

**CADDIE™ Medical Device Software**

# Unlocking the Power of Intelligent Endoscopy



*\*Images captured using CF-H190i scopes.*

# The Need for Early Colorectal Cancer Diagnosis

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

## Challenges in Colonoscopy

### Polyp Detection

Up to 25% of adenomas are missed during colonoscopies.<sup>2</sup>

Notably, each 1% increase in adenoma detection rate correlates to a 3% decrease in the risk of cancer incidence.<sup>3</sup>



5k+

new patients diagnosed each day with colorectal cancer<sup>1</sup>

2.5k+

patients' lives lost each day<sup>1</sup>

# Olympus Has Been Partnering With Hospitals for Over 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 Longstanding 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



**2023**

Launch of EVIS X1™ system



Proven expertise.  
Enhancing your  
excellence in care.

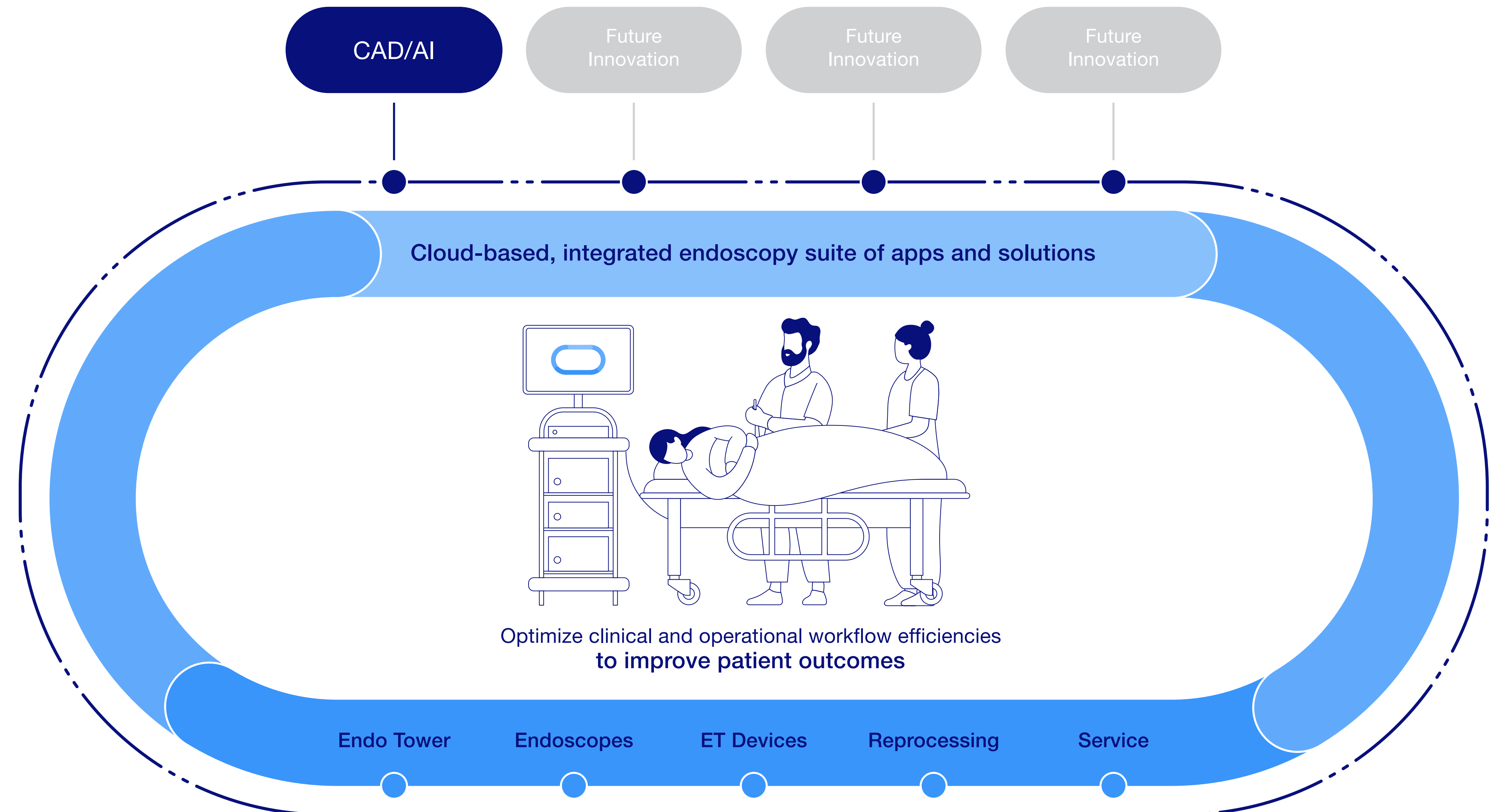
**~50M**  
colonoscopies  
performed world-  
wide each year using  
Olympus® devices.<sup>4</sup>

