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 counterclockwise 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 1b. 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 0 (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 RESPONDS: F111111.DEM (The order of these files may change)
                   F111111.BP
                   F111111.SC
                   F111111.DIS
                   F111111.TM (NOTE: .DIS only on program when field center uses their tracker)
                   F111111.HR
                   F111111.BPi

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.