OLYMPUS

OLYSENSE CAD/AI

CADDIE™ Medical Device Software

Unlocking the Power of Intelligent Endoscopy

The Need for Early Colorectal Cancer Diagnosis

Across the globe, there are over 5,000 new patients diagnosed with colorectal cancer every day, with more than 2,500 patients' lives lost. The need for early detection has never been more critical.[1]

Challenges in Colonoscopy

Polyp Detection and Characterization

Up to 26% of adenomas are missed during colonoscopies.[2] Notably, each 1% increase in adenoma detection rate correlates to a 3% reduction in the risk of cancer incidence.[3]

Workflow Efficiency

Staffing shortages are impacting service delivery, with growing demand projected to lengthen wait times for histopathology results.[4]

Colonoscopy Quality

89% of post-colonoscopy colorectal cancers have avoidable factors, including poor bowel preparation and shortcomings in cecal intubation.[5]

5k+

new patients diagnosed each day with colorectal cancer[1]

2.5k+

patients' lives lost each day[1]

Olympus Has Been Partnering With Hospitals for Nearly 75 Years

Olympus Recognizes the Growing Demands Placed on Today's Endoscopy Services

Olympus solutions are specifically designed to empower GI endoscopy departments to deliver the highest standard of patient care, while supporting their operational, clinical, and financial goals.

With a deep understanding of healthcare system pressures, Olympus continues to evolve its solutions to meet the changing needs of hospitals and clinicians.

A Proven Partner in Endoscopy Innovation

Guided by its purpose—to make people's lives healthier, safer, and more fulfilling—since introducing the first widely adopted gastrocamera in 1950, Olympus has been a trusted partner, providing solutions that support clinicians in elevating the field of endoscopy.

1950
World's first practical gastrocamera

2020
Launch of EVIS X1™ system

Proven expertise. Enhancing your excellence in care.

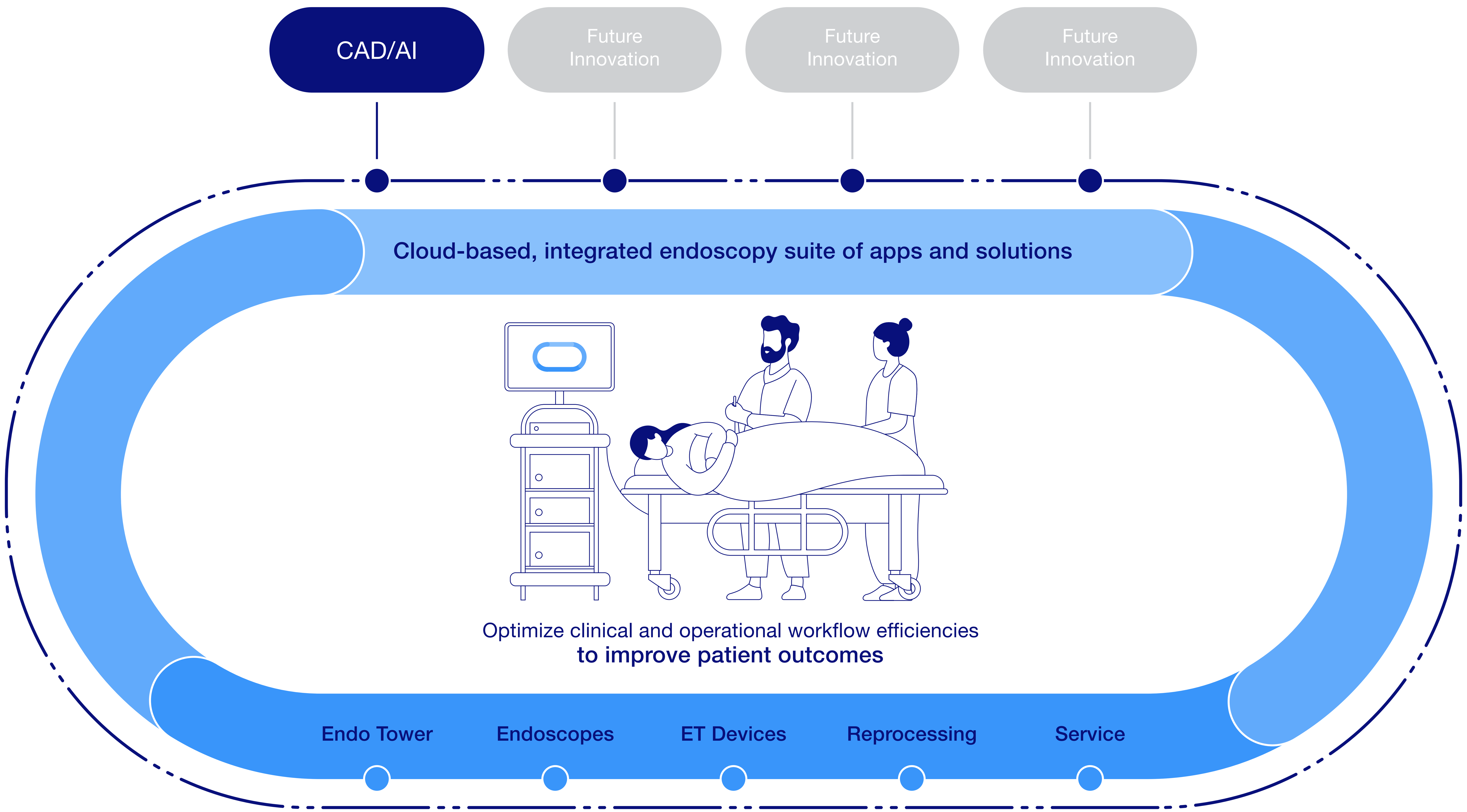
~50M
colonoscopies performed world-wide each year using Olympus devices.[6]