# Unlocking the Power of Intelligent Endoscopy

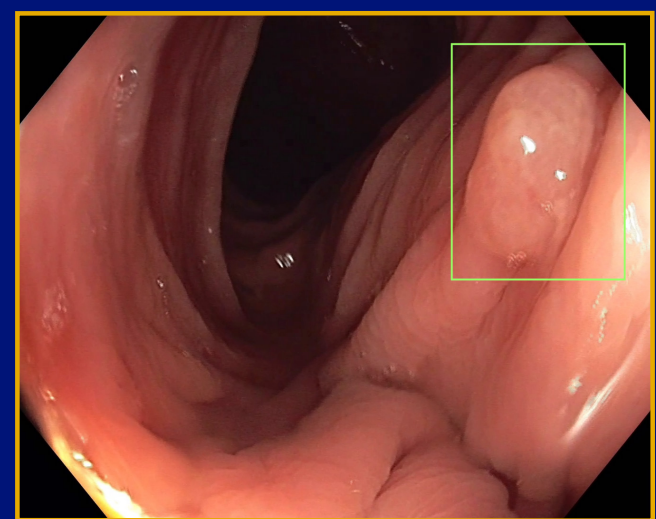
## Connecting AI-driven Endoscopy Solutions with Established Olympus® Equipment

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.

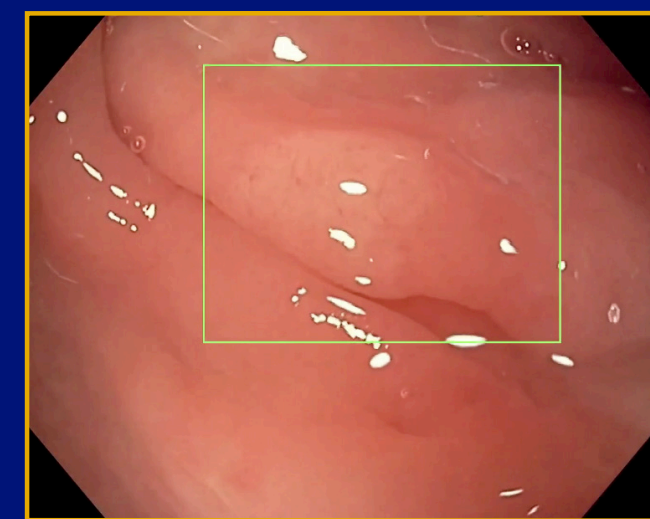


With the CADDIE™ medical device software, Olympus aims to leverage cloud-based AI to aid detection of high-risk and hard-to-detect lesions.<sup>5</sup>



*Image captured using CF-H190L scope.*

Polyp Detection



*Image captured using CF-H190I scope.*

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 suspected colorectal polyps only.<sup>6</sup>

