ThrombUS+ Study A Annotation Manual

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Horizon Innovation Action | Agreement No. 101137227
HORIZON-HLTH-2023-TOOL-05-05
Co-funded by the European Union

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Disclaimer

ThrombUS+ is an Innovation Action Project co-funded by the European Union, under HORIZON-HLTH-2023-TOOL-05-05 “Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery”.

Document Control Page

Project	
Grant Agreement:	101137227
Acronym:	ThrombUS+
Title:	Wearable Continuous Point-of-Care Monitoring, Risk Estimation and Prevention for Deep Vein Thrombosis
Type:	Innovation Action
Start:	1 January 2024
End:	30 June 2027
Programme:	Horizon Europe
Call Identifier:	HORIZON-HLTH-2023-TOOL-05-05
Call Topic	Harnessing the potential of real-time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery
Website:	http://thrombus.eu/

Revision History			
Version	**Date**	**Modification**	**Contributors**
0.1	14 Apr 2026	New content - Outline	S. Didaskalou [ATHENA]
0.2	3 June 2026	Updated based on v5.6 version of the software	S. Didaskalou [ATHENA]

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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.

Cite this Document as

Didaskalou S, Portoakllidis N, Kaldoudi E, ThrombUS+ Study A Annotation Manual, ThrombUS+ Horizon Europe Innovation Action, EC Grant Agreement No. 101137227, 20 April 2026.
https://doi.org/10.5281/zenodo.19577782

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 dataset 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 the 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 anonymizing, labelling and annotating the data using the US-DICOMizer application. The resulting data will be used for the development of the ultrasound AI models within the ThrombUS+ project. After completing the labeling and annotation process the exported .zip file should be uploaded to the eCRF system, for the respective patient. This .zip file includes both the anonymized DICOM files and the respective .json files with the labels and annotations.

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 on the keyboard.

Follow the next steps for all files in the "Ordered files" list:

1. Preview file
2. 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 similar files in the list (i.e. if an image (video) is previewed, the current cropping box will be applied to all images (videos) in the list). Ensure the cropping box is set correctly for all files.
3. Select the appropriate tag to describe leg laterality and the anatomical site of the respective file, using the radio buttons, on the right side.[1]
4. Repeat the process for all files until all filenames turn green in the "**Ordered files**" list, and all files have a tag.
5. Set the patient ID in the "Patient ID" field and press "**Anonymize Loaded Images**".
6. Wait for the process to complete, anonymized files will be transferred to the "**Anonymized DICOM files**" list.
7. **Optional**: To save the anonymized files without proceeding to labeling and annotation, press **"Export to ZIP files".** This will export all anonymized files to a .zip, without any labels or annotations. This file can be loaded later using the "Load .zip" button to proceed with the labelling and annotation process.

3. Labelling and Annotation

Labelling and annotating a DICOM file involves three steps. First, **labels are applied for classifying the entire** DICOM file**,** either referring to the entire image, or to the entire video (i.e. to all frames of a multi-frame DICOM). Second, image-based or frame-based labels are applied for classifying the **selected image** or **the current frame**, in the case of a multi-frame DICOM, based on the ACEP grading score. The third and final steps involves annotating visible anatomical structures, such as vascular structures. Access to the labelling and annotation tools is restricted only to anonymized DICOM files, so labelling and annotation should always follow the anonymisation.

[1] Didaskalou, S., Drosatos, G., Moustakidis, P., Sarafis, F., Sotiriadou, A., Velicka, L., Rimatis, M., Balciuniene, N., Grandone, E., & Kaldoudi, E. (2025). ThrombUS+ Study A Ultrasound Data Collection Manual (0.8). Zenodo. https://doi.org/10.5281/zenodo.16913651

3.1. Record-based labelling

Aim: To classify the entire DICOM file (either an image or the entire multi-frame DICOM) with respect to **leg laterality**, the **scanning location and DICOM type**, based on the Data Collection Manual, and with respect to the presence of **Thrombosis**. In the case of multi-frame DICOM the **Vein Compressibility** should also be annotated.

