Atherosclerosis Risk in Communities Study Protocol

Manual 11

Sitting Blood Pressure

Visit 4

Version 4.0

August 1997

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FOREWORD

This manual, entitled <u>Sitting Blood Pressure. Version 4</u>, 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 and 13 through 18. 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.

ARIC Study Protocols and Manuals of Operation

MANUAL

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1. SITTING BLOOD PRESSURE PROTOCOL

1.1 Introduction

As blood pressure rises, so does risk of ischemic heart disease and its complications. The range of normal blood pressures is wide. Even within the "normal" range, risk increases as the upper limits are approached. Usually, blood pressures are expressed as systolic pressure/diastolic pressure; values exceeding 140/90 mmHg are considered to be hypertensive for adults. Middleaged persons with a diastolic blood pressure of 90-104 mmHg (so-called "mild" hypertension) have a risk of heart attack that is about 70 percent higher than that of persons with a diastolic pressure under 80 mmHg (normal value). Persons with a diastolic blood pressure exceeding 104 mmHg (moderately severe to severe hypertension) have a risk more than twice that of those with a normal value. Hypertension is an especially strong risk factor for stroke and, to a lesser extent, for peripheral vascular disease. Most of the knowledge of the consequences of high blood pressure arises from studies of sitting arm blood pressure, as described in this section. Less is known about the health consequences of blood pressure measured after a prolonged period of rest, or after assuming the upright position. The latter are also measured in ARIC, as described later in this Manual.

Sitting blood pressure in the fourth exam (Visit 4) is measured in a resting state, using 2 measurements with a random zero sphygmomanometer. The random zero machine has two advantages over the fixed zero manometer. Digit preference does not appear in the data. It may still exist in the reading itself, but it is "removed" from the data by the use of the randomly chosen zero point. More importantly, it prevents the blood pressure technician from knowing the actual value, and therefore removes judgements about blood pressure levels for readings close to critical values such as 90 diastolic. It should be noted, however, that the random zero machines tend to yield blood pressures which are about 1.5 mmHg less than those obtained when using a fixed zero machine. Within person variation in blood pressure is substantial, even within a few minutes and particularly under conditions perceived as stressful. Use of two replicate readings tends to reduce this short-term variation.

1.2 Standardized Clinic Procedures

Correct measurement of blood pressure is of the utmost importance to the success of this study. It is essential that the procedure described below for measuring blood pressure be followed exactly. Major differences in blood pressure measurement methodology among health professionals from several countries have been observed despite the fact that international recommendations on blood pressure measurement were established in 1939 by a joint committee of the American Heart Association and the Cardiac Society of Great Britain and Ireland. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

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1.3 Description of the Equipment

1.3.1 Stethoscope

A standard Littman stethoscope with a bell is used. Korotkoff sounds are best heard with the bell because of their low pitch. Stethoscope tubing should be about 10-12 inches from the bell piece to "Y" branching. This length provides optimal acoustical properties and allows the observer to read the sphygmomanometer at eye level and in a comfortable position. Earpieces should fit comfortably and snugly in the ears. Four points should be observed in using the stethoscope.

- 1. The ear pieces should be directed downwards and forwards into the external ear canal.
- 2. The ear pieces should be tight enough to exclude outside sound but not so tight that they cause discomfort.
- 3. The valve between the bell and the diaphragm should be turned in the correct direction.
- 4. The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery - immediately below the cuff and medial to the cubital fossa above the medial epicondyle of the radius and posterior to the biceps muscle. Light pressure accentuates low-pitched sound and avoids compression murmurs. Pressing too heavily with the stethoscope over the brachial artery causes turbulent flow in the artery and a murmur can be heard which may prolong the apparent duration of phase 4.

1.3.2 Sphygmomanometers

Standardized Hawksley random-zero instruments are used for all clinic visits. Standard Baum manometers are used for determining peak inflation level.

The mercury manometer consists of a screw cap, a face with numbers, a lined glass column, a reservoir containing mercury, rubber tubing, and a metal case. The rubber tubing from the mercury manometer connects to the rubber tubing from the inflatable rubber bladder of the cuff. As the inflatable rubber bladder is filled with air, the air pressure in the bladder travels through the connecting rubber tubing. The pressure pushes the mercury out of the reservoir and into the lined glass column. The number for each line is read when the rounded top of the mercury, the meniscus, is level with it. If the meniscus is exactly between the lines, the reading is made from the line immediately above, i.e., rounded up to the nearest even number.

