



Actiware Spectrum®

Actigraphy Operations Manual

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1. BACKGROUND

Wrist actigraphy is a technique for measuring movements of a limb over an extended recording period (days to weeks). The signals generated by wrist movement are sensed by a tiny micro-computer contained within the “watch” and translated into “activity” counts. Algorithms have been developed to translate these activity counts to “epochs” (or “periods”) that correspond to times when a person is likely to be asleep or wake.

Actigraphy provides the ability to estimate sleep duration, sleep patterns (including timing of sleep and napping) and disturbed sleep (awakenings during the sleep period) more accurately than questionnaire. It is easier to use than other approaches, such as polysomnography. Newer devices such as the ones that will be used in MESA also collect data on environmental light, which can help researchers understand the conditions surrounding the monitoring.

Actigraphy is being performed in MESA to provide reliable estimates of the duration, timing and patterns of sleep in study participants. This information is important given recent research that has shown that insufficient sleep is associated with cardiovascular disease risk factors and cardiovascular disease as well as poor daytime functioning.

Within 6 months of the MESA Core Exam 5, participants will be visited in their homes by a MESA-Sleep team to collect additional sleep information. At this visit (which will also include a hookup for overnight polysomnography and a sleep questionnaire), the participant will be shown how to use the sleep watch. The participant will be instructed to wear the watch on the non-dominant wrist for 7 24-hour periods (minimum of 5 nights, including at least one weekend/non-work day period). The watch will be worn for 7 evenings of sleep with one evening coinciding with the in-home PSG recording. The participant also will be instructed on completing a diary concurrently, recording times the watch was taken off and bed and wake times. This will provide a “backup” in case there are questions about the recording.

2. EQUIPMENTS AND SUPPLIES

The equipment that will be used for this study, the Actiwatch Spectrum® (from Philips Respironics, Inc) is a small device that will be worn on the non-dominant wrist. The Actiwatch Spectrum® contains a solid-state piezoelectric accelerometer (sensitive to 0.025G and above), lithium battery, microprocessor, non-volatile 1Mbits of memory, and associated circuitry. The orientation and sensitivity of the accelerometer are optimized for highly effective sleep-wake inference from wrist activity, which has been previously validated. The device is designed to be compact, lightweight, waterproof, and to detect movement, time “off the wrist” and environmental light. After the watch data are scored by the Brigham and Women’s Sleep Reading Center, a number of summary measurements will be generated for each participant, including: average sleep duration and sleep efficiency (percentage of time in bed spent asleep). This information can be provided to the participant as feedback and also will be used in analysis of other study data.

Each MESA site will receive:

- Actiwatch Spectrum® device (10 watches)
- Actiwatch Spectrum® communications docking station
- USB plug attachment with 6ft USB cord
- Actiwatch® software

3. SETTING UP THE SPECTRUM SOFTWARE

Actiware® is a Windows compatible program that is used to initialize Actiwatch Spectrum® actigraphs and to download data from the devices.

The CD and software installation guide are provided with the Actiwatch Spectrum®.

- 1) Insert the Actiware® software CD into your computer’s CD or DVD drive.

- 2) Click the **Install Respiration Actiware** in the window that automatically displays when the CD is inserted.
 - If the window does not automatically appear...
 - a. Select **Start > My Computer**.
 - b. Select the CD/DVD drive on the list and double-click.
 - c. Select **CDMENU.EXE** and double-click to open.
 - d. Click on **Install Respiration Actiware** to install the software.
 - a. Within 30 days of installation, activate your software.
 - b. E-mail mm.service@respiration.com with the last 8 digits of the Proof of Purchase Number on the back of the CD case.
 - c. Respiration Customer Service will send you an e-mail with the activation code within a couple of hours.
 - d. Once activation code is received, open the Actiware® software, then select **Enter Activation Key**. *If it's not activated, Actiware will stop working after 30 days.*
 - e. Enter Activation Key and Registration Name exactly as written in the e-mail.

4. CONNECTING AN ACTIWATCH SPECTRUM®

An Actiwatch Spectrum® communication docking station is necessary to communicate with an Actiwatch Spectrum® device.

- 1) Connect the USB communication cable to any available USB port on your computer.
- 2) Connect the other end of the cable to the USB port on the Actiware Spectrum® Communications Dock. The cable may be threaded through the cable-keeper on the back of the dock.
- 3) Wait for a few moments while the Actiwatch Spectrum® Communications Dock drivers are automatically installed.
- 4) Open the Actiware® software.
- 5) From the main menu bar select **Communications > Actiwatch Console**.

The Actiwatch Console wizard is displayed.



- 6) On the Actiwatch Communications Console, click on **Actiwatch Spectrum**.

- The status of the connection appears as either 'Connected' or 'Disconnected'. If 'Connected' does not appear, try another USB port on your computer. Click on **Refresh Status**.
 - 'Too many docks' may appear if more than one Actiwatch Spectrum® communication is connected.
- 7) Place an Actiwatch Spectrum® in the communications docking station by placing it face up with the sensor windows matching the illustration on the communications docking station.
 - 8) Wait a few seconds for the Actiwatch Communications Console to refresh or click **Refresh Status** to read the Actiwatch Spectrum status.
 - 9) Click on the expansion arrow to view the Actiwatch Spectrum® configuration details.

5. CONFIGURING AN ACTIWATCH® SPECTRUM FOR A SUBJECT

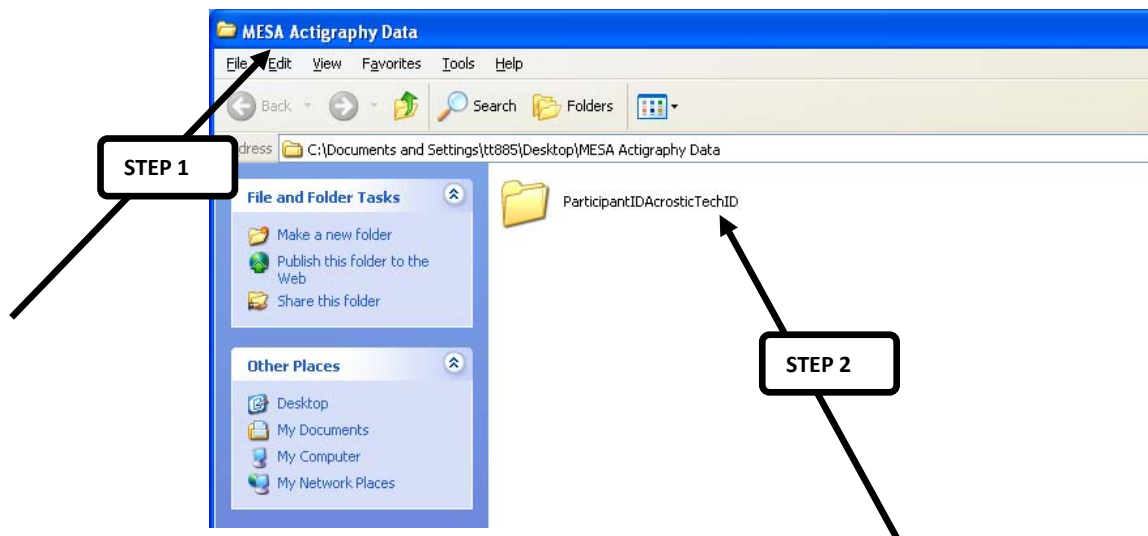
Before an Actiwatch is given to a subject, it must be configured with basic subject information and data collection parameters.

- 1) Creating an Actigraph Folder for all MESA participants
 - a. **On your desktop**, right click your mouse.
 - b. Select **New > Folder**.
 - c. Name the new folder "**MESA Actigraph Data**". This folder will contain all MESA actigraph data.

Step 1 needs to be performed only once. If more than one researcher is in charge of actigraph data, make sure the MESA Actigraph Data folder is created in a folder that all research staff can access.

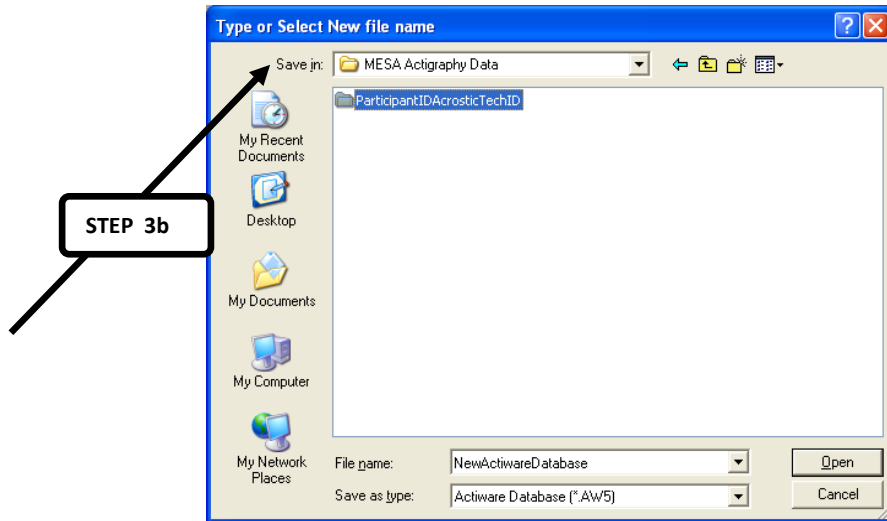
- 2) Creating a Actigraph Folder for a new MESA participant
 - a. Open **MESA Actigraph Data** folder (created in the previous step).
 - b. Select **File > New > Folder**.
 - c. Name the new folder "**ParticipantIDXXXXX1234**" ("ParticipantIDAcroscopicTechID"). This folder will contain the actigraph database for the participant and the participant's sleep diary.

Step 2 is performed for each new MESA participant; essentially, a new data folder (which will contain the participant's actigraph data and sleep journal) is created for each participant.

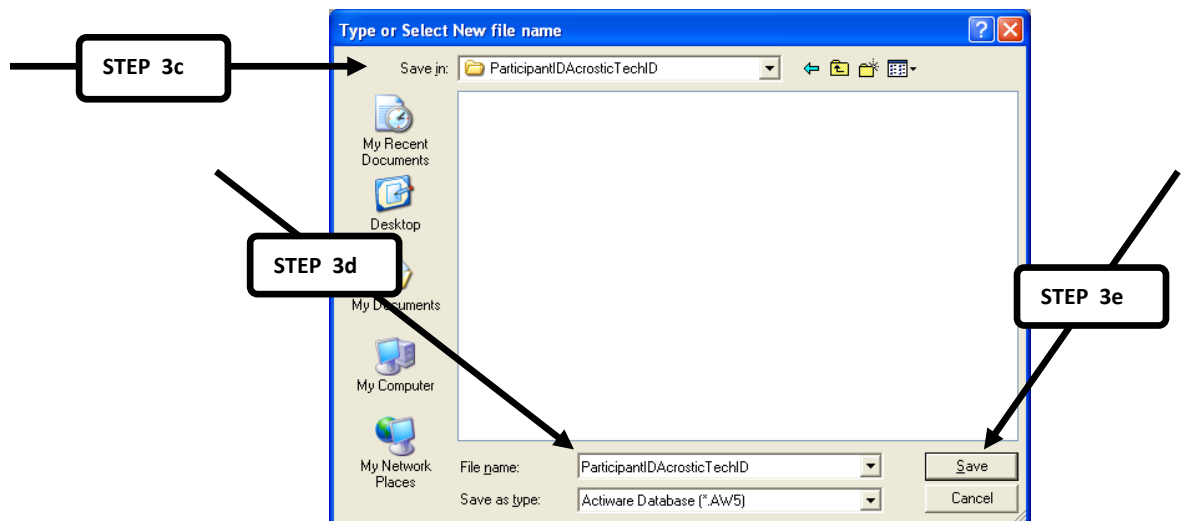


- 3) Creating a Database in the **Respironics Actiware 5 Software**
 - a. Select **File > Database > New**.

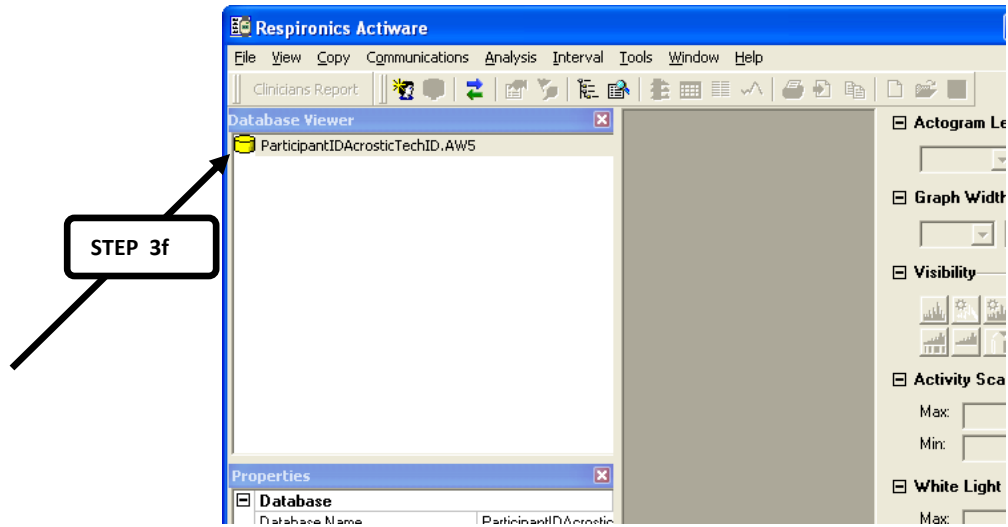
- b. Select the drop down menu next to “Save in” and find the directory that contains your **MESA Actigraph Data** folder.



- c. Find and double-click the folder named with your participant’s ID – this folder should open and now appear in “Save in:” drop down menu.
NOTE: AT THIS STEP, THE PARTICIPANT FOLDER SHOULD NOT CONTAIN ANY ACTIGRAPH FILES.
- d. Under the file name, type “ParticipantIDXXXXX1234”. A new database WILL be created for each participant.
- e. Select **Save**.



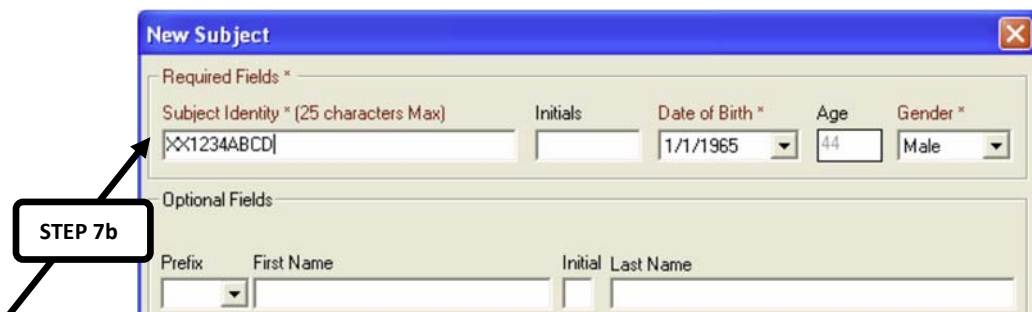
- f. This will appear as the active database in the database viewer on the left.



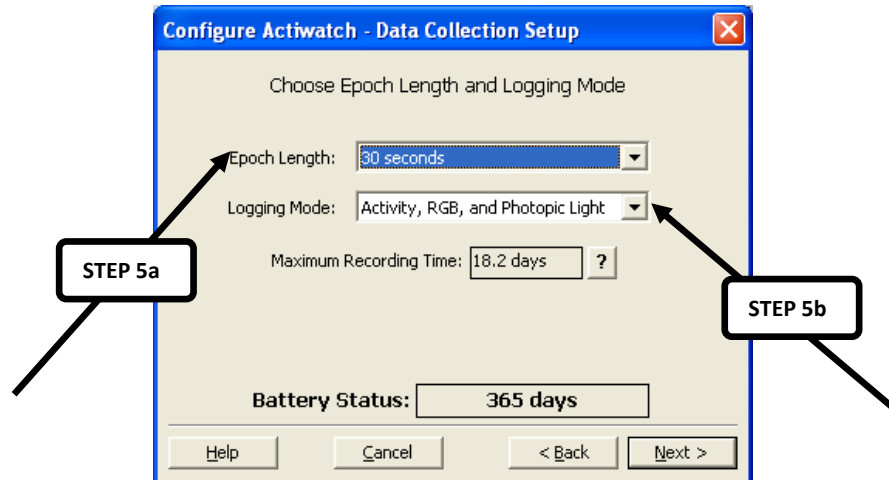
- 4) Select **Communications > Actiwatch Console**
- 5) Select the device you want to configure.
- 6) Click **Configure**.

*If the Actiware device selected has data in its memory, the **Retrieve** button is outlined. Click **Retrieve** if the data has yet to be retrieved. Configuring an Actiwatch Spectrum will delete all previous physiological data on device. Always retrieve data before configuring the Actiware devices.*

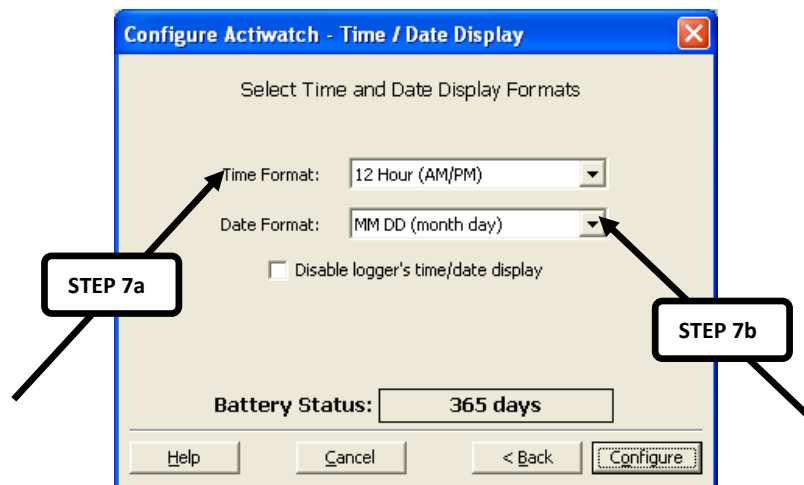
- 7) Create a New Subject
 - a. Click **New Subject** to create one.
 - b. Type the subject name as MESA participant ID, acoustic, and technician ID (**ParticipantIDXXXXX1234**). The participant ID should match the database ID. No other fields are necessary – three fields are listed as ‘required’, but they are not used in data analysis. Default data can be left.
 - c. Click **OK**.
 - d. You are returned to the Select Subject window, with the new ID as the selected subject. Make sure that the participant ID and the database file name are both the same. Click **Next**.



- 8) Configure the Data Collection Set Up.
 - a. Select the Epoch Length to be **30 seconds**.
 - b. Select the Logging Mode to be **Activity, RGB and Photopic Light**.
 - c. Click **Next**.



- 9) Configure the Start Time and Duration
 - a. Uncheck the box next to 'Start collecting data as soon as possible'.
 - Begin data collection to start on the evening of the scheduled home visit (5PM, in most cases).
 - b. Select the Data Collection Recording to be **Log Until Full**.
 - c. Choose to change the time zone in which the data will be collected by clicking the **Time Zone** button. (This will also affect the time displayed on an Actiwatch Spectrum).
 - d. Click **Next**.
- 10) Configure the Time/Date Display
 - a. Select the Time Format to be **12 hours (AM/PM)**.
 - b. Select the Date Format to be **MM DD (Month Day)**.



- 11) Click **Configure** to proceed with configuration.
- 12) A new window will appear asking if you wish to configure now. Click **Continue** to proceed.
- 13) A prompt is displayed confirming that the configuration is complete. Click **OK**.
- 14) Allow the Communications Console to refresh by selecting **Refresh Status**.
- 15) Select the Actiwatch Spectrum device.
- 16) Click on the expansion arrow and confirm that that the watch information and collection start time is correct.
- 17) Remove the device from the Communication Dock.

6. PARTICIPANT AND THE ACTIWATCH SPECTRUM®

At the home visit the participant will receive:

- Actiwatch Spectrum®
- Information Sheet
- Sleep Diary

1) Actiwatch Spectrum®

The procedures for wearing the Actiwatch and the data collection forms (sleep diary pages) should be explained to the participant and any questions should be answered at that time. Items to be explained to the participant include:

a. **Filling Out the Sleep Diary:**

Show the diary to the participant. Begin by asking the participant's prior wake time, observing him to complete the first entry (from the prior day). Explain that before bed that night and then every night for the subsequent 6 nights, he will also enter the time he will be shutting the lights off before going to sleep at night. The date and day of the week for each page should be filled out by the staff to aid in correct completion of the diary. If the participant refuses to complete the diary, they should still be given an Actiwatch to wear and should be encouraged to fill in as much data as possible.

b. **Wearing the Actiwatch:**

The Actiwatch should be worn on the non-dominant wrist and should be securely fastened around the wrist. It should be worn just as a wrist watch would be worn. If the participant's skin is particularly irritable, a thin cloth wristband or some sort of padding can be worn underneath the Actiwatch so that it is not in contact with the wrist – the Actiwatch *must* still be securely fastened to the wrist. However, the watch should not be too tight either—a small finger should be able to be fit under the watch band. The Actiwatch should not dangle from the wrist or slide around. However, when engaged in contact sports (football) the watch should be removed to avoid damage.

*If the Actiwatch is not fastened properly on the wrist, there will be a **flashing** black border on the display of the Actiwatch.*

c. **Actiwatch Event Marker**

Participants should be instructed to press the event marker when going to sleep for the evening and when awoken in the morning. The event marker is the smaller button located on the right side of the Actiwatch. In order to mark an event, **the button should be pressed for approximately 3+ seconds**, until Time Display blinks “- - -” for a few seconds before returning back to original time display. Techs should demonstrate what the Actiwatch Display looks like when the event marker is pressed when first giving the watch to the participant.




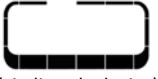


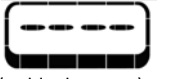
d. **Removing the Actiwatch:**

The Actiwatch does *not* have to be removed when bathing and/or during water sports. It can be worn while showering or bathing for up to 30 minutes. When the Actiwatch or band does get wet, remove the watch and wipe the underlying skin dry to avoid possible irritation. Once skin is dry, the watch can be replaced on wrist and worn as normal.

e. **When to Wear the Actiwatch:**

The Actiwatch should be worn from the time the participant is given the watch until the day that it is returned to the clinic staff from participant's home (usually a 7 day period). Study staff should confirm that the Actiwatch has already began collecting data before they leave the participant's home – this can be done by making sure that there is a **circling** black border on the display of the Actiwatch. Participants should also be told when it is okay to stop wearing the Actiwatch – the morning of the day that the Actiwatch is to being returned.

f. Appearance of the Actiwatch:

Visual Indicators	Description	Visual Indicators	Description
	Shows the time of day	 (flashing)	Indicates that the device is not fastened properly on your wrist. It might be too loose or too tight. Refasten the device to your wrist until the flashing stops.
	When you press the backlight button and hold it for 3 seconds, the date is shown as MM-DD.	(Backlight turns on)	Indicates that the backlight button has been pressed. The backlight button automatically turns off after 5 seconds.
 (circling clockwise)	The circling black border indicates that data collection has begun.	 	When these symbols appear, the Actiwatch Spectrum's battery is running low. Call study staff if this occurs.
(A pattern appears on the display and the backlight turns on briefly)	Indicates that you have successfully marked an event by pressing the Marker Button for 3+ seconds.	 (or blank screen)	Indicate the data collection is complete or that the device is in sleep mode. Call study staff if this occurs.

A summary of the above information with critical points should be provided to the participant. An example of an information sheet is provided in the appendix. The information sheet should be reviewed with the participant.

2) Sleep Diary

The participant will start using the sleep diary on the night of at home sleep exam. They will complete 7 days of the sleep diary (7 nights coinciding with Actiwatch Spectrum® data collection, the evening of PSG hook up, and the morning that the Actiwatch is returned back to study staff).

As long as the participant has the Actiwatch, they will continue to wear it. The study aims to collect a minimum of 5 days (and one "weekend" day) of Actiwatch® data for ALL participants. If less data are collected, attempt to have the participant repeat the recordings.

You may want to suggest that the participant keep the sleep diary by their bed or other convenient so that they remember to fill it out. The diary should be completed every night prior to going to bed.

3) Return of Actiwatch and Sleep Diary

Set up a time frame for the participant to return the Actiwatch from their home to study staff. When Actiwatch and sleep diary are received, staff should review material for completeness and ask subject about any relevant missing information.

7. SHIPPING AN ACTIWATCH SPECTRUM® BACK FROM PARTICIPANT

How the Actiwatch device is retrieved from the participant should be customized at each site according to local resources and what has worked before in MESA. The site can choose to directly pick up the Actiwatch device from the participant's home or to use UPS, Fed-Ex or a courier. However, a padded addressed mailer should be provided if using a mailing.

When the Actiwatch is returned log in the return date and note any problems with data retrieval as noted below.

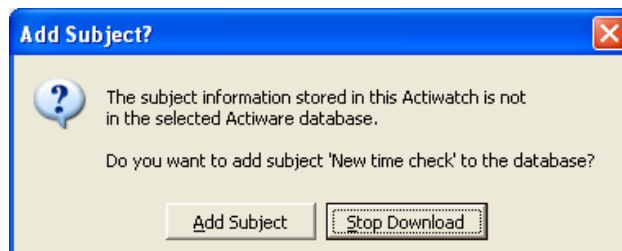
8. RETRIEVING DATA FROM ACTIWATCH SPECTRUM®

We strongly recommend that actigraph data be processed on a single computer. However, if your site is using more than one computer for actigraph data, make sure the data is retrieved on the same computer that the device was configured on.

- 1) Open the Respiroics Actiware 5 Software.
- 2) Select **File > Database > Open**
- 3) Select the drop down menu next to “**Look in**” and find the directory that contains your **MESA Actigraph Data** folder.
- 4) Find and double-click the folder named with your participant’s ID – this folder should open and now appear in “**Look in:**” drop down menu.
NOTE: AT THIS STEP, THE PARTICIPANT FOLDER SHOULD CONTAIN ONE ACTIGRAPH FILE.
- 5) Double-click on the single actigraph file located in the folder in order to open the database.
- 6) The database is now visible in the Database Viewer and should have a **single head icon** located underneath the database.
- 7) Place the Actiwatch Spectrum® securely on the communications docking station.
- 8) Select **Communications > Actiwatch Console** from the main menu bar.
- 9) Select the Actiwatch Spectrum device you are using from the Actiwatch Communication Console.
- 10) Make sure the checkbox next to **Launch Actogram** is selected.
- 11) Click **Retrieve** to continue. Depending on how large the file is, this may take several minutes.

- If you attempted to retrieve the data from an Actiwatch that was configured in a different database...
 - a. You will be prompted to add subject ‘ParticipantIDXXXXX1234’ to database.
 - b. Select **Stop Download**.
 - c. Open the database in which this Actiwatch was originally configured before attempting to retrieve again.

The retrieved data should be added into the database with the corresponding file name.



- 12) When retrieval is finished, save the data retrieved by clicking the **Save Data** button.
- 13) You now have three choices (below). Choose one and click **Next**.

Continue the data collection.

- DO NOT SELECT THIS OPTION.

Configure the device for a new subject.

- Choose this option if the device is going to be immediately reconfigured and given to a new participant.

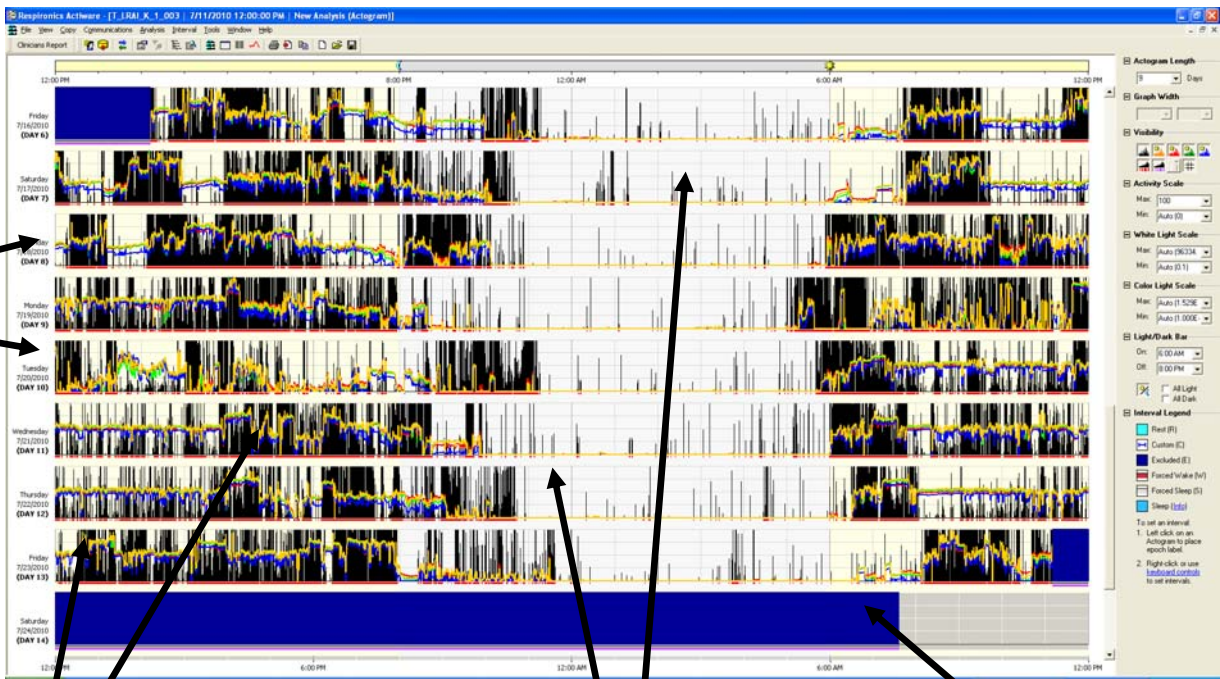
Put Actiwatch to sleep for later use.

ACTIGRAPHY

- Choose this option if the device isn't immediately going to a new participant. This action causes the device to be put into low power sleep mode. The display turns off after a few seconds. Pressing the left marker button, or putting the device back into the dock wakes it up.
 - a. After selecting this option, a new prompt will appear. Select **Put Actiwatch to Sleep**.
 - b. Select **OK**.
 - c. The Actiwatch display should turn off after a few seconds.

14) Review participant's actogram recording.

- Confirm that...
 - a. There is a minimum of 5 nights recorded.
 - b. There aren't any substantial periods of time that the Actiwatch was "off-wrist".



STEP 8a
Each row indicates a 24h day of recording – from 12PM to 12PM.

STEP 8a
Black lines indicate activity.

STEP 8a
White indicates period of "low activity" –sleep.

STEP 8b
Dark blue indicates "off-wrist"

If upon downloading the data you find that the participant did not wear the Actiwatch correctly or that data were not collected for the appropriate length of time, you should ask the participant to re-wear the Actiwatch.

If some data was collected, but not 5 full nights, and the participant refuses to re-wear the Actiwatch, you should still send the data file to BWH.

If there are no data available on the file and the participant will not re-wear the Actiwatch, you should make record of it on the study log. This file still needs to be sent to the BWH Sleep Reading Center.

15) Once data has been retrieved and saved, close out of Actiware software.

9. RETRIEVING SLEEP JOURNAL FROM PARTICIPANT

- 1) Review over participant's sleep journal and make sure all information is complete.
- 2) Scan sleep journal into computer.
- 3) Save as a .pdf file using "**ParticipantIDXXXXX1234_SJ**" as the naming convention.
- 4) Save the sleep journal in the participant folder in which the participant's actigraph data is located. (See Section 5.2)

10. SENDING THE DATA TO BWH Sleep Reading Center

Each site will send *weekly* actigraphy raw data to BWH using an encrypted zipped file. The scheduled day that data will be sent should be coordinated between specific sites and BWH reading center.

The participant folder that will be encrypted, zipped, and sent to BWH Sleep Reading center should be found in the **MESA Actigraph Data** folder created in Section 5.

The encrypted zip file should include:

- The raw database file created for the participant with collected data.
- A PDF of the Participant's sleep journal.

It is important the folders and files sent to the reading center are named correctly to prevent loss or replacement of important raw data. The standardized naming conventions for data to be sent to BWH are as follows:

- ZIP file – "**ParticipantIDXXXXX1234.zip**"
The ZIP file should automatically have the same name as the folder being zipped.
- Folder [to be unzipped from ZIP file] – "**ParticipantIDXXXXX1234**"
- Data Files [found in folder]:
 - Actigraph Database file – "**ParticipantIDXXXXX1234.AW5**"
 - Sleep Journal – "**ParticipantIDXXXXX1234_SJ.pdf**"

1) Username and Password

- a. Each clinical site will receive a designated username and password that will be used for data upload. This password will be changed periodically to ensure security. Sites will be notified in advance when a change is to occur. The user name and password will be sent to the site Project Coordinator.

2) SFTP Software and Connection

Uploading of data to the Sleep Reading Center will be done via Secure (SSH) File Transfer Protocol (SFTP), which provides additional security for research data during transmittal. Sites uploading data will need FTP client software installed on the designated computer and may need to configure their firewall to allow outgoing traffic for SFTP on port 22. The site institution's IT personnel should be able to assist in this configuration.

a. FTP Client Software

A number of FTP client software packages which support SFTP transfers are available free or for purchase. The Sleep Reading Center recommends [FileZilla](http://filezilla-project.org/download.php), (<http://filezilla-project.org/download.php>) but this is not required. The installation and configuration of FTP client software is the responsibility of the site.

b. Connection Information

The following information can be used to connect to the Sleep Reading Center SFTP server:

- Host: Phslxftp2.partners.org
- Port: 22
- Server Type: SFTP (SSH File Transfer Protocol)
- Logon Type: Select normal to receive options for User and Password
- User: *(the site FTP username provided by the Sleep Reading Center)*

- Password: *(the site FTP password provided by the Sleep Reading Center)*

The procedure for sending actigraphy data to BWH Sleep Reading Center is the same procedure for sending PSG data. Please refer to PSG manual for steps.

If the wrong ID was used in the subject field (when initializing device) or when naming the database file, please e-mail Tricia Tiu (ttiu@partners.org) at BWH to let her know this happened and she will take care of it.

If you have questions about uploading files or have difficulty connecting, please contact the Sleep Reading Center: Susan Surovec (ssurovec@partners.org) at (216) 702-6050.

If you require your IT person to contact someone at Partners directly they can contact Brad McKenna (bmckenna@partners.org) at (617) 726-0331.

11. MAINTAINING AN ACTIWATCH LOG

A log should be maintained at the clinic so that the locations of the Actiwatch devices are known at all times. An example log is included in the Appendix. It can be modified as individual clinics see necessary. A serial number (EX. A01785) for each Actiwatch can be found on the backside of each Actiwatch. This should be used as the Actiwatch ID.

12. CLEANING OF ACTIWATCH SPECTRUM®

After each participant, the Actiwatch should be cleaned before reconfiguring and given out to a new participant.

- 1) Soak the Actiwatch in warm water and a mild detergent for 5 minutes.
- 2) Rinse and dry with a soft cloth.

Do not use abrasives or alcohol.

If the watch band is especially soiled, it may be wiped more vigorously with disinfectant wipes. The wipes may NOT be used on the watch portion of the device.

If the watch band is still soiled after thorough scrubbing, it may be replaced with a new band provided by Philips Respironics.

13. BATTERY MANAGEMENT

The battery in the Actiwatch Spectrum® should last 1 to 2 years based on usage (1 year for continuous usage). The battery cannot be replaced by the user and should be returned to Respironics for replacement. Contact Respironics Product Support for instructions.

14. SHIPPING AN ACTIWATCH SPECTRUM® TO RESPIRONICS

After approximately 12 to 14 months of use, each actigraph will be returned to Philips Respironics to have the battery replaced. A schedule will be set and provided to each site. In addition, malfunctioning watches—those not keeping time, fail to transmit data, produce error codes, also need to be returned to Philips Respironics after contacting the BWH Sleep Reading Center and discussing the problem.

15. QUALITY ASSURANCE FOR THE ACTIWATCH

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

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

- 1) Overview of Actigraphy Operations Manual, including detailed use of Actiwatch, the software, and the communications dock.
- 2) Hands-on training for initializing and downloading/saving of files.
- 3) Overview of Actiware Spectrum® Software Manual

16. CERTIFICATION

Each staff member handling the Actiwatch devices needs to successfully complete 3 initializations, downloading, file checking, and the saving to the assigned folder. These should be done with a certified technician present. Actigraphy data for the certifications will be collected on healthy volunteers.

17. TROUBLESHOOTING SOLUTIONS FOR AN ACTIWATCH SPECTRUM®

Error Message or Condition	Solution
'Disconnected' is displayed	<ul style="list-style-type: none"> a. Check the cable connections on the docking station and the computer. b. Connect the docking station to a different USB port on your computer. c. Verify installation of the software drivers: Select Start > Control Panel > System > Hardware tab > Device > Manager. Two items should be listed with the name, 'Actiwatch Spectrum Communications Dock'. If they are not listed, or if they're listed with yellow exclamation points, disconnect the communications doc, uninstall Actiware and reinstall it from the installation CD.
'Too many docks' is displayed	Caused when more than one Actiwatch Spectrum® communications dock is connected to the computer at the same time.
'Error' is displayed	Disconnect the Actiwatch Spectrum® communications dock then reconnect it.
Logger not found, insert logger into communications dock	<ul style="list-style-type: none"> a. The Actiwatch Spectrum® may not be docked properly. It may be upside down, not pressed securely into place or backwards. Verify that the Actiwatch Spectrum is installed exactly the same as the installation on the top of the communications dock. b. The Actiwatch Spectrum® may have a weak or dead battery.

NOTE:

Actiwatch devices that do not keep time correctly may still be recording movement correctly. If time is not being maintained correctly, transmit the data to the BWH Reading Center and note this. Arrangements will be made to replace the watch.

Appendix