Procedure Manual for MRI Examination of the Knee:

Osteoarthritis Initiative: A Knee Health Study

OAI

MRI PROTOCOL MANUAL:

Osteoarthritis Initiative: A Knee Health Study

Baseline, 12-, 24-, 36-, 48-,72- and 96-month visits (18- or 30-month visits)

06 May 2013

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1.0 INTRODUCTION

The purpose of this manual is to standardize the MRI acquisition and assessment procedures among the centers participating in the OAI study.

1.1 Participant Cohorts and Schedule of MRI Examinations

The OAI participants are split into three cohorts. The progression cohort consists of participants with symptomatic knee OA at the beginning of the study. The incidence cohort consists of participants who do not have symptomatic knee OA at the beginning of the study, but who have a high risk of developing knee OA. The control cohort consists of participants who do not have knee symptoms or radiographic evidence of tibiofemoral knee OA at the beginning of the study.

In general, participants in all three subcohorts will have MRI examinations of the right and left knee at the 72- and 96-month visit, unless indicated otherwise on the Data from Prior Visits Report for that particular visit. At the 96-month visit, all participants will also have MRI examinations of the "thigh". Bone ancillary study participants will additionally have a trabecular MR sequence of the same knee as previously examined at the 96-month visit.

1.2 The Knee MRI Exam

The MRI exam order should be: Right Knee, Left Knee. If the right knee is not eligible for MRI (generally because it has been replaced, which the MRI technologist will know from the MRI Screening Form), it will not be imaged. Instead, the left knee will be imaged using the LEFT KNEE STD protocol (which includes the sagittal T2-map sequence). If the left knee is ineligible, it is not imaged.

In some cases, a metallic implant or foreign body not noted on the Screening Form will be observed in the localizer images of the right knee. If these produce significant artifacts that may obscure visualization of the articular cartilage, exclude the T2 MAP. And instead include the T2 MAP on the LEFT KNEE STD protocol for the left knee, unless it too has an implant or foreign body. In that case, also exclude the T2 MAP on the left knee.

The knee imaging protocols are as follows:

Both knees are to be imaged:	use RIGHT KNEE STD and LEFT KNEE STD protocols
Right knee is ineligible:	use LEFT KNEE STD protocol (includes T2 MAP)
Left knee is ineligible:	use RIGHT KNEE STD protocol (includes T2 MAP)
Both knees are to be imaged but right has metallic implant:	use RIGHT KNEE STD (exclude T2 MAP) and LEFT KNEE STD (include T2 map) protocols
Both knees are to be imaged	use RIGHT KNEE STD (exclude T2 MAP) and

and both have metallic implants: LEFT KNEE STD (exclude T2 MAP)

Date of Birth, Sex, and Weight are entered appropriately, and Patient Position should be Feet-First Supine. OAI Right (Left) Knee should be selected from the Study drop-down list.

1.3 Procedure for Repeat Exams

Repeat exams should be performed as quickly as possible. **Ideally, MRIs of insufficient quality should be identified by the MRI technologist at the time of acquisition and repeated immediately.**

Repeat exams should be taken within 3 weeks of the original MRI.

2.0 Knee MRI Exam Specifics

2.1 Positioning the Participant for the Knee MRI

Proper participant set up should ensure correct positioning of the knee and sufficient participant comfort to limit motion artifacts.

1. The knee coil base should be positioned on the table in alignment with the alignment marks on the table.
2. The knee coil should be used in only the L60 or R60 positions.
3. The knee pad should be inserted into the coil; this is the only pad that should be used beneath the knee such that the correct angle of flexion can be achieved in a consistent manner. The pad should be positioned such that it over hangs the coil edge by -1.5cm.
4. The knee should be positioned in the coil such that the bottom of the patella is aligned with the center mark of the coil.
5. The leg should be in a relaxed, neutral position.
6. The foot should be vertical, with medial foot and the big toe orthogonal to the bed. The foot should be sandbagged to retain this position.
7. The air cushion should be positioned centered on the patella (remove air first, leave valve open) before securing the top and bottom halves of the RF coil.
8. A positioning strap should be used secure both the coil and the contralateral knee. Pads should be used to ensure patient comfort.
9. The landmark position should be the center of the RF coil (align with marks) which should correspond to the bottom of the patella.

2.2 Definitions of Sequences and Coil Placement

OAI MRI protocol and specific parameters, including all sequences for both right and left knee exams, are included in Appendix I. At the beginning of an exam, the entire Right (Left) Knee protocol can then be copied from the sequence library into the active window of the scanner console. **Only minor changes in TR, when prompted by the scanner due to SAR limits, and phase oversampling should then be necessary; other parameters should not be changed**. However, it is easy to inadvertently change sequence parameters, especially when copying slice and sat band positions using the "Copy Parameter" command. Due caution should be exercised to avoid mistakes.

Right Knee Std Exam (RF coil positioned at R60):

The Right Knee Std Exam consists of the following acquisitions (with scan duration in minutes). Scan slice / slab center locations and oblique angulation should be identical for similar acquisition planes (*i.e.,* all sagittal acquisitions should be prescribed the same; likewise all coronal scans should be prescribed the same). The scan acquisition order should not be changed; otherwise, long term SAR will be increased. Please note that the scan times detailed below are estimates, and actual times may vary somewhat.

No.	Scan	Duration in Minutes		
		R knee	L knee	Total
1	**Localizer (3-plane)**	0.5	0.5	**1.0**
2	**COR IW TSE**	2.25	2.25	**4.5**
3	**SAG 3D DESS WE**	10.6	10.6	**21.2**
4	*COR MPR SAG 3D DESS WE*	*0.0*	*0.0*	*0.0*
5	*AXIAL MPR SAG 3D DESS WE*	*0.0*	*0.0*	*0.0*
6	**SAG IW TSE FS**	3.8	3.8	**7.6**
7	**SAG T2 MAP 120 mm FOV**	10.6	-	**10.6**
8	*T2 Maps*	*0.0*	-	*0.0*
10	**Thigh**	5.5		**5.5**
	Total	43.8	17.2	**61.0**

Notes: *The reconstructions (MPRs) can be done at any point after acquisition of the DESS sequence, even during other sequence acquisitions.*

The SAG T2 MAP is acquired in the right knee only, unless the right knee is a knee replacement or there are metallic implants or foreign bodies seen on the right knee localizer, in which case this sequence is performed on the left knee (see knee imaging protocols on page 15). Starting in Spring 2010, automatic calculation of the T2 maps using the Siemens MapIt software was implemented.

The "Thigh" exam is always performed last, this is to enable capture of the knee imaging exam should the subject fatigue or wish to terminate participation in either the MRI exam or in the overall study.

Left Knee Std Exam (RF coil positioned at L60):

The Left Std Knee Exam is identical to that for the Right Knee, except that the Sag T2 Map sequence is omitted. Again, scan slice / slab center locations and oblique angulations should be identical for similar acquisition planes (*i.e.,* all sagittal series are prescribed the same; all coronal acquisitions are prescribed the same). Likewise the scan acquisition order should not be changed; otherwise long term SAR will be increased.

IMPORTANT: Participants with metallic implants in an eligible right knee should have the STD knee protocol (including the SAG T2 MAP) acquired on their left knee and the right knee MR exam should exclude the SAG T2 MAP.

2.3 Imaging Sequences for the Knee MRI

The sequence descriptions and standardized prescription of slice and sat band locations are described.

2.3.1 Localizer (3-plane)

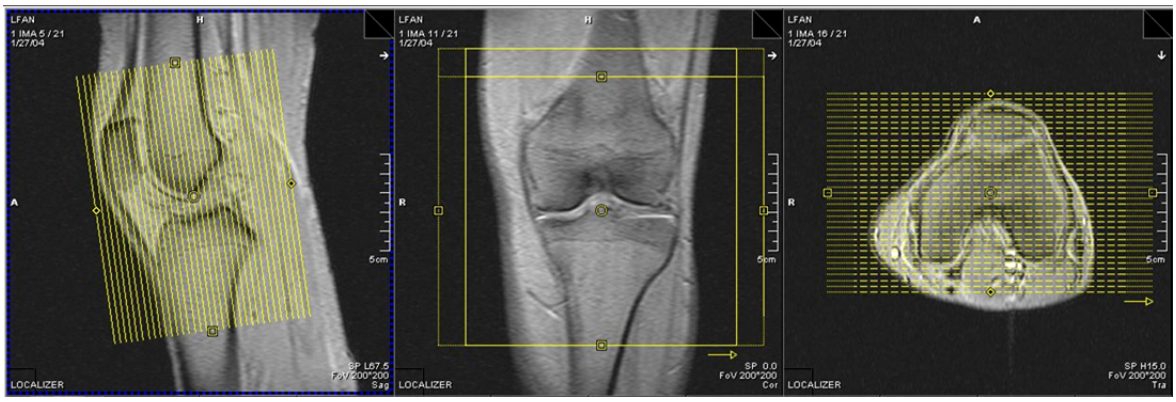
This is a conventional three-plane localizer. Offsets for R60 and L60 coil positions are pre-programmed into the corresponding exam sequences.

2.3.2 COR IW TSE

The **Coronal IW exam** is intended for evaluation of joint alignment, cartilage morphology, osteophytes, the body of the menisci, collateral ligaments and for the presence / extent of subchondral bone cysts and attrition.

This Coronal scan is a double oblique acquisition. The slices are prescribed from the axial localizer with the largest femoral condyles and from the mid-joint sagittal and coronal localizers. The slices are first oriented such that they align (are parallel to) the posterior femoral condyle surface on the axial localizer. Next, using the sagittal localizer, move the center of the imaging FOV to the tip of the femur in the joint. Then, move (rotate) the top (superior) center of the imaging FOV to the center of the femoral shaft (diaphysis). Now, the alignment is correct and results in a line tangential to the posterior femoral condylar surfaces in the axial plane, and parallel to the femoral-tibial axis in the sagittal plane. Finally, move (translate only!!) the imaging FOV (without changing either alignment axes) such that joint is centered.

Check all three localizer planes to ensure that the joint capsule is fully covered (including patellar / quadriceps ligaments and complete posterior femoral condyle) and only subcutaneous fat regions will overlap. *Please note for the 72-month and 96-month MR exams, the number of slices has been decreased from 35 to 31 and the TR has been reduced from 3700 to 3000 msec. With proper FOV placement, number of slices to cover correct anatomy should never be more than 31. With use of the 8-channel coil, the phase oversampling is decreased to 0%.*



Scan prescription for Coronal IW TSE

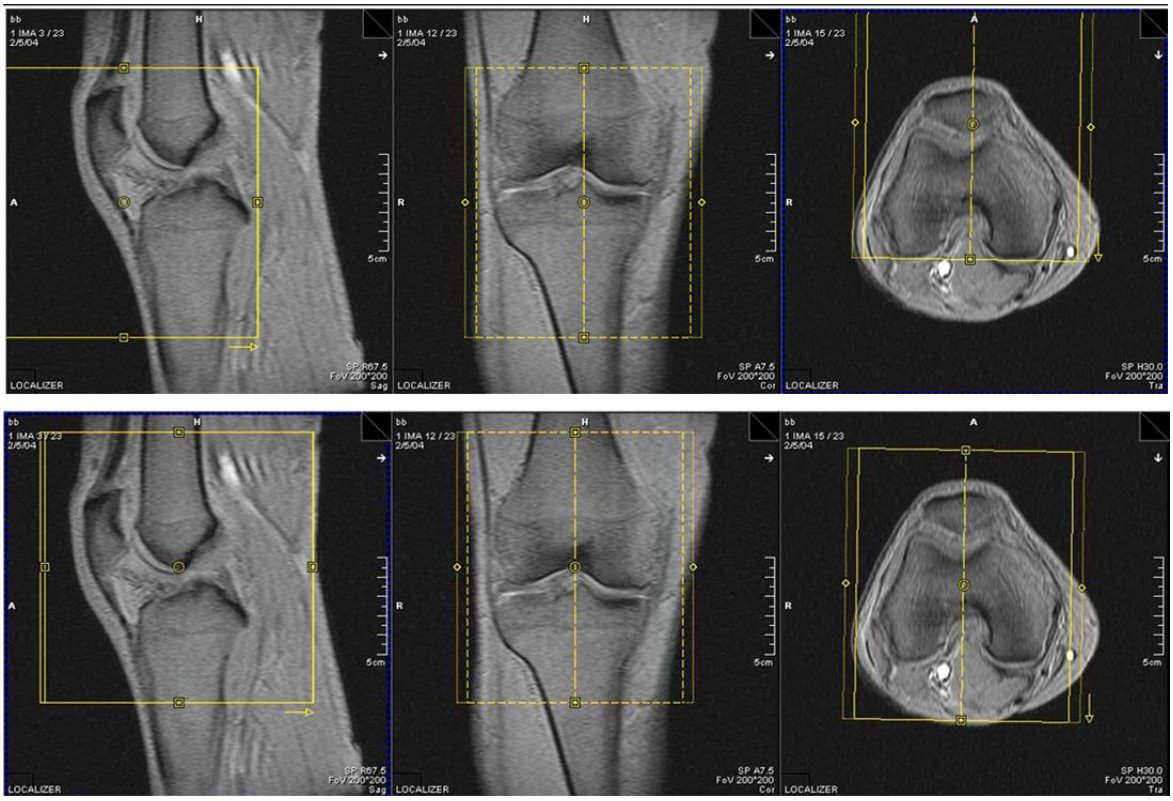
With large knees, slice coverage and phase aliasing artifact issues may occur with this 140mm FOV acquisition. Adjust the imaging locations such that only regions of subcutaneous fat overlap.