1.3.3 Random-Zero Mercury Manometer

The random-zero (R-Z) manometer has all the parts of the standard mercury manometer. In addition, it has a device built into the box-shaped back that changes the level of mercury in the calibrated glass tube. The device includes a second mercury reservoir the size of which can be changed to hold a larger or smaller amount of the mercury and therefore allow different amounts of mercury to remain in the calibrated glass tube and the outside reservoir. The size of the second reservoir is changed by turning a wheel on the side of the wooden box. The second reservoir is opened and closed with a Bellows control valve on the face of the manometer.

1.3.4 Cuffs and Bulbs

Proper size of the cuff is essential for accurate blood pressure measurement. Field Centers have four standardized cuffs available - small adult, adult, large adult, and thigh cuff. The standardized cuff sizes are used for the measurement of sitting blood pressure. The standard cuffs provided are by the Baum Company for the sitting, and by Dinamap for the postural measurements at the Ultrasound work station.

The range markings on commercial cuffs overlap from size to size and do not offer a precise guideline. In the ARIC Study arm size is measured, and the cuff size is selected as follows:

Small Adult< 24 cm	Cuff Si	ize Arm	Circu	nfer	ence
	Small Ad	dult	<	24	cm
Large Adult 33 to 41 cm	Ad	dult	24 to	32	cm
	Large Ad	dult	33 to	41	cm
Thigh > 41 cm	TÌ	high	>	41	cm

Table 1. Determination of cuff size based on arm circumference

1.4 Blood Pressure Measurement Instructions

Some of the many extraneous factors influencing blood pressure are controlled by standardizing the measurement technique and the environment in which the measurement is made. Uncontrolled factors (temperature, time of day, arm circumference, recent use of caffeine, identity of the observer) are recorded, so that they can be taken into account during analysis.

ARIC participants are reminded during the scheduling of Visit 4 to avoid caffeine (from tea, coffee, chocolate, and soft drinks), eating, heavy physical activity, smoking and alcohol intake for twelve hours prior to the clinic visit. Current drug intake, including medications affecting blood pressure and non-prescription drugs, is recorded on the day of the examination. A detailed history of alcohol intake history is also recorded.

1.5 Staff Preparation for Participant Visit

In relating to the ARIC participants, remember that participation in the study is voluntary. Participants are given full explanation and instructions about the preparation for the blood pressure examination and an opportunity for questions. The setting in which blood pressure measurements are made is standardized and takes place in a separate, quiet room where no other activity is taking place, and where temperature fluctuations are minimal. Clinic scheduling procedures establish consistent appointment times to minimize as much as possible the impact of daily blood pressure variation.

1.6 Measurement Procedures

The sitting arm blood pressure is measured two times at Visit 4. It takes approximately 10 minutes to make two blood pressure measurements including the initial five minute rest.

Once the participant is given instructions and explanations, and the equipment has been checked, blood pressure measurement begins. The following steps must be followed precisely. The procedure is described here employing the ARIC paper form. When using the ARIC Direct Data Entry System, calculations are performed by the system.

- 1. If the participant indicates that there is a medical or post-surgical reason for not having the blood pressure measured on the right arm (or if the right arm is missing), reverse chairs and proceed with the left arm. Indicate on the Itinerary Form and on the Sitting Blood Pressure form Note Log that the left arm is used. If in doubt, or if the participant prefers not to have a blood pressure taken on either arm, consult with the supervisor.
- 2. Determine the arm circumference using the following procedure.

The participant stands facing away from the observer with the right arm flexed at 90 degrees at the elbow, hand across midsection. The observer determines and marks the tip of the olecranon (elbow).

The participant straightens the arm, allowing it to hang loosely at the side. The observer then determines and marks the posterior tip of the acromion process (shoulder bone). Using a centimeter tape, the observer measures the length of the upper arm between the two marks and marks the midpoint (+).

The observer wraps the tape around the arm over the midpoint mark, making sure that the tape is level. The arm circumference is measured to the nearest centimeter, rounding down, and is recorded.

- 3. Seat the participant with right arm on table. The bend at the elbow (cubital fossa) should be at heart level. Legs should be uncrossed and feet comfortably flat on the floor, not dangling. Be sure that the chair head support is comfortable and the participant is able to relax the neck and shoulder muscles as much as possible.
- 4. Palpate the brachial artery (just medial to and above the cubital fossa), and mark this location for stethoscope placement. Choose the correct cuff size and wrap the cuff on the arm with the center of the bladder over the artery. If the participant seems particularly apprehensive, delay wrapping the cuff until after the five minute wait.
- 5. Record the time. Start five minute timer. Allow a five minute wait before taking the blood pressure. Conversation should be limited. However, a brief explanation of the procedure can be repeated at this time if necessary. The smoking and fasting questions may be asked after timing is begun.
- 6. After the 5 minute rest, check the heart rate. Then, connect the cuff to a standard manometer and establish the pulse obliteration pressure by slowly inflating while palpating the radial artery until pulse is no

longer felt. Deflate and disconnect the cuff. Record the pulse obliteration pressure. Record the R-Z maximum zero number (found next to mercury column). Calculate and record the peak inflation level (i.e., pulse obliteration pressure + R-Z maximum zero number + 30).

- 7. Measurement 1: Connect the cuff to the random-zero manometer. Open the bellows control valve and wait until the mercury settles. Using downstrokes only turn the thumbwheel two or three times. Note: Do not spin the thumbwheel. Inflate rapidly to the R-Z peak inflation level. Holding the pressure constant with the bulb, wait 5 seconds. Close the bellows control valve. Place the bell of the stethoscope on the brachial artery and slowly deflate the cuff (2 mm per second) while listening. Record the 1st and 5th phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic blood pressure (phase 1). The first slence in a series of at least two silences is recorded for diastolic blood pressure (phase 5), not the last sound heard. Disconnect the cuff and record the zero reading.
- 8. Measurement 2: Have the participant raise measurement arm for five seconds. After waiting another 25 seconds with the participant's arm on the table, repeat the measurement as in step 7 above and disconnect cuff.

Blood pressure calculations are made for the first and second readings. When using paper forms, subtract the zero value from the readings to get the actual (corrected) systolic and diastolic blood pressure measurement. This is done on the worksheet at the end of the form. Because of the importance of the blood pressure averages, to inform the participant and for the purpose of referral, all arithmetic is done with a calculator.

If for any reason the observer is unable to complete, or has forgotten to complete any portion of the exam (and the participant is gone), draw two horizontal lines through the space(s) on the form, if using paper forms. This is the correct way to indicate missed information. If an entire reading is missed and the participant is still sitting at the blood pressure work station, completely deflate the cuff and start over with a replacement reading. However, under no other circumstances may a replacement reading be obtained. Always wait at least 30 seconds between readings.

1.7 Procedure for Changing the Peak Inflation Level

Occasionally the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. The observer immediately deflates the cuff by releasing the thumbscrew <u>and</u> disconnecting the cuff tube. Then have the participant hold the cuff-wrapped arm vertically for five seconds. As shown below in Table 2, draw a line through the previously recorded Pulse Obliteration Pressure and Peak Inflation Level. Increase each number by ten and write the new number above the original one, as shown below. When using the Direct Data Entry system, the Peak Inflation Level values change automatically when the Pulse Obliteration Pressure is changed. Proceed with blood pressure measurement, starting at the new Peak Inflation Level.

130 120	
<u>+ 22</u>	
+ 30	
<u></u>	
=182	
<u> 172 </u>	
	- 120 + 22 + 30 =182

Table 2. Changing the Peak Inflation Level on paper forms.

1.8 Reporting the Blood Pressure Results to the Participant

Using a calculator, average the first and second corrected R-Z readings and record the average on the form if using paper forms. Record this average on the transmittal slip or itinerary form in the participant's folder, and mention the results to the participant. State clearly the systolic and diastolic pressure, and offer to write down these values for the participant.

1.9 Stopping Rules for Elevated Blood Pressure

The medical care referral guidelines for elevated blood pressure are summarized in Table 3. When a person has one or more sitting blood pressure measurements $\geq 260/130$ mm Hg (emergency referral), the ARIC physician is consulted and arrangements are made to transport the person to an emergency care facility. The ARIC physician is also consulted and the participant is advised to seek immediate medical care (same day) when one or more systolic blood pressure measurements are between 210 and 259 mm Hg or the diastolic pressure is between 120 and 129 mm Hg (immediate referral). In both circumstances, the remaining procedures and interviews in Visit 4 are canceled and Visit 4 is rescheduled as appropriate. When one or more systolic blood pressure levels are between 180 and 209 mm Hg or the diastolic is between 110 and 119 (urgent referral), the ARIC physician and interviews are conducted, unless the physician recommends otherwise.

Table 3. Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-V, 1993) Guidelines

Referral Classification	Examination Findings	Recommendation to Participant ¹	Explanation to Participant
Emergency Referral	SBP ≥ 260 or DBP ≥ 130	Transportation to emergency care facility. Stop exam and reschedule clinic visit.	Your BP is very high.
Immediate Referral	SBP 210-259 or DBP 120-129	Consult with ARIC MD. Refer to source of care immediately (today). Stop exam and reschedule clinic visit.	Your BP is very high.
Urgent Referral	SBP 180-209 or DBP 110-119	Consult with ARIC MD and proceed unless otherwise indicated. Refer to source of care within 1 week.	Your BP is high.
Routine Referral	SBP 160-179 or DBP 100-109 SBP 140-159	Refer to source of care within 1 month. Refer to source	Your BP is elevated. Your BP is
	Or DBP 90-99	of care within 2 months.	elevated.
No Referral	SBP 130-139 or DBP 85-89	Recheck in 1 year (no ARIC referral)	Your BP is high normal.
	$SBP < 130^{2}$ or $DBP < 85^{2}$	Recheck in 2 years (no ARIC referral)	Your BP is normal.

¹ If the systolic and diastolic categories are different, follow recommendations for the shorter time follow-up (e.g. 160/85 mm Hg should be evaluated or referred to source of care within 1 month).

² Unusually low readings should be evaluated for clinical significance.

1.10 Sitting Blood Pressure Training and Certification

At each field center a minimum of three clinic staff persons are trained for measuring sitting blood pressure. They need not be health professionals, but

they must be trained and certified by ARIC in the blood pressure measurement technique. Observers should also have experience in relating to people.

The first training session begins with a description and demonstration of the correct blood pressure measurement procedure. Trainees listen to the 1st (training) audio-cassette tape, taking the test sequences until they are confident they can identify 1st and 5th phase Korotkoff sounds. Then, they use the 2nd tape until they have passed the test. After passing the second test, they are given the 3rd tape test. Alternated with the tapes are actual practice sessions with live subjects under the instruction and observation of the training supervisor. Some live practices may be done with a standard stethoscope, but most employ the Y-tube stethoscope. After the first day of training, each trainee is given a cuff and manometer (no stethoscope) to take home and practice control of the valve. This is done by wrapping the cuff on a jar or bottle and alternately pumping up and dropping the mercury at a steady rate of 2 mm per second. After two or three sessions, trainees are also given a stethoscope to practice on family or friends. Out-of-class practice is very important to build confidence. Practice time allowed in class is not enough without outside practice time. Once each trainee has passed the third tape test, he or she does at least two live readings with the training supervisor on the Y-tube stethoscope. The readings must agree within 4 mm and the average must agree within 3 mm. If they do not, the trainee needs additional practice with tapes and live subjects. The training supervisor also verifies that the trainee understands and follows proper procedures.

Additional time is allowed for instruction and mastering the use of the Random-Zero device. Trainees are certified after passing tape tests 2 and 3 (tape 4 is held in reserve for recertification) and at least 2 live readings. Observers are recertified every six months by taking and passing tape 3 or 4 and two readings with the blood pressure supervisor on a Y-tube stethoscope.

It is the responsibility of each field center to conduct recertification procedures and report to the Coordinating Center when the procedures are complete.

1.10.1 Tapes

The ARIC Study uses four tapes of Korotkoff sounds. Tape 1 is a training tape. Tape 2 is a practice tape. Tapes 3 and 4 are test tapes. A new trainee listens to tape 1, goes to tape 2 and repeats it as often as necessary. Tape 3 is taken as a test. It, too, may be repeated if necessary. Tape 4 is held in reserve for the six month recertification. Tapes 3 and 4 are alternated thereafter for recertification.

1.10.2 Using the Cronus Stop Watch with the Prineas Blood Pressure Tapes

The Cronus stopwatch, model 3-S, is an interval timer and is the preferred timing device to be used with the training tapes. Of the various options, it seems to be the simplest and easiest to read. It is generally available at a local sporting goods store. The address of the manufacturer is:

Cronus Precision Products, Inc. 2895 Northwestern Parkway Santa Clara, CA 95051 USA

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If only Phase 1 and Phase 5 are learned, two ordinary stop watches may be used. Using one in each hand, both are started at the beep; one is stopped when the first Korotkoff sounds are heard and the other stopped at disappearance. The interval watch is preferred even if Phase 4 is not being recorded because it is much easier to change one's mind if sounds change, and it is easier to read.

- 1. Turn on the stop watch and press the reset button.
- 2. Start the tape, wearing headphones. At the beginning of each tape is a timing sequence, with no Korotkoff sounds. When the beep is heard, start the watch by pressing the button at the top. Stop the watch with the button at the top when the second beep is heard. Record the time elapsed to the nearest 10th of a second on the top of the student form.
- 3. Press reset button. When the tape announces sequence 1, start the watch at the beep.
- 4. When the first Korotkoff sound is heard, stop the watch with the button at the top. Record the time elapsed to the nearest 10th of a second. The watch continues to run internally.
- 5. When the Phase 5 (disappearance) is heard, stop the watch. Record the time elapsed to the nearest 10th of a second. Press reset. Repeat steps 3 thru 5 for each sequence. Remember that the tapes were designed for a special timing device. The answers given are double the stop watch values. At the end be sure to turn off the stop watch in order to save batteries. To score the tests, add all the sequences, and divide by the number of sequences. The average should be within plus or minus one second.

1.10.3 Y Tube Stethoscope Observations

Y Tube stethoscope observations are made in conjunction with the blood pressure tapes during initial training and for biannual quality control. The trainer has the observer-trainee go through the entire blood pressure measurement procedure using a quality control checklist. The observer and trainer listen with the Y Tube and record the values on separate sheets. Two measurements on one subject are obtained. Measurements by the trainer and the trainee should agree within 4 mmHg on any one reading (systolic or diastolic) and averages should agree within 3 mmHg.

1.11 Quality Control

To ensure the accuracy of the blood pressure measurements throughout the study, quality control measures are developed centrally and applied at all field centers. These measures include:

- 1. recruitment of the most qualified personnel
- 2. standardized training and certification
- 3. retraining and recertification
- 4. biannual observation of data collection by supervisors, using the checklist given in Appendix III. One checklist is used for each technician and mailed to the Coordinating Center each quarter.
- 5. frequent staff meetings to provide feedback
- 6. editing of data, both manual and by computer
- 7. a quality assurance program administered by the Coordinating Center
- 8. biannual simultaneous Y Tube observation of each technician by the blood pressure supervisor
- 9. equipment maintenance program

1.12 Technician Training and Quality Control

Blood pressure technicians are trained centrally prior to participant recruitment. New technicians hired after the start of the study are trained locally by the Study Coordinator or a designated "Blood Pressure Supervisor". Recertification occurs every six months. Prior to certification, each technician is required to have a clinical hearing test.

The Coordinating Center directs a blood pressure quality assurance program to review six-monthly data. This includes quality analysis and review of blood pressure data, comparing means for each technician with the values for all technicians, by center. These statistics are adjusted for weight, age and sex of the participants. Digit preference is also monitored for each technician.

1.13 Equipment Maintenance

Each field center is responsible for the proper operation and maintenance of its equipment. Maintenance responsibility is assumed by the blood pressure supervisor and all staff are instructed to report any real or suspected equipment problems to that person promptly.

All checks, inspections, cleanings and problems indicated are documented and recorded by date in a permanent log. Problems and solutions are also recorded. A copy of this log is given in Appendix IV.

1.13.1 Random Zero and Standard Sphygmomanometers

The Random Zero manometer is inspected once a week and the standard manometer once a month. These inspections include a check of:

- 1. the zero level of the standard manometer
- 2. mercury leakage
- 3. manometer column for dirt or mercury oxide deposit
- 4. condition of all tubing and fittings.

The equipment is cleaned if inspection indicates it is needed, or at least once a year. Specific instructions for the random zero device are provided in Appendix I, and for the standard manometer in Appendix II. In addition, every two months the accuracy of the random zero instrument is checked using a standard manometer and a Y connection, as described in Appendix V.

1.14 Referral of Hypertensives

As shown below in Table 3, blood pressure referral levels are made based on the findings of the ARIC examination which are consistent with the recommendations given in the fifth report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (1993). The average of the first and second resting blood pressure readings is used.

Appendix I. Check Procedures and Maintenance Instructions Random Zero Sphygmomanometer

