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General StepWatch™ Information and Care

What is the StepWatch?

The StepWatch™ Step Activity Monitor (US Patent # 5,485,402) (SAM) 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 are recorded every minute between downloads. The SAM is attached to a person's ankle using a comfortable elastic band. The SAM works with a docking station and software for data downloading, analysis and display on either an IBM-compatible or MAC personal computer.

The SAM 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%.

Care of the Monitor

The SAM is a very durable instrument, but should not be thrown against hard surfaces, torqued, crushed or punctured. The case is permanently sealed to prevent tampering and to insure that the monitor is waterproof. The anticipated battery life is at least 7 years with continuous use and longer with non-continuous use. The SAM can be returned to Cyma to have the battery replaced. To preserve the integrity of the battery, the SAM should not be left in temperatures exceeding 110 degrees Fahrenheit (such as on the dashboard of a car in warm weather, an oven or clothes dryer) or in temperatures below 0 degrees Fahrenheit.

Cleaning the Monitor and Strap

The SAM is designed for multi-participant use. It should be cleaned by wiping it with a germicidal wipe between each use. The PDI Super Sani-Cloth is recommended. Do not use any other solvents. Do not autoclave. The docking station is NOT waterproof; to clean it, wipe with a soft cloth moistened with mild soap and water.

The straps provided with the monitor should also be cleaned between each use by first washing it with an antibacterial hand soap (such as a surgical scrub) and then dipping it in alcohol. Allow it to drip dry.

In highly infectious situations (i.e. a patient reports he had poison ivy or ring worm near his ankle while wearing the SAM) discard the strap.

Setting up the StepWatch Program and Data Files:

The StepWatch system is for use with Windows 98 / ME / 2000 / XP.

Installing the USB driver for the StepWatch Dock:

1. Using the enclosed USB cable, plug in your dock to your USB equipped PC.
2. Your PC will recognize that a new USB device has been plugged in and ask you to insert the disk with the driver. Upon inserting the CD it will search and find the driver. If it does not find the driver, choose to install the driver from a location and then browse to the folder on the CD labeled "StepWatch USB Driver-F050". Select and continue.
3. You may be prompted with a warning that the USB driver has not been Windows approved. Choose to continue and install the driver.
4. A second installation will occur very similar to the last one, which will install a virtual port called "StepWatch Dock".
5. You may again be prompted with a warning that the driver has not been Windows approved. Choose to continue and install the driver.

Installing the StepWatch Software:

1. The StepWatch Analysis Software was originally sent to you on a CD. However, an updated version of the software (32 beta Y) became available in March, 2006 and should be used from this point forward.
2. It is important that the new version of the StepWatch Analysis Software is installed in a consistent physical location on all computers so we can use DataStream (FTP) application to find participant files. Therefore, please install the StepWatch software in "C:\Program Files\StepWatch".
3. To download the new software go to the following address:
<http://homepage.mac.com/stepwatch/betatest/FileSharing3.html>
Password: whynot
Click on the "Download" button and click on the "Save" option, not "Run" when prompted by the browser. If you have problems saving to "C:\Program Files\StepWatch" please contact Deb Martin (MartinD@edc.pitt.edu). If you have problems installing the new software in general please contact David Boone (david@cymatech.com) and Wendy King (kingw@edc.pitt.edu).
4. After installing the new software (version Y) please delete any old versions of the StepWatch Analysis Software that you already have.

StepWatch Library

Your StepWatch Library will automatically be created when you install the StepWatch software: C:\Program Files\StepWatch Library

The StepWatch Library should contain two folders or directories - Program Files and Client Files: C:\Program Files\StepWatch Library\Client Files

DO NOT move your StepWatch application or your Library.

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 Cyma technical support personnel.

Participant Files

Your Client Files folder or directory exists within your StepWatch Library. You should save your StepWatch data files to the main Client Files folder. StepWatch data files should only be downloaded to the one computer your site designated for SAM download (the DCC installed the necessary file transfer software on that computer). Unattended transfer of these files (DataStream) will occur once a day at 12:00 PM as long as the computer is on at that time. The DataStream process will rename all files in the Client Files folder by adding a date stamp to the file name, transfer them to the DCC and move them to the Archive folder that is in the Client Files folder of the SAM computer. Please contact Deb Martin (martind@edc.pitt.edu) with any questions regarding transferring the data.

The new beta version of the software does not include sample data. However, Wendy King from the DCC has emailed you sample data files as attachments. Please contact her if you have problems opening these files. kingw@edc.pitt.edu.

