



# LLFS Carotid Ultrasound Reading Center Visit 3 Methods of Operation

Version 1.0

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***Ultrasound Research Lab*****Table of Contents**

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### **Overview of LLFS**

The Long Life Family Study (LLFS) is a National Institute on Aging (NIA) sponsored multi-center study to identify the phenotypic measures associated with longevity and to determine the extent to which genetic factors play a role in exceptional survival. The first exam period took place between 2006 and 2009 at 3 US field sites (Boston, Pittsburgh and NYC) and Southern Denmark field site. Exams were conducted as home visits. Approximately 1200 participants, about half women and primarily of Caucasian descent, were recruited at each field site. The US field sites recruited the majority of the study sample from the Medicare 2004 Denominator file from The Center for Medicare and Medicaid Services (CMS). Additional study participants were recruited from other research studies and from the general public through advertisements and mailers (i.e. brochures, newspaper and web-based ads, community presentations and radio announcements). The participant selection criteria for family eligibility were that the family contained at least the following, all of whom must be willing to enroll in the study: 1) a long-lived proband (age  $\geq 80$  years), 2) at least one living sibling (age 80 or older) and 3) at least one offspring of the proband or sibling. In addition, the study sought to enroll a spouse of one of the offspring (a control subject). If available, the offspring's other parent was recruited when possible. Once these criteria were met, a phone survey was conducted with the potential Proband to determine whether s/he was part of an eligible family (Family Longevity Scoring System (FLOSS)  $\geq 8.0$  based on preliminary data from the Denmark site).

In the second exam period an ultrasound of the left and right common carotid arteries was obtained on all participants present at this exam. This exam was conducted as a home visit. From these ultrasound scans, we were able to obtain information on the common carotid intima media thickness (IMT) and carotid plaques. These measures provided important information on vascular aging in the LLFS.

In the third exam period that will take place between 2020 and 2023 a repeat ultrasound exam of the left and right common carotid arteries will be performed on participants attending the in person visits. From this exam we will assess change in measures of vascular aging including common carotid IMT and adventitial diameter and carotid plaque..

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### **2. Overview of the Carotid Ultrasound Training Scanning Protocol**

#### **2.0 Summary**

B-mode, static carotid artery images for measurement of carotid intima media thickness (CIMT) and lumen and adventitial diameters will be acquired with a high-resolution linear array variable frequency ultrasound transducer (12L5 6-10 MHz) with superimposed simultaneous ECG recording for image standardization. Magnified, gray scale images of the carotid artery on the right and left sides of each participant will be obtained. Static images will be acquired with the participant lying supine and the head rotated 45 degrees away from the side of study with two separate images on each side captured at the distal common carotid artery (CCA) at end-diastole of the ECG tracing. Captured images will show optimal visualization of the intima-media complex of the far and near wall of each image studied over a 1-cm distal CCA length of the artery. At the URL Reading Center, quantitative analysis will be performed on the near and far walls of each image. Qualitative analysis will also be performed of all static images at the URL Reading Center.

Using B-mode, both sides of the neck are imaged in cross-section and the transducer is moved laterally until the jugular vein and the CCA are stacked with the former above the latter. In this position, the central image line passes along the common diameter of both vessels. The scan head is rotated around the central image line 90 degrees maintaining the jugular vein stacked above the CCA while obtaining a longitudinal view of both vessels. In this longitudinal view, the CCA near and far wall are horizontal. The proximal portion of the carotid bulb (at least 50%) is included in all images. Minimum gain necessary for clear visualization of structures is used. Emphasis of ultrasound imaging is on the distal 1 centimeter of the CCA and standardized on the ECG since this is the site of least variability. The images of the CCA will be sent to the URL for quality control and interpretation. For each participant, the depth of field, frequency, and other instrumentation settings will be standardized for the entire study. This will allow for the lowest amount of data differentiation across all sites. Periodic Quality Control images will be reviewed at the URL to verify and assess sonographer accuracy.

#### **2.1 Background**

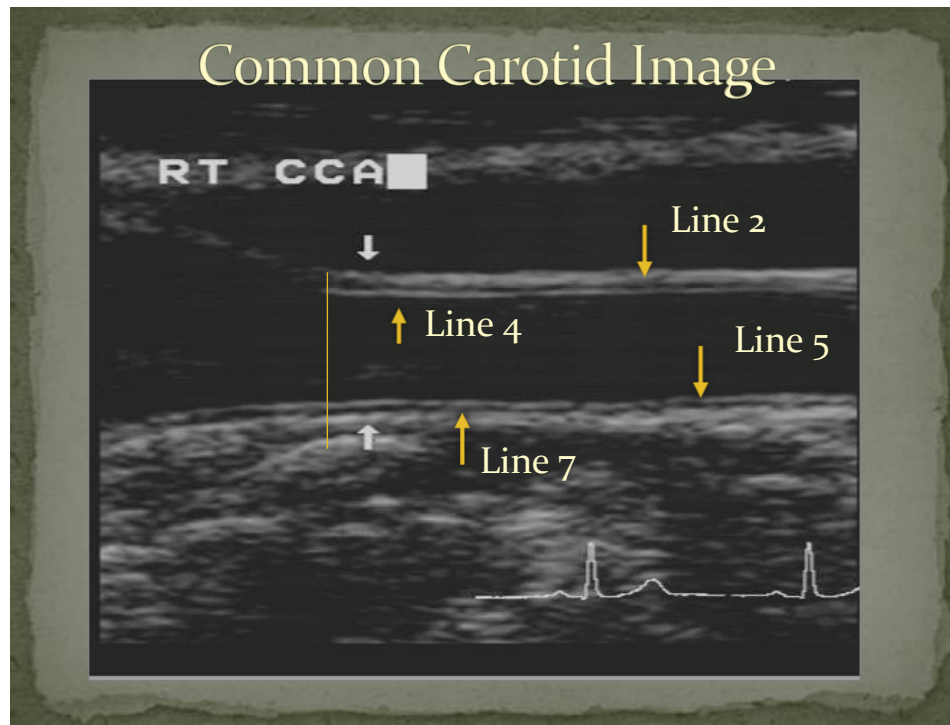
Wall boundaries can be demonstrated with high-resolution ultrasound imaging. They appear as two parallel echogenic lines separated by a hypoechoic space in longitudinal views of the carotid

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arteries. The artery walls are usually best observed in the common carotid artery (CCA) where the vessel courses parallel to the skin surface and is located at a right angle to the ultrasound beam.

The first echo along the far wall results from the lumen-intima interface and the second, normally brighter, echo along the far wall originates from the media-adventitia interface. Between these interfaces lies the media, which appears as an echolucent zone. The distance between the first two lines corresponds to the combined thickness of the intima and media. Due to its collagen content the adventitia is quite echogenic and appears as a bright zone highlighted along its inner margin by the media.

#### **Common Carotid Image**



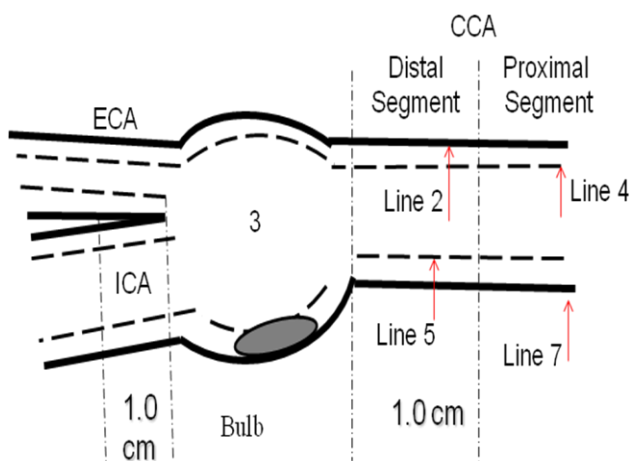
It is more difficult to image the interfaces where the near and far walls of the vessels are curvilinear and not at right angles to the ultrasound beam. Other causes for loss of wall interface that are not related to scanning technique are the presence of plaques and the presence of fat in the arterial wall. (Plaque refers to a focal protrusion into the lumen from the wall of 50% or greater than the thickness of the adjacent wall.) Images are magnified to clarify the display of the arterial interfaces. The interfaces can also be seen along the near wall but the lines may be disrupted and the echoes weaker because the ultrasound beam has attenuated from tissue to fluid. At times, it may seem impossible to maximize both the near and far wall interfaces on the

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same image. However it is imperative that all scanning angles are utilized (i.e. anterior, posterior, lateral) as well as a heel-toe technique or rotation of the participant's head to demonstrate near and far wall interfaces on the same image.

### **2.2 Introduction to the Carotid Ultrasound Scanning Protocol**

The extracranial carotid arteries are the largest arteries in the neck. The right common carotid artery (RCCA) originates from the brachiocephalic artery on the right and the left common carotid artery (LCCA) originates directly from the aortic arch. Each common carotid artery ascends in the neck lateral to and posterior to the trachea. At the approximate level of the thyroid cartilage, slightly below the angle of the mandible, the CCA bifurcates into the external and internal carotid arteries.



The CCA dilates from the carotid bulb proximal to the bifurcation into the internal and external carotid arteries. The origin of the bulb can be recognized in most, though not all participants. The carotid artery bulb is defined as the site where the artery begins to dilate slightly and the vessel walls curve out, i.e.: they are no longer parallel to each other. The bulb is elliptically shaped and geometrically complex in the longitudinal

view. The tip of the flow divider also marks the origin of the internal and external carotid arteries. It is usually situated at the midpoint or upper two-thirds of the carotid bulb. The external carotid artery lies anterior and slightly medially to the internal carotid artery in 90% of individuals. In the remaining 10% the orientation is reversed. The external carotid artery is usually smaller than the internal and it has branches that supply the neck and face. The internal carotid artery has no branches in the neck and ascends into the calvarium to supply the brain.

The carotid ultrasound protocol requires the capture of static grayscale images and real-time cine clip loops from the right and left CCA and identified plaques according to a standard protocol which will be discussed later. The real-time clips are intended to help the image analyst in his/her task. Occasional artifacts can be more readily recognized with the aid of the dynamic clips.

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### **2.3 Scan Identification – Labeling and Log Sheets**

The URL will provide a sample of CD labeling and log sheets to each site. Site specific and individually numbered CD's will enable the long-term storage of LLFS data at each site. A log sheet is completed for each CD. Multiple participants will fit onto each CD and will be maintained at each site for the duration of the study. Electronic transfer of the images is described in the data transmission protocol portion section 4.0. The log sheet is Attachment 1 (Section 6) of this document.

When completing the log sheet, take time to write legibly and double check the participant's Study ID and Participant Name Code. ID errors can be difficult and time consuming to trace.

### **2.4 Scanning Data Collection Form**

A procedure form, *URL Carotid IMT Worksheet*, will be completed for every participant by the sonographer. The data from *URL Carotid IMT Worksheet* forms are entered into REDCAP MATRIX (LLFS data entry system). The form is located in Section 7 of the *LLFS Sonographer Training Manual* and details on how to complete this form are described below.

### **2.5 Machine Set-up, Probe Frequency and Magnification**

Pre-sets have been defined for the GE Logiq e ultrasound machine and are located in the exam pre-set section as LLFS. The settings will be set at the start of the study and should not be altered. Each machine will have only one probe. The probe that will be used for LLFS is a 12L5. The probe frequency is set to 6-10 MHz for the CCA protocol.

#### GE Logiq e Carotid Ultrasound Pre-sets

Frequency:	10 MHz
Gain:	Preset 70 to variable
E/A	3/3
Map:	L/0
Depth:	4 cm
DR:	90
FR:	37 Hz
AO:	96%
XBeam:	On
BStr:	Off
Focal zones:	1 (position—mid artery)



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All images of the CCA are scanned **magnified**.

