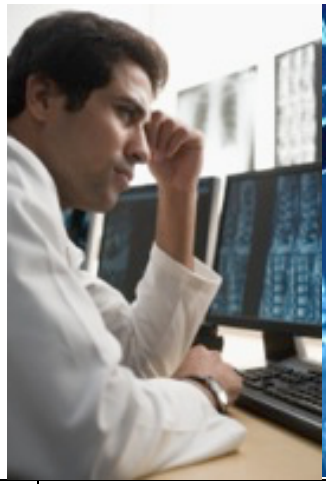
Imaging Procedure Manual

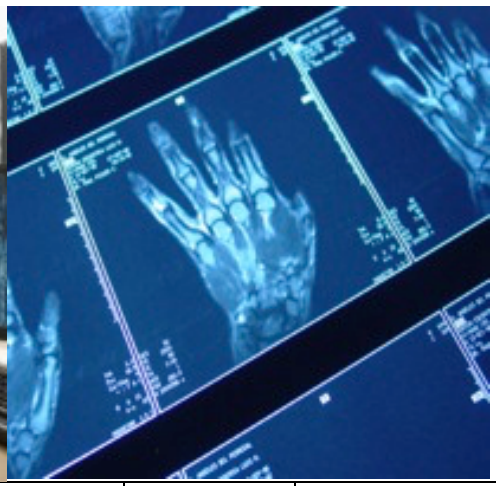
Sonoma Biotherapeutics

A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis

Protocol: *SBT777101-01*

Acquiring MR Images of the Hand and Wrist





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This imaging manual has been reviewed and approved for use by:

Name / Title	***Signature***	***Date***
Peter Countryman Chief Operating Officer Spire Sciences, Inc.	Signed by: Peter Countryman 087F83DD9942411...	2/19/2025
Ari Bitton Director, Clinical Operations Sonoma Biotherapeutics	DocuSigned by: Ari Bitton C66A36E409A840D...	2/19/2025

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1. Study Objectives and Implications for Imaging

Sonoma Biotherapeutics (Sonoma) protocol SBT777101-01 is a multi-center, Phase 1, open-label, dose ranging study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of intravenous SBT777101 in subjects with active rheumatoid arthritis (RA) and an inadequate response to prior biologic or targeted synthetic disease modifying anti-rheumatic drug (b/tsDMARD) therapies with different mechanisms of action.

Candidate subjects with RA will be recruited and enrolled from approximately 10 sites/ Prior to receiving the study drug, patients will undergo magnetic resonance imaging (MRI) of a target hand and wrist in order to quantify osteitis, erosions, joint-space narrowing, tenosynovitis, and intra-articular synovitis. The hand and wrist imaged will be determined by the investigator based on which is clinically most severe at screening. In the absence or a clear clinical exam, the hand and wrist with more historical disease will be imaged, or, the dominant hand. Subjects will undergo follow-up MRI of the same hand/wrist at ~4 weeks, ~12 weeks and 24-48 weeks.

Images will be acquired before and after intravenous administration of gadolinium-based contrast to maximize sensitivity and specificity for inflammation. In the event that gadolinium is contraindicated, non-contrast MRI may be considered based on discussion with the Sponsor and *with prior approval by Spire*. Two expert radiologists at Spire Sciences (Spire) will score the images arranged side-by-side and in random order (blinded to visit dates) using the RA MRI Scoring (RAMRIS) and Cartilage Loss Scoring (CARLOS) methods, developed by Dr. Peterfy, one of the reading radiologists in this study. High-quality images will be essential for accurate assessments.

Note that your site's radiologist does not need to review the images prior to sending them to Spire for central reading. The imaging is being done for clinical research not patient management, and every subject participating in the study will have given informed consent to undergo the imaging exclusively for the research objectives of the study and knows that the imaging is not part of their standard medical care.

Imaging for this study, as for other clinical trials, requires the images to support research questions about groups of subjects rather than the clinical management of individual patients. Additionally, images from the multiple different imaging facilities, study subjects and serial visits must be able to be pooled with minimal technical differences among the images and to be able to support the needs of the central radiologists who will read the images and be responsible for their assessment.

The imaging protocols in this manual have been designed to meet these needs and may be different from those used on your daily clinical practice. However, the pulse sequences used are consistent with standards of care and are available on most MRI scanners used

clinically. Every effort has been made to minimize disruption to your local routines and to keep patient burden to a minimum.

In addition to this manual covering MR image acquisition technique, the person at your site designated to upload the images (study coordinators and/or imaging technologists) will receive a separate manual containing image upload instructions. Please contact Spire (as specified below) if you have any questions regarding the image uploading process.

2. Spire's Role and Contact Details

Submitting images or other logistics:

Alexander Peterfy, Clinical Project Manager: alex.peterfy@spiresciences.com
Phone : +1.415.225.2186 (9:00 am – 5:00 pm Eastern)

or

Peter Countryman, PhD, Scientific Director: peter.countryman@spiresciences.com
Phone: +1.510.915.0915 (12:00 pm – 8:00 pm Eastern)

Image acquisition or repeat requests:

Nicole Williamson, RT, MR Image Quality Specialist:
qc-ati-450-ra-201@spiresciences.com
Phone: +1.202.41-SPIRE (+1.202.417.7473)

3. Site Qualification Steps

Qualifying your site to participate in this study will consist of confirming equipment and technologist capabilities, followed by two technologists (primary and backup) from each participating imaging facility reviewing this manual and a recorded presentation outlining the imaging procedure, followed by successful completion of an on-line quiz to verify that the technologists have reviewed and understood the materials. The final step in qualification will be Spire Science's acceptance of a test scan from your site using the study protocol. Test images should be acquired and submitted well in advance of imaging the first subject at your site, so as to allow sufficient time to make any necessary corrections to your site's imaging protocol.

1. Site Questionnaire

Information about your facility's imaging equipment along with contact and shipping information for those who will be responsible for uploading images (study coordinators or

technologists) will be requested from the study coordinators, who may request your assistance to ensure Spire has the correct information. (See Appendix 1)

2. Study Materials

Once Spire has completed questionnaires from your imaging facility, you will receive by email electronic copies of the MRI procedure manual, the image upload procedure manual and links to the training presentation and online quiz. You will also receive a hand positioning aid for MRI, called the M-frame.

3. Training

All technologists who will acquire images for this study at your facility must undergo training, including reviewing the manual and the 30-min training presentation and completing an on-line quiz, prior to imaging any study subjects. Two technologists should be trained at each facility to ensure a backup is available if needed. If new technologists are added to the study, they too must complete training prior to scanning any study subjects. Once the technologists have completed the training and passed the quiz, a Training Completion Form will be sent to your site's Principal Investigator (PI), study coordinator, imaging technologists and Sonoma.

