OMOM HD

Capsule Endoscopy System

JINSHAN | Life Insights
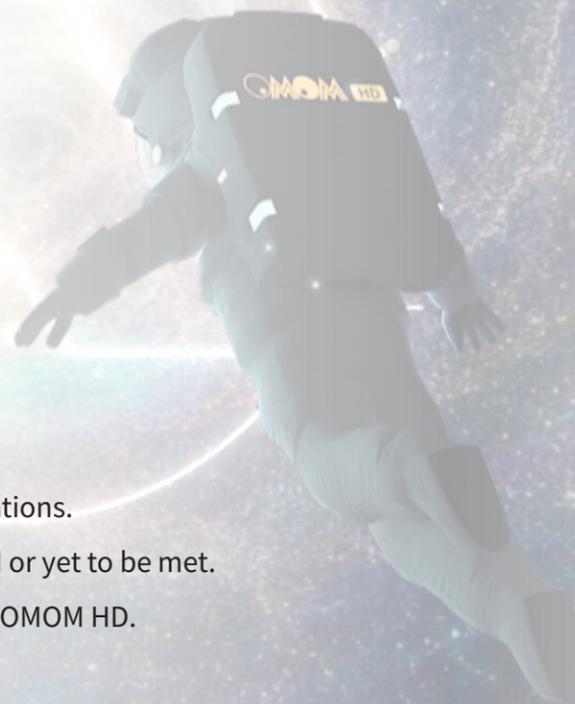
LESS IS MORE

We learn. We listen. We create.

We have been learning from our past successes and frustrations.

We have been listening to our valued customers' expectations fulfilled or yet to be met.

Now, we have created the smartest capsule endoscopy system, OMOM HD.

Reading cannot be easier.

Integrated with the evolving Artificial Intelligence and the most advanced optical technology, the latest OMOM HD capsule endoscopy system aims to assist healthcare professionals with unprecedented ease of interpreting capsule endoscopy studies.
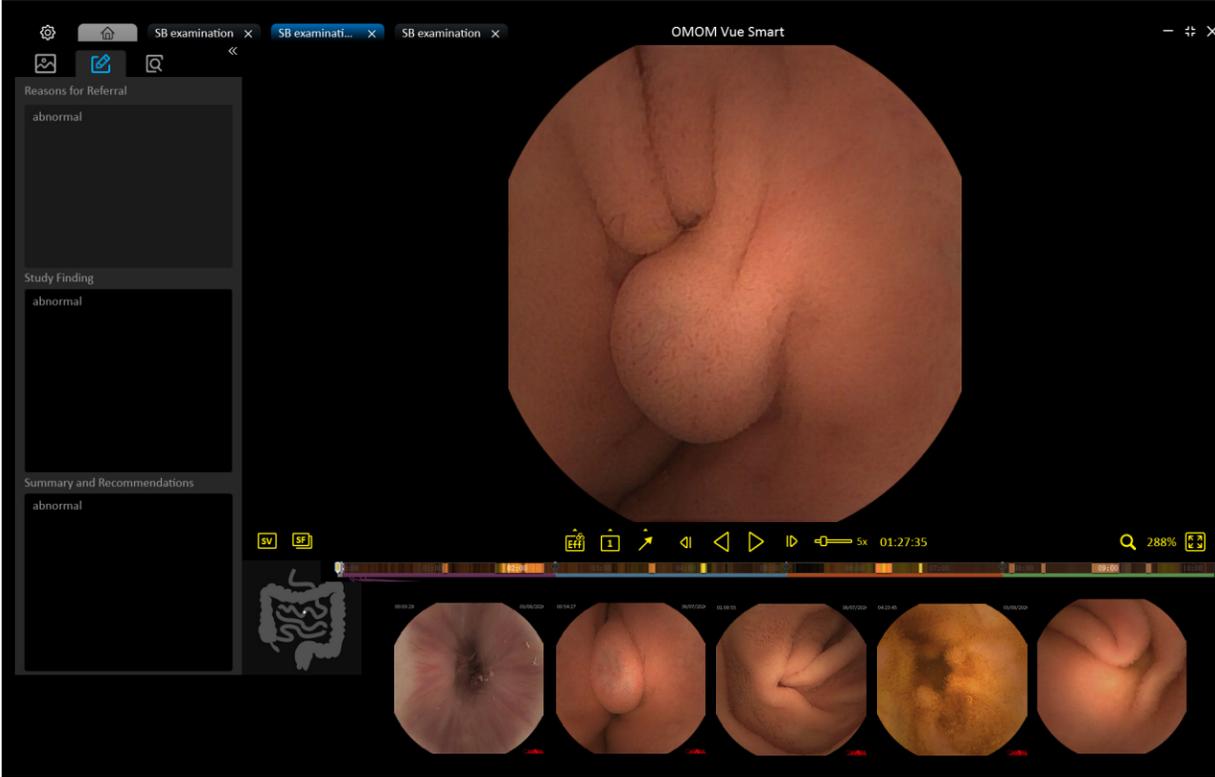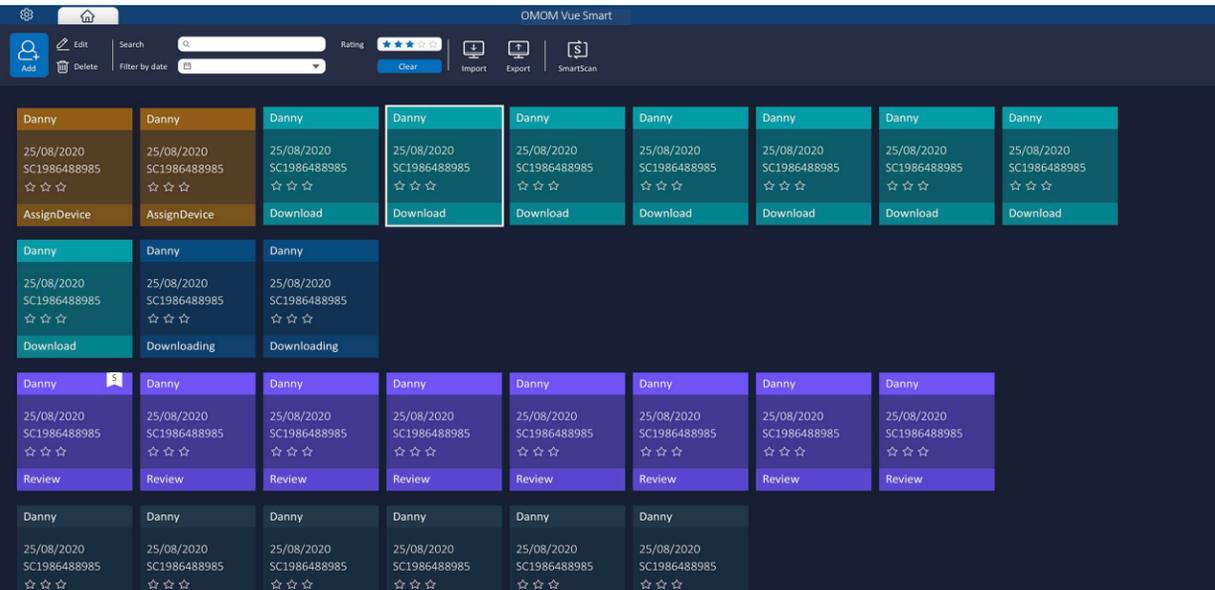
Less Reading Time, More Evident Details.
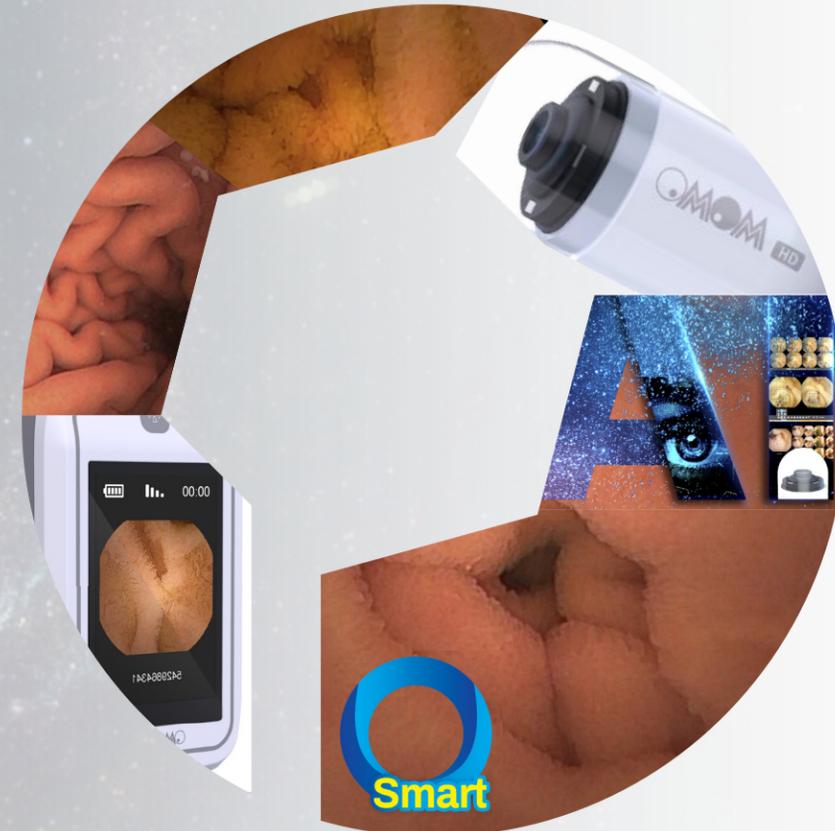
OMOM HD
Your Ultimate Choice of
Small Bowel Capsule Endoscopy

Reading made Smart

The new face - *Vue Smart*

With major upgrade on patient management center and reading screen, the new *Vue Smart* software offers healthcare providers even more user-friendly interface and stress-free reading experience.


AI-Powered, Smarter Ever.

With our advanced AI algorithms, the *Vue Smart* is at the new technological frontier in redundancy deletion, lesion detection and classification that guarantees easier-than-ever interpretation as well as improved clinical outcomes.

SmartScan

Utilizing our proprietary algorithms, **SmartScan** processes the raw files by deleting up to 90% redundancy, identifying and tagging as many as 16 types of abnormalities. After *Smartscaning*, the *SmartView* and *SmartFinding* are ready for use.
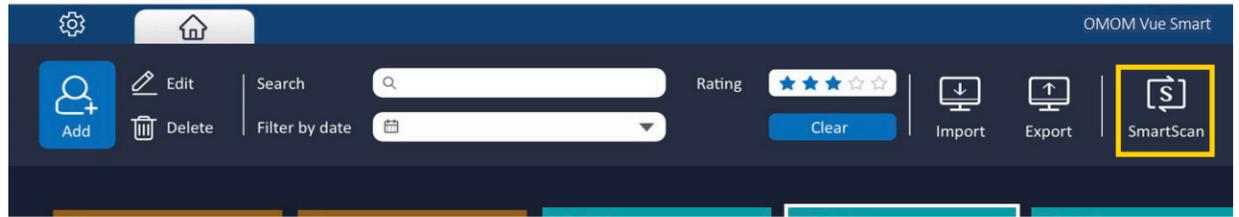
SmartView

SmartView reading mode will only play the pictures picked up by *Smartscan*, assisting users in quickly navigating through the full video. Highlighted marks above the time bar show the images which can be displayed as a short video.

SmartFinding

By capturing the most prominent characteristics of selected images with predictive results, **SmartFinding** helps doctors by displaying the abnormalities and suggesting descriptions. Images are displayed as page view.
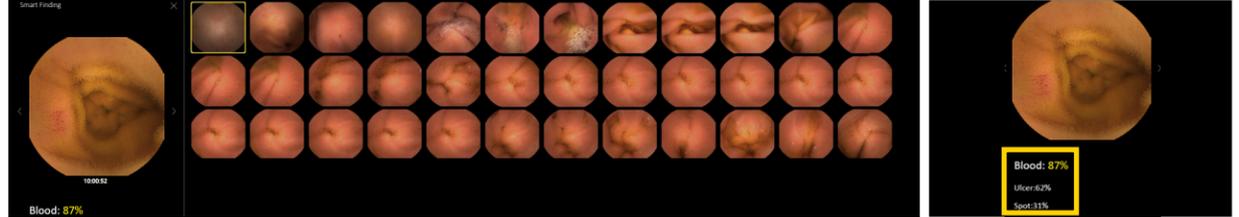
Horizon Unbounded

Pushing the boundary on capsule hardware, our new OMOM HD delivers superior image quality powered by our new optical technology. With more evident details from higher resolution images, ultra-wide-angle view, *SpeedSense* technology and longer battery life, OMOM HD ushers in the era of simple but confident diagnosis.

Industry-leading Features

512*512 Pixel

>300% improved resolution
Unparalleled clarity

2. Dydis   11 x 25,4 mm
3. Vaizdų filmavimo trukmė   12 val.
4. Kapsulės filmavimo kampas   172°
5. Matymo gylis   0-5 cm
6. Vaizdo perdavimas   bevieliu būdu

✓ ### 2-10 FPS

Enhanced sampling frequency.
Upgrade by SpeedSense

✓ ### 172 Degrees

Ultra-wide viewing angle
Improved tissue coverage

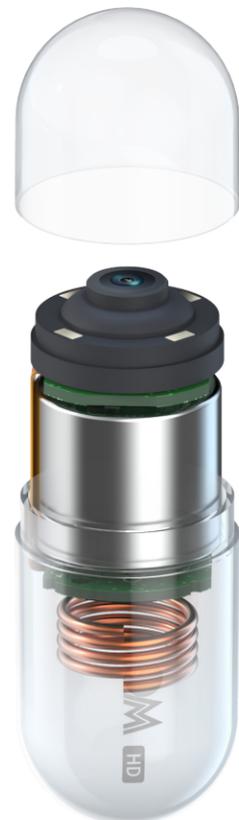✓ ### 12 Hours

Increased capsule working hours
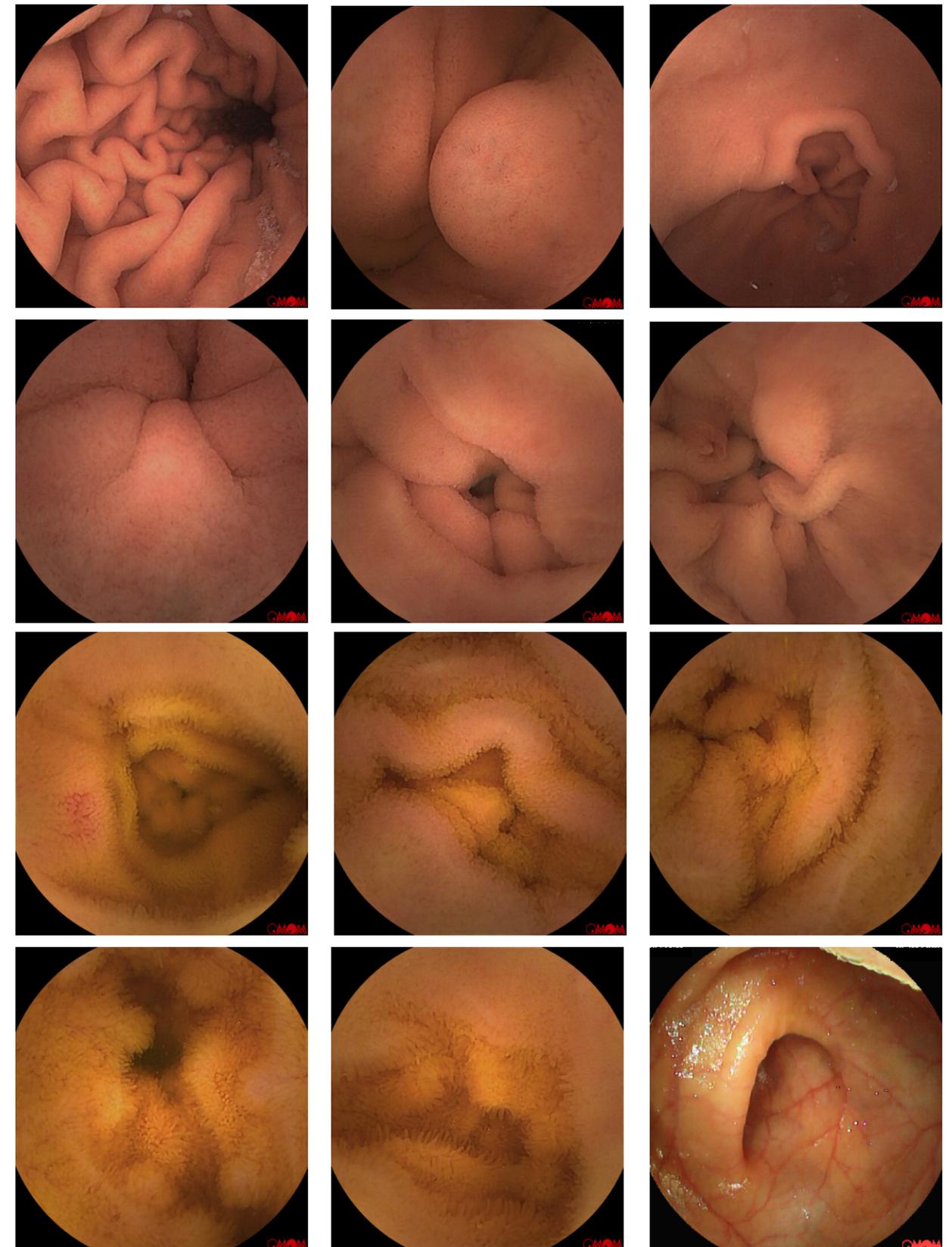Extended reach and duration

✓ ### Compact capsule

Ergonomic design.
Dimension 25.4mm*11mm
Weight 3g

Disposable belt cover

Disposable belt cover is now available as contact-free option.

Case Gallery

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CE 0197

OMOM HD Smart Capsule Endoscopy System

Kapsulinės endoskopijos kapsulės

Type SC100 ✓

User's Manual

Chapter 1: System Overview

The OMOM HD smart capsule endoscopy system (hereinafter referred to as 'capsule endoscope') mainly consists of three parts: **the HD Smart Capsule** (hereinafter referred to as '**Capsule**'), **the Image Recorder** (hereinafter referred to as '**Recorder**'), and the **Vue Smart Workstation** (hereinafter referred to as the '**Vue Smart**').

The components of the system are as follows:

1. Capsule

Capsule takes GI images and transmits them to the recorder.

The capsule is deactivated by magnetic switch in its packing box (figure below). Break seal and open the packing box, the capsule starts to work with LED blinking.
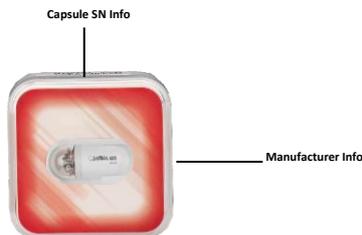
To deactivate the capsule, place it back in the packing box with the logo upwards, and cover the lid, then LEDs should stop blinking. If failed, rotate the capsule as little adjustment and cover the lid until blinking stops.

Recycle and Disposal

The capsule designs for single use. Do not recycle it for other use.

Service Conditions

- Keep away from high magnetic fields. Take the corporate video as an example, if you would kindly recall it, the initial plan was to hire a company to simply edit the video, with no additional footage or photo shooting and it
- Working temperature should be between 5℃-40℃.
- Within a short distance, do not open two capsules simultaneously.
- Keep the capsules in packing box until use.
- Store the capsules only in packaging supplied with the product.
- Do not use a capsule if its package is damaged.

- Do not use a capsule which cannot be activated .
- Keep the capsule away from strong magnetic fields (such as MRI devices) and metal objects.

2. Recorder

✓ The recorder receives and stores images transferred from capsule and displays in real-time. It consists of antenna units which receive and transmit signals, a recorder which processes images, a memory card which stores images and a rechargeable lithium battery. Accessories include a charger, a recorder waist belt, a recorder pouch and a USB cable.

Antena priima ir perduoda signalą, įrašymo įrenginys apdoroja vaizdus, atmintis kortelė išsaugo vaizdus

shown below:
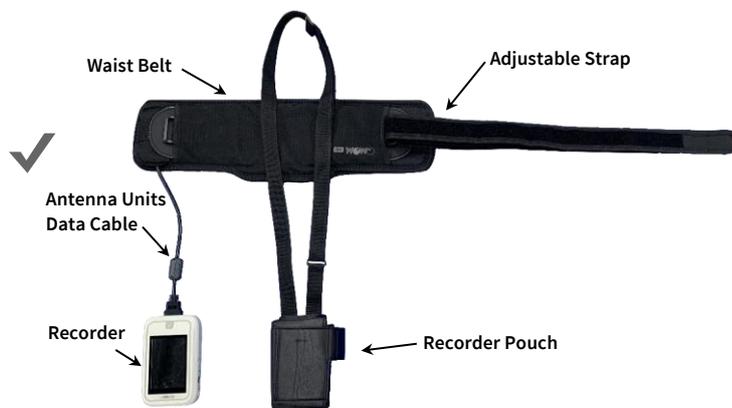
Components and Exterior: Waist Belt, Antenna Units and Recorder

Exterior: Recorder
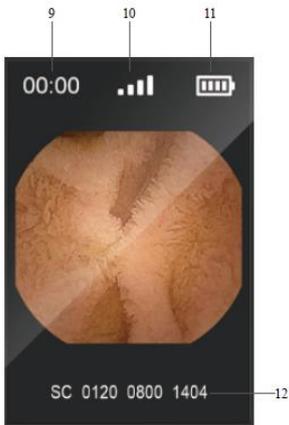
Exterior: Screen

Table-Recorder

#	Component	Note
1	Charging Port	Connected to the charger
2	Charging Indicator	Green light with blinking indicates the recorder is charging. Green light without blinking indicates charging completed
3	USB Port	Connect recorder to the workstation computer
4	Power	Turn on / off the recorder

5	Screen Switch	Multi-functional button
		• Switch on / off the screen display
		• Confirm the pairing of the recorder and capsule pairing
		• Confirm the formatting the recorder
		• Keep pressing to enter capsule signal searching mode
6	Screen	The main display of the recorder displays the relevant information during capsule endoscopy procedure
		Display Time, Signal Indicator, Battery Indicator (Power status of recorder), Image captured by capsule and S / N of current capsule
7	Connect Antenna Unit	Communication with the capsule
8	ACT Indicator	Constant flashing indicates the recorder is on. Flickering indicates the images transmitting
9	Time	Display the current working time
10	Signal Indicator	Indicating the signal level between the capsule and recorder
11	Battery Indicator	Display power status of the recorder
12	S / N	Display the serial number of the capsule which paired with Recorder

Įrašymo įrenginio ekranas rodo aktualią informaciją kapsulinės endoskopijos metu.
Laiką, signalo indikatorius, baterijos indikatorius, vaizdus gautus iš kapsulės, kapsulės S/N

Attention

The capsule transmits images at a specific frequency. Occasionally, interference from external devices transmitting in the same bandwidth may interrupt or limit the capsule transmission. The following possible cases could occur:

• Car or house alarm: These may cause momentary transmissions loss.

Depending on the proximity of the car or house alarm transmitter to the ingested capsule, there could be a momentary interference that should not damage the capsule video.

• Police / Fire stations radio equipment: These may cause more extended transmission durations loss.

Depending on the proximity of the car or house alarm transmitter to the ingested capsule, this could cause longer duration interference, possibly causing gaps in the capsule video.

Signal Indicator

The signal indicator is shown on the screen, which indicates the signal strength between the capsule and antenna. Signal status is shown in table below:

Signal Indicator	Description	Signal Level	Statement
▂▄▆█	4 lights on	>85%(saturation)	Strong signal
▂▄▆	3 lights on	60%-85%	Good signal

	2 lights on	35%-60%	Poor signal (The recorder may not receive all images)
	1light on	10%-35%	
×▯▯▯	All off	0	No Signal (The recorder cannot receive images)

Battery Indicator

The battery indicator is shown on the screen, which indicates the battery level. Power status is shown in table below:

Battery Indicator	Description	Battery Level
	4 lights on	>85% (saturation)
	3 lights on	60%-85%
	2 lights on	35%-60%
	1 light on	10%-35%
	All off	< 10%

Attention

• Before the CE examination, make sure the Recorder is fully charged.

ACT Indicator (ACT)

The status of power on / off and working is shown in table below:

ACT Indicator	Statement
On	The recorder is on and ready to work
Off	The recorder is off
Flickering	Images receiving

Charging Indicator (CHG)

The charging status of the recorder is shown in table below:

CHG Indicator	Statement
On with blinking	Charging
On without blinking	Charge complete

10

Sound Indicator

The single beep with yellow ACT indicator ON indicates low battery.

🔔**Attention**
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- Charging at low battery level may prolong its lifespan.

On / Off

- **Power On**- Keep pressing the power button (on / off) for 5 seconds until you hear a beep sound.
- **Power Off**-Keep pressing the power button (on / off) until it shows Power Off on the screen.

On/Off

3. Vue Smart Workstation

The Vue Smart Workstation's Version: 7.2.

Main functions are provided for user:

- Patient management.
- Pair the capsule with the recorder before examination.
- Export the recorder's image data after the examination.
- Images analysis and diagnose description.
- Fill in and print report.
- Export and import patients' data.
- SmartScan to identify the lesions automatically

🔔**Attention**
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- The SmartScan function must be authorized, and is available for HD capsule.
- The Vue Smart Workstation's display resolution supports 1024×768 above pixel, and 32 bits color.

4. Accessories

Power Adapter

The adapter has input end and output end. Unplugging any end can cut off the power in case of the emergency.

Specification:

- AC input: 100-240Vac, 0.6-0.4A, 47-63Hz
- DC output:5.3V ⎓3.77A MAX ⊖—◉—⊕

⚠ Warning

- Do not disassemble the adapter without permission.
- Do not touch the power adapter with wet hands or dip it into liquid.
- Do not apply this power adapter to other devices.

USB Cable

Connect the recorder and the computer for the data transmission.

Indications and Contraindications

1. Indications

This product is intended to diagnose GI tract diseases, especially for the following categories of patients:

- Obscure GI bleeding and iron deficiency anemia
- Suspected Crohn disease
- Suspected small intestinal tumor
- Small intestinal polyp syndrome
- Doubtful malabsorption syndrome (celiac disease, etc.)
- Non-steroid anti-inflammatory drug related small bowel mucosa damage
- Patients who are in need of excluding the small intestinal diseases

⚠ Warning

- Potential risks of CE include obstruction, capsule retention and aspiration. In some instances, intervention is required to remove the capsule.
- Capsule retention has been reported in approximately 1.4% of CE procedures. Retrospective studies have reported retention rates of 0% to 1.6% in patients with suspected IBD, and of 5.2% to 13% in patients with known IBD. Patient factors associated with a higher risk of retention include known CD, strictures or other obstruction, pelvic or abdominal radiation, or suspected tumor. Capsule retention may require endoscopic or surgical retrieval of the capsule[1].

[1]. Robert A. Enns, et al. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. Gastroenterology. 2017 Feb; 152(3): 497-514.

2. Contraindications

The following cases should require further caution in using CE (relative contraindications):

- Patient with dysphagia.
- Patient with confirmed or suspected gastrointestinal tract obstruction, stricture, and fistula.

Appendix B: Detailed Functions of the Recorder

Connecting or disconnecting Recorder and Sensor

Connecting

Insert the sensor connector into the recorder's slot toward the direction shown as below until you hear a click.

Disconnecting

Press and hold the buttons on both sides until it is pulled out.

Pairing--- Connected Recorder and Capsule

Appendix G: Technical Parameters

System Specification

Specification and Parameter of the Capsule

Specification	Parameter
Capsule Type	SC1
Physical Characteristics	Size: Φ11.4*25.4mm
	Weight: 3.0g
	Shell Material: Medical polymeric material
Optical Characteristics	Visual Angle(In the air): 172°
	Depth of Field(In the air): 0~50mm
	Resolution (In the air): 8 lp /mm
Operating Characteristics	Working Condition: Temperature: 5~40˚C Relative Humidity: ≤85% Atmosphere: 860hPa~1060hPa
	Sampling Rate: 2 ~ 10 fps
	Working Hour: 12h Working Voltage: 3V Working Current: 12mA Working Temperature: 5~40˚C
Storage Condition	Temperature: 0~50˚C Relative Humidity: ≤80% Atmosphere: 860hPa~1060hPa
Other Characteristics	Image resolution: Support 512 * 512 pixel resolution Color depth: 24-bit true color
	Impermeability: IPX8
	Transmit / receiving frequency: 430MHz to 437 MHz

Technical Characteristics of the Recorder:

Specification	Parameter
Recorder Type	SC-RD1
Size	136*83*36mm
Power	A built-in Lithium battery
Continuous Operating Hours	15 hours
Storage Capacity	32GB
Number of Units Received by Antenna Array	Four
Battery Capacity	≥9000mAh
USB Port	USB 2.0
Weight of the Recorder	< 0.8 kg
Working Condition	Temperature: 5~40˚C Relative Humidity: ≤85% 860hPa~1060hPa
Storage Condition	Temperature: 0~50˚C Relative Humidity: ≤80% Atmosphere: 860hPa~1060hPa
Transmit / receiving frequency	430 MHz to 437 MHz

Characteristics of the Vue Smart Workstation

Specification	Parameter
Language	EN / DE / FR / ES / IT / RU / TR / PT / TC
Output Format	BMP, JPEG, AVI, PDF, Word
Display Frame Frequency	1 ~ 30fps
Input the patient's info	
During the examination, keep viewing the working status of the capsule endoscope in real-time and controlling the working status	
Be able to monitor multiple recorders simultaneously	

Classification