Manual 6A

Ultrasound Assessment: Ultrasound Scanning Procedures for Visit 2

The National Heart, Lung, and Blood Institute
of the National Institutes of Health

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY PROTOCOL

MANUAL 6A

ULTRASOUND ASSESSMENT: ULTRASOUND SCANNING PROCEDURES FOR VISIT 2

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FIGURE LEGEND

1. INTRODUCTION

The second ultrasound examination of participants in the ARIC cohort (Visit 02) consists of the following components: (1) ultrasonic imaging of the carotid arteries in the neck (scanning of the popliteal arteries has been discontinued in Visit 02); (2) measurement of carotid artery distensibility upon completion of the ultrasonic imaging exams; and (3) monitoring of arterial blood pressure throughout the ultrasound examination. This ARIC manual (6A) details the procedures to be followed in the ultrasound scanning of the carotid arteries and a brief description of the procedures for measuring arterial distensibility. A complete manual of operations for arterial distensibility is published as Manual 6C. The procedures for monitoring arterial blood pressure are outlined in this manual, and detailed instructions are given in the Dinamap Service Manual, which is included with each Dinamap. Interpretation of the ultrasound examination performed at the ARIC Ultrasound Reading Center (URC) is described in the Ultrasound Reading Protocol (Manual 6B). Additional detail on the procedures to measure arterial blood pressure and the rapid sequential blood pressure monitoring are described in Section 1, Manual 11 of the ARIC protocol, Sitting Blood Pressure and Postural Changes in Blood Pressure and Heart Rate.

2. SELECTION OF ULTRASOUND SYSTEM

The ultrasound system selected for use in the ARIC study is the Biosound 2000 II sa. Selection was based on the results of a series of detailed protocols performed on systems provided by four different manufacturers, and included in-vitro tests on excised arteries, measurement of the transmitted pressure pulse with a miniature hydrophone probe, routine system performance measurements on phantom test objects, and in-vivo evaluations which included considerations of ease of use by the sonographer.

3. ARTERIAL SITES AND ANATOMIC STRUCTURES TO BE EXAMINED

In order to obtain a noninvasive quantitative measure of early atherosclerotic disease in the ARIC cohort, ultrasonic imaging methods are used. The carotid arteries which are the principal suppliers of blood to the brain are a common location for early disease, primarily within or in close proximity to the bifurcation. These arteries, generally located within a few centimeters of the skin surface, are well suited to examination with high resolution ultrasonic imaging methods. The ARIC ultrasound examination concentrates on the segment in the right and left carotid artery known as the carotid bifurcation (See Figure 1). Ultrasound is attempted at 14 defined sites within this area. The sites to be examined are longitudinally visualized in the vertical third of the B-mode image screen with the wall boundaries positioned as nearly as possible vertically on the screen.

3.1 Priority for Boundary Visualization

In most instances, it is not possible to simultaneously obtain high quality longitudinal images of both the near and far wall boundaries of the arterial segment being examined in the same image frame. This condition results primarily from the highly specular nature of the ultrasonic reflections from the blood-intima boundaries and the general deviation of the arterial geometry from a cylindrical shape. Consequently, priorities are placed on which

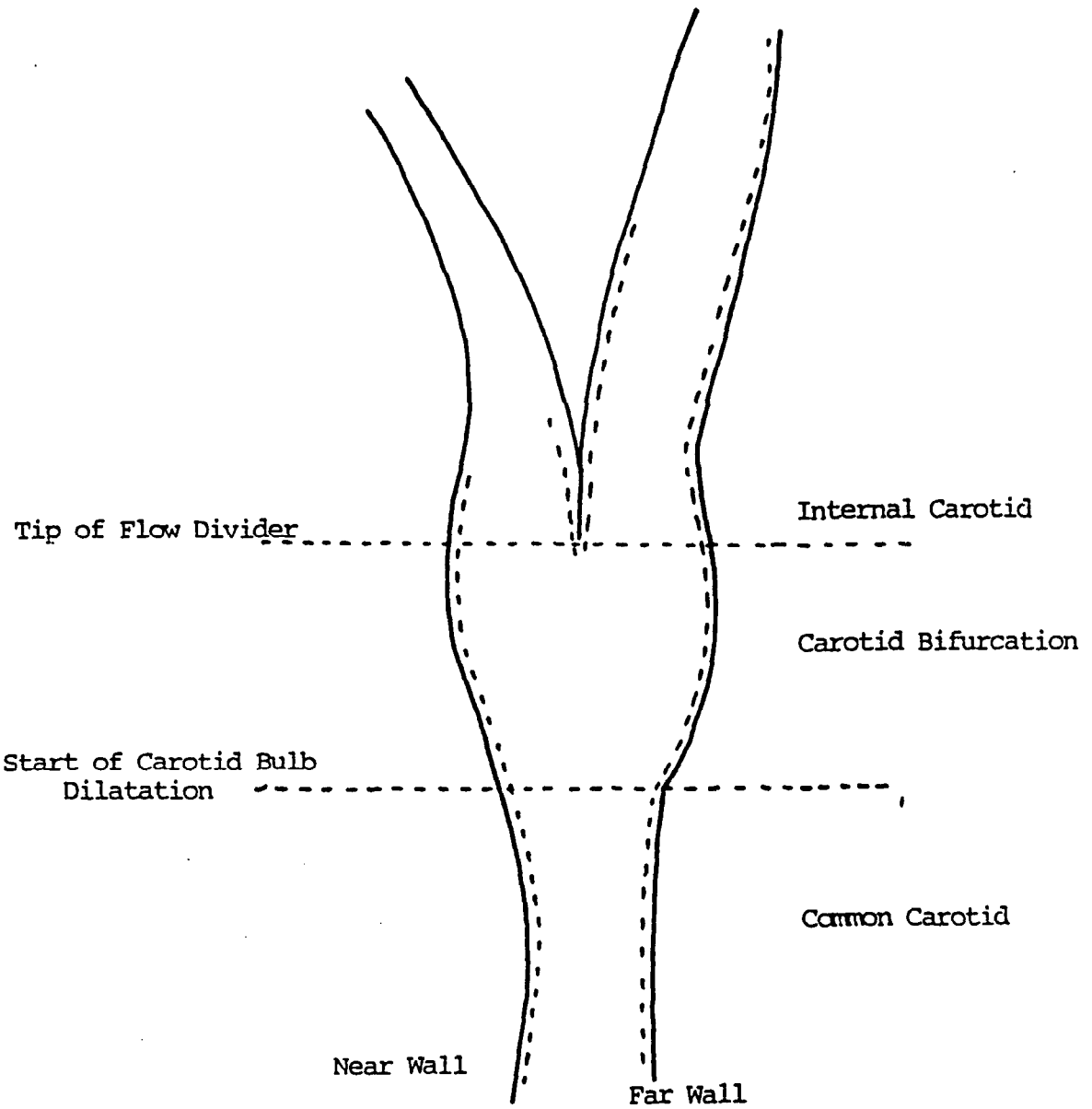


Figure 1. Schematic of Carotid Artery Segments Interrogated

arterial wall boundaries should be visualized with the others being visualized if possible but with potentially lesser quality.

The two most important wall boundaries to be visualized are first, the media-adventitia boundary on the far wall and second, the adventitia-media boundary on the near wall. This permits the outer boundaries of the media to be identified. The third most important boundary is the far wall blood-intima, which is visualized if good images of the first two boundaries can be maintained. Fourthly, if possible without losing this third boundary, the intima-blood boundary on the near wall is visualized. An image of the common carotid artery in which all four boundaries are visualized is shown in Figure 2. This sequence of priorities is used when imaging any segment of the carotid arteries with the exception of the internal carotid, which is discussed in Section 3.2.5.

3.2 The Carotid Arteries

3.2.1 Anatomical References

The arterial segments defined for ultrasonic examination are referenced to certain anatomical landmarks which are normally identifiable within the carotid system. One is the tip of the flow divider which defines the position along the vessel where the internal carotid artery and external carotid artery begin. A second, but less clearly delineated, is the location where the common carotid artery begins to widen into the carotid bifurcation or bulb. These landmarks are illustrated in Figure 1. In order to image defined segments referenced to these landmarks, longitudinal images are required. During each image sequence the cursor on the Biosound image screen is placed at the vertical level of the appropriate landmark for use in the reading of the B-mode images at the Ultrasound Reading Center.

3.2.2 Optimal Interrogation Angle

The optimal ultrasonic interrogation angle which permits clear identification of the anatomical references on the B-mode images depends upon specific anatomical features of the participant. This dependence of interrogation angle on the individual patient requires that great care be given during the initial stages of the examination to identify this angle. It depends upon both the ultrasound transducer position and the orientation of the head of the participant.

If the proximal segments of the internal and external carotid arteries lie in a common plane, it should be possible to interrogate the bifurcation from an angle which provides an image characterized by a "Y" appearance. This is illustrated in Figure 3. From this angle, the location of the two anatomical references can normally be seen. In some individuals, it is often difficult to sharply define the origin of the bifurcation if a pronounced widening does not occur, but it is most likely to be visible from this angle.

If the proximal segments of the internal and external carotid arteries do not lie in a common plane, it may be impossible for the sonographer to obtain the characteristic "Y" appearance at the bifurcation. Either one or the other of the branches can be imaged at a given interrogation angle but not both. In many cases, repositioning of the head of the participant may permit the two

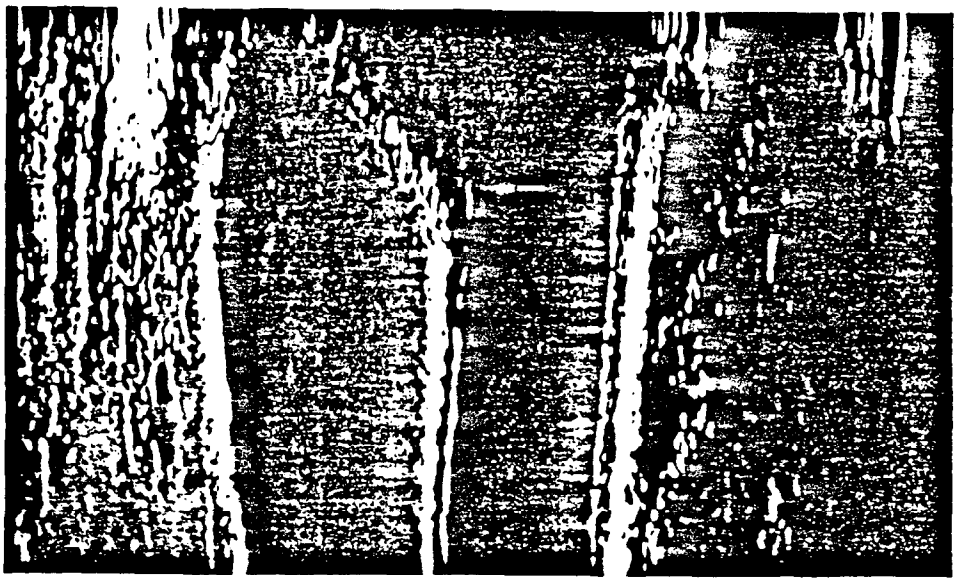


Figure 2. Common Carotid Artery (All Four Boundaries Visualized)

Figure 3. The Bulb

arteries to more closely approach a common plane. Often careful attention to this position and small head angle changes will permit the "Y" to be visualized.

If repositioning of the head does not yield the desired result, it should nevertheless be possible to identify the anatomical references by observing a sequence of images taken as first one and then the other arterial branch is imaged as the transducer interrogation angle is changed. In this case, the optimal angle is defined as the midpoint between where the first one and then the other arterial branch is well visualized.

3.2.3 The Common Carotid Artery

3.2.3.1 The Common Carotid Optimal

The first images of the common carotid artery are obtained at the optimal interrogation angle. They are referenced to the origin of the bifurcation where the common carotid begins to widen into the bulb. The segment located 10 mm proximal to this landmark is the focus of attention.

3.2.3.2 Common Carotid Standard Interrogation Angles

The common carotid artery is also scanned at two additional interrogation angles defined relative to the vertical and horizontal planes. For these interrogations, the patient's head is positioned at 45° relative to the surface of the examination table using a foam wedge, as described in Section 10. These interrogation angles are measured using the carpenter level attached to the transducer handle. One position (anterior) corresponds to an interrogation angle of +55° from the horizontal. The second (posterior) corresponds to an interrogation angle of -10° from the horizontal. Images are acquired at each of these angles and once again the focus of the sonographer is the 10 mm segment proximal to the origin of the bifurcation. Great care must be exercised to assure that the anatomical reference (origin of the bulb) is once again marked with the cursor. It will in general be necessary to observe images close to the optimal angle to identify the level of this landmark and then move laterally while rotating the transducer angle without slipping up or down the vessel.

3.2.4 The Carotid Bifurcation

The segment of the carotid bifurcation extending 10 mm proximal to the tip of the flow divider is now imaged. In some participants this may extend into the common carotid for a few millimeters. The sonographer must return to the optimal angle and place the cursor at the level of the tip of the flow divider. Images are then acquired at this interrogation angle taking great care to use the priority sequence of boundary visualization described above. After completing the internal carotid artery, the sonographer returns to the bifurcation. The far wall and near wall are imaged separately in two additional views, as described in Section 3.2.6.

3.2.5 The Internal Carotid Artery

The segment of the internal carotid artery extending 10 mm distal from the tip of the flow divider is now imaged. Images are acquired of this segment once

again marking the tip of the flow divider as the anatomical landmark. It is important to carefully distinguish between the internal and external carotid arteries using two criteria: (1) normally the internal has a significantly larger diameter than the external; (2) the blood flow velocity pattern in the two vessels, as determined with Doppler ultrasound, is distinctly different (see below). Used together, these two considerations permit the internal carotid artery to be identified with a high degree of confidence.

During the initial scanning procedure it is necessary to distinguish clearly between internal and external carotid arteries. Tributaries originating from the external carotid artery are occasionally viewed with B-mode ultrasound to help in this differentiation. In most cases, Doppler ultrasound is more efficient and specific for this separation. The method and criteria for this identification are as follows:

A B-mode image is obtained of the carotid bifurcation where the common carotid artery divides. In some instances the best anatomical angle will show the flow divider as well as the proximal internal and external carotid arteries. In the remaining cases the flow divider and only one vessel can be seen from a single angle. In those instances the other artery can be visualized by gently rocking the ultrasound probe back and forth in angle or position or both. Doppler is used to differentiate internal and external carotid arteries in these instances. To obtain a Doppler sample of each artery, the Doppler sample volume is placed into the branch farthest from skin surface. Using the instrument cursor and the knob on the joystick, the sample volume is made small enough to be totally within the lumen. The Doppler footswitch is depressed and released. The sonographer observes the tracing on the TV monitor and listens to the Doppler signal. If the ultrasound probe is in the internal carotid artery, the flow pattern will be that of a low-resistance bed. This signal has a rapid upstroke and a quasi-steady flow through systole and diastole. The flow continues throughout the cardiac cycle and begins to increase again at the next systole.

The flow pattern is graphically displayed near the zero baseline. Flow directed toward the head and away from the heart throughout the cycle is represented as a tracing above the baseline in Figure 4. If the Doppler signal does not correspond to the expected pattern, the cursor is placed within the other branch of the common carotid artery. The external carotid artery is usually nearer the skin surface when viewed from an anterior angle and is a high-resistance vessel. The characteristics of Doppler signal in this vessel are a forward flow with a sharp upstroke and sometimes a reversal of the flow at diastole (multiphasic). The hallmark of a high-resistance artery is cessation of flow before the onset of the next systole as defined in Figure 5.

Abnormal flow is demonstrated by turbulence within the lumen and disruption of normal flow. This is identified in the Doppler signal by broadening the Doppler spectrum. Severe narrowing of the artery lumen is identified by an increase in the expected peak systolic frequency. If occlusion is present there will be no Doppler signal, in which case the external and internal carotid arteries can be defined by the external being more anterior to the internal anatomically. If flow is sampled from the common carotid artery, there will be a rapid systolic up-stroke with small reversal of flow and a quasi-steady flow throughout diastole. This is a combination of internal and external carotid flow patterns, as shown in Figure 6.