4. Test Scan

After your imaging facility's technologists have successfully completed the training, your facility will be asked to submit a test scan using a volunteer without intravenous contrast. If your facility's IRB does not permit volunteer scanning, a phantom, such as a water bottle, can be used instead. The test scan is to ensure that the correct imaging parameters have been installed on the MRI system to be used and that your facility can successfully transfer images to Spire through the AG Mednet upload network (see below). Spire will check the images and scan parameters, and will either request a repeat test scan, or notify your site that the test scan has been approved. Only one successful test scan per imaging facility is required.

5. Electronic Image Transfer to Spire

Once images have been acquired, please transfer them to Spire immediately – on the same day if possible. Image transfers are done through the AG Mednet image upload network. AG Mednet's Desktop Agent is easy to use, and should not require any help from your IT department to install. All that's needed is a standard networked computer or laptop. Images can be burned onto CDs and uploaded by logging into the web portal and completing a prepopulated transmittal form. The system is fully compliant with all international regulations on patient privacy, and it takes care of image anonymization on its end, so there's no need for extra software or time spent on that by anyone at your site. Confirmation of successful submission is provided in a pop-up window on the Desktop

Agent as well as by email. A separate manual for the AG Mednet system will be provided, but as noted above, the system is easy to use.

6. Notice of Qualification

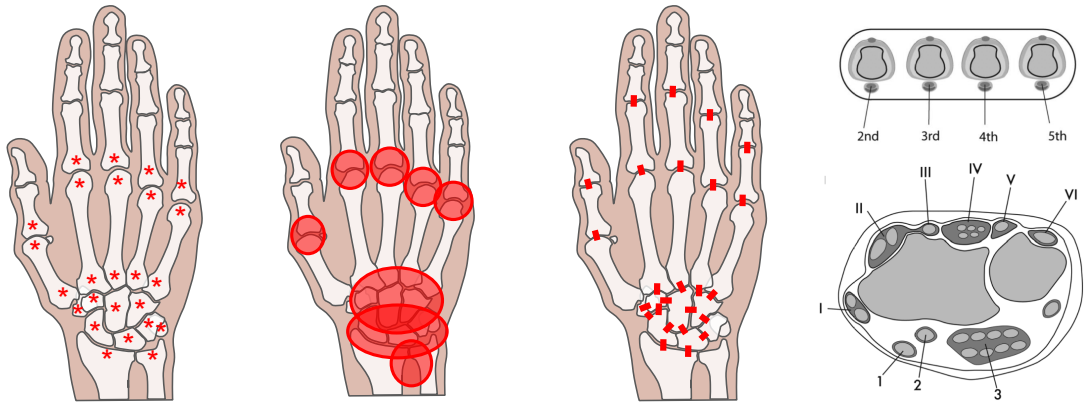
Once the above steps have been completed, Spire will send a notice of qualification to your site's PI, study coordinator and imaging technologists as well as to Sonoma, and your site can begin imaging subjects for the study.

4. MRI Goals and Procedural Overview

Imaging Goals

In contrast to MRI in clinical practice, in which the technique is tailored to the individual patient and the preferences of the local radiologist who will read the images, MR images for clinical trials are acquired from multiple subjects at multiple medical centers and must be able to be pooled without significant technical differences between the different sites, subjects or serial visits. Additionally, the images must meet the unique needs of the scoring and measurement methods that will be used, which differ from those used in clinical practice, as well as the needs of the central radiologists who will perform the assessments and be ultimately accountable for them. This places a greater emphasis on consistency in subject positioning and image quality in order to ensure accurate interpretation and maximum sensitivity to change.

Scans of the target hand and wrist (determined by the investigator to be the most severely affected, have more historical disease, or are the dominant hand) acquired at screening, ~Week 4, ~Week 12, and Week 24-48 will be viewed side-by-side to identify minute changes in bone erosion, cartilage loss, osteitis (inflammation within the bone), synovitis (inflammation of the synovial lining of the joint) and tenosynovitis (inflammation of the synovial lining of the tendon sheath). Twenty-five different bones in each hand/wrist will be scored for erosion and osteitis, each on a scale of 0-10, eight joints will be scored for synovitis on a scale of 0-3 and 13 tenosynovial compartments will be scored from 0 to 3 using the RAMRIS method (Fig. 1). Also, 25 joints will be scored from 0-4 for cartilage loss using the CARLOS 9-point scale.



A. B. C. D.

Figure 1. RAMRIS and CARLOS Locations. Locations to be scored for bone erosion and osteitis (A) and synovitis (B) using RAMRIS; cartilage loss (C) using CARLOS; and tenosynovitis (D) using RAMRIS.

Key Image-Quality Goals

1. Complete coverage all locations to be scored (in-plane and through-plane)
2. Comparable cross-sectional anatomy on serial visits
3. High signal-to-noise ratio and signal homogeneity
4. Absence of artifacts obscuring any locations to be scored

MR Scanner and Coil Requirements

Only 1.5T and 3.0T whole-body scanners and transmit-receive (Tx/Rx) coils, ideally knee coils, are acceptable for this study. Please contact Spire if you have any questions about this.

The reason for requiring Tx/Rx coils is to minimize RF power absorption (SAR) by obviating the need to use the body coil. The local coil must also allow enough room to accommodate the M-frame and markers for consistent anatomical positioning and correct identification of laterality, and provide 160-180 mm field of view (FOV) with good signal-to-noise ratio.

The same scanner and coil must be used at all time points for a given subject.

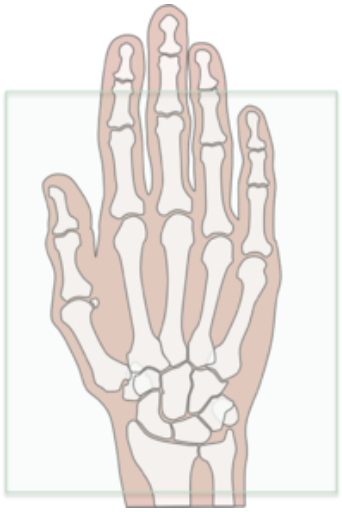


Figure 2: FOV for coronal hand/wrist images, and slice extent for axial images. Critical anatomical coverage includes interphalangeal joint (IP) 1, proximal interphalangeal joints (PIP) 2-5, metacarpophalangeal joints (MCP) 1-5, carpometacarpal joints (CMC) 1-5, all carpal bones and joints, and the radiocarpal and distal radioulnar joints. Thus, the FOV should extend from just before the metaphyseal-diaphyseal junction of the ulna proximally to the midshaft of middle phalanx 3 distally.

The M-Frame

An acrylic positioning aid, called the M-frame, will be needed to image subjects reproducibly for this study (Fig. 3.) The M-frame immobilizes the bones and joints of the hand and wrist in optimal position for RAMRIS and CARLOS evaluation. It also serves as a landmark for aligning coronal slices, and provides direct verification that the correct hand/wrist was imaged. The hand/wrist is secured to the M-frame with latex-free self-adhesive bandages. T1 markers, such as vitamin-E capsules (not provided), should be placed in the three wells on the left side of the curved upper surface of the M-frame to allow definitive determination of which hand/wrist (left or right) was imaged.

