



ARIC

**ATHEROSCLEROSIS RISK
IN COMMUNITIES STUDY**

Manual 6A

Ultrasound Scanning

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

Atherosclerosis Risk in Communities Study Protocol

Manual 6

Ultrasound Assessment

Part A: Ultrasound Scanning

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FOREWORD

This manual, entitled Ultrasound Assessment, Part A: Ultrasound Scanning, is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality assurance for the different study procedures.

The version status of each manual is printed on the title sheet. The first edition of each manual is Version 1.0. Subsequent modifications of Version 1 (pages updated, pages added, or pages deleted) are indicated as Versions 1.1, 1.2, and so on, and are described in detail in the Revision Log located immediately after the title page. When revisions are substantial enough to require a new printing of the manual, the version number will be updated (e.g., Version 2.0) on the title page.

ARIC Study Protocols and Manuals of Operation

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**Manual 6: Ultrasound Assessment
Part A: Ultrasound Scanning**

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1. INTRODUCTION

The examination of participants in the ultrasound area in each of the four ARIC field centers consists of the following components: (1) ultrasonic imaging of the popliteal artery in the leg; (2) ultrasonic imaging of the carotid arteries in the neck; (3) measurement of carotid artery distensibility and blood pressure upon completion of the ultrasonic imaging exams; (4) monitoring of blood pressure throughout the ultrasound examination; and (5) beat-to-beat monitoring of heart rate and rapid sequential blood pressure monitoring during a postural change exam at the conclusion of the study. This ARIC manual details the procedures to be followed in each of these components. Interpretation of the ultrasound examination performed at the ARIC Ultrasound Reading Center (URC) is described in the Ultrasound Reading Protocol. The postural change examination is detailed in ARIC Manual 11.

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. A detailed description of the selection process is available in the literature.

3. SONOGRAPHER TRAINING AND MONITORING

3.1 Training

The sonographer training program consists of a series of training sessions (120 hours) at the Ultrasound Reading Center (URC) in Winston-Salem, North Carolina, followed by homework practice assignments at the respective field centers. The initial sessions (60 hours) consist of lectures, demonstrations and practical laboratory experience on the following topics:

1. Overview of the ARIC Study
2. Role of the Ultrasound Reading Center
3. Ultrasonic Physics I, including basic physics concepts, units of measurement, and mathematics arising in the medical applications of ultrasound
4. Overview of atherosclerosis and a detailed discussion of the normal artery wall
5. Ultrasonic Physics II, including a discussion of the properties of ultrasonic waves, reflection at boundaries and scattering from small objects

6. Ultrasonic Physics III, including the Doppler effect, ultrasound transducers and sound beams
7. Pathology of Atherosclerosis, including dissection of arterial specimens
8. Principles of Ultrasonic Instrumentation, including pulse-echo imaging systems, pulsed Doppler systems, and spectral analysis
9. Basic operation of the Biosound 2000 II sa
10. Instrument Performance Monitoring
11. Principles of Ultrasound Arterial Scanning

The remaining sessions (total of 60 hours) consist of detailed studies and practice of the ARIC ultrasound protocol, including the use of the Study Flow Panel, IBM personal computer, the Dinamap automated blood pressure instrument and the arterial wall tracker. The training program concludes with a final exam to demonstrate mastery of the ARIC Ultrasound Scanning Protocol. Successful completion of this demonstration is the first step toward initial sonographer certification. After the sonographers return to their respective field centers after the training period, the first 15 ARIC participant studies from each sonographer are received and evaluated for protocol adherence by staff members of the Ultrasound Reading Center. The criteria for successful completion of this phase and for initial certification are the following, judged from recordings on the 3/4" video tapes: 20 mm length and proper recording of the dimensional marker; vertical alignment of the arterial segment being examined; placement of the arterial segment within middle third (horizontal) of the image; correct identification of anatomic references within the carotid arteries; proper sequential examination of arterial segments; correct placement of the cursor over specific anatomic references, audio labeling of the tape segment that demonstrates the best quality image; appropriate use of gain settings and field focus and correct identification and recording of views from optimal angles. The detailed results of these evaluations are sent to sonographers through electronic mail along with documentation that the sonographer being evaluated has either been certified or requires further training.

The annual recertification procedure, in addition to the above described initial certification, requires detailed data analyses on lumen diameters and area, as well as combined intimal-medial thickness and area measurements for each sonographer. As the database increases, acceptable quantitative standards for intra- and intersonographer variability will be determined and comparison with these data used for recertification.

Continual training and updating on equipment and software is provided by written materials and field center visits from Ultrasound Reading Center personnel.

3.2 Monitoring

Sonographer performance is monitored throughout the ARIC study both at the field center and the Ultrasound Reading Center. At the field center, the field center ultrasound director reviews video cassettes

from participant studies periodically, at least every three weeks. His/her primary purpose is to ensure the quality of the study data and adherence to the scanning protocol, communicating directly with the sonographers for this purpose. 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 or a cursor indicating the location of an anatomical landmark. The Doppler images are evaluated for proper artery identification. The field center ultrasound director identifies scanning protocol difficulties and changes in sonographer performance at the field center. The field center ultrasound director identifies scanning protocol difficulties such as equipment problems, interruptions in the participant flow, difficult participant studies, absence of ECG signals, etc.

Sonographer performance is also monitored at the URC using a sequence of quality control procedures as defined later in this protocol. The quality control procedures consist of comparing results of repeat studies on an identical site and angle on the individual participants by the same as well as a second sonographer. Data obtained from those studies are used as a basis for decisions pertaining to acceptable quality levels of variability.

At the Ultrasound Reading Center, 15% of the participant studies are reviewed in their entirety from the video cassette for monitoring sonographer quality. The reviewer evaluates adherence to the scanning protocol, overall quality of the study, number and clarity of arterial interfaces, and presence and location of anatomical landmarks in B-mode image. The Doppler images are evaluated for proper artery identification. This evaluation is more detailed than the corresponding evaluation at the field centers.

The ultrasound 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.

Ultrasound Reading Center personnel work closely with individual sonographers by telephone, periodic feedback by mail, and through site visits from the URC. Recertification sessions at the URC maintain a high level of quality throughout the study.

4. ULTRASOUND AREA INSTRUMENTATION

4.1 Ultrasound Instrumentation

4.1.1 Description

A simplified diagram of the Biosound 2000 II sa is shown in Figure 1. Some principal features include: a rigid steel and aluminum semi-portable main frame cabinet housing the electronics and control console; a control console panel containing controls for operation which include video gain and TGC (Tune Gain Control), transducer activation (power on/off), Doppler sample volume, and mirror (on/off) movement; two black and white video monitors with audio for information display; a spectrum analyzer for use with Doppler signals; and two hand-held transducer assemblies (a primary and identical secondary backup). For a detailed description of these features refer to the manufacturer's Operator's Manual.

Two horizontal lines are drawn by the sonographer on the right TV monitor which divide the image portion of the viewing screen into three equal horizontal segments and provide a standard location for cursor placement when scanning the carotid arteries. The lines are drawn with a Sharpie fine point marker or similar felt tip pen. When recording images on video cassettes, the target segment of the artery being studied (i.e., popliteal, common carotid, carotid bifurcation or internal carotid artery) is placed in the middle segment. In the case of the carotid arteries, at least one of the reference sites (i.e., the origin of the bulb or the flow divider) lies in the area on or just outside the two lines.

Two video cassette recorders (VCR) are used with the Biosound instrument. A SONY 3/4" VCR is used to record the images sent to the Ultrasound Reading Center. The SONY VCR records the ultrasound images at a broadcast quality level, which provides significantly improved image quality on a television monitor. The recording time available for each 3/4" video cassette is approximately 60 minutes.

A Panasonic 1/2" VCR is used to provide backup at the field center. All of the examination results recorded on the SONY VCR are recorded on the Panasonic VCR.

The RMI Tissue-Mimicking Ultrasound Phantom (RMI Model 409) is used for daily performance checks on the Biosound system. The phantom includes three targets ranging from 2 to 6 mm in diameter, as well as thin filaments located 1 to 4 cm from the top surface of the phantom.

4.1.2 Checkout - General

Each sonographer should carefully read the manufacturer's Operator's Manual provided by Biosound with each instrument.

The Biosound 2000 II sa system must be serviced after shipment and before initial use. To protect the warranty, the initial general checkout and all servicing must be performed by an authorized Biosound, Inc., service representative. In the event of improper performance of the system, Biosound should be notified immediately by telephone at 1-800-428-7378. Additionally, sonographers should contact the Ultrasound Reading Center (1-919-722-2015) whenever service is required so that an accurate central log of servicing requirements at all field centers is maintained.

When setting up the ultrasound area in the field centers, at least six inches of space are required behind the instrument chassis to ensure adequate ventilation. A dedicated, single circuit, 115 VAC, 15 AMP, 60 Hz electrical outlet is required. Operating other devices on the same circuit may cause interference with the Biosound system.

The Probe Select Switch, located just above the cursor joystick, is placed in the A position. The Mirror Switch (also identified as the Scan Switch) located above the Tape-Live Switch, is placed in the ON position. For B-Mode ultrasound imaging, the Cursor Switch, located just above the Probe Select Switch, is in the image position. The Doppler Footswitch is used as prescribed by this protocol.

The time and date are checked daily and corrected if necessary by pressing the proper buttons on the separate hand-held Medasonics control panel. The time and date appear in the lower lefthand corner of the left TV monitor.

4.1.3 Daily Checkout

4.1.3.1 Instrument Warm-Up

The Biosound 2000 II sa is turned on by pushing in the black button on the right side of the instrument, just below the keyboard. The instrument should warm up for a minimum of thirty minutes prior to the first examination each day and remain on until the conclusion of the last study of that day.

4.1.3.2 Initial Instrument Settings

The center of the probe is marked with a water-resistant marking pen, such as a Sharpie fine point, and is checked prior to each exam. This line is used for orientation during the popliteal scan as instructed in Section 6.4. The brightness and contrast controls on the video monitor are set approximately 1/3 of a clockwise turn from the maximum counter-clockwise position. The Pulse Cross Button is in the OFF position or to the point where the gray scale at the top of the screen is clearly visualized (i.e., the first block, going from left to right, is black. The last block is white with the blocks in the middle progressing from

dark to light). For the left monitor, the Scan Size Button is depressed. These control positions are checked and set prior to each ultrasound examination.

Initial instrument settings (which are set prior to each examination) are as follows:

Video gain.....5.0
TGC.....5.0
Doppler gain...5.0

4.1.4 Video Cassette Preparation

The power to both the SONY and Panasonic video cassette recorders is turned on at the same time as the ultrasound instrument, i.e., at least thirty minutes prior to the first examination.

When using the 3/4" video cassettes for the first time or any time after shipping, place the cassette into the video cassette recorder. Press the FAST FORWARD button and let the cassette wind to the end of the tape. The VCR will automatically stop at the end of the tape, and then REWIND the tape until the cassette stops. The cassette is now ready for use. This procedure evens the edges of the magnetic tape and results in longer tape life. (See Appendix 1, Step Numbers.)

4.1.5 Preliminary Instrument and Video Cassette Recorder Checkout

After warm-up but before the first participant examination each day, the sonographer checks the operation of the VCR. If a new video cassette is to be used, the sonographer prepares the video cassette as described in Section 4.1.4. If a video cassette has been previously recorded, the sonographer should write down the elapsed recorded cassette time.

The sonographer places a small amount of gel on the transducer probe. The RECORD and PLAY buttons on the SONY VCR are pressed simultaneously. Allow about five seconds for the VCR to come up to speed. Variations in the image are introduced by lightly touching the gel with the index finger. A short recording of five to ten seconds is made, then the STOP button is pushed. Allow about five seconds for the VCR to complete the stop operation. Press the REWIND button to rewind the cassette to the beginning or the elapsed time recorded earlier. The Biosound Tape/Live switch is changed to the TAPE position; the SONY VCR PLAY button is pressed, to review the section of tape just recorded; the VCR STOP button is pressed. After a five-second pause, the REWIND button is pressed and the cassette rewound again to the elapsed time recorded earlier. Be careful not to rewind past this time, to prevent destroying the previously recorded information. The Biosound Tape/Live switch is then returned to the LIVE position.

The sonographer verifies that the SONY VCR audio channels are operational by testing in record and then playback. Both audio channel gain controls are set at "6" on the audio dial at the same time the image record is checked.

Audio channel 1 is connected to the Study Flow Panel for the Study Code and Sonographer Identification Tone. The channel 1 level is checked by depressing the Audio Record Footswitch. The SONY VCR Audio Limiter switch MUST be in the ON position. The channel 1 Audio Level is adjusted so the Audio Level Meter Pointer is at the 0 dB position. This position is the junction between the white and red scale sections on the Audio Level Meter. The gain control should not be moved until the next calibration check.

Audio channel 2 is connected to the microphone and is checked with the microphone input in record and playback. The channel 2 Audio Level is adjusted for acceptable microphone playback levels.

Operation of the VCR is described in the SONY instruction manual. Tape heads are cleaned periodically according to these instructions.

Similar checks are performed on the Panasonic VCR according to its instruction manual. Checks on the VCRs may be performed either separately or simultaneously.

4.1.6 Ultrasound Equipment Performance Check

Perform the following instrument performance protocol at the beginning of each day after the Biosound ultrasound system has been permitted to warm up for a period of at least 30 minutes. Refer, as necessary, to the instruction manual accompanying the RMI Tissue Mimicking Ultrasound Phantom (Model 409) for proper care and maintenance of the test phantom.

Place the ultrasound phantom upright on the examination table with the short side of the rectangular case parallel to the longer side of the table and the section containing the three static simulated vessels on your left, as viewed from the head of the examination table. Position the phantom so that the top surface to which the transducer will be applied is located approximately where the participant's common carotid arteries will be located during the carotid scanning protocol.

Clean the top surface of the phantom with a damp cloth or paper towel to remove residue. Half-fill the water tray on the top of the phantom with tap water to permit efficient coupling of the ultrasound transducer to the tissue equivalent medium. An alternative is to use ultrasound gel as the coupling medium.

A two-minute segment of B-mode phantom images is recorded at the beginning of each day's scan as described below. Use a separate video tape to record only phantom images. Selected frames are read at the Ultrasound Reading Center to quantitatively document the ultrasound system imaging characteristics. Label the first phantom tape according to the following format: (example)

PHANTOM - F - 86 - 09 - 12 - 001

F = the field center code - F, W, J or M
86 = year at first date on cassette

09 = month of first date on cassette
12 = month at final date on cassette
001 = sequential numbering of all phantom cassettes beginning with 001
at each field center

During the time between the month of the first date on the cassette and the month of the final date, leave the final date blank. This label should be placed in the position of the Video Cassette Number in Figure 16. The video cassette box should also be labeled as shown in Figure 17.

After completing two weeks of phantom recordings on this tape, ship the partially filled cassette to the URC with the current shipment of B-mode tapes. While this tape is being reviewed, use a second video tape for phantom recordings. These two phantom tapes will be exchanged at two-week intervals to monitor performance of the Biosound instrument.

Type in the phantom serial number on the first line of the graphics display at the top of the Biosound image screen. Type in the date, field center location, and the transducer serial number 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.

Adjust both the Biosound video gain and TGC controls to their maximum (10, full clockwise) positions and maintain them in these positions until instructed to change them. Move the cursor to the vertical center position used in Doppler segments of the protocol and leave it in this position for the entire performance check. Turn the Transducer power on (place Off/Active switch to ACTIVE position, which illuminates the adjacent red light) and place the system in the normal B-scan imaging mode. Place the transducer focus switch in the "FAR" focus position.

Make a preliminary scan of the phantom, successively obtaining longitudinal scans of the three static simulated vessels using a slow and continuous movement from left (6mm diameter vessel) to right (2mm diameter vessel). After the vessels have been satisfactorily imaged using minimal transducer pressure, return the transducer to the far left position again and record a second similar scan 30 seconds in length on the SONY VCR. The record mode is entered by simultaneously pressing the RECORD and PLAY buttons on the SONY remote control box or on the VCR. As the transducer is moved from left to right, pause briefly at each vessel. Rock the transducer back and forth to clearly visualize the walls and lumen of the simulated vessels. Hold each image for approximately five seconds. Exert minimum transducer pressure as you proceed, and produce an image where the walls of the vessel are as vertical as possible. Depress the PAUSE or STOP button on the VCR after recording.

Now obtain a transverse cross-section of the simulated vessels, keeping the transducer focus switch in the "FAR" focus position. Position all three vessels so that they are viewed on a single image. Press the RECORD and PLAY buttons on the SONY VCR and record a ten-second

segment, again rocking the transducer slightly to clearly image the echoes from the posterior walls of the vessel. Press the VCR PAUSE or STOP button on the VCR after this ten-second segment is recorded.

Move the transducer laterally to the right to image the four thin filaments located between 1cm and 4cm below the surface. Rock the transducer slightly to obtain a transverse view of the filaments. Position the image in the vertical center of the screen, as confirmed by the cursor in the vertical center position. Be sure that the transducer focus switch on the left side of the probe is still in the "FAR" focus position. Press the RECORD and PLAY buttons on the SONY and record a ten-second segment of this scan, rocking the transducer as necessary to obtain the brightest image. Press the PAUSE or STOP button on the VCR after completion of the recording.

While keeping the transducer in the same location, place the transducer focus switch in the "NEAR" focus position and obtain a transverse image of the filaments. Again, be certain the filaments are centered. Record a ten-second segment and leave the VCR in RECORD mode as you proceed to the next step. Reduce video gain to the "3" setting and the TGC to the minimum ("0", or full counterclockwise) position. Hold this image for approximately ten seconds. Press the STOP button on the VCR after completion. Remove the video tape from the VCR.

This concludes the daily instrument performance test on the RMI phantom. Carefully remove the water or the coupling gel from the phantom and place the phantom in its storage location.

A representative of the Ultrasound Reading Center visits each field center twice a year to make additional ultrasound system performance measurements. This includes monitoring the transmitted ultrasonic pressure pulse waveform and determination of the spatial-peak temporal-peak intensity using a miniature hydrophone probe. This information is important from the standpoint of safety as detailed in the American Institute of Ultrasound in Medicine - National Electrical Manufacturers Association (AIUM-NEMA) Safety Standard for Diagnostic Ultrasound Equipment.

4.1.7 Ultrasound Equipment Maintenance

The Biosound System is designed to require minimal maintenance. Internal components must be serviced by a qualified Biosound Inc. representative. The telephone number for service is 1-800-428-7378.

The air filter is vacuumed every thirty days and is washed or changed every six months. See Operator's Manual (page 22) for details.

4.1.8 Number of Studies Per Video Cassette

There shall be no more than four complete participant studies per 3/4" 60 minute video tape. The exact number of complete studies per cassette depends on the time per participant; however, under no circumstances should a participant study be divided between two cassettes.

4.2 Study Flow Panel

4.2.1 Description

The Study Flow Panel display is shown in Fig. 2.

The B-mode ultrasound examination consists of one popliteal and two carotid artery studies and involves a maximum of 14 steps. These steps are performed in a similar sequence for each participant. A Study Flow Panel 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.

For example, if a sonographer is imaging the left common carotid artery longitudinally from the anatomic reference, the lights labeled NORMAL, COMMON CAROTID, LEFT, B-MODE LONG, and OPTIMUM ANGLE will be illuminated and visible to the sonographer.

4.2.2 Operation

To start a study, the sonographer momentarily depresses the study START switch on the Study Flow Panel. The Biosound is set to the calibrate mode, and a 20mm line is placed in the middle of the screen, as described in Section 6.6.1 and Figure 5. The SONY VCR RECORD and PLAY buttons are pressed simultaneously, and after a delay of at least 20 seconds the sonographer depresses the Audio Record Footswitch for about five seconds. This process automatically records the study START code on one of the audio channels of the SONY VCR. The ultrasound examination is then performed.

When the Audio Record Footswitch is depressed at the beginning of a step, a digital code is automatically sent to the audio channel 1 on the SONY VCR and Panasonic VCR. This code is used by the Ultrasound Reading Center to identify the specific examination step being performed. When the Audio Record Footswitch is released, the Study Flow Panel is advanced one step, and the lights specifying the scanning step to be performed next are illuminated.

If the sonographer must repeat or skip a particular scanning step, the manual UP or DOWN switch is momentarily depressed and released until the appropriate study code appears and panel lights are lit. If the sonographer must skip a study code, toggle the manual UP switch on the Study Flow Panel once to advance to the next study code. If a step is skipped, do not depress the Audio Record Footswitch.

Whenever the Biosound Doppler Footswitch is pressed to change the display from B-mode to Doppler or Doppler to B-mode or the SONY VCR is changed from PAUSE to RECORD, at least 20 seconds should elapse before pressing the Audio Record Footswitch. In other circumstances, at least 20 seconds must elapse between successive pressing of the Audio Record Footswitch.

To terminate an ultrasound examination, the sonographer momentarily depresses the STUDY COMPLETE toggle switch on the Study Flow Panel, and depresses the Audio Record Footswitch for five seconds. This process automatically places the study STOP code on audio channel 1 of the SONY VCR. The VCR's should be in the RECORD mode during this time.

4.3 Blood Pressure Instrumentation

A series of blood pressure measurements is made during the ultrasound examination. The purposes are: (1) to provide baseline supine blood pressure measurements, (2) to determine postural changes in blood pressure which occur when participants stand up after the ultrasound examination is complete, (3) 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. Carefully read ARIC protocol Manual 11 and the Dinamap Operation Manual before performing the blood pressure measurements. (Refer to the section on postural change exam in Manual 11.)

4.3.1 Description

The Dinamap Monitor Model 1846 SX is a microprocessor-controlled noninvasive device housed in an 11" x 11" x 5" dark blue metal case that is self-supporting. Performance, technical specifications, and calibration procedures are detailed in the Operation Manual.

4.3.2 Blood Pressure Setup

4.3.2.1 Blood Pressure Measurement/Lower Extremity

The first part of the Ultrasound Scanning Protocol involves the popliteal artery, which is palpated at the crease behind the knee. The participant is in the prone position during this part of the examination, which takes approximately ten minutes.

Following the procedures described in Manual 11, a blood pressure cuff of suitable size is selected and placed around and above the ankle of the same leg that is to be used for the popliteal B-mode scan. Socks or footwear, if present, are removed before placing the blood pressure cuff. The blood pressure is measured above the ankle as soon as the study is started and then at the end of the popliteal ultrasound scan.

4.3.2.2 Blood Pressure Measurement/Upper Extremity

The second part of the Ultrasound Scanning Protocol involves the carotid arteries in the neck, which takes approximately 35 minutes. The participant is in the supine position during this portion of the exam.

Several times during the carotid artery exam, the blood pressure is measured in the right brachial artery (see Manual 11). The final supine measurement, immediately after completion of the carotid ultrasound examination, is used to determine arterial distensibility and to gather baseline measurements for determining postural changes in blood pressure.

After the baseline measurement, the participant is assisted to an upright position. Blood pressure measurements are continued at about 20-second intervals for two minutes. (See the section on postural change examination in Manual 11.)

4.3.2.3 Recording Blood Pressure Data

The Dinamap Monitor displays the measured values of four parameters in digital form: heart rate, systolic, diastolic and mean arterial pressure. Data are collected and stored on diskette by the IBM-PC.

4.3.2.4 Standardization and Maintenance of Blood Pressure Equipment

Refer to Section 7, Performance Verification, of the Dinamap Operation Manual and to Manual 11. Verification of calibration is performed at least once a month or when there is doubt that the monitor is working properly. Adjustments are made only if the calibration readings described are not obtained. A standard mercury manometer is required to perform the calibration. A convenient troubleshooting guide is also included at the end of Manual 11.

4.4 Computer System IBM-PC

The data acquisition, timing, and storage in the field center ultrasound area are under the control of a personal computer modified for these functions. The computer interacts with the ultrasound area equipment to perform the following tasks:

1. To obtain participant data, such as identification number, birthdate, race, and gender.
2. To establish files for participant data with appropriate names and file extensions.
3. To determine the left/right leg for ultrasound examination based on the participant identification number.
4. To keep a record of the study steps performed, including quality control studies, from the Study Flow Panel.
5. To control the Dinamap automated blood pressure instrument during the popliteal and carotid artery ultrasound examinations, the carotid artery distensibility measurement, and the postural change protocol.
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 calculate heart rate on a beat-by-beat basis at the end of the carotid artery examination and the postural change protocol.

8. To record all these data on hard disk for temporary storage and on diskette to send to the Ultrasound Reading Center.

4.4.1 Overview

The PC-based "US" program running on the PC in the ultrasound work station is designed to control leg artery selection, collect various data during the study, and to assist the sonographer in performing the ultrasound and postural change protocols. There is minimal sonographer interaction with the computer, which allows the sonographer to concentrate on obtaining high quality B-mode images and postural change examination data.

The data collected by the "US" program consists of: (1) participant demographic and descriptive data, (2) study codes and audio footswitch depression times for performing each step of the examination, (3) periodically recorded blood pressure, arterial distensibility, and heart rate and blood pressure data during the postural change examination.

The sonographer is required to interact with the computer: (1) during the initial questionnaire, (2) at the beginning of the postural change examination, (3) at the time the participant's feet touch the floor during the postural change examination, and (4) 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.

4.4.2 Detailed Operational Instructions

The following instructions should not be considered as the scanning protocol; instead, they describe how the computer system supports the protocol.

Before turning on the PC at the ultrasound work station, make sure the Dinamap and the Study Flow Panel are on. The PC at the ultrasound work station is turned on, and a "C" prompt displayed. The ultrasound program is activated by typing "US" on the keyboard, and the system responds by displaying the 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, he or she may move back to make corrections by using the cursor (arrow) keys.

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: The time is read from the computer clock and is confirmed by pressing the RETURN key. If a change is required, the entire time must be retyped.

SONOGRAPHER IDENTIFICATION: Three digits corresponding to the unique code that identifies each sonographer in the ARIC study are used to identify the initial sonographer.

RACE: Enter W (white), B (black), or O (other).

GENDER: Enter M (male) or F (female).

BIRTHDATE: Enter the participant's birthdate 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.

1. DIZZY ON STANDING UP - Record if the participant reports that he/she becomes dizzy upon standing to alert the sonographer that special care should be taken during the postural change protocol. Answer Y (yes) or N (no).

WHILE THESE QUESTIONS ARE DISPLAYED ON THE SCREEN, THE OPERATOR MAY MOVE BACK TO CORRECT INFORMATION WITH THE ARROW KEYS ON THE KEY PAD.

After the form is completed, the information is stored and the screen clears. A new screen asking for a data file is displayed. The operator then types: /EXIT. Do not depress the computer RETURN key at this time. Check the blood pressure cuff (and change alarm settings if necessary) and verify that the heart rate signal is received by the system as displayed by the visual and audible signals. The RETURN key is now depressed.

If an error is made at this time, the system asks for a "form" name. The appropriate response is to press the F4 key, and the system asks for the data file again. Once this has been typed, the screen is cleared and "ARIC Ultrasound Program" appears on the screen. This screen displays participant ID number, the last study code, the elapsed time since the beginning of the ultrasound exam, and the time of day. The elapsed time and time of day may advance in small leaps, sometimes skipping a few seconds. Displaying these times is of low priority to the system, and if it is busy with some other operation it will wait

until it has completed the operation to update the time displayed on the screen.

FROM THIS POINT UNTIL THE COMPLETION OF THE ULTRASOUND SCANNING PROTOCOL THE OPERATOR IS NORMALLY NOT REQUIRED TO TOUCH THE COMPUTER KEYBOARD.

After the computer RETURN key is pressed in response to the /EXIT message, the sonographer presses the START STUDY switch on the Study Flow Panel and sets the Biosound ultrasound scanner to the calibrate display. The 20mm calibrate line is displayed on the video monitors. The PLAY and RECORD switches are depressed simultaneously on the SONY VCR. After at least 20 seconds' delay, the Audio Record Footswitch is depressed for about five seconds, and the computer automatically takes and records a blood pressure measurement. The last study code on the screen will show a "12".

The leg scan is performed and the artery located to record the image. The Audio Record Footswitch is then depressed and held for five cardiac cycles. Fifteen seconds after Audio Record Footswitch is depressed, the system automatically takes the blood pressure again. This provides blood pressure measurements before and after the popliteal scan. The last study code will be either a "17" or a "1", depending on which artery was studied.

The Study Flow Panel indicates the next vessels to be scanned. The computer remains dormant until the next time the Audio Record Footswitch is depressed. When the sonographer presses the Audio Record Footswitch, the system again takes a blood pressure automatically. The system then enters an automatic phase, during which it continues to take blood pressures every five minutes. Since the system is "unaware" of the status of the ultrasound exam, the blood pressure determinations will occur at different phases of the scanning procedure.

Automatic blood pressure determinations continue every five minutes until the last evaluation (i.e., internal carotid, left, B-mode, optimal angle) of the ultrasound protocol is reached. At the time of this final B-mode scan the automatic every-five-minute phase of blood pressure determinations is completed by taking a last blood pressure measurement.

Following this last B-mode scan the arterial distensibility measurement study is performed according to the protocol. The sonographer prepares to collect the arterial distensibility data and, when ready, depresses the Audio Record Footswitch. A message appears on the screen asking the sonographer to wait until the data from the distensibility scan are acquired and stored by the program on the C: disk. This process requires approximately five seconds. After the recording is complete, the system again performs a blood pressure determination.

Following the arterial distensibility studies, the ultrasound protocol is complete and is followed by the postural change examination as described in Manual 11. Briefly, a message is displayed on the screen indicating that the system is ready to begin the postural change

examination. The sonographer instructs the participant about the postural change examination. When the sonographer wishes to begin the supine portion of the postural change study, the F1 key is depressed. The screen is cleared and replaced by a display showing the participant's ID, the study number with a "1" indicating the initial part of the postural change examination, elapsed time (in decimal minutes), the time the study is to run (2 minutes), number of heart beats which have occurred, and statistics on blood pressure and heart rate.

Once the F1 key is depressed, heart rate is measured on a beat-to-beat basis, and blood pressure is determined as fast as the Dinamap allows--about 20-second intervals. With each heartbeat and blood pressure measurement the data on the screen are updated. These data include the last measurements of heart rate and blood pressure.

The computer continues to collect these data for two minutes, and then a new message appears on the screen indicating the end of the supine portion of the examination and that the computer is ready to collect data from the standing portion of this same examination.

As instructed in the postural change protocol (ARIC Manual 11), the sonographer immediately asks the participant to stand. When the participant starts to rise from the examination table, the sonographer should depress the F4 key on the computer. When the participant's feet are placed squarely on the floor, the sonographer or assistant depresses the F5 key. The screen clears and is replaced by a screen similar to the screen of the supine phase of the study. The study number now shows a "2", indicating the second phase of the postural change examination. The computer collects heart rate and blood pressure data until the end of this examination phase.

When this phase of the postural change protocol is completed, the screen clears and displays a form which is completed after the participant departs. The first item on the post-examination screen asks the sonographer to rate his/her judgment of scan quality as (E) excellent, (G) good, (F) fair, or (P) poor.

The second item asks if any departures from the protocol occurred. If there were none, "N" is entered followed by RETURN, and the system skips to the third item on the screen. If departures occurred, a "Y" is entered and the sonographer records an answer for each detailed question: (1) whether there were incomplete B-mode, arterial distensibility, or postural change studies, and (2) whether the standing portion of the postural change examination was collected with the participant sitting or leaning, i.e., not free-standing as specified in the protocol. In each case an N or Y is entered.

The third item on the screen requests information about discomfort during the study. Detailed questions are skipped if there was no discomfort. If there was discomfort, the questions ask in which portion of the study the discomfort occurred.

Lastly, any notes the sonographer wishes to attach to the participant's record are solicited. These notes can be entered in the space provided on the screen.

After completion of this information, the screen clears and the information is stored and is safe from computer malfunction. A new screen asking for a data file appears, and the operator responds by typing:
 \EXIT

If an error is made at this time, the system asks for a "form" name. To correct the error the sonographer depresses the F4 key. The system asks for the data file again, and the operator types the /EXIT command again. Once this has been entered the work at this station is completed for this participant.

4.4.3 Data Transfer and Archiving

A maximum of four participant studies are recorded on each SONY video cassette. With each video cassette there is a corresponding diskette containing the information collected on the ultrasound work station computer.

At the end of each study, the data collected on the computer reside only on the hard disk (C:). When all three or four studies on a video cassette have been collected, the data on the hard disk must be moved to a diskette to be mailed with the corresponding video cassette tape. This is accomplished by placing a diskette into the (A:) drive and closing the door. As an example, assume the participant studies on the video cassette have the study IDs F111111, F222222, and F333333. The information on the hard disk (or C: drive) is moved to the diskette by typing:

```
SONOGRAPHER: COPY F111111.* A:

COMPUTER F111111.DEM (The order of these
RESPONDS: F111111.BP files may change)
          F111111.SC
          F111111.DIS
          F111111.TM (NOTE: .DIS only on program when field
                    center uses their tracker)
          F111111.HR
          F111111.BP1

          7 file(s) copied
```

SONOGRAPHER: COPY F222222.* A:

COMPUTER F222222.DEM (The order of these
 RESPONDS: F222222.BP files may change)
 F222222.SC
 F222222.DIS
 F222222.TM
 F222222.HR
 F222222.BP1

7 file(s) copied

SONOGRAPHER: COPY F333333.* A:

COMPUTER F333333.DEM (The order of these
 RESPONDS: F333333.BP files may change)
 F333333.SC
 F333333.DIS
 F333333.TM
 F333333.HR
 F333333.BP1

7 file(s) copied

After these files are copied to the diskette, the sonographer removes the diskette and places the appropriate video cassette and participant ID labels on: (1) the video cassette (see Fig. 16), (2) the video cassette box (see Fig. 17), and (3) the diskette (see Fig. 18). The video cassette is then ready to be placed in the weekly mailing batch.

To complete the weekly batch for mailing, a final diskette is prepared to inventory all cassettes/diskettes that are in the box. The sonographer places a new diskette in the (A:) drive and types:

SONOGRAPHER: COPY PREINFO.DAT A:

COMPUTER
 RESPONDS: PREINFO.DAT
 1 file(s) copied

SONOGRAPHER: COPY POSTINFO.DAT A:

COMPUTER
 RESPONDS: POSTINFO.DAT
 1 file(s) copied

The diskette is removed, a label with "PRE/POST INFO DISK" written on it and the appropriate ARIC Batch Shipping Log are attached, and the diskette is placed on top of the cassettes to be shipped to the URC in this batch. Before closing the box, the mailer is given to the data coordinator who updates the inventory before the shipment is mailed.

4.5 Arterial Wall Tracker

The arterial wall tracker is a dual channel zero-crossing tracker supplied by AUTREC in Winston-Salem, North Carolina. Each arterial wall tracker 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 as 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 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 10mm arterial diameter. The second output channel is an ac coupled output calibrated for arterial diameter changes of 0 to 1mm. Both output channels are calibrated for a 50 ohm load resistor.

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 8.6 of this protocol.

5. 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 (Fig. 3).

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 should be checked for one blink each heartbeat. Interference, loose ECG pads, or a faulty cable will cause more than one blink each heartbeat.

5.1 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.

5.2 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 and behind one knee. During the examination, 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.

5.3 Participant Apparel

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

The popliteal artery of the lower extremity will be evaluated on one side. To gain access to the skin surface of the area behind the knee, roll up the pant leg on the side to be evaluated. If necessary, a linen sheet or cloth can be draped over the back of the thigh in such a way that the acoustical gel can be applied to the skin surface overlying the popliteal crease at the back of the knee.

5.4 Participant Identification

5.4.1 Description of Data to be Entered

Each participant is assigned a 5 1/4" diskette that will accompany him/her throughout his/her visit to the field center. This diskette contains a record consisting of participant identification number, name, gender, and birthdate. These data are used to identify the participant at the Ultrasound Reading Center.

5.4.2 Entry Instructions - Computer

Participant demographic data are entered in the computer as detailed in section 4.4.2.

5.4.3 Entry Instructions - Biosound Image Screen

Before each participant B-mode scan, type in the date, participant ID number, field center location, and sonographer code number 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.

6. POPLITEAL ARTERY

6.1 Popliteal Artery Introduction

The popliteal artery is a direct continuation of the femoral artery which begins as this vessel exits from the adductor hiatus and extends to the lower border of the popliteus muscle, where it divides into the anterior and posterior tibial arteries. The popliteal artery extends above and below the midpart of the back of the knee and is usually behind a companion vein 3-4 cm below skin surface. Sonographer training includes "detailed review of anatomical chart and observation of the dissection of cadavers (of the popliteal and carotid artery systems).

6.2 Selection of Leg to be Examined

Only one popliteal artery is examined by ultrasonography. The side is determined by the participant's identification code. The right popliteal artery is selected for examination if the fifth digit in the subject identification code is an even number, otherwise the left popliteal artery is examined.

Selection of the popliteal artery is done automatically by the PC upon entering the participant ID number. The appropriate side indicator on the Study Flow Panel is illuminated and indicated on the PC screen.

6.3 Participant Position

The subject is aided in assuming a prone position on the examining table, with his/her head resting comfortably on a pillow. The ultrasound equipment is placed next to the examining table in a way that allows the sonographer to have access to the popliteal region, the instrument controls, TV monitor, Study Flow Panel, and foot pedals.

6.4 Identification of Site for Transducer Placement

Find the popliteal crease at the back of the knee. This is a single or series of creases that cross the skin horizontally on the back of the knee joint. If a single crease is present, draw a line with a Sharpie fine point marker over the crease for orientation purposes. If two or more creases are present, flex the lower leg to determine the position of the major crease and then mark it as described above. The ultrasound probe is aligned perpendicular to the crease in such a way that the center mark on the probe overlies the skin crease. A number of participants will have relatively dark skin on which ink marks will not show. In these cases, care must be taken to align the probe surface as described above on the skin crease, without the aid of the ink mark.

6.5 Preliminary Scan

6.5.1 Criteria for Satisfactory Image of the Popliteal Artery

The optimal B-mode ultrasound image is defined on the basis of clear visualization of the following arterial tissue interfaces at the site of the external anatomical reference, i.e., the skin crease:

1. Near Wall (artery wall nearest skin surface)
 - (a) adventitial - medial (Boundary 2, B2)
 - (b) intimal - lumen (Boundary 3, B3)

2. Far Wall
 - (a) lumen - intimal (Boundary 4, B4)
 - (b) medial - adventitial (Boundary 5, B5)

Linear distances, calibrated on the basis of the recorded 20.0 mm dimensional marker, are made from B-mode images at the Ultrasound Reading Center. At eleven sites along the length of the artery, near wall thickness (the distance between B2 - B3), lumen diameter (B3 - B4) and far wall thickness (B4 - B5) are determined from peak systolic images. Inability to visualize or to mark the frames that demonstrate these interfaces with the audio tone results in loss of data points. If B2 is not visualized, near wall thickness cannot be measured; lack of interface B3 means that neither lumen diameter nor near wall thickness can be measured; if B4 is not demonstrated, neither lumen diameter nor far wall thickness can be determined, and if B5 is absent, far wall thickness cannot be measured.

The length of each of the described interfaces is also important. The Ultrasound Reading Protocol requires determination of eleven equally spaced points along each 10.0 mm segment of artery for each of the four interfaces being measured. These data are not only used to estimate the length of each interface but are important in determining lumen, near wall, and far wall areas.

The easiest and most reliably imaged interfaces are B2 and B5, the medial adventitial boundaries of the near and far walls, respectively. These interfaces are highly reflective and are apparent at very low gain settings. B3 and B4, lumen-intimal boundaries, are, in normal arteries, usually less reflective and therefore not prominent at lower gain settings. Once B2 and B5 are visualized, the arterial image should be aligned with the ultrasound beam, and the gain increased to demonstrate B4 and B3. Care should be exercised in increasing the gain so that boundaries B2 and B5 do not become obscured.

If all four interfaces cannot be visualized within an acceptable time frame, the priority for boundary pairs is as follows: (1) B5-B4; (2) B2-B3; (3) B4-B3.

Arterial curvature, tortuosity, kinking, or the presence of mineral deposits or arteries that are more than 3.0 cm from skin surface may result in less than optimal detection of these interfaces.

If the above or large atherosclerotic lesions are not present, it is usually possible to visualize the majority of the above interfaces both on the near and far arterial walls. (See Fig. 4). If all four interfaces cannot be clearly visualized, the sonographer should attempt to visualize as many as possible.

6.5.2 Instrument Settings

The following controls shall be set as initial values:

- (a) Video Gain.....5
- (b) TGC.....5
- (c) Doppler Gain.....5
- (d) Probe Focus Switch....FAR
- (e) Tape/Live Switch.....LIVE
- (f) Probe Select Switch...Midway between A and B
- (g) Mirror Switch.....ON

6.5.3 Preliminary Popliteal Artery Scan Procedure

The purpose of the preliminary popliteal artery scan is to identify the 3.0 cm segment of this vessel to be studied. The preliminary scan is not recorded on the SONY VCR or the Panasonic VCR.

A liberal amount of Aquasonic-100, Ultrasound Transmission Gel (or equivalent) is applied on the skin surface overlying the popliteal arterial segment to be studied and on the probe surface. The probe is oriented so the distal end of the popliteal segment is at the bottom of the TV monitor screen and the more proximal segment at the top of the monitor screen (Fig. 4). The precise probe orientation is parallel to the popliteal artery with the middle of the probe overlying the marked knee crease. The transducer is applied with minimal pressure to the back of the knee. The transducer probe is slowly moved until the popliteal artery image is obtained. The Probe Focus Switch is placed in the appropriate field (i.e., mid, far). If the popliteal artery image is in the middle of the TV monitor screen, use the mid-field focus. If the image is in the right third of the monitor screen, use the far-field focus.

Using small movements of the probe, the sonographer then aligns the artery as nearly vertical as possible on the monitor. Care must be used to ensure that the mark on the surface of the probe is oriented exactly over the skin crease, i.e., the sonographer should not slide the transducer up or down on the back of the knee. However, in order to vertically align the artery on the monitor and to demonstrate the near and far wall interfaces, it is frequently necessary to either slide the transducer medially or laterally, i.e., toward or away from the longitudinal midline of the knee, or to rotate the transducer slightly while keeping the mark directly on the skin crease.

Video gain and TGC gain settings are adjusted so that the maximum number of interfaces on both near and far walls are visualized. Each of the gain settings is then reduced to the lowest setting that allows clear visualization of these interfaces. Frequently the popliteal vein

and artery are both present within the scanning field. The popliteal artery can be distinguished from the popliteal vein by its pulsating wall characteristics. If the artery cannot be clearly distinguished from the vein anatomically, the Doppler should be used with one of the methods described below.

1. The probe is rotated to the cross-sectional position over the popliteal crease. Some manipulation of the probe may be necessary to image clearly the cross section of the popliteal artery in the center of the scan. The Doppler sample volume is moved to the middle of the artery lumen by using the cursor joystick. The Doppler sample volume length is adjusted to 1.0 mm using the knob at the top of the joystick. The Doppler angle is observed through the center of the screen. The probe is angled cephalad about 20°, and the Doppler Footswitch depressed and released. Doppler waveforms will appear on the TV monitor. Slight adjustments in probe position and angle may be necessary to optimize the waveform. The waveform is evaluated to ensure correct discrimination between popliteal artery and the adjacent vein. The Doppler Footswitch is depressed again to return to B-mode. The probe is then returned to the longitudinal position with the probe center over the popliteal crease in preparation for recording the longitudinal B-mode image of the popliteal artery.
2. In some, if not the majority of cases, it may be more efficient and proficient to use Doppler on the longitudinal image rather than the cross-sectional image described in the previous paragraph. The method for acquiring the Doppler signal from the longitudinal image is exactly as described above except that the probe is not rotated during the preliminary scan.

6.6 Data Recording Scan

6.6.1 Start Code and Calibration

To start a study, 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. Place the horizontal cursor 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, turn the knob at the top of the cursor joystick counterclockwise until the length of the line is precisely 20.0 mm. (see Fig. 5).

When the cursor line is set, the sonographer momentarily depresses the START switch on the Study Flow Panel and then simultaneously presses the RECORD and PLAY buttons on the SONY VCR. After a delay of at least 20 seconds, the sonographer depresses the Audio Record Footswitch for about 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. The sonographer then presses the PAUSE or STOP

button on the SONY VCR or can continue to the popliteal artery scan. The ultrasound examination is then performed.

6.6.2 Longitudinal B-Mode Scan of Popliteal Artery

When the Audio Record Footswitch is released after the calibration display has been recorded, the Study Flow Panel proceeds to the next step and will display NORMAL, POPLITEAL, RIGHT OR LEFT (SIDE), B-MODE LONGITUDINAL, and KNEE. If this information is not displayed, the UP and/or DOWN switch is depressed to correct the display information. The probe is aligned longitudinally over the popliteal artery, with the center of the probe perpendicular to the knee crease. The popliteal artery is imaged, and with fine probe movements this view is optimized (as described in 6.5.1). Once this view is obtained and the blood pressure determination is complete, simultaneously press the RECORD and PLAY buttons of the Panasonic VCR and then simultaneously press the RECORD and PLAY buttons on the SONY VCR. With both video cassettes recording, the popliteal artery image is optimized again. When the best image is obtained, the Audio Record Footswitch is depressed for at least five complete cardiac cycles and is then released. The PAUSE or STOP button is then depressed on the SONY VCR Control Panel and on the Panasonic VCR. When the Audio Record Footswitch is released, the Study Flow Panel automatically advances and displays the next step to be done in the protocol.

After the Audio Record Footswitch is released and 15 seconds have elapsed, a second blood pressure measurement is taken. Please note that the ankle cuff should not be removed until the second blood pressure measurement is complete. If the cuff is removed before it deflates, the Dinamap alarm will sound and the Dinamap will require resetting.

In order for the ultrasound component of ARIC to produce valid and reliable data, it is important that sonographers understand how images are selected for measurement purposes. Only the first eight frames from each of the first three cardiac cycles after the Audio Record Footswitch is pressed are selected. The audio signal combined with the ECG wave forms is used to identify this region of the tape. Study Codes designated by the panel lights on the Study Flow Panel are recorded and used to select the arterial segment under study. If the transducer moves during the initial five seconds after the Audio Record Footswitch is depressed, or if the subject swallows or moves, the images will be inferior for measurement purposes. Repositioning of the transducer during this audio signal may help get better interpretable images. If movement of the subject or transducer does happen during the initial recording of the audio signal, that segment must be repeated. In that case, the Study Flow Panel must be reset using the UP/DOWN switches, and at least 20 seconds of continuing tape recording must elapse before pressing the Audio Record Footswitch for that arterial segment. This procedure is the same regardless of whether popliteal or carotid arteries are being evaluated.

7. POPLITEAL ARTERY QUALITY CONTROL

After completion of the normal popliteal artery study, the quality control (QC) envelope labeled "popliteal artery" is opened. If the instructions are "no quality control studies are to be performed," proceed to the carotid artery studies.

If the instructions are "perform a quality control study," depress the toggle switch on the Study Flow Panel labeled NORMAL/QC to the QC position and then depress the DOWN toggle switch until the Study Flow Panel lights show QUALITY CONTROL, POPLITEAL, the SIDE, i.e., RIGHT or LEFT just completed, B-MODE, LONGITUDINAL, and KNEE.

If the quality control instructions request an intrasonographer QC study, the same sonographer repeats the QC popliteal artery study. If the quality control instructions request an intersonographer QC study, the second sonographer enters the ultrasound area and performs the QC popliteal artery study.

If the quality control sonographer is the same individual who has just completed the popliteal study, i.e., intrasonographer QC, the exam proceeds as described in the next paragraph. If, however, an intersonographer QC study is required, that individual's three-digit identification number must be entered in the appropriate header information on the Biosound instrument. In that case, the previous sonographer's ID code is erased and the second sonographer's ID code is keyed in the appropriate position.

The quality control study sonographer orients the ultrasound transducer over the popliteal artery and performs the exact procedures described in Section 6.6.2, Longitudinal B-Mode Scan of Popliteal Artery. Simultaneously press the RECORD and PLAY buttons on the Panasonic VCR and then the RECORD and PLAY buttons of the SONY VCR. When the best popliteal artery image is obtained, depress the Audio Record Footswitch for at least five complete cardiac cycles. Press the PAUSE or STOP buttons on both video cassette recorders.

At the end of the popliteal quality control study, both VCRs should be in the STOP or PAUSE position. The toggle switch on the Study Flow Panel labeled NORMAL/QUALITY CONTROL is moved to the NORMAL position and the UP toggle switch is depressed one or several times until the following indicators are lighted: NORMAL, CAROTID ARTERY, COMMON CAROTID, RIGHT SIDE, B-MODE LONGITUDINAL, and OPTIMAL ANGLE. The instrumentation is now set up for the initial scan of the carotid arteries. If the quality control study was an intersonographer study, the first sonographer should re-enter his/her three-digit ID code on the Biosound screen. The participant is then assisted to a sitting position before lying down in a supine position for the carotid ultrasound examinations. Care must be taken not to generate tangles or body wrapping of the ECG leads or other cables.

8. CAROTID ARTERY

8.1 Carotid Artery Introduction

The extracranial carotid arteries, the largest arteries in the neck, originate from the aortic arch. Each common carotid artery ascends in the neck lateral to and slightly posterior to the trachea. At the approximate level of the thyroid cartilage, the common carotid artery bifurcates into the external and internal carotid arteries. Proximal to the bifurcation of the internal and external carotid arteries, the common carotid artery dilates to form the carotid bifurcation. In general, the common carotid arteries have no other branches in their course paralleling the trachea. The bulb is geometrically complex, elliptically shaped on cross-section. Its walls are curved, and in many cases this region is not parallel to the skin surface. The external carotid artery has several branches which supply the organs and musculature of the neck. The internal carotid artery is a direct extension of the common carotid artery as it ascends through the upper neck and usually has no tributaries in this area.

8.2 Participant Position

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. 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 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 should be 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 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.

8.3 Selection of Site

The right carotid artery is evaluated first. The appropriate lights are illuminated on the Study Flow Panel.

For the purposes of the ARIC study the extracranial carotid arteries may be divided into three anatomically defined segments: (1) distal common carotid artery, (2) the carotid bifurcation, and (3) the internal carotid artery.

1. Distal Common Carotid - This segment is defined as the distal 1.0 cm segment of the common carotid artery immediately proximal to the origin of the carotid bifurcation. The key anatomic feature required for valid and reliable identification of this segment is the origin or crest of the carotid bifurcation, i.e., the beginning of the dilatation associated with the bifurcation. This crest in normal arteries is usually elliptical or circular in cross section with its greatest diameter being visualized from the angle which demonstrates the V shape of the flow divider separating the internal and external carotid arteries. For the ARIC study, visualization and recording of the distal 1.0 cm of the common carotid artery from an anatomic reference angle is required. The key anatomical reference is the lip or crest at the origin of the bulb, at the angle that best demonstrates the V-shaped view of the flow divider that separates internal from external carotid arteries. (See Figure 7.)
2. Carotid Bifurcation - This segment is defined as the carotid bifurcation and has two anatomic references that allow its reliable identification. The inferior extent of the carotid bifurcation is the same reference feature that defines the superior extent of the distal common carotid artery, i.e., the crest at the origin of the carotid bifurcation. The superior extent of the carotid bifurcation is defined as the highest point in the arc of the flow divider that separates the origin of the internal carotid artery from the external carotid artery. For the purposes of the ARIC study, the anatomical reference required to define the most cranial extension of the carotid bifurcation must contain information on the location of the superior arc of the flow divider (either the V-shape or cursor placement that demonstrates its position). Usually, the angle that best demonstrates this structure will be lateral or posterior lateral and will be the same angle used to define the optimal angle view of the distal common carotid artery segment. (See Figure 8.)

The length of the carotid bifurcation, i.e., the linear distance between the arc of the flow divider and the crest at the origin of the bulb, can and does vary among subjects. It is important that sonographers focus their efforts on clear images which contain the bulb interfaces and both references.

3. Internal Carotid Artery - This segment is defined as the proximal 1.0 cm of the internal carotid artery. The key anatomic feature in identifying this segment is the highest point in the arc of the flow divider that separates the internal from the external carotid artery. (See Figure 9.)

The three segments of the carotid arteries are examined sequentially. The distal common carotid artery will be viewed and recorded from three angles. The carotid bifurcation and internal carotid artery are interrogated from a single angle, by definition the anatomic reference angle. This angle is defined as that which visualizes the flow divider, the origin of the bulb, and as many as possible of the four arterial interfaces as described in Section 6.5.1. The remaining two angles from which the distal common carotid artery will be viewed are defined as anterior and posterior angles. These two additional angles are preset. A small construction-type level is attached to the long, straight handle on the transducer at the field center. When the level is rotated to the P position and leveled, the interrogation of the artery occurs at the posterior angle, specifically -10° from the horizontal. Similarly, when rotated to the A position and leveled, the interrogation of the artery occurs at the anterior angle $+55^\circ$ from the horizontal. (See Fig. 6). When, as instructed later in this protocol, the artery is visualized from the anterior angle of the distal common carotid artery, the transducer handle is rotated anteriorly until the air bubble within the level in the A position is between the two indicator lines as shown in the drawing. When the protocol instructs visualizing the posterior angle, the transducer is rotated posteriorly until the air bubble with the level in the P position is between the two indicator lines. (See Figs. 7-10.)

8.4 Initial Scan

The purpose of the initial carotid artery scanning procedure is to identify the distal common carotid artery segment, the carotid bifurcation, and the internal and external carotid arteries and both anatomical references. The initial scan is for sonographer orientation and is not recorded.

8.4.1 Criteria for Optimal Image of Carotid Arteries

The criteria for identification of the images necessary for morphometry include identification of the anatomical references described in Section 8.3 and the tissue interfaces associated with the arterial wall and lumen (See paragraph 6.5.1 and Figs. 7-10).

1. NEARWALL INTERFACES
 - (a) adventitial - medial
 - (b) intimal - lumen
2. FARWALL INTERFACES
 - (a) lumen - intimal
 - (b) medial - adventitial

8.4.2 Instrument Settings

8.4.2.1 Ultrasound Instrument - Image

The initial instrument control settings are as follows:

- (a) Video Gain.....5.0
- (b) TGC.....5.0
- (c) Doppler Gain.....5.0
- (d) Probe Range Switch.....MID
- (e) Tape/live Switch.....LIVE
- (f) Probe Select Switch.....Midway between A & B
- (g) Mirror Switch.....ON

8.4.2.2 Ultrasound Instrument - Cursor Placement

For the carotid B-mode scans, the cursor is set in a standard and stationary position in the middle portion of the TV monitor, aligned with either the upper horizontal line drawn on the monitor, or the lower horizontal line drawn on the TV monitor, depending on whether the right or left carotid artery is being scanned (refer to Section 4.1.1). For the right common carotid artery, place the cursor on the upper line and orient the B-mode image so that the origin of the crest of the bulb is in conjunction with the cursor. The cursor is also placed on the upper line when scanning the carotid bifurcation with the superior arc of the flow divider being on or at the level of the cursor. When the right internal carotid is being imaged, the cursor is placed on the lower line with the reference point, i.e., the superior arc of the flow divider being on or at the level of the cursor.

The B-mode images on the left side are inverted; therefore, the cursor placement for the left carotid is opposite those used in examining the right carotid artery. For the common carotid and the carotid bifurcation, the cursor is placed on the lower horizontal line with the origin of the bulb being the anatomic reference point for the common carotid artery and the superior arc of the flow divider being the anatomic reference for the bulb. The internal carotid artery is imaged with the cursor placed on the upper line and the superior arc of the flow divider on or at the level of the cursor.

8.4.3 Initial Scan Procedure

A liberal amount of Aquasonic-100, Ultrasound Transmission Gel or the equivalent is applied to the right side of the neck and to the surface of the ultrasound probe. The video cassette recorders are not used during this preliminary scan. The B-mode examination begins in the lower part of the neck between the clavicle and mandible with the transducer surface oriented parallel to the common carotid artery. Using fine movements of the probe, the common carotid artery is brought into view and the probe is moved superiorly to demonstrate the carotid bifurcation and proximal internal carotid artery.

During the initial scanning procedure it is necessary to distinguish clearly between internal and external carotid arteries. Although

tributaries originating from the external carotid artery may occasionally be viewed with B-mode ultrasound to help in this differentiation, Doppler ultrasound in most cases is more efficient and specific for this separation. The method and criteria for this identification are as follows:

Obtain a B-mode image 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, place the Doppler sample volume into the branch farthest from skin surface. Using the instrument cursor and the knob on the joystick, make the sample volume small enough to be totally within the lumen. Depress and release the Doppler Footswitch. Observe the tracing on the TV monitor and listen 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.

Note the graphic display near the zero baseline. Flow directed towards the head and away from the heart throughout the cycle is represented as a tracing above the baseline in Fig. 11. If the Doppler signal does not correspond to the expected pattern, place the cursor 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 Fig. 12.

Abnormal flow is demonstrated by turbulence within the lumen and disruption of normal flow. This is identified in the Doppler signal by broadening of 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 Fig. 13.

At the end of this initial scan, check the Study Flow Panel for lights of NORMAL, COMMON CAROTID, SIDE, B-MODE LONGITUDINAL, and OPTIMUM ANGLE. If necessary, toggle the manual UP or DOWN switch until these lights are illuminated.

8.5 Data Recording Scan

8.5.1 Distal Common Carotid Artery (Right Side)

The anatomical reference (optimal) angle was identified during the initial scan. A longitudinal view of the distal common carotid artery is visualized again using B-mode ultrasound. Field focus is then set in the appropriate range, i.e., near, mid, or far, depending on the depth of the artery from skin surface. Instrument gain settings are adjusted to the lowest settings that show as many of near and far wall interfaces as possible, as described in Section 8.4.1. The origin of the carotid bifurcation, distinguished by the beginning of the dilation, is identified and placed at the level of the cursor on the TV monitor. With the anatomical references of the distal common carotid artery present on the TV monitor, the PLAY and RECORD buttons are simultaneously pressed on the Panasonic VCR and on the SONY VCR. Fine probe movements are used to focus the image if necessary. Allow at least 20 seconds of pre-record time. The Audio Record Footswitch is depressed for at least five continuous cardiac cycles, and then released. When the footswitch is released the Study Flow Panel lights will display NORMAL, DISTAL COMMON, RIGHT, B-MODE LONGITUDINAL, and ANTERIOR. The transducer level is rotated to the A position. The transducer is rotated anteriorly until the bubble in Level A is between the indicator lines on the level. Field focus is then set in the most appropriate range position. With as many of the near and far wall interfaces in view at the lowest gain settings possible, using fine probe movements if necessary to optimize the images, the Audio Record Footswitch is depressed for at least five continuous cardiac cycles and is then released. When this is done, the Study Flow Panel automatically advances the angle light to POSTERIOR. The transducer level is rotated to the P position. The transducer is rotated to the posterior view until the bubble in Level position P is between the indicator lines. Field focus is then set in the most appropriate range position. When this angle has been established, as many of the arterial interfaces are in view as possible, and instrument gain settings adjusted, depress the Audio Record Footswitch for at least five cardiac cycles. The footswitch is then released, and the Study Flow Panel advances to DOPPLER, OPTIMUM ANGLE. The manual UP switch is toggled to advance the Study Flow Panel to the next step, which is the CAROTID BIFURCATION, i.e., Doppler is not used at this time.

Keeping the artery in focus on the TV monitor, the sonographer rotates the transducer back to the optimum angle and moves the probe moved superiorly until the carotid bifurcation with its anatomical references is visualized.

8.5.2 Carotid Bifurcation (Right Side)

The angle of interrogation that best demonstrates the carotid bifurcation will be close to that view of the anatomical reference (optimal) angle used to examine the distal common carotid artery. Place the image so that the superior arc of the flow divider is on or at the level of the cursor aligned with the upper line on the TV monitor. Adjust the field focus depending on the distance from skin surface to the artery wall.

With this image of the carotid bifurcation on the TV monitor, depresses the Audio Record Footswitch for at least five continuous cardiac cycles and then release. The Study Flow Panel will automatically advance to INTERNAL CAROTID.

8.5.3 Internal Carotid Artery (Right Side)

The origin of the internal carotid artery is defined by a single anatomical reference, i.e., the superior part of the flow divider arch. The proximal 1.0 cm of the internal carotid artery can usually be best viewed only from a single angle. The method used to establish this view is to move the transducer superiorly after examining the carotid bifurcation. The transducer is then rocked back and forth to differentiate internal from external carotid artery. Field focus is then adjusted as described previously. When this image of the internal carotid artery is attained, with the flow divider on or at the level of the cursor and after optimizing the view with fine probe movements the Audio Record Footswitch is depressed for at least five continuous cardiac cycles. The footswitch is then released and the Study Flow Panel indicates DOPPLER. Toggle the UP switch to advance to the left side.

This completes the ultrasound examination of the RIGHT SIDE of the carotid arteries. Press the PAUSE or STOP buttons on both the video cassette recorders.

8.5.4 Right Carotid Artery Quality Control

After the carotid artery study has been terminated and the VCRs have been switched to the STOP mode, the quality control envelope labeled "right carotid artery" is opened. If the instructions are "no quality control studies are to be performed," then continue to the next procedure in the left common carotid artery.

If the instructions are to perform a quality control study, then place the NORMAL/QUALITY CONTROL switch on the Study Flow Panel to the QUALITY CONTROL position. Toggle the UP or DOWN switch on the Study Flow Panel until the prescribed quality control study appears correctly on the light displays.

If the quality control instructions request an intrasonographer QC study, the same sonographer repeats the QC carotid artery study specified. If the quality control instructions request an inter-sonographer QC study, the second sonographer enters the ultrasound area and performs the QC carotid artery study specified. If the same sonographer is requested to perform the QC study (i.e., intrasonographer QC) no changes are required for ID information on the monitor. If, however, the QC study requires another sonographer to repeat the same scan, that individual should key in his/her identification code on the Biosound instrument, replacing that of the other individual.

The sonographer obtains a satisfactory image or other prescribed information, such as described in Section 8. When the ultrasound data are satisfactory, simultaneously depress the PAUSE or RECORD and PLAY buttons on the SONY VCR.

Wait for about 20 seconds before depressing the Audio Record Footswitch for five cardiac cycles. The Study Flow Panel identifies this segment of video tape as a quality control segment. Release the footswitch. Momentarily depress the STUDY UP COMPLETE switch on the Study Flow Panel to return the STUDY FLOW to the left common carotid artery. If the quality control study was an intersonographer study, the first sonographer should re-enter his/her three-digit ID code on the Biosound screen.

8.5.5 Carotid Artery Examination (Left Side)

At the completion of the studies on the right side of the neck, a similar series of evaluations is performed on the left side. Examination of the left side is identical to the right side with two exceptions: (1) the Biosound probe is rotated 180° when examining the left, and (2) arterial distensibility studies are done only on the left. Probe rotation is necessary because of the probe design. If the probe is not rotated 180° for the left side examination it abuts against the mandible and may preclude visualization of the carotid bifurcation or the internal carotid artery. When the probe is rotated, the arterial image is inverted on the TV monitor, i.e., the carotid bifurcation and internal carotid artery appear at the bottom of the screen (see paragraph 8.4.2.2).

The inverted image requires that the placement of the cursor be on the lower line of the screen for the common carotid and carotid bifurcation scan.

At the completion of the ultrasound examination of the left carotid arteries, the PAUSE or STOP buttons are pressed on both video cassette recorders. Preparations and adjustments are made for the arterial distensibility studies.

8.5.6 Sonographer Response to Presence of a Significant Plaque

The methods, criteria, and techniques described in this protocol are to be followed regardless of the presence or absence of lesions. If a sonographer believes that a significant vascular abnormality is present, based on criteria developed by the field center ultrasound director, this information should be relayed to the field center coordinator or his/her designee immediately after the participant examination is finished in the ultrasound laboratory. Under no circumstances should this impression be conveyed directly or indirectly by the sonographer to the participant.

8.6 Carotid Artery Distensibility Study

The Study Flow Panel lights should display NORMAL, COMMON CAROTID, LEFT, DISTENSIBILITY, OPTIMUM ANGLE. The participant remains in the supine position with the blood pressure cuff attached to the right brachial artery. The head is once again tilted 45° toward the right to provide easy access to the left common carotid. The triangular shaped wedge should be positioned exactly as described previously in this protocol.

The transducer holder is moved into position adjacent to the table near the location of the left carotid artery which is to be examined. The transducer is mounted in the holder with the handle nearly horizontal. The transducer focus switch is placed in the MID focus setting and the transducer activated.

A liberal amount of ultrasonic gel is applied to the skin covering the common carotid artery. A longitudinal image of the carotid at the anatomical reference angle, as defined previously, is now obtained so that both the tip of the flow divider and the origin of the crest of the carotid bifurcation can be viewed. The transducer is moved along the common carotid toward the sternum until the origin of the crest is located at the extreme lower center of the image, just prior to disappearing from view. Care is taken to obtain as many as possible of the four interfaces discussed earlier by small angulations of the transducer. Final adjustments are made using the transducer holder fine position controls.

Instruct the participant to remain as still as possible during the next several minutes. Tell him that this portion of the study will be completed after the next blood pressure reading is taken.

Check to see that the cursor switch is in the DOPPLER position and that the cursor is located in the exact vertical center of the image. Place the origin of the cursor at the far left of the screen and increase the length of the cursor to 15 mm. The rf signals to be analyzed lie along this line of the image. By making small transducer position adjustments, be sure that strong arterial wall echoes are present along this image line.

Place the mirror switch in the STOP position. Leave the participant and turn to the arterial wall tracker located on the desk to your right.

Observe the rf signals from the single image line on the oscilloscope screen. Identify the location of the lumen by its absence of echoes and center the lumen on the oscilloscope screen by adjusting the "delay time position" control. The echoes arising from the anterior wall should be visible in the left half of the screen and those arising from the posterior wall on the right half of the screen. Make the following adjustments while observing the rf echoes on the oscilloscope screen. Refer to the diagram in Fig. 14.

Place the long rectangular window (A) so that it is approximately centered above the anterior wall echo complex by adjusting the Range (A) control on the arterial wall tracker. Place the second long rectangular window (P) so that it is approximately centered above the posterior wall echo complex by adjusting the Range (P) control.

You should now observe both short and long "spikes" riding on the two windows, those on the (A) window pointing up and those on the (P) window pointing down. If the long spikes are moving (right to left to right, etc.) periodically with each heart beat, the tracker is functioning correctly. If the echoes are not of sufficient amplitude,

adjust the gain control on the arterial wall tracker until the long spikes are "tracking."

Using the Position (A) control, place the short spike directly above the portion of the anterior wall echo closest to the lumen. Depress the Track (A) button and observe the long spike jump to the position previously occupied by the short spike. Observe that the long spike is once again "tracking." Repeat this procedure, as necessary, until the anterior wall position is being properly "tracked."

Using the Position (P) control, place the short spike directly above the portion of the posterior wall echo closest to the lumen. Depress the Track (P) button and observe the long spike jump to the position previously occupied by the short spike. Observe that the long spike is once again "tracking." Repeat this procedure, as necessary, until the posterior wall position is being properly "tracked."

As both walls are being properly tracked, obtain a characteristic arterial wall trace (see Fig. 15) by running the strip chart on the arterial wall tracker at a speed of 50 mm/sec. While obtaining this trace, depress the "C" key on the IBM-PC so that a minimum of five cardiac cycles of data can be collected for analysis. Stop the strip chart.

If patient motion during the course of data collection results in inconsistent tracking, repeat the adjustments of the Position and Track controls to re-acquire consistent stripchart tracings.

If satisfactory distensibility data have been obtained, place the mirror switch in the ON position and simultaneously press the RECORD and PLAY buttons on the SONY VCR. Press the Audio Record Footswitch for about five seconds and release. Press the STOP button on the SONY VCR. The arterial distensibility data are acquired and stored on diskette at the PC during this time.

If quality data cannot be acquired within a five-minute period after completion of the preceding exam of the carotid arteries, terminate the distensibility study. Do not press the Audio Record Footswitch. Complete the ultrasound scan by following the terminate procedure described on page 11 of this manual.

Finally, obtain a blood pressure reading from the Dinamap immediately following the collection of arterial wall tracking data. This is done in the manual mode by depressing the "B" key on the IBM-PC.

Now remove the ultrasound transducer from the participant's neck, remove the gel, and return the ultrasound transducer holder mount to its storage location. Place the mirror switch in its normal position.

9. CAROTID ARTERY QUALITY CONTROL

After the carotid artery study has been terminated and the VCRs have been switched to the STOP mode, the quality control envelope labeled "left carotid artery" is opened. If the instructions are "no quality control studies are to be performed," then continue to the next procedure, i.e., momentarily depress the STUDY COMPLETE switch on the Study Flow Panel. Simultaneously press the PAUSE or RECORD and PLAY buttons on the SONY VCR. Wait for at least 20 seconds and then depress the sonographer Audio Record Footswitch for about five seconds. Wait for 5-10 seconds, then depress the STOP button on the SONY VCR.

If the instructions are to perform a quality control study, then place the NORMAL/QUALITY CONTROL switch on the Study Flow Panel to the QUALITY CONTROL position. Then toggle the UP or DOWN switch on the Study Flow Panel until the prescribed quality control study appears correctly on the light displays.

If the quality control instructions request an intrasonographer QC study, the same sonographer repeats the QC carotid artery study specified. If the quality control instructions request an inter-sonographer QC study, the second sonographer enters the ultrasound area and performs the QC carotid artery study specified. If the same sonographer is requested to perform the QC study (i.e., intrasonographer QC) no changes are required for ID information on the monitor. If however, the QC study requires another sonographer to repeat the same scan, that individual should key in his/her identification code on the Biosound instrument, replacing that of the other individual.

The sonographer obtains a satisfactory image or other prescribed information, such as described in Section 8. When the ultrasound data are satisfactory, simultaneously depress the PAUSE or RECORD and PLAY buttons on the SONY VCR.

Wait 20 seconds before depressing the Audio Record Footswitch for five cardiac cycles. The Study Flow Panel identifies this segment of video tape as a quality control segment. Release the footswitch. Momentarily depress the STUDY UP COMPLETE switch on the Study Flow Panel. Press the Audio Record Footswitch for about five seconds. Wait 5-10 seconds, then press the PAUSE or STOP button on the SONY VCR. Return the NORMAL/QUALITY CONTROL switch on the Study Flow Panel to the NORMAL position.

10. POSTURAL CHANGE EXAMINATION

Refer to separate the postural change examination section of Manual 11.

11. LOCAL FIELD CENTER REVIEW OF VIDEO CASSETTES

The 3/4" video cassettes from the preceding week are assembled on Friday afternoon at each field center, and selected study results are reviewed by the field center ultrasound director or his/her appointee. After local review, the 3/4" video cassettes are mailed to the Ultrasound Reading Center no later than the following Tuesday afternoon. Mailings to the Reading Center should not arrive on Easter Monday.

12. LABELING AND MAILING TO THE ULTRASOUND READING CENTER

12.1 Labeling of Video Cassettes

Each video cassette shall be labeled with the video cassette number and no more than four participant identification numbers as shown in Fig. 16. 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 container is also labeled with the video cassette number. The position of the label is shown in Fig. 17.

Video cassette labels shall identify the field center and be 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 Fig. 19.

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 Fig. 18.

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:

1. Video cassettes for the participant ultrasound studies completed the previous week.
2. Diskettes for the participant ultrasound studies

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completed the previous week. Each diskette is placed in the video cassette case with the same identification number.

3. A copy of the week's log sheet for each field center (Fig. 19).
4. A diskette with the Preinfo.dat and Postinfo.dat information.
5. A copy of the ARIC Batch Shipping Log Sheet for the week.

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. Each year mailing schedules for the holidays will be distributed by the Ultrasound Reading Center.

12.5 Package Labeling

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

1. Field center personnel sending the package.
2. Field center return address.
3. The batch shipping number from the ARIC Batch Shipping Log Sheet.
4. Address label to the Ultrasound Reading Center:

ARIC Ultrasound Reading Center
4310-78 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 Thursday following the Tuesday mailing.

12.6 Verification of Mailing Contents

After the Ultrasound Reading Center librarian 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 will be sent to each field center. Any missing items as well as any necessary action will be described.

12.7 Field Center Video Cassettes

The 1/2" video cassettes remain at the field centers for backup purposes. They may be used for review should 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 the field center consists of the following two statements:

1. The minimum lumen diameter was _____mm in the left carotid. Ninety-five percent of participants have lumen diameters greater than _____mm at this site.
2. The minimum lumen diameter was _____mm in the right _____carotid. Ninety-five percent of participants have lumen diameters greater than _____mm at this site.

The ninety-five percent levels are determined from measurements made at these sites by the Ultrasound Reading Center.

13.2 Alert Report

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

On the day of the reading, after 4 p.m. Eastern time, the chief reader or his/her designee will notify the appropriate field center by electronic mail. The report will consist of:

1. Participant identification number
2. Participant last name, first and middle initial
3. Date of birth
4. Race and gender
5. Examination date
6. Site(s) of minimum lumen diameter (less than or equal to 2 mm)

Field centers should respond by electronic mail to the Ultrasound Reading Center when an alert value notification has been sent to them. As soon as possible, but no later than the following workday, identical information will be sent from the Ultrasound Reading Center to the field center by regular mail.

14. PARTICIPANT SAFETY PRECAUTIONS

See Manual 2.

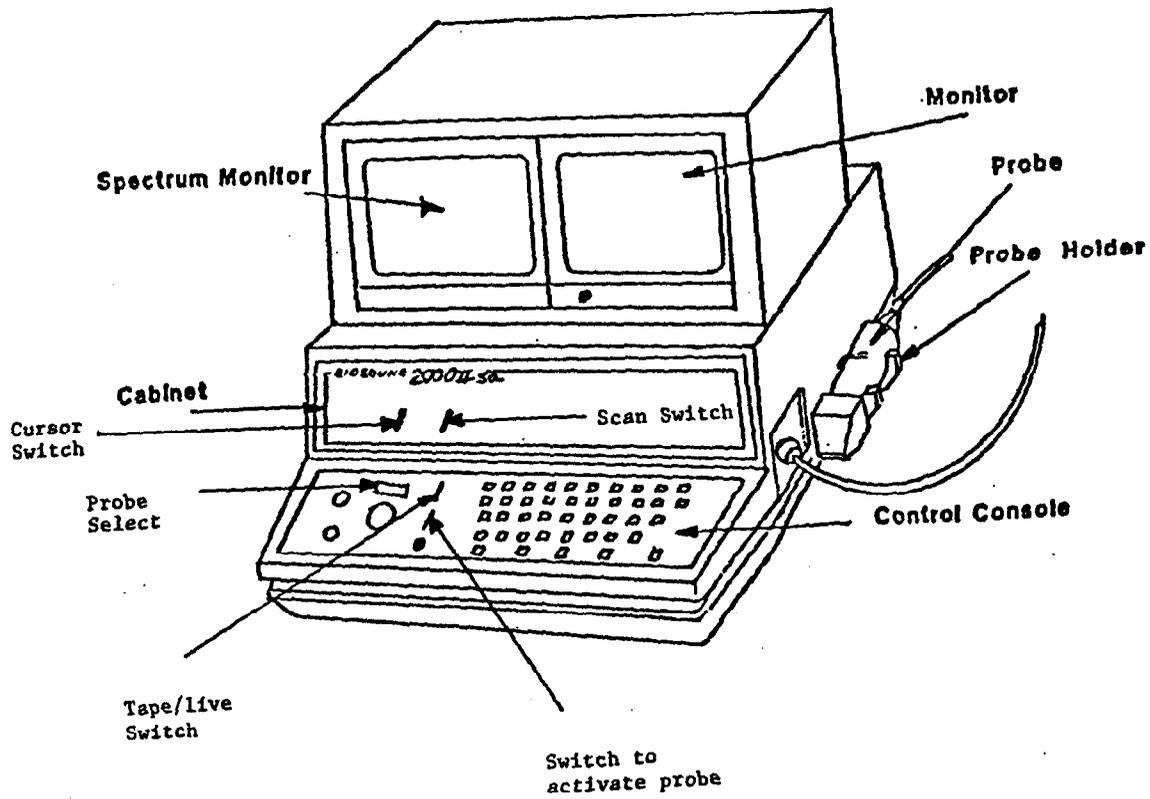


Figure 1. Biosound 2000 II sa (Simplified)

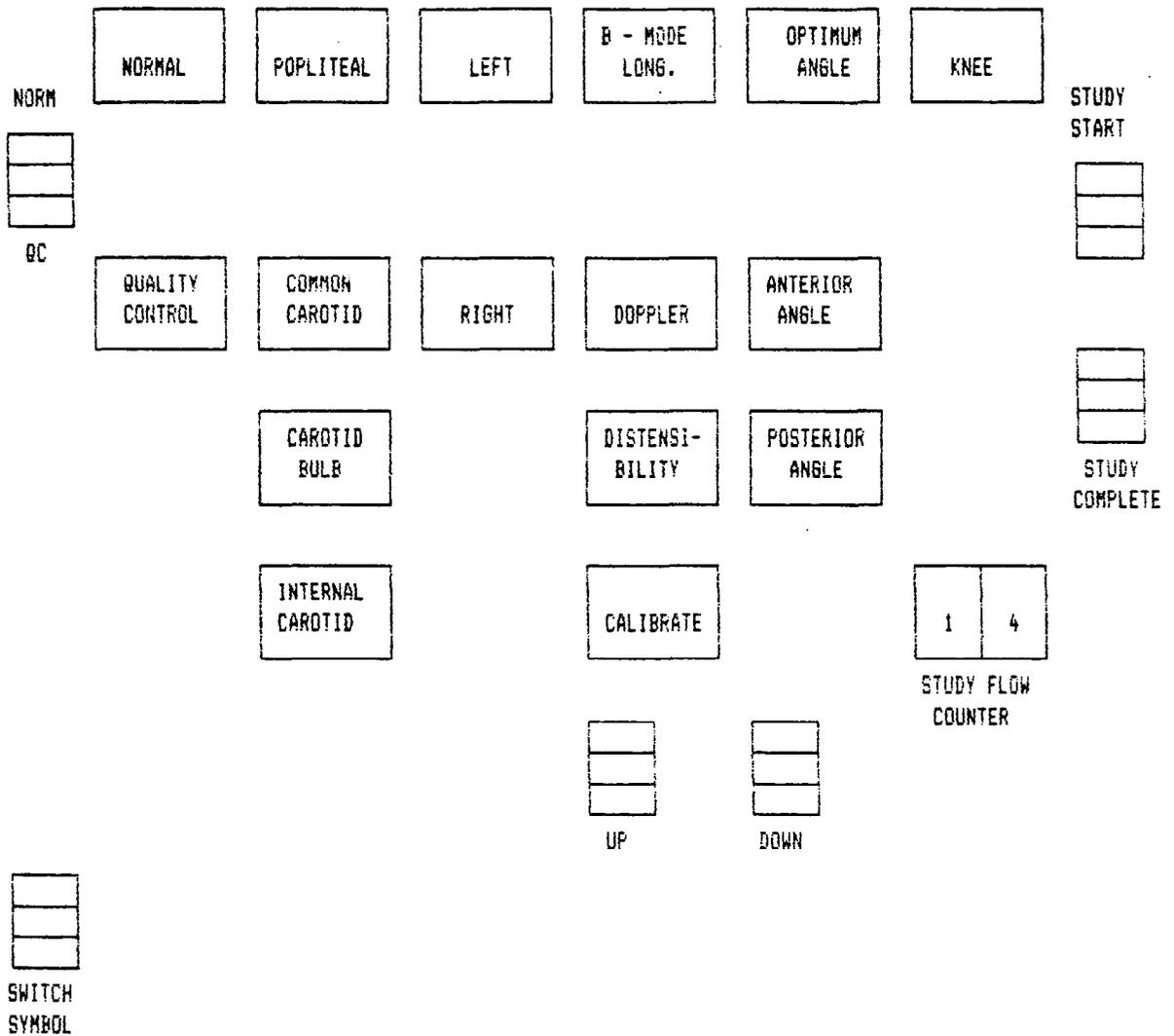
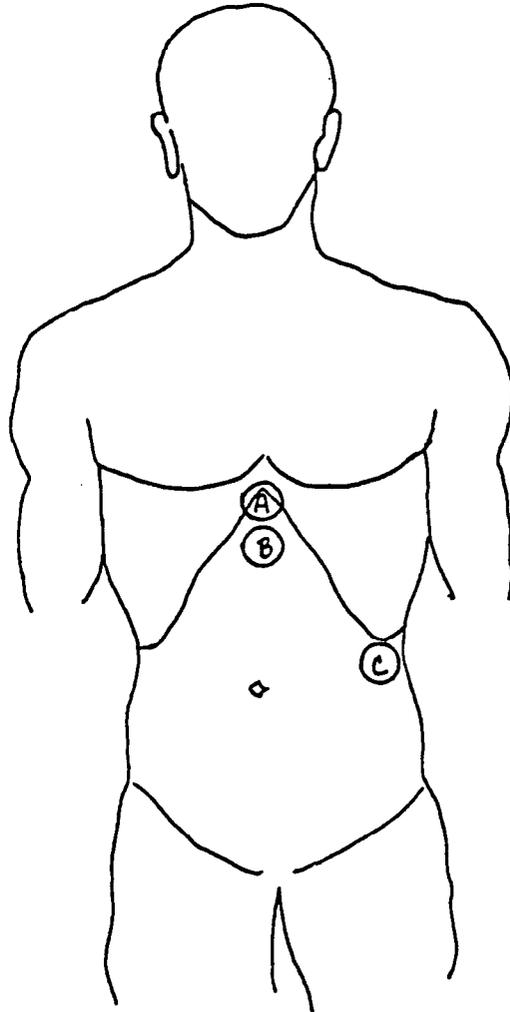


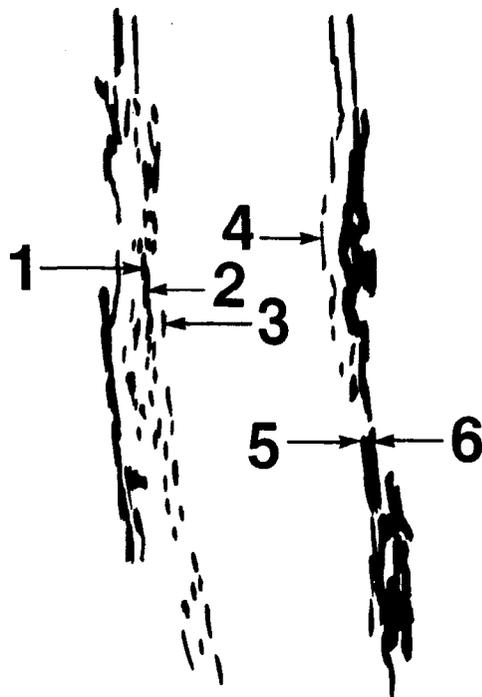
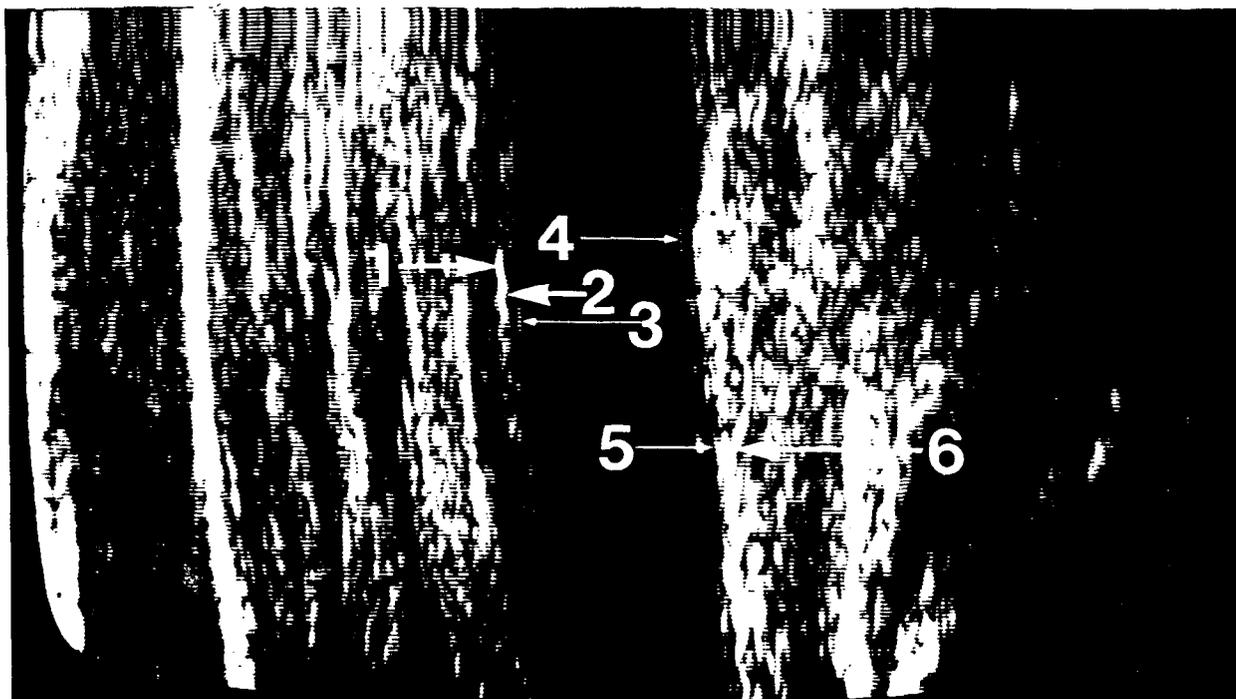
Figure 2. Study Flow Panel



- A - superior xyphoid electro pad (RA)
- B - inferior xyphoid electrode pad (RL)
- C - left lateral abdominal area (LA)

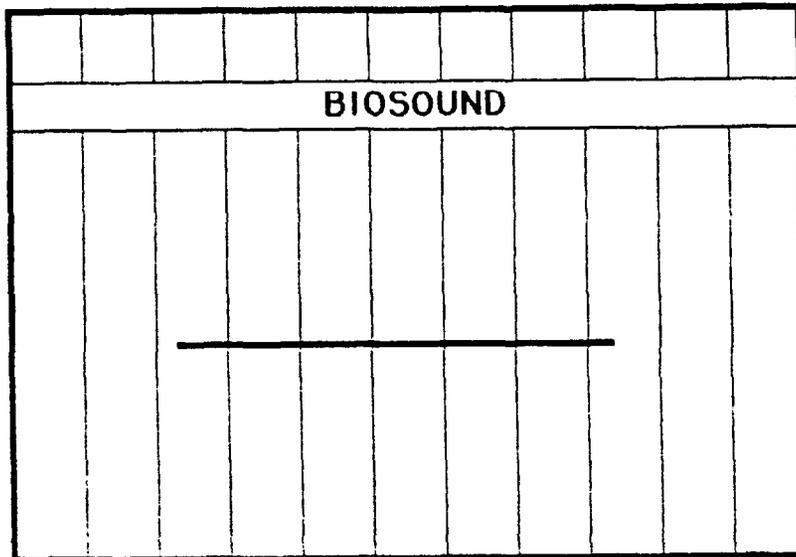
Figure 3. Placement of ECG Pads

Left Popliteal Artery



1. Periadventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 4. Left Popliteal Artery



In reference to section 6.6.1 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 5. Calibration Grid

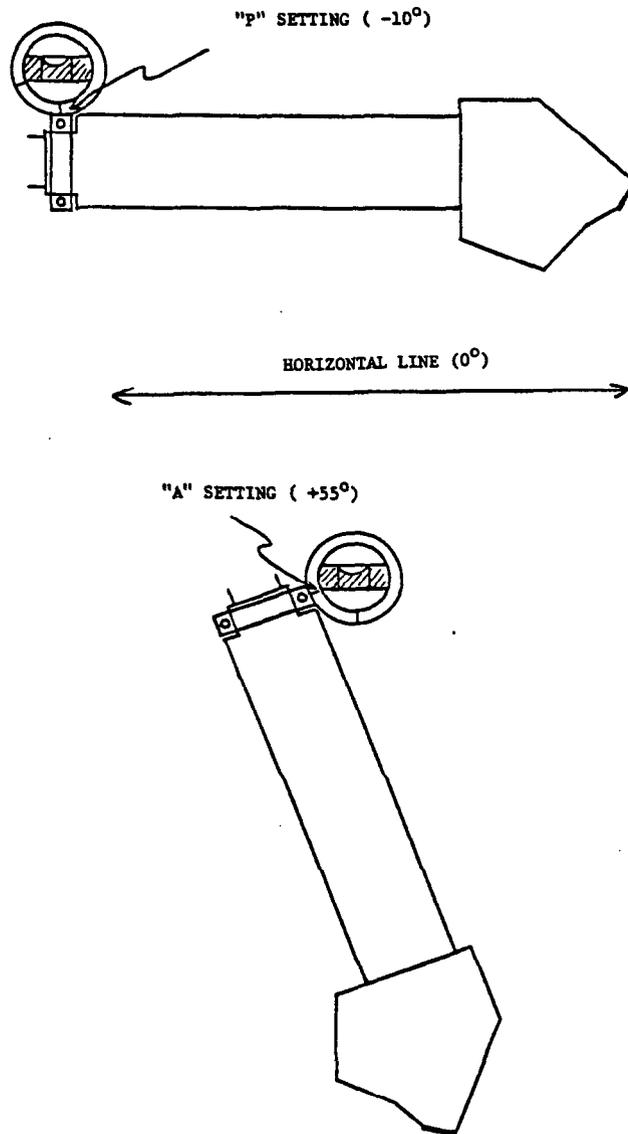
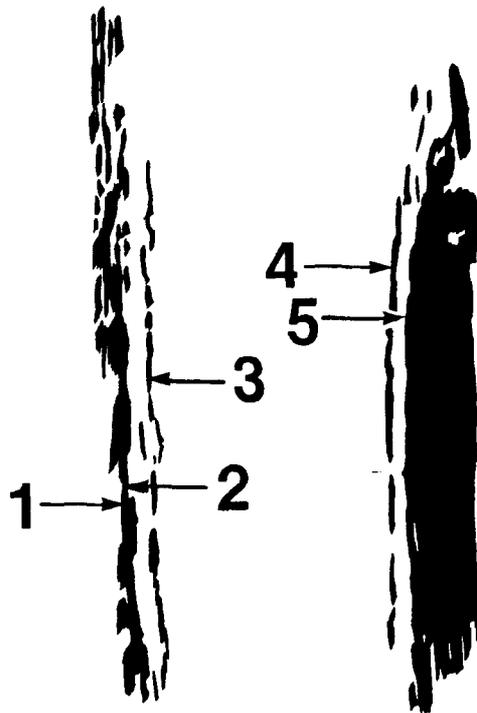
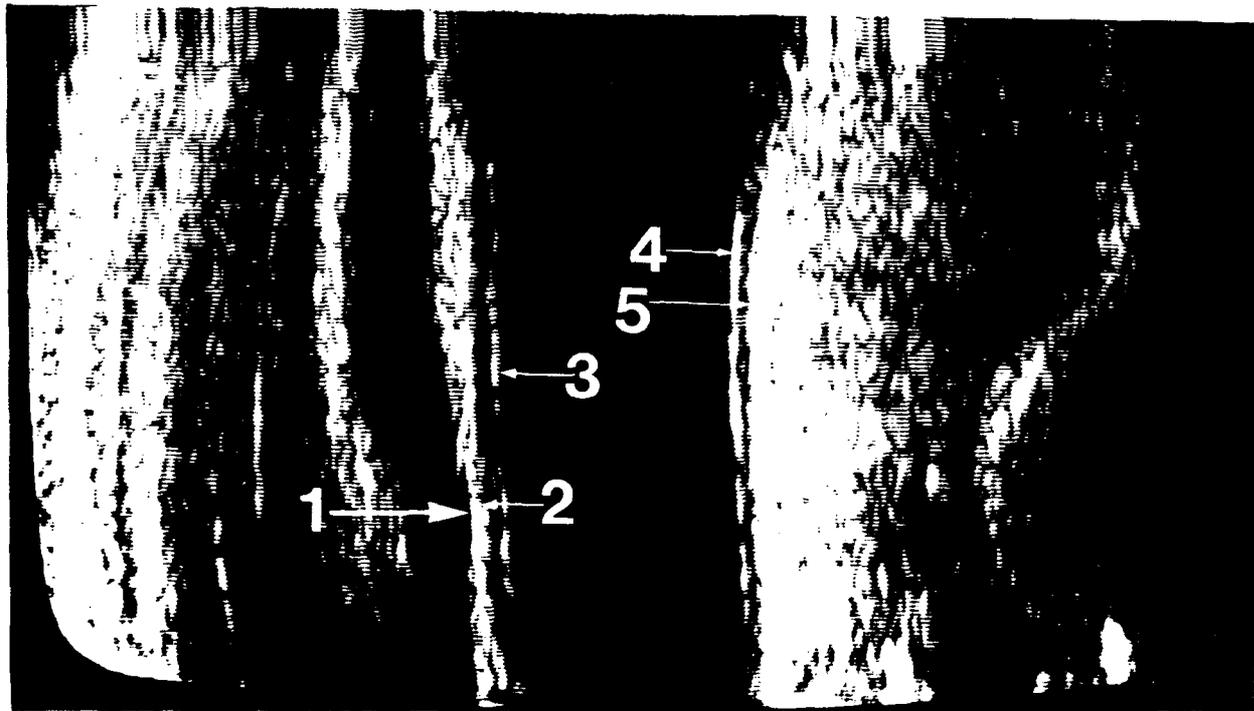


