

DOC-4554 CT LVAS Imaging Protocol

For the chest CT scans, the radiologic technologist shall acquire a paired inspiration-expiration chest CT of the patient.

1. Imaging Protocol

- A standard non-contrast CT Chest protocol is recommended
- For the CT Scan, acquire a paired inspiration-expiration Chest CT of the patient
- Use the same resolution settings for both, the inspiration and expiration CT
- CT Scans acquired at deep inspiration and at deep expiration respectively

2. Patient Setup and Configuration

- The paired inspiration-expiration breathing phases shall be captured in a single study.
- Scan the patient in a supine position for both imaging breathing phases, aligning longitudinal axis of body with longitudinal axis of the CT scanning bed.
- Use imaging and reconstruction parameters consistent with a standard non-contrast CT Chest protocol (refer to Table 1)
- Field of View (FOV):
 - o Ensure patient's arms are out of the FOV, for example, by placing them above the head
 - o Ensure coverage is cranial-caudal lung apices through to lung bases
 - o FOV shall include the entire lungs (e.g., 1cm beyond the edge of the patient)
- It is recommended to do a verbal breath hold command for both inspiration and expiration series.



3. CT LVAS Input Imaging Requirements

To produce a CT LVAS Report, the inspiration and expiration CT images must meet the accepted requirements listed in Table 1. If the input images do not meet the criteria below, the images will be rejected, and no analysis will be undertaken.

Table 1: CT Requirements

■ 4DMedical	CT Requirements	
	Accepted	Rejected
Pixel Spacing	≤ 1.0mm	> 1.0mm
Slice Thickness	≤ 2.5mm	> 2.5mm
Slice Interval	≤ 2.5mm	> 2.5mm
Respiratory Phase	Inspiration/Expiration	Inspiration or Expiration Only
Study	Single Study	> 1 Study
Filetype	Uncompressed	Compressed
	Lossless Compression	
Patient Position	Supine/Supine	If the input data is not of adequate quality, the output CT LVAS Report results will reflect the input data quality.
Contrast	None	
Artifact	None	
Motion	None	
FOV	Unobstructed view of entire lungs	

3.1 Lung Volume Difference

CAUTION: The total lung volume difference between the inspiratory and expiratory CT images must be more than 0.5 liters (or more than 10% of the expiration CT volume). If the measured volume is less than 0.5 liters or 10% of the expiration CT volume, then no Report will be generated.

NOTICE: If the expiratory to inspiratory volume change is less than 0.8 liters and 20% of expiratory volume, the low values may be related to the image acquisition process and may not be representative of the patient's actual lung function.

If the notice is present on the Report and is not believed to be due to an error in the image acquisition, please contact 4DMedical using the information in the Instructions for Use, Section 10.



Document Revision History

Version	Brief Description of Changes
0	Initial release of document
1	Update to title of Document to be more representative of document content. Integrating the Imaging Protocol content from the IFU and adding the information regarding minimum volume requirements and CT low volume acquisition (Section 3.1 of this document). Removal of Example Breathing Instructions. Addition of recommendation for verbal breath hold command.
2	Updated accepted pixel spacing criteria in Table 1 from \leq 2.5mm to \leq 1.0mm and rejected pixel spacing from >2.5mm to >1mm.

DOC-4554 | V2 Page 3 of 3