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OLYMPUS

INSTRUCTIONS FOR USE

CADDIE

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1 Product Description

CADDIE is artificial intelligence based medical device software. CADDIE interfaces with the video feed generated by an endoscopic video processor during a colonoscopy procedure.

The software is intended to be used by trained and qualified healthcare professionals as an accompaniment to video endoscopy for the purpose of drawing attention to regions with visual characteristics consistent with colonic mucosal lesions (such as polyps and adenomas).

CADDIE analyses the data from the endoscopic video processor in real-time and provides information to aid the endoscopist in detecting and/or characterizing suspected colorectal polyps, if they are in the field of view of the endoscope.

The areas highlighted by CADDIE are not to be interpreted as definite polyps or adenomas. The responsibility to make a decision as to whether or not a highlighted region contains a polyp or is an adenoma lies with the user. The endoscopist is responsible for reviewing CADDIE suspected polyp areas and confirming the presence or absence of a polyp and its classification based on their own medical judgement.

2 Intended Purpose

1. CADDIE is intended to be used by trained and qualified healthcare professionals (users) as an accompaniment to video endoscopy.
2. CADDIE can draw attention to regions with visual characteristics consistent with different types of colonic mucosal abnormalities.
3. CADDIE is trained to process colonoscopy video frames that may contain regions consistent with colorectal lesions like polyps, including diminutive and flat polyps.
4. CADDIE 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 action is taken according to the standard clinical practice.

3 Intended Patient Population

CADDIE 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 User

CADDIE is intended to be used by trained and qualified healthcare professionals for colonoscopy.

5 Contraindications

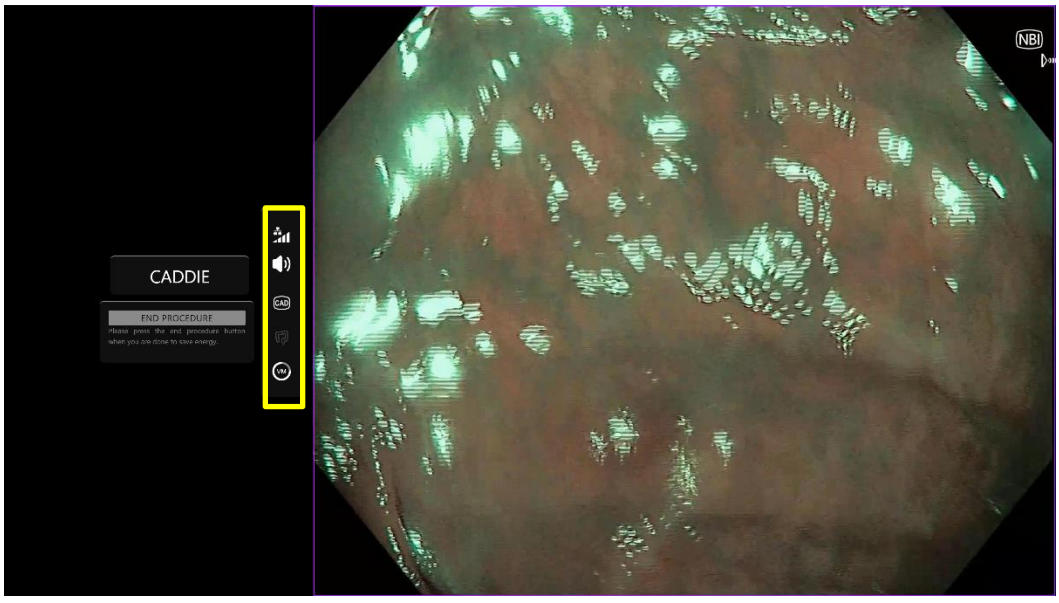
1. CADDIE should not be used when the colonoscopy is operating on a known or suspected perforation of the bowel.
2. CADDIE should not be used to assess severity, extent or complications of ulcerative colitis, Crohn’s disease and diverticular disease.
3. CADDIE should not be used on patients contraindicated for colonoscopy.

6 Warnings, Limitations and Precautions

1. Only to be used by qualified healthcare professionals for colonoscopy and healthcare professionals trained in the use of CADDIE.
2. CADDIE is a clinical support tool, not to be used as a replacement to histopathology.
3. If the patient has had an appendectomy or any other surgery affecting the caecum such as right hemicolectomy or ileocaecal resection the functionality of the caecum warning may be limited.
4. Avoid overreliance on the device.
5. If the network indicator signals no network connection, normal clinical practice should resume.
6. Please ensure that you can hear an audio alert after pressing the pedal on the device label page if enabled.
7. Please ensure that the endoscope is connected through the frame capture card to the client PC.
8. Please verify that the endoscope image is displayed after pressing the pedal on the device label page.
9. 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 Notification Symbols

Notification symbols panel is displayed on the left-hand side of the endoscopy image area, see highlighted yellow region in the figure below.



7.1 Network Quality

The network quality is represented by a network connection symbol, the number of white bars represent 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 CADDIE software will not be able to function as intended.

Network connection symbols: (a) > 100 ms and detection not responding; (b) > 100 ms; (c) 66 – 100 ms; (d) 33 – 66 ms; (e) < 33 ms.

7.2 Detection Status

The detection status is indicated by the symbol shown below. When detection is ‘on,’ the AI-enabled detection symbol will be displayed. When detection is ‘off,’ a strikethrough version of the symbol will appear to indicate that AI detection is inactive. This can be turned on and off by triggering a switch. Whilst the detection status is on, the device will display bounding boxes around regions of the video feed with the visual characteristics of colonic polyps.

a) b)

Detection status (a) off or (b) on. If the caecum is detected and detection is off, this symbol will flash three times along with the caecum symbol.

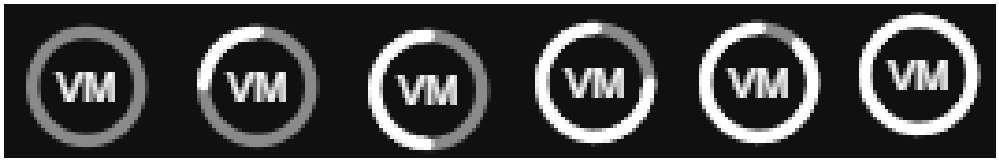
7.3 Audible Alert Status

The audible alert status is represented by a volume symbol. When it appears with a strike-through, it indicates that the audible alert is off. This will be off when detection is off and on when detection is on, unless sound is disabled by the user. If disabled, it will stay off.

Audible alert status (a) on, (b) off and (c) volume slider.

7.4 Visible Mucosa Display

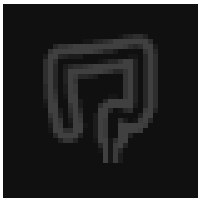
The amount of visible mucosal membrane is visualised using a Grey/ White pie chart symbol that rounds up or down to the nearest quarter (25%) of the visible mucosal membrane except for the upper bound where the resolution is doubled. Grey represents membrane not visible and White represents visible membrane.



From left to right: <12.5%; 12.5-37.4%; 37.5-62.4%; 62.5-87.5%; 87.5-93.75%, >93.75 estimated ratio of visible mucosa

7.5 Caecum Notification

If caecal landmarks are captured in a freezeframe, the user will be given a warning that the caecum has been reached. The below symbol will appear, flashing up three times before disappearing. If detection is turned off the cross symbol will also flash three times along with the caecum symbol. If detection is on, the caecum symbol will flash three times on its own.



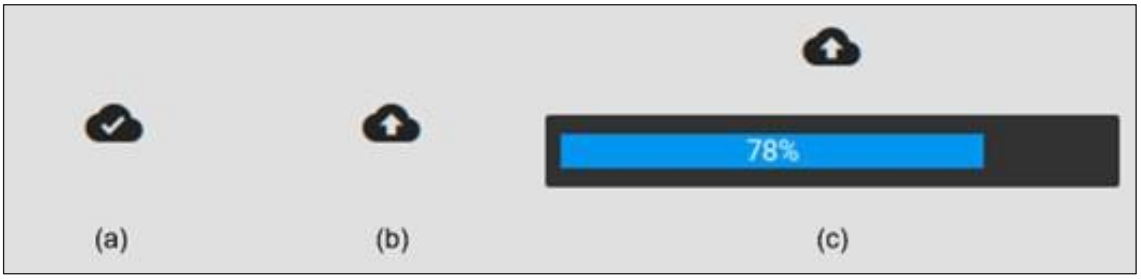
Note: if the patient has had an appendectomy, some landmarks may not be recognised by CADDIE. In this instance, the caecum warning might not indicate, and the detection turned off symbol will also not flash.

7.6 Upload Indicator

Once uploading is complete, the symbol will become a tick, indicating it is finished uploading as seen in figure (a).

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 (b).

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 (c).

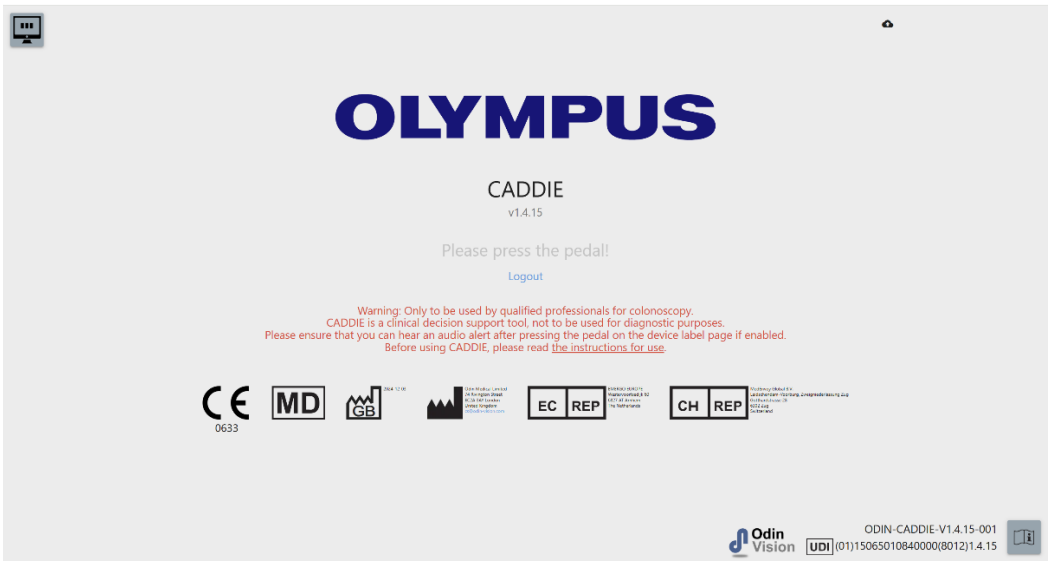


8 Use

1. The device can be accessed through a supported browser at the following web address (URL): https://caddie.odin-vision.com. The login page is illustrated below.

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 CADDIE is automatic.

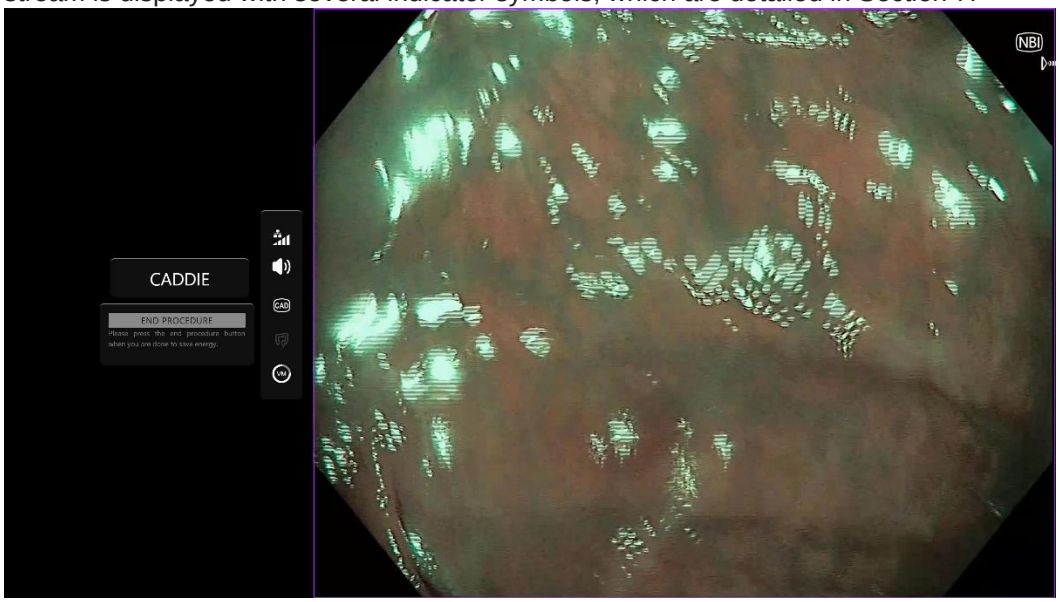
2. The username and password are to be entered. After a successful login, the label page will be displayed as illustrated below.