Unlocking the Power of Intelligent Endoscopy

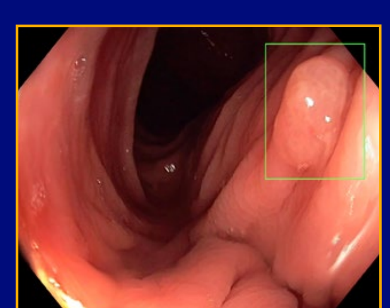
Connecting AI-driven Endoscopy Solutions with Established Olympus Equipment

Designed to address GI endoscopy unmet needs by supporting early diagnosis of colorectal cancer, Olympus introduces the OLYSENSE™ Platform, a cloud-based, integrated and scalable digital endoscopy suite of seamlessly connected apps and solutions, that create a sophisticated, simple and scalable intelligent endoscopy ecosystem.

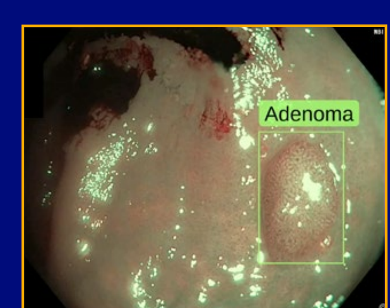
A key component of the OLYSENSE Platform is its CAD/AI portfolio, which includes the CADDIE™ medical device software.



With the CADDIE™ medical device software, Olympus aims to leverage cloud-based AI to aid detection of high-risk and hard-to-detect lesions.[7]



