

 Smart Capsule 2
Capsule Endoscopy Systems
User Manual

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Conventions

Clickable screen elements, such as menu, button are shown in blue bold letters with brackets:
[Clickable Elements].

System components and messages from the software are displayed in blue italic form with comma:
'Would you like to continue?'

Certain safety and precautionary information may appear in this manual, please read them carefully and follow strictly.

Titles	Connotation
 WARNING	Warns you about conditions which could harm human body.
 CAUTION	Warns you about conditions which could damage the device.
 ATTENTION	Emphasized note or useful information

Abbreviations

Certain items might be abbreviated for short, these would appear in **BOLD BLACK TEXT**, they are listed as follows:

Abbreviations	Full Text
JINSHAN	Chongqing Jinshan Science & Technology (Group) Co.,Ltd.
CE	Capsule Endoscopy
Capsule	OMOM Smart Capsule
Recorder	Image Recorder
VUE	OMOM® VUE workstation software

Legal Statement

Purpose

This manual is intended for the OMOM® capsule endoscopy system (Type JS-ME-I).

OMOM® capsule endoscopy system is designed for gastrointestinal tract visualization, and is not intended for any other purpose.

Copyright

This manual is under the copyright protection of **JINSHAN**.

It is against the law to revise, translate or copy content in this manual in any form without permission.

This manual may be changed without prior notice

Trademark

“OMOM” is a trademark registered by **JINSHAN**.

Authorization

JINSHAN secures all designs and production procedures of the capsule endoscopy system by authorization.

- No unit or individual is allowed to lend, transfer or sell the product in any form without our authorization.
- **JINSHAN** is not liable for any unauthorized use of licensed products.
- **JINSHAN** holds no liability to conditions caused by unauthorized artificial damage or tempering of this system and/or its components.
- **JINSHAN** reserves the right to change design within the scope of the law without prior notice.
- Any after-sale service and maintenance should be carried out only by the staff from **JINSHAN** or its designated agents. Warranty for this product is void if any unauthorized party made alterations or attempts to repair it.
- The termination of any authorization will be regarded as a state of non-authorized. Any prior obtained materials must be destroyed at first notice. Any party failed to do so will be liable for infringement.

European compliance statement

JINSHAN declares that the OMOM Capsule 2 is in compliance with the requirements of Annex II excluding Section 4 of the directive 93/42/EEC. Registration No. HD 60109014 0001

Important handling information

CAUTION

Storage

Store the capsule and device between shift or for an extended period of time, keep them in a safe, cool and dry location.

- Keep the capsule and device away from children's reach.
- Keep the capsule and device away from radioactive or electromagnetic fields and metal objects.
- Keep the capsule package in its paper box. Do not take it out and stack them tightly to save space.
- To retain battery efficiency for extended period of time, fully charge the recorder each month.

Transportation

All components of this product can be transported with the common means. Take care during transport and keep them away from squashes, bumps, crushes or sudden drop.

Recorder maintenance

Turn off the device after each procedure.

Clean the recorder

Clean the recorder with the medicinal alcohol.

Clean the waist belt

Clean the waist belt with regular cleansing agents, take out the recorder before cleaning.

Wash the The lining of the waist belt with water and detergent.

Disposal and recycling information

Batteries are installed in the capsule and recorder. When you decide to dispose of this product and/or its battery, do so in accordance with local environmental laws and guidelines.

The manufacturer's declaration

The manufacturer is not responsible for the following conditions:

- Capsule or device altered by unauthorized personnel.
- Failure to follow the instructions in this manual by the user.

Power

- Do not charge the device during the procedure. Always fully charge the device prior to procedure.
- Only use charger provided by **JINSHAN** to charge the recorder and do not use the charger for other devices.
- Only use plug appropriate to your local standard.
- Only plug charger into sockets a three-wire grounding plug. This plug fits only a grounded AC outlet.

Liquid Exposure

- Keep your devices and accessories away from sources of liquid, such as drinks, oils, lotions and so on.
- Protect your devices from dampness, humidity, or wet weather, such as rain, snow, and fog.

Do not handle the device wet hands.

Indications, contraindications, adverse effects, warnings and cautions

Indications

The OMOM Capsule Endoscopy is intended for visualization of the small bowel mucosa. It may be used in the following conditions:

- Suspected Obscure GI bleeding and iron deficiency anemia
- Suspected Crohn's disease
- Suspected small intestinal tumor
- Small intestinal polyp syndrome inspection
- Suspected or uncontrollable digestive syndrome (celiac disease, etc)
- Non-steroid anti-inflammatory drug related small bowel mucosa impairment inspection
- Patients who need to be ruled out of other small bowel diseases

Contraindications

Proceed with caution performing CE inspection on the following cases::

- Patients with dysphagia
- Patients with confirmed or suspected congenital digestive tract malformation, small intestine diverticulum, gastrointestinal tract obstruction, stricture and fistula
- Patient with implanted pacemaker or other electronic devices
- Patients under 18 or over 70
- Patients with pathological diseases
- Pregnant patients

Absolute contraindication

- Patients not qualified for or refuse to abdominal surgery.

Adverse events

Large quantities of clinical trials suggest the CE procedure is generally safe and tolerable for patients. However, there might be conditions where patient experience some adverse effects or discomfort such as:

- Allergies caused by polymer material.
- Unexpected or unpreventable pathological changes during the examination.
- Capsule retention.
- Failed examination.
- Obstruction, perforation, mucosal injury or bleeding.

Summaries in published literature identify the risk of retention to be 1.3%~1.4%, for obscure gastrointestinal bleeding to be 1.2%, for Crohn's disease to be 2.6%, and for neoplastic lesions the rate of retention is 2.1% as compared to healthy volunteers [1].

[1]. Chinese Society of Digestive Endoscopy. The Guidelines Clinical Practice for Chinese Capsule Endoscopy Chinese Journal of practical internal Medicine, 2014, 34(10):984-991

 WARNING

Product Related

- Capsules from damaged or contaminated packages must not be used.
- Expired capsules must not be used.

Safety issues in clinical practice

- The device mentioned by this manual must be used by qualified medical staff with medical trainings.
- MRI procedure must not be performed before excretion of the capsule is confirmed.
- This manual only provides information in regard of proper handling and operation of the OMOM CE system. Clinical judgements and protocols are left to the discretion of individual healthcare professional.

System Overview

The capsule endoscopy system (hereinafter referred to as 'CE') is applicable to gastrointestinal inspection.

After being ingested by a patient, the capsule will move along the gastrointestinal tract, take pictures, and transmit images wirelessly to the recorder, which is carried by the patient for the duration of this procedure.

After the procedure is complete, image data from the recorder is downloaded to a computer for healthcare provider to review and generate a report.

Essential Performance

OMOM Capsule

The capsule is designed to capture images and transmit image data to the recorder.

Recorder

The recorder is designed to receive data from the capsule and display real-time images from the data feed.

System components

Capsule

The capsule is miniaturized camera designed specifically for the visualization of gastrointestinal tract. It contains a camera module, a power module, a wireless transceiver module all enclosed in a biocompatible plastic casing.



Capsule package

Each capsule is sealed in a sterilized package, with product's specifications and compliance certificate label attached at its bottom. Capsule will start flashing when the cap is lifted and turn off when cap is covered.



#	Function
1	Peel off this sticker to open the package.
2	Serial number and barcode.

Recorder and accessories



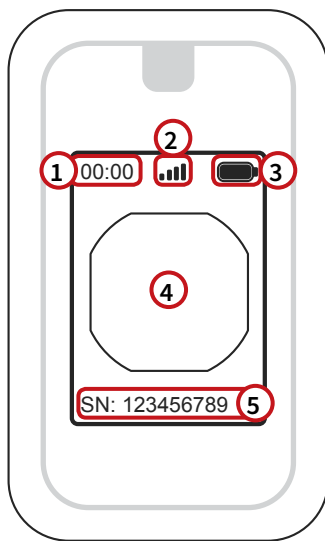
#	Name	Function
1	Pouch with shoulder strap	Hold the recorder during recording.
2	Waist belt with antenna	Receive capsule signal.
3	Adjustable strap	To hold the waist belt to patient's waist.
4	Connector	Connect the waist belt to the recorder.