1. **Leg Laterality:** Defines the laterality of the visualized leg. This is prefilled automatically based on the selected Tag during anonymisation. Can be changed if it was set wrong during the anonymisation. Available values are:
    - **Left**
    - **Right**
2. **Scanning Location and DICOM type:** Define the anatomical site of the acquired DICOM including the type of the DICOM, based on the Ultrasound Scanning Protocol. This is prefilled automatically based on the selected Tag during anonymisation. Can be changed if it was set wrong during the anonymisation. Available values are:
    - **Common Femoral Vein Random Image**: For images acquired in the anatomical position of the common femoral vein (Scanning Location 1)
    - **Common Femoral Vein**: For multi-frame DICOM files, which corresponds to compression in the common femoral vein (Scanning Location 1).
    - **Great Saphenous Vein Random Image**: For images acquired in the anatomical position of the great saphenous junction (Scanning Location 2).
    - **Great Saphenous Vein**: For multi-frame DICOM files, which corresponds to compression in the great saphenous junction (Scanning Location 2).
    - **Femoral Vein Random Image**: For images acquired in the anatomical site of femoral vein (Scanning Location 3).
    - **Femoral Vein**: For multi-frame DICOM files, which corresponds to compression in the femoral vein (Scanning Location 3).
    - **Femoral Vein Doppler Random Image**: For images acquired in the anatomical site of femoral vein, supplemented with colour Doppler (Scanning Location 3)
    - **Femoral Vein Doppler:** For multi-frame DICOM files supplemented with colour Doppler, acquired in the anatomical position of the femoral vein (Scanning Location 3).
    - **Popliteal Vein Random Image**: For images acquired in the anatomical site of popliteal vein (Scanning Location 4).
    - **Popliteal Vein:** For multi-frame DICOM files, which corresponds to compression in the popliteal vein (Scanning Location 4).
    - **Optional View:** For images that is not included in the abovementioned cases, usually for images where a thrombus is directly visible, without the need of compression.
3. **Thrombosis:** Defines the presence of thrombosis in the respective image or the multi-frame compression video. The available values are:
    - **“Empty”:**
    - **Yes**
    - **No**

    For Images:

- If **image is of inadequate quality** and no visible structures are recognisable (ACEP Grading score 1 or 2; see below), select the "Empty" value.
- If **image is of adequate quality** (ACEP grading score 3, 4 or 5; see below):
  - If a **thrombus** is visible select "**Yes**".
  - If a **thrombus** is **not** visible select "**No**".
- for a multi-frame **compression video**:
  - select "**Yes**" if **thrombosis** is diagnosed
  - select "**No**" if **no thrombosis** is diagnosed

4. **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 set the value to "**Empty**".
5. **Review:** This field is reserved for define if the record has undergone a reviewing process, following the initial labelling and annotation process. This field should be left unchecked, otherwise instructed by the principal investigator. If record is under review, ensure your unique ID has been set under the settings tab. The unique ID will be provided by the ThrombUS+ consortium.
6. **Protocol Deviation:** This box is used to define if the respective data has not been acquired according to the Data Collection Protocol. If selected, a text box for typing the reason this video deviates from the Data Collection Protocol will appear. In the box 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- or frame-based labels and annotations

These steps include the labelling of specific images of frames from a multi-frame DICOM file, based on the ACEP grading score and the annotation of vascular or other structures, if visible, if visible.

3.2.1. ACEP Grading Score label:

Aim: Label the ultrasound image or the specific frame of a multi-frame DICOM based on image's quality to determine their suitability for diagnostic purposes. The label are based on the American College of Emergency Physicians (ACEP) five-point grading scale, as shown in Table 1. Those scores are summarized as:

- **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	Minimal criteria met for diagnosis, recognizable structures but with	Minimal criteria met for diagnosis, all structures imaged well, and	Minimal criteria met for diagnosis, all structures imaged with excellent image quality

	insufficient for diagnosis	some technical or other flaws	diagnosis easily supported	and diagnosis completely supported

3.2.2. Annotation of vascular or other Structures

Aim: To accurately annotate the contours of vascular structures, such as the veins and arteries, per anatomical site, or other anatomical structures that can visually be identified. These annotations should be included in all images, or individual frames of a multi-frame DICOM for which the **ACEP grading score have been set to 3 or greater**. For files that the ACEP grading score have been set to 1 or 2, the tools for annotating will not be accessible. The available annotation classes for this specific task includes:

1. **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.
2. **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
3. **Clots**: Visible thrombus/clots within the veins.
4. **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/frames/videos during **ThrombUS+ Clinical Study A and Clinical Study B1**. Frames must be annotated based on the diagnostic criteria used during a DVT exam to capture clinically relevant information.

4.1. For an image:

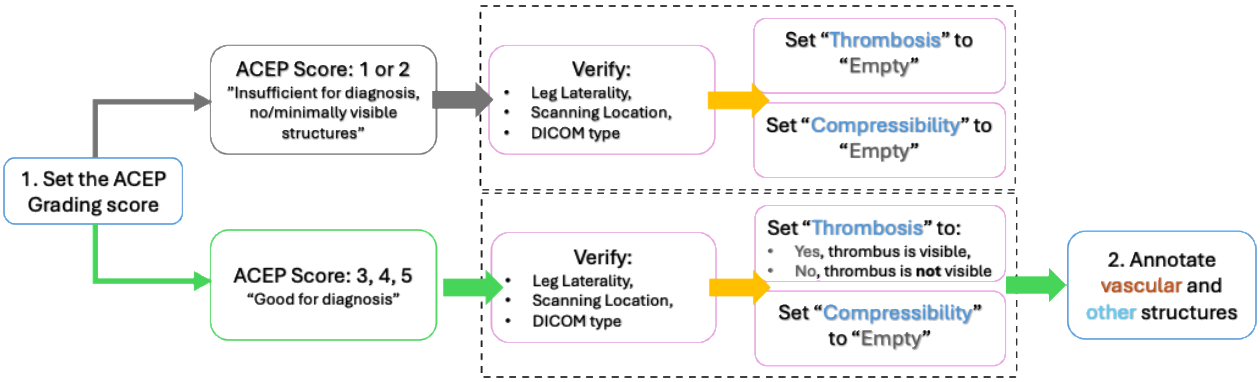


Figure 1. Flow chart summarizing the steps for labelling and annotating images.

1. **Set the actual ACEP grading score**:

– For an image with **ACEP** grading score of **1 or 2**:

- If possible, ensure the appropriate **leg laterality**, **scanning location and DICOM** type was set correctly during the anonymisation. If not, set the correct values. If the quality of the image does not allow to identify leg laterality or the scanning location, at least ensure that the selected DICOM type is "…Random Image".
- Leave the "**Thrombosis**" and "**Compressibility"** fields to "**Empty**", because ACEP grading 1 or 2, are defined as "insufficient for diagnosis, no or minimally recognizable structures" (Table 1).
- Similar, no vascular structures should be annotated, and the annotations tools will not be accessible.

– For an image with **ACEP** grading score of **3, 4 or 5**:

- Ensure the appropriate **leg laterality**, **scanning location and DICOM** type was set correctly during the anonymisation. If not, set the correct values.
- Set the Thrombosis field to "**No**" if NO thrombus is visible within the respective veins.
- Set the Thrombosis field to "**Yes**" if a thrombus is visible within the respective veins.
- Set the Compressibility field to "**Empty**", because the compressibility cannot be assed from a static image.

2. **Annotate** all visible vascular or other structures, using the annotation tools available, for images that the **ACEP grading** score was set to **3, 4 or 5.** Add as less points as possible to accurately trace the structures.

