

HYPERFINE

Hyperfine Announces FDA Clearance of Optive AI™ Software, Introducing the Most Substantial Image Quality Improvement Ever for the Swoop® System

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Latest Swoop® System software delivers a substantial leap in image quality for AI-powered portable MR brain imaging.

GUILFORD, Conn.--(BUSINESS WIRE)--May 28, 2025-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the world's first FDA-cleared AI-powered portable MRI system for the brain—the Swoop® system—today announced FDA clearance of its next-generation software. This tenth-generation release delivers a substantial leap in image quality for ultra-low-field MR imaging.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20250528571999/en/>



Comparison of Swoop® system FLAIR images showing current image quality and new Optive AI™ software image quality.

These advanced AI algorithms are applied across all sequences.

Earlier this year, Hyperfine released the software at select clinical sites where early users responded enthusiastically to the image quality improvements, with some reporting that image quality is approaching that of conventional 1.5 tesla MRI scanners. This feedback underscores the clarity and consistency of the new images that can enhance patient care.

"This software release marks the beginning of a transformative era for Hyperfine. The advanced AI algorithms integrated into our new software platform dramatically elevate image quality at ultra-low field strength, enabling more confident diagnoses at the point of care. We previewed Optive AI™ software at the recent American Society of Neuroradiology annual meeting and received outstanding feedback. It's the strongest signal yet of where we're headed—and how far AI-powered portable MRI imaging can go," said Rafael O'Halloran, Hyperfine Vice President of Technology.

"Optive AI™ software is our tenth software release since initial FDA clearance and marks a critical inflection point in the evolution of Swoop® system technology—the first of two major technology milestones we have been looking forward to this year. The significant image quality enhancements enabled by Optive AI™ software will serve as a catalyst for our 2025 growth strategy, supporting expansion into new hospital sites of care and our entry into the neurology office market," said Tom Teisseyre, Hyperfine Chief Operating Officer.

Hyperfine plans to initiate the rollout of Optive AI™ software to accounts in the third quarter of 2025.

For more information about the Swoop® AI-powered portable MRI system, please visit hyperfine.io.

About the Swoop® Portable MR Imaging® System

The Swoop® Portable MR Imaging® system is U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. It is a portable, ultra-low-field magnetic resonance imaging device 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. The Swoop® system is also CE marked in the European Union and is UKCA marked in the United Kingdom. The Swoop® system is commercially available in a select number of international markets.

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, AI-powered, 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 hyperfine.io.

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Forward-Looking Statements

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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