2.3.3 SAG 3D DESS WE

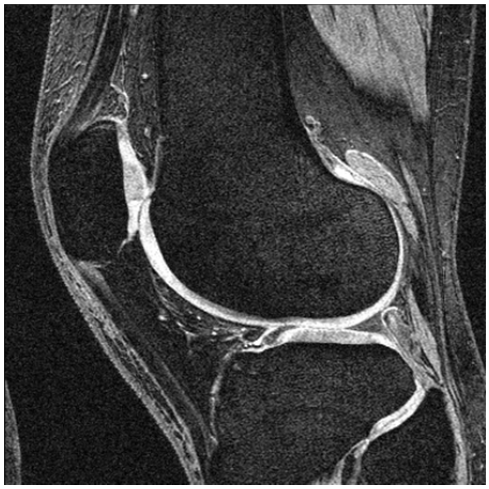
The **Sagittal 3D DESS with Water Excitation** is a single oblique acquisition, oriented such that the sagittal slices are perpendicular to a line tangential to the posterior surfaces of the femoral condyles. This acquisition will provide information for total joint cartilage thickness and volume. In addition, information about osteophytes, subarticular bone cysts and bone attrition, and possibly collateral ligaments will be available.

First, find the axial localizer slice with the largest cross-section through the condyles and the mid-joint sagittal and coronal localizer. The correct oblique angle is identified by moving (rotating and translating) the 3D imaging FOV (box) such that its posterior limit just touches both of the posterior condylar surfaces. Then, without changing the angulation, center the box over the knee. Now check the imaging FOV such that it is centered in the coronal and sagittal planes, and adjust if necessary.

The number of slices should always be 160. Do not change the number of slices in the protocol, even for small knees. For large knees, percent phase or slice oversampling may need to be increased to prevent aliasing artifacts from obscuring cartilage.

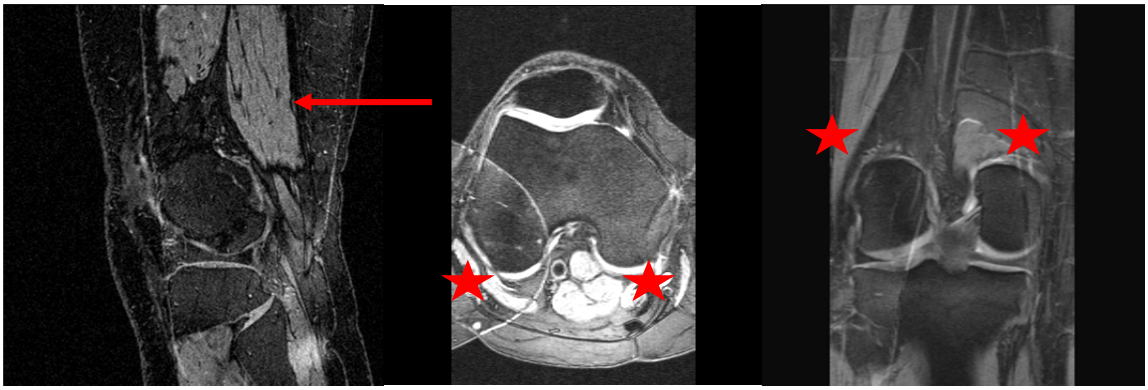


Scan Prescription for Sagittal 3D DESS with Water Excitation



Scan Example of Sagittal 3D DESS with Water Excitation

Care must be taken with slice prescription of any of the Sagittal 3D acquisitions because the 14cm FOV may result in aliasing in large knees. Aliasing artifacts are acceptable as long as patellar, femoral, and tibial cartilage are not obscured. Two examples of unacceptable aliasing artifacts from the sagittal 3D acquisitions are located below.

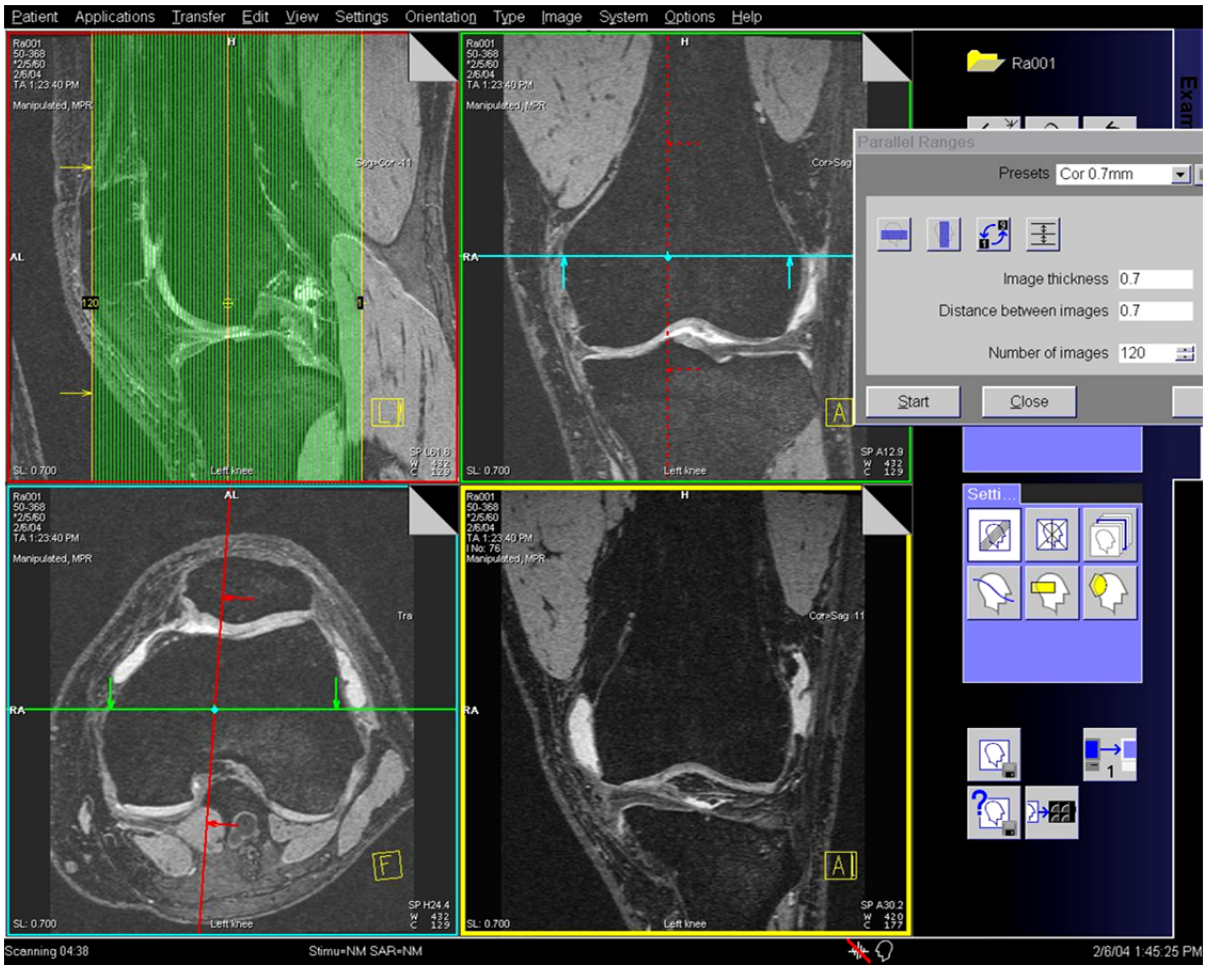


Example of gross slice under coverage (sagittal acquisition with axial and coronal MPR). Red stars and arrows identify aliasing.

Example of a more subtle artifact which impinges only on the cartilage of one condyle (equally unacceptable). This artifact should be eliminated by positioning the imaging FOV such that the wrap only occurs in the subcutaneous fat.

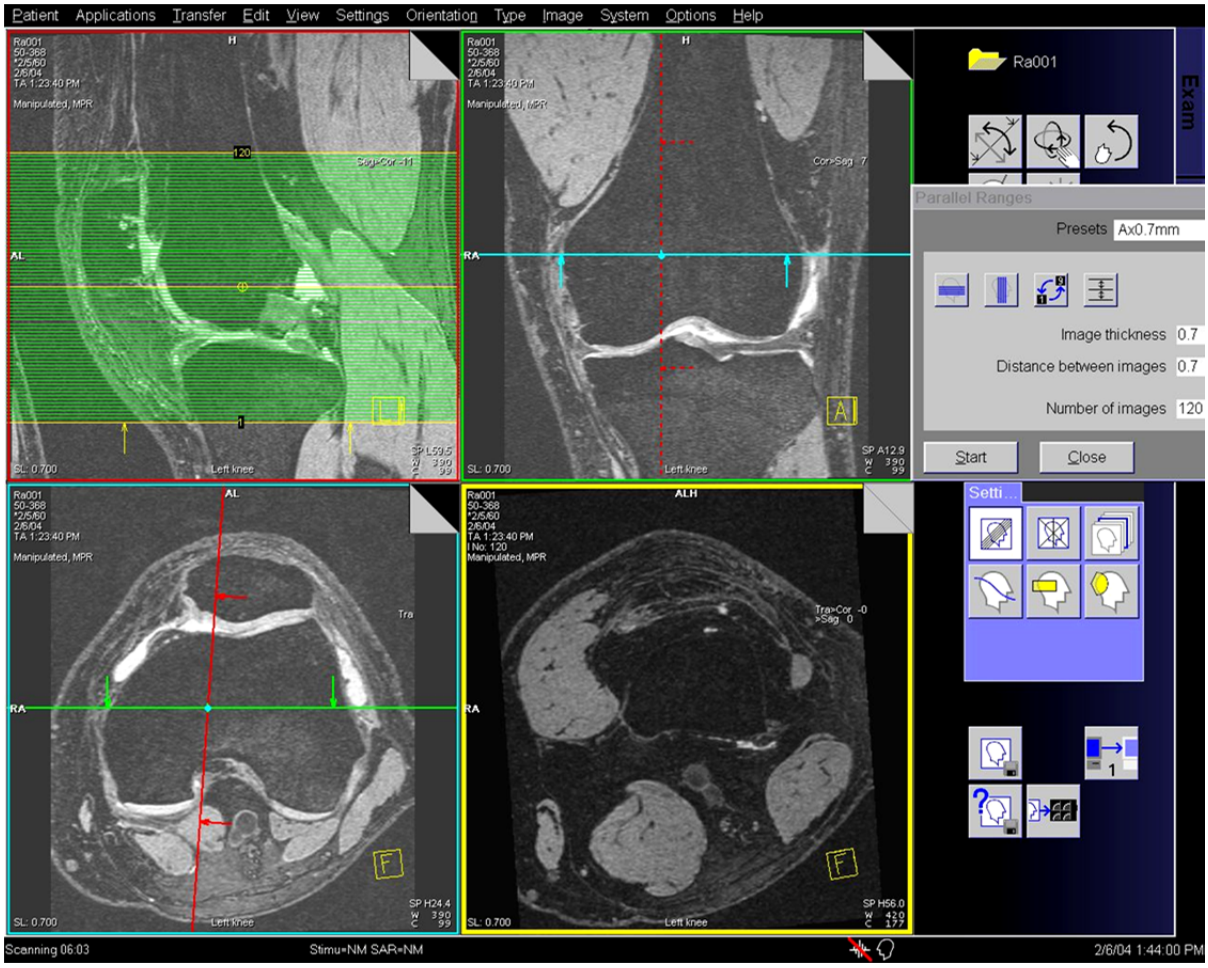
2.3.4 COR MPR SAG 3D DESS WE

The **Coronal multi-planar reformatting of the Sagittal 3D DESS with Water Excitation** does not require further acquisition. Please perform 1.5mm Coronal MPR reformats (approximately 64 slices) of the Sagittal 3D DESS with Water Excitation. The coronal reconstructions should be obliqued to correspond to the slices in the primary coronal acquisitions. The number of slices to cover correct anatomy should be 64. Coverage should be as defined in Section 3.4.7.2.



