorder and then put them into the pocket of the Host as shown in Figure 6-7.



Figure 6-7 AKRI-1 Belt-examining cloth Dressing View

6.2.2 Operation Description

The LED indicator light, On/Off button, screen display button, USB port, belt port, screen on the AKRI-1 Data Recorder, and the power-on indicator light, data port, power port on the base.

All of the equipment corresponding identifications and positions are as shown in Figure 6-8.



Figure 6-1 Operation Panel of AKRI-1 Data Recorder

- (1) Charging Indicator Light
- (2) Status Indicator Light
- (3) Telecommunication Indicator Light
- (4) Power-on Button
- (5) Screen Control Button
- (6) Display Screen
- (7) USB port
- (8) Power-on Indicator Light on Base
- (9) Data port on Base
- (10) Power port on Base

6.2.2.1 Description of Indicator Light

- Press and hold the Power-on button for a long time to boot the AKRI-1 Data Recorder. At this time, it will display the current state on the Display Screen.
- To power off the AKRI-1 Data Recorder, please click the corresponding button of ESView Software for the operation.
- If the AKRI-1 Data Recorder cannot detect the information of the capsule for 30 minutes, and cannot connect to the computer via the USB port, it would be automatically power off to save power.
- If the telecommunication indicator light flash green, which means received the capsule's data is received normally.
- If the telecommunication indicator light flash yellow, which means there have some abnormality, but the capsule's data has received.
- If the telecommunication indicator light does not shine, which means there have no capsule's data received.
- The Status Indicator Light is green usually, and it will be yellow in case of the following situations:
 - (1) Low Battery; (2) Belt not Connected; (3) Other Equipment Exception;
- The Charging Indicator Light will constant on if powered on, and goes out if unconnected with the power. If the Data Recorder is not full charged, the Charging Indicator Light will flash yellow, if it is filled with charge, the Charging Indicator Light will flash green.

- Press the Screen Display button to light the screen for 30s. If it is pressed again during the display, it will count the time again to display for 30s. The information displayed on the screen is as follows:
Row 1: (1) Telecommunication Status Icon. (2) Battery Icon: Battery charge level.
Row 2: (1) Wireless Channel. (2) The Pattern State of Small Intestine.
Row 3: Checkin state/Time of Examination. It will display “No Entry” if not entered. Otherwise, it will display the time of examination.
Row 4: Error Information. If there have no error information, no display on it.
- The base can charge and transmit data. The Power-on Indicator Light will flash green when the power port of the base is power-on. It can transmit data when the base is connected to the computer via data port.

**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.**

Chapter 7: USING THE LOCATOR

7.1 Operation Panel

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



Figure 7-1: Keys and Indicators of Locator

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

7.2 Use

7.2.1 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 to 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.

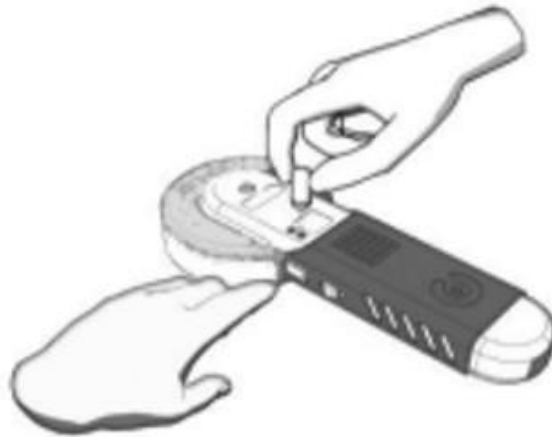


Figure 7-2: Schematic Diagram of turning-on the Capsule

7.2.2 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.

7.2.3 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 automatically shut down after 10 minutes without any operation.

