

Embrace[®] Neonatal MRI System Passes All Mandated ACR Accreditation Tests on Small ACR MRI Phantom



Embrace[®] Neonatal MRI System

Transforming Neonatal Neuroimaging *Inside* the NICU

Accreditation of Advanced Diagnostic Imaging Suppliers

Background:

“Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) amended section 1834(e) of the Social Security Act (the Act), requires suppliers of the technical component of advanced diagnostic imaging (ADI) services to be accredited by a designated accrediting organization in order to receive Medicare reimbursement. This accreditation requirement for ADI suppliers was effective January 1, 2012. CMS has the statutory authority to designate accrediting organizations which accredit suppliers furnishing the technical component of ADI services. These requirements do not apply to hospitals or critical access hospitals.”

It is up to each site to decide whether to apply to any of the four approved organizations (the American College of Radiology, the Intersocietal Accreditation Commission, The Joint Commission, and RadSite) for accreditation of their Embrace Neonatal MRI System. The major purpose of these accreditation programs is to ensure the technical and clinical quality of MRI examinations performed on a variety of MRI scanners of different vintages, operating at different field strengths with different accessories including RF coils, gradient coils, pulse sequences and other imaging options. The ACR MRI accreditation program, established in 1987 (1), is the most widely used in the field. A complete description of the data required for submission for ACR MRI Accreditation is provided on the ACR web site below:

<https://accreditationsupport.acr.org/support/solutions/articles/11000063276-complete-accreditation-information-mri>

Most neonatal MRI scanners will be hospital based, and thus will be exempt from requiring ACR accreditation for reimbursement. The additional factors that motivate sites to become an ACR accredited MRI site have been described by Serai et al. (2). These are centered around the fact that the evaluations required for ACR accreditation can be employed to establish best practices for assessing and monitoring critical quality control that influences the quality of the clinical MRI studies on neonates and their diagnostic value.

The Center for Medicare and Medicaid Services (CMS) web site provides the regulations governing the requirements for accreditation of the Embrace MRI system.

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers>

Table 1. Head and Neck Module

Head and Neck Module (old)	Head and Neck Module (new)
• Brain for TIA	• Brain for TIA or stroke
• IAC (IAC/temporal bone)	• IAC (IAC/temporal bone)
• Brain for suspected demyelinating disease*	• Brain for suspected demyelinating disease, encephalitis, or acute disseminated encephalomyelitis
• Pituitary with contrast enhancement•	• Pituitary with contrast enhancement
• Orbits for vision loss*	• Orbits for vision loss or tumor

Source: ACR MRI Accreditation Program requirements.

Note: IAC = ingernal auditory canal; TIA = transient ischemic attach.

*Specialty scans.

Reproduced from page 1024 of Serai et al (3).

Briefly, the elements of the accreditation process required by the ACR that can form the basis of best practices are the evaluation of the qualifications of MRI personnel, establishing that an MRI scanner passes its initial acceptance test, the establishment of a weekly quality control program, required safety policies, and MR image quality, including a peer-reviewed assessment of examples of clinical and phantom images, as well as continuous practice improvement. To qualify for ACR MRI facility accreditation, each neonatal MRI site must achieve a well-defined measure of quality and performance for the clinical examination types routinely performed. Embrace is currently approved by the FDA as a head only system. The protocols for clinical images, designated as the Head and Neck Module, required by the ACR have recently been approved for pediatric studies and are summarized in Table 1 (reproduced from Serrai et al. (3)). Note that since contrast agents are rarely used in neonatal studies, clinical examples for the protocols involving the injection of contrast agents are not required.

Aspect Imaging is committed to assisting sites in establishing and maintaining a high standard of diagnostic imaging performance. Accordingly, we initiated an internal program to ensure every Embrace would pass the scanner specific tests for ACR MRI accreditation and whether the ACR mandated phantom based weekly Quality Control program could help us achieve this goal.

As Embrace is a 1.0 T permanent magnet system, we were interested in reviewing the success rate of becoming an ACR Accredited MRI site for comparable MRI system. Cumulative statistics of the percentage of submissions to the ACR accreditation program that passed on the initial submission by April 2004 published by Weinreb et al.(1) are summarized in Table 2.