2.3.5 AXIAL MPR SAG 3D DESS WE

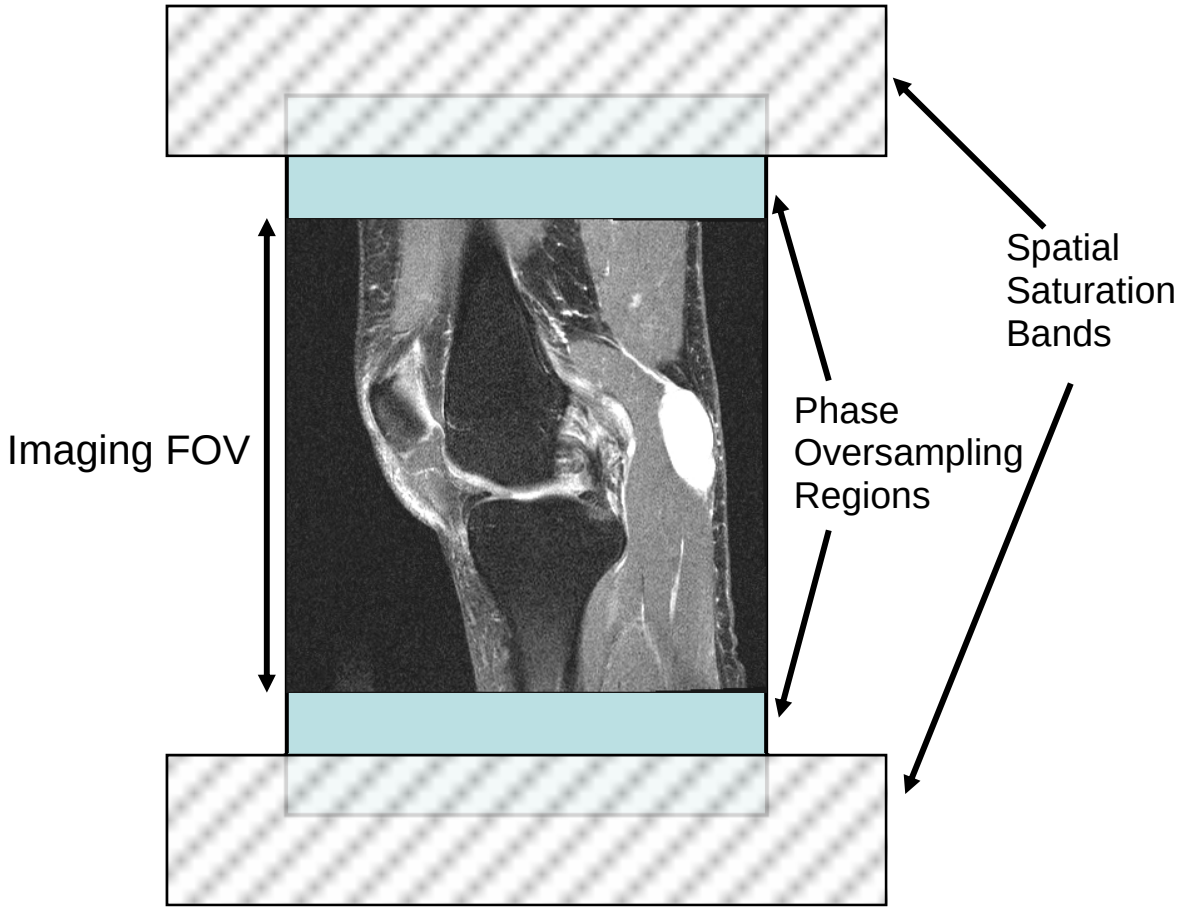
The **Axial multi-planar reformatting of the Sagittal 3D DESS with Water Excitation** does not require further acquisition. Please perform 1.5mm Axial MPR reformats (approximately 64 slices) of the Sagittal 3D DESS with Water Excitation. The number of slices to cover correct anatomy should be 64. Coverage should be as defined in Section 3.4.7.3.



2.3.6 SAG IW TSE FS

The **Sagittal IW with Fat Suppression exam** is for evaluation of the anterior and posterior femoral and tibial osteophytes and for the presence / extent of subchondral bone cysts and attrition.

This Sagittal scan is a single oblique acquisition, oriented such that the sagittal slices are perpendicular to a line tangential to the posterior surfaces of the femoral condyles. The easiest manner to create this scan prescription is to copy the center of the slice locations from the 3D DESS image, move the imaging FOV slightly superior such that the bottom of the imaging FOV is just below the tibial ephiphysis. Move both the superior and inferior saturation bands outside the imaging FOV such that their starting locations in approximately the middle of the phase oversampling regions (see diagram below).

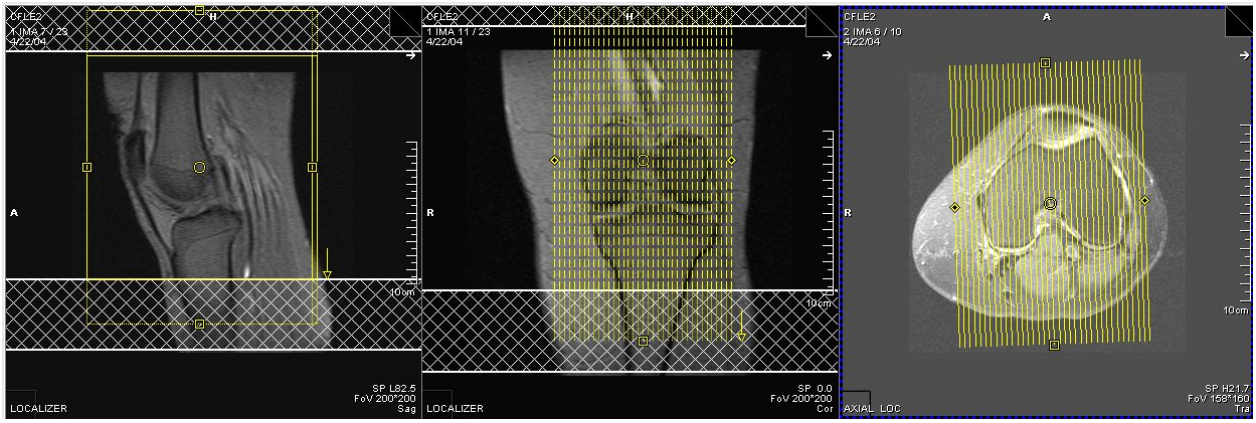


However, if this exam needs to be repeated, the instructions follow. First, find the axial localizer slice with the largest cross-section through the condyles and the mid-joint sagittal and coronal localizer. The correct oblique angle is identified by first rotating and translating the imaging FOV such it is aligned with and touches both of the posterior condylar surfaces (appears to be an oblique coronal acquisition). Then, without changing the angulation, perform a right mouse click and select make slices orthogonal (now appears to be sagittal oblique acquisition). Finally, center the imaging FOV (translate only!!) over the knee in the axial plane. Now check the imaging FOV such that it is centered in the coronal and sagittal planes, and adjust if necessary.

Finally, using the sagittal localizer, move the imaging FOV superiorly such that the bottom (inferior) part of the imaging FOV is slightly below the tibial epiphysis. Move both the superior and inferior saturation bands such that their starting locations are outside the imaging FOV and in approximately the middle of the phase oversampling regions (diagram above).

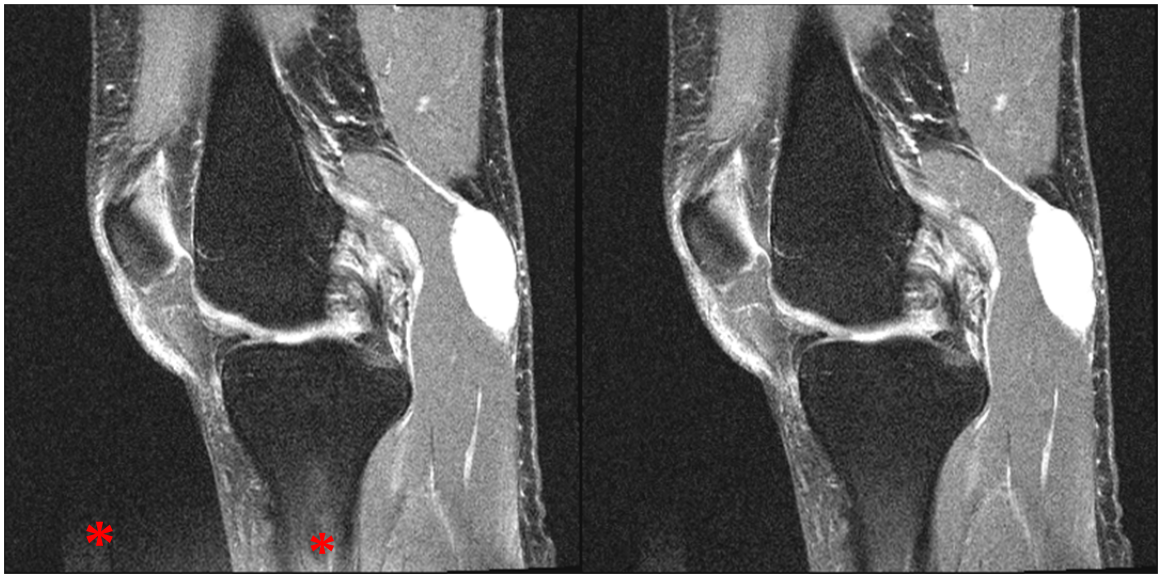
Adjust the imaging locations such that only regions of subcutaneous fat overlap.

Please note for the 72-month and 96-month MR exams, the imaging FOV has decreased from 160mm to 140mm, the number of slices has been decreased from 37 to 33 and the TR has been reduced from 3200 to 3000 msec. Typically 33 slices will cover anatomy with proper FOV placement. If needed to cover anatomy, a small increase in the number of slices for large knees is acceptable. For large knees, the sequence is still considered acceptable if the only issue is that the fibular head is not covered. With use of the 8-channel coil, the phase oversampling is decreased to 20%.



Scan prescription for Sagittal IW TSE

Head/foot aliasing artifacts (* on left image) and flow artifacts are minimized (right) by placing the spatial saturation bands in the middle of the phase oversampling region.



2.3.7 SAG T2 MAP 120 mm FOV

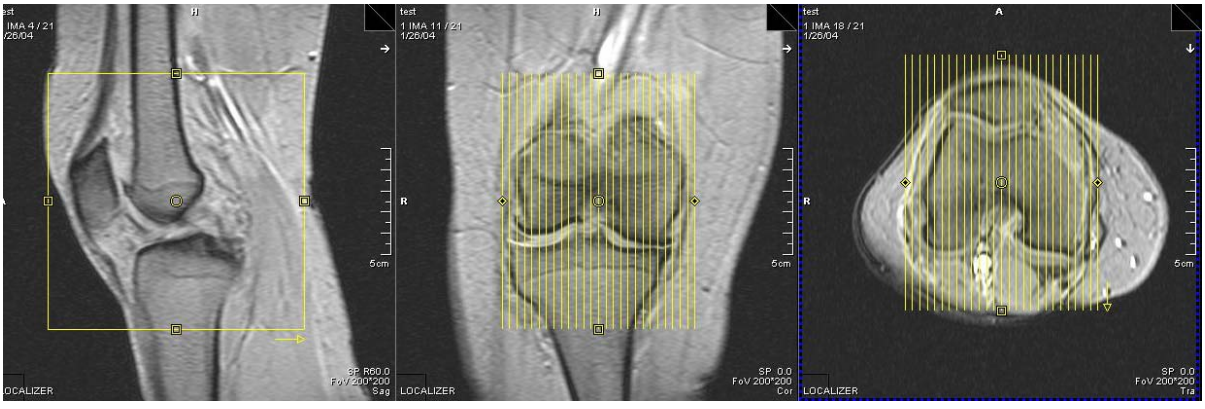
The **Sagittal T2 mapping sequence** is a small FOV exam intended to cover both the patellar and femoral / tibial cartilage only. Using this acquisition, the cartilage morphology and condition, the anterior and posterior meniscal horns, the cruciate ligaments, anterior / posterior femoral and tibial osteophytes, superior / inferior patellar osteophytes, as well as subchondral bone cysts and attrition may be assessed.

This Sagittal scan is a single oblique acquisition, oriented such that the sagittal slices are perpendicular to a line tangential to the posterior surfaces of the femoral condyles. The easiest manner to create this scan prescription is to copy the center of the slice locations from the 3D DESS image and move (translate) the imaging FOV to minimize the impact of any phase wrap. Check in both the Sagittal and Coronal localizer planes!

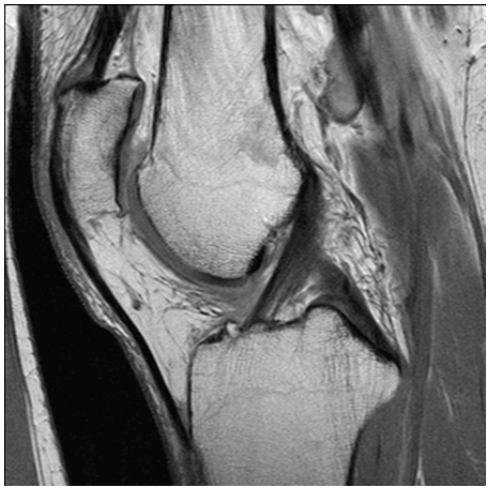
If this exam needs to be repeated, the scan prescription instructions follow. First, find the axial localizer slice with the largest cross-section through the condyles and the mid-joint sagittal and coronal localizer. The correct oblique angle is identified by first rotating and translating the imaging FOV such it is aligned with and touches both of the posterior condylar surfaces (appears to be an oblique coronal acquisition). Then, without changing the angulation, perform a right mouse click and select make slices orthogonal (now appears to be sagittal oblique acquisition). Finally, center the imaging FOV (translate only!!) over the knee in the axial plane. Now check the imaging FOV such that it is centered in the coronal and sagittal planes, and adjust if necessary.