Using the Dock

You may find it convenient to always leave the SAM docking station plugged in to your computer. If you plug and unplug it between use, 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 docking station does not require battery power. It draws power from the USB connection.

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 is 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”).

Communications

After installation if your computer is not registering the SAM dock, use the pop-up menu in **Communications** to specify the port into which you plugged the dock. (To find the Communications page go to “Edit”, then “Preferences” and from there choose the “Communications” tab.) If you are not sure which port to choose, try all choices. 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.

Setting Preferences

Before you start to collect data, you need to set the Preference options which affect how the data are recorded, displayed and analyzed. You access the Preference options from the Edit or StepWatch menus (depending on your operating system). Once you initially set the preference options (as described below) you should not change them during the course of LABS 2. You only need to set them once. However, if you set up the SAM software on multiple computers it is important that you set the Preference options on each computer.

Start with “General” preferences:

Units

Select **English** units. This will affect both height measurements (inches) 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. If you are currently using the European date style, change to English units if you experience problems.

LED Flashes

The red LED blinks each time a step is detected. Set the LED to blink **100 times** at the beginning of a recording session. You will use the LED flashes to quickly assess the appropriateness of your settings by watching your participant walk and making sure the light blinks once for each step.

Days to Record

Set the default running time for each monitoring session to **15 days**. Unless downloaded earlier, the StepWatch will always run at least this number of days, and may run slightly longer.

Percent Time Active

Set this to **35%**.

Auto-Exclude

Specify that days **with less than 5% of the average step count** will be automatically excluded from analysis when your data are downloaded. The function only applies when data are first downloaded. Auto-excluded days may later be included by editing the time selection for the day in the Edit Time window.

Activity Level Definitions

Check the box for **double counts** to estimate number of steps for both legs.

Set **30** for Low, which means that all intervals with 1 - 30 steps/minute will be counted as Low Activity.

Set **80** for Medium, which means that all intervals with 31- 80 steps/minute will be counted as Medium Activity. Set **150** for High, which means that all intervals with over 80 steps/minute will be counted as High Activity. The High value (**150**) 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.

Display Options

Select the “**Draw Grid Lines for Step Rates**” option so that horizontal step rate grid lines are drawn in the daily step plots on your screen and in printing. Do not select the “**Display Activity Level as Color Bands**” option which controls whether color bands for Low and Moderate activity are shown in the step plots on your screen and in printing.

Special

Go to the “Special” tab under Preferences and type the following Report Title: **LABS 2 Stepwatch Activity Report**. It will appear on pages printed from the StepWatch software. There is also an option of typing a Footer and subtitle. However, you should leave these blank.

Programming the Monitor: Easy Start Programming:

There are two ways to program the SAM to record data. You will use the **Easy Start** method.

Easy Start is accessed through the "Start Recording Activity" command in the Monitor menu. This option provides enough flexibility to set up the SAM appropriately for most participants and applications, while protecting you from unexpected results.

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 SAM, 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 participant description (see directions below).

Tips

Running email, an internet browser, or intensive networking software in the background when you are programming or downloading your SAM can occasionally cause errors. It is always best to quit such background applications before initiating communications.

Participant Description

Height

Please enter the participant's height in inches from their LABS 1 pre-op form.

Quick Stepping

The Quick Stepping setting allows you to accurately measure activities such as running or jogging with a short and/or rapid stride. However, indicating YES for the Quick Stepping setting has a fairly strong affect on the StepWatch performance, so it **should be used with caution**. We anticipate that you will never answer "yes" to the Quick Stepping questions for LABS participants at baseline; however, at follow-up visits this feature may occasionally need to be accessed.

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 participant likes or knows how to do from those they are likely to undertake during the monitoring session. For instance if a participant does an activity like spinning twice a week for an hour but otherwise does no quick stepping, it is better to try to accurately measure the majority of their movement for the week and thus quick stepping would not be appropriate. Please note that 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 participant "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

Walking Speed

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 participant. For her height, is her normal walking speed slow, average, or fast? Most people will fall in the average category.

Answering 'YES' to Quick Stepping disables this command.

Range of Speeds

This setting influences how broad a range of step rates the StepWatch will "expect." For most people, a moderate range is appropriate. Some participants, however, rarely change their walking speed because of habit, preference or (most commonly) physical limitations. Still fewer walk at both slow and fast extremes.

It can be difficult to evaluate whether a person "regularly engages in both extremes." The following examples may help with the determination. Remember, a person must regularly use **BOTH** extremes to qualify.

