Accelerometry Protocol (Actigraph Model GT1M)

The purpose of this document is to provide explicit and detailed instruction on how to collect accelerometry measurements.

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 ActiLife6 software installed.

2. **Safety Considerations**
   There are no known risks associated with use of the monitors. The accelerometers are not designed to be worn in a wet environment, so moisture **does** pose a problem. Monitors need to be taken off for swimming, showering, bathing. Okay to sweat in them or get a little wet. Also, take them off for sleeping. The monitor does not emit radiation, electrical current, vibration, or heat and it can be worn under a shirt without causing discomfort. The device is intended to be worn or stored securely fastened at all times to a waistband. 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.

3. **Equipment**
   Computer
   USB cables
   GT1M
   Elastic belts
   Instruction sheet/log
   Postage paid padded envelope

4. **Training and Certification**
   Certification procedures for accelerometer data collection are to be completed after the training. Each staff will be required to collect data on 3 subjects for a minimum of 60 minutes. This amount of time allows for the person being certified to see a variety of different counts that could include different intensities of movement.

5. **General Measurement Procedures**

   a. 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 red light. The accelerometer is fully charged when the LED is no longer blinking but emitting a solid LED light (Charging time generally takes no longer than 4 hours.)

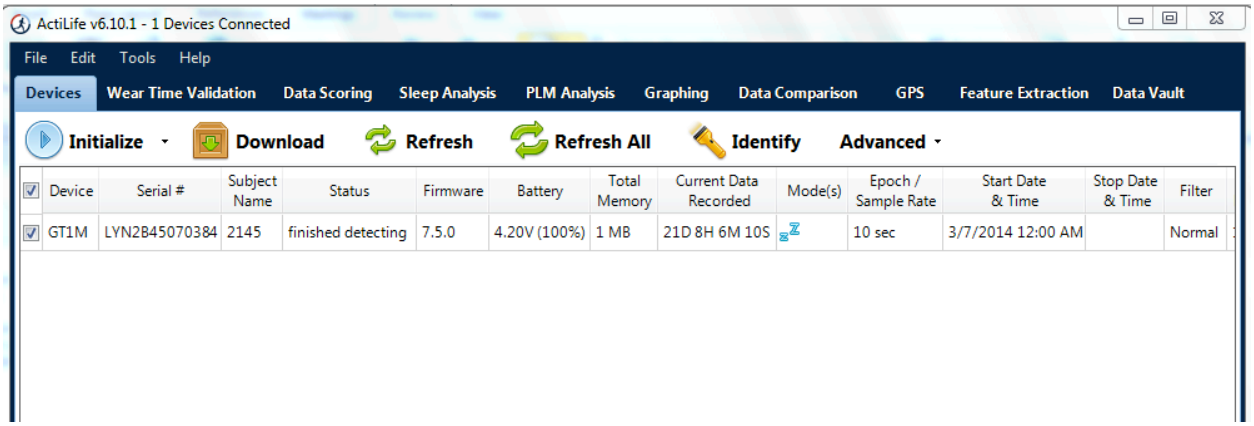
      If the accelerometers have not been used for more than 3 months, fully drain the battery by fully charging the meter and placing on a shaker for 7 consecutive days. Fully charge the meter again before initializing.

   b. Initializing the Accelerometers

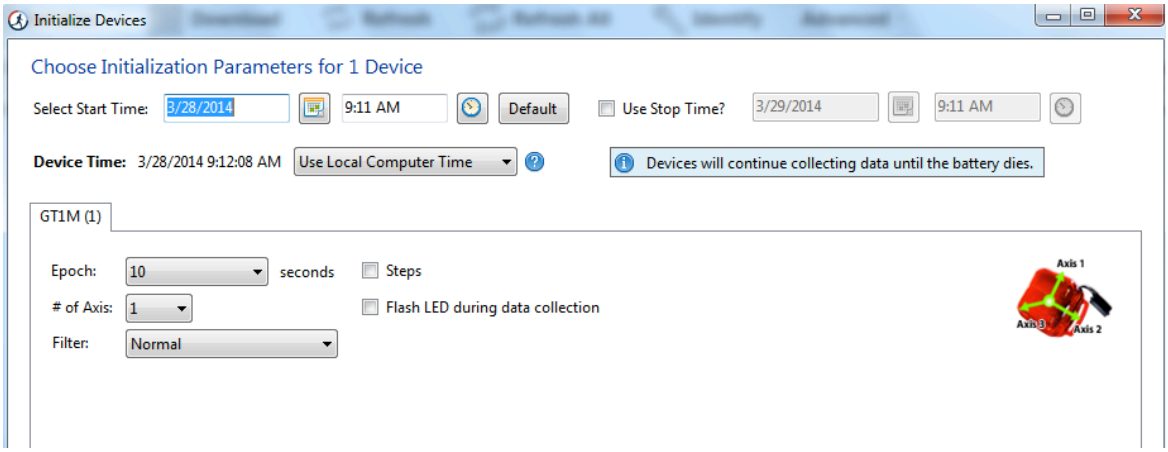
      The accelerometers must be initialized before collecting data. Initialization may be done the day before or the day of the visit. The start date and time should be programmed for the day AFTER the

visit at 12:00 AM. If the visit is rescheduled, the accelerometer must be reinitialized with the correct start date.

1. Launch ActiLife6 .
2. Connect the accelerometer to the computer cable (may take several seconds to be recognized).



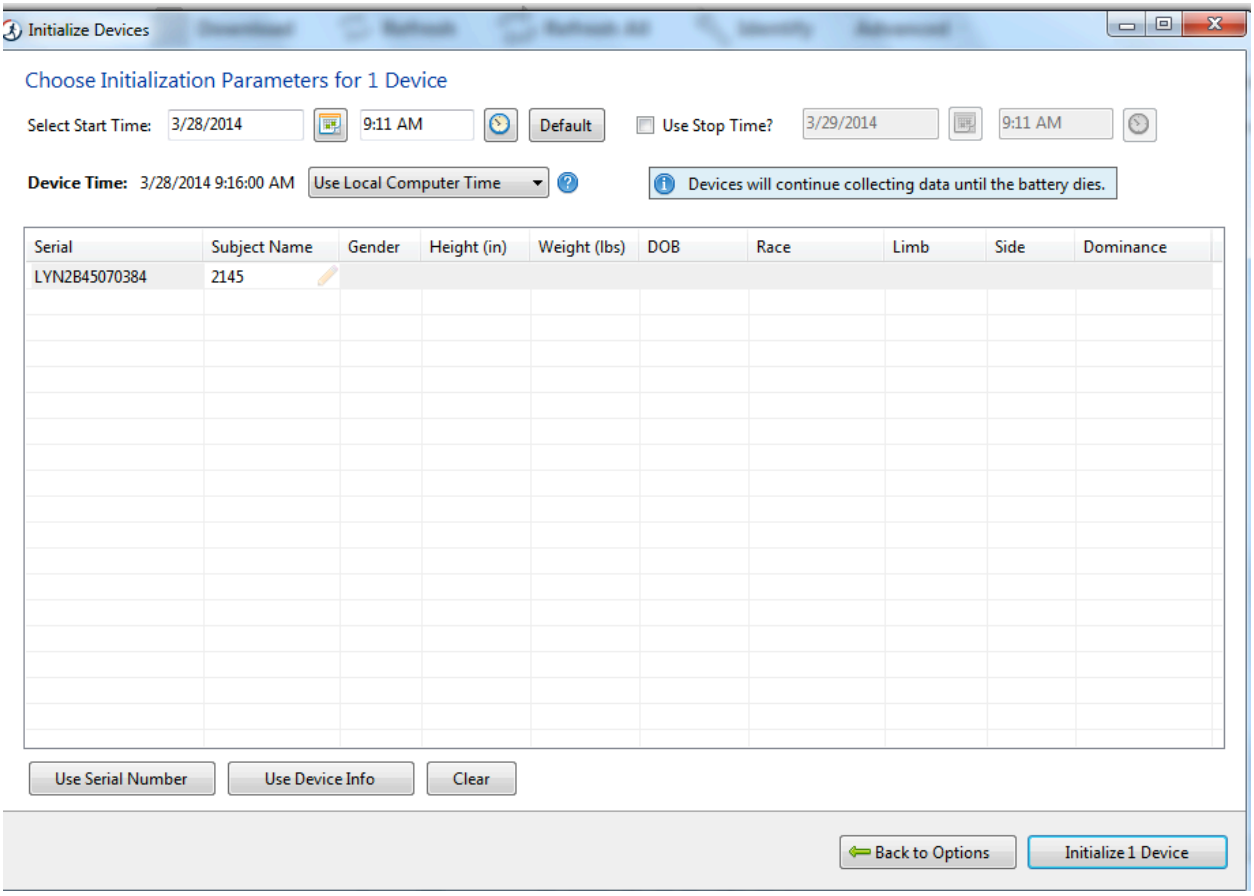
3. Once the accelerometer is found, check the “battery percentage”. It needs to be 100% to be used. (If it is not, recharge the battery or choose a different monitor).
4. Click “Initialize”. This will bring up a drop down menu. Choose “Regular Initialization ”. A smaller screen will appear with several initialization options:



Select the following options to set the specific data collection parameters for the participant.

- Epoch: 10 seconds
- Axis: 1
- Filter: Normal
- Start Date: Date after the subject visit or Date after the day accelerometer was given out
- Start Time: 12:00 AM
- De-select Stop Time: This feature will not be used.

Choose "Enter Subject Info…" at the bottom right corner to bring up the "Subject Name" screen. (This allows users to enter a unique subject ID for the attached device. This data will be stored on the device and will be available at download.)



- At the bottom of the screen, select the "Use device Info" button.
- Serial Number: Automatically pulled from the device
- Subject Name: Enter Subject ID number
- Click "Initialize 1 Device" at the bottom of the screen. The green bar in the "Progress" column will move across until completed. The "Status" column will change to "finished initializing" when the initialization process is complete.

5. Remove the accelerometer from the cable. Place the accelerometers are on the appropriate size belts (S, M, L, or XL depending on participant size).

c. Give the Accelerometer to the Participant

Explain the accelerometer procedures to the participant (calling the device an "Activity Monitor" 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.

Leave the participant with an accelerometer log and instructions. **The expected dates for wearing the device should be recorded in pencil on the log *before* the visit.**

d. Accelerometer Reminder Call

A reminder call should be made 1-3 days after the initial visit to remind participants to keep wearing the activity monitor and answer any questions. This call should be made before the weekend and with at least 4 days left of monitoring (e.g. If the initial visit is on a Thursday, the reminder should be on Friday). Leave the following message if there is no answer:

"This is <NAME> calling from the <STUDY NAME>. I'm calling to see how you are doing with wearing the activity monitor. If you have any questions, please give us a call at 612-xxx-xxxx. If not, we will see you on <Date & Time of Visit> for your next visit. Thanks!" OR

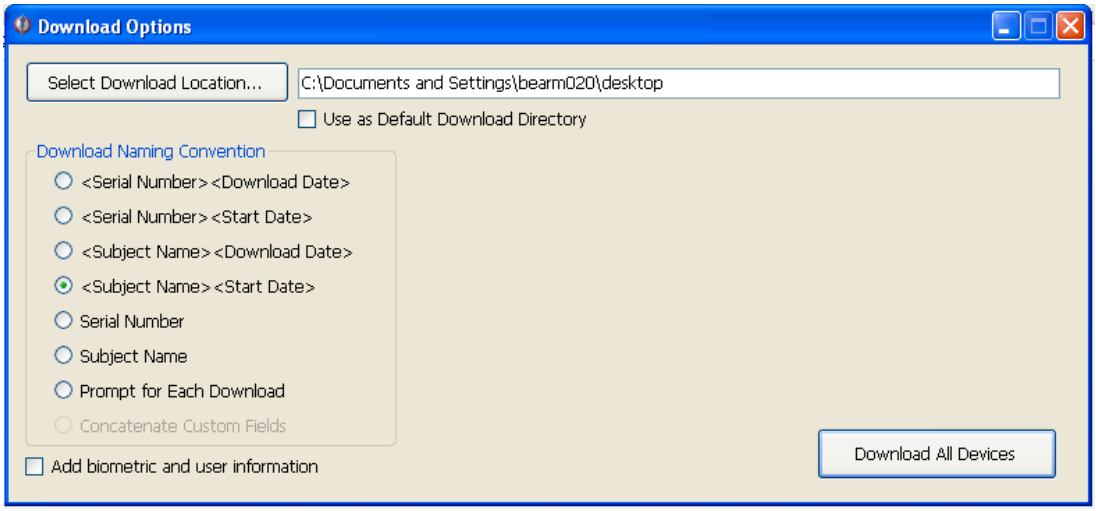
You can send the following email 1-3 days after the initial visit:

"Hello,
I am checking in to see how you are doing with wearing the activity monitor from <STUDY NAME>. Do you have any questions about the monitor? If you have any questions, please contact me know by email (Your email address) or phone (Your phone number). Do not forget to mail back the monitor at the end of your wear period <DATE> (i.e., Thursday February 28th).
Thanks,
Name, Title, Phone, Email"

e. Collecting and Downloading the Accelerometers

The accelerometers will be downloaded as soon as possible after receiving by mail or in person to ensure that data recorded properly:

1. Launch ActiLife6.
2. Connect the accelerometer to the computer cable (may take several seconds to be recognized).
3. Click "Download" to bring up the "Download Options" screen.

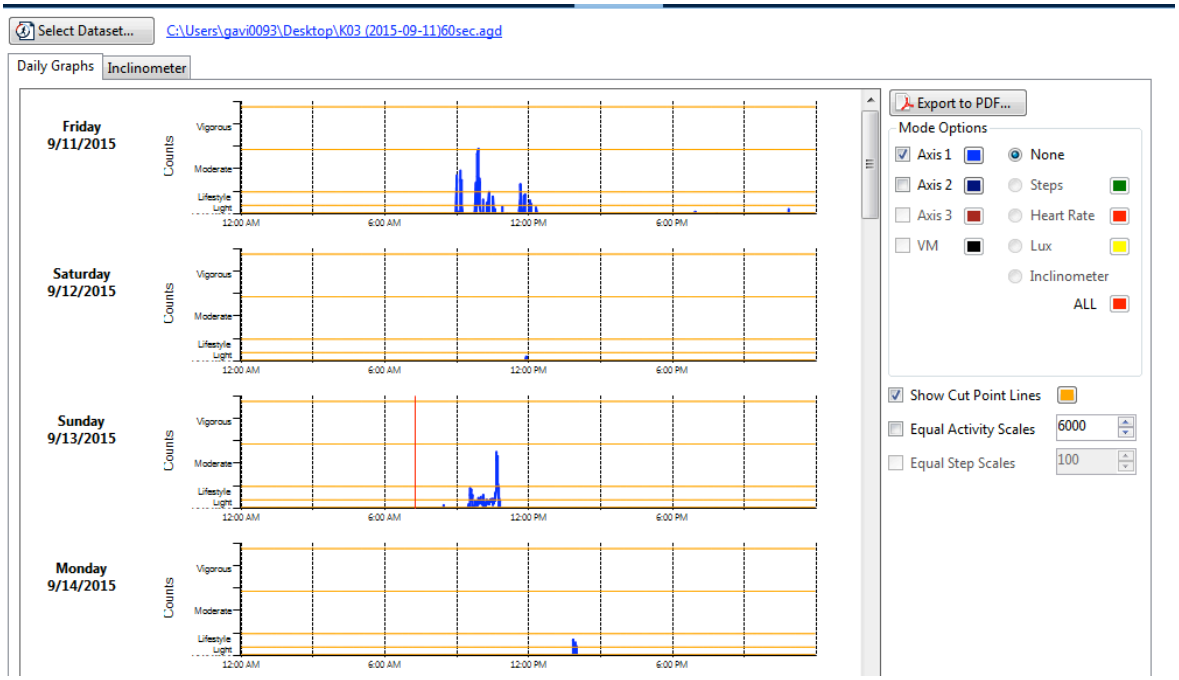


- Click the “Select Download Location” button and select the desktop. Click OK.
- Under “Download Naming Convention” select “<Subject Name> <Start Date>”.
- De-select “Add biometric and user information”.
- Make sure that the download location is set to the appropriate place. The default is the downloads folder.
- Click “Download All Devices”. This will take you back to the main screen.

4. Wait until the “Status” column states “Finished Downloading” and the “Progress” column is completely green before disconnecting the GT1M accelerometer.

f. Checking Accelerometer Data

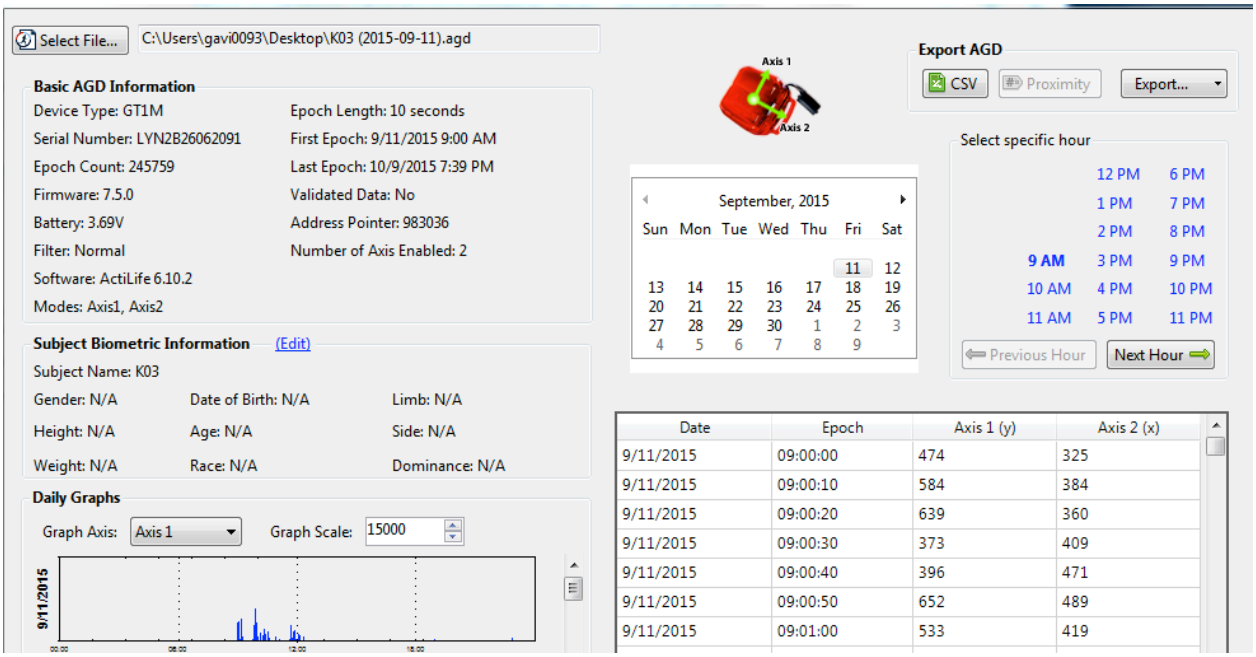
1. On the main menu select the “Graphing” tab.
2. Click “Select Dataset” and select the .agd file that was just downloaded from the desktop (Should have the subject id number and the start date).
3. This will bring up the “Daily Graphs “ window:



4. Click “Export to PDF…” then “Create PDF”.
5. Save the pdf file using the subject id number as the file name.
6. Open the pdf and check to make sure there are at least 4 complete days of data (see Appendix 2 for an example of a complete and incomplete data).
7. If there was a device failure (not all monitoring days show on the graph), contact the participant to ask if they would be willing to re-wear the activity monitor.

g. Saving the data as a CSV file

1. All data is collected at a 10 second Epoch, but is saved at a 60 second Epoch CSV.
2. Open the agd file for the participant.
3. In the AGD File Viewer, Select “Export …” drop down menu.



4. Click “reintegrate to a larger Epoch”. Select “60 seconds”.
5. Open the 60 second agd file, which will be created on the Desktop.
6. In the AGD File Viewer Select “Export Data To…” and “Export to Data Table (CSV)”
7. Save all files (Graph pdf, Actigraph agd, and Excel file) on the appropriate server.

Reference

Linde JA, Jeffery RW, Crow SJ, Brelje KL, Pacanowski CR, Gavin KL, Smolenski DJ. The Tracking Study: description of a randomized controlled trial of variations on weight tracking frequency in a behavioral weight loss program. Contemp Clin Trials. 2015 Jan;40:199-211. doi: 10.1016/j.cct.2014.12.007. Epub 2014 Dec 19. PMID: 25533727.

Appendix 1—Accelerometer Script

"You should wear your activity monitor for <##> days, or until we collect them on <Date of 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 while you are awake.

"We want you to wear the monitor as much of the day as possible. It is important for the monitor to be worn 12 hours or more a day, so if you are awake 14 hours and you take it off for things like showering, bathing, or changing clothes, that means it is really important to always put it back on as soon as you can so you are wearing it as much time as possible.

"The only time you should remove the activity monitor belt is when you are showering (or swimming or other activities in water) and when you go to bed. Sweating or wearing the monitor in the rain will not hurt the monitor, so you should wear it when you play sports or games.

"If you need to take the monitor off, put it somewhere that it will not be bumped, dropped, or broken. When you take the monitor off to go to bed, put it right next to your bed so you remember to put it on first thing in the morning when you wake up.

[Show the sample graphs of a week of activity 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. The belt should be snug, but comfortable. You can wear the monitor over or under your clothes, whichever you prefer.

[Give the GT1M to participant. 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.]

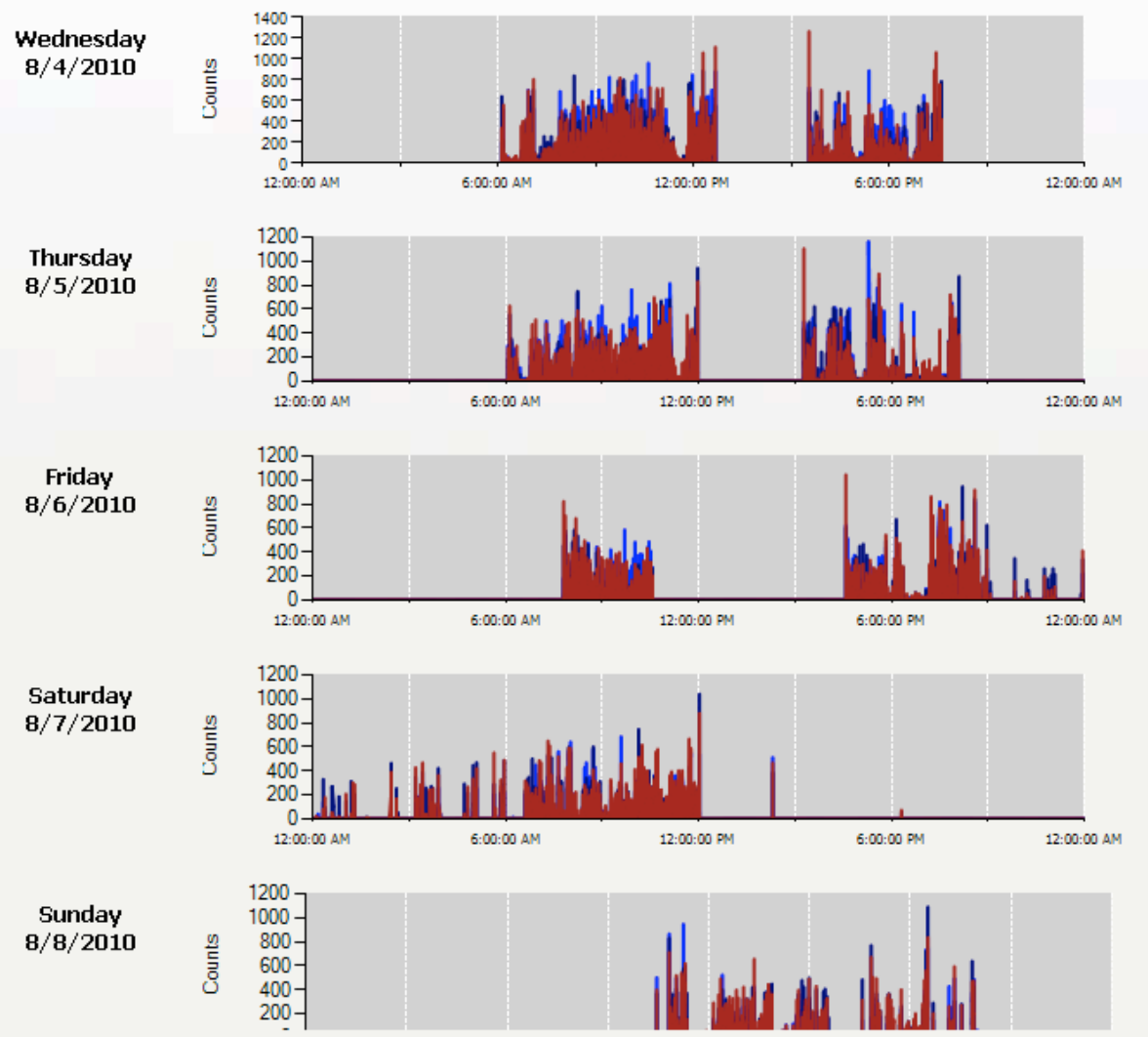
[Give the participant accelerometer log and instructions sheet.]

"Here is a log where we would like you to keep track of what time you wake up and put the belt on each morning and what time you take it off and go to bed each night. It also has some reminders about how to wear the belt."

"Do you have any questions?"

Appendix 2—Sample Graphs

1. Typical Monitoring



2. Device Failure