 clsa élcv Canadian Longitudinal Study on Aging Étude longitudinale canadienne sur le vieillissement	Title:	Carotid Intima Media Thickness		
	Version Date:	2015-JUL-27	Document Number:	SOP_DCS_0011
	Effective Date:	2015-JUL-29		
Data Collection Site (DCS)	Version:	4.1	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:

Not applicable

5.0 Definitions:

Not applicable

6.0 Equipment:

- GE VIVIDi

7.0 Supplies:

- Aquasonic Ultrasound gel;
- 3 – Meditrace Foam 230 electrodes;
- Mild dishwashing detergent;
- Two clean, soft, lint-free cloths;
- Water;
- Two spray bottles:
 - 1 filled with a gentle dish detergent and water solution; and,
 - 1 filled with clean water;
- Kleenex or tissues; and,
- Pillow and neck roll.

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. The participant must rest for 5-10 minutes before the test begins (complete steps 1 to 8 during the rest time) if the ECG was not performed.

Step 2: Press the on/off switch on the VIVIDi machine to turn it on. Press **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 - the additional VIVIDi training manual*.

Step 3: Use the trackball to select the phrase **Create New Patient** on the screen and press **Set**. Enter only the participant interview ID (in the participant number box). Then select **Create Patient** to begin.

The application will be pre-set for the 12L probe and a vascular scan. Frequency of 11 Mhz, depth of 4cm, with one focal point. Note that the location of the focal point can be adjusted to be as close as possible to the far (bottom wall) of the carotid artery.

Step 4: Explain the procedure to the participant before starting. Here are some suggestions:

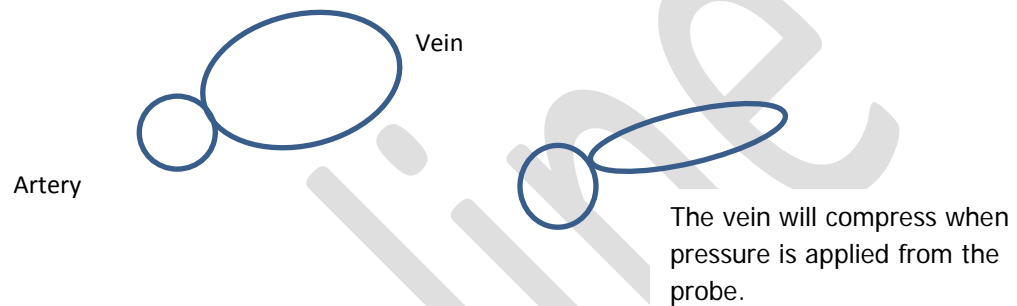
- Now I am going to take an ultrasound image of your neck
- I am going to attach 3 electrodes to you. They will not send an electrical current into your body, but instead measure the current of the heart. (Then explain to the participant where the electrodes will be placed).
- Next I will place an ultrasound probe on your neck and I will place some gel on the probe. It will be cold, but won't stain.
- Can you move your chin up and angle it slightly over in the direction?
- Do you have any questions? When the probe is on your neck, please do not talk because talking will affect the image.

Step 5: Place 3 electrodes on the participant: one just below the left clavicle (attach the LA-black lead) and another just below the right clavicle (attach the RA-white lead). The final electrode is placed on either the left or right side of the body just below the rib cage (attach the LL [Lower limb]-red lead). Clip the

