



**USB Docking Station 3.1
and Activity Monitor
SW1001/SW1002
User Manual**



StepWatch™ 3.1 User's Manual

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The StepWatch Step Activity Monitor (SAM) is a highly accurate ankle-worn ambulatory activity monitor, the size of a small pager. The StepWatch is attached to a person's ankle by means of a band or cuff. The StepWatch works with a docking station and software that handles set-up, downloading, display, analysis, and many other functions. You will need a computer running either a Windows or Mac operating system. The Software is intuitive to use, and flexible.

This manual is similar to but not identical to the Help available within the StepWatch software. Look there for further information. The material in this manual that specifically relates to the older StepWatch 2 system is in a lighter font. The rest of the material relates to the StepWatch 3 system or both.

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I. General StepWatch™ Information and Care

The StepWatch™ Step Activity Monitor (US Patent # 5,485,402) is a research and clinical tool for long-term assessment of ambulatory function in the real world. It is an ankle-worn, microprocessor-controlled step counter, which unobtrusively measures how mobile a person is throughout daily life. Step counts can be recorded every minute for up to two months between downloads (one month for the StepWatch 2). The true maximal recording time depends on the activity of the individual subject and, thus, can only be estimated.

The StepWatch Activity Monitor detects steps for a wide variety of normal and abnormal gait styles and cadences ranging from a slow shuffle to a fast run. When properly used, accuracy typically exceeds 98%. You should expect accuracy at or near this level. Contact StepWatch technical support if your accuracy is notably lower (see “Contact Information” at the back of this manual.)

A body of published research demonstrates that functional differences in gait activity can be clearly and objectively measured with the StepWatch in a wide range of human (and large animal) populations. A StepWatch Bibliography lists currently known publications using the StepWatch at www.orthocareinnovations.com.

The StepWatch has been cleared by the US government FDA as a class II device, and is a powerful tool for assessment and description of ambulatory activity and quantification of outcomes.

A. Care of the StepWatch Hardware

The StepWatch 3 is designed to provide maintenance free performance for the life of the product. With proper use and care this is limited only by the battery life, which is typically 7 years under heavy use.

Temperature extremes, particularly high temperatures will reduce battery life. Avoid leaving it in hot places such as the dashboard of a car in the hot sun. Maximum life will be achieved at room/body temperature. **NEVER PLACE THE STEPWATCH IN ANY TYPE OF OVEN OR AUTOCLAVE as this could potentially cause the lithium battery to rupture or explode, possibly creating a hazard.**

The StepWatch is very durable and can tolerate rough handling and real-life wear and tear. Factory calibration of the sensor threshold is permanent and won't change in normal use. This is a sensitive instrument however, and should be treated with care and respect to maintain the highest possible accuracy. Extreme shock/vibration may

affect the sensor threshold, decreasing accuracy; examples include severe drops onto concrete and going through clothes washer/dryer.

The StepWatch 3 is “waterproof”. This means swimming, wading, water aerobics; bathing and showering are all okay. Some water activities however may create extreme pressures that may be harmful. Among these are water skiing and scuba diving. The StepWatch was not designed to tolerate dishwashers, clothes washers, pressure washers, steam cleaners, high-pressure hose nozzles.

1. Cleaning and Sanitizing

The StepWatch is designed for multi-patient use. The StepWatch 3 monitor may be cleaned using a cloth dampened with mild soap and water or isopropyl alcohol. (PDI Super Sani-Cloth disposable germicidal wipes have been successfully tested on the StepWatch 3.) Strong detergents or solvents will damage the plastic and will void your warranty. Do not soak the StepWatch in any type of cleaner or solvent. Dry the StepWatch 3 at room temperature. **NEVER PLACE THE STEPWATCH IN ANY TYPE OF OVEN OR AUTOCLAVE.**

The docking station is NOT waterproof. The StepWatch 3 Dock may be cleaned using a cloth dampened with mild soap and water or isopropyl alcohol. Strong detergents or solvents may damage the plastic and will void your warranty. The StepWatch 3 Dock is not waterproof. Do not soak the StepWatch Dock in any type of cleaner or solvent. Dry the StepWatch 3 Dock at room temperature. **NEVER PLACE THE STEPWATCH DOCK IN ANY TYPE OF OVEN OR AUTOCLAVE.**

The StepWatch 3 straps and cuffs may be cleaned with mild soap and water. Dipping in isopropyl alcohol may sanitize them. Hand wash. Machine washing or drying may cause shrinkage and hasten deterioration of the elastic. In highly infectious situations consider them as single patient use items.

2. Service and Repair

The StepWatch and the StepWatch Dock are not user-serviceable, Opening or tampering will void your warranty. They are factory repairable/refurbishable; contact Orthocare Innovations for details.

3. Disposal



This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electronic and electrical equipment.

The “Li” designation on the symbol indicates the presence of a lithium battery.



Lithium battery warning: Fire, explosion and burn hazard- do not short-circuit, recharge, incinerate, expose to temperatures above 212F, disassemble, puncture or expose contents to water. Dispose of the battery properly.

B. Setting up the StepWatch Program and Data Files

Follow the instructions included with your order for installing the software on your computer. When you enter the serial number, all letters should be capital. All 0 are zero not the letter, and hyphens need to be entered as shown. At installation you can choose where on your computer to copy the StepWatch folder or directory, which contains the application and Library. *The application will not run from the CD-ROM.*

1. StepWatch Library

Your StepWatch Library should always be in the same folder or directory as your StepWatch application.

The StepWatch Library should contain two folders or directories - Program Files and Client Files.

If you move your StepWatch application without moving your Library to the same folder or directory, the program will create a new library as soon as you run it. The preferences you had previously set up will not be recognized, any database information you had entered will not be available, and the program will not have access to the Help files. To correct this, you need to delete (throw away) the newly created library and place the old library into the same folder or directory as your StepWatch application.

2. Program Files

The Program Files folder or directory exists within your StepWatch Library. This contains files essential to your program set-up and database.

Never alter, delete or move your Program Files out of your StepWatch Library unless instructed to do so by Orthocare Innovations technical support personnel.

3. Client Files

Your Client Files folder or directory exists within your StepWatch Library. We suggest that you store your StepWatch data files here. You may create sub-folders or sub-directories within it for organizing your data files, add files to it, delete files from it, or change file names within it. If you want to keep your data files elsewhere, you can put an alias or shortcut to that location in your "Client Files" to facilitate quick navigation. We have included a directory called "Sample Data in your Client Files". Within it is a demo data file for your interest. (See "Appendix B: Demo Date File" on page 41.)

C. Using the Dock

Be sure the StepWatch application is not running when you plug-in or unplug the dock.

The StepWatch is placed on the dock face down (red side down) so that it fits into the indentation on the top of the dock.

The System 3 Dock features lights that indicate its communications status:

- **Fading blue light** - The dock is plugged into the computer and has power. It is OK to unplug the dock when the light is like this but not during any other light condition.
- **Steady Green and Blue Lights** - The program is running and the correct USB port is selected in StepWatch program preferences so that the software can communicate with the dock. If the blue light is steady but the green light is not on, the correct port has not been selected. It is OK to take a StepWatch monitor off the dock in this state.
- **Steady Red and Blue Lights** - There is a monitor on the dock and the dock is communicating with it. **DO NOT REMOVE THE MONITOR.** Wait until the green light comes on again before removing the monitor.
- **Flashing Red and Blue lights** - Error, see "Troubleshooting" on page 37.

Replacing Batteries for Dock Versions earlier than Version 3

Early versions of the docking station require battery power. Weak batteries can cause communications irregularities or failed communications. If you are suddenly experiencing such problems, replace the dock batteries: remove the 4 rubber feet on the bottom of the dock then use a Phillips screwdriver to remove the screws that hold the dock case together. Holding the dock upside down, carefully remove the bottom. You will see the 3 AA batteries. *Take care not to drop the electronics card when replacing the batteries.* The card is not fastened into the dock box. Do not over tighten the screws upon reassembly, or the threads may strip.

The Version 3 docking station does not require battery power. It draws power from the USB connection.

D. Setting Preferences

Before you start to collect data, we recommend familiarizing yourself with each of the following preference options because they affect how the data is recorded, displayed and analyzed. You may change your preference settings by choosing “*Preferences*” from the “*Edit*” or “*StepWatch*” menus (depending on your operating system). Further information is available in StepWatch Help.

Select whether you would like to use English or Metric units. This will affect both height measurements (inches or centimeters) and date formats (order of day and month, and characters separating day, month and year). The date format you choose should be the same as what is used by your computer operating system. (The European date style does not currently affect in all locations where dates appear.)

1. LED Flashes

The red LED on the StepWatch can be set to blink up to 100 times at the beginning of the recording session. It blinks each time a step is detected. You can use the LED flashes to quickly assess the appropriateness of your settings by watching your client walk and making sure the light blinks once for each step. Be sure your client is not also trying to look at the StepWatch because this creates a gait pattern that does not reflect typical movements. When using Advanced Programming, this preference is overridden by the number you specify on the programming screen. You may specify up to 255 LED blinks.

