Abbott Receives FDA Clearance And CE Mark For Next-Generation Ultreon™ 3.0 AI-Powered Coronary Imaging Platform

- Ultreon 3.0 is the first advanced optical coherence tomography (OCT) system in the U.S. and Europe that integrates high resolution coronary plaque images and AI-automated insights through the artery
- The integrated imaging platform is designed to enable fast, intuitive decision making for physicians while treating complex coronary disease to open clogged arteries
- The AI enabled software helps physicians size and position the stent more accurately, which can lead to better results for patients

ABBOTT PARK, Ill., April 28, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it received U.S. Food and Drug Administration (FDA) clearance and CE Mark for its next-generation Ultreon™ 3.0 Software. This marks a major step forward as it brings coronary imaging and AI-automated insights together in one system to support better patient outcomes and help reduce risks.

Ultreon 3.0 is an artificial intelligence (AI) powered imaging platform that uses optical coherence tomography (OCT) to give doctors real-time planning guidance while they perform minimally invasive procedures to open blocked heart arteries known as percutaneous coronary intervention (PCI). This technology allows physicians to use OCT images to see the detailed structure of the blockage and incorporates AI to assess the type of plaque causing the blockage, helping the doctor choose the best location and size of the stent to improve blood flow. The platform offers a fully integrated workflow to support faster, more precise procedures.

"Ultreon 3.0 represents a pivotal step forward in how we treat and ultimately care for our patients. This next-generation platform, combining imaging and AI, doesn't just improve upon existing technology — it leapfrogs it," said Evan Shlofmitz, D.O., interventional cardiologist, director of interventional cardiology, St. Francis Hospital and Health Center in Roslyn, NY. "By delivering greater clarity, speed, and clinical insight, Ultreon 3.0 accelerates the path to more confident clinician decision making and transformative patient care."

"Abbott's Ultreon 3.0 offers a single, AI-driven platform that quickly and easily captures the images physicians need to fully understand the size and angle of the blockage, and create an actionable plan to help the patient," said David M. Leistner, interventional cardiologist and professor of cardiology, Frankfurt, Germany. "Every second and every decision matters when treating patients who have blockages in their coronary arteries, and Ultreon 3.0 enables faster, more informed clinical choices that can have a real impact on patients."

The next-generation software features a one-second OCT pullback, which is a high-speed infrared light-based imaging technique that quickly captures detailed cross-sectional views of the coronary artery, offering higher resolution readings than intravascular ultrasound (IVUS) and with low or zero contrast. Minimizing the amount of contrast may be helpful in some patients with kidney disease, who represent approximately 25% of people with coronary artery disease.[i] The AI and software capabilities of Ultreon 3.0 include the following additional benefits:

- A clear understanding of the size, shape, and location of a coronary blockage, enabling optimal stent placement to maximize blood flow and guide treatment planning.
- A post-procedure assessment to ensure the stent improved blood flow in the artery.
- A streamlined setup and enhanced AI-automated insights that simplify physicians' workflow.
- Easily acquired images from inside blood vessels and ability to efficiently plan procedures, specifically tailored for patients with complex coronary disease.

"Complemented by our leading coronary portfolio, Ultreon 3.0 makes OCT imaging more intuitive and powerful for physicians, reimagining imaging into a tool for precision-guided intervention before and after procedures," said Ethan Korngold, M.D., chief medical officer at Abbott's vascular business. "Advancements like Ultreon 3.0 showcase Abbott's leadership in AI-powered imaging and as a trusted partner in delivering smarter, more personalized coronary care."

Ultreon 3.0: Advancing Complex PCI:

Complex PCI is a specialized procedure used to treat severe coronary artery disease. PCI involves treating challenging lesions—or plaques—that have built up in a patient's coronary arteries. Some patients will require multiple stents to address the lesions. More than 600,000 people in the U.S. and more than 885,000 in Europe undergo PCI each year.[ii,iii]

Ultreon 3.0 is an AI solution that meets real-world needs, advances clinical precision, and supports more consistent care delivery. Built on the success of Ultreon 2.0, this platform introduces enhanced AI capabilities to provide a simple, fast, and precise solution for complex coronary PCIs.

For important safety information on Ultreon 3.0 Software, visit: https://www.cardiovascular.abbott/us/en/hcp/products/percutaneous-coronary-intervention/intravascular-imaging/ultreon-software/important-safety-information.html

About Abbott:
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

Connect with us at www.abbott.com and on LinkedIn, Facebook, Instagram, X and YouTube.

[i] Mehdi, A., Taliercio, J. J., & Nakhoul, G. (2020, November 1). *Contrast media in patients with kidney disease: An update* Cleveland Clinic Journal of Medicine. https://www.ccjm.org/content/87/11/683#:~:text=Nevertheless%2C%20CI%2DAKI%20remains%20real,24%25%20of%20patients%2C%20respectively.

[ii] Masoudi FA, Ponirakis A, de Lemos JA, Jollis JG, Kremers M, Messenger JC, et al. Trends in U.S. Cardiovascular Care: 2016 Report From 4 ACC National Cardiovascular Data Registries. J Am Coll Cardiol. 2017;69(11):1427–50.

[iii] Cook S, Walker A, Hügli O, Togni M, Meier B. Percutaneous coronary interventions in Europe: prevalence, numerical estimates, and projections based on data up to 2004. Clin Res Cardiol. 2007;96(6):375-382. doi:10.1007/s00392-007-0513-0.

SOURCE Abbott

For further information: Abbott Media: Alicia Swanson, (669) 210-7204, Abbott Financial: Mike Comilla, (224) 668-1872

Additional assets available online:

