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**Manufacturer: Mini Mitter Company, Inc.
Model(s): ActiReader**

Manual
(Part 1 of 3)



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



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

Mailing and Shipping Address

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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

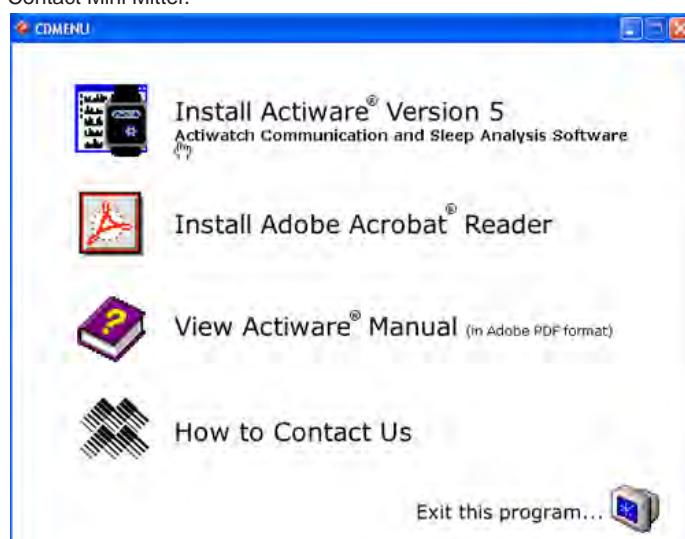
Note: *You must be a member of the Administrator's group in order to install this software.*

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@sleelab.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.

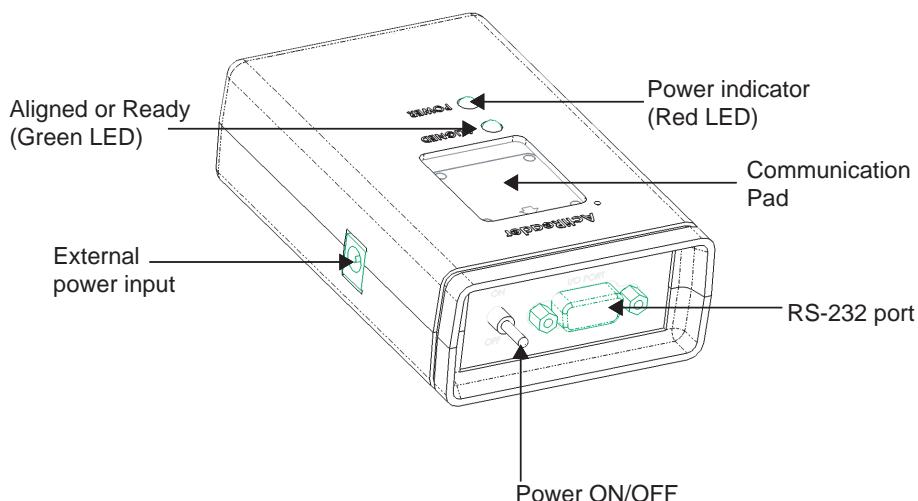
- **Power ON/OFF switch**

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

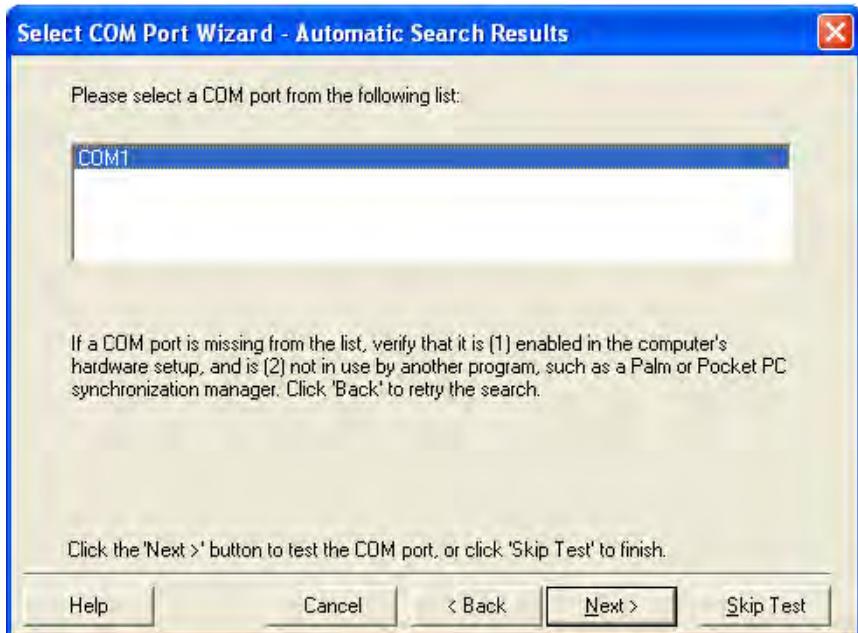


COM Port Wizard Welcome window



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



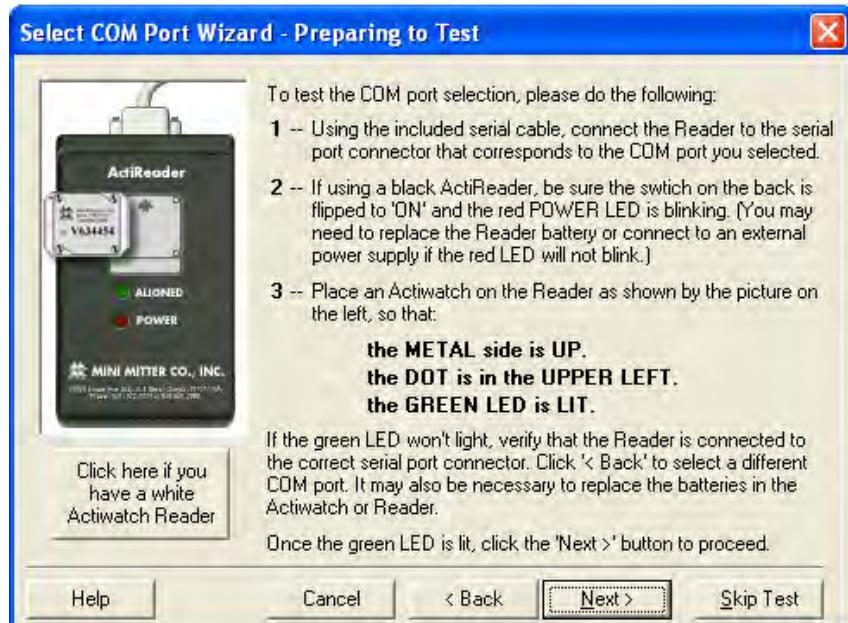
4. Click **Next** to proceed to the Communications Port Test.

***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).

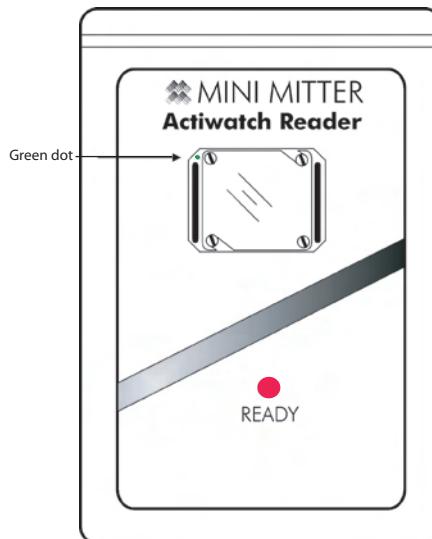
Actiwatch Reader

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

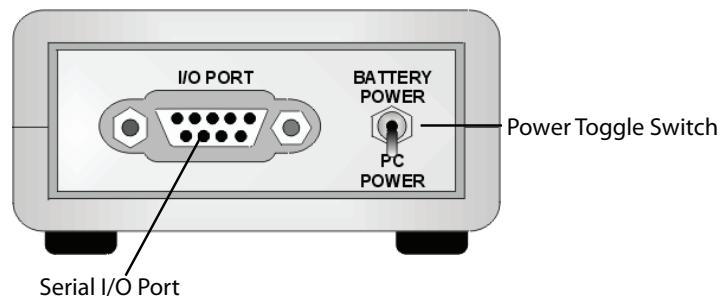
However, please keep the following in mind when using the Actiwatch Reader:

- 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.