Table 2. Pass Rates of The ACR Accreditation Test by Magnetic Field Strength <1.0T as of April 2004

Field Strength	Total Applications	Initial Pass	Initial Fail	First Round Total*	Initial Pass Rate	Initial Fail Rate
<0.5 T	1704	571	898	1469	38.9%	61.1%
0.5-0.6 T	158	42	73	115	36.5%	63.5%
0.7-1.0 T	687	319	272	591	54.0%	46.0%
Total	2549	878	1243		49%	51 %

Reproduced from page 497 of Weinreb et al.(1).

We also reviewed references to the experience of consultants who perform the ACR MRI Accreditation Tests and other quality control evaluations. Dr. NessAiver has been working with MRI scanners for over 30 years, and in that time has become one of the most widely respected names in the field. He currently sits on the American College of Radiology's (ACR) Committee on Quality Assurance in Magnetic Resonance Imaging, and has spent the last 15 years at Simply Physics developing and perfecting QC programs for every type of scanner and situation. Dr. NessAiver has posted a summary of his experiences performing ACR mandated annual performance evaluations on over 204 MRI scanners from 8 vendors spanning a 10 year period between 2001 and 2011. He found that 78% of all scanners, and 85% of permanent Magnet systems had Image Quality issues.

(see: <http://www.simplyphysics.com/MRI%20QA%20RSNA%202011.pdf>)

Another experienced consultant is Dr. Robert A. Bell, President of R.A. Bell and Associates (RAB) which provides assistance to healthcare groups regarding the technical and operational aspects of MRI. Dr. Bell is one of the primary architects of the technical portion of the American College of Radiology (ACR) MR Accreditation program and of the ACR MRI phantom now recognized as a standard in the industry. To date, he has conducted annual system performance testing on over 2,500 MRI scanners ranging in field strengths from 0.2T to 3T. In the interest of full disclosure, Dr. Bell is a technical consultant to Aspect Imaging. His experience is similar to Dr. NessAiver, with approximately 80% of MRI scanners having image quality issues found through their ACR mandated annual performance evaluations.

Embrace, as a small bore permanent magnet 1.0T scanner, qualifies as a Speciality Magnet, 1.0T and "other than extremity magnet" in the ACR MRI Accreditation program. The ACR developed a specific phantom that was designed to fit into the bore of extremity magnets and is suitable for every system. Descriptions of this phantom and the testing procedures are given in the two ACR web sites listed below. The ACR requires the acquisition of five series taken on the small ACR phantom to be submitted with an application for MRI accreditation.

<https://www.acraccreditation.org/-/media/ACRAccreditation/Documents/MRI/SmallPhantomGuidance.pdf?la=en;>

<https://accreditationsupport.acr.org/support/solutions/articles/11000061036-mri-small-phantom-testing-instructions>

Aspect Imaging has developed a specific cradle to hold this phantom. The specific details of the pulse sequences specified for these five series are provided on pages 4 and 5 of the ACR Small Phantom Guidance Document. Briefly the first three series are specified by the ACR and they are referred to as the ACR T1 (used both in the sagittal and axial scan planes) and ACR T2 (axial only). The last two series are referred to as the Site T1 and Site T2 series and are the pulse sequences used clinically by each site. The quantitative metrics required for each of seven tests mandated by the ACR are summarized in Table 3.

Table 3. ACR mandated test for the small MRI phantom		
Geometric Distortion	ACR T1 Sagittal Localizer	1,3
High Contrast Spatial Resolution	ACR T1, ACR T2 or site T1 and T2 series*	1
Slice Thickness Accuracy	ACR T1, ACR T2 or site T1 and T2 series*	1
Slice Position Accuracy	ACR T1, ACR T2	1
Image Intensity Uniformity	ACR T1, ACR T2	4
Percent Signal Ghosting	ACR T1	5
Low Contrast Object Detectability	ACR T1, ACR T2 or site T1 and T2 series*	6, 7

*Each site can choose either the ACR series or the Site Series but must use both T1 and T2 from the same series

Examples of the MR images acquired with the ACR T1 protocol are shown in Figure 1.

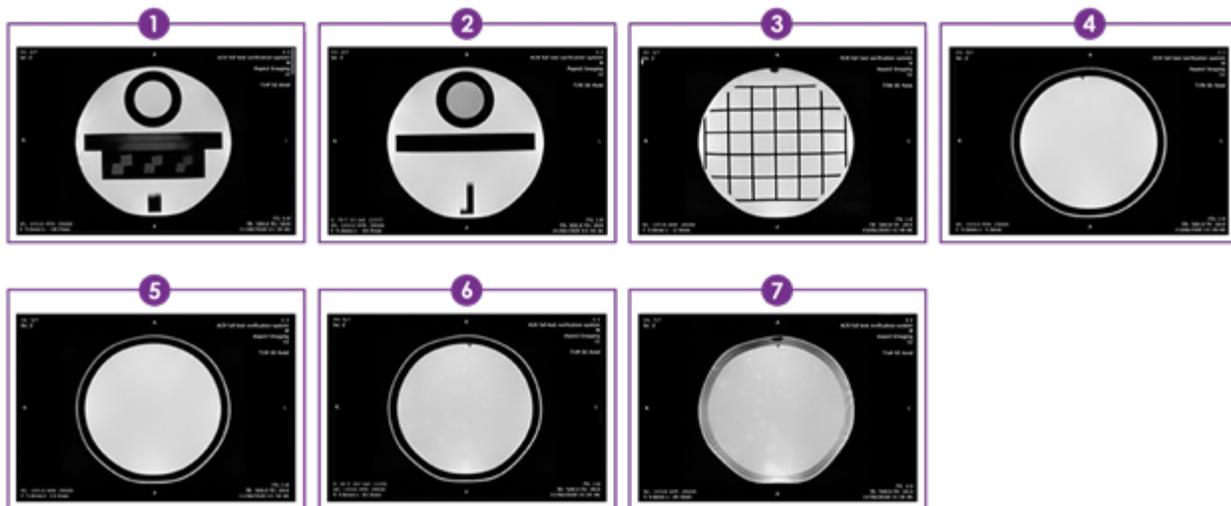


Figure 1: Axial MRI Images of the Small ACR Phantom Acquired Using the ACR T1 Sequence

In the course of running the ACR T1 and T2 sequences we found that we were able to modify the pulse sequences within allowable limits (set by the ACR) to pass these tests. We tested the performance (pass/fail) and reproducibility of the final versions of these sequences on three different Embrace systems by running them ten times on each. A summary of the final results is presented in Table 4.

Table 4. A Summary of Results Obtained on the ACR Mandated Accreditation Tests

ACR Test	Pulse Sequence	Metric Mean and Standard Deviation (STD)*	Pass/Fail
Geometric Accuracy	ACR T1	98.0 mm in both A-P and S-I dimensions	Pass
High Contrast Spatial Resolution	Site T1	0.7 mm	Pass
High Contrast Spatial Resolution	Site T2	0.7 mm	Pass
Slice Thickness Accuracy	Site T1	4.38 mm(STD 0.06)	Pass
Slice Thickness Accuracy	Site T2	4.91 STD mm (0.13)	Pass
Slice Position Accuracy	ACR T1	Delta 0.0 mm	Pass
Slice Position Accuracy	ACR T2	Delta 0.17mm (STD 0.34)	Pass
Image Intensity Uniformity	ACR T1	94.8%(STD 1.82)	Pass
Image Intensity Uniformity	ACR T2	89.5% (STD 2.97)	Pass
Percent Signal Ghosting	ACR T1	0.009% (STD 0.005)	Pass
Low Contrast Object Accuracy	Site T1	20 (number)	Pass

*STD is the relevant standard deviation of the 30 measurements performed for each test.

Aspect Imaging provides the validated imaging protocol that will produce results that meet or exceed the criteria set by the ACR. Aspect Imaging also provides both example images, imaging protocol parameters, and a document with frequently asked questions (FAQs) about the ACR accreditation process.

The standard deviations reported in Table 4, determined for all of the quantitative metrics required, are within the tolerance limits set by the ACR for each quantitative test. These results demonstrate that Embrace MRI systems will pass all of ACR mandated phantom tests.

References

1. Weinreb J, Wilcox PA, Hayden J, Lewis R, Froelich J. ACR MRI accreditation: yesterday, today, and tomorrow. *Journal of the American College of Radiology* : JACR. 2005;2(6):494-503.
2. Serai SD, Jones BV, Podberesky DJ, Coley B. Is It Time for a Dedicated Pediatric MRI ACR Accreditation Program? *Journal of the American College of Radiology*. 2013;10(4):274-8.
3. Serai SD, Rigsby CK, Kan HJ, Panigrahy A, Hernanz-Schulman M, Anupindi SA. Inclusion of Pediatric-Specific Indications and Procedures in the New ACR MRI Accreditation Program. *Journal of the American College of Radiology*. 2018;15(7):1022-6.