7.2.4 Charge the Locator

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 8: TROUBLESHOOTING

8.1 ESView Warnings

Warning Message	Cause	Action
Fails to add patient information	Recording fails	Add patient information again
Complete addition of patient information	Record added	Click “Confirm” to exit the dialog box
Save change of patient information	Record changed	Click “Confirm” to exit the dialog box
Cancel change of patient information	Confirm cancel	Click “Confirm” to confirm cancel, or click “Cancel” to undo it
Delete patient information	Confirm deletion	Click “Confirm” to confirm deletion, or click “Cancel” to undo it
Add case completed	Record added	Click “Confirm” to exit the dialog box
Delete case information	Confirm deletion	Click “Confirm” to confirm deletion, or click “Cancel” to undo it
Connection error	Cannot connect to the data recorder, need to check if USB is connected properly	Click “Confirm” and reconnect the data recorder to USB
Data export warning	Data export is not completed	Click “Yes” to stop data export or “No” to continue export
Exit video view	Exit video view	Click “Yes” to exit the image browser, click “No” or “Cancel” to undo it
Confirm exit	Confirm exit	Click “Confirm” to exit the software or “Cancel” to undo it
Print error	Printer error	Check printer power and printer settings

8.2 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
	Capsule is not activated	Activate the capsule again
	Equipment failure	Contact technical support personnel
Real-time image is not transmitted to computer	Transmission problems with Data Recorder	See below actions
	Capsule is not activated	Activate the capsule using the Locator

8.3 Data Recorder

Exception	Possible Cause	Action
Turn the power switch on, and LED or screen are not lit up	Low battery	Charge the system for 8 hours
	Device malfunction	Contact a technical support staff
An image is not transmitted to your computer in real-time	The capsule is not activated	Use Locator to activate the capsule
	Signal transceiver of the recorder is invalid	Contact a technical support staff

8.4 Locator

Problem	Possible Cause	Action
Turn the power switch on, and LED not lit up	The battery is dead	Charge the system again for 8 hours
	Device malfunction	Contact technical support staff

Cannot activate the capsule	Capsule malfunction	Contact technical support staff
	Device malfunction	Contact technical support staff

**WARNING**

- If problem cannot be addressed with the above actions, please contact ANKON Technologies Customer Support.

Chapter 9: MAINTENANCE

9.1 Cleaning the Data Recorder Vest

After each procedure, the examination vest can be sprayed with 70% IPA and then wiped with a clean, dry cloth and air dried for at least 15 minutes. The outer layer of fabric can be washed in water. The layer inside that contains the antenna and cables is not washable, it is not in direct contact with the human body and does not require cleaning itself.

The Data Recorder vest should be cleaned as follows:

1. Take the Data Recorder out of the vest.
2. The outer layer of fabric is fastened to the inspection suit by a snap button. Remove the outer layer of fabric and immerse it in warm water with neutral soap for 20 minutes.
3. Gently rub and then dry it.

The Vest cleaning method specified in this Chapter applies to the vest disassembly and cleaning AKR-1 Data Recorder and AKRI-1 Data Recorder.



CAUTION

- Do not dry clean or iron the vest.

9.2 Cleaning the Data Recorder and Locator

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

Note:

As the equipment is equipped with batteries inside, please use a cotton ball dipped with 70% isopropyl alcohol and then squeeze excessive alcohol out from the cotton ball before using it for wiping to avoid alcohol flowing into the equipment through the seams when wiping edges of the equipment.

9.3 Sterilization of capsule endoscope and treatment method after sterilization package damage

The capsule endoscope has been sterilized by ethylene oxide before ex-factory, and should not be used after the sterilization package is damaged. The capsule endoscopes are processed in accordance with local regulations regarding the disposal of electronic products.

Chapter 10: TECHNICAL SPECIFICATIONS

10.1 Data Recorder (AKR-1/AKRI-1)

Operating performance:

Recording time:	8 hours (2fps)
Storage capacity:	≥ 4 GB
Battery type:	Lithium battery, 3.6-4.2 VDC, ≥2500 mAh
Ambient temperature:	5~40°C / 41~104°F
Storage temperature:	0~40°C / 32~104°F
Safety type:	Built-in power supply type BF continuous running equipment
Grade of waterproof:	IPX0

RF Performance

2.4GHz AKR-1

Frequency:	2400~2483.5 MHz
Bandwidth:	≤3 MHz
Modulation:	GFSK
Emission Power:	≤10 mW(E1RP)

915MHz AKRI-1

Frequency Range:	902MHz-928MHz
Bandwidth:	≤1 MHz
Modulation Technique:	8-FSK, GFSK
Transmit power:	≤10mW(e.i.r.p.)

Adaptor:

AKR-1

Input:	100-240 V a.c , 50/60 Hz, 500 mA
Output:	5.2 V=2 A d.c
Protection	class: class II, continuous duty

AKRI-1

Input:	100-240 V a.c , 50/60 Hz, 500 mA
--------	----------------------------------

Output: 5.0 V=2 A d.c
Protection class: class II, continuous duty

Note: The data recorder incorporates a built-in RF module, while the module is completely shut down by software during operation.

FCC ID:

Data Recorder (AKR-1) FCC ID: 2A6BYAKR-1

Data Recorder (AKRI-1) FCC ID: 2A6BYAKRI-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.



WARNING

- The user shall avoid using RFID technology near the device while it is operating.

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

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:

FOV(entrance pupil): $120^{\circ} \pm 15\%$ FOV(distal window): $160 \pm 10\%$

DOF: 0 mm~30 mm

Resolving power: ≥ 6 lp/mm

Image performance:

Frame rate: 0.5~6 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: ≥ 8 hoursBattery type: Silver oxide cell ≥ 35 mAh

Rated voltage: 3V DC

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

Chemical safety: Resistance to dissolve when pH ranges from 2-8

Operating temperature: $20 \sim 40^{\circ}\text{C}$ / $68 \sim 104^{\circ}\text{F}$ Storage temperature: $0 \sim 40^{\circ}\text{C}$ / $32 \sim 104^{\circ}\text{F}$ RH: $\leq 85\%$

Grade of waterproof: IPX8

RF Performance

2.4GHz AKES-11SW

Frequency: 2400~2483.5MHz

Bandwidth: ≤ 3 MHz

Modulation: GFSK

Emission Power: ≤ 10 mW(E1RP)

915MHz AKES-11SI

Frequency Range: 902MHz-928MHz

Bandwidth: $\leq 4\text{MHz}$

Modulation Technique: 8-FSK, GFSK

Transmit power: $\leq 10\text{mW(e.i.r.p.)}$

FCC ID:

Capsule(AKES-11SW) FCC ID: 2A6BYAKES-11SW

Capsule(AKES-11SI) FCC ID: 2A6BYAKES-11SI

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.



WARNING

- The user shall avoid using RFID technology near the device while it is operating.

10.3 Locator

Locating performance:

Probing distance: $\leq 150\text{ mm}$

Operating performance:

Battery type: Lithium battery, 3.6-4.2 V DC, $\geq 2500\text{mAh}$

Ambient temperature: $5\sim 40^{\circ}\text{C}$ / $41\sim 104^{\circ}\text{F}$

Storage temperature: $0\sim 40^{\circ}\text{C}$ / $32\sim 104^{\circ}\text{F}$

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

Grade of waterproof: IPX 0

Adaptor:

Input: 100-240 V a.c, 50/60 Hz, 500 mA

Output: 5.2 V=2 A d.c

Protection class: class II, continuous duty

10.4 ESView Software

ESView software runs on the PC.

- 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

10.5 Guidance and Manufacturer's Declarations

NaviCam Small Bowel Capsule Endoscopy System complies with the requirements of IEC 60601-1-2:2014, EN 60601 1-2:2015.

10.5.1 Data Recorder

Guidance and manufacturer's declaration - electronic emissions		
The Data Recorder is intended for use in the electromagnetic environment specified below. The user of the Data Recorder should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
Radiated emissions CISPR 11	Group 1	The Data Recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class A	The harmonic current test and The voltage fluctuation and flick test are not necessary
Harmonic Emissions	N/A	