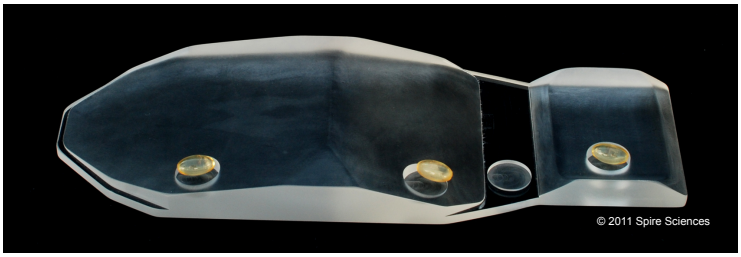


Figure 3. The M-frame positioning device with vitamin-E markers.

Image Quality Control

Once images are received by Spire, they will be checked to ensure that the examination complied with the imaging protocol parameters, that the subject's fingers and hand/wrist were properly positioned with the M-frame, that anatomical coverage was complete, that image slices were correctly aligned and landmarked, and that the images show adequate graphic quality in terms of contrast-to-noise ratio, homogeneity of fat suppression and

absence of any artifacts that may interfere with accurate analysis. Follow-up images will be compared to those of prior visits to ensure that the anatomy was sectioned reproducibly.

Based on these checks, Spire Science's radiology team will designate each examination as either:

- Optimal
- Not Optimal – do not repeat
- Not Optimal – repeat

Spire will send an Image Quality Report to the site within 1 business day of receipt of the examination. If there are suggestions for improving image quality, they will be noted in the comments section of the Report.

If images are rejected due to insufficient quality for reliable analysis, "**Not Optimal – Repeat)**" will be checked on the Image Quality Form, and Spire will contact you by email or phone to notify you to schedule a repeat examination. Should this happen, it is important to bring the subject back for a repeat examination as soon as possible but definitely before initiating treatment for the baseline scan in order to prevent biasing the study results. The disease features analyzed in this study, particularly inflammation, can change quickly, so it is important that images be acquired as close as possible to the originally scheduled visit dates. As soon as the repeat images are acquired, the same procedure should be used to submit the images to Spire, except the box for "Repeat Exam" should be selected on the Transmittal Form.

5. Performing the MRI Examination

Setting up for the Exam and Preparing the Subject

Before the subject arrives, recall the saved scan protocol for this study in order to avoid having to enter the parameters manually. Once the scan protocol is loaded, about 10-15 minutes should be allowed for subject setup.

Please follow your facility's protocol for screening the subject for possible contraindications to MRI. Final approval for subject MR scanning safety is the responsibility of your facility.

Once you've completed subject screening, allowed the subject to void and change into a dressing gown, if necessary, provide appropriate ear protection. When the subject is ready to be scanned, fit the target hand and wrist (the one determined by the investigator to be the most severely affected) with an M-frame, and prepare IV access prior to placing the subject in the magnet. The M-frame must be used on all study subjects and at every visit in order to ensure consistency in slice orientation.

The M-frame has three wells along its left superior margin in which T1 markers, such as vitamin-E capsules, are to be placed. The M-frame must be oriented with the curved surface upwards and the marker wells on the left. The subject's palm should rest comfortably but firmly against the curved surface of the M-frame, with the fingers extended and together (not spread apart) and the thumb pressed up against the side of the hand on the surface of the frame, as shown in Fig. 4. The thumb must not be off the frame.

The fingers, hand and wrist are then firmly but comfortably secured to the M-frame with a self-adhesive bandage, ensuring that the T1 markers remain in place. These markers provide direct verification on the MR images that the correct extremity was imaged and that the M-frame was positioned properly.

Figure 4. Positioning the subject's hand and wrist with the M-frame.

With the M-frame securely in place, the subject should be positioned in the magnet prone, with the arm of the hand/wrist to be imaged extended over the head and the palm facing down in the knee coil as close to the center of the magnet bore as possible. If an offset is used, please note the offset value in the Study Log, and ensure the same offset is used for all time points for that subject. There is a tendency for ulnar deviation of the wrist in this position. Try to minimize this, and keep the hand/wrist as aligned as possible with the forearm, without making the subject uncomfortable. Use cushions and straps as needed to hold the subject's hand and wrist firmly in place and to make the subject as comfortable as possible. Increased subject comfort will decrease the likelihood of motion and lower the chances of needing a repeat examination.

Note, if because of shoulder inflammation or some other reason the subject cannot lay prone with the hand over the head, an alternative approach may be used *with approval by Spire* (Appendix 2).

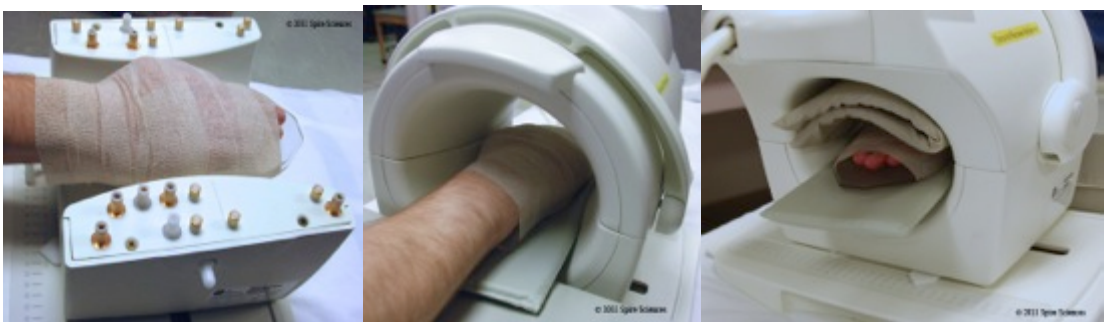


Figure 5. Positioning the hand/wrist/M-frame in a knee coil.

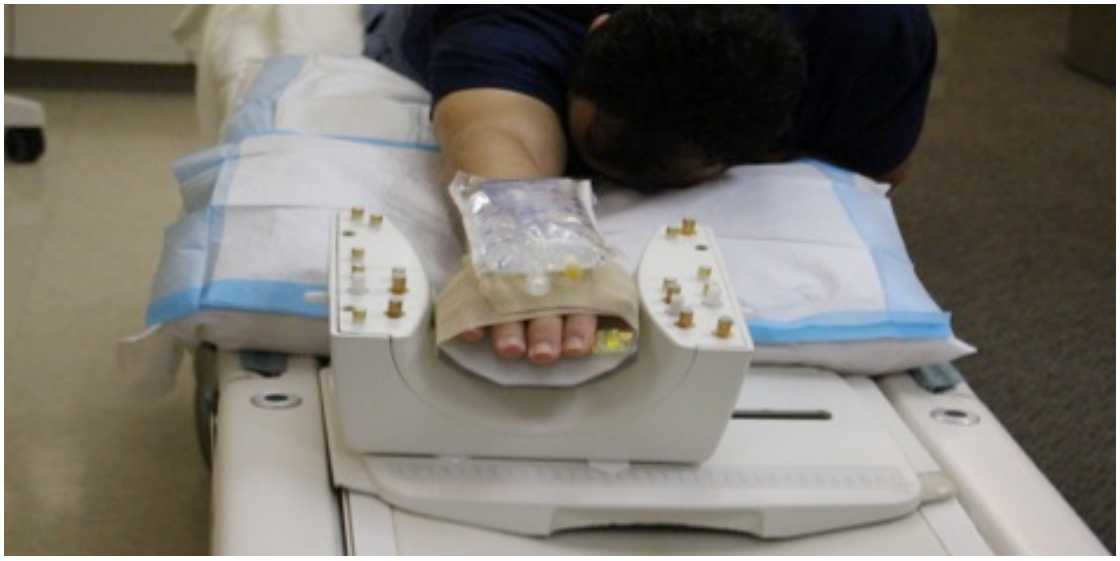


Figure 6. Optimizing field homogeneity. A 250 mL saline bag should be placed over the fingers and hand/wrist to optimize fat saturation or water excitation.

