Sitting Blood Pressure and Ankle-Brachial Index Manual

Exam 4

July 25, 2024

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1 SITTING BLOOD PRESSURE OVERVIEW

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. Classification and staging of hypertension are more precise where systolic rather than diastolic is the principle criterion. Both systolic and diastolic blood pressure elevations are associated with increasing risk for cardiovascular disease. Middle-aged 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 (optimal 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.

Sitting blood pressure in Exams 1 and 2 was measured in a resting state, using 2 measurements with a random zero sphygmomanometer. Given the NIH mandate to reduce or eliminate the use of mercury in sphygmomanometry, the JHS conducted a blood pressure comparability study comparing BP measurements using the OMRON and the random zero mercury sphygmomanometer In Exam 2.

1.1 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 a joint committee of the American Heart Association and the Cardiac Society of Great Britain and Ireland established international recommendations on blood pressure measurement in 1939. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

Standardizing the measurement technique and the setting in which the measurement is taken controls some of the many extraneous factors influencing blood pressure. Uncontrolled factors (temperature, time of day, arm circumference, recent use of caffeine or tobacco, and identity of the observer) are recorded, so that they can be taken into account during analysis.

JHS participants are reminded during the scheduling of Exam 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. Participants are asked to take their blood pressure medications as usual prior to coming to the clinic for their Exam 4 visit. A detailed history of alcohol intake history is also recorded.

1.2 Staff Preparation for Participant Visit

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 the impact of daily blood pressure variation.

1.3 Classification and Referral Guidelines for Blood Pressure

The classification of blood pressure for adults is summarized in Table 1. The medical care referral guidelines for elevated blood pressure are summarized in Table 2. When a person has one or more sitting blood pressure measurements where the systolic reading exceeds 260 mm Hg or the diastolic reading exceeds 130 mm Hg (emergency referral), the JHS physician is consulted and the arrangements are made to transport the person to an emergency care facility. The JHS 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 3 are cancelled and Visit 3 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 JHS physician is notified for urgent referral unless the physician recommends otherwise.

Table 1.0 Classification of Blood Pressure for Adults, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) Guidelines

Category*	SBP (mm Hg)		DBP (mm Hg)
Normal	<120	and	<80
Pre Hypertension	120-139	or	80-89
Stage 1 Hypertension	140-159	or	90-99

Stage 2 Hypertension	≥160	or	≥100

When SBP and DBP fall into different categories, use the higher category.

Table 2.0 Medical Care Referral Guidelines for Blood Pressure, Based on Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII, 2003) 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 JHS 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 JHS 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	Refer to source of care within 1 month	Your BP is elevated.
	SBP 140-159 or DBP 90-99	Refer to source of care within 2 months	Your BP is elevated.
	SBP 120-139 or DBP 80-89	Recheck in 1 year (no JHS referral)	Your BP is in the pre-hypertension range
	SBP < 120[2]or DBP < 80	Recheck in 2 years (no JHS referral)	Your blood pressure is normal

1.4 Blood Pressure Referrals

As shown in Table 2, blood pressure referral levels are made based on the findings of the JHS examination which are consistent with the recommendations given in the seventh report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (2003). The average of three resting blood pressure readings is used.

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). Unusually low readings should be evaluated for clinical significance.[2]

2 SITTING BLOOD PRESSURE

Staff will use the Omron HEM907XL automated BP monitor for Exam 4.
The design and operation of the Omron HEM907XL are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and estimation of the systolic and diastolic BP levels by oscillometric methods. All readings are to be recorded to the nearest digit.

2.1 Equipment and Supplies

- Omron HEM-907XL or sphygmomanometer
- 5 cuff sizes, including thigh cuff
- Tape measure
- Foot stool
- Chair with arm support
- Timer
- Alcohol wipes
- Antibacterial wipes
- Tissue
- Gauze
- Water soluble ink pens
- SBP form

2.2 Data Collection

The sitting blood pressure form in Appendix 9 is used to record arm circumference, cuff size, blood pressure measurements, tine of measurement, and pulse rate.

2.3 Exclusion Criteria

- Persons with rigid arteries such that an occlusion pressure cannot be reached.
- Persons with bilateral amputations of arms.
- Persons who fit any of the above categories are recorded as missing data.
- If a participant has undergone a mastectomy of the right breast or has other reasons to omit right arm pressures, the left arm will be used for measures.

2.4 Cuff Size Selection and Application

The proper cuff size must be used to avoid under- or over-estimation of BP. Cuff size refers to the cuff's bladder, not the cloth. To choose the appropriate cuff size, the participant's arm will be measured first. In addition, the cuffs must be HEM907 XL-compatible (see manual in Appendix 1). If the right arm cannot be used, the left may be used. This change must be noted on the sitting blood pressure form.

2.4.1 Measurement of Arm Circumference

- Have participant remove his/her upper garment, or clear the upper arm area so that an unencumbered measurement may be made.
- Have the participant stand, with the right arm hanging and bending the elbow so that the forearm is horizontal (parallel) to the floor.
- Measure arm length from the acromion (bony protuberance at the shoulder) to the olecranon (tip of the elbow), using the *Gulick II* anthropometric tape.
- Mark the midpoint on the dorsal surface of the arm.
- Have the participant relax arm along side of the body.
- Draw the tape snugly around the arm at the midpoint mark. *Tape should be horizontal and should not indent the skin*.
- Measure and record the arm circumference in centimeters on the SBP form. Arm circumference and cuff size are in Table 3.

Table 3 Arm Circumference and Cuff Size

Cuff Size	**Arm Circumference (cm)**
Small	17-22 cm
Adult	22-32 cm
Large	32-42 cm
X Large	42-50 cm
Thigh	51cm+

2.4.2 Special Situations

The length and width of the cuff's bladder should encircle at least 80 percent of the length of the upper arm, and 40 percent of the width of the arm. If the upper arm is relatively short with a large circumference (> 50 cm), it may be difficult to fit a thigh cuff in a way that meets protocol. In this case, an appropriately sized cuff is wrapped around the participant's forearm, supported at heart level. The cuff size should be selected according to the forearm diameter, measured at the (approximate) midpoint of the forearm's

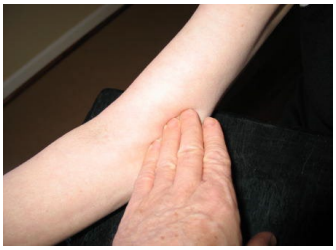
length. *Note: when taking the blood pressure on the forearm reverse the cuff, so that the marker referring to the brachial artery is at the elbow.*

Blood pressures measured on the forearm tend to overestimate the systolic and diastolic pressures, but they provide a good estimate of the systolic blood pressure in circumstances when a cuff is too small for a large arm, which can lead to misclassification of an individual as hypertensive. *Record the use of the R/L forearm in item 1 of the SBP form and add a note log to this effect.*

2.4.3 Placing the Blood Pressure Cuff

1. Ensure the participant is seated, legs uncrossed and feet flat on the floor, in a quiet room, with the elbow and forearm resting comfortably on the armrest of the BP measurement chair (or table), with the palm of the hand turned upward. The area to which the cuff is to be applied must be bare (free of clothing).

2. Locate the brachial artery by palpation and mark the skin with a small dot, using a water soluble ink pen. (The brachial artery is usually found just medial and superior to the cubital fossa, posterior to the biceps muscle and slightly toward the body). For brachial artery palpation, fingertips or thumb may be used (see figures to the right).



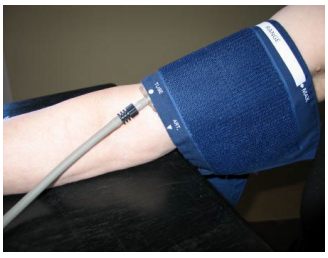
3. Place the appropriate cuff around the upper right arm so that:
    a. The midpoint of the length of the bladder lies over the brachial artery.
    b. The cubital fossa is at heart level.

NOTE: The midpoint of the length of the bladder should be confirmed by folding the bladder in two.

4. Place the lower edge of the cuff, with its tubing connections, about 1 inch above the natural crease across the inner aspect of the elbow (the cubital fossa).

5. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward, making sure the long edges of the cuff lie on top of each other as the cuff is wrapped around.

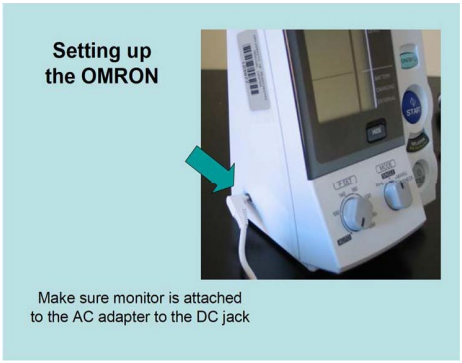
6. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.



NOTE: The cuff should not be wrapped too tightly around the arm.

2.4.4 Omron HEM-907XL Set-up

1. Check to ensure the monitor is attached to the AC adapter, DC jack, and plugged in. Make sure the AC sign is visible in the lower window.



2. Push the ON/OFF (power) button for more than three seconds while holding the START button simultaneously: F1 is displayed in the first window and three inflation (3) is displayed in the middle window. If needed push the DEFLATION (deflation control)/Measurement Result Display Switch Button to change the set value to 3 inflations.

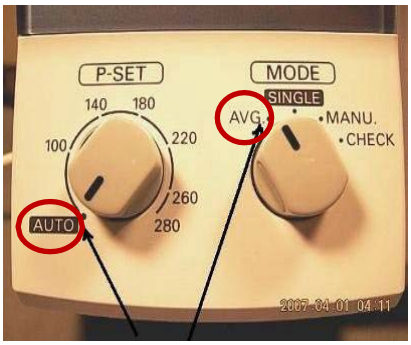
3. Push the START button and F2 function is displayed in the first window and 0 waiting time is displayed in the middle window. If needed push the DEFLATION (deflation control)/Measurement Result Display Switch Button and change the set value to 0 sec waiting time.

4. Push the START button and F3 function is displayed in the first window and inflation interval 30 second time is displayed in the bottom window. If needed push the DEFLATION (deflation control)/Measurement Result Display Switch Button and change the set value to 30 seconds measurement interval.

Table 4 *Settings for Omron HEM-907XL*		
Function #	**Items to set**	**Set value**
F1	Number of inflations	3 times
F2	Waiting time to start the first inflation	0 sec
F3	Inflation interval	30 sec

2.4.5 Measuring Blood Pressure

1. Plug the Omron machine into the electric outlet and push the ON/OFF button to turn on the power.



2. Set the P-SET (inflation level) to AUTOMATIC
3. Set the MODE to AVG. The monitor will automatically take three measurements one minute apart displaying the first, second, third, and average blood pressure readings.
4. Connect the air tube to the main unit by attaching the air plug to the base of the air connector. Connect the cuff to the air tube attached to the Omron unit.
5. Explain the procedure and allow the participant to rest for 5 minutes. Leave the room and set the timer located on the bin outside of the exam room.

6. After re-entering the room after the 5 minute rest period, press **START** on the Omron unit button to start the measurements. The cuff will inflate automatically and deflation will begin after the Omron detects no oscillometric waves. The dial will show sequentially in the bottom panel of the LCD screen 1st, 2nd, and 3rd measurements with 30 seconds between each listing.

7. After the first and second measurements are displayed, there will be a preset 30 second interval before the beginning of the next measurement. During this time have the participant raise their cuffed arm above their hands as in Figure 21 for the count of 5 and then return to the original resting position with the arm supported with the cubital fossa at heart level. Do not clench the fist. This is done after the 1st and 2nd measurements, to avoid venous congestion in the arm that may not have dissipated after inflation of the cuff – which in turn could increase the pressure recorded on subsequent measurements.

2.4.6 Manual Blood Pressure Readings-Sphygmomanometer

The sphygmomanometer is used by staff trained in the auscultatory blood pressure technique to determine systolic and diastolic blood pressure for participants with an arm circumference larger than 50cm. The manual is in Appendix 2.

1. Participant position

The patient should sit or lie comfortably. The arm should be fully supported on a flat surface at heart level. (If the arm's position varies, or is not level with the heart, measurement values obtained will not be consistent with the patient's true blood pressure.) When seated, the patient should have their back and arm supported, and their legs should not be crossed. The patient should relax prior to measurement comfortably for five minutes and should refrain from talking or moving during
measurement. Observer should view manometer in a direct line to avoid "parallax error."

2. Apply the cuff

Nylon cuffs are specially designed to promote the precisely accurate determination of blood pressure. Index and range markings ensure use of the correct cuff size. The artery mark indicates proper cuff positioning.

Place the cuff over the bare upper arm with the artery mark positioned directly over the brachial artery. The bottom edge of the cuff should be positioned approximately one inch (2-3cm) above the antecubital fold. Wrap the end of the cuff not containing the bladder around the arm snugly and smoothly and engage adhesive strips

NOTE: If the unit is equipped with a calibrated nylon cuff, featuring Index and Range markings, a correct fit may be verified by checking that the Index Line falls between the two Range Lines

3. Inflate the cuff

Close the valve by turning thumbscrew clockwise.

Palpate the radial artery while inflating the cuff. Be sure to inflate cuff quickly by squeezing bulb rapidly.

Inflate cuff 20-30 mmHg above the point at which the radial pulse disappears.
NOTE: Cuff pressure range is 0 mmHg to 300 mmHg.

4. Position the Stethoscope

Position the chestpiece in the antecubital space below the cuff, distal to the brachium. Do not place chestpiece underneath the cuff, as this impedes accurate measurement. Use the bell side of a combination stethoscope for clearest detection of the low pitched Korotkoff (pulse) sounds.

5. Deflate the cuff

Open valve to deflate the cuff gradually at a rate of 2-3 mmHg per second.

6. Measurement
Record the onset of Korotkoff sounds as the systolic pressure, and the disappearance of these sounds as diastolic pressure. (Some healthcare professionals recommend recording diastolic 1 and diastolic 2. Diastolic one occurs at phase 4.)

NOTE: It is recommended that K4 be used in children aged 3 to 12, and K5 should be used for pregnant patients unless sounds are audible with the cuff deflated, in which case K4 should be used. K5 should be used for all other adult patients.

After measurement is completed, open valve fully to release any remaining air in the cuff. Remove cuff.

2.4.7 Recording the Blood Pressure Measurements

After all the inflations are finished, the average of the three systolic pressures, diastolic pressures and pulse rates is displayed. Record these average measures on the SBP form in items 14-16. Push the DEFLATION button to toggle to the first set of measures and record the 1st set on the SBP form in items 5-7. Repeat this process by pushing the DEFLATION button to display and record the 2nd and 3rd sets of measures on the SBP form in Items 8-10 and 11-13, respectively.

Safety Note: *Average heart rate values that are 44 bpm or lower, or 110 bpm or greater, should be brought to the attention of the Field Center manager on site before participant leaves the field center. The study nurse should evaluate the possible reasons for an abnormally high or low heart rate and consult with the Cardiologist on call to refer the study participant for evaluation by their provider of care or to an emergency department, if deemed appropriate.*

An average heart rate value of 44 bpm or lower, or 110 bpm or greater does not require that a seated blood pressure per the protocol be repeated. An evaluation performed by a clinician may include a seated blood pressure, which is not recorded on the SBP form.

Push the ON/OFF button. This ends the blood pressure measurements for the participant.

2.5 Reporting Blood Pressure Values

The participant's blood pressure values are not discussed at the blood pressure station nor during the measurement process. The staff will have informed the participant that the blood pressure values and other results will be printed out and discussed with the participant at the end of the visit. If pressed, the staff can add that the research protocol requires that results not be discussed during the exam. The

Omron display and the computer monitor should be turned away from the participant so that the blood pressure values being recorded are not easily visible.

The average systolic and diastolic blood pressure values are reported to the study participant at the end of the exam and also as part of the consolidated report of study results that the field center sends to the study participant (and their health care provider, if instructed by the participant). In each case, the average systolic and diastolic pressure values recorded on the form are retrieved from REDCap and displayed in the report, with the narrative statement that corresponds to that value and whether the participant has reported being on antihypertensive treatment. The blood pressure results are reviewed with the participant during the exit interview, at which time JHS staff explain the recommended follow-up for the pertinent blood pressure level according to the 2017 Evidence-Based Guideline for the Management of High Blood Pressure in Adults.

As a participant safety procedure, if the average blood pressure is ≥180 mm Hg systolic or ≥120 mm Hg diastolic, the staff tells the participant that the procedure will be repeated as part of study protocol, removes the cuff and locates the brachial artery by palpation as shown in Figure 11, and repeats the blood pressure measurement steps. This second set of blood pressure values is recorded on the SBP form and entered into REDCap instead of the first set.

If the average blood pressure of the second set of readings is ≥200 mm Hg systolic or ≥120 mm Hg diastolic, the staff closes out the data entry screen per protocol, interrupts the field center examination and notifies the supervisor of this immediate alert situation. With input from the Field Center manager, JHS staff then assist the participant in scheduling a same-day visit to their health care provider, or arranges transportation to the nearest emergency room for a medical evaluation of the participant's blood pressure. If the average blood pressure of the second set of readings is 180-199 mm Hg systolic or 110-119 mm Hg diastolic, the field center examination may proceed, and JHS staff assists the participant in scheduling an appointment with a medical professional within 48 hours, to determine whether treatment should be started or changed.

2.6 Sitting Blood Pressure Training and Certification

All blood pressure technicians are trained locally by the lead technician prior to participant recruitment. Technicians are not required to be health professionals but must be trained and certified in the blood pressure technique. The certification requirement consist of two observations by the trainer on cuff size agreement and adherence to the BP measurement protocol. The primary technician must complete four BP procedures each month to maintain certification while the back-up technician must complete two each month. Recertification occurs every six months for technicians and annually for the lead technician. The checklist for observation of blood pressure measurements is in appendices 3, 6, and 8.

It is the responsibility of the Clinic Staff to conduct recertification procedures and report to the Clinic Manager when the procedures are complete. The trainer or lead technician should submit the certification request form (CRF) in Appendix 4 to the Coordinating Center for final evaluation.

2.7 Quality Control

To ensure the accuracy of the blood pressure measurements throughout the study, quality control measures are developed by the Data Management team and applied by Clinic Staff. These measures include:

1. Recruitment of the most qualified personnel
2. Standardized training and certification
3. Retraining and recertification
4. Observation of data collection by supervisors, using the checklist given in Appendix 3 every 6 months. One checklist is used for each technician and sent to the Coordinating Center each quarter.
5. Frequent staff meetings to provide feedback
6. Editing of data, both manual and by computer
7. Quality assurance program administered by the Coordinating Center.
8. Simultaneous Y Tube observation of each technician by the blood pressure supervisor every 6 months
9. Equipment maintenance program

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. These statistics are adjusted for weight, age and sex of the participants. Digit preference is also monitored for each technician.

2.8 Equipment Maintenance

Special attention must be placed on assessment and maintenance of the equipment's accuracy as per the manual in Appendix 5. The Clinic is responsible for the proper operation and maintenance of equipment. Maintenance responsibility is assumed by assigned staff and all staff are instructed to report any real or suspected equipment problems to the Clinic Manager or designee 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 7.

2.8.1 Omron

Staff will maintain all blood pressure equipment used in the field center. The steps that staff follow to check and maintain Omron equipment include the following:

- Omron HEM-907XL: Weekly. Wipe the monitor with a soft, damp cloth moistened with disinfectant alcohol, or diluted detergent. Complete cleaning by wiping the monitor with a soft, dry cloth.
- Blood pressure cuffs: Check the inflation cuff for cleanliness, and wipe between each use with disinfectant wipes.

Property Management will need to tag all new equipment and BioMed will need to inspect equipment annually.

2.8.2 Sphygmomanometer

Pocket Gauge: After measurement, fully exhaust cuff then wrap cuff around gauge and bulb and store in zippered carrying case.

NOTE: This product will maintain the safety and performance characteristics specified at temperatures ranging from 50°F to 104°F (10°C to 40°C) at a relative humidity level of 15% to 85%.

This device can be safely stored at temperatures ranging from -4°F (-20°C) to 131°F
(55°C) with a relative humidity of 90%.

Manometer: Your pocket aneroid gauge requires minimal care and maintenance.
The manometer may be cleaned with a soft cloth but should not be dismantled under any circumstances.

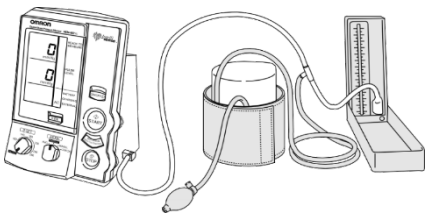
Should the indicator needle of the manometer rest outside the oval calibration mark, then the manometer must be re-calibrated to within ±3mmHg when compared to a reference device that has been certified to national or international measurement standards. A manometer whose indicator needle is resting outside of this mark is NOT acceptable for use.

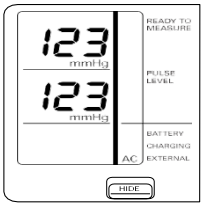
In the event that the gauge is ever in need of calibration, simply return for service.
Damaged or broken parts will be replaced as needed at a minimal charge. Refer to the warranty for specific details of warranty coverage. The manufacturer recommends a calibration check every 2 years

2.9 Equipment Calibration

Omron

Staff will calibrate all Omron units every three (3) months and document the results on the Omron BP Monitor Maintenance and Calibration Log in Appendix 5. Accuracy of pressure display can be checked in the CHECK Mode. Follow the steps below to calibrate each unit:





1. Connect the manometer, inflation bulb, cuff, and the monitor with the T-tube as shown in the figure on the right.
2. Tightly wrap the cuff over a sturdy cylinder.
3. Release the valve of inflation bulb to remove the air inside the cuff completely.
4. Push the ON/OFF (power) Button to turn on the monitor.
5. Set the MODE Selector to “CHECK”.
6. Close the valve of inflation bulb and inflate the cuff to the pressure to be checked, based on the manometer read.
7. Compare the pressure values displayed on the monitor to the one on the manometer.

Check result
Accuracy of the monitor is validated to be ±3 mmHg or 2% of standard manometer reading. If your result shows a difference exceeding the tolerance, contact Omron Healthcare’s Customer Service at 1-877-216-1336.

Sphygmomanometer

The manufacturer recommends a calibration check every 2 years. Should the indicator needle of the manometer rest outside the oval calibration mark, then the manometer must be re-calibrated to within ±3 mmHg when compared to a reference device that has been certified to national or international measurement standards. A manometer whose indicator needle is resting outside of this mark is NOT acceptable for use. In the event that the gauge is ever in need of calibration, simply return for service. Damaged or broken parts will be replaced as needed at a minimal charge. See the manual in Appendix 2.

3. ANKLE-BRACHIAL INDEX OVERVIEW

The ratio of the ankle blood pressure to the arm blood pressure (measured at the brachial artery) provides a measure of lower extremity arterial disease (circulation problems). The ankle-brachial index (ABI) is reduced to less than 1.0 when there is obstruction to blood flow in the legs. The ABI is a non-invasive measure of atherosclerosis. The ABI is associated with atherosclerotic disease in other vascular beds and predicts cardiovascular mortality.

3.1. Equipment/Supplies

- Unetixs Multilab Series II System
- Remote Cuff Selector
- Air Hoses (at least four)
- Remote Control to operate system
- Doppler Probe
- Doppler conducting jelly
- BP Cuffs in two sizes:
- SC – 10 Cuff
- SC – 12 Cuff
- Tissues to clean/remove conducting jelly
- Black, waterproof eyeliner pencil
- Tegaderm
- USB Flash Drive
- Flexible measuring tape

3.2. Exclusions

The below exclusion items are intended to determine the presence of any reasons the ABI measurements cannot be completed. Any participant who meets one or more of the below criteria should not complete ABI measurement. For each possible exclusion, circle "Y" for yes or "N" for no on the **ABI DATA COLLECTION FORM** (**APPENDIX 10**). For any "Y" response, conclude the procedure, informing the participant of the reason. Participants who fit any of the below categories are recorded as missing data.

1. Persons with any open wounds in the ankle or arm cuff area (with the exception of lesion due to venous puncture due to a blood draw)
2. Persons with bilateral amputation.
3. Persons unable to lay at supine.
4. Persons who have had a double mastectomy.

4 ABI PROCEDURE

4.1 Participant Set-Up Procedure

1. Initiate the process by telling the participant about the ABI process, reading the script at the beginning of the **ABI DATA COLLECTION FORM**:

   "You will have blood pressures checked in your arms and legs. The method used to do this is similar to how your doctor would typically measure your blood pressure. An ultrasound device will be used allowing you to hear the blood flow while the blood pressure is taken. There is no more discomfort involved beyond having a blood pressure cuff inflated on your arms and ankles."

2. Arms below the shoulder and legs below the knee should be bare. Ask the participant to remove shoes and stockings so that the ankles are bare.
   a. It is advisable to have either a gown or some other covering over the participant to ensure they stay warm during the exam. A cold examination room can cause vasoconstriction, which can negatively affect the results.

3. Have the participant lie supine on a comfortable horizontal examination table. The head and heels must be at the same level, and therefore the table must be long enough so that for each participant, the entire head and both feet must be on the table, not overhanging.
   a. An oversized examination table must be available at the field center for tall study participants because having the feet even slightly lower than the rest of the body will produce an invalid ABI measurement.

4. For the specific circumstance when the participant has a lesion that is a venous puncture due to a blood draw performed before the ABI measurement, apply a Tegaderm dressing over the puncture site and perform the measurement as described.
   a. In this situation, the Doppler probe should be disinfected with a Clorox Disinfecting Wipe both before and after insonation.

5. Have the participant rest quietly in the supine position (ask them to refrain from talking) for at least 5 minutes before beginning the measurement procedure.

6. While the participant is resting, place four BP cuffs on the participant. See images and Table 1 below for placement location and cuff orientation.
   a. When wrapping, place the tubing connector of the cuff on the medial side of the limb, this will ensure the bladder of the cuff is covering the area where the vessels are anatomically located.

b. Cuffs should be wrapped snugly but ensure that there is space for one finger to fit between the cuff and the skin.
c. Lift the participant's limb when applying the cuff. Instruct the participant to remain relaxed, stay still, and to refrain from helping you (e.g. lifting the arm to facilitate placement of the cuff).
d. Ensure there is no unusual folding or wrinkling of the cuff.

Table 1. Cuff Sizes for Arm and Ankle

Cuff Size		
SC – 10	10 centimeters wide	Use for calf, ankle, and arm sites
SC – 12 sites	12 centimeters wide	Use for above the knee and high thigh

Right arm

Left arm

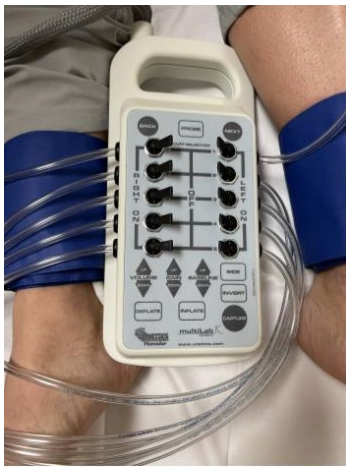
Right ankle

Left ankle

7. Obtain the Remote Control Cuff Selector and position it between the participant's feet, as seen below:

    a. When the switches are in the center position, all air valves will be closed, and no air will be directed to the cuffs.

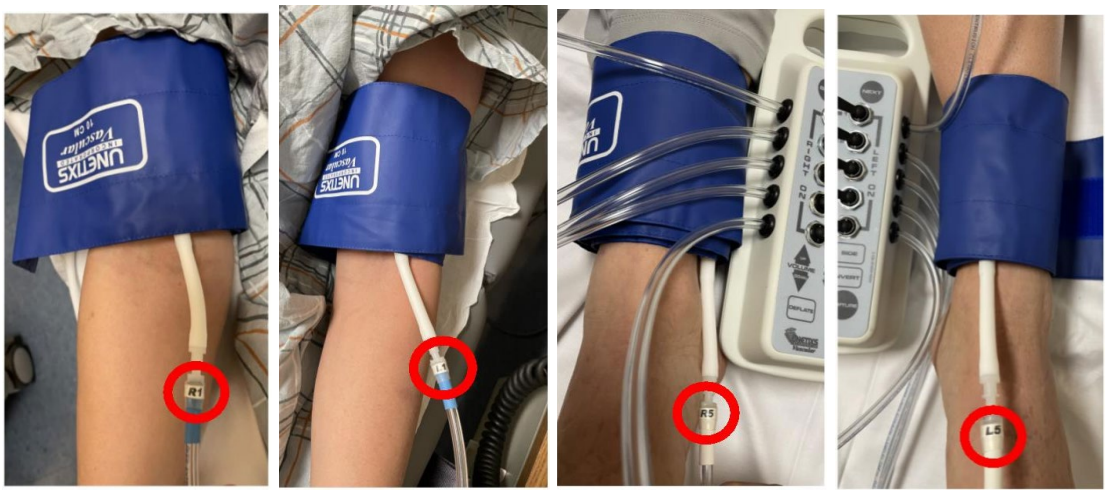
    b. Make sure only one switch is open at a time (further explanation will be provided in following steps).



All switches are in the "closed" position

8. Ensure all four cuffs are attached to the appropriate hose on the Remote Control Cuff Selector.
    a. Right arm cuff → **R1**
    b. Left arm cuff → **L1**

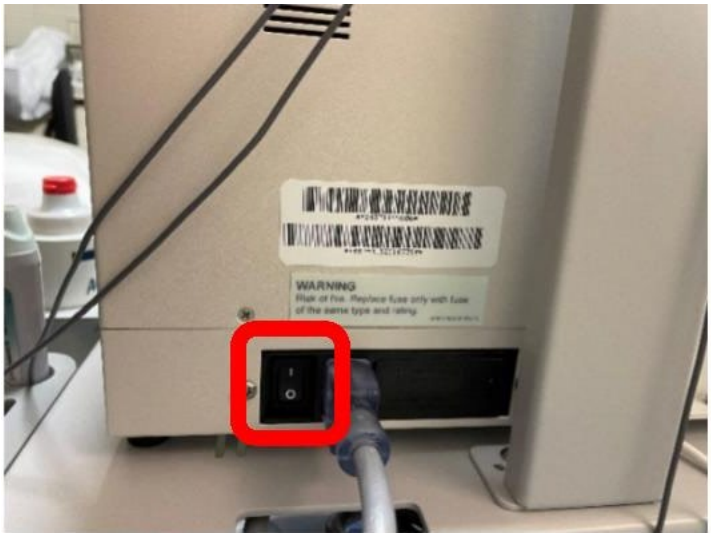
c. Right ankle cuff → **R5**
d. Left ankle cuff → **L5**



9. Once all four cuffs are in place and connected to the Remote-Control Cuff Selector, and the 5 minutes of resting are complete, you may begin the measurements as described below. Before you begin the procedure, instruct the participant to remain relaxed, stay still, and to refrain from helping you (e.g. lifting the arm to facilitate placement of the cuff). Once you begin the procedure, explain the steps to the participant as you proceed.

4.2 *Initializing the Device*

1. Plug in the Mulitlab device to a power outlet
2. Turn on the device and printer using the power switch, located on the back of the monitor, in the bottom left corner:

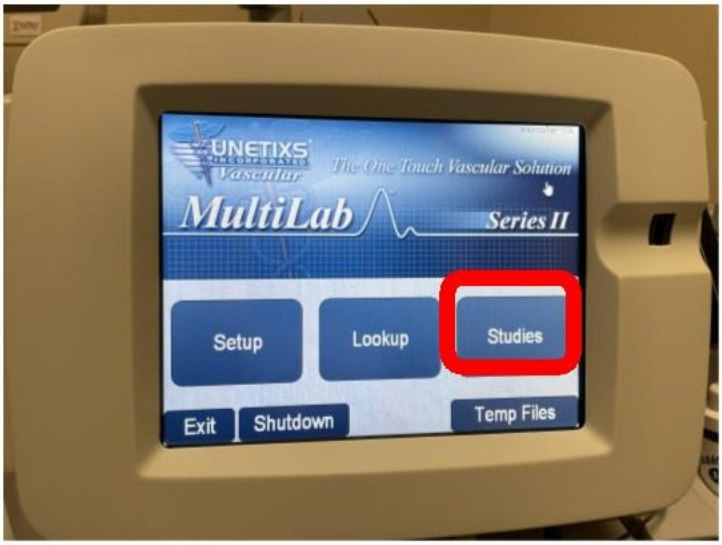


3. Once powered up, select **S2WIN** located on the desktop, as shown below:

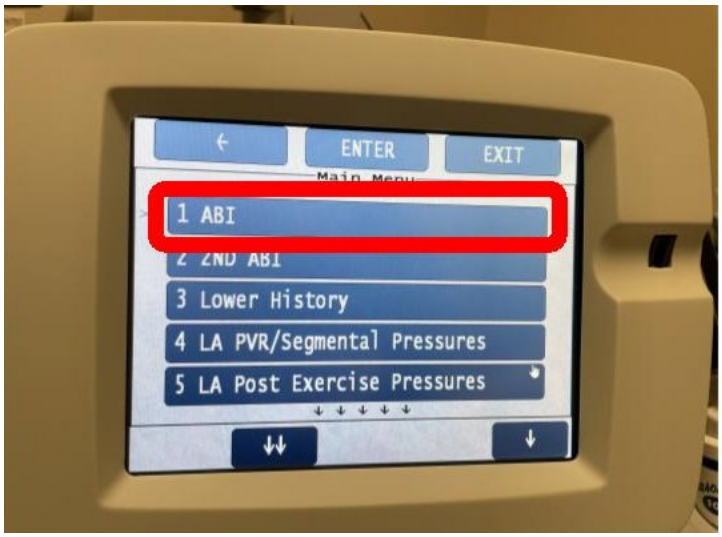
4. Once powered up, the first screen you will see is the Start Screen, as shown below:

4.3 Monitor Set-Up for ABI Measurements

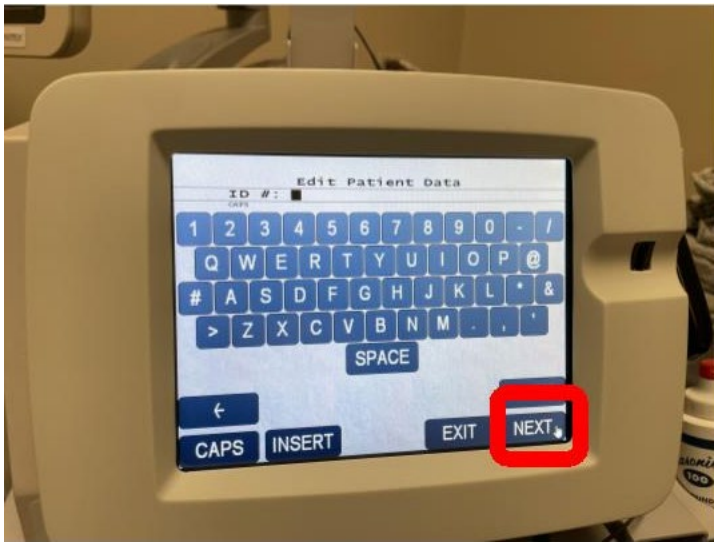
1. On the start screen, select **Studies**:



2. Select **1 ABI**



3. Click Next unit you reach the screen titled **Edit Patient Data – ID #.** Enter participant ID. Participants are labelled as J100001, J100002, J100003, and so on. Because two sets of ABI measurements are collected on every participant, use "_1" or "_2" to identify the two sets. For example, the first participant will be labeled as "J100001_1" for the first measurements and "J100001_2" for the second. Click **Next.**



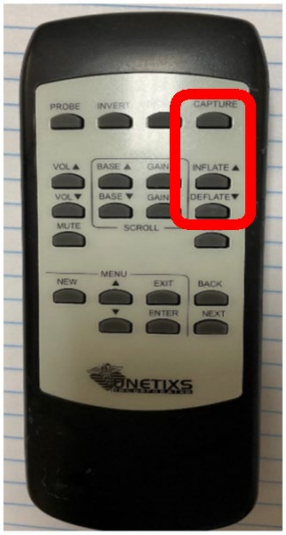
4. Enter your initials on the screen titled **Edit Patient Data – Operator.** Click **Next.**

4.4. General Guide to Blood Pressure Readings

1. Mark the location of maximal pulse or Doppler signal on each artery with a waterproof eyeliner pencil to improve the speed and accuracy of locating them the second time and to help maintain position.
2. Following any previous inflation, wait at least 30 seconds after cuff has completely deflated before reinflation.
3. Listen throughout the entire range of deflation, past the systolic reading (the pressure where the first regular sound is heard) for 10 mmHg. Three

consecutive beats should be heard for any valid systolic blood pressure reading.

4. The remote control is useful when the screen is out of reach. The buttons on the remote control function in the same way as the buttons on the screen. The commonly used buttons on the remote have been highlighted below:



5. In a small percentage of participants, you may not be able to find the posterior tibial or dorsalis pedis pulse. If you are having trouble, be patient and continue to search for at least three minutes. If you are still unable to locate a pulse, select **CAPTURE** on the screen. Then select **SET OUTPUT**. Enter the text 'UTL' (stands for Unable To Locate) for that artery.
6. In a small percentage of participants, you may not be able to fully occlude the artery. This is indicated when the Doppler sounds do not stop and/or the waveform on the screen does not fully flat-line when the cuff is inflated to 200 mmHg. If full occlusion is not obtained, select **CAPTURE** on the screen. Then select **SET OUTPUT**. Enter the text 'CNO' (stands for Could Not Occlude) for that artery.

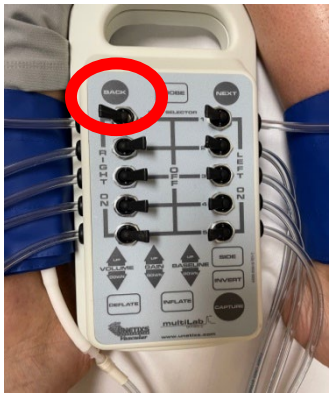
4.5. Order of Blood Pressure Measurements

1. Right Brachial Pressure
2. Left Brachial Pressure
3. Right Ankle Pressure – Dorsalis Pedis
4. Right Ankle Pressure – Posterior Tibial
5. Left Ankle Pressure – Dorsalis Pedis
6. Left Ankle Pressure – Posterior Tibial

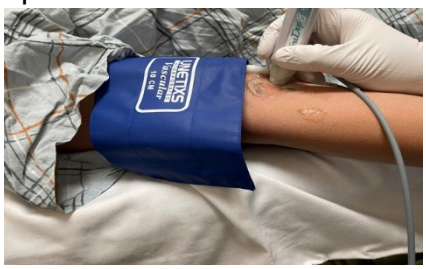
Key point: This sequence is repeated twice, so every participant has two sets of measurements.

4.6 Right Brachial Pressure

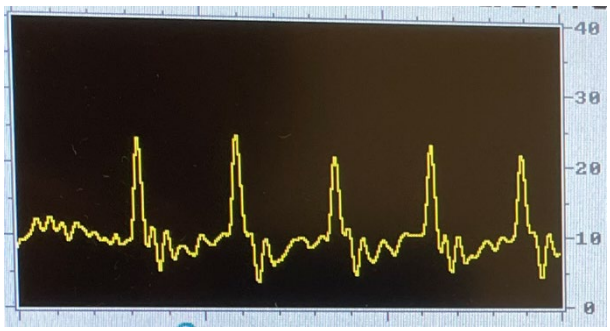
1. Ensure the Right Brachial cuff is attached to the hose labelled **R1.** Set the appropriate air valve on the Cuff Selector to the **open** position, as shown below:



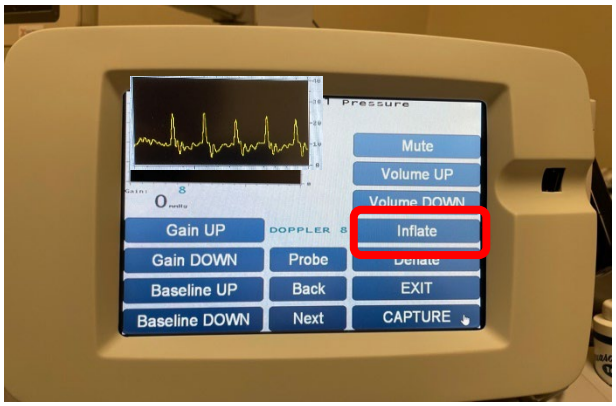
2. By palpation, locate the brachial artery (antecubital fossa). Sometimes an arm or ankle pulse will not be palpable but can be found with the Doppler.
3. Apply ultrasound jelly over brachial artery.
4. Locate brachial artery using Doppler pen probe. Place the probe in line with the artery and move it from side to side until the strongest pulse is heard. Don‘t press too hard on the artery with the probe.



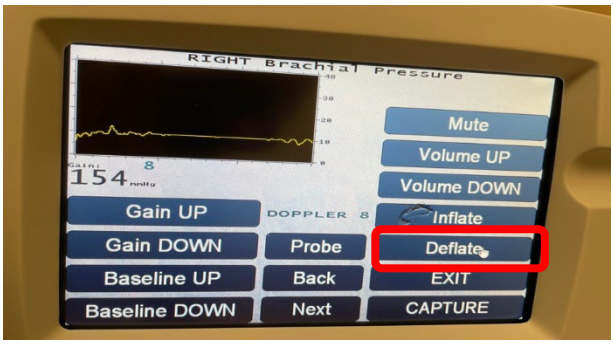
5. Rest your hand comfortably so that the probe is secured in place once a strong pulse is heard. Hold the Doppler Probe absolutely still. It can easily slip off the artery.
6. Ensure the heading on the monitor reads **Right Brachial Pressure**.
7. When the Doppler probe is in the correct position and a strong pulse is heard, visualize a clear waveform on the screen. Sample waveform below:



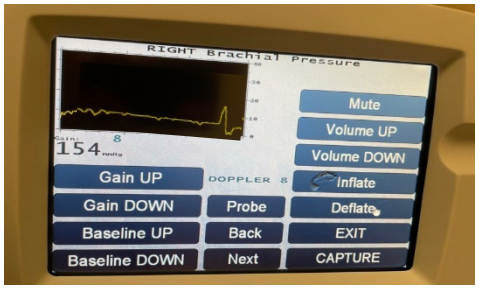
8. When the Doppler sound is strong and the waveform is visualized, click **Inflate**.



9. When the Doppler sounds stops and the waveform on the screen flat-lines, click **Deflate**.



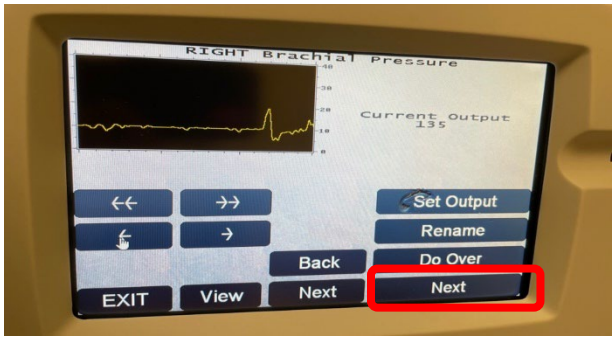
10. When the Doppler sound is heard and the waveform reappears on the screen, follow for at least three consecutive beats, then click **Capture**.



11. Use the ← and → buttons on the screen to adjust the waveform so that the peak overlaps with the right border of the screen.
    a. This peak should be when the waveform first reappeared on the screen and when the Doppler sounds were clearly heard after deflating the cuff.
        i. The pressure displayed under “Current Output” (in the below picture, 135 mmHg) represents the pressure in the cuff when

the **Capture** Button was clicked. Make sure to scroll back to the first pulse to ensure that the Peak Systolic Pressure is displayed under “Current Output”.

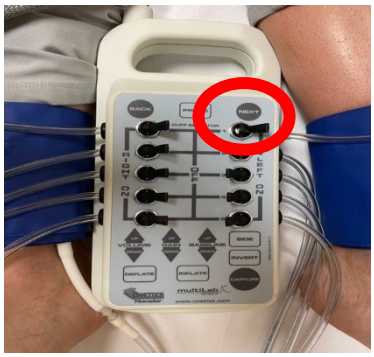
b. When the waveform has been appropriately adjusted, click **Next**.



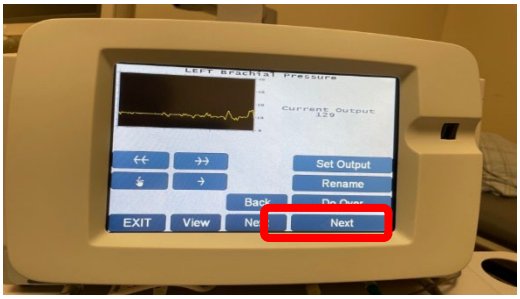
12. Set the **R1** air valve on the Cuff Selector to the **closed** position before starting the next measurement.

4.7 Left Brachial Pressure

13. Ensure the Left Brachial cuff is attached to the hose labelled **L1.** Set the appropriate air valve on the Cuff Selector to the **open** position, as shown below:



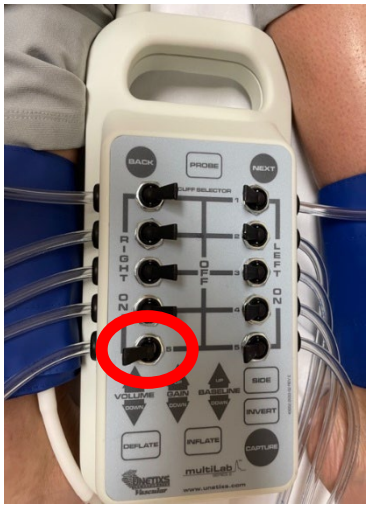
14. Ensure the heading on the monitor reads **Left Brachial Pressure**. Repeats steps 2 - 11 on the left arm.
15. Once all step are completed, your screen should look similar to the one below. Click **Next** to move to the next measurement.



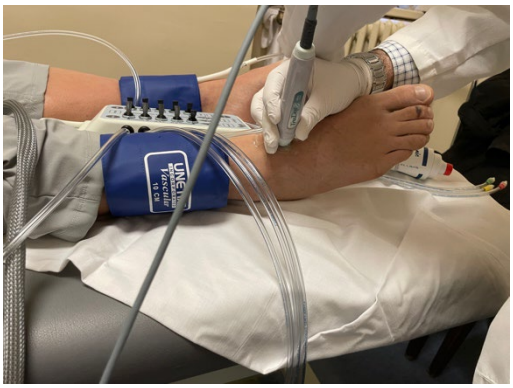
16. Set the **L1** air valve on the Cuff Selector to the **closed** position before starting the next measurement.

4.8 Right Dorsalis Pedis Pressure

17. Ensure the Right Ankle cuff is attached to the hose labelled **R5.** Set the appropriate air valve on the Cuff Selector to the **open** position, as shown below:

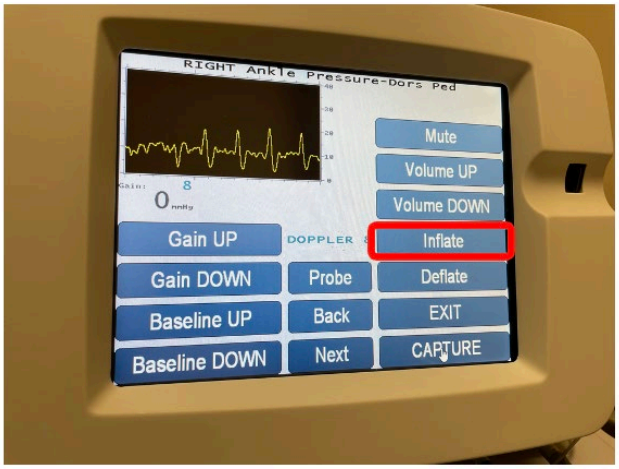


18. By palpation, locate the dorsalis artery. Sometimes an arm or ankle pulse will not be palpable but can be found with the Doppler.
19. Apply ultrasound jelly over the dorsalis pedis artery.
20. Locate dorsalis pedis artery using Doppler pen probe. Place the probe in line with the artery and move it from side to side until the strongest pulse is heard. Don‘t press too hard on the artery with the probe. Mark the location of maximal pulse or Doppler signal on the artery with eyeliner pencil.

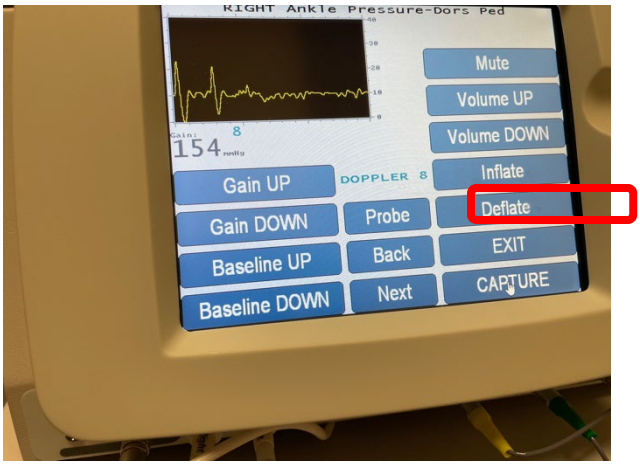


21. Ensure the heading on the monitor reads **Right Ankle Pressure – Dorsalis Pedis**.

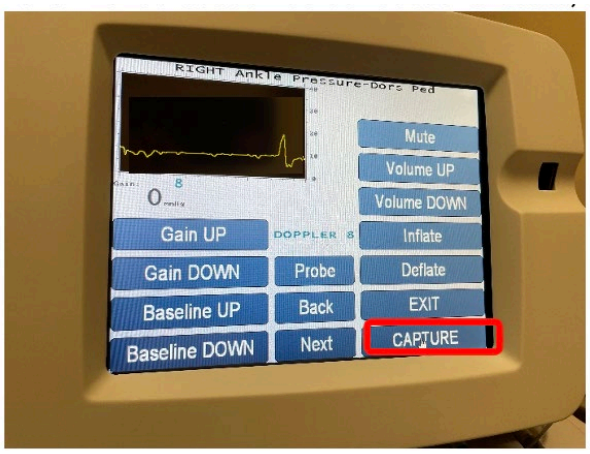
22. The procedures for obtaining the ankle pressure measurements are similar to the brachial pressures.
23. When the Doppler probe is in the correct position and a strong pulse is heard, visualize a clear waveform on the screen. Then click **Inflate**.



24. When the Doppler sounds stops and the waveform on the screen flat-lines, click **Deflate**.



25. When the Doppler sound is heard and the waveform reappears on the screen, follow for at least three consecutive beats, then click **Capture**.

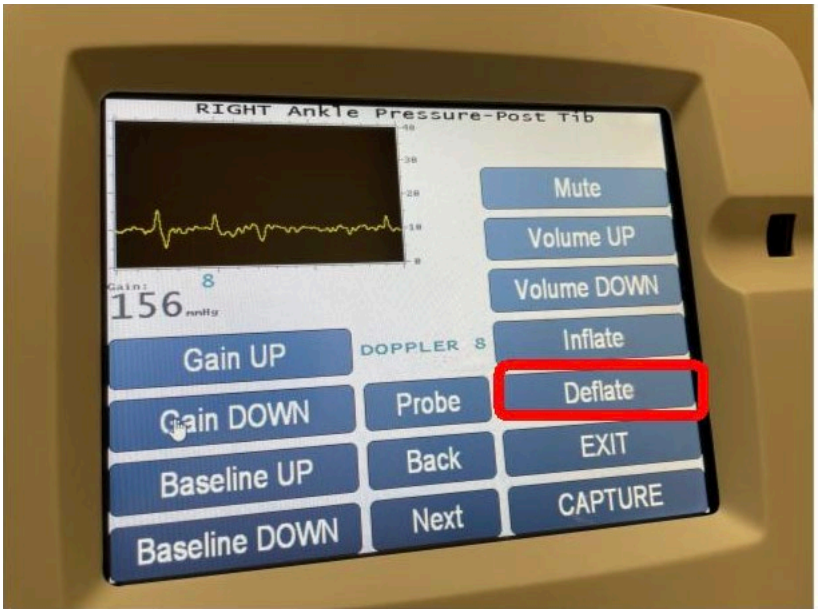


26. Use the ← and → buttons on the screen to adjust the waveform so that the peak overlaps with the right border of the screen.
    a. This peak should be when the waveform first reappeared on the screen and the Doppler sounds were clearly reheard after deflating the cuff.
    b. When the waveform has been appropriately adjusted, click **Next**.

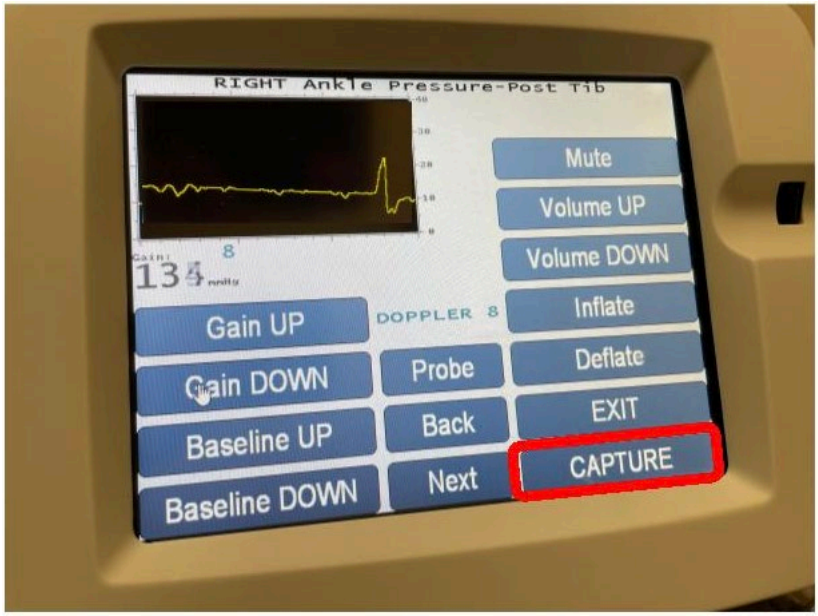
4.9 Right Posterior Tibial Pressure

27. Locate posterior tibial artery using Doppler pen probe. Place the probe in line with the artery and move it from side to side until the strongest pulse is heard. Don‘t press too hard on the artery with the probe.

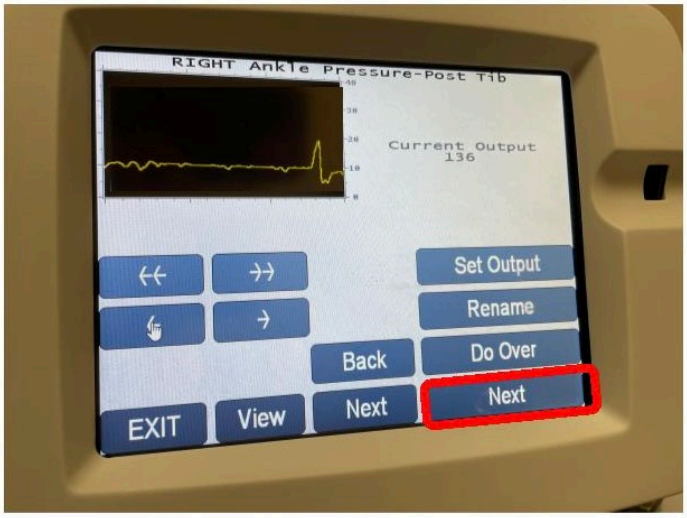
28. Ensure the heading on the monitor reads **Right Ankle Pressure – Posterior Tibial**.
29. When the Doppler probe is in the correct position and a strong pulse is heard, visualize a clear waveform on the screen. When the waveform is visualized, click **Inflate**.
30. When the Doppler sounds stop and the waveform on the screen flat-lines, click **Deflate.**



31. When the Doppler sound is heard and the waveform reappears on the screen, follow for at least three consecutive beats, then click **Capture**.



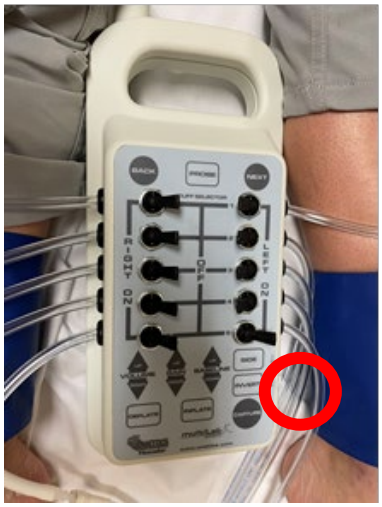
32. Use the ← and → buttons on the screen to adjust the waveform so that the peak overlaps with the right border of the screen.
    i. This peak should be when the waveform first reappeared on the screen and the Doppler sounds were clearly reheard after deflating the cuff.
    ii. When the waveform has been appropriately adjusted, click **Next**.



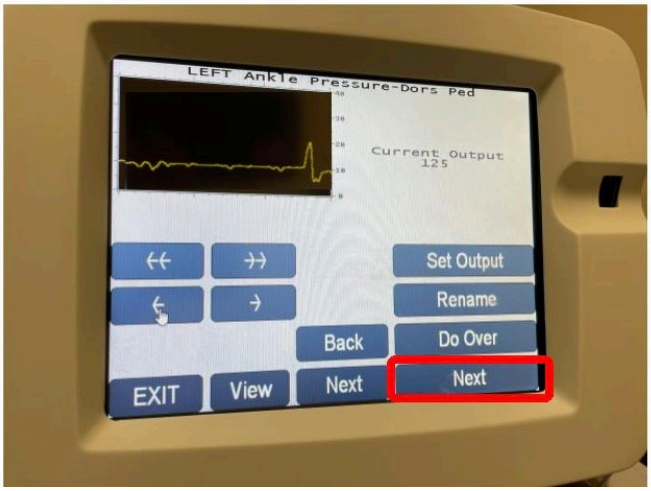
33. Set the **R5** air valve on the Cuff Selector to the **closed** position before starting the next measurement.

4.10 Left Dorsalis Pedis Pressure

34. Ensure the Left Ankle cuff is attached to the hose labelled **L5.** Set the appropriate air valve on the Cuff Selector to the **open** position, as shown below:

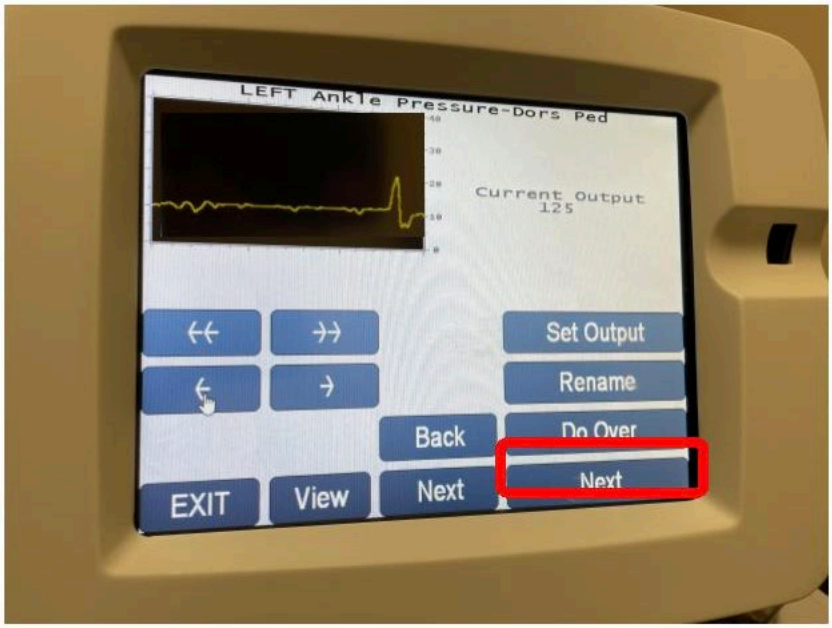


35. Ensure the heading on the monitor reads **Left Ankle Pressure – Dorsalis Pedis**. Repeat steps 18 – 26 on the left side.
36. Once all steps are completed, your screen should look similar to the one below. Click **Next** to move to the next measurement.



4.11 Left Ankle Pressure – Posterior Tibial

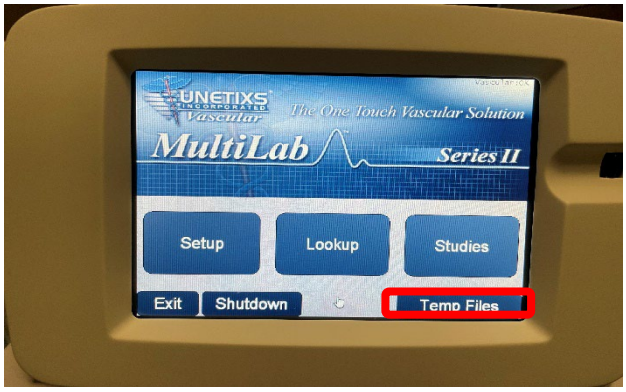
37. Ensure the heading on the monitor reads **Left Ankle Pressure – Posterior Tibial**
38. Repeat steps 29-32 on the left leg.
39. Once all steps are completed, your screen should look similar to the one below. Click **Next** to complete measurement collection.



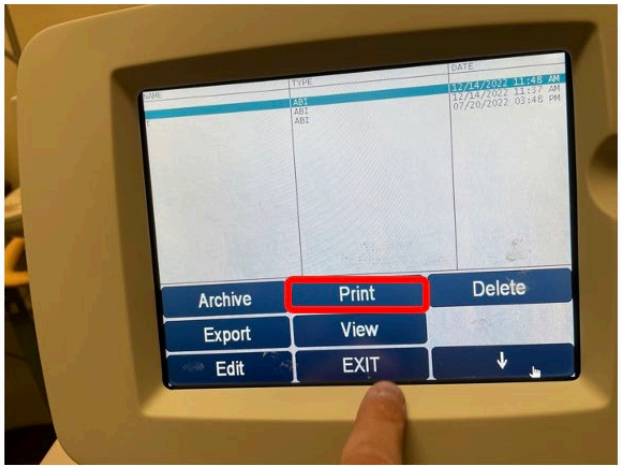
40. Set the L**5** air valve on the Cuff Selector to the **closed** position.
41. Two sets of measurements are collected on every participant.
<u>Restart this procedure from step 1.</u>

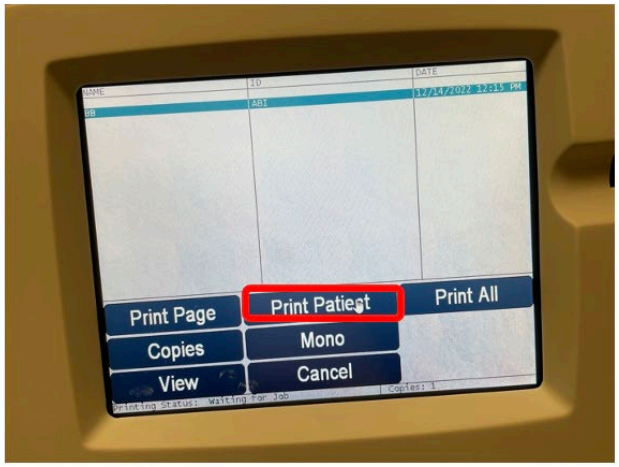
4.12. Printing Participant Data

1. Ensure the printer is connected to the device via the USB port at the back of the monitor.
2. On the home screen, select **Temp Files** to access the participants' ABI studies

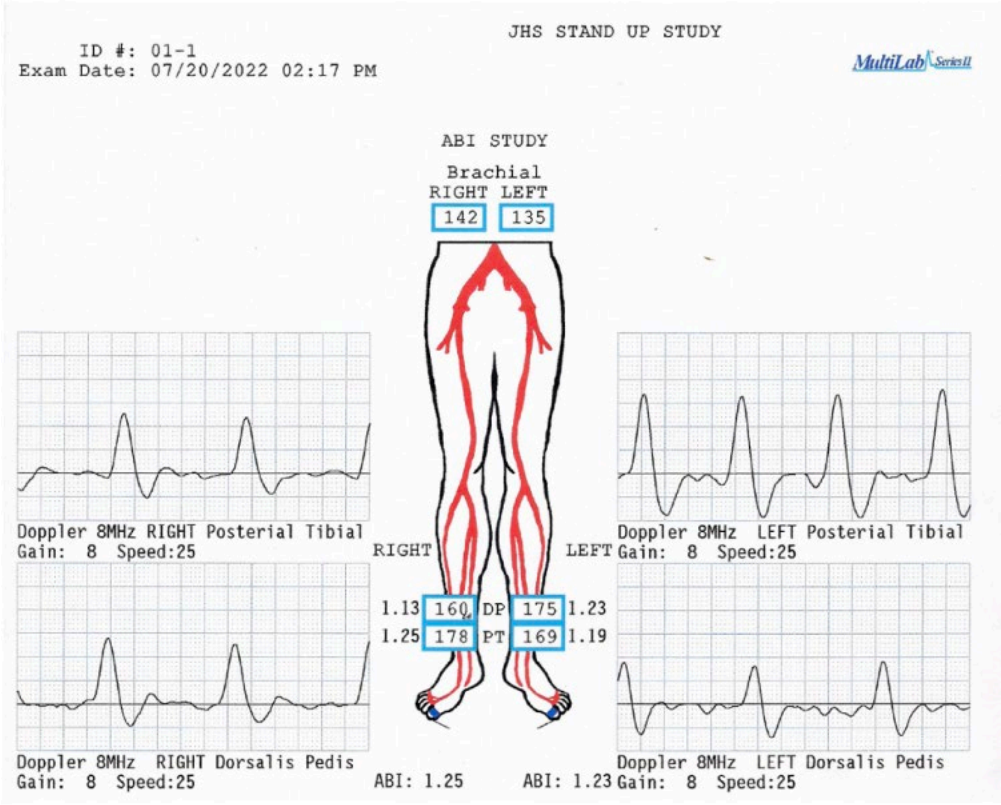


3. Select the file to be exported; selected file will be highlighted blue. Once the correct file is highlighted, select **Print.** A new screen will appear. Select **Print Patient** on that screen.



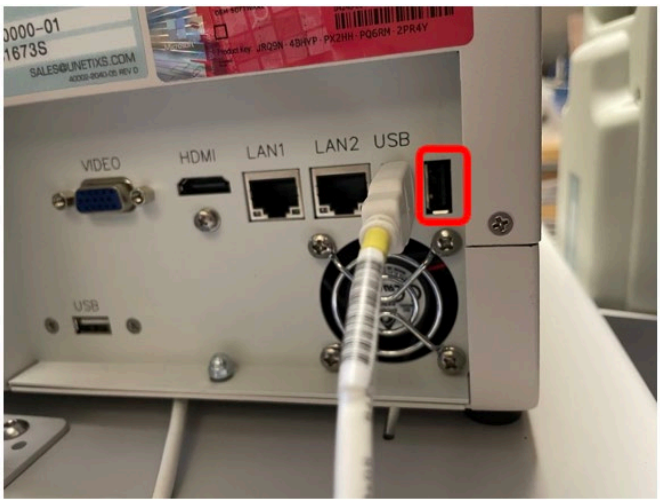


4. An example of the report sheet is included below. Store the printed report in the corresponding participant folder.

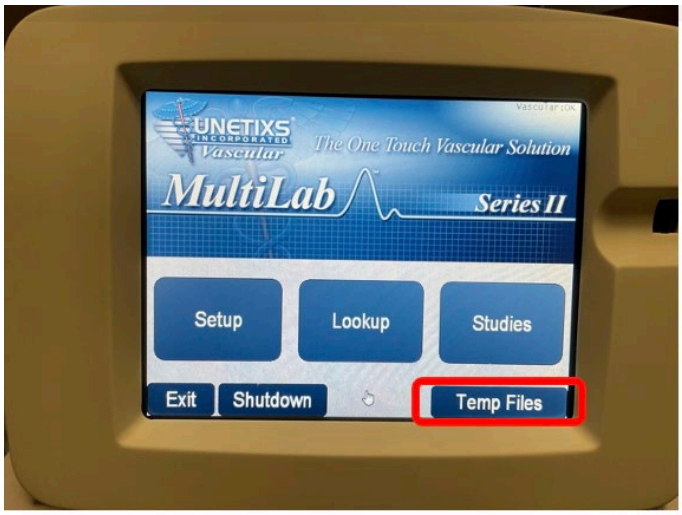


4.13. Exporting Participant Data

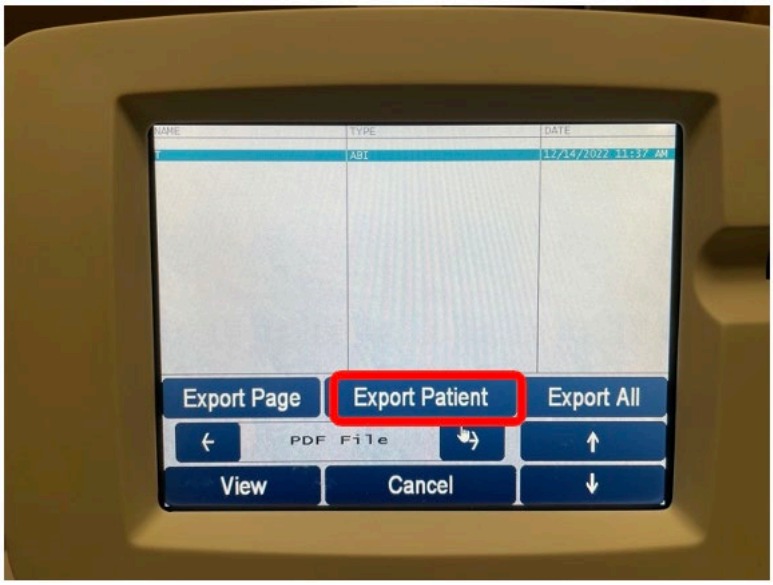
1. A USB flash drive will be required to export participant data.
2. On the back of the monitor, visualize the USB port on the bottom right side. The printer cord (black) may be plugged in; remove printer cord during export procedure. Plug USB flash drive into empty port.



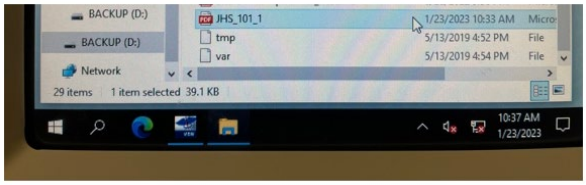
3. On the home screen, select **Temp Files** to access the participants' ABI studies.



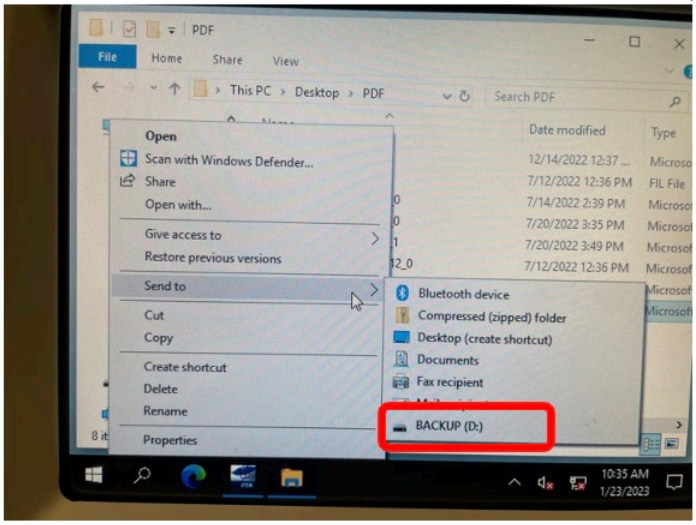
4. Select the file to be exported; selected file will be highlighted blue. Use the ← and → buttons on the screen to select **PDF File** as the export format, as shown below. Select **Export Patient**



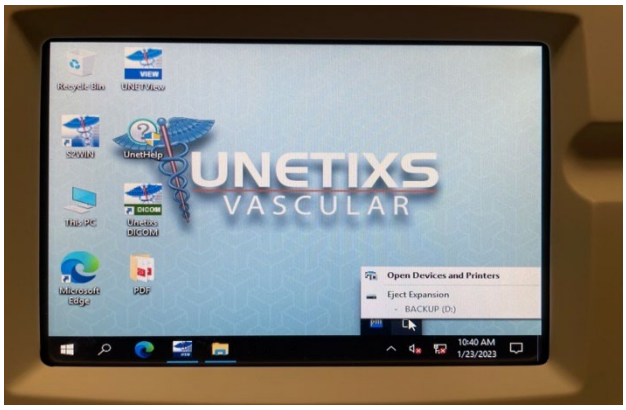
5. Once the necessary files have been exported, close out of the program by selecting **Exit** on the home screen.
6. On the desktop, located the folder titled **PDF** and select the icon. The exported files should appear in this folder.



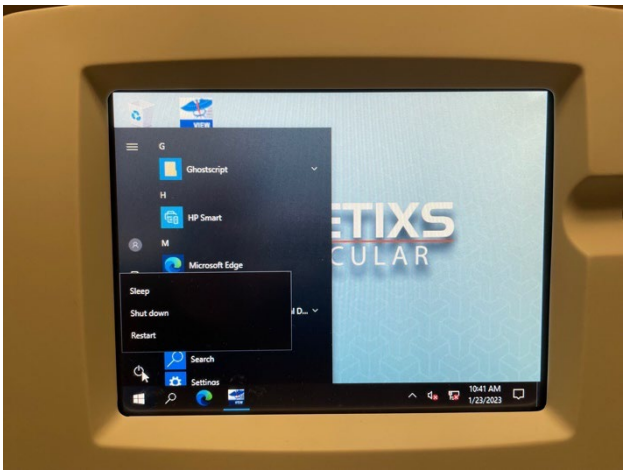
7. Right click on the file. Select **Send To** and then select the USB Flash drive (in this example, the name of the flash drive is “BACKUP”).



8. Once the file has been exported, close the **PDF folder**. Eject the USB Flash Drive by clicking on the **^** icon on the bottom right of the screen. Select the flash drive icon and select **Eject Expansion**. Unplug the flash drive from the device.

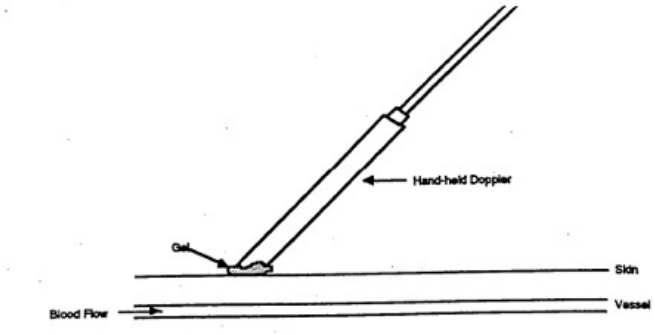


9. Once data collection and export is complete, select the **Start** icon on the desktop and shut down the machine. Switch off the power button on the back of the monitor and unplug the device from the power outlet.



4.14. Using the Doppler Probe

1. In order to hear the signal above background noise, the instrument must be pushed in toward the artery. Angling the beam upstream improves the signal. For deeper vessels, the unit will have to be tilted back toward perpendicular, but NOTE: the instrument works poorly or not at all if held fully perpendicular to the flow. It must always be angled into and IN LINE with the flow. See figure below:



2. In some places along the posterior tibial artery, there is anatomical hiding of the vessel by muscle or tendons. Move up or down the vessel a little to find the best signal above background noise.
3. The purpose of the Doppler is to determine that blood is or is not flowing under the cuff. For correct interpretation, the probe MUST be centered directly over the artery and must not be moved while inflating the cuff.
4. Mark the location of maximal pulse or Doppler signal on the brachial artery and both posterior and tibial arteries with eyeliner pencil to improve the speed

and accuracy of localizing them the second time and to help maintain position.

5. Hold the Doppler pen absolutely still while inflating and deflating the cuff; moving a few millimeters will lose the pulse.
6. Always use enough jelly to ensure good contact.
7. Use only ultrasound gel: The probe consists of two crystals; one for transmitting the ultrasound waves and the other for receiving the reflected waves. If either crystal is damaged, the probe will not work properly or will not work at all. The crystals are covered by epoxy resin. This resin is attacked by any gel or liquid containing the chloride ion. Therefore, NEVER use ECG paste or cream as the contact medium between the skin and the crystals. Use AQUASON IC or any gel made for ultrasonic physical therapy equipment. In an emergency use any surgical jelly or lubricant, even Vaseline or mineral oil. Remove the gel after use with a soft tissue. Do not immerse the Doppler Probe in any liquid. If the probe has dried gel on it, wipe it clean with alcohol, Sani-Cloth Bleach Germicidal Disposable Wipes, Sani Professional No-Rinse Sanitizing Multi-Surface Wipes, or SONO Wipes. Do NOT scrape off the gel because this may damage the epoxy coating.
8. Abnormal Doppler Noise: On occasion there are unusual noises from the Doppler that do not indicate a problem with the Doppler. The normal sound will become obvious with experience in performing this test. Following are some common complaints and their causes.
    a. Popping noises when the probe is first placed on the skin. Scratchy sound at first. Cause: bubbles in the gel that are moving and/or popping. Also hair movement can cause noise. Remedy: Use a new glob of gel that looks clear, push down enough so hair is immobilized, and just wait a few seconds for things to settle down. If the noise isn't there when the probe is clean (no gel) and suspended in the air, the Doppler and/or probe are probably not at fault.
    b. Bad static when the dry probe is moved in the air. Cause: a loose connector where the probe connects to the instrument, a broken shield wire in the cable either at the connector or as it comes out of the probe. This can be diagnosed by wiggling the wire or connectors gently. There is NORMALLY some static generated when the cable is flexed, but it isn't severe. Remedy: QC Officer will arrange to replace probe or get connectors fixed.
    c. High-pitched tone. Cause: radio interference from a mobile service, police station nearby, even another Doppler working nearby. Usually occurs near large open windows, rarely in the center of the building. Remedy: Move to another room.
    d. Howling noise when the probe with gel on it is held or laid on a table. Cause: acoustic feedback through the probe acting as a microphone. If it doesn't occur without gel on the probe, everything is OK

5 MAINTENANCE AFTER EACH USE

1. After completing the ABI measurements, thoroughly clean the Doppler probe and cuffs. Please note that the Doppler must be completely clean and dry between participants.
2. The following products are approved for the **Doppler Probe**
    a. Alcohol
    b. SONO Wipes
    c. Sani Professional No-Rinse Sanitizing Multi-Surface Wipes
    d. Sani-Cloth Bleach Germicidal Disposable Wipes
    e. DISPATCH Hospital Cleaner/Disinfectant with Bleach
3. To disinfect the cuffs, spray or wipe entire surfaces of cuff with disinfectant until wet. Allow the cuff to remain visibly wet for a minimum of 10 minutes to insure complete disinfection. Wipe dry with clean cloth. The following disinfectants are compatible with the **cuffs**:
    a. Hydrogen peroxide
    b. Hydrogen peroxide with Silver (Sanosil)
4. The following product is approved for the **Touch Screen**:
    a. PDI Easy Clean cleaning wipes
5. The following products are approved for **exterior surfaces** except the touch screen surface:
    a. 70% isopropyl alcohol (IPA)
    b. Oxivir Tb
    c. Protex spray or wipes
    d. Sani-Cloth HB (QUAT based)
    e. Sani-Cloth Plus (QUAT/IPA based)
    f. DISPATCH Hospital Cleaner/Disinfectant with Bleach
6. Further cleaning guidelines can be found in the *MultiLab Series II Operator's Manual* starting on page 10.

5.1. Preventative Maintenance – General

1. Check the connectors on the cable assemblies to insure that the connections are secure
2. Check that all the ventilations slots are clear of obstructions and dust. Vacuum if necessary.
3. Inspect all cable assemblies (including power cables) for damage or wear. Replace any suspect cables.
4. Inspect blood pressure cuffs for signs of wear and air leakage, replace as needed.
5. Check monitor base to ensure clamps are secure and that the monitor base is undamaged.
6. Check nuts and bolts used to secure the wheels to the cart to ensure tightness.
7. Check all exposed hardware for tightness and correct functionality.

The module from the unit should be returned to the factory once every 24 months for calibration (this service is included in Unetixs Inc. service contracts).

6 DATA FILING/ENTRY

1. Neatly record the measured pressure for each limb on the **ABI DATA COLLECTION FORM**.
2. If you were unable to locate a pulse, enter a systolic pressure of "000" for that artery, circle "*No*" with respect to whether a pressure was obtained for this artery, and select "*Unable to locate artery*" as the reason.
3. If you were unable to fully occlude an artery (i.e. waveform still present with cuff inflation), enter a systolic pressure of "000" for that artery, circle "*No*" with respect to whether a pressure was obtained for this artery, and select "*Unable to occulde*" as the reason.

7 CALCULATION OF THE ABI

Calculation of the ABI will be completed by data analysts at Columbia University Medical Center. For your information, the procedure is given below.

The ABI denominator: There is only one ABI denominator per participant for both the left and right ABIs. This denominator is the higher arm systolic blood pressure.

The right ABI numerator is defined as the higher of 1) the right posterior tibial systolic blood pressure or 2) the right dorsalis pedis systolic blood pressure.

The left ABI numerator is defined as the higher of 1) the left posterior tibial systolic blood pressure or 2) the left dorsalis pedis systolic blood pressure.

The right ABI is the right ABI numerator divided by the ABI denominator.

The left ABI is the left ABI numerator divided by the ABI denominator.

8 QUALITY ASSURANCE

8.1 Training

The technician must be certified with training in the proper operation and application of the blood pressure apparatus and doppler using standardized technique. The technician should also have a working knowledge of this manual of operations. Technicians will be trained in-person by Dr. Diaz and the Unetixs company representative. Trainings will include:

1. A thorough review of the forms, instructions, and protocol
2. Demonstration of appropriate techniques
3. Practice in the use of the apparatus on volunteers
4. Practice dealing with problem situations

5. Practice handling participants' comments and recording relevant information on the note logs
6. Review of post-interview responsibility for the ABI data
7. Compare measurements with those made by trainer (Goal: obtain measurements within ± 2 mm Hg of that observed by a trainer)

8.2 Certification

Each trainee must do at least three live readings with Dr. Diaz observing. The readings at each site must agree within 4 mmHg. Dr. Diaz also verifies that the trainee understands and follows proper procedures using a quality control checklist (**APPENDIX 11, ABI**). If a trainee does meet all requirements (demonstrate appropriate procedures/technique, have good agreement with repeated measurements), the trainee needs additional practice. Only technicians certified by Dr. Diaz will be permitted to conduct ABI measurements.

Re-certification is completed biannually (January and July) and requires the completion ABI measurements on two separate volunteers with replicate measures obtained for each. Agreement within 4 mmHg on any one reading, (systolic). Results must be sent to Dr. Diaz. In addition, annual recertification via direct observation will occur during Dr. Diaz's annual site visit. The readings must agree within 4 mmHg.

8. DATA MONITORING

Dr. Diaz will direct an ABI quality assurance program to review six-monthly data. This includes quality analysis and review of blood pressure/ABI data, comparing means for each technician with the values for all technicians. These statistics are adjusted for weight, age and sex of the participants. Chi-square tests of proportion will be used to test for significant differences across each technician.

APPENDIX

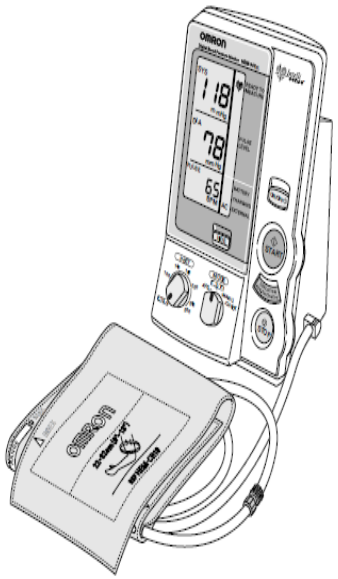
OMRON®

INSTRUCTION MANUAL

IntelliSense® Blood Pressure Monitor

Intelli sense®

Model HEM-907XL



Thank you for purchasing the OMRON IntelliSense® Blood Pressure Monitor.

Please thoroughly read this Instruction Manual before using this monitor to ensure safe and accurate use.

Please keep this manual near the monitor all the time for future reference.

Table of Contents

EXEMPTIONS

OMRON does not accept liability and warranty becomes void under the following circumstances:

1. When persons, not authorized by OMRON, perform repairs or modifications of this product.
2. When use and/or operation of this device is adversely effected by a device not manufactured by OMRON.
3. When use and/or operation of this device is adversely effected by use of parts, not authorized by OMRON, to repair or modify this product.
4. When Notes on Safety or Instructions for Use contained in this manual are not followed.
5. When use and/or operation of this device is effected by an act of God, such as fire, earthquake, flood or other natural disasters.

1. The product and contents of this Instruction Manual may be changed without prior notice.
2. We have prepared the contents of this Instruction Manual thoroughly. However, if an inadequate description or error is found, please let us know.
3. Reproducing or copying any or all of this Instruction Manual without OMRON's written consent is prohibited.

EXEMPTIONS

OMRON does not accept liability and warranty becomes void under the following circumstances:

1. When persons, not authorized by OMRON, perform repairs or modifications of this product.
2. When use and/or operation of this device is adversely effected by a device not manufactured by OMRON.
3. When use and/or operation of this device is adversely effected by use of parts, not authorized by OMRON, to repair or modify this product.
4. When Notes on Safety or Instructions for Use contained in this manual are not followed.
5. When use and/or operation of this device is effected by an act of God, such as fire, earthquake, flood or other natural disasters.

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2. We have prepared the contents of this Instruction Manual thoroughly. However, if an inadequate description or error is found, please let us know.
3. Reproducing or copying any or all of this Instruction Manual without OMRON's written consent is prohibited.

NOTES ON SAFETY

• The warning signs and the sample icons shown here are listed to insure safe and accurate use.
• The icons and meanings are as follows.

Warning sign	Contents
⚠Warning	Indicates matters in which death or severe bodily damage may arise as a result of incorrect handling.
⚠Caution	Indicates matters in which bodily harm or material damage* may arise as a result of incorrect handling.

* Material damage refers to a wide range of damage involving your house, household goods, domestic animals, and pets.

Examples of signs	
	The △ icon indicates caution (including warning and danger). Matters involving actual caution are indicated by text or pictures in or near △. The pictured icon refers to "caution for flammability".
	The ⃠ icon indicates prohibitions (what you cannot do). Matters involving actual prohibitions are indicated by text or pictures in or near ⃠. The pictured icon refers to "prohibition to disassemble".
	The ● icon indicates something that is compulsory (always follow). Matters involving actual compulsory actions are indicated by text or pictures in or near ●. The pictured icon refers to "unplugging the power source plug".

⚠Warning	
Self diagnosis of measured results or treatment is dangerous. Please follow the instruction of the doctor or healthcare provider. If cuff inflation does not stop, remove the cuff or pull out the air tube from the main unit. If battery fluid gets into your eye or comes in contact with skin, wash the effected area with water repeatedly. Immediately consult a doctor for treatment.	
Do not wrap the cuff over an arm to which intravenous injection or transfusion is being conducted, or when otherwise contraindicated. Do not connect the air tube or the cuff to other equipment which is connected to an intracorporeal organ. Air embolisms may result.	
Do not use this unit in the presence of flammable gas or anesthetics or in a high pressure oxygen room or oxygen tent. Do not use the battery pack for devices other than for this unit. Do not disassemble the battery pack.	
Do not touch the AC adapter with wet hands.	

NOTES ON SAFETY

⚠Caution	
Unplug the AC adapter from the electric outlet if this unit is unused for an extended period of time. Unplug the AC adapter from the electric outlet when installing, removing, or cleaning the unit.	
Confirm readings with a stethoscope when an irregular pulse wave is displayed or when the measured value is questionable or erratic. Use an AC adapter indicated for use with a power supply of 110 VAC. Do not share an electric outlet with other unit or electric appliance. After cleaning this unit, dry it well before plugging the AC adapter in the electric outlet. If this unit fails to perform as indicated, discontinue use, turn off the unit, unplug the AC adapter from the electric outlet, and contact OMRON's repair department.	
Do not disassemble or modify this unit.	
Do not use any cuff other than the models exclusive for this unit. Do not use this unit on infants. Do not use this unit on patients using a pump oxygenator. Do not use an AC adapter or battery pack not specified for this unit.	

NOTES ON SAFETY

⚠Caution	
Do not use a cellular phone near this unit. Do not use this unit in a vehicle. Do not install the parts and/or instruments not specified for this unit. Do not use a broken power cord or AC adapter.	
Do not install or store this unit where it may come in contact with water or liquid medication. This is a Class II device with double isolation. Earth pin is not for protective purposes.	

General advice

Do not place or put anything on this unit.

Do not drop this unit.

Turn off power to the unit and unplug the AC adapter from the electric outlet before moving the unit.

Read the instruction manual of the other devices to be used at the same time with this unit, to understand and be aware of the interaction between the devices.

When using the unit
- Do not inflate the cuff without being wrapped over the arm.
- Do not use a damaged cuff.
- Be sure that patients do not touch the Buttons of this unit.

After using the unit
- Do not disinfect this unit by autoclave or gas sterilization (EtO, gluteraldehyde, or high concentration ozone).

Do not install or store this unit in the following places.
- Under the direct sunlight,
- Dusty or salty environment,
- Places having slope, vibration, and/or shock,
- Storage of chemicals or where combustable gas may be generated,
- Under high temperature and high humidity.

NOTES ON SAFETY

Maintenance and inspection

1. Check the unit operation on regular basis.
2. If this unit has not been used for more than three months, be sure to check that this unit operates normally and safely before use.

Troubleshooting

If device error 9 (Er9) occurs, take the following procedure promptly:

(1) Remove the cuff from the patient's arm.

(2) Turn off the power of the unit and unplug the AC adapter from the electric outlet.

(3) Display "Out of use" on this unit so that it cannot be used.

(4) Contact Omron for repair service (1-877-216-1336).

FEATURES OF THE PRODUCT

OMRON IntelliSense™ Blood Pressure unit, Model HEM-907XL is developed to measure blood pressure and pulse rate accurately and simply in a doctor's office, examination room, or patient bedside.

• One-button operation

Simply wrap the cuff and push the START Button. Blood pressure and pulse rate are automatically measured by the oscillometric method.

• Automatic pressure setting

When the P-SET (Pressure Setting) Knob is set to "AUTO," the unit will automatically inflate the cuff to the optimal pressure according to each patient's blood pressure. Pre-setting inflation level is not necessary.

• Noiseless operation

This unit operates so quietly that it can be used in the patient room at night.

• Average Mode (AVG Mode)

In the AVG Mode, this unit will automatically measure for two or three times. The average of systolic and diastolic blood pressures and pulse rate are displayed. Each measurement can also be shown individually. The number of measurements, waiting time before first measurement, and the interval can be changed.

• Auscultation Mode (MANU Mode)

You can measure auscultatory blood pressure by using a stethoscope, with automatic cuff inflation and deflation by this unit. Because the cuff pressures during deflation are displayed digitally and synchronized with the heart beat, they can be read with accuracy. After taking systolic reading you can accelerate cuff deflation to shorten measurement time.

• Large and easy to read display

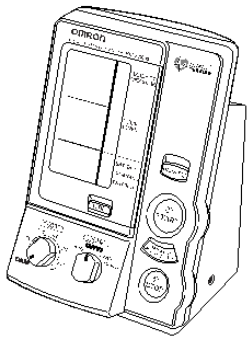
Large and easy to read figures are displayed on the LCD display.

The IntelliSense™ Monitor inflates the cuff to the ideal level with each use. No adjustments are required by the user to select an inflation level. This is especially convenient for hypertensive users and for people with certain arrhythmia or heart disorders, because their blood pressure is likely to fluctuate. The advantage is Personalized Inflation for maximum comfort.

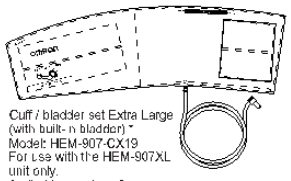
COMPONENTS OF THE PRODUCT

Main unit

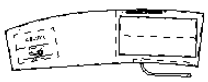
IntelliSense™ Blood Pressure Monitor, Model HEM-907XL



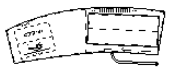
Accessories (Included and also available separately)



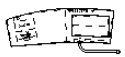
Cuff / bladder set Extra Large (with built-in bladder) *
Model: HEM-907-CX19
For use with the HEM-907XL unit only.
Applicable arm circumference: 17" to 20" (42 to 50 cm)



Cuff / bladder set Large (with built-in bladder) *
Model: HEM-907-CL19
Applicable arm circumference: 13" to 17" (32 to 42 cm)

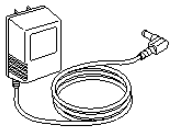


Cuff / bladder set Medium (with built-in bladder) *
Model: HEM-907-CR19
Applicable arm circumference: 9" to 13" (22 to 32 cm)

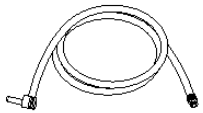


Cuff / bladder set Small (with built-in bladder) *
Model: HEM-907-CS19
Applicable arm circumference: 7" to 9" (17 to 22 cm)

AC adapter
Model: HEM-AC-J



Air tube 1.0 m (39 1/3") *
Model: HEM-TUBE-100X



The air tube is available for the large, medium or small cuff size.
It is NOT for use with the extra-large cuff size.

Battery pack (48H907N)
Model: HEM-907-PBAT

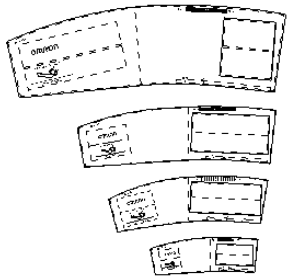
Instruction Manual

Items identified with an asterisk (*) are consumables and not covered by the guarantee.

COMPONENTS OF THE PRODUCT

Options (not included)

Cuffs without bladder *



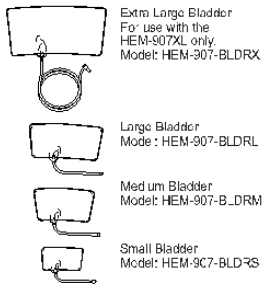
Extra Large Cuff
For use with the HEM-907XL only.
Model:HEM-907-CUFFX

Large Cuff
Model:HEM-907-CUFFL

Medium Cuff
Model: HEM-907-CUFFM

Small Cuff
Model: HEM-907-CUFFS

Bladders *

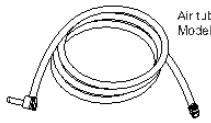


Extra Large Bladder
For use with the HEM-907XL only.
Model: HEM-907-BLDRX

Large Bladder
Mode : HEM-907-BLDRL

Medium Bladder
Model: HEM-907-BLDRM

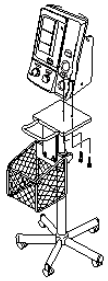
Small Bladder
Model: HEM-907-BLDRS



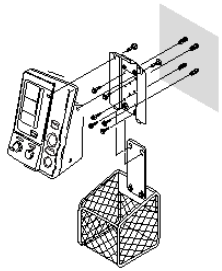
Air tube 1.3 m (51 1/6") *
Model: HEM-TUBE-130

The air tube is available for the large, medium or small size cuff.
It is NOT for use with the extra-large cuff size.

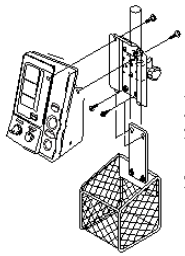
Exclusive Stand
Model: HEM-907-STAND



Wall-hanging kit
Model: HEM-907-WKIT



Pole-mounting kit
Model: HEM-907-PKIT



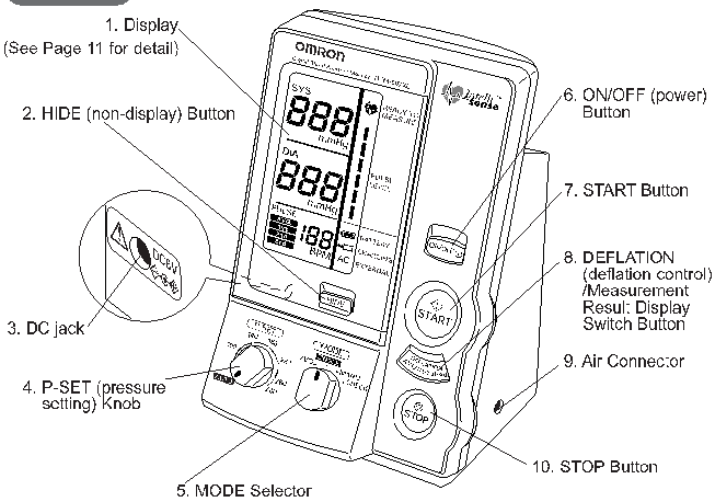
Items identified with an asterisk (*) are consumables and not covered by the guarantee.

Accessories and options are subject to change without prior notice.

FEATURES AND FUNCTIONS

Names of the Parts

Main unit



1. Display: Displays blood pressure and, pulse rate readings, and oscillation pulse level.

2. HIDE Button: Switches display and non-display of measured results.

3. DC jack: Connects the AC adapter.

4. P-SET (pressure setting) Knob: In the AUTO position, inflation level is automatically set. Otherwise, inflation level can optionally be set manually between 100 and 280 mmHg.

5. MODE Selector: Selects the operation mode.

- One-time Measurement Mode (SINGLE Mode): Measurement with automatic inflation.
- Average Mode (AVG Mode): Automatically measures two (or three) times consecutively.
- Auscultation Mode (MANU Mode): Automatic inflation, automatic deflation, and pressure display for auscultation (does not measure blood pressure).
- Check Mode (CHECK Mode): Checks the accuracy of pressure display. Displays only pressure.

6. ON/OFF (power) Button: Turns on or off the unit.

7. START Button: Starts the measurement.

8. DEFLATION (deflation control) /Measurement Result Display Switch Button:

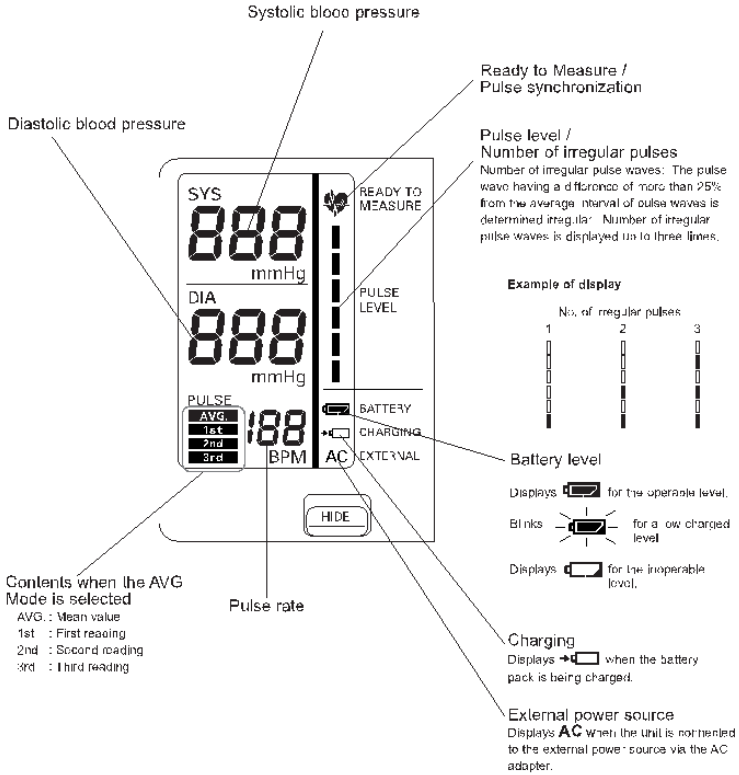
- In the MANU Mode, deflates the cuff by approximately 5 to 10 mmHg with each push during deflation.
- In the AVG Mode, switches the display of average values and the measurement results with each push.

9. Air Connector: Connects the air tube.

10. STOP Button: Stops the measurement and deflates air rapidly.

FEATURES AND FUNCTIONS

Display



Functions setting

(1) Inflation level setting (P-SET)

AUTO (Automatic setting): Can be used when the SINGLE, AVG, or MANU Mode is selected. The unit estimates the systolic blood pressure during inflation and inflates to a proper cuff pressure (approximately 30-40 mmHg above the patient's systolic pressure).

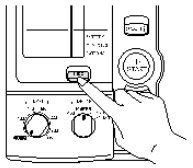
Manual level setting: Inflation level can be set manually between 100 and 280 mmHg. Set the level to 30 to 40 mmHg higher than the expected systolic pressure.

- To set the P SET to "AUTO," turn the P SET Knob counterclockwise as far as it goes until you can hear a click.
- In the "AUTO" setting, inflation level may not be set automatically when the systolic blood pressure is more than 220 mmHg. Use the unit in the manual setting.
- If the cuff has not been inflated to the necessary level, it may be re-inflated automatically.

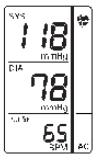
(2) Non-display function (HIDE)

Use to prohibit the display of measurement results. However, the cuff pressure during measurement is displayed.
This function can be used in the SINGLE and AVG Modes.

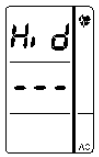
By pushing the (HIDE) Button, display or non-display of status is switched alternatingly.



Display



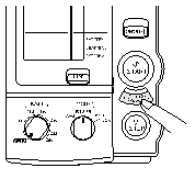
Non-display



(3) Manual deflation control (DEFLATION / AVG/Measurement)

Accelerate deflation by pushing the DEFLATION (deflation control) / Measurement Result Display Switch Button during deflation in the measurement by the MANU Mode.

With each push of the (DEFLATION) Button, cuff is deflated rapidly in increments of 5 to 10 mmHg.



List of Functions for each Mode

Function \ Measurement Mode	Single (S NGHT) Mode	Average (AVG) Mode	Accumulation (MANU) Mode	Check (CHECK) Mode
Inflation level setting	●	●	●	—
Non-display function	●	●	—	—
Manual deflation control	—	—	●	—

(4) AVG Function setting

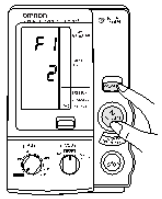
You can set the number of measurements, the waiting time until the 1st measurement, and the measurement interval for the AVG Mode.

Function #	Items to set	Set value
F1	Number of measurements	**2 times** or 3 times
F2	Waiting time until the start of 1st measurement	**0 sec**, 3 min, 5 min, or 10 min.
F3	Measurement interval	5 sec, 30 sec, **1 min.** or 2 min.

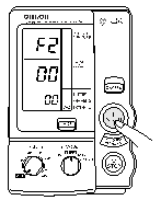
Note: The bold letters represent the factory-set values.

Procedure to change the set values

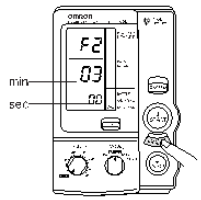
1) When the power is OFF, push the ON/OFF (power) Button for more than three seconds while holding the START Button; F1 is displayed.



2) Push the START Button and select the function to set from F1 to F3. Each time you push the START Button, the functions change in the order of (F1→F2→F3→).



3) Push the DEFLATION (deflation control)/Measurement Result Display Switch Button and change the set values.



4) When the setting is finished, push the ON/OFF (power) Button to turn off the power. The setting is changed.

HOW TO APPLY THE CUFF

The cuff of OMRON IntelliSense™ Blood Pressure Monitor HEM-907XL plays an important role of collecting the information on blood vessels. Please wrap the cuff according to the procedure, below.

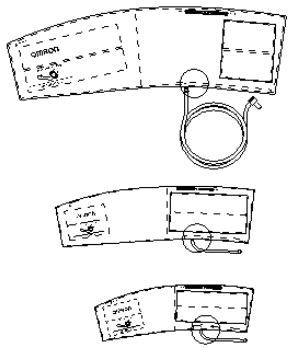
⚠Warning

Do not wrap the cuff over an arm to which intravenous injection or transfusion is being conducted, or when otherwise contraindicated.

Do not connect the air tube or the cuff to other equipment which is connected to intracorporeal organ. Air embolisms may result.

General advice

- Do not inflate the cuff without being wrapped over the arm.
- Do not use a damaged cuff.

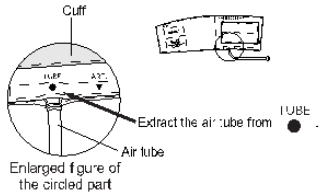


1. Select the cuff according to the arm size

Arm circumference	Name of the cuff
(7" - 9") 17-22 cm	HEM-907-CS19 (Small)
(9" - 13") 22-32 cm	HEM-907-CR19 (Medium)
(13" - 17") 32-42 cm	HEM-907-CL19 (Large)
(17" - 20") 42-50 cm	HEM-907-CX19 (Extra Large)

- Check the following before applying the cuff.

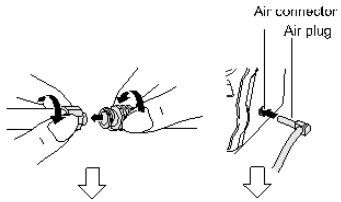
1) The bladder is correctly installed in the cuff.
2) The bladder is not twisted inside the cuff.
3) The bladder tube is protruding from the cuff as shown in the Figure on the right.



2. Connect the air tube securely.

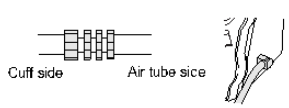
To use the cuff in small, medium or large size

- Connect the air tube to the main unit by securing the air plug to the base of the air connector.
- Securely connect the air tube and the cuff/bladder set by rotating the luer connection as shown in the Figure on the right.



To use the cuff in extra large size only

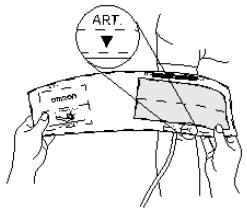
The extra large cuff comes with an air tube with an integrated air plug. Connect the air plug of the cuff to the air connector securely when connecting to the main unit.



HOW TO APPLY THE CUFF

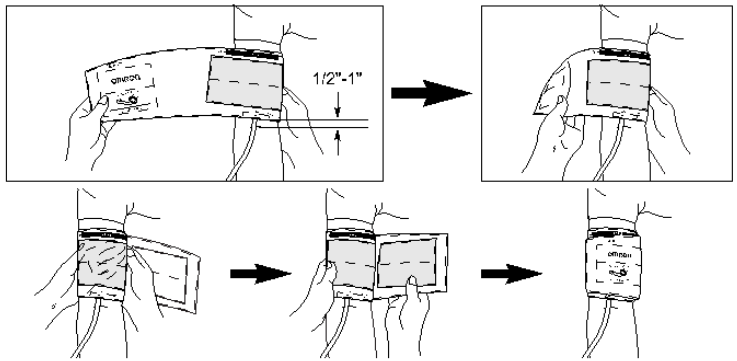
3. Place the right or left hand of the patient with the palm of hand facing upward.

4. Align the Artery Position Mark ART. ▼ with the brachial artery.



5. Wrap the cuff snugly using both hands and securely fasten it with the Velcro™ tape. At this time, the lower edge of the cuff must be placed 1/2" to 1" above the inner side of elbow joint.

- If the INDEX is positioned outside the RANGE, select the cuff suitable for the patient's arm circumference and wrap it again.
- Wrap the cuff so that you can insert only one finger between the cuff and arm.



6. Keep the level of the cuff at the same level as the heart during the measurement.

HOW TO USE THE POWER SOURCE

How to use the AC adapter

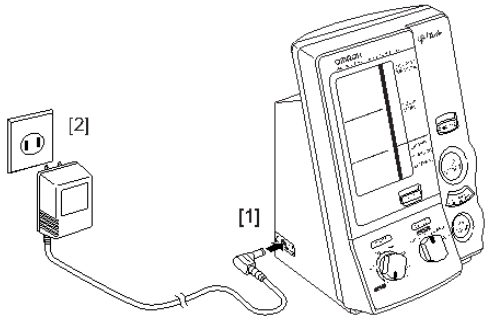
⚠Warning	
Do not use this unit in the presence of flammable gas, or anesthetics, or in a high pressure oxygen room or oxygen tent.	
Do not touch the AC adapter with wet hands.	

⚠Caution	
Be sure to use the AC adapter from the power supply of 110 VAC.	
Do not install or store this unit where it may come in contact with water or liquid medication. This is a Class II device with double isolation. Earth pin is not for protective purposes.	

General advice
• Read the instruction manual of the other devices to be used at the same time with this unit to understand and be aware of the interaction between the devices.

Connect the AC adapter to the DC jack of the main unit [1] and the electric outlet [2].

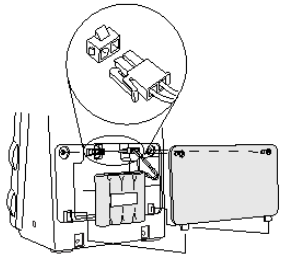
NOTE: When the AC adapter is connected and the unit is turned off, the AC adapter charges the installed rechargeable battery.



HOW TO USE THE POWER SOURCE

Installation and Replacement of Battery Pack

⚠Warning	
If battery fluid gets into your eye or comes in contact with skin, wash the affected area with water repeatedly. Immediately consult a doctor for treatment.	
Do not use the battery pack for devices other than for this unit. Do not disassemble the battery pack.	



1. Remove both screws on the upper portion of the battery cover of this unit, and remove the cover.
2. Disconnect the old battery pack from the connector and replace with a new one.
3. Install the battery cover and fasten it with both screws. Be careful not to pinch the lead wire.
4. Connect the main unit to the AC adapter to charge the new battery. The battery is not charged when you purchase the monitor. When you use the battery for the first time, charge it for more than twelve hours before use.

HOW TO USE THE POWER SOURCE

Battery life
- You can use the unit for approximately three hundred measurements with one charge.
- Approximate life of battery is two years. However the battery life from each charging may be shortened depending on the state of using. If the interval between charging becomes short and the icon appears frequently, replace it.

Charging time
- At approximately five seconds after connecting the AC adapter, the unit will start battery charging automatically.
- While the battery is being charged, the icon turns on.
- The battery can be completely charged in approximately twelve hours.

Battery low
- When the icon starts to blink, twenty to thirty measurements remain on the battery. However if the Battery Low Mark starts to blink, charge it soon.
- If the icon is displayed, the battery is low and the unit cannot operate. Please charge the battery.

Automatic Power Off
- When using the unit with the battery, the unit will turn off automatically after five minutes of inactivity.
- While the AC adapter is connected, the Auto Power Off function does not work.

HOW TO MEASURE BLOOD PRESSURE

⚠Warning
If cuff inflation does not stop, remove the cuff or pull out the air tube from the main unit.

General advice
• Patients should not touch the unit.

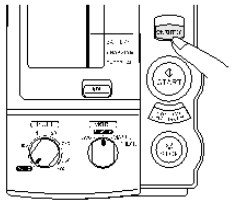
⚠Caution
Confirm readings with the stethoscope when an irregular pulse wave is displayed or when the measured value is questionable or erratic.
Do not use a cellular phone near this unit. Do not use this unit in a vehicle.

List of Measurement Modes

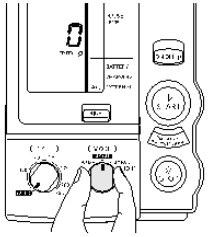
To measure only once	SINGLE Mode	Refer to Page 20.
To measure two times (or three times) automatically and consecutively	AVG Mode	Refer to Page 22.
To measure by using a stetho-scope	MANU Mode	Refer to Page 24.

HOW TO MEASURE BLOOD PRESSURE (IN SINGLE MODE)

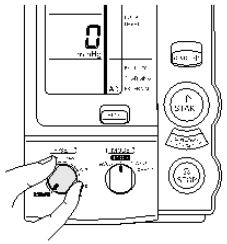
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to "SINGLE".



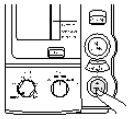
3. Set the P-SET (inflation level) Knob to "AUTO" or to the target pressure value.

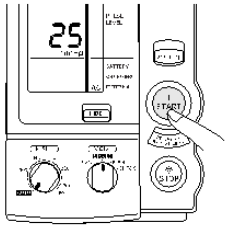


4. Measure the patient's arm size, and wrap appropriate cuff over the patient's arm. (Refer to Pages 14 and 15.)

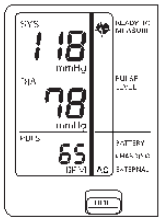
HOW TO MEASURE BLOOD PRESSURE (IN SINGLE MODE)

5. Push the START Button to start the measurement.
   - Do not push the START Button without wrapping the cuff.
   - If you want to stop measurement, push the STOP Button. The cuff will rapidly deflate.

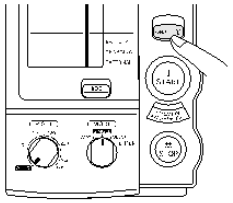




6. The measurement results are displayed.
   - While the battery pack is in use, the monitor will turn off automatically after five minutes of inactivity and the display (measurement results) will disappear. (Automatic Power Off)



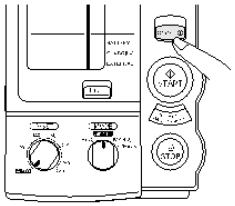
7. Push the ON/OFF (power) Button to turn off the power.



If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 28 and start the measuremen: again.

HOW TO MEASURE BLOOD PRESSURE (IN AVERAGE MODE)

1. Push the ON/OFF (power) Button to turn on the power.

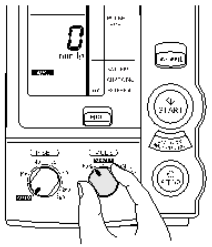


2. Set the MODE Selector to "AVG".

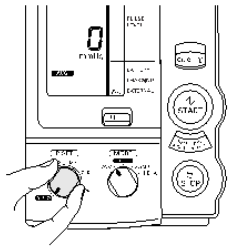
   The factory-set values are set as follows:

   - Number of measurements: 2
   - Waiting time until the 1st measurement: 0 sec.
   - Interval: 1 min.

   To change these factory-set values, refer to Page 13.



3. Set the P-SET (inflation level setting) Knob to "AUTO" or the target pressure value.



4. Measure the patient's arm size and wrap appropriate cuff over the patient's arm. (Refer to Pages 14 and 15.)

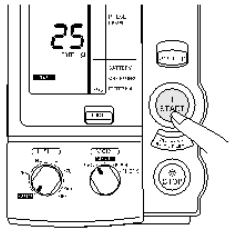
HOW TO MEASURE BLOOD PRESSURE (IN AVERAGE MODE)

5. Push the START Button to start the measurement.

   After the pre-select waiting time, the unit takes the 1st measurement.

   After displaying the results of 1st measurement, subsequent measures occur automatically at the specified intervals.

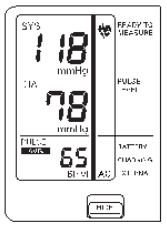
   - For setting the number of measurements, the waiting time until the 1st measurement, and the interval, refer to Page 13.
   - If you want to stop measurement, push the STOP Button. The unit will rapidly deflate.
   - If an error occurs during measurement, the monitor will automatically start measurement again. If a second error occurs, measurement will automatically stop.
   - Do not push the START Button without wrapping the cuff.



6. The measurement results are displayed.

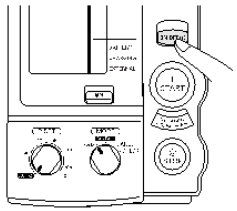
   After all the measurements are finished, average values will be displayed.

   Each time the DEFLATION (deflation control) / Measurement Result Display Switch Button is pushed, the measurement results for each reading and the average value will be displayed.



   - While the battery is in use, the monitor will turn off after five minutes of inactivity and the display (measurement results) will disappear. (Automatic Power Off)

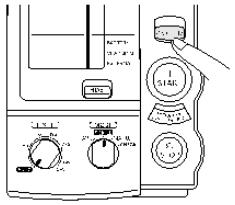
7. Push the ON/OFF (power) Button to turn off the power.



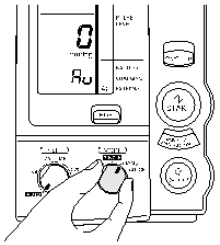
If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 28 and start the measurement again.

HOW TO MEASURE BLOOD PRESSURE (IN MANUAL MODE)

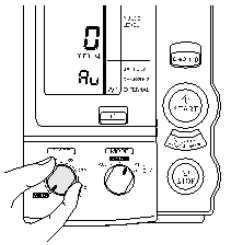
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to "MANU".



3. Set the P-SET (inflation level setting) Knob to "AUTO" or the target pressure value.

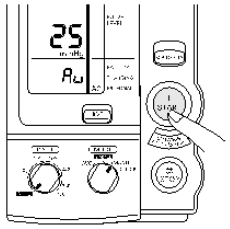


4. Measure the patient's arm size and wrap appropriate cuff over the patient's arm. (Refer to pages 14 and 15.)

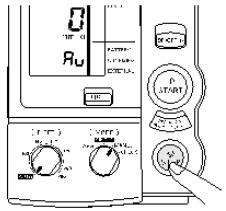
HOW TO MEASURE BLOOD PRESSURE (IN MANUAL MODE)

5. Place the stethoscope on the patient's arm.

6. Push the START Button to start the measurement.
   - Do not push the START Button without wrapping the cuff.
   - Do not squeeze or press the cuff during the measurement.
   - If you want to inflate again after the start of deflation, push the START Button.
   - If you want to accelerate deflation after the start of deflation, push the DEFLATION (deflation control) / Measurement Results Display Switch Button. Each time the Button is pushed, cuff is deflated rapidly in increments of 5 to 10 mmHg.

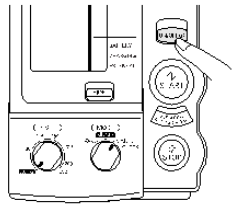


7. Take the readings.



8. Push the STOP Button to remove air inside the cuff.
   - The unit does not automatically deflate in the MANU Mode.

9. Push the ON/OFF (power) Button to turn off the power.



If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 26 and start the measurement again.

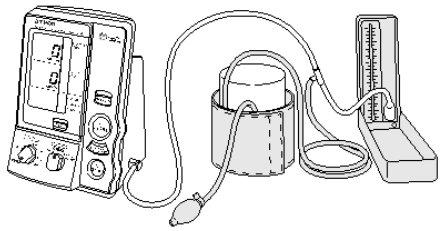
HOW TO CHECK PRESSURE ACCURACY (IN CHECK MODE)

Accuracy of pressure display can be checked in the CHECK Mode.

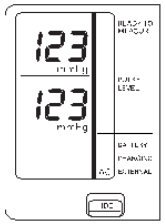
What you need to prepare

(1) Calibrated mercury manometer (including inflation bulb), (2) T-tube, (3) two air tubes, and (4) a sturdy cylindrical shaped object on which the cuff is wrapped.

How to check



1. Connect the manometer, inflation bulb, cuff, and the monitor with the T-tube as shown in the figure on the right.
2. Tightly wrap the cuff over a sturdy cylinder.
3. Release the valve of inflation bulb to remove the air inside the cuff completely.
4. Push the ON/OFF (power) Button to turn on the monitor.
5. Set the MODE Selector to "CHECK".
6. Close the valve of inflation bulb and inflate the cuff to the pressure to be checked, based on the manometer read.
7. Compare the pressure values displayed on the monitor to the one on the manometer.



Check result

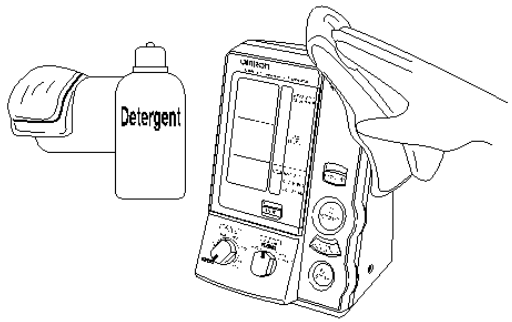
Accuracy of the monitor is validated to be ±3 mmHg or 2% of standard manometer reading. If your result shows a difference exceeding the tolerance, contact Omron repair department (1-877-216-1336).

HOW TO CLEAN THE UNIT AFTER USE

⚠Caution	
When cleaning this unit, unplug the AC adapter from the electric outlet.	
After cleaning this unit, dry it well, before plugging the AC adapter in the electric outlet.	

General advice
• Do not clean this unit with gasoline, paint thinner, or high concentration alcohol.
• Do not disinfect this unit by autoclave or gas sterilization (EtO, gluteraldehyde, or high concentration ozone.)

1. Wipe the monitor with a soft, damp cloth diluted with disinfectant alcohol, or diluted detergent.
2. Complete cleaning by wiping the monitor with a soft, dry cloth.



LIST OF ERROR CODES

Error code	Explanation	How to correct
Er 1	Inflation error • When the pressure does not exceed 12 mmHg within the set time after the start of inflation • When the inflation does not reach the set cuff pressure within the specified time after the start of inflation	• Confirm that the air tube connecting the cuff and the main unit is connected securely. • Confirm that the air flow in the air tube connecting the cuff and the main unit isn't being restricted. • Confirm that the cuff is wrapped correctly (refer to pages 14 and 15). • Check bladder for leaks and, if necessary, replace the bladder with new one (option).
Er2	Deflation error • When the deflation speed is too fast during the measurement • When the deflation speed is too slow during the measurement • When the measurement does not finish within the specified time after starting the measurement	
Er3	Overpressure error • The cuff pressure exceeded 299 mmHg.	• Confirm that air flow in the air tube connecting the cuff and the main unit isn't being restricted.
Er4	Insufficient inflation error • Blood pressure could not be measured due to insufficient inflation level.	• If the measurement is made by setting the P-SET to "AUTO", ask the patient not to move during the inflation. • Confirm that the P-SET is securely set to "AUTO". Turn the Knob counterclockwise as far as it goes until you can hear a click sound. • If the measurement is made by manual inflation level setting, set the value to 30 to 40 mmHg higher.
Er5	Indeterminable blood pressure error • Blood pressure could not be measured even when the cuff pressure reached the specified pressure.	• Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
Er6	Low pulse level error • Pulse wave was too small.	• Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
Er7	Blood pressure error • Relationship between systolic and diastolic pressures was abnormal	• Ask the patient not to move during the measurement. • Check the patient for arrhythmia.
Er8	Pulse rate error • Pulse rate did not stay within the range of 30 to 199 beats/min.	
Er9	Device error • Main unit malfunction.	• Contact Omron's repair department toll-free at (1-877-216-1336).

TROUBLESHOOTING

If the unit malfunctions during use, please check the following:

Trouble	What to inspect	How to correct
The unit inflates to abnormally high (low) pressure.	Is the cuff wrapped correctly?	Wrap the cuff correctly, and measure again. (Refer to Page 14 and 15.)
	Is the patient moving during inflation?	Ask the patient not to move during measurement, and measure again.
	Does this patient have arrhythmia?	Set the P-SET to 30 to 40 mmHg higher than estimated systolic pressure of the patient, then measure.
The monitor cannot measure blood pressure. Measured values are abnormally high (low).	Check the patient's condition.	After checking the patient with the stethoscope refer to the "list of error codes". (Refer to Page 28.)
	Is the patient moving during the measurement?	Ask the patient not to move during measurement, and measure again.
	Does the patient have an arrhythmia?	Set the P-SET to 30 to 40 mmHg higher than estimated systolic pressure of the patient, then measure.
	Is the size of the cuff correct and is it wrapped correctly?	Select the cuff according to the patient's arm circumference, wrap it correctly, then measure again. (Refer to Pages 14 and 15.)
	Is the level of the brachium to which the cuff is wrapped at the same level as the heart?	Keep the level of the brachium to which the cuff is wrapped at the same level as the heart, then measure again.
	Are the patient's clothes restricting normal blood flow to the arm?	Remove the clothing and measure again.

CAUTION

CAUTION:

Changes or modifications not expressly approved by Omron Healthcare, Inc. could void the user's authority to operate this product.

NOTE:

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)

This product has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the product on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the product and receiver.
- Connect the product into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for Canada only)

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled "Digital Apparatus", ICES-003 of the Canadian Department of Communications.

Cet appareil numerique respecte les limites de bruits radioelectriques applicables aux appareils numériques de Classe B prescrites dans la norme sur le matériel brouilleur "Appareils Numériques", NMB-003 édictée par le ministre des communications.

CLASSIFIED C UL US 58JN

Medical Equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1 and CAN/CSA C22.2 No. 601.1

FIVE YEAR LIMITED WARRANTY

Your HEM-907XL IntelliSense™ Automatic Blood Pressure Monitor is warranted to be free from manufacturing defects for a period of five years under normal use. The five year warranty excluces the monitor cuff. The cuff is warranted for a one year period. This warranty extends only to the original retail purchaser.

Should repair be needed within the warranty period, ship the unit prepaid to **Omron Healthcare, Inc., 300 Lakeview Parkway, Vernon Hills, IL 60061, Attn: Service Dept.**, together with $5.00 for return shipping and insurance. Be sure to include the model number of your unit and your phone number on any correspondence.

We will either repair or replace (at our option) free of charge any parts necessary to correct defects in the materials or workmanship.

The above warranty is complete and exclusive. The warrantor expressly disclaims liability for incidental, special, or consequential damages of any nature. (Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above warranty may not apply to you.)

Any implied warranties arising by the operation of law shall be limited in duration to the term of this warranty. (Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.)

This warranty gives you specific legal rights, and you may have other rights which vary from state to state. As a condition to operation of your warranty, the enclosed registration card must be completed and sent to us within 10 days from the date of purchase.

FOR CUSTOMER SERVICE CALL TOLL FREE:
1-877-216-1336

SPECIFICATIONS

Name:	OMRON Digital Automatic Blood Pressure Monitor
Model:	**HEM-907XL**
Display:	Digital display
Measurement:	Oscillometric method
Measurement Range:	Pressure; 0 to 299 mmHg Pulse rate; 30 to 199 beats/min
Accuracy:	Pressure; Within ±3 mmHg or 2% Pulse rate; Within ±5% of reading
Inflation:	Automatic inflation with pumping
Deflation:	Automatic deflation by electromagnetic control valve
Air Release:	Automatic rapid air release by electromagnetic control valve
Pressure Detection:	Electrostatic capacity semi conductor pressure sensor
Power supply:	AC adapter (120 VAC, 60 Hz, 20 VA) or Battery pack (4.8 VDC, 6W)
Electric Shock Protection Method:	Class II B type
Operating Temperature and Humidity:	50°F to 104°F (10 to 40°C), 30 to 85% RH, IPX 0 Rating
Weight of Main Unit:	Approx. 32 oz (910 g)
External Dimensions:	Approx.5 1/2" (W) x 8"(H) x 5 1/6"(D) 139 (W) x 203 (H) x 131 (D) mm
Accessories:	Cuff / bladder set Extra Large, Cuff / bladder set Large, Cuff / bladder set Medium, Cuff / bladder set Small, AC adaptor, Battery pack, air tube (1.0 m), Instruction Manual (with guarantee card)
Options:	Cuff Extra Large (without bladder), cuff Large (without bladder), cuff Medium (without bladder), cuff Small (without bladder), Bladder Extra Large, bladder Large, bladder Medium, bladder Small, air tube 1.3 m (51 1/6"), Stand exclusive for this unit, wall hanging kit, pole mounting kit

* Please note that specifications may be changed without prior notice.

Appendix 2. Sphygmomanometer Manual

Cuff Cleaning and Disinfecting

NOTE: Use one or more of the following methods and allow to air dry:

- Wipe with mild detergent and water solution (1:9 solution). Rinse.
- Wipe with Enzol per manufacturer's instructions. Rinse.
- Wipe with .5% bleach and water solution. Rinse.
- Wipe with 70% isopropyl alcohol.
- Launder with mild detergent in warm water, normal wash cycle. Remove bladder first. Cuff is compatible with 5 wash cycles.

Low Level Disinfection

Prepare Enzol enzymatic detergent according to the manufacturer's instructions. Spray detergent solution liberally onto cuff and use a sterile brush to agitate the detergent solution over entire cuff surface for five minutes. Rinse continuously with distilled water for five minutes. To disinfect, first follow the cleaning steps above, then spray cuff with 10% bleach solution until saturated, agitate with a sterile brush over entire cuff surface for five minutes. Rinse continuously with distilled water for five minutes. Wipe off excess water with sterile cloth and allow cuff to air dry.

⚠ **CAUTION:** Do not iron cuff.

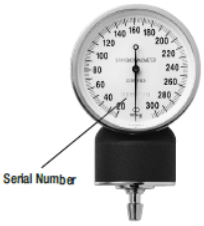
⚠ **CAUTION:** Do not heat or steam sterilize cuff.

Manometer Quality Control

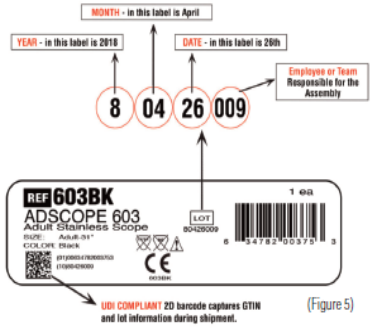
A serial number and lot number are automatically assigned to every aneroid during manufacturing, ensuring every item is "controlled."

The serial number can be located on the faceplate of each aneroid (Figure 4).

The lot number is located on the box end label (Figure 5).



(Figure 4)



(Figure 5)

Standards

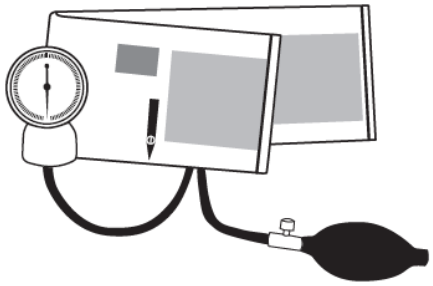
ANSI/AAMI/ISO 81060-1:2007 • EN/ISO 81060-1: 2012

Disposal

When your sphygmomanometer has reached its end of life, please be sure to dispose of it in accordance with all regional and national environmental regulations. Devices that have become contaminated should be disposed of in accordance with all local ordinances and regulations.

Aneroid Sphygmomanometer

Use, Care, & Maintenance



Warranty

The manufacturer warrants its products against defects in materials and workmanship under normal use and service as follows:

- Warranty service extends to the original retail purchaser only and commences with the date of delivery.

Warranty duration is as follows:

Manometer	Inflation System
5 YEARS	1 YEAR
10 YEARS	1 YEAR
[illegible] YEARS	[illegible] YEARS
LIFE	3 YEARS

What Is Covered: Calibration, repair, or replacement of parts and labor.

What Is Not Covered: Transportation charges. Damages caused by abuse, misuse, accident, or negligence. Incidental, special, or consequential damages. Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

Implied Warranty: Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law). This warranty gives you specific legal rights and you may have other rights which vary from state to state.

To Obtain Warranty Service: Send item(s) postage paid to: Warranty Service Center, 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

For Australian Consumers

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonable foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Device Description and Intended Use

An aneroid sphygmomanometer is used by professional healthcare providers and individuals trained in the auscultatory blood pressure technique to determine systolic and diastolic blood pressure in humans.

Contraindications

Aneroid sphygmomanometers are contraindicated for neonate use. Do not use with neonatal cuffs or neonate patients. Review the size chart (right) for proper limb range usage.

Size Chart

Cuff	Size	Limb Range Inches	CM
Infant	7I	3.5 to 5.5	9 to 14
Child	9C	5.1 to 7.6	13 to 19.5
Sm. Adult	10SA	7.4 to 10.6	19 to 27
Adult	11A	9 to 15.7	23 to 40
Lg. Adult	12X	13.3 to 19.6	34 to 50
Thigh	13T	15.7 to 25.9	40 to 66

Symbol Definitions

The following symbols are associated with your aneroid sphygmomanometer.

Symbol	Definition
	Important Warning/Caution
	Not made with natural rubber latex
	Phthalate Free
	Circumference Size

Symbol	Definition
CE	Conforms to EU Standards
EC REP	Authorized European Representative's Information
	Manufacturer's Information
	Temperature Limit
	Humidity Limitation

General Warnings ⚠

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately could lead to patient injury, illness, or death.

⚠ **WARNING:** Do not allow a blood pressure cuff to remain on patient for more than 10 minutes when inflated above 10 mmHg. This may cause patient distress, disturb blood circulation, and contribute to the injury of peripheral nerves.

⚠ **WARNING:** If luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intra-vascular fluid systems, allowing air to be pumped into a blood vessel. Immediately consult a physician if this occurs.

⚠ **WARNING:** Safety and effectiveness with neonate cuff sizes 1 through 5 is not established.

⚠ **WARNING:** If this equipment is modified, appropriate inspection and testing must be conducted to ensure its continued safe use.

⚠ **WARNING:** Do not apply cuff to delicate or damaged skin. Check cuff site frequently for irritation.

⚠ **WARNING:** Only use the cuff when the range markings indicated on the cuff show that the proper cuff size is selected, otherwise erroneous readings may result.

⚠ **WARNING:** Allow space between patient and cuff. Two fingers should fit in this space if the cuff is correctly positioned.

⚠ **WARNING:** Do not apply cuff to limbs used for IV infusion.

⚠ **WARNING:** Patient should remain still during measurement to avoid erroneous readings.

Measurement Procedure

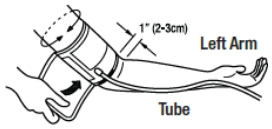
1. Patient Position

The patient should sit or lie comfortably. The arm should be fully supported on a flat surface at heart level. (If the arm's position varies, or is not level with the heart, measurement values obtained will not be consistent with the patient's true blood pressure.) When seated, the patient should have their back and arm supported, and their legs should not be crossed. The patient should relax prior to measurement comfortably for five minutes and should refrain from talking or moving during measurement. Observer should view manometer in a direct line to avoid "parallax error."

2. Apply the Cuff

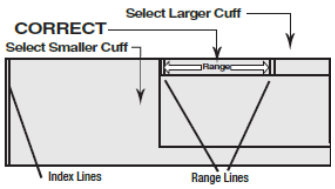
Nylon cuffs are specially designed to promote the precisely accurate determination of blood pressure. Index and range markings ensure use of the correct cuff size. The artery mark indicates proper cuff positioning.

Place the cuff over the bare upper arm with the artery mark positioned directly over the brachial artery. The bottom edge of the cuff should be positioned approximately one inch (2-3cm) above the antecubital fold. Wrap the end of the cuff not containing the bladder around the arm snugly and smoothly and engage adhesive strips (Figure 1).



(Figure 1)

NOTE: If the unit is equipped with a calibrated nylon cuff, featuring Index and Range markings, a correct fit may be verified by checking that the Index Line falls between the two Range Lines. (Figure 2).



(Figure 2)

3. Inflate the Cuff

Close the valve by turning thumbscrew clockwise.

Palpate the radial artery while inflating the cuff. Be sure to inflate cuff quickly by squeezing bulb rapidly.

Inflate cuff 20-30 mmHg above the point at which the radial pulse disappears.
NOTE: Cuff pressure range is 0 mmHg to 300 mmHg.

4. Position the Stethoscope

Position the chestpiece in the antecubital space below the cuff, distal to the brachium. Do not place chestpiece underneath the cuff, as this impedes accurate measurement. Use the bell side of a combination stethoscope for clearest detection of the low pitched Korotkoff (pulse) sounds.

5. Deflate the Cuff

Open the valve to deflate the cuff gradually at a rate of 2-3 mmHg per second.

6. Measurement

Record the onset of Korotkoff sounds as the systolic pressure, and the disappearance of these sounds as diastolic pressure. (Some healthcare professionals recommend recording diastolic 1 and diastolic 2. Diastolic one occurs at phase 4.)

NOTE: It is recommended that K4 be used in children aged 3 to 12, and K5 should be used for pregnant patients unless sounds are audible with the cuff deflated, in which case K4 should be used. K5 should be used for all other adult patients.

After measurement is completed, open valve fully to release any remaining air in the cuff. Remove cuff.

⚠ **WARNING:** When using with an infant or child cuff, extra care must be taken to prevent over-inflation. With smaller cuffs (infant or child) the cuff can inflate to over 300mmHg with just two full compressions of the bulb. To prevent discomfort or injury to the patient and damage to the instrument, bulb should only be partially squeezed, so that each "stroke" inflates the cuff in 40mmHg to 60mmHg increments until inflated to the desired level.

⚠ **CAUTION:** To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within a temperature range of 50°F (10°C) to 104°F (40°C), with a relative humidity range of 15%-85% (non-condensing).

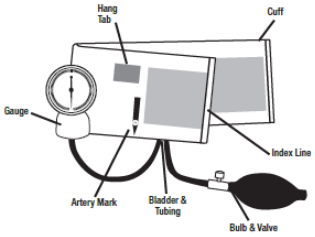
⚠ **CAUTION:** Extreme altitudes may affect blood pressure readings. Your device has been designed for normal environmental conditions.

Operation of Pocket Aneroids

This booklet contains operating and maintenance information for pocket aneroid sphygmomanometers. Please read and retain.

Your pocket aneroid sphygmomanometer consists of an aneroid manometer (gauge), complete inflation system, (latex-free inflation bladder, squeeze bulb, and the valve), a zippered carrying case, and operating instructions.

Most models come preassembled and ready for use. If assembly is required, attach gauge and bulb and valve assemblies to the tubes as shown in illustration. To facilitate, use alcohol or soapy water.



Care and Maintenance

STORAGE

Pocket Gauge: After measurement, fully exhaust cuff then wrap cuff around gauge and bulb and store in zippered carrying case.

NOTE: This product will maintain the safety and performance characteristics specified at temperatures ranging from 50°F to 104°F (10°C to 40°C) at a relative humidity level of 15% to 85%.

This device can be safely stored at temperatures ranging from -4°F (-20°C) to 131°F (55°C) with a relative humidity of 90%.

Manometer: Your pocket aneroid gauge requires minimal care and maintenance.

The manometer may be cleaned with a soft cloth but should not be dismantled under any circumstances.

NOTE: Store gauge with valve in full exhaust position.

(Figure 3)

Should the indicator needle of the manometer rest outside the oval calibration mark (Figure 3), then the manometer must be re-calibrated to within ±3 mmHg when compared to a reference device that has been certified to national or international measurement standards. A manometer whose indicator needle is resting outside of this mark is NOT acceptable for use.

In the event that the gauge is ever in need of calibration, simply return for service. Damaged or broken parts will be replaced as needed at a minimal charge. Refer to the warranty for specific details of warranty coverage.

The manufacturer recommends a calibration check every 2 years.

Appendix 3. Checklist for Observation of Blood Pressure Measurements

Instructions: This checklist documents observation of technicians certified to perform blood pressure by supervisors. Quarterly checklists and logs are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 2).

Tech ID: Supervisor ID: Date:

	Yes	No	Comments
1. Checks function settings on OMRON unit (ENTER, 3 inflations, 30)			
2. Checks Mode and P-setting on OMRON unit			
3. Makes sure AC adapter for OMRON unit is securely connected (tends disconnect from unit)			
4. Checks AC adapter cord and tubing for cracks			
5. Cleans all the equipment			
6. Allows subject to rest for five full minutes			
7. Performs arm measurement and cuff selection properly			
8. Identified brachial pulse location properly			
9. Proper cuff placement			
10. Attaches cuff to monitor			
11. Uses proper settings on OMRON unit			
12. Turns monitor on with ON/OFF button			
13. Sets MODE selector to AVG			
14. Sets P-SET knob to AUTO			
15. Pushes START button			
16. Records 1st, 2nd, 3rd and average systolic and diastolic BP readings and average heart rate			
17. Instructions to participant are clear			
18. Holds arm vertically for 5 seconds between readings			
19. Informs participant of average readings			

Comments:

Appendix 4. Certification Request Form

Instructions: This form documents which procedures/interviews a staff member is certified for and how they received certification. It is submitted by the **Trainer** or **Study Coordinator** to the Coordinating Center (CC) for final evaluation and assignment of staff code number.

Tech ID: Date:

Staff name:

Code number (if already assigned):

Coordinating Center Use Only
Assigned staff code number: _____
Date Received:_____Processed by _____

Specify for which procedure/interviews the staff member has completed certification requirements and describe specific actions that were taken to achieve these steps (including supervisors or certified staff members who observed the process).

Procedure & Interview	Date Certified	*Certification Method (choose all that apply)	CC approval (Y/N)
General Interview			
Medical Interview			
Food Frequency Questionnaire			
Informant Interview			
Informed Consent			
Anthropometry			
Sagittal Abdominal Diameter			
Sitting Blood Pressure			
Neurocognitive Test			
Physical Function			
Pulse Wave Velocity			
Ziopatch			
Electrocardiography			
Echocardiogram			

Brain MRI			
Venipuncture			
Urine			
Results Reporting			
Letters sent to Participants with Reports of Exam Results			
Data Inventory			
Referrals			
Exit Interview			
Participant Safety			

*1 = Attended JHS training meeting
2 = Certified by central trainer
3 = Direct observation by the local certified lead staff member in specified area
4 = Completed written exam
5 = Completed practice. Specify how many sets of practice were performed, and the differences of the measurements compared to the local trainer's for local certification.
6 = Other (specify)
7 = N/A (not applicable to the staff member)
8 = Attended webinar

Appendix 5. Omron BP Monitor Maintenance and Calibration Log

Instructions: This checklist documents the quarterly checks for the OMRON BP machine. There should be one such log done every quarter. If there is more than one BP monitor used indicate the checks with a separate log for each monitor. Quarterly checklists are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 2).

Tech ID: Date:

Blood Pressure Measurement **OMRON unit #:**

	Yes/No	If YES, action
Cracking		
Holes		
Worn outer cloth of Velcro		
Leakage of cuff bladder		
Calibration Check with Pressure-Vacuum Meter		
Smooth descent of OMRON LED mm Hg from 280 to 100 mm Hg		
Observed pressure values 250 to 20 mm Hg, in approximant decrements of 20 mm Hg	**OMRON (mm Hg)**	**Pressure-Vacuum Meter (mm Hg)**
Measurement Number 1		
Measurement Number 2		
Measurement Number 3		
Measurement Number 4		
Measurement Number 5		
Measurement Number 6		
Measurement Number 7		
Measurement Number 8		
Measurement Number 9		
Measurement Number 10		
Measurement Number 11		
Measurement Number 12		

Appendix 6. Checklist for Biannual Observation of BP Technicians by BP Supervisor

BP Technician Code #_____ Observer Code #_____

Date Observed ____/____/_____

_____

Instructions: 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. Supervisor should recheck all measurements and procedures.

	Yes	No
ALL:		
Measures arm for correct cuff size	( )	( )
Palpates brachial artery	( )	( )
Marks pulse point	( )	( )
Wraps cuff center of bladder over brachial pulse	( )	( )
Leaves subject for full five minutes of rest	( )	( )
Instructs on Posture	( )	( )
Work station free of excessive noise	( )	( )
Explanation of procedure	( )	( )

	Yes	No
OMRON		
Assure unit is properly plugged into wall unit	( )	( )
Push ON/OFF button to turn on power	( )	( )
Set the MODE for AVG (if off site) Set the MODE for MANU if on site	( )	( )
Set the P-SET to AUTO (if off site) Set the P-SET to = Item 15 SBP-B (if on site)	( )	( )
Wrap the proper size cuff on arm	( )	( )
Press the START button to take measurement	( )	( )
Records the first measurement	( )	( )
Records the second measurement	( )	( )
Records the average measurement (if off site)	( )	( )
Push the ON/OFF button to turn the power off	( )	( )
Inform the participant of the average reading	( )	( )

Special Comments:

_____

_____

_____

Appendix 7. JHS Monthly Log for Sitting Blood Pressure Station

Month_____Year_____

Weekly Check Procedures:

		Week				
		1	2	3	4	5
1.	Date of Check					
C.	Check Omron for Accuracy	_____	_____	_____	_____	_____

E. List the problem encountered, the date, and the actions taken below:

_____

_____

_____

Monthly Check Procedures:

C. Accuracy check for Omron monitor (to be performed every two months)

Date of Check: _____

Problems found on accuracy check? ( ) Yes ( ) No

If yes, list problems found and corrective action taken:

_____

_____

_____

D. 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 8. Form for Recording Simultaneous Blood Pressure Observations on a Volunteer by Two Technicians

Instructions:

Biannually, each technician should be part of a pair of technicians who simultaneously measure blood pressure using an Y-tube on a volunteer (not a JHS participant). Each technician should separately record his/her measurements on a standard paper JHS 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.

Technician IDs: 1st ID: _____ 2nd ID:_____ Date: _____

		1st Technician	2nd Technician	Difference
a.	Initial arm circumference (cm)	_____	_____	_____
b.	Initial cuff size selected	_____	_____	_____
c.	Pulse Obliteration Pressure	_____	_____	_____
d.	First SBP	_____	_____	_____
e.	First DBP	_____	_____	_____
i.	Second SBP	_____	_____	_____
j.	Second DBP	_____	_____	_____
n.	Average Net SBP	_____	_____	_____
o.	Average Net DBP	_____	_____	_____

ACTION TAKEN IF DIFFERENCES BETWEEN TECHNICIANS EXCEED LIMITS SPECIFIED:

_____

_____

_____

_____

_____

	Omron Technician
1	Apply the *Omron* appropriate sized cuff to the participant's arm with the arrow at the brachial artery (same size used during the core exam Blood Pressure measurement).
2	
3	Turn on the *Omron*. Turn the P-SET dial on the *Omron* to the P-Set level estimated in #5 (RZ) above. Turn the MODE on the *Omron* to **MANUAL**.
4	Place the double Y-stethoscope earpieces into ears, holding the bell over participant's artery.
5	Press **START** on the *Omron*, cuffs will inflate.
6	Watch the *Omron*.
7	Listen for the onset of 1st (sounds) and 5th (disappearance) Korotkoff phase sounds.
8	When the cuff is completely deflated and the *Omron* is at "0," record the systolic and diastolic BP levels from the *Omron* (Item 24 for 1st reading).
9	

Appendix 9. Sitting Blood Pressure Form

SITTING BLOOD PRESSURE

ID NUMBER: J _____ _____ _____ _____ _____ _____

VISIT: 0 4

NAMECODE: _____ _____ _____ _____ _____ _____ _____

ADMINISTRATIVE INFORMATION

0a. Completion Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

0b. Staff ID: ___ ___ ___

0c. Method of Data Collection:
In-house ☐ 1
Off-site ☐ 2

A. ARM MEASUREMENTS

1. Arm used for sitting blood pressure measurement (choose one):

Right (preferred) ☐ 1
Left ☐ 2

2. Arm circumference: ___ ___ . ___ cm

3. Cuff size (arm circumference in brackets):

Small {17.0-21.9 cm, HEM -907-CS19} ☐ 1
Adult {22.0-32.5 cm HEM-907- CR19} ☐ 2
Large {32.6-42.5 cm HEM-907- CL19} ☐ 3
X Large {42.6-50+ cm HEM-907 CX19} ☐ 4

4. Time of measurement: ___ ___ : ___ ___
HH MM

(Record the time of the beginning of the first blood pressure measurement.)

B. FIRST BLOOD PRESSURE / PULSE RATE

___ ___ ___

5. Systolic ..... mmHg

6. Diastolic ..... ☐☐☐ mmHg

7. Pulse ..... ☐☐☐ bpm

C. Second blood pressure / pulse rate

8. Systolic ..... ☐☐☐ mmHg

9. Diastolic ..... ☐☐☐ mmHg

10. Pulse ..... ☐☐☐ bpm

D. THIRD BLOOD PRESSURE / PULSE RATE

11. Systolic ..... ☐☐☐ mmHg

12. Diastolic ..... ☐☐☐ mmHg

13. Pulse ..... ☐☐☐ bpm

E. AVERAGE BLOOD PRESSURE / PULSE RATE

14. Systolic ..... ☐☐☐ mmHg

15. Diastolic ..... ☐☐☐ mmHg

16. Pulse ..... ☐☐☐ bpm

Appendix 10. Ankle-Brachial Index Blood Pressure Form

ANKLE–BRACHIAL INDEX BLOOD PRESSURE

ID NUMBER: J | | | | | | | VISIT: 0 4

ADMINISTRATIVE INFORMATION

0a. Completion Date: | | / | | / | | | | 0b. Staff ID: | | |

Month Day Year

"You will have blood pressures checked in your arms and legs. The method used to do this is similar to standard blood pressure measures. An ultrasound device will be used allowing you to hear the blood flow while the blood pressure is taken. There is no more discomfort involved beyond having a blood pressure cuff placed on your arms and ankles."

A. EXCLUSIONS

1. Does the participant have any open wounds in the ankle or arm cuff area?

Yes ☐ 1 → Exclude; end of form
No ☐ 0

2. Has the participant undergone bilateral amputation?

Yes ☐ 1 → Exclude; end of form
No ☐ 0

3. Is the participant unable to lay supine?

Yes ☐ 1 → Exclude; end of form
No ☐ 0

4. Has the participant had a double mastectomy?

Yes ☐ 1 → Exclude; end of form

No ☐ 0

B. FIRST MEASUREMENTS – Peak Systolic Pressure (Record in this order)

5. Right brachial: ☐☐☐ mm Hg
6. Left brachial: ☐☐☐ mm Hg
7. Right dorsalis pedis: ☐☐☐ mm Hg
8. Right posterior tibial: ☐☐☐ mm Hg
9. Left dorsalis pedis: ☐☐☐ mm Hg
10. Left posterior tibial: ☐☐☐ mm Hg

C. SECOND MEASUREMENTS – Peak Systolic Pressure (Record in this order)

11. Right brachial: ☐☐☐ mm Hg
12. Left brachial: ☐☐☐ mm Hg
13. Right dorsalis pedis: ☐☐☐ mm Hg
14. Right posterior tibial: ☐☐☐ mm Hg
15. Left dorsalis pedis: ☐☐☐ mm Hg
16. Left posterior tibial: ☐☐☐ mm Hg

D. REASONS PROCEDURE WAS NOT COMPLETED

17. *If right brachial pressure was not obtained,* identify reason:
    Unable to occlude ☐ 1
    Unable to locate artery ☐ 2
    Other, specify: ☐ 3

    17a. _____

18. *If left brachial pressure was not obtained,* identify reason:
    Unable to occlude ☐ 1
    Unable to locate artery ☐ 2
    ☐

Other, specify: ☐ 3

18a. _____

19. *If right dorsalis pedis pressure was not obtained,* identify reason:

Unable to occlude ☐ 1
Unable to locate artery ☐ 2
Other, specify: ☐ 3

19a. _____

20. *If right posterior tibial pressure was not obtained,* identify reason:

Unable to occlude ☐ 1
Unable to locate artery ☐ 2
Other, specify: ☐ 3

20a. _____

21. *If left dorsalis pedis pressure was not obtained,* identify reason:

Unable to occlude ☐ 1
Unable to locate artery ☐ 2
Other, specify: ☐ 3

21a. _____

22. *If left posterior tibial pressure was not obtained,* identify reason:

Unable to occlude ☐ 1
Unable to locate artery ☐ 2
Other, specify: ☐ 3

22a. _____

Appendix 11. ABI Certification Check Sheet

Stand Up JHS Ancillary – ABI Certification Check Sheet

Study Staff _____

Date _____

Observer _____

ABI Preparation		Yes	No
	Staff assesses participant eligibility		
	Staff identifies all necessary equipment: - Unetixs Multilab Series II - Remote Cuff Selector and air hoses - Remote control to operate device - Doppler Probe - Doppler Conducting Jelly - BP Cuffs (SC – 10 and SC –12) - Tissues to remove conducting jelly - Black, waterproof eyeliner pencil - Tegaderm - USB Flash Drive		
Participant Set-Up Procedure		**Yes**	**No**
	Staff explains ABI process to participant with the following script: *"You will have blood pressures checked in your arms and legs. The method used to do this is similar to how your doctor would typically measure your blood pressure. An ultrasound device will be used allowing you to hear the blood flow while the blood pressure is taken. There is no more discomfort involved beyond having a blood pressure cuff inflated on your arms and ankles."*		
	Staff instructs participant to remove excess clothing. If examination room is cold, staff provides gown or extra covering - Arms below the shoulder and legs below the knee should be bare		
	Staff instructs participant to lie supine, with the head and heels at the same level - Head and feet are on the examination table, not overhanging		
	Staff checks participant for lesions via venous puncture. If present, staff applies Tegaderm over the site		

	Staff applies all four BP cuffs on participant (right arm, left arm, right ankle, left ankle) - Staff ensures snug fit (tests with one finger under the cuff) - Staff ensures no unusual folding or wrinkling of the cuff		
	Staff place Remote Control Cuff Select between participants feet ensuring all valves closed		
	Staff connects all four cuffs to the appropriate air hose on the Remote Control Cuff Selector: - Right arm cuff – R1 - Left arm cuff – L1 - Right ankle cuff – R5 - Left ankle cuff – L5		
	Staffs instructs participant to rest, stay still and refrain from talking for 5 minutes before starting ABI measurements		
Monitor Set-Up Procedure		**Yes**	**No**
	Staff powers on the MultiLab Device and opens the S2WIN Program		
	Staff starts an ABI study		
	Staff accurately labels the study with the participant ID, as described in the protocol (ex. JHS_101_1)		
ABI Testing		**Yes**	**No**
	Staff completes *Right Brachial Pressure* measurement - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain Peak Systolic Pressure		
	Staff completes *Left Brachial Pressure* measurement - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain Peak Systolic Pressure		
	Staff completes *Right Dorsalis Pedis Doppler* - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe		

	- Follows procedures described in protocol to obtain waveform		
	Staff completes *Right Ankle Pressure – Dorsalis Pedis* measurement - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain Peak Systolic Pressure		
	Staff completes *Right Posterior Tibial Doppler* - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain waveform		
	Staff completes *Right Ankle Pressure – Posterior Tibial* measurement - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain Peak Systolic Pressure		
	Staff completes *Left Dorsalis Pedis Doppler* - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain waveform		
	Staff completes *Left Ankle Pressure – Dorsalis Pedis* measurement - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain Peak Systolic Pressure		

	Staff completes *Left Posterior Tibial Doppler* - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain waveform		
	Staff completes *Left Ankle Pressure – Posterior Tibia*l measurement - Ensures the correct air valve on the Cuff Selector is open - Locates and marks the appropriate artery - Applies ultrasound jelly - Locates the artery using the Doppler pen probe - Follows procedures described in protocol to obtain Peak Systolic Pressure		
	Staff completes testing by disconnecting all BP cuffs and hoses from participant		
	Staff answer any questions participants may have		
Device Maintenance After Participant		**Yes**	**No**
	All equipment is thoroughly cleaned with approved products as highlighted in the protocol		
ABI Data Management		**Yes**	**No**
	Staff locates participant files to export/print		
	Staff prints participants' study reports and identifies where to store (ex. Secure, participant study file)		
	Staff uses USB flash drive to export participants' study reports		
	Staff demonstrates correct shutdown of program and device once data management procedures are complete		