

HYPERFINE

Swoop® Portable MR Imaging System™ White Paper

Hyperfine Deep Learning Image Reconstruction

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Introduction

The Swoop Portable MR Imaging System is a transformational diagnostic Magnetic Resonance Imaging system. Cleared by the FDA in 2020 for brain imaging for patients of all ages, Hyperfine designed the system for use by qualified and trained health care professionals. The Swoop system allows clinicians to acquire high-quality images at a patient's bedside in settings where MR imaging was not previously accessible such as emergency departments, intensive care units, and operating rooms outside the sterile field. The Swoop system's portability potentially decreases transport-related adverse events, enables timely diagnosis and interventions, and can reduce cost and length of stay in various ways, including removing the need to transport patients to a conventional MRI system.

Hyperfine took advantage of advancements in machine learning, cloud computing, and hardware design to create an affordable portable system that will potentially obviate the need for outdated equipment, reduce site infrastructure needs, and increase access to time-critical diagnostics. To that end, Hyperfine received FDA clearance (K212456) in November 2021 for its deep learning image reconstruction techniques that enhance the quality of images generated by a portable MRI system at a patient's bedside. The Swoop system uses these innovative techniques to reconstruct T1, T2, and FLAIR images using a single deep learning image reconstruction pathway. This unique approach allows images from a low-field portable MR imaging system to elevate the diagnostic value of portable MRI.

“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

What is deep learning?

Deep learning is a subfield of machine learning that utilizes artificial neural networks (ANN). An ANN is a mathematical model with tunable parameters that can be specialized and trained for a predictive task of interest. Such training is done by presenting the ANNs with training data, a set of known input-output pairs from the task of interest, and adjusting network parameters to optimize for the highest accuracy of prediction on the training data. Once the network is trained and has learned how to generate a given output, the system can apply that algorithm to a similar new input.

ANNs and Magnetic Resonance image reconstruction.

Conventional MR image reconstruction algorithms do not optimally account for noise and sampling artifacts.¹ Iterative reconstruction techniques, such as CS² and CG-SENSE,³ have computational and accuracy limitations. Since noise and sampling artifact sources are well-understood, a training pipeline can simulate them and construct a large training dataset. Given a training dataset of noisy and noiseless image pairs, with and without artifacts, a network can be trained to take noisy input with artifacts and generate an output with fewer artifacts. Hyperfine progressed existing deep learning reconstruction approaches⁴ and designed a novel network to enable non-uniform reconstruction on relatively noisy low-field multi-channel MRI data. This reconstruction method yields significantly improved image quality.

What is the Hyperfine advanced image reconstruction process?

Hyperfine used deep learning algorithms for its advanced image reconstruction process. This approach improves

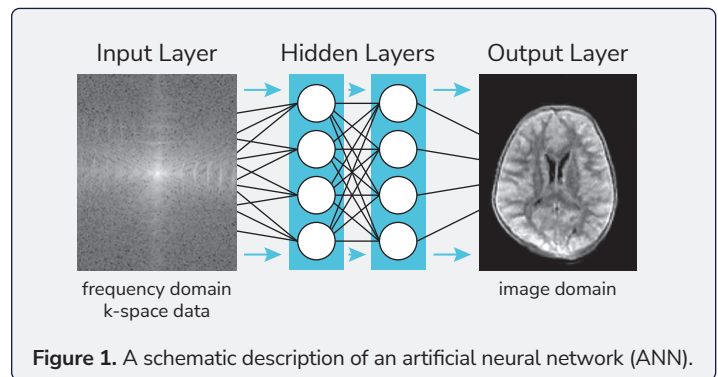
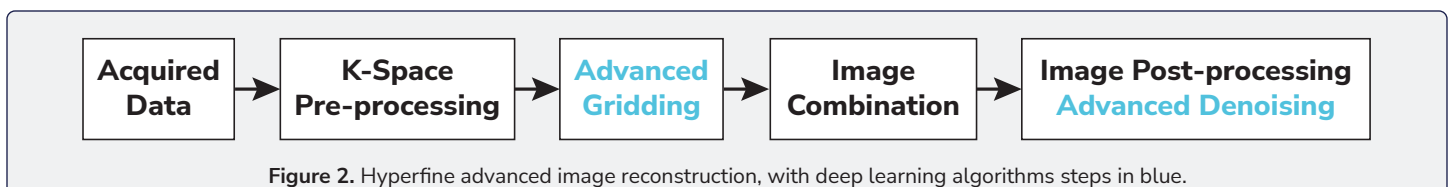


