



National Health and Nutrition Examination Survey (NHANES)

National Youth Fitness Survey (NYFS)
Physical Activity Monitor (PAM)
Procedures Manual



January 2012



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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).¹

NHANES data have been used to examine physical activity levels and compliance with physical activity recommendations. Self-reported physical activity information has been collected in all NHANES using questionnaires. Objective measurements of movement using a physical activity monitor (PAM) were included in NHANES 2003–2006. NHANES participants 6 years of age and older were asked to wear a small accelerometer device on a waist belt for 7 days. Results from the NHANES 2003–2004 accelerometry component were published in 2007 and provided a different picture of the activity levels of the U.S. population compared to the questionnaire data.² Forty-two percent of children ages 6–11 years met the recommendation to obtain at least an hour of physical activity on most days of the week, whereas only 8 percent of adolescents ages 12–19 years achieved this goal.

A physical activity monitors (PAM) or accelerometer will be used to monitor the physical activity levels of participants by recording body movement during everyday activities such as walking. While a PAM for measuring physical activity is currently being fielded for ages 6 years and older in NHANES, a number of studies have found the accelerometer to be a valid tool for measuring physical activity in children as young as 3 years.³⁻⁵

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.

1.3 Eligibility

All participants ages 3-15 years are eligible for the PAM component. Participants who are missing arms bilaterally will be excluded since it will not be possible to attach the monitor to the wrist. Individuals who use canes, walkers, or wheelchairs are eligible for this component. There is no reason to exclude mentally impaired or handicapped individuals who have assistance with their monitors from a parent/guardian because there is no contraindication.

1.4 Risks

The PAM is powered by a 4-volt watch battery, which does not present a shock hazard when worn in a wet environment. It does not emit radiation, electrical current, vibration, or heat and it can be worn under shirt or coat sleeves without causing discomfort. The lithium battery is housed securely inside the device.

Possible risks include accidental swallowing of the monitor. However, the dimensions of the monitor are 1.8 in long x 1.3 in diameter x a depth of 0.6 in, difficult for a young child to swallow. Safety concerns have not been reported from studies in which the accelerometer has been worn by children ages 3-5 years. 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 PAM parts (including the batteries) are either in sealed compartments or require special tools to remove.

A 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 parents/guardians and participants.

1.5 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 NYFS participants 3-15 years of age using the Actigraph GT3X-plus Activity Monitor. The approximate amount of time required per person to explain the component and fit the activity monitor in the mobile center (MC) 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

1. U.S. Department of Health and Human Services (2008). *2008 Physical Activity Guidelines for Americans*. ODPHP Publication No. U0036.
2. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, and McDowell M. (2008). Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc*, 40, 181-8.
3. Vale SM, Santos RM, da Cruz Soares-Miranda LM, Moreira CM, Ruiz JR, and Mota JA. (2010). Objectively measured physical activity and body mass index in preschool children. *Int J Pediatr*, pii: 479439. Epub 2010, Jul 11.
4. Pfeiffer KA, Dowda M, McIver KL, and Pate RR. (2009). Factors related to objectively measured physical activity in preschool children. *Pediatr Exerc Sci*, 21, 196-208.
5. Pate RR, Almeida MJ, McIver KL, Pfeiffer KA, and Dowda M. (2006). Validation and calibration of an accelerometer in preschool children. *Obesity*, 14, 2000-6.

2. EQUIPMENT AND SUPPLIES

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

2.1 Equipment

- Multi-port USB hub
- USB cables for USB port hub
- Dymo label printer
- Red triangular plastic tool
- Metal Lufkin tape measure

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.
- Wrist straps in five sizes
- Alcohol pads
- 2 X 2 inch gauze pads
- Dymo labels 1inch x1inch
- Physical Activity Monitor Information and Instructions sheet as a color print (See Appendix A.)
- PAM Description and Photo sheet (See Appendix B.)
- 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 examiners. 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
Red triangular plastic tool	5
Metal Lufkin tape measure	2
Dymo label printer	1
Supplies	
Actigraph GT3X-plus monitors	120
Velcro Wrist straps in 5 sizes:	
8 inches	TBD
9 inches	TBD
10 inches	TBD
11 inches	TBD
12 inches	TBD
Dymo labels, 1inch x1inch	2
Alcohol pads	2 boxes
2 X 2 inch gauze pads	2 sleeves
PAM Kit: (assembled at warehouse):	120
(1) Padded mailer with pre-affixed business reply postage and fragile labels	
(2) Color Physical Activity Monitor Information and Instructions sheet	
(3) PAM Description and Photo sheet	
Calendar	1
Laminated PAM hand card talking points in English/Spanish/Chinese/Korean/Vietnamese	1

2.4 Exam Room Set Up

The PAM component, including supplies, is based primarily in the MC interview room. However, a small charging station and supply of wrist bands are kept at the coordinator's desk in order to facilitate the flow of activities when the interview room is being used for a dietary or MC interview. Exhibits 2-2 through 2-4 depict the set-up in both areas. The wrist bands are stored in the cabinet drawers under the charging station.

Exhibit 2-2. PAM set-up in interview room



Exhibit 2-3. PAM set-up at coordinator's desk

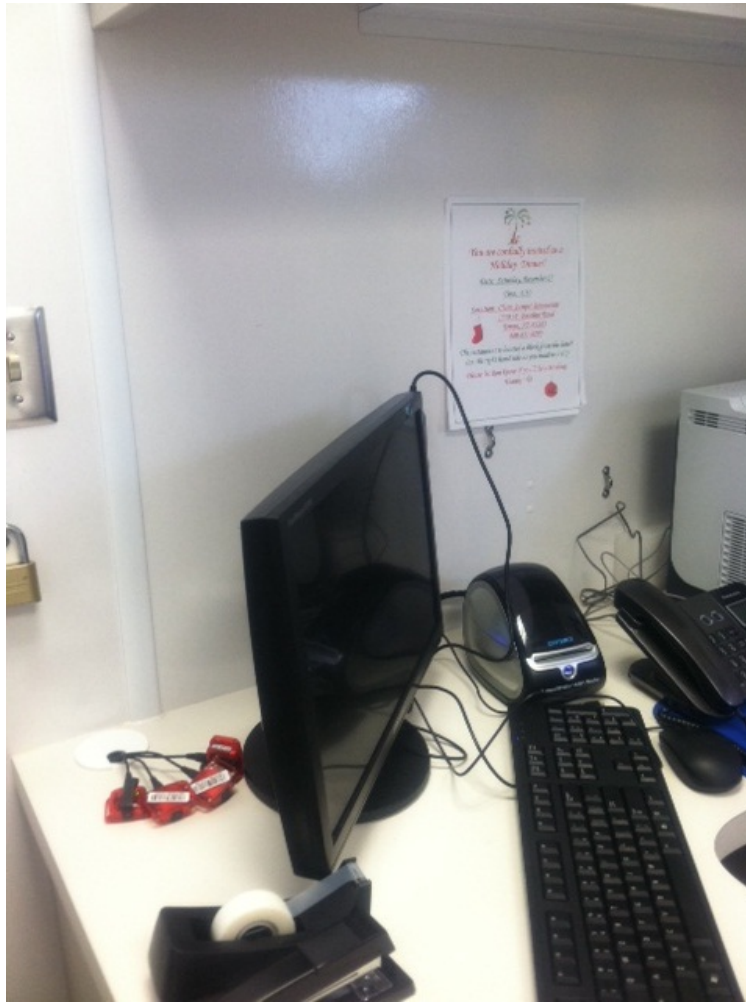


Exhibit 2-4. Small charging station under coordinator's desk



2.4.1 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 2-5 describes the 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
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)

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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 MC SP appointment schedule, plan to charge at least 20 monitors per night; retrieve the monitors from the supply box.
2. Inspect the USB cable for cracks, tears, or exposed wires.
3. Inspect each monitor for any broken or cracked cases, missing screws from the back plate, and broken or missing black discs or O rings.
4. Inspect each monitor for the flashing red light.
5. 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.
6. The monitors should be left on the USB cables until ready for use.
7. During a session, after a monitor has been used, connect another monitor to the charging station to maintain an adequate supply of charged monitors.

3. PROTOCOL

3.1 General Overview

All primary sample persons (SPs) ages 3-15 years 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 center and their parents/guardians will be given instructions to take home. After the 7-day period is over, SPs will mail back the monitor in the postage-paid envelope provided. Once the monitor has been returned, a remuneration check for \$40 will be mailed to the participant. Parents or guardians 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 finding their ID number from the drop down box, or scan the SPID barcode from the info sheet for that scheduled session. The following screen will appear. (Exhibit 3-1 and 3-2) Notice the dark green dots and the bright red dots on the bottom.

Exhibit 3-1. PAM screen after scanning SP ID for ages 3-5

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Initialize the Physical Activity Monitor

Is your child left or right-handed?

Which hand do they use more often when they are eating, drawing, and grabbing things?

Place the monitor on the following arm

Monitor placement

Other (specify)

Was the monitor given to the SP?

Device Found Serial # Valid Battery Level Good

Initialize

Device Initialized SP ID Verified Serial # Verified Sample Rate Verified Start Time Verified Battery Level Good

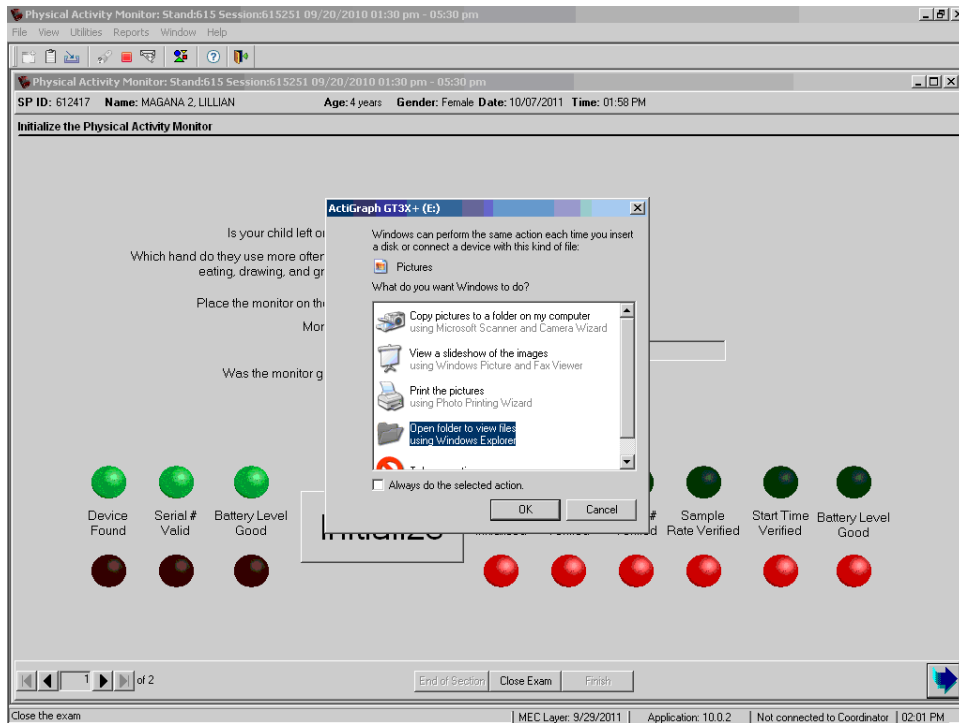
Ready MEC Layer: 9/29/2011 Application: 10.0.2 Not connected to Coordinator 01:57 PM

Exhibit 3-2. PAM screen after scanning SP ID for ages 6-15

1. After the SP ID has been 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. Fill out a defective monitor slip to note the reason for the faulty monitor and attach it to the monitor with a rubber band.
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 3-3). 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.¹

¹ The dialogue box may take a minute to come up, but do not initialize any monitors if this box fails to appear.

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



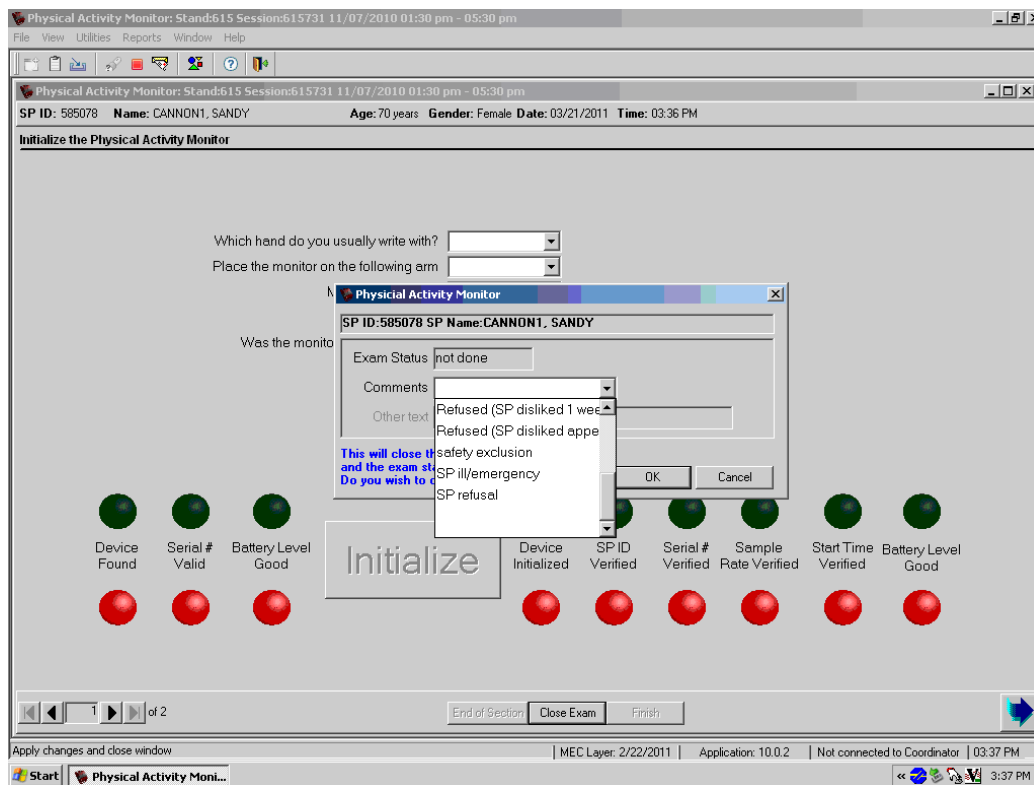
3. While waiting for the dialogue box to appear, introduce the component to the participant and the parent/guardian by using the suggested script below.

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, every day, 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?

If the SP and parent agree 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 3-4. Disconnect the PAM from the USB cable and reconnect it to the multiport USB hub so it remains charged.

Exhibit 3-4. 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 in the ISIS application.

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 3-5). For LED light activity on the PAM unit, refer to Exhibit 2-2 in Chapter 2.

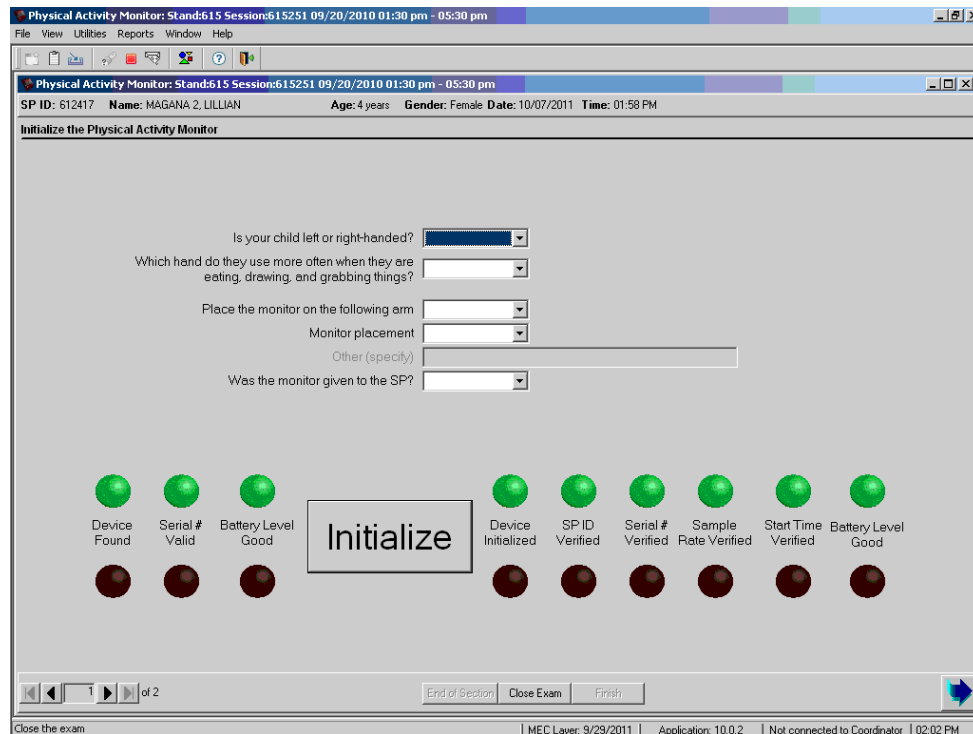
Exhibit 3-5. Screen showing Initialize button after PAM is connected to ISIS monitor

The screenshot displays the 'Physical Activity Monitor' software window. The title bar reads 'Physical Activity Monitor: Stand:615 Session:615251 09/20/2010 01:30 pm - 05:30 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window area shows patient information: 'SP ID: 612417', 'Name: MAGANA 2, LILLIAN', 'Age: 4 years', 'Gender: Female', 'Date: 10/07/2011', and 'Time: 01:58 PM'. Below this is the section 'Initialize the Physical Activity Monitor'. It contains several dropdown menus: 'Is your child left or right-handed?', 'Which hand do they use more often when they are eating, drawing, and grabbing things?', 'Place the monitor on the following arm', 'Monitor placement', 'Other (specify)', and 'Was the monitor given to the SP?'. In the center is a large 'Initialize' button. To the left of the button are three green dots, and below them are three red dots. To the right of the button are six green dots, and below them are six red dots. The status bar at the bottom shows 'Close the exam', 'MEC Layer: 9/29/2011', 'Application: 10.0.2', 'Not connected to Coordinator', and '02:02 PM'.

Device Found	Serial # Valid	Battery Level Good	Initialize	Device Initialized	SPID Verified	Serial # Verified	Sample Rate Verified	Start Time Verified	Battery Level Good
●	●	●	Initialize	●	●	●	●	●	●
●	●	●		●	●	●	●	●	●

1. Before initialization, make sure the Windows dialogue box has come up 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 3-6).

Exhibit 3-6. 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. The data collection period will start at the END of the SP’s scheduled session.

- 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 parents of the 3-5 year olds, "Is your child left or right-handed?" Enter the parent's response in the drop-down box (Exhibit 3-7). For SPs ages 6-15, ask them "Which hand do you usually write with?" Enter the SP's response in the drop-down box (Exhibit 3-8).

Exhibit 3-7. Drop-down box with options to determine dominant arm for ages 3-5

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Initialize the Physical Activity Monitor

Is your child left or right-handed?

Which hand do they use more often when they are eating, drawing, and grabbing things?

Place the monitor on the following arm

Monitor placement

Other (specify)

Was the monitor given to the SP?

Initialize

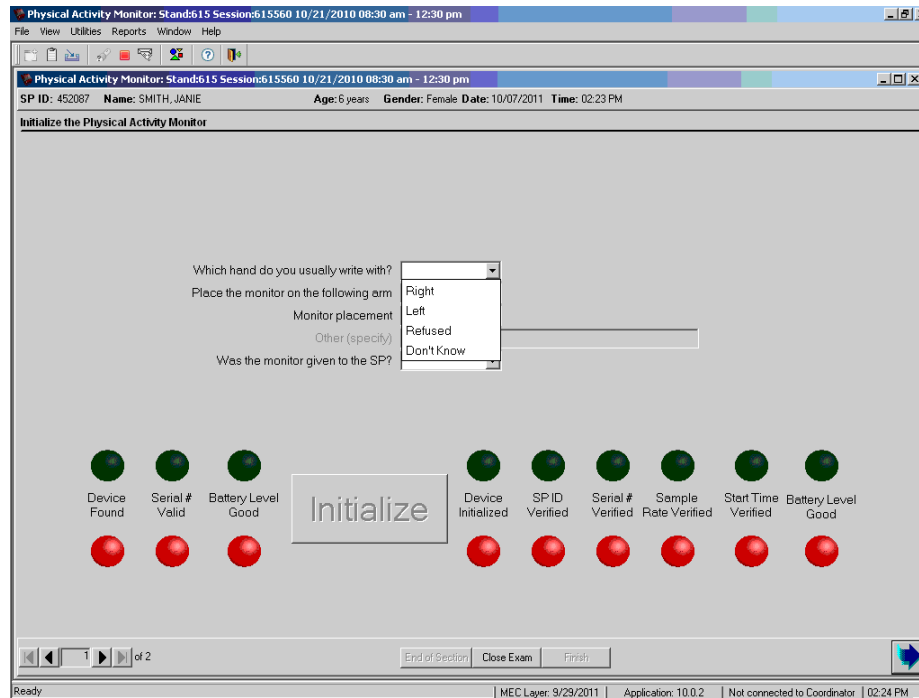
Device Found	Serial # Valid	Battery Level Good	Device Initialized	SP ID Verified	Serial # Verified	Sample Rate Verified	Start Time Verified	Battery Level Good
☐	☐	☐	☐	☐	☐	☐	☐	☐

1 of 2

End of Section Close Exam Finish

Close the exam MEC Layer: 9/23/2011 Application: 10.0.2 Not connected to Coordinator 02:03 PM

Exhibit 3-8. Drop-down box with options to determine dominant arm for ages 6-15



- If the parent for the 3-5-year-old or SPs ages 6-15 answer “right,” the **nondominant** arm will be the left; if they answer “left,” the **nondominant** arm will be the right.
- If the parent of the 3-5-year-old does not know or refuses the question, the next question will be highlighted, “Which hand do they use more often when they are eating, drawing, and grabbing things?” See Exhibit 3-9. If the parent does not know or refuses the question, by default the monitor should be placed on the left arm of the SP.

Exhibit 3-9. Options for second question for ages 3-5-year-olds

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Initialize the Physical Activity Monitor

Is your child left or right-handed? Don't Know

Which hand do they use more often when they are eating, drawing, and grabbing things?

Place the monitor on the following arm

Monitor placement

Other (specify)

Was the monitor given to the SP?

Initialize

Device Found Serial # Valid Battery Level Good

Device Initialized SP ID Verified Serial # Verified Sample Rate Verified Start Time Verified Battery Level Good

1 of 2

End of Section Close Exam Finish

Ready MEC Layer: 9/29/2011 Application: 10.0.2 Not connected to Coordinator 02:05 PM

- For SPs ages 6-15, if they do not know or refuse 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 data entry field (Exhibit 3-10), “Place the monitor on the following arm” will automatically be prefilled by ISIS based on the parent’s and SP’s response to the previous question to determine the nondominant arm. 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 3-10. Prefilled box for nondominant arm selection

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Initialize the Physical Activity Monitor

Is your child left or right-handed? Right

Which hand do they use more often when they are eating, drawing, and grabbing things?

Place the monitor on the following arm Left

Monitor placement

Other (specify)

Was the monitor given to the SP?

Device Found Serial # Valid Battery Level Good

Initialize

Device Initialized SP ID Verified Serial # Verified Sample Rate Verified Start Time Verified Battery Level Good

End of Section Close Exam Finish

Close the exam MEC Layer: 9/29/2011 Application: 10.0.2 Not connected to Coordinator 02:03 PM

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.²

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

- 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 Exhibit 3-11.

² The ranges listed in the table are estimates; therefore a larger or smaller wrist strap may be used if necessary.

Exhibit 3-11. 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 drop-down box in the ISIS application. See Exhibit 3-12.

Exhibit 3-12. Options for monitor placement on selected arm

Physical Activity Monitor: Stand#615 Session#615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Physical Activity Monitor: Stand#615 Session#615251 09/20/2010 01:30 pm - 05:30 pm

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Initialize the Physical Activity Monitor

Is your child left or right-handed? Don't Know

Which hand do they use more often when they are eating, drawing, and grabbing things? Left

Place the monitor on the following arm Right

Monitor placement

Other (specify)

Was the monitor given to the SP?

Dorsal

Palmer

Other

Device Found Serial # Valid Battery Level Good

Initialize

Device Initialized SP ID Verified Serial # Verified Sample Rate Verified Start Time Verified Battery Level Good

Ready MEC Layer: 3/23/2011 Application: 10.0.2 Not connected to Coordinator 02:09 PM

- The SP's parent/guardian 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 3-13.

Exhibit 3-13. Screen of “Other” for monitor placement with comment

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Initialize the Physical Activity Monitor

Is your child left or right-handed? Don't Know

Which hand do they use more often when they are eating, drawing, and grabbing things? Left

Place the monitor on the following arm Right

Monitor placement Other

Other (specify) Will put monitor on dorsal side after soccer game today

Was the monitor given to the SP?

Device Found Serial # Valid Battery Level Good Initialize Device Initialized SP ID Verified Serial # Verified Sample Rate Verified Start Time Verified Battery Level Good

Ready MEC Layer: 9/29/2011 Application: 10.0.2 Not connected to Coordinator 02:10 PM

3.3.3 Procedures for Returning the Monitor and Review of Written Instructions

- Grab a padded envelope 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 smaller children 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 the 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 be placed in their report of findings envelope and given to them when they leave the MC.
 - 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's parent/guardian 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 3-14. 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 3-15.

Exhibit 3-14. Screen with pop-up box if monitor not given after initialization

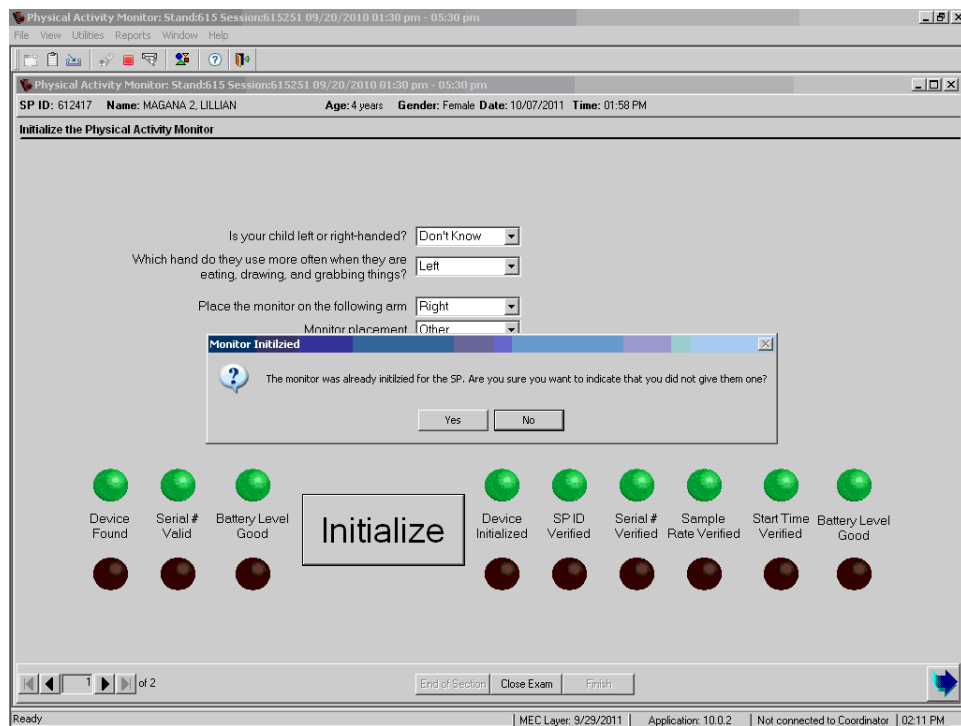
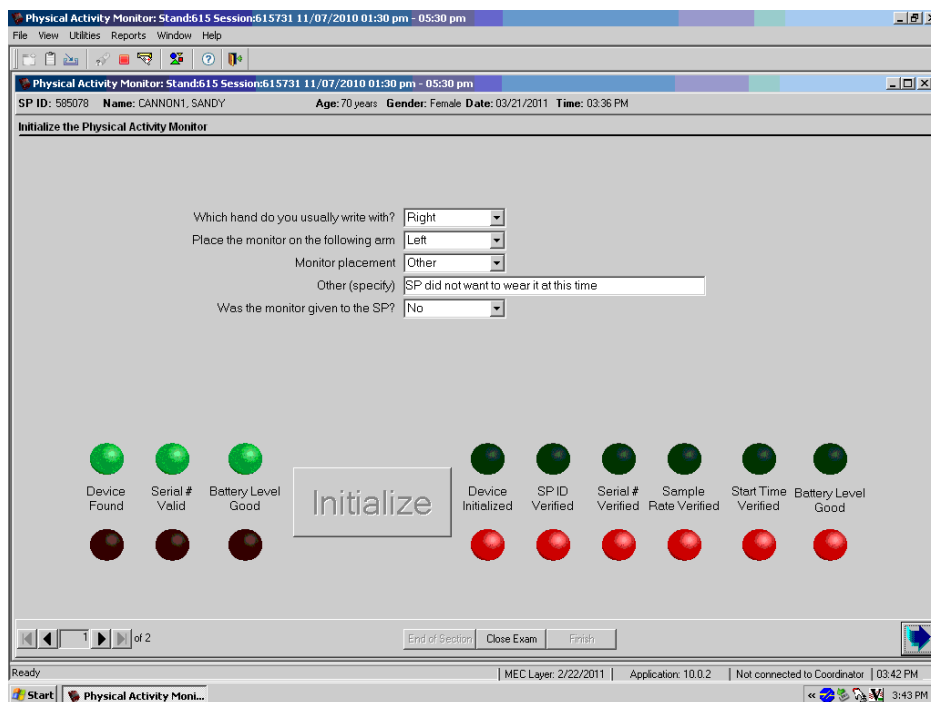


Exhibit 3-15. Screen after monitor not given to SP with “Initialize” button not highlighted



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.” See Exhibit 3-16.

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).

Exhibit 3-16. Exam status coded as “Not Done” with comment options

Physical Activity Monitor: Stand615 Session615251 09/20/2010 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

SP ID: 612417 Name: MAGANA 2, LILLIAN Age: 4 years Gender: Female Date: 10/07/2011 Time: 01:58 PM

Physical Activity Monitor Status

Status

☐ Complete

☐ Partial

☒ Not Done

Comments

Other text:

Language Barrier

no time

other, specify

physical limitation

Refused (SP disliked 1 week co

Refused (SP disliked appearar

2 of 2

End of Section Close Exam Finish

Ready MEC Layer: 9/29/2011 Application: 10.0.2 Not connected to Coordinator 02:13 PM

Appendix A

**Physical Activity Monitor
Information and Instructions**



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.

Appendix B

Physical Activity Monitor Description and Photo



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 (4 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