



National Health and Nutrition Examination Survey (NHANES)

Physical Activity Monitor (PAM) Procedures Manual



April 2011

TABLE OF CONTENTS

<u>Chapter</u>		<u>Page</u>
1	PHYSICAL ACTIVITY MONITOR STUDY	1-1
	1.1 Background.....	1-1
	1.2 Description of the Physical Activity Monitor (PAM).....	1-2
	1.3 Overview of the Protocol.....	1-3
	REFERENCES	1-4
2	EQUIPMENT AND SUPPLIES.....	2-1
	2.1 Equipment.....	2-1
	2.2 Supplies.....	2-1
	2.3 Inventory Management.....	2-2
	2.4 PAM Room Set Up.....	2-3
	2.4.1 Beginning of Stand Activities	2-3
	2.4.2 Charging the Actigraph Monitors	2-3
3	PROTOCOL	3-1
	3.1 General Overview.....	3-1
	3.2 Examination Procedures	3-1
	3.3 Procedures for Assigning a PAM to an SP	3-3
	3.3.1 Initialization of the Actigraph Physical Activity Monitor... ..	3-4
	3.3.2 Wrist Selection and Monitor Placement.....	3-6
	3.3.3 Procedures for Returning the Monitor and Review of Written Instructions.....	3-11
	3.3.4 Completing the Remaining Drop-Down Boxes in the ISIS Application.....	3-12
List of Appendixes		
A	Physical Activity Monitor Description and Photo – English and Spanish.....	A-1
B	Physical Activity Monitor Information and Instructions – English and Spanish.....	B-1
C	PAM Wrist Strap Size Chart.....	C-1
D	Physical Activity Monitor Spanish Scripts.....	D-1

TABLE OF CONTENTS (CONTINUED)

List of Tables

<u>Table</u>		<u>Page</u>
3-1	Placement of PAM on dominant arm.....	3-7
3-2	PAM Wrist Strap Size Chart.....	3-9

List of Figures

<u>Figure</u>		<u>Page</u>
3-1	Threading the wrist strap through the PAM.....	3-9

List of Exhibits

<u>Exhibit</u>		<u>Page</u>
2-1	PAM Inventory par levels.....	2-2
2-2	LED indicator lights.....	2-4
3-1	PAM screen after scanning SP ID	3-1
3-2	Windows default screen with Actigraph GT3X+(F;) dialogue box.....	3-2
3-3	Screen when “Close Exam” button clicked with exam status and comment options.....	3-3
3-4	Screen showing Initialized button after PAM is connected to ISIS monitor ...	3-4
3-5	Screen after monitor initialization with all green dots brightened and red dots darkened.	3-5
3-6	Drop-down box with options to determine dominant arm.....	3-6
3-7	Prefilled box for nondominant arm selection.....	3-8
3-8	Options for monitor placement on selected arm	3-10
3-9	Screen of “Other” for monitor placement with comment	3-11
3-10	Screen with pop-up box if monitor not given after initialization.....	3-13
3-11	Screen after monitor not given to SP with “Initialize” button not highlighted	3-13

1. PHYSICAL ACTIVITY MONITOR STUDY

1.1 Background

In October 2008, the Federal Government issued its first-ever Physical Activity Guidelines for Americans to provide science-based guidance on the types and amounts of physical activity that provide substantial health benefits for Americans. (2008 Physical Activity Guidelines for Americans <http://www.health.gov/paguidelines/guidelines/default.aspx>)

The Guidelines state that “Being physically active is one of the most important steps that Americans of all ages can take to improve their health.” It goes on to say that “Children and adolescents should do 60 minutes (1 hour) or more of physical activity daily” AND “...adults should do at least 150 minutes a week of moderate-intensity, or 75 minutes a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous intensity aerobic activity”.

These conclusions were based, in part, on an expanded body of scientific literature that demonstrated the relationship between physical activity and health. Namely, physical inactivity is an independent risk factor for coronary heart disease (Berlin and Colditz, 1990). In the United States, a significant percentage of deaths from coronary heart disease, colon cancer, and Type 2 diabetes are attributable to sedentary lifestyle (Blair and Morrow, Jr., 1998).

Moderate-intensity activity is even beneficial to overall health (Pate, JAMA, 1995) because it contributes to improved glucose tolerance and blood lipid profile levels. The American College of Sports Medicine, the Centers for Disease Control and Prevention, the American Heart Association, the National Institutes of Health, and the President’s Council on Physical Fitness and Sports, recommend regular, moderate-intensity physical activity.

The U.S. Surgeon General’s Report on Physical Activity and Health reported that more than 60 percent of Americans do not engage in regular physical activity and that 25 percent do not engage in any activity (DHHS, 1996). The report reaffirmed the importance of regular moderate or vigorous-intensity activity. Furthermore, physical activity data on children, particularly children in the 6-11 year age group are lacking. Proxy information on physical activity levels among youth are not useful because

children spend large amounts of time away from home and they also engage in sporadic periods of activity that are difficult to document, let alone quantify.

The results of the 2003-2006 NHANES PAM data have been analyzed and includes a minute-by-minute recording of the waking hours over 7 days in nearly 6,800 children, adolescents, and adults. The data suggested that 42 percent of children aged 6-11 years met the current 60 minutes per day recommendation, but only 8 percent of adolescents met this goal, and fewer than 5 percent of adults met the 30 minutes or more of physical activity per day.

Recognizing (1) the potential benefit of increased levels of physical activity to address the persistently high prevalence of obesity and overweight in the United States among adults (Flegal, JAMA, 2010); (2) the continued concern about the excess weight among children (as seen in NHANES 2007-2008 data) (Ogden, JAMA, 2010); and (3) the need for further physical activity data for the U.S. population, the National Cancer Institute (NCI) of the National Institutes of Health submitted a proposal to NCHS in 2010 to pilot test and field a new PAM in NHANES 2011+.

The PAM study of NHANES is sponsored by the following organizations:

- The National Institutes of Health (NIH);
- Department of Defense; and
- The CDC National Center for Health Statistics (NCHS).

1.2 Description of the Physical Activity Monitor (PAM)

When worn on the wrist, the physical activity monitor measures body movements at the wrist, including those like the swinging of the arm during activities like walking or jogging. Another important feature of the monitors is that they record intensity of movement over time. Many physical activity recommendations are based on moderate or vigorous activity levels. The monitor can detect fast versus slow movements, and the amount of time spent doing different levels of physical activity can be measured. The goal is to have 7 full days of activity information from survey participants.

There are no known risks associated with use of the monitors. The activity monitors are designed to be worn in a wet environment, so this does not pose a danger. The PAM is powered by a 3-volt lithium ion battery, which does not present a shock hazard when worn in a wet environment. The lithium ion battery is housed securely inside the device. The PAM device does not emit radiation, electrical current, vibration, or heat and it can be worn under shirt or coat sleeves without causing discomfort.

There is a small risk of accidental choking if the device is removed from the wrist band and left within reach of small children or pets. The PAM device dimensions are ~2 inches x 1.5 inches x 0.5 inches. The device is intended to be worn or stored securely fastened at all times to a wristband, ~0.8” wide. There is no reason for the device to be removed from the wristband. All other components in the PAM (including the batteries) are either in sealed compartments or require special tools to remove.

The other potential hazard is that the wristband could catch on something. The wristband should be securely fastened to the wrist while in the possession of the participant. Information about potential safety concerns will be included in written materials that are given to the survey participants and proxies.

1.3 Overview of the Protocol

The examination procedure will be described in detail in Chapter 3, Examination Protocol.

The physical activity component will be conducted with NHANES examinees 6+ years of age. Individuals who are missing both hands and both arms will be excluded because it will not be possible to attach the monitor to the participant in the desired location. If the person has a prosthetic arm and wishes to participate, then the PAM can be worn on the prosthesis. The approximate amount of time required per person to explain the component and fit the activity monitor in the mobile examination center (MEC) is five (5) minutes or less per person. The results of the physical activity monitor will not be reported to the participants, because the data are being obtained for research purposes and are not clinical measures.