image quality by reducing image noise and blurring. The Hyperfine advanced image reconstruction process replaces the linear image reconstruction step with advanced “gridding,” followed by advanced denoising, as described below.

Advanced Gridding. This step converts the data from the spatial frequency domain (k-space data) to the image domain. Unlike traditional MRI systems that use non-uniform fast Fourier transform (FFT-gridding) operations, the Hyperfine advanced gridding step uses deep learning to reduce undersampling artifacts and produce sharper images. It helps minimize blurring and artifacts, compensating for the inherent limitations in portable, low field MRI scanner design. This approach uses the k-space data, which is more effective than other MRI post-processing approaches that rely on the final reconstructed MRI images.¹

Advanced Denoising. This post-processing step operates on the final image. Advanced denoising is applied in small patches across the entire image, removing noise from the signal while preserving clinically relevant information.



1. Zwart, Nicholas R., Kenneth O. Johnson, and James G. Pipe. “Efficient sample density estimation by combining gridding and an optimized kernel.” *Magnetic resonance in medicine* 67.3 (2012): 701-710. <https://doi.org/10.1002/mrm.23041>
2. Lustig, Michael, et al. “Compressed sensing MRI.” *IEEE signal processing magazine* 25.2 (2008): 72-82. <https://doi.org/10.1109/MSP.2007.914728>
3. Pruessmann KP, Weiger M, Boernert P, Boesiger P. Advances in sensitivity encoding with arbitrary k-space trajectories. *Magn Reson Med* 45(4):638-651; 2001. <https://doi.org/10.1002/mrm.1241>
4. Muckley, Matthew, et al. “Results of the 2020 fastMRI Challenge for Machine Learning MR Image Reconstruction”, *IEEE Trans. on Med. Imaging*, 40(9):2305-2317; 2021. <https://doi.org/10.1109/tmi.2021.3075856>

What are the benefits of deep learning?

Hyperfine advanced image reconstruction provides the foundational enabling technology for a wide variety of use cases for low-field portable MRI. This includes clinical settings such as the ICU, OR (outside the sterile field), and ED that could benefit from better delineation of pathology and anatomic features in a timely manner. With the unique Hyperfine advanced image reconstruction process, the image quality of Swoop system T1, T2,

and FLAIR scans is significantly improved with a 60% increase in signal-to-noise ratio (SNR) compared to the image quality of Swoop images produced using conventional linear reconstruction. This improvement can result in a greater degree of confidence in acute clinical diagnosis.

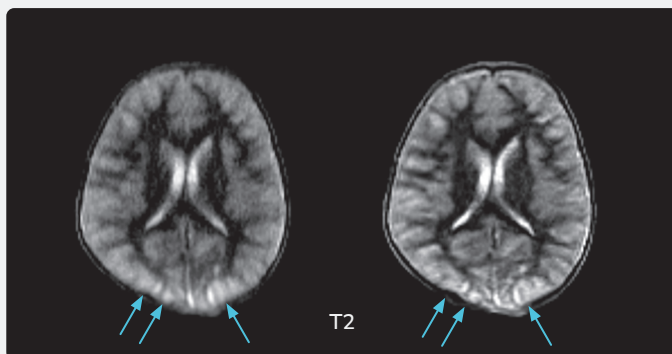
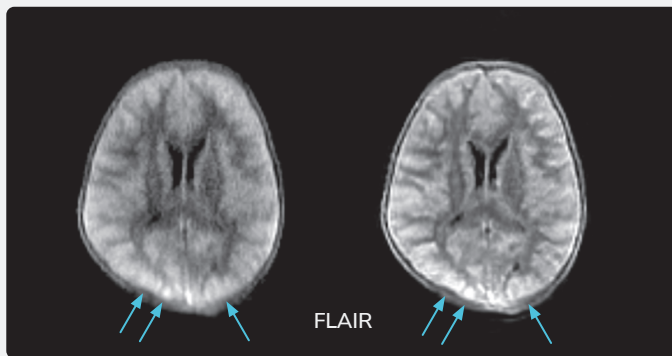
The sample clinical cases below demonstrate the described improvements.

T2 and FLAIR images from the Swoop system: linear versus advanced image reconstruction.

Sample Clinical Case 1

Before:
Linear (Conventional)
Reconstruction

After:
Advanced Image
Reconstruction

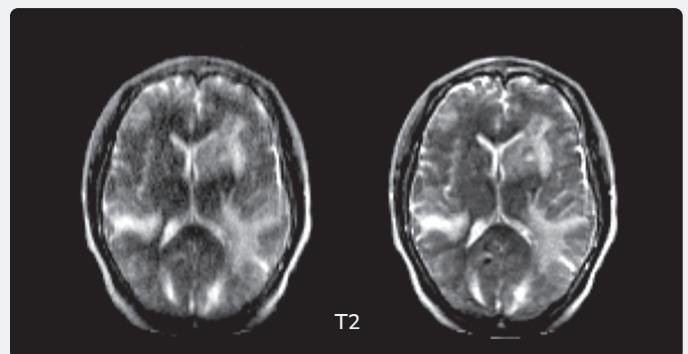
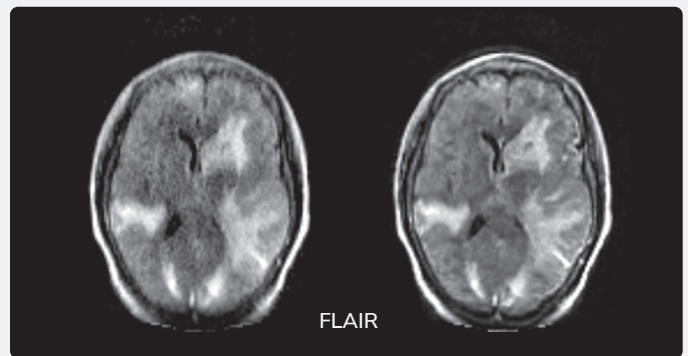


5-year old comatose boy presenting with fever. EEG is noted to be asymmetric. Swoop scan obtained immediately following EEG shows multiple focal regions of cortical edema and local mass effect. The cortical detail is more clearly seen with higher definition utilizing advanced image reconstruction. The patient is from a sub-Saharan tropical country. The diagnosis is cortical cerebral malaria.