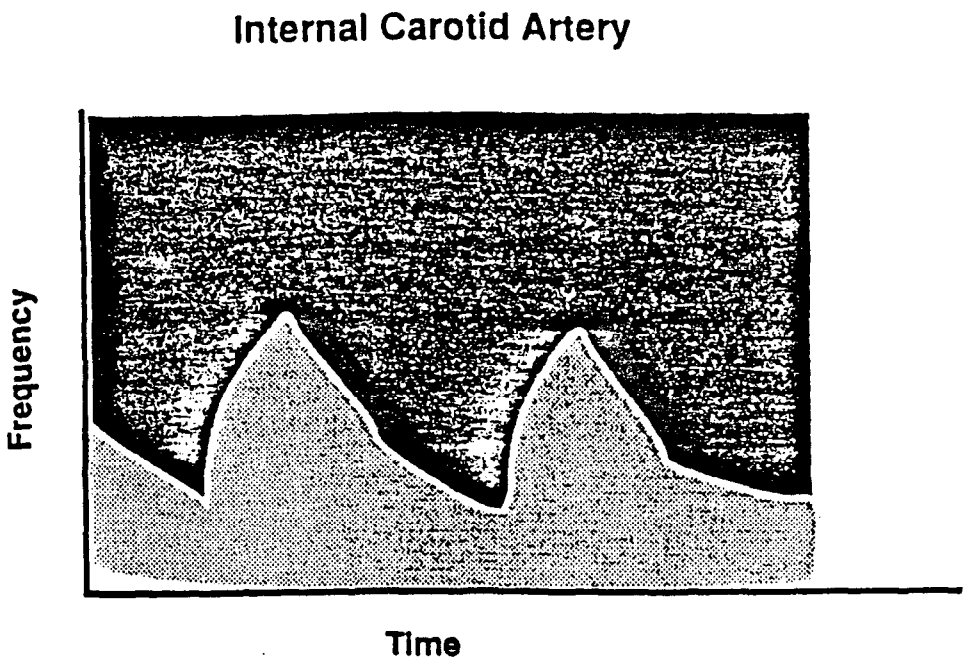


Figure 4. Doppler Tracing: Internal Carotid Artery

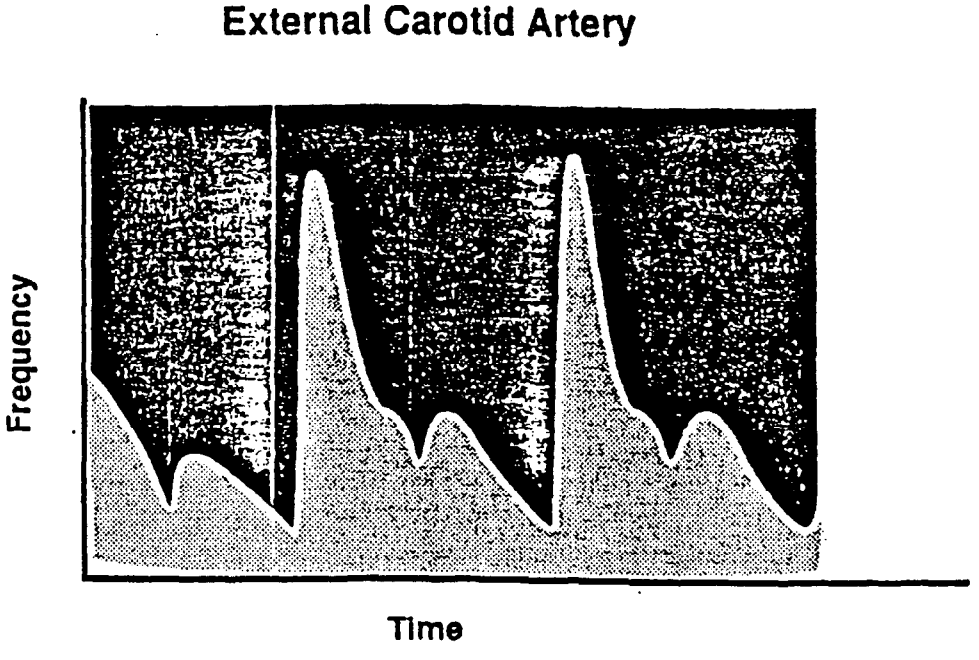


Figure 5. Doppler Tracking: External Carotid Artery

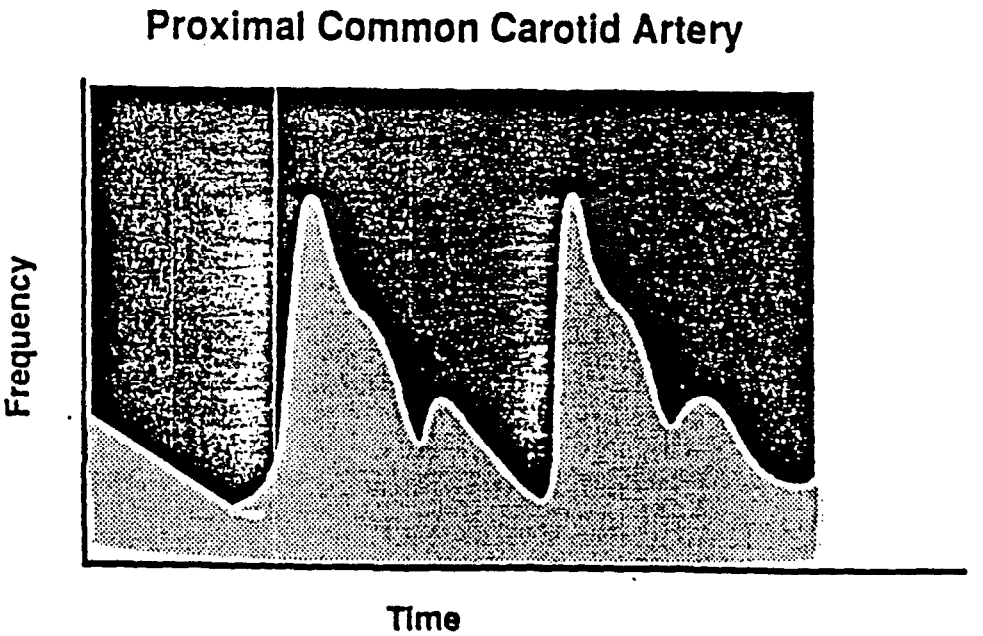


Figure 6. Doppler Tracing: Combination of Internal and External Carotid Flow Patterns

Because of the more varied positioning and geometry of the internal carotid, the sequence of priorities to be used when imaging this segment is modified from that used in the common and bifurcation. The two far wall boundaries should receive highest priority, the near wall adventitia-media interface next priority and finally the near wall intima-blood boundary.

3.2.6 Independent Views of the Far and Near Bulb Walls

3.2.6.1 Far Wall

After imaging the far wall of the internal, the carotid bulb at the optimal angle is imaged again. This image should appear as described in Section 3.2.3.2. The ultrasound probe is tilted along the arterial axis in such a manner that the far wall of the bulb becomes vertical in the center of the display screen. the quality of the near wall echoes will deteriorate. At this time, small changes in probe angle are made to image the far wall intima and media interfaces. After the far wall image is obtained, the probe is rotated back to obtain the carotid bulb optimal angle image again.

3.2.6.2 Near Wall

The probe is rotated along the axis of the artery so that the near wall of the bulb is now oriented vertically in the center of the display screen. the quality of the far wall echoes will deteriorate. Small changes in probe angle are made to image the near wall intima and media interfaces.

3.3 Cursor Placement by Site and Side

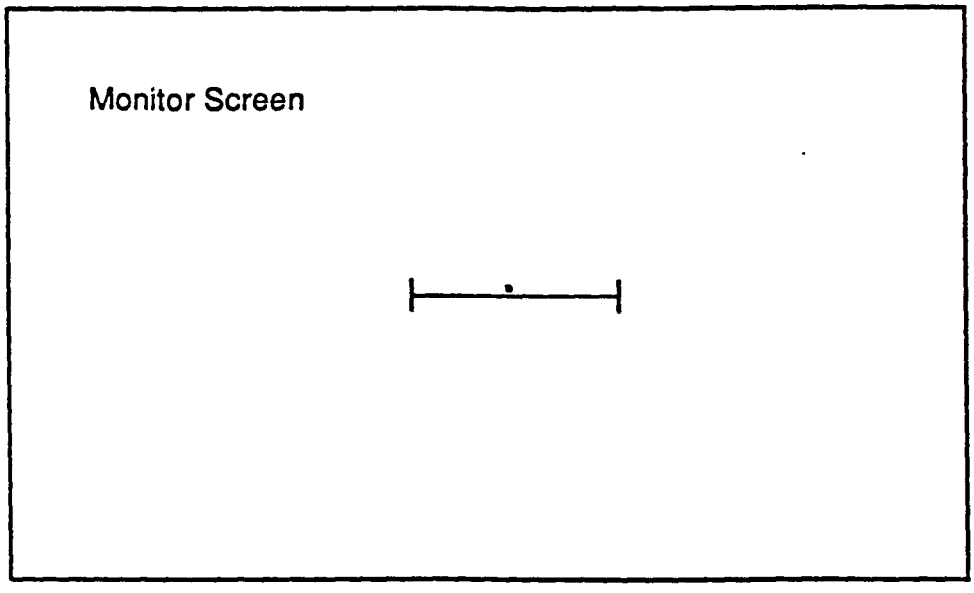
3.3.1 Ultrasound Monitor

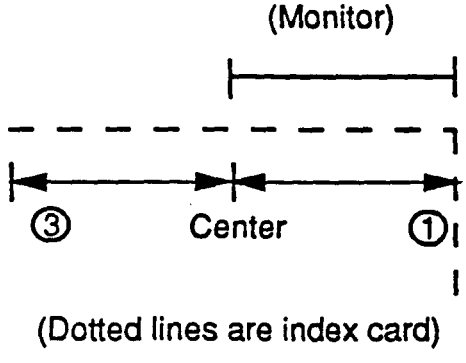
Set the Biosound video monitor used to display the ultrasound images to the larger size. To do this, the sonographer sets the Biosound scan size control to the OUT position (larger of the two sizes). When the monitor is set to this size, measurements are larger than normal. The sonographer marks the video monitor screen glass to define an optimum imaging area as follows.

a. While in the calibration mode, the sonographer places the cursor in Doppler mode, center position, so that the line appears as a horizontal line in the middle of the screen. The length of the calibration line is adjusted to 5.0 mm, as indicated in the upper right of the monitor screen. The 5.0 mm calibration line should be in or very near the center of the screen, as shown in Figure 7a.

b. The right corner edge of a 3" x 5" index card is placed just underneath the 5.0 mm calibration line on the monitor, and the sonographer marks two lengths of that 5.0 mm calibration line onto the card. She starts the measurement from the right edge of this card, (mark #1) which serves as the starting mark. The center mark is the end of one 5.0 mm measurement and is the pivot point in step d. Mark #3 is the end of the second 5.0 mm measurement. See Figure 7a, upper right corner.

c. The length of the calibration line on the monitor is increased to 20.0 mm. This 20.0 mm calibration line is centered on the screen.

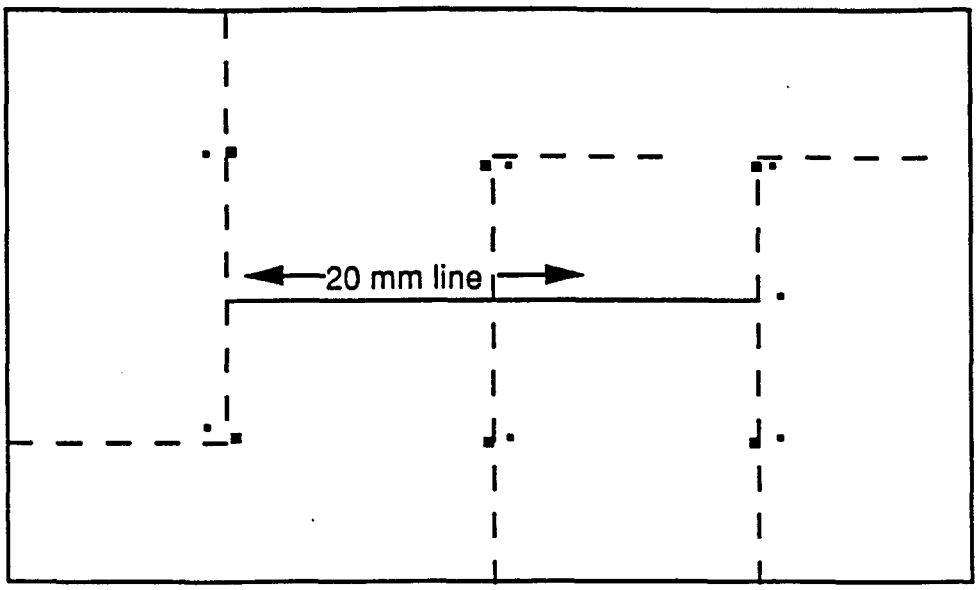




(Dotted lines are index card)

Marking two 5.0 mm measurements on index card.

Figure 7a. 5.0 mm Calibration Line



(Dotted lines are index card)

Figure 7b. Using index card to mark 5.0 mm dots above and below 20.00 mm calibration

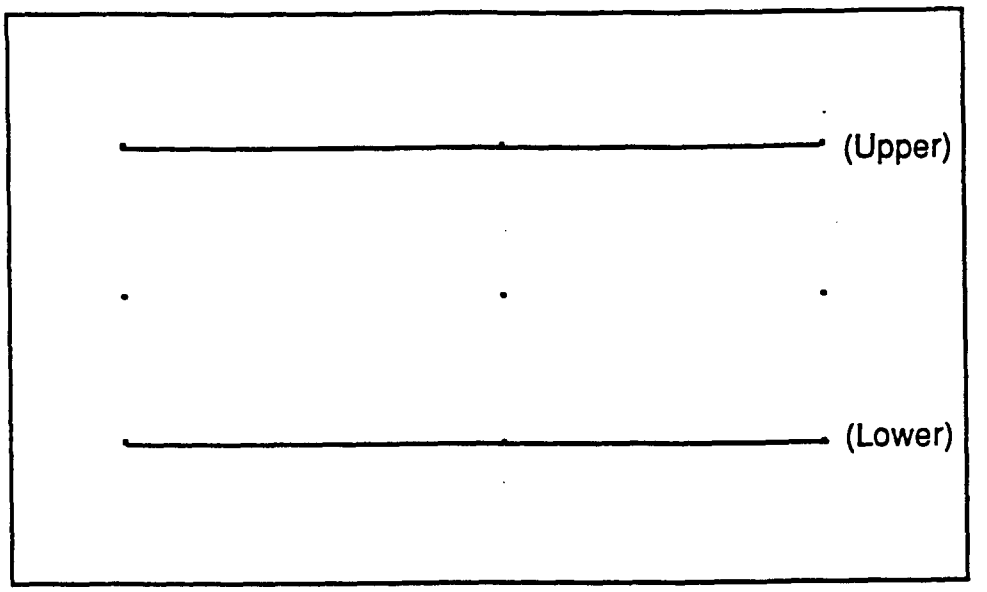


Figure 7c. Upper and lower imaging boundaries after drawing line through dots.

d. The index card is pressed against the monitor. The sonographer makes sure the center measurement mark on the card matches the center of the 20.0 mm calibration line on the monitor, and turns the card to a vertical position, keeping the center points as a pivot. A "Sharpie" fine point felt marker is used to place dots on the monitor glass, aligning the dots with marks one and three on the 3" x 5" index card. A mark is made above and below the center of the 20.0 mm calibration line on the monitor.

e. The 3" x 5" index card is positioned first to one end and then to the other end of the 20.0 mm line on the monitor. The sonographer uses the method in step (d) each time to make a dot above and below the 20.0 mm calibration line. The sonographer has now put six dots on the monitor: three above and three below the 20.0 mm calibration line (Figure 7b).

f. A line is drawn with a ruler through the three points above and below the 20.0 mm calibration line. The upper line is the upper imaging boundary, and the lower line is the lower imaging boundary. (Figure 7c)

This completes the monitor glass marking. An optimum imaging area is now defined in the middle 10.00 mm of the monitor image screen.

3.3.2 Common Carotid Cursor Placement

The common carotid artery image is oriented so that the arterial walls appear vertically on the monitor screen. The cursor length is set to its minimum length of 1.0 mm for the right common carotid artery. The ultrasound probe is moved so that the upper imaging boundary passes through the origin of the bulb on both near and far arterial walls. The cursor is placed on the upper imaging boundary, approximately in the center of the lumen. The optimum ultrasound image appears between the upper and lower imaging boundaries. For the left common carotid artery, the ultrasound probe is moved so that the lower imaging boundary passes through the origin of the bulb on both near and far arterial walls. The cursor is placed on the lower imaging boundary approximately in the center of the lumen. The optimum ultrasound image appears between the lower and upper imaging boundaries. Figure 8a shows a right common carotid artery, and Figure 8b shows the left common carotid artery.

3.3.3 Bulb Area Cursor Placement

The landmark for all images in the bulb area is the tip of the flow divider. In some views, the tip of the flow divider may disappear, but the cursor should indicate its location on the monitor screen.

For the right side, the tip of the flow divider is placed on the upper imaging boundary. The cursor is placed on the upper imaging boundary at the tip of the flow divider. The cursor is placed within the lumen as shown in Figure 9a. The optimum ultrasound image appears between the upper and lower imaging boundaries.