With large knees, phase aliasing artifact will probably occur with this 120mm FOV acquisition. Adjust the imaging locations such that only regions of subcutaneous fat overlap.

Note: only 27 slices are required for the T2 exam. Always use 27 slices which should cover correct anatomy with proper FOV placement. In the very rare cases (usually large knees with severe OA), where 27 slices does not cover bone to bone, center the imaging FOV over the tibia. Do not vary or increase the number of slices. For large knees, the meniscus does not need to be covered, as long as the cartilage coverage is adequate.



Scan prescription for Sagittal T2 map



Acquisition on a small knee

Allowed phase wrap for this acquisition would occur only in the subcutaneous fat regions as shown by the red arrows

3.0 Thigh MRI Exam Specifics

3.1 Positioning the Participant for the Thigh MRI

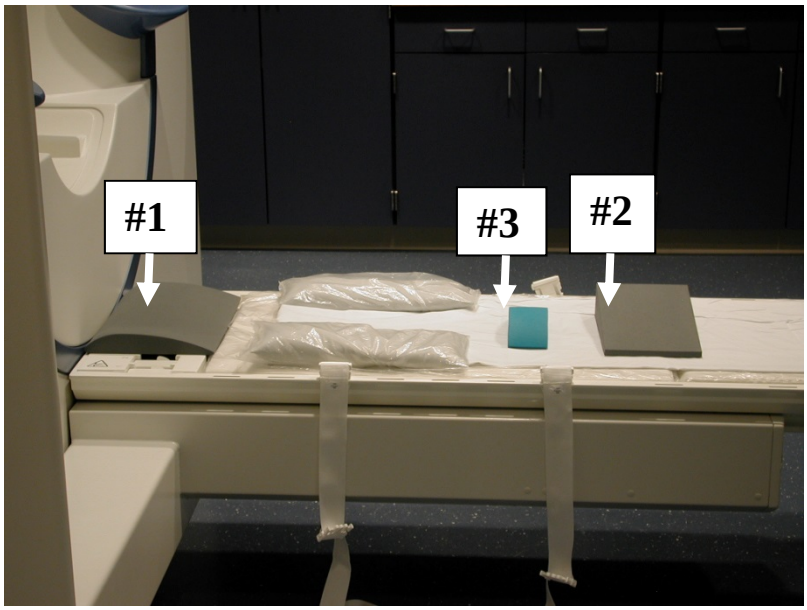
1. Assess eligibility for thigh examination. Participants with knee or thigh prostheses are not eligible. If participant is ineligible, indicate appropriately on form. Participants will not be re-scheduled specifically for the thigh examination.
2. Following the two knee MRI exams, the knee coil should be removed for the thigh acquisitions and the table cushion replaced. *Have the participant remain on the table, sit up and turn legs to the side so that pads and cushions can be put into place.*
3. Place positioning sponge (see #1 in photo on next page) at the foot end of the table.
4. Ask the participant to lie supine on the table in a feet-first orientation. The legs should be relaxed and straight in the center of the MR patient table, but not inverted or everted. The participant's feet should be at the very end of the table and should be supported by the foam wedge. If the participant cannot lie in this position, note whether there is inversion or eversion of the feet and whether the shift from midline is MILD (10-30 DEGREES), MODERATE (30-45 DEGREES) or EXTREME (MORE THAN 45 DEGREES) on the OAI MRI Transmittal Form.
5. The hips should be aligned with the long axis of the patient table. If the participant cannot lie flat on the table, note this on the protocol completion form in the comments.
6. The large foam wedge spacer (see #2 in photo on next page) should be placed between the knees at the level of the patella with about 3" of the narrow (tapered) side located above the knee joint and facing upward.

Note: On some larger subjects, it may be necessary to remove this wedge spacer between the knees so that their legs will not be spread too far apart.

7. Place one thin (1 cm) blue foam pad (see #3 in photo on next page) between the ankles.
8. Place long sandbags along the length of outside of each of the lower legs to keep legs from everting (rolling outward), or if eversion is the only position they can maintain, from everting further.
9. The feet should be nearly vertical but relaxed. The feet should be lightly taped to hold them in place, and the legs sandbagged to retain this position.
10. Two positioning straps should be used just above and just below the knees to maintain the position.
11. Landmarking: Palpate the apex of the patella. The landmark position should be 15cm above the patellar apex. If the patellar apex cannot be palpated, estimate where this apex should be. A plastic ruler cut off at precisely 15 cm has been supplied to facilitate this landmarking so that the mid thigh region will be in the center of the field of view.

Note: If participant is not able to proceed far enough into scanner bore to landmark at 15 cm, re-landmark at a position that allows them to go as far into the scanner bore as possible.

12. Place earplugs and headphones back on participant. Indicate to participant that this last scan should take less than 10 minutes.



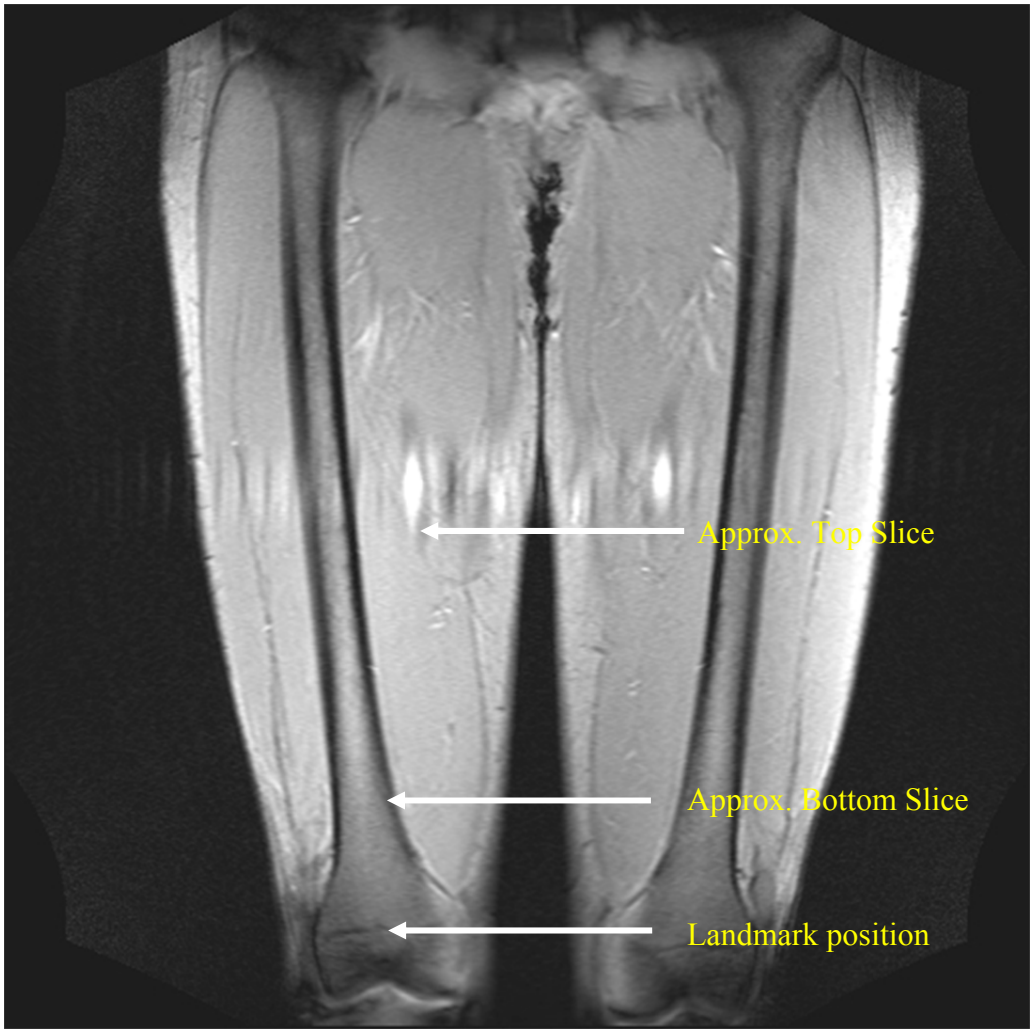
Placement of pads for thigh MRI acquisition.

Positioning of participant for thigh MRI acquisition.

3.2 Imaging Sequences for Thigh MRI

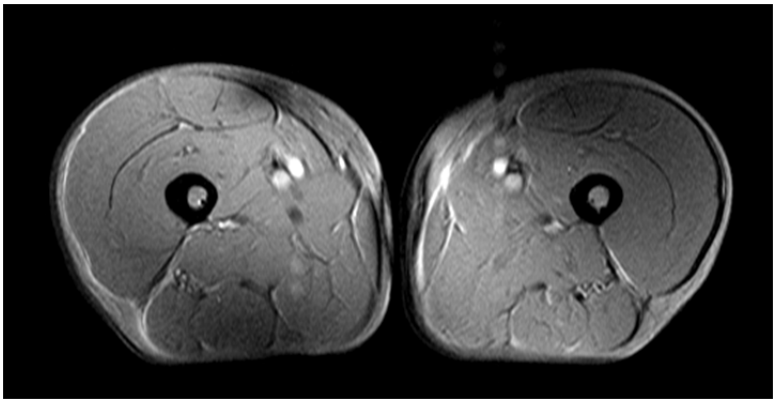
3.2.1 LOCALIZER

1. The bi-planar (Coronal and Axial) localizer should cover the femoral-tibial joint and proximally.
2. The Localizer needs to have sufficient spatial resolution along the S/I axis on the coronals to identify the right medial femoral epiphysis.



3.2.2 AXIAL T1-WEIGHTED IMAGES

1. Choose the coronal localizer that best visualizes the right femoral epiphysis. Position the axial T1W scans such that the bottom slice is at the medial femoral epiphysis of the RIGHT knee (red arrow represents the bottom slice; the top arrow represents the approximate top slice location). For the scan of the thigh, a set of 27 contiguous axial images will be obtained. 13.5 cm will be covered,
2. Offset the bottom of slices (5mm/skip 0mm slices are selected) by 10cm (100 mm) toward the head (This will mean subtracting 100 from the F mid-slice location).
3. Perform manual 3D Shimming. Iterate 3 times please.
4. Please ensure that the imaging FOV covers the entire thigh circumferential region on the axial localizers.
5. Using the axial localizers, check the R/L and A/P positioning the of the axial T1W acquisitions to obtain as many slices as possible which contain all the subcutaneous fat from both the right and left leg.
6. If FDA SAR limits are encountered, increase the number of concatenations to three (3). DO NOT change TR or TE.

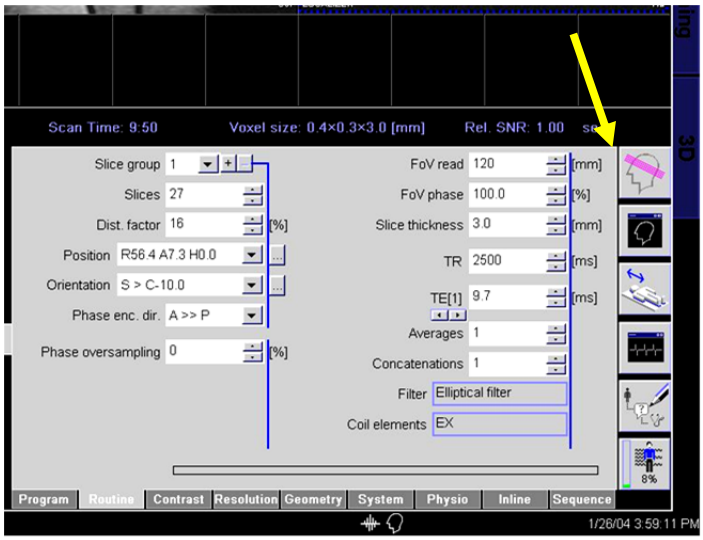


Example of Thigh Axial T1-Weighted Image.

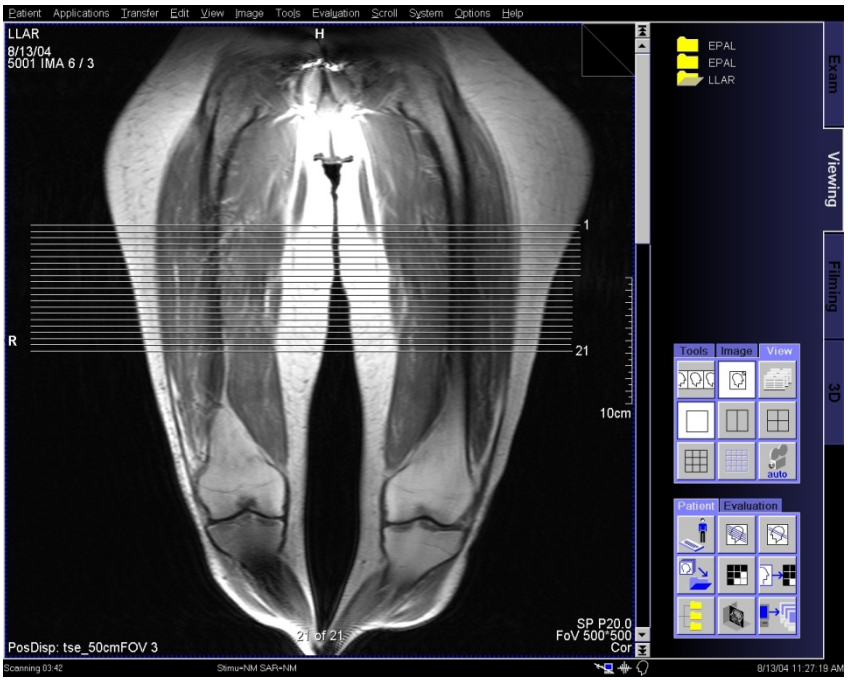
3.2.3 REFERENCE IMAGE

Please create, store, backup and transmit to a reference image (coronal localizer on which the center location of the T1W axial slices are displayed). To capture the reference image (coronal image from which the axial images were prescribed):

1. Complete the T1W axial acquisition;
2. Display the T1W axial series in a viewing window on the Trio system (not the Leonardo workstation!);
3. Select the position display series button on the task card (right side, choose the option with the small head with lines across it – see yellow arrow).



