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Medtronic announces CE Mark for the next generation GI Genius™ module and ColonPRO™ software

Empowering endoscopists with meaningful insights

Medtronic plc (NYSE:MDT), a global leader in healthcare technology, announced it has received CE Mark approval for ColonPRO™, the 4th generation software for AI-assisted colonoscopy.

Leveraging deep learning algorithms, ColonPRO™ has been designed to support endoscopists in optimising colonoscopy practice. The new software represents a significant leap forward in AI- assisted colonoscopy by offering endoscopists further insights with real-time polyp size estimation and comprehensive procedural highlights1.

Introduced in 2019, GI GeniusTM was the first AI system to receive CE Mark and FDA clearance (in 2021) for the detection of colorectal polyps. Trained to analyze colonoscopy images containing regions consistent with colorectal lesions, the system has proven its ability to detect and characterize polyps1,2,3,4.

Evidence shows that when using GI Genius over a standard colonoscopy, adenoma detection rates increase up to 14.4% and reduce adenoma miss rates by approximately 50%.2,3 In addition, a recent randomized controlled trial4 demonstrated that GI Genius safely supports “diagnose-and- leave” strategies, potentially reducing unnecessary resections without compromising safety.

Accurate polyp measurement plays a critical role in determining appropriate surveillance intervals and improving patient outcomes. The real-time polyp sizing module (CADs) has been validated in the *METER* study and achieved 85.8% accuracy4F5, significantly higher than the <60% typically reported in routine practice5F6, and supported accurate post-polypectomy surveillance intervals.

Finally, the quality module (CADq) offers clinicians the ability to optimize colonoscopy practice with automated measurements of key quality metrics such as inspection times, cecum detection and bowel cleanliness.

Together, these modules form a clinically proven and fully integrated AI suite designed to enhance every phase of colonoscopy – from detection to diagnosis and quality assessment.

The GI Genius module has also been redesigned to deliver improved performance and support a variety of future real time AI applications through a single platform. The new operating system and hardware bring to life the AI

AccessTM platform and will enable clinicians to run multiple applications, providing access to AI insights and optimizing workflow documentation practices.

“Medtronic is committed to equip endoscopists with the critical insights they need to enhance outcomes and achieve greater procedural experience,” said Darin Wilson, WE-APAC Business Director. “The GI Genius intelligent endoscopy system has been rigorously validated across more than 30 clinical trials and 10 RCTs6F7, demonstrating its effectiveness and reliability in real-world settings. ColonPROTM brings a new level of insights to help optimise and standardise colonoscopy practice. Designed to be future-ready, it also offers the flexibility to integrate an expanding range of AI applications, ensuring endoscopists always have access to the latest innovations."

To learn more about GI Genius™ and ColonPRO™, please visit our website: https://www.medtronic.com/en-ie/c/healthcare-professionals/endoscopy/gi-genius-colonpro.html

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more.

Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE: MDT), visit www.Medtronic.com(opens new window), and follow @Medtronic on LinkedIn.

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[1] CPRO-MN01-EU: User Manual of software ColonPRO EU.

[2] Repici et Al. Efficacy of Real-Time Computer-Aided Detection of Colorectal Neoplasia in a Randomized Trial. Gastroenterology. 2020 Aug;159(2):512-520.e7.

[3] Wallace et Al. Impact of Artificial Intelligence on Miss Rate of Colorectal Neoplasia. Gastroenterology.2022 Jul;163(1):295-304.e54

[4] Antonelli et al. Safety of artificial intelligence-assisted optical diagnosis for leaving colorectal polyps in situ during colonoscopy (PRACTICE): a non-inferiority, randomised controlled trial. The Lancet Gastroenterology & Hepatology, Volume 10, Issue 10, 915 – 923

[5] Antonelli et Al. Clinical implications of computer-aided real-time size estimation of colorectal polyps during colonoscopy: a prospective study. Endoscopy. 2025 Oct 2.

[6] Cheloff et Al. Accuracy of Visual Estimation for Measuring Colonic Polyp Size: A Systematic Review and Meta-Analysis Official journal of the American College of Gastroenterology | ACG120(10):2251-2259, October 2025.

[7] https://cosmoimd.com/gi-genius/

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