In the two views of the bulb, when only the far wall or the near wall is imaged, the tip of the flow divider is placed on the upper imaging boundary. The cursor is also placed on the upper imaging boundary. The ultrasound probe is manipulated until the far or near wall image is optimized. The cursor is then moved to a position along the upper imaging boundary near the wall

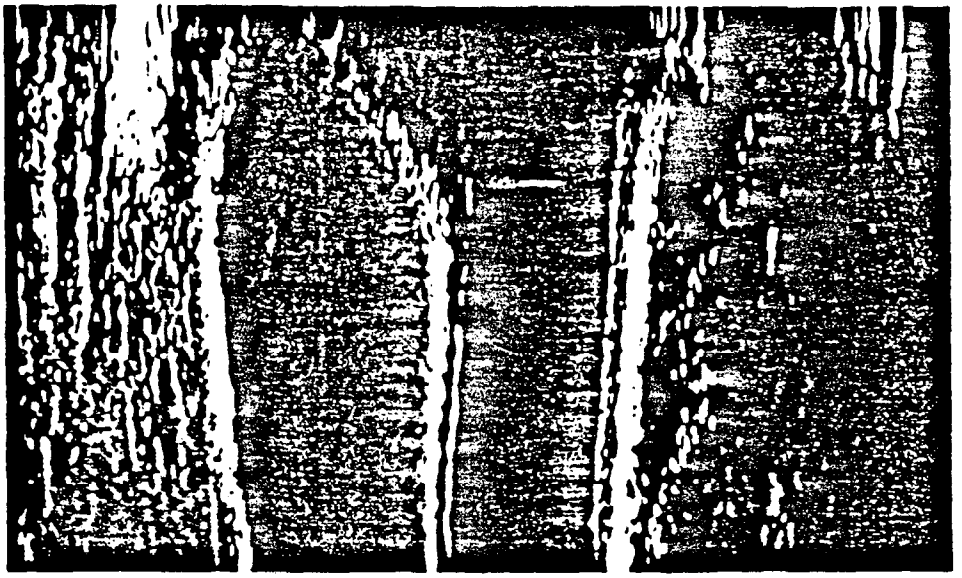


Figure 8a. Right Common Carotid - Optimal Angle

Figure 8b. Left Common Carotid - Optimal Angle

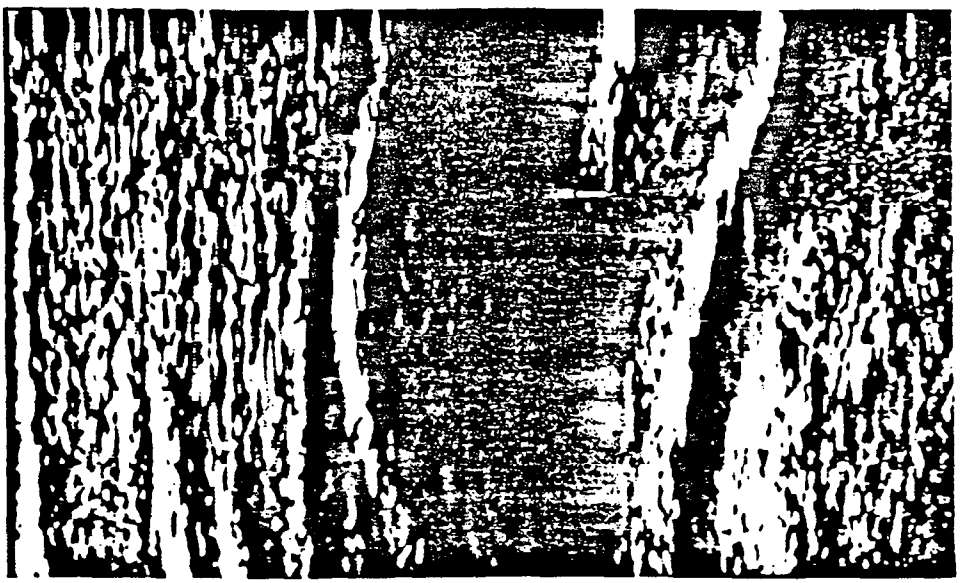


Figure 9a. Right Carotid Bulb - Optimal Angle

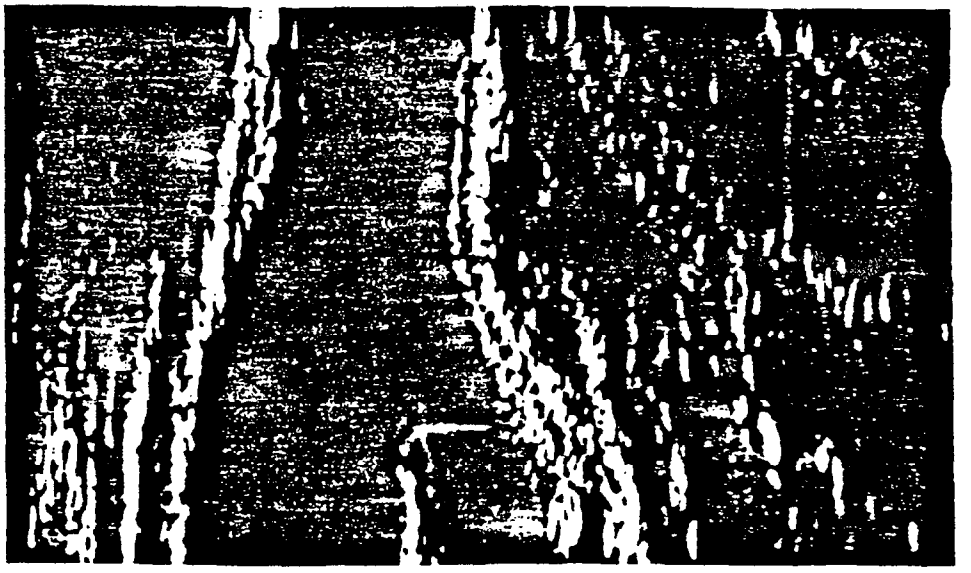


Figure 9b. Left Carotid Bulb - Optimal Angle

interfaces being imaged. The cursor should not interfere with the wall interfaces being imaged, but remain in the lumen area.

For the left side, the tip of the flow divider is placed on the lower imaging boundary. The cursor is placed on the lower imaging boundary at the tip of the flow divider as shown in Figure 9b. The optimum ultrasound image appears between the lower and the upper imaging boundaries.

In the two views of the bulb, when only the far wall or the near wall is imaged, the tip of the flow divider is placed on the lower imaging boundary. The ultrasound probe is manipulated until the far or near wall image is optimized. The cursor is then moved to a position along the lower imaging boundary near the wall interfaces being imaged. The cursor should not interfere with the wall interfaces being imaged, but remain in the lumen area.

3.3.4 Internal Carotid Cursor Placement

The landmark for the internal carotid artery is the tip of the flow divider. Primarily, the far wall of the internal carotid is imaged.

For the right side, the tip of the flow divider is placed on the lower imaging boundary. The cursor is placed on the lower imaging boundary approximately in the center of the lumen as shown in Figure 10a. The optimum ultrasound image appears between the lower and upper imaging boundaries.

For the left side, the tip of the flow divider is placed on the upper imaging boundary. The cursor is placed on the upper imaging boundary approximately in the center of the lumen as shown in Figure 10b. The optimum ultrasound image appears between the upper and lower imaging boundaries.

4. SONOGRAPHER TRAINING, CERTIFICATION AND MONITORING

4.1 Training

The sonographer training program includes training sessions held at the respective field centers and the Ultrasound Reading Center, followed by practice scans and certification steps at the field centers.

4.1.1 Stage 1

During the initial week, a new sonographer works with the ARIC certified sonographers at the field center to observe the ultrasound area activities, become familiar with the equipment, read the introductory material supplied by the URC, and become familiar with this scanning protocol.

4.1.2 Stage 2

At the Ultrasound Reading Center, the second week (40 hours) consists of lectures, demonstrations, and practical laboratory experience, on the following topics:

a. Overview of the ARIC study.
b. Role of the Ultrasound Reading Center.

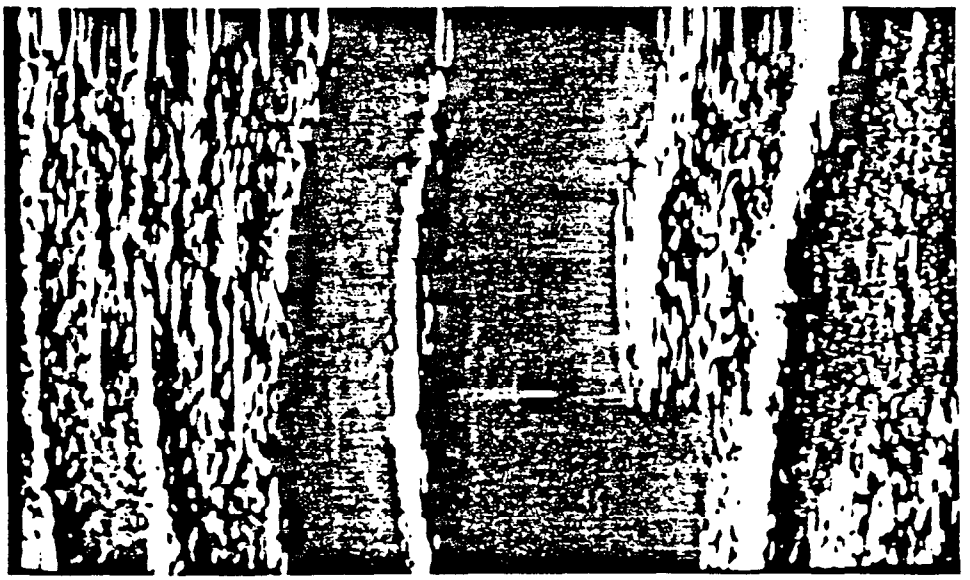


Figure 10a. Right Internal Carotid

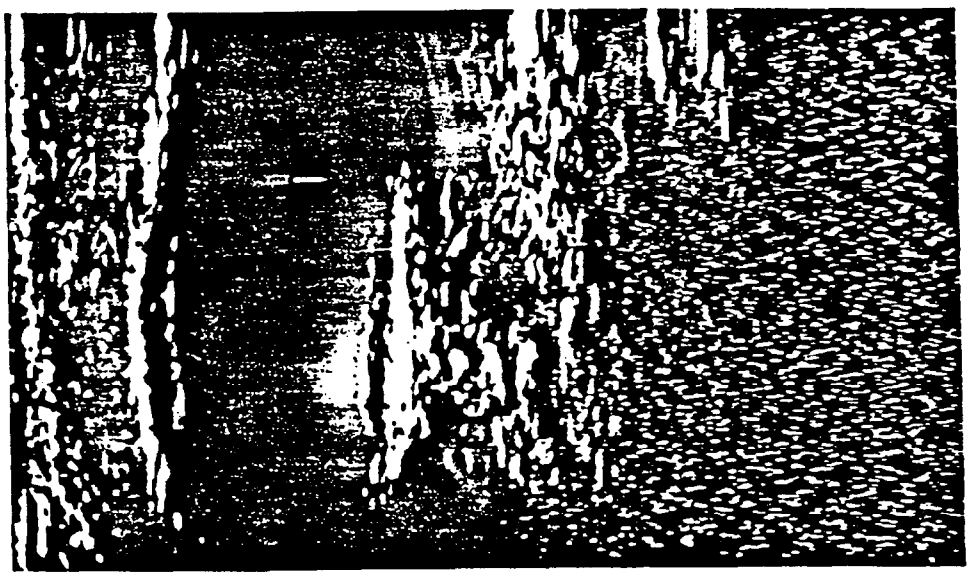


Figure 10b. Left Internal Carotid

c. Ultrasonic Physics I, including basic physics concepts, units of measurement, and mathematics arising in the medical applications of ultrasound.
d. Overview of atherosclerosis and a detailed discussion of the normal artery wall.
e. Ultrasonic Physics II, including a discussion of the properties of ultrasonic waves, reflection at boundaries and scattering from small objects.
f. Ultrasonic Physics III, including the Doppler effect, ultrasound transducers and sound beams.
g. Pathology of Atherosclerosis, including dissection of arterial specimens.
h. Principles of Ultrasonic Instrumentation, including pulse-echo imaging systems, pulsed Doppler systems, and spectral analysis.
i. Basic operation of the Biosound 2000 II sa.
j. Instrument Performance Monitoring.
k. Principles of Ultrasound Arterial Scanning.

The remaining central training time (15 hours) is spent practicing scanning technique and the ARIC protocol, including the use of the study flow panel, IBM personal computer, the Dinamap automated blood pressure instrument and the arterial wall tracker.

4.1.3 Stage 3

After a sonographer returns to the field center, scans are performed using the ARIC protocol on at least ten volunteers. These scans are done under the direct supervision of the chief sonographer who guides, evaluates, offers suggestions for improvements, and answers questions as they arise. Each scan is reviewed with the new sonographer, and strengths and weaknesses are identified.

The chief sonographers complete a Sonographer Evaluation Form for each practice study (Figure 11). The number and quality of arterial wall interfaces are evaluated and rated at each interrogation site. When the chief sonographer is satisfied that the supervised volunteer scans comply with standards of quality of interfaces, image alignment, cursor placement, interrogation angles and overall quality of scanning and distensibility, the chief sonographer notifies the Ultrasound Reading Center that the sonographer has completed the supervised volunteer phase. A video cassette with the last two scans and the corresponding Sonographer Evaluation Forms are forwarded to the URC for review and concurrence.

4.1.4 Stage 4

After approval by the Ultrasound Reading Center, the new sonographer performs scans on study participants under the direct supervision of the chief sonographer. The chief sonographer is responsible for the quality of the images but the novice sonographer assigns his/her ID number to these studies. At least ten participant scans are performed in this mode. All such studies are identified and sent to the URC for evaluation along with the normal weekly shipment of tapes.

These scans are carefully reviewed by the Ultrasound Reading Center personnel for certification quality. A running window of ten scans is tracked, and when

B-MODE STUDY SCAN EVALUATION FORM

SONOGRAPHER NAME & ID:_____ EXAM DATE:_____ REVIEW DATE:_____

PART. ID_____ CASSETTE ID:_____ TAPE COUNTER(SCAN):_____:_____ TO_____:_____

DIMENSIONAL MARKER:_____ TAPE LABELING:_____ GRAY SCALE:_____ HEARTBEAT REG._____ REVIEWER___

PRELIMINARY SCAN (From Protocol) "The common carotid, bulb and internal carotid are scanned... . Locate the origin of the bulb and the tip of the flow divider, and determine the optimal angle."

☐ ACCEPTABLE ☐ UNACCEPTABLE ☐ NOT DONE_____

DOPPLER USED ☐ YES ☐ NO

48 RCC-OA COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

OPTIMAL ◁ ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

49 RCC-AA COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

50 RCC-PA COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

80 R BIF COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

OPTIMAL ◁ ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

112 R INT COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

OPTIMAL ◁ ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

84 R BIF-FAR COMMENTS:_____

4 - 5 E G F A P U_____

CURSOR-Vicinity/wall Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

92 R BIF-NEAR COMMENTS:_____

2 - 3 E G F A P U_____

CURSOR-Vicinity/wall Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

SUMMARY:_____ APPROX. TIME SPENT :

_____ RT. SIDE + Q.C. - :

_____ _____

E=Excellent(11-8 paired pts) G=Good (7-5) F=Fair (4-3) A=Adequate P=Problems U=Unacceptable

QUALITY CONTROL: Site-_____ Study Code-_____ Comments:_____

4-5 E G F A P U_____

2-3 E G F A P U_____

OPTIMAL ANGLE (If applicable): ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement

PRELIMINARY SCAN (From Protocol) "The common carotid, bulb and internal carotid are scanned... . Locate the origin of the bulb and the tip of the flow divider, and determine the optimal angle."

☐ ACCEPTABLE ☐ UNACCEPTABLE ☐ NOT DONE_____

DOPPLER USED ☐ YES ☐ NO

32 LCC-OA COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

OPTIMAL ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

33 LCC-AA COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

34 LCC-PA COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

64 L BIF COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

OPTIMAL ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

96 L INT COMMENTS:_____

4 - 5 E G F A P U_____

2 - 3 E G F A P U_____

OPTIMAL ☐ YES ☐ PROBABLY ☐ NO

CURSOR: In Lumen Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y N

68 L BIF-FAR COMMENTS:_____

4 - 5 E G F A P U_____

CURSOR-Vicinity/wall Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y

76 L BIF-NEAR COMMENTS:_____

2 - 3 E G F A P U_____

CURSOR-Vicinity/wall Y N At Landmark Y N On Boundary Line Y N *Image Screen Placement Y

SUMMARY:_____ APPROX. TIME SPENT :

_____ LEFT SIDE + Q.C. - :

_____

E=Excellent(11-8 paired pts) G=Good (7-5) F=Fair (4-3) A=Adequate P=Problems U=Unacce

eight of ten are acceptable, the sonographer is certified by the Ultrasound Reading Center.

4.2 Monitoring

Sonographer performance is monitored throughout the ARIC study at the respective field centers and the Ultrasound Reading Center.

4.2.1 Monitoring at Field Center

The chief sonographer at each field center reviews one study per month per sonographer including his or her own. The chief sonographer may elect to have another sonographer review her study or she may review it herself. The chief sonographer fills out a Sonographer Evaluation Form for each review (Figure 11).

The chief sonographer's primary purpose in reviewing these studies is to ensure the quality of the study data and adherence to the scanning protocol. The B-mode images are evaluated for overall image quality, the presence and clarity of the arterial wall boundaries, and the presence of anatomical landmarks and a cursor indicating the location of an anatomical landmark and the vessel lumen.

The time of the month for sonographer review for each sonographer is determined by the chief sonographer, but is not the same from month to month. It is recommended by the Ultrasound Reading Center that only one review per week be performed to reduce the time commitment during any one week. The study to be reviewed is chosen at random by a computer program called SONO.QC.

The chief sonographer pulls the chosen study of the week and reviews it on the Sony 3/4" VCR before the study is sent to the URC. For each study review, the chief sonographer or her assigned reviewer completes a Sonographer Evaluation Form, and all comments are discussed with the sonographer concerned. A copy of this form is kept at the field center, and a copy is sent to the Ultrasound Reading Center in the weekly shipment of video cassettes. The Ultrasound Reading Center reviews the same tape as discussed in Section 4.2.2.

