
ACTIGRAPHY

1. Background and Rationale

The equipment that will be used for this study, the Sleep-watch-W (Ambulatory Monitoring, Inc) actigraph, is a small device that will be worn on the non-dominant wrist for at least 3 24-hour periods. 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

- **SleepWatch-0**
- **Interface Unit and cables**
- **Act2000 Software**
- **Black electrical tape**
- **Watch batteries**
- **9-volt batteries (for IU)**
- **alcohol swabs**
- **watchbands**
- **terry-cloth wristbands (optional)**

3. Setting up the Act2000 software

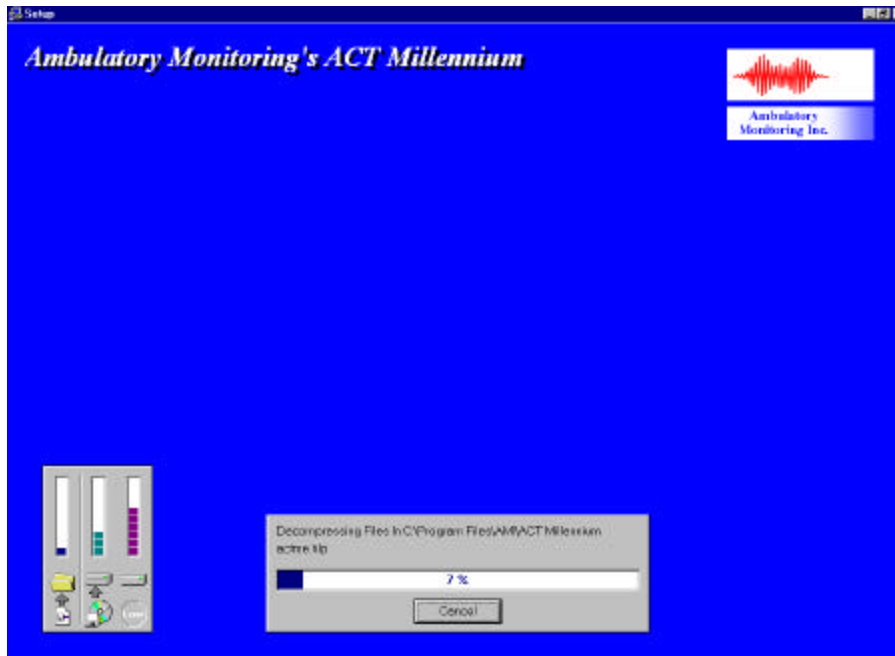
ACT 2000 is operational software developed by Ambulatory Monitoring Inc. (AMI) to initialize and download all of these actigraphs.

The software has been provided to you by AMI on compact disc (CD). After following these steps, ACT 2000 can be installed on your computer. Once the program has been installed, you will not need the CD to start ACT 2000.

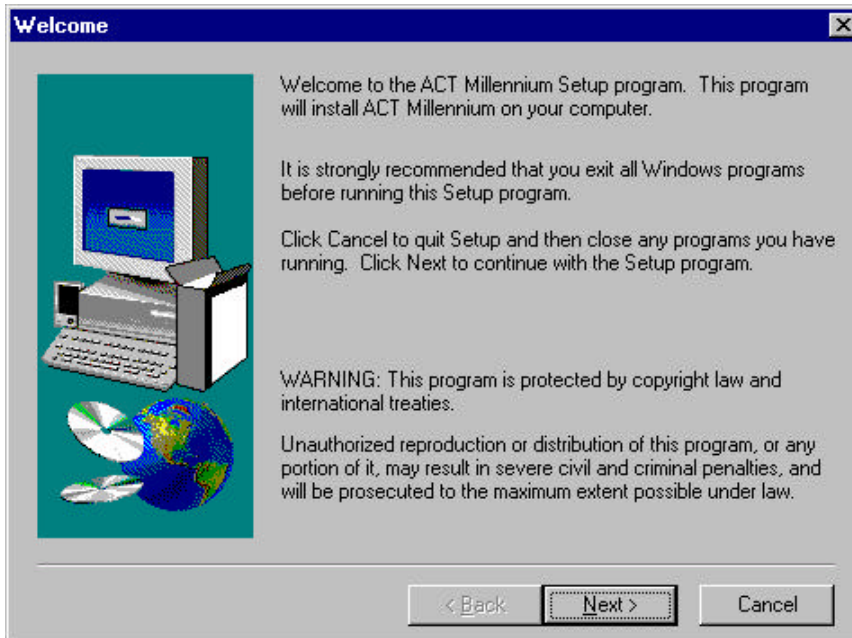
To begin installation of software insert the CD into the CD ROM drive of your computer (probably drive e:\) once the computer is powered on. If you have autoinstall on your computer a window will pop up in a few seconds instructing you what to do. If you do not have autoinstall you will need to go through the following steps:

- a) Double click on the My Computer icon or find it through Explorer.
- b) Double click on drive e:\ (or your CD ROM drive).
- c) Double click on the "setup.exe" icon.

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

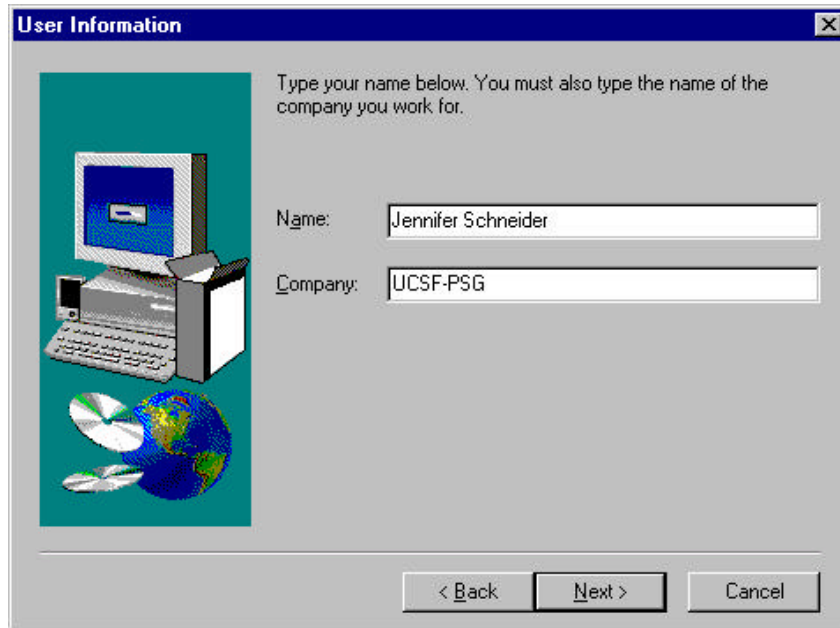


You will be able to watch the progress of the installation from this screen. As the installation progresses you will see:



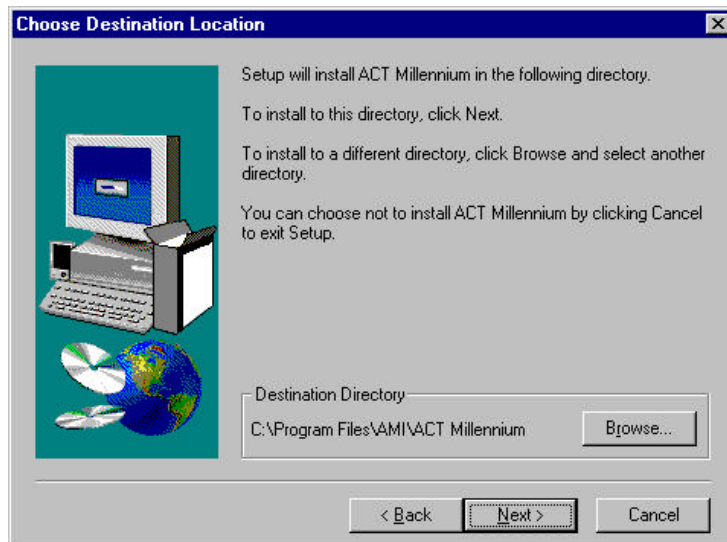
Click the "Next" button.

At the next window:



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

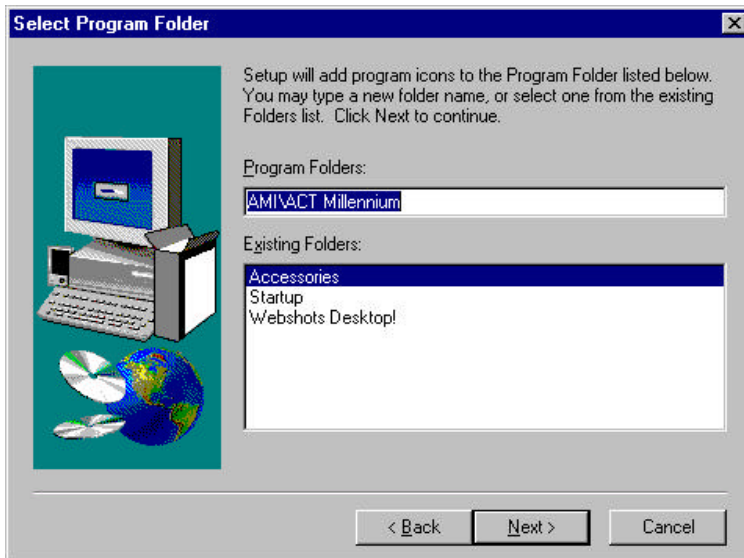
Then you will be asked to choose a destination for the program on your computer:



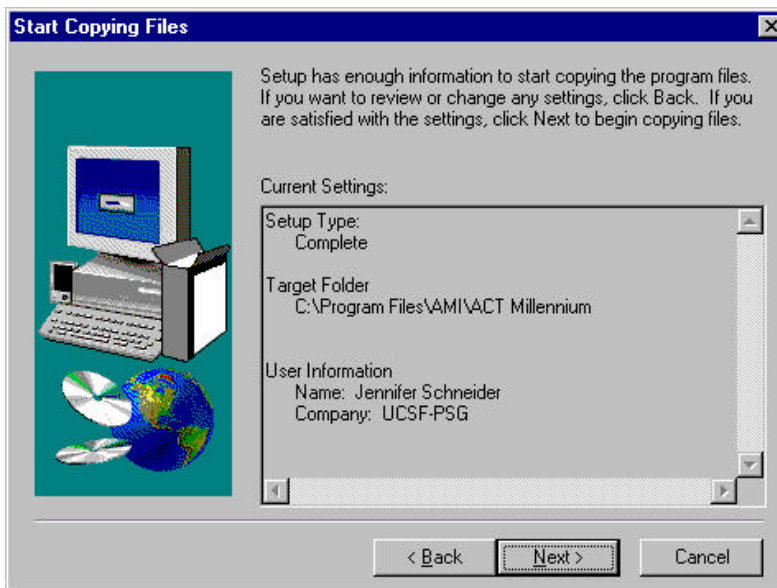
If you do not change anything on this screen the program will automatically be placed in the “Program files” folder on your computer. In most cases this is fine, however if you want the program to be installed in a different location click on the “Browse” button and select a location. Then select “OK”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

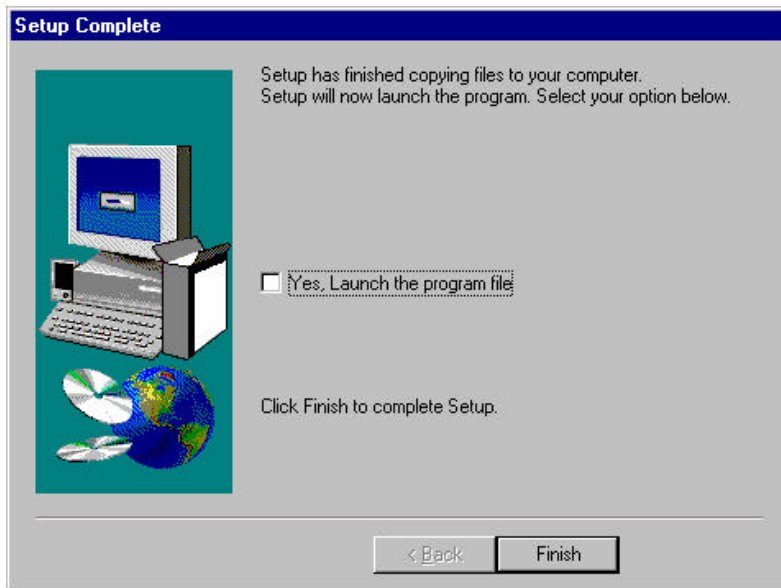


Leave this as is and hit the "Next" button.



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".

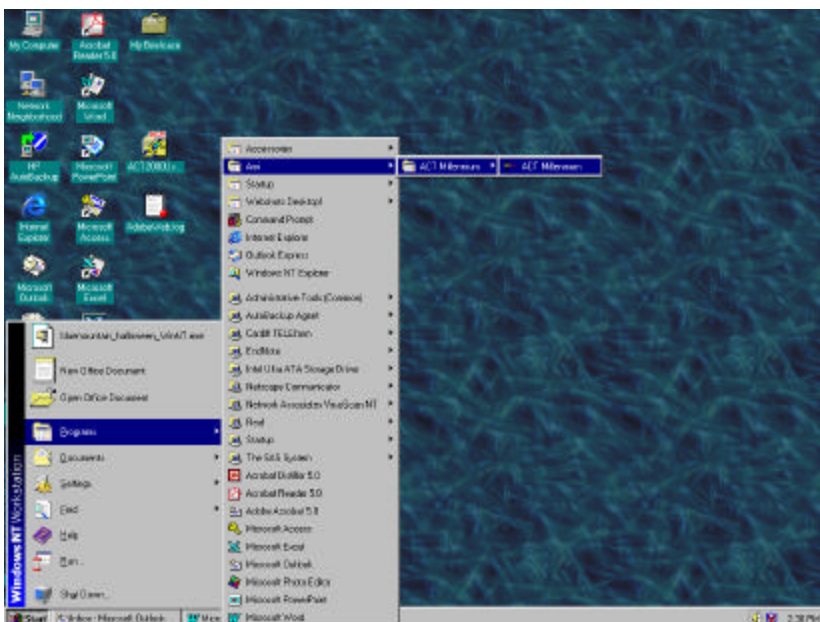
When all files have been transferred you will see the following window:



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”.

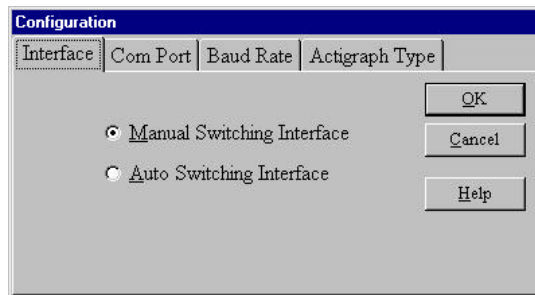
5. Setting up the SleepWatch

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.

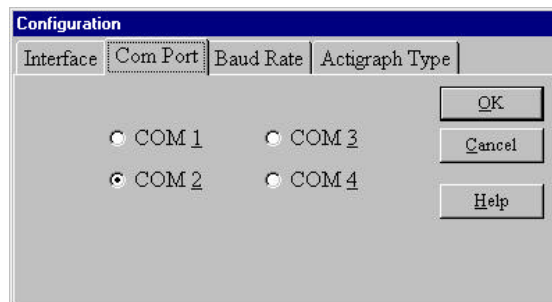
- a) Connect the serial cable to the IU and then plug the other end of the cable into an available serial port (9-pin port) on the back of your computer. (The IU requires a 9-volt battery.)
- b) Once the IU is connected to the computer turn the silver toggle switch on the back of the IU until the green 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 “Edit”.
- d) You need to set the configurations to match the requirements of the SleepWatch and software that we are using.

A configuration window with 4 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.

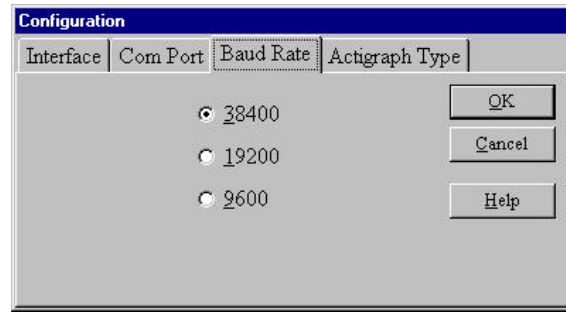
Select the Manual Switching Interface under the “Interface” tab and then click on the Com Port tab, do not click on “OK” (this will cause the Configuration window to close).



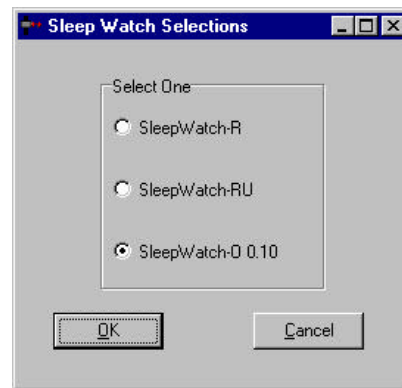
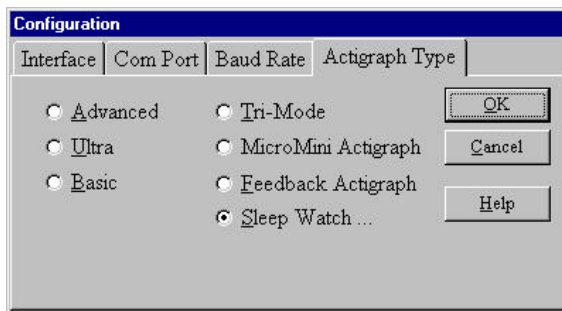
Select any COM PORT (try starting with COM 1 or COM 2) and click on the “Baud Rate” tab.



Select a Baud rate of 38400 and click on the “Actigraph Type” tab.

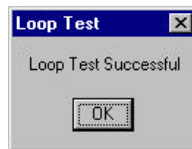


Select SleepWatch and click “OK”. Then select SleepWatch-O 0.10 on the second screen and click on “OK”.

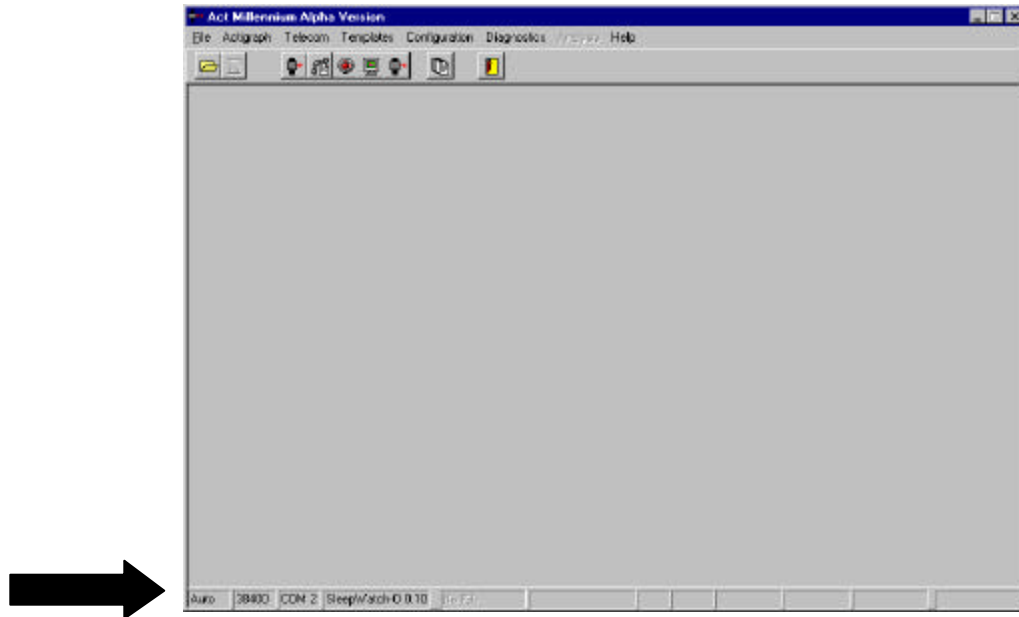


- e) Now you need to make sure that the correct configurations have been selected. Go to the “Diagnostics” menu and select “Loop Test”.
- f) Make sure the IU is turned on (green light on). Hold the black button on the back of the IU and click on “OK” for the loop test (hold the button until you get a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

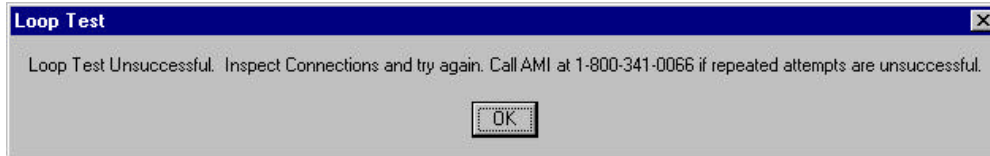
If you get the following message everything is configured correctly, click “OK”.



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, 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. 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.

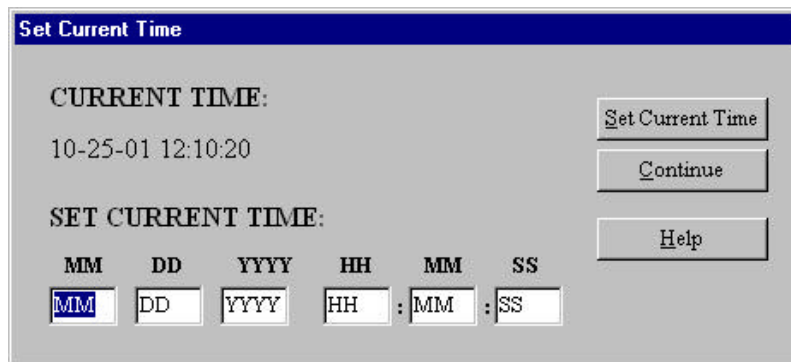
Turn the IU on and insert the SleepWatch into the IU so that it is secured in the holder. Put the watch in the IU so that the 4 gold pins on the side of the watch are touching the IU. Remember to clean any tape residue off of the pins using an alcohol swab before placing the watch in the IU.

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.

Go to the “Actigraph” menu and select “Initialize”. Switch the toggle switch on (green light will appear).

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 18.

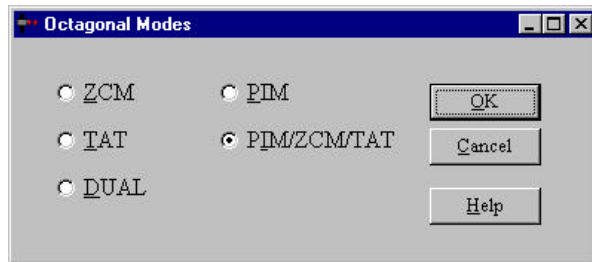


Hit “Continue” once the correct time appears under “Current Time:”

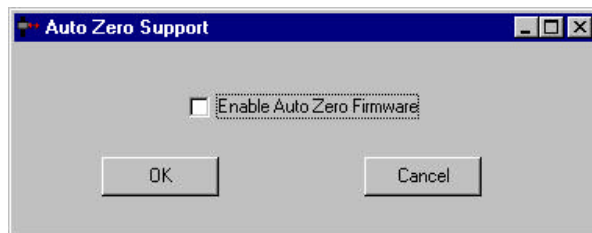
Select SleepWatch and click on “OK”. Then select SleepWatch-O 0.10 and hit “OK”.



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



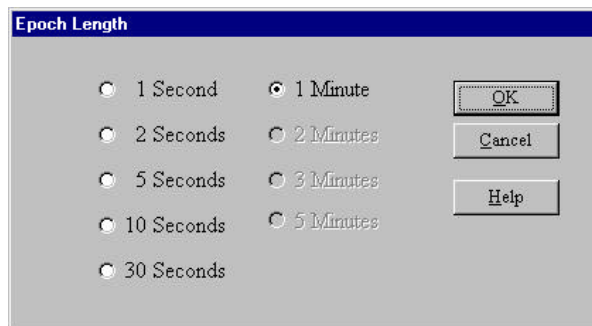
De-select the enabling auto-zero box (so there is no check in the box) and click on “OK”.



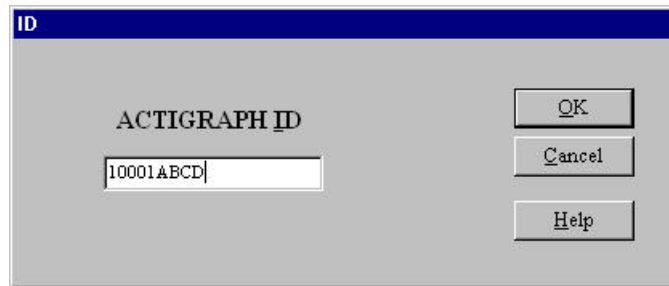
Select the record events box (so there is a check in the box) and click on “OK”.



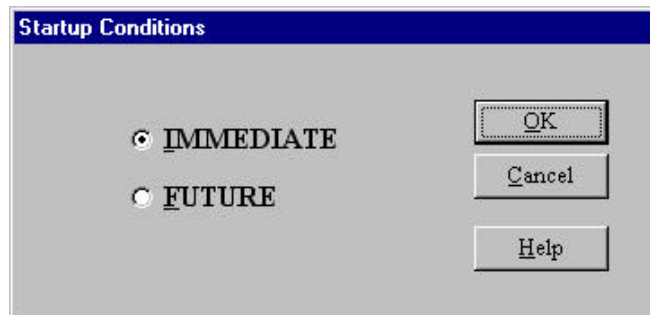
Set the epoch length for “1 minute” and click on “OK”.



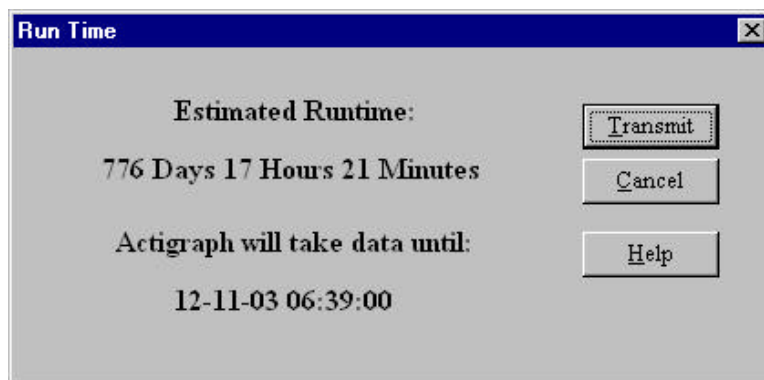
Enter the participants SOF ID and acoustic (for example: 10001ABCD) into the box and click on “OK”.



Set the start up time for “Immediate” and select “OK”.



This window tells you the runtime of the watch based on memory available in the SleepWatch, it does not take into consideration the battery life of the watch. Do not be concerned with the data indicated (unless it is less than 7 days from the current date).



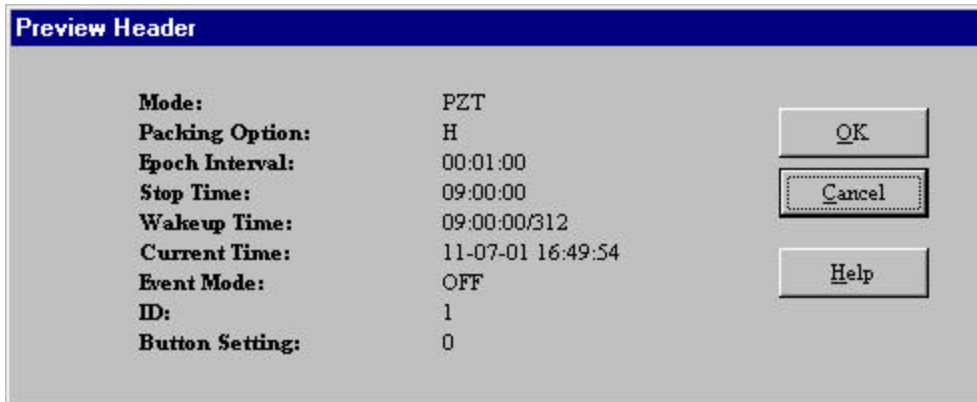
Click on “Transmit”.

A window that displays all of the settings you have selected will appear and you have the opportunity to check that these are correct.

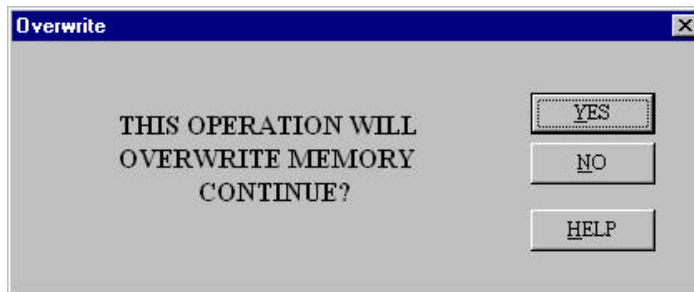
Again, the wakeup time refers to when the watch will begin collecting data, so for all SOF Visit 8 participants this should give you the current time. Do not be concerned with

the stop time. The time to stop collecting data can not be set on the sleep watch model that is being used in this study. Until data is downloaded and the watch is re-initialized it will continue to collect data. The excess data will be cut during data cleaning with the aid of the sleep diary.

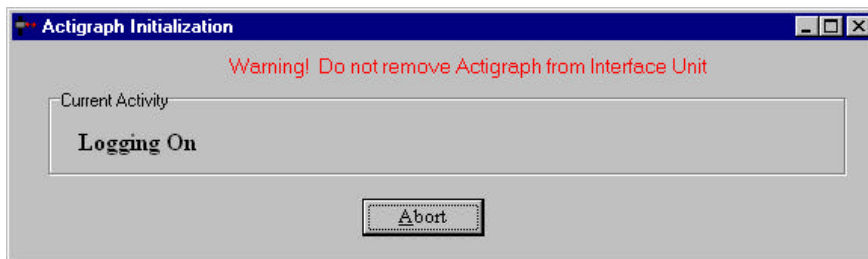
If something is not right on the Preview Header window you can cancel and go back and change the settings. Once settings are correct click on “OK”.



You will be asked if it is ok to overwrite the memory of the SleepWatch, click on “Yes”.



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.

7. 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 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. For women with particularly thin wrists a terry cloth wrist band or some sort of padding, can be worn underneath the watch so that it is not loose 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 ok 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.
- 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 dates can be filled in at the top of all pages by the clinic staff to clarify when to complete the forms.
- 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 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 visits the clinic they will complete 5-7 days of the sleep diary (3-5 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 Begins	SleepWatch Data Collection Begins	SleepWatch Data Collection Ends	Sleep Diary Ends	SleepWatch Picked Up from Home	Number of Days of SleepWatch Data Collected
Monday	Monday Evening	Tuesday Morning	Friday Morning	Friday Morning	Friday	3
Tuesday	Tuesday Evening	Wednesday Morning	Monday Morning	Monday Morning	Monday	5
Wednesday	Wednesday Evening	Thursday Morning	Monday Morning	Monday Morning	Monday	4
Thursday	Thursday Evening	Friday Morning	Monday Morning	Monday Morning	Monday	3
Friday	Friday Evening	Saturday Morning	Tuesday Morning	Tuesday Morning	Tuesday	3

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.

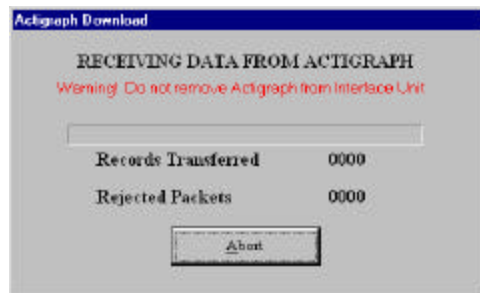
- d) The participant should be instructed on when to begin filling in information using the Sleep Diary. They should also be told when it is ok to stop wearing the watch (9:30 am on the day that the watch is being picked up from their home).

- 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.

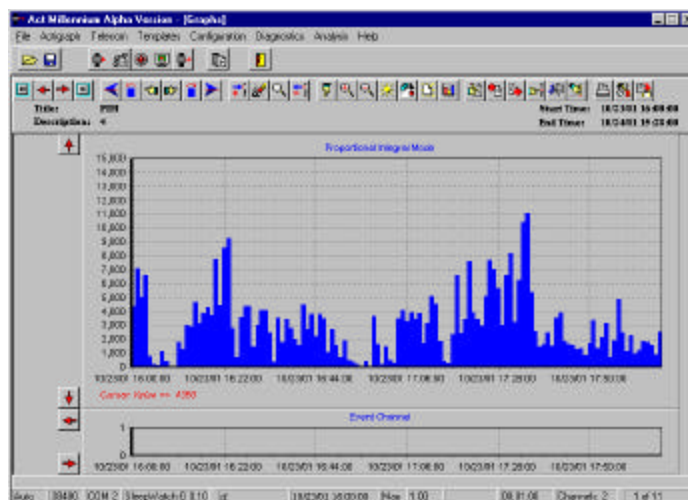
8. Downloading Data from the SleepWatch

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 a .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”).

- Open Act 2000 on the computer. Place the SleepWatch in the IU and make sure that the toggle switch is ON.
- From the Actigraph menu select “Download”.
- Click on “OK” when you see the window that says “Ensure interface unit is set to communicate.”
- 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 “SOFIDAcroscopic” (using the ID and Acroscopic of the participant who most recently wore the watch, eg. 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. Close the program.
- f) Remove the watch from the IU and turn the IU off.

9. Sending the Data to Coordinating Center

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.

- a) Address an e-mail to sofdatauploads@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 SOFID and Acroscopic.
- c) Insert/attach the file ‘SOFidAcroscopic.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 mailed to the Coordinating Center, Attn: Terri Blackwell.
- h) Complete the Actigraphy form (page 21) in the Clinic Interview 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.

10. 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