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

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

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)
- exercising on a Stair Master
- bicycling with a moderately fast cadence

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.)

Answering 'YES' to Quick Stepping disables this command.

Leg Motion

From the time the participant 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 SAM senses. Look at the motion of their leg/ankle rather than their whole gait. It is helpful to observe them as they walk to greet you. It is common for people to walk differently than they usually would if they know that they are being observed.

Dynamic/fidgety:

If your participant 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 participant 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 gentle/or geriatric defined 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 participant. 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. When in doubt about the correct setting, select normal and test by observing the participant walk wearing the monitor. If the SAM double counts steps the cadence is too high and if the monitor does not count steps, the cadence is too low. Troubleshooting these events is listed in the verify settings section.

Add notes

Enter the participants ID followed by an underscore and then the time period in the notes field (example: 2550001DR_12). (Do not enter a space between the underscore and time period.) **This is the only way the participant ID and time period will be included in the downloaded data file when the monitor is returned.** Please check and double check that you have entered in this information correctly. Time period codes are below:

Baseline= 01

12 month follow-up = 12

24 month follow-up = 24

36 month follow-up = 36

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.

Verify the Settings

Once the programming is completed, you should confirm the appropriateness of your settings by having the participant walk at their normal pace while you observe the LED blinks. The LED should blink one time per step as your participant walks at their normal speed. You should also have them walk at the "slowest pace they would normally walk" and the "quickest pace they would normally walk." 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. Watch to see that the SAM is not double blinking on slow steps, or missing fast steps.

Your participant should not try to look at the monitor as this will change their walking pattern. If you are walking with your participant, do not lead them or trail too far behind as this may influence their natural pace. If possible, stand still at their side and simply observe.

If the SAM is not responding appropriately, take it off, put it back in the docking station and revisit the Easy Start questions (quick stepping, walking speed, range of speeds,

and leg motion). Then, repeat these procedures with the new settings to verify that the SAM is properly detecting steps.

Tips

If the SAM is double counting, go toward settings for slower walking speeds. If that is not enough, go toward more dynamic gait. If that is not enough, fudge on the subject's height. Represent them as taller (by 5 inches at first).

If the SAM is undercounting, try to assess whether the problem is steps taken too quickly, or very gentle motion. Adjust accordingly with either the walking speed or the leg motion parameters in the Easy Start.

Be sure your participant understands that the LED will only flash for the first 100 steps that they take. The SAM is still recording data even though they light is not blinking. The flashing light is used as a simple tool to examine cadence settings.

If you have questions you may contact Cyma for advice (help@cymatech.com). Please notify the DCC on any contact with Cyma (kingw@edc.pitt.edu). 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.

Warnings:

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.

Giving the Monitor to LABS 2 Participants

Review the directions on the first two pages of the participant's activity diary with each participant before giving them a SAM to wear home. In addition, go over how to fill out Day 1 of the diary, specifically addressing the section requesting an assessment of awake hours that they were not wearing the SAM and show the participant the make-up days after day 7 in the diary in case they have any days to make-up. Even though the participant will not fill out the diary the day they are given the SAM ask them to wear the SAM home so that they are less likely to forget about it the next day.

Explain that the monitor should be returned, by mail, in the provided envelope no matter how much it was worn, within 11 days of the date it was taken home. Once it is received, the participant will get a physical activity report. Also, mention the expense of the monitor (\$500.00) and the importance of it's return.

Get Personal:

A key to the success of using SAMs in LABS 2 is that coordinators are personal and proactive in planning for compliance with the subjects. Talk the subject through an individualized plan for remembering to put the monitor on in the morning (complete with specifics about where they will put the monitor at night if they are taking it off), and stress the importance of wearing it all day during data collection. Also, let the participant know that he or she may wear the SAM 24 hours a day, including in the shower or pool (but not in a very hot bath or hot tub). Then show the participant two examples of activity reports. The second report should have a couple days with greater than 10 hours of wear, a couple days with less than 10 hours of wear, and a couple days of no wear. Explain that we are unable to use the data from several days on the activity report because the SAM was not worn for much of the day. A personalized plan does not take a lot of time to develop. Subjects typically respond well to the interest you show in their life, and the result is higher quality data.

Keeping Track of the SAMs:

Please use the log (see appendix) to keep track of your site's SAMs. It includes participant ID, SAM serial number, date SAM given out, and the date by which you expect to receive the SAM.

