

ACCELEROMETRY (AX3)

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1. Background and rationale

Accurate and reliable assessment of gait and physical activity remains an important measurement for epidemiologists, exercise scientists, clinicians, and behavioral researchers. Recent advances in accelerometers, which quantify body movements by measuring acceleration in multiple planes, offer a cost-effective way to objectively record gait and physical activity. Accelerometry is considered to be the “gold standard” for measuring gait and habitual physical activity.

For this MOST examination, we will use a small (2.3cm x 3.2cm x 0.7cm), lightweight (11gm) activity monitor (AX3 Logging Accelerometer, Axivity Ltd, York, UK) that will be worn on a belt on the lower back. All participants will start wearing the device at the end of their 144-month clinic visit and be given a self-addressed postage-paid envelope to mail the device back to the clinic at the end of 7 days' time.



Figure 1. AX3 logging accelerometer

2. Equipment and supplies

- AX3 Logging Accelerometer (60 units per site)
Axivity Ltd
The CORE
Bath Lane
Newcastle upon Tyne
NE4 5TF
United Kingdom
Tel: +44 (0) 1904 215 950
Fax: +44 (0) 1904 215 966
Contact: info@axivity.com
Website: www.axivity.com
- Multidock (includes software)
- 3M Microfoam surgical tape, 3 inch wide roll
- Beekley X-spots
- Marker (e.g., Sharpie)
- Elastic waist (ActiGraph) belts
- White nail polish

- “Ouchless” elastic bands
- IPA wipes
- Loctite Plastics Bonding System glue
- PC connected to internet
- Axivity OmGui software installed on the PC

2.1 Maintenance

After each use, the surfaces of the AX3 should be cleaned (any adhesive removed) and sanitized using an isopropyl alcohol-based wipe (70% concentration).

From time to time the connector of the AX3 may require cleaning or sanitizing (depending on wear environment and wear frequency). Connector pins can be cleaned with electronic contact cleaner. In the case where excessive debris is built up in the connector, debris must first be carefully removed using a soft brush, pin or tweezers before sanitizing. In the process of removing debris an airduster may also prove useful.

Plastic bonding glue may be used to adhere the bottom end of the AX3 onto the body of the AX3 monitor if needed.

2.2 Service and repair

The AX3s come with a 12 month warranty. For problems with the AX3, email info@axivity.com. Also consult the Axivity FAQs at <http://axivity.com/faq> for solutions to common problems encountered.

3. Safety issues and exclusions

All participants being seen for a 144-month clinic visit are eligible for this exam.

There are no general safety issues for this exam. It is most important that the participant is reliable and can be counted on to wear the accelerometer for 7 days and will return the accelerometer to the clinic.

The AX3 should be placed on the participant’s back after their MOST MRI is acquired.

The elastic belt with the AX3 attached should be removed during showers and water activity, and while sleeping.

4. Pre-exam procedures

4.1 Materials to have available

Have available for each participant being seen in clinic that day:

- Fully charged AX3 monitor
- Accelerometer (AX3) Distribution Form
- 3M Microfoam surgical tape, 3 inch wide roll
- Marker (e.g., Sharpie)
- Elastic waist belt (Actigraph belt) with top of belt buckle painted white
- Beekley X-spot
- “Ouchless” elastic band
- Activity Monitor Participant Questionnaire (Appendix 1) and Instructions (Appendices 2 & 3)
- Postage-paid, pre-addressed envelope for return of the AX3 and Participant Questionnaire

5. Detailed measurement procedures

5.1 Introduction

The AX3 activity monitor will be attached to an elastic belt that will hold it in place against the pelvis. “Top” should be written on the end of the AX3 that is opposite from the end that has the down arrow. The AX3 should be worn with this arrow pointing down, and the USB connector and flashing LED at the bottom.

5.2 Explain use of AX3 to participant

On the day of the participant visit the examiner will explain the accelerometry study to the participant:

Script: "This little device, when worn on the lower back, is able to sense the movements of the body and measure how you walk and move in different environments over a 7 day period. The movement of your body when you walk and during other activities is known to make an important contribution to bone and joint health. Advances in technology available in this monitor can assess fine details of walking and many other activities that may affect the way your joints and bone change with age and respond to joint pain. So, to help us study these questions, we'd like to ask you to wear this device for 7 days and then return it to us by mail."

“The device will be secured to an elastic belt with hypoallergenic surgical tape and worn under your clothing so that it can be held firmly in place on the bones of your lower back where the spine connects to the pelvis. In this location it can record your movement in all directions.”

Show the participant an AX3 monitor, belt and a sample of the tape. Or, you can show a monitor and a completely assembled belt with monitor attached.

Script: “You should put on the belt and monitor in the morning and remove it when you go to bed and when you shower/bathe or swim. The monitor itself is water-proof, but for your comfort you need to keep the belt and tape dry.”

“It’s important to know that the monitor does not have ability to record where you are or where you have gone while you are wearing it. It records up and down, back and forth, and side to side movements that occur during walking and other activities.”

“We ask you to wear it all day for 7 straight days to provide this information under all different conditions. This is an important part of the study. We’d like you to try this.”

If the participant agrees to wear the monitor and the examiner deems the participant to be reliable and likely to continue wearing and return the monitor, then the examiner will explain how to wear the AX3 and then fit the AX3 on the participant.

Administer the PASE physical activity questionnaire (see Appendix 4 for more details).