- 1. Check cap of manometer column to be sure it fits properly and is tight. The 0 ring or seal must be seated correctly. Clean cap of any mercury (Hg) beads or dust. The cap should be firmly finger tight. Any time the mercury seems to 'bounce' in the column of either a standard manometer or random zero (R-Z) manometer, it may be due to a loose cap. Check the opening. If it becomes blocked, the mercury column falls too slowly due to a vacuum effect. This may result in false high readings and an erratically oscillating column. This procedure should be carried out for both standard manometers and R-Z's.
- Remove back of case (two screws at top of face and two at bottom rear of case). Swing back from the left around the thumb screw on the right side. Check for spring placement it should be in line. Tighten all screws except the one holding the bellows plate in place.
- 3. Wrap an arm cuff around a bottle or can.
- 4. With reservoir value open (newer models do not have a reservoir value) and bellows value closed, pump mercury to top of column (270-290 mmHg). If the mercury holds at a steady level for 15 seconds or drops 2-4 mm, that system is airtight.
- 5. With the high pressure still in the system, close the reservoir and disconnect cuff to see if that valve holds steady pressure. If a leak is discovered in the reservoir valve, remove hose and valve (with Allen wrench). Valve handle unscrews or lifts off. There are two 0 rings on the valve stem. Clean stem and replace 0 rings. Use stopcock grease in 0 rings and valve.
- 6. If the closed reservoir valve is tight, but there was a leak with it open, check the inflation assembly. There may be a leak in the bulb, valve, or cuff. To test the inflation assembly, immerse each section, especially valves and tubing connections in water while the pressure is high and watch for air bubbles. To test the tubing of the Hg reservoir, put soapy water on it. Most leaks occur at or near tubing connections or from valves. If a valve leaks, sometimes a shot of silicone lubricant on the thumb screw and worked in will solve the problem. Otherwise it may need to be replaced. Tubing leaks near a connector can be repaired by removing the connector, cutting off 1/2 to 3/4 inches and replacing the connector. Lubricate a sharp knife with soapy water to make the cut, and lubricate the cut tube to make it easier to reattach.
- 7. Turn R-Z with back toward you. With bellows valve open, retract mercury to just below the plexiglass valve chamber. Close the bellows valve, pump mercury to top and visually check that leakage does not occur at that valve point. If Hg rises into the chamber, the valve needs repair. Replacing 0 rings on that valve can be done locally if someone is qualified to do it. It is a more difficult job than on the reservoir valve. Otherwise it should be sent to Baum. A serious leak in this valve can affect blood pressure readings. Whenever the manometer tube

seems dirty in the area of the 'zeros' or if the Hg seems to hang up there, the tube should be cleaned. A dirty tube can affect 'zero' readings. To clean tube, set cam at lowest zero. Pump up, close bellows valve, release pressure. This leaves little mercury in the column. Tilt manometer, getting rest of mercury out of glass and into reservoir. Close reservoir valve. Lean manometer at angle so that no mercury is in glass. Remove the tube and clean tube and seats. Check to be sure the rubber gaskets are seated properly. Replace tube. This procedure should be done only by a qualified person in a controlled setting. The manometer is set in a catch basin so that no mercury can escape. There should be a rap-type vacuum pump available to pick up any small spills.

- 8. Check "maximum" and "minimum" zeros and of bellows and cam function. (This must be done only if there are doubts about the values of those zeros or functions; or if Hg has been added or lost.)
 - a. Release all pressure and open the bellows valve. The large thumb wheel with the black rubber "tire" and the cam against which it is pressed should turn freely without binding. If they do bind, bring in the R-Z.
 - b. Inflate the system while watching the large (about 2-1/4" diameter) disc above and to the left of the bellows valve chamber. (Bellows valve is still open.) As pressure rises one can see the disc, a piston, pushed toward the back plate until a ring around the center of the disc touches the forward rim of the cam. That rim is tapered, and thus determines how far the piston can move, depending on the position of the taper in relation to the ring at the center of the piston a matter of change in normal operation of the R-Z. The distance that the piston can move before being stopped by the cam determines the volume of Hg in the bellows chamber, hence the volume of Hg left in the rest of the manometer.
 - c. To read "maximum" zero, release pressure with bellows valve still open. Turn the cam so that the point of its taper nearest the piston will be hit by the ring of the piston. (It may take an inflation and deflation or two before you find the correct cam position, which allows the minimum volume of Hg in the bellows chamber, hence maximum Hg in the rest of the system.) Inflate to about 200 mmHg, close the bellows valve, release pressure and read the zero as usual; this is the "maximum". Repeat the procedure once or twice, checking the cam position to make sure you get the same reading. Note that this is not a fixed value for if you were to inflate to 300 before closing the bellows valve, the reading would be lower; and inflation to 120-130 would give a higher value. For this reason, always record the maximum zero reading when taking blood pressures.
 - d. "Minimum" zero is measured as in c above, except that the cam is turned so that the piston can travel its maximum. It is usually nearly 20 mm lower than the "maximum" and should not be closer than about 4 mm to the 0 on the manometer tube scale.

- e. Replace the rear case, putting it over the thumb wheel first. Start all four screws before tightening any. Take care not to cross thread.
- f. After a series of blood pressure readings or before transport, open the bellows valve to drain Hg from that chamber, then close it and the reservoir valve. Between readings, the bellows valve should be left on "open" so that pressure on the bellows is not left in the device.

Appendix II. Maintenance Procedures for Standard Sphygmomanometer

The following checks should be conducted at least every month, and a log kept of the dates and the people carrying out the troubleshooting (see Appendix IV).

