



National Health and Nutrition Examination Survey (NHANES)

Health Tech/Blood Pressure
Procedures Manual



May 2009

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1. OVERVIEW AND PURPOSE OF THE HEALTH TECH/BLOOD PRESSURE STUDY

1.1 Introduction and Background

Accurate measurement of blood pressure (BP) is a major public health concern; it is essential for hypertension screening, as well as for disease management. In the period of 2005-2006, 29 percent of the U.S. adult population was hypertensive or taking medication for hypertension. Blood pressure has been measured with the mercury sphygmomanometer for many years but with new technologies available, alternative blood pressure devices have taken center stage. The rapid pace of the development of automated sphygmomanometers with improving accuracy and reliability combined with increasing affordability has meant that these devices have now replaced the mercury sphygmomanometer in many settings.

During the 2007-2008 NHANES cycle, a blood pressure methodology study was successfully completed in order to develop a preliminary understanding of alternative blood pressure devices - namely the OMRON HEM-907 XL. The purpose of the study was to validate the OMRON HEM-907 XL by assessing its accuracy according to industry standards using a convenient sample. Initial findings indicate the OMRON machine passed both the American and British protocols. Because of systematic measurement differences between blood pressure devices, comparison of blood pressure values between different populations or within populations over time is hampered when different blood pressure devices have been used.¹ Therefore, one pertinent question still needs to be addressed - how will the national estimate of hypertension prevalence be affected if an automated machine is used to replace the mercury sphygmomanometer?

NHANES must be able to compare the measurements taken by the mercury device to those taken by a possible successor device in such a way that trends over time in blood pressure prevalence can be accurately maintained and followed. Furthermore, these results would help to better compare blood pressure values in research studies that used different blood pressure devices.

¹ Stang A, Moebus S, Mohlenkamp S, Dragano N, Schmermund a, et al. Algorithms for Converting Random-Zero to Automated Oscillometric Blood Pressure Values, and Vice Versa. *American Journal Epidemiology* 2006 164(1):85-94.

1.2 New Blood Pressure Protocol

The current NHANES Blood Pressure protocol will be modified by adding an additional instrument to perform blood pressure - the OMRON HEM 907 XL automated machine. All NHANES participants aged 8 years and older will have blood pressure measurements taken. The physician will take all reportable blood pressure measurements. In addition, the physician will take all OMRON measurements for participants aged 8-11 years. For participants aged 12+, the physician will be assigned to take an OMRON measurement for 50 percent of the participants. The remaining 50 percent of participants will have a mercury and OMRON measurement taken by a health technologist. All OMRON results will be recorded by a blood pressure observer at the conclusion of the exam, just prior to the status screen for the examination, so as to eliminate disruption of the examination flow.

The mercury sphygmomanometer reading will remain the official blood pressure reading for the survey. Since the physician will be doing reportable blood pressure measurements on all participants, existing procedures regarding clinical referrals for blood pressure levels will apply.

The results obtained by the OMRON machine will not be mentioned or discussed with the sample participant (SP). When the OMRON device is used, the display monitor will be hidden using the HIDE feature and will not be visible to either the health technologist or physician taking the measurement or the sample participant.

2. EQUIPMENT AND SUPPLIES

2.1 Description of Equipment & Supplies

The health technologist (HT) maintains, tracks, and orders all equipment and supplies necessary for the conduct of all aspects of the blood pressure component.

2.2 Inventory

For the purposes of inventory management, equipment is designated as non-consumable items, and supplies are those items that are depleted throughout a stand and used on a daily basis. At the beginning and end of each stand, the HT will inventory all component-specific equipment and supplies. Supplies ordered from the warehouse by the previous team during teardown should be onsite when the next team arrives to set up a new stand. HTs will check all newly received supplies against the associated packing lists before incorporating them into the existing inventory. After reconciling the supplies, the health tech will stock the exam room. Any needed items should be noted on the inventory list, or if needed immediately, reported to the chief technologist and to the MEC manager, and documented in the Unusual Field Occurrence (UFO) system.

2.3 Blood Pressure Equipment (Non-Consumables)

Equipment is selected that meets the requirements for obtaining the required data and creates the best opportunity for minimal data collection error. All equipment is regularly subjected to quality control checks. Quality control procedures for blood pressure equipment are described in detail in Chapter 4, Blood Pressure Equipment Quality Control.

- Baumanometer[®] calibrated mercury true gravity wall model sphygmomanometer;
- Baumanometer[®] calibrated mercury true gravity wall portable desk model sphygmomanometer (2);
- OMRON HEM-907XL Intellisense[®] Automatic Oscillatory Device digital blood pressure monitor, wall mounted;

- Oregon Scientific EMS 100 digital thermometer with digital interface to the desktop computer in the BP room;
- Baumanometer Calibrated V-Lok[®] cuffs with Latex Inflation Bulb, Air-Flo Control Valve in four sizes: child, adult, large adult, and thigh;
- Littman Cardiology III stethoscope;
- Y-tubing;
- Stop watch;
- Steel measuring tape;
- Foam foot pads;
- Calibration cylinders-small, medium, large, X-large;
- Adjustable height chairs;
- Stainless steel scissors;
- Calculator;
- Pliers;
- Luer lock;
- Stethoscope eartips (small);
- Disposable pillow (17" X 23"); and
- Vinyl arm support pad.

2.3.1 Blood Pressure Supplies (Consumables)

- Cosmetic Pencils – black (2) and white (2);
- Cosmetic pencil sharpener
- Baby oil drop dispenser bottle;
- Sani-Cloth germicidal towelettes;
- 2" x 2" gauze pads;
- Latex gloves;
- Masking tape;

- Disposable pillow covers;
- Band-aids; and
- Black magic marker.

2.3.2 Description of Blood Pressure Equipment and Supplies

- **Baumanometer[®] calibrated mercury true gravity wall model sphygmomanometer.** The sphygmomanometer is factory calibrated to true gravity, and is guaranteed by the manufacturer to remain scientifically accurate without need for recalibration. The mercury-gravity manometer consists of a calibrated cartridge glass tube that is optically clear, easy to clean, and abrasion resistant. The mercury reservoir at the bottom of the tube communicates with a compression cuff through a rubber tube. When air pressure is exerted on the mercury in the reservoir by pumping the pressure bulb, the mercury in the glass tube rises and indicates how much pressure the cuff applies against the artery. The manometer is connected to the wall for ease of accurate visualization. See Section 3.6 of this chapter for mercury handling procedures.
- **OMRON HEM-907XL Intellisense[®] Automatic Oscillatory Device digital blood pressure monitor, wall mounted.** Developed specifically for use in the clinical office setting and other health care environments, this device determines blood pressure by oscillometric measurement and displays systolic blood pressure, diastolic blood pressure, and pulse rate using an LCD digital monitor. It has the ability to automatically measure and store up to three sequential readings, and has a “hide” feature that hides measurements during acquisition, which is useful in this research. The pressure measurement range for this device is 0 to 280 mmHg. The OMRON is calibrated to the mercury manometer for routine quality assurance procedures.
- **Oregon Scientific EMS 100 digital thermometer.** This thermometer automatically captures the ambient room temperature and records it directly into the ISIS HTBP application.
- **Baumanometer Calibrated V-Lok[®] cuffs with latex inflation bulb, air-flow control valve.** These cuffs come in four sizes: child, adult, large adult, and thigh. The cuffs are used with all three blood pressure instruments: mercury, aneroid, and OMRON. The Calibrated[®] V-Lok[®] compression cuff is made of urethane-coated Dacron, an unyielding material that exerts an even pressure on the inflatable bladder inside the cuff. The compression cuffs have Velcro fasteners that adhere to them to keep the cuff in position when placed on the arm. The cuff size is determined by the circumference of the arm. The size of the cuff and the bladder used influences the accuracy of the blood pressure readings—if the cuff is too narrow, the observed blood pressure is overestimated (higher than it really is), and if it is too wide, the reading may be underestimated (lower than it really is).

- **Littman Cardiology III stethoscope.** The stethoscopes used for listening to Korotkoff sounds are Littman™ Cardioscope III for adults and Littman™ Classic II pediatric for children. These stethoscopes are of the very highest acoustical quality. They have a bell and diaphragm chest piece, and an acoustical rating *by the manufacturer* of 9 on a scale of 1-10, with a rating of 10 having the best acoustical attributes. The construction uses a single-lumen rubber tubing connection between the ear tubes and the chest piece. The ear tubes can be adjusted to fit the particular user at an anatomically correct angle, and the plastic ear covers come in different sizes allowing the user to match the best ear canal size to achieve an acoustically sealed ear fit. All parts of the stethoscope can be cleaned for use between SPs. The bell of the stethoscope is used to auscultate the Korotkoff sounds for blood pressure measurements. Each technologist is provided with his or her own stethoscope.

- **Y-tubing.** The Y-tubing is required for calibrating the OMRON HEM-907XL against the mercury manometer.

- **Stop watch.** The stop watch is used to measure a 60-second pulse rate during the exam.

- **Wall clock.** A 12" face clock with a second hand may be used to measure a 60-second pulse.

- **Steel measuring tape.** A retractable steel measuring tape is used to take upper arm length and circumference measurements.

- **Calibration cylinders small, medium, large, X-large (plastic).** These cylinders are used for calibrating the sphygmomanometers and OMRON:
 - Plastic Thigh Cuff Can 20" or 51.5 cm
 - Large Arm Cuff Metal Can 13" or 33.5 cm
 - Standard Cuff Metal Can 10.5" or 26.5 cm
 - Child Cuff Metal Can 8.5" or 22 cm

- **Room thermometer.** A digital thermometer measures the ambient room temperature.

- **Adjustable height chairs.** The technologists and participant are all seated during the exam. Adjustable height chairs enable positioning of the SP so that the feet rest directly on the floor, as well as assuring that the measurement technologists can adjust their seats for optimal viewing of sphygmomanometers.

- **Foot stool.** A foot stool is used to adjust the SPs feet so that the feet rest directly on the floor.

- **Stainless steel scissors.** For use to cut the sleeve of the SP disposable shirt when taking blood pressure.

- **Pliers.** Pliers may be needed when changing luer locks.
- **Luer lock.** Replaces a leaking or defective luer.
- **Stethoscope eartips (small).** Replaces worn eartips for the stethoscope.
- **Disposable pillow (17" X 23").** The pillow can be used to support the SPs arm when taking pulse or blood pressure.
- **Arm support pad.** Used to elevate the SPs arm to the heart level.

2.3.3 Blood Pressure Supplies - Description

- **Cosmetic pencil – black and white, and cosmetic pencil sharpener.** When measuring the upper arm circumference, the technologist will make any body marks on the SP using a wax-based cosmetic pencil. The health tech will use an appropriate color so that the markings are clearly visible on the SP's skin.
- **Baby oil drop dispenser bottle.** Baby oil is used for removing cosmetic pencil marks from the SP's skin. A small drop dispenser holds the oil for use during exams. Refills are obtained from a larger bottle of baby oil that is associated with the anthropometry component.
- **2" x 2" gauze pads.** The pads are used to wipe off cosmetic pencil marks with baby oil.
- **Sani-Cloth germicidal towelettes.** Disposable germicidal wipes are used to clean and disinfect the Dacron cuffs between participants.
- **Masking tape.** Tape is used to pull together the cuts that were made on the SP outfit shirt when measuring the upper arm circumference.
- **Alcohol wipes.** Used to clean the steel measuring tape.
- **Mercury Spill Kit.** Used to control and clean a mercury spill.
- **Disposable pillow covers.** For use between SPs.
- **Band-aids.** Replace when the examiner must remove the bandaid that was applied during the phlebotomy.
- **Black magic marker.** Used to denote the size of BP cuff and arm circumference on the SP exam outfit shirt.
- **Wastebasket.**

2.4 Equipment Set Up

Before setting up, the HTs should verify that all equipment and supplies are in the room. Any pieces of equipment that are missing should be reported to the home office component staff who will notify NCHS staff.

All mercury manometers, OMRONs, and Oregon Scientific thermometers on the MECs are tracked in the Equipment Tracking System (ETS) maintained by the MEC manager. Provide the MEC manager with the serial numbers present on each manometer at the beginning of each stand.

2.5 Tear-down Procedure

At the end of each stand, prepare the equipment for transport as follows:

1. Pack up and secure all supplies and equipment into the dedicated plastic bins and store in the lower trailer compartment.
2. Secure wall-mounted mercury manometer with the padded protector. The installed wall mounted manometers do not require packing for MEC transport. See next section for more detailed manometer handling procedures.
3. The OMRON will remain securely fastened to the wall. Disconnect the OMRON from the power source for tear down.

2.6 Handling Instructions for Mercury Manometers

2.6.1 Mercury Safety Considerations

According to the manufacturer, the elemental mercury used in Baum manometers is safely contained in the reservoir and Mylar[®] Clad Calibrated Cartridge glass tube. Since February of 1995, Baum has applied several layers of very strong and crystal clear Mylar[®] film to the glass tubes, which strengthen the tube and maintain its structural integrity even if the inner glass is broken. The Mylar[®] sheath ends close to the tube's top end, and a fingernail can detect the change in the tube's outer diameter, which indicates that this tube has the Mylar film.

A mercury sphygmomanometer should be handled with extreme care. The instrument should not be dropped or treated in any way that could result in damage to the

manometer. Regular quality control checks are conducted to ensure that there are no leaks from the inflation system and that the manometer has not been damaged so as to cause a loss of mercury. The Baum mercury manometers are designed to minimize mercury releases from its closed system; however, there are two ways in which mercury can be released from the manometers.

One way has to do with the lever that holds the glass tube in place on top of the device only on the wall-mounted units. The lever is only supposed to be moved by a service technician when the sphygmomanometer is removed from the wall and lying on its right side. If this lever is inadvertently flipped back while the instrument is upright on the wall, the glass tube is released and the mercury spills out of the bottom of the tube. Baum has added a safety feature to this release lever, with the addition of a “set screw” that prevents an accidental movement of the lever without a tool. If the unit has not been retrofitted with the “set screw,” a safety modification is available free of charge from Baum. The “lever lock,” is simply a small piece of metal bent at a 90 degree angle that is easily slipped behind the lever to immobilize it. The lock can still be removed with no problem using a screwdriver, but spills are prevented because users cannot remove the lever lock without some effort. The lock simply eliminates the potential for anyone to accidentally flip the release lever.

The second manner in which mercury could be released is if the glass tube is damaged in some way. With the application of Mylar[®] to the glass tube, the incidence of glass tube damage has been drastically reduced.

Loss of mercury will occur if the glass tube is broken in either the wall-mounted or portable manometer. Care should be taken in handling and storing the manometer to prevent this. If the tube appears cracked, check for any spilled mercury near the wall-mounted manometer.

2.6.2 Required Procedure for Handling Spilled or Leaking Mercury

The following procedure is recommended for handling spilled or leaking mercury:

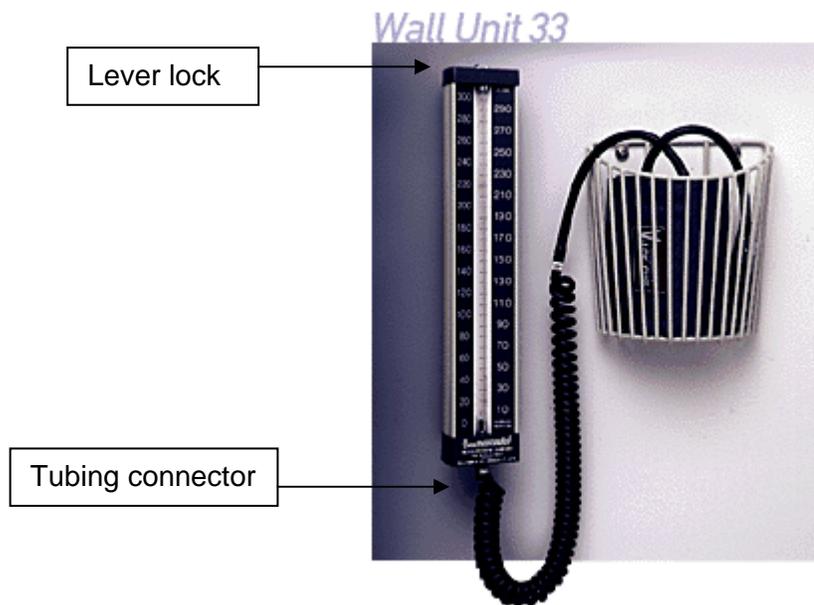
- If you discover a mercury spill, you should not attempt to clean up for yourself.
- Do not touch mercury with your bare hands or attempt to vacuum or clean up the spill.

- Leave the area in which there was a spill, taking the SP to a separate waiting area.
- Close the door to the area or room if possible.
- Immediately notify the MEC manager and NCHS staff; the MEC physician is trained in mercury spill procedures, and will clean the spill.
- Obtain replacement equipment.

2.6.3 Packing, Storing, and Shipping Mercury Manometers

Follow these instructions for packing, unpacking, storing and/or shipping a wall mounted mercury manometer.

Wall-mounted Units

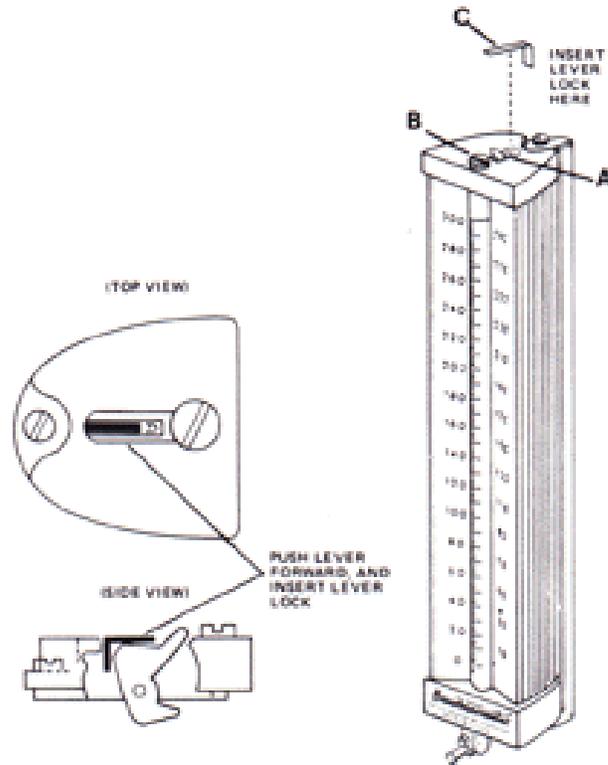


1. Remove the coiled tubing from the instrument.
2. Attach a red cap firmly to the tubing connector on the instrument to seal.
3. Check that the lever lock is in place on top of instrument. If not, see attached instructions for inserting a lever lock.
4. Remove the instrument from the wall unit.
5. Place instrument in a zip closable bag and seal closed.
6. Place the instrument (in bag) into storage box.
7. Place storage box into zip closable bag and seal closed.
8. Wrap manometer box with bubble wrap.
9. Place in storage container in the HTBP/GTT room for storage, or if shipping back to the warehouse, pack the manometer securely with bubble wrap in a box. The amount of mercury contained in a manometer does not require special shipping procedures in compliance with the regulations pertaining to hazardous materials.

Unpacking Manometers (Wall-mounted units):

1. Carefully inspect outer bag for mercury droplets. If no mercury is seen, open bag and remove manometer box.
2. Open box and remove manometer. Inspect inner bag for mercury droplets. If no mercury is seen, open bag and remove manometer.
3. Check that the lever lock is in place on top of instrument. If not, see attached instructions for inserting a lever lock.
4. Reattach manometer to wall mount.
5. Remove red cap from tube connector and reconnect tubing.

Lever Lock Insertion Instructions



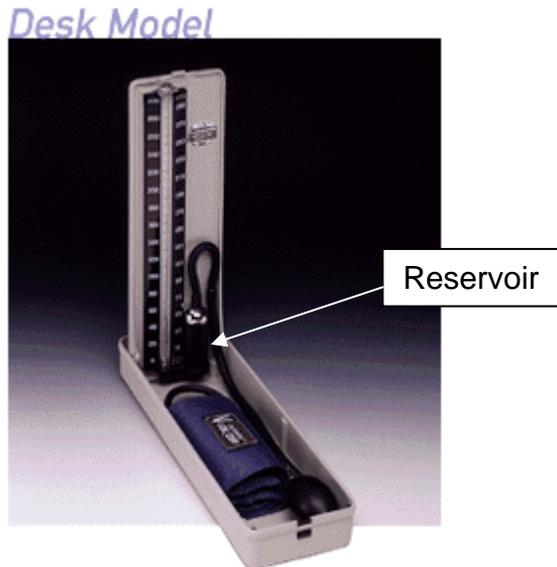
Purpose

To prevent tampering with the cartridge tube release lever and accidental release of mercury.

Procedure

Push lever 'A' forward (toward the chrome plated cap 'B') and insert lever lock 'C' as shown in diagram.

Desk-top Models



Packing Desk-top manometers:

1. Remove tubing from top of reservoir.
2. Tilt manometer onto reservoir-side. Mercury should be contained in reservoir.
3. Place red cap firmly on reservoir opening while manometer is on its side.
4. Stand manometer up. Close.
5. Place manometer in zip closable bag and seal closed.
6. Place manometer (in bag) into storage box.
7. Place storage box into zip closable bag and seal closed.
8. Wrap manometer box with bubble wrap.
9. Place in storage container in HTBP/GTT room for transport to next stand.

Unpacking Manometers (Desk-top model):

1. Carefully inspect outer bag for mercury droplets. If no mercury is seen, open bag and remove manometer box.
2. Open box and remove manometer. Inspect inner bag for mercury droplets. If no mercury is seen, open bag and remove manometer.
3. Open manometer and place upright on table.
4. Remove red cap from reservoir and reconnect tubing.

3. BLOOD PRESSURE PROTOCOL

3.1 General Overview

3.1.1 SPs Included for Blood Pressure, Heart Rate, and Pulse Measurements

Mercury blood pressures and radial pulses are measured on all SPs 8 years of age and older by the physician. The new protocol for blood pressure as noted in Chapter 1 will employ the use of both auscultatory (mercury sphygmomanometer) and oscillatory (OMRON) measures. The physician will continue to take all blood pressures on SPs age 8 and above using the mercury manometer. The physician will also be responsible for taking all OMRON measures on children ages 8 – 11, and 50 percent of SPs age 12 and above using a randomized assignment scheme in ISIS to determine the order of the device to be used, i.e., mercury first or OMRON first. The remaining 50 percent of the comparison blood pressure measurements will be taken by health technologists. Therefore, 50 percent of SPs age 12 and older will have their blood pressure taken in two different examinations; one series of three mercury measurements will be taken by the physician and another two series of three measurements each with the mercury and OMRON devices by the HT.

The results obtained by the OMRON device will not be mentioned or discussed with the sample participant. During the OMRON measurements, the display monitor will be hidden using a HIDE feature and will not be visible to the HT taking the measurement or the SP. The data entry of the OMRON measurements will be performed by a “recorder” assigned by the coordinator. The blood pressure recorder will enter the OMRON results on the “OMRON Data Capture Screen” as detailed later in this chapter.

3.1.2 Talking Points

The following talking points should be used when explaining the exam to the SP:

- “The NHANES program is testing two different devices to measure blood pressure. During this exam we will be taking your blood pressure with two different devices. One is the traditional mercury blood pressure device and the other is an electronic digital device. We are going to take a series of three measurements with each device.

- First, I will take your pulse and then I will measure your blood pressure.
- Before taking your first blood pressure reading there will be a 5-minute waiting period.
- During the waiting period, and while we are taking your BP, we ask you to relax, keep both of your feet flat on the floor, and it is very important not to talk/converse. I also will not talk because talking and moving changes your BP.
- The first time I inflate the cuff, I will not be taking your blood pressure—I am measuring how high I need to inflate the cuff when I take your blood pressure.
- When I inflate the cuff it may feel tight and you will feel some pressure. The repeated measurements may cause slight discomfort in your arm and tingling in your hand for 1 or 2 minutes. It will go away after a little while.
- We are not going to give you the results of these measurements. The blood pressure that the doctor takes is the blood pressure that is reported to you.
- Do you have any questions?

3.1.3 SPs Excluded from Blood Pressure, Heart Rate, and Pulse Measurements

SPs are excluded from blood pressure measurement if they have any condition that could potentially cause them harm or discomfort or would prevent accurate blood pressure measurement. Specifically, BP measurements are not done when both arms have a rash, gauze/adhesive dressings, casts, are withered, puffy, have tubes, open sores, hematomas, wounds, arteriovenous (AV) shunt, or any other intravenous access device. Also, women who have had an axillary nodal biopsy or resection, or a unilateral radical mastectomy do not have their blood pressure measured in the affected arm. If there is a condition with both arms, the blood pressure is not taken.

Some conditions that may affect BP are noted, but these conditions do not exclude SPs from BP measurement. SPs are asked if they have had any food, coffee, cigarettes, or alcohol in the past 30 minutes. Although intake of coffee and cigarettes could affect blood pressure, this information is not used to exclude SPs from blood pressure measurement. There are no protocol specific reasons for excluding SPs from heart rate or pulse measurement.

3.1.4 Procedures for Measuring Pulse and Blood Pressures

These are the instructional procedures for health technologists to follow when measuring BPs, heart rate, and pulse. Health technologists are taught during training to follow these protocol specific procedures exactly when measuring blood pressures and counting pulses.

3.1.4.1 Selecting the Arm for Pulse and Blood Pressure Measurement

For the purpose of standardization, both pulse and blood pressure are measured in the right arm unless specific SP conditions prohibit the use of the right arm, or, if SPs self-report any reason that the blood pressure procedure should not use the right arm. If the measurements cannot be taken in the right arm, they are taken in the left arm. If the left arm is used, turn the chair to face the wall so that the left arm is resting on the table, and tilt the manometer away from the view of the SP. In all cases, if there is a problem with both arms, the blood pressure is not taken.

3.1.4.2 Position SP for Pulse and Blood Pressure Measurements

Ask the SP to sit all the way to the back of the chair so that the spine is straight. Instruct the SP to rest quietly for 5 minutes prior to blood pressure measurement. The arm and back should be supported and the legs should be uncrossed with both feet flat on the floor. The arm should be bared and unrestricted by clothing with the palm of the hand turned upward and the elbow slightly flexed. The arm should be positioned so that the midpoint of the upper arm is at the level of the heart. The location of the heart is the junction of the fourth intercostal space and the lower left sternal border.

Small or short SPs may need the chair position raised or lowered to correctly position for the BP measurement. If necessary, place SP's feet on a foot stool or stackable foam pads to correctly stabilize the feet. Very tall SPs may need to place their arm on an arm rest or pillow to bring their upper arm to the correct position. During the 5 minute resting phase, the pulse/heart rate can be measured after 3 minutes.

3.1.4.3 Locating the Pulse Points

Locating the Radial Pulse: Position SP with the right palm upward. Palpate the radial pulse on the flexor surface of the wrist, laterally, with the pads of the index and middle fingers.

Locating the Brachial Pulse in the upper arm (for BP cuff placement): Position SP with the right palm turned upward and the arm slightly bent at the elbow. Palpate the brachial pulse in the groove between the bicep and tricep muscles above the elbow with the pads of the index and middle fingers. Using an eyeliner pencil, mark the spot where the pulse is most strongly palpated. **The center of the cuff bladder is placed at this point.**

Locating the Brachial Pulse at the Antecubital Space: The brachial pulse is traced from the bicep and tricep space until palpated in the medial aspect of the antecubital fossa. Mark the spot using the eyeliner pencil. This is the point where the bell of the stethoscope is placed to listen for the BP. If the pulse cannot be felt in the arm, check the radial pulse. If no radial or brachial pulse is palpable on the right arm, use the left arm unless contraindicated. If a radial pulse is apparent, whether or not the brachial pulse can be felt, the blood pressure measurement should be attempted.

3.1.5 Blood Pressure Cuff Size and Application

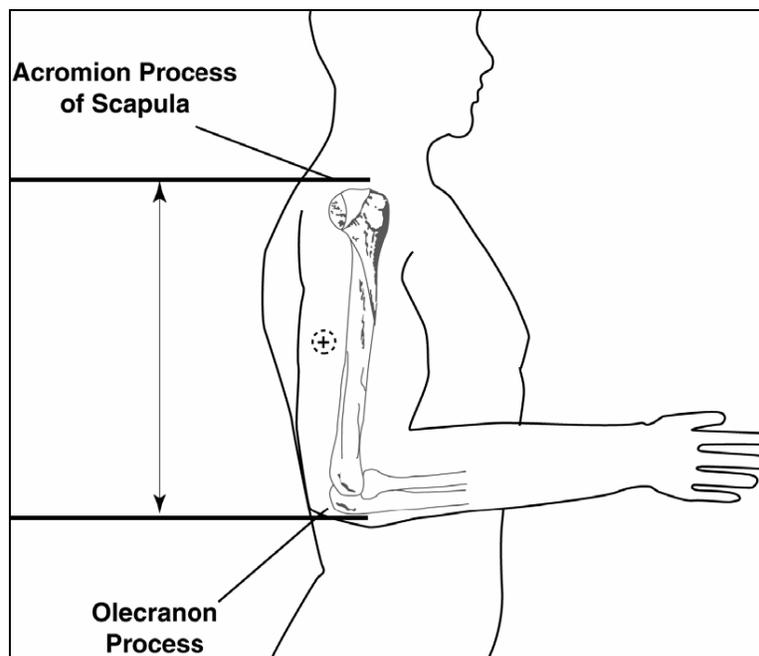
The first step to obtain an accurate BP is to use an accurate cuff bladder size. The length and width of the cuff's bladder should encircle at least 80 percent of the length of the upper arm, and 40 percent of the width of an adult's arm. The length and width of the cuff should encircle 100 percent of the arm in children less than 13 years old. The index lines found on most BP cuffs are not used to guide cuff application in this study. Arm length and circumference measurement are specified in detail below per the *NHANES Anthropometry Procedures Manual*.

3.1.5.1 Arm Circumference Protocol to Determine Cuff Size

To reliably measure circumferences on the arm, upper arm length must first be measured and the midpoint located and marked. Stand behind the SP and have the SP stand erect with feet together and the right arm flexed 90° at the elbow with the palm facing up. On the right scapula, locate and mark with

a horizontal line the uppermost edge of the posterior border of the acromion process (see Exhibit 3-1). Hold the zero end of the measuring tape at this mark and extend the tape down the posterior surface of the arm to the tip of the olecranon process (the bony part of the mid-elbow). Note the length of the upper arm and record to the nearest 0.1 cm, keeping the tape in position. Make a horizontal mark with a cosmetic pencil at the midpoint at the posterior aspect of the arm. Cross this mark (+) with another mark that lies in a plane extending from the acromion to the olecranon process. This point defines the site at which both the mid-arm circumference is measured.

Exhibit 3-1. Upper arm bony landmarks



Using a centimeter tape, determine the midpoint of the upper arm by measuring the length of the arm between the acromium and olecranon process (between the shoulder and elbow).*

Mark the midpoint of this measurement with a cosmetic pencil.*

Measure the circumference of the bare upper arm at the midpoint.*

* These measurement instructions are available in more detail in the *NHANES Anthropometry Procedures Manual*.

Find the arm circumference under column 4 in Table 3-1, Arm circumference and acceptable cuff size.

Table 3-1. Arm circumference and acceptable cuff size

Cuff size	Bladder width (cm)	Bladder length (cm)	Arm circumference ¹
Child	9	17	17-21.9
Adult	12	22	22-29.9
Large adult	15	32	30-37.9
Adult thigh	18	35	38-47.9

¹ Adapted from Human Blood Pressure Determination by Sphygmometry, American Heart Association.

Application of the cuff:

1. Use the cuff size from column 1 associated with the arm circumference in column 4. (Example: If the arm circumference at midpoint is 36 cm, use the large adult cuff.)
2. Position the *rubber bladder* over the brachial artery at least **1” above the crease of the elbow**. For long thin arms, the cuff should be placed in the middle of the arm. Place the marker on the inner part of the cuff directly over the brachial artery.
3. Wrap the cuff in a circular manner in such a way that the wrapped cuff is smooth, snug, and no more than 2 fingers can be fit under the cuff.
4. Check the fit of the cuff to ensure that it is secure but not tight.

3.1.5.2 Determine the Maximum Inflation Level (MIL)

NOTE: The MIL will be obtained by palpation before any blood pressure is taken, regardless of the order in which the devices are assigned. For the individuals randomized to the OMRON/mercury condition, the MIL will first be obtained using the mercury device even if OMRON is the first randomized method of measurement.

Determine the maximum inflation level (MIL) after the SP has been seated and resting quietly for **approximately 4 minutes**. The MIL or palpatory method provides an approximation of the

systolic blood pressure. The MIL is the highest level to which the cuff should be inflated when the actual measurement is made. The MIL is determined as follows:

- The mercury manometer should be positioned at the eye level of the examiner so the mercury meniscus can be easily read without parallax.
- Locate the radial pulse in the right arm;
- Inflate the cuff quickly to a pressure of 70 – 80 mm Hg;
- Then inflate the cuff in increments of 10 mm Hg until the radial pulse is no longer palpable (palpated systolic);
- Continue inflating the cuff in increments of 10 mm Hg to a final measure that is 30 mm Hg above the pressure where the pulse was last palpated. This number is the MIL. Note this measurement and record in the application;
- Rapidly deflate the cuff, confirm the return of the pulse, and disconnect the tubing between the cuff and the manometer; and
- If unable to obtain the MIL on the first attempt, wait 1 minute and repeat the process. Enter the MIL in the **MIL Field** in the ISIS system.

3.1.5.3 Mercury Manometer Blood Pressure Readings

Three consecutive blood pressure readings are obtained, using the same arm. If a blood pressure measurement is interrupted or you are unable to get one or more of the readings, a fourth attempt may be made.

The following procedures are used for seated blood pressure readings using the mercury manometer:

- Place earpieces of the stethoscope into the ear canals;
- Confirm that the stethoscope head is in the low-frequency (bell) position. The bell is recommended because it may be better suited to hear the low frequency sounds;
- Position the bell of the stethoscope over the brachial artery and hold it firmly in place, making sure that the head makes contact with the skin around its entire circumference. If possible, avoid allowing the cuff, tubing, or bell to come in contact with each other;

- Position the bell of the stethoscope over the brachial artery pulsation just above and medial to the antecubital fossa;
- Rapidly and steadily, inflate the cuff to the MIL;
- When the MIL is reached, open the thumb valve and smoothly deflate the cuff at a constant rate near 2-mm Hg per second (one mark or dial tick per second) while listening for systolic and diastolic blood pressure sounds;
- Keep the center of the manometer at eye level;
- Watch the top of the mercury column (meniscus) as the pressure in the bladder falls and note the level of the manometer pressure when the first repetitive sounds are heard (Phase I) and when they disappear (Phase V);
- Continue steady deflation at 2 mm Hg per second for at least another 10 mm Hg past where the last sounds were heard;
- Rapidly deflate the cuff and disconnect the manometer tubing from the inflation cuff between measurements to ensure the cuff deflates completely to zero (begin 30 second-count);
- Wait 30 seconds between readings with the SP resting quietly;
- While waiting for the 30 second count between measurements, record Phase I (the level of the pressure on the manometer at the first appearance of repetitive sounds) as the systolic blood pressure reading;
- Record Phase V (the point at which the last sound is heard) as the diastolic blood pressure reading;
- If Phase I or Phase V occurs between the millimeter marks on the glass column, round **upward** to the nearest digit;
- Take a second set of measurements and record the systolic and diastolic pressures in the system;
- Disconnect the manometer tubing and wait 30 seconds between readings with the SP resting quietly; and
- Take the third measurement and record the systolic and diastolic pressures in the system.

If enhancement techniques were needed (see Section 3.1.6), enter this in the system for that reading. If you are unable to get a blood pressure reading for some reason, deflate the cuff and enter this in the system as “Could Not Obtain.”

3.1.6 Procedures to Enhance the Brachial Pulse Sounds

If an SP's blood pressure sounds are difficult to hear, two methods can be used to increase the intensity and loudness of the sounds:

1. Elevate the SP's arm before and during inflation, and then lower the arm after the cuff has been inflated. Blood pressure is then determined in the usual manner. **Or**,
2. Inflate the cuff, and then have the subject open and close his or her fist several times (6 to 8 times). Blood pressure is then determined in the usual manner.

When an enhancement method is used to measure blood pressures (BP), check **“enhancement” field** on the data entry screen for that measurement.

3.1.7 Additional Blood Pressure Measurement Guidelines

If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. See the procedures in the above section for enhancing the sounds at the brachial pulse. Check enhancement techniques in the box on the blood pressure screen.

- If a BP measurement was interrupted, use the following guidelines:
 - The maximum number of cuff inflations for each SP in the mercury measurement is **five**, counting all MIL attempts and blood pressure attempts. The rationale for this is twofold: to minimize the discomfort to the SP of frequent cuff inflations and to accomplish data collection for this measurement within the time allowed.
 - If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. See the procedures in the above section for enhancing the Korotkoff sounds at the brachial pulse. Check enhancement techniques in the box on the Blood Pressure screen.
 - If the difference between the MIL and the 1st systolic measurement is less than 10 mm Hg or greater than 50 mm Hg, the system will prompt the examiner to

3.1.7.1 Hard Edit Limits for Blood Pressure

A hard edit is a limit imposed by the system that prevents data entry above or below the specified instrument or measurable limits. When entries are recorded that are outside these limits, the system displays a message that the value is out of range and sends a “popup message” asking that the value be reentered. The system will not allow entries that are outside the specified hard edit limits. The hard edits imposed by the system are listed below:

- Systolic blood pressure and maximum inflation level cannot be greater than 300 mm Hg. This is the upper range of the measurement device. The mercury manometer has a minimum and maximum scale of 0 to 300, respectively. It is impossible to get a reading above or below this level.
- Systolic and diastolic blood pressure and maximum inflation level can be even numbers only. This is a function of the measurement device. The manometer displays the readings in increments of 2.
- Systolic blood pressure must be greater than diastolic blood pressure.
- If there is no systolic blood pressure, there can be no diastolic blood pressure. (There can be a systolic measurement without a diastolic measurement.)
- Systolic blood pressure cannot be zero (diastolic blood pressure can be zero).

3.1.7.2 Soft Edit Limits for Blood Pressure

A soft edit is a limit imposed by the system if a value is outside the predefined edit limits for the SP being measured. The predefined edits are based on NHANES III data. When measures outside these values are recorded, the system displays a “popup message” warning that the limit is out of range, and asks if the measurement is correct. The person entering the data has the option of editing or accepting

- Exception: If there is one diastolic reading of zero and one (or more) with a number above zero, the diastolic reading with zero is not used to calculate the diastolic average.
 - If two out of three are zero, the one diastolic reading that is not zero is used to calculate the diastolic average.

3.1.8 Procedure for OMRON HEM-907XL

This protocol is written for use with the OMRON HEM-907XL automated blood pressure monitor. Special attention must be placed on assessment and maintenance of the instrument's accuracy as per the manual that accompanies the instrument.

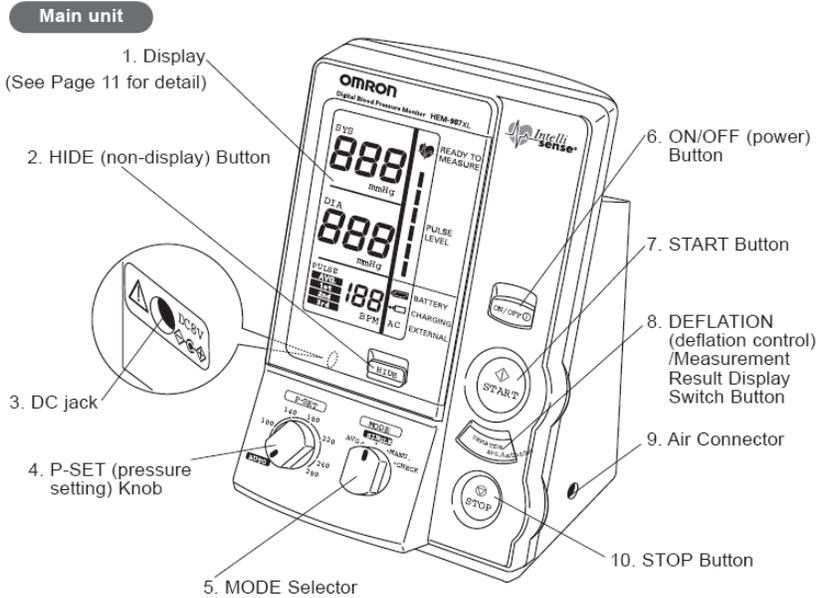
The design and operation of the OMRON HEM-907XL are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and estimation of the systolic and diastolic blood pressure levels by oscillometric methods. **The OMRON will be in HIDE mode during the entire blood pressure measurements.**

3.1.8.1 Setting the OMRON

Below is a diagram and description of the features and functions of the OMRON HEM-907XL.

FEATURES AND FUNCTIONS

Names of the Parts



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.

At a start of each session:

- Check that the monitor is attached to the AC adapter and to the DC jack and plugged in (see Exhibit 3-2) and that the AC sign (see Exhibit 3-3) is visible in the lower window.

Exhibit 3-2. The OMRON showing plugged in DC jack



Confirm that the battery level is displayed for the operable level—see Exhibit 3-3 below.

Exhibit 3-3. AC sign visible in lower window



Battery level

Displays  for the operable level.

Blinks  for a low charged level

Displays  for the inoperable level.

Charging

Displays  when the battery pack is being charged.

External power source

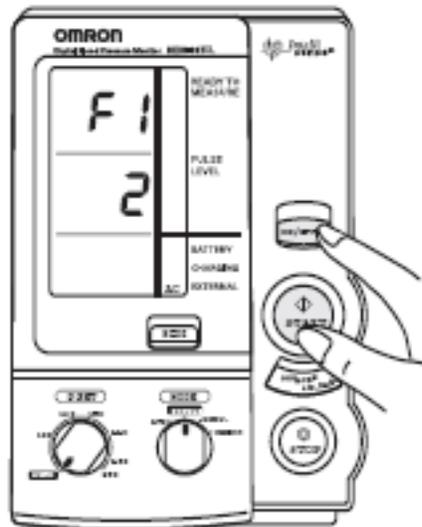
Displays **AC** when the unit is connected to the external power source via the AC adapter.

3.1.8.2 Procedures to Set the Values for the OMRON Protocol

A total of five settings must be selected for the OMRON Protocol. For this protocol, the OMRON will be set to three consecutive inflations (measures), 0 seconds waiting time to start the first inflation, and 30 seconds between inflations. Follow the steps below:

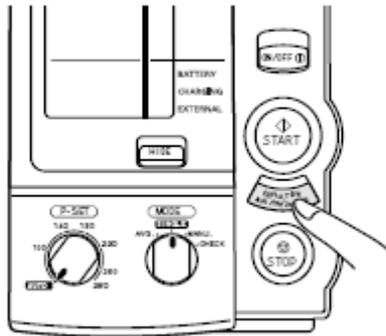
Function Setting 1: Number of Inflations (F1)

When power is OFF, Push the ON/OFF (power) button for more than 3 seconds while holding the START button simultaneously: F1 is displayed in the top window. Make sure that 3, (denoting three inflations) is displayed in the middle window (see Exhibit 3-4).



In the above diagram, the middle window denotes 2 inflations. To change the setting:

- Push the DEFLATION button (the deflation button also functions as a display switch) to change the set value to three inflations as indicated in the photo below.



Deflation /Result Display Switch Button

Press the deflation button until you see “3” displayed in the middle window (Exhibit 3-4).

Exhibit 3-4. F1 setting, indicating 3 inflations



Function Setting 2: the waiting time until the start of the 1st measurement (F2)

To set F2, push the START button; each time you push the START button, the functions change in the order of F1→F2→F3, then back to F1.

- Push the START button and F2 function is displayed in the first window and 0 waiting time is displayed in the middle window (see Exhibit 3-5).

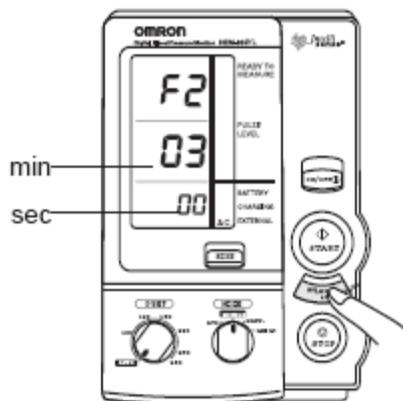
Exhibit 3-5. The F2 function setting to 0 seconds waiting time until the first measurement



If the display in the middle window is not 00, push the DEFLATION button and change the set value to 0 seconds waiting time.

Function Setting 3: the Measurement Interval (F3) to 30 Seconds between inflations

- Push the START button to access the F3 function, which is displayed in the top window.



Note that the display shows the setting in the top row, Minutes in the second row, and seconds in the third row.

Exhibit 3-6. The F3 function and inflation interval



To change the value to 30 seconds, push the DEFLATION/Measurement Result Display Switch Button and change the set value to 30 sec measurement interval.

Saving the Function Settings

Turn off the OMRON by pushing the ON/OFF button; this will save the settings, and the settings will be saved when the machine is turned on again. At the beginning of every session, confirm that the F1, F2, and F3 settings are correctly designated.

Setting the Mode Selector Switch to measure BP in Average mode:

- Push the ON/OFF button to turn on the power; and
- Set the MODE selection to AVG (see Exhibit 3-7).

Exhibit 3-7. Settings for BP in AVG mode



Setting the P-SET Switch--Inflation Level Setting

In the AUTO position, the inflation level is automatically set. Set the P-SET (inflation level) knob to **AUTO** (see Exhibit 3-7).

Setting the Non-Display Function (HIDE)

Finally, place the the OMRON in the “HIDE” mode by pressing the “HIDE” button. push the HIDE button. The word “Hid” will appear in the top window.



Summary of the Settings

The OMRON is now set to take 3 measurements at 30 second intervals with no waiting time before the first inflation; the OMRON will determine the inflation level, and the average mode will enable the display to reflect all three measurements, as well as the average of the three measurements. Ensure that:

1. F1 = 3
2. F2 = 0
3. F3 = 30
4. MODE = Avg.
5. P-SET = AUTO
6. Non-Display Function = HIDE

OMRON Set Up Procedure

1. Start with the OMRON in the “off” position
2. P-Set (inflation limit setting) = AUTO
3. MODE setting = AVG
4. Function Settings:

Function Number	Definition	Set Value
F1	Number of inflations	3
F2	Waiting time to start the first inflation	0 seconds
F3	Inflation interval	30 seconds

5. To access the function settings, the OMRON must be off.
 - a. Press the On/Off button together with the START button simultaneously for 3 seconds. F1 is displayed in the top window.
 - b. F1 is the number of readings/inflations you want the OMRON to conduct. If you need to change the setting, push the deflation button to change the set value to 3 inflations. The “3” appears in the middle window.
 - c. To move to F2, push the START button. All values should be 00. If you need to change the setting, push the deflation button to change the set value to 00.
 - d. To move to F3, push the START button. Note that the middle window indicates minutes, the bottom window indicates seconds. Ensure that the middle window indicates 00, and the bottom window indicates 30. Use the deflation button to change the set value to 30 seconds if necessary.
6. The OMRON is now set. Turn off machine to save the settings.

3.1.8.3 Taking the OMRON Blood Pressure Measurements

- Connect the air tube to the cuff that was used to determine the MIL:
 - For all cuff sizes small, medium, large, and thigh, connect the air tube to the main unit by attaching the air plug to the base of the air connector; and
 - Connect the cuff to the air tube attached to OMRON unit.
- **Make absolutely sure that the inflation control valve is closed;**
- Confirm that the OMRON is set to the HIDE mode;
- Press START button.
- Monitor the display to ensure that that the machine is inflating properly and there is no error (ERR) message displayed on the monitor, particularly during the first 10 seconds after pressing the start button. **The ERR message is usually the results of the inflation valve not tightly closed.** Keep the HIDE condition on for all three inflations.

- 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 around the arm.

OMRON Inflation Error Troubleshooting Procedures

- If you notice that the OMRON is not completing the cycle of 3 inflations, take the OMRON out of the HIDE mode to determine if there is an error code displayed on the OMRON LED.
- Troubleshoot the error using the guidelines on the laminated pages from the OMRON Manufacturer manual, see below for List of Error Codes and Troubleshooting.
- If you can correct the problem, turn off OMRON, turn it back on, place in HIDE mode, and attempt to get the OMRON readings a second time.
- If you can not correct the problem, discontinue the OMRON measurement for that SP, and continue to the end of the exam.
- When you reach the OMRON Data Capture Screen, and no OMRON measurements were taken, a recorder is not needed for this outcome. The HT who measure the blood pressure will hit the “Enter” key on the keyboard. A dialogue box will appear asking “Do you wish to skip due to time constraints?” Answer Yes (this will take you to the OMRON Status Screen.) The OMRON Status screen will appear as “Not Done,” and you will enter a comment such as “Equipment Failure,” and finish the exam.

LIST OF ERROR CODES

Error code	Explanation	How to correct
E_r1	<p>Inflation error</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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.
E_r2	<p>Deflation error</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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).
E_r3	<p>Overpressure error</p> <ul style="list-style-type: none"> • The cuff pressure exceeded 299 mmHg. 	<ul style="list-style-type: none"> • Confirm that air flow in the air tube connecting the cuff and the main unit isn't being restricted.
E_r4	<p>Insufficient inflation error</p> <ul style="list-style-type: none"> • Blood pressure could not be measured due to insufficient inflation level. 	<ul style="list-style-type: none"> • 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.
E_r5	<p>Indeterminable blood pressure error</p> <ul style="list-style-type: none"> • Blood pressure could not be measured even when the cuff pressure reached the specified pressure. 	<ul style="list-style-type: none"> • Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
E_r6	<p>Low pulse level error</p> <ul style="list-style-type: none"> • Pulse wave was too small. 	<ul style="list-style-type: none"> • Confirm that the cuff is wrapped correctly (refer to pages 14 and 15).
E_r7	<p>Blood pressure error</p> <ul style="list-style-type: none"> • Relationship between systolic and diastolic pressures was abnormal. 	<ul style="list-style-type: none"> • Ask the patient not to move during the measurement.
E_r8	<p>Pulse rate error</p> <ul style="list-style-type: none"> • Pulse rate did not stay within the range of 30 to 199 beats/min. 	<ul style="list-style-type: none"> • Check the patient for arrhythmia.
E_r9	<p>Device error</p> <ul style="list-style-type: none"> • Main unit malfunction. 	<ul style="list-style-type: none"> • Contact Omron Healthcare's Customer Service 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.

When the OMRON has completed the measurements, disconnect the air tube from the cuff, remove the cuff from the SP's arm, and maintain the setting in the HIDE mode. **Do not turn off the OMRON—this will result in the loss of data.** When the end of the BP exam is reached in the ISIS application, the OMRON recording screen will appear before the “Finish Exam” screen. At this point, the coordinator will have assigned an observer, a trained technologist, to stand by to be ready to enter the room to record the OMRON measurements after the HT releases the SP from the room. It is imperative to maintain efficient MEC flow that the recorder enters the BP component room in a timely manner and record the OMRON results.

3.1.8.4 Recording the OMRON Results in the OMRON Data Capture Screen—The BP Recorder

The BP recorder will push the HIDE button and unhide the OMRON results. Results captured by the OMRON device will include fields for 8 separate entries, four systolic entries, and four diastolic entries. The observer will type in the results twice on two separate screens (double keying the entries). Extreme care must be taken when transcribing these measurements. The ISIS application will recognize a discrepancy if the data entered on the two screens is not consistent. The procedure for entering the OMRON BP results into the OMRON Data Capture Screen is located on Page 38 of this section.

3.1.9 Data Entry Screens for Pulse and Blood Pressure

The following sections instruct the HTs how to carry out the data entry for the Blood Pressure component. The ISIS screens are displayed as a visual reference.

3.1.9.1 ISIS Blood Pressure Data Entry

Exhibit 3-8. Default blood pressure screen

File View Utilities Reports Window Help

HT Blood Pressure: Stand:430 Session:430430 01/15/2005 08:30 am - 12:30 pm

SP ID: 721422 Name: WILLIAMS_1, CORY Age: 26 years Gender: Male Date: 04/17/2009 Time: 10:54 AM

Blood Pressure

Meal
Have you had any of the following in the past 30 minutes? (Check each that applies.) food alcohol coffee cigarettes

Arm/Cuff
Arm selected: Right Left Could not obtain Cuff size:

Timer, min.
1 2 3 4 5

Pulse/MIL
30 sec pulse: 60 sec pulse:
 x 2 = Regular Irregular
Pulse type: Radial
Room temperature: 71.8 °F
Maximum inflation level: mm Hg
 Could not obtain

- A timer on the right side of the screen starts a 5-minute count when this screen is opened. The timer is used to help determine when the pulse, MIL, and blood pressure measurements are to be made.
- The room temperature will be captured into the ISIS application from the Oregon Scientific Wireless Indoor/Outdoor Thermometer connected via USB to the computer. Confirm that the data capture is present. If the temperature displayed on the screen does not match the digital read out on the Oregon Scientific thermometer, please correct the temperature in the screen.
- Ask if the SP has had food, alcohol, coffee, or cigarettes in the last 30 minutes. Check all that apply. These are not exclusionary questions-- answering "Yes" does not eliminate the SPs from the blood pressure component.
- The pulse should not be taken until the SP has been resting quietly for **at least 3** minutes. The SP should be seated quietly during this time to allow the heart rate and blood pressure measurements to stabilize to a standard resting state.

- The MIL should not be taken until the SP has been resting quietly for **at least 4** minutes.
- The blood pressure should not be taken until the SP has been resting for **at least 5** minutes.
- The default for “Arm/cuff” is the right arm. If the left arm is used, click on left.
- If “Could not Obtain” is selected, the cuff size, MIL, and blood pressure fields are disabled.

Exhibit 3-9. Blood pressure cuff size

- Check which arm is being used for the BP. The system defaults to the right arm.
- Select the BP cuff size from the drop-down menu. The sizes of cuffs are child, adult, large adult, and adult thigh.
- If the cuff size is not selected before the Next button is pressed, a message is displayed with a reminder to select cuff size.
- The default site for taking the pulse is radial. If the radial pulse is not palpable, try the brachial. If a brachial pulse is obtained, select and record brachial from the drop-down menu of the “Pulse Type” field.

- Enter the 30-second pulse in the “30-sec pulse” field. The system will automatically calculate the 60-second heart rate and display it on the screen.
- Note whether the heart rate was regular or irregular. If the heart rate was irregular, click the box indicating irregular.
- The default pulse type is radial. If the pulse type was brachial, use the drop-down menu to change the pulse type to brachial.
- If the HT tries to exit from this screen before recording the pulse measurement, a system message is displayed: “Please, enter Pulse or check Could not Obtain.”
- Click OK to this message and record the 30-sec pulse in the “30-sec pulse” field.

Exhibit 3-10. Select Irregular pulse

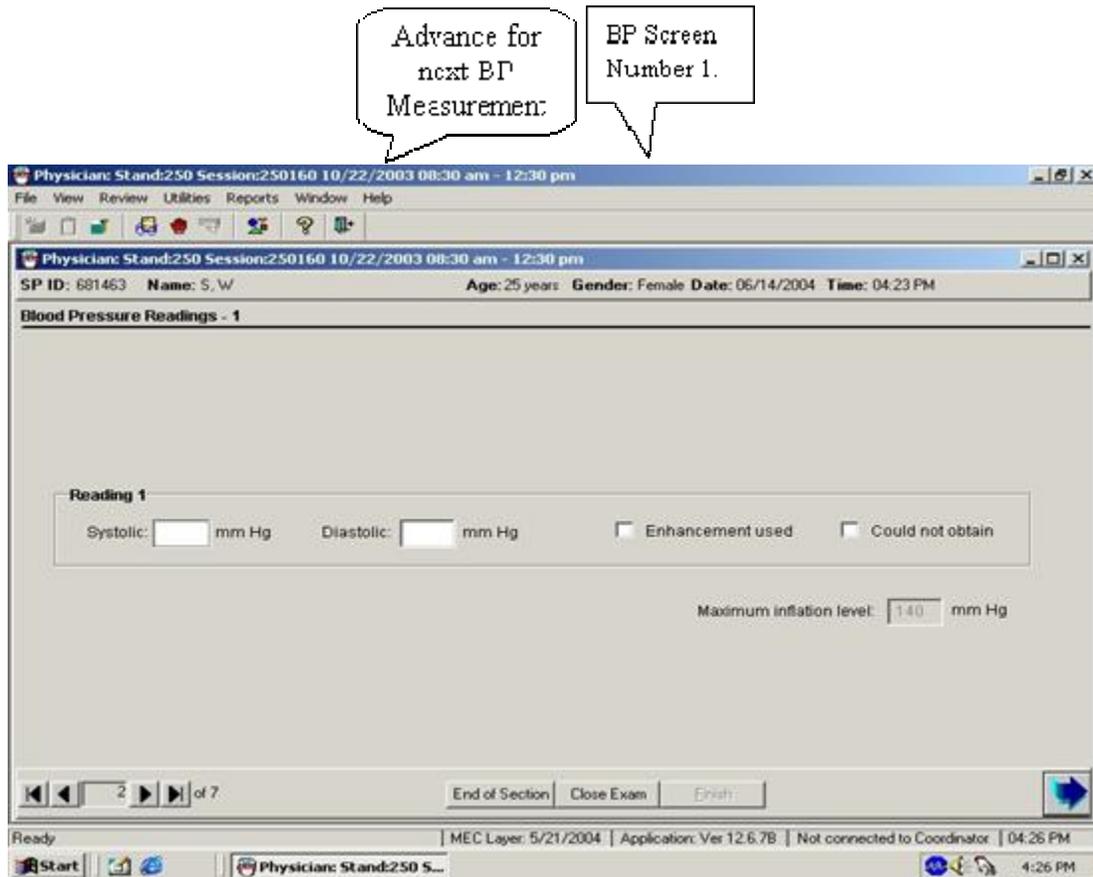
The screenshot shows a medical device interface with three main sections:

- Meal:** A section titled "Meal" with the question "Have you had any of the following in the past 30 minutes? (Check each that applies.)" and four checkboxes: "food", "alcohol", "coffee", and "cigarettes".
- Arm/Cuff:** A section titled "Arm/Cuff" with "Arm selected:" and three radio buttons: "Right" (selected), "Left", and "Could not obtain". It also has "Cuff size:" with a dropdown menu set to "large". To the right is a "Timer, min." section with a progress bar and numbers 1 through 5.
- Pulse/MIL:** A section titled "Pulse/MIL" with "30 sec pulse: 60 sec pulse:" and a calculation field showing "46 x 2 = 92". It has two radio buttons: "Regular" and "Irregular" (selected). Below is "Pulse type:" with a dropdown menu set to "Radial". To the right are "Room temperature:" with a field set to "74.8" and "°F", and "Maximum inflation level:" with an empty field and "mm Hg". There is also a checkbox for "Could not obtain".

- Get the maximum inflation level (MIL) and enter this in the “Maximum inflation level” data entry field. If a number greater than 300 is entered a message is displayed: “The value you entered is out of range. Please reenter your reading.” The mercury manometer does not register numbers greater than 300.
- Alternatively, if the MIL is too low, the application will display the same hard edit alert.
- If the Next button is entered before the MIL is entered, the system will display a message: “Please enter MIL or check “Could not Obtain.” If “Could not Obtain” is selected for MIL, an attempt should be made to get a blood pressure measurement.

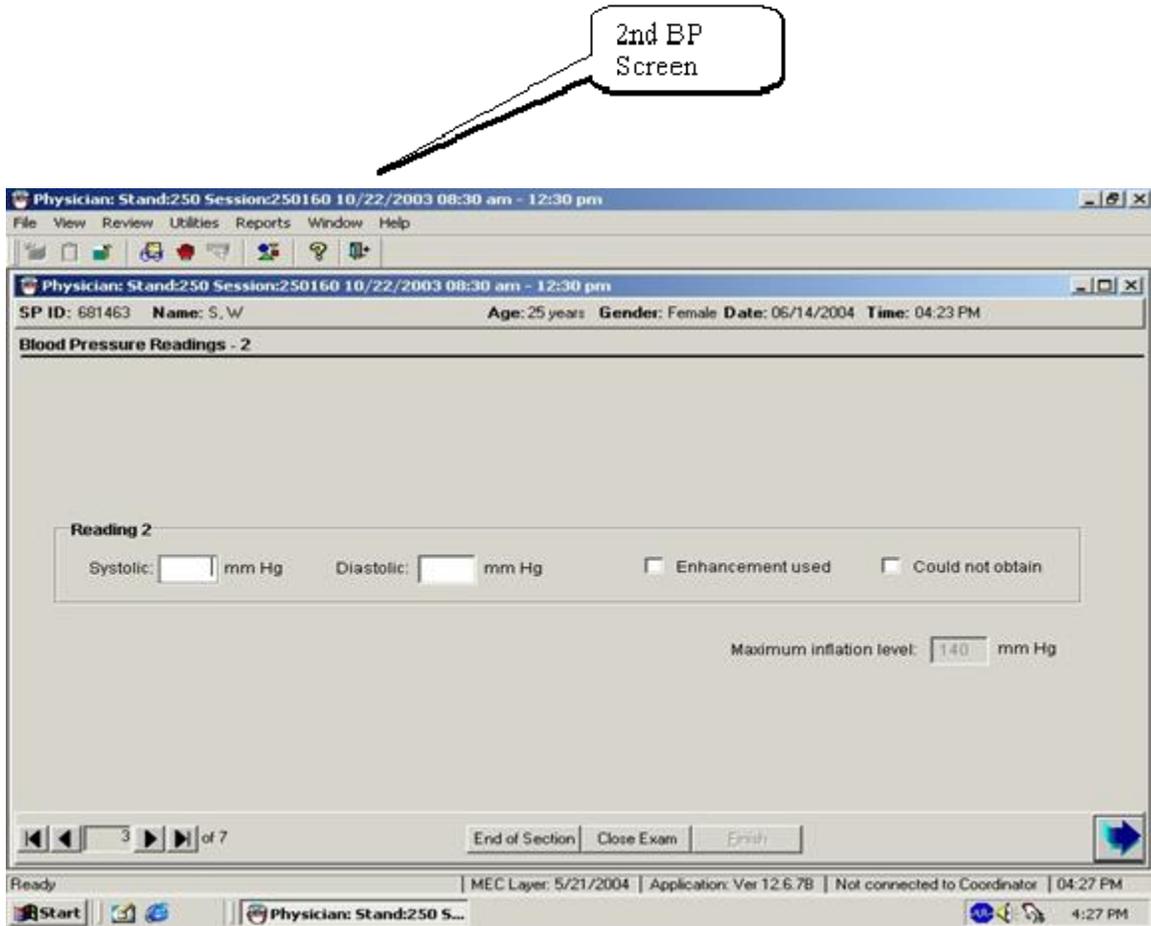
3.1.10 Blood Pressure Measurement Screens

Exhibit 3-11. Default Blood Pressure data entry screen



- Blood pressures are measured 3 times with a 30-second pause between each successive measurement.
- If you are unable to get a blood pressure measurement, check “Could not Obtain” for that measurement.
- If the blood pressure is difficult to hear, enhancement methods may, and should, be used. See Section 4.2.3.11 for a description of these methods. If the enhancements are used, click on the “Enhancement” button for that measurement.
- **Each BP measurement is recorded on a new screen. Advance the screen after each successive BP measurement. Do not go back to review previous BPs before taking the next measurement.**

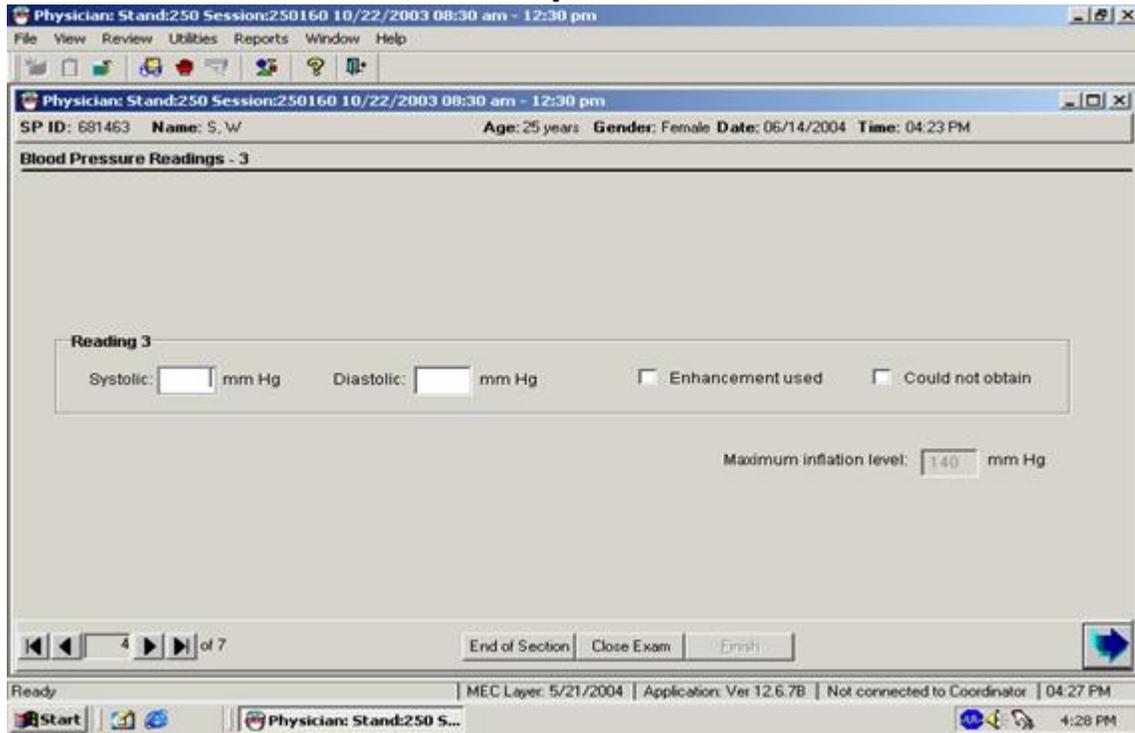
Exhibit 3-12. Blood Pressure Readings screen 2



- Take the second BP using the same techniques as BP 1.
- Record the 2nd BP, and advance the screen.

Exhibit 3-13. Blood Pressure Readings screen 3

BP measurement 3



- Take the third BP using the same techniques as BPs 1 and 2.
- Record the 2nd BP, and advance the screen.

Exhibit 3-14. Blood Pressure Readings screen 4

Take the 4th BP only if one of the 1st 3 was recorded as a "Could Not Obtain".

Physician Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

File View Review Utilities Reports Window Help

Physician Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

SP ID: 601463 Name: S, W Age: 25 years Gender: Female Date: 06/14/2004 Time: 04:23 PM

Blood Pressure Readings - 4

Reading 4

Systolic: mm Hg Diastolic: mm Hg Enhancement used Could not obtain

Maximum inflation level: 140 mm Hg

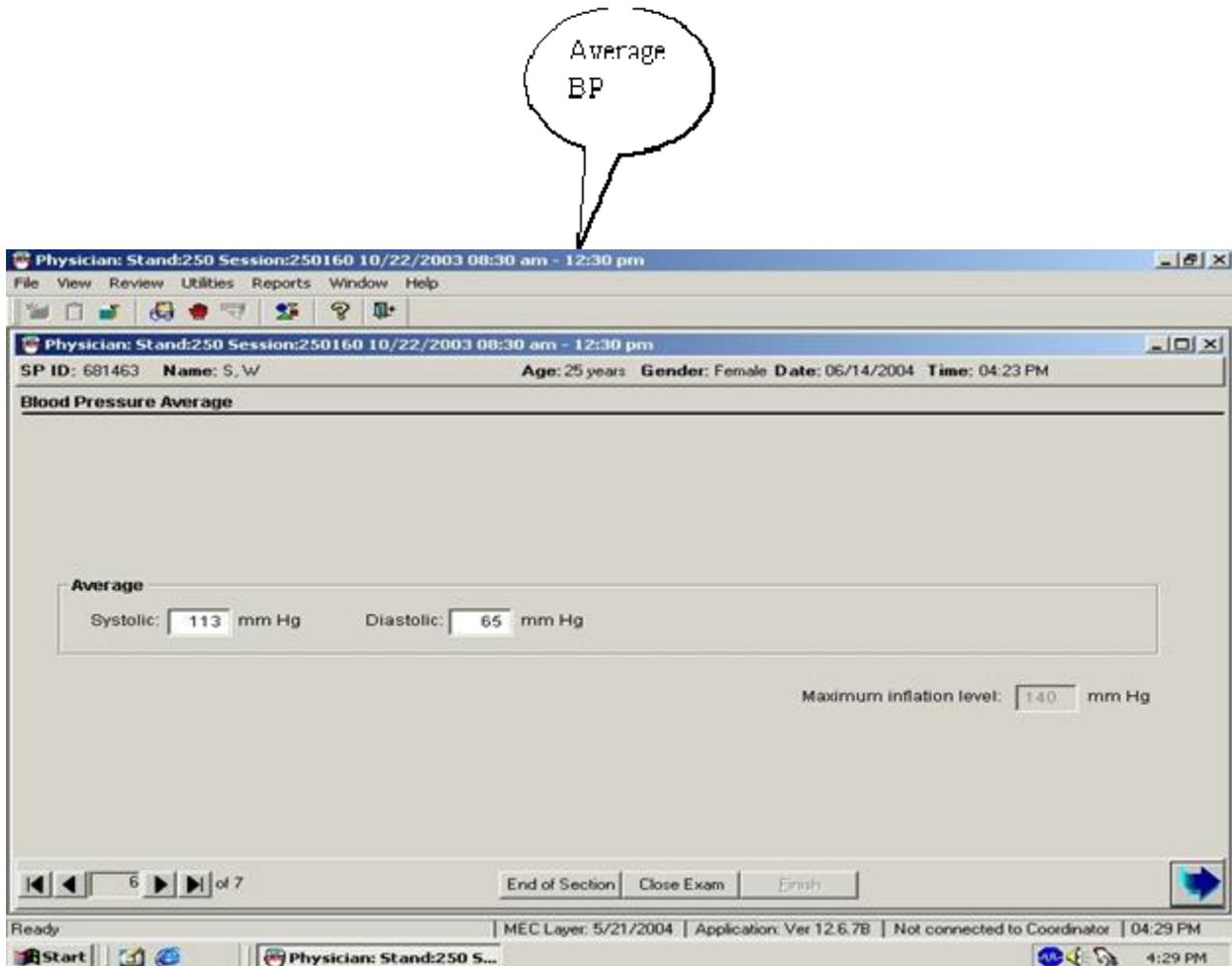
End of Section Close Exam Finish

Ready | MEC Layer: 5/21/2004 | Application: Ver 12.6.7B | Not connected to Coordinator | 04:28 PM

Physician Stand:250 S... 4:29 PM

- If any of the first three measurements are checked as "Could not Obtain," the BP section of the application will open up another field to allow a fourth measurement.
- Take the fourth measurement and record the results.
- The maximum number of times the cuff should be inflated for blood pressure measurements is five including all MIL measurements.
- The increment of the mercury manometer markings are in 2-millimeter intervals. All end digit BP measurements should be recorded as even numbered digits. If an odd number is entered as the end digit for either the systolic or diastolic measurement, a message is displayed: "**Number must be even!**"
- Click OK to this message. Reenter the correct measurement and continue with data entry or measurement.
- If the systolic BP entered is greater than the MIL, a message is displayed: "SBP should be less than MIL. Please, redo your MIL."
- Redo the MIL and record. The maximum number of times the cuff can be inflated is five.

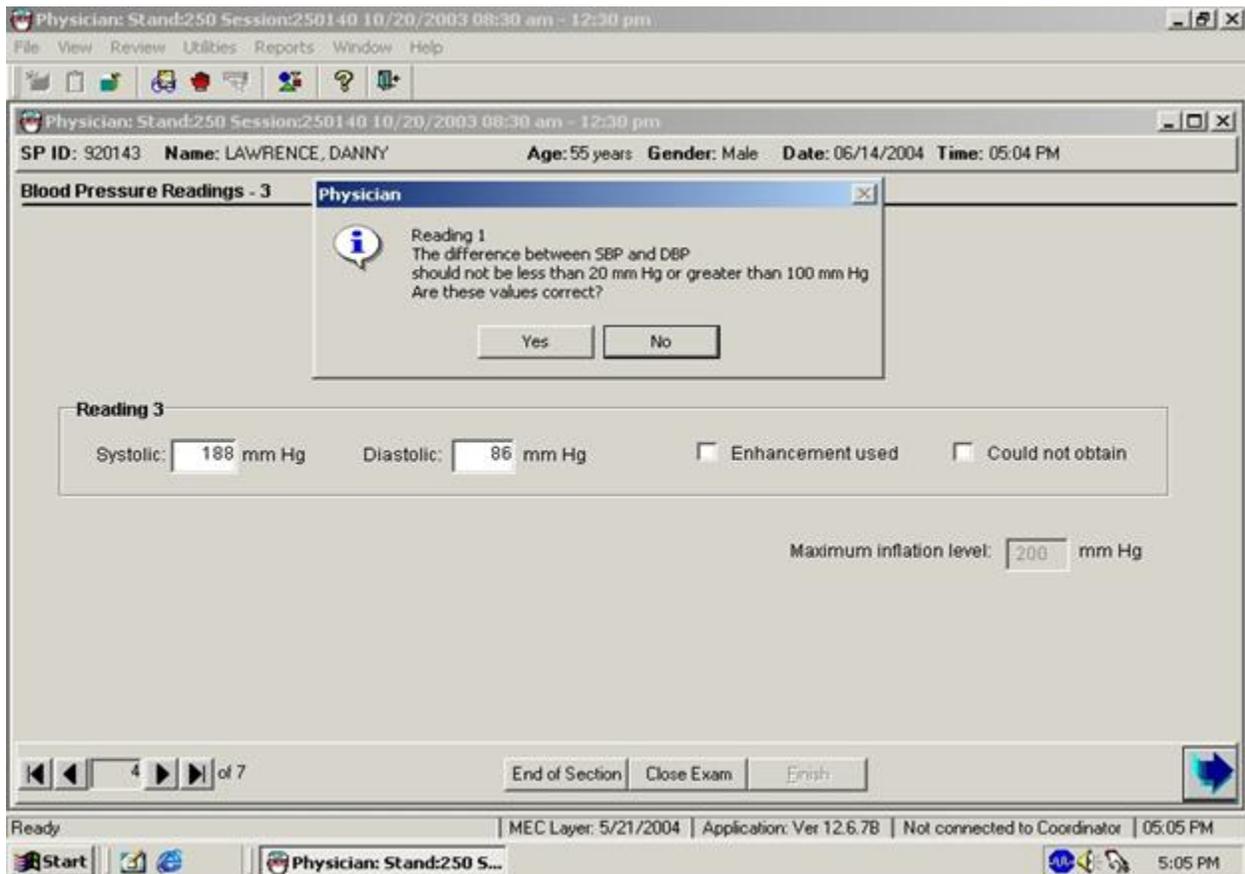
Exhibit 3-15. Averaging systolic blood pressure



- There must be a MIL recorded for every SP.
- Ideally, every SP has three blood pressure measurements recorded.
- When three systolic blood pressure readings are recorded, the systolic average is calculated by the system as the average of the **last two systolic measurements**.
- When only one systolic blood pressure reading can be obtained, the one systolic reading is calculated by the system as the average.
- When only two systolic blood pressure readings can be obtained, the first systolic reading is discarded and the second systolic blood pressure measurement is calculated by the system as the systolic average.
- If all diastolic readings are zero, the average diastolic BP is calculated by the system as zero (0).

- If there is one diastolic reading of zero and one or more readings with a diastolic above zero (0), the system uses only the nonzero diastolic readings to calculate the average diastolic BP.
- If two out of three diastolic readings are zero (0), the system uses the one nonzero diastolic reading to calculate the average diastolic BP.
- When the average BP appears, tell the SP his or her BP.

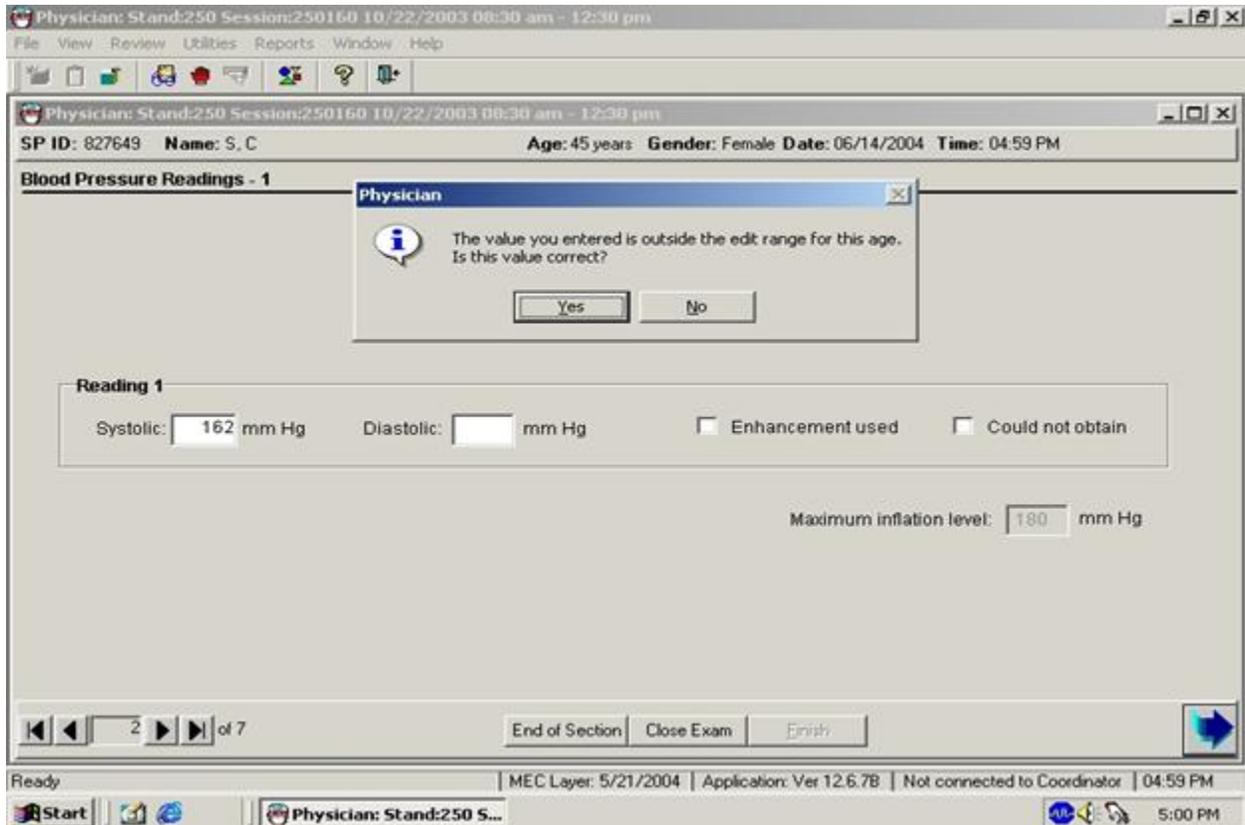
Exhibit 3-16. Edit allowable systolic and diastolic blood pressure



- If the difference between the systolic and diastolic BP is less than 20 mm Hg or more than 100 mm Hg, the application edits asks for verification of accuracy. This is a soft edit, and the application is prompting the examiner to confirm that the entry is accurate.
- If the measurements are correct, click "Yes."
- If the measures are incorrect, click "No," and reenter the measurements.

3.1.11 Blood Pressure Edit Limits

Exhibit 3-17. Edit range limits for blood pressure



- If a systolic or diastolic value is outside the edit range for that SP, (age specific) the system displays a message: “The value you entered is outside the range for this age. Is this value correct?”
- If the value entered is correct, click “Yes,” and proceed with the data entry.
- If the response is not correct, click on “No” and reenter the value, then proceed with the examination.

3.1.12 Blood Pressure Component Status and Comments

Exhibit 3-18. Comments in blood pressure component

Physician: Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

File View Review Utilities Reports Window Help

Physician: Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

SP ID: 681463 Name: S, W Age: 25 years Gender: Female Date: 06/14/2004 Time: 04:23 PM

Blood Pressure Status

Status

Complete
 Partial
 Not Done

Comments: [Dropdown Menu]

Other text: [Text Box]

End of Section Close Exam Finish

Ready | MEC Layer: 5/21/2004 | Application: Ver 12.6.7B | Not connected to Coordinator | 04:30 PM

- If all the measurements were entered, the system sets the default last screen for the component status to “Complete.”
- If one or more of the measurements were not recorded, the system sets the component status to “Partial.”
- If the Component Status is partial, select the appropriate comment from the drop-down menu.
- The comments in the menu are:
 - Safety exclusion: SP is excluded due to a situation that may cause him or her harm or discomfort such as applying or inflating a cuff on an arm with visible edema, lesions, or other conditions.
 - SP refusal: SP refuses all or part of the examination.
 - No time: SP is unable to complete the examination due to time restrictions.

- Physical limitation: SP has a physical limitation that prevents examination completion.
- Communication problem: HT is unable to communicate instructions for the examination adequately.
- Equipment failure: There is a malfunction of the equipment.
- SP ill/emergency: SP became ill while in the middle of the examination.
- Interrupted: Session was interrupted due to natural phenomena or other event.
- Poor cuff fit: If cuff does not fit properly, the blood pressure measurements should not be taken.
- Other, specific: If none of the standard comments apply, select “Other” and specify the reason for the status in the open text field.

3.1.13 OMRON Data Capture Screen

The HT who took the blood pressure measurements will not perform this function under any circumstance; the BP recorder is the only person assigned with completing this portion of the exam data entry.

Exhibit 3-19. OMRON Data Capture screen 1

Physician: Stand:430 Session:430930 03/06/2005 08:30 am - 12:30 pm

SP ID: 195300 Name: HARRIS_3, PENNY Age: 8 years Gender: Female Date: 03/03/2009 Time: 10:58 AM

Omron Data Capture Screen 1

Omron Tech:

Average

Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 1

Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 2

Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

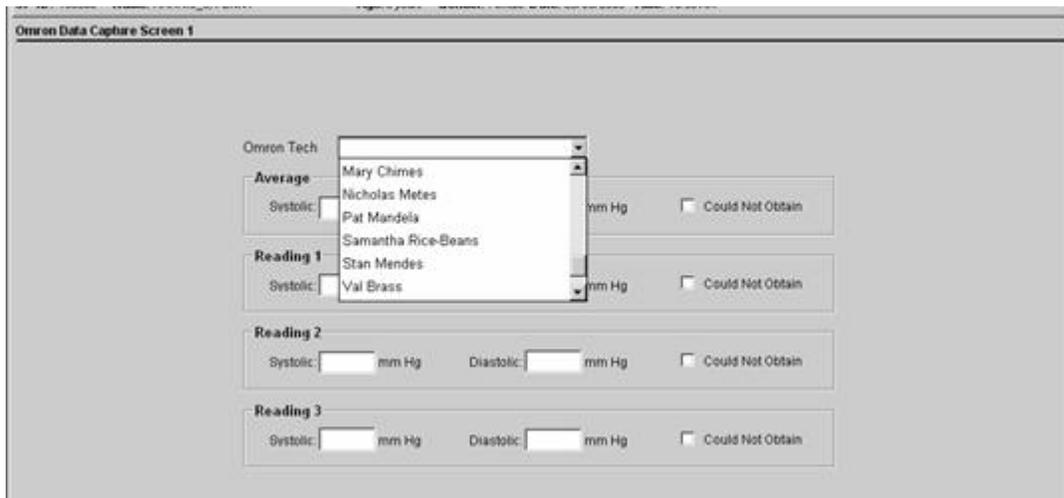
Reading 3

Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

End of Section Close Exam Finish

- This screen will appear at the end of the blood pressure exam. When the HT sees this screen, the recorder will have been assigned by the coordinator, and will be standing by to enter the exam room.
- The HT will release the SP from the room, and at that time the recorder may enter the exam room.
- The recorder must transcribe the readings from the OMRON into the ISIS application.

Exhibit 3-20. OMRON Tech drop-down box

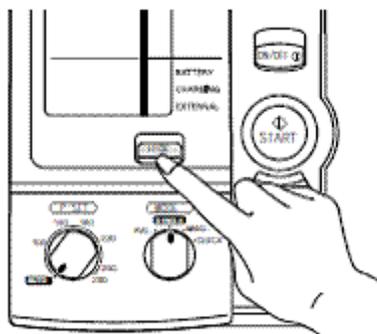


- Select the appropriate name from the OMRON Tech drop-down box as in Exhibit 3-20.

The OMRON Tech will only be required to use two buttons on the OMRON to access the BP readings: the HIDE button and the DEFLATION button. The DEFLATION button is a dual function switch that toggles through the 3 BP measurements when the OMRON is set in the AVG mode.

1. Press the HIDE button to take the display out of the HIDE mode.

Exhibit 3-21. OMRON Hide button



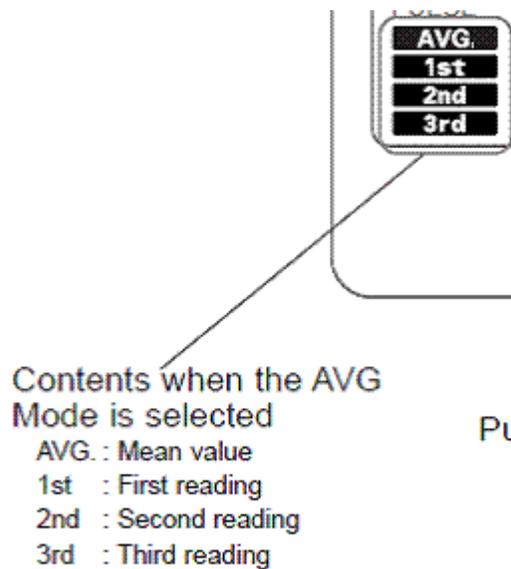
2. The first BP reading to appear on the OMRON display is the calculated average of the three measures. Record these numbers into the first line of the OMRON Data Capture Screen.
3. To move on to the value of the first BP reading, press the DEFLATION button.

Exhibit 3-22. Deflation button



Each time the DEFLATION button is pushed, the results for each reading will be displayed associated with the bottom window indicating the current reading, either Avg, 1st, 2nd, or 3rd, as in the exhibit below.

Exhibit 3-23. AVG Mode reading indicator



4. To obtain the value of the second BP result, press the DEFLATION button, and record.
5. To obtain the value of the third BP result, press the DEFLATION button to advance to the third reading, and record.

Note** ISIS will not allow an entry field to be advanced if the block is blank; the cursor will remain in the empty block until something is entered into the field. Therefore, there is no possibility to have a partial entry into any OMRON Data Capture field.

Exhibit 3-24. Completed OMRON Data Capture screen 1

Physician: Stand-430 Session:430930 03/06/2005 00:30 am - 12:30 pm
SP ID: 196300 Name: HARRIS_3, PENNY Age: 8 years Gender: Female Date: 03/09/2009 Time: 10:58 AM

Omron Data Capture Screen 1

Omron Tech: Nicholas Metes

Average
Systolic: 119 mm Hg Diastolic: 72 mm Hg Could Not Obtain

Reading 1
Systolic: 127 mm Hg Diastolic: 74 mm Hg Could Not Obtain

Reading 2
Systolic: 114 mm Hg Diastolic: 76 mm Hg Could Not Obtain

Reading 3
Systolic: 117 mm Hg Diastolic: 76 mm Hg Could Not Obtain

End of Section Close Exam Error

- When reading 3 is recorded, thus completing all the fields, advance to the next screen (Exhibit 3-25).

Exhibit 3-25. OMRON Data Capture screen 2

Physician: Stand-430 Session:430951 03/08/2005 01:30 pm - 05:30 pm

Omron Data Capture Screen 2

Average
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 1
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 2
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 3
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

End of Section Close Exam Error

- Continue to toggle through the BP readings using the DEFLATION button to record the readings a second time.

Exhibit 3-26. Completed OMRON Data Capture screen 2

The screenshot shows a software window titled "Physician: Stand:430 Session:430951 03/08/2005 01:30 pm - 05:30 pm". Below the title bar, patient information is displayed: "SP ID: 543948 Name: CLEAVER_6, THEODORE Age: 12 years Gender: Male Date: 03/10/2009 Time: 03:25 PM". The main area is titled "Omron Data Capture Screen 2" and contains four sections for blood pressure data:

Section	Systolic (mm Hg)	Diastolic (mm Hg)	Could Not Obtain
Average	119	72	<input type="checkbox"/>
Reading 1	127	74	<input type="checkbox"/>
Reading 2	114	76	<input type="checkbox"/>
Reading 3	117	76	<input type="checkbox"/>

At the bottom left, there are navigation arrows and a page indicator "2 of 4". At the bottom right, there are buttons for "End of Section", "Close Exam", and "Print", along with a blue arrow icon.

- When reading 3 is recorded, using the advance arrow in the right corner, advance to the next screen, OMRON Data Capture Screen 3. If the readings were entered the same on Data Capture Screens 1 & 2, the OMRON Data Capture Screen 3 will appear as below; all fields will be grayed out, and the OMRON tech will be unable to change anything on the screen.

Exhibit 3-27. OMRON Data Capture screen 3: No errors made in data entry

The screenshot shows a software window titled "Physiatric Stand-430 Session:430921 03/05/2005 01:30 pm - 05:30 pm". The patient information at the top includes "SP ID: 651757", "Name: HOLLAND_5, USA", "Age: 30 years", "Gender: Female", "Date: 03/09/2009", and "Time: 11:53 AM". The main area is titled "Omron Data Capture Screen 3" and contains four data entry sections:

Section	Systolic (mm Hg)	Diastolic (mm Hg)	Could Not Obtain
Average	117	79	<input type="checkbox"/>
Reading 1	114	71	<input type="checkbox"/>
Reading 2	118	84	<input type="checkbox"/>
Reading 3	120	81	<input type="checkbox"/>

At the bottom, there are navigation buttons: "End of Section", "Close Exam", and "Print", along with a "3 of 4" indicator and a blue arrow button.

Data Capture Screen Edits

The “double keying” of the BP readings minimizes user data entry error, and the system has several features to detect errors when the readings do not agree. These features prompt the recorder to review the data entered to ensure the correct transcription of the OMRON readings into ISIS. Common mistakes to avoid while entering the data include:

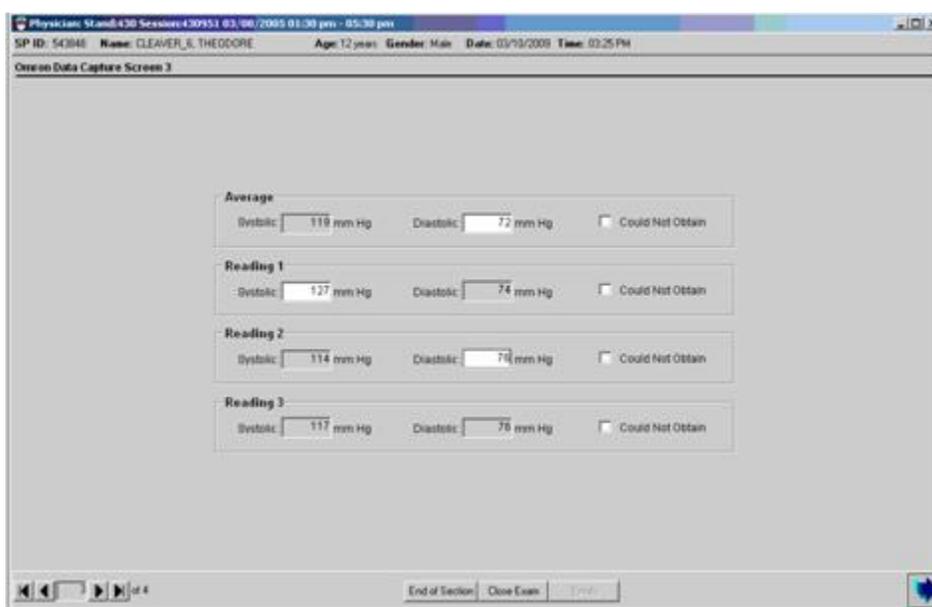
- Rushing through the data entry. If you take your time, and carefully move through the measurements, it will ultimately save time if you transcribe the results correctly the first time.
- Pressing the On/Off button prematurely—if the On/Off button is accidentally pushed, the data is permanently lost. **Do Not** touch the off/on button until you have exited the OMRON Data Capture Screen.

Data Entry Error Edit Alerts

If a data entry error is detected by ISIS, the OMRON Data Capture Screen 3 will appear with the fields that need to be corrected as enabled; the entries that do not need corrected will appear grayed-out. See below:

You do not have to reverse through the screens to correct the entries. What is required is to review the OMRON displays for the enabled fields, toggle through the displays, and re-enter the data into OMRON Data Capture Screen 3.

Exhibit 3-28. Corrected Data Capture Entries on screen 3



The screenshot displays the OMRON Data Capture Screen 3 interface. At the top, a status bar shows patient information: SP ID: 543848, Name: CLEAVER, S, THEODORE, Age: 12 years, Gender: Male, Date: 03/19/2009, Time: 02:25 PM. The screen title is "Omron Data Capture Screen 3". The main area contains four sections for blood pressure readings:

Section	Systolic (mm Hg)	Diastolic (mm Hg)	Status
Average	119	72	Could Not Obtain
Reading 1	127	74	Could Not Obtain
Reading 2	114	70	Could Not Obtain
Reading 3	117	70	Could Not Obtain

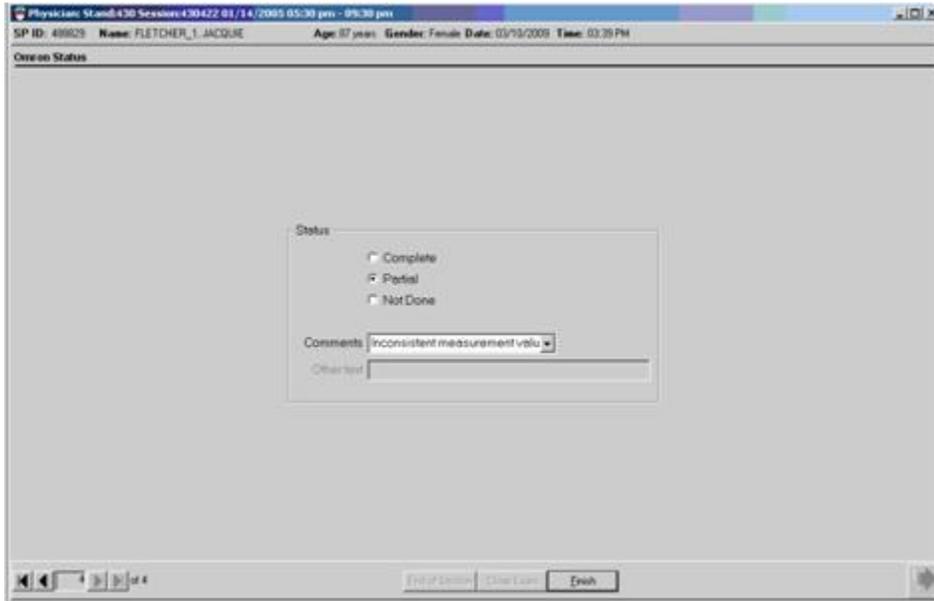
At the bottom, there are navigation controls: a set of arrows (left, right, home, end) and buttons for "End of Section", "Close Exam", and a blue arrow icon.

This is the only opportunity to correct the data entry errors. If the OMRON tech enters another error, the following status screen will appear: the OMRON Status will be marked as a partial exam, and automatically inserted comment will indicate "Inconsistent measurement values".

The goal as data collectors is to never see this OMRON Status. At this point if this message is displayed, it is still possible to back up to OMRON Data Capture Screen #1 using the lower left hand arrows to the first OMRON Data Capture screen and re-enter all the readings, proceed to the second OMRON Data Capture Screen and re-enter the data. This is not an ideal scenario because of the length of time that is being added to the exam to re-enter all of the readings, but it is an option if the recorder gets

the “inconsistent measurement values” message. The primary objective is to transcribe the OMRON readings precisely.

Exhibit 3-29. Inconsistent measurement values



The ISIS application will impose no hard or soft edit alerts for any values in the OMRON Data Capture screens. This will allow an unlimited range of values to be measured by the OMRON, but the recorder must be aware that the application will accept a digit such as 0, or 999. It is impossible to over-emphasize the care that must be taken when entering the data. Inconsistent values will result in lost data.

Exhibit 3-30. No digit high/low edits

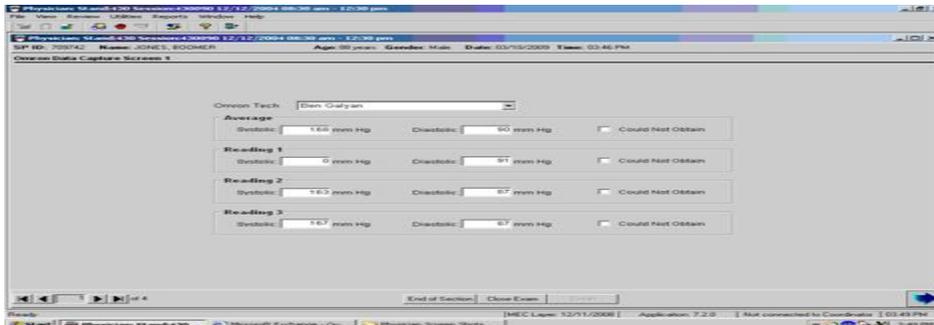


Exhibit 3-31. OMRON Data Capture screen: Skip due to no OMRON measurements obtained

The screenshot displays the OMRON Data Capture interface. At the top, the 'Omron Tech' dropdown menu is set to 'Frank Lucas'. Below this, there are sections for 'Average', 'Reading 1', 'Reading 2', and 'Reading 3', each with a 'Systolic' input field. A modal dialog box titled 'Health Technician Blood Pressure' is open, containing the following fields: 'Exam Status' (set to 'partial'), 'Comments' (set to 'other, specify'), and 'Other text' (containing 'Error 7 displayed on Omron'). Below these fields, a message reads: 'This will close the exam, saving all results and the exam status. Do you wish to close the exam?' with 'OK' and 'Cancel' buttons. At the bottom of the dialog, there is a checkbox labeled 'Could Not Obtain'. The main interface at the bottom shows a navigation bar with 'End of Section', 'Close Exam', and 'Finish' buttons, and a status indicator '8 of 11'.

In the rare event that the OMRON readings were not completed during the blood pressure exam, select “Close Exam” at the OMRON Data Capture Screen. The HT will notify the coordinator that the recorder will not be needed, and the HT may indicate that OMRON readings were not done. The HT will enter a comment code that explains the reason the OMRON was not done in the drop down box in the OMRON Status Screen.

Summary: OMRON Data Entry Procedure

OMRON

1. Reveal BP readings by pressing the “HIDE” button.

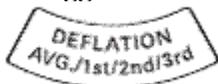


2. The reading numbers are displayed in the box on the left lower corner of the LED display of the OMRON.



The first BP reading to appear on the OMRON display is the calculated mean of the three measures, denoted in the left lower corner as AVG.

3. To move to the 1st BP reading, press the “DEFLATION” button. The DEFLATION button acts as a toggle switch between the 4 BP readings.



4. Repeat step 3 to advance to the 2nd and 3rd readings.

ISIS Application

1. Access OMRON Tech dropdown box, and select your name.
2. Carefully enter the data into OMRON Data Capture Screen 1.
3. Advance to OMRON Data Capture Screen 2 and enter data.
4. Advance to OMRON Data Capture Screen 3
5. Review Screen 3. If all entries are grayed-out, there is no disagreement in the entries on Screens 1 & 2, and you may advance to the Exam Status (final) screen, and close exam.
6. If the screen contains enabled fields, do not reverse back in the application. Toggle through the readings on the OMRON to the desired reading, and carefully re-enter the data on Screen 3.
7. Advance to the Exam Status (final) screen, and close exam.

4. QUALITY CONTROL

4.1 Elements of the Quality Control Program

To ensure complete and accurate data collection, the quality control program for the blood pressure study will take place in mobile examination centers (MECs) and will consist of the following major elements:

- Training and calibrating of the health technologists with a gold standard expert;
- Monitoring equipment and equipment repair, and verifying weekly calibrations; and
- Site visit observations by NCHS and Westat.

4.2 Training and Calibrating of Health Technologists with a Gold Standard Expert

The protocol for blood pressure measurement follows procedures developed by the American Heart Association. The health technologists underwent initial training and certification in blood pressure measurement through a training program provided by an independent expert consultant. This certification process included didactic presentations, video presentations that included listening to and recording Korotkoff sounds, and practice listening to blood pressures of volunteers with a certified instructor. Certification is achieved when technologists meet all requirements of the training program and undergo quarterly monitoring by the consultant. Ongoing training needs as identified by the home office staff and NCHS will be assessed and scheduled.

4.3 Monitoring Equipment and Equipment Repair

The equipment and room supplies need to be checked on a regular basis. Some checks are completed daily and others need only be completed on a weekly basis or at the beginning and end of each stand. These checks include calibration checks, maintenance inspection of equipment and supplies, and preparation of the room and equipment for the session exams. The specific timeframes for equipment QC are as follows: start of stand, daily, weekly, and end of stand.

All of the quality control (QC) processes are recorded into the computer application, which reminds the health technologists to perform the time sensitive QC procedures. If the QC procedures have not been completed for that time period, this message will be displayed at each logon until the QC procedures have been completed for that time period. The home office component staff monitors the equipment QC completion rates, and provides feedback and/or retraining as warranted.

Each time you log onto the application, the system will remind you to do quality control (QC) checks if the checks have not been completed for that time period. The specified QC checks performed at the beginning of stand, daily, weekly, and end of stand are selected by the technologist. If you do not have time to do the checks when you logon, you can bypass this message and complete the checks at a later time. However, this message will be displayed each time you logon until you have completed the checks for that time period. After you have completed the checks and entered this in the system, the message box with the reminder will not be displayed again until the appropriate time period has passed.

4.3.1 Maintenance of Equipment

Technologists maintain all equipment used in their component. The following sections specifically state the requirements that technologists follow to check equipment and maintain equipment used for the BP measurements. The following items are checked on a routine basis.

4.3.2 Inflation System

1. Cuff material is clean, intact.
2. Clean all cuffs with Sani-wipe.
3. Velcro is functional and free of lint/debris.
4. Rubber tubing and inflation bulb is smooth, has no cracks or tears.
5. Pressure control valve opens and closes smoothly without sticking.

4.3.3 Littmann Cardiology III Stethoscopes

1. Check the stethoscope for cracks in the tubing.
2. Earpieces are securely attached.
3. Head of stethoscope is securely attached to tubing.
4. Diaphragm is secure, no cracks.

4.3.4 Mercury Sphygmomanometer

1. The shape of the meniscus (top of the column of mercury) should be a smooth, well-defined curve. If not, replace the equipment. This is usually caused by dirt/oxidation in the mercury or the glass tube.
2. Check that the mercury rises easily in the tubing and mercury does not bounce noticeably when inflated. If the mercury does not rise easily in the tube, or if the mercury column bounces noticeably as the valve is closed, replace the equipment.
3. Disconnect the inflation system from the cuff and confirm that the meniscus of the mercury in the glass manometer tube is zero.
4. Check for cracks in the glass tube.
5. Check the screw at the top of the calibrated glass tube to make sure it is securely in place.
6. Check the coiled air tube for cracks, tears.
7. Follow the inflation system testing protocol to test for air leaks:
 - Connect each size cuff to the inflation system and wrap it around the corresponding calibration cylinder;
 - Inflate to 250 mm Hg;
 - Open valve and deflate to 200 mm Hg and close valve; and
 - Wait for 10 seconds; if mercury column drops more than 10 mm Hg, there is an air leak in the system; and
 - If a leak is detected, change the cuff, check the coiled tubing and repeat the test.

4.3.5 Omron HEM-907XL

1. Wipe the monitor with a soft, damp cloth.
2. Confirm function settings: (F1 = 3 inflations, F2 = 0 waiting before 1st inflation, and F3 = 30 second interval between inflations).
3. Mode setting = average, P-Set = AUTO.
4. Make sure that the AC adapter cord of the OMRON unit is securely plugged in. (It has a tendency to get disconnected from the unit.)
5. Check the air tube for cracks, and confirm that the tube is securely attached to the Omron.
6. Follow the Omron calibration protocol:
 - Connect the mercury manometer, adult cuff, and the Omron air tube with the T-tube;
 - Tightly wrap the adult cuff over the calibration cylinder;
 - Release the valve of the inflation bulb to remove the air inside the cuff completely;
 - Push the ON/OFF button to turn on the monitor;
 - Set the MODE selector to "CHECK;"
 - Close the valve of the inflation bulb and inflate the cuff to 300, 250, 200, 150, 100, 60, and 0 mm Hg;
 - Compare the pressure values displayed on the monitor to the one on the mercury manometer and record the OMRON reading at each level;
 - The Omron should be validated to be ± 3 mmHg of the manometer reading.
 - If the Omron readings are not falling within ± 3 mm Hg, re-check the inflation system, and repeat the Omron calibration; if the Omron continues to fail the calibration procedure, replace the Omron, send the unit back to the NHANES warehouse, and submit a UFO that explains what was observed during the calibration procedure.

4.4 Frequency of QC Procedures

The designated intervals for the BP QC procedures are: start of stand, daily checks, weekly checks, and end of stand checks.

4.4.1 Daily QC Checks

These checks should be done on a daily basis:

1. The level of mercury in the glass tube is zero;
2. The shape of the meniscus is smooth and well defined;
3. The mercury rises easily in the tubing and does not bounce noticeably; and
4. No cracks are in the glass tube.

4.4.2 Weekly QC Checks

Check the following each week:

1. Complete daily checks;
2. Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears;
3. Check the stethoscope diaphragm for cracks;
4. Complete the inflation system testing protocol to test for air leaks with the mercury manometer; and
5. Perform the Omron calibration protocol at 300 mm, 250 mm, 200 mm, 150 mm, 100 mm, 60 mm, and 0 mm Hg.

4.4.3 Start of Stand Checks

At the start of stand, complete the following:

1. The daily checks; and
2. The weekly checks.

4.4.4 End of Stand Checks

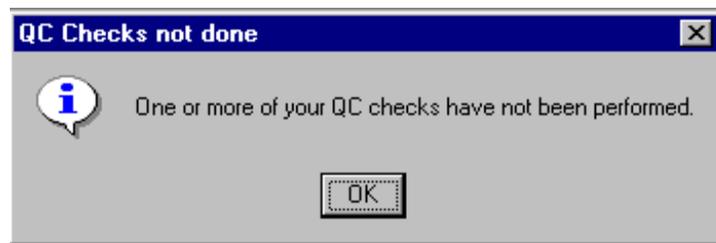
The end of stand checks consist of:

1. Performing the Omron calibration protocol at 300 mm, 250 mm, 200 mm, 150 mm, 100 mm, 60 mm, and 0 mm Hg.

4.5 ISIS Data Entry Screens for QC on Equipment

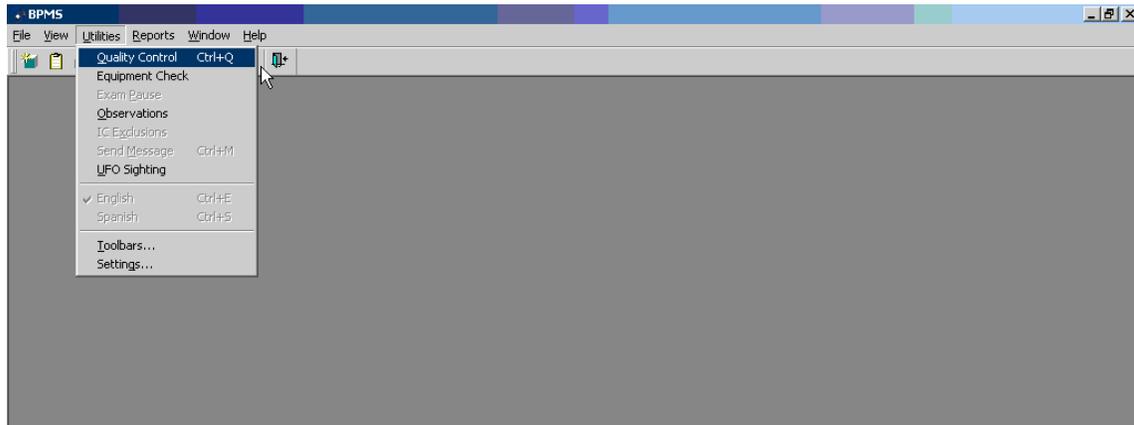
4.5.1 Data Entry Screens for QC on Equipment

When you log onto the application before the Quality Control checks are performed, the system displays a message: “One or more of your QC checks have not been performed.”



Click “OK” to this message. When you want to complete the QC checks, select “Utilities,” then select Quality Control from the menu.

Exhibit 4-1. Quality Control selection under utilities menu



Clicking on the QC icon from the Toolbar can also access the QC screens. When QC is selected from the Utilities menu, the session pick-up box will be displayed. Select the current session.

Exhibit 4-2. Session Pick-Up box

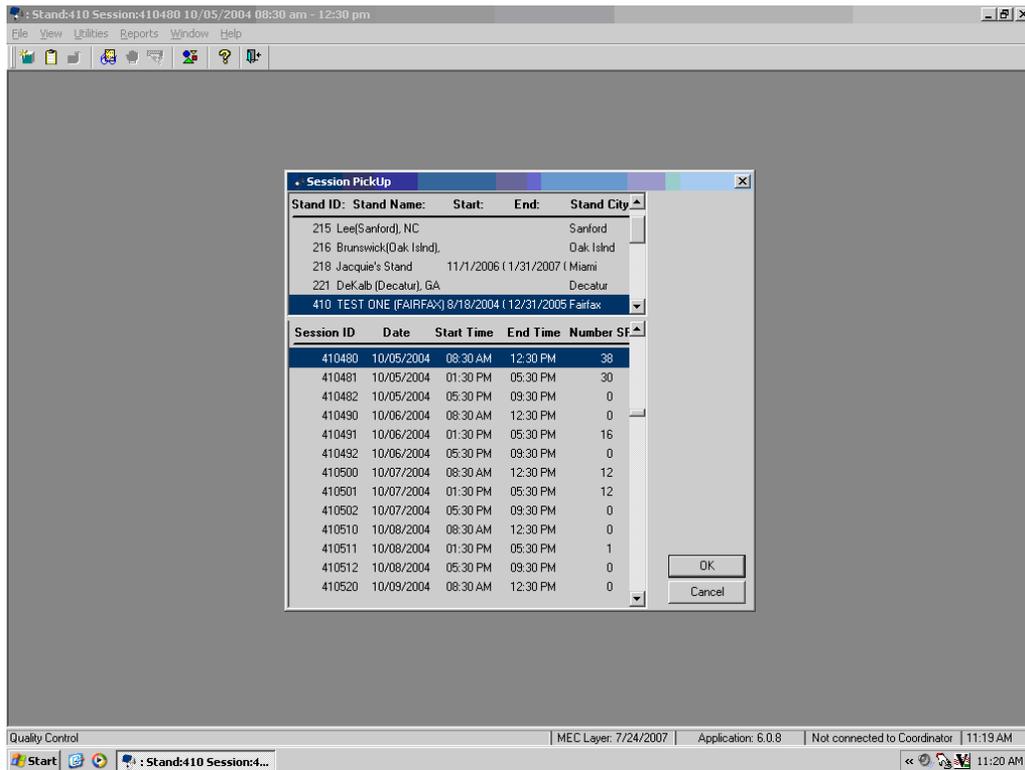
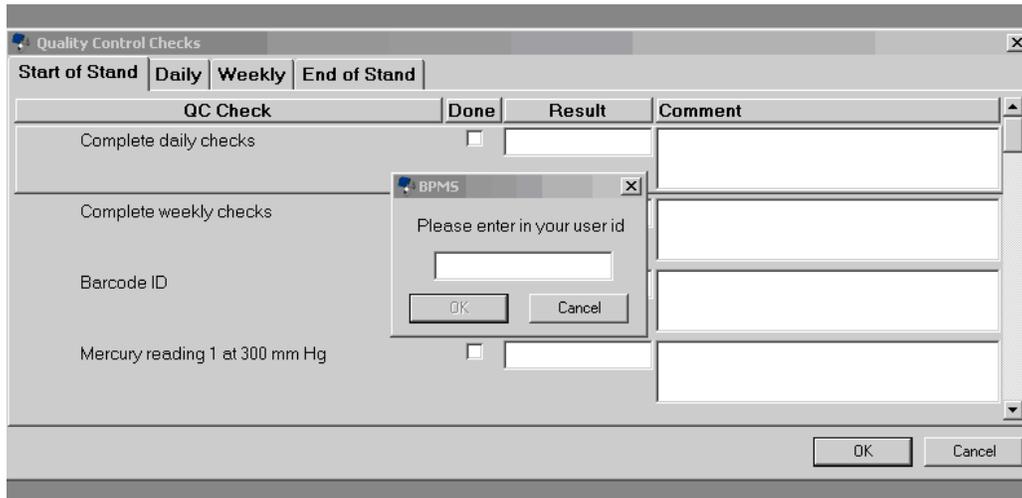


Exhibit 4-3. Quality Control logon

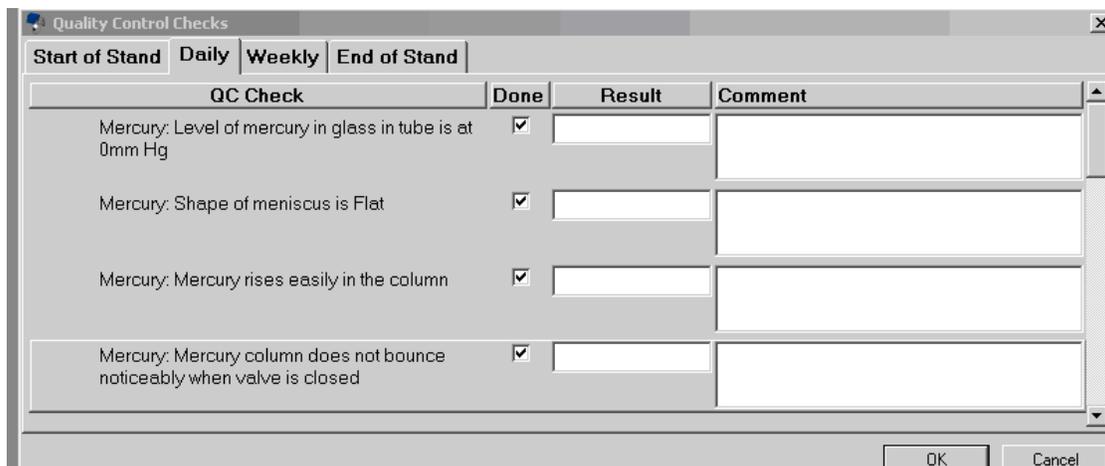


Each technologist will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period. Enter your User ID and click “OK.” If you do not want to do the QC checks at this time, click “Cancel.” You will still be able to conduct the exam.

4.5.2 Daily Checks

On the QC screens, check “Done” for the listed items when that item has been completed (Exhibits 4-4 to 4-7).

Exhibit 4-4. Quality Control daily checks (1 of 4)



You are not required to enter anything in the “Result” or “Comment” fields unless there is a problem. The “Result” field is used to enter values for selected QC items if required. The “Comments” field is used to enter information about problems encountered with the QC item check.

Exhibit 4-5. Quality Control daily checks (2 of 4)

The screenshot shows a software window titled "Quality Control Checks" with a tabbed interface. The "Daily" tab is selected. Below the tabs is a table with four columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of checks, each with a checked "Done" box and empty "Result" and "Comment" fields. A vertical scroll bar is on the right side of the table. At the bottom right of the window are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
Mercury: Glass manometer tube has no cracks	<input checked="" type="checkbox"/>		
Mercury: Glass manometer tube is clean	<input checked="" type="checkbox"/>		
Mercury: Cap at the top of the calibrated glass tube is securely in place	<input checked="" type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the next items on the list.

Exhibit 4-6. Quality Control daily checks (3 of 4)

The screenshot shows the same "Quality Control Checks" window, but with the scroll bar moved down to reveal the next four items. The table structure and "Done" checkboxes are the same as in Exhibit 4-5. The "QC Check" column now lists: "Wipe both sides of BP cuffs with disinfectant wipes (wipe after each use)", "Aneroid: Check needle placement is within the box", "Aneroid: Needle rise easily when pumped", and "Aneroid: Needle does not bounce noticeably when the valve is closed". The "Result" and "Comment" fields are empty. The "OK" and "Cancel" buttons are visible at the bottom right.

QC Check	Done	Result	Comment
Wipe both sides of BP cuffs with disinfectant wipes (wipe after each use)	<input checked="" type="checkbox"/>		
Aneroid: Check needle placement is within the box	<input checked="" type="checkbox"/>		
Aneroid: Needle rise easily when pumped	<input checked="" type="checkbox"/>		
Aneroid: Needle does not bounce noticeably when the valve is closed	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-7. Quality Control daily checks (4 of 4)

The screenshot shows a software window titled "Quality Control Checks" with a close button (X) in the top right corner. Below the title bar are four tabs: "Start of Stand", "Daily", "Weekly", and "End of Stand". The "Daily" tab is selected and highlighted. The main area contains a table with three columns: "QC Check", "Done", "Result", and "Comment".

QC Check	Done	Result	Comment
Aneroid: Glass manometer tube has no cracks	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>
Onron: Check Pressure setting (P-set) knob is set to AUTO	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>
Onron: Check if Mode selector is set to AVG	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>
Onron: Check if AC adaptor is connected	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>

At the bottom right of the window are two buttons: "OK" and "Cancel".

If there is a problem with one of the items, enter a value if appropriate and then enter a comment in the Comment box briefly describing the nature of the problem. Report the problem to the MEC manager. Note in the Comments field that the MEC manager has been informed.

When you are finished with the daily item checks, click "OK" to close the QC box.

4.5.3 Weekly Checks

Exhibit 4-8. Quality Control weekly checks (1 of 9)

The screenshot shows the same "Quality Control Checks" software window, but now the "Weekly" tab is selected and highlighted. The table contains four rows of weekly checks.

QC Check	Done	Result	Comment
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>
Mercury reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>
Mercury reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>
Mercury reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>

At the bottom right of the window are two buttons: "OK" and "Cancel".

Check “Done” for each item on the weekly checks when complete (Exhibit 4-9). Use the scroll bar to move to the remaining items.

Exhibit 4-9. Quality Control weekly checks (2 of 9)

The screenshot shows a dialog box titled "Quality Control Checks" with a tabbed interface. The "Daily" tab is selected, indicated by a checkmark. The "Weekly" tab is also visible. Below the tabs is a table with three columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of checks, each with a checked "Done" box, an empty "Result" field, and an empty "Comment" field. The checks are: "Mercury reading 4 at 150 mm Hg", "Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears", "Mercury reading 5 at 100 mm Hg", and "OMRON reading 2 at 250 mm Hg". A scroll bar is visible on the right side of the table. At the bottom right of the dialog box are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
Mercury reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input checked="" type="checkbox"/>		
Mercury reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-10. Quality Control weekly checks (3 of 9)

This screenshot is identical to Exhibit 4-9, showing the "Quality Control Checks" dialog box with the "Daily" tab selected. The table contains the same four rows of checks, all with "Done" boxes checked and empty "Result" and "Comment" fields. The scroll bar on the right is visible, and the "OK" and "Cancel" buttons are at the bottom right.

QC Check	Done	Result	Comment
Mercury reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input checked="" type="checkbox"/>		
Mercury reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-11. Quality Control weekly checks (4 of 9)

The screenshot shows a dialog box titled "Quality Control Checks" with a close button (X) in the top right corner. Below the title bar are four tabs: "Start of Stand", "Daily" (which is selected with a checkmark), "Weekly", and "End of Stand". The main area contains a table with three columns: "QC Check", "Done", "Result", and "Comment". The table lists four items, each with a checked "Done" box, an empty "Result" box, and an empty "Comment" box. The items are: "OMRON reading 1 at 300 mm Hg", "OMRON reading 2 at 250 mm Hg", "OMRON reading 3 at 200 mm Hg", and "OMRON reading 4 at 150 mm Hg". A vertical scrollbar is on the right side of the table. At the bottom right of the dialog box are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
OMRON reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-12. Quality Control weekly checks (5 of 9)

The screenshot shows the same "Quality Control Checks" dialog box, but the table now displays items 5 through 8. The "Done" column for all items is checked. The items are: "OMRON reading 5 at 100 mm Hg", "OMRON reading 6 at 60 mm Hg", "OMRON reading 7 at 0 mm Hg", and "Gauge reading 1 at 300 mm Hg". The "Result" and "Comment" columns are empty for all items. The vertical scrollbar is visible on the right side of the table. "OK" and "Cancel" buttons are at the bottom right.

QC Check	Done	Result	Comment
OMRON reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-13. Quality Control weekly checks (6 of 9)

The screenshot shows a dialog box titled "Quality Control Checks" with tabs for "Start of Stand", "Daily", "Weekly", and "End of Stand". The "Daily" tab is selected. A table lists four QC checks, each with a "Done" checkbox, a "Result" input field, and a "Comment" input field. The "Done" checkboxes are all checked. A scroll bar is visible on the right side of the table.

QC Check	Done	Result	Comment
OMRON reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-14. Quality Control weekly checks (7 of 9)

The screenshot shows the same "Quality Control Checks" dialog box, but with a different set of four QC checks. The "Done" checkboxes are all checked. A scroll bar is visible on the right side of the table.

QC Check	Done	Result	Comment
Aneroid reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
Aneroid reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-15. Quality Control weekly checks (8 of 9)

QC Check	Done	Result	Comment
Aneroid reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
Aneroid reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-16. Quality Control weekly checks (9 of 9)

QC Check	Done	Result	Comment
Gauge reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
Aneroid reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
Gauge reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		
Aneroid reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		

When you are finished with the weekly daily item checks, click “OK” to close the QC box.

4.5.4 Start of Stand Checks

Start of stand checks consist of the completion of all daily and weekly checks.

Exhibit 4-17. Quality Control start of stand (1 of 9)

QC Check	Done	Result	Comment
Complete daily checks	<input type="checkbox"/>		
Complete weekly checks	<input type="checkbox"/>		
Barcode ID	<input type="checkbox"/>		
Mercury reading 1 at 300 mm Hg	<input type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-18. Quality Control start of stand (2 of 9)

QC Check	Done	Result	Comment
Mercury reading 2 at 250 mm Hg	<input type="checkbox"/>		
Mercury reading 3 at 200 mm Hg	<input type="checkbox"/>		
Mercury reading 4 at 150 mm Hg	<input type="checkbox"/>		
Mercury reading 5 at 100 mm Hg	<input type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-19. Quality Control start of stand (3 of 9)

The screenshot shows a software window titled "Blood Pressure Study Quality Control Checks". It has a tabbed interface with "Start of Stand", "Daily", "Weekly", and "End of Stand" tabs. The "Daily" tab is selected. Below the tabs is a table with three columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of data:

QC Check	Done	Result	Comment
Mercury reading 6 at 60 mm Hg	<input type="checkbox"/>		
Mercury reading 7 at 0 mm Hg	<input type="checkbox"/>		
OMRON reading 1 at 300 mm Hg	<input type="checkbox"/>		
OMRON reading 2 at 250 mm Hg	<input type="checkbox"/>		

At the bottom right of the window are "OK" and "Cancel" buttons. A vertical scrollbar is visible on the right side of the table area.

Use the scroll bar to move to the remaining items.

Exhibit 4-20. Quality Control start of stand (4 of 9)

The screenshot shows the same software window as Exhibit 4-19, but the table now displays items 7 through 10:

QC Check	Done	Result	Comment
OMRON reading 3 at 200 mm Hg	<input type="checkbox"/>		
OMRON reading 4 at 150 mm Hg	<input type="checkbox"/>		
OMRON reading 5 at 100 mm Hg	<input type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input type="checkbox"/>		

The "OK" and "Cancel" buttons are still present at the bottom right. The scrollbar is positioned lower than in the previous screenshot, indicating that the user has scrolled down the list.

Use the scroll bar to move to the remaining items.

Exhibit 4-21. Quality Control start of stand (5 of 9)

QC Check	Done	Result	Comment
OMRON reading 7 at 0 mm Hg	<input type="checkbox"/>		
Gauge reading 1 at 300 mm Hg	<input type="checkbox"/>		
Aneroid reading 1 at 300 mm Hg	<input type="checkbox"/>		
Gauge reading 2 at 250 mm Hg	<input type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-22. Quality Control start of stand (6 of 9)

QC Check	Done	Result	Comment
OMRON reading 7 at 0 mm Hg	<input type="checkbox"/>		
Gauge reading 1 at 300 mm Hg	<input type="checkbox"/>		
Aneroid reading 1 at 300 mm Hg	<input type="checkbox"/>		
Gauge reading 2 at 250 mm Hg	<input type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 4-23. Quality Control start of stand (7 of 9)

The screenshot shows a software window titled "Blood Pressure Study Quality Control Checks". It has a tabbed interface with "Start of Stand", "Daily", "Weekly", and "End of Stand" tabs. The "Daily" tab is selected. Below the tabs is a table with three columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of data:

QC Check	Done	Result	Comment
Aneroid reading 2 at 250 mm Hg	<input type="checkbox"/>		
Gauge reading 3 at 200 mm Hg	<input type="checkbox"/>		
Aneroid reading 3 at 200 mm Hg	<input type="checkbox"/>		
Gauge reading 4 at 150 mm Hg	<input type="checkbox"/>		

At the bottom right of the window are "OK" and "Cancel" buttons. A vertical scroll bar is visible on the right side of the table.

Use the scroll bar to move to the remaining items.

Exhibit 4-24. Quality Control start of stand (8 of 9)

The screenshot shows the same software window as Exhibit 4-23, but the table now displays QC checks 4, 5, and 6. The "QC Check" column contains:

QC Check	Done	Result	Comment
Aneroid reading 4 at 150 mm Hg	<input type="checkbox"/>		
Gauge reading 5 at 100 mm Hg	<input type="checkbox"/>		
Aneroid reading 5 at 100 mm Hg	<input type="checkbox"/>		
Gauge reading 6 at 60 mm Hg	<input type="checkbox"/>		

The "Done", "Result", and "Comment" columns are empty for all rows. The "OK" and "Cancel" buttons are at the bottom right, and a scroll bar is on the right side of the table.

Use the scroll bar to move to the remaining items.

Exhibit 4-25. Quality Control start of stand (9 of 9)

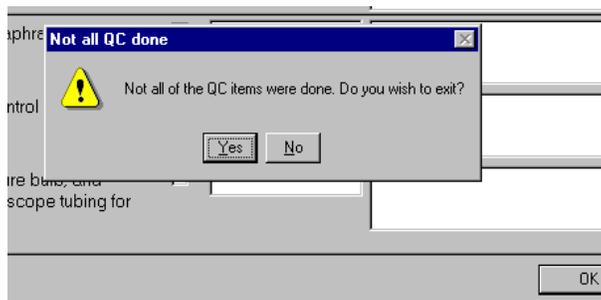
QC Check	Done	Result	Comment
Gauge reading 6 at 60 mm Hg	<input type="checkbox"/>		
Aneroid reading 6 at 60 mm Hg	<input type="checkbox"/>		
Gauge reading 7 at 0 mm Hg	<input type="checkbox"/>		
Aneroid reading 7 at 0 mm Hg	<input type="checkbox"/>		

When you have completed all checks, click “OK” to close the QC box.

4.5.5 End of Stand Checks

The end of stand checks consist of the calibrations screens as in Exhibits 4-17 through 4-25. When you have completed all checks, click “OK” to close the QC box. If you do not check that all items are complete, the system will display this message: “Not all the QC items were done. Do you wish to exit?”

Exhibit 4-26. Quality Control incomplete entry



If you want to complete the items before exiting, click “No” to this message and complete the items. If you do not wish to complete all QC checks, click “Yes” to this message. If all QC items were not complete, the system will remind you each time you logon that the QC checks are not complete.