



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEV DUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 25, 2025

Jeffery Shovelin
jshoveli@ecuhealth.org

Exempt from Review

Record #: 4757
Date of Request: April 4, 2025
Facility Name: ECU Health Medical Center
FID #: 933410
Business Name: Pitt County Memorial Hospital, Incorporated
Business #: 1443
Project Description: Acquire two portable MRI scanners solely for research
County: Pitt

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-179(a). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Gregory F. Yakaboski
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

April 4, 2025

Ms. Micheala Mitchell
Chief, Healthcare Planning and Certificate of Need
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

FILED ELECTRONICALLY

RE: Request for Exemption Pursuant to G.S. 131E-179 / Pitt County Memorial Hospital, Inc., d/b/a ECU Health Medical Center / Acquire Two (2) Portable MRI Scanners for Research Activity / Pitt / FID #: 933410

Dear Ms. Mitchell,

Pitt County Memorial Hospital, Inc., d/b/a ECU Health Medical Center (hereinafter EHMC) plans to acquire two Hyperfine Swoop Portable MR Imaging Systems. The total cost of each system is \$461,188. Because they are portable, there is no construction or renovation required. EHMC plans to use the portable MR imaging scanners in a research capacity only to evaluate the possible clinical applications and patient outcomes for ED patients, pediatric patients requiring sedation, and patients in the neurosciences ICU. EHMC believes that because the equipment will only be used for research purposes, the proposed portable MR imaging systems are not subject to review under GS 131E-179. Specifically, GS 131E-179 Research Activities states:

- a) *Notwithstanding any other provisions of this Article, a health service facility may offer new institutional health services to be used solely for research or incur the obligation of a capital expenditure solely for research, without a certificate of need, if the Department grants an exemption. The Department shall grant an exemption if the health service facility files a notice of intent with the Department in accordance with rules promulgated by the Department and if the*

The Hyperfine Swoop Portable MR Imaging system (hereinafter "Swoop system") is the world's first portable MR imaging system capable of providing neuroimaging at the point of care, allowing for the timely diagnosis and treatment of acute neurological conditions within a broad range of clinical settings. Unlike traditional high-field MRI scanners (1.0T, 1.5T, etc.), the Swoop system is a 0.064T (or 64mt) brain-only, without contrast, MR imaging system. While it does not and cannot function as a traditional MRI (see attached comparison and vendor information), the Swoop system is technically classified as one under GS 131E-176 (14m) because of its use of nuclear magnetic resonance technology. As such, Swoop would be considered a new institutional health service under GS 131E-176 (16)(f1)(7).

The Swoop system is a relatively new technology. There are currently no portable MRI systems operating in NC. EHMC's proposal would be the first. As with any newly emerging technology, EHMC, as a tertiary academic medical center, would like to evaluate the possible clinical applications and associated impacts on patient quality and outcomes of this new imaging modality. To evaluate future applications and uses, EHMC is proposing to acquire two Swoop systems for the hospital and use the equipment in a research capacity only to test its capabilities, functionality, results, and outcomes. EHMC will initially focus on three specific patient populations for this research activity. These specific patient populations include:

1. Initial assessment of the severity of head trauma patients with pacemakers, implants, and/or other metal foreign objects.
2. Pediatric patients needing a head MRI that today also require sedation
3. Serial monitoring of recovery progress of acute stroke patients in an ICU.

NOTE: Swoop will not replace traditional MRI scans in the diagnosis and treatment of patients. It will be used in conjunction with it.

b) Department finds that the offering or obligation will not:

- 1) *Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;*

As stated above, EHMC will be using the Swoop systems for research activity only. As a result, EHMC will not charge the patient for any portable MR scans performed on the proposed equipment. Therefore, the proposed project will not affect the patient charges for the provision of medical or other patient care services.

- 2) *Substantially change the bed capacity of the facility; or*

The Swoop systems will have no impact on the bed capacity of EHMC.

- 3) *Substantially change the medical or other patient care services of the facility.*

As stated above, the Swoop systems will not replace traditional MRI scans in the diagnosis and treatment of patients. It will be used in conjunction with it. Therefore, the proposed project will not substantially change the medical or other patient care services offered by EHMC.

- c) *After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, in a manner which affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining a certificate of need from the Department; provided, however, that any facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.*

Upon approval of this exemption, EHMC will continue to operate the Swoop systems solely for research purposes only and will not charge for any MRI scans performed on the equipment. If/when it is determined through its research activity that there are proven clinical benefits and the technology has valid applications for the provision of medical or other patient care services, EHMC will obtain the appropriate certificate of need (CON) approvals to do so. EHMC will maintain the Swoop system as research activity only with no impact on patient charges until such time approvals are granted.

d) Any of the activities described in subsection (a) of this section shall be deemed to be solely for research even if they include patient care provided on an occasional and irregular basis and not as a part of the research program.

EHMC affirms that all MRI scans performed on the Swoop systems will be solely for research purposes even if they include patient care provided on an occasional and irregular basis and not as a part of the research program.

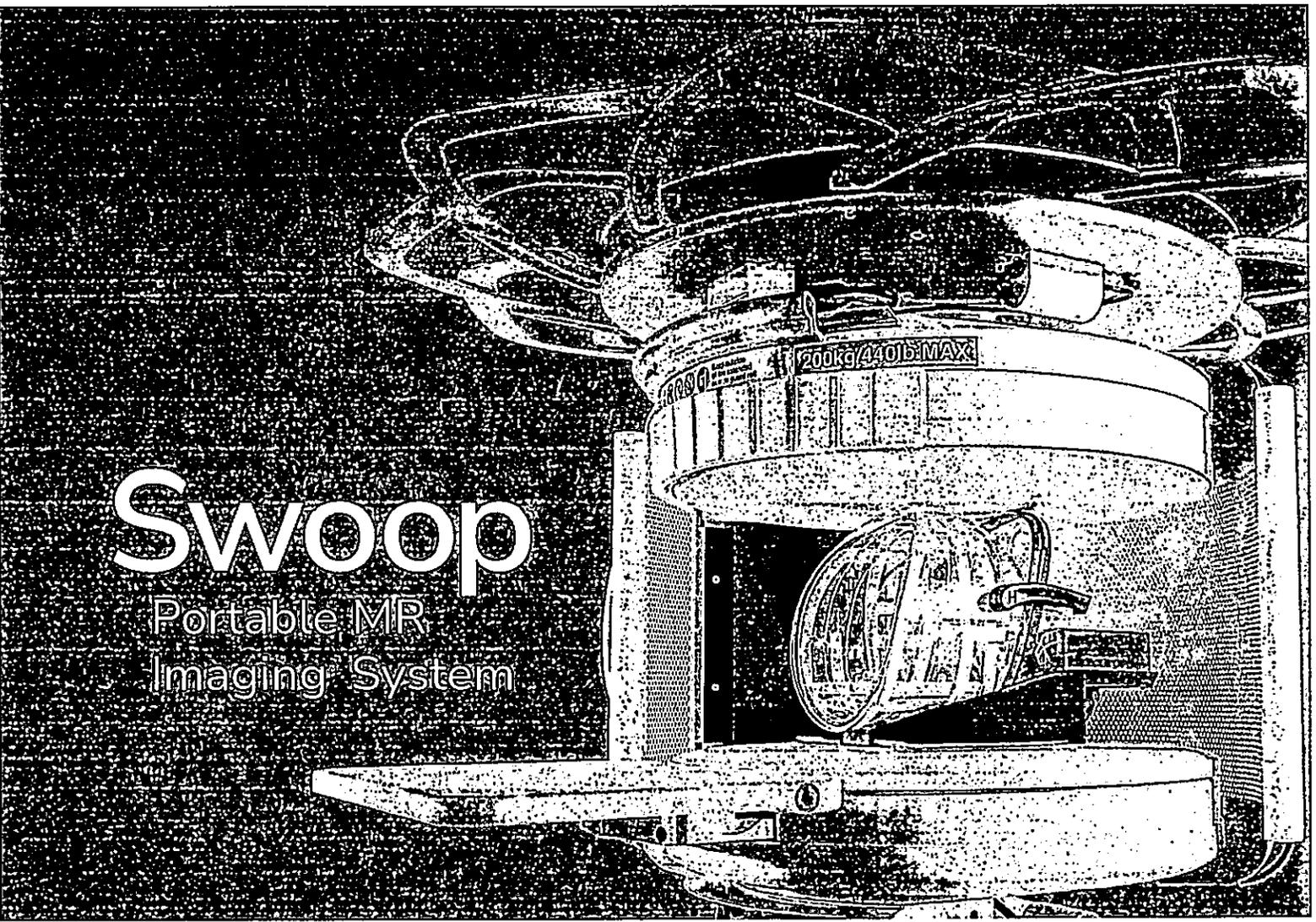
Since the proposal meets the definition of "Research Activity" as defined in GS 131E-179, EHMC believes the project is exempt from CON review. Therefore, EHMC requests approval of an exemption status for the proposed project.

If you require additional information or clarification, please contact me at (252) 847-3631 or jshoveli@ecuhealth.org.

Thank you.


Jeffrey Shevelin

VP of Business Planning and Strategy, ECU Health
PO Box 6028, Greenville NC 27835-6028
252-847-3631
jshoveli@ecuhealth.org



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

HYPERFINE.

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®

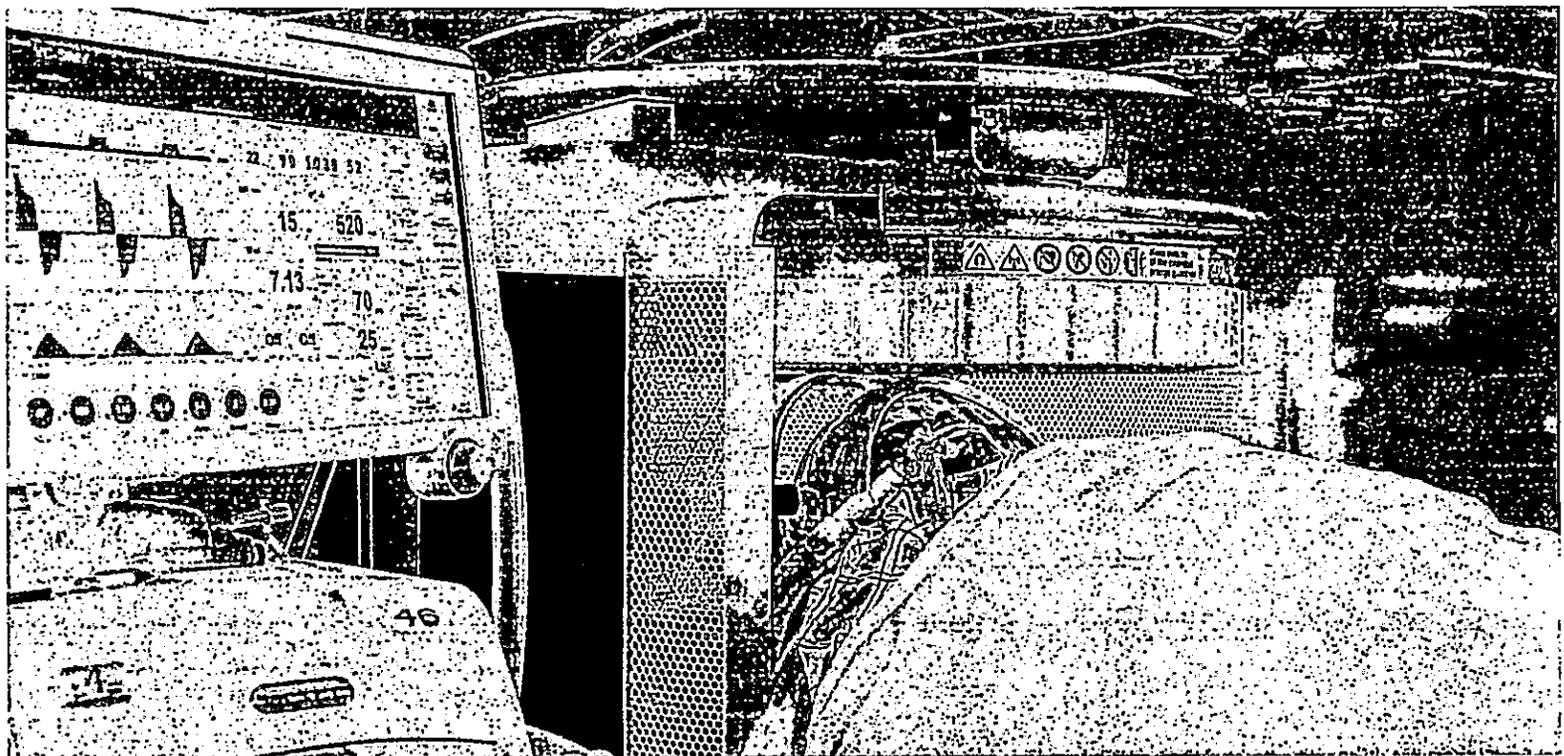
mobile digital device, the operator can initiate a scan and generate, display, and export images of the brain within minutes—offering clinicians workflow efficiencies with the potential to impact critical decision-making without transporting the patient away from the point of care.

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***



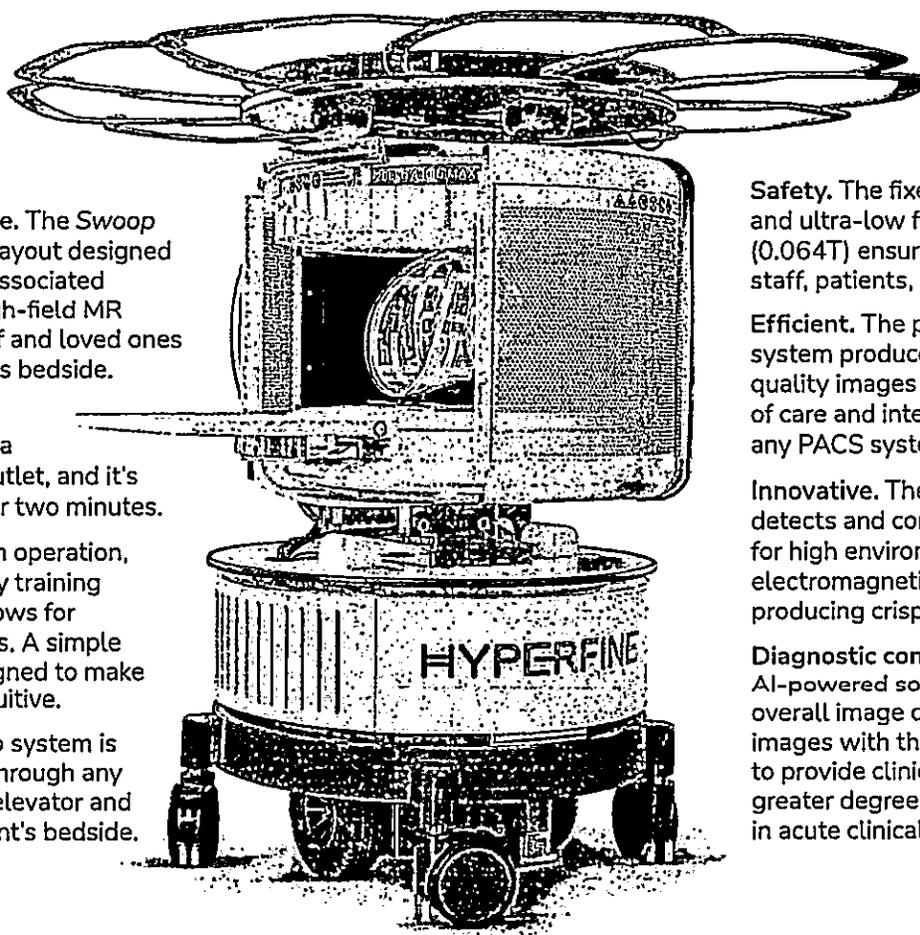
The Swoop Portable MR Imaging System

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.



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.



Review Sample Case Images



Review Selected Publication Highlights



View List of Hyperfine, Inc. Clearances



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).

Reimbursement CPT Codes

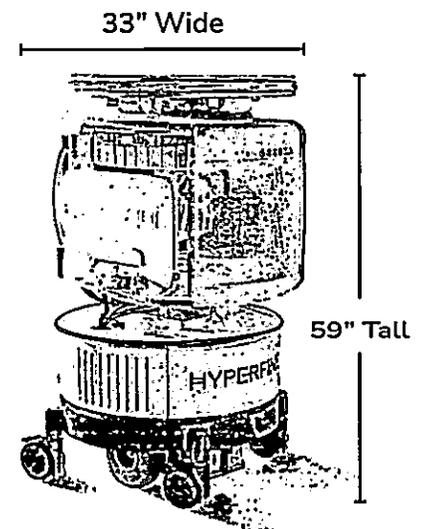
CPT 70551 (global reimbursement): Magnetic resonance (e.g., proton imaging, brain (including brain stem); without contrast material), CPT 70551-26 (professional component), and CPT 70551-TC (technical component).

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 v3

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HYPERFINE®

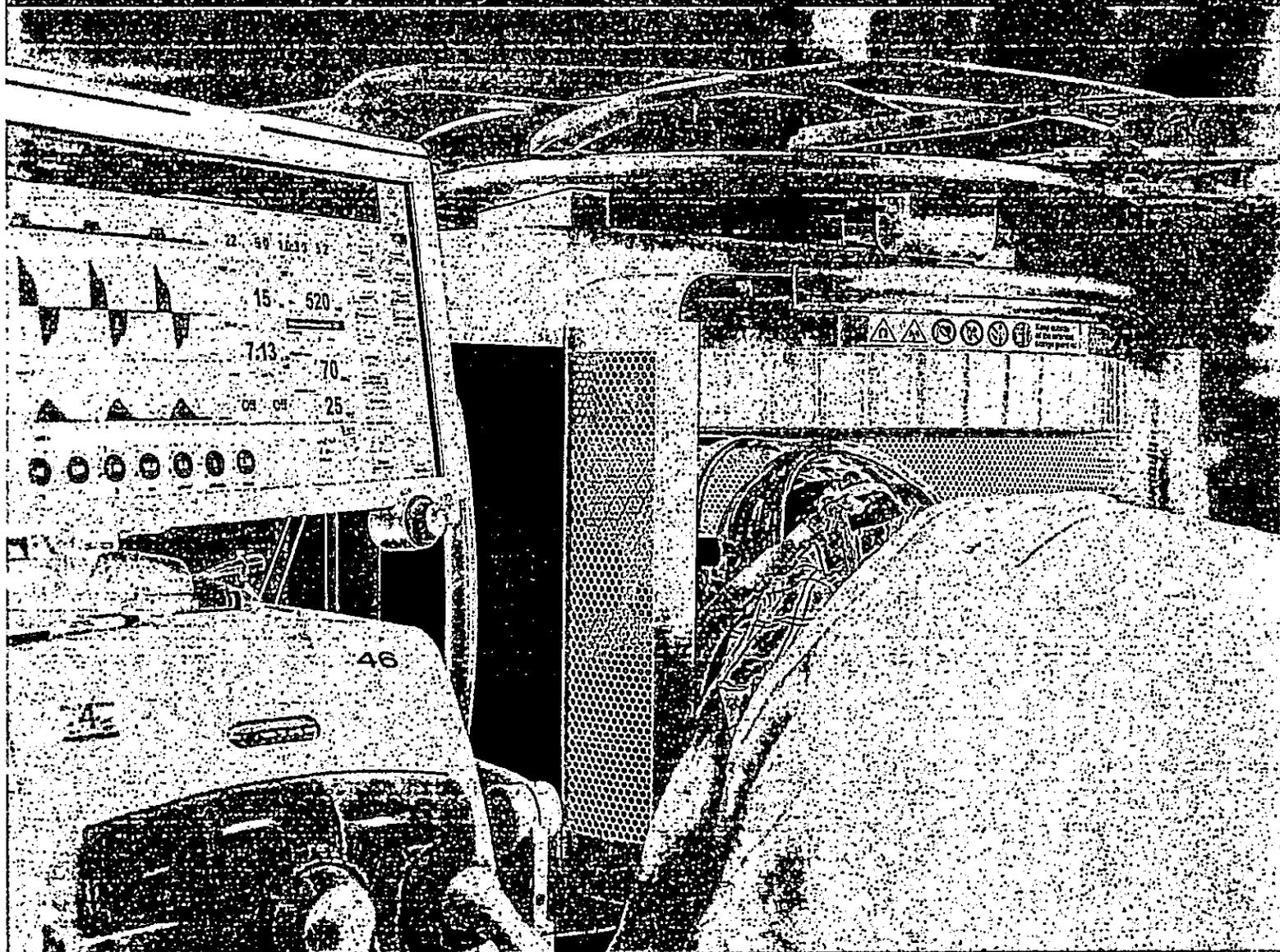
hyperfine.io

🐦 @hyperfine hyperfine.io/contact-us (866) SWOOP-MR

HYPERFINE®

Swoop® Portable MR Imaging® System

Point-of-Care Imaging in Neurocritical Care Settings



The Swoop Portable MR Imaging system:

Produces images at the point of care, without transport.

Improves critical care neuroimaging workflow^{1,2}.

Images enable rapid diagnoses and treatment of patients^{3,4}.

The Swoop Portable MR Imaging system is indicated for use as 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.

Ultimately sequence choice and plane selection decisions should be made with the clinical and radiology teams in consultation together, and should be selected based on the clinical question to be answered. Below are example use cases and the sequences physicians have found useful in their examinations for producing images that provided information relevant to the clinical questions listed. This information is meant to be a reference only.

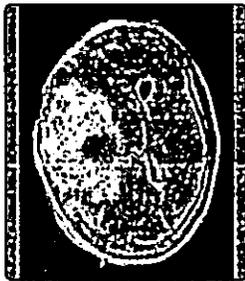
Examples use cases:

Post-operative Trauma Follow-up Assessment

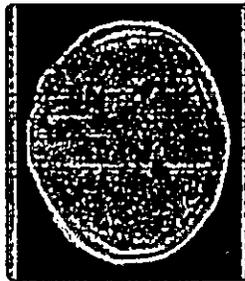
Recommended Sequences: Run based on which sequence(s) the pathology has been previously best seen.

Patient History: A 35-year-old female found unresponsive was brought into the emergency room. An emergent head CT revealed a massive traumatic intraparenchymal hemorrhage. Clinicians immediately took the patient to the operating room for decompression.

Diagnosis: Post-operatively, physicians used the Swoop system at the patient's bedside. The images assisted them in assessing the extent of mass effect, midline shift, and tissue viability for prognostication.



