

ACTIGRAPHY

1. Background

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 5 24-hour periods (minimum of 3 nights). The watch will be worn for 5 evenings of sleep. The 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

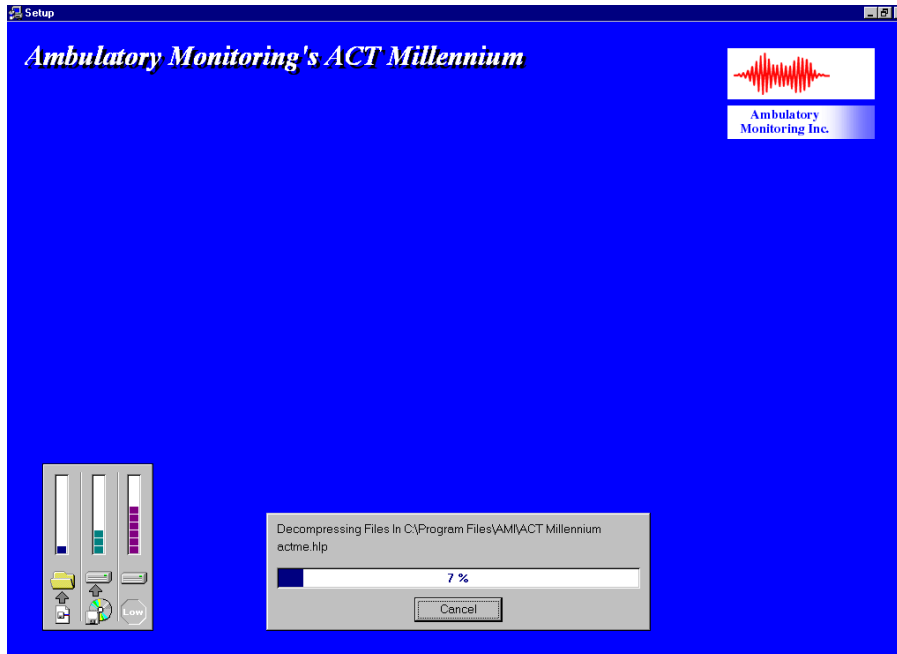
- **Octagonal Motionlogger SleepWatch (catalog no. 26.10)**
- **Octagonal Motionlogger interface unit and cables**
- **ActME Software**
- **Black electrical tape**
- **3 volt Lithium Watch batteries (CR2430)**
- **9-volt batteries (for IU)/or electrical cord**
- **alcohol swabs**
- **watchbands (come with the watch)**
- **terry-cloth wristbands (optional)**

3. Setting up the ActME software

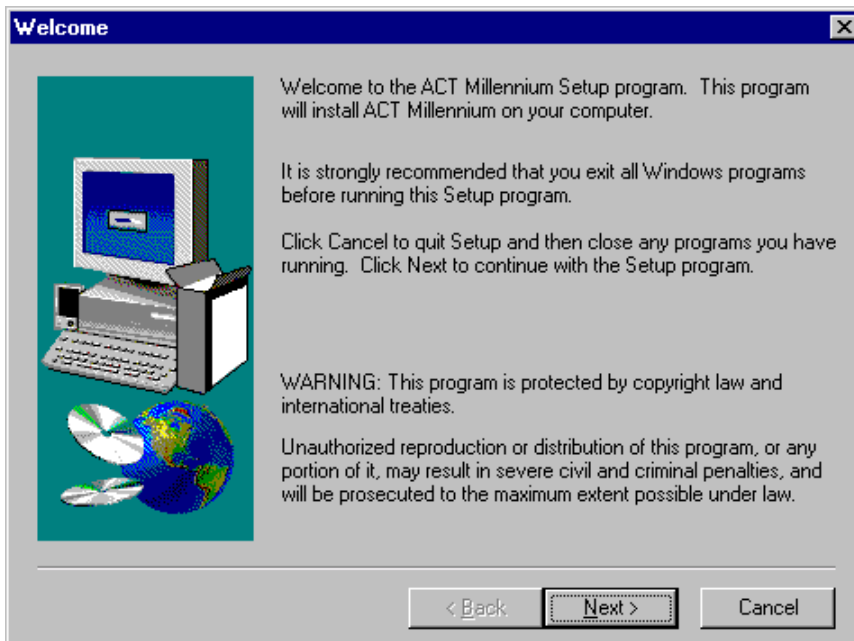
ACTMe version 3.5.13.2 is a Windows program that is used to initialize motionlogger actigraphs, and to download data from the devices.

The software is available for download at the AMI website http://www.ambulatory-monitoring.com/software_updates.html. You will need to scroll down the page to find the download for ActMe_ver3.5.13.2.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:

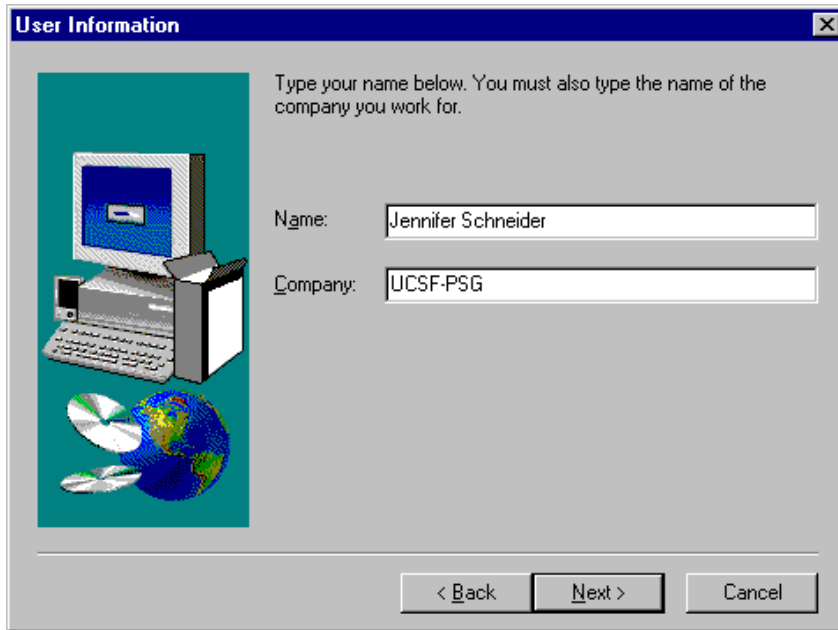


You will be able to watch the progress of the installation from this screen. As the installation progresses you will see:



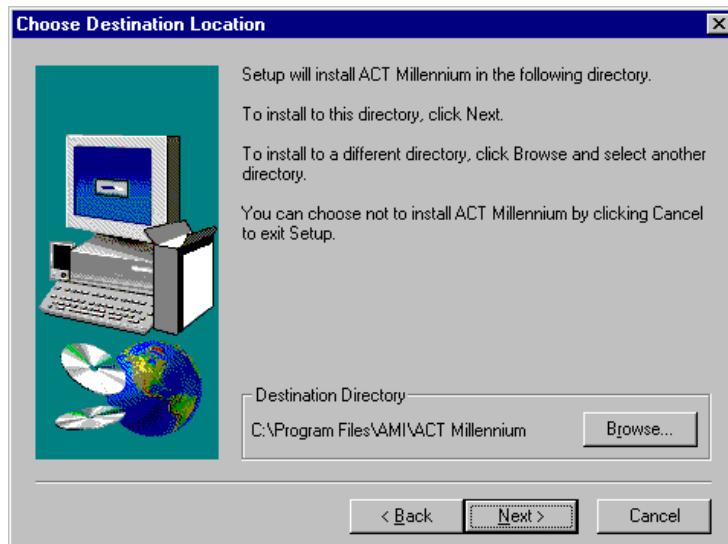
Click the "Next" button.

At the next window:



Enter your name and the name of the clinic. Click “Next” button.

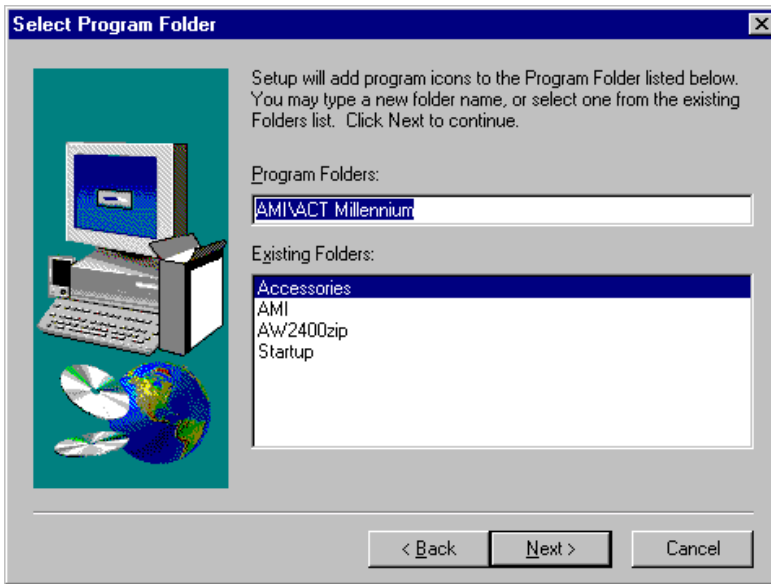
Then you will be asked to choose a destination for the program on your computer:



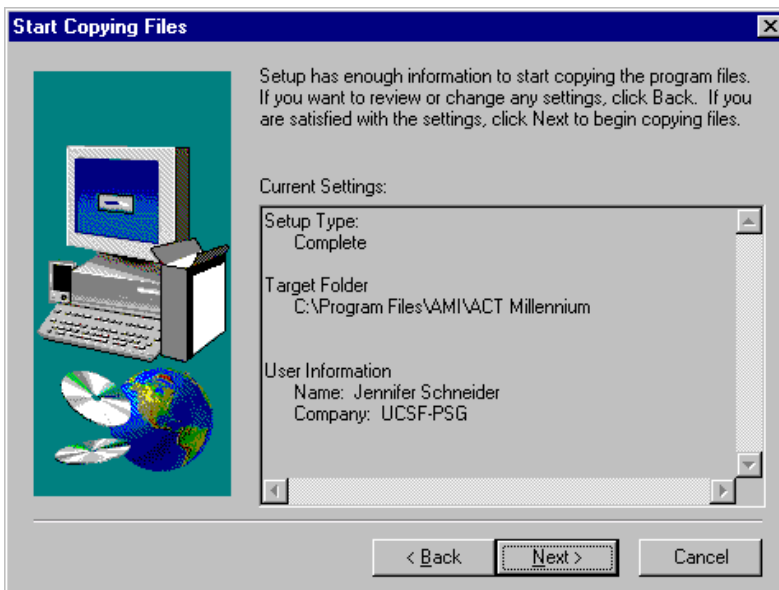
If you do not change anything on this screen the program will automatically be placed in the “Program files” folder on your computer. In most cases this is fine, however if you want the program to be installed in a different location click on the “Browse” button and select a location. Then select “OK”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

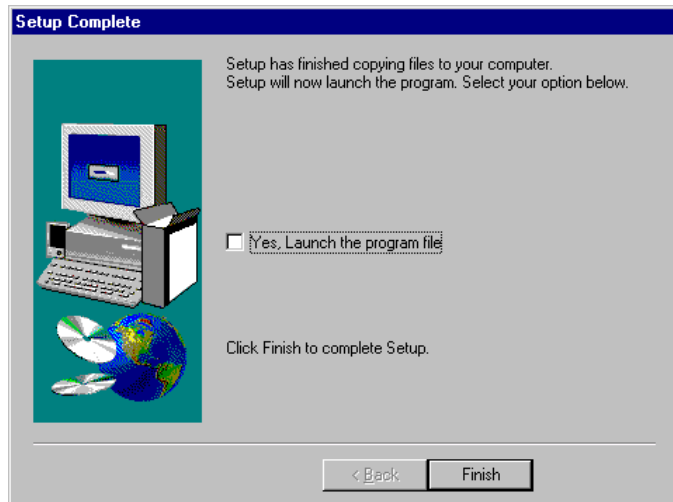


Leave this as is and hit the "Next" button.



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".

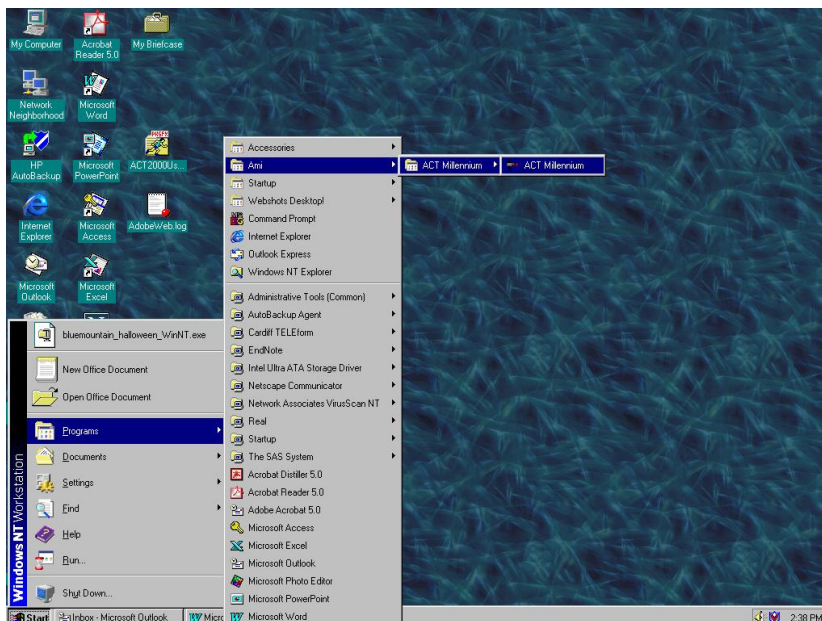
When all files have been transferred you will see the following window:



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”.

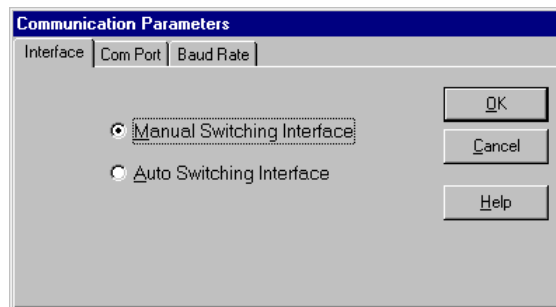
5. Setting up the SleepWatch

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.

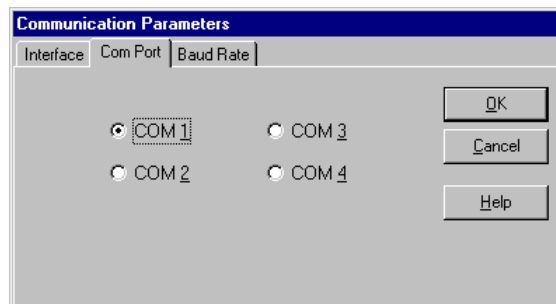
- a) Connect the serial cable to the IU and then plug the other end of the cable into an available serial port (9-pin port) on the back of your computer. (The IU requires a 9-volt battery or can be used with an AC adaptor.)
- b) Once the IU is connected to the computer turn the silver toggle switch on 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).
If the green light does not come on, try a different serial port on the computer until you find one that works.
- 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 you will save them and they will be your default settings, they will not need to be changed every time you open the program.

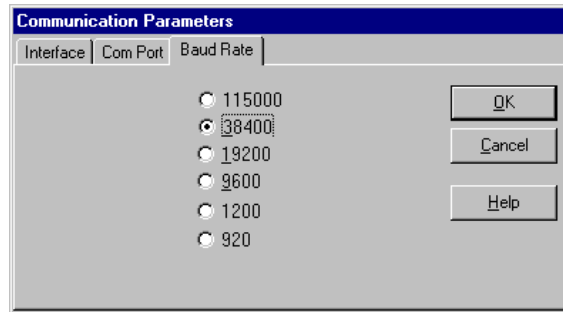
Select the Manual Switching Interface under the “Interface” tab and then click on the Com Port tab, do not click on “OK” (this will cause the Configuration window to close).



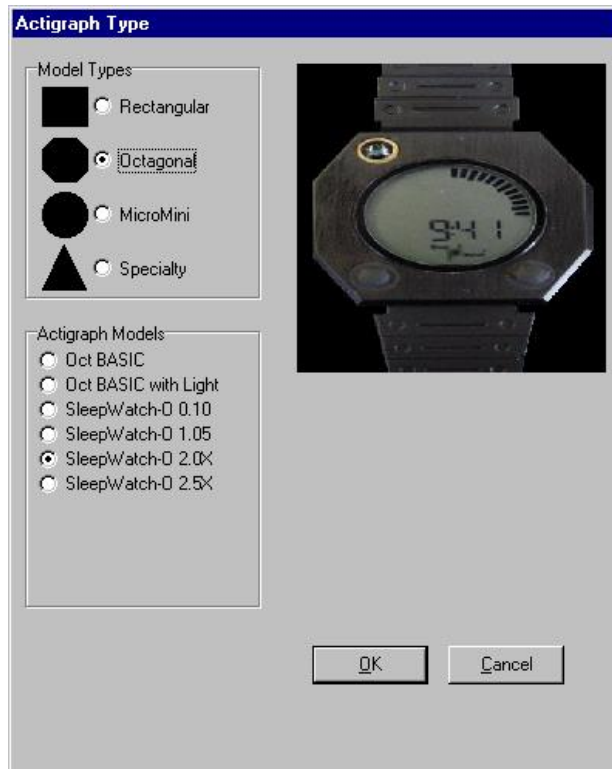
Select any COM PORT (try starting with COM 1 or COM 2) and click on the “Baud Rate” tab.



Select a Baud rate of 38400 and click OK.

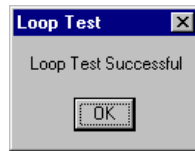


Next click on the “Configuration” menu and select “Actigraph Type”. If the watch is version 2.0 select Octagonal and SleepWatch-O 2.0X and click “OK”. If the watch is version 0.10 select Octagonal and SleepWatch-O 0.10 and click “OK”. The version appears on the metal plate on the back of the watch.

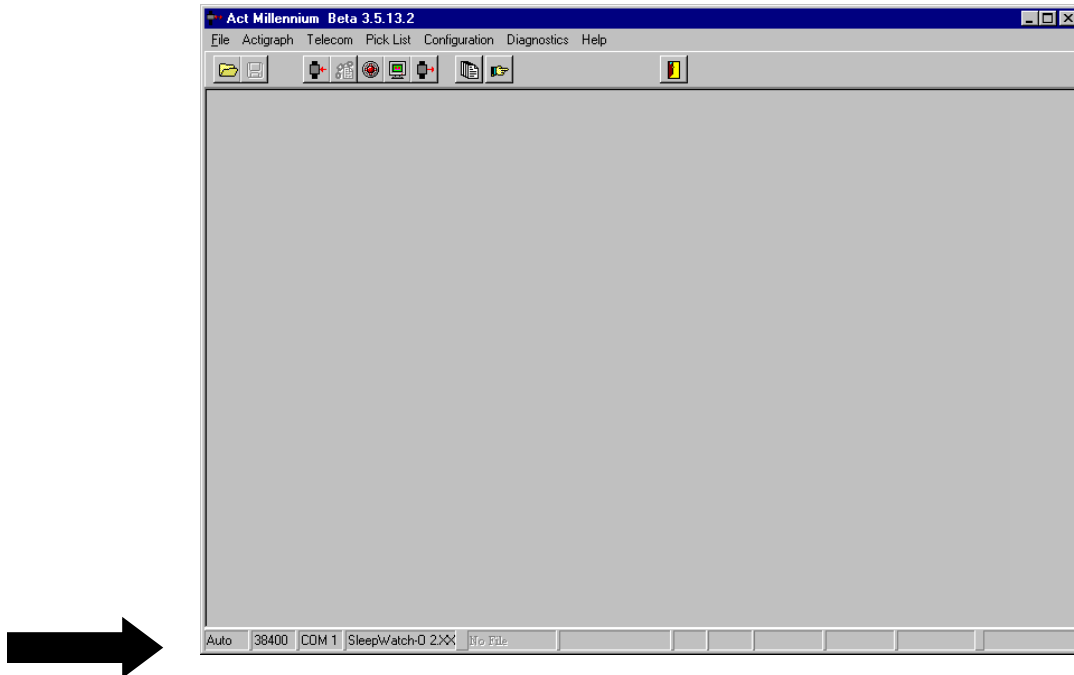


- e) Now you need to make sure that the correct configurations have been selected. Go to the “Diagnostics” menu and select “Loop Test”.
- f) Make sure the IU is turned on (green light on). Hold the black button on the back of the IU and click on “OK” for the loop test (hold the button until you get a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

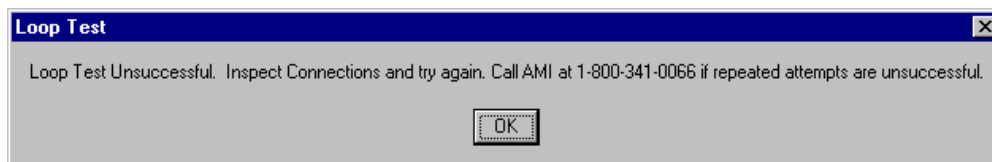
If you get the following message everything is configured correctly, click “OK”.



Proceed to save the settings by going to the “Configuration” menu and selecting “Save”. The settings always be viewed 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 check the life of the battery. To do this, place the SleepWatch into the IU and within the File menu 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 sleepwatch log in the clinic. Discard used batteries in an environmentally safe manner.

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.

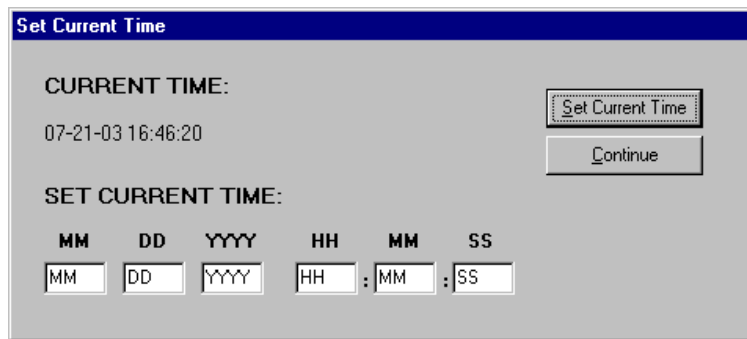
Turn the IU on and insert the SleepWatch into the IU so that it is secured in the holder. Put the watch in the IU so that the 4 gold pins on the side of the watch are

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 “Actigraph” menu and select “Initialize” or use the initialize icon on the toolbar. Turn the toggle switch to on (green light will appear).

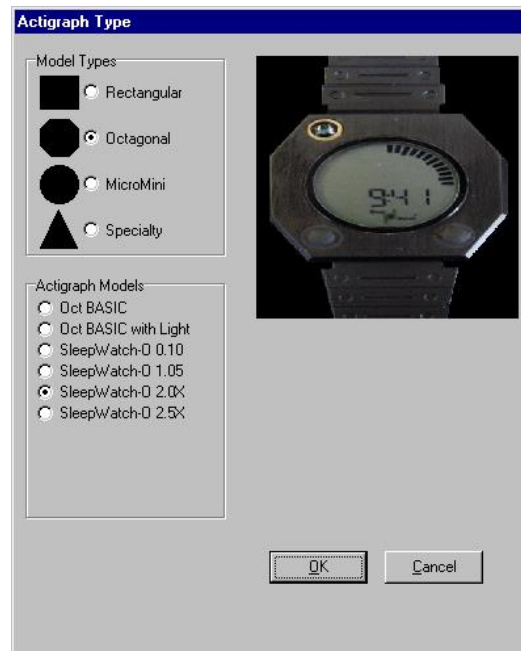
When the “Set Current Time” window appears check that the time is correct. The program uses military time. The program sets its time according to the internal time on your computer so you need to make sure that the time setting on your computer is correct (AM/PM). If you need to change the time you can do so by filling in the boxes at the bottom of the pop-up window, be sure to use Military time, a table is provided on page 20. If you need to change the time click on “Set Current Time”.

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



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.

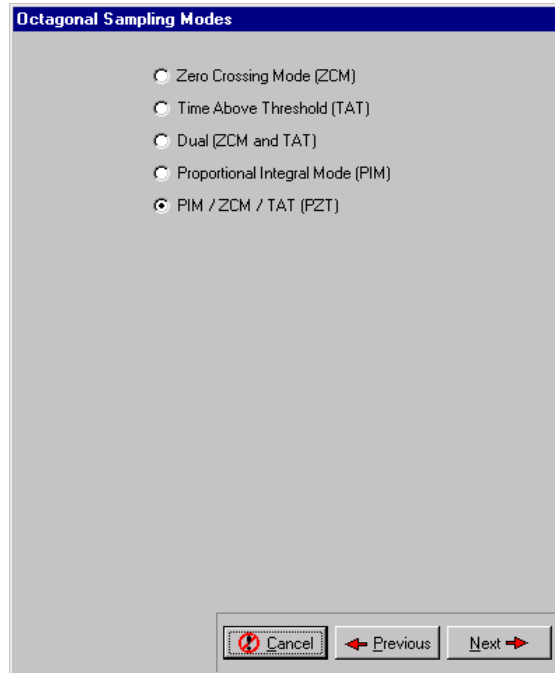
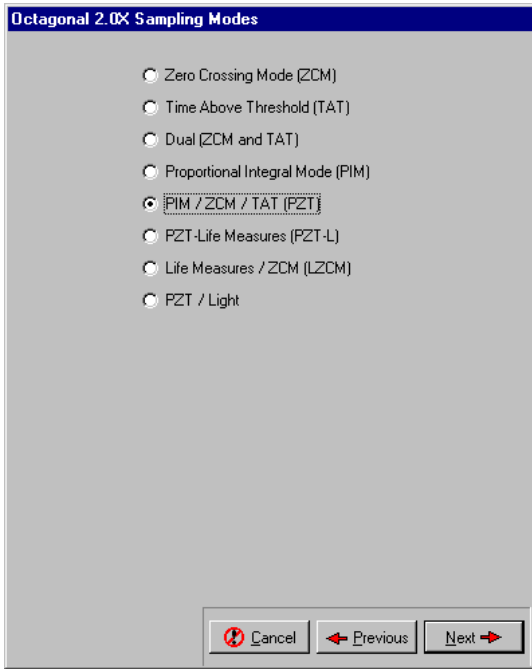
Click on “OK” once you have selected the correct model type and actigraph type.



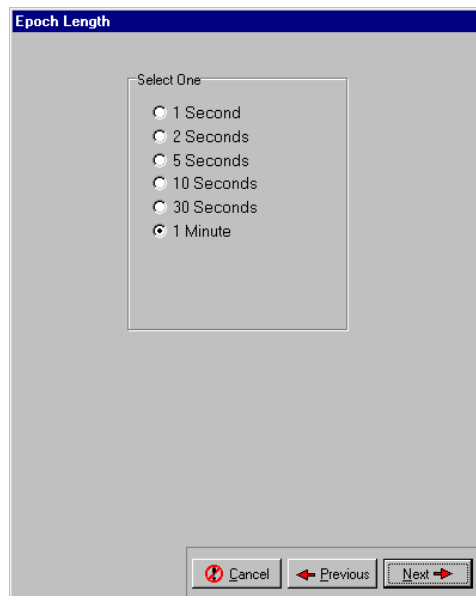
Select “PIM/ZCM/TAT (PZT)” and click on “OK”.

Screen appears like this for Version 2.0X:

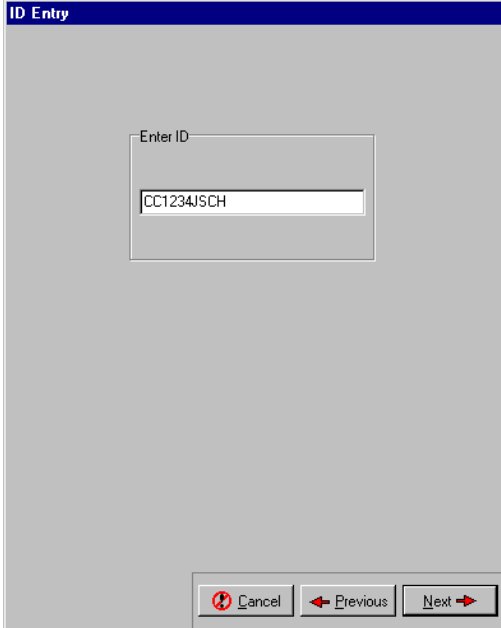
Screen appears like this for Version 0.10:



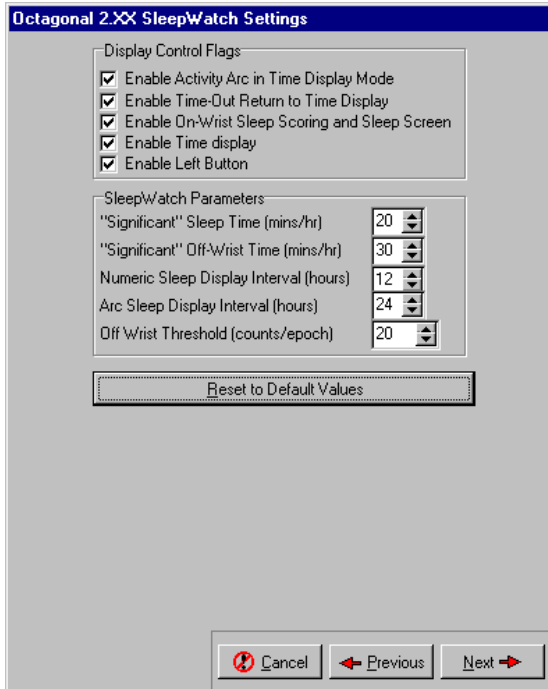
Set the epoch length for “1 minute” and click on “Next”.



Enter the participants MrOS ID and acrostic (for example: CC1234JSCH) into the box and click on “Next”.

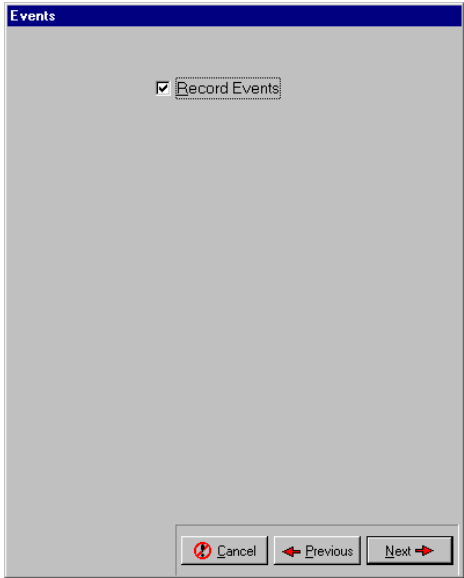


On the Octagonal 2.XX “SleepWatch Setting” tab click on “Reset to Default Values” and click “Next”. This screen does not appear for the Octagonal 0.10, so this step is skipped.

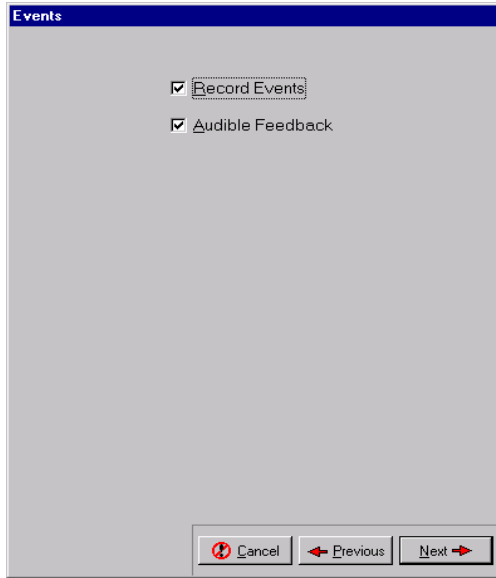


Leave the “Record Events” box checked for Octogonal 2.0X and “Record Events” and “Audible Feedback” checked for Octogonal 0.10 Select “Next”.

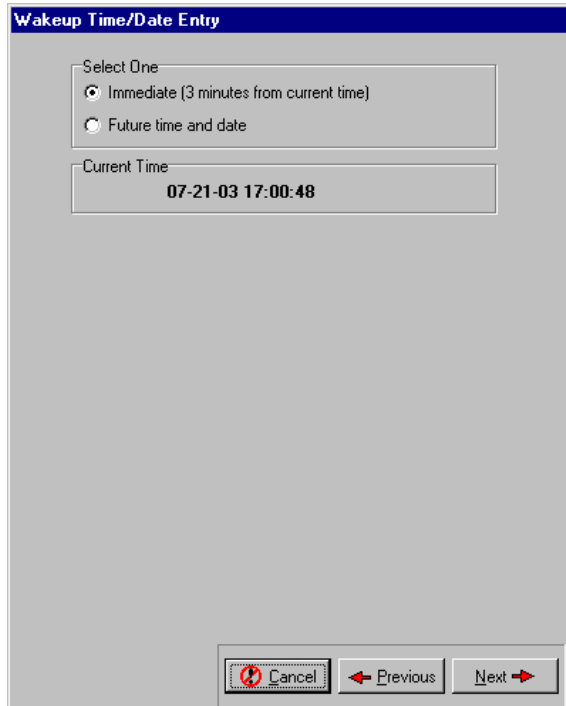
Screen appears like this for Version 2.0X



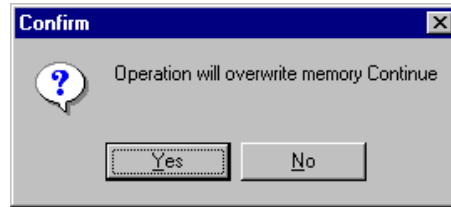
Screen appears like this for Version 0.10



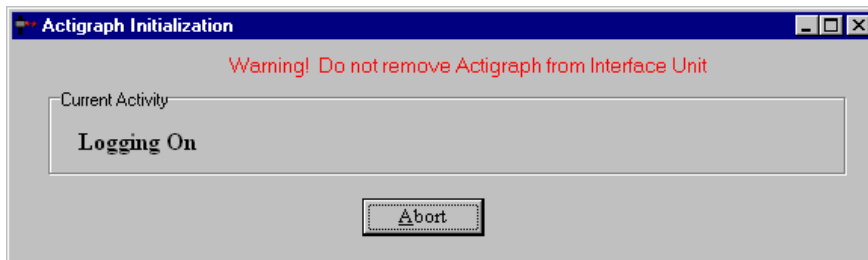
Select “Immediate” and click on “Next”. Before selecting next, double check that the current time is correct.



You will 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.



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.

At the visit the participant will receive:

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

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 and any 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 a terry cloth wrist band or some sort of padding, can be worn underneath the watch so that it is not in contact with the wrist, 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). It is ok for the watch 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 watch - the watch should be worn from the time the participant leaves their clinic 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 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 watch - 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.
 - 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 watch should already be set to start collecting data when the participant puts it on at their clinic 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 visits the clinic they will complete 5-7 days of the sleep diary (3-5 nights 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 Begins	SleepWatch Data Collection Begins	SleepWatch Data Collection Ends	Sleep Diary Ends	SleepWatch Picked Up from Home	Number of Nights of SleepWatch 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 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 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.

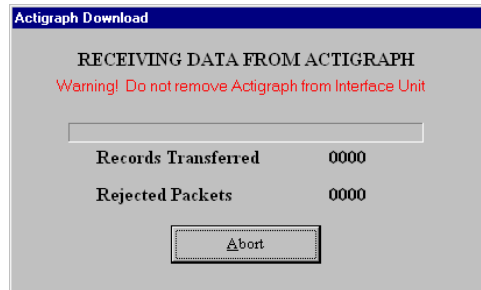
You may want to suggest that the participant keep the sleep diary by their bed or other convenient spot so that they remember to fill it out. At the end of every day they should fill in any missing information about their activity for that day. In the morning they should record information about their 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 watch 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 watch. 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 watch is picked up from the participant. The only new information on this page is the question about what time they took the watch off and left it off. If the participant still has the watch on when staff arrive to collect the watch and diary, that is the time that should be recorded.
- 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.
- f) When the watch 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.

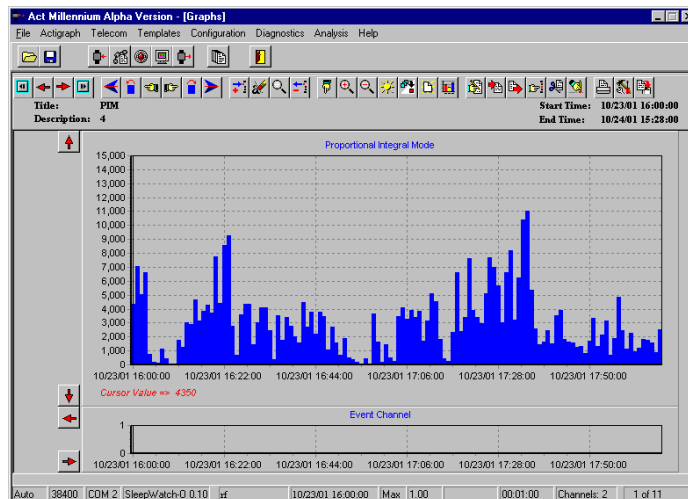
9. Downloading Data from the SleepWatch

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) Click on “OK” when you see the window that says “Ensure interface unit is set to communicate.”
- d) You will see the following window while data is being downloaded:



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.



- e) Once download is completed successfully you will be prompted to save the file. Click on “Yes” and save the file as “MROSIDAcroscopic” (using the ID and Acroscopic of the participant who most recently wore the watch, eg. CC1234JSCH). 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. Close the program. Make sure that the MrOS 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).
- f) 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 at the end of this chapter. If some data was collected, but not 3 full nights and they refuse to rewear the watch you should send the data file to mrosdatauploads@psg.ucsf.edu. If there is no data available on the file and the participant will not rewear the watch you should enter ‘0’ days in question 4 on the Actigraphy checklist and do not need to send the .ami file to the Coordinating Center.

When you save the data (remember to save it as an ‘.ami’ file without application area) it will be saved as ‘MROSidAcroscopic.ami’ (ex. CC1234JSCH.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.

- a) Address an e-mail to mrosdatauploads@psg.ucsf.edu (the address can be found in the Global Address book)
- b) The subject of the e-mail should be the participant’s MROSID and Acroscopic.
- c) Insert/attach the file ‘MROSidAcroscopic.ami’ to the e-mail.
- d) Do not include any text in the e-mail.
- e) Send the e-mail.
- f) 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.
- g) The sleep diary pages should be sent into the data system by fax or digital sender the same as other clinic and SAQ forms. A copy also needs to be mailed to the Coordinating Center,
Attn: Terri Blackwell.
- h) 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 watch should always be worn on the non-dominant hand if possible, exceptions to this should be rare.
- 2) The date that the watch is given to the participant will almost always be the same as the clinic visit date. If no watch is available or the participant is unable to take the watch 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 watch is retrieved from the participant should be recorded.

- 4) The number of days that data was collected can be obtained from looking at the .ami file.
- 5) Please indicate if the diary was completed and the extent of the completeness.

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.

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