The cross reference image will automatically display and it will be automatically saved to the Trio data base with a 5001 number. It may be necessary to manually send this reference image to the Leonardo workstation. See figure below for an example.



4.0 Criteria for Assessing Quality of MR Images

The quality of the MRIs must be sufficient to allow for an accurate determination of morphological features of the knee.

4.1 Central MR Image Quality Control

The following image characteristics will be evaluated as part of the quality assessment:

Good Anatomical Coverage	Proper FOV placement and adequate number of slices for each sequence as specified
Aliasing	Aliasing can be tolerated as long as structures of interest are not obscured
Participant Motion	Usually can be avoided by use of pads and sandbags, and by instructions to participant
Pulsatile Motion	Artifacts from the popliteal artery are often unavoidable, but can be minimized by proper placement of sat bands
Chemical Shift	Minimized by proper choice of band-width and frequency encode direction. The optimal phase encode direction and receiver bandwidth has been pre-programmed into each sequence, and should not be changed.
Fat Saturation Failure	Partial fat sat failure is tolerable at the image periphery as long as the contrast of structures of interest (for example, cartilage or bone marrow edema) is not compromised.
Susceptibility Effects	May arise from implants and other metallic objects; acceptable if they do not obscure structures of interest

Occasionally, problems such as patient motion, susceptibility artifacts, etc, cannot be avoided. Those should be noted in the Comments section of the Transmittal form, particularly if they are likely to recur in any repeat examination.

4.2 On-site MR Image Quality Control

The MR Technologists are the primary gatekeepers to ensure only good quality MR exams are incorporated into the OAI image database. Not only must the technologists acquire each MR exam as described in the protocol, they must also inspect each image series, immediately re-acquiring those which do not meet the specifications detailed below, and send only the best image series for archive.

The following MR acquisitions must pass quality checks on every visit:

- Sagittal 3D DESS WE (both Right and Left knees)
- Coronal and Axial MPR of 3D DESS WE (both Right and Left Knees)

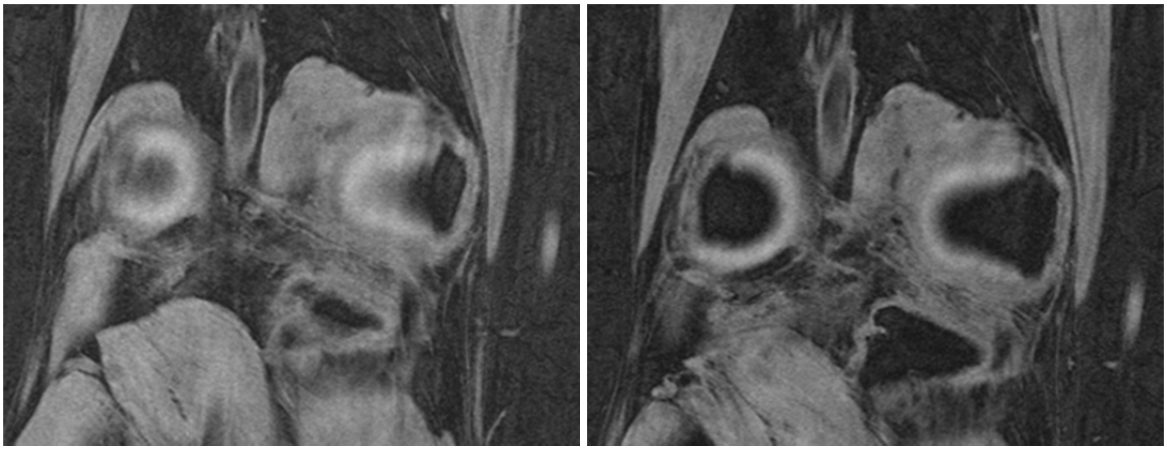
Sequence specific criteria follow:

4.2.1 Sagittal 3D DESS WE

- Cartilage must be measurable over the entire tibial plateau, femoral condyles, trochlea and patella. Scan must be repeated for any reason this is not accomplished, including incomplete anatomical coverage, aliasing, severe motion, *etc*.
- Anatomic coverage must extend slightly beyond the bones of interest (tibia, femur, patella) and cartilage, but does not need to span the complete soft tissue nor does it need to span the full fibular head. Complete coverage of the patella is desirable, but not required.
- Coverage should be checked using the 3D reformat page (MPR) to ensure that soft tissue aliasing does not wrap onto the bones of interest or cartilage.

4.2.2 Coronal MPR of Sagittal 3D DESS WE

- Cartilage must be measurable over the entire tibial plateau and femoral condyles. Scan must be repeated for any reason this is not accomplished, including incorrect slice orientation (see next bullet), incomplete anatomical coverage, aliasing, severe motion, *etc*.
- Posterior femoral condyles must appear within a maximum of 1 consecutive slices (double bulls eye as shown on left starts slice 1). Ideally the medial and lateral femoral condyles appear in the same slice as shown in this example.



- Anatomic coverage must extend slightly beyond the bones of interest (tibial plateau and complete femur) and cartilage, but does not need to span the complete soft tissue nor does it need to span the full fibular head. Coverage of the complete patella is not required

4.2.3 Axial MPR of Sagittal 3D DESS WE

- Cartilage must be measurable over the entire patella and femoral trochlea. MPR must be repeated for any reason this is not accomplished, including incomplete anatomical coverage, *etc*.
- Anatomic coverage must include all osteophytes and extend above the patella as well as below the tibial plateau. It is not necessary to span the complete soft tissue nor does the MPR need to span the full fibular head. Coverage of the complete patella and all osteophytes is required.

4.2.4 Sagittal IW TSE FS

- The complete joint and joint capsule must be contained in this exam because it is intended for evaluation of the effusion volume, the anterior and posterior femoral and tibial osteophytes and for the presence / extent of subchondral bone cysts and attrition.
- Anatomic coverage must include all osteophytes and extend posteriorly to include the popliteal artery and anteriorly to completely cover the patella. Superiorly it is necessary to cover as much of the supra-patellar pouch as possible and to cover below the tibial plateau inferiorly. It is not necessary to span the complete soft tissue medially / laterally. However, the lateral extent should span the full fibular head. For large knees, the sequence is still considered acceptable if the only issue is that the fibular head is not covered. Coverage of the complete patella and all osteophytes is required.
- Head/foot aliasing artifacts and flow artifacts should be minimized.

4.2.5 Coronal IW TSE

- Orientation as specified for Coronal MPR of Sagittal 3D DESS WE
- The complete joint must be contained in this exam because it is intended for evaluation of joint alignment, cartilage morphology, osteophytes, the body of the menisci, collateral ligaments and for the presence / extent of subchondral bone cysts and attrition.
- Anatomic coverage must include all osteophytes and extend posterior to the femoral condyles as well as anterior to the patella. It is necessary to include the collateral ligaments medially / laterally as well as the complete fibular head. Coverage of the complete patella and all osteophytes is also required.

4.2.6 Sagittal T2 Map (MSME)

- This exam is focused on evaluation of the patellar and femoral / tibial cartilage only. Using this acquisition, the cartilage morphology and condition, the anterior and posterior meniscal horns, the cruciate ligaments, anterior / posterior femoral and tibial osteophytes, superior / inferior patellar osteophytes, as well as subchondral bone cysts and attrition may also be assessed, however their coverage is not paramount.
- Anatomic coverage of the T2 map should be bone to bone (medial – lateral) and must not include aliasing in the patellar cartilage. It should include all osteophytes. But does not need cover the patella.

5.0 Quality Assurance of the MRI system

The Quality Assurance procedures in the Osteoarthritis Initiative have been designed with these specific aims in mind:

1. Provide uniformly high quality artifact-free images from all sites
2. Provide longitudinal consistency across all sites of key image characteristics such as signal-to-noise, contrast-to-noise, signal homogeneity, local and global distortion
3. Provide a means to compare MR data acquired from each of the four 3T systems
4. Minimize need to repeat imaging by correcting slowly developing problems before image quality is affected

5.1 Procedures for Quality Assurance of the MR System and Associated Coils

All coils and cables must be visually inspected for loose components, breaks, and cracks weekly. Siemens field service engineers will perform preventative maintenance at all sites on a monthly basis and should perform full TUNEUPs no less frequently than quarterly.

There are DAILY, WEEKLY, MONTHLY, and ANNUAL QA procedures:

DAILY:	OAI RF Coil S/N and channel check; OAI Study Phantom geometry and S/N check
WEEKLY:	Head Coil S/N check Backup RFcoil S/N and channel check Physical inspection of all coils, phantoms, magnet bore, screen room door
MONTHLY:	1. Daily QA, T2 measurement, and 3D volume acquisition with the OAI study phantom using the study RF coil. 2. Modified ACR Phantom Test Protocol using the head coil; this should be performed 2 weeks after 1. 3. Siemens Preventative Maintenance by Field Service Engineer. (Note: Each of these four tests should be scheduled for different weeks of the month.)
ANNUAL:	ACR Acceptance Testing (standard and modified protocol).

5.2 Daily Quality Assurance Procedures

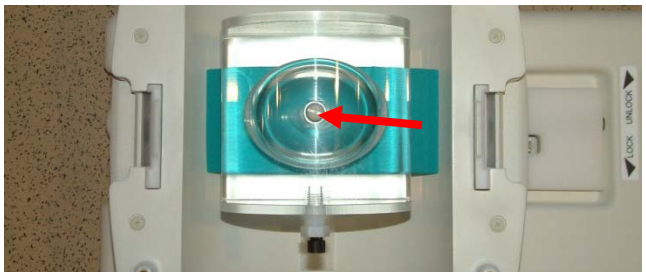
The following quality assurance protocol should be followed DAILY:

- The OAI specific QA phantom is cylindrical (inside diameter 114mm, inside length 114 mm) and contains a hollow sphere of 57 mm inside diameter; each compartment contains a different concentration Gd-DTPA solution.
- The knee coil should be positioned at the R60 (Monday, Wednesday, Friday) or L60 (Tuesday, Thursday, Saturday) location.
- If it becomes necessary to change the study phantom during the study, please use "OAIB" as the last four characters in the Patient ID. Continue to increase the number by one for each phantom that is used.

Phantom Set-Up:

Hint: Mark the center of the coil to align the phantom. Mark the coil positioner so the R60 and L60 positions are easily visualized.

- Place the coil in the same location on the patient table.
- Set up the study phantom in the center of the 8-channel coil without any cushions or pads. Secure the top half of the coil and then wedge one thin (1cm) green cushion on the bottom front and one thin (1cm) green cushion on top of the coil back. The phantom should be positioned such that the fill ports are vertical and the air bubbles are in the top fill port (see photo below).

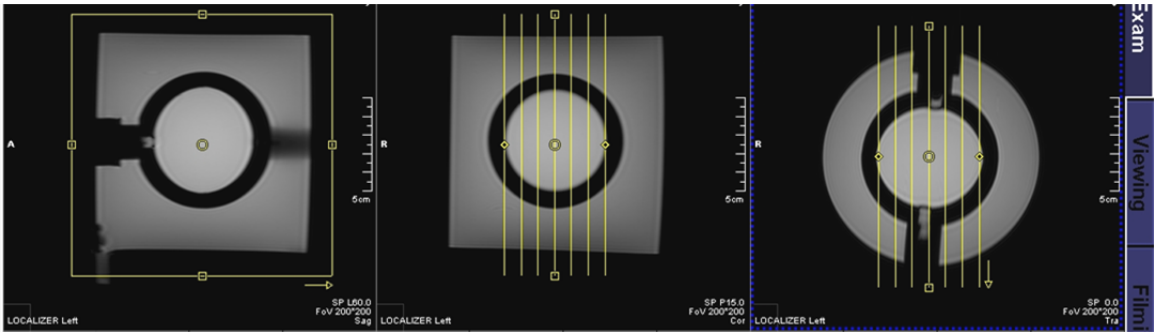


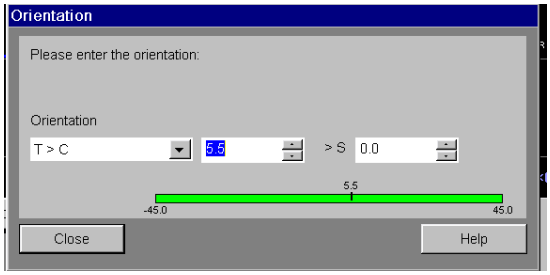
- Secure the top of the coil, ensuring that the coil is orthogonally aligned to the magnet bore.
- Landmark on the center coil mark using the laser beam.
- Let the phantom settle for 2-3 minutes.

