Adding and Deleting Subjects

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

Adding Subjects (Patients)

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

1. Select File > New Subject from the main menu bar.

The New Subject window is displayed.

2. Fill in the three required fields: Identity, Date of Birth, and Gender, and other demographic data, if available.

Notice that Age is automatically computed.

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

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

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

Deleting and Hiding Subjects

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

Connecting a Legacy Actiwatch

An ActiReader or an Actiwatch Reader is necessary to communicate with a legacy Actiwatch. Connection to a desktop computer or a laptop computer is very similar to any other peripheral device.

Notes :

- Use only an IEC/UL/CSA 60950 compliant computer with ActiReader.
- Follow the recommendations supplied with your computer when connecting peripheral devices. Most manufacturers suggest powering down the computer while connecting hardware.



ActiReader connected to computer

- 1. Connect the serial communication cable (supplied) to a COM port on your computer.
- Connect the other end of the communication cable to ActiReader. ActiReader power must be ON for proper communication. If the Power light does not blink when the switch is in the ON position, the ActiReader battery must be replaced or the external power supply must be used.
- 3. Open the Actiware software. Select Communications > Actiwatch Console from the menu bar.
- 4. Click on ActiReader/Legacy Actiwatch .
- 5. From the drop-down menu, select the COM Port to which you connected.

Note : Refer to <u>Troubleshooting_Connections_</u> for assistance with the COM port selection.

Using ActiReader

Note: For regulatory purposes, the communication frequency of ActiReader was updated. Actireaders serial numbers R5349 and higher are designed for use with updated Actiwatch Score devices (serial numbers D821628 and higher) only. It is not compatible with prior versions of Actiwatch Score or with Actiwatch 16/64 or Actiwatch L.

Updated ActiReader devices (REF 1063543) have the Respironics logo directly above the Communication Pad on the front of the device near the top. Older ActiReader devices display dual branding (Respironics/Mini Mitter) under the red LED Power Indicator on the front of the device near the bottom.

Updated Actiwatch Score devices (REF 1063545) have a black label surrounding the event marker button and score display on the front of the device.



ActiReader

Updated Devices



ActiReader components		
ltem	Description	
1	External Power Source - ActiReader can be powered from an external power source (supplied). When plugged in, it will disconnect the battery to conserve it.	
2	Power ON/OFF switch - This switch will connect or disconnect ActiReader from its power source, whether AC or battery.	
3	Power (Red LED) - Whether using external power or the internal battery, the red LED will light when the Power switch is ON.	
4	Communication Pad - This recessed area ensures Actiwatch is placed properly.	
5	Aligned (Green LED) - When the Actiwatch is aligned properly and the communication wizard is active, this green LED will light.	
6	Serial Port - This is where the serial cable connects to ActiReader. The other end connects to the COM port on the computer.	

Using Actiwatch Reader

Note : Actiwatch Reader is not compatible with updated Actiwatch Score devices.

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 recess for aligning the Actiwatch, place the Actiwatch over the image and slide it up and down until the Ready LED is lit.
- The small dot on Actiwatch must be in the same corner as the small dot on the reader.
- Researchers with laptop computers may switch the Actiwatch Reader to Battery Power for proper function.
- If using battery power, you may need to periodically replace the reader battery. Refer to <u>Battery Management</u> for details.
- As with the ActiReader, the COM port selection in the software must be correct, and the communications wizard must be running, for the Ready LED to be lit.

Activity Counts

An activity count is a relative measurement used to express changes in activity based on the following points:

- 1. The component used to measure activity is an accelerometer.
- 2. This sensor outputs 32 samples per second either analog or digital depending on the type of accelerometer is in the Actiwatch.
- 3. These outputs are filtered to create activity values for inputs into a validated algorithm.
- 4. The sum of the peak activity values for each second of data monitored over an epoch is the activity count for that epoch.
- 5. The algorithm was validated against PSG for sleep endpoints.

Actiwatch Score and ActiReader Specifications

This section discusses the use of standard wrist bands, marker buttons, Actiwatch cleaning procedures, specifications for Actiwatch Score and ActiReader, EMC information, and an emissions declaration.

Standard Wrist Bands

Standard Actiwatch wrist bands are washable and disposable. Extra bands and batteries are available from Philips Respironics. 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 Philips Respironics, and a soft, nylon band with hook and loop fastener. Other means to attach Actiwatch may be used.

Marker Button

The marker button is a switch that is used to enter a numerical score in response to an audible reminder. It can also be used to turn the annunciator on and off.

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.

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.

To turn off the annunciator:

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

To turn 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.

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 audible reminder 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. Actiwatch Score will not acquire activity data during the brief time the LEDs are lit, such as when setting score values.

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.

Specifications for Actiwatch Score

Environmental

	Operating	Storage
Temperature	0 Deg. C to 40 Deg. C	-10 Deg. C to 50 Deg. C
	(32 Deg. F to 104 Deg. F)	(14 Deg. F to 122 Deg. F)
Relative Humidity	0 to 95% RH	0 to 95% RH
Atmospheric Pressure	500 to 1060 kPa	
	(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.

Specifications for ActiReader

Environmental

	Operating	Storage
Temperature	0 Deg. C to 40 Deg. C	-10 Deg. C to 50 Deg. C
	(32 Deg. F to 104 Deg. F)	(14 Deg. F to 122 Deg. F)
Relative Humidity	0 to 95% RH	0 to 95% RH
Atmospheric Pressure	500 to 1060 kPa	
	(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: Battery Type: Battery Life: AC Voltage Source:	DB9 Serial Port (a compatible USB to serial port adapter can be used) 9V Lithium (Eveready L522) 6 Months 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.

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	Group 1	This device uses RF energy only for its internal function. Therefore, its RF
CISPR 11		emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	This device is suitable for use in all establishments, including domestic
CISPR 11		establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions	Class A	
IEC 61000-3-2		
Voltage fluctuations/ Flicker emissions	Complies	
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 this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Envir
Electrostatic Discharge (ESD)	±6V contact	±6 kV contact	Floors should be wood,
IEC 61000-4-2	±8V air	±8 kV air	tile. If floors are covered material, the relative hu least 30%.
Electrical fast Transient/burst	±2kV for power supply lines	±2kV for supply mains	Mains power quality sho
IEC 61000-4-4	±1kV for input/output lines	±1kV for input/output lines	typical home or hospital
			It is noted certification to obtained recognizing that download of data to the not considered to cause download is stopped, the that and error has occur would then reinitiate the Interference that would is anticipated to be of sh that the subsequent dow successful.
Surge	±1kV differential mode	±1kV differential mode	Mains power quality sho
IEC 61000-4-5	±2kV common mode	±2kV common mode	typical home or hospital
Voltage dips, short interruptions and voltage variations on power	<5% UT (>95% dip in UT) for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	Mains power quality sho typical home or hospital
supply input lines	40% UT (60% dip in UT)	40% UT (60% dip in UT) for	
IEC 61000-4-11	for 5 cycles	5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
		<5% UT (>95% dip in UT)	

<5% UT (>95% dip in UT) for 5 sec	for 5 sec	

Note: $\mathbf{U}_{T}^{}$ 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
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields levels characteristic of a typical typical home or hospital environ
IEC 61000-4-8			
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF commune equipment should be used no clo
IEC 61000-4-6	150 kHz to 80 MHz		part of the device, including cab
Radiated RF			recommended separation distance
IEC 61000-4-3	3 V/m	3 V/m	from the equation applicable to of the transmitter.
	80 MHz to 2.5 GHz		It is noted certification to IEC 60 obtained recognizing that interru download of data to the reader of not considered to cause harm. V download is stopped, the user is that and error has occurred and would then reinitiate the download
			Interference that would interrupt is anticipated to be of short dura that the subsequent download w successful.
			Recommended Separation Di
			$d = 1.2\sqrt{P}$
			$d = 1.2\sqrt{P}$ 80 MHz to 800 MH
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GH
			where P is the maximum output of the transmitter in watts (W) a the transmitter manufacturer an recommended separation distance (m).
			Field strengths from fixed RF tra determined by an electromagneti survey ^a should be less than the level in each frequency range ^b .
			Interference may occur in the vi equipment marked with the follo

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.							
Note 2: These guidelines may not a structures, objects and people.	ipply in all situations. E	lectromagnetic	propagation	is affected	by absorption	and reflection	

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electrom environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field stren location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to very operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating
- 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	Separation Distance According to Frequency of Transmitter (m)					
Output of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz			
(W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$			
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.

Emissions Declaration

Hereby,

Respironics Inc.

1001 Murry Ridge Lane

Murrysville, PA 15668 USA

declares that this class 1 radio equipment is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EEC.

Note: You may request a "Declaration of Conformity" for this product from the Regulatory Affairs Department by contacting Product Support: Phone: +1 (541) 598-3800 or 800-685-2999

Actogram/Graph Tab

This tab contains the default settings for the Actogram or Graph. Changing control settings for one or more of these properties does not affect any open Actograms or Graphs. To view the changes, close and reopen the Actogram or Graph.

Actogram/Graph Parameters

Actogram Length

This control sets the default number of days displayed in the visible part of the Actogram window.

Component Visibility

These buttons hide or show information in the Actogram.

Graph Width

This control sets the displayed width of the Graph.

Activity Scale (counts)

This control adjusts the minimum and maximum value of activity counts displayed on the Actogram.

While Light Scale (lux)

This control adjusts the minimum and maximum illuminance value displayed on the Actogram.

Color Light Scale (μ W/cm²)

This control adjusts the minimum and maximum irradiance in (μ W/cm²) value displayed on the Actogram.

Color Light Scale (photons/cm²/s)

This control adjusts the minimum and maximum flux in (photons/cm²/s) value displayed on the Actogram.

Light/Dark Bar

This control adjusts the time bar above the Actogram and light/dark shading.

All Light (24 hours of light on) check box

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

All Dark (24 hours of light off) check box

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

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

Analysis Tab

Actiware analyzes the recorded data in accordance with the parameter settings on this tab. Definitions of each analysis parameter are given below. You can also display the definitions of each parameter by holding your mouse cursor over the parameter names on the left side of the **Analysis** tab. This displays the definition at the bottom of the window.

Active Analysis : Parameters in this column correspond to the currently selected analysis.

New Analysis : Parameters in this column correspond to any newly created analysis. These parameters are applied by default when opening an analysis. These default values are unique to each Windows logon user name.

- Click the << button to set Active Analysis parameter settings equal to New Analysis parameter settings.
- Click the >> button to set New Analysis parameter settings equal to those of the Active Analysis.
- Click the Restore Defaults button to reset to the factory released parameter settings.

Analysis Parameters

Wake Threshold Selection

Use this control to select a method for calculating wake threshold. If Automatic is selected, the wake threshold is computed based on the mean activity value.

Wake Threshold Value

The minimum number of activity counts required for an epoch to be scored as wake. This threshold value is compared to the value calculated by the Actiware sleep/wake detection algorithm for each epoch. If the value calculated for an epoch is above the wake threshold, then the epoch is scored as wake.

Refer to the Wake Threshold Selections and Wake Threshold Values table for additional information.

Note : By increasing the wake threshold value, fewer epochs are scored as wake.

Sleep Interval Detection Algorithm

Use this control to select the method for calculating sleep onset and sleep end:

- The **Immobile minutes** option uses the number of minutes scored as immobile as the basis for identifying sleep start and sleep end times. This is the recommended option.
- The **Sleep epochs** option uses a number of epochs scored as sleep as the basis for identifying sleep start and sleep end times.

Note: Sleep onset and sleep end are calculated automatically once a rest interval is set.

Immobile Minutes for Sleep Onset

Use this control to set the number of immobile minutes required to calculate sleep onset. Beginning with the first epoch of a rest interval, the algorithm identifies the first group of epochs of the selected length for which all epochs but one are scored as immobile. Sleep onset is then set to the first epoch of the period satisfying these requirements.

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

Immobile Minutes for Sleep End

Use this control to set the number of immobile minutes required to calculate sleep end. Beginning with the last epoch of a rest interval, the algorithm identifies the last group of epochs of the selected length for which all epochs but one are scored as immobile. Sleep end is then set to the last epoch of the period satisfying these requirements.

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

Epochs for Sleep Onset

Use this control to set the number of epochs scored as sleep that is required to calculate sleep onset. Beginning with the first epoch of a rest interval, the algorithm identifies the first group of epochs scored as sleep that is at least this number of epochs in length. Sleep onset is then set to the first epoch of the period satisfying these requirements.

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

Epochs for Sleep End

Use this control to set the number of epochs scored as sleep that is required to calculate sleep end. Beginning with the last epoch of a rest interval, the algorithm identifies the last group of epochs scored as sleep that is at least this number of epochs in length. Sleep end is then set to the last epoch of the period satisfying these requirements.

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

Actogram Start Hour

The hour at which the Actogram and daily intervals begin. This setting affects daily interval statistics.

Light Threshold (White)

This control is used to calculate Time Above Light Threshold (TALT). Actiware will quantify the amount of time that the Actiwatch was exposed to light levels above this threshold for a given interval (Actiwatch-L, Actiwatch2, Actiwatch Spectrum only).

Light Threshold (Red, Green, Blue)

This control is used to calculate Time Above Light Threshold (TALT) for each color channel. Actiware will quantify the amount of time that the Actiwatch was exposed to light levels above this threshold for a given interval (Actiwatch Spectrum only).

RGB Light Units

Units of red, green, blue light applied to measurements, statistics, and data output. Irradiance has units of μ W/cm² (microwatts per squared centimeter). Flux has units of photons/cm^2/s (photons per squared centimeter per second).

Refer to the Actogram/Graph View toolbar section for additional information.

Audit Trails

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

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

To view the audit trail right-click on a saved analysis and select the **Audit Trail** menu item. Each row in the left side of the window represents either a new data record or a change to an existing record.

The change list on the left side of the Audit Trail window displays the date, type of change, unique ID, and digital signature information (Clinical Trials version Only) for each change. Click on a row in the table to highlight an item. The Properties area on the right side displays the details of the change for the highlighted item.

When a highlighted row represents an edit, the Prior Value column contains the values before the edit.

The most powerful feature of the Audit Trail window is the ability to display all previous revisions of records. When an Actiwatch data item is highlighted, the **Show Graph** button is enabled. If you highlight an analysis row, then all the buttons are enabled and you can create an audit version of an Actogram, Statistics Table, or a Data List.

If the analysis has been edited and saved, then multiple rows are displayed. Highlighting the last row reflects the most recent version of the analysis. Pressing the **Show Actogram** button displays the current Actogram in the normal display window, except the title is preceded with the word **Audit**. Select other rows to display previous versions.

Note: Closing the Audit Trail window closes all Actograms, Data Lists, and Statistics Tables that were created by the Audit Trail window. To view historical audit items, keep the Audit Trail window open and either move it out of the way, or minimize it.

Auto Intervals Tab

Actiware is capable of inserting multiple types of intervals into the Actogram automatically. This tab allows you to change the settings.

When a New Analysis is Opened

Select the **Convert off-wrist time to Excluded Intervals** check box to have the software automatically include all off-wrist time in excluded intervals. This applies to all new analyses (Actiwatch Spectrum only).

Note: The Actiwatch Spectrum device is capable of determining when it is off the subject's wrist. For each epoch the device records on or off wrist status.

Select the **Automatically Set Major Rest Intervals** check box to automatically create rest intervals for periods of low activity that are longer than three hours, when a New Analysis window is opened. This will be an approximation of when the subject was in bed or resting for an extended period of time.

Select the **Automatically Set Minor Rest Intervals** check box to automatically create rest intervals for periods of low activity that are shorter than three hours, when a New Analysis window is opened. This will be an approximation of when the subject was napping.

Automatically Set Major Rest Intervals Settings

Select the **Detect only one Rest Interval per day** check box to detect one rest interval per 24 hours. This will be the longest rest interval for that 24-hour period.

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

Note: This setting only applies if the Detect only one Rest Interval per day setting is enabled.

Automatically Set Minor Rest Intervals Settings

Sensitivity : Select High to detect more minor rest intervals; select Low to detect fewer minor rest intervals.

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

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

Automatic Method

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

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

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

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

2. Major Rest Intervals (for periods of low activity that are three hours or longer in duration)

Set using Tools > Automatically Set Major Rest Intervals.

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

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

3. Minor Rest Intervals (for periods of low activity that are shorter than three hours)

Set using Tools > Automatically Set Minor Rest Intervals.

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

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

Exporting Data - Batch Processing

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

Note: For detailed tutorials on how to Export Data please visit http://www.learnactiware.com/tutorials_____

Batch Processing – Individual Export Files

This creates multiple comma-separated variable length (.csv) ASCII text files that can be opened directly by Microsoft Excel. They can contain the data and analysis results for individual analyses.

Tip: One ASCII file is created for each Actiware Analysis selected for export.

Use the Text File Export Batch Wizard, accessible by selecting **Tools > Text File Export Batch** from the main menu bar to create the file (or many standard individual export files).

Batch Processing – Combined Export File

This creates a comma-separated variable length (.csv) ASCII text file that can be opened directly by Microsoft Excel. It contains the data and analysis results from multiple analyses.

Tip: A single ASCII file containing the combined results from all selected analysis is created.

Use the Text File Export Batch Wizard, accessible by selecting **Tools > Text File Export Batch** from the main menu bar to create the file (or many standard individual export files).

Note: Combined export files are not available for epoch-by-epoch data.

To execute a batch export:

- 1. Select Tools > Text File Export Batch from the main menu bar.
- 2. Confirm that the currently active database contains the data you want to export and click Next.
- 3. Select either Individual Export Text Files or Combined Export File based on your requirements.
- 4. Select the destination of the exported data by clicking the Browse button.
- 5. Click the **Options** button to make any changes to the data selected to export.
- 6. Click Next.
- 7. Select the analyses that you want to include in the export file by clicking the applicable check boxes.
- 8. Click Next.

Notes :

- The check boxes 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.
- Hidden subjects are shown in the display.
- If you do not want to be prompted, should an error occur during the export process, select Suppress Error Messages.

- 9. Select the **Overwrite Existing Files** check box if you want to overwrite existing export file(s) without being prompted.
- 10. Click Next.
- 11. Select the **De-identify Patient Data** check box if you would like to erase patient data from the export file.
- 12. Click Next to process your data and create the export.
- 13. Click **OK** to acknowledge the completion of the batch export process.
- 14. Click **Finish** to complete the Export Batch Wizard.

Note : If any errors occur, you have the option to view the log file for details by selecting View Log.

Tip: You may select the Browse button to open the destination folder for your exports.

Battery Management

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

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

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

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

Actiwatch Spectrum PRO or Plus Battery

The battery in the Actiwatch Spectrum PRO and Plus is a lithium ion rechargeable battery. The battery is automatically recharged whenever the Actiwatch is connected to the computer or plugged into an AC outlet via the USB cable except when it is in Sleep Mode.

Total recharge time from depleted to full is approximately 2 hours. With a full charge, the Actiwatch Spectrum PRO has sufficient battery life for a typical 50 day study. With a full charge, the Actiwatch Spectrum Plus has battery life for a 60 day study. With 20 minutes of charging the Spectrum PRO or Plus device has sufficient charge to carry out a typical 14 day study.

The battery cannot be replaced by the user and should be returned to Philips Respironics for replacement, if necessary. Contact Product Support for instructions.

The display on the Spectrum PRO and Plus including a battery icon indicating charge status. Additionally, during charging, the display's backlight will blink; when fully charged the display's backlight will be constantly lit.

Actiwatch Spectrum Plus and PRO devices should be fully charged after use and put into the sleep mode before storage. Batteries for Actiwatch Spectrum Plus and PRO devices in storage should be checked and recharged every 9-10 months to maintain performance.

Devices stored longer than 10 months without recharging will lock and will require service to unlock the device.

Data is still available when the device is locked, but the device cannot be used to collect additional data.

Actiwatch Spectrum Battery

The battery in the Actiwatch Spectrum should last 1 to 2 years based on usage (\sim 270 days for continuous usage). The battery cannot be replaced by the user and should be returned to Philips Respironics for replacement. Contact <u>Product</u> <u>Support</u> for instructions.

Actiwatch 2 Battery

It is recommended that the Actiwatch 2 battery be charged before each use. The Actiwatch 2 battery automatically recharges each time it is in the Communications Dock and either plugged into the computer or plugged into an AC outlet. Total recharge time may take between 12 and 24 hours. The battery cannot be replaced by the user and should be returned to Philips Respironics for replacement, if necessary. Contact <u>Product Support</u> for instructions.

Actiwatch 2 devices should be fully charged after use and put into the sleep mode before storage. Batteries for Actiwatch 2 devices in storage should be checked and recharged every 4-6 weeks to maintain best performance.

Note: Philips Respironics recommends charging the device for a full 24 hours between each use to optimize battery life.

ActiReader Battery Replacement

- 1. Disconnect the AC electrical supply and set the Power toggle switch to OFF.
- 2. Turn the ActiReader over so the battery cover is facing up.

- 3. Slide the battery cover in the direction of the arrow.
- 4. Carefully remove the battery from the housing unit and gently disconnect the battery terminals.
- 5. Replace the battery.
- 6. Slide the battery cover back into place on the ActiReader.
- 7. Set the Power toggle switch to the ON position.
- 8. Verify the red LED Power light is blinking.

Legacy Actiwatch Batteries

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

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

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

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

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

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

Changing an Actiwatch 16/64/L or Score Battery

- 1. Remove the band from the watch. Use the screwdriver supplied to loosen (approximately five full turns) or remove the screws in the slots in the battery cover of the Actiwatch.
- 2. Carefully remove the battery cover. If you have loosened the screws, press down slightly and rotate the cover clockwise. If you have removed the screws, simply lift the cover free from the frame.
- 3. Remove the battery and discard properly.

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

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

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

- 5. Place a new O-ring into the channel in the back cover using the following technique:
 - Pre-stretch the O-ring by gently flexing it in several directions.
 - Place a portion of the O-ring in the channel and hold it with your thumb or finger.
 - Use a finger on the other hand to guide the O-ring into the channel.
 - Be sure that the O-ring is properly seated in the channel, and is not twisted or deformed.

- 6. Place a new battery into the Actiwatch case, positive (+) side up.
- 7. Replace the back cover on Actiwatch and replace the screws. If the screws have not been removed completely, rotate the back cover counterclockwise until the slots in the back are firmly seated around the screws, and the back is square with the case.
- 8. Tighten all four screws in an "X" pattern until all screws are snug. Take care not to over-tighten to the extent of stripping the threads or twisting off the heads.

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

Cleaning Instructions

Actiwatch 2

Cleaning the Actiwatch 2 Plastic Case

Actiwatch 2 may be cleaned by using a cloth moistened with a detergent and warm water. Do not use an alcohol based detergent on the plastic case parts.

Cleaning the Actiwatch 2 battery contacts

Debris and lotion may accumulate in the four battery contacts on the back of the Actiwatch 2. These should be cleaned between each use using a cotton swab and a very small amount of isopropyl alcohol.

Note: Excess alcohol may compromise the seals of the device.

Cleaning the Actiwatch 2 Band

The Actiwatch 2 bands are disposable, but when detached from the device may be cleaned with detergents including those with an alcohol base.

Actiwatch Spectrum

Cleaning the Actiwatch Spectrum Plastic Case

Actiwatch Spectrum may be cleaned by using a cloth moistened with a detergent and warm water. Do not use an alcohol based detergent on the plastic case parts.

Cleaning the Actiwatch Spectrum Band

The Actiwatch Spectrum bands are disposable, but when detached from the device may be cleaned with detergents including those with an alcohol base.

Legacy Actiwatches (AW16/64/L/Score)

Cleaning the Actiwatch Score Device

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

Clean the Actiwatch Score 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 Score back on the clean band.

Cleaning the Actiwatch Score Band

Actiwatch Score 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.

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Clinicians Report Tab

The Clinicians Report contains an Actogram and summary statistics and is designed to provide clinicians with the statistics they require to review patient sleep/wake history. This report can also be used to submit for reimbursement. The report is generated as an RTF (Rich Text Format) file which allows the user to record the reasons for using the device and interpretation of the results in specific fields.

To set the Clinicians Report configuration options:

- 1. Select **Tools > Options** from the main menu bar.
- 2. Click on the **Clinicians Report** tab, and enter/specify criteria for the report in the following sections:
- Header :
 - Click the **Include Letterhead Graphic** check box if you want to place a logo in the letterhead area of the report. GIF, BMP, or JPG graphic file formats are acceptable.
 - If you selected the **Include Letterhead Graphic** options, click the **Browse** button to locate the graphic image file on your computer.
 - Type or select the amount of **Header** space to provide at the top of the report when using company letterhead paper.
- Body :
 - Actogram days per page The number of days to display in a report page. Each row represents 24 hours from the Actogram start hour. These statistics are based on the rest and sleep intervals that start in that 24-hour day.
 - Bed Time The start time of the longest rest interval in that 24-hour day.
 - Get Up Time The end time of the longest rest interval in that 24-hour day.
 - Time in Bed The sum of the durations for all rest intervals that are associated with the 24-hour day.
 - Total Sleep Time The sum of the total sleep time for all sleep intervals associated with the 24-hour day.
 - Onset Latency The sum of the onset latency for all sleep intervals associated with the 24-hour day.
 - Sleep Efficiency The total sleep time divided by time in bed multiplied by 100.
 - **WASO** The total number of minutes scored as wake within the sleep intervals associated with the 24-hour day.
 - # Awakenings The total number of wake bouts within the sleep intervals associated with the 24-hour day.

Note : The Summary Statistics section of the Clinicians Report is a table of minimum, maximum, and mean values reported during the data collection session for each selected statistic.

• Report Folder Location :

- Click the **Browse** button to select the folder in which the Clinicians Reports will be saved. The name of the report has the following format: 'Actigraphy Report--SUBJECTID_X.RTF' where SUBJECTID is the subject ID associated with the analysis and X is the number added if there are more than one report with that name. The first report with that name has no '_X', the second report is '_1'.
- Footer :
 - Enter an optional institution or company name (up to 40 characters) to appear at the bottom center of each report page.

To generate a Clinicians Report:

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

2. Select File > Clinicians Report from the main menu bar, or click the Clinicians Report button on the toolbar.

Note: The report is displayed as an RTF file in your computer's default RTF reader software, such as Microsoft Word. Actiware will attempt to open your default RTF Viewer. Once the report has been created your RTF viewer will be minimized. The report and any changes are not saved within the Actiware Software.

To edit the Clinicians Report:

- 1. Enter the rationale for using the Actiwatch with this patient in the Indications for Use box.
- 2. Enter the interpretation of the activity data in the Interpretations box.

Configuring a Legacy Actiwatch

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

Install the ActiReader or Actiwatch Reader prior to configuring an Actiwatch (refer to <u>ActiReader</u> or Actiwatch Reader for details), and connect the ActiReader or Actiwatch Reader to the computer prior to beginning the configuration procedure below.

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

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

1. Start the Configure Actiwatch wizard:

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

The Configure Actiwatch Wizard opens.

- b. Select the ActiReader/Legacy Actiwatch device.
- c. Remove the wrist/foot bands from the Actiwatch (optional), as the bands may interfere with proper Actiwatch placement.
- d. Place the Actiwatch on the reader.

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



Actiwatch Alignment

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

- e. To configure the Actiwatch device, click Configure .
- f. You may be prompted to retrieve any data currently in memory. If you want to continue the configuration without retrieving the data, click **Discard and Continue**.
- g. Click **Next** to continue.

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

- **Change Battery**—wizard will guide you through the battery replacement process (see Actiwatch Battery Replacement later in this manual).
- Changed Battery, update --wizard will update the database with the new battery information.
- Ignore wizard will ignore the Low Battery Warning.
- h. Click Next to continue.
- 2. Edit Subject Information:
 - a. Select an existing Subject from the drop-down list or click the **New Subject** button to add a new subject to the database.

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

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

- b. Click Next when you have completed editing/adding subject information.
- 3. Set Data Collection Parameters:
 - a. Select a Start Time and date from the drop-down lists.
 - b. Select an Epoch Length from the drop-down list.

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

When selecting epoch length, consider the following:

- If actual recording time is in red, then the battery may need to be changed.
- Time zone selection should be where the data will be collected, not the current time zone of the computer location.
- When configuring the Actiwatch for sleep analysis, use an epoch length of 2 minutes or less, otherwise sleep analysis statistics will not be calculated.

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

* Actual start delay time may be limited by battery life

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

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

Recording Time Table (for epochs > 15 seconds)

15	30 sec	1 min	2 min	5 min	10 min	15 min
sec						
2.8	5.6	11.2	22.5	56.4	112.8	169.3
11.3	22.7	45.4	90.8	~180*	~180*	~180*
3.7	7.5	15.1	30.2	75.7	151	~180*
5.6	11.2	22.4	44.9	~90*	~90*	~90*
	Sec 2.8 11.3 3.7	Sec 2.8 5.6 11.3 22.7 3.7 7.5	Sec	sec	sec	sec 2.8 5.6 11.2 22.5 56.4 112.8 11.3 22.7 45.4 90.8 ~180* ~180* 3.7 7.5 15.1 30.2 75.7 151

	Actual	recording	time	may	be	limited	by	batter	/ life
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Note: Actiwatch-L devices manufactured before July 1st, 1999 have 32K memory and shorter recording times. Note : Maximum battery life is 180 days for Actiwatch16, Actiwatch64, and Actiwatch-L, and 90 days for Actiwatch Score

c. Confirm the Time Zone displayed.

This is the default time zone as set on your computer. If you want to change it, for the Actiwatch configuration, click the associated **Edit** button and select a new time zone.

d. Click Next to continue with the wizard.

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

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

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

- 4. Set Actiwatch Score Audible Reminder:
 - a. Click the Enable Audible Reminder check box.
 - b. Use the following buttons to add or remove audible reminders from the list:
 - Add Single Reminder
 - Add Recurring Reminders
 - · Delete Selected (select items in list)
 - Clear List
 - c. To print the list of audible reminders, click the Print List button.
 - d. Click Next to continue.

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

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

Actiwatch Score

Battery Life

The battery life for Actiwatch Score is primarily affected by the following:

The number of score entries (whether prompted by an audible reminder 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):

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

Configuring an Actiwatch 2 or Actiwatch Spectrum

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

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

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

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

- 1. Insert the Actiwatch 2 or Actiwatch Spectrum into the appropriate Communications Dock.
- 2. Select **Communications > Actiwatch Console** from the main menu bar.
- 3. Select the device you want to configure.

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

- 4. To configure the Actiwatch device, click Configure .
- 5. You may be prompted to retrieve any data currently in memory. If you want to continue the configuration, without retrieving data, click **Discard and Continue**.
- 6. Select an existing subject from your database, or click New Subject to create one, then click Next.
- 7. Select the Epoch Length and the Logging Mode, and click Next.

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

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

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

meeterian keeptang mile (uuys)							
Logger Type	15 sec	30 sec	1 min	2 min	5 min		
Actiwatch 2 (activity only)	22	~30*	~30*	~30*	~30*		
Actiwatch 2 (activity + light)	7	15	30	~30*	~30*		
Actiwatch Spectrum (activity only)	44	88	180	270	~270*		
Actiwatch Spectrum (activity + colored light)	9	18	36	72	182		
Actiwatch Spectrum (activity + white light)	14	30	60	120	~270		

Theoretical	Recording	Time	(days)
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* Actual recording time may be limited by battery life.

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

9. You can also choose to change the time zone in which the data will be collected by clicking the **Time Zone** button. This will also affect the time displayed on an Actiwatch Spectrum. When finished, click **Next**.

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

- 10. If you are configuring an Actiwatch Spectrum, you will be prompted to choose date and time settings, or you can choose to disable the LCD display entirely.
- 11. Click Configure to proceed with the configuration or click Cancel to make changes.
- 12. A confirmation message appears stating that configurations have been selected and prompting you to continue. Confirm by clicking **Erase and Continue**.

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

13. Remove the device from the Communication Dock.

Configuring an Actiwatch Spectrum PRO or Plus

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

Connect the Actiwatch Spectrum PRO or Plus to the computer prior to beginning the configuration procedure below.

Press the right-side button to wake up the device if it is in Sleep Mode.

CAUTION ! Configuring an Actiwatch Spectrum PRO or Plus will delete all previous physiological data from the devices. Always 'Retrieve' data before configuring the Actiwatch devices. To stop this wizard, select the **Cancel** button. To retrieve data, refer to <u>Retrieve Data from an Actiwatch Spectrum PRO or Plus</u>.

Actiwatch Spectrum PRO

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

- 1. Connect Actiwatch Spectrum PRO to the computer using the USB cable.
- 2. Select **Communications** > Actiwatch Console from the main menu bar.
- 3. Select the device you want to configure.

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

- 4. To configure the Actiwatch device, click Configure .
- 5. You may be prompted to retrieve any data currently in memory. If you want to continue the configuration, without retrieving data, click **Discard and Continue**.
- 6. Select an existing subject from your database, or click New Subject to create one, then click Next.
- 7. Select the Epoch Length and the channels of data that you want to be recorded. Once you have made your choices, click **Next**.

For Actiwatch Spectrum PRO, you can include one or two subjective scoring parameters (Score A and Score B). You can additionally provide scoring parameter names that will be included in reports and exports.

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

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

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

Logger Type	15 sec	30 sec	1 min	2 min	5 min
Actiwatch Spectrum PRO (activity only)	~50*	~50*	~50*	~50*	~50*
Actiwatch Spectrum PRO (activity + light)	~50*	~50*	~50*	~50*	~50*

Theoretical Recording Time (days)

* Actual recording time may be limited by battery life. Actiwatch Spectrum PRO has a maximum battery life of approximately 50 days of typical use when configured to provide audible and vibratory reminders and to collect Activity, Light, and Score data. The "Estimated Recording Time" field will display the amount of time the device will collect data based on available battery life, the enabled channels, and chosen reminder schedule.

Marker and Score data are recorded only when an event is recorded. Hence the data usage is negligible when compared to the above table.

- 8. You may choose to begin data collection as soon as possible by checking the box, or select a Start Time. You may also choose to collect data until the memory is full by checking the box, or you may enter a data collection duration.
- 9. You can also choose to change the time zone in which the data will be collected by clicking the **Time Zone** button. This will also affect the time displayed on an Actiwatch Spectrum. When finished, click **Next**.

Note: Data collection may not begin immediately. Typically, data collection begins within two minutes when no reminders are selected, or 4 minutes if reminders are chosen.

- 10. Choose date and time settings and beeper volume. Additionally you can choose to disable the LCD display entirely.
- 11. Click the **Advanced** button to adjust settings related to whether the beeper will emit for off-wrist and data collection start. For Spectrum PRO, an additional setting controls whether manual score entries are enabled. Click **Next**.
- 12. Adjust the minimum and maximum allowable subjective score input value, then click Next.
- 13. To configure the Actiwatch Spectrum PRO to provide reminders to the subject to enter scores, check the **Enable Score Reminders** check box.
 - Click **Add** to display the "Reminder Schedule" window to choose the settings for a score reminder schedule. Select whether this schedule is for Score A, Score B, or both. On the left, choose the times of days for the reminders. On the right, select which days and how many days to repeat the daily schedule. Additionally, each reminder can be randomized within a selected number of minutes from the nominal time. Click **OK** to save the changes and add the schedule, or click **Cancel** to discard the schedule.
 - Click Edit to modify an existing reminder schedule, or click Delete to remove one from the list.
 - Click **Save** to write the list of reminder schedules to an ASPRS (Actiwatch Spectrum PRO Reminder Schedule) file; or click **Load** to read a list of reminder schedules from an ASPRS file.
 - Multiple reminder schedules can be combined. Click **Add** to create an additional schedule of reminders. Duplicates are automatically removed.
 - If you want to see the resulting list of reminders, click **Show List**. If you click **Back** and adjust the start time or score channels, the list will be regenerated.
- 14. When finished, click the **Configure** button. A confirmation message appears stating that configurations have been selected and prompting you to continue. Confirm by clicking **Erase and Continue**.

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

15. Disconnect the device from the USB cable and slide the USB door closed.

Actiwatch Spectrum Plus

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

- 1. Connect Actiwatch Spectrum Plus to the computer using the USB cable.
- 2. Select **Communications** > Actiwatch Console from the main menu bar.
- 3. Select the device you want to configure.

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

- 4. To configure the Actiwatch device, click Configure .
- 5. You may be prompted to retrieve any data currently in memory. If you want to continue the configuration, without retrieving data, click **Discard and Continue**.
- 6. Select an existing subject from your database, or click New Subject to create one, then click Next.
- 7. Select the Epoch Length and the channels of data that you want to be recorded. Once you have made your choices, click **Next**.

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

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

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

Logger Type	15 sec	30 sec	1 min	2 min	5 min
Actiwatch Spectrum Plus (activity only)	~60*	~60*	~60*	~60*	~60*
Actiwatch Spectrum Plus (activity + light)	~60*	~60*	~60*	~60*	~60*

Theoretical Recording Time (days)

* Actual recording time may be limited by battery life. Actiwatch Spectrum Plus has a maximum battery life of approximately 60 days of typical use when configured to collect Activity and Light data. The "Estimated Recording Time" field will display the amount of time the device will collect data based on available battery life and the enabled channels.

Marker data are recorded only when an event is recorded. Hence the data usage is negligible when compared to the above table.

- 8. You may choose to begin data collection as soon as possible by checking the box, or select a Start Time. You may also choose to collect data until the memory is full by checking the box, or you may enter a data collection duration.
- 9. You can also choose to change the time zone in which the data will be collected by clicking the **Time Zone** button. This will also affect the time displayed on an Actiwatch Spectrum. When finished, click **Next**.

Note: Data collection may not begin immediately. Typically, data collection begins within two minutes when no reminders are selected.

- 10. Choose date and time settings and beeper volume. Additionally you can choose to disable the LCD display entirely.
- 11. Click the **Advanced** button to adjust settings related to whether the beeper will emit for off-wrist and data collection start.
- 12. Click Configure to proceed with the configuration or click Cancel to make changes. .
- 13. A confirmation message appears stating that configurations have been selected and prompting you to continue. Confirm by clicking **Erase and Continue.**

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

14. Disconnect the device from the USB cable and slide the USB door closed.

Connecting an Actiwatch 2

An Actiwatch 2 Communication Docking Station is necessary to communicate with an Actiwatch 2 device. Connection to a desktop computer or a laptop computer is very similar to any other peripheral device.

- 1. Connect the USB communication cable to any available USB port on your computer.
- 2. Connect the other end of the cable to the USB port on the Actiwatch 2 Communications Dock. The cable may be threaded through the cable-keeper on the back of the dock.



Notes : The USB cable that connects to the PC or AC adapter must always be installed or removed with the Actiwatch 2 out of the dock. If switching between PC and AC adapter, the Actiwatch 2 should be removed from the Communications Dock, then replaced after the cable has been switched. Do not disconnect the Communications Dock from the computer during communications, such as when the Actiwatch Console is refreshing or the device is being configured or data are being retrieved.

- 3. Wait a few moments while the Actiwatch 2 Communications Dock drivers are automatically installed.
- 4. Open the Actiware software.
- 5. From the main menu bar select **Communications** > Actiwatch Console.

The Actiwatch Communications Console wizard is displayed.

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

The connection status of the dock is displayed.

7. Place an Actiwatch 2 in the communications docking station by holding it an angle with the marker button on the Actiwatch 2 above the indentation of the communications docking station. The front of the communications docking station is slightly flexible, allowing the Actiwatch 2 to be pushed into place.


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

- **Steady red** communications docking station is connected but an Actiwatch 2 is not docked or not communicating.
- Steady or blinking green Actiwatch 2 is docked and the battery is charging.

Note : To optimize battery life, please allow the device to charge for 24 hours.

- 8. Wait a few seconds for the Actiwatch Communications Console to refresh, or click **Refresh Status** to read the Actiwatch 2 status.
- 9. Click on the expansion arrows ($\stackrel{\bigstar}{>}$) to view the Actiwatch 2 configuration details.

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

Connecting an Actiwatch Spectrum

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

- 1. Connect the USB communication cable to any available USB port on your computer.
- 2. Connect the other end of the cable to the USB port on the Actiware Spectrum Communications Dock. The cable may be threaded through the cable-keeper on the back of the dock.



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

- 3. Wait a few moments while the Actiwatch Spectrum Communications Dock drivers are automatically installed.
- 4. Open the Actiware software.
- 5. From the main menu bar select Communications > Actiwatch Console .

The Actiwatch Console wizard is displayed.

6. On the Actiwatch Communications Console, click on Actiwatch Spectrum .

The connection status of the dock is displayed.

7. Place an Actiwatch Spectrum in the communications docking station by placing it face up with the sensor windows matching the illustration on the top of the communications docking station.



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

Actiwatch Spectrum status.

9. Click on the expansion arrows (\checkmark) to view the Actiwatch Spectrum configuration details.

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

Connecting an Actiwatch Spectrum PRO or Plus

Actiwatch Spectrum PRO or Plus devices connect directly to the computer via a USB cable. Connection to a desktop computer or a laptop computer is very similar to any other peripheral device.

- 1. Connect the USB communication cable to any available USB port on your computer.
- 2. On the back of the Actiwatch Spectrum PRO or Plus device, slide the USB door cover open.
- 3. Connect the other end of the cable to the USB port on the Actiwatch Spectrum PRO or Plus.



- 4. Wait a few moments while the Actiwatch Spectrum PRO/Plus drivers are automatically installed.
- 5. Open the Actiware software.
- 6. From the main menu bar select **Communications** > Actiwatch Console .

The Actiwatch Communications Console wizard is displayed.

- 7. On the Actiwatch Communications Console, click on Actiwatch Spectrum PRO or Actiwatch Spectrum Plus.
- 8. Wait a few seconds for the Actiwatch Communications Console to refresh, or click Refresh Status to read the Actiwatch device status.
- 9. Click on the expansion arrows ($\stackrel{\scriptstyle{\scriptstyle{\scriptstyle{\times}}}}{}$) to view the Actiwatch configuration details.
- 10. When communications are finished with the Actiwatch, disconnect the USB cable and slide the USB door so that it is closed.

Refer to <u>Possible errors/troubleshooting</u> solutions for Actiwatch Spectrum PRO or Plus if you have difficulties making a connection.

Data List Tab

Use the check boxes on this tab to select the columns in the Data List window, exported files, and printed reports that include epoch by epoch data.

Data List Columns

Line Number - Line number in the list. **Epoch Number** — Epoch number of the record. Day Number - Day number since the start of data collection. Elapsed Seconds - Elapsed seconds since the start of data collection. **Date** – Date of the current line in the list. **Time** — Time of the current line in the list. Off-Wrist Status (Actiwatch Spectrum only) - 0 equals on-wrist, 1 equals off-wrist, NaN equals invalid. Activity – Activity value. Event Marker -1 equals event marker press, 0 equals no marker press. White Light – White light value. Red Light - Red light value. Green Light - Green light value. Blue Light — Blue light value. Score Parameter (Actiwatch Spectrum PRO only) - A or B, indication of which parameter this score relates to. Score Value - Score value. Score Type - Manual, scheduled, or no response. Sleep/Wake Score - 0 equals sleep, 1 equals wake, or NaN. Mobility Score - 0 equals immobile, 1 equals mobile, or NaN. Interval Status - Active, Rest, Rest-Sleep, Excluded, or N/A. S/W Status - Forced Sleep, Forced Wake, Excluded, or N/A.

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

See Viewing the Data List for additional information.

Database Management

Actiware will store all of your data records in a proprietary database format. Using the functions listed below will allow a user to create new databases, create backup copies or copy data from one database to another.

All functions listed below can be accessed by selecting File > Database from the main menu bar.

New	This function creates a new database. A common use of this function is to create a new database that will contain all records for a particular study.
Open	This function allows you to open any previously created database.
Save As	This function allows you to save a copy of the currently opened database Actiware opens this new database by default.
Backup	This function allows you to create a backup copy of the database. Tip: Philips Respironics recommends that backup copies of your database are stored on a secure server that has a regular backup schedule.
Export	This function allows you to copy specific subjects and analysis to another Actiware database. Refer to <u>Exporting Subjects between Actiware Databases</u> for details.
Show Current	This function allows you to view file details on the currently opened database including its specific location on your computer or network.

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.

The tree structure is explained below:

Level	🔁 Demo Database.AW5	Content
1st Level (Subject/subject name/identifier)	 564738291 4/9/1999, 8:45:00 AM New Analysis 	Subject identity (sorted alphabetically or numerically)
2nd Level (Actiwatch data date, time)	Custom Intervals	Actiwatch Data (sorted by date)
3rd Level (Analysis)	Rest & Excluded Intervals	Analysis Name (sorted alphabetically)

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

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

Note: Philips Respironics recommends not using the Demonstration Database for your data collections.

To create a new database:

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

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

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

To re-display it, if it should become closed, select **View > Database Viewer** from the main menu bar. Refer to the <u>Database Management</u> topic for additional information.

Electronic Signatures (Actiware CT Only)

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

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

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

- Data
- Public Key
- Digital Signature

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

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

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

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

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

Actiware CT software does not provide the ability to change the contents of an electronic record that has already been created. Instead, any change to a record (subject, Actiwatch data, or analysis) is recorded as a new revision with a new digital signature. Any attempt to change a data record manually will make the file unusable by the software. Also, each time an electronic record is created, you must sign the document, and your user name and full name, along with date and time of signing, are embedded in the record.

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

Export Tab

Use the **Export** tab to specify the items you want to include in exports. The **Export** tab applies to the copy and paste functions as well. Select the check boxes that are necessary to include the information required in your exports.

- General Export Options group. This option group is used to select interval types you export.
 - Click the Show Selected Interval Types check box to enable selection of the interval types listed below it.
 - Click the **'Interval Type' Column** check box to include a column in the table containing the interval type name (e.g., Rest, Active).
 - Click the 'Audit Trail ID' Column check box (available in Actiware CT only) to include an audit trail column with a unique identifier for the purpose of audit trails in the export file.
- Combined Export File Options group. These apply to combined export files only.
 - Click the **Single Row Header** check box to include only a single row of header information. This is especially useful when exporting to a database.
 - Click the **Database Friendly Column Names** check box to change the column headers to a simpler format designed for database import. Spaces in column names are converted to underscores and all characters in column names are forced to lower case. Column names are limited to a length of 32 characters.
- Individual Export File Options group. These apply to individual export files only.
 - Click the **Full Header** check box to include a complete listing of subject data and analysis properties at the beginning of the export file.
 - Click the Marker/Score List check box to include the list of markers or scores in the report.
 - Click the **Epoch-by-Epoch** List check box to include a list of measured or calculated data values for each epoch.

Exporting Data - Single File

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

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

Standard Individual Export File

CSV File

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

To create this file:

- 1. Select **File > Export** from the main menu bar or click the **P** icon on the Standard toolbar.
- 2. Select the **De-identify Patient Data** check box if you would like to erase patient data from the export file.
- 3. Click Browse to enter a file name and location.

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

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Windows Clipboard Method

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

- 1. Select Copy > Export Text.
- 2. Paste the contents into your program of choice by pressing CTRL + V.

Fast[™] Export File

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

To create this file:

- 1. Select File > FAST Export from the main menu bar.
- 2. Select the **De-identify Patient Data** check box if you would like to erase patient data from the export file.
- 3. Click Browse to enter a file name and location.

Exporting Subjects Between Actiware Databases

Actiware allows you to export subjects from one Actiware database to another.

Note : For detailed tutorials on how to Export Data please visit http://www.learnactiware.com/tutorials

To export subjects:

- 1. Select File>Database>Export .
- 2. Confirm that the database with the records you wish to export is shown as the 'Source Database'.
- 3. Select the records for export by clicking the appropriate check boxes.
- 4. Select the target database:
 - a. Click the Browse button to select an existing Actiware database.
 - b. Click the New button to create a new Actiware database.
- 5. Once a target database is chosen and the appropriate records are selected, click the ">" button located in the middle of the screen.

The records will appear within the Target database.

- To attach all records from the currently opened Actiware Database to an e-mail:
- 1. Select File > Email database.

Note : This function does not work with web-based e-mail applications.

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. This appears as a pink arrow below the Actogram with a time stamp and epoch information. Refer to Epoch Label Definitions for additional information.
- 2. Use the keyboard arrow keys to move the epoch label to the desired interval start time.
- 3. To place the interval START flag, press the keys for the interval type you want to create:
 - **R** to set rest interval start
 - C to set custom interval start
 - E to set excluded interval start
 - W to set forced wake interval start
 - S to set forced sleep interval start
- 4. Use the keyboard arrow keys to move the epoch label to the desired interval end time.
- 5. To place the interval END flag, press the key for the interval type you want to create:
 - SHIFT + R to set rest interval end
 - SHIFT + C to set custom interval end
 - SHIFT + E to set excluded interval end
 - SHIFT + W to set forced wake interval end
 - SHIFT + S to set forced sleep interval end

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

- 6. Use one of the following hot-key combinations to set the type of interval you want:
 - CTRL + R to insert rest interval
 - CTRL + C to insert custom interval
 - CTRL + E to insert excluded interval
 - CTRL + W to insert forced wake interval
 - CTRL + S to insert forced sleep interval

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

Refer to Setting Intervals for additional information.

FIPS Compliance

The Actiware software is able to function if the FIPS (Federal Information Processing Standard) compliant algorithms for encryption, hashing, and signing are turned on in the Windows operating system.

Formats Tab

Should you wish to specify a date format, time format, or decimal point symbol you may do so here. These settings affect the .CSV, .TXT, .RTF, copy-to-clipboard, and printed report outputs produced by the software.

Note: To edit 'Locale' settings, go to Control Panel > Panel Regional and Language Options.

Use these settings to specify how you want selected items within the exported output and reports to be formatted.

- Select an alternate date format using the **Date Format** selection box or enter your own custom format using the information below.
 - D = Display the day as a number without a leading zero (1 31).
 - DD = Display the day as a number with a leading zero (01 31).
 - DDD = Display the day as an abbreviation (Sun Sat).
 - DDDD = Display the day as a full name (Sunday Saturday).
 - M = Display the month as a number without a leading zero (1 12).
 - MM = Display the month as a number with a leading zero (01 12). If m immediately follows h or hh, the minute rather than the month is displayed.
 - MMM = Display the month as an abbreviation (Jan Dec).
 - MMMM = Display the month as a full month name (January December).
 - YY = Display the year as a 2-digit number (00 99).
 - YYYY = Display the year as a 4-digit number (1000 9999).
 - / = Date separator. In some locales, other characters may be used to represent the date separator. The date separator separates the day, month, and year when date values are formatted. The actual character used as the date separator in formatted output is determined by your system settings.
- Select an alternate time format using the **Time Format** selection box or enter your own custom format using the information below.
 - H = Display the hour as a number without leading zeros (0 23).
 - HH = Display the hour as a number with leading zeros (00 23).
 - M = Display the minute as a number without leading zeros (0 59).
 - MM = Display the minute as a number with leading zeros (00 59).
 - S = Display the second as a number without leading zeros (0 59).
 - SS = Display the second as a number with leading zeros (00 59).
 - AMPM = Use the 12-hour clock and display the AM string literal as defined by your system with any hour before noon; display the PM string literal as defined by your system with any hour between noon and 11:59 P.M. AMPM can be either uppercase or lowercase, but the case of the string displayed matches the string as defined by your system settings.
 - : = Time separator. In some locales, other characters may be used to represent the time separator. The time separator separates hours, minutes, and seconds when time values are formatted. The actual character used as the time separator in formatted output is determined by your system settings.
- Select an alternate character to use as the decimal point separator using the **Decimal Point Symbol** selection box. This controls what character is used to separate whole numbers from fractional numbers when floating point decimal numbers are displayed. There are three choices:
 - Period
 - Comma

- The current Locale setting (from Control Panel > Regional and Language Options).
- Select an alternate number of digits to display after the decimal point using the **Precision** selection box. The range of acceptable values is 0 through 10.
- Select an alternate field delimiter for export files using the **Column Delimiter** selection box. This is useful in outputs where column-separated values are displayed (such as comma delimited files or tab delimited files). Allowable characters are comma, period, pipe (|), forward slash (/), or Tab (ASCII value 9). If a delimiter other than comma is used, then text-only export files (such as Individual or Combined Export files) are written with a .TXT extension, otherwise the .CSV extension is used. This setting has no effect on the copy-to-clipboard, Printed Report, or Clinicians Report.
- Select an alternate symbol for invalid data values using the **Invalid Data Indicator** selection box or type in a custom character/string. The purpose of this indicator is to specify characters that indicate a reported value in the output is invalid or impossible to calculate. The default setting is NaN. Also, the * was used for indication that some statistics were not supposed to be computed for certain intervals (e.g., Sleep Efficiency for a Rest Interval). Now this setting is being used instead of *. In addition to your own invalid data indicator, you may also choose NaN or a period.
- Click Restore Defaults to return the settings to Actiware's defaults settings.

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

General Tab

Use the **General** tab to access and change the following settings:

- Select a COM port from the drop-down menu. (This option only applies to the ActiReader and Actiwatch Reader devices.)
- Select the Automatically Open Actiwatch Console When Communications Dock is Connected (same as Console 'Auto Show') check box if you want the communications console to automatically open whenever a communications dock is connected.
- Click the **Reset Reminder Notes** button to reset the **Don't show this message again** message boxes so that they will reappear when necessary.

Viewing the Graph

The Graph differs from the Actogram because it displays Actiwatch data along a single axis. Depending on the type of Actiwatch used, the Graph displays activity data, white light, red, green, and blue light, sleep/wake, wrist on/off, manual score, scheduled score, and marker data.

To view a data Graph:

1. Select **View > Graph** from the main menu bar, or click the Graph icon standard toolbar. It may also be activated automatically by clicking in the Actogram.

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

Notes :

- To display the values at a single point in time, left click and a red line appears on the Graph. The values for that epoch are displayed in a box below the Graph. Refer to the Epoch Label Definitions table for additional information.
- To move the red line left or right, press the left or right arrow keys on your keyboard. Pressing the arrow keys when the red line is not present scrolls the Graph one data point left or right.
- The <u>Actogram/Graph View toolbar</u> on the right side of the main window allows the viewing properties for the Graph to be changed.
- To zoom in, place the mouse at the left edge of the area of interest, then click and drag a rectangle to the right, then release.
- To zoom out, right-click on the Graph and click Refresh Graph.
- To move forwards and backwards through the time frame, use the horizontal scroll bar at the bottom of the Graph window.
- Data is displayed as defined in the <u>Actogram</u> section.

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

- Print the Graph (select **File > Print Graph** from the main menu, or right-click the Graph and select **Print Graph** from the pop-up menu).
- Copy a picture of the Graph to the Windows Clipboard (select **Copy > Graph** from the main menu).

Immobile and Mobile Definitions

Actiware will score an epoch as mobile or immobile based on the level of activity generated during that epoch. An immobile score is the result of less than 1 activity count per 15 seconds. A mobile score will be the result of 1 or more activity counts per 15 seconds.

The following chart illustrates:

Sample Bate	Will be scored	Will be scored
Sample Rate	as Immobile	as Mobile
15 Seconds	0	>= 1
30 Seconds	< 2	>= 2
1 Minute	< 4	>= 4
2 Minutes	< 8	>= 8

Import Actiwatch Data (AWD) Files

This option is used to import data to the currently open database. You can import data files collected with previous versions of Actiware, including AWD files from Actiwatch 16/64, Score, Light, and Cambridge Neurotechnology's AW7 devices.

To import an AWD file:

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

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

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

Importing/Exporting Data

To view tutorials on exporting data, please visit <u>http://www.learnactiware.com/tutorials</u>.

Using the Main Window

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

- Database Viewer
- Properties Viewer
- <u>Actogram</u>

Menu and tool bars display commonly used functions. Tool tips appear when the mouse is positioned over items in the toolbar.

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

- Left-click on items to view properties in the Properties Viewer.
- Left-click on the + or box to expand or collapse the tree view.
- Right-click on items to display commonly used functions such as adding subjects, importing AWD files or viewing the <u>audit trail</u>.
- Double-click on items to expand the tree view or view Actograms.

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

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

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

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

- Subjects are sorted (alphanumerically) by subject ID.
- Actiwatch Data entries are sorted by data collection start time.
- Analyses are sorted by their saved names.

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

Toolbar Icons

	roorbai		
"Clinicians Report"	Button to generate the Clinicians Report		Display Statistics Table
2	Create a new subject		Display the Data List
7	Import an AWD file	5	Display data as a Graph
ų,	Refresh	6	Print an Actiware report
11	Show Actiwatch Console	þ	Export a data file

P	Edit Properties		Copy export text to Clipboard
\$ 9	Show audit trail	D	Create a new analysis
111	Show Database Viewer	Q	Open an analysis
	Show Properties Viewer		Save an analysis
朝	Display Actogram		

Add Interval Method

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

- 1. Select Interval > Add Interval from the main menu bar (Ctrl+I).
- 2. Use the control in the Add Interval window to select the interval type.
- 3. Use the controls to set the interval start time (date and time).

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

4. Use the controls to set the interval end time (date and time).

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

Note: If you want to create this interval for all days, check the Repeat for all days check box.

5. Click the Add Interval(s) button.

Refer to Setting Intervals for additional information.

Overview

This online help describes the features available in the Actiware and Actiware CT software applications. Both applications are part of the Actiwatch activity monitoring system. The Actiware software allows users to save and process actigraphy data and generate reports and data files.

Actiware and Actiware CT are Windows® based software applications design to do the following:

- Configure the Actiwatch device (such as <u>Actiwatch</u>, <u>Actiwatch</u> 2, <u>Actiwatch</u> <u>Spectrum</u>, <u>Actiwatch</u> <u>Spectrum</u> <u>PRO</u>).
- Retrieve data from the Actiwatch device (such as the Actiwatch, Actiwatch 2, Actiwatch Spectrum, Actiwatch Spectrum Plus or Actiwatch Spectrum PRO) using an ActiReader or a communication dock to a computer running the Actiware software.
- View clinical data.
- Analyze the data.
- Manage subject (patient) information .
- Generate findings and print reports.
- Export raw data or statistics for external analysis or archive.

Intended Use

The Actiwatch devices are wrist-worn activity data recorders that can record data relevant to circadian rhythms and sleep parameters in any instance where quantifiable analysis of physical motion is desirable.

In addition, the Actiwatch Spectrum PRO device has a built-in score pad that allows the subject to assign and enter a numeric score. The score pad can be used as a substitute or in addition to the traditional patient diary used in conjunction with activity data recording.

Note: Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the Member State in which the user and/or patient is established.

Actiware and Actiware CT

Actiware and Actiware CT are software programs 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. Data can be displayed on-screen in graphic form and on printed reports in tabular form. The software does not perform diagnosis.

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.

Clinical Trials

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

- Restrict access to only authorized users.
- Embed electronic signatures in data files.
- Secure data files with digital signatures.

- 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 Supports the Following Languages:

- English
- French
- Spanish
- Italian
- Dutch
- Norwegian
- Swedish
- Japanese
- German

Daylight Savings Time (DST)

Upon configuration, the Actiwatch device obtains the current time directly from the computer. When collecting data over a DST change it is important to know that the Actiwatch data does not adjust with the DST time change.

Some models of Actiwatch devices with clock displays may adjust the displayed time, however this will not change the time for the data being collected.

Owner Responsibilities

The Actiwatch equipment and the authorized components and accessories are designed to function as described in their respective product documentation. Read the product documentation carefully before attempting to use Actiware, the Actiwatch equipment, components, and accessories.

Following is a list of the owner's responsibilities :

- Replace faulty components when necessary to ensure safe and reliable operation using parts supplied by or approved by Philips Respironics.
- Monitor device performance and stop using equipment which is not functioning properly until all necessary maintenance has been completed, and a factory-authorized service representative has certified the equipment as ready for use.
- Do not modify the communications dock, ActiReader devices or any of its accessories.

The user/owner of the Actiwatch equipment shall have the sole responsibility and liability for any injury to persons or damage to property (including the Actiwatch equipment) resulting from any of the following circumstances :

- Operation not in accordance with supplied operating instructions
- Maintenance not in accordance with authorized maintenance/operations instructions
- Maintenance by anyone other than a factory-authorized service representative
- · Modification of the equipment or accessories
- · Use of damaged or unauthorized components or accessories

The Actiwatch device is to be used only for the purposes for which it was sold.

Caution : Do not operate a computer during electrical storms. If a power failure goes beyond battery backup, information could be lost or the equipment could be damaged.

Other Cautions:

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

Warnings:

- The provider should read and understand this entire help system before using this device.
- This help system serves as a reference. The instructions in this manual are not intended to supersede the health care professional's instructions regarding the use of this device.
- Do not dispose of lithium batteries in fire or flame. An explosion may result. Dispose only in accordance with manufacturer's recommendation or local regulations.
- Operation of the device may be adversely affected by:
 - Electromagnetic fields exceeding the level of 10 V/m in the test conditions of EN 60601-1-2.
 - Magnetic fields (e.g., MRI).
- If you notice any unexplained changes in the performance of this device or if the enclosure is broken, discontinue use. Contact Product Support and replace any damaged parts before continuing use.
- ActiReader and Actiwatch docking stations To avoid electrical shock, disconnect the AC power supply before cleaning. DO NOT immerse the AC power supply in any fluids.

Security Measures Regarding EPHI (Electronic Personal Health Information)

Actiware is a software-only product. Due to the intended use of this software, it does not contain an emergency access mode. Actiware users do not need to have admin privileges.

The customer is responsible for maintaining the hardware on which this software is installed. Philips Respironics suggests that you adhere to the following recommendations for maintaining the security of patient information: • Install and maintain regular updates and security patches to your computer's operating system.

- Install and maintain regular updates of anti-virus, anti-malware software. Antivirus software is not a component of Actiware; however, we strongly advise you to install an antivirus program that Philips has validated for use with Actiware. Philips Healthcare has validated McAfee antivirus software for use with Actiware.
- Actiware does not automatically clear the screen, which may contain patient data. You may adjust screen saver settings in Windows to automatically or manually clear the screen and to require a login when restoring the screen.
- If you store backups for long-term archival purposes, be aware that storage media technology changes over time and the media you choose for storage should be usable in the future.
- When you store patient information on external media, the media should be protected appropriately (i.e., stored securely).
- When removing a computer from service or replacing a disk drive containing patient information from a computer, ensure that the disk drive (in either case) is either destroyed or erased securely so that the information on it cannot be read.
- The default location for data is a folder called "Actiware Data" in the "Documents" folder. Make sure all data in this folder is deleted when uninstalling Actiware from a computer.
- Create and implement disaster recovery and backup policies that protect patient data stored in Actiware.
- For optimal system security, include the following system security measures in your policies:
- Restrict booting up from external drives, such as a USB drive, in the boot sequence.
- Disable unused I/O device interfaces.
- Remove or disable and rename unused operating system accounts.
- Analyze services and ports and remove or disable those that are not required.
- Physical security: examples include locks, cameras, key cards, sensors, etc., for restricting unauthorized access. It is recommended that the computers running Actiware, or any healthcare-related application, are secured from theft and/or located in a locked/controlled environment.
- Operational security: for example, access and authorization controls, change management, network segmentation based on data classification, password protection of BIOS, disabling external drives, disabling unused ports/services. Use a firewall to filter open ports in use.
- Procedural security: for example, locking unattended workstations, defining role-access for each user, prohibiting authentication credential sharing, requiring passwords for each account, developing termination checklists, performing risk management (i.e., performing risk assessments and mitigating identified risks), etc.
- Security policies: for example, ensuring that the system service documentation and media are securely stored, and that systems adhere to your security policies.
- Training and awareness.
- Contingency planning.

Symbols

The symbols shown below may be found on ActiReader and may be found throughout this online help. Refer to <u>http://www.symbols.philips.com</u> for a description of the symbols used on this device and its packaging.

Symbols	Meaning				
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Ĩ	Attention, consult accompanying documents
	Electronic Instructions for Use Indicates that relevant information for use of the product is available in electronic form.
1	Packaging Unit To indicate the number of pieces in the package
MD	Medical Device Indicates that the item is a medical device
UDI	Unique Device Identifier Indicates the Unique Device Identifier
yyyy-mm-dd	Date and Country of Manufacture To indicate the date on which the device was manufactured and to indicate the country of manufacture of the product
★	Type BF Applied Part
	Canadian/US Safety Certification
IPX2	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees per IEC 60529
IPX7	Protected against the effects of temporary immersion in water (Actiwatch 64, Actiwatch 16, Actiwatch- Light).
5738	Alignment indicator (ActiReader)
Ι	Power On indicator (ActiReader)
	DC Power (ActiReader)
F©	Compliant with Part 15 of the FCC rules
9V ===== Lithium only	9 Volt Lithium battery
X	Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC

Print Report Tab

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

- Click the **Full Header** check box to include a complete listing of subject data and analysis properties on the first page of the printed report.
- Click the **Actogram** check box to include the Actogram graphic in the report. You can select the number of Actogram days to print per page.
- Click the **Statistics** check box (and sub-boxes) to include statistics for various types of intervals.

Printing Reports

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

Note: The contents of the printed report can be customized by selecting **Tools > Options** from the main menu bar.

To generate a standard report:

- 1. Open an analysis by double-clicking on its icon in the Database Viewer.
- 2. Select File > Print Report from the main menu bar, or click the Print icon 🖨 on the Standard toolbar.
- 3. Change the printing options and click Print.

To generate a Clinicians Report:

- 1. Open an analysis by double-clicking on its icon in the Database Viewer.
- Click on the Clinicians Report button on the standard toolbar, or select File > Clinicians Report from the main menu bar.

The report is generated and displayed in your computer's default RTF reader application. You can add optional Indications for Use & Interpretation text in the spaces provided on the first page before printing/saving the report. See <u>Clinician's Report</u> for details.

Properties Viewer

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

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

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

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

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

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

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

Quick Method

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

- 1. Hold down the **CTRL** key on the keyboard.
- 2. Click the left mouse button where you want the start of the interval to be. A flag for the start of the interval appears. This will include the word '**Start**' and the time.
- 3. While still holding down the **CTRL** key, click the right mouse button where you want the end of the interval. A flag for the end of the interval appears. This will include the word `**End'** and the time.

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

- 4. Using one of the following hot-key combinations, set the type of interval you want:
 - CTRL + R to insert rest interval
 - CTRL + C to insert custom interval
 - CTRL + E to insert excluded interval
 - CTRL + W to insert forced wake interval
 - CTRL + S to insert forced sleep interval

The new interval is automatically drawn in the Actogram display. Confirm that the correct interval type has been inserted using the legend on the right side of the window.

Refer to Interval Definitions for additional information.

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

Removing Intervals

To remove a single interval:

• Click the left mouse button in the interval you want to delete and press the **Delete** key.

To remove all intervals:

• Right click on the Actogram and select Clear All Intervals .

To remove all intervals of a specific interval type:

• Use the Interval menu and select the interval type you want to remove.

Refer to Setting Intervals for additional information.

Retrieving Data from a Legacy Actiwatch

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

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

To retrieve data from an Actiwatch:

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

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

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

The Actiwatch Console opens.

- 4. Select the ActiReader/Legacy Actiwatch device.
- 5. Click **Retrieve** to continue.

Actiware communicates with the Actiwatch device and retrieves the data.

- 6. When the data retrieval is finished, you are prompted to save the data by clicking the **Save Data** button. You can also elect to display the data in an Actogram by selecting the **Launch Actogram** check box.
- 7. When data retrieval is complete, remove the Actiwatch device from the communication docking station.

Retrieving Data from an Actiwatch 2 or Actiwatch Spectrum

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

To retrieve data from an Actiwatch:

1. Place the Actiwatch on the communications docking station.



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

The Actiwatch Communication Console opens.

- 3. Select the appropriate Actiwatch device.
- 4. Click Retrieve to continue.

Actiware communicates with the Actiwatch device and retrieves the data.

- 5. When the data retrieval is finished, you are prompted to save the data by clicking the **Save Data** button. You can also elect to display the data in an Actogram by selecting the **Launch Actogram** check box.
- 6. You now have three choices (below). Choose one and click Next.
 - Continue the data collection.
 - · Configure the device for a new subject.
 - Put Actiwatch to sleep for later use. This action causes the device to be put into low power sleep mode. The display turns off after a few seconds. Pressing the left marker button, or putting the device back into the dock wakes it up. If storing for long periods, checking and recharging the Actiwatch 2 battery every 4-6 weeks will help maintain performance.
- 7. When data retrieval is complete, remove the Actiwatch device from the communications docking station.
Retrieving Data from an Actiwatch Spectrum PRO or Plus

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

To retrieve data from an Actiwatch Spectrum PRO or Plus:

- 1. Connect Actiwatch Spectrum Plus to the computer using the USB cable.
- 2. Select **Communications > Actiwatch Console** from the main menu bar.

The Actiwatch Communication Console opens.

- 3. Select the appropriate Actiwatch device.
- 4. Click Retrieve to continue.

Actiware communicates with the Actiwatch device and retrieves the data.

- 5. When the data retrieval is finished, you are prompted to save the data by clicking the **Save Data** button. You can also elect to display the data in an Actogram by selecting the **Launch Actogram** check box.
- 6. You now have three choices (below). Choose one and click Next.
 - Continue the data collection.
 - Configure the device for a new subject.
 - Put Actiwatch to sleep for later use. This action causes the device to be put into low power sleep mode to preserve battery life and for long term storage. Be sure to fully charge the device (approximately 2 hours) before storing the device for an extended period. If storing for long periods, checking and recharging the battery every 9-10 months will help maintain performance. The device display will be blank when asleep. To wake the device, connect it to the USB cable and press right button.
- 7. When communicate is complete, disconnect the Actiwatch device from the USB cable and slide the USB door cover closed.

Saving an Analysis

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

To save an analysis:

- 1. Right click in the Actogram
- 2. Select the Save Analysis option from the pop-up menu.
- 3. Type a name and click **Save**.

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

Tip: When an unsaved Actogram is closed, Actiware prompts you to save and name the analysis.

Scoring and Analyzing Data

Scoring and analyzing your data usually involves setting rest and excluded intervals. Actiware software automatically produces the selected statistics for each interval.

Tips:

- All intervals are set by first identifying and defining the start and end times and then creating the appropriate interval. For more information refer to <u>Setting Intervals</u>.
- Refer to http://www.learnactiware.com/tutorials for online tutorials.

Example of the Scoring Process -- Rest Interval

1. Identify bed times

Using all inputs available determine the points in time where the subject went to bed with the intent to sleep each day. For example, compare event markers or diary entries to the time where activity decreases. Do not expect an exact match; subjects are not as precise as the Actiwatch. Using these inputs, make your best estimate of bed time.

Potential inputs for bed time and get-up time:

- Patient sleep diary
- Event markers in the Actogram
- Activity information in the Actogram
- Sleep/wake scores in the Actogram
- Light information in the Actogram



- 2. Insert rest interval start time (refer to Setting Intervals for details)
- 3. Identify get-up time

1

2

3

Using all inputs available, determine the point in time where the subject got out of bed and began their active period for each day. For example, compare event markers or diary entries to the time where activity increases at the end of a period of low activity. Do not expect an exact match; subjects are not as precise as the Actiwatch. Using these inputs, make your best estimate of the get-up time.

- 4. Insert rest interval end time
- 5. Insert the rest interval
- 6. Identify nap times
- 7. Identify the nap start and select the interval start
- 8. Identify the nap end and select the interval end
- 9. Insert the rest interval
- 10. Identify and exclude invalid data

Security

NOTICE: Click here for FIPS compliance notice.

How to create or change your password

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

1. Press <**Ctrl** ><**Alt** ><**Delete** > on your keyboard.

- 2. Click Change a Password .
- 3. Enter the old password.
- 4. Enter your new password (twice) and click Ok.

Login

When you launch the Actiware software application, the Security Log On window appears with your Windows user name auto-populated.

- 1. Enter the **User name** and **Password** that you would normally use to access the Windows operating system. (For more information on user names and passwords, refer to <u>How to create or change your password</u>.)
- 2. Click **OK**.

Note: Your local IT administrators may be able to assist you with log in and password issues. Please contact them prior to contacting Philips Respironics product support.

Additional Authorization

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

- 1. Enter your $\ensuremath{\textbf{User}}$ name and $\ensuremath{\textbf{Password}}$.
- 2. Review the signature meaning.
- 3. Add any comment text in the space provided.
- 4. Click the Sign and Save button.

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

All subjects' information defined by HIPAA as Personal Health Information is encrypted in the Actiwatch PRO and PLUS devices when configured using Actiware version 6.0.5 and later.

Auto Log Off

Actiware will automatically log you off after 10 minutes of inactivity.

Account Lockout

Actiware will automatically lockout your account after 5 invalid password attempts. After 10 minutes, you will be able to login again.

Database Validation and Back-up

The database is validated and automatically backed-up when:

- Opening a database.
- Retrieving data from an Actiwatch.
- Closing a database and exiting Actiware.

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

Export Files

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

Setting Intervals

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



Item	Description
1	Sleep/wake scores are shown below activity. Red indicates wake. White indicates sleep.
2	Excluded intervals are represented by dark blue shading.
3	Event markers are shown as blue wedges.
4	Rest intervals are represented by aqua shading.
5	Sleep intervals are represented by blue shading.

Epoch Label Definitions

	Epoch Label Definitions		
AC	Activity counts recorded for the epoch		
1	Lux recording for the epoch		
r	Red light irradiance or flux for the epoch		
g	Green light irradiance or flux for the epoch		
b	Blue light irradiance or flux for the epoch		
М	Marker button was depressed during the epoch		
On Wrist/Off Wrist	Status for the epoch		
S	Sleep or wake score for the epoch		
sc	Score value		

Note: If an asterisk is appended to the epoch label, then there is more than one score value in that epoch. Mouse over the score indicator above the Actogram day or see the Data List for the full list of scores for that epoch.

Interval Definitions

Rest intervals

These are periods of time when the subject activity is low and the subject is likely to be at rest. When set, they are indicated on the Actogram by aqua shading. Typically this will be used to indicate the in-bed period. Actiware will automatically apply the sleep interval detection algorithm once a rest interval is defined.

The first data point in the rest interval is used for the bed time and the last data point as the get-up time.

Sleep Intervals

These are periods of time when the subject is likely to be asleep. These intervals are created automatically by the software once a rest interval is defined. They represent the periods of time between sleep onset and sleep end and are indicated by blue shading.

Active Intervals

These are periods of time when the subject activity indicates that they are alert and moving. Active Intervals are created automatically when rest intervals are set and include all periods not included in a rest or excluded interval. No shading is used to indicate these intervals.

Excluded Intervals

These are periods of time that are excluded from all analytical calculations. These intervals are intended to indicate when subjects remove the Actiwatch or for periods of invalid data. These are generally set manually and are indicated by dark blue shading. When **Convert off-wrist time to Excluded Intervals** is selected on the Auto Intervals tab in the Tools menu, any off-wrist event is automatically shown as an excluded interval (Actiwatch Spectrum only).

Custom Intervals

These are periods of time that are of interest for any reason. These are commonly used for shorter periods of rest that may contain naps. 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 manually.

Forced Wake (Advanced Users Only)

These are periods of time for which the sleep/wake scores for each epoch have been manually forced 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 (Advanced Users Only)

These are periods of time for which the sleep/wake scores for each epoch have been manually forced to sleep. This is typically used if the subject is known to be sleeping but there is significant movement. Epochs included in this type of interval are indicated by a gray mark below the X axis of the Actogram.

Note: Custom, excluded, forced wake and forced sleep intervals can be overlapped. However, due to the automatic creation of sleep intervals, rest intervals cannot be overlapped. If you attempt to overlap rest intervals, they will be combined into one interval.

There are several ways to set intervals:

<u>Automatic method</u>

- Quick method
- Fine control method
- Add interval method

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

Setting Options

The Options window in Actiware allows you to customize the software's functionality and data properties.

To open the Options window:

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

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 which can be set by the researcher. (Refer to the <u>Analysis tab > Wake Threshold Value</u> section for additional information.) 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 ≤ Wake Threshold Value
- Wake = Total Activity Counts > Wake Threshold Value

Calculating Total Activity Counts

Actiware calculates total <u>activity counts</u> 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



Item	Description	
1	Epoch being scored as sleep or wake	

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

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

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

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

If the resulting value is less than or equal to the wake threshold value, the epoch would be scored as sleep.

Wake Threshold Values

The total number of activity counts is compared to the wake threshold value. Thresholds are listed in the following table.

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

The automatic wake threshold is based upon a sum of the activity counts for the entire data set.

*The Automatic Wake Threshold is calculated as follows:

Automatic Wake Threshold = ((sum of activity counts) divided by (MOBILE TIME)) multiplied by 0.88888.

Refer to the Wake Threshold Selection on the Analysis tab for additional information.

Definition of Mobile:

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

Statistics Tab

Use this tab to select the statistics used for analysis.

Changes made here impact displayed, exported, and printed statistics. Place the cursor over an item to see a brief definition of that item.

Interval Information

Start Date - The date for the first epoch of any given interval.

Start Day - The day of the week for the first epoch of any interval.

Start Time - The time for the first epoch at the start of any given interval.

Duration - The time elapsed between the start time and the end time of any given interval, in minutes.

End Date - The date for the last epoch of any given interval.

End Day - The day of the week for the last epoch of any given interval.

End Time - The time for the last epoch at the end of any given interval.

On/Off Wrist Status (Actiwatch Spectrum only)

Off-Wrist Time - The total number of epochs between the start time and the end time of the given interval that the Actiwatch indicated it was not on the subject's wrist, multiplied by the epoch length in minutes.

%Off-Wrist - Total off-wrist time divided by interval duration multiplied by 100.

Activity Statistics

Total AC - The sum of all valid physical activity counts for all epochs for the given interval.

Avg AC/min - The average of all valid physical activity counts for all epochs for the given interval divided by the epoch length in minutes.

Avg AC/epoch - The average of all valid physical activity counts for all epochs for the given interval.

Std AC - The standard deviation of all valid physical activity counts for all epochs for the given interval.

Max AC - The largest valid physical activity value recorded during the given interval.

Total Invalid Time (activity) - The epoch length in minutes multiplied by the total number of epochs for a given interval for which the physical activity count value is invalid. This may occur under multiple circumstances including excluded intervals, device error, communication error, data corruption, time the logger is in the docking station, or time between data collection sessions.

%Invalid AC - The total invalid time (activity) divided by interval duration multiplied by 100.

Sleep/Wake Statistics

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

Sleep statistics marked with an asterisk (*) will be altered if the **Enhanced Sleep Statistics** check box is checked. This applies to sleep intervals only. Refer to the Enhanced Sleep Statistics section below for details.

Sleep Time* - The total number of epochs for the given interval scored as sleep by Actiware (or manually set as sleep by you) multiplied by the epoch length in minutes.

% Sleep* - The percentage of epochs in an interval that are scored as sleep. Scored total sleep time divided by (interval duration minus total invalid time (sleep/wake)) multiplied by 100.

Sleep Bouts - The total number of continuous blocks of epochs where each epoch is scored as sleep for the given interval.

Avg Sleep Bout* - The scored total sleep time divided by the number of sleep bouts for the given interval.

Onset Latency - The time required for sleep to start after initiating the intent to sleep. The time between the start of a given rest interval and the sleep interval start time, in minutes, and is controlled by the sleep interval detection algorithm.

Snooze Time - The time required to become active after sleep end. The time between the end of a given sleep interval and the end of the rest interval, and is controlled by the sleep interval detection algorithm.

Sleep Efficiency* - The percentage of time spent in bed sleeping. Scored total sleep time divided by (interval duration minus total invalid time (sleep/wake)) of the given rest interval multiplied by 100.

WASO* (Wake After Sleep Onset) - This is the total number of epochs between the start time and the end time of the given sleep interval scored as wake by Actiware software (or manually set as wake by you using Actiware software) multiplied by the epoch length in minutes.

Note: WASO is identical to scored total wake time when the given interval is a sleep interval.

Wake Time* - The total number of epochs between the start time and the end time of the given interval scored as wake by Actiware software (or manually set as wake by you) multiplied by the epoch length in minutes.

% Wake* - The percentage of epochs in an interval that are scored as wake. Scored total wake time divided by (interval duration minus total invalid time (sleep/wake)) multiplied by 100.

Wake Bouts - The total number of continuous blocks of epochs where each epoch is scored as wake for the given interval.

Avg Wake Bout* - The scored total wake time divided by the number of wake bouts for the given interval.

Invalid Time SW - The total number of epochs for the given interval for which the sleep/wake scoring algorithm did not have enough data to determine a sleep or wake score multiplied by the epoch length in minutes.

Note: The insufficient data condition can be caused by invalid or manually excluded epochs.

%Invalid SW - The percentage of epochs for a given interval for which the sleep/wake scores are invalid. Total invalid time (sleep/wake) divided by interval duration multiplied by 100.

Enhanced Sleep Statistics - (For advanced users only) When enabled, eight sleep statistics (marked with * above) are altered using a software algorithm. This algorithm applies PSG-derived correction factors and uses statistics from surrounding major rest periods to alter the sleep statistics for a particular sleep interval. As a result, the algorithm is most effective with multiple rest intervals. Press the **Advanced** button to adjust this setting.

Note: This applies to sleep intervals (and associated summary statistics) only; statistics for rest, custom, active, or daily intervals are not affected. As a result of enabling this feature, the affected statistics (marked with * above) may result in values greater than the associated rest interval. For instance, wake time, sleep time, %sleep and others may be greater for the sleep interval than the associated rest interval.

Mobility Statistics

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

Immobile Time - The total number of epochs for the given interval scored as IMMOBILE by Actiware software multiplied by the epoch length in minutes.

% Immobile - The percentage of epochs in the given interval scored as immobile. Scored total immobile time divided by (interval duration minus total invalid time (activity)) multiplied by 100.

Immobile Bouts - The total number of continuous blocks of epochs where each epoch is scored as immobile for the given interval.

Avg Imm Bout - The scored total immobile time divided by the number of immobile bouts for the given interval.

#1min Imm Bouts - The number of immobile bouts that are one minute in length for the given interval.

%1min Imm Bouts - The percentage of immobile bouts that are one minute in length for the given interval.

Mobile Time - The total number of epochs for the given interval scored as MOBILE by Actiware software multiplied by the epoch length in minutes.

% Mobile - The percentage of epochs in the given interval scored as mobile. Mobile time divided by (interval duration minus total invalid time (activity)) multiplied by 100.

Mobile Bouts - The total number of continuous blocks of epochs where each epoch is scored as mobile for the given interval.

Avg Mob Bout - The scored total mobile time divided by the number of mobile bouts for the given interval.

Fragmentation Index - This is an index value that includes mobility and short sleep bouts. The sum of percent mobile and percent one minute immobile bouts divided by the number of immobile bouts for the given interval.

Score Statistics (Actiwatch Score and Actiwatch Spectrum PRO)

Scores - The total number of manual scores plus the number of scheduled scores entered by the subject for the given interval.

Manual - The total number of manual scores entered by the subject for the given interval.

Avg Score - The sum of all score values divided by the total of score values for the given interval.

Avg Manual - The sum of all manual score values divided by the number of manual score values for the given interval.

Avg Scheduled - The sum of all scheduled score values divided by the number of scheduled scores for the given interval .

No Responses - The number of scheduled scores for which no response was received for the given interval.

Scheduled - The total number of scheduled scores entered by the for the given interval.

Std Score - The standard deviation of all score values for the given interval.

Std Manual - The standard deviation of all manual score values for the given interval.

Std Scheduled - The standard deviation of all scheduled score values for the given interval.

Additional Score Statistics (Actiwatch Spectrum PRO only)

Note: A late score means a scheduled score responded to 5 to 15 minutes after the reminder time.

Late Scores - The total number of late scores for the given interval.

Avg Late - The sum of all late score values divided by the total number of late score values for the given interval.

Std Late - The standard deviation of all late score values for the given interval .

Light Statistics

Illuminance is used for white or photopic light measurements and is expressed in lux. Colored (RGB or red-green-blue) light is measured in irradiance or flux. Irradiance has units of μ W/cm² (microwatts per squared centimeter). Flux has units of photons/cm²/s (photons per squared centimeter per second).

Note : Irradiance/flux (red-green-blue light) statistics apply to the Actiwatch Spectrum, Spectrum PRO and Spectrum Plus.

Total Exposure - The sum of all valid light data in minutes.

Avg Light - The average light value for the given interval.

Std Light - The standard deviation of the light values for the given interval.

Max Light - The largest light value for the given interval.

TALT - The total accumulation of time, in minutes, during which the Actiwatch was exposed to an intensity of illumination above the given illuminance or irradiance/flux threshold.

Invalid Time L - The total number of epochs for the given interval for which the light value is invalid. This may occur under multiple circumstances including excluded intervals, device error, communication error, data corruption, time the logger is in the docking station, or time between data collection sessions.

% Invalid Time L - Total invalid time (illuminance or irradiance/flux) divided by interval duration multiplied by 100.

Advanced - Press this button to adjust the Enhanced Sleep Statistics setting described in the Sleep/Wake Statistics section of this help topic.

Note: For all above standard deviation statistics, standard deviation is computed with (n - 1) rather than (n) in the denominator of the variance.

See Viewing Statistics for additional information.

Product Support

Visit these Respironics web sites to find additional products, services, and assistance: www.respironics.com www.philips.com/actigraphy

Contact Product Support if you need assistance with the Actiware software or Actiwatch hardware: 1.724.387.4000 (USA only)

Email: <u>Respironics.Service10@Philips.com</u>

https://www.usa.philips.com/healthcare/sites/actigraphy/support

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Actogram

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

The Actogram provides the ability to select periods of time, known as intervals, and to provide statistics for them. (See <u>Setting Intervals</u> for details.)

To open an Actogram:

- 1. In the Database Viewer, click the + sign next to a Subject.
- 2. Click the + sign next to the Actiwatch Data record.
- 3. Double-click on New Analysis .

This process can be repeated for any Actiwatch data in the database.

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

The time scale is set by default so that midnight is in the center, thereby making the sleep periods easier to see. However, noon, midnight, and noon are adjustable by changing the "Actogram Start Hour" analysis property in the Options window under the <u>Analysis tab</u>.

Actogram Data Display

Note: The Actiwatch Spectrum can be configured to collect color light (RGB or red-green-blue) data. These are displayed in the Actogram as red, green, and blue lines. These data can be displayed as irradiance or flux. (Refer to RGB light units in the <u>Analysis</u> tab.)



Item	Description
1	Noon
2	Midnight
3	Noon

4	Black lines indicate activity data	
5	Excluded intervals are represented by dark blue shading	
6	Off-wrist indicated by magenta bar	
7	Color light (red-green-blue)	
8	Sleep/wake scores are shown below activity. Red indicates wake.	
9	Rest periods are represented by blue shading	
10	Sleep/wake scores are shown below activity. White indicates sleep	
11	White light data shown in yellow	
12	Epoch label	

Actogram Sleep/Wake and Interval Display



Item	Description	
1	Sleep/wake scores are shown below activity. Red indicates wake. White indicates sleep.	
2	Custom interval	
3	Excluded intervals are represented by dark blue shading.	
4	Event markers are shown as blue wedges.	
5	Rest intervals are represented by aqua shading.	
6	Sleep intervals are represented by blue shading.	
7	Invalid data intervals are represented by grey	

|--|

Refer to <u>Setting Intervals</u> for more information on definitions and setting intervals.

Actiwatch Score Data

Score Data from an Actiwatch Score device can additionally be displayed on the Actogram.

There are three types of Score data:

- **Scheduled Scores** These are score values where the patient responded to the scheduled audible reminder you programmed. These scores appear as magenta lines on the display.
- Manual Scores These scores were entered manually, without an audible reminder. They appear as green lines on the display.
- **No Response** When the patient does not respond to a scheduled audible reminder, 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 tab 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** tab.

To generate statistics based on score data, use **Tools > Options**, 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.

Actiwatch Spectrum PRO Data

Score Data from an Actiwatch Spectrum PRO device can additionally be displayed on the Actogram. Spectrum PRO can record up to two parameters, A and B. Score A data are indicated as a magenta line on the Actogram, whereas Score B data are indicated as a green line. Additionally, each Spectrum PRO event type is indicated differently on the Actogram:

- **Schedules Scores** These are score values where the patient responded to the scheduled reminder you programmed. These scores appear as an asterisk at the top of the Actogram day.
- Late Scores These are scores where the patient responded to the schedule reminder you programmed, but responded 5 to 15 minutes after the initial reminder. These scores also appear as an asterisk at the top of the Actogram day.
- Manual Scores These scores were entered manually, without a reminder. They appear as a diamond on the on the top of the Actogram day.
- **No Response** When the patient does not respond to a scheduled reminder, this is represented by a small red triangle.

With Spectrum PRO, more than one score value can be recorded per epoch. In the Actogram, the first score for the epoch is drawn on the Actogram. However, the full list of scores for the epoch can be seen by placing your mouse over the indicator (asterisk, triangle, or diamond) at the top of the score value in the Actogram. Additionally, the full list of scores can be seen the Marker Score List.

Per epoch score data can be seen in the Data List tab along with activity data, and can be exported along with activity data and per epoch sleep analysis results. In addition, the Marker/Score List is provided that includes only the score data. The Score, Score Parameter 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** tab.

To generate statistics based on score data, use **Tools > Options**, 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.

Actogram/Graph View Toolbar

This section refers to the collection of tools on the right side of the Actiware software window.

These controls are used to adjust the viewing properties of an Actogram or Graph and are available only when an Actogram is present and selected. Changes made to these settings are immediately visible in the currently selected Actogram.

Actogram Length : Controls the number of days displayed in the visible part of the Actogram window. Select a value or type it directly into this control to set the number of days.

Graph Width : Controls the time scale for the Graph when the Graph is selected. Note: This does not apply to the Actogram window.

Activity	Show or hide activity data
White	Show or hide white light data
Red Green Blue	Show or hide Red/Green/Blue light da
Sleep/wake score	Show or hide sleep/wake scoring
Off-wrist	Show or hide off-wrist
Scores	Show or hide subjective scores, (Actiwatch Score only)
1 A	Show or hide A parameter subjective scores, (Actiwatch Spectrum PRO only)
ть	Show or hide B parameter subjective scores, (Actiwatch Spectrum PRO only)
Fid Grid	Show or hide grid
Time bar	Show or hide the time bar

Visibility : These controls hide/show the data items in the Actogram.

Activity Scale: Adjusts the maximum value of activity counts displayed on the Actogram and Graph. Select a value or type it directly into this control to set the activity scale.

White Light Scale : Adjusts the maximum illuminance value displayed on the Actogram and Graph. White light is displayed on a logarithmic scale in units of lux. Select or type directly into this control to set the scale.

Color Light Scale: Adjusts the minimum and maximum values for the colored light displayed on the Actogram and Graph. Color light is displayed on a logarithmic scale in units of μ W/cm² or photons/cm²/s. Select it or type it directly into this control to set the scale. To adjust the colored light units, use the Edit Analysis Parameters window or <u>Analysis</u> tab of the Options window.

Light/Dark Bar: Use these controls to change the settings for the time bar at the top of the Actogram. Adjusts the Day/Night value displayed on the Actogram represented by the sun and the moon. Select it or type it directly into this control to set the scale.

Interval Legend: Provides a convenient reminder of the color scheme used for displayed intervals. Click the keyboard controls link to display quick reminders on how to set intervals. Refer to <u>Setting Intervals</u> for details.

To save your current Actogram/Graph control settings as the default settings:

1. Select View > Save Current Actogram View as My Default View from the main menu bar.

Troubleshooting Connections

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

Note : If the following solutions do not resolve the issue, please contact Product Support.

Troubleshooting solutions for an Actiwatch Spectrum PRO or Plus

Error Message or Condition	Solution
"Disconnected" is displayed	Check the cable connections on the Actiwatch USB connector and the computer. While connected to the PC, press the right button on the Actiwatch to wake it from deep
	Connect the docking station to a different USB port on your computer. Replace USB cable .
"Error" is displayed	Disconnect the Actiwatch Spectrum PRO or Plus then reconnect it.
"Battery Lockout" is displayed	The Actiwatch has experienced an unrecoverable problem with the internal battery. Yo download the data from the device but will be unable to charge the battery or reconfigure device. Please contact Product Support for assistance.

Troubleshooting solutions for an Actiwatch 2

Error Message or Condition	Solution
"Disconnected" is displayed	Check the cable connections on the docking station and the computer.
	Connect the docking station to a different USB port on your computer.
	Replace USB cable.
"Error" is displayed	Disconnect the Actiwatch 2 communications dock then reconnect it.
Red light displayed with the device docked	Actiwatch 2 may not be docked properly. Adjust the device in the docking station until t LED turns solid or blinks, indicating a good connection.
	Inspect and clean the four contacts on the back of the device to ensure they are clear and lotion that will inhibit connections.

Troubleshooting solutions for an Actiwatch Spectrum

Error Message or Condition	Solution
"Disconnected" is displayed	Check the cable connections on the docking station and the computer. Connect the docking station to a different USB port on your computer. Replace USB cable.
"Error" is displayed	Disconnect the Actiwatch Spectrum communications dock then reconnect it.
Logger not found, insert logger into Communication Dock.	The Actiwatch Spectrum may not be docked properly. It may be upside down, not prese into place or backwards. Verify that the Actiwatch Spectrum is installed exactly the san illustration on the top of the communication dock. The Actiwatch Spectrum may have a weak or depleted battery. Confirm the communication window on the face of the device is not obscured.

Troubleshooting solutions for an Actiwatch Score

This section discusses possible problems related to hardware and potential solutions.

Problem	Possible Cause	Potential Solution
ActiReader green LED fails to light when Actiwatch Score is placed on the ActiReader.	Actiwatch Score device is not placed on the ActiReader properly	Place Actiwatch Score on the up. Check the diagram on th on the Actiwatch Score and ActiReader should be in the

1	1	device until the green LED li
ActiReader and computer will not communicate when COM port is selected.	COM port settings are incorrect.	Verify that the COM port set (Communications > Actiwato "ActiReader/Legacy Actiwato select a COM port) match th which the reader is attached
	USB to Serial Adaptor or COM port is not properly configured or enabled in Windows.	Check Windows Device Mana drivers from adapter manufa Support for additional assista
	Cable or ActiReader device may be faulty	Verify by using the cable and computer. Contact Product S assistance.
	Actiwatch Score device may be damaged.	Verify by using another Activ ActiReader. Contact <u>Product</u> assistance.
Sciettedi	Actiwatch Score device is not compatible with the ActiReader version in use.	Confirm Actiwatch Score and
		Actiwatch Score devices that front are compatible with Ac the Respironics logo directly Pad on the front of the device
		Actiwatch Score devices that front are compatible with Ac branding (Respironics/Mini M Power Indicator on the front bottom.
		Contact Product Support for
	Actiwatch Score battery may be dead or expiring or battery was improperly installed.	See "Changing a Legacy Act <u>Management</u> .
ActiReader green LED lights, but Actiwatch Score fails to communicate.	Actiwatch Score device is not compatible with the ActiReader version in use.	Confirm Actiwatch Score and
		Actiwatch Score devices that front are compatible with Ac the Respironics logo directly Pad on the front of the device
		Actiwatch Score devices that front are compatible with Ac branding (Respironics/Mini M Power Indicator on the front bottom.
		Contact Product Support for
Receive error message when trying to select COM Port in software.	USB to Serial Adaptor or COM port is not properly configured or enabled in Windows.	Check Windows Device Mana drivers from adapter manufa Support for additional assist

Viewing Statistics

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

- Time in bed
- Total sleep time
- Wake after sleep onset
- Sleep efficiency
- Number of wake bouts
- Sleep onset latency

Statistics for all intervals are automatically calculated by Actiware <u>once they have been set</u>. Many sleep statistics are only available on the **Sleep** tab on the Statistics Table.

To view the Statistics Table:

- 1. Select **View > Statistics Table** from the main menu bar, or click the Statistics icon (
- 2. Click on the tabs to view calculated statistics for each type of interval.

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

Tip: Hold the mouse pointer over each statistic column to see a brief description.

The statistics that are present in the table are based upon options that are selected from the Tools menu on the <u>Statistics</u> tab.

Viewing the Data List

The Data List allows you to view the epoch by epoch data recorded for the selected Actogram. Additionally, it is possible to view a complete listing of event marks and recorded scores (Actiwatch Score only).

To display the Data List:

- 1. Select **View > Data List** from the main menu bar, or click the Data List icon (III) on the standard toolbar.
- 2. Click the Epoch-by-Epoch List tab or the Marker/Score List tab to view each type of list.
- 3. Use the vertical and horizontal scroll bars to move up and down each list and to pan across data columns as necessary.

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

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

The columns that are present in the Data List are based upon options selected from the Tools menu on the <u>Data List</u> tab.