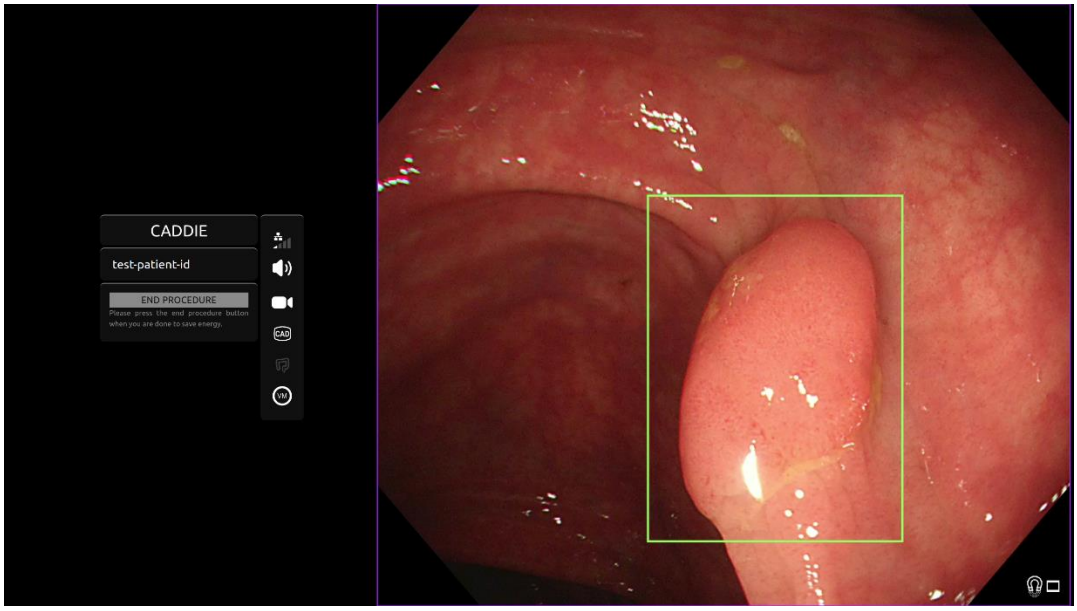
3. The product's unique device identifier (UDI), which identifies the specific version of the software for device traceability can be accessed by pressing the 'i' key on the keyboard and is displayed in the lower right-hand corner of the start-up screen next to the instructions for use (booklet) symbol.