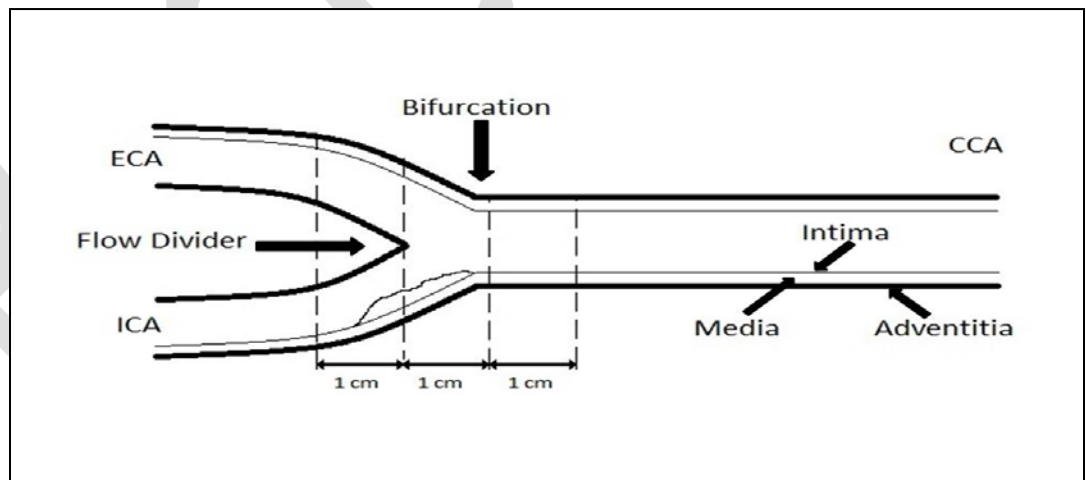
long electrode leads to the participant's shirt or gown so that the cord is not pulling on the leads.

Step 6: The participant's head must be 45° in the opposite direction of the probe (with the chin pointed up). Apply ultrasound gel to the probe.

Step 7: Using the probe find the area of measurement. The arrow on the side of the probe should be pointed inwards toward the participant. It may be easier to **start** with a cross sectional view. The carotid image must be taken in a **linear** view. When you have found the carotid artery, turn the probe 90 ° for the **linear** view with the v point **up** the body. The probe should also be at a 90° angle to the neck.



Step 8: Locate the bifurcation of the common carotid artery (CCA) and keep it just on the left side of the screen.



NOTE: Intima Media Thickness (IMT) is assessed in a longitudinal view, where the double-line pattern is observed, strictly perpendicular to the ultrasound beam. Localization of the CCA bifurcation is necessary to help in repositioning during follow-up. IMT should be measured on the far wall along a 10 mm length.

Step 9: 3 consecutive cardiac cycles (cineloop) need to be captured. When you have a clear image, press **Store**, to preview the saved cineloop. If the cineloop is

good, then press **Store** again, to accept. If the cineloop is not ideal, press **Freeze** to delete.

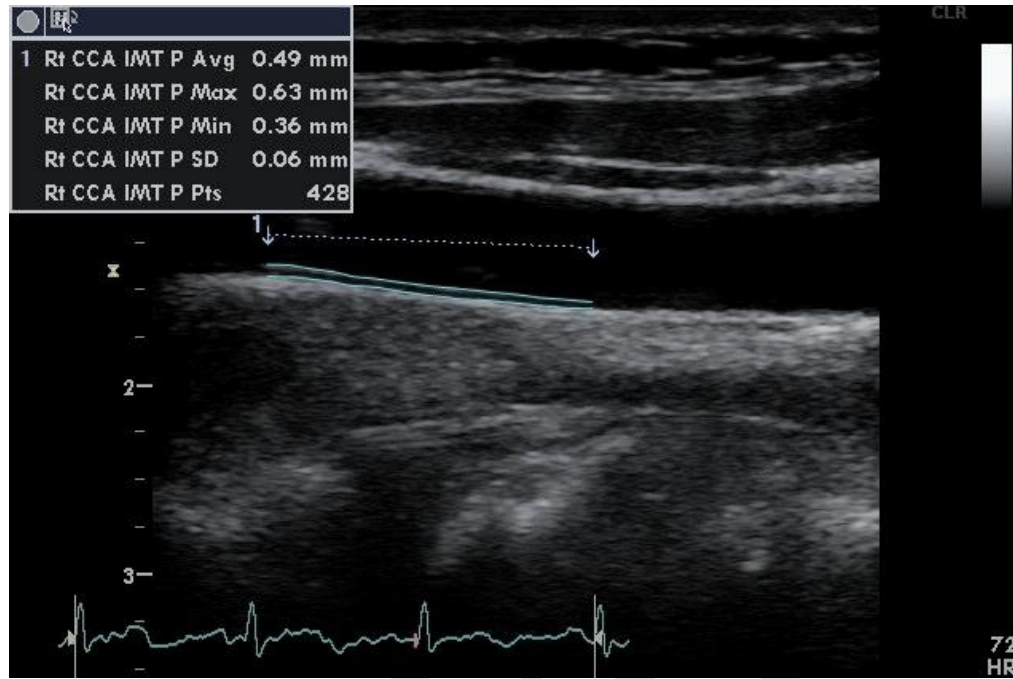
Ideal consecutive cycles- 3 complete heart beats with a clear double line pattern of the IMT and bifurcation visible.

