2. 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.

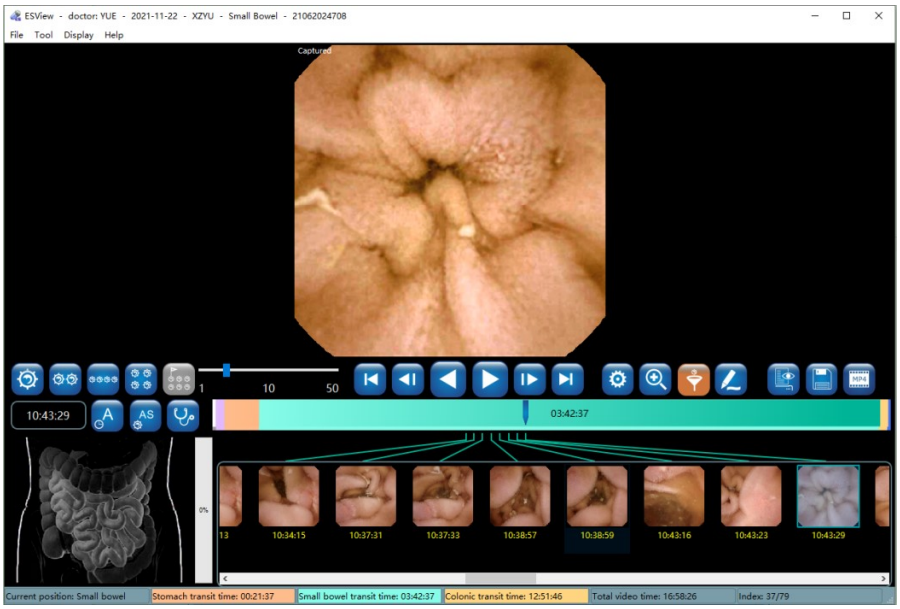


Figure 4-39: Filter Browsing Mode

4.4.9 Option Setting

1. In the main software interface, select “Tool” → “Option” to access the option setting interface (Figure 4-40).

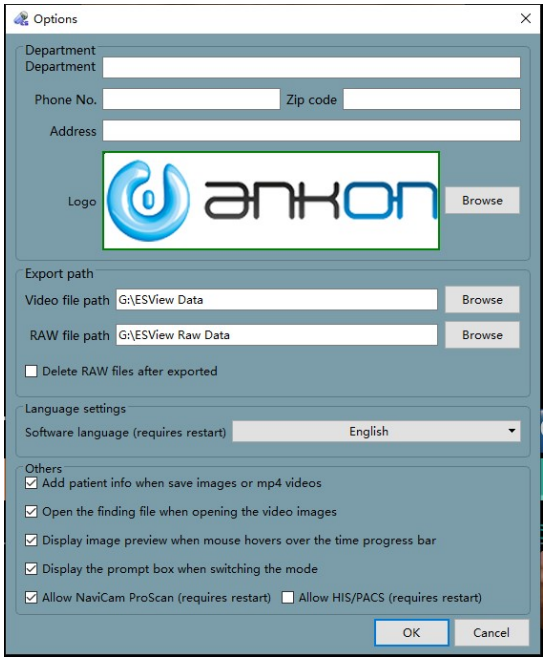


Figure 4-40: Option Setting Interface

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.

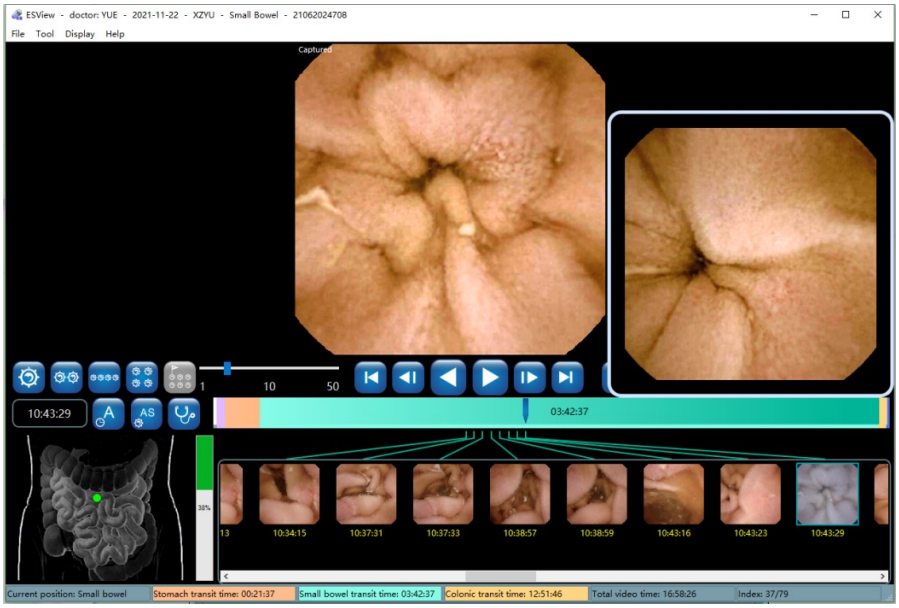


Figure 4-41: Image Preview

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.

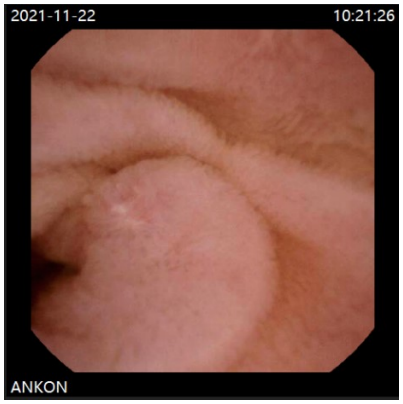


Figure 4-42: Saved Image Showing Patient Information

4.4.10 NaviCam ProScan

NaviCam ProScan feature contains two main 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.

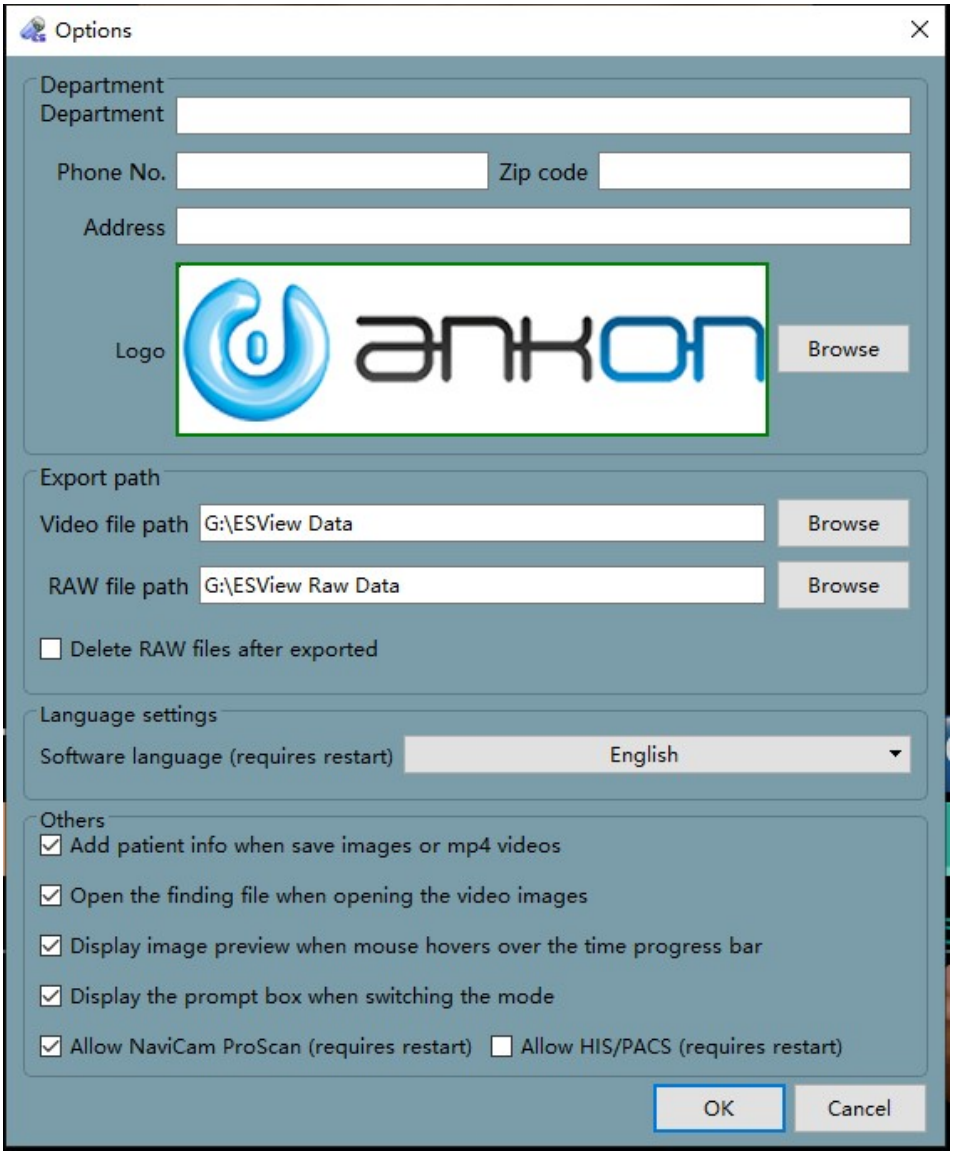


Figure 4-43: **ProScan Feature Option**

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.

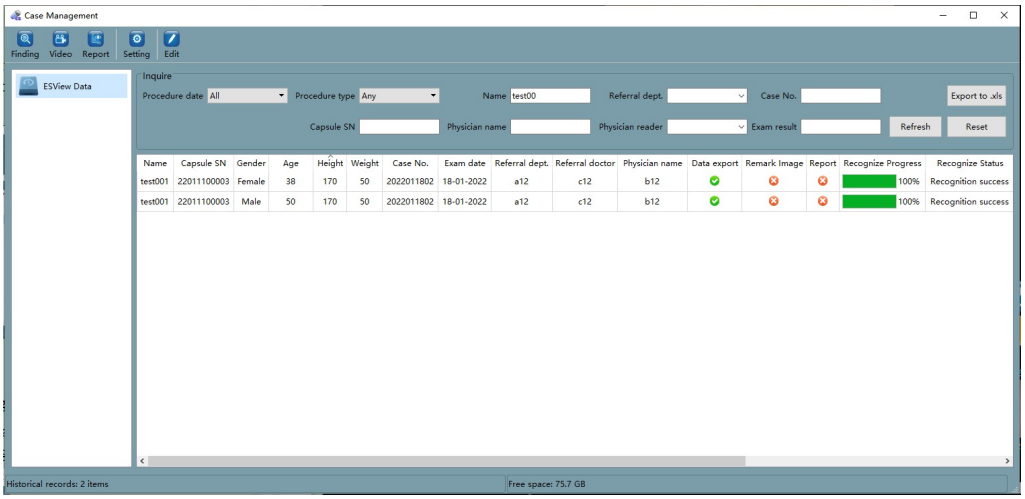


Figure 4-44: **Recognize Progress**

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 can be displayed by selecting “File” → ”Open Video”. The icon will appear 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.

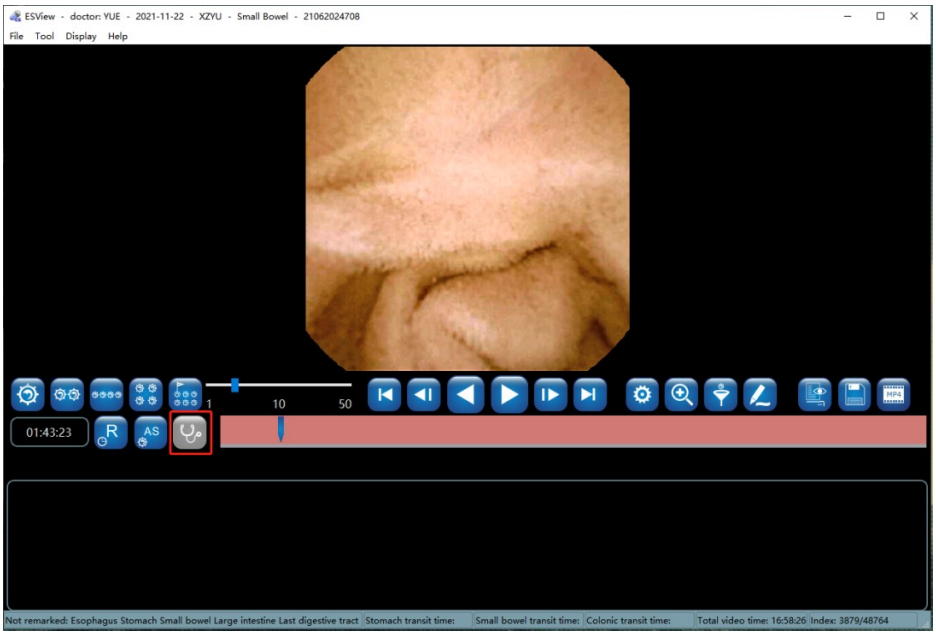


Figure 4-45: NaviCam ProScan function is enabled

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

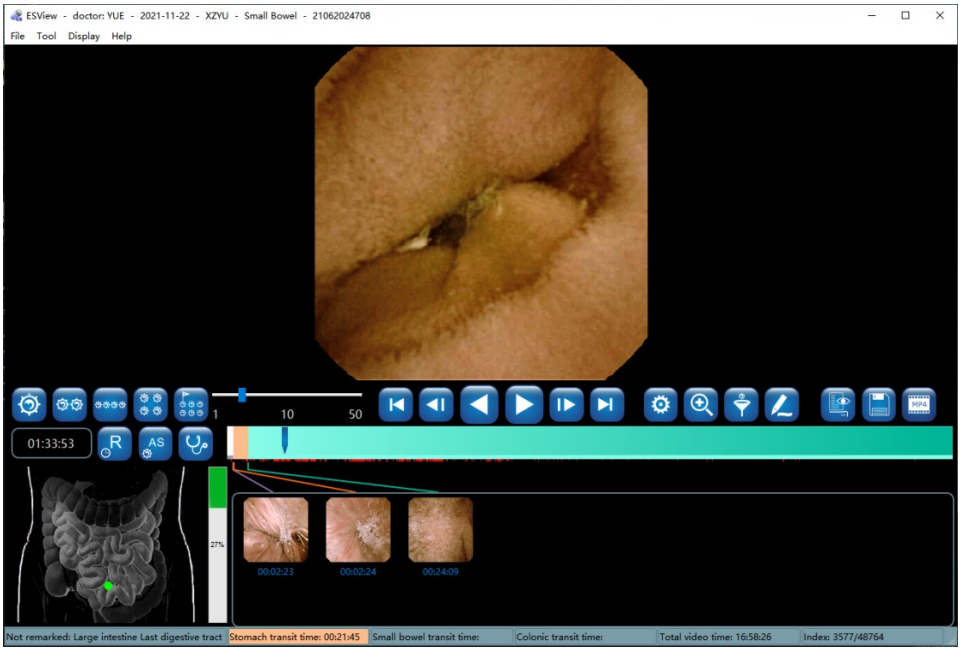


Figure 4-46: NaviCam ProScan Total Images Mode

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.

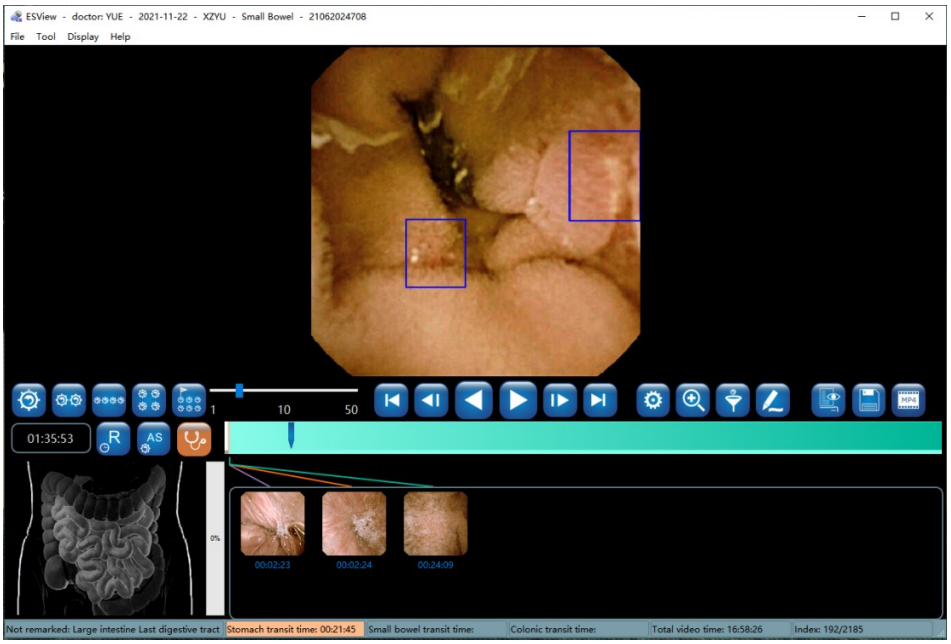


Figure 4-47: NaviCam ProScan Mode

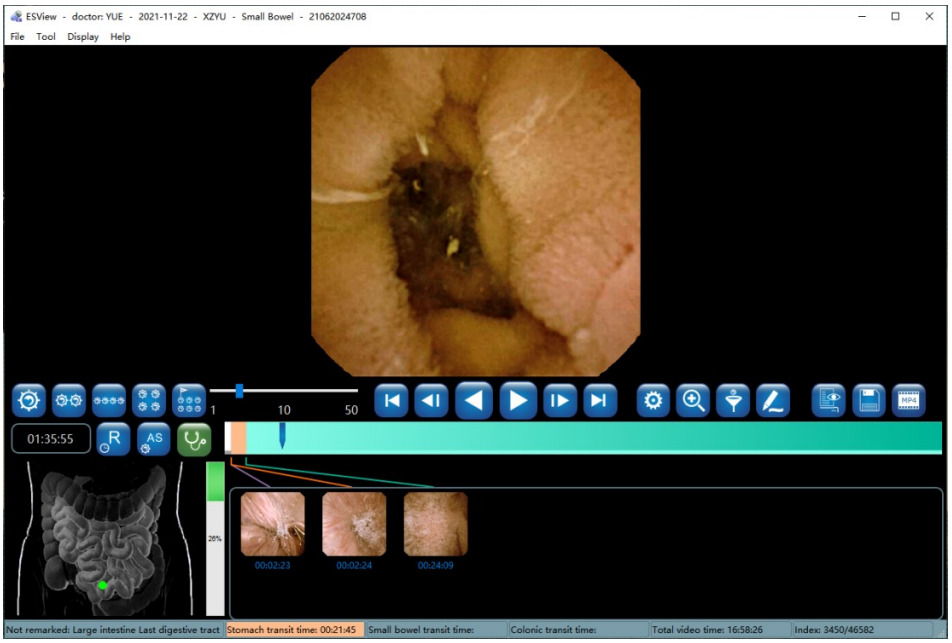


Figure 4-48: NaviCam ProScan* Normal Images *Mode

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.

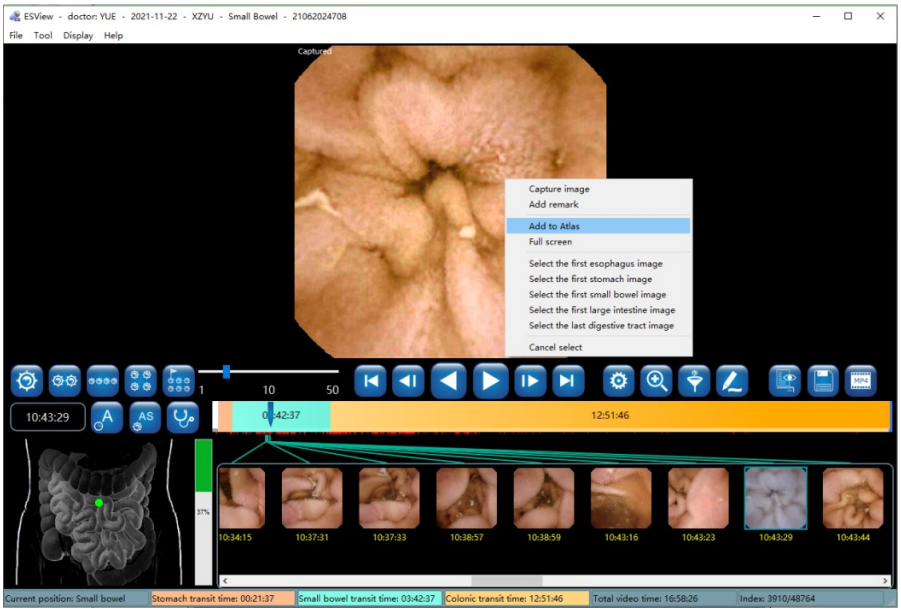


Figure 4-49: Add to Atlas

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.

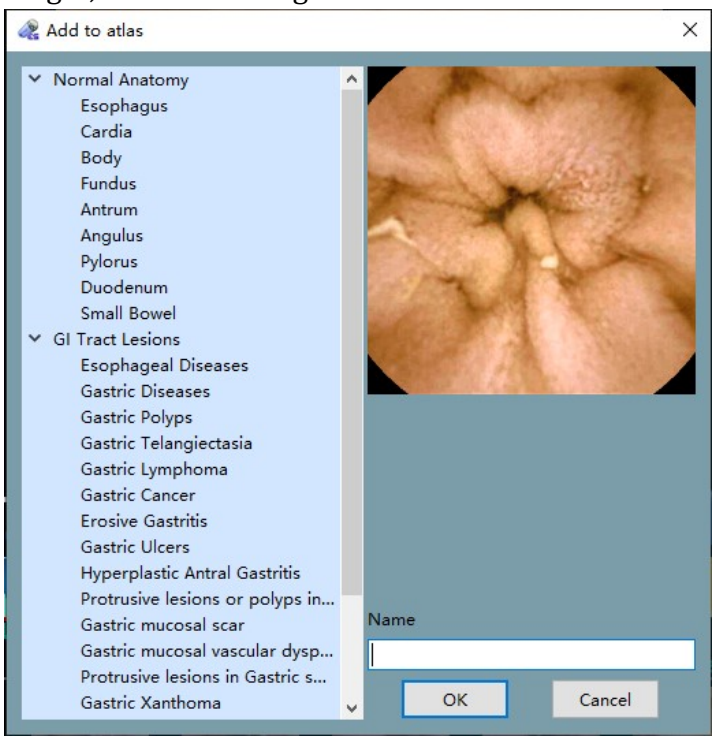


Figure 4-50: Add to Atlas Interface

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.

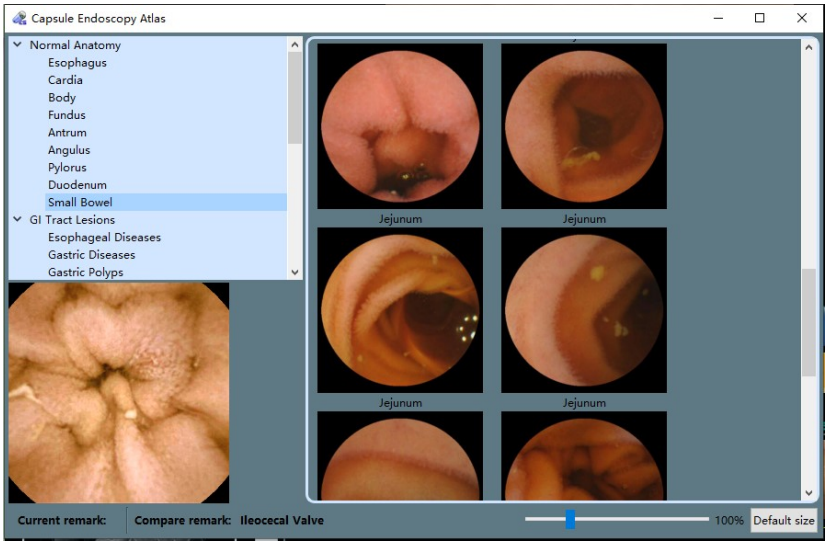


Figure 4-51: Capsule Endoscopy Atlas Interface

4.5 Report Generation

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

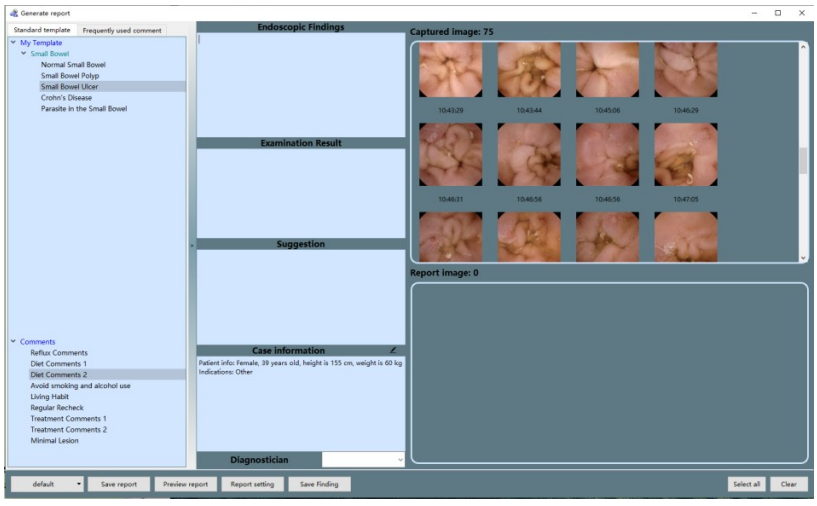


Figure 4-52: Report Generation Interface

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).

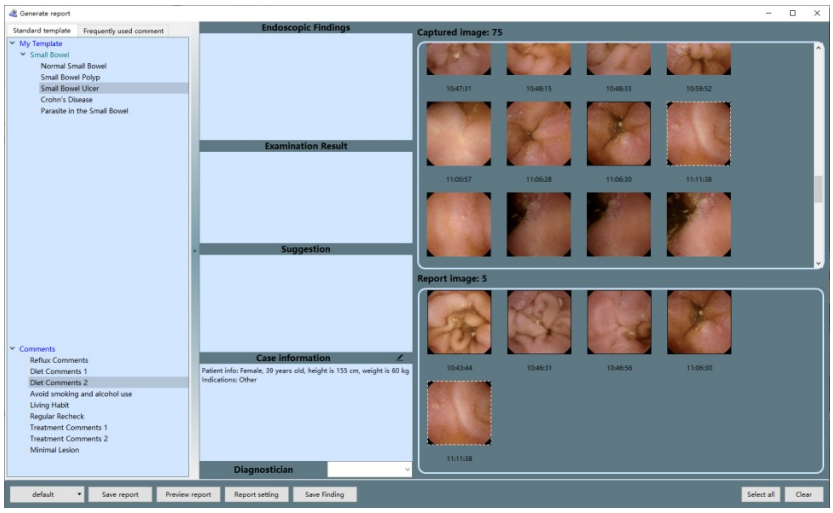


Figure 4-53: Select Images for Report

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).

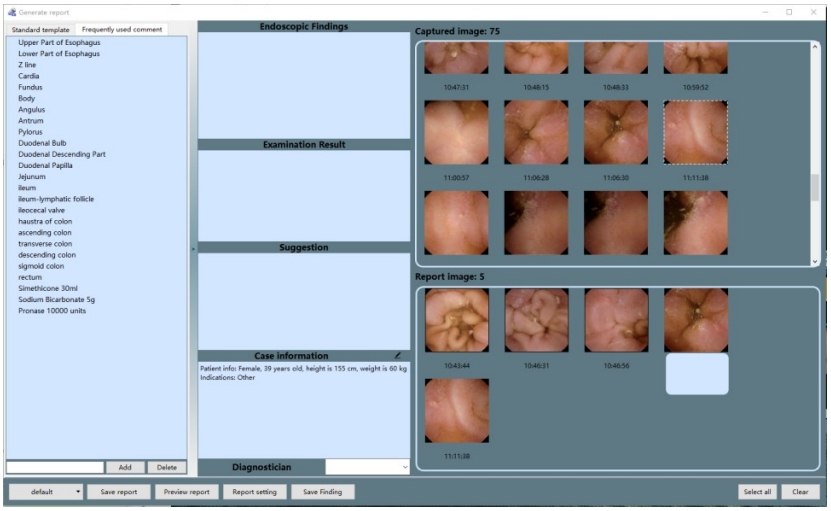


Figure 4-54: Edit Report Image Comment

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.

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.

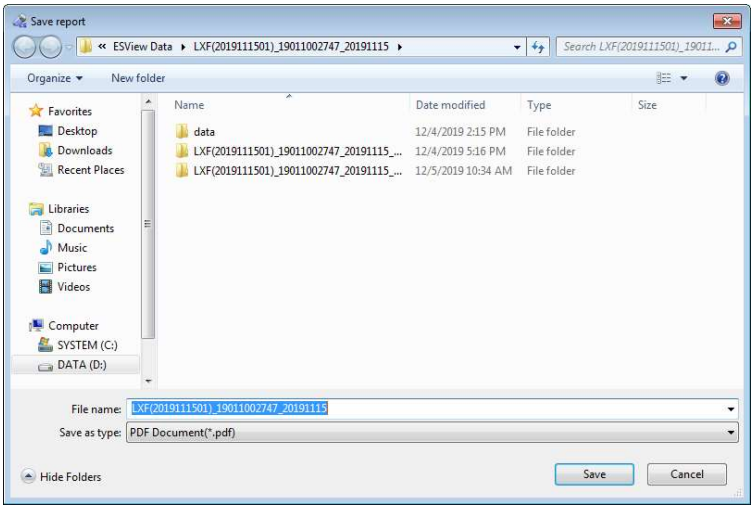


Figure 4-56: Save Report in .pdf Format

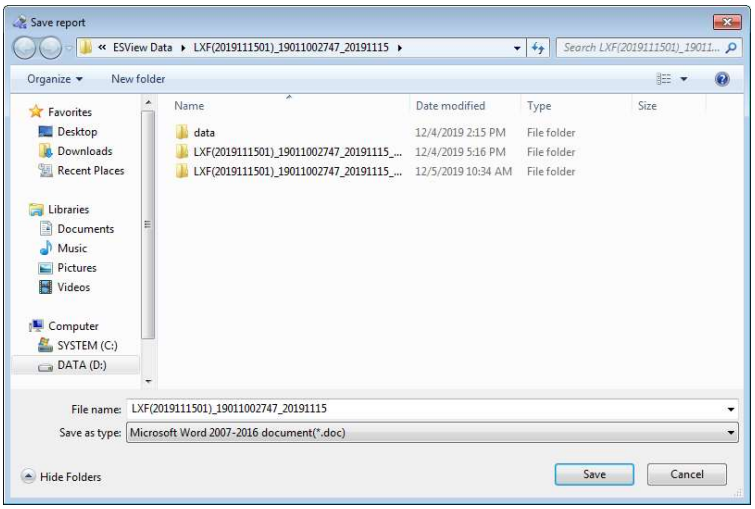


Figure 4-57: Save Report in .doc Format

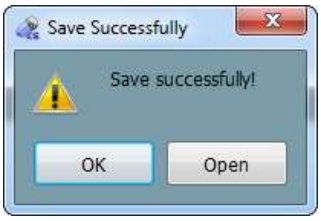


Figure 4-58: Saving Success Dialog Box

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.

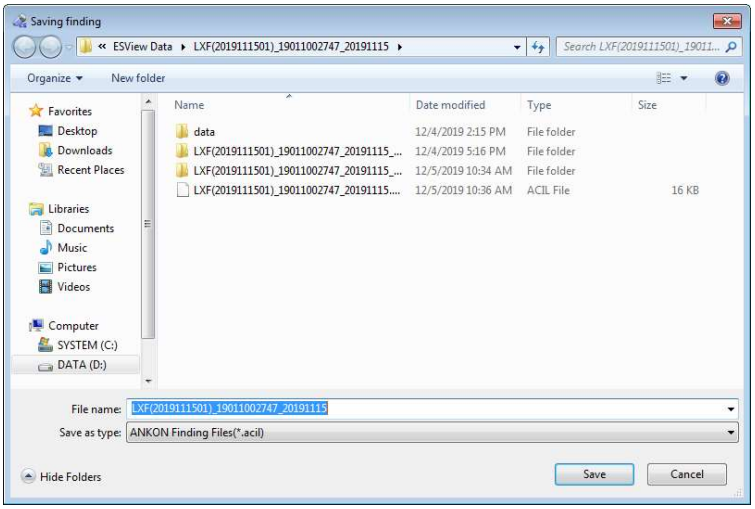


Figure 4-59: Save Finding Interface

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.

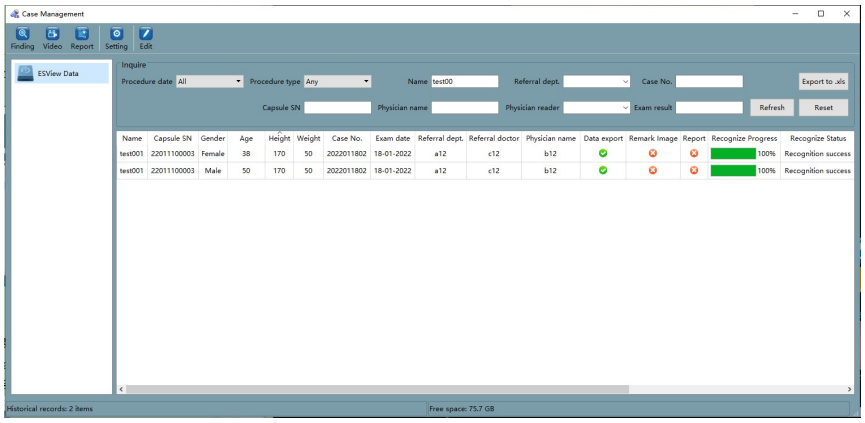


Figure 4-60: Case Management Interface

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.

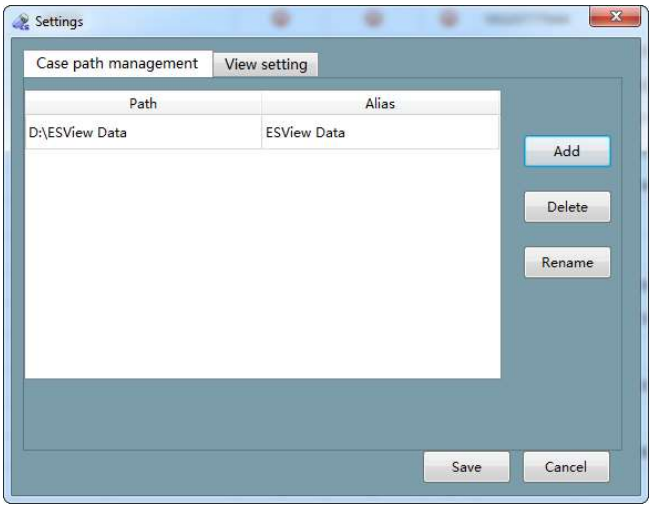


Figure 4-61: Add Case Data Storage Path Interface

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 date 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.

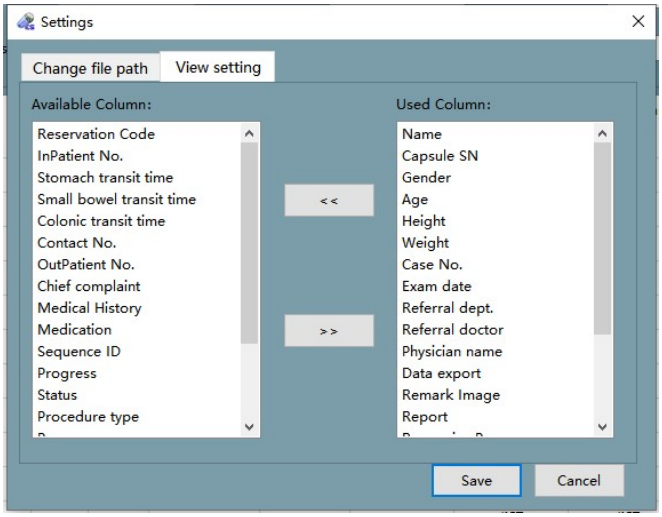


Figure 4-62: View Setting Interface

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.

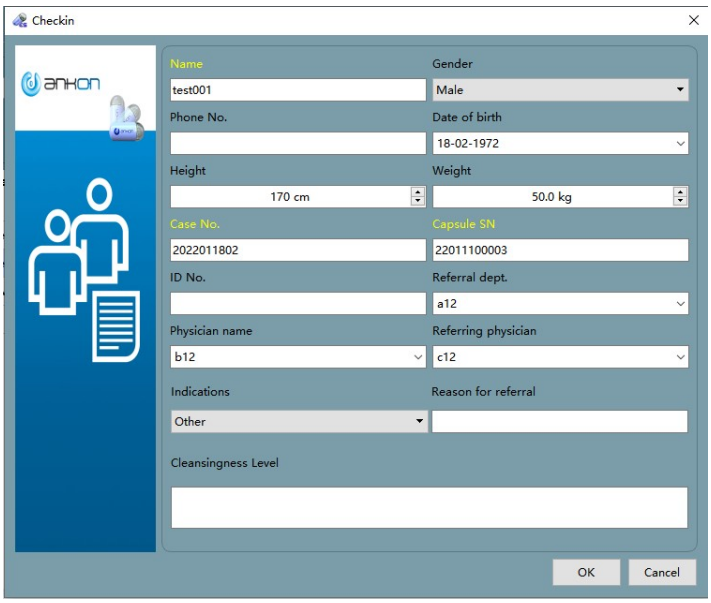


Figure 4-63: Patient Information Editing Interface

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).

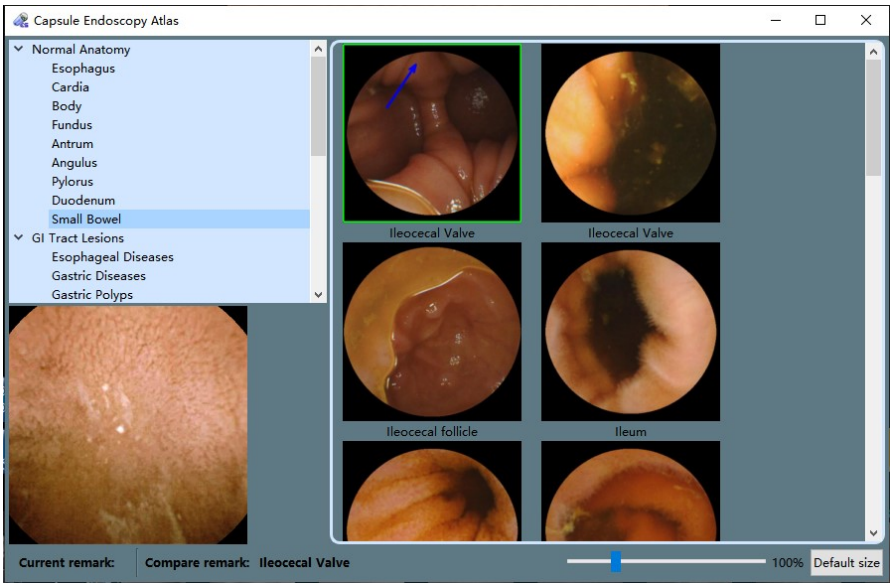


Figure 4-64: Capsule Endoscopy Atlas Interface

2. 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.

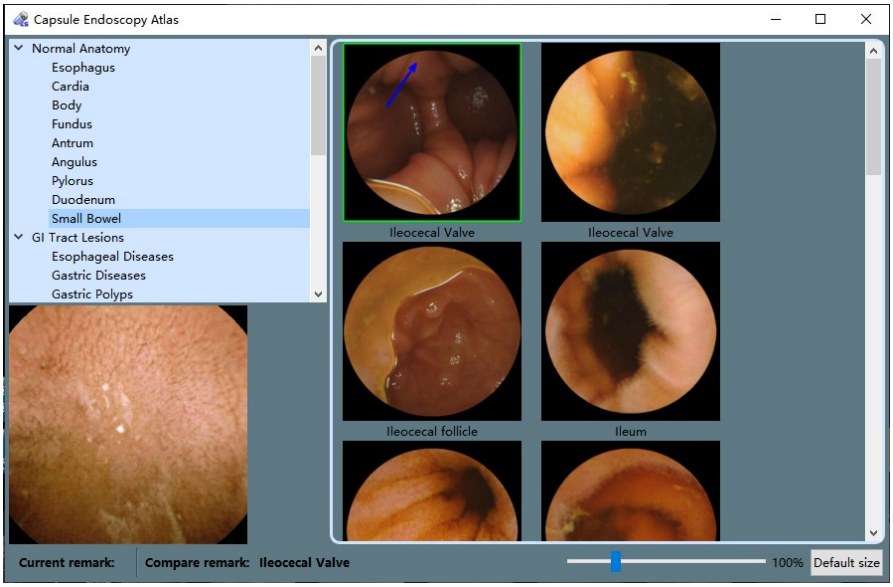


Figure 4-65: Normal Anatomy Images of Small Bowel

3. 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.

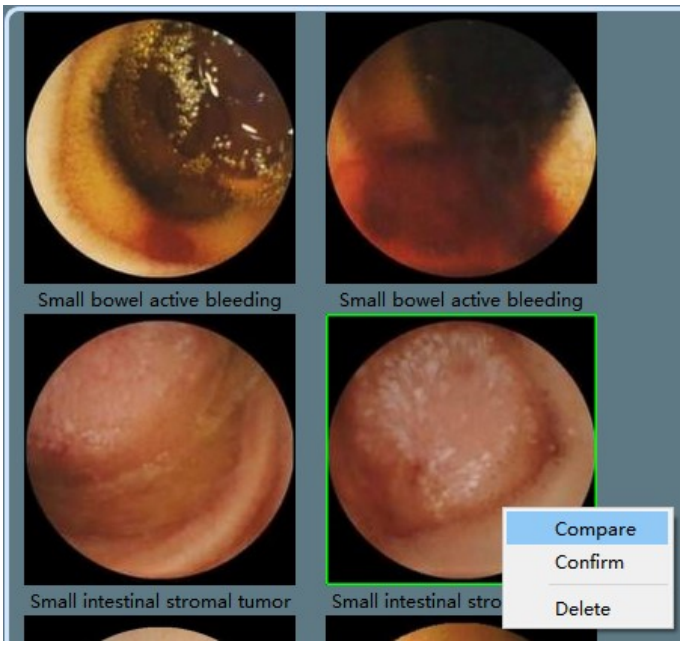


Figure 4-66: Comparison Between Exam Image and Atlas Image

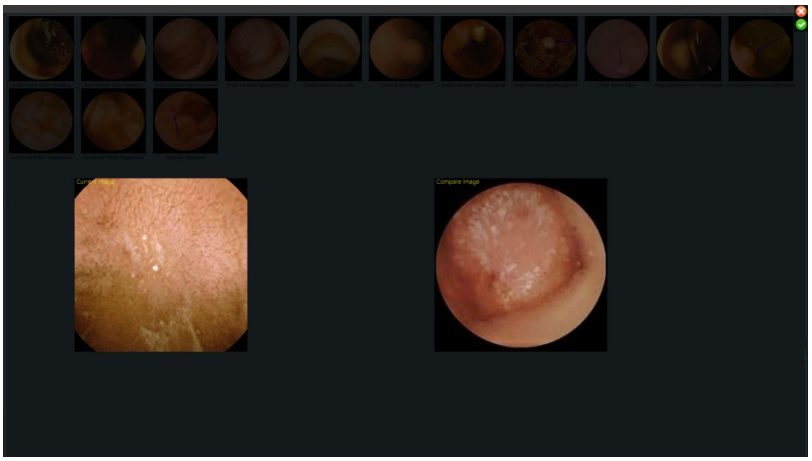


Figure 4-67: Image Comparison Interface

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).

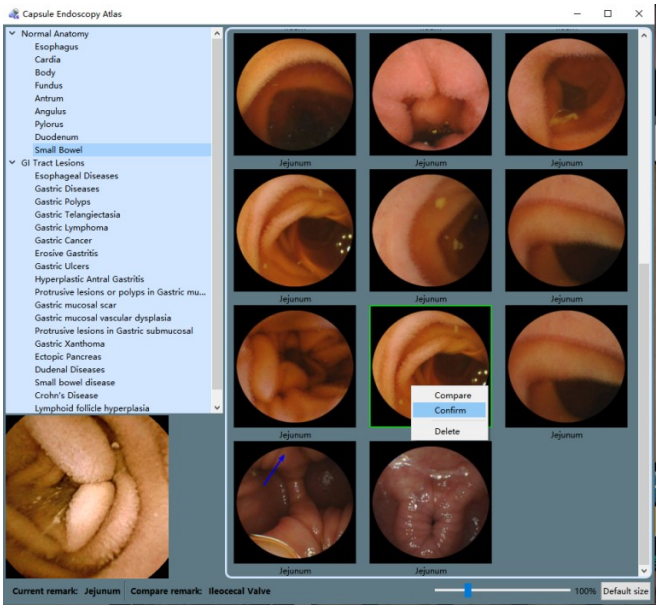


Figure 4-68: Confirm Comparison Result

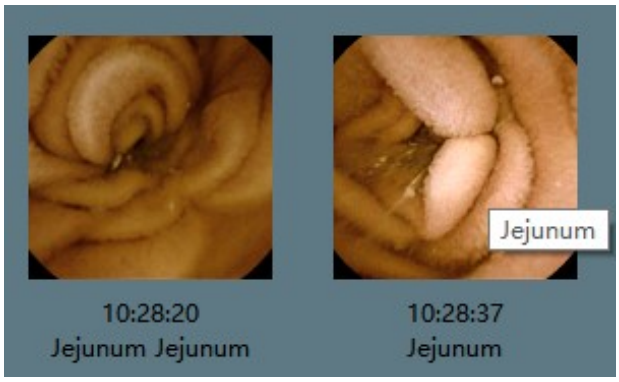


Figure 4-69: Name of Atlas Image Added as a Comment to the Exam Image

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).

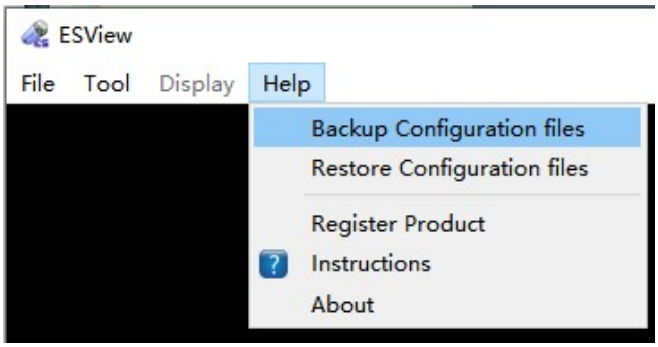


Figure 4-71: Backup Configuration File

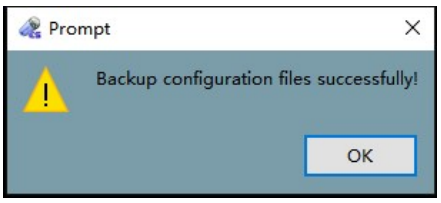


Figure 4-72: Dialog Box to Confirm Successful Backup of the Configuration Files

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.

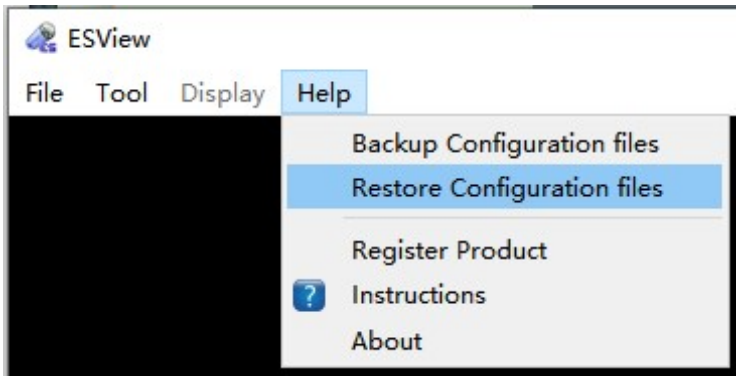


Figure 4-73: Restore Configuration File Manually

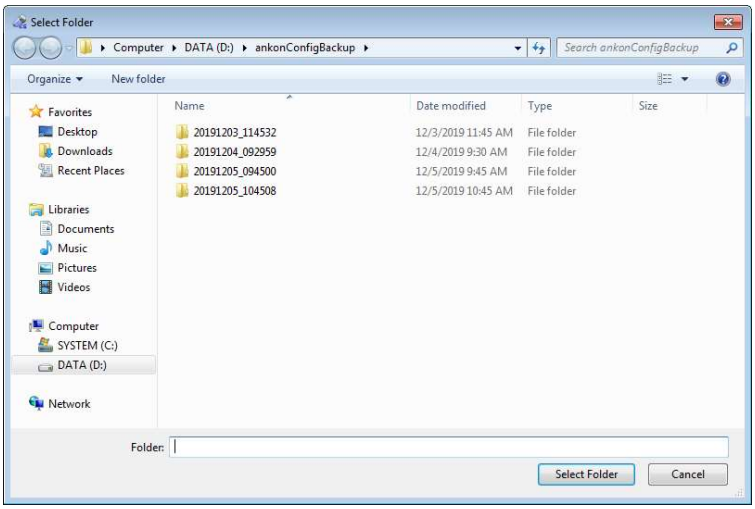


Figure 4-74: Restore Configuration File Selection Interface

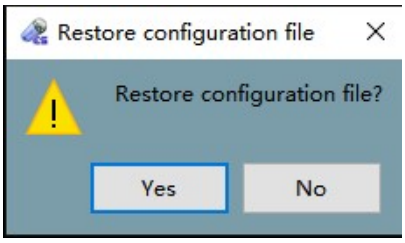


Figure 4-75: Dialog Box to Confirm Configuration File Restore

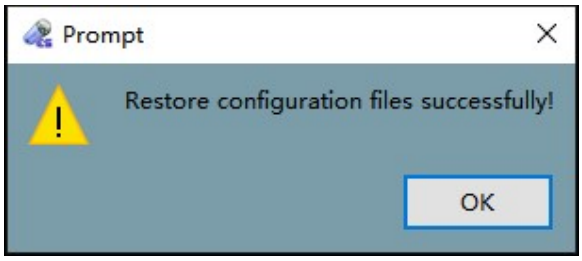


Figure 4-76: Dialog Box to Confirm Successful Restore

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.

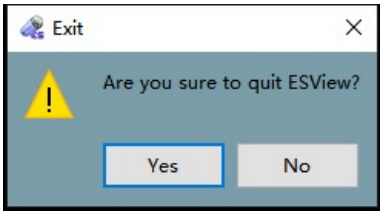


Figure 4-77: Exit Dialog Box

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.

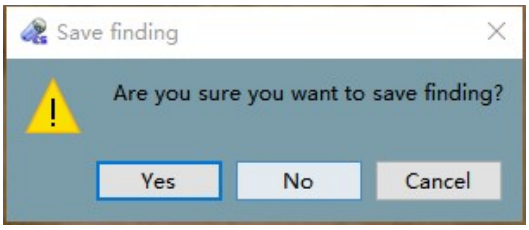


Figure 4-78: Save Finding Dialog Box

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.

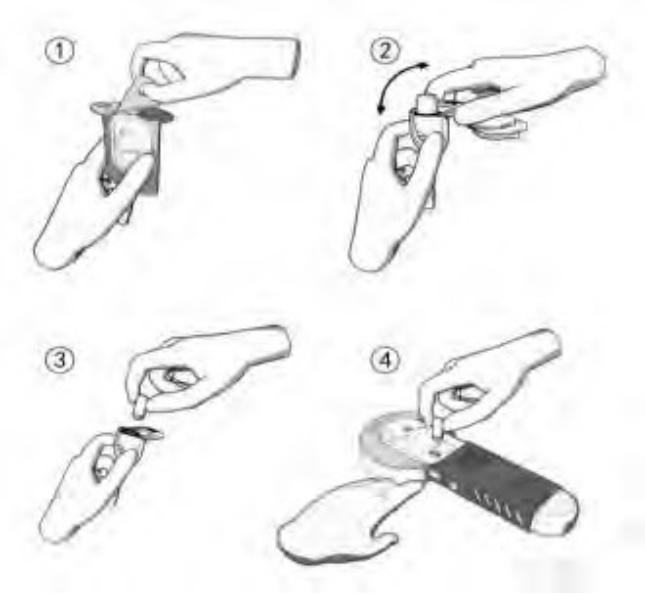


Figure 5-1: Schematic Diagram of Capsule Activation for Use

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.**
- **The capsule is provided sterile. Do not use a capsule if package is damaged.**
- **Disposal of capsules should be done according to local regulation for disposal of electronic products.**

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.

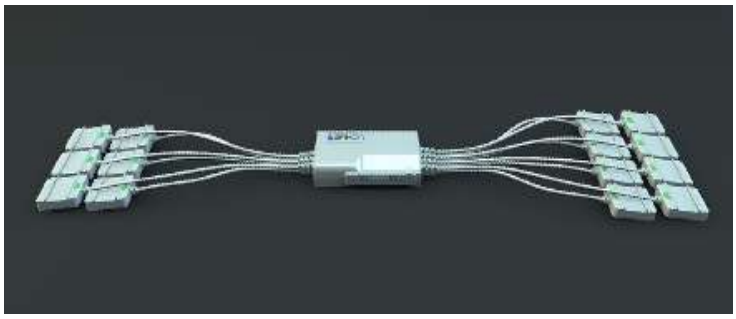


Figure 6-1: Data Recorder (AKR-1)

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℃ tested under 40℃ ambient temperature. Since the data recorder does not contact patient skin directly, the temperature will not cause burn or other hazard to patients and operators, and the contact duration can be longer than 10 minutes.

Figure 6-2: AKR-1 Data Recorder Vest

WARNING

- **Data Recorder AKR-1 can only be used with Capsule AKES-11SW.**

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.

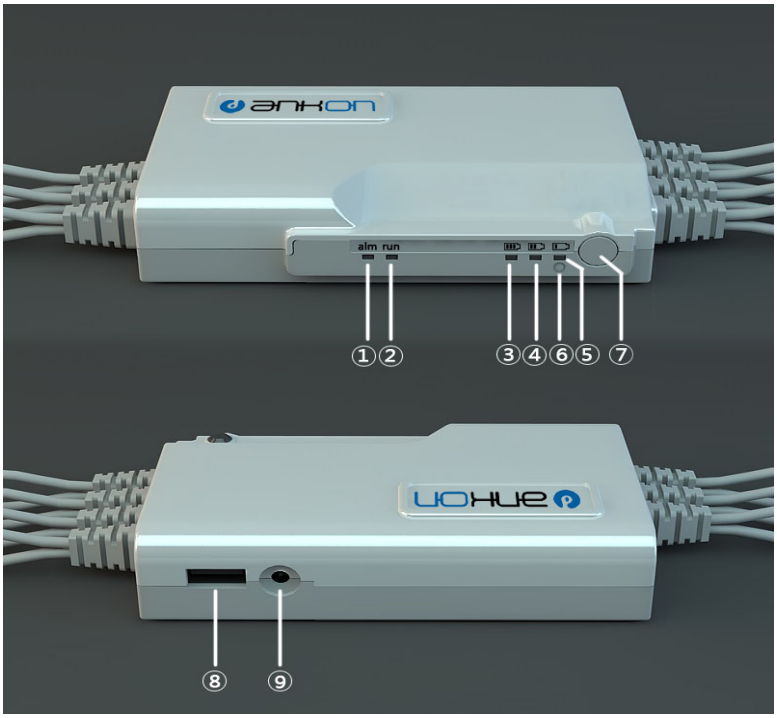


Figure 6-3 AKR-1 Data Recorder Operation Manual

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

Hold down the power switch without releasing until all the five LEDs (marked as ①②③④⑤ in Figure 6-3) are lit up to power on the Data Recorder normally. Click the related button in the 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 ③④⑤LEDs are all lit up, more than 70% when ④⑤ LEDs are lit up, and 40% when ⑤ LED is lit up. If only ⑤ LED is on/off flashing, the remaining battery capacity is very limited. If the Data Recorder is powered on and being charged,

these three LEDs will be on and off flashing in a cycle manner. If the white LED charge indicator (marked as in ⑥ in Figure 6-3) keeps lighting up, it indicates that it is under charging (it will be lit up once it is charged regardless of the status of the Data Recorder power). 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, as shown in Figures 6- 4, 6- 5, and 6- 6 respectively.

Figure 6- 4: AKRI-1 Data Recorder Host

Figure 6- 5: AKRI-1 Belt-Examining Cloth

Figure 6- 6: AKRI-1 Charging Base

WARNING

- **Data Recorder AKRI-1 can only be used with Capsule AKES-11SI.**

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 in the pocket of the Host as shown in Figure 6-7.

Figure 6- 7 AKRI-1Belt-Examining Cloth Dressing View

6.2.2 Operation Description

Through the display of the indicators, interactive operation of the buttons, interface on the Host to realize AKRI-1 Data Recorder function , including the following:

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- 8: 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 3 seconds 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, click the Turn On/Off button in ESView Software Interface.
- If the AKRI-1 Data Recorder cannot detect the information of the capsule for 30 minutes and cannot connect to the software of Rtdisplay via USB port, it would be automatically power off to save power.
- If the telecommunication indicator light flashes green, it means the capsule's data are adequately received.
- If the telecommunication indicator light flashes yellow, it means some abnormalities occurred, but the capsule's data has been received.
- If the telecommunication indicator light does not flash, it means no capsule's data have been received.
- The Status Indicator Light is should be green. It will turn yellow in the following situations:

  (1) Low Battery; (2) Belt not Connected; (3) Other Equipment Exception.
- The Charging Indicator Light remains on when power is on and turns off if power is disconnected. If the Data Recorder is not full charged, the Charging Indicator Light will flash yellow, if it is fully charged, 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: Check-in 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 will appear.
- The base can charge and transmit data. The Power-on Indicator Light will flash green when the power port of the base is powered-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.

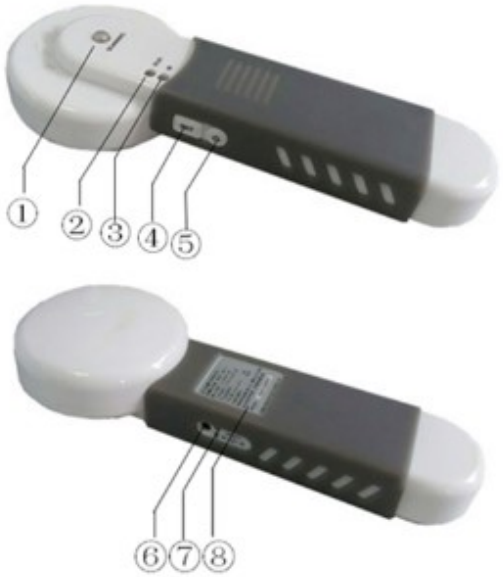


Figure 7-1: Keys and Indicators of Locator

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

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.

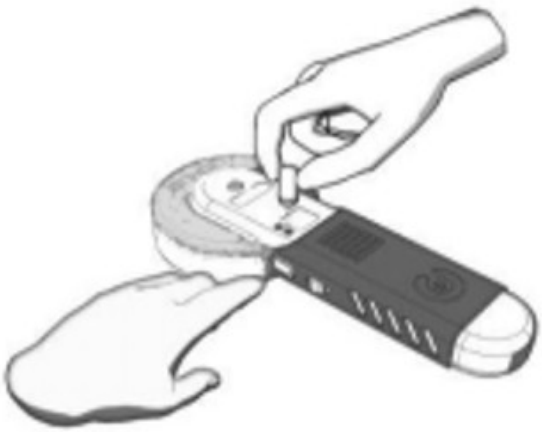


Figure 7-2: Schematic Diagram of turning-on the Capsule

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	Replace the capsule
	Capsule is not activated	Activate the capsule again
	Equipment failure	Contact technical

Problem	Cause	Action
Real-time image is not transmitted to computer	Transmission problems with	See below actions
	Capsule is not activated	Activate the capsule

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/Belt-Examination Cloth

After each procedure, the examination vest/belt should 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. For the vest, the inside layer that contains the antenna and cables is not washable, it is not in direct contact with the human body and does not require cleaning.

The Data Recorder vest/belt should be cleaned as follows:

1. Take the Data Recorder out of the vest/belt.
2. 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.

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 from the cotton ball before using it for wiping to avoid alcohol flowing into the equipment through the seams when wiping the edges of the equipment.

CHAPTER 10: TECHNICAL SPECIFICATIONS

10.1 Data Recorder (Model 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

Environmental operating conditions

a temperature range to +5 ℃to +40 ℃

a relative humidity range of 15% to 90%, non-condensing but no requiring a water vapour partial presssure greater than 50 hPa and

An atmospheric pressuer range of 700 hPa to 1060 hPa

Environmental conditions of transport and storage

Temperature Limit：-25 ℃~70 ℃
Humidity Limit：0% ~90%
Pressure Limit：700 hPa~1060 hPa

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

Degrees of protection provided by enclosures: IP22

Shelf Life of AKR-1/AKRI-1：5 years

RF Performance

2.4GHz AKR-1

Frequency:	2400~2483.5 MHz
Bandwidth:	≤3 MHz
Modulation:	GFSK
Emission Power:	≤10 mW(e.i.r.p)

915MHz AKRI-1

Frequency Range:	902MHz-928MHz
Bandwidth:	≤4 MHz

Modulation Technique:	8-FSK
Transmit power:	≤10mW(e.i.r.p.)

Adaptor:

UE15WCP1-052200SPA for Model 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

UE10WCP1-050200SPA for Model 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(Model AKES-11SW/AKES-11SI)

Physical performance:

Length:	27 ± 1.0 mm
Diameter:	11.8 ± 0.5mm
Weight:	4.5 ± 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°±15%
FOV(distal window):	160±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 hours
Battery 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

Environmental operating conditions

a temperature range to +5 ℃to +40 ℃

a relative humidity range of 15% to 90%, non-condensing but no requiring a water vapour partial presssure greater than 50 hPa and

An atmospheric pressuer range of 700 hPa to 1060 hPa

Environmental conditions of transport and storage

Temperature Limit：-25 ℃~70 ℃
Humidity Limit：0% ~90%
Pressure Limit：700 hPa~1060 hPa

Degrees of waterproof: IPX8

RF Performance

2.4GHz AKES-11SW

Frequency:	2400~2483.5MHz
Bandwidth:	≤3MHz
Modulation:	GFSK
Emission Power:	≤10mW(e.i.r.p)

915MHz AKES-11SI

Frequency Range:	902MHz-928MHz
Bandwidth:	≤4MHz
Modulation Technique:	8-FSK
Transmit power:	≤10mW(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 (Model AKS-1)

Locating performance:

Probing distance:	≤150 mm

Operating performance:

Battery type:	Lithium battery, 3.6-4.2 V DC, ,≥2500mAh
Safety type:	Built-in power supply type BF continuous running equipment
Grade of waterproof:	IPX 0

Environmental operating conditions

a temperature range to +5 ℃to +40 ℃

a relative humidity range of 15% to 90%, non-condensing but no requiring a water vapour partial presssure greater than 50 hPa and

An atmospheric pressuer range of 700 hPa to 1060 hPa

Environmental conditions of transport and storage

Temperature Limit：-25℃～70℃
Humidity Limit：0% ～90%
Pressure Limit：700 hPa～1060 hPa

Adaptor:

UE15WCP1-052200SPA for Model AKS-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

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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electronic emissions</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Radiated emissions
CISPR 11</td><td>Group 1</td><td rowspan="2">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.</td></tr>
<tr><td>Conducted emissions
CISPR 11</td><td>Class A</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>N/A</td><td rowspan="2">The harmonic current test and The voltage fluctuation and flick test are not necessary because the Data Recorder isn't intended to be connected to the PUBLIC MAINS NETWORK.</td></tr>
<tr><td>Voltage fluctuations and flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

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 ment - 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	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, ±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	Voltage dips： 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° ,315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	Voltage dips： 0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° ,315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	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.
	Voltage interruptions 0% UT; 250/300 cycle	Voltage interruptions 0% UT; 250/300 cycle	
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 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	
Harmonic Emissions IEC 61000-3-2	N/A	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.
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%.

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.			
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	Voltage dips： 0% UT; 0.5 cycle	N/A	N/A
variations on power supply input Lines IEC 61000-4-11	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		
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	
Harmonic Emissions IEC 61000-3-2	N/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.
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 transient/burst IEC 61000-4-4	±2 kV for power supply Lines ±1 kV for input/output Lines	±2 kV for power supply Lines	Mains power quality should be that of a typical commercial or hospital environment.

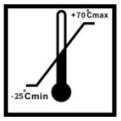
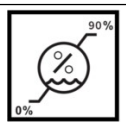
Guidance and manufacturer's declaration - electromagnetic immunity			
The Locator is intended for use in the electromagnetic environment specified below. The user of the Locator should assure that it is used in such an environment.			
Surge IEC/EN 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV, ±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	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.			

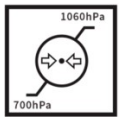
Guidance and manufacturer's declaration - electromagnetic immunity			
The Locator is intended for use in the electromagnetic environment specified below. The of the Locator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic 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 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
	Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please

Symbol	Description
	recycle where facilities exist. Check with your local Authority or retailer for recycling advice."
	Nameplate of Data Recorder（AKR-1）
	Nameplate of Locator (AKS-1)
	Nameplate of Data Recorder（AKRI-1）
	Keep dry
	This Side Up
	Stacking Limit (Not Exceed 3 Layers)
	Temperature Limit -25℃~70℃ (transport and storage)
	Humidity Limit 0%~90% (transport and storage)

Symbol	Description
	Pressure Limit 700hPa~1060hPa