Polyp Detection



Polyp Characterization

Bowel Cleanliness

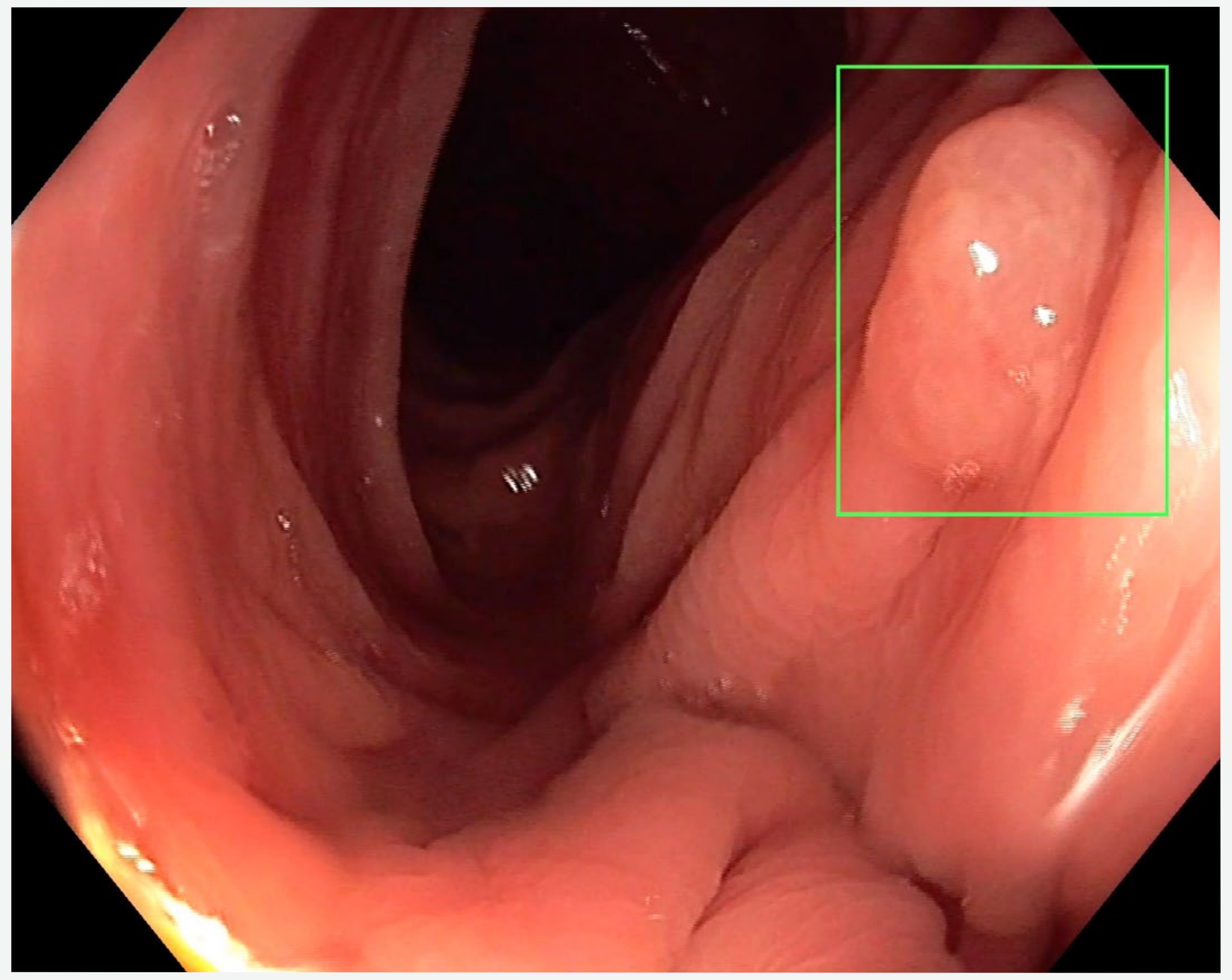
High-Risk and Hard-to-Detect Lesions

What Is CADDIE Software?

The CADDIE software is a cloud-based AI-driven solution that assists endoscopists in detecting and characterizing suspected colorectal polyps and potential early signs of colorectal cancer.[8]

It is powered by the OLYSENSE™ Hub, connected to Olympus imaging equipment on the endoscopy tower. The OLYSENSE Hub enables secure data sharing through a hybrid architecture that combines cloud based and on-premise information systems.