Step 10: cIMT Measurement (this can be done later, but before the data are transferred)

- Use the Trackball button to select the pointer and move to the desired thumbnail image, then press **Set**.
- Press **2D (located on the right side)** to freeze the image and give you the ability to scroll to the correct frame in the cardiac cycle.
- Using the red cursor scroll to an the first diastolic point where the intima layer is clearly visible. Press **Measure**, select **CCA IMT**, then **CCA IMT POST** appears and select **Right** or **Left**.



- Place the vertical cursor above the anatomical reference point on the left (the narrowing after the bifurcation), press **Set** (to anchor the first point).
- Then extend the cursor to the right and the Region of Interest (ROI) box will appear (toward the narrowing after the bifurcation). Aim for a box size of about 500 points. **NOTE:** If 500 pts cannot be achieved the minimum points should be 250 pts if there is obvious plaque or loss of image. It is better to get a clear IMT with 250 pts than to get 500 pts.
- Move the ROI box up or down to cover the posterior wall of the carotid vessel, press **Set** to anchor in the 2nd point. The detected contours will be drawn. If not drawn, select a point closer to the intima layer.
- The box on the left will display the average, maximum, minimum cIMT, Standard deviations and the number of successful cIMT measurements (points).



*Picture above does not show the bifurcation.

- Press **Transfer** (located in the right menu box) then **Store**.
- NOTE: You can re-analyze the IMT again if the analysis was incorrect.
- **Repeat cIMT Measurement at the diastolic point in the next 2 frames.**

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 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 the leftside cIMT.

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

Step 14: On the left side repeat **steps 8 to 13** again.

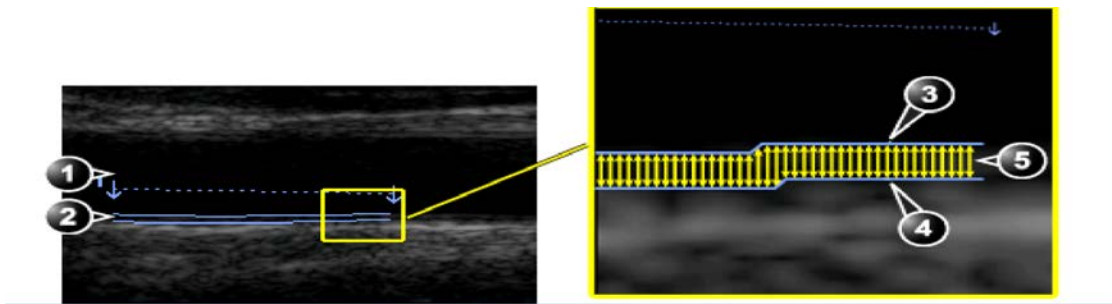
Step 15: Have the participant remove their own electrode patches.

Step 16: Remove the coupling gel by wiping the probe lens with a soft lint-free cloth.

Step 17: Dampen one soft, clean cloth using the spray bottle containing the pre-mixed mild detergent and water and wipe the probe and cables.

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 soft towel.



Step 20: When all measurements are completed, and before sending, check that all images are labeled and the correct numbers have been saved.

