

E-SCOPICS ANNOUNCES NEW FDA CLEARANCE FOR HEPATOSCOPE[®] WITH EXPANDED CAPABILITIES IN MANAGING LIVER DISEASE COMPLICATIONS, ADVANCED ELASTOGRAPHY IMAGING FEATURES, AND IMPROVED COMPATIBILITY TO BE PRESENTED AT DDW 2026

The addition of a dedicated spleen exam workflow with real-time 2D transient elastography imaging, compliance with the ultrasound elastography standard IEC 63412-1, compatibility with macOS-based laptops, and connectivity to EHR systems reinforce Hepatoscope’s positioning as the global technology leader in non-invasive ultrasound tests for liver disease assessment.

AIX-EN-PROVENCE, France and SAINT-LOUIS, MO – (BUSINESS WIRE) — E-Scopics, the medtech innovator advancing ultrasound access at the point of care, today announced the U.S. FDA clearance of new enhancements to its Hepatoscope5[®] platform, marking a significant milestone in its product expansion. These advanced features will be presented during the exhibition at the Digestive Disease Week[®] 2026 in Chicago, IL, June 3 to 5, booth #2039.

Hepatoscope now includes a dedicated Spleen Exam workflow, expanding its clinical utility in the non-invasive assessment of complications of cirrhosis. The system incorporates optimized acquisition parameters, including an adjusted vibration frequency and region of interest tailored to spleen anatomy, improving the reliability of high stiffness values.

“Hepatoscope is unique because it combines real-time ultrasound imaging and transient elastography in a single, highly portable device. This allows me to use the system literally at the bedside for hospitalized patients, in the outpatient consultation room, or in my community-based private practice,” said Dr. Olivia Pietri, private practice hepato-gastroenterologist at Saint-Joseph Hospital in Marseille, France. “What is particularly compelling is the ability to assess spleen stiffness under direct image guidance at the bedside. This opens new possibilities for evaluating cirrhotic patients and managing them more proactively, while maintaining the reproducibility and ease of use clinicians need in everyday practice.”

Hepatoscope continues to advance its elastography imaging capabilities and 2DTE achieves full compliance with the international IEC 63412-1 standard for the mapping of tissue stiffness. The standard defines optimal visualization of heterogeneities across the continuum of liver stiffness values. In implementing this standard, Hepatoscope enables better visualization of small stiffness changes, which may benefit treatment monitoring.

With this clearance, Hepatoscope becomes the first ultraportable liver assessment solution that complies with this demanding regulatory standard and is capable of real-time tissue elastography imaging.

“Elastography plays an essential role in evaluating the severity of chronic liver diseases by measuring how shear waves propagate through tissue such as the liver and spleen,” said Claude Cohen-Bacrie, founder and CEO of E-Scopics. “The compliance with the IEC 63412-1 standard imposes clear explanations about shear wave propagation speed measurements and optimal visualization of 2DTE. Hepatoscope is now the only ultraportable ultrasound system with both real-time ultrasound imaging plus tissue elasticity imaging, for liver and spleen assessment, at the point of care.”

The software-based ultrasound imaging and quantification platform, initially launched on Windows OS laptops, is now also compatible with macOS systems. Laptops equipped with Apple M3 chips or later and macOS 14 Sonoma can now serve as hosts for Hepatoscope, offering healthcare organizations greater flexibility in deployment and simplifying implementation across diverse IT environments.

Hepatoscope also introduces deeper integration into clinical workflows through conformity with the HL7[®] FHIR[®] R4 standard, enabling direct connectivity with electronic health record (EHR) systems. Operators can securely log in, access appointment schedules, select patients directly from institutional worklists and automatically export exam

reports to the EHR upon completion. These enhancements reduce administrative burden, accelerate exam throughput and support seamless integration into routine clinical practice.

About E-Scopics: E-Scopics S.A.S is a French medtech company that advances the accessibility, affordability and ease of use of premium ultrasound tools at the point of care. Its agile software platform has dematerialized and automated ultrasound imaging technologies, creating an Ultrasound-as-a-Service model with specific applications sold via pay-per-use or subscription business models. The company's first product, Hepatoscope, leverages quantitative imaging capabilities to help clinicians assess liver fibrosis, steatosis, and liver disease complications non-invasively at the bedside. To learn more, visit www.escopics.com.

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