Manual 37
Orthostatic Hypotension Procedures
ARIC Visit 10

Version 2.1 – 8/14/2023

Orthostatic Hypotension (OH)
Manual of Procedures
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MANUAL REVISIONS

Date	Version	Section	Revision Summary
2/28/2023	1.4	Appendices	Removed OH results letter template, threshold values, and interpretations. These will now appear in a separate document on the ARIC website (with this manual). Renumbered appendices.
4/18/2023	2.0	Appendix F	Added information about the Blood Pressure Stand-Alone Visit as Appendix F.
8/11/2023	2.1	Appendix G, H, I	New appendices added (G-I) with instructions for completing accuracy checking on the OH Omron device with the SimCube.

1 OVERVIEW

1.1 PURPOSE

Orthostatic hypotension (OH), a temporary state of low blood pressure that occurs upon standing, is common among older adults and has been associated with an increased risk of falls, dementia, and cardiovascular disease. In this ancillary study, we will perform an OH assessment in ARIC participants. The OH protocol is an optional ancillary study.

1.2 WHEN

- Consent
    - During Visit 10. Participants will be asked to participate in the OH protocol later in the day.
    - A Legally Authorized Representative (LAR) may provide consent for participants (e.g., participants with dementia are eligible if their LAR consents).
- Visit 10 protocol
    - During Visit 10 after the ARIC seated BP assessment (SBP).
    - Note, this protocol will be offered for in-clinic visits **only** and is not available for home visits.

1.3 WHO

- 1 physical examiner for OH measurements; a second examiner is optional for safety purposes.

1.4 EQUIPMENT, MATERIALS, AND SUPPLIES

- Clinic bed (height 28 inches/92 centimeters)
- Stepping stool
- 2-3 clinic pillows (consider disposable pillow cases)
- Chair (in case participant needs to sit)
- 1 mobile bedside table/arm rest
- Stopwatch
- Omron HEM-907XL BP monitor with 4 blood pressure cuffs (image to the right)
- Omron HEM-907XL BP monitor stand with basket for Omron
- Hand-held calculator

1.5 FORMS, LOGS, AND SCRIPTS

- CDART Data Collection Forms
    - Orthostatic Hypotension Blood Pressure Form (OBP)
        - OBP-Orthostatic Hypotension Non-CDART Form: This version of the OBP form is more conducive to data collection and can be completed on paper before entering into CDART.
    - Orthostatic Hypotension Symptom Questionnaire (OSQ)
- Scripts and Instructions
    - ARIC Orthostatic Hypotension Protocol Instruction Script

1.6 CONSENT PROCESS

- OH is incorporated into the standard ARIC consent form. A Legally Authorized Representative (LAR) may provide consent for participants. This will be noted on the standard ARIC consent form.
- Participants with a LAR can participate with the consent of their LAR.
- Participants are free to decline OH at any point in the visit (e.g., they may sign the consent that includes OH but later decide not to take part in this assessment).

1.7 INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

- All participants who provide informed consent are eligible to participate in OH.
- If the participant has a LAR, they are still eligible to participate in OH with the consent of their LAR.
- A wheelchair is **not** an exclusion. If the participant can stand for the protocol with assistance (i.e., support from staff, walker, cane, table, wall, etc.), this is okay.

Exclusion criteria:

- Failure to receive consent from participant or LAR.
- Elevated ARIC Seated Blood Pressure (see section 3.2 for safety protocols). If a participant has an average Systolic Blood Pressure ≥200 or Diastolic Blood Pressure ≥120 mmHg, the exam will be stopped for the participant to receive urgent care. The participant will be ineligible for the OH protocol. These safety parameters are identical to ARIC's safety procedures for seated blood pressure. The OH protocol will be performed directly after the ARIC Seated Blood Pressure so that staff can determine a participant's eligibility.
- Arm circumference of > 50 cm (i.e., if a participant is unable to use the extra-large cuff). See arm cuff sizes and arm circumference ranges for the Omron HEM-907 XL below.
    - Note: In borderline cases, such as an arm circumference of 50.1- 50.5 cm, staff may round to 50 cm to err on the side of including the participant.

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)

2 STUDY PROCEDURES

2.1 SET-UP

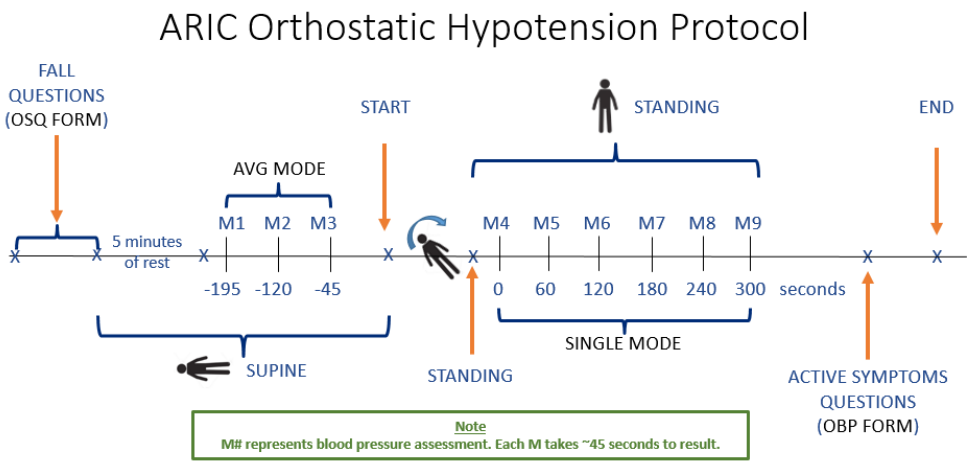
- Check that Omron is programmed to obtain **3** blood pressure measurements separated by 30 seconds each in "AVG" mode (see **Appendix A. Procedure for Programming Omron** for more details).
  - Note: This can be changed to 1 or 2 measurements if a participant expresses a preference for fewer measurements.
- Affix participant-specific label onto the OBP and OSQ forms if collecting those forms on paper.

2.2 QUESTIONNAIRE ADMINISTRATION

- Timing: Prior to the physical assessment.
- Administer the Orthostatic Hypotension Symptom Questionnaire (OSQ) form (this should be interviewer-administered).

2.3 SPECIFIC ORTHOSTATIC HYPOTENSION ASSESSMENTS

2.3.1 Overview



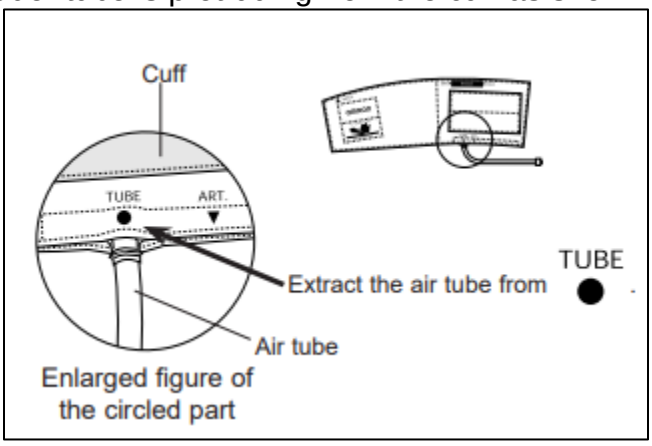
Participants will lie supine for 5 minutes. Afterward, a set of 3 blood pressure measures will be performed using the Omron HEM-907XL, which should be programmed to separate each measure by 30 seconds. When the last of the 3 measurements is recorded, participants will be asked to stand up with their arm resting on an adjacent bedside table or arm rest at heart level. We will record the time it takes for participants to stand up.

Immediately after the participant is upright and both feet are planted on the floor the Omron will be initiated to obtain standing blood pressure measurements, using **the**

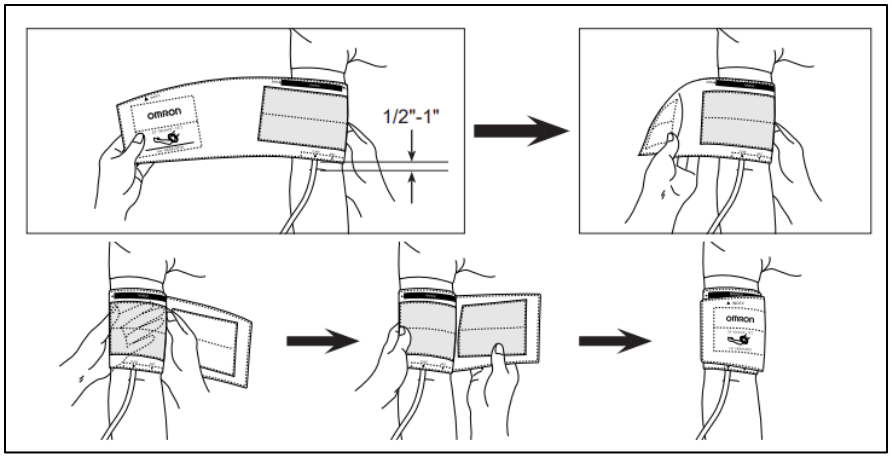
single measurement mode (See **Appendix C** for how to take a measurement in single mode) and the stopwatch. BP measurements should be measured immediately after standing (0 minutes), 1 minute after standing, 2 minutes after standing, 3 minutes after standing, 4 minutes after standing, and 5 minutes after standing (total 6 standing assessments).

2.3.2 Prior to OH Assessment with Participant in Room

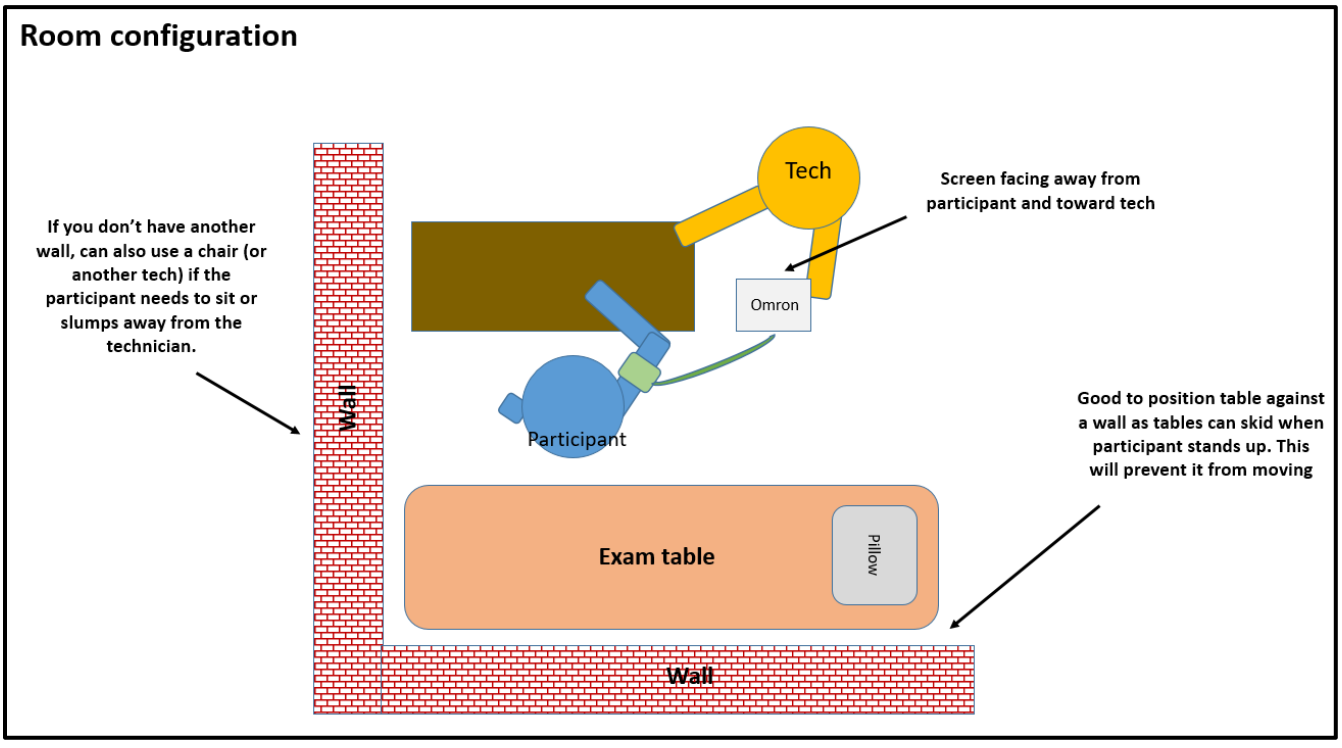
- Confirm the participant's subject ID and participant code.
- Determine the appropriate cuff size for the participant. Note: If the participant has an arm circumference of more than 50 cm, they will be ineligible to participate (note in borderline cases staff may round to 50 cm to err on the side of including the participant).
  - Measure arm if necessary (follow procedures in Section 10. Sitting Blood Pressure of the **ARIC Manual 2 Home and Field Center Procedures ARIC Visit 7 Study Protocol**).
  - Before applying the cuff, check the following:
    - The bladder is correctly installed in the cuff.
    - The bladder is not twisted inside the cuff.
    - The bladder tube is protruding from the cuff as shown in the figure below:



  - Place the appropriate cuff size on the participant
    - Staff should feel for brachial artery (just medial to and above the cubital fossa) and wrap the cuff over the artery about 1/2-1" above the participants elbow on their non-dominant arm (unless otherwise stated).
    - The cuff should be positioned over bare skin.
    - Check the fit of the cuff to ensure that it is secure, but not too tight. The cuff should be of uniform pressure against the arm. The cuff should be snug enough to fit 2 fingers just underneath both ends of the cuff.



- While the participant is standing, pre-position a bedside table or arm rest to about heart level that will allow the participant's arm to rest comfortably on a pillow outstretched at 70-80 degrees from their torso.
- Read the OH Protocol Instruction Script.
  - Monitor whether the participant anticipates needing assistance (i.e. help from staff, walker, cane, table) to stand or if they have safety concerns.



2.3.3 Supine Protocol

- PROCEDURE NOTE: At any point during OH blood pressure assessments, if the participant is noted (or requests) to "flex" or wiggle their hand, this is permitted if it occurs immediately after the completion of a blood pressure

determination, during the 30 second interval between the end of one cycle and the beginning of the next. This is helpful if the participant expresses discomfort due to venous congestion in the hand, which occurs rarely.

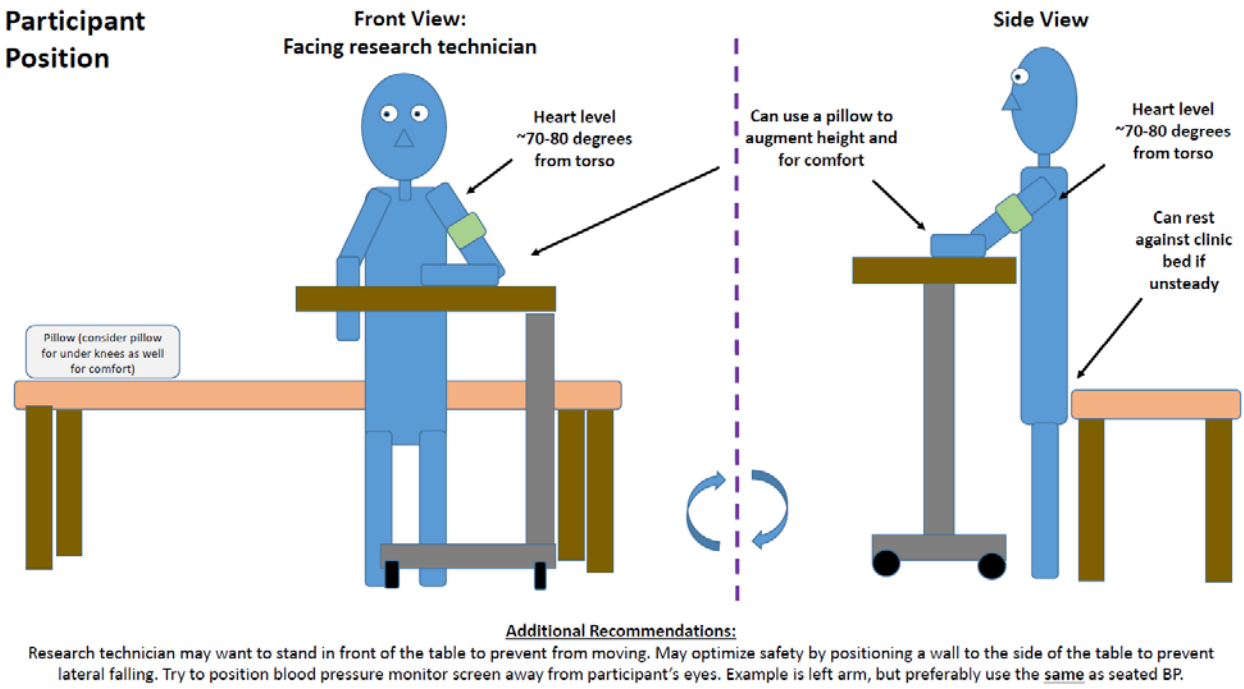
- In the standing position, position cuff on participant's same arm as used for the seated assessment.
  - Arm used should be documented on question #1 on the OBP form. Document the participant's dominant arm on the OBP form as well.
- Ask the participant to lie down on the clinic bed. Confirm that the cuff has not shifted during change in positions. If it has shifted, readjust the cuff to be in the appropriate position.
- Attach cuff to the Omron HEM-907XL.
- Ensure the Omron is in average mode to provide the average value after the three supine measurements. To revisit each measurement in the avg mode, the deflating button can be used to toggle between the readings.
  - Program settings should be as follows: **(See Appendix A** for more detailed instructions on measuring a blood pressure in AVG mode)

    Note: Remember to use the deflating button to toggle between settings (changing options)
    - F1: 3 (this sets the number of measurements to be 3 consecutive measurements).
    - F2: 5 (this sets the wait time before the 1st measurement to 5 minutes. This is the 5 minute rest period before the OH assessment).
    - F3: 30 (this sets the measurement interval. There will be a 30 second rest between deflation and re-inflation of each measurement).
- Tell participant: **We will now begin the orthostatic blood pressure assessment. Please lie down on the bed motionless, without talking, with your arms at your side. I will return after 4 minutes.**
- Once the participant is on the bed, if needed, provide pillow(s) under knees or head for participant's comfort.
- Start the stopwatch and push the START button. Record the time that the START button is pressed on the OBP form.
- At 4 minutes, return to the room and confirm Omron settings.
- If participant has fallen asleep, provide a gentle nudge on the arm.
- Before the 5th minute, alert the participant that the blood pressure measurements are about to begin. They will start automatically.
  - The Omron should be preprogrammed for 3 measurements separated by **30 seconds** each. (**See Appendix A and B** for more details related to taking a measurement in AVG mode)**.**
- Record systolic blood pressure, diastolic blood pressure, and heart rate with each result along with the average.
- Recommended: Use the hand-held calculator to calculate a manual average for comparison with the Omron reported average. This additional step will allow you to identify any transcription errors before the Omron data are cleared. Note: Only the Omron reported average should be recorded on the OBP form and into CDART.

- **<u>Change the OMRON mode from average to "single."</u> (See Appendix C for more detailed instructions)**

2.3.4 Transition from Supine-to-Standing

- **<u>SAFETY NOTE:</u>** There is a fall risk at this point; resist any pressure to rush participant, as safety is the first priority.
  - Assistance may be provided to the participant to help them get up.
  - If the participant feels dizzy or uncomfortable, instruct them to lean against the table, and then help them into the chair if necessary.
  - Staff should use their clinical judgment to ensure the safety of the participant – if there are concerns about participant's ability to safely stand and remain standing, the protocol may be completed in a seated position, and this should be documented on the OBP Data Collection Form.
  - Providing assistance or early termination should be documented in the Staff Observation section of the OBP Data Collection Form.
- Tell the participant: **When I say the word "start", I want you to get up off the bed as quickly and <u>safely</u> as you can and stand facing the wall. Once you are standing, the machine will start taking your blood pressure. If you feel dizzy when you get up, lean back against the bed. If you do not feel dizzy, stand away from the bed. Once you are standing, please rest your arm on the pillow/table by the bedside in a relaxed position.**
  - If necessary, repeat the instructions to ensure the participant understands this sequence.
- Remove any pillows under the participant's knees to avoid interference.
- When ready, say: **<u>"START"</u>**.
- Begin stopwatch.
- Watch the participant's position relative to the examination table; monitor for safety concerns.
- At the same time, position the arm rest/table to the side of the participant for them to rest their arm outstretched at a 70-80 degree angle from their torso (note the height of the table should have been pre-determined, before the participant was supine and should not require adjustment as this point).



2.3.5 Standing Blood Pressure Assessment

- Immediately after ensuring that both feet are planted on the ground and that the participant is upright and standing, press the ON/OFF button first, then push the "START" button on the Omron and "LAP" or "RESTART" on the stopwatch. Record the time required to move from supine to standing. Accurate documentation of the time period from supine to standing is important (if the 1/100th sec is <0.5 round down; >=0.5 round up).
- NOTE: Monitor for shifting of the cuff when standing. Reposition the cuff to best of your ability if needed.
- NOTE: Avoid prolonged time-to-stand if safety permits (i.e., > 15 seconds) as this affects change in blood pressure. Time-to-stand should be **documented** on the OBP form.
- Record the resulting systolic blood pressure, diastolic blood pressure, and heart rate (0 minutes).
- At 1 minute, 2 minutes, 3 minutes, 4 minutes, and 5 minutes on the stopwatch repeat measurements by pressing start on the Omron and recording the measurements. Note: all times are calculated from the time both feet are planted on the ground in the standing position. If delayed, may start Omron ≤15 seconds of scheduled start time. If delayed beyond 15 seconds, skip measurement to return to the appropriate schedule for the next measurement. Staff will document the reason for delay and skipping measurement on the OBP form as a notelog.
- Allow participant to stand for a total of 6 minutes. It is important to obtain complete data collection whenever possible. Participants fatigued from standing can lean against the clinic bed or rest on the table (**make sure any wheels on the table are locked!**). If they are unable to keep standing despite these interventions, they may sit for the remainder of the assessment. Note, that their

arm should be elevated at heart level in the seated position. Please document whether they are seated or standing on the OBP form. Please document the reason for leaving the standing position in the Staff Observation section of the OBP form.

- At 6 minutes (which should be after the 6th blood pressure measurement), ask the participant the following two questions:
  - **Did you feel dizziness, lightheadedness, faint, or like you might black out in the process of standing up? Please rate on a scale from 1 to 5, with 1 being "no symptoms" and 5 being the "worst possible."**
  - **Did you feel dizziness, lightheadedness, faint, or like you might black out at any time while standing? Please rate on a scale from 1 to 5, with 1 being "no symptoms" and 5 being the "worst possible."**
- Record symptom rates.
  Note: Because these are single readings, the monitor does not save the measurements. Hence staff needs to document these readings as per each measurement.
  Staff should always remember to turn the knob back to 'AVG' mode after each participant.
- Say: **Thank you. The blood pressure assessments are now complete**, remove the cuff from the participant's arm, and ask the participant to sit in the chair.
- **Save and reload** the OBP form for CDART to calculate the average standing systolic, diastolic, and HR measurements on the OBP form. You will need to save the form again before closing.
- Immediately complete the Staff Observation section of the OBP form.
- Return the Omron to "AVG" mode in preparation for the next assessment. Turn off Omron.

2.4 SAFETY

During the course of the OH protocol, it is possible to encounter clinically concerning blood pressure measurements. All extremely low or high blood pressure values should be verified in the seated position 5 minutes after the protocol is complete. If the extreme blood pressure values continue, follow the ARIC safety algorithm for seated blood pressure.

The OH protocol will take place **after** the ARIC Seated Blood Pressure. Following standard ARIC safety protocols, if a participant has an average Systolic Blood Pressure (SBP) ≥200 or Diastolic Blood Pressure (DBP) ≥120 mmHg, the exam will be stopped in order for the participant to receive urgent care. The participant will be ineligible for the OH protocol.

If a participant is eligible for the OH protocol, but experiences elevated or low blood pressure aligned with the measures below, follow this protocol:

2.4.1 Elevated Blood Pressure

- If the average of the 3 **supine** or 6 **standing** measurements is SBP ≥210 mm Hg or DBP ≥130 mm Hg, complete the procedure and then verify blood pressure in the **seated** position after 5 minutes of rest.
- If the average of 3 **seated** measurements is SBP≥200 mm Hg or DBP≥120 mm Hg, stop procedure and send participant to the emergency room; notify study clinician. Note: this is the same safety threshold that is used in standard ARIC blood pressure assessments (see Table 1).

2.4.2 Low Blood Pressure

- If the average of the 3 **supine** or 6 **standing** measurements is SBP≤80 mm Hg or DBP≤30 mm Hg, complete the procedure and then verify the blood pressure in the **seated** position after 5 minutes of rest.
- If the average of 3 **seated** measurements is SBP≤90 mm Hg or DBP ≤40 mm Hg and the participant demonstrates symptoms of low blood pressure (light-headedness, dizziness, pre-syncope, imbalance), then stop the procedure and send participant to the emergency room. May provide water or an electrolyte enriched beverage (e.g., a sports drink) if symptoms continue after being seated. Note: the standard ARIC blood pressure assessment manual does not have a safety threshold for low blood pressure.

The ARIC safety algorithm for seated blood pressure is as follows:

“As a participant safety procedure, if the average [seated] blood pressure is equal to or greater than 200 mmHg systolic or equal to or greater than 120 mmHg diastolic, the technician 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 5 of this section [Manual 2], and repeats the [seated] blood pressure measurement steps. This second set of blood pressure values is recorded on the form and entered into the DMS instead of the first set. If the average blood [seated] pressure still is equal to or greater than 200 mmHg systolic or equal to or greater than 120 mmHg diastolic, the technician 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 supervisor or clinic manager, ARIC personnel then assist the participant in scheduling a visit to their provider of care during the same day, or arranges transportation to the nearest emergency room for a medical evaluation of the participant's blood pressure."

3 DATA AND RESULTS REPORTING

3.1 DATA TRANSFER

All data should be entered into the CDART system per standard ARIC procedures.

3.2 RESULTS REPORTING

Results will be provided to participants using a CDART report based on the OH Results Report Template, which can be found on the ARIC website with this manual (MOP 37 Results Letter Templates). OH Results will be a part of the Visit 10 Summary of Results Report.

4 TRAINING AND CERTIFICATION

Training webinars will be held prior to the ancillary study start date. After the initial training webinars, study coordinators are responsible for training new staff using certified examiners based on standardized MOP and QxQ instructions.

All staff performing OH must be trained and certified by ARIC in the Sitting Blood Pressure (SBP) technique.

Training will include:

- Read and study the manual, forms, and QxQs.
- Attend ARIC training session on administration techniques (or review training video).
- Practice on other staff or volunteers.
- Discuss problems and questions with local expert or QC officer.

Certification will include:

- Complete training requirements.
- Recite exclusions.
- Conduct exam on two volunteers according to protocol, as demonstrated by a completed OH Certification Checklist (Appendix E).
- The administration of the OH protocol must be observed **one time for one staff member** by Stephen Juraschek. Following completion of this step, this certified staff member may then certify other staff. There are two acceptable methods of completion:
    - Record administration of the OH protocol and upload the video to your institution's file share program (e.g., OneDrive, Dropbox). Notify Stephen Juraschek (sjurasch@bidmc.harvard.edu) and Fredrick Larbi Kwapong (flarbikw@bidmc.harvard.edu) via email that a file is ready for their review. Note: before recording, ensure that the volunteer participant consents to being filmed for training purposes.
    - Schedule a virtual certification session with Dr. Juraschek and complete the observation in real time

5 APPENDIX MATERIALS

APPENDIX A. PROCEDURE FOR PROGRAMMING THE OMRON 907XL (OSCILLOMETRIC DEVICE) IN AVG MODE

(4) AVG Function setting

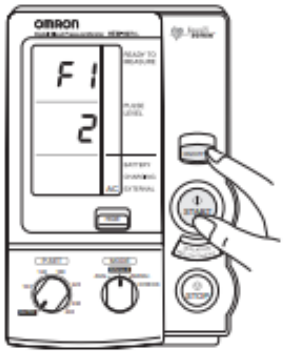
You can set the number of measurements, the waiting time until the 1st measurement, and the measurement interval for the AVG Mode.

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.

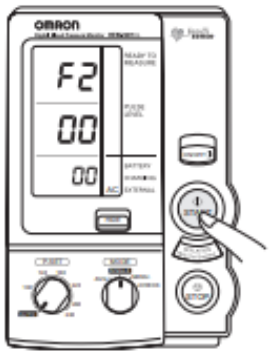
Note: The bold letters represent the factory-set values.

Procedure to change the set values

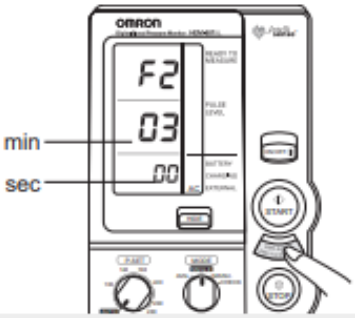
1) When the power is OFF, push the ON/OFF (power) Button for more than three seconds while holding the START Button; F1 is displayed.



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.



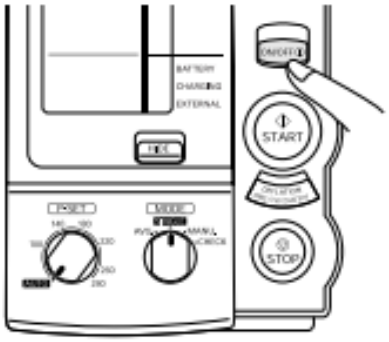
3) Push the DEFLATION (deflation control)/Measurement Result Display Switch Button and change the set values.



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

APPENDIX B. HOW TO MEASURE BLOOD PRESSURE IN AVERAGE MODE

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

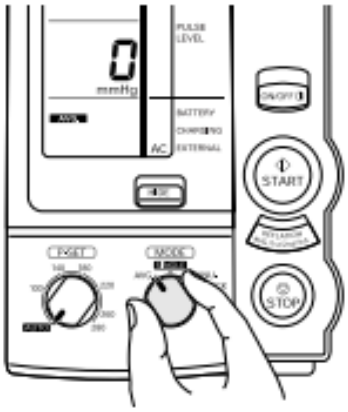


2. Set the MODE Selector to “AVG”.

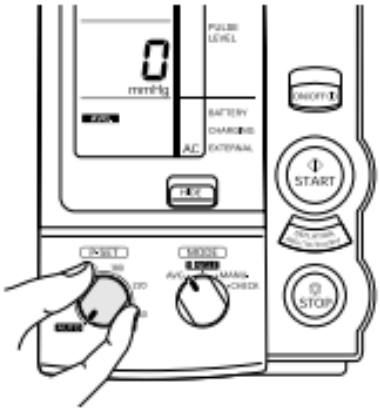
   The factory-set values are set as follows:

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

   To change these factory-set values, refer to Page 14.



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

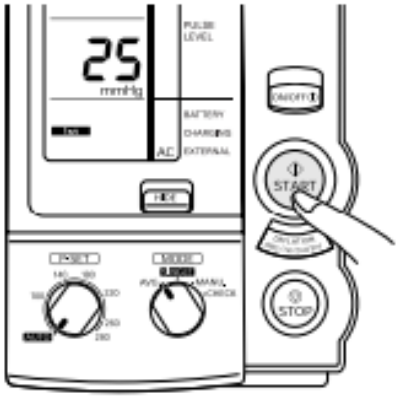


4. Measure the patient’s arm size and wrap appropriate cuff over the patient’s arm. (Refer to Pages 15 and 16.)

5. Push the START Button to start the measurement.

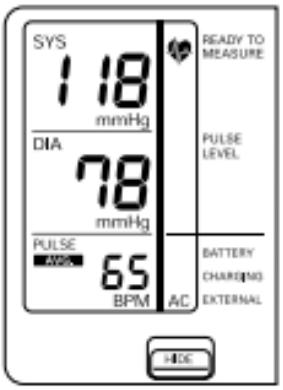
   After the pre-select waiting time, the unit takes the 1st measurement.
   After displaying the results of 1st measurement, subsequent measures occur automatically at the specified intervals.

   - For setting the number of measurements, the waiting time until the 1st measurement, and the interval, refer to Page 14.
   - 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.



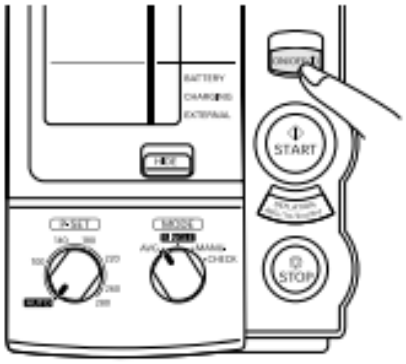
6. The measurement results are displayed.

   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)

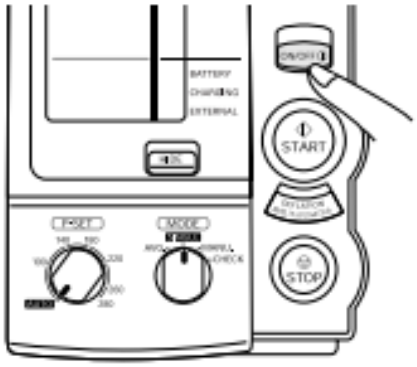
7. Push the ON/OFF (power) Button to turn off the power.



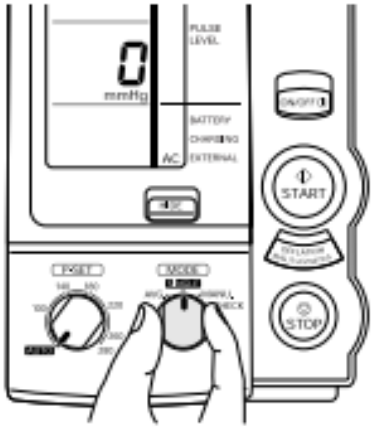
If the monitor determines that the pressure value is not correct, an error display appears (Er1 to 9). In this case, refer to Page 29 and start the measurement again.

APPENDIX C. HOW TO MEASURE BLOOD PRESSURE IN SINGLE MODE

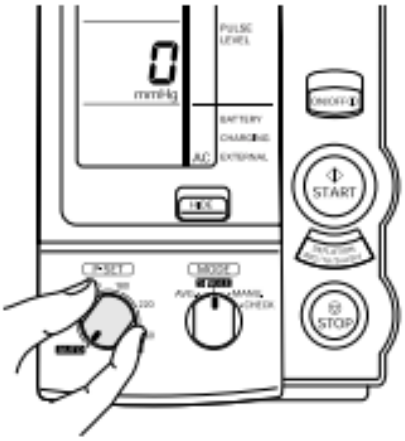
1. Push the ON/OFF (power) Button to turn on the power.



2. Set the MODE Selector to “SINGLE”.



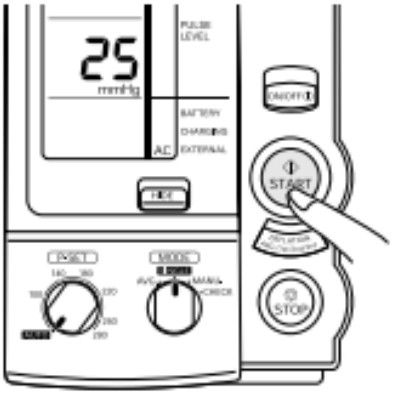
3. Set the P-SET (inflation level) Knob to “AUTO” or to the target pressure value.



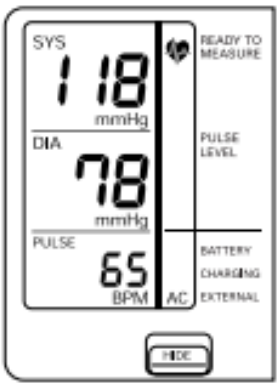
4. Measure the patient’s arm size, and wrap appropriate cuff over the patient’s arm. (Refer to Pages 15 and 16.)

5. Push the START Button to start the measurement.

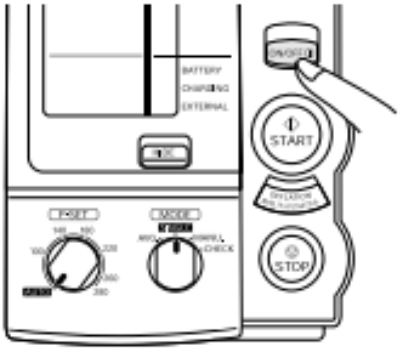
- Do not push the START Button without wrapping the cuff.
- If you want to stop measurement, push the STOP Button. The cuff will rapidly deflate.



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 29 and start the measurement again.

APPENDIX D. OMRON ERROR CODES

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 13 and 14). • 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 13 and 14).
Er6	Low pulse level error • Pulse wave was too small.	• Confirm that the cuff is wrapped correctly (refer to pages 13 and 14).
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 Healthcare's Cusomer Service toll-free at 1-877-216-1336.

APPENDIX E: CERTIFICATION CHECKLIST

Name of staff member being observed: _____

Name of staff member observing: _____

Date _____

First steps

- ☐ Review MOP37
- ☐ Review OBP and OSQ forms and QxQs
- ☐ Complete in-person training. For staff hired after the in-person training, they should review the video recording of the training.

Prior to the participant arriving:

- ☐ Set up video camera (if recording for certification)
- ☐ Ensure that the Omron HEM-907XL is set to "AVG" mode and programmed for 5 minutes delay followed by 3 blood pressure measurements separated by 30 seconds each.

Prior to the OH assessment (with participant in room):

- ☐ Confirm participant's ID
- ☐ Confirm consent (OH is incorporated into the standard ARIC consent form)
- ☐ Administer the Orthostatic Hypotension Symptom Questionnaire (OSQ) form
- ☐ Determine appropriate BP cuff size (measure arm circumference if necessary)
    - ☐ Document cuff size, arm used, and participant's dominant arm on Orthostatic Hypotension Blood Pressure Form (OBP).
    - ☐ Inquire about participant comfort lying flat and offer to use a pillow underneath participant's arm to ensure comfort
    - ☐ Pay attention to whether the participant may need assistance to stand or if he/she has safety concerns
- ☐ Ask participant to stand and pre-position armrest table so the participant's arm will rest comfortably outstretched at 70-80 degrees from his/her torso.
- ☐ Read all questions and possible answers
    - ☐ Accurately documents participants answers
- ☐ Ask participant to lie down on the clinic bed
    - ☐ Provides pillow under participant's knees or head for comfort
- ☐ Read the OH Introduction Script

Supine OH Assessment:

- ☐ Connect cuff to OMRON device and places cuff on participant's bare arm (non-dominant or same arm that participant has been using for all previous ARIC BP measurements)
- ☐ Turn on Omron HEM-907 XL
- ☐ **Ensure Omron HEM-907XL is in AVG mode programmed for 5 minutes delay with 3 measurements separated by 30 seconds each**
- ☐ Start stopwatch and press OMRON "START" button to start 5 minute countdown. Inform participant the measurements are going to start automatically after the countdown.
- ☐ Re-enter room after 4 minutes and ensures participant is lying properly (arms at his/her side)
- ☐ Ensure that the participant is not sleeping
- ☐ Record systolic blood pressure, diastolic blood pressure, and heart rate, along with the **average** on the OBP Form and ensures correct transcription
- ☐ **Changes the OMRON mode from AVG to single**

Standing OH Assessment

- ☐ Read script (in the MOP) that gives the participant instructions for standing up and instructs them to "start"
- ☐ Begin stopwatch immediately as they say "start" to record time required to go from supine to standing – records on the OBP form
- ☐ Monitor safety concerns as participant is standing
- ☐ As soon as participant is standing, press "START on Omron and "lap" on the stopwatch to record first measurement at 0 minute.
- ☐ Press "START on Omron at 1 minute, 2 minutes, 3 minutes, 4 minutes, and 5 minutes to record BP measurements
- ☐ Records all blood pressure measurements and heart rate on the OBP Form
- ☐ After the 6th standing BP measurement, ask the participant the two symptom questions and records answer on the OBP Form (the questions are ideally asked in the standing position)
- ☐ Complete Staff Observation section on the OBP Form

Video Upload and Sharing (if completing for certification)

- ☐ Upload the video recording of the OH assessment to your institution's file share program (e.g., OneDrive, Dropbox).
- ☐ Notify Stephen Juraschek (sjurasch@bidmc.harvard.edu) and Fredrick Larbi Kwapong (flarbikw@bidmc.harvard.edu) via email that a file is ready for their review.

To be completed by staff member observing the OH assessment:

What did they do well?

_____
_____
_____

How could they improve their skills?

_____
_____
_____

Do they need additional training and support? ¨ Yes ¨ No

If so, we will meet on _____ to review _____
and then another QC will occur on _____.

Reviewer's signature: _____

Observed staff signature: _____

THANK YOU FOR YOUR PARTICIPATION IN ARIC.

APPENDIX F: BLOOD PRESSURE STAND-ALONE VISIT

In order to provide participants with additional flexibility, field center staff may offer participants the option of returning to the ARIC clinic for a stand-alone blood pressure visit. This visit is entirely optional and should only be offered to participants who voluntarily express interest in completing the blood pressure ancillary protocols (ABPM, HBPM, OH). The intention of the BP stand-alone visit is to provide accommodation for participants who may not have the time or ability to complete these protocols during the regular ARIC Visit 10 clinic exam. This visit **must be completed within 4 months of ARIC Visit 10.**

Staff will first review and complete the informed consent process

The BP Stand-Alone visit consists of the following protocols that should be completed in the listed order:

- ARIC Sitting Blood Pressure (SBP)
- Orthostatic Hypotension (OSQ, OBP)
- Home Blood Pressure Monitoring (HBP, HBPR, VAS)
- Ambulatory Blood Pressure Monitoring (ABP, ABPR)

When completing the seated blood pressure for the stand-alone visit, **staff must utilize the SBP form in the Visit Ancillaries form group**. Do not use the SBP form in the V10 / NCS form group. Please note that there will be no alerts or results reporting generated from the SBP form collected for this separate visit; field center staff should reference the alert values indicated in the SBP form itself and follow the standard ARIC protocol for any concerning blood pressures.

The Blood Pressure Stand-Alone Visit Checklist can be found on the ARIC website at the following location: V10 / NCS Forms and QxQs (unc.edu) [Cohort > Current Visit Forms, QxQs, and Manuals > V10 / NCS Forms and QxQs]

APPENDIX G: ACCURACY CHECK PROTOCOL FOR OH

Purpose:

SimCube simulation system provides non-invasive blood pressure (NIBP) simulation in a small, portable, easy to use package. In addition to the NIBP simulation, optional ECG, respiration and invasive blood pressure simulation are available. For the purpose of our ancillary study, the SimCube simulation system will be used for accuracy check for the Spacelabs 90227 OnTrak Ambulatory Blood Pressure Monitoring (ABPM) device and the Omron HEM-907XL device. Accuracy checking for the Omron HEM-907XL will be reviewed here; information on accuracy checking for the ABPM device can be found in MOP 38.

When:

Accuracy checks for Omron HEM-907XL device will be conducted semiannually and documented on the Omron BP Device Maintenance and Accuracy Check Log (Appendix H).

Who:

Technicians will maintain all blood pressure equipment used in their clinic.

Device:

Supplies:

- SimCube NIBP simulator
- Power Supply (6V DC)
- NIBP adapters
- Battery Boost Converter
- Carrying case for the device
- Cuff Jacket

SimCube NIBP simulator

NIBP Adapter Set

Battery Boost Option

Cuff Jacket

Setup Procedure:

- Plug the SimCube power supply into an AC outlet
    - You should use only the power supply provided with your SimCube system. The power supply provided is 6V DC, 1.8amp, center positive, 2.1mm jack.
- Connect the power jack into the SimCube power receptacle.

Note: Many power supplies use the same plug, and connecting the SimCube simulator to the wrong power supply may damage it. Be sure to use the original plug from the manufacturer.

- Wait for the power-up sequence to complete. When this step is complete, the display will show 0.0 on the simulator. During the power-up sequence, the simulator will zero its pressure, so please remove all connections from the NIBP bulkhead to allow the SimCube to accurately zero to atmosphere. This step may take up to 15 seconds to complete.
- Select the desired mode by pressing the Yellow Mode button. Each time the mode button is pressed, the mode will be changed and the LED indicating the new mode will be lit.

Note: if the SimCube transitions into sleep mode (after approximately 30 seconds of non-use) to conserve power, the first press of the mode button will illuminate the display and a second press will be required to move to the next mode. The mode desired for this accuracy check is **NIBP Adult (120/80).** This simulates a patient with blood pressure of 120/80 mm Hg, heart rate of 70 bpm, mean pressure of 97 mm Hg, and pulse volume of 1 ml.

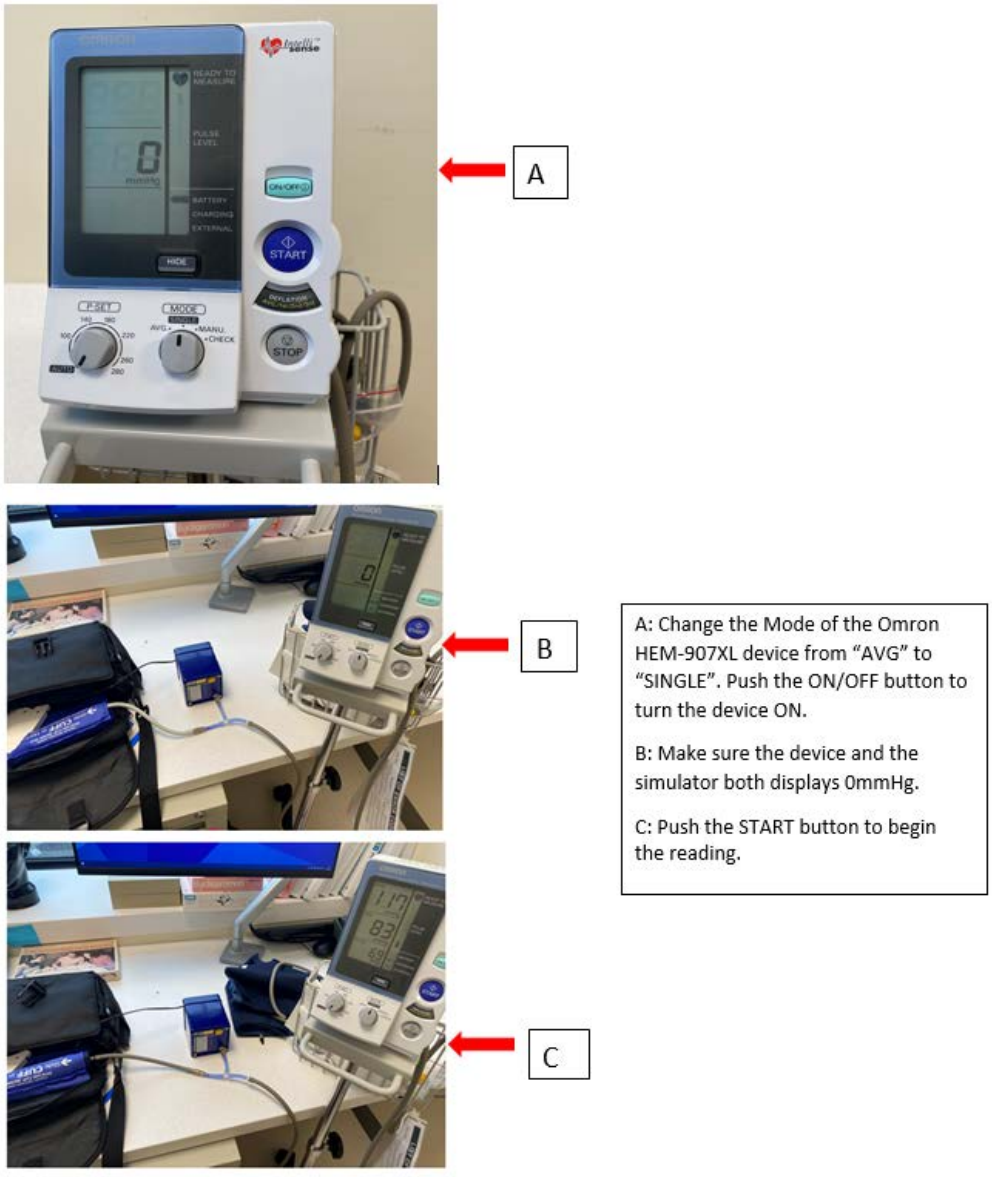
- Start the accuracy check by connecting the SimCube simulator in line with the monitor's cuff and hose as shown in Figure 1. Different monitors will require different adapters. Using a SimCube cuff jacket can improve reading capture and consistency. Generally, the smaller cuff jacket sleeve volume is best for most monitors. To use the cuff jacket, wrap the cuff and insert into the desired sleeve. If not using the cuff jacket, wrap the cuff snugly around itself or around a solid object and place in an area safe from accidental motion.

Accuracy Check for Omron HEM-907XL:

- Connect the power supply of the Omron HEM-907XL device to the AC outlet.
- Change the MODE of the device from "AVG" to "SINGLE".
- Press the ON/OFF button to turn the device "ON".
- Make sure the display on the device is 0 mm Hg.
- Push the mode button on the simulator to select NIBP Adult (120/80).
- Push on the "START" button to begin the reading. The device will measure above 150 mm Hg. You should expect a gradual decrement in the mm Hg from both the Omron HEM-907XL device and the SimCube simulator till it measures 120/80 mm Hg +/- 3 mm Hg on the Omron HEM-907XL device.

Note: if final measurement on the device is greater than or less than +/- 3 mm Hg of the simulated value of 120/80, run the accuracy check 2 additional times. If you continue to get higher or lower readings, document the result in the Omron BP monitor maintenance and accuracy check log as failed and arrange for shipment to Omron Company for troubleshooting.

Figure 1



Leak Testing Cuff Sizes for Omron HEM-907XL:

For leak testing, connect the SimCube simulator and the manual pump bulb in line with the monitor's cuff (placed in the sleeve) as shown in Figure 2. Manually pump the bulb to >/= 150 mm Hg and observe a gradual decrement in the reading on the simulator. A sudden drop in the reading indicates leakage in cuff bladder, cracking or holes in the tube. Document the result in the device maintenance and accuracy check log as failed and arrange for shipment to the Omron Company for troubleshooting.

Figure 2

The LED on the simulator should read 0.0 before you begin to manually pump the bulb. You should expect an increase in size of the cuff with every pump of the bulb. When you reach 150mmHg on the simulator, observe for a gradual decrement in the mmHg.

Battery Operation:

SimCube SC-4kit may be operated on battery power using the battery boost option. The battery boost allows the user to switch between AC power and four “AA” batteries and it easily integrates with the SimCube padded carrying case. The battery boost is designed to operate with alkaline batteries for simplicity and convenience, however, please note that using NiMH batteries will provide the highest battery performance. While rechargeable batteries may be used, an external charger is required to recharge these batteries. When the batteries are depleted, the battery level indicator on the battery boost will illuminate a red LED and the SimCube may re-boot to further indicate the need to replace the batteries.

Note: When the battery level indicator lamp is red, your simulator may continue to operate, but values should not be trusted. Always confirm battery level LED is green when doing simulation on battery power. When your simulator is not in use, switch the battery boost to the “Batt OFF” position to avoid draining the batteries.

APPENDIX H: OMRON BP DEVICE MAINTENANCE AND ACCURACY CHECK LOG

Instructions: This checklist documents the semiannual checks for the OMRON BP machine. One log should be completed for each semiannual check. If there is more than one BP monitor used, indicate the checks with a separate log for each monitor.

TECH ID NUMBER: | | | | FIELD CENTER | | DATE: ☐☐/☐☐/☐☐☐☐ Month Day Year

Blood Pressure Measurement **OMRON SERIAL #:**_____

	Y/N	**If YES, action**
Availability of all sizes of cuffs		
Cracking		
Holes		
Worn out cloth of Velcro		
Leakage of cuff bladder		
Accuracy Check with SimCube SC-4kit ***(Observe a gradual decrement in the mm Hg from both the Omron device and the SimCube SC-4kit till it measures 120/80 mm Hg +/- 3 mm Hg)***		

Comments:

_____

_____

APPENDIX I: SIMCUBE TROUBLESHOOTING TIPS

SYMPTOM	SOLUTION
Readings inconsistent or no reading at all	If using Battery Boost, be sure the Batt On/Off switch is ON and the Batt Level LED is green. If the Level LED is Red or dark, replace the batteries with a fresh set.
Readings inconsistent, error message (C05) on Welch Allyn 52000	Reduce/Control cuff volume and movement by inserting the cuff into the small sleeve of the Pronk Cuff Jacket Duo.
During NIBP simulation, monitor continually inflates cuff without reading	Check for leak in hose and cuff. Use standard adult size cuff only for adult and hyper modes. Neo mode requires size 3 or 4 (8-13cm) cuff to be effective. Reduce/Control cuff volume and movement by inserting either adult or neo size cuff into the small sleeve of the Pronk Cuff Jacket Duo.
Alaris / IVAC 4410 does not get readings	This device calculates diastolic during inflation. Wait until it is done with its first inflation cycle; it will automatically restart inflation and will get reading.
IVAC 4200 does not get readings	The IVAC 4200 is primarily an auscultatory blood pressure monitor, in fact there is a microphone built into the cuff itself. However, these monitors also have an oscillometric algorithm and will get consistent readings if you remove the cuff from the hose and connect the hose directly to the SimCube simulator.
Can't get RESP waveform on Datascope	Reconfigure snaps to the following: black lead to white RA, red lead to black LA and white lead to green RL.
Battery Boost Option does not charge batteries	This is by design. In order to allow customers to use off the shelf alkaline batteries, no charge current is applied to the batteries being used.
Readings are always high/low on specific model/manufacturer	Each model of monitor has a different algorithm for calculating NIBP values; therefore different models, even from the same manufacturer, can yield different results. Use the SimCube Sample Reading Chart as a reference.
Respiration does not count	The amplitude of the respiration signal was carefully selected to ensure that monitors will not count if 60hz noise is present. Some monitors may require an adjustment to increase resp size in order to get an accurate respiration rate.

SimCube won't read 0 (shows ––) at power up	During power on initialization, SimCube auto zeroes pressure itself. Therefore, vent circuit to atmosphere at power up and wait 15 seconds for auto zero to complete, signified by 000.0 on display of SimCube models SC-1, SC-2, SC-3 and SC-4 and SC-5 SW version up to 4.5. SC-5 version 5.0 or higher will display 0.0 when zeroed to atmosphere.
Can't connect 12 Leads to snaps	Order ECG snap extender, part number ECG EXTEND.
No heart rate on EASI configured Telemetry	When viewing AVR or V2 lead, change the V lead to V6 snap.
ECG is Noisy	The noise may point to a ground loop issue. Check for ground loop noise by running the SimCube on battery power to see if the noise still exists. If it is present, check to see that the monitor under test has its A/C filter(s) enabled. Please note that monitors may have more than one filter that filter out of different frequencies.
Unable to resolve problem	**Contact Pronk Technologies' Technical Support at:** (800) 541-9802