

ACTIGRAPHY

1. Background

The equipment that will be used for this study, the Actiwatch® 2 (from Phillips Respironics, Inc) actigraph, is a small device that will be worn on the non-dominant wrist for 5 24-hour periods (minimum of 3 nights). The actigraph will be worn for 5 evenings of sleep. The actigraph contains a solid-state piezoelectric accelerometer (sensitive to 0.025 G and above), an ambient light monitor, a rechargeable lithium battery, microprocessor, non-volatile 1Mbits of memory, and associated circuitry. The orientation and sensitivity of the accelerometer are optimized for highly effective sleep-wake inference from wrist activity, which has been previously validated. This device has been successfully used to collect similar data in many other populations. The output from the actigraph supplies information about percent sleep, number of awakenings per night, length of awakenings at night, percent wake, napping behavior (number of naps and length of wake periods between naps) and variables that summarize patterns of circadian rhythms.

2. Equipment and Supplies

- **Actiwatch® 2 device**
- **Actiwatch® 2 communications dock**
- **USB plug attachment with 6 ft USB cord**
- **Actiware® Software**
- **watchbands (come with the actigraph)**
- **terry-cloth wristbands (optional)**
- **Additional docking stations with AC adapter and USB cord (optional)**

3. Setting up the Actiware® Software

Actiware® version 5.54 is a Windows program that is used to initialize Actiwatch® 2 actigraphs, and to download data from the devices.

The CD and software installation guide is provided with the Actiwatch® 2.

Step 1: Insert the Actiware software CD into your computer's CD or DVD drive.

Step 2:

- Click ***Install Respironics Actiware*** in the window that automatically displays when the CD is inserted.
- If the window does not automatically appear, then select ***Start>MyComputer***.
- Select the CD/DVD drive on the list and double-click.
- Select CDMENU.EXE and double-click to open it.
- Click on ***Install Respironics Actiware*** to install the software.

The software is now installed on your computer.

Step 3: The software now needs to be activated. Call Respiroics (1-800-345-6443) within 30 days of loading the software to receive an activation code. You will need the proof of purchase number found on the back of the folder that contained the installation CD. Once you have the code, open the software by double-clicking on the Respiroics Actiware 5 icon on your desktop, then select the button for “Enter activation Key”.

4. Connecting the Communications Dock

Connect one end of the USB cable to your communications dock and the other end to your computer.

If you have multiple communications docks you can use the additional docks for charging the internal Actiwatch® 2 batteries. Connect the additional USB cable to the additional communications dock, then to the appropriate AC adapter. Plug into the outlet.

NOTE: The USB cable that connects to the PC or the AC adapter must always be installed or removed with the Actiwatch® 2 device **OUT** of the communications dock.

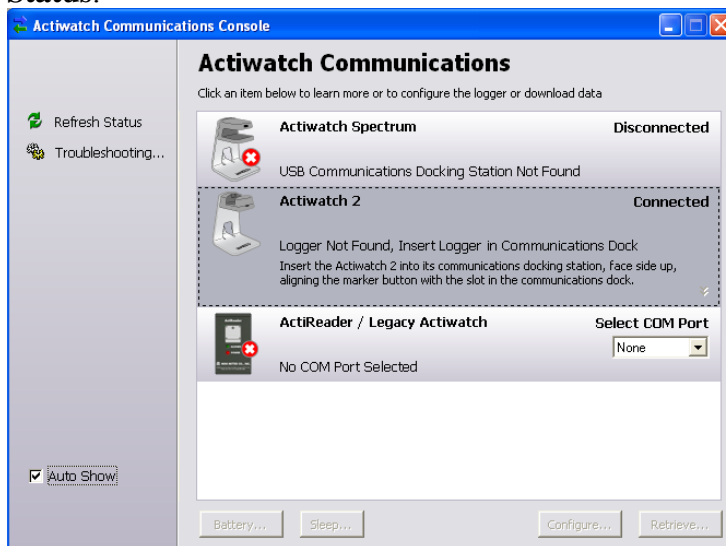
5. Configuring the Actiwatch® 2 for Data Collection

1) Open the Actiware® software

2) From the main menu bar select Communications>Actiwatch Console, or click in this



3) On the Actiwatch Communications Console, click on Actiwatch 2 (shown below). The status of the connection will show as either “Connected” or “Disconnected”. If “Connected” does not appear, try another USB port on your computer. Click on **Refresh Status**.



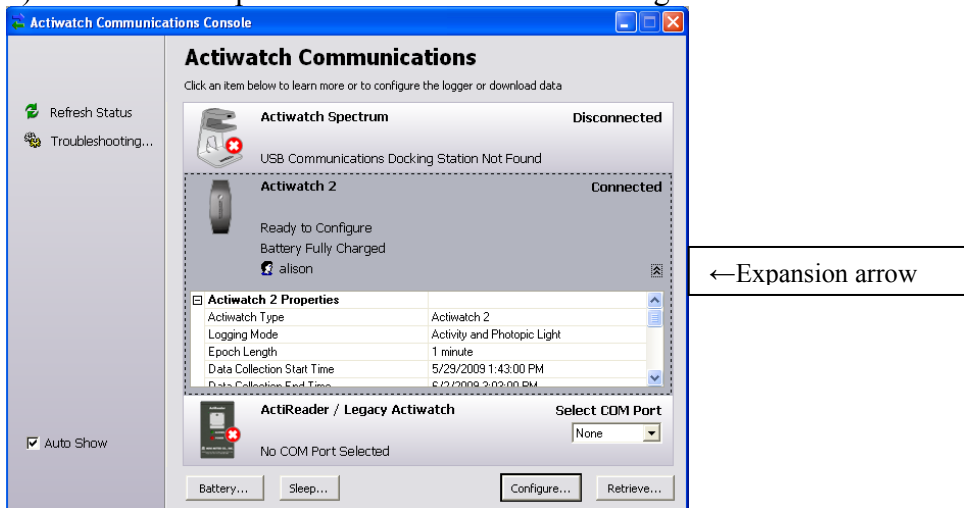
4) Place the Actiwatch® 2 in the docking station by holding it at an angle with the event marker button on the Actiwatch® 2 above the indentation on the communications docking station. The front of the communications docking station is slightly flexible, allowing the Actiwatch® 2 to be pushed into place.

Once the dock is connected and the Actiwatch® 2 is in place, the light in front of the dock will be:

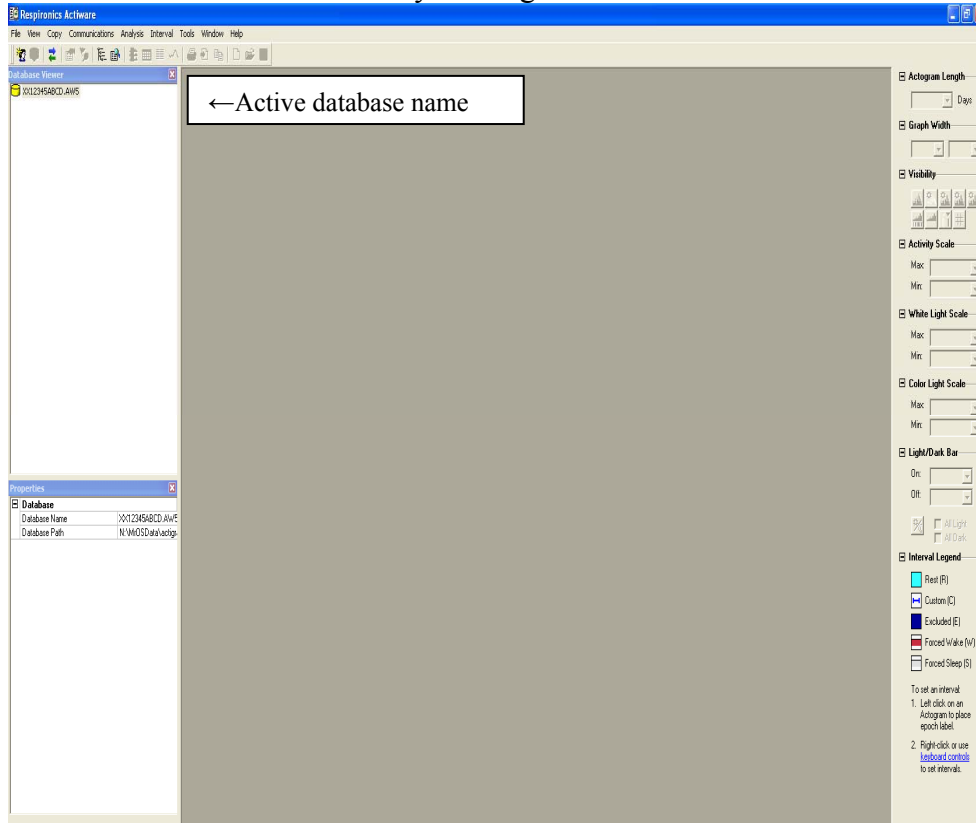
- RED if the docking station is connected but no Actiwatch® 2 is docked or it is not communicating
- FLASHING GREEN if an Actiwatch® 2 is docked but the batteries are not fully charged
- SOLID GREEN if an Actiwatch® 2 is docked and the batteries are fully charged.

5) Once the Actiwatch® 2 is docked, wait a few seconds for the communications console to refresh, or click **Refresh Status**.

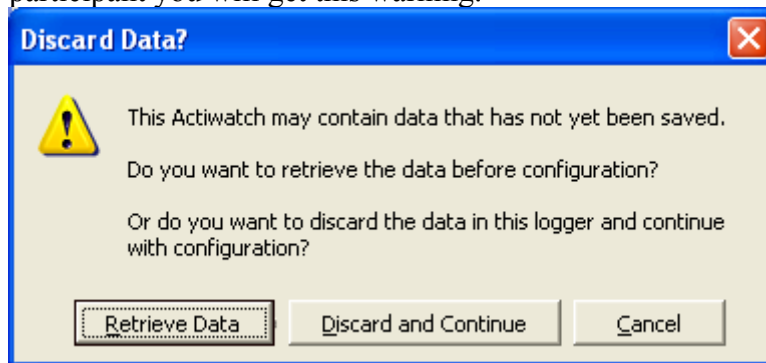
6) Click on the expansion arrows to view the configuration details.



7) Create a new database for each participant. Select File>Database>New. Select the file name to be the participant ID and acoustic (example: XX1234ABCD.AW5). You can see that this is the active database by looking in the database viewer to the left.

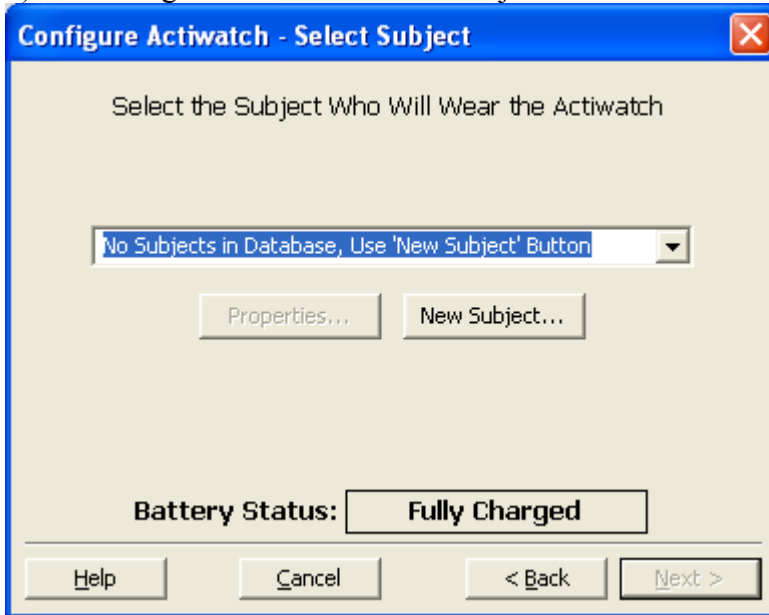


8) Click **Configure**. If the actigraph was previously collecting data for another participant you will get this warning:

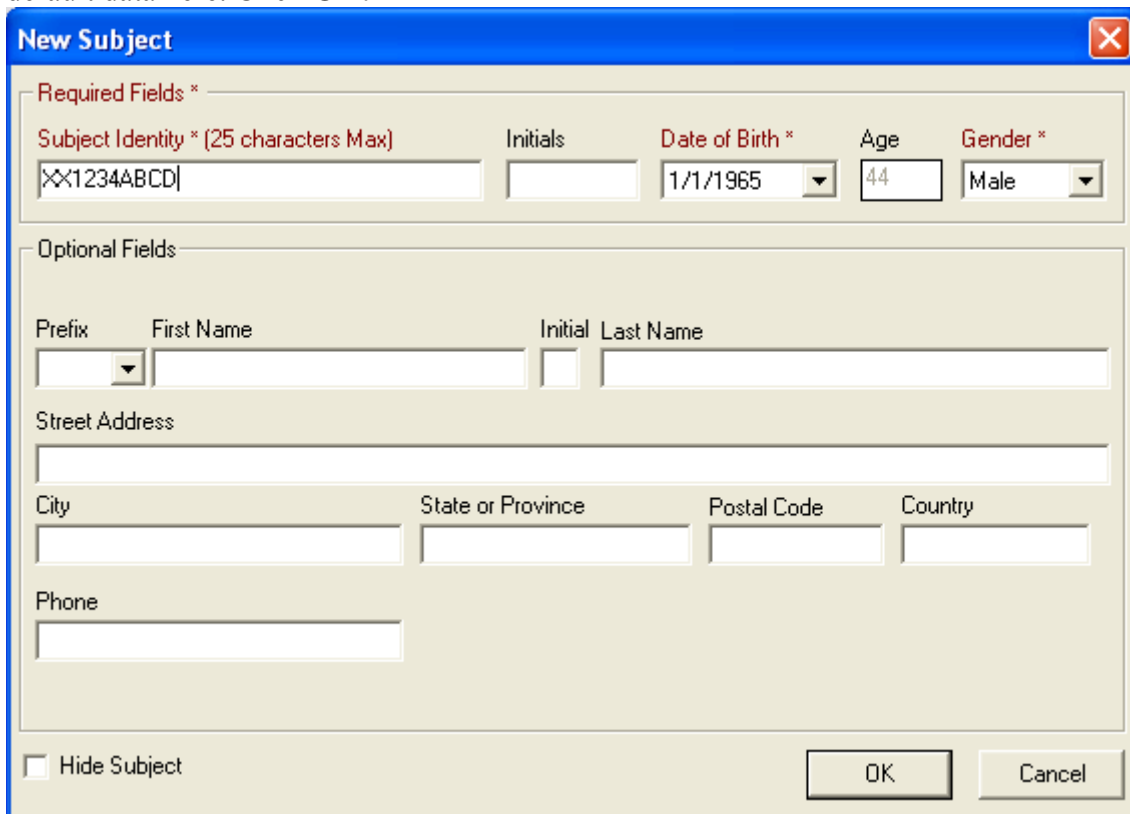


If data has not yet been saved, select **Retrieve Data** (see below). Otherwise select **Discard and Continue**.

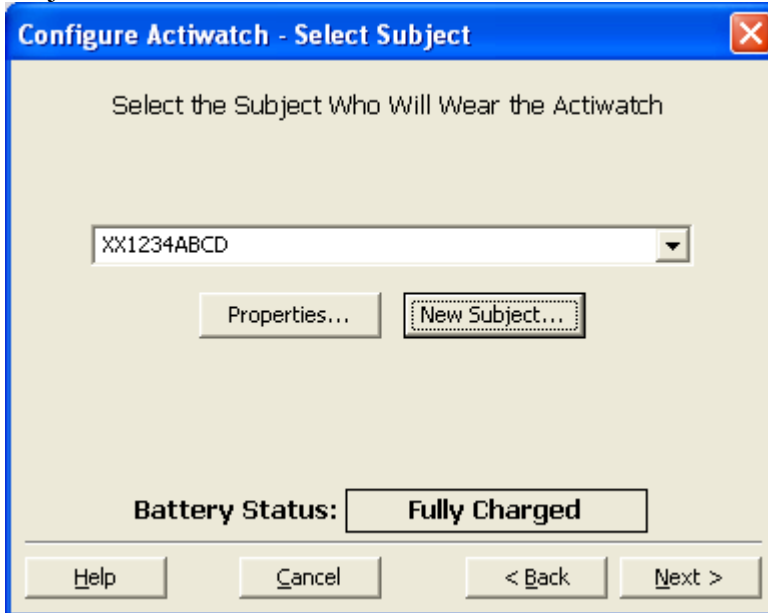
9) You will get a screen to select a subject.



In the database you just created for this participant, click “new subject”. Type the subject name as ID and acrostic (XX1234ABCD). No other fields are necessary. Three fields are listed as “required” but they are not used in the data analysis. You can just leave the default data here. Click **OK**.

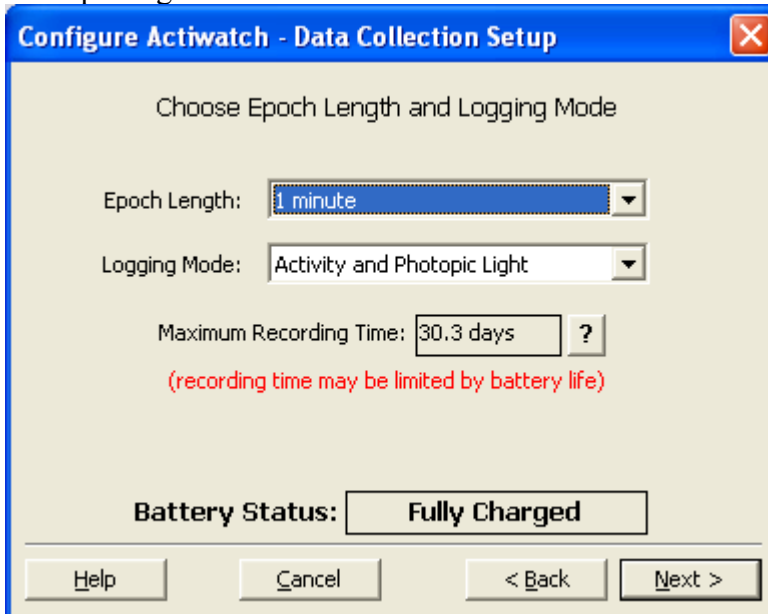


10) Now you are returned to the “select subject” window, with the new ID as the selected subject. Click “next”.



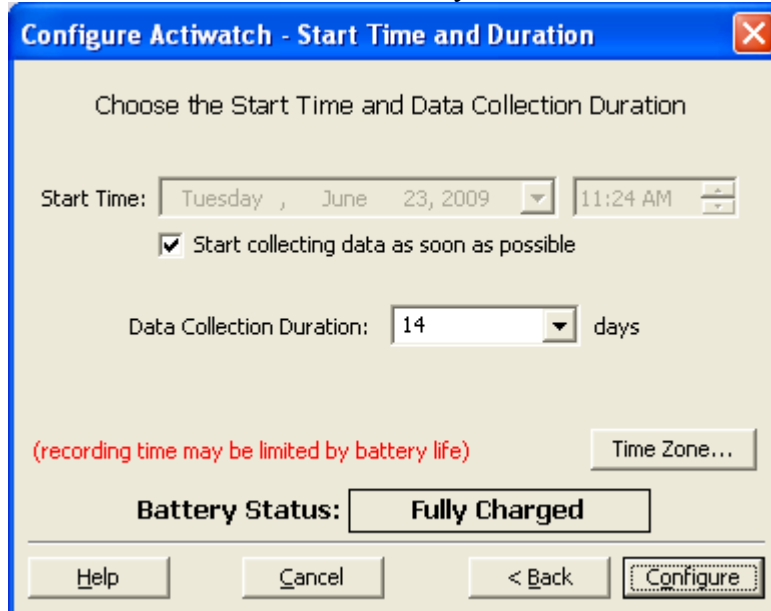
The screenshot shows a dialog box titled "Configure Actiwatch - Select Subject". The main instruction is "Select the Subject Who Will Wear the Actiwatch". A text box contains the ID "XX1234ABCD". Below it are two buttons: "Properties..." and "New Subject...". At the bottom, there is a "Battery Status:" label with a box containing "Fully Charged". Navigation buttons at the very bottom include "Help", "Cancel", "< Back", and "Next >".

11) Select the epoch length to be 1 minute, select the logging mode to be Activity with Photopic Light. Click **Next**.

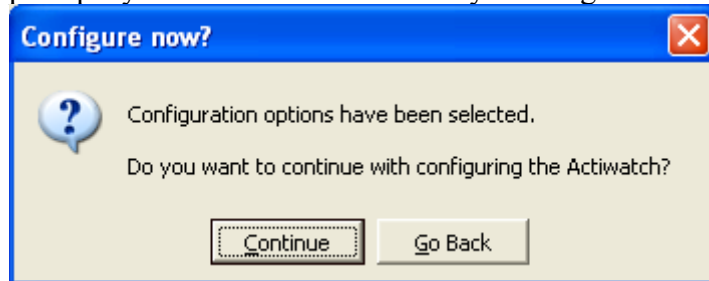


The screenshot shows a dialog box titled "Configure Actiwatch - Data Collection Setup". The main instruction is "Choose Epoch Length and Logging Mode". There are two dropdown menus: "Epoch Length:" set to "1 minute" and "Logging Mode:" set to "Activity and Photopic Light". Below these is a "Maximum Recording Time:" field set to "30.3 days" with a help icon "?". A red note below reads "(recording time may be limited by battery life)". At the bottom, there is a "Battery Status:" label with a box containing "Fully Charged". Navigation buttons at the very bottom include "Help", "Cancel", "< Back", and "Next >".

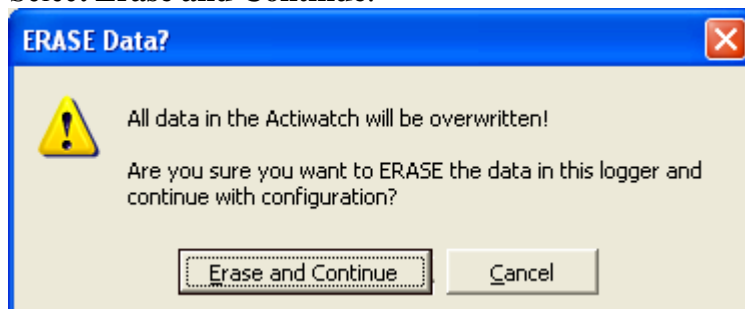
12) Choose data collection to begin as soon as possible (checkbox). Click on the time zone button to confirm it is set for your time zone. Click **configure**.



13) a confirmation message appears stating the configurations have been selected and prompts you to continue. Confirm by clicking **Continue**.



14) If the actigraph previously held data for another participant you will get this message. Select **Erase and Continue**.



15) You will get a message that the activation is complete. Remove the actigraph from the communications dock.

6. Battery Charging

The batteries in the Actiwatch® 2 are rechargeable. They are not be replaced by the user. If replacement is necessary, the actigraph has to be returned to Respironics.

It is recommended that the battery be fully charged before each use. This can be done by placing the actigraph on the communications docking station connected to a PC, or a docking station connected to an AC adaptor. When fully charged, the LED light on the front of the docking station will be solid green. While charging, it will blink green.

You can check the status of the battery charge by viewing the viewing the status on the actiwatch communications console.

7. Participant and the Actiwatch® 2

a) The actigraphs will be distributed at the patient's clinic.

At the visit the participant will receive:

- Actiwatch® 2
- Terry Cloth Wrist Band (optional)
- Information Sheet
- Sleep Diary forms (located on MrOS web site)

The device cannot be used in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide. If the participant wears a defibrillator or if the participant or anyone in the participants household uses oxygen then he cannot wear the actigraph. No data will be collected. Please fill out the Actigraphy Checklist accordingly. If oxygen is being used within the same facility as the participant (i.e. retirement home/assisted living) it is fine for them to wear the actigraph as long as the participant is not sharing a room with the oxygen user. Participants using CPAP can safely use the actigraph.

Please see the Actiware Software Manual for information about exposures that may damage the actigraph (e.g. X-ray, MRI)

The procedure for wearing the actigraph and the data collection forms (sleep diary pages) should be explained to the participant while they are in the clinic and any questions should be answered at that time. Items to be explained to the participant include:

- 1) Wearing the actigraph - the actigraph should be worn on the non-dominant wrist and should be securely fastened around the wrist (but not tight). It should be worn just as a wrist watch would be worn. If the participant's skin

is particularly irritable a terry cloth wrist band or some sort of padding, can be worn underneath the actigraph so that it is not in contact with the wrist, but it must be securely fastened on the wrist. The actigraph should not dangle from the wrist or slide around.

- 2) Removing the actigraph - the actigraph should only be removed when bathing and/or during water sports (such as swimming). It is ok for the actigraph to get splashed during activities like washing dishes, but it should not be immersed in water for any great length of time.
 - 3) When to wear the actigraph - the actigraph should be worn from the time the participant leaves their clinic visit until the morning that the clinic staff picks the actigraph up from their home. This will vary for participants due to the clinic schedule and weekends and should be clearly explained while the participant is at their clinic visit. See table below.
 - 4) Completing sleep diary - the sleep diary should be explained to the participant while they are in the clinic. The date and day of the week for each page should be filled out by the clinic staff to aid in correct completion of the diary. If the participant refuses to complete the diary they should still be given an actigraph to wear and should be encouraged to fill in as much data as possible.
 - 5) Appearance of the actigraph. There is no digital watch display on these models. While the participant is wearing the actigraph they may hit the button on the side of the actigraph. This will not change the way that the data is collected and will not disrupt anything. They should be told not to worry if this happens.
 - 6) A summary of the above information with critical points should be provided to the participant. An example of an information sheet can be found on the MrOS web site. The information sheet should be reviewed with the participant before they take it home with them. The sheet will provide them with a phone number to call should they have further questions after leaving the clinic.
- b) The actigraph should already be set to start collecting data when the participant puts it on at their clinic visit. The participant will be wearing the actigraph the day of their visit so that they get used to wearing the actigraph. At first, the participant will likely be very conscious of the actigraph and will be more inclined to alter activity or fidget with the actigraph. By wearing the actigraph for part of a day before data is collected that we are interested in the awareness will likely be diminished and not be as much of a bias.
- c) The participant will start using the sleep diary on the night of their clinic visit. Depending on when the participant visits the clinic they will complete 5-7 days of the

sleep diary (3-5 nights coinciding with Actiwatch® 2 data collection, the evening of the clinic visit, and the morning that the actigraph is picked up from the home).

Clinic Visit	Sleep Diary Begins	Actiwatch® 2 Data Collection Begins	Actiwatch® 2 Data Collection Ends	Sleep Diary Ends	Actiwatch® 2 Picked Up from Home	Number of Nights of Actiwatch® 2 Data Collected
Monday	Monday Evening	Monday Morning	Saturday Morning	Saturday Morning	Monday	5
Tuesday	Tuesday Evening	Tuesday Morning	Sunday Morning	Sunday Morning	Monday	5
Wednesday	Wednesday Evening	Wednesday Morning	Monday Morning	Monday Morning	Monday	5
Thursday	Thursday Evening	Thursday Morning	Tuesday Morning	Tuesday Morning	Tuesday	5
Friday	Friday Evening	Friday Morning	Wednesday Morning	Wednesday Morning	Wednesday	5

The schedule above is necessary to accommodate for clinics not working on the weekends. As long as the participant has the actigraph they will continue to wear it. A minimum of 3 days of Actiwatch® 2 data will be collected for ALL participants.

- d) The participant should be instructed on when to begin filling in information using the Sleep Diary. They should also be told when it is ok to stop wearing the actigraph (9:30 am on the day that the actigraph is being picked up from their home).

Participants should be instructed to fill out as much of the diary as they can. If they are unwilling or unable to complete the sleep diary they should still wear the actigraph. For reluctant participants, give them a sleep diary and ask them to do the best they can. When staff collect the diaries from the participants they may be able to get some basic overall information from participants that did not fill out the diaries. For example, when diaries are blank you could ask the participant “What time do you ‘normally go to bed’, ‘normally get up’? “ You could also ask, “Do you normally take naps, and if so at a certain time or for how long?” Even this very general information will be helpful for cleaning of the data and determining wake/awake periods in the data file.

You may want to suggest that the participant keep the sleep diary by their bed or other convenient spot so that they remember to fill it out. At the end of every day they should fill in any missing information about their activity for that day. In the morning they should record information about their previous nights sleep and that days awakening.

1. Sleep Diary Day 1-This page should be filled out by all participants the day of their clinic visit. Information about actigraph removals, naps, periods of inactivity, and a self-rated activity for the day are requested.

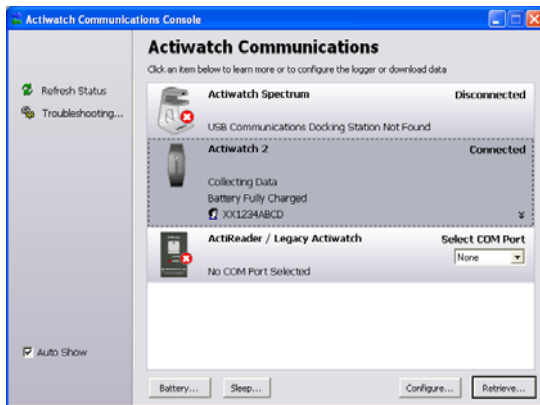
2. Supplemental Diary Page-This page will be filled out for all days between the first and last day that the participant wears the actigraph. The dates will be written on the forms for the participants and the correct number of forms should be included in their sleep diary packet. This page asks for night time routine and morning routine information and times. Additionally, it asks all of the same questions that are on the Sleep Diary Day 1 form. When describing the diary to the participant, be sure to enforce that their best guess on times is ok, they do not have to leave questions blank if they can not remember the exact times. Questions that may require further explanation include the difference between time getting in bed and time trying to go to sleep. The time that they got in bed is just that, when they got into bed. If they sit in bed and read or watch tv then they would put the time that they stopped reading or watching tv as the time they tried to go to sleep. The same circumstances may apply to the morning. If they wake up and read in bed or lie in bed for awhile before physically getting out of bed the times for waking up and getting out of bed will be different. However, it is quite possible that some participants will have the same time for getting in bed and going to sleep and for waking up and getting out of bed.
 3. Sleep Diary Last Day-This form is filled out the morning that the actigraph is picked up from the participant. The only new information on this page is the question about what time they took the actigraph off and left it off. If the participant still has the actigraph on when staff arrive to collect the actigraph and diary, that is the time that should be recorded.
- e) Set up a timeframe for picking the actigraph up from the home and let them know that they will receive a call prior to someone coming to their home to confirm their presence.
 - f) When the actigraph is picked up by a staff person the sleep diary should be reviewed for completeness. Any missing information should be questioned at that time and confusing or illogical answers should be corrected. If the diary is not picked up by a clinic staff member (eg. Courier service or mailed to the clinic) the participant should be phoned and asked about the relevant missing information.

8. Downloading Data from the Actiwatch® 2

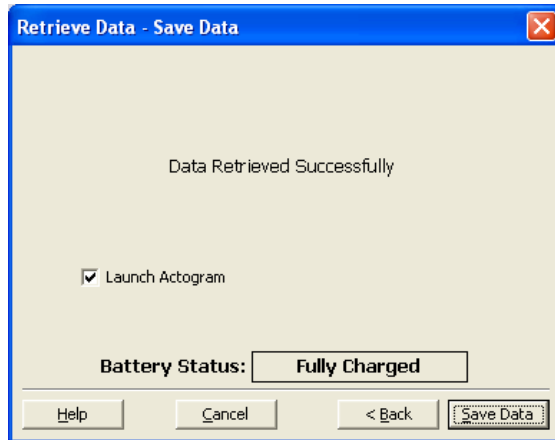
When an actigraph is returned after a participant has worn it for the specified time, the data needs to be downloaded from the actigraph to the clinic computer. The data then needs to be sent as an .AW5 file to the Coordinating Center for analysis.

- 1) Open Actiware® 5 on the computer. Place the Actiwatch® 2 in the communications docking station.
- 2) Select **Communications>Actiwatch Console** from the main menu bar.

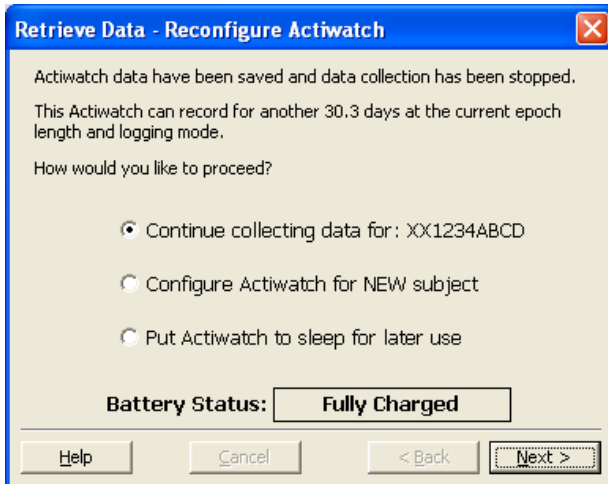
3) Select the Actiwatch device by clicking on the Actiwatch 2 section. Click **Retrieve** to continue.



4) When retrieval is finished you will be prompted to save the data by clicking Save Data button. Save the data.



5) Now you have 3 choices: “Continue collecting data for:” will keep collecting data under this same participant ID. Select “Configure the Actiwatch for a NEW subject” if you are setting up the actigraph for data collection on another participant. Select “Put Actiwatch to sleep for a later use” if you are not planning on using the actigraph. This conserves battery life. After the actigraph is in sleep mode, pressing the left marker button or placing it in the docking station will wake it up.



9. Sending the Data to Coordinating Center

If upon downloading the data you find that the participant did not wear the actigraph correctly or that data was not collected for the appropriate length of time you should ask the participant to re-wear the actigraph. If some data was collected, but not 3 full nights and they refuse to rewear the actigraph you should send the data file to the Coordinating Center. If there is no data available on the file and the participant will not rewear the actigraph you should enter '0' days in question 4 on the Actigraphy checklist and do not need to send the .AW5 file to the Coordinating Center.

When you save the data it will be saved as 'MROSidAcrostic.AW5' (ex. XX1234ABCD.AW5) in C:\Documents and Settings\My Documents\Actiware Data. This file, specific for the participant, needs to be sent electronically to the Coordinating Center.

Transfer of data will occur via the Coordinating Center's secure website. Secure remote access to the website is provided by the Juniper Networks Instant Virtual Extranet (IVE) appliance which sits behind our network firewall.

Authorized users will be given a login id and password.

- Log onto our secure website (<http://ive.sfcc-cpmc.net>)
- Click on MROSAccel folder
- Click on Upload File
- Browse for the file you wish to upload and then click "Upload"

Retain a copy of the file on the clinic computer hard drive until you receive notification from the Coordinating Center that it is ok to delete the file.

If the wrong ID and/or Acrostic were used in the Subject Field (when initializing the device) or when naming the file, please email Terri Blackwell at the Coordinating Center to let her know this happened and she will take care of it.

The sleep diary pages should be kept at the clinic in participant's chart. The original diary from the participant may need to be transcribed onto a new teleform if the writing will not fax in well. They should be faxed into the Coordinating Center data system.

- a) Complete the Actigraphy Checklist form in the clinic packet.

IMPORTANT: The Actigraphy Checklist must be sent into the data system before the Sleep Diary is sent (if Sleep Diary arrives, but the Actigraphy Checklist has not been entered in the system the Diary will be rejected).

- 1) Indicate whether or not the participant received an actigraph and if they did not record the reason. The actigraph should always be worn on the non-dominant hand if possible, exceptions to this should be rare.
- 2) The date that the actigraph is given to the participant will almost always be the same as the clinic visit date. If no actigraph is available or the participant is unable to take the actigraph on the day of their visit but agrees to wear it at a later time the appropriate date should be recorded.
- 3) The date that the actigraph is retrieved from the participant should be recorded.
- 4) The number of days that data was collected can be obtained from looking at the .AW5 file.
- 5) Please indicate if the diary was completed and the extent of the completeness.

Maintaining an Actigraph Log, Cleaning of Actigraph

A log should be maintained at the clinic so that the location of the actigraphs is known at all times. An example log is included in the Appendix, it can be modified as individual clinics see necessary. A serial number (ex. A01785) for each actigraph can be found on the back side of the actigraph. This should be used as the Actigraph ID.

If needed, clean the device with a soft cloth moistened with mild detergent and water to remove dirt and stains. Do not use abrasives or alcohol.

10. Quality Assurance for the Actigraph

Each interviewer charged with the responsibility of initializing, downloading or any other handling of the actigraph will be required to meet performance standards that indicate an understanding of the actigraph's battery life and recharging, use of communications dock and software, and explaining the actigraph and sleep diary completion to the participant. Only personnel who meet these standards will be certified and approved to handle the actigraphs and instruct the participants.

Personnel will be required to attend a training session, or undergo local training by a certified technician. Training will consist of:

1. Overview of Actigraphy Operations Manual - including detailed use of the actigraph, the software and the communications dock.
2. Hands-on training for initializing, and downloading/saving of files. Transfer of actigraphy file to Coordinating Center will also be shown but may not be required for each personnel (this requires a secure web site with limited access.) There will be a discussion of some common questions from participants, and other problems that may occur.
3. Overview of Actiware® Software Manual.

Certification

Besides completing the requirements in the Actigraph Certification form, each personnel needs to successfully complete 3 initializations, downloading, file checking and the saving to the assigned folder. These should be done with a certified technician present. Actigraphy data for the certifications will be collected on healthy volunteers.

Table 1. Military Time Table

1:00AM	0100	1:00PM	1300
2:00AM	0200	2:00PM	1400
3:00AM	0300	3:00PM	1500
4:00AM	0400	4:00PM	1600
5:00AM	0500	5:00PM	1700
6:00AM	0600	6:00PM	1800
7:00AM	0700	7:00PM	1900
8:00AM	0800	8:00PM	2000
9:00AM	0900	9:00PM	2100
10:00AM	1000	10:00PM	2200
11:00AM	1100	11:00PM	2300
12:00PM	1200	12:00AM	2400

