



Rest assured

Actiwatch systems provide reliable and continuous objective, real-time sleep/wake history for your studies involving outcome measures in sleep

PHILIPS

RESPIRONICS

Continuous monitoring of objective

Our Actiwatch devices provide objective and long-term validated monitoring and measurement of sleep/wake activity. To help you implement this technology, we provide comprehensive service offerings that help make integration easy and reduce the burden for you, your study site staff and subjects.

Our actigraphy devices continuously monitor sleep/wake activity through an internal accelerometer. The data collected enables your staff to correlate an objective measurement of response to drug administration.

The valuable information collected by our Actiwatch 2 and Actiwatch Spectrum devices eliminates, or acts as an adjunct to, other costly and restrictive collection methods and helps you to assess the efficacy of the drug being studied.



Actiwatch 2

Actiwatch Spectrum

Gain insight you would not otherwise obtain

Sleep/wake endpoints involve the objective and subjective monitoring of activity. A polysomnogram, however, is costly, requires trained specialists, and is confined within a clinical setting. This makes it challenging to monitor subjects over multiple days and nights. Diaries have the potential drawback of not being filled out in real-time and being biased due to memory recall.

Our Actiwatch devices are worn 24/7 and collect data for up to weeks at a time while in the subjects' natural environment. You can gain insight into subjects' real-world activities while enabling them to be ambulatory and comfortable. Subject compliance is enhanced due to the easy "wear it and forget it" nature of the devices.



Actigraphic measures are strong real-world indices of subjects' sleep.^[2-4] In an insomnia study*, two-thirds of the subjects slept better at home than in a lab.¹

¹ Hauri PJ, Wisbey J. *Sleep*. 1992;15:293-301

² Vallieres A, Morin CM. *Sleep*. 2003;26:902-906.

³ Usui A, et al. *Psychiatry Clin Neurosci*. 2000;54:374-376.

⁴ Cole RJ, et al. *Sleep*. 1992;15:461-469.

*Actiwatch is not cleared with a specific claim for insomnia.

Actiware-CT Print Report			
Analysis Name: New Analysis	Date of Birth: 1965-01-01	Site: 0123	Gender: Male
Subject ID: S001	Data Collection Start: 2007-04-09, 08:45:00 AM	Data Collection End: 2007-04-14, 05:09:00 PM	Actiwatch SN: V631234
Audit Trail ID: <S3DAC91B443F342CEA6A355CB31A1B5E0E3E>-%QAF303166E84E95A74A643251994250%-%@New Analysis@>			
Night of:	Evening Marker	Morning Marker	Marker Use
2007-04-14			X
2007-04-13			X
2007-04-12	01:01:00 AM	10:50:00 AM	✓
2007-04-11	11:03:00 PM	06:59:00 AM	✓
2007-04-10	10:59:00 PM	08:09:00 AM	✓
2007-04-09			X

Example of date- and time- stamped marker button activity/inactivity.

sleep/wake activity data

Actigraphy has been used by recognized leaders in the field of sleep medicine in hundreds of research studies. It is helpful when trying to capture primary and secondary endpoints involving sleep/wake activity as it relates to insomnia, depression, and pain. Our Actiwatch devices have been used in numerous clinical studies to help with the selection of subjects during screening, assessment of drug efficacy and validation of dose response reporting.

The Actiwatch offers:

- Objectivity – patient recording activity in the home environment provides real-world sleep history information and is a valuable adjunct to subjective sleep diaries and polysomnography.
- Enhanced protocol compliance – if using paper diaries as a monitoring method, subjects may not always adhere to the prescribed protocol. Our devices help enhance study compliance as subjects are more apt to adhere to the prescribed protocol when it is easy for them to comply.
- Reliability – Actiwatch can be worn 24 hours a day, 7 days a week. It is water-resistant and rugged enough to endure normal household wear so data can be collected reliably throughout the day.

Actiwatch key features and benefits:

- More objective data than diaries and questionnaires
- Reliable and validated data
- Helps to enhance patient compliance
- Offers a low cost per subject price model, a fraction of the cost compared to PSG
- Easy to implement, providing low burden to the site and the subject
- Non-restrictive monitoring locations
- Non-surgical and ambulatory
- Sensitive to movement in all directions
- 21 CFR part 11 electronic record compliant
- Provides auditable data
- May help to expedite study timeline

We bring more to your study than just technology

We complement our technology offerings with a complete suite of services to reduce your site burden and allow your team to do what they do best. Our clinical study specialists assist your staff by providing:

- Dedicated, toll-free support
- Central data scoring, analysis and delivery
- Customized software
- Inventory management and logistics
- Site training
- Protocol advising
- Equipment leasing

Team up with an experienced leader

We have worked with well-known companies on more than 30 clinical trials and have the experience that can help your clinical trial succeed. You'll benefit from this experience through our expertise and a variety of services specifically customized for individual study needs.

These service offerings focus on helping your study sites incorporate and implement actigraphy easily and with minimal burden.

A clinical trial study involving an Actiwatch device concluded that: by monitoring subjects in a non-restrictive environment, as opposed to a study site, natural activity data was able to be collected. Additionally, the burden on the site was lowered as an on-site monitor was not necessary during data collection and inventory. Inventory management and scoring functions were performed by Philips Respironics.

**Philips Healthcare is part of
Royal Philips Electronics**

How to reach us

www.philips.com/healthcare

Fax: +31 40 27 64 887

Asia

+852 2821 5888

Europe, Middle East, Africa

+31 40 27 87246

Latin America

+55 11 2125 0764

North America

+1 425 487 7000

800 285 5585 (toll free, US only)

Philips Respironics

20300 Empire Avenue, Building B-3

Bend, OR 97701

Customer Service

+1 541 598 3800

800 685 2999 (toll free)

Respironics Europe, Middle East, Africa

+33 1 47 52 30 00

Respironics Asia Pacific

+852 3194 2280

www.philips.com/respironics

For more information about Actiwatch for your clinical studies or our other clinical trial technologies or services, visit: www.philips.com/clinicaltrials

Respironics and Actiwatch are trademarks of Respironics, Inc. and its affiliates. All rights reserved.



©2009 Koninklijke Philips Electronics N.V. All rights are reserved.

Philips Healthcare reserves the right to make changes in specifications and/or to discontinue any product at any time without notice or obligation and will not be liable for any consequences resulting from the use of this publication.

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

PrintTech SB 03/12/09 MCI 4102175