Sophisticated Leveraging Artificial Intelligence to Improve Lower GI Endoscopy

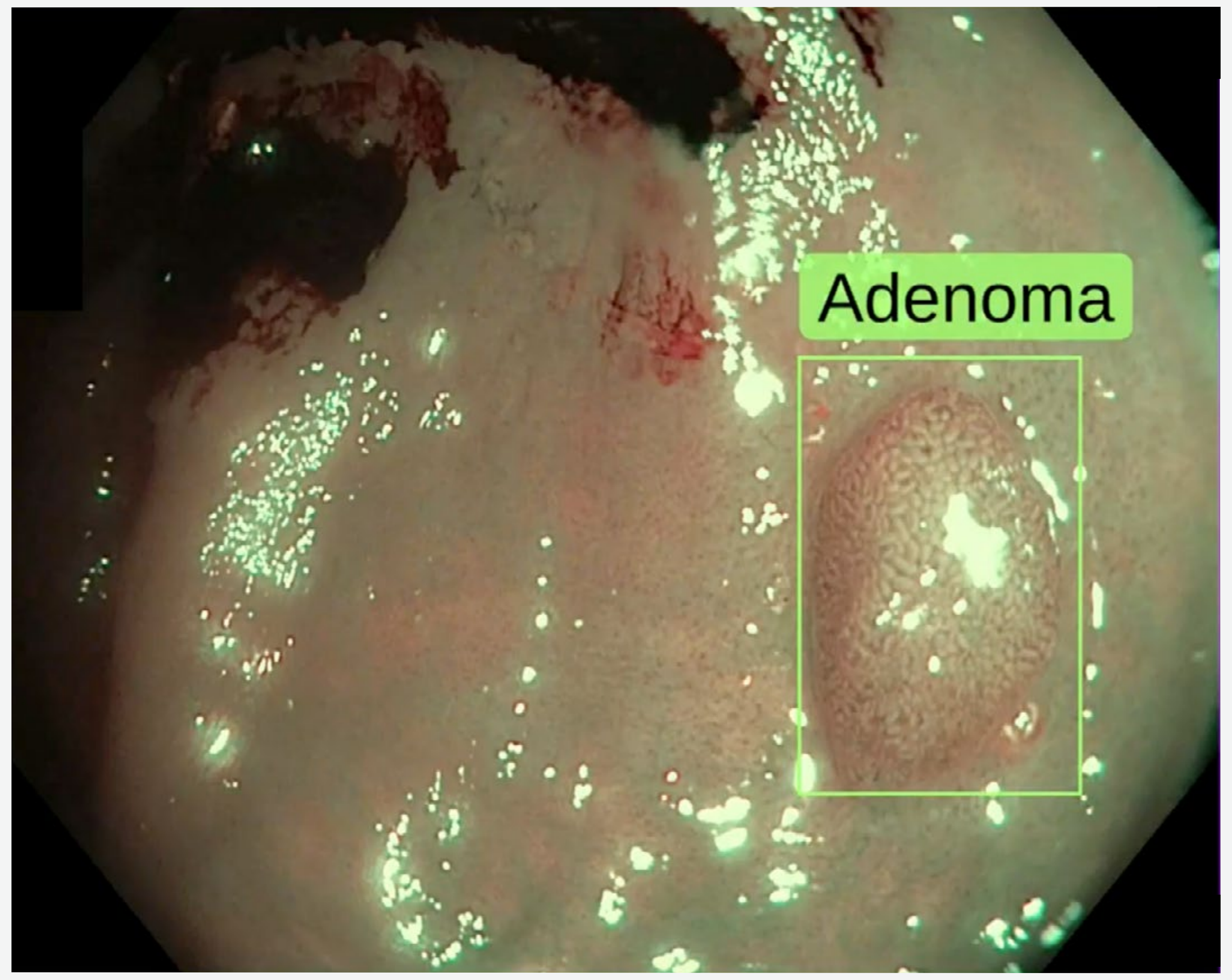


AI for Polyp Detection

The CADDIE™ software analyzes data from the endoscopic processor in real time, acting as a second pair of expert eyes. It highlights suspected colorectal polyps using green bounding boxes and provides visual cues to support the endoscopist in detection.[9]

Focused on enhancing colonoscopy accuracy, the CADDIE software's AI Polyp Detection Algorithm was developed using a robust dataset of 162,207 image frames capturing 1,711 polyps from 906 patients. This foundation enables reliable, real-time performance.[10]

With the CADDIE software, endoscopists detect at least one adenoma in 7.4% more colonoscopies (absolute increase in adenoma detection rate, ADR).[11]



AI for Polyp Characterization

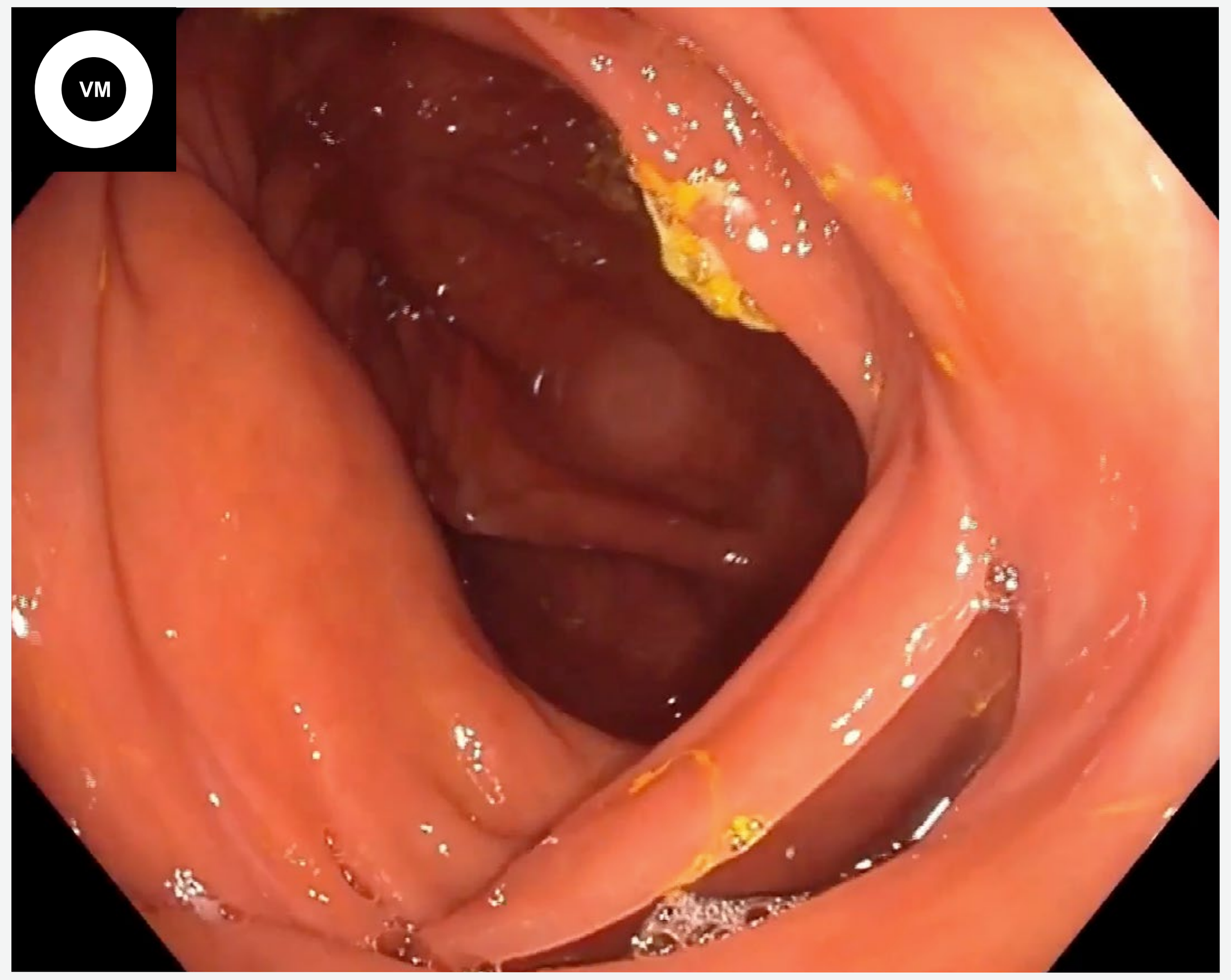
The CADDIE software displays information relating to the visual characteristics of colonic polyps, enabling the endoscopist to characterize the highlighted tissue as adenoma or non-adenoma.[9]

Endoscopists can use optical diagnosis to decide the histology of a polyp and follow clinical guidelines for resection and histopathology.[12]

Optical diagnosis means patients can benefit from same-day results, reducing unnecessary waiting time.

Leveraging Artificial Intelligence to Improve Lower GI Endoscopy

Continued

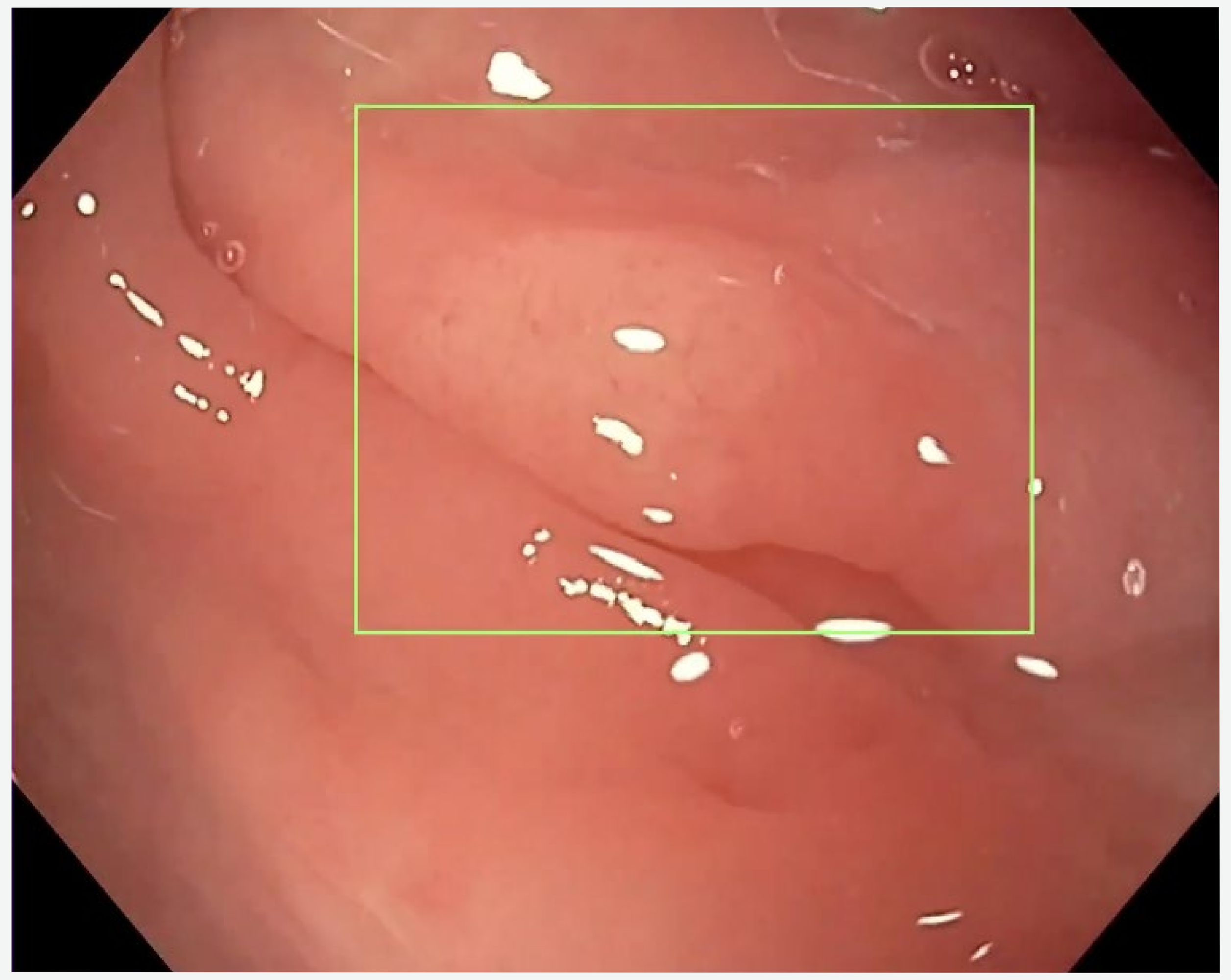


AI for Bowel Cleanliness

Incomplete bowel preparation can result in hidden colorectal mucosa and hinder polyp detection.

The CADDIE™ software provides an additional aid for the endoscopist—an easy-to-view and intuitive on-screen live display, showing the percentage of visible mucosa in the endoscope's field of view.[13]

The CADDIE software's artificial intelligence can identify images containing the appendiceal orfice (AO) and remind users to switch on polyp detection for the withdrawal phase.[14]



High-Risk and Hard-to-Detect Lesions

Combining human expertise with data driven insights, the CADDIE software aids detection of high-risk lesions—such as sessile serrated lesions (SSLs), large polyps and adenomas—as well as hard-to-detect SSLs and non-polypoid lesions. This capability has generated the following results (per colonoscopy)[7]:

- 136% relative increase in the detection of large polyps (>10mm).[7]
- 93% relative increase in the detection of large adenomas (>10mm).[7]
- 57% relative increase in the detection of flat adenomas.[7]
- 230% relative increase in the detection of sessile serrated lesions (SSL).[7]

Simple and Scalable

The CADDIE™ Software Has a Simple, User-Friendly Interface That Integrates Into the Clinical Workflow

Easy to Use

Visual information and audio alerts direct the user's attention to regions of interest.[12]

Due to the intuitive nature of the CADDIE™ software, minimal training is required.

The software enables hands-free interaction during the procedure. The foot pedal controls detection and characterization.[15]

Simple Setup

The CADDIE software is viewed on the main endoscopy monitor, without the need for additional monitors in the endoscopy room.[9]

The system can integrate with existing clinical workflows and endoscopy equipment such as Olympus EVIS X1 CV-1500, EVIS EXERA III CV-190 and EVIS LUCERA ELITE CV-290.[16]

The cloud-based device requires a network connection. The CADDIE software does not interact with hospital IT systems and only requires a standard internet port to be opened.[17]

Cloud-Based Software

The secure cloud-based software uses the OLYSENSE™ Hub connected to the endoscopy tower to stream the video from the hospital to the cloud. The system analyzes the images in the cloud in real time and sends the results back to the endoscopy monitor for the endoscopist to view.[13]

Automatic Updates

The CADDIE software enables instant and remote-based updates, ensuring the latest AI without requiring a service professional on-site to install software updates.

With the OLYSENSE™ Platform and its suite of CAD/AI applications—including CADDIE, CADU™, and SMARTIBD™ softwares—Olympus is unlocking the power of intelligent endoscopy, aiming to support endoscopists improve outcomes and significantly impact the fight against cancer.

References

- The CADDIE™ software's AI polyp detection algorithm was developed using 162,207 image frames of 1,711 polyps from 906 patients.[18]
- In total 318,603 frames were used in the development datasets (162,207 polyp frames and 156,396 non-polyp frames). Some 1,296 polyps from 714 patients had histology and additional metadata that may include size, location and morphology.[18]
- 98.3% sensitivity rate based on object-level true positive rate.[10]
- The frame-level false positive rate — the proportion of frames (%) in which the CADDIE™ software detects a box (> 0.5 seconds) that is not a histopathologically confirmed polyp is 1.54%.[10]
- 7.3% absolute increase in adenoma detection rate (ADR) when using CADDIE (43.2%) compared to standard of care (35.9%).[7]

1] Bray Freddie, Laversanne Mathieu, Sung Hyuna, Ferlay Jacques, Siegel Rebecca L., et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries CA: A Cancer Journal for Clinicians, 2024 (3), 229-263 DOI: 10.3322/caac.21834.

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3] D. A. Corley et al., "Adenoma Detection Rate and Risk of Colorectal Cancer and Death ABSTRACT," n engl j med, vol. 14, no. 3, pp. 1298–306, 2014, doi: 10.1056/ NEJMoa1309086.

4] Meeting pathology demand: histopathology workforce census. Royal College of Pathologists (2018).

5] Anderson R, Burr NE, Valori R. Causes of Post-Colonoscopy Colorectal Cancers Based on World Endoscopy Organization System of Analysis. Gastroenterology. 2020;158(5):1287-1299.e2. doi:10.1053/j.gastro.2019.12.031.

6] Numbers of US, Germany, France, UK, Italy, Spain, Japan, Canada, Poland, South Korea, Australia, India, Russia (as of 2022); China (as of 2019 including annual averages from 2019 to 2022 forecasts).

7] Data not peer-reviewed/published at time of document creation, Data on file with Odin Medical Ltd, EAGLE Trial — NCT05730192.

8] Data on file with Odin Medical Ltd., UsNe-001, UsNe-002 and PrRq-062.

9] Data on file with Odin Medical Ltd., PrRq-002.

10] Data on file with Odin Medical Ltd., OD-007329-TR - ODIN-CADDIE-AIDR AI/ML Development Report

11] Data on file with Odin Medical Ltd., CADDIE AI Trial - NCT04325815.

12] Data on file with Odin Medical Ltd., PrRq-001.

13] Data on file with Odin Medical Ltd., UsNe-027, PrRq-033 and PrRq-037.

14] Data on file with Odin Medical Ltd., UsNe-028, PrRq-034 and PrRq-038.

15] Data on file with Odin Medical Ltd., UsNe-009.

16] Data on file with Odin Medical Ltd., OD-003126-WI-6-ODIN-WI-012 — installation Instructions.docx.pd.

17] Data on file with Odin Medical Ltd., UsNe-040 and PrRq-062.

18] Data on file with Odin Medical Ltd., OD-005433-TC — 16.14 — ODIN-CADDIE-FDA — Algorithm description.

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OD-009625-MC