OLYMPUS®

INSTRUCTIONS FOR USE

CADU

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1 Product Description

CADU is artificial intelligence (AI)/machine learning (ML) based medical device software. CADU interfaces with the video feed generated by an endoscopic video processor during an endoscopy procedure. CADU is intended to be used by trained and qualified clinicians as an accompaniment to video endoscopy for the for the analysis of potential dysplasia and early neoplasia.

CADU analyses the data from the endoscopic video processor in real-time and provides information that aids the endoscopist in characterising the tissue in the field of view of the endoscope.

The areas highlighted by CADU are not to be interpreted as definite dysplasia. The responsibility to make a decision as to whether or not a highlighted region contains dysplasia lies with the user. The endoscopist is responsible for reviewing CADU information and confirming the presence or absence of dysplasia based on their own medical judgment.

2 Intended use

1.CADU is intended to be used by trained clinicians (users) as an accompaniment to video Endoscopy for the analysis of potential dysplasia.

2.CADU is trained to process endoscopy video frames that may contain regions visually consistent with dysplasia in Barrett’s oesophagus.

3.CADU 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

CADU is designed for use in patients undergoing an upper GI endoscopy, for the investigation of dysplasia in Barrett’s Oesophagus, whether for surveillance, screening or diagnostic purposes. CADU is not designed for use in pregnant women or in patients under the age of 18 years.

4 Intended User

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

5 Contraindications

1.CADU should not be used on patients contraindicated for endoscopy.

2.CADU should not be used to help detect potential dysplasia in the Stomach or duodenum.

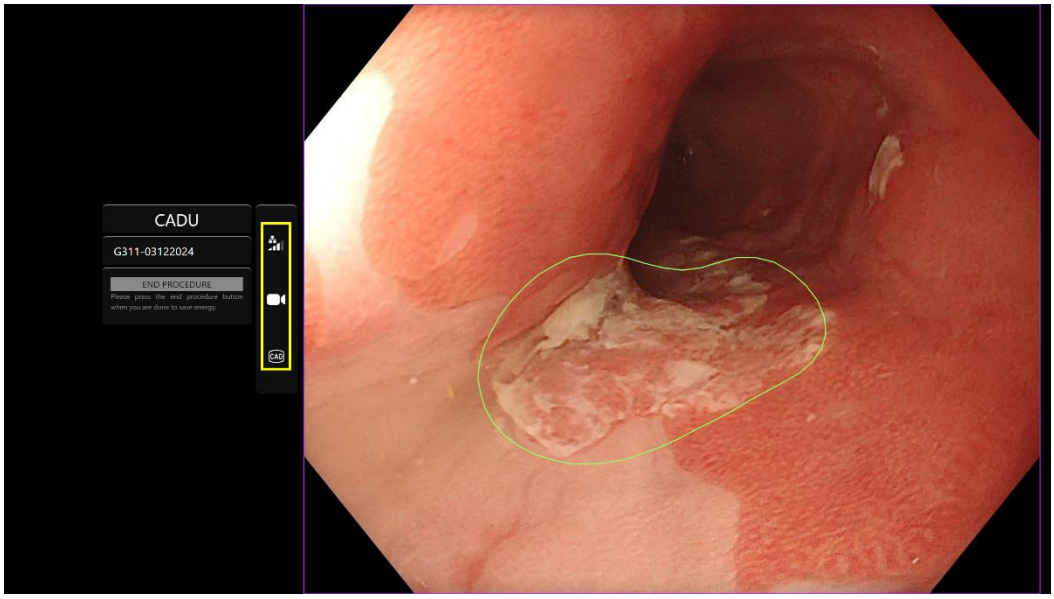
3.CADU should only be used in the Barrett’s segment of the Oesophagus

6 Warnings, limitations and precautions

1. Only to be used by qualified professionals for endoscopy and healthcare professionals trained in the use of CADU.
2. CADU is a clinical support tool, not to be used as a diagnostic tool or a replacement to histopathology.
3. Avoid overreliance on the device.
4. If the network indicator signals no network connection, normal clinical practice should resume.
5. Please ensure that the endoscopy image processor is connected through the frame capture card to the client PC.
6. Please verify that the endoscope image is displayed after pressing the pedal on the device label page.
7. 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.
8. Inadequate cleaning preparation can directly impact the ability of the CADU system to function as intended.
9. The use of CADU on patients with severe esophagitis may result in unknown performance of CADU