4. The upload indicator is displayed in the upper right-hand corner of the start-up screen.

5. CADDIE 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 7.

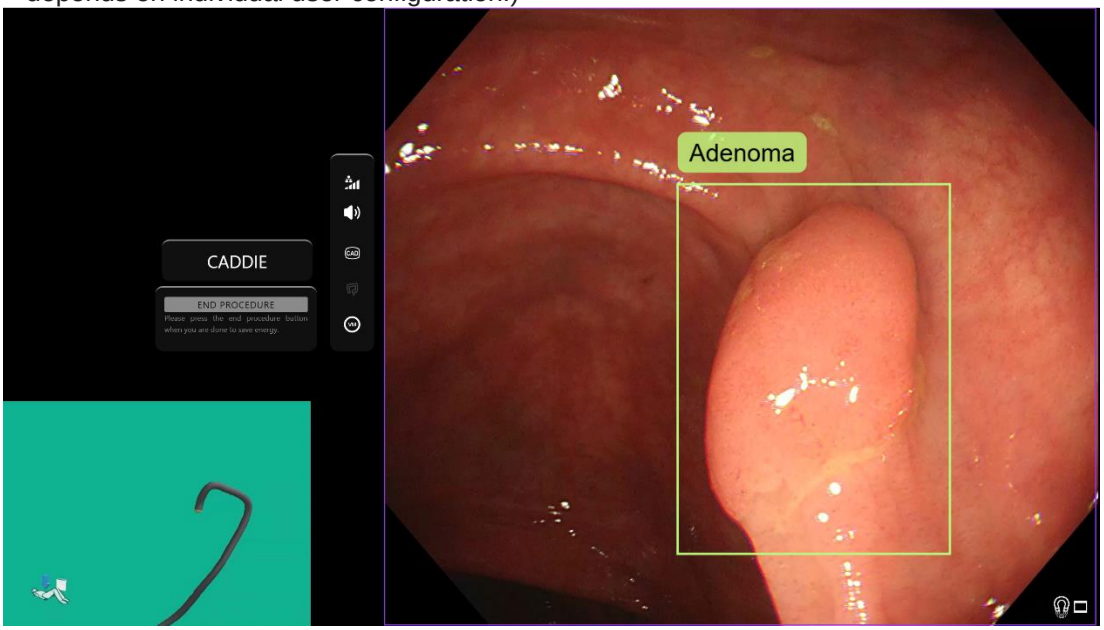


6. Polyp Detection: The device highlights areas with the visual characteristics of colonic polyps, if they are in the field of view of the endoscope. The highlighting is visualised through bounding boxes.



7. The detection can be enabled and disabled through a switch; for example, by a long press of the foot pedal. If disabled, the polyp detection bounding box will not be visualised anymore. The detection status notification symbol is a cross and the strike-through audible alert symbol is displayed, as seen below. An additional “DETECTION OFF” notification is displayed. While the pedal is pressed, a loading bar will be displayed around the detection icon as well as at the bottom of the notification indicating that detection is being enabled or disabled..

8. Polyp Tissue Characterization: The device can be used to analyse the visual characteristics of a still, virtual chromoendoscopy image and provide information to aid the user to characterize the tissue. This is done by first centring the area of interest on the endoscopy feed and allowing the endoscope to focus. Next, a switch can be triggered, i.e., short pedal press, and the results are displayed. 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 in the respective bounding box, i.e. “Adenoma”, “Non-Adenoma” or “Uncertain”. (Availability of characterization feature depends on individual user configuration.)

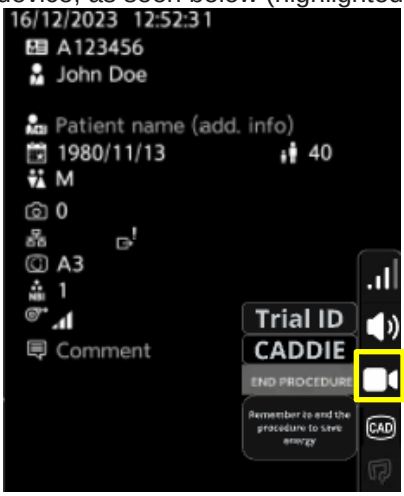


9. If the information displayed is “Uncertain” the camera should be repositioned to centre the tissue and focused before characterization is attempted again.

10. Additional supporting information is presented on the left-hand side of the image area as notification symbols. The notification symbols are detailed in Section 7.

11. The user has the option to configure the detection sound alert. It can be disabled or enabled with a preconfigured key (“M” by default) or by clicking on the sound icon. The volume can be adjusted by hovering over the sound icon and adjusting the slider that is displayed, see Section 7.3.

12. 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).



9 Interpretation of Results

9.1 Highlighting Areas with the Visual Characteristics of Colonic Polyps

The device is intended to highlight areas that show the visual characteristics of colonic polyps. The areas are not to be interpreted as definite polyps. The responsibility to make a decision as to whether or not a highlighted region contains a polyp lies with the user.

9.2 Characterization and Feature Analysis

The characterization and feature analysis 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 optical diagnosis or histopathology. (Availability of characterization feature depends on individual user configuration.)

9.3 Visible Mucosa Estimation

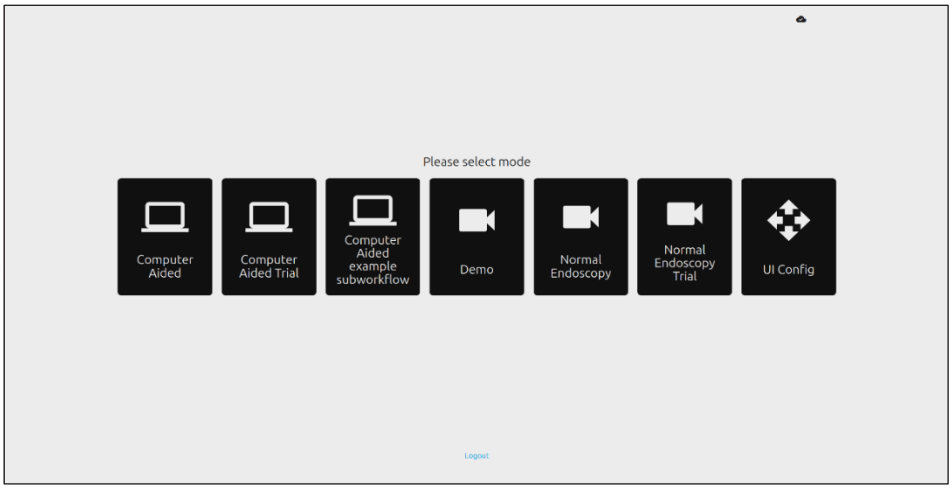
The visible mucosa estimation pie chart is a risk mitigation measure. It is an objective indicator of the visibility of the mucosal membrane. It can indicate to the user how effective the bowel preparation has been which will directly impact the ability of the CADDIE software to function as intended.

9.4 Caecum Detection

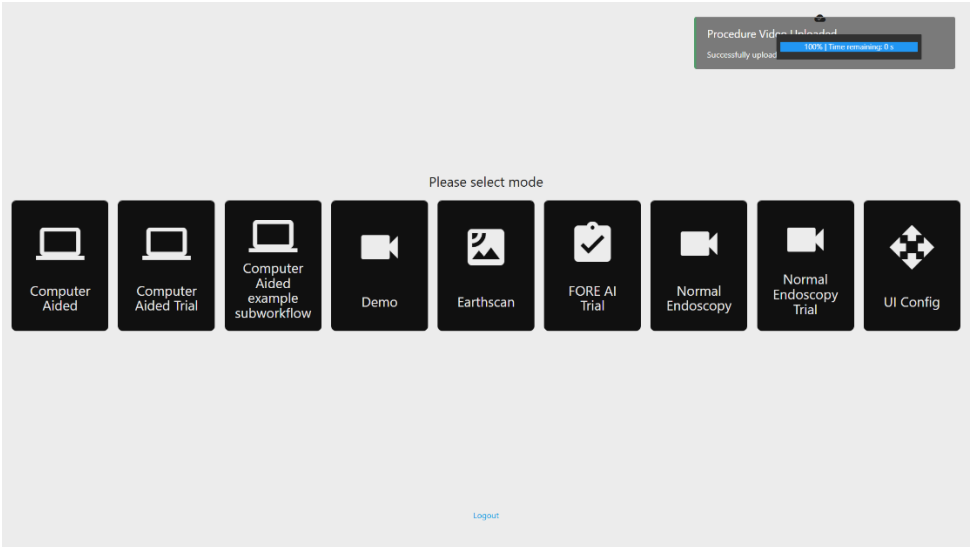
The caecum detection warning symbol is a risk mitigation measure. It prompts the user to verify that the CADDIE software detection mode is enabled before inspection begins.

10 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). 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.