Figure 6. Level Drawings for Anterior/Posterior Angles

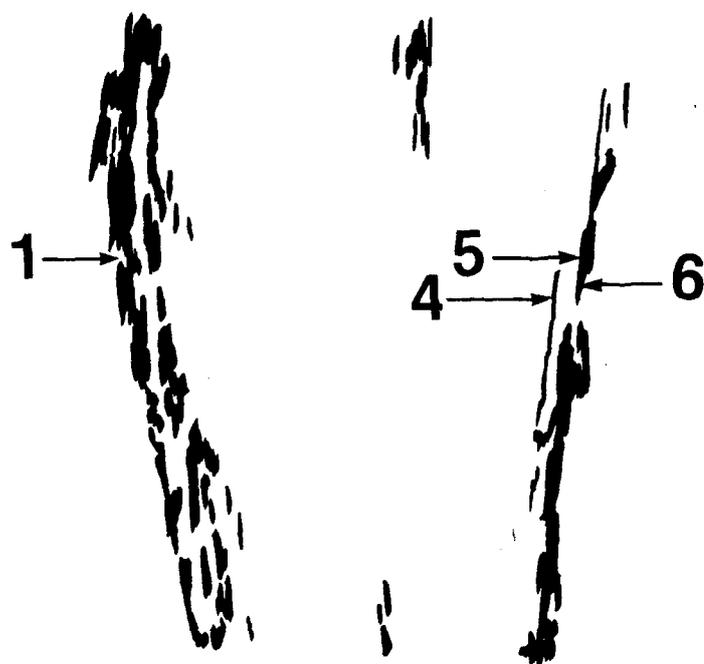
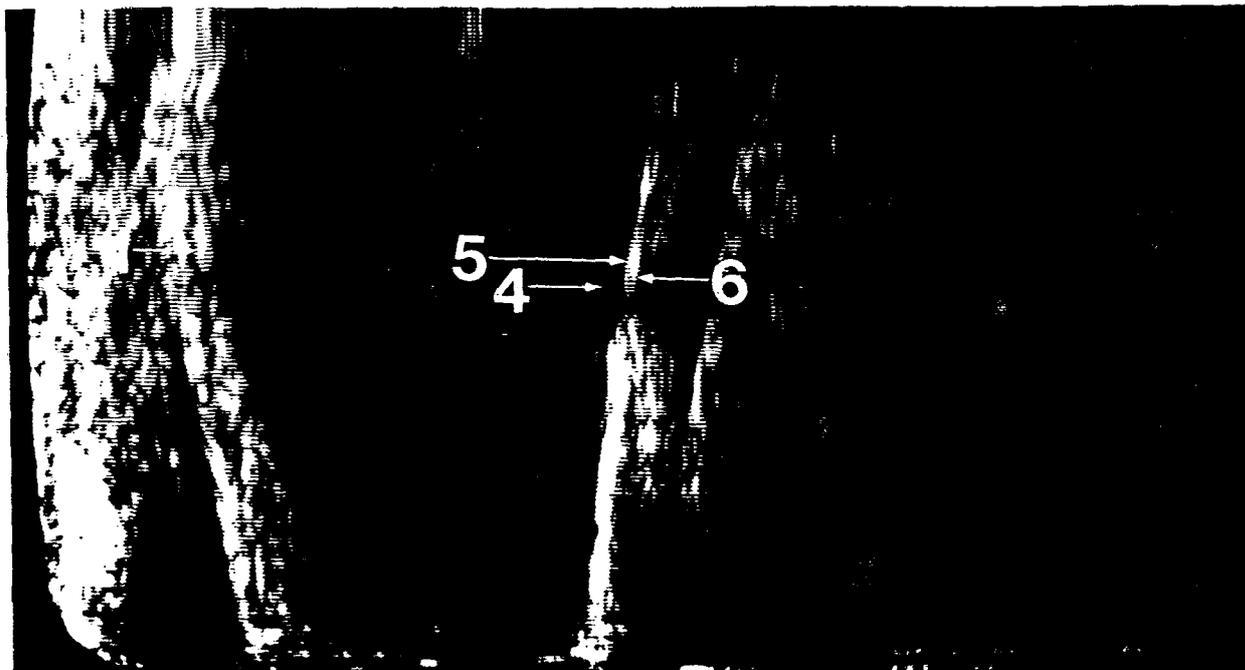
Right Common Carotid Artery



1. Periadventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 7. Right Common Carotid Artery

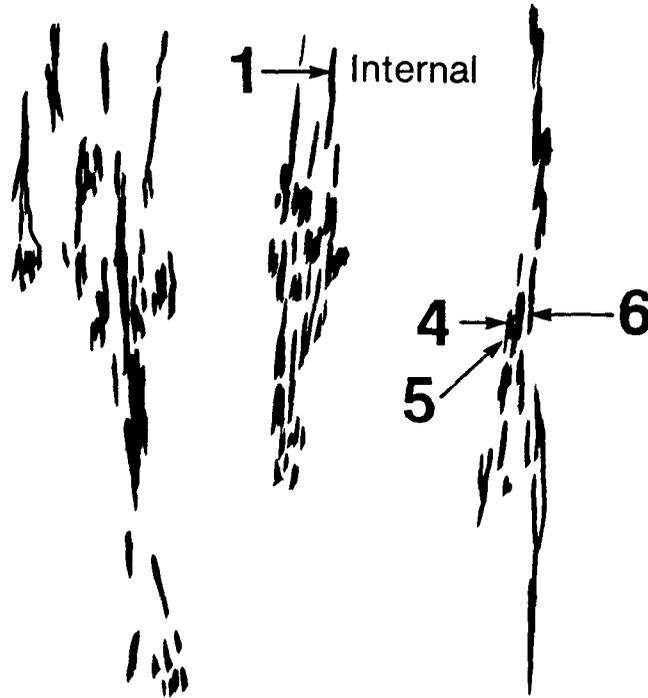
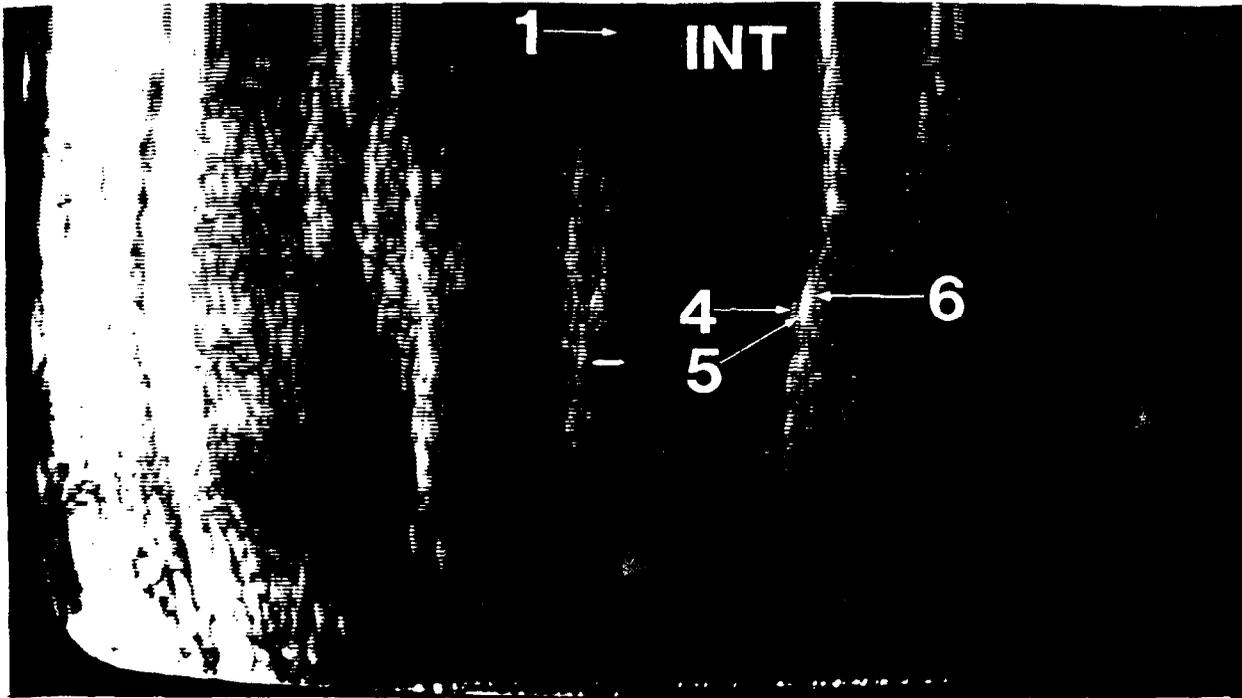
Right Carotid Bifurcation



1. Periadventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 8. Right Carotid Bifurcation

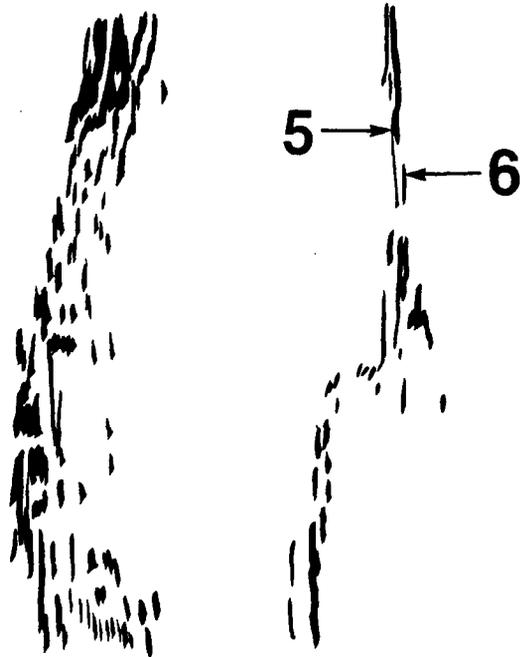
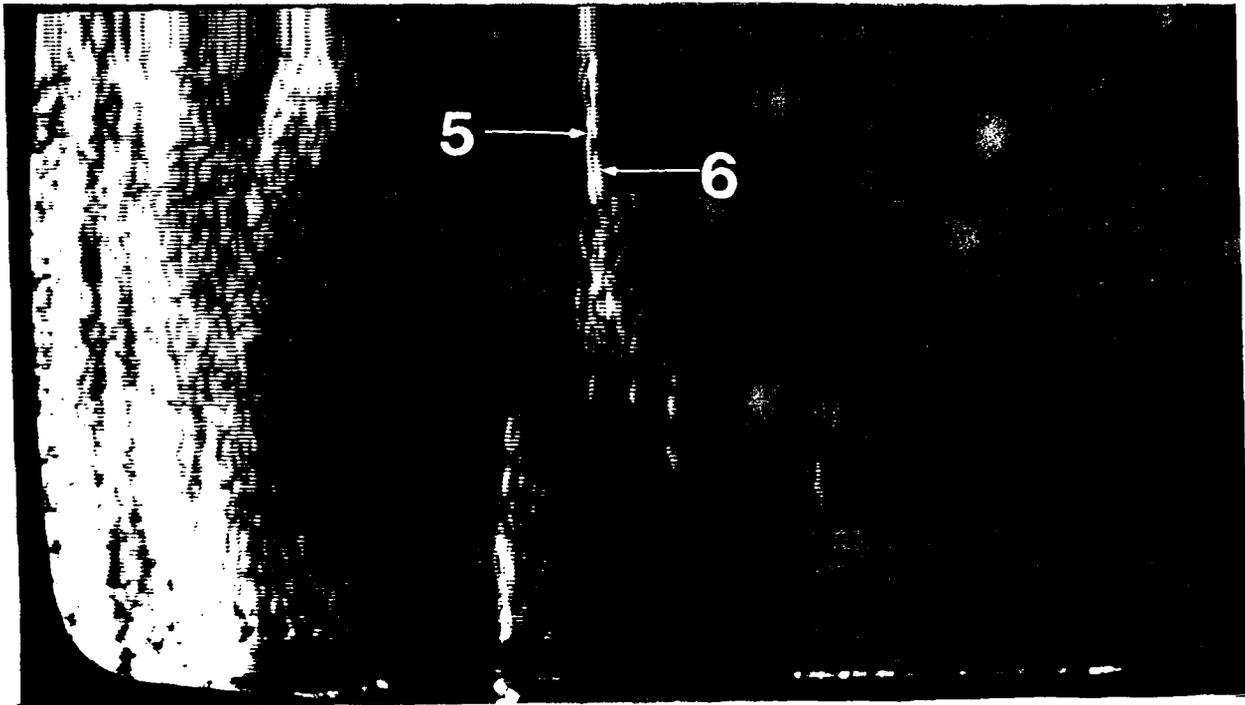
Right Internal Carotid Artery



1. Periadventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 9. Right Internal Carotid Artery

Left Internal Carotid Artery



1. Periadventitial - adventitial near wall interface
2. Adventitial - medial near wall interface
3. Intimal - lumen near wall interface
4. Lumen - intimal far wall interface
5. Medial - adventitial far wall interface
6. Adventitial - periadventitial far wall interface