5.3 Setting up the AX3 for a participant

1. Start the OmGui software.
2. Choose a fully charged AX3.
3. Connect the AX3 to the computer. A row with the DeviceID number will appear in the Device Browser Pane at the top of the program window. Highlight the row with DeviceID number to be assigned to the participant. Make sure the battery level shows fully charged. If the battery is not fully charged, then disconnect it and choose another one until you find one that is fully charged.
4. On the AX3 Distribution Form, confirm in participants chart that the MOST ID and acoustic prepopulated on the REDCap form are correct. Record the monitor DeviceID number on the form.
5. With the correct DeviceID number highlighted in the Device Browser Pane, click the “Clear” button in the tool bar to erase any data already on the AX3. When the AX3 is cleared, the “Clear” button goes gray and cannot be selected. (The AX3 device can also be cleared during the data transfer procedure after being returned to the clinic by the participant.)
6. Check that the correct DeviceID is highlighted in the Device Brower pane, then click on the “Record” button on the toolbar. This will bring up the Recording Settings dialog box (Fig 4).
7. Use the dialog box to configure the AX3 device to start recording by (see Figure 2 on the next page):
 - a. Enter the numeric portion of the participant’s MOSTID in the “Recording Session” box.
 - b. “Sample Freq” is set to 100Hz and Range (\pm g) is set to 8.
 - c. Button labeled “Interval” is checked.
 - d. Set “Delay” to 0 days.

- e. Ensure that the “Start Date” is current (or if programming the AX3 the day before giving it to the participant, enter tomorrow’s date).
 - f. Enter 8 in the “Duration days” box, 0 in the “Duration hours” box, and 0 in the “Duration minutes” box.
 - g. Set “Start Time” to 16:00.
 - h. The “End Date” and “End Time” are calculated automatically.
 - i. Enter UAB or UI in the “Study Center” box and MOST in the “Study Code” Box.
 - j. Enter your Operator ID (Staff ID number) in the “Operator Box” and also on the AX3 Distribution Form.
 - k. Enter the MOSTID and Acrostic (with no space between) in the “Subject Code” data entry box.
 - l. Ensure that the “Flash during recording” is checked and “Unpacked data” is NOT checked.
 - m. Leave all other boxes empty.
 - n. Click the OK button to close the window and program the AX3.
8. Select and highlight the row in the Device Browser pane with the selected AX3 with the MOST ID number in “Session ID” column. The Recording Interval in the “Recording” column should be displayed in green. Click on the “Identify” button on the toolbar. The LED on the selected AX3 will start flashing, and then unplug that AX3.
 9. The AX3 is now recording and is ready to place on the participant.
 10. With the AX3 in hand, complete the AX3 Distribution Form (MOST ID number and Acrostic will be prepopulated in REDCap).
 11. If the participant agrees to wear the tape on their lower back, “wore tape” should be written in item #7 (Comments) on the AX3 Distribution Form; if the participant refused to wear the tape on their lower back, “refused tape” should be written in item #7 (Comments) on the AX3 Distribution Form.
 12. The Start Date and Start Time programmed into the AX3 should be entered into the “Date and time the AX3 was set to begin recording” field on the Accelerometry (AX3) Distribution Form.
 13. The Start Date and Start Time should be written in item A, and the End Date should be written in Item B on the Activity Monitor Participant Questionnaire.

Figure 2. Data Entry in Record Dialog Box for Cleared AX-3 Accelerometer

Type in numeric portion of MOST ID

Set to 100

Make sure to select "Interval" and that "Start Date" is current AND enter 16:00 for the "Start time"

Set duration to 8 days, 0 hrs, 0 mins

Type in UAB or UI

Enter operator ID

Check "Flash during recording"

Set to 8

Type in MOST ID and Acrostic with no spaces e.g.: MB01234ABCD

5.4 AX3 placement and instructions

Script: “We attach the monitor to the inside of the belt using padded surgical tape that is made by the 3M company. This provides a cushion between the monitor and your back. The arrow on the tape over the monitor should be pointed up when you put on the belt.”

Script: “We also put a small piece of tape on your lower back where there is a natural depression that identifies the place where the monitor should be resting while you wear it. The tape is hypoallergenic and should not irritate most people’s skin even when worn for up to 7 days.”

If the participant does not agree to have tape placed on their back:

Script: “We will put a small ink mark using a red marker on your lower back where there is a natural depression that identifies the place where the monitor should be resting while you wear it. I will have you feel where the ink mark is so you know where to place the monitor.”

5.4.1 Fitting the monitor

Fit the monitor on the participant after the MOST MRI is acquired, and ideally while there is about 30 minutes left in their visit. This way they will be able to tell what it feels like before leaving the clinic and can report any problems or discomfort that needs to be addressed before they leave the clinic.

Rubbing alcohol can be used to clean skin prior to attachment.

Script: “Can I place this small piece of tape on this location of your lower back now?”

1. Have the participant lower the elastic bands on their pants/underwear (same level all around) enough for you to mark the L5-S1 midpoint (see Figure 3).
2. Mark the point between L5-S1 with a red marker (e.g., Sharpie).

Script: “With the monitor in this location it should be comfortable to wear it; in fact most people completely forget that they are wearing it.”

