MEDICAL IMAGING SERVICES

AbbVie M16-098

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Upadacitinib in Subjects with Active Ankylosing Spondylitis

Image Acquisition Guideline

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AbbVie - 235818 Image Acquisition Guideline

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Author: Sally Warner / Stephanie Mullen

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PAREXEL International

ABBVIE Protocol M16-098 M16-098 235818 Image Acquisition Guideline

Version: 1.0

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Document Approvals

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Document Revision History

Version	Date	Author Description	
1.0	19-JUL-17	Stephanie Mullen/ Sally Warner	Initial release of the document
2.0	19-Sept-17	Stephanie Mullen/ Sally Warner	Including low-dose CT parameters

Introduction

PAREXEL Informatics has developed the following acquisition guidelines for standardization of the study imaging components across radiology centers participating in the AbbVie study M16-098. Provided here are image acquisition guidelines for the following imaging modalities:

- X-Ray Sacroiliac Joints and Spine
- MRI Sacroiliac Joints and Spine
- CT Spine

Important Notes

- Regularly scheduled imaging for this study should be acquired in strict adherence to these guidelines.
- Images sent to PAREXEL shall be clear of any marks, writings, measurements or annotations.
- Keep imaging data (including raw/original data) digitally archived until PAREXEL has provided feedback on the quality of the images.
- All confidential site and patient information must be de-identified prior to sending the data to PAREXEL.
- Image data is sent to PAREXEL within 48 hours of acquisition

IMPORTANT: Imaging modality, anatomical coverage and acquisition parameters should remain consistent across all imaging visits for any given study subject.

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IMAGE TRANSFER METHODS

Electronic Transfer preferred

- o For transfer of digitally acquired images, please submit using a digital transfer method (i.e. E-Transfer, CD-ROM, DVD).
- o Images shall be in uncompressed DICOM format
- o eTransfer will automatically blind patient and site info in the image header

Hardcopy Film: for conventional X-ray only

- o Hardcopy X-ray Films only: For transfer of conventionally acquired images collected on film.
- o Original X-Rays should be provided to PAREXEL.
- o Please complete and apply subject labels provided by PAREXEL.
- o Use PAREXEL provided shipping supplies for courier shipment to PAREXEL.
- O Original X-rays should be marked as such and will be returned to the site as soon as possible following acceptance at PAREXEL if requested. All copied originals will require approval by PAREXEL to ensure image quality is not lost in copying.

IMAGING SCHEDULE

Imaging	Anatomy and			Visit/Week			
	Views/ Sequences	Screening Visit 1	Baseline Day 1, Visit 2 (±3 days)	Week 14 (-7 days ±3 days)	Week 52 (±3 days)	Week 104 (±7 days)	
X-Ray	Pelvis AP view (SI Joints)	X^1					
X-Ray	Spine lateral view (cervical, thoracic and lumbar)	X^1				X^2	
MRI	Spine (cervical, thoracic and lumbar) - Sagittal T1 and STIR		X^3	X		X	
MRI	SI Joints – oblique coronal T1 and STIR		X^3	X		X	
CT			X^4		X	X^5	

The x-rays of the spine and pelvis will not be required during the Screening Period if the subject had a previous anteroposterior pelvis x-ray and lateral spine x rays within 90 days of the Screening Period, provided that the x-rays are confirmed to be adequate for the required evaluations and are deemed acceptable by the central imaging vendor.

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² X-rays of the spine will be obtained at the Week 104 Visit. If a subject prematurely discontinues the study and/or study drug, depending on the time of discontinuation, new x-rays of the spine may be needed.

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- Subjects who prematurely discontinue from the study and/or study drug before Week 76 will not have x-rays performed at the PD Visit.
 - o If the subject continues study participation, the subject will follow the regular visit and an x-ray will be performed at the Week 104 Visit.
- Subjects who prematurely discontinue from the study and/or study drug at or after Week 76 will have x-rays performed at the PD Visit.
 - o If the subject continues study participation, the subject will follow the regular visit, but an x-ray will not be performed at the Week 104 Visit.
- ³ MRI should be performed prior to or at Baseline in subjects who meet eligibility criteria. If a subject has a condition that could interfere with the ability to perform an MRI prior to enrollment, the site must discuss this with the AbbVie TA MD. If a site is unable to obtain the MRI prior to or at Baseline, a window of 3 days post-dose will be allowed. If a site is unable to obtain the MRI at the Week 14 visit, a window of -7/+3 days will be allowed. If a site is unable to obtain the MRI at the Week 52 visit, a window of ±7 days will be allowed.
- ⁴ If a site is unable to obtain the low dose CT of the whole spine prior to Baseline Visit, a window of 2 weeks (14 days) post-dose will be allowed. If a site is unable to obtain the CT at the Week 52 visit, a window of ±7 days will be allowed.
- For subjects participating in the low dose CT scan substudy who prematurely discontinue from the study drug for any reason prior to Week 104 but after Week 76 should have a CT scan performed at or within 2 weeks of the PD Visit. If a site is unable to obtain the CT at the Week 104 visit, a window of -7/+14 days will be allowed.

