

E-Scopics Receives FDA 510(k) Clearance for Hepatoscope-Derived Fat Fraction (HDFF) to Further Expand the Accessibility of Point-of-Care Non-Invasive Assessment of Fatty Liver

Aix-En-Provence, France and Saint-Louis, MO, USA (June 10, 2026)— E-Scopics, a pioneer in advanced point-of-care liver imaging, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its new Hepatoscope-Derived Fat Fraction (HDFF) technology. The feature combines the Quantitative Ultrasound parameters that were already available on the system: ultrasound attenuation and backscattering coefficient. HDFF demonstrated a 0.93 (95%CI: 0.89-0.95) correlation coefficient with MRI-PDFF reference standard and a 0.93 (95%CI: 0.87-0.97) AUROC for the detection of liver steatosis (MRI-PDFF > 5%). This feature further empowers clinicians to non-invasively estimate intra-hepatic fat at the point of care, providing an objective and accessible tool for the assessment and management of Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD).

MASLD has emerged as one of the most prevalent chronic liver diseases worldwide, affecting an estimated one-third of adults and placing millions at risk for progressive liver fibrosis, cirrhosis, liver cancer, and cardiovascular complications. Despite the growing burden of disease, quantitative assessment of liver fat has traditionally required magnetic resonance imaging (MRI), a costly and often inaccessible diagnostic option. Conventional ultrasound, while widely available, typically provides only qualitative information regarding the presence of fatty liver disease. At the same time, the availability of new therapies for patients with MASH with advanced fibrosis (Rezdiffra, Madrigal Pharmaceuticals, and Wegovy/Kayshild, Novo Nordisk) demand objective, quantitative tools that can help clinicians identify appropriate patients, establish disease baselines, and monitor treatment response.

“The decrease of liver steatosis has been shown to be an early sign of treatment response for recently approved MASH therapies in patients without cirrhosis,” said Pr Arun Sanyal, MD, Director of the Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University. “The interest of quantifying liver fat was further confirmed by the recent study results of survodutide: in patients living with obesity and/or MASLD, a reduction of liver fat was associated with significant weight loss and reduction of visceral fat. In routine practice, clinicians need accessible and reliable tools to estimate liver fat at the point of care if we want to handle efficiently the epidemic of fatty liver disease before patients progress to advanced fibrosis. This is expected to favor detection, surveillance and monitoring of SLD patients in primary care, outside of specialized hepatology clinics.”

The FDA clearance of HDFF marks a significant advancement in liver disease management by bringing an intra-hepatic fat fraction assessment directly to the point of care. Beyond the clinical advantages, HDFF has the potential to significantly expand access to quantitative liver assessment by reducing the economic barriers associated with advanced imaging. Quantitative liver fat measurement has traditionally required MRI-based studies, which can cost patients and healthcare systems more than \$1,000 per examination and often involve lengthy scheduling delays, limiting access for many patients who could benefit from earlier detection and ongoing monitoring. In contrast, ultrasound-based liver evaluations are substantially less expensive and are already widely available across primary care, endocrinology, obesity medicine, and hepatology practices. By integrating quantitative liver fat assessment directly into a routine point-of-care Hepatoscope examination, E-Scopics is helping make objective liver health measurements more accessible to a broader patient population while reducing costs and improving workflow efficiency for healthcare providers.

“Healthcare professionals need reliable and specific non-invasive tools to assess liver steatosis in routine care,” acknowledged Pr Jérôme Boursier, MD, Head of the Department of Hepato-Gastroenterology and Digestive Oncology, University Hospital of Angers, France. “Fatty liver is a warning sign that should draw attention to the liver, especially in patients at risk of metabolic disorder, ie. with type 2 diabetes, obesity and/or cardiovascular risk factors. Once fatty liver is detected, further risk-stratification can be triggered, in particular looking at the level of liver fibrosis using liver stiffness measurement. Portable systems that can both estimate fat fraction and assess liver stiffness are ideal for point-of-care assessment. This will enable physicians to provide adequate and personalized patient care for their patients.”

The HDFF feature is designed to integrate seamlessly into existing Hepatoscope examinations, enabling healthcare providers to obtain ultrasound-derived fat fraction estimates in real time without additional imaging appointments or referrals. It further expands the capabilities of the Hepatoscope platform, which is designed to bring advanced quantitative liver imaging and assessment technologies into primary care, endocrinology, obesity medicine, hepatology, and other clinical settings where early identification of liver disease is increasingly critical.

“Liver disease is increasingly becoming a major public health challenge, especially in relation to the rapid growth of obesity, type 2 diabetes, and metabolic syndrome. Clinicians still lack access to practical tools that provide objective measurements of liver fat that can help identify liver disease before patients progress to advanced fibrosis or cirrhosis,” said Claude Cohen-Bacrie, Founder and CEO of E-Scopics. “The FDA clearance of Hepatoscope-Derived Fat Fraction represents an important milestone in our mission to democratize advanced non-invasive liver assessment tools. By delivering fat fraction estimates during a quick, convenient, and cost-effective routine point-of-care examination, we can help clinicians identify disease earlier, monitor patients more effectively, and support more personalized treatment decisions. As therapies have started to become available for fibrotic MASH, clinicians will increasingly need scalable, quantitative tools to support patient identification, treatment selection, and ongoing disease monitoring.”

About E-Scopics

E-Scopics is dedicated to advancing point-of-care imaging technologies that make sophisticated diagnostic information more accessible to healthcare providers and patients. Through its Hepatoscope platform, the company is helping transform the detection, assessment, and monitoring of liver disease by delivering actionable clinical insights directly at the point of care.

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