UAL Phantom Procedures (Sites without ACR Accredidation)

The image quality of the study scans will affect the quality of the image analysis results and scoring results. The imaging procedures depend on the quality of the acquired images. This quality depends on the quality of the scanner and the imaging equipment, adherence to the specified imaging protocol, and the performance of the technologist. The quality of the scanner is first checked and then subsequently monitored by imaging the Uniformity and Linearity (UAL) phantom with the MRI scanner used for this study.

Filling the Phantom with Distilled Water

Before imaging, unscrew the three openings so that air can escape through the opposite hole. Fill the UAL phantom slowly with approximately 12 liters of **distilled water** using the water bottle that was provided. Air bubbles should not be present. After the main section of the phantom has been filled, fill the raised reservoir as indicated below with the red arrow.
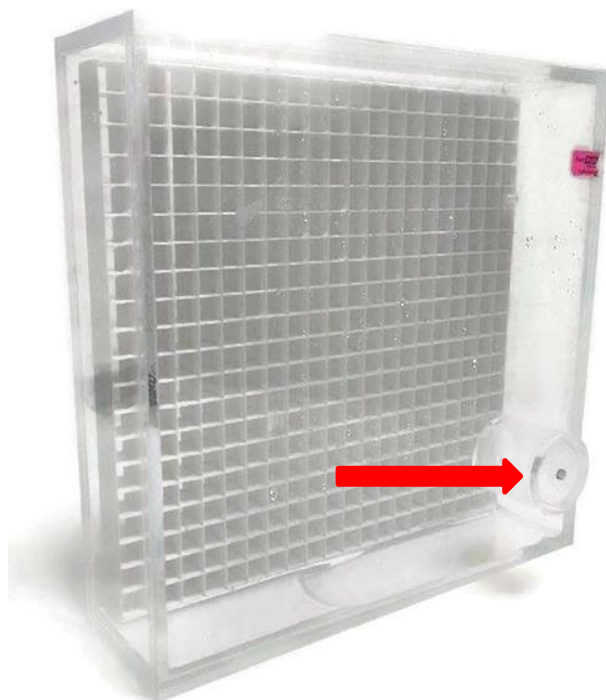

Figure 2 UAL Phantom

UAL Phantom & Scan Entry

At the scanner, both the Patient ID and Patient Name should be the site number with a dash and then "UAL" (example: 101-UAL). In addition, the Study Description would be the site number and the Date of Birth would be the current year.

MR Imaging the UAL Phantom

The phantom is imaged in both the coronal plane and in the axial plane. For coronal images, position the phantom flat on the MRI table; please do not remove the table pad. Below, the coronal view of the UAL Phantom is pictured.
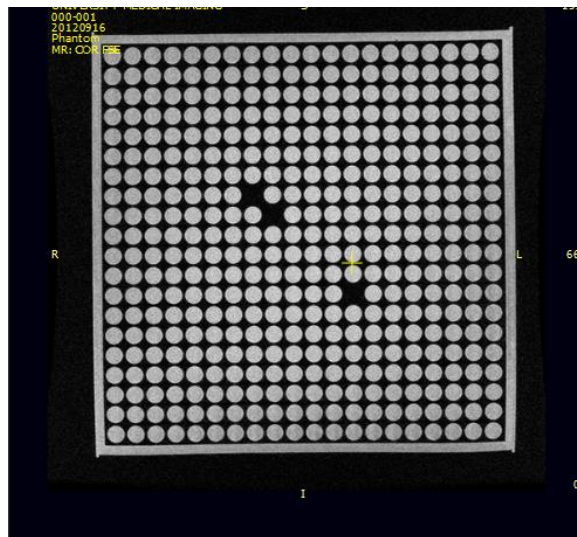

Figure 3 Coronal View

For axial imaging, position the phantom on the table so that it stands on its side across the width of the table. Secure it using Velcro straps. Below is an image of what the axial view of the UAL Phantom would look like:
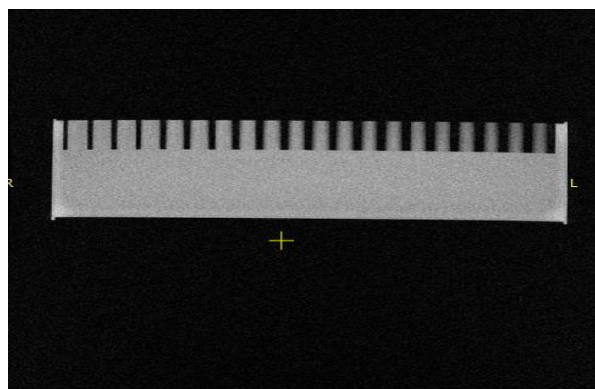

Figure 4 Axial View

UAL Phantom Imaging Protocol

Sequence	2D Fast Spin echo
Repetition Time (TR)	4000
Echo Time (TE)	60
Echo Train Length (ETL)	8

Slice thickness	3 mm
Space between slices:	3 mm
Matrix	512 x 384
Field of View (FOV)	36 cm

UAL Phantom Quality Check

In order to ensure a high quality UAL Phantom scan, check that the following things have taken place:
- The landmark is at the center of the UAL Phantom
- The scan covers the entire UAL Phantom so that the first and last images do not have any part of the phantom in them
- The whole phantom needs to be in the image field without any corners being cut
- Make sure that the naming convention for this scan has a 3-digit site number, a dash, and then "UAL" (example: 101-UAL)

Saving and Transferring Phantom Images

Save the image series into the site's data archival system as you would any routine clinical study using the naming convention described above. Then transfer the image data to Qmetrics as described in the section named "Image Data Transfer to Qmetrics."

