CHAPTER 16

PHYSICAL MEASUREMENTS

(Revised 3-2010)

Alternate Height Measurement protocol for participants with severe kyphotic posture or large posterior added.

(Revised 11-2009)

Height; rounding examples added as Appendix B

(Revised 6-2009)

Weight measure clarification added:

If a participant's balance is unstable making it difficult to obtain the two weight measures, staff may instruct them to lightly touch a mounted bar, wall, chair, walker to provide balance. It is strongly recommended to locate your scale next to a wall or bar. If this is not possible at your site, a chair or walker can be placed in front of the scale. Only the lightest touch should be used (use the finger tips, do not allow the participant to grip or use entire hand). Usually the weight will lock once the participant's balance is stabilized for a short moment using the

method described above.

(Revised 12-2008)

Various corrections to typos, clarifications and information pertaining to Phase III added. All 12-2008 and 16.2 ABI revisions of 6-2006 have been underlined in the text.

(Revised 6-21-2006)

Changes are underlined in each section

Summary of Changes:

16.2. ANKLE BRACHIAL INDEX Section

CHAPTER 16

PHYSICAL MEASUREMENTS

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PHYSICAL MEASUREMENTS

16.1. MEASUREMENT OF WEIGHT, HEIGHT, WAIST

16.1.1. Overview of Body Size Measurements

Change in body weight is the primary measure of effectiveness of the intervention in this trial. Although weight can be measured with accuracy and precision using relatively simple equipment, the preparation of the subject, standardization of procedure, and maintenance of equipment are critical in order to obtain reliable data. Body weight relative to height, expressed as Quetlet's index, or body mass index (BMI, kg/m^2), is an index of fatness and is highly correlated with more direct measures of body fat. Waist circumference and changes in waist circumference are indicators of subcutaneous and visceral fat deposits in the abdominal region and have been shown to be independently associated with cardiovascular disease.

All measurements are to be made with the participants wearing light clothing, e.g., a short sleeve shirt or blouse (or surgical gown), shorts, socks and without shoes (for weight and height). A supply of shirts and shorts (or gowns) should be maintained at the clinic for participants who forget to wear or bring the appropriate clothes for body size measurements. Participants should be sure pockets are empty.

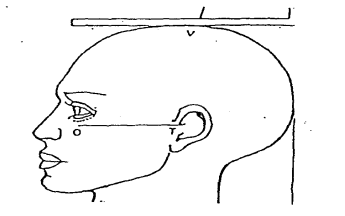
Body size measurements should preferably be taken by staff who <u>are masked</u> to the intervention assignment of the participant. If possible, measurements, especially waist circumferences, should be taken by a team of two persons, one acting as observer and the other as recorder. The observer takes the

measurements, reporting the results to the recorder, who repeats them. The observer keeps the measuring instrument in place until the recorder repeats the number. The recorder generally checks the examinee's position during the procedure. If a second observer is not available, a mirror can be used to check for the correct position (e.g., whether the tape is horizontal for waist circumferences). Body weight and waist circumference will be measured at baseline and annual visits throughout the study. Body height will be measured at baseline, annual visits 4, 8 and 12.

16.1.2. Body Height

A wall-mounted stadiometer graduated in centimeters with a horizontal measuring block (or fixed angle) is to be used. If the stadiometer is not wall-mounted, you will need a level to ensure that the horizontal measuring block is level.

The subject stands erect on the platform with his/her back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane is defined by the lower margin of the bony orbit - the bony socket containing the eye - and the most forward point in the supratragal notch -the notch just above the anterior cartilaginous projections of the external ear). The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The subject's height is recorded to the nearest 0.5 cm. Ask the subject to step away, raise measuring block and ask subject to return and repeat measure. The subject should be instructed to stand as straight as possible with feet flat on the floor.



ORBITALE:	Lower margin of eye socket
TRAGION:	Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE:	Orbitale tragion line horizontal

The following alternate protocol may be used to obtain the height measure on participants with extreme kyphotic posture or a large posterior. In these instances it may not be possible to obtain contact between the head board and scalp when the participant's back is against the wall-plate. In this case, measure height with the participant standing sideways (side of arm and shoulder in contact with the wall-plate) and positioned so that the headboard contacts the scalp. The head should be in the Frankfurt Horizontal Plane. There is no modification to the BP, Weight, Waist and Height Form; however, you should record that the participant was measured in the sideways position in the source document so that follow-up measurements can be made in the same position.

16.1.3. Body Weight

Two Tanita BWB 800 digital scales (Tanita Corp., Arlington Heights, IL) are provided for each clinical site. The scales should be set to be read in kilograms. Ideally, body weight is measured in the morning after voiding and before breakfast. If this is not possible, efforts should be made to weigh each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids).

The subject should be instructed to stand still in the middle of the scale platform with head erect and eyes looking straight ahead. Record the weight in kilograms to the nearest 0.1 kg as indicated on the digital display. Ask the subject to step off the scale and check that the digital display returns to zero. Repeat the measurement and record the weight.

All weight measurements will be taken and reported in kilograms. Participants with full limb amputations (that have occurred since randomization) or participants who are wearing casts should have a weight measure taken. Note this on the form in the space provided.

If a participant's balance is unstable making it difficult to obtain the two weight measures, staff may instruct them to **lightly** touch a mounted bar, wall, chair, or walker to provide balance. It is strongly recommended to locate your scale next to a wall or bar. If this is not possible at your site, a chair or walker can be placed

in front of the scale. Only the lightest touch should be used (use the finger tips, do not allow the participant to grip or use entire hand). Usually the weight will lock once the participant's balance is stabilized for a short moment using the method described above

16.1.3.1. Quality Control

Instructions on the use of the scale and warranty information were shipped with the scales. These documents should be stored in a convenient location for future reference. Follow the manufacturer's instructions in putting the scales into service and using them. The scale must be positioned on a level floor. Never drop a weight on, or subject the scale platform to shock loading and do not store equipment or weights on the platform. Moving of scales should be avoided, and calibration should be rechecked after moving a scale to a new location.

The weight used for calibrating the scale should be stored on the floor adjacent to the scale and used according to the manufacturer's instructions. Recalibration of this weight is not necessary unless some damage has been incurred.

16.1.3.2. Weekly Calibration Checks

Calibration checks will be carried out prior to the weighing of the first subject at the start of the study, at least weekly thereafter so long as subjects are scheduled for measurement visits, and before weighing a subject after a period of time greater than one week during which no weight measurements were made. At each calibration, values will be recorded in a log maintained for this purpose (Appendix 16.A.). The log will be reviewed during site visits.

The tolerance on a scale capable of weighing up to 200 kg will be considered as ± 0.1 kg (one scale division). Deviations of more than one scale division will require corrective action, specifically, the scale must be shipped to the manufacturer for calibration. Contact Tanita Technical Assistance at 1-877-682-

6482. Tanita will provide you with an authorization number and instructions on shipping the scale.

The calibration procedure described below is a compromise between frequent time-consuming checking in order to rule out a rare and improbable event (i.e., scale failure), and the highly undesirable event of having erroneous or missing weight data in a study largely focused on weight loss.

16.1.3.3. Calibration Procedure

Calibration checks should be carried out on equipment in its normal location. A class F certified 20 kg calibration weight will be used for checking scale calibration. The calibration weight should be stored and used according to manufacturer's instructions (which should be saved and filed along with accompanying certificates).

The calibration weight should be stored on the floor against the wall near the scale, NOT on an elevated surface. This will keep carrying the weight to a minimum. Staff should review the recommended procedures for lifting heavy objects (bend at the knees, keep back straight, etc.) Sites might assign a staff member who is more physically capable to do the calibration on a regular basis. Finally, the 20 kg weight could be replaced with two calibrated 10 kg weights. A good procedure for placing the calibration weight is to put the weight in the center of the scale platform leaving some room at the edges for the feet.

The following procedure checks the repeatability of readings and the linearity of the scale in a portion of the working range.

1. Place the 20 kg weight (gently) on the scale platform. Record the weight indicated on the scale.

2. Remove the weight from the scale platform and allow the display to return to zero.
3. Step (or have an assistant step) on the scale. Record the weight indicated on the scale.
4. Step off the scale. Allow the display to return to zero.
5. Have the assistant step on the scale platform while holding the 20 kg weight. Record the scale reading.
6. Step off the scale. Allow the display to return to zero.

Repeat the six steps above at least once, then compare the values obtained.

If the repeated weighing of the calibration weight, or the assistant's weight, or the weight of the assistant plus the calibration weight do not yield the same values each time, or, if the weight of the assistant plus the calibration weight is more than 0.1 kg different from the sum of the two weighed individually then the scale is probably faulty. Contact Tanita (as described above) for instructions on how to ship the scale to them for calibration.

Results of the above tests should be recorded in the calibration log, signed and dated by the person performing the calibration, and the form will be retained as part of the study documentation. If the tests indicate that the equipment is out of tolerance or faulty, the nature of the deviation and the action taken should be noted as a comment on the calibration form.

16.1.3.4. Annual Commercial Calibration

- Annually, beginning one year from the date a new scale is placed into service, or if the scale is not new, before the date the scale is placed into service and annually until all Year 4 visits have been completed. The manufacturer of the scale (Tanita) shall be

engaged to certify the calibration of the scale. Once all participants enter Phase III, annual calibration of the weight scales will not be necessary. Weekly calibration of the scales as outlined in the MOP will continue. Service and repairs should be performed as needed. If service is required, instructions found in this Chapter should be followed.

Contact information:
Tanita Corporation of America, Inc.
2625 South Clearbrook Drive
Arlington Heights, Illinois 60005, USA
Phone: (847) 640-9241
Fax: (847) 640-9261
Customer Service: (847) 640-9241

Calibration must be carried out with a sufficient number of test weights to load the machine at four or more points across its working range. A calibration certificate should be issued by the commercial contractor recording:

- the date of calibration
- serial number of the scale
- test weights used and scale readings at those test weights
- deviations observed at each load
- the nature of any adjustments or corrections made to the scale (i.e., before/after readings)
- Name and signature of the technician who carried out the calibration

This certificate will be kept in the log along with the record of weekly site staff calibrations.

16.1.4. Waist Girth

The Gulick II Tape Measure (model 67020) will be used for accuracy in obtaining duplicate waist girth measurements. The design of the tape measure eliminates

the guesswork by applying a known amount of tension (four ounces) to the measuring tape. When used properly, tape tension is always four ounces. Therefore, accurate measurements are possible no matter who is doing the measuring.

The Gulick II is standardized equipment for Look AHEAD. An ordinary tape measure (without the special four ounce tension indicator device) will vary in measurement and is dependent on how tightly the tape is pulled. If you pull harder and harder, tissue compression will be greater and greater, and the measured circumference will become smaller and smaller. Two consecutive measurements are usually quite different. If two or more people take the same measurement, the results rarely agree. It is clear that only by applying a constant tension (as the Gulick II does), can accurate and repeatable measurements be taken.

The Gulick II Tape Measure uses a no-stretch, retractable tape with both Metric and English gradations (centimeters and inches). The tape is non- metallic, thereby eliminating the discomfort of a cold object touching the skin and any possibility of scratches or cuts. The self-retracting tape is kept at the desired length until the retract button is pushed.

The most important part of the Gulick II Tape Measure is the tensioning device attached to the measuring tape. Its function is to provide a known amount of tension while a measurement is being taken. Each individual tensioning device is calibrated to indicate precisely a four ounce tension. Note that a stainless-steel *compression* spring is used. This guarantees that the calibration will last a lifetime, since it is impossible to “over-compress” a spring of this type.

To take measurements: Pull an appropriate amount of tape out of the housing. Wrap the tape once around the waist (see instructions below). Align the tape's "zero line" along side of the tape graduations. Use the Metric units (cm). Now simply pull on the end of the tensioning mechanism until the **calibration point** is just seen. Read the measurement next to the tape's "zero line".

What is meant by "calibration point": When you pull slightly harder and harder on the tensioning device, two colored beads will be seen separated by a silver disk. When you are pulling with exactly four ounces of force, you will see a silver disk separating the two beads. When you see one of the two beads, you are at the "calibration point". Remember, four ounces is not a great deal of force, in fact, it is approximately equal to the force required to lift a stack of 20 U.S. quarters. So don't pull so hard that the beads start to disappear into the end cap of the tensioning device. That is too much force.

Ideally, waist circumference would be measured in the morning after voiding and before breakfast. If this is not possible, efforts should be made to measure each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids).

Participants should stand with feet together. The measure should be taken around the abdomen horizontally at midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. Mark the midpoint on both sides using a washable marker. (Participant may be asked to assist in passing the tape around the abdomen by holding the end of the tape in position). The tape should be aligned with the markings and positioned in the horizontal plane at the correct height. At this point, it may be helpful to mark the position of the tape on the participant's back in order to insure proper placement for the second reading. The participant should be asked to keep relaxed arms at

the sides and to breathe naturally. Ask the participant to breathe in, out, and hold at the end of a normal exhalation. Record circumference to the nearest 0.1 centimeter. Remove the tape and repeat the procedure. If the tape cannot be made horizontal across the waist markings, default to the right hip.

16.2. ANKLE BRACHIAL INDEX

16.2.1. Introduction/Rationale

Lower extremity arterial disease manifests in individuals with diabetes mellitus at a higher rate than in the non-diabetic population, and may be associated with other complications of the disease. Arterial occlusion can be a precursor to intermittent claudication, ischemic leg pain at rest, foot or limb ulceration and gangrene. Arterial wall calcification has been shown to coincide in some cases with disturbed lipoprotein profiles, hypertension, peripheral sensory neuropathy, overt nephropathy and proliferative retinopathy. The Ankle Brachial Index (ABI) measurement is a non-invasive procedure that can be easily performed by a certified technician in the clinical setting. Abnormal findings on an ABI procedure done during a standard visit with a Look AHEAD participant could alert researchers to the likelihood of peripheral arterial disease (PAD).

16.2.2. Background

The ABI is a useful tool for detecting the development of obstructive changes to the arteries in the leg or calcification of their walls. Vessel occlusion is most frequently due to atherosclerotic plaques. ABI measurement, therefore, is a technique that enables early detection of atherosclerosis.

The ABI is computed by dividing the ankle systolic blood pressure by the arm systolic blood pressure. In normal individuals, ankle pressures are similar to (or somewhat higher than) arm pressures when the patient is supine. When arterial occlusive disease is present, a low ABI (less than 0.9 is considered to represent

presence of PAD) is found. When ABI is confirmed to be lower than 0.4, referral to the participant's physician will be recommended on the Participant Report. A high ABI (greater than 1.3) combined with a difference of 75 mmHg or more between arm and ankle pressures (ankle pressure being the higher) or a SBP reading greater than 300 at any ankle site is suggestive of arterial wall calcification (leading to a non-compressible vessel). Diabetes is associated with an increased prevalence of this condition. In the setting of a non-compressible vessel, the ABI is not an accurate measure of PAD. Follow-up or diagnosis of this condition, done by the participant's local physician, might include a toe pressure done in the setting of a vascular laboratory.

16.2.3. Schedule of Administration

ABI determination is performed at baseline and annual visits 1, 2, 3, and 4. It is suggested that ABI measurement be done at the beginning of a visit, second only to the seated blood pressure measurement. This will help to avoid any effect on pressures caused by potentially stressful anthropometric measurements, phlebotomy or questionnaires.

Contraindications: Persons with venous stasis ulceration, thrombophlebitis or other pathology that precludes placing a cuff around the ankle (e.g., open wound) should not undergo ABI determination. A note should be made in the study chart on the ABI source document explaining the reason that the procedure is not being done. This should also be noted on the Incomplete Visit Form.

Some post-mastectomy patients may also refuse blood pressure measurement on the affected arm. In such a case, only the unaffected arm should be used. The reason should be noted in the study chart and on the ABI form at item 1.i .The correct response for this situation would be "No", with a brief explanation added at "Why Not?".

16.2.4. Required Equipment, Materials & Personnel

Doppler: Assessment of ankle and arm systolic pressures is performed using a continuous-wave Doppler system. A hand-held device is used to evaluate the blood pressure in the brachial, dorsalis pedis and posterial tibial arteries. Look AHEAD will use the Medsonics BF4B Vascular Doppler instrument. Alternatively, an audible doppler instrument can be used (Elite Model No. 100 from Nicolet Vascular, Catalog No. EN50).

Sphygmomanometer: A standard manometer with tubing that can be detached from the cuff is preferred. (Note that many hospitals are phasing out mercury manometers; you should check with your institution's environmental safety committee to determine whether you should use an alternative device).

If you are changing from a mercury manometer to an aneroid instrument during the study the following cross calibration procedure should be followed and documented:

1. Check the zero calibration and the integrity of the pressure system on the new instrument as described under maintenance below.

2. Before retiring the mercury manometer, a cross calibration check should be performed by inserting a Y or T connector in the tubing and pressurizing the mercury and aneroid instruments simultaneously. The difference should not exceed 2 mm/Hg at any point. On initially putting into service an aneroid instrument, it should also be checked against the mercury instrument for differential lag. With the cuff secured around a cylinder, pressurize the instruments simultaneously to 240 mm/Hg, then open the airflow valve to release the pressure at approximately 2 mm/Hg per second. Follow the readings on both instruments as the pressure drops to confirm that the values track closely. Maintenance checks should be performed monthly on the sphygmomanometer

used for ABI determination. A log should be maintained to document these maintenance checks. The following tests are suggested:

1. With the instrument placed flat on a table and the inflation system disconnected, the level of the mercury in the column should read such that the top of the meniscus is on the zero line when the eyes are level with this line. For an aneroid instrument, with the inflation system disconnected the manometer needle should rest within the zero band.

2. With the inflation system reconnected, the cuff should be secured around a cylinder. The airflow valve should be closed and the instrument inflated until the pressure rises to 240 mmHg. The airflow valve should then be slowly opened and the pressure allowed to fall to 200 mmHg. The valve should then be closed; at which time the pressure should remain stable. If the pressure continues to fall, there is an air leak. To localize the leak, the system should be re-inflated to 240 mmHg and the tubing pinched at various locations. Appropriate replacement of the tubing, cuff or valve should be performed.

3. For a mercury manometer, with the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If a leak occurs, the cap should be tightened. If the leak persists, the silicone rubber that provides a seat for both ends of the glass tube should be replaced. This should not be done in the clinic, because any mercury leaks are likely to lead to extensive decontamination procedures by the local environmental protection units. Any maneuver that could result in mercury spills or leaks should be done in local bioengineering units or their equivalents. All leaks should be reported immediately.

4. For an aneroid manometer, if a mercury instrument or other standard is not available for periodic calibration checks, it should be checked by a bioengineering department or a commercial provider of such services at 6-month intervals.

Cuffs: A standard type cuff used for measurement of arm blood pressure should be used at the ankle also. The need for appropriately sized cuffs for obese arms

applies to the ankles as well. Cuff width for any site should equal approximately 40% of the limb circumference. Three adult size cuffs should be available for the ABI procedure, as well as one small and one large cuff for those subjects who may require them.

Other materials: Ultrasound transmission gel, transeptic cleansing solution spray for the Doppler, 2inX2in gauze sponges (or tissues) for gel removal and equipment cleaning and replacement batteries (9V) are required. A dark-colored cosmetic pencil or Sharpie is also useful for marking the locations of pulses after the first measurements are recorded so that they can be found again if repeat measurements are necessary.

Personnel: Only technicians who have been certified by the Program Coordinator or another certified Look AHEAD staff member should perform the Ankle Brachial Index measurement on study participants. These technicians should preferably be masked to participants' intervention assignments.

16.2.5. Procedures

Preparation: The participant should remove shoes and stockings and roll up trousers so that the ankles are bare to mid-calf. Both arms should also be bare. The subject should lie supine on the examining table, with the feet at the free end. The arterial pulses are located and marked.

The brachial artery is located on both arms by palpation of the antecubital fossa. A mark with the cosmetic pencil or Sharpie will make the pulse easy to locate again when the Doppler transducer is applied.

The ankle/foot arteries on both legs are located by palpation and marked. The dorsalis pedis artery is found on the dorsum of the foot. It is often palpable in the metatarsal region, proximal to the space between the great toe and the second toe. Another location where it may be palpated is at the top of the foot, where

the foot meets the ankle. The posterior tibial artery lies posterior to the medial maleolus.

The right arm cuff and the left arm cuff is applied with the bladder and arrow on the cuff aligned with the arterial markings the have been made on the participant's arms.

The right leg cuff and the left leg cuff is applied so the **midpoint of the bladder is aligned over the posterior tibial artery.**

A minimum of five minutes should pass after the patient lies down, before the first reading is taken. This rest will allow any changes in pressure that might have occurred due to walking to stabilize.

Observe the following in obtaining the pressure:

1. **Only systolic pressures are recorded**. The technician should listen to the pulse during inflation of the cuff and continue to inflate 30 mmHg beyond the point of pulse obliteration.
2. The Doppler transducer should be placed at a 45 to 60 degree angle lengthwise along the artery so that the best velocity signals will be obtained. Sufficient gel should be applied to fill the angle between the skin and the transducer. At each site, the gel should be applied just prior to cuff inflation in order to prevent the gel from dissolving and pooling under the limb. Care must also be taken to maximize the signal by slowly moving the probe back and forth over the artery to obtain the loudest signal. When the loudest signal is obtained, the measurement should be made.
3. Cuff deflation must be slow (2 mmHg/sec) to accurately determine the point at which blood flow is restored in the artery. The pressure is recorded at the point at which the Doppler signal first appears during deflation.

4. When taking the blood pressure in the ankle, the technician should keep an eye on his/her hand while pumping up the cuff to avoid having the hand slide off the vessel (a very common mistake which leads to underestimating the pressure). The gel may be wiped from the site after the blood pressure is recorded.

Collecting the Blood Pressure Readings: All readings should be recorded on the Look AHEAD Ankle-Arm Blood Pressure and Waist Form. It is recommended that a second staff person be available to record the blood pressure readings. This allows the technician to proceed efficiently from one site to the next and ensures that all readings are correctly recorded.

There are three components to the procedure:

1. Determine the "High Pressure Arm".
    a) Take a reading of the systolic pressure in the Right Arm and record the reading in item 1.a.
    b) Take a reading of the systolic pressure in the Left Arm and record the reading in item 1.b.
    c) Mark the box in Item 1.c corresponding to the arm with the highest pressure. This will be referred to as the High Pressure Arm.
    d) In cases where the same pressure is obtained for the right and left arms, the right arm will be designated as the High Pressure Arm in item 1.c.

2. Collect blood pressures at ankle sites.

Once the High Pressure Arm has been determined, proceed to collect pressures at the ankle sites designated and record the pressures on the form in items 1.d through 1.g. It is not necessary to realign the cuff for each ankle pressure on a leg.

Item: 1.d = Right dorsalis pedis

1.e = Right tibialis posterior

1.f = Left dorsalis pedis

1.g = Left tibialis posterior

3. Repeat the blood pressure measurement of the High Pressure Arm (same arm as designated in item 1.c on the form.) Record this arm pressure in item 1.h.

16.2.6. Calculation of the ABI

The calculation of the ABI is not required, but may be done at the time of the clinic visit using Section B of the form. The items in Section B will not be included in the data entry screen for this form.

Two ABI measures may be calculated (one for the right and one for the left ankle). The formula for each calculation is the following:

$$\text{Right ABI} = \frac{\text{Higher Right Ankle Pressure (choose from dorsalis pedis and tibialis posterior)}}{\text{Higher Arm Pressure (mm Hg)}}$$

$$\text{Left ABI} = \frac{\text{Higher Left Ankle Pressure (choose from dorsalis pedis and tibialis posterior)}}{\text{Repeated measure of Higher Arm Pressure (mm Hg)}}$$

EXAMPLE

Right ABI = $\frac{\text{Higher Right Ankle Pressure}}{\text{Higher Arm Pressure}} = \frac{92 \text{ mm Hg}}{164 \text{ mm Hg}} = 0.56$

A systolic blood pressure reading of greater than 300 mm Hg at any ankle site should be confirmed by a second reading. A reading greater then 300 mm Hg likely indicates significant arterial wall calcification, which would make the measurement inaccurate. If a second technician confirms the reading of greater than 300 mm Hg, the Program Coordinator should be informed.

The ABI will be calculated and included in the annual Participant Report, along with a notation that any value less than 0.4 may indicated circulation problems in the leg and should be followed up by the participant's private physician.

An asterisk in place of an ABI value on the annual Participant Report indicates that the measurement was not done or that it could not be calculated because there was missing data.

16.2.7. Quality Control

All technicians performing ABI determination on Look AHEAD participants must be certified for this procedure by the Program Coordinator or another certified instructor. Certification must be renewed annually.

Maintenance checks should be performed monthly on the sphygmomanometer used for ABI determination. A log should be maintained to document these maintenance checks. The following tests are suggested:

1. With the instrument placed flat on a table and the inflation system disconnected, the level of the mercury in the column should read such that the top of the meniscus is on the zero line when the eyes are level with this line.

2. With the inflation system reconnected, the cuff should be secured around a cylinder. The airflow valve should be closed and the instrument inflated until the mercury rises to 240 mmHg. The airflow 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. To localize the leak, the system should be re-inflated to 240 mmHg and the tubing pinched at various locations. Appropriate replacement of the tubing, cuff or valve should be performed.

3. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If a leak occurs, the cap should be tightened. If the leak persists, the silicone rubber that provides a seat for both ends of the glass tube should be replaced.

4. If the mercury becomes dirty over time and oxide is deposited on the inside of the glass tube, the instrument should be sent out for cleaning. No staff person should attempt this cleaning.

The Doppler transducer should be tested for battery failure prior to use for ABI measurement. The tester should apply gel at his/her own radial artery, position the transducer, then listen for biphasic pulse sounds. If pulse sounds are faint when volume is adjusted, or not present, batteries should be replaced.

16.3. SEATED BLOOD PRESSURE

16.3.1. Introduction/Rationale

Blood Pressure (BP) level is a major risk factor for coronary heart disease, congestive heart failure and stroke. Heart rate reflects autonomic nervous system function and cardiovascular fitness. Risk for serious cardiovascular events is especially high for people who have diabetes and for persons who are

overweight or obese. Given that the Look AHEAD study population is comprised of subjects who have type 2 diabetes and are overweight, careful monitoring of these measurements is an essential component of study data collection.

16.3.2. Background

Individuals with type 2 diabetes who are overweight are at particularly high risk of cardiovascular and all-cause mortality, as are individuals with low levels of physical activity or poor fitness levels. Documented changes in heart rate and blood pressure measurements over time, when these measurements have been taken by trained personnel under controlled conditions, can be indicators of improvement or diminishment in fitness, and therefore of increased or decreased risk for cardiovascular event.

16.3.3. Schedule of Administration

Seated blood pressure and heart rate measurement is performed at screening/ baseline, and at all annual visits through study closeout.

It is suggested that seated blood pressure and heart rate measurements be done at the beginning of a visit, but only after the participant has been sitting quietly for at least five minutes. The five-minute rest preceding the first measurement will allow blood pressure and heart rate to stabilize after movement or activity, such as walking.

During this five minute resting period, participants should NOT be engaging in any of the following: reading, filling out forms, talking or crossing their legs or ankles.

Clinic staff should explain the blood pressure procedures to the participant prior to the five minute rest period. Participants should be educated about how blood pressure can be affected by any of the above, and told that the five minute resting period helps the Look AHEAD study obtain more accurate measurements. Making these the first procedures done in a participant's visit will help to avoid any physiological response which might occur due to stress related to anthropometric measurements, phlebotomy or questionnaires.

16.3.4. Required Equipment, Materials & Personnel

Dinamap Monitor Pro 100: This automated device offers the advantages of greater accuracy when compared with manual mercury sphygmomanometry along with reduced potential for observer biases and decreased demand on staff in terms of training and effort in data collection. All Look AHEAD locations will use only this instrument for the seated blood pressure measurement.

Cuffs: Cuff size will be determined by arm circumference. Each of the following cuff sizes should be available: Adult, Large Adult, Thigh and Long Large Adult.

Measuring tape: To be used for measurement of the participant's arm circumference.

Other materials: A dark-colored cosmetic pencil is also helpful for marking the skin when finding the location of the arm circumference measurement.

Personnel: Only technicians who have been certified by the Program Coordinator or another certified Look AHEAD staff member should perform the seated blood pressure and heart rate measurements on study participants.

Printer Set-up:

Printer paper is loaded by pressing the notched (thumb print) indentation on the printer door to open. With the monitor turned on, place the roll of paper in front of the silver roller and the paper will automatically feed. As the paper touches the plates, it will begin to auto-feed into the printer. Once the paper begins feeding, slip the loose end through the slot in the door, close it and press the notched indentation to lock it.

The gray knob at the upper right of the monitor functions in a manner similar to a computer mouse. Rotate the knob to highlight options on the display. Push the knob to select a highlighted option (like “clicking” with the mouse).

It will be most advantageous to preset the printer with automatic printing as the default setting. This eliminates having to change the printer setting with each subject. To set the printer to this default, use the following steps:

1. With the monitor turned on, turn the gray knob to highlight MORE... and press. Next turn the gray knob to highlight SERVICE and press.
2. To enter Clinician Service Mode, a series of four code numbers must be entered. Highlight and press, in order, the numbers 1, 2, 3 and 4. Turn the gray knob to again highlight MORE... and press. Next turn to highlight PRINT and press. When the question appears RESTORE PRINT MODE ON POWER UP?, highlight YES and press.

3. Turn the monitor off, and then back on. Turn the gray knob to highlight PRINT and press. When AUTO/MAN is highlighted in the PRINT menu, press the gray knob to toggle between options until the option PRNT:AUTO appears on the lower right side of the screen. Return to the main menu by highlighting MAIN and pressing. The printer is now set for automatic printing.

The printed tape that comes out of the Dinamap should be kept in the participant's source document or clinic chart. The telephone number to order paper for the Dinamap is 1-800-558-5102.

16.3.5. Setting Initial Target Inflation

It has been recommended that we set the initial target inflation pressure as a permanent default at 180 mm Hg. The instructions are in the Dinamap manual but have been summarized as follows:

1. Select MORE… from the main menu
2. Select SERVICE… from the next menu
3. Select the numbers 1, 2, 3, 4 sequentially to access the clinician service menu (page 57 in operations manual)
4. Select PRESS and adjust the target pressure to 180 mm Hg by turning the gray knob, then press the knob to set (page 58)
5. Select OK and press, then select MAIN

Remember that the target inflation pressure can be adjusted at any time from the main menu by selecting SET BP and changing as desired. However, once the monitor is powered off the clinician service default of 180 mm Hg returns on power-up.

16.3.6. Procedures

Preparation: First it is necessary to determine the participant's right arm circumference, in order to select the appropriate cuff size for the blood pressure measurement. This is done by the following steps:

1. Ask the participant to bare the right arm and hold it at the side of the body with the elbow flexed to 90 degrees and palm up.
2. Measure the length of the arm from the acromion process (bony extremity that forms the highest point of the shoulder) to the olecranon process (tip of the elbow) and determine the halfway point in this length. Mark this midpoint on the posterior surface of the arm.
3. Have the participant relax the arm along the side of the body and place the measuring tape around the arm at the midpoint mark.
4. Holding the tape parallel to the floor, draw it around the arm with a degree of tension that keeps it snug against the skin, but without indentation of the flesh.
5. Measure the right arm circumference to the nearest tenth of a centimeter and record on the data form. Note that this measurement is not meant to be a precise anthropometric measurement, it is meant to determine appropriate cuff size only.
6. Using the arm circumference measurement, determine the correct cuff size according to the chart that follows:

Arm Circumference	Cuff Size
17-25 cm	Small Adult
23-33 cm	Adult

31-40 cm	Large Adult
38-50 cm	Thigh (or Large Adult Long, see text)

The sizes for cuffs are overlapping in order to have some flexibility in choice. The first choice for cuff should always be for the larger size. However, if the participant is small in stature, the smaller cuff size might be used to avoid having the cuff slide up over the shoulder or down the antecubital fossa.

If a participant's upper arm circumference would indicate use of the thigh cuff, but the arm is too short for the cuff, or the cuff does not remain secured when inflated, the Large Adult Long arm cuff should be used. Difficulty with placement is often a problem with obese participants, resulting in readings that are too high or too low when compared with a manual measurements.

Taking the seated blood pressure and heart rate readings:

The subject should be seated with both feet flat on the floor and the right forearm resting on the table. Palpate the antecubital fossa and position the cuff around the arm so that the midpoint of the bladder length is at heart level, and the cuff arrow marked "artery" is aligned with the brachial artery. Cuffs are labeled with range and index lines. The correct cuff has been selected if the index line is within the range as the cuff is wrapped around the arm. The cuff should be wrapped snugly enough that no more than one finger-width distance exists between cuff and skin.

Have the participant rest for five minutes prior to taking the first measurement. To begin the procedure, push the green and orange START/STOP button at the lower right corner. This will inflate the cuff and initiate the first reading. Once the

reading is obtained, the data will appear on the screen, and the cuff will automatically deflate. The print out will begin to emerge from the printer.

After a minimum 30-second wait, push the START/STOP button to obtain the second reading. When this reading is completed, tear the print out from the printer and record the first and second blood pressure readings. Record the heart rate data from the first reading as the pulse on the data forms.

If the cuff accidentally becomes inflated and it is not on a limb, it can be manually deflated by unscrewing the cuff from the cord and manually pressing the air out.

Note: Monitor battery and screen life are optimized if the monitor is left plugged in, but is turned off at the ON/OFF button when the device will not be used for several hours, or until another day.

16.3.7. Quality Control

All technicians performing the seated blood pressure and heart rate measurements on Look AHEAD participants must be certified. Certification must be renewed annually.

Annual calibration of the Dinamap Pro 100 instrument should be done by the manufacturer, GE Medical Systems. To set up a return of the machine, call 1-800-558-7044. There is an option on voice mail for "service dispatch". Press that option and set up a return for calibration. Each clinic will be given an authorization number for return. If you desire a loaner, you must ask for customer service, and will need to provide a purchase order number to insure that the loaner is returned. You will be charged if it is not returned. Fees for calibration of the instrument have ranged from $300-600 over the course of the study. Confirm

the charges before proceeding with the process. A service and maintenance contract implemented 8-2008 will cover the cost of calibration/ maintenance and repairs. You must provide the serial number and indicate that a service warranty is in place before sending the device. The service/maintenance agreement number is 1-C7DDoK.

Reference

Look AHEAD Research Group. Cardiovascular effect of intensive lifestyle intervention in type 2 diabetes. N Engl J Med. 2013 Jul 11;369(2):145-54. doi: 10.1056/NEJMoa1212914. Epub 2013 Jun 24. Erratum in: N Engl J Med. 2014 May 8;370(19):1866. PMID: 23796131.

Appendix 16.A. Scale Calibration Log

Scale Model & S/N:							
Date	20 kg	Tech. Wt.	Tech + 20 kg	20 kg	Tech. Wt.	Tech + 20 kg	Initials/Comments

Appendix 16.B. HEIGHT rounding to the nearest .5 cm Examples

Recording Height (from newsletter 11-2009)

Chapter 16 of the MOP indicates the following protocol for the recording of height: the subject's height is recorded to the nearest 0.5 cm. Some sites have previously rounded the measure while others have not. It is important to follow the MOP exactly so height is being recorded in a standardized manner. Please see the chart below as a quick reference and example of rounding to the nearest 0.5 cm.

Ht	Rounded
150.1	150.0
150.2	150.0
150.3	150.5
150.4	150.5
150.5	150.5
150.6	150.5
150.7	150.5
150.8	151.0
150.9	151.0