### **2.6 Subject Demographics**

Participant information is entered on the ultrasound demographic information screen to identify the scan as a LLFS scan. The information on this page identifies the scan data with the proper participant. Demographics should follow as below:

To enter subject information on the GE Logiq e demographic information screen

- Patient ID: Study ID
- Last Name: *Participant Name Code (\*Boston site will enter Study ID again here from the carotid worksheet)*
- First Name: LLFS Assigned Tech ID

### **2.7 Participant Position**

The carotid ultrasound procedures are performed with the subject in the supine position on the bed. The subject is made comfortable in a position that allows head rotation to either side. For the elderly the participant may need to be permitted to sit up. The sonographer is seated to the right of the participant near the participant's head. The head is rotated 45 degrees away from the side being scanned.

In the case of a participant being unable to lie flat or sit in a reclining chair due to medical issues, such as back problems or respiratory issues, **the participant should not be scanned**. It is very difficult to obtain the required images from a sitting position and would only add stress to the participant.

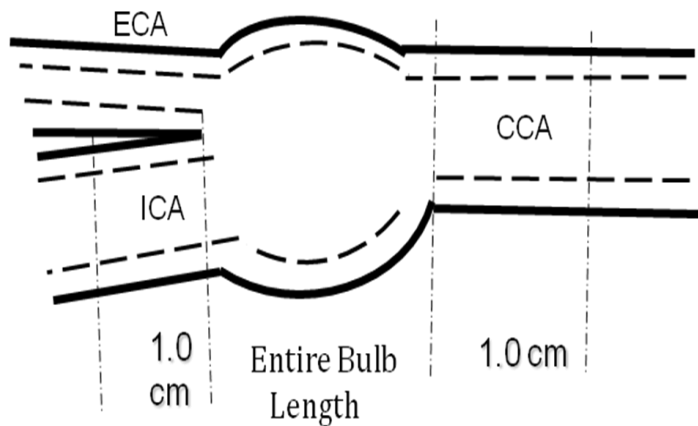
If you should run into this issue please document this on the carotid worksheet (refer to attachment) :

- Was Carotid Exam completed: **NO**
- Reason: **Participant unable**

Also please explain the reason at the bottom of the page – ***Additional Comments***

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### **2.8 Anatomical Sites of Interest and Definitions**



The extracranial carotid arteries are divided in four anatomically defined segments: the distal CCA, carotid bulb, the ICA, and the ECA. The lateral extent of each segment is defined relative to the tip of the flow divider, which is typically the most clearly defined anatomical reference in the carotid system. All segments are of interest but for the LLFS only the distal CCA segment will be measured for CIMT.

**\*If plaque is identified anywhere within the extracranial arteries on either side, cine loops must be recorded and plaques identified must be recorded within the specific segment on the *URL Carotid IMT Worksheet*.\***

#### **Definitions:**

1. Distal common carotid: the 1 cm segment of the common carotid artery proximal to the origin of the carotid bulb, where the walls of the artery are parallel to one another. The end of the distal common carotid artery is marked by the dilatation of the vessel walls, which is the carotid bulb.
2. Carotid bulb: this segment is defined as the entire distance between the common carotid dilatation and the tip of the flow divider. No still images will be obtained, except in the presence of plaque.
3. Internal carotid artery: this segment is defined as the segment that originates from the tip of the flow divider and feeds the brain blood flow. No still images will be obtained, except in the presence of plaque.

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4. External carotid artery: this segment originates at the bulb/flow divider and is usually smaller in diameter than the ICA. This vessel feeds the face blood flow. No still images will be obtained, except in the presence of plaque.

### **2.9 Imaging Sequence**

#### Detailed Scanning Protocol

1. Explain the tests and answer any questions.

#### **Sample Participant Script:**

This test allows us to measure the amount of thickening in the walls of your arteries. It will also determine if there is any blockage in your artery. It uses ultrasound and the test is painless. You will be asked to lie quietly while the arteries on both sides of your neck are imaged with ultrasound. Cool, water soluble, hypoallergenic gel is placed on your neck and a smooth probe is moved up and down your neck. During the test, your heart rhythm is monitored so we know at what point in the heart cycle the image is obtained. This test takes about 30-50 minutes.

2. Have the participant lie flat on his/her back. Depending on the set up in the home this may most likely be on a bed. Attach ECG leads, on the right and left upper chest, under the clavicle and the left lower chest under the rib cage. \*If necessary for participant comfort/privacy you may place the ground lead on the back of the right hand.
3. Enter participant information as follows:
  - Patient ID--Study ID
  - Last Name—Participant Name Code (*\*Boston site will enter Study ID again here from the carotid worksheet*)
  - First Name—LLFS Assigned Tech ID
4. Select LLFS Carotid image preset.

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5. Perform a scout scan in the transverse plane recorded as a 30 heartbeats cine clip. A second cine clip can be obtained if the person scanning feels not all segments have been adequately visualized. *Slowly* moving up the neck, identifying any plaques, the CCA, carotid bulb, ICA and ECA. These can be referred to as “area of interest” if it is a plaque, and “wall thickening” if only thickness is noted.
6. Rotate transducer to the longitudinal plane, moving *slowly* up the neck, again identifying plaques and the branch vessels. Record as a 30 heartbeat cine clip. A second cine clip can be obtained if the person scanning feels not all segments have been adequately visualized. Make sure to identify all plaques on *all* walls in each segment, sliding on and off of the vessel in the longitudinal projection to identify any plaque on the medial wall of a vessel. **Record a cine clip of the plaque if a plaque is seen.** This will allow the URL Reading Center to evaluate plaque in the future if necessary. Show the plaque in both transverse and longitudinal views as well as adjacent areas to document proof of plaque and its location. Demonstrate within the clip if the plaque displays acoustic shadowing.
7. Depress the Zoom (white button) key to enter zoom function. Click once to magnify image.
8. Demonstrate the RT distal common carotid artery (CCA) with 50% of the bulb seen in the image and at least 1 cm of the CCA immediately proximal with the far wall optimized in the image. Make sure the image is annotated with side & segment.
9. Capture the CCA image in the proper ECG segment by holding the transducer still in the distal segment of the CCA, while demonstrating at least 50% of the bulb in the image & then depressing the freeze image button. The last 15-20 seconds of imaging will be saved on the system. Use the scroll button to move through the cine loop and select the image that best displays both the near and far intimal walls on the “R” or upstroke segment of the ECG cycle. **See ECG example page 15.** (The distal common carotid artery is the segment of the common carotid artery *immediately proximal* to the origin of the carotid bulb. The end of the distal common carotid artery is marked by the dilatation of the vessel walls, which is the carotid bulb). Scroll back through the frames and select the best image on the R wave from the cine loop. Acquire image.
10. Obtain a second RT image of the distal CCA following the protocol in #9. Afterwards unfreeze the image.

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11. Freeze the image of the RT distal common carotid artery (CCA) with 50% of the bulb seen in the image and at least 1 cm of the CCA immediately proximal with the near and far wall optimized in the image. This is the acquisition of the adventitia diameter. Scroll back through the frames and select the best image on the R wave from the cine loop. Acquire image.
12. Obtain a fourth RT image of the distal CCA following the protocol in #11. Afterwards, unfreeze the image.
13. Undo zoom. Proceed to the LT side and follow the protocol step outlined in steps # 5-7 for scout scans and #8 & 9 for the LT CCA cine clip. Freeze the image of the LT distal common carotid artery (CCA) with 50% of the bulb seen in the image and at least 1 cm of the CCA immediately proximal with the far wall optimized in the image. Scroll back through the frames and select the best image on the R wave from the cine loop. Acquire image.
14. Obtain a second LT image of the distal CCA following the protocol in #11.
15. Unfreeze the image.
16. Freeze the image of the LT distal common carotid artery (CCA) with 50% of the bulb seen in the image and at least 1 cm of the CCA immediately proximal with the near and far wall optimized in the image. Scroll back through the frames and select the best image on the R wave from the cine loop. Acquire image.
17. Obtain a second LT image of the distal CCA following the protocol in #16.

**Note:** *All distal CCA images should optimize the segment of the common carotid artery immediately proximal to the origin of the carotid bulb.*

**Images obtained for intima media thickness (IMT) and diameter measures are as follows:**

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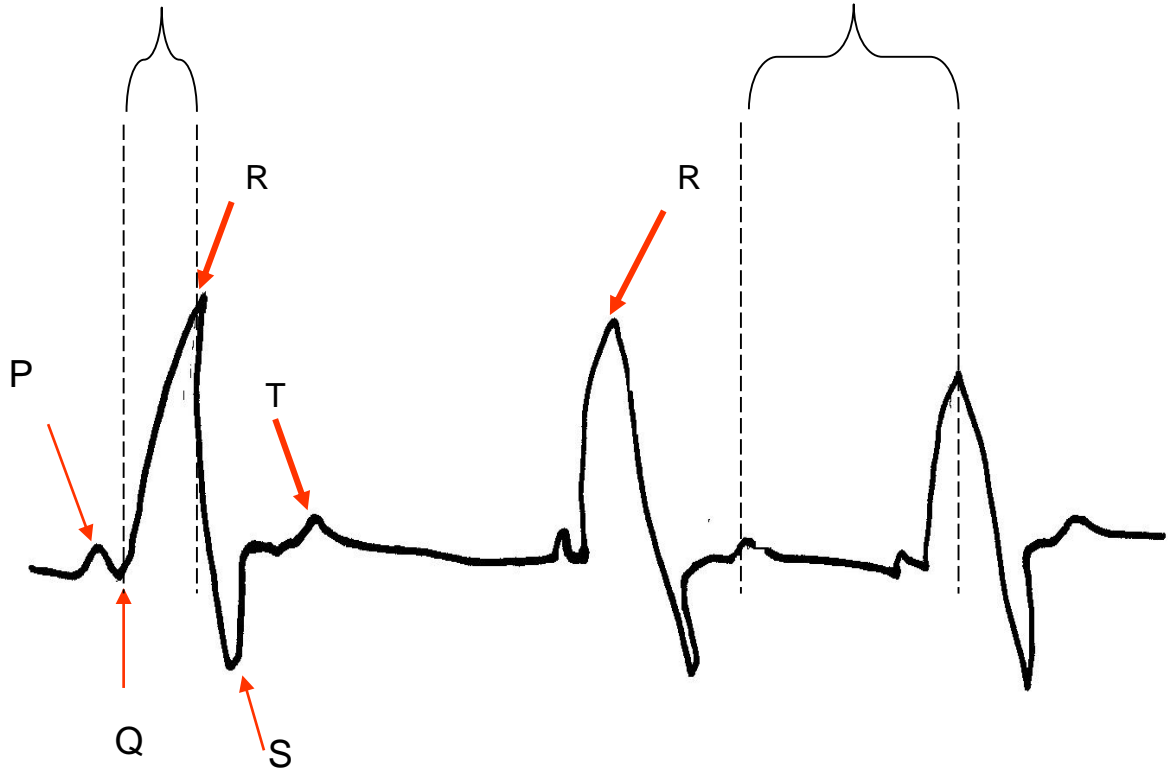
Side	Image capture #	Image captured
Right	1	Distal CCA <b>far</b> wall
	2	Distal CCA <b>far</b> wall
	3	Distal CCA both walls
	4	Distal CCA both walls
Left	5	Distal CCA <b>far</b> wall
	6	Distal CCA <b>far</b> wall
	7	Distal CCA both walls
	8	Distal CCA both walls

Draw all plaques on the *URL Carotid IMT Worksheet*. (Plaques are localized areas within the IMT which project into the lumen and are greater than 50% of the surrounding tissue). Document the grade and number of plaques ***immediately after the scout scan*** to ensure correct placement. Properly select the correct anatomical picture that closely correlates to the true anatomy of the vessel for each side and fill in plaque location as well as any corresponding wall thickness. Demonstrate acoustic shadowing that may obliterate visualization of the total plaque/segment.

*Ultrasound Research Lab*IMT Images Captured **During DIASTOLE**

**Capture images on  
UPSTROKE of "R"**

**DIASTOLE**



It is important that the CCA images are always obtained in the diastole portion of the cardiac cycle as end diastole is the portion of the cardiac cycle when the lumen is smallest and the vessel shows the least movement. Arterial walls are typically more clearly displayed in these images. Scout Scan The purpose of the scout scan is to orient the sonographer to the participant's carotid artery anatomy. The sonographer should locate the bifurcation and distinguish which vessel is the internal and which is the external carotid artery. The site of maximal wall thickening and plaque location in the near or far wall, in the bulb or ICA should be identified. If wall thickening or plaque is seen in any segment of the carotid artery, translate their location to the *URL Carotid Worksheet*.

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Participant ID: \_\_\_\_\_ Exam Date: \_\_\_\_\_

**B. Right Plaque and Wall thickening**



**C. Left Plaque Index**

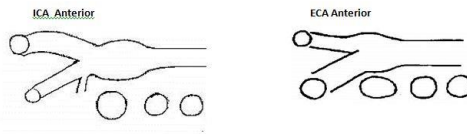
	1-Prox CCA	2-Distal CCA	3-Bulb	ICA	ECA
1. Segment adequately visualized	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )
2. Any plaques visualized	Y ( ) Go to C3		N ( ) Go to C6		
3. No. of Lesions					
4. Plaque Grade* (0, 1, 2, 3)					
5. Calcified Plaque	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )

\*Velocities done if Plaque Grade is ≥ 3 in any segment please complete URL Carotid Doppler Velocity Worksheet

6. <input type="checkbox"/> ANT (15° to 60°)	<input type="checkbox"/> LAT (10° to -10°)	<input type="checkbox"/> POST (-15° to -60°)
7. Technically Difficult Study (TDS)	<input type="checkbox"/> YES* → Specify reason(s): <input type="checkbox"/> NO Go to 8	<input type="checkbox"/> Tortuous vessel <input type="checkbox"/> Participant movement <input type="checkbox"/> Deep Vessels <input type="checkbox"/> Morbidly obese <input type="checkbox"/> Other
8. Machine Failure <input type="checkbox"/> YES * Indicate reason for machine failure	<input type="checkbox"/> NO Go to D	

\*Additional Comments: \_\_\_\_\_

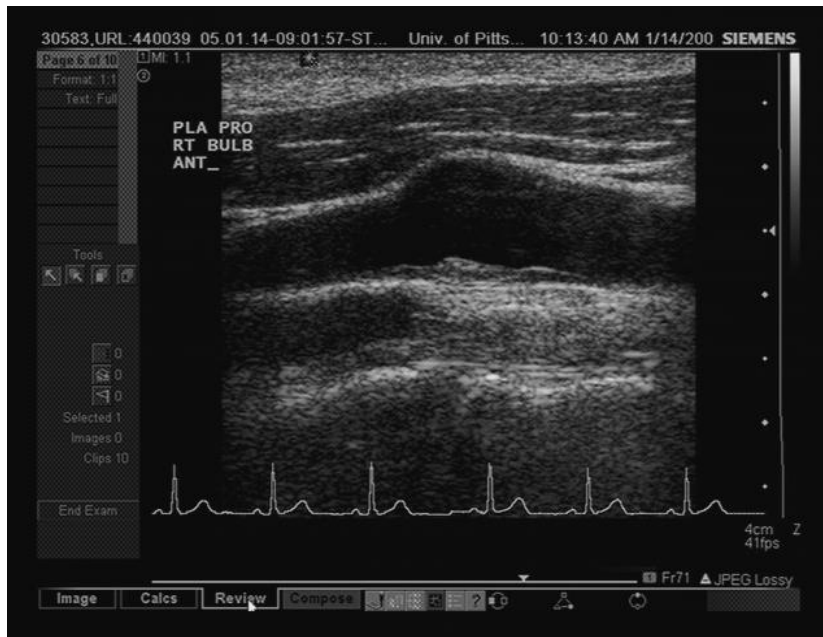
**D. Left Plaque and Wall thickening**



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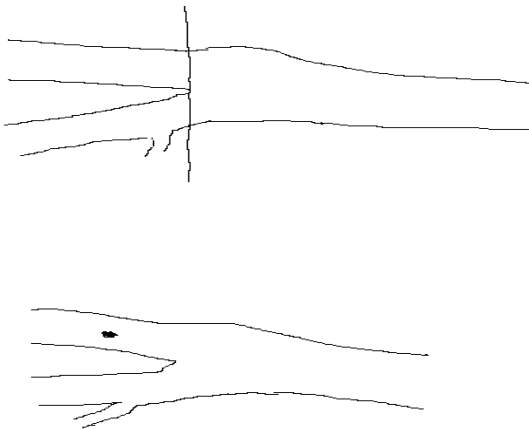
- The entire plaque should be shown with good shoulders. Shoulders are defined as where the plaque begins and ends—the connection to the intima walls. There should be continuous wall continuity throughout the entire plaque.





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- Be sure to check through the cine for the best image.
- Back wall plaques should be drawn in on worksheet.
- All plaques should be clearly demonstrated on the longitudinal scout scan. Someone other than the original sonographer should be able to clearly see all plaques on cine loop. If there is artifact on the clip that looks like it could be thickening or plaque indicate it on the scan.
- Images need to be captured in diastole.



Whether a plaque is located in the bulb or in the ICA or ECA (or in both the bulb/ICA and bulb/ECA) is determined by whether the plaque is proximal or distal to the flow divider. This is determined (for our lab - at this time) as if drawing a *straight* line through the flow divider (as shown in the diagram to the left). Plaques to the right of the line are in the bulb. Plaques to the left of the line are in the ECA or ICA. Plaques that are divided by the straight line are in both (starting in the bulb and extending into the ICA or ECA). Back wall plaque will be drawn on the worksheet clearly demonstrating that it is on the back wall (not touching the near or far walls) as shown in diagram to the left.

#### **2.9.1 GE Logiq e Machine Protocol**

Available in Section 12 of the Sonographer Training Manual.

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### **2.10 Response to a Potentially Clinically Significant Stenosis – (Alert Process)**

#### **LLFS CAROTID ULTRASOUND ALERT POLICY AND PROCEDURE**

There may be some participants who will have a potentially clinically significant finding (see specific Alert Criteria below) on the LLFS carotid ultrasound scan. To address this, the URL has developed a policy and procedure for such findings. The policy is that all scans will be reviewed for potentially clinically significant findings by the URL and communicated to the sites in a timely fashion. The procedure will involve coordination between the sites and the URL as follows:

#### **Transmission of Scans to URL**

Scout scans will be transmitted to the URL server, along with the corresponding log sheets at least weekly. Please note that if the site personnel, at time of examination, believes there is a finding of potential clinical significance, he or she should alert the URL by indicating it on the log sheet and contacting the URL by email or phone. This should be done within 48 hours. The site personnel should not notify the study participant of any potential findings at any time during the study visit.

#### **Alert Screening by URL Sonographer**

The URL sonographer assigned to LLFS will screen the scans according to the timeline below. Should a potentially clinically significant finding be noted, an alert process will be initiated by the assigned URL sonographer. At the Reading Center, the ALERT process will consist of reviewing all images, scout scans, and forms for this participant. The URL sonographer will then complete the top portion of the *Action Form for Carotid Ultrasound Alerts* and forward with images and carotid worksheet to the URL physician. **The URL coordinating sonographer will confirm receipt by the URL physician via phone or e-mail.**

#### **Recommendation by URL Physician to URL Sonographer**

The URL physician will recommend whether the finding is of potential clinical significance as well as the potential urgency. If not of clinical significance, a routine report will be generated. In the event that the URL physician does consider the findings to be of potentially clinical significance, he will advise the URL coordinating sonographer to contact the field site project coordinator and/or field site PI or site designated medical personnel (this may be site PI, site MD, site nurse) within 48 hours as per MOP Chapter 6 Alerts.

#### **Communication of URL Sonographer to Field Site Project Coordinator**

The URL sonographer will contact the field site project coordinator within 48 hours or sooner via email regarding the presence of a potentially clinically significant finding along with any comments of the URL Physician. The Field Site Project coordinator will inform the site PI.

#### **Field Site Internal Communications and participant notification**

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The Field Site Project Coordinator will contact the designated clinician to assess the sonographic findings, and to determine whether the results are unanticipated and/or clinically significant. Most potentially clinically significant findings are asymptomatic, but still may be of clinical significance to report. The Field Site Project Coordinator will then confer with the site PI or field site physician to determine the need to call the participant's physician or to send the results via letter to the participant and physician. (Provided permission to contact the physician has been obtained). If the participant does not have a physician, the field site PI will refer him or her to an appropriate medical professional. Following a phone call, a results letter will be sent to the participant and his/her physician (with his/her permission) signed by the study site PI and/or site designated medical personnel. Since this is a limited research protocol, the letter should include this statement:

"This study was done for research purposes only and does not include all views that would be obtained in a clinical study. We do not make any diagnoses or recommend treatment. This information is being provided to you in the event that it may assist with your medical care (or the care of your patient)."

### **Resolution of ALERT report at field site**

Once the ALERT has been resolved at the field site, the lower portion of the *Action Form for Carotid Ultrasound Alerts* will be completed by site project coordinator for site specific data entry. A file with all relevant documentation (results reports, dates of contact, etc.) will be kept for each alert in the participant's chart.

### **Timeline**

The scans are to be transmitted daily but no later than 4 days to accommodate weekends. The screening process should begin at the URL within 72 hours and no longer than one week of the receiving the scout scans from the site, and reported by the URL back to the field site within 48-72 hours. The field site should resolve the alert notification within one week of receiving the URL report. Scheduling of visits before long holiday breaks should take into account the need screen for alerts. Alerts should be resolved within 3 weeks of exam.

### **Immediate Alerts: Criteria for URL sonographer to notify URL Physician immediately**

- 1) An aneurysm or dissection which is currently leaking.
- 2) A moving structure within the carotid artery, i.e.: loose plaque, thrombus or intimal tear (recent trauma must have occurred).

### **Urgent Alerts: Criteria for URL sonographer to notify URL physician within 48 hours**

- 1) Any grade 3\* plaque (> 50% diameter reduction, long view)
- 2) Any other reason for the sonographer to be concerned

### ***Ultrasound Research Lab***

**\*Plaque Grade:** *Plaque grade is an estimate of the extent of focal plaque in the carotid artery segments visualized. Each carotid segment (CCA, Bulb, ICA and ECA) is assessed and scored individually using the criteria that follows:*

Estimated percentage of stenosis	Grade
1-29% (one small plaque)	1
30-49% (1 medium plaque or several small plaques)	2
50-100% (1 large. plaque or several plaques w/ at least 1 medium plaque)	3

#### **Procedure for Reporting Alerts to Steering Committee and OSMB**

All sites will report alerts during the Field Operations and Steering Committee conference calls. These alerts will be documented in the LLFS Observational Study Monitoring Board (OSMB) report.

#### **2.11 Scanning Summary**

Real-time gray scale imaging of both CCA's are presented in two parts:

- Part 1 – Scout scans are performed in the transverse and longitudinal planes first on the right and then on the left. All scout scans are to be recorded as cine clips.
- Part 2 – Longitudinal cine clip of the CCA on each side is saved first and then 2 separate still images are captured for each side on the specific portion of the cardiac cycle focusing on the far wall interface.
  - The CCA image captures the distal 1 cm of the CCA proximal to the carotid bulb.
  - Probe frequency is set at 10 MHz.
  - Magnification is used according to established protocol.
  - Although all projections should be assessed to determine the best image, interfaces are generally seen well using a posterior-lateral projection and hence depict the lumen-intima and media-adventia interfaces over a 1cm length of the vessel. From this image, the CCA IMT is obtained.
  - The images should be obtained parallel across the monitor as this makes automated measuring more precise.

### ***Ultrasound Research Lab***

- Part 3 - Longitudinal cine clip of the CCA on each side is saved first and then 4 separate still images are captured for each side on the specific portion of the cardiac cycle focusing on the near and far wall interfaces.
  - The CCA image captures the distal 1 cm of the CCA proximal to the carotid bulb.
  - Probe frequency is set at 10 MHz.
  - Magnification is used according to established protocol.
  - Although all projections should be assessed to determine the best image, interfaces are generally seen well using a posterior-lateral projection and hence depict the lumen-intima and media-adventia interfaces over a 1cm length of the vessel. From this image, the CCA IMT is obtained.
  - For reproducibility purposes, both the double-line patterns of the near and far wall interfaces need to be optimally displayed. Simultaneous display of near and far wall interfaces is necessary for performing diameter measurements.
  - The images should be obtained parallel across the monitor as this makes automated measuring more precise.

#### **Key Reminders for Scanning:**

1. *Naming of images:*

In order to have the proper identification appear on the image it has been determined that the labeling sequence needs to follow this method. (This ensures the correct reading sequence for the Reading Center.)

- Label both Scout scans—Scout (RT or LT)
- Select the correct side sequence marker (1 RT CCA, etc.)

2. *Vessel Marker:*

- Remember to keep vessel take-off identifier clear of the vessel walls. (see example page 22)

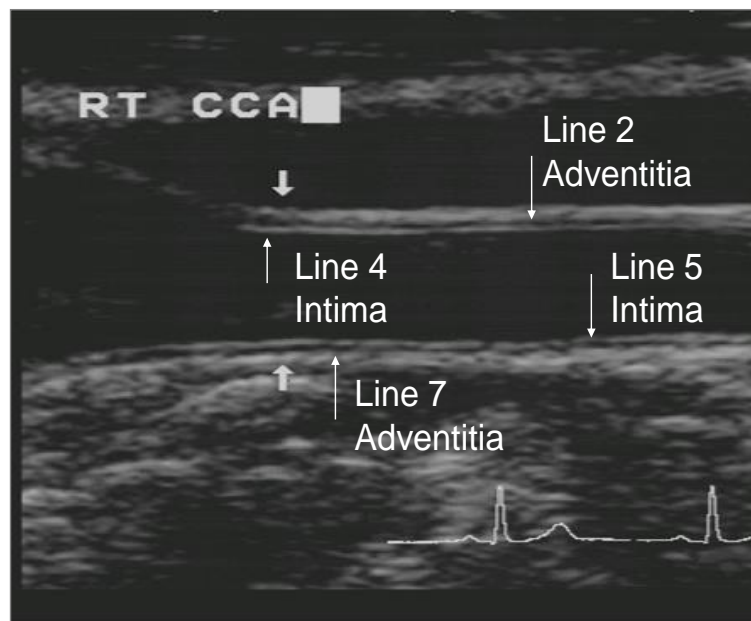
#### **2.12 Criteria for Satisfactory Images**

The criteria for optimal B-mode ultrasound image of the carotid arteries is defined as the clear visualization on long axis views of arterial interfaces, internal arterial landmarks, and lesions.

### ***Ultrasound Research Lab***

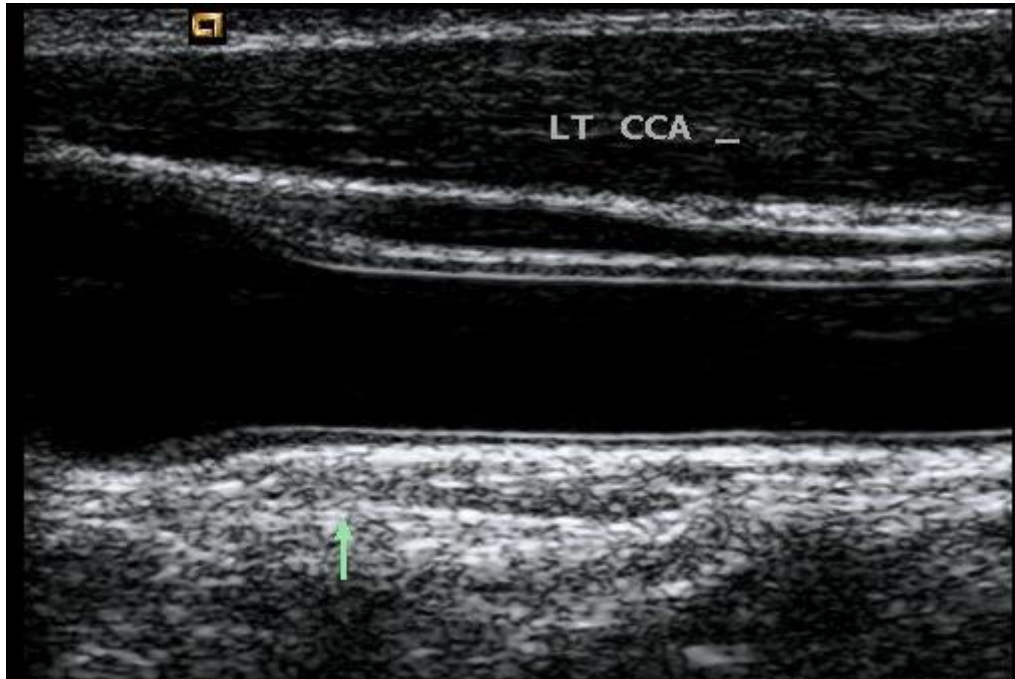
1. Near wall- arterial wall nearest the probe
  - a) Adventitia -media interface (Line 2)
  - b) Intima-Lumen interface (Line 4)
2. Far wall- arterial wall further away from probe
  - a) Lumen-Intima interface (line 5)
  - b) Media-Adventitia interface (line 7)

## IMT Interfaces



## ***Ultrasound Research Lab***

**Optimal image:**



The area of interest will be in the middle of the image and the probe will be aligned to show as much of the vessel as possible. The sonographer should optimize the visualization of the interfaces by adjusting gain settings, probe projection, and heel-toe angle of the probe. To clearly visualize the intimal linings, the gain setting may be set higher than it is for a clinical study. Satisfactory images are properly magnified using the assigned protocol setting in all scan planes.

### **2.13 Imaging Priorities**

All effort should be made to obtain both RT and LT CCA images in all participants with visualization of the far wall in the 1<sup>st</sup> two images on each side and both the near wall and far wall for the last two images on each side. This can be achieved by utilizing the “heel-toe” effect to effectively obtain the images for evaluation on the correct portion of the ECG cycle.

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### **3. Overview of Carotid Ultrasound Analysis Protocol**

#### **3.0 Preview and Review of a Carotid Ultrasound Study**

Upon receipt of the LLFS images, image log sheet and *URL Carotid IMT Worksheet*, the scans and information will be reviewed by the URL Reading Center reader for information related to specific scan situations, images captured out of order, errors in labeling, or other technical difficulties encountered during the scanning procedure.

The images and cine clips will be downloaded onto the URL server for the reader to analyze using a computer based program called Artery Measurement System (AMS) II (v 2.0) to perform the CIMT, lumen diameter and adventitial diameter measurements from each still CCA image.

#### **3.1 Calibration**

The first step in the carotid analysis process is calibration within the AMS program. It is necessary to calibrate each image in order to convert the computer unit, pixels, to centimeters. To calibrate an image the reader positions the calibration tool such that it demarcates the 1-cm distance between calibration marks on the image. Although each image is calibrated using the AMS software package it is imperative to follow the established protocol for zooming the image so that all images across all sites are standardized to ensure consistency in the data for LLFS.

#### **3.2 The interfaces**

The goal of the reader and the AMS package is to identify the leading edges of the interfaces and “draw” the lines needed to calculate IMT. It is imperative that the interfaces or lines of data are seen continuously without breaks across the image for 1cm or greater. (See optimal image on page 22.)



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The following line numbers correspond to specific anatomic interfaces as defined below:

<b>Line Number</b>	<b>Interface</b>	<b>Wall</b>
Line 2	Adventitia-Media interface	Near Wall
Line 4	Intima-Lumen interface	
Line 5	Lumen-Intima interface	Far Wall
Line 7	Media-Adventitia interface	

The AMS program uses an algorithm that measures the pairs of lines or interfaces of the near wall, far wall, vessel width, lumen and adventitial diameter. AMS calculates the distance between the pairs of lines and reports the minimum, maximum and the mean values with standard deviation in millimeters.

### **3.3 Image Quality Scores**

An image quality score will be assigned to each image from all LLFS sites and recorded on the *URL Quality Control Feedback Form*. This score is based on the quality of the image and the reader's confidence that the lines demonstrated represent the true interfaces. Although the score is subjective; the following is a guideline for scoring the CCA images as well as any imaged plaque within the BULB and the ICA.

#### **Image Scoring**

- 1—**Unacceptable**: unable to identify interfaces needed in image.
- 2—**Poor**: Near and far wall interfaces identified but with breaks in the lines and/or less than 1 cm of measurable data with gains set at substandard levels.
- 3—**Good**: All interfaces identified with clear lines and 1 cm of measurable data.
- 4—**Excellent**: Interfaces clearly defined with optimized gain settings, over 1 cm of measurable data, no artifacts seen within the image and defined takeoff of the bulb.

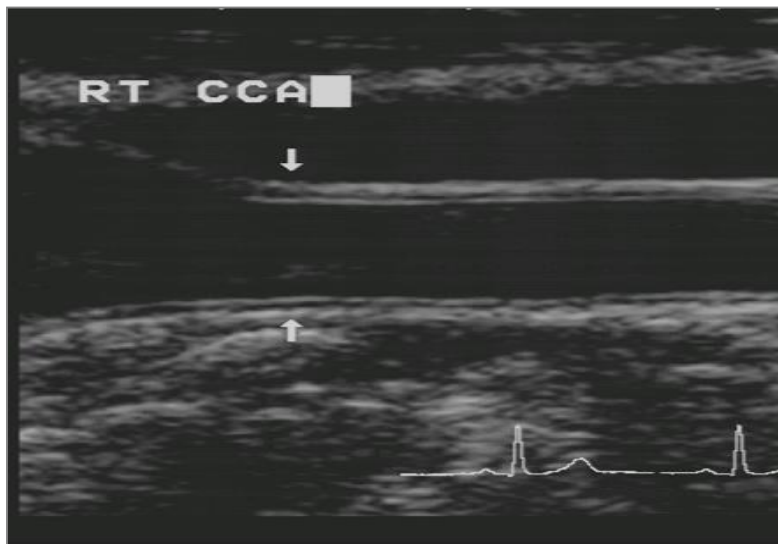
## ***Ultrasound Research Lab***

### **3.4 Sonographer Assessment of Arterial System**

Qualitative assessment of the carotid artery system will be assessed by the site sonographer and recorded on the *URL Carotid IMT Worksheet*. Although only the CCA will be imaged, the Bulb and ICA will be visualized and any evidence of plaque or increased thickening of the intima, in any of the segments, will be recorded on the worksheet. As discussed earlier this should occur after each side is imaged rather than after the scan is completed. The following guidelines should be used as an example when completing the worksheet:

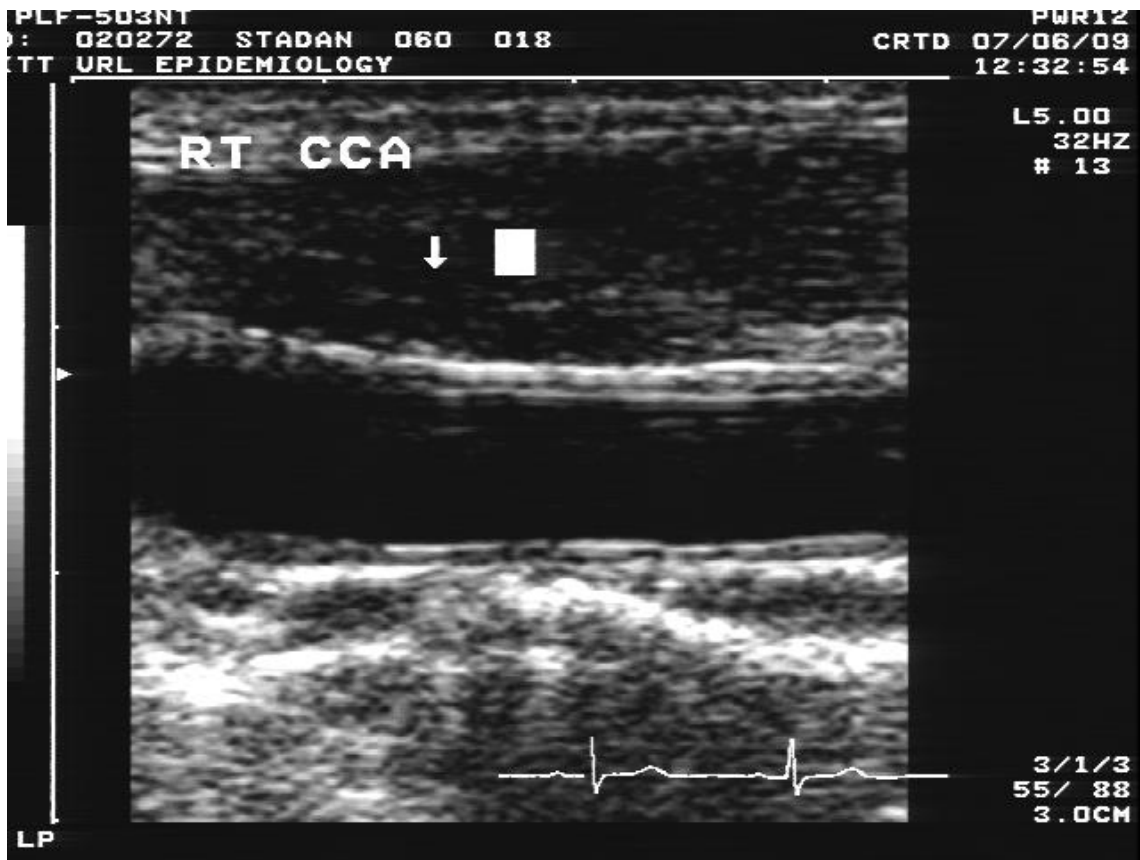
- Normal through Severe thickening illustrations

Normal—Healthy age appropriate wall interfaces



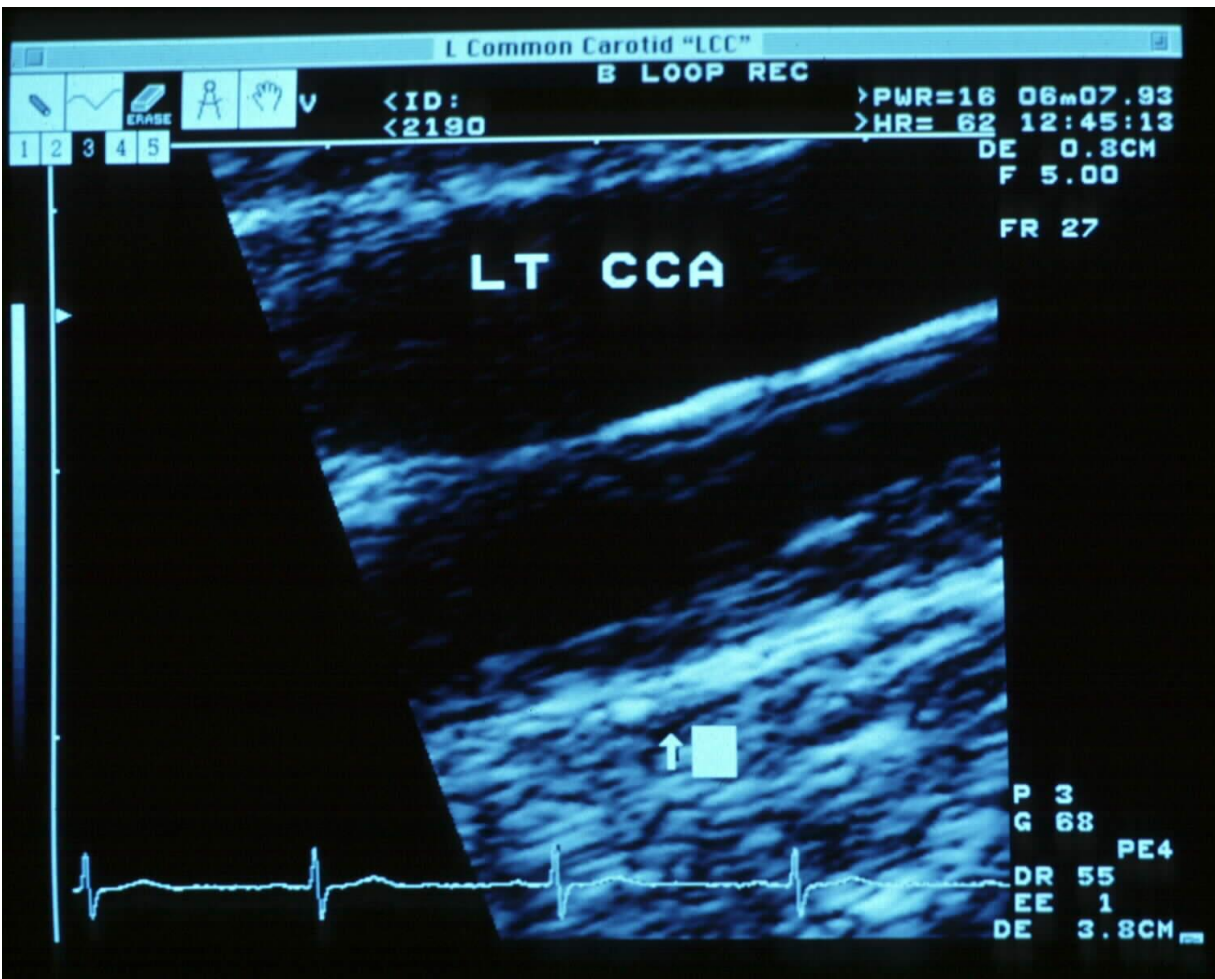
*Ultrasound Research Lab*

Mild to moderate thickening



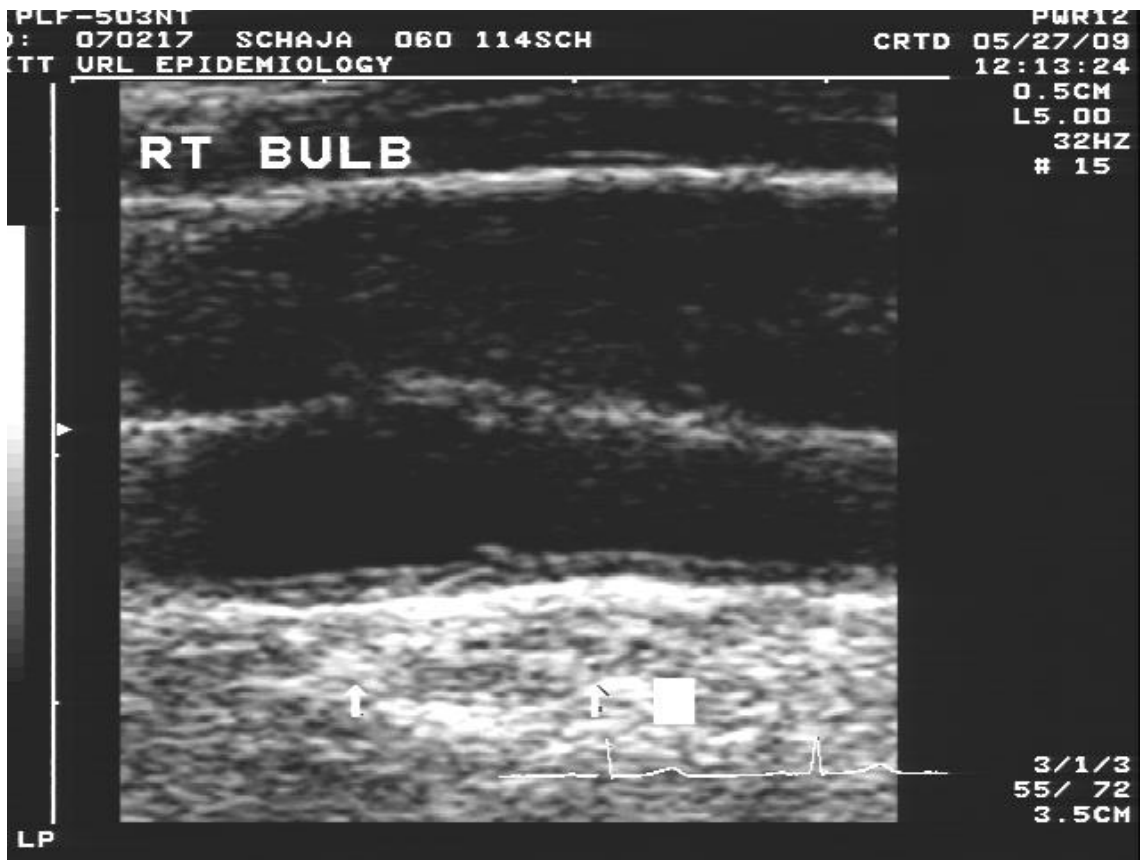
*Ultrasound Research Lab*

Moderate to Severe thickening (CCA)



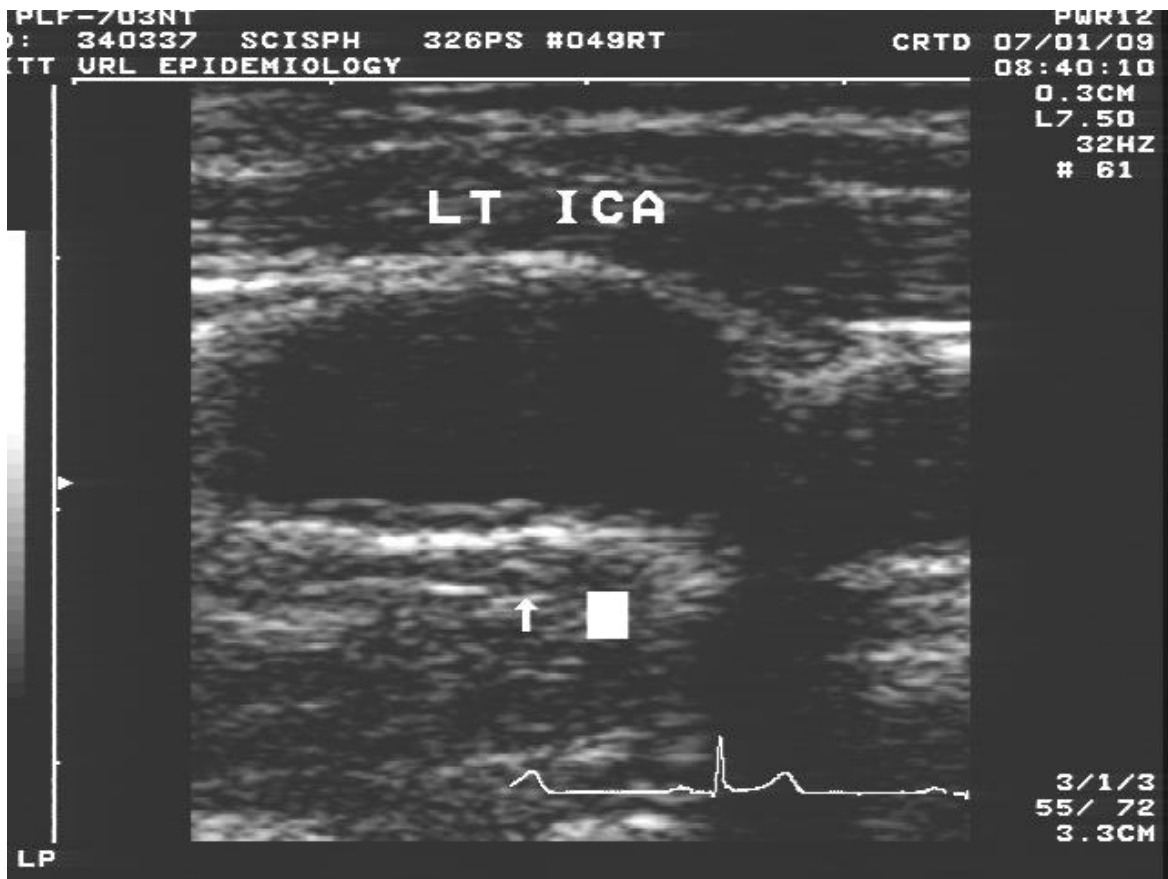
**Ultrasound Research Lab**

Moderate thickening-- Bulb



**Ultrasound Research Lab**

Moderate thickening-- ICA

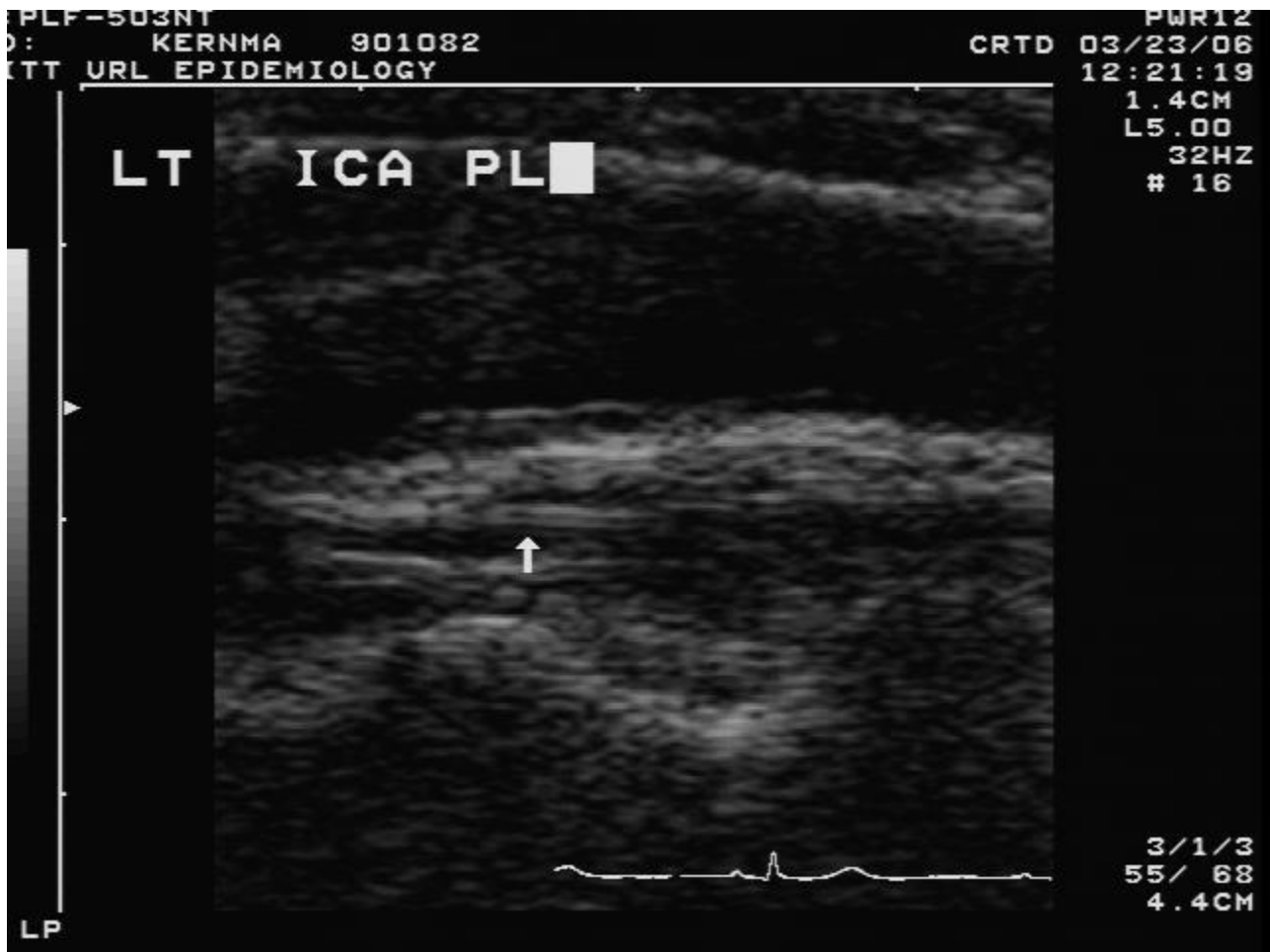


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As previously discussed, plaques are localized areas within the IMT which project into the lumen and are greater than 50% of the surround tissue. An example of each plaque and its grade are demonstrated on the following pages.

- Plaque Grade illustrations

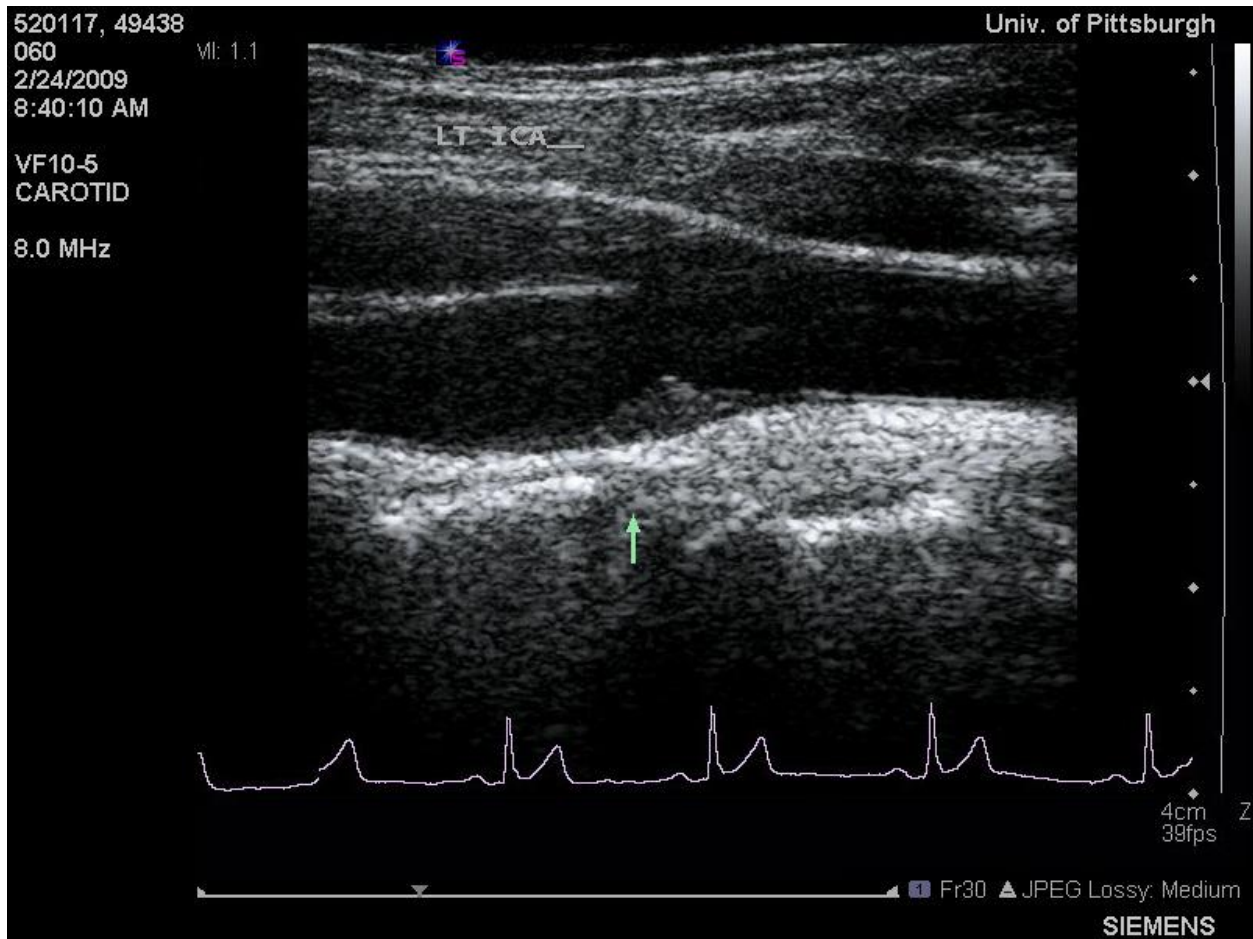
Grade 1 1-29% (one small plaque)





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Grade 2 30-50% (1 med. plq or several small plqs)





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Grade 3 50-100% (1 lg. plq or several plqs )



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**URL Carotid IMT Worksheet** data entry fields that need to be completed by the site sonographer so the reading center sonographer is able to review if there is a question related to the interpretation of the interfaces.

- IF no plaques are present, then check N on #2 below.
- IF plaques are present, check Y on #2 below and count total plaques in each segment and record that number in the appropriate box with the corresponding grade.
- IF plaque is present, determine if calcified and check yes or no according to its characteristics.

	1-Prox CCA	2-Distal CCA	3-Bulb	ICA	ECA
<b>1. Segment adequately visualized</b>	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )
<b>2. Any plaques visualized</b>	Y ( ) proceed to 3		N ( ) proceed to 6		
<b>3. No. of Lesions</b>					
<b>4. Plaque Grade*</b>  (0, 1, 2, 3)					
<b>5. Calcified Plaque</b>	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )

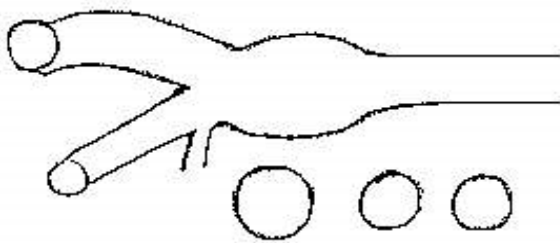
*\*Velocities done if Plaque Grade is ≥ 3 in any segment please complete URL Carotid Doppler Velocity Worksheet*

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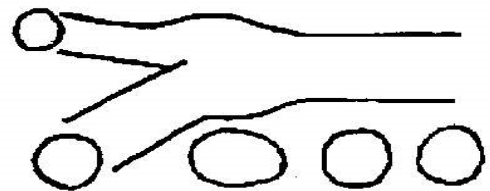
Use the following pictures to illustrate any evidence of thickening and its location.

Also draw accurate location and total amount of plaques that were marked on the *URL Carotid IMT Worksheet* corresponding to the participant's anatomy i.e. ICA in the near field or ICA in the far field.

ICA



ECA



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### **4. Data Transmission**

#### **4.0 Data Media**

##### **4.01 Image Transfer to USB**

Images will need to be transferred from the US system to a USB drive for storage at each individual site permanently. Images can be saved after each participant, daily or even weekly. Daily would be the best method as you can check-off each participant on the LLFS log sheet following the saving. The following steps need to be followed to save to a USB drive:

1. Place a USB into the serial 1 slot on the left side of the machine.
2. Select Patient key.
3. Click on data transfer in the upper left hand corner of the screen.
4. Under task, select export.
5. Highlight exam(s) needing to be transferred in the upper box.
6. Make sure that "To:" is USB Drive 1.
7. Click transfer.
8. Spinning hourglass will be displayed while transferring is taking place. Do not leave this screen until it is complete.
9. Once complete, select exit.
10. Click on eject key (fourth key to the right top row). Select USB1. This allows you to safely remove your USB. Select exit.

Carotid ultrasound images are transmitted to the URL Ultrasound Reading Center via the DataStream icon on the Desktop of the GE Logiq e. Please follow the protocol in section 4.4. Locally images will be recorded on CD-R/ or R/W. CD media will be maintained at each individual site and also will be backed up on an external drive. When the study is finished, the CD's will stay at each site but the external back up drive will be returned to the Coordinating Center and stored permanently at the URL facility.

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The DataStream file should contain only **8 still images and 4-6 cine clips** per participant as requested by the protocol. Additionally, cine clips for plaque need to be sent depending on presence of plaque. If additional still images are submitted to the Reading Center, the study will be rejected and the site will be asked to submit only the still images required by the protocol. The proper imaging sequence needs to be strictly followed as previously stated with the right side imaged first then the left side.

At the Ultrasound Reading Center the images will be stored digitally and analyzed on the AMS software program that the URL uses. Just a reminder that all images will be reviewed as part of an ongoing Quality Control process for the LLFS.

### **4.1 Study Forms**

The *URL Carotid IMT Worksheet* needs to be completed for each participant and all data fields need to be completed to ensure complete data management continuity for the investigators and researchers. Also this allows for ongoing data tracking for the LLFS. *URL Carotid IMT Worksheet can be found in section 7 of the LLFS Sonographer Training Manual.*

#### **4.11 Missing Information Codes**

These are standard LLFS missing codes that will need to be used for data that are missing on the carotid exam forms to be completed at the sites and by the reading center (URL).

<b>Code</b>	<b>Definition</b>
<b>-1</b>	➤ <b>O (Other problem)</b>
<b>-2</b>	➤ <b>P (Protocol violation)</b>
<b>-3</b>	➤ <b>U (Unavailable) or N (not applicable)</b>
<b>-4</b>	➤ <b>R (Participant refused)</b>

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### **4.2 Log Sheets**

The URL Reading Center will provide master copies of the log sheet. The master log sheet is located in Section 6 of the *LLFS Sonographer Training Manual*. This makes it possible to track and organize the numerous CD's and forms that will be kept at each site as well as those that are transmitted to the URL Reading Center. It is important that the sonographers carefully label the CD's and the corresponding log sheets. The CD will be labeled and will contain the following information: study name, CD number, site ID and site location. The log sheet enables the reader to quickly locate each study on the LLFS Server and to obtain pertinent information from the *URL Carotid IMT Worksheet* regarding particular cases. The sonographer completes the appropriate sections of the log sheet for each subject they scan. The items recorded on the log sheet are:

- **Scan Date**- the date of the carotid scan
- **Participant IDCD#**- the URL Reading Center ID number assigned to the participant
- **Participant Name Code**- the ID number assigned by the LLFS site
- **Tech ID**- the LLFS sonographer ID number assigned by the URL Reading Center
- **Comments**- communication from the sonographer to the reader
- **Plaque**- if any plaque within the system, indicate by circling appropriate location of plaque
- **Date URL received** – the date the URL receives the log sheet
- **Reader ID** - ID number of the reader at the URL Reading Center
- **DOR** – date of read

Transmission of the log sheet as well as the *URL Carotid IMT Worksheet* can be accomplished either through the mail or by fax at the end of each scan week. If forms are available to be submitted electronically please submit via email to the Coordinating Sonographer.

The value of sonographer-reader communication cannot be overstated. Use the Comment section of the log sheet to communicate any deviations from the norm. Include notes about protocol, plaques, problems or difficulties encountered. (An example would be if images were saved out of order.) The reader utilizes the data in this field to assist in evaluating the scan and images. All efforts by the scanning sonographer to reduce the guesswork for the reader in the analysis of the images will result in better outcome data and will be greatly appreciated.

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### **4.3 Electronic Data Transfer**

DataStream is the application that will be used to automatically transfer files (images and video clips) from a participating research center to a central repository server for reading. This software is typically installed on a designated computer at a participating research center and is designed to transfer all files located in a 'transfer' folder on a daily schedule.

Clinical center personnel interact very little with the DataStream process because it is an application that is scheduled to automatically run in the background. The process is configured in the host computer's task scheduler to run at 12 noon each day. To summarize the process, it starts up automatically, it scans a specific 'transfer' folder (C:\DICOM) for new ultrasound data, it verifies that the filenames are properly named, it transfers the data to the URL and then it exits until the next scheduled run time.

In the event that we would need to run DataStream manually, there is a batch file (DataStream.bat) or an executable file (DataStream.exe) added to the computer's desktop that can be used for this purpose. To execute DataStream manually, simply double-click on the file icon on the desktop.

#### **4.3.1 DataStream Installation**

The *DataStream installer creates all folders, files and scheduled jobs* that are necessary to transfer CT scans to the central server on a daily basis. Specifically, the DataStream installer creates a 'DICOM' folder at the root of the designated DataStream computer's C: Drive. It also creates subfolders used by the DataStream system while processing and transferring images/files to the central repository server. The DICOM folder and subfolders should not be removed. However, if these folders are accidentally deleted, the DataStream software will recreate them for you during the next scheduled run time.

#### **Accessing the installation guide**

For information on how to prepare for the installation of DataStream, we recommend that you read the installation guide as an initial step. This guide contains information that includes a brief overview of DataStream, system requirements of a suitable DataStream computer and a step-by-step description of the installation process.

<https://www12.edc.gsph.pitt.edu/URL/LLFS/DataStream/URLDataStreamInstallationGuide.pdf>

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### **Finding the right computer for DataStream installation**

Each center should identify a computer that can be used to store LLFS participant images and video clips that will be transferred to the URL central repository server. The computer must have a Microsoft Windows operating system to utilize the DataStream transfer software. The ideal DataStream computer would be one that is dedicated to the ultrasound data transfer process. But, this is not a requirement. Independent of whether the DataStream computer is dedicated or shared, the computer must be easily accessible to the technician who will be routinely copying the new participant image files. Additionally, it is preferred that the computer remain online at all times to avoid the interruption of a file transfer.

### **What is the recommended computer configuration for this process?**

- Operating System must be Microsoft Windows (Windows 10 or 7 is preferred)
- Memory recommendation is 4 GB or higher
- Hard drive should have 500 GB or more of storage available
- Network connection should be wired/cable and not wireless
- Public Internet address should be limited to one or a few subnets. A static address is preferred. The Internet address must resolve to a recognizable name in order for it to pass through the enterprise firewall system at the URL.
- Computer Firewall and Anti-virus software should be up-to-date and routinely maintained

### **Will you receive support and help with DataStream installation and testing?**

Yes. We have assembled a list of the primary contacts at each center who we believe can help with DataStream installation. Jeffrey O'Donnell, the URL Field Support Manager, will initiate contact and work with each center until the process has been fully validated. If you have questions or need technical support, you may contact Jeff O'Donnell at (412) 624-5539 or [odonnellj@edc.pitt.edu](mailto:odonnellj@edc.pitt.edu).

### **Accessing the installation files**

Once contact has been made with your center, you will be instructed to browse to this address to find the installation files specifically configured for your center.

<https://www12.edc.gsph.pitt.edu/URL/LLFS/DataStreamInstallationFiles/>



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### **4.3.2 Transferring Ultrasound Files to the URL central server**

The process for transferring files from the GE Ultrasound computers to the URL repository involves a few simple steps.

1. **Export a participant's files to the USB flash drive** using the export feature on the GE Ultrasound laptop device. A flash drive has been provided by the URL for this purpose. (Use an 8 or 16 GB 3.0 USB drive but not SanDisk brand).
2. **Insert the flash drive into the DataStream computer.**
3. **Copy the exported files from the USB flash drive to the C:\DICOM folder** on the DataStream computer. At a majority of centers, the drive letter that will be used to copy and store a participant's files will be the C: drive. However, some centers may install and/or use a secondary hard drive in the DataStream computer. If this is the case at your center, please substitute that drive letter for C: when reading this documentation.

*It is important that the files are copied to the \DICOM folder correctly.* Generally, we would like to see a participant's files under a top most folder that is the Participant ID (8 digit number). The GE export feature should export the files with the Participant ID as the top-most folder automatically.

C:\DICOM

\02122523 <- All participant 02121513 files should be in/under this folder

\78123456 <- All participant 78123456 files should be in/under this folder

*Note: It is ok to copy more than one participant's files to the DICOM folder for a single transfer. DataStream can transfer multiple participant files in a single session.*

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4. **Delete the participant files from the flash drive.** It is recommended that the flash drive be kept clean and organized by removing a participant's files after the files have been copied to the DataStream computer. This will help avoid confusion over which participants' files should be transferred.
  
5. **Allow DataStream to transfer the files automatically** at the pre-determined scheduled time. Typically, DataStream is scheduled to run at 12 PM local time at each of the centers. If for some reason it would be necessary to manually start the DataStream process, simply left-click on the desktop icon that matches the one above to the left of the section 4.3.2 title.



### **4.3.3 Remote control access & troubleshooting**

On occasion, it may be necessary to establish a secure and encrypted remote connection to your designated DataStream computer. It is not common that the URL would have to do this. However, in some cases it might be more efficient to allow us the ability to troubleshoot and correct an issue that you may be experiencing. If this were to be necessary, URL technical support will contact you directly and ask you to install remote control software. Once an issue is corrected, we will ask you to uninstall the software for security purposes.

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#### **4.4 Valid only if DataStreaming link is not functioning properly.**

#### **(11/09)4.4 Shipping Scan CD's, Log Sheets and Procedure Forms to the URL**

The LLFS ultrasound scans are recorded to CD's and shipped to the URL Reading Center in the event datastreaming is not working. Please follow the procedure below:

##### **CD Shipment guidelines**

1. Carotid scans must be saved on CD-R or CD-RW compact disc and clearly labeled with the study acronym or name and consecutively numbered.
2. Make a second copy of the CD before mailing to prevent lost data if the CD becomes lost or damaged.
3. CD must be protected within bubble wrap and mailed in a clearly labeled, sturdy envelope.
4. Use a mailing system that assigns a tracking number to the package. (i.e.: Fedex or UPS)
5. The following forms need to accompany the CD:
  - a. A copy of the corresponding participant log sheet for the entire CD.
  - b. One copy of the *URL Carotid IMT Worksheet* for each participant.
6. Mail the CD **weekly** to:

University of Pittsburgh  
Ultrasound Research Lab  
Attn: Tonee Marasco  
130 N. Bellefield Ave., Suite 444  
Pittsburgh, PA 15260
7. Any questions, please contact the Ultrasound Research Lab at 412-383-1452.

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### **5. Clinical Center Sonographers**

#### **5.0 Sonographer Certification**

### **Certification Requirements**

#### **1. Scanning site staff attends Training Session at the URL Reading Center**

Training session attendance is mandatory. Training begins at 8:00 AM and ends at 4:00 PM October 28- November 1, 2019. The training session consists of lecture time, scanning practice, demonstration of the analysis process, knobology, and a review of administrative procedures.

- a. Practice *at least* 10 full scans where protocol is demonstrated correctly; if ½ scans are done (one side) do 10 right and 10 left. A certified technologist must observe *at least* half of the practice scans and give direct verbal and/or written feedback.
- b. Five full pre-certification scans demonstrating correct protocol and captured images must be obtained. A certified tech will review and read images.
- c. ***NOTE: Pre-certification scans rejected due to image quality will be reviewed by a second reader.***

#### **2. Trained site staff are required to practice for 2 months between training session and certification visit**

- a. 3-5 scans per week will need to be performed and submitted to the URL Reading Center for review after training has occurred. This will allow for the techs to maintain practice and assure the Reading Center that each site sonographer stays current with the protocol.
- b. The Reading Center will advise each site on the quality of their images on a weekly basis. Additional scans may be required depending on the image quality and adherence to the LLFS scanning protocol.

#### **3. Scanning site staff participates in certification at the local site**

Certification session attendance is mandatory. Certification will take place over at least two full days. Dates to be determined for each site. The URL QC sonographer will travel to each site to certify the staff conducting carotid scans for their site. Alternatively, RAs will come to

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Pittsburgh to be certified. In certain situations, certification may take place at the site by a previously certified and qualified site RA.

- a. No less than 10 one-sided full certification scans, by both the trainee and a certified tech, must be completed. All scans must be readable to satisfy certification requirements.
  - b. ***NOTE: certification scans rejected due to image quality will be reviewed by a second reader.***
  - c. Accurate documentation is required for certification.
  - d. The read electronic files from the certified tech must be analyzed by the URL Reading Center before the new tech is certified.
4. Final certification will be obtained if the site staff meets all of the following criteria:
- a.  $\geq 80\%$  images with overall image quality of good or better (based on *URL Carotid Duplex Scan Feedback Form*).
  - b. Intraclass correlation of  $\geq 0.80$  in CCA\_IMT between site staff scans and URL certifying sonographer scans.
  - c. Mean absolute difference in CCA\_IMT of  $\leq 0.05$  between site staff scans and URL certifying sonographer scans.
  - d. At least 20 scout scans obtained per protocol for verification of best image selection and plaque identification
  - e. Worksheets accurately completed
5. If additional techs will be scanning at any of the sites, that tech will need to complete certification according to the URL Reading Center protocol that is identified above.
6. Once certified, all techs need to perform 2 carotid scans per month to maintain certification status through the URL Reading Center.
7. **If sonographer inactivity occurs for a primary or secondary sonographer of more than 2 consecutive months the site must perform 2 recertification CIMT exams to maintain certification status. The URL Reading Center will contact the site prior to expiration of CIMT certification.**

\*Official notification of sonographer certification will be sent via e-mail to the sonographer, site PI and study coordinator (see letter in Appendix).

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### **5.1 Sonographer Quality Control**

Following initial certification sonographer performance will be evaluated to monitor and assure quality control. The URL Reading Center has found it best to minimize the number of sonographers thereby limiting problems prospectively rather than retrospectively adjusting data.

To assure IMT scans and worksheet transcription protocols are adhered to, the following quality control (QC) procedure is recommended by the Ultrasound Research Laboratory (URL) reading center.

#### **Ongoing Image QC:**

Image QC will be done on a quarterly basis. Intra-sonographer variability will be assessed from the data obtained by repeating **five** randomly selected participants in each quarter by re-scanning one side only. The same side needs to be scanned for a given QC assessment. It is recommended that the sonographers alternate participant side scanned for QC on a quarterly basis (some sonographers have difficulty scanning one side versus the other). The worksheets are to be sent to the Ultrasound Research Lab for assessment at the end of the quarter (See shipping guidelines in Section 4.4 of the training manual). Deadlines for each will be determined by the start of each site's clinic visits. The scans and images will be critiqued at the Ultrasound Research Lab to be sure the worksheet transcription, scan protocol and plaque identification is followed correctly. Feedback will be sent individually to each site. If scans are suboptimal, remedial training will be provided. The PI will make the decision if scans should continue until the sonographers meet the recommended goals.

**RECERTIFICATION OF TECHNOLOGIST:** Will be done every year. The site sonographers will be scheduled to visit the University of Pittsburgh Ultrasound Research Lab. Alternatively the URL certifying sonographer will visit the site to recertify the site staff. There will be 10-20 volunteers scheduled to have scans. A designated technologist from the URL will scan one side of each participant; the site technologist will then scan the same side.

### **5.2 Ultrasound Research Lab—Sonographer Communication**

Experience with other studies has demonstrated the need for rapid and frequent communication between the URL Reading Center and the sonographers. Sonographers are asked to keep notes and to use the Reader Comments field on the log sheet so that they may provide direction to the URL Reading Center when necessary. Sonographers are encouraged to

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email or call the coordinating sonographer to discuss problems or questions with scanning or protocol as they arise. This will be coordinated with each site individually. At this time, Quality Assurance (QA) will take place on the US machines.

If a sonographer submits unacceptable or un-analyzable studies, the URL reading sonographer will alert the site sonographer as well as the site PI. An unacceptable study is defined as one from which very little or no data can be obtained. Unusable studies can be the result of poor images or failure to follow the protocol (e.g. images out of order). Continued poor performance by a sonographer will result in telephone call to the sonographer and the project director. Severe cases of persistent poor quality will warrant a memo to the site and be retained at the URL Reading Center. If necessary the URL Reading Center will request that the sonographer discontinue scanning for the study until improvement is made.

Throughout the exam period the URL Coordinating Sonographer will schedule a monthly conference call with the LLFS sonographers to review protocol issues as well as general ultrasound scanning questions. Also, the sonographers at each site will receive periodic emails from the Coordinating Sonographer to see if there are any site specific questions. The site sonographer should not hesitate to contact the Coordinating Sonographer either through email or a phone call to ask questions or to verify information from the training session or manual. It is better to be proactive about a concern rather than allowing it to wait for an unspecified period of time.

#### **5.3 Ultrasound Research Lab—Report on Sonographer Performance**

In addition to the periodic emails sent to each site sonographer, a sonographer quality control report will be generated monthly per site based on the *URL Carotid Duplex Scan Feedback Form* (see Section 10 of the training manual). This will be used to evaluate every image generated for the LLFS. The report will track each sonographer's performance based on an image quality score as well as measurability of the CCA segment. Copies of the report will be distributed to the PI's for review and their feedback as pertaining to their specific site. The URL Reading Center requests that this report be filed and retained on site in the LLFS training manual.

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### **5.4 Replacement or Retraining of a Sonographer**

If a sonographer resigns or is replaced due to poor performance, a replacement must be trained and certified prior to performing scans on research subjects. Consistent poor performance by a sonographer will initiate a call of encouragement by the Coordinating Sonographer. As discussed earlier in Section 5.2 of the training manual continued poor performance will result in the URL Reading Center will request the sonographer re-train at the URL Reading Center. A new sonographer can be introduced to the protocol by a certified sonographer, but the new sonographer will not be certified to conduct participant exams until they attend an URL Reading Center training session. Contact the URL Reading Center immediately if the need to train a new sonographer becomes apparent.

### **5.5 Achieving and Maintaining Quality Ultrasound Data**

Quality carotid ultrasound data begins with the site sonographer. The sonographer produces the images on which the URL Reading Center will use to measure the CIMT calculations. As has been discussed, a poor set of images results in a poor and sometimes incomplete set of data. The URL Reading Center is entirely dependent upon the site sonographers to provide clear images and to explain any conditions, anatomical or procedural that vary from the norm.



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### **5.6 Sample Certification Letter**

June 13, 2008

Dear XXXX,

Congratulations!

This letter serves as official notification that you have met the University of Pittsburgh Ultrasound Research Laboratory (URL) certification standards for carotid duplex scanning using the Terason T3000 Ultrasound System.

The certification scans that you completed met all three of the URL's standards for certification. Below are some specifics as to what the standards are and how you fulfilled them. For the purpose of this letter, I am only evaluating the CCA IMT (common carotid artery intima-media thickness) measurement.

The **first** thing we look at is if your scans and the certified tech's scans (in this case NAME) correlate well. This means that when you have thicker IMT (intima-media thickness) values the other tech also gets thicker IMT values, and vice versa. So as the wall thickens both techs' data look about the same. When yours goes up, hers goes up... when yours go down, hers go down. The correlation between your IMT values and NAME was 0.91 (a value of 1 represents perfect correlation).

The **second** piece is to see how much difference there is in IMT values between your scan and the certified tech's scan. We like to see these values to be around 0.03 mm. Most of yours were pretty close ranging from -0.09 to 0.04. The mean absolute difference between your IMT values was 0.03. We also look to see that there are no patterns in the difference in IMT between the two techs. There was not a statistical difference between you and NAME's values.

The **third** piece is to evaluate the source of variation in IMT. This is called the intraclass correlation (ICC). It evaluates how much of the variability comes from the patient, the sonographer and the reader. We strive for 0.85 or above and yours was 0.92. One of the variables that drives this number is the range of IMT values and since you and NAME were able to scan participants with a wide range of ages, this worked in your favor.

Additionally, we also make sure that the new tech is following scanning protocol and completing the data entry worksheets correctly. As far as the scanning protocol, the images that you obtained followed the protocol specified during your training. Moreover, **Tonee**, the URL's quality control sonographer, has indicated that your images were of **excellent quality**. **Tonee** has also indicated that you now consistently provide the correct number of images. This helps **Tonee** in completing her reading efficiently.

**In summary**, you did a great job and you are now certified to do scans. For ongoing quality control, the plan, as specified during your training session, is to do **5** scans per tech per quarter for the first year and then **10** scans annually thereafter. In both cases, you and NAME will need to scan the same participants twice. Please refer to the training manual for specifics.

Please let me know if you have any questions concerning your certification.

Sincerely,

Emma Barinas-Mitchell, PhD  
Assistant Professor  
Director, Ultrasound Research Laboratory  
Department of Epidemiology Graduate School of Public Health

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### **Summary**

To reiterate how to maintain high quality ultrasound data:

- Acquire clean images that clearly display the intimal linings and any lesions within the carotid system. These areas are top priority as they are what will be measured by the URL Reading Center and reported to each site as useable data. It can be expected that in order to clearly display the intimal linings the lumen may have to contain more artifacts than the typical clinical study but not so many that the intimal lining cannot be identified. This is a fine line that needs to be followed and this is why research sonographers are being trained in standardized methodology and require certification to perform research CIMT exams.
- Follow the image order stated by the protocol.
- Input the participant correctly according to the study protocol
- Do not change image settings as these are standardized for each machine and the study.
- Magnify only according to study protocols.
- Use the Comment section of the log sheet to communicate to the URL Reading Center.
- Properly use the cine protocol to identify and capture the scout scan and plaques
- Verify the participants study ID and follow the stated protocol for assigning the URL ID as this is very important.
- Complete the *URL Carotid IMT Worksheet* after scanning each side as the information will be fresh in your mind.
- Contact the URL Reading Center or Coordinating Sonographer immediately if there are questions related to the imaging protocol, machines or data transfer.