- 1. With the instrument placed flat on the table, and the inflation system disconnected, the level of mercury should read zero in the standard instrument. If the reading is either above or below the zero mark, mercury should be added or withdrawn until it does read zero. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted.
- 2. The inflation system should then be reconnected, and the cuff rolled around a bottle and secured. The valve should be closed on the Air Flo system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flo valve should then be slowly opened and the mercury allowed to fall to 200 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following step should be taken:
- 3. The system should be reinflated until the column rises to 200 mmHg. The tubing should be pinched at various locations to localize the area of the leak. Appropriate replacement of the tubing, cuff, or valve should be performed.
- 4. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leak persists or the mercury is seen at the bottom of the tube, the silicone rubber which provides a seat for both ends of the glass tube should be replaced.
- 5. With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. The instrument should be laid nearly on its side (on a tray) so that the mercury will return to the reservoir and none can be seen in the glass tube. The tube should be removed carefully and cleaned out using the long pipe cleaner supplied with the instrument. The tube should then be replaced and the zero level rechecked.

Since mercury is a toxic substance all maintenance procedures must be performed carefully and with attention to safety. Mercury should not be allowed to get in contact with rings and other jewelry.

(Maintenance instructions for the standard sphygmomanometer are adapted from those given for the MRFIT study in <u>Controlled Clinical Trials</u>, Vol. 7, No. 3 (Supplement), Sept. 1986.

Appendix III. Checklist for Biannual Observation of BP Technicians By BP Supervisor

BP Technician Code #	Observer Code #
Date Observed//	
Field Center	

<u>Instructions</u>: For each item, check "yes" or "no" in the space provided to indicate if the procedure is carried out correctly. Record any comments in the blank line between that item and the next. For certain items specific parts of the procedure which are important are listed separately. All measurements and procedures should be rechecked by supervisor.

	Yes	5	No)
Measures arm for correct cuff size	()	()
Palpates brachial artery	()	()
Marks pulse point	()	()
Wraps cuff center of bladder over brachial pulse	()	()
Leaves subject for five minutes rest Instructs on Posture Full five minutes for rest allowed Work station free of excessive noise Explanation	()))	(((()))
Count radial pulse 30 seconds record reading	()	()
Finds Pulse obliteration point using standard manometer	()	()
Calculates peak inflation, standard manometer	()	()
Calculates peak inflation, R-Z	()	()
If computer is down use the formula (pulse obliteration pressure + R-Z maximum zero number + 30)	_			
Explanation	()	()
Connects R-Z tube to cuff	()	()
Sure reservoir lever open (newer devices have no lever)	()	()
Opens bellows valve and waits full 3 seconds for mercury to settle	()	()
Turns thumb wheel (down strokes only)	()	()

.

	Ye	8	N	o	
Places stethoscope in ears	()	()	
Inflates rapidly to R-Z peak	()	()	
Counts full 5 seconds with pressure steady	()	()	
Closes bellows knob	()	()	
Places bell on brachial pulse	()	()	
Deflates cuff 2 mmHg per second	()	()	
Deflates cuff after 2 absent sounds	()	()	
Records readings	()	()	
Disconnects tubes	()	()	
Reads zero value	()	()	
Subtracts zero value from each BP reading,					
if using paper form	()	()	
Instructs to hold arm vertical for full 5 seconds	()	()	
Waits at least 30 seconds before proceeding	()	()	
Repeats R-Z readings	()	()	
Informs participant of average readings	()	()	
Special Comments:					

Appendix IV.	ARIC Monthly Log	for Sitting Bloc	d Pressure Station
		-	

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		Fiel	d Cente	rFJ	M	_₩	Month	l <u></u>	_ Year_	<u> </u>	
Week	ly Che	eck Pro	cedures	:		1	й 2	leek 3	4	5	
1.	Rando	om-Zero	Sphygm	omanomet	er:						
	Date	of Che	ck		-						
A.		Check	Tube fo	r Oxide	Dust _						
в.		Check	Cap for	Tightne	.88 _						
	Proc	edures	perform	ed only	if the	ere apj	pear to	be pro	blems:		
c.									at top o		
				and Perf r of wee			-	3 1 2	34	5	
D.									nove cap place cap		anometer
				rformed r of wee		-		12	34	5	
E.		List t	he prob	lem enco	ountere	ed, th	e date,	, and th	ne actio	ns take	n below:
											

. . '

Monthly Check Procedures:

Accuracy Check on Random-Zero Sphygmomanometer (to be performed every 2 months):									
Date last accur	acy check p	performed:							
Is an accuracy	check due t	his month?	() Yes	() No					
Date accuracy c	heck perfor	cmed, if du	le:						
Problems found	on accuracy	check?	() Yes	() No					
If yes, list pr	oblems four	nd and corr	ective act	ion taken:					
• · · · · · · · · · · · · · · · · · · ·	<u></u>								
									
	<u> </u>				· · · · · · · · · · · · · · · · · · ·				
Random Zero Spł	nygmomanome	ter Check							
Standard	200	170	140	100	60				
Random Zero									
Zero									
Corrected									
R-Z Measure*									
Corrected R-Z n Note that this standard.					mHg of the				

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B. Standard sphygmomanometer check:

Date of check: _____

A. Check cap for tightness

B. Check tube for oxide dust

C. Check that mercury is at zero with no pressure

List any problems found and corrective action taken:

C. Measuring tape for arm circumference worn or stretched

Tape measure has been tested as part of Anthropometry station procedures. () Yes () No

If no, perform tape measure calibration check:

Check by holding the zero mark of the tape against the ruler used to measure standing height at the 150 cm. mark. If the 30 cm. mark on the tape used for arm circumference falls outside the range 119.5 to 120.5 on the standing height ruler it should be replaced.

Date of check:

Point on height ruler where 30 cm. on tape falls

Appendix V. Accuracy Check on the Random-Zero Sphygmomanometer

This check should be performed every two months, using a standard manometer and a Y connector. Check that the mercury level of the standard device reads zero with no pressure in the system. If it does, it should be treated as accurate and having an adequate supply of mercury.

To perform the accuracy check on the R-Z instrument, attach the two arms of the Y connector directly to the reservoirs of the R-Z and standard devices, using Latex tubing. Attach the base of the Y connector to a cuff with an Air Flo control valve and bulb. To attach the Latex tubing to the reservoirs or to a valve, it may be helpful to moisten the openings of the tubing to allow the tubing to slip onto the desired parts. Wrap the cuff around a bottle or can.

First open the Air Flo valve to insure that all pressure is out of the system. Check the zero level of the standard device. Next, turn the R-Z valve to the OPEN position. Close the Air Flo valve and inflate both machines until the mercury level in the standard device is at the 250 mmHg level. After 5 seconds, close the R-Z valve. Allow the mercury in the standard manometer to drop to 200 mmHg. Record the exact levels of mercury in the RZ and standard device. Repeat the procedure at 170 mmHg, 110 mmHg, 80 mmHg and 60 mmHg. Release the air from the Air Flo valve. When the mercury in the R-Z instrument has stabilized and the standard is at zero, record the zero reading from the R-Z. Subtract this value from the R-Z readings.

The results should agree with the comparable readings on the standard instrument within ± 2 mmHg. If this agreement is not found at all levels, repeat the procedure. If the disagreement is constant, stop using the instrument and contact the manufacturer.

Worn parts should only be changed as necessary (when there is disagreement between the R-Z and standard devices). Only those parts in the parts kit should be changed. No attempt should be made to change the rubber diaphragm or bellows.

Note: These instructions are adapted from the procedures employed by the MRFIT study, described in <u>Controlled Clinical Trials</u>, Vol. 7, No. 3 (Supplement), September 1986.

Instructions: Biannually, each technician should be part of a pair of technicians who simultaneously measure blood pressure using a Y-tube on a volunteer (not an ARIC participant). Each technician should separately record his/her measurements on a standard paper ARIC SBP form. The blood pressure supervisor should then transfer the results to this form and calculate the differences between the two sets of measurements. If the difference on any individual measurement is greater than 4 mmHg, or if the averages of the two readings for each technician differ by more than 3 mmHg, the supervisor should indicate the corrective action taken on this form. Any further sets of simultaneous measurements for a given pair should appear on a new form.

Tec	<u>chnician IDs:</u> 1st ID:	2nd ID:	Date:	<u></u>
		lst Technician	2nd Technician	Difference
a.	Initial arm circumference (cm)			
b.	Initial cuff size selected		<u> </u>	
c.	Pulse Obliteration Pressure			
d.	First SBP			
e.	First DBP			
f.	First Zero Reading			
g.	First Net SBP Corrected for Zero	<u></u>		
h.	First Net DBP Corrected for Zero			<u> </u>
i.	Second SBP			
j۰	Second DBP			
k.	Second Zero Reading			
1.	Second Net SBP Corrected for Zero	<u></u>		
m.	Second Net DBP Corrected for Zero			
n.	Average Net SBP			······································
٥.	Average Net DBP			•

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ACTION TAKEN IF DIFFERENCES BETWEEN TECHNICIANS EXCEED LIMITS SPECIFIED: