

A detailed view of the Swoop Portable MR Imaging System. The device is a compact, white, cylindrical unit with a clear, dome-shaped patient enclosure. It is mounted on a white base with a red emergency stop button. A red safety rail is visible above the unit. A label on the side of the unit reads "200kg/440lb MAX" and "Keep outside of the extended safety guard rail".

Swoop[®]

Portable MR Imaging[®] System

The Challenge of Imaging in the Critical Care Environment

Neuroimaging in intensive care units (ICU) is essential for diagnosing potential toxic-metabolic or structural brain injuries. However, transporting an ICU patient for neuroimaging involves potential risks and costs. Numerous studies have indicated a prevalence of adverse events during patient transport, with rates ranging from 22% to 79%. The risks include adverse events due to the physicality of transport, environmental changes, and repositioning of monitoring equipment. These interruptions can lead to treatment delays, disrupt critical care, and result in issues such as deterioration of respiratory function after returning from transport—extending ICU stays, and potentially resulting in worse long-term outcomes¹.

Despite its inherent challenges, neuroimaging remains a crucial part of care for neurocritical patients. Transporting patients for conventional high-field MR imaging is time-consuming, costly, and laden with multiple risks, such as physical separation between the patient and nurse, posing a potential delay in case of an emergency¹.

While the risks associated with transport need to be carefully considered, there is also a downside to delays in obtaining conventional high-field MR imaging that can impact patient outcomes negatively, especially in brain injury cases. Hospital turnaround times for ICU imaging results vary widely, but logistical and clinical challenges often add hours to this process¹.

1. McLean B, Thompson D. MRI and the Critical Care Patient: Clinical, Operational, and Financial Challenges. *Crit Care Res Pract*. 2023;2023:2772181. Published 2023 Jun 6. doi:10.1155/2023/2772181

The Swoop system brings MR brain imaging within reach.

The Swoop system is the only FDA-cleared portable MR brain imaging system that combines ultra-low-field magnetic resonance imaging with artificial intelligence-powered software to provide brain imaging at the point of care, helping to inform the timely diagnosis and treatment of acute conditions within a broad range of clinical settings.

The Swoop portable MR brain imaging system expands patient access while being more cost-effective than conventional high-field imaging systems. And, unlike high-field MR imaging, which requires specialized infrastructure and radiologic technicians, Swoop system operation, navigation, and safety training are simple, allowing for expanded user access.

The Swoop system is easy to use. It can be driven directly to a patient's bedside and plugged into a standard electrical outlet. Utilizing the provided Apple® iPad Pro®

mobile digital device, the operator can initiate a scan and generate, display, and export images of the brain within minutes—offering clinicians workflow efficiencies with the potential to impact critical decision-making without transporting the patient away from the point of care.

For the patient, the Swoop system is a convenient and potentially low-stress experience. In addition to potentially reducing transport-related adverse events, with the Swoop system, patients can remain safe and comfortable with family and caregivers by their side. It is helpful in diverse environments, can reduce the time a patient would otherwise have to wait for a conventional MRI scan, and provides expanded access to patients who might not be candidates for high-field MR imaging at the time of care².

2. Prabhat AM, Crawford AL, Mazurek MH, et al. Methodology for Low-Field, Portable Magnetic Resonance Neuroimaging at the Bedside. *Front Neurol.* 2021;12:760321. Published 2021 Dec 10. doi:10.3389/fneur.2021.760321

“Point-of-care MRI saves us time, delivering real-time imaging of cerebral tissue while allowing continuous patient monitoring by their nurses and intensive care doctors.”

*—Andrew Baker, MD, FRCPC, St. Michael's Hospital, Unity Health Toronto,
Chief of the Departments of Critical Care and of Anesthesia;
Medical Director of the Surgery and Critical Care Program*



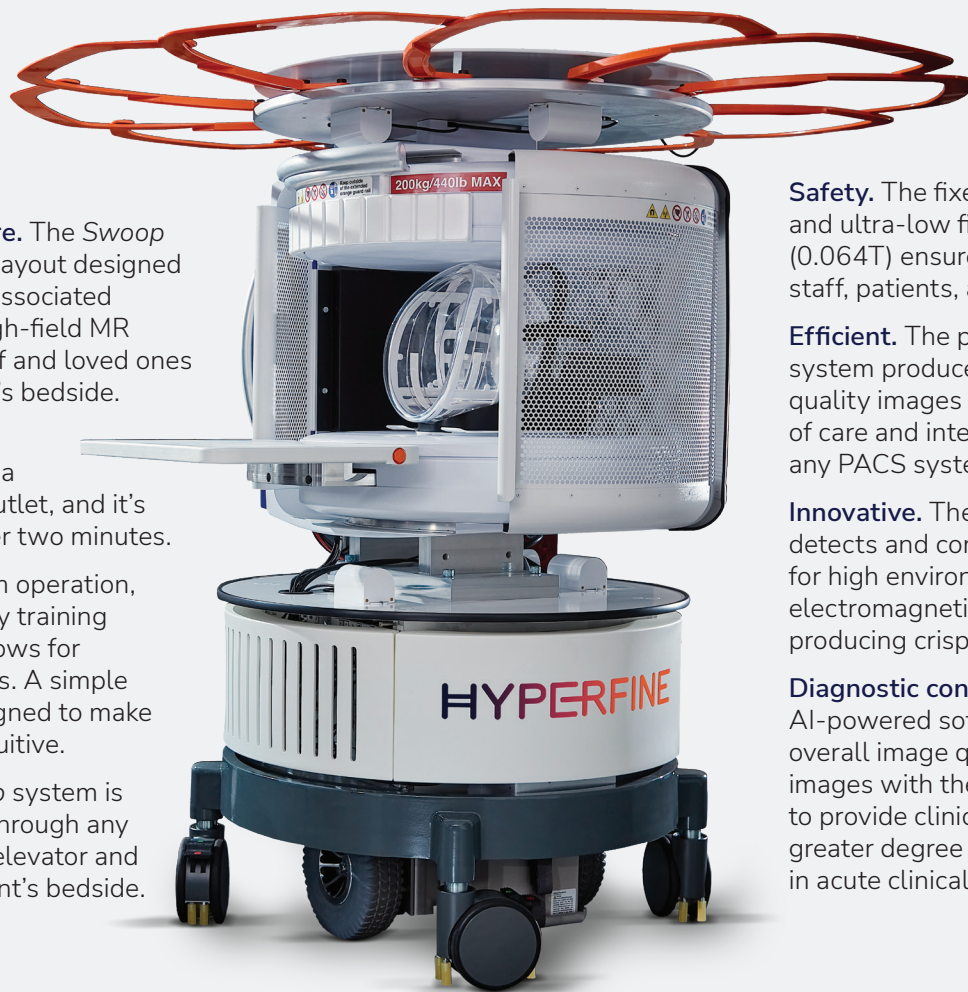
Patient-centered care. The *Swoop* system has an open layout designed to decrease anxiety associated with conventional high-field MR imaging. Clinical staff and loved ones remain at the patient's bedside.

Set up in minutes.

Plug the system into a standard electrical outlet, and it's ready to scan in under two minutes.

User friendly. System operation, navigation, and safety training are simple, which allows for expanded user access. A simple user interface is designed to make the exam process intuitive.

Portable. The *Swoop* system is easy to maneuver—through any 34-inch doorway or elevator and straight to your patient's bedside.



Safety. The fixed magnet design and ultra-low field strength (0.064T) ensure low risk to staff, patients, and loved ones.

Efficient. The portable *Swoop* system produces diagnostic-quality images at the point of care and integrates with any PACS system.

Innovative. The *Swoop* system detects and compensates for high environmental electromagnetic interference, producing crisp, clear images.

Diagnostic confidence. AI-powered software improves overall image quality to deliver images with the potential to provide clinicians with a greater degree of confidence in acute clinical diagnosis.



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Reimbursement

Reimbursement coding refers to coding classification systems and medical nomenclature. CPT codes are used by hospital outpatient departments, ambulatory surgery centers, independent diagnostic testing facilities (IDTF), and physicians to describe professional services and procedures.

Medicare reimbursement for diagnostic imaging procedures is comprised of a **professional component**, the amount paid for the physician's interpretation and report, and a **technical component**, the amount paid for all other services (including staffing and equipment costs). When combined and paid to the same individual or entity, this amount is often referred to as the total or **global reimbursement**.

| CPT Code | Description |
|----------|---|
| 70551 | Global reimbursement Magnetic resonance (e.g., proton) imaging, brain (including brain stem); without contrast material |
| 70551-26 | Professional component |
| 70551-TC | Technical component |

Swoop System Specifications

The Swoop portable MR brain imaging system can go nearly anywhere. Compact and highly portable, the Swoop system is at home in ICUs, pediatric facilities, or anywhere else you can imagine.

The Swoop system magnet is 64 mT. The system stands 59 inches tall and 33 inches wide and weighs approximately 1,400 pounds. Imaging sequences include T1, T2, FLAIR, and DWI (with ADC map)—all directed by a user interface on an iPad Pro® (included).



Regulatory Clearances

- **February 2020.** The world's first bedside magnetic resonance imaging (MRI) system, specifically for brain imaging of patients aged two and up. (US FDA K192002)
- **August 2020.** For brain imaging of all patient ages. (US FDA K201722)
- **July 2021.** Additional automatic alignment and motion correction features to the Swoop Portable MR Imaging system. (US FDA K211818)
- **November 2021.** Deep learning image reconstruction techniques that enhance the quality of T1, T2, and FLAIR images generated by a portable MRI system at a patient's bedside. (US FDA K212456)
- **June 2022.** Adds a new T1 (Standard) sequence optimized for imaging inside the brain and a new Fast T2 sequence with a shorter scan time. (US FDA K221393)
- **December 2022.** Improved DWI image quality due to increased signal-to-noise ratio. Expanded field of view for T1, T2, and FLAIR sequences. Retrained advanced reconstruction models. (US FDA K223247)
- **February 2023.** Significantly improved DWI image quality and more robust compensation for subtle patient motion. Improved noise correction and uniformity correction for all sequences. (US FDA K230208)
- **October 2023.** Adds advanced denoising for DWI image post-processing. Improved image quality for all sequences. (US FDA K232760)

View the Full List of
Hyperfine, Inc. Clearances



The Swoop Portable MR Imaging System

Hyperfine, Inc. designed the Swoop system to address the limitations of current imaging technologies and bring MR brain imaging within reach.

The Swoop system is a portable, ultra-low-field MR brain imaging system designed to be available when and where clinicians need it so they can make timelier treatment decisions and manage and monitor patients for better care and outcomes. The system provides ready access to soft tissue brain imaging vital to triage and treatment decisions—especially critical

in situations where conventional brain imaging is not practical or possible.

The Swoop system is an efficiency and cost-control platform as much as a brain imaging system. The system can extend access to diagnostic-quality MR brain imaging and help effectively triage to shorten stays and free up beds for the best use of hospital capacity as an alternative to tightly scheduled and high-cost conventional high-field MR imaging for critical care and ICU patients.

AI-powered software.

The Swoop system uses artificial intelligence algorithms to improve overall image quality and support diagnostic confidence.

1. Tablet controller. A 12.9-inch iPad Pro® mobile digital device (included) makes exam setup, scan initiation, and image export simple.

2. Power supply. The Swoop system plugs into a regular wall outlet and is ready to scan in less than two minutes. Astonishingly efficient, the system uses just 900 watts, about the same power as a coffee maker.

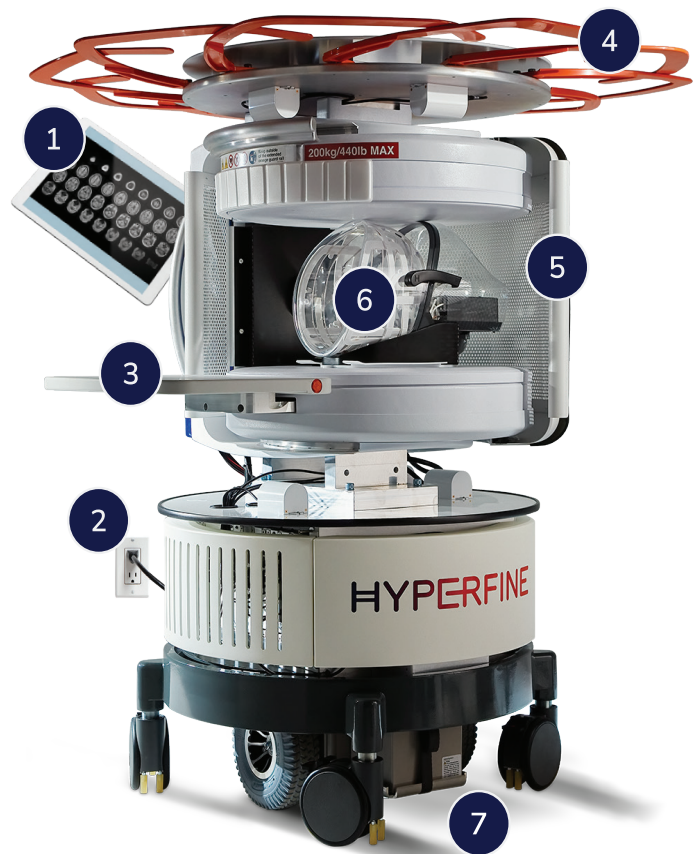
3. Transfer bridge. The transfer bridge unfolds for easy bedside patient loading. Fold the bridge back up to move the system to your next patient.

4. Gauss guard. The system assures safety with a convenient 5-gauss-line guard that quickly expands and contracts

5. Shield door. Operation requires no external shielding with built-in continuous 'noise cancellation' of electromagnetic interference and the specific design of our shield door.

6. Head coil. A multi-channel removable head coil comes encased in clear, durable, and easy-to-disinfect polycarbonate plastic.

7. Casters and joystick. The Swoop system easily moves between patients, courtesy of a joystick and powered drive wheels.



Indications for Use: The Swoop® Portable MR Imaging® system 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.

LBL-001459 v2

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