	Title:	Carotid Intima Media Thickness		
clsa élcv Canadian Longitudinal Study on Aging Étude longitudinale canadienne sur le vieillissement	Version Date:	2019-OCT-28	Document Number:	SOP_DCS_0011
	Effective Date:	2019-DEC-16		
Data Collection Site (DCS)	Version:	4.4	Number of Pages:	8

1.0 Purpose:
The purpose of this document is to describe the standardized procedure for measuring carotid intima media thickness (cIMT).

2.0 Scope:
This document is to be used by DCS staff when measuring participants' cIMT.

3.0 Responsibilities:
DCS staff are responsible for performing the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:
- **SOP_DCS_0041 -** VIVIDi Maintenance

- **MAN_DCS_0011_1** - Additional Training Manual Carotid Intima Media Thickness

- **MAN_DCS_0011_2** - cIMT Image Reference Guide

5.0 Definitions:
Not applicable

6.0 Equipment:
- GE VIVIDi

7.0 Supplies:
- Aquasonic Ultrasound gel;

- 3 – Meditrace Foam 230 electrodes;

- Cleaning solution of either P Spray or CaviWipes;

- Scott brand, SHOP towels for multipurpose use;

- Rubber or Nitrile gloves;

- Kleenex or tissues;

- Pillow and neck roll; and.

- Step stool to assist getting on/off exam table.

8.0 Procedure Steps:
Contraindications:
- Participant unable to stand without the assistance of another person.

NOTE: Interviewers are required to ask participants whether they have a pacemaker, or degenerative disk issues in the neck. Interviewers must add a comment if either is present.

Step 1: Have the participant lay down on the examination table. Place a pillow under their knees and a neck roll under their neck (only if patient wishes – it is sometimes easier for a patient to tilt their head back without a neck roll). If an ECG was not performed prior to beginning cIMT measurements, the participant must rest for a minimum of 5 minutes BEFORE starting. **steps 2-8** below can be completed during this "rest" period.

Step 2: Press the *on/off* switch on the VIVIDi machine to turn it on. Press the **Patient** button on the left. Press **Log on** (use the trackball to move to log on) and then press **Set.**
NOTE: Please be sure to log in to the VIVIDi machine under your user name. For steps of how to change the user name, see *MAN_DCS_0011_1 - Training Manual Carotid Intima Media.*

Step 3: Use the trackball to move to the onscreen button **Create New Patient,** and press **Set**. Enter ONLY the participant interview ID number in the participant number box, then select or push the soft-key **Create Patient** to begin.

> **NOTES:**
> - This application is pre-set for a vascular scan using a 12L probe with settings: frequency of 12 Mhz; depth of 3 cm; one focal point.
>
> - Focal point location can be moved closer to the far (bottom) wall of the carotid artery by pressing the **Focus** soft-key, then pressing the **left arrow head** to lower the focal point (moving closer to the far wall) and the **up arrow head** to raise it.

Step 4: Explain the procedure to the participant before starting. Here are some suggestions:
- "I'm going to take an ultrasound image of the blood vessels in your neck."

- "I'll attach 3 surface recording electrodes to you, 2 near your collarbones, and one below your left (or right) ribcage. These will record the electrical signal from your heart, which is needed to assess the neck ultrasound images. No current flows from them or the machine into your body—they are only recording information from you."

- "I'll place this ultrasound probe (show probe to participant) on your neck, with some gel on its end that helps me get a clear image. The gel feels cool, but won't stain your skin or clothes. Apart from the slight pressure and coolness of the probe on your skin, you won't feel anything at all. Any questions before I start?"

- "Please stay quiet and relax during the test, and I'll let you know if I need you to move or adjust your position."

Step 5: Place 3 electrodes on the participant for recording ECG: 1 below the left clavicle (attach the LA-black lead); 1 below the right clavicle (attach the RA-white lead); 1 below the ribcage on either the left or right side (attach the LLred lead). Clip the long electrode leads to the participant's shirt or gown so that its weight is not pulling on the leads and electrodes.

