CHAPTER 11

ACCELEROMETRY

11.1 INTRODUCTION/RATIONALE

An objective assessment of physical activity has become reasonably standard, and in some cases required, for publication of physical activity intervention trials particularly where a significant portion of the activity intervention was conducted at home (non-supervised). Thus, accelerometry measurements will be obtained on all LIFE participants at **baseline, 6 months, 12 months and 24 months** during their participation in the study. Collection of accelerometry data will be used to objectively evaluate change in physical activity levels within and between Physical Activity and Successful Aging groups over the duration of the study.

11.2. PROTOCOL OVERVIEW

All participants at each site will participate in the accelerometry study. Participants will have the procedure explained to them and have the accelerometer placed on their right hip prior to their 400-meter walk if their walk occurs on baseline visit 1. If the 400 meter walk occurs on baseline visit 2 then the participant will be wearing the monitor – the participant should not take off the monitor until after the 400 meter walk (please see section 11.7). The participant will wear the monitor during the walk test and for the remainder of the clinic visit. **They will be instructed to wear the monitor for the remainder of that day (until bedtime), and then to wear the monitor for the next seven days during all waking hours (except for showers, baths, etc).** Wearing the monitor during the 400-meter walk will provide an opportunity for the participant to wear the monitor under supervision while exercising. They will be given written instructions on what they need to do each day and a phone number to call with questions. **They will return the monitor to the clinic after the seven days of recording.** When the monitor is removed from the waist, participants will be instructed to place the monitor in the 'off' position. The 'off' position is clearly labeled on the monitor (see figure below).

Once the monitor is returned to the clinic, a staff member will download the data to a PC using the USB cord and ActiLife software (version 5) and briefly review it for completeness and quality. The accelerometry data will be stored on the PC and uploaded to the DMAQC.

The main analyses performed will be to compare (a) total counts per day (b) minutes of light, moderate, and vigorous physical activity per day in participants assigned to the both the Physical Activity and Successful Aging groups.

11.3   EQUIPMENT

ActiGraph's new GT3X activity monitor has been selected for use in the LIFE study as it is the mostly widely used and validated accelerometer available and its predecessor (ActiGraph model 7164) was used successfully in the LIFE-P accelerometry sub-study.

11.3.1. Accelerometer

The ActiGraph is lightweight and compact unit with a weight of 27 grams and dimensions of 1.5" x 1.44" x .70" (3.8cm x 3.7cm x 1.8cm) that uses a solid state triaxial accelerometer to collect motion data on three axes. ActiGraph GT3X activity monitor measures and records time varying accelerations ranging in magnitude from approximately 0.05 to 2.5 G's. The accelerometer output is digitized by a twelve-bit (12) Analog to Digital Convertor (ADC) at a rate of thirty times per second (30 Hertz). Once digitized, the signal passes through a digital filter that band-limits the accelerometer to the frequency range of 0.25 to 2.5 Hz. This frequency range has been chosen to detect normal human motion and to reject changing accelerations within the pass band. Each sample is summed over a user specified interval of time called an 'epoch.'

11.3.2. Connection/Downloading

The GT3X has a direct USB 2.0 connection, which alleviates the need for secondary equipment such as a Reader Interface Unit or Docking Station.

11.3.3. Battery

The GT3X uses rechargeable Lithium Polymer battery is capable of providing power for up to 20 days without recharging. Recharging is accomplished by connecting the GT3X to any standard USB port. It takes approximately three hours to charge a fully depleted battery.

11.3.4. Data Storage

The GT3X contains 16 MB of flash memory and is capable of storing data according this protocol (1 second epochs) for over 3 weeks. Similar to hard drives in a computer, the GT3X's flash memory is non-volatile, meaning that it holds its content without the need of a power supply. In the event of a complete power loss, data is safely stored and accessible once the unit is connected to a USB port.

11.3.5. Computer and Software for Data Storage and Transfer to DMAQC

To operate this protocol a personal computer is needed with ActiLife software, version 5. Upload instructions are described in 11.10.

11.3.6. Software Installation Instructions

Initial installation of the ActiLife software will be handled by the DMAQC. Please do not select to upgrade the software when they periodically become available by Actigraph Inc. The DMAQC will upgrade the software periodically, after new releases have been tested thoroughly. If it has not been installed on your computer, please contact Delilah Cook at drcook@wakehealth.edu or Cindy Stowe at cstowe@wakehealth.edu at the DMAQC.

11.3.7. ActiGraph Initialization

Double click ActiLife icon on desktop and open the program. This icon is an ActiLife "template" that DMAQC constructed to ensure all parameters are equal across field centers.   The software window is labeled "Template: Life Study Template Ver 1.1" in the right hand corner. Restart the template icon if this is not noted in the right hand corner.

Plug USB cable into PC and into ActiGraph and click on INITIALIZE DEVICE located in the upper left hand corner. Please note that ActiLife suggests using the same USB port each time.

Select the following options, as demonstrated in the screen shots below.
- After clicking "Initialize" device, a window will appear. DMAQC created a template that automatically provides the needed settings. There is no additional accelerometer input to provide as part of the initialization procedure
- Click "Enter Subject Info…."

Except for the date, time, and name fields it should look exactly like this:
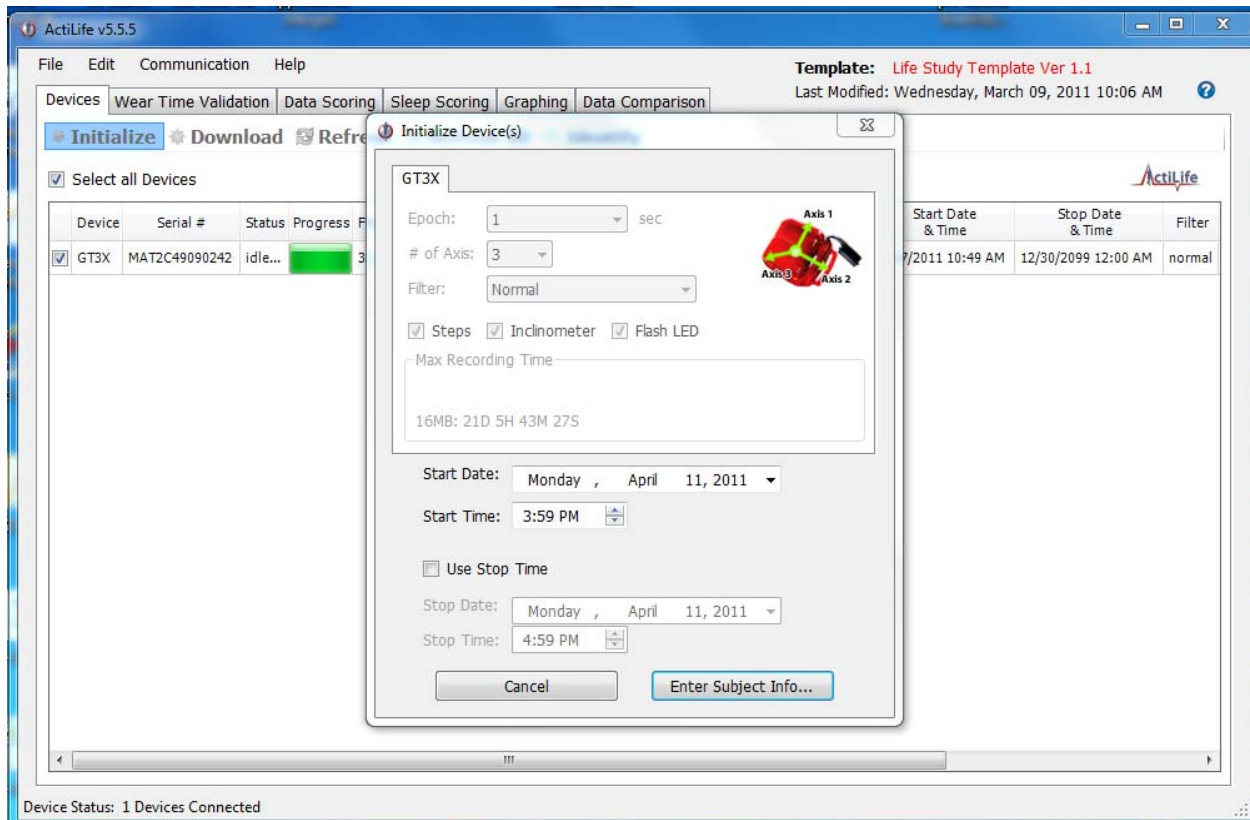
Select the following options after clicking on "Enter Subject Info…."

- A window will appear for you to enter participant information.
- Click on the "clear" button to remove the previously tagged subject name information
- Enter the following:
  - AAAAA=acrostic
  - NNNNNNN=patid (7 digits)
  - VVV=visit code (SV1, SV2, F06, F12, or F24)**
  - The line should read AAAAANNNNNNNVVV (See screenshot on next page)
  - Click on "Initialize all" to initialize the monitor

** If a device is being initialized so that a participant can wear the accelerometer for additional days due to insufficient data, a dead battery, or any other reason, please add "-2" to the end of the Subject Name. The line should read AAAAANNNNNNNVVV-2.

11.4. PARTICIPANT SELECTION

All LIFE participants at each site will be identified to participate. Participants in both arms of the study, Physical Activity and Successful Aging, are to be enrolled in this project.

11.5. PARTICPANT INSTRUCTIONS

At the baseline and the 6-, 12-, 24-month follow up visits, a LIFE clinic staff member will explain the purpose of the accelerometry study to each participant that was selected. The following description of the project should be provided to each participant.

> *We would like to measure your <u>normal</u> physical activity over the <u>**next 7 days**</u>. We can measure this by having you wear this monitor on your waistband. You wear it on your right side, just over your hip (demonstrate). We would like you to wear it from the time you get up in the morning until you go to bed at night. However, since the monitor is NOT waterproof, you will need to remove it while showering or taking a bath. When you remove the monitor please place it in the off position, which is clearly labeled on the monitor (show the label). When you place the monitor on this side it records that it is off the body. We will call you in a couple days to see if you have any questions about the monitor. You can also call us if you have any questions (show them the contact number on the instruction sheet). It is very important that you don't do any extra activity just because you are wearing the monitor. Just do your normal routine over the next 7 days. If we are unable to <u>**schedule a visit over this time**</u>, we will ask you to mail back the monitor with a pre-addressed package.*

Give the participant the "waist monitor instructions" in Appendix A.

Show the participant an Actigraph monitor and demonstrate how/when it should be worn during waking hours for the next 7 days. Staff shows the participant how to wear the monitor using the elastic belt. While there are different size elastic belts (36,48,60), the 36 and 48 inch belts should work for most participants. **The most important point is making sure the belt fits snugly against the participant's body.** The monitor should be positioned securely over the right hip so that the device lays upright and flat against the body. It is important that the monitor/belt be properly placed on the body every time the participant puts in on. They will be shown and given the instruction sheet. (see Appendix A).

11.6 MONITOR INITIALIZATION
The monitor needs to be initiated prior to the participant arriving for each accelerometry visit. Please see 11.3.7 for detailed directions.

11.7   RECORDING DURING THE 400-METER WALK
Just before starting the 400-meter walk, give the Actigraph monitor to the participant and ask him/her to put the monitor on according to the prior instructions. If the 400 meter walk occurs on the second screening visit (after the participant has been wearing the accelerometer), do not take off the monitor until after the walk is completed at the end of the second screening visit. Provide 400 meter walk instructions and assistance as needed. The monitor is to be worn on the right hip of each participant. This placement is secure, non-obtrusive and has been shown to work well for detecting ambulation, including slow walking. It is important that the exact clock time for when the 400-meter walk test was started and completed is noted. This information must be entered on to the 400-meter walk data collection form. **NOTE: If for some reason a participant cannot perform the 400-meter walk, they should still be provided an Actigraph monitor with instructions to wear it and return it on the seventh day (same protocol).**

11.8.   PARTICIPANT INSTRUCTIONS FOR NEXT SEVEN DAYS
At the end of the visit, check to see if the participant has any questions about the Actigraph or what he/she is to do for the next seven days. Be sure they have their instruction and point out the phone number they can call with any questions. Also tell them you plan to call them in two days to check how they are doing and if they have any questions about the wearing of the monitor. The monitor is to be worn starting soon after getting out of bed until just before going to bed at night. It is not to get wet, so it needs to be taken off for baths, showers and swimming.

11.8.1. FOLLOW-UP TELEPHONE CALL
On the second or third day after each participant's accelerometer visit, the participant should be called to determine how they are doing and to answer any questions about the monitor. If they cannot be reached by phone, leave a reminder message on their voice mail or answering machine, letting them know to call the clinic with any questions about the monitor. **The participant should be reminded to mail back the accelerometer after 7 days or to bring it back to the clinic if the next visit is sooner.** For follow-up visits (6 mo, 12 mo and 24 mo) a follow-up phone call is optional and site specific. The intervention team should have an opportunity to encourage the participant to wear the monitor.

11.9.   RETURN OF MONITOR TO CLINIC AND DATA DOWNLOAD
The monitor will be returned to the clinic by (a) priority mail to the clinic from the participant in a pre-paid envelope provided to the participant at each accelerometry visit or (b) returned in person to the LIFE assessment staff by the participant. Once it is returned, the LIFE staff member responsible for downloading the data from the monitor to the computer will perform the data download procedure using the ActiLife software as outlined here.

1. plug the accelerometer into PC via USB cable
2. Double-click the ActiLife icon on the computer desktop

3. Select "Download" option in upper left hand corner of ActiLife software. A window will appear asking you to "Download all devices". This window will ask you to enter: ACROSTIC, PATID, VISITCODE. Note that the VISITCODE field typically consists of 3 characters, however the field allows for up to 5 characters to accommodate instances in which the device was worn a second time due to insufficient data. You <u>DO NOT</u> need to enter the additional information that is listed in the boxes. Enter this information and select "Download all devices" to begin the downloading procedure.


4. After you select "Download all devices" the screen will disappear and you will see a bright green progress on the main window that fills as the data are being downloaded. Downloading time vary on the amount of time the monitor was collecting data. Once downloading is complete, a message "finished downloading" will appear under the status menu.
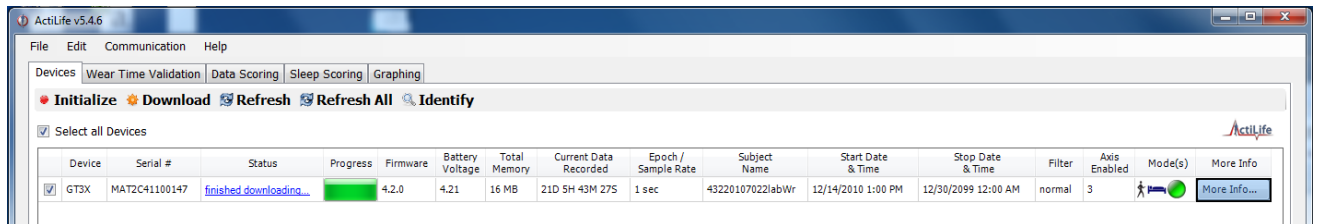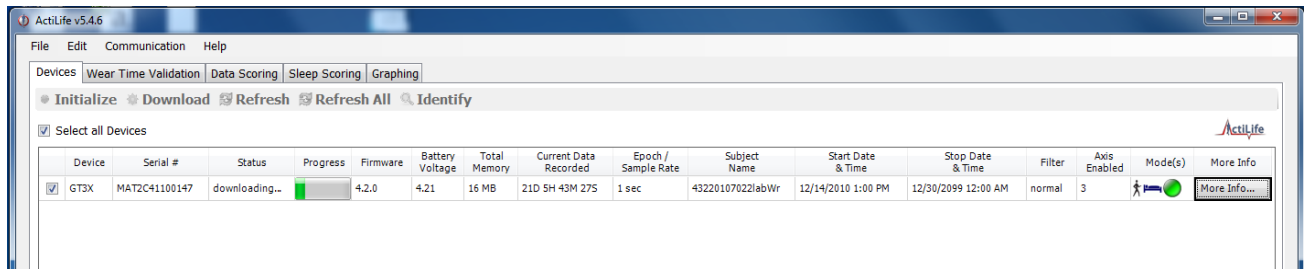
5. These next steps will provide you an opportunity to review the file to ensure that the participant wore the monitor for our goal of a minimum of ≥5 days. This process requires several steps.

> 5a. Navigate to the "Graphing" tab on the main menu.
>
> 5b. "Select Dataset…" button and navigate to the file you just downloaded. Once you select the file, a window will appear asking you to reintegrate the file. Select "Yes". You will not harm the original file by doing so. This step simply takes a snapshot of the data for you to view in a simplified manner.
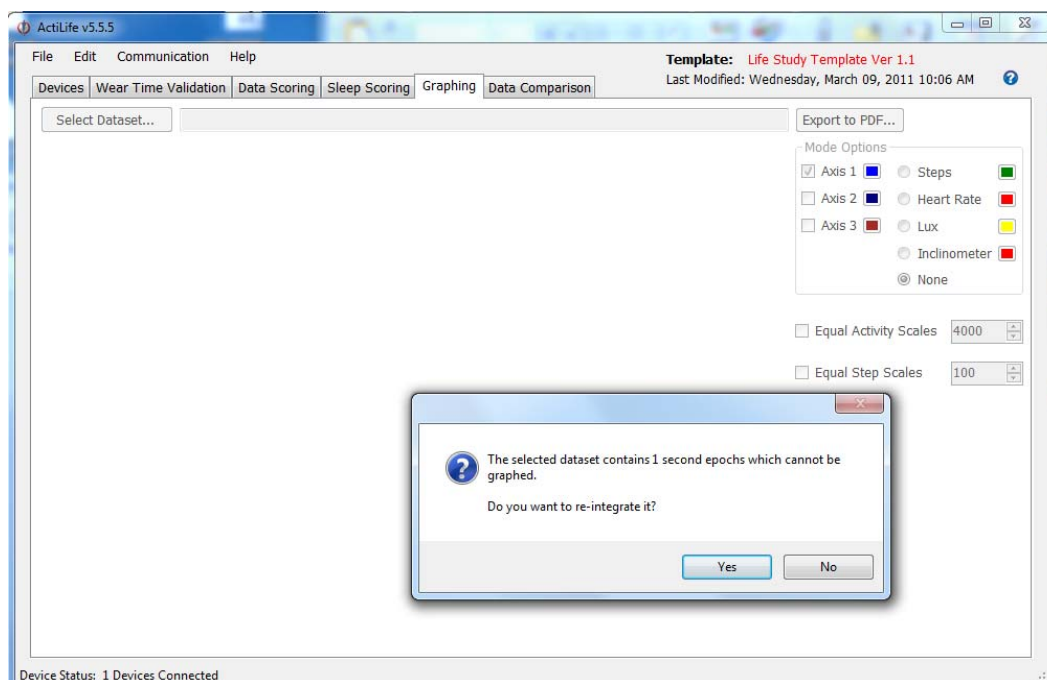
5c. Upon clicking "Yes", another window will appear asking you to select the "epoch length you would like to reintegrate to". Choose the default of 60 seconds and select "OK".
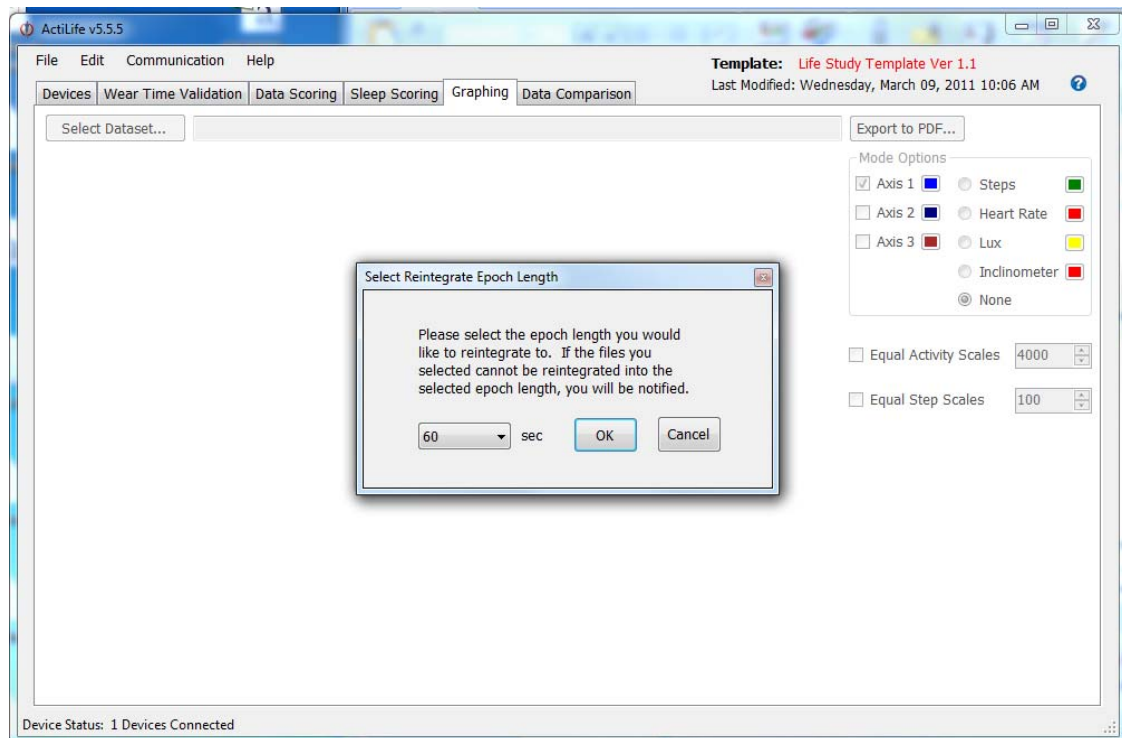
5d. The time it takes to reintegrate a file is dependent on the speed of your computer and size of the file. Don't be alarmed if the process takes a few minutes. When finished a window will appear as seen below.
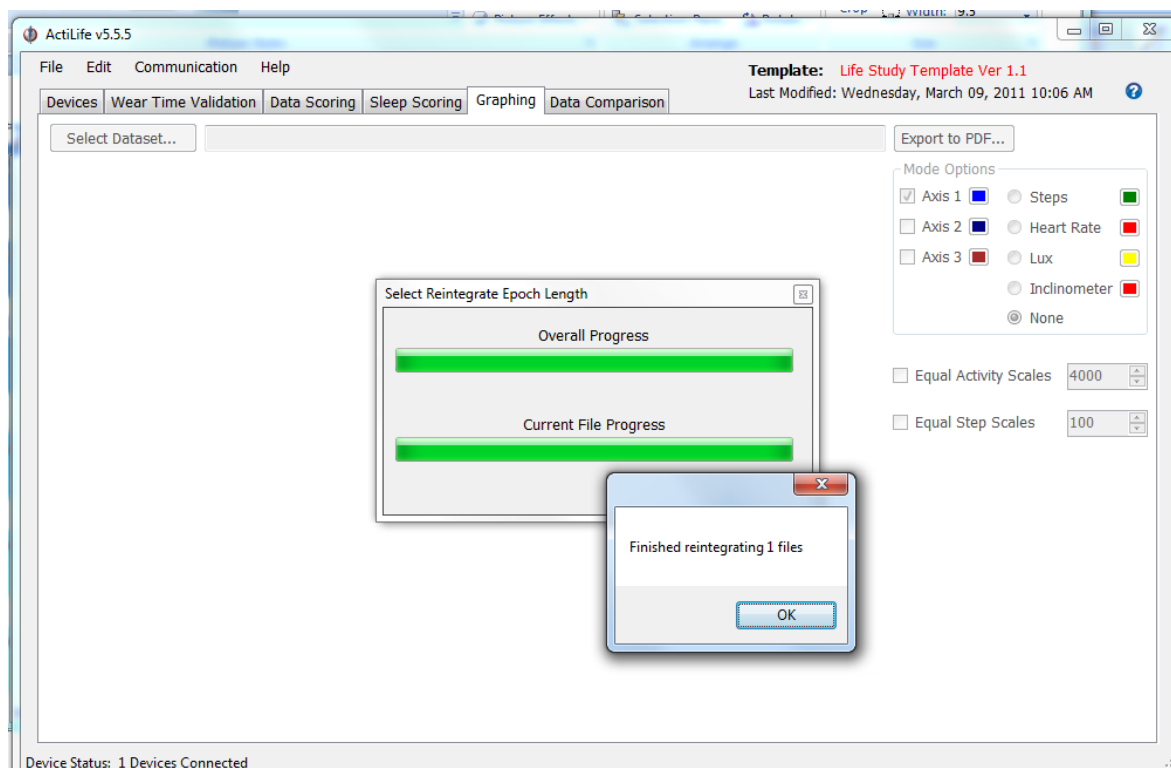
6. After selecting "OK", the file will load atomically and be displayed for you to evaluate the amount of data collected. Evaluate the number of days collected. Our minimum goal is to collect at least five days (≥ 5 days) each having ~10 hours of time when the monitor was worn and the participant was awake. You are completed with the downloading procedure.

- If you see <u>adequate data</u>, no additional steps are needed.
- If there are <u>no data present</u>, either the participant did not wear the accelerometer at all (not likely) or the device is not functioning properly.

    o **If this is the case, and you are sure it was not just a dead battery, initialize a different accelerometer and ask them to wear it again and return it on the 7th day**. When initializing the device for the participant to wear again, be sure to add "-

2" to the end of the Subject Name. The line should read AAAAANNNNNNNVVV-2. Contact __ at DMAQC to discuss replacement/repair of this unit. Do not use that unit again until this has been addressed.

- o **If you are sure it was a dead battery, recharge the battery, initialize the device and ask them to wear again for 7 days.** When initializing the device for the participant to wear again, be sure to add "-2" to the end of the Subject Name. The line should read AAAAANNNNNNNVVV-2.
- If there are data present but it is not adequate (i.e. does not reach criteria described above), ask the participant to wear the accelerometer again and return it on the 7th day. Re-initialize a **new fully recharged** device and place on participant. When initializing the device for the participant to wear again, be sure to add "-2" to the end of the Subject Name. The line should read AAAAANNNNNNNVVV-2. Re-read the instructions to the participants. Emphasize to the participant to wear the monitor at all times except while showering, taking a bath and when sleeping. If the participant had mailed the monitor to the clinic then telephone the participant about the error and re-read instructions. Reinitialize another monitor and send to the participant for wearing. Also include in your mailing a self-addressed package for returning the monitor.
- For any participant asked to wear the accelerometer again, re-emphasize the importance of wearing the device everyday and for the full day. **Also, provide them with another pre-stamped addressed envelope (addressed to the person responsible at your site) so that they can return the accelerometer by mail in 7 days.**

9. Click on the X in the upper right corner to close the window.

11.10. TRANSFER OF DATA TO DMAQC

Within 24 hours of receiving the ActiGraph from the subject and downloading data to the PC, the data files should be uploaded to LIFE website by double-clicking on the LIFE Data Upload icon on the computer's desktop. The upload will be completed automatically. Below is the icon to use.

11.11. Repairs and Replacements
If your site has an accelerometer malfunction or damage you should contact ___
and identify yourself
as part of the LIFE study. If instructed to return your ActiGraph please send to __along with a packing slip that explains the problem. In addition it is a good idea to tag (i.e. label tape) any returned accelerometer with your site's name and any identifiers you feel necessary. Depending on how many accelerometers your site needs, you may or may not be sent a replacement.

11.12. Troubleshooting
If the ActiGraph is collecting data and the monitor is properly initialized (Flash LED is checked) then the monitor will flash every 3-4 seconds. This indicates that the monitor is collecting data. If the monitor gives 2 consecutive flashes this indicates a "low battery". Please recharge fully before distributing.

11.13. Data used for analysis

This section can be ignored by the LIFE assessors.

We will ask participants to return the monitors on the seventh day. Our goal is to collect at least five days (≥ 5 days) each having ~10 hours of time when the monitor was worn and the participant was awake. For data analysis, we will use the first five days (possibly not consecutive) with at least 10 hours of wear time. Non-wear time will be determined through evaluating each 60 minute epoch for activity counts. Those epochs with zero activity counts will be assumed to be non-wear time and will be removed from the collection day. Because this approach provides the investigators enough information about wear-time, the participants will **NOT** be required to maintain a home log. We will also ask participants to set the monitor in the off position during home use (inclinometer column will read "0" in the off position). This added piece of information that is logged with data will confirm the approach of evaluating each 60 minute epoch.

11.14 Tracking accelerometers

Monitors can be lost very easily in the clinic because participants will sometimes bring them in person and other times send them by mail. The investigators have adopted a tracking log to help prevent the loss of monitors. Therefore, it is required that assessors log when each monitor is sent out and when it is returned (either in person or by mail). This is necessary step to track and help locate a monitor that appears to be lost. The monitor log in **Appendix B** shows an example form that each clinic site will adopt to track accelerometers. The clinic is welcome to modify the log as necessary and the form does not need data entered through DMAQC.

11.15 Follow-up accelerometry

Accelerometers will be included in the 6 mo, 12 mo and 24 mo clinic visits. Participants will receive a monitor prior to the 400-meter walk during their clinic visit. The monitor will be worn during the 400-meter walk and then the participant will take the same monitor home.

A pre-stamped envelope will be provided to the participant at the assessment visit. Participants may return the monitor by mail after 7 days of wearing. The participant can also return the monitor to their interventionist. The interventionist will place the monitor in an envelope and return to the assessment team. Individual sites can determine the best or combination of methods that fits their specific workflow.

Waist Monitor Instructions

Every morning you will put on the activity monitor and remove it each evening just before you go to bed. Place the monitor in the "off" position with the label facing up (see picture) any time you take off the monitor. The activity monitor will be worn until you return to the clinic or if a LIFE staff member asks to return the monitor by mail. During this time, please live your life as you normally do.

Wearing the waist monitor

1. Using the belt provided, lock elastic band snugly with the monitor around waist. Position the monitor so that it rests over your hip bone directly underneath your RIGHT armpit. Refer to picture for proper placement.

2. Keep the monitor on all day, including when you may take a nap.

3. The monitor MUST be removed when bathing (either bath or shower) or when going swimming. DO NOT GET THE MONITOR WET!

4. Please place monitor in "off" position with label facing up (see picture). Remove the monitor at night just before bedtime. If you have any problems with placing the monitors, or think they may not be working, please call the number listed below and we will call you back.

If you have any questions please call

Appendix B

Accelerometer tracking log

LIFE staff ID (person who initialized)	Monitor number (last 3 digits of serial number)	LIFE PATID	Date sent out	Date Returned
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
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