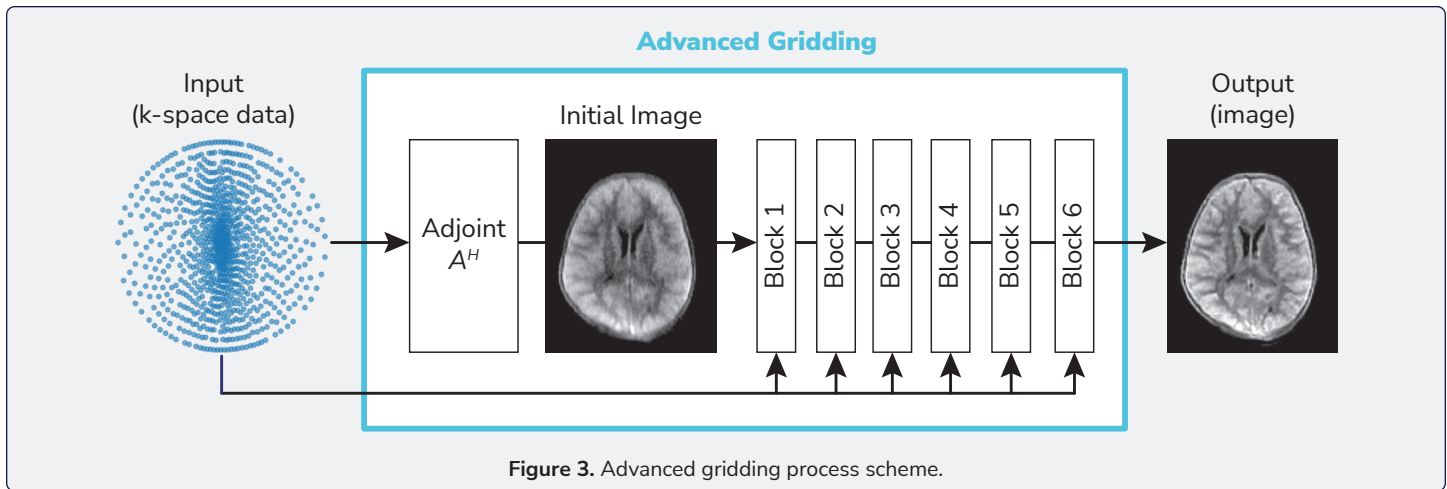
Sample Clinical Case 2

Before:
Linear (Conventional)
Reconstruction

After:
Advanced Image
Reconstruction



62-year old female with prior history of breast carcinoma treated with local therapy and was in a normal state of good health until new-onset seizure. Due to the patient's unstable condition while in the emergency department, the patient was imaged at the bedside using Swoop. Images show multiple intracranial metastatic lesions with surrounding mass effect and vasogenic edema, more clearly delineated with advanced image reconstruction.



How is data fidelity ensured?

Hyperfine took the following steps to ensure that the reconstructed image has data integrity with the original data acquisition (i.e., does not remove or introduce any new data):

- The training dataset for the neural networks consists of data that capture variability seen in low-field scan acquisitions.
- Learning is local and applied in small patches across the entire image to avoid introducing features specific to the training image dataset.
- The advanced gridding step compares each block in the deep learning network to the original k-space data (as seen in figure 3). This process confirms data integrity with the initial measurements from the k-space to show there is no modification to the initial measurements, preventing the algorithm from introducing inconsistent or removing relevant features.
- Hyperfine performed two validation studies to demonstrate that the advanced reconstruction algorithm produces images of improved quality that are comparable in fidelity to that of linear reconstruction. Four independent, expert ABR-certified neuroradiologists reviewed side-by-side image sets taken with the Swoop Portable

MR Imaging System. One set of images was generated using advanced reconstruction, and the other set was generated using linear reconstruction. The reviewers were asked to rate both image sets using quality and fidelity-based metrics. A total of 228 images were rated across both studies. The validation results show that the Swoop Portable MR Imaging System with advanced reconstruction performs better than linear reconstruction for all quality metrics, and there were no significant differences in fidelity metrics between the two algorithms.

Conclusion

Hyperfine advanced image reconstruction improves image quality with deep learning algorithms for Swoop system T1, T2, and FLAIR sequences. The system uses deep learning algorithms to optimize raw data prior to transforming the data into an image and further enhances the images through advanced denoising in the image post-processing step. Hyperfine designed the deep learning algorithms to preserve the integrity of diagnostic information and prevent the introduction of new artifacts during the advanced reconstruction process. The Swoop Portable MR Imaging System with advanced reconstruction has been successfully validated by independent expert radiologists and is FDA-cleared for sale in the US.

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