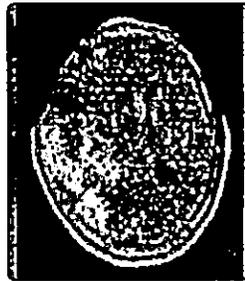
FLAIR



T1 (Standard)



Fast T2



DWI

Post-op Infarct

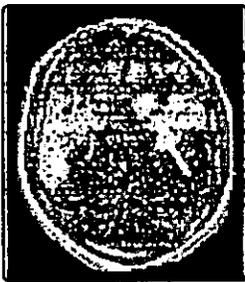
Recommended Sequences (in order): FLAIR, DWI with ADC, T1 (Standard), Fast T2

Patient History: A 56-year-old male with a history of prior transsphenoidal pituitary resection recently underwent a pterional approach for additional resection. On post-op day one, the patient experienced a seizure and coded, presenting with new neurological signs, including right-sided weakness and a non-responsive pupil.

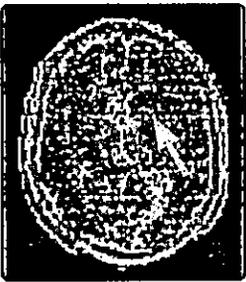
Diagnosis: Swoop system images assisted the physicians in promptly diagnosing this unstable, immediate post-operative patient.



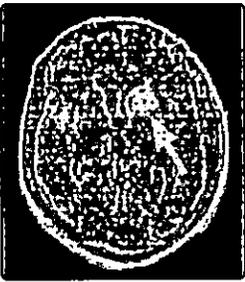
FLAIR



DWI



ADC



T1 (Standard)



T2

The Swoop system is not intended to apply color overlays to images. Colors are added for clarity and are not reflective of the original images.

Studies show that clinicians can use the Swoop system at the point of care for assessing: change in patient symptoms with an unknown cause^{1,3,5,6}, follow-up scans for clinically suspected or known strokes greater than 5mm², change in ventricular size with or without intervention^{6,7}, change in an intraparenchymal hematoma^{2,8}, change in extra-axial collection⁷, change in the imaging appearance of infarct¹, to follow or confirm stability⁴, mass effect and potential for midline shift⁹, and change post-thrombectomy¹⁰.

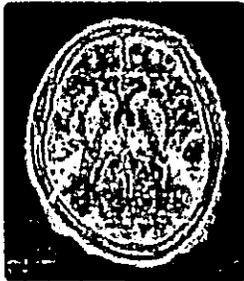
Examples use cases:

Post-cardiac Arrest Anoxia

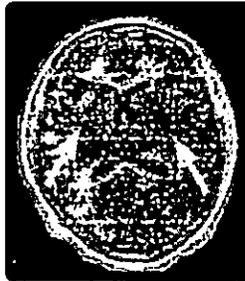
Recommended Sequences: Run based on which sequence(s) the pathology has been previously best seen.

Patient History: A 31-year-old man, post-drug overdose, presented in the ED and experienced cardiac arrest. Physicians administered naloxone for opioid reversal. Critically ill and unresponsive, having undergone prolonged resuscitation, the patient was transferred to the ICU.

Diagnosis: Swoop system images, taken after five days, assisted the physicians in identifying cerebral anoxia and sub-acute infarcts in the deep gray matter of the dorsal midbrain, bilateral thalami, and basal ganglia, guiding the decision to withdraw life support.



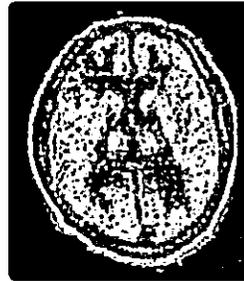
FLAIR



T1 (Standard)



Fast T2



DWI

Post-operative ICU Exam

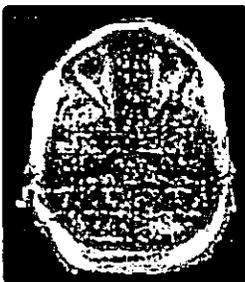
Recommended Sequences: Run based on which sequence(s) the pathology has been previously best seen.

Patient History: A 39-year-old female with a history of recurrent metastatic non-small cell lung carcinoma. She now presents with a growing right-sided posterior fossa mass. Physicians used the Swoop system in the ICU twelve hours after surgery to assess her condition.

Diagnosis: Swoop system images showed a total resection with no evidence of hemorrhage, significant edema, mass effect, or obstructive hydrocephalus. Following the exam, physicians transferred the patient out of the ICU on postoperative day one, saving time and cost.



