DCE - MRI Team

"Phantom DCE – MRI Study"

Study Protocol

Status: Draft

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Contact

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Revision History

Revision	Date	Author	Reason for change, and identify all documents effected by change	Minor or Major Change
V001	28Oct2008	Gudrun Zahlmann	First version of study protocol	
	1 Nov 2008	Michael Buonocore	Miscellaneous additions and changes. Addition of Appendices 1, 2 and 3.	Major
V003	4 Nov 2008	Gudrun Zahlmann	Miscellaneous additions after discussion Michael - Gudrun	Major
V004	6 Nov 2008	Gudrun Zahlmann	Adjustment of imaging sites and imaging schedule after team conference call	Minor
V005	7 Nov 2008	Gudrun Zahlmann	Adjustment of image analysis site and workflow	Minor
V006	13Nov 2008	Gudun Zahlmann	Data transport details and data analysis basics	Minor
V007	19Apr2009	Edward Jackson	Made changes to acquisition procedures based on baseline scans of the QIBA DCE-MRI phantoms	Major
V008	28 Oct 2009	Edward Jackson	Provided more detail on phantom placement and scanning procedures.	Minor

Contents

1 SUMMARY

The overall objective of the Quantitative Imaging Biomarker Alliance (QIBA) is to enhance the use of quantitative imaging methods in clinical practice. In a first set of activities together with pharmaceutical companies is to enable those companies to run multi-center clinical trials across imaging vendors, by reducing variance inherent among differing hardware and software platforms. A first application area is cancer trials.
Volumetric CT, FDG-PET and DCE-MRI have been identified as the most promising imaging techniques for this specific application.

Although those imaging techniques have different clinical development status – volumetric CT is already in clinical practice versus DCE-MRI as novel imaging technique in rather exploratory status – its use in multi-centre clinical trials cross imaging vendor has not been investigated. Clinical trials require comparable quantitative measures out of images. Therefore three working groups have been set up under QIBA to work with all relevant stakeholders on finding solutions.

In a QIBA workshop in May 2008 comparable imaging quality has been identified as first step on the way to make quantitative imaging results in clinical trials comparable.

The QIBA DCE-MRI team has agreed that imaging across GE, Philips and Siemens MR scanners, based on the same phantom, a generic imaging protocol, and well defined image and data analysis, will provide an understanding how different the quantitative results really are. This will form the basis for a clinical test – re-test study as validation of the phantom study findings.

The imaging procedure is based on a well defined phantom (a modified ADNI design) and will be performed using two different 1.5T MR scanners per imaging company (one newer scanner, one in widespread use). Imaging will be performed at select US clinical sites. Image and resulting data analysis will be performed centrally to provide a consistent analysis quality for further decision making. The phantom study is planned for three months.

2 INTRODUCTION

Clinical trials are the appropriate means to prove the validity of a research based novel idea in a clinical application. Novel therapeutic ingredients in the form of a new drug must show their medical efficiency by forming a group of trial subjects that utilize the new drug compared to a placebo or a current standard drug treatment. The same is valid for new diagnostic means and procedures. Clinical trials rely on quantitative measures of the response of the biological system to the therapeutically or other intervention.

Quantitative parameters like volumes (CT), SUV (FDG-PET) or R1 maps (DCE-MRI) allow measuring those complex responses of the human body, especially in cancer clinical trials. Quantization of imaging content is usually done on a per patient and per imaging modality basis. Due to the international and multi-site nature of cancer trials, with up to several thousand trial subjects, quantitative results need to be comparable in order to assure the necessary trial data quality.

Currently images are captured from the different participating clinical sites in a trial and then made comparable by the special knowledge of imaging CROs (contract research organizations) or trial sponsor imaging groups. This is time consuming and error prone. To change this situation a cross vendor initiative is necessary that investigates the comparability of images of a specific imaging procedure. This is only useful if all stakeholders including pharmaceutical companies, clinicians and radiologists, governmental bodies and regulatory organizations are working together. The Quantitative Imaging Biomarker Alliance (QIBA) of the RSNA is aimed to build this platform. Volumetric CT, FDG-PET and DCE-MRI are the most interesting imaging candidates for cancer clinical trials. This study investigates DCE-MRI.

3 AIMS OF THE STUDY

The aim of this study is to compare DCE-MRI images from GE, Philips and Siemens MR scanners based on phantom imaging with a generic imaging protocol. The following questions will be addressed:

- How reliable and practical is the proposed phantom imaging procedure as a tool for image quality assessment prior to and during clinical trials?
- Are surface/body coil ratio images useful for correcting RF receiver sensitivity variations?
- What is the reproducibility of R1, M0, SNR and CNR on each scanner?
- What are the differences in the slope of the relationship between the change in signal intensity and the change in R1 across different vendor's scanners?

4 DESIGN AND DURATION OF THE STUDY

The study will be a prospective phantom study. The duration of the study will be **3 months.** Two phantoms will be shipped to five sites for performing imaging on a total of six MR scanners according to a specific imaging protocol (see Appendices). Images will be stored and analyzed at one site designated for image and data analysis. This study is supported by RSNA.

5 RESPONSIBILITIES

5.1 Coordinating Investigators

Merck Research Laboratories

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RSNA

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5.2 Imaging Sites

1. MD Anderson Cancer Center:

Section of MR and Ultrasound Physics

Supervisor:

Dr. Edward F. Jackson
Tel.: +1 713-745-0559
Fax: +1 713-794-1767
EM: ejackson@mdanderson.org

MRI Systems:

GE (New): TRM (12.x)[1]

[1] SW version in brackets

GE (old): BRM (9.1x)
For comparison imaging at start and after all imaging procedures at the end of the study: GE (old): LX-CRM (12x)

2. Dept. of Radiology, University of Pennsylvania

Supervisor:
Dr. Mitchell Schnall / Dr. Mark Rosen Tel.:
Fax:
EM:

MRI Systems:
Siemens (New): Avanto (VB15)
Siemens (Old): Symphony or Sonata (VA25A)

3. Dept. of Radiology, University of Chicago:

Supervisor:
Dr. Gregory Karczmar Tel.:
Fax:
EM:

MRI Systems:
Philips (New): Achieva 1.5T XR system with 2.6 software and dual gradients

4. UC Davis Imaging Research Center

Supervisor:
Michael H. Buonocore Tel.: 916-734-0395
Fax: 916-734-8750
EM: mhbuonocore@ucdavis.edu

MRI Systems:
GE (Old): LX-CRM (9.1x)

5. Duke University

Supervisor:
Dr. Cecil Charles Tel.:
Fax:
EM:

MRI Systems:
Philips (Old): Integra 9.4

5.3 Quality Assurance

For Phantom quality:

MD Anderson Cancer Center:
Section of MR and Ultrasound Physics

Supervisor: Dr. Edward F. Jackson
Tel.: +1 713-745-0559
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For Image quality:

VirtualScopics:

Supervisor: Dr. Edward Ashton
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5.4 Image Analysis

VirtualScopics:

Supervisor: Dr. Edward Ashton
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Fax: +1 (585) 218-7350
EM: ashton@virtualscopics.com

5.5 Data Analysis

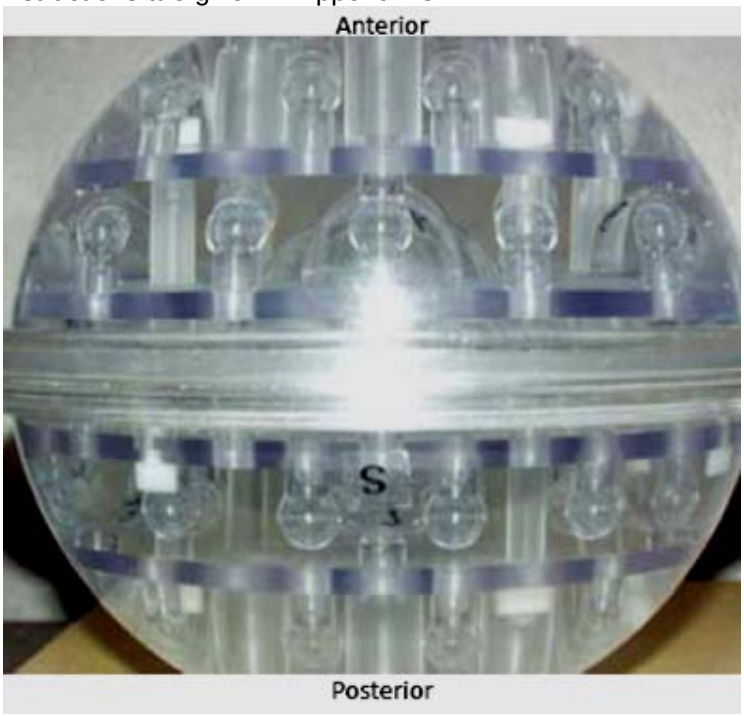
Data Analysis Center(s): (TO BE DETERMINED)

Tel.:
Fax:
EM:

6 METHODS

6.1 Phantom

QIBA DCE-MRI phantom design is based on the experience of the Alzheimer's disease Neuroimaging Initiative (ADNI, http://www.adni-info.org/), and The Imaging Response Assessment Teams (IRAT, http://www.aaci-cancer.org/irats/index.asp) Network. The critical design features are illustrated in Appendix 1. Setup instructions for this phantom are given in Appendix 2. Scanning Instructions are given in Appendix 3.



Two phantoms were purchased using NCI funding provided as a NCI RIDER subcontract to Edward Jackson (M.D. Anderson Cancer Center). The phantom provider is 'The Phantom Laboratory, Inc.', who is also the ADNI and IRAT DCE-MRI Subcommittee phantom provider.

6.2 Generic imaging protocol

The following generic imaging protocol will be used for all MR scanners used in the study:

Rotation A (also repeated 1 week later)	**Time (min)**	
Scout & Setup	5	
Ratio images - body coil receive	2	
Ratio images - phased array coil receive	2	
SNR images - phased array coil receive (8 separate acquisitions with 1 excitation each)	2	
R1 VFA acquisition	8	
DCE (40 phases)	6	
		25
Rotation B		
Scout & Setup	5	
Ratio images - body coil receive	2	
Ratio images - array coil receive	2	
SNR images - phased array coil receive (8 separate acquisitions with 1 excitation each)	2	
R1 VFA acquisition	8	
DCE (6 phases)	1	
		20
Rotation C		
Scout & Setup	5	
Ratio images - body coil receive	2	
Ratio images - array coil receive	2	
SNR images - phased array coil receive (8 separate acquisitions with 1 excitation each)	2	
R1 VFA acquisition	8	
DCE (6 phases)	1	
		20
Rotation D		
Scout & Setup	5	
Ratio images - body coil receive	2	
Ratio images - array coil receive	2	
SNR images - phased array coil receive (8 separate acquisitions with 1 excitation each)	2	
R1 VFA acquisition	8	
DCE (6 phases)	1	
		20
Rotation A'		
Scout & Setup	5	
Ratio images - body coil receive	2	
Ratio images - array coil receive	2	
SNR images - phased array coil receive (8	2	

separate acquisitions with 1 excitation each)		
R1 VFA acquisition	8	
DCE (40 phases)	6	
		25
	OVERALL	110

7 DATA COLLECTION AND MONITORING

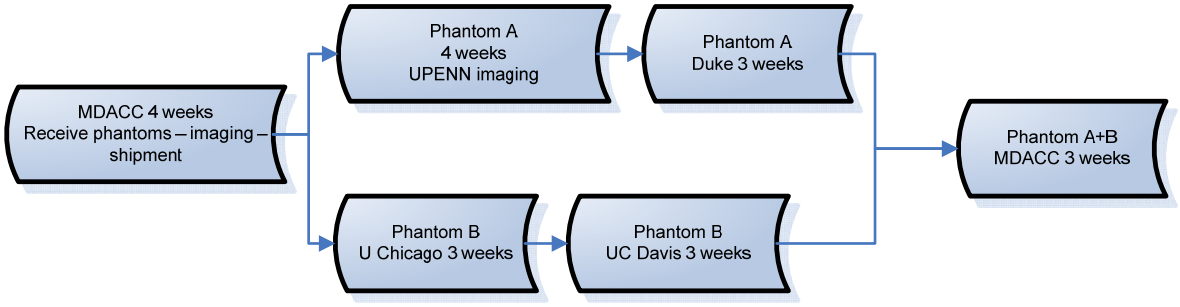
Imaging is performed according to the phantom setup instructions and the generic imaging protocol. Acquired images from each imaging site will be sent to the imaging analysis location using the existing NCI technical solution. (Contact: John Freyman NCI.) It is intended to store the images of this study centrally in the imaging archive of the NCI.
Monitoring of the study is performed by the Coordinating Investigators (Evelhoch, Zahlmann, Buonocore, Jackson). There will be regular conference calls regarding study progress, data quality and image analysis progress.

8 Study responsibilities and assigned personnel

8.1 Study Progress

Jeffrey Evelhoch is the lead of this phantom imaging study. Additional contact persons regarding the general study are Gudrun Zahlmann, Michael Buonocore, or Edward Jackson. The contact person for questions regarding phantom setup is Edward Jackson. For questions regarding the scanning protocol: Edward Jackson is the contact person for GE systems, Mark Rosen is the contact person for Siemens systems, and Greg Karczmar is the contact person for Philips systems.
The 2 phantoms will be delivered to MD Anderson first. After parallel assessment of both phantoms (quality measurement at start of study) and measuring with one trial scanner (GE), the phantoms will be sent, in parallel, to sites as follows:
(1) Phantoms are of comparable quality regarding the imaging procedure:

- MD Anderson ships one phantom to U Chicago and the second to U Penn for imaging
- U Penn having 2 scanners for the trial will provide images within 4 weeks
- Duke, U Chicago and UC Davis use one scanner for the trial each and will complete the imaging within 3 weeks
- U Penn sends its phantom to Duke
- U Chicago send the phantom to UC Davis
- All images are sent to the image analysis site
- Duke and UC Davis send the phantoms back to MD Anderson
- MD Anderson performs second quality assurance measurement (end of study)



The overall imaging procedure will require approximately 14 weeks in case no delays or unforeseen events (e.g. scanner non-availability, phantom leakage) occur.

Three-day FedEx shipping will be used. The shipments shall be scheduled on Tuesdays to assure receipt at the next site on Fridays.

8.2 Imaging site progress

Five clinical centers will perform the imaging procedure on a total of six MR scanners. At each site, one QIBA DCE-MRI team member from that site will be responsible for completing the imaging procedures at that site. After completion, the image package is sent to the image analysis site (VirtualScopics, Ed Ashton) and the coordinating investigators are informed.

Each site will provide at least one picture and a description of the scanner setup. A detailed outline of the scan procedure using a GE scanner is provided in section 17.

The detailed scan parameters and pulse sequences to be used by the different imaging sites are provided in section 18 and any deviations from the stated parameters should be noted and submitted to the Coordinating Investigators and the imaging analysis core (VirtualScopics).

8.3 Quality assurance

Phantom quality assurance

MD Anderson will carry out imaging procedures on the two purchased phantoms to acquire independent R1 measurements of the contrast spheres in the phantoms, and to identify any systematic differences with respect to contrast agent concentrations or geometric distortion before the first trial measurement at MD Anderson (start of study) and after all imaging procedures at the imaging sites (end of study). MD Anderson will provide a QA report at the end of the study.

Image quality assurance

VirtualScopics will do a basic image quality check right after receiving images from imaging sites. In case any problem is identified the image analysis centre will contact the imaging site directly for problem resolution. This will be done before the phantom is sent from this active imaging site to the next one. Image analysis centre reports any issues to coordinating investigators.

In case there is a problem with a phantom the imaging site or image analysis site consults MD Anderson and a final decision on next steps need to be made together with the Coordinating Investigators. VirtualScopics will provide a QA report at the end of the study.

Test procedure
Before the official start of the phantom study, a test procedure will be performed. MD Anderson will provide test imaging data using the phantom and QA imaging protocol. After initial quality assessment by MD Anderson, these images will be sent to VirtualScopics. There, again, a quality assessment will be performed. Then the newly developed image analysis software will be applied. All results will be communicated to the Coordinating Investigators for review. After confirmation of acceptable procedures and results, the phantom study can be started with the first trial imaging at MD Anderson.

8.4 Image and data analysis

All acquired images will be transferred electronically to VirtualScopics. The image analysis will be performed according to the procedures in this study protocol (cp. 9). Images collected at all sites, and the results of image analysis, will be made available to all sites represented on the QIBA DCE-MRI team. Data analysis relevant for the results of the phantom study outcome will be carried out by the data analysis site according to the description in 10.

Other QIBA DCE-MRI teams can do image and or data analysis as well on their own responsibility.

The development of the image analysis software by VirtualScopics will require approximately 2 weeks.

9 IMAGE ANALYSIS

The central image analysis site will analyze the images according to the following instructions:1. Co-register images from each acquisition

2. Define 3D ROI for each contrast sphere (region growing, with conservative edges)
3. Determine R1 for each contrast sphere from inversion recovery (IR) spin echo images*
4. Use full volume 3D voxel-wise analyses
5. Calculate ratio image from Ratio acquisition protocol images
   a. Determine average ratio for each contrast sphere ROI
   b. Evaluate feasibility of fitting to 3D model
   c. Evaluate impact of 2X acquisitions on a & b
6. Signal (contrast) evaluation (including reproducibility & ratio correction, ROI averaging before/after analysis)
7. SNR evaluation (including reproducibility & ratio correction, ROI averaging before/after analysis)
8. CNR evaluation (including reproducibility & ratio correction, ROI averaging before/after analysis)
9. R1 evaluation (R1 and M0 including reproducibility & ratio correction, ROI averaging before/after analysis)

*To be acquired at MD Anderson and, possibly, at a reduced number of subsequent sites.
Regarding #1, co-registration of images is not required provided that subsequent ROI analysis is done in a way that compensates for any misregistration. Regarding #2, #4 and #5b, although 3D analysis is preferred, multiple 2D analyses will be accepted.

10 DATA ANALYSIS

Parameters derived from Image Analysis will be analyzed across MRI scanners and manufacturers. The following analyses will be made:

1. Dependence of signal intensity on R1 and location in phantom (8 locations (spheres) and 5 rotations) with and without ratio corrections for ROI averaging before/after analysis

    Uses data from instruction 5 & 6 of Image Analysis

2. Short term (within session) and long term (across sessions) temporal stability of signal (short: immediate without repositioning; long: 1 week) for ROI averaging before/after analysis

    Uses data from instruction 6 of Image Analysis

3. R1 measurement for each rotation for ROI averaging before/after analysis

    Uses data from instruction 9 of Image Analysis

4. Stability of filling solutions

    Uses data from instruction 3 of Image Analysis

5. Comparison of spatial dependence of M0 and ratio

    Uses data from instructions 5 & 9 of Image Analysis

6. Noise characteristics of RF coil receiver sensitivity maps (ratio map)

    Uses data from instructions 5, 6, 7 & 8 of Image Analysis

7. SNR & CNR (single image and stability) for ROI averaging before/after analysis

    Uses data from instructions 7 & 8 of Image Analysis

The usefulness of this approach to data collection and analysis will be determined based on the experiences of the imaging sites, the image and data analysis sites, and the overall management team.

Basic data analysis will be explorative using basic statistics like mean value and SD. QIBA DCE-MRI investigators may carry out more advanced data analyses, which will be shared with the group during a subsequent teleconference/WebEx session.

11 HUMAN SUBJECTS AND DATA PROTECTION

Because this study involves imaging a phantom only, there are no specific human subjects' concerns. Images and data from image analysis will be stored at one location and made publicly available after image collection and analysis.

12 PROTOCOL CHANGES

After the phantom study has started, any change from the written procedures in this study protocol by one of the participating sites, whether required to complete their participation or not, requires review and agreement of the Coordinating Investigators. Participating sites requiring or requesting a change must submit their request in writing (e.g., via e-mail) to the Lead Investigator.

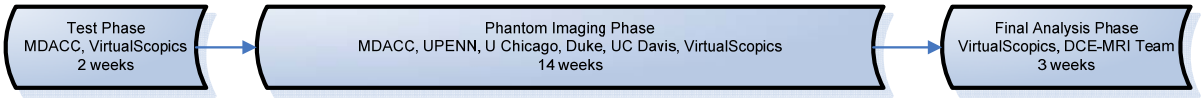
13 REPORTS AND PUBLICATIONS

At the end of the phantom imaging study a Study Report will be generated. Requests for publications based on this Report, or based on the original images and or data from this study, require review and approval by the Coordinating Investigators.

After publication of the study results all images, image analysis parameters, data analysis as well as the used analysis software will be made publicly available via the NCIA (National Cancer Imaging Archive).

14 STUDY TIMELINE

The overall study timeline is as follows:



After completion of the test phase (cp. 8.3), the phantom imaging will be performed at the five imaging sites under quality assurance and image analysis of VirtualScopics. After completion of the last QA scan at MD Anderson all data are ready for final analysis. After publication of the results, all data and results are archived and ready for public access.

15 SIGNATURES

15.1 Coordinating Investigators

Dr. Evelhoch _____ _____

Dr. Zahlmann _____ _____

Dr. Buonocore _____ _____

Dr. Sullivan _____ _____

Dr. Bresolin _____ _____

15.2 Imaging Site Supervisors

Dr. Jackson _____ _____

Dr. Schnall _____ _____

Dr. Karczmar _____ _____

Dr. Buonocore _____ _____

Dr. Charles _____ _____

15.3 Image Analysis Site Supervisor

Dr. Ashton _____ _____

16 Appendix 1: Phantom Design

Some of the figures and captions in Appendix 1 and Appendix 2 are reproduced with permission from the MRI Subcommittee of the Imaging Response Assessment Teams (IRAT) Network (http://www.aaci-cancer.org/irats/index.asp). Others were added or edited by Edward Jackson to accurately represent the two phantoms used in this particular study.

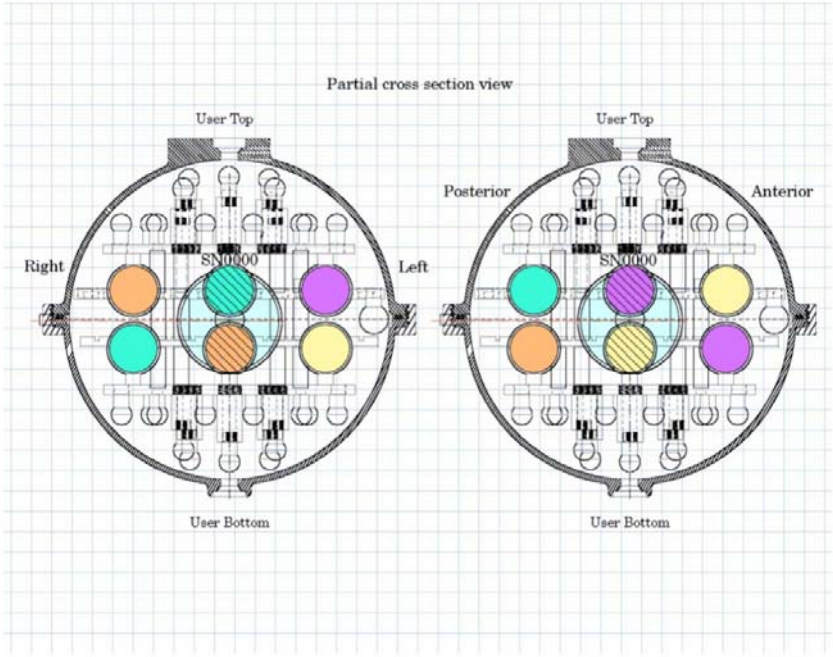
Figure 1: Sketch of modified ADNI Phantom: Cross hatch indicates spheres out of center plane	

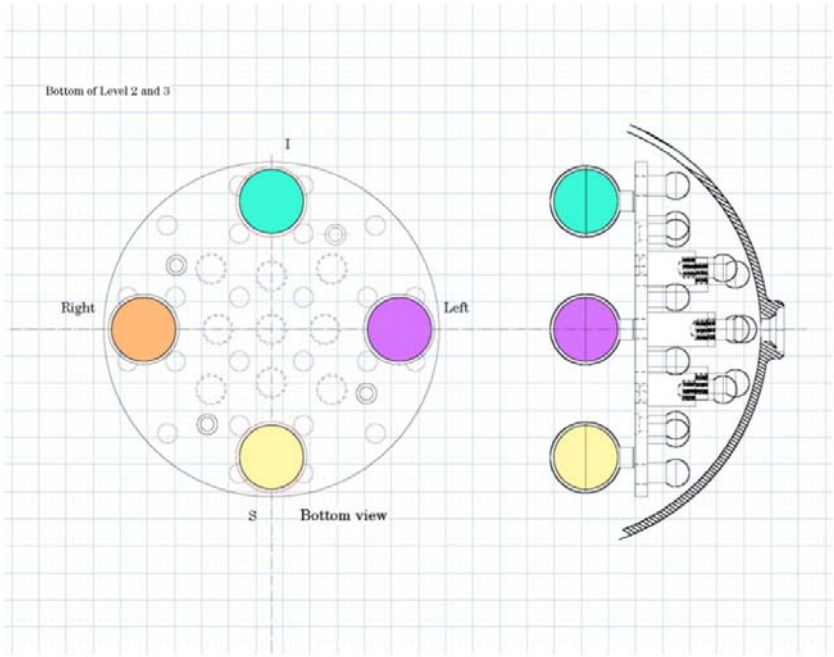
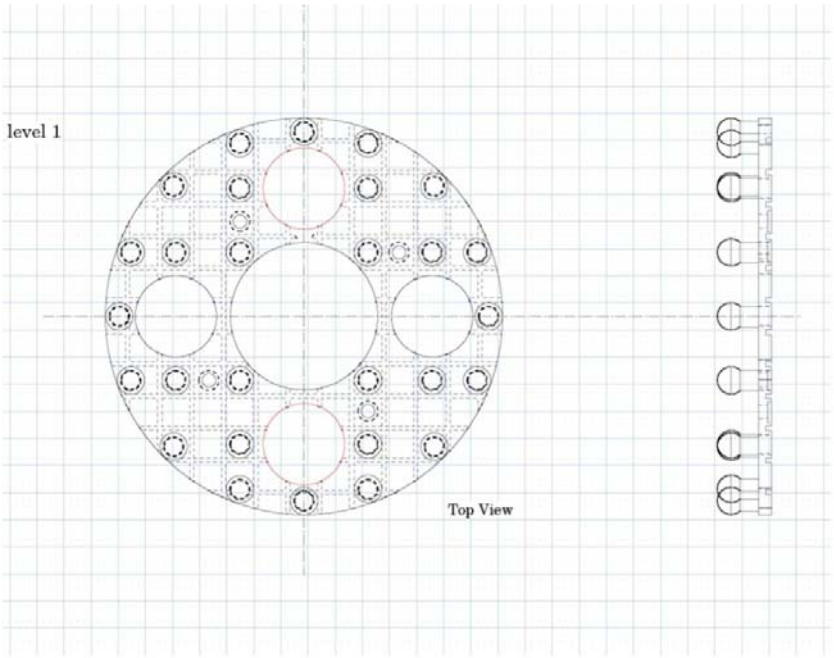
Figure 2:Sketch showing 2 extras spheres mounted on top plate (this is reflected on the bottom plate)	
Figure 3: Sketch showing change of plate for plane 1.	

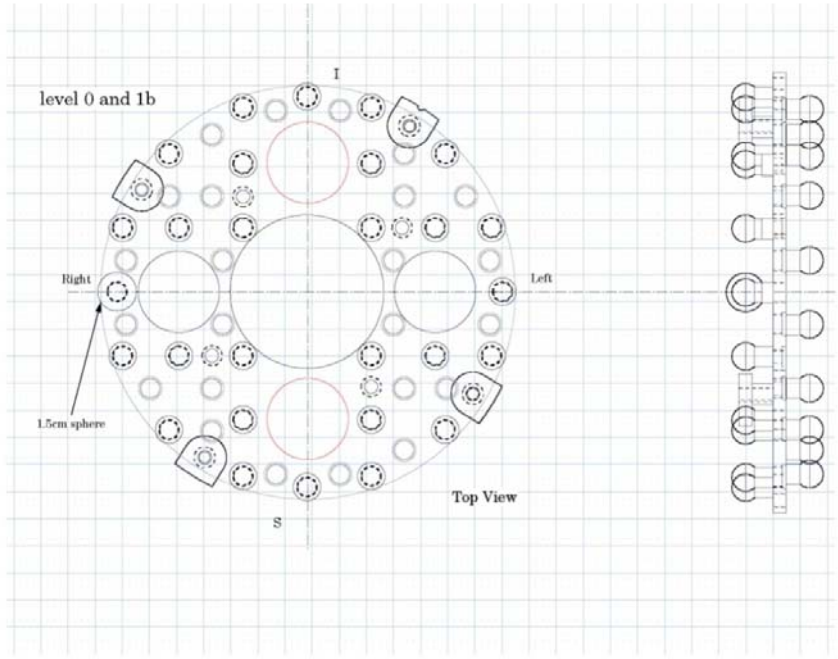
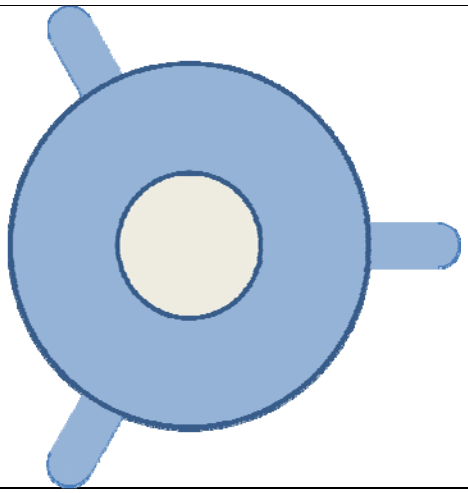
Figure 4: Sketch showing change of plate for plane 0 and plane 1b.	
Figure 5: Shape of protuberance from base of ADNI phantom.	

Figure 6:Position of cut-out "Star" on birch board to fit protuberance.

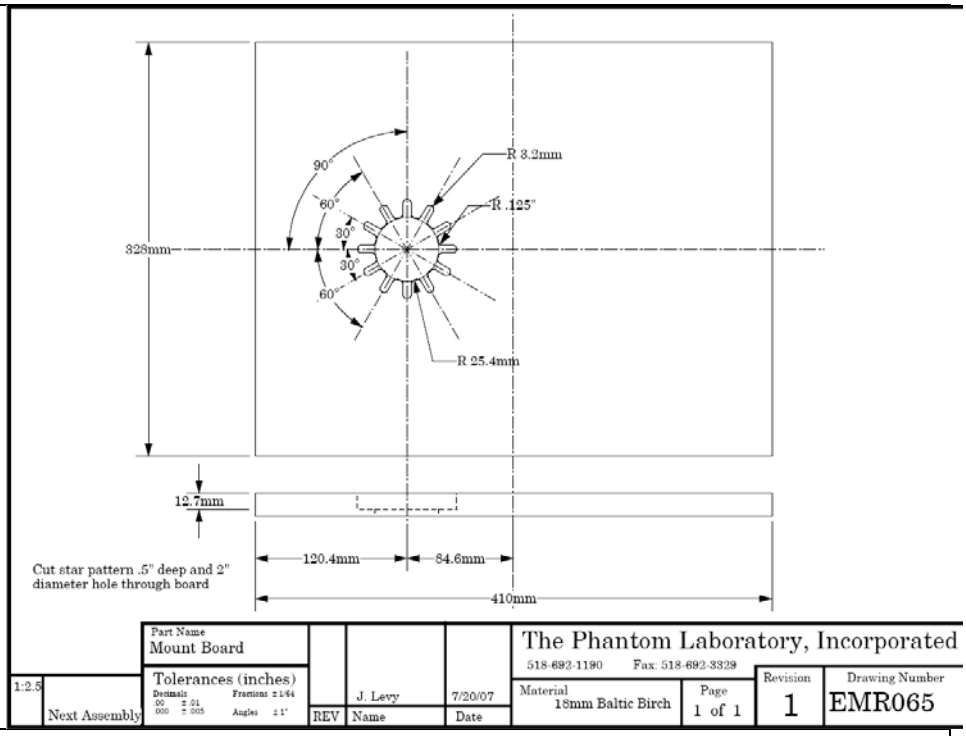


Figure 7: Torso Phased-Array RF Coil, and position of spherical phantom and cuboid.

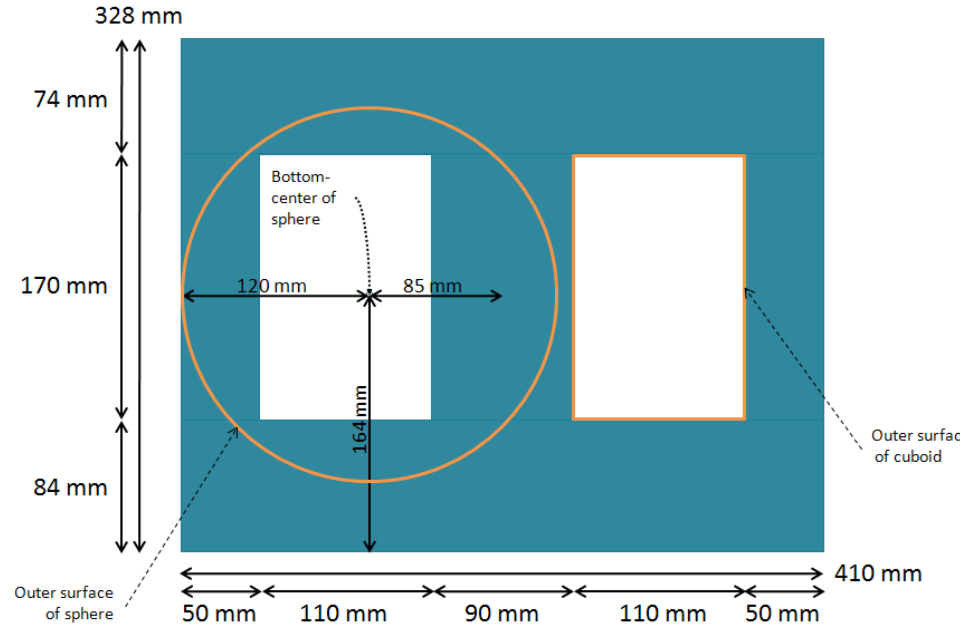
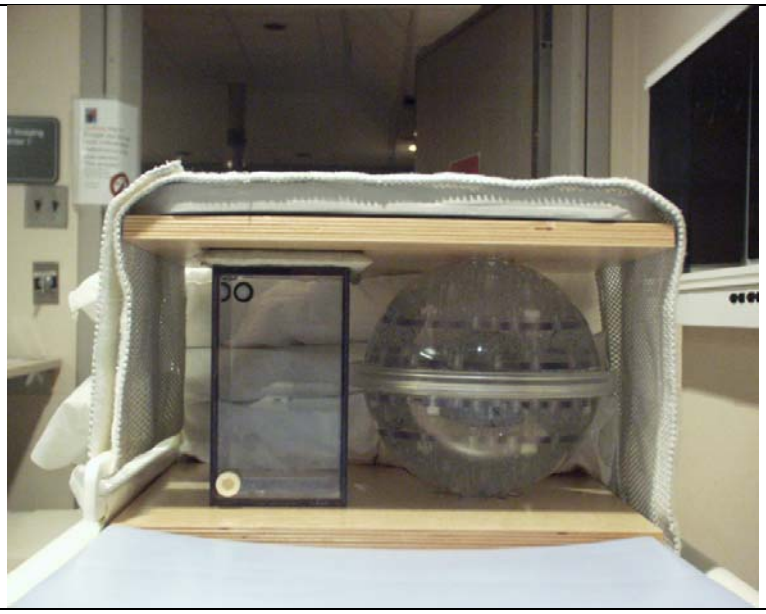


Figure 8: Final configuration of spherical phantom, cuboid phantom, birch board support, phased array RF coil, and strap supports. Straps must be tight so that top birch board is parallel to bottom board, and top and bottom boards are aligned vertically.	

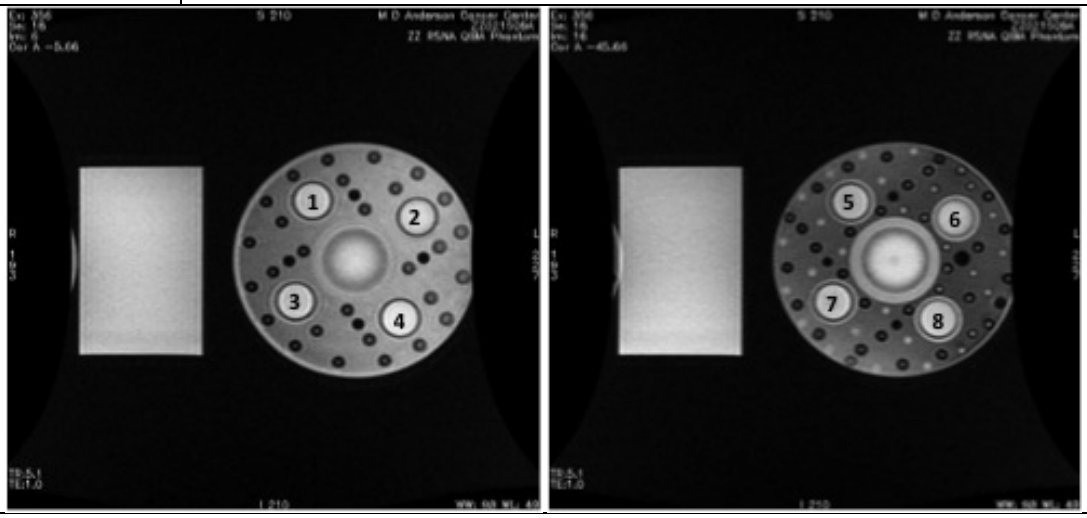


Figure 9: Images of the phantom in Position A (with the "I" marker facing away from the magnet). The measured T1 values (from the IR-based measurements) from each of the numbered spheres are as follows: 1: 390 ms, 2: 523 ms, 3: 760 ms, 4: 298 ms, 5: 624 ms, 6: 340 ms, 7: 446 ms, 8: 959 ms. Spheres 1-4 are in the more anterior section and spheres 5-8 are in the posterior section.

17 Appendix 2: Phantom Setup Instructions

Some of the figures and captions in Appendix 1 and Appendix 2 are reproduced with permission from the MRI Subcommittee of the Imaging Response Assessment Teams (IRAT) Network (http://www.aaci-cancer.org/irats/index.asp). Others were added or edited by Edward Jackson to accurately represent the two phantoms used in this particular study.

These instructions explain the phantom setup on a GE Signa MRI system using a 4-channel torso phased array coil. The instructions are readily adaptable for phantom setup on other vendors' MRI systems.

A. Initial setup of the DCE-MRI phantom on the patient table

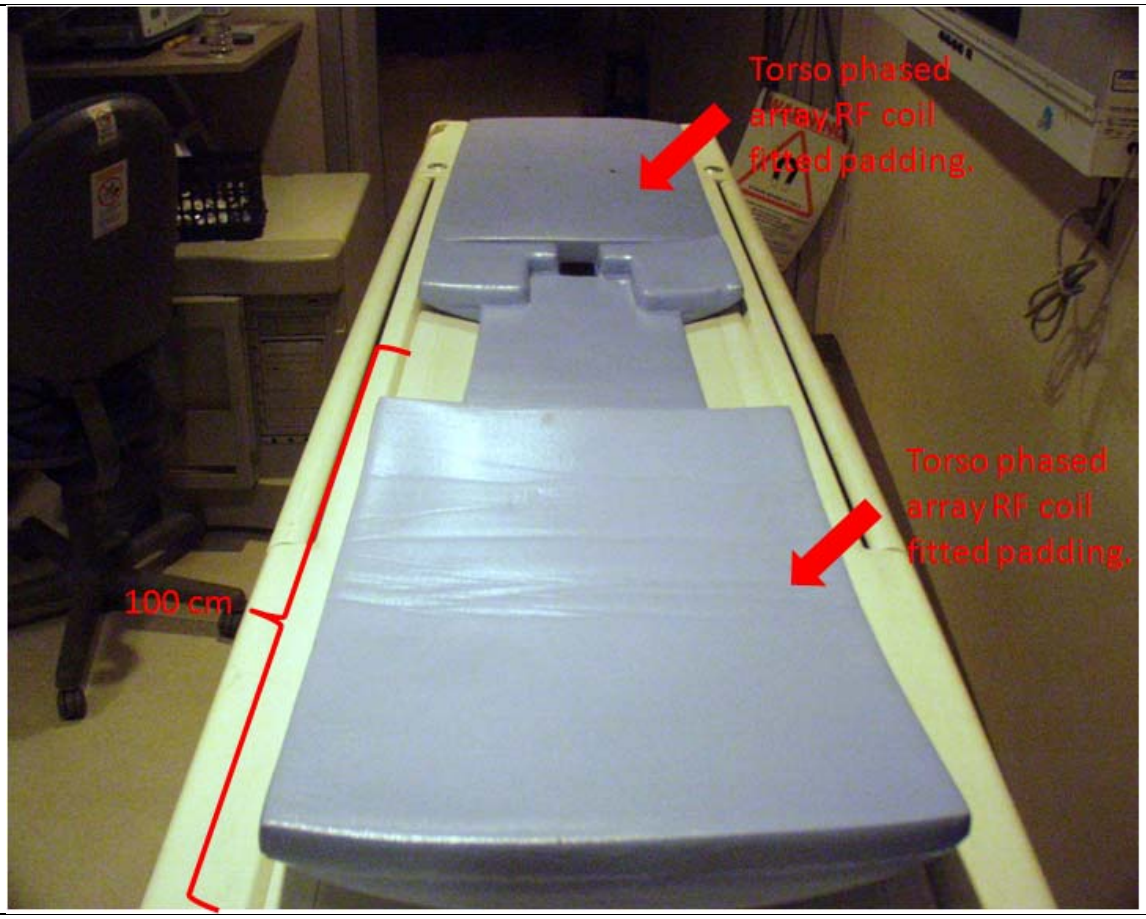


Figure A.1. Put the torso array pad on the patient table so that there a flat surface for placement of the birch boards. The center of the molded cutout of the pad should be placed approximately 100 cm from the front edge of the patient table.

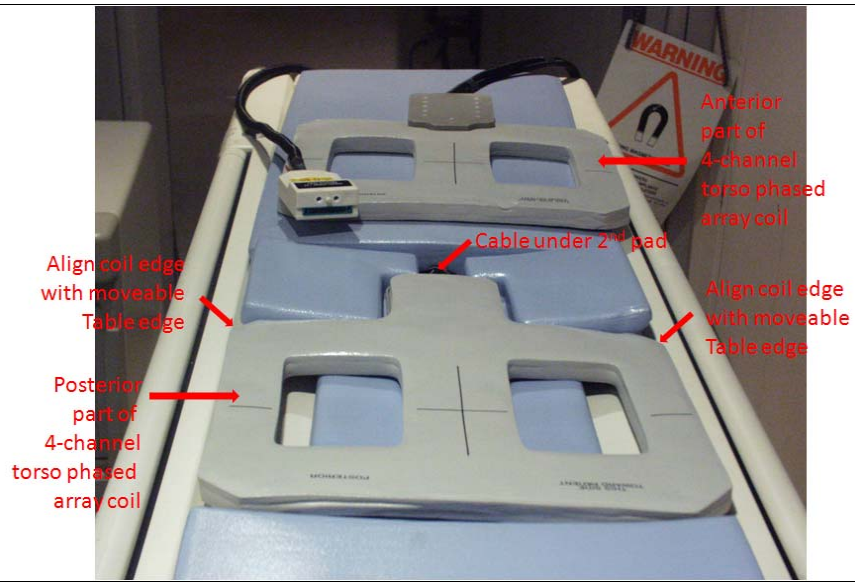


Figure A.2. Place the posterior part of the abdominal (torso) phased array coil in the molded cutoff of the pad. Make sure that you have put the coil cable under the 2nd pad, in the track of the 2nd pad. Make sure that the cabling of the coil reaches to the RF coil plug receptacle located at the magnet end of the table.

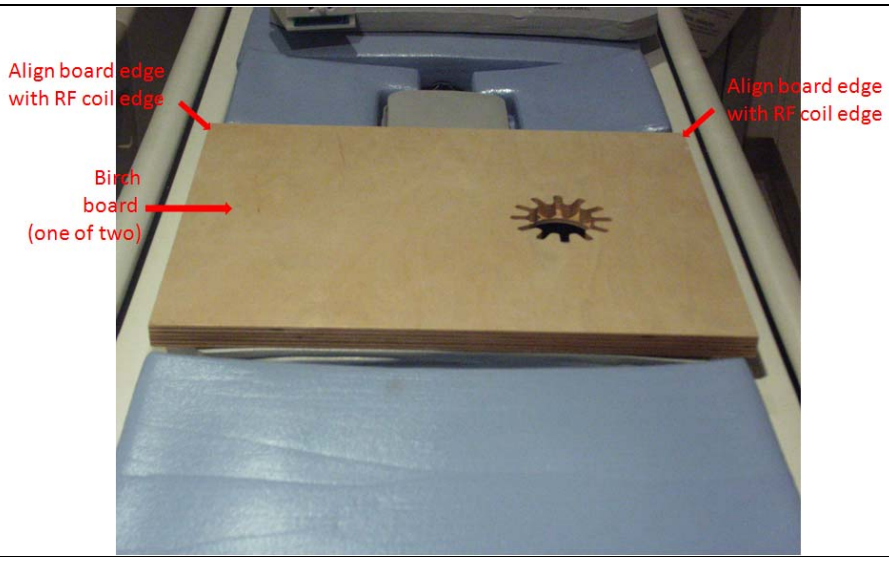


Figure A.3. Place one birch board (note there are two birch boards that are exactly the same) on the top of posterior coil. For the GE abdominal 4-channel torso phased array RF coil for EchoSpeed MRI systems, the width and length of the birch board match exactly those of the coil. Be sure to place the birch board so that the star cutout is located on the patient's right side for a "Feet First" orientation. In other words, if you are at the end of the table facing the magnet center, the star should be on your right side of the table. Be sure that the coil and the birch board are placed exactly in the center of the table in the R/L direction. No portion of the cable, nor the birch board should over hang the boundary of the moving part of the patient table.

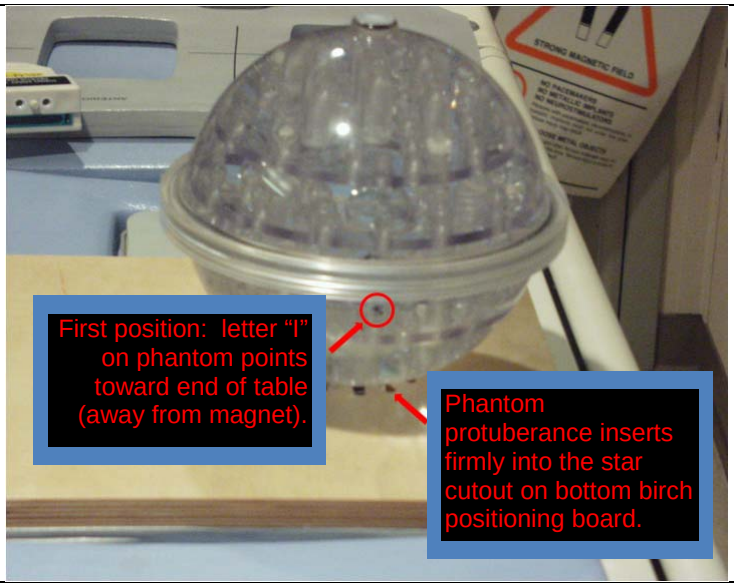


Figure A.4. Fit the protuberance of the spherical phantom into the star shaped cutout of the birch board. This creates a tight fit of spherical phantom such that the phantom cannot tip from an upright position. Check the markings of the spherical phantom. The letter "I" (for "Inferior" should be pointed away from the magnet center, towards the far end of the table. **Make sure a fiducial marker (provided) is secured to the phantom just below the "I" inscription, and that two fiducial markers (provided) are secured to the phantom above the "R" inscription.**

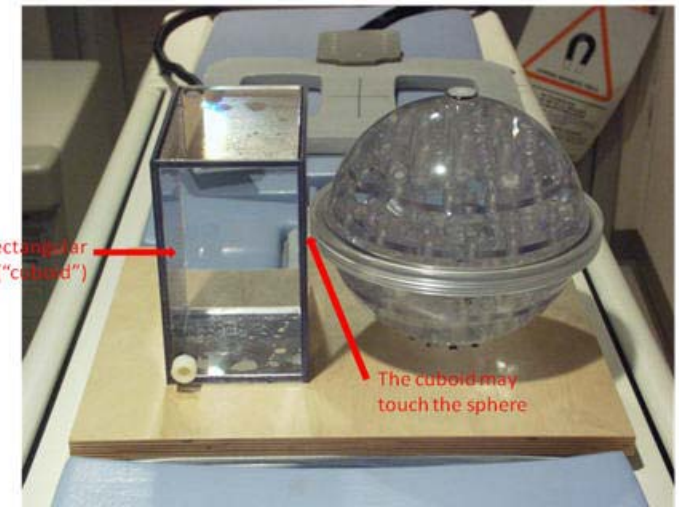


Figure A.5. The cuboid ("rectangular block") is the other important piece of the two-piece phantom. This cuboid should be placed directly on top of the birch board and immediately to the left of the spherical phantom. In the superior/inferior direction, center the cuboid relative to the spherical phantom. The cuboid wall should touch the plastic middle seam of the spherical phantom. NOTE: If the cuboid is delivered empty, it should be filled with ~1 gal of distilled water and one vial of NaCl (provided).

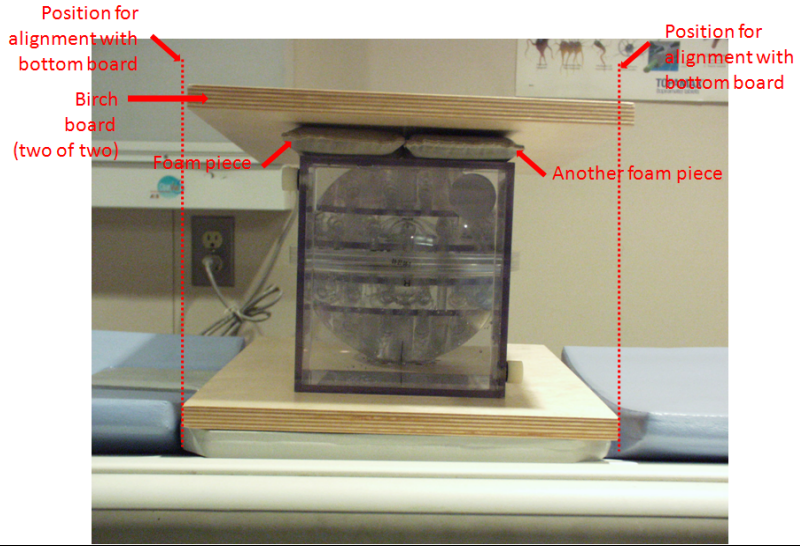


Figure A.6. Place foam positioning pads on top the cuboid. Note that these foam pads will be compressed and help hold the cuboid in place when the top birch board is placed on top of it. Place the 2nd birch board on top of the spherical phantom and the cuboid. The circular protuberance of the spherical phantom should be centered in the star cutout of the birch board. The birch board is not held in this configuration so be careful to hold its position while proceeding with the setup.

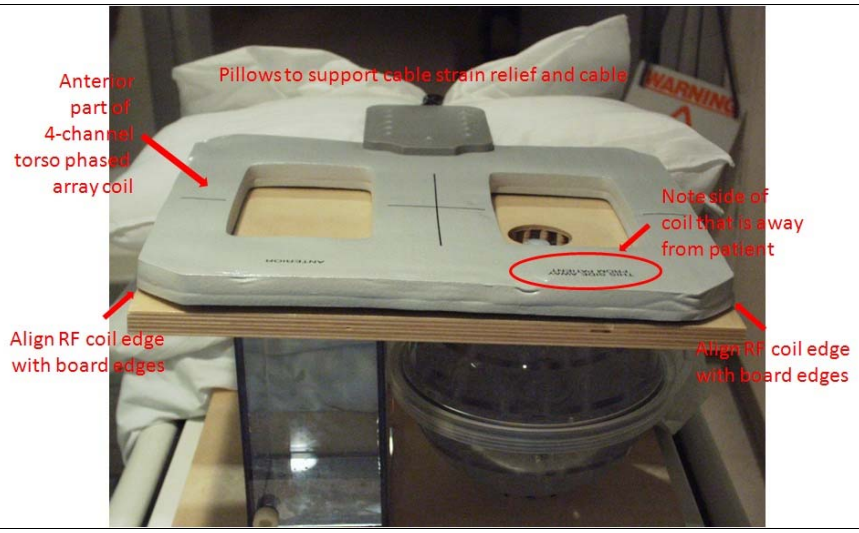


Figure A.7. Place the anterior part of the phased array RF coil on top of the top birch board. Also, make sure that this top assembly of coil and board align with the bottom assembly of board and coil. Use multiple pillows (or equivalent, but pillows seem to be best!) to support the cable and the extension of the top part of the phase array RF coil. The pillows will support the weight of the cable and cable strain relief, and will help to stabilize the top part of the RF coil on the birch board.

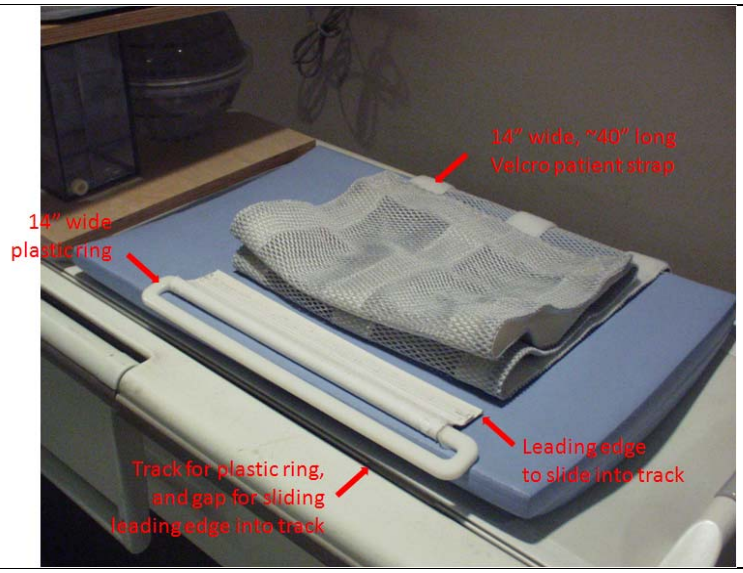


Figure A.8. On the patient table of the GE system, slide the wide (about 14" long) plastic ring assembly into the track along the left side of the table. On the right side of the table, slide the broad patient strap into the track. This patient strap is approximately 40" long and will serve to secure the total assembly of coil, birch board, spherical phantom and cuboid and make it a rigid structure.

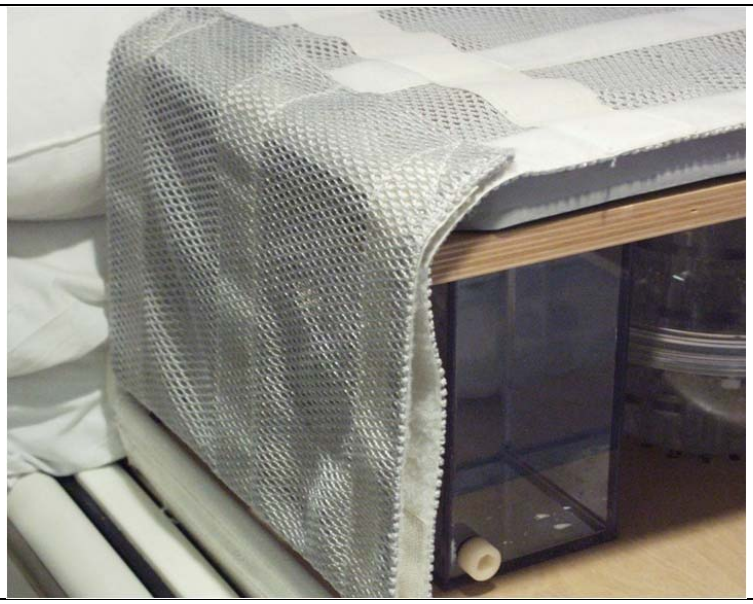


Figure A.9. Wrap the patient strap tightly around the total assembly. From the left side of the table, the strap should be carried over the assembly, carried down and put through the plastic ring on the right side of the table, and then pulled down. Prior to Velcro-ing the patient strap to itself along the top side, adjust the top assembly consisting of coil and birch board so that they are horizontal (parallel to the table), and also are aligned with the bottom assembly. There should be minimal pull down of the top assembly on either side.

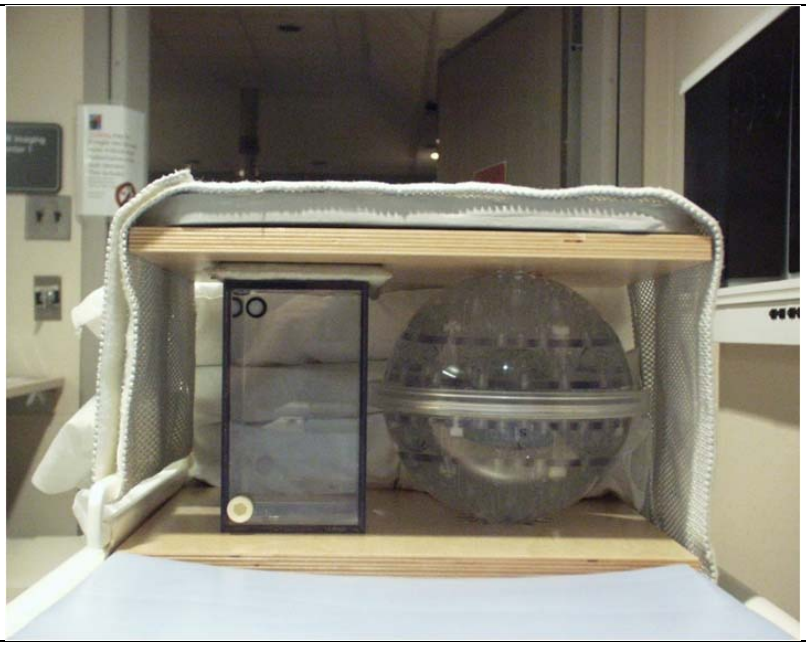


Figure A.10. Release the strap to adjust the top birch board and RF coil and achieve a horizontal orientation and alignment of the top assembly with the bottom assembly. Also, the patient strap should not be so tight as to cause the RF coil to flex. The flex will invariably cause a gap to form between the birch board and the RF coil. The gap will cause the RF coil to pick up less signal from the phantom, and hence should be minimized.

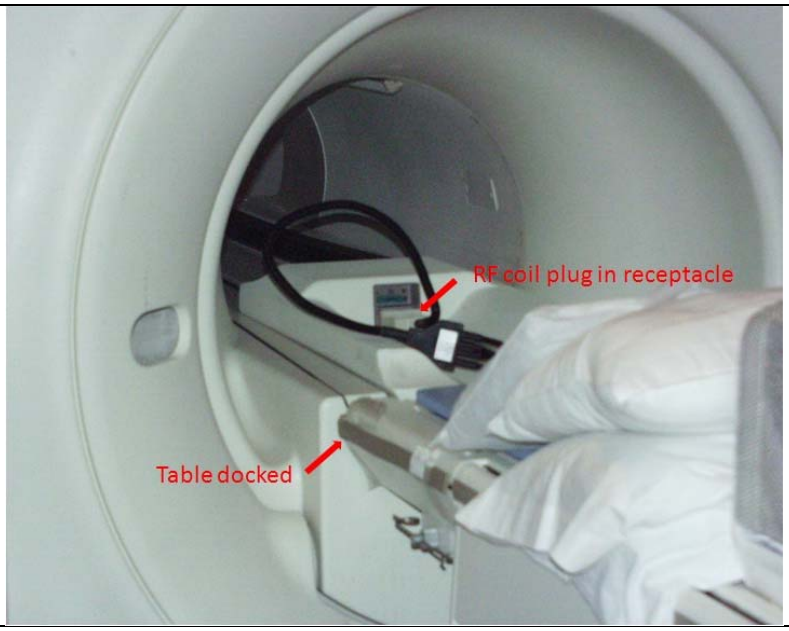


Figure A.11. Move the patient table with the final phantom assembly into the magnet room. Dock the patient table to the magnet, and insert the coil plug into the lower receptacle.

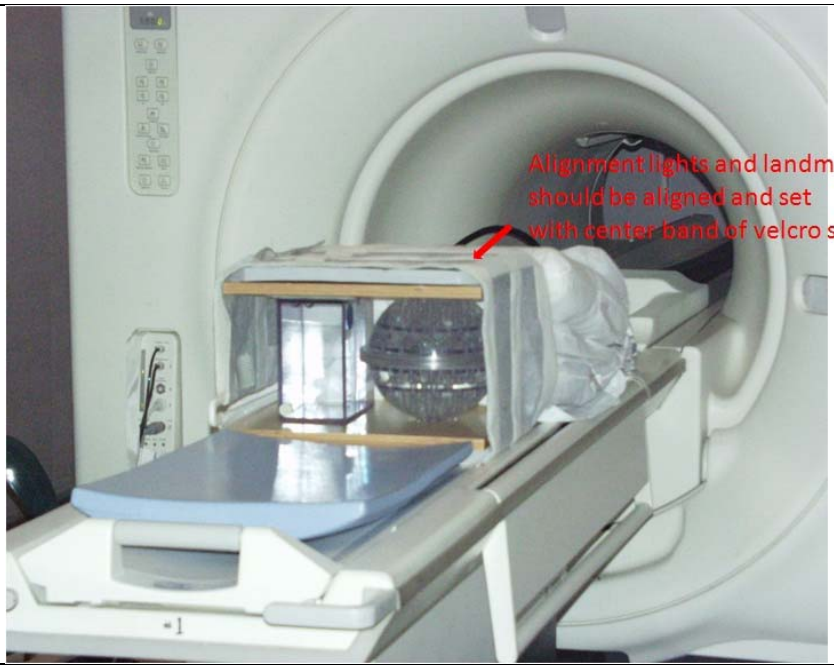


Figure A.12. Turn on the alignment lights, and move the table such that the assembly is bisected by the alignment lights. Make final adjustments of the assembly so that the alignment lights bisect the assembly both in the superior/inferior direction, AND the right/left direction. The alignment lights help to show the presence of poor alignment of the top and bottom parts of the total assembly. Set the landmark, and hit the Advance to Scan button to move the total assembly into the center of the magnet. After completing the protocol, bring the patient table to the "Home" position.

B. Disassembly, phantom rotation, and reassembly of setup (4 times)

Do the following steps to sequentially rotate the phantom 90 degrees around a vertical axis. Note, the figures showing the rotation were taken with the table outside of the magnet room. Normally, this procedure will be carried out in the magnet room, with the patient table remaining docked to the magnet.

To rotate the phantom, it is best to have the table near in the "Home" or "Landmark" position in order to have room for rotating the phantom. You will be rotating the spherical phantom counterclockwise by 90 degrees. The rotation will place the "L" marker such that it faces the end of the table (away from the magnet). Through this process which allows rotation of the spherical phantom, you need to be very careful that the bottom assembly does not move. With some practice, one can rotate the phantom to all positions without removing the upper coil and upper birch board. In any case, make temporary marks with a marker on the edge of the patient table, on both sides of the table, to serve as reference points for the location of the lower birch board. The marks can be aligned with the inferior or superior edge of the birch board, or both. Be sure to align the birch boards with these marks after the phantom rotation and reassembly is completed.

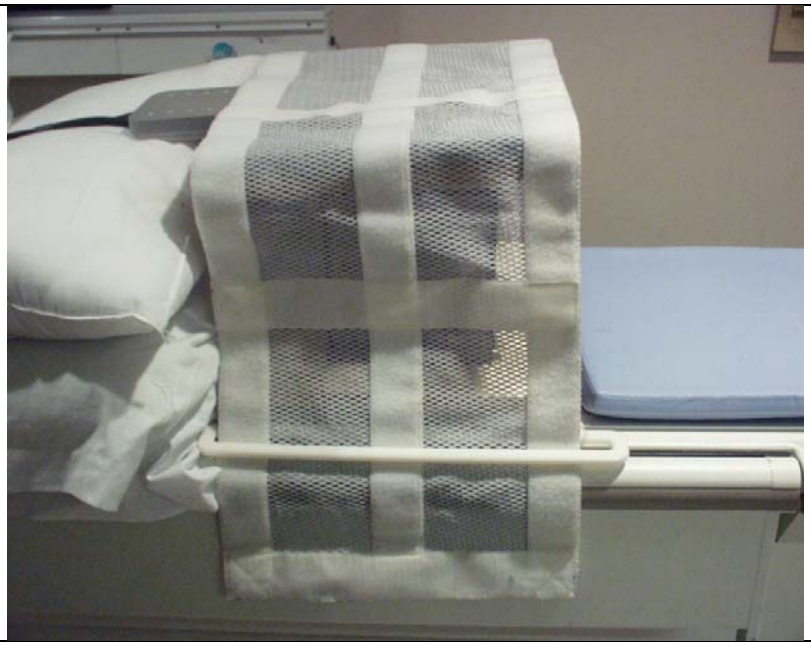


Figure B.1. Loosen the total assembly by releasing the Velcro attachment of the patient strap to itself. This action will eliminate the horizontal orientation of the top assembly and also the alignment of the top and bottom assemblies.

Figure B.2(a). Without allowing the lower birch board to move, lift the spherical phantom out of the star cutout of the birch board. Rotate the spherical phantom by 90 degrees and reset the phantom in the star cutout.

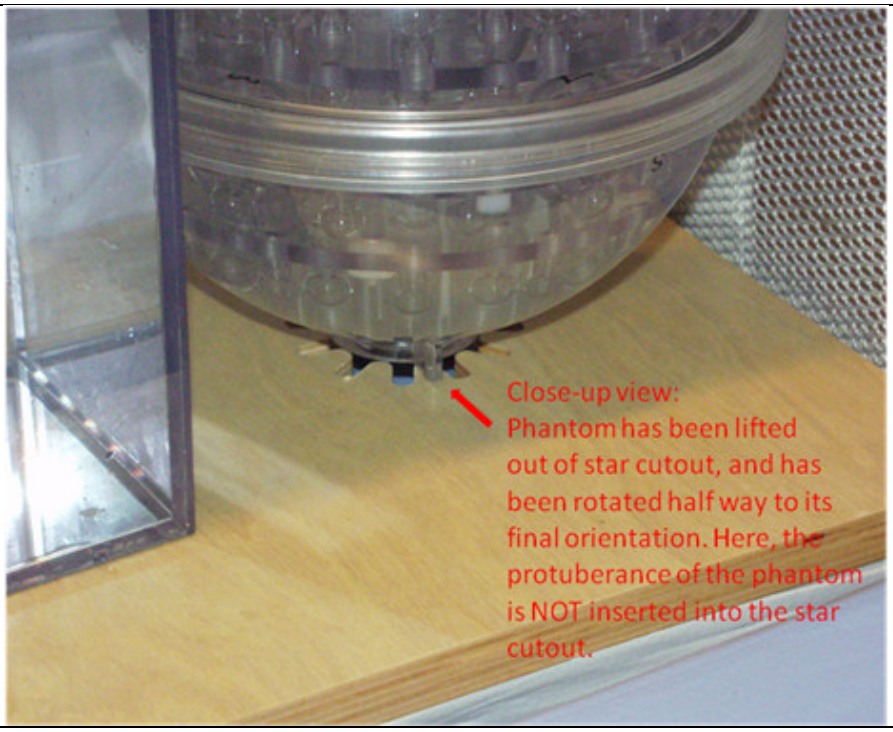


Figure B.2(b): Close up view of phantom position midway through rotation

In this second position, the "L" marker will be facing the end of the table (away from the magnet).

In the third position, the "S" marker will be facing the end of the table (away from the magnet).

In the fourth position, the "R" marker will be facing the end of the table (away from the magnet).

In the fifth position, the "I" marker will again be facing the end of the table (away from the magnet).

In each position: Verify the cuboid is touching the seam of the spherical phantom and is centered in the superior/inferior direction. Verify that the foam pieces are on top of the cuboid. Then, reestablish the original position of the bottom birch board (based on the marks that you made on the edges of the table!), the horizontal orientation of the top assembly, the alignment of the top and bottom assemblies, and finally check that the RF coil is flush against the top birch board. It is required that the total assembly does not change its position during the phantom rotation process. As the position of the assembly has not changed, press "Advance to Scan" to put the assembly back to the isocenter of the magnet.

18 Appendix 3: Scan parameter values

Each imaging site is responsible for submitting to the Coordinating Investigators a formal listing of the specific scan parameters and their values used for each sequence on each MR scanner. These formal listings will result from the work done to set up each of the sequences from the generic protocol given below. For example, when the Siemens system is used, the pdf file output generated by the MR system that lists all parameter settings for all scans should be provided to the Coordinating Investigators.

Each site should provide scan parameters and their values for the following sequences, which are included in the Generic Imaging Protocol listed above (see Section 6: Methods):

1. Scout scan (prescribe using a Head First, Supine orientation),

2. Ratio body coil receive scan,

3. Ratio phased array coil receive scan,

4. SNR scan (same as ratio phased array scan but with 8 separate acquisitions of 1 excitation each),

5. R1 mapping scan, and

6. Dynamic contrast enhanced (DCE) scan.

18.1 Generic dynamic contrast enhanced (DCE) protocol

Prescribe scans using a Head First, Supine setup.
3D fast spoiled gradient recalled echo (FSPGR) or equivalent
Body XMT
Phased array RCV
Extended dynamic range (on GE scanners – results in 32-bit digitization)
No parallel imaging
No magnetization preparation
Coronal acquisition
Frequency encode S/I
TE as short as possible (<1 ms)
TR as short as possible (3-6 ms)
Temporal resolution ≤10 sec
Flip angle: 30 deg
±31.25 kHz receiver bandwidth (i.e., 250 Hz/pixel)
Region appropriate FOV (recommend 42 x 34 cm)
80% phase encoding FOV (34 cm for a 42 cm FE FOV)
Partial Fourier (“fractional echo”) as needed
As many slices per acquisition as possible (~12 prior to zero fill)
8 mm slice thickness with slice interpolation
256 x 160 acquisition matrix
Reconstruction 2x resolution in all directions (i.e., 1 zero fill both in-plane and through-plane)

18.2 Generic ratio image protocol

All parameters the same as for dynamic protocol except:

Single acquisition phase
15 degree flip angle
8 NEX (averages)
Scan time: ~1:04 min

Repeat second time with body RCV

18.3 Generic SNR protocol

All parameters the same as for dynamic protocol except:

Eight individual acquisitions
15 degree flip angle
1 NEX (average)
Scan time: ~0:08 min per acquisition; 8 x 0:08 min total

18.4 Generic R1 mapping protocol

All parameters the same as for dynamic protocol except:

Single acquisition phase
For GE scanners: Set Turbo Mode to 0 (under User CVs). This will lengthen TE and TR (and scan time), but will force the TE and TR values to be the same for all flip angles.
2, 5, 10, 15, 20, 25, 30 degree flip angles
4 NEX (averages)
0:43 min/flip angle (on GE scanner using Turbo Mode of 0; TE=1.04 ms, TR=5.13 ms)

18.5 Detailed GE protocol parameters (for HD w/CRM gradients)

Generic Ratio Protocol	
B0:	1.5T
Grad Subsystem:	CRM
Coil:	Torso PA / Body Coil
Slice orientation:	Oblique Coronal
Sequence:	3D FSPGR
Imaging Options:	EDR, MPH, ZIP2, ZIP512
User CVs:	Turbo=2 / Slice res=100%
Grad Mode:	N/A
TE (ms):	0.8

TR (ms):	3.8
Flip Angle (deg):	15
Bandwidth:	+/- 32 kHz
NEX:	8
FOV (cm):	42
Phase FOV:	0.8
Slice Thickness (mm):	8
# locs per slab:	16
Acquisition matrix:	256 x 160
Freq Direction:	S/I
Acq Time (min):	1:04

Generic T1 Mapping Protocol	
B0:	1.5T
Grad Subsystem:	CRM
Coil:	Torso PA / Body Coil
Slice orientation:	Oblique Coronal
Sequence:	3D FSPGR
Imaging Options:	EDR, MPH, ZIP2, ZIP512
User CVs:	**Turbo=0** / Slice res=100%
Grad Mode:	N/A
TE (ms):	1.0
TR (ms):	5.1
Flip Angle (deg):	2, 5, 10, 15, 20, 25, 30
Bandwidth:	+/- 32 kHz
NEX:	4
FOV (cm):	42
Phase FOV:	0.8
Slice Thickness (mm):	8
# locs per slab:	16
Acquisition matrix:	256 x 160
Freq Direction:	S/I
Acq Time (min):	43 sec / flip angle

If Turbo=1 or 2 is used, the TR varies with flip angle. Even with Turbo=0, TR may vary for >30 deg flip angle.