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OLYMPUS

INSTRUCTIONS FOR USE

SMARTIBD

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1 Product Description

SMARTIBD is an artificial intelligence (AI)/machine learning (ML) based medical device software. SMARTIBD interfaces with the video feed generated by an endoscopic video processor during a colonoscopy procedure.

SMARTIBD is intended to be used by trained and qualified clinicians as an accompaniment to video endoscopy for the purpose of assisting the assessment of the disease activity for ulcerative colitis based off the mucosal appearance.

SMARTIBD analyses the data from the endoscopic video processor in real-time and characterizes disease activity in the field of view of the endoscope, in line with the MAYO scoring system for the endoscopic appearance.

The areas characterized by SMARTIBD are not to be interpreted as definite characterization of ulcerative colitis disease activity. The responsibility to make a decision as to whether or not there is ulcerative colitis present, and the degree of disease activity, lies with the user. The endoscopist is responsible for reviewing suspected areas and confirming the presence or absence of ulcerative colitis, and the degree of disease activity based on their own medical judgment.

2 Intended Use

1. SMARTIBD is intended to be used by trained clinicians (users) as an accompaniment to video Endoscopy for the analysis of ulcerative colitis.
2. SMARTIBD is trained to process colonoscopy video frames that may contain regions visually consistent with grades of activity of ulcerative colitis.
3. SMARTIBD can analyse the visual characteristics and provide information to aid the user to characterize the tissue. This information is interpreted by the user and appropriate actions taken according to the standard clinical practice.

3 Intended Patient Population

SMARTIBD is intended to be used on any patients over the age of 18 that have been referred for a colonoscopy procedure for the investigation of the colorectal mucosa, whether for screening, surveillance, symptomatic or diagnostic purposes. This does not include pregnant women for which no clinical evaluation has been carried out.

4 Intended Users

SMARTIBD is intended to be used by trained and qualified healthcare professionals for endoscopy.

5 Contraindications

1. SMARTIBD should not be used when the colonoscopy is operating on a known or suspected perforation of the bowel.
2. SMARTIBD should not be used on Pregnant women, for which no clinical evaluation has been completed.
3. SMARTIBD should not be used to assess severity, extent or complications of Crohn’s disease or diverticular disease.
4. SMARTIBD should not be used on patients contraindicated for colonoscopy.

6 Warnings, Limitations and Precautions

1. Only to be used by qualified healthcare professionals for colonoscopy.
2. SMARTIBD is a clinical support tool, not to be used as a replacement for clinical judgement or histopathology.
3. Avoid overreliance on the device.
4. Please ensure that the endoscope is connected through the frame captured card to the client PC.
5. Please verify that the endoscope image is displayed after pressing the pedal on the device label page.
6. Please verify that the purple image area is defined correctly around the endoscopy image stream. Please contact us if the area needs to be recalibrated.
7. Use on a non-compatible endoscopy system could result in unknown performance.
8. Inadequate bowel preparation can directly impact the ability of SMARTIBD to function as intended.

7 SMARTIBD Setup

1. SMARTIBD is accessed via a secure Chromium web browser on a computer that must meet the minimum software and hardware requirements (detailed in section 12).
2. The computer takes the endoscopy video feed from the endoscopy image processor. It is connected to the frame captured card on the client (off-the-shelf) computer via an SDI cable.
3. The computer is plugged into the video in of the existing main endoscopy monitor observed by the endoscopist.
4. It is recommended that SMARTIBD is interacted with using a pedal paired with the space bar. The pedal is connected to the client (off-the-shelf) computer via USB.
5. SMARTIBD is logged into with a username and password on a webpage.

8 Notification Symbols

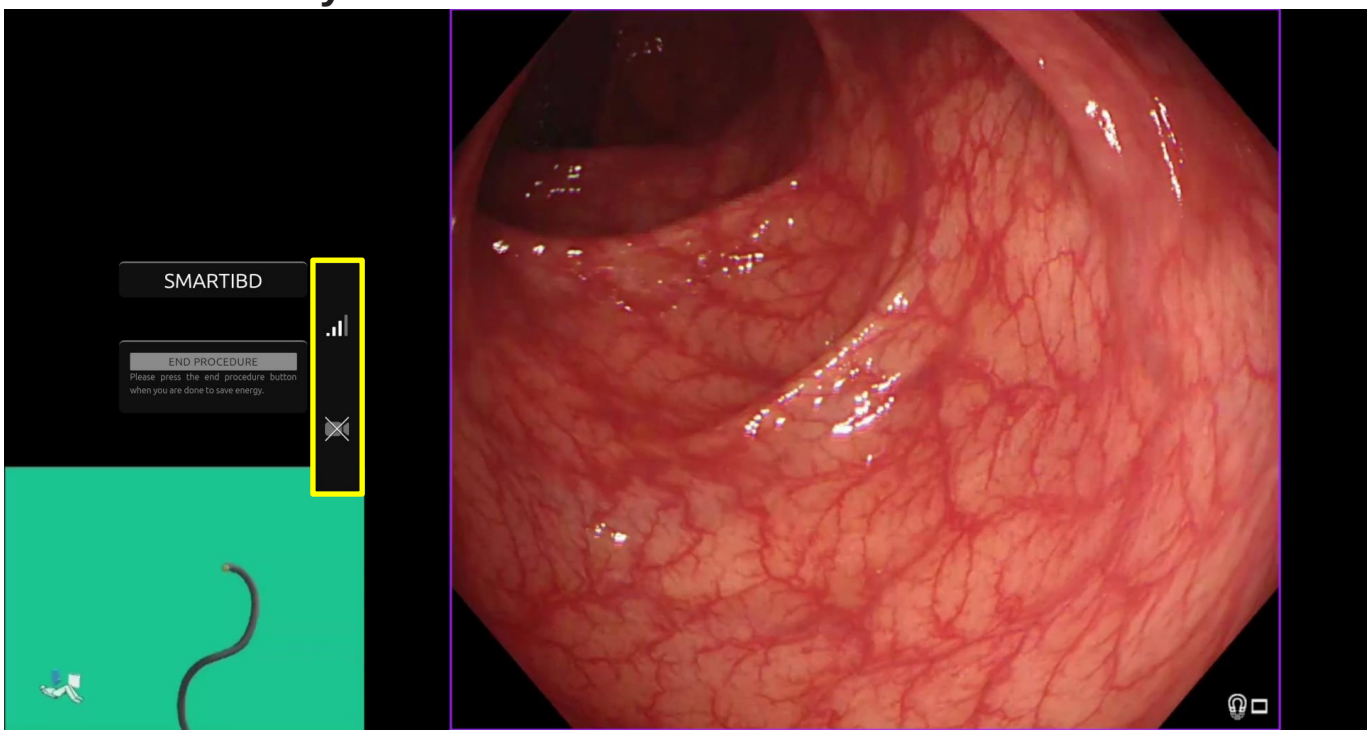

Figure 1: Notification Symbols

8.1 Network Quality

1. The notification symbols panel is displayed on the left-hand side of the endoscopy image area, as shown in the highlighted yellow region in the figure 1.
2. The network quality is represented by a network connection symbol. The number of bars represents the quality of the network. The lower the network the connection the higher the latency and delay in the information provided. A strike-through red symbol represents no network connection available. If the network indicator signals no network connection, normal clinical practice should resume, as the SMARTIBD software will not be able to function as intended. Note that these symbols are not an indication of Wi-Fi signal strength.
3. **Note:** A wired connection is recommended, as Wi-Fi connections might be less stable.

Figure 2: Network Connection Symbols: (a) > 100 ms and characterisation not responding; (b) > 100 ms; (c) 66 – 100 ms; (d) 33 – 66 ms; (e) < 33 ms.

8.2 Upload Indicator

1. Once uploading is complete, the symbol will become a tick, indicating it is finished uploading as seen in figure 3 (a).
2. Once a procedure is finished and if recording was enabled, the video will begin to upload. Demonstrated by the symbol with an up arrow as seen in figure 3 (b).
3. If a user wishes to see the progress, they can hover the mouse and see a percentage. Example at 78% complete as seen in figure 3 (c).

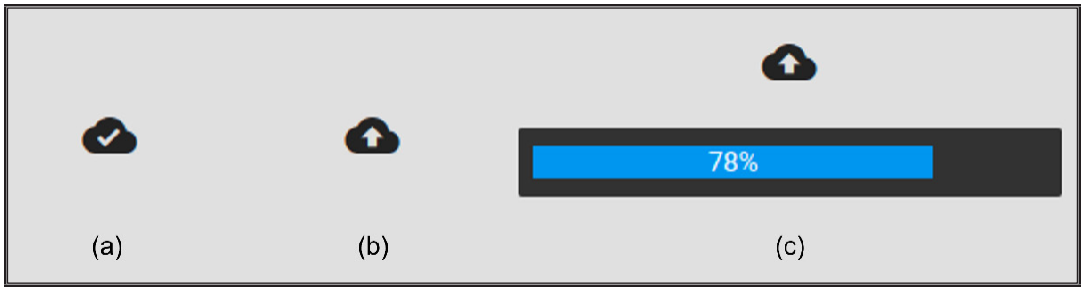

Figure 3: Upload Indicator

9 Use

1. The device can be accessed through a supported browser (Chromium v83 or higher (for example, Google Chrome or Microsoft Edge)) at the following web address (URL): https://smartibd.odin-vision.com. The login page is illustrated below.

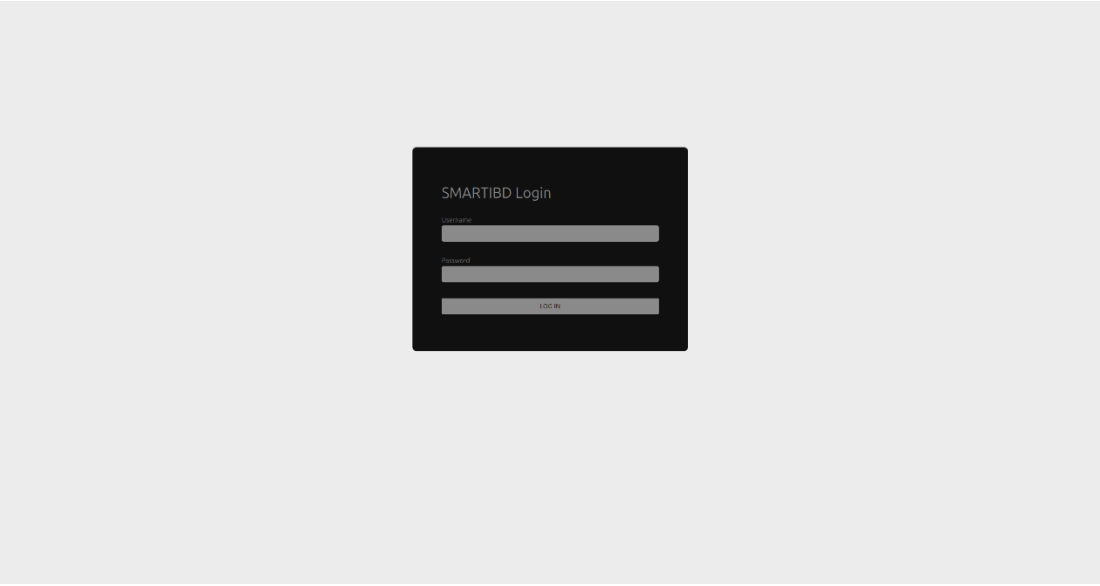

Figure 4: Login Page

Note: On a locally deployed version of the software (where the host computer and client computer are the same), the user is not required to enter credentials. The device starts up automatically when the computer is switched on and logged into by the user. Login for SMARTIBD is automatic.

2. The username and password are to be entered. After a successful login, the label page will be displayed as illustrated below.

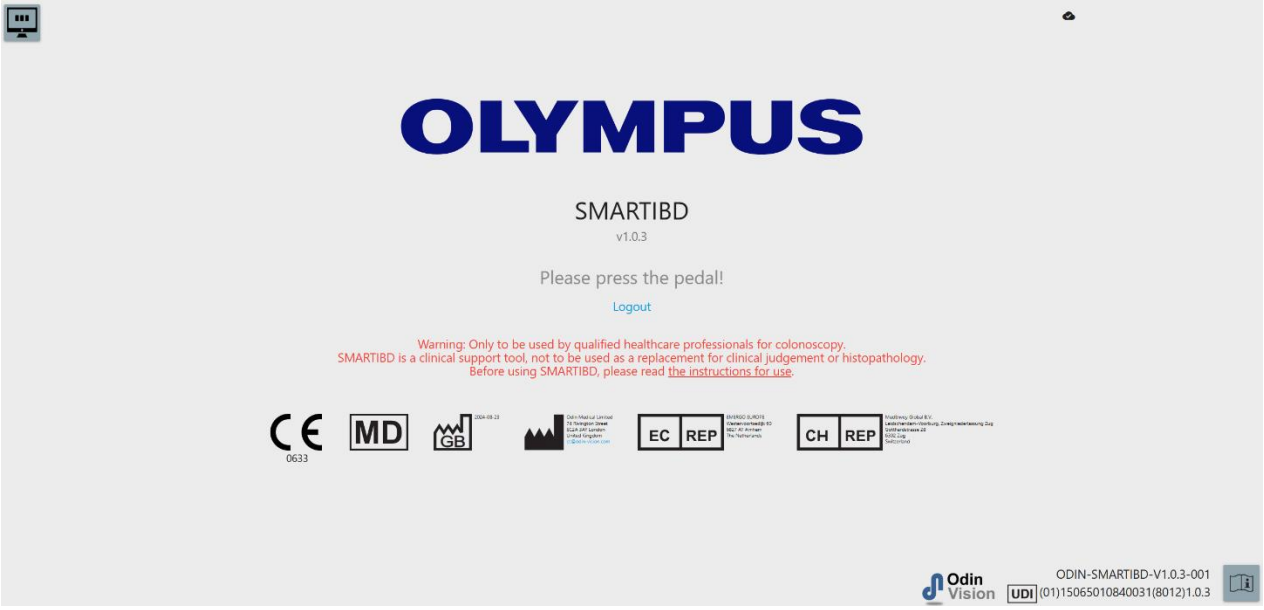

Figure 5: Label Page

3. The “Instructions for use”, can be accessed through a mouse click on the icon in the lower right corner.
4. The product’s unique device identifier (UDI), which identifies the specific version of the software for device traceability can be accessed by pressing the i key on the keyboard and is displayed in the lower right-hand corner of the start-up screen next to the instructions for use (booklet) symbol.
5. SMARTIBD is started by triggering a switch (this can be done by pressing the foot pedal or a configured key of the keyboard attached to the client computer). The endoscope image stream is displayed with several indicator symbols, which are detailed in Section 8.

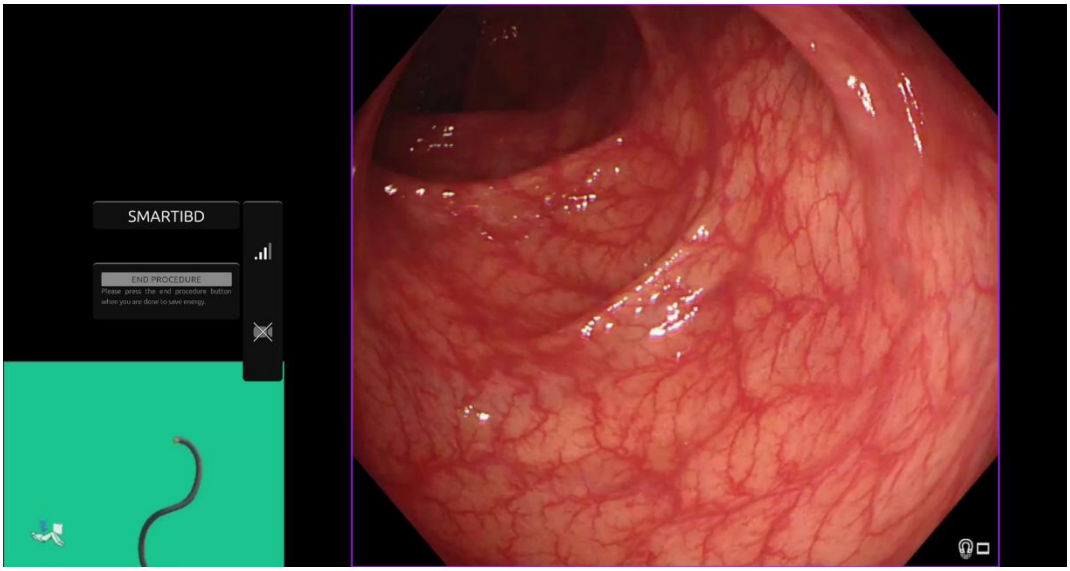

Figure 6: Endoscopic procedure

6. Characterisation information for the Ulcerative Colitis MAYO score can be triggered with a short press of the pedal. The information will be displayed on the screen for 5 seconds. The displayed data can support clinical decisions; however, the device is not designed to be used as a diagnostic tool. The resulting supporting information is displayed at the top of the image area, i.e. MAYO Score: “0”, “1”, “2”, “3” or “Uncertain”.

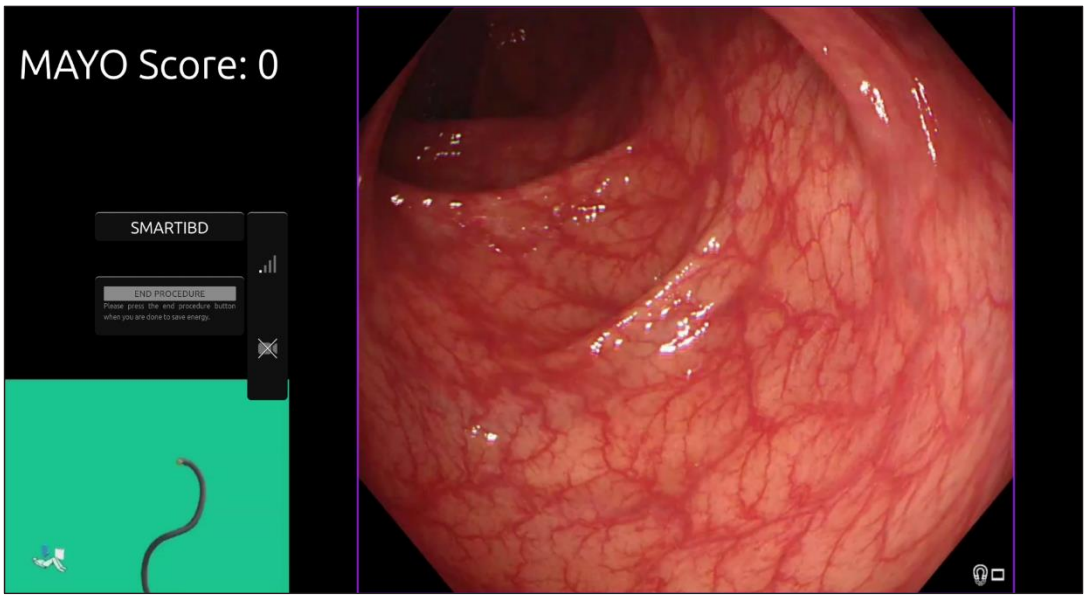

Figure 7: Characterisation Information displayed

7. If the information displayed is “Uncertain” the camera should be repositioned to centre the tissue and focused before characterization is attempted again.
8. Additional supporting information is presented on the left-hand side of the image area as notification symbols. The notification symbols are detailed in Section 8.
9. If configured, video and other data (no patient data) can be recorded during the procedures. The user is notified if data recording is in progress by displaying a camera icon in the status bar of the device, as seen below (highlighted in yellow).

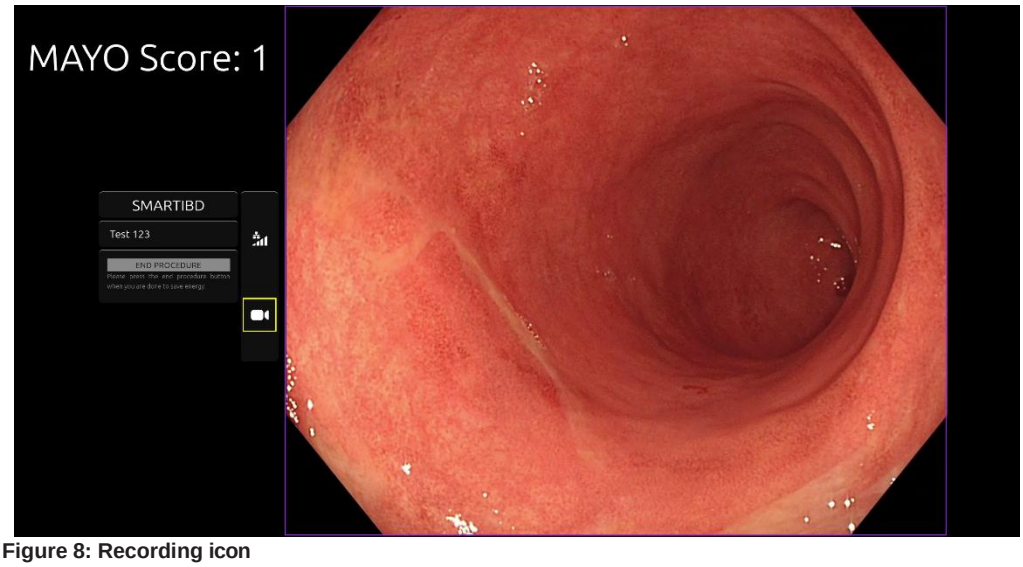

Figure 8: Recording icon

10 Interpretation of Results

1. **Characterisation:** The characterization information displayed, when requested, is for decision support only. The information should not be interpreted as a clinical, diagnostic decision. It is solely to support the decision-making process of the user. It should not be used to substitute clinical decision or histopathology.

11 Clinical Trial Modes

1. Clinical trial modes can be configured for certain users. Such modes can contain additional features to the above. The clinical trial modes cannot be accessed by a user not involved in a clinical trial. If clinical trial mode is configured, the following page is shown after login and before the greeter page (options for modes might vary). The user can cycle and select a clinical trial mode using the pedal. A short press will move the selected mode (larger and lighter box) (Figure 9). Holding down the pedal for 2 seconds then releasing it will select the workflow. A loading box around the selected mode will indicate when the pedal can be released (Figure 10).

Figure 9: Workflow selection

Figure 10: Workflow Selected

2. In Computer Aided Trial mode, users will be redirected to the SMARTIBD greeter page, as detailed in section 8.2. Starting the trial procedure with SMARTIBD involves following the on-screen instructions. Additional features for the trial may be enabled.
3. In all clinical trial modes, the current mode is continuously displayed in the top left corner.
4. The upload indicator is available in the top right-hand corner.

12 Minimum System Specification

12.1 Minimum Client System Specifications

CPU	Intel i3 (8th gen) or equivalent
RAM	4 GB
Network connection	8 Mbit upload, 1 Mbit download. For optimum performance a wired connection is required
Browser	Chromium (v 83 or higher) – for example, Google Chrome or Microsoft Edge
Frame capture card	Compatible with the endoscopy system to be used
Monitor	Primary endoscopy monitor or equivalent secondary monitor
Audio speakers	Suitable for the work environment

12.2 Minimum Host System Specifications

CPU	Intel i7 (8th gen) or equivalent
RAM	16 GB
Network connection	1 Mbit upload, 20 Mbit download. For optimum performance a wired connection is required
GPU	NVIDIA Turing GPU, at least NVIDIA RTX 2070
Operating system	Linux OS with Linux Kernel 4.15, e.g. Ubuntu Linux 18.04 or higher

13 Compatibility with Other Devices

1. The software does not interface directly with devices, except for the client computer. The device interacts through the client computer with the frame capture device to receive the endoscopic video feed. The device interacts with a monitor through the client computer, to display information on the monitor.
2. SMARTIBD is compatible with endoscopic video processors and scopes that are equipped with high definition (HD) or higher image quality resolutions. SMARTIBD has not been tested on endoscopy systems with an image quality resolution less than HD. The performance of SMARTIBD may be negatively affected and vary if used on endoscopy systems with lower image quality resolutions.
3. SMARTIBD is compatible with white light imaging light modalities. SMARTIBD has been tested using Olympus video processors with white light imaging. The performance of SMARTIBD using other manufacturers' video processors or virtual chromoendoscopy modalities may be negatively affected and vary.

14 Performance Characteristics of the Device

1. Non-clinical (bench) performance testing included the validation of the algorithm of SMARTIBD on multiple datasets to evaluate accuracy. A summary of the results is presented below.
2. SMARTIBD was evaluated on its ability to differentiate between different grades of Ulcerative Colitis (UC) on video frames from a standard colonoscopy procedure. The dataset included frames of varying severity of UC, annotated based on the Mayo Endoscopic Score. Only frames where 3 annotators agree on the Mayo Score annotation are used for this study. These image-level annotations were used as ground truth reference standards.
3. The average clip accuracy of the model is 82.38%, which shows the SMARTIBD model reaches adequate performance for grading ulcerative colitis.
4. SMARTIBD demonstrates satisfactory performance at the frame level for grading Ulcerative Colitis using the Mayo Scoring System. The performance of SMARTIBD on an independent site and an independent endoscopic video processor has also been demonstrated.

15 IT Security Measures

1. Users should use a strong password for their SMARTIBD login and protect their login credentials in accordance with their organisations security policies.
2. Users should use virus protection, firewalls and any other cybersecurity protections (including operating system updates) per local requirements on computers used to access the SMARTIBD software in accordance with their organisations security policies.
3. When using computers to access the SMARTIBD software, users should follow their organisations security policies and be cautious of communications that may be phishing or other cybersecurity attacks. Users should be cautious of clicking links that claim to be an Odin Vision website or the SMARTIBD software.
4. The manufacturer recommends that the client computer used to access the SMARTIBD website is set up on a virtual LAN (VLAN) to isolate all network traffic from other hospital systems.
5. For on-premises (local) deployment of SMARTIBD, the manufacturer recommends that the server used to host the SMARTIBD software service is set up on a virtual LAN (VLAN) to isolate all network traffic from other hospital systems.

16 Basic UDI-DI, UDI-DI, product code, catalogue number or other unambiguous reference allowing traceability

Table1 : Basic UDI / UDI-DI / Software Version

Basic UDI-DI	5065010840OD04PF
UDI-DI	(01)15065010840031
Software version number	1.0.3
Full UDI (DI+PI)	(01)15065010840031(8012)1.0.3
Product code	R5001249
Catalogue number	SMARTIBD

17 Contact Information

1. For questions, information or Customer Support, please contact Odin Vision in either of the following ways:

   Email: cs@odin-vision.com

   Online: odin-vision.com
2. Any serious incident that has occurred in relation to the device should be reported to the manufacturer (Odin Medical Limited, trading as Odin Vision) and the competent authority or regulatory agency of the state in which the user and/or patient is established without delay.
3. Any cybersecurity incident that has occurred in relation to the device should be reported to the manufacturer (Odin Medical Limited, trading as Odin Vision) without delay.

18. Glossary of Medical Device Symbols

Symbol	Symbol Title	Meaning of Symbol/Description	Standard (or Regulation) Title	Standard (or Regulation) Reference
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.4.3
			Graphical symbols for use on equipment.	ISO 7000-1641
	Manufacturer	Indicates the medical device manufacturer.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.1.1
			Graphical symbols for use on equipment.	ISO 7000-3082
	Medical device	Indicates the item is a medical device.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.7.7
	Country of manufacture	To identify the country of manufacture of products. In the application of this symbol, the "CC" shall be replaced by either the two letter country code or the three letter country code defined in ISO 3166 1 (Codes for the representation of names of countries and their subdivisions — Part 1: Country codes The date of manufacture may be added adjacent to this symbol.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.1.11
			Graphical symbols for use on equipment.	IEC 60417-6049
	Unique device identifier	Indicates a carrier that contains unique device identified information.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.7.10
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.4.4
			Graphical symbols for use on equipment.	ISO 7000-0434A or ISO 7000-0434A
	CE Marking	CE Marking indicates that the product complies with Regulation (EU) 2017/745	Regulation (EU) 2017/745	EU 2017/745, Article 20
	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.1.2
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland	Information sheet - Obligations Economic Operators CH, associated with Art. 51 para. 1 MedDO (812.213 Medical Devices Ordinance of 1 July 2020 (MedDO))	MU600_00_016, page 5 footnote 7
	Importer	Indicates the entity importing the medical device into the locale	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.1.8
			Graphical symbols for use on equipment.	ISO 7000-3725

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