



**The Prospective Physical Activity, Sitting and Sleep consortium:
Preferred protocol for thigh-worn accelerometer measurements**

STANDARD OPERATING PROCEDURES MANUAL

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STANDARD OPERATING PROCEDURES MANUAL

AIM

The purpose of this document is to provide guidance to researchers for a consistent method of collecting thigh-worn accelerometry data. This document will cover information on three different accelerometer devices and assumes that researchers have little or no previous experience using accelerometers. Similar protocols have been used in various large epidemiological studies to measure tens of thousands of participants, including the 1970 British Birth Cohort, the Australian Longitudinal Study on Women's Health, and the Trøndelag Health Study (HUNT) in Norway.

WHAT IS ProPASS

ProPASS is an international research collaboration platform of cohorts using thigh-worn accelerometry to explore the effects of physical activity, posture, and sleep patterns on a wide range of health outcomes. The ultimate goal of the ProPASS consortium as a data resource is to promote collaborative individual participant and prospective meta-analyses on physical activity, posture, and sleep. For detailed information, please visit www.propassconsortium.org

WHAT IS AN ACCELEROMETER

Accelerometer is a wearable physical activity monitor detecting movement, vibrations and orientating changes in all 3-axis. This is a research device that will allow the researchers to accurately measure all physical activity that people do, as well as posture (i.e. time spent standing, sitting or reclining). The information recorded by the accelerometer activity monitors will let the researchers understand the link between physical activity pattern and health in much more detail. The accelerometer **does not have a camera, microphone or GPS** to track people's location or private life.

MEASUREMENT PROTOCOLS FOR DATA COLLECTION

AIM

The purpose of this document is to provide guidance to researchers for the preferred protocol for collecting thigh-worn accelerometer data for The Prospective Physical Activity, Sitting and Sleep (ProPASS) consortium. Technical information about brands/models of three accelerometers that this manual cover is provided in the Appendix 1.

EXCLUSION CRITERIA

We recommend that the following groups of participants to be excluded from the accelerometry measurements:

- people who are allergic to plasters or adhesives
- people who are allergic to low-density polyethylene (LDPE; the plastic packaging of the activity monitors)
- people with a skin condition that would prevent them from wearing the monitor (e.g. broken skin / eczema on their legs)
- people who may go through a metal detector/security checkpoint (e.g. at an airport) during the measurement period

CONSENT

Please check with your local Institutional Review Board/Research Ethics Committee the ethical and consent requirements for this kind of measurement. In most jurisdictions, written consent will be required for participants. The exact requirements will be country specific.

WEAR TIME

The participant will be given to wear the accelerometer continuously for 24 hours for a minimal period of 7 full days.

ATTACHMENT OF DEVICE AND ACCELEROMETER WEAR SITE

The accelerometer will be fitted on the anterior aspect of the participant's thigh, 10 cm above the proximal part of patella and should not come in conflict with pockets nor be a hinder for movement. It will be placed medially on the thigh, on the muscle belly. Further information and detailed guidance on attachment of device and accelerometer wear site are provided in section 3 of this document.

ACCELEROMETER RECORDING SHEET

Please ask participants to fill in the *accelerometer recording sheet* that includes the sleep diary (times that the participant went to and got out of bed), and the date and times the accelerometer fell off, or was removed. An example of recording sheet is provided in the Appendix 2.

MATERIALS AND PREPARATION OF ACCELEROMETERS DURING FIELDWORK

MATERIALS

- ✓ Accelerometer device (Axivity, ActivPAL or Actigraph)
- ✓ USB2 cable (Micro cord) to connect the device with the computer and charging
- ✓ USB Charger hub for changing accelerometer device
- ✓ Computer with the relevant accelerometer initiation / data downloading software installed
- ✓ Bottle of Ethanol (70%)
- ✓ Information for the participant
- ✓ Sticky tape (e.g. 3M 9088, 19mm with)
- ✓ Transparent dressing, for example 3M Tegaderm or another type of medical grade waterproof dressing (or e.g. Opsite Flexifix)
- ✓ Waterproofing sleeve (e.g. nitrile sleeve) or tape (For ActivPAL, Axivity and Actigraph are waterproof.)
- ✓ Paper towels. To wash the skin before attachment.
- ✓ Microfiber cloth
- ✓ Accelerometer recording sheet /sleep diary

Cleaning accelerometers

- ✓ Remove all tape from the sensors.
- ✓ Spray the sensors with ethanol (70%).
- ✓ Let it work for a few seconds and wipe with a microfiber cloth.

Preparing accelerometer for data collection

- ✓ Charge the accelerometer. Every device has different charging requirements. Please consult the manufacturer's manual.

- ✓ Program and set up the accelerometer devices. Set up the accelerometers for a minimal duration **7 full days (i.e. 8 nights)**. Every device uses different software to program and set up the devices. Please consult manufacturer's manual. Instructions for programming Axivity and ActiGraph accelerometers are presented in the Appendix 3.
- ✓ If the device is no waterproof (this is the case for ActivPAL), cover the devices with a waterproof coat using a nitrile sleeve or water-resistant tape (see box below). Please consult the manufacturer's manual for waterproof requirements.
- ✓ Record serial number of the accelerometers. After the devices have been initialised, record the serial number of the device for each participant.

Box 1: Using the nitrile sleeve (ActivPAL is used for illustrative purposes)				
Step 1	Step 2	Step 3	Step 4	Step 5
Take a nitrile sleeve and unroll it over the accelerometer.	Use scissors to cut off the thick opening of the nitrile sleeve when necessary	Pull the nitrile sleeve tight over the accelerometer and fold the excess into a triangle (along the dotted lines, see example below).	Tuck the triangle up onto the bottom (black) surface of the accelerometer and use sticky tape to stick it down	Draw a stick figure on the top side of the accelerometer
				

ATTACHMENT OF ACCELEROMETER (ALL BRANDS/MODELS)

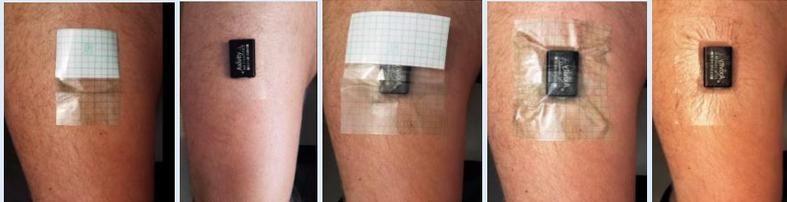
Accelerometer wear site

The accelerometer will be fitted on the anterior aspect of the participant's thigh, 10 cm above the proximal part of patella and should not come in conflict with pockets nor be a hinder for movement.

It will be placed medially on the thigh, on the muscle belly (Axivity AX3 is used in the figure).

Box 2: Location of accelerometer fitting

10 cm above the proximal part of patella



Note: ActivPAL3 Micro and Axivity AX3 accelerometer are used for illustrative purposes.

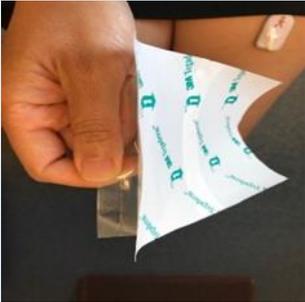
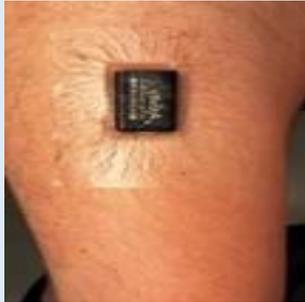
Attachment

- ✓ **Clean the skin.** The device should be attached on clean skin. Wash the area where the device will be attached with ethanol (70%) and a paper towel. Check if the skin is free of lotion, sunscreen, and other skincare products.
- ✓ **Ask the participant to sit and to rest the leg.** Choose a table and nearby chair to prepare the attachment of the device.
- ✓ **Attach transparent dressing on the thigh at the accelerometer wear site.** Attach the transparent dressing directly on the skin. Follow the instructions on the box below.
- ✓ **Remove the cover on the double-sided tape and place the sensor vertically on top of the dressing/tape on skin.** Place the device on accelerometer wear site. Please make sure that the stick figure is facing up, and the head of the stick figure is towards the hip (ActivPAL). For

Axivity, remove the cover on the double-sided tape and place the sensor vertically on top of the Flexifix, with the USB opening pointing downwards. For Actigraph, place the accelerometer vertically, with the USB pointing downwards.

- ✓ **Cover the accelerometer device with the transparent dressing on the thigh.**
- ✓ **Ask the participant to wear the accelerometer device for the full measurement period (e.g. 7 full days).** The accelerometer is waterproof and can stay on during showering and swimming.
- ✓ **Ask the participant to fill in the accelerometer recording sheet/sleep diary for the full measurement period (e.g. 7 full days).** At the end of the accelerometer wear period, carefully peel the transparent dressing off the skin and put it in the bin.

Box 3: Attaching transparent dressing on the thigh at the accelerometer wear site

Step 1	Step 2	Step 3
<p>Take the transparent dressing and peel off the white backing paper</p> 	<p>Line up the measuring strip on the transparent dressing directly over the accelerometer and apply the exposed adhesive dressing. Smooth the dressing down over the device and skin.</p> 	<p>Remove the protective sheet and smooth the dressing down again. Make sure all the edges are stuck down</p> 

Note 1: 3M Tegaderm is used below for illustrative purposes. Other transparent dressings (e.g. Opsite Flexifix) may have slightly different instructions for application.

Note 2: ActivPAL3 Micro and Axivity AX3 are used for illustrative purposes.

DOWNLOADING DATA

Every device uses different software to download data (Please consult Appendix 3). Once the accelerometer is returned and plugged into a computer, a data quality check should be performed. The software provided by the manufacturer of each device visualization of the acceleration can be used. Spikes and different random patterns should be visible in the signal for the whole measurement period. If the acceleration signal is flat for several days (or the whole period), then the accelerometer has not been worn and no wear time is registered. After the data has been downloaded, the size of the output file should be inspected. The file size should be around 150 MB (at 50Hz) for it to be a complete recording. If the file size is significantly lower e.g. <120 MB, than a malfunction in the device battery has probably occurred. If the size of the file is significantly larger e.g. 300MB, then wrong sampling frequency has been used.

FREQUENTLY ASKED QUESTIONS (FAQS)

1. WHAT IS THE ACTIVITY MONITOR?

The accelerometer is a small device that records information continuously about physical activity and posture. The device records physical activity and posture during normal daily activities such as standing up, walking or running. It also captures inactive periods such as time spent sitting or sleeping.

2. DOES THE MONITOR TRACK LOCATION OR KNOW WHERE PARTICIPANTS ARE?

There is no GPS in it, so we cannot see where they are or who they are with.

3. WHICH ACTIVITIES ARE REGISTERED?

The only activities that are registered are lying down, sitting, standing, walking, running and biking. Therefore, if participants perform other activities like swimming or strength training, they will not be registered.

4. HOW IS THE ACTIVITY SENSOR WORN?

It is fixed directly to the skin with an adhesive dressing. The sensor is water and dust proof (or is covered by a nitrile sleeve) and can be worn during all types of activities, including sports like swimming, running, football etc.

5. HOW LONG DO THE PARTICIPANTS NEED TO WEAR IT FOR?

Participants should leave it on for 7 full days (8 nights). The monitor should not be taken off at any time during this period, unless necessary. If the monitor is removed, the data collected during that time will not reflect their true activity levels. The monitor is designed to be worn comfortably at night.

6. SHOULD PARTICIPANTS TAKE IT OFF WHEN THEY ARE IN THE SHOWER?

No. It is waterproof. They can even wear it in the bath or while swimming. We would like the participant to wear it when they are doing all activities, including

water sports, and it is safe for them to do this.

7. IS THERE ANYTHING ELSE PARTICIPANTS NEED TO DO?

Participant are asked to complete a sleep diary for the period that they are wearing the activity monitor. Having this information about their sleep patterns will help us to understand and explain different patterns of activity that have been recorded by the activity monitor.

8. WHAT IF A PARTICIPANT IS TAKING A FLIGHT OR GOING THROUGH A SECURITY POINT?

If they are taking a flight or walking through a security point where they might need to go through a scanner, they should remove the monitor before they leave to travel. They should record on the sleep diary the date and time the monitor was taken off. They should not reattach the monitor to their thigh.

9. WHAT IF THE PARTICIPANT IS SICK OR CANNOT DO MUCH PHYSICAL ACTIVITY FOR ANY REASON DURING THE DAYS THEY ARE WEARING THE DEVICE?

They should wear the monitor as normal. We are interested in their physical activity patterns no matter how inactive or active they are.

10. WHAT IF THEY DON'T WEAR THE MONITOR FOR THE FULL 7 DAYS?

If they have to take the monitor off before the end of their 7 days, they should use the sleep diary to record the date and time they did so, and why they took it off. If this occurs, they should return the monitor and do not reattach the monitor.

11. DOES THE BAND USED TO ATTACH THE MONITOR CAUSE ALLERGY?

The dressing used to attach the monitor is regularly used in hospitals but is quite likely to cause some minor skin irritation (e.g. itching). On removal of the device it is normal to see some redness around the skin area where the device was attached that will disappear within a few hours. In the unlikely event that the dressing does cause severe skin irritation they should remove it and not reattach

the monitor to their thigh. If the unlikely event of severe skin irritation occurs, participants should remove it immediately and don't reattach it. Even though they remove it before the 7 days, we still get valuable data from their participation.

12. DOES THE SENSOR MEASURE SEXUAL ACTIVITIES?

It does not measure if participants have sex. The device records physical activity and posture during normal daily activities such as standing up, walking or running. It also captures inactive periods such as time spent sitting or sleeping.

13. DOES THE SENSOR EMIT RADIATION?

No, there is no radiation coming from the sensor.

14. ARE THERE ANY SITUATIONS WHERE IT MUST BE REMOVE?

If a participant is having a MRI scan, they have to remove the accelerometer.

15. THE SENSOR ARE BLINKING, WHAT DOES THAT MEAN?

Occasionally the sensor blink and this is completely normal.

16. CAN THE SENSOR START TO BEEP?

No, the sensor do not beep, or give away any other sounds.

17. CAN SENSOR GET HEATED AND GIVE ME BLISTERS?

No, the sensor does not get heated.

18. DOES THE SENSOR RECORD SOUND?

No, the sensor does not record any sound.