

# Stepwatch™



# StepWatch Step Activity Monitor US Patent # 5,485,402

**A tool for  
accurately,  
objectively,  
and easily  
measuring long-term ambulatory activity...**

The StepWatch step activity monitor is a patented, highly accurate, unobtrusive instrument worn on the ankle (Figure 1). Consisting of a sensor, electronics and battery molded into a urethane case, the StepWatch is a very durable, sealed, waterproof device. It neither requires nor allows any adjustment or maintenance by the subject. The StepWatch measures 6.5 cm long x 5 cm wide x 1.5 cm thick and weighs 65 grams (2.3 oz). The inner surface of the case is curved. Two elastic attachment straps insure that the monitor remains securely attached to the ankle without irritating the skin or damaging the cosmetic cover of a prosthesis. Alternatively, the straps can be removed and the monitor worn in a soft cotton/lycra sleeve at the ankle.



Figure 1. StepWatch

The StepWatch records step counts in short, adjustable time intervals over extended monitoring periods. For example, the StepWatch is normally used to collect one minute time intervals for two to four weeks. This allows patterns of activity and rest to be measured, as well as overall activity (Figure 2).

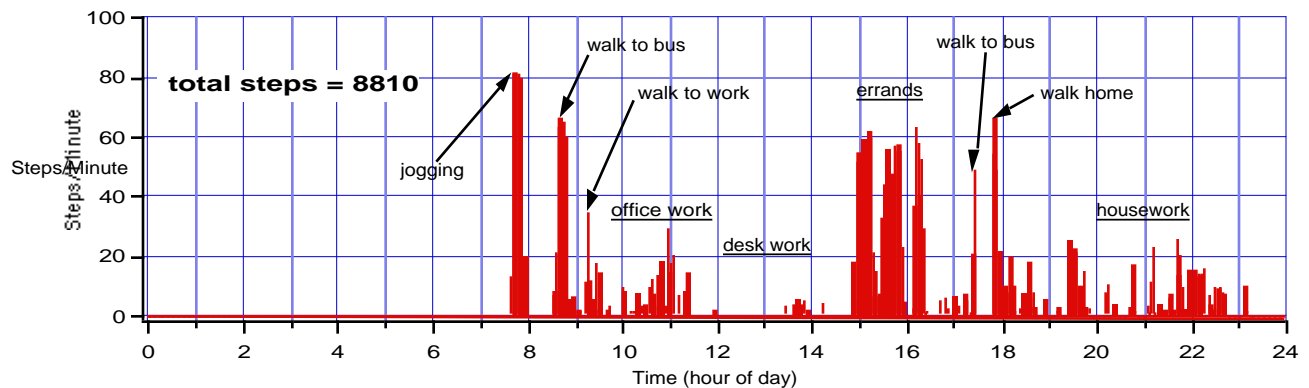


Figure 2. Twenty-four hours of StepWatch data with specific activities detailed



## StepWatch Step Activity Monitor US Patent # 5,485,402

Detailed profiles can be generated relating to issues such as the intensity and duration of peak activity, the ability of a subject to sustain a given level of activity, and the relationship between activity and rest patterns. These can give insight into a subject's real world ambulatory function that cannot be obtained through the use of a simple pedometer or through time consuming and expensive gait laboratory testing.

StepWatch accuracy has consistently been found to exceed 99% across a wide range of subjects. (For specifics on accuracy, see manuscripts 1,2, 3, 6, 7, 9 of attached publications list.) In addition, because subjects are only required to wear the StepWatch, the nuisance of activity logs and the questions of accuracy and subjectivity inherent to questionnaires are avoided.

### StepWatch Operation

#### Setting Up The Monitor For Use And Retrieving Data

The StepWatch is programmed and downloaded using a computer connected to a docking station (Figure 3).

The dock communicates with the StepWatch via infrared light. To program the StepWatch, basic performance and sensitivity settings are entered on the computer screen. A summary of settings is provided later in this document. The StepWatch's sensitivity can be optimized for a subject's gait characteristics, although a generic setting for a slow, normal or fast ambulator is generally sufficient to attain highly accurate data. If desired, the effectiveness of the chosen settings can be easily verified during a short test trial.



Figure 3. StepWatch on Docking Station



## **Some Past and Current Investigations**

The StepWatch has many possible applications in medicine. For example, it can be used to monitor the effectiveness of rehabilitation programs, or to determine whether a treatment allows or motivates the patient to walk more. Studies completed or currently in progress may provide context with regard to potential clinical and research applications of the StepWatch. These studies include:

### **1) Description of subject populations:**

- A) Levels and patterns of activity of males with advanced diabetes.
- B) Activity levels in children with and without physical disability
- C) Wandering behavior with Alzheimer's disease
- D) Activity of horses in stalls (for equine fracture management)

### **2) Measurement of Outcome**

- A) Dynamic elastic response foot vs. rigid keel foot in lower limb prostheses
- B) Elastomeric suspension liner vs. traditional foam liner for trans-tibial prostheses
- C) Ambulatory activity before and after elective lower limb amputation
- D) Effect of exercise program on activity of Alzheimer's patients
- E) Effect of exercise program on activity of elderly women following hip fracture
- F) Effect of exercise program on recovery of stroke patients
- G) Effect of total hip replacement on ambulatory activity
- H) Effect of cartilage replacement on activity in a sheep model and in humans
- I) Effect of spinal implants on ambulatory activity

### **3) Basic and Clinical Science**

- A) Association of total hip prosthesis wear rates with ambulatory activity  
(Awarded the Hip Society's prestigious Charnley Award (2000) for important advances in the management of hip disorders. Study by the authors of manuscript 2 in attached publications list.)
- B) Relationship between cognitive function and physical performance after stroke
- C) Relationship between activity levels in children and obesity
- D) Estimation of habitual plantar pressures from step and standing activity
- E) Tracking of recovery following lower limb amputation
- F) Relationship between self-selected walking velocity and ambulatory activity level



## System Costs

(Pricing Subject to change without notice)

Component	Cost
StepWatch step activity monitor	\$800
Computer Interface Dock Communication Software Software Support For 1 year	\$2,500

For current pricing and availability contact:

Prosthetics Research Study  
675 South Lane Street, Suite 100  
Seattle, WA 98104

Telephone: (206) 903-8136  
Fax: (206) 903-8141  
Email: [info@prs-research.org](mailto:info@prs-research.org)  
World Wide Web: [www.prs-research.org](http://www.prs-research.org)

## Computer Requirements and Software

Development of new software to allow communications, data viewing, filtering and basic analysis is currently nearing completion. This software is both PC and Mac compatible, and simplifies the process of programming and downloading the StepWatch. It is available for purchase in its current beta-version. Updates will be supplied free of charge until the software reaches its final release form. A computer with at least 16 MB RAM and a processor speed of at least 50 MHz is needed. The machine must have a working serial or USB port.



## Summary of StepWatch programmable settings

Setting	Type	Description
Start Time	Recording	Date and time to begin recording - can be immediately or in the future.
Interval	Recording	How often data are recorded (i.e. sampling period). This setting also determines the maximum length of the monitoring period.
Cadence	Sensitivity	Determined by the typical step rate of the subject (fast, medium, slow).
Motion	Sensitivity	The character of leg motion in the subject's gait (gentle, normal, vigorous).
Days to Record	Recording	Sets date and time to end monitoring. (A "maximum" check box allows specifying will continue until the memory is full.)
Count Scaling	Recording	Enable if step count per interval is expected to exceed 255.
LED Flashes	Accuracy Testing	The number of times (0 to 255) the StepWatch's indicator light will blink. The light blinks each time a step is detected. Used to verify that monitor is set accurately. Does not blink during normal use.
Notes	Record-keeping	Text (80 characters) which is stored in the StepWatch memory for uses such as subject or trial identification..
Threshold	Sensitivity	The sensitivity of the sensor to leg motion. This setting is only changed from its default if the desired sensitivity cannot be achieved by adjusting the "Motion" setting.



## **Some publications involving the StepWatch**

(most available upon request)

1. Coleman KL, Smith DG, Boone DA, Joseph AW, del Aguila MA: Step Activity Monitor: Long-Term Continuous Recording of Ambulatory Function, *J Rehabil Res Dev*, Vol 36, No1, 8-18, 1999. [on-line URL: <http://www.vard.org/jour/99/36/1/cole361.htm>]
2. Shepherd EF, Toloza E, McClung CD, Schmalzried TP: Step Activity Monitor: Increased Accuracy in Quantifying Ambulatory Activity, *J Orthop Res*, Vol 17, No5, 703-708, 1999. [This is a reporting on a study conducted with total hip replacement patients. Reprints may be requested from T. Schmalzried at Joint Replacement Institute, 2400 S. Flower St., Los Angeles, CA 90007, USA E-mail: [jri\\_oh@compuserve.com](mailto:jri_oh@compuserve.com)]
3. McDuffee LA, Stover SM, Coleman K: Limb Loading Activity of Adult Horses Confined to Box Stalls in an Equine Hospital Barn, *Am J Vet Res*, Vol 61, No3, 234-237, 2000.
4. Smith DG, Boone DA, Coleman K, Legro M: Outcome Assessment in Prosthetics and Orthotics. In: Berke GM, Langdon SD, eds. *Proceedings of the 23rd AAOP Annual Meeting & Scientific Symposium*, San Francisco, CA, 27-30, March 12-15, 1997.
5. Smith DG, Coleman KL, del Aguila MA, Boone DA: Functional Ambulation of Geriatric Male Diabetics: Correlation of Step Count Based Gait Assessment with the SF-36. *Proceedings of the 65th Annual Meeting of the American Academy of Orthopaedic Surgeons*, New Orleans, LA, March 19-23, 1998.
6. Coleman KL, del Aguila MA, Boone DA, Smith DG: Self-Selected Walking Velocity as a Measure of Function: Relationship to Real World Ambulatory Activity of Diabetics. In: Soede M, Verbout AJ, Swart M, eds. *IXth World Congress of the International Society for Prosthetics and Orthotics*, Amsterdam, The Netherlands, 371-373, June 28-July 3, 1998.
7. Coleman KL, Boone DA, Smith DG, Mathews DE, Laing LS: Functional Outcome Assessment Using Objective Measures of Patient Satisfaction and Gait Activity: A Comparison of 2 Feet. In: Soede M, Verbout AJ, Swart M, eds. *IXth World Congress of the International Society for Prosthetics and Orthotics*, Amsterdam, The Netherlands, 690-692, June 28-July 3, 1998.
8. Smith DG, Coleman KL, Boone DA: Improved Activity Following Elective Trans-Tibial Amputation for Pain: Outcome Assessment by Long-Term Activity Monitoring (A Case Report). In: Soede M, Verbout AJ, Swart M, eds. *IXth World Congress of the International Society for Prosthetics and Orthotics*, Amsterdam, The Netherlands, 728-730, June 28-July 3, 1998.
9. Coleman KL, Boone DA, Laing LS, Mathews DE, Czerniecki JM, Sangeorzan BJ: Quantification of Prosthetic Treatment Outcomes - Elastomeric Liner & Locking Pin Suspension vs Pelite Liner & Neoprene Sleeve Suspension. *Second National Department of Veterans Affairs Rehabilitation Research and Development Conference Proceedings*, Arlington, VA, 100, February 20-22, 2000.
10. Macko RF, Heuber E, Shaughnessy M, Boone DA, Coleman KL, Smith GV, Silver KHC, Gardner AW: Portable Ambulatory and Activity Monitoring in Hemiparetic Stroke Patients. *Second National Department of Veterans Affairs Rehabilitation Research and Development Conference Proceedings*, Arlington, VA, 208, February 20-22, 2000.