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

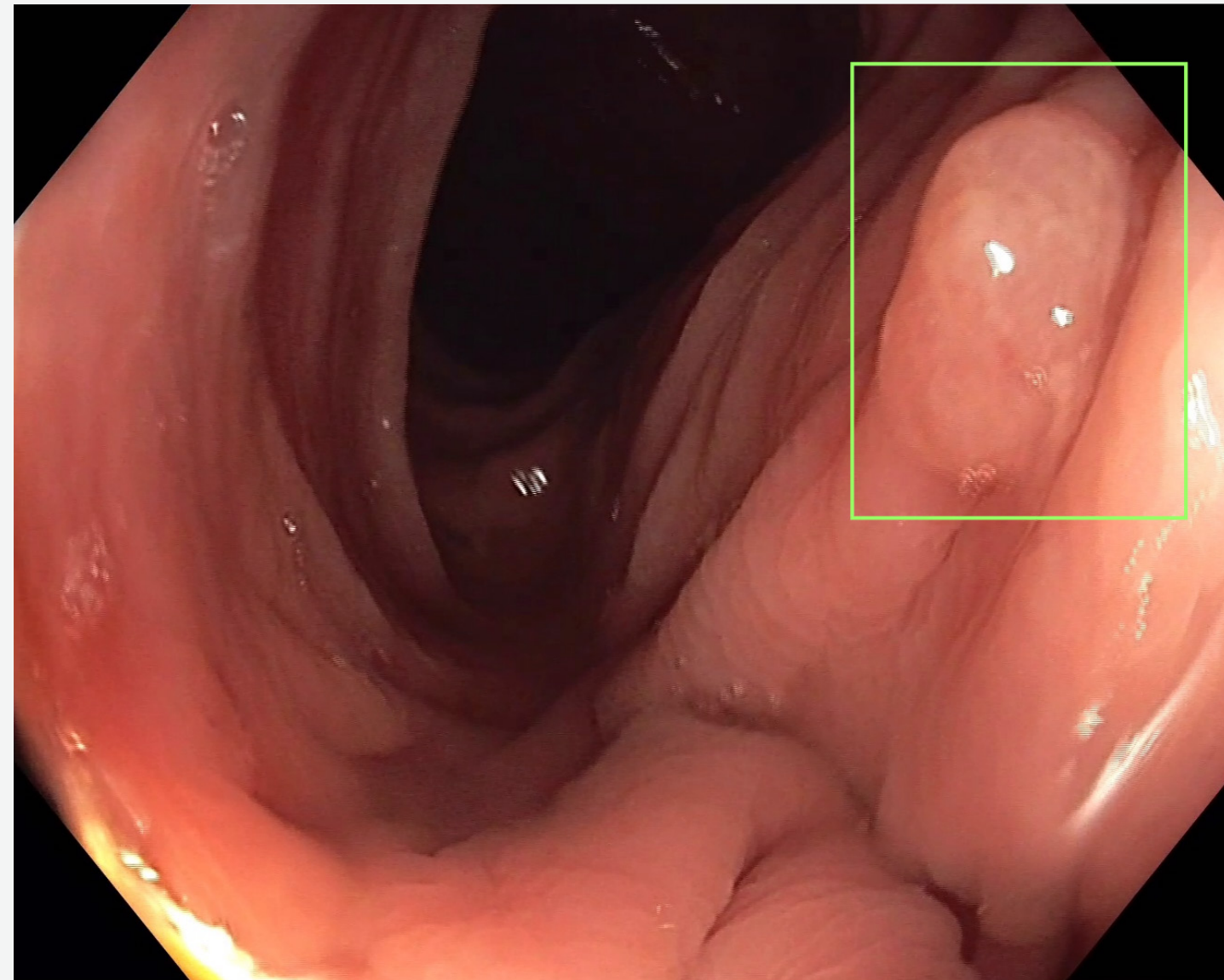


Image captured using CF-H190L scope.

