HYPERFINE

Swoop® Portable MR Imaging System™

White Paper

Clinical Use Cases for the Hyperfine Swoop Portable MR Imaging System

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Introduction

Hyperfine is a mission in the form of a company. We aim to maximize access to MR imaging. We strive to serve more patients and providers by making MR imaging portable, accessible, and easy to use. The Swoop Portable Imaging System is free from the (literal and figurative) walls surrounding MRI since its introduction over 40 years ago.

Today's Clinical Challenge

MRI (magnetic resonance imaging) uses a powerful magnetic field, radio waves, and a computer to create detailed pictures of the body's internal structures, like the brain and skull. Doctors use these images to diagnose a variety of medical conditions. However, fixed conventional MRI systems can be inconvenient and inaccessible for providers and patients, especially when time is critical. Transport to the MR suite demands complicated scheduling coordination—assembling teams of clinicians to help move and disconnect patients from ventilation, monitoring, and medications and, often, 4- to 6-hour patient backlogs. All of these complications compromise the utility of MRI as a diagnostic tool in time-sensitive settings. Furthermore, high capital investments, electrical power needs, and significant maintenance requirements present barriers to adoption across all populations, acutely so for developing countries and rural geographies.

The Hyperfine Solution

Hyperfine designed the Swoop system to address the limitations of current imaging technologies and make MRI accessible anytime, anywhere, and to any patient. The Swoop system wheels directly to a patient's bedside, plugs into a standard electrical outlet, and is controlled by an Apple iPad®. The system captures images displaying the head's internal structure, and within minutes, results are available.

Designed to complement fixed conventional MRI systems, the Swoop Portable MR Imaging System enables critical decision-making capabilities across clinical settings such as neurointensive care units, emergency departments, pediatrics, COVID units, ambulatory outpatient settings,

> "We refuse to accept barriers to accessible, equitable care, and we intend to make the previously impossible both possible and affordable by delivering MR imaging to the patient, wherever the patient is."
>
> – **Jonathan M. Rothberg,** Hyperfine Founder

and more. New user training on Swoop system operation, device navigation, and device safety is easy. What's more, the complete system costs less than the annual service contract alone for most conventional MRI systems.

"The global MRI market is on the brink of a new era as word of the once 'mythical' affordable and portable MRI spreads," commented Poornima Srinivasan, Consultant at Frost & Sullivan. "With its groundbreaking design, Hyperfine's portable MRI can extend access to cost-effective imaging and, subsequently, its clinical utility and healthcare value and settings, and geographical regions worldwide."

Regulatory Clearances

Hyperfine, Inc. has received FDA 510(k) clearances as follows:

February 2020 The world's first bedside Magnetic Resonance Imaging (MRI) system, specifically for brain imaging of patients aged two and up. (K192002)

August 2020 The category-defining portable MRI technology, the Swoop Portable MR Imaging System, for brain imaging of all patient ages. (K201722)

January 2021 Deep learning analysis software. These advanced artificial intelligence (AI) applications measure brain structure and pathology in images acquired by the Swoop system through tools featuring automatic measurement of ventricular volume, brain extraction, brain alignment, and midline shift—a clinical measure of brain injury. (K202414)

July 2021 Additional automatic alignment and motion correction features to the Swoop Portable MR Imaging System. Automatic alignment provides images in standard anatomical orientation, regardless of the patient's physical orientation. Motion correction detects and reacquires diffusion-weighted images (DWI) data if corrupted by motion. (K211818)

Use Cases for the Swoop Portable MR Imaging System

Presented here are several potential use cases for the Swoop Portable MR Imaging System. Please note that these do not represent all possible applications of this technology.

Acute Mental Status Change in an ICU Setting

Acute altered mental status refers to the sudden onset of a change in cognitive function or level of consciousness (Douglas and Josephson, 2011). Reports of the incidence of delirium in patients in intensive care range from 11–82% (Sutter and Stevens, 2013). While many patients are often comatose when admitted to intensive care, one study showed that 10% of patients not comatose upon admission went on to develop coma during their stay (Sutter and Stevens, 2013).

The current standard of care for acute mental status change in an ICU setting is clinical observation and/or CT (portable or fixed) or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care of acute mental status change in an ICU setting, providing rapid point-of-care identification of the underlying pathology (i.e., intraparenchymal and/or intraventricular hemorrhage, new mass lesions, extra-axial hematoma/collection, or stroke).

"Low-field, portable MRI can be deployed successfully into intensive care settings. This approach may hold promise for portable assessment of neurological injury in other scenarios, including the emergency department . . . and resource-limited environments," said Kevin Sheth, MD, Professor of Neurology and Neurosurgery; Executive Director of the NNCTU and Vice-Chair for Clinical and Translational Research in the Departments of Neurology and Neurosurgery; Vice-Chair, Clinical & Translational Research, Neurology & Neurosurgery; Division Chief, Neurocritical Care and Emergency Neurology.

Post-Op Hematoma

A hematoma is a collection of blood due to an injury of one or more blood vessels. Postoperative intracranial hematomas are a potentially severe complication of intracranial surgery (Fukamachi et al., 1986; Chung et al., 2015). These may result in a significant mass effect and the potential for midline shift (MLS) and herniation.

Epidural hematoma (EDH) can occur after intracranial surgery, with a reported incidence of approximately 1% (Chung et al., 2015). Although hematomas are relatively rare after intracranial surgery, published mortality rates range from 13–41% (Bullock et al., 1990; Kalfas and Little, 1988; Gerlach et al., 2004; Palmer et al., 1994).

The current standard of care for post-op hematoma is CT (portable or fixed) or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for postoperative hematoma, providing rapid point-of-care identification along with an assessment of mass effect and surrounding edema along with the ability to characterize tissue changes.

"MRI is widely used as a follow-up exam for unrevealing CT examinations due to its superior contrast resolution, which is essential in diagnosing acute ischemia, encephalitis, and mass lesions. In a group of critical care patients who had both MRI and CT examinations, MRI revealed clinically relevant findings that would have been missed with CT, including ischemia, subtle hemorrhagic lesions, sequelae of trauma, infection, and metabolic findings," said Daniel Chow, MD, Co-Director, Center for Artificial Intelligence in Diagnostic Medicine, Radiological Sciences School of Medicine; Assistant Professor-in-Residence, Radiological Sciences School of Medicine; Co-Director, Precision Health through Artificial Intelligence (PHAI) School of Medicine.

Acute Intraparenchymal Hematoma

An acute intraparenchymal hematoma (IPH) is a collection of blood in the tissue of the brain presenting with a sudden onset of symptoms. It can be caused by various underlying conditions, including but not limited to hypertension, tumors, vessel malformations, and trauma (Tenny and Thorell, 2020). Acute IPHs cause 10–20% of strokes, and an increase in incidence is associated with age (Tenny and Thorell, 2020).

The current standard of care for acute intraparenchymal hematoma is CT (portable or fixed) or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for acute intraparenchymal hematoma. The system provides rapid point-of-care identification of intraparenchymal hematomas and the assessment of mass effect and edema upon the surrounding tissue.

Extra-axial Hematomas

A subdural hematoma (SDH) is a collection of blood located between the dura and the arachnoid. These are the two outermost layers of the three meningeal layers surrounding the brain. SDHs typically result from ruptured bridging veins, which travel from the brain's cortical layer through the meninges to drain into the superior sagittal sinus. SDHs can compress the brain, increasing intracranial pressure, and can be life-threatening if not treated quickly. The occurrence of acute SDHs following severe head injury ranges from 5–25%, and the mortality rates range from 36–79% (Karibe et al., 2014). Acute SDHs result from trauma to the head, causing blood to accumulate and intracranial pressure to increase quickly, whereas chronic SDHs result from the slow accumulation of blood over time. Chronic SDHs typically occur more often in older populations and often occur from much less severe trauma to the head than acute SDHs. Chronic SDHs also typically present without the presence of acute blood but rather more CSF-like fluid. There is a high success rate for effectively treating chronic SDHs; however, it is difficult to diagnose without clinical imaging (Yang and Huang, 2017).

An epidural hematoma (EDH) is a collection of blood located between the skull and the dura, the outermost meningeal layer. EDHs typically result from a skull fracture tearing an underlying blood vessel. Like SDHs, EDHs can be life-threatening if not treated quickly. EDHs occur in approximately 10% of traumatic brain injuries (TBIs) that require hospitalization, and the mortality rate is approximately 15% (Khairat and Waseem, 2021). However, with quick diagnosis and treatment, patients with EDHs typically have an excellent prognosis.

The current standard of care for SDHs and EDHs is CT (portable or fixed) or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for subdural hematoma, providing rapid point-of-care identification of extra-axial collections along with the mass effect, if any, upon the underlying brain parenchyma. In addition, the unique portability of the system allows for closer

continued follow-up without burdens placed upon institutional conventional high field scanners of ancillary staff.

Hydrocephalus De Novo

Hydrocephalus is the buildup of CSF (cerebrospinal fluid) in the cerebral ventricles. This buildup leads to increased ventricle size and a subsequent increase in intracranial pressure (Rekate 2009). Caused by an obstruction of the normal flow or an issue with normal absorption of CSF into the venous system, hydrocephalus in adults is often secondary to other pathologies (Bergsneider et al., 2008). Hydrocephalus can occur at any age; however, it occurs most frequently in infants and adults over 60 years of age, with an incidence rate of 17 per 100,000 adult patients (Bir et al., 2016). Without prompt treatment, acute hydrocephalus can lead to brain herniation and death (Koleva and De Jesus, 2021); therefore, timely diagnosis and treatment are of great importance.

The current standard of care for hydrocephalus is CT or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care of hydrocephalus de novo by providing a rapid point-of-care diagnosis of alterations in ventricular size. Additionally, Swoop provides automated calculation of ventricular volumes in adult patients via Hyperfine's advanced AI applications in patients over the age of 18.

Hydrocephalus Follow-Up

Depending on the underlying cause of hydrocephalus, long-term follow-up is often needed. Although the mortality rate for children with hydrocephalus is highest in the first few years after treatment with a shunt, hydrocephalus-related deaths can occur decades after initial treatment (Gmeiner et al., 2017). Shunts have a relatively high failure rate (10–20%), especially within the first year after insertion (Kazemi et al., 2007). Pediatric hydrocephalus has a mortality rate ranging from 0–3%, depending on the length of follow-up (Vinchon et al., 2012).

Various imaging modalities assess shunt failure (Khalatbari and Parisi, 2021). Plain-film x-ray and CT currently used to monitor shunts raise concerns over the cumulative effects of repeated exposure to ionizing radiation (Smyth et al., 2008). Fixed conventional high-field MRI is an alternative; however, the exams are costly and may require sedation and disrupt the scanner's busy and tight schedule. Fast scanning protocols for use with high field systems have recently been employed, potentially obviating the need for sedation.

The current standard of care for hydrocephalus follow-up is CT or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care of hydrocephalus follow-up by providing a rapid point-of-care diagnosis of alterations in ventricular size. Additionally, Swoop provides automated calculation of ventricular volumes in adult patients via Hyperfine's advanced AI applications. These applications also allow for easy comparison of volume changes over time.

Midline Shift

Midline shift (MLS) is the lateral distortion of the midline structures of the brain due to any lesion that exerts an asymmetric mass effect on the brain parenchyma. There is a relationship between the extent of MLS and outcome in patients with traumatic brain injury (Jacobs et al., 2011; Puffer et al., 2019). The presence of MLS is associated with increased intracranial pressure, which may lead to reduced cerebral perfusion (Lipper et al., 1985; Lobato et al., 1988; Quattrocchi et al., 1991; Ross et al., 1989; Young et al., 1981; Maas et al., 2005).

The current standard of care for a midline shift is CT or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for midline shift, making possible rapid point-of-care identification along with automated calculation via Hyperfine's advanced AI applications.

Mass Lesion

Mass lesions are pathological processes resulting from various pathologies, including infections (abscess) and brain tumors (benign or malignant). Mass lesions are often visible on MR and CT images, and lesion features assist in the differential diagnosis process. Brain and central nervous system tumors occurred at an incidence of 23.8 per 100,000 in the United States between 2013–2017, with approximately one-third being malignant (Ostrom et al., 2020). Although they occurred at a lower rate in children (6.1 per 100,000), roughly two-thirds of the brain and CNS tumors in children were malignant (Ostrom et al., 2020). Brain abscesses

account for approximately 8% of intracranial mass lesions in developing countries and 1 to 2% in developed countries (approximately 0.4 cases per 100,000) (Osenbach and Loftus 1992; Sharma et al., 2000).

The current standard of care for a mass lesion is CT or fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care of mass lesions by providing rapid point-of-care identification using non-contrast studies. This new standard of care allows for visualization of both vasogenic and infiltrative surrounding edema.

Large Vessel Occlusion (LVO) Stroke

Large vessel occlusions (LVOs) include acute blockages of the intracranial internal carotid artery (ICA), proximal middle, anterior, and posterior cerebral arteries (MCA, ACA, and PCA, respectively), intracranial vertebral artery (VA), and basilar artery (BA) (Malhotra et al., 2017; Dozois et al., 2017; Rai et al., 2017). Quick identification of LVOs is vital for management decisions and outcomes. LVOs are responsible for anywhere between 24–46% of acute ischemic strokes (AISs) (Malhotra et al., 2017; Dozois et al., 2017; Smith et al., 2009). The presence of an LVO results in a 4.5-fold increase in the risk of death (Smith et al., 2009). LVOs cause roughly one-third of acute AISs. However, LVOs account for a disproportionate rate of dependency (60%) and mortality (90%) after AIS (Malhotra et al., 2017).

The current standard of care for LVO stroke is CT with angiography (CTA) ± perfusion (CTP) or fixed conventional MRI ± perfusion (MRP). The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for LVO stroke, making possible rapid point-of-care identification of diffusion abnormalities for mechanical thrombectomy decisions.

"Hyperfine provides a compact, mobile, truly portable, and self-shielding MRI that can acquire excellent images in the most demanding clinical environments, including ICU patients on ventilators and multiple monitoring devices. My team and I found the MRI invaluable in diagnosing ischemic and hemorrhagic strokes in critically ill patients (located in 7 different ICUs) during the peak of the COVID crisis. A Swoop Portable MR Imaging System is now permanently stationed in our neurosurgical ICU. Our early results in a comparative study show excellent concordance between Swoop at 0.064 T and images acquired at 1.5 T!" –Michael Schulder, MD, FAANS, Professor and Vice-Chairman, Department of Neurosurgery, Zucker School of Medicine at Hofstra/Northwell.

Stroke Follow-Up

Patients with recurrent ischemic stroke are at increased risk of additional infarcts, disability, and mortality (Sacco et al., 1997; Jørgensen et al., 1997); therefore, serial follow-up is necessary after the initial presentation of ischemic stroke. In one study, 30% of ischemic stroke patients demonstrated silent new ischemic lesions (SNILs) within 90 days of initial presentation (D. W. Kang et al., 2004). FLAIR images and DWIs acquired at 1.5 T five and 30 days after patients presented with ischemic stroke could predict subsequent recurrent ischemic stroke and vascular events (Kang et al., 2016).

The current standard of care for stroke follow-up is fixed conventional MRI, which is more accurate than CT at detecting chronic ischemic stroke (Kidwell et al., 2004). The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for stroke follow-up, making possible rapid point-of-care identification of chronic lesions on FLAIR/T2 scans.

Acute Small Lacunar Type Infarct (<5mm)

Lacunar infarcts are small regions of dead tissue in the deep cerebral white matter, basal ganglia, or pons caused by a lack of blood supply resulting from occlusion of perforating arteries that supply these subcortical areas of the brain (Bamford and Warlow, 1988). One-fourth of all ischemic strokes and one-fifth of all strokes are of lacunar type (Sudlow and Warlow 1997). Lacunar strokes have long-term effects, leaving approximately 30% of patients dependent (Bamford et al., 1991).

The current standard of care for acute small lacunar type infarct is fixed conventional MRI as CT is less sensitive (He et al., 2018). The efficacy of using the Swoop Portable MR Imaging System to diagnose acute small lacunar top infarct (less than 5mm) is indeterminate at this time.

Chronic Small Lacunar Type Infarct

Lacunar infarcts are small regions of dead tissue in the deep cerebral white matter, basal ganglia, or pons

caused by a lack of blood supply resulting from occlusion of perforating arteries that supply these suwsis for patients presenting with lacunar type infarcts is much better than those with non-lacunar type. However, after five years, the recurrence and mortality rates are similar (Venkataraman et al., 2021).

The current standard of care for chronic small lacunar type infarct is fixed conventional MRI. The Hyperfine Swoop Portable MR Imaging System presents new paradigms in the standard of care for chronic small lacunar type infarct, making possible rapid point-of-care identification of lesions on FLAIR/T2 scans.

Subarachnoid Hemorrhage

Subarachnoid hemorrhage (SAH) is bleeding that occurs within the brain's subarachnoid space due to a ruptured vessel (Tenny and Thorell, 2020). The subarachnoid space is filled with cerebrospinal fluid (CSF) to provide cushioning for the brain. Blood mixing with the CSF can irritate the cerebral vasculature vasa vasorum leading to potentially life-threatening vasospasm. SAH causes approximately 5% of strokes (Tenny and Thorell, 2020).

The current standard of care for subarachnoid hemorrhage is CT. While MRI can be used to identify subarachnoid hemorrhage, it requires advanced MR sequences (e.g., T2*-weighted) and has lower sensitivity than non-contrast CT (Mitchell et al., 2001). The sequences available on the Hyperfine Swoop Portable MR Imaging System are relatively insensitive to SAH (Mitchell et al., 2001). Therefore, clinicians should not use the system when SAH is suspected.

"At the current point of time, The Hyperfine Swoop Portable MR Imaging System does not have a role in the setting of establishing a diagnosis of subarachnoid hemorrhage," says Edmond Knopp, MD.

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About Hyperfine

The Hyperfine Swoop Portable MR Imaging System addresses limitations of current imaging technologies and makes MRI accessible anytime, anywhere, to any patient. The game-changing system wheels to a patient's bedside, where it plugs into a standard electrical outlet and uses an Apple iPad® for control. Images display within minutes, enabling critical decision-making capabilities across various clinical settings. Designed as a complementary system to fixed conventional MRI, new users can quickly train on system operation, navigation, and safety. The complete Swoop system costs less than the annual service contract for most fixed conventional MRI systems.

In August 2020, the Swoop system received market-ready FDA clearance for portable MR imaging of the brain and head for patients of all ages. In January 2021, it received additional clearance for its Advanced AI Applications image analysis software.

Leading organizations have recognized the Swoop system as one of the most innovative health care technologies available today. Fast Company magazine recognized the system as a 2021 World Changing Idea honoree in two categories. MD+DI awarded the Swoop system a gold Medical Design Excellence Award. Swoop won the ACEP 2020 incubatED Medical Device Innovation Challenge as a solution that will shape the future of emergency medicine. Fierce Medtech recognized Hyperfine as a 2020 Fierce 15 company. Aunt Minnie named Hyperfine as one of two 2020 finalists for Best New Radiology Vendor. Hyperfine also received the Best Practices Product Innovation Award from Frost & Sullivan, who described disruptive Swoop technology as a "massive leap forward to democratizing MRI." CES 2021 selected the system as an Innovation Awards Honoree.