IEC 61000-3-2		because the Data Recorder isn't intended to be connected to the PUBLIC MAINS NETWORK.
Voltage fluctuations and flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Data Recorder is intended for use in the electromagnetic environment specified below. The user of the Data Recorder should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply Lines ±1 kV for input/output Lines	±2 kV for power supply Lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input Lines IEC 61000-4-11	<p>Voltage dips :</p> <p>0% UT; 0.5 cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>0% UT; 1 cycle and 70% UT; 25/30 cycles</p> <p>Single phase: at 0°</p>	<p>Voltage dips :</p> <p>0% UT; 0.5 cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>0% UT; 1 cycle and 70% UT; 25/30 cycles</p> <p>Single phase: at 0°</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Data Recorder requires continued operation during power mains interruptions, it is recommended that the Data Recorder be powered from an un-interruptible power supply or a battery.
	<p>Voltage interruptions : 0% UT; 250/300 cycle</p>	<p>Voltage interruptions : 0% UT; 250/300 cycle</p>	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	<p>30 A/m</p> <p>50 Hz or 60 Hz</p>	<p>30 A/m</p> <p>50 Hz or 60 Hz</p>	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Data Recorder is intended for use in the electromagnetic environment specified below.			
The user of the Data Recorder should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

			Portable and mobile RF communications equipment should be used no closer to any part of the Data Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 kHz – 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 V 150 kHz – 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

10.5.2 Capsule

Guidance and manufacturer's declaration - electronic emissions		
The Capsules are intended for use in the electromagnetic environment specified below.		
The user of the Capsules should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance

Radiated emissions CISPR 11	Group 1	The Capsules uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class B	The Capsules are suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Capsules are intended for use in the electromagnetic environment specified below.			
The user of the Capsules should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply Lines ± 1 kV for input/output Lines	N/A	N/A
Surge IEC/EN 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input Lines IEC 61000-4-11	Voltage dips : 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% UT; 250/300 cycle	N/A	N/A

Guidance and manufacturer's declaration - electromagnetic immunity			
The Capsules are intended for use in the electromagnetic environment specified below. The user of the Capsules should assure that it is used in such an environment.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical

			commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Capsules are intended for use in the electromagnetic environment specified below.			
The user of the Capsules should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of a Capsule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 kHz – 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

10.5.3 Locator

Guidance and manufacturer's declaration - electronic emissions
The Locator is intended for use in the electromagnetic environment specified below.
The user of the Locator should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
Radiated emissions CISPR 11	Group 1	The Locator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class A	The harmonic current test and The voltage fluctuation and flick test are not necessary because the Locator isn't intended to be connected to the PUBLIC MAINS NETWORK.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	N/A	














Guidance and manufacturer's declaration - electromagnetic immunity			
The Locator is intended for use in the electromagnetic environment specified below. The user of the Locator should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast	±2 kV for power supply Lines	±2 kV for power supply	Mains power quality should be that of a typical









transient /burst IEC 61000-4-4	± 1 kV for input/output Lines	Lines ± 1 kV for input/output Lines	commercial or hospital environment.
Surge IEC/EN 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interrupti ons and voltage variations on power supply input Lines IEC 61000-4-11	Voltage dips : 0% UT; 0.5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° Voltage interruptions : 0% UT; 250/300 cycle	Voltage dips : 0% UT; 0.5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° Voltage interruptions : 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Data Recorder requires continued operation during power mains interruptions, it is recommended that the Locator be powered from an un-interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic Field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields Should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

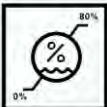
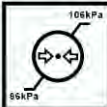
Guidance and manufacturer's declaration - electromagnetic immunity			
The Locator is intended for use in the electromagnetic environment specified below. The of the Locator should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Locator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 kHz – 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 V 150 kHz – 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

Chapter 11: SYSTEM LABELING

Followings are labels of the system components:

Symbol	Description
	Serial Number
	Manufacturer
	Date of Manufacture
	Type B Applied Part
	Type BF Applied Part
	Do not re-use
	Sterilized using ethylene oxide
IPX8	IP Code(10m,2h)
	Batch Code
	Use by
	Non-ionizing electromagnetic radiation
	Do not use if package is damaged
	Refer to instruction manual/booklet
	Caution

	<p>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.”</p>
	<p>Nameplate of Data Recorder (AKR-1)</p>
	<p>Nameplate of Locator (AKS-1)</p>
	<p>Nameplate of Data Recorder (AKRI-1)</p>
	<p>Keep dry</p>
	<p>This Side Up</p>
	<p>Stacking Limit (Not Exceed 3 Layers)</p>
	<p>Temperature Limit 0°C~40°C (Shipping Package)</p>

	Humidity Limit 0%~80% (Shipping Package)
	Pressure Limit 86kPa~106kPa