**** Patient safety in relation to image acquisition is the responsibility of the Investigator sites. ****

For inquiries regarding these guidelines, please contact:

235818 Team

Email: 235818-imaging@parexel.com

Fax: 1-833-655-7221

Thank you for your participation and cooperation in this clinical study.

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Related to: SOP-PI.MI-WW-002 Page 6 of 25

IMAGE ACQUISITION GUIDELINES

LATERAL CERVICAL SPINE (X-RAY)

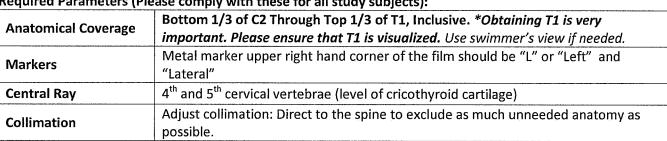
- Parameters and positioning used during Screening imaging for the patient should be kept consistent for all follow up imaging.
- Appropriate shielding of the eyes, thyroid, breast region and gonads should be performed without obscuring the vertebrae of interest.
- Please document when left lateral is not possible and the right side was used for lateral spine views. This should be handled consistently for a patient throughout the study.
- Complete Image Transmittal Form with all exposure information.

LATERAL CERVICAL SPINE X-RAY

PATIENT POSITIONING:

- 1. Position patient standing or sitting in a chair with a horizontal beam (left lateral if possible for consistency). Alternatively, a cross-table lateral film can be obtained with the patient supine. Patient should be instructed to elevate chin slightly to prevent superimposition of the upper C-Spine.
- 2. Place both arms at side in comfortable position: use voluntary or assisted arm traction as necessary to obtain a clear view of the top of Thoracic level 1(T1)*. While sitting or standing, assisted traction may be gained by the use of weights or sandbags.
- 3. If necessary a swimmer's view can be obtained to visualize top of T1.

Required Parameters (Please comply with these for all study subjects):



Suggested Parameters (Can use institutional standard, but must be consistent within notient for study):

Breathing Instructions	Quiet breathing for exposure and no swallowing.		
Imaging System Bucky (wall) or static grid technique			
Scattering Grid	Preferred		
Film/Focus distance	79 in (200 cm) be consistent across timepoints		

TP-PI MI-WW-008-11 Effective Date: 04 Mar 16 Related to: SOP-PI.MI-WW-002 Swimmer's view alternative

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Imaging KvP and mAs	75-85 kVp. 10-15 mAs may vary based on body size.	
Exposure Time	Breathing technique; approx. 2 second exposure	
Film Size	10x12 inches (25x30cm) (May vary based on body size)	

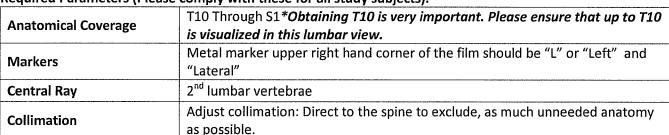
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LATERAL THORACO-LUMBAR SPINE (X-RAY)

PATIENT POSITIONING:

- 1. Place patient on table in lateral position (left lateral if possible for consistency) with legs flexed for comfort and support.
- 2. Place support under patient's head.
- 3. Place both arms at right angles to anterior surface of body and flex elbows for comfort.
- 4. Place supports between knees and ankles and under knee next to table (for support and to aid in maintaining lateral position).
- 5. Place support under mid lumbar region to position long axis of spine parallel to table.
- 6. Complete Image Transmittal Form for all exposure information.