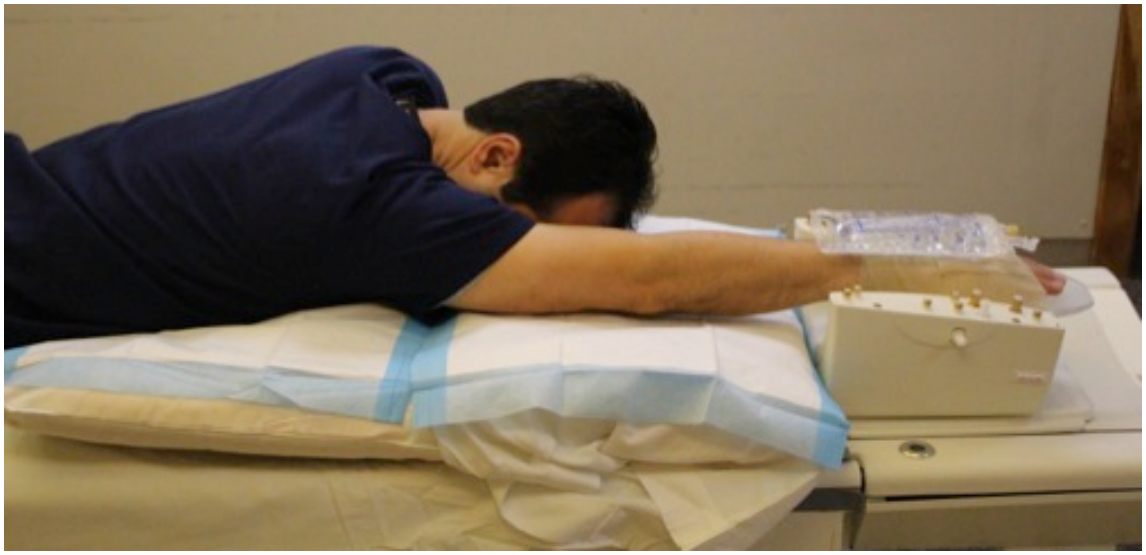


Figure 7. Prone, over-the-head positioning. To ensure subject comfort, the entire upper torso of the subject should be elevated to the height of the coil opening. The shoulder and arm should be well supported so that the subject is not using their own strength to maintain the position.

Coil Selection

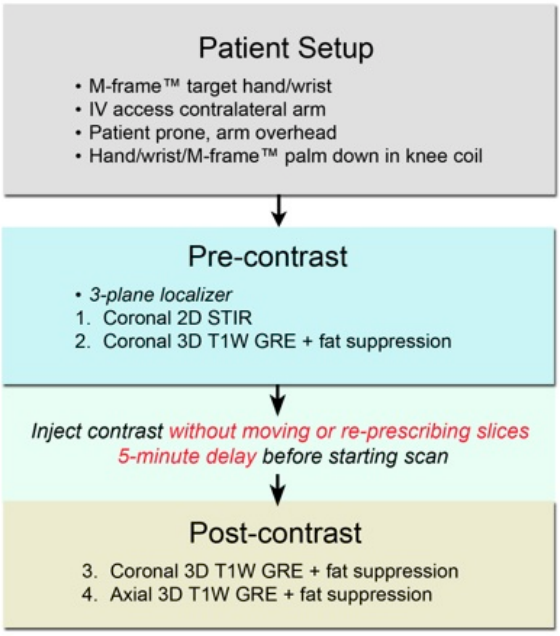
Please use the coil you would normally use for knee imaging to obtain the necessary FOV. Recommended options include Knee Coil, Siemens Tx/Rx CP Extremity Coil, and Medium and Large Flex coils.

Entering Subject Identifiers at the Scan Console

The subject's name and other private health information will be removed from the image files before they are uploaded to Spire via the AG Mednet network. Nevertheless, it can help to avoid confusion at upload time if the subject identifiers are already present in the image file. We therefore recommend entering the following fields at the scan console:

- Subject ID: <Site Number, 3 digits>"-"<Subject Number, 3 digits>
  Example: 012-001 (For test scans, use <Site Number, 3 digits>"-00000".
  Example: 012-000).
- Subject Birth Year: Subject's birth year, with 01 for month and 01 for day in YYYYMMDD format. Note, the month and day are always 01
  Example: 19680101,
- Subject History (or "comment" or "additional information" if Subject History not available): Visit in format of "Test Scan," "Screening," "Week 8," "Week 24," or "Unscheduled."

Examination Sequence: For 180-mm and 160-mm FOV



Allow 45 min for total examination time including subject setup

Spire will work with you to develop and install a protocol optimized for your specific site and MRI system prior to imaging the first patient. The following are examples of such protocols for illustrative purposes.

Example Pulse Parameters: Knee coils, Siemens Tx/Rx CP Extremity Coil

Series	*3 Plane* Localizer	*Coronal* 2D STIR	*Coronal* 3D T1W GRE + fat suppression	*Axial* 3D T1W GRE + fat suppression
Pulse Sequence /Options				
GE		IR, TI 150	SPGR: Fat Sat	SPGR: Fat Sat
Philips			3D WATS	3D WATS
Siemens			Flash or VIBE: WE	Flash or VIBE: WE
Thickness (mm)	5	3	1.5	1.5
Slice Gap (mm)	5	0	0	0
Slices	10	20	40	90
NSA/NEX		2	1	1
Frequency		384	512	256
GE		384	512	256
Philips: Voxel		0.47	0.35	0.62
Siemens		384	512	256
Phase		256	256	192
GE		256	256	192
Philips: Voxel		0.7	0.7	0.83
Siemens: Phase resolution		89%	50%	75%
FOV	260	180 (75%)	180	160
TE (ms)		30-50		
GE			Minimum	Minimum
Philips			3-14	3-14
Siemens			3-14	3-14
TR (ms)		3000-6000	20-40	20-40
Phase Direction		RL	RL	AP
Echo Train		7-11	1	1
Flip Angle		-	20	20
Bandwidth				
GE : Hz		25-31	15-22	15-22
Philips : WFS		Maximum	Maximum	Maximum
Siemens		80	70 (120 acceptable)	70 (120 acceptable)
Est. time	1:00	5:30	5:00	6:30
Comments				
GE	Site Preference	NPW OFF. FC On	NPW OFF, Zip 2 Off	NPW OFF, Zip 2 Off
Philips		NPW OFF	NPW OFF, Overcontiguous slices off	NPW OFF, Overcontiguous slices off
Siemens		Phase Oversampling set to 0	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off