Recorder buttons and ports



#	Name	Function
1	Wake button	- Wake or turn off the screen. - Confirm '<i>Capsule SN</i>'/format recorder in capsule linking.
2		Connector port to the antenna belt
3	ACT light	- Light on: device is powered on. - Light off: device is powered off. - Blinking: transmission between capsule and the recorder.
4	AC port	Connect the recorder with the charger
5	Charge light	- Light on: device is charging. - Light off with AC power: device is fully charged. - Blinking: overheat.
6	USB port	Connect recorder to the computer.
7	Power button	Press and hold 2 seconds to turn on/off recorder.
8	Screen	Display images and information.

Screen Display of the recorder



#	Name	Function
1	Time	
2	Signal	Indicating the signal strength between the capsule and antenna
3	Battery	Indicating the battery level
4	Image zone	Displaying real-time images from the capsule
5	Text zone	Displaying ' <i>Capsule SN</i> ' and other information

AC Charger

Use AC charger to plug into local power grid and charge the recorder.

USB cable

Connect the recorder to computer.

Encryption Stick

Plug into USB port on computer to authorize VUE.

VUE workstation software

VUE is designed to prepare device for recording, downloading data, import and export, review and generate report. Read subsequent chapters for detailed explanation.

Patient preparation, ingestion and download

Preparation

The physician should confirm whether the patient is suitable for the capsule endoscopy and rule out possible contraindications. The procedure should be explained to the patient and Consent Form signed.

Diet and other preparations

The day before procedure

- Start the prescribed liquid diet after lunch.
- No eating or drinking 10 hours before the procedure, except sip of water to facilitate medication.

The day of the procedure

- No medication 2 hours before procedure.
- The patient should wear comfortably with no more than two-piece clothing.
- The patient should not wear any lipstick to avoid smearing the lens.

Bowel preparation

It is at the physician's discretion to choose the type of cleansing medications and its dosage.

ATTENTION

- The quality of bowel preparation will affect the quality of image captured.
- To minimize the interference of mucosal secretion, ingest capsule as soon as cleansing is complete.

Device preparation

Prepare the following items before patient's arrival:

- Capsule
- Recorder with waist belt, pouch and shoulder strap.
- Computer with VUE Workstation.
- Drinking water.

ATTENTION

- Keep the capsule and recorder from radioactive or electromagnetic field interference.
- Make sure your recorder is fully charged and data from last procedure is downloaded.
- Capsule's package is intact, capsule is flashing and not beyond its expiration date.

Scheduling

- To avoid interference from other capsules. Do not schedule two patients taking capsules in the same room at the same time, or have them to staying in the same room during recording.

Format recorder, link capsule, ingestion and download

Choose your workflow

The flexible design of VUE allows user to input patient information, format the recorder, link the capsule and start the recording; or the user could format the recorder and link capsule and start recording immediately without the need of a computer.

Data from the recorder will only be downloaded to patient with matching serial number.

You can design your own workflow while maintaining precision and avoiding errors.

Here are two typical scenarios

Scenario 2	Scenario 2
* Add Patient	Format Recorder and Link Capsule
* Format Recorder and Link Capsule	Ingestion, ask patient to wear the recorder
Ingestion, ask patient to wear the recorder	Post ingestion instructions
Post ingestion instructions	Recording
Recording	* Add Patient
* Download	* Download

* You need to connect recorder to computer in this step

Add and save patient prior to procedure

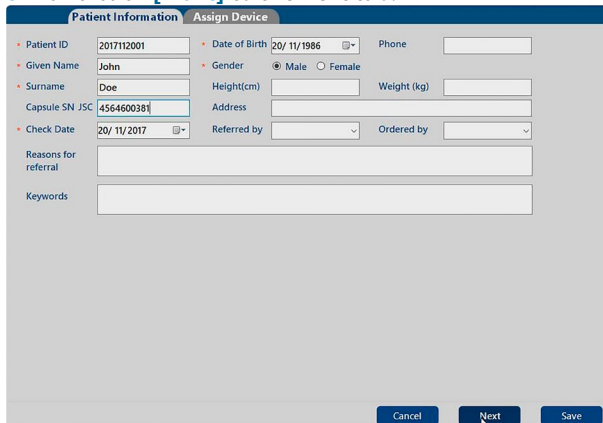
If you need to save patient information prior to procedure, for example one day before procedure, do that as follows:

1. Click  on the menu bar.
2. In the popup window, input all relevant patient information, please note you have to fill sections with an asterisk ('Patient ID', 'Given Name', 'Surname', 'Check Date', 'Date of Birth', 'Gender'), you may type in input 'Capsule SN' or do so during procedure.
3. Click **[Save]** at the bottom of the window.
4. An orange card with patient name will appear in the front of the patient library. When you are ready to proceed, click **[Assign Device]** to jump back to the point you left.

Scenario 1 / Prepare device with PC

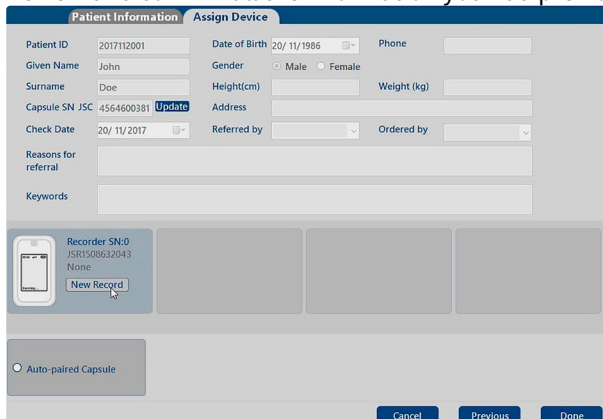
Add Patient, format recorder and link capsule

1. Click  on the menu bar.
2. In the popup window, input all relevant patient information, please note you have to fill sections with an asterisk ('*Patient ID*', '*Given Name*', '*Surname*', '*Check Date*', '*Date of Birth*', '*Gender*') and '*Capsule SN*' and click **[Next]** to the next tab.



- When you enter '*Capsule SN*', only type in the 10-digit numbers, you don't need to type in prefix letters ('*JSC*').
- If you don't have a patient ID system at your facility, simply type in any number.

3. Review and confirm all the information you had previously entered.



- If you need to revise any part, click **[Previous]** button to return to last page and make edits.
 - If you didn't connect the recorder to the computer, do it now.
4. When the recorder is connected to the computer, you can see a recorder icon appear in the window, if multiple recorder is connected, you can identify by their serial number.
 5. Click **[New Record]** next to the recorder icon.
 - You need to format recorder to start a new recording, all data including image and capsule information will be erased. You need to confirm this action if data from previous recording is not downloaded.
 6. Remove the box containing capsule from Tyvek pack, remove the seal at side of the box and lift up the lid. The capsule should start flashing. Place the box next to the waist belt and the recorder will try to link the capsule with the serial number you entered.

7. When the capsule is linked to the capsule, the screen will display a message: *'Capsule paired to xxx. Recording start'*

The screenshot shows the 'Assign Device' screen in the VUE software. A central blue dialog box displays a link icon and the text: 'Capsule paired to 4564600381. Recording start.' The background form contains patient details: Patient ID (2017112001), Date of Birth (20/11/1986), Gender (Male), Surname (Doe), Capsule SN (JSC 4564600381), Check Date (20/11/2017), and an 'Update' button next to the serial number. At the bottom, there are 'Cancel', 'Previous', and 'Done' buttons. A status bar at the very bottom indicates 'Paired to JSC4564600381'.

- If you had accidentally entered a wrong serial number or change the Capsule. Click **[Update]** button next to the serial number. Enter a new number and click **[Confirm]**. VUE will automatically link to the capsule with new serial number.
8. Click **[Done]** to exit preparation.
 - A new patient card is created in the patient library.

Ingestion

1. Ask the patient to wear the belt around the waist and place the recorder with pouch on the side.
2. Ask the patient to pick up the capsule from the package box without touching the front part of the capsule. Put the camera facing the patient and pause a few seconds to take face pictures for record.
 - You can have the patient wear sterile gloves for sanitary considerations.
3. Ask the patient to swallow the capsule and avoid scratching the capsule with teeth.
4. Have patient drink water to help capsule descend.
5. Have the patient wear the waist belt and recorder pouch
6. Use real-time monitoring to confirm the capsule had entered the stomach.
7. Post ingestion instructions

Download

1. Retrieve recorder when the patient returned to hospital.
2. Plug in charger, turn the recorder on and connect it to computer.
3. You will be notified at the downright corner when the recorder is communicating with VUE, and the patient card with matching serial number will turn blue. Click **[Download]** to start

The screenshot shows a patient card for 'John Doe'. It includes the date '20/11/2017', the capsule serial number 'JSC4564600381', and five empty star rating boxes. At the bottom, there is a red-outlined 'Download' button.

