



ThrombUS+ Study A Annotation Manual

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About ThrombUS+

Deep vein thrombosis (DVT) is the formation of a blood clot within the deep veins, most commonly those of the lower limbs, causing obstruction of blood flow. In 50% of people with DVT, the clot eventually breaks off and travels to the lung to cause pulmonary embolism. Clinical assessment of DVT is notoriously unreliable because up to 2/3 of DVT episodes are clinically silent and patients are symptom free even when pulmonary embolism has developed. Early diagnosis of DVT is crucial and despite the progress made in ultrasound imaging and plethysmography techniques, there is a need for new methods to enable continuous monitoring DVT diagnosis at the point of care.

ThrombUS+ brings together an interdisciplinary team of industrial, technology, regulatory, social science and clinical trial experts to develop a novel wearable diagnostic device for point-of-care, operator free, continuous monitoring in patients with high DVT risk. The device will combine autonomous, AI driven DVT detection based on a novel wearable ultrasound hardware, impedance plethysmography and light reflection rheography for immediate detection of blood clot formation in the lower limb. Activity and other physiological measurements will be used to provide a continuous assessment of DVT risk and support DVT prevention via serious gaming. The aggregated data will drive an intelligence decision support unit that will provide accurate monitoring and alerts. Extended reality will be used to guide experts to design exercises and patients to use the device optimally.

ThrombUS+ is intended for use by postoperative patients in the ward, during long surgical operations, cancer patients or otherwise bedridden patients at home or in care units, and women during pregnancy and postpartum. ThrombUS+ will use big data sets for AI training collected in the project via 3 large scale clinical studies and will validate the outcome in the clinical setting via 1 early feasibility study and 1 multi-center clinical trial.

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Terms and Definitions

Term	Definition
AI	Artificial Intelligence
EC	European Commission
EU	European Union
DICOM	Digital Imaging and Communications in Medicine
ACEP	American College of Emergency Physicians

Executive Summary

ThrombUS+ Study A aims to collect and create a labelled ultrasound image data set containing ultrasound image series and video clips of patients that undergo routine ultrasound scans on lower limbs, because of suspected deep vein thrombosis. The data will be used to train an AI model within ThrombUS+ project to achieve automated detection of deep vein thrombosis on conventional ultrasound scans. This document describes in detail the steps required to anonymize and annotate the acquired image series and videos using the US-DICOMizer application.

1. Introduction

This document (manual) outlines the step-by-step procedure for anonymising and annotating data using the US-DICOMizer application. The resulting data will be used for the development of the AI models for the ThrombUS+ project. The .zip file created after anonymisation and labelling includes the anonymised DICOM files and their respective .json files with the labels. This .zip file should be uploaded into the eCRF system, in the respective patient.

2. Anonymization

Transfer the acquired data to the local computer where the US-DICOMizer is installed. Load the DICOM files using one of the available import options. Add the DICOM files that should be anonymized to the “Ordered files” list one by one, or all files by pressing the <F6> button of the keyboard.

Follow the next steps for all files in the “Ordered files” list:

- Preview file
- If the cropping box is not set correctly upon preview, use the “**Auto**” or “**Mode**” buttons for setting it automatically. If none of these methods work, adjust the box by manually adjusting its edges. Press the “Apply” button.
 - **Optional:** before applying the cropping box, select the “**to all**” to apply the cropping box to all files in the list. Ensure the cropping box is set correct to all files.
- Select the appropriate tag to describe the anatomical site of the respective file.
- Repeat the process for all files until all filenames turn green in the “**Ordered files**” list, and all files have a tag.
- Set the patient’s ID in the “Patient ID” field and press “**Anonymize Loaded Images**”
- Wait for the process to complete, anonymized files will be transferred to the “**Anonymized DICOM files**” list.

3. Labelling

Labelling a DICOM file involves three steps. First, labels classify the **entire file**. Then, annotations are added to individual frames. These annotations include image grading using the **ACEP scale** and labelling visible **vascular** or **other structures**. Access to the labelling process is restricted to anonymised DICOM files so labelling should always follow anonymisation.

3.1. File Classification

1. **Goal:** To classify the entire DICOM file with respect to the visualized **anatomical site** as per the Data Collection Manual, and with respect to the presence of **Thrombosis**. In case of multi-frame DICOM the **Vein Compressibility** should also be annotated.
2. **Classification:**
 - **Tag:** This is the tag to discriminate the anatomical site of the acquired DICOM file and selected during the anonymisation process. It is read automatically, but can be changed if required.
 - **Thrombosis:** Defines the presence of thrombosis. The available options are:
 - “Empty”
 - Yes

- **No**

In case of the inadequate images, the **“Empty”** value should be selected.

If thrombus can be visualized in an image, set the Value to **Yes**.

- **Compressibility:** Defines the compressibility of the vein during compression. The available values are:

- **“Empty”**
- **Yes**
- **Partial**
- **No**

In case of an image where compressibility cannot be defined leave the value to **“Empty”**.

- **Review:** Check this value if performing the label review process, otherwise leave it empty. If label review is performed, ensure your unique ID has been set under the settings tab.
- **Protocol Deviation:** This box is to define if data is not acquired according to the Data Collection Protocol. If selected, a text for typing the reason this video should be excluded will appear. Type the reason of deviation. E.g. “video contains two compressions instead of one”, or “vein of interest goes out of view during compression” or similar.

3.2. Image Grading

1. **Goal:** Evaluate ultrasound image quality to determine their suitability for diagnostic purposes.
2. **Label:** Classification Tag based on the American College of Emergency Physicians (ACEP) five-point grading scale Table 1.
 - **Scores 1-2:** Non diagnostic.
 - **Scores 3-5:** Diagnostic

Table 1. Diagnostic grading scales according to ACEP

Grading Scale	1	2	3	4	5
Grading scale definition	No recognizable structures, no objective data can be gathered	Minimally recognizable structures but insufficient for diagnosis	Minimal criteria met for diagnosis, recognizable structures but with some technical or other flaws	Minimal criteria met for diagnosis, all structures imaged well, and diagnosis easily supported	Minimal criteria met for diagnosis, all structures imaged with excellent image quality and diagnosis completely supported

If grading score of 1 or 2 is selected the panel for labelling of structures will not be activated. In all other cases the structure labelling pane will be activated.

3.3. Labelling of Vascular Structures

1. **Goal:** Accurate identification and labelling of anatomical structures and potential pathologies.
2. **Label:** Segmentation mask (anatomical structures tracing) for the following categories:
 - **Target Veins:** Key focus for DVT diagnosis:
 - **Common Femoral Vein #1:** in the scanning location #1 (inguinal ligament).

- **Common Femoral Vein #2:** in the scanning location #2 (Great Saphenous junction).
- **Great Saphenous Vein #2:** in the scanning location #2 (Great Saphenous junction).
- **Femoral Vein #3:** in the scanning location #3.
- **Popliteal Vein #4:** in the scanning location #4.
- **Accompanying Arteries:** Helps distinguish arteries from veins and supports pressure assessments:
 - **Common Femoral Artery #1:** in the scanning location #1 (inguinal ligament).
 - **Common Femoral Artery #2:** in the scanning location #2
 - **Deep Femoral Artery #2:** in the scanning location #2
 - **Femoral Artery #2:** in the scanning location #2
 - **Femoral Artery #3:** in the scanning location #3
 - **Popliteal Artery #4:** in the scanning location #4
- **Clots:** Thrombi clots.
- **Other:** Pathologies or structures that may be mischaracterized as DVT (other pathology class)

4. Labelling Instructions

The following is a set of instructions for the annotation of the ultrasound images/videos during ThrombUS+ Clinical Study A. Frames must be annotated based on the diagnostic criteria used during a DVT exam to capture clinically relevant information.

- In a DICOM video, please disregard the first four frames and **begin labelling from the fifth** frame onward.
- On average, **5 to 7 frames should be annotated per video** to balance data richness and labelling efficiency.
- For an inadequate DICOM image, **apply the corresponding ACEP grading score and, if image quality permits (ACEP grade ≥ 2), segment (trace) all visible structures, including veins, arteries, and clots.**

The key frame selection criteria for the DICOM videos include:

1. Non-compressed/Neutral phase (1 frame):

- a) Frames where veins are of **their original shape and size** representing the neutral non-compressed state (Figure 1).
- b) In some cases, the video may begin in a partially compressed state. **If the neutral phase of the vessels appears later in the clip, after compression is released, please ensure it is still annotated.**

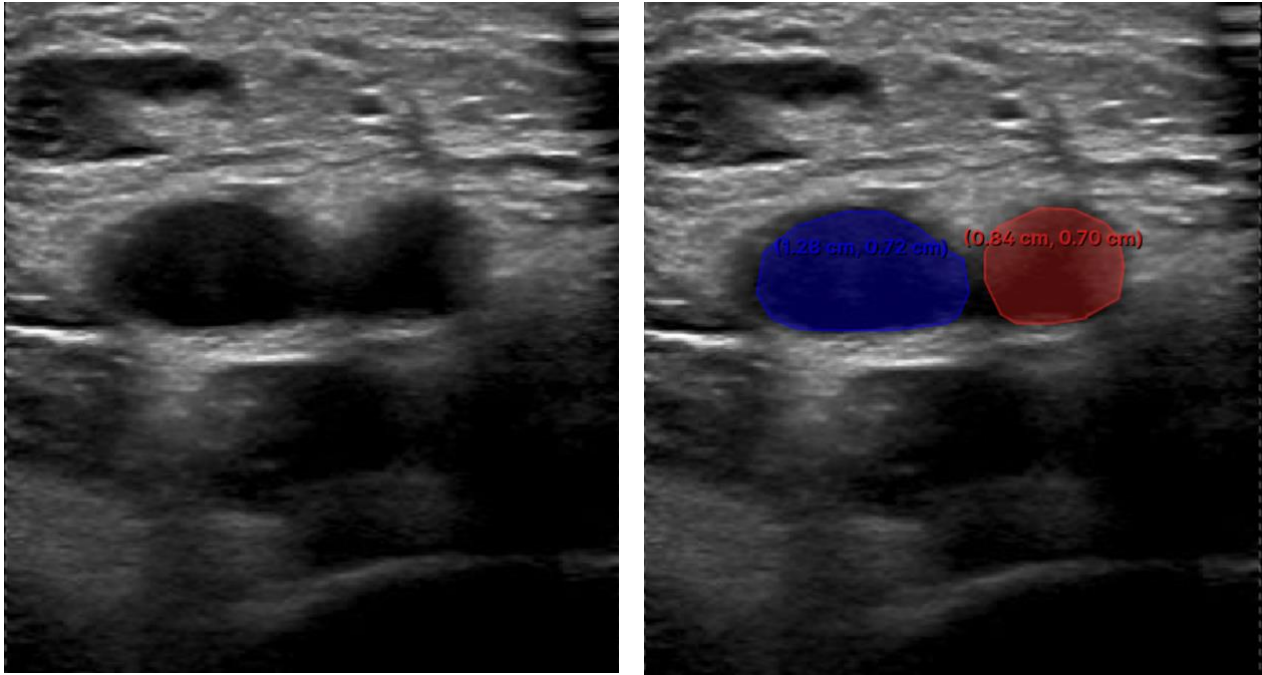


Figure 1. An example of annotating arteries and veins in the non-compressed/ neutral phase. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

2. Mild-Compression Phase (2-3 frames):

- a) Frames where veins are **partially compressed** (Figure 2).
- b) A total of 2-3 frames should be labelled.
 - One frame should be selected a few frames after the neutral phase, where the vein has visibly decreased in size.
 - Another should be chosen a few frames before the vein is fully compressed or collapsed, showing a significant reduction in size.
 - If possible, an additional frame can be included between these two points.

