RESPIRONICS®

Acti*watch*® Spectrum & **Acti***watch*® 2

TECHNICIANS GUIDE

Intended Use

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

Warnings & Cautions

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

Warnings

A warning indicates the possibility of injury.

- If the device becomes damaged, discontinue use and return it for a replacement.
- Discontinue use if the device wearer shows signs of skin reddening or inflammation.

Cautions

A caution indicates the possibility of damage to the device.

- Do not attempt to take the device apart. No user-serviceable parts are inside.

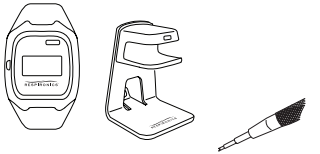
Notes

- The USB cable that connects to the computer or AC adapter must always be installed or removed with the Actiwatch 2 out of the dock.
- If switching between the computer and AC adapter, the Actiwatch 2 should be removed from the Communications Dock, then replaced after the cable has been switched.
- Do not disconnect the communications dock from the computer during communications (i.e. during data transmission or configuration).

System Contents

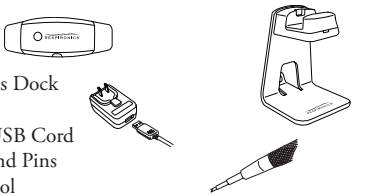
Your package may include some or all of the following.

Actiwatch® Spectrum System



- Actiwatch Spectrum Device
- Actiwatch Spectrum Communications Dock
- Watch Band Replacements and Pins
- Watch Band Replacement Tool

Actiwatch® 2 System



- Actiwatch 2 Device
- Actiwatch 2 Communications Dock
- USB Wall Plug Attachment
  with 6 ft (1.83 m) USB Cord
- Watch Band Replacements and Pins
- Watch Band Replacement Tool

Actiware® Software

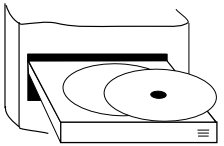
- CD, Instructions and System Requirements

System Instructions

- This Technicians Guide
- Clinicians Guide
- (10) Wearer Guides
- Watch Band Replacement Guide (in package with watch bands and tool)
- Hospital Band Guide (in package with hospital bands; for Actiwatch 2 only)

Preparing Actiwatch for a Patient

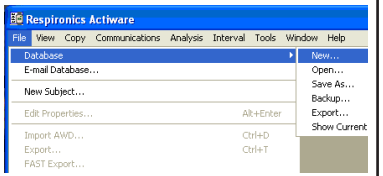
Step 1
Insert the Actiware software CD into your computer's CD drive.



Click ***Install Respironics Actiware***. (See the Software Installation Guide for system requirements and complete instructions.)

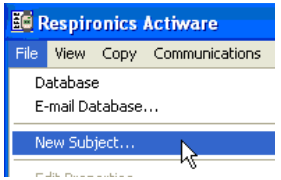
Step 2
Create a new database.

File > Database > New...

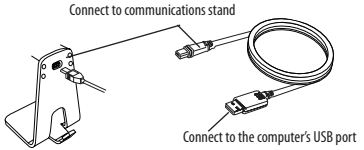


Step 3
For each new patient, create a new patient record with a **unique** Subject ID in the database.

File > New Subject...

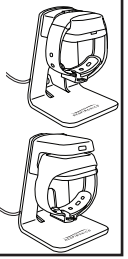


Step 4
After the software is installed, connect one end of the USB cable to your communications dock and the other end to your computer.



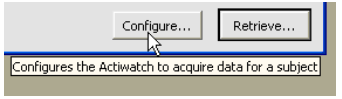
Step 5
Position the Actiwatch on its communications dock, as shown here.

If you are using Actiwatch 2, make sure it is plugged into the computer to establish communications and recharge the internal battery. (Actiwatch Spectrum cannot be recharged. For battery replacement return it to Respironics.)

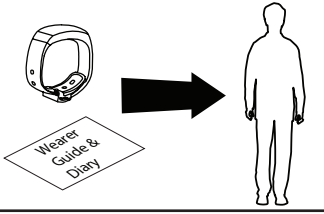


Step 6
Click the Console button to open the Actiwatch Console.

Step 7
Choose either Actiwatch 2 or Actiwatch Spectrum to configure the device. Then click on the Configure button at the bottom of the screen.



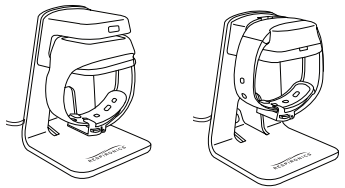
Step 8
Confirm that the Actiwatch is clean and fully charged. Show the patient the proper way to wear the device. Deliver the device to the patient with the Wearer Guide.



Retrieving Actiwatch Data

Step 1

Position the Actiwatch on its communications dock, as shown below.

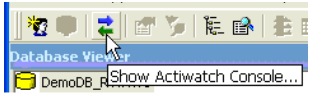


Actiwatch Spectrum

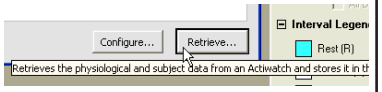
Actiwatch 2

Step 2

Click on the Console button (shown below).



Then click on the Retrieve button at the bottom of the window to retrieve the patient data and store it in the database.



How to Contact Respironics

If you need to contact Respironics directly, call the Respironics Customer Service department at 1-800-345-6443 (US and Canada only) or 1-724-387-4000. You can also use the following address:

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668
www.respironics.com

Symbol Key

The following symbols appear on the device or in this manual.

	USB Port
	Follow Instructions for Use
IPX7	Protected against the effects of temporary immersion in water
	DC Power
	Canadian/US Certification
	Type BF Applied Part

Cleaning

Make sure the Actiwatch device is clean before delivering it to the patient. It may be cleaned with a soft cloth moistened in mild detergent and water to remove dirt and stains. Do not use abrasives or alcohol as they may damage the device.

Maintenance

It is recommended that Actiwatch be returned to Respironics after one year of field use.

Disposal

Dispose of the device in accordance with local regulations.

Specifications

Standards Compliance

This device is designed to conform to the following standards:

IEC 60601-1 - Medical Electrical Equipment Part 1: General Requirements for Safety

IEC 60601-1-2, 2nd Edition - Medical Electrical Equipment Part 1-2: General Requirements for Safety. Collateral Standard: Electromechanical Compatibility - Requirements and Tests.

IEC 60601-1 Classification

Type of Protection Against Electric Shock: Internally Powered

Degree of Protection Against Electric Shock: Type BF Applied Part

Degree of Protection Against Ingress of Water: IPX7

Mode of Operation: Continuous

EMC Information

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

This Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Radiated Emissions CISPR 11	Group 1 Class B	This Device uses RF energy only for its internal function. Therefore, its RF radiated emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Conducted Emissions CISPR 11	This Device is a battery operated device; therefore, these test requirements are not applicable	
Harmonic Emissions IEC 61000-3-2		
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3		

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that 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	±6 kV Contact ±8 kV 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	This Device is a battery operated device and has no patient-coupled cables nor I/O cables which are longer than 3 meters in length; therefore, this test requirement is not applicable.		
Surge IEC 61000-4-5	This Device is a battery operated device; therefore, these test requirements are not applicable.		
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11			
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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			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. **Recommended Separation Distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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 strength 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, field strengths should be less than 3 V/m.

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Device.

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

Rated Maximum Output Power of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (meters)		
	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 of the transmitter manufacturer.
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.

Warranty

Respironics warrants that the Actiwatch 2 device and the Actiwatch Spectrum device (each a "Product") will be free from defects in materials or workmanship for a period of one (1) year from the date of delivery to the purchaser. During the warranty period, Respironics, at its option, will repair or replace the defective Product, or issue a credit for the purchase price of the Product. Shipping costs to Respironics are the responsibility of the purchaser. The foregoing repair, replacement or credit remedy will be the sole remedy for breach of this warranty.

Without limiting the foregoing, this warranty does not cover damage to the Product caused by accident, misuse, abuse, negligence, failure to operate under conditions of normal use and in accordance with the terms of the user manual, failure to maintain in accordance with the applicable service manuals, alteration or any defects not related to materials or workmanship. This warranty does not cover damage that may occur in shipment. This warranty does not apply to any Product or individual parts that have been repaired or altered by anyone other than Respironics or an authorized Respironics service center. This warranty does not apply to any Product that is not purchased new.

RESPIRONICS DOES NOT MAKE AND HEREBY SPECIFICALLY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

In no event shall Respironics be liable for lost profits, loss of good will, or incidental or consequential damages, even if Respironics has been advised of the possibility of the same. No other person or entity is authorized to make any warranties on behalf of Respironics, and Respironics disclaims any warranties other than this warranty.

Laws vary from state to state and some states do not allow the exclusion or limitation of implied warranties or the disclaimer of incidental and consequential damages. Accordingly, the laws of your state may give you additional protections. In addition, if you are located outside of the United States, the laws of your country may give you additional rights.

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