ACR Procedures (for ACR accredited/US Sites)

Many US sites participate in the American College of Radiology program[1] which includes a component that evaluates image quality standards for MRI. In order to maintain membership within this program, sites must submit a qualification scan of an ACR phantom every 6 months which is then evaluated by the American College of Radiology Association for compliance. In addition to sending the qualification scan to the ACR, the site would also send this scan to Qmetrics. It is recommended that the site send their qualifying ACR scan to Qmetrics at the same time that they send the scan to the ACRA.

Any US sites that do not participate in the ACR program should refer to the section "For European Sites or Those Without ACR Accreditation" on page 9 above.

ACR Naming Convention

The naming convention for this particular scan should include the 3-digit site number, a dash, and then "ACR." This will help Qmetrics distinguish the type of image data that is received.

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[1] American College of Radiology and American College of Radiology Association, http://www.acraccreditation.org/Modalities/MRI

Saving and Transferring Phantom Images

Save the image series into the site's data archival system as you would any routine clinical study using the naming convention described above. Then transfer the image data to Qmetrics as described in the section named "Image Data Transfer to Qmetrics."

Volunteer Scans

The volunteer scan helps Qmetrics ensure that the site understands and is able to implement the protocol successfully, and also allows an opportunity to improve that protocol, if needed.

After the UAL Phantom scan has been submitted and approved, the site will scan a volunteer using the site-specific protocol that has been established by Qmetrics. The volunteer can be anyone, including a staff member. Once approved by Qmetrics, the site is ready to scan the first patient.

Study MRI Scans

Scheduling Study Subjects for Imaging

Your Investigator's Study Coordinator will schedule study subjects for imaging using your routine patient scheduling procedure. The study subject must be pre-screened for imaging contra-indications according to your sites pre-screening guidelines.

During the scheduling the study coordinator will identify:
- Study name
- Subject's study ID number
- Index knee (the knee to be imaged)
- Visit (Screening, 1 mo, 12mo , 24mo, or 36mo)

The Subject's ID number will be a 3-digit number, a dash, and another 3-digit number. The first three digits will correspond to the investigator's country and site number while the last three digits correspond to the subject number (Example: 101-001). The sponsor will be made aware of any deviation from the protocol and this will result in a Memo to File.

When scanning a volunteer, the naming convention would be the 3-digit site number, a dash, and then "Vol" so that it is easily discernable within the data upload portal (Example: 101-Vol). The naming convention doesn't change, despite the time point and the number of rescans.

Prescreening the Study Subject for MRI

All study subjects must be pre-screened for MR imaging contra-indications according to the site-specific clinical screening procedure. All subjects with contra-indications for MR imaging will be excluded from the study.

ALL acquired STUDY MRIs must use the same imaging protocol and T2 phantom belt.

Subject Preparation Before Imaging

This study does not require specific preparation. Follow your imaging center's guidelines regarding subject's clothing, time of arrival, etc.

Subject Imaging Procedures

1. **Subject Preparation**
   - Identify the subject; check wrist name tag and other identifiers used by your imaging center, then verify which knee is the index knee.
   - Screen for MR imaging contra-indications according to your site's guidelines and screening forms.

   If there are no contra-indications, continue to the next step.

2. **Subject Positioning**
   Position the knee coil on the gantry to accommodate feet-first position of the subject and the side of the index knee. Strap the T2 phantom belt around the knee so that the T2 phantoms are laterally just distal to the patella. Secure the strap using the Velcro.
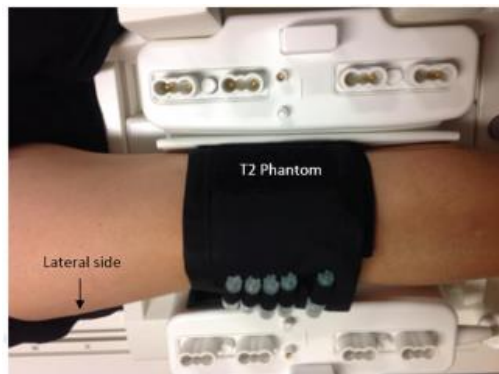

Figure 5 T2 Phantom belt placement

   Use a knee bag or folded towel under the knee for subject comfort. Position the footrest at the end of the table and strap the subject's foot to it for stability. Make sure the Subject's knee is at the center mark of the coil at the caudal end of the patella.