Required Parameters (Please comply with these for all study subjects):



Suggested Parameters (Can use institutional standard, but must be consistent within patient for study):

Breathing Instructions	Breath hold on exhalation or breathing technique		
Imaging System	Bucky (screen) or static grid technique		
Film/Focus distance	40 inches (102 cm)		
Imaging kVp and mAs	80-90 kVp, 80-100 mAs, may vary based on body size		
Exposure Time	Manual < 1.0 second exposure Automated Central photocell		
Film Size	14x17 inches (36x43 cm) (May vary based on body size)		

X-ray Image quality review:

- Orthogonal view with spine positioned parallel to film
- Anatomical coverage complete and consistent with Screening
- Patient positioning and acquisition parameters consistent with Screening
- Vertebrae visible and unobstructed for assessments of vertebral shape/deformities



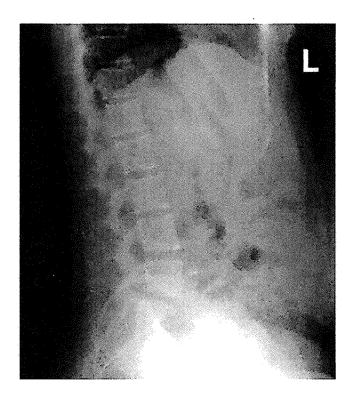


IMAGE ACQUISITION GUIDELINES

AP PELVIS (SACROILIAC JOINTS X-RAY)

- The table below shows <u>preferred</u> parameters. Please use parameters as close to these as possible.
- Once these values have been selected, they shall remain consistent throughout this examination and study follow-up examinations.
- Appropriate shielding of the eyes, thyroid, breast region and gonads should be performed without obscuring the anatomy of interest.

OBJECTIVE: Clear, orthogonal view of sacroiliac joints for assessment of sacroiliitis **PATIENT POSITIONING** (see diagram next page):

- 1. Place the subject on the table in the supine position.
- 2. Center the mid-sagittal plane of the body to the midline of the grid, and adjust it in a true supine position.
- 3. Flex the elbows and rest the hands on the upper chest.
- 4. The heels should be placed 20-25 cm (8 10 inches) apart.
- 5. Medially rotate both feet and lower limbs the same degrees.
- 6. Immobilize the legs with a sandbag across the ankles, if needed.
- 7. Check the distance from the anterior superior iliac spine to the table and make sure the pelvis is not rotated.
- 8. Center the cassette/receptor midway between anterior superior iliac spine and the pubic symphysis. The cassette/receptor will be about 2 inches (5 cm) inferior to the pubic symphysis in average-sized subjects.
- 9. If the pelvis is deep, palpate for the crest of the ilium and adjust the position of the cassette so that its upper border will project 1 to $1\frac{1}{2}$ inches (2.5 to 3.8 cm) above the crest of the ilium.

Required Parameters (Please comply with these for all study subjects):

Anatomical Coverage	Clear view of both Sacroiliac joints (see image on next page)		
Markers	Metal marker in the upper right hand corner of the image should be "R" or "Right" and "AP"		
Central Ray Direction	Caudo - cranial 10- 20 degrees (orthogonal to SIJ)		

Suggested Parameters (Use clinical standard for optimal imaging on your instrument)

Breathing Instructions	Suspend
Imaging System Bucky screen technique	
Film/Focus distance 40 inches (100 cm) see film/focus distance note above	
Imaging kVp	65-85 kVp, may vary based on body size
	Manual < 1.0 second exposure
Exposure Time	Automated Central photocell
Central Ray	Perpendicular to the midpoint of the cassette/receptor
Film Size 14x17 inches (35x43 cm)	

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AP PELVIS X-RAY - POSITIONING

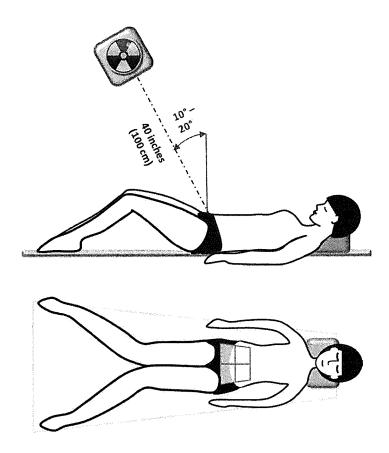
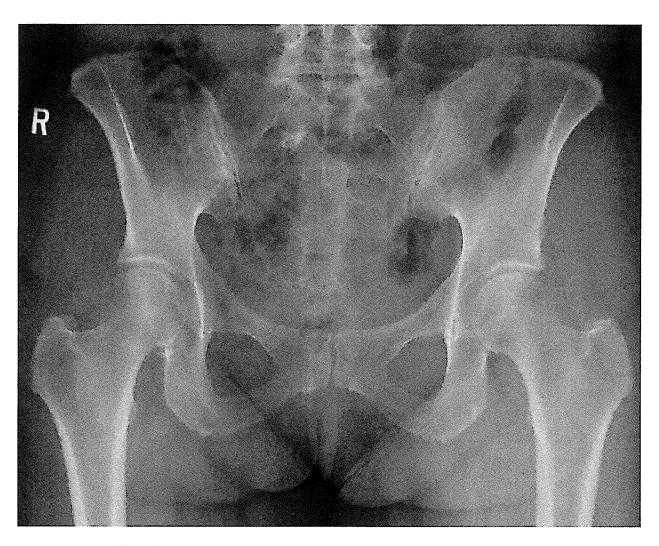