2. Days to Record

This preference sets the default running time for each monitoring session initiated with the regular programming mode. The programming window provides an option to change the setting for a particular monitoring session. Unless downloaded earlier, the StepWatch will always run at least this number of days, and may run slightly longer. You may want to set the StepWatch to record several days longer than your intended session so that if the client forgets to wear the monitor, you can extend the data collection session without your client having to return the monitor for re-programming.

3. Percent Time Active

We recommend not changing this number from the default 35%. If you have extremely active or inactive subjects **and** are trying to record as long as possible, contact StepWatch technical support for further advice.

4. Auto-Exclude

This function allows you to specify that days with relatively few or no steps are to be automatically excluded from analysis when your data are downloaded. The function only applies when data are first downloaded. Editing the time selection for the day in the “*Edit Time*” window may later include auto-excluded days.

5. Activity Level Definitions

All step counts are based on the steps for one leg.

The values you associate with Low and Medium Activity will be the upper limit for those categories. For example, 15 for Low means that all intervals with 1 - 15 steps/minute will be counted as Low Activity, and the Medium category will begin at 16 steps/minute. The High value does not set an upper limit for High Activity.

Instead, this number controls the scale of the y-axis for plotting of the step data on your screen and for printing.

We strongly recommend deciding on your Activity Level definitions once and leaving your preferences that way. This will allow you to directly compare results from different files and will reduce the potential for inconsistencies in your analyses and comparisons.

Note on Activity Level Definitions:

In our previous research with disabled populations, 15 and 30 for Low and Medium activity were effective limits. With those definitions, time spent at medium level activity tended to be a very strong marker of functional differences.

In our normative data collection, we have favored 15 and 40 for the Low and Medium limits as these seemed to be natural break points in our aggregate distributions of activity intensity with normative subjects. These definitions have also been effective in distinguishing between the U.S. DHHS "Healthy People 2010" descriptions of "moderate" and "vigorous" activities. Further research is needed to inform us all on the most appropriate categorization schemes.

6. Display Options

The "Draw Grid Lines for Step Rates" option controls whether horizontal step rate grid lines are drawn in the daily step plots on your screen and in printing. The "Display Activity Level as Color Bands" option controls whether the orange and yellow color bands for Low and Moderate activity are shown in the step plots on your screen and in printing. These color bands can be helpful references for visual inspection of your data, but they can also be misperceived. Remember that when the line representing any data point passes through and beyond a given band, that line is counted in the interval within which it peaks. When you change either of these settings, you will need to close and re-open any open files to see the effect.

7. Communications

Use the pop-up menu to specify the port into which you plugged the StepWatch dock. You may verify whether your selection is correct with the check dock function in the "Communications Test" of the Monitor menu or by looking to see that the green light is showing on the dock.

8. Footer Note for Printing

On the "Preferences Printing" tab window you can customize a footer of up to 25 characters that will appear on pages printed from the StepWatch software.

E. Programming the Monitor

There are two ways to program the StepWatch to record data:

- **Easy Start** is accessed through the "Start Recording Activity" command in the Monitor menu. This option provides enough flexibility to set up the StepWatch appropriately for most clients and applications, while protecting you from unexpected results. You control the StepWatch settings indirectly by describing the gait characteristics of your client. We recommend you use this method unless you have an unusual application.

To initiate "Easy Start" programming place the monitor face down on the dock and select "Start Recording Activity" from the "Monitor" menu. The software will read some information from the StepWatch, and the docking station will show a red light while it is communicating. **DO NOT MOVE THE STEPWATCH WHILE THE RED LIGHT IS ON.** This will take a few seconds. The Start StepWatch screen will then appear. Complete the client description.

- **Advanced Programming** allows direct access to all the StepWatch settings and accommodates unusual uses. Use this option only if you have thoroughly familiarized yourself with the settings. Carefully study instructions for using the Advanced options and consult with Orthocare Innovations if you have questions.

Prior to programming you may want to confirm that you have the preferences set as you wish them. (See "Setting Preferences on page 8.)

1. Client Description

a. Height

This setting strongly affects the maximum rate at which the StepWatch can identify steps. In general, a person's height is inversely related to step rate, meaning a taller person will often have a slower step rate than someone shorter.

If you do not know your client's height, give your best estimate. If you are off by a few inches, your accuracy will not be greatly affected. If you are estimating, it's better to guess shorter than to guess taller unless your client is prone to restless, fidgety movements.

b. Quick Stepping

A key to accurately identifying quick stepping activities is to distinguish overall walking or running speed from how quickly steps are being taken. Some activities, like running with long strides, involve traversing the ground rapidly without taking steps much more quickly than walking. Other activities, like vigorous dancing, involve moving the feet quickly without the body traversing the ground quickly.

It is also important to distinguish activities the client *likes* or *knows how* to do from those they *are likely to undertake* during the monitoring session.

Indicating YES for the “Quick Stepping” setting has a fairly strong affect on the StepWatch performance; so if you are uncertain, choose NO. If you are in question about whether an activity qualifies, have the client "demonstrate their moves."

Examples of quick stepping activities might be:

- Running or jogging with a short and/or rapid stride
- Vigorously playing sports such as basketball, soccer, volleyball, racquetball, tennis
- Jumping rope (with more than one jump per rope cycle)
- Romping energetically with a child or dog
- Fast dancing
- "Spinning" on a bicycle
- High-impact aerobics

c. Walking Speed

Answering **YES** to “Quick Stepping” disables this command.

Evaluating a person's normal walking speed relative to their height is likely an unfamiliar concept. The intent is to identify how quickly steps are being taken rather than the absolute speed at which a person traverses the ground. Comparing extremes in height helps illustrate the concept. Consider a small child, an average height mother, and a very tall father walking together at the same speed. If they are maintaining the mother's normal comfortable speed (and all are unimpaired), the child would be walking quite quickly relative to his height, and the father would be walking slowly relative to his height.

Apply that concept to your client. For her height, is her normal walking speed slow, average, or fast? Most people will fall in the average category.

d. Range of Speeds

Answering **YES** to “Quick Stepping” disables this command.

This setting influences how broad a range of step rates the StepWatch will "expect". For most people, a moderate range is appropriate. Some clients, however, rarely change their walking speed because of habit, preference or (most commonly) physical limitations.

It is more difficult to evaluate whether a person "regularly engages in both extremes". The following examples may help with the determination. Remember, a person must regularly exercise BOTH extremes to qualify.

Examples of the slow extreme might be:

- Walking with a slow-moving elderly person
- Walking with a young child
- Meandering, window shopping
- Slow pacing with a long stride

The key is to identify whether the person regularly walks such that the leg is in the swinging phase for a long time.

Examples of the fast extreme might be:

- Fast walking (e.g. for exercise or within a job that requires moving quickly through large spaces)
- Jogging or running with a fairly long stride (Note: if a person regularly runs with a short rapid stride, the Quick Stepping designation will be YES and the Range question will not be relevant)
- Bicycling with a moderately fast cadence
- Exercising on a Stair Master

Note that bicycling appears to the StepWatch as walking. If a person regularly bicycles, it is helpful to get some idea of how quickly they pedal ("spinning" vs. moderate pedaling vs. slow pedaling.)

e. Leg Motion

From the time the client is in your presence, observe how they move.

It is the motion at the leg and ankle that is most relevant since that is what the StepWatch will be sensing. Look at the motion of their leg/ankle rather than their whole gait.

- **Dynamic/fidgety:** If your client is especially fidgety or tends toward quick, abrupt movements, use the "*Fidgety and/or Dynamic*" setting. Most children fall into this category. This setting may also be appropriate for people who are foot tappers, especially heel tappers.
- **Gentle/geriatric:** If the client moves very slowly or gently, use the "*Gentle and/or Geriatric*" setting. This designation may also be appropriate for people who regularly undertake activities with subtle steps (usually in confined areas) if you are having trouble "capturing" those steps. Examples of those types of activities might be:
 - Working behind a counter or at a workbench
 - Dancing gently
 - Cooking in a small kitchen

If you are unsure, program a monitor with the "*Normal*" setting and put it on the client. Have them demonstrate their movements. Watch whether the StepWatch light blinks when they take steps. If you are regularly missing steps, try using the "*Gentle and/or Geriatric*" setting.

Be careful about assuming a "Gentle and/or Geriatric" setting for persons who walk with a prosthesis, walker, cane or crutches. It is important to watch the motion of the leg in these cases. Often the leg swings forward fairly rapidly and a "Normal" setting is appropriate. "Normal" is also appropriate for older people whose ankle and leg motion is flexible.

- **Normal:** Most people fall in the "normal" category.

f. Recording Time and Notes

Before initiating programming, you have the option of changing when the monitor will start and stop recording, and adding notes. Notes will be shown in the downloaded data file.

2. Initiate Programming

When you are satisfied with your description, click the Start button to initiate programming. Programming will take a few seconds. When programming is completed, the green light on the docking station will come on, and the software will tell you when recording will start.

3. Verify the Settings

Once the programming is completed, you may wish to confirm the appropriateness of your settings by watching the LED blink one time per step as your subject walks at their normal speed. You may also have them walk at the "slowest pace they would normally walk" and the "quickest pace they would normally walk." Your subject should not try to look at the monitor, as this will change their walking pattern. Watch to see that the StepWatch is not double blinking on slow steps, or missing fast steps. If you are walking with your subject, do not lead them or trail too far behind as this may influence their natural pace. If possible, stand still at the front, back or side and simply observe.