Figure 6 Foot rest placement

3. **Landmark**

   Should be in the center of the coil.

4. **Subject Identification**

   Enter subject's study ID into the Patient ID and Patient Name fields, the index knee in the Study Description field, and enter a date of 1/1/2016 into the Date of Birth field. Do not fill in subject's height, weight, address or any other personal health information corresponding to the subject.

   Note: any time that the Subject's study ID isn't correctly assigned to image data will result in a protocol deviation and a Memo to File.

5. **MR scanning**

   Select the Anika imaging protocol from your scanner's imaging protocol library. Scan the subjects according to this MR imaging protocol. Please follow the order of imaging sequences as indicated in the protocol; this protocol is also in Appendix A.

6. **Documentation**

   All image series acquired during this session need to be recorded in your patient log book.

7. **Image Quality Check**

   Check the quality of acquired images according the following guidelines. Please do not let the subject off the table before verifying good image quality.
   - The FOV of all images must cover the *bony components* of the knee
   - No wrap in the area of imaged bones or ligaments
   - T2 phantoms must be visible
   - No motion artifact
   - Homogenous fat suppression
   - No zipping or overlapping slices
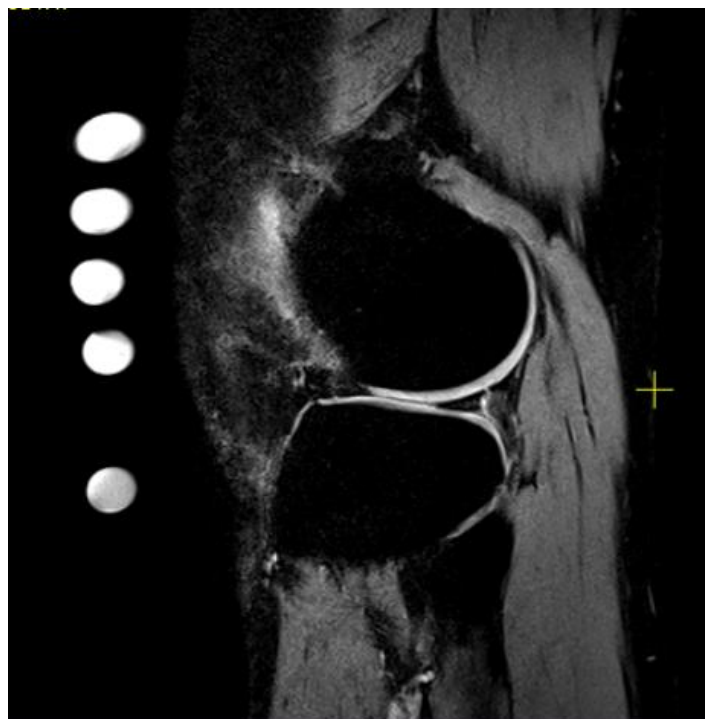   - See Figure 7 for acceptable images versus unacceptable images in Figures 8 & 9

Figure 7 Acceptable: high quality 3D sequence showing good fat suppression, no patient motion, and all T2 phantoms in the phantom belt

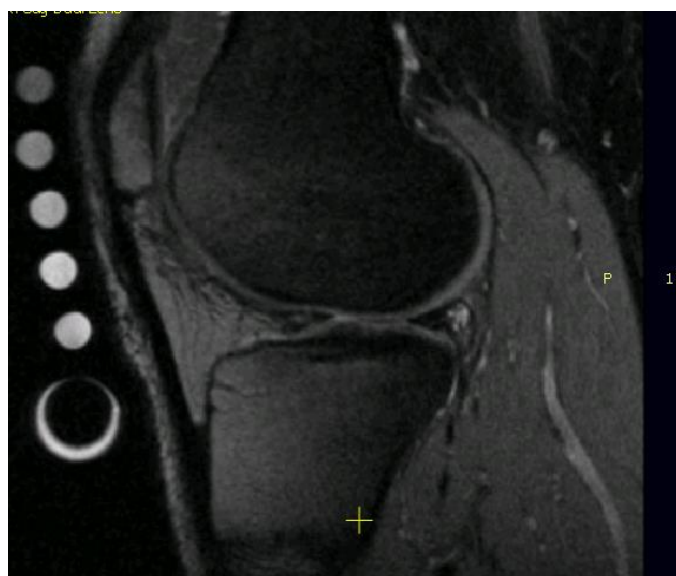*Figure 8 Unacceptable: first echo of dual echo series shows considerable subject motion*

Figure 9 Unacceptable: shows no fat suppression, leading to water suppression in the anterior knee

8. Rescanning

If you find image quality of one of the image series unacceptable, rescan that series.

9. **Saving image data**

Save the image data on your site's image archival system as you routinely do.

10. **Create copy of image data on CD**

Save all image series onto the CD (the imaging series only). Please do not add any viewer or compress the files.