



Relief for pain studies

Actiwatch Score provides reliable subjective scoring and objective sleep/wake history for your subjective response studies

PHILIPS

RESPIRONICS

Reliable, real-time subjective scoring

Are you using all the tools available when it comes to measuring subjective reactions to drug efficacy? With the Actiwatch Score, subjects can enter their response in real-time to parameters such as pain, fatigue and sleepiness. The device also provides ambulatory objective endpoint data over multiple days and nights which enables subjects to be in their own natural environment throughout the trial. You can gain insight into drug efficacy while reducing the burden on your subjects and your study sites.

The Actiwatch Score device enables real-time subjective scoring, of measurements such as pain, via an audible prompt and keypad that allows subjects to enter a numerical rating score of 0-10. Subjects simply press a button to enter their score and they are done. This easy, real-time scoring capability replaces the subject burden and quality concerns associated with paper diaries. And by not having to manage the data on-site, the burden is reduced for your CRO partners and staff.

Continuous monitoring of objective data

The device continuously monitors sleep/wake activity through an internal accelerometer. The data collected enables your staff to correlate an objective measurement of response to drug administration with the subjective score recorded on the keypad. This valuable combination of information eliminates other costly and restrictive collection methods while enabling you to gain long-term insight into drug efficacy you could not obtain otherwise. Centrally scored and aggregated data are provided to you in easy-to-read customized reports by our staff specialists.



The Actiwatch Score has been used in multiple studies to help customers gain insight into:

- Time-specific pain relief and intensity difference on a scale evaluation
- Worst pain intensity in a given period
- Percentage of pain relief after drug administration
- Concurrent improvements in pain intensity with measured sleep disturbances
- Improvements in overall sleep quality, reduced awakenings from pain and increased duration of sleep
- The complex interaction between reduced pain and improved sleep

Get data you would not otherwise obtain

Generally, sleep/wake endpoints can be obtained through objective monitoring (a PSG) and subjective monitoring (such as paper diaries). A polysomnogram, however, is costly, requires trained specialists, and is confined within a clinical setting, making it challenging to monitor subjects over multiple days and nights. Paper/subjective diaries have the potential drawback of not being completed in real-time and being biased due to memory recall.



Actiwatch Score key features and benefits:

- Activity data is more objective than paper diaries
- High degree of data quality
- Helps to enhance protocol compliance
- Offers a low cost per subject price model, a fraction of the cost compared to a polysomnogram (PSG)
- Easy to implement, providing low burden to the site and the subject
- Non-restrictive monitoring
- Electronic subjective scoring instead of written subjective scoring – complemented with objective activity data
- Noninvasive and ambulatory
- Enables integral subjective scoring continuously for up to 21 days
- 21 CFR part 11 electronic record compliant

The Actiwatch Score has been used in numerous clinical trials to screen subjects, collect objective outcomes, and log a subjective sense of measures such as sleep, pain and fatigue.

The Actiwatch Score offers:

- Objectivity – recording activity in the home environment provides real-world sleep history information and is a valuable adjunct to subjective sleep diaries and questionnaires
- Subjectivity – enables a real-time subjective score to be easily entered and recorded on a wrist-worn device
- 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 – able to be worn 24 hours a day, 7 days a week. Splash-proof and rugged enough to endure normal household wear so data can be collected reliably throughout the day.
- Ease of use – provides large, red numbers for easy viewing of the display window and an easy-to-press button for input of a subject’s selective score

Audible prompt and scoring features:

- Programmable to a set schedule or to sound at random intervals
- Subject can enter multiple unprompted scores
- Scores are superimposed on the activity data record to help correlate physical activity or activity of daily living with the subjective measure chosen in advance

An actual trial involving the Actiwatch Score concluded that simultaneously collecting the compound measurement of standalone objective and subjective data measures saved time. It also provided accurate and validated data to better determine the difference in the comparative measures of analgesic effect on their subjects.

We bring more to your study than just technology

Our innovative and reliable technology is complemented by a complete suite of service offerings that help reduce the burden of implementing actigraphy for your CRO partners and staff. Our staff assists your sites 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

You’ll get the benefit of our experience in having helped numerous companies with their clinical studies through our innovative and reliable technology, years of expertise and a variety of services specifically customized for individual study needs.

Our combination of technology and services is what sets us apart and is why more than 30 sponsors have relied on us to help them collect data that’s not available by other means. Our devices are recognized by leading sleep medicine researchers and we are a global leader in providing clinical study solutions in the area of actigraphy.

Actiware CT Score Compliance Report																	
Analysis Name: New Analysis				Site ID: Site 123													
Subject ID: Subject4A-H6		Date of Birth: 1/1/1965		Gender: Male													
Data Collection Start: 8/04/2008 10:29:00 AM			Data Collection End: 8/17/2008 1:36:00 PM		Actiwatch SN: XB2302												
Audit Trail ID : <\$473278903479585473>																	
Week 1	Total Score: 28		Compliant Days: 6														
Date	8/04/2008	8/05/2008	8/06/2008	8/07/2008	8/08/2008	8/09/2008	8/10/2008										
Day	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7										
Avg Score	4	5	NA	5	4	5	5										
Week 2	Total Score: 31		Compliant Days: 5														
Date	8/11/2008	8/12/2008	8/13/2008	8/14/2008	8/15/2008	8/16/2008	8/17/2008										
Day	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7										
Avg Score	5	NA	NA	6	7	7	6										
<table border="1"> <thead> <tr> <th colspan="2">Summary for this download:</th> </tr> </thead> <tbody> <tr> <td>Total days: 14</td> <td>Days with one score: 4</td> </tr> <tr> <td>Compliant days: 11</td> <td>Days with multiple scores: 7</td> </tr> <tr> <td>Non-compliant days: 3</td> <td>Combined average score: 5</td> </tr> <tr> <td>% compliant days: 79%</td> <td>Compliant subject: <input type="checkbox"/></td> </tr> </tbody> </table>								Summary for this download:		Total days: 14	Days with one score: 4	Compliant days: 11	Days with multiple scores: 7	Non-compliant days: 3	Combined average score: 5	% compliant days: 79%	Compliant subject: <input type="checkbox"/>
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Example of subjective response scores occurring throughout the day.

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

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