- Downloading runs in the background, you can perform other activities during this process.
- If connection between the recorder and computer is lost, VUE will try to reconnect automatically
- Multiple downloads will be commence consequentially.

4. When downloading is complete, the patient card will turn purple and the bottom part will display **[Review]** and ready to review.
5. You may now disconnect the recorder, turn it off and charge it for next procedure.
 - Recorder with latest firmware will turn off automatically after downloading is complete to ensure a full charge. Ask your distributor or service team if your recorder is eligible for this feature.

Scenario 2 / Prepare device without PC

Formatting recorder and pairing with capsule without PC

1. Place the recorder on a flat surface and avoid interference. Turn on the recorder, the screen will display 'Searching'.
 - Recorder can only link a new capsule after its previous data had been downloaded for data security. You need to download the data or format it on a computer before linking a new capsule.
2. Remove the box containing capsule from Tyvek pack, and place it next to the recorder, remove the seal at side of the box and lift up the lid, the capsule should start flashing.



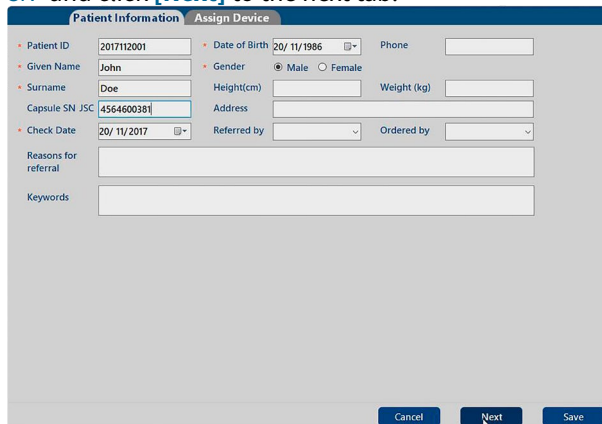
3. When the recorder found a capsule, the serial number will be displayed on the bottom part of the recorder with a question mark.
4. Press the top button on recorder to confirm. The recorder will ask if you want to format the recorder, press again to confirm.
5. After formatting is complete, real-time images will display on the recorder screen.

Ingestion

1. Ask the patient to wear the belt around the waist and place the recorder with pouch on the side.
2. Ask the patient to pick up the capsule from the package box without touching the front part of the capsule. Put the camera facing the patient and pause a few seconds to take face pictures for record.
 - You can have the patient wear sterile gloves for sanitary considerations.
3. Ask the patient to swallow the capsule and avoid scratching the capsule with teeth.
4. Have patient drink water to help capsule descend.
5. Have the patient wear the waist belt and recorder pouch
6. Use real-time monitoring to confirm the capsule had entered the stomach.
7. Post ingestion instructions

Add Patient

1. Click  on the menu bar.
2. In the popup window, input all relevant patient information, please note you have to fill sections with an asterisk ('*Patient ID*', '*Given Name*', '*Surname*', '*Check Date*', '*Date of Birth*', '*Gender*') and '*Capsule SN*' and click **[Next]** to the next tab.

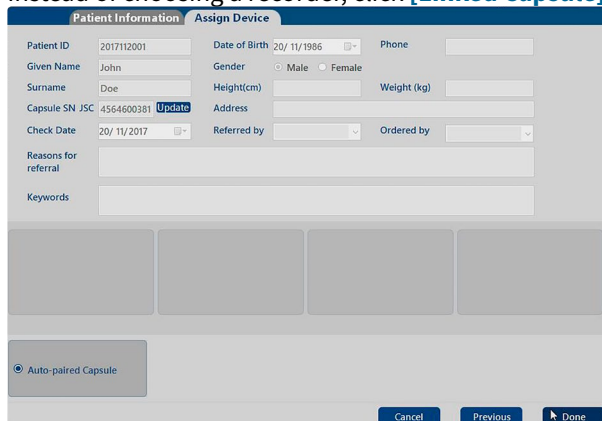


The screenshot shows the 'Patient Information' tab of the 'Add Patient' form. The form contains the following fields and values:

Field	Value
Patient ID	2017112001
Date of Birth	20/ 11/1986
Phone	
Given Name	John
Gender	☒ Male ☐ Female
Surname	Doe
Height(cm)	
Weight(kg)	
Capsule SN JSC	4564600381
Address	
Check Date	20/ 11/2017
Referred by	
Ordered by	
Reasons for referral	
Keywords	

At the bottom of the form are three buttons: 'Cancel', 'Next', and 'Save'.

- When you enter '*Capsule SN*', only type in the 10-digit numbers, you don't need to type in prefix letters ('*JSC*').
 - If you don't have a patient ID system at your facility, simply type in any number.
3. Review and confirm all the information you had previously entered.
 - If you need to revise any part, click **[Previous]** button to return to last page and make edits.
 4. Instead of choosing a recorder, click **[Linked Capsule]**.



The screenshot shows the 'Assign Device' tab of the 'Add Patient' form. The form contains the following fields and values:

Field	Value
Patient ID	2017112001
Date of Birth	20/ 11/1986
Phone	
Given Name	John
Gender	☒ Male ☐ Female
Surname	Doe
Height(cm)	
Weight(kg)	
Capsule SN JSC	4564600381 Update
Address	
Check Date	20/ 11/2017
Referred by	
Ordered by	
Reasons for referral	
Keywords	

Below the form are four empty rectangular boxes. At the bottom left is a button labeled 'Auto-paired Capsule'. At the bottom right are three buttons: 'Cancel', 'Previous', and 'Done'.

5. Click **[Done]** to exit to '*Patient Library*'.

Download

1. Retrieve recorder when the patient returned to hospital.
2. Plug in charger, turn the recorder on and connect it to computer.
3. You will be notified at the downright corner when the recorder is communicating with **VUE**, and the patient card with matching serial number will turn blue. Click **[Download]** to start.
 - Downloading runs in the background, you can perform other activities during this process.
 - If connection between the recorder and computer is lost, VUE will try to reconnect automatically.
 - Multiple downloads will be commence consequentially.

John Doe
20/11/2017
JSC4564600381
☆☆☆☆☆
Download

4. When downloading is complete, the patient card will turn purple and the bottom part will display **[Review]** and ready to review.
5. You may now disconnect the recorder, turn it off and charge it for next procedure.
 - Recorder with latest firmware will turn off automatically after downloading is complete to ensure a full charge. Ask your distributor or service team if your recorder is eligible for this feature.

Ask patient to wear the recorder

1. Fasten one side of adjustable belt to the waist belt.
2. Put the Recorder into the pouch.
3. Wear the Recorder pouch over the shoulder.
4. Threading the adjustable belt through the back of the Recorder pouch and fix it on the other side of the waist belt to a tight but not stringent state.

Post ingestion instructions

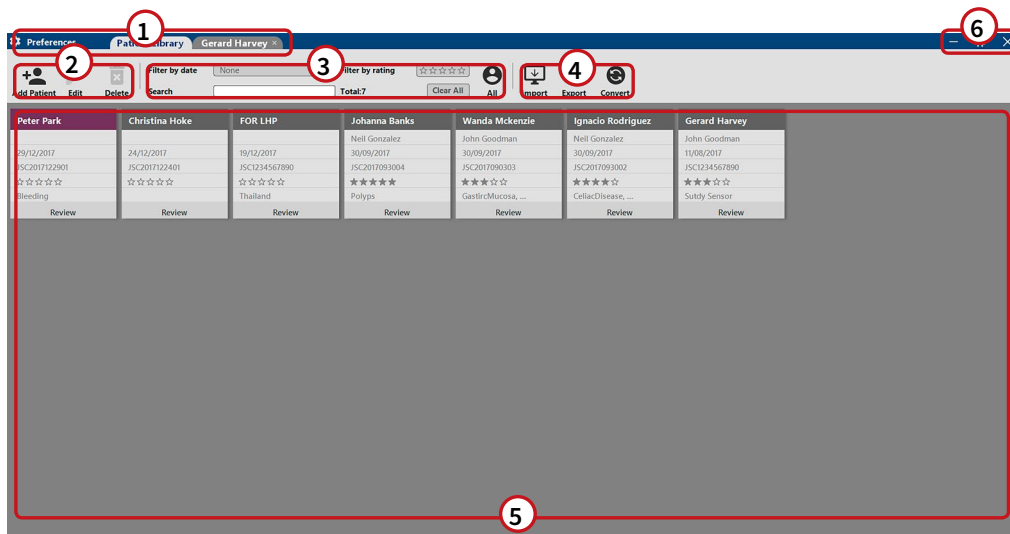
The patient is allowed to leave the facility and resume daily activities with following instructions:

- Recording takes 8-12 hours.
- No intensive labor or exercises during recording.
- The patient may have drinking water 2 hours after ingestion.
- The patient may have light snacks 4 hours after ingestion and resume normal diet 12 hours after ingestion.
- Keep away from strong electromagnetic fields such as MRI devices until the recording is complete.
- Keep away from sources of interference such as: car or house alarm, radio equipment such as broadcasting station from fire or police stations until the recording is complete.
- Do not temper with the device or touch its buttons unless explicitly instructed to by the facility staff.
- Check the ACT indicator on the recorder from time to time. The light should blink 2 times every second. Ask facility staff for instructions if the light stopped blinking.
- If the patient is experiencing any discomfort such as headache, nausea, vomiting and stomachache, he or she should contact facility staff immediately.
- The patient can take off recorder after 12 hours and be careful not to bend the waist belt. Return device back to the facility at appointed time.

VUE: manage, search, import, export and convert cases

Layout

When you first login to VUE, you will be presented with '*Patient Library*'. It is very easy to manage patients and perform various functions here. Function buttons are organized in different groups for easy access.



Zone	Function
1	Switch tasks between ' <i>Patient Library</i> ', opened cases and ' <i>Preferences</i> '
2	Add, edit or delete patients
3	Search and rate patients
4	Import, export and convert patients
5	Patient list
6	Minimize, collapse/expand window and exit application

Switch tasks

You can click tabs to switch between '*Patient Library*', '*Preferences*' and up to 4 opened cases.

You can use hot key [Alt + ~] to switch to *Patient Library* and [Alt + 1/2/3/4] to switch to first, second, third and fourth opened case.



Add, edit or delete patients

Add patient

Click  to add a new patient, for detailed guide to add a new patient, input information and link capsule, refer to Patient preparation and download chapter.

Edit patient information

Click on a single patient card to select it, then click  to edit patient information. When you are done, click [Save] to apply modification or [Cancel] to not to save them.

ATTENTION

You can only edit capsule serial number if the case is not yet downloaded. You should do so if a wrong serial number was entered and you are unable to download the case.

Delete patient

Click on a single patient card to select it, then click  to delete a patient. You need to click [Yes] in the popup window to confirm this action.

CAUTION

This action is irreversible, and deleted patients can not be recovered.

Search

You can use one or more search filters to find a patient.

Filter by date

None

Filter by rating

☆☆☆☆

Search

Total:7

Clear All

All

By date

Click the triangle to choose display patients from different time periods.

By rating

Click any number of stars to display patients with certain number of star ratings.

Search by text

Type in any text in the blank zone to display patients with associated words.

Start over

To clear all filter and start over, click [\[Clear all\]](#)

Statistics

The number after words '*Total*' is the number count of patients matching current search filter.

Scenario mode

Click  to switch between scenario modes to only display patients at certain stages of the workflow.



Show all patients



Show patients in prepare, recording or downloading stage.



Show patients with downloaded data and with finished reports.

Import, export and convert patient case

Import

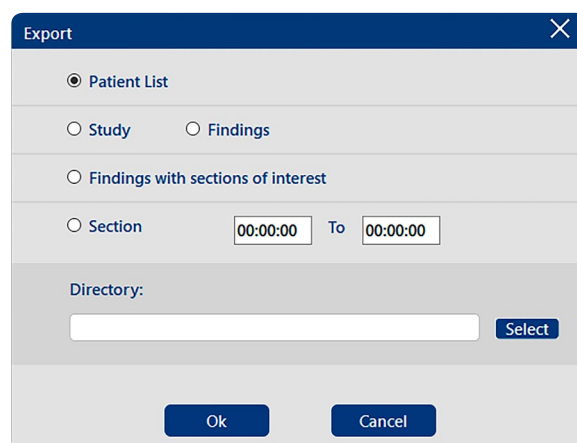
1. Click  on the menu bar
2. Select the .vue file to import
3. If the same patient already exists in the library, choose **[Merge]** or **[Overwrite]**.
 - **[Merge]** will combine texts and findings in both files
 - **[Overwrite]** will replace the existing file.

Export

You can export patient case and import it on another computer. Different export modes are available.

[Patient List]	Export information of all selected patient as .xls file
[Study]	Export whole case
[Findings]	Export texts and finding pictures
[Findings with sections of interest]	Export texts and finding pictures with short video
[Section]	Export case within a time range

1. Click  on the menu bar
2. Choose a export mode
3. Click **[Select]** and choose destination folder.
4. Click **[OK]** to start



The image shows a screenshot of the 'Export' dialog box. It has a title bar with 'Export' and a close button. Inside, there are five radio button options: 'Patient List' (selected), 'Study', 'Findings', 'Findings with sections of interest', and 'Section'. The 'Section' option has two time input fields: '00:00:00' and '00:00:00' separated by 'To'. Below these options is a 'Directory:' label, a text input field, and a 'Select' button. At the bottom are 'Ok' and 'Cancel' buttons.

Convert legacy data: single case

To convert single patient data from previous generation software('Image Station 6'), do as follows:

Convert Legacy Case(s)

☐ Convert Library ☒ Convert A Single Case

Choose this option if you want to convert whole library. Choose this option if you want to convert a single case.

Locate Case folder you wish to convert

C:\Case_old\Demo_One_20160519

* Patient ID * Date of Birth Phone

* Given Name * Gender ☒ Male ☐ Female

* Surname Height(cm) Weight (kg)

* Capsule SN JSC Address

Check Date Referred by Ordered by

Reasons for referral

Keywords

☒ Merge to Active Library

☐ Export to selected location

Freespace Required: 2.63G

1. Click  on the menu bar
2. In the popup window, click **[Convert a single case]** option
3. Click **[Select]** and locate the folder containing data
4. Type in relevant patient information with asterisk (*)
5. Select **[Merge to Active Library]** to merge into current library or **[Export to selected location]** to export to a folder, click **[Select]** and choose a destination for this option.
6. Click **[Begin]** to start conversion.

Convert legacy data: whole library

To convert whole patient library from previous generation software('Image Station 6'), do as follows:

Select	Patient Name	Check Date	Capsule SN	Referred by	Reasons for referral	Conversion Status
☒	Demo Old	29/11/2017	JSC2017112901			
☒	Demo02 Old	29/11/2017	JSC2017112802			

1. Click on the menu bar
2. In the popup window, click **[Covert Library]** option
3. Click **[Select]** and locate the .mdb file containing patient information
4. Click and select all the patients you wish to convert
5. Select **[Merge to Active Library]** to merge into current library or **[Export to selected location]** to export to a folder, click **[Select]** and choose a destination for this option.
6. Click **[Begin]** to start conversion.

Patient list

Patient card

Each patient is represented as a card, on which relevant information are show in the following order: '*Patient Name*', '*Attending Physician*', '*Procedure Date*', '*Capsule SN*', '*Rating*' and '*Keywords*'.

John Doe
Dr. John Goodman
2018/03/31
JSC123456789
★☆☆☆☆
Keywords

The color of the card indicate and help user easily identify the stage patient is in:

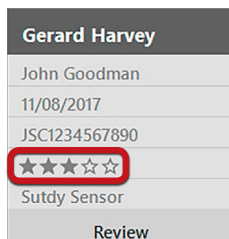


Preview

Hover your mouse over a patient card to get a preview of its content without opening it.

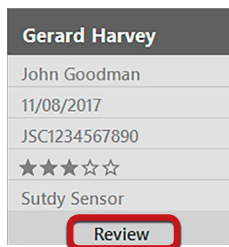
Rate patients

You can give your patient case a rating from 1 to 5 stars and find them faster using Filter by rating function. To rate a patient, hover your mouse over a patient card with hollow stars, click to give it a rating, click on another star to change the rating, click on the left of the first star to clear.



Review case

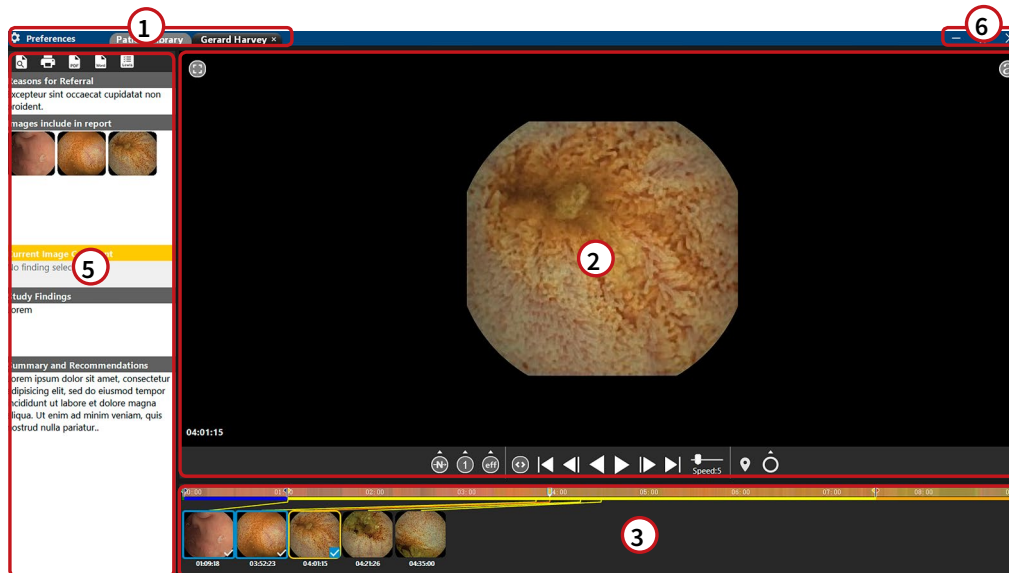
To review a patient, click [\[Review\]](#) on the patient card.



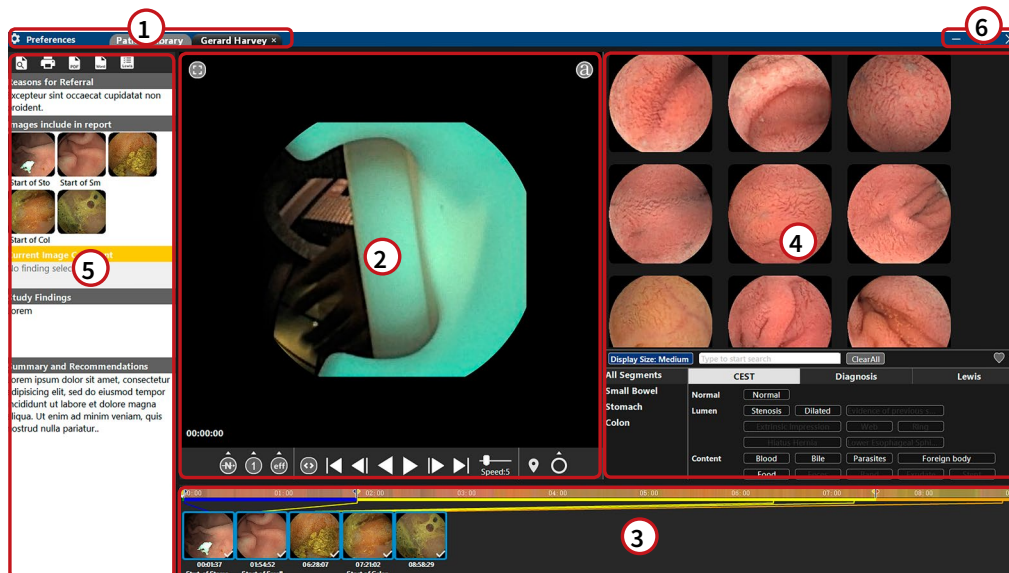
VUE: review and report

Layout

When you open a patient case, the default layout will look like this:



When you turn on the '*Atlas*', the layout will look like this:



You can customized the layout by revealing or hiding the '*Report*' and '*Atlas*' zone.

Zone	Reveal / hide icon	Reveal / hide hot key	Function
1			Switch tasks between ' <i>Patient Library</i> ', opened cases and ' <i>Preferences</i> '
2			Image and play tools
3			Progress bar and findings
4		G	Reveal or hide ' <i>Atlas</i> ' zone
5		T	Reveal or hide ' <i>Report</i> ' zone
6			Minimize, collapse/expand window and exit application

Image zone

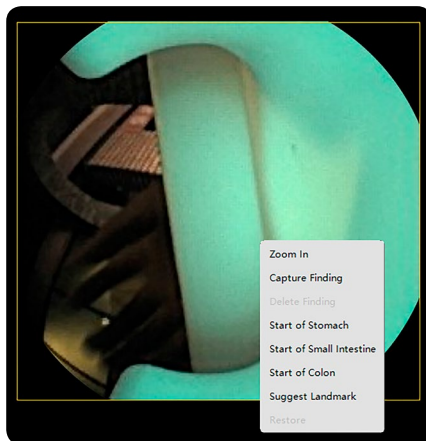
This is the place image is displayed. Time code is at the down left corner.

Save a frame to findings

Double click on an image to save it to '*Findings*'. It will also be automatically added to the report.

Right click menu

Right click on an image to perform the following functions:



Command	Function
[Zone in]	Zone in one image when 2 or more images is displayed
[Capture Finding]	Save this image to ' <i>Findings</i> '. It will also be automatically added to the report.
[Delete Finding]	Delete this image from ' <i>Findings</i> '. Only available if an image from ' <i>Findings</i> ' zone.
[Start of Stomach]	Mark this point as the ' <i>Start of Stomach</i> '
[Start of Small Intestine]	Mark this point as the ' <i>Start of Small Intestine</i> '
[Start of Colon]	Mark this point as the ' <i>Start of Colon</i> '
[Suggest Landmark]	Let VUE suggest landmarks
[Restore]	Clear all markings on this image, this action will not delete text from the ' <i>Comment</i> '.

Play tools

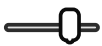
You can play, pause, adjust play speed, switch to different play modes and effects, make custom landmark and make a mark here.



- Play mode, number of images display and image enhancement

Icon	Function
	Play mode Click here to choose play modes
	Play mode - Normal
	Play mode - Quickview Skip images that are too similar.
	Play mode - SGIB Only images with suspect bleeding will be displayed
	Number of images display Click here to choose 1, 2, 4, 8 or 15 images in display
	Number of images display - 1/2/4/8/15 Display 1, 2, 4, 8 or 15 images
	Image enhancement Click here to choose from image enhancement effects
	Image enhancement - no effects Apply no image enhancement
	Image enhancement - ICE 1/2/3 Apply ICE effect to help you observing capillaries, tissue textures and morphology to highlight possible lesions.
	Image enhancement - Hemoglobin enhancement Apply red coLOr enhancement to help identify possible bleeding

- Play control

Icon	Function
	Switch image size to maximum / default
	Play backward / forward Click once or Space key to pause, click once more to continue
	Backward / forward 1 frame You can use the '←' and '→' on the keyboard for the same function
	Jump to Start / End of video
	Play speed Drag to change the play speed. You can also use '↑' or '↓' on the keyboard to increase or decrease the play speed.

ATTENTION

The play control icons will appear in red () in SGIB play mode(). They will return to normal once switched back to other modes.

- Landmark and marking

Icon	Function
	Custom landmark Click once to landmark on the progress bar, click once more on the same position to delete.
	Markings Click here to choose marking tools
	Markings - circle Draw a circle on the image
	Markings - circle Draw a line on the image
	Markings - arrow Draw an arrow on the image

ATTENTION

To clear markings, right click on the image and choose [\[Restore\]](#).

Progress bar and findings zone

Saved findings will be displayed here.

Progress bar

The progress bar indicate the whole duration of the recording, the current location of progress and the locations of '*Start of Stomach*', '*Start of Small Intestine*' and '*Start of Colon*'



Icon	Function
	Indicate the current location of the whole progress. Drag and move to go forward / backward.
	' <i>Start of Stomach</i> ' landmark, drag and move this icon to change the location of this landmark.
	' <i>Start of Small Intestine</i> ' landmark, drag and move this icon to change the location of this landmark.
	' <i>Start of Colon</i> ' landmark, drag and move this icon to change the location of this landmark.
	Last paused location, click to jump to this location. You can also use hotkey [R] to jump to this location and start playing
	' <i>Custom Landmark</i> '
	A red line indicates possible bleeding

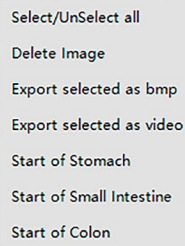
Select / deselect finding

Selecting or deselecting a finding will add or remove it from the final report. To do that, click the down right corner of a finding.



