

Certification Exhibit

**FCC ID: JIAAWR1
IC: 6041A-AWR1**

**FCC Rule Part: 15.209
IC Radio Standards Specification: RSS-210**

ACS Report Number 08-0085 - 15C

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

Manual
(Part 1 of 3)



A Shared Vision. A Shared Future.

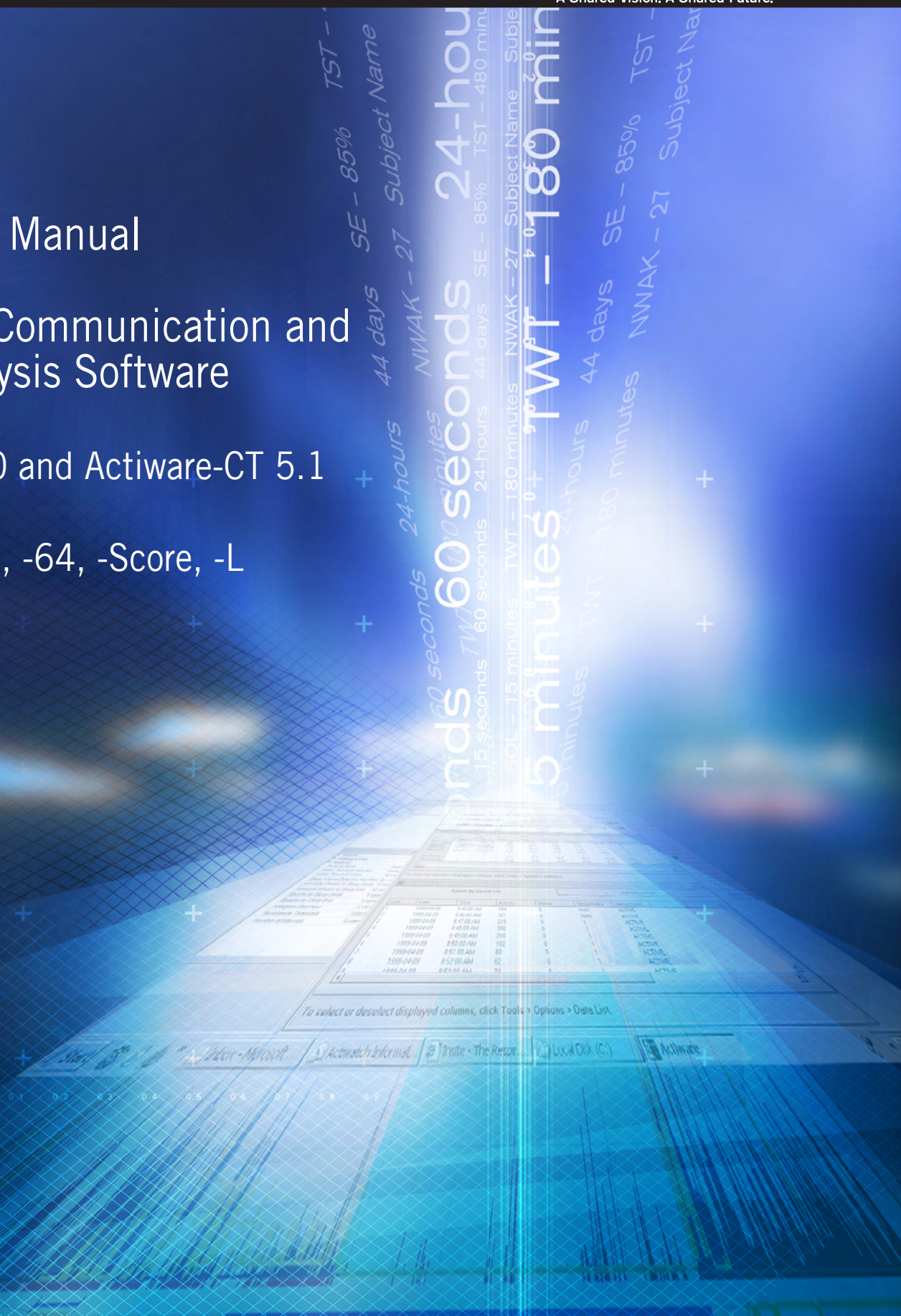
Instruction Manual

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.

Respironics, Mini-Mitter, Actiwatch, and Actiware are registered trademarks of Respironics, Inc. and its affiliates.
Windows is a registered trademark of Microsoft Corporation.
Pentium is a registered trademark of Intel.

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

© 2006 Respironics, Inc. and its affiliates. All rights reserved.

Mini Mitter, a Respironics Company

WARRANTY POLICY

1. **WARRANTY :** Mini Mitter, a Respironics Company, warrants that upon delivery the goods sold hereunder will be free of defects in materials and workmanship, and such goods will substantially conform to the specifications furnished by the Seller, and to any drawings or specifications furnished to the Buyer by the Manufacturer (Mini Mitter, a Respironics Company) if approved by the Manufacturer.
 - a) **Commencement of Warranty** – The warranty period begins on the date of delivery.
 - b) **Duration of Warranty** – The goods sold hereunder are warranted for a period of twelve months, except PDT-4000 and PDT-4000HR, which are warranted for two years.
 - c) **Third Party Product Warranty** – Third party products purchased by Buyer through the Manufacturer are covered by the third party's warranty and ARE NOT COVERED BY THE MANUFACTURER WARRANTY.
 - d) **Place of Repair or Replacement.** Buyer must return the defective or nonconforming goods upon request to Mini Mitter, a Respironics Company, at 20300 Empire Avenue, Building B-3; Bend, OR 97701, 800-685-2999 (US or Canada only) or 1-541-598-3800, not later than 15 days after the Manufacturer's receipt of notice of the alleged defect or nonconformance. Buyer shall prepay transportation charges. The Manufacturer shall pay for the return of the goods to Buyer. No goods are to be returned to the Manufacturer without prior authorization and a valid Return Authorization (RA) number.
 - e) **Limitation of Warranty** – The foregoing warranty shall not apply to defects resulting from (a) improper or inadequate maintenance by Buyer; (b) unauthorized modification of the goods; (c) operation of the goods outside of the environmental specifications for the goods; (d) neglect, misuse or abuse of the goods or (e) modification or integration with other goods not covered by a Mini Mitter, a Respironics Company, warranty when such modification or integration increases the likelihood of damage to the goods.
 - f) **Technical assistance** – The warranty set forth above shall not be enlarged, diminished or affected by and no obligation or liability shall arise from the Manufacturer's rendering of technical advice, assistance or services in connection with Buyer's order of the goods furnished hereunder. The Buyer is not relying on the Manufacturer's skill or judgment to select or furnish suitable goods.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND THE MANUFACTURER GIVES NO OTHER WARRANTY WRITTEN OR VERBAL, EXPRESS OR IMPLIED. MINI MITTER, A RESPIRONICS COMPANY, SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANT-ABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE MANUFACTURER'S STANDARD WARRANTY POLICY COVERING ANY OF THE MANUFACTURER'S PRODUCTS SHALL BE NULL, VOID, AND OF NO EFFECT IF THE BUYER OR ANY THIRD PARTY USES THAT PRODUCT FOR ANY USE OTHER THAN THE INTENDED USE OF THAT PRODUCT.

2. **LIMITATION OF REMEDIES AND LIABILITY.** The remedies provided herein are Buyer's sole and exclusive remedies. The Manufacturer shall have no responsibility other than, at the Manufacturer's option, to repair or replace defective or nonconforming goods or to refund the purchase price of defective or nonconforming goods in the event of breach of any warranty. IN NO EVENT SHALL THE MANUFACTURER BE LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS) WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY. In the event that any limitation of warranty or disclaimer of liability is found to be unlawful or inapplicable, or to have failed of its essential purpose, the Manufacturer's liability shall be limited to the amount paid by the Buyer for the specific goods that caused such liability.

MINI MITTER, a Respironics Company

SOFTWARE LICENSE AGREEMENT

NOTICE TO USER: BY CLICKING THE "I ACCEPT THE TERMS IN THE LICENSE AGREEMENT" BUTTON, THE USER ("YOU") AGREE(S) TO BE BOUND BY THE TERMS OF THIS SOFTWARE LICENSE AGREEMENT ("AGREEMENT"). BY CLICKING YES YOU ACCEPT ALL THE TERMS AND CONDITIONS OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, THE RESTRICTIONS ON: USE CONTAINED IN SECTION 2; TRANSFERABILITY IN SECTION 4; WARRANTY IN SECTION 6; AND LIABILITY IN SECTION 7. YOU AGREE THAT THIS AGREEMENT IS ENFORCEABLE LIKE ANY WRITTEN NEGOTIATED AGREEMENT SIGNED BY YOU. IF YOU DO NOT AGREE TO BE BOUND TO THE TERMS AND CONDITIONS OF THIS AGREEMENT, YOU MAY OBTAIN A REFUND OF ANY AMOUNT YOU ORIGINALLY PAID IF YOU: (A) DO NOT USE THE SOFTWARE AND (B) RETURN THE SOFTWARE, WITH PROOF OF PAYMENT, TO THE LOCATION FROM WHICH IT WAS OBTAINED WITHIN THIRTY (30) DAYS OF THE PURCHASE DATE.

1. **Definitions.** "Software" means (a) all of the contents of the files, disk(s), CD-ROM(s) or other media with which this Agreement is provided, including but not limited to (i) MINI MITTER or third party computer information or software; (ii) related explanatory written materials or files ("Documentation"); and (b) upgrades, modified versions, updates, additions, and copies of the Software, if any, licensed to you by MINI MITTER (collectively, "Updates"). "Use" or "Using" means to access, install, download, copy or otherwise benefit from using the functionality of the Software in accordance with the Documentation. "Permitted Number" means one (1) unless otherwise indicated under a valid license (e.g. volume license) granted by MINI MITTER. "Computer" means an electronic device that accepts information in digital or similar form and manipulates it for a specific result based on a sequence of instructions. "MINI MITTER" means MINI MITTER, a Respironics Company, 20300 Empire Ave., Bldg B-3, Bend, Oregon 97701.

2. **Software License.**

2.1 Grant. MINI MITTER owns all intellectual property in the Software. MINI MITTER hereby grants you a limited, non-exclusive license to Use the Software only in accordance with the terms of this Agreement and for the purposes described in the Documentation. Use of some third party materials included in the Software may be subject to other terms and conditions found in a separate license agreement.

2.2 General Use. You may install and Use a copy of the Software on your compatible Computer, up to the Permitted Number of Computers.

2.3 Backup Copy. You may make one backup copy of the Software, provided your backup copy is not installed or used on any Computer. You may not transfer the rights to a backup copy unless you transfer all rights in the Software as provided under Section 4.

2.4 No Modification. You may not alter or modify the Software or create a new installer for the Software. The Software is licensed and distributed by MINI MITTER for Use with its data collection hardware products.

3. **Intellectual Property Ownership and Copyright Protection.** The Software and any authorized copies that you make are the intellectual property of and are owned by MINI MITTER. The structure, organization and code of the Software are the valuable trade secrets and confidential information of MINI MITTER. The Software is protected by law, including without limitation, the copyright laws of the United States and other countries, and by international treaty provisions. Except as expressly stated herein, this Agreement does not grant you any intellectual property rights in the Software and all rights not expressly granted are reserved by MINI MITTER. You hereby recognize that MINI MITTER retains all intellectual property rights in the Software, Documentation and all MINI MITTER confidential information, including without limitation, all corrections, modifications and other derivative works to the Software. You hereby assign to MINI MITTER all intellectual property rights you may now or hereafter possess in the Software, Documentation and MINI MITTER confidential information, and all derivative works thereof and you agree to execute all documents, and take all actions, that may be necessary to confirm such rights. You agree to observe complete confidentiality with respect to the MINI MITTER confidential information; not to disclose, or permit any third party or entity access to, the MINI MITTER confidential information (or any portion thereof) without prior written permission of MINI MITTER, and to insure that any employees, or any third parties who receive access to the MINI MITTER confidential information, are advised of the confidential and proprietary nature thereof and are prohibited from copying, utilizing or otherwise revealing the MINI MITTER confidential information. You agree to employ with regard to the MINI MITTER confidential information commercially reasonable procedures that are no less restrictive than the strictest procedures used by it to protect its own confidential and proprietary information.

4. **Restrictions.**

4.1 Notices. You shall not copy the Software except as set forth in Section 2. Any copy of the Software that you make must contain the same copyright and other proprietary notices that appear on or in the Software, indicating that the Software are owned by MINI MITTER.

4.2 No Modifications. You shall not modify, adapt or translate the Software. You shall not reverse engineer, decompile, disassemble or otherwise attempt to discover the source code of the Software.

4.3 Transfer. You may not, rent, lease, sublicense, assign or transfer your rights in the Software, or authorize all or any portion of the Software to be copied onto another user's Computer except as may be expressly permitted herein. You may, however, transfer all your rights to Use the Software to another person or legal entity provided that: (a) you also transfer (i) this Agreement, and (ii) the Software and all other software bundled or pre-installed with the Software, including all copies, Updates and prior versions, to such person or entity; (b) you retain no copies, including backups and copies stored on a Computer; and (c) the receiving party accepts the terms and conditions of this Agreement and any other terms and conditions upon which you legally purchased a license to the Software. Notwithstanding the foregoing, you may not transfer education, pre-release, or not for resale copies of the Software.

5. **Updates.** If the Software is an Update to a previous version of the Software, you must possess a valid license to such previous version in order to Use such Update. All Updates are provided to you on a license exchange basis. You agree that by Using an Update you voluntarily terminate your right to Use any previous version of the Software. As an exception, you may continue to Use previous versions of the Software on your Computer after you Use the Update but only to assist you in the transition to the Update, provided that: (a) the Update and the previous versions are installed on the same computer; (b) the previous versions or copies thereof are not transferred to another party or Computer unless all copies of the Update are also transferred to such party or Computer; and (c) you acknowledge that any obligation MINI MITTER may have to support the previous versions of the Software may be ended upon availability of the Update. All Updates will be provided to you in the sole discretion of MINI MITTER.

6. **LIMITED WARRANTY.**

6.1 Limited Warranty. MINI MITTER warrants for a period of twelve (12) months after the date of delivery to you (the "Warranty Period"), the following: (a) that the Software will perform in substantial compliance with the Documentation, provided that it is used with the data collection hardware, Computer hardware and with the operating system for which it was designed, (b) that the media on which the Software is distributed is substantially free from significant defects in materials and workmanship. MINI MITTER shall have no obligation to provide warranty services if the defect in the Software is caused by malfunction of non-MINI MITTER hardware or software, by modification of the Software not made by MINI MITTER, by operator error, or by use of the Software that is not in accordance with the operating instructions and Documentation for the Software.

6.2 Disclaimer. EXCEPT AS PROVIDED IN SECTION 6.1, MINI MITTER AND ITS SUPPLIERS MAKE NO WARRANTIES OR REPRESENTATIONS, WHETHER EXPRESS OR IMPLIED WHETHER BY STATUTE, COMMON LAW, CUSTOM, USAGE OR OTHERWISE, AS TO ANY MATTER INCLUDING WITHOUT LIMITATION NONINFRINGEMENT OF THIRD PARTY RIGHTS, MERCHANTABILITY, INTEGRATION, SATISFACTORY QUALITY, OR FITNESS FOR ANY PARTICULAR PURPOSE. The provisions of Section 6 and Section 7 shall survive the termination of this Agreement, howsoever caused, but this shall not imply or create any continued right to Use the Software after termination of this Agreement.

6.3 Warranty Claims. Warranty claims must be made in writing during the Warranty Period and within seven (7) days of the observation of the defect, accompanied by evidence satisfactory to MINI MITTER. All Software should be returned to MINI MITTER or the MINI MITTER distributor from which it was purchased and shall be shipped by the returning party with freight and insurance paid.

7. **LIMITATION OF LIABILITY.** IN NO EVENT WILL MINI MITTER OR ITS SUPPLIERS BE LIABLE TO YOU FOR ANY DAMAGES, CLAIMS OR COSTS WHATSOEVER OR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL DAMAGES, OR ANY LOST PROFITS OR LOST SAVINGS, EVEN IF A MINI MITTER REPRESENTATIVE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGES, CLAIMS OR COSTS OR FOR ANY CLAIM BY ANY THIRD PARTY. THE FOREGOING LIMITATIONS AND EXCLUSIONS APPLY TO THE EXTENT PERMITTED BY APPLICABLE LAW IN YOUR JURISDICTION. MINI MITTER'S AGGREGATE LIABILITY AND THAT OF ITS SUPPLIERS UNDER OR IN CONNECTION WITH THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT PAID FOR THE SOFTWARE, IF ANY. MINI MITTER is acting on behalf of its suppliers for the purpose of disclaiming, excluding and/or limiting obligations, warranties and liability as provided in this Agreement, but in no other respects and for no other purpose.

8. **Export Rules.** You agree that the Software will not be shipped, transferred or exported into any country or used in any manner prohibited by the United States Export Administration Act or any other export laws, restrictions or regulations (collectively the "Export Laws"). In addition, if the Software is identified as export controlled items under the Export Laws, you represent and warrant that you are not a citizen, or otherwise located within, an embargoed nation (including without limitation Iran, Iraq, Syria, Sudan, Libya, Cuba, North Korea, and Serbia) and that you are not otherwise prohibited under the Export Laws from receiving the Software. All rights to Use the Software are granted on condition that such rights are forfeited if you fail to comply with the terms of this Agreement.

9. **Governing Law.** This Agreement will be governed by and construed in accordance with the substantive laws in force in the State of Oregon, USA, without regards to its conflicts of laws principles.

10. **Term.** The term of this Agreement shall begin on your acceptance and continue until the Agreement is terminated.

10.1 Termination for Cause. In the event of any material breach of this Agreement, the non-breaching party may terminate this Agreement by giving thirty (30) days' prior written notice to the other party; provided, however, that this Agreement shall not terminate if the other party has cured the breach prior to the expiration of such thirty (30) day period.

10.2 Termination for Insolvency. Either party may terminate this Agreement, without notice, (i) upon the institution by or against the other party of insolvency, receivership or bankruptcy proceedings, (ii) upon the other party's making an assignment for the benefit of creditors, or (iii) upon the other party's dissolution or ceasing to do business.

10.3 Return of Materials. Upon termination of this Agreement for any reason, you shall return to MINI MITTER all copies of the Software, confidential information, Documentation and all other tangible materials related to the Software, including without limitation, all modifications and derivative works thereof.

11. General Provisions. If any part of this Agreement is found void and unenforceable, it will not affect the validity of the balance of this Agreement, which shall remain valid and enforceable according to its terms. This Agreement shall not prejudice the statutory rights of any party dealing as a consumer. This Agreement may only be modified by a writing signed by an authorized officer of MINI MITTER. Updates may be licensed to you by MINI MITTER with additional or different terms. This is the entire Agreement between MINI MITTER and you relating to the Software and it supersedes any prior representations, discussions, undertakings, communications or advertising relating to the Software.

12. Notice to U.S. Government End Users. The Software and Documentation are "Commercial Items," as that term is defined at 48 C.F.R. §2.101, consisting of "Commercial Computer Software" and "Commercial Computer Software Documentation," as such terms are used in 48 C.F.R. §12.212 or 48 C.F.R. §227.7202, as applicable. Consistent with 48 C.F.R. §12.212 or 48 C.F.R. §§227.7202-1 through 227.7202-4, as applicable, the Commercial Computer Software and Commercial Computer Software Documentation are being licensed to U.S. Government end users (a) only as Commercial Items and (b) with only those rights as are granted to all other end users pursuant to the terms and conditions herein. Unpublished-rights reserved under the copyright laws of the United States. Manufacturer is MINI MITTER, a Respironics. Company, 20300 Empire Ave., Bldg B-3, Bend, Oregon 97701, USA. For U.S. Government End Users, MINI MITTER agrees to comply with all applicable equal opportunity laws including, if appropriate, the provisions of Executive Order 11246, as amended, Section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974 (38 USC 4212), and Section 503 of the Rehabilitation Act of 1973, as amended, and the regulations at 41 CFR Parts 60-1 through 60-60, 60-250, and 60-741.

13. Compliance with Licenses. You agree that upon request from MINI MITTER or MINI MITTER's authorized representative, you will within thirty (30) days fully document and certify that Use of any and all Software at the time of the request is in conformity with your valid license from MINI MITTER.

14. Specific Exceptions.

14.1 Pre-release Product Additional Terms. If the product you have received with this license is pre-commercial release or beta Software ("Pre-release Software"), then the following Section applies. To the extent that any provision in this Section is in conflict with any other term or condition in this Agreement, this Section shall supersede such other term(s) and condition(s) with respect to the Pre-release Software, but only to the extent necessary to resolve the conflict. You acknowledge that the Software is a pre-release version, does not represent final product from MINI MITTER, and may contain bugs, errors and other problems that could cause system or other failures and data loss. Consequently, the Pre-release Software is provided to you "AS-IS," and MINI MITTER disclaims any warranty or liability obligations to you of any kind. WHERE LIABILITY CANNOT BE EXCLUDED FOR PRE-RELEASE SOFTWARE, BUT IT MAY BE LIMITED, MINI MITTER'S LIABILITY AND THAT OF ITS SUPPLIERS SHALL BE LIMITED TO THE SUM OF FIFTY DOLLARS (U.S. \$50) IN TOTAL. You acknowledge that MINI MITTER has not promised or guaranteed to you that Pre-release Software will be announced or made available to anyone in the future, MINI MITTER has no express or implied obligation to you to announce or introduce the Pre-release Software and that MINI MITTER may not introduce a product similar to or compatible with the Pre-release Software. Accordingly, you acknowledge that any research or development that you perform regarding the Pre-release Software or any product associated with the Pre-release Software is done entirely at your own risk. During the term of this Agreement, if requested by MINI MITTER, you will provide feedback to MINI MITTER regarding testing and use of the Pre-release Software, including error or bug reports. If you have been provided the Pre-release Software pursuant to a separate written agreement, your use of the Software is also governed by such agreement. You agree that you may not and certify that you will not sublicense, lease, loan, rent, assign or transfer the Pre-release Software. Upon receipt of a later unreleased version of the Pre-release Software or release by MINI MITTER of a publicly released commercial version of the Software, whether as a stand-alone product or as part of a larger product, you agree to return or destroy all earlier Pre-release Software received from MINI MITTER and to abide by the terms of the license agreement for any such later versions of the Pre-release Software. Notwithstanding anything in this Section to the contrary, if you are located outside the United States of America, you agree that you will return or destroy all unreleased versions of the Pre-release Software within thirty (30) days of the completion of your testing of the Software when such date is earlier than the date for MINI MITTER's first commercial shipment of the publicly released (commercial) Software.

If you have any questions regarding this Agreement or if you wish to request any information from MINI MITTER please use the address and contact information included with this product to contact us.

Thank You!

... for purchasing products from Mini Mitter, a Respironics Company. If you need assistance with Actiwatch; remember, support continues after the purchase. If you have any problems or questions, please call our Technical Support staff of technicians, engineers, and scientists. We are available by telephone, fax, e-mail, or web site.

Contacting Technical Support

Mailing and
Shipping
Address

Mini Mitter, a Respironics Company
20300 Empire Avenue, Bldg. B-3
Bend, OR 97701 USA

Telephone

(800) 685-2999 (US and Canada only)
(541) 598-3800

Fax

(541) 322-7277

E-Mail

mm@respironics.com

Web site

www.minimitter.com
www.respironics.com

Table of Contents

Software License Agreement	iv
Contacting Technical Support.....	vii
 INTRODUCTION AND SETUP	 1-1
Indications for Use	1-2
Intended Use	1-2
Warnings and Cautions	1-3
Symbols.....	1-5
Installation Prerequisites.....	1-6
Installing from a CD.....	1-7
Uninstallation Procedures	1-11
ActiReader Setup.....	1-14
Actiwatch Reader	1-20
ActiReader Battery Replacement Procedures	1-21
 GETTING STARTED	 2-1
Main Window.....	2-2
Actogram.....	2-8
Setting Intervals.....	2-10
Viewing Statistics	2-17
Exporting Data	2-19
Print Report.....	2-21
New Subject	2-22
Deleting/Hiding Subjects	2-23
 COMMUNICATIONS	 3-1
Configure Actiwatch.....	3-1
Retrieve Data from Actiwatch.....	3-7
 ADVANCED USAGE	 4-1
Program Options	4-2
Analysis Parameter Definitions.....	4-4
Data List	4-10
Text File Batch Export.....	4-11
Import AWD Files.....	4-14
Graph.....	4-16
 CLINICAL TRIALS.....	 5-1
Audit Trail	5-3
Introduction to Electronic Signatures	5-6
Database Validation and Back-up.....	5-7
Export Files.....	5-7
 SLEEP/WAKE ANALYSIS	 A-1
 STATISTIC DEFINITIONS.....	 B-1
 ACTIWATCH HARDWARE	 C-1
ACTIWATCH-L.....	C-5
ACTIWATCH-SCORE	C-8
Actiwatch Battery Replacement Procedure.....	C-13
Actiwatch Cleaning Procedure.....	C-17
 SPECIFICATION	 D-1
 EMC INFORMATION	 E-1

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:










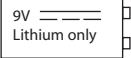
- Repairs and adjustments must be performed by Mini Mitter/Respironics authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Dispose of these devices in accordance with local regulations.

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

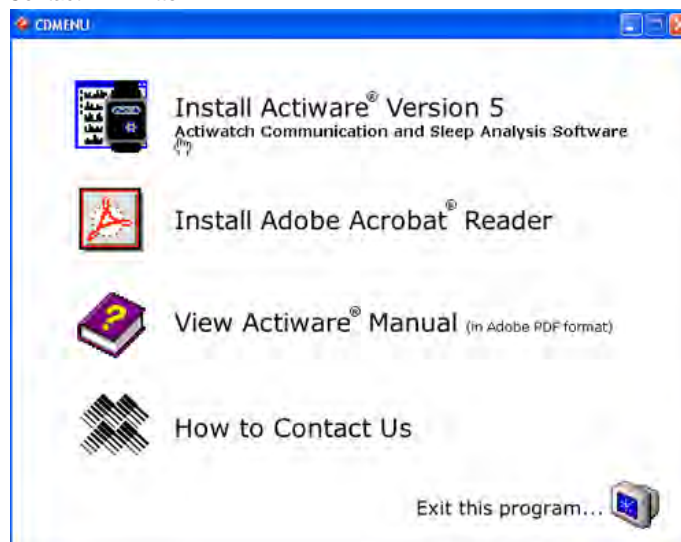
Note: You must be a member of the Administrator's group in order to install this software.

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.

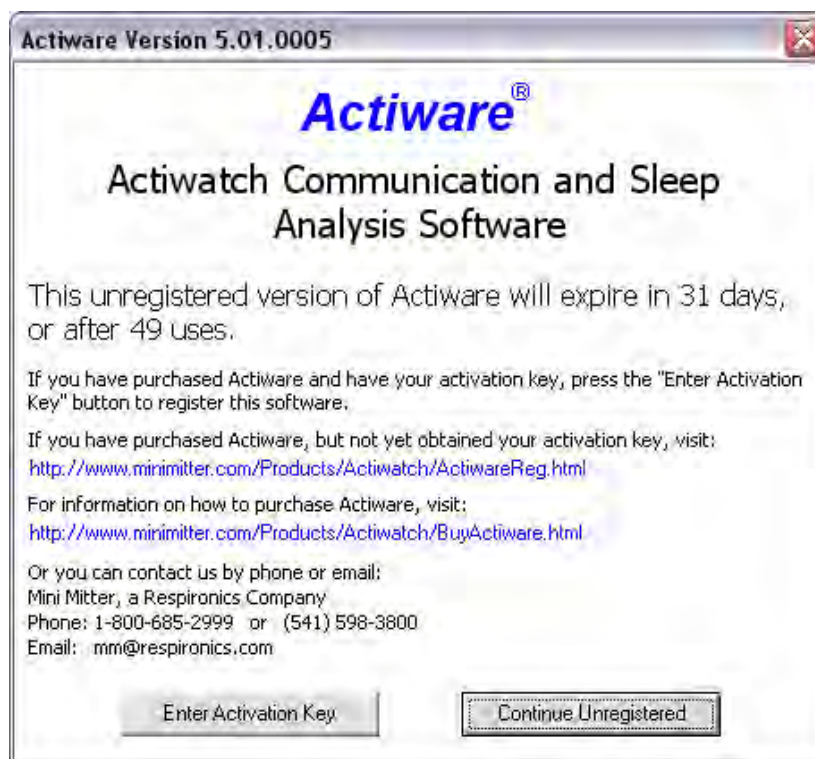
Note: Actiware-CT requires the user to authenticate using their Windows or Network username and password. Please contact your local administrator with any issues or questions.

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.

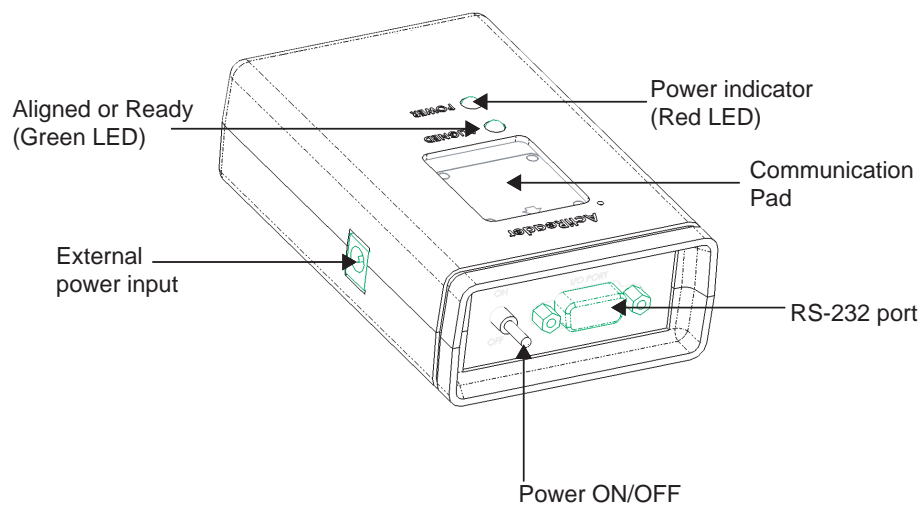
- **Power ON/OFF switch**

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).

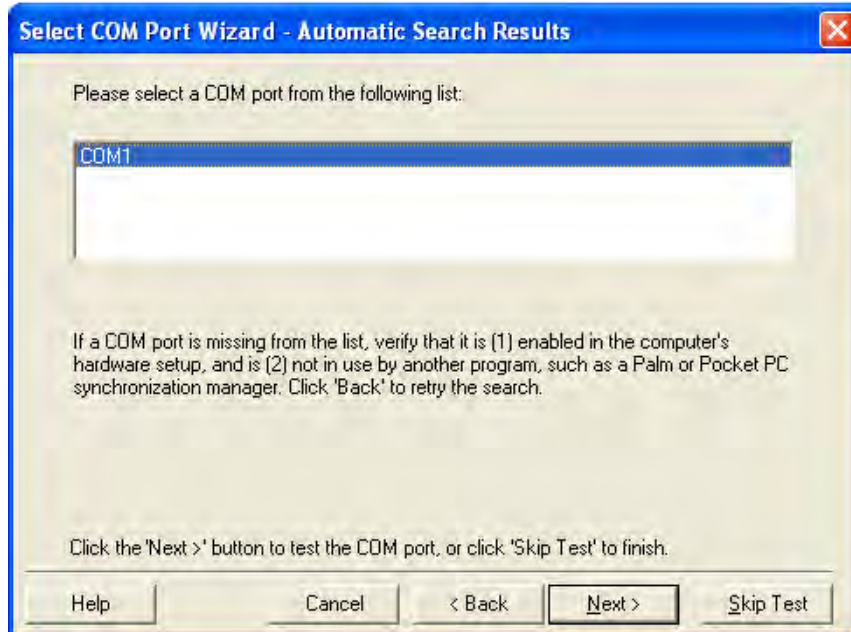
Start the COM Port Wizard





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



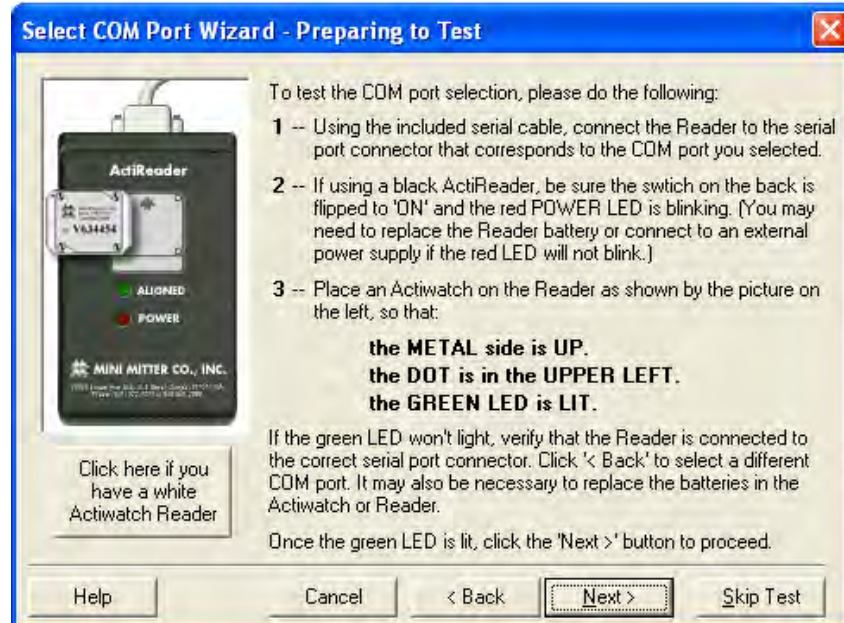
4. Click **Next** to proceed to the Communications Port Test.

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).

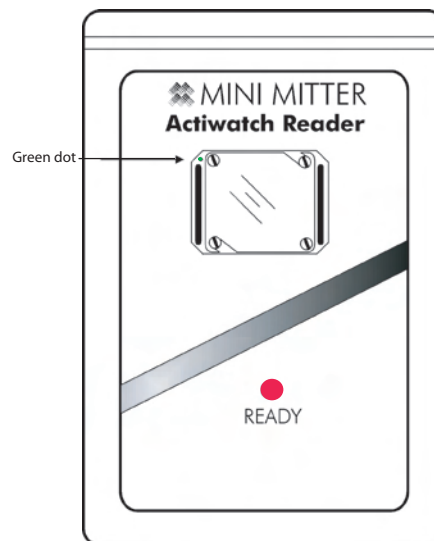
Actiwatch Reader

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

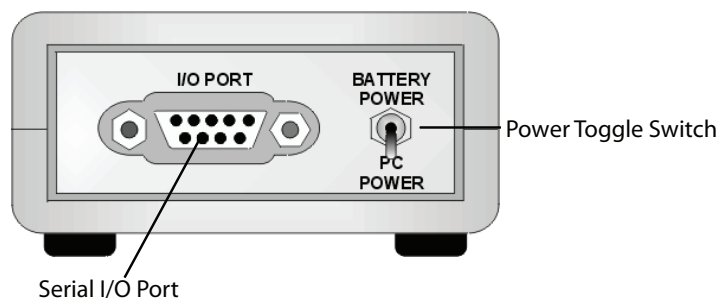
However, please keep the following in mind when using the Actiwatch Reader:

- 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.*