Once a monitor has been programmed, do not double-check your settings by reading recorded activity or reading current settings. Both of these actions will stop the recording, and no data will be logged until the monitor is reprogrammed.

If you have programmed a monitor to start recording but it has not yet begun, do not try to read recorded activity until it has had time to record at least one interval.

If the StepWatch is not detecting steps as accurately as you wish and your attempts to adjust the Easy Start parameters does not help, review "Verify Cadence and Sensitivity Settings" in the "Advanced Programming" section on page 32.

The key to getting optimal results is balancing the Motion Sensitivity and the Cadence settings. If you have questions, contact Orthocare Innovations for advice. Virtually any gait style can be monitored accurately, but the difficult ones require more in depth understanding of how the settings relate to each other and respond particular gait styles.

F. Wearing the Monitor

- The StepWatch 3 should be worn on the outside or inside (medial or lateral) aspect of either leg just above the anklebone. Wearing on the outside is usually preferred.
- If you are using an older version of the monitor – the StepWatch 2 – place it on the outside of the right ankle or the inside of the left ankle for maximum accuracy.
- The StepWatch may be worn over a sock for added comfort. Cotton lycra cuffs are available as an alternative to straps for attachment. Both come in various sizes.
- Be sure the StepWatch is oriented RIGHT-SIDE-UP. It will not record step data when it is upside-down. Take some time to instruct your subject/patient about monitor orientation and to assure that they understand. This is also an opportune time to discuss where they will put the monitor when they take it off and what cues they will use to remember to put it on again. Being specific will facilitate compliance.
- If the StepWatch 3 monitor is being worn during water activities, transferring it to a dry strap afterwards may be desirable.

A sample instruction sheet for subjects/patients is available in the StepWatch Help file.

II. General Data Information

A. Download Your Data

Place the monitor face down on the dock and select “Read Recorded Activity” in the Monitor menu to download the data from your StepWatch. This will take a few seconds unless you have a very large file.

Do not remove the monitor from the dock while it is communicating (while the red light on the dock is on).

If you are unable to read a monitor see “Troubleshooting” on page 37, and the program Help files within the software program.

Prior to Reading a monitor, be sure the preferences are set as you wish. If you have not moved your StepWatch program out of it’s home directory (you should not), the preferences will remain as the last user set them. If multiple people are using the system, check the preference settings for the divisions between activity levels. We recommend maintaining consistent activity level settings for all your data files. The defaults are advisable for most applications. See “Setting Preferences” on page 8 for further discussion.

If you accidentally select “Start Recording Activity...” When you mean to read recorded activity, allow the communications to continue until the start StepWatch screen appears, then click cancel. Your data will not be compromised.

B. View Your Data

When the data have been read you will see 4 tabbed windows.

- **“Summary Information”** includes the monitor ID, notes you entered, the time the monitor was programmed, started, and read, a list of days the monitor was running, other information pertaining to monitor settings, and a graphical representation of the data for any chosen day.
- **“Edit Time”** graphically shows minute-by-minute step plots of each day and allows you to select the time that will be included in your analysis. Double click on any day to access tools for including or excluding the day, or parts of the day, in your analysis.
- **“Activity/Rate”** show various analyses of the data described below.
- **“Activity/Time”** show various analyses of the data described below.

The software menus provide options for printing and exporting the raw data and analyses. You can copy the graphics and text from the *“Summary Information”* and *“Activity/Rate”* and *“Activity/Time”* screens by using the *“copy all text”* and *“copy graph”* options in the Edit menu. There is also a database you can populate.

C. Representations of the Step Data

1. Graphical Representations of the Data

There are several tools providing graphical representations of the data. For a more complete understanding of the analysis calculations see *“Analysis Variables and Calculations”* on page 18.

a. Daily Step Plots

Daily Step Plots show the raw data for each day with time (on 24 hour clock) across the bottom, and steps per minute on the vertical axis. Each small vertical line is one minute (if you have recorded in one minute intervals). The data represent step counts only for the leg being monitored. (Multiply step counts by 2 to compare with most other monitors).

b. Pie Charts

Two types of pie charts on the Activity/Rate window compare a chosen day to the average for the included time in your data file. One shows the percentage of time spent at high, moderate, and low activity (and inactive if you wish) for both the average of all included time and the included time on a selected day. The other shows the percentage of steps taken at high, medium, and low levels of activity during the included time.

c. Bar Graphs

Bar graphs in the Activity/Rate window provide the option of showing minutes or steps for all of the days during the monitoring session at any combination of high, medium, or low activity levels. If you sort by one of the data columns at the top of the page (by clicking on its header) the bar graphs will reflect this sorting.

d. Bar Charts

Bar charts on the Activity/Rate window compare activity levels during included time for a selected day with the averages for all included time in the file. The orange bars represent the average percentage, with the total minutes accumulated at this activity level on top. The yellow bars show whichever day is selected. The bar represents the time at that activity level as a percent of included time for that day. The total minutes at that activity level for the selected day are on top of the yellow bar.

e. Sustained and Peak Activity Chart

The Sustained Activity Chart on the Activity/Time window shows graduated bars for the highest activity level sustained for continuous periods of 1, 5, 20, 30 and 60 minutes each day, and the line graph shows the peak activity index which is the average of the highest 30 minutes of the day regardless of when they occurred (i.e. no requirement for continuity). The plots show the average for the entire monitoring period as well as each individual day. These measures are further described in the "Activity Time Calculations" in the "Analysis Variables and Calculations" section.

f. Week Report

In Print Preview, you can generate a report for up to 7 days that gives the average steps per day (on one leg); the average number of minutes, the percent of active time, and the percent of all time at each activity level; and a maximum sustained effort/accumulated peak effort chart. This is in a format suitable for distribution to clients. Go to Print or Print Preview in the File menu to access this.

g. Database Tools

Several further tools for analyses and graphical representation of the data are available for records in the database. These include tracking of a person over time, and comparisons between groups of people. Refer to the database section for further information.

h. Spreadsheets

See "Export Data" on page 22 for descriptions of using spreadsheets.

D. Filtering Data for Analysis

To specify which data you want included in your analysis, click on the "Edit Time" tab of your data file. This shows a step plot for each day recorded with time (on a 24 hour clock) along the bottom and steps per minute on the vertical axis. Each data line indicates the number of steps taken in 1 minute (if you have recorded in 1 minute intervals). If you are using the "Auto Exclude" option in "Preferences" (see page 8) you may see that some days are excluded already.

1. Shift Time

If you wish to move data from one day to another you may want to use the *"Shift Time"* function in the *"Monitor Utilities"*. Shifting time allows you to adjust the starting time of a file by whole hours in either direction. For example, if you have a person whose activity runs past midnight, and you want to use their continuous *"waking hours"* as the basis for your statistics, you can shift the data to accommodate this.

"Shift Time" removes any existing editing of included time. If you are matching data to a log you may wish to keep a copy of the unshifted file while you are lining up time with the data.

2. Change Included Time

To change the time that is included or excluded in your analysis, double click on any day in the *"Edit Time"* window. An editing time window will open where you may alter the time that is included in a variety of ways:

a. Start/Stop Bars

Use your cursor to drag the *"Start Time"* and *"Stop Time"* bars across the plotted data. If you do not see these bars, they are at both ends of your plotted data. Move the cursor to either end until it becomes an "I" shape. Hold the mouse button down and drag. Release the button when the bar is in the desired location. You can use the digital time controls for fine adjustments.

b. Digital Time Controls

Use the digital time controls by clicking on the hour or minutes indicator for the start or stop time, then click on the arrows to the right of the numbers to control the number.

c. Include/Exclude Day

Click the *"Include Entire Day"* or *"Exclude This Day"* to achieve the desired result.

d. Include/Exclude Range

Use the *"Include Range"* or *"Exclude Range"* toggle buttons to control whether the time between your *"Start"* and *"Stop Time"* bars is included or excluded for analysis.

e. Reset to Original

Use the *"Reset to Times Recorded"* button to reset the day to the original state. This can be especially useful for partial days at the beginning and the end of a recording session.

f. Make All Days the Same

The *"Make All Days the Same"* check box applies the time selection for the day being edited to all the days in your file. This function can save you a lot of time (and clicking) in some circumstances.

When you are satisfied with your time selection, click the OK button.

Partial Days: Be aware that your average statistics for percent time at the various activity levels and percent time inactive are referenced to your included minutes (total time at each level for all days divided by total included minutes for all days). If you are not including entire days or the same amount of time for each day, these results can be misleading.

Database Records: Changing the included/excluded time in your database records will NOT update the analysis results. To do this, you must change the time in a data file then re-submit it to the database (and delete the original record). If you have not saved the data file, simply open the database record in question and use the "Save As" command to save a new file. Edit the file, then re-enter it into the database.

E. Analysis Variables and Calculations

All step counts are for one leg. Counts should be doubled for direct comparison to standard pedometer representations.

1. Averages

All averages are based on the whole and partial days you have chosen to include for analysis. Days that are entirely excluded will appear in italicized text in your analysis windows, but will not be included in the averages.

a. Average Step Total

This is the average step total of all included days regardless of whether parts of the days are excluded. If you are only including entire days, this average will be the same as the "Average Included Steps". Days that are entirely excluded are not included in this calculation. For days in which some time is excluded, the entire step count for the day is included in this calculation.

b. Average Included Steps

This is the daily average of the steps taken during all included time. It is the sum of all included steps divided by the number of whole or partial included days.

c. Average Minutes at None, Low, Medium and High Activity

These variables reflect the percentage time spent at each activity level during the included time *relative to the total included time*. The percentages are calculated using the total minutes accumulated at each level divided by the total included minutes for all days. They are not the numeric averages of the percentage for each day relative to the included minutes for that day.

d. Average Steps at Low, Medium and High Activity

These measures are the average steps per day accumulated at each activity level for all included time.

Designations for Low, Medium and High Activity Levels: If you change your preferences for the divisions between activity levels, your statistics will automatically be re-calculated

once you re-open a data file. If you are working with records in your database, however, you will need to save the record as a file (using the "Save As" command), then make the desired changes to the file. Next, delete the original database record and re-enter your new file as a record in the database.

2. Activity/Rate Calculations

Note: To sort your days by any measure, click on the title bar for that measure in the statistics table in the "Activity/Rate" window.

a. Step Total

Total number of steps in the day regardless of whether any or all of the day is excluded.

b. Steps Included

Total number of steps in the time included for analysis.

c. Minutes Included

Total number of minutes in the day included for analysis.

d. Minutes None

Total minutes of the time included for analysis in which no steps were recorded.

e. Minutes Low

Total minutes of the time included for analysis in which the step count fell between and inclusive of 1 and the limit set in preferences for Low Activity.

f. Minutes Medium

Total minutes of the time included for analysis in which the step count fell between and inclusive of the Low Activity limit +1 and the limit set in preferences for Medium Activity.

g. Minutes High

Total minutes of the time included for analysis in which the step count was greater than the Medium Activity limit set in preferences.

h. Steps Low

Total steps accumulated during the time included for analysis at step counts between and inclusive of 1 and the limit set in preferences for Low Activity.

i. Steps Medium

Total steps accumulated during the time included for analysis at step counts between and inclusive of the Low Activity limit +1 and the limit set in preferences for Medium Activity.

j. Steps High

Total steps accumulated during the time included for analysis at step counts greater than the Medium Activity limit set in preferences.

3. Activity/Time Calculations

a. Sustained Activity Measures: Max 1, Max 5, Max 20, Max 30, Max 60

Each of these measures is derived by scanning the included time of a day with a "window" of the designated width (1, 5, 20, 30 or 60 minutes) and by extracting the maximum number of steps achieved at any continuous interval of that duration. That maximum is then divided by the duration of the interval to give the average steps per minute of that best performance.

For example, for the 60-minute sustained activity calculation, the steps between 12:00 AM and 1:00 AM are summed. Then the steps between 12:01 AM and 1:01 AM are summed. That process is continued for the entire day (or entire included time). The maximum sum is divided by 60 to give the average of the highest sustained 60-minutes for the day.

b. Activity Index: Best 30 Minutes

The Activity Index represents the average step rate of the highest 30 minutes of the included time in a day, regardless of when they occurred. They may be scattered across the day. This differs from the Sustained Activity Measures that represent continuous blocks of time.

To sort your days by any measure, click on the title bar for that measure in your statistics table in the Activity/Time window.

4. Handling Data Files

a. Save and Save As

The "Save" command under the File menu allows you to save step data to a file on your hard disk and to save alterations to a file already existing on your hard disk. If the file does not already exist on your hard disk (i.e. the data have just been read from the StepWatch or are from a database record for which there is no discrete file), a window will open that allows you to name the file and choose where to save it. If you are saving a file that you have opened from your hard disk, you will not be asked to name or choose the location for the file.

The "Save As" command under the file menu allows you to name and choose the location for saving a data file on your hard disk. This allows you to assign a new name to a data set. This is useful, for instance, if you have changed the time included for analysis and want to preserve both the old and new versions.

With either "Save" or "Save As", the specifications for the time you have chosen to include or exclude for analysis will be saved with the file. The excluded data will not be lost and will be available for inclusion later.

Note that the "Save" and "Save As" commands DO NOT SAVE RECORDS to the to neither database nor do they save alterations to database records. To save data to the database, you

must use the "Add [file name] to Database" command in the Database menu. See "Adding a Record to the Database" and "Altering a Database Record" on page 30 for further discussion.

Windows Users Only

On Windows machines, the StepWatch software automatically puts a .swb extension on the suggested file name when you use the "Save" or "Save As" commands. Some versions of Windows (such as XP) provide an option in the Control Panels (Folder Options/View) for showing or hiding extensions of known file types. If your control panel is set to hide file extensions, you will not see the .swb in the suggested file name when you use the "Save" or "Save As" commands. If you edit the suggested file name, the (invisible) .swb extension will not be appended to the name actually assigned to the file.

In that case, to make your Open file list show the StepWatch data files, you have 3 options:

- You may explicitly add a .swb to the end of each StepWatch file name when saving files.
- You may change your "Control Panel" setting to show file extensions.
- You may select "All Files" in the "File Type" pop-up menu in the navigation window that opens when you use the "Open File" command.

b. Opening and Closing Files

The following functions work for StepWatch files but not for database records.

- **Open:** The Open command allows you to open a data file created by the StepWatch 2 or StepWatch 3 program. To open files from previous versions of the StepWatch software, you must use the Import Data command.
On machines running Windows, all files in a directory which end with .swb will show up in the list of StepWatch Document file types showing in your Open dialog box. To see files not ending with .swb, you will need to select the "All Files" from the File Type pop-up menu in your Open screen.
The Open command will not open database records. For further discussion, see help for "Opening a Database Record" on page 30.
- **Open Recent:** The Open Recent command allows you to quickly access any of the last 5 data files that were opened. The data files are discrete files stored on your hard disk, in contrast to database records. If you move a file on your hard disk, the Open Recent command will not be able to find that file until it has been re-opened.
- **Import Data:** The Import Data command allows you to import data files from versions of the StepWatch software prior to 2.0 and step activity spreadsheet files exported from StepWatch software. Once a file is imported, you may use the Save or Save As... commands to store the file in your current StepWatch format. You may also add the file to your database. The Import command will not open database records or files made with the Save Raw File command.

If you intend to share data via email exchange, the most reliable method is to export your raw data file into spreadsheet format, and attach it to your email correspondence

in that format. The recipient can then import the data and save it in the native StepWatch format or as a database record.

- **Close:** The Close command closes any data window including a database record. If the window contains step activity data that have not been saved to a file, you will be asked whether you want to save the file before closing.

c. Moving Data and Analyses to Other Software

These functions work for both files and database records.

- **Export Data:** Step data may be exported to a tab-delimited spreadsheet using the Export Data option from the File menu. The first 27 rows of the exported file contain the StepWatch set-up and recording information. Row 24 indicates which data intervals were included for analysis using the convention: [include or exclude indicator]*[starting interval]*[ending interval]. The Include indicator is "i" and the Exclude indicator is "x." The counting is referenced to the first interval after midnight. (That interval is 1). The raw step data starts at row 28 and is divided into columns by day. The first column is time. You may use these files to perform custom analyses. Exported data files may later be imported back into the StepWatch program if the first 27 rows are unchanged.
- **Export Analysis:** Results of the Activity/Rate and Activity/Time analyses may be exported to a tab-delimited spreadsheet format using the Export Analysis option in the File menu. Both the average of the included time across all days and the results for each day are reported.
- **Copy All Text:** You may copy your analysis results directly out of the StepWatch software by going to the "Activity/Rate" or "Activity/Time" screen and selecting Copy All Text in the Edit menu. You do not need to have any text highlighted. Results of all analysis measures except the percent time at each activity level for each day in the file or database record will be copied.
If you Copy All Text from the Summary screen, the StepWatch setup information will be copied. After you have copied the text, simply use the paste command in another application to transfer your data into that program.
- **Copy Graph:** You may copy the charts and graphs from the "Summary", "Activity/Rate", and "Activity/Time" screens of a file or database record by selecting the Copy Graph option in the "Edit" menu. It will copy the image that is showing. Then, you may paste it into any application with compatible graphics support.
- **Moving Database Analyses to Other Software:** The Database Group Statistics function has an option to export the results to a tab-delimited file. Also, you can use the Copy All Text command in the Edit menu to move the results of the Database Summary and the Comparisons to other software.

d. Printing Results

These functions work for both data files and database records.

- **Page Setup:** The Page Setup command under the File menu gives the standard page set up options applicable for your chosen printer driver. Note that on many machines running Windows, your page margins will need to be set at zero for the printing to work properly.
- **Print Preview and Print:** Most of the information visible in the downloaded StepWatch file or database record may be printed. A one-week summary report can also be selected. Both the Print and Print Preview commands in the File menu allow you to specify which days of data to print, the number of charts to include per page, and the type of text or graphical data (e.g. Statistics, Daily Step Plots, etc.). You must choose at least one data type.

Prior to initiating the Print Preview, we recommend you check your Page Setup settings. If you want to use different page setups for printing the different data types for a file, you will need to select those data types in separate Print Preview or Print sessions, and modify your Page Setup between sessions. If you are using a computer running Windows, and your previewed or printed pages seem clipped at the edges, use the Page Setup to set all four margins to zero. Preferences also allow you to control whether the colored bands designating low and medium activity levels and the horizontal grid lines are shown on step plots, and give you the option of customizing text in the footer.

III. Overview of Using the StepWatch Database

- The StepWatch database is a powerful tool. It is important to familiarize yourself with the workings before implementing it into your projects. It is not difficult to use, but it is important for you to familiarize yourself with some of its basic principles, functions and terminology.
- **The database is NOT meant to serve as the means for storing all your data.** Its purpose is storing your "good," finalized, filtered data. While you are "playing" with your data, it's best to store the files in folders on your hard disk (e.g. the "Client Files" folder in the StepWatch Library). Every data set you enter into the database will influence your summary measures.
- To help distinguish between data stored independently in folders on your computer and data stored in the database, we use the following terminology:
FILE = a monitoring session stored OUTSIDE OF the database.
RECORD = a monitoring session stored IN the database.
You, (the user) enter information about your client then attach their data file as a database record. Once you have added a file to the database it becomes a "record." Your file will also remain, separately.

- **The database does NOT dynamically recalculate results when you make changes to your preferences (e.g. cut-offs for low, medium and high activity) or to the filtering parameters of a file or record.** The way to make the analysis results for a record reflect changes to program preferences, the record's time filtering, or the client's date of birth is explained in "Altering a Database Record."
- If you open and make changes to a file (stored on your hard disk outside of the database), the changes will NOT be reflected in your database records or database summary measures even if you had previously submitted that file as a database record. The software keeps no connection between the file and the record.
- You may assign your clients to groups that you or others define. The database gives summary statistics for: users, clients, and groups, and individual statistics for the current user's clients. It also provides comparisons of individuals to themselves over time, individuals to groups or the whole database, and comparison of a group to another group or the whole database.
- You may work with the database as a public or private user. As a private user your individual client records are private and if you need comparisons and summary measures that reflect only your private data, you can establish private groups or private IDs and assign your clients to those.
- Most database summary measures for groups designated as "public" and the "Everyone" group are influenced by records input by all users at your site who have clients assigned to those groups. See "Group Stats" for the exception to this.

Some database capabilities are new additions to the StepWatch software. We have tested for bugs, but if you find discrepancies please notify us. As a standard data safety precaution, we recommend you create an independent back up of database records by storing your downloaded files in the "Client Files" of your StepWatch Library or elsewhere on your hard drive or backup disks. (If you wish to back up the database itself, see the Note in "Restoring Database from Backup").

If you ever suspect that your database is corrupted, do not quit the StepWatch program. See instructions for "Restore Database from Backup" in "Troubleshooting".

A. Database Users

You may use the database as either a general user (Public) or a private user. As a private user, you will be able to set up groups that are either public or private. No other users will have access to your individual client records or your private groups. Others will have access to summary measures from your public groups and will be able to include their own clients in your public groups. Others will not have access to your individual client records even if your client is included in public groups.

1. Public User

If you choose to access the database as a Public user, simply select Log In from the Database menu. Then click the Log In button. As a public user, you have access to summary measures from any public group and will be able to add records to any public group. Remember that any record you add will affect the summary measures of the public groups to which your client is assigned, so be sure you are only adding quality data. It is also important to realize that any others logging in as public will have full access to all of the individual client records you store here.

2. Private User

To create a Private User account, select Log In from the Database menu. Click the New User button and then give yourself a user name and password. Click the Log In button. Remember your password!

a. Change User Name/Password

To change your password, log into your user account then select My User Account from the Database menu. Type and verify your new password in the fields provided. You can also use this screen to rename your account. If you want to transfer your data to another user on a different computer, contact Orthocare Innovations for instructions.

b. Delete a User Account

To delete a user account, log in to the account then select My User Account from the Database menu. Click the Delete button. Deleting an account will delete all the clients, data records, and public and private groups that were created/input through that user account. An exception to this is if a group contains other user's clients it will not be deleted. Deleting a user account may not be reversed except by restoring the database from backup before quitting the StepWatch program.

The public user account may not be deleted.

B. Using User-Defined Groups

Creating custom groups to which you assign clients is one of three means available for customizing the organization of your database records, generating summary statistics, and comparing clients. (The other two means are specifying Private IDs and including or excluding clients from the "Everyone" group.) Each client may be assigned to two custom groups.

You may create a new group by using the "Add New Group" command in the "Database" menu. A window will open that allows you to name the group and enter notes describing the group. You may create as many custom groups as you wish.

Once you have created a group, you may assign a client to that group at any time by selecting the desired group from the pop-up menu in the "Add" or "Edit Client" option in the "Database"

menu. You may also add clients and activity records to other users' public groups. For further information on assigning clients to groups see "Add a New Client" on page 27.

If you are logged into the database as a private user, you have the option to make the group either private or public.

1. Private Groups

If you make the group private, no other users will be able to add clients to the group. Other users will be able to see that your private group exists in their Database Summary, but they will not be able to see summary data.

2. Public Groups

If you make the group public, other users will be able to add clients to the group, see summary data for the group and add descriptive notes to the group. Other users will NOT be able to delete the group, or see individual client data that has not been entered from their user account.

If you create a group while logged into the database as the public user, your groups will automatically be public. All other users will be able to add clients to the group and view summary data for the group. Anyone logged in as Public would be able to see individual client data for the group or to delete the group.

The summary data in all places except Group Stats ("Database Menu" option) reflect all clients who have been assigned to the group by all users. You will not be able to access individual client data for clients assigned to your group by other users. Others' data will, however, be reflected in your public group's summary statistics. Group Stats provides individual and group summary data only for the clients the logged in user has assigned to the group.

3. Editing and Deleting Groups

You may alter the name or description of a group using the Edit Group option in the Database menu. Changes made to either will be updated automatically for clients already assigned to the group.

A Public Group that has any other user's clients in it should not be changed to private.

Use caution when deleting groups. Confirm that no clients are assigned to the group before deleting it. You can use the Group Stats function to obtain a list of your clients assigned to the group, then change each client's assignment using the "Add or Edit Client" function. If the group is public and other users have clients assigned to the group they will need to remove their clients from the group also. To delete the group, use the "Edit Group" option in the Database menu. Select the group you wish to delete from the pop-up menu that lists all groups accessible to you. Click the Delete button. You are only able to delete groups (private or public) that you have created from your user account.

Deleting a group will not delete clients or activity records.

C. Using The Everyone Group

The Everyone Group is a special public group that is meant to provide summary and comparison measures for the entire database. By default all clients are included in the "Everyone" group. You may exclude any client from Everyone by clicking the check box for "Exclude this client from the Everyone group" when you Add or Edit a Client. Including a client in "Everyone" does NOT allow other users to access the individual data for that client. Others will only be able to see summary statistics for the Everyone Group and the individual data that they have added. All users at your site can add data to and view summary statistics for the "Everyone" group.

The "Everyone" group provides the overall summary statistics for the database at your site. When you use the "Compare Client to Database" option in the Compare functions of the Database menu, you are comparing your client to the averages of all records of all clients included in "Everyone".

D. Clients

To enter a record into the database, you must first set up a "Client" with whom the record is associated.

1. Add a New Client

Select "Add or Edit Client" from the Database menu. Click the New Client button at the bottom of the window and enter your client information. The last name or identification code, gender, date of birth, and postal zip code are required fields. The information shown in the Contact Info tab includes when the information on this client was last modified. The client information is stored separately from the database and, except for date of birth, may be modified independently of the database. When you have completed entering the client's information click either "Save" if you wish to enter another client, or "Done".

You may choose to associate a client with any or all of three kinds of groupings: "User-Defined Groups," "Private ID", and the "Everyone Group". A client must have an activity monitoring record assigned to them to be counted in a group.

a. Assigning Client to User-Defined Groups

You may associate a client with up to two custom groups (created by you or other users) by using the pop-up menus for group assignments. The pop-up menu will allow you to select any public or private group you have created within your user account and any public group created by other users. If you add data to any public group, be aware that your data will be included in the summary measures that all other users will see. If the owner of a public group is going to delete that group or make it private, you should remove your client's assignment to that group first.

Note: The primary and secondary groups to which a client is assigned are treated as equivalent to each other in database comparisons. The primary and secondary groups do not limit or qualify each other.

b. Assigning Client a Private ID

The Private ID is a special kind of group that is not available for other users to see or access in any form. Within your user account, you can use the Private ID as a basis of comparison for clients or groups using the Compare functions in the Database menu. If another user designates the same private ID, your comparisons will not include their clients.

The Private ID can facilitate applications in which it is impractical to create groups for all possible classifications. For example, you might use it to encode International Classification of Disease (ICD) categories.

The Private ID can also allow you to designate subgroups within your groups for exploratory purposes. For example, within a group of clients with limb amputation, you might create subgroups with the Private IDs "diabetes," "traumatic," and "other" to explore whether there are differences related to amputation etiology.

c. Including Client in the Everyone Group

By default all clients are included in the "Everyone" group. You may exclude any client from "Everyone" by clicking the check box for "Exclude this client from the "Everyone" group" when you "Add" or "Edit a Client". "Everyone" is a public group to which all users can add data and view summary data. The "Everyone" group is meant to provide overall summary data for the database. When you use the "Compare Client to Database" option in the compare functions of the Database menu, you are comparing your client to all records of all clients included in Everyone. Including a client in the "Everyone" group only includes that person in the database summary statistics but will NOT allow other users to access the individual data for that client.

When you have completed entering the client information if you wish to enter another client click "Save" otherwise click "Done".

2. Edit a Client

After you have added a client to your database, you may use the "Add" or "Edit Client" function in the Database menu to update the client information at any time. Select the client you wish to edit from the list. When finished, click "Save" or "Done". Once edited, all new client information with the exception of changes to date of birth will be associated with both previous and future records for that client.

a. Editing Date of Birth

If the date of birth has originally been entered erroneously, you will need to delete and re-enter any step data records previously submitted to the database for that client. . If you do not do this, the records entered previous to the correction will not reflect the correct age.

In this situation, the safest way to delete and re-enter a record from the database is as follows.

- Make the date of birth change in the client information using the Edit Client function in the Database menu, then click "Save".
- Open any step data record submitted for that client previous to the birthdate change using the "Open Activity Record from Database" option in the Database menu.
- Save the record to a file on your hard disk using the "Save As" command in the File menu.
- Delete the record from the database using the "Delete Activity Record from Database" option in the Database menu.
- Re-submit the file to the database using the "Add File [file name] to Database" option in the Database menu. To do this, the file you want to add must be in the active window (the one in front) on your screen.

You do NOT need to delete and re-enter database records when you make other changes such as when you change the Groups, Private ID or Everyone inclusion/exclusion assignments for a client. Database summary measures will automatically reflect these changes.

If you wish to change the group designation for all clients in a group, see the suggestion in "Editing and Deleting Groups" on page 26.

b. Delete a Client

To delete a client, choose the "Add" or "Edit Client" option in the Database menu. Select the client you wish to delete from the list. Click the "Delete" button and click "Save" or "Done". Deleting a client will delete all the step activity records in the database that have been assigned to that client. This action may not be reversed except by "Restoring the Database from Backup" before quitting the StepWatch program.

E. Handling Database Records

To add step data to your database, you must have the step activity data file as the active window (the one in front) on your computer screen. This can be either data just downloaded from your StepWatch or data from an opened or imported file on your computer.

1. Before Adding a Record to the Database

- You must previously have added the associated client to the database using the "Add" or "Edit Client" function in the Database menu. You may then assign multiple step activity records to any one client.
- Be sure your "Low Activity" and "Moderate Activity" level preferences are set to the levels you want. The setting for High Level activity does not affect your statistics. (See "Activity Level Definitions" for a discussion of choosing activity levels). If you make a change to your preferences, you need to close and re-open your file before submitting it to the database. We recommend deciding on your activity level settings before you

start data analysis, then leaving the levels constant to avoid inconsistencies in your data.

- Be certain that you have specified the desired included and excluded time for every day in your data file. Once you have submitted a record to the database, you cannot alter this without deleting the record and reentering it with the desired changes. See *"Filtering Data for Analysis"* and *"Altering a Database Record"* below on this page for more information.

2. Adding a Record to the Database

When you are satisfied that your file is in order, select the *"Add [file name] to Database"* option in the Database menu. A window will open that allows you to choose the client to whom the record will be associated from a pop-up menu of all clients you have entered. You may sort this list by clicking on the header for any of the columns. When you select the appropriate client, you may add notes associated with the data. These notes will be visible to you anytime you use the *"Open Record from the Database"* command. Click *"Add Record"* to submit the data to the database.

If you have already entered the same data into the database, a warning message will appear, giving you the option to proceed or cancel. This warning does not occur if one of the files has been time shifted (See *"Filtering Data for Analysis: Shift Time"* on page 17).

3. Opening a Database Record

To view a record from the database, use the *"Open Activity Record from Database"* option from the Database menu. A window will open which allows you to specify the client with whom the record is associated via a popup menu. When you select a client, you will see a list of data records associated with that client. Click on the chosen one to highlight it then click the *"Open"* button.

4. Altering a Database Record

To make the analysis results for a record in the database reflect changes to your program preferences, inclusion or exclusion times, or the client's date of birth, you must re-enter the file in the database with the desired changes and delete the old record from the database.

If you open and make changes to a FILE (stored on your hard disk outside of the database), the changes will NOT be reflected in your database records or database summary measures even if you had previously submitted that file as a database record. Also, if you open a database record and alter included time, the software will ask if you want to save this as a File. Doing so makes a File -- not a database Record; nothing in the database will have been changed.

The most advisable way to alter a database record is:

- If applicable, make and save changes to your program Preferences (e.g. *"Low Activity"* or *"Medium Activity"* level designations) or the client's date of birth.

- Using the "Open Activity Record from Database" option in the Database menu, open the step data record that needs to be changed.
- Make the desired changes (e.g. altering the time included for analysis).
- Save the data to a file on your hard disk using the "Save As" command in the File menu.
- Delete the record from the database using the "Delete Activity Record from Database" option in the Database menu.
- Re-submit the file to the database using the "Add File [file name] to Database" option in the Database menu. To do this, the file you want to add must be in the active window (the one in front) on your screen.

F. Database Comparisons

The "Compare Functions" in the Database menu allow you to compare individual clients to themselves over time, to groups, and to the database. You may also compare groups to the entire database or subsets of the database.

When you choose one of the "Compare" options (Client to Self, Client to Database or Group to Database) a window opens for you to select the individual or group you wish to compare. For client comparisons you may limit this selection list to only one gender or sort it by clicking on any of the headings. Then a window will open that provides information about the client or group selected and allows options for limiting the group/or whole database against which you are comparing your client or group. The limitations can be specified by age, gender, group, or "Private ID". The age limitation may be within a specified number of years plus or minus or may be a specific age range. Note: If you limit the comparison by private ID you will only be comparing to your own clients who have that "Private ID".

When you compare a client or group to the database, you are comparing against all records in the database assigned to the "Everyone" group. If the client or members of the group you are comparing is/are included in "Everyone", their data will also be represented in the Everyone statistics. Likewise, if you compare a client to a group of which they are a member, the client's data will be represented in the group's statistics.

The menu items for "Client Comparisons to Normal Activity" and "Group Comparisons to Normal Activity" are not yet implemented.

G. Summarizing Statistics

1. Full Database Summary Measure

"My Database Summary" in the Database Menu provides summary statistics about the database without showing information on the individual clients or other users private groups. The number of database users, summary information on the gender and age of your clients and their activity is given. The summary information for the "Everyone" group, all public groups, and your private groups includes the total days analyzed, the average number of days analyzed per client, and the minimum and maximum number of days analyzed per client. The

number, gender and the age average and range of clients in the group are provided. Summary statistics include the average, minimum and maximum averaged daily step count, the time spent at high, medium, and low activity, and inactive as well as the activity and peak indexes. Each individual's statistics used in these calculations are derived from the average of each day that has time included for analysis. The individual client's statistics are not viewed in this summary.

If you have a large database, generating summary statistics will take some time.

2. Group Statistics for Your Clients

The "Group Stats" option in the Database Menu uses only your clients in its calculations; other users' clients are not included. It allows you to view summary measures for your groups and individual clients. Group summary measures provided are the average, standard deviation, minimum, maximum, and median for each of the following: age, daily step totals, percent of time at high, medium, and low activity, percent of time inactive, the activity index, the peak average number of steps at 60, 30, 20, and 5 continuous minutes, and the peak one minute.

Each individual's statistics reflect averages across all days with included time in their database record. The groups may be limited by gender, and the gender of each individual is indicated.

If your database has more than one user, only the clients of the user currently logged in are included.

If a client has more than one record included in the database, each record is counted as if it were for a separate individual; in this particular calculation the number of people reported in the group is actually the number of records assigned to the group.

IV. Overview of Advanced Programming

You have the option to manually specify your StepWatch settings using the "Advanced Programming" mode. This can be accessed through the "Utilities" portion of the Monitor menu.

Advanced Programming should only be used if you are experienced with the StepWatch. This mode gives you direct access to the many StepWatch settings and allows you to customize its response for unusual clients or applications in ways not permitted by the regular Start mode. If you use the Advanced Mode without understanding the controls, you can program the StepWatch to behave in ways you did not intend. This will not hurt the StepWatch, but could reduce the quality of your data.

When you launch "Advanced Programming", the settings currently stored in the StepWatch memory will be read and displayed. You may alter any of these settings within limits. If you

are unsure whether your choices are appropriate, you can click the "Reset to Defaults" button to return the settings to their default state, and then reconsider how to modify them. (No matter how you change the settings in the Advanced programming, if you return to the regular "Start", the settings always begin as the default and be altered appropriately). When you are satisfied with your settings, click the "Start" button to initiate programming.

The "Sensitivity" setting is based on the individual calibration value for each StepWatch. This information is available in the calibration panel. **The same settings will have different effects on the performance of different monitors.** The specific values of all other Advanced Programming settings give consistent results between monitors.

A. Sensitivity

The Sensitivity and the Cadence are the most important settings for customizing your StepWatch to the gait style of any client. The "Sensitivity" determines how much movement is necessary for a step to be detected. The setting is dependent both on the mechanics of the client and the particular threshold level of each individual monitor. The following table gives you the recommended ranges, but you may want to go outside them for clients with unusual gait styles. You can see the threshold on the advanced programming screen in the scrolling field labeled "Calibration".

It is important to remember that RAISING the numerical value of the Sensitivity setting makes the StepWatch LESS SENSITIVE to movement.

SUGGESTED SENSITIVITY SETTINGS BASED on THRESHOLD VALUES

Calibrated Threshold	Suggested Setting	Setting Range*
1.05	16	12 to 20
1.06	15	11 to 19
1.07	14	10 to 18
1.08	13	9 to 17
1.09	12	8 to 16
1.10	11	7 to 15
1.11	10	6 to 14
1.12	9	5 to 13
1.13	8	4 to 12
1.14	7	3 to 11

*This range is a starting point. You may want to go outside of it for unusual clients

B. Cadence

Sensitivity and Cadence are the most important settings for customizing your StepWatch to the gait style of any client. The "Cadence" effectively limits how quickly steps can be detected and helps you avoid double counting steps. The "Cadence" is set in increments of 1/100ths of a second.



RAISING the numerical value of the “*Cadence*” will LOWER the maximum rate at which steps can be detected. So the higher the “*Cadence*” number, the less often it will be ready to count a new step. The “*Cadence*” value should be set as high as is possible without missing steps at your client's most rapidly stepping pace.

Normal values for adults are 60 - 80. Bias toward the higher numbers for people who take steps very slowly or who have long legs, bias toward the lower numbers for people who take steps quickly or have short legs. Children without disability are often in the 40 - 60 range.

To find out what the normal cadence is for a particular height, program the monitor with quick start at that height and all settings at normal. After it starts to run, read the monitor then start it with advanced programming. The cadence shown will be the cadence for a person of that height with normal gait and normal walking speeds.

C. Other Advanced Programming Settings

1. Threshold

The Threshold is the first level of the StepWatch's sensitivity to acceleration. At the time of manufacture, the threshold is calibrated in "G-force" response to a resolution of 0.001 G. The threshold is stored to the StepWatch memory.

You can see your StepWatch's threshold by using the “*Read Current Settings*” command in the “*Utilities*” section of the “*Monitor*” menu or by launching “*Advanced Programming*”. The threshold value is also recorded on the calibration sheet provided with your StepWatch, and shown on the summary window of a downloaded file. All StepWatch 3 monitors have only a Null threshold, which is shown on the calibration panel.

The older StepWatch 2 monitors have three thresholds, but should normally be used at the one identified as the default.

If you are using the “*Advanced Programming*” to start your StepWatch, be sure to check that you have selected the desired “*Sensitivity*” to match the monitor's threshold calibration value (See discussion of Sensitivity above).

2. Mode

The StepWatch operates in three different states. Through “*Advanced Programming*”, you can explicitly set it to any of the states. The “*Advanced Programming*” screen will always open with “*Record*” set as the default. You will not need to change this except under the guidance of StepWatch tech support personnel.

3. Interval

This setting determines how frequently step counts are recorded. The recording interval (epoch) is set in seconds with options ranging from 3 to 180. **We strongly recommend using 60 (1 minute) for long-term monitoring sessions.** One-minute intervals will allow you to directly compare your data with that collected by others using this standard unit. StepWatch 3 units can generally collect 6 – 8 weeks of data at 1-minute intervals.

StepWatch 2 units can generally collect 3 – 4 weeks at 1-minute intervals.

You may wish to use shorter intervals for accuracy trials.

4. Count Scaling

This is a simple multiplicative compression scheme which allows you to record numbers larger than 255 per recording interval (epoch). The “Count Scaling” should normally be left at 1. If you use 1-minute intervals, you won't need to use “Count Scaling” because your step counts will not exceed 255 per epoch. If you use intervals greater than 2 minutes, you may want to use a “Count Scaling” greater than 1.

5. Data Compression

This should be kept “ON” because it extends your maximum monitoring time and it reduces the demand on your StepWatch battery. It allows the monitor to use less recording space for inactive time. There is no 'down side' to using this.

6. Days to Record

The maximum days to record is determined by the interval, the use of rest time compression, the percent time active set in Preferences and whether you are using a StepWatch 2 or StepWatch 3 monitor. See further description in “Setting Preferences” on page 8.

7. LED Flashes

In “Advanced Programming” you specifically set the number of LED flashes each time. The number set in preferences is ignored. For a further description see “Setting Preferences” on page 8.

8. Battery

If you wish to check the battery level on a monitor you can see an estimate of the percent battery life remaining in the panel with calibration information. (This information is also available in “Read Current Settings” and on the “Summary” page of every downloaded file).

9. Start Time and Notes

In “Advanced Programming” you are able to set the start time for now or later, but not later in another time zone. You may also enter notes that will appear in the data file on the “Summary” window. When you are satisfied with your settings click the “Start” button.

D. Verify Cadence and Sensitivity Settings

Be sure that you have specified an adequate number of LED flashes for the following procedures. You should check that your settings work correctly with each client by having them walk at their normal pace while you observe the LED blinks. If the StepWatch is not responding appropriately, use the guidelines below to adjust settings. Then, observe the response to the following two conditions:

1. Have your client walk at the slowest pace they would ever normally walk.

Watch the StepWatch light to see that steps are not being double counted. If you are seeing double counts you have two options:

- Increase your Cadence value, **or**
- If your client has very dynamic motion at the ankle and utilizes a wide range of cadences, RAISE the numerical value of the Sensitivity setting while keeping the Cadence value small enough to accurately capture fast cadences.

2. Have your client walk at the fastest pace they would ever normally walk.

Watch the light to see that steps are not being missed. If you see missed steps or if you notice that the light tends to blink at different points in the gait cycle during consecutive steps (which may make you feel uncertain about what you have observed) you have two options:

- You can lower the Cadence value and try again, **or**
- If your client has unusually gentle motion at the ankle (like with shuffling gait), you may need to LOWER the numerical value of the Sensitivity setting to avoid missing steps.

Be sure your client does not try to look at the blinking light for this will cause them to walk with a distorted gait. If they routinely run or do other quickly stepping activities, you may want to have them demonstrate the activity so you can evaluate the performance of the monitor by watching the light blink or by doing an accuracy trial.

Be sure your client understands that the LED will not be flashing during their monitoring session. If your client expects the monitor to flash, they may assume it is not working when they do not see flashes and decide not to wear it.

E. Accuracy Trials

If you want to conduct accuracy trials, you may wish to use a recording interval of 10 to 15 seconds rather than 1 minute because, to locate your accuracy trial in the exported data, you need to have zeros in the file before and after the trial. When using a recording interval of 10 or 15 for an accuracy trial, note the time you begin and have your client sit or stand still for 30 seconds or more immediately before and immediately after the accuracy trial. The trial will thus be sandwiched by zeros that will allow you to locate it and match up the manual step

counts. During accuracy trials, it is helpful to have two observers both using hand held tally counters (available in office supply stores). Having two observers with hand-held counters allows them to talk casually with the client, thus reducing gait changes due to self-consciousness; it also lessens the effect of observer counting errors.

During the trial, LED flashes should be set to a minimal number so the StepWatch does not cue observers' counts. Have the client walk at his/her normal pace in an unobstructed area, with the observers walking alongside or following. Be sure the observers are counting only when the leg wearing the StepWatch takes a step (rather than when steps are taken with each leg.) It takes some practice to count accurately because an observer's own walking cadence can interfere with counting the client's steps. If your accuracy trials are short, any error by the observers will result in a relatively large misrepresentation of the StepWatch accuracy.

When the trial is completed, download the data and export it to a spreadsheet file using the "Export Data" command in the "File" menu. Open the file in your spreadsheet program. Scroll down to the time at which you conducted the trial. If your client stood still for an adequate time before and after the trial, the walking trial will appear as a string of similar values with zeros immediately before and after. Average the observers' manual counts and compare with the StepWatch count.

If you are conducting accuracy trials but wish to use the cadence and sensitivity settings as determined for your client by the quick start functions, program the monitor using this means. After the monitor has begun recording, reprogram it with advanced start and change only the Interval and LED flashes.

V. Troubleshooting

The StepWatch program provides some tools to assist in troubleshooting including messages during the program operation and several diagnostic tools in the menu. The "Help" functions available in the software are also useful and, for some topics, provide more information than this manual. Check the Orthocare Innovations web site for a list of known issues and fixes; otherwise, Orthocare Innovations for technical assistance.

A. Communications Errors

If you are not able to read your StepWatch or if the red and blue lights are flashing on your StepWatch 3 dock:

- Check the connections between the dock and the computer.
- Make sure the StepWatch is properly aligned on the dock.
- Make sure there are no bright lights shining on the StepWatch. Halogen lights can be especially troublesome. [Sunlight from some angles can also cause problems with StepWatch 2 docks and require shielding.](#) The infrared lights of some motion analysis systems also make shielding necessary.
- Verify that your Communications Preferences have the correct port specified.

- Verify that the computer can communicate with the dock and the StepWatch by using the “*Communications Test*” below on this page.
- Check that you do not have email or Internet browser software running in the background. Intensive networking software can also cause errors.
- Sometimes simply waiting for a while before attempting to read the StepWatch again solves the problem.
- If you have not replaced the batteries in your StepWatch 2 dock recently, you may need to do so. Frequent problems with the same monitor are often the first indication that you need to change your dock batteries. Some monitors require greater dock battery power than others for effective communication. To replace batteries see “*Using the Dock*” on page 7. (The StepWatch 3 dock does not have batteries).

If you are not able to solve the problem, contact Orthocare Innovations Technical Support. It is helpful if you have the exact wording of any error message and just when it occurs. We are happy to try to help you try to solve the problem.

B. Communications Test

You may use the Communications Test (in the “*Utilities*” portion of the “*Monitor*” menu) to check that your communications preferences and hardware are set up correctly and the StepWatch software is able to “talk to” the docking station and StepWatch.

- Click the “*Check Dock*” button to verify that your computer is in communication with the docking station. You do not need to have a StepWatch on the dock to do this.
- You may click the “*Check StepWatch*” button to verify that your StepWatch is properly communicating. The “*Communications Test Advanced Settings*” should only be used with StepWatch technical support.

C. Read Current Settings

You can use the “*Read Current Settings*” option in the “*Utilities*” section of the “*Monitor*” menu to quickly verify the settings in your StepWatch memory. Do not use this to verify the settings after you have programmed a monitor, as it will stop the monitor from recording. This function is intended to provide a means for conveniently checking the settings or notes in the memory of a monitor not in use. You can also use it to verify that a StepWatch is asleep and see the threshold calibration.

Caution: If you have programmed a StepWatch to start recording but it has not yet started recording it is especially important that you, DO NOT read current settings. Doing so can cause inconsistencies in parameters written to the StepWatch memory which can cause short-term errors in programming and downloading. The damage is not permanent, but you may have to wait for a day or more before the StepWatch returns to its normal state.

D. View Communications Log

The Communications Log keeps a record of every time you program and download any StepWatch. This may be useful to you if you are unsure of the location or the state of a monitor. The log does contain all your monitor setup information, but in a fairly cryptic form.

E. Restoring Database from Backup

To protect you from data loss due to file corruption following a computer crash, power failure or other source, a database backup is automatically stored in the "Program Folder" in your StepWatch Library every time you quit the StepWatch program.

IF YOU SUSPECT THAT YOUR DATABASE IS CORRUPTED, DO NOT QUIT THE STEPWATCH PROGRAM. Use the "Restore Database from Back Up" option from the "Utilities" portion of the Database menu to revert to the database as it was the last time you quit the StepWatch program.

If you quit the StepWatch program with a corrupted database, the corrupted database will be saved to back up and you will not be able to restore the database using this command. Contact StepWatch Technical Support for possible help. We are developing the means to \ rebuild your database from log records that exist in your Program Files provided you have not altered or deleted this folder or directory.

If you wish to make your own database back up you can duplicate the "Client Database" and "Activity Database" files that are in the Program Folder/Directory of the Library in you StepWatch application. Move these duplicates out of the StepWatch folder, and store them elsewhere. If you have a large database it is not a bad idea to do this once in awhile.

Appendix A: Hardware Specifications

A. StepWatch 3.0 Monitor Specifications

Size	75 x 50 x 20 mm
Weight	38 grams
Battery	750mAh Lithium
Battery Life	Depends on usage. 7 years with heavy use
Accuracy	>98% independently validated
Sensitivity	User adjustable via software
Sampling Rate	128/sec
Housing	Thick polycarbonate. Injection molded
Attachment	Highest accuracy at ankle, elasticized strap or cotton Lycra cuff
Recording Time	Up to 60 days minimum at full resolution
Resolution	1 minute is standard, user adjustable from 3-180 seconds
Memory	32KB, includes 64-character user notes field
Temperature	Operating 0° to 50°C / Storage: -20° to 70°C
Shock / Drop	Survives multiple drops to concrete
Tamperproof	Permanently sealed
Waterproof	Yes
Floats	Yes
Factory refurbishable	Yes
FDA	Cleared by the FDA as a class II medical device

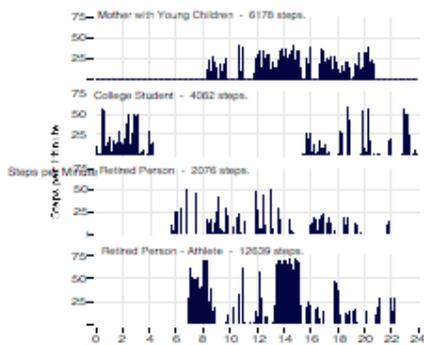
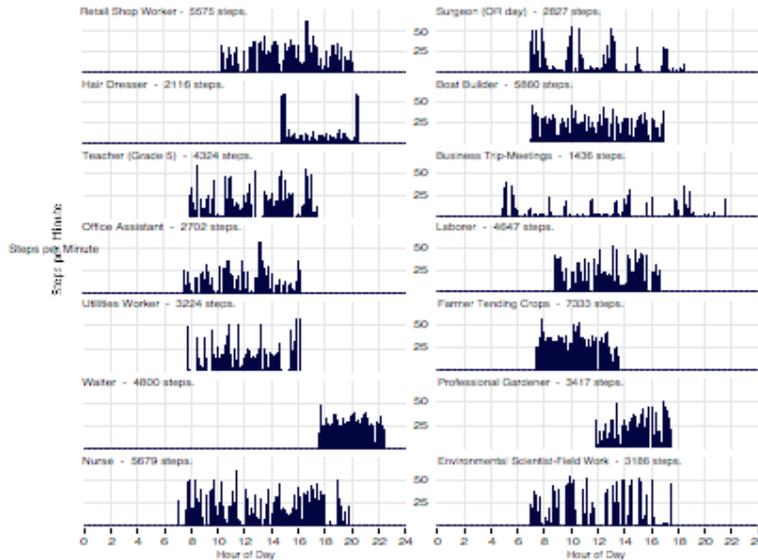
B. StepWatch 3.0 Dock Specifications

Size	106 x 68 x 31 mm
Weight	150 Grams
Communication	USB to computer, IR to SAM
Batteries	Not required
Power Consumption	100 mA max
LED status indicators	3

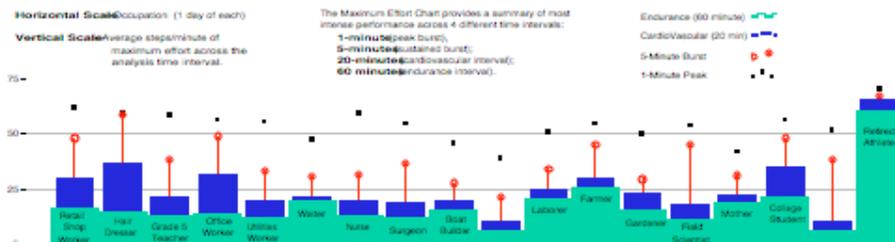
Appendix B: Demo Data File

Ambulatory Activity by Occupation

How much walking is involved? Take a look.



Maximum Effort Chart for Sample Occupations



Data and analyses provided by Cyma, Inc. Project funded by NIH SBIR Phase I Grant # 1-R43-HD39036-01.

Appendix C: Instructions for Wearing the StepWatch

Instructions for Wearing the StepWatch



ORIENTATION: The StepWatch must be worn with the rounded end UP. The writing on the case should appear right-side up to someone standing beside you.

PLACEMENT: The StepWatch is worn just above the ankle bone on either side of either leg. It should not be worn on the front or back of the ankle.

Adjust the velcro strap for comfort. Do not fasten it overly tightly. If you want additional padding, you can wear an extra sock. Alternatively, you may stick moleskin to the back of the monitor. Be sure the strap is in place before attaching the moleskin.



SCHEDULE: Put the StepWatch on right away when you get up in the morning, and wear it throughout the day. When you take it off at night, put it somewhere that you will remember to put it on first thing in the morning such as with your glasses, clock or watch.



CARE: Do not leave the StepWatch in hot places such as on the dashboard of a car. Please treat it with reasonable care as you would other electronic equipment. Do not throw it, cut into it, or remove the label.

The StepWatch is waterproof. You can bathe or swim with it. The wet strap may be removed and dried. If you want to wash the StepWatch, wipe it with mild soap and water, or alcohol then towel or air dry.

WEAR DAILY UNTIL the end of the day on: _____

RETURN YOUR STEPWATCH ON: _____

If you have questions, feel free to contact us at:

Development Credits

StepWatch™ 3.1 Software © 2005 was developed by:

- David Boone and James Beck - Software Development & Programming
- Kim Coleman - Software Design and Documentation
- Linda Laing - Quality Assurance Testing, Manual

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Many of the Orthocare Innovations staff members have worked together in research and clinical applications for over a decade. We have brought our multi-faceted experience to the StepWatch, attempting to create a powerful tool that is flexible and relevant, yet easy to use.

We know that your needs, applications and computer platforms are extremely diverse. We welcome your feedback - positive and negative - as we continue our efforts.

Besides this manual, on-line help is included with your software. Stay tuned to www.orthocareinnovations.com for further developments as we continue to improve the software and hardware, and tailor services for specific clinical and research applications. Do not hesitate to contact us.

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