

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29
STORES SECTION(CNC)**

T. No. 145/CNC/NI&INR/2024-25/St.

Dated: 19.05.2025

Sub:- Purchase of "Intraoperative MR Imaging System-01No." for department of NI&INR on proprietary basis-Inviting comments thereof.

The CNC (AIIMS) is in the process to purchase of **Intraoperative MR Imaging System-01No.** for department of NI&INR, CNC, AIIMS, New Delhi-29 on proprietary basis from M/s. Hyperfine Operating Corp., USA through Indian agent M/s. Jona Techsystems Private Limited. The proposal submitted by M/s. Jona Techsystems Private Limited and PAC documents are attached.

The above documents are being uploaded for open information to submit Suggestion/objections/comments, if any, by any manufacturer/Supplier firm regarding proprietary nature of the equipment/item, within 15 days of issue of this document on AIIMS website by giving Tender No. **145/CNC/NI&INR/2024-25/St.** The comments/objections should be submitted in the office of Stores Officer (CNC), Room No. 3, 1st Floor, New Pvt. Ward, CNC at AIIMS, New Delhi-29 on or before **03.06.2025 upto 03.00 PM**, failing which it will be presumed that any other vendor is having no comment to offer and purchase process will be initiated further for purchase of item as per procedure. No suggestions/objections will be considered after 03.06.2025.

for file
19/5/2025

**STORES OFFICER
(CNC, AIIMS, N.DELHI-29)**

Encl: Related documents enclosed.

Intraoperative MR Imaging System Technical Specification on proprietary Basis for the Department of NI & INR, NSC, CNC, AIIMS, New Delhi- 29

1. System should be portable to move from one place to another through the wheelbase to OTs & ICU. Latest version of the equipment to be provided. All standard accessories to be provided along with the machine in a ready to use configuration.
2. System dimension should be (150x97x81) CM (HxWxD)
3. Patient weight support should be minimum 150KG
4. Magnet Field strength should be 63.3+- 2.0 mT, should have permanent magnet 0.3 T magnet strength or more.
5. Patient accessible Bore size should be 61cm X 31.5cm (WxH)
6. Magnet bore size should be 36cm
7. System should not require any shielding (return path works as a shield)
8. System should work on permanent magnet shims electricals first order shims
9. Temporal field stability should be 0- 1500 ppm/hr (typical)
10. Maximum field strength 200mT
11. Maximum gradient amplitude X:24.3 mT/m, Y:22.9 mT/m, Z: 38.5 mT/m
12. Rise Time zero to max will be X:2.1ms, Y:2.0 ms, Z:3.8 ms
13. Cooling should be natural convective
14. Peak acoustic output should be max 90-106d db
15. Transmit coil design should be linear
16. Receive coil design should be 8-channel array
17. Anatomical range intended should be head
18. Imaging sequences are T1,T1 (Gray/white), T2, Fast T2, FLAIR, DWI and ADC
19. Acquisition type orientation capability for T1,T2 and FLAIR should be 3D: axial, sagittal, coronal
20. System electrical requirement should be 15 A, 100-230 VAC 50/60Hz with motor drive battery pack
21. System should be supplied with advanced denoising filters.
22. Images should be exported in Dicom format
23. Should be integrated with existing Department PACS with wifi connectivity.
24. System should be quoted with 2 years of warranty and addition 8 years of CMC
25. All consumables and accessories should be quoted separately with prices. Prices to be frozen for next 10 years. Startup kit to be provided for initial 2 yrs along with equipment at free of cost.

Use dept.
Sanyo

Dr. Samir Vyas
(External Expert)
(PGIMER, Chandigarh)

Dr. Anuj Garg
(CMAMC)
(External Expert)

Prasan

Rajeshwar

26/12/24

(Both External Expert attended online mail Concurrence has been attached)

HYPERFINE	Description: EU Declaration of Conformity Template	
	Title: 7.3-13-Form-3	Version: 1
	Description: DoC for Swoop Portable MR Imaging System – EU	
	Title: DOC-001447	Version: 1

Manufacturer's Authorisation Form

Date:- Nov 20, 2024

To
The Director
All India Institute of Medical Sciences
Ansari Nagar, New Delhi-110029
India

Dear Sir,

Ref: Your Bid documents No. Hyperfine Dated:

We, Hyperfine Operations, Inc. Who are proven and reputable manufacturers of **Swoop® Portable MR Imaging® System** (name and description of the goods offered in the bid) having factories at Hyperfine Inc, 351, New Whitefield St. Guilford, CT06437. Hereby authorize Messrs **Jona Techsystems Private Limited, 235, Office Complex, Jhandewalan Extension, New Delhi- 110055.** (name and address of the agent) to submit a bid, process the same further and enter a contract with you against your requirement as contained in the above referred bid documents for the above goods manufactured by us.

We also state that we are not participating directly into this bid for the following reason(s) We Hyperfine do not have any direct operation in India and Jona Techsystems Private limited is our exclusive partner for India.

We further confirm that no supplier or firm or individual other than Messers **Jona Techsystems Private Limited, 235, Office Complex, Jhandewalan Extension, New Delhi- 110055.** (Name and address of the above agent) is authorized to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us. We also hereby extend our full warranty, CAMC as required for the goods and services offered for supply by the above firm against this bid document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent and the spares for the equipment shall be available for the lifetime of the equipment.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly.

We also confirm that in case we change appointment Indian agent during comprehensive warranty/CAMC period, all accepted liabilities will be fulfilled /accepted by me (OEM) or our new appointed Indian agent without any additional cost and conditions.

Yours Faithfully,

HYPERFINE OPERATIONS, INC.

Signature:

Brett Hale

Name:

Brett Hale

Title:

CFO & CAO

351 New Whitfield Street, Guilford, Connecticut, 06437

Proprietary Technology Confirmation Hyperfine Statement

1. I am the Chief Executive Officer of Hyperfine Operations, Inc., the company that designed and sells the Swoop® Intraoperative / Portable MR Imaging® System (the Device).
2. I confirm, to the best of my knowledge, and the knowledge of the organization that I represent, the following information about the Device, is true and correct:
 - a. The Device is the first FDA (US Food and Drug Administration) cleared Intraoperative / portable MRI machine for producing images that display the internal structure of the head.
 - b. The Device is Intraoperative / portable by virtue of being on wheels and having a motor to allow a user to drive the Device at low speed. The Device is designed to fit through a standard US hospital doorway and be moved to a patient bedside or OT under its own power and does not require a room that contains radiofrequency shielding.
 - c. The Device draws about 900 watts of electrical power during operation.
 - d. The Device offers an array of imaging sequences including Diffusion Weighted Imaging (DWI), T1 standard, T1 gray/white, T2, T2 Fast, and Fluid Attenuated Inversion Recovery (FLAIR).
 - e. The Device generates a magnetic field having a ~64mT (0.064T) strength in the imaging volume, and the magnetic field is generated by permanent magnets.
 - f. The Device is production-level and goes through rigorous manufacturing testing.

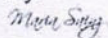
The clearance under 2(a), and the aspects of the Device under 2(b-f) make the Device unique and this a non-fungible good. The device is covered by numerous US and international patents (see list attached) related to the low field strength, portability, size, weight and imaging sequences.

Hyperfine, Inc. maintains a list of patents relevant to our device, the Swoop® ultra-low-field Intraoperative / portable MR brain imaging system, on our company website, which can be accessed at <https://hyperfine.io/hyperfine-inc-patents>. The list is updated once a year.

I confirm that the foregoing is true and correct to the best of my knowledge.

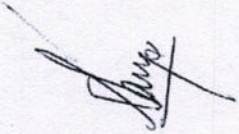
Dated: 12/23/2024

By:



Maria Sainz

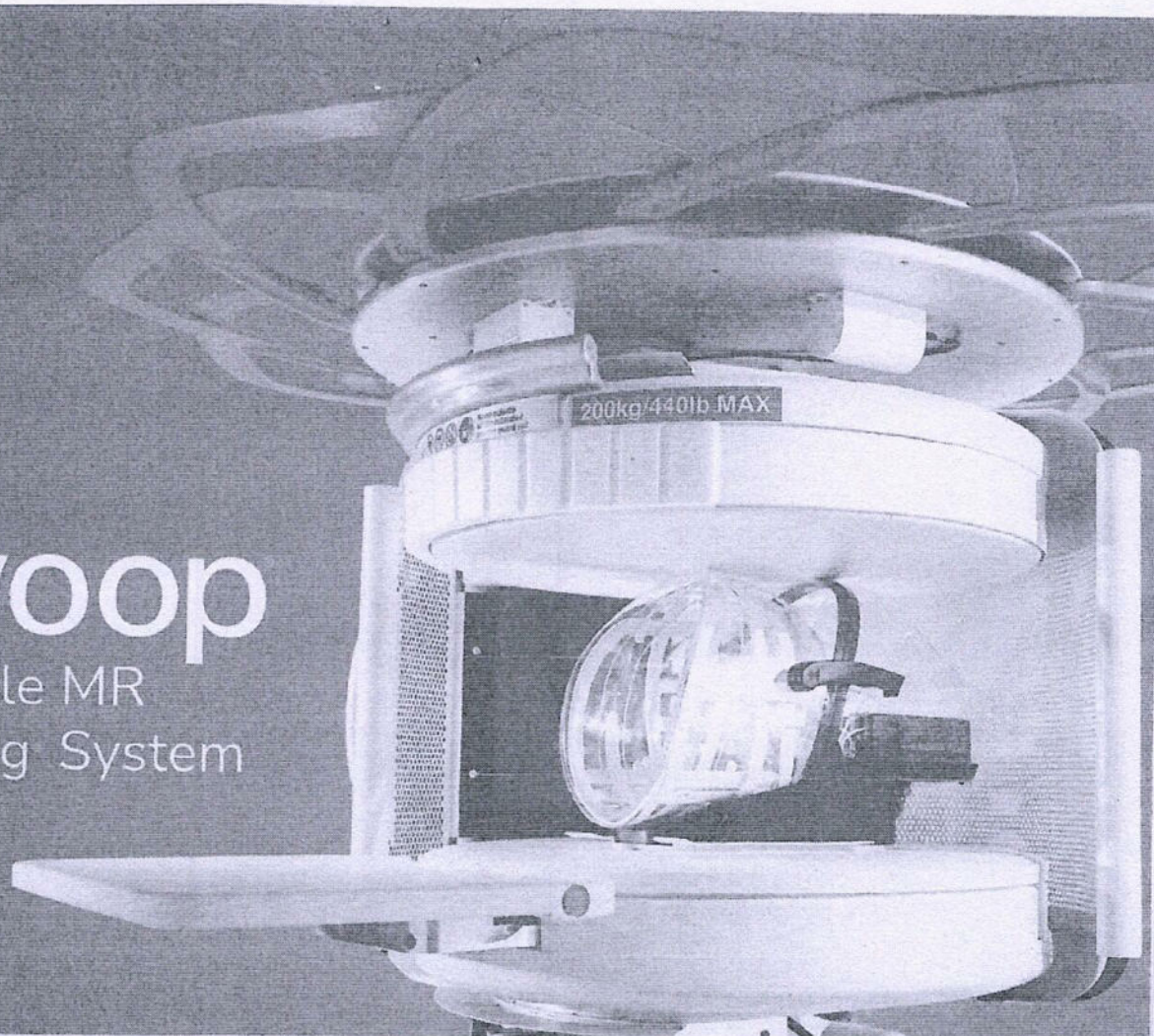
Chief Executive Officer



HYPERFINE

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®

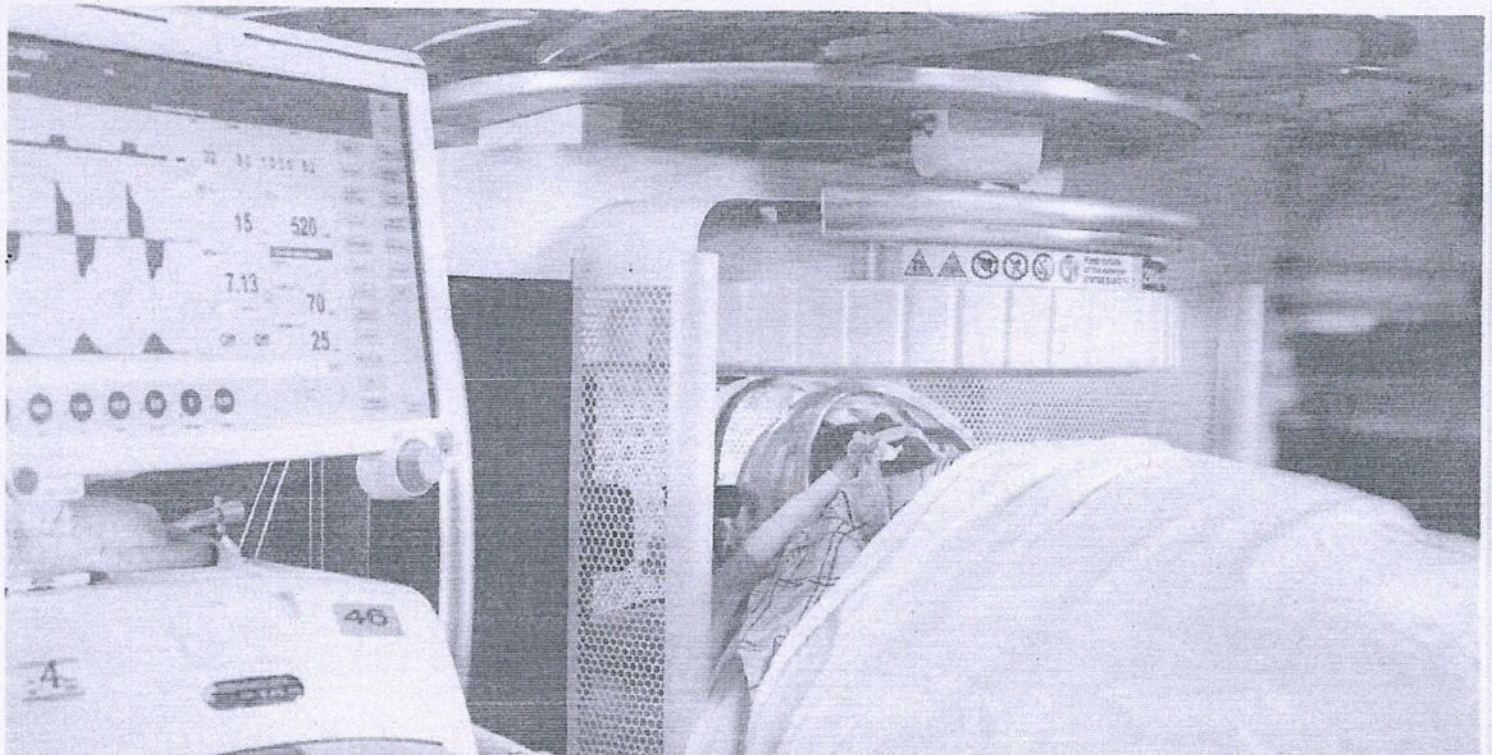
mobile digital device, the operator can initiate a scan and generate, display, and export images of the brain within minutes—offering clinicians workflow efficiencies with the potential to impact critical decision-making without transporting the patient away from the point of care.

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



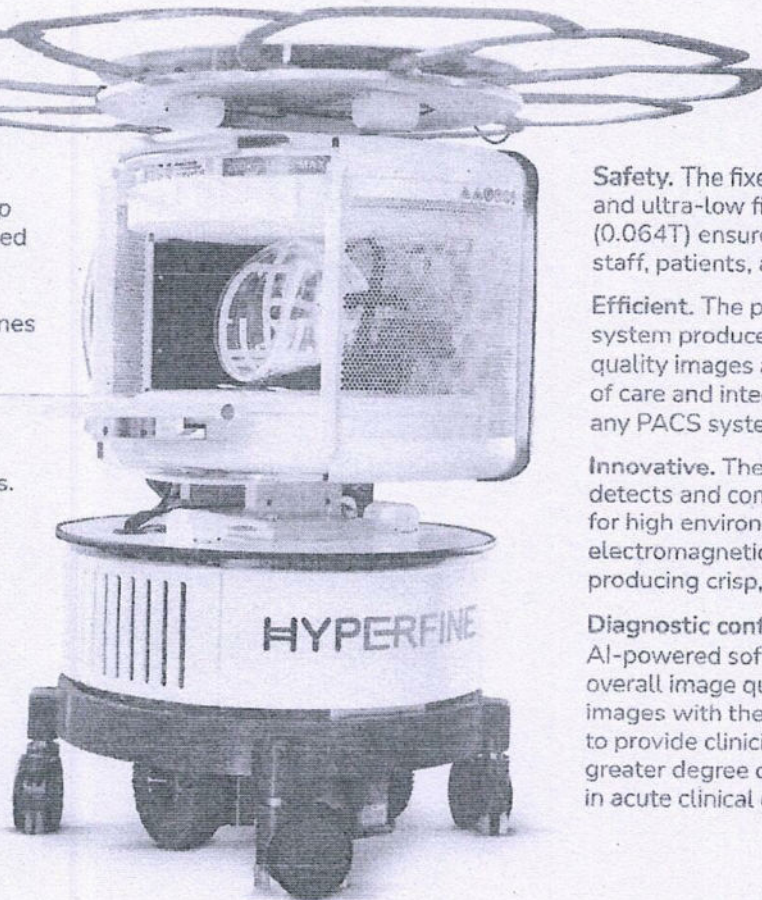
Patient-centered care. The Swoop system has an open layout designed to decrease anxiety associated with conventional high-field MR imaging. Clinical staff and loved ones remain at the patient's bedside.

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.

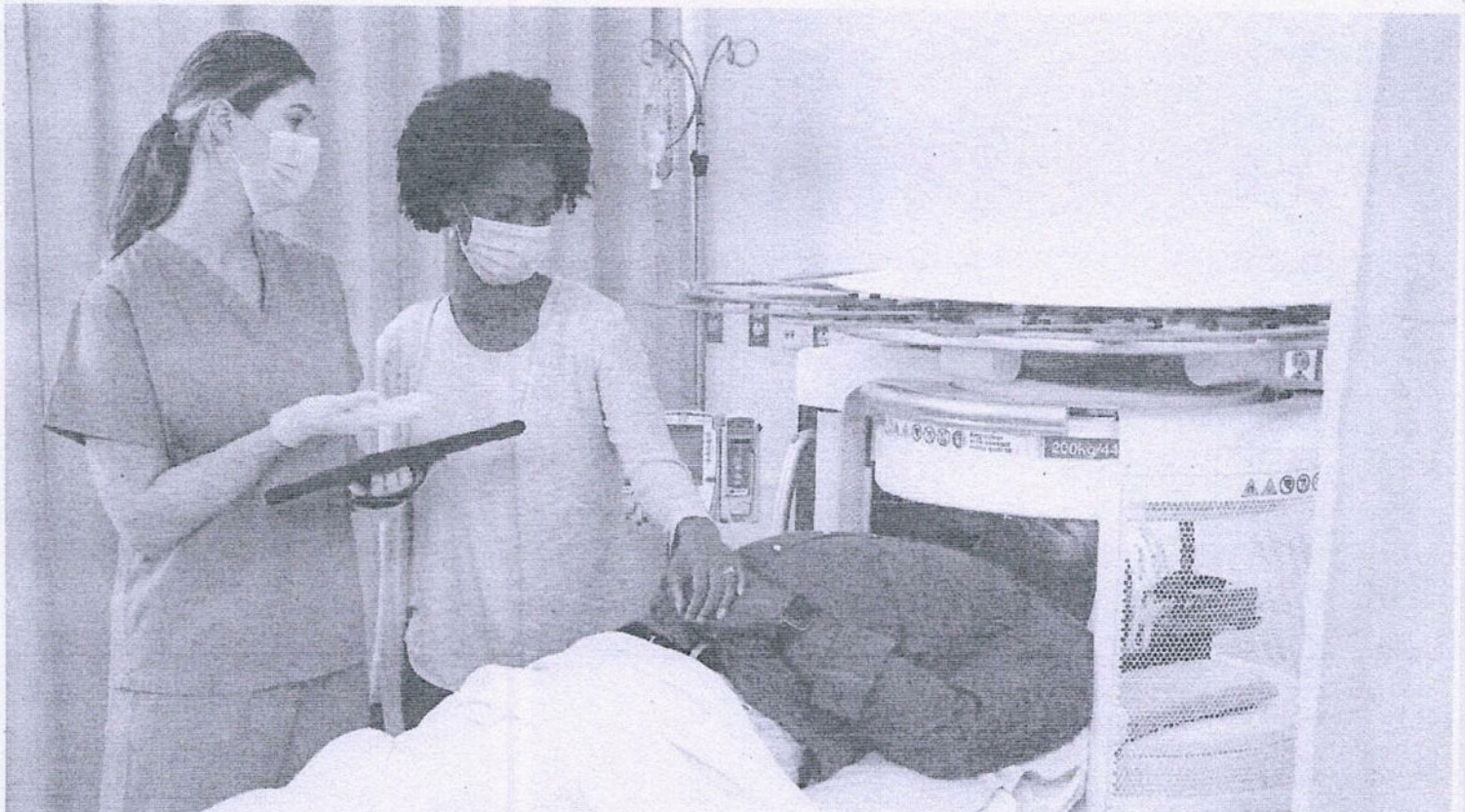


Safety. The fixed magnet design and ultra-low field strength (0.064T) ensure low risk to staff, patients, and loved ones.

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.



Learn About Advanced
Image Reconstruction



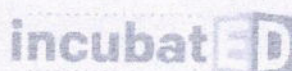
Review Sample
Case Images



Review Selected
Publication Highlights



Awards, Recognition, and Partnerships



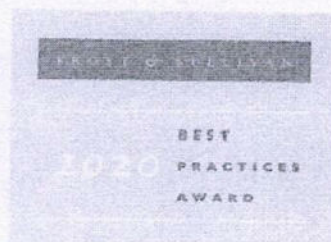
BILL & MELINDA
GATES foundation



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WINNER



WORLD
CHANGING
IDEAS 2021



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THE BEST OF RADIOLOGY
FINALIST

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.

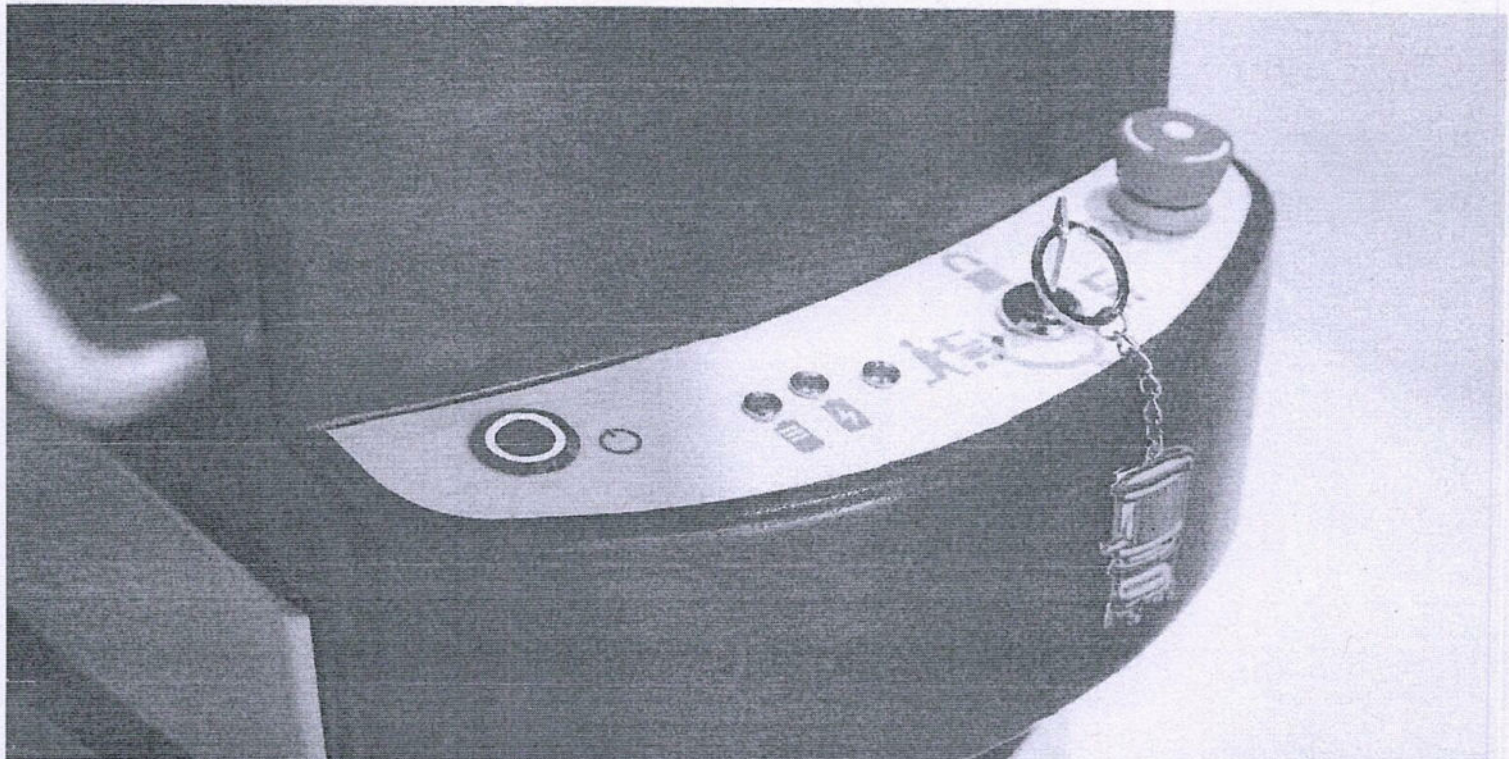
The Swoop system magnet is 64 mT. The system stands 59 inches tall and 33 inches wide and weighs approximately 1,400 pounds. Imaging sequences include T1, T2, FLAIR, and DWI (with ADC map)—all directed by a user interface on an iPad Pro® (included).



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.

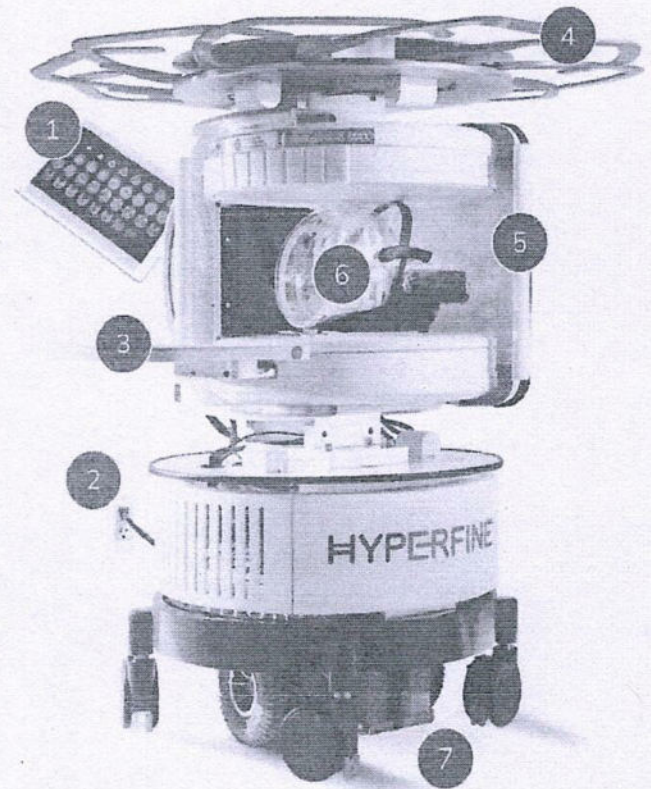
3. Transfer bridge. The transfer bridge unfolds for easy bedside patient loading. Fold the bridge back up to move the system to your next patient.

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.

HYPERFINE.

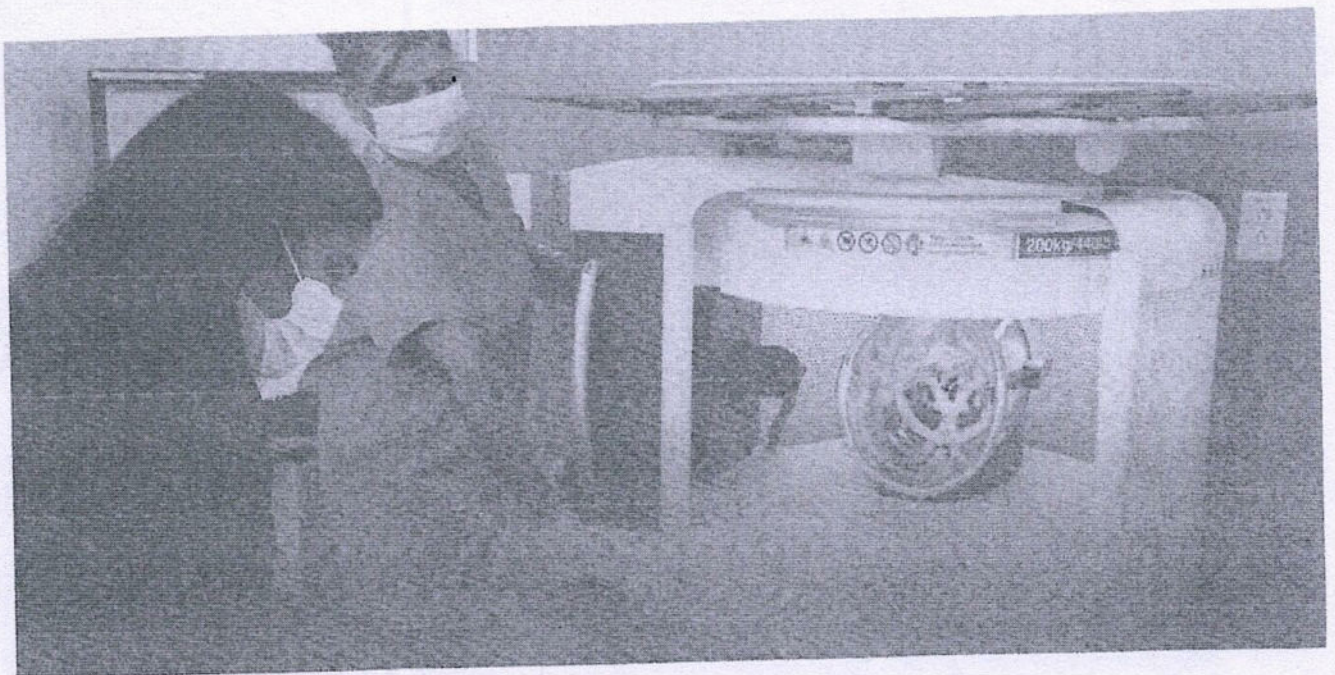
hyperfine.io

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



HYPERFINE

Hyperfine® – The Swoop® System World's First FDA-Cleared Portable Point-of-Care MRI™ for Brain Imaging



Transforming Patient Care Around the World

Jon Technologies



RADIOSURGERY GLOBAL

www.rsglobal.co.uk
info@rsglobal.co.uk



HYPERFINE

26th December 24

All India Institute of Medical Sciences
 Cardiothoracic and Neurosciences Centre AIIMS (C. N. Centre)
 Sri Aurobindo Marg, Ansari Nagar,
 Ansari Nagar East, New Delhi, Delhi 110029, India

SUBJECT **Hyperfine Swoop System – Proposal & Quotation**
World's First FDA-Cleared Proprietary Portable Point-of-Care MRI™ for Brain Imaging

Dear Sir

Thank you for giving us an opportunity to submit our proposal and quotation for our Hyperfine Swoop System – World's First FDA-Cleared proprietary Portable technology Point-of-Care MRI™ for Brain Imaging by Hyperfine Inc. United States.

Benefits of Point-of-Care MRI™

Point-of-care

Improved Safety Profile

Enabling Tech (AI-driven)



Diagnostic imaging at low magnetic field strength, allowing clinicians to quickly scan, diagnose, and treat patients at the patient's bedside.



Designed to provide brain images that enable physicians to rapidly diagnose and treat patients regardless of stability or location in the hospital.



Moves to a patient's bedside, fits through hospital doorways, plugs into a standard electrical wall outlet, and is controlled by an Apple® iPad® mobile digital device.

Apple and iPad are registered trademarks of Apple Inc.

Brain imaging within reach.

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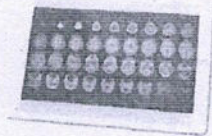
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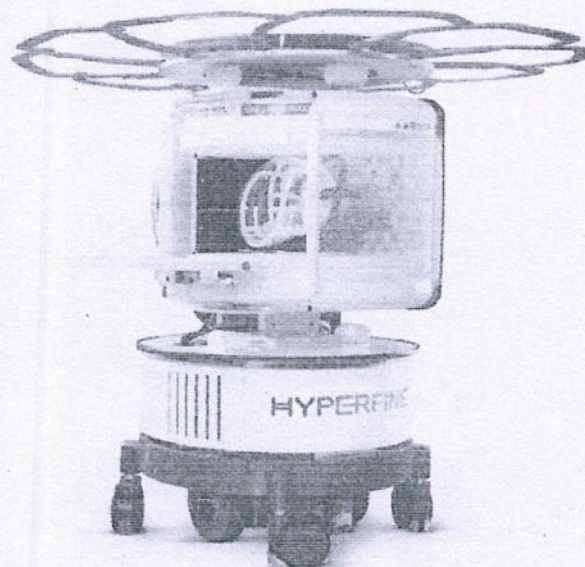


HYPERFINE

AI Enabled



- Improved T1, T2, and FLAIR image quality by reducing image blurring and noise.
- Unique advanced image reconstruction pipeline, developed using deep learning.
- Advanced gridding optimizes Swoop system spatial frequency domain data (k-space data) before transforming the data into an image.
- Advanced denoising is applied in small patches across the entire image, removing noise from the signal while preserving critical information.



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The Swoop System Brings MRI to the Patient.

Designed to provide brain images that enable physicians to rapidly diagnose and treat patients regardless of stability or location in the hospital.

Produces diagnostic images at low magnetic strength, allowing clinicians to quickly scan, diagnose, and treat patients.

Wheels directly to a patient's bedside, fits through hospital doorways, plugs into a standard electrical outlet, and is controlled by an Apple® iPad® mobile digital device.

Apple and iPad are registered trademarks of Apple Inc.



MRI and the Critical Care Patient: Clinical, Operational, and Financial Challenges



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%.

About 5 million patients are admitted to the ICU annually in the U.S., with around 20% requiring transport for MRI procedures. The associated costs lead to an estimated annual expense of \$1.79 billion for the U.S. healthcare system related to MRI transport-associated adverse events in ICU patients.

McLean, B. et al. MRI and the Critical Care Patient: Clinical, Operational, and Financial Challenges. Critical Care Research and Practice (2023). <https://www.frontiersin.org/journal/10.3389/fccp.2023.777210>

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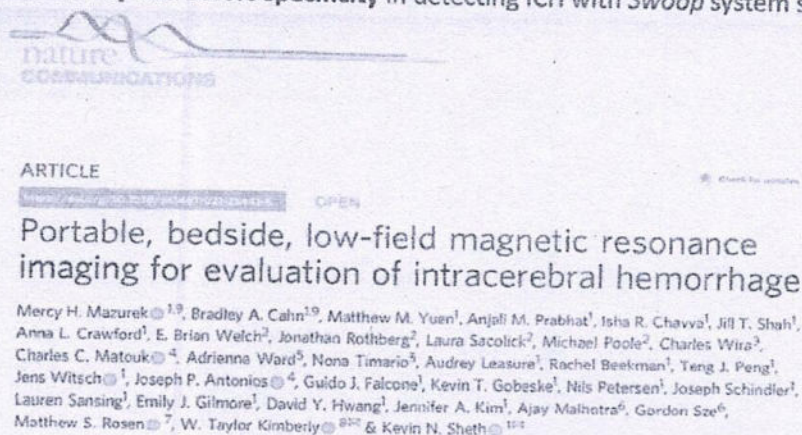
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Summary of Selected ICU Clinical Publications

- Study of 144 pMRI [Swoop system] exams to evaluate intracranial hemorrhage (ICH) shows 80.4% sensitivity and 96.6% specificity in detecting ICH with Swoop system scans



- T2-weighted, fluid-attenuated inversion recovery and diffusion-weighted imaging sequences significantly correlated with stroke severity and functional outcome at discharge. Low-field pMRI detected infarcts in (90%) of patients across cortical, subcortical, and cerebellar regions.

Portable, low-field magnetic resonance imaging enables highly accessible and dynamic bedside evaluation of ischemic stroke

SCIENCE ADVANCES

10376 59

Abstract

Brain imaging is essential to the clinical management of patients with ischemic stroke. Timely and accessible neuroimaging, however, can be limited in clinical stroke pathways. Here, portable magnetic resonance imaging (pMRI) acquired at

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- In a critically ill cardiac arrest population in whom MR imaging is often not feasible, low-field MRI can be deployed at the bedside to identify hypoxic-ischemic brain injury (HIBI). MRI, a highly valued prognostic tool to assess secondary brain injury and neuro-deterioration, can often be delayed due to patient and systems-related factors.



Available online at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Clinical paper

Bedside monitoring of hypoxic ischemic brain injury using low-field, portable brain magnetic resonance imaging after cardiac arrest

Rachel Beekman^{a,*}, Anna Crawford^a, Mercy H. Mazurek^a, Anjali M. Prabhat^a, Isha R. Chavva^a, Nethra Parasuram^a, Noah Kim^a, Jennifer A. Kim^a, Nils Petersen^a, Adam de Havenon^a, Akhil Khosla^a, Shyoko Honiden^a, P. Elliott Miller^a, Charles Wira^a, James Daley^a, Seyedmehdi Payabvash^a, David M. Greer^a, Emily J. Gilmore^a, W. Taylor Kimberly^a, Kevin N. Sheth^a

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Technical compliance sheet .

Specifications	Yes/No
1. System should have portable to move from one place to other through wheelbase	Yes Comply
2. System dimension should be (150x97x81) CM (HxWxD)3	Yes Comply
3. Patient weight support should be minimum 150KG	Yes Comply
4. Magnet Field strength should be 63.3+- 2.0 mT, should have permanent magnet.	Yes Comply
5. Patient accessible Bore size should be 61cm X 31.5cm (WxH)	Yes Comply
6. Magnet bore size should be 36cm	Yes Comply
7. System should not require any shielding (return path works as a shield)	Yes Comply
8. System should work on permanent magnet shims electricals first order shims	Yes Comply
9. Temporal field stability should be 0-1500ppm/hr (typical)	Yes Comply
10. Maximum field strength 200mT	Yes Comply
11. Maximum gradient amplitude X:24.3 mT/m, Y:22.9 mT/m, Z: 38.5 mT/m	Yes Comply
12. Rise Time zero to max will be X:2.1ms, Y:2.0 ms, Z:3.8 ms	Yes Comply
13. Cooling should be natural convective	Yes Comply
14. Peak acoustic output should be max 90-106d db	Yes Comply
15. Transmit coil design should be linear	Yes Comply
16. Receive coil design should be 8-channel array	Yes Comply
17. Anatomical range intended should be head	Yes Comply
18. Imaging sequences are T1,T1 (Gray/white), T2, Fast T2, FLAIR, DWI and ADC	Yes Comply
19. Acquisition type orientation capability for T1,T2 and FLAIR should be 3D: axial, sagittal, coronal	Yes Comply
20. System electrical requirement should be 15 A, 100-230 VAC 50/60Hz with motor drive battery pack	Yes Comply
21. System should supply with advance denoising filters.	Yes Comply
22. Images should be exported in dicom format	Yes Comply
23. Should have capability for pacs	Yes Comply
24. System Cover with 2 years of warranty and addition 8 years of CMC	Yes Comply
25. We have Quoted Rate of separately of accessories.	Yes Comply

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