



Hyperfine Announces FDA Clearance of the First Optive AI™ Software Update with Advanced Diffusion Imaging Capability, Focused on Enhancing Stroke Detection with the Swoop® System

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A new multi-direction DWI sequence, the latest Swoop® system software, and the first advancement in Hyperfine's Optive AI™ software, delivers clearer, higher-quality images for stroke diagnosis, enhancing the value of the Swoop® system in acute neurological care.

GUILFORD, Conn.--(BUSINESS WIRE)--Dec. 15, 2025-- [Hyperfine, Inc.](#) (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared AI-powered portable MRI system for the brain—the Swoop® system—today announced that it has received FDA clearance for a new multi-direction diffusion-weighted imaging (DWI) software sequence. This advancement delivers substantially improved image quality and diagnostic confidence for stroke detection, marking a significant expansion of the Swoop® system's clinical capabilities in acute neurological care.

The new DWI sequence acquires and averages signals from multiple directions, similar to the method used in high-field MRI scanners, to produce cleaner, more consistent images. The multi-direction acquisition method minimizes factors that can obscure stroke pathology, resulting in clearer lesion visualization that translates to improved sensitivity for detecting smaller strokes and greater specificity in confidently distinguishing true infarcts—critical factors for diagnostic accuracy. Hyperfine's existing single-direction DWI sequence remains available and provides a time advantage for extremely urgent situations where rapid imaging is essential to meet stroke treatment protocols. Both DWI sequences are available for all models of the Swoop® system.

"From a clinical perspective, adding this multi-direction DWI sequence is a game-changer for stroke imaging with portable MRI," said Edmond Knopp, Hyperfine Chief Medical Officer. "The ability to more confidently detect smaller stroke lesions is particularly valuable for critical care settings, including cardiac ICUs, post-procedure follow-up imaging, and baseline assessments for emergency department triage and discharge decisions. Meanwhile, our single-direction DWI is faster and aligns well with stroke protocols, which is a real advantage in ultra-urgent situations, such as when clinicians need to determine whether to administer thrombolytic therapy."

"Our multi-direction DWI sequence is the first of many advancements planned for our Optive AI™ software, cleared six months after the initial clearance, and represents a pivotal milestone in expanding the Swoop® system's role in stroke care," said Maria Sainz, President and Chief Executive Officer of Hyperfine, Inc. "This enhanced imaging capability strengthens our clinical utility for stroke triage by delivering the high-quality diffusion imaging that clinicians need, coupled with the portability and accessibility that define the Swoop® system. Hyperfine is well poised to capture significant opportunity in stroke diagnosis and expand our presence across multiple hospital care settings."

For more information about the Swoop® AI-powered portable MRI system, please visit [HyperfineMRI.com](#).

About the Swoop® Portable MRI Systems

The Swoop® Portable MR Imaging® Systems are U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. They are portable, ultra-low-field magnetic resonance imaging devices for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

About Hyperfine, Inc.

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking health technology company that has redefined brain imaging with the Swoop® system—the first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of professional care. The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging. Founded by Dr. Jonathan Rothberg in a technology-based incubator called 4Catalyzer, Hyperfine, Inc. scientists, engineers, and physicists developed the Swoop® system out of a passion for redefining brain imaging methodology and how clinicians can apply accessible diagnostic imaging to patient care. For more information, visit [HyperfineMRI.com](#).

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This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Actual results of Hyperfine, Inc. (the "Company") may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company's goals and commercial plans, the benefits of the Company's products and services, and the Company's future performance and its ability to implement its strategy. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the success, cost and timing of the Company's product development and commercialization activities, including the degree that the Swoop® system is accepted and used by healthcare professionals; the impact of COVID-19 on the Company's business; the inability to maintain the listing of the Company's Class A common stock on the Nasdaq; the Company's inability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is

currently marketing or developing; the size and growth potential of the markets for the Company's products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of the Company's products and services and reimbursement for medical procedures conducted using the Company's products and services; the Company's estimates regarding expenses, revenue, capital requirements and needs for additional financing; the Company's financial performance; and other risks and uncertainties indicated from time to time in Company's filings with the Securities and Exchange Commission, including those under "Risk Factors" therein. The Company cautions readers that the foregoing list of factors is not exclusive and that readers should not place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

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