

# HYPERFINE

## Hyperfine, Inc. Launches AI-powered Brain Imaging Software for Enhanced Image Quality and Ease of Use

January 9, 2024

*The latest software, the eighth generation of Swoop® system software, has obtained CE and UKCA approval*

GUILFORD, Conn.--(BUSINESS WIRE)--Jan. 9, 2024-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that has redefined brain imaging with the world's first FDA-cleared portable magnetic resonance brain imaging system—the *Swoop®* system—today announced the launch of the AI-powered eighth generation of *Swoop®* system software. The software's diffusion-weighted imaging (DWI) AI denoising feature received U.S. Food and Drug Administration (FDA) clearance in October 2023, and it has been rolled out at select sites over the past several weeks through a limited market release. The latest software improves *Swoop®* system image quality and introduces valuable ease-of-use features, including a real-time aid for more precise patient loading and positioning and a streamlined image upload process.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20240109012126/en/>



Hyperfine, Inc. has redefined brain imaging with the world's first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system—the *Swoop®* system (Photo: Business Wire)

time-saving aid and helped improve image acquisition.

"The software update on the *Swoop®* system has been most beneficial to our workflow. We are now able to view each series as it is being performed and can communicate with the technologist whether additional series are needed. Additionally, we can communicate with clinicians any critical findings in real-time without having to wait for the whole study to be completed," says Jennifer Villa Frabizzio MD, neuroradiologist, Radiology Group of Abington.

Hyperfine, Inc. will roll out software updates for the *Swoop®* system to users in the coming weeks.

For more information about the *Swoop® Portable MR Imaging®* system, please visit [hyperfine.io](https://hyperfine.io).

### **About Hyperfine, Inc. and the *Swoop® Portable MR Imaging®* System**

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking medical technology company that has redefined brain imaging with the *Swoop®* system—the world's first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of care. The *Swoop®* system received initial U.S. Food and Drug Administration (FDA) clearance in 2020. It is a portable ultra-low-field magnetic resonance brain imaging device for producing images that display the internal structure of the head where a 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 has been approved for brain imaging in several countries, including Canada and Australia, has UKCA certification in the United Kingdom, CE certification in the European Union, and is also available in New Zealand.

The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging and data solutions. 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. Traditionally, access to costly, stationary, conventional MRI technology can be inconvenient or not available when

With CE and UKCA certifications for this latest software, Hyperfine, Inc. is well positioned for future international expansion, bringing the *Swoop®* system to a broader global market.

"Our latest AI-powered software, the eighth generation of our proprietary software platform, embodies our commitment to supporting clinicians in critical decision-making," remarked Tom Teisseyre PhD, Chief Operating Officer of Hyperfine, Inc. "Our focus on image quality with this latest software has been on the DWI sequence, which is key in stroke imaging. Since its first FDA clearance in 2020, we've been dedicated to continually enhancing image quality and workflow efficiencies to define best-in-class, user-centric, ultra-low field MR brain imaging."

Over 50 exams were performed in hospitals taking part in the limited market release phase, and users commented favorably on DWI image quality. Participating sites confirmed that the new streamlined upload feature materially shortened upload completion times, and the fast-positioning check was a

needed most. With the portable, ultra-low-field *Swoop*® system, Hyperfine, Inc. is redefining the neuroimaging workflow by bringing brain imaging to the patient's bedside. For more information, visit [hyperfine.io](http://hyperfine.io).

Hyperfine, *Swoop*, and Portable MR Imaging are registered trademarks of Hyperfine, Inc.

### **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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