IMAGE ACQUISITION GUIDELINES

AP PELVIS (SACROILIAC JOINTS X-RAY)



X-ray Image quality review:

- Orthogonal view with beam angled so it is perpendicular to sacrum
- Anatomical coverage complete and consistent with Screening
- Patient positioning and acquisition parameters consistent with Screening
- Sacro-illiac joints visible and unobstructed for assessments of sacro-illitis (sclerosis, erosions, ankylosis)

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IMAGE ACQUISITION GUIDELINES

SPINE MRI SAGITTAL CERVICAL, THORACIC, AND LUMBAR

- This is NOT a routine total spine examination. Please use optimal Field Of View for the upper spine (C2-T10) and lower spine (T8-S1) examinations.
- Please ensure complete anatomical coverage, appropriate visibility of edema on STIR sequence and limited artifact (motion, pulsatile, incomplete FS, etc.).

Scanner Type		1.5 Tesla or 3.0 Tesla					
Coil		Posterior Spine Coil					
Patient Orientation		Standard Supine, knees supported, spine as straight as possible (L-R)					
Breath	ning Instructions		None				
Scout	Sequences		Scout – axial, coronal,	and sagi	ttal planes		
Study Sequences		1) 2D Sagittal T1,T1 FLAIR, TSE or FSE, without fat suppression 2) 2D Sagittal STIR See scan details in the table below					
Scan Locations/Coverage:		2 Segments: must include complete coverage of the vertebral body including posterior elements (zygoapophyseal, costovertebral joints, and spinous processes) *: Cervical & Upper Thoracic: C2-T10 Lower Thoracic & Lumbar (T8-S1) * For tall patients > 2 segments may be used to ensure complete coverage.					
Slice	Slice Thickness		3 mm maximum for Cervical & Upper Thoracic 4 mm maximum for Lower Thoracic & Lumbar				
Skip/g	ap (slice spacing	}	≤1 mm				
Perce	Percent phase sampling		60 - 80% (or optimal)				
FOV	FOV		380 mm (or optimal) (Rectangular FOV may be used to reduce scan time)				
Contra	ast Agent		None				
Phase	direction		Head/Foot				
	TR		-600 ms (or optimal)		TR	4000-4500 ms (or optimal)	
	TE	12-	20 ms (or optimal)		TE	40-60 ms (or optimal)	
	Slice Acquisition	Inte	rleaved		TI	150 (220 for 3T) ms	
	Averages/ NEX 2 (c		r optimal)		Averages/ NEX	1 – 2 (or optimal)	
T1	Matrix (FEVPE)		x 256 optimal)	STIR	Matrix (FExPE)	512 x 256 (or optimal)	
	Echo Train Length	3 -			Echo Train Length	7-12 (or optimal)	
	Pixel BW	130	Hz/Pixel (or optimal)		Pixel BW	250 Hz/Pixel (or optimal)	
	Concatenations 1 (c		r optimal)		Saturation Band	Anterior saturation slab. Ensure complete across FOV.	

- The STIR sequences are most important for the assessments of bone marrow edema and these sequences take longer to acquire, please prioritize them. We recommend doing the STIR first to mitigate increased risk of motion artifact with later scans.
- Please save the protocol/parameters in your MRI machine so that the same parameters can be used throughout the study with each subject at every time point.
- Please ensure complete anatomical coverage, appropriate visibility of edema on STIR sequence, limited artifact (motion, pulsatile, etc.)

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IMAGE ACQUISITION GUIDELINES

SACROILIAC MRI

- The table below shows suggested parameters. Please use parameters as close to these as possible to produce high quality images.
- Once the MRI protocol at baseline passes QC then the same parameters should be used consistently at follow up visits.

OBJECTIVE: Clear view of entire spine and sacroiliac joints for the primary assessment of bone edema. No contrast medium should be administered for any of these MRI sequences.