Example Pulse Parameters: Large and Medium Tx/Rx Flex Coils

Series	*3 Plane* Localizer	*Coronal* 2D STIR	*Coronal* 3D T1W GRE + fat suppression	*Axial* 3D T1W GRE + fat suppression
Pulse Sequence /Options				
GE		IR, TI 150	SPGR: Fat Sat	SPGR: Fat Sat
Philips			3D WATS	3D WATS
Siemens			Flash or VIBE: WE	Flash or VIBE: WE
Thickness (mm)	5	3	1.5	1.5
Slice Gap (mm)	5	0	0	0
Slices	10	20	40	90
NSA/NEX		2	1	1
Frequency		256	512	256
GE		256	512	256
Philips: Voxel		0.63	0.31	0.63
Siemens		256	512	256
Phase		192	256	192
GE		192	256	192
Philips: Voxel		0.83	0.63	0.83
Siemens: Phase resolution		75%	50%	75%
FOV	260	160	160	160
TE (ms)		30-50		
GE			Minimum	Minimum
Philips			3-14	3-14
Siemens			3-14	3-14
TR (ms)		3000-6000	20-40	20-40
Phase Direction		RL	RL	AP
Echo Train		7-8	1	1
Flip Angle		-	20	20
Bandwidth				
GE : Hz		25-31	15-18	15-18
Philips : WFS		Maximum	Maximum	Maximum
Siemens		80	70 (120 acceptable)	70 (120 acceptable)
Est. time	1:00	6:30	6:00	7:30
Comments				
GE	Site Preference	NPW OFF. FC On	NPW OFF, Zip 2 Off	NPW OFF, Zip 2 Off
Philips		NPW OFF	NPW OFF, Overcontiguous slices off	NPW OFF, Overcontiguous slices off
Siemens		Phase Oversampling set to 0	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off

Note, only macrocyclic gadolinium-based contrast, such as Dotarem (gadoterate meglumine), Prohance (gadoteridol) or Gadavist (gadobutrol) should be used. Please do not use linear chelates, such as Magnavist (gadopentetate dimeglumine), Omniscan (gadodiamide), Eovist (gadoxetate disodium), MultiHance (gadobenate dimeglumine) or OptiMARK (gadoversetamide).

Slice Prescription

To ensure the comparability of cross-sectional anatomy on serial examinations, a key image-quality goal of this study, scans must be meticulously aligned in both orthogonal planes. This is important because even a few degrees difference in slice angulation between visits can obscure or mimic changes in erosions, osteitis, synovitis or cartilage loss. High resolution, e.g., 3-mm slice thickness, three-plane localizers facilitate reproducible landmarking and alignment.

Alignment of coronal sections should be based on the axial localizer, with the slices oriented parallel to the flattened palmar surface on the M-frame at the level of MCP-1 (Fig. 8). Slices should also be aligned on the sagittal localizer with the dorsal cortex of the shaft of the 3rd metacarpal (MC-3). In-plane coverage should include PIP 2-5, all the bones and joints of the thumb, MCP 2-5, and all carpal bones and joints, including the radius, ulna and entire distal radioulnar joint (Fig. 2). Through-plane coverage should extend from the most dorsal skin to the most palmar skin of the hand and wrist between PIP 3 and the distal radioulnar joint.

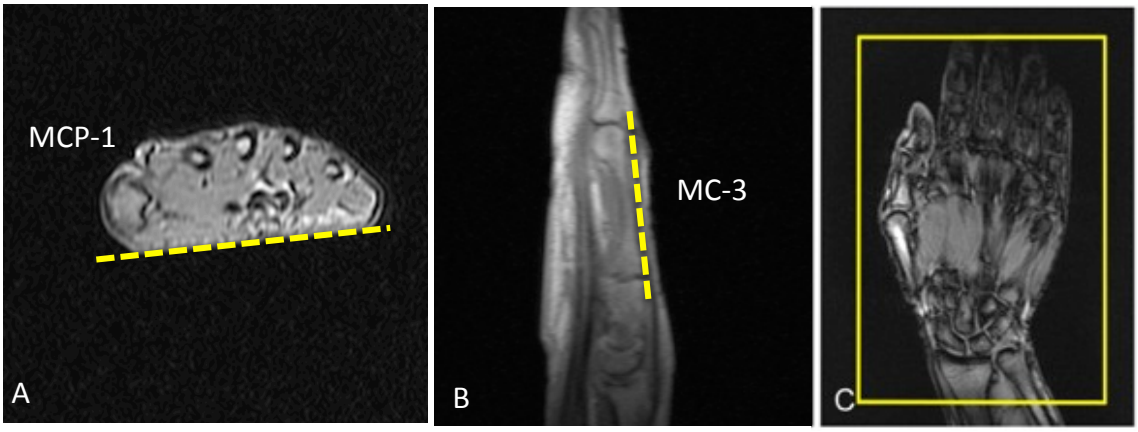


Figure 8: Biplanar alignment of coronal scans. Axial (A) and sagittal (B) localizers showing landmarks for aligning coronal slices. C. approximate FOV for coronal scan.

For the axial scan, the first alignment should be based on the sagittal localizer, with slices again oriented parallel to the dorsal cortex of the shaft of the MC-3, as in Fig. 9. The second alignment should be based on the coronal localizer, with the slices parallel to a line connecting the distal tips of the radial and ulnar styloids. Axial through-plane coverage should include the distal radioulnar (DRU) joint proximally and the MCP joints distally.

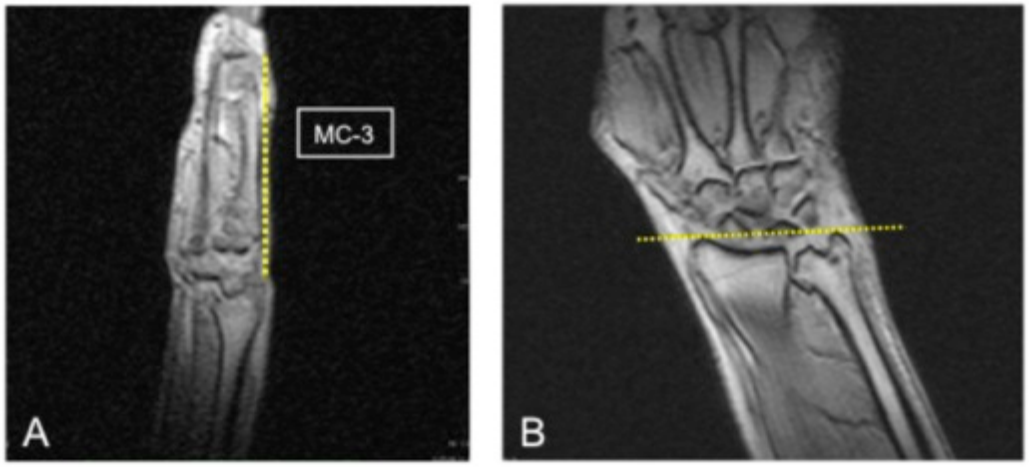


Figure 9. Biplanar alignment of axial scans. Sagittal (A) and coronal (B) localizers showing landmarks for aligning axial slices.