4.2. For compression videos:

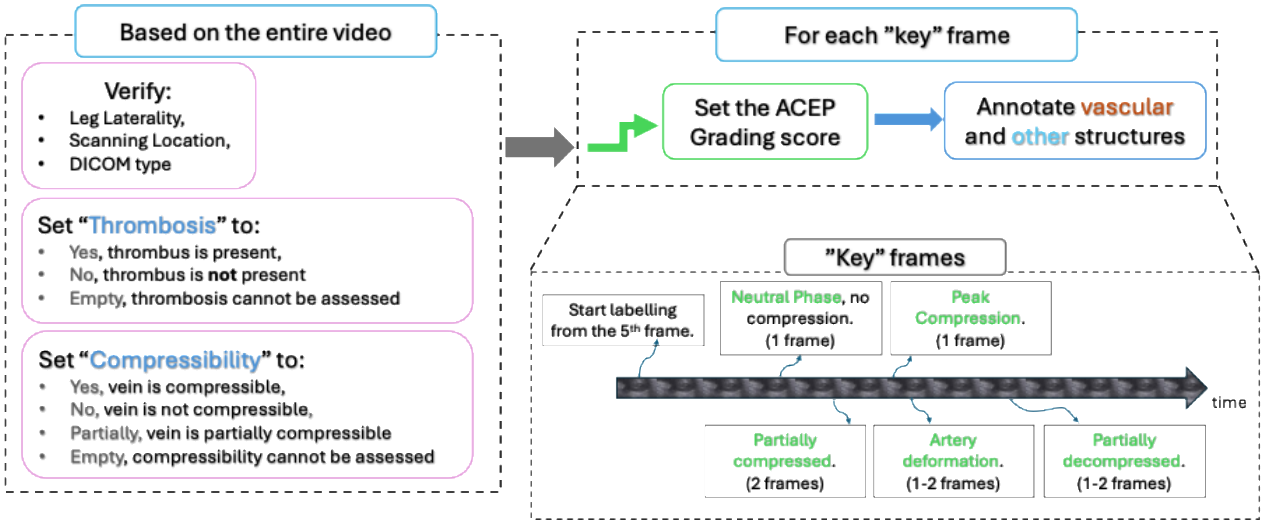


Figure 2. Flow chart summarizing the steps for labelling and annotating compression videos. The "key" frames that should be labelled and annotated are also indicated.

1. Ensure the appropriate **leg laterality** and **scanning location and DICOM type** was set correctly during the anonymisation. If not, set the correct values.
2. Explore and asses the entire compression video to set the "**Thrombosis**" and "**Compressibility**" values.
    a. If from the video the "Thrombosis" or vein "Compressibility" cannot be defined, set the respective values to "Empty".
    b. Activate the **Protocol Deviation** checkbox and type the reason the Thrombosis and/or Compressibility cannot be assessed (e.g. "vein moves out of field of view during compression", etc.).
    c. If "**Thrombosis**" and "**Compressibility**" can be defined, but the video deviates from the data acquisition protocol, activate the **Protocol Deviation** checkbox and note the reason of deviation (e.g., "video contains two compressions instead of one", etc.)
3. **Label and annotate key frames** from the entire video.
    a. Do NOT label or annotate the first 4 frames and **begin the labelling and annotation** from the **5th (**or more if possible**)** frame onward.
    b. On average, **5 to 7 frames** should be labelled and annotated per video to balance data richness and labelling efficiency.
    c. The key frame selection criteria are:
        i. **Non-compressed/ Neutral phase (1 frame):** frames where veins are of their original shape and size, representing the neutral non-compressed state (Figure 3).
            - Set the **ACEP** grading score.
            - **Annotate** all visible structures, including, **veins, arteries, clots, or other structures.** Add as less points as possible to accurately trace the structures.
            - 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.**

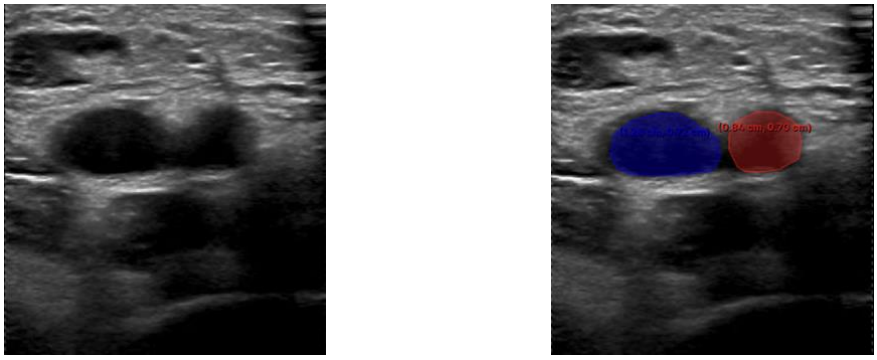


Figure 3. An example of annotating arteries and veins in the non-compressed/ neutral phase. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

ii. **Mild-Compression Phase (2-3 frames):** Frames where veins are **partially compressed** (Figure 4).

- One frame should be selected a few frames after the neutral phase, where the vein has visibly decreased in size.
  - Set the **ACEP** grading score.
  - **Annotate** all visible structures, including, **veins, arteries, clots, or other structures.** Add as less points as possible to accurately trace the structures.
- Another should be chosen a few frames before the vein is fully compressed or collapsed, showing a significant reduction in size.
  - Set the **ACEP** grading score.
  - **Annotate** all visible structures, including, **veins, arteries, clots, or other structures.** Add as less points as possible to accurately trace the structures.
- **Ideally**, an additional frame can be included between these two points.