Right click menu

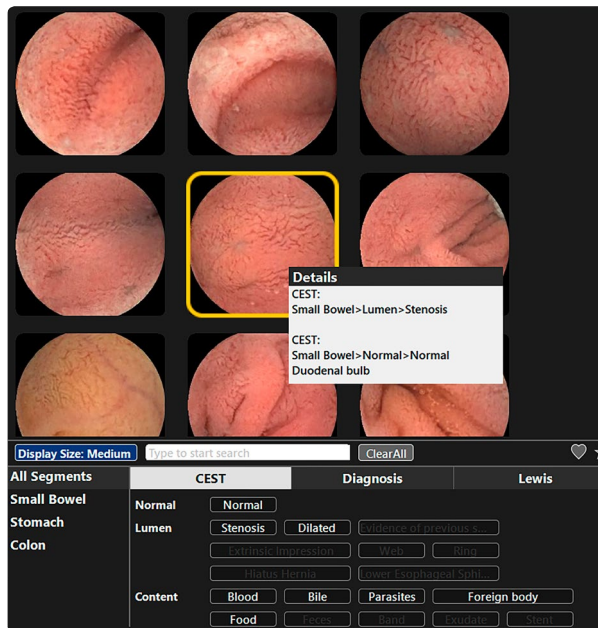
Right click on an image to perform the following functions:



Command	Function
[Select/Unselect all]	Add or remove all images in the ' <i>Findings</i> ' from the ' <i>Report</i> '
[Delete Image]	Delete this image from ' <i>Findings</i> '.
[Export selected as bmp]	Export all selected findings to a folder as .jpg format
[Export selected as video]	Export all selected findings as short video segment to a folder as .avi format
[Start of Stomach]	Mark this point as the ' <i>Start of Stomach</i> '
[Start of Small Intestine]	Mark this point as the ' <i>Start of Small Intestine</i> '
[Start of Colon]	Mark this point as the ' <i>Start of Colon</i> '

Atlas zone

The new '*Atlas*' adopted keyword system to help you find images faster than ever before.



Details

Move cursor over an image and pause to see detailed information.

Zone in

Click on an image to expand to full size for better comparison. Click once more to return browsing.

Display size

Click [\[Display Size\]](#) to cycle between three image sizes.

Search by keyword

Click on a keyword block to reveal images with this keyword, you can click multiple keyword block to see images with intersected keywords.

Search by text

You can type in any text in the text box to reveal images with words entered.

Search by segment

Click [\[All Segments\]](#), [\[Small bowel\]](#), [\[Stomach\]](#) or [\[Colon\]](#) to reveal images in designated anatomical location.

Report zone

You can write report in this zone while review images. You can also make comment on a finding when it's selected.



Reasons for Referral
Excepteur sint occaecat cupidatat non proident.

Images include in report


Current Image Comment
No finding selected

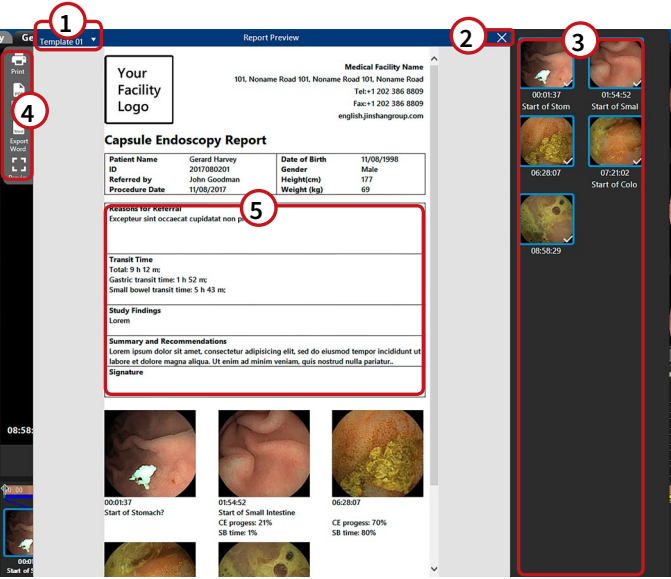
Study Findings
Lorem

Summary and Recommendations
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud nulla pariatur..

Click buttons on the top of this section to perform functions listed below

Icon	Function
	Go to report preview mode
	Print out report
	Export report as PDF format
	Export report as Word format
	Open ' Lewis Score ' panel

Report preview



When you click , the report preview window will appear. You can perform the following actions.

Zone	Function
1	Click to switch report templates
2	Exit this window
3	Click the down right corner of an image to add or remove from the final report
4	Print, export as word or PDF, or preview the print result.
5	Edit report texts

Lewis Score

Lewis Score provides reference to clinical diagnosis by measuring degree and extent of mucosal damage based on visual inspections. Score is calculated based on quantitative and qualitative descriptions of villous edema, ulcers, and stenosis.

This score indicates the severity of intestinal inflammatory lesions and can be used to evaluate the therapeutic effect of treatment.

Term	Explanation
Score count	• Normal or no clinically insignificant mucosal inflammation: CESI<135 • Mild mucosal inflammation: $135 \leq \text{CESI} < 790$ • Moderate to severe mucosal inflammation: $\text{CESI} \geq 790$
Appearance (of villi)	Edema where width of villi is equal or greater than height of villi. Evaluated villi in mucosa distinct and separated from an ulcer rather than contiguous to a mucosal break.
Circumferential Extent	Portion of the entire image involved by the lesion, based on the entire lesion including its collar. This value is entered for the largest ulcer in the tertile.
Few (ulcers)	2–7 lesions.
Long segment	Equal to 11–50% of a tertile.
Multiple (ulcers)	8 or more lesions.
Short segment	Less than or equal to 10% of a tertile.
Tertile	One third of small bowel as calculated by the transit time of the OMOM capsule in the small bowel. • 1st SB Tertile is the proximal third of the small bowel. • 2nd SB Tertile is the middle third of the small bowel. • 3rd SB Tertile is the distal third of the small bowel.
Whole segment	Greater than 50% of a tertile.
Ulceration	Mucosal break with white or yellow base surrounded by a red or pink collar.

To calculate the score, click and choose options in each category respectively in 3 segments. Click on the tab to switch between segments, the score will be automatically calculated.

VUE: installation, activation and preferences

Intallation

Requirements

For a smooth performance, please ensure your computer met the hardware and software minimum requirements.

Operating System	Windows 7 SP3, Windows 8 SP3 or Windows 10
CPU	Intel Core i3 or G4400 AMD Ryzen R3 or Athlon X4, A8 7650k
Memory	4GB
Storage	1.2~1.5GB per single case
Graphics	Integrated graphics with 256 MB VRAM (Independent graphic card recommended)
Display	1366*768 (1920*1080 strongly recommended)

Security Software

Any security software (e.g. Anti-Virus, Firewalls) may cause conflict or crush the software. It is recommended you uninstall any such software before proceeding.

Compatibility

Data from '*Image Station 6*' is not compatible with **VUE**. However, you can convert old cases to enjoy the benefits of the new platform.

Update from older versions

If you are to upgrade the software from an older version, run the installation application as usual. Choose 'Repair' in the second window.

All existing cases, user name, saved passwords and activation status will be preserved.

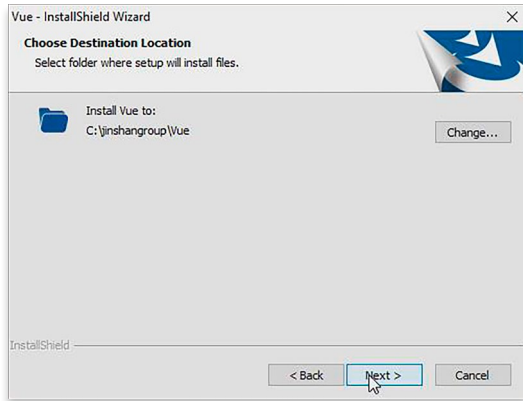
Adjust display ratio and resolution

Make sure your system display scale is 100%.

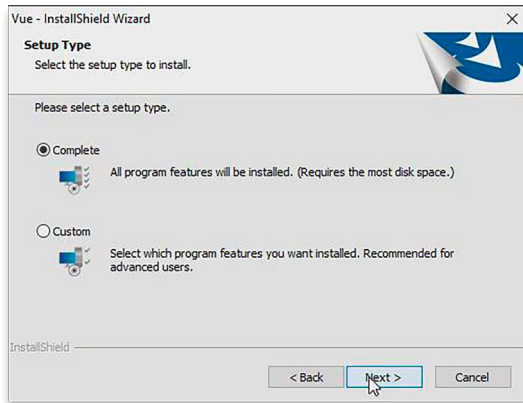
Use highest resolution possible, 1920 * 1080 is recommended.

Setup

1. Run the installation program as a local administrator.
 - You may need to install '*Microsoft Visual C SP1*' and '*.Net Framework 4*' first. They are included in the installation application and will run automatically.
2. Click [Change] to change installation path. Click [Next] to continue.



3. Select [Complete] mode and click [Next] to continue.



4. Allow the installation of recorder's driver.

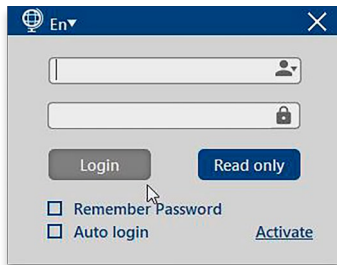


5. Installation complete.

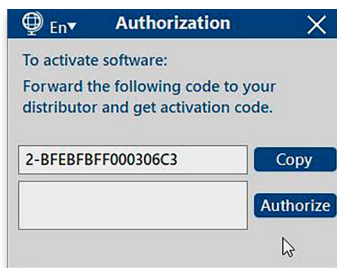
Activation

You may need to activate VUE before using it. You can use a 'USB Encryption Stick' or activate with a code. To use a activation code:

1. Click **[Activate]** in the start up window.



2. Feed the request code to your distributor or sales representative and get the activation code.



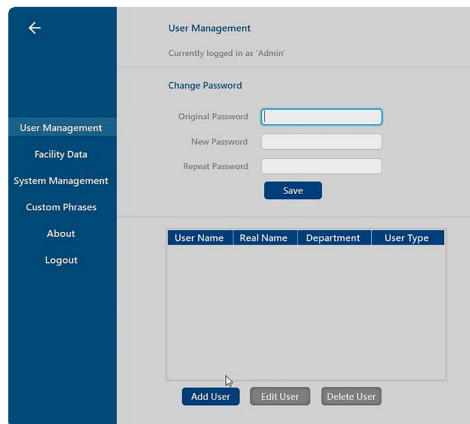
3. Type in the activation code and click **[Authorize]**, VUE will reboot.

Preferences

Click [\[Preferences\]](#) on the top to access systematic preferences.

User Management

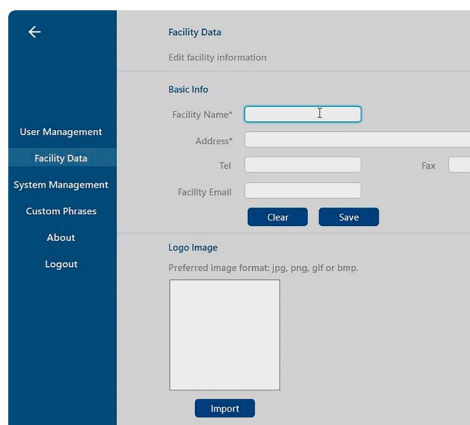
You can change the password for the current user, add, edit or delete user here.



The screenshot shows the 'User Management' page. On the left is a dark blue sidebar with a back arrow at the top and a menu containing 'User Management' (highlighted), 'Facility Data', 'System Management', 'Custom Phrases', 'About', and 'Logout'. The main content area has a header 'User Management' and a sub-header 'Currently logged in as: Admin'. Below this is a 'Change Password' section with three input fields: 'Original Password', 'New Password', and 'Repeat Password', followed by a 'Save' button. Underneath is a table with columns 'User Name', 'Real Name', 'Department', and 'User Type'. The table body is currently empty. At the bottom of the main area are three buttons: 'Add User' (highlighted), 'Edit User', and 'Delete User'.

Facility Data

You can edit facility information and import logo displayed in reports here.



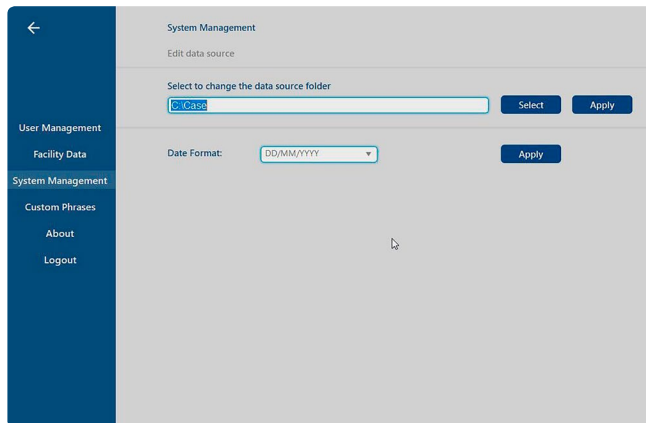
The screenshot shows the 'Facility Data' page. The sidebar is identical to the previous page, with 'Facility Data' highlighted in the menu. The main content area has a header 'Facility Data' and a sub-header 'Edit facility information'. Below this is a 'Basic Info' section with four input fields: 'Facility Name*' (highlighted), 'Address*', 'Tel', and 'Fax'. There is also a 'Facility Email' input field. Below these fields are 'Clear' and 'Save' buttons. Underneath is a 'Logo Image' section with the text 'Preferred image format: jpg, png, gif or bmp.' and a large empty square box. At the bottom of this section is an 'Import' button.

To edit facility information, fill in text boxes and click [\[Save\]](#), click [\[Clear\]](#) to erase all texts.

Click [\[Import\]](#) to import logo picture.

System Management

You can change the date format and data path here.



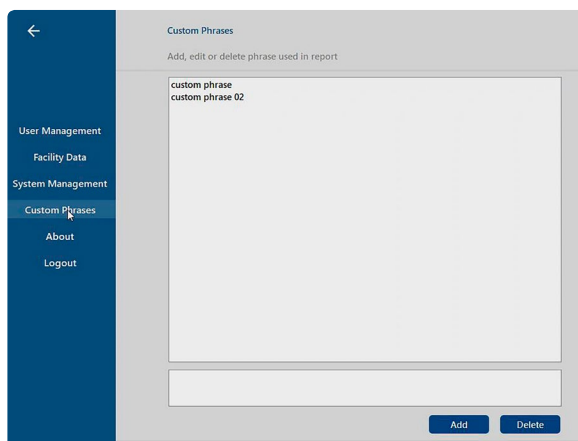
The screenshot shows the 'System Management' section of a web application. On the left is a dark blue sidebar with a back arrow and menu items: 'User Management', 'Facility Data', 'System Management' (highlighted), 'Custom Phrases', 'About', and 'Logout'. The main content area has a title 'System Management' and a subtitle 'Edit data source'. It contains two sections: 'Select to change the data source folder' with a text input field containing '2/Case', a 'Select' button, and an 'Apply' button; and 'Date Format:' with a dropdown menu showing 'DD/MM/YYYY' and an 'Apply' button.

To change the default save path, or switch to an existing data path, click **Select** and choose a new folder, click **Apply**, VUE will reboot to reflect the change.

To change date format, choose one of three date display modes, click **Apply**, VUE will reboot to reflect the change.

Custom phrases

You can add or remove custom phrases here.



The screenshot shows the 'Custom Phrases' section of the web application. The sidebar is identical to the previous screenshot, with 'Custom Phrases' highlighted. The main content area has a title 'Custom Phrases' and a subtitle 'Add, edit or delete phrase used in report'. It features a large text area containing two lines: 'custom phrase' and 'custom phrase 02'. Below this is an empty text input field. At the bottom right are 'Add' and 'Delete' buttons.

To add new phrase, type in the second text box and click **Add**.

To delete a phrases, select one in the top text box and click **Delete**.

Copyright

Click here to learn about copyright information.

Logout

Click here to logout and return to login window.