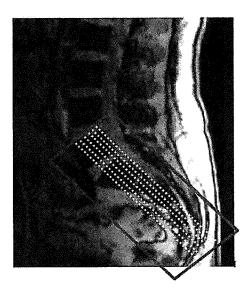
1114. 1	to contrast media	in should be administe	oreu re	n any or mese in	arti sequences.				
	ScannerType	1.5 Tesla or 3.0 Tesla							
	Coil	Posterior spine coil ONLY							
	Patient Positioning	Standard Supine, knees supported, spine as straight as possible (L-R)							
Bre	athing Instructions	None	None						
	Scout Sequences	Scout 1) Scout images in 3 planes, axial scout to include hip joints.							
	All are Required	Scout 2) Repeat axial if necessary – see required scan locations for study sequences below.							
H .	(Please see slice	Scout 3) True sagittal sc							
l no	sitioning diagrams	Center - S1 vertebra							
an	d examples below)	Angle 1 - from axial s							
		Angle 2 - from coron	alscout	- longitudinal axis o	fsacrum				
	Study Sequences	1) 2D T1 Oblique corona 2) 2D STIR tilted coronal	, 15⊏0	r r be, without fat st	ppression				
	armay acquences	See scan details in the ta		rw					
					sition plane being parallel to the				
		longitudinal axis of the sac	crum ("ti	ited coronal" or "ser	ni-coronal")				
		Centering point of stack-	Centering point of stack						
ł	Scan	Left/right-midline							
	ocations/Coverage	Head/Foot-Atscleroticscarformed by vestigial disc between S1 and S2							
fo	r Study Sequences	Anterion/Posterior- place posterior edge of stack at posterior border of S2							
		Angles:							
		a. Perpendicular to above "true sagittal scout"							
		b. Tilt forward until parallel to posterior surface of S2 15 (or optimal to ensure complete coverage)							
# of Slices		**Please note 6 slices must include SU**							
Scan FOV		300 mm square (consistent throughout the study)							
	Slice Thickness	4 mm							
	Skip/gap (slice	10% gap (0.4 mm spacing)							
<u> </u>	spacing)		V						
<u> </u>	Contrast Agent	None							
	Phase Encoding	Left/Right or Anterior/Posterior							
		(whichever produces less artifact on your system)							
	Oversampling	100%							
Spa	itial Fat Saturation	Anteriorsaturationslab	Anteriorsaturationslab						
	TR	500-600 ms (or optimal)		TR	4000-4500 ms (or optimal)				
	TE	12-20 ms (or optimal)		TE	40-60 ms (or optimal)				
	Slice Acquisition	Interleaved	STIR	TI	150 (220 for 3T) ms				
	Averages/NEX	1		Averages/NEX	1				
T1	Matrix (FEx PE)	512 x 256 (or optimal)		Matrix (FEx PE)	384 x 256 (or optimal)				
l	Echo Train	3-4		Echo Train	7-12 (or optimal)				
	Length Pixel BW	120 HalDivol (as a stime)		Length					
l	Concatenations	130 Hz/Pixel (or optimal) 1 (or optimal)		Pixel BW	250 Hz/Pixel (or optimal)				
	Concatenations	r (or optimal)		Spatial Fat	Ensure complete across FOV (i.e.				
	1			Saturation	check shimming)				

IMAGE ACQUISITION GUIDELINES

Sacral coronal study images – planned from True Sagittal Scout

Anatomy diagrams below demonstrate what is required for SI joints to assist with planning for MRI technicians. First acquire a set of true sagittal scouts (first set of diagrams) then use these to plan the tilted coronal views of SI joint

Alignment of Coronal slices tilted forward to parallel the longitudinal axis of the sacrum. Dash yellow lines indicate 6 out of 15+ slices must include SIJ for accurate assessment.



Centering point of stack: Left/right – midline Head/Foot - At sclerotic scar formed by vestigial disc between S1 and S2.



IMAGE ACQUISITION GUIDELINES

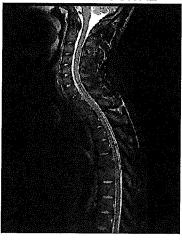
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SPINE MRI EXAMPLES OF GOOD QUALITY T1 AND STIR IMAGES

T1 UPPER SAGGITAL



STIR UPPER SAGGITAL



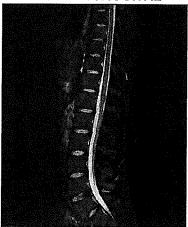
MRI Image quality review:

- High quality in-plane resolution
- No motion/breathing artifacts that will interfere with assessments
- Complete anatomical coverage
- Consistent positioning and parameters between subsequent visits

T1 LOWER SAGGITAL



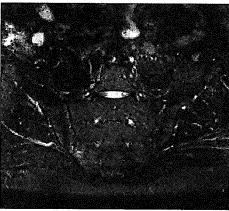
STIR LOWER SAGGITAL



T1 SI JOINTS



STIR SI JOINTS



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IMAGE ACQUISITION GUIDELINES

SPINE CT CERVICAL, THORACIC, AND LUMBAR

OBJECTIVE: Clear view of entire spine for the primary assessment of vertebral syndesmophytes. No contrast medium should be administered for this CT scan.

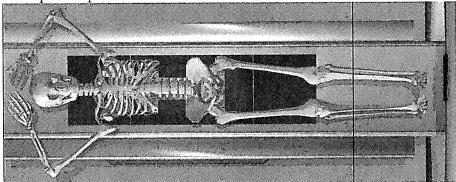
- This is NOT a routine total spine CT examination. Please use optimal Field Of View for the spine (C2-S1) imaging.
- Please ensure complete anatomical coverage, appropriate visibility of vertebral bone detail without artifact.

Patient Preparation

- Remove all metal objects that will be in the scan field.
- It would be ideal to have the patient change into a medical gown but the decision can be made on the feasibility of that approach by the operator.
- Do not scan a patient that:
 - o has had intravenous contrast administered within the past 24 hours
 - o has high density barium contrast in the bowel
 - o is pregnant or may be pregnant

Patient Positioning

- 1. Legs should be straight with the heels out and the toes pointed inward.
- 2. Have patient place arms over head.



CT SPINE IMAGING GUIDELINES

Note: The following guidelines are strongly recommended for all CT acquisitions. If deviations are required due to local site preferences, scanner limitations or patient specific scan needs, please note on in the comments during image transfer.

CT Patient Biography in DICOM Header:

- Create only one biography per patient.
- At follow up, select the original biography and make any necessary changes.

First Name: Enter Study Site #

Last Name: Enter Subject's Allocation #

Height: Enter height Weight: Enter Weight Sex: Female/Male

Table height: Enter table height

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CT Spine Acquisitions

Scan Localizer

- Start a lateral localizer scan at base of the skull and extend to the top of the sacrum
- Make sure the scan length is long enough to include the L5/S1 joint.
- Allow patient to breathe normally during the scan; do not use full inspiration.

Prescribing and taking the Axial Scans

- Lateral localizer, superior (start) position for the scan series to include all of the disc space above the top vertebra to be analyzed and the inferior (end) position for the scan series to include all of coverage below the bottom vertebra to be analyzed.
- C2 through L5 must be completely captured (include bottom of C1 and top of S1)

Spine CT Acquisit	ion Parameters		
KVp	120 kVp. If possible, a lower kVp (e.g., 80 to 100 kVp) should be used to keep radiation dose to a minimum.		
mAs*	The mAs should be modified as needed to ensure the CTDIv is low please see detailed steps for current modulation below.		
Slice thickness*	1mm		
Slice increment* Same as slice thickness (pitch = 1)			
Scan Field of View	Large body (e.g., 50cm): must include the whole patient including soft tissue		
Reconstruction Field of View (DFOV)	380 mm		
Matrix	512		
Reconstruction Field Coordinates	X=0, Y=0		
Reconstruction Algorithms	Standard kernel		
Localizer	Lateral Spine; C2- S1: very important to see L5/S1		
Coverage	Base of the skull to top of sacrum level 1 (Please do not include the skull)		
Multi-planar reformat	Yes, Sagittal and Coronal Plane		

^{*} These parameters are suggested but may vary by CT scanner and should be modified according to the below steps for current modulation in order to obtain low dose CT scans.

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Key points for obtaining low dose CT scans:

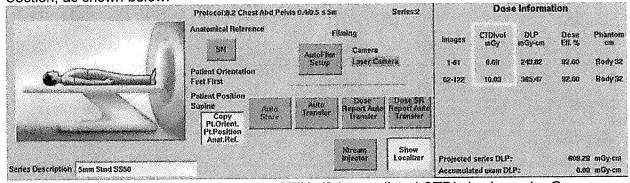
- 1. **Current modulation**: This study will have patients across a broad range of body sizes. Therefore, please adjust the maximum mAs as appropriate for that body habitus while ensuring that the current modulation is used.
- 2. Please use **Iterative Reconstruction Algorithms** so that the dose can be reduced and optimal bone imaging can be realized.
- 3. Metallic objects on clothing: Please ensure that no metallic objects on clothing are present during the scan, e.g., zippers etc. It would be ideal to have the patient change into a medical gown but the decision can be made on the feasibility of that approach by the operator.
- 4. Patient Positioning: Please position patients at the iso-center (both horizontal and vertical axes) to avoid noisy images and in-turn an increase in radiation dose due to the automated exposure control. This is even more crucial in this study due to the challenges associated with the study population. If patient positioning becomes very difficult, turning off the automated tube current modulation should be explored.

Current Modulation steps unique to each manufacturer (GE, Siemens, Toshiba, Philips, Hitachi)

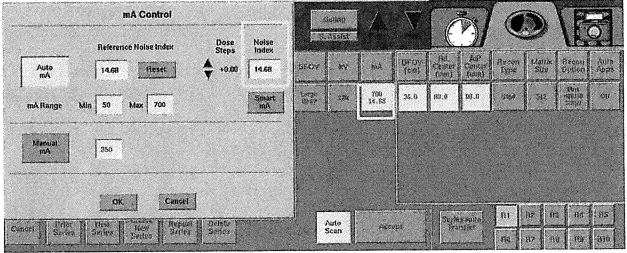
GE CT - CTDlv Adjustment

1. Displayed CTDIv

After the scout images are acquired, the CTDIv to be delivered is displayed in the "Dose Information" Section, as shown below.



2. Tune the Noise Index to lower the CTDIv if the predicted CTDIv is above 4 mGy



ABBVIE Protocol M16-098 M16-098 235818 Image Acquisition Guideline

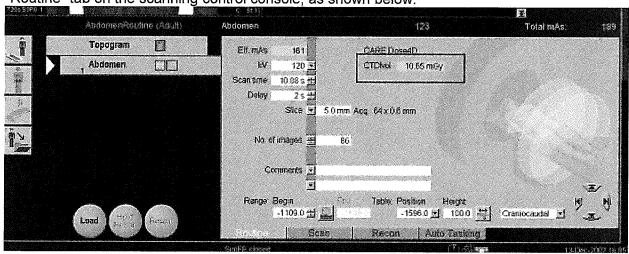
Version: 1.0

In AEC mode, the Noise Index in the "mA Control" determines the level of acceptable noise in the scan setting. **Increase** the Noise Index to **Iower** the displayed CTDIv to 4 mGy or below.

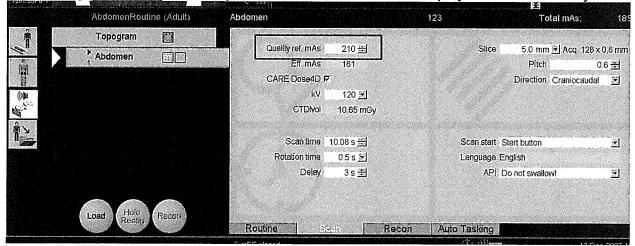
Siemens CT – CTDIv Adjustment

Displayed CTDIv

After the topograms (scout images) are acquired, the CTDIv to be delivered is displayed in the "Routine" tab on the scanning control console, as shown below.



2. Tune the Quality Reference mAs to lower the CTDIv if the predicted CTDIv is above 4 mGy In AEC mode, the "Quality ref. mAs" in the "Scan" tab determines the level of acceptable noise in the scan setting. **Decrease** the Quality reference mAs to **lower** the displayed CTDIv to 4 mGy or below.



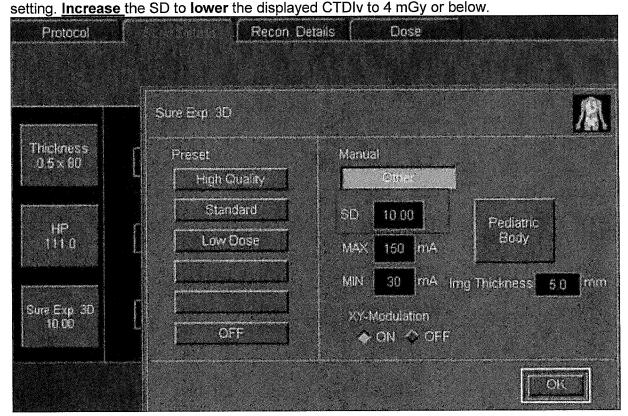
Toshiba CT - CTDIv Adjustment

1. Displayed CTDIv

After the scanograms (scout images) are acquired, the CTDIv to be delivered is displayed in the "Dose"

tab on the scanning control console, as shown below. Recon. Details Scan Details Protocol La DOSE Reference info. Notification Value Planned Dose Dose Calculation Method mGy 7.5 Scan Total CTOI vol mGv 3998 DLP mGy.cm mGy.cm Z-Axis Efficiency Completive CTDI voi 7.5 mGyProfesol Total 3998 OLP mGy.cm

2. Tune the SD to lower the CTDIv if the predicted CTDIv is above 4 mGy In AEC mode, the "SD" in the "Scan Details" tab determines the level of acceptable noise in the scan patting. Increase the SD to lower the displayed CTDIv to 4 mGy or holow.

