

NET-Works Main Trial Accelerometry Protocol

The purpose of this document is to provide explicit and detailed instruction on how to collect accelerometry measurements in the NET-Works main study data collection. Each index child participant and one parent will wear the device respectively for 7 complete days.

1. Confidentiality Considerations

There are no confidentiality issues with respect to wearing the accelerometer. Any information on the instrument can be obtained only by using a computer that has the ActiLife software installed.

2. Safety Considerations

There are no known risks associated with use of the monitors. The accelerometers are designed to be worn in a wet environment, so moisture does not pose a problem. The monitor does not emit radiation, electrical current, vibration, or heat and it can be worn under a shirt without causing discomfort. For very young children, there is a *small* risk of accidental choking if the device is removed from the waistband and is left within reach of small children or pets. The device is intended to be worn or stored securely fastened at all times to a waistband, ~0.8" wide. There is no reason to remove the device from the waistband. All other components in the ActiGraph (including the batteries) either are in sealed compartments or require special tools to remove. The devices are safe for pregnant women.

3. Equipment

Laptops	Elastic belts (child and adult sizes)
USB cables (GT3X+ & GT3X)	Sticker Log/Instruction sheet
GT3X+ Monitor with caps and/or	If Found Stickers on the bottom of monitors
GT3X Monitor with caps	Mystery Bag, if applicable (24M & 36M)
Laminated Acc Graphs showing 7 days	

4. Software

The devices work with Actilife Software. The software is updated frequently. When prompted that a new version of Actilife is available, the software must be updated. The firmware for the device is updated automatically by the Actilife software.

5. Training and Certification

Certification procedures for accelerometer data collection are to be completed after staff training. Each staff will be required to collect data on herself for a minimum of three days. This amount of time allows for staff to see a variety of different counts that could include different intensities of movement. The staff person can experience wearing the belt which will help with coaching and training participants. The data from these certification wears will be put into a certification folder on the server.

6. General Measurement Procedures

a. Software Program Setup

Units of Measurement should be set to Metric. This can be selected upon installation of the software or by selecting "Options" from the "Edit" menu.

b. Charging the Accelerometer

Accelerometers must be sufficiently charged in order to be initialized for data collection. This can be done by connecting the accelerometer to a powered hub or a USB port on the computer. During

charging the device will emit a flashing LED. The accelerometer is fully charged when the LED is no longer blinking but emitting a solid LED light. In order to be initialized and used for a participant the accelerometer must be charged to 99- 100%. (Charging time should take no longer than 4 hours.)

Accelerometers should not be left on the charger for extended period of time. Similarly, the accelerometers should not be left to uncharged with a dead battery for an extended period of time.

c. Initializing the Accelerometers

The accelerometers must be initialized before collecting data. Initialization may be done the day before, or the day of, the home visit. The start date and time should be programmed for the day AFTER the home visit at 12:00 AM. If the home visit is rescheduled, the accelerometer will be reinitialized with the correct start date.

For follow-up visits it's important that the same model that was used at baseline is used for the parent and the child. If a GT3X+ (Child) monitor was used for both the parent and child at baseline those same models will be used for follow-up visits (12M, 24M, 36M).

See Accelerometer Initialization "Cheat Sheet " document for specific instructions.

A naming convention is used for accelerometry files. The participant ID, the time point, and the number of the wear are used to identify files. The participant ID is the 6 digit family ID, the time point is T00 for baseline, T12 for 12-month follow-up, T24 for 24-month follow up, T36 for 36-month follow-up. "C" or "A" identifies the child or adult. The last number "1" or "2" indicates a first wear or a re-wear (second wear).

For example 6_ _ _ _ _ T12C2. This participant is a child completing a re-wear for the 12-month follow-up visit.

d. Accelerometer Coaching and Instructions to the Participant

Explain the accelerometer procedures to the parent (calling the device an "Activity Monitor" or a "belt" instead of an accelerometer.) See the script in Appendix 1.

- The "Activity Monitor" should be *worn snugly, but comfortably*, on the right hip either above or beneath clothing with the sticker on the bottom.
- Explain to the family this is a very important outcome of the study so we want to make it as easy (and fun!) as possible for them to comply with wearing the monitors.
- Also let them know that the monitors are very expensive, specialized pieces of equipment, and to make sure they don't lose it as they are costly to replace.
- Show the laminated graph to explain what the monitor collects (physical activity information) and what it does not collect (location information).
- We can explain that each of our 534 families wears the belts for seven days each year to help us learn more about activity patterns. We can use the 7-day graph visual aid to emphasize the importance of wearing the belt all day.
- Explain that when the staff returns for Home Visit #2 (8 days later) they are required to check the monitors to see if they were worn for the required amount of time.

- Tell the parent that if they were NOT worn enough, they will be asked to re-wear the monitors for another week. This can be done in a friendly, but straight-forward, firm way.
- Instruct families to wear the monitors every day, all day (including overnights/sleeping) for 7 days or more, only to be taken off if getting wet. Ideally the data gathered should be for 7+ days.
- Baseline: Part of Eligibility: The child is required to wear their monitor to continue in the study. This point needs to be discussed during the informed consent process, during the explanation/fitting of the accelerometers, and once again before leaving Home Visit #1. Remind the family that not only is this required for eligibility, but also for them to receive their \$30 gift card. Confirm with the family that they understand, in an effort to collect enough data and reduce the chances for non-payment and hurt feelings
- Follow –Up (12M, 24M, 36M): We will tell the participant that it’s important to collect a full week of physical activity information each year that they’re participating in the study. We’ll ask how it went with the belts last year and address any questions or concerns. We explain that we come back for the second visit to check to see how much information was collected and that we’ll ask them to wear the belts again if there’s not enough information. We will talk about the accelerometer wear at the beginning of the visit and at the end of the visit.

Baseline: The minimum amount of time for the child to remain eligible for the study is 4 days (3 weekday and 1 weekend day) at 6 hours per day of wear time during waking hours. We do want parent accelerometer information as well, and need to encourage them to wear their monitor as much as the child. Parents will not be asked for a re-wear if not enough data was collected on the parent. Ultimately, it is the child’s data that will determine continued study eligibility.

Follow-Up (12M, 24M, 36M): We need to collect 7 days of activity information from children and adult participant at each time point to evaluate NET-Works program. If the child did not collect enough information we will request a re-wear. If the child collected at least three weekdays and one weekend for at least 6 hours per day we will not request a re-wear. If the child does not have this minimum amount we will request that they wear the monitors for another full week. Re-wears for adult participants are not necessary if we have the minimum amount for the child.

In an effort to make it friendlier to kids (and thus increase wear time) the NET-Works staff will employ several techniques:

- Fit the parent and the child with the monitors to ensure sticker is on the bottom and that the belt is the correct size for comfort and feasibility. Extra belts should be brought to the visit and the size changed, if necessary.
- Sticker Log - Leave the family with a Sticker Log and enough stickers (14, already cut into sections) so Child and Parent can fill in all days with a sticker. Tell the child that if they wear the monitor all day, they can put a sticker on right before going to bed.
- Mystery Bag – For 24M and 36M. The parent can give the child one toy from the bag for each full day that the child wears the belt.
- Stuffed animal – If age appropriate, we can take the stuffed animal out of the suitcase and talk to the child about how the animal is wearing the belt. We can explain that the child gets to wear the belt just like the animal.
- Certificate of Completion can be given at HV2
- Mention that the belts can be worn through belt loops for both parent and child.

- Make sure the parent and the child are wearing the monitor when you leave the house
- Emphasize that this is something special that the parent and the child are doing together
- Allow the child to decorate their monitor with stickers
- Have the child choose a name for their monitor and write it on the Sticker Log
- Staff will wear their own accelerometer while meeting with the family
- Create a story around a favorite superhero/princess of the child's choosing and encourage the child to wear the monitor because (for example) Batman is looking for special little kids who can wear the monitor every day, he needs your help in wearing it, and he'll be patiently waiting to get it back next week to see if you did a good job!
- In an effort to increase wear time in all families, ask the parent how their accelerometer experience was during the previous year(s). Ask if they remember wearing it, if there were barriers to wearing it, how the child re-acted to the monitor, etc.
- For older children, we can check for understanding before we leave the visit. "What are you going to do with the belt?" "How many days are you going to wear it?" We can tell the older children that we are going to come back to check to make sure that they wore it.

e. Accelerometer Reminder Call

After returning to the office, move the date forward in FileMaker to the next day. This call should be made after the home visit to remind participants to keep wearing the activity monitor and answer any questions or provide support. A second call should be made on day 4 of the family wearing the belts.

Voicemail:

"This is <data collector's name> calling from NET-Works. Thank you again for letting us come to your house for the visit! I wanted to remind you and <child's name> to wear your accelerometers for the full week until our next visit. This is a very important part of data collection. Please remember to wear them all day and while you're sleeping and only take them off if you're going to get wet. If you are having any problems with wearing the accelerometers please call me so we can make it easier for you and your child to wear it. Let me know if you have any questions or if there's anything that I can do to help! Thank you again! My phone number is <data collector's personal phone number>."

In person:

"This is <data collector's name> calling from NET-Works. Thank you again for letting us come to your house for the visit! I mentioned at our visit that I would be calling twice this week to remind you and <child's name> to wear your accelerometers for the full week until our next visit. How is it going with wearing the accelerometers? Are you and your child having any problems with wearing it?"

f. Home Visit #2

The second home visit should be scheduled for 8 days (or shortly thereafter) after the previous home visit. This will allow for 7 full days of wear time. Schedule appropriately with the staff and family, and record it in Google Calendar and the database.

At Home Visit #2, collect and download both monitors. If both were worn the required amount of time at this visit, thank the family, remind them that a \$30 gift card will be mailed to them after a

complete check of all the study data, and give the parent and child their \$10 gift card at the end of the visit.

If the download shows that the child monitor was worn less than the required amount of time, ask if they would be willing to re-wear the monitors for another week.

- MINIMUM WEAR TIME: (also listed on the visit checklist)
 - 6 hours per day (360 minutes)
 - 4 days
 - at least 3 weekdays and 1 weekend day
- If a re-wear is required and agreed to, schedule Home Visit #3 for 8 days out. Repeat the reminder call and scheduling as above. This third visit will be the last. Simply pick up the monitors, and if necessary, complete the third food recall. Do NOT download monitors at the house, rather do that upon return to the office

If the child wore the monitor for the required amount of time but the parent did not have the minimum wear time we will not ask the family to do a re-wear. If the parent met the minimum requirements, but the child did not we can ask that the child complete a re-wear. The child can do a re-wear on their own or the parent and child can both complete a re-wear if the parent feels that will increase compliance for the child. Discuss this with the parent to see which might be a better option for their family.

As mentioned above, an NDSR recall may also be done at Home Visit #3 if staff is having a difficult time getting a hold of the family for a phone recall. Set up NDSR on the computer (and bring a Food Amounts Booklet) before leaving the office if there may be a chance of performing a recall.

g. Re-Wear and Reduced Re-Wear

If not enough data was collected, or if the monitor(s) failed during the first accelerometer wear, by either the child or the parent, we will ask the family to re-wear the monitors. It is important to go to the second home visit with new, initialized accelerometers. Do NOT re-initialize the previously worn monitors as the battery life will be reduced. An exception can be made for the GT3X monitor since we have limited numbers of that model available and GT3X models have a better battery life. There are two options for monitor re-wear:

- **Full Repeat Wear** = If a participant has little wear recorded, then a full repeat wear for another 7 days should be requested.
- **Reduced Repeat Wear** = If significant wear has been recorded, but not enough to meet minimum wear requirements, and then opt for a reduced repeat wear. For example, if the monitor is worn consistently during the week, but there is not enough weekend wear to meet the minimum, instruct the participant to only wear the repeat wear monitor during the upcoming weekend, and schedule the pickup accordingly.
- NOTE: when in doubt, err on the conservative side and request the full repeat wear.

h. Downloading and Wear Time Validation

See Accelerometer Download and Wear Time validation on the Accelerometer Cheat Sheets for specific instructions. There are different versions depending on whether you're using the GT3X+ for the parent or the GT3X.

i. Saving Acc Files to the server

The parent and child acc files must be saved to the server after the visit in the appropriate location. The files are saved to the desktop during download (See the Accelerometer Cheat Sheets)

After the visit, drag all four accelerometry files from the desktop to your individual folder within the Data Transfer folder on the server.

When the files are on the server, drag the files into the Acc Files Processed folder on your desktop. For GT3X+ models, the raw files will be uploaded to the RCU. The 60sec Agd files will be only used for wear time validation. For GT3X models, the 1 second epoch files will be uploaded to the RCU and the 60sec Agd files will only be used for wear time validation. However, all files should be saved in your individual folder within the Data Transfer folder on the server.

The wear time validation file should also be saved to the server after the visit in the appropriate location. Drag the file from desktop to the server to make a copy. When the file is on the server, drag the file into a folder on your desktop.

j. PAM Form

When returning from the visit, after the files have been saved to the server fill out the PAM (Physical Activity Monitor) form in FileMaker. Create a new PAM form for each wear for the parent and the child.

- *Index Child ID*
- *Re-enter ID*
- *Visit number* – 00 for baseline, 12 for 12-month, etc
- *Person code*
 - "a" for adult
 - "c" for child
- *If A2 is wearing the belt, "Not A1" should be checked.*
- *If re-wear, why was wear 1 incomplete – fill in this field only for the PAM form for a re-wear*
- *Serial Number* – Record the serial number on the back of the device.
- *Date Initialized*—Date that the monitor was initialized. This is usually the day before the visit.
- *Staff ID*
- *Battery %age*—this should be 99 or 100%
- *Firmware*—This helps the device run. This can be found in the main device window in Actilife.
- *Initialization start Date*—the date/time that the monitor is set to being recording. In most cases this is the day after the measure-me visit.

- *Date ppt start*—the date/time that the participant is fitted with the monitor. In most cases this will be the date/time of the home visit. The device has not yet begun to record at this time.
- *Time ppt start*— the date/time that the participant is fitted with the monitor. In most cases this will be the date/time of the home visit. The device has not yet begun to record at this time.
- *Wear end date* –The date/time the monitor is picked up. In most cases this will be at a Measure Me visit. This is not determined by looking at the activity graph.
- *Wear end time*-- The date/time the monitor is picked up. In most cases this will be at a Measure Me visit. This is not determined by looking at the activity graph.
- *Download date*—This is the date the device was downloaded. In most cases this will be the day of a Measure-Me visit.
- *Download battery %*--This is the battery charge when the device was downloaded. It should be checked immediately upon opening Actilife. In most cases this will be done the day of a Measure-Me visit.
- *Wkdays > 6 hrs*—This is the number of weekdays with at least 6 hours of valid wear time.
- *Wkend > 6 hrs*-- This is the number of weekend days with at least 6 hours of valid wear time.
- *U of M outcome*
 - *Not Due*—In process. The participant is wearing the monitor.
 - *Monitor Failure*—When downloading the data, the device malfunctions or will not communicate.
 - *Battery Failure*—When downloading the data the device indicates there was a battery failure and as a result of the wear time was short of the minimum requirements.
 - *User Failure*—The monitor was not worn for the minimum amount of time.
 - *Lost Device*
 - *Staff Error*—An error occurred in initializing the monitor.
 - *Refusal*—The participant decided not to wear the device or refused a re-wear.
 - *Complete*—The participant wore the device for the minimum amount of time.
 - *Complete When Pooled*—The participant reached the minimum amount of time by combining days from the first wear and the re-wear.

k. Mailing belts

For challenging situations we can use the mail as one method of getting belts returned. SASEs should be left at No-show HV2s or no-show HV3s. Padded SASE Envelopes are kept in our bags at all times. If a participant is unable to be reached for a HV2 and we drop by the house, an envelope should be left with a note explaining that when we receive the belts we can send the \$30 gift cards.

Reference

Sherwood NE, French SA, Veblen-Mortenson S, Crain AL, Berge J, Kunin-Batson A, Mitchell N, Senso M. NET-Works: Linking families, communities and primary care to prevent obesity in preschool-age children. *Contemp Clin Trials*. 2013 Nov;36(2):544-54. doi: 10.1016/j.cct.2013.09.015. Epub 2013 Oct 9. PMID: 24120933.

Appendix 1—Accelerometer Script Example

“You and your child should wear your activity monitors for 7 days, or until we collect them on <Date of next home visit>. Wearing the monitor is a very important part of our study! Let’s go through the instructions for wearing the monitor. The monitor is attached to a belt that will be worn around your waist. Please wear the monitor all day and all night. The only time you should remove the activity monitor belt is when you are showering or taking a bath (or swimming or other activities in water). The activity monitors are expensive and will get broken if they get wet. Sweating or wearing the monitor in the rain will not hurt the monitor, so you should wear it when you play sports or games. The monitor collects information about physical activity and does not track your location. It’s not connected to the internet.

Since this is such an important part of our study we will download the information from the monitor at the next visit to make sure we have enough information. If you and your child were not able to wear the monitor for the minimum amount of time we will bring another set and ask you to wear the activity monitors for another week. (Baseline only: We also need to have the monitors worn for the full week in order to get your family the \$30 gift card in the mail after these Measure-Me visits and to get your put into one of the two study groups.)

[Show the sample activity graphs and explain that the spikes are movement and where there is nothing on the chart, this person wasn’t wearing the monitor.]

“It is important that you always wear the monitor in the same location on your waist, and that the monitor is worn over your right hip bone **with the sticker on the bottom**. The belt should be snug, but comfortable. You and your child can wear the monitor over or under your clothes, whichever you prefer.

[Give the GT3X to parent. Have them try on the belt to ensure it is the right size and they know where it is supposed to be worn and how to hook and unhook the belt. Adjust length of belt as needed.]

[Give the parent the Sticker Log and explain to both parent and child that if they wear the monitors all day they can put a sticker on the log right before going to bed. Also allow the child to decorate the monitor with the extra stickers in the suitcase to make it friendlier to kids. Try to have the child give their monitor a name, again in an effort to make it more friendly, and increase wear.]

“On the sticker log are also a few quick instructions in case you forget, and our phone number if you need to call us for anything. At that time, when we check the information its gathered, if it looks like you wore it every day, *(to child)* we’ll have a certificate for you for doing such a great job! We’ll call you tomorrow to check in on how it’s going. What questions do you have?