Endo Protocol EN3835-210

Quick Reference Guide for MR Image Acquisition of the Shoulder

1.5T MRI Scanners

MRI Visits

Screening

Day 95 / End of Study

Early Termination

Unscheduled

MR Imaging Protocol

For each subject, at ***Screening*** visit only, both shoulders should be imaged, as follows:

Left Shoulder

1. *3-Plane localizer(s)*
2. *Axial 2D IW [1] FSE fat sat*
3. *Coronal oblique 2D IW FSE fat sat*
4. *Coronal oblique 2D T1-w FSE*
5. *Sagittal oblique 2D T2-w FSE fat sat*
6. *Sagittal oblique 2D T1-w FSE*

Right Shoulder

7. *3-Plane localizer(s)*
8. *Axial 2D IW FSE fat sat*
9. *Coronal oblique 2D IW FSE fat sat*
10. *Coronal oblique 2D T1-w FSE*
11. *Sagittal oblique 2D T2-w FSE fat sat*
12. *Sagittal oblique 2D T1-w FSE*

At **each follow-up visit**, the target shoulder should only be imaged, as follows:

1. *3-Plane localizer(s)*
2. *Axial 2D IW FSE fat sat*
3. *Coronal oblique 2D IW FSE fat sat*
4. *Coronal oblique 2D T1-w FSE*
5. *Sagittal oblique 2D T2-w FSE fat sat*
6. *Sagittal oblique 2D T1-w FSE*

The entire protocol should be programmed into your scanner and saved as **Endo EN3835-210** at the beginning of this clinical trial.

Once approved by Bioclinica this protocol should be recalled and used without alteration for each MRI. To ensure consistency, review the subject's **Screening** MRI before scanning for a follow up visit.

==========

1 – IW is the abbreviation for intermediate-weighted.

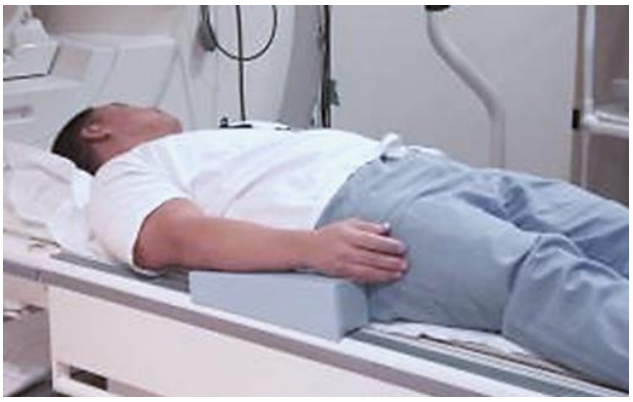
Target Shoulder for MR Imaging

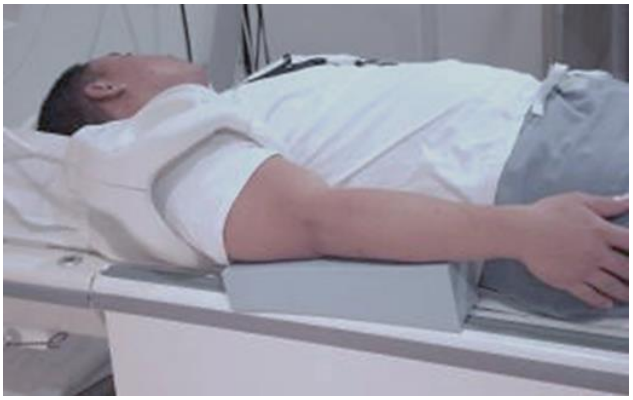
- The Principal Investigator (PI) will designate the affected shoulder as the target shoulder to be imaged during all follow-up time points.
- Personnel at the MRI facility should not make decisions regarding laterality of the target shoulder. If there is doubt or ambiguity regarding laterality before MRI exam, the PI/Study Coordinator should be contacted for clarification.
- For a given subject, the target shoulder will not change between timepoints.

Subject Preparation and Positioning

Proper subject preparation is critical for obtaining high-quality images. Follow these guidelines and make sure to consistently cover all preparatory steps during each subject-visit.

- The laterality of the target shoulder should correctly be entered through the scanner console.
- All loose metal objects should be removed as well as metal-containing jewelry and clothing (zippers, belts, snaps). It is recommended that the subject be dressed in a hospital gown.
- A dedicated shoulder coil should be used for imaging, if available.
- The subject should use the headphones, if available. Alternatively, provide the subject with earplugs and make sure he/she can hear your comments during imaging.
- The target shoulder should be as close as possible to the center of the magnet bore.
- Position the subject supine with the arm extended by the side of the torso.
- Elevate the elbow and align the humerus parallel to the table. If the subject can tolerate, he/she should keep the hand in externally rotated (palm up) position. Use pads, straps and/or sandbags, as needed, to immobilize the hand and the arm.
- Provide the subject with blanket(s) and additional pads, as needed, to ensure comfort and immobility during imaging.
- When moving the table inside the scanner, use laser lights to zero in on the shoulder joint.
- Prior to scanning, instruct the subject to keep the target arm/shoulder still and breathe in a shallow manner.
- During imaging, monitor the subject at all times.

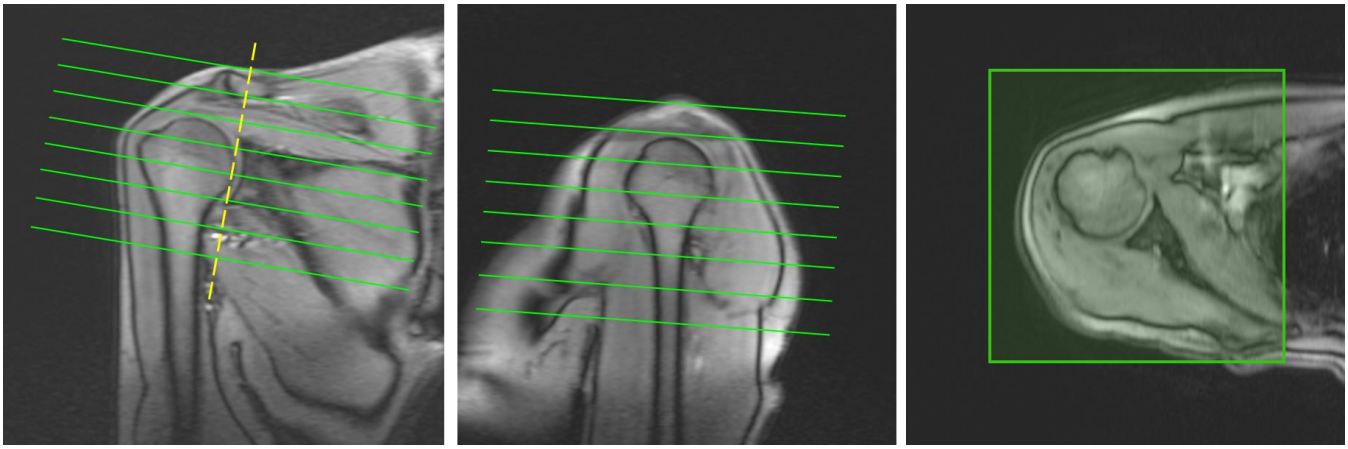




Anatomical Coverage and Slice Prescription - 1

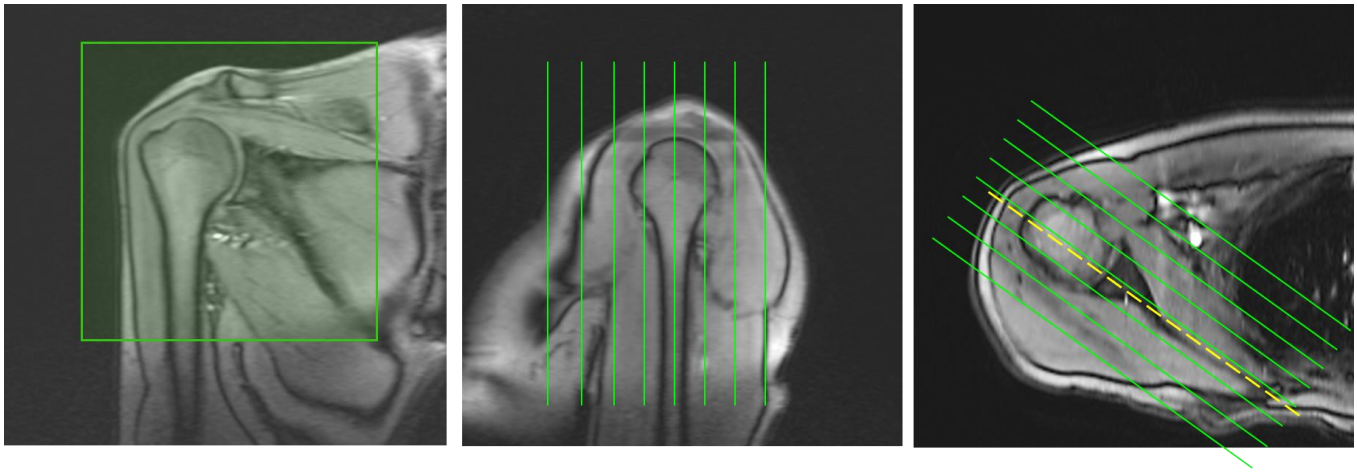
Axial scan (sequence 2 and 8)

- On a coronal localizer sequence identify the slice(s) on which the acromioclavicular joint and inferior tip of the glenoid are well observed. Based on this, identify the axis of the glenohumeral joint. Prescribe the slices perpendicular to this axis. The stack of slices should cover from above the acromioclavicular joint to at least 12mm (4 slices) below inferior edge of the glenoid.
- On a sagittal localizer sequence identify the slice(s) on which the humerus is well observed. The slices in the stack should be perpendicular to the shaft of the humerus.



Coronal oblique scans (sequences 3, 4 and 9, 10)

- On an axial sequence identify the slice(s) on which the humeral head, the scapula, and the supraspinatus tendon can be well observed. Based on this, identify the axis of the scapula (parallel to the supraspinatus tendon). Prescribe the slices parallel to this axis. The stack of slices should cover the entire shoulder joint from coracoid process anteriorly to ~12mm (4 slices) past the shoulder joint capsule posteriorly.
- On a sagittal localizer sequence identify the slice(s) on which the humerus is well observed. The slices in the stack should be parallel to the shaft of the humerus.



Anatomical Coverage and Slice Prescription - 2

Sagittal oblique scans (sequences 5, 6 and 11, 12)

- On an axial sequence identify the slice(s) on which the humeral head, the scapula, and the supraspinatus tendon can be well observed. Based on this, identify the axis of the scapula (perpendicular to the supraspinatus tendon). Prescribe the slices parallel to this axis. The slice stack should cover the entire shoulder joint from the deltoid muscle laterally to ~12mm (4 slices) past the glenoid medially
- On a coronal oblique sequence identify the slice on which the humeral head and glenoid can be well observed. Angulate the slices parallel to the axis of the glenohumeral joint.

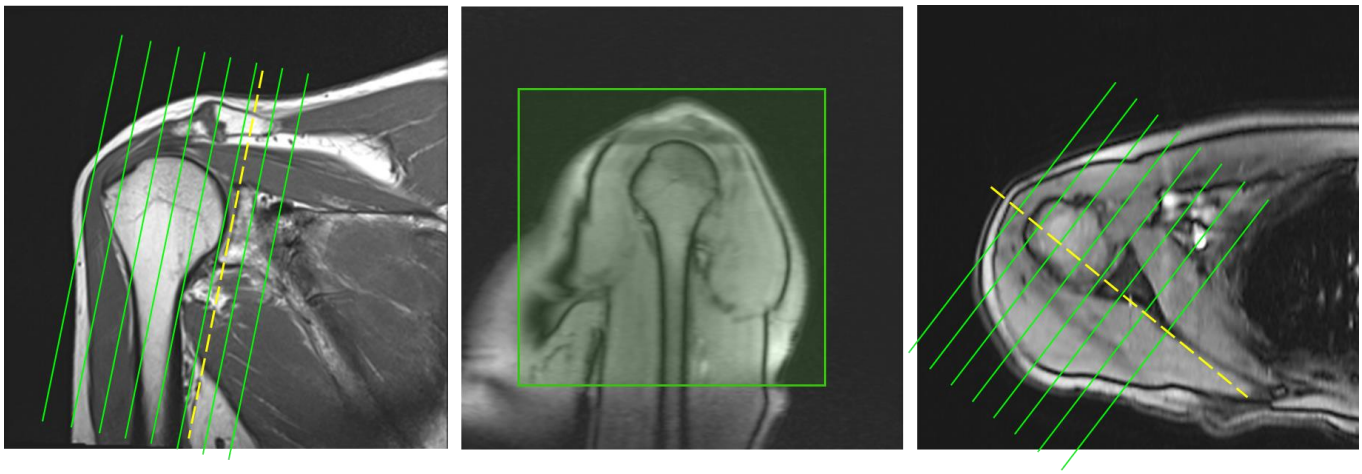


Image Acquisition Parameters

To setup and save each sequence refer to the table below. The sequences are based on suggested acquisition parameters that are typical for 1.5T MRI scanners. Depending on specific hardware/software versions, some settings may vary. Start with your routine clinical sequences and modify settings as indicated below. The imaging protocol for your scanner should be saved at study initiation and subsequently used for all subjects. Consistency in acquisition across all visits is especially important!

	Sequence 2/8	*Sequence 3/9*	*Sequence 4/10*	*Sequence 5/11*	*Sequence 6/12*
Sequence name	*Axial 2D IW FSE fat sat*	*Coronal oblique 2D IW FSE fat sat*	*Coronal oblique 2D T1-w FSE*	*Sagittal oblique 2D T2-w FSE fat sat*	*Sagittal oblique 2D T1-w FSE*
Sequence type/ technique	*tse2d1 – Siemens; FSE-XL – GE; TSE - Philips	*tse2d1 – Siemens; FSE-XL – GE; TSE - Philips	tse2d1_3 – Siemens; FSE-XL– GE; TSE-Philips	*tse2d1 – Siemens; FSE-XL – GE; TSE - Philips	tse2d1_3 – Siemens; FSE-XL– GE; TSE-Philips
Image orientation	Axial	Oblique coronal		Oblique sagittal	
Scan Mode	2D	2D	2D	2D	2D
Imaging options	fast, EDR, VBW – GE; Fast imaging YES, MS - Philips				
FOV (freq × phase) [mm × mm]	160 x 160	160 x 160	160 x 160	160 x 160	160 x 160
Acquisition Matrix (frequency × phase)	256×100% - Siemens 256×256 – GE Voxel size (mm): 0.625×0.625 - Philips	320×100% - Siemens 320×320 – GE Voxel size (mm): 0.5×0.5 - Philips		320×100% - Siemens 320×320 – GE Voxel size (mm): 0.5×0.5 - Philips	
TR [ms]	4000 - 6000	4000 – 6500	400 - 750	4000 – 6000	400 - 750
TE [ms]	35 - 45	35 - 45	8 – 12 (Min full for GE)	90 - 120	8 – 12 (Min full for GE)
Slices[1]	24	22 - 26	22 - 26	22 - 26	22 - 26
Slice thickness [mm]	3	3	3	3	3
Slices gap [mm]	0.3 (10%)	0.3 (10%)	0.3 (10%)	0.3 (10%)	0.3 (10%)
Averages/NEX/NSA	2	2	2	2	2
Phase/Foldover direction	A-P	H-F		A-P	
Frequency dir. (GE)	R-L	R-L		H-F	
Oversampling (Phase)	As needed	40-50% - Siemens; NPW - GE; Foldover suppression ON - Philips			
ETL/Turbo factor	5 - 11	5 - 11	3	5 - 11	3
Bandwidth/water-fat shift	120-180Hz/px - Siemens; 15-24kHz - GE; 1.1-1.8px - Philips				
Fat suppression	Fat Sat - Siemens Fat - GE SPAIR - Philips		None	Fat Sat - Siemens Fat - GE SPAIR - Philips	None
Flow comp.	Yes	Yes	Yes	Yes	Yes
Sat band (anterior)	N/A	Sat band - Siemens/GE; Rest slab - Philips			
Approximate acquisition time [min]	3 - 5	3 - 5	3 - 5	3 - 5	3 - 5

1 – adjust the number of slices, as needed, to attain required anatomical coverage.

Entering Subject Information Through the Scanner Console

In order to ensure subject confidentiality, please enter the following information into the electronic MRI header:

- **"Subject Information"** enter the 4-digit Site Number followed by the 4-digit Subject Number

  EXAMPLE: 0001-0007

- "**Subject History**" enter Visit name and laterality of target shoulder.

  EXAMPLE: Day 95, Left

Possible entries for Visit name:

Screening
Day 95 / End of Study
Early Termination
Unscheduled

Submitting Datasets to Bioclinica

The data to be sent from the imaging site should contain both the imaging study and the transmittal form. There are two options for sending data to Bioclinica:

- Electronic transfer using SMART - **the preferred method of submission**
- Postal mail/courier service.

Electronic Data Transfer Using SMART

SMART is a web-based portal that allows sites to submit images via secure file transfer protocol (FTP). It eliminates delays and expenses associated with shipping images via courier. The Transmittal Form (TF) is completed and submitted electronically as well.

Sending Data Using Courier Service

The complete package should contain a CD with imaging data and the completed TF.

Export the data to the CD in **uncompressed DICOM** format. Use an indelible marker to write on the CD. Indicate the following:

- Study Protocol Number (Endo EN3835-210)
- Subject Identifiers (Site Number and Subject Number)
- MRI Exam Date (DD-MMM-YYYY)
- Visit Name

Sending a Package to Bioclinica

1. Complete the sender sections of the air waybill, keeping a copy for tracking purposes.
2. Place the TF and CD for each patient-visit into a shipping envelope. Keep the copy of the TF for your records.
3. Call courier to schedule package pick-up.

Ship data to: EN3835-210 (10008597) Study Team
Bioclinica, Inc.
7707 Gateway Blvd, Third Floor
Newark, CA 94560 USA
Email: EN3835-210.Study.Support@bioclinica.com