REFERENCES

- Berlin, J.A. and Colditz, G.A. (1990). A meta-analysis of physical activity in the prevention of coronary heart disease. *American Journal of Epidemiology*, 132, 612-628.
- Blair, S.N. and Morrow, Jr. J.R. (1998). Introduction: Cooper Institute/American College of Sports Medicine 1997 Physical Activity Intervention Conference. *American Journal of Preventative Medicine*, 15, 255-256.
- Pate, R.R., Pratt, M., Blair, S.N., Haskell, W.L., Macera, C.A., Bouchard, C., Buchner, D., Ettinger, W., Heath, G.W., King, A.C., et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA*. 1995 Feb 1;273(5):402-7. Review.
- Flegal, K.M., Carroll, M.D., Ogden, C.L., and Curtin, L.R. Prevalence and trends in obesity among US adults, 1999-2008. *JAMA*. 2010 Jan 20;303(3):235-41.
- Ogden, C.L., Carroll, M.D., Curtin, L.R., Lamb, M.M., and Flegal, K.M. Prevalence of high body mass index in US children and adolescents, 2007-2008. *JAMA*. 2010 Jan 20; 303(3):242-9.
- U.S. Department of Health and Human Services (1996). The U.S. Surgeon General's Report on Physical Activity and Health. (SN 017-023-00196-5).
- U.S. Department of Health and Human Services (2008). 2008 Physical Activity Guidelines for Americans. ODPHP Publication No. U0036.

2. EQUIPMENT AND SUPPLIES

The equipment and supplies used in the Physical Activity Monitor (PAM) component are described below:

2.1 Equipment

- Multiport USB hub
- USB cables for USB port hub
- Dymo label printer
- Red triangular plastic tool
- Metal Lufkin tape measure
- Plastic containers for PAM storage and faulty PAMs
- Plastic bin for each wrist strap size

2.2 Supplies

- Actigraph GT3X-plus monitors: According to the manufacturer, the monitor measures 1.81" x 1.33" x 0.6", and weighs approximately 19 grams. The case is water resistant to 1 meter for up to 30 minutes. The rechargeable lithium ion battery provides power for 10 days between charges.
- Wrist straps in six sizes
- Alcohol pads
- 2 X 2 inch gauze pads
- Dymo labels 1inch x 1inch
- Physical Activity Monitor Information and Instructions Sheet as a color print
- PAM Description and Photo Sheet
- 6" X 8 ¾ " yellow self-sealing bubble padded mailer with business reply postage and fragile label pre-affixed

- Calendar
- Laminated PAM hand card talking points in English/Spanish/Chinese/Korean/
Vietnamese

2.3 Inventory Management

The PAM component will be managed by the health technologists. The par level is set at the following levels (see Exhibit 2-1).

Exhibit 2-1. PAM Inventory par levels

Equipment	SOS Count
Multi-port USB hub	3
USB cables	2
Power cord for USB hub	1
Red triangular plastic tool	5
Metal Lufkin tape measure	2
Dymo label printer	1
Supplies	
Actigraph GT3X-plus monitors	350
Storage box(for wriststraps and monitors)	10
Velcro Wrist straps in 6 sizes:	
8 inches	100
9 inches	200
10 inches	200
11 inches	100
12 inches	40
13 inches	15
Dymo labels 1inch x1inch	2
Alcohol pads	2 boxes
2 X 2 inch gauze pads	2 sleeves
PAM Kit: (assembled at warehouse):	350
1-Padded mailer with pre-affixed business reply postage and fragile labels	
2- Color Physical Activity Monitor Information and Instruction Sheet	
3-PAM Description and Photo Sheet	

2.4 PAM Room Set Up

2.4.1 Beginning of Stand Activities

After the inventory count has been verified, the component is readied for examinations by:

- Examining USB hub, confirm that the hub is connected to an electrical outlet.
- Inspect USB cables for cracks, tears, or exposed wires.

2.4.2 Charging the Actigraph Monitors

The Actigraph battery is charged by connecting the device to a standard USB port. Charging time will depend on the battery life, but typically will not exceed 4 hours for a fully depleted battery. Once the battery is completely charged (max voltage of approximately 4.18V), the LED light will remain illuminated. Exhibit 2-2 describes the indicator lights.

Twenty or more Actigraph monitors will be charged simultaneously on a multi-port USB hub. The monitors should be connected to the multi-hub USB port and be left to charge for at least 4 hours each day. This should occur during set up, and at the end of each examination day. Follow these steps:

1. According to the MEC SP appointment schedule, plan to charge at least 20 monitors per night; retrieve the monitors from the supply box.
2. Inspect each one for any broken or cracked cases, missing screws from the back plate, and broken or missing black discs or O rings.
3. Inspect each monitor for any flashing red or green lights.
4. Connect each monitor to a USB cable from the charging station. It should take 2-3 hours to charge the monitors, but it may require up to 4 hours if the battery is completely discharged.
5. The monitors should be left on the USB cables until ready for use.

Exhibit 2-2. LED indicator lights

Description of Actigraph LED Indicator Lights

Actigraph GT3X+ When <u>Connected</u> to the USB Hub and PC	
Red LED (Fault Indicator)	
2 Flashes	Li-Ion Battery is Faulty
Green LED	
1 Flash	Battery charging
Multiple Flashes	Communicating with PC via USB
Steady On	Battery Fully Charged
ActiGraph GT3X+ When <u>Not Connected</u> to PC	
Red LED (Faulty Indicator)	
No Flashing (LED Off)	Normal operating condition or battery dead
2 Flashes	Low Battery (use ActiLife Lifestyle software to check for remaining battery life) The unit needs to be recharged
3 Flashes	- Unexpected Battery Failure (Temporary battery power loss) or - Battery Level has fallen below 3.1V and the unit has entered Halt Mode
Green LED	
No Flashing (LED Off)	Actively collecting data ("Flash Mode" disabled) or battery dead
1 Flash	- Delay before start mode (the LED always flashes prior to starting data collection) - Actively taking data ("Flash Mode" enabled – not recommended)
2 Flashes	N/A
3 Flashes	- End of memory reached (Device no longer collecting data) - Battery died while unit was in delay before start mode (no data collected on device)

Updated 3-22-11

3. PROTOCOL

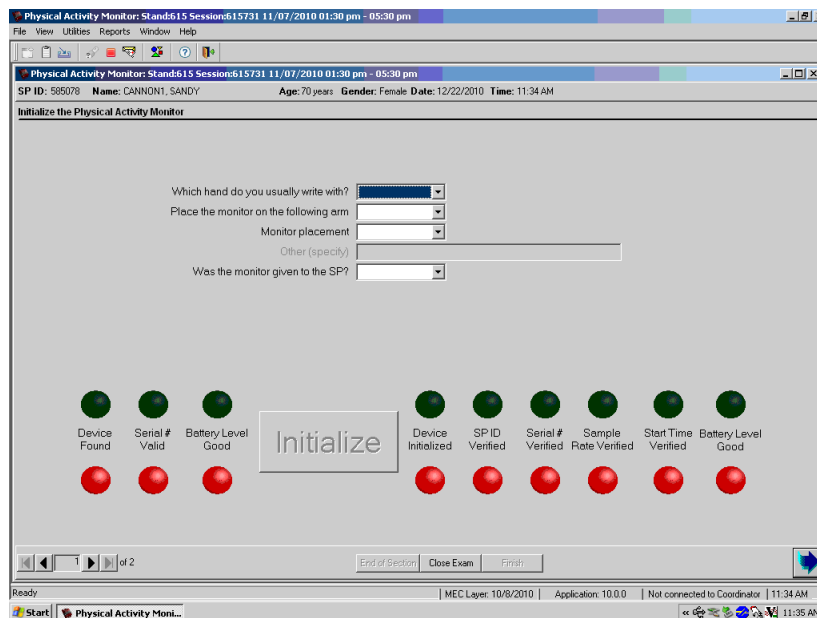
3.1 General Overview

All primary sample persons (SPs) ages 6 years and older are eligible for the physical activity monitor (PAM) component. Participants will wear the monitor on their wrist for a 7-day period. SPs will be fitted with the monitor before they leave the mobile examination center (MEC) and given instructions to take home. After the 7-day period is over, SPs will mail back the monitor in the postage-paid envelope provided. Parents or guardians of children ages 16 years and younger will be required to accompany children due to the detailed instructions for wearing the PAM and the mailing procedures.

3.2 Examination Procedures

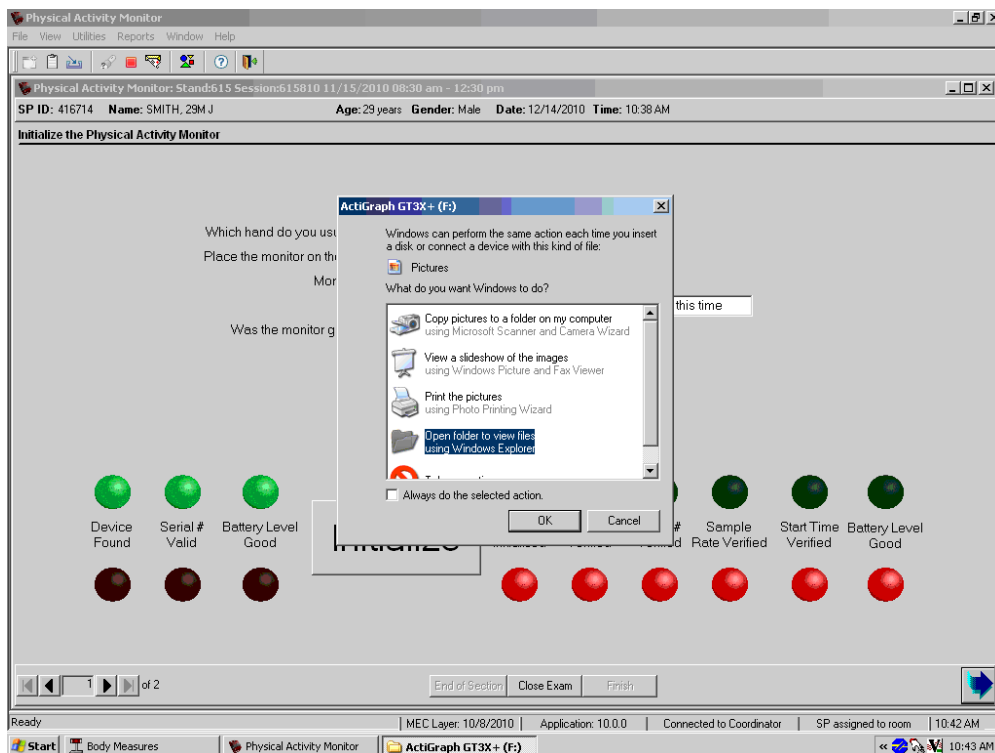
Open the PAM application and log the SP into the exam by scanning the barcode on the SP ID bracelet or manually type the SP ID when the SP arrives in the examination room. The following screen will appear. (Exhibit 3-1) Notice the dark green dots and the bright red dots on the bottom.

Exhibit 3-1. PAM screen after scanning SP ID



1. After the SP ID bracelet is scanned, select a fully charged monitor (solid LED light) from the multiport USB hub. Inspect the monitor for any cracks in the case, missing screws from the back plate, or for a broken or missing black disc or O ring. If the monitor is defective, place the monitor in the bin marked “faulty” and select another monitor from the hub. Make a note of the reason for the faulty monitor and attach it to the monitor.
2. Connect the monitor to the USB cable that is attached to the ISIS monitor. When the default Windows box, “ActiGraph GT3X+ (F:)” automatically appears, the “Open folder to view files using Windows Explorer” will be highlighted (Exhibit 3-2). Always click on the “Cancel” button to close this dialogue box. If the dialogue box does not come up at all, disconnect the monitor and reconnect another PAM to the ISIS monitor and wait for the box to pop up*.

Exhibit 3-2. Windows default screen with Actigraph GT3X+(F;) dialogue box



3. While waiting for the dialogue box to appear, introduce the component by using the suggested script below.

In this room I will tell you about the physical activity monitor. This wrist monitor records body movement of everyday activities such as walking. We ask that you wear this monitor for 7 full days, all day, everyday, even while bathing and sleeping. It is water resistant.

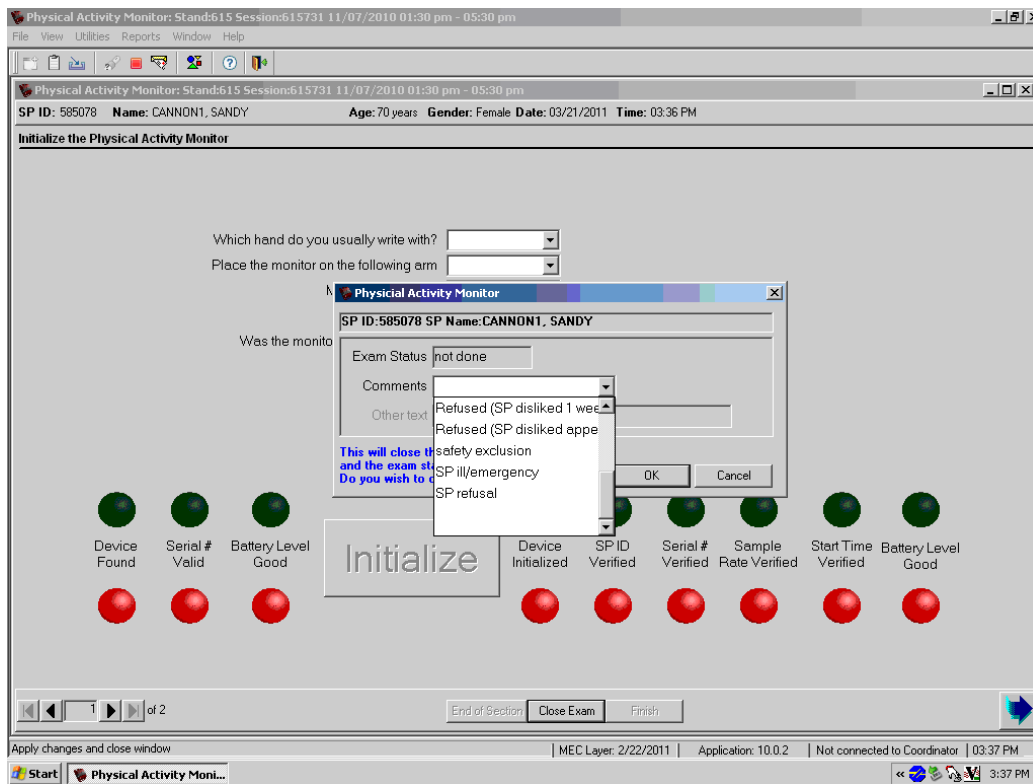
* The dialogue box may take a minute to come up, but do not initialize any monitors if this box fails to appear.

After the 7-day period is over, you will remove the monitor and mail it back in this postage-paid envelope. When we receive the monitor we will mail you a check for \$40. Is that okay?

If the SP agrees to participate, continue with the initialization procedures.

If the SP does not want to participate, click on “Close Exam,” and then select the appropriate comment under the “Comments” tab. See Exhibit 3-3. Disconnect the PAM from the USB cable and reconnect it to the multiport USB hub so it remains charged.

Exhibit 3-3. Screen when “Close Exam” button clicked with exam status and comment options



3.3 Procedures for Assigning a PAM to an SP

When the SP agrees to wear the activity monitor, the following steps are necessary.

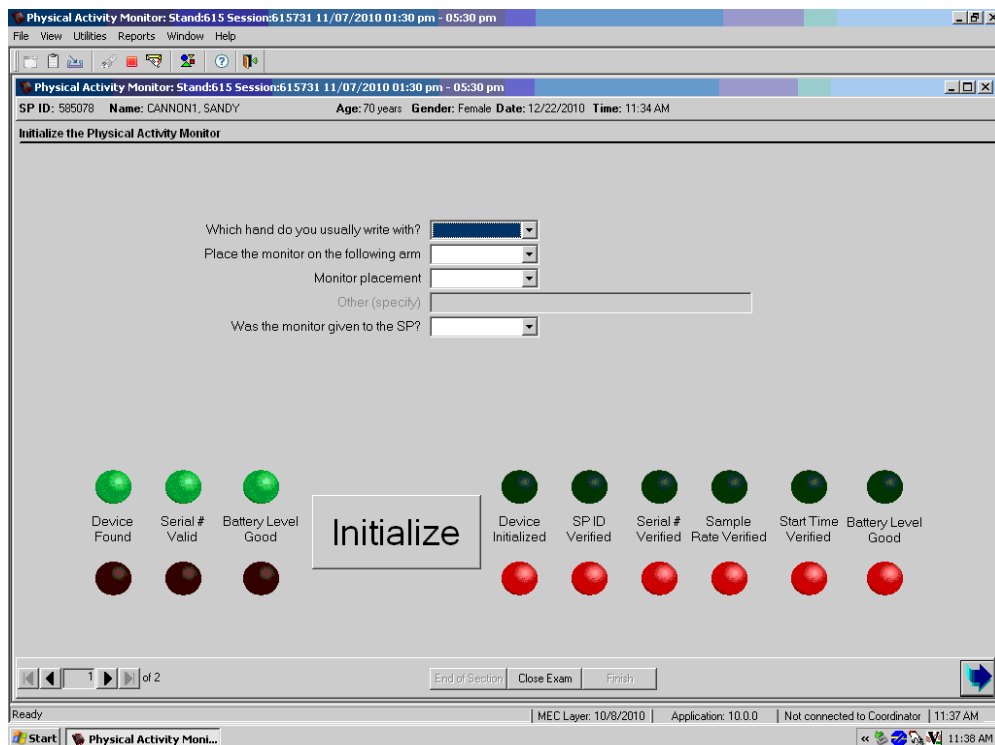
1. Initialization of the Actigraph physical activity monitor—this programs the monitor and assigns the SP ID number to the monitor;

2. Wrist selection and monitor placement- Fit a wrist strap to the SPs nondominant arm to apply the monitor;
3. Procedures for returning the monitor and review of written instructions; and
4. Completing the drop-down boxes at the top of the screen.

3.3.1 Initialization of the Actigraph Physical Activity Monitor

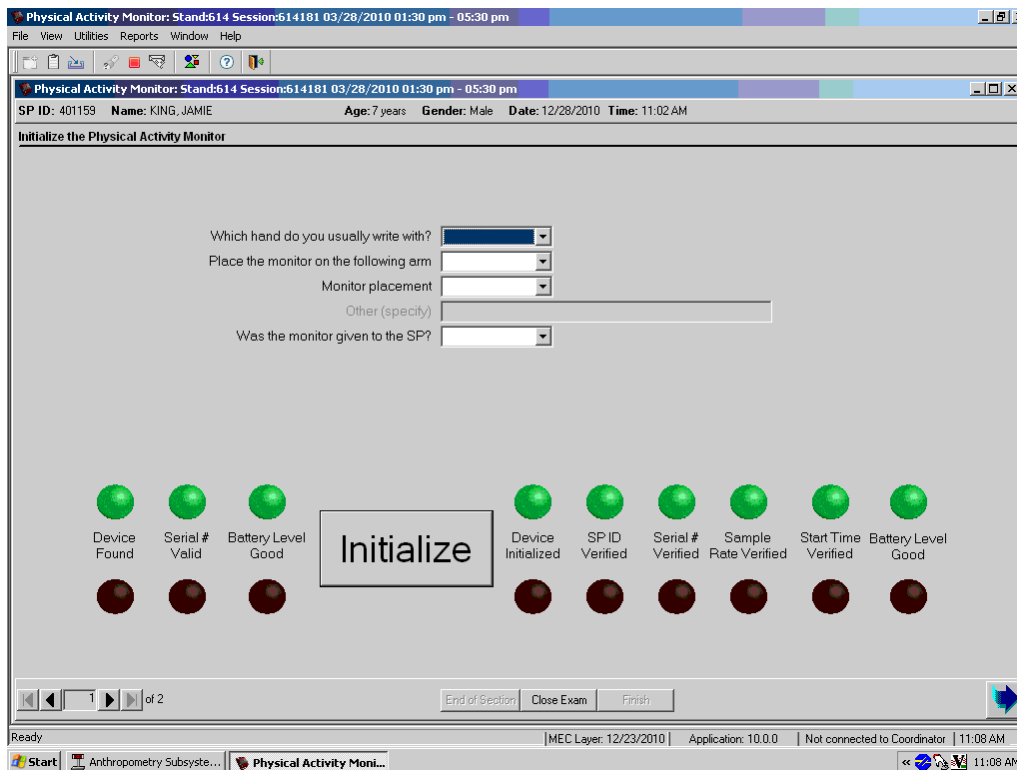
When the physical activity monitor is connected to the computer monitor, the application will recognize the device and start its process of internal system checks. The application is testing the activity monitor to verify that the serial number is recognized and valid, and if the battery level is sufficient to record data for 7 days. If the monitor meets these criteria, the first three green dots to the left of the “Initialize” button will brighten to a light green, and the first three red dots below the green dots will darken. The initialize button will also be highlighted signaling the monitor is ready to be initialized (Exhibit 3-4). For LED light activity on the PAM unit, refer to Exhibit 2-2 in Chapter 2.

Exhibit 3-4 Screen showing Initialized button after PAM is connected to ISIS monitor



1. Before initialization, make sure the Windows dialogue box has come and has been canceled. Click on the “Initialize” button; the initialization should only take a few seconds to complete. When the remaining (6) green dots have brightened and the remaining red dots have darkened in color, the initialization process of the monitor is complete (Exhibit 3-5).

Exhibit 3-5. Screen after monitor initialization with all green dots brightened and red dots darkened.



2. Disconnect the PAM monitor from the USB cable. It is important to note that after the monitor has been successfully initialized, the “Initialize” button will remain highlighted. This allows another monitor to be initialized in case the first one is found to be technically or structurally faulty.
 - a. If the remaining dots to the right of the Initialize button fail to turn bright green and the red dots do not darken, unplug the monitor and place it in the bin marked “faulty” with a note stating the problem. Select another monitor from the charge station and connect it to the USB cable. Follow the same steps as above. The application will allow the initialization of as many monitors that are required to obtain a properly functioning monitor.
 - b. After the monitor has been initialized, unplug it from the USB cable. A single flashing green LED light will appear, and continue to flash until the monitor is ready to collect data. The data collection period will start at the END of the

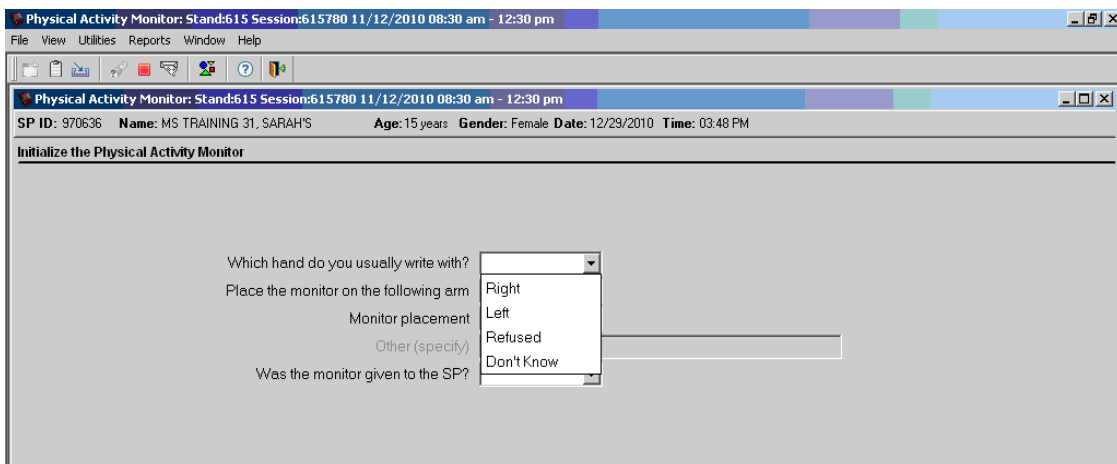
SP's scheduled session; at that time no visible LED light should be displayed on the monitor.

- c. A Dymo label will print from the printer with the SP's ID and their assigned symbol. Place the label on the back of the monitor and explain to the SP that this is their symbol to distinguish their monitor from other household members with the same physical activity monitor.
- d. Show the inside of the monitor to the SP, and instruct them not to plug the monitor into any electrical or computer cord. Use the red triangular plastic tool to seal the monitor. Gently turn the black disc for one and a half rotations only; over-tightening the black disc may create extra tension causing the disc to break away from the monitor. If the black disc breaks or is defective place it in the "faulty" bin and select another monitor to initialize. Make sure to note why the monitor is labeled as "faulty".

3.3.2 Wrist Selection and Monitor Placement

The physical activity monitor should be placed on the SP's **nondominant** arm, i.e., the arm used less frequently. Most people tend to typically write with their dominant hand: therefore in order to determine the **nondominant** arm, ask the SP "Which hand do you usually write with?" Enter the SP's response in the drop-down box (Exhibit 3-6).

Exhibit 3-6. Drop-down box with options to determine dominant arm



- If the SP answers “right,” the **nondominant** arm will be the left; if the SP answers “left,” the **nondominant** arm will be the right.
- If the SP does not know or refuses the question, by default the monitor should be placed on the left arm of the SP.
- If the SP is unable to have the monitor placed on the **nondominant** arm, place it on the dominant arm. Some of the reasons for placing the monitor on the dominant arm may include:
 - SP has one arm;
 - SP has a cast, injury, or other health concern on the **nondominant** arm;
 - SP wears a watch, jewelry, or wrist device that is not removable on their **nondominant** arm; and
 - SP is only willing to participate if the monitor is on the dominant arm.

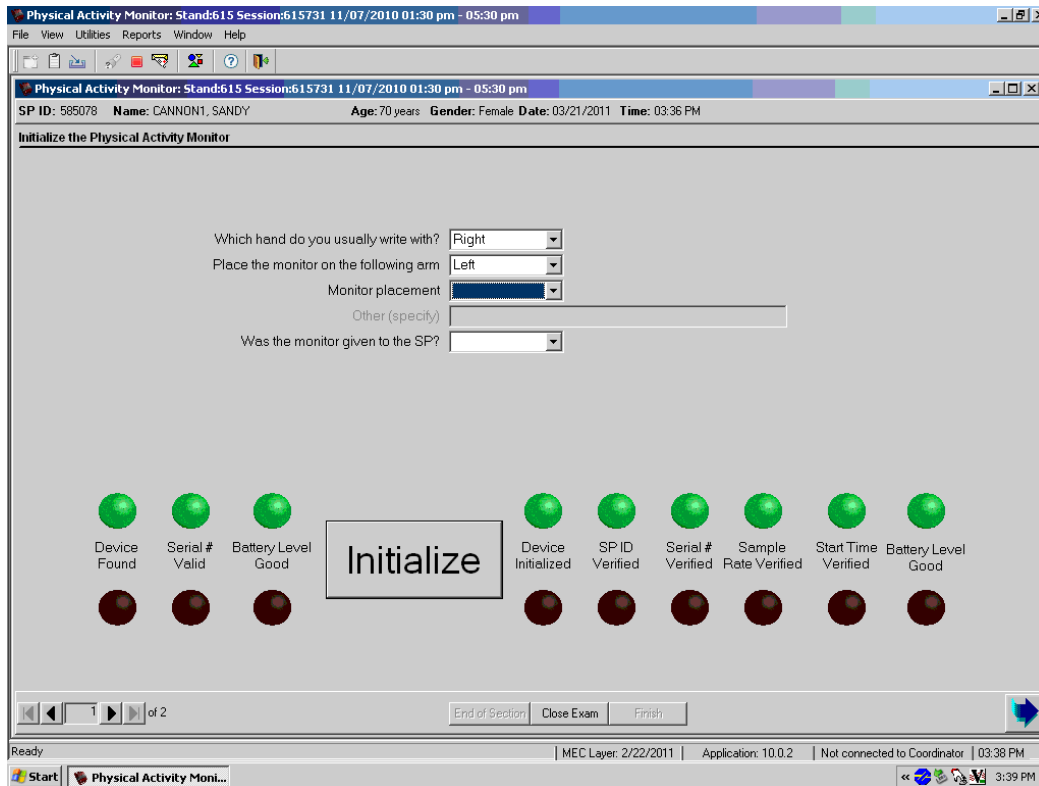
NOTE: If the SP has a prosthetic arm, the monitor may be placed on that device if it is the **nondominant** arm.

The second data entry field (Exhibit 3-7), “Place the monitor on the following arm” will automatically be prefilled by ISIS based on the SP’s response to the first question, “Which hand do you usually write with?” See Table 3-1. If the monitor is placed on the dominant or opposite arm, make sure to change the drop-down box with the correct data entry field.

Table 3-1. Placement of PAM on dominant arm

If the dominant arm is:	Place the monitor on the:
Right	Left
Left	Right
Refused	Left
SP Does not know	Left

Exhibit 3-7. Prefilled box for nondominant arm selection



3.3.2.1 Fitting the SP With the Wrist Strap

- If the SP has a watch, jewelry, or any other device on the arm selected for the monitor placement, ask the SP to remove these items and place them in the empty container provided. They may wear them on the other arm or put them back on the same arm after the physical activity monitor has been fitted.
- Use the metal Lufkin tape to measure the SP's wrist in centimeters. Measure the wrist a couple of centimeters above the wrist bone. From the table below (Table 3-2), select the appropriate strap size for the SP.[†]

[†] The ranges listed in the table are estimates; therefore a larger or smaller wrist strap may be used if necessary.

Table 3-2. PAM Wrist Strap Size Chart

Wrist Measurement (cm)	Wrist Strap Size
< 13.3 cm	8 inch strap
13.4 – 15.7 cm	9 inch strap
15.8 – 18.0 cm	10 inch strap
18.1 – 20.9 cm	11 inch strap
21.0 – 23.9 cm	12 inch strap
> 24 cm	13 inch strap

- Make sure to clean the metal Lufkin tape with an alcohol swab and dry with a piece of gauze after each use.
- Select the appropriate strap size, and attach it to the monitor by threading the Velcro strap with the fuzzy side up through the side loops of the monitor. The strap should thread underneath so that the back of the monitor is lying on top of the fuzzy side of the strap, and the logo and phone number are visibly displayed on the PAM monitor. See Figure 3-1.



Figure 3-1. Threading the wrist strap through the PAM

3.3.2.2 Fitting the SP With the Monitor

- Place the monitor on the dorsal side (top of the arm) of the SP's designated wrist, similar to wearing a watch with the black disc facing toward the fingers. Note, if the monitor is placed on the SP's right arm, the monitor's appearance will seem

backwards, however this IS the correct placement. The logo and phone number should be upside down if the monitor is placed on the right arm.

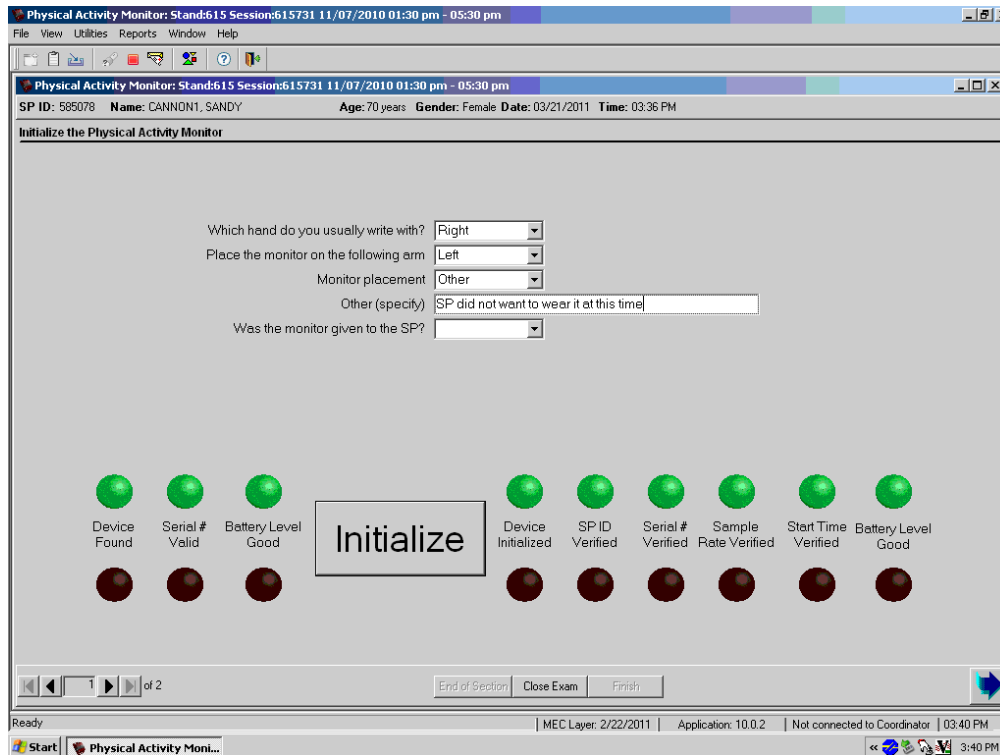
- The monitor should fit snugly on the SP's wrist so there is no loose movement, but not too tight where it restricts blood flow, causes redness, or discomfort. **Make sure the SP is comfortable with the placement.** If the SP is not comfortable with the placement, adjust the strap to either loosen the fit or tighten the fit as long as the physical activity monitor does not move freely on the SP's arm. Keep in mind comfort equals compliance.
- The dorsal side is the preferred side for the placement of the monitor, however if the SP insists on wearing it on the palmar side of the wrist make sure to capture the correct orientation of the monitor placement in the third drop-down box in the ISIS application. See Exhibit 3-8.

Exhibit 3-8. Options for monitor placement on selected arm

The screenshot shows the 'Physical Activity Monitor' software interface. At the top, the window title is 'Physical Activity Monitor: Stand:615 Session:615731 11/07/2010 01:30 pm - 05:30 pm'. Below the title bar, there is a menu bar with 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main content area displays the following information: 'SP ID: 585078', 'Name: CANNONI, SANDY', 'Age: 70 years', 'Gender: Female', 'Date: 03/21/2011', and 'Time: 03:36 PM'. Below this, the text 'Initialize the Physical Activity Monitor' is displayed. The interface contains several dropdown menus: 'Which hand do you usually write with?' (set to 'Right'), 'Place the monitor on the following arm' (set to 'Left'), and 'Monitor placement' (set to 'Dorsal'). A text input field for 'Other (specify)' is also present. Below these, a question asks 'Was the monitor given to the SP?'. At the bottom of the main area, there is an 'Initialize' button. To the left of the button are three green circles labeled 'Device Found', 'Serial # Valid', and 'Battery Level Good'. To the right of the button are six green circles labeled 'Device Initialized', 'SP ID Verified', 'Serial # Verified', 'Sample Rate Verified', 'Start Time Verified', and 'Battery Level Good'. Below the main area, there is a navigation bar with 'End of Section', 'Close Exam', and 'Finish' buttons. The Windows taskbar at the bottom shows the system tray with the time '03:39 PM' and the date '2/22/2011'.

- The SP may also choose to take the monitor with them and put it on later. If the monitor was not placed on the SP, then select “Other” under “Monitor Placement” and type the reason why the monitor was not placed on the SP. See Exhibit 3-9.

Exhibit 3-9. Screen of “Other” for monitor placement with comment



3.3.3 Procedures for Returning the Monitor and Review of Written Instructions

- Grab a padded envelope from the holder on the wall and remove the PAM Information and Instruction Sheet (purple writing) and the PAM Description and Photo. On the PAM Information and Instructions sheet, fill in the day and time when the SP can remove the monitor. The SP should remove the monitor on the morning AFTER the seventh day of their MEC appointment.

For example, if the SP’s MEC appointment is Thursday, Feb 10, 2011 regardless of their session, the date filled in should be Friday, Feb 18, 2011.

Instruct the SP to remove the monitor on the morning of their calculated date and to place the monitor in the postage-paid padded envelope provided and drop in any U.S. postal mailbox.

- From the PAM Information and Instructions sheet, review the additional points listed below with the SP.
 - It is not a tracking device, nor does it record heart rate.
 - When the monitor and wrist strap get wet, you may blot them dry with a towel.

- Keep it away from small children(less than 6 yrs) and pets.
 - If you do get questioned about the monitor at school, camps, or places of employment, you may show them the PAM Description and Photo sheet.
 - After your 7 day period is over, remove and discard the Velcro wrist strap. Mail back only the monitor.
 - If you have any questions about the monitor, call the toll free number at the bottom of the sheet.
- Place the two PAM sheets back in the padded envelope. Write the SP's name on a Post-it note and place on the padded envelope to give to the coordinator after completing the exam. Explain to the SP the padded envelope with the instruction sheets will placed in their report of findings envelope and given to them when they leave the MEC.
 - At this time, make sure to return any jewelry or items that were removed from the designated arm to the SP if not already done.

3.3.4 Completing the Remaining Drop-Down Boxes in the ISIS Application

The last question in the application asks whether the SP was given a physical activity monitor.

- If the SP leaves with the monitor placed on their wrist, select "Yes."
- If the SP decides to take the monitor with them and put it on later, select "Yes."
- If the SP decides not to take the monitor, then select "No."

A pop up message will appear stating, "The monitor was already initialized for the SP. Are you sure that you want to indicate that you did not give them one?" See Exhibit 3-10. Select "Yes." After clicking "Yes," the "Initialize" button will be grayed out and the last six green dots will darken and the red dots will brighten. See Exhibit 3-11.

Exhibit 3-10. Screen with pop-up box if monitor not given after initialization

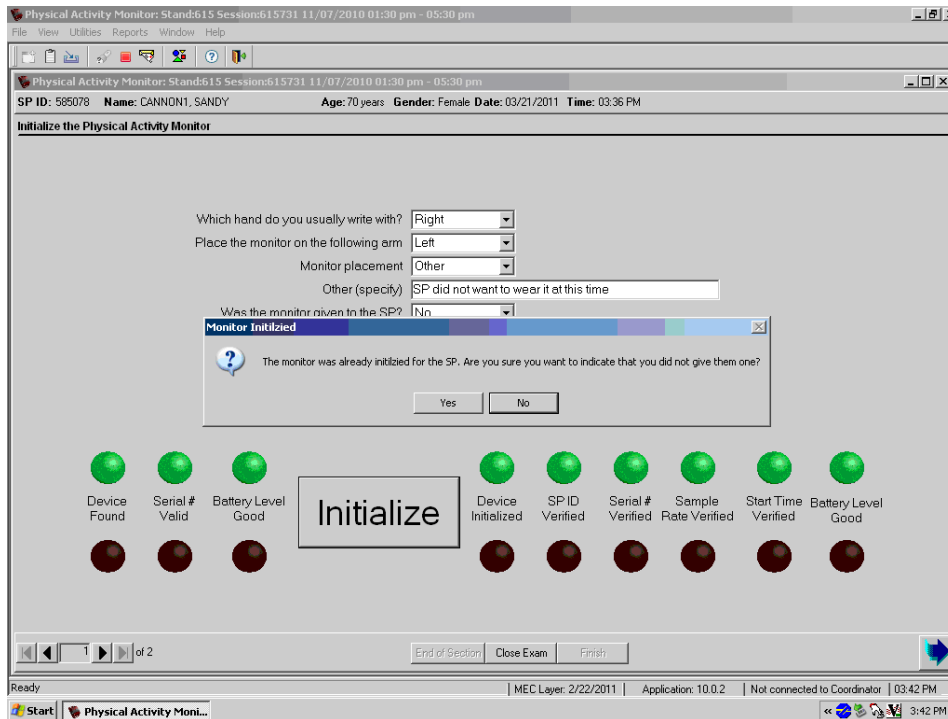
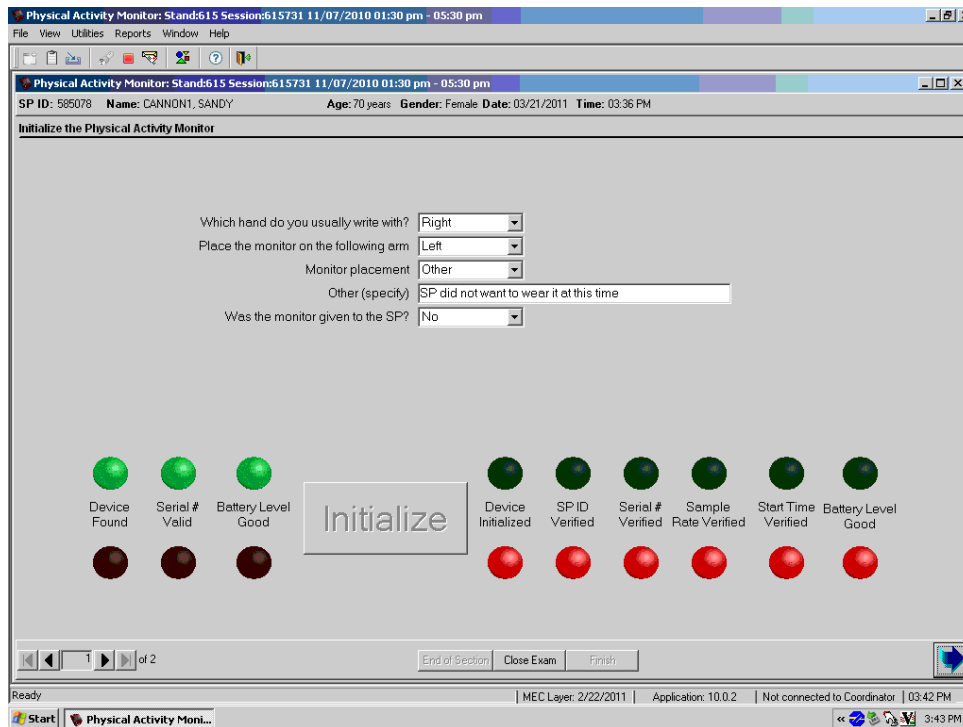


Exhibit 3-11. Screen after monitor not given to SP with “Initialize” button not highlighted



Click on the bottom right arrow to move to the next screen for the exam status. If the SP was given a monitor, then the exam status will be coded as “Complete.” If the SP was not given a monitor, then the exam status will be coded as “Not Done.” Select the appropriate option under the Comments box if the exam was “Not Done.”

These options may include:

- Communication problem;
- Equipment failure;
- Interrupted;
- Language Barrier;
- No time;
- Other, Specify;
- Physical limitation;
- Safety exclusion;
- SP ill/emergency;
- Refusal (SP disliked 1 week commitment);
- Refusal (SP disliked appearance of PAM); and
- Refused (SP did not specify reason).

Appendix A

Physical Activity Monitor Description and Photo – English and Spanish

PHYSICAL ACTIVITY MONITOR DESCRIPTION AND PHOTO

The Centers for Disease Control and Prevention (CDC) conducts the National Health and Nutrition Examination Survey (NHANES) to study the health of the U.S. population. As part of this study, a group of survey participants will wear a physical activity monitor **on the wrist**. A picture of the monitor is shown below. The activity monitor records body movements during normal daily activities such as walking or jogging. The activity monitor records no other information except light and time of day. Its battery life is 10 days. It is water resistant up to 1 meter for 30 minutes.



Photograph of the NHANES Physical Activity Monitor

The monitor is manufactured by Actigraph of Pensacola, Florida. The monitor is safe, durable, and comfortable to wear. A single polymer lithium ion (3 Volt) battery powers the monitors. The NHANES Ethics Review Board reviewed the survey procedures and equipment for safety.

Survey participants will wear the activity monitor 24 hours a day for 7 days while sleeping and awake, including activities related to school, camp, or work whenever possible. The monitor can be worn while in the bath, shower, or when swimming. If it must be removed for any reason, simply reattach the monitor to the wrist as soon as possible.

If you have additional questions please call the NHANES Survey Toll-Free Information Line Number: 1- 888-458-4762

DESCRIPCIÓN Y FOTO DEL MONITOR DE ACTIVIDAD FÍSICA

Los Centros para el Control y la Prevención de Enfermedades (CDC, por sus siglas en inglés) llevan a cabo la Encuesta Nacional de Examen de Salud y Nutrición (NHANES, por sus siglas en inglés) para estudiar la salud de la población en Estados Unidos. Como parte de este estudio, un grupo de participantes en la encuesta usará un monitor de actividad física **en la muñeca**. A continuación verá una foto del monitor. El monitor graba los movimientos del cuerpo durante actividades cotidianas como caminar o trotar. La única información que el monitor graba es la hora del día y las condiciones de luz. La pila dura 10 días. El monitor es resistente al agua hasta profundidades de 1 metro, durante 30 minutos.



Foto del monitor de actividad física para NHANES

El fabricante del monitor es Actigraph en Pensacola, Florida. El monitor es seguro, durable y cómodo para usar. El monitor funciona con una pila de ión de litio (3 voltios). La Junta Directiva de Ética de NHANES revisó la seguridad de los procedimientos y el equipo de la encuesta.

Los participantes de la encuesta usarán el monitor de actividad 24 horas al día durante 7 días mientras están dormidos y cuando están despiertos y se incluirán actividades relacionadas con la escuela, campamentos o el trabajo cuando sea posible. El monitor se puede usar cuando la persona se está bañando o si va a nadar. Si por alguna razón debe quitárselo, simplemente vuélvalo a poner en la muñeca tan pronto como sea posible.

Si tiene alguna pregunta, puede llamar gratis a la línea de información sobre la encuesta NHANES al 1-888-458-4762.

Appendix B

Physical Activity Monitor Information and Instructions – English and Spanish



PHYSICAL ACTIVITY MONITOR INFORMATION & INSTRUCTIONS

PLEASE REMOVE THE MONITOR ON _____.

➤ **What is an activity monitor?**

An activity monitor is a small device that records information about body movement during everyday activities such as walking. The monitor is safe, and uses a battery similar to a watch battery for power. It is **not** a GPS tracking device, nor does it record heart rate. Many studies with children and adults have used activity monitors.

➤ **What am I supposed to do with the activity monitor?**

The monitor will start recording data today after you leave the Mobile Exam Center.

1. We ask that you wear the monitor for 7 days, all day and night. It is worn on the wrist like a watch and should fit snugly around your wrist.
2. The monitor is water resistant so it can be worn when taking a bath, shower, or swimming. If the monitor and wrist strap get wet you may blot them dry with a towel.
3. If you must take the monitor off for any reason, remember to put it back on the same wrist as soon as possible with the black disk facing toward the fingers.
4. If the monitor is removed, please keep it away from small children (less than age 6) and pets to avoid accidents.
5. Do not plug the monitor into any electrical or computer cord.

➤ **What do I do after I have worn the monitor for 7 days?**

At the end of the 7-day period mail back the monitor only. Remove and discard the strap from the monitor, and then place the monitor in the postage-paid padded envelope that you were given. Drop the envelope in any United States Postal Service mailbox as soon as possible. When we receive the monitor we will mail you a check for \$40. If the monitor is not returned, you will not be paid.

➤ **What if I get questioned about the monitor?**

A separate document, the Physical Activity Monitor Description and Photo page, is included in case you need to provide schools, camps, or places of employment with information about the monitor. If questioned about the monitor when passing through metal detectors at airports and work sites, please show the description to security personnel. If a security guard insists that you remove the monitor, simply reattach it to the same wrist after passing through the security checkpoint.

➤ **Who do I contact if I have questions?**

If you have any questions about the monitor, please call our office at the toll-free number **1-888-458-4762**, which is also printed on the monitor.



PHYSICAL ACTIVITY MONITOR INFORMATION & INSTRUCTIONS

POR FAVOR QUÍTESE EL MONITOR EL _____.

➤ **¿Qué es un monitor de actividad?**

Un monitor de actividad es un pequeño aparato que graba información del movimiento del cuerpo durante actividades cotidianas, como caminar. El monitor es seguro. Funciona con pilas similares a las de un reloj. **No** es un sistema de posicionamiento global (GPS) ni tampoco graba la frecuencia cardíaca. Muchos estudios con niños y adultos han usado monitores de actividad.

➤ **¿Qué es lo que debo hacer con el monitor de actividad?**

El monitor comenzará a grabar información hoy después de que usted se vaya del Centro Móvil de Examen.

1. Le pedimos que use el monitor durante 7 días, durante todo el día y toda la noche. El monitor se usa en la muñeca, como un reloj y se debe ajustar bien a la muñeca.
2. Es resistente al agua así que no es necesario que se lo quite para darse un baño, ducharse o si va a nadar. Si el monitor y la pulsera se mojan, simplemente puede secarlos con una toalla.
3. Si por alguna razón se tiene que quitar el monitor, recuerde volver a ponérselo en la misma muñeca tan pronto como sea posible. Póngaselo de modo que el disco negro le quede apuntando hacia los dedos.
4. Si se quita el monitor, para prevenir accidentes manténgalo fuera del alcance de los niños pequeños (menores de 6 años) y de las mascotas.
5. No enchufe/conecte el monitor a ningún cable eléctrico o de computadora.

➤ **¿Qué debo hacer después de haber usado el monitor durante 7 días?**

Al final de los 7 días, envíe por correo únicamente el monitor. Quítele la pulsera y ponga el monitor en el sobre acolchonado con envío pre-pagado que le dieron. Ponga el sobre en cualquier buzón del Servicio Postal de Estados Unidos lo más pronto posible. Cuando recibamos el monitor, le enviaremos por correo un cheque por 40 dólares. Si no envía el monitor, no recibirá el pago.

➤ **Y, ¿si me preguntan sobre el monitor?**

Adjunto encontrará otro documento con la Descripción y Foto del Monitor de Actividad Física, en caso de que necesite dar información sobre el monitor a escuelas, campamentos o lugares de trabajo. Si al pasar por un detector de metal en un aeropuerto o lugar de trabajo, le preguntan sobre el monitor, por favor muéstrela al personal de seguridad la descripción del monitor. Si un guardia de seguridad insiste en que debe quitarse el monitor, simplemente se lo puede volver a poner en la misma muñeca después de pasar por el punto de seguridad.

➤ **¿Con quién me puedo comunicar si tengo preguntas?**

Si tiene alguna pregunta, llame gratis al número **1-888-458-4762**. El monitor también lleva impreso este número.

Appendix C

PAM Wrist Strap Size Chart

PAM Wrist Strap Size Chart

Wrist Measurement (cm)	Wrist Strap Size
< 13.3 cm	8 inch strap
13.4 – 15.7 cm	9 inch strap
15.8 – 18.0 cm	10 inch strap
18.1 – 20.9 cm	11 inch strap
21.0 – 23.9 cm	12 inch strap
> 24 cm	13 inch strap

Appendix D

Physical Activity Monitor Spanish Scripts

PHYSICAL ACTIVITY MONITOR
SPANISH SCRIPTS

In this room I will tell you about the physical activity monitor. This wrist monitor records body movement of everyday activities such as walking. We ask that you wear this monitor for 7 full days, all day everyday even while bathing and sleeping. It is water resistant. After the 7 day period is over, you will remove the monitor and mail it back in this postage paid envelope. When we receive the monitor we will mail you a check for \$40. Is that okay?

En esta habitación le hablaré acerca del monitor de actividad física. El monitor de pulsera registra los movimientos del cuerpo al hacer sus actividades diarias, tal como caminar. Le pedimos que use este monitor durante 7 días completos, es decir todo el día cada uno de los 7 días, incluso mientras se baña y duerme. Es resistente al agua. Después de terminar el periodo de 7 días, quítese el monitor y mándelo por correo en este sobre pre-pagado. Cuando recibamos el monitor le mandaremos un cheque por 40 dólares. ¿Está bien?

If you do have to take the monitor off for any reason, just make sure you put it back on (1) as soon as possible, (2) on the same wrist, and (3) with the black disc facing toward the fingers.

Si tiene que quitarse el monitor por cualquier motivo, simplemente asegúrese de ponérselo nuevamente (1) tan pronto como sea posible, (2) en la misma muñeca y (3) con el disco negro apuntando hacia los dedos.

PHYSICAL ACTIVITY MONITOR
SPANISH SCRIPTS

- it is not a tracking device, nor does it record heart rate*
- when the monitor and wrist strap get wet, you may blot it dry with a towel*
- keep it away from small children and pets*
- do not plug the monitor into any electrical or computer cord*
- if you do get questioned about the monitor at school, camps, or places of employment, you may show them the PAM description and photo sheet (show it to the SP)*
- after your 7 day period is over, remove and discard the Velcro strap. Place the monitor in the postage paid padded envelope and drop it in any mailbox. Mail back **only** the monitor*
- if you have any questions about the monitor call the toll free number at the bottom.*

- este no es un aparato de rastreo, ni registra los latidos del corazón*
- cuando el monitor y la pulsera se mojan, los puede secar suavemente con una toalla*
- manténgalo fuera del alcance de niños pequeños y de mascotas*
- no enchufe/conecte el monitor a ningún cable eléctrico ni de computadora.*
- si le hacen preguntas acerca del monitor en la escuela, campamentos o lugares de trabajo, puede mostrar la hoja de descripción y foto del monitor de actividad física (show it to the SP)*
- al terminar el periodo de 7 días, desprenda y deseche la pulsera de Velcro. Ponga el monitor en el sobre acolchonado con envío pre-pagado y póngalo en cualquier buzón de correo. Mande **únicamente** el monitor.*
- si desea hacer alguna pregunta acerca del monitor, llame al número gratis que hay a continuación.*