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

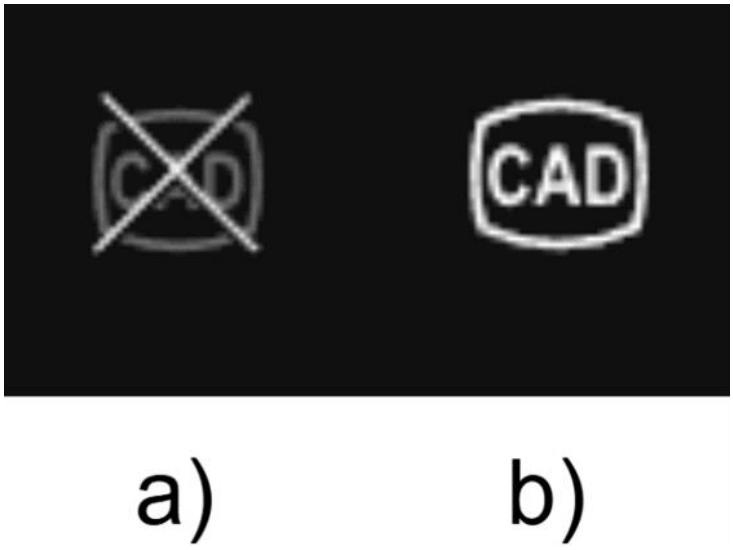
The network quality is represented by a network connection symbol, the number of white bars represent the quality of the network; the lower the network the connection the higher the latency and delay in the information provided. A strike-through red symbol represents no network connection available. If the network indicator signals no network connection, normal clinical practice should resume, as CADU will not be able to function as intended.

a) b) c) d) e)

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 in the yellow box. 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.



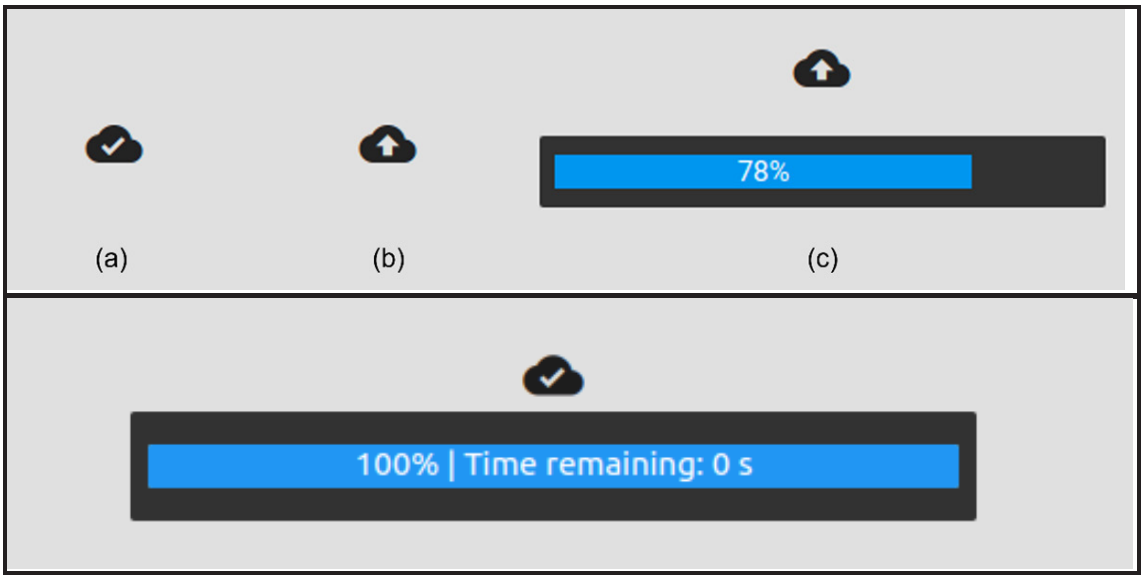
Detection status (a) off or (b) on.

7.3. 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).