Right cIMT- 5 images (1 loop (3 cardiac cycles), 3 STILL_IMAGE files and 1 SR file)

Left cIMT- 5 images

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. This is usually done after the participant leaves.

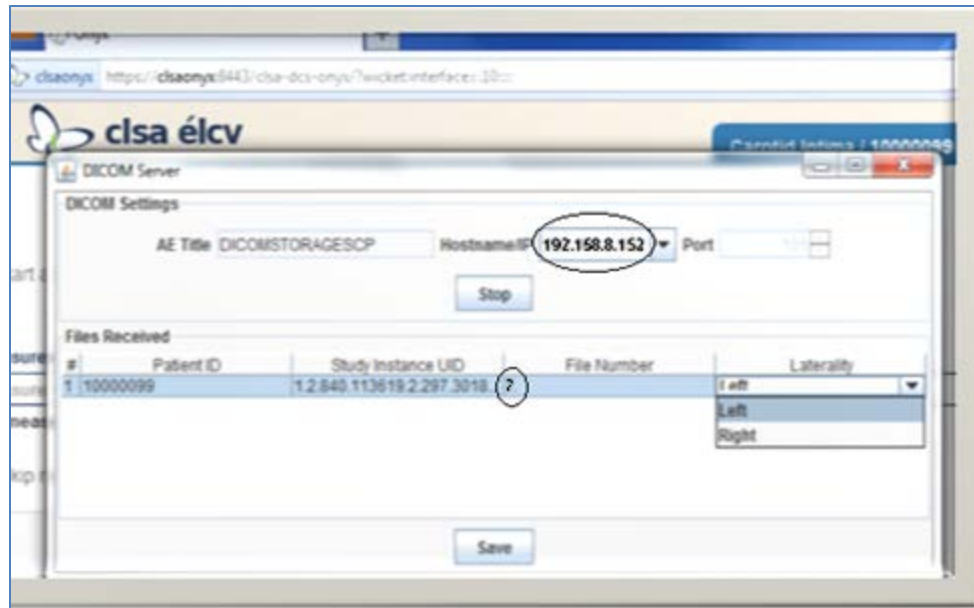
Step 23: Press **Start**, and then **Start** again to open the DICOM server. Select **Stop** and then change the Hostname/IP to your actual site (e.g. Mac's starts with 192). Press **Start**.

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 one saved exam at a time (e.g., right carotid intima) and press **Set**. You must send one of the cIMT images first, for example the right cIMT. 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 done. Press the **Hide** button to close this window.

Step 26: Back to Onyx: When the expected images 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.

NOTE: You need to wait until 7 files have transferred for the cIMT.



Step 27: Back to VIVIDi: Go back to the Patient List and select the left cIMT to send (repeat **Steps 25-26**).

Step 28: Still in Onyx: Press **Save**. 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.

At the end of the day all successfully transferred images must be deleted, refer to the additional training manual for the VIVIDi to delete.

9.0 Documentation and Forms:

- **CRF_DCS_0011** - Carotid Intima-media Thickness Case Report Form
- **MAN_DCS_0011_1** - Additional Training Manual Carotid Intima Media Thickness-
- **MAN_DCS_0011_2** - cIMT Image Reference Guide

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.

Baseline Revision History:

New Version #	Revision Date	Revision Author	Content Approval
4.1	2015-JUL-27	Lorraine Moss	Mark Oremus
Summary of Revisions			
Updated required files that are now being taken: 75 image files (1 loop (3 cardiac cycles), 3 STILL_IMAGE files, and 13 SR files).			
New Version #	Revision Date	Revision Author	Content Approval
4.0	2015-JUN-15	Lorraine Moss	Mark Oremus
Summary of Revisions			
Updated Supplies list and added Steps 16-19 to describe final cleaning instructions.			
Removed Steps that referred to taking the carotid artery plaque image, which has been removed for Follow-Up 1.			
Updated required files that are now being taken: 75 image files (31 loops (3 cardiac cycles each), one 3 STILL_IMAGE files, and one 3 SR files).			
Step 10, point three , clarified: Using the red cursor scroll to an end the first diastolic frame point where the intima layer is clearly visible.			
Added as last point in Step 10: Repeat cIMT Measurement at the diastolic point in the next 2 frames.			
New Version #	Revision Date	Revision Author	Content Approval
3.2	2014-AUG-20	Lorraine Moss	Mark Oremus
Summary of Revisions			
SOP formatting updated.			
Wording of Scope, Purpose and Responsibilities updated and clarified.			
Updated the CI section “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.”			
Clarified Step 6: “The participant’s head must be 45° in the opposite direction of the probe (with the chin pointed up). Apply ultrasound gel to the probe.”			
Clarified Step 12: Searching for carotid artery plaque: When you have located the carotid again, press the Freeze button twice to reset the memory. Visualize the region of the bifurcation and the proximal internal carotid artery; move the probe slowly along the artery down towards the body and then slowly back up to the bifurcation. Press Store , and then Select All to acquire the whole sweep and then Store again to accept it.			
New Version #	Revision Date	Revision Author	Content Approval
3.1	2013-Oct-1	Lorraine Moss	Mark Oremus
Summary of Revisions			
Step 2 – Added NOTE: Please be sure to log in to the VIVIDi machine under your user name. Added reference to VIVIDi Additional Training Manual.			
Step 7 edit (in italics) – It may be easier to <i>start</i> with a cross sectional view. <i>The carotid image must be taken in a linear view.</i> When you have found the carotid artery, turn the			

probe 90 ° for the <i>linear</i> view with the v point up the body.			
<p>Step 9 edit (in italics) - The box on the <i>left</i> will display the average, maximum, minimum cIMT, Standard deviations and the number of successful cIMT measurements (points).</p> <ul style="list-style-type: none"> Then extend the cursor to the right and the Region of Interest (ROI) box will appear toward the narrowing after the bifurcation). Aim for a box size of about 500 points. <p>NOTE: If 500 pts cannot be achieved the minimum points should be 250 pts if there is obvious plaque or loss of image that.</p>			
<p>Step 17 (in italics and crossed out) – When all measurements are completed, and before sending, check that all images are labeled and the correct numbers have been saved.</p> <ul style="list-style-type: none"> → Right cIMT- 5 images (3 loops (3 cardiac cycles each), one STILL_IMAGE file and one SR file and one saved measurement) → Right Plaque- 1 image → Left cIMT- 5 images → Left Plaque- 1 image 			
Step 21 - image of screenshot updated			
<p>Step 24 – (edits crossed out)</p> <p>NOTE: You need to wait until 5 files have transferred for the cIMT, for plaque it is only 1. Some sites may have 2 files transferred for plaque.</p>			
New Version #	Revision Date	Revision Author	Content Approval
3.0	2013-Jan-22	Lorraine Moss	Mark Oremus
Summary of Revisions			
Various formatting changes throughout document			
Added step 16 in section 6.0			
Changed numbering from step 16 in section 6.0			
Step 7 in section 6.0 updated to turn the probe a different direction.			
Added cIMT reference Guide to section 7.0			
Changed the second sentence in step 5 to read “The final electrode is placed on either the left or right side.....”			
Added to Step 9 cIMT Measurement , fifth arrow, NOTE: If 500 pts cannot be achieved the minimum points should be 250 pts if there is obvious plaque or loss of image that.			
<p>Step 4 changed to read – Explain the procedure to the participant before starting. Here are some suggestions:</p> <ul style="list-style-type: none"> → Now I am going to take an ultrasound image of your neck → I am going to attach 3 electrodes to you. They will not send an electrical current into your body, but instead measure the hearts current. Then explain where they go. → Next I will place ultrasound probe on your neck. And will place some gel on the probe. It will be cold, but won’t stain. → Can you move your chin up and angle it slightly over in the direction → Do you have and questions.... When the probe is on your neck, please do not talk since it will affect the image. 			
Updated the CI section			