2. Computer Aided Trial mode will redirect to the CADDIE greeter page shown above in section 8.2 Following the on-screen instructions begins the trial procedure with CADDIE. Additional trial features might be enabled.
3. In all modes for clinical trials it is displayed at all times in the top left corner what mode the user is currently in.
4. The upload indicator is available in the top right-hand corner



11 Minimum Specifications

11.1 Minimum Client System Specifications – Cloud Deployment

CPU	Intel i3 (8th gen) or equivalent
RAM	4 GB
Network connection	20 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 (providing native resolution and framerate of image processor) • Resolution: 720x1280 (HD) • Frame rate: 25 Hz
Monitor	Primary endoscopy monitor or equivalent secondary monitor (providing native resolution and framerate of image processor) • Resolution: 720x1280 (HD) • Frame rate: 25 Hz
Audio speakers	Suitable for the work environment
Operating System	Microsoft Windows 10 or higher

11.2 Minimum Host System Specifications – Local Deployment

CPU	Intel i7 (8th gen) or equivalent
RAM	16 GB
Browser	Chromium (v 83 or higher) - – for example, Google Chrome or Microsoft Edge
Frame capture card	Device to be compatible with the endoscopy system to be used with
Monitor	To match the resolution of the monitor of the endoscopy system
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

12 Compatibility with Other Devices

The software does not interface directly with devices, except for the client computer. The device interacts through the client computer with a compatible frame capture card to receive the endoscopic video feed. The device interacts with a monitor through the client computer to display information on the monitor. For minimum client system specifications, see section 11.

CADDIE is compatible with endoscopic video processors and scopes that are equipped with high definition (HD) or higher image quality resolutions.

CADDIE has not been tested on endoscopy systems with an image quality resolution less than HD. The performance of CADDIE may be negatively affected and vary if used on endoscopy systems with lower image quality resolutions.

CADDIE is compatible with white light imaging and virtual chromoendoscopy light modalities.

CADDIE has been tested using Olympus video processors with white light and Narrow Band Imaging (NBI). The performance of CADDIE using other manufacturers' video processors or virtual chromoendoscopy modalities may be negatively affected and vary.

13 IT Security Measures

1. Users should use a strong password for their CADDIE login and protect their login credentials in accordance with their organizations 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 CADDIE software in accordance with their organisations security policies.
3. When using computers to access the CADDIE 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 CADDIE software.
4. The manufacturer recommends that the client computer used to access the CADDIE 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 CADDIE, the manufacturer recommends that the server used to host the CADDIE software service is set up on a virtual LAN (VLAN) to isolate all network traffic from other hospital systems.

14 Performance Characteristics of the Device

Non-clinical (bench) performance testing included the validation of the algorithms of CADDIE on multiple datasets to evaluate sensitivity and specificity. In all datasets, CADDIE performed as expected and met predefined performance criteria. The ability of CADDIE for polyp detection, polyp tissue characterisation and polyp feature tissue classification were assessed. A summary of the results are presented below.

Polyp detection:

The ability of CADDIE to differentiate between normal mucosa and polyp tissue on retrospectively obtained video frames of standard full length HD white-light colonoscopic procedures of 268 patients were assessed and the results were compared to the historical control (known polyp status per frame).

A total of 630 polyps were excised and subsequently sent to histology from 219 cases. The total number of polyp frames of these videos were 582,891 frames. The dataset also comprises 49 full length white-light colonoscopies without polyps. The total number of frames of these videos were 1,110,552 frames. Breakdown of Test set based on histopathology, locations, morphology and various sizes (diminutive: ≤5mm, Small: ≤10mm large: >10mm) of polyp were reported. Mean False Positive Objects per patient (94.3), mean False Alarms per minute per patient (for >200ms was 7.6), mean Frame Sensitivity (68.3) and Per Polyp Sensitivity [100 % (628/628)] at different levels of detection persistence were reported (95% CI).