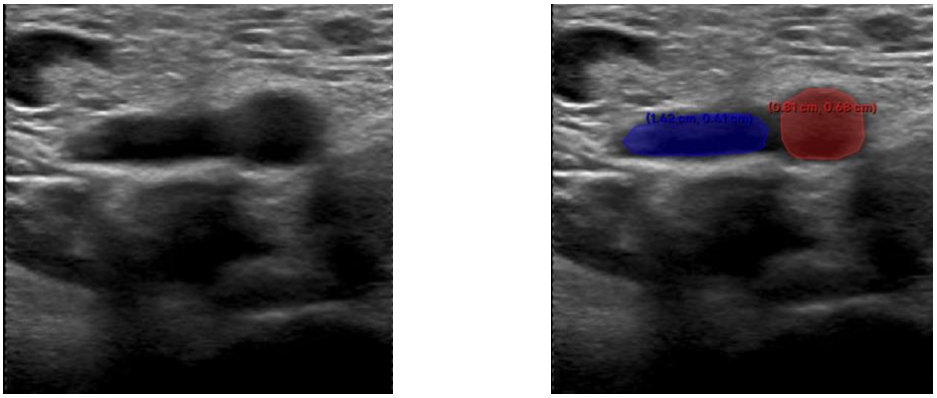


Figure 4. An example of annotating arteries and veins in a partially compressed state. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

iii. **Peak Compression Phase (1frames):** Frames where veins **either collapse or fail to collapse** under applied pressure should be labelled (Figure 5).

- **For normal patients (1 frame):** 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 (1 frame):** 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).
    - Set the **ACEP** grading score.
    - **Annotate** all visible structures, including, **veins, arteries, clots, or other structures.** Add as less points as possible to accurately trace the structures.

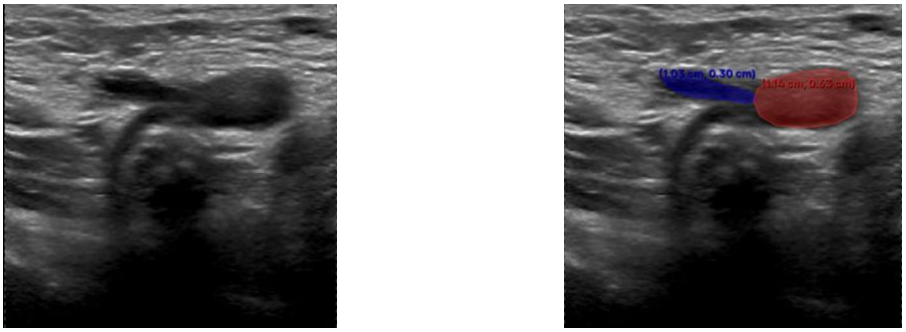


Figure 5. An example of annotating arteries and veins in a fully compressed state. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

iv. **Artery Deformation (1-2 frames):** In addition to the previously mentioned frames, please also annotate frames capturing the deformation of the arterial walls. This marks the point at which compression should be stopped, **especially in pathological cases where the compression increases** and the vein fails to collapse. In normal patients, if artery deformation is not visible, this step can be skipped. **In pathological patients, annotate 2 frames because data are limited for this specific case.**

- Set the **ACEP** grading score.
- **Annotate** all visible structures, including, **veins, arteries, clots, or other structures.** Add as less points as possible to accurately trace the structures.

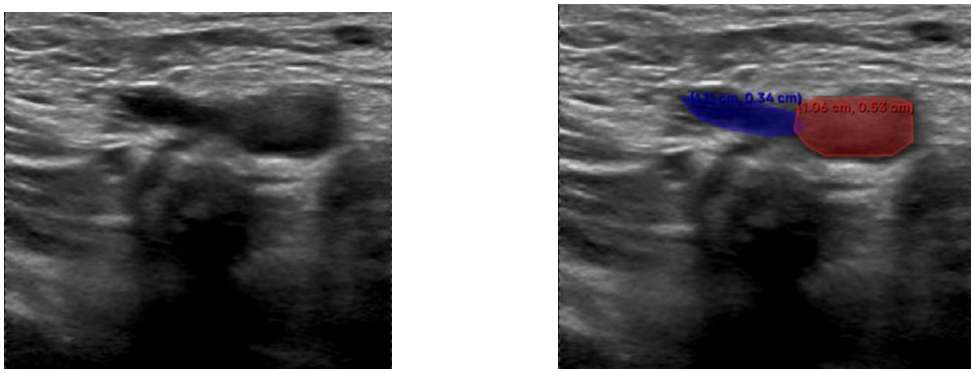


Figure 6. An example of annotating deformed arteries. Left: a single frame from a multi-frame DICOM file. Right: Annotation of CFV (blue) and CFA (red).

v. **Mild-Decompression Phase (1-2 frames):** Frames where veins are **partially compressed** (during the decompression phase) (Figure 4).

– One frame should be selected a few frames after the peak compression phase, where the vein has visibly increase in size.
  - Set the **ACEP** grading score.
  - **Annotate** all visible structures, including, **veins, arteries, clots, or other structures.** Add as less points as possible to accurately trace the structures.

– **Ideally**, an additional frame should be included when the vein has obtained its original size (neutral phase).

5. US-DICOMizer Annotation Interface

After anonymizing, all anonymized DICOM files will appear under the "Anonymized DICOM files" list. The main user interfaces components for performing the labelling and annotation are the "**Image Preview**", including the sliding bar to navigate through a multi-frame DICOM file, the list with available a**nonymized files**, and the "**Annotation**" panel, including all required labelling and annotation fields and tools (Figure 7).

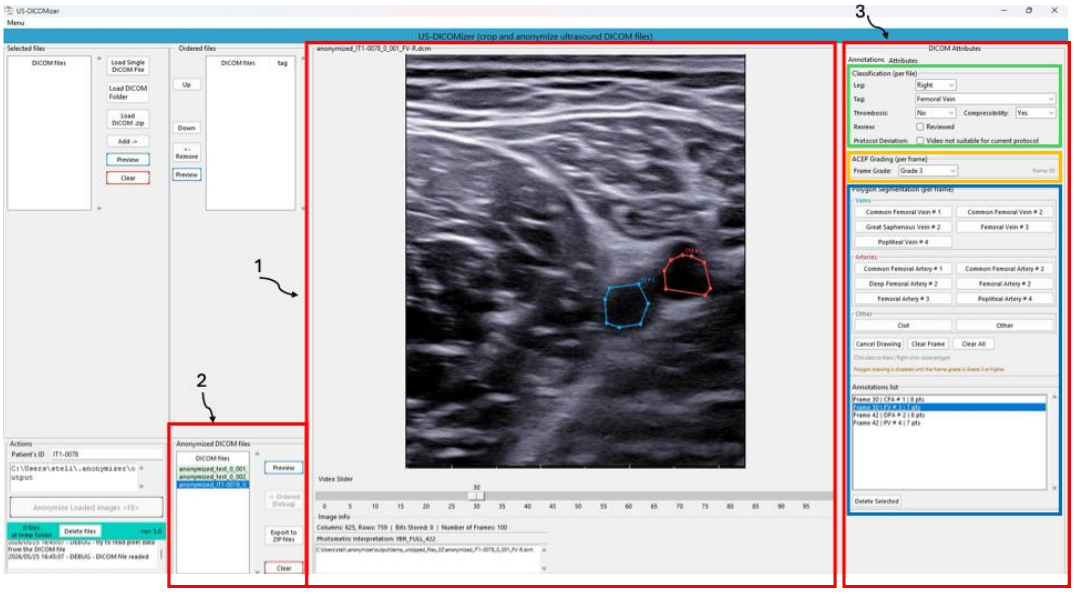


Figure 7. The US-DICOMizer main interface components for labelling and annotating anonymized ultrasound files. 1) The preview panel, where the currently selected ultrasound image or frame is visualized, including all annotations added to the specific image or frame. 2) The list with the anonymized DICOM files. 3) The labelling and annotation panel, which includes all required fields and tools for image and video labelling and annotation. Fields in green box, represent labels that are file-based. The ACEP grading score dropdown menu is enclosed in a yellow box, while the tools for annotating vascular or other structures on the currently displayed image/frame are enclosed within the blue box.

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” (leg laterality and anatomical site) 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.

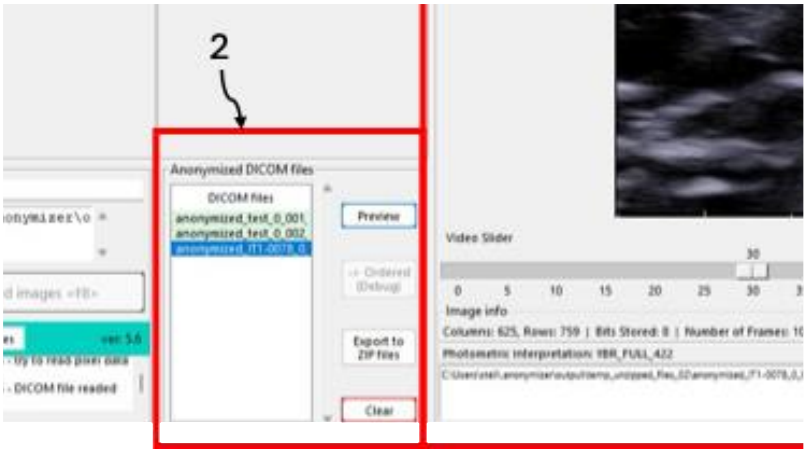
3. Polygon Segmentation (per frame)

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.

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

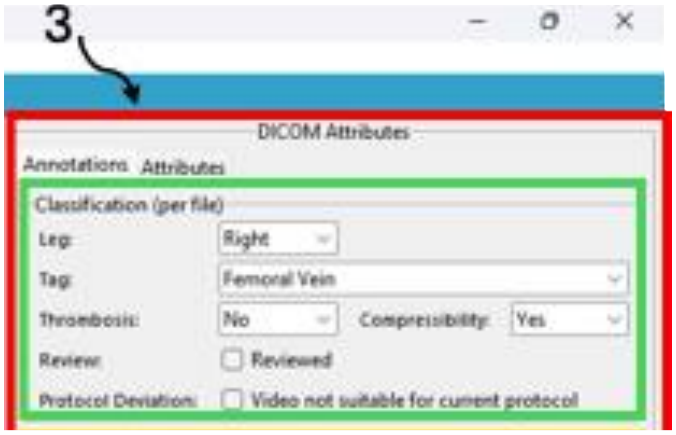
Step 1. Select and preview the anonymized DICOM file
From the "**Anonymized DICOM files**" list:

a) Select a file and press the "Preview" button (or double click)



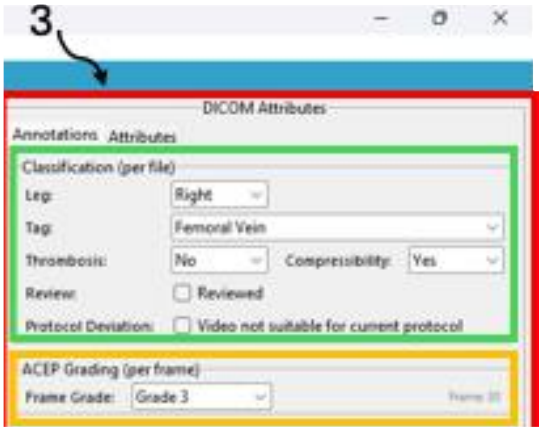
b) Use the Video Slider to scroll through the video.

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.

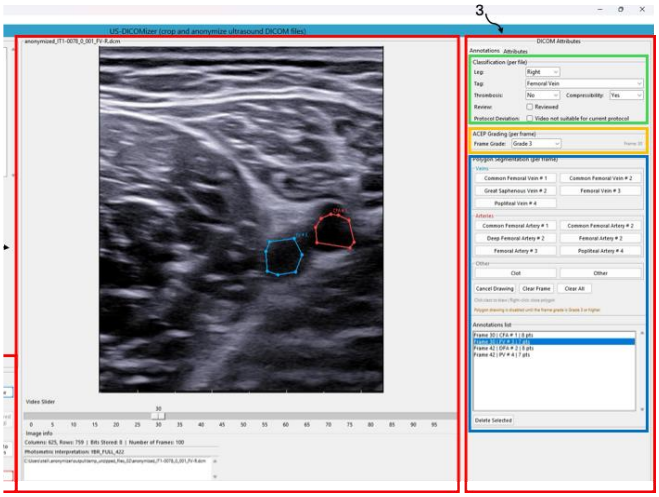
a) Select the appropriate structure to label.

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.



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.