4.2.2 Monitoring at the Ultrasound Reading Center

At the Ultrasound Reading Center, studies are monitored at the transcription station to identify equipment problems, such as excessive artifact in images, missing heartbeats, etc.

Sonographer performance is monitored at the Ultrasound Reading Center using a sequence of quality control procedures. The quality control procedures consist of (1) comparing results given by the same sonographer of repeat studies on a randomly selected identical site and angle of individual participants, (2) monthly reports containing statistics of boundary visualization by sonographer and field center. The reports are generated and distributed by the Ultrasound Reading Center.

In addition, the Ultrasound Reading Center independently reviews the same participant studies reviewed by the chief sonographers at the field centers. A sonographer evaluation form is completed and scored at the URC, and the results are compared to the score on the chief sonographer's form. Any significant

differences between scores, or any significant problems, are discussed with the chief sonographers to resolve the differences. Results of these sonographer evaluations are used to help maintain high standards for participant studies and are part of an ongoing sonographer recertification process.

The Ultrasound Reading Center readers read the ultrasound images from all the data collection procedures and the quality control images. Image interpretation results from study images and quality control images from the same site and angle are compared for use in sonographer quality control procedures. The purpose of these studies is to check for repeatable images and interpretation results within acceptable error bounds. The results of the quality levels for each sonographer are reported to the ARIC Coordinating Center and the field centers periodically. As discussed in Section 4.2.1, each sonographer has one randomly selected study per month reviewed by her field center chief sonographer. This same study is reviewed at the URC, and feedback is provided to the sonographer and chief sonographer.

4.3 Recertification

4.3.1 Annual Recertification

ARIC sonographers are certified annually. When a sonographer's certification anniversary date is reached, five randomly selected scans performed during the last ten weeks are reviewed and evaluated at the Ultrasound Reading Center. Four of five must be acceptable for recertification. The results from these evaluations, the monthly evaluations and the quarterly repeatability reports are considered in annual recertification.

4.3.2 Recertification of Sonographers Who Have Been Absent or Who Have Not Maintained the Required Number of Scans

4.3.2.1 If the sonographer is absent less than two months or is not maintaining the minimum number of required studies (20/month averaged over two months):

a. The sonographer remains on her current annual recertification schedule;
b. the chief sonographer updates sonographer on any changes in procedures;
c. the sonographer scans 20 participants per month;
d. the monthly review of a randomly selected scan by chief sonographer and URC resumes and/or continues.

4.3.2 If the sonographer is absent 2-12 months:

a. The chief sonographer updates sonographer on any changes in procedures;
b. the sonographer observes a minimum of five participant scans;
c. the first five scans done by sonographer are done under direct supervision of chief sonographer, reviewed by chief sonographer and by the Ultrasound Reading Center;
d. when the Ultrasound Reading Center determines four of five scans are acceptable, sonographer is recertified.

4.3.3 If the sonographer is absent twelve or more months OR a major change in protocol has occurred:

a. The chief sonographer updates sonographer on changes in procedures;
b. sonographer observes a minimum of five scans;
c. sonographer performs a minimum of five practice scans on volunteers under direct supervision of chief sonographer, and chief sonographer evaluates these scans to determine when sonographer may begin participant scans;
d. the first five scans on participants are reviewed by chief sonographer and Ultrasound Reading Center;
e. when the Ultrasound Reading Center determines four of five scans are acceptable, sonographer is recertified;
f. In many cases, a training session involving an Ultrasound Reading Center member may be necessary. This will be determined by many factors, including the length of absence, extent of changes in protocol, sonographer's past performance, and chief sonographer's or the reading center's impression of initial scans.

5. SUMMARY OF CHIEF SONOGRAPHER DUTIES

a. Assists the Ultrasound Reading Center in training new sonographers as described in Section 4.1.3, Stage 3.
b. Responsible for reviewing one study per month per sonographer at the field center. The chief sonographer selects one study per week at random and completes a Sonographer Evaluation Form on that study. A copy of the form is kept at the field center, and another is sent to the Ultrasound Reading Center. The completed form is reviewed with the sonographer. The chief sonographer may have another sonographer review one of her studies per month, or she may review it herself.
c. Responsible for reviewing the quality control reports from the Coordinating Center and Ultrasound Reading Center for:
   1) Average number of points per interface
   2) Mean absolute differences in repeat studies
   The chief sonographer, with the help of the Ultrasound Reading Center, reviews the quality control data prepared by the Ultrasound Reading Center for the field center, and for each sonographer at that field center. Current values and trends are reviewed, and if problems arise, the chief sonographer and the Ultrasound Reading Center work together to implement solutions.
d. Responsible for reviewing the distensibility data reports from the Ultrasound Reading Center. The chief sonographer reviews the data by field center and sonographer. Current values and trends are reviewed and when necessary, the chief sonographer and the Ultrasound Reading Center work together to implement solutions.
e. Responsible for reporting ultrasound area equipment problems to the Ultrasound Reading Center.
f. Responsible for scheduling preventive maintenance visits and other service calls as needed.
g. Responsible for communication with the Ultrasound Reading Center.
h. Responsible for sonographer recertification as outlined in Section 4.3.2.

The estimated time-effort required, exclusive of training new sonographers, is 10 percent.

6. ULTRASOUND AREA INSTRUMENTATION

The ultrasound area instrumentation consists of a Biosound 2000 II sa ultrasound imaging system, a Panasonic AG-6300 1/2" Video Cassette Recorder, a Sony VO 5800H Video Cassette Recorder, an RMI 414B Tissue Mimicking Ultrasound Phantom, a computer, a study flow panel, a Dinamap automated blood pressure machine, an AUTREC dual channel arterial wall tracker, a Tektronix 2215A oscilloscope and a dual channel strip chart recorder.

The equipment was designed and selected to assist the sonographer in adhering to the protocol steps. A brief description of each piece of equipment is presented.

6.1 The Biosound 2000 II sa Ultrasound Imaging System

The Biosound 2000 II sa system is a high resolution ultrasound imaging system designed for relatively shallow anatomical structures such as the extracranial carotid arterial system. Images of the arteries are obtained using a nominal 8 MHz transducer driven by a motor in a sector scan format. The sector scan format is presented in a rectilinear format with a nominal lateral view of 2 cm and a depth of 4 cm.

In addition to the B-mode image, Doppler signals from the arteries can be obtained, processed and displayed in a frequency versus time format. The Doppler information is used primarily for arterial identification.

Two video cassette recorders (VCR) are connected to the Biosound 2000 II sa. The two VCRs record the ultrasound video information on the video channel of the video cassettes.

6.2 The Video Cassette Recorder

The Sony VO 5800 H 3/4" video cassette recorder is the primary video recorder. The Sony was chosen to provide superior image quality over the 1/2" VHS quality cassettes. The 3/4" video cassettes are sent to the Ultrasound Reading Center for interpretation.

The Panasonic AG-6300 1/2" VHS is the secondary or backup video cassette recorder. The 1/2" video cassettes are stored at the field centers until the Ultrasound Reading Center has notified the field center that data has been obtained from the 3/4" video cassettes. The 1/2" video cassettes can then be recycled at the field centers. If the 3/4" cassettes are not acceptable, the 1/2" video cassettes are sent to the Ultrasound Reading Center.

6.3 The RMI Tissue-Mimicking Ultrasound Phantom

A modified RMI 414B tissue mimicking ultrasound phantom is used periodically for performance checks on the Biosound 2000 II sa. The phantom has arterial mimicking targets of various diameters and depths. These targets can be scanned from both longitudinal and transverse directions, and the images and video information can be evaluated to assess system performance. The check results are recorded on 3/4" video cassettes and sent to the Ultrasound Reading Center.

6.4 The IBM PC-XT Computer

The IBM PC-XT computer is used for multiple purposes in the ultrasound area. The computer interacts with the sonographer and ultrasound area equipment to perform the following tasks:

1. To obtain participant data, such as the ARIC identification number, birth date, race, and gender.
2. To establish files for participant data with appropriate names and file extensions.
3. To keep a record of the study steps performed, including quality control studies, from the Study Flow Panel.
4. To determine the frequency of quality control studies and the arterial sites where the quality control studies are performed.
5. To control the Dinamap automated blood pressure instrument during carotid artery ultrasound examinations, and the carotid artery distensibility measurement.
6. To control an analog-to-digital converter to digitize and store data from the arterial wall tracker for distensibility calculations and waveform processing.
7. To record all these data on hard disk for temporary storage and on diskette to send to the Ultrasound Reading Center.

The sonographer is required to interact with the computer: (1) during the initial questionnaire, (2) during the distensibility study, and (3) at the completion of the study. The computer program interfaces with the Study Flow Panel and interfaces with and controls the Dinamap blood pressure monitor. Instructions from the Study Flow Panel determine when to take blood pressures, and the computer program sends instructions to the Study Flow Panel to control selection.

6.5 The Study Flow Panel

The B-mode ultrasound examination consists of bilateral carotid artery studies and involves a maximum of 18 steps, performed in a similar sequence for each participant. A Study Flow Panel (Figure 12) assists the sonographer during the examination. This panel has a series of small, labeled lights indicating the current step being performed or the next step to be performed. Automatic sequencing is done after the completion of each step. A manual override is available in case of changes in the sequence, i.e., to repeat or select a particular step, or for quality control.

The Study Flow Panel also controls a record status indicator function. This function is indicated by a small box with three status LED's. After the AUDIO RECORD footswitch is depressed and released, the red (WAIT) LED comes on for about 20 seconds. During this time, the Study Flow Panel is disabled so that audio tones cannot appear on the VCR audio channels any closer than 20 seconds. This time interval is necessary to ensure proper operation of optical disk recorders at the Ultrasound Reading Center. Approximately 15 seconds after the red light comes on, the yellow (GET SET) LED comes on. About 5 seconds remain for the Study Flow Panel to be disabled. If the sonographer depresses the AUDIO RECORD FOOTSWITCH during the time the red and/or yellow LED's are on, the Study Flow Panel does not respond. After about 20 seconds, the green LED (GO) comes on, and the Study Flow Panel is enabled for normal operation.

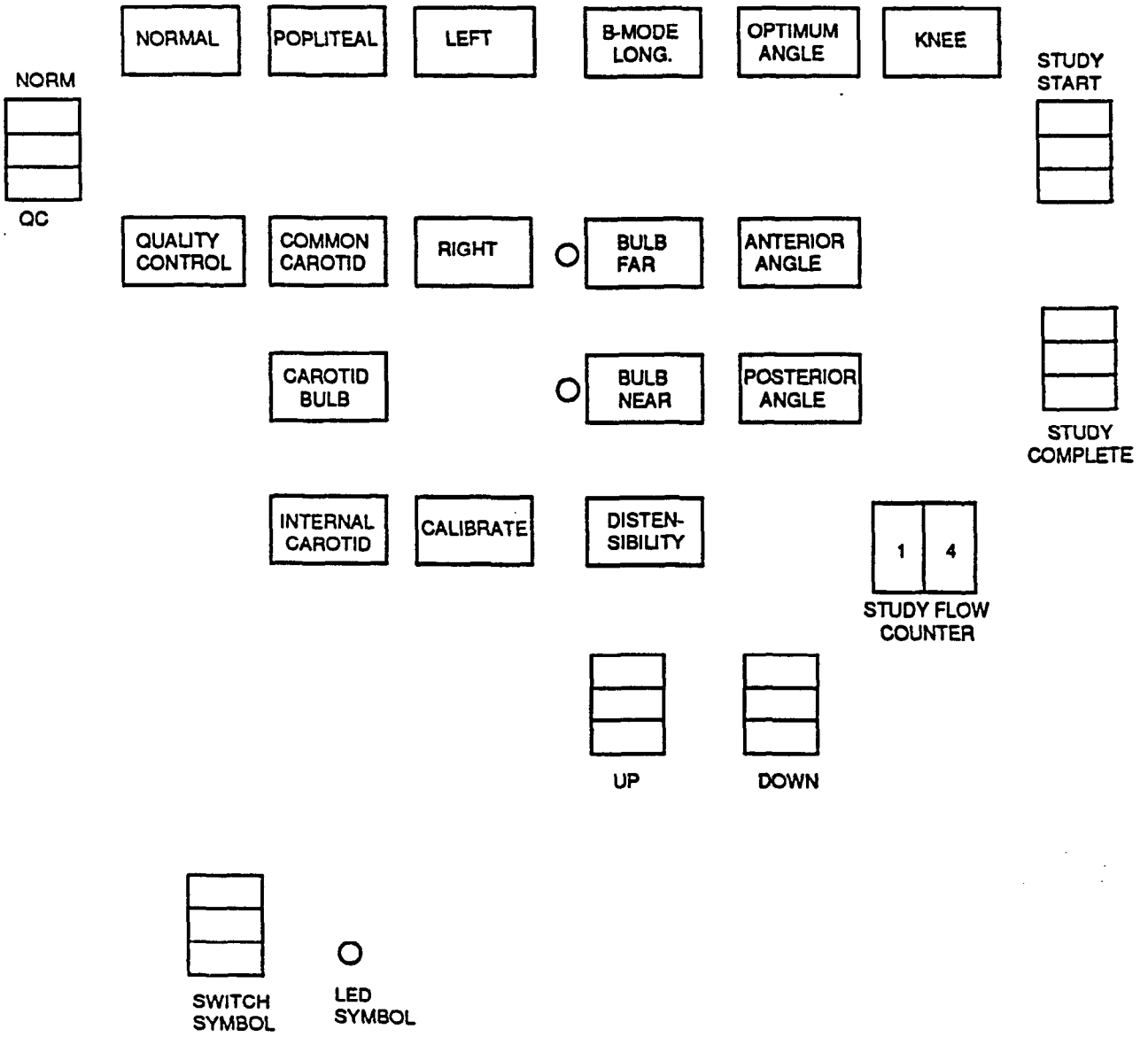


Figure 12. Study Flow Panel

The Study Flow Panel interacts with the computer on several levels. The study code in digital format is sent to the computer over a parallel port line. In addition, the Study Flow panel sends the study code from a serial port to one audio channel of the VCRs.

ECG leads from the participant are connected to the Study Flow Panel. The R-wave from each cardiac cycle is detected and a second audio tone is sent to the VCR audio channel. These tones are used to synchronize the cardiac cycles relative to the R-wave of the ECG at the Ultrasound Reading Center.

6.6 Dinamap Automated Blood Pressure

A series of blood pressure measurements are made during the ultrasound examination. The purposes are: (1) to provide baseline supine blood pressure measurements, (2) to provide the pulse pressures required for calculating artery distensibility, and (4) to estimate an ankle-arm index.

Blood pressure is measured using the Dinamap Model 1846 SX, an automated device which operates using oscillometric techniques. ARIC Manual 11 and the Dinamap Operation Manual should be read carefully before performing the blood pressure measurements. The timing of blood pressure measurements and the sequencing of the Dinamap Model 1846 SX are determined by codes from the Study Flow Panel and the computer. These processes are automatic and do not require any sonographer intervention.

The Dinamap Service manual is included with each machine when it is purchased. If that manual is lost, another can be ordered from the Dinamap zone office. Order Part #328368, Cost: $90. Zone offices are: Minnesota, 1-800-824-9017; Washington, 1-800-524-2818; Mississippi and North Carolina, 1-800-237-5591.

6.7 The AUTREC Dual Channel Arterial Wall Tracker Oscilloscope and Strip Chart Recorder

The arterial wall tracker is used to measure the change in arterial diameter during the cardiac cycle as part of the distensibility measurements, described in Section 11 of this protocol and fully described in ARIC Manual 6C, Distensibility. It is a dual channel zero-crossing tracker supplied by AUTREC in Winston-Salem, North Carolina. Each channel is an analog system with feedback to track continuously the range of a zero crossing in the near or far arterial wall echo complex. The arterial wall diameter (a function of time during the cardiac cycle) is determined from the time difference between the selected zero crossing in the near wall of each complex and the initial zero crossing from the far wall of the blood-lumen interface.

The undetected, or rf, echo waveforms from the near and far walls of the left common carotid artery are displayed on the oscilloscope along with tracking gates for the near and far wall echoes. These waveforms help the sonographer correctly identify the arterial wall echoes and position the tracking gates within each echo complex.

The resolution of the arterial diameter measurements is limited by the noise in the rf echo complexes. Under typical operating conditions, details in wall motion and arterial diameter are available on two output channels. One output channel is a dc coupled output, calibrated for a 0 to 10 mm arterial diameter.

The second output channel is an ac coupled output calibrated for arterial diameter changes of 0 to 1 mm. Both output channels are calibrated for a 50 ohm load resistor.

The outputs of the arterial wall tracker are sent to the dc and ac channels of the strip chart recorder. The strip chart recorder produces a strip chart of each waveform, at a paper speed of 50 mm/s. A slower paper speed of 2.5 mm/s is provided for calibration of this unit.

7. EQUIPMENT MAINTENANCE

Equipment maintenance is performed periodically.

7.1 Biosound 2000 II sa Ultrasound Imaging System

Each field center is required to have Biosound representatives perform a preventive maintenance check four times a year. More frequent service visits may be required if any problems occur between scheduled preventive maintenance visits.

