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## ACTIGRAPHY

### 1. Background and Rationale

The equipment that will be used for this study, the Octagonal Sleep-watch (catalog no. 26.100 Ambulatory Monitoring, Inc) actigraph, is a small device that will be worn on the non-dominant wrist for at least 3 24-hour periods. We would prefer the watch to be worn for 4 nights, but 3 nights are the minimum. This actigraph contains a piezoelectric linear accelerometer (sensitive to 0.003 g and above), a microprocessor, 32K RAM 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 older schizophrenic patients, in community dwelling elderly, and in demented elderly. 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

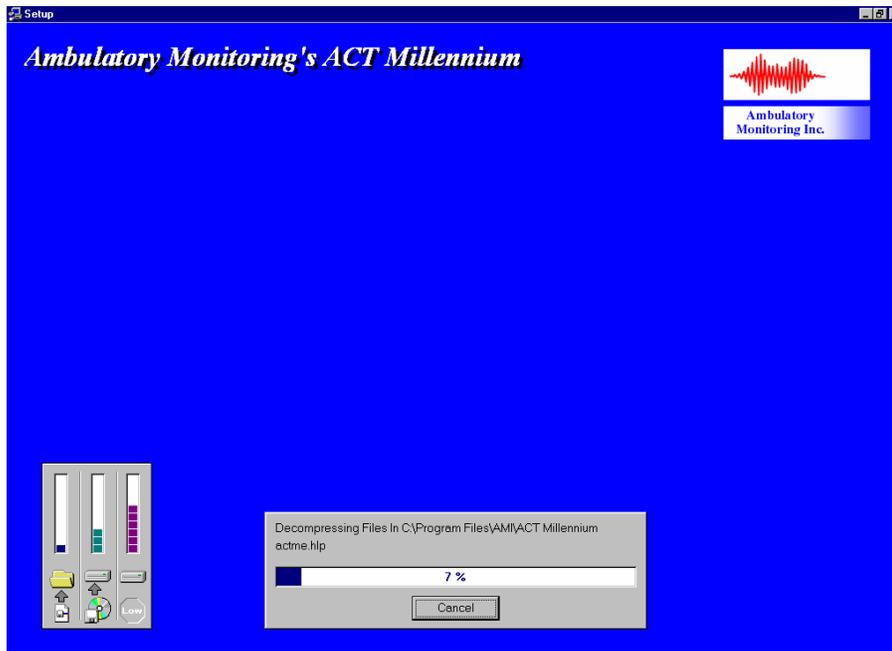
- **Octagonal Motionlogger SleepWatch (catalog no. 26.100)**
- **Octagonal Motionlogger interface unit and cables**
- **ACTMe Software**
- **Black electrical tape**
- **3 volt Lithium Watch batteries (CR2430)**
- **9-volt batteries (for IU)/or electrical cord**
- **alcohol swabs**
- **watchbands**
- **terry-cloth wristbands (optional)**
- **Supplies for participants to mail the watch back to the clinic**

### 3. Setting up the ACTMe software

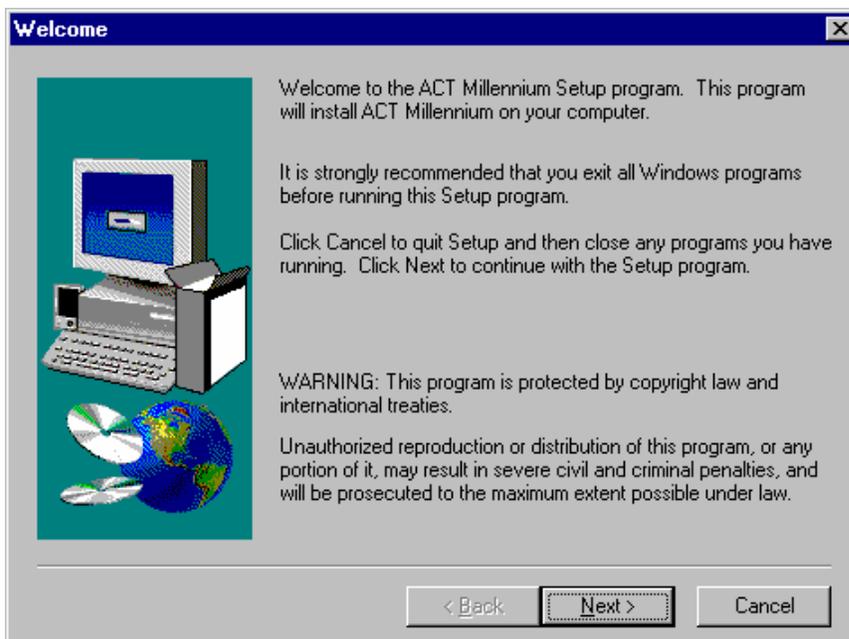
ACTMe version 3.10.13.1 is a Windows program that is used to initialize motionlogger actigraphs, and to download data from the devices.

The software is available for download at the AMI website [http://www.ambulatory-monitoring.com/software\\_updates.html](http://www.ambulatory-monitoring.com/software_updates.html). You will need to scroll down the page to find the download for ActMe\_ver3.10.13.1.zip. When you click on the file with your mouse you will be given the option to open or save, you should click on 'Save' and enter c:\programfiles as the directory to save the file to. When the download is complete use Explorer to find c:\programfiles\AMI\ActMe and open this folder. Find the setup.exe file and open it, this will begin the extraction of the files and will guide you through set up. You are now ready to install ACTMe on your desktop computer. Once the program has been installed, you will not need to go to the web site to start the program.

When you double click on setup.exe you will get a pop-up window telling you that the software is being installed. Then the screen below will appear on your computer:

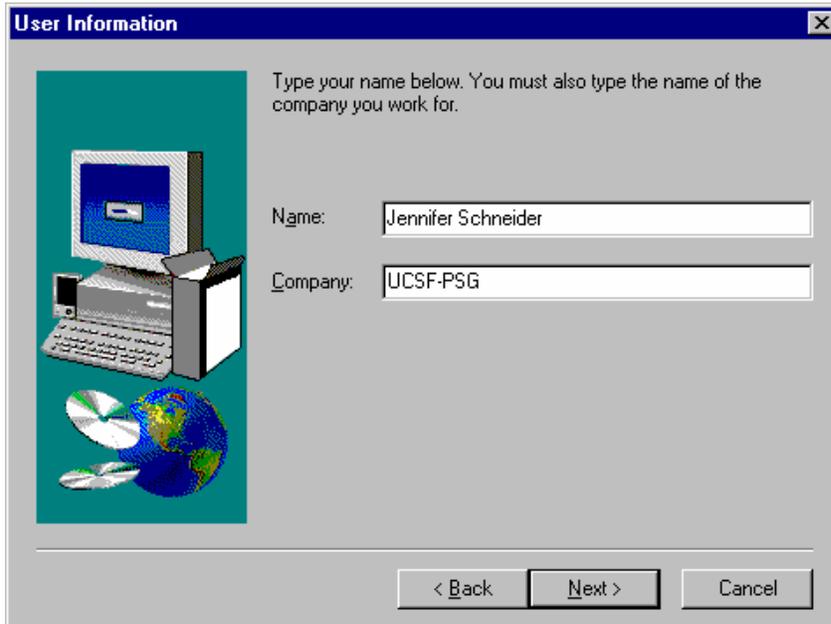


You will be able to watch the progress of the installation from this screen. As the installation progresses you will see:

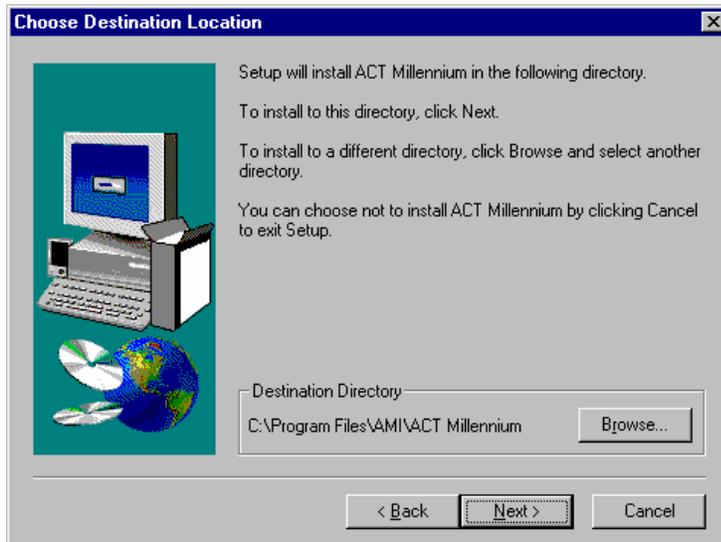


Click the "Next" button.

The next window that appears has “User Information” in the header. Enter your name and the name of the clinic (e.g. UCSF, U of MN). Click “Next” button.



Then you will be asked to choose a destination for the program on your computer:



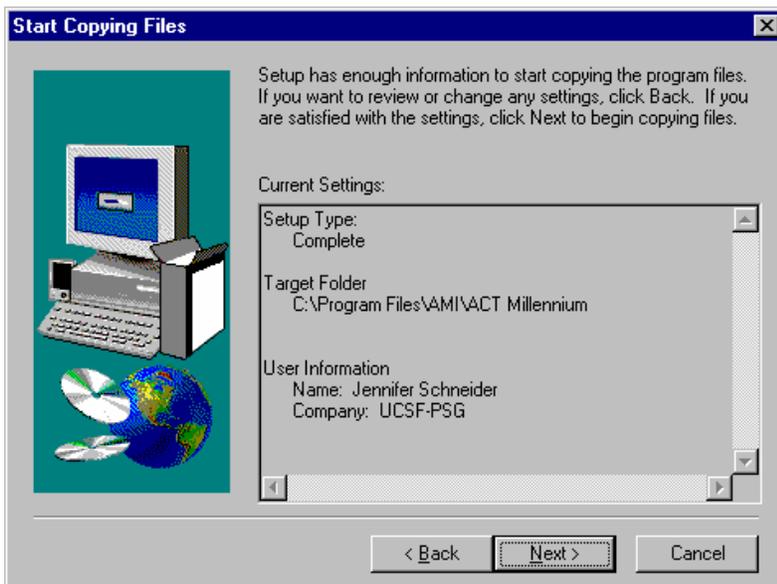
If you do not change anything on this screen the program will automatically be placed in the “Program files” folder on your computer. In most cases this is fine, however if you want the program to be installed in a different location click on the “Browse” button and select a location. Then select “OK” and hit the “Next” button to move to the next screen.

Be sure to make note of the destination directory so that you will be able to find the program on your computer once the installation process is complete.

Next you will be prompted to select a program folder:

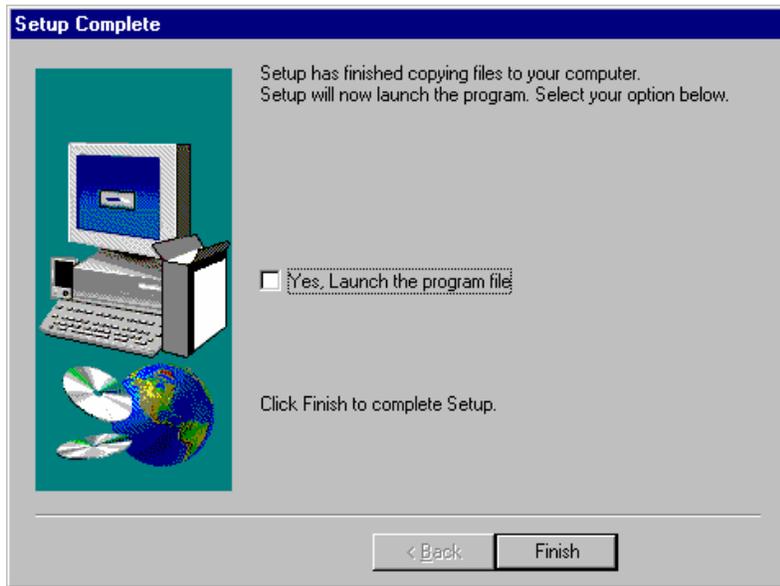


Leave this as is and hit the “Next” button.



The above window indicates where the program is going to be installed on your computer. Make a note of this so that you will be able to find the program once you have completed the set up process. Click on “Next”.

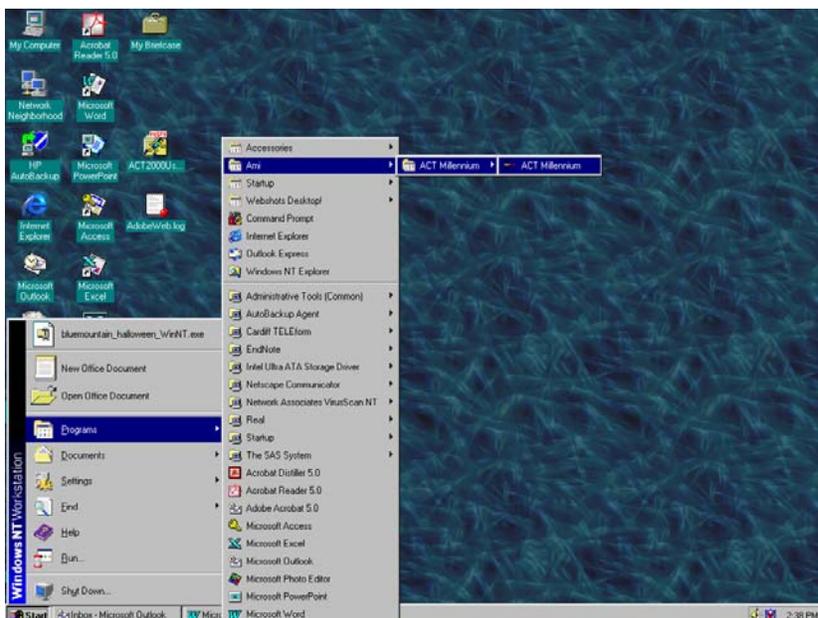
When all files have been transferred you will see the following window:



If the box is checked, de-select it by clicking in the box to make the check disappear and then select “Finish”. The software is now installed on your computer.

#### 4. Opening the Program

To open the AMI program so that you can set-up the SleepWatch for use and download data once you have collected information from participants go to Start Menu→Programs →AMI→ACT Millenium→ACT Millenium. If you put a shortcut to the program on your desktop you will have .dat files that appear on your desktop after each use of the program. To avoid having these files on your desktop, do not put a shortcut icon on your desktop and simply go through the Program menu to reach the application.



When the program window opens, hit “OK”.

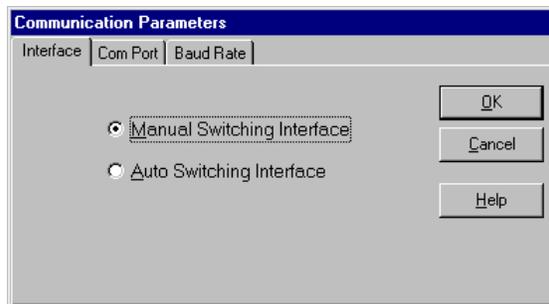
## 5. Setting up the SleepWatch

The interface unit (IU), the box that allows you to program and download data from the SleepWatch to your personal computer, needs to be connected to your computer.

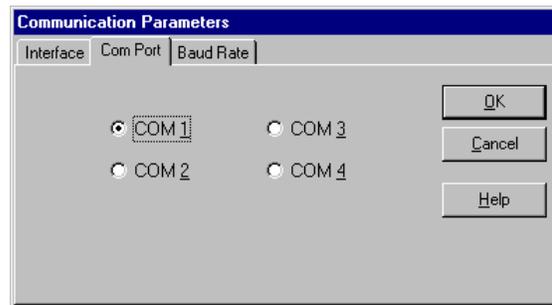
- a) Connect the serial cable to the IU and then plug the other end of the cable into an available serial port (9-pin port) on the back of your computer. (The IU requires a 9-volt battery or can be used with an AC adaptor.)
- b) Once the IU is connected to the computer turn the silver toggle switch on the back of the IU until the green light next to the switch turns on. The green light indicates that the power is on. (If using batteries to operate the IU, turn the toggle off when you are not using the IU to conserve batteries).
- c) When the light is on, go to the “Configuration” menu and select “Communications”.
- d) You need to set the configurations to match the requirements of the SleepWatch and software that we are using.

A configuration window with 3 tabs will appear. You need to go through all tabs and select the correct settings. Once the settings are correct and saved they will be your default settings and will not need to be changed every time you open the program.

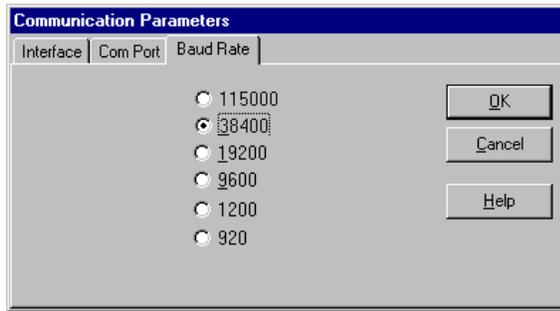
Select the Manual Switching Interface under the “Interface” tab and then click on the Com Port tab, do not click on “OK” (this will cause the Configuration window to close).



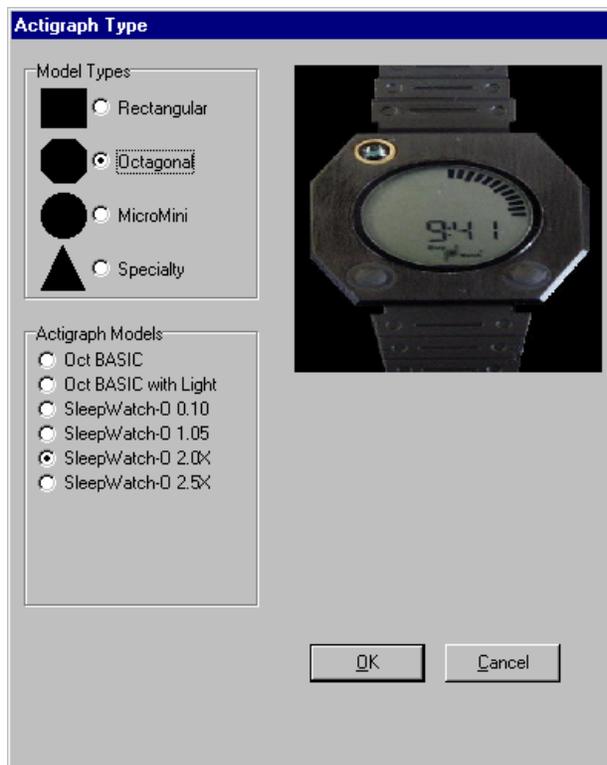
Select any COM PORT (try starting with COM 1 or COM 2) and click on the “Baud Rate” tab.



Select a Baud rate of 38400 and click OK.

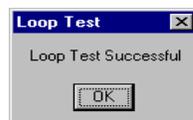


Next click on the “Configuration” menu and select “Actigraph Type”. If the watch is version 2.0 select Octagonal and SleepWatch-O 2.0X and click “OK”. If the watch is version 0.10 select Octagonal and SleepWatch-O 0.10 and click “OK”. The version appears on the metal plate on the back of the watch.

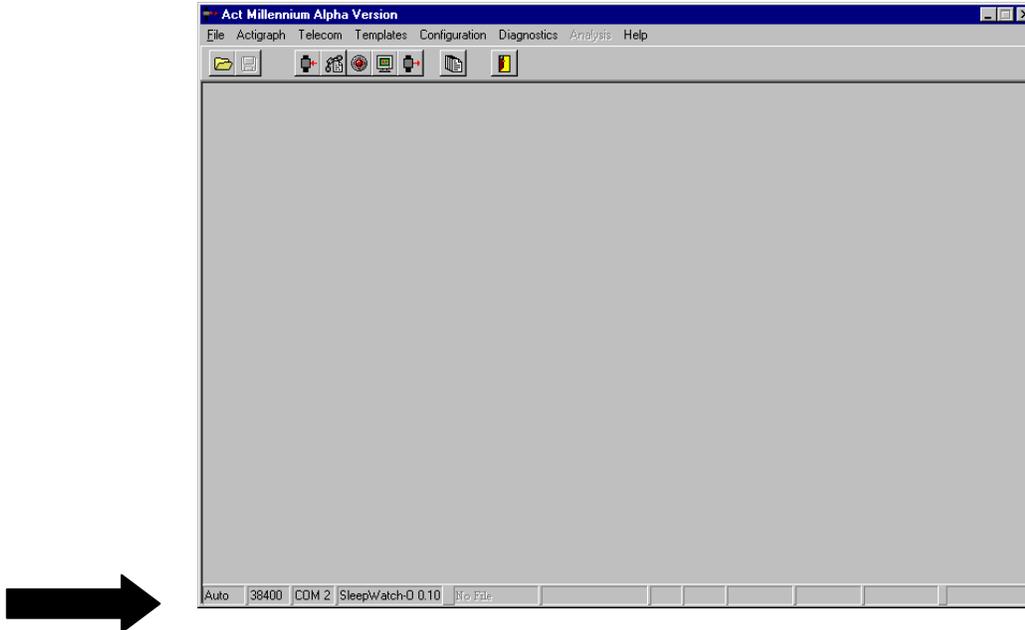


- e) Now you need to make sure that the correct configurations have been selected. Go to the “Diagnostics” menu and select “Loop Test”.
- f) Make sure the IU is turned on (green light on). Hold the black button on the back of the IU and click on “OK” for the loop test (hold the button until you get a “loop test successful” message).

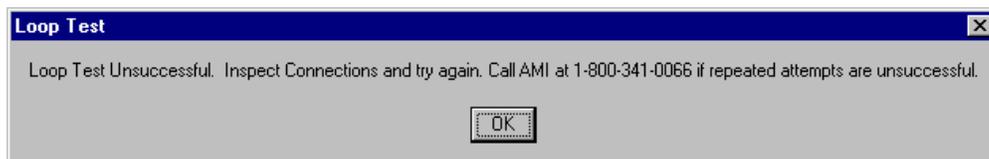
If you get the following message everything is configured correctly, click “OK”.



Proceed to save the settings by going to the “Configuration” menu and selecting “Save”. The settings can always be checked by looking at the lower left portion of the computer screen.



If you see the following message when you run the loop test, there is an error. You need to change the Com Port that you selected in the configuration setup. Click on “OK” and go to the “Configuration” menu and then to the “COM PORT” tab and select a different COM PORT.



Then run the loop test until you get the “Loop test successful” message. Continue changing the selected COM PORT until you have run a successful loop test. Once it is successful, save your settings as described above. The above steps will only need to be done the first time you set up the IU to your computer. As long as the IU remains attached to your computer and you have saved the configurations you do not have to configure the computer again, you will only have to repeat the Initialization and Downloading steps for each participant. These processes are described in the following two sections.

## 6. Configure the Battery Log

The battery log feature will prevent you from giving a watch with a low battery to a participant. To activate this feature you need to go to the “Configuration” menu and select “Battery Logs”.

	Warning	Refusal
Rectangular	21 days	30 days
MicroMini	3500 hours	4000 hours
Octagonal	30 days	40 days
Octagonal Basic	21 days	30 days

You should enter 30 days in the Warning column for the Octagonal and enter 40 days for Refusal for the Octagonal; you do not need to change any of the other settings on the Battery Log Parameters window. When you have entered the correct information, click on “OK”.

NOTE: Each time you put the watch into the IU to initialize download a file, check the life of the battery. To do this, place the SleepWatch into the IU and after the download is completed, go to the File menu and select “Summary”. “Battery Runtime Days” can be displayed. The battery life of the DL2430 or compatible Lithium Coincell battery used is approximately 60 days. Make sure you continually check the battery life when distributing watches and record the battery life on the sleep watch log in the clinic. Discard used batteries in an environmentally safe manner.

NOTE: Always use fresh batteries. Whenever you replace a battery, the software reads it as a new (fresh) battery and begins battery life at “0” days. Reusing batteries will give inaccurate battery life readings.

NOTE: The first time you initialize a watch or the first time you initialize a watch after putting a new battery into the watch, hit the reset button (black button) on the back of the IU before starting the initialization process.

## 7. Initializing the SleepWatch to Collect Data

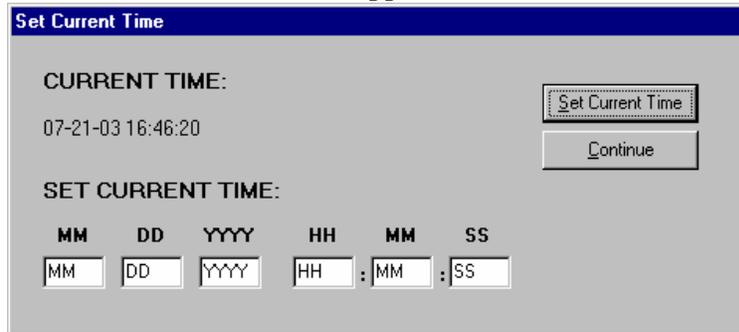
This section describes what you will have to do before each participant wears a watch. The same steps need to be followed each time a watch is initialized.

Turn the IU on and insert the SleepWatch into the IU so that it is secured in the holder. Put the watch in the IU so that the 4 gold pins on the side of the watch are touching the IU. Remember to clean any tape residue off of the pins using an alcohol swab before placing the watch in the IU.

Go to the “Actigraphy” menu and select “Initialize” or use the initialize icon on the toolbar. Switch the toggle switch on (green light will appear). When the “Set Current Time” window appears, check that the time is correct. The program uses military time.

The program sets its time according to the internal time on your computer so you need to make sure that the time setting on your computer is correct (AM/PM). If you need to change the time you can do so by filling in the boxes at the bottom of the pop-up window, be sure to use Military time(see table 1 in the appendix).

Hit “Continue” once the correct time appears under “Current Time:”



**Set Current Time**

CURRENT TIME:  
07-21-03 16:46:20

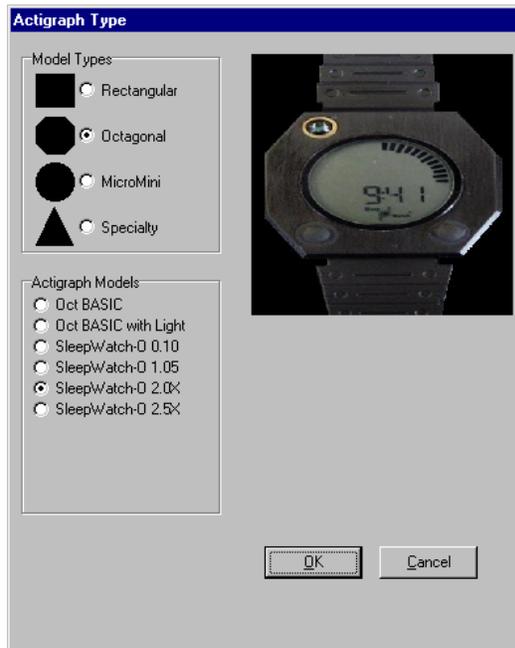
SET CURRENT TIME:

MM DD YYYY HH MM SS  
MM DD YYYY HH : MM : SS

Set Current Time  
Continue

Select the actigraph type you are using (either 2.0X or 0.10). Either select Octagonal and SleepWatch-O 2.0X or select Octagonal and SleepWatch-O 0.10.

Click on “OK” once you have selected the correct model type and actigraph type.



**Actigraph Type**

Model Types:

- Rectangular
- Octagonal
- MicroMini
- Specialty

Actigraph Models:

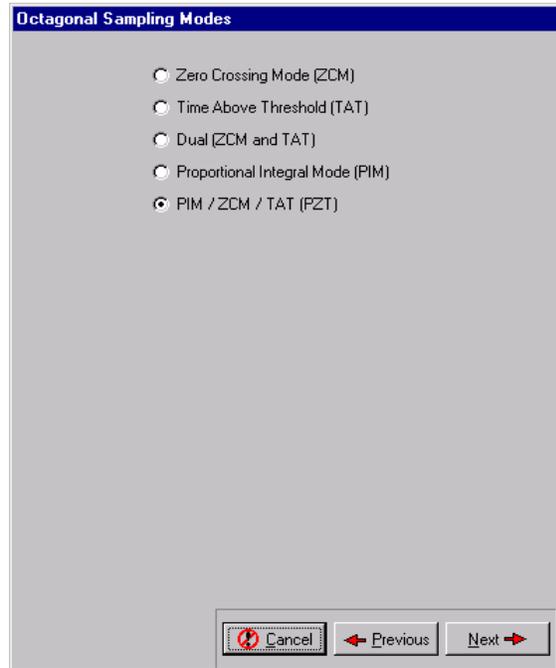
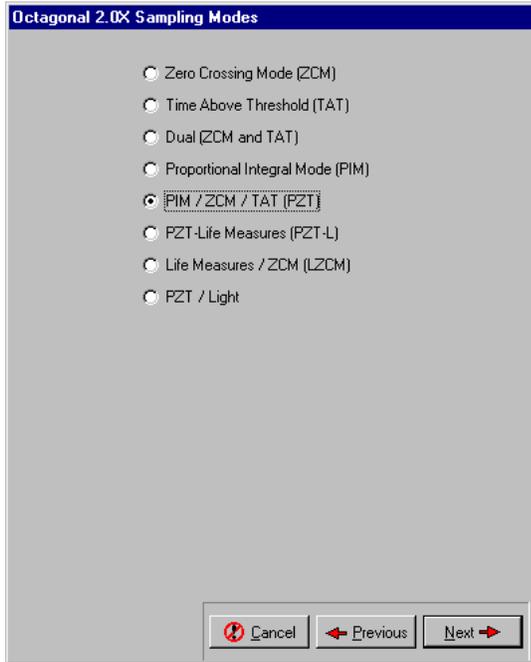
- Oct BASIC
- Oct BASIC with Light
- SleepWatch-O 0.10
- SleepWatch-O 1.05
- SleepWatch-O 2.0X
- SleepWatch-O 2.5X

OK Cancel

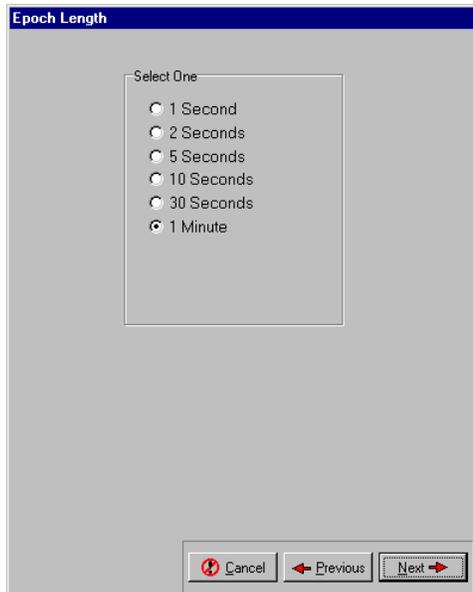
Select “PIM/ZCM/TAT(PZT)” and click on “OK”.

Screen appears like this for Version 2.0X:

Screen appears like this for Version 0.10:

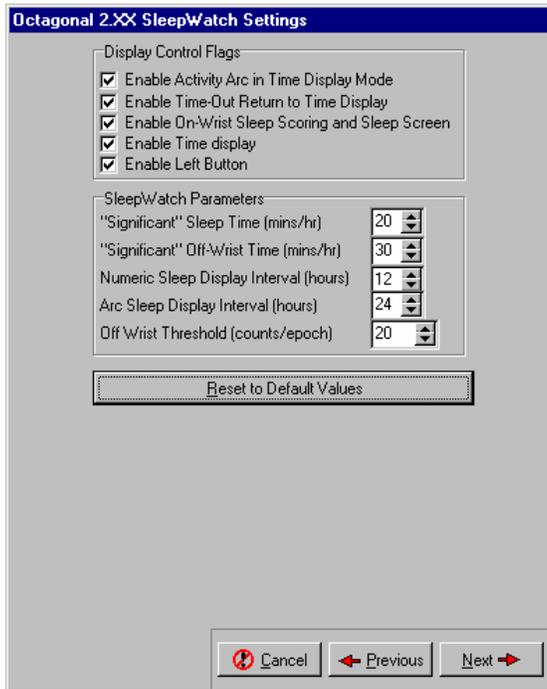


Set the epoch length for “1 minute” and click on “Next”.



The next window that appears has “ID Entry” in the header. Enter the participants SOF ID and acrostic (for example: 10001ABCD) into the box and click on “Next”.

On the Octagonal 2.XX “SleepWatch Setting” tab click on “Reset to Default Values” and click “Next”. This screen does not appear for the Octagonal 0.10, so this step is skipped.

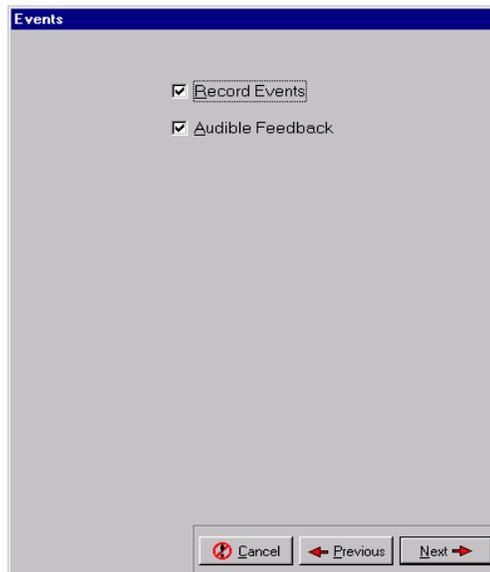


Leave the “Record Events” box checked for Octagonal 2.0X and “Record Events” and “Audible Feedback” checked for Octagonal 0.10. Select “Next”.

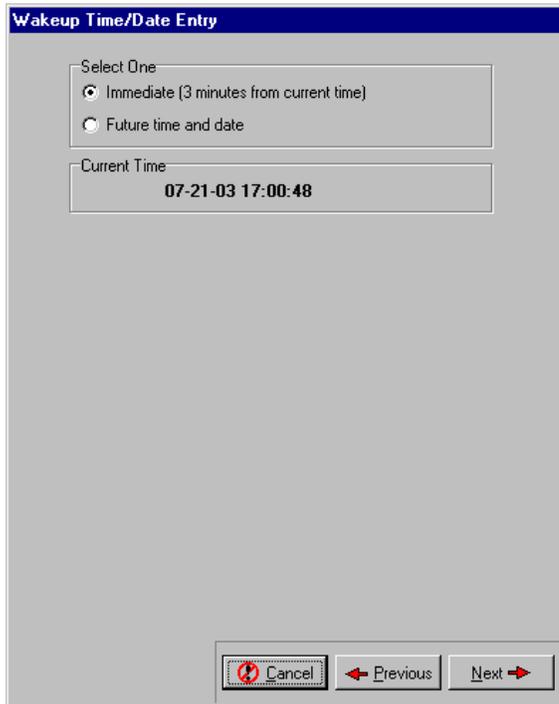
Screen appears like this for  
Version 2.0X



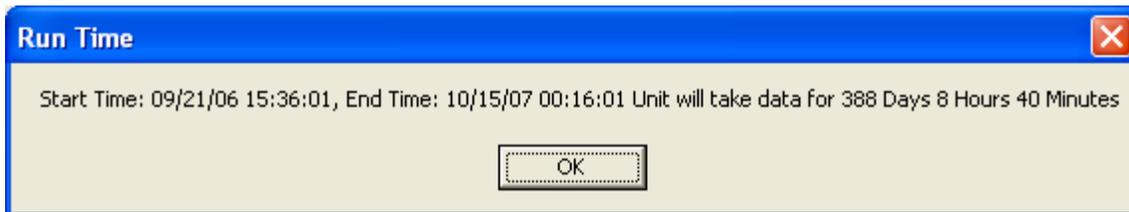
Screen appears like this for  
Version 0.10



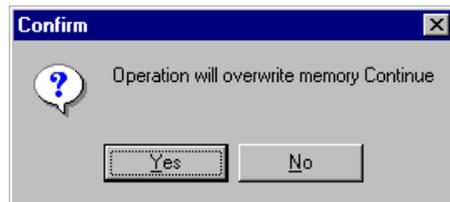
Select “Immediate” and click on “Next”. Before selecting next, double-check that the current time is correct.



You will get a message about how long the run time is. Click “OK”



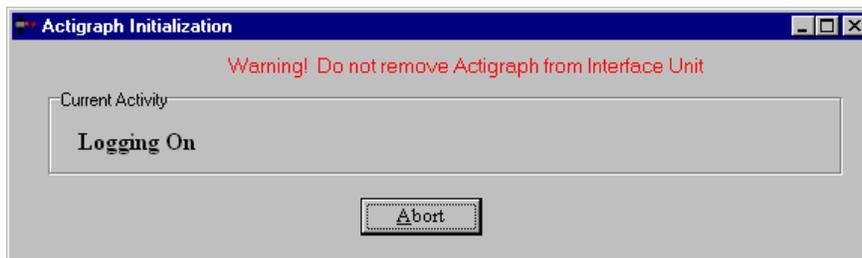
You will be asked to confirm that you want to continue with the initialization, select “Yes”. If at this point you realize that you have not downloaded data from a previous participant you can select “No” and download data and then go through the initialization process again.



You will be prompted to place the watch in the interface unit. Make sure the watch is in place and click “OK”:



The watch will go through the initialization process and you must not remove the watch from the IU until this is complete and you are prompted to do so.



Once the initialization is complete a message will appear indicating that initialization was successful. At that point you can remove the watch. The watch is now ready to collect data. (If you are using a battery to run the IU turn the toggle switch off to conserve the battery.)

To eliminate the risk of a leakage current the pins on the side of the watch should be covered with a small piece of black electrical tape. When the patient returns the watch this tape will need to be removed before the data is downloaded from the watch. Clean the pins with alcohol swabs to ensure that there is no remaining residue. If the pins are not completely clean there may be a problem downloading the data from the watch.

## 8. Participant and the SleepWatch

- a) The watches will be distributed at the patient’s clinic visit or when a staff member goes to a home for a visit.

At the visit the participant will receive:

- SleepWatch
- Terry Cloth Wrist Band (optional)
- Information Sheet
- Sleep Diary forms (located on SOF Website). The diary should be filled out by the clinic staff prior to giving to the participant(fill in the date and day of the week for the data collection)
- Mailing supplies to return the watch (if clinic is not picking up the watches)

The procedure for wearing the watch and the data collection forms (sleep diary pages) should be explained to the participant while they are in the clinic (or home visit) and any

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questions should be answered at that time. Items to be explained to the participant include:

- 1) Wearing the watch - the watch 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 or for women with particularly thin wrists a terry cloth wrist band or some sort of padding can be worn underneath the watch, but it must be securely fastened on the wrist. The watch should not dangle from the wrist or slide around.
- 2) Removing the watch - the watch should only be removed when bathing and/or during water sports (such as swimming or water aerobics). It is okay for the watch to get splashed during activities such as washing dishes, but it should not be immersed in water for any great length of time. Dropping the watch or accidentally banging it against hard surfaces could easily damage the sensitive motion-reading device inside. Suggest to the participants that they be over a carpet or soft surface when removing the watch.
- 3) When to wear the watch - the watch should be worn from the time the participant leaves their clinic visit or home visit until the morning that the clinic staff picks the watch up from their home. This will vary for participants due to the clinic schedule and weekends. 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. The form number at the top of the sleep diary supplement page corresponds to day. The first supplement page should be form number 2, the second is form number 3, and so on. The first page of the diary is considered to be page 1. 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 watch - there should be a moving "arc" visible in the top half of the watch face. This shows that the watch is recording movement information. The face on the watch should display the correct time when given to the participant. However, while the participant is wearing the watch they may hit the buttons on the front of the watch and alter what is displayed on the face of the watch. 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, but to call the clinic for instructions on how to adjust the watch back to the correct time.
- 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 SOF website. 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 watch should already be set to start collecting data when the participant puts it on at their clinic visit (or their home visit). The participant will be wearing the watch the day of their visit so that they get used to wearing the watch. At first, the participant will likely be very conscious of the watch and will be more inclined to alter activity or fidget with the watch. By wearing the watch 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 visit occurs the clinic they will complete 5-7 days of the sleep diary (4-5 days coinciding with SleepWatch data collection, the evening of the clinic visit, and the morning that the watch is picked up from the home).

Clinic Visit	Sleep Diary and Data Collection Begins	SleepWatch Data Collection Ends	Sleep Diary Ends	SleepWatch Returned	Number of Nights of SleepWatch Data Collected
Monday	Monday	Friday Morning	Friday Morning	Friday	4
Tuesday	Tuesday	Saturday Morning	Saturday Morning	Saturday	4
Wednesday	Wednesday	Monday Morning	Monday Morning	Monday	5
Thursday	Thursday	Monday Morning	Monday Morning	Monday	4
Friday	Friday	Tuesday Morning	Tuesday Morning	Monday	4

The schedule above is necessary to accommodate for clinics not working on the weekends. As long as the participant has the watch they will continue to wear it. A minimum of 3 days of SleepWatch 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 watch (9:30 am on the day that the watch is being picked up from their home).

Participants should be instructed to fill out as much of the sleep 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 night’s sleep and that day’s awakening.

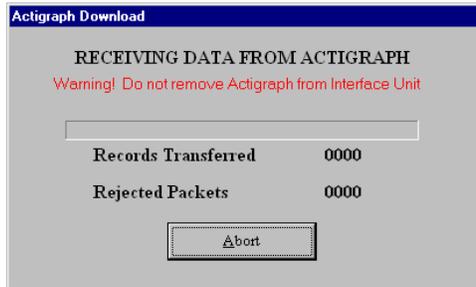
- 1) Sleep Diary Day 1 – For the first watch wearing at the visit, this should be filled out by all participants the day of their visit. It should include information about watch removals and naps for that day.
  - 2) Middle Days (between first day and last day) – These pages will be filled out for all the following days that the participant wears the watch. The day and dates will be written on the form for the participants. The form number at the top of the sleep diary supplement page corresponds to day, and should be filled out by the clinic staff. The first supplement page should be form number 2, the second is form number 3, and so on. The first page of the diary is considered to be page 1. When describing the diary to the participant, be sure to enforce that their best guess on times is okay; 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 page is filled out the last morning.
- e) Set up a timeframe for picking the watch 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. The watch and diary may need to be mailed back to the clinic. Insure the timely and safe return by supplying a padded envelope with postage.

## **9. Downloading Data from the SleepWatch**

When a watch is returned after a participant has worn it for the specified time, the data needs to be downloaded from the watch to the clinic computer. The data then needs to be sent as an .ami file to the Coordinating Center for analysis (the data will default to being a .dat file so you need to change this by using the drop down menu in the Save As window and select “AMI File Without Application Area”).

- a) Open ACTMe on the computer. Place the SleepWatch in the IU and make sure that the toggle switch is ON.
- b) From the Actigraph menu select “Download”.

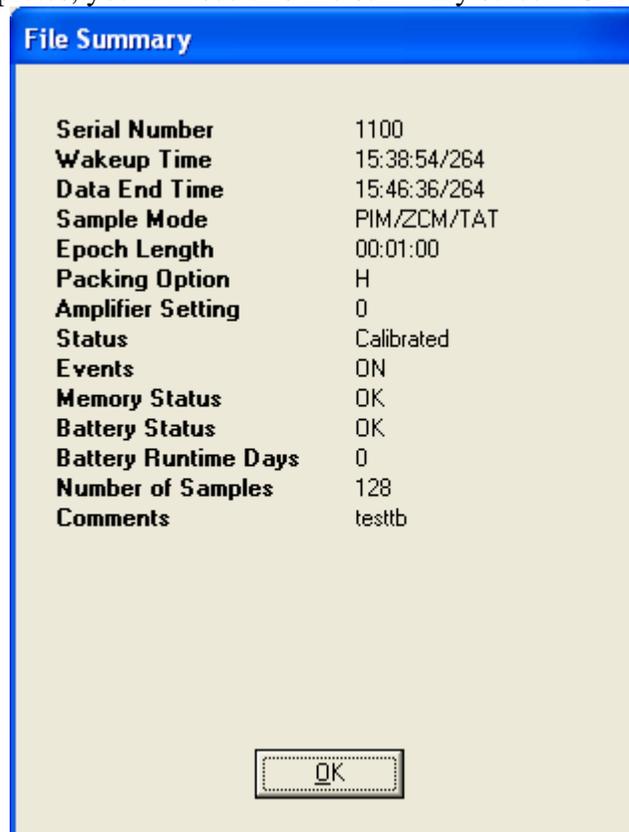
c) You will see the following window while data is being downloaded:

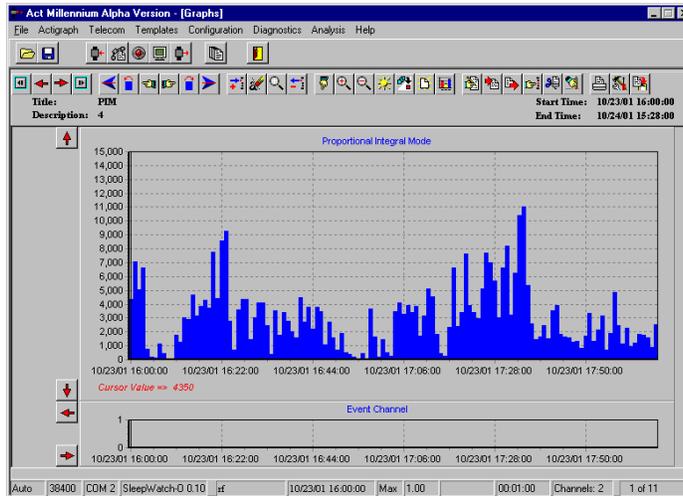


Your IU battery may be low if the downloading freezes up. Check the light at the back of the IU. If red, replace battery and try downloading again. Another problem may be too much electrical tape residue on the watch's 4 pins. This results in inaccurate downloading and loss of full information. Clean pins completely with alcohol swabs before putting watch in the IU.

If you get a message that says the download was aborted remove the SleepWatch from the IU and run a loop test to ensure that the correct COM PORT is still selected. Then begin the download process again after replacing the watch in the IU. If you are told that the download occurred but there were rejected packets try to download again after adjusting the watch to make sure it is secure in the IU.

When download completes, you will see this file summary screen. Click "OK".





Once download is completed successfully you will be prompted to save the file. Click on “Yes” and save the file as “SOFIDAcroscopic” (using the ID and Acroscopic of the participant who most recently wore the watch, e.g. 10001ABCD). You must save the file as an “AMI file without application area”, you can do this by using the pull down box next to the file type box. Before you close the file, go under “File”, then “Summary” to list “Battery Run Days”. Record that number on the Actigraphy Log Sheet for that watch. Also, look at the file itself to see if there were any watch or wearing problems (see Potential Watch Problems in the appendix). You can view the file by “DAYS” by clicking on the “SUN” icon in the menu bar. Each view is a 24-hour period. It will be easier to tell the difference between daytime and nighttime activity and to see if the watch was off for a long period of time. Close the program. Make sure that the SOF ID on the watch file matches the ID of the person that wore the watch. Verify that the dates that appear in the file match the dates on the diary (the dates that the participant wore the watch).

d) Remove the watch from the IU and turn the IU off.

## 10. Sending the Data to Coordinating Center

If upon downloading the data you find that the participant did not wear the watch correctly or that data was not collected for the appropriate length of time you should ask the participant to re-wear the watch. (Examples of “Bad files” are shown in the appendix). If file is complete, or if some data was collected, but not 3-5 full nights and they refuse to re-wear the watch you should send the data file to the coordinating center, described below.

When you save the data (remember to save it as an ‘.ami’ file without application area) it will be saved as ‘SOFidAcroscopic.ami’ (ex. 10001ABCD.ami) in C:\Program Files\AMI\ActMillenium\ (unless you installed the program in a different directory). This file, specific for the participant, needs to be sent electronically to the Coordinating Center.

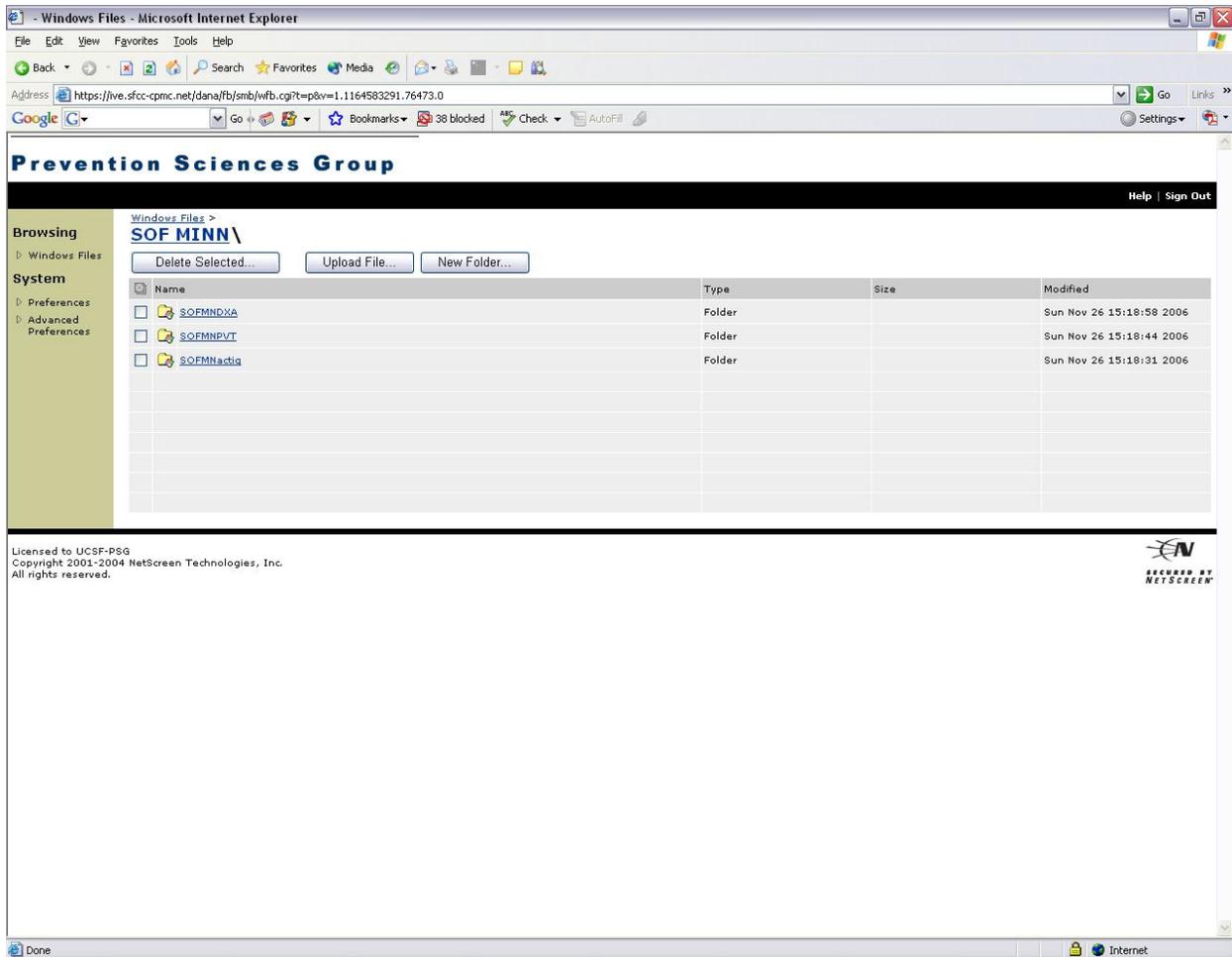
Transfer of data will occur via the Coordinating Center's secure website. Secure remote access to the website is provided by the Juniper Networks Instant Virtual Extranet (IVE) appliance which sits behind our network firewall.

Authorized users will be given a login id and password

- Log onto our secure website (<http://ive.sfcc-cpmc.net>)
- Choose your authorized role
- Choose your folder (see picture below: SOFMNactig or SOFPIactig)
- Choose “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.

Example of file transfer website for MN site:



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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. Also, a copy of each diary needs to be mailed to the Coordinating Center, Attn: Terri Blackwell. Her contact information is listed below.

Terri Blackwell  
SF Coordinating Center  
185 Berry Street, Lobby 4, Suite 5700  
San Francisco, CA 94107-1762

Complete the Actigraphy Checklist form (page 1 of sleep forms) in the clinic packet.

- 1) The number of days that the participant wears the watch should include the day that the watch was given to the participant and the day that the watch was picked up from the participant's home (the number of days should match the number of pages of sleep diary completed by the participant).
- 2) Question 6 on the actigraphy form can be transferred from the "Last Day" page of the Sleep Diary.
- 3) The Actigraphy form will be faxed or scanned into the data system, like all other clinic forms.

## **11. SleepWatch and IU Maintenance (issues not addressed in this protocol)**

See Attached Motionlogger User's Guide. Setting the time that is displayed on the watch and installation of batteries are described in the User's guide.

### **Maintaining an Actigraph Log**

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. S/N 228) for each watch can be found on the bottom side of the watch. This should be used as the Watch ID.

## **12. Quality Assurance for the Actigraph (Sleep Watch)**

Each interviewer charged with the responsibility of initializing, downloading or any other handling of the Actigraph (Sleep Watch) will be required to meet performance standards that indicate an understanding of the watch's two visual functions, battery life and voltage readings, use of interface unit, and cautions related to the watch's sensitive inner workings. Only personnel who meet these standards will be certified and approved to handle the watches 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 Manual - including detailed use of the Actigraph, the software and the Interface Unit.
2. Hands-on training for initializing, wearing of the watch and downloading/saving of files. Transfer of Actigraphy file to CC will also be shown but may not be required for each personnel (this requires a secure web site with limited access.) Each personnel involved with Actigraphy, will be required to wear an Actigraph for one over-night period. They will be required to download/save the file and print out the visual tri-mode activity report, and discuss results. There will be a discussion of some common questions from participants, watch problems, battery problems, and other situations that may occur. Monthly Actigraphy conference calls are suggested.
3. Overview of AMI's Motionlogger User's Guide

### **Certification**

Besides completing the requirements in the Sleep Watch 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 Measurement Reliability Studies**

At the beginning and ending of the study, each actigraph will be calibrated using equipment developed by Ambulatory Monitoring, Inc., to ensure that accurate measurements are being obtained. Watches generating differences that exceed acceptable limits (to be determined) will be returned to the manufacturer for evaluation and repair, if necessary.

### **13. Quality Assurance for the Sleep Diaries**

Each interviewer, who will be instructing and reviewing Sleep Diaries and transferring data to the **Actigraphy Checklist Form**, will be required to complete training on the Sleep Diary, and have a "Sleep Diary Certification Form" on file. Training and certification requirements are in the Appendix following.

In addition, the **first 5 completed Sleep Diaries** will be faxed to the Coordinating Center for quality monitoring. Photocopy the Sleep Diaries and fax to the SOF Senior Actigraphy Technician Terri Blackwell (address on previous page).

Actigraphy monitors will perform a 100% review of all diaries.

### **Participant Instruction on How to Complete the Diaries**

Trained and certified study staff will instruct each participant on how to fill in the Sleep Diary by using the instructions on the **Sleep Watch Information Sheet**. Examples of these are in the Appendix.

**14. Appendices**

Include all of the following:

1. Actigraph Watch Log Sheet
2. Actigraphy Checklist Data Entry Form
3. Sleep Watch Information Sheet
4. Actigraphy Training and Certification
5. Sleep Diary
6. Sleep Diary Training and Certification
7. Potential Watch Problems
8. Military Time Table



**Actigraphy Checklist Form (CRF Form)**



## *Actigraphy Sleep Watch Information Sheet*

Thank you for agreeing to participate in the SOF Sleep Study. You will be wearing the watch for a number of days and nights in order for us to monitor sleep quality and your activity.

### **Things to Remember About Wearing the Sleep Watch:**

- The watch measures motion. It will tell us when you are sleeping quietly or restlessly and how active you are during the day. The Sleep Diary is used to interpret this information correctly.
- Appearance of the watch: The watch displays the time-of-day, allowing you to keep track of time without needing to wear another watch. The watch buttons on the side may get bumped, changing the time display. Do not worry if the display is altered, we are still getting the motion information that we need and at the time it occurs. Continue to record the times for your diary using any clock and call a staff person to help you correct the display.
- Wearing the watch: The watch should be worn at **all** times, except when bathing or participating in water sports. It should be worn on the non-dominant wrist and should fit snugly enough so that it doesn't slide around. (You may wear a thin cloth wristband under the watch band if you experience any discomfort from the watch band.)
- You will wear the watch home from your visit and start recording the information in your Sleep Diary that day.
- Please record your "To Bed/Sleep" times, "Rising" times and "Nap" times every day as indicated in your Sleep Diary.
- Take your watch off in the morning of the last day. Make sure that your Sleep Diary information is complete.
- Return of the watch and Sleep Diary: We will give you information on when the clinic staff will pick the watch up at your home, or information on returning by mail.
- **Contact Information:** If you have questions about wearing the watch or about filling out the diary, please call:

## SOF Sleep

### ACTIGRAPHY CERTIFICATION

**Clinic name:**            **Minneapolis**    **Pittsburgh**

**Staff member name:** \_\_\_\_\_ **Staff ID #:** \_\_\_\_\_

#### **TRAINING REQUIREMENTS**

- ◆ Read and study manual
- ◆ Attend training session on techniques (or observe administration by experienced examiner)
- ◆ Practice
- ◆ Discuss problems and questions with local expert or QC officer

#### **CERTIFICATION REQUIREMENTS**

- ◆ Complete training requirements
- ◆ Know how to describe the procedure to participant
- ◆ Operate the watch including initializing and downloading

#### **Actigraphy**

- Configure the SleepWatch® software (Act Millenium)
- Initialize SleepWatch® in the interface unit (IU)
- Use correct settings for:
  - Current time (military time), actigraph type, octagonal mode, epoch, SOF ID, startup conditions. Place tape over 4 pins. After 3 minutes, observe that arc is moving.
- Correctly keep track of actigraph and battery life (days) using log sheet
- Prepare the sleep diary form for participant
- Explain the procedures for wearing the SleepWatch® and filling out the Sleep Diary to the participant
- Download data from SleepWatch®, recording battery life, comparing visual information from Actig file to Sleep Diary, and saving file correctly
- Address any inconsistent or missing information
- Upload file to CC and send separate e-mail of file's upcoming arrival and any pertinent information associated with specific file.

**Trainer Name:** \_\_\_\_\_

**Trainer Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Sleep Diary (Teleform)**

## SOF Sleep

### SLEEP DIARY CERTIFICATION

**Clinic name:**            **Minneapolis**    **Pittsburgh**

**Staff member name:** \_\_\_\_\_ **Staff ID #:** \_\_\_\_\_

#### **TRAINING REQUIREMENTS**

- ◆ Attend training session on techniques (or observe administration by experienced examiner)
- ◆ Practice on volunteers
- ◆ Discuss problems and questions with certified staff member

#### **CERTIFICATION REQUIREMENTS**

- ◆ Complete training requirements
- ◆ Know how to describe the procedure to participant
- ◆ Answer questions to avoid any misunderstanding on information desired
- ◆ Correct errors on sample completed diary used for testing

#### **Sleep Diary**

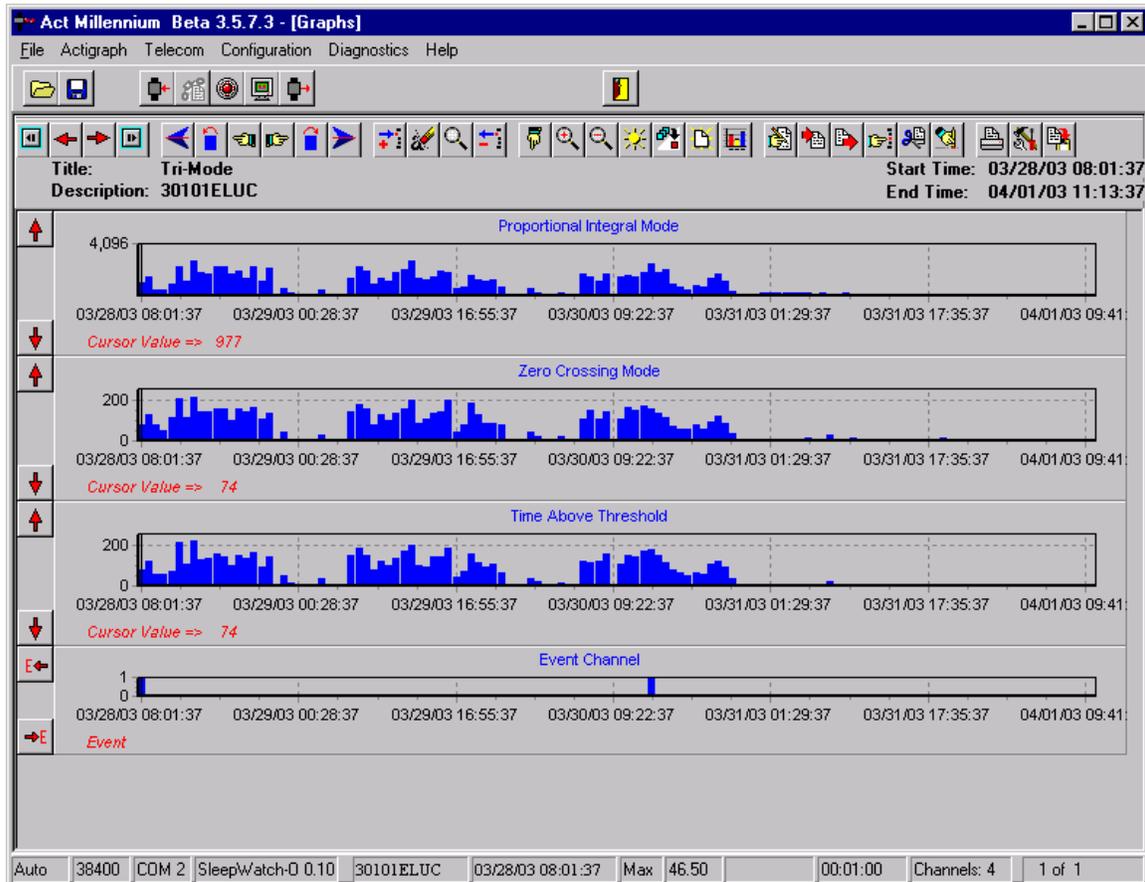
- Correctly mark participant's ID and Acrostic
- Fill in appropriate "Day of the Week" and "Date" for each of the pages
- Using the "Sleep Watch Info Sheet",
  - Explain the difference between the "in bed" and "to sleep" times and the "woke up" and "out of bed" times in case there may be some confusion.
  - Stress the importance of recording these times for Sleep Study results
  - Explain about "Watch off" times
  - Point out the locations for "Nap" times:
- When the diary is returned with the Sleep Watch, check for completeness:
  - There should be times for the "To Bed/Sleep" and "Rising".
  - Either the "Yes" or "No" spot is circled with time indications if "Yes"
- Fill in the appropriate answer of the Actigraphy Checklist form regarding completeness of Sleep Diary.
- Compare diary with actual Actigraphy file to see if participant left watch off (for a night) but didn't indicate on the Sleep Diary.
- Address any inconsistent or missing information
- Copy the Sleep Diary and mail copy to CC, Atten: Terri Blackwell

**Trainer Name:** \_\_\_\_\_

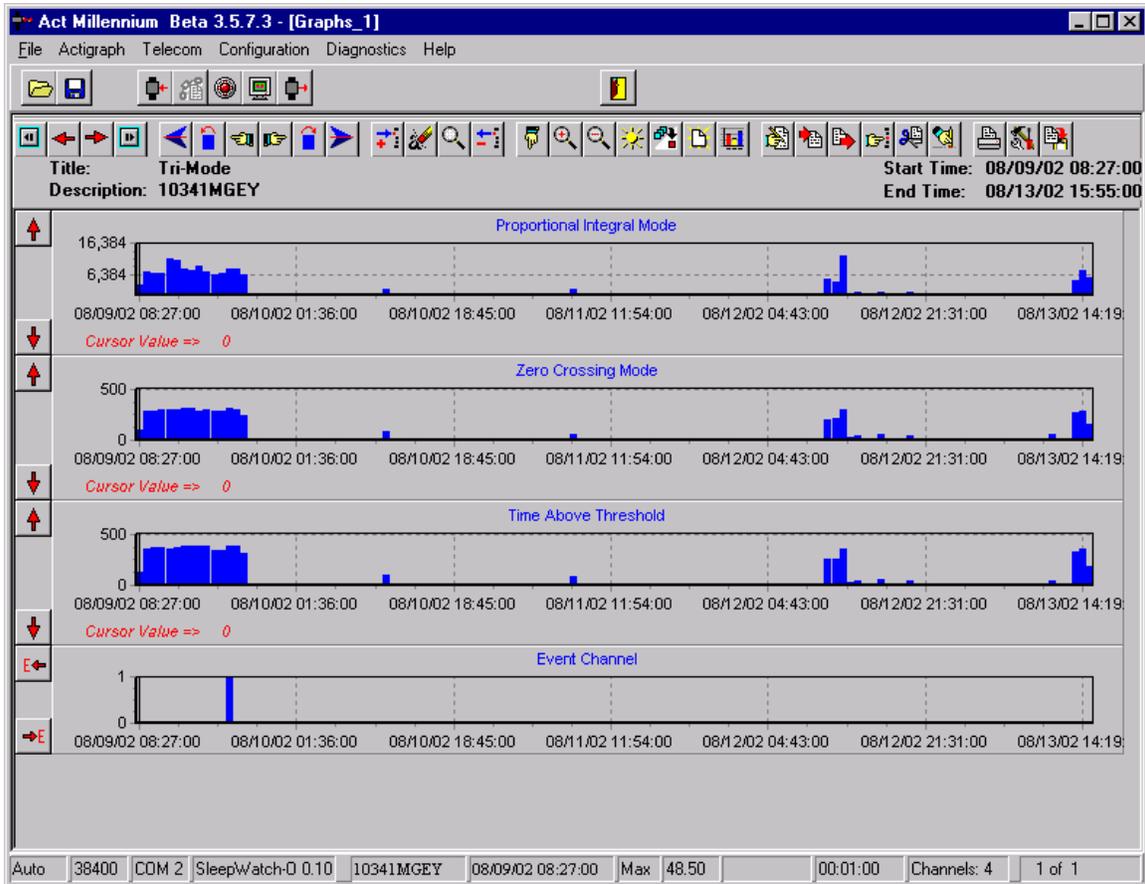
**Trainer Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Potential Watch Problems:**

This is an example of a watch with “fading” problems. Notice after around 09:22 on 3/30/03 the data activity levels get very low and fade out.



This is an example of a watch that was worn for part of the first day and, then removed. You can see there is no activity until the watch is picked up by the clinic staff a few days later.



**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