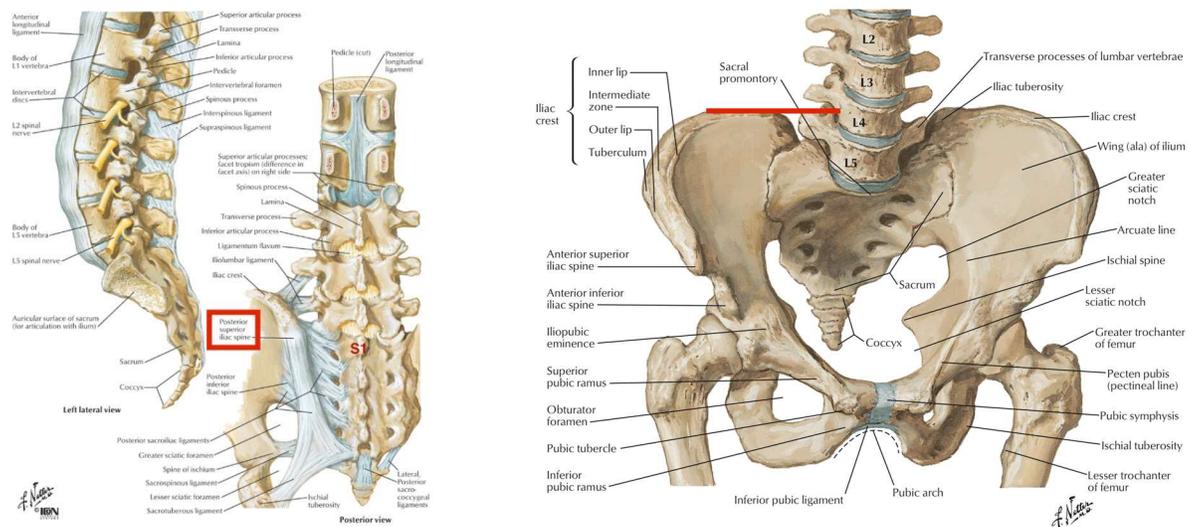


Figure 3. Anatomic Location of S1

3. If the participant agrees, attach a piece of 3M tape on the skin centered over the point made with the red marker. This piece of tape should be the same shape and just a little bit bigger than the AX3 footprint. This will help the participant guide the AX3 to the correct location when putting the belt on and adjusting the position after the belt is on. This should be located at just about where the underwear waist band will be for most people. See Figure 4.



Figure 4. Tape centered over midpoint between L5-S1

4. Use an Actigraph belt. Use "ouchless" elastic bands or some sort of sleeve of your own devising to hold the excess belt lengths that extend beyond the buckle onto the belt.
5. Attach the AX3 to the inside of the belt, with the writing on the face of the AX3 facing toward the belt. (See Figures 5-7.)
6. Use a piece of 3M tape from a 3 inch wide roll, cut to about 2 by 3 inches to attach the AX3 to the belt. See Figure 5.

- a. Place the piece of 3M tape adhesive side up on a flat surface, with the longer dimension perpendicular to the belt.
- b. Place the AX3 in the center of the tape with the printed surface facing up and the arrow toward you. See Figure 5.



Figure 5. AX3 centered on tape.

- c. Place the belt on top of the AX3, with what will be the inside of the belt in contact with the printed surface of the AX3. The length of belt between the AX3 and the buckle should be the same in both directions. See Figure 6.



Figure 6. Belt placed on top tape and AX3.

- d. The Actigraph belt buckle end with the Actigraph logo on it should be on the left, with the logo facing out and right side up when buckled. Be sure the USB port and flashing light will be facing down towards the participant's feet when the belt is worn. You can mark the "up" direction on the monitor for the participant (but note that even a "sharpie" will smear).

- e. Wrap the 3M tape around the AX3 and onto the outside of the belt. The tape should overlap itself by about 1/2 to 1 inch. There will be a seam where the overlapping tape ends, and this will be facing away from the participant's skin. Press the tape firmly around the belt for a tight fit. See Figure 7.



Figure 7. Tape wrapped around AX3 and belt.

- f. Write the word “Up” and then the word “Outside” in marker with an arrow pointing towards the top of the AX3. See Figure 8.
- g. Place the Beekley X-spot on top of the tape at the top of the AX3.

Script: “Can I try fitting the belt with the monitor attached around you now? We have found that the data will be of better quality if you wear the belt directly over your skin, so I’d like to try it that way and see how it feels. The belt should be at the same level all the way around your middle.”

7. Have the participant lower their pants just enough so that the belt and AX3 are in contact with their skin when the AX3 is directly over the 3M tape guide patch that was placed on the skin. Adjust the belt so that the AX3 is centered over and resting on the small patch of 3M tape.
8. If the participant refuses to have tape placed on the back, guide their hand to where the spot was marked with a red marker on their back so they know where the AX3 should be placed. Then fit the participant with the belt so that the AX3 is centered over and resting on the marked spot at the L5-S1 midpoint.
9. Adjust the belt to the desired tightness for the participant, making sure that the length of belt from the AX3 to the buckle is the same in both directions. It should be tight enough to hold the AX3 flat against the participant's body as they move around, bend over, etc. See Figures 8-9.



Figure 8.



Figure 9.

10. After fitting and adjusting the belt and monitor so that it is correctly positioned over the small piece of tape on their back, have the participant reach around behind and feel how the monitor sits on the tape in the center of their back.
11. Have the participant feel the “sticker with the small metal ball” on top of the monitor to ensure the monitor is facing right side up.
12. Tell the participant that the data will be of better quality if they wear the belt directly over their skin.
13. Then ask the participant to pull their pants/underwear up and over so that they are covering the monitor and belt. Have them walk and then sit in a chair to see how that feels. See Figures 10-11.



Figure 10.



Figure 11.

Script: “How does that feel?”

14. Now have the participant practice taking off the belt and then putting it back on until it is clear that they know how to do it.

Script: “The part of the belt buckle with the word “Actigraph” on it should always be on your left side and facing outward so that you can see it (upside down). The white paint on top of the belt buckle should be facing up.”

15. Have the participant feel the belt all the way around their waist to make sure there are no twists in the belt, and remind them to do this when putting the belt on at home. Also remind them how to orient the belt buckle (see script above) so that the direction of the AX3 is correct. The participant should center the monitor over the piece of tape on their back marking the correct location, and then pull the waist band of their pants/underwear up over the monitor. Show them the pictures on the instruction sheet.
16. If the participant does not want to wear the belt directly over the skin or they find that it irritates their skin, the belt can be worn over their underwear or undershirt. Have them practice putting on the belt and adjusting the AX3 location by feeling under the waist band of their underwear or their undershirt for the tape marking the correct location, and then adjusting the belt so that the AX3 is in the correct location on their back.