Figure 10. Left Internal Carotid Artery

Internal Carotid Artery

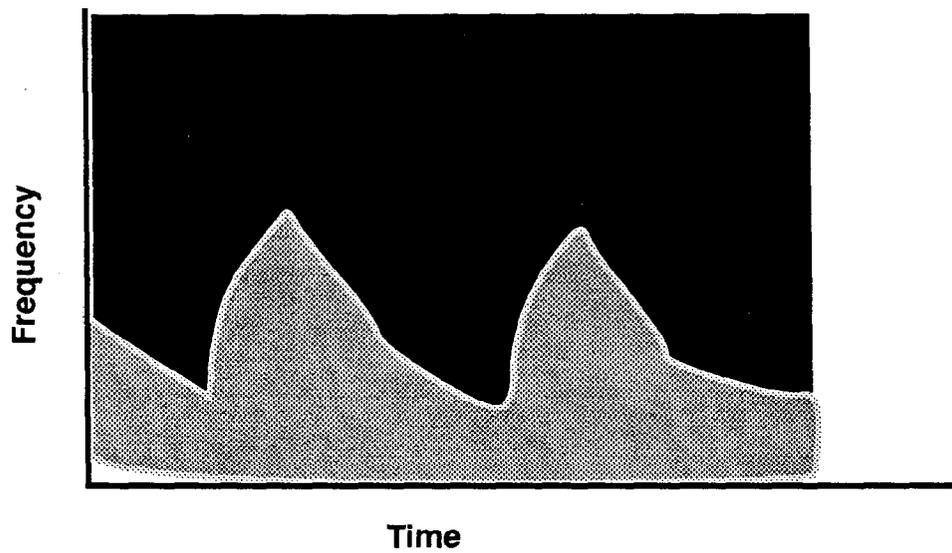


Figure 11. Doppler Tracing: Internal Carotid Artery

External Carotid Artery

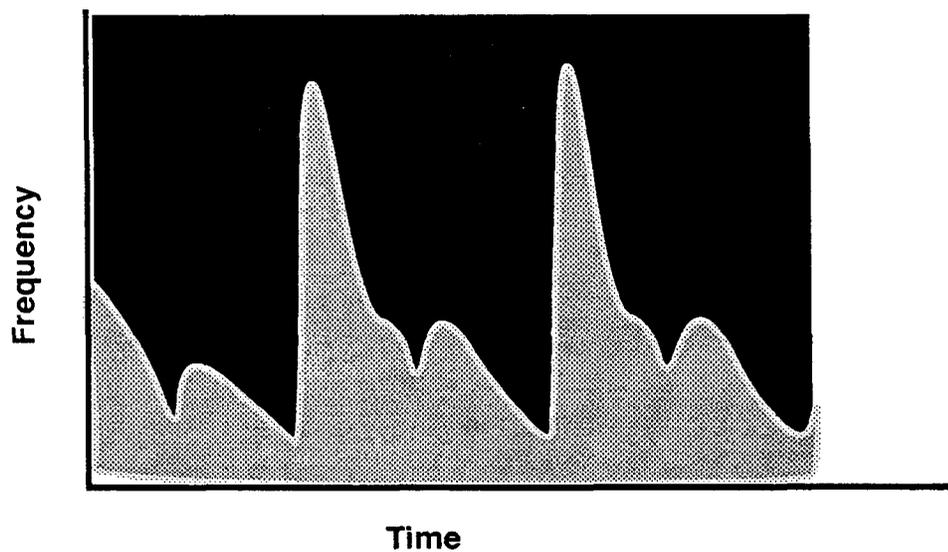


Figure 12. Doppler Tracing: External Carotid Artery

Proximal Common Carotid Artery

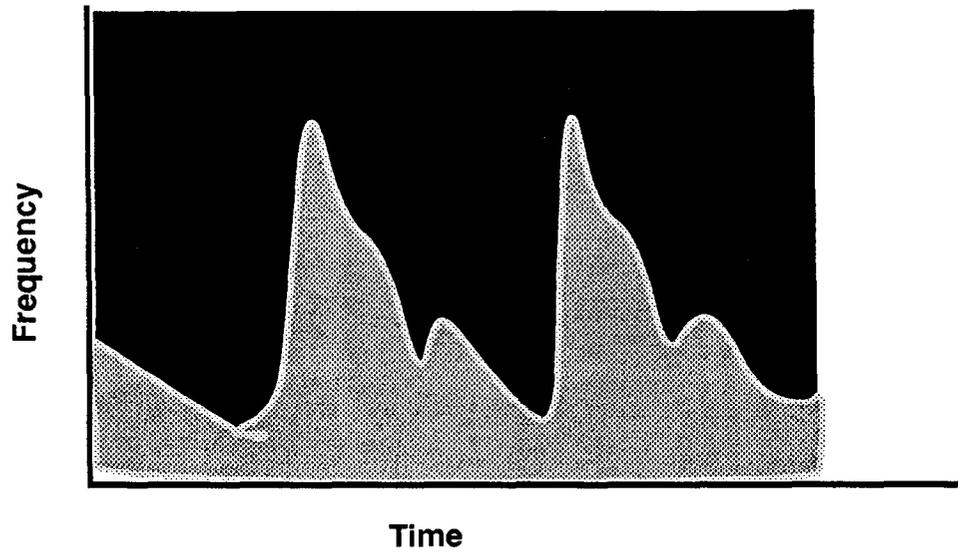


Figure 13. Doppler Tracing: Proximal Common Carotid Artery

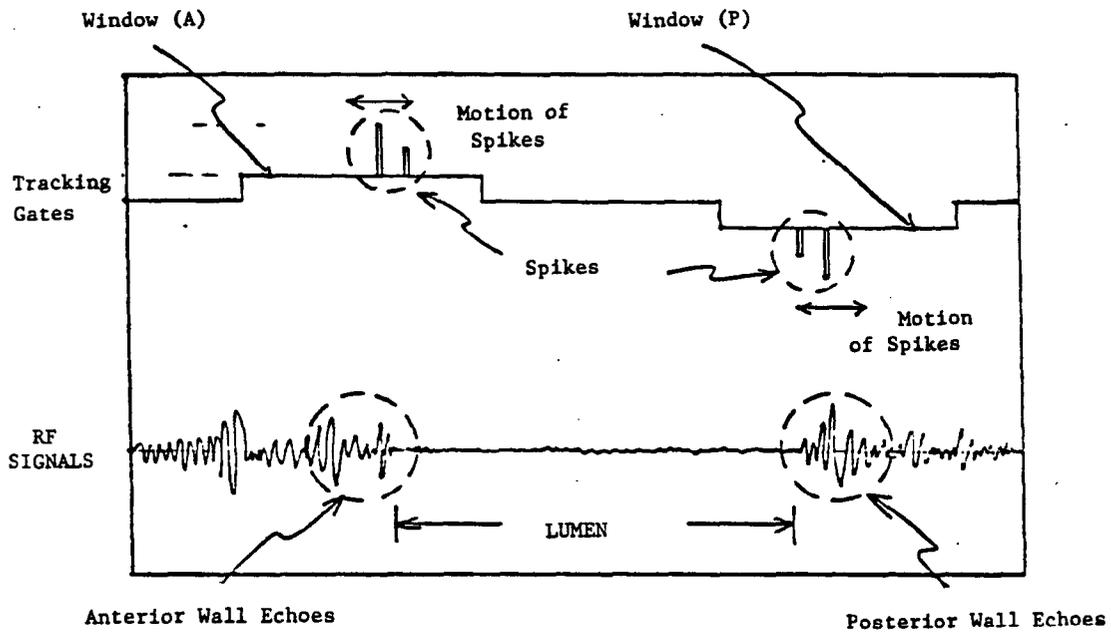


Figure 14. Oscilloscope Screen

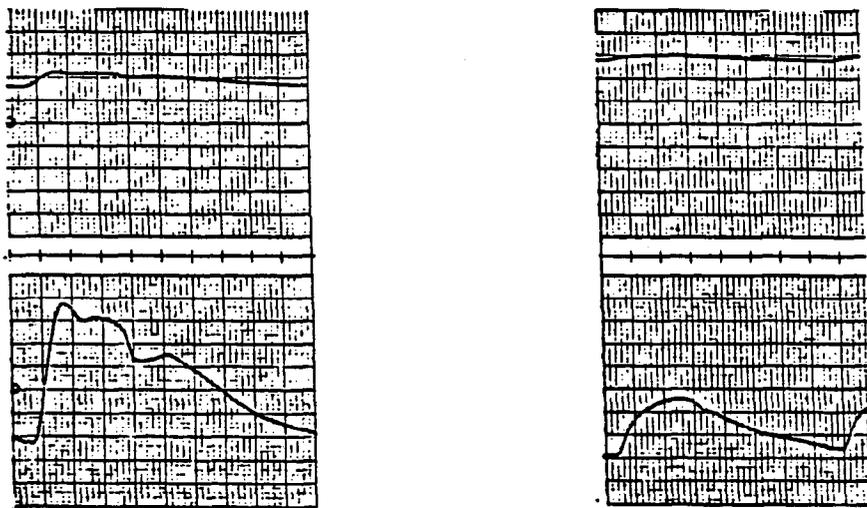


Figure 15. Characteristic Strip Chart Recordings

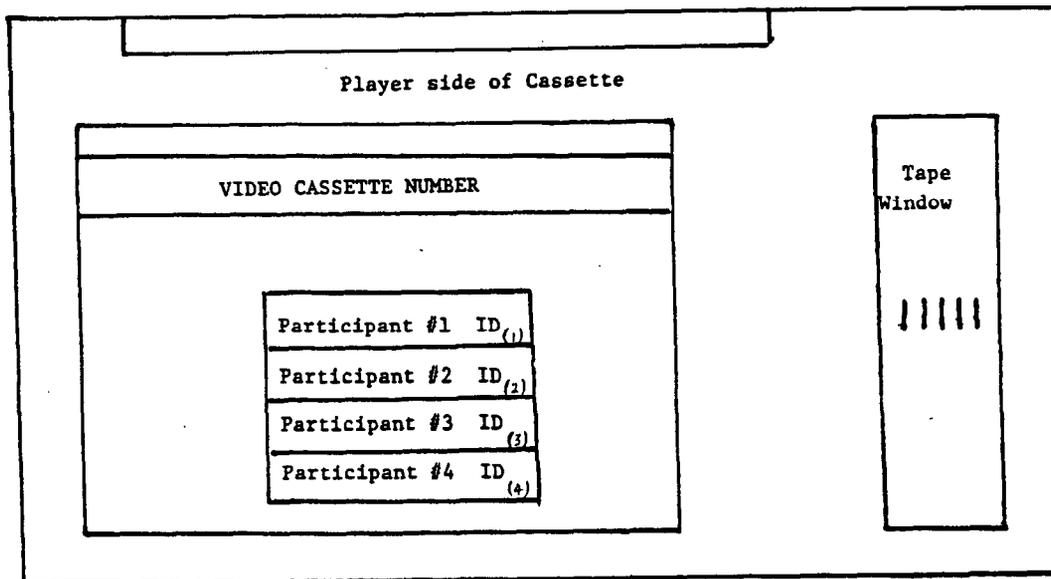


Figure 16. Video Cassette Labels

VIDEO CASSETTE BOX

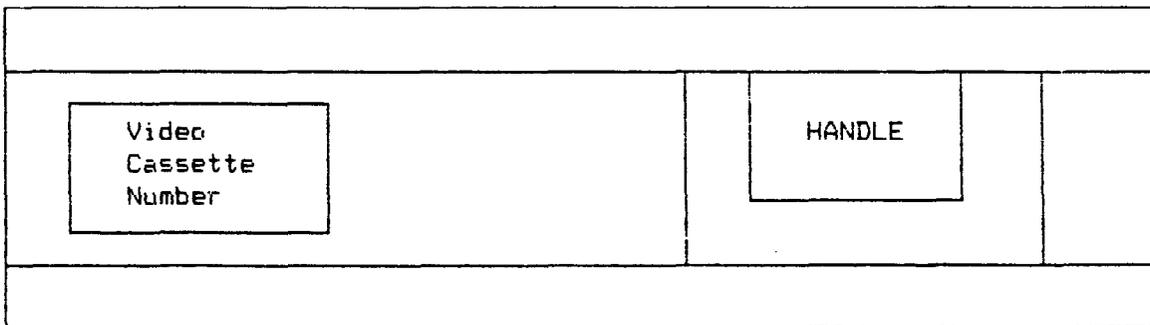


Figure 17. Video Cassette Box Labels

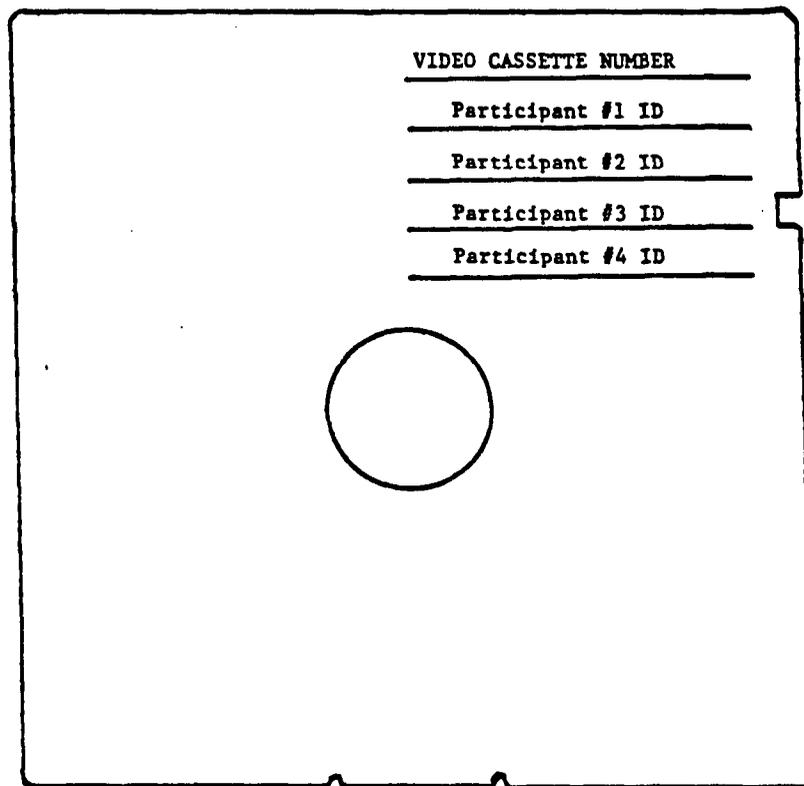


Figure 18. Diskette Labels

Appendix 1. STEP NUMBERS FOR ULTRASONOGRAPHY

Step Number	Description	SONY VCR	PC	Dinamap	Comments
		Turn on	Turn on C>US Answer preinfo screen	Turn on. Place cuff on ankle.	
				Take manual BP to check cuff. Adjust if necessary.	
Press Study Start=00	Calibration	RECORD		Take an ankle BP	Calibrate biosound, Wait at least 20 seconds after image is on the screen before pressing Audio Record Footswitch
01	Popliteal B-mode Knee	RECORD, then PAUSE (Not recording)		After Foot- switch is released, take ankle BP.	Wait at least 20 seconds after pressing VCR PAUSE or RECORD/PLAY or switching between B-mode & Doppler mode or pressing Audio Record Footswitch again.
If Popliteal QC Repeat		RECORD QC Study, then PAUSE			Put NORMAL/QC SWITCH to QC on Study Flow Panel. Toggle DOWN Switch to step 01. Repeat B-mode scan of pop- liteal. Put NORMAL/QC Switch back to NORMAL. Toggle up SWITCH until Study Flow Panel code reads 02.
				Change BP cuff to arm. Take manual BP to check cuff. Adjust if necessary. BP taken automatically every 5 minutes until end of scan.	

Step Number	Description	SONY VCR	PC	Dinamap	Comments
02	Common Carotid Right B-mode Long Optimum	RECORD			Wait at least 20 seconds after pressing VCR PAUSE or RECORD/PLAY or switching between B-mode and Doppler mode or pressing Audio Record Footswitch again.
03	Common Carotid Right B-mode Long Anterior				Wait at least 20 seconds between Audio Record Footswitch activations.
04	Common Carotid Right B-mode Long Posterior				
05	Carotid Bulb Right B-mode Long Optimum				
06	Internal Carotid Right B-mode Long Optimum				
		PAUSE			
If Right Carotid QC Study		RECORD QC study then PAUSE			Put NORMAL/QC switch to QC on Study Flow Panel. Toggle UP/DOWN switches so panel lights indicate the QC study prescribed. Repeat study at QC location. Put NORMAL/QC switch back to NORMAL. Toggle UP switch until Study Flow Panel code reads 07. Move transducer to Left Carotid.
07	Common Carotid Left B-mode Long Optimum	RECORD			Wait at least 20 seconds after pressing VCR PAUSE or RECORD/PLAY or switching between B-mode and Doppler mode or pressing Audio Record Footswitch again.

Step Number	Description	SONY VCR	PC	Dinamap	Comments
08	Common Carotid Left B-mode Long Anterior				Wait at least 20 seconds between Audio Record Foot-Switch activations.
09	Common Carotid Left B-mode Long Posterior				
10	Carotid Bulb Left B-mode Long Optimum				
11	Internal Carotid Left B-mode Long Optimum			Take last 5 minute cycle BP.	
		PAUSE			Prepare for distensibility. Set transducer in holder. Acquire common carotid arterial wall echoes. Check strip chart for distensibility waveforms.
12	Common Carotid Left Distensibility Optimum	RECORD			
		PAUSE		Take BP.	Final BP during ultrasound examination.
If Left Carotid QC Study		RECORD QC study then PAUSE			Put NORMAL/QC switch to QC Study Flow Panel. Toggle UP/DOWN switches so panel lights indicate the QC study prescribed. Repeat study at QC location. Put NORMAL/QC switch back to NORMAL. Toggle UP switch until Study Flow Panel code reads 13.

Step Number	Description	SONY VCR	PC	Dinamap	Comments
13	Study Complete. Press STUDY COMPLETE switch. Wait at least 20 seconds, then press Audio Record Foot-Switch for about 5 seconds.	RECORD			End of ultrasound exam.
			Press F1 KEY	Heart rate & BP taken for two minutes	Start postural
			Press F4 KEY		Participant starts to rise.
			Press F5 KEY when feet on floor.		Postural change exam, standing position.
			Answer postinfo screen		
			Type \exit		End of participant ultrasound area examinations.