Sending Reminder Letters to Participants:

A letter (see appendix) should be sent by mail to the participant the day that they receive the SAM so that they receive the letter a day or two later. It may be helpful to have participants complete the address portion of the envelope, to ensure that the appropriate address is used.

SAM Retrieval:

The SAM should be returned within 2 weeks (14 days) after it was taken home. If a SAM is not returned on time a letter (see appendix) should be sent and the call protocol should be followed to try to contact the participant by telephone. If you have not been able to contact the participant by telephone, or if you still have not received the SAM three weeks (21 days) after a participant takes a monitor try reaching the participant by the means outlined in the participant contact section (peoplesearch). All such losses should be noted on your log and periodic participant contact should be attempted and noted.

Downloading Your Data

When you receive a SAM by mail you should try to download the data from the monitor as soon as possible and no later than one week after receipt. 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 probably 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 and the program Help files.

Tips

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 correct divisions between activity levels (30, 80, 150).

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

Viewing Your Data and Printing the Participant Report

When the data have been read you will see 4 tabbed windows. The first window give you "Summary Information" which includes the monitor ID, notes (participant ID_timeperiod), 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.

Print Preview... and Print

Most of the information visible in the downloaded StepWatch file may be printed. However, for LABS 2 you only need to print the **Client Week Report**. Print the report **before** filtering data (described below).

Page Setup...

The Page Setup command under the File menu gives the standard page set up options applicable for your chosen printer driver. Prior to initiating the Print Preview, we recommend you check your Page Setup settings. 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.

Recall, in preferences you chose not to "show color bands," but to show the horizontal grid lines on step plots (by checking "draw grid lines").

Determining adequate wear of the SAM

Ideally we will get seven days of activity data on each participant. However, we will likely be able to include participants in analysis as long as we have four days worth of activity data. If a participant does not wear the SAM for at least 4 "valid" days (defined as at least 10 hours of wear) we will ask him/her to wear the SAM again.

To determine if a participant has worn the SAM for at least 4 “valid” days please follow these directions:

- Click on the “Edit Time” tab of your data file for 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.
- Double click on each day to evaluate it individually.
- Exclude days with less than 10 hours of wear.
 - Use the new “Exclude night rest” option which should exclude all non-wear time: time before the first movement of the day and after the last movement of the day.
 - After you have excluded non-wear time, the number of included hours/minutes will appear in blue at the top of the box. If fewer than 10 hours are included in a day, exclude the **entire** day. If 10 or more hours are included, include the **entire** day.
 - Based on the Auto Exclude option in Preferences you may see that some days are excluded already.
- Occasionally you will have some scenarios that require extra attention:
 - There may be a day when there appears to be a few steps taken several hours after the monitor was taken off...maybe when the monitor was getting moved. In cases like this the “exclude night rest” option will have included extra time at the end of the day. If it is not obvious whether the monitor was worn for 10 hours you will have to manually change the end parameter to exclude time from when it appears the monitor was actually taken off. To manually change the end parameter, click on the second time in “time range” and then drag a bar from the right side of the screen until there is “real” movement. After fixing the end parameter use the included hours/minutes that appear in blue at the top of the box to determine whether to include or exclude the day.
 1. See date 10/5/03 in demo file 1 for an example of this.
 - There may be a day with movement from midnight until 1 or 2 am and then not again until morning. Because we define days as midnight to midnight we count this “late night” movement with the “next day.” However, the “exclude night rest” option excludes this late night movement. Therefore you will have to mentally add on this time to the total time given.
 1. See date 11/14/05 in demo file 4 for an example of this.
 - There may be a day that includes more than 10 hours of wear but it appears that the subject may have removed the Stepwatch for a period or have been asleep. In any given day, if at least 10 hours are included, but there appears to be a no-wear period of 2 hours or longer, subtract the no-wear period from the included hours to determine whether there are 10 or more hours of wear.
 - Examples of when to exclude the day 1) A total of 11 hours with one 2 hour period of no-wear (because only 9 hours of activity). 2) A

total of 17 hours with one 9 hour period of no-wear (because only 8 hours of activity).

- Example when to include the day: 1) A total of 11 hours with two 90 minutes of no-wear (because a no-wear period must be 2 hours to be subtracted).
- If you are unsure if a participant has worn the SAM for 4 valid days please submit a help desk request for review of the data file. The subject of the help desk request should be "SAM data file." The description should be "maybe not 4 days of wear."
- Note, the Stepwatch software may not allow you to exclude all days in a file. If you are unable to exclude the last day but it is invalid, you may save the file with the last day included.

Less than 4 days of data?