Step 6: Ask the participant to tilt their chin up slightly, and turn their head slightly away from you (this works for some people, however straight back will work too) or toward you, depending on what side of the neck you are working on and your room setup. The participant should be as comfortable as possible with this positioning during the test.

Step 7: Apply a generous amount of ultrasound gel to the probe, and place it on the participant's neck. Start by finding the area of interest. Though the final carotid image must be taken in a **longitudinal** view, it may be easier to start in **cross sectional** view (optional). Cross sectional view is achieved by pointing the arrowhead on the side of the probe toward the midline of the participant's neck. When you find the carotid artery in cross-sectional view (the jugular vein will be visible as well), hold the probe in place but turn it 90 ° for longitudinal view **with the arrowhead pointing superiorly (toward the top of the head).**

Vein

Artery

The vein will compress when pressure is applied from the probe.
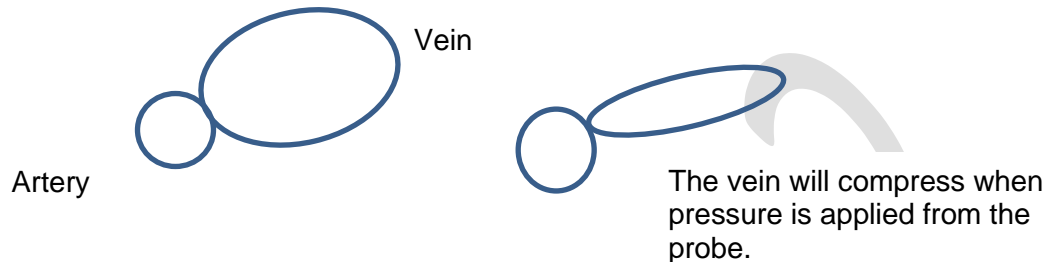
Step 8: Slide the probe superiorly (toward the head) or inferiorly (toward the feet) until the bifurcation of the common carotid artery (CCA) appears on the left side of the screen. This is the ideal location for imaging and carotid IMT measurements, and will help to standardize repositioning during follow-up assessments. **Optimize IMT visualization** through contrast enhancement using the TGC sliders and rotary gain dial, and by making small changes to the probe position with subtle fanning/sweeping/side to side tilt, heel/toe and/or twisting/corkscrew movements. The layers of the IMT MUST be clearly visualized.
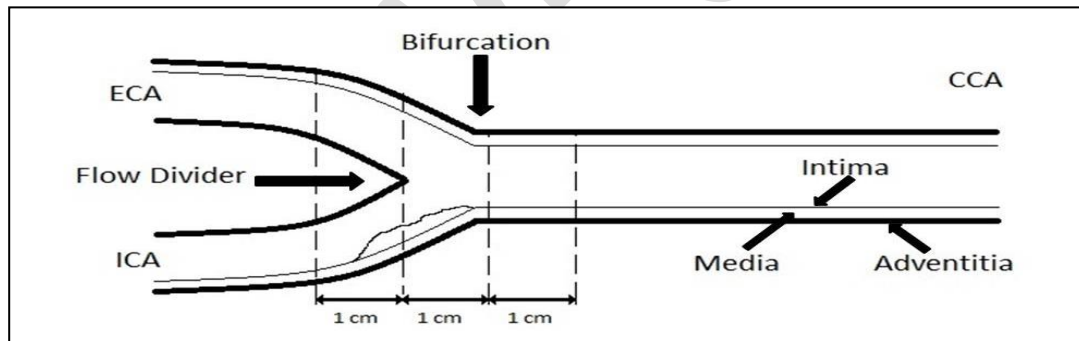
NOTE: IMT is assessed in longitudinal view from the arterial far wall, along a 10mm length. The IMT appears as a double line, perpendicular to the ultra sound beam.

Step 9: When you have a clear image of the IMT, observe at least 3 consecutive cardiac cycles (cineloop) then press **Store** to preview the saved cineloop (recording). If the cineloop is:

- **Good quality** and the IMT is clearly visible, press **Store** again to accept the cineloop.

- **Not ideal**, press **Freeze** to delete it and repeat **Steps 7-9** as required.

    An ideal cineloop shows the carotid bifurcation on the left side of the image, includes 3 complete cardiac cycles on the ECG tracing, and shows a clear double line pattern of the IMT.

Step 10: cIMT Measurement can be done immediately after the cineloop is saved, or later but before the data are transferred.

- Push the **Trackball** button to activate the curser, use the trackball to move the cursor and select the thumbnail image representing the stored cineloop, then press **Set**. The cineloop will play and repeat.

- Press the **2D** button **(located on the right side)** to freeze the cineloop so you can scroll through it frame by frame using the ECG tracing as your guide.

- In 2D mode, use the trackball to move the red cursor along the ECG tracing to the first cardiac cycle, to a point **at or near the end-diastolic point where the IMT is clearly visible.** Press **Measure**, select **CCA IMT,** then **CCA IMT POST,** and select **Right** or **Left**.

- Use the trackball to move to the desired starting point for the cIMt measurement, ideally just to the right of the carotid bifurcation and within the lumen of the artery, above the intima and not touching it. Press **Set** to anchor the starting point of the measurement.

- Use the trackball to move the cursor to the right of the measurement starting point, **ideally 500 points** away as indicated in the Region of Interest (ROI) box shown on screen. Press **Set** to anchor the measurement end point in the artery lumen above the IMT.
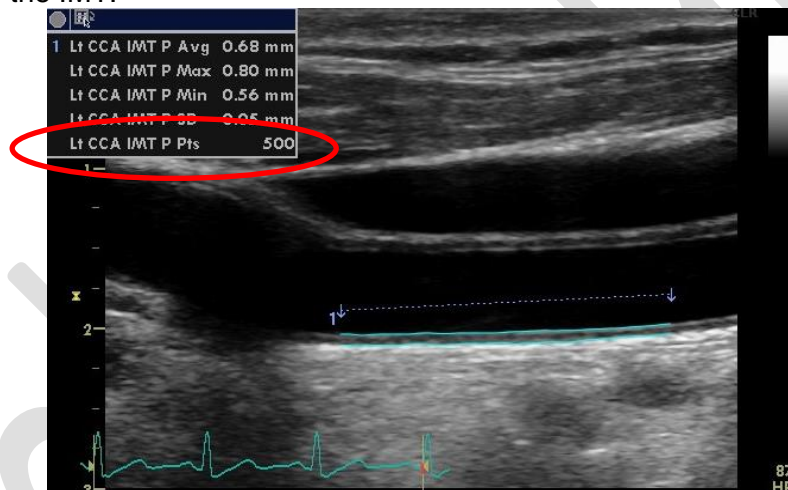
- The IMT measured will be outlined blue on screen, and should be relatively straight and uniform from start to end (see Figure 1). If the intima or media outlines deviate off the target, particularly at the start or end of the measurement, discard the measurement (do not Store it) and try again. Try to anchor the measurement start and end points closer to the intima but not touching it, or try a starting point more distal to the (right of the) carotid bifurcation.

  NOTE: If a quality IMT measurement cannot be achieved with 500 points in the ROI, include less IMT (fewer points) but not less than 250. The more points included in the ROI and the IMT measurement (up to 500 points), the better. IMT is calculated at each point included in the ROI (Figure 2).

- The onscreen box (upper left of screen) shows data for the IMT measured in the ROI, including average, maximum, and minimum IMT, the standard deviation and the number of successful IMT measurements (points) included in the analysis.

Figure 1:
Shows the start of the carotid bifurcation, at the IMT measurement starting point.
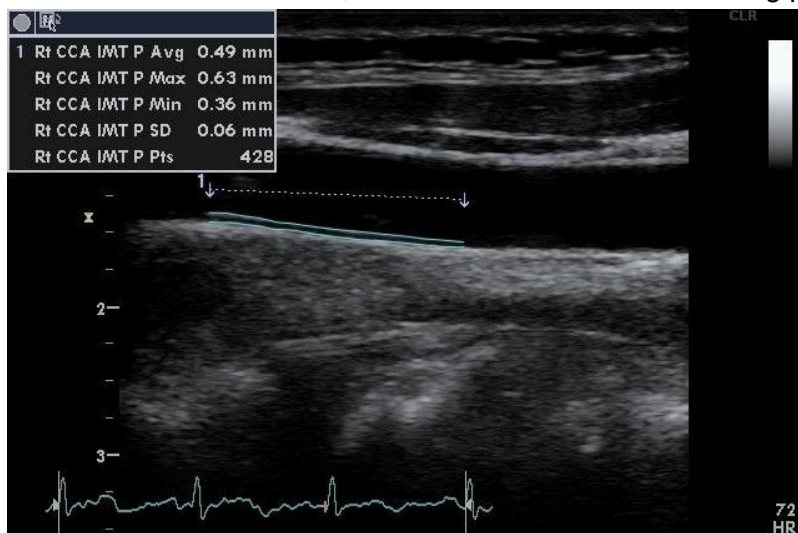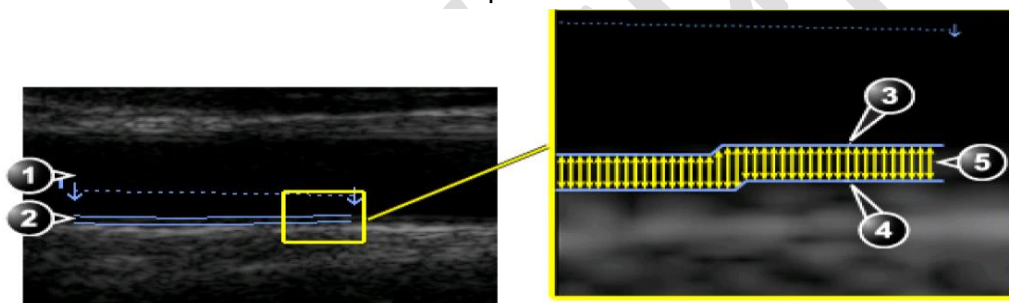

Figure 2:
1. lumen of the artery
2. artery wall, with intima and media outlined in blue;
3. intima;
4. media;
5. intima-media thickness measured at each point included in the RO

- When satisfied with measurement quality, press the onscreen **Transfer** button (located in the right menu box) then press **Store.**

- **Complete a cIMT measurement at or near the end-diastolic point in the next 2 cardiac cycles. There should be 3 cIMT measurements in total, one for each of 3 cardiac cycles.**

Step 11: Press the **Patient** button and select **Current Patient Information** and **Set** (this will store all the images to the hard drive). Select the image just completed, press **Set** (if it is already selected you don't need to press set). Move to the bottom left of the screen to click on the **Code** button then press **Set,** click on the **Add** and press **Set**. Highlight the appropriate side/label for these images, e.g., "Right carotid intima", and double click **Set** and then **Done**.

Step 12: Once the previous image is coded, press the **More** button at the bottom of the screen. Then click on **Add Exam** to begin tests on the opposite side.

Step 13: Give the participant a tissue to remove the gel from their neck or offer to wipe the area for them.

Step 14: Repeat **Steps 8 to 13** for the cIMT measurement on the opposite side.

Step 15: Have the participant remove their own electrode patches.

Step 16: Remove the coupling gel by wiping the probe lens with a Scott Towel.

Step 17: Wipe the probe and cables with either Cavi Wipes (use gloves) for 3 minutes; or, P Spray by dampening one Scott Towel before wiping the probe and cables.
NOTE: If using P-Spray wait 10 minutes before moving to the next step. If using Cavi Wipes continue immediately.

Step 18: Dampen a second cloth with water and wipe the probe and cables until all soap is removed.

Step 19: Dry the probe and cables with a Scott Towel.

Step 20: When all measurements are completed, and before file transfer, check that all images are labeled and 5 files have been saved for both right and left sides: **1 cineloop including 3 cardiac cycles; 3 still image files including cIMT measurements; 1 SR file**

Step 21: Press the **Patient** button. Select **End Exam** button.