Daily QA Scan Acquisition and Analysis:

- Run the OAI Daily Phantom protocol:
    - 3-plane localizer
    - Sagittal 2D IW TSE. The first slice should be at one edge of the inner sphere; the last slice should be at the other edge of the inner sphere as shown below. This will allow more reproducible positioning of the center slice to be at the center of the inner sphere.

      Prescription Hints: Prescribe the series SAGITTAL to the phantom (single oblique acquisition). Ignore the screw positions. Center outer slices such that equal amounts of fluid (white) are on either side of the slices.

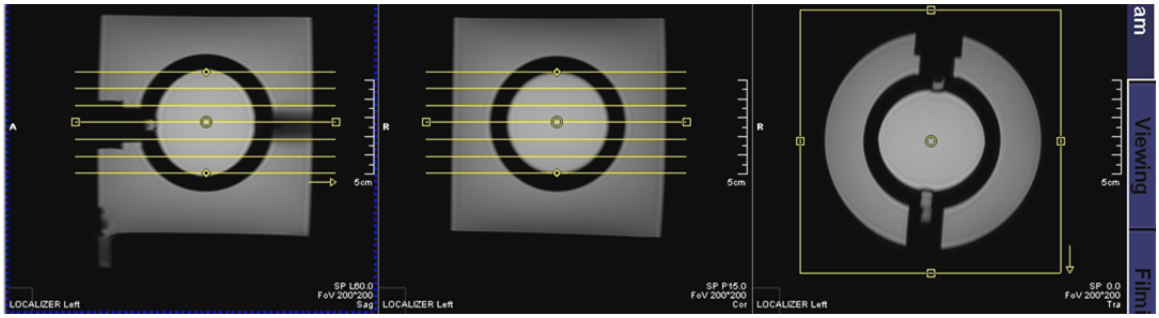




Scan prescription for Sagittal 2D IW TSE

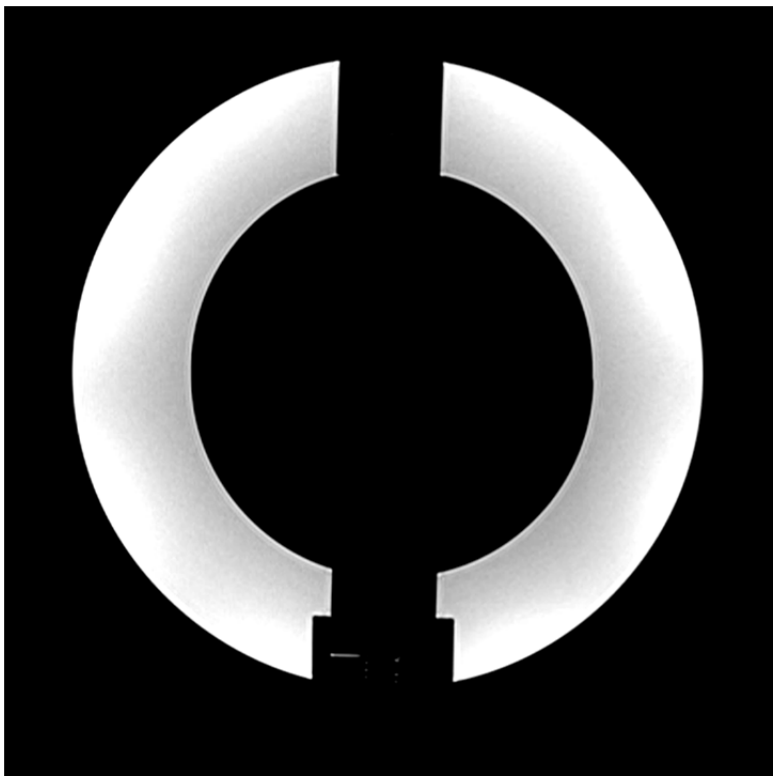
    - Axial 2D IW TSE. The first slice should be at one edge of the inner sphere; the last slice should be at the other edge of the inner sphere as shown below. This will allow more reproducible positioning of the center slice to be at the center of the inner sphere.

      Prescription Hints: Prescribe the series AXIAL to the phantom from the sagittal series (double oblique acquisition). Ignore the screw positions. Center outer slices such that equal amounts of fluid (white) are on either side of the slices.

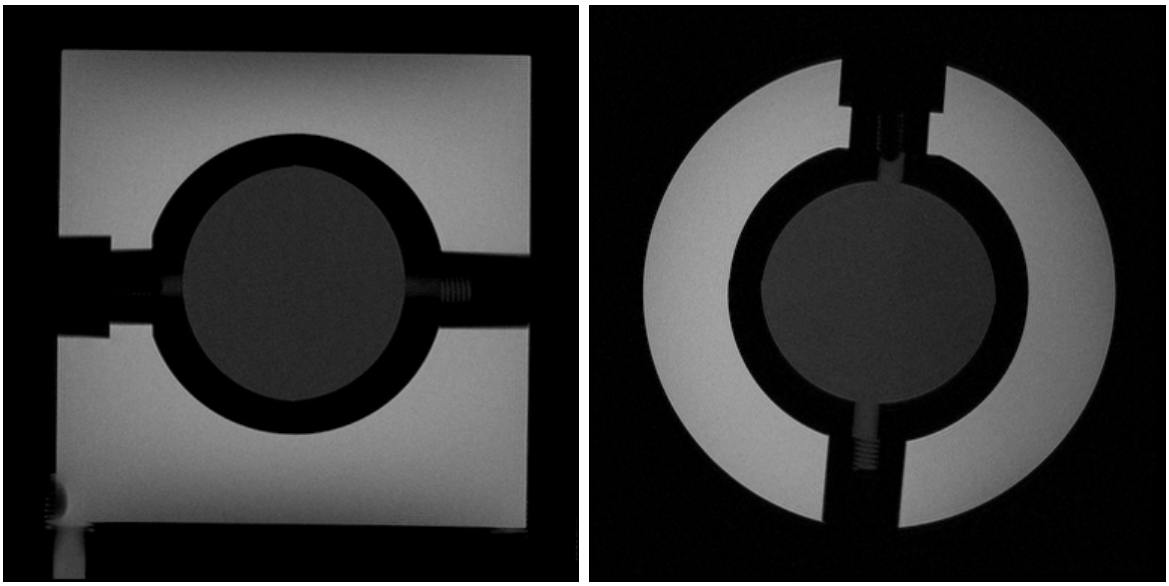


Scan prescription for Axial 2D IW TSE

- For analysis, select the center axial and sagittal slices as shown below. Look to see if any coil elements are missing (uniform outer sphere means no missing coil elements).

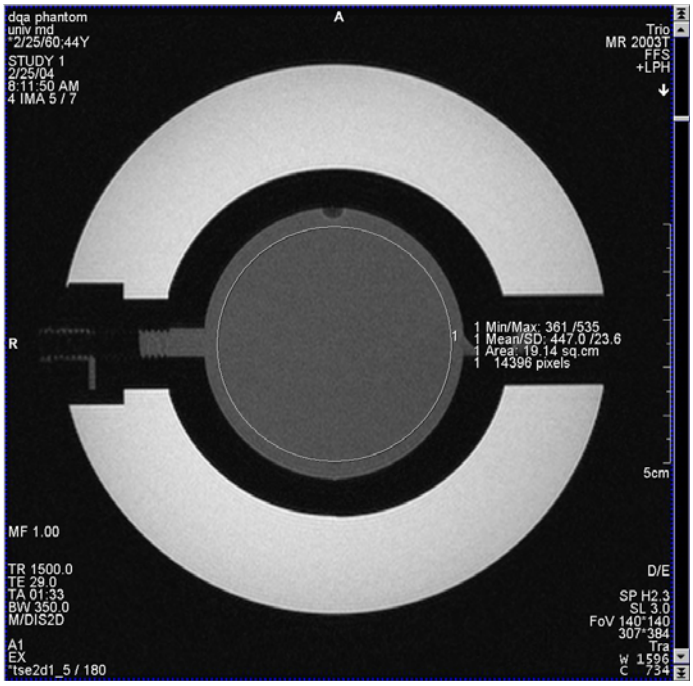


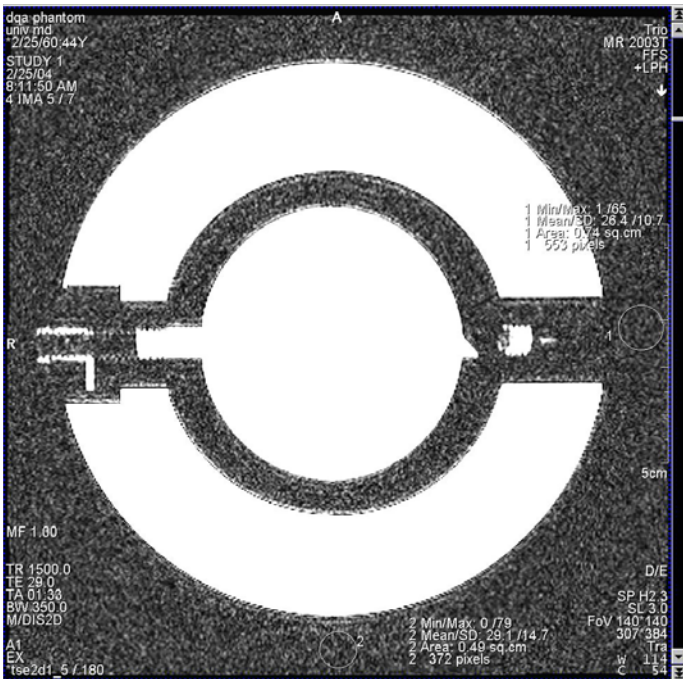
- Vary the window/level settings from minimum to maximum and look for intensity inhomogeneities. Although the signal intensity will vary across the FOV, the variations should be approximately symmetrical. Failure of coil elements or gradients will often first appear as inhomogeneities or distortions in the FOV. Increases in the signal intensity of "ghost" images along the phase encode direction are another indicator that system will require an extensive service and tune-up. Visual comparisons to reference images from the preceding day or week will be helpful.



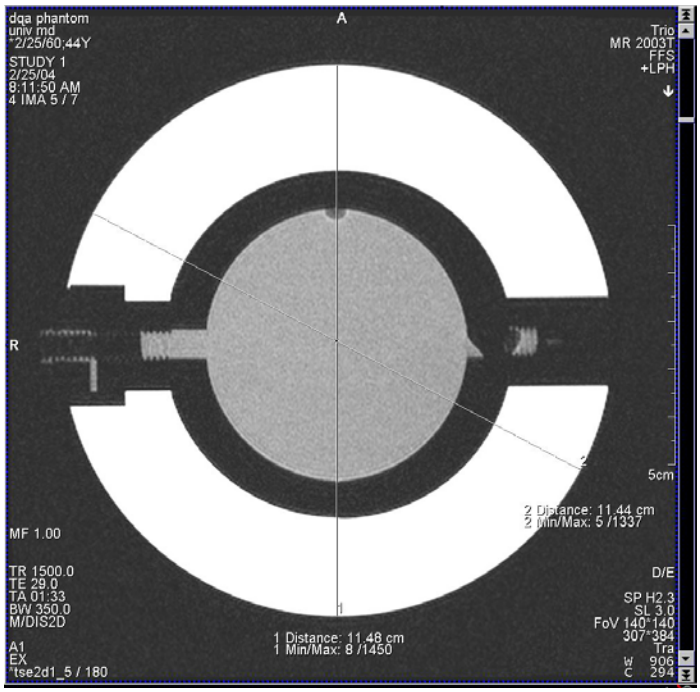
- Using a circular ROI that largely covers the inner portion of the sphere (around 14 cm^2), measure and record (on the Daily QA log sheet) the signal intensity mean and standard deviation in the center of the sphere in the center axial slice. Measure noise signal intensity in an elliptical ROI of about 0.5-1.0 cm^2 outside of the phantom in both frequency and phase directions (left or right, top or bottom). Record values in the Daily QA Log Sheet. Day-to-day variations should be less than the following limits:

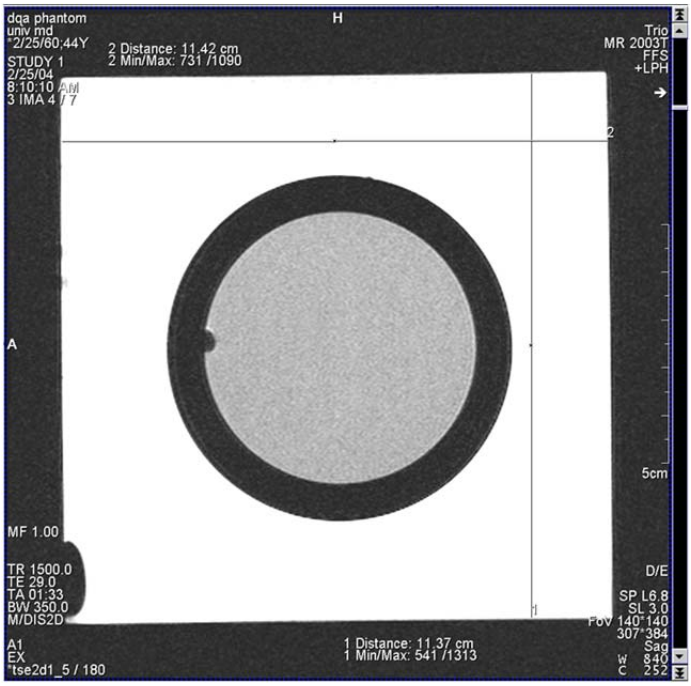
Signal Intensity	5 %
Signal Std Dev	10 %
Noise	10 %
Ghosting	10 %





- Using the ruler tool on both axial and sagittal images, measure the maximum horizontal and vertical inside dimensions of the cylinder. The apparent diameter will vary depending upon the window/level settings. Set Window at zero and level to the mean signal intensity measured above. Observed diameters and lengths should be 114 mm ± 1 mm. Record on Daily QA logsheet.





