7. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

7.1 Rationale

Study participants will wear a portable motion sensor (i.e., accelerometer) to measure the frequency, duration, and intensity of physical activity over 7 days. The accelerometer provides an objective measure of physical activity that will supplement the interviews for self-reported regular physical activity. SOL CASAS staff will give each participant the instructions for wearing the device near the end of the SOL CASAS study visit and provide each participant with instructions on how the device should be returned to the SBLRC.

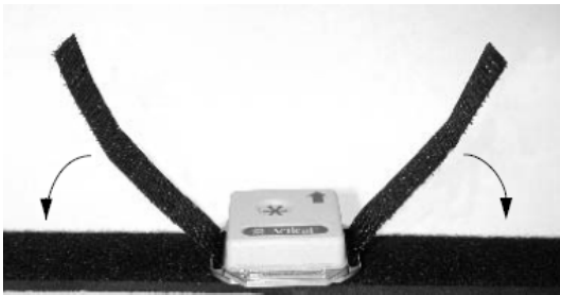
7.2 Technical Information about the ActiCal Accelerometer

The ActiCalTM (MiniMiter Respironics®, Bend, OR) accelerometer (model 198-0302-00) is a small, lightweight motion sensor that is attached to a belt and worn on the body. The Actical device measures the occurrence and intensity of motion in all directions by generating an electrical signal proportional to the force of the displacement. A microprocessor inside the accelerometer digitizes the signals, sums and stores them as "activity counts" over a user-defined time interval that can be as short as 1 second. Data can be collected and stored for approximately 6 weeks before being downloaded for data analysis. In addition to the activity counts per unit of time, the average time spent in light, moderate, and vigorous activity can be estimated.

7.3 Protocol

SOL CASAS staff will give the participant an accelerometer following the administration of study visit questionnaires. Study staff will select the appropriate size waist strap for the participant. The waist strap should be about 2-3 inches greater than the participant's waist.

Thread the Actical unit onto the waist strap as pictured below. With the belt loop on the right, the orientation of the arrow on the monitor should be facing up.

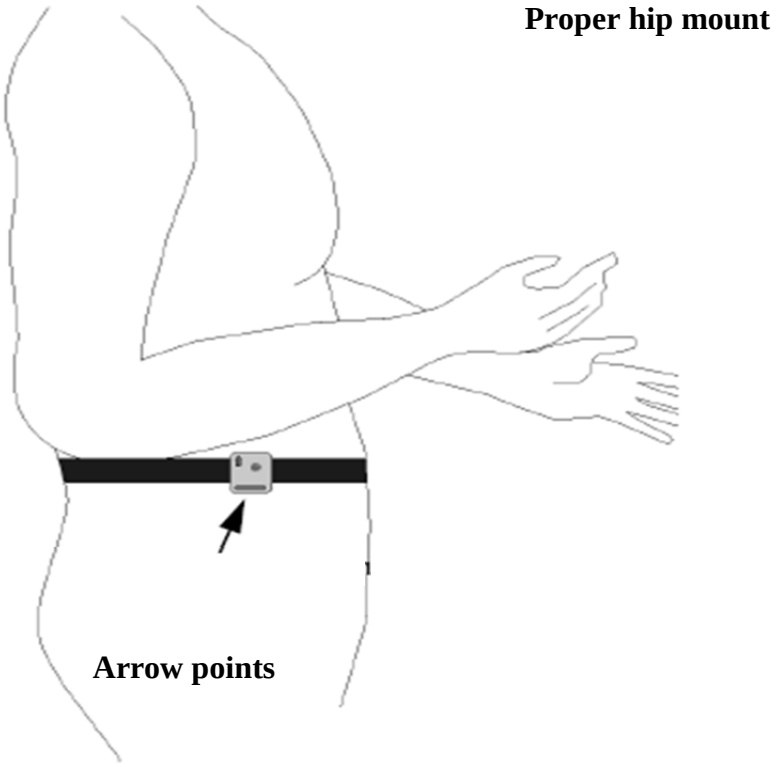


Study staff will briefly describe the purpose of physical activity monitoring (please Appendix 5 for a sample script) and ask participants to undertake their normal activities for the week while wearing the monitor. Staff will emphasize that participants should <u>not</u> engage in activities that they ordinarily would not engage in, specifically because they are wearing activity monitors.

Staff will demonstrate how the device is worn, and specify that it is worn over the right hip on the waist strap. The belt should be mounted on the body so that the device rests on the iliac crest (the uppermost and widest of the three bones constituting either of the lateral halves of the pelvis) of the hip with the arrow pointed up (toward the head). The Actical should be snug against the body (but not tight) so that it does not bounce around. The unit can be worn underneath or on top of clothing, whichever is most comfortable to participants. During the SOL CASAS study visit, participants will practice putting the monitor on properly with study staff present to provide feedback.

Generally, based on best research practices recommendations, we will measure 7 days of recording so that we can capture intra-individual variability in total, moderate and vigorous activity and increase the likelihood of capturing at least four days of activity—the length at which reliability is at least 0.80. Participants are asked to wear the accelerometer continuously over 7-days and to remove it only for swimming, showering, and sleeping.

Figure 1: Proper placement of the Actical



Participants are told that a staff member will call them two times during the week to answer any questions or concerns about the device and to make sure that the instructions are clear. The phone call also provides staff with the opportunity to remind participants to wear the monitor continuously. Before leaving the SOL CASAS study visit, staff will give participants a brochure (Appendix 4) with instructions for using the Actical. This pamphlet will also include the date indicating when the participant should stop wearing the device. Participants will be given the option of returning the Actical device to the SBLRC or having a staff pick up the device from their home. Staff will call participants again two weeks after completion of the recording period if their accelerometer has not been returned to the examination clinic.

Please see Appendix 7 frequently asked questions about the accelerometer device.

A sample Actogram will be showed to participants the day of the study visit when they are being fitted with the device. This sample Actogram will help research staff convey to the participants the type of data the device will be collecting as well as the importance of adherence. During the study visit, participants are told that they can request a copy of the actogram when they return the device after the seven days.

7.4 Equipment and Supplies

The following items are needed to conduct the accelerometry portion of SOL CASAS:

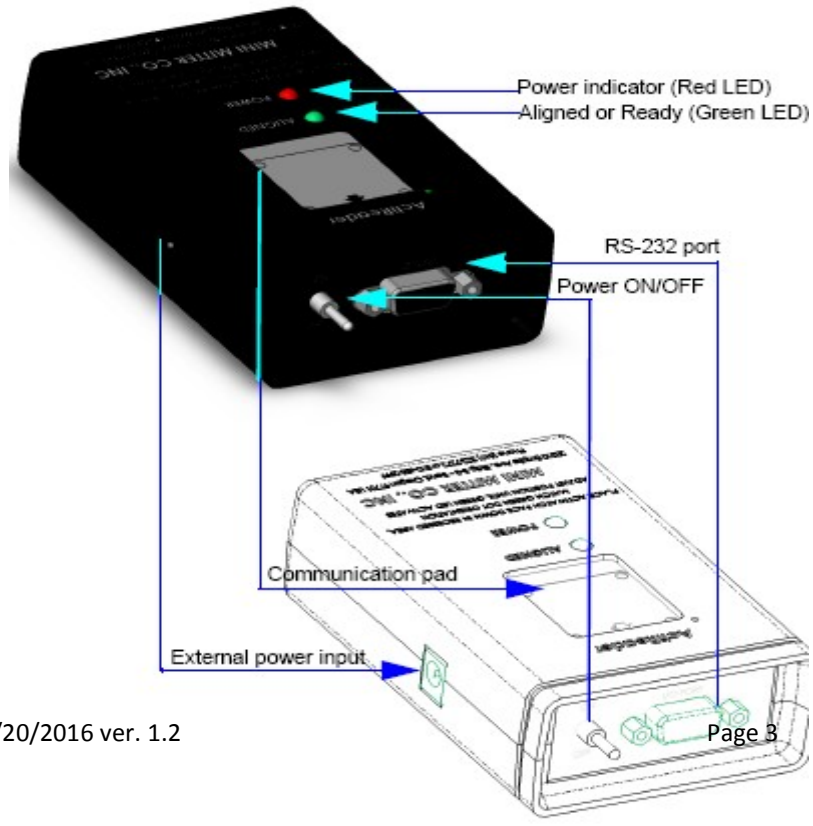
- Actical devices
- Waist straps of varying sizes
- 2 ActiReader units
- Cables with USB adapter for connecting the ActiReaders to the computer
- Actical software v3.10 to load onto the study computer
- User's manual for the Actical
- "O-rings" (to be checked when replacing batters)
- CR2025 lithium coin cell ion batteries

The ActiReader will be connected to the study computer. The computer does not need to be dedicated to collecting the accelerometry data; however, it should be available whenever units are returned so that data can be downloaded and stored when the units are received.

7.5 Initial Hardware and Software Set-up

Actical software must be installed on each PC (laptop or desktop) that will be used for initializing and reading Actical data. Detailed installation instructions are provided in the Actical User's Manual found online. A hard copy should be present at each field center and the coordinating center.

Figure 2: The ActiReader Device



1. Install the Actical software by loading the installation CD into your drive and follow software installation instructions.
2. Connect one end of the serial communication cable to a USB COM Port on the PC and the other end to the ActiReader (Figure 2). As soon as the reader is plugged into the PC, a window should pop up saying which COM Port you are connected to (e.g., COM 2).
3. When you first open the Actical 3.10 software, go to Reader > COM Port and select the appropriate port number (e.g., COM 2)

4. Test the ActiReader set by selecting: Reader > Test Reader. Follow the prompts through the test procedure. If the test fails, follow the prompts to correct the problem.
5. If the Belkin adapter cable is not recognized and you are using a 64-bit Windows 7 system, you may need to download a special driver (contact Jordan Carlson jacarlson@cmh.edu).

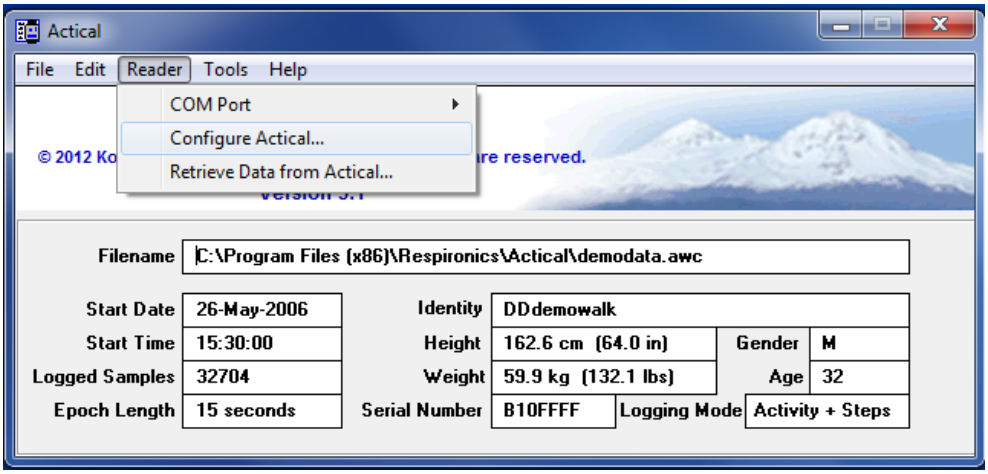
This procedure should be repeated for each computer/ActiReader used in the study.

7.6 Initializing the Actical Device

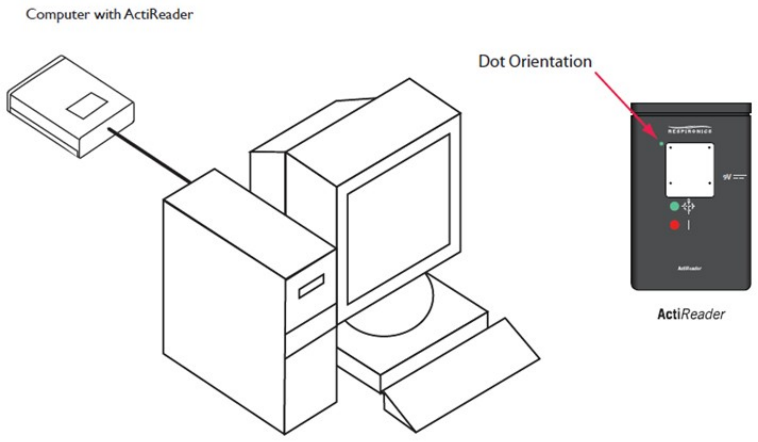
Initialization of the Actical device should not take place before the participant arrives to the South Bay Latino Research Center (SBLRC). Once the participant arrives, the study staff should select an Actical and record the monitor serial number and participant ID in the accelerometry tracking log. Then the study staff should initialize the accelerometer using the following steps:

Each Actical device must be uploaded with set-up information (initialization) prior to collecting data. This is done within the Actical 3.10 software and then loaded onto the Actical device using the ActiReader.

1. Open the Actical main window and select Reader > Configure Actical, and follow the prompts that alert you that setting up a device will erase previously stored data.

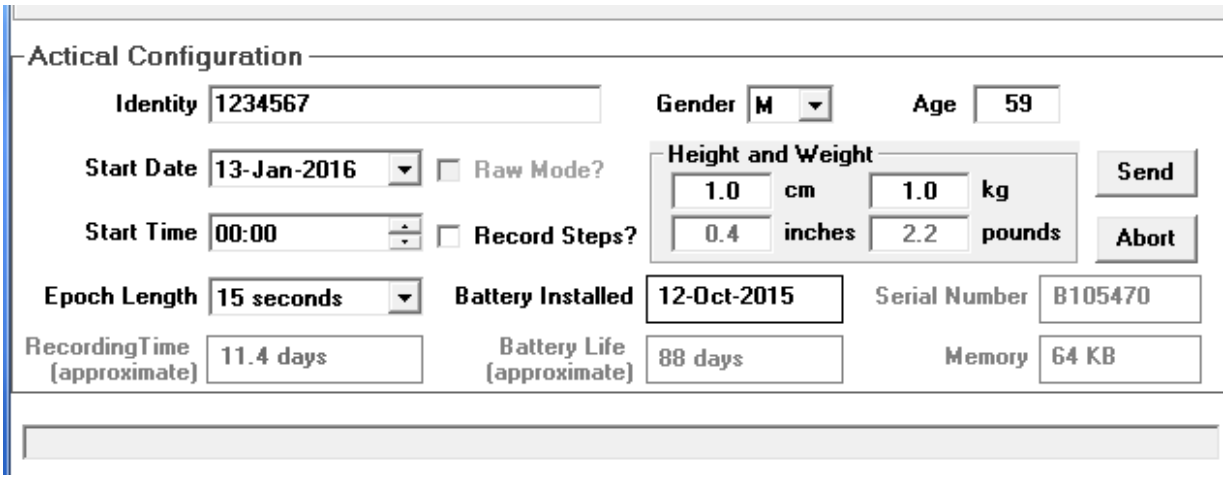


2. Click “Yes” in response to the question “Do you want to continue?”
3. Place the Actical device on the ActiReader by aligning the green dot in the metal back of the communication pad, the green LED will light up. The “communication” bar at the bottom of the screen will demonstrate a connection.



4. Click “Okay”.
5. Check the battery life displayed under the battery fitted date. If the value is less than 5 days, then replace the battery even if the battery was not scheduled to be replaced.
6. Under “Identify” enter the participant ID number. Enter gender and age as appropriate. The start date should be the next day’s date and the start time should be entered as 00:00 (midnight). Epoch length should be set to 15 seconds using the drop down menu. Enter 1.0 for height and weight because these values will not be used for SOL CASAS.

    - The participant should leave the study visit wearing the actical device even though the device won’t be recording any data until midnight of the next day. This is so that staff can observe that the participant is wearing the device correctly and to ensure that data will be collected in the event that the participant is still awake and moving about when midnight approaches. The participant should not be told that the device is not collecting data when they put it on.
    - For example, if a participant arrives and completes the study visit on 1/12/2016, the start date and time would be set as follows:



7. When all the information has been entered, click “Send”. The information will be sent to the Actical device.
8. The initialization progress will be shown by the red bar at the bottom of the window.
9. Remove the device from the reader, put it back in the plastic case, and label the case with the participant ID number. The case should then be stored with the participant chart until

the time of the CASAS study visit.

10. During the study visit, staff will place the Actical device on a belt for the participant to wear. The participant should start wearing the device during the visit. The staff should demonstrate to the participant how to put on, wear, and remove the belt as outlined in the brochure (Appendix 4).
11. Arrangements for the return of the accelerometer should established at this time.

7.7 Instructions for using the Accelerometer

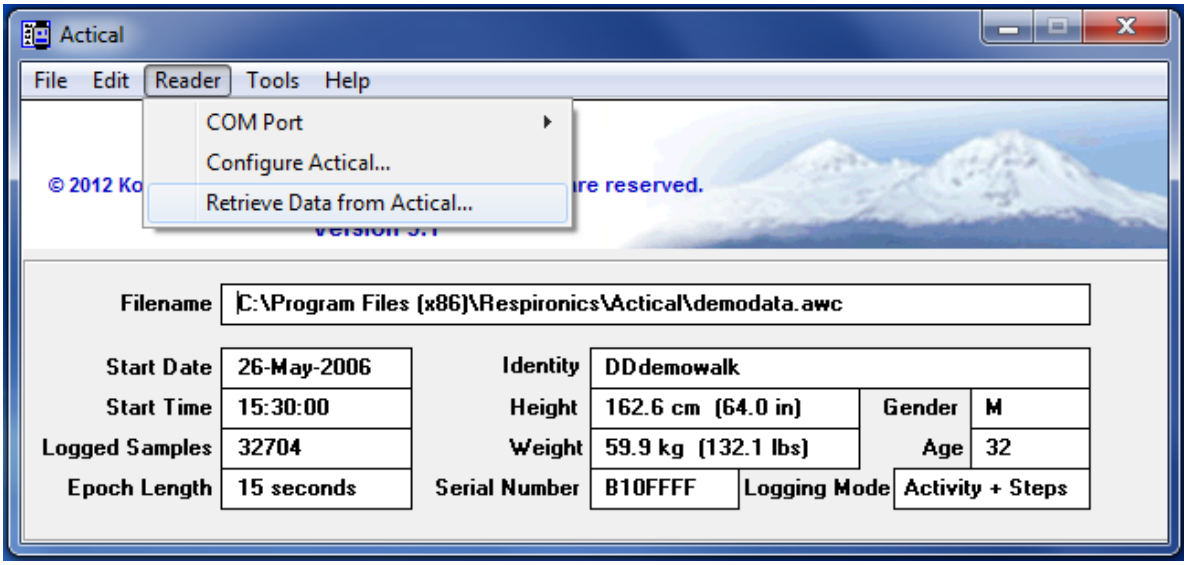
A brochure (Appendix 4) with instructions for the use and return of the accelerometer should be given to the participant before he or she leave the SBLRC and should include the following points:

1. What the accelerometer is and what it records;
2. Importance of wearing it every day, all day;
3. Proper placement of the accelerometer;
4. Importance of returning the accelerometer promptly;
5. Expect telephone calls two times during the week following the clinic visit to make sure the participant is wearing the accelerometer and understands the instructions;
6. Expect telephone call to check up on the return of the accelerometer if it is not received back within two weeks of completing the protocol.

7.8 Downloading the Data

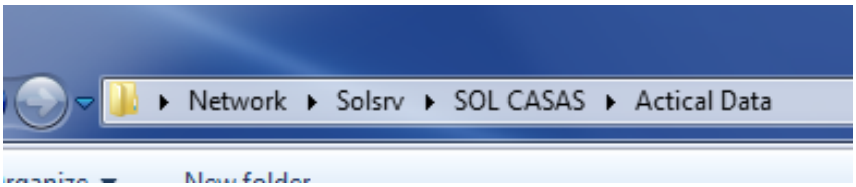
As soon as the accelerometer is returned, download the data. This should be done on the same computer on which the accelerometer was initialized.

1. Place the device into the ActiReader and open the Actical 3.10 software.
2. Click on Reader > Retrieve Data from Actical. The data download will be shown by the red progress bars at the bottom of the window. A prompt will tell you when the download is complete.

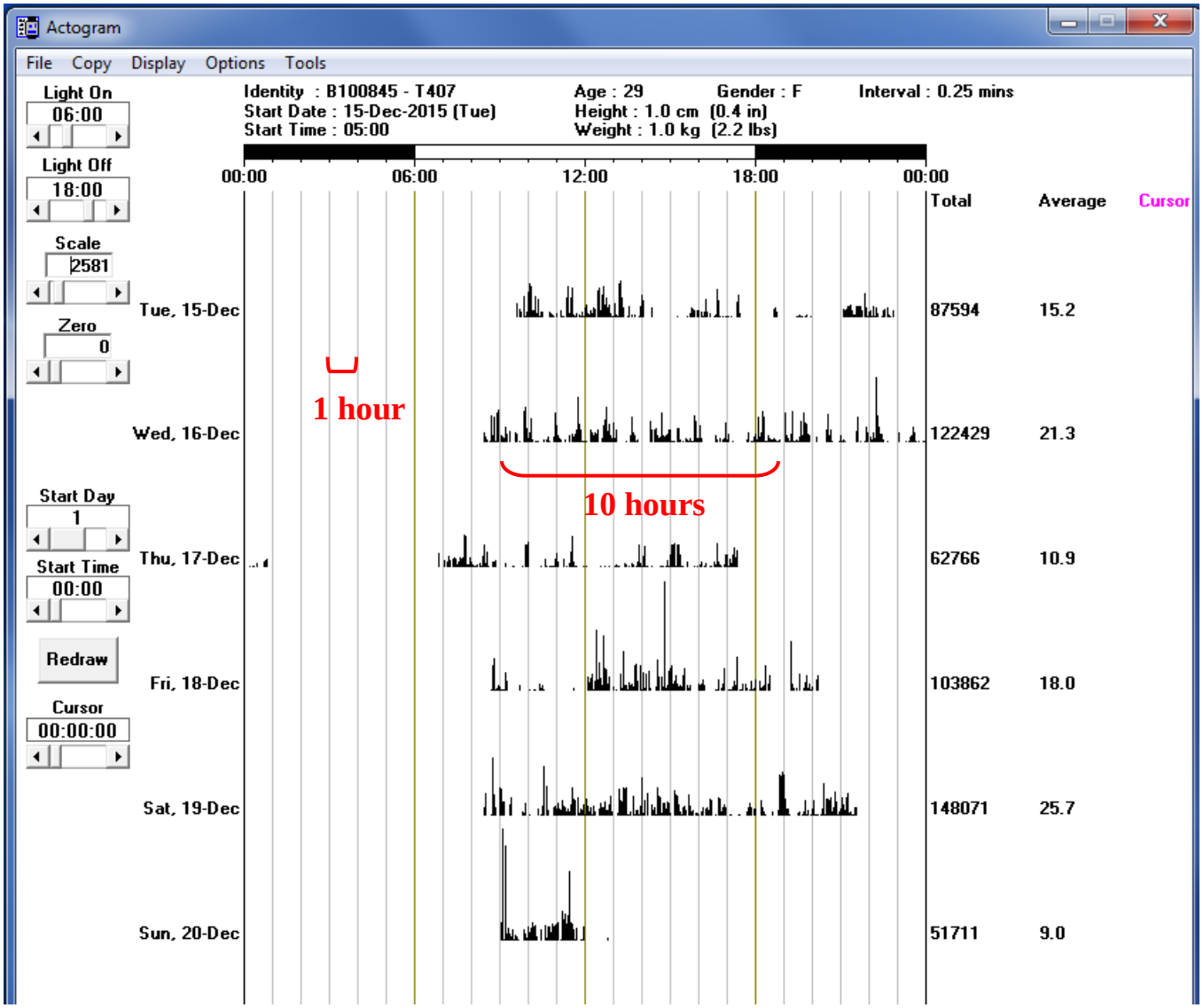


3. Once the download is complete, a window will appear stating “Actical Data Retrieved Successfully”. Click “Save Data Now”, assure that the file name is appropriate (select the default name, but remove the “list” part. Therefore, the file name is the participant ID and will have the extension awc). Select the appropriate location (shown below) to

save the file to. After saving, navigate to the folder to assure the .AWC file was saved appropriately. Path to folder:



4. Next, check to assure that the participant wore the device for the required minimum wear time of at least 4 days with at least 10 hours per day.
    a. Click on Tools > Actogram.
    b. Count how many days have at least 10 hours of wear time. Each vertical grey line that extends from the top to the bottom of the window represents 1 hour. The vertical black lines within each day show movement and indicate the times when the device was worn. When there are no vertical black lines, it means the participant was not wearing the device. In general, you should identify, for each day, where the black lines start and end, and calculate the time frame (i.e., number of hours) between those start and end points. The only exception to this method of calculating wear time is that gaps of over 120 minutes of non-wear (i.e., no lines) in the middle of the day should be excluded from the total wear time calculation.
    c. If the participant has not worn the device for at least 10 hours per day on at least 4 days, they should be asked to rewear the device for 7 more days. Note that a new device will need to be initialized to collect data again. So you will need to initialize another device and give it to the participant before he or she leaves the field center..



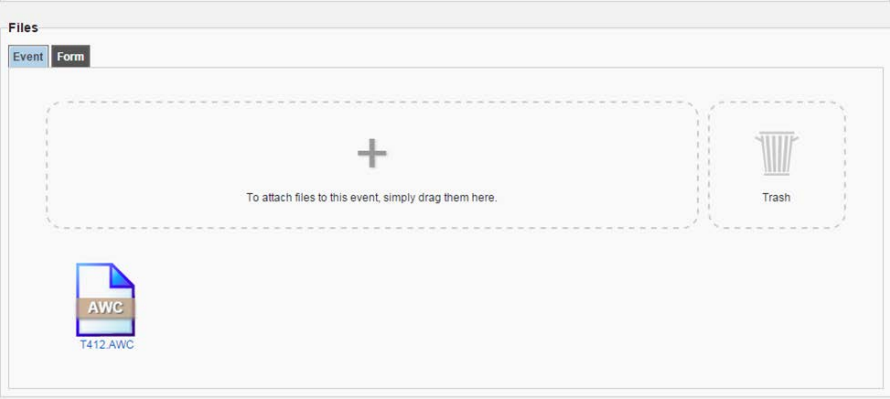
7.9 Quality Control

It is important that each Actical unit not be worn more than 4 times since the quality of data collected can diminish after 5+ uses. The number of times an Actical unit is used will also be tracked in the Inventory log to ensure it does not exceed 4 uses. After 4 wears, remove the Actical from circulation by placing it in the box labeled "Acticals used 4 times in SOL CASAS".

7.10 Transmitting Data to the Coordinating Center

Actical files will be sent to the Coordinating Center by uploading the files to CDART.

1. Go to the CDART website and log in: https://cdart2.cscc.unc.edu/CDART2/login.jsp.
2. Use the search box to find Subject's ID. Click on the subject's ID to open the forms.
3. Click on "edit form" (the red pencil icon) for the (CEL) CASAS Eligibility form.
4. Click and drag your chosen file from the Actical Data folder to the event area.
    a. Once the file is uploaded, it will appear below this area.
    b. To discard this attached file, simply drag it to the defined "Trash" area.
5. Click on save when the chosen file is uploaded to the appropriate subject's CASAS Eligibility form.



7.11 Equipment Maintenance

7.11.1 Cleaning

The Actical devices should be disinfected after each participant use by wiping the surface with a non-alcohol based germicide such as Lysol disinfectant wipes. Cleaning should only be carried out when the battery cover is in place and fully sealed.

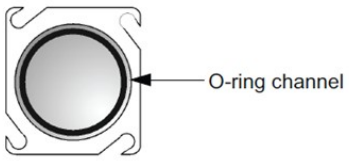
Waist straps should be rinsed in a cleansing solution such as Tide and hang to dry after each use.

7.11.2 Battery Replacement

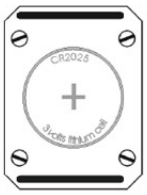
The Actical unit runs on a CR2025, 3-volt, 220-m-Amp-hour Lithium Manganese cell battery. The battery is required for data collection, reading, and writing. Although stored data are not lost after the battery has run down, it is important to change the batteries after every other use. A battery indicator light on the reading device will display a green light when the battery is charged. A log of battery changes should be kept for each Actical device.

The steps are as follows:

1. Remove the strap from the watch and use the flathead screwdriver to loosen and remove the 4 screws on the slots in the battery cover of the device.
2. Turn the cover clockwise to display the battery (if the screws are loosened). Life the cover off if the screws are removed.
3. Remove the battery and discard.
4. Clean the O-ring channel with a dry, lint-free cloth (DO NOT USE ALCOHOL).

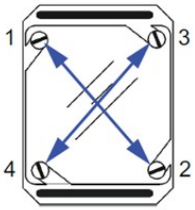


5. Place the clean O-ring into the channel on the back cover by pre-stretching the O-ring by gently flexing it in several directions. Be sure that it is properly sealed in the channel and is not twisted or deformed.
6. Place a new battery into the Actical case, positive (+) side up.



7. With the green dot in the upper-left corner and the back cover upright to the able to read the wording, rotate the back cover counterclockwise until the slots in the back are firmly sealed around the screws and the back is square with the case (or replace the cover and screw it firmly back on).
8. Tighten all 4 screws in an "X" pattern until snug.

CAUTION! DO NOT over-tighten the screws. They can be stripped easily.



9. Test the Actical battery by placing it on the ActiReader. A green LED light indicates successful battery placement and installation.
10. Record the Battery Fitted Date in the Actcal set up.

For any technical questions or product support, please contact Philips Respironics at 1-800-685-2999.