Step 22: Open the *Carotid Intima* stage in Onyx. **Scan** the participant's barcode to open the Onyx session.

Step 23: Press **Start,** and then **Start** again to open the DICOM server. Select **Stop** and then change the Hostname/IP to your actual site (e.g. Mac's starts with 192). Press **Start**.

Step 24: Return to the VIVIDi: press the **Patient** button and go to the **Patient List** by clicking on the participant table at the bottom of the screen**,** select the ID of the participant by moving the cursor over the "+" sign (of that participant) and press **Set**.

Step 25: Select Right Carotid Intima (or Left if the right side was not completed) and press **Set**. Press the **Export** button, click on **Ok** and then the **Copy** button. Wait until all files have copied, then press **Ok** and next select the **Done** button. **Optional:** Press Alt and S at the same time to reveal the DICOM spooler. Wait until the status of both files "status" says <u>done</u>. Press the **Hide** button to close this window.

Step 26: **In Onyx:** When all 5 files have transferred, click on the white space below the word "laterality". Select either the "Right" or "Left", depending on which side the image is from.
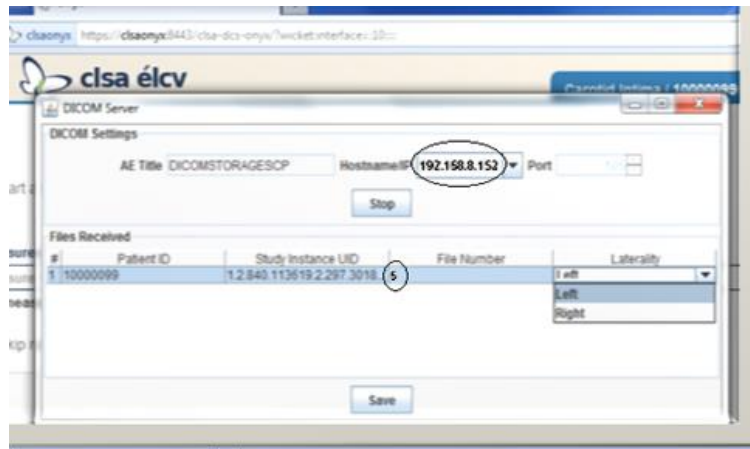
Step 27: **In VIVIDi:** Go back to the Patient List and select the left cIMT, repeat **steps 25-26**.

Step 28: **In Onyx:** Press **Save** at the bottom of the Dicom Server box. An *Upload box* will appear, follow the instructions. Select the "skip remaining measurements" if the image was only done on one side, type in the reason for the missing measurement. Click on **Refresh** if necessary, then **Next**. The *Conclusion* screen will appear and indicate that you have completed the measurements.

Step 29: Click **Finish**. The *Carotid Intima: Finish* window will pop up.

Step 30: Indicate in the **Comment** field in Onyx if there was anything that may have affected or influenced the measurement. Ensure that comments do not contain any personally identifying information.

Step 31: Click **Continue** to return to the status page.

After completing their quality review (approximately once a month) of the images the super user will notify the staff that they can delete the images from the machine.

9.0 Documentation and Forms:
Not applicable

10.0 References:
- Touboul PJ, Hennerici MG, Meairs S, Adams H, Amarenco P, Bornstein N, et al. Mannheim carotid intima-media thickness consensus (2004-2006). An update on behalf of the Advisory Board of the 3rd and 4th Watching the Risk Symposium, 13th and 15th European Stroke Conferences, Mannheim, Germany, 2004, and Brussels, Belgium, 2006. Cerebrovasc Dis. 2007; 23(1):75-80.

- Vivid i/Vivid q User Manual. Volume 1. Revision 2. Freiburg: General Electric Co.; 2008.

F2 Revision History:

New Version #	Revision Date	Revision Author	Content Approval
4.4	2019-OCT-28	Lorraine Moss	Harriet Sauve
Summary of Revisions			
General formatting throughout documents.			
Updated paragraph after step 31.			
Updated Step 5 – 7			