



A Shared Vision. A Shared Future.

Instruction Manual

Actiwatch Communication and Sleep Analysis Software

Actiware® 5.0 and Actiware-CT 5.1

Actiwatch-16, -64, -Score, -L

Actireader

The screenshot displays a software application window titled "Actiwatch-Communication". The main area shows a "Sleep by Epoch List" table with the following data:

| Epoch | Date | Time | Activity | U-Motion | Sleep/Wake | Notes |
|-------|------------|------------|----------|----------|------------|--------|
| 1 | 1999-04-09 | 8:45:00 AM | 694 | 5 | Wake | NOISE |
| 2 | 1999-04-09 | 8:47:00 AM | 231 | 5 | Wake | ACTIVE |
| 3 | 1999-04-09 | 8:47:00 AM | 229 | 5 | Wake | ACTIVE |
| 4 | 1999-04-09 | 8:48:00 AM | 298 | 5 | Wake | ACTIVE |
| 5 | 1999-04-09 | 8:48:00 AM | 169 | 5 | Wake | ACTIVE |
| 6 | 1999-04-09 | 8:50:00 AM | 182 | 5 | Wake | ACTIVE |
| 7 | 1999-04-09 | 8:51:00 AM | 60 | 5 | Wake | ACTIVE |
| 8 | 1999-04-09 | 8:52:00 AM | 60 | 5 | Wake | ACTIVE |
| 9 | 1999-04-09 | 8:53:00 AM | 73 | 5 | Wake | ACTIVE |

To select or deselect displayed columns, click Tools > Options > Data List.

Navigation buttons at the bottom include: Start, Stop, Next, Previous, Back, Forward, Home, Help, File, Edit, Tools, Options, View, Window, and Exit.

Actiwatch®-16 / Actiwatch®-64 Actiwatch®-L / Actiwatch®-Score Actiware® 5.0 / Actiware®-CT 5.1

Actiwatch Communication and Sleep Analysis Software

Instruction Manual



A Shared Vision. A Shared Future.

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ActiReader is covered by the following US patent numbers: 6,129,663. Other patents pending.

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Thank You!

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Contacting Technical Support

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1

INTRODUCTION AND SETUP

Actiware / Actiware-CT

Actiware and Actiware-CT are Windows® based application software packages that are 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

Actiware-CT is also capable of clinical trial tracking and auditing in accordance with 21 CFR Part 11.

This manual describes the functions of the Actiwatch and outlines 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. You can view and analyze the rhythmicity of long-term activity-rest patterns.

Indications for Use

Intended Use

Actiware / Actiware-CT is for use only in a clinical, research, or home care provider setting.

Actiwatch-16/64

The Actiwatch®-16 or -64 is an ultra-compact, lightweight, wrist-worn activity monitor that can be used to analyze circadian rhythms, automatically collect and score data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable. An Event Marker button is available that allows the subject (patient) to enter time-stamped information and events of significance.

Actiwatch-L

The Actiwatch®-L is an ultra-compact, lightweight, wrist-worn activity and illuminance monitor that can be used to analyze circadian rhythms, automatically collect and score data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable. The Actiwatch-L does not have an Event Marker button.

Actiwatch-Score

The Actiwatch®-Score is a compact, lightweight, wrist-worn activity monitor that can be used to analyze circadian rhythms, automatically collect and analyze data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable. In addition, the Actiwatch-Score has a built-in score pad that allows the subject to subjectively assign and enter a score from 0 to 15. The score pad can be used as a substitute or in addition to the traditional patient diary used in conjunction with activity monitoring.

This system is designed to conform to the following standards:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-1 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems for Safety
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60950-1 Information Technology Equipment - Part 1: General Requirements for Safety

Important! Actiwatch 16/64, -L, -Score are not intended for use as diagnostic devices; they are intended for use as physiological parameter recorders.

Warnings and Cautions

CAUTION! US federal law restricts this device to sale by or on the order of a physician.

WARNING!

A warning indicates the possibility of injury to the user or operator.

WARNING:

- 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. Only dispose 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 Mini Mitter/Respironics Technical Support and replace any damaged parts before continuing use.
- ActiReader Only - To avoid electrical shock, disconnect the AC power supply before cleaning. DO NOT immerse the AC power supply in any fluids.

CAUTION!

A caution indicates the possibility of damage to the device.

CAUTION:

- Repairs and adjustments must be performed by Mini Mitter/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.

Note

Places emphasis on an operating characteristic.

***Note:** Additional Warnings, Cautions, and Notes may appear throughout this manual.*

Symbols

| Symbol | Meaning |
|-------------|--|
| | Attention, consult accompanying documents |
| | DC Power |
| | Type BF Applied Part |
| | Canadian/US Safety Certification |
| IPX2 | Protected against vertically falling water drops when enclosure tilts up to 15 degrees. |
| IPX7 | Protected against the effects of temporary immersion in water (Actiwatch 64, Actiwatch 16, Actiwatch-Light) |
| | Alignment Indicator (ActiReader) |
| | European Declaration of Conformity (conformance to Radio and Telecommunications Terminal Equipment (RTTE) Directive) |
| | European Declaration of Conformity (conformance to Medical Device Directive (MDD)) |
| | On (Power) |
| ○ | Off (Power) |
| | Use 9V Lithium battery only |

Installation Prerequisites

System Requirements

- Microsoft Windows® 2000 or XP operating system
Windows XP Professional required for Actiware-CT
- Computer with 2 GHz or higher process clock speed recommended;
500 MHz minimum requirement
- 512 MB RAM; 128 MB RAM minimum requirement
- 300 MB or higher recommended; 50 MB required for installation
- Super VGA (1280 x 1024) resolution video adapter and display
recommended; SVGA (800 x 600) minimum requirement
- CD-ROM or DVD drive (for installation)
- Keyboard and Microsoft Mouse or compatible pointing device
- 9-pin or 25-pin RS-232 communications serial port
- UL 1950, IEC 60950, or EN60950 approved computer
- Printer (optional)
- Note: Data for use by Actiware must reside on the local hard drive. It is not recommended to install the program files or data on a network drive.

*Note: Actiware / Actiware-CT was created for use with Windows®.
Windows is a registered trademark of the Microsoft® Corporation.*

Note: Before beginning the installation procedure, make sure that no other applications are currently running on the computer. This includes Microsoft Office® and any other utilities. These can interfere with proper installation, resulting in software conflicts.

First Time Installation If this is the first time Actiware will be installed, please continue to *Installing Actiware* later in this section.

Upgrading If you are upgrading from a previous version of Actiware (or Sleepwatch or Rhythmwatch) you should remove any previously installed versions.

See *Uninstallation Procedures* later in this section.

CAUTION! Before proceeding, back up any previously gathered data prior to installation. Store in a secure location, either on a floppy disk, CD-ROM, or within a separate drive space.

Installing Actiware / Actiware-CT

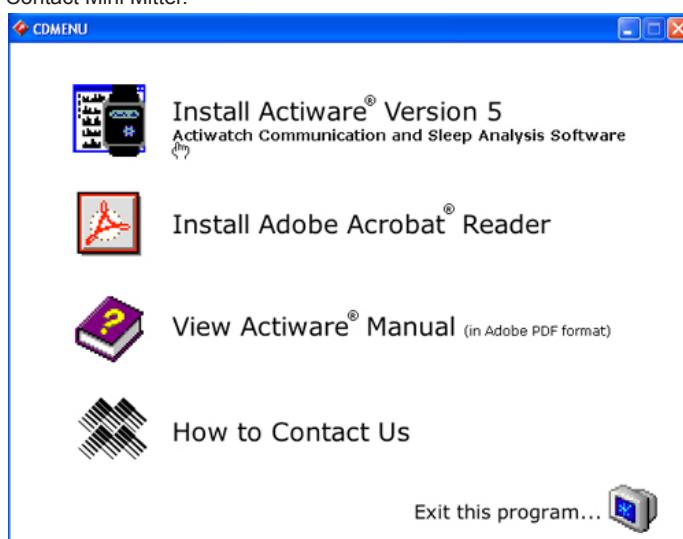
Note: You must be a member of the Administrator's group in order to install this software.

Note: Users of Actiware (Research Version) must be a member of the Power User or Administrator's group in order to run the software. Actiware-CT (version 5.1 or greater) users do not need to be a member of the Power User or Administrative group.

Installing from a CD

1. Insert the CD-ROM into the CD/DVD drive and wait a moment for the Installation Menu to appear. If the CD/DVD drive does not accommodate the autorun function, then select Start > My Computer and select the CD/DVD drive from the list and double-click to access the files. Select CDMENU.EXE and double-click.
2. Select **Install Actiware Version 5** from the menu.

Installation Menu provides several options: Install Actiware, Install Adobe Reader, View Manual, Contact Mini Mitter.



3. The InstallShield™ Wizard will guide you through the installation process.
4. Check the radio button for **I accept the terms in the license agreement**. Click the **Next** button to continue.

End-User License Agreement



Important! The Software License Agreement **must** be accepted before installation will occur.

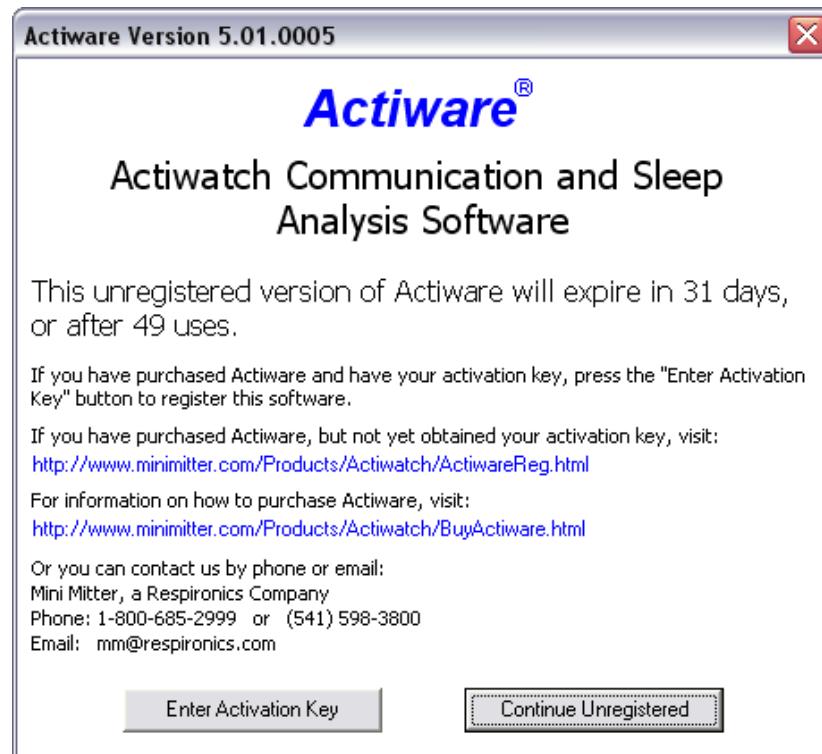
Note: Actiware-CT requires the user to authenticate using their Windows or Network username and password. Please contact your local administrator with any issues or questions.

Registering Actiware

Both versions of Actiware have a “try it before you buy it” feature. You may download or otherwise obtain an evaluation copy of Actiware and use the software prior to purchasing it. An activation key cannot be obtained without first paying for a license; however this does not prevent you from installing and running a full featured copy of Actiware for 30 days or 50 uses. Even if you have purchased Actiware, it is not necessary to immediately register Actiware. Please press the **Continue Unregistered** button to access Actiware software and contact technical support via e-mail (mm@respironics.com) at a convenient time to obtain your activation key.

NOTE: Registration is not needed for Actiware-CT 5.1 or greater.

Actiware activation window



When you purchase Actiware, a *Proof of Purchase* certificate will be shipped with the installation CD. There will be a Proof of Purchase code printed on the certificate. This code will always begin with “POP-xxxx-xxxx...” and cannot be entered into the software and applied as an activation key. To obtain an activation key, you will need to contact Mini Mitter/Respironics and give the Proof of Purchase code to a customer service associate. The best and most efficient method to contact technical support is via e-mail (mm@respironics.com). You may also call technical support at 800.685.2999 during normal business hours of 8 am to 5 pm PST. The associate will then generate an activation key and e-mail it to you. Once the activation key is applied to Actiware, it will never expire and will be valid for all future versions of Actiware 5.x. The key however, will not work in a future version 6.0 or greater.

Note: To deter the misuse of activation keys, the key can only be applied for 7 days after it is generated.

There are two parts to an activation key: the e-mail address of the registered user and the key itself. A key is very long and will look something like the following:

sleepdoctor@sleeplab.com
000016-BEMQ97-ZKNNYC-Z19ZG9-G11W7U-0TWCZT-U8W8C4-Z0WRG4-ZBJXKT-NC20CA

When you receive your activation key, cut and paste the *Registered User's* e-mail and key as shown and press **Enter Key**.

Enter the Activation Key



Registration entitles the registered user access to technical support. When contacting technical support, you may be required to provide your registration information.

Uninstallation Procedures

CAUTION! Before uninstalling, back up any previously gathered data and store in a secure location, either on a floppy disk, CD-ROM, or within a separate drive space.

Automatically Uninstalling Previous Actiware Versions

1. Select Start > Control Panel > Add or Remove Programs.
2. Review the list for any Actiware application currently installed (Actiware-Rhythm, Actiware-Sleep, RhythmWatch, SleepWatch). Select the Actiware version from the list. If the Actiware software is not in the list, a manual uninstallation will be required.
3. Click the Remove button.
4. When the confirmation pop-up window appears, select Yes to remove Actiware.

This completes the automatic uninstall process. Delete any desktop or toolbar icon shortcuts you may have created.

Manually Uninstalling RhythmWatch 2.82 or earlier

1. Using Windows Explorer, review the contents of the RhythmWatch installation folder (commonly C:\RHYTHMW). Copy any .AWD data files to a secure location such as a floppy disk or separate drive space.
2. Delete the installation folder (C:\RHYTHMW) and its contents.
3. Remove the RhythmWatch program folder from the Start menu. This can be accomplished using the Start > Settings > Taskbar and Start Menu item, or by right-clicking on the Start button and selecting Open. Also, delete any desktop icon shortcuts you may have created.

This completes the uninstall process for RhythmWatch 2.82 or earlier.

Manually Uninstalling SleepWatch 2.82 or earlier

1. Using Windows Explorer, review the contents of the SleepWatch installation folder (commonly C:\SLEEPW). Copy any .AWD and .AWS data files to a secure location such as a floppy disk or separate drive space.
2. Delete the installation folder (C:\SLEEPW) and its contents.
3. Remove the SleepWatch program folder from the Start menu. This can be accomplished using the **Start > Settings > Taskbar and Start Menu** item, or by right-clicking on the **Start** button and selecting **Open**. Also, delete any desktop icon shortcuts you have created.

This completes the uninstall process for SleepWatch 2.82 or earlier.

Manually Uninstalling Actiware-Rhythm or Actiware-Sleep 3.0

1. Using Windows Explorer, review the contents of the Actiware installation folder (commonly C:\ACTIWARE for version 3.0). Copy any .AWD and .AWS data files to a secure location such as a floppy disk or separate drive space.
2. Delete the installation folder (C:\ACTIWARE) and its contents.
3. Remove the Actiware-Sleep or Actiware-Rhythm program folder from the Start menu. This can be accomplished using the **Start > Settings > Taskbar and Start Menu** item, or by right-clicking on the **Start** button and selecting **Open**. In addition, delete any desktop icon shortcuts you have created.

This completes the uninstall process for Actiware 3.0.

Manually Uninstalling Actiware-Rhythm or Actiware-Sleep 3.1 or later

1. Using Windows Explorer, review the contents of the Actiware installation folder (commonly C:\Program Files\Actiware). Copy any .AWD, .AWS and .SWS data files to a secure location such as a floppy disk or separate drive space.
2. Remove the installed version of Actiware using the Add/Remove Programs icon in Control Panel. An item labeled Actiware – Sleep or Actiware – Rhythm should be listed here. Select it and click the **Add/Remove** button.
3. Follow the online instructions. Once the uninstall program has completed, all program files and shortcuts will have been removed. Also, delete any desktop icon shortcuts you created.

This completes the uninstall process for Actiware 3.1 or later.

Manually Uninstalling Actiware-Rhythm or Actiware-Sleep 4.0 or later

1. Using Windows Explorer, review the contents of the Actiware installation folder (commonly C:\Program Files\Actiware). Copy any .AWD, .AWS and .SWS data files to a secure location such as a floppy disk or separate drive space.
2. Remove the installed version of Actiware using the Add/Remove Programs icon in Control Panel. An item labeled Actiware – Sleep or Actiware – Rhythm should be listed here. Select it and click the **Add/Remove** button.
3. Follow the online instructions. Once the uninstall program has completed, all program files and shortcuts will have been removed. Also, delete any desktop icon shortcuts you created.

This completes the uninstall process for Actiware 4.0 or later.

Automatically Uninstalling Actiware / Actiware-CT 5.0 or later

1. Select Start > Control Panel > Add or Remove Programs.
2. Select Actiware Version 5 from the list. Click the **Remove** button.
3. When the confirmation pop-up window appears, select **Yes** to remove Actiware.

This completes the uninstall process for Actiware 5.0 or later. Also, delete any desktop icon shortcuts you created.

ActiReader Setup

Connecting ActiReader

ActiReader or an Actiwatch Reader is necessary to communicate with an Actiwatch. Connection to a desktop computer or a laptop computer is very similar to any other peripheral device. Upon starting Actiware, you will be prompted to set up the COM port to recognize the ActiReader.

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

Computer with ActiReader



Note: If you have an earlier design of Actiwatch Reader, refer to Actiwatch Reader later in this manual.

ActiReader

1. Connect the serial communication cable (supplied) to a COM port on your computer. Actiware's Select COM Port Wizard will assist in determining and setting up the appropriate COM port. The COM port can be changed at anytime.
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 battery must be replaced (See *Replacing the ActiReader Battery* later in this manual) or the external power supply must be used.

- **External Power Source**

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

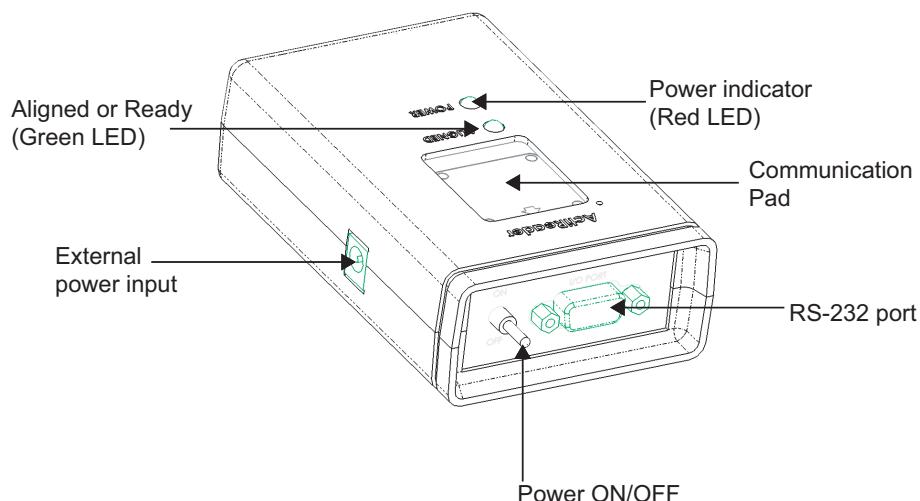
- **Power ON/OFF switch**

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

- **POWER (Red LED)**

Whether using external power or the internal battery, the red LED will light when the Power switch is **ON**.

ActiReader Features



- **ALIGNED (Green LED)**

When the Actiwatch is aligned properly and the communication wizard is active, this green LED will light.

- **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.

- **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.

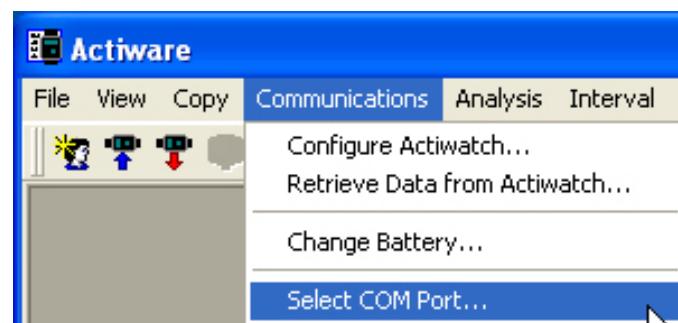
Note: The ‘ALIGNED’ green LED will not light until appropriate portions of the Communications Wizard are in use when the COM port is on (see page 3-1, later in this manual).

Selecting the COM Port

1. Open the Actiware software program.
2. From the menu toolbar, select **Communications > Select COM Port**.

This will start the COM Port Wizard which will assist you in searching for an available serial communication port on the computer (See illustration on next page).

Start the COM Port Wizard

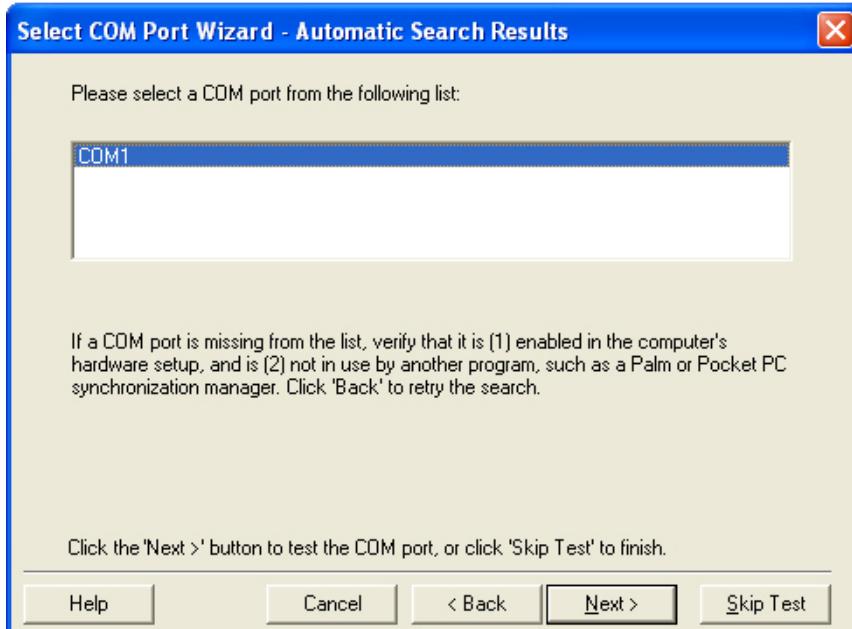


COM Port Wizard Welcome window



3. Click the **Next** button and the Wizard will search for available COM ports. When the search is completed, use your mouse to highlight the COM port to which you connected the ActiReader.

Select the COM port from the list provided by the Automatic Search Results



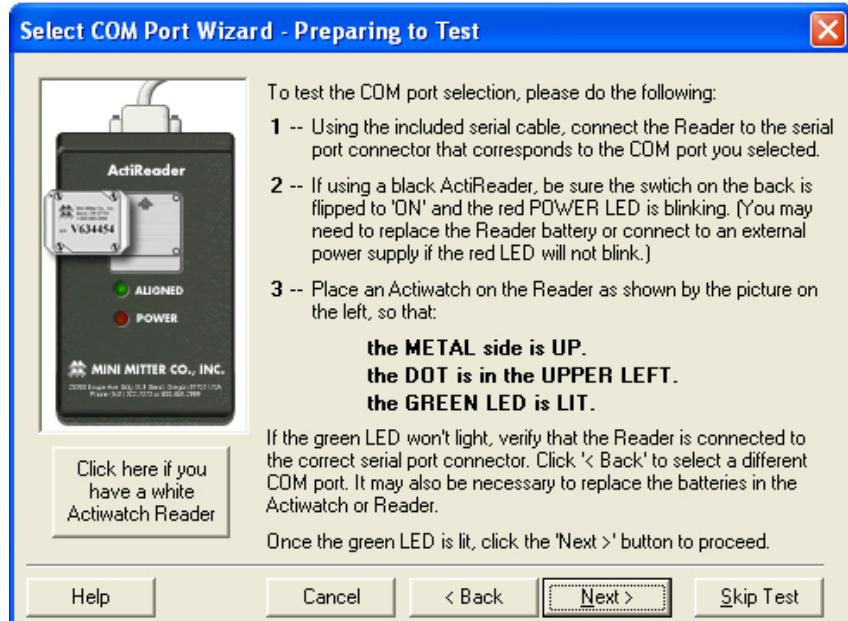
4. Click **Next** to proceed to the Communications Port Test.

Note: The ActiReader must be functioning correctly and be connected to the computer to complete the COM port selection. The Actiwatch must be metal side up (Serial Number up) to successfully communicate with the ActiReader.

5. Verify that ActiReader is connected correctly using the 3-point checklist.
If correct, select the **Next** button. You can also use the **Skip Test** button, but the connection between the computer and ActiReader will not be tested.

If using a white Actiwatch Reader, click the appropriate button in the wizard or see *Actiwatch Reader* later in this section.

3-point check list and Actiwatch Reader differences are embedded in the COM Port Wizard



If the Communications Test fails, a help window will appear to assist with troubleshooting potential causes. Review each possible explanation.

When ActiReader is successfully connected to the computer, the **Finished!** window will appear.



6. Select **Finish to exit the wizard.**

Upon completing the COM Port Wizard, you can configure an Actiwatch for subject use or retrieve collected data (see *Communications* in Section 3 of this manual).

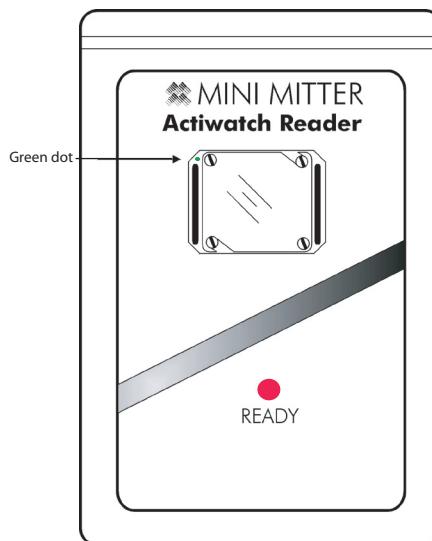
Actiwatch Reader

Actiwatch Reader and ActiReader are very similar in their operation. Installation and setup are the same.

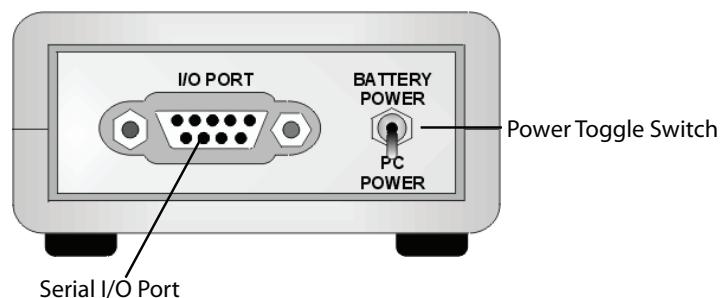
However, please keep the following in mind when using the Actiwatch Reader:

- The Actiwatch Reader is white. The ActiReader is black.
- 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 replace the reader battery periodically (see *Replacing ActiReader Battery* later in this section).
- 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.

Actiwatch Reader top panel with orientation dot



Actiwatch Reader



ActiReader Battery Replacement Procedures

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.

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.

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.

2

GETTING STARTED

WARNING! Actiware / Actiware-CT is for use only in a clinical, research, or home care provider setting.

The workspace of the Actiware program is similar to many software applications. Dockable windows give the user direct access to the Actiwatch or subject data stored in the selected database. They also provide control over analysis viewing and exports.

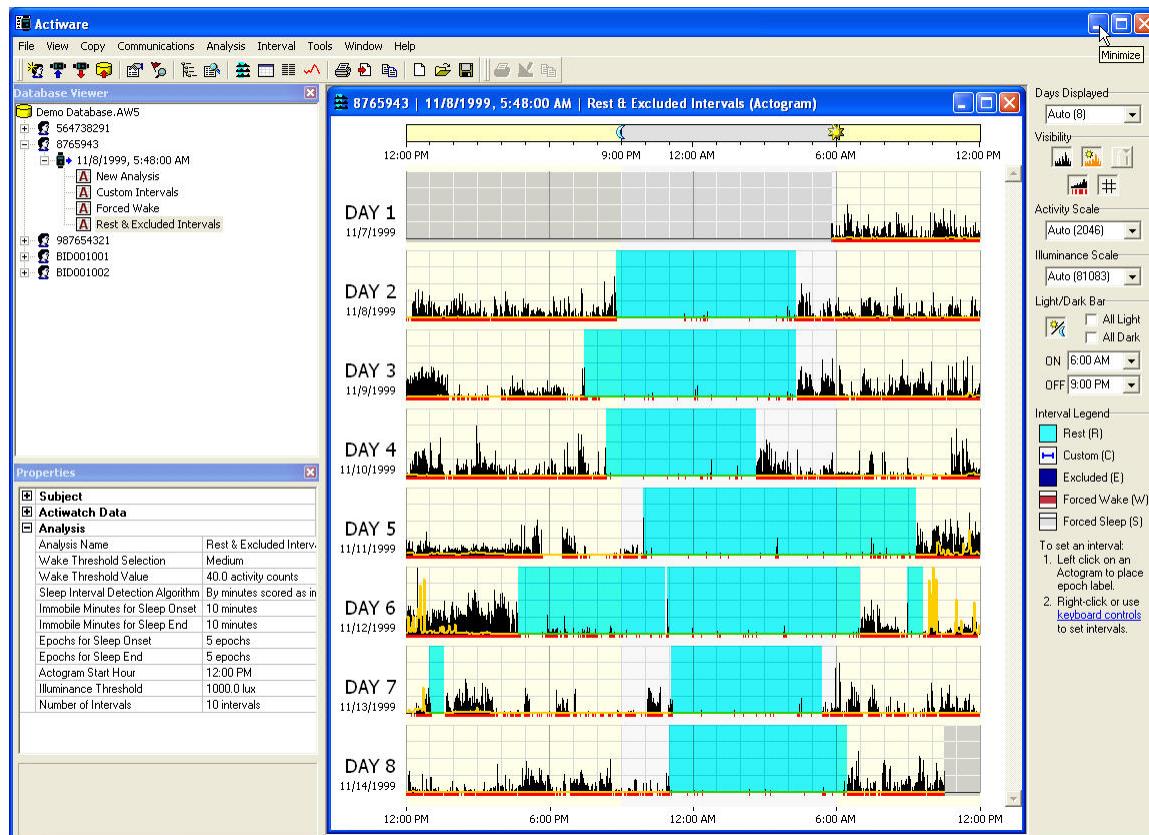
The Database Viewer and the Properties Viewer are docked at the left side of the main Actiware window by default. The Actogram View toolbar is shown on the right side of the main Actiware window.

Actiware databases are organized in a hierarchical fashion. The top level is the subject level. The second level is the Actiwatch data for that subject. The third level is for saved analyses of the Actiwatch data. You can navigate through this hierarchy by clicking on the + (plus sign) or - (minus sign) buttons to the left of the subject or Actiwatch data icons.

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

Main Window

Actiware workspace, full-window



The main Actiware window can be broken into three main sections:

- Toolbars
- Database Viewer
- Properties viewer

Toolbars



The Menu Bar is similar to most software applications. Keyboard shortcuts, actuated by pressing the **ALT** key plus the hotkey letter, (identified by an underscore) can be used to navigate through the toolbar menus.

The Standard toolbar, just below the Menu Bar, includes shortcuts to associated functions within the Actiware software program. Hover your mouse over the icon for a short text description.

Standard Toolbar Icons

| | | | |
|---|---------------------------------|--|---------------------------------|
|  | Create A New Subject |  | Edit Subject, Data, or Analysis |
|  | Configure My Actiwatch |  | Show Audit Trail |
|  | Retrieve Data from My Actiwatch |  | Open the Database Viewer |
|  | Import an .awd File |  | Open the Properties Viewer |

The following four icons determine how the data are shown in the **Analysis** window.

| | | | |
|---|---------------------------------------|--|-------------------------|
|  | Display Data as an Actogram |  | Display the Data List |
|  | Display Statistics within an Interval |  | Display Data as a Graph |

| | | | |
|---|-----------------------------------|--|----------------------------|
|  | Print an Actiware Report |  | Create a New Analysis File |
|  | Export a Data File |  | Open an Analysis File |
|  | Copy Export Text to the Clipboard |  | Save an Analysis File |

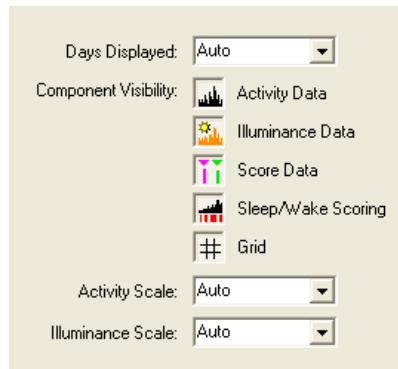
The **Graph** toolbar provides access to functions that are available only when viewing a graph.

| | | | |
|---|-----------------------------------|--|-----------------------------|
|  | Print a Graph |  | Copy Graph to the Clipboard |
|  | Edit the Graph Display Properties | | |

The Actogram View toolbar is used for adjusting 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.



- **Days Displayed:** controls how many days are displayed in the visible part of the Actogram window. Use the scroll bar on the right of the Actogram to see the remaining days. Pull down or type directly into this control to set the number of days.
- **Visibility:** these buttons hide and show the data items in the Actogram:

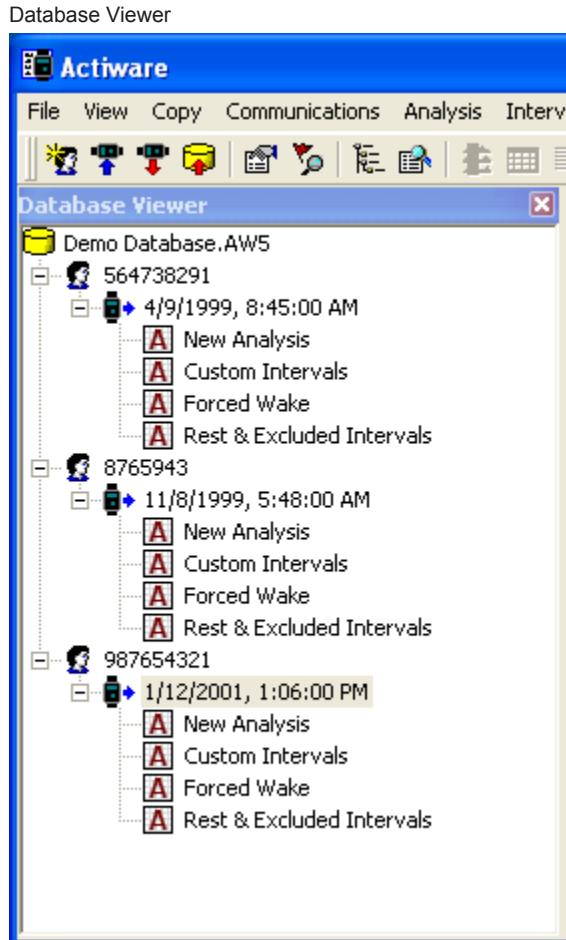


- Activity Scale: adjusts the maximum value of activity counts displayed on the Actogram. Pull down or type directly into this control to set the activity scale.
- Illuminance Scale: adjusts the maximum illuminance value displayed on the Actogram. Pull down or type directly into this control to set the scale.
- Light/Dark Bar: use these controls to show or 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. See Setting Intervals later in this section.

To save your current Actogram View settings as default settings, click **View > Save Current Actogram View as My Default View**. Or, to restore your default view settings, click **View > Restore My Default Actogram View**.

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.



Subjects, Actiwatch data, and Analyses are shown as indicated below:

| Level | Content |
|-------------------------------|--|
| 1st Level (Subject) | Subject Identity (Sorted Alphabetically or Numerically) |
| 2nd Level (Actiwatch Data) | Local Start Time (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 and using the popup menu.

Actiware automatically loads the last used database or when run for the first time, the Demonstration Database. To create a new database, click **File > Database > New** and use the Windows file selection to select a filename and location. Other database functions (such as Open, Save As, Backup, and Export) can be accessed from the **File > Database** menu.

The Database Viewer can be undocked or docked by clicking and dragging the window title bar. In addition, it can be resized or closed. To show again, use the **View > Database Viewer** menu.

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.

Click the + or – next to the Subject, Actiwatch Data, or Analysis 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, the properties related to the *Rest & Excluded Intervals* analysis are displayed. Note that the Subject and Actiwatch data properties are also displayed.

Properties Viewer window

| Properties | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Subject |
| Identity | 564738291 |
| Full Name | Mrs Janet C Hanson |
| Gender | Female |
| Date of Birth | 8/8/1939 |
| Age (current) | 66 years |
| Age (start of data collection) | 59 years |
| Street Address | 5674 W 123rd St |
| City | New York |
| State | NY |
| Postal Code | 11143 |
| Country | USA |
| <input checked="" type="checkbox"/> | Actiwatch Data |
| Actiwatch Type | Actiwatch 16/64 |
| Data Collection Start Time | 4/9/1999, 8:45:00 AM |
| Data Collection End Time | 4/14/1999, 5:09:00 PM |
| Time Zone | (GMT-08:00) Pacific Time (US & Canada); Tijuana |
| 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 |
| Illuminance Calibration Factor | Not Available |
| <input checked="" type="checkbox"/> | 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 |
| Immobile Minutes for Sleep Onset | 10 minutes |
| Immobile Minutes for Sleep End | 10 minutes |
| Epochs for Sleep Onset | 5 epochs |
| Epochs for Sleep End | 5 epochs |
| Actogram Start Hour | 12:00 PM |
| Illuminance Threshold | 1000.0 lux |
| Number of Intervals | 0 intervals |

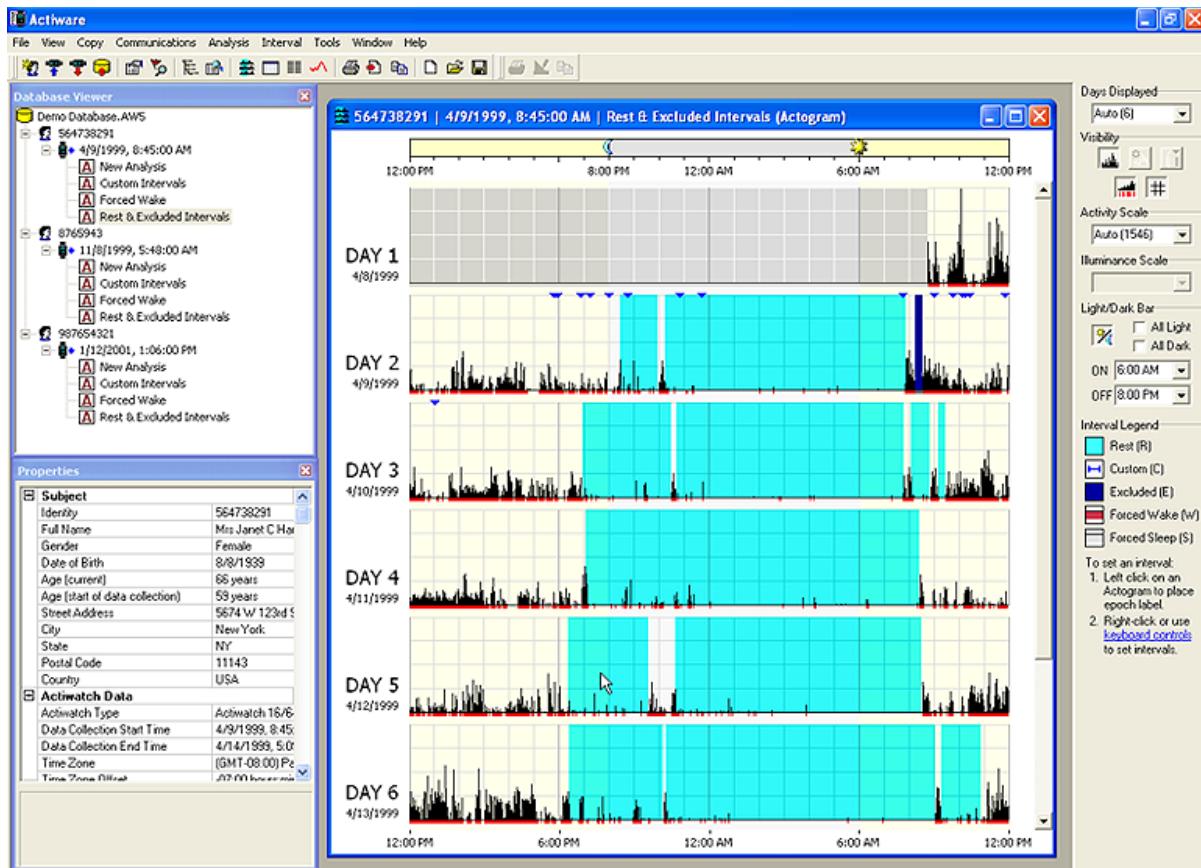
Items in the Properties Viewer can be edited by double-clicking the item.

The Properties Viewer can be undocked or docked by clicking and dragging the window title bar. In addition, it can be resized or closed. To show again, use the **View > Properties Viewer** menu.

Actogram

An Actogram is a graphic view of the rest/activity history of a subject. Data are displayed in stackable 24-hour periods which allow the user to immediately determine sleep/wake patterns.

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 later in this section.)



There are multiple ways to open an Actogram. The most direct way is:

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.
3. Double-click on New Analysis. An Actogram will be displayed.

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

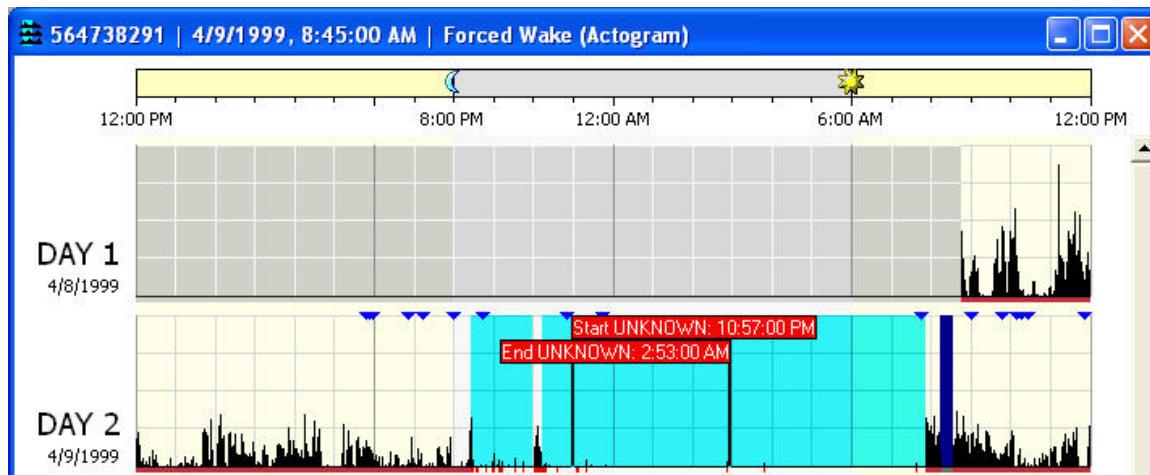
You can also open an Actogram by clicking the **View > Actogram** menu, or by clicking the icon on  the Standard toolbar at the top of the window.

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

Note: The sleep/wake scoring algorithm is applied automatically to the activity in the entire data set. Epochs scored as wake are indicated by a red mark below the X axis, whereas epochs scored as sleep have no mark below the X axis.

Setting Intervals

Adding an Interval Selection to an Actogram



An interval is a user-defined selection of time that allows you to graphically select and analyze data for statistical calculations. 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. The interval types that are available:

- Rest – user defined
- Sleep – automatically determined from Rest intervals
- Active – automatically determined from Rest intervals
- Excluded – user defined
- Forced Wake Score – user defined
- Forced Sleep Score – user defined

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. They must be set by the user and 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 will use 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 will be set using the Analysis parameter values that are indicated on the Analysis tab of the **Tools > Options** window. Once you have set a Rest Interval, a Sleep Interval will automatically be 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 program 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 must be set by the user and are indicated by dark blue shading.

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 the user.

Forced Wake

These intervals are periods of time for which the Sleep/Wake score has been forced by the user 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 the user to Sleep. This typically is 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 three ways to set intervals. The quick method uses the mouse and hotkey combinations:

Quick Method

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.

Interval Start Time



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

Interval End Time



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 hotkey combinations, set the type of interval you want:

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

The new interval will be 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.

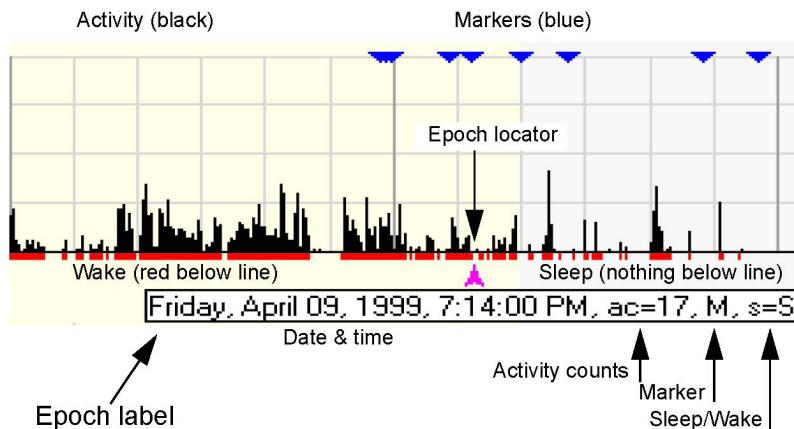
*Note: During the interval creation process you can press the keyboard **Escape** key to clear the markers.*

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 (\leftarrow , \rightarrow , \uparrow , \downarrow) to move the epoch label to the desired interval start time.

Close-up of Interval Markers on Actogram



3. To place the interval start marker, press one of the following keys based on the interval type you want to create:

| | |
|---|---------------------------------|
| R | Set REST interval start |
| C | Set CUSTOM interval start |
| E | Set EXCLUDED interval start |
| W | Set Forced WAKE interval start |
| S | 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 hotkey combinations based on the interval type you're creating:

| | |
|-----------|-------------------------------|
| SHIFT + R | Set REST interval end |
| SHIFT + C | Set CUSTOM interval end |
| SHIFT + E | Set EXCLUDED interval end |
| SHIFT + W | Set Forced WAKE interval end |
| SHIFT + S | Set Forced SLEEP interval end |

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 above, use one of the following hotkey combinations to set the type of interval you want:

| | |
|----------|------------------------------|
| CTRL + R | Insert REST interval |
| CTRL + C | Insert CUSTOM interval |
| CTRL + E | Insert EXCLUDED interval |
| CTRL + W | Insert Forced WAKE interval |
| CTRL + S | 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 type in the date and time values for the interval start and end times, such as if you have a patient sleep diary, use the following procedure:

1. Click **Interval > Add Interval**.

This will launch the Add Interval window.

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.

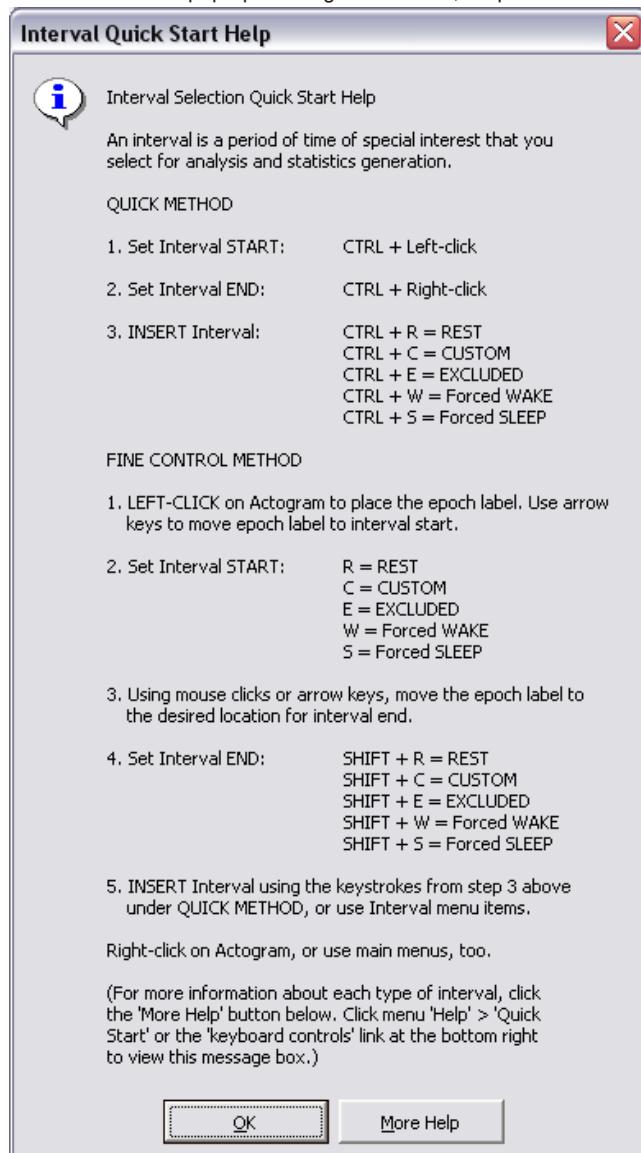
You can repeat steps 2 through 5 for each interval without closing the Add Interval window.

Note: 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.

Interval Quick Start Help

The Interval Quick Start Help message provides an overview of the interval functions. To display this message, click the keyboard controls link on the bottom of the Actogram View toolbar, or click **Help > Quick Start > Interval Selection**.

Interval Quick Start pop-up message. To access, Help > Quick Start > Interval Selection



Removing Intervals

To remove a single interval simply 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).

Viewing Statistics

The Statistics Table is one of two main ways to display the calculated sleep/wake output. Interval, activity, mobility, sleep, illuminance, and score statistics are automatically calculated for intervals that are set by the user.

1. View > Statistics Table

Click on the tabs at the top of the window to view calculated statistics for different types of intervals. Use the scrolling tools to move through the list of intervals or to view different columns of statistics.

Statistics Table

| | Rest | Active | Sleep | Custom | Daily | Summary |
|---------------|-------------------------|--------------------------|-----------------------|-------------------------|--------------------|-----------------------------------|
| Day 1 | Start Date 1/12/2001 | Start Time 1:06:00 PM | End Date 1/13/2001 | End Time 12:00:00 PM | Total AC 416020 | Avg AC/min 302.78 |
| Day 2 | 1/13/2001 | 12:00:00 PM | 1/14/2001 | 12:00:00 PM | 326487 | 226.73 |
| Day 3 | 1/14/2001 | 12:00:00 PM | 1/15/2001 | 12:00:00 PM | 409422 | 284.32 |
| Day 4 | 1/15/2001 | 12:00:00 PM | 1/16/2001 | 12:00:00 PM | 388019 | 269.46 |
| Day 5 | 1/16/2001 | 12:00:00 PM | 1/17/2001 | 12:00:00 PM | 360973 | 250.68 |
| Day 6 | 1/17/2001 | 12:00:00 PM | 1/18/2001 | 12:00:00 PM | 341992 | 237.49 |
| Day 7 | 1/18/2001 | 12:00:00 PM | 1/19/2001 | 12:00:00 PM | 332075 | 230.61 |
| Day 8 | 1/19/2001 | 12:00:00 PM | 1/20/2001 | 12:00:00 PM | 262993 | 182.63 |
| Day 9 | 1/20/2001 | 12:00:00 PM | 1/21/2001 | 12:00:00 PM | 294980 | 204.85 |
| Day 10 | 1/21/2001 | 12:00:00 PM | 1/22/2001 | 12:00:00 PM | 445690 | 309.51 |
| Day 11 | 1/22/2001 | 12:00:00 PM | 1/23/2001 | 12:00:00 PM | 409948 | 284.69 |
| Day 12 | 1/23/2001 | 12:00:00 PM | 1/24/2001 | 12:00:00 PM | 387716 | 269.25 |
| Day 13 | 1/24/2001 | 12:00:00 PM | 1/25/2001 | 10:07:00 AM | 326195 | Maximum Activity [counts] 2260 |
| <i>n</i> | * | * | * | * | 13 | 13 |
| Average(n) | * | * | * | * | 361731.52 | 2142.85 |
| Std Dev(n-1) | * | * | * | * | 53183.26 | 37.58 |
| | | | | | 609.42 | 0.00 |
| | | | | | 0.06 | 97.01 |

Controlling the Content of the Statistics Table

1. Tools > Options



This will launch the Options pop-up window.

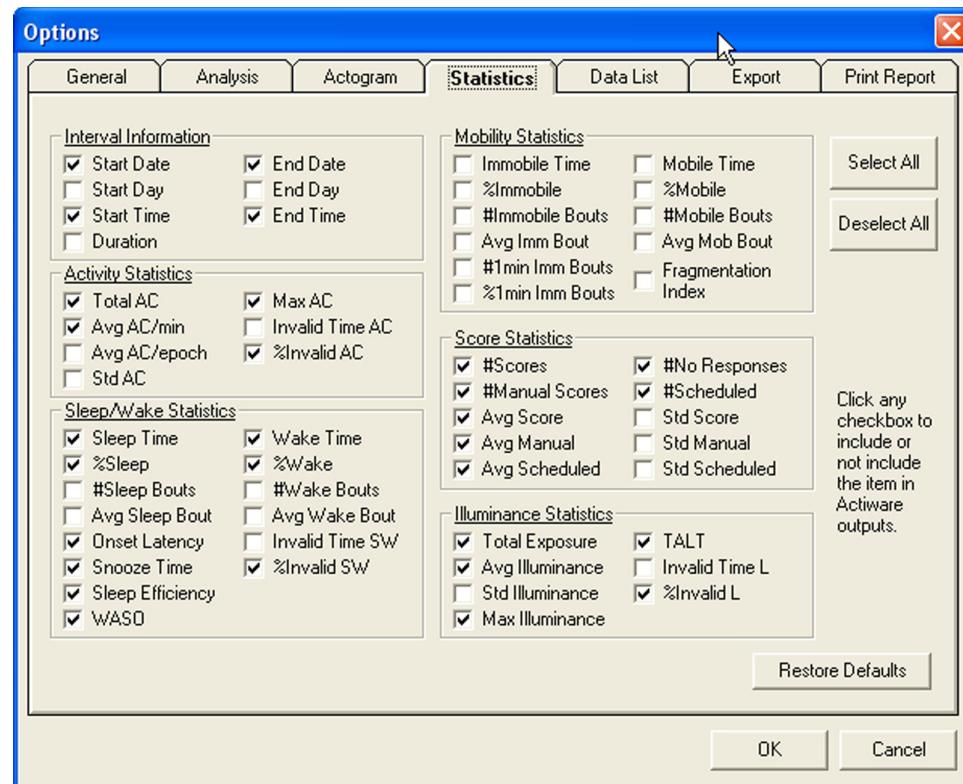
2. Statistics

Select the **Statistics** tab (mouse-click) to view the available statistic properties. Check those statistics that you want to include. Actiware includes **Select All**, **Deselect All**, and **Restore Defaults** buttons for ease of use.

3. Click **OK** to save your selections or **Cancel** to unaccept.

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

Tools > Options > Statistics



See *Advanced Usage* in Section 4 for statistic definitions.

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

Exporting Data

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 program of your choice.

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

Standard Individual Export File

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



To create this file, click **File > Export** menu or click the button on the Standard toolbar. You will be prompted for a file name using the standard Windows dialog box.

*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 by clicking **Copy > Export Text**. Then paste into your program of choice using the Clipboard paste function (commonly CTRL + V keyboard hotkey).

FAST™ Export File¹

This is a tab delimited ASCII text file (.txt) 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, click **File > FAST Export**. You will be prompted for a file name using the standard Windows dialog box.

¹ FAST™ is a trademark of NTI, Inc.

Combined Export File

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

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

See *Batch Export* in *Advanced Usage*, Section 4, for details.

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

Print Report

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

To generate the report, click **File > Print Report**, or click the  button on the Standard toolbar. You will be presented with a Windows printer dialog where you can select the printer, number of copies, and paper orientation (such as Portrait or Landscape).

Note: The contents of the printed report can be customized using the **Tools > Options** window. Use the Statistics and Print Report tabs to select what content you would like for the printed report.

New Subject

Once a database exists it can be populated with subjects and subject collected data. To add or edit a subject, first open the database. **Select File > Database > Open**, as described on the previous page.

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

1. Click **File > New Subject**.

This will open a New Subject window to allow for the capture of demographic data.

2. Fill in the three required fields: **Identity, Date of Birth and Gender**

For Identity, we suggest using a blind descriptor or nickname of the subject. Notice that Age is automatically computed.

Important! Because you can import subjects from other databases, Actiware allows more than one subject with the same ID. Therefore, you need to be sure you choose a subject ID that does not already exist in the currently open database.

3. If you desire, fill in the remaining fields.

For HIPAA considerations, these fields are optional.

When USA or Canada is entered into the Country field, a dropdown list for the State/Province area will become available. Additionally, the Phone field will be optimized for the (###) ###-#### format. To enter a non-US or non-Canadian state code or phone number, enter the Country first.

Deleting/Hiding Subjects

For purposes of data tracking, you cannot delete subjects from a database. You can hide them by checking the **Hide Subject** 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 **View Hidden Subjects**.

3 COMMUNICATIONS

The Actiware software is used to configure the Actiwatch device and retrieve data from the Actiwatch through the use of the ActiReader.

To set up the ActiReader, see *Installation and Setup* in Section 1 of this manual.

Configure Actiwatch

Overview

This wizard will configure an Actiwatch for data collection. This wizard assumes that the ActiReader or Actiwatch Reader is connected to the computer and the appropriate COM port is selected. Please refer to *Section 1* of this manual for setting up the ActiReader and selecting a COM port.

The **Configure Actiwatch Wizard** will guide you through several windows. As with other Actiware wizards, you can make changes at each window. You can also travel between windows using the **Back** and **Next** buttons, or **Cancel** to close the wizard.

Use the **Show/Hide Actiwatch Details** button to view additional information associated with the watch.

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, proceed to **Retrieve Data from Actiwatch** later in this section.*

Configure Actiwatch Wizard Welcome window



Configure Actiwatch

Configure Actiwatch

1. Communications > Configure Actiwatch

This will launch the Configure Actiwatch Wizard.

2. Remove the wrist/foot bands from the Actiwatch (optional).

The bands may interfere with proper Actiwatch placement.

3. 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.

4. Click **Next** to continue.

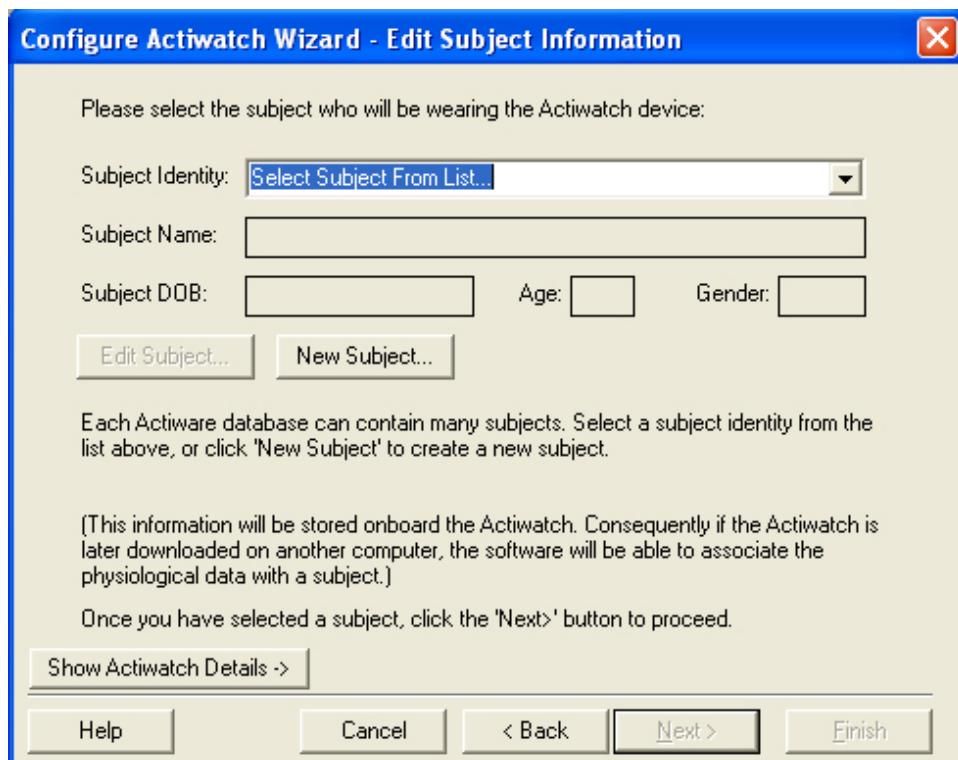
The wizard will check the Actiwatch serial number and battery life. If a **Low Battery Warning** appears, please choose one of the three options from the pop-up window. If the warning does not appear, proceed to step 6.

- 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.

5. Click **Next** to continue.

Edit Subject Information

Select subject from the dropdown list or use the 'New Subject' button to add a new subject to the database.



6. Select a current subject from the dropdown list and then click **Edit Subject** to make updates.

When an existing subject is selected from the dropdown menu, the areas below (Subject Name, Subject DOB, Age, and Gender) will pre-populate with the information stored in the database.

Note: The subject must be in the current data file to be accessible from the dropdown menu.

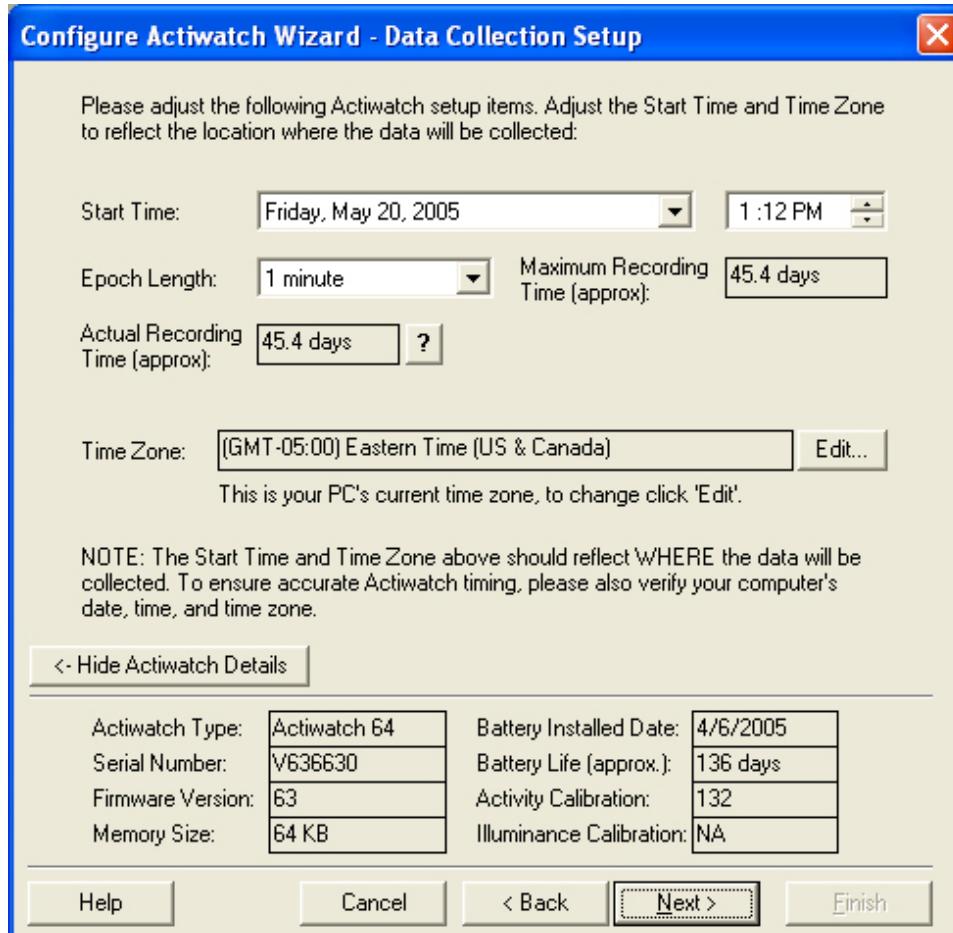
Click **New Subject** to configure Actiwatch for a new subject.

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

Data Collection Setup

During the Data Collection Setup, you can configure the Actiwatch setup items, including start time, epoch length, and time zone with a simple mouse click.

Expanded window displaying the Actiwatch Details.



Epoch length

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:

- 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 | 228 days |
| 15 minutes | 96 | 342 days |

Note: For sleep analysis it is recommended 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.

Recording Time

Displays the time at which the activity monitor will fill its memory with samples based on the epoch length selected.

Recording Time Table (for epochs > 0.25 minutes)

| Memory | 0.25 min | 0.5 min | 1 min | 2 min | 5 min | 10 min | 15 min |
|----------|----------|---------|-------|-------|-------|--------|--------|
| AW-16K | 2.8 | 5.6 | 11.2 | 22.5 | 56.4 | 112.8 | 169.3 |
| AW-64K | 11.3 | 22.7 | 45.4 | 90.8 | 227 | 454 | 681 |
| AW-L | 3.7 | 7.5 | 15.1 | 30.2 | 75.7 | 151 | 225 |
| AW-Score | 5.6 | 11.2 | 22.4 | 44.9 | 112 | 224 | 336 |

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

NOTE: Maximum battery life is 180 days for AW16, AW64, and AW-L, and 90 days for AW-Score.

8. Click **Next** when you have completed editing/adding data collection information.

If you are configuring an Actiwatch-Score, continue below. If configuring an Actiwatch-16/64 or Actiwatch-L, skip ahead to step 10.

Actiwatch-Score

If you are configuring an Actiwatch-Score, a Score Range window will appear and you will now be required to set the minimum and maximum score ranges.

Set the ranges by typing in the numeric value (0-15) or use the scroll arrows.

9. Click **Next** to continue.

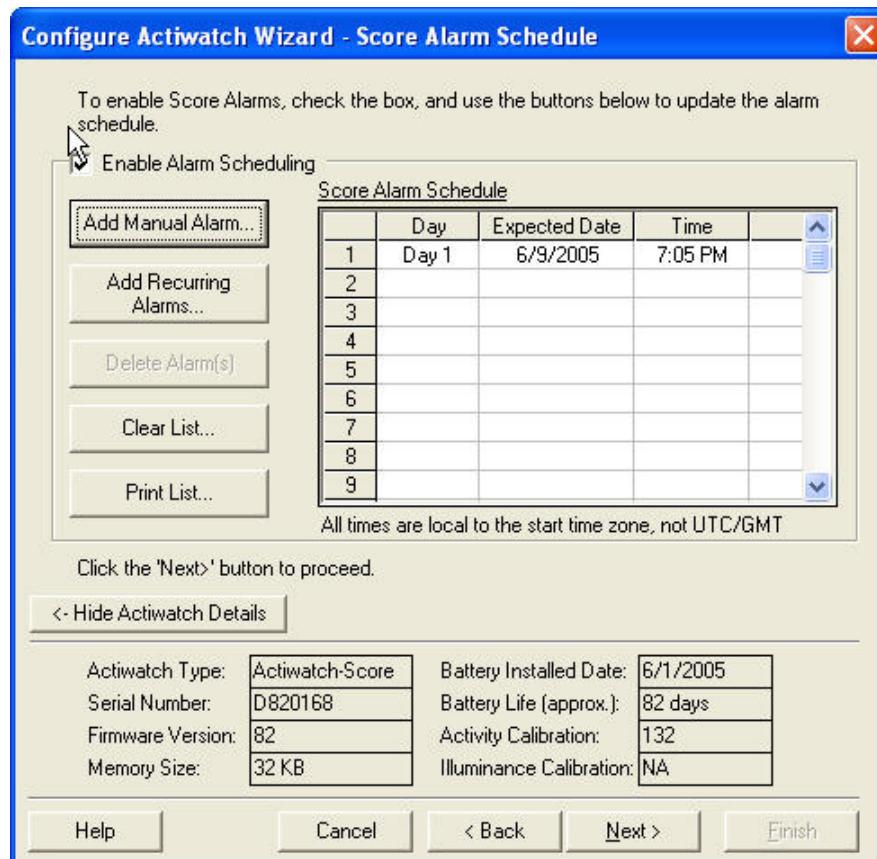
Actiwatch-Score Alarm

Click the **Enable Alarm Scheduling** box and format the Score Alarms with the following actions.

- Add Manual Alarm
- Add Recurring Alarm
- Delete Alarms (select item in list)
- Clear List
- Print List

After establishing the Actiwatch-Score Alarm schedule, you can print a listing.

Actiwatch-Score Alarm window



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

10. Click **Next** to continue.

The Configure Actiwatch process is in operation. When prompted, remove the Actiwatch.

11. Click **Finish** to complete the Configure Actiwatch Wizard.

Retrieve Data from Actiwatch

Overview

This wizard will assist you in retrieving the physiological data from an Actiwatch device. When the retrieval process is complete, the resulting data will be written to your selected database for analysis and export.

This wizard assumes that the ActiReader or Actiwatch Reader is connected to the computer and the appropriate COM port is selected. Please refer to *Installation and Setup* in Section 1 of this manual.

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.*

Retrieve Data from Actiwatch Wizard Welcome window



Retrieve Data from Actiwatch

Retrieve Data from Actiwatch

1. Communications > Retrieve Data from Actiwatch.

Start the Retrieve Data from Actiwatch Wizard. Click **Next** to continue.

2. Remove the wrist/foot bands from the Actiwatch (optional).

The bands may interfere with proper Actiwatch placement.

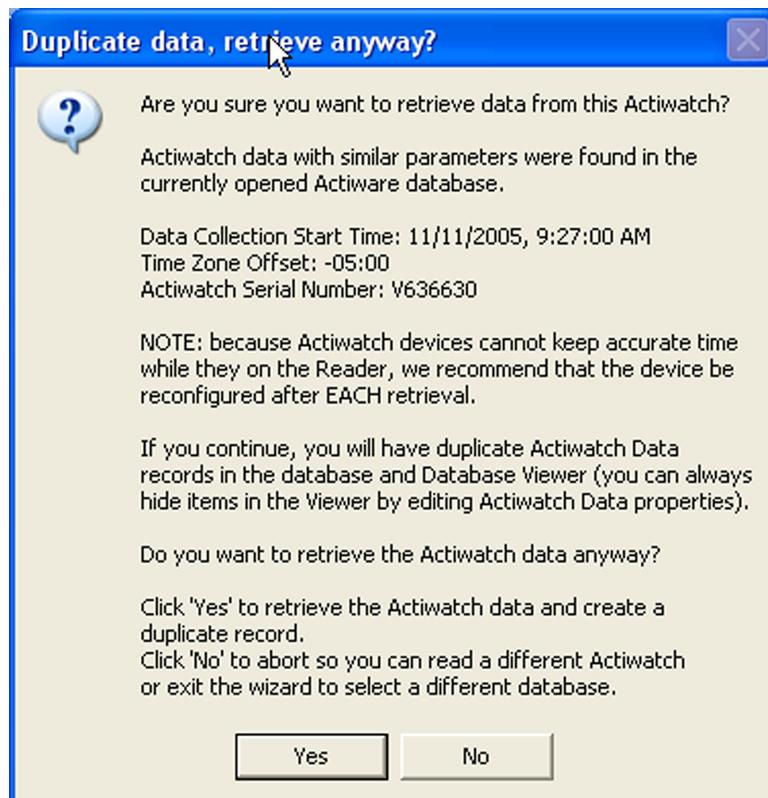
3. Place the Actiwatch on the reader.

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.

4. Click **Next** to continue.

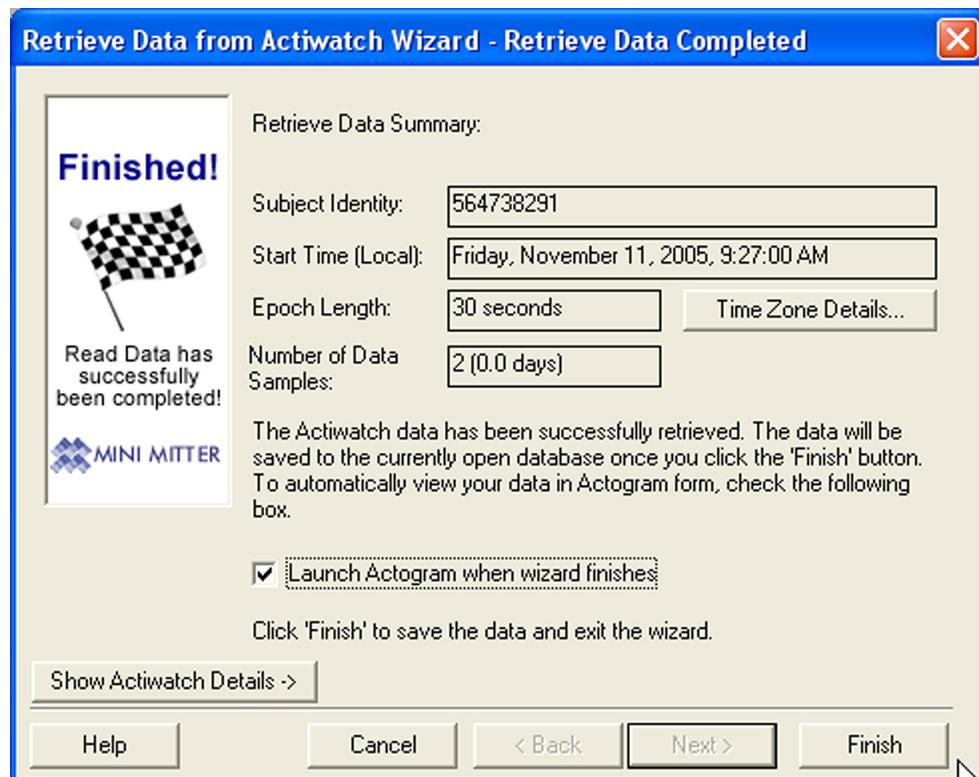
Actiware will communicate with the Actiwatch device and retrieve the data. If you receive a **Duplicate data, retrieve anyway** message, you have the option to abort the retrieve process by selecting the **No** button, or create a duplicate record by selecting the **Yes** button and continue retrieving the data.

Duplicate data window



5. When the **Retrieval Successful!** message appears, click the **OK** button.
6. Check the **Launch Actogram when the wizard finishes** box to view the Actogram data immediately.
7. Click the **Finish** button to exit the wizard.

Retrieve Data Complete window



Note: Actiware-CT requires the user to ‘Sign and Save’ the data by using a Windows or Network username and password. Please contact your local administrator with any issues or questions.

Note: Actiwatch-Score may occasionally make a short “chirping” sound during communications. This is normal. DO NOT remove the device from the reader until instructed.

4

ADVANCED USAGE

Actiware provides greater flexibility to researchers and clinicians when viewing and analyzing data. Advanced users can take advantage of the Actiware Toolbars to manipulate how the data is viewed and exported.

Items covered in this section:

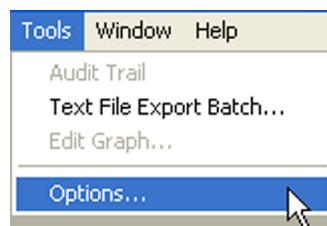
- Program Options (Tools > Options)
- Data List
- Batch Export
- Import AWD files
- Graph

Your input is vital to us. Please explore the program fully and give us your feedback. Please feel free to contact us with any questions or comments on this software.

Program Options

Customize the Actiware software and data properties through the program options window. Select **Tools > Options** from the main menu bar to access the option tabs.

Tools > Options

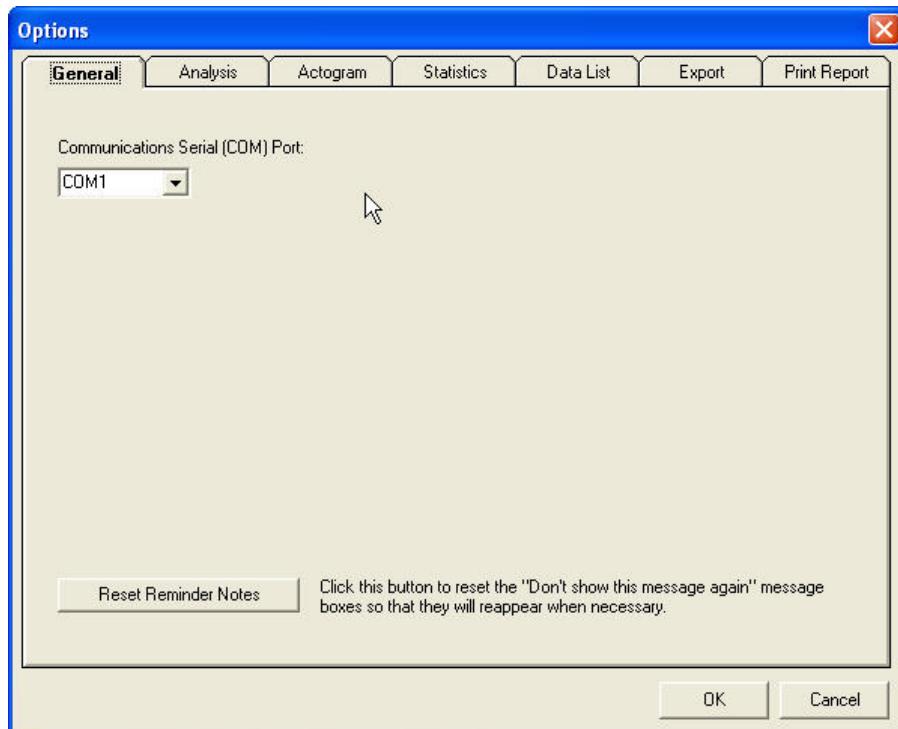


Note: After you have finished making all of your changes in the options window, click **OK** to accept or **Cancel** to not accept.

General Tab (Tools > Options > General)

Select the COM port from the dropdown menu. To reset all Help Window reminders, check the **Reset Reminder Notes** button.

Tools > Options > General



Analysis Tab (Tools > Options > Analysis)

An *analysis* includes *parameter settings* and *interval settings* as inputs. Use the Analysis tab for setting parameter values (see Section 2 for how to set intervals). Definitions of each analysis parameter are given on the next few pages. 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.

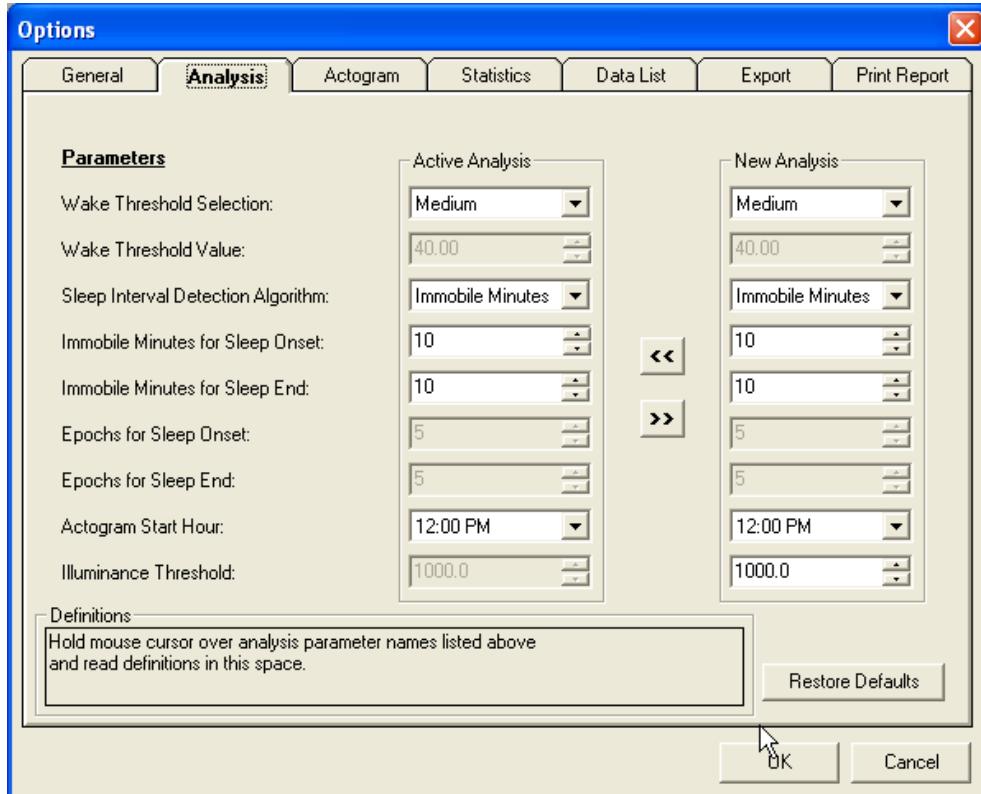
New Analysis refers to a newly created analysis, so the analysis parameter settings shown in the New Analysis frame are default values. These default values are unique to each Windows logon username and are used each time a New Analysis window is opened.

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.

Tools > Options > Analysis



Analysis Parameter Definitions

Wake Threshold Selection

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

Wake Threshold Value

The number of activity counts used to define wake. Detail: 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 (See *Appendix A* for further information).

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 will be 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 only applied 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 will be 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 only applied 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 will be automatically set to the first epoch of the first section of consecutive epochs scored as sleep “THIS” many epochs long. Note: This parameter is only applied 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 will be automatically set to the last epoch of the last section of consecutive epochs scored as sleep “THIS” many epochs long. Note: This parameter is only applied 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.

Illuminance Threshold

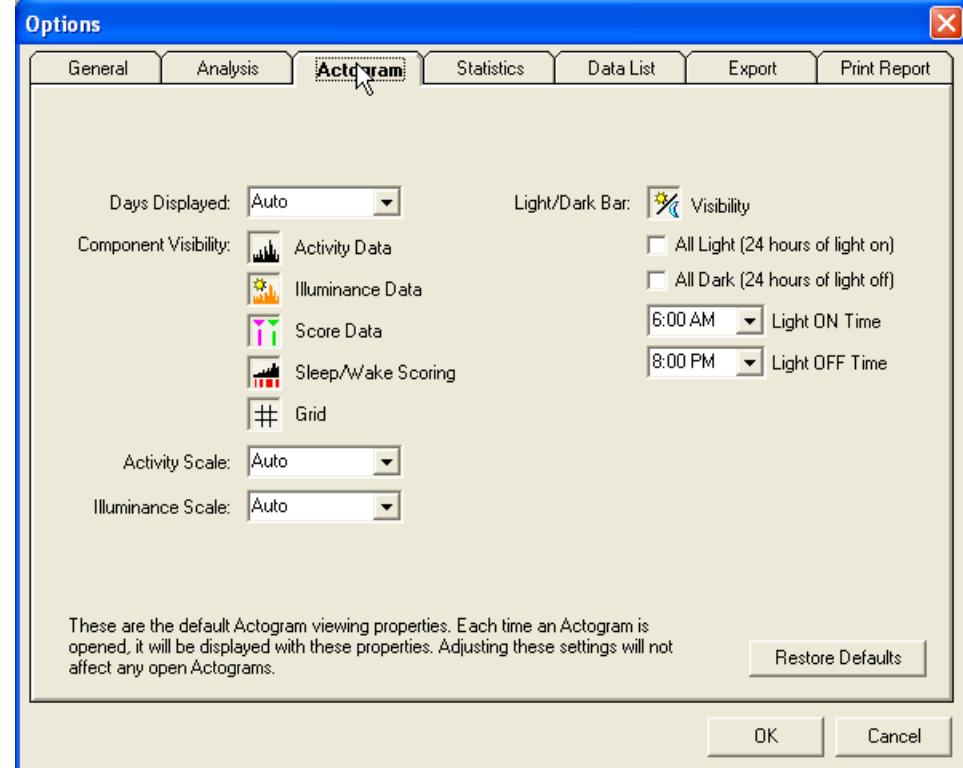
Level of illuminance, in lux, that is compared to the intensity of illumination the Actiwatch-L is exposed to, for the purpose of calculating the Time Above Illuminance Threshold statistic for given time intervals (Actiwatch-L only).

Actogram Tab (Tools > Options > Actogram)

These are the default Actogram viewing properties. Each time an Actogram is opened, it will be displayed with these properties. Adjusting these properties will not affect any open Actograms. To view the changes, close and reopen the Actogram.

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

Tools > Options > Actogram

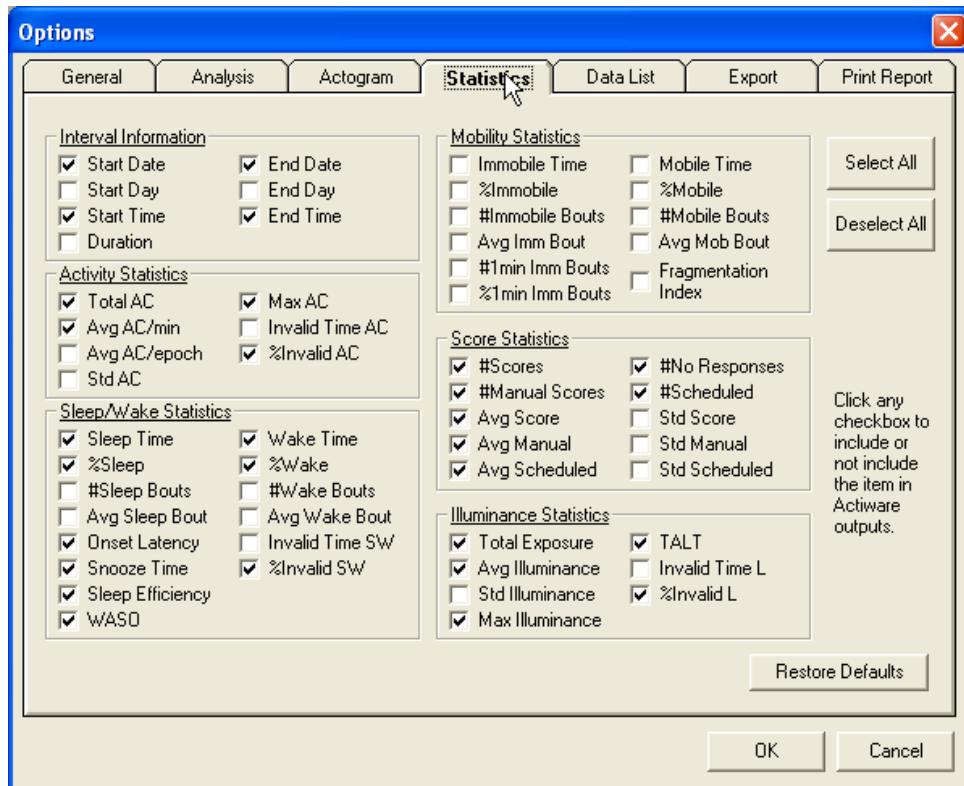


Statistics Tab (Tools > Options > Statistics)

Select the items of data displayed from the analysis. Changes made here will 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 to the factory released settings.

Tools > Options > Statistics



See *Appendix B* for a definition of each statistic.

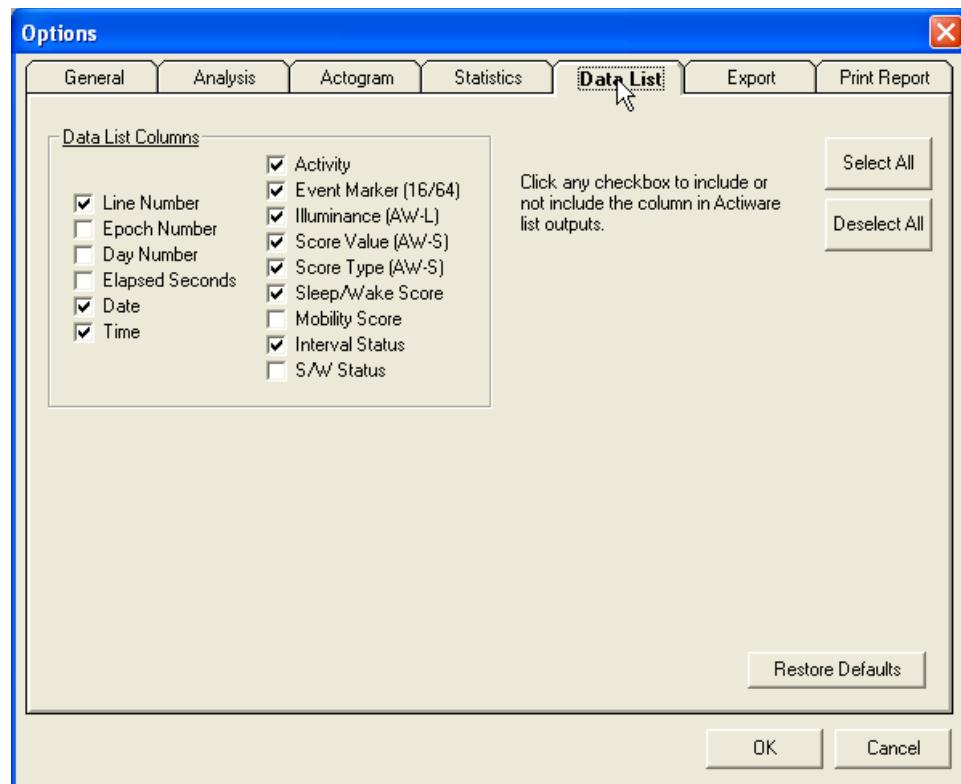
Data List Tab (Tools > Options > Data List)

Select the columns to be displayed in the Data List window. Changes made on this tab will 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 the factory presets.

Changes made in the **Tools > Options > Data List** window will be immediately displayed in the **View > Data List** window.

Tools > Options > Data List

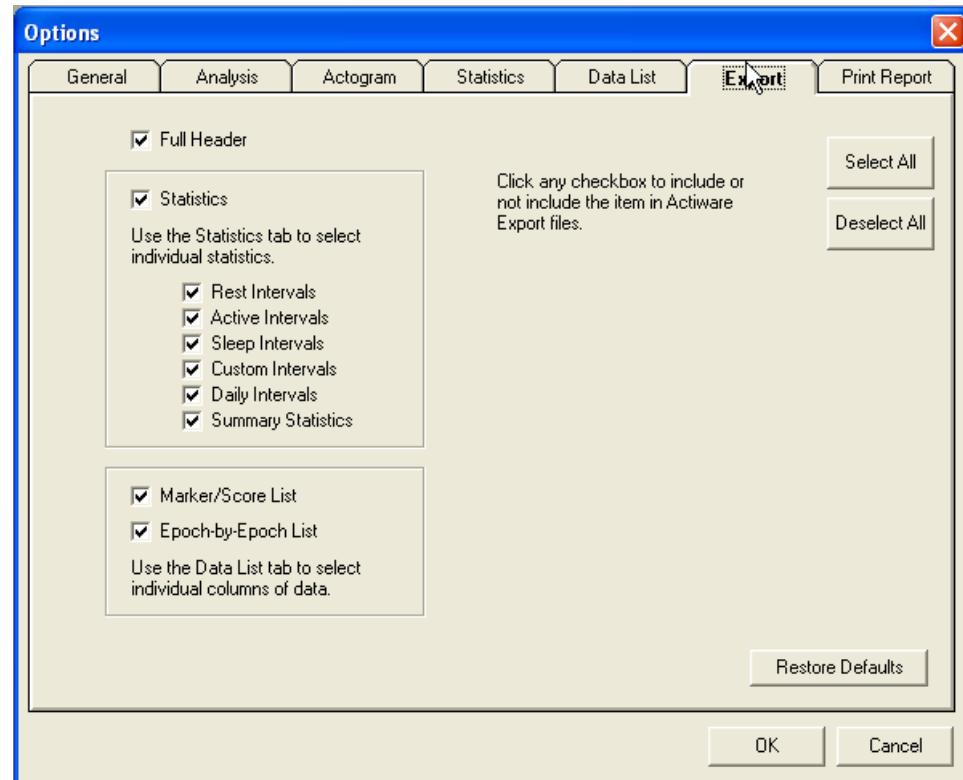


Export Tab (Tools > Options > Export)

Select the items you want to include in your export file (also applies to the Copy > Export Text to windows clipboard function in the non-CT version of Actiware). Use the **Statistics** tab to select individual statistics. Use the **Data List** tab to select individual columns of data.

Click **Select All** to select all of the types of data. Click **Deselect All** to uncheck all of the types of data. Click **Restore Defaults** to return the settings to the factory presets.

Tools > Options > Export

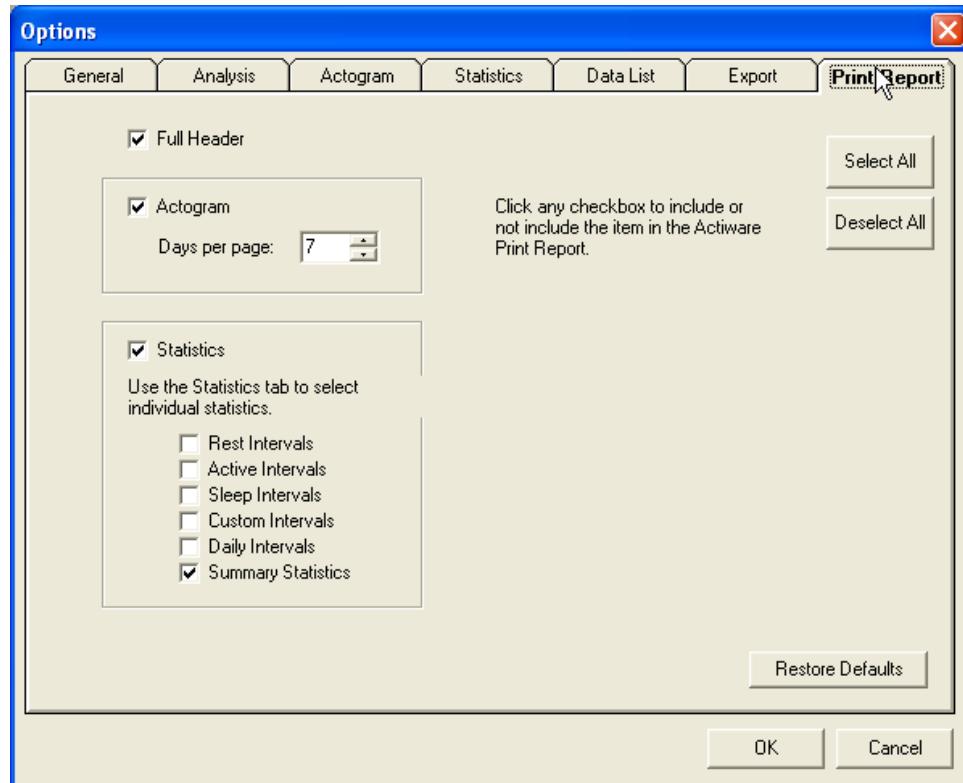


Print Report Tab (Tools > Options > Print Report)

Select the items you want to include in your printed report. Click the **Full Header** box to include a first page of header information (recommended). Click the **Actogram** box to include the Actogram graphic in the report. You can select the number of Actogram days to print per page. Click the **Statistics** box (and sub-boxes) to include statistics for various types of intervals (by default the report will include Summary Statistics only). Use the **Statistics** tab to select individual statistics.

Click **Select All** to select all of the types of data. Click **Deselect All** to uncheck all of the types of data. Click **Restore Defaults** to return the settings to the factory presets.

Tools > Options > Print Report



Data List

1. View > Data List



You have selected to view a listing of the currently active data as a function of time (epoch-by-epoch).

2. Click the Epoch-by-Epoch List tab or the Marker/Score List tab to view the data list for that type.

Use the 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.

View > Data List

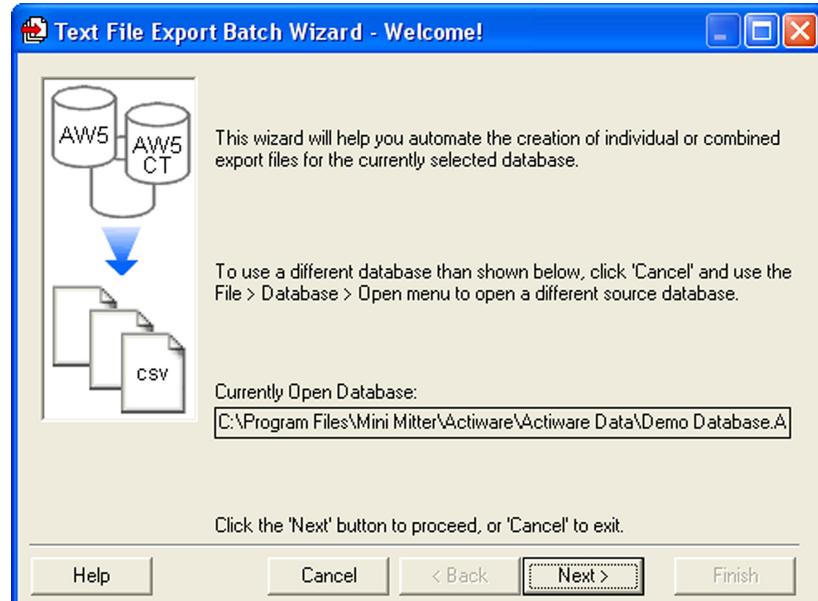
| Epoch-by-Epoch List | | | | | | | Marker/Score List |
|---------------------|----------|------------|----------|--------|------------|-----------------|-------------------|
| Line | Date | Time | Activity | Marker | Sleep/Wake | Interval Status | Interval St |
| 1 | 4/9/1999 | 8:45:00 AM | 684 | 0 | NaN | ACTIVE | |
| 2 | 4/9/1999 | 8:46:00 AM | 361 | 0 | NaN | ACTIVE | |
| 3 | 4/9/1999 | 8:47:00 AM | 229 | 0 | 1 | ACTIVE | |
| 4 | 4/9/1999 | 8:48:00 AM | 398 | 0 | 1 | ACTIVE | |
| 5 | 4/9/1999 | 8:49:00 AM | 288 | 0 | 1 | ACTIVE | |
| 6 | 4/9/1999 | 8:50:00 AM | 182 | 0 | 1 | ACTIVE | |
| 7 | 4/9/1999 | 8:51:00 AM | 60 | 0 | 1 | ACTIVE | |
| 8 | 4/9/1999 | 8:52:00 AM | 62 | 0 | 1 | ACTIVE | |
| 9 | 4/9/1999 | 8:53:00 AM | 73 | 0 | 1 | ACTIVE | |
| 10 | 4/9/1999 | 8:54:00 AM | 34 | 0 | 1 | ACTIVE | |
| 11 | 4/9/1999 | 8:55:00 AM | 21 | 0 | 1 | ACTIVE | |
| 12 | 4/9/1999 | 8:56:00 AM | 23 | 0 | 1 | ACTIVE | |
| 13 | 4/9/1999 | 8:57:00 AM | 208 | 0 | 1 | ACTIVE | |
| 14 | 4/9/1999 | 8:58:00 AM | 328 | 0 | 1 | ACTIVE | |
| 15 | 4/9/1999 | 8:59:00 AM | 237 | 0 | 1 | ACTIVE | |
| 16 | 4/9/1999 | 9:00:00 AM | 270 | 0 | 1 | ACTIVE | |
| 17 | 4/9/1999 | 9:01:00 AM | 125 | 0 | 1 | ACTIVE | |
| 18 | 4/9/1999 | 9:02:00 AM | 385 | 0 | 1 | ACTIVE | |
| 19 | 4/9/1999 | 9:03:00 AM | 684 | 0 | 1 | ACTIVE | |
| 20 | 4/9/1999 | 9:04:00 AM | 531 | 0 | 1 | ACTIVE | |
| 21 | 4/9/1999 | 9:05:00 AM | 424 | 0 | 1 | ACTIVE | |
| 22 | 4/9/1999 | 9:06:00 AM | 514 | 0 | 1 | ACTIVE | |
| 23 | 4/9/1999 | 9:07:00 AM | 261 | 0 | 1 | ACTIVE | |
| 24 | 4/9/1999 | 9:08:00 AM | 194 | 0 | 1 | ACTIVE | |
| 25 | 4/9/1999 | 9:09:00 AM | 194 | 0 | 1 | ACTIVE | |
| 26 | 4/9/1999 | 9:10:00 AM | 298 | 0 | 1 | ACTIVE | |
| 27 | 4/9/1999 | 9:11:00 AM | 229 | 0 | 1 | ACTIVE | |
| 28 | 4/9/1999 | 9:12:00 AM | 42 | 0 | 1 | ACTIVE | |
| 29 | 4/9/1999 | 9:13:00 AM | 34 | 0 | 1 | ACTIVE | |
| 30 | 4/9/1999 | 9:14:00 AM | 18 | 0 | 0 | ACTIVE | |
| 31 | 4/9/1999 | 9:15:00 AM | 20 | 0 | 0 | ACTIVE | |
| 32 | 4/9/1999 | 9:16:00 AM | 7 | 0 | 0 | ACTIVE | |
| 33 | 4/9/1999 | 9:17:00 AM | 27 | 0 | 0 | ACTIVE | |
| 34 | 4/9/1999 | 9:18:00 AM | 1 | 0 | 0 | ACTIVE | |
| 35 | 4/9/1999 | 9:19:00 AM | 5 | 0 | 0 | ACTIVE | |
| 36 | 4/9/1999 | 9:20:00 AM | 3 | 0 | 0 | ACTIVE | |
| 37 | 4/9/1999 | 9:21:00 AM | 0 | 0 | 0 | ACTIVE | |
| 38 | 4/9/1999 | 9:22:00 AM | 1 | 0 | 0 | ACTIVE | |
| 39 | 4/9/1999 | 9:23:00 AM | 60 | 0 | 1 | ACTIVE | |
| 40 | 4/9/1999 | 9:24:00 AM | 0 | 0 | 0 | ACTIVE | |

To select or deselect displayed columns, click Tools > Options > Data List.

Text File Batch Export

This option is used when you want to export data from multiple analyses for the currently open database. You can elect to send these data to individual text files or to the same composite file.

Text File Export Batch Wizard Welcome window



1. Tools > Text File Export Batch

This will launch the Export Batch Wizard. Confirm that the currently active database is the one you want to export from.

2. Click Next.

Select the type of output you require (individual files for each analysis, or a combined file for multiple analyses).

Select destination of the exported data



3. Click **Browse.**

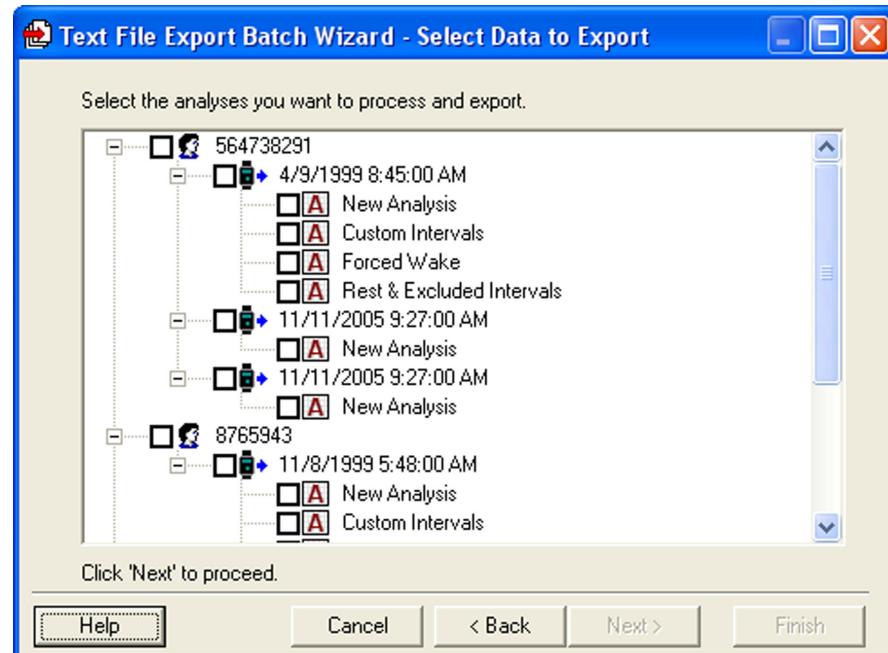
Use this button to determine the destination for any export output using the **Browse** button and the Windows File Dialog.

4. Click the **Options button to make any changes.**

5. Click **Next.**

6. Select the data that you want to include in the export file by checking the boxes.

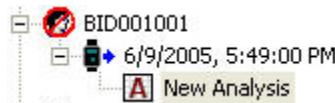
Select data to export



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.

Hidden data is indicated by the red circle and the diagonal line.



7. Suppress Errors Messages box.

When this box is checked, you will not be prompted if an error occurs during the batch process. If a file already exists, an automatic filename will be created.

8. Overwrite Existing Files box.

Indicate if you want to overwrite existing export file(s) without being prompted.

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

More options are available when using the Text File Export Batch Wizard

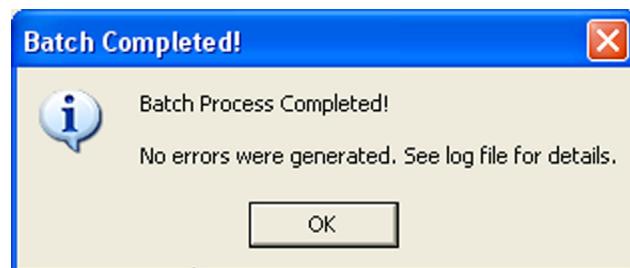


10. Click **OK when the batch process is completed.**

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.

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

Batch Completed! pop-up window



Import AWD Files

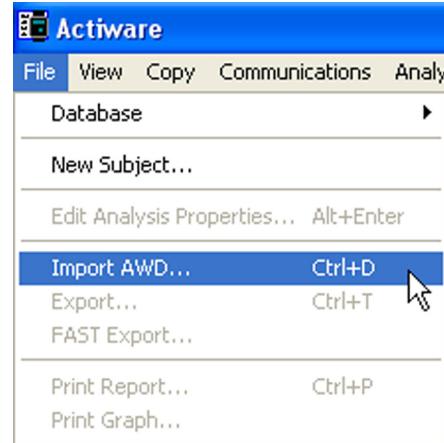
Note: .AWS files cannot be imported. Only .AWD (Actiwatch) files can be imported.

Import AWD

You can import data files collected with previous versions of Actiware (Actiware-Sleep/Rhythm v3.4 and earlier).

1. Left mouse click to highlight the subject you want to import the AWD file to. If you do not already have a subject created, use **File > New Subject** menu.
2. Click **File > Import AWD**.

File > Import AWD

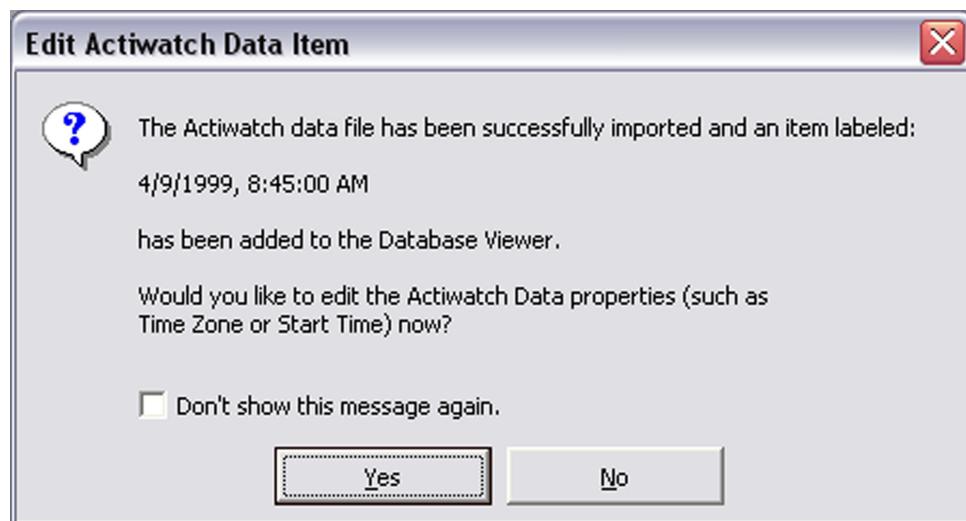


3. Use Windows File Dialog to Browse to the location of the AWD files. Select the file and click **OK** to import. When the file is successfully imported a pop-up window will appear.

Note: The identity from the AWD file is not imported. You must select or create the correct subject when importing.

4. Click **Yes** to edit the Actiwatch Data properties or click **No** to bypass.
5. The data is ready for analysis.

Edit Actiware Data



Graph

View View

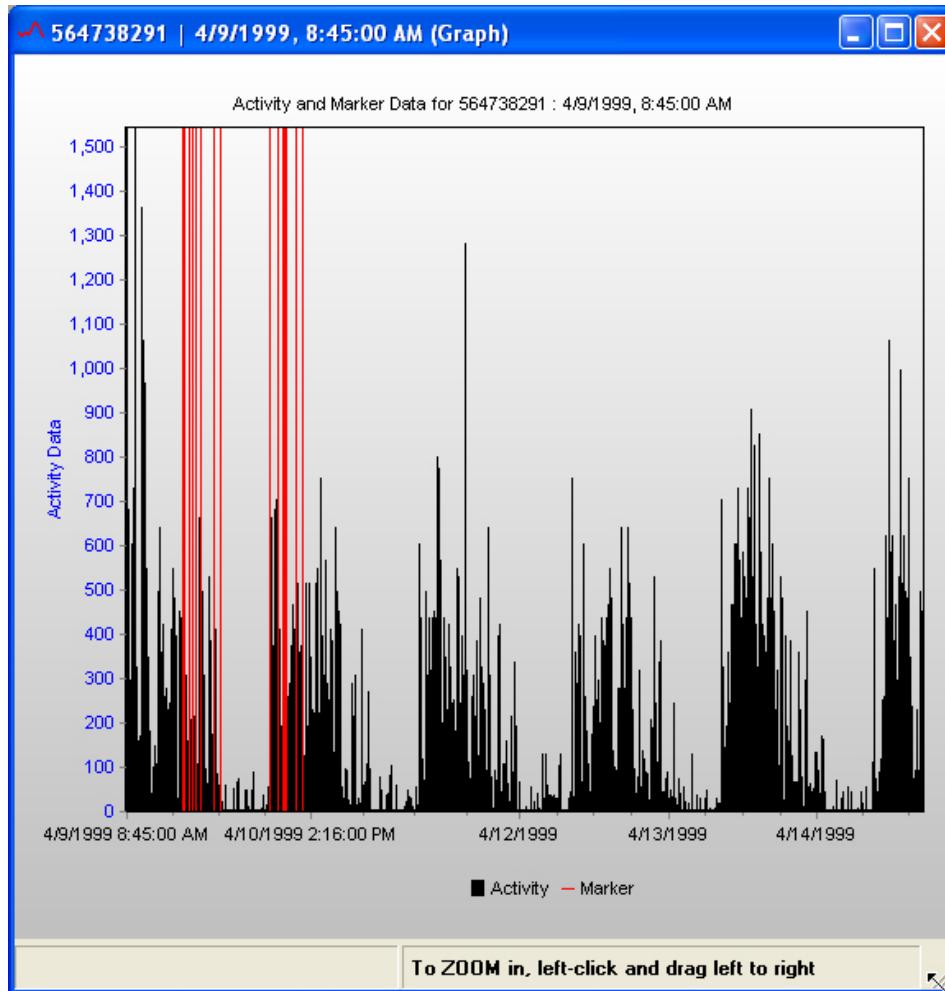
The Actiware toolbars provide many new features to assist you with the data.

Graph

1. View > Graph 

This is the Graph window for viewing Actiwatch data along a single axis.

View > Graph



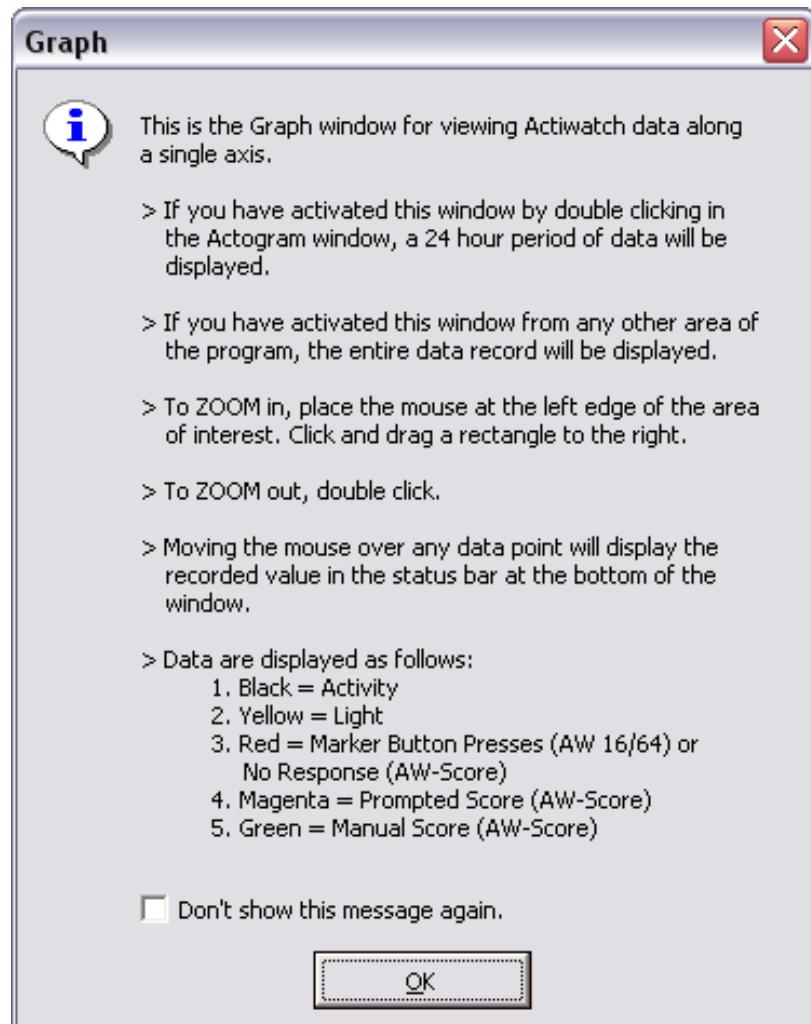
Graph Icons

2. View > Toolbars > Graph 

When viewing a graph, the Graph Icons are available in the standard toolbar.

These icons allow you to

1. Print the graph.
2. Edit Graph Display Properties.
3. Copy a picture of the graph to the Windows Clipboard.



The Graph Help window provides useful information when using the Graph view.

Edit Graph Display Properties

1. Tools > Edit Graph



This more advanced feature allows you to edit the Graph GUI, display and printing features, and plotting parameters of the graph.

5

CLINICAL TRIALS

Actiware-CT (clinical trial) software is designed especially for customers who are concerned about data security and compliance with 21 CFR Part 11. New features have been included in the software that

- 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.

Actiware-CT operates in the same manner as Actiware. Section 5 outlines the security features in CT. Please refer to *Getting Started* in Section 2 for information on using the software.

Note: *Actiware-CT requires you to authenticate using your Windows or Network username and password. Please contact your local administrator with any issues or questions.*

Note: *Actiware-CT requires the Windows 2000 Professional or the Windows XP Professional operating system.*

Authenticate When you launch the Actiware-CT program, the Security Log on window will appear. To access the program, you must log on with your **User Name** and **Password** that you would normally use to access the Windows operating system.

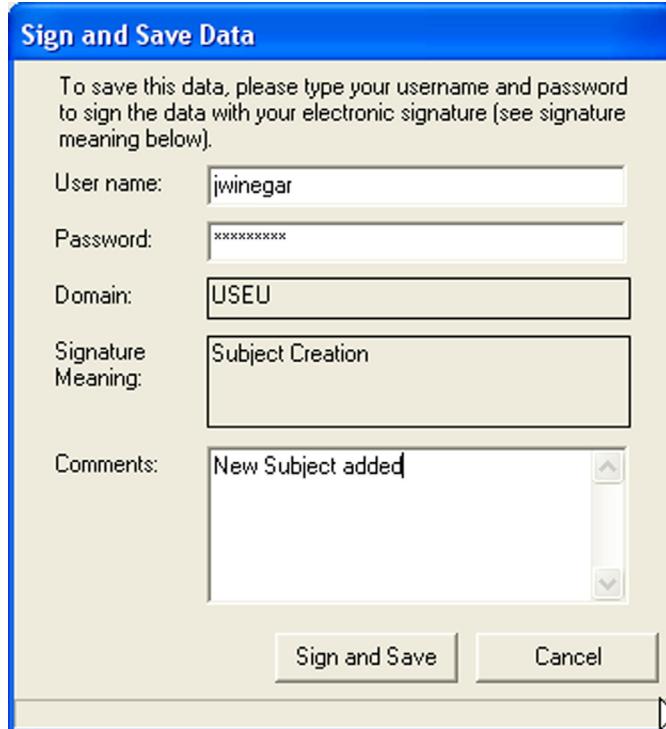
Security Log on window



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 will prompt you for your user name and password.

1. Enter User Name and Password.
2. Review the signature meaning.
3. Add any comments.
4. Click the **Sign and Save** button.

Sign and Save window



5. 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.

Audit Trail

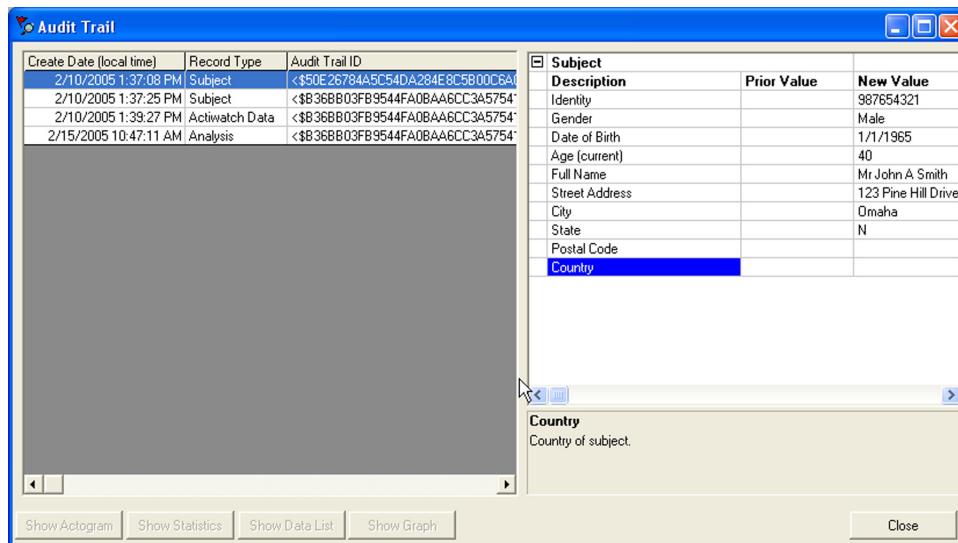
The Audit Trail feature of Actiware 5.0 is designed to display all changes made to subjects, Actiwatch data items and analyses. Because the relationship between these items is hierarchical, the Audit Trail window will display all the parents of any selected item.

If an analysis is selected for Audit Trail display, then the Audit Trail will show all changes for that analysis, it's 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 it's parent subject will be displayed in the Audit Trail window.

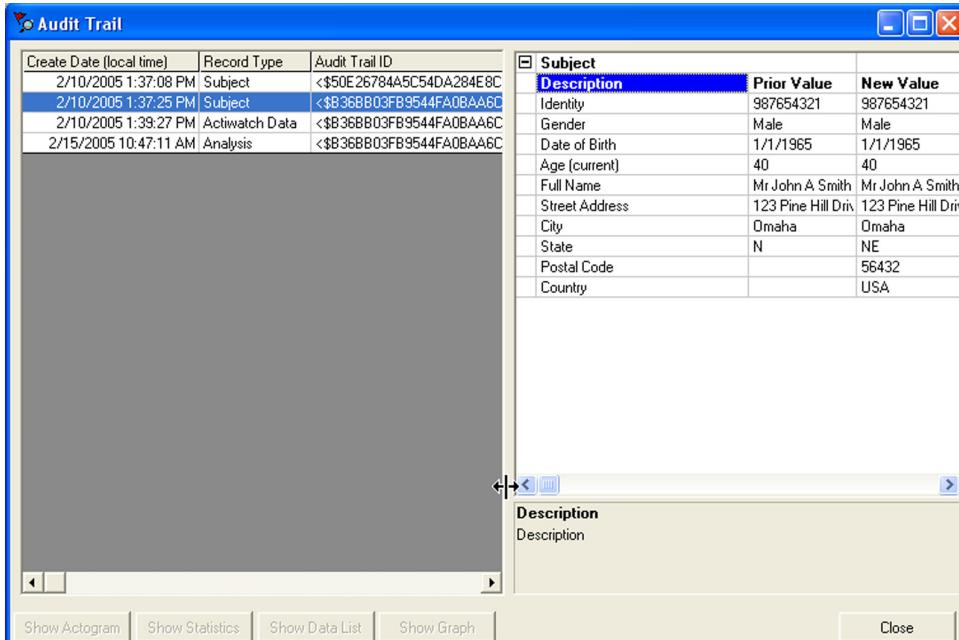
The picture below is the product of right-clicking on a saved analysis and selecting the Audit Trail menu item. Each row in the left side of the window represents either a record creation or a change to a record. In the screen shot below, there are five audit trail records: a subject creation and an edit to that subject, an Actiwatch data record creation and both an analysis creation and an edit to the same analysis. Note that the row that is highlighted is for a subject creation and no value is listed in the right hand display for *Prior Value* as there is no prior record.

Results of right-clicking on a saved analysis and selecting the Audit Trail menu item.



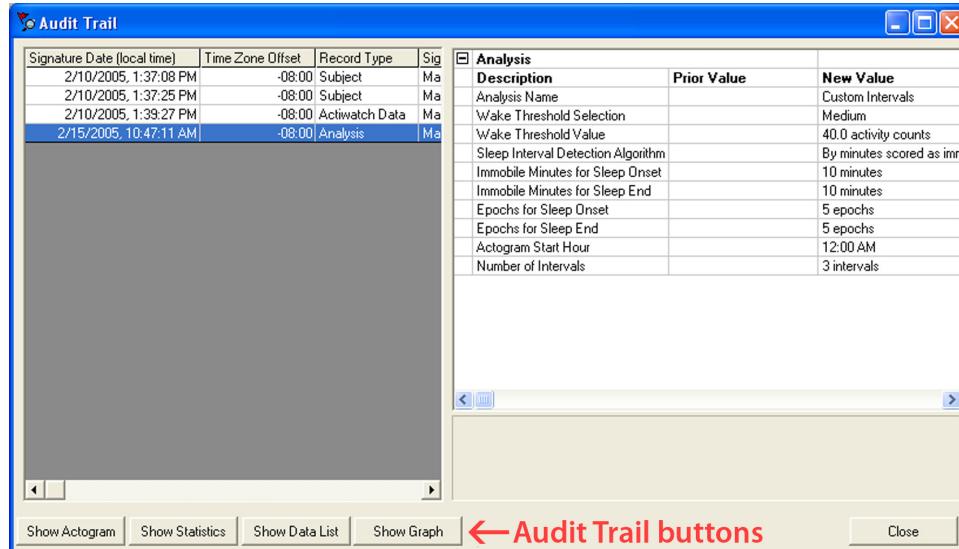
When a highlighted row represents an edit, such as the second line below, then the *Prior Value* column will contain the values before the edit.

Highlight the row to see prior and new values.



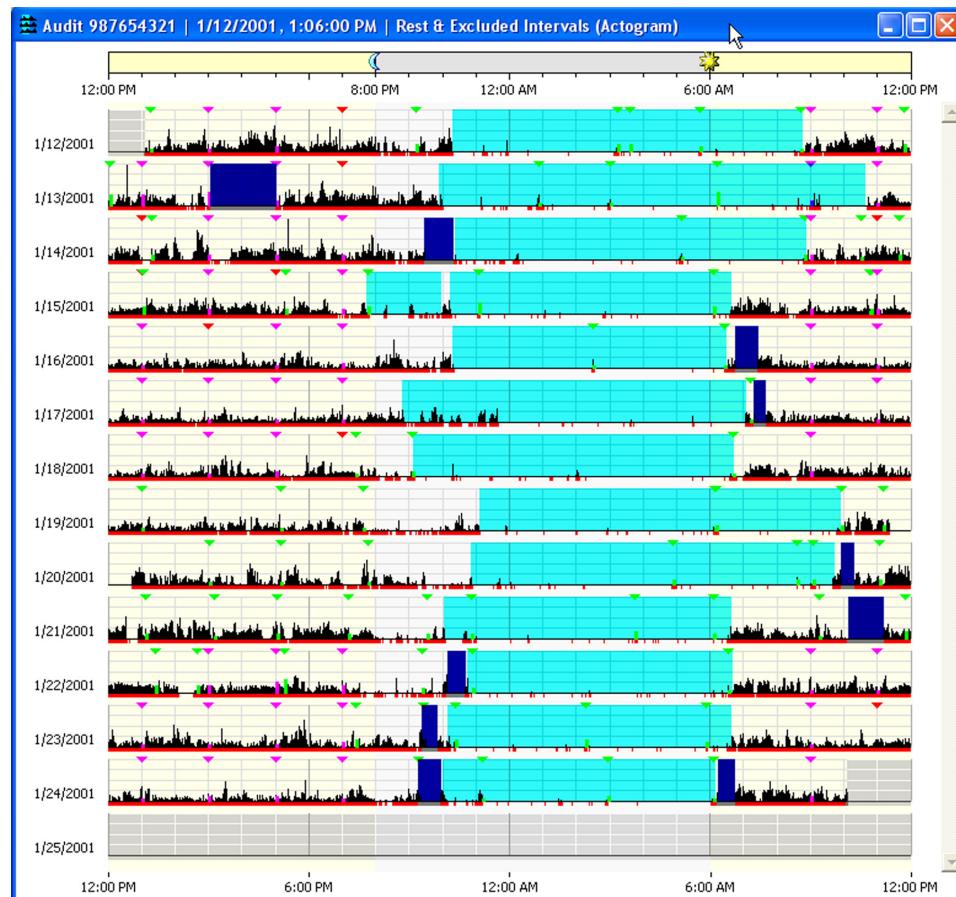
Note that in the two previous pictures the buttons at the bottom of the screen were not enabled. The most powerful feature of the Audit Trail window is the ability to display all previous revisions of records. When an Actiwatch data item is highlighted, the **Show Graph** button will be enabled. If you highlight an analysis row, then all the buttons will be enabled and you can create an audit version of an Actogram, statistics table or a data list.

Audit Trail window provides the ability to view all previous revisions of the record.



If the analysis has been edited and saved, then multiple rows will be displayed, such as the picture above. Highlighting the last row will reflect the most recent version of the analysis. Pressing the **Show Actogram** button will display the current Actogram in the normal display window except the title will be preceded with the word **Audit** as shown below.

Audit Actogram window



Note: Closing the Audit Trail window will close 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 open Actogram will be closed and the new one will replace it. The same holds true for statistics tables and data lists. Items created from the Audit Trail window cannot be edited.

Introduction to Electronic Signatures

To use Actiware-CT you will be 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, the user must sign with their username and password and 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 has been completed, 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 special 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, this means 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, the user must sign the document, and the user's 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.

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-CT.

This means that 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. We do this to assist our customers in complying with 21 CFR Part 11.

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

A SLEEP/WAKE ANALYSIS

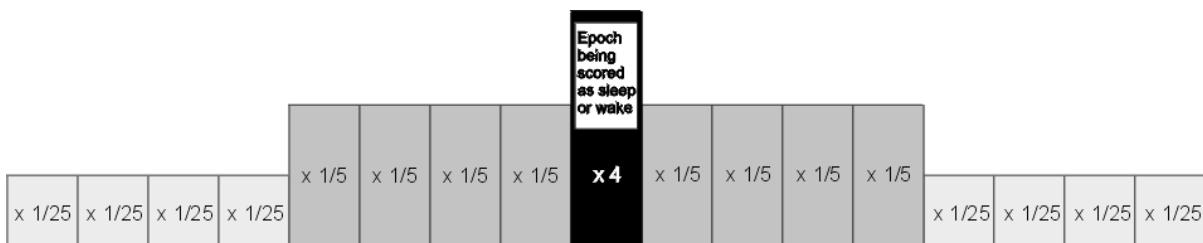
Actiware scores all epochs as either sleep or wake. Whether a particular epoch is scored as wake is determined by comparing activity counts for the epoch in question and those immediately surrounding it, to a threshold value set by the researcher. If the number of counts exceeds the threshold, the epoch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

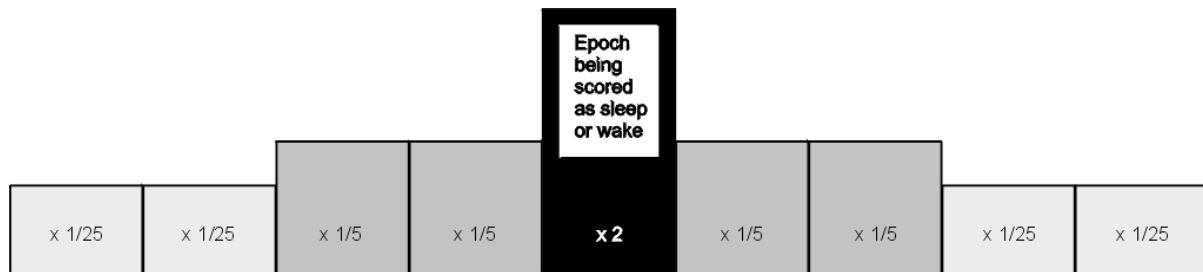
Calculating Total Activity Counts

Actiware calculates total activity counts based on the sampling epoch. Below are four diagrams showing how this scoring calculation is done.

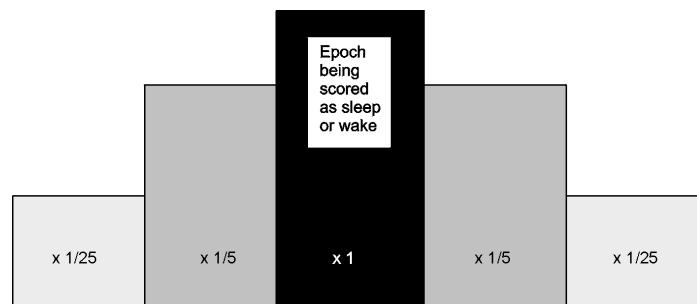
15-second
sampling
epochs



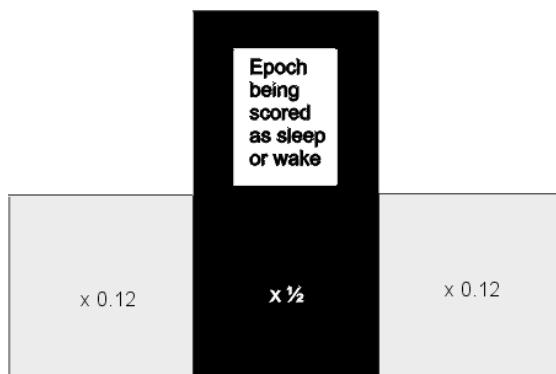
30-second
sampling
epochs



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 would be:

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

If this value is less than or equal to the wake threshold value (next paragraph) 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 table below.

| Wake Threshold Selection | Wake Threshold Value* |
|--------------------------|--|
| Low | 20 |
| Medium | 40 |
| High | 80 |
| Automatic | <u>Computed automatically based on activity data</u> |
| 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 (see below for definition of MOBILE);
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 would have to be greater than or equal to four to be scored as MOBILE.

B STATISTIC DEFINITIONS

Statistic Definitions

(In the order, left to right, in which they appear in the statistics table window when all are selected.)

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).

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).

Interval Duration

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

Total Activity

The sum of all valid physical activity counts [see Total Invalid Time, below] for all epochs from the Start Time to the End Time of the given interval.

Average Activity Per Minute

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.

Average Activity Per Epoch

The average of all valid physical activity counts for all epochs from the Start Time to the End Time of the given interval.

Standard Deviation of Activity

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.)

Maximum Activity

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 in 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 (so the Total Invalid Time is in minutes).

Percent Invalid (Activity)

- a) The percentage of Total Invalid Time (Activity) [see above] to the Interval Duration [see above]. b) (Total Invalid Time (Activity) divided by Interval Duration) multiplied by 100.

Total Invalid Time (Sleep/Wake)

(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 (so the Total Invalid Time is 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 – how much before and after being a function of the Epoch Length.

Percent Invalid (Sleep/Wake)

- a) The percentage of Total Invalid Time (Sleep/Wake) [see above] to the Interval Duration [see above]. b) (Total Invalid Time (Sleep/Wake) divided by Interval Duration) multiplied by 100.

Sleep 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 on Tools > Options > Analysis.

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 [see below] to (Interval Duration [see above] 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.

Wake After Sleep Onset (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 the practitioner using Actiware software) multiplied by the Epoch Length in minutes (so the Wake After Sleep Onset is in minutes). Note: Wake After Sleep Onset is identical to Scored Total Wake Time [see below] when the given interval is a Sleep Interval.

Scored Total 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 the practitioner using Actiware software]) multiplied by the Epoch Length in minutes (so the Scored Total Wake Time is in minutes). Note: In order to be scoreable as SLEEP or WAKE, an epoch must have a valid physical activity count [see Total Invalid Time (Sleep/Wake), above], 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.

Percent 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.

Number of 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.

Average Duration of Wake Bouts

The Scored Total Wake Time [see above] divided by the Number of Wake Bouts [see above], for the given interval.

Scored Total 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 the practitioner using Actiware software]) multiplied by the Epoch Length in minutes (so the Scored Total Sleep Time is in minutes). Note: In order to be scoreable as SLEEP or WAKE, an epoch must have a valid physical activity count [see Total Invalid Time (Sleep/Wake), above], 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.

Percent 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.

Number of 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.

Average Duration of Sleep Bouts

The Scored Total Sleep Time [see above] divided by the Number of Sleep Bouts [see above], for the given interval.

Scored Total 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 (so the Scored Total Immobile Time is in minutes)
Note: In order to be scoreable as IMMOBILE or MOBILE, an epoch must have a valid physical activity count [see Total Invalid Time (Activity), above].

Percent 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.

Number of 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.

Average Duration of Immobile Bouts

The Scored Total Immobile Time [see above] divided by the Number of Immobile Bouts [see above], for the given interval.

Scored Total 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 (so the Scored Total Mobile Time is in minutes). Note: In order to be scoreable as IMMOBILE or MOBILE, an epoch must have a valid physical activity count [see Total Invalid Time (Activity), above].

Percent 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.

Number of 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.

Average Duration of Mobile Bouts

The Scored Total Mobile Time [see above] divided by the Number of Mobile Bouts [see above], for the given interval.

Number of Immobile Bouts 1 Minute in Duration

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.

Percentage of Number of Immobile Bouts 1 minute in duration to the Number of Immobile Bouts

a) The percentage of Number of Immobile Bouts 1 Minute in Duration to the Number of Immobile Bouts [see above], for the given interval. b) (Number of Immobile Bouts 1 Minute in Duration divided by Number of Immobile Bouts) multiplied by 100.

Fragmentation Index

The sum of Percent Mobile [see above] and Percent Immobile Bouts Less Than 1-Minute Duration to the Number of Immobile Bouts, for the given interval. Also known as the Index of Restlessness or Movement and Fragmentation Index.

Total Illuminance Exposure

(The sum of all valid illuminance data, in Lux, from an Actiwatch-L [see Total Invalid Time (Illuminance), below] for all epochs from the Start Time to the End Time of the given interval) multiplied by the Epoch Length in minutes (so the Total Illuminance Exposure is in Lux-minutes).

Average Illuminance

The average of all valid illuminance data for all epochs from the Start Time to the End Time of the given interval.

Standard Deviation of Illuminance

The standard deviation of all valid illuminance 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.)

Maximum Illuminance

The datum of highest value (greatest average intensity of illumination during an epoch) from the set of all valid illuminance 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 – the highest intensity of illumination the Actiwatch-L was exposed to during the interval.

Time Above Illuminance Threshold

a) (The total number of epochs between the Start Time and the End Time of the given interval with valid illuminance data greater than the given Illuminance Threshold) multiplied by the Epoch Length in minutes (so the Time Above Illuminance Threshold is in minutes). b) The total accumulation of time, in minutes, during which the Actiwatch-L was exposed to an intensity of illumination above the given Illuminance Threshold.

Total Invalid Time (Illuminance)

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

Percent Invalid (Illuminance)

a) The percentage of Total Invalid Time (Illuminance) [see above] to the Interval Duration [see above]. b) (Total Invalid Time (Illuminance) divided by Interval Duration) multiplied by 100.

Total Number of Scores

The Number of Manual Scores [see below] plus the Number of Scheduled Scores [see below] entered by the subject while wearing Actiwatch-Score, and not manually excluded later by the practitioner using Actiware software, from the Start Time to the End Time of the given interval.

Number of Manual Scores

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

Number of Scheduled Scores

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

Number of No Responses

The number of No Responses to Scheduled Scores (that are not manually excluded by the practitioner using Actiware software), from the Start Time to the End Time of the given interval.

Average 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 [see above], for all epochs from the Start Time to the End Time of the given interval.

Average Manual Score

The sum of all Manual Score Values [that are not manually excluded] divided by the Number of Manual Scores [see above], for all epochs from the Start Time to the End Time of the given interval.

Average Scheduled Score

The sum of all Scheduled Score Values [that are not manually excluded] divided by the Number of Scheduled Scores [see above], for all epochs from the Start Time to the End Time of the given interval.

Standard Deviation of All Scores

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.)

Standard Deviation of Manual Scores

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.)

Standard Deviation of Scheduled Scores

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.)

C ACTIWATCH HARDWARE

All communication with Actiwatch is accomplished using an ActiReader that is connected to a computer via an RS-232 Serial Port. This connection to the computer supplies power and communication instructions. Settings made prior to the start of data collection, as well as all data values, are communicated through this device. The Actiwatch and ActiReader communicate using short range radio telemetry. Readers are not “unit specific,” i.e., any Actiwatch may communicate with any ActiReader or Actiwatch Reader.

There are four models of Actiwatch currently available:

Actiwatch®-64

Actiwatch-64 contains 64 KB of on-board memory. Chronobiological studies can be conducted over several weeks because intervals longer than five minutes may be selected. An event marker button allows subjects to mark times at which important events occur.

Actiwatch®-16

Similar to the Actiwatch-64, but Actiwatch-16 has 16 KB of memory.

Actiwatch®-L

Actiwatch-L measures activity and ambient light exposure (illuminance). Actiwatch-L does not have an event marker button.

Actiwatch®-Score

Actiwatch-Score measures activity and subjective weighting of specific times or events.

Accelerometer

The shape of the accelerometer makes it most sensitive to motion changes in certain orientations. However, it is an omnidirectional sensor, resulting in sensitivity to motion changes in all directions. The Actiwatch stores an integration of movement (including directional aspects) as activity “counts”. The sampling frequency is 32 Hz.

Accelerometer orientation



Sensor Calibration and Reproducibility

Each Actiwatch has been programmed with a calibration coefficient to normalize data between watches. During calibration at the factory, all Actiwatch devices are normalized to remove most, if not all variation between devices. Regardless of this feature, we emphasize that relative levels of activity within a data set, or as measured by the same device, should be used for drawing inference rather than absolute values between units. This is due to the great variation in mounting the device.

Note: To obtain the most repeatable results, it is important to develop a standardized mounting and positioning protocol.

Time Keeping

The computer clock sets the Actiwatch start time. Within the device a crystal oscillator keeps elapsed time. When a sampling epoch is chosen, Actiwatch waits a specific number of oscillations before storing the number of activity counts. This also applies to delayed starting times. The time-keeping circuitry does not initiate until the device has been removed from the reader.

Note: For Actiwatch 16/64 (SN prior to V90xxxx) and Actiwatch-L, the time-keeping function of the device will not start while on the ActiReader. These Actiwatch devices cannot keep time while retrieving data. The Actiwatch Score and Actiwatch 16/64 (SN V90xxxx and later) may keep time while on the ActiReader for short durations. You should still reconfigure the watch after retrieving data.

Telemetric Communications Link

Actiwatch requires no external communications port for configuration or data retrieval. Communication between Actiwatch and ActiReader is established via a wireless link.

Water Proof

Actiwatch-16, 64, and Actiwatch-L devices are waterproof to IEC Standard 60529 IPX7. They are water tight to a depth of 1 meter for 30 minutes. These devices will tolerate normal daily experiences such as shower, spa (hot tub), swimming, skiing, rain, household chores, etc. Actiwatch-Score is drip-tight to IEC Standard 60529 IPX2. It is resistant to dripping and light splashing of liquids.

CAUTION! Prolonged submersion or exposure exceeding the above limits may cause damage to the device.

CAUTION! When replacing the battery, it is very important that the rubber O-ring in the battery compartment also be changed. The back mounting panel should be firmly screwed in place to achieve a waterproof seal. The waterproof seals of all Actiwatch devices are checked before leaving the factory. To preserve this integrity, it is imperative you follow the procedures in the Change Battery Wizard.

Standard Wrist Bands

Standard Actiwatch wrist bands are washable and disposable. Extra bands and batteries are available from Mini Mitter. Bands may also be interconnected if the device is to be worn on locations other than the wrist. Longer bands for use around the ankle are also available from Mini Mitter, and a soft, nylon band with hook and loop fastener. Other means to attach Actiwatch may be used as long as the protocols of mounting and positioning are followed.

Marker Button

Actiwatch-16, Actiwatch-64, and Actiwatch-Score models are equipped with a marker switch on the device's front panel. When depressed this button provides tactic feedback alerting the subject to a successful marking of the date and time. A light sensor in Actiwatch-L replaces the marker button.

Animal Case

Both Actiwatch-16 and Actiwatch-64 can be fitted in the Actiwatch animal case. This case protects Actiwatch from water, soil, shock, and gnawing. It does not affect performance.

Actiwatch-L

The specifications and functions in this manual for Actiwatch-L pertain to those devices manufactured on or after July 1, 1999. These devices are easy to identify as they have a serial number that begins with the letter "P." Actiwatch-L devices manufactured before July 1, 1999 have serial numbers beginning with "L." These previous devices have different functional specifications and are not supported by Actiware version 5 or later. If you have questions, contact Mini Mitter for additional information.

Actiwatch-Score

This device provides the means to subjectively "score" by two methods.

- Auditory/flashing-display from device

An alarm sounds and the LED display flashes alerting the user to subjectively weight the event. The annunciation times are chosen during the device configuration. An example of this use would be a request of the user to judge the level of sleepiness every half-hour during a long task.

- Arbitrary input from user

In this "manual" mode the user inputs a level of subjective weighting commensurate with the event. An example of this use might be a level of recurring headache pain through the day, or perhaps a level of depression.

Actiwatch-Score devices with serial numbers beginning with "N" are not supported by Actiware version 5 or later. If you have questions, contact Mini Mitter for additional information.

Actiwatch-L and Actiware combine hardware and software functions to determine light (illuminance) exposure for subjects monitored with the Actiwatch-L. Actiware will configure and retrieve data from an Actiwatch-L. When light (illuminance) data are available, Actiware will display them in the Actogram, Graph, Data List, and Statistics Table.

Actiwatch-L does not include a marker button. It is replaced with a light sensor. Hence no marker data are available in the analysis windows for Actiwatch-L devices.

Light Sensor Type

Actiwatch-L has a photodiode for sensing incoming light (illuminance). This optical sensor has a spectral sensitivity approximating that of the human eye.

Light Sensor Performance

The light-measuring performance of the AW-L is as follows:

| Parameter | Value | Condition or Unit |
|---|-----------------|---------------------------------|
| Peak spectral sensitivity | 580 | nm (nanometers) |
| Wavelength window | 330 to 720 | nm |
| Minimum illuminance sensitivity | 0.1 | lux |
| Maximum illuminance sensitivity | 150,000 | lux |
| Linearity | 2% | Typical from 0.1 to 150,000 lux |
| Uncertainty | <10% | Typical from 400 to 800 nm |
| Resolution | 2% of lux value | Typical |
| Temperature variation of spectral sensitivity | <0.1% | From 400 to 800 nm |
| Angular response | ±50 degrees | to 1/2 power point |
| Active area | 5.16 | mm ² |

Recommended Calibration

We recommend factory calibration of Actiwatch-L every 12 months. Contact Mini Mitter Technical Support for information.

Influences

There are various factors that may influence the light (illuminance) data collected by Actiwatch-L. The most likely to occur are as follows.

Sensor positioning

The angle at which light impacts Actiwatch-L can result in variations in readings. This is true of all light sensing devices. It is important that researchers develop a standardized location on the subject to enable Actiwatch-L to minimize this variable.

Condition of the lens

Light (illuminance) measurement varies greatly with a buildup of materials on the lens. It is important to check for dirt, moisture, and other obscuring debris prior to initiating data collection. Keeping the device clean will help avoid this problem. Clean as you would eyeglasses, with a soft cloth moistened with water.

Inadvertently covering Actiwatch-L

The light sensor may inadvertently be covered by clothing or other items. The unit may be detached from the band and used on a visor or other piece of clothing to minimize this possibility. Analysis of data should always take these variables into account.

Illuminance Data

Illuminance data (“light data”) retrieved from Actiwatch-L are stored in the Actiware database along with activity data. Illuminance data are expressed in the SI (System International) unit of lux (see “Definitions for Actiwatch-L” on the following page).

Light Analysis is integrated seamlessly into Actiware. Instead of having a separate window for analyzing illuminance data, the Actogram, Graph, Data List, and Statistics Table can be used for light analysis.

Actiwatch-L Actogram Data



Illuminance data are displayed in the Actogram as an orange line graph superimposed over the activity data. You can use the Actogram View toolbar to adjust the Illuminance Scale, the vertical height of the illuminance data.

Illuminance data are also shown in Graph as an orange line.

Per epoch Illuminance data can be seen in the Data List along with activity data, and can be exported along with activity data and per epoch sleep analysis results. The Illuminance column can be shown or hidden in the Data List or Export files by adjusting settings in the **Tools > Options > Data List** window.

To select illuminance statistics, use **Tools > Options** window, Statistics tab. The selected illuminance statistics will be included for Rest, Active, Daily, and Custom Intervals. This will cause these statistics to be included for Rest, Active, Daily, and Custom Intervals. You can create Custom Intervals for analyzing periods of interest, without using or affecting sleep statistics. See *Advanced Usage*, section 4 for help in creating intervals.

Definitions for Actiwatch-L

The following definitions are specific when analyzing data from an Actiwatch-L.

Illuminance

Intensity of illumination. The luminous flux incident on a given surface per unit area. Measured in lux.

Luminous Flux

Rate of flow of radiant energy as evaluated by the luminous sensation that it produces. The luminous flux is obtained from the radiant flux of the source corrected according to the effect it has on the observer, i.e. according to the spectral sensitivity of the receptor.

Lux

SI (System International) unit of illuminance. One lumen uniformly incident on an area of one square meter.

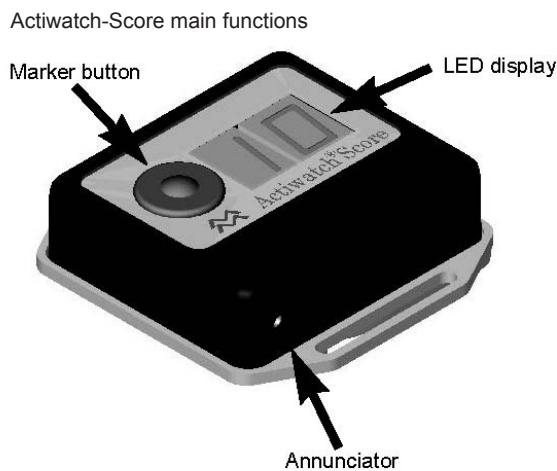
Light

The agent that causes a visual sensation when it falls on the retina of the eye (a narrow section of the electromagnetic spectrum).

ACTIWATCH-SCORE

Actiwatch-Score is an activity monitor with an annunciator, an event marker button, and an illuminated numerical display. It allows the application of subjective levels to time stamped events. The front panel of Actiwatch-Score has a marker button, 2-digit, 7-segment direct-read LEDs, and an annunciator.

Actiwatch-Score activity data is identical to other Actiwatch models. Actiwatch-Score is unique in that the marker button allows the user to “score” an event.



Actiwatch-Score Setup

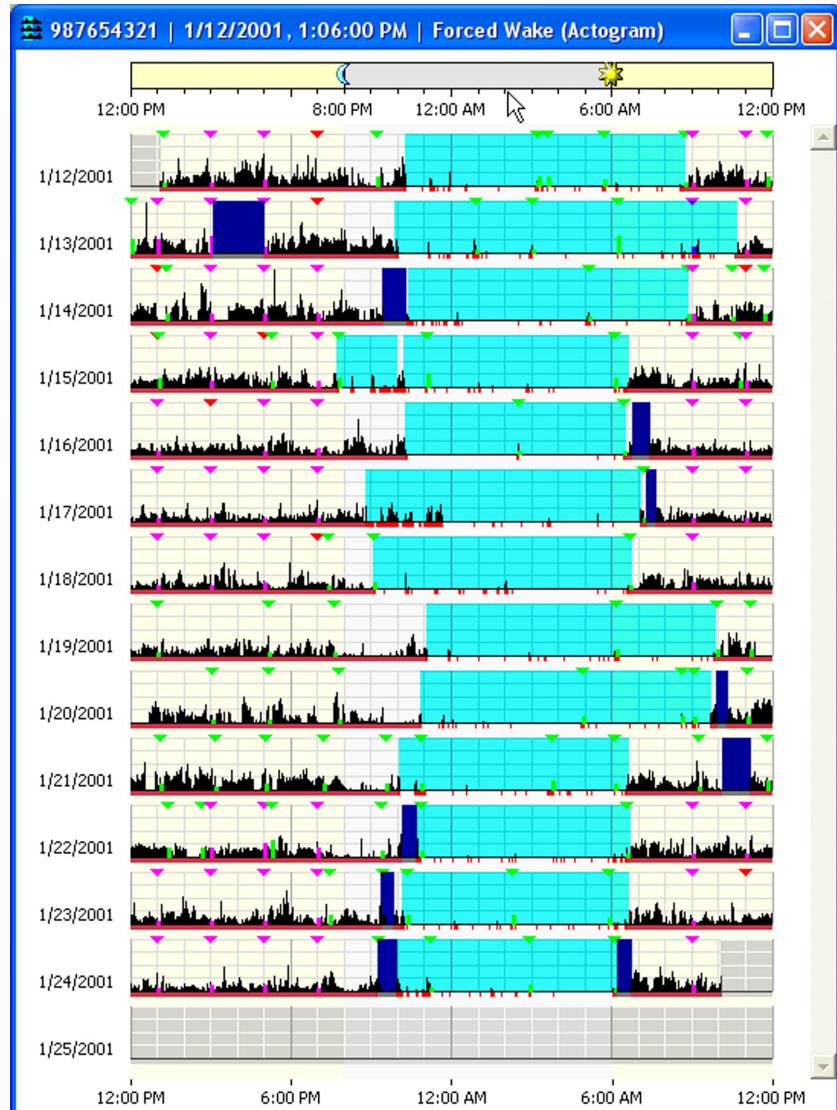
For all Actiwatch devices, the Actiwatch-Score is configured using the Configure Actiwatch Wizard. This wizard provides the means to program the scoring range (any range from 0 through 15), and schedule audible alarms. Audible alarms are used to remind the patient to enter a subjective score value into the Actiwatch.

Once the data have been downloading into Actiware using the Retrieve Data from Actiwatch wizard, you can analyze your Score Data.

Score Analysis

Score Analysis is integrated seamlessly into Actiware. Instead of having a separate window for analyzing score data, the Actogram, Graph, Data List, and Statistics Table can be used for score analysis.

Actiwatch-Score Actogram Data



There are three types of Score data.

Scheduled Scores

These are score values where the patient responded to the scheduled alarm you programmed. These scores appear as magenta lines on the display.

Manual Scores

These scores were entered manually, without an alarm. They appear as green lines on the display.

No Response

When the patient does not respond to a scheduled alarm, this is represented by a small red triangle.

Only one score can be recorded per epoch.

The score value and score type can be seen by placing your mouse over the triangle at the top of the score value in the Actogram.

Per epoch score data can be seen in the Data List along with activity data, and can be exported along with activity data and per epoch sleep analysis results. In addition, a Marker/Score List is provided that includes only the score data. The Score and Score Type columns can be shown or hidden in the Data List or Export files by adjusting settings in the **Tools > Options > Data List** window.

To generate statistics based on score data, use the Tools > Options window, Statistics tab to include Score Statistics. This will cause these statistics to be included for Rest, Active, Daily, and Custom Intervals. You can create Custom Intervals for analyzing periods of interest, without using or affecting sleep statistics. See *Getting Started* in section 2 for help in creating custom intervals.

| | |
|-------------|--|
| Annunciator | The annunciator is a miniature horn that generates a “chirp” form of audible announcement. The annunciator sound exits through the side of the case. The annunciator is water-resistant as well as the case. |
|-------------|--|

Turning off the annunciator

1. Hold the marker button down 3 seconds.
2. The LED will display **OF** to verify the annunciator is off.

Turning on the annunciator

1. Hold the marker button down for 3 seconds.
2. The LED will display **On** to verify the annunciator is on.

*Note: After setup, the annunciator is reset to **On**.*

| | |
|---------------|--|
| Marker Button | The marker button is a switch that is used to respond to an audible event and enter a score to “weight” the event. It can also be used to turn the annunciator on and off. |
|---------------|--|

Scheduled Events

During a scheduled event, if the marker button is pressed the annunciator will silence, and the score range minimum value chosen during setup will replace the two dashes. Each subsequent press of the marker will increment the display until it reaches the score range maximum value chosen during setup. If the marker button is pressed one more time, the display will begin again at the minimum value.

Manual Event

During a “manual” event, i.e., when no alarm is sounded but a marker is entered, the display will show two dashes. If the annunciator is enabled, Actiwatch-Score will beep once per second for 10 seconds, or until the event is scored.

Note: Once the marker button is pressed, released, and pressed again and held, the LED will increment once per second.

LED Display

The display is a 2-digit, 7-segment LED. In addition to displaying the score (event weighting), there are other functions as well.

- When an event is to be scored, the annunciator will beep once per second for 10 seconds. If the annunciator is disabled, only the LED will activate.
- The display will show the annunciator status (on or off) after the marker button is pressed and held for 3 seconds (refer to *Annunciator* on preceding page).

Note: AW-Score will not acquire activity data during the brief time the LEDs are lit, such as when setting score values.

Battery Life The battery life for Actiwatch-Score is primarily affected by:

- The number of score entries (whether prompted by an alarm or not)
- Time taken to enter a score (when the LEDs are lit) The following table is the battery life in days as a function of the average scores per day, and the average score entry time (approximate):

| Score events entered by day | Time taken to enter score | | |
|-----------------------------|---------------------------|----------|----------|
| | 10 sec | 20 sec | 30 sec |
| 5 | 139 days | 123 days | 110 days |
| 10 | 123 days | 100 days | 84 days |
| 20 | 100 days | 73 days | 57 days |
| 40 | 73 days | 47 days | 35 days |

Actiwatch Battery Replacement Procedure

Nearly all Actiwatch devices use the CR2025 coin-cell battery. The methods used to change the battery are identical for all current 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 kits available from Mini Mitter.

CAUTION! *The latest Actiwatch-Score models (serial numbers having a D prefix, e.g. Dxxxxx) use a CR 2025 battery. Earlier Actiwatch- Score models (serial numbers having an N prefix, e.g. Nxxxxx), use a CR 2032 battery. These batteries are not interchangeable, and may result in electronic or mechanical destruction. Use of the improper battery will void the warranty.*

Battery Change Wizard

Actiware 5.0 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.

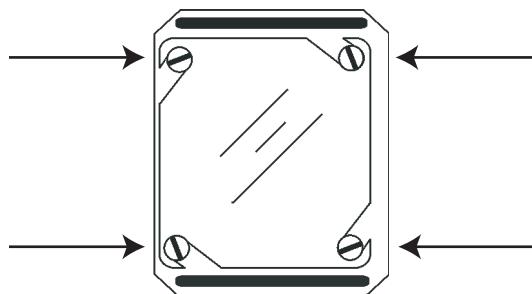
The Actiwatch battery is a CR2025, 3-Volt, 220-mAmp-hour Lithium Manganese cell. To properly install this battery, specific items may be required. These items are included in the Battery Change Kit from Mini Mitter.

Typical Battery Replacement Kit

| Description | Quantity |
|-----------------------------------|----------|
| O-ring | 6 |
| Battery, 3V lithium cell (CR2025) | 6 |
| Screwdriver, flat head | 1 |
| Screw, machine, 1.6 x 6 mm | 24 |
| Cotton swabs | 12 |
| Instructions | 1 set |

Additional materials that may be required:
Denatured alcohol
X-Acto® knife blade (flat tip) or similar sharp knife

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 discard. See warning below!

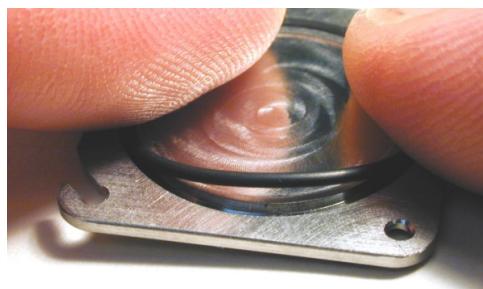
WARNING! *Dispose of lithium batteries appropriately. Do not incinerate due to risk of explosion.*

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

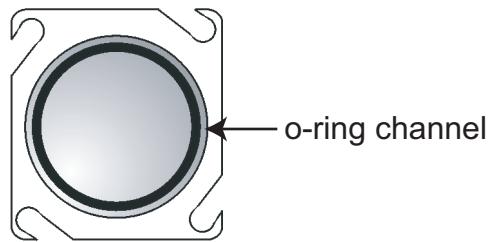
4. Thoroughly clean the O-ring channel with alcohol.

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

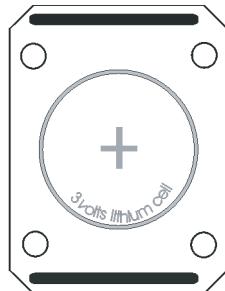
5. Place a new O-ring into the channel in the back cover as shown below. Use the following technique:
 - Pre-stretch the O-ring by gently flexing it in several directions.
 - Place a portion of the O-ring in the channel and hold it with your thumb or finger as shown below.



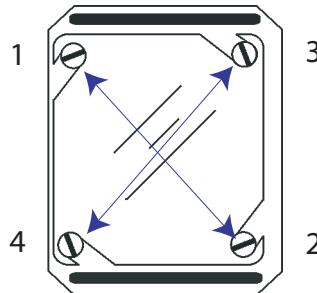
- Use a finger on the other hand to guide the O-ring into the channel.
- Be sure that the O-ring is properly seated in the channel, and is not twisted or deformed.



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



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.

Actiwatch Cleaning Procedure

The Actiwatch and band may be cleaned by using a cloth moistened with a mild detergent and warm water. Do not use bleach, alcohol, cleaning solutions containing alcohol, or any strong household cleaners.

Cleaning the Actiwatch Band

Actiwatch bands can be washed and reused. However, it should be noted that Actiwatch studies involve mounting Actiwatch on the body. With some subjects, this may raise particular sensitivities with respect to reusing the bands, and that should be taken into consideration. Additional bands are inexpensive and are available from the manufacturer. Clean the band as follows.

- 1 Remove the band from the device.
- 2 Hand wash the band in warm water with a mild detergent. Rinse.
- 3 Gently dry with a paper towel or soft cloth, or air dry.

Cleaning the Actiwatch Device

Only when the battery cover is installed and the fully sealed should Actiwatch be cleaned.

CAUTION! Do not clean this device while the battery cover is off.

Clean the Actiwatch device as follows.

- 1 Clean with the battery cover on.
- 2 Wet a corner of a clean cloth with warm water. Add a drop or two of mild detergent to the wet cloth and gently wipe the Actiwatch device. Wet another corner with warm water and wipe away soap residue.
- 3 Gently dry with a paper towel or soft cloth.
- 4 Mount the Actiwatch back on the clean band.

D

SPECIFICATION

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Actiwatch®-L

Actiwatch-L measures activity and ambient light exposure (illuminance). Actiwatch-L does not have an event marker button.

Actiwatch®-Score

Actiwatch-Score measures activity and subjective weighting of specific times or events.

Specification for Actiwatch-16/64

ENVIRONMENTAL

| | Operating | Storage |
|----------------------|--|--------------------------------------|
| Temperature | 0° C to 40° C (32° F to 104° F) | -10° C to 50° C (14° F to 122° F) |
| Relative Humidity | 0 to 95% RH | 0 to 95% RH |
| Atmospheric Pressure | 500 to 1060kPa (5600 feet to sea level) | |

PHYSICAL

| | | | |
|--------------------------|------------------------------|--------------------------------|--|
| Dimensions: | 29 L x 37 W x 12 H (mm) | | |
| Weight: | 16 grams | w/o band with standard band | |
| | 22 grams | | |
| Case Material: | Polyurethane/Polyester Alloy | | |
| Frame and Battery Cover: | Titanium | | |
| Standard Wrist Band: | Nylon with buckle | | |

ELECTRICAL

| | |
|--|---|
| Battery Type: | CR 2025 Lithium |
| Battery Life: | 6 Months Typical |
| Protection Against Electric Shock: | Internally powered |
| Degree of Protection Against Electric Shock: | Type BF Applied Part |
| Modes of Operation: | Continuous |
| Electromagnetic Compatibility: | The device meets the requirements of EN 60601-1-2, second edition (2001). |
| Fuses: | There are no user-replaceable fuses. |
| Degree of Protection Against Ingress of Water: | Water tight to a depth of 1 meter for 30 minutes IEC Standard IPX7 |

FUNCTIONAL

| Parameter | Value | Note |
|---------------------------|---|---|
| Accelerometer sensitivity | 0.05 g-force | |
| Accelerometer bandwidth | 3 Hz to 11 Hz | |
| Sampling epochs | 15 and 30 seconds, 1, 2, 5, 10, and 15 minutes | Actiware-PLM software configures Actiwatch to sample at 2 second epoch length. |
| Memory | 16 or 64 kB | 16 kB in Actiwatch-16 only |

STANDARDS COMPLIANCE

| Test Standard | Description |
|---------------|--|
| IEC60601-1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |
| IEC60601-1-1 | Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems |
| IEC60601-1-2 | Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| IEC60950-1 | Information Technology Equipment - Safety - Part 1: General Requirements |

DISPOSAL

When necessary, dispose of the device and accessories in accordance with local regulations.

Specification for Actiwatch-Score

ENVIRONMENTAL

| | Operating | Storage |
|----------------------|--|--------------------------------------|
| Temperature | 0° C to 40° C (32° F to 104° F) | -10° C to 50° C (14° F to 122° F) |
| Relative Humidity | 0 to 95% RH | 0 to 95% RH |
| Atmospheric Pressure | 500 to 1060kPa (5600 feet to sea level) | |

PHYSICAL

| | | |
|--------------------------|-------------------------|--------------------|
| Dimensions: | 37 L x 35 W x 12 H (mm) | |
| Weight: | 19 grams | w/o band |
| | 25 grams | with standard band |
| Case Material: | Glass-filled Nylon | |
| Frame and Battery Cover: | Titanium | |
| Standard Wrist Band: | Nylon with buckle | |

ELECTRICAL

| | |
|--|---|
| Battery Type: | CR 2025 |
| Battery Life: | 3 Months Typical |
| Protection Against Electric Shock: | Internally powered |
| Degree of Protection Against Electric Shock: | Type BF Applied Part |
| Modes of Operation: | Continuous |
| Electromagnetic Compatibility: | The device meets the requirements of EN 60601-1-2, second edition (2001). |
| Fuses: | There are no user-replaceable fuses. |
| Degree of Protection Against Ingress of Water: | Dripping and light splashing of liquids IEC Standard 60529 IPX2 |

FUNCTIONAL

| Parameter | Value | Note |
|----------------------------|---|-----------------|
| Accelerometer sensitivity | 0.05 g-force | |
| Accelerometer bandwidth | 3 Hz to 11 Hz | |
| Sampling epochs | 15 and 30 seconds, 1, 2, 5, 10, and 15 minutes | |
| Memory | 32 kB | |
| Scoring levels | 0 to 15 | User-selectable |
| Number of scores per epoch | One | |

STANDARDS COMPLIANCE

| Test Standard | Description |
|---------------|--|
| IEC60601-1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |
| IEC60601-1-1 | Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems |
| IEC60601-1-2 | Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| IEC60950-1 | Information Technology Equipment - Safety - Part 1: General Requirements |

DISPOSAL

When necessary, dispose of the device and accessories in accordance with local regulations.

Specification for Actiwatch-L

ENVIRONMENTAL

| | Operating | Storage |
|----------------------|--|--------------------------------------|
| Temperature | 0° C to 40° C (32° F to 104° F) | -10° C to 50° C (14° F to 122° F) |
| Relative Humidity | 0 to 95% RH | 0 to 95% RH |
| Atmospheric Pressure | 500 to 1060kPa (5600 feet to sea level) | |

PHYSICAL

| | | |
|--------------------------|-------------------------|--------------------------------|
| Dimensions: | 29 L x 37 W x 11 H (mm) | |
| Weight: | 16 grams 22 grams | w/o band with standard band |
| Case Material: | Glass-filled Nylon | |
| Frame and Battery Cover: | Titanium | |
| Standard Wrist Band: | Nylon with buckle | |

ELECTRICAL

| | |
|--|--|
| Battery Type: | CR 2025 |
| Battery Life: | 3 Months Typical |
| Protection Against Electric Shock: | Internally powered |
| Degree of Protection Against Electric Shock: | Type BF Applied Part |
| Modes of Operation: | Continuous |
| Electromagnetic Compatibility: | The device meets the requirements of EN 60601-1-2, second edition (2001). |
| Fuses: | There are no user-replaceable fuses. |
| Degree of Protection Against Ingress of Water: | Waterproof / Watertight to a depth of 1 meter for 30 minutes IEC 60529 IPX7 |

DISPOSAL

When necessary, dispose of the device and accessories in accordance with local regulations.

FUNCTIONAL

| Parameter | Value | Note |
|---------------------------------|---|---------------------------------|
| Accelerometer sensitivity | 0.05 g-force | |
| Accelerometer bandwidth | 3 Hz to 11 Hz | |
| Sampling epochs | 15 and 30 seconds, 1, 2, 5, 10, and 15 minutes | |
| Memory | 64 kB | |
| Sensor Type | Photodiode | On-board sensor |
| Spectral response | CIE Y-curve | Approximate |
| Wavelength window | 330 to 720 | nm |
| Minimum illuminance sensitivity | 0.1 | lux |
| Maximum illuminance sensitivity | 150,000 | lux |
| Linearity | 2% | Typical from 0.1 to 150,000 lux |
| Resolution | 2% of lux value | Typical |

STANDARDS COMPLIANCE

| Test Standard | Description |
|---------------|--|
| IEC60601-1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |
| IEC60601-1-1 | Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems |
| IEC60601-1-2 | Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| IEC60950-1 | Information Technology Equipment - Safety - Part 1: General Requirements |

Logging Capacity versus Amount of Memory

| Bytes | EPOCH LENGTH (minutes) | | | | | | |
|-------------------------|------------------------|------|------|------|------|------|------|
| | 0.25 | 0.50 | 1.00 | 2.00 | 5.00 | 10.0 | 15.0 |
| Actiwatch-16 (kB) | 2.8 | 5.6 | 11.2 | 23 | 56 | 113 | 170 |
| Actiwatch-64 (kB) | 11.3 | 22 | 45 | 90 | 227* | 365* | 365* |
| Actiwatch-L (32 kB) | 2.8 | 5.6 | 11.3 | 28 | 56 | 113 | 170 |
| Actiwatch-Score (32 kB) | 5.5 | 11.1 | 22 | 44 | 111+ | 223+ | 334+ |
| Actiwatch-L (64 kB) | 3.7 | 7.2 | 15 | 30 | 75 | 151 | 227* |

*Limited by 180 day battery life.

+Limited by 90 day battery life.

Specification for ActiReader

ENVIRONMENTAL

| | Operating | Storage |
|----------------------|--|--------------------------------------|
| Temperature | 0° C to 40° C (32° F to 104° F) | -10° C to 50° C (14° F to 122° F) |
| Relative Humidity | 0 to 95% RH | 0 to 95% RH |
| Atmospheric Pressure | 500 to 1060kPa (5600 feet to sea level) | |

PHYSICAL

Dimensions: 114 L x 72 W x 34 H (mm)
Weight: 158 grams
Case Material: ABS plastic

ELECTRICAL

| | |
|--|---|
| Data Port | DB9 Serial Port (a compatible USB to serial port adapter can be used) |
| Battery Type: | 9V Lithium (Eveready™ L522) |
| Battery Life: | 6 Months Typical (Turn off ActiReader when not being used) |
| AC Voltage Source: | 100 to 240 V AC , 50/60 Hz |
| DC Voltage Source: | 9-12V DC (when operated with the external DC power adaptor accessory) |
| AC Current: | 0.4 A maximum |
| DC Current: | 1.5 A maximum |
| Protection Against Electric Shock: | Internally powered |
| Degree of Protection Against Electric Shock: | Type BF Applied Part |
| Sterile | Non-Sterile |
| Modes of Operation: | Continuous |
| Electromagnetic Compatibility: | The device meets the requirements of EN 60601-1-2, second edition (2001). |
| Fuses: | There are no user-replaceable fuses. |
| Power Supply Model Nos: | DSA-0151D-12 |

STANDARDS COMPLIANCE

| Test Standard | Description |
|----------------------|--|
| IEC60601-1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |
| IEC60601-1-1 | Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems |
| IEC60601-1-2 | Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| IEC60950-1 | Information Technology Equipment - Safety - Part 1: General Requirements |

DISPOSAL

When necessary, dispose of the device and accessories in accordance with local regulations.

Hereby,

Mini Mitter Company, Inc.
A Respiromics, Inc. Company
20300 Empire Avenue, Building B-3
Bend, OR 97701,

declares that this class 1 radio equipment is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EEC. It complies with the following harmonized standards for radio equipment: EN 300 220-3 V1.1.1 (2000-09), EN 301 489-01 V1.4.1 (2002-08), and EN 301 489-03 V1.4.1 (2002-08).

Dan Burns 12-20-05

Dan Burns
Manager, Quality Assurance

E

EMC INFORMATION

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment - Guidance |
|---|------------|--|
| RF emissions CISPR 11 | Group 1 | This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ Flicker emissions IEC 61000-3-3 | Complies | |

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|--|---|---|---|
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ±6V contact ±8V air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast Transient/burst IEC 61000-4-4 | ±2kV for power supply lines ±1kV for input/output lines | ±2kV for supply mains ±1kV for input/output lines | Mains power quality should be that of a typical home or hospital environment. It is noted certification to IEC 60601-1-2 is obtained recognizing that interruption of the download of data to the reader due to EMI is not considered to cause harm. When a download is stopped, the user is prompted that an error has occurred and the user would then reinitiate the download. Interference that would interrupt a download is anticipated to be of short duration such that the subsequent download would be successful. |
| Surge IEC 61000-4-5 | ±1kV differential mode ±2kV common mode | ±1kV differential mode ±2kV common mode | Mains power quality should be that of a typical home or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | <5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec | Mains power quality should be that of a typical home or hospital environment. |
| Note: U_T is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

| Immunity test | IEC 60601 Test Level | Compliance Level (FDA) | Electromagnetic Environment - Guidance |
|--|-----------------------------|------------------------|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment. |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. It is noted certification to IEC 60601-1-2 is obtained recognizing that interruption of the download of data to the reader due to EMI is not considered to cause harm. When a download is stopped, the user is prompted that an error has occurred and the user would then reinitiate the download. Interference that would interrupt a download is anticipated to be of short duration such that the subsequent download would be successful. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | Recommended Separation Distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:  |

| |
|--|
| Note 1: At 80 MHz and 800 MHz the higher frequency range applies. |
| Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people |
| a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. |
| b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m. |

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum Power Output of Transmitter (W) | Separation Distance According to Frequency of Transmitter (m) | | |
|---|---|--|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

MINI MITTER®

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