Mean Frame Sensitivity along with the 95% confidence interval and Per Polyp Sensitivity for different levels of Intersection over Union (IoU) area between predicted box and ground-truth box were reported. IoU thresholds were 0, 5%, 10%, 20%, 30%, 40%, 50%. For instance, for 50% of IoU thresholds, mean Frame Sensitivity and Per Polyp Sensitivity were 57.3 and 99.7% ((5% CI). Performances of CADDIE when analysing all the 1,693,443 frames in the test set, appearing within the range of > 0 seconds, calculated using two different statistical methods. Mean of True Positive Rate per Frame (95% CI) grouped by polyp histology, lesion size and video processors and mean False Positive Rate per Frame were calculated and reported. Overall mean of True Positive Rate per Frame and mean False Positive Rate per Frame were (95% CI) were 69 with polyps detection rate of 100% (630/630) from 219 videos and 5.3 from 49 videos, respectively. Mean adenoma was 72.6 with polyps detection of 100% (151/151) from 85 videos. Mean large size lesion (>10mm) was 77.7 with polyp detection rate of 100% (25/25) from 20 videos. Bootstrap analysis (1000 iterations) was carried out to find out the overall mean of True Positive Rate per Frame and mean False Positive Rate per Frame were (95% CI). Object TPR of CADDIE with a persistence of 500ms is 98.24% which satisfies the success criteria in the protocol.

Polyp tissue characterisation:

The ability of CADDIE to differentiate between different types of polyps (between adenomas and non-adenomas) on retrospectively recorded video frames of 231 patients underwent standard colonoscopy procedures were assessed and the results compared to the histology ground truth. CADDIE follows ESGE postpolypectomy surveillance guidelines (European Society of Gastrointestinal Endoscopy) and characterises polyps into two categories: adenoma and non-adenoma. CADDIE performances were assessed in bench testing executed on an independent data set comprising 331 video sequences of polyps from 231 procedures, during which a total of 482 polyps were excised and subsequently sent to histology. From these, after the histology analysis, 297 had been characterised as adenomas, 134 as hyperplastics and 49 as sessile serrated lesions (SSL). The total number of frames of these video sequences is 48,307 frames, containing all of them polyps.

Breakdown of Test set based on histopathology, locations, morphology, types of endoscope and various sizes (diminutive: ≤5mm, Small: ≤10mm large: >10mm) of polyp were reported.

Diminutives (0-5mm) and all polyps breakdowns, True Positive Rate per Frame and False Positive Rate per Frame grouped by polyp histology, lesion size, video processors, image type and image quality were reported. On testing CADDIE on a dataset consisting of 231 patients of which a total of 482 polyps were excised and subsequently sent to histology. The per frame True Positive Rate was found to be 89.02% [89.00, 89.03] and the per frame False Positive Rate 9.51% [9.49, 9.53]. Additionally, out of the 482 polyps, 309 from 175 patients were categorised as diminutive (size between 0 and 5 millimetres). The diminutive per frame TPR was found to be 87.45% [87.44, 87.47] and the per frame FPR 7.64% [7.61, 7.67]. The performance of CADDIE satisfies the criteria – the diminutive polyps per frame TPR must be greater than 80%.

15 Traceability

Table1 : Basic UDI / UDI-DI / Software Version

Basic UDI-DI	5065010840OD01P9
UDI-DI	(01)15065010840000
Software version number	1.4.15
Full UDI (DI+PI)	(01)15065010840000(11)(8012)1.4.15
Product code	R5001220
Catalogue number	CADDIE

16 Contact Information

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

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 of the member state in which the user and/or patient is established without delay.

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.

16 Glossary of Medical Device Symbols

Symbol	Symbol Title	Meaning of Symbol/Description	Standard (or Regulation) Title	Standard (or Regulation) Reference
	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
	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
	Country of manufacture	To identify the country of manufacture of products. In the application of this symbol, GB shall refer to Great Britain. 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
	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
	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
	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
	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
	CE Marking	CE Marking indicates that the product complies with Regulation (EU) 2017/745	Regulation (EU) 2017/745	EU 2017/745, Article 20

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Approved By:

COO - Luke Sampson	Tue Dec 3 15:38:39 GMT 2024
Approved	`fhH4CC2MgCDN8FCnUIPADSbZYcI`

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3	Tue Dec 3 2024	Approved	Rachael Ford
2	Thu Nov 28 2024	Superseded	Rachael Ford
1	Mon Jun 24 2024	Superseded	Dominic Salisbury
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