After filtering the data, if a participant has three or fewer days of included activity an attempt should be made to re-do the SAM portion of the LABS 2 exam.

Before contacting a participant by phone to gauge their willingness to wear the SAM (again), review the participant's diary and SAM data to figure out whether the participant didn't wear the SAM at all, wore it only one or two days or only wore it for partial days. Note, if the diary indicates the SAM was worn but the monitor shows no activity, the participant may have worn the SAM upside down. After reviewing their activity data, call the participant and first thank them for returning the SAM. Then explain the problem and ask if they would be willing to try wearing the SAM again. If yes, either schedule a time for them to come in to get the SAM and go over the directions, or go over the directions by phone and send the SAM by mail (Note: you do not need to see the participant in person again. Simply go to Monitor Menu > Utilities > Read and Restart... This will re-start the monitor with the same settings as it had previously. Be sure to save to data file before doing the Read and Restart). Follow the standard protocol ("Giving the Monitor to LABS 2 participants"). In addition, two to three days after the participant received the SAM, call the participant and ask whether they having any concerns/questions about the SAM and thank them again for their participation. If the participant is not willing to try wearing the SAM again make a note in their LABS 2 file that they were contacted regarding the SAM and refused.

Representations of the Step Data

Graphical Representations of the Data

There are several tools providing graphical representations of the data. However, for the purpose of LABS 2 we will not be using most.

Client Week Report

In Print Preview, generate a Client Week Report. This is in a format suitable for distribution to participants. This should be sent to the participant by mail within one week

of the return of the SAM along with a letter that explains the report (see Appendix). See *Printing Results*.

Analysis Variables and Calculations

Step counts are for both legs so counts are comparable to a standard pedometer.

Averages

All averages are based on the whole 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.

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.

Average Minutes at None, Low, Medium and High Activity

These variables reflect the minutes and 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.

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.

Step Total

Total number of steps in the day regardless of whether a day is excluded.

Steps Included

Total number of steps in the time included for analysis.

Minutes Included

Total number of minutes in the day included for analysis. Will always be 0 or 1440.

Minutes None

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

Minutes Low

Total minutes of the time included for analysis in which the step count fell between and inclusive of 1 and 30.

Minutes Medium

Total minutes of the time included for analysis in which the step count fell between 31 and 80.

Minutes High

Total minutes of the time included for analysis in which the step count was greater than 80.

Handling Data Files

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. Save all files to the main Client File folder or directory which exists within your StepWatch Library. If the file does not already exist on your hard disk (i.e. the data have just been read from the StepWatch), a window will open that allows you to name the file and choose where to save it. **The file should be named as the participants ID followed by an underscore and then the time period (example: 2550001DR_12).** (Do not enter a space between the underscore and time period.). Please check and double check that you have entered in this information correctly. Time period codes are below:

Baseline= 01

12 month follow-up = 12

24 month follow-up = 24

36 month follow-up = 36

Note, 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 if needed.

If you are downloading a re-do: **The file should be named as the participants ID followed by an underscore and then the time period (example: 2550001DR_12).** The unattended file transfer (DataStream) will rename the file with a timestamp prior to transfer and will place the file in the Archive folder. The original file, therefore, will also be maintained in the Archive directory. Please contact Deb Martin with any questions related to this process (martind@edc.pitt.edu).

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:

1. You may explicitly add a .swb to the end of each StepWatch file name when saving files.
2. You may change your Control panel setting to show file extensions.

3. 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.

Opening and Closing Files

The following functions work for StepWatch files.

Open

The Open command allows you to open a data file created by the StepWatch 3 program.

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.

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.

Close

The Close command closes any data window. 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.

Sending Files to the DCC

After data files are filtered and saved to the Client folder in the SAM library they will need to be transmitted to the DCC. StepWatch data files should only be downloaded to the one computer your site designated for SAM download (the DCC installed the necessary file transfer software on that computer). Unattended transfer of these files (DataStream) will occur once a day at 12:00 PM as long as the computer is on at that time. The DataStream process will rename all files in the Client Files folder by adding a date stamp to the file name, transfer them to the DCC and move them to the Archive folder that is in the Client Files folder of the SAM computer. Please contact Deb Martin with any questions related to this process (martind@edc.pitt.edu).

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 Cyma web site for a list of known issues and fixes. Beyond that Cyma provides technical assistance.