## AI for Polyp Detection

The CADDIE™ software analyzes data from the endoscopic processor in real time. It highlights suspected colorectal polyps using green bounding boxes and provides visual cues to support the endoscopist in detection.<sup>7</sup>

The CADDIE software enables hands-free interaction with detection controlled by a foot pedal.<sup>9</sup>

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. Additionally, CADDIE's software AI Algorithm training data includes an **enriched data set of clinically significant polyps**, such as large polyps and SSLs.<sup>8</sup>

This deliberate data set curation is designed to deliver clinical accuracy and performance. When using CADDIE software, endoscopists experience a **7.3% absolute increase in Adenoma Detection Rate (ADR.)**<sup>5</sup>

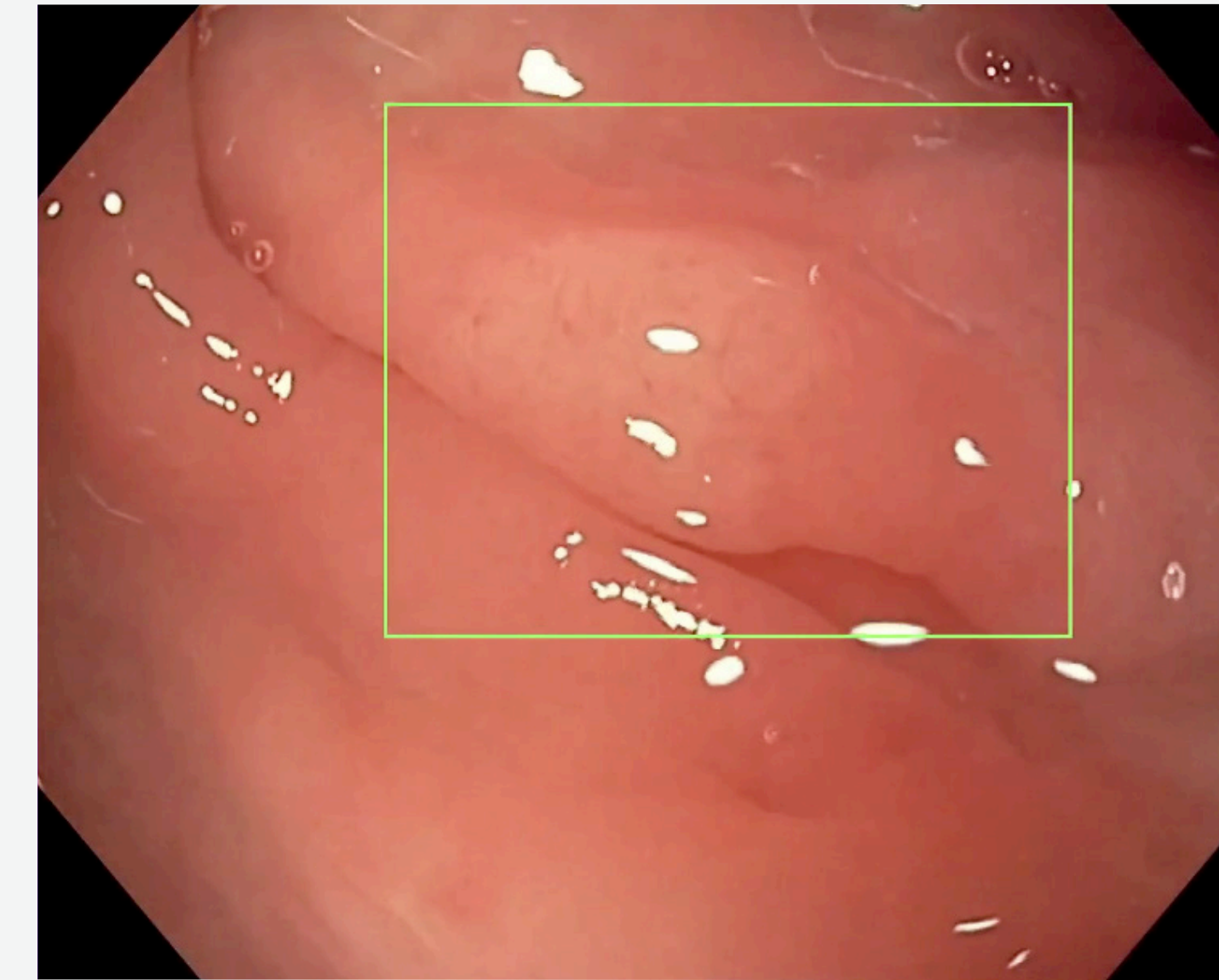


Image captured using CF-H190I scope.

## 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.<sup>5</sup> This capability has generated the following results (per colonoscopy)<sup>5</sup>:

- **136% relative increase in the detection of large polyps (>10mm).**<sup>5</sup>

- **93% relative increase in the detection of large adenomas (>10mm).**<sup>5</sup>
- **57% relative increase in the detection of flat adenomas.**<sup>5</sup>
- **230% relative increase in the detection of sessile serrated lesions (SSL).**<sup>5</sup>

**Fair Balance Statement:** The CADDIE™ computer-assisted detection device is intended to assist the gastroenterologist in identifying suspected colorectal polyps only.

The gastroenterologist is responsible for reviewing CADDIE™ suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. The CADDIE™ device is not intended to replace a full patient evaluation, nor is it intended to be relied upon to make a primary interpretation of endoscopic procedures, medical diagnosis or recommendations of treatment/course of action for patients. The CADDIE™ computer-assisted detection device is limited for use with standard white-light endoscopy imaging only.

# 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.<sup>10</sup>

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.<sup>9</sup>



## Simple Setup

The CADDIE software can be configured for single-monitor use or with a second monitor.<sup>11</sup>

The system can integrate with existing clinical workflows and endoscopy equipment<sup>12</sup> such as the Olympus CV-1500 EVIS X1™ endoscopy system and Olympus CV-190 EVIS EXERA III™ endoscopy system.<sup>13</sup>

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.<sup>14</sup>



## 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.<sup>15</sup>



## 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 the CADDIE software, Olympus is unlocking the power of intelligent endoscopy, aiming to support endoscopists improve outcomes and significantly impact the fight against cancer.

# Product Claims

- The CADDIE™ software's AI polyp detection algorithm was developed using 162,207 image frames of 1,711 polyps from 906 patients.<sup>16</sup>
- 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.<sup>16</sup>
- 98.2% sensitivity rate based on object-level true positive rate.<sup>8</sup>
- 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%.<sup>8</sup>
- 7.3% absolute increase in adenoma detection rate (ADR) when using CADDIE software (43.2%) compared to standard of care (35.9%).<sup>5</sup>

# References

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.
2. Zhao S, Wang S, Pan P, et al. Magnitude, Risk Factors, and Factors Associated With Adenoma Miss Rate of Tandem Colonoscopy: A Systematic Review and Meta-analysis. Gastroenterology. 2019;156(6):1661-1674. e11.doi:https://doi.org/10.1053/j.gastro.2019.01.260 (https://www.sciencedirect.com/science/article/pii/S0016508519303609).
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4. Based on the Company's research, as of March 2025
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6. Data on file with Odin Medical Ltd., TCP-001.
7. Data on file with Odin Medical Ltd, TCP-001, TCP-002.
8. Data on file with Odin Medical Ltd., OD-007599-BT — ODIN-CADDIE-CER-FDA-BT Polyp Detection Bench Testing Report V1.4.13. Data is based on direct comparisons between use and non-use of CADDIE™ device.
9. Data on file with Odin Medical Ltd, TCP-005, FDA-TCU-019.
10. Data on file with Odin Medical Ltd, TCP-003, TCU-015.
11. Data on file with Odin Medical Ltd, TCP-001, TCP-002, TCP-003.
12. Data on file with Odin Medical Ltd., OD-003126-WI-6-ODIN-WI-012 — Installation instructions.
13. Data on file with Odin Medical Ltd, TCU-001, TCU-003, FDA-TCU-022.
14. Data on file with Odin Medical Ltd, TCU-001.
15. Data on file with Odin Medical Ltd, FDA-TCU-025, FDA-TCU-026, FDA-TCU-027, FDA-TCU-028.
16. Data on file with Odin Medical Ltd., OD-005433-TC — 16.14 — ODIN-CADDIE-FDA — Algorithm description.

As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications, accessories and service offerings may be required.

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