2009

Add Health Wave IV Documentation

Cardiovascular and Anthropometric Measures

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1. Introduction

During the Wave II and III in-home interviews, Add Health collected measures of respondent height and weight. To better understand the social, behavioral and biological linkages in health trajectories as the Add Health cohort ages through adulthood, the Wave IV study design included an expanded set of anthropometric measures as well as several new measures of cardiovascular health. The Wave IV cardiovascular and anthropometric measures were collected in the following order:

- Blood pressure cuff size
- Systolic blood pressure (SBP, mmHg)
- Diastolic blood pressure (DBP, mmHg)
- Pulse rate (PR, beats/min)
- Height (cm)
- Weight (kg)
- Waist circumference (cm)

In addition, the Add Health Wave IV data set includes the following constructed measures, derived from those listed above:

- Blood pressure classification¹
- Pulse pressure (mmHg)
- Mean arterial pressure (mmHg)
- Body mass index (BMI, kg/m²)
- BMI classification²

This document summarizes the rationale, measurement, equipment, protocol and data cleaning procedures for each of the cardiovascular and anthropometric measures collected at Wave IV. It also documents how constructed variables were derived from the cardiovascular and anthropometric measures collected in the field. Documentation of other Wave IV biological measures, including metabolic, inflammatory, immune and genetic measures, will be provided in separate reports.

2. General Overview of Data Collection

A Blaise computer-assisted interview (CAI) program guided trained and certified field interviewers (FIs) through collection of all cardiovascular and anthropometric measures. Help screens with step-by-step measurement instructions were accessible within the program. Each FI also carried a Job Aids Booklet that served as a quick reference guide to study protocols.

Respondents were free to decline any or all measurements while participating in other components of the interview. However, if a respondent's blood pressure cuff size could not be measured for any reason, no blood pressure reading was taken. If the respondent was incarcerated at the time of the interview and policies or practices at the correctional facility prevented collection of a particular measurement (e.g., the facility would not permit use of a tape

measure to measure waist circumference), the respondent could chose to participate in collection of the other measures. In the Wave IV data set, any measures that are missing due to unique circumstances at correctional facilities are coded as legitimate skips.

As explained below, FIs provided respondents with written documentation of their systolic and diastolic blood pressures at the time of the interview. However, particular care was taken to prevent respondents from becoming embarrassed or self-conscious about their anthropometric measures. FIs, for example, were trained to remain courteous and professional at all times, never calling attention to or commenting on a respondent's height, weight or waist circumference. FIs were also trained not to share anthropometric measures with respondents unless they specifically requested them.

Some measurement protocols were revised in the period between the Wave IV Pretest (conducted in 2007) and the Main Study (conducted in 2008-09). Where the Pretest and Main Study data collection protocols differed significantly, this report documents the key differences between them. Pretest cases in the Wave IV data set are flagged for identification.

3. Blood Pressure Cuff Size

3.1 Rationale

Arm circumference was measured to guide selection of an appropriately-sized blood pressure cuff for the cardiovascular measures.

3.2 Measurement

The field interviewer measured the circumference of the arm on which the blood pressure reading would be taken. For each measurement, the FI recorded the arm to be measured (right or left) and the cuff to be used. Cuff sizes were recorded as "Adult," "Large adult," or "Large adult, but arm exceeds large adult size cuff."

3.3 Equipment

A 16-inch, low-stretch, fiberglass tailor's tape (Exhibit 1) marked with (1) a 13-inch threshold and (2) the words "Adult" and "Large" printed in permanent ink to the left and right of the threshold.

Exhibit 1. Tailor's tape used to determine blood pressure cuff size.



3.4 Protocol

3.4.1 Main study

FIs used the respondent's right arm for the arm circumference and blood pressure measurements, unless one of the following contraindications was present:

- open sores, wounds, gauze dressings or rashes;
- casts, splints or shunts;
- intravenous (IV) catheters or other attached medical devices;
- swelling, withering or paralysis; or
- arm on same side as prior mastectomy.

All female respondents were asked specifically whether they had had a mastectomy and, if so, on which side. If there were contraindications to using the right arm for measurement, the left arm was used. If there were contraindications on both arms, no arm circumference or blood pressure measurements were taken.

To measure arm circumference accurately, FIs asked respondents to remove bulky outer garments (e.g., sweaters or jackets) and, if applicable, push up their shirt sleeves to expose the upper arm. FIs also instructed respondents to relax their shoulders and allow their arm to be measured while hanging loosely at their side.

FIs wrapped the 16-inch tailor's tape around the respondent's upper arm, midway between the shoulder and elbow. If the measured circumference was < 13 inches, FIs recorded the cuff size as "Adult." If the circumference was 13-16 inches, FIs recorded it as "Large adult." If the respondent's arm was > 16 inches—meaning that the two ends of the tailor's tape did not meet when wrapped around the arm—FIs recorded it as "Large adult, but arm exceeds large adult size cuff." For respondents in the latter category, FIs were trained to proceed with the blood pressure reading, if possible, using the "Large adult" cuff.

3.4.2 Pretest variations

During the Pretest, FIs used a SECA 200 English-increment circumference tape measure to measure arm circumference to the nearest 1/4 inch. The FI keyed this measurement into the CAI instrument, which was programmed to calculate and display the appropriate cuff size. If the measured arm circumference was < 12 inches, the "Adult" cuff was used. If the circumference was \ge 12 inches, the "Large adult" cuff was used.

3.5 Constructed variables

No constructed variables were derived from the arm circumference measure.

3.6 Data cleaning

For all cases, cuff size skip logic was checked for consistency. For example, if a respondent refused the arm circumference measurement, no cuff size should have been recorded.

Because FIs were instructed to record arm circumference during the Pretest and cuff size during the Main Study, the cuff size variable was computed for Pretest respondents. Also, due to protocol changes, the "Large adult" cuff was used in the Pretest, whereas the "Adult" cuff was used in the Main Study, to measure blood pressure of respondents with an arm circumference of 12-12.75 inches. Pretest respondents whose arm measurements were between 12 and 12.75 inches are flagged in the data file.

4. Cardiovascular Measures

4.1 Rationale

Blood pressure and pulse rate were measured because of their established relationship with cardiovascular disease morbidity and mortality.

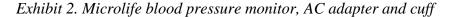
4.2 Measurement

Trained and certified field interviewers measured respondents' resting, seated systolic and diastolic blood pressures (mmHg) and pulse rate (beats/minute). Three serial measurements were performed at 30-second intervals.

4.3 Equipment

Factory calibrated, Microlife BP3MC1-PC-IB oscillometric blood pressure monitor (MicroLife USA, Inc.; Dunedin, FL) recommended for clinical and home use by the British Hypertension Society (Exhibit 2). Accessories: Adult cuff (S101, for arm circumferences: 9.5-13.25 in) and Large adult cuff (S102, for arm circumferences: 12-16 in). Monitor specifications:

- Weight: 735 g (with batteries)
- Size: 160 (W) x 140 (L) x 98 (H) mm
- Storage Temperature: 20°C-50°C (-4°F -122°F)
- Humidity: 15%-90% relative humidity maximum
- Operation Temperature: 10°C-40°C (50°F-104°F)
- Display: Liquid crystal display (LCD)
- Measuring Method: Oscillometric
- Pressure Sensor: Capacitive
- Measuring Range: 30-280 mmHg (SBP and DBP); 40 to 200 beats/min (PR)
- Cuff Pressure Display Range: 0-299 mmHg
- Measuring Resolution: 1 mmHg
- Accuracy: ±3 mmHg (SBP & DBP); ±5 % (PR)
- Power Source: [1] 4 AA batteries, 1.5V [2] AC Adapter 6V DC 600 mA (4.5-6 V DC)





4.4 Protocol

4.4.1 Main Study

As discussed in the cuff size protocol above, all blood pressure measurements were taken on the right arm, absent contraindications. Respondents were asked to remove bulky outer garments and to push up their sleeve to expose the arm to be measured.

If the respondent had left his or her seat for any reason during the five minutes prior to the blood pressure measurement, the FI had the respondent rest in the seated position for five minutes before proceeding with the reading. All respondents were asked to sit still and silently with both feet on the floor and legs uncrossed during the entire series of blood pressure measurements. FIs were trained to position the face of the Microlife monitor away from the respondent, outside of his or her view.

For each respondent, the FI administered three separate readings at 30 second intervals. A timer programmed into the CAI instrument guaranteed the duration of the inter-reading interval. A visual cue and audible chime alerted the FI when the 30-second interval had ended and the next reading was to begin. During each interval, FIs instructed respondents to raise their elbow to the level of the shoulder and hold the arm upward at a 90 degree angle for five seconds. Immediately following each of the three readings, FIs keyed SBP, DBP and PR into the CAI instrument. The first set of readings was keyed once. To ensure accuracy of the results reported to respondents, the second and third SBP and DBP were keyed twice and discrepant entries identified in real time.

If the Microlife blood pressure monitor delivered an error message in place of a reading, interviewers recorded the result as "999 - equipment malfunction." To resolve the problem generating an error message, FIs referred to the Job Aids Booklet, which included a list of

possible error codes with recommended courses of action. If three errors were encountered during the course of the blood pressure measurements, the CAI instrument prompted the field interviewer to discontinue use of the monitor and contact his or her field supervisor. Any monitors or cuffs that were known to be malfunctioning were withdrawn from the field.

Following collection of the three blood pressure readings and all anthropometric measures, the CAI instrument guided the FI through completion of a blood pressure results form, which the FI then gave to the respondent. On this form the FI recorded the date of the reading, the average of the second and third SBP, the average of the second and third DBP, and an appropriate recommendation for follow-up with a health care provider, as calculated and displayed by the CAI instrument, which was programmed to take risk factors into consideration (see below). If either the second or third reading was not obtained, the respondent was given the result of the single available reading. If both the second and third readings were missing, no results were reported to the respondent. Recommendations as to when to follow up with a health care provider (i.e., 2 years, 1 year, 2 months, 1 month, 1 week, or "Today") were based on guidelines of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7)¹ and took the following factors into account:

- Average SBP and DBP;
- Calculated BMI;
- Reported pregnancy status;
- Reported current smoking status; and
- Reported history of high blood cholesterol, diabetes, heart disease, chronic kidney disease, and/or stroke.

When average systolic and diastolic blood pressures did not fall within the same follow-up category, the earlier of the two follow-up periods was recommended. When JNC7 guidelines recommended that the respondent follow up with a health care provider on the day of the reading (average SBP > 179 with risk factor present, or average DBP > 109 with risk factor present), the CAI instrument prompted the FI to offer to call a health care provider, friend or relative with whom the respondent could discuss the results. Additionally, the blood pressure results form included general information on risk factors for heart disease and contact information for the American Heart Association.

To help ensure data quality and accuracy, pressures generated by a factory-calibrated pressure meter (Netech DigiMano, Model 2000; Netech Corporation; Farmingdale, NY) over a range of 40-280 mmHg were compared with pressures measured by all MicroLife monitor / cuff pairs returned from the field after the Main Study was complete. See Appendix A for Microlife Blood Pressure Monitor Calibration Form and Protocol.

4.4.2 Pretest variations

During the Pretest, the blood pressure results form was completed and given to the respondent at the end of the interview, rather than after the anthropometric measures.

4.5 Constructed variables

4.5.1 Systolic and diastolic blood pressures and pulse rate

Systolic blood pressure, diastolic blood pressure and pulse rate were constructed as the average of measures 2 and 3. When either the second or third measure was missing, the other single measure was used. In cases where both measures 2 and 3 were missing, the first measure was used. The Wave IV data set includes a variable to indicate the number of measures from which SBP, DBP and PR were constructed.

4.5.2 Blood pressure classification

Blood pressure classification was constructed for all respondents based on guidelines from the Seventh Report of the Joint National Committee on Prevention Detection, Evaluation, and Treatment of High Blood Pressure (JNC7). JNC7 Categories are defined as follows:

JNC7 Category	SBP (mmHg)		DBP (mmHg)
Normal	<120	and	<80
Pre-hypertension	120–139	or	80–89
Hypertension, Stage 1	140–159	or	90–99
Hypertension, Stage 2	≥160	or	≥100

4.5.3 Pulse pressure

The single pulse pressure measure was constructed as the average of the difference between systolic and diastolic blood pressures using measures 2 and 3. When either the second or third measure was missing, the difference between systolic and diastolic blood pressure for the other single measure was used. In the cases when both measures 2 and 3 were missing, the difference between the first systolic and diastolic blood pressures was used. The formula is:

$$((SBP2 - DBP2) + (SBP3 - DBP3))/2$$

4.5.4 Mean arterial pressure

Mean arterial pressure was conventionally approximated as the weighted sum of systolic and diastolic blood pressure at the second and third readings, where the weights for SBP (1/3) and DBP (2/3) reflect the typical contributions of ventricular systole and diastole to the duration of the cardiac cycle. When either the second or third measure was missing, the other single measure was used. In cases where both measures 2 and 3 were missing, the first measure was used. The formula is:

$$(((SBP2 + (2*DBP2))/3) + ((SBP3 + (2*DBP3))/3))/2$$

4.6 Data cleaning

Skip logic was evaluated for all measures. Distributions of manually keyed systolic and diastolic blood pressures also were examined for digit preference of FIs, values exceeding the Microlife-specified ranges of measurement, and outliers.

5. Height

5.1 Rationale

Height was measured to enable computation of body mass index (see below), an independent predictor of cardiovascular disease risk factors, morbidity and mortality, as well as a primary tool used in characterizing the epidemiology of obesity in the U.S.

5.2 Measurement

Height was measured to the nearest 0.5 cm for all respondents who were capable of maintaining a standing position without assistance.

5.3 Equipment

Carpenter's square, steel tape measure (1 mm graduation; 7.5 m maximum), and pre-printed, adherent Post-it note (Exhibit 3).

Exhibit 3. Height measurement equipment





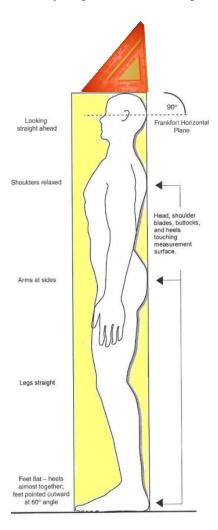
5.4 Protocol

5.4.1 Main study

To maintain data quality, field interviewers were trained to measure height against a smooth wall in an area without rugs or carpeting, if possible. The FI asked the respondent to remove his or her shoes and any hat, hair ornaments or other accessories that could affect the measurement. If the respondent refused or was unable to remove his or her shoes or interfering accessories, the FI was trained to measure the height of those items separately and record the results in the CAI instrument.

The respondent was instructed to take a deep breath and stand as tall as possible against the wall, with their feet flat on the floor, both heels together and toes pointed slightly apart. The FI checked to be sure that the respondent's weight was evenly distributed and that their head, shoulder blades, buttocks and heels touched the wall, to the extent possible. The FI also aligned the respondent's head in the Frankfurt position (Exhibit 4), with the horizontal line from the ear canal to the lower border of the orbit of the eye parallel to the floor and perpendicular to the wall. Height was measured at the end of the respondent's normal exhalation.

Exhibit 4. Head in Frankfurt position with carpenter's square



To take the measurement, the FI rested the carpenter's square firmly on top of the respondent's head so that the sides of the square that form a right angle were flush with the wall and resting on the respondent. The FI then placed the top edge of a Post-it note at the bottom edge of the square, marking the respondent's height, and asked the respondent to step away from the wall. Next, the FI used the tape measure to measure the distance from the floor to the top of the Post-it note, asking the respondent to hold the bottom end of the tape in place, if necessary. The FI measured height to the nearest 0.5 cm and printed the measurement on the Post-it note, in the space marked "Height," before removing the Post-it note from the wall. The FI used the same Post-it note to temporarily record the weight and waist circumference before entering all three measurements into the computer.

5.4.2 Pretest variations

During the Pretest, height was measured to the nearest 1/4 inch, using a steel tape measure with 1/16 inch graduations. The measurement was recorded in whole feet and whole and quarter inches.

5. 5 Constructed variables

Measured height was used in the construction of body mass index (see section 6.5).

5.6 Data cleaning

The skip logic and distribution of manually keyed height were checked for inconsistencies, digit preference of FIs and outliers. If the respondent wore shoes, hair ornaments, etc. during the height measurement, the measured height of these items was subtracted from the respondent's height. Pretest height measurements recorded in feet and inches were converted to centimeters.

6. Weight

6.1 Rationale

Weight was measured to enable computation of body mass index (see below), an independent predictor of cardiovascular disease risk factors, morbidity and mortality, as well as a primary tool used in characterizing the epidemiology of obesity in the U.S.

6.2 Measurement

Weight was measured to the nearest 0.1 kg for all respondents who were capable of standing unassisted.

6.3 Equipment

Health-o-meter 844KL High Capacity Digital Bathroom Scale (Jarden Corporation; Rye, NY) (Exhibit 5). Specifications:

- 200 kg / 440 lbs maximum capacity
- 0.1 kg / 0.1 lb graduations
- 12 5/8" x 12 5/8" platform
- 4.5 lbs
- Digital display
- 4-point load cell
- Lithium battery
- No moving parts
- Automatic shut-off after 30 seconds of inactivity
- Low battery warning display ("Lo")

Exhibit 5. Health-o-meter 844KL digital scale



6.4 Protocol

6.4.1 Main study

During FI training, each FI set the graduation switch on the bottom of his or her scale to "kg" and placed tape over the switch to maintain the metric setting. FIs were also trained to check the switch in the field before each measurement to ensure that weight results were recorded in kilograms.

To measure a respondent's weight, the field interviewer placed the scale on a hard, flat surface, avoiding rugs and carpeting, if possible. The FI asked the respondent to remove their shoes and any change, wallets or keys from their pockets. Respondents were not asked to remove any

clothing. The FI instructed the respondent to stand on the scale with their weight evenly distributed, looking straight ahead. The FI recorded the weight to the nearest 0.1 kg on the preprinted Post-it note for later entry into the computer. If the respondent weighed over 200 kilograms, the scale displayed the message "OL." In these cases, for data entry purposes, the FI recorded the weight as "201."

To ensure the quality and accuracy of the weight measurements, field interviewers were required to perform a weekly calibration of the digital scale and submit the results to their supervisors. For every week of active data collection, each FI measured and reported the weight of (1) himself/herself, (2) the Add Health laptop computer, and (3) himself/herself holding the laptop computer. If the summed weights of the FI and the computer differed from the measured weight of the FI holding the computer by more than 1 kg, the field interviewer immediately notified his or her field supervisor of the discrepancy. FIs were also instructed to immediately report any problems with or damage to the scales. Any scales with suspected problems were withdrawn from the field and replaced.

6.4.2 Pretest

During the Pretest, weight was measured to the nearest 0.2 lb using a Tanita HD351 digital bathroom scale with a maximum capacity of 440 lbs (200 kg) and graduations of either 0.2 lb or 0.1 kg. For Pretest respondents whose weight exceeded 440 lbs, a value of "441" was keyed into the computer. The Tanita scale was not available in the quantities needed for the main study, necessitating the switch to the Health-o-meter 844KL.

6.5 Constructed variables

Body mass index (BMI) was calculated according to the metric imperial formula:

BMI
$$(kg/m^2)$$
 = weight (kg) / height (m^2)

In addition, all respondents were assigned a BMI classification according to the categorization scheme recommended by the National Institutes of Health Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults²:

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1 = underweight (16.5 - <18.5 kg/m<sup>2</sup>)

2 = normal (18.5 - <25 kg/m<sup>2</sup>)

3 = overweight (25 - <30 kg/m<sup>2</sup>)

4 = obese I (30 - <35 kg/m<sup>2</sup>)

5 = obese II (35 - <40 kg/m<sup>2</sup>)

6 = obese III (\ge40 kg/m<sup>2</sup>)
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6.6 Data cleaning

The skip logic and distribution of manually keyed weight were checked for inconsistencies, digit preference of FIs, and outliers. Outlying differences between self-reported and measured weights were also examined in the context of respondent gender, height, waist and Wave III

weights, when available. If measured weight was inconsistent with sex, self-reported weight, waist and height measures, the weight variable was assigned the code 889.

7. Waist Circumference

7.1 Rationale

Waist circumference is positively correlated with abdominal fat content. Waist circumference was measured because a disproportionate excess of abdominal relative to total body fat is an independent predictor of cardiovascular disease risk factors, morbidity and mortality. It too is a primary tool used in characterizing the epidemiology of obesity in the U.S.

7.2 Measurement

Waist circumference was measured to the nearest 0.5 cm at the superior border of the iliac crest for all respondents capable of standing unassisted, including pregnant women.

7.3 Equipment

SECA 200 metric-increment circumference tape measure (Seca Corp., North America East; Hanover, MD) (Exhibit 6). Specifications:

- 200 cm maximum range
- 1 mm graduations
- 2-sided cm scaling
- 90 x 25 x 65 mm
- 50 g
- Fiberglass tape
- Plastic case
- Automatic roll-up
- End-peg positioned



Exhibit 6. SECA 200 tape measure

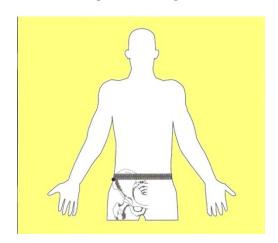
7.4 Protocol

7.4.1 Main study

FIs asked respondents to remove bulky outer garments and stand relaxed, breathing normally, with their weight evenly distributed. To locate the iliac crest, FIs placed their hands on the abdomen at the bottom of the rib cage and gently palpated downward until encountering the left and right superior borders of the pelvis. To avoid surprise and put the respondent at ease, FIs were trained to demonstrate the examination on themselves before touching respondents.

Once the upper left and right borders of the iliac crest were located, FIs asked respondents to mark the locations with their own hands so that FIs could measure the waist. FIs wrapped the SECA tape around the waist at the level of the superior iliac crest, making sure that the tape was not twisted and remained parallel to the floor (Exhibit 7). When FIs could not easily reach around the respondent, they were allowed to ask the respondent to do so and then hand the tape measure back to the FI for adjustment. The protocol also allowed FIs to walk around the respondent with the tape, if needed. The measurement was taken at the end of the respondent's normal exhalation and recorded on a Post-it note for subsequent entry in the CAI instrument. Any broken or malfunctioning SECA tapes were reported and replaced immediately throughout data collection.

Exhibit 7. Tape measure placement



7.4.2 Pretest

During the Pretest, waist was measured to the nearest 1/4 inch with a SECA English-increment circumference measuring tape (1/8 inch graduation).

7.5 Constructed variables

No constructed variables were derived from the waist circumference measurement.

7.6 Data cleaning

The skip logic and distribution of manually keyed waist measurements were checked for inconsistencies, digit preference of FIs, and outliers. Pretest waist measurements recorded in whole and partial inches were converted to centimeters.

8. References

¹ Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr, Jones DW, Materson BJ, Oparil S, Wright JT Jr, Roccella EJ; Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and

Blood Institute; National High Blood Pressure Education Program Coordinating Committee. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertension 2003;42(6):1206-1252.

² National Institutes of Health. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults--The Evidence Report. Obes Res 1998;6(S2):51S-209S.

Appendix A: Microlife Blood Pressure Monitor Calibration Form and Protocol Tech ID: FI Cuff: FI Monitor: Test Date: Cuff: ADULT or LARGE ADULT Visual Check NO MATCHING TUBING ◆ TUBE HAS HOLES? Y NO MATCHING TUBING ◆ CUFF HAS WORN OUTER CLOTH OR VELCRO?Y NO MATCHING CUFF ◆ TUBE LEAKS? Y NO MATCHING TUBING ◆ CUFF HAS LEAKAGE OF CUFF BLADDER? Y NO MATCHING CUFF ◆ COMMENTS: **Calibration Check with Pressure-Vacuum Meter** Observed pressure values on the Digimano Pressure-Vacuum Meter and the Microlife from 280 to 20 (± 2) mmHg in approximate decrements of 20 (± 2) mmHg. **MEASUREMENT NUMBER DIGIMANO MICROLIFE** 1 (280)..... mmHa mmHg L **2** (260)..... mmHa 3 (240)..... mmHg 4 (220)..... mmHg...... mmHg **5** (200)..... mmHg..... mmHg **6** (180)..... mmHg..... mmHg 7 (160)..... mmHg..... mmHg 8 (140)..... mmHg..... mmHg 9 (120)..... mmHg..... mmHg **10** (100)..... mmHg...... mmHg 11 (80)..... mmHg..... mmHg mmHg..... 12 (60)..... mmHg

mmHg......

mmHg.....

mmHg

mmHg

Equipment Required for Blood Pressure Monitor Calibration

DigiMano Digital Pressure/Vacuum Meter, Netech Model 2000 (range: 0-300 mmHg). Blood Pressure Calibration Kit (syringe; silicone tubing; T adapter; Luer-lock; Velcro tape; valve cap) Microlife 3MC1-PC_IB Oscillometric Blood Pressure Monitor ADULT and LARGE ADULT blood pressure cuffs

Testing Protocol

The following sequence of steps details the Microlife accuracy testing protocol.

- 1. Plug in and connect the AC adapter to the Microlife.
- 2. Seal the pressure release hole on the back of the Microlife with Velcro tape.
- 3. Record Tech ID, Field Interviewer number on the cuff package (FI Cuff), Field Interviewer number on the monitor (FI Monitor), and date on the form. The FI cuff number is found on the Ziplock bag and the FI Monitor number is on the back of the monitor. Use the code of 999 if the cuff does not have a FI number.
- 4. Circle ADULT on the form to indicate that the ADULT cuff is being evaluated.
- 5. Inspect the ADULT cuff tubing for holes or cracks which would allow air to leak out. Cracking is commonly found around the connection points to the sphygmomanometer and cuff. Answer questions on form about holes and cracking.
- 6. Inspect the ADULT cuff for signs of wear-and-tear to the outer cloth casing and Velcro fabric. Record your evaluation on the form.
- 7. Attach ADULT cuff to ADULT PVC pipe and place the pipe vertically on the table. Tightly connect the ADULT cuff tubing to the Microlife. The bottom edge of the cuff should rest 1 inch (black mark) above the end of the PVC pipe. The small white arrow (Artery Mark) on the cuff should be pointing down. You should be able to fit 2 fingers between the pipe and the cuff.
- 8. Connect the black L adapter on the ADULT cuff to the Microlife.
- 9. Turn on the Microlife to inflate the ADULT cuff to determine if the bladder within the ADULT cuff is leak-proof. Answer the questions on the form about ADULT cuff damage, air leakage, and tube leakage.
- 10. Disconnect the ADULT cuff tubing from the Microlife.
- 11. Remove the black connector from the ADULT cuff tubing and put aside.
- 12. Holding in the black lead screw on the syringe, screw and pull the grey plunger past the 60 cc mark (to the end of the syringe). Connect the white silicone tubing to the syringe by rotating it to engage the Luer Lock.
- 13. Snugly connect the black ADULT cuff tubing to the Y adapter on the white silicone tubing.
- 14. Connect the white silicone tubing to the Microlife with the black L adapter.
- 15. Turn on the DigiMano. Check for the low battery light and change the battery if necessary.
- 16. Ensure that the red light below "mmHG" on the DigiMano is flashing, indicating that the correct measurement (millimeters of mercury) is selected.
- 17. Zero the pressure vacuum meter by pressing the zero button on the front of the DigiMano. The display should read 0.0.
- 18. Pick up the syringe and then press the ON/OFF START button on the Microlife to start the reading.

- 19. When the Microlife stops inflating the cuff, while watching the DigiMano, adjust the pressure in the syringe until the *DigiMano* displays a stable value near 280 mmHG (+/- 2 mmHG). If stability is a problem, examine the calibration system, listen for air leaks, and reseal the pressure release hole on the back of the Microlife with the Velcro tape.
- 20. Slowly release the pressure in 20 mmHG decrements <u>according to the readings on the *DigiMano</u>*. Coarse adjust the pressure by holding in the black lead screw and pulling or pushing the grey plunger, as needed. Fine adjust the pressure by rotating the grey plunger. Carefully record on the form the pressure readings from the DigiMano and Microlife at 20 mmHG decrements, i.e. from 280, to 260, ..., to 60, and finally to 20 mmHG.
- 21. Disconnect the ADULT cuff from the white tubing. Place the black L adapter back in the cuff tubing. Put the ADULT cuff in the Ziplock bag.
- 22. Disconnect the syringe from the white silicone tubing by rotating it to disengage the Luer Lock.
- 23. Remove the LARGE ADULT cuff from the Ziplock bag. The LARGE ADULT cuff has a valve that needs to be sealed before taking the measurements. Seal this valve by replacing the stem and the short black tubing with a black plastic cap.
- 24. Using another form, record Tech ID, Field Interviewer number on the cuff package (FI Cuff), Field Interviewer number on the monitor (FI Monitor), and date on the form. The FI cuff number is found on the Ziplock bag and the FI Monitor number is on the back of the monitor. Use the code of 999 if the cuff does not have a FI number.
- 25. Circle LARGE ADULT on the form to indicate that the LARGE ADULT cuff is being evaluated.
- 26. Inspect the LARGE ADULT cuff tubing for holes or cracks which would allow air to leak out. Cracking is commonly found around the connection points to the sphygmomanometer and cuff. Answer questions on form about holes and cracking.
- 27. Inspect the LARGE ADULT cuff for signs of wear and tear to the outer cloth casing and Velcro fabric. Record your evaluation on the form.
- 28. Attach LARGE ADULT cuff to LARGE ADULT PVC pipe and place the pipe vertically on the table. Tightly connect the LARGE ADULT cuff tubing to the Microlife. The bottom edge of the cuff should rest 1 inch (black mark) above the end of the PVC pipe. The small white arrow (Artery Mark) on the cuff should be pointing down. You should be able to fit 2 fingers between the pipe and the cuff.
- 29. Connect the black L adapter on the LARGE ADULT cuff to the Microlife.
- 30. Turn on the Microlife to inflate the LARGE ADULT cuff to determine if the bladder within the LARGE ADULT cuff is leak proof. Answer the questions on the form about LARGE ADULT cuff damage, air leakage, and tube leakage.
- 31. Disconnect the LARGE ADULT cuff tubing from the Microlife.
- 32. Remove the black connector from the LARGE ADULT cuff tubing and put aside.
- 33. Holding in the black lead screw on the syringe, twist and pull the grey plunger past the 60 cc mark (to the end of the syringe). Connect the white silicone tubing to the syringe by rotating it to engage the Luer Lock.
- 34. Snugly connect the LARGE ADULT cuff black tubing to the Y adapter on the white silicone tubing.
- 35. Connect the white silicone tubing to the Microlife with the black L adapter.
- 36. Turn on the DigiMano. Check for the low battery light and change the battery if necessary.
- 37. Ensure that the red light below "mmHG" on the DigiMano is flashing, indicating that the correct measurement (millimeters of mercury) is selected.

- 38. Zero the pressure vacuum meter by pressing the zero button on the front of the DigiMano. The display should read 0.0.
- 39. Holding the syringe, press the ON/OFF START button on the Microlife to start the reading.
- 40. When the Microlife stops inflating the cuff, while watching the DigiMano, adjust the pressure in the syringe until the *DigiMano* displays a stable value near 280 mmHG (+/- 2 mmHG). If stability is a problem, examine the calibration system, listen for air leaks, and reseal the pressure release hole on the back of the Microlife with the Velcro tape.
- 41. Slowly release the pressure in 20 mmHG decrements according to the readings on the *DigiMano*. Coarse adjust the pressure by holding in the black lead screw and pulling or pushing the grey plunger, as needed. Fine adjust the pressure by rotating the grey plunger. Carefully record on the form the pressure readings from the DigiMano and Microlife at 20 mmHG decrements, i.e. from 280, to 260, ..., to 60, and finally to 40 mmHG.
- 42. Disconnect the syringe from the white silicone tubing by rotating it to disengage the Luer Lock.
- 43. Disconnect the LARGE ADULT cuff from the white tubing. Place the black L adapter back in the cuff tubing.
- 44. Remove the black plastic cap from the valve on the LARGE ADULT cuff and replace it with the stem and the short black tubing.
- 45. Put the ADULT cuff in the Ziplock bag.
- 46. Remove the Velcro tape from the back of the monitor.
- 47. Return the Microlife to the bag, attach the cuffs, and put them in the box with the tested monitors.

NOTE: If pressure is lost during the calibration process, do the following:

- 1. Disconnect the syringe from the white silicone tubing by rotating it to disengage the Luer Lock.
- 2. Holding in the black lead screw on the syringe, twist and pull the grey plunger past the 60 cc mark (to the end of the syringe). Connect the white silicone tubing to the syringe by rotating it to engage the Luer Lock.
- 3. Ensure that the red light below "mmHG" on the DigiMano is flashing, indicating that the correct measurement (millimeters of mercury) is selected.
- 4. Zero the pressure vacuum meter by pressing the zero button on the front of the DigiMano. The display should read 0.0.
- 5. Holding the syringe, press the ON/OFF START button on the Microlife to start the reading.
- 6. Adjust the DigiMono to next pressure on the list. Continue taking the measurements.