HYPERFINE. **Swoop**[®] Portable MR Imaging System[™] White Paper

The Clinical and Business Value of Portable Point-of-Care MRI

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Abstract

A new portable, point-of-care MRI system (the Swoop Portable MR Imaging System) addresses the clinical risks, logistical challenges, and high costs associated with conventional hospital MRI scanning for some patients. Research installations and commercial users are now observing real-world results. Based on those early results, operational modeling, and published research, a robust benefit theory indicates that Swoop supports a solid clinical and business case.

History of MRI

The introduction of commercial magnetic resonance imaging (MRI) devices in the early 1980s represented a significant step forward in clinical imaging. MRI is superior to other imaging technologies in its ability to show soft tissues at high resolution; it is also safer since, unlike CT scanning, it does not involve cancer-causing ionizing radiation.^{1, 2}

Over the past four decades, researchers and vendors have competed to introduce high-field MRI scanners with increasingly powerful magnets and better imaging techniques, along with more sophisticated software to process the massive images they produce.

As magnets and machinery became increasingly powerful, they grew in size and complexity. Today, top-of-the-line 3 Tesla machines cost over \$3 million to purchase plus hundreds of thousands more for the

1. What are the Radiation Risks from CT? (2018, November 3). FDA. <u>https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/what-are-radiation-risks-ct</u>

"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

Deck, M. D. F. et al. (1989). Computed tomography versus magnetic resonance imaging of the brain a collaborative interinstitutional study. Clinical Imaging, 13(1), 2–15. <u>https://doi.org/10.1016/0899-7071(89)90120-4</u>

construction required to house the device.³ With patient support areas and installation costs included, bringing just one MRI scanner online can cost over \$5 million.

Operating an MRI scanner requires crews of trained staff, which along with maintenance on the MRI machine, dedicated facilities, and administrative support, cost approximately half a million \$USD annually.⁴ Despite these costs, the clinical advantages of MRI have led to increased demand. Growing demand and the high cost of MRI purchase and installation have led to a capacity crunch in many hospitals. Hyperfine customers report typical waits to schedule and perform a conventional MRI scan of 4 to 10 hours, with some hospitals seeing delays as long as 24 to 48 hours for ICU patients.

Transportation of patients from the emergency department, intensive care units, and other hospital and ambulatory locations to the MRI is a significant logistical challenge with inherent potential risks to the patient. Transport from these locations often involves transferring patients off multiple devices (e.g., ventilator, IV pumps, EKG) and requires nursing, respiratory therapist, anesthesia, and other staff to provide support during transportation and in the MRI suite. Clinicians must then reverse the procedure upon completion of the imaging study. We estimate a typical MRI patient transport costs \$200 or more in staff time alone.⁵

Patient transportation to the MRI, especially from the ICU, is also a clinical risk. The operational and clinical disruptions described above frequently result in adverse events (AE), including cardiac rapid response, tube/line positioning issues, adverse drug events, magnet-related events, and new medication (e.g., sedation) requirements. Study results vary, several papers report transportation-related AE rates of 26 to 79 percent and hospital-borne AE costs of at least \$2,000.^{6,7,8,9,} ¹⁰ Not only is it risky to move the patient, but the time away from therapy and other care extends ED, ICU, and overall hospital lengths of stay and increases costs.

A New, Portable Alternative MRI

Clinicians can address these challenges for many patients with a new, portable, ultra-low-field MRI scanner (the Swoop Portable MR Imaging System). This scanner has a .064 Tesla magnet (versus 1.5 Tesla for most conventional MRIs). In addition, the system design includes a motorized platform that drives easily through hospital corridors, elevators, and patient care areas.

Portable, bedside MRI has many potential advantages, including:

- Elimination of the need to transport patients to and from a fixed conventional MRI system
- A quieter and less intimidating experience for some (e.g., children, claustrophobics); supporters can be present for scans, reducing anxiety, need for sedation, and improving patient experience
- Shorter overall cycle times, from ordering an MRI until there are results reported
- Superior soft tissue image resolution and diagnostic accuracy over non-contrast CT
- Reduced clinical risks and adverse events compared to CT or fixed conventional MRI for certain types of patients
- Much lower costs than fixed conventional MRI, requiring no special rooms, construction, power supply, cooling, and fewer safety measures and staffing requirements
- Significant ease of operation compared to fixed conventional MRI—any clinician or approved health-care professional can safely operate the system

10. Mello, M. M. et al. (2007). Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement. Journal of Empirical Legal Studies, 4(4), 835–860. https://doi.org/10.1111/j.1740-1461.2007.00108.x

^{3.} Glover, L. Why does an MRI cost so darn much? First Look MRI. Retrieved June 18, 2021, from https://www.firstlookmri.com/doctors-notes/cost-mri.html

^{4.} How Much Does it Cost to Operate an MRI? Retrieved June 18, 2021, from http://proimagingservices.com/wp-content/uploads/2014/10/How-Much-does-it-Cost-to-Operate-an-MRI.pdf

Hyperfine estimate based on staff time involvement reported by customers and national labor rates. Calculated using the Swoop Benefit Estimation Templates (BET).
Jia, L. et al. (2016). High incidence of adverse events during intra-hospital transport of critically ill patients and new related risk factors: A prospective, multi-

center study in China. Critical Care (London, England), 20, 12. <u>https://doi.org/10.1186/s13054-016-1183-y</u>

^{7.} Smith, I. et al. (1990). Mishaps during transport from the intensive care unit. Critical Care Medicine, 18(3), 278–281. <u>https://doi.org/10.1097/00003246-199003000-00006</u>

Martin, M. et al. (2017). Secondary Insults and Adverse Events During Intrahospital Transport of Severe Traumatic Brain-Injured Patients. Neurocritical Care, 26(1), 87–95. <u>https://doi.org/10.1007/s12028-016-0291-5</u>

^{9.} Parmentier-Decrucq, E. et al. (2013). Adverse events during intrahospital transport of critically ill patients: Incidence and risk factors. Annals of Intensive Care, 3(1), 10. https://doi.org/10.1186/2110-5820-3-10

More details and references about these potential advantages are provided below.

Based on early customer experience with portable MRI use, published studies, and engineering models, we believe that the primary operational and business benefits to hospitals include:

- Increased MRI scan volumes and revenues
- Shorter Emergency Department lengths of stay and cost reductions
- Shorter ICU lengths of stay and cost reductions
- Avoidance of transportation risks and costs
- Potential to extend treatment window for stroke patients and increased treatment revenues

Increased MRI Scan Volumes

Lengthy waits to get a fixed conventional MRI due to high demand and long transport times mean that MRI is not a viable alternative for some patients who could benefit from this imaging modality. On the other hand, clinicians can complete portable point-of-care MRI imaging many hours faster, leading to additional revenues from more convenient bedside scans.¹¹ In addition, perhaps ten to twenty percent of current fixed conventional MRI scans could instead be performed on a portable MRI, freeing conventional MRI system capacity for additional highly reimbursed outpatient scans.¹²

Emergency Department Length of Stay & Cost Reductions

Emergency Departments (EDs) are often near capacity, with long patient wait times. Not only does this represent poor customer service, but it is also a clinical risk. Busy EDs go on diversion, and some patients leave without being seen, representing lost visit revenues and potential hospital admissions.

Based on early customer experience, portable, point-ofcare MRI results are available in the ED at least 3 to 5 hours faster than fixed conventional MRI results.¹³ Thus, avoiding MRI-related delays should lead to faster diagnosis and more timely treatment, reduce ED lengths of stay, shorten wait times, and improve the patient experience. An hour in the ED costs at least \$58, according to one study;¹⁴ therefore, reducing ED length of stay by three hours for one patient would save \$174.

Suppose an ED is at capacity and experiencing admission delays, diversion, and patients leaving without being seen. In that case, a three-hour length of stay reduction opens an admission slot for an additional paying patient. This additional ED patient would generate \$400 in patient revenue at typical rates.¹⁵ For the 26 percent of those patients (the national average)¹⁶ admitted to the hospital, an additional \$4,000 of new patient revenue would be received.

Hospital LOS and Cost Reductions

Hospital ED waits for conventional MRI can be long, but typically ICU waits are even longer. Hyperfine customers and prospects report that MRI delays for ICU patients are often double those in EDs, commonly 6 to 10 hours, with some reporting over 24 hours.¹⁷ MRI-related delays and transportation result in discontinued therapy, take patients out of an ideal therapeutic environment, and add to ICU lengths of stay. Given the high cost of ICU care (\$300 per hour according to one study),¹⁸ a five-hour reduction in ICU length of stay for one patient would save a hospital \$1,500.

In addition, faster MRI turnaround times for discharge orders conditional on a negative MRI scan would allow earlier patient discharge, and in some cases, save up to a day of care.

Transportation Safety Improvements & Cost Reductions

As previously noted, transporting a patient from the ED, ICU, or another hospital unit to the fixed conventional MRI system is a time-consuming undertaking,

17. Customer data on file at Hyperfine.

^{11.} Based on Hyperfine customer interviews.

^{12.} Based on Hyperfine customer presentation during a Becker's Healthcare webinar titled Frictionless Imaging, dated April 27, 2021.

^{13.} Customer data on file at Hyperfine.

^{14.} Schreyer, K. E. & Martin, R. (2017). The Economics of an Admissions Holding Unit. Western Journal of Emergency Medicine, 18(4), 553–558. <u>https://doi.org/10.5811/westjem.2017.4.32740</u>

^{15.} ROI Calculator. Retrieved June 18, 2021, from https://www.studergroup.com/special/roi-calculator

^{16.} Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. ACEP Now. Retrieved June 18, 2021, from <a href="https://www.acepnow.com/article/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/latest-da

^{18.} Gyldmark, M. (1995). A review of cost studies of intensive care units: Problems with the cost concept. Critical Care Medicine, 23(5), 964–972. <u>https://doi.org/10.1097/00003246-199505000-00028</u>

with an inherent risk of adverse events (AE). Eliminating MRI transport could avoid AEs and save \$2,000 each for 26 to 79 percent of transported patients. In addition, avoiding patient transportation to the conventional MRI scanner would save \$200 or more in staff costs for each of those same patients—both according to our previously cited references.

Extending the Treatment Window

For patients that arrive in the emergency department with stroke indications, time is of the essence. Most hospitals use a 4.5-hour "window" from the onset of stroke symptoms during which clinicians can safely provide clot-busting therapy (thrombectomy or thrombolysis (tPA)). More recent (2019) guidelines from the American Heart Association (AHA) and American Stroke Association (ASA) indicate that healthcare providers could potentially extend that window.¹⁹ However, making that decision often requires rapid MRI results. Portable, point-of-care MRI may give enough information fast enough to allow additional life-saving treatments for some patients. Medicare and other payers also reimburse hospitals a substantially higher rate if those treatments are provided.

Conclusion

The point-of-care Swoop Portable MR Imaging System offers potentially significant clinical and operational value, particularly in hospital emergency and intensive care departments. Potential benefits include:

- Increased MRI scan volumes and revenues,
- Shorter ICU and Emergency Department lengths of stay and cost reductions,
- Avoidance of transportation risks and costs, and
- The potential to extend the treatment window for stroke patients and increase treatment revenues.

19. Powers, W. J. et al. (2019). Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. https://doi.org/10.1161/STR.00000000000211

Acknowledgment

Thank you to Devin Zell and Lori Arlinghaus for their assistance.

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.

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