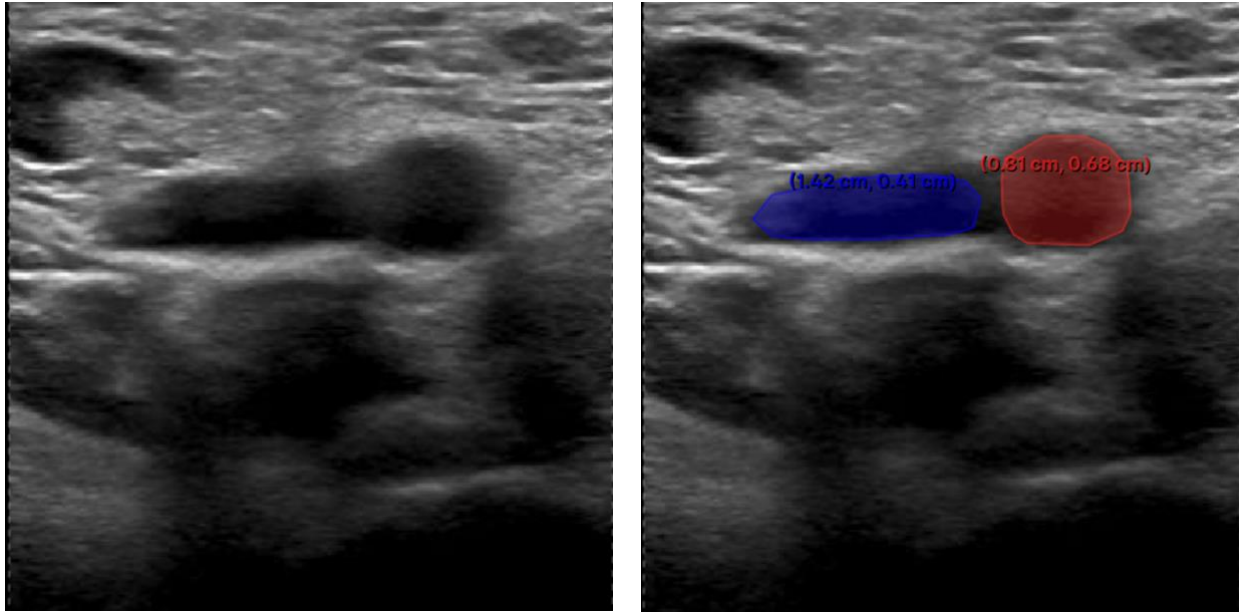


Figure 2. An example of annotating arteries and veins in a partially compressed state. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

3. Peak Compression Phase (1 frame):

- a) Frames where veins **either collapse or fail to collapse** under applied pressure should be labelled.
 - **For normal patients:** The vein will collapse completely, and this frame should be labelled. Even if the collapsed vein is difficult to distinguish, a very thin segmentation mask (tracing) should be applied where its border is best estimated.
 - **For pathological patients:** The vein will not fully compress, but a segmentation mask is still required at the frame where peak pressure is applied (usually when the accompanying artery is slightly deformed).

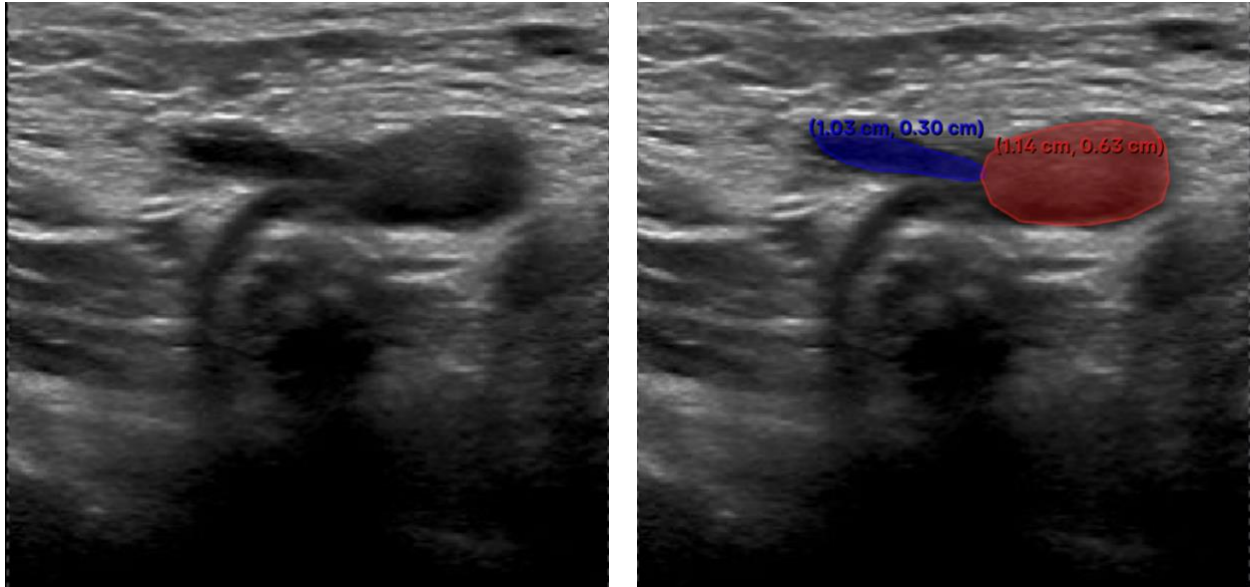


Figure 3. An example of annotating arteries and veins in a fully compressed state. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

4. Artery Deformation (1-2 frames):

- a) In addition to the previously mentioned key frames, where all visible veins, arteries, and clots are labelled, please also annotate **1-2 frames capturing the deformation of the arterial walls**.
- b) This marks the point at which compression should be stopped, especially in pathological cases where the compression increases, and the vein fails to collapse.

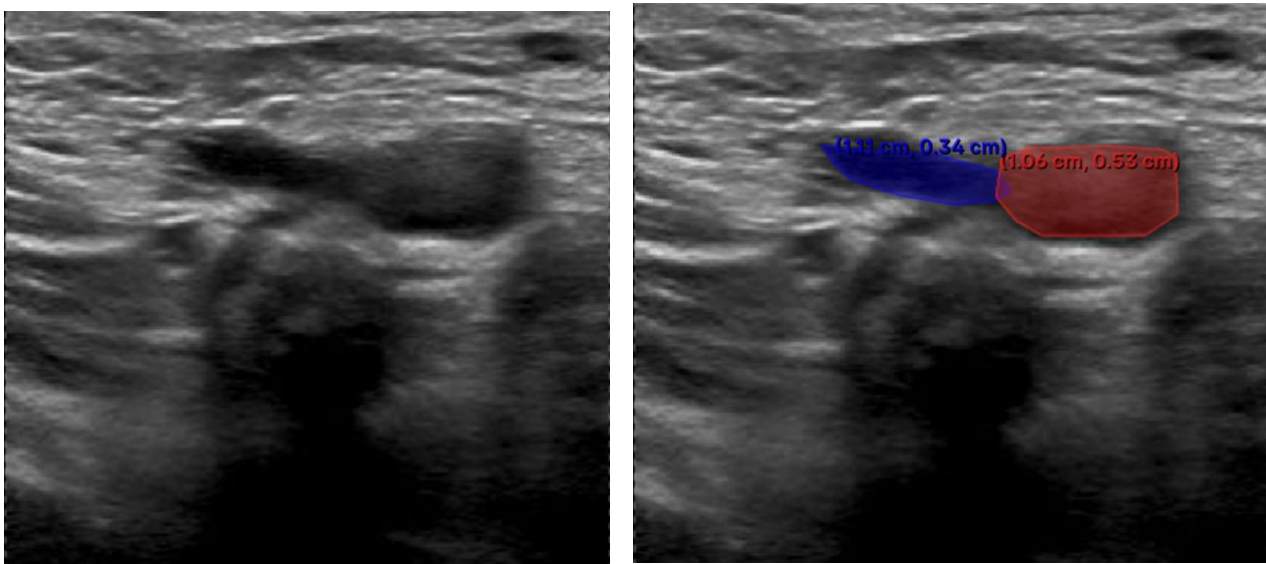


Figure 4. An example of annotating deformed arteries. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

5. US-DICOMizer Annotation Interface

After anonymizing, all anonymized DICOM files will appear under the “Anonymized DICOM files” list. The main use interfaces components for performing the labelling are the “**Image Preview**” with the sliding bar, the list with available anonymized files, and the “**Annotation**” panel, with all required labelling functionalities (Figure 5).

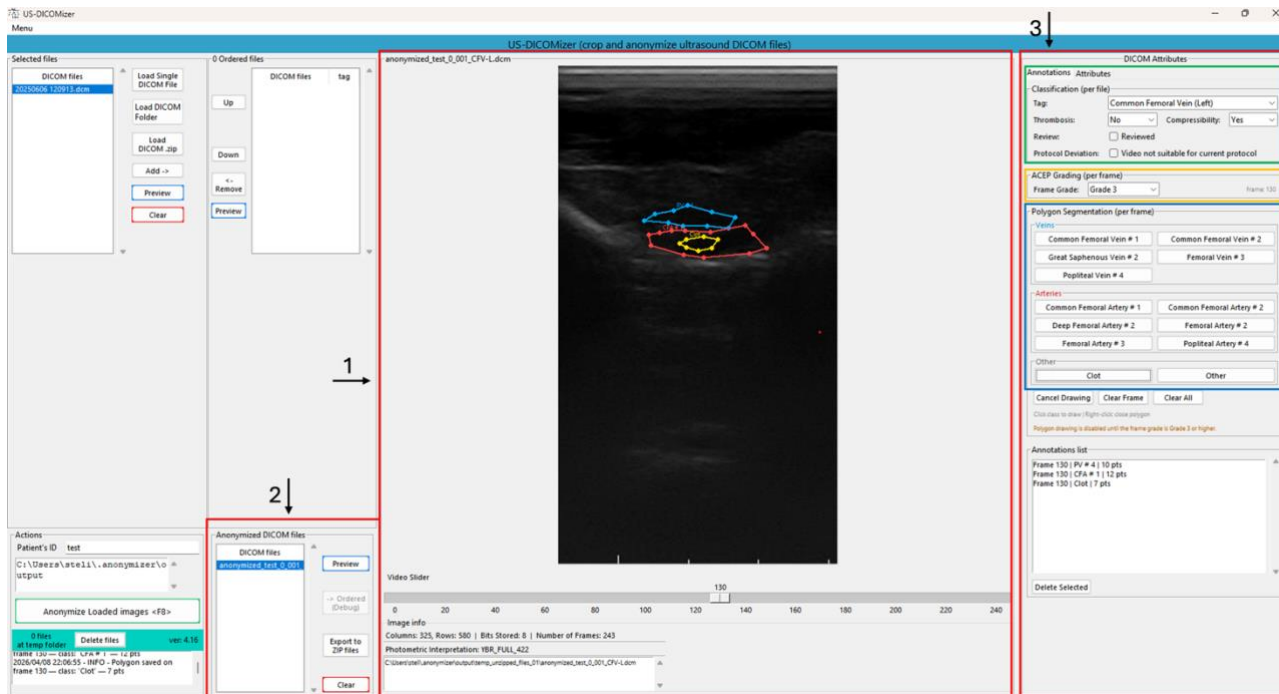


Figure 5.

After previewing an anonymized file, the “Annotation” panel will load all available annotations/labels for this specific file. The Annotation panel is divided in three individual components, as per labelling steps.

1. Classification (per file)

The panel contains labels that apply to the entire DICOM file. The “Tag” attribute is automatically set based on the tag that was selected during the anonymization step, however, it can be adjusted if required.

2. ACEP Grading (per frame)

The ACEP grading panel contains a dropdown menu with five different options, based on the ACEP grading score. The selected grading is applied to the specific frame that is currently visualized, in the case of a multi-frame DICOM file.

3. Polygon Segmentation (per frame)

This panel contains all the required buttons for selecting and drawing the respecting structures, required by this the annotation manual. To draw a structure, click on the respective label and then apply points in the image. To finalize the annotation, use the right click.

6. Step-by-Step DICOM Video Labelling Procedure

The following guide outlines the step-by-step process for **labelling key frames** in a multi-frame **DICOM clip**. This process should be repeated for each key frame specified in **Chapter 3**, which includes:

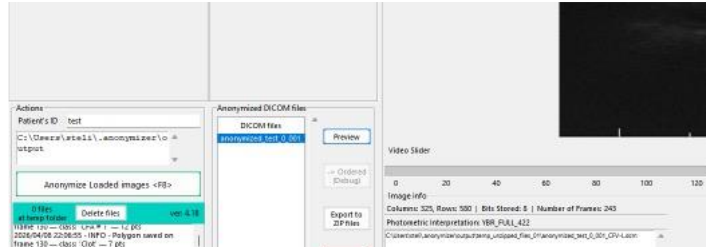
- Non-compressed/Neutral Phase (1 frame).
- Mid-Compression Phase (2-3 frames).
- Peak-Compression Phase (1 frame).
- Artery Deformation (1-2 frames).

Table 2. Steps to be followed for a multi-frame DICOM file annotation.

Step 1. Select and preview the anonymized DICOM file

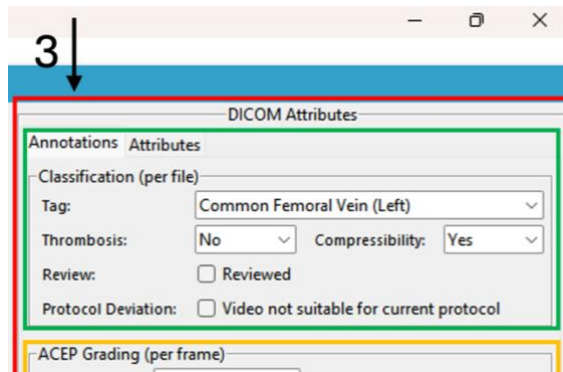
From the “Anonymized DICOM files” list:

- a) Select a file and press the “Preview” button (or double click)



- b) Use the Video Slider to scroll through the video.

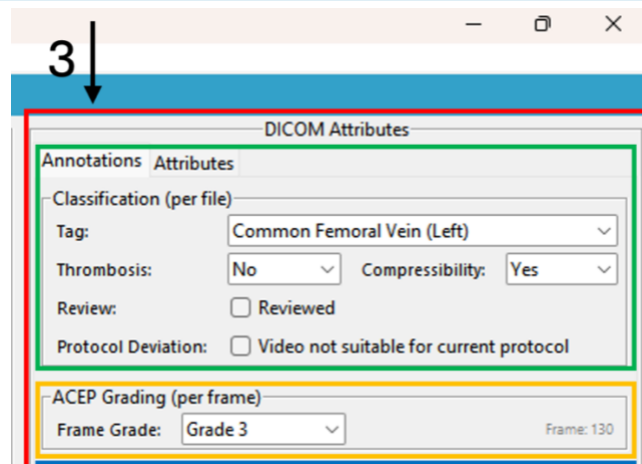
- c) Verify the Tag based on the anatomical site visualized in the image, set the Thrombosis to Yes or No and the Compressibility of the respective vein. If file is reviewed check the respective box, and if the video has not been acquired based on the acquisition protocol, check the “Protocol Deviation” box, and type your response in the field that will appear.



Step 3. Apply the ACEP grading score

Use the Video Slider to find the 1st frame where vein is uncompressed (neutral phase). Degrade the first four frames. Start annotation from the fifth frame.

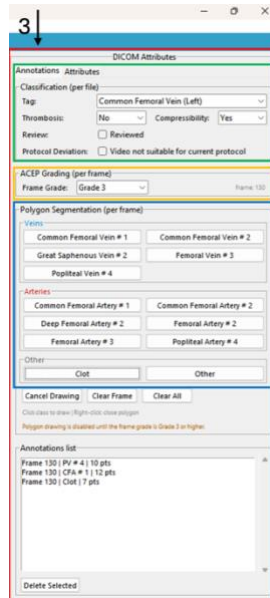
- a) Select the appropriate ACEP grading. The selected ACEP applies to the specific frame, indicated on the right side of the panel.



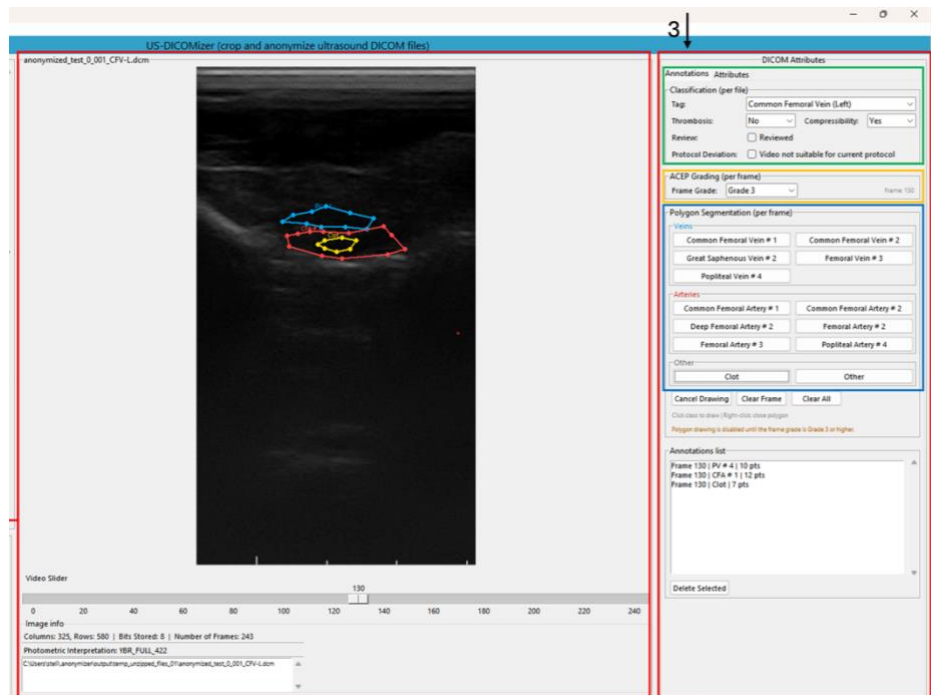
Step 4. Apply the segmentation masks

Use the functionality provided in the Polygon Segmentation panel.

- a) Select the appropriate structure to label.



- b) Press left-clicks to add points to annotate the periphery of the structure. Use as few points as possible to annotate the structure precisely.
- c) To finalize an annotation, press right-click.
- d) From the Polygon Segmentation panel, select the next structure to annotate and repeat steps b) and c).
- e) By pressing the “Clear drawing:” button, the currently drawn annotation will be deleted. Pressing the “Clear Frame” all annotations of the current frame will be deleted.



- f)

Step 5. Navigate to the next frame

Proceed with the next frame and repeat **Steps 3 and 4.**

- a) All Polygons draw will appear under the “Annotation list”.
- b) Double clicking an annotation will navigate to the respective frame of the polygon.
- c) Pressing the “Clear All” button will delete all

annotations from the current file.

- d) Click on the desired frame in the timeline.

Step 8. Export to .ZIP

When annotating all anonymized files is finalized, press the “Export to ZIP files” button, to create a .zip file with all DICOM and annotations. Upload the file to eCRF system and proceed with the next subject.