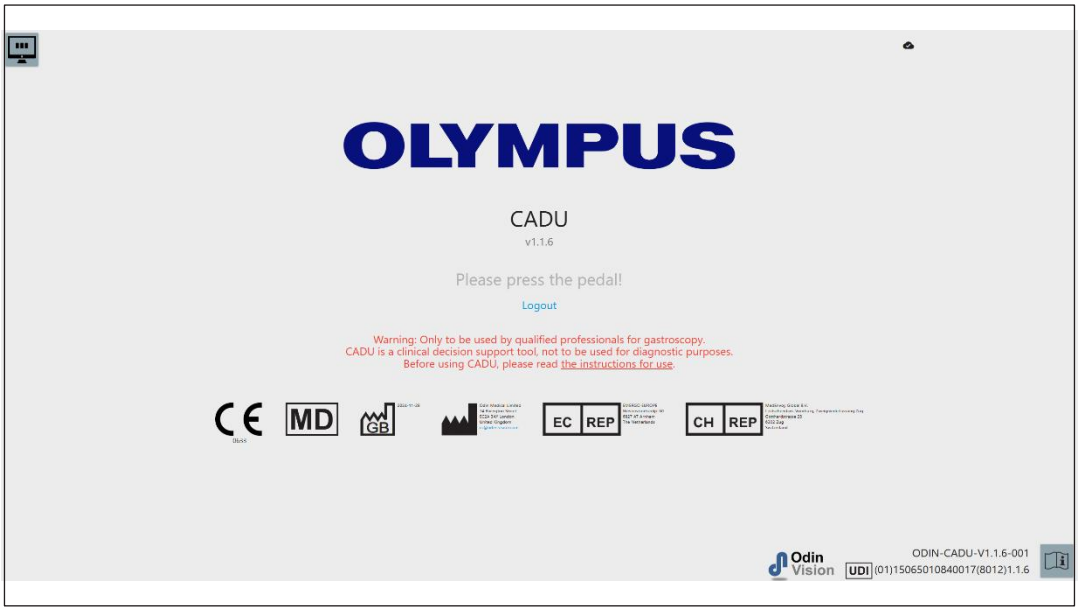


8 Use

The device can be accessed through a supported browser at the following web address (URL): https://.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 CADU is automatic.

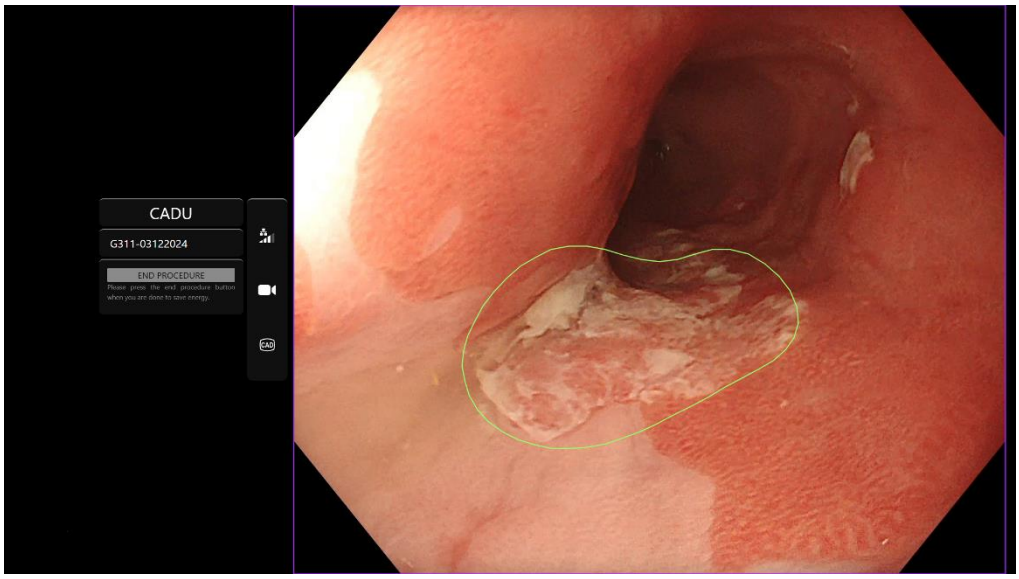
1. The username and password are to be entered. After a successful login, the label page will be displayed as illustrated below.



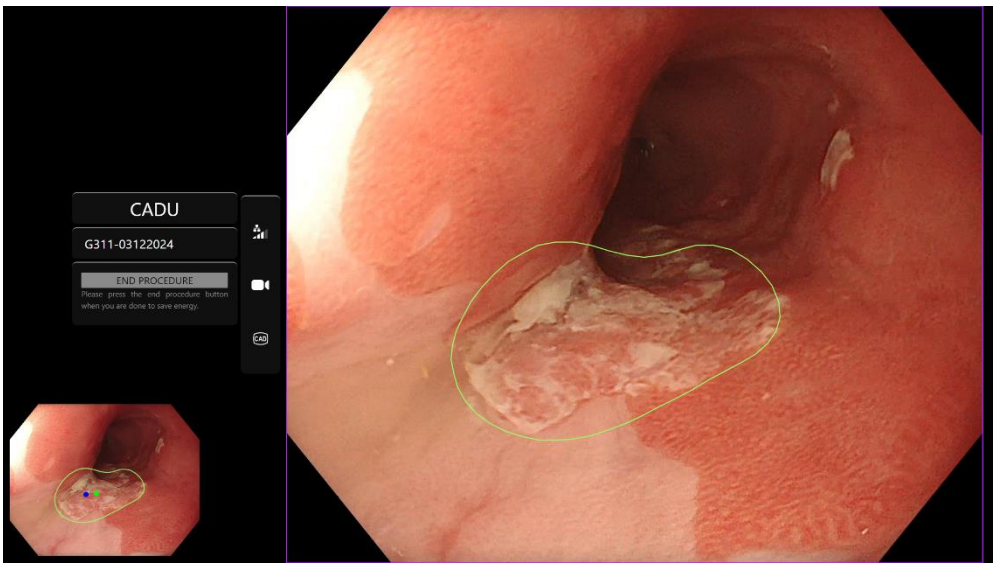
2. The product's unique device identifier (UDI), which identifies the specific version of the software for device traceability can be accessed by pressing the 'i' key on the keyboard and is displayed in the lower right-hand corner of the start-up screen next to the instructions for use (booklet) symbol.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

4. On this screen information is presented to you, the warnings are in the centre of the screen as are the following: "Only to be used by qualified professionals for gastroscopy. CADU is a clinical decision support tool, not to be used as a diagnostic purposes".

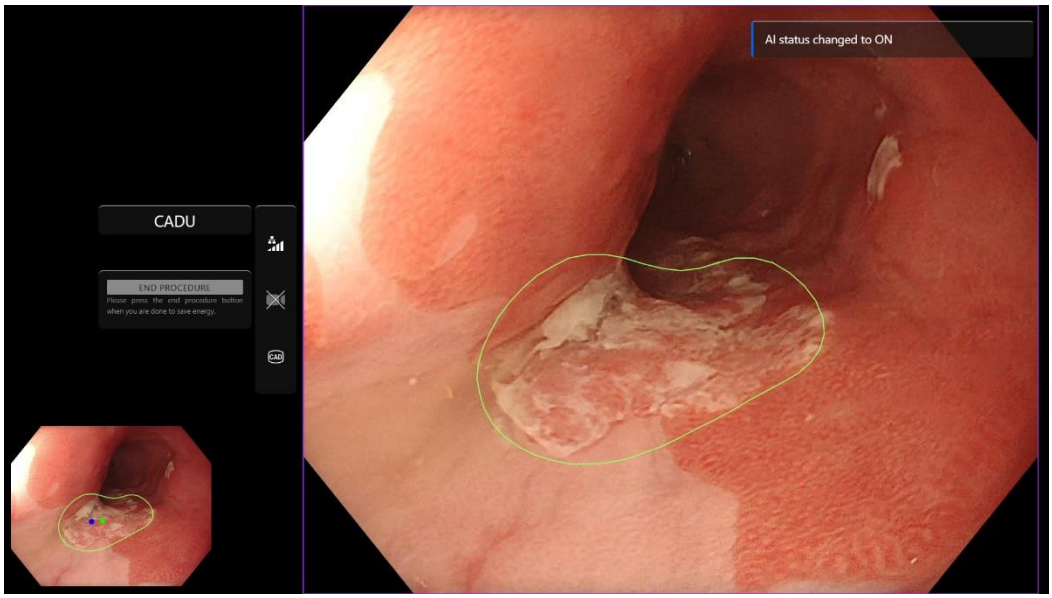
5. Also displayed on this screen is the manufacturer contact details.
6. In the bottom right-hand corner, there is an icon representing the electronic instructions for use (eIFU), if you click on this icon it will bring you to a PDF version of the instructions for use.
7. In the top right-hand corner, there is an icon representing the upload indicator, if a user wishes to see the progress they can hover the mouse and see a percentage.
8. The product's unique device identifier (UDI), which identifies the specific version of the software for device traceability is displayed in the lower right-hand corner of the start-up screen next to the instructions for use (booklet) symbol.
9. The upload indicator is displayed in the upper right-hand corner of the start-up screen.
10. CADU is started by pressing the foot pedal attached to the client PC. The endoscope image stream is displayed with the network quality indicator symbol, which is detailed in Section 7. An example is shown below.
11. **Note:** You should see the CADU interface should be displayed at this point (see image below). Please ensure that the endoscope is connected through the frame capture card to the client computer and that the endoscope video feed is displayed with the purple image area defined correctly. This has been calibrated for your specific system, if the stack or monitor are changed then this might need recalibration, please contact us if this is the case.



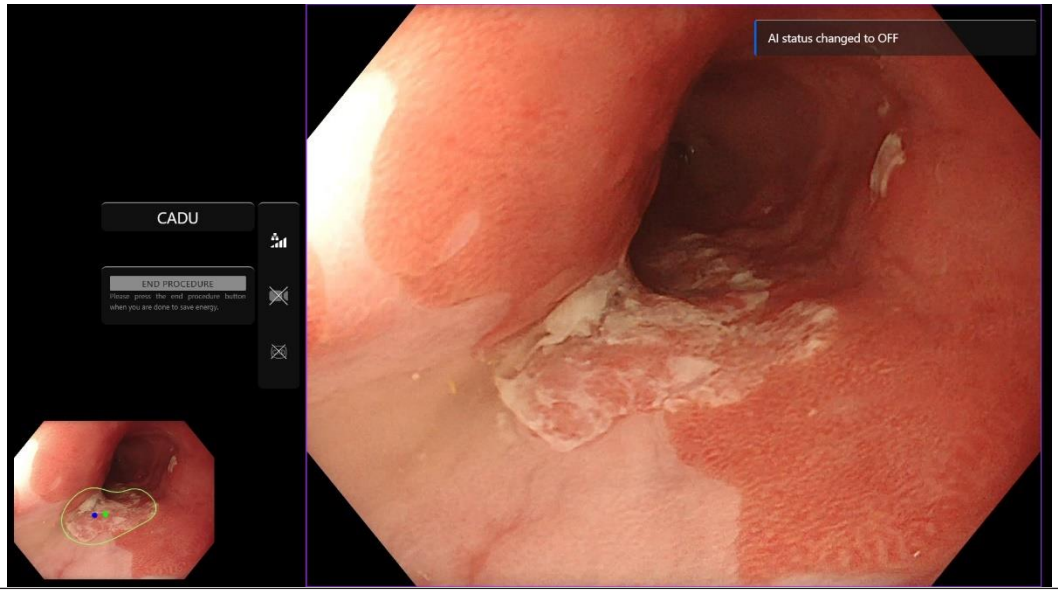
12. CADU can be used to provide information regarding the visual characteristics of tissue in the field of view. When detection is on CADU will present a region of interest (shown as a green boundary) when it detects regions of interest with visual characteristics consistent with Dysplasia.
13. Once the region of interest is stable, the user can take a freeze frame, this will take a snap-shot of the image and display the freeze frame to the side of the main endoscopy feed. Points of interest in the form of blue and green dots will be displayed. The Green dot rep-resents the geometric centre of the boundary displayed and the blue dot the point of highest likelihood of abnormal tissue.
14. The additional image to the side of the main feed will remain until another freeze frame is taken. CADU is intended to highlight areas with the visual characteristics consistent with different types of tissue abnormalities, such as dysplasia. These areas are not to be interpreted as definite dysplasia. The end decision lies with the user.



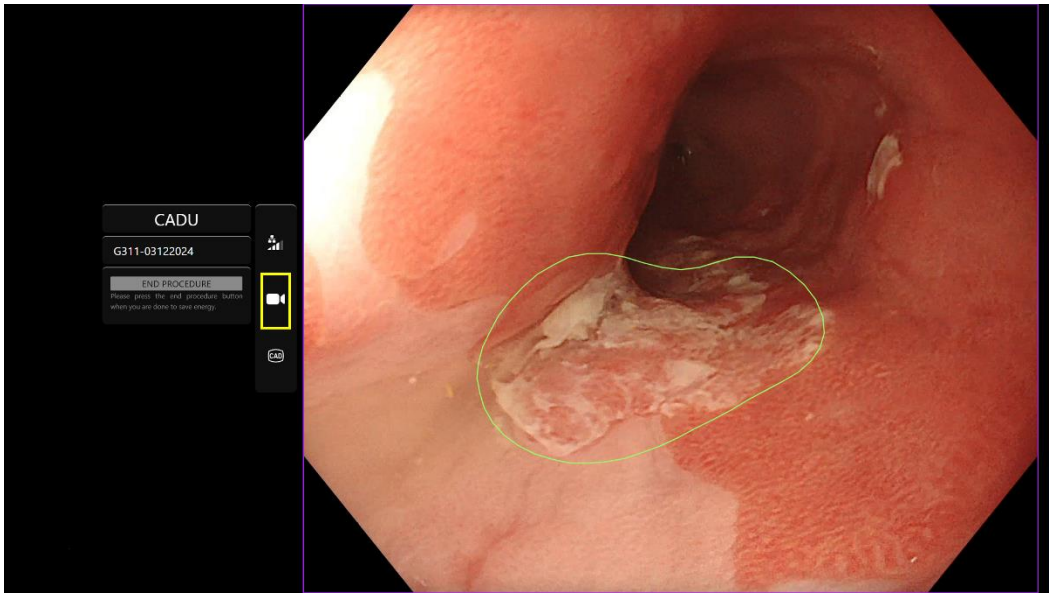
15. Turning Detection ON: When CADU is started, detection will automatically be off. The detection is turned on using a switch, in this case a long press of the pedal. You must press the pedal for over 3 seconds. TRIGGER SWITCH/PERFORM LONG PRESS OF PEDAL. The detection symbol will change from a strikethrough version to the active AI-enabled detection symbol when AI detection is activated.
16. Turning Detection OFF: The detection is turned off using the switch, with a long press of the pedal. You must press the pedal for over 3 seconds. TRIGGER SWITCH/PERFORM LONG PRESS OF PEDAL. "The detection symbol will change from the active AI-enabled detection symbol to the strikethrough version when AI detection is deactivated.



"In the screenshots below, the region of interest (shown as a green boundary) is visible whilst CADU detection is enabled, and a region of interest is detected. The screenshot below shows the message confirming that detection is on ‘Detection ON’ and when detection is off ‘Detection OFF’.



17. 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).



