CT Chest Teton High-Res

Updated 05/01/24
Reviewed 05/14/25

Indication - interstitial pulmonary fibrosis (IPF).
Use CT chest HRCT without Contrast charge. Do not use regular CT chest charge.

GENERAL SCAN NOTES

Move the patient's arms over his/her head if possible. Remove any metal from the imaging field of view.
Have the patient cough a few times to clear secretions. This reduces incidence of small lung nodules.
Topogram - lung apices through diaphragm (obtained during end inspiration).
Craniocaudal scan coverage - lung apices through adrenal glands on both phases (obtained during end inspiration).
Adjust FOV (field of view) on topogram to smallest without cropping anatomy.
Scan parameters for the supine end inspiratory phase are the same as routine chest protocol.
Scan parameters for the supine end expiratory phase are the same as low-dose chest protocol.
IV Contrast: not given for this protocol.
For **GE scanners**, it is essential for the 1st recon thickness on the scanner to match the 1st recon thickness in this protocol book for the prescribed Noise Index to be valid. The 1st recon should generally be the thickest recon in the protocol.

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SIEMENS PARAMETERS & RECONS

For the **Supine End Inspiration** phase:

	Scan Mode	kV	mAs	Care Dose	Care kV & Lvl	Pitch	Acq	Coll	Rot Time	Scan Time
Sensation 16	spiral	120	100	on	NA	1.15	16	0.75	0.5	10.9
Go Up 32	spiral	130	51	on	on 80	1.50	32	0.7	0.8	7.1
Sensation 64	spiral	120	100	on	NA	1.40	64	0.6	0.5	5.6
Definition 64	spiral	120	110	on	on	1.20	64	0.6	0.5	6.5
Go Top 64	spiral	120	62	on	on 80	1.20	64	0.6	0.33	2.1
Drive 128	spiral	120	66	on	on	1.20	128	0.6	0.5	3.3
Force 192	spiral	110	51	on	on	1.20	192	0.5	0.5	2.6

Name of Series	Thick	Interval	Kernel	Window	IR Lvl	Recon Direction	
AX INSP LUNG	3.0	3.0	Br57 / B70f	lung	3	head/feet	
AX INSP SOFT	3.0	3.0	Br40 / B41f	mediastinum	3	head/feet	
COR INSP SOFT	3.0	3.0	Br40 / B41f	mediastinum	3	front/back	
SAG INSP SOFT	3.0	3.0	Br40 / B41f	mediastinum	3	left/right	
AX INSP HRCT	**1.0**	**0.8**	**Bl57 / B80f**	**lung**	**3**	**head/feet**	**Teton specific recon.**
COR INSP HRCT	1.0	5.0	Br57 / B70f	lung	3	front/back	
AX INSP MIPS	8.0	3.0	Br40 / B41f	lung	3	head/feet	

For the **Supine End Expiration** phase:

	Scan Mode	kV	mAs	Care Dose	Care kV & Lvl	Pitch	Acq	Coll	Rot Time	Scan Time
Sensation 16	spiral	120	**60**	on	NA	1.15	16	0.75	0.5	10.9
Go Up 32	spiral	130	**31**	on	on 80	1.50	32	0.7	0.8	7.1
Sensation 64	spiral	120	**60**	on	NA	1.40	64	0.6	0.5	5.6
Definition 64	spiral	120	**66**	on	on	1.20	64	0.6	0.5	6.5
Go Top 64	spiral	120	**37**	on	on 80	1.20	64	0.6	0.33	2.1
Drive 128	spiral	120	**40**	on	on	1.20	128	0.6	0.5	3.3
Force 192	spiral	110	**31**	on	on	1.20	192	0.5	0.5	2.6

Name of Series	Thick	Interval	Kernel	Window	IR Lvl	Recon Direction	
AX EXP HRCT	**1.0**	**0.8**	**Bl57 / B80**	**lung**	**3**	**head/feet**	**Teton specific recon.**

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GE PARAMETERS & RECONS

For the **Supine End Inspiration** phase:

	Scan Type	SFOV	kV	mA Range	Noise Index	Smart mA	Slice Thick	Beam Coll	Pitch	Speed	Rot Time	Dose Red	ASIR	Scan Time
LS 16	helical	large	120	100-440	16.36	on	2.5	20	1.375	27.50	0.5	NA	NA	5.5
Opt 540	helical	large	120	100-440	16.36	on	2.5	20	1.375	27.50	0.5	NA	NA	5.5
LS VCT 64	helical	large body	120	100-650	18.38	on	2.5	40	1.375	55.00	0.4	50	50	2.2
Disc VCT 64	helical	large body	120	100-650	18.38	on	2.5	40	1.375	55.00	0.4	NA	NA	2.2

Name of Series	Thickness	Interval	Recon Algorithm	Window Width/Level	Recon Direction	
AX INSP LUNG	**2.5**	**2.5**	**lung**	**1600/-600**	**head/feet**	**Must be first recon.**
AX INSP SOFT	2.5	2.5	std full	400/40	head/feet	
COR INSP SOFT	2.5	2.5	std full	400/40	front/back	
SAG INSP SOFT	2.5	2.5	std full	400/40	left/right	
AX INSP HRCT	**1.25**	**1.0**	**bone plus full**	**1600/-600**	**head/feet**	**Teton specific recon.**
COR INSP HRCT	1.25	5.0	bone plus full	1600/-600	front/back	
AX INSP MIPS	8.0	3.0	std full	1600/-600	head/feet	

For the **Supine End Expiration** phase:

	Scan Type	SFOV	kV	mA Range	Noise Index	Smart mA	Slice Thick	Beam Coll	Pitch	Speed	Rot Time	Dose Red	ASIR	Scan Time
LS 16	helical	large	120	100-300	**36.20**	on	1.25	20	1.375	27.50	0.5	NA	NA	5.5
Opt 540	helical	large	120	100-300	**36.20**	on	1.25	20	1.375	27.50	0.5	NA	NA	5.5
LS VCT 64	helical	large body	120	50-300	**36.01**	on	1.25	40	0.984	39.375	0.5	30	70	3.8
Disc VCT 64	helical	large body	120	50-300	**36.01**	on	1.25	40	0.984	39.375	0.5	NA	NA	3.8

Name of Series	Thickness	Interval	Recon Algorithm	Window Width/Level	Recon Direction	
AX EXP HRCT	**1.25**	**1.0**	**bone plus full**	**1600/-600**	**head/feet**	**Teton specific recon.**

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PHILIPS PARAMETERS & RECONS

For the **Supine End Inspiration** phase:

	Scan Mode	kV	Avg mAs	Dose Index	3D Dose	Pitch	Detect	Colli	Rot Time	Scan Time
Incisive 128	helical	120	92	19	on	1.00	64	0.625	0.75	5.6

Name of Series	Thick	Interval	Filter	Window	iDose	Recon Direction	
AX INSP LUNG	3.0	3.0	YA	lung	3	head/feet	
AX INSP SOFT	3.0	3.0	B	mediastinum	3	head/feet	
COR INSP SOFT	3.0	3.0	B	mediastinum	3	front/back	
SAG INSP SOFT	3.0	3.0	B	mediastinum	3	left/right	
AX INSP HRCT	**1.0**	**0.8**	**YA**	**lung**	**3**	**head/feet**	**Teton specific recon.**
COR INSP HRCT	1.0	5.0	YA	lung	3	front/back	
AX INSP MIPS	8.0	2.0	B	lung	3	head/feet	

For the **Supine End Expiration** phase:

	Scan Mode	kV	Avg mAs	Dose Index	3D Dose	Pitch	Detect	Colli	Rot Time
Incisive 128	helical	120	**55**	19	on	1.00	64	0.625	0.75

Name of Series	Thick	Interval	Filter	Window	iDose	Recon Direction	
AX EXP HRCT	**1.0**	**0.8**	**YA**	**lung**	**3**	**head/feet**	**Teton specific recon.**

Table 1: Historical HRCT Imaging Parameters (Screening/V1)	
Parameter	**Description**
Collimation	Sub-millimeter
Rotation Time	Shortest possible
Pitch	Highest possible
Tube Potential*	120 kVp
Tube Current*	≤ 240 mAs
Radiation Dose Control	Per institutional requirements (1-3 mSv recommended for inspiratory acquisition; ultralow-dose CT with < 1 mSv should be avoided)
Reconstruction Slice Thickness	≤ 1.5 mm (series with slices thicker than 1.5 mm will not be accepted)
Reconstruction Slice Gap	**Contiguous, overlapping. or interspaced slices (slice gap > 0 mm is permitted)**
Reconstruction Algorithm	High spatial frequency (bone/sharp); iterative reconstruction if available and validated
Reconstruction Orientation	Axial
Field-of-View (FOV)	Thoracic axial slices from most extreme lung apices to most extreme lung bases (costophrenic recesses included)
Acquisitions**	Single breath-hold full inspiration Single breath-hold full expiration
Image format	DICOM
Artifact	Images should not be significantly degraded by motion or metal artifact

**Tube current and potential should be adjusted based on subject size and dose control protocol*
*** Full inspiration is mandatory for all HRCT timepoints; expiratory scans are recommended for assessment of air trapping*

Table 2 below provides the minimum specifications for diagnostic on-study HRCT scan required for IPF assessment[1]

Table 2: On-Study HRCT Imaging Parameters (Screening/V2)	
Parameter	**Description**
Collimation	Sub-millimeter
Rotation Time	Shortest possible
Pitch	Highest possible
Tube Potential*	120 kVp
Tube Current*	≤ 240 mAs
Radiation Dose Control	Per institutional requirements (1-3 mSv recommended for inspiratory acquisition; ultralow-dose CT with < 1 mSv should be avoided)
Reconstruction Slice Thickness	≤ 1.5 mm (series with slices thicker than 1.5 mm will not be accepted)
Reconstruction Slice Gap	**Contiguous or overlapping (slice gap > 0 mm is NOT permitted)**
Reconstruction Algorithm	High spatial frequency (bone/sharp); iterative reconstruction if available and validated
Reconstruction Orientation	Axial
Field-of-View (FOV)	Thoracic axial slices from most extreme lung apices to most extreme lung bases (costophrenic recesses included)
Acquisitions**	Single breath-hold full inspiration Single breath-hold full expiration
Image format	DICOM
Artifact	Images should not be significantly degraded by motion or metal artifact

**Tube current and potential should be adjusted based on subject size and dose control protocol*
*** Full inspiration is mandatory for all HRCT timepoints; expiratory scans are recommended for assessment of air trapping*

During QC of Historical **Screening/V1** HRCT scans, ERT QC will raise a query if any of the following is detected:

- Field-of-view coverage does not include the entire left and right lung

Appendix 1: The Image Management Solution (IMS)

1.0 IMS Access and Training

1.1 Site User Access and Training

ERT will provide web-based training sessions for sites detailing the processes required to create subjects, add timepoints for subjects, and upload timepoint images in the IMS. Detailed instructions, workflows, and descriptions of IMS eCRF content are also provided in the Appendix of this document.

Following the training and completion of training documentation, ERT will email trained site users with a link to ERT's Global Single Sign-on (GSSO) page and associated registration instructions. If the site user has not previously registered for an ERT study, he/she will be required to self-register. **Note sites must use the Google Chrome internet browser to access and use the ERT IMS platform (Internet Explorer/Microsoft Edge do not support the IMS functionality).**

Site users should only use their designated accounts to access the study. If the person responsible for transferring imaging via the IMS is absent for an extended period, a new user at the site should be identified with a training request submitted to ERT for the user. Additionally, if a site user is no longer employed at the site or participating in the study, the site should notify ERT to inactivate the user's access to the study. Sites should contact the ERT Customer Care for any technical issues pertaining to the use of the IMS. Detailed instructions for image upload will be provided to the site in the IMS Image Transfer Instructions document.

1.2 Sponsor User Access and Training

ERT will provide a representative(s) from United Therapeutics access to the "data review" user role in the IMS. This is a read-only user role for United Therapeutics to review the information completed by the site user(s), QC user(s), and/or central reviewer(s). The data review user(s) will be able to:

- View all subject timepoints and their current workflow status
- View submitted images for timepoints within the IMS (post-QC)
- View reader annotations (read-only)
- View completed eCRFs/Reports:
    - Timepoint Submission
    - Reader Assessments
    - Timepoint QC
- Download Reports:
    - Site Compliance Report - provides an overview of site submission information, current workflow states, and number of submission cycles for each timepoint
    - QC Compliance Report - provides an evaluation of QC performance for each timepoint (outstanding query information and turnaround time)
    - Image Analysis Compliance Report - provides an evaluation of a central reviewer's performance for timepoint (read status and turnaround time)
    - User Access and Activity Report - provides a summary of the users that have access to the study, their training dates, activation status, and date/time of last access to the study
    - Imaging Study Tracker Report - provides an overall status for each timepoint created in the study and any associated queries
    - Eligibility Reports

The data review user(s) must complete an ERT IMS training session before ERT will grant the user access to the study.

2.0 IMS Image Upload

Following the creation of timepoints in the IMS, sites will be required to upload associated HRCT images prior to timepoint IMS eCRF signoff. The IMS platform does not require the sites to install or download any plugins to support the upload process.

The expected format of the images for this study is DICOM. The process for upload is detailed below:

- Images for upload can be selected as single files, multiple files within a folder or by selecting an entire folder of images.
    - For reduced size and faster transfers, it is recommended that images required for upload are placed in a single folder, "zipped" and uploaded as a single file.
- The IMS will display the number and total size of files selected for upload and will display a status bar indicating the transfer progress.
    - Note that the site user may use the browser and computer to perform other tasks during the upload but should not close the upload page to avoid interruption of the transfer.
- Once the upload is complete, the uploaded images will be queued and processed by ERT's server.
    - The upload page will indicate how many images are in the queue ("pending") and processing ("running"). When all images have been processed the transfer status will move to "Loading Complete".
- After all files are uploaded, several items including thumbnails, acquisition date, series description, number of images per series, and modality will be shown for each image/series uploaded.
- If the site user believes an image/series was uploaded in error, he/she may "archive" the image/series preventing downstream user (ERT QC, readers, etc.) access. A change reason will be required and stored in the study's audit trail.

3.0 IMS Image De-Identification

During the "processing" step of the image upload process described above, a copy of the original images will be created and common DICOM header tags that often contain PHI will be cleared or replaced. The Patient ID DICOM tag will be replaced with the Subject ID and the Accession DICOM tag will be replaced with the Timepoint ID (a full description of DICOM tags that will be edited will be defined in the study's Requirements Specification). Original images will be archived and encrypted, preventing downstream users of the IMS (ERT QC, readers, etc.) from accessing or downloading the images.

Post-processing, ERT QC Specialists will review HRCT to determine if additional sources of PHI such as annotations of the subject's name or medical record number are present in the images. If any images contain such PHI, they will be archived preventing downstream user access. If these images are required for centralized review, ERT QC will perform a redaction of the PHI.

4.0 IMS Image Display

Once a given image/series is processed by the ERT server, it may be viewed in the IMS by ERT study personnel, the site user, ERT reviewers, and sponsor/CRO. The IMS viewer will allow the users to zoom, pan, adjust window/level, view DICOM header tags and advance frames/slices (note that central reviewers will not be able to view DICOM header tags).

Additionally, manufacturer, serial number, date of birth, gender DICOM tags extracted from HRCT image series prior to de-identification will be presented above the viewer (visible to all users except the central reviewers).