Trouble shooting

Capsule, linking capsule to recorder and ingestion

Issue	Possible cause and action
Capsule is not flashing or flashing weakly after opening the cap.	Put the capsule back into the package in its default orientation, close the cap and open cap again.
	Check the surrounding of the capsule and make sure there are no other capsules working nearby.
	Check your surroundings and make sure there's no radioactive or electromagnetic field interference.
	Replace with a new capsule, keep the capsule in question for customer service.
Capsule keeps flashing in its seat after closing the cap.	Open the cap, rotate the capsule till the end marked with a logo to point at the packaging gap, then close the cap.
Recorder failed to link to the capsule or display real-time images.	Move the capsule closer to the recorder waist belt.
	Make sure there are no other capsules(including other brands) working nearby
Recorder f is not picking up signal or displaying images after patient ingests the capsule.	Adjust the position of the waist belt
	Check your surroundings and make sure there's no significant radioactive or electromagnetic field interference.
	If the capsule is still in the esophagus and the patient can feel it, instruct the patient to drink water and keep swallowing until it passes through.

Recorder

Issue	Possible cause and action
Failure to turn on the recorder.	The recorder's battery is low, make sure it's fully charged before the procedure. If the recorder is still not responding after long period of charging, the the recorder's battery might have reached its cycling limit, contact your distributor or our service team for further inspections
Recorder shuts down immediately after turning on	The recorder's battery is low, make sure it's fully charged before the procedure. If this issue is still present even the recorder is fully charged, contact your distributor or our service team for inspections.
The battery is depleting unusually fast.	The operating temperature is too low. The recorder's battery might have reached its cycling limit, contact your distributor or our service team for further inspections.
The charging indicator light (CHG) is not lighting up during charging.	The recorder will not charge at full capacity, turn on the recorder to check if the battery icon is displaying at full capacity. Change the charger Contact your distributor or our service team for further inspections.
Battery icon in the display indicate a high level capacity but the working hours is short.	Always fully charge the device till the charging indicator light is off before each procedure. The battery icon in the display is not representative of the actual capacity of the battery.
Unstable signal/image	Adjust the position of the waist belt Check your surroundings and make sure there's no radioactive or electromagnetic field interference.

Recorder sound

The speaker in the recorder may indicate following conditions:

Recorder state	Sound	Explanation
Idle	Single beep with ACT light blinking	Low battery level
	Three beeps with ACT light blinking	Memory card is not properly installed
	Three beeps with ACT light blinking	Memory card full
Transmitting	Single beep with ACT light blinking	Low battery level
	Three beeps with ACT light blinking	Memory card full
	Five beeps with ACT light blinking	Low battery level, the device will shut down soon.

VUE Workstation

Issue	Possible cause and action
Unable to launch the application / The application shuts down for no reason	Make sure you are logged in as a local administrator and turn off any security software.
	Check if your computer meets the minimum requirement for the application.
	Uninstall and install the application.
Recorder is not displayed in the application after connecting to the computer	Make sure you have installed the driver properly.
	Change the USB cable
	Try another USB port on the computer.
Unable to print reports	Make sure you have installed printer driver in your operating system, the printer is turned on and connected to your computer.

Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic emissions

Capsule Endoscopy System JS-ME-I is intended to be used in the following electromagnetic environments specified below.

Emissions Test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group 1	Capsule Endoscopy System JS-ME-I 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
RF emissions CISPR11	Class [A]	Capsule Endoscopy System JS-ME-I is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC61000-3-2	Class [A]	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration-electromagnetic immunity

Capsule Endoscopy System JS-ME-I is intended to be used in the electromagnetic environment specified below.

Immunity test	IEC60601	Compliance Level	Electromagnetic environment guidance
Electrostatic discharge(ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	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 IEC61000-4-4	±2KV for power supply lines ±1KV for in-put/ output lines	±2KV for power Supply lines ±1KV for in-put/ output line	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC61000-4-5	±1KV line(s) to line(s) ±2KV line(s) to earth	±1KV line(s) to line(s) ±2KV 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 IEC61000-4-11	<5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5%UT (>95% dip in UT) for 5 sec	<5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5%UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Capsule Endoscopy System requires continued operation during power mains interruptions, it is recommended that the Capsule Endoscopy System be powered from an stable power supply or a battery
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3A/m	3A/m	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

Capsule Endoscopy System JS-ME-I is intended to be used in the electromagnetic environment specified below.

Immunity test	IEC60601	Compliance Level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of Capsule Endoscopy System JS-ME-I, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d = 1.2$ 80MHz to 800 MHz $d = 2.3$ 800MHz to 2.5 GHz Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note3: P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Note4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, Should be less than the compliance level in each frequency range^b.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Capsule Endoscopy System JS-ME-I is used exceeds the applicable RF compliance level above, Capsule Endoscopy System JS-ME-I should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Capsule Endoscopy System JS-ME-I.

b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m

Recommended separation distances between portable and mobile RF communications device and Capsule Endoscopy System JS-ME-I

Capsule Endoscopy System JS-ME-I is intended to be used in an electromagnetic environment with controlled radiated RF disturbances.

Keep a minimum distance between the device and portable and mobile RF communications device (transmitters) in association with its maximum output power as listed below.

Rated maximum output power of transmitter	Minimum distance from transmitter in association with its frequency (m)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed, the recommended minimum distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the minimum distance for the higher frequency range applies.

Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical specifications

Capsule

Type	JS-MEC-I
Size and weight and material	Size: 11.0*25.4mm
	Weight $\leq 4.5\text{g}$
	Shell material: medical polymeric material
Optical	Illumination: 6 white LEDs
	Visual Angle(In the air): 157°
	Depth of Focus(In the air): 0~35mm
	Resolution (In the air): 8 lp /mm
Image	Sampling rate: 3fps ± 1
	Image resolution: 320 by 240 pixel
	Color depth: 24-bit true color
Operating environment	Temperature: 5~40 °C
	Relative Humidity: $\leq 85\%$
	Atmospheric pressure: 860hPa~1060hPa
Battery and power	Built-in lithium battery
	Battery life: 10 $\pm$ 2hour
	Voltage: 3V
	Current: 12mA
Ingress of Liquids (IEC 529)	IPX8
Storage	Temperature: ideally 71° F or 22° C
	Relative humidity: 0 ~ 85%
	Atmospheric pressure: 860hPa ~ 1060hPa

Recorder

Type	JS-MER-I
Weight	< 0.8 kg
Connecting port	USB2.0
Internal Storage	16 GB memory card
Operating environment	Temperature: 5~40 °C
	Relative Humidity: ≤85%
	Atmospheric pressure: 860hPa~1060hPa
Battery	Built-in lithium battery
	Battery life: 12±2 hours
	Capacity: 7200mAh
	Current: 12mA
	Charge to full time: up to 8 hours
Storage	Temperature: ideally 71° F or 22° C
	Relative humidity: 0 ~ 85%
	Atmospheric pressure: 860hPa ~ 1060hPa

Power Adaptor

P/N	9NA0251601
AC input	100-240Vac, 1.0-0.6A, 50-60Hz
DC output	5V — 5A MAX (25wMAX)

Vue workstation software

Language	English, Deutsch, Français, Español, Русский язык, 简体中文
Image output	bmp, avi

Classification

Capsule Endoscope

Protection against electrical shock	Internally powered device
Degree of protection against electric shock	BF applied part
Ingress of Liquids (IEC 529)	IPX8
Use with Flammable Anesthetics (Flammable anesthetic proof mixtures with oxygen or nitrous oxide)	Not for use in the presence of flammable anesthetics
Equipment mode of operation	Continuous

Image Recorder

Protection against electrical shock	Internally powered device
Degree of protection against electric shock	No applied part,no classification
Ingress of Liquids (IEC 529)	IPX0
Use with Flammable Anesthetics (Flammable anesthetic proof mixtures with oxygen or nitrous oxide)	Not for use in the presence of flammable anesthetics
Equipment mode of operation	Continuous

System labels

The following table listed labels appear in this product

	
Do not reuse	Expiration Date
	
Sterilized by Ethyleneoxide	CE Certification
	
Ingress Protection: 8	Read instructions before use
	
Manufacturer	Date of manufacture
	
Serial Number	Batch code
	
Catalogue number	Device Type of BF
	
Caution	This side up
	
Fragile	Keep Dry
	
Stacking layer limit: 3	Not disposable with household waste
	
Authorized representative in the European Union	



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