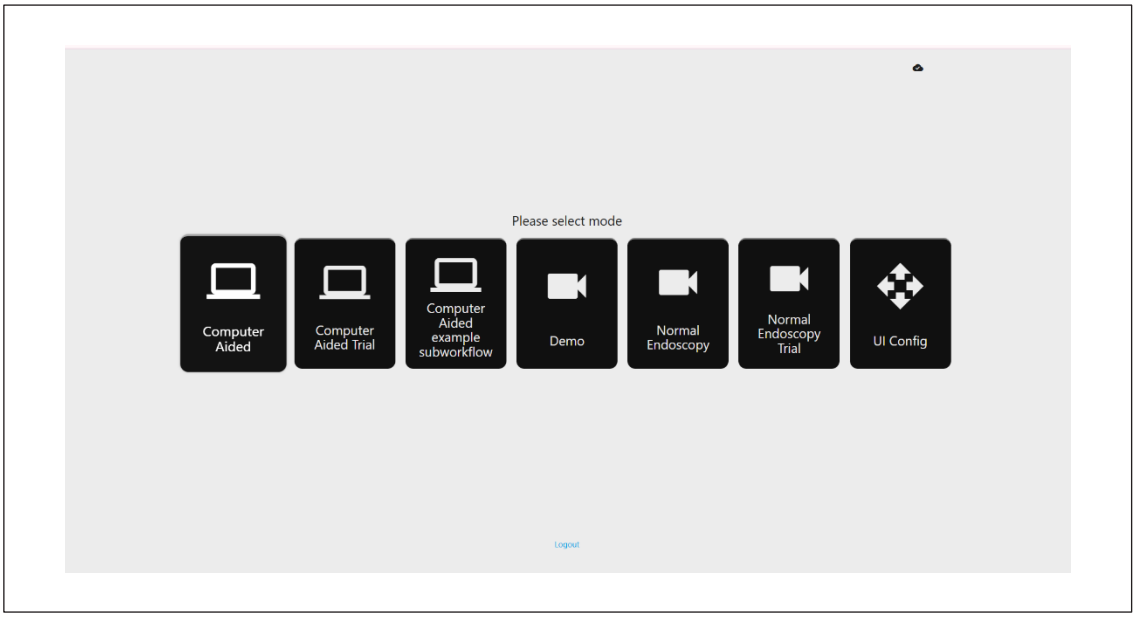
9 Interpretation of Results

9.1 Highlight areas and points with the Visual Characteristics of Dysplasia

The device is intended to highlight areas with visual characteristics consistent with different types of tissue abnormalities, such as dysplasia. Points of interest can be visualized that are relative to the areas. The areas and points are not to be interpreted as definite abnormalities. The responsibility to decide as to whether a highlighted region is abnormal or not lies with the user. The points of interest are represented by a blue and a green dot. The green dot represents the geometric centre of the boundary displayed and the blue dot the point of highest likelihood of abnormal tissue. This information is not intended to guide clinical action.

10 Clinical Trial Modes

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.



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

11 Minimum System Specification

11.1. Minimum Client System Specifications

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

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

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

13 IT Security Measures

1. Users should use a strong password for their CADU 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 CADU software in accordance with their organisations security policies.
3. When using computers to access the CADU 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 CADU software.
4. The manufacturer recommends that the client computer used to access the CADU 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 CADU, the manufacturer recommends that the server used to host the CADU 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

1. Non-clinical (bench) performance testing included the validation of the algorithms of CADU on multiple datasets to evaluate sensitivity and specificity. A summary of the results are presented below.
2. On testing CADU the patient-level sensitivity was 98.68% and the false alarm rate was 4.22 alarms per minute. On the image subset of this data, the frame-level sensitivity was 86.78%, the frame-level specificity was 77.55% and the intersection over union was 41.13%. These results were reported considering a frame a true positive if the IOU > 0, and if the persistence > 0 seconds.
3. The patient-level sensitivity was 98.68% which shows that the CADU reaches adequate performance for dysplasia segmentation.
4. The results also show that adequate patient-level sensitivity is achieved with different endoscopes, video processors, lesion types, and countries. The performance was evaluated at different persistence rates, showing that adequate patient-level sensitivity is achieved with a consecutive persistence of up to 500 milliseconds, meaning that lesions are detected for longer than just “short bursts”. Regarding the false positive rate, the results show a false alarm rate of 4.22 per minute, with a frame specificity of 98.48%. Importantly, this rate drops to 2.00 false alarms per minute when only considering predictions that are 100 milliseconds long, or longer.

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

Table 1: Basic UDI / UDI-DI / Software Version

Basic UDI-DI	5065010840OD02PB
UDI-DI	(01)15065010840017
Software version number	1.1.6
Full UDI (DI+PI)	(01)15065010840017(11)(8012)1.1.6
Product code	R5001248
Catalogue number	CADU

16 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 of the member 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.

17. 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 0633	CE Marking	CE Marking indicates that the product complies with Regulation (EU) 2017/745	Regulation (EU) 2017/745	EU 2017/745, Article 20
EC REP	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
CH REP	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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Approved By:

COO - Luke Sampson	Tue Dec 3 13:06:01 GMT 2024
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5	Fri May 21 2021	Superseded	Daniel Toth
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