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## BLOOD PRESSURE AND PULSE

### 1. Background and Rationale

Blood pressure and pulse will be included as a Visit 9 measurement as well as a Sleep/Cognition Sub-study measurement. As a general marker of cardiovascular health, ascertaining if someone has high blood pressure is important since untreated high blood pressure can lead to heart failure (as a result of an enlarged heart), aneurysms (or small bulges that can form in blood vessels), and kidney failure (as a result of narrowing of blood vessels in the kidney). High blood pressure can also cause arteries to harden faster, which can result in heart attacks, strokes and kidney failure. Lastly, high blood pressure can cause blood vessels in the eyes to burst or bleed, which could result in vision changes or blindness.<sup>1</sup>

Recent studies have linked hypertension and cardiovascular disease with various sleep conditions such as obstructive sleep apnea. To determine if hypertension is related to sleep disorders and other outcomes in older women, blood pressure measurements will be recorded for participants during the ninth study visit.

### 2. Equipment and Supplies

- Automatic blood pressure monitor (Omron HEM-780)
- Arm cuff (ComFit cuff)
- AC Adapter
- 4 AA batteries
- Storage case
- chair with back support

### 3. Maintenance of Blood Pressure Monitor

To keep your digital blood pressure monitor in the best condition and protect the unit from damage follow the directions listed below:

- **Keep the monitor in the storage case** when not in use. Make sure the AC Adapter is placed under the main unit so that it does not damage the display.
- **Do not forcefully bend** the arm cuff or air tube. Do not fold tightly.
- **Clean the monitor with a soft dry cloth.** Do not use any abrasive or volatile cleaners.
- Do not attempt to clean the cuff. Never immerse the monitor or any components in water.
- **Store the monitor in a safe and dry location.** Do not subject the monitor to extreme hot or cold temperatures, humidity and direct sunlight.

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<sup>1</sup> National Heart Lung and Blood Institute (2006). What is high blood pressure?. *NHLBI Diseases and Conditions Index*. Retrieved October 12, 2006 from [http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP\\_WhatIs.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_WhatIs.html)

- **Avoid subjecting the monitor to strong shocks**, such as dropping the unit on the floor.
- **Remove the batteries** if the unit will not be used for three months or longer. Always replace all the batteries with new ones at the same time.
- **Use the unit consistent with the instruction provided in this manual.** Use only authorized parts and accessories.

#### 4. Participant and Exam Room Preparation

To ensure a reliable reading follow these recommendations:

- The participant should avoid eating, smoking, and exercising for 30 minutes before taking a measurement, and rest for at least 5 minutes, following the application of the cuff, before taking the measurement.
- Do not interview the participant during this time or ask her to read anything.
- Since stress raises blood pressure, avoid taking the measurement if the participant appears to be experiencing stress. If this is the case, wait until a different point in the exam to perform the measurement.
- Measurements should be taken in a quiet place.
- The participant should remove tight-fitting clothing from her left arm.
- The participant should be seated in a chair with her feet flat on the floor and her left arm resting on a table so that the cuff is at the same level as her heart.
- The participant should remain still and not talk during the measurement.

#### 5. Preparing the Blood Pressure Monitor

##### 5.1 Battery Installation

1. Press the t indicator on the battery cover and slide the cover off in the direction of the arrow.
2. Install 4 “AA” size batteries so the + (positive) and - (negative) polarities match the polarities of the battery compartment as indicated.
3. Replace the battery cover.

##### 5.1.1 Battery Replacement

Low Battery Indicator: When the Low Battery Indicator appears on the display screen remove all the batteries. Replace with four new batteries at the same time. Long-life alkaline batteries are recommended.

After replacing the batteries, reset the date and time. (See below.)

**NOTE:** Measurement values stored in the memory will not be deleted during battery replacement.

##### 5.2 Using the AC Adapter

Use only the authorized Omron AC Adapter, Model Number HEM-ADPT1, with this monitor. Use of any other adapter may cause damage to the monitor and will void the user warranty.

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### 5.2.2 To connect the AC Adapter

Insert the AC Adapter Plug into the AC Adapter Jack on the back side of the monitor as illustrated. Plug the AC Adapter into a 120V AC outlet (60 cycles). To disconnect the AC Adapter, remove the AC Adapter from the electrical outlet first and then remove the AC Adapter Plug from the monitor.

**NOTE:** The monitor is designed not to draw power from the batteries when the AC Adapter is used.

### 5.3 Setting the Date and Time

The Blood Pressure Monitor automatically stores up to 90 measurement values with the date and time. The monitor also calculates an average reading based on the last three measurement values. Set the monitor to the current date and time before taking a measurement for the first time. If the current date and time is not set, a default date and time will display.

#### 1. TO START THE SETTING

- a. Press the Date/Time Setting button to adjust the date and time. The year flashes on the display.

#### 2. SETTING THE YEAR

- a. The year can be set between 2004 and 2030. When the display reaches 2030, it will return to 2004. Press the MEMORY up button to advance by increments of one year.
- b. Press the Date/Time Setting button to set the current year. The month flashes on the display.
- c. **NOTE:** Press the down memory button to decrease the day and time values by increments of one. Press and hold the memory down button to increase
- d. **NOTE:** Press the MEMORY down button to decrease the day and time values by increments of one. Press and hold the MEMORY up button to increase or memory down button to decrease the date and time values faster.

#### 3. SETTING THE MONTH

- a. Press the MEMORY up button to advance by increments of one month. Press the Date/Time Setting button to set the current month. The day flashes on the display.

#### 4. SETTING THE DAY

- a. Press the MEMORY up button to advance by increments of one day.
- b. Press the Date/Time Setting button to set the current day. The hour flashes on the display.

#### 5. SETTING THE HOUR

- a. The time is set using AM or PM. Press the MEMORY up button to advance by increments of one hour. Press the Date/Time Setting button to set the current hour. The minutes flash on the display.

## 6. SETTING THE MINUTE

- a. Press the MEMORY up button to advance by increments of one minute. Press the Date/Time Setting button to set the current minute. The year flashes on the display.
7. Press the **START/STOP** button to turn the display off.

## 6. Detailed Measurement Procedures

### 6.1. History of Mastectomy

1. Ask the participant if she has had a mastectomy. If she reports a history, take the measurement on opposite arm.
2. If she has had a double mastectomy, ask her if they were radical mastectomies and/or if she has ever been cautioned by a health care provider not to have her blood pressure taken. If the participant is unsure and/or if you are not certain that it is safe, do not conduct this measurement and proceed to the next exam.

### 6.2. Participant Preparation

3. Make sure the air plug is securely inserted in the main unit.
4. Ask the participant if she has had a mastectomy. If not, take the measurement on opposite arm. If she has had a double mastectomy, ask her if they were radical mastectomies and/or if she has ever been cautioned by a health care provider not to have her blood pressure taken. If you are not certain that it is safe, do not conduct this measurement.
5. Have the participant remove tight-fitting clothing from her upper arm.
6. Have the participant sit in a chair with her feet flat on the floor, and place her arm on a table so the cuff is level with her heart.  
Hold the grip on the cuff securely with your hand.
8. Have the participant turn the palm of her hand upward.
9. Apply the cuff to her left upper arm so the blue strip is on the inside of her arm and aligned with her middle finger. The air tube runs down the inside of her arm.  
The bottom of the cuff should be approximately 1/2" above her elbow.
10. Wrap the cuff firmly in place around her arm using the closure strip.

#### 6.2.1 Applying the Cuff to the Right Arm

1. When taking a measurement using the right arm use this instruction for Step 6.
  - a. Apply the cuff to your right upper arm so the grip is centered on the inside of your inner arm. The bottom of the cuff should be approximately 1/2" above your elbow.
  - b. **NOTE:** Be careful not to rest your arm on the air tube. This will restrict the flow of air to the cuff

### 6.3 Rest Period

Ask the participant to sit with both feet flat on the floor and to rest without talking for five minutes before measuring their blood pressure. Instruct the participant on the correct posture with the back supported and both feet flat on the floor. The work station should be free of excessive noise and the participant should not be interviewed nor asked to read anything at this time.

### 6.4 Taking the Measurement

The monitor automatically determines your ideal inflation level. In rare circumstances when a higher inflation may be necessary, the monitor automatically re-inflates the cuff up to 30 mmHg higher than the initial inflation and restarts the measurement.

- Press the START/STOP button.
- All display symbols appear on the screen. The cuff starts to inflate automatically.
- NOTE: To stop the inflation or measurement, push the START/STOP button. The monitor will stop inflating, start deflating, and will turn off.
- Inflation stops automatically and the measurement is started.
- As the cuff deflates, decreasing numbers appear on the display.
- A Heart Symbol flashes at every heartbeat.
- Blood pressure and pulse rate are displayed.
- Record the values on the Blood Pressure and Pulse TeleForm.
- Press the START/STOP button to turn the monitor off.
- NOTE: The monitor will automatically turn off after five minutes.

### 6.5 Displaying the Results

- When the measurement is complete, the arm cuff completely deflates, and blood pressure and pulse rate are displayed.
- Every time you complete a measurement the monitor stores the blood pressure and pulse rate in the memory.
- The Blood Pressure Monitor automatically stores up to 90 measurement values.
- When 90 sets of measurement values are stored in the memory, the oldest record is deleted to save the most recent measurement values.

#### 6.5.1 Displaying the Average Value

The monitor also calculates an average reading based on the values of the three most recent measurements taken. If the date and time is not set, the measurement values will not be stored in the memory correctly.

- Press the MEMORY down button. The average value symbol will display on the screen with the average reading.

#### 6.5.2 Displaying the Measurements

The date and time is alternately displayed with the measurement values.

- **Press the MEMORY down button** to display the most recent measurement values on the screen.

- Press the **MEMORY up button** to display the oldest measurement values.
- **NOTES:** Press the button repeatedly to display the next values. Press and hold the button to display the values faster.
- Press the **START/STOP button** to turn the power off.

### 6.5.3 Deleting All Values Stored in the Memory

You cannot partially delete records stored in the memory. All records will be deleted.

- Press and hold the **MEMORY down button and START/STOP button** simultaneously for more than 2 seconds.

## 7. Potential Problems and Solutions

### Problem 1:

- No power.
- No display appears on the unit.

### Solution 1:

- Replace worn batteries.
- Check the battery installation for proper placement of the battery polarities.

### Problem 2:

- Measurement values appear too high or too low.
- Blood pressure varies constantly.

### Solution 2:

- Many factors including stress, time of day, how you wrap the cuff, may affect your blood pressure.
- Review the sections “Participant and Exam Room Preparation” and “Detailed Measurement Procedures” above.

## 8. Omron HEM-780 User Guide

For additional instructions, please refer to the Omron Instruction Manual.

## 9. Alert Values

There are two levels of alert values for the blood pressure measurement: immediate referrals and alerts. The alert values are provided below along with suggested guidelines for handling both levels of alerts. However, protocols for immediate referrals and alerts will be determined locally, at each clinical site.

Immediate referrals are potential emergencies which may require immediate notification of the participant and (if so requested by the participant) her primary physician or other available health care provider. These are findings made at the time of the clinic or home visit. Depending on the specific protocol for your site, the site staff may contact the SOF study investigator for a clinical diagnostic assessment, determine whether immediate referral is indicated or may send the participant directly to their physician or to an emergency room. Participants receiving immediate referrals are those who would be

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advised to go directly from home to their physician or to a hospital. With participant's consent (obtained verbally at the time of the alert), study physician would contact the participant's referring physician directly. Alternatively, sites may choose to send the participant directly to their physician or to an emergency room.

Findings requiring immediate referral at the time of the clinic visit are as follows:

- Blood pressure (awake, seated):

**Systolic blood pressure  $\geq 220$  mm Hg**

OR

**Diastolic blood pressure  $\geq 120$  mm Hg**

Alerts are related to abnormalities detected at the time of the clinic or home visit which require medical attention but generally not on an emergency basis. In most cases, notification of the participant should be sent by mail within 10 days. However, certain alerts may require more immediate attention at the discretion (and responsibility) of the study physician. Therefore, all immediate referrals should be reviewed by the study investigator no later than the next business day following the observation of the alert condition. If the study physician judges the condition to require more immediate attention, the study investigator or their designate has the responsibility of contacting the participant directly by phone to discuss the need for medical follow-up and to seek consent to notify the participant's referring physician about the condition. If the participant refuses permission to contact a physician or medical care provider on their behalf, then the study investigator or their designate should minimally refer the participant by providing a listing of specialists (e.g. cardiologists) or medical care facilities the participant could contact for medical care follow-up of this elevated blood pressure.

Clinic visit findings requiring an alert are as follows:

- High Blood pressure (awake, seated) (on EITHER the second or third reading):

**Systolic blood pressure  $\geq 180$  or  $\leq 90$**

OR

**Diastolic blood pressure  $\geq 110$**

- Low Blood pressure (awake, seated) (on EITHER the second or third reading):

**Systolic blood pressure  $\leq 90$**

As a reference, please also refer to the table below for NHLBI guidelines for normal, prehypertensive and hypertensive blood pressure<sup>2</sup>.

Category	Systolic (top number)	Diastolic (bottom number)
Normal	Less than 120	Less than 80
Prehypertension	120-139	80-89
High blood pressure		
Stage 1	140-159	90-99
Stage 2	160 or higher	100 or higher
Note: When systolic and diastolic blood pressures fall into different categories, the higher category should be used to classify blood pressure level. For example, 160/80 mmHg would be stage 2 high blood pressure		
Note: There is an exception to the above definition of high blood pressure. A blood pressure of 130/80 mmHg or higher is considered high blood pressure in people with diabetes and chronic kidney disease.		

## 10. Quality Assurance

### 10.1. Training Requirements

Clinical experience with blood pressure measurement is required. In addition, training should include:

- Read and study SOF Operations Manual and Omron Instruction Manual
- Observe administration by experienced examiner.
- Practice on volunteers
- Compare measurements with those made by experienced colleagues
- Discuss problems and questions with local expert

### CERTIFICATION REQUIREMENTS

- Complete training requirements
- Demonstrate how to set the date and time
- Explain how to prepare the participant for the measurement.
- Demonstrate how to display the measurements.
- Recite alert values
- Conduct exam on two volunteers while being observed by QC officer
- Performs exam according to protocol as demonstrated on completed QC checklist

### QUALITY ASSURANCE CHECKLIST

#### Blood Pressure

- Explains procedure
- Wraps cuff snugly, centering bladder over brachial artery
- Five minute rest period before measurements

<sup>2</sup> National Heart Lung and Blood Institute (2006). What is high blood pressure?. *NHLBI Diseases and Conditions Index*. Retrieved October 12, 2006 from [http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP\\_WhatIs.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_WhatIs.html)

- ❑ Records reading on TeleForm.
- ❑ Reviews forms for completeness
- ❑ Tells participant BP reading