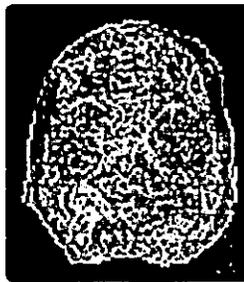
FLAIR



T1 (Standard)



DWI

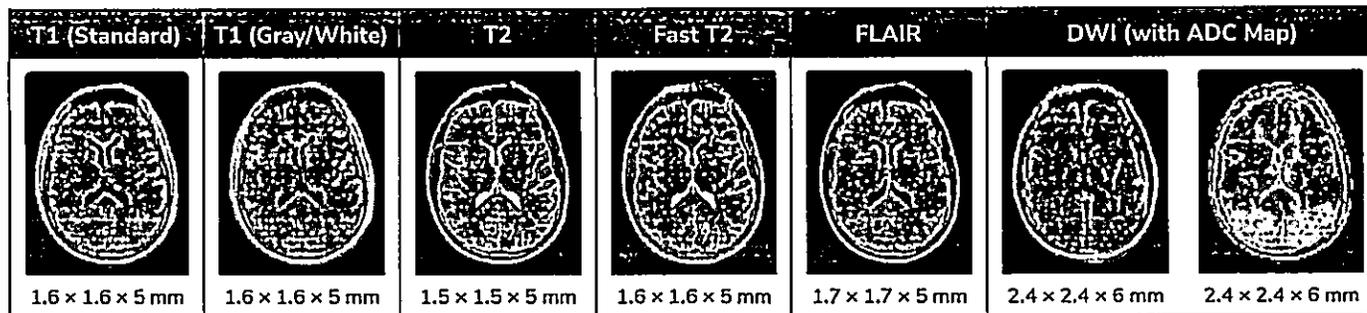


ADC

The Swoop system is not intended to apply color overlays to images. Colors are added for clarity and are not reflective of the original images.

Swoop System Sequences

The Swoop system offers T1, T2, fluid-attenuated inversion recovery (FLAIR), and diffusion-weighted imaging (DWI) with apparent diffusion coefficient (ADC) map sequences (with two T1 and T2 variations). The T1, T2, and FLAIR sequences are available in the axial, coronal, and sagittal planes.



Endnotes

- 1 Kuoy E, Glavis-Bloom J, Hovis G, et al. Point-of-Care Brain MRI: Preliminary Results from a Single-Center Retrospective Study. *Radiology*. 2022;305(3):666-671. doi:10.1148/radiol.211721. doi:10.1148/radiol.211721
- 2 Mazurek MH, Cahn BA, Yuen MM, et al. Portable, bedside, low-field magnetic resonance imaging for evaluation of intracerebral hemorrhage. *Nat Commun*. 2021;12(1):5119. Published 2021 Aug 25. doi:10.1038/s41467-021-25441-6
- 3 Turpin J, Unadkat P, Thomas J, et al. Portable Magnetic Resonance Imaging for ICU Patients. *Crit Care Explor*. 2020;2(12):e0306. Published 2020 Dec 21. doi:10.1097/CCE.0000000000000306
- 4 Yuen MM, Prabhat AM, Mazurek MH, et al. Portable, low-field magnetic resonance imaging enables highly accessible and dynamic bedside evaluation of ischemic stroke. *Sci Adv*. 2022;8(16):eabm3952. doi:10.1126/sciadv.abm3952
- 5 Sheth KN, Mazurek MH, Yuen MM, et al. Assessment of Brain Injury Using Portable, Low-Field Magnetic Resonance Imaging at the Bedside of Critically Ill Patients. *JAMA Neurol*. Published online September 8, 2020. doi:10.1001/jamaneurol.2020.3263
- 6 Beekman R, Crawford A, Mazurek MH, et al. Bedside monitoring of hypoxic ischemic brain injury using low-field, portable brain magnetic resonance imaging after cardiac arrest. *Resuscitation*. 2022;176:150-158. doi:10.1016/j.resuscitation.2022.05.002
- 7 Sien ME, Robinson AL, Hu HH, et al. Feasibility of and experience using a portable MRI scanner in the neonatal intensive care unit. *Arch Dis Child Fetal Neonatal Ed*. 2023;108(1):45-50. doi:10.1136/archdischild-2022-324200
- 8 Mazurek MH, Parasuram, NR, Peng TJ et al. Detection of Intracerebral Hemorrhage Using Low-Field, Portable Magnetic Resonance Imaging in Patients With Stroke. *Stroke*. 2023;54:2832-2841. doi:10.1161/STROKEAHA.123.043146
- 9 Sheth KN, Yuen MM, Mazurek MH, et al. Bedside detection of intracranial midline shift using portable magnetic resonance imaging. *Sci Rep*. 2022;12(1):67. Published 2022 Jan 7. doi:10.1038/s41598-021-03892-7
- 10 Sujjantararat N, Koo AB, Jambor I, et al. Low-Field Portable Magnetic Resonance Imaging for Post-Thrombectomy Assessment of Ongoing Brain Injury. *Stroke*. 2023;3:e000921. Published 2023 Jul 24. doi:10.1161/SVIN.123.000921