Communications Errors

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

1. Check the connections between the dock and the computer.
2. Make sure the StepWatch is properly aligned on the dock.
3. Make sure there are no bright lights shining on the StepWatch. Halogen lights can be especially troublesome. The infrared lights of some motion analysis systems also make shielding necessary.
4. Verify that your Communications Preferences have the correct port specified.
5. Verify that the computer can communicate with the dock and the StepWatch by using the "Communications Test".
6. Check that you do not have email or internet browser software running in the background. Intensive networking software can also cause errors.
7. Sometimes simply waiting for a while before attempting to read the StepWatch again solves the problem.
8. If you are not able to solve the problem, contact Cyma Technical Support. It is helpful if you have the exact wording of any error message and just when it occurs. They are happy to try to help you try to solve the problem.

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.

1. 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.
2. 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 Cyma technical support.

Read Current Settings

Never use this feature.

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.

Technical Support...

Any time that you contact the Cyma corporation for technical support please cc the DCC. If you speak to Cyma by phone please send a brief email to the DCC describing your reason for contacting them and the resolution of your problem.

Cyma Corporation
6405 218th St. SW, Suite 100
Mountlake Terrace, WA 98043, USA
Phone: (425) 771-0797
Fax: (206) 219-1144
Web: www.cymatech.com
Email: help@cymatech.com

Appendix A: Sample Data

There is a sample data file called “DemoData.swb” in a folder called Sample Data inside your Participant Files folder. (On windows machines set to not display file extensions, the file name will appear as DemoData.) *Note: the sample data was provided with the first version of the SAM software that you loaded. It is not provided with the latest beta version of the software.*

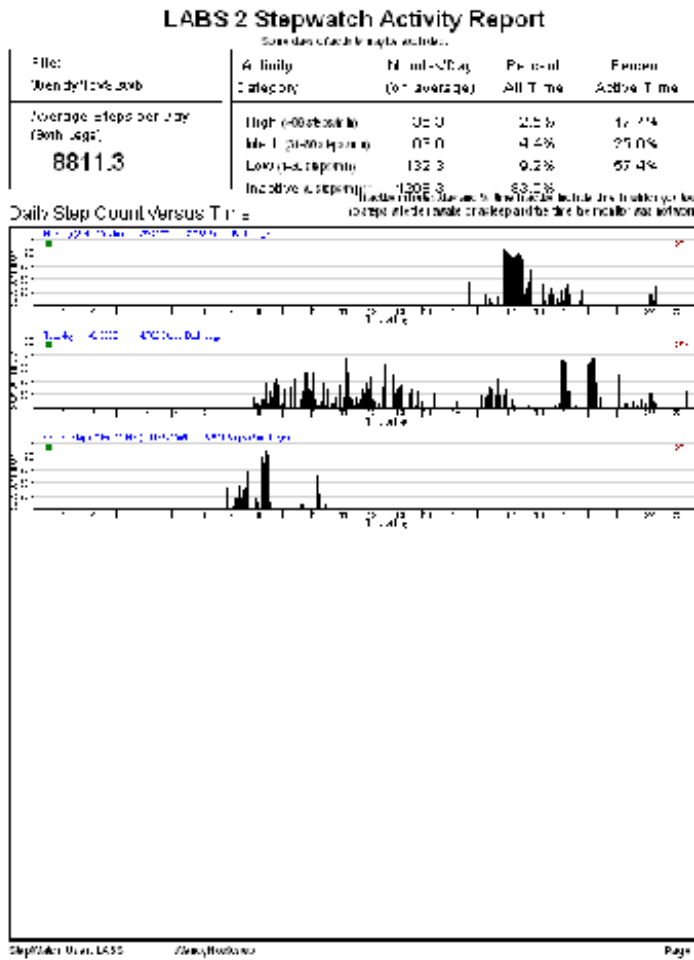
Open the demo file either by double clicking on the file or using the “Open” command in the File menu and navigating to the Sample Data folder. This file contains days that are entirely included, entirely excluded and partially included for analysis. You can use this file to practice interpreting the data and to experiment with many StepWatch program functions.

The activities undertaken by the participant include:

- Saturday June 29: Nine short holes of golf around noon. Facilitating children's parties and transportation in the afternoon and evening.
- Sunday June 30: A 1.5 hour drive to a wilderness area in the afternoon. Casual exploration of the wilderness area.
- Monday July 1: Office work until 6 PM. Vigorous house cleaning in the evening.
- Tuesday July 2: Quiet office work all day. Attending a child's little league baseball game in the evening.
- Wednesday July 3: Office tasks in the morning. Golf in the early afternoon. Errands by foot in the late afternoon. To a friend's house for dