KNEE MRI 1.0 T

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1. Introduction

1.1 Background and rationale

The Multicenter Osteoarthritis (MOST) Study is a multicenter epidemiological study of risk factors for knee osteoarthritis, and includes a focus on structural changes in the knee assessed by MRI. Participants in this study must have symptomatic knee OA (defined in terms of frequent knee pain and X-ray findings of knee OA at baseline) or be at high risk of developing OA based on the presence of risk factors. MR images of the knee were obtained in all participants without contraindications at baseline and 30 months (Second Follow-up Visit). Follow-up knee MR images were also obtained in a subset of participants at 15 months (First Follow-up Visit). Additional follow-up visits at 60 months and 84 months are now planned.

1.2 Purpose of the manual (1.0 T MRI)

This manual is intended for the MRI technologists, principal investigators, and study coordinators at the clinical centers. The purpose of this manual is to standardize the imaging techniques and administrative procedures related to the MRI component of the MOST for evaluating participants with OA of the knee. The manual describes the MRI techniques to be used along with the procedures for documentation and transfer of the MRI data to the Coordinating Center at the University of California, San Francisco (UCSF).

The role of the UCSF Coordinating Center will be to:

- train and certify the clinic OrthOne MRI technologists
- monitor the performance of the MRI technologists throughout the study
- check all OrthOne MRI scans for completeness, protocol adherence, and quality as soon as possible after they arrive at the UCSF Coordinating Center
- provide immediate feedback to the MRI technologists when quality and protocol problems are detected
- request repeat MRI scans as needed to correct problems
- inventory and archive all MRI scans
- provide bimonthly (every other month) Quality Assurance reports to the UCSF Coordinating Center and the MOST investigators on scans received, quality issues, and scans read in the previous month
- work with site MRI technologists and ONI, Inc. to evaluate scanner performance and need for maintenance and service during the study
- organize the OrthOne scans for reading
- read the OrthOne scans using the WORMS methods

1.3 Design of OrthOne study component

The MR component of the MOST comprises bilateral imaging, using the OrthOne scanner, of the knee joints in 2700 participants (about 90% of the study population) who do not have contraindications for the MR examination (see Section 3.1 of this manual – MRI contraindications).

Baseline and 30-month follow-up visit bilateral knee imaging has already been performed on all participants who did not have contraindications for the MR examination, along with unilateral knee imaging of a subset of participants at a 15-month interim visit. Participants are now returning for imaging at 60 month and 84 month follow-up visits.

These MRIs will be performed using a 1.0 T dedicated system (OrthOne) with a circumferential extremity coil. Imaging procedures will include axial, and sagittal proton density weighted sequences with fat saturation, and coronal STIR sequences on both knees. Additionally, a single knee only may be scanned with a 3-point Dixon sequence for cartilage evaluation when there is sufficient time to do so (this would always be the same knee on which the 3-point Dixon sequence was obtained at baseline). Sequences completed on a participant's knee at baseline will be repeated on that knee during the follow-up MR-imaging at the 60-month and 84-month visits. The total imaging acquisition time required for MRI of both knees including participant set-up will be approximately 60 minutes (30 minutes for one knee).

1.4 Training of MRI technologists

Each clinic will hire one or more dedicated MRI technologists to perform scans on the OrthOne scanner. This person must successfully complete the OrthOne training provided by the manufacturer, ONI Corporation.

A representative from the UCSF Coordinating Center will travel to the study clinic to further train and certify the technologists in the MOST procedures. The MRI QA and Reading Center will certify trained technologists in the MOST protocol. Certification will be based on the results of the training session and a review of 10 volunteer/participant knee scans. Appendix 3 shows the certification form.

Only designated and certified technologists should perform the MOST examinations. A unique MOST staff ID number will identify each technologist involved in the study.

2. Equipment and supplies

The OrthOne is a Magnetic Resonance Imaging (MRI) system designed specifically for imaging the human extremities (knees will be imaged in MOST). ONI Incorporated manufactures the 1.0 Tesla MRI scanner. The OrthOne Operator's Guide (ONI Part # 2000-9006, April 2006, Revision B), should be referenced for information about the equipment and software operation.

ONI Medical Systems Incorporated
301 Ballardvale Street, Suite 4
Wilmington, MA 01887

ONI Customer Service 1-978-658-0020
Toll free: 888-775-7788
FAX: 978-658-0898
Email: info@onicorp.com

2.1 Service and maintenance

The OrthOne is a complicated medical imaging device and must be maintained by ONI trained service personnel. The system requires preventive maintenance four times annually. Warranty and onsite service and preventive maintenance are specified in the sales agreement. Each clinical center is responsible for equipment service requests and preventive maintenance.

3. Safety issues and exclusions

Screening is required for all participants to determine if the participant is at risk of injury from the MRI exam. For safety reasons, participants will be screened for contraindications and hazards. The MRI technologist must thoroughly understand specific contraindications and hazards for the OrthOne system (OrthOne Operators Guide, pages 2-1 to 2-13).

3.1 MRI contraindications

The following are contraindications for the 1.0 T MRI scanner:

1. weight greater than 350 lbs.
2. surgery in the past two months (except surgeries/procedures on approved list-see Appendix 6)
3. electronic implant or device, such as cochlear implant
4. magnetically-activated implant or device, such as magnetically-activated dental implant or dentures, or magnetic eye implant
5. heart pacemaker
6. implanted heart defibrillator
7. internal electrodes or wires, such as pacemaker wires or bone growth / bone fusion stimulator wires
8. neurostimulation system, such as spinal cord stimulator or gastric electrical stimulation system
9. surgically implanted insulin or drug pump
10. tissue expander with magnetic port, such as inflatable breast implant with magnetic port
11. brain aneurysm surgery, brain aneurysm clip(s) or coil(s)

The following implants/metal injuries may be MRI safe and require medical documentation showing that it is safe for the participant to have an MRI scan:

1. stent, filter, coil or clips
2. shunt (spinal or intraventricular)
3. surgically implanted hearing device (not a regular hearing aid) or prosthesis in your ear

4. eyelid spring, wire or weights
5. penile implant or prosthesis (men only)
6. heart valve
7. injury in which metal fragments entered your eye and you had to seek medical attention
8. injury by a metal object such as shrapnel, BB, or bullet

The following conditions are contraindications for a specific knee:

1. knee replacement or knee surgery with metal implants such as pins, screws, staples, etc. (only knee with knee replacement or metal implants is not scanned)
2. leg does not fit in the knee coil

MRI exclusion questions are asked by the MRI technologist prior to the MRI scan to determine whether the participant will be excluded from this examination (section 9.0 shows the relevant 1.0 T Knee MRI data collection form questions #2 to #10). If the participant answers "Yes" or "Don't know/Refused" to questions #3 to #5, they should not have an MRI scan unless they have medical documentation that it is safe to have an MRI scan (see Questions #6 to #6a). For Question #8, the participant should not have an MRI scan of the knee that has had a total knee replacement or surgery with metal implants. The MRI technologist needs to review the 1.0 T Knee MRI data collection form Questions #2 to #8 to confirm that participant should not be excluded for safety reasons. The MRI technologist will sign Question #9 "Is participant eligible for a 1.0 T knee MRI scan?" after reviewing the MRI exclusion questions, and confirming that the participant does not have any specific potential safety hazards. If there are any special exceptions to a MRI safety question, and the participant has medical documentation confirming that the metal implant or metal injury is MRI safe, a photocopy of the medical documentation will be placed in the participant's chart and/or note made in the participant's chart. The onsite investigator will determine what is acceptable medical documentation for MRI safety and study staff authorized by the onsite investigator will sign Question #6a. Further MRI safety information can be found at http://www.mrisafety.com/. A copy of the Reference Manual for Magnetic Resonance Safety, Implants and Devices: 2008 Edition should be located in the MRI suite (refer to MOST Equipment List 60-month Follow up Visit on the MOST website for ordering information), or the online website at http://www.mrisafety.com/list_search.asp can be used to search for safety information about particular implants/devices.

4. Participant and exam room preparation

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

4.1 Participant positioning

Positioning of the participant's knee in the gantry must be reproducible from visit to visit to allow accurate comparison of serially acquired images. **The MRI technologist should view the baseline knee MRI scan and match the baseline scan participant positioning in the knee coil as closely as possible.** If the knee is in internal or external rotation on the baseline scans,

match follow-up scans in the same degree of rotation. During follow-up scans, the technologist can put the knee further into the gantry to obtain more complete coverage. If the tibia was incompletely covered in the baseline sagittal and coronal sequences, this should be corrected in the follow-up scan positioning. Generally, the participant sits in a chair with the leg in neutral position and the patella pointing straight up rather than in slight external rotation, as is commonly done in clinical imaging protocols. External rotation is more difficult to reproduce on serial exams and complicates image interpretation in this study. Additionally, the knee must be well immobilized in the circumferential extremity coil with foam padding. If possible, try to keep some space (even just a thin cotton cloth) between the knee and coil to reduce 'coil noise.'

How to properly position a participant's knee in the magnet is described in detail in the following section (for handling of the patient chair, positioning of the RF coil and handling of the laser alignment light, please refer to the OrthOne Operator's Guide as referenced):

1. Place the 180 mm diameter RF Coil into the system (pages 4-1 and 4-2 OrthOne Operator's Guide).
2. Place the leg rest into the retracted position (page 4-8 OrthOne Operator's Guide).
3. Bring the chair back and chair base into the full upright position (page 4-5 OrthOne Operator's Guide).
4. Unlock the chair and position it in the approximate position leaving a gap for participant access between the magnet and chair. Relock the chair.
5. Adjust the heel rest.
6. Seat the participant in the chair.
7. Have the participant place their foot of the leg to be imaged in the entrance of the RF coil. The other foot should be placed on the footrest on the base of the chair or on the floor.
8. Measure 250 mm from the knee to the upper leg.
9. Unlock the chair and gently roll it until the reference point is aligned with the laser alignment light (page 4-3 OrthOne Operator's Guide).
10. Properly position the participant's heel into the heel rest and secure the heel rest.
11. Lock the chair wheels.
12. From the participant's side, insert foam wedges around the participant's leg for stability and comfort during the scan.

4.2 Participant comfort and prevention of motion artifacts

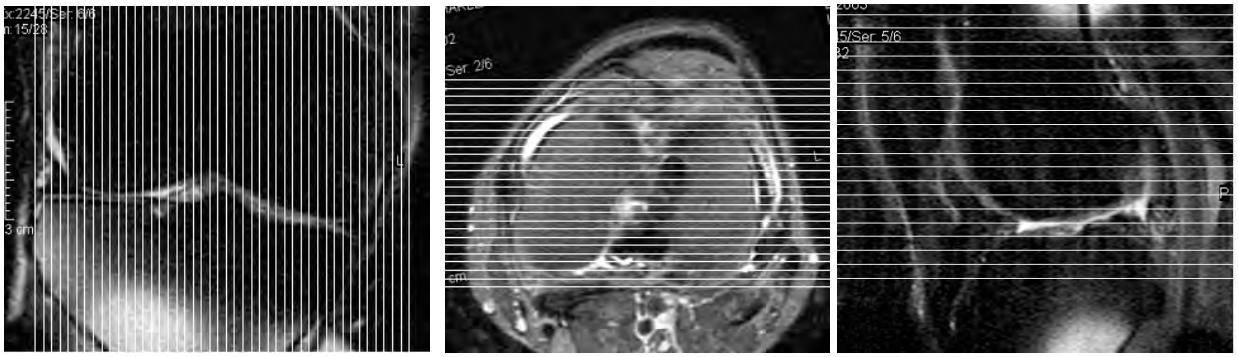
The comfortable positioning of the participant at the beginning of the examination is critical to limiting motion artifacts. Care should be taken in properly placing the cushions and pads around the knee in the extremity coil. Earplugs should be included along with pillows, blankets and verbal reassurance. The participant should be told to not move during the scan. **When the technologist sees motion during the scan, the sequence(s) should be repeated.**

5. MRI sequence protocols

5.1 Imaging planes set-up

Special care should be taken in the planning of the sequences. For follow-up scans, the MRI technologist should view the baseline MRI sequences and set-up the imaging planes exactly as was done during the baseline image acquisition. Complete anatomical coverage in each plane is very important for the reading. See examples of correct planning (Fig.1). Internal/external rotation should be matched as closely as possible to baseline. Adjustments further in or out of scanner can be made at follow-up for best quality coverage and images (see MOST 1.0 T MRI Atlas CD).

Figure 1: Correct planning for complete coverage of anatomy



Sagittal Plane **Coronal Plane** **Axial Plane**

5.2 Imaging parameters

All parameters for MOST should be pre-programmed into the MRI computer to limit the potential for human error. The total examination time including 10 minutes for participant set-up, is approximately 60 minutes for both knees (30 minutes for one knee).

The MR system should be checked on a weekly basis and logged in the QA log to confirm that these pre-programmed sequence parameters are in adherence with the protocol as documented below.

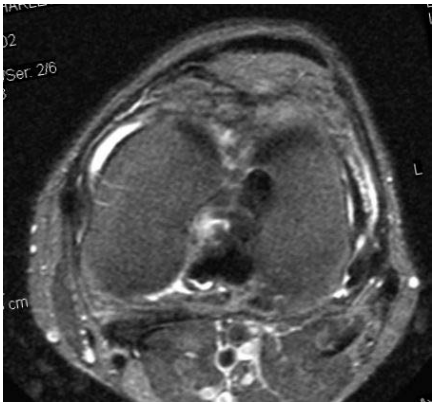
If sequence parameters are individually adjusted to improve image quality, please indicate the non-standard sequence and explain why on the “Comments” section of the 1.0 T Knee MRI Data Collection Form at Question #12 for the relevant knee and sequence.

Localizer: 25 sec

Prescan: 15 sec.

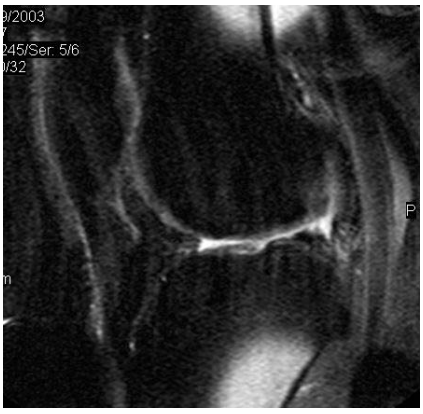
The knee may require repositioning for the second repeat localizer before the main set of sequences is performed.

1. Axial FSE PD Fat Sat



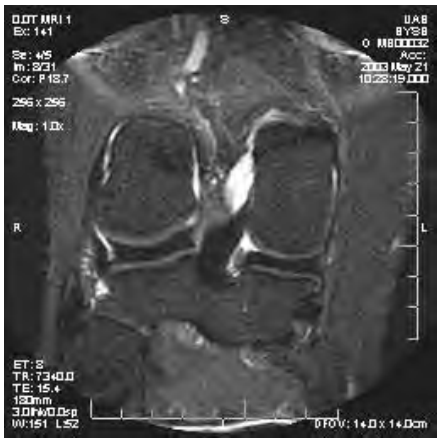
TR: 4700 msec.
TE: 13.2 msec.
Thickness: 3 mm
Gap : 0
Slices : 26-38
Frequency x Phase: 288 x 192
Band width: 45
Nex : 2
Prescan: water
FOV: 140
Frequency direction: A/P
Echo train: 8
Set center frequency: water
Time: 2 min 59 sec.

2. Sagittal FSE PD Fat Sat



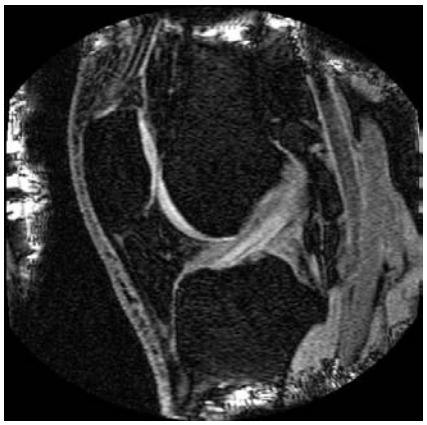
TR: 4800 msec.
TE: 35 msec.
Thickness: 3 mm
Gap: 0
Slices: 30-38
Frequency x Phase: 288 x 192
Nex: 2
Flip angle: 90
FOV: 140
Frequency direction: H/F
Echo train: 6
Set center frequency: water
Time: 4 min 44 sec (when Echo train is 6 time = 6 min 17 sec).

3. Coronal STIR sequence



TR: 7820 msec.
TE: 15 msec.
TI: 100 msec
Thickness: 3 mm
Gap: 0
Slices: 28-38
Frequency x Phase: 256 x 256
Nex: 2
Flip angle: 90
FOV: 140
Frequency direction: H/F
Echo train length: 6-8
Time: less than 6 min

4. Three-Point Dixon 3D sequence
(right knee or the same knee as at baseline)



TR: 30 msec.
TE: 6.6 msec.
Thickness: 2 mm
Gap: 0
Frequency x Phase: 300 x 160
Nex: 3
Flip angle: 35
Bandwidth (kHz): 40
FOV: 140
Slices: ≥ 42 slices (enough slices to cover the entire knee)
Frequency direction: N/A
Echo train: 1
Center: 0,0,0
Time: ~ 9 minutes

6. Detailed MRI exam instructions

Refer to the OrthOne Operators Guide, section 5 *Prescribing a New Exam* for information about entering participant information and performance of an OrthOne MRI examination.

6.1 Labeling the images

The following information should be entered into the MRI image header, by using "Patient Entry Screen" and "Scan Setup Screen" on the OrthOne computer, so that the information will appear on the images sent to the Coordinating Center at UCSF.

Patient Entry Screen

1. Patient ID = MOST Participant ID#
2. Patient Name = random 4-letter MOST Acrostic
3. Birth Date – leave blank
4. Sex = enter gender (male or female)
5. Age = leave blank
6. Weight = enter weight from page 3 of the Clinic Visit workbook (exam will not begin unless weight value is entered)
7. Operator = enter staff MOST ID#

Scan Setup Screen

Anatomy = select either Left Knee or Right Knee from the pull-down menu

6.2 Examination Procedures and Scanning Large Knees

The procedures for the examination are outlined in the OrthOne Operator's Guide sections 5-6 through 6-8, and will be covered during the onsite OrthOne training provided by ONI, Corp. Each knee will have a unique examination number.

For each of the sequences used in MOST, the MRI scanner has a predefined default value for the number of slices to be scanned (axial sequence = 26 slices, sagittal sequence = 32 slices, coronal sequence = 28 slices). When using these numbers of slices (or less) and coverage of all relevant anatomy is allowed, then the pulse sequence parameters TR specified in section 5.2 will be allowed by the scanner.

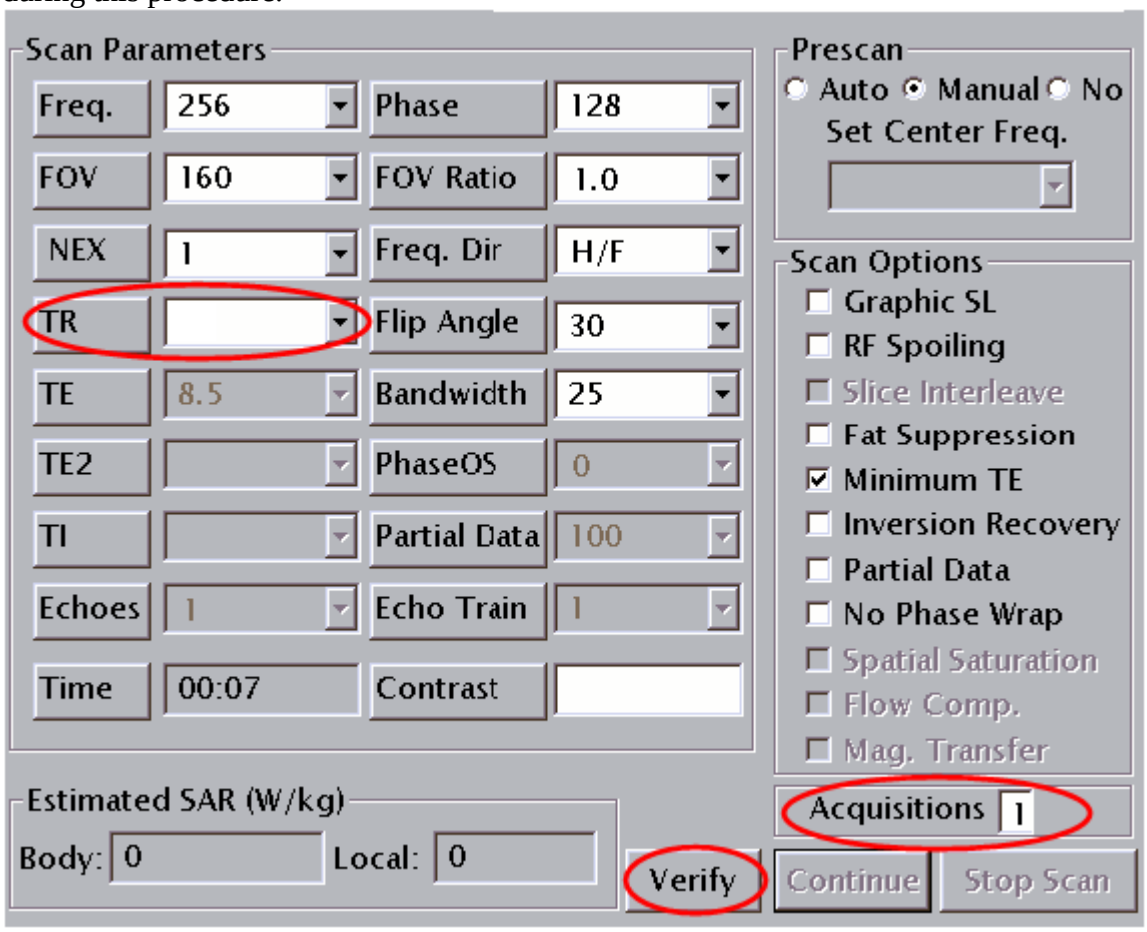
For large knees, increasing the number of slices may be required to cover the correct amount of knee anatomy. In such cases, the MRI tech needs to check whether the parameter "Acquisitions" on scanner console doubles from a value of 1 to a value of 2 which will double the scan time.

In such cases, the MRI tech needs to increase the value of TR to ensure that "Acquisitions" returns to a value of 1. To do this, click the left mouse button over the 

button on the scanner display to see what "parameter hint" the scanner gives. The scanner will report the minimum value that TR has to be for "Acquisitions=1". TR needs increasing to slightly above that value. Page 5-17 of the OrthOne Operators Guide describes how to use "parameter hints".

So for large knees, increase the value of TR to be slightly higher than the minimum value shown by the "parameter hint" (maybe 10 or 20ms higher) and then click the "Verify" button and ensure that there are no problems. For very large knees, TR may get as large as 9000ms for the coronal sequence and sagittal sequence and for the axial sequence values approaching 6000ms might be required.

The following figure shows the relevant parts of the scanner display which will need to be used during this procedure.



IMPORTANT: Never scan a knee when the value for Acquisitions is 2 – ALWAYS keep increasing TR followed by clicking Verify until Acquisitions=1 is allowed.

6.3 Completing the 1.0 T Knee MRI data collection form

Data is recorded on the data collection form. Refer to MOST Data Management operations manual for instructions in completing scannable forms.

- The MOST ID# and Acrostic will be preprinted on the form, but must be verified by matching the ID badge the participant is wearing and the ID, ACROSTIC and name in the participant's study chart before the MRI is completed.
- The first section of the form, Questions #1 - #10, is filled out before the participant goes for the MRI. These questions determine if the participant is ineligible for the MRI scan because of safety exclusions.

- The MRI technologist reviews Questions #1 - #10 to confirm that the questions have been completed and that there are no participant MRI hazards, and initials and dates Question #9 of the data collection form.
- Questions #11 to #12 confirm whether an MRI was obtained, and which pulse sequences were acquired for each knee. If any pulse sequences were not acquired, record that and the reason why.
- If scan parameters were changed (e.g., increased number of slices), or there were technical problems (e.g., auto-prescan failed), enter the reason at the "Comments:" section of Question #12 for the relevant knee and pulse sequence.
- .If there were any other problems affecting image quality (e.g., participant couldn't stay still, fat saturation failure), record those at the "Comments:" section of Question #12.

The 1.0 T Knee MRI data collection form should be faxed to the UCSF Coordinating Center with the rest of the clinic visit data collection forms.

6.4 1.0 T Knee MRI Weekly log of Exams Acquired

Specific information regarding the MRI exam's recorded during a day is to be recorded on the 1.0 T Weekly Log of MRI Exams Acquired (see Appendix 1). This spreadsheet can be downloaded from the MOST Website (http://www.keeptrack.ucsf.edu)

Use this log to record:

1. The Unique numeric exam number assigned by the scanner.
2. The date of the exam.
3. The MOSTID of the participant being scanned.
4. The Acrostic of the participant being scanned.
5. The knee (L or R) being scanned.
6. The Operator ID of the person performing the scan.
7. The sequences obtained ("A" = axial, "S" = sagittal, "C" = coronal) usually "ASC" would be entered, unless the scan is a repeat request, or the previous scan has been aborted and a new one done for just a few sequences.
8. Any sequences that were obtained a 2nd time (using the same "A","S","C" abbreviations)
9. Comments (See Section 6.5). If the scan is a "repeat request" note that in the comment field.
10. Leave the final field blank until an e-mail has been received from the Coordinating Center confirming that the images have been received.

Only use the comments field for comments relating to the complete MRI exam (e.g., "repeat request"). Use the 1.0T Knee MRI data collection form (Question #12 "Comments") to record comments about images from individual pulse sequences.

The completed weekly log should be faxed to Jing Li, MD at the Coordinating Center (Email: jli@psg.ucsf.edu / Fax: (415) 514-8150) once per week (on Friday afternoon, or Monday morning)

6.5 QA checks of MRI images by MRI technologist

The MRI technologist is responsible for ensuring that the quality of the examination and images is evaluated *before* the participant is released from the examining room. Poor quality images (those that exhibit any of the quality problems described below) should be repeated. If the image cannot be improved, the reason should be stated in the "Comments" field on the 1.0 T MRI Weekly Log form. Please detail any participant or equipment issues, e.g. large knee/thigh or knee pain/participant cannot stay still.

Each participant's scans should be checked for:

1. Completeness

   Were all of the sequences done during the baseline MRI scan acquired? If not, record which sequences were not obtained and why using Question #12 of the 1.0T Knee MRI data collection form. Check "No" and enter the reason not acquired.

2. Protocol adherence

   The data has been acquired using the correct MRI parameters in strict accordance to this MRI manual (see section 5). At the beginning of each week the MRI technologist should check the sequence parameters and make sure those programmed on the MR system matched those on the protocol. In some cases, the exact MRI parameters cannot be achieved for one reason or another, e.g., the TR or field of view may have to be increased slightly for an unusually large knee to achieve full anatomical coverage. Please indicate non-standard sequence and explain why on the "comments" section of the log sheet.

   Note: Please indicate any deviation from the MRI protocol and explain the reason for deviation on the comments section of Question #12 of the 1.0T Knee MRI data collection form.

3. Image quality

Images should be checked at the time of the exam by the MRI technologist for possible problems listed below before the participant is released or the images are written to the DICOM server. Images that do not meet these quality criteria should be reacquired. If the problem cannot be resolved with reacquisition, record the reason for the problem using Question #12 of the 1.0T Knee MRI data collection form for each sequence and knee (right/left) affected, and indicate the reason on the Comments section of the form.

- **Incomplete coverage of anatomy**
  Complete coverage of anatomy in all planes is very important as otherwise the examination will be incomplete and the scans might not useful for radiologist reading. See section 5.1 (Figure 1) for examples of correct planning. In case anatomy is insufficiently covered the sequence should be repeated. If the baseline scan had incomplete coverage, the technologist should try to get more complete anatomical coverage during follow-up. Meniscus and/or tibia artifact should be avoided with complete tibia coverage in the sagittal sequence.

- **Motion artifacts**
  Positioning the participant comfortably using cushions and pads around the knee, and emphasizing the importance of lying still can minimize participant motion artifacts (Refer to section 4.1 Participant positioning). Images degraded by participant motion artifacts should be repeated after correcting any causes of participant discomfort or anxiety. Often verbal reassurance is sufficient to allay mild participant anxiety. However, physical limitations or severe claustrophobia may require that the participant not complete the MRI exam.

- **Fat saturation failure or omission**
  Frequency-selective fat saturation must be used in the proton density weighted fast spin echo sequences. It eliminates chemical shift artifacts along cartilage margins and is essential for detecting bone marrow edema. Fat saturation failure can occur in areas of irregularly shaped anatomy, such as the patella. Usually, this artifact does not extend to the patellar cartilage, but it can interfere with assessment of patellar marrow edema. Accidental omission of the frequency-selective fat saturation pulse is a significant oversight. If frequency-selective fat suppression was incidentally not applied, the sequence should be repeated. If incomplete fat saturation occurs, the FOV should be optimized. Complete coverage of the tibia will limit the partial fat saturation failure artifact in the sagittal sequence.

- **Susceptibility artifacts/Metallic artifacts**
  Since ferromagnetic materials typically have large susceptibilities, field distortions and artifacts are prominent around implanted metal objects. As participants with prior knee surgery will be included in the study, metallic artifacts may occur at MR imaging. These artifacts cannot be avoided. These images should be sent to the MRI QA and Reading Center in the usual way, with the problem noted on the log sheet.

The MRI QA staff will determine whether the image quality is sufficient for reading despite the artifacts.

- **Wraparound/Aliasing**
  The use of "No-Phase-Wrap" software should avoid aliasing. Increasing the FOV to encompass the entire anatomic dimension of the knee in the affected direction will also help to eliminate aliasing. As an alternative strategy, the frequency and phase-encoding axis may be swapped so that the shorter dimension of the object (knee) is oriented in the phase-encoding direction.

- **Low SNR**
  Low signal to noise ratio (SNR) often manifests itself as images which are grainy and with low contrast between different types of tissue, and when no other problem such as motion or metallic artifacts are present.

6.6 Longitudinal QA

Regularly scheduled image-based QA tests (Daily Quality Assurance or DQA) will be done to verify the proper working condition of the system (OrthOne Operator's Guide, section 3-4 to 3-6 and Appendix 4). Document the QA scan as "DQA" on the MRI Log. The oil-water phantom should be scanned weekly with the proton density fast-spin echo, coronal STIR, and 3-Point Dixon sequences.

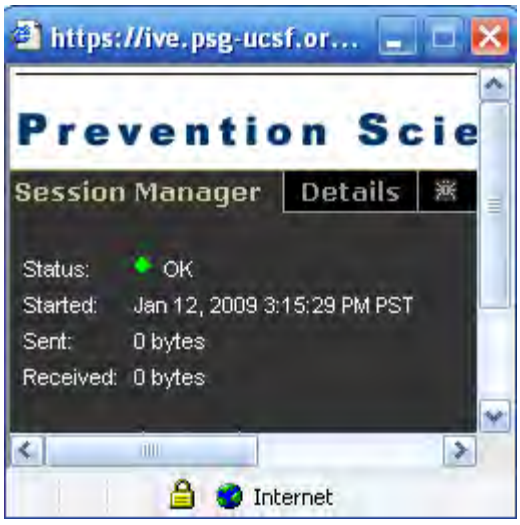
6.7 Electronic transfer of images from the OrthOne scanner

After a participant has been scanned, and their exam details recorded on the 1.0 T MRI Weekly Log, the participant's images should be transferred electronically from the OrthOne to eFilm on the PC in the scanner room, in preparation for electronic transfer to the Coordinating Center.

This is done using the "Archive" button on the top right of the main display on the OrthOne scanner and using the "Transfer" option to perform a DICOM image transfer to the eFilm Workstation.

6.8 Setting up secure DICOM image transfers

To create a secure data transfer link to the Coordinating Center for DICOM image transfers, the MRI technologist should go to the website https://ive.psg-ucsf.org and log in using their username and password. They then should choose the "DICOM" role offered by the website. A small "Session Manager" pop-up window will appear. After a short time, the window will appear similar to the one shown below:



Once the “green light” and “OK” status message show, this window can be minimized, but do NOT close or quit the window completely, otherwise the secure connection will be closed.

As long as the user is logged on to the PC, we suggest that they leave this window open (or minimized). If it is closed, or disappears for any reason, go back to https://ive.psg.ucsf.org and log in again and chose the DICOM role.

6.9 Electronic transfer of images to the Coordinating Center

The MRI technologist is responsible for ensuring the correct completion of the 1.0 T MRI Weekly Log of Exams Acquired *after each participant is scanned and before the images are transferred to the Coordinating Center*.

Once the transfer from the OrthOne scanner to eFilm workstation has completed, the transfer process to the Coordinating Center should be started. This can happen for each participant individually, or can be done in one session at the end of the day. If the transfer from the OrthOne has not completed by the end of a work day, the transfer to the Coordinating Center can also be started the following morning.

Daily, send an e-mail to Jing Li at the Coordinating Center (jli@psg.ucsf.edu) listing the Exam #s that have been sent, and Cc: the e-mail to John Lynch (jlynch@psg.ucsf.edu). If no exams have been performed and transferred, then send an e-mail stating that fact.

Fax the completed 1.0 T MRI Weekly Log to Jing Li, MD at the Coordinating Center (Email: jli@psg.ucsf.edu / Fax: (415) 514-8150) once per week (on Friday pm, or Monday am).

To initiate the transfer of images to the Coordinating Center from eFilm, select the Exams #s for transfer, click the "Send" button and chose "UCSF Archive" as the destination. **We suggest selecting one participant's images at a time**. The eFilm software will then automatically send the images to DICOM server software on the PC and that DICOM server software will automatically forward the images over a secure and encrypted connection to the Coordinating Center.

Please ensure that a participant's images have all been transferred from the OrthOne before initiating transfer from eFilm to the Coordinating Center

If the "Session Manager" window for the secure DICOM transmission closes, it can simply be restarted by logging into http://ive.psg-ucsf.org and choosing the DICOM role.

Image transfers to the Coordinating Center will be paused if the "Session Manager" is not running, but as soon as it is restarted, transfers will resume automatically

Do NOT delete images from the OrthOne scanner or eFilm on the Workstation, until you have received an e-mail confirmation that they have been received at the Coordinating Center.

Within 48 hours of image transfer from eFilm, an automated e-mail listing whether the exams have been received at the Coordinating Center will be sent back. The MRI Technologist should check daily that all the exams on the 1.0 T MRI Exam Log have been received completely at the Coordinating Center.

If there are any exams from the 1.0 T MRI Exam Log which are not listed as being completely received at the Coordinating Center in the automated e-mail, then the MRI technologist should resend those from eFilm to the Coordinating Center.

7. Image QA at the UCSF Coordinating Center

7.1 QA review of participant images

Upon receiving the images, the UCSF Coordinating Center will check the images against the 1.0 T Weekly log of MRI Exams Acquired (Appendix 1) to ensure that all sequences in the protocol were included and that the pulse parameters used were in agreement with the protocol. The images will also be checked for adequate anatomical coverage and the presence of artifacts.

The MOST MRI QA center staff will send the repeat and/or resend requests for MRI scans to the clinical sites as a MOST numbered memo every 2 weeks. Repeat examinations should be performed as soon as possible.

If problems with image quality or protocol adherence are encountered, the UCSF Coordinating Center will work directly with the clinical site to correct the problem.

Request for repeat scans, in the event that the initial scan is unusable or missing, will be sent as a MOST numbered memo. While it is important to have usable scans on all eligible participants, we realize that practical considerations may make it difficult for some participants to return for a repeat MRI. Therefore, it will be left up to the clinical and professional judgment of the study coordinator and onsite investigator to decide whether to re-contact the participant. If a participant is not re-contacted or refuses to undergo a repeat MRI, the study coordinator must notify the MRI QA and Reading Center, so that this can be noted in the database comments field, and the repeat request cancelled.

7.2 QA Review of daily phantom scans

During the first several weeks of the study, the UCSF Coordinating Center perform QA of the daily phantom scans as soon as the scans are received. Thereafter, QA of the phantom scans is done on a weekly basis.

8. Questions and contact information

Questions regarding the MRI techniques outlined in this manual should be directed to:

John Lynch, Ph.D.
MOST MRI QA Director
Phone: (415) 514-8092
Fax: (415) 514-8150
jlynch@psg.ucsf.edu

Questions regarding completion of log forms or data management should be directed to:

Jing Li, M.D.
MOST MRI QA Specialist
Phone: (415) 514-8173
Fax: (415) 514-8150
jli@psg.ucsf.edu

The mailing address is:

UCSF Coordinating Center
Department of Epidemiology and Biostatistics
University of California, San Francisco
185 Berry St., Lobby 5, Suite 5700
San Francisco, CA 94107-1762

9. 1.0 T Knee MRI data collection form

39947

Visit	MOST ID #	Acrostic	Date Form Completed	Staff ID#
O 60-month O 84-month			Month / Day / 2 0 Year	

OrthOne 1.0 T Knee MRI

O First knee MRI O Repeat knee MRI

Confirm that this is the correct participant: Ask their name, confirm in chart that the name matches the MOST ID# and Acrostic at the top of this form.

1. Was participant eligible for MRI at time of Follow-up Telephone Interview?
(Examiner Note: Refer to Data from Prior Visits Report)

O Yes

O No → Not eligible for MRI. Go to Page 69, Question #9, and mark "No."

2. Does participant weigh > 350 lbs (>159.1 kg)?
(Examiner Note: Do not re-weigh participant. Check weight measurement on page 33 in the Follow-up Clinic Visit Workbook.)

O Yes → Not eligible for MRI. Go to Page 69, Question #9, and mark "No."

O No

3. Have you had any surgery in the past 2 months?

O Yes

3a. What type of surgery was it?

When was the surgery? (***Examiner Note: If participant unsure, please probe.***)

Month / Day / Year

3b. Does the surgery require a 2-month wait before an MRI can be performed?
(Examiner Note: Refer to the list of MRI-safe surgeries/procedures that do not require a 2-month wait. If the surgery or procedure does not require a 2-month wait, mark "No".

O Yes → Not eligible for MRI at this time. Go to Page 70, Question #11a and #11b, and mark "Participant scheduled for a later date." Schedule MRI for 2 months after surgery date. Complete and scan Pages 68, 69, 70, and 71 when participant returns for MRI.

O No → Go to Page 68, Question #4.

O No → Go to Page 68, Question #4.

O Don't know → Go to Page 68, Question #4.

37394

Visit	MOST ID #	Acrostic
○ 60-month ○ 84-month		

OrthOne 1.0 T Knee MRI

○ First knee MRI ○ Repeat knee MRI

4. The next few questions will be about specific implants. Please tell me whether you currently have any of the following implanted in your body:			
i. Electronic implant or device, such as a cochlear implant	○ Yes	○ No	○ Don't know/Refused
ii. Magnetically-activated dental implant or dentures, magnetic eye implant, or other magnetic device	○ Yes	○ No	○ Don't know/Refused
iii. Heart pacemaker	○ Yes	○ No	○ Don't know/Refused
iv. Implanted heart defibrillator	○ Yes	○ No	○ Don't know/Refused
v. Internal electrodes or wires, such as pacemaker wires or bone growth/ bone fusion stimulator wires	○ Yes	○ No	○ Don't know/Refused
vi. Neurostimulation system, such as spinal cord stimulator or gastric electrical stimulation system	○ Yes	○ No	○ Don't know/Refused
vii. Surgically implanted insulin or drug pump	○ Yes	○ No	○ Don't know/Refused
viii. Tissue expander with magnetic port, such as inflatable breast implant with magnetic port	○ Yes	○ No	○ Don't know/Refused
ix. Brain aneurysm surgery, brain aneurysm clip(s) or coil(s)	○ Yes	○ No	○ Don't know/Refused

4a. ***Examiner Note:***
Are any of the above items in Question #4 marked "Yes" or "Don't Know/Refused"?

○ Yes → Not eligible for MRI. Go to Page 69, Question #9, and mark "No." ○ No

5. Please tell me whether any of the following is currently implanted in your body:			
i. Stent, filter, coil, or clips	○ Yes	○ No	○ Don't know/Refused
ii. Shunt (spinal or intraventricular)	○ Yes	○ No	○ Don't know/Refused
iii. Vascular access port or catheter, such as a central venous catheter or PICC line	○ Yes	○ No	○ Don't know/Refused
iv. Surgically implanted hearing device (not a regular hearing aid) or prosthesis in your ear	○ Yes	○ No	○ Don't know/Refused
v. Eyelid spring, wire or weights	○ Yes	○ No	○ Don't know/Refused
vi. Penile implant or prosthesis ***(men only)***	○ Yes	○ No	○ Don't know/Refused
vii. Heart valve	○ Yes	○ No	○ Don't know/Refused

5a. Since your last visit to the MOST clinic on *[month/year]*, have you had an injury in which metal fragments entered your eye and you had to seek medical attention? ***(Examiner Note: Refer to Data from Prior Visits Report for month/year of last MRI scan.)*** ○ Yes ○ No ○ Don't know/Refused

5b. Since your last visit to the MOST clinic, have you had an injury in which metal fragments such as shrapnel, BB, or bullet entered your body? ○ Yes ○ No ○ Don't know/Refused

15461

Visit	MOST ID #	Acrostic
○ 60-month ○ 84-month		

○ First knee MRI ○ Repeat knee MRI

OrthOne 1.0 T Knee MRI

6. Are any of the items in Question #5 or Questions #5a - 5b on the previous page marked "Yes" or "Don't Know/Refused"? ○ Yes ○ No

6a. Does the participant have medical documentation that shows that it is safe to have an MRI scan?
(Examiner Note: If documentation is not already in the chart, ask participant if they brought medical documentation showing that it is safe to have an MRI.)

○ Yes → Place documentation in participant's chart and have authorized staff person sign here: _____

○ No → Not eligible for MRI. Go to Question #9, and mark "No."

7. Is there any other reason why this participant would not be eligible for an MRI?

○ Yes → What is the reason? _____ → Not eligible for MRI. Go to Question #9, and mark "No."

○ No

8. Has the participant had a knee replacement (where all or part of their joint was replaced), or knee surgery with metal implants in either knee? ***(Examiner Note: Refer to Data from Prior Visits Report, Page 14, Q#31d and Q#31fii, Page 15, Q#33d and Q#33fii, Page 39, Q4, and Page 55, Q1 in Follow-up Clinic Visit Workbook or ask.)***

○ Yes

Which knee was replaced or has metal implants?

○ Right → Do not scan right knee.

○ Left → Do not scan left knee.

○ Both knees → Not eligible for MRI. Go to Question #9 and mark "No."

○ No

9. Is the participant eligible for an OrthOne 1.0 T knee MRI scan?

○ Yes → Tech. signature: _____

○ No → Go to Page 70, Question #11.

10. Which knee(s) is being scanned?
(***Examiner Note: To determine which knee(s) to scan: Scan both knees unless contraindicated - refer to Question #8 above.***)

○ Right knee ○ Left knee ○ Both knees

44534

Visit	MOST ID #	Acrostic	Date Form Completed	Staff ID#
○ 60-month ○ 84-month			Month / Day / 2 0 Year	

○ First knee MRI ○ Repeat knee MRI

OrthOne 1.0 T Knee MRI

11. a. Was an MRI obtained of the right knee?

○ Yes ○ No →

Why wasn't a right knee MRI obtained? ***(Mark only one)***

- ○ Participant not eligible
- ○ Participant had right total knee replacement
- ○ Participant's leg did not fit in MRI scanner
- ○ Participant refused
- ○ Participant scheduled for a later date
- ○ Other ***(Please specify:*** _____)

b. Was an MRI obtained of the left knee?

○ Yes ○ No →

Why wasn't a left knee MRI obtained? ***(Mark only one)***

- ○ Participant not eligible
- ○ Participant had left total knee replacement
- ○ Participant's leg did not fit in MRI scanner
- ○ Participant refused
- ○ Participant scheduled for a later date
- ○ Other ***(Please specify:*** _____)

18998

Visit	MOST ID #	Acrostic	Date of Scan
O 60-month O 84-month			___ / ___ / 20___ Month / Day / Year

MOST

OrthOne 1.0 T Knee MRI

O First knee MRI O Repeat knee MRI

MRI Technologist ID# ___

12. Was an OrthOne 1.0 T knee MRI reviewed and obtained for each of the following sequences?

a. Right knee scan

i. Was the baseline right knee scan viewed?
O Yes O No → Reason: _____

ii. Axial
O Yes O No → Reason: _____

iii. Sagittal
O Yes O No → Reason: _____

iv. Coronal STIR
O Yes O No → Reason: _____

v. 3 Point Dixon ***(Examiner Note: Refer to Data From Prior Visits Report to see if 3 Point Dixon should be obtained.)***
O Yes O No → Reason: _____

b. Left knee scan

i. Was the baseline left knee scan viewed?
O Yes O No → Reason: _____

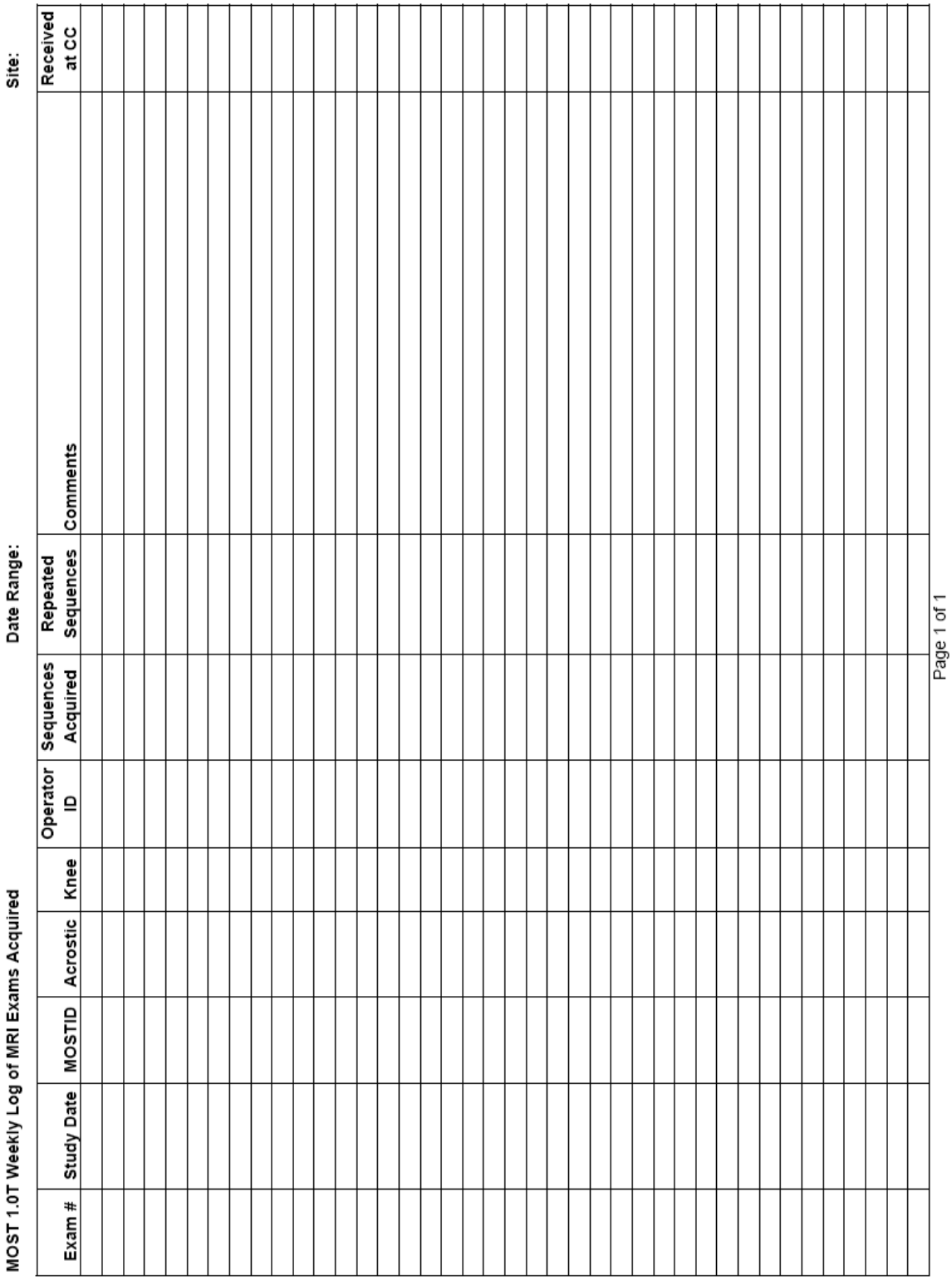
ii. Axial
O Yes O No → Reason: _____

iii. Sagittal
O Yes O No → Reason: _____

iv. Coronal STIR
O Yes O No → Reason: _____

v. 3 Point Dixon ***(Examiner Note: Refer to Data From Prior Visits Report to see if 3 Point Dixon should be obtained.)***
O Yes O No → Reason: _____

Appendix 1 1.0 T Knee MRI Weekly Log of Exams Acquired



MOST 1.0T Weekly Log of MRI Exams Acquired

Date Range:

Site:

Exam #	Study Date	MOSTID	Acrostic	Knee	Operator ID	Sequences Acquired	Repeated Sequences	Comments	Received at CC

Page 1 of 1

Appendix 2 Daily Quality Assurance Procedures

ONI Memorandum

TO:	MOST Study Staff
FROM:	Jon Trudeau, Xiaole Hong, Pete Roemer
SUBJECT:	System Daily Quality Assurance Testing
DATE:	03/21/2003
CC:	Bob Kwolyk, Mike Balistreri

Purpose

The following is a recommendation from ONI Inc. for tests to be run on the OrthOne MRI system to ensure proper operation during the MOST study. This recommendation is related to ongoing testing as opposed to the tests to be run prior to initial system turnover. It is not ONI's intent to impose specific tests but rather make recommendations for consideration by the MOST study investigations.

The tests described below are recommended based on the importance of maintaining the highest possible fat suppression volume. A summary of the tests described is:

1. Monitor and maintain magnet room temperature. Large changes in room temperature affects shim as noted below.
2. Run top-level signal-to-noise tests on all RF coils being used.
3. Monitor the fat suppression volume on an Oil/Water phantom using the 3D Dixon Sequence.
4. Monitor the fat suppression volume on an Oil/Water phantom using a frequency selective Fast Spin Echo sequence.

Over time the amount of testing may be reduced. For example, it may be perfectly acceptable to use the human images en lieu of the images of the Oil/Water Phantom.

Attached is an example data sheet for recording information. Some pass-fail criteria remain asTBD (To Be Determined) and should be adjusted based on initial experience with the system.

Room Temperature

Due to the nature of the Magnet design and the use of passive shimming, the magnet homogeneity can vary with room temperature. It is therefore important to maintain temperature stability of the magnet room in order to maintain the largest possible fat suppression volume for frequency selective suppression methods. Inversion Recovery and the 3D Dixon sequence are not sensitive to small variations in shim.

ONI's recommendation is the maintenance of the magnet room temperature to 3 degrees Celsius or better if feasible. Given the importance of the temperature, it is also recommended that the temperature be recorded for trending analysis.

Page 1 of 6

Imaging Tests

The following tests should run by the MRI technologist at the beginning of each day. These tests should be run under a single exam so the results may be backed-up and viewed at a later date for reference. Sample test data sheets are provided.

- *180mm RF Coil SNR:* This test verifies the proper operation of the system as a whole in addition to verifying the proper operation of the 180mm RF coil.
    1. Run the procedure outlined in the 'Running the Daily QA Test' section of the Operator's Guide.
    2. In the resulting image (viewed from the 2D Viewer or Scan Display), a summary line will be displayed (refer to Figure 1). Record the following values:
        - » Test results (pass/fail)
        - » Receiver Gain (RXG)
        - » Transmitter Gain (TXG)
        - » Signal Mean (IS)
        - » Signal-to-Noise Ratio (SNR)
        - » Artifact-to-Noise Ratio (ASR)
- *123mm RF Coil SNR:* This test verifies proper operation of the 123mm RF coil. ***It should be run only on days when the 123mm RF coil will be used.***
    1. Run the procedure outlined in the 'Running the Daily QA Test' section of the Operator's Guide except use the 123mm RF coil and change the following scan parameters in the Daily QA sequence: Thickness=3.5 (keep number of slices = 1), Freq=512, Bandwidth=50. Record the values of Receive Gain (RG) and Transmit Gain (TG) set by Automatic Prescan (use the manual prescan window).
    2. When the acquisition is complete (it will report that the test failed due to the wrong coil being used), bring up the image in Scan Display.
    3. Record/calculate the following values:
        - » Receiver Gain
        - » Transmitter Gain
        - » Mean of center ROI (A)
        - » Average of Stdv of right and left ROIs (B)
        - » Average of Stdv of top and bottom ROIs (C)
        - » Signal-to-Noise Ratio (A/B)
        - » Artifact-to-Noise Ratio (C-B)/A

    As an example, from Figure 1, A=577.4, B=(4.4+4.2)/2=4.3, C=(4.5+4.4)/2=4.45, SNR=577.4/4.3=134.3, ASR=(4.45-4.3)/577.4=0.03%.

Page 2 of 6

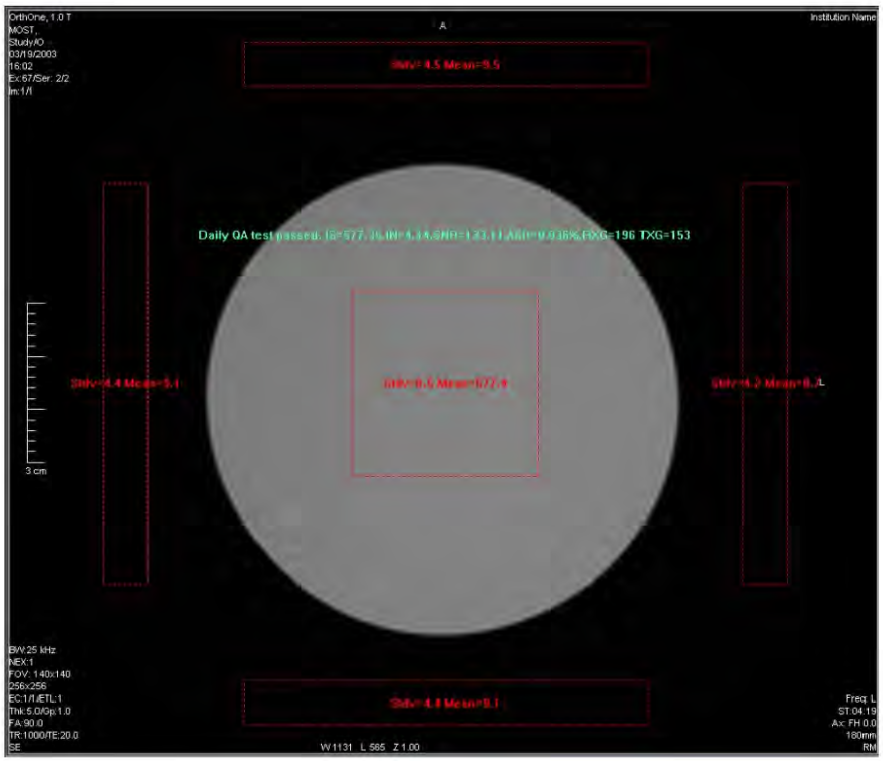


Figure 1: Example of SNR image in Scan Display using the 180mm RF coil

- *3-point Dixon Fat Separation:* This test verifies the proper operation of the system (shim, RF, etc.) as it relates to the Dixon sequence.
    1. With the 180mm RF coil in the magnet bore, place the Oil/Water phantom into the DQA foam holder and place the phantom in the RF coil.
    2. Using a sagittal single slice spin echo sequence with Freq Dir set to H/F and FOV=160, set the center frequency using the Center Frequency Fine mode of the Manual Prescan page.
    3. Run Receive Gain mode and move the phantom along the direction of the bore until the object projection is centered in the field of view (refer to Figure 2).

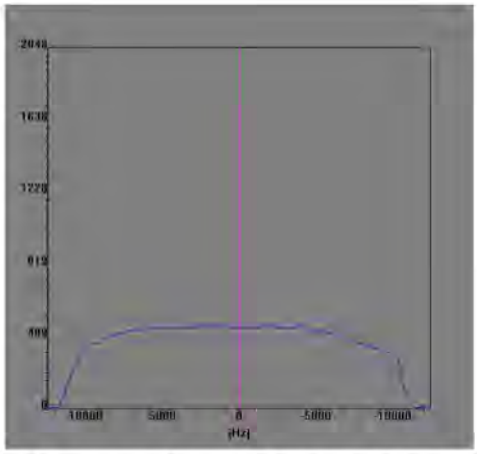


Figure 2: Example of the projection of a sagittal slice when the Oil/Water phantom is centered

4. Run the Gradient Shim function.
5. Exit the Manual Prescan window, select and run the sagittal Dixon sequence after reducing the number of slices to 20.
6. In slice number 11, draw a 10cm long ROI using the ROI tool in the water part of the phantom (refer to Figure 3).
7. Record the Mean (Av) of the ROI.
8. Calculate and record the intensity uniformity (1 – [Mx – Mn] / [Mx + Mn]).
9. Draw an ROI using the ROI tool in the oil part of the phantom (refer to Figure 3).
10. Record the Mean (Av) of this ROI.
11. Calculate and record the ratio of the mean of the oil signal divided by the mean of the water signal.

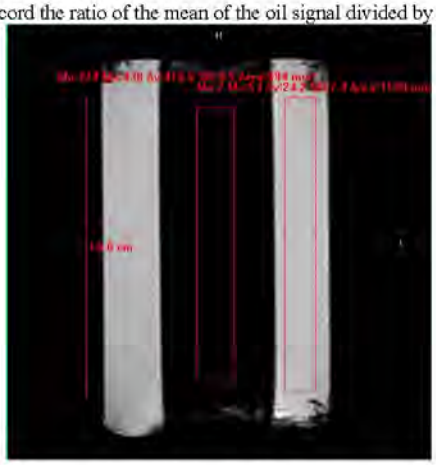


Figure 3: Example of ROIs for the 3-point Dixon sequence test

Page 4 of 6

- *FSE with Fat Suppression:* This test gives an indication of the imaging volume in which frequency selective fat suppression will work properly.
    1. If not already placed properly, center the Oil/Water phantom in the 180mm RF coil as described above.
    2. Run the sagittal fat-suppressed FSE sequence except reduce the number of slices to 11, reduce the TR to 2000 msec, and decrease NEX to 1.
    3. Set the W/L Width value to 10 and the Level value to half of the Mean of the water signal.
    4. In slice number 6, measure and record the distance of proper fat suppression along the center of the phantom (refer to Figure 4).

Figure 4: *Example measurement for the FSE Fat Suppression test*

Sample Daily Test Data Sheet

Site:_____ Date:_____

180mm RF Coil Test

Variable	Min	Measured	Max
Test results (pass/fail)	-		-
Signal Mean (IS)	-		-
Signal-to-Noise Ratio (SNR)	110		140
Artifact-to-Noise Ratio (ASR)	0		1%
Receiver Gain (RXG)	-		-
Transmitter Gain (TXG)	120		160

123mm RF Coil Test

Variable	Min	Measured	Max
Mean of center ROI (A)	-		-
Average on Stdv of right and left ROIs (B)	-		-
Average on Stdv of top and bottom ROIs (C)	-		-
Signal-to-Noise Ratio (A/B)	114		136
Artifact-to-Noise Ratio (C-B)/A	0		1%
Receiver Gain	-		-
Transmitter Gain	40		60

3-point Dixon Test

Variable	Min	Measured	Max
Water Signal Mean	-		-
Uniformity	TBD		-
Oil Signal Mean	-		-
Oil/Water Ratio	-		TBD

FSE Fat Suppression Test

Variable	Min	Measured	Max
Fat Suppression Distance	TBD		-

Page 6 of 6

Appendix 3 1.0 T Knee MRI Technologist Certification Form

This form is to be used to request OrthOne MRI technologist certification. Each technologist will receive a technologist ID for the MOST study. Be certain that each OrthOne knee MRI is obtained according to the protocol. OrthOne knee MRI's should be sent to the Coordinating Center in the usual manner. The images will be reviewed for image quality and protocol adherence by:

Jing Li
UCSF Coordinating Center
Department of Epidemiology & Biostatistics
University of California, San Francisco
85 Berry Street, Suite 5700
San Francisco, CA 94107
Phone: (415) 514-8173 ♦ Fax: (415) 514-8150 ♦ E-mail: jli@psg.ucsf.edu

After a new technologist has completed 10 scans, please complete the following information, & fax the completed form to Jing Li: Fax (415) 514-8150:

1. MOST Field Center: ☐ University of Alabama ☐ University of Iowa
2. Clinic Coordinator: _____
3. Certification of an OrthOne knee MRI technologist is requested for:

Name: _____MOST Staff ID#_____

4. Date(s) MRIs were sent: _____
5. The 10 sets of OrthOne knee MRIs submitted to the Coordinating Center for certification are:

	Participant ID	**Knee MRI Date**
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

6. Clinic Coordinator signature:_____ Date _____

This section to be completed by the Reading Center:

1. Date Request Received: _____
2. Action Recommended: Pass without comment: _____
   Pass with comment: _____
   Fail: resubmit _____
3. Comments:_____
4. Signature of certifier: _____ Date_____
5. This completed form has been given to Susan Averbach: (415) 514-8150 Date: _____

Appendix 4 MRI-Safe Surgeries

MRI Safety: Surgeries on this list do <u>not</u> require a 2-month wait period:

- adhesion destruction or manipulation (nonsurgical)
- biopsy without surgical incision
- cyst removal with needle
- dental bridgework
- dental fillings
- destruction of kidney, bladder, or urethral stones by forced ultrasound energy
- dilation and curettage (D&C) not for terminating pregnancy and not following delivery
- injections:
  injection of anesthetic into peripheral nerve
  injection of anesthetic into spine
  injection of non-anesthetic into spine
- joint or ligament injection
- insertion of catheter for intravenous fluids into vein (not indwelling catheter)
- non-metallic foreign body removal (such as glass)
- periodontal surgery
- radial keratotomy
- rubber-banding of hemorrhoids
- skin biopsy / skin cancer removal
- spinal tap without implant
- suturing of a superficial cut
- wart removal