This material is for general information only and is not intended to substitute for formal medical training or certification. Hyperfine, Inc. does not provide clinical training, nor does it provide or evaluate physician credentialing or train physicians in procedures or techniques. Before performing an MR scan, physicians are responsible for receiving sufficient training and proctoring to ensure that they have the skill and experience necessary to protect the health and safety of the patient. For technical information, including full cautions and warnings on using the Swoop system, please refer to the instructions for use (LBR-000339). Read all instructions carefully. Failure to properly follow instructions, notes, cautions, warnings, and danger messages associated with this equipment may lead to serious injury or complications for the patient. While clinical studies support the use of the Swoop system for portable cranial magnetic resonance imaging, individual results may vary.

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hyperfine.io

LBL-002141 v4

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✉@hyperfine hyperfine.io/contact-us (866) SWOOP-MR

Swoop- The Hyperfine Solution

Swoop, the world's first MR imaging system capable of providing neuroimaging at the point of care, can inform the timely diagnosis and treatment of acute conditions within a broad range of clinical settings.

The Swoop Portable MR Imaging System expands patient access while being more cost-effective than conventional high-field MRI systems. And, unlike high-field MRI, which requires specialized infrastructure and radiologic technicians to operate, Swoop system operation, navigation, and safety training is simple, which allows for expanded user access.

For the clinician, 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 iPad®, the operator can initiate a scan and capture, display, and export images of the brain within minutes—offering clinicians workflow efficiencies with the potential to impact critical decision-making without the need to transport the patient away from the point of care.

For the patient, Swoop is a convenient and potentially low-stress experience. It is helpful in diverse environments, can reduce the length of time a patient has to wait for an MRI scan, and provides expanded access to patients who might not otherwise be candidates for an MRI at the time of care.

Swoop is a 0.064T or 64mt brain-only MR imaging system containing permanent vertical magnets. Unlike a High-Field fixed magnet, Swoop does not require helium to cool the system. It uses AI and DL to provide crisp and clear T1, T2, Flair, and DWI (with an ADC map). The system uses a standard 120V wall plug and glides between patients' courtesy of a joystick and a powered wheel drive. Since Swoop is a single modality imaging device, it is exempt from ACR. (See attached letter)

	Swoop	Mobile MRI	Fixed MRI
Field strength	0.064T	1.5T+	
Shielding	No shielding required	Shielding required	
Imaging capability	Brain-only	Full Body	
Imaging location	Point of Care at bedside	Transport patient to trailer	Transport patient to radiology
Magnet type	Permanent	Helium-cooled	
Power	120V 900W	480V 25+KW	
Operator	Any trained healthcare professional	Licensed MR tech	
Accreditation	ACR exempt	ACR accredited	
Safety Profile	No documented adverse events (MAUDE database)	Adverse events from heating & projectile	
Setup cost	No setup costs	Site prep required	Construction required
System cost	<\$500,000		\$1,500,000+

HYPERFINE®

American College of Radiology Exemption Memo

The Hyperfine, Inc. *Swoop® Portable MR Imaging®* system is exempt from the testing methods used by the American College of Radiology to grant accreditation as those testing protocols are not compatible with the *Swoop* system.

As such, a healthcare facility's ACR MR accreditation is independent of their use of the *Swoop* system. Healthcare facilities are encouraged to contact the ACR accreditation office after *Swoop* system deployment to obtain a written device exemption directly from the ACR accreditation office.

Sincerely,

Khan Siddiqui, MD
Chief Medical Officer / Chief Strategy Officer
Hyperfine, Inc.

June 2023
LBL-002533 v0

351 New Whitfield Street, Guilford, Connecticut, 06437

From: [Shovelin, Jeffrey](#)
To: [Yakaboski, Greg](#)
Cc: [Stancil, Tiffany C](#)
Subject: [External] ECU Health Medical Exemption Request: Portable MRI for Research Activity
Date: Friday, April 4, 2025 2:22:58 PM
Attachments: [EHMC Research Exemption Letter - Portable MRI - FINAL.pdf](#)

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Attached is a request for exempt status for ECU Health Medical to acquire portable MRI systems for neuroscience research activity. Please let me know if you have any questions or need additional information. Also, please confirm receipt. Thank you!

Jeff Shovelin
VP - Business Planning & Strategy
ECU Health
PO Box 6028
Greenville, NC 27835-6028
Office: (252) 847-3631 / Cell: (252) 714-5156
jshoveli@ecuhealth.org