The air filter on the Biosound 2000 II sa is removed and cleaned every 30 days. This helps to encourage air flow to keep the equipment cool and operating more reliably.

7.2 Video Cassette Recorders

The recording heads of each VCR are cleaned about every six months to prevent degradation of the recorded images. This task is performed by qualified personnel, since improper procedures or materials could be damaging.

7.3 RMI 414 B Tissue Mimicking Ultrasound Phantom

The RMI 414B phantom is checked weekly to be sure all seals are tight and that the tissue mimicking gel inside has not dried out.

7.4 IBM PC-XT Computer

In general, no maintenance is required on the PC-XT computer with the exception that the clock battery is replaced annually. In case of any system problems, the field center data coordinator contacts the nearest authorized repair facility.

7.5 Study Flow Panel

No maintenance is required for the Study Flow Panel. If problems do occur, AUTREC personnel are contacted.

7.6 Dinamap Automated Blood Pressure

It is recommended that the Dinamap Model 1846 SX be calibrated every six months. Calibration is required at least once each year, using calibration procedures starting at page 99 in the Dinamap service manual. This manual comes with each Dinamap purchase.

7.7 AUTREC Dual Channel Arterial Wall Tracker
Oscilloscope and Strip Chart Recorder

In general, an annual maintenance check is recommended for these instruments. AUTREC personnel are contacted if problems arise.

8. DAILY PROCEDURES

8.1 Equipment

Before any studies begin, each day the equipment in the ultrasound area is turned on and warmed up for a minimum of 30 minutes in the following order:

a. Biosound - Put the probe switch in the active position. The transducer motor must be running to assure proper warmup and subsequent system operation.
b. Study flow panel
c. Strip Chart
d. Dinamap
e. Panasonic and Sony VCRs
f. Arterial wall tracker
g. Oscilloscope
h. Computer and printer

8.2 Supplies

The supplies to be used for each day are checked. This includes the following:

a. Video cassettes - Both 3/4" cassettes for the Sony VCR and 1/2" cassettes for the Panasonic VCR. The 3/4" cassettes and 1/2" cassettes are run on FAST FORWARD and then REWOUND before using.
b. Participant ID Labels - identification labels are applied to the video cassettes and the floppy disks used to store participant information.
c. ECG leads and coupling gel
d. Aquasonic gel
e. Paper wipes

8.3 Tracker Calibration

After the 30 minute warmup period, the strip chart is calibrated with the arterial wall tracker, as described in ARIC Manual 6C, Arterial Distensibility.

8.4 Computer

After the 30 minute warmup period, at the C:> prompt, type US <return> to bring up the computer program for the first participant.

8.5 Ultrasound Equipment Performance Check

The following instrument performance protocol is done every Wednesday morning after the Biosound ultrasound system has been permitted to warm up for at least 30 minutes. The procedure is always repeated (a) After a manufacturer's service call is performed on the Biosound instrument, or (b) After the transducer is repaired or replaced.

Proper care and maintenance of the test phantom is documented in the instruction manual accompanying the RMI Tissue Mimicking Ultrasound Phantom (Model 414B). The phantoms are stored in a resealable airtight plastic container. A few drops of water are added to this container before sealing to minimize desiccation of the tissue mimicking material. Phantom specifications can be obtained in this manual as well.

The mode RMI 414B ultrasound phantom is placed upright on the examination table with the LONG side of the rectangular case parallel to the longer side of the table. One end of the phantom contains filaments ranging from 1.0 to 7.0 cm in depth. The other end contains filaments ranging from 0.5 to 4.0 in depth. The end containing the filaments ranging from 0.5 to 4.0 cm is positioned closest to the head of the table (see Figure 13).

The top surface of the phantom is cleaned with a damp cloth or paper towel to remove residue. The water tray on the top of the phantom is half filled with tap water to permit efficient coupling of the ultrasound transducer to the tissue equivalent medium. DO NOT USE GEL AS THE COUPLING MEDIUM. Minimal pressure is exerted on the phantom surface with the transducer throughout the scan. Excessive pressure on the phantom surface can cause severe damage to the phantom.

A two minute segment of B-mode phantom images is recorded during this check as described below. Use a separate 3/4" video tape to record only phantom images. Selected frames are read at the Ultrasound Reading Center to quantitatively document the ultrasound system imaging characteristics.

The Sony 3/4" tape recorder is turned on and placed in the record-pause mode. Type in the date, the field center location, sonographer ID number, and transducer serial number on the first line of the graphics display at the top of the Biosound image screen. Type the phantom serial number, the gain setting (6) the TGC setting (5), and focus setting (F=FAR) on the second line of the display. This information will be used at the Ultrasound Reading Center to monitor instrument performance at each of the four field centers.

EXAMPLE: 04/25/88 JACKSON 099 TRNS 8888
414B/1111 GN/6 TGC/5 FOCUS F

The Biosound Video Gain is adjusted to read "6" and the TGC "5" and are maintained in these positions. Move the cursor to the vertical center position used in the Doppler segments of the protocol, and make certain it is kept in the vertical center when it is moved during the performance check. The transducer power is turned ON (place OFF/ACTIVE switch to ACTIVE position, which illuminates the adjacent red light) and the system is placed in the normal B-scan imaging mode. The transducer focus switch is turned to the "Far" focus position.

The sonographer enters the RECORD mode by turning off the pause switch on the Sony 3/4" recorder and scans the phantom. The probe is held in the right hand. To obtain the images in this procedure the long dimension of the white transducer plate is parallel to the long dimension of the phantom. She obtains a cross-sectional view of the most superficially (2cm) located simulated vessels and then positions the larger (6 mm diameter) of the three vessels in the vertical center of the screen, as confirmed by the cursor in the vertical

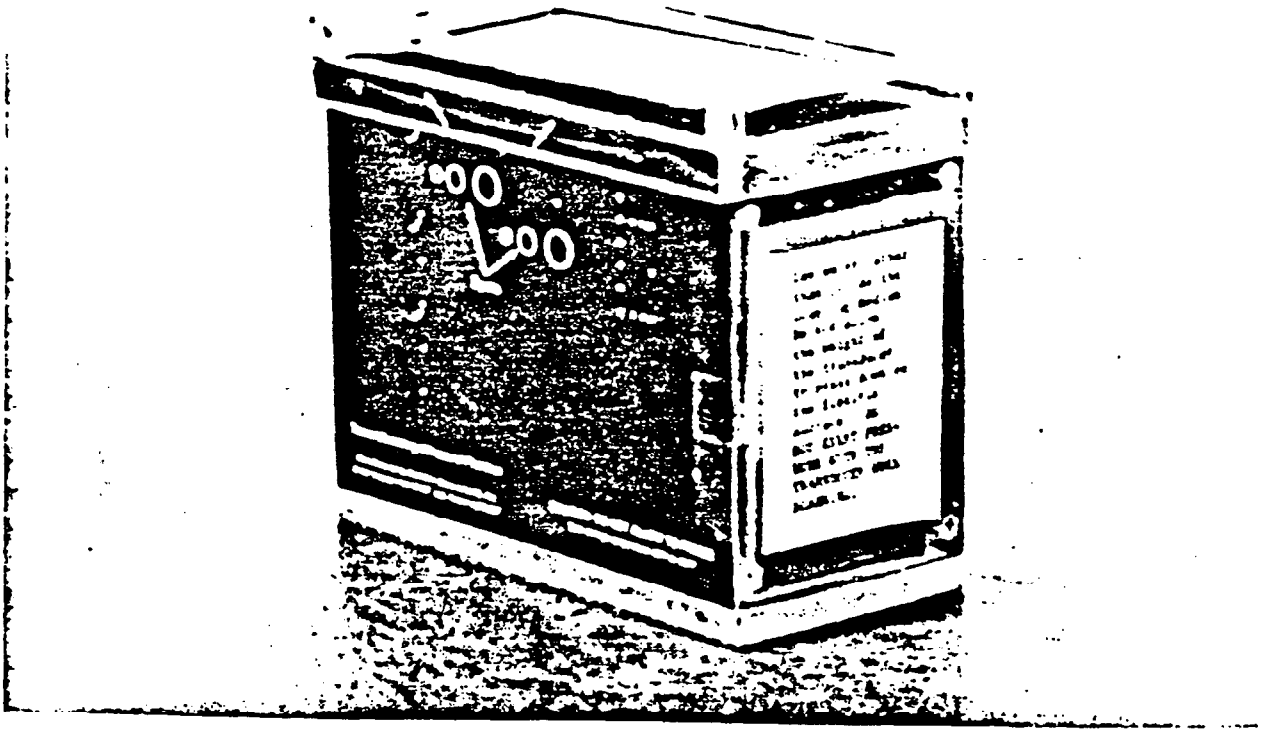


Figure 13. Orientation of Phantom

center position. The cursor should be positioned within the outline of the vessel, insuring that it does not obscure the reflections from the near or far walls (Figure 14). When a satisfactory image is seen on the screen, the audio record footswitch is depressed to mark this point on the tape with an audio tone for the Ultrasound Reading Center. The image is held and marked for approximately ten seconds.

The sonographer moves the transducer toward the head of the table in order to view the set of filaments ranging from 0.5 to 4.0 cm. These are also viewed in cross-section, making certain the transducer focus switch is in the "Far" position. Using the cursor as a guide, the filaments are lined up so that they are centered horizontally across the center of the screen (Figure 15). The cursor is positioned in the middle of the screen, taking care to avoid obscuring any of the filament reflections. When a satisfactory image is seen, the audio record footswitch is depressed for approximately ten seconds to mark this image. The reflections of the deeper filaments will have gaps in them due to shadowing caused by the filaments superficial to them (Figure 15). Those gaps are used as an aid in lining up the filaments properly.

This concludes the weekly instrument performance test on the RMI phantom. The water is carefully removed from the phantom, and the phantom is returned in its storage location.

Each phantom tape is labeled according to the following format:

PHANTOM - F - 86 - 09 - 12 - 001

F = the field center code - F, J, M, or W
86 = the year at first date on cassette
09 = the month of first date on cassette
12 = the month at final date on cassette
001 = sequential numbering of all phantom cassettes beginning with 001 at each field center

The space designating the month of the final date is left empty until the cassette is completed. This label is placed on the video cassette as shown in Figure 16 a. The video cassette box is also labeled as shown in Figure 16 b.

At the end of each week, the partially filled cassette is shipped to the Ultrasound Reading Center with the current shipment of B-mode tapes. A second tape is used to record the next week's scan(s) and a third tape for the week after. These three tapes are rotated until they are full. Completed tapes are stored at the Ultrasound Reading Center, and another tape is started at the field center when this occurs.

8.5.1 Additional Points to Remember

While doing scans with the phantoms, a sonographer who notices obvious changes in:

a. The shape of simulated vessels (these should appear circular),
b. the gain settings required to obtain adequate images, or
c. the focal settings required to obtain images

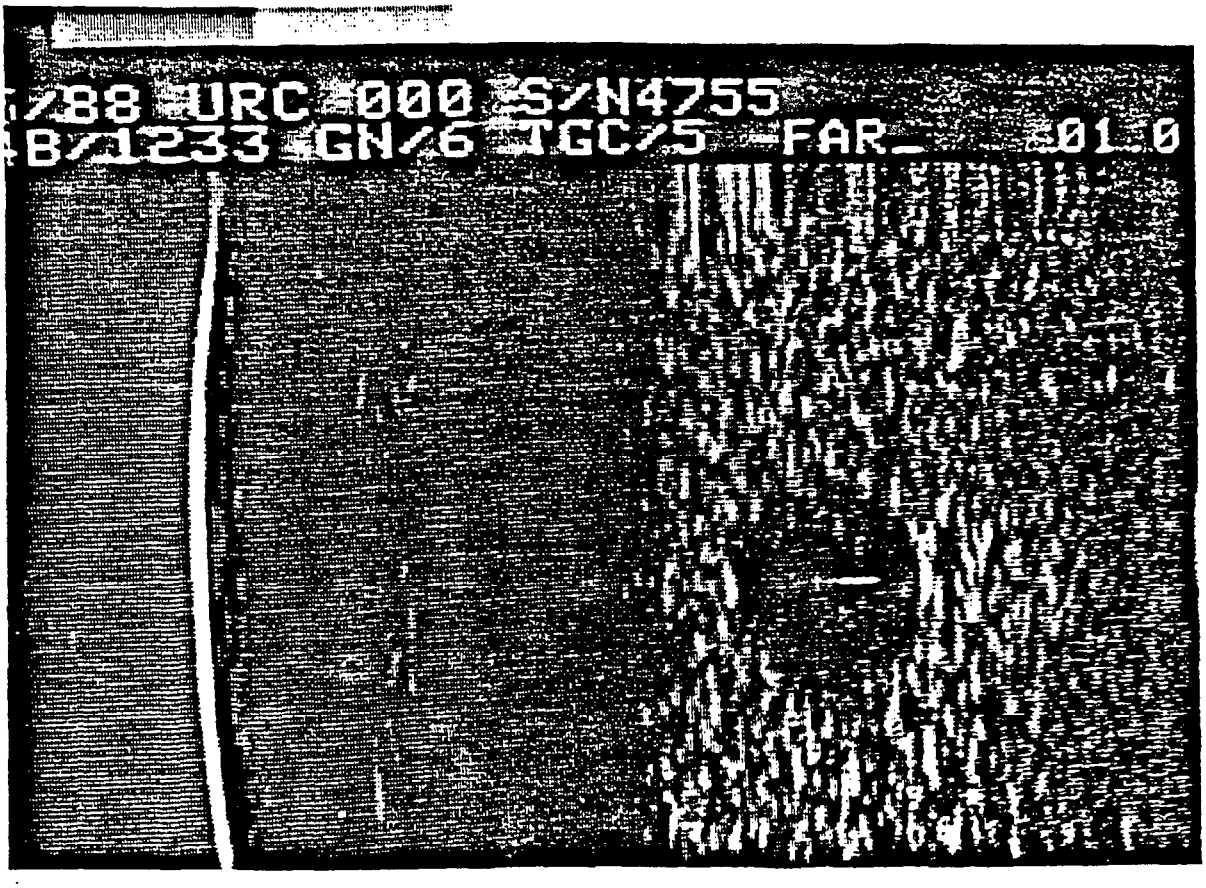


Figure 14. Cross sectional or Transverse View of Simulated Vessel

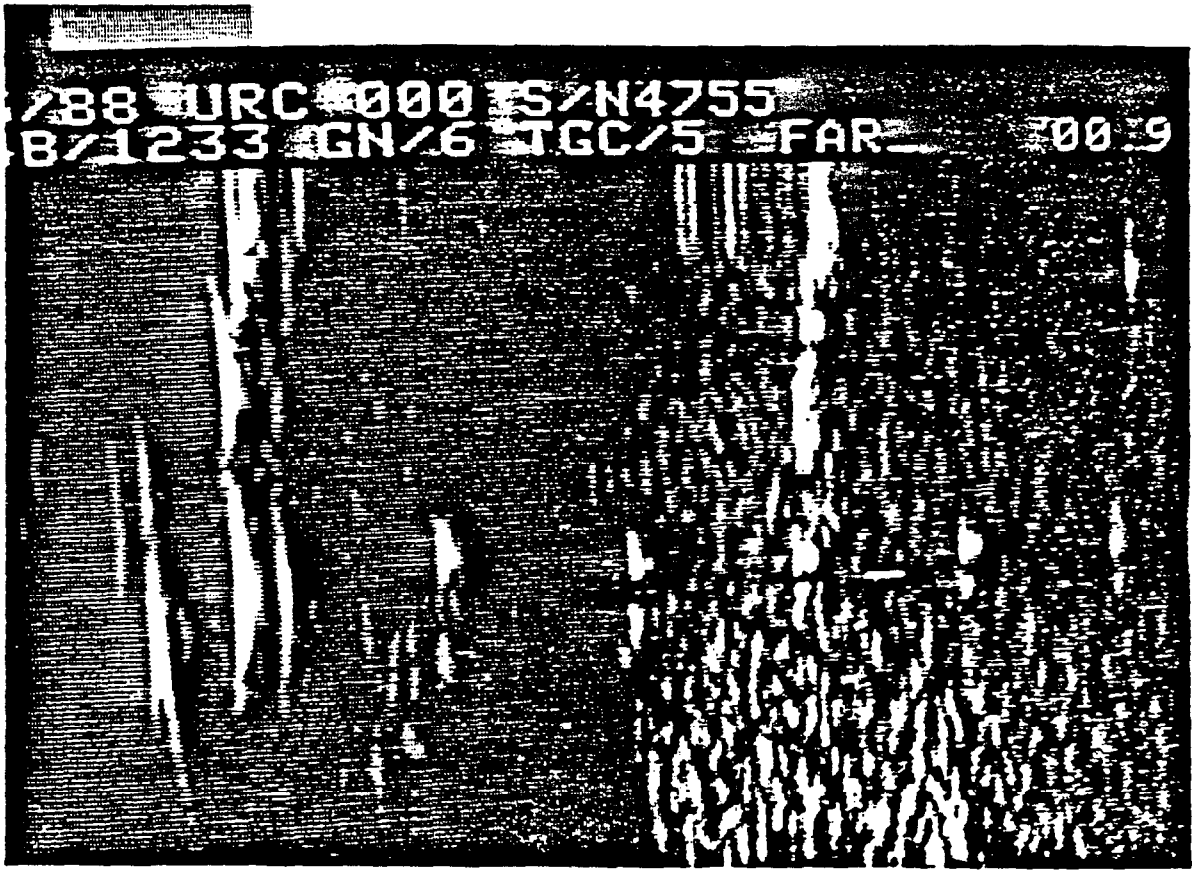


Figure 15. Cross-Sectional View of Filaments

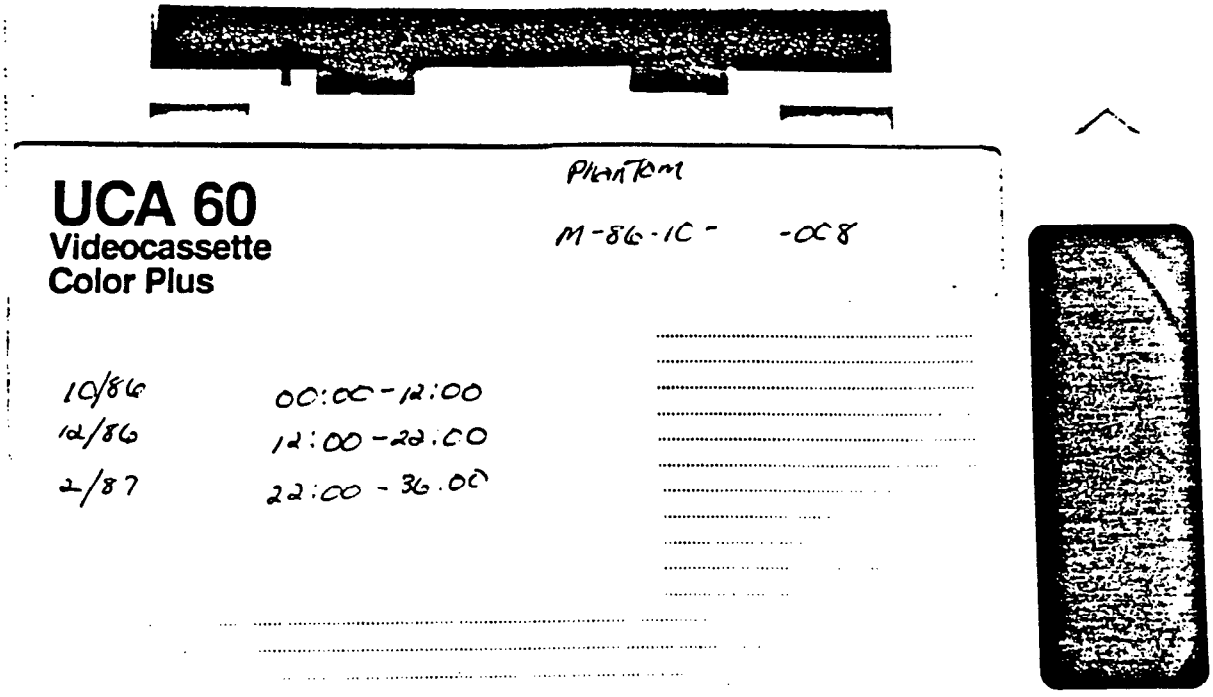


Figure 16 a. Videocassette Labelling

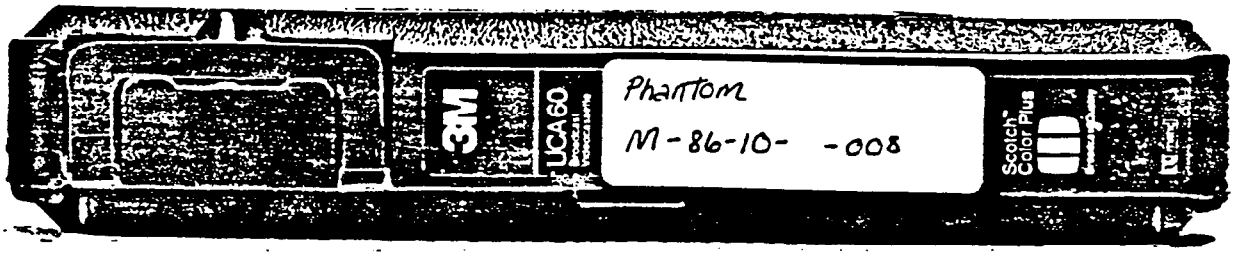


Figure 16 b. Videocassette Box Labelling

contacts the Ultrasound Reading Center (1-919-759-2137) and the Biosound person authorized to work with the ARIC instrument (Pauline Martinelli, 1-800-428-7378). Other Biosound personnel should not work on the instrument unless specifically authorized by Ms. Martinelli.

If the phantom begins to cave in or pucker, contact the Ultrasound Reading Center immediately.

Store the phantom in the airtight container with a few drops of water.

Vary the location of the transducer on the phantom when doing the scans, i.e., position in the center, left of center, right of center (Figure 17).

Notify the Ultrasound Reading Center by phone or electronic mail whenever the Biosound instrument is serviced. Follow up by sending a copy of the Biosound Service Report to the Ultrasound Reading Center.

9. PARTICIPANT PRELIMINARIES

The participant is seated on the examination table. If ECG pads are not present, two electrode pads are placed vertically in the xyphoid area and a third pad is placed in the left lateral abdominal areas below the last rib (Figure 18).

The ECG cable in the ultrasound area is connected to the ECG electrodes. The cable lead labeled RA is connected to the superior xyphoid electrode pad. The cable lead labeled RL is connected to the inferior xyphoid electrode pad. The cable lead labeled LA should be connected to the left lateral abdominal area electrode pad. The ECG cable leads are placed laterally and attached to the waistband of the participant's gown to reduce spurious signals and keep the cables out of the way during the postural change examination.

The connector end of the cable is checked for a secure contact with the ECG terminal on the Study Flow Panel. The green ECG light on the Study Flow Panel is checked for one blink each heartbeat. Interference, loose ECG pads, or a faulty cable will cause more than one blink each heartbeat.

9.1 Participant Status

The participant will have been asked to refrain from smoking, vigorous exercise, and drinking coffee, tea and soft drinks containing caffeine during the night preceding and the day of the ultrasound examination, since these may alter heart rate and/or blood pressure.

9.2 Participant Orientation to Ultrasound Examination

After the participant enters the ultrasound area, the sonographer describes in general terms the examination to be done. A suggested statement follows:

"Ultrasound is a new painless and low-risk method to examine arteries using sound waves which you cannot hear but which are able to "see" arteries under your skin. Before the ultrasound exam begins, a thin gel will be applied to the skin, and an instrument will be placed on it. This procedure will be used to look at the arteries on both sides of your neck. During the examination,

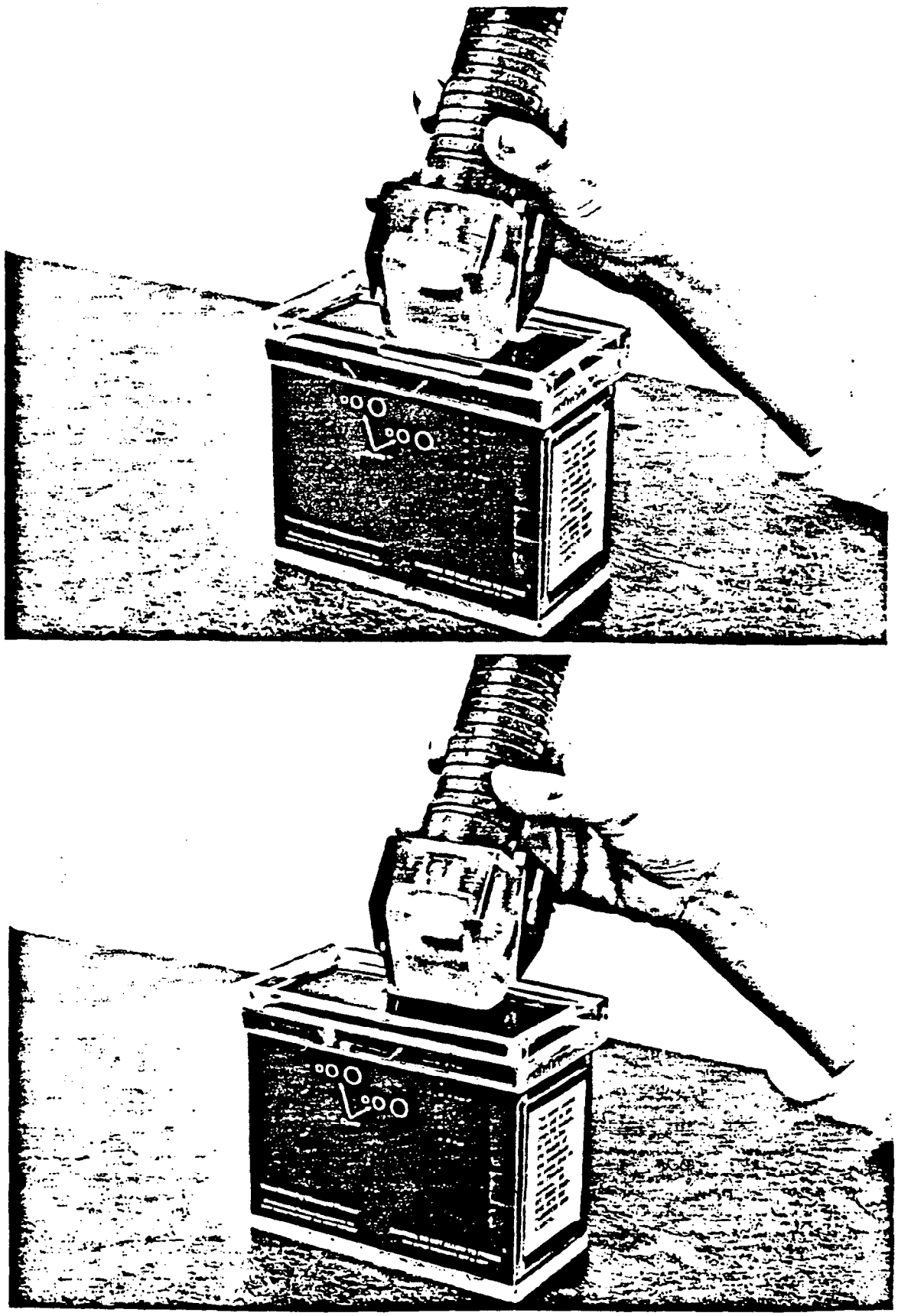
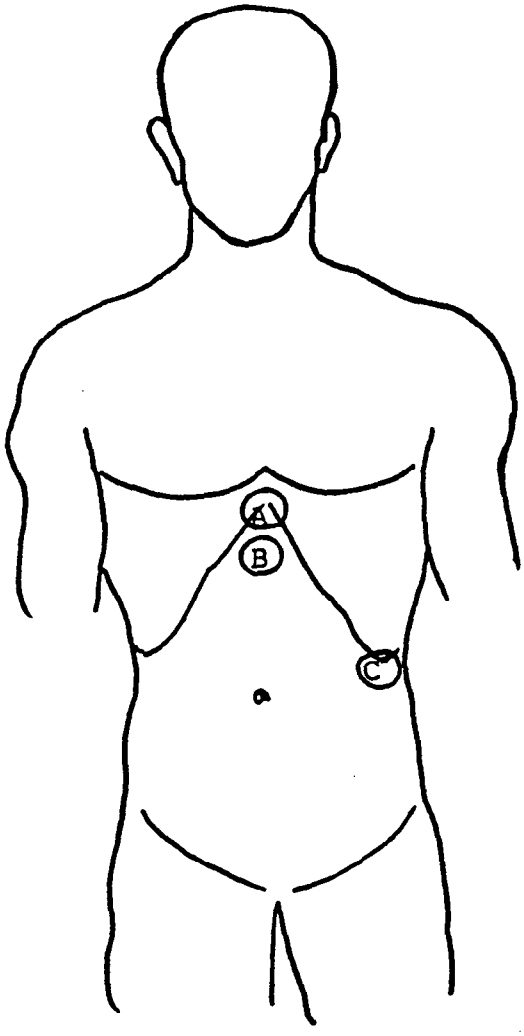


Figure 17. Varying Point of Contact Between Probe and Phantom



A. Superior Xyphoid Electrode Pad (RA) - White

B. Inferior Xyphoid Electrode Pad (RL) - Green

C. Left Lateral Xyphoid Electrode Pad (LA) - Black

Figure 18. Placement of ECG Pads

you will hear the noise and feel the vibrations of a small motor that is located within the instrument. Occasionally you will also hear the amplified sound of blood flowing through your arteries. The complete ultrasound examination should be completed within forty-five minutes."

During this discussion, the sonographer should remember that the examination to be done is not diagnostic in nature, and that all questions asked by the participant that relate to the presence or absence of arterial disease should be referred to the medical director of the field center or to his on-site representative. Information to be given to the participant or his/her physician is described in ARIC Manual 2.

9.3 Participant Apparel

The ultrasound component of this examination requires easy access to the skin overlying arteries in the neck. Participants wear loose fitting apparel provided by each field center. Jewelry present on the head and neck, including gold chains, necklaces and earrings, is removed prior to scanning.

9.4 Study Preliminaries

9.4.1 Equipment Status

a. Before each participant B-mode scan, the date, participant ID number, field center location, and sonographer code number are typed in on the first and/or second line of the graphics display at the top of the Biosound image screen. This information is used at the URC to monitor sonographer quality control.

b. The study flow panel is reset after insuring that all equipment has been turned on by depressing the STUDY START toggle switch.

c. The US program is accessed on the PC by typing US after the C>: and pressing the <enter> key.

d. The system responds by displaying a preliminary questionnaire.

9.5 Preliminary Questionnaire

All questions in this program may be answered in either upper or lower case letters. The RETURN key is pressed after completing each field on the screen. When the sonographer enters information on the screen, the arrow keys on the keyboard may be moved back to make corrections.

The floppy disk is inserted in the A drive.

The operator completes the questionnaire as follows:

NAME: The operator enters the first five characters of the participant's last name, followed by first and middle initials. The software displays all of this entry in upper case letters.

STUDY NUMBER: The operator enters the field center identification code, i.e., an "F", "J", "M", or "W", followed by the remainder of the

participant ID. After verifying the entry, the RETURN key is depressed.

DATE: The date from the computer will be displayed, and if correct, the RETURN is depressed. If the date is incorrect, the entire date must be retyped (MM/DD/YY). When corrected and verified, the RETURN key is depressed.

TIME: If the time displayed on the monitor is correct, the operator confirms by pressing the RETURN key. If a change is required, the entire time must be retyped.

SONOGRAPHER IDENTIFICATION: The operator types the three digits corresponding to the unique code that identifies each sonographer in the ARIC study.

RACE: Type the participant's race: W (white), B (black), or O (other).

GENDER: Type the participant's gender: M (male) or F (female).

BIRTH DATE: Type the participant's birth date MM/DD/YY. Months are entered from 01 (January) through 12 (December). Days are entered 01 through 31, depending on specific date. Months and days must be entered as two-digit numbers.

9.6 Preparation for Ultrasound Examination

Questions up to, but not including, the question regarding dizziness are answered. When participants arrive, the operator asks if they get dizzy when they stand or sit suddenly. Responses are typed as Y or N.

a. Participants are positioned on the examination table in a supine position, with their legs resting comfortably on a pillow.

b. A blood pressure cuff of suitable size is selected and placed around the biceps above the elbow crease on the arm, following the procedures described in Manual 11.

c. The sonographer explains the blood pressure measurements procedure as she places the cuff on the participant's arm.

d. A practice blood pressure is taken by pressing the manual switch on the Dinamap.

e. The computer screen is checked to verify that all questions answered in the preliminary screen are correct. If they are not, the arrow keys are moved through the screen to make corrections.

f. When all information is correct, an affirmative response to the question, "Is all information correct?" is made by typing "Y".

g. The sonographer places both the Sony and Panasonic VCRs in the "RECORD" mode.

h. The sonographer verifies that the PC screen and the study flow panel indicate the calibration to be done next. The PC monitor should read "last code 75," and the study flow panel should have a calibration code lighted. She presses the START STUDY switch on the study flow panel. The CALIBRATION indicator light should light up.

i. The sonographer obtains the calibration display on the Biosound by placing the Probe Select switch to the A position. Vertical lines should appear on the right TV monitor. The horizontal cursor is placed in the middle of the screen with the cursor joystick. If the length of the cursor line is less or greater than 20.0 mm, the knob at the top of the cursor joystick is turned counterclockwise until the length of the line is precisely 20.0 mm. (See Fig. 19). It is essential that the LEFT end of the line lies to the RIGHT of the second vertical line from the left edge of the screen.

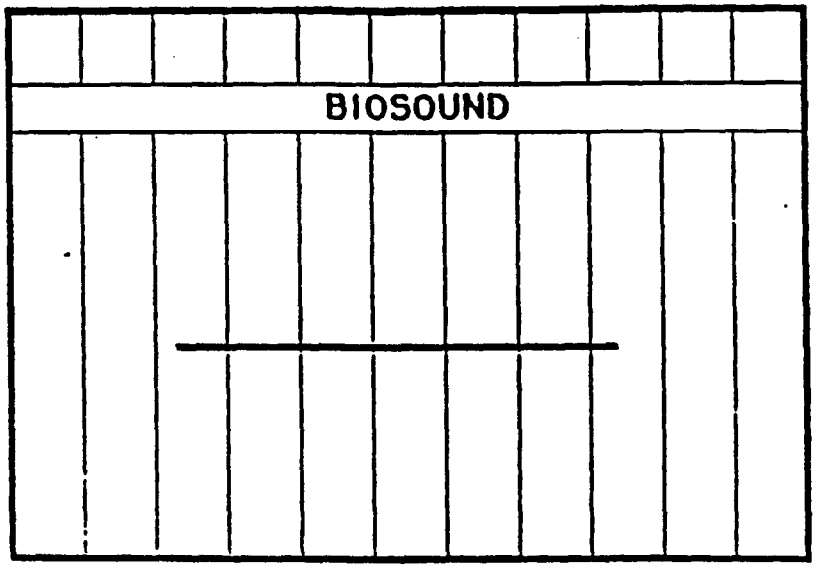
j. When the cursor line is set, the sonographer momentarily depresses the START switch on the study flow panel after making certain the SONY has been recording for at least 20 seconds. After a delay of at least 20 seconds, the sonographer depresses the AUDIO RECORD FOOTSWITCH for at least five seconds. This process automatically records the calibration display from the Biosound, records the Study Start Code on audio channel 1 of the SONY VCR, and automatically takes and records a blood pressure measurement.

10. CAROTID SCANS

The subject is supine during the carotid artery examination and is made comfortable in a position that allows head rotation to either side. The sonographer is seated at the end of the exam table that is nearer the participant's head. The top of the head is about one to three inches from the end of the exam table.

The ECG leads are checked to make certain they have remained securely attached. Place a pillow underneath the participant's legs, behind the knees, in order to afford lower back comfort.

Orientation of the participant's head is as follows: the participant is asked to look straight up at the ceiling. A triangular shaped, firm foam rubber wedge shaped in a 45-45-90 degree form is used to position the head in a standard way. Two (2) one-inch self-adhesive Velcro strips are attached, adhesive side down, against the examining table. The first strip is placed across the table six inches from the head end of the table and the second strip six inches below the first one. These strips have two purposes: (1) to keep the foam rubber wedge from slipping to the side during the ultrasound examination; (2) to assure that the participant's head is always positioned the same distance from the end of the examination table and sonographer. The edge of the foam wedge nearest the end of the table is positioned directly on the first Velcro strip and is attached to it by pressing down. The angles of the wedge are 45°, 45° and 90°. The base of the wedge, i.e., the side defined by one of the 45° angles and the 90° angle, is placed on the examination table next to the side of the neck to be evaluated in such a way that the 90° angle is furthest from the midline of the face. This positions the 45° angle closest



In reference to section 9.6 of the scanning protocol, the above diagram demonstrates where the cursor line should be placed in relation to the gradicule lines. The cursor line should extend across the vertical lines and should measure 20.0 mm in length.

Figure 19. Calibration Screen

to midline. The wedge is then gently pushed toward the midline of the head until the 45° angle edge touches the scalp. The participant is then asked to rotate his head toward the foam rubber wedge until the side of the head just above the ear rests against it. The ultrasound equipment is positioned so that the sonographer has access to the neck and all instrument controls, TV monitor, and foot pedals.

The blood pressure cuff is applied to the right arm except in the cases noted in Manual #11, Sitting Blood Pressure, Section 1.6.

10.1 Right Carotid Scan

10.1.1 The head and neck are positioned for the exam of the right carotid. The foam rubber wedge is placed on participant's left side and the head is rotated toward the foam rubber as outlined in section 10.

10.1.2 The Sony 3/4" video cassette recorder is taken off pause and recording is resumed.

10.1.3 The common carotid, bulb and internal carotid are scanned for orientation purposes. Locate the origin of the bulb and the tip of the flow divider, and determine the optimal angle.

10.1.4 The sonographer determines which artery is the internal carotid artery. The cursor is placed in the "Doppler" mode on the Biosound instrument panel. The cursor is first moved into one branch of the artery and then the other. The doppler footswitch is depressed in order to view the doppler spectra on the Biosound screen. The footswitch is depressed again to stop the doppler. This is repeated in each branch. The internal carotid artery is identified, based on the criteria outlined in Section 3.2.5.

10.1.5 The sonographer verifies that the study flow panel indicates RIGHT COMMON OPTIMAL to be scanned.

10.1.6 The ultrasound probe is moved proximally to view the distal centimeter of the right common carotid artery. The cursor is placed in the lumen as described in Section 3.3.2. The best possible image of the right common carotid artery in the optimal angle is obtained as outlined in section 3 and as shown in Figure 8 a.

10.1.7 The study flow panel's GREEN LED should be on. The sonographer presses the audio record footswitch for at least five cardiac cycles to mark this site on the video tape.

10.1.8 The first automatic blood pressure is taken at this point.

10.1.9 The sonographer moves the level on the probe to the anterior position. The probe is rotated to the correct position for the ANTERIOR view as indicated by the bubble in the level.

10.1.10 The sonographer verifies that the flow panel indicates RIGHT COMMON ANTERIOR. She optimizes the arterial interfaces at this site and angle and when the best possible image is obtained and the study

flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.1.11 The level on the probe is moved to the posterior position. The probe is rotated down to the correct position for the POSTERIOR view as indicated by the bubble in the level.

10.1.12 The sonographer verifies that the flow panel indicates RIGHT COMMON POSTERIOR. She optimizes the arterial interfaces at this site and angle, and when the best possible image is obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.1.13 The probe is rotated back to the optimal angle and moved distally to the bulb area. The cursor is placed at the tip of the flow divider (Section 3.3.3). The arterial interfaces are optimized at this site and angle, as shown in Figure 9a.

10.1.14 The study flow panel indicates RIGHT BULB. The sonographer optimizes the arterial interfaces at this site, and when the best possible image is obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.1.15 The probe is moved distally to the proximal centimeter of the internal carotid artery.

10.1.16 The study flow panel should indicate Right Internal Carotid Artery. The cursor is placed into the correct position at the tip of the flow divider as discussed in Section 3.3.4 and as shown in Figure 10 a. The sonographer optimizes the far wall arterial interfaces, and when the best possible image of the intima media interfaces on the far wall are obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.1.17 The Study Flow Panel should indicate the RIGHT BULB FAR WALL OPTIMAL ANGLE. The probe is moved back to the bulb area to obtain an image of the bulb at the optimal angle. The probe is slowly tilted along the arterial axis so that the far wall of the bulb becomes vertical in the center of the display screen. The sonographer optimizes the intima-media interfaces on the far wall, as shown in Figure 20 a. During this maneuver, the near wall echoes will deteriorate. When the far wall interface echoes are optimized and the study flow panel's green LED is on, press the AUDIO RECORD FOOTSWITCH for at least five consecutive cardiac cycles, marking the site on video tape.

10.1.18 The Study Flow Panel should indicate the RIGHT BULB, NEAR WALL, OPTIMAL ANGLE. The probe is slowly tilted along the arterial axis back toward the optimal angle and then beyond so that the near wall of the bulb becomes vertical in the center of the display screen.

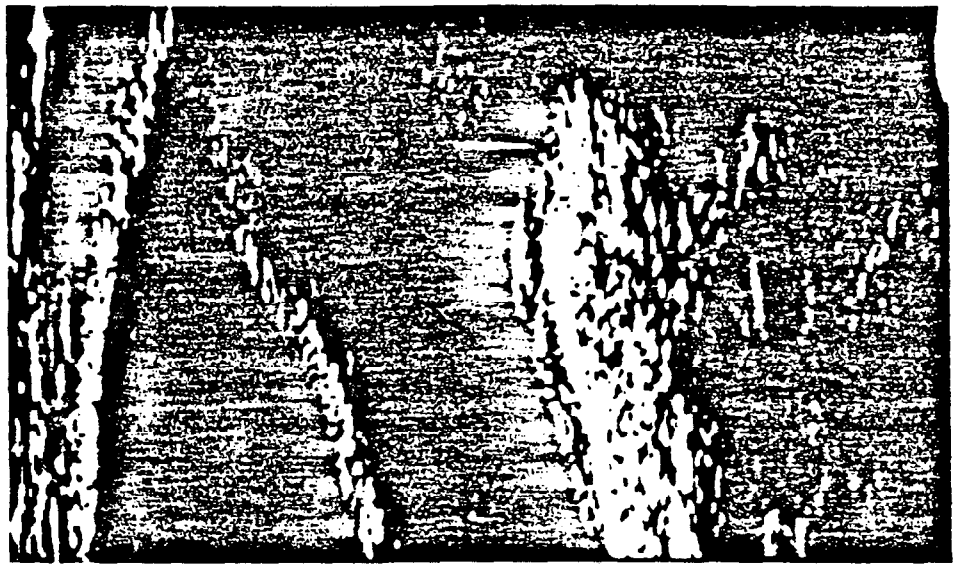


Figure 20 a. Right Carotid Bulb - Far Wall

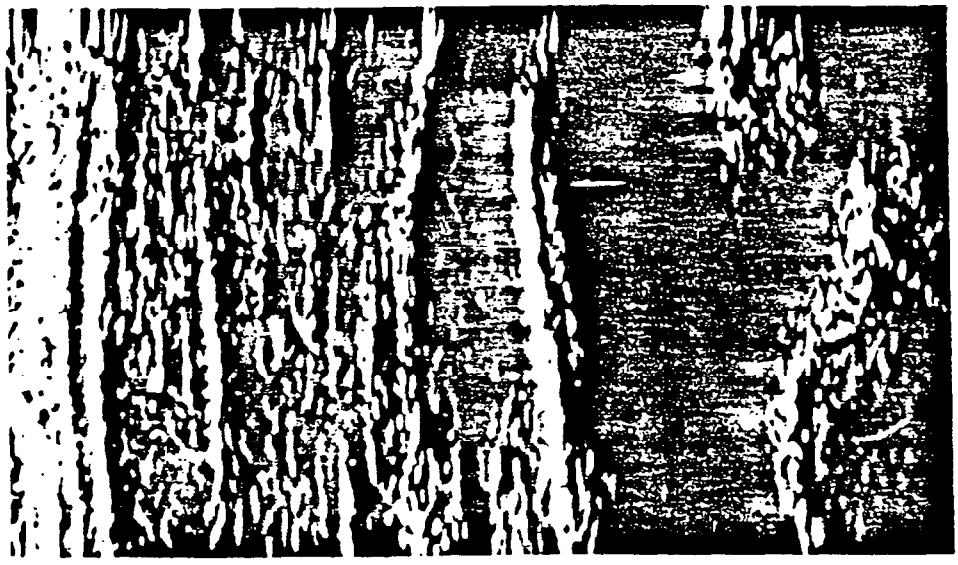


Figure 20 b. Right Carotid Bulb - Near Wall

The sonographer optimizes the media-intima interfaces on the near wall, as shown in Figure 20 b. During this maneuver, the far wall echoes will deteriorate. When the near wall interface echoes are optimized and the study flow panel's green LED is on, press the AUDIO RECORD FOOTSWITCH for at least five consecutive cardiac cycles, marking the site on video tape.

10.1.19 The sonographer looks at the PC to see if a site will be repeated on the right side for quality control purposes. If a quality control repeat scan is not required, the sonographer skips ahead to scan the Left Common Optimal (Section 10.1.22).

10.1.20 The probe is removed from the neck. The sonographer toggles the study flow panel until the quality control site indicated by the computer is lighted on the study flow panel. The NORMAL/QC switch is depressed.

10.1.21 The sonographer obtains an image of the quality control site and angle, moves the cursor to the appropriate landmark and optimizes the arterial interfaces. When the study flow panel's green LED is on and the best possible image has been obtained, press the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.1.22 Toggle the study flow panel up/down switches until LEFT COMMON OPTIMAL is indicated on the study flow panel.

10.1.23 Set the Sony VCR on pause.

10.1.24 The gel is wiped from the participant's neck and the head and neck are repositioned for the left side scan.

10.2 Left Carotid Scan

10.2.1 The foam rubber wedge is placed on the participant's left side and the head is rotated toward the foam rubber pillow as outlined in section 10.

10.2.2 The Sony 3/4" VCR is taken off pause and recording resumed.

10.2.3 The common carotid, bulb and internal carotid artery are scanned for orientation purposes. The origin of the bulb and the tip of the flow divider are located, and the optimal angle is determined.

10.2.4 The internal carotid artery is identified. The cursor is placed in the "doppler" mode on the Biosound instrument panel. The cursor is first moved into one branch of the artery and then the other. The doppler footswitch is depressed in order to view the doppler spectra on the Biosound screen. The footswitch is depressed again to stop the doppler. This is repeated in each branch. The internal carotid artery is identified based on the criteria outlined in Section 3.2.5.

10.2.5 The sonographer verifies that the study flow panel indicates the LEFT COMMON OPTIMAL is to be scanned.

10.2.6 The ultrasound probe is moved proximally to view the distal centimeter of the left common carotid artery. The cursor is placed in the lumen (Section 3.3.2). The best possible image of the left common carotid artery in the optimal angle is obtained, as outlined in section 3 and shown in Figure 8 b.

10.2.7 The study flow panel's green LED should be on. The sonographer presses the audio record footswitch for at least five cardiac cycles to mark this site on video tape.

10.2.8 The sonographer moves the level on the probe to the anterior position. The probe is rotated to the correct position for the ANTERIOR view as indicated by the bubble in the level.

10.2.9 The sonographer verifies that the study flow panel indicates LEFT COMMON ANTERIOR. She optimizes the arterial interfaces at this site and angle, and when the best possible image is obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.2.10 The level on the probe is moved to the posterior position. The probe is rotated down to the correct position for the POSTERIOR view as indicated by the bubble in the level.

10.2.11 The study flow panel should indicate LEFT COMMON POSTERIOR. The sonographer optimizes the arterial interfaces at this site and angle, and when the best possible image is obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.2.12 The probe is rotated back to the optimal angle and moved distally to the bulb area. The cursor is placed at the tip of the flow divider (Section 3.3.3). The sonographer optimizes the arterial interfaces at this site and angle as shown in Figure 9 b.

10.2.13 The study flow panel should indicate LEFT BULB. The sonographer optimizes the arterial interfaces at this site, and when the best possible image is obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.2.14 The sonographer moves the probe distally to the proximal centimeter of the internal carotid artery.

10.2.15 The study flow panel should indicate LEFT INTERNAL CAROTID. The cursor is placed into the correct position at the tip of the flow divider as discussed in section 3.3.4, and as shown in Fig 10 b. The sonographer optimizes the far wall arterial interfaces, and when the best possible image is obtained and the study flow panel's green LED is on, presses the audio record footswitch, holding it down for at least five cardiac cycles, marking the site on video tape.

10.2.16 The Study Flow Panel should indicate the LEFT BULB FAR WALL OPTIMAL ANGLE. The probe is moved back to the bulb area to obtain an image of the bulb at the optimal angle. The probe is slowly tilted along the arterial axis so that the far wall of the bulb becomes vertical in the center of the display screen. The sonographer optimizes the intima-media interfaces on the far wall, as shown in Figure 21 a. During this maneuver, the near wall echoes will deteriorate. When the far wall interface echoes are optimized and the study flow panel's green LED is on, the AUDIO RECORD FOOTSWITCH is pressed for at least five consecutive cardiac cycles, marking the site on video tape.

10.2.17 The Study Flow Panel should indicate the LEFT BULB NEAR WALL OPTIMAL ANGLE. The probe is slowly tilted along the arterial axis back toward the optimal angle and then beyond so that the near wall of the bulb becomes vertical in the center of the display screen. The sonographer optimizes the media-intima interfaces on the near wall, as shown in Figure 21 b. During this maneuver, the far wall echoes will deteriorate. When the near wall interface echoes are optimized and the study flow panel's green LED is on, the AUDIO RECORD FOOTSWITCH is pressed for at least five consecutive cardiac cycles, marking the site on video tape.

10.2.18 The sonographer looks at the PC to see if a site will be repeated on the left side. If no quality control scans are required, the sonographer skips ahead to distensibility (Section 11).

10.2.19 The probe is removed from the neck. The sonographer toggles the study flow panel until the quality control site indicated on the PC screen is lighted on the study flow panel. The NORMAL/QC switch is depressed.

10.2.20 The sonographer obtains an image of the correct site and angle, moves the cursor to the appropriate landmark and optimizes the arterial interfaces. When the study flow panel's green LED is on and the best possible image has been obtained, the audio record footswitch is pressed, holding it down for at least five cardiac cycles, marking the site on video tape.

10.1.22 The study flow panel is toggled to DISTENSIBILITY.

11. DISTENSIBILITY

11.1 The sonographer verifies that the Study Flow Panel is indicating Distensibility.

11.2 When 20 seconds have elapsed since the last B-mode image was marked, as indicated by the green light on the study flow panel, the audio record footswitch is momentarily pressed to begin the distensibility program. This also starts the distensibility blood pressure measurements.

11.3 The Sony 3/4" VCR is turned to PAUSE, and the Panasonic 1/2" VCR is turned off.

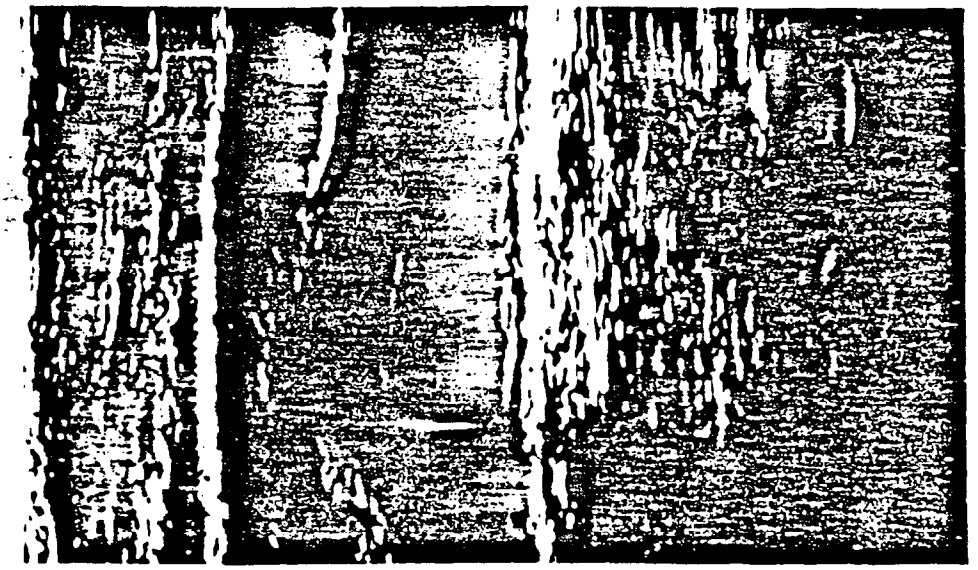


Figure 21 a. Left Carotid Bulb - Far Wall

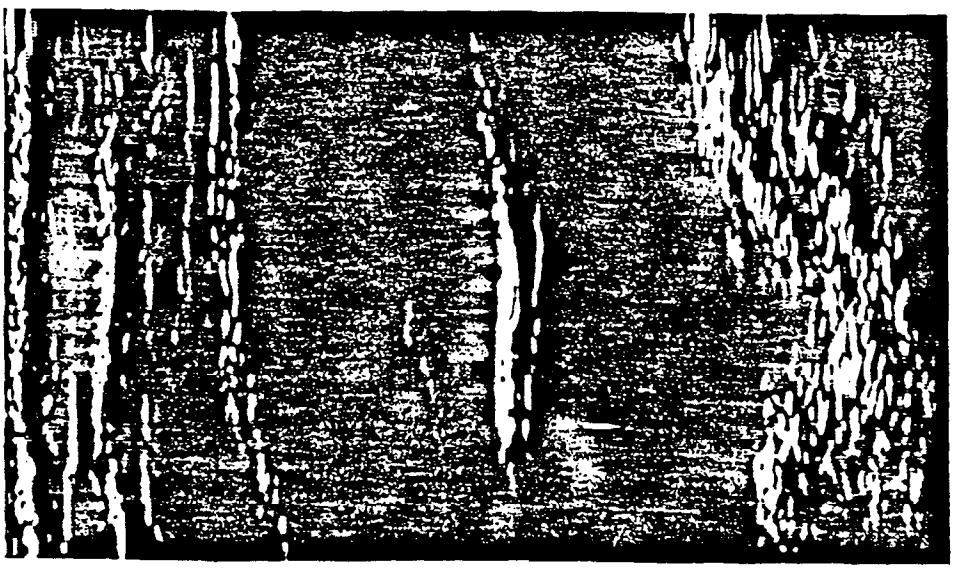


Figure 21 b. Left Carotid Bulb - Near Wall

11.4 The sonographer follows the distensibility protocol, located in ARIC Manual 6C, Distensibility.

12. LABELING AND MAILING TO THE ULTRASOUND READING CENTER

12.1 Labeling of Video Cassettes

Each video cassette is labeled with the video cassette number and no more than four participant identification numbers, as shown in Figure 22 a. The numbers in parentheses in the lower right corner of the participant ID label indicate the order of participant studies on the video cassette. Note that the video cassette number appears only once on the video cassette itself.

The video cassette box is also labeled with the video cassette number. The position of the label is shown in Figure 22 b.

Video cassette labels identify the field center and are numbered sequentially. The starting numbers for each field center are listed below:

Forsyth	F10000X
Jackson	J30000X
Minnesota	M50000X
Washington County	W70000X

The final character, shown as an "X" here, is a code check character. Each field center maintains a log that records the video cassette number and the participant identification numbers on that cassette. A typical log sheet is shown in Figure 23.

12.2 Labeling of Diskettes

Each diskette is labeled with the diskette number (which is identical to the video cassette number) and the participant identification numbers. The position of these labels is shown in Figure 24.

The diskette is placed inside its matching video cassette case for shipping.

12.3 Content of Mailing

Each weekly mailing from the field centers to the Ultrasound Reading Center contains:

a. Video cassettes for the participant ultrasound studies completed the previous week.
b. Diskettes for the participant ultrasound studies completed the previous week. Each diskette is placed in the video cassette case with the same identification number.
c. A copy of the week's log sheet for each field center (Figure 23).
d. A diskette containing the participant files.
e. A copy of the ARIC Batch shipping Log sheet for the week.
f. A video cassette containing that week's phantom scan(s).
g. Biosound Service Report, if appropriate.

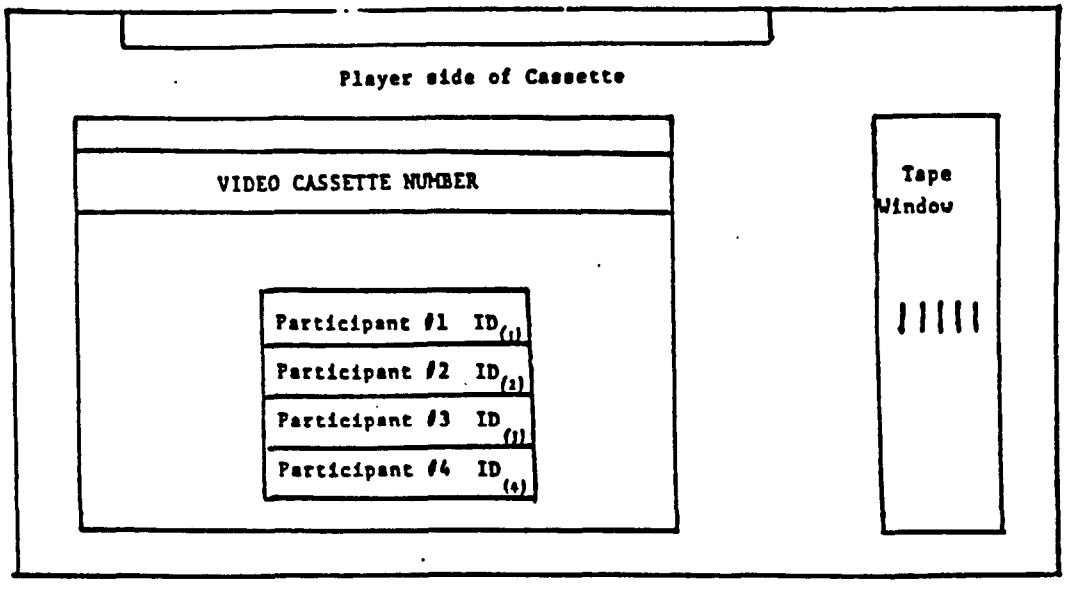


Figure 22 a. Videocassette Labels

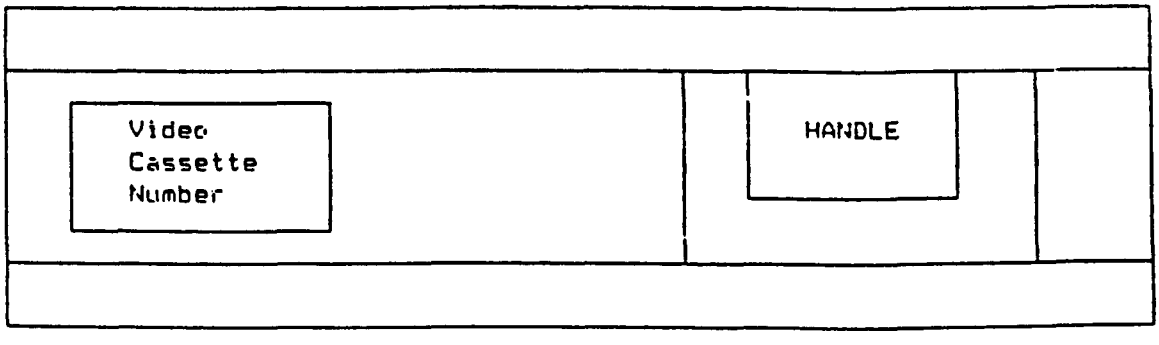
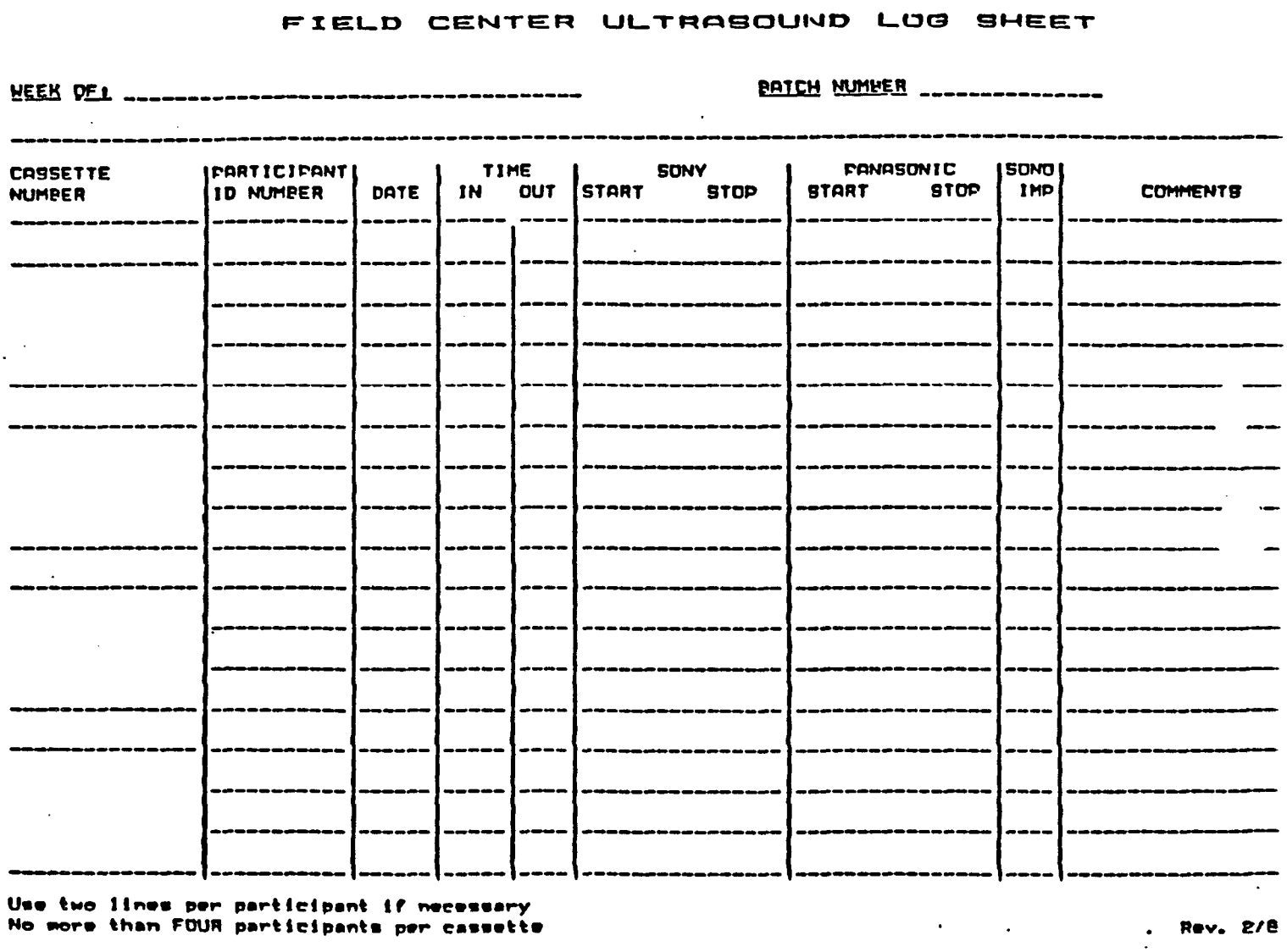


Figure 22 b. Videocassette Box Labels



FIELD CENTER ULTRASOUND LOG SHEET

WEEK OF: _____ BATCH NUMBER _____

CASSETTE NUMBER	PARTICIPANT ID NUMBER	DATE	TIME IN	TIME OUT	SONY START	SONY STOP	PANASONIC START	PANASONIC STOP	SONO IMP	COMMENTS

Use two lines per participant if necessary
No more than FOUR participants per cassette

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Figure 23. Typical Field Center Ultrasound Log Sheet

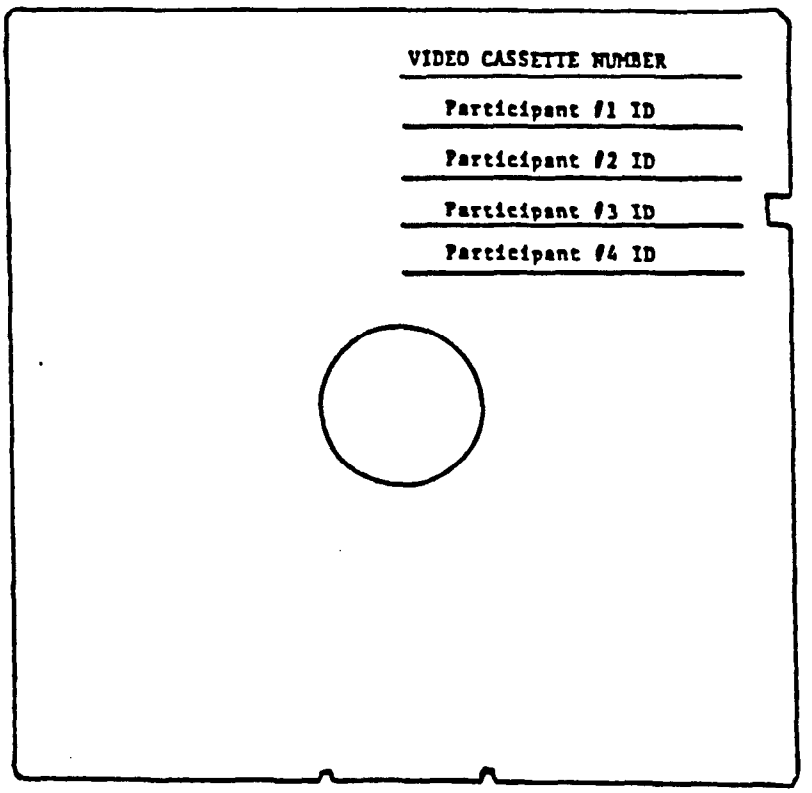

Figure 24. Floppy Disk Labels

12.4 Frequency of Mailing

The video cassettes, diskettes and lists described in Section 12.3 are mailed each week no later than Tuesday afternoon to the Ultrasound reading Center. The Ultrasound Reading Center needs these cassettes no later than Wednesday afternoon.

12.5 Package Labeling

The address label from each field center has the following information:

a. Field center personnel sending the package.
b. Field center return address.
c. The batch shipping number from the ARIC Batch Shipping Log sheet.
d. Address label to the Ultrasound Reading Center:

ARIC Ultrasound Reading Center
4310 Enterprise Drive, Suite C
Winston-Salem, North Carolina 27106

Mailing is by services guaranteeing package arrival at the Ultrasound Reading Center no later than midafternoon on the Wednesday following the mailing.

12.6 Verification of Mailing Contents

After the Ultrasound Reading Center logs in the video cassettes and diskettes and checks the contents against the lists of item (3) in Section 12.3, verification of the mailing contents are sent to each field center. Any missing items as well as any necessary action are described.

12.7 Field Center Video Cassettes

The 1/2" video cassettes remain at the field centers for backup purposes. They are used for review if an alert value be found in the participant studies. After notification from the Ultrasound Reading Center that the participant studies have been read, these 1/2" cassettes may be used again by the field centers.

13. REPORT FROM ULTRASOUND READING CENTER TO FIELD CENTER

13.1 Routine Report

The ultrasound report to each field center is a weekly list of participant studies read the previous week and an alert designation whenever an alert condition was detected at the Ultrasound Reading Center. The list consists of the following information:

a. Participant Identification numbers
b. Participant last name, first and middle initial
c. Date of birth
d. Race and gender
e. Examination date
f. Alert (Yes or Blank)

13.2 Alert Report

If the minimum lumen diameter in the extracranial carotid system at the sites imaged in this protocol is less than or equal to 2 mm, an alert value report protocol is initiated.

On the day of the reading, the chief reader or his/her designee notifies the appropriate field center by electronic mail. The report consists of:

a. Participant identification number
b. Participant last name, first and middle initial
c. Date of birth
d. Race and gender
e. Examination date
f. Site(s) of minimum lumen diameter (less than or equal to 2 mm)

14. PARTICIPANT SAFETY PRECAUTIONS

See Manual 2.