



Manual 37  
Orthostatic Hypotension Procedures  
ARIC Visit 10

Version 0.1 – 11/01/2021

DRAFT



**Orthostatic Hypotension (OH)**  
**Manual of Procedures**  
**Table of Contents**

<b>1</b>	<b>OVERVIEW.....</b>	<b>3</b>
1.1	Purpose.....	3
1.2	When.....	3
1.3	Who.....	3
1.4	Equipment, Materials, and Supplies .....	3
1.5	Forms, Logs, and Scripts.....	3
1.6	Consent Process .....	4
<b>2</b>	<b>STUDY PROCEDURES.....</b>	<b>5</b>
2.1	Set-up .....	5
2.2	Questionnaire Administration .....	5
2.3	Specific Orthostatic Hypotension Assessments .....	5
2.3.1	Overview .....	5
2.3.2	Prior to OH Assessment with Participant in Room.....	6
2.3.3	Supine Protocol .....	6
2.3.4	Transition from Supine-to-Standing .....	7
2.3.5	Standing Blood Pressure Assessment.....	8
<b>3</b>	<b>DATA AND RESULTS REPORTING .....</b>	<b>9</b>
3.1	Data Transfer .....	9
3.2	Safety.....	9
3.2.1	Elevated Blood Pressure.....	9
3.2.2	Low Blood Pressure .....	10
3.3	Results Reporting .....	10
<b>4</b>	<b>TRAINING AND CERTIFICATION .....</b>	<b>10</b>
<b>5</b>	<b>APPENDIX MATERIALS.....</b>	<b>13</b>
	Appendix A. Procedure for Programming the Omron 907XL (oscillometric device).....	13
	Appendix B. Omron Error Codes .....	14

# **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 orthostatic hypotension assessment in ARIC participants. The OH protocol is an optional ancillary study.

## **1.2 WHEN**

- Consent
  - Beginning of visit 10. Participants will be asked to participate in the OH protocol later in the day.
- Visit 10 protocol
  - During Visit 10 after the ARIC seated BP assessment.

## **1.3 WHO**

- 1 physical examiner for orthostatic hypotension 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 tables/arm rests
- Stopwatch
- Omron HEM-907XL BP monitor with 4 blood pressure cuffs
- Omron HEM-907XL BP monitor stand with basket for Omron

## **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 that is more conducive to data collection 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.

DRAFT

## 2 STUDY PROCEDURES

### 2.1 SET-UP

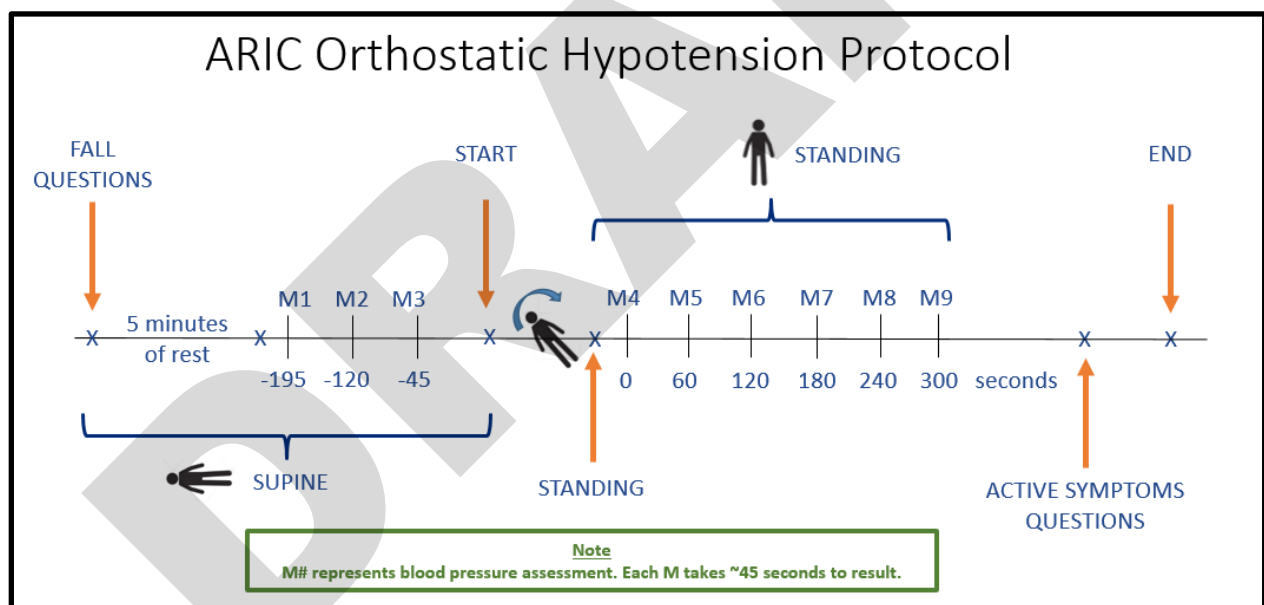
- Check that Omron is programmed to obtain 3 blood pressure measurements separated by 30 seconds each and in “AVG” mode (see Procedure for Programming Omron diagram in Appendix A).
  - Note: this can be changed to 1 or 2 measurements if a participant expresses a preference for fewer measurements.
- Affix participant-specific label onto the OSB 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

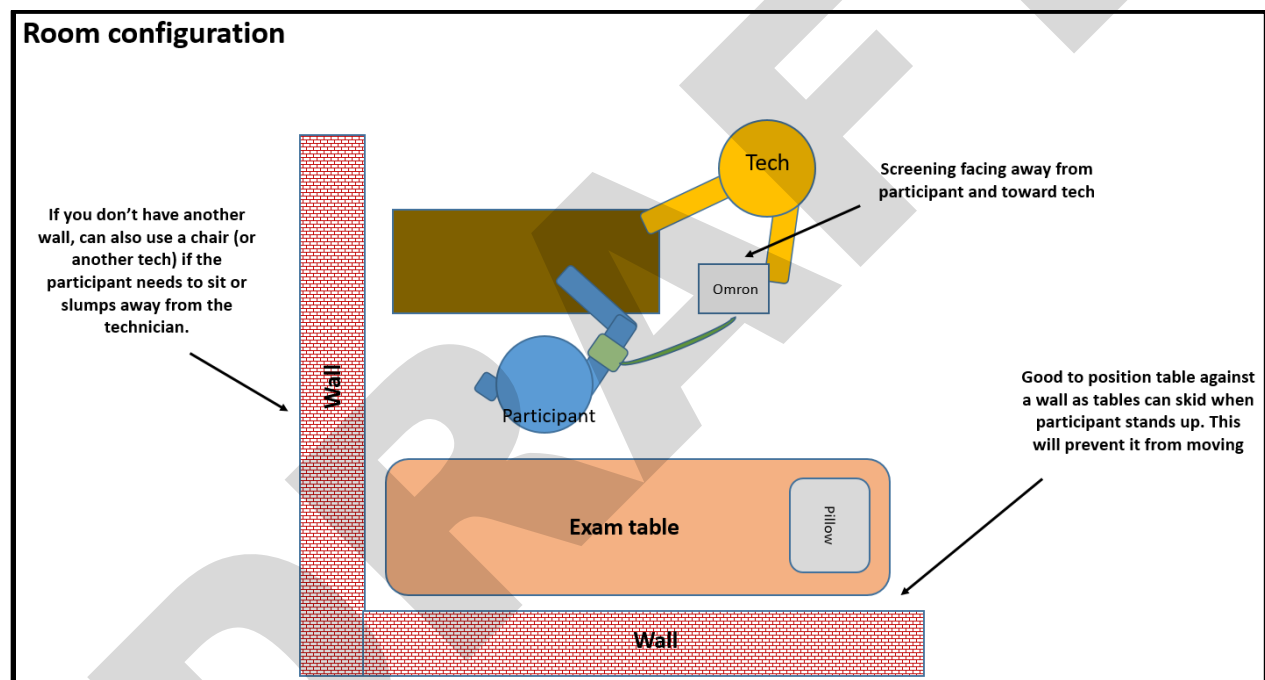


Participants will lie supine for 5 minutes. Afterward, a set of 3 blood pressure measures will be performed using an Omron that is programmed to separate each measure by 30 seconds. When the last of the 3 measurements is recorded, participants will be asked to stand up with their arm resting on an adjacent bedside table at heart level. 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 and a stopwatch, BP measurements will be timed to start 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 assessments).

### 2.3.2 Prior to OH Assessment with Participant in Room

- Confirm the participant's ID and participant code.
- Determine the appropriate cuff size for the participant.
  - Measure if necessary (follow procedures in ARIC Field Center Procedures MOP).
- While participant is standing, pre-position a bedside table(s) 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 Instruction Script.
  - Monitor for whether the participant anticipates needing assistance to stand or if they have safety concerns.



### 2.3.3 Supine Protocol

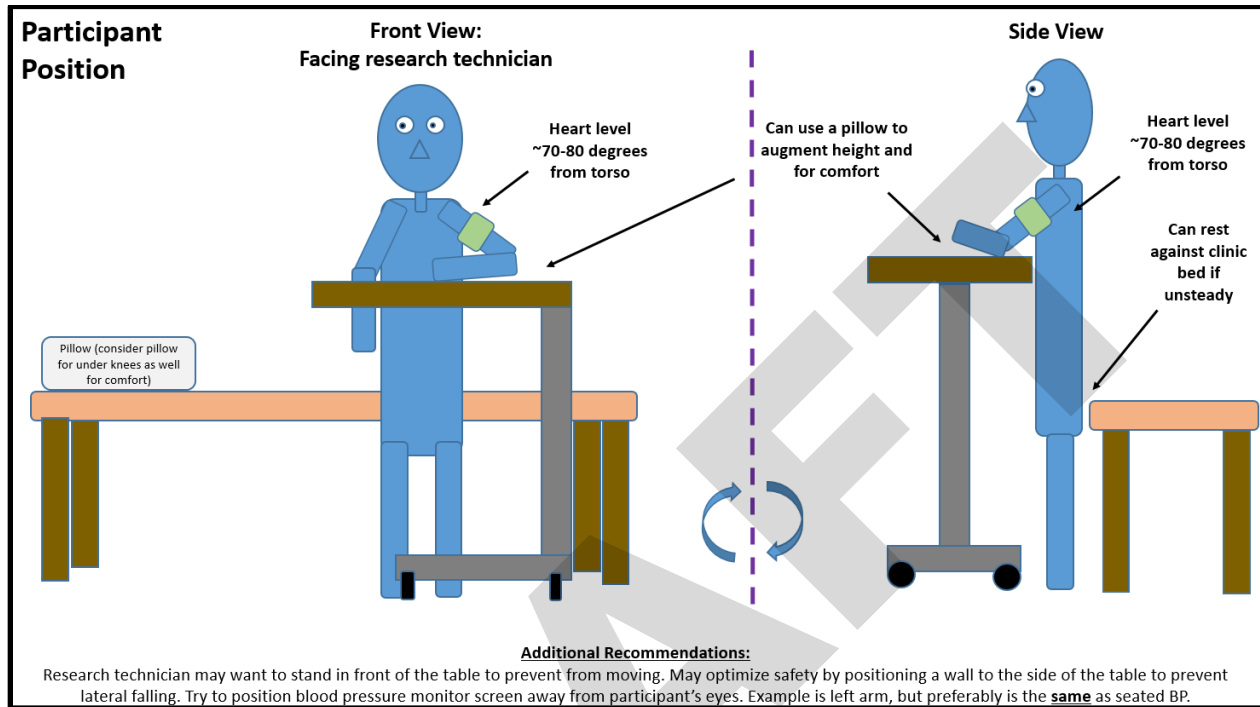
- **PROCEDURE NOTE:** At any point during OH blood pressure assessments, if the participant is noted (or requests) to "flex" or wiggle their hand, this is permitted if it occurs immediately after the completion of a blood pressure determination, during the 30 second interval between the end of one cycle 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 the OBP form.
- Ask the participant to lie down on the clinic bed. Confirm that the cuff has not shifted during change in positions.

- Attach cuff to Omron 907XL.
- Ensure Omron is in average mode to provide the average value after the three supine measurements.
- 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.
- At 4 minutes, return to the room and confirm Omron settings.
- If participant has fallen asleep, provide a gentle nudge on the arm.
- At 5 minutes, say: **I will now begin the blood pressure assessments**, and push the Omron "start" button.
  - The Omron should be preprogrammed for 3 measurements separated by **30 seconds** each.
- **Record** systolic blood pressure, diastolic blood pressure, and heart rate with each result along with the average.
- Check against a manual average and fix any transcription errors.
- **Change the OMRON mode from average to "single".**

#### 2.3.4 Transition from Supine-to-Standing

- **SAFETY NOTE:** there is a fall risk at this point; resist any pressure to rush participant, as safety is first priority.
  - Assistance may be provided to 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 safely 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 the sequence.
- Remove any pillows under the participant's knees to avoid interference.
- When ready, say: **"START"**.
- Begin stopwatch.
- Watch the participant's position relative to the examination table, being sure to 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 at 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 “START” on the Omron and “LAP” or “RESTART” on the stopwatch. Record the time required to move from supine to standing.
- **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.
- 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.
- 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 6<sup>th</sup> 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.
- 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.

### 3 DATA AND RESULTS REPORTING

#### 3.1 DATA TRANSFER

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

#### 3.2 SAFETY

During the course of the OH protocol, it is possible to encounter clinically concerning blood pressure measurements. All extreme 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.

##### 3.2.1 Elevated Blood Pressure

- If the average of the 3 **supine** or 6 **standing** measurements is **SBP  $\geq$ 210 mm Hg or DBP  $\geq$ 130 mm Hg**, complete the procedure and then verify blood pressure in the **seated** position after 5 minutes of rest.
- If average of 3 **seated** measurements is **SBP $\geq$ 200 mm Hg or DBP $\geq$ 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).

### 3.2.2 Low Blood Pressure

- If the average of the 3 supine or 6 standing measurements is **SBP≤80 mm Hg or DBP≤30 mm Hg**, then complete the procedure and then verify the blood pressure in the seated position after 5 minutes of rest.
- If 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 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.”*

### 3.3 RESULTS REPORTING

Results will be provided to participants using a CDART reported based on the OH results report template.

## 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.

The examiner requires no special qualifications or experience to perform this assessment. Training will include:

- Read and study the manual.
- Attend ARIC training session on administration techniques (or observe administration by experienced examiner).
- 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 Checklists.

DRAFT

**Table 1. Blood pressure monitoring threshold values for results reported as normal, abnormal, or alerts and interpretations included in the report to study participants/their provider of health care**

Threshold values/ Trigger conditions	Reported to participant as:			Script for report
SBP 90-119 and DBP 50-79	Normal			Your blood pressure was normal. Please recheck it in one year. If you are being treated for high blood pressure, your healthcare practitioner may have given you a schedule for your next check-up. Please follow that schedule.
SBP 120-129 and DBP 50-79	Normal			Your blood pressure was somewhat elevated, according to recent guidelines. Please recheck it in 3-6 months. If you are being treated for high blood pressure, your physician may have given you a schedule for your next check-up. Please follow that schedule.
SBP 130-139 or DBP 80-89		Abnormal		Your blood pressure was high, according to recent guidelines. You should have your blood pressure checked within two months by a physician. If you are being treated for high blood pressure please see your physician.
SBP 140-179 or DBP 90-119		Abnormal		Your blood pressure was quite high. You should have your blood pressure checked within a month by a physician. If you are being treated for high blood pressure, please see your physician.
SBP 180-199 or DBP 110-119			Alert. Arrange for medical evaluation within 48 hrs.	Your blood pressure was very high. At the time of your ARIC visit we indicated that you should see a medical professional within 48 hours to determine whether treatment should be started or changed. If you have not done so already, please see your physician without delay.
SBP $\geq$ 200 or DBP $\geq$ 120			Alert. Stop the exam & arrange for same-day eval.	Your reading was very high. At the time of your ARIC visit we indicated that you should see a medical professional within hours to determine whether treatment should be started or changed. If you have not done so already, please see your physician without delay.

## 5 APPENDIX MATERIALS

### APPENDIX A. PROCEDURE FOR PROGRAMMING THE OMRON 907XL (OSCILLOMETRIC DEVICE)

#### (4) Function setting

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

	Items to set	Set value
F1	Number of measurements	<b>2</b> times, 3 times
F2	Waiting time until the start of 1st measurement	0 sec, 3 min, 5 min, and 10 min.
F3	Measurement interval	5 sec, 30 sec, <b>1 min</b> , and 2 min.

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

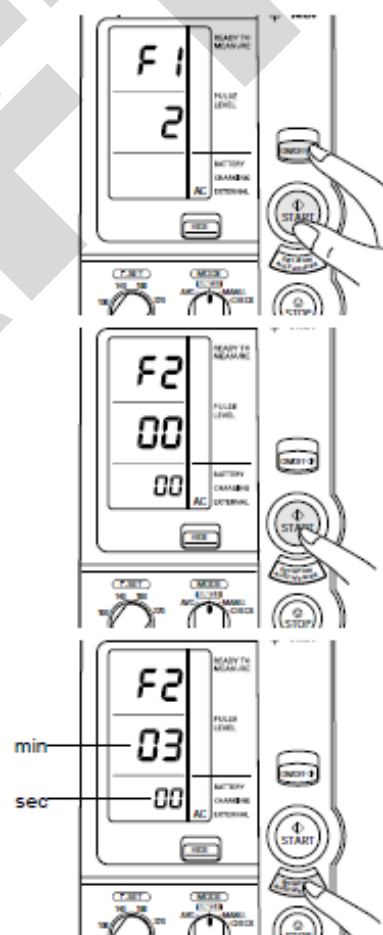
#### Procedure to change the set values

- 1) When the power is OFF, push the ON/OFF (power) Button for more than three seconds while holding the START Button and change the mode to the Setting Change Mode. (F1 is displayed.)

- 2) Push the START Button and select the items from F1 to F3. Each time you push the START Button, the items change in the order of  $F1 \rightarrow F2 \rightarrow F3$ .

- 3) Push the DEFLATION (deflation control)/Display Switch Button to change the set values.

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



## APPENDIX B. OMRON ERROR CODES

# LIST OF ERROR CODES

Error code	Explanation	How to correct
<b>E<sub>r</sub>1</b>	Inflation error <ul style="list-style-type: none"> <li>When the pressure does not exceed 12 mmHg within the set time after the start of inflation</li> <li>When the inflation does not reach the set cuff pressure within the specified time after the start of inflation</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the air tube connecting the cuff and the main unit is connected securely.</li> <li>Confirm that the air flow in the air tube connecting the cuff and the main unit isn't being restricted.</li> </ul>
<b>E<sub>r</sub>2</b>	Deflation error <ul style="list-style-type: none"> <li>When the deflation speed is too fast during the measurement</li> <li>When the deflation speed is too slow during the measurement</li> <li>When the measurement does not finish within the specified time after starting the measurement</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the cuff is wrapped correctly (refer to pages 13 and 14).</li> <li>Check bladder for leaks and, if necessary, replace the bladder with new one (option).</li> </ul>
<b>E<sub>r</sub>3</b>	Overpressure error <ul style="list-style-type: none"> <li>The cuff pressure exceeded 299 mmHg.</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that air flow in the air tube connecting the cuff and the main unit isn't being restricted.</li> </ul>
<b>E<sub>r</sub>4</b>	Insufficient inflation error <ul style="list-style-type: none"> <li>Blood pressure could not be measured due to insufficient inflation level.</li> </ul>	<ul style="list-style-type: none"> <li>If the measurement is made by setting the P-SET to "AUTO", ask the patient not to move during the inflation.</li> <li>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.</li> <li>If the measurement is made by manual inflation level setting, set the value to 30 to 40 mmHg higher.</li> </ul>
<b>E<sub>r</sub>5</b>	Indeterminable blood pressure error <ul style="list-style-type: none"> <li>Blood pressure could not be measured even when the cuff pressure reached the specified pressure.</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the cuff is wrapped correctly (refer to pages 13 and 14).</li> </ul>
<b>E<sub>r</sub>6</b>	Low pulse level error <ul style="list-style-type: none"> <li>Pulse wave was too small.</li> </ul>	<ul style="list-style-type: none"> <li>Confirm that the cuff is wrapped correctly (refer to pages 13 and 14).</li> </ul>
<b>E<sub>r</sub>7</b>	Blood pressure error <ul style="list-style-type: none"> <li>Relationship between systolic and diastolic pressures was abnormal.</li> </ul>	<ul style="list-style-type: none"> <li>Ask the patient not to move during the measurement.</li> </ul>
<b>E<sub>r</sub>8</b>	Pulse rate error <ul style="list-style-type: none"> <li>Pulse rate did not stay within the range of 30 to 199 beats/min.</li> </ul>	<ul style="list-style-type: none"> <li>Check the patient for arrhythmia.</li> </ul>
<b>E<sub>r</sub>9</b>	Device error <ul style="list-style-type: none"> <li>Main unit malfunction.</li> </ul>	<ul style="list-style-type: none"> <li>Contact Omron Healthcare's Customer Service toll-free at 1-877-216-1336.</li> </ul>