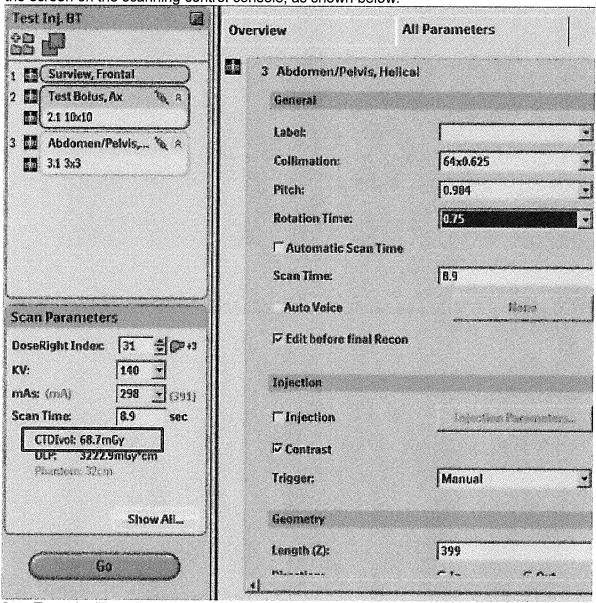


Philips CT - CTDlv Adjustment

Displayed CTDIv

After the Surviews (scout images) are acquired, the CTDIv to be delivered is displayed in the left side of

the screen on the scanning control console, as shown below.

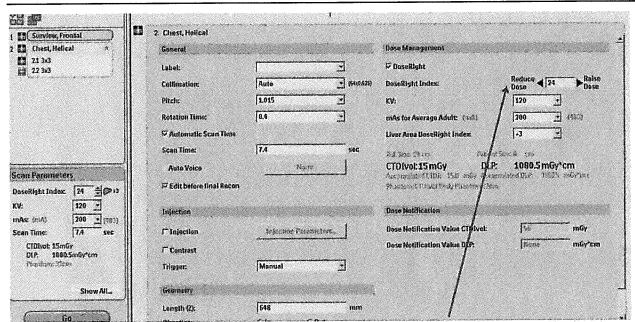


Tune the "DoseRight Index" to lower the CTDIv if the predicted CTDIv is above 4 mGy In AEC mode, the "Dose Right Index" in the "Dose Management" section determines the level of acceptable noise in the scan setting. **Decrease** the "DoseRight Index" (toward the "Reduce Dose" direction) to lower the displayed CTDIv to 4 mGy or below.

PAREXEL International

ABBVIE Protocol M16-098 M16-098 235818 Image Acquisition Guideline

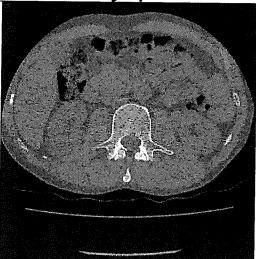
Version: 1.0



Hitachi CT - CTDlv Adjustment

Tune up the "Standard Deviation (SD)" parameter in the IntelliEC user interface of a Hitachi scanner to lower the predicted CTDIv to 4 mGy.

Good Quality Spine CT Scan



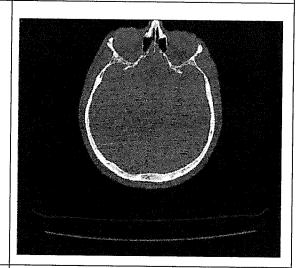
Good Quality Spine CT Scan

- Patient is centered and includes complete C2-L5 coverage
- Good bone detail



POOR Quality Spine CT scan

- Patient is substantially shifted to one side
- · Anatomy is outside the scan field
- Degrades the field uniformity correction
- Causes noise and artifacts in the tissue



POOR Quality Spine CT scan

 Acquisition includes skull, please start below the skull

COMMON ISSUES SEEN WITH CT

Please do your best to try and avoid queries. Here are some common CT problems that you should try to avoid:

- Incorrectly or inconsistently positioning the patient
- Low signal to noise, particularly insufficient SNR with larger patients
- Incorrect acquisition parameters
- Missing vertebrae

was walked and the two facilities are allowed to entered by facilities appropriate the entered and the entered

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