Examples of Acceptable Image Quality

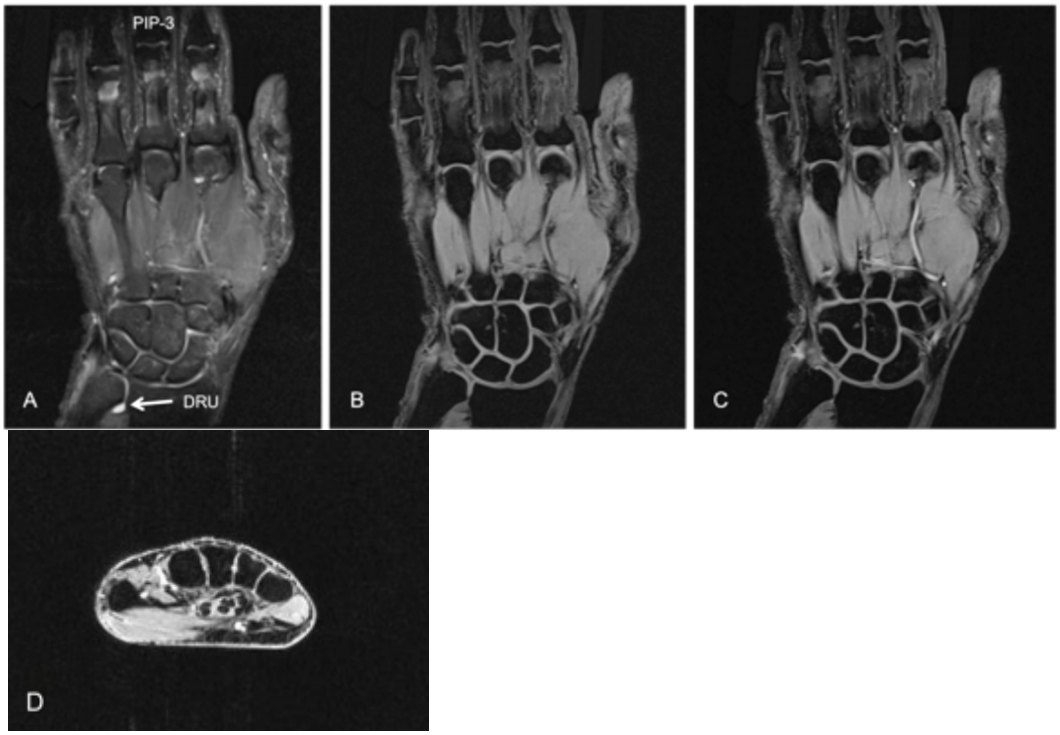


Figure 10. Acceptable image quality. Coronal STIR (A), T1-weighted fat-suppressed 3D GRE pre- and post-contrast (B-C), and post-contrast axial 3D GRE (D). Note complete anatomical coverage (in-plane) from the DRU proximally to PIP-3 distally; homogeneous signal and fat suppression on images B-D, high contrast-to-noise ratio, no artifacts, and sharp delineation of articular cartilage on fat-suppressed 3D GRE (B).

Examples of Unacceptable Image Quality: Common Problems

Poor Coil Positioning

It is important not only that the anatomy of interest be included in the FOV, but also that the coil be properly centered over this region to avoid peripheral signal drop off (Fig. 11).

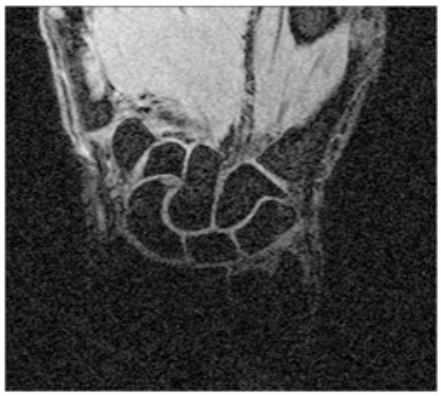


Figure 11. Signal drop off. The coil was positioned too distally resulting in signal drop off proximally over the radius, ulna and distal radio-ulnar joint cavity. As a result, these regions would not be evaluable, and a repeat examination would be necessary.

Motion Artifacts

During the examination set up, the subject must be secured in a comfortable position to avoid motion during acquisition (Fig. 12). This is particularly important in subjects with active inflammation and pain.

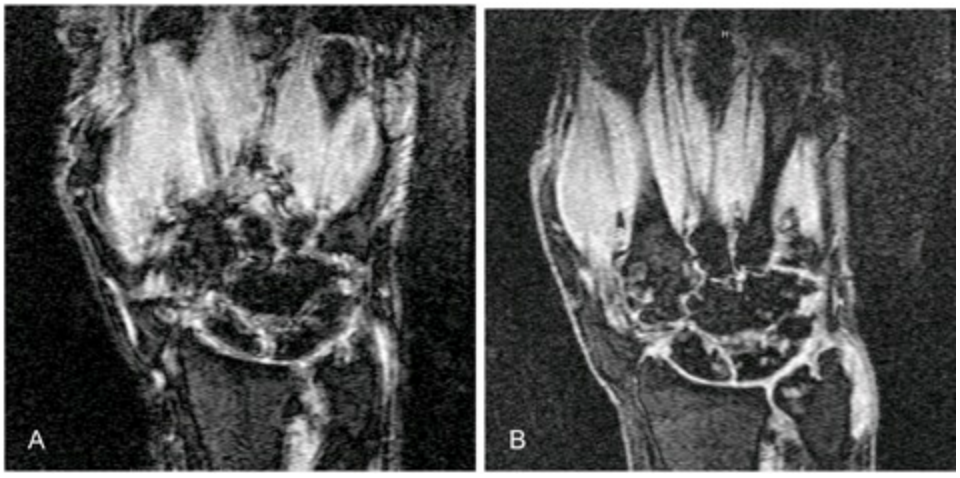


Figure 12. Subject motion. Initial 3D GRE scan (A) shows loss of sharpness due to subject motion. Some erosions can still be discerned, but blurring is too severe to allow accurate monitoring of change. Repeat scan (B) without motion delineates erosions more clearly.

Vascular Pulsation Artifacts

Pulsation artifacts are common on STIR images, and can obscure and confuse findings, particularly osteitis (Fig. 13). Flow compensation and saturation bands can suppress this artifact; although, flow compensation usually adds too much time to 3D GRE to be practical.

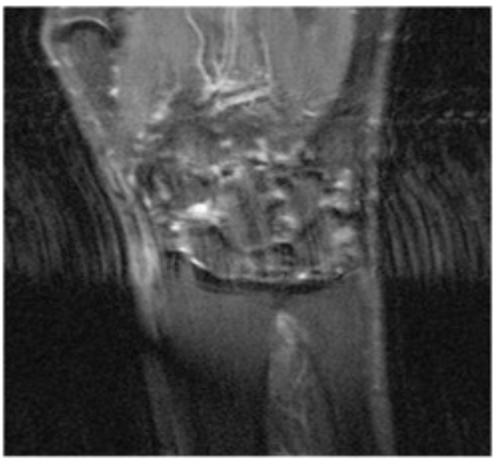


Figure 13. Vascular pulsation artifacts. STIR image shows ghosting artifacts across the wrist due to vascular pulsation. Synovitis can still be assessed, but osteitis is difficult to evaluate in several of the carpal bones.

Inconsistent slice orientation and alignment between visits

Comparable cross-sectional anatomy on serial visits is a key requirement for accurate and sensitive image analysis using RAMRIS and CARLOS. This is because images from different visits are compared side-by-side in order to detect small changes in bone erosion, cartilage loss, osteitis and synovitis in individual subjects. Variable orientation of the slices on serial scans complicates analyses because differences in the obliquity of section through erosions and other disease features can obscure or simulate change (Fig. 14).

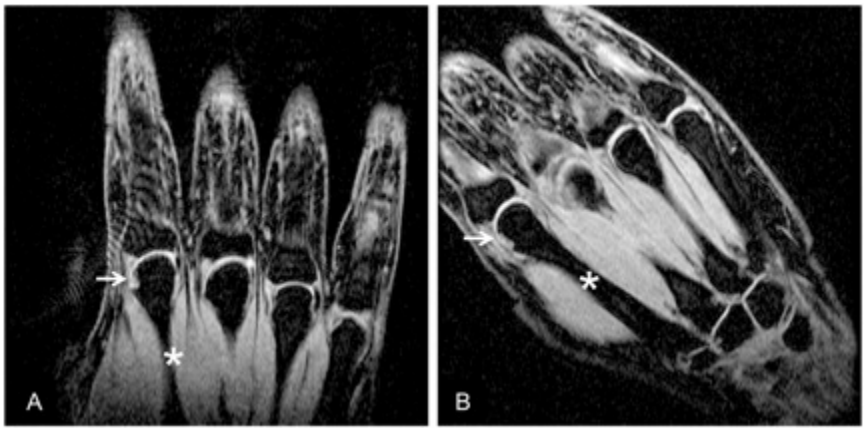


Figure 14. Inconsistency between serial examinations. Besides the obvious in-plane rotation of image B relative to image A, note that more of the shaft of MC-2 (asterisk) is visible on image B despite both of the scans being localized to the same slice showing the erosion in distal MC-2 (arrow). This indicates that the angulation of the coronal slices relative to the sagittal localizer differed slightly between the two scans, and therefore that the plane of section through the MC-2 erosion also differed, making any assessment of change less certain.

Appendix 1

Site and MRI Facility Information Sheet

Site Information:	
*Site number:	
*PI first, last name:	
*PI Institution name:	
*Study Coordinator name:	
*State:	
*Country:	
Who will upload study images—the study coordinator or the MRI technologists?	
*MRI facility or Hospital/Clinic name:	
MRI Facility Information:	
*MRI street address:	
*MRI city:	
*MRI state or province:	
*MRI zip/postal code:	
*MRI country:	
*Primary MRI technologist name:	
*Primary MRI technologist phone:	
*Primary MRI technologist email:	
Back-up MRI Technologist name: (if known)	
Back-up MRI Technologist email: (if known)	
M-Frame Shipment information	
Should the M-frame, or MRI hand positioner, be sent to the site address or the imaging facility address? (Please note, if shipped to site, the site will be responsible for ensuring the M-frame is provided to the imaging facility.)	☐ Site ☐ Imaging Facility

Appendix 2

Alternative MRI Techniques

If because of shoulder involvement or some other reason for the subject not being able to lay prone with the hand over the head, the following alternative approaches may be used *with prior approval by Spire*.

Alternative 1: Hand Parallel to Table

With this alternative technique, the MCPs and wrist are scanned separately, and the coil is repositioned to cover each region respectively. Phase Wrap or Phase Oversampling should be used on coronal sequences.

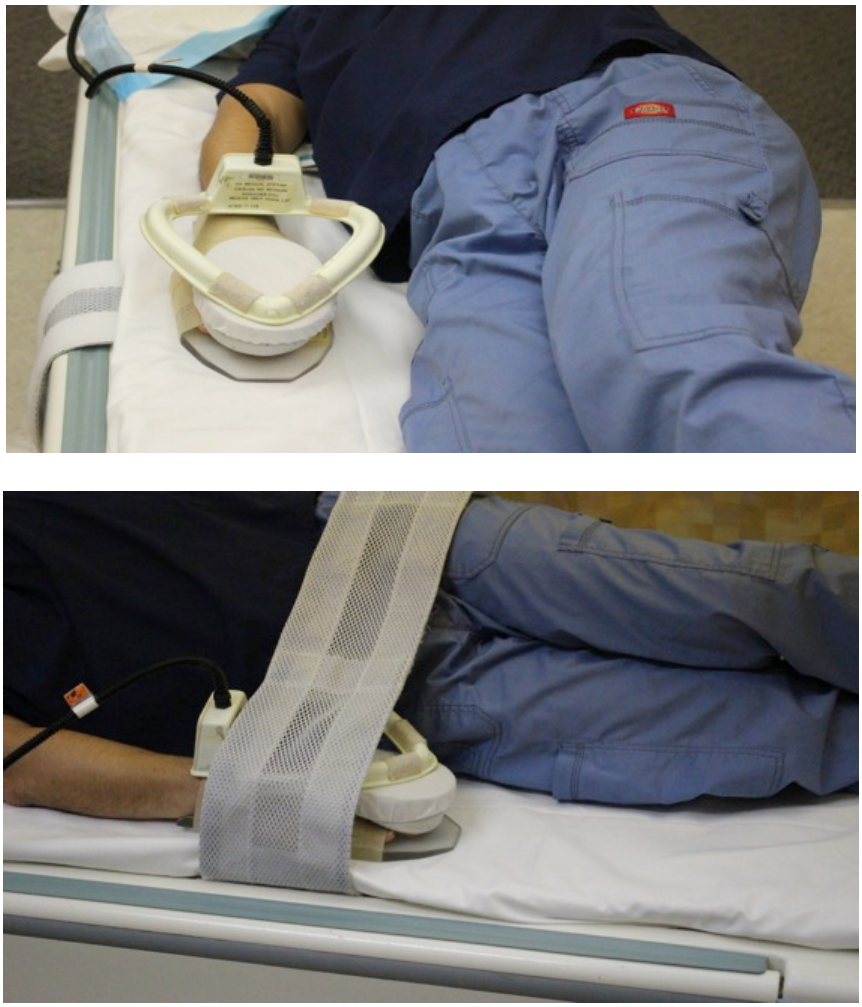


Figure A1. Small flex and surface coil technique with hand parallel to table. The subject should be positioned slightly on their side to allow the hand and wrist to be as close to the center of the table as possible. Pads and straps should be used to secure the coil and the subject.

Example Pulse Parameters: Small Flex and Surface Coils (Hand Parallel to Table)

Series	*3 Plane* Localizer	*Coronal* 2D STIR	*Coronal* 3D T1W GRE + fat suppression	*Axial* 3D T1W GRE + fat suppression
Pulse Sequence /Options				
GE		IR, TI 150	SPGR: Fat Sat	SPGR: Fat Sat
Philips			3D WATS	3D WATS
Siemens			Flash or VIBE: WE	Flash or VIBE: WE
Thickness (mm)	5	3	1.5	1.5
Slice Gap (mm)	5	0	0	0
Slices	10	20	40	45
NSA/NEX		1	1	1
Frequency		256	512	256
GE		256	512	256
Philips: Voxel		0.47	0.23	0.47
Siemens		256	512	256
Phase		192	192	192
GE		192	192	192
Philips: Voxel		0.63	0.63	0.63
Siemens: Phase resolution		75%	38%	75%
FOV	260	120	120	120
TE (ms)				
GE		30-50	Minimum	Minimum
Philips			3-14	3-14
Siemens			3-14	3-14
TR (ms)		3000-6000	20-40	20-40
Phase Direction		SI	SI	AP
Echo Train		7	1	1
Flip Angle		-	20	20
Bandwidth				
GE : Hz		15.63	15.63	15.63
Philips : WFS		Maximum	Maximum	Maximum
Siemens		80	70 (120 acceptable)	70 (120 acceptable)
Est. time	1:00	4:30	4:00	3:30
Comments				
GE	Site Preference	NPW ON. FC On	NPW ON, Zip 2 Off	NPW OFF, Zip 2 Off
Philips		NPW ON	NPW ON, Overcontiguous slices off	NPW OFF, Overcontiguous slices off
Siemens		Phase Oversampling On	Phase Oversampling On. Slice resolution 100%, Interpolation off	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off

Alternative 2: Hand Perpendicular to Table

As with Alternative 1, the MCPs and wrist are scanned separately, and the coil repositioned to cover each region respectively. Phase Wrap or Phase Oversampling should not be used. To achieve an anatomically coronal scan, the sagittal plane must be selected.

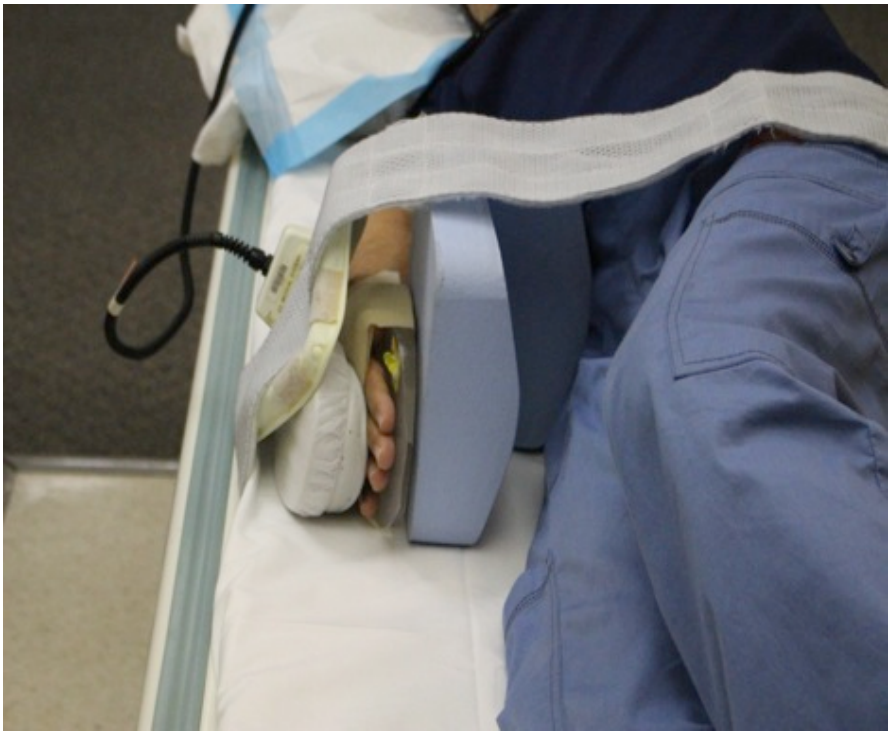


Figure 9. Small flex and surface coil technique with hand perpendicular to table. The subject should be positioned slightly on their side to allow the hand and wrist to be as close to the center of the table as possible. The arm should be placed vertically with the palm facing the subject and the thumb up. A pad should be placed between the subject and the coil to stabilize the positioning. Pads and straps should be used to secure the coil and the subject.

Example Pulse Parameters: Small Flex and Surface Coils (Hand Perpendicular to Table)

Series	*3 Plane* Localizer	*Coronal Anatomy: Select SAGITTAL on scanner* 2D STIR	*Coronal Anatomy: Select SAGITTAL on scanner* 3D T1W GRE + fat suppression	*Axial* 3D T1W GRE + fat suppression
Pulse Sequence /Options				
GE		IR, TI 150	SPGR: Fat Sat	SPGR: Fat Sat
Philips			3D WATS	3D WATS
Siemens			Flash or VIBE: WE	Flash or VIBE: WE
Thickness (mm)	5	3	1.5	1.5
Slice Gap (mm)	5	0	0	0
Slices	10	20	40	45
NSA/NEX		1	1	1
Frequency		256	512	256
GE		256	512	256
Philips: Voxel		0.47	0.23	0.47
Siemens		256	512	256
Phase		192	192	192
GE		192	192	192
Philips: Voxel		0.63	0.63	0.63
Siemens: Phase resolution		75%	38%	75%
FOV	260	120	120	120
TE (ms)		30-50		
GE			Minimum	Minimum
Philips			3-14	3-14
Siemens			3-14	3-14
TR (ms)		3000-6000	20-40	20-40
Phase Direction		***AP***	***AP***	AP
Echo Train		7	1	1
Flip Angle		-	20	20
Bandwidth				
GE : Hz		15.63	15.63	15.63
Philips : WFS		Maximum	Maximum	Maximum
Siemens		80	70 (120 acceptable)	70 (120 acceptable)
Est. time	1:00	4:30	4:00	3:30
Comments				
GE	Site Preference	NPW OFF. FC On	NPW OFF, Zip 2 Off	NPW OFF, Zip 2 Off
Philips		NPW OFF	NPW OFF, Overcontiguous slices off	NPW OFF, Overcontiguous slices off
Siemens		Phase Oversampling set to 0	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off	Phase Oversampling set to 0. Slice resolution 100%, Interpolation off