RESPIRONICS®

Acti*ware*® and **Acti***ware*® CT
Software Manual

Acti*watch*® **Communication and Sleep Analysis
Software**

Actiwatch Communication and Sleep Analysis Software

Actiware and Actiware CT Software Manual

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ActiReader is covered by the following US patent numbers: 6,129,663. Other patents pending. All other trademarks are owned by their respective companies.

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1

Introduction to Actiware and Actiware CT

Overview

This manual describes the functions of the data analysis and file management features available in the Actiware and Actiware CT software applications. Both applications are part of the Actiwatch activity monitoring system. The Actiware software analyzes the rhythmicity of long-term activity-rest patterns and generates findings in the forms of reports and data files.

The process consists of the following steps:

- Configure the Actiwatch device (such as the Actiwatch, Actiwatch 2, or Actiwatch Spectrum).

- Attach the Actiwatch to the subject (patient).

- Obtain the Actiwatch and diary from the subject at the end of the predetermined test period.

- Transfer data from the Actiwatch device (such as the Actiwatch, Actiwatch 2 or Actiwatch Spectrum) using an ActiReader (legacy) or a communication dock for Actiwatch 2 or Spectrum, to a computer running the Actiware software.

- Analyze the data.

- Generate findings and print reports.

Actiware and Actiware CT are Windows-based software applications designed to do the following:

- Manage subject (patient) information

- Configure Actiwatch devices for data collection

- Retrieve clinical data from Actiwatch devices

- View clinical data

- Analyze data for sleep parameters and rhythmicity

- Export raw data or statistics for external analysis or archive

Intended Use

The Actiwatch is an ultra-compact, lightweight, wrist-worn activity and ambient light monitor that can be used to analyze circadian rhythms, automatically collect and store data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable.

Actiware and Actiware CT

Actiware and Actiware CT are Windows-based software applications for use by clinicians, researchers, or homecare providers and designed to gather, store, manage, and view circadian rhythms and light data collected by Actiwatch devices. Data can be displayed on-screen in graphic form and on printed reports in tabular form. The software does not perform diagnosis.

Clinical Trials

Actiware CT is also capable of clinical trial tracking and auditing in accordance with 21 CFR Part 11. Several features have been incorporated into the software:

- Restrict access to only authorized users.

- Embed electronic signatures in data files.

- Secure data files with digital signatures.

- Detect and report unauthorized access.

- Record all changes to subject and data properties, as well as analysis settings and results.

- Provide an audit trail window to view versions and electronic signatures.

Owner Responsibilities

The following list incorporates the owner's responsibilities:

- Replace faulty components when necessary to ensure safe and reliable operation using

parts supplied by or approved by Respironics.

- Stop using equipment which is not functioning properly until all necessary maintenance has been completed and a factory-authorized service representative has certified the equipment as ready for use.

- Do not modify the communication dock, ActiReader devices, or any of its accessories.

Cautions and Warnings

Cautions:

- *U.S. Federal law restricts this device to sale by, or on the order of, a licensed physician.*

- *Repairs and adjustments must be performed by Respironics authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.*

- *Dispose of these devices in accordance with local regulations.*

Warnings:

- *The provider should read and understand this entire manual before using this device.*

- *This manual serves as a reference. The instructions in this manual are not intended to supersede the health care professional's instructions regarding the use of this device.*

- *Do not dispose of lithium batteries in fire or flame. An explosion may result. Dispose only in accordance with manufacturer's recommendation or local regulations.*

- *Operation of the device may be adversely affected by:*
  - *Electromagnetic fields exceeding the level of 10 V/m in the test conditions of EN 60601-1-2*
  - *Operation of high frequency (diathermy) equipment*
  - *Defibrillators or short wave therapy equipment*
  - *Radiation (e.g., X-ray, CT)*
  - *Magnetic fields (e.g., MRI)*

- *Do not use this device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.*

- *If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, or if the enclosure is broken, discontinue use. Contact Respironics Product Support and replace any damaged parts before continuing use.*

- *ActiReader and Actiwatch docking stations - To avoid electrical shock, disconnect the AC power supply before cleaning. DO NOT immerse the AC power supply in any fluids.*

System Requirements

- UL 1950, IEC 60950 compliant, or EN60950 approved computer.

- Computer with 2 GHz or higher process clock speed recommended; 500 MHz minimum requirement.

- Actiware requires Microsoft Windows® 2000, Windows® XP Professional, or Windows® Vista operating system; Actiware CT requires Microsoft Windows® 2000, Windows® XP Professional, Windows® Vista Business, or Windows® Vista Ultimate operating system.

- 512 MB RAM recommended; 128 MB RAM minimum requirement.

- 300 MB or higher of disk space recommended; 50 MB minimum required for installation.

- Super VGA (1280 x 1024) resolution video adapter and display recommended; XGA (1024 x 768) minimum requirement.

- CD-ROM or DVD drive (for installation).

- Keyboard and mouse.

- USB port (for Actiwatch Spectrum and Actiwatch 2 devices)*.

- Printer (optional).

*__Note__: *If you are using a model of Actiwatch other than Actiwatch Spectrum or Actiwatch 2, you will need either a serial port or USB port. For more information, contact Customer Service at 1-800-345-6443.*

Software Installation Instructions

Note: *Data for use by Actiware must reside on the local hard drive. Do not install the program files or data files on a network drive.*

STEP 1

Insert the Actiware software CD into your computer's CD or DVD drive.
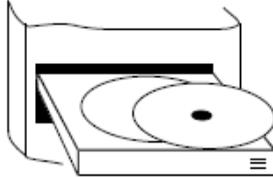
STEP 2

- Click **Install Respironics Actiware** in the window that automatically displays when the CD is inserted.

- If this window does not automatically appear, then select **Start > My Computer**.

- Select the CD/DVD drive on the list and double-click.

- Select **CDMENU.EXE** and double-click to open.

- Click on **Install Respironics Actiware** to install the software.

STEP 3

After Actiware is installed, connect one end of the USB cable to your communications dock and the other end to your computer. See the Technicians Guide for detailed setup instructions. If using a legacy Actiwatch such as Actiwatch-16/64, Actiwatch-L, and Actiwatch-Score, refer to the Connecting an ActiReader or Actiwatch Reader sections of this manual.
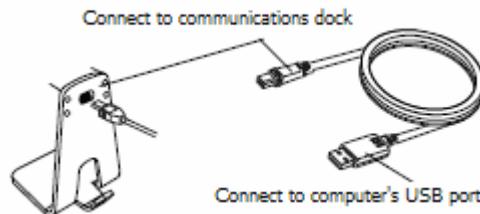
STEP 4

Call Respironics (1-800-345-6443) within 30 days of installation to activate your software using the proof of purchase number on the back of the CD case. (If it's not activated, Actiware will stop working after 30 days.)

Additional Documentation

Additional documentation is available in the form of PDF (Portable Document Format) files from Respironics, Inc. (http://global.respironics.com/manualsandliterature.asp). You will need Adobe's Reader application to view the PDF files. If you do not have Adobe Reader, you may download a free copy of it from www.adobe.com.

- **Wearer's Guide**

    Contains essential "what to do" and "what not to do" information for the subjects (patients) on the wearing of Actiwatch devices.

- **Technician's Guide**

    Contains information on configuring Actiwatch 2 and Actiwatch Spectrum devices and instructions for subjects on how to wear those Actiwatch devices.

- **Clinician's Guide**

    Contains instructions on how to install and use the Actiware software and how the software relates to the hardware.

- **Watch Band Replacement Guide**

    Contains illustrations for changing the watch bands on the Actiwatch 2 and Actiwatch Spectrum.

- **Hospital Band Guide**

    Contains illustrations for attaching hospital bands to Actiwatch 2.

Product Support

Contact Respironics if you need assistance with the Actiware software or Actiwatch hardware.

Mailing and Shipping Address	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668, USA
Telephone	800-345-6443 (US and Canada only) 1-724-387-4000
E-mail Address	mmsupport@respironics.com
Web Sites	www.actiwatch.respironics.com www.respironics.com

Chapter

2

Hardware Components

Connecting an Actiwatch 2

An Actiwatch 2 Communication Docking Station is necessary to communicate with an Actiwatch 2 device. Connection to a desktop computer or a laptop computer is very similar to any other peripheral 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 Actiwatch 2 Communications Dock. The cable may be threaded through the cable-keeper on the back of the dock.
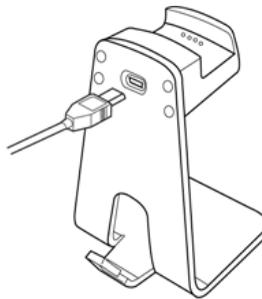
Actiwatch 2 Communications Dock

Notes: *The USB cable that connects to the PC or AC adapter must always be installed or removed with the Actiwatch 2 out of the dock. If switching between the PC and AC adapter, the Actiwatch 2 should be removed from the Communications Dock, then replaced after the cable has been switched. Do not disconnect the Communications*

Dock from the computer during communications, such as when the Actiwatch Console is refreshing or the device is being configured or data are being retrieved.

3. Wait a few moments while the Actiwatch 2 Communications Dock drivers are automatically installed.

4. Open the Actiware software.

5. From the main menu bar select **Communications > Actiwatch Console**.

   The Actiwatch Communications Console wizard is displayed.

6. On the Actiwatch Communications Console, click on **Actiwatch 2**.

   The status of the connection appears as either "Connected" or "Disconnected." If "Connected" does not appear, try another USB port on your computer. If "Connected" does appear, the computer is communicating properly with the communications docking station. "Too many docks" may appear if more than one Actiwatch 2 Communications Dock is connected.

7. Place an Actiwatch 2 in the communications docking station by holding it an angle with the marker button on the Actiwatch 2 above the indentation of the communications docking

station. The front of the communications docking station is slightly flexible, allowing the Actiwatch 2 to be pushed into place.

With the Actiwatch 2 in place, the LED indicates the status as follows:

- **Steady red** - *communications docking station is connected but an Actiwatch 2 is not docked or not communicating.*

- **Steady green** - *Actiwatch 2 is docked and the battery is fully charged.*

- **Blinking green** - *Actiwatch 2 is docked and the battery is charging.*

8. Wait a few seconds for the Actiwatch Communications Console to refresh, or click **Refresh Status** to read the Actiwatch 2 status.

9. Click on the expansion arrows (⯆) to view the Actiwatch 2 configuration details.

Refer to *Possible errors/troubleshooting solutions for Actiwatch 2* if you have difficulties making a connection.

Connecting an Actiwatch Spectrum

An Actiwatch Spectrum communication docking station is necessary to communicate with an Actiwatch Spectrum device. Connection to a desktop computer or a laptop computer is very similar to any other peripheral 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.
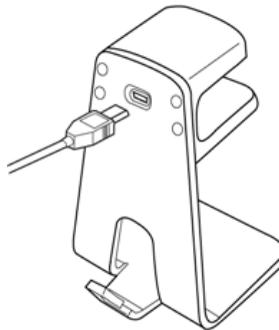
Actiware Spectrum Communications Dock

Note: *Do not disconnect the Communications Dock from the computer during communications, such as when the Actiwatch Console is refreshing or the device is being configured or data are being retrieved.*

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3. Wait 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. If "Connected" does appear, the computer is communicating properly with the docking station. "Too many docks" may appear if more than one Actiwatch 2 communication docking station 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 arrows (⌄) to view the Actiwatch Spectrum configuration details.

Refer to *Possible errors/troubleshooting solutions for an Actiwatch Spectrum* if you are trouble making a connection.

Configuring an Actiwatch 2 or Actiwatch Spectrum

Before an Actiwatch is given to a subject, it must be configured with basic subject information and data collection parameters. The Configure Actiwatch Wizard presents several windows to make the configuration quick and easy.

Connect the Actiwatch 2 or Actiwatch Spectrum Communications Dock to the computer prior to beginning the configuration procedure below.

Caution!   *Configuring an Actiwatch 2 or Actiwatch Spectrum will delete all previous physiological and data the devices. Always 'Retrieve' data before configuring the Actiwatch devices. To stop this wizard, select the **Cancel** button. To retrieve data, refer to* Retrieve Data from an Actiwatch 2 or Actiwatch Spectrum.

To configure an Actiwatch 2 or Actiwatch Spectrum for subject use, complete the following procedure:

1. Insert the Actiwatch 2 or Actiwatch Spectrum into the appropriate Communications Dock.

2. Select **Communications > Actiwatch Console** from the main menu bar.

3. Select the device you want to configure.

Note: *If the Actiwatch device selected has data in its memory, the **Retrieve** button is outlined. If you have not yet retrieved the data, click **Retrieve** now.*

4. To configure the Actiwatch device, click **Configure**.

5. You may be prompted to retrieve any data currently in memory. If you want to continue the configuration, without retrieving data, click **Discard and Continue**.

6. Select an existing subject from your database, or click **New Subject** to create one, then click **Next**.

7. Select the Epoch Length and the Logging Mode, and click **Next**.

    Epoch Length is the period of time Actiwatch will accumulate activity counts before saving the sample to memory. Select the epoch length by clicking in this field. The choices will appear sequentially.

Note: *For sleep analysis, it is recommended that you select an interval of one minute or less. Data with sampling epochs of greater than two minutes cannot be analyzed using Actiware.*

The Recording Time is the time at which the activity monitor will fill its memory with samples based on the epoch length selected.

Theoretical Recording Time (days)

Logger Type	15 sec	30 sec	1 min	2 min	5 min
Actiwatch 2 (activity only)	22	~30*	~30*	~30*	~30*
Actiwatch 2 (activity + light)	7	15	30	~30*	~30*
Actiwatch Spectrum (activity only)	44	88	180	360	~365*
Actiwatch Spectrum (activity + RGB light)	9	18	36	72	182
Actiwatch Spectrum (activity + white light)	14	30	60	180	302

* Actual recording time may be limited by battery life.

8. You may choose to begin data collection as soon as possible by checking the box, or select a Start Time. You may also choose to collect data until the memory is full by checking the box, or you may enter a data collection duration. You can also 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. When finished, click **Next**.

Note: *Data collection may not begin immediately. Typically, data collection begins within two minutes.*

9. If you are configuring an Actiwatch Spectrum, you will be prompted to choose date and time settings, or you can choose to disable the LCD display entirely.

10. Click **Configure** to proceed with the configuration or click **Cancel** to make changes.

11. A confirmation message appears stating that configurations have been selected and prompting you to continue. Confirm by clicking **Erase and Continue**.

    A progress bar is displayed while the software configures the device. When the configuration is complete, an information prompt is displayed.

12. Remove the device from the Communication Dock.

Retrieving Data from an Actiwatch 2 or Actiwatch Spectrum

The Actiwatch Console wizard takes you through the steps necessary to transfer data from the Actiwatch to an Actiware database. After the transfer, you can then analyze the data and generate reports.

To retrieve data from an Actiwatch:

1. Place the Actiwatch on the communications docking station.

Actiwatch 2 communications docking station

Actiwatch Spectrum communications docking station

2. Select **Communications > Actiwatch Console** from the main menu bar.

   The Actiwatch Communication Console opens.

3. Select the Actiwatch device.

4. Click **Retrieve** to continue.

   Actiware communicates with the Actiwatch device and retrieves the data.

5. When the data retrieval is finished, you are prompted to save the data by clicking the **Save Data** button. You can also elect to display the data in an actogram by selecting the **Launch Actogram** check box.

6. You now have three choices (below). Choose one and click **Next**.

   - *Continue the data collection.*

   - *Configure the device for a new subject.*

   - *Put Actiwatch to sleep for later use. 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.*

7. When data retrieval is complete, remove the Actiwatch device from the communications docking station.

Connecting a Legacy Actiwatch

An ActiReader or an Actiwatch Reader is necessary to communicate with a legacy Actiwatch. Connection to a desktop computer or a laptop computer is very similar to any other peripheral device. Upon starting Actiware, you may set up the COM port to recognize the ActiReader from within the Actiware Communications Console wizard. (Select Communications > Actiwatch Console from the main menu.)

Actiwatch Reader and ActiReader are very similar in their operation. Installation and setup are the same. However, please keep the following in mind when using the Actiwatch Reader:

- The Actiwatch Reader is white. The ActiReader is black.

- The Actiwatch Reader and ActiReader both work with the Actiwatch-16/64, Actiwatch-L, and Actiwatch-Score legacy devices.

- Instead of a slot for aligning the Actiwatch, place the Actiwatch over the image and slide it up and down until the Ready LED is lit.

- The small dot on Actiwatch must be in the same corner as the small dot on the reader.

- Researchers with laptop computers may switch the Actiwatch Reader to Battery Power for proper function.

- If using battery power, you may need to periodically replace the reader battery. Refer to Battery Management for details.

- As with the ActiReader, the COM port selection in the software must be correct, and the communications wizard must be running, for the Ready LED to be lit.

Note: *Follow the recommendations supplied with your computer when connecting peripheral devices. Most manufacturers suggest powering down the computer while connecting hardware.*
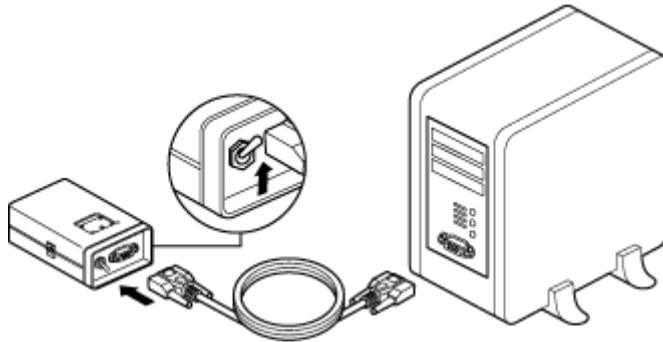
ActiReader connected to computer

1. Connect the serial communication cable (supplied) to a COM port on your computer.

2. Connect the other end of the communication cable to ActiReader. ActiReader power must be ON and the red LED Power light should be blinking. If the Power light is not blinking, the ActiReader battery must be replaced or the external power supply must be used.

3. Activate the Actiware software. Select **Communications > Actiwatch Console** from the menu bar.

4. Click on **ActiReader/Legacy Actiwatch**.

5. From the drop-down menu, select the COM Port to which you connected.

6. Click on **Configure**. The Configure Actiwatch Wizard guides you through the configuration steps. If the green LED does not light, select another COM Port and repeat the configuration procedure. If the green LED is lit and the configuration wizard verifies communication with the Actiwatch, proceed to Configuring an Actiwatch.

   o *External Power Source*

   ActiReader can be powered from an external power source (supplied). When plugged in, it will disconnect the battery to conserve it.

   o *Power ON/OFF switch*

   This switch will disconnect ActiReader from its power source, whether AC or battery.

   o *POWER (Red LED)*

   Whether using external power or the internal battery, the red LED will light when the Power switch is ON.
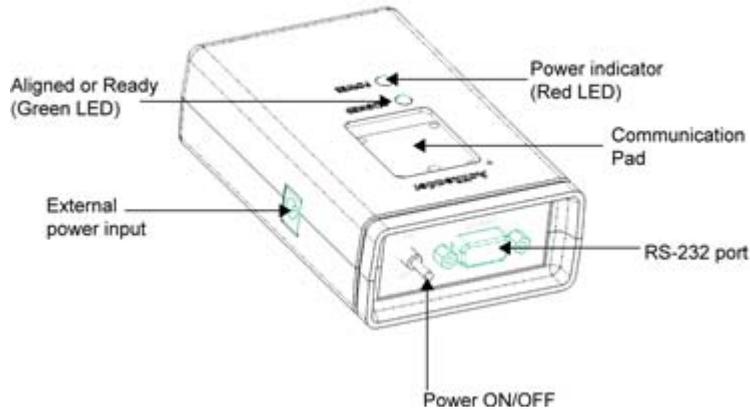
Parts of an ActiReader

o **ALIGNED (Green LED)**

When the Actiwatch is aligned properly and the communication wizard is active, this *green* *LED will light. The 'ALIGNED'* *green* *LED will not light until appropriate portions of the Communications Wizard are in use when the COM port is on.*

o **Communication Pad**

This slot ensures Actiwatch is placed properly. On the back of the Actiwatch is a *green* *dot in one corner. When the dot is aligned with the* *green* *dot on ActiReader, the* *green* *LED on the ActiReader will light. This indicates that communication between the two devices is possible.*

o **Serial Port**

This is where the serial cable connects to ActiReader. The other end connects to the COM port on the computer.

Note: *The "back" of the Actiwatch is metal. The "front" or "face" of the device is plastic.*

Configuring a Legacy Actiwatch

This section applies to legacy Actiwatch devices such as Actiwatch-16/64, Actiwatch-L, and Actiwatch-Score. Before an Actiwatch is given to a subject, it must be configured with basic subject information and data collection parameters. The Configure Actiwatch Wizard presents several windows to make the configuration quick and easy.

Install the ActiReader or Actiwatch Reader prior to configuring an Actiwatch (refer to ActiReader or Actiwatch Reader for details), and connect the ActiReader or Actiwatch Reader to the computer prior to beginning the following configuration procedure.

Caution*!* *The Configure Actiwatch wizard will delete all setup information and data stored in the Actiwatch. To stop this wizard, select the* **Cancel** *button. To retrieve data, refer to* Retrieve Data from Actiwatch*.*

To configure an Actiwatch for subject use, complete the following procedure:

1. Start the Configure Actiwatch wizard:

    a. Select **Communications > Actiwatch Console** from the main menu bar.

       The Configure Actiwatch Wizard opens.

    b. Select the ActiReader/Legacy Actiwatch device.

    c. Remove the wrist/foot bands from the Actiwatch (optional), as the bands may interfere with proper Actiwatch placement.

    d. Place the Actiwatch on the reader.

       The **green** *dot on the metal side of the Actiwatch must align with the* **green** *dot on the ActiReader. Verify that the metal side is facing up, the* **green** *dots are adjacent, and the* **green** *LED 'ALIGNED' light is on.*
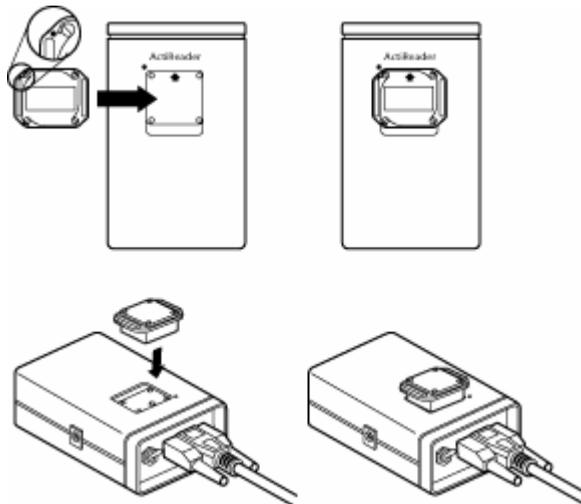
Actiwatch Alignment

Note*:   If you have not yet retrieved the data, click* **Retrieve** *now.*

    e. To configure the Actiwatch device, click **Configure**.

f.   You may be prompted to retrieve any data currently in memory. If you want to continue the configuration without retrieving the data, click **Discard and Continue**.

g.   Click **Next** to continue.

The wizard checks the Actiwatch serial number and battery life. If a Low Battery Warning appears, choose one of the three options from the pop-up window. If the warning does not appear, proceed to the next step.

- *****Change Battery** - wizard will guide you through the battery replacement process (see Actiwatch Battery Replacement later in this manual).*

- *****Changed Battery, update** - wizard will update the database with the new battery information.*

- *****Ignore** - wizard will ignore the Low Battery Warning.*

h.   Click **Next** to continue.

2. Edit Subject Information:

a.   Select an existing Subject from the drop-down list or click the **New Subject** button to add a new subject to the database.

***Note**:   You can edit the current, existing Subject by clicking the **Edit Subject** button.*

When an existing subject is selected from the drop-down list, the Subject Name, Subject DOB, Age, and Gender boxes are filled in.

b.   Click **Next** when you have completed editing/adding subject information.

3. Set Data Collection Parameters:

a.   Select a Start Time and date from the drop-down lists.

b.   Select an Epoch Length from the drop-down list.

Epoch Length is the period of time Actiwatch will accumulate activity counts before saving the sample to memory. Select the epoch length by clicking in this field. The choices will appear sequentially.

When selecting epoch length, consider the following:

If actual recording time is in red, then the battery may need to be changed.

Time zone selection should be where the data will be collected, not the current time zone of the computer location.

When configuring the Actiwatch for sleep analysis, use an epoch length of 2 minutes or less, otherwise sleep analysis statistics will not be calculated.

Epoch Length	Number of Epochs per Day	Maximum Delay in Start Time*
15 seconds	5760	5 days
30 seconds	2880	11 days
1 minute	1440	22 days
2 minutes	670	49 days
5 minutes	288	114 days
10 minutes	144	~180 days*
15 minutes	96	~180 days*

* Actual start delay time may be limited by battery life.

Note: *For sleep analysis, it is recommended that you select an interval of one minute or less. Data with sampling epochs of greater than two minutes cannot be analyzed using Actiware-Sleep analysis.*

The Recording Time is the time at which the activity monitor will fill its memory with samples based on the epoch length selected.

Recording Time Table (for epochs > 15 seconds)

Memory	15 sec	30 sec	1 min	2 min	5 min	10 min	15 min
Actiwatch-16K	2.8	5.6	11.2	22.5	56.4	112.8	169.3
Actiwatch-64K	11.3	22.7	45.4	90.8	~180*	~180*	~180*
Actiwatch-L	3.7	7.5	15.1	30.2	75.7	151	~180*
Actiwatch-Score	5.6	11.2	22.4	44.9	~90*	~90*	~90*

* Actual recording time may be limited by battery life.

Note: *Actiwatch-L devices manufactured before July 1st, 1999 have 32K memory and shorter recording times.*

Note: *Maximum battery life is 180 days for Actiwatch-16, Actiwatch-64, and Actiwatch-L, and 90 days for Actiwatch-Score.*

c.   Confirm the Time Zone displayed.

This is the default time zone as set on your computer. If you want to change it, for the

*Actiwatch configuration, click the associated **Edit** button and select a new time zone.*

d. Click **Next** to continue with the wizard.

   If you are configuring an Actiwatch-Score, a Score Range window appears.

   - *Set the minimum and maximum score ranges by entering numeric values (0-15) or by using the scroll arrows.*

   - *Click **Next** to continue.*

   If configuring an Actiwatch-16/64 or Actiwatch-L, skip to step 5.

4. Set Actiwatch Score Alarm:

   a. Click the Enable Alarm Scheduling check box.

   b. Format the Score Alarm Schedule parameters and print them using the following buttons:

      - **Add Manual Alarm**

      - **Add Recurring Alarm**

      - **Delete Alarms** *(select item in list)*

      - **Clear List**

      - **Print List**

   c. Click **Next** to continue.

Caution*!*   *Do not remove the Actiwatch from the ActiReader during the Configure Actiwatch Wizard process until instructed to do so.*

5. When prompted, remove the Actiwatch from the reader and click **Finish** to complete the Configure Actiwatch Wizard.

Retrieving Data from a Legacy Actiwatch

This section applies to legacy Actiwatch devices such as Actiwatch-16/64, Actiwatch-L, and Actiwatch-Score. The Actiwatch Console wizard takes you through the steps necessary to transfer data from the Actiwatch to an Actiware database. After the transfer, you can then analyze the data and generate reports.

Caution*!*   *The Actiwatch cannot collect data while on the reader. Consequently, do not put the Actiwatch on the reader until you are ready to stop data collection and retrieve the data from the Actiwatch.*

To retrieve data from an Actiwatch:

1. Remove the wrist/foot bands from the Actiwatch (optional), as the bands may interfere with proper Actiwatch placement.

2. Place the Actiwatch on the reader.

    The green dot on the metal side of the Actiwatch must align with the green dot on the ActiReader. Verify that the metal side is facing up, the green dots are adjacent and the green LED 'ALIGNED' light is on.

3. Select **Communications > Actiwatch Console** from the main menu bar.

    The Actiwatch Console opens.

4. Select the ActiReader/Legacy Actiwatch device.

5. Click **Retrieve** to continue.

    Actiware communicates with the Actiwatch device and retrieves the data.

6. When the data retrieval is finished, you are prompted to save the data by clicking the **Save Data** button. You can also elect to display the data in an actogram by selecting the **Launch Actogram** check box.

7. When data retrieval is complete, remove the Actiwatch device from the communication docking station.

Battery Management

Locate the appropriate device below and follow the corresponding instructions to change its battery, or to return the device to Respironics for battery replacement.

Caution!   *The black ActiReader model uses a 9V Lithium battery. The white Actiwatch Reader uses a standard 9V battery. These batteries are not interchangeable, and may result in damage to your device. Use of the improper battery will void the warranty.*

Caution!   *It is important that you thoroughly read the following information prior to changing the battery. Failure to follow procedures may result in immediate or subsequent damage to the device.*

Warning!   *Do not dispose of lithium batteries in fire or flame. An explosion may result. Only dispose in accordance with manufacturer's recommendation or local codes.*

Actiwatch Spectrum Battery

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.

Actiwatch 2 Battery

It is recommended that the Actiwatch 2 battery be charged before each use (the software will indicate that the battery is 'Fully Charged' or 'Not Fully Charged'). The Actiwatch 2 battery automatically recharges each time it is in the Communications Dock and either plugged into the computer or plugged into an AC outlet. When the battery is recharged using the Actiwatch Communications Console, the status of the battery is updated on the screen every 10 seconds. Total recharge time may take between 12 and 24 hours. The battery cannot be replaced by the user and should be returned to Respironics for replacement, if necessary. Contact Respironics Product Support for instructions.

ActiReader Battery Replacement

1. Disconnect the AC electrical supply and set the Power toggle switch to OFF.

2. Turn the ActiReader over so the battery cover is facing up.

3. Slide the battery cover in the direction of the arrow.

4. Carefully remove the battery from the housing unit and gently disconnect the battery terminals.

5. Replace the battery.

6. Slide the battery cover back into place on the ActiReader.

7. Set the Power toggle switch to the ON position.

8. Verify the **red** LED Power light is blinking.

Legacy Actiwatch Batteries

This information applies to the Actiwatch-16/64, Actiwatch-L, and Actiwatch-Score devices only. Nearly all Actiwatch devices use the CR2025 coin-cell battery. The methods used to change the battery are identical for all legacy devices. If you have an earlier Actiwatch, refer to the Instruction Manual for that device, or read the Battery Change Instructions included with the Battery Change Kit available from Respironics.

Actiware contains a Change Battery Wizard. The wizard will take you through the process step-by-step, from replacing the battery to testing the Actiwatch and changing the battery fitted date.

Caution!   *It is important that you thoroughly read the following information prior to changing the battery. Failure to follow procedures may result in immediate or subsequent damage to the product.*

Caution!   *To retain the integrity of the waterproof seal, it is recommended that you change the O-ring in the battery compartment at the same time you change the battery.*

The Actiwatch battery is required for data collection, reading, and writing. Actiwatch has a non-volatile memory, i.e., data stored are not lost after the battery has run down. If you are attempting to read a device with a low battery, the Ready LED will still light on the reader. It is recommended that you keep a log of the battery changes for each Actiwatch.

The Actiwatch battery is a CR2025, 3-Volt, 220-mAmp-hour Lithium Manganese cell. To properly install this battery, specific items may be required. These items are included in the Battery Change Kit from Respironics.

Changing an Actiwatch battery

1. Remove the band from the watch. Use the screwdriver supplied to loosen (approximately five full turns) or remove the screws in the slots in the battery cover of the Actiwatch.

2. Carefully remove the battery cover. If you have loosened the screws, press down slightly and rotate the cover clockwise. If you have removed the screws, simply lift the cover free from the frame.

3. Remove the battery and properly discard.

Caution!   *Use extreme care to avoid scratching the metal surface of the device or battery cover. Scratches can cause the watch to leak.*

4. Thoroughly clean the O-ring channel with alcohol.

Caution!   *Prior to assembling the Actiwatch, check carefully for lint, hairs, or other debris which may compromise the seal integrity.*

5. Place a new O-ring into the channel in the back cover using the following technique:

    - Pre-stretch the O-ring by gently flexing it in several directions.

    - Place a portion of the O-ring in the channel and hold it with your thumb or finger.

    - Use a finger on the other hand to guide the O-ring into the channel.

    - Be sure that the O-ring is properly seated in the channel, and is not twisted or deformed.

6. Place a new battery into the Actiwatch case, positive (+) side up.

7. Replace the back cover on Actiwatch and replace the screws. If the screws have not been removed completely, rotate the back cover counterclockwise until the slots in the back are firmly seated around the screws, and the back is square with the case.

8. Tighten all four screws in an "X" pattern until all screws are snug. Take care not to over-tighten to the extent of stripping the threads or twisting off the heads.

Caution!   *DO NOT over tighten the screws. They can be easily stripped.*

Troubleshooting Connections

Making a good connection with the device is usually a matter of device placement within the docking station or firmly connecting the cables between the computer and the docking station. The tables below present the most common problems and their solutions.

Troubleshooting solutions for an Actiwatch 2

Error Message or Condition	Solution
"Disconnected" is displayed	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 2 Communications Dock." If they are not listed, or if they're listed with yellow exclamation points, disconnect the communications dock, uninstall Actiware and reinstall it from the installation CD.
"Too many docks" is displayed	Caused when more than one Actiwatch 2 communications dock is connected to the computer at the same time.
"Error" is displayed	Disconnect the Actiwatch 2 communications dock then reconnect it.

Error Message or Condition	Solution
Red light displayed with the device docked	Actiwatch 2 may not be docked properly. Adjust the device in the docking station until the green LED turns solid or blinks, indicating a good connection.

Troubleshooting solutions for an Actiwatch Spectrum

Error Message or Condition	Solution
"Disconnected" is displayed	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 dock, 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 Communication Dock.	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 illustration on the top of the communication dock. b. The Actiwatch Spectrum may have a weak or dead battery.

<u>Notes</u>

Chapter

3

Basic Actiware Features

Adding Subjects

Once a database exists it can be populated with subjects and data collected from subjects.

Adding Subjects (Patients)

To add a new subject to a database, do the following:

1. Select **File > Database > Open** from the main menu bar to open a database.

2. Select **File > New Subject** from the main menu bar.

    The New Subject window is displayed.

3. Fill in the three required fields: Identity, Date of Birth, and Gender, and other demographic data, if available. For HIPAA considerations, these fields are optional.

    Notice that Age is automatically computed.

    When USA or Canada is entered into the Country field, a drop-down list for the State/Province area becomes available.

    The Phone field is optimized for the (###) ###-#### format. To enter a non-US or non-Canadian state code or phone number, enter the Country first.

Important!   *Because you can import subjects from other databases, Actiware allows more than one subject with the same ID. Therefore, be sure you choose a subject ID that does not already exist in the currently open database. For Identity, it is suggested that you use a blind descriptor or nickname of the subject.*

Deleting Subjects

For purposes of data tracking, you cannot delete subjects from a database. You can hide them by checking the **Hide Subject** check box. Once hidden, a subject will not appear in the Database Viewer. Hidden subjects may be revealed by right clicking in the Database Viewer and selecting **Show Hidden Data**.

Using the Main Window

The Main window is where the majority of data analysis is performed. The main Actiware window consists of three main sections:

- Database Viewer
- Properties Viewer
- Actogram

The menu and toolbars display commonly used functions. Tool tips appear when the mouse is positioned over items in the toolbar.

Use the Database Viewer to add subjects, locate Actiwatch data or saved analyses.

1. Left-click on items to view properties in the Properties Viewer.

2. Left-click on the + or - box to expand or collapse the tree view.

3. Right-click on items to display commonly used functions such as adding subjects, importing AWD files or viewing the audit trail.

4. Double-click on items to expand the tree view or view Actograms.

Use the Properties window to view saved information about a subject, Actiware data, or analysis parameters. The contents of this window are linked to the highlighted item in the Database Viewer. These may be edited by selecting the Properties button from the toolbar.

Double click on an Analysis to view an Actogram in the main portion of the Main window.

The workspace of the Actiware software is similar to many software applications. Dockable windows give you direct access to the Actiwatch or subject data stored in the selected database. They also provide control over analysis viewing and exports. The Database Viewer and the Properties Viewer are docked at the left side of the main Actiware window by default. The Actogram View toolbar is shown on the right side of the main Actiware window.

Actiware databases are organized in a hierarchical fashion. The top level is the subject (patient) level. The second level is the Actiwatch data for that subject. The third level is for saved analyses of the Actiwatch data. A few things to remember:

- Subjects are sorted by subject ID.
- Actiwatch Data entries are sorted by data collection start time.

- Analyses are sorted by their saved names.

The main menu bar is similar to most software applications. Keyboard shortcuts, actuated by pressing the **ALT** key plus the underlined letter (hot-key), identified by an underscore, can be used to navigate through the toolbar options. Hovering your mouse pointer on an icon causes a short text message about the icon to display.

File   View   Copy   Communications   Analysis   Interval   Tools   Window   Help
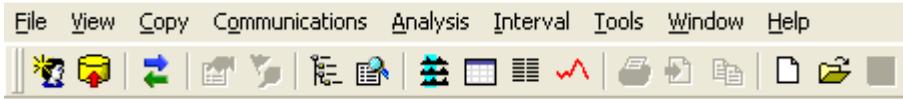
Toolbar Icons

	Create a new subject		Display the Data List
	Import an AWD file		Display data as a graph
	Show Actiwatch Console		Print an Actiware report
	Edit Subject, data or analysis		Export a data file
	Show audit trail		Copy export text to Clipboard
	Show Database Viewer		Create a new analysis file
	Show Properties Viewer		Open an analysis file
	Display Actogram		Save an Analysis file
	Display statistics table		

Database Viewer

The Database Viewer is used to provide a hierarchical tree view of the data in your currently selected database. Below is an example view from the Demonstration Database that is provided with Actiware.

Note: *Actiware does not support multi-user, simultaneous access to the same Actiware database.*

The tree structure is explained below:
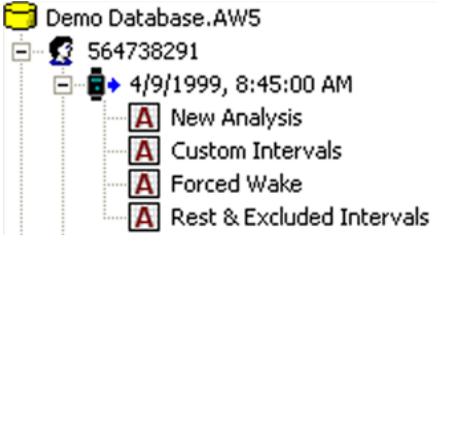
Level		Content
1st Level (Subject/subject name/identifier)	Demo Database.AW5 ⊟ 564738291 ⊟ 4/9/1999, 8:45:00 AM — [A] New Analysis — [A] Custom Intervals — [A] Forced Wake — [A] Rest & Excluded Intervals	Subject identity (sorted alphabetically or numerically)
2nd Level (Actiwatch data date, time)		Actiwatch Data (sorted by date)
3rd Level (Analysis)		Analysis Name (sorted alphabetically)

Commonly used functions can be accessed by right-clicking on an item in the Database Viewer, then selecting them from the pop-up menu.

Actiware automatically loads the last used database, or when run for the first time, the Demonstration Database.

To create a new database:

1. Select **File > Database > New** and, using the Windows file selection window, select a filename and location.

    Other database functions (such as Open, Save As, Backup, and Export) can also be accessed from the File > Database menu.

The Database Viewer can be undocked or docked by clicking and dragging its window title bar. It can also be resized or closed.

To re-display it, if it should become closed, select **View > Database Viewer** from the main menu bar.

Properties Viewer

The Properties Viewer displays information for the database item that is currently selected in the Database Viewer; hence, the Database Viewer and Properties Viewer are linked.

Note: *The Actiwatch properties displayed will vary depending on the type of Actiwatch device.*

Properties	
□ Subject	
Identity	564738291
Full Name	Mrs Janet C Hanson
Gender	Female
Date of Birth	8/8/1939
Age (current)	67 years
Age (start of data collection)	59 years
Street Address	5674 W 123rd St
City	New York
State	NY
Postal Code	11143
Country	USA
□ Actiwatch Data	
Actiwatch Type	Actiwatch 16/64
Data Collection Start Time	4/9/1999, 8:45:00 A
Data Collection End Time	4/14/1999, 5:08:00
Logging Mode	Activity Only
Time Zone	(GMT-08:00) Pacific
Time Zone Offset	-07:00 hours:minutes
Epoch Length	1 minute
Number of Data Samples	7704 samples
Number of days	5.35 days
Battery Installed Date	Not Available
Actiwatch Serial Number	V631234
Actiwatch Firmware Version	63
Activity Calibration Factor	Not Available
□ Analysis	
Analysis Name	New Analysis
Wake Threshold Selection	Medium
Wake Threshold Value	40.0 activity counts
Sleep Interval Detection Algorithm	By minutes scored as
Immobile Minutes for Sleep Onset	10 minutes
Immobile Minutes for Sleep End	10 minutes
Epochs for Sleep Onset	Not Used
Epochs for Sleep End	Not Used
Actogram Start Hour	12:00 PM
Number of Intervals	0 intervals

Click the + or – next to the **Subject**, **Actiwatch Data**, or **Analysis** type, to expand or collapse the properties related to that database item.

Left-click on an item to see a description of the property in the notes area at the bottom of the window. For instance, left-clicking on the Rest & Excluded Intervals analysis causes its corresponding properties to be displayed.

Items in the Properties Viewer can be edited by double-clicking on them.

The Properties Viewer can be undocked or docked by clicking and dragging its window title bar. It can be resized or closed.

To re-display it, should it become closed, select **View > Properties Viewer** from the main menu bar.

Actogram

An actogram (also known as a raster plot) is a graphic view of the distribution of rest and activity periods for a subject throughout the day. Individual 24-hour periods, called strip charts, are *stacked* one above the other, to make evident the sleep/wake patterns across multiple days.

Actiware Software User's Guide
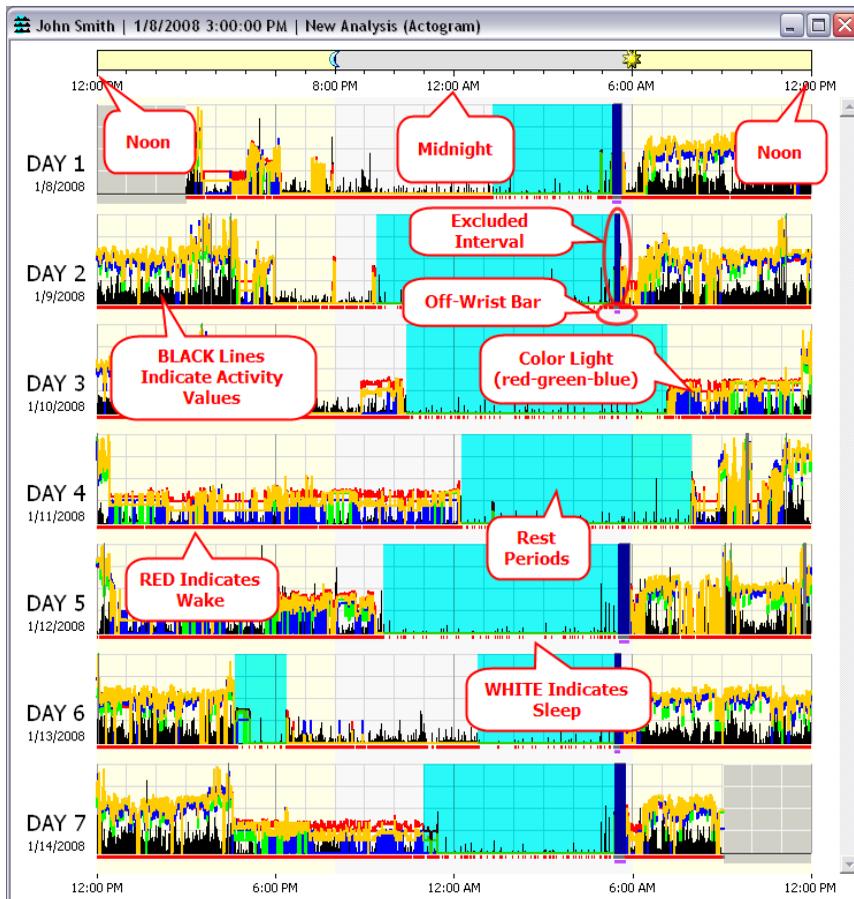
The time scale is set by default so that midnight is in the center, thereby making the sleep periods easier to see. However, noon, midnight, and noon are adjustable by changing the "Actogram Start Hour" analysis property in the Options table under the Analysis tab.

Activity data are expressed in **black**. Event markers are shown as **blue** wedges. Sleep Wake Scores are shown below activity. Light data are shown in **yellow** (some models).

Excluded Intervals are shown in **dark blue**.

The Off-Wrist Bar, shown in **magenta** below the Sleep/Wake bar, indicates when the Actiwatch Spectrum was not on the subject's wrist.

The Actiwatch Spectrum can be configured to collect color light (RGB or red-green-blue) data. These are displayed in the actogram as **red**, **green**, and **blue** lines. These data can be displayed as irradiance or flux. (Refer to RGB light units in the **Tools > Options > Analysis** tab.)

Illuminance (white or photopic light) data can be acquired with Actiwatch-L, Actiwatch 2, or Actiwatch Spectrum. These data are displayed in the Actogram as **orange** lines.

Actograms make it easy to recognize and score intervals of rest, such as time in bed or naps. Once identified, rest periods are shown in **aqua**.

The actogram provides the ability to select periods of time, known as intervals, and to provide statistics for these times of interest. (See *Setting Intervals* for more information.)

There are multiple ways to open an actogram, including the most direct:

1. In the Database Viewer, click the + sign next to a Subject to expand.

2. Click the + sign next to the Actiwatch Data record to expand it.

3. Double-click on **New Analysis**.

    An actogram is displayed.

This process can be repeated for any analysis (such as Custom Intervals) shown in the Database Viewer.

You can also open an actogram by selecting **View > Actogram** from the main menu bar, or by clicking the Actogram icon on the Standard toolbar at the top of the main window.

Actogram/Graph View toolbar

Use the Actogram/Graph View toolbar (displayed on the right side of the window) to adjust the view settings for the actogram.

The Actogram/Graph View toolbar is used to adjust the viewing properties of an actogram and is available only when an actogram is present. Changes made to this toolbar are immediately visible in the currently selected actogram.

- **Actogram Length**: controls the number of days displayed in the visible part of the Actogram window. Use the scroll bar on the right of the actogram to see the remaining days. Select a value or type it directly into this control to set the number of days. If the days of data are less than or equal to 2, then the Auto value is 3. If the days of data are 3 to 13, then Auto is equal to the number of days of data. If days of data are equal to or greater than 14, then Auto is equal to 14.
- **Graph Width**: adjusts the time scale for the graph. The time scale can be set to a specified number of minutes, hours, days, weeks, or months.
- **Visibility**: these buttons hide/show the data items in the actogram.
- **Activity Scale**: adjusts the maximum value of activity counts displayed on the actogram. Select a value or type it directly into this control to set the activity scale. The Max. Auto value is equal to the maximum activity value in the data set. The Min. Auto value is equal to the minimum activity value in the data set (usually 0).
- **White Light Scale**: adjusts the maximum illuminance value displayed on the actogram. Select it or type it directly into this control to set the scale. The Max. Auto value is the maximum white light value in the data set. The Min. Auto value is the minimum white light value in the data set.
- **Color Light Scale**: adjusts the minimum and maximum values for the RGB light displayed on the actogram. Color light is displayed on a log scale in units of $\mu W/cm^2$ or photons/cm^2/s. Select it or type it directly into this control or set the scale. To adjust the RGB light units, use the Edit Analysis Parameters window or Analysis tab of the Options window. The Max. Auto value is the maximum color light value in the data set. The Min. Auto value is the minimum white light value in the data set.
- **Light/Dark Bar**: use these controls to show/hide the bar at the top of the actogram to set the light on/light off time, or to set the light to all on (24 hours of light) or all off (24 hours of dark).
- **Interval Legend**: provides a convenient reminder of the color scheme used for displayed intervals. Click the keyboard controls link to display quick reminders on how to set intervals. Refer to *Setting Intervals* for details.

To save your current Actogram/Graph View settings as default settings:

1. Select **View > Save Current Actogram View as My Default View** from the main menu bar. Or, to restore your default view settings, select **View > Restore My Default Actogram View**.

Setting Options

The Options window in Actiware allows you to customize software's functionality and data properties so as to maximize its ability to provide you with the most thorough analysis possible.
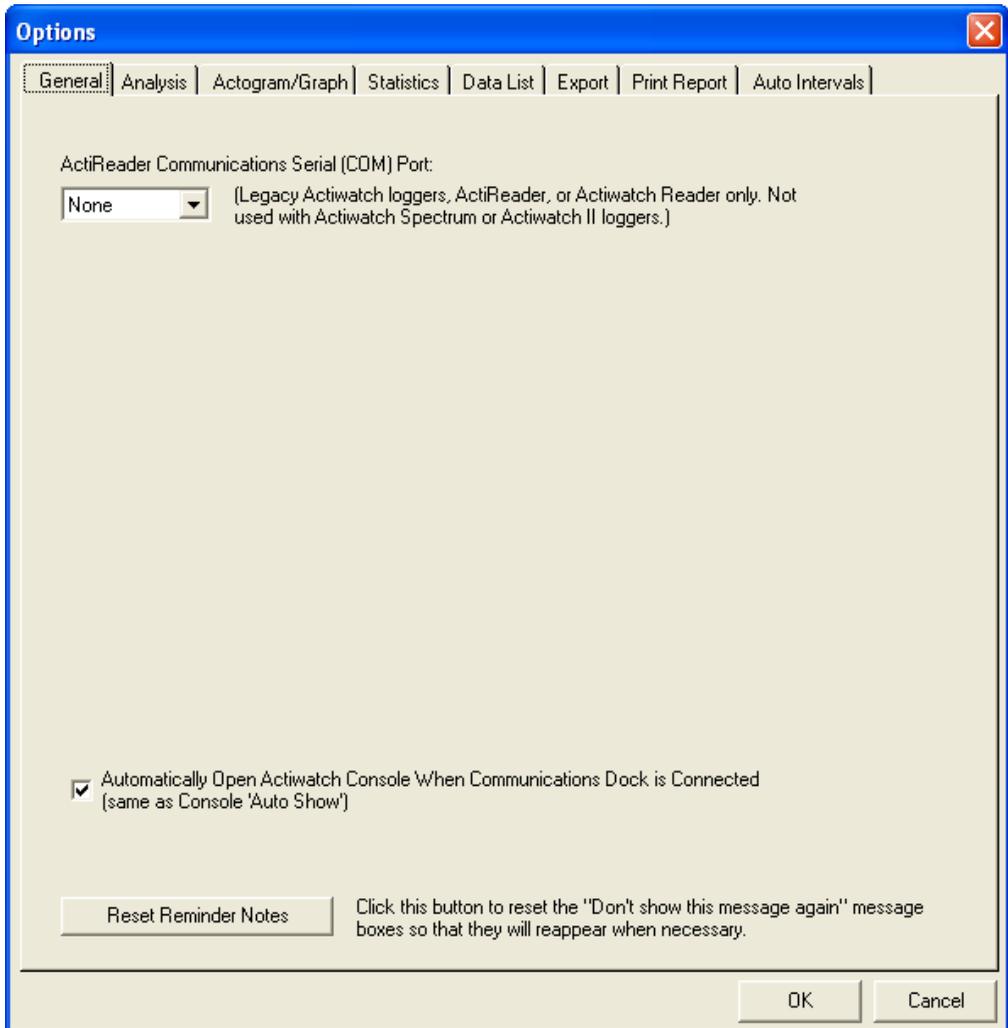
The Options window contains seven tabs from which you can tailor the software:

- **General**
- **Analysis**
- **Actogram**
- **Statistics**
- **Data List**
- **Export**
- **Print Report**
- **Auto Intervals**

To open the Options window:

1. Select **Tools > Options** from the main menu bar.

2. Click on a tab and make your selections.

3. When finished, click **OK** to accept or click **Cancel** to close the Options window without saving changes.

General Tab

Use the **General** tab to access and change the currently selected COM port.

- Select a COM port from the drop-down menu. (This option only applies to the ActiReader and Actiwatch Reader devices.)

- Select the **Automatically Open Actiwatch Console When Communications Dock is Connected (same as Console 'Auto Show')** check box if you want the console to automatically open whenever the communications dock is connected. This has the same affect as choosing the **Auto Show** check box on the Actiwatch Communications Console window.

- Click the **Reset Reminder Notes** button to reset the **Don't show this message again** message boxes so that they will reappear when necessary.

Analysis Tab

An analysis includes parameter settings and interval settings as inputs. Use the **Analysis** tab for setting parameter values (refer to *Setting Intervals*). Definitions of each analysis parameter are given below. You can also see the definitions of each parameter on-screen when running the Actiware software by holding your mouse cursor over the parameter names on the left side of the **Analysis** tab.

Active Analysis refers to the currently selected analysis, so the analysis parameter settings shown in the Active Analysis frame are those of the currently selected analysis.

New Analysis refers to a newly created analysis, so the analysis parameter settings shown in the New Analysis frame are default values. These default values are unique to each Windows logon username and are used each time a New Analysis window is opened.

- Click the << button to set Active Analysis parameter settings equal to New Analysis parameter settings.

- Click the >> button to set New Analysis parameter settings equal to those of the Active Analysis.

- Click the **Restore Defaults** button to reset to the factory released parameter settings.

Analysis Parameters

Wake Threshold Selection

Selected level or method of setting the Wake Threshold. If Automatic is selected, the Wake Threshold is computed automatically based on activity data.

Wake Threshold Value

The number of activity counts used to define wake. The level of activity that is compared to a value (x) generated by the Actiware sleep algorithm for each epoch. If (x) is above the Wake Threshold, then the epoch is scored as wake. The higher the Wake Threshold, the fewer the number of epochs scored as wake.

Sleep Interval Detection Algorithm

This determines the basis for calculating sleep onset and sleep end. The first option uses the number of minutes scored as immobile. By selecting this option, the parameter settings for epochs for sleep onset and sleep end can be edited. The second option uses a number of epochs scored as sleep. By selecting this option, the parameter settings for immobile minutes for sleep onset and epochs for sleep end can be edited.

Note: *This is a means of automatically setting sleep onset and sleep end intervals, not rest intervals.*

Immobile Minutes for Sleep Onset

After the start of each rest interval, the start of each sleep interval is automatically set to the first epoch of the first section of consecutive epochs "THIS" many minutes long with all but one epoch in the section scored as immobile.

Note: *This parameter is applied only if the Immobile Minutes option is selected as the sleep interval detection algorithm.*

Immobile Minutes for Sleep End

Prior to the end of each rest interval, the end of each sleep interval is automatically set to the last epoch of the last section of consecutive epochs "THIS" many minutes long with all but one epoch in the section scored as immobile.

Note: *This parameter is applied only if the Immobile Minutes option is selected as the sleep interval detection algorithm.*

Epochs for Sleep Onset

After the start of each rest interval, the start of each sleep interval is automatically set to the first epoch of the first section of consecutive epochs scored as sleep "THIS" many epochs long.

Note: *This parameter is applied only if the Sleep Epochs option is selected as the sleep interval detection algorithm.*

Epochs for Sleep End

Prior to the end of each rest interval, the end of each sleep interval is automatically set to the last epoch of the last section of consecutive epochs scored as sleep "THIS" many epochs long.

Note: *This parameter is applied only if the Sleep Epochs option is selected as the sleep interval detection algorithm.*

Actogram Start Hour

The hour at which actogram rows and daily intervals begin. This setting affects daily interval statistics.

Light Threshold

These threshold parameters refer to the levels of white, red, green, and blue light that is compared to the intensity of illumination the device is exposed to, for the purpose of calculating the Time Above the white, red, green, and blue light threshold statistic for given time intervals (Actiwatch-L, Actiwatch 2, and Actiwatch Spectrum only).

RGB Light Units

Units of component (red, green, blue) light measurement, applied to measurements, statistics, and data output. Irradiance has units of uW/cm^2 (microwatts per squared centimeter). Flux has units of photons/cm^2/s (photons per squared centimeter per second).

Actogram/Graph Tab

Each time an actogram is opened, it is displayed based on the properties set in this tab. Selecting one or more of these properties does not affect any open Actograms and Graphs. To view the changes, close and reopen the windows.

Actogram/Graph Parameters

Actogram Length

This parameter controls the number of days displayed in the visible part of the Actogram window. Use the scroll bar on the right of the actogram to see the remaining days. Select a value or type it directly into this control to set the number of days.

Component Visibility

These buttons hide/show the activity, light color, score, sleep/wake, and off wrist status data items in the actogram as well as button to toggle on/off the background grid and the light/dark bar displayed across the top of the actogram.

Graph Width

Use this parameter to set the displayed width of the graph. Choose a numeric value from the drop-down and the time units from the associated drop-down list.

Activity Scale (counts)

This parameter adjusts the maximum value of activity counts displayed on the actogram. Select a value or type it directly into this control to set the activity scale.

While Light Scale (lux)

This parameter adjusts the minimum and maximum illuminance value displayed on the actogram. Select it or type it directly into this control to set the scale.

Color Light Scale (μW/cm2)

This parameter adjusts the minimum and maximum irradiance in (μW/cm2) value displayed on the actogram. Select it or type it directly into this control to set the scale.

Color Light Scale (photons/cm2/s)

This parameter adjusts the minimum and maximum flux in (photons/cm2/s) value displayed on the actogram. Select it or type it directly into this control to set the scale.

Light/Dark Bar

This parameter adjusts the daytime/nighttime bar above the actogram and light/dark shading on the actograms. Select or type directly into this control to set the daylight start and stop times.

All Light (24 hours of light on) check box

Changes the light/dark bar and actogram shading to indicate the subject was in light for the duration of the analysis.

All Dark (24 hours of light off) check box

Changes the light/dark bar and actogram shading to indicate the subject was in darkness for the duration of the analysis.

You may click the **Restore Defaults** button to reset the software to its default settings.

Statistics Tab

Use the **Statistics** tab from the Options window to select the items of data displayed from the analysis.

Changes made here also impact exported and printed data, and the statistics table window contents. Place your cursor over an item to get a brief definition of that item.

- Click **Select All** to include all items in your statistical analysis.

- Click **Deselect All** to remove all items from your statistical analysis.

- Click the **Restore Defaults** button to reset parameters to their default settings.

- Click one or more of the **Statistics** options (defined below) available to include them in the Actiware outputs.

Note: NaN means not a number. It occurs when Actiware is unable to compute a number. The cause is usually invalid or insufficient data.

Statistic Parameters

Interval Information

Start Date - The date at the start of the given Rest, Active, Sleep, Custom or Daily Interval (the date of the start of the first epoch of the given interval).

Start Day - The day at the start of the given Rest, Active, Sleep, Custom or Daily Interval (the day of the start of the first epoch of the given interval).

Start Time - The time at the start of the given Rest, Active, Sleep, Custom, or Daily Interval (the start of the first epoch in the given interval).

Duration - The time elapsed between the Start Time and the End Time of the given interval, in minutes.

End Date - The date at the end of the given Rest, Active, Sleep, Custom or Daily Interval (the date of the end of the last epoch of the given interval).

End Day - The day at the end of the given Rest, Active, Sleep, Custom or Daily Interval (the day of the end of the last epoch of the given interval).

End Time - The time at the end of the given Rest, Active, Sleep, Custom, or Daily Interval (the end of the last epoch in the given interval).

On/Off Wrist Status

Off-Wrist Time - The total number of epochs between the Start Time and the End Time of the given interval that the Actiwatch indicated that it was not on the subject's wrist, multiplied by the Epoch Length in minutes (Actiwatch Spectrum only).

%Off-Wrist - a) The percentage of Off-Wrist Time to the Interval Duration. b) Total Off-Wrist time divided by Interval Duration multiplied by 100. (Applies to Actiwatch Spectrum only.)

Activity Statistics

Total AC - The sum of all valid physical activity counts for all epochs from the Start Time to the End Time of the given interval.

Avg AC/min - The average of all valid physical activity counts for all epochs from the Start Time to the End Time of the given interval divided by the Epoch Length in minutes.

Avg AC/epoch - The average of all valid physical activity counts for all epochs from the Start Time to the End Time of the given interval.

Std AC - The standard deviation of all valid physical activity counts for all epochs from the Start Time to the End Time of the given interval. The standard deviation is computed with (n – 1) rather than (n) in the denominator of the variance.

Max AC - The largest of any valid physical activity count for all epochs from the Start Time to the End Time of the given interval.

Total Invalid Time (Activity) - The total number of epochs between the Start Time and the End Time of the given interval for which the physical activity count was found to exceed the maximum possible value from a properly functioning Actiwatch (i.e., invalid data due to rare hardware error, communication error, or data corruption), plus the total number of epochs with valid physical activity counts manually excluded from the data set by the practitioner using Actiware software, multiplied by the Epoch Length in minutes. (The Total Invalid Time is in minutes).

%Invalid AC - a) The percentage of Total Invalid Time (Activity) to the Interval Duration. b) Total Invalid Time (Activity) divided by Interval Duration multiplied by 100.

Sleep/Wake Statistics

For a definition of how Actiware scores data as SLEEP or WAKE, refer to Sleep/Wake Analysis.

Sleep statistics marked with an asterisk (*) will be improved if the **Enhanced Sleep Statistics** check box is checked. This applies to sleep intervals only. See the Enhanced Sleep Statistics listed below.

Sleep Time* - The total number of epochs between the Start Time and the End Time of the given interval scored as SLEEP by Actiware software (or manually set as SLEEP by you) multiplied by the Epoch Length in minutes.

Note: *In order to be scorable as SLEEP or WAKE, an epoch must have a valid physical activity count, and in addition there must be a sufficient number of epochs before and after the epoch being scored that also have valid physical activity counts.*

% Sleep* - a) The percentage of Scored Total Sleep Time to (Interval Duration minus Total Invalid Time (Sleep/Wake)), for the given interval. b) Scored Total Sleep Time divided by (Interval Duration minus Total Invalid Time (Sleep/Wake)) multiplied by 100.

 # Sleep Bouts - The total number of continuous blocks, one or more epochs in duration, with each epoch of each block scored as SLEEP, between the Start Time and the End Time of the given interval.

Avg Sleep Bout* - The Scored Total Sleep Time divided by the Number of Sleep Bouts, for the given interval.

Onset Latency - a) The time elapsed between the Start Time of a given Rest Interval and the following Sleep Start Time, in minutes. b) The time required for the onset of sleep after first attempting to get to sleep (i.e., from the "lights out" time). Calculated using the analysis setting made by selecting Tools > Options > Analysis from the main menu bar.

Snooze Time - a) The time elapsed between Sleep End Time and the End Time of a given Rest Interval, in minutes. b) The time elapsed between the end of sleep and the time lights are switched on or the subject gets out of bed.

Sleep Efficiency* - a) The percentage of Scored Total Sleep Time to Interval Duration minus Total Invalid Time (Sleep/Wake), for the given Rest Interval. b) Scored Total Sleep Time divided by (Interval Duration minus Total Invalid Time (Sleep/Wake)) of the given Rest Interval multiplied by 100.

WASO* - The total number of epochs between the Start Time and the End Time of the given Sleep Interval scored as WAKE by Actiware software (or manually set as WAKE by you using Actiware software) multiplied by the Epoch Length in minutes.

Note: Wake After Sleep Onset is identical to Scored Total Wake Time when the given interval is a Sleep Interval.

Wake Time* - The total number of epochs between the Start Time and the End Time of the given interval scored as WAKE by Actiware software (or manually set as WAKE by you) multiplied by the Epoch Length in minutes.

Note: In order to be scorable as SLEEP or WAKE, an epoch must have a valid physical activity count, and there must be a sufficient number of epochs before and after the epoch being scored that also have valid physical activity counts.

% Wake* - a) The percentage of Scored Total Wake Time to Interval Duration minus Total Invalid Time (Sleep/Wake), for the given interval. b) Scored Total Wake Time divided by (Interval Duration minus Total Invalid Time (Sleep/Wake)) multiplied by 100.

 # Wake Bouts - The total number of continuous blocks, one or more epochs in duration, with each epoch of each block scored as WAKE, between the Start Time and the End Time of the given interval.

Avg Wake Bout* - The Scored Total Wake Time divided by the Number of Wake Bouts, for the given interval.

Invalid Time SW - The total number of epochs between the Start Time and the End Time of the given interval for which the sleep/wake scoring algorithm did not have enough data to determine a SLEEP or WAKE score multiplied by the Epoch Length in minutes.

Note: The insufficient data condition can be caused by invalid or manually excluded physical activity data at the epoch, and/or immediately before the epoch, and/or immediately after the epoch–-the amount before and after is a function of the Epoch

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Length.

%Invalid SW - a) The percentage of Total Invalid Time (Sleep/Wake) to the Interval Duration. b) Total Invalid Time (Sleep/Wake) divided by Interval Duration multiplied by 100.

Enhanced Sleep Statistics - When checked, eight sleep statistics (marked with * above) are enhanced or improved using a software algorithm. This algorithm applies PSG-derived correction factors and uses statistics from surrounding major rest periods to improve the sleep statistics for a particular sleep interval. *Note: This applies to Sleep Intervals only; statistics for Rest, Custom, Active, or Daily intervals are not affected.*

Mobility Statistics

For a definition of how Actiware scores data as MOBILE or IMMOBILE, refer to the definition of MOBILE in Sleep/Wake Analysis.

Immobile Time - The total number of epochs between the Start Time and the End Time of the given interval scored as IMMOBILE by Actiware software multiplied by the Epoch Length in minutes.

Note: *In order to be scorable as IMMOBILE or MOBILE, an epoch must have a valid physical activity count.*

% Immobile - a) The percentage of Scored Total Immobile Time to (Interval Duration minus Total Invalid Time (Activity)), for the given interval. b) (Scored Total Immobile Time divided by (Interval Duration minus Total Invalid Time (Activity)) multiplied by 100.

 # Immobile Bouts - The total number of continuous blocks, one or more epochs in duration, with each epoch of each block scored as IMMOBILE, between the Start Time and the End Time of the given interval.

Avg Imm Bout - The Scored Total Immobile Time divided by the Number of Immobile Bouts, for the given interval.

#1min Imm Bouts - The total number of continuous blocks 4 epochs in duration; if Epoch Length = 15 seconds, 2 epochs in duration; if Epoch Length = 30 seconds, 1 epoch in duration; if Epoch Length = 60 seconds (not applicable if Epoch Length is greater than 60 seconds), with each epoch of each block scored as IMMOBILE, between the Start Time and the End Time of the given interval.

%1min Imm Bouts - a) The percentage of Number of Immobile Bouts 1 Minute in Duration to the Number of Immobile Bouts, for the given interval. b) The number of Immobile Bouts 1 Minute in Duration divided by Number of Immobile Bouts multiplied by 100.

Mobile Time - The total number of epochs between the Start Time and the End Time of the given interval scored as MOBILE by Actiware software multiplied by the Epoch Length in minutes.

Note: *In order to be scorable as IMMOBILE or MOBILE, an epoch must have a valid physical activity count.*

% Mobile - a) The percentage of Scored Total Mobile Time to (Interval Duration minus Total Invalid Time (Activity)), for the given interval. b) Scored Total Mobile Time divided by (Interval Duration minus Total Invalid Time (Activity)) multiplied by 100.

 # Mobile Bouts - The total number of continuous blocks, one or more epochs in duration, with each epoch of each block scored as MOBILE, between the Start Time and the End Time of the given interval.

Avg Mob Bout - The Scored Total Mobile Time divided by the Number of Mobile Bouts, for the given interval.

Fragmentation Index - The sum of Percent Mobile and Percent Immobile Bouts Less Than 1-Minute Duration to the Number of Immobile Bouts, for the given interval. This is also known as the Index of Restlessness or Movement and Fragmentation Index.

Score Statistics

 # Scores - The Number of Manual Scores plus the Number of Scheduled Scores entered by the subject while wearing Actiwatch-Score, and not manually excluded later by you, from the Start Time to the End Time of the given interval.

 # Manual - The number of Manual Scores entered by the subject while wearing Actiwatch-Score, and not manually excluded later by you, from the Start Time to the End Time of the given interval.

Avg Score - The sum of all Manual Score Values (that are not manually excluded) plus the sum of all Scheduled Score Values (that are not manually excluded) divided by the Total Number of Scores, for all epochs from the Start Time to the End Time of the given interval.

Avg Manual Score - The sum of all Manual Score Values (that are not manually excluded) divided by the Number of Manual Scores, for all epochs from the Start Time to the End Time of the given interval.

Avg Scheduled - The sum of all Scheduled Score Values (that are not manually excluded) divided by the Number of Scheduled Scores, for all epochs from the Start Time to the End Time of the given interval.

 # No Responses - The number of No Responses to Scheduled Scores (that are not manually excluded by the user of Actiware software), from the Start Time to the End Time of the given interval. (Actiware Score device.)

 # Scheduled - The number of Scheduled Scores entered by the subject while wearing Actiwatch-Score, and not manually excluded later by you, from the Start Time to the End Time of the given interval.

Std Score - The standard deviation of all Manual Score Values (that are not manually excluded) together with all Scheduled Score Values (that are not manually excluded) for all epochs from the Start Time to the End Time of the given interval. The standard deviation is computed with (n – 1) rather than (n) in the denominator of the variance.

Std Manual - The standard deviation of all Manual Score Values (that are not manually excluded) for all epochs from the Start Time to the End Time of the given interval. The standard deviation is computed with (n – 1) rather than (n) in the denominator of the variance.

Std Scheduled - The standard deviation of all Scheduled Score Values (that are not manually excluded) for all epochs from the Start Time to the End Time of the given interval. The standard deviation is computed with (n – 1) rather than (n) in the denominator of the variance.

Light Statistics

Illuminance (white or photopic light) has the units of Lux. Color (RGB or red-green-blue light) can be displayed in Irradiance or Flux. Irradiance has units of uW/cm^2 (microwatts per squared centimeter). Flux has units of photons/cm^2/s (photons per squared centimeter per second). Use the *Analysis Tab* to adjust the color light units that are used.

Illuminance (white light) statistics apply to the Actiwatch-L, Actiwatch 2, and Actiwatch Spectrum only. Irradiance/Flux (red-green-blue light) statistics apply to the Actiwatch Spectrum only.

Total Exposure - The sum of all valid light data, in Lux, (white light), or valid irradiance/flux data, in the selected units (red, green, blue) for all epochs from the Start Time to the End Time of the given interval multiplied by the Epoch Length in minutes.

Avg Light - The average of all valid light (white) or irradiance/flux (color) data for all epochs from the Start Time to the End Time of the given interval.

Std Light - The standard deviation of all valid light (white) or irradiance/flux (color) data for all epochs from the Start Time to the End Time of the given interval. The standard deviation is computed with (n – 1) rather than (n) in the denominator of the variance.

Max Light - The datum of highest value (greatest average intensity of light (white) or irradiance/flux (color) during an epoch) from the set of all valid light or irradiance/flux data for all epochs from the Start Time to the End Time of the given interval; i.e., the peak value in the data set minus the highest intensity of light the Actiwatch was exposed to during the interval.

TALT - a) The total number of epochs between the Start Time and the End Time of the given interval with valid light data greater than the given Illuminance or Irradiance/Flux Threshold multiplied by the Epoch Length in minutes. b) The total accumulation of time, in minutes, during which the Actiwatch was exposed to an intensity of illumination above the given Illuminance or Irradiance/Flux Threshold.

Invalid Time L - The total number of epochs between the Start Time and the End Time of the given interval in which the light or irradiance/flux datum was found to exceed the maximum possible value from a properly functioning Actiwatch; i.e., invalid data due to rare hardware fault, communication error, or data corruption, plus the total number of epochs with valid light or irradiance/flux data manually excluded from the data set by you, multiplied by the Epoch Length in minutes.

% Invalid Time L - a) The percentage of Total Invalid Time (Illuminance or Irradiance/Flux) to the Interval Duration. b) Total Invalid Time (Illuminance or Irradiance/Flux) divided by Interval Duration multiplied by 100.

Data List Tab

Use the **Data List** tab to select the columns to display in the Data List window.

Changes made on this tab also impact the content of exported files and printed reports.

- Click **Select All** to include all items in the Data List.

- Click **Deselect All** to remove all items from the Data List.

- Click **Restore Defaults** to return the settings to Actiware's default settings.

- Click one or more of the **Data List Column** options (defined below) to include them in the data list.

Data List Columns

Line Number - Line number in the list.

Epoch Number - Epoch number of the measurement.

Day Number - Day number since the start of data collection.

Elapsed Seconds - Elapsed seconds since the start of data collection.

Date - Date of the current line in the list.

Time - Time of the current line in the list.

Off-Wrist Status - One of 0 (on-wrist), 1 (off-wrist), or NaN (not a number: Actiware was unable to compute a number due to invalid or insufficient data) for the epoch.

Activity - Activity measurement for the epoch.

Event Marker - Indicates if the event marker button was pushed during the epoch.

White Light - White light value for the epoch.

Red Light - Red light value for the epoch.

Green Light - Green light value for the epoch.

Blue Light - Blue light value for the epoch.

Score Value - Score value for the epoch.

Score Type - Type of the score (manual, scheduled, or no response) for the epoch.

Sleep/Wake Score - One of 0 (sleep), 1 (wake), or NaN for the epoch.

Mobility Score - One of 0 (immobile), 1 (mobile), or NaN for the epoch.

Interval Status - One of Active, Rest, Rest-Sleep, Excluded, or *(N/A) for the epoch.

S/W Status - One of manually set Forced Sleep, Forced Wake, Excluded, or *(N/A) interval for the epoch.

See *Viewing the Data List* for additional information.

Export Tab

Use the **Export** tab to specify the items you want to include in an export data file. (The **Export** tab also applies to the **Copy > Export Text** to windows clipboard function in the non-CT version of Actiware).

- Click the **Full Header** check box to include a first part of header information.

- Click the **Statistics** check box (and sub-boxes) to include statistics for various types of intervals (by default the report will include Summary Statistics only).

- Click the **Marker/Score List** check box to include the list of markers or scores in the report.

- Click the **Epoch-by-Epoch List** check box to include a list of measured or calculated data values for each epoch.

- Click **Select All** to select all of the types of data.

- Click **Deselect All** to undo the selection of all the types of data.

- Click **Restore Defaults** to return the settings to Actiware's default settings.

Print Report Tab

Use the **Print Report** tab to specify the items you want to include in a printed report.

- Click the **Full Header** check box to include a first page of header information.

- Click the **Actogram** check box to include the actogram graphic in the report. You can select the number of actogram days to print per page.

- Click the **Statistics** check box (and sub-boxes) to include statistics for various types of intervals (by default the report will include Summary Statistics only).

- Click **Select All** to select all of the types of data.

- Click **Deselect All** to undo the selection of all types of data.

- Click **Restore Defaults** to return the settings to Actiware's default settings.

Auto Intervals Tab

The Actiwatch Spectrum device is capable of determining when it is off the subject's wrist. The device places event markers in the stored data to indicate when the off-wrist status changes.

For analysis purposes, the off-wrist time can be automatically converted to excluded intervals. Select the **Convert off-wrist time to Excluded Intervals** check box to have the software automatically show all off-wrist time as excluded intervals. This applies to all new analyses. (The option can also be selected directly from the Tools menu.)

Select the **Automatically Set Major Rest Intervals** check box to cause Actiware to automatically create rest intervals for the major sleep periods (longer than 3 hours), when a New Analysis window is opened. (This will be an approximation of when the subject was in

bed or resting for an extended period of time.)

Note: *Selecting **Tools** > **Automatically Set Major Rest Intervals** is equivalent to the option above except that the menu option applies to an already open analysis. If rest intervals exist in the currently open analysis, then you will be prompted to combine overlapping intervals or replace the existing intervals with the Auto Rest intervals. This function respects the state of the **Detect only one Rest Interval per day** check box and the **Use Event Markers to adjust Rest Interval start and end times** check box (defined below).*

Select the **Automatically Set Minor Rest Intervals** check box to cause Actiware to automatically create rest intervals for periods of time when the subject appeared to be napping (sleep periods shorter than 3 hours), when a New Analysis window is opened. (This will be an approximation of when the subject was napping.)

Note: *Selecting **Tools** > **Automatically Set Minor Rest Intervals** is equivalent to the option above except that the menu option applies to an already open analysis. If rest intervals exist in the currently open analysis, then you will be prompted to combine overlapping intervals or replace the existing intervals with the Auto Rest intervals. This function respects the state of the **Minor Rest Intervals Sensitivity** and **Minimum Minor Rest Interval Size** settings (defined below).*

Select the **Detect only one Rest Interval per day** check box and to cause Actiware to detect 1 rest interval per 24 hours (the longest rest interval for that 24-hour period) when the **Automatically Set Major Rest Interval** is evaluated. This 24-hour day is based on the day shown in the Actogram, which is based on the Actogram Start Hour analysis parameter (see *Analysis tab*).

Select the **Use Event Markers to adjust Rest Interval start and end times** check box to cause Actiware to force the start and end of the major rest interval to the nearest event marker. For the start of the rest interval, Actiware will search up to half the rest interval duration after, then 30 minutes before, the rest interval start time for an event marker. If one is found, the event marker time becomes the start of the rest interval. Conversely, for the end of the rest interval, Actiware will search up to half the rest interval duration before, then 30 minutes after, the rest interval end time for an event marker. If one is found, the event marker time becomes the end of the rest interval. This setting only applies if the **Detect only one Rest Interval per day** setting is enabled.

Sensitivity (minor rest intervals): Select **High** to detect more minor rest intervals, select **Low** to detect fewer minor rest intervals.

Minimum Minor Rest Interval Size: This is an indication of the shortest allowable rest interval that will be detected by the Minor Rest Interval algorithm. It is controllable from 15 to 75 minutes.

A sensitivity setting of Medium and a Minimum Minor Rest Interval Size of 40 are recommended for best results. Testing has revealed that the Minor Rest Interval algorithm is most effective at those settings.

Setting Intervals

Analyzing your data involves setting intervals. An interval is a period of time of special interest that you select for analysis and statistics generation. Interval selections can be made by right-clicking on an Actogram and choosing the appropriate option or by using the main menu. For calculation of statistics for specific periods of time, it is necessary to select intervals and assign an interval type to them. The Interval feature in Actiware provides a robust data selection, exclusion, and quantitative tool.
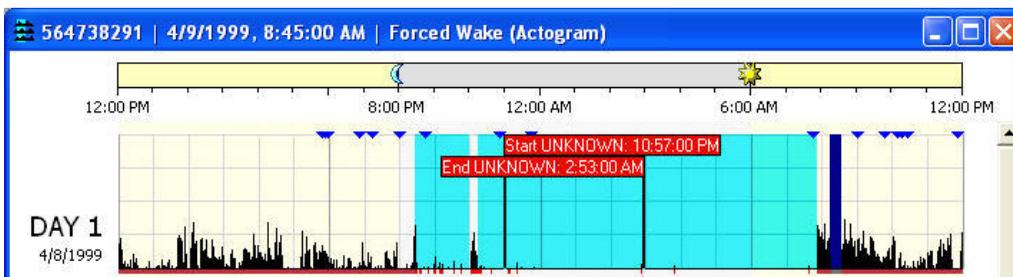
Rest intervals

These are intervals of data that contain periods of time when the subject activity is low and the subject is likely to be at rest. You must set them and, when you do, they are indicated on the actogram by light blue shading. Typically this will be used for the In Bed Period. By setting a Rest Interval you are directing the program to apply the Sleep Interval Detection algorithm for generating Sleep Periods.

This algorithm uses the first data point in the rest interval as the Bed Time and the last data point as the Get up Time. From these points, the Sleep Onset and Sleep End is set using the Analysis parameter values that are indicated on the Analysis tab of the Options window. Once you have set a Rest Interval, a Sleep Interval is automatically created within it.

Sleep Intervals

Data in these intervals represent periods of time in which the subject is likely to be asleep. These intervals are created automatically by the software once a Rest Interval has been set. They represent the period of time between Sleep Onset and Sleep End but are not indicated by any shading.

Active Intervals

Data in these intervals represent periods of time in which subject activity indicates that they are alert and engaged in physical activity. These intervals contain all those data that are outside of Rest Intervals. Active Intervals are created automatically when Rest Intervals are set. No shading is used to indicate these intervals.

Excluded Intervals

Data in these intervals are excluded from all analytical calculations. These intervals are designed for use when subjects remove the Actiwatch or for other invalid periods of data.

These are generally set by you and are indicated by dark blue shading. When Convert off-wrist time to Excluded Intervals is selected (Actiwatch Spectrum only), any off-wrist event is automatically shown as an excluded interval.

(The Actiwatch Spectrum is capable of determining when it is off the subject's wrist. The device places event markers in the stored data to indicate when the off-wrist status changes. For analysis purposes, the off-wrist time can be automatically converted to excluded intervals by selecting the Convert off-wrist time to Excluded Intervals check box found by selecting **Tools > Options > Auto Intervals** tab.)

Custom Intervals

These are intervals of data that are of some interest for any reason. Typically these are used for illuminance calculations when using an Actiwatch-L or numerical rating scale values when using the Actiwatch Score. They may also be used for assessing activity during specific periods of the day. They are indicated on the actogram by a blue bar above the activity data, and must be set by you.

Forced Wake

These intervals are periods of time for which the Sleep/Wake score has been forced by you to Wake. This is typically used if the subject is known to be awake, but very inactive, or as an alternative to excluding data. Epochs included in this type of interval are indicated by a magenta mark below the X axis of the actogram.

Forced Sleep

These intervals are periods of time for which the Sleep/Wake score has been forced by you to Sleep. This is typically used if the subject is known to be sleeping but there is significant movement. Epochs included in this type of interval are indicated by a gray mark below the X axis of the actogram.

Note: *Custom, Excluded, Forced Wake and Forced Sleep intervals can be overlapped. However, due to the automatic creation of Sleep intervals, Rest intervals cannot be overlapped. If you attempt to overlap Rest intervals, they will be combined into one interval.*

There are several ways to set intervals:

- Automatic method
- Quick method
- Fine control method
- Menu and sleep diary method

Note: *During the interval creation process you can press the keyboard **Escape** key to clear the markers.*

Automatic Method

Actiware can automatically create three types based on automated software algorithms:

1. Excluded Intervals (for times that Actiwatch Spectrum indicated it was not on the wrist)

Set using **Tools > Convert Off-Wrist Time to Excluded Intervals**.

Or whenever a New Analysis is opened, by checking the **Convert off-wrist time to Excluded Intervals** box via the **Tools > Options > Auto Intervals** tab.

2. Major Rest Intervals (for rest periods 3 hours or longer in duration)

Set using **Tools > Automatically Set Major Rest Intervals**.

Or whenever a New Analysis is opened, by checking the **Automatically Set Major Rest Intervals** box via the **Tools > Options > Auto Intervals** tab.

Refer to *Auto Intervals* tab for settings that affect the way Major Rest Intervals are determined.

3. Minor Rest Intervals (for nap-like rest periods shorter than 3 hours)

Set using **Tools > Automatically Set Minor Rest Intervals**.

Or whenever a New Analysis is opened, by checking the **Automatically Set Minor Rest Intervals** box via the **Tools > Options > Auto Intervals** tab.

Refer to *Auto Intervals tab* for settings that affect the way Minor Rest Intervals are determined.

Quick Method

The quick method uses the mouse and hot-key combinations:

1. Hold down the **CTRL** key on the keyboard.

2. Click the left mouse button where you want the START of the interval to be.

3. While still holding down the **CTRL** key, click the right mouse button where you want the END of the interval.

   If you set an interval flag in the wrong location and want to move it, repeat the above process. Also, by holding down the CTRL key and the mouse button, you can drag the flag to the precise location you want.

4. Using one of the following hot-key combinations, set the type of interval you want:

   - *CTRL + R to Insert REST interval*
   - *CTRL + C to Insert CUSTOM interval*
   - *CTRL + E to Insert EXCLUDED interval*
   - *CTRL + W to Insert Forced WAKE interval*
   - *CTRL + S to Insert Forced SLEEP interval*

The new interval is automatically drawn in the actogram display. See the legend on the right side of the window (on the Actogram View toolbar) to see how the intervals are indicated on the actogram.

Note: *During the interval creation process you can press the keyboard **Escape** key to clear the markers.*

Fine Control Method

To set your intervals graphically to the nearest epoch, use the following procedure:

1. Click the left mouse button on the actogram to place the epoch label.

2. Use the keyboard arrow keys (⬇, ⬆, ⬅, ➡) to move the epoch label to the desired interval start time.
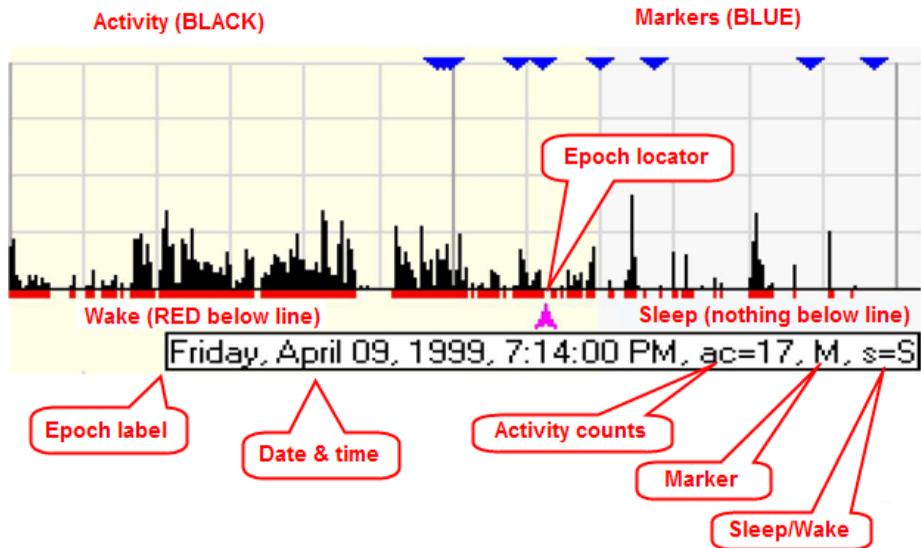
3. To place the interval START marker, press one of the following keys based on the interval type you want to create:

    -   *R* to set REST interval start

    -   *C* to set CUSTOM interval start

    -   *E* to set EXCLUDED interval start

    -   *W* to set Forced WAKE interval start

    -   *S* to set Forced SLEEP interval start

4. Once again, click the left mouse button on the actogram to place the epoch label, and use the arrow keys to place the epoch label at the desired interval end time.

5. To place the interval END marker, press one of the following hot-key combinations based on the interval type you're creating:

    -   *SHIFT + R* to set REST interval end

- *SHIFT + C* to set CUSTOM interval end

- *SHIFT + E* to set EXCLUDED interval end

- *SHIFT + W* to set Forced WAKE interval end

- *SHIFT + S* to set Forced SLEEP interval end

Tip: *If you set an interval flag in the wrong location and want to move it, repeat the above process.*

6. As with the Quick Method, use one of the following hot-key combinations to set the type of interval you want:

- *CTRL + R* to insert REST interval

- *CTRL + C* to insert CUSTOM interval

- *CTRL + E* to insert EXCLUDED interval

- *CTRL + W* to insert Forced WAKE interval

- *CTRL + S* to insert Forced SLEEP interval

Note: *During the interval creation process you can press the keyboard **Escape** key to clear the markers.*

Menu and Sleep Diary Methods

If you prefer to enter the date and time values for the interval start and end times, such as when using a subject sleep diary, use the following procedure:

1. Select **Interval > Add Interval** from the main menu bar.

    The Add Interval window opens.

2. Select the Interval Type:

- *Rest*

- *Excluded*

- *Custom*

- *Forced Sleep*

- *Forced Wake*

3. Set the Interval Start Time (date and time).

    You can type in the date or use the interactive calendar to select the date. You can type in the time or use the arrows to scroll to the appropriate time

4. Set the Interval End Time (date and time).

Note: If you want to create this interval for all days, check the Repeat for all days check box. This will create an interval every 24 hours starting with the interval start time, with the duration equal to the configured interval.

5.   Click the **Add Interval(s)** button to add the interval, or **Close** to cancel.

You can repeat steps 2 through 5 for each interval without closing the Add Interval window.

Tip: You can also click the right mouse button in the actogram, or use other sub-menus under the Interval main menu to set interval markers or insert intervals.

Removing Intervals

To remove a single interval, click the left mouse button in the interval you want to delete, then press the **Delete** key.

To remove all intervals, right click on the actogram and select **Clear All Intervals** (also accessible from the Interval menu)

To remove all intervals of a specific interval type, use the Interval menu, or the corresponding keyboard shortcuts (such as **CTRL** + **ALT** + **C** to clear all custom intervals).

Scoring and Analyzing Data

Scoring and analyzing your data involves setting intervals and identifying them as either sleep or wake periods. By marking rest periods and nap periods as rest intervals, the Actiware software can automatically produce sleep statistics for each interval.

Tip: Refer to Quick Method and Fine Control Method for details on using the mouse and keyboard keys to set intervals

Scoring process Steps

1.   Identify bed times

   Use all inputs to determine the points in time where the subject went to bed with the intent to sleep each day and when the subject got out of bed for the last time:

   - *Diary*

   - *Event Marker*

   - *Activity Information*

   - *Sleep/wake Scores*

   - *Light Information*

Compare event markers or diary entries to the time where Activity decreases. Don't expect an exact match. Subjects aren't as precise as the Actiwatch.
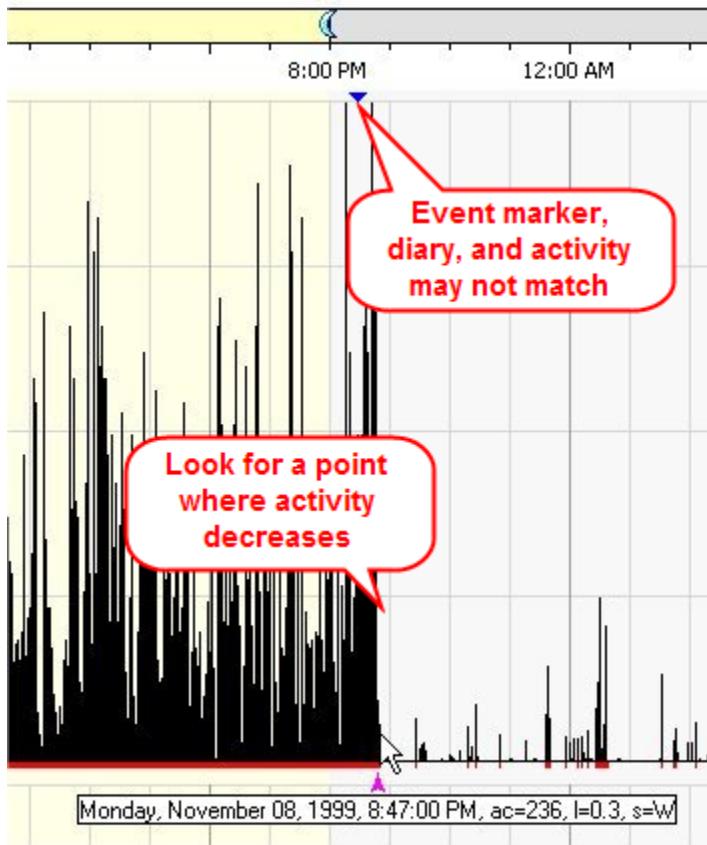
Click the mouse to view the time, activity, and sleep/wake score at that point.
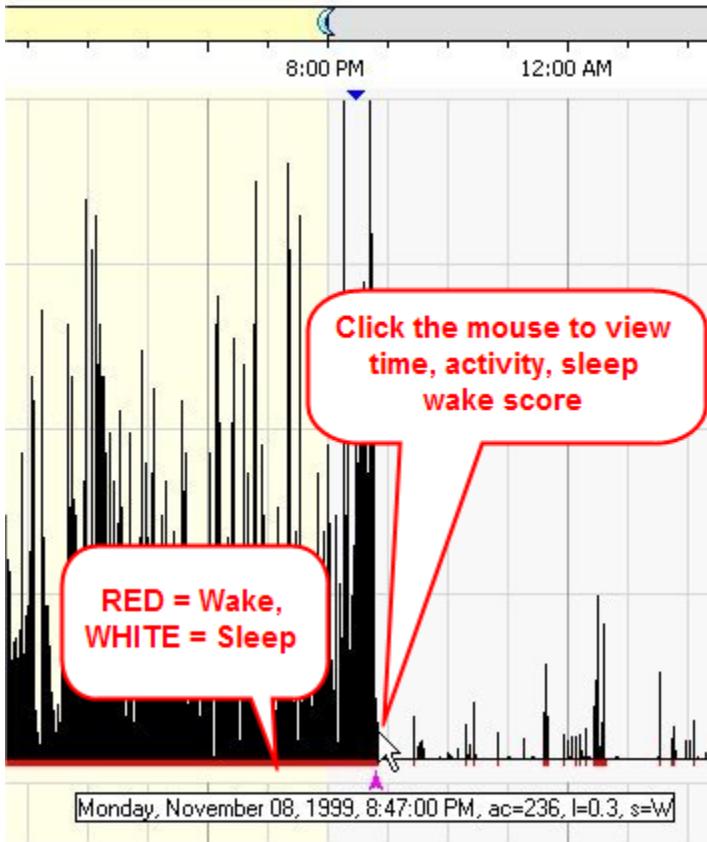
2. Select rest interval start time

    - *Use common sense to identify a bed time considering all of these inputs. Precision is not required.*

    - *Right click on the chosen time and select Set Interval Start from the pop-up menu.*

8:00 PM   12:00 AM   6:0

Start UNKNOWN: 8:47:00 PM

Red flag appears at interval start time

Right click and select Set Interval Start

Monday, November 0   99, 8

Save Current View as My Default View	
Restore My Default View	
Save Analysis	
Save Analysis As...	
Edit Analysis Properties...	F2
Set Interval Start	
Set Interval End	
Insert Rest Interval	Ctrl+R
Insert Excluded Interval	Ctrl+E
Insert Custom Interval	Ctrl+C
Insert Forced Sleep Interval	Ctrl+S
Insert Forced Wake Interval	Ctrl+W
Clear Interval	Del
Clear All Intervals...	
Refresh	F5
Help	F1

3. Identify get-up time

    Compare event markers or diary entries to the time where activity increases. Don't expect a precise match.

    - *Red or white marks below activity indicate sleep or wake. Look for transition.*

    - *Click the mouse to view the time, activity, and sleep/wake score at any point.*

Start UNKNOWN: 8:47:00 PM

RED = Wake,
WHITE = Sleep

Click the mouse to
view time, activity,
sleep wake score

Tuesday, November 09, 1999, 4:20:00 AM, ac=384, l=25.5, s=W
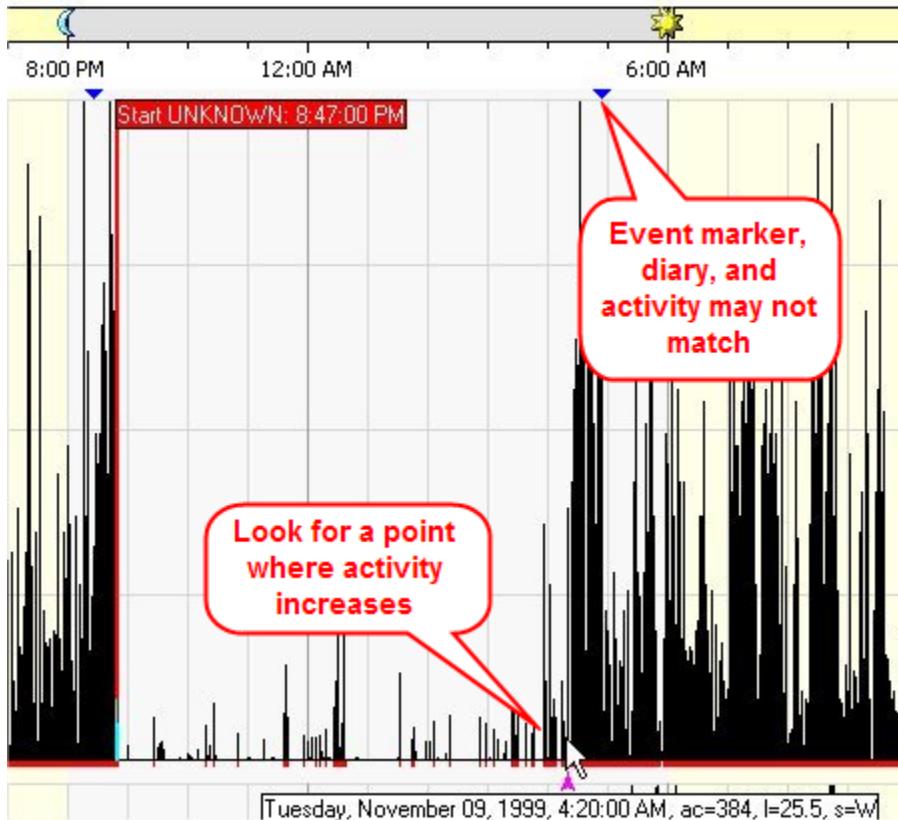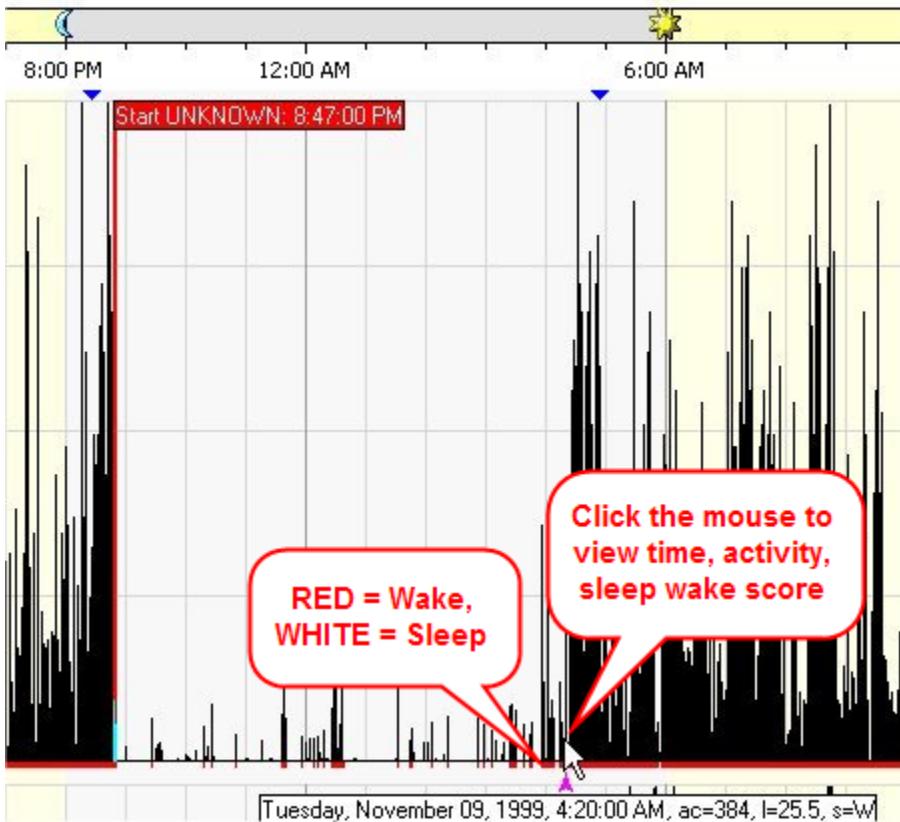
4. Select rest interval end time.

- *Use common sense to identify a get up time considering all of these inputs. Precision is not required.*

- *Right-click on the chosen time and select Set Interval End from the pop-up menu.*
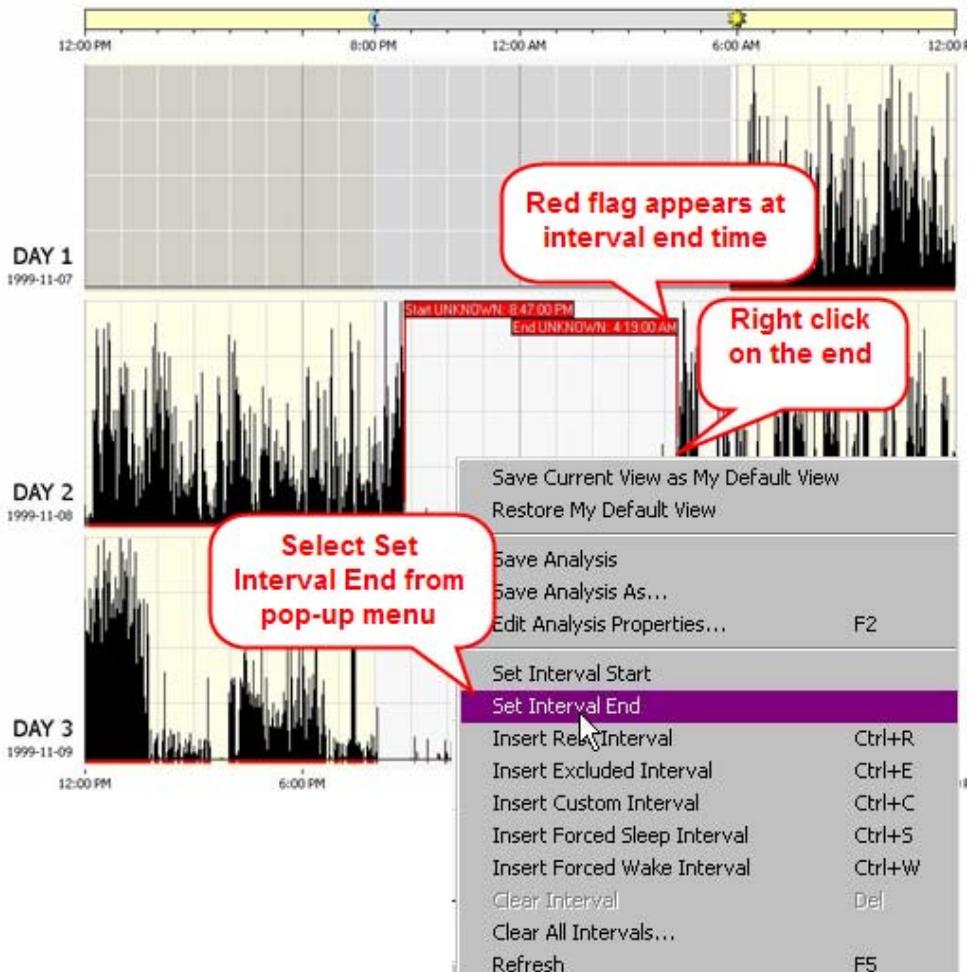
5. Insert the rest interval**.**

- *Right-click and select Insert Rest Interval from the pop-up menu.*
- *Rest intervals appear in blue.*
- *Repeat for other days*
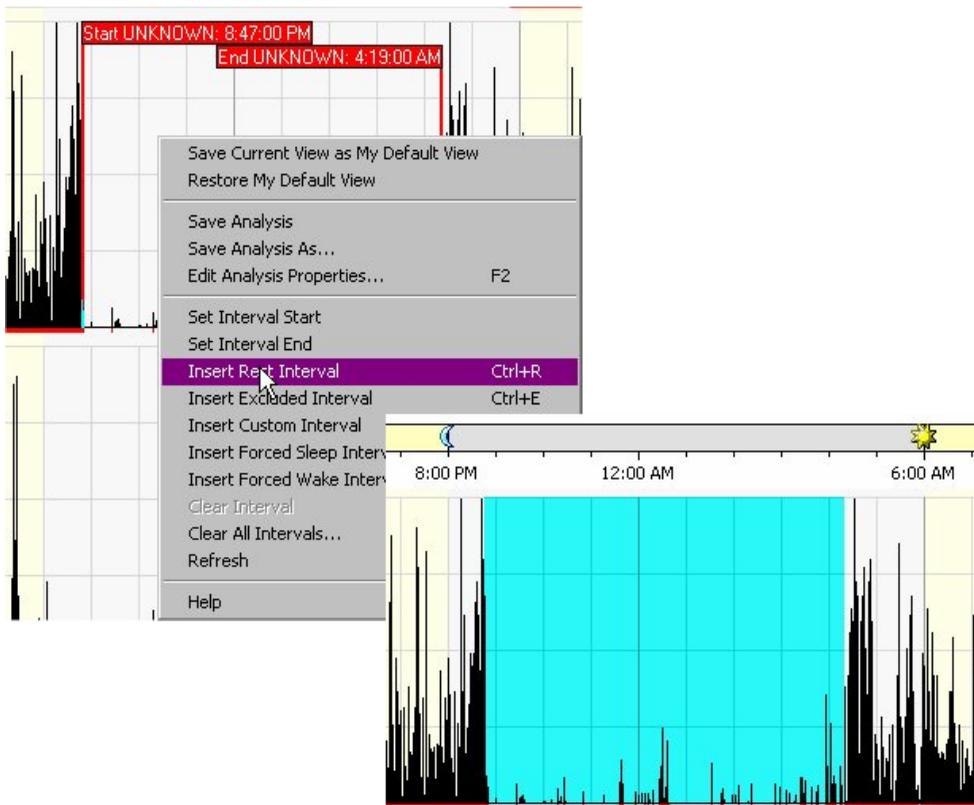
6. Identify nap times

    Utilize all inputs to identify periods of inactivity/rest during typically active periods that are at most a few hours long:

    - *Sleep logs/diaries*
    - *Event marks*
    - *Decreases in activity*
    - *Sleep/wake scoring (red & white markings)*

Potential naps
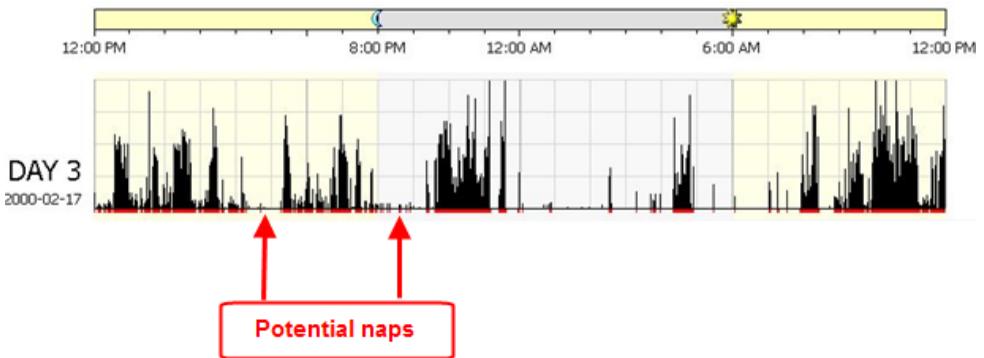
7. Identify the nap start and select the interval start.

- *Use diary, event marker data if available.*

- *Locate periods of inactivity using activity data itself or red & white markings on actogram.*

- *Set Interval Start and End Times as with the Time in Bed for major sleep periods.*

First, left-click to select time

Start UNKNOWN: 4:13:00 PM

Then, right-click to set the start flag

8. Identify the nap end and select the interval end.

- *Use diary, event marker data if available.*

- *Locate point of resumed activity using activity data itself or red & white markings on actogram.*

- *Set Interval Start and End Times as with the Time in Bed.*
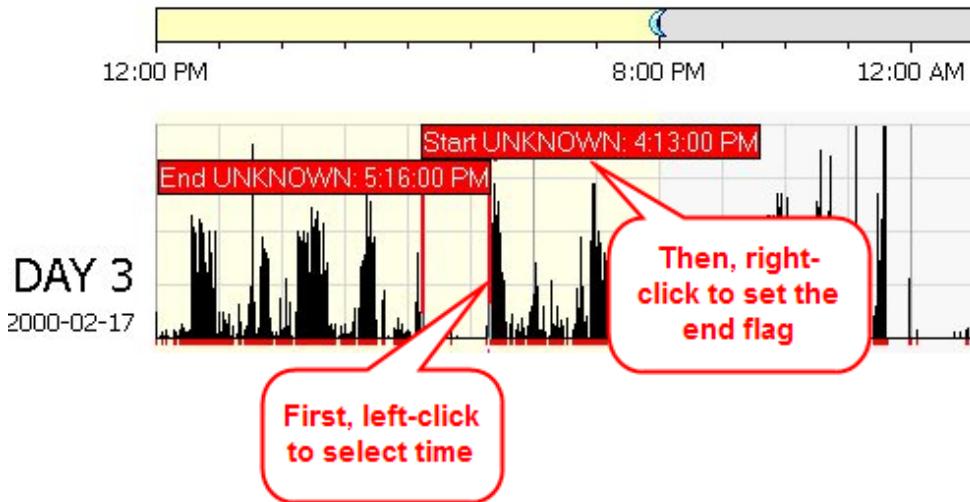
9. Insert the rest interval.

- *Right-click and select Insert Rest Interval from the pop-up menu.*
- *Rest intervals appear in blue.*
- *Repeat for other naps.*
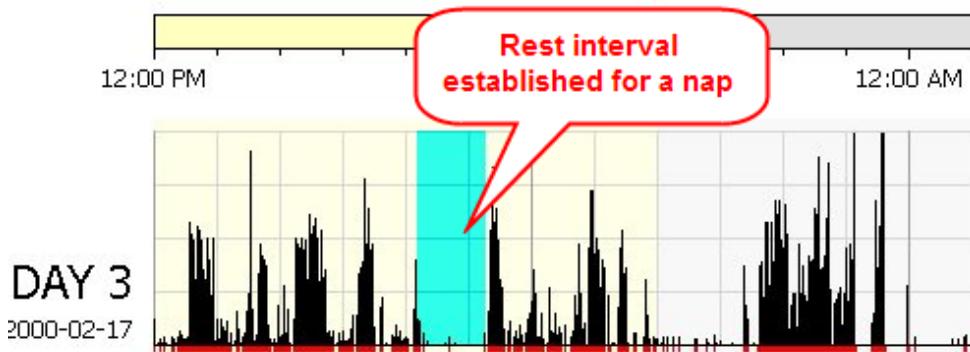
10. Identify and exclude invalid data.

- *Exclude data from consideration/calculations.*
- *Excluded because of removal or other concerns.*
- *Identify interval start and end times and insert an Excluded interval.*
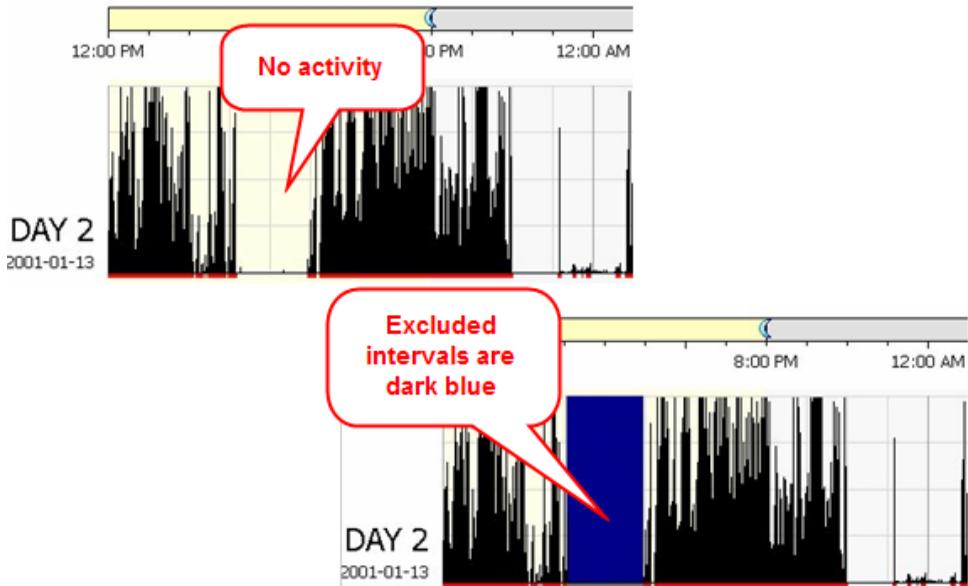
Once intervals of rest are marked, it is easy to determine if they follow a pattern.

- *Are rest intervals of a relatively consistent length?*

- *Are rest intervals consistent in their distribution through the day?*

- *Are there rest intervals during typical sleep times, or do they indicate naps?*

Some examples of rest or sleep wake patterns include the following:

- Normal vs. irregular sleep patterns

Normal
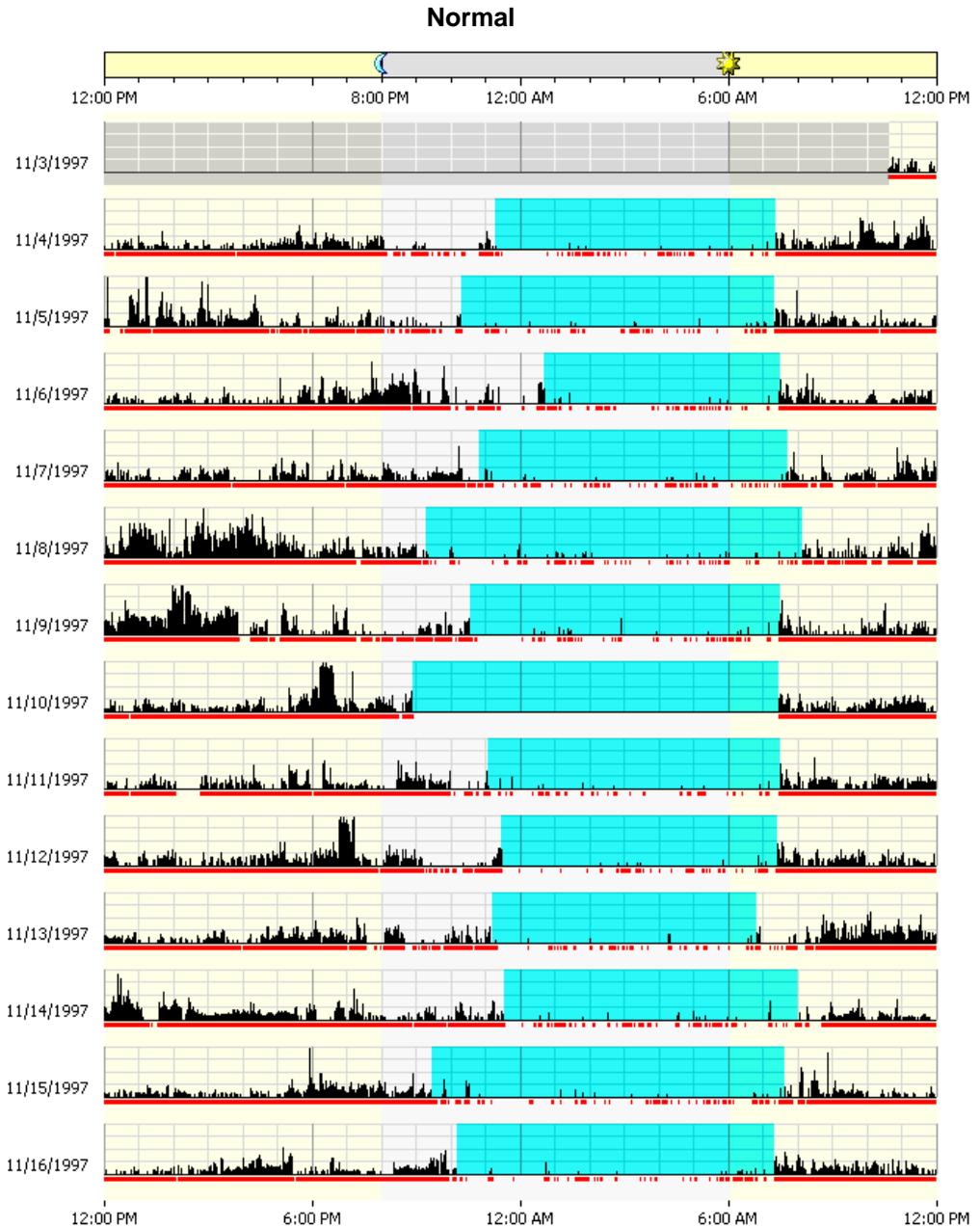
Irregular (insomniac)
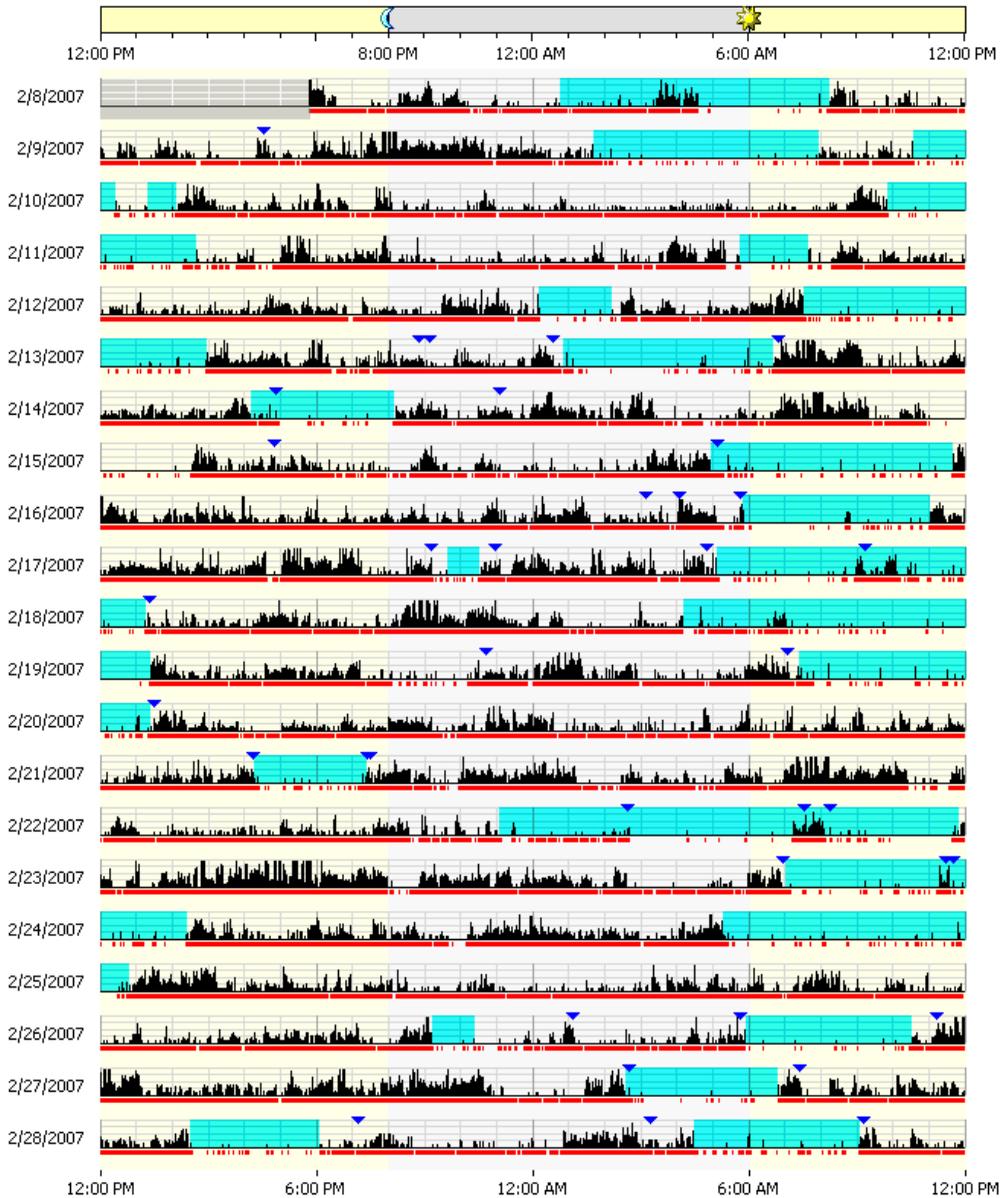
- Delayed sleep phase
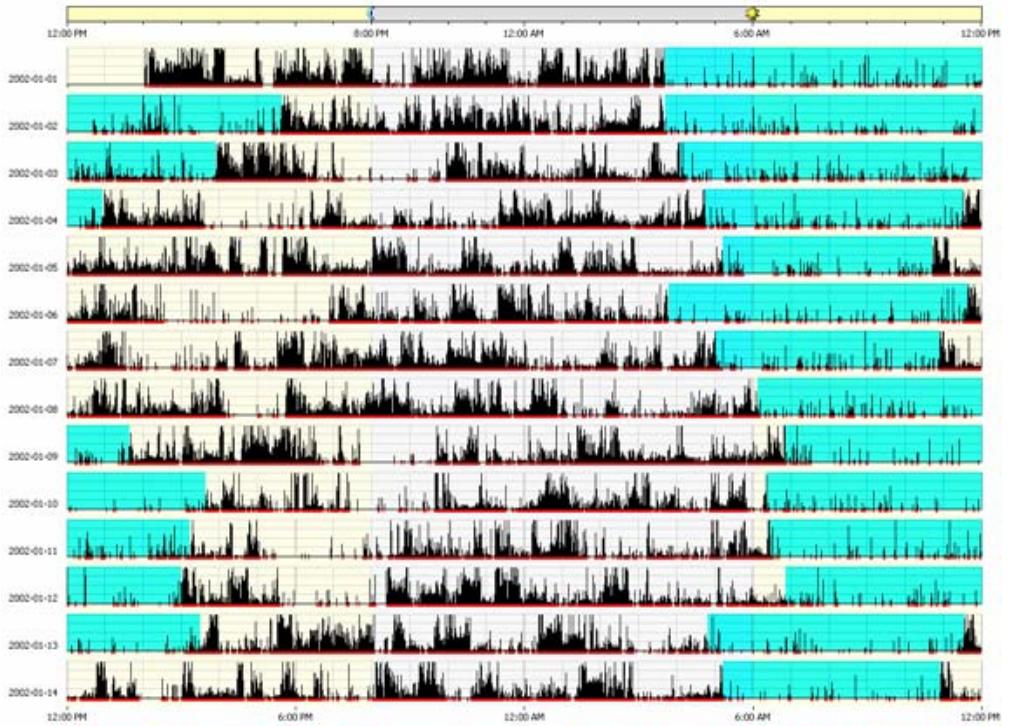
- Non-entrained (Circadian) or free-running
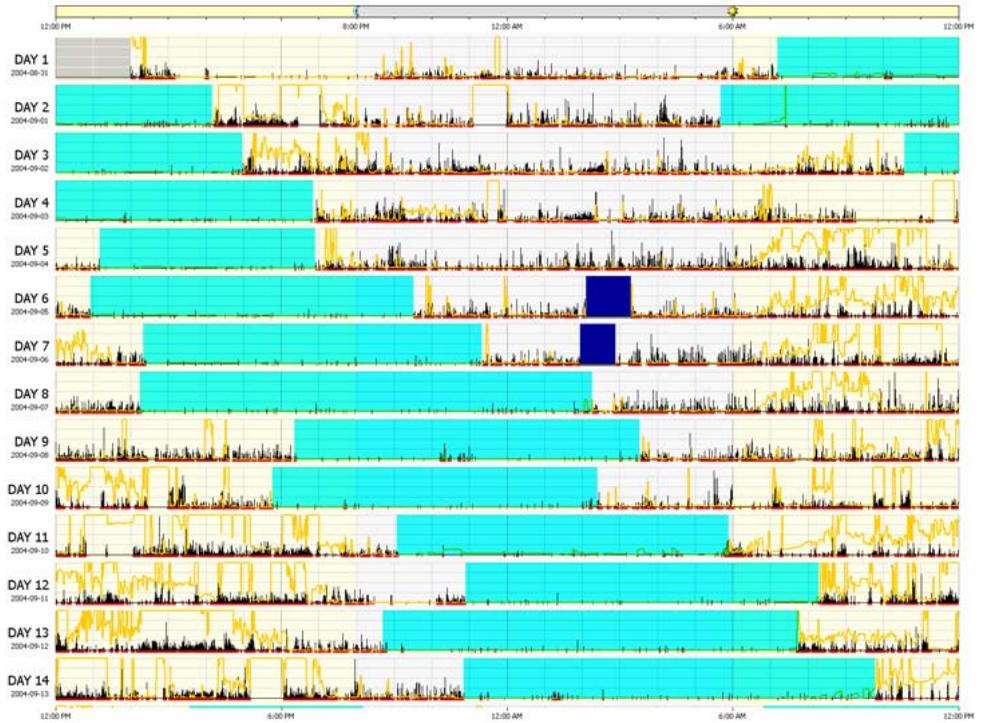
- Shift work sleep disorder
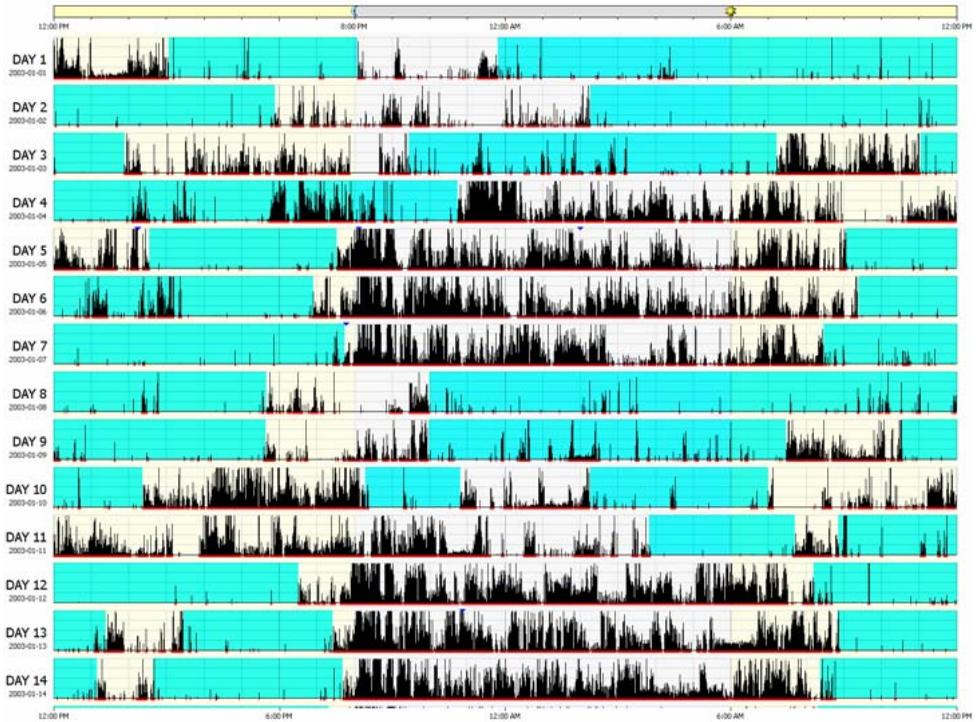
The patterns can also help you to understand basic sleep scheduling and provide some general insights:

- *Good/poor sleep hygiene*

- *Circadian rhythms disorders*

- *Compliance with schedule-based therapies*

- *Continued compliance during follow up*

Sleep/Wake Analysis

Actiware scores all epochs as either sleep or wake. Whether a particular epoch is scored as wake is determined by comparing activity counts for the epoch in question and those immediately surrounding it, to a threshold value set by the researcher. If the number of counts exceeds the threshold, the epoch is scored as wake. If it falls below, or is equal to, the threshold, the epoch is scored as sleep.

Sleep $=$ Total Activity Counts $\leq$ Wake Threshold Value

Wake $=$ Total Activity Counts $>$ Wake Threshold Value

Calculating Total Activity Counts

Actiware calculates total activity counts based on the sampling epoch. Below are four diagrams showing how this scoring calculation is done.
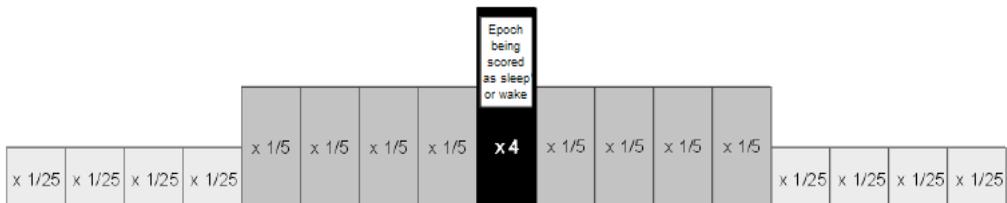
15-second sampling epochs
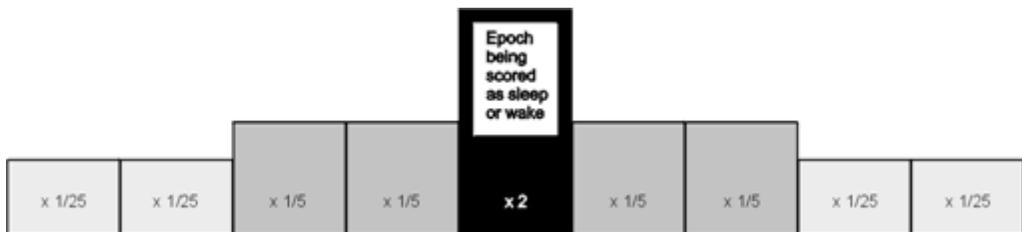
30-second sampling epochs
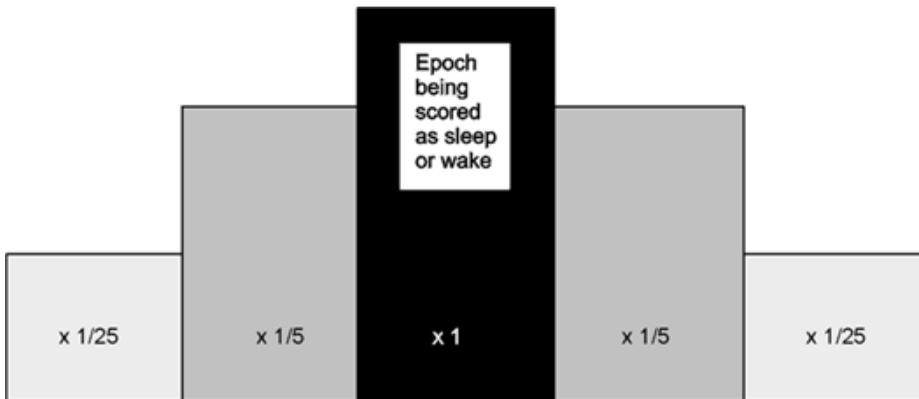
1-minute sampling epochs
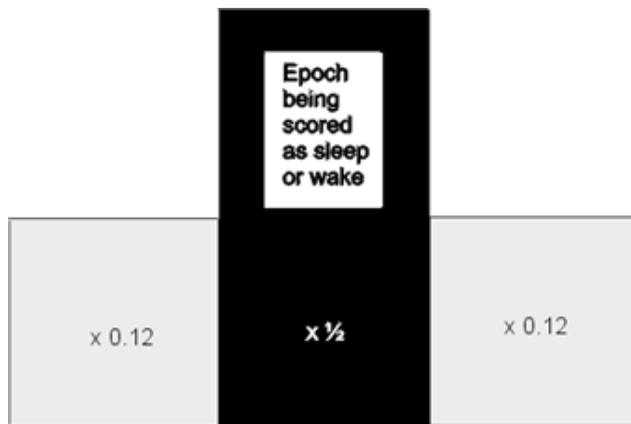
2-minute sampling epochs

For instance, assume a 1-minute sampling epoch and the following activity values on/and surrounding the time 12:00.

Time	Corresponding Activity Data
11:58	100
11:59	42
12:00	20
12:01	13
12:02	67

The total activity value for the 12:00 epoch is computed using this formula:

$$100 * (1/25) + 42 * (1/5) + 20 + 13 * (1/5) + 67 * (1/25) = 37.68$$

If this value is less than or equal to the wake threshold value (below) then the epoch would be scored as sleep.

Wake Threshold Values

The total number of activity counts calculated above is compared to the wake threshold value selected by the researcher. These thresholds are listed in the following table.

Wake Threshold Selection	Wake Threshold Value*
Low	20
Medium	40
High	80
Automatic	Computed automatically based on activity data
Custom	User-selectable value

*The Automatic Wake Threshold Value calculation is this:

1. Sum the activity counts for all epochs of the data set.

2. Count the number of epochs scored as MOBILE for the data set (the definition of MOBILE follows).

3. Compute the MOBILE TIME (number of epochs scored as MOBILE from step 2 multiplied by the Epoch Length) in minutes.

4. Compute the Auto Wake Threshold = ((sum of activity counts from step 1) divided by (MOBILE TIME from step 3)) multiplied by 0.88888.

Definition of Mobile

An epoch is scored as MOBILE if the number of activity counts recorded in that epoch is greater than or equal to the epoch length in 15-second intervals. For example, there are four 15-second intervals for a 1-minute epoch length; hence, the activity value in an epoch must be greater than, or equal to, four, to be scored as MOBILE.

Viewing Statistics

Actigraphy and Polysomnography (PSG) share terminology but are different technologies and are applied under different circumstances. The following parameters, tracked over time, are the most important in Actigraphy:

- Time In Bed
- Total Sleep Time
- Wake After Sleep Onset
- Sleep Efficiency
- Number of Wake Bouts
- Sleep Onset Latency

Statistics for rest periods as well as for sleep periods are automatically calculated. Many sleep statistics are only available on the **Sleep** tab on the Statistics Table.

To view the Statistics Table:

1. Select **View > Statistics Table** from the main menu bar, or click the Statistics icon (☐) on the standard toolbar.

2. Click on the tabs at the top of the window to view calculated statistics for each type of time interval.

   Use the horizontal and vertical scroll bars to move through the list of intervals or to view different columns of statistics. You may want to maximize the window size by clicking the 'Maximize' button in the upper-right corner.

3. Hold the mouse pointer over each statistic column to see a brief description of each statistic.

4. Use the **Interval > Add Interval** menu, or use the Actogram to add and clear intervals.

Use the Options window to specify the content shown on the Statistics Table:

1. Select **Tools > Options** from the main menu bar.

   The Options window opens and displays several tabs.

2. Click on the **Statistics** tab and select options to include or exclude from the Statistics Table.

   Actiware includes Select All, Deselect All, and Restore Defaults buttons for ease of use.

3. Click **OK** to save your selections.

   Your selections appear in the Statistics Table and are included in exported and printed data.

Note: *The selections that you make here also impact the content of exported files and printed reports.*

See *Statistics Tab* for additional information.

Viewing the Data List

The Data List allows you to view a listing of the currently active data as a function of time (epoch-by-epoch).

To display the Data List:

1. Select **View > Data List** from the main menu bar, or click the Data List icon (▦) on the standard toolbar.

   The Data List window is displayed.

2. Click the **Epoch-by-Epoch List** tab or the **Marker/Score List** tab to view each type of list.

3. Use the vertical and horizontal scroll bars to move up and down each List and to pan across data columns as necessary.

   You may want to maximize the window size by clicking the 'Maximize' button in the upper right corner.

4. Hold the mouse pointer over each data column to see a brief description of the data in each column.

Use the Options window to specify the content shown on the Data List Columns:

1. Select **Tools > Options** from the main menu bar.

   The Options window opens and displays several tabs.

2. Click on the **Data List** tab and select options to include or exclude from the Data List Columns.

   Actiware includes Select All, Deselect All, and Restore Defaults buttons for ease of use.

3. Click **OK** to save your selections.

   Your selections appear in the Statistics Table and are included in exported and printed data.

See *Data List Tab* for additional information.

Viewing the Graph

The Graph window displays Actiwatch data along a single axis. Depending on the type of Actiwatch used, the graph will display activity data, white light, red, green and blue light, sleep/wake, wrist on/off, manual score, scheduled score, and marker data..

To view a data graph:

1. Select **View > Graph** from the main menu bar, or click the graph icon on the standard toolbar.

   The actogram data is displayed in a Graph window. When viewing a graph, the graph icons are available in the standard toolbar.

Notes:

- To display the values at a single point in time, left-click and a red line appears on the graph. The values for that epoch are displayed in a box below the graph.

- To move the red line left or right, press the left and right arrow keys on your keyboard. Pressing the arrow keys when the red line is not present scrolls the graph one data point left or right.

- To change the time scale, select a time period (minutes, hours, etc.) and a numeric value from the Actogram/Graph View toolbar.

- To select or deselect items to display, toggle the "visibility" buttons on the Actogram/Graph View toolbar.

- To change the activity scale, white light scale, or color light scale, change the appropriate drop-down on the Actogram/Graph View toolbar.

- If you activate the graph by double-clicking in an actogram window, a 24-hour period of data is displayed.

- If you activate the graph from any other area of the application, the entire data record is displayed.

- To zoom in, place the mouse at the left edge of the area of interest, then click and drag a rectangle to the right, then release.

- To zoom out, right-click on the graph and click **Refresh Graph**.

- To move forwards and backwards through the time frame, use the horizontal scroll bar at the bottom of the graph window.

- Left-clicking the mouse on any data point displays the recorded value in the status bar at the bottom of the window.

- Data is displayed according to the following colors:

  - **Black** = Activity

  - **Yellow** = White light

- RGB Light:
  - Red
  - Green
  - Blue
- Score or Marker Indicators:
  - **Red** = No Response
  - **Blue** = Marker button presses (Actiwatch-16/64) or No Response (Actiwatch-Score)
  - **Magenta** = Prompted score (Actiwatch-Score)
  - **Green** = Manual score (Actiwatch-Score)

You may perform one of the following functions with the graph:

- Print the graph (select **File > Print Graph** from the main menu, or right-click the graph and select **Print Graph** from the pop-up menu).

- Copy a picture of the graph to the Windows Clipboard (select **Copy > Graph** from the main menu).

Saving an Analysis

You can save your settings and results for any Actogram Analysis at any time.

To save an analysis:

1. Right click in the actogram

2. Select the **Save Analysis** option from the pop-up menu.

3. Type a name for the Actogram Analysis and click **Save**.

You can also save an analysis by selecting **Analysis > Save** from the main menu. This is especially helpful when an actogram is not already open.

Printing Reports

You can generate a printed report of your actogram and statistical results for the currently selected analysis.

Note: *The contents of the printed report can be customized by selecting **Tools > Options** from the main menu bar to display the Options window. Use the **Statistics** and **Print Report** tabs to select the content you want to include in the printed report. You may specify any of the available statistical elements, the actogram, and one or more*

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interval types.

To generate a report:

1. Open an analysis by double-clicking on its icon in the Database Viewer.

2. Select **File > Print Report** from the main menu bar, or click the Print icon 🖨 on the Standard toolbar.

    The Windows Print window is displayed.

3. Select the printer, number of copies, paper orientation (such as Portrait or Landscape), etc. and click **OK**.

Importing/Exporting Files

Import Actiwatch Data (AWD) Files

This option is used to import data to the currently open database. You can import data files collected with previous versions of Actiware (Actiware-Sleep/Rhythm v3.4 and earlier).

Note: AWS files cannot be imported. Only AWD (Actiwatch) files can be imported.

To import an AWD file:

1. From within the database view, left-click on a subject to which you want to import the AWD file. (If you do not already have a subject created, select **File > New Subject** from the main menu bar to open a subject.)

2. Select **File > Import AWD** from the main menu bar.

    The Select File to Open window is displayed.

3. Locate the AWD file to import, and click **OK**.

    When the file is successfully imported, a confirmation message is displayed.

4. Click **Yes** to edit the Actiwatch Data properties or click **No** to bypass.

    The data is now ready for analysis.

Exporting Data - Single File

Once you have added intervals and analyzed your data, you can export the retrieved raw data or statistical results to a text file that can be easily loaded into Microsoft Excel, FAST, or a database application of your choice for additional processing.

There are three types of export files that can be created using Actiware:

•   Standard Individual Export File

This is a comma separate variable-length (.csv) ASCII text file that can be opened directly by Microsoft Excel. It contains the data and analysis results for one analysis.

To create this file, select **File > Export** from the main menu bar or click the icon on the Standard toolbar. When prompted, enter a file name and location.

Note: *The contents of the export file can be customized using the Tools > Options window. Use the Statistics, Data List, and Export tabs to select what content you would like in the export file.*

Instead of creating a file, you can copy the file contents directly to the Windows Clipboard:

1. Select **Copy > Export Text**.

2. Paste the contents into your program of choice by pressing **CTRL + V**.

- Fast™ Export File

This is a tab-delimited ASCII text (.txt) file designed specifically for importing into the Fatigue Avoidance Scheduling Tool™ software. A short header, sleep/wake scores, and per epoch time stamps for the currently selected analysis are included in this export file.

To create this file:

1. Select **File > FAST Export** from the main menu bar.

2. When prompted, enter a file name and location.

- Combined Export File

This is a comma-separated variable length (.csv) ASCII text file that can be opened directly by Microsoft Excel. It contains the data and analysis results for intervals from multiple analyses. These analyses can be taken from any number of subjects or Actiwatch data records in the currently opened database.

Use the Text File Export Batch Wizard, accessible by selecting **Tools > Text File Export Batch** from the main menu bar to create the file (or many Standard Individual Export Files).

Note: *Actiware CT does not allow you to select Copy > Export Text or File > FAST Export because these are unsecured outputs that do not contain an electronic or digital signature.*

Batch Exporting Data - Multiple Files

This option is used to export data from multiple analyses from the currently open database. You can elect to send the data to individual text files or to a single composite file.

To execute a batch export:

1. Select **Tools > Text File Export Batch** from the main menu bar.

    The Text File Export Batch Wizard opens.

2. Confirm that the currently active database contains the data you want to export and click **Next**.

3. Select the type of output you require (**Individual Export Text Files** for each analysis, or **Combined Export File** for multiple analyses).

4. Select the destination of the exported data by clicking the **Browse** button.

5. Click the **Options** button to make any changes to the data selected to export.

6. Click **Next**.

    The Select Data to Export window is displayed.
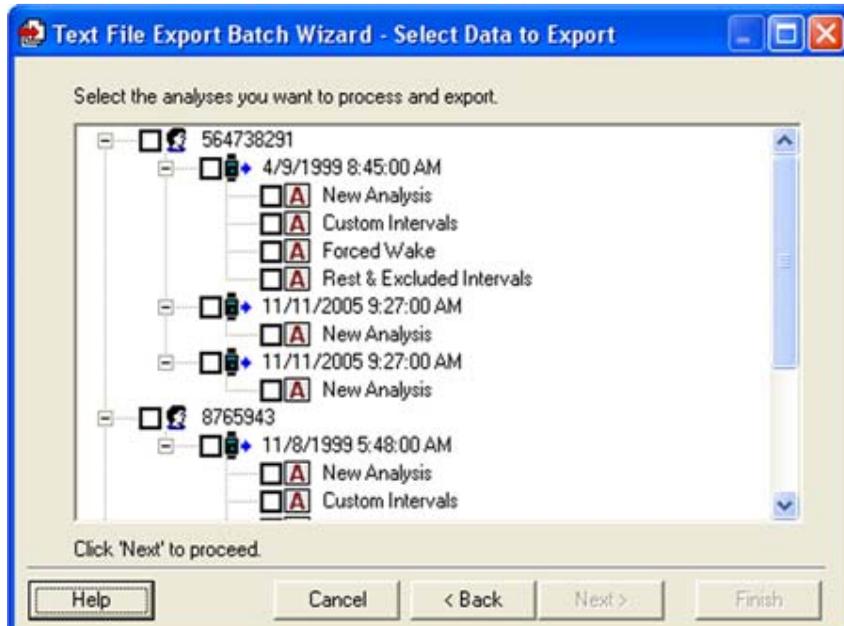
Hidden data is indicated by a red circle with a diagonal line through it.
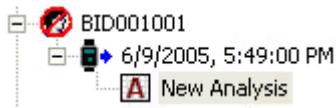
7. Select the analyses that you want to include in the export file by clicking the applicable check boxes and click **Next**.

Note: The controls for this window are hierarchical. If you select a subject, or Actiwatch data entry all analyses associated with that subject or Actiwatch data set will be included in the export file.

Note: Hidden subjects are shown in the display.

8. Select the **Suppress Errors Messages** check box if you do not want to be prompted should an error occur during the batch process.

   Note: If a file already exists, an automatic filename will be created.

9. Select the **Overwrite Existing Files** check box if you want to overwrite existing export file(s) without being prompted.

10. Click **Next** to process your data and create the export.

11. Click **OK** to acknowledge the completion of the batch export process.

   If any errors occur, you have the option to view the log file for details. You can also Restart the batch process. If you restart the process you may choose to overwrite the existing file or rename the file.

12. Click **Finish** to complete the Export Batch Wizard.

Notes

Chapter

4

Advanced Actiware Features

Security

When you launch the Actiware CT software application, the Security Log on window appears.
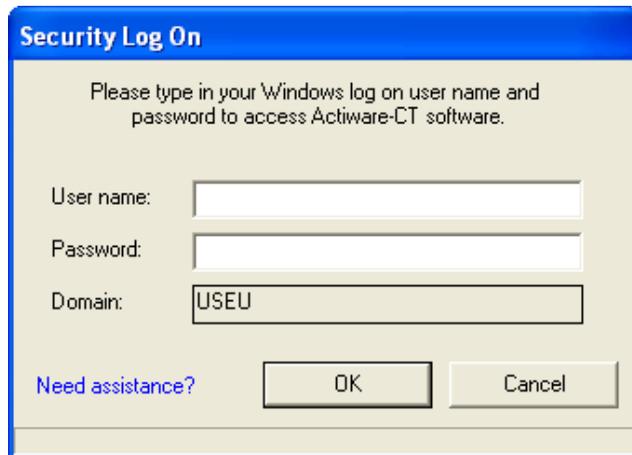
1. Enter the **User name** and **Password** that you would normally use to access the Windows operating system. (For more information on user names and passwords, refer to *How to determine your log in user name* and *How to create or change your password*.)

2. Click **OK**.

    *When you are adding a new subject, attempting to save a file, or making any changes to a subject, Actiwatch data, or analysis, Actiware CT prompts you for your **User name** and **Password**.*

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3. Enter your **User name** and **Password**.

4. Review the signature meaning.

5. Add any comment text in the space provided.

6. Click the **Sign and Save** button.

   The file now carries your electronic signature and an Audit Trail is attached to the data file. The meaning of the signature is also recorded in the data file.

Database Validation and Back-up

The database is validated and automatically backed-up when:

- Opening a database.

- Retrieving data from an Actiwatch.

- Closing a database and exiting Actiware.

Each record's digital signature is verified and each revision history is checked. Hence, any attempt to delete or change data stored in an Actiware database is detected, making the database inaccessible.

Export Files

Export files created by Actiware, both individual and combined export files, are signed with an electronic signature, including a digital signature. The purpose is to assist customers in complying with 21 CFR Part 11.

For assistance in verifying this signature for your validation purposes, please contact product support.

How to determine your log in user name

1. Click **Start**.

2. Right-click on **My Computer**.

3. Click **Manage**. The Computer Management window opens.

4. Expand **Local Users and Groups**.

5. Expand **Users**. This is a list of all local users.

6. Find your account in the **Full Name** column. The corresponding item in the **Name** column is the user name you *must* use to log into Actiware CT.

7. Close the Computer Management window.

How to create or change your password

Actiware CT does not allow BLANK passwords. Do the following to set a password:

1. Click **Start > Control Panel**.

2. Double-click on **User Accounts**.

3. Click on your user name.

4. Click **Create a password** (or **Change my password** if you need to reset it).

5. Enter a password (twice) and click Create Password.

6. Close the User Accounts window.

Audit Trails

The Audit Trail feature of Actiware is designed to display all changes made to subjects, Actiwatch data items, and analyses. Because the relationship between these items is hierarchical, the Audit Trail window displays all the parents of any selected item.

If an analysis is selected for Audit Trail display, then the Audit Trail shows all changes for that analysis, its parent Actiwatch data item, and the subject that owns both of them.

If an Actiwatch data item is chosen for Audit Trail display, then that Actiwatch data item and its parent subject is displayed in the Audit Trail window.

The picture below is the product of right-clicking on a saved analysis and selecting the **Audit Trail** menu item. Each row in the left side of the window represents either a new data record or a change to an existing record. In the graphic below, there are five audit trail records: a subject creation and an edit to that subject, an Actiwatch data record creation, and both an analysis creation and an edit to the same analysis. Note that the highlighted row is for a subject creation and no value is listed in the right-side display for Prior Value, since there is no prior record.
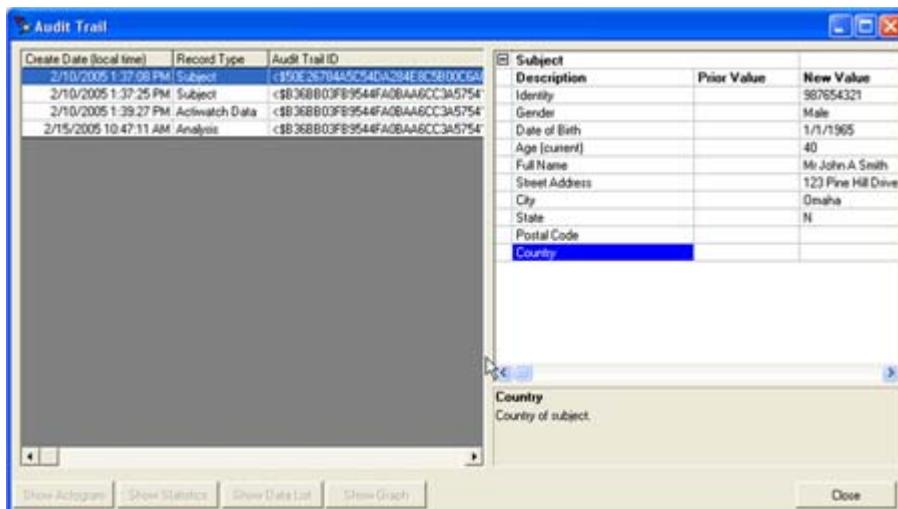
The change list on the left side of the Audit Trail window displays the date, type of change, unique ID, and digital signature information (Clinical Trials version Only) for each change. Click on a row in the table to highlight an item. The Properties area on the right side displays the details of the change for the highlighted item.

When a highlighted row represents an edit, such as the second line in the example below, then the Prior Value column contains the values before the edit.
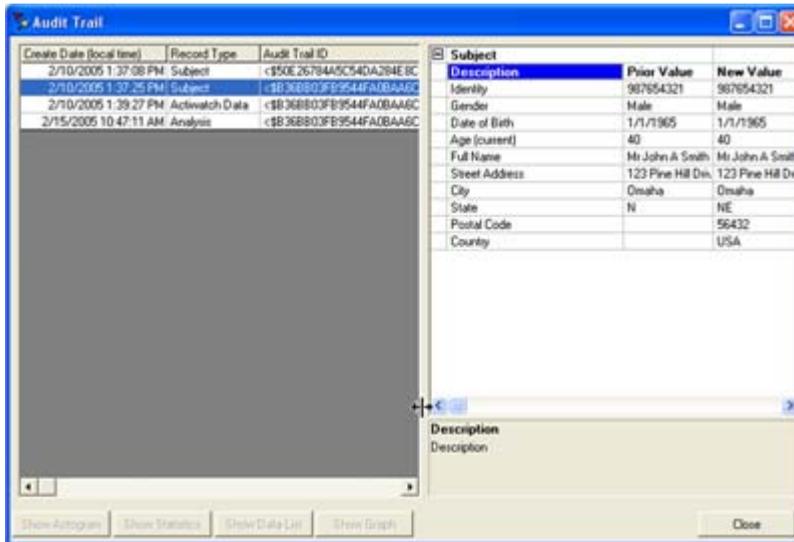
In the two previous figures, the buttons at the bottom of the screen were not enabled. The most powerful feature of the Audit Trail window is the ability to display all previous revisions of records. When an Actiwatch data item is highlighted, the **Show Graph** button is enabled. If you highlight an analysis row, then all the buttons are enabled and you can create an audit version of an actogram, statistics table, or a data list.
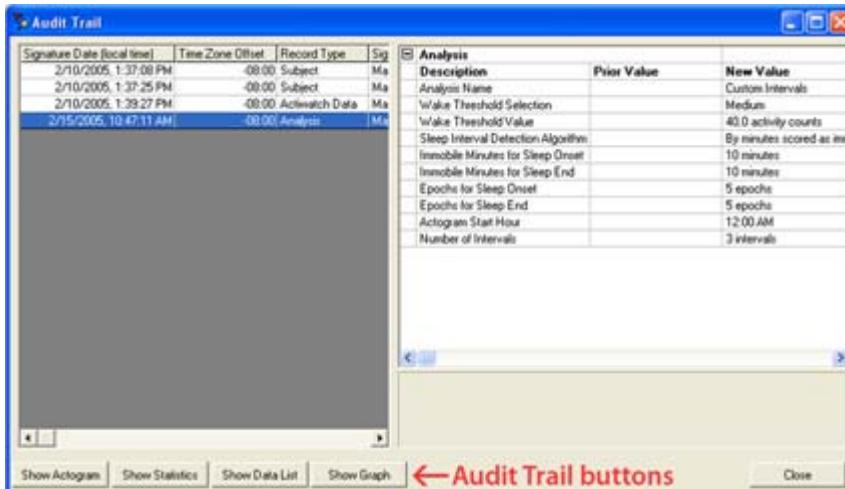
If the analysis has been edited and saved, then multiple rows are displayed, as shown in the figure above. Highlighting the last row reflects the most recent version of the analysis. Pressing the **Show Actogram** button displays the current actogram in the normal display window, except the title is preceded with the word **Audit**, as shown below.
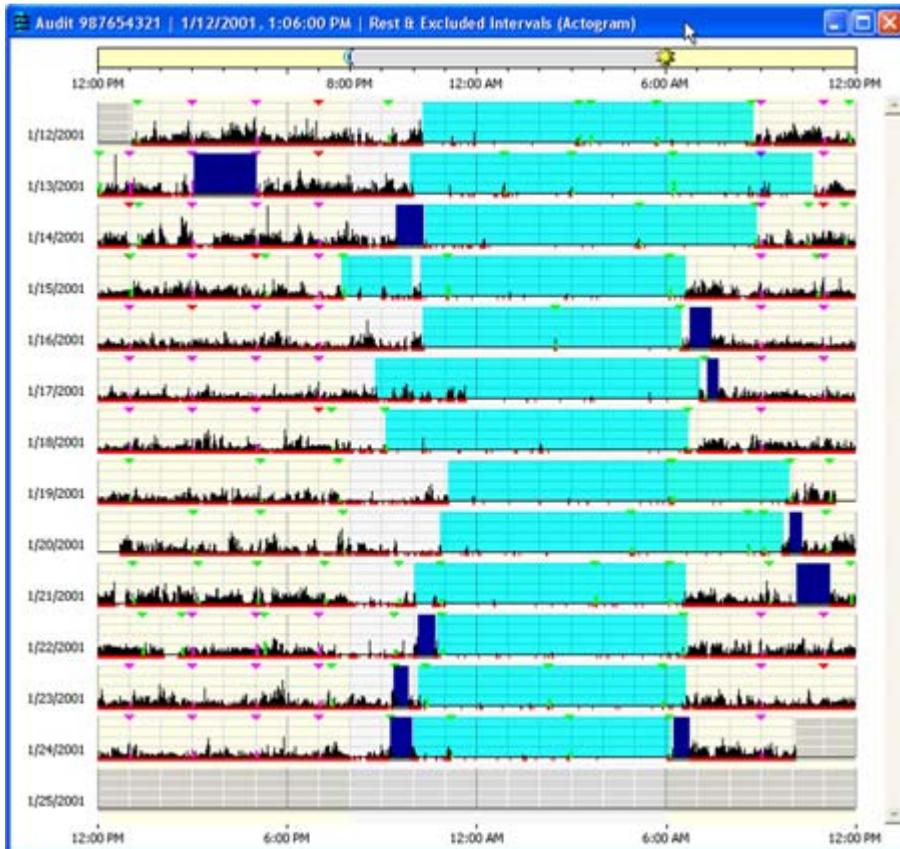
Note: Closing the Audit Trail window closes all Actograms, data lists, and statistics tables that were created by the Audit Trail window. To view historical audit items, keep the Audit Trail window open and either move it out of the way, or minimize it.

To view a past revision of the analysis, highlight the desired row and click the **Show Actogram** button, etc. Only one audit actogram can exist. If an audit actogram is open and a new audit actogram is created, the currently opened actogram is closed and the new one replaces it. The same holds true for statistics tables and data lists. Items created from the Audit Trail window cannot be edited.

Electronic Signatures

To use Actiware CT you are required to log on. The log on procedure is part of the security Actiware CT offers to protect the data that is acquired from Actiwatch.

Each time a record is created or revised, you must sign with your username and password, after which time an electronic signature is created and attached to the record.

The electronic signature in Actiware CT is considered to be the equivalent of a handwritten signature executed on paper. When the signature process is complete, the resulting secure record consists of three parts:

- Data

- Public Key

- Digital Signature

Upon signing and saving the data record, a secret, private key is used to encrypt a set of characters that represent the data. This is called a hash, or digest of the data. The result of this encryption process is the digital signature.

The data in the record is saved along with the digital signature and a public key. The public key is used to decrypt the digital signature when the record is read. When the record is read and the signature verified, the result of decrypting the digital signature (the original hash) is compared to a hash computed from the contents read from the record.

When the two hash results are found to be identical the signature is verified, and the file has not been altered or corrupted (including the signature elements that identify the signer: user name and full name, as well as the public key and digital signature).

Actiware CT Provision	Result
Authentication	The identity of the signer can be determined by anyone.
Integrity	Any alteration can be detected.
Non-repudiation	Verifies the origin or delivery of data. Protects the signer because the recipient cannot change the file. Protects the recipient because the signer cannot deny they sent it.

Because integrity is assured and authentication and non-repudiation are provided, the digital signature/public key/user name/full name inserted in every digitally signed output file can be considered the legally binding equivalent of a traditional handwritten signature.

Actiware CT software does not provide the ability to change the contents of an electronic record that has already been created. Instead, any change to a record (subject, Actiwatch data, or analysis) is recorded as a new revision with a new digital signature. Any attempt to change a

data record manually will make the file unusable by the software. Also, each time an electronic record is created, you must sign the document, and your user name and full name, along with date and time of signing, are embedded in the record.

Note: *Each revision to the data file is preserved and signed/hashed separately.*

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Acti*ware*® and Acti*ware*® CT

Actiwatch Communication and Sleep Analysis Software

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