Decision Tree for Daily QA Exam:

- If the system fails any test, check coil connections (both plugs as well as the top/bottom latch), and coil and phantom positions. Repeat test.
- If the system fails a second time, repeat test with the alternate knee coil.
- If the system fails with the alternate knee coil, reboot the system with the head coil and SNR phantom (let phantom settle for 3-5 minutes), run Head Coil S/N DIP (Customer QA Menu), and record on the SNR log sheet. If the Head S/N does not pass, repeat the measurement once again. If the Head S/N passes, run the knee coil S/N DIP (let phantom settle for 3 minutes) using the Customer QA Menu and record on the SNR log sheet. If the Knee S/N does not pass, repeat the measurement once again. If the Knee S/N passes, re-test the daily QA exam with the knee coil.
- If the system fails the two Head S/N tests, call Siemens Service.
- If the system fails the two Knee S/N tests, try the test on an alternate knee coil. If the system continues to fail the Knee S/N test, call Siemens Service.
- If the system still fails the Daily QA exam, call Siemens Service.

5.3 Weekly Quality Assurance Procedures

- At least once per week run the Siemens S/N test (Options, Customer QA Menu) on the head coil and phantom.
- At least once per week run the Siemens S/N test (Options, Customer QA Menu) on all knee coils and phantom; check S/N level; for signal in all coil channels.
- Inspect all phantoms for leaks, cracks, or other damage.
- Inspect the head and knee coils, paying special attention to cable insulation, strain relief fittings, and connectors. Clean and disinfect coil housings. Request replacement RF coil from Siemens.
- Inspect the magnet bore for presence of foreign objects. Clean and disinfect.
- Test the squeeze ball.
- Inspect the magnet room and clean as necessary. Check and clean RF seals (including fingers and jambs) on door and other penetrations.

5.4 Monthly Quality Assurance Procedures

There are four different monthly QA procedures. Each test should be scheduled for a different week of the month. The four tests are:

1. Daily QA, T2 measurement, and 3D volume acquisition with the OAI study phantom.
2. Siemens Body Coil S/N and Calc Artifacts QA
3. Modified ACR Phantom Test Protocol
4. Siemens Preventative Maintenance by Field Service Engineer

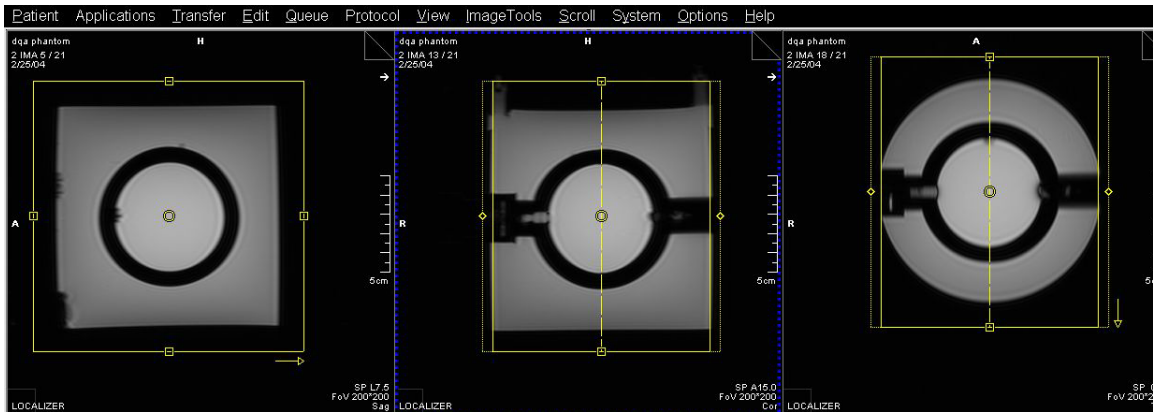
5.4.1 Knee Coil – OAI Study Phantom

The OAI Study Monthly Phantom protocol consists of the Daily QA exam plus a Sagittal T2 map and a Sagittal 3D DESS acquisition of the OAI study phantom. No measurements are done by the site. The exam will be will be analyzed using an automated software program specifically for these phantom images.

- The knee coil should be positioned at the R60 or L60 location on alternate months.
- If it becomes necessary to change the study phantom during the study, please use "OAIB" as the last four characters in the Patient ID. Continue to increase the number by one for each phantom that is used.

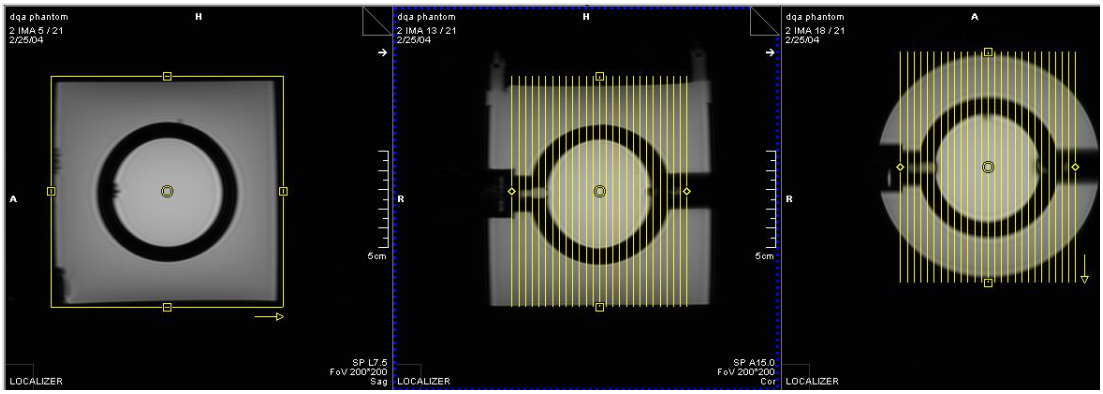
Monthly OAI Study Phantom QA Scan Acquisition and Analysis:

- Run 3-plane localizer
- Axial and Sagittal 2D IW TSE (prescribe as shown for the Daily QA procedure)
- Sag 3D DESS (straight sagittal, no oblique); use scan prescription as shown, be certain to scan sagittal to the phantom (single oblique acquisition):



Scan prescription for Sag 3D DESS

- Sagittal T2 Map sequence (prescribe sagittal to the phantom as shown for Sagittal IW TSE in the Daily QA procedure)



Decision Tree for Monthly OAI Study Phantom QA Exam:

- The signal, noise, and ghost levels as well as the cylinder inner dimensions in the 2D images, the T2 map, and volume of the sphere in the 3D image stack will be analyzed using an automated software program specifically for these phantom images.
- If the inside sphere volume measured from the 3D image acquisition differs from the absolute volume by more than 5%, a repeat exam will be requested at the earliest opportunity.
- If the inside length of the phantom measured from the 3D image acquisition differs from the absolute length by more than 1% (of 125 = 1.25mm), a repeat exam will be requested at the earliest opportunity.
- The T2 values of the solutions contained within the phantom will be calculated from the multi-echo images. If the calculated values vary from the known values by more than 5 ms, a repeat exam will be requested at the earliest opportunity.
- If the system fails a repeat exam, the site will be instructed to call Siemens service.

5.4.2 Body Coil S/N and Calc Artifacts Tests

- These tests use the Siemens Body Loader and Spherical Phantom (D240). Refer to the instructions in the Siemens Syngo MR Software, Options, Customer QA menu.
- Position body loader on the patient table. Note: this will likely require the assistance of a second person.
- Position the spherical phantom in its holder and insert the assembly into the body loader. Ensure that the arrow on the phantom holder is pointing toward the magnet bore.
- Align loader and phantom with the laser crosshairs.
- Select Options, Customer QA from the operating menu.

- Select the coil from the Active Coil selection list.
- Select the Body S/N DIP checkbox.
- Select the Calc Artifacts checkbox.
- Click on the Start button.

Decision Tree for Body Coil S/N and Calc Artifacts Tests:

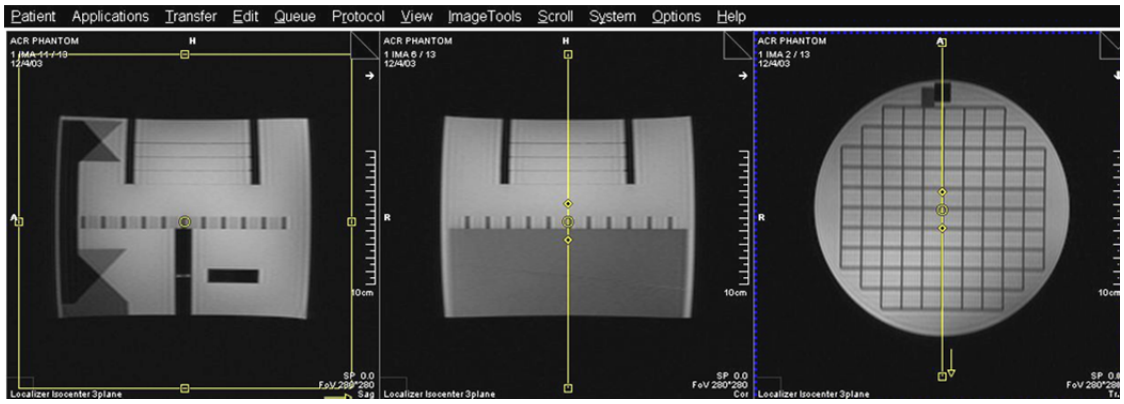
- If the system fails any one of the tests, check the positions of the phantoms (refer to Customer QA menu instructions) and repeat the exam.
- If the system fails a second time, reboot the system with the head coil and SNR phantom in position, let the phantom settle for 3-5 minutes, run Head Coil S/N DIP (Customer QA Menu), and record on the SNR log sheet. If the Head S/N passes, then re-run the body coil tests. If the system fails the Head S/N test, try once again. If the Head S/N continues to fail, call Siemens Service.
- If the system continues to fail Body S/N after two attempts and after passing the Head S/N, contact Siemens Service.

5.4.3 Head Coil – ACR Phantom

- The ACR evaluation utilizes a complex cylindrical phantom (inner diameter 148mm, inner length 190mm) with positioning marks and a holder suitable for reproducible use in the head coil.
- If it becomes necessary to change the study phantom during the study, please use "ACRB" as the last four characters in the Patient ID. Continue to increase the number by one for each phantom that is used.
- The ACR phantom and the holder (cradle) should be carefully positioned in the head RF coil to maintain alignment. The nose label should be up and the chin label should point away from the magnet.
- Landmark on the center of the phantom (which should be aligned to the center of the head coil). Move to isocenter and let settle for 2-3 minutes.

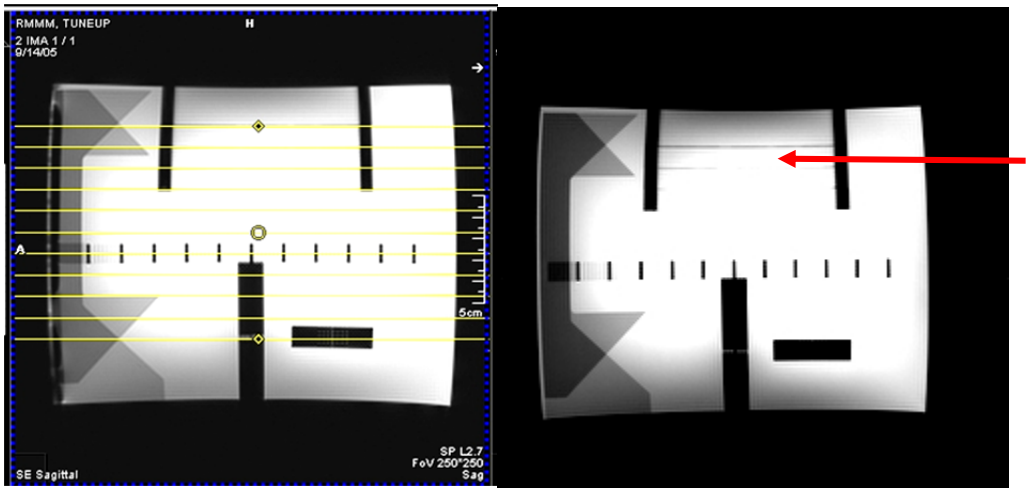
ACR Phantom Monthly QA Scan Acquisition and Analysis:

- Run the Monthly ACR Phantom protocol:
    - 3-plane localizer is performed
    - Sagittal single plane acquisition is prescribed from isocenter. Two acquisitions are run, one without and one with Large FOV Correction Filter.



Scan prescription for Axial IW exams

- Prescribe the Axial IW exams from the (first) single slice sagittal acquisition (without the Large FOV filter correction applied). The first of the 11 slices should be aligned with the first low contrast object as shown in the figure below.



Decision Tree for ACR Phantom Monthly QA Exam:

- The images will be analyzed using an automated software program written based on the following criteria ("Phantom Test Guidance for the ACR MRI Accreditation Program"). The reporting criteria are more stringent for the OAI than they would be for a clinical exam:

- Geometric Accuracy
    1. Inside end-to-end length 148 ± 1.0 mm;
    2. Inside diameter 190 ± 1.0 mm.
- High contrast spatial resolution ≤ 0.9 mm
- Slice thickness accuracy 3 mm ± 1.0 mm
- Slice position error ≤ 2 mm
- Percent Signal Ghosting ≤ 1.0 %; service call if > 0.5%

- If the system fails the repeat exam, the site will be instructed to call Siemens service.

5.4.4 Siemens Preventative Maintenance

Siemens field engineers will perform preventative maintenance on a monthly basis.

5.5 Annual Quality Assurance Procedures

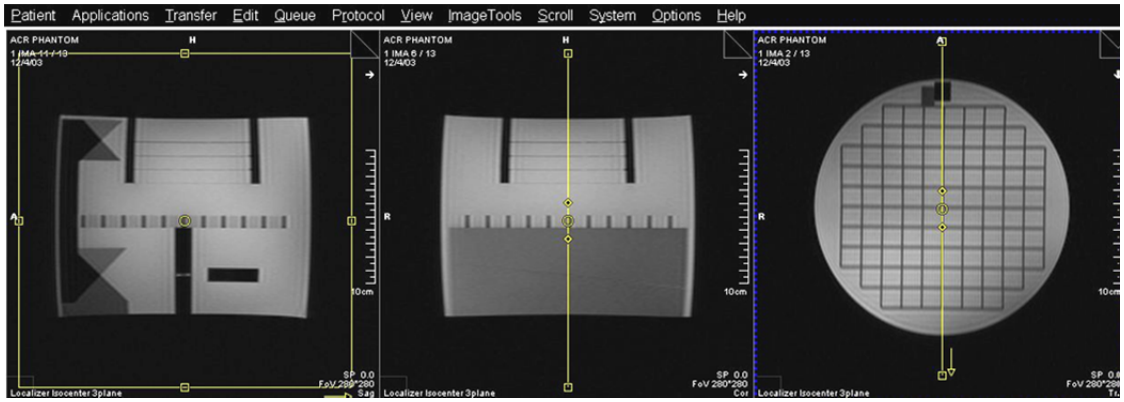
An annual ACR acceptance test must be done using the head coil and the ACR phantom.

- If it becomes necessary to change the study phantom during the study, please use "ACRB" as the last four characters in the Patient ID. Continue to increase the number by one for each phantom that is used.

- The ACR phantom and the holder (cradle) should be carefully positioned in the head RF coil to maintain alignment. The nose label should be up and the chin label should point away from the magnet.
- Landmark on the center of the phantom (which should be aligned to the center of the head coil). Move to isocenter and let settle for 2-3 minutes.

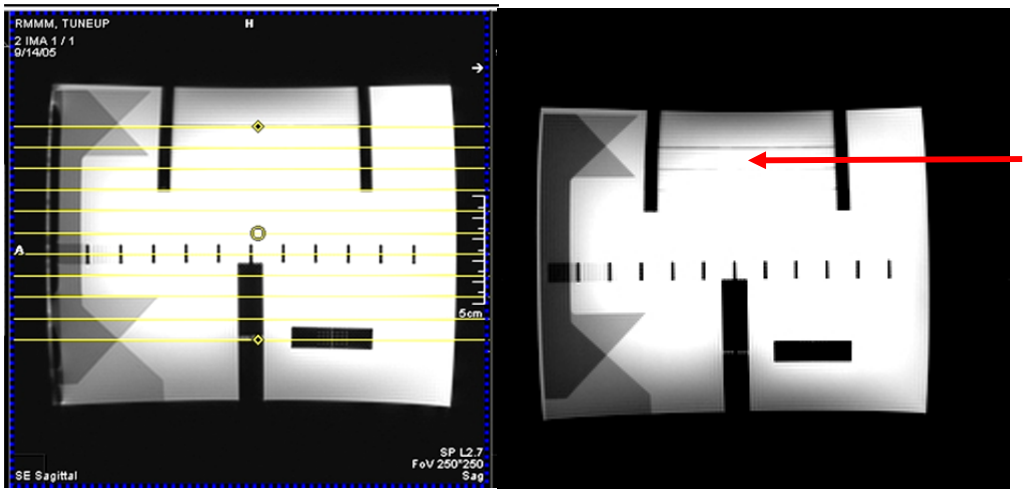
ACR Phantom Annual QA Scan Acquisition and Analysis:

- Run the Annual ACR Phantom protocol:
    - 3-plane localizer is performed
    - Sagittal single plane acquisition is prescribed from isocenter. Two acquisitions are run, one without and one with Large FOV Correction Filter.



Scan prescription for Axial IW exams

- Prescribe the Axial T1W and PD/T2W exams from the (first) single slice sagittal acquisition (without the Large FOV filter correction applied). The first of the 11 slices should be aligned with the first low contrast object as shown by the red arrow in the figure below.



- Prescribe the Axial IW exams from the (first) single slice sagittal acquisition (without the Large FOV filter correction applied) in the same manner as described above.

Decision Tree for ACR Phantom Annual QA Exam:

- The T1W, PD, T2W, and IW images will be analyzed using an automated software program written based on the following methodology ("Phantom Test Guidance for the ACR MRI Accreditation Program"). The reporting criteria are more stringent for the OAI than they would be for a clinical exam:
    - Geometric Accuracy
        1. Inside end-to-end length 148 ± 1.0 mm;
        2. Inside diameter 190 ± 1.0 mm.

- High contrast spatial resolution ≤ 0.9 mm
- Slice thickness accuracy 5 mm ± 0.7 mm for SE sequences; 3mm ± 1.0mm for TSE sequences
- Slice position error ≤ 2 mm
- Percent Signal Ghosting ≤ 2.5 % for SE sequences; < 1.0% for TSE sequences (service call if > 0.5%)

- If the system fails the repeat exam, the site will be instructed to call Siemens service.

APPENDIX I MRI Protocol Details

	3-plane LOC	2D TSE	3D DESS	2D TSE	2D MSME	2-plane LOC	Thigh Axial
Weighting	**T1W**	**Int**	**T2***	**Int**	**T2 Map**	**T1W**	**Int**
Plane	3-plane	Coronal	Sag	Sagittal	Sagittal	2-plane (Coronal, Axial)	Axial
Fat Sat	No	No	WE	Yes	No	No	No
Matrix (phase)	128	307	307	307	269	256	384
Matrix (freq)	256	384	384	384	384	512	512
No. of slices	23	31	160	33	27	12	27
FOV (mm)	200	140	140	140	120	400	500
Slice thickness (mm)	5	3	0.7	3	3	10	5
Skip (mm)	1	0	0	0	0.5	0; 300	0
Flip Angle (deg)	40	180	25	180	n/a	60	180
TE/TI (ms)	5	29	4.7	30	10, 20, 30, 40, 50, 60, 70	5	10
TR (ms)	10	3000	16.3	3000	2700	10	600
BW (Hz/pixel)	300	352	185	250	250	250	199
Chemical Shift (pixels)	1.8	1.3	0	0	1.8	1.8	2.2
NAV (NEX)	1	1	1	1	1	1	1
Echo train length	1	7	1	5	1	1	1
Phase Encode Axis	A/P, R/L	R/L	A/P	S/I	A/P	A/P, R/L	A/P
Phase Partial Fourier (8/8 = 1)	1	1	1	1	1	1	1
Readout Partial Fourier (8/8 = 1)	1	1	1	1	1	1	1
Slice Partial Fourier (8/8 = 1)	1	1	0.75	1	1	1	1
Options:		elliptical k-space filter and large FOV filter	elliptical k-space filter, elliptical sampling, large FOV filter	elliptical k-space filter and large FOV filter	elliptical k-space filter and large FOV filter		elliptical k-space filter and large FOV filter; ascending slice order, 2 concatenations, no FlowComp
Distance Factor (%)	50	0	0	0	16	0; 300	0
Phase Oversampling	0	0	0	20	0	0	0
Slice Oversampling	0	0	10	0	0	0	0
Phase Resolution	50	80	80	80	70	50	62.5
Averaging Technique	Short Term	Short Term	Short Term	Short Term	Short Term	Short Term	Short Term
Gradient Rise Time	Fast	Fast	Fast	Fast	Fast	Normal	Normal
RF Amplitude	Normal	Normal	Fast	Normal	Normal	Low SAR	Normal
X-Resolution (mm)	0.781	0.365	0.365	0.365	0.313	0.781	0.977
Y-Resolution (mm)	1.56	0.456	0.456	0.456	0.446	0.781	0.814
Scan time (min)	***0.5***	***2.25***	***10.6***	***3.75***	***10.6***	1.5	3.8

APPENDIX II MRI QA Protocol Details

	Daily / Monthly QA Knee Coil Localizer	**Daily QA 2D TSE**	**Daily QA 2D TSE**	**Monthly QA 2D TSE**	**Monthly QA 2D TSE**	**Monthly QA 3D DESS**	**Monthly QA 2D MSME**	**Head Coil Localizer**	**ACR Localizer**	**ACR Localizer (Large FOV Filter)**	**Monthly OAI IW ACR**	**Annual T1W ACR**	**Annual PD / T2W ACR**
Pulse Sequence	**fl2d1**	**tse2d1_5**	**tse2d1_5**	**tse2d1_5**	**tse2d1_5**	**de3d1**	**se**	**fl2d1**	**se2d1**	**se2d1**	**tse2d1_5**	**se2d1**	**se2d2**
Plane	3-plane	Sagittal	Axial	Sagittal	Axial	Sagittal	Sagittal	3-plane	Sagittal	Sagittal	Axial	Axial	Axial
Fat Sat	No	No	No	No	No	WE	No	No	No	No	No	No	No
Matrix (phase)	128	307	307	307	307	307	269	128	256	256	555	256	256
Matrix (freq)	256	384	384	384	384	384	384	256	256	256	704	256	256
No. of slices	21	7	7	7	7	160	21	13	1	1	11	11	11
FOV (mm)	200	140	140	140	140	140	120	300	250	250	250	250	250
Slice thickness (mm)	5	3	3	3	3	0.7	3	5	20	20	3	5	5
Skip (mm)	2.5	6	6	6	6	0	0.5	2.5	10	10	7	5	5
Flip Angle (deg)	40	180	180	180	180	25	90	40	90	90	180	90	90
TE/TI (ms)	5	19	29	19	29	4.7	10, 20, 30, 40, 50, 60, 70	5	20	20	29	20	20 / 80
TR (ms)	10	1750	1750	1750	1750	16.3	2700	10	200	200	1750	500	2000
BW (Hz/pixel)	180	352	352	352	352	183	250	280	300	300	355	160	300
Chemical Shift	2.4	1.3	1.3	1.3	1.3	0	1.8	1.6	1.4	1.4	1.2	1.5	1.5
NAV (NEX)	1	1	1	1	1	1	1	1	1	1	2	1	1
Echo train length	1	5	5	5	5	1	1	1	1	1	5	1	1
Phase Encode Axis	A/P, R/L	A/P	A/P	A/P	A/P	A/P	A/P	A/P, R/L	A/P	A/P	R/L	R/L	R/L
Phase Partial Fourier	1	1	1	1	1	1	1	1	1	1	1	1	1
Readout Partial Fourier	1	1	1	1	1	1	1	1	1	1	1	1	1
Slice Partial Fourier	1	1	1	1	1	0.75	0.75	1	1	1	1	1	1
Distance Factor (%)	50	0	0	0	0	20	16	50	50	50	333	100	100
Phase Oversampling	0	0	0	0	0	0	0	0	0	0	0	0	0
Slice Oversampling	0	0	0	0	0	10	0	0	0	0	0	0	10
Phase Resolution	50	80	80	80	80	80	70	50	100	100	80	100	100
X-Resolution (mm)	1.09	0.365	0.365	0.365	0.365	0.365	0.313	1.172	0.977	0.977	0.355	0.977	0.977
Y-Resolution (mm)	2.10	0.456	0.456	0.456	0.456	0.456	0.446	2.344	0.977	0.977	0.450	0.977	0.977
Scan time (min)	***0.5***	***1.8***	***1.8***	***1.8***	***1.8***	***10.5***	***10.6***	***0.4***	***0.8***	***0.8***	***6.5***	***2.8***	***8.5***