5.4.2 Instruction for wearing and returning the monitor

After fitting the monitor, complete the date/time the participant starting wearing the belt and monitor, and the date the belt and monitor should be removed when going to bed (see section 5.3) on the Activity Monitor Participant Questionnaire (Appendix 1), and review and give to the participant. Hand the participant the Activity Monitor Instructions (AX3 with tape on back) (Appendix 2) and review them (see script below). If the participant refuses to have tape placed on the back, hand the participant the Activity Monitor Instructions (AX3 without tape on back) (Appendix 3).

Script: “We’d like you to try to wear the monitor every day for 7 straight days. You should stop wearing the monitor when you go to bed on the 7th day. It should be worn at all times except when you are in bed at night and while showering, swimming or other water activity.

“If the piece of tape on your lower back comes off, position the monitor as best you can in the natural depression in the center of the very lowest part of your back. The clinic will have marked this location with a red marker.”

“If the monitor falls off of the belt, mail the monitor and belt back to the clinic.”

Review the instruction sheet, questionnaire, return envelope and procedures for returning the monitor with the participant and answer any questions they may have.

Script: “After you have worn the monitor for 7 days, complete the questionnaire about your experience wearing it and mail the monitor, belt and the questionnaire to the clinic in this postage paid envelope.”

“Do you have any questions?”

6. Downloading participant’s data after return of AX3 and completing AX3 Return Form

1. Start the OmGui software. In the File menu select “File > Choose working folder” from the menu bar and choose the folder name with the date for Monday of the current week. (e.g.: C:\AX3\20151020). Data uploaded during the current week should be kept in that folder. The date should always correspond to the beginning of that work week (e.g., the date for that Monday even if the Monday itself is a holiday).
2. If this folder does not already exist, create a new one for the current week named for the date of Monday of this week in the format YYYYMMDD (e.g.: 20151020 if the date is October 20, 2015). [In Windows 7, select: Computer C drive then AX3. Click the “Make new folder” button and type in the date in YYYYMMDD format (see Figure 10 below).

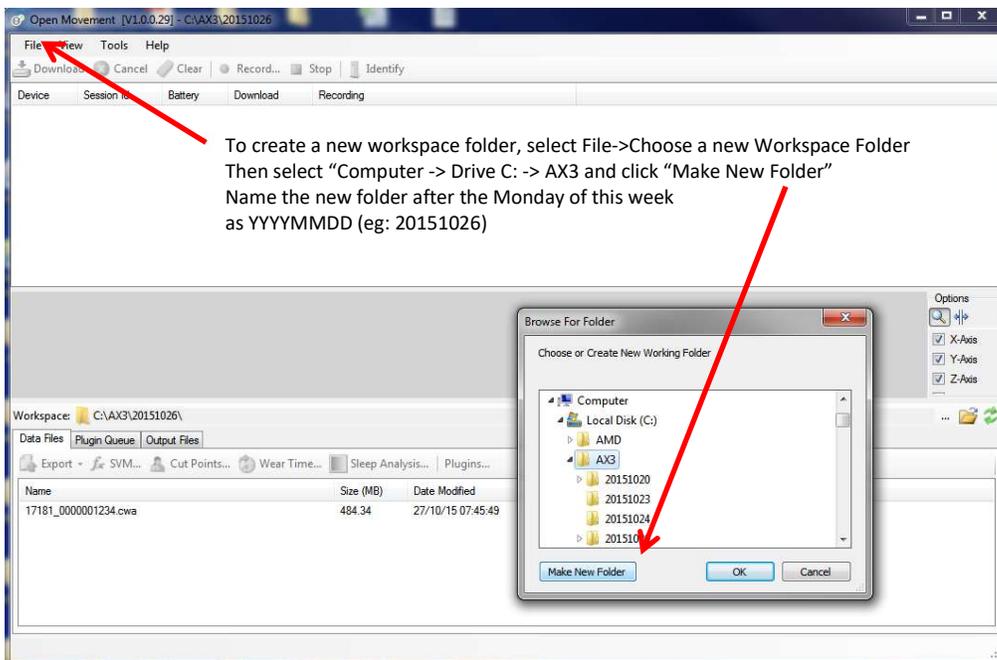
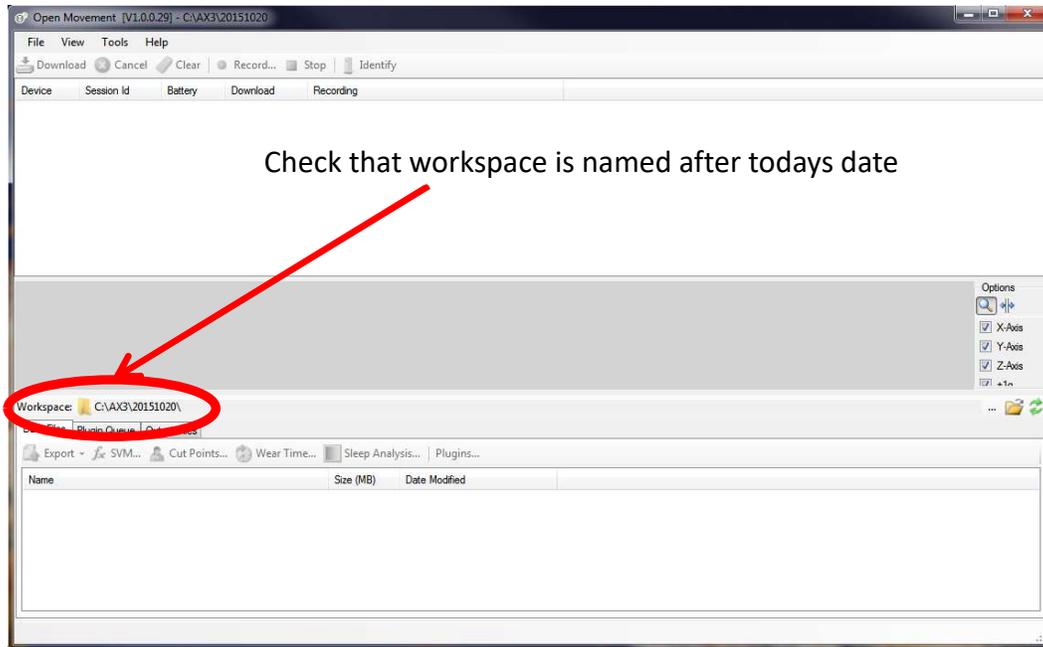


Figure 10

3. The new folder name will appear as the Workspace halfway down the main program window (see Figure 11 below).

**Figure 11**

4. The following steps can now be performed and the AX3 Return Form completed for any AX3 accelerometers that have been received:

- a. Open an AX3 return mail package, which should contain an AX3 device and an Activity Monitor Participant Questionnaire.
- b. Connect the AX3 to the computer. The DeviceID number for this AX3 and the MOST ID (under SessionID) will appear in the Device Browser pane. Record the DeviceID number on the AX3 Return Form. The “Recording” column will show the Recording Interval if the device is still recording data, or “Stopped (with data)” if no longer recording. If the “Recording Interval” is displayed, click “Stop” in the menu bar and “Stopped (with data)” will be displayed.
- c. Check that the SessionID number next to the DeviceID number matches the numeric part of the MOSTID on the AX3 Return Form, and mark “Yes” for Question 2 on the AX3 Return Form. If an error is noted, record “No” for Question 2 on the AX3 Return Form and enter the actual SessionID value on the form (this might be a mistyped MOSTID value for example).
- d. Check that the DeviceID displayed in the software matches the ID on the returned activity monitor.
- e. Check the battery level of the AX3 and record on the AX3 Return Form whether it was 0%.
- f. Check if there are long periods where the accelerometer trackings are flat that are not account for by sleep and record on the AX3 Return Form.
- g. Check if the Activity Monitor Participant Questionnaire was returned and completed and record on the AX3 Return Form.
- h. Click the “Download” button on the toolbar.

- i. The data will start to download from the AX3 and could take up to 12 minutes. When complete, the Download column will display “Complete”
- j. Once download is complete select the Data File tab on the Workspace pane. A file named DeviceID_SessionID.cwa will appear in the working folder window at the bottom of the screen. You may have to ensure that the “Data Files” tab is selected in the lower program window pane.
- k. Highlight the correct .cwa file by clicking on it, and you should see a trace of the accelerometer values (see Figure 12 below). Be sure that the “X-axis”, “Y-axis” and “Z-axis” boxes to the right of the window are checked.
- l. Move the mouse to the left side of the tracing and check that the data shown matches the date that the AX3 was given to the participant.
- m. If there are long periods of a day or more where the accelerometer tracings are flat, make a note of this on the AX3 Return Form, but you should expect to see regular flat periods when the participant sleeps.
- n. If the participant returns the device but not the Participant Questionnaire, call the participant and attempt to get the data (either over the phone if participant is willing or ask them to mail the Participant Questionnaire to the clinic).
- o. Once the AX3 Return Form data have been submitted, disconnect the AX3 from the computer.
- p. Confirm that the downloaded AX3 data is on the computer before deleting data from the monitor.
- q. The date field at the top of the AX3 Return Form should be the date the data is downloaded from the AX3 device to the clinic’s local computer; the date in Section II; Question #4 should be the date the participant wrote on the Participant Questionnaire (Question #4: “What is today’s date?”)
- r. If the AX3 Return Form has been marked that the Participant Questionnaire was not returned and Participant Questionnaire is received later, complete a repeat (“Repeat exam 1”) AX3 Return Form. In addition:
 - i. Mark “No” to Question #1 (Was the AX3 returned?)
 - ii. Mark “Yes” to Question #5
 - iii. Explain the situation in Question #6 (Comments) (e.g., “Participant Questionnaire returned after device returned”)
 - iv. Complete Section II AX3 Participant Questionnaire, Questions #1-4



Figure 12

7. Belt washing

The belts should be washed after it is returned by a participant and before it is distributed to next participant. White nail polish should be re-applied to the top of the Actigraph belt buckle if needed.

8. Alert values/follow-up/reporting to participants

There are no alert values.

9. Data upload procedures

At the end of any day where .cwa files have been downloaded from AX3 devices, the operator will need to check that the laptop is left switched on and that files have synchronized to the UCSF ftp server. This is done by clicking on an icon in the bottom right of the screen. See section 4 of the MOST Secure Data Transfer Operations Manual for more details.

10. Data archiving procedures

In this situation, “to archive” simply means to move the AX3 data files someplace other than the hard drive of the computer used to download the data from the AX3 devices. Archiving may become necessary if the computer hard drive fills up and free space must be created. Each .cwa file is an independent data file and may be moved around freely. You may use Windows Explorer to move these files to the alternate storage media, e.g. an external hard drive. How you name the archive folder is at the clinic’s discretion. In general, begin archiving the oldest .cwa files first.

11. Lost accelerometry device

In the event that the AX3 device is not returned to the clinic and deemed as lost, be sure to complete an AX3 Return Form noting the AX3 was not returned and why (e.g., lost).

12. Quality assurance

12.1 Training requirements

No special qualifications or experience are required to perform this assessment. Training should include:

- Read and study manual
- Attend MOST training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

12.2 Certification requirements

- Complete training requirements
- Demonstrate setup and return procedures for AX3
- Conduct exam on two volunteers
 - According to protocol, as demonstrated by completed QC checklist

12.3 Quality assurance checklist

Day of clinic visit

- AX3 software (OmGui) launched
- AX3 explained to participant
- AX3 connected to the computer, checked that it appears in the Device Browser Pane at the top of the program window under the correct Device ID number, and that they battery level is fully charged
- AX3 configured on the computer properly
- Selected the Identify button on the toolbar
- Checked that the LED on the AX3 is flashing
- AX3 unplugged from computer and given to participant
- Participant shown how to place AX3 correctly on body
- Pertinent date/times completed on Activity Monitor Participant Questionnaire
- Activity Monitor Participant Questionnaire & Activity Monitor Instructions shared with participant
- Procedure for returning AX3 explained to participant
- Participant instructed to walk after placement of AX3
- Complete packet compiled for participant
- Participant asked if they have any questions
- AX3 Distribution Form completed correctly; the correct MOST ID, Acrostic, and Device ID number recorded on the form
- “Wore tape” or “refused tape” accurately noted in Comments field on AX3 Distribution Form
- Form reviewed for completeness

After return of AX3

- Folder for the week created and appropriately named
- AX3 software (OmGui) launched
- Correct DeviceID number recorded on the AX3 Return Form
- Checked that the Session ID number next to the Device ID number matches the numeric part of the MOSTID; if an error is noted enter the actual SessionID value on the AX3 Return Form (this might be a mistyped MOSTID value for example)
- Checked the battery life of the AX3
- Checked if there are long periods of flat tracings not accounted for by sleep
- Downloaded data to correct folder (folder for that week) on computer
- Performed final checks on data
- AX3 unplugged from computer and placed in charging station
- AX3 Return Form completed correctly, and the correct MOST ID, Acrostic, and Device ID number recorded on the form
- Participant questionnaire data recorded correctly into AX3 Return Form
- Form reviewed for completeness
- Belts washed between each use

13. Data collection forms

Please see the Overview of the 144-month Follow-up Visit Operations Manual for an overview of the data collection forms, information on whether each form is in REDCap or Teleform, and where the forms can be accessed on the study website.

Appendix 1 Activity Monitor Participant Questionnaire



**Activity Monitor Participant
Questionnaire**

MOST ID #	Acrostic	<input type="radio"/> With Tape
<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="radio"/> Without Tape

- A. The belt and monitor was worn by the participant starting on: _____ at _____ am/pm.
- B. The monitor should be worn for 7 days until going to bed on _____.

★ When you have finished wearing the monitor, please answer these questions. Then place the belt, monitor, and this completed form in the postage paid return envelope and send via US Mail to the MOST clinic.

1. Were you able to wear the activity monitor for 7 days?

Yes

No →

a. For how many days did you wear it? _____ days

b. Why were you not able to wear it for 7 days?

2. Please briefly describe any problems or discomfort you had while wearing the monitor.

3. Has anything happened in the week you wore the monitor that changed your normal activity level?

Yes

No

Please choose all that apply:

Severe weather

Sick/not feeling well

Hospitalization

Other *Please describe:* _____

4. What is today's date?

		/			/				
Month			Day			Year			

MOST
Activity Monitor Participant Questionnaire
Clinic Note: Do not fax form, data to be entered into REDCap
Version 1.2, 8/16/2016

Appendix 2 Activity Monitor Instructions (AX3 with tape on back)**Activity Monitor Instructions**

Note: The monitor does not have the ability to record where you are.

Instructions for wearing the activity monitor (see pictures on the next page):

- The monitor is attached to the inside of the elastic belt with hypo-allergenic, padded 3M Surgical Tape.
- The clinic has placed a piece of 3M tape in the small depression in your lower back to mark the location where the monitor should rest when you are wearing the belt.
- The monitor should be on the inside of the belt and sit directly on top of this piece of tape on your back. If you find the belt is irritating your skin, you can wear it over the elastic band of your underwear or over a thin undershirt. Make sure the monitor is directly over the piece of tape on your back.
- You should put on the belt and monitor in the morning and remove it when you go to bed and when you shower/bathe or swim. The monitor is water-proof, but for your comfort it's best to keep the belt and tape dry.
- When you put on the monitor, adjust the belt so that the monitor is again sitting snugly on top of the piece of tape on your back. The belt should be at the same level all the way around your middle.
- The white paint on top of the belt buckle should be facing up.
- Feel the belt all the way around your waist to ensure it is not twisted; then feel for the sticker with the metal ball on top of the monitor to ensure the monitor is right side up.
- Wear the monitor during the day for all 7 days. This will provide the study with valuable information. Your participation is appreciated.

Troubleshooting:

- If the piece of tape on your lower back comes off, position the monitor as best you can on the small depression of your lower back. The clinic will have marked this location with a marker.
- If the monitor falls off the belt, complete the Activity Monitor Participant Questionnaire and return the monitor and belt to the clinic.

MOST
Activity Monitor Instructions (AX3 with tape on back)
Version 1.3, 4/18/2017

1) Small patch of 3M hypoallergenic surgical tape to guide placement of the monitor.



2) Activity monitor should be centered over and rest snugly on the tape. Feel the sticker with the small metal ball on top of the monitor to ensure the monitor is facing right side up.



3) The belt should be at the same level all the way around. Note orientation of the Actigraph label on the belt buckle. Also note that the white paint on top of the belt buckle should be facing up. Feel all the way around your waist to ensure belt is not twisted.



4) Pull elastic bands of underwear, pants, skirts etc. up over the belt and monitor.



MOST
Activity Monitor Instructions (AX3 with tape on back)
Version 1.3, 4/18/2017

Appendix 3 Activity Monitor Instructions (AX3 without tape on back)**Activity Monitor Instructions**

Note: The monitor does not have the ability to record where you are.

Instructions for wearing the activity monitor (see pictures on the next page):

- The monitor is attached to the inside of the elastic belt with hypo-allergenic, padded 3M Surgical Tape.
- The clinic has placed a small ink mark in the small depression on your lower back to mark the location where the monitor should rest when you are wearing the belt.
- The monitor should be on the inside of the belt and sit directly on top of this ink mark on your back. If you find the belt is irritating your skin, you can wear it over the elastic band of your underwear or over a thin undershirt. Make sure the monitor is directly over the mark on your back.
- You should put on the belt and monitor in the morning and remove it when you go to bed and when you shower/bathe or swim. The monitor is water-proof, but for your comfort it's best to keep the belt and tape dry.
- When you put on the monitor, adjust the belt so that the monitor is again sitting snugly on top of the ink mark on your back. The belt should be at the same level all the way around your middle.
- The white paint on top of the belt buckle should be facing up.
- Feel the belt all the way around your waist to ensure it is not twisted; then feel for the sticker with the metal ball on top of the monitor to ensure the monitor is facing right side up.
- Wear the monitor during the day for all 7 days. This will provide the study with valuable information. Your participation is appreciated.

Troubleshooting:

- If the monitor falls off the belt, complete the Activity Monitor Participant Questionnaire and return the monitor and belt to the clinic.

MOST
Activity Monitor Instructions (AX3 without tape on back)
Version 1.3, 4/18/2017

1) An ink mark has been placed on your lower back.



2) Activity monitor should be centered over and rest snugly on top of the ink mark placed on the small depression of your lower back. Feel the sticker with the small metal ball on top of the monitor to ensure the monitor is facing right side up.



3) The belt should be at the same level all the way around. Note orientation of the Actigraph label on the belt buckle. Also note that the white paint on top of the belt buckle should be facing up. Feel all the way around your waist to ensure belt is not twisted.



4) Pull elastic bands of underwear, pants, skirts etc. up over the belt and monitor.



MOST
Activity Monitor Instructions (AX3 without tape on back)
Version 1.3, 4/18/2017

Appendix 4 Conducting the Physical Scale for the Elderly (PASE) Interview

The PASE interview is currently being administered to all participants. Ask the participant if they are willing to spend an additional few minutes in the clinic answering questions about their physical activity. If the participant agrees, access the PASE REDCap form via the MOSTv4 study website, and conduct the interview. Ask the participant each of the 11 PASE activity questions, showing response cards as indicated on the forms. (See Interviewing Guidelines Operations Manual Chapter 2E, Appendix 2: Physical Activity Scale for the Elderly (PASE) interviewing guidelines.)

Appendix 5 Fitting the Participant with 3M Tape (No Belt)

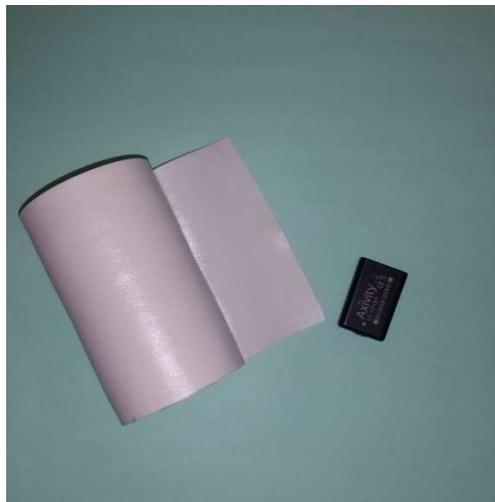
1. Background

It is at the clinics' discretion to use the 3M tape rather than the belt to affix the AX3 to the participant. The participant may prefer tape, the clinic may not have a clean belt available and the participant is willing to wear the tape, etc.

2. Introduction

The AX3 will be worn for up to 7 days adhered to the participant's lower back between L5 and S1. Two pieces of 3M Microfoam Surgical Tape will be used to attach the monitor to the bare skin. "Top" should be written on the end of the AX3 that is opposite from the end that has the down arrow. The AX3 should be worn with this arrow pointing down, and the USB connector and flashing LED at the bottom.

The AX3 can be worn while showering, bathing, in a hot-tub/whirlpool or in the swimming pool.



Appendix 5, Figure 1a. 3M Microfoam Surgical Tape, 4 inch roll
(and 2 inch roll not shown here)



Appendix 5, Figure 1b. 3M Microfoam Surgical Tape, 4x7 inch patch

Figure 1a represents the 3M Microfoam Surgical Tape, 4 inch and 2 inch rolls. Figure 1b represents the 4x7 inch patch 3M Microfoam Surgical Tape.

3. Explain use of AX3 to participant

On the day of the participant visit the examiner will explain the accelerometry study to the participant:

Script: "This little device, when worn on the lower back, is able to sense the movements of the body and measure how you walk and move in different environments over a 7 day period. The movement of your body when you walk and during other activities is known to make an important contribution to bone and joint health. Advances in technology available in this monitor can assess fine details of walking and many other activities that may affect the way your joints and bones change with age and respond to joint pain. So, to help us study these questions, we'd like to ask you to wear this device for 7 days and then return it to us by mail."

"The device will be worn in contact with the pelvis bones of your lower back using padded and hypoallergenic surgical tape made by 3M."

Show the participant an AX3 monitor and a sample of the tape.

Script: "The monitor is waterproof and the tape water resistant, so you won't need to remove it when showering, bathing or swimming."

"The monitor needs to be placed low down on your back so it is on the pelvis because that is a stable bone that allows measurement of trunk movement in all directions."

"It's important to know that the monitor does not have the ability to record where you are or where you have gone while you are wearing it. It records up and down, back and forth, and side to side movements that occur during walking."

"This is an important part of the study. We'd like you to try this."

If the participant agrees to wear the monitor and the examiner deems the participant to be reliable and likely to continue wearing and return the monitor, then the examiner will explain how to wear the AX3 and then fit the AX3 on the participant.

Administer the PASE physical activity questionnaire (see Appendix 4 for more details).

Set up the AX3 as described in Section 5.3 in the main body of this chapter.

4. AX3 placement and instructions

Describe how, and where, on their back the monitor will be placed. Show the participant the photographs depicting this.



Appendix 5, Figure 2a. AX3 face down on adhesive side of 5” by 4” of tape



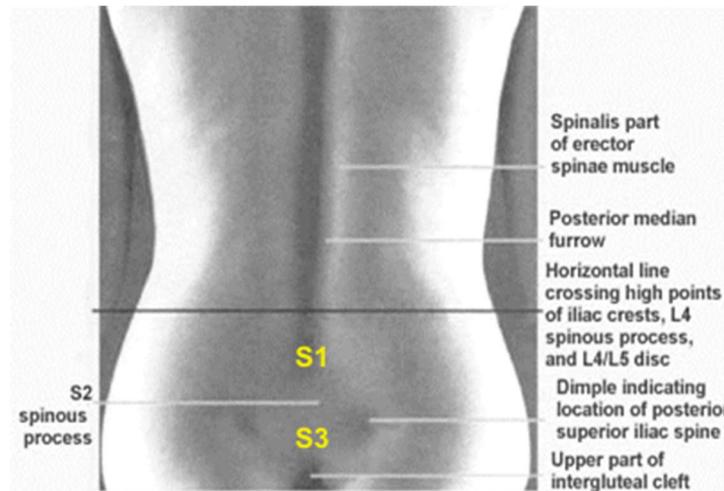
Appendix 5, Figure 2b. AX3 face up on non-adhesive side of 5” by 4” of tape



Appendix 5, Figure 3a. AX3 sandwiched between 2 pieces of surgical tape
(adhesive side of 4" x 5" piece facing up)



Appendix 5, Figure 3b. AX3 sandwiched between 2 pieces of surgical tape
(non-adhesive side of 4" x 5" piece facing up)



Appendix 5, Figure 4. Location on the small of the back where the monitor is worn



Appendix 5, Figure 5. AX3 on the back of a male participant

Script: “First we put the monitor between two pieces of padded surgical tape that is made by the 3M company. This provides a cushion between the monitor and your back and ensures that it will not fall out while you wear it. The adhesive side of the larger piece of tape will hold it in place on your back. The tape is hypoallergenic and should not irritate most people’s skin even when worn for up to 7 days.”

“The monitor will be placed on the pelvis in the small of your back where there is a natural depression. Placed here it should be comfortable to wear it continuously day and night; in fact most people completely forget that they are wearing it.”

“The monitor should be worn at all times, even while showering, swimming and other water activity and while sleeping.”

“Most of the time the monitor will stay in place on your back for 5-7 days until you are ready to remove it for mailing back to the clinic.”

“I’d like to attach the monitor now while there is still a little time left in your visit so that you can see how it feels. Let us know if it’s causing discomfort so we can adjust it before you leave.”

5. Fitting the monitor

Fit the monitor on the participant after the MOST MRI is acquired, and ideally while there is about 30 minutes left in their visit. This way they will be able to tell what it feels like before leaving the clinic and can report any problems or discomfort that needs to be addressed before they leave the clinic.

Rubbing alcohol can be used to clean skin prior to attachment.

Mark the location of S1 with a permanent red marker.

From the 4 inch wide roll of surgical tape or 4 by 7 inch patch, cut a piece about 4.5 inches long (length may vary by size of participant and based on experience).

Lay the tape down with adhesive side facing up. Place the monitor approximately in the center as shown in Figure 2a, face down (side with the printing on the adhesive surface of the tape). [ALT: Lay the tape down with the removable backing facing down and the nonadhesive side facing up. Place the monitor approximately in the center as shown in Figure 2b, with the side with the printing facing up.] The bottom of the monitor (micro USB port end and arrow pointing down) closest to you.

From the 2 inch wide roll of surgical tape, or remainder of the 4x7 patch, cut a piece that is about 2 by 3 inches long. Place this piece squarely over the monitor (adhesive side on the monitor surface and longer dimension of tape parallel to the longer dimension of monitor). Press this piece of tape down over the sides of the monitor and onto the adhesive side of the larger piece of tape (Figure 3a). [ALT: From the 4 inch wide roll of tape, cut a piece that is 3x4 inches. Place this piece squarely over the monitor (adhesive side on the monitor surface and longer dimension of tape parallel to the longer dimension of monitor). Press this piece of tape down over the sides of the monitor and onto the adhesive side of the larger piece of tape (Figure 3b)]. Mark which end is the “top” with a sharpie. (Figure 3a).

The monitor and tape sandwich is now ready to place on the participant’s back.

With the participant standing erect, [ALT peel off the removable backing and] place the sandwich in the middle of the lower back with the bottom end of the monitor just above the mark for S1 (hence the monitor will be sitting between S1 and L5). (Figures 4, 5 and 6.)

“The attachment will also continue to strengthen as you wear it under your clothes.”

“After 7 days, remove the monitor and tape, or ask someone to remove them for you. The date and time on this form shows when 7 days have passed.”

“If before 7 days have passed the tape becomes so loose that the monitor falls off, or is about to fall off, remove the tape and monitor.”

“When you have finished wearing the monitor, please answer these questions about your experience wearing it. Then place the monitor and this completed form in the postage paid return envelope and send via US Mail back to the study clinic.”

“Do you have any questions?”

7. Downloading participant’s data after return of AX3

Download the AX3 participant data and complete the AX3 Return Form as described in Section 6 in the main body of this chapter.