Hyperfine Announces First Patients Enrolled in PRIME Study Aimed at Accelerating Adoption of AI-Powered Portable MRI in Emergency Departments

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The real-world study will assess the clinical and operational impact of portable MRI across diverse patient types in ED settings.

GUILFORD, Conn.--(BUSINESS WIRE)--Jul. 31, 2025-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared AI-powered portable magnetic resonance imaging (MRI) system for the brain—the Swoop® system —today announced the enrollment of the first patients in the PRIME (Portable Rapid Imaging for Medical Emergencies) study. This study aims to evaluate the potential of AI-powered portable MRI technology to transform triage in the emergency department (ED) setting.

The PRIME study at Yale School of Medicine builds on the ACTION PMR study, which demonstrated the utility of AI-powered portable MRI in the diagnosis and management of stroke patients in emergency department settings. Expanding the scope of patients studied, the PRIME study will include a broad and diverse set of patients presenting in an emergency department and assess the technology's potential effectiveness and efficiency as a triage tool for a wide range of brain-related emergency medical conditions. Unlike ACTION PMR, the PRIME study is being conducted using the recently released next-generation Swoop® system powered by Optive AI™ software. PRIME will be one of the first studies using the new software's advanced image quality that provides sharper anatomical detail, thus potentially enabling greater pathology detection.

Hyperfine's portable MRI technology has established its value in healthcare institutions, providing high-quality brain imaging at the bedside for critically ill adult and pediatric patients. Timely access to MRI in emergency department settings is still a challenge for many hospitals. Prolonged patient boarding in EDs has been cited as the top priority for hospital leaders, as evidenced in the December 2024 article in Becker's Hospital Review [1]. By removing the traditional barriers associated with access to conventional MRI scanners—such as wait times, shortage of dedicated MRI technologists, cost, and immobility—portable MR imaging enables faster, more efficient decision-making in emergency department settings.

The PRIME study will enroll patients in a Level 1 emergency department, assessing a broad spectrum of emergency medical conditions. "By evaluating the potential of portable MRI in this real-world setting, this study aims to determine if a portable MRI system can provide diagnostic imaging capabilities that can be quickly integrated into the ED workflow to improve patient care decisions in real time," said Dr. Kevin Sheth, Professor of Neurology and Neurosurgery at the Yale School of Medicine and principal investigator for the PRIME study, who is working in close collaboration with his co-PI Dr. Adam De Havenon.

"Given many EDs don't have ready access to MRI, this study could alter paradigms of advanced imaging access and utilization in the ED," said Dr. Charles Wira, Associate Professor of Emergency Medicine at Yale University. "The Hyperfine portable MRI system could immediately provide ED clinicians and consulting physicians with critical imaging data at the point of care, helping them to make more informed, faster decisions when every second counts."

"Hyperfine is thrilled to collaborate with Yale on this transformative project. The Yale team has worked with portable brain MRI since the technology's early days," said Maria Sainz, President and CEO of Hyperfine. "Through the PRIME study, they demonstrate a bold vision for how portable MRI can accelerate triage in emergency care. The next-generation Swoop® system, powered by Optive AI™ software, provides more clinically valuable image quality that we expect will drive greater adoption in the emergency setting and help address the widespread clinical and economic challenges of ED boarding."

Hyperfine is committed to advancing the role of portable MRI in emergency care of the brain, one of the sites of care where access to conventional MRI is challenging. The PRIME study represents a strategic initiative within the broader Hyperfine hospital market strategy to drive commercial growth, demonstrating how the placement of portable MRI systems in emergency departments can unlock timely diagnostic access and improve clinical workflows at the point of care.

For more information about the Swoop® system, please visit HyperfineMRI.com.

For more information about the PRIME study, including enrollment details and eligibility criteria, please visit ClinicalTrials.gov.

1. ED boarding: 10 things to know. *Becker's Hospital Review* . https://www.beckershospitalreview.com/care-coordination/ed-boarding-10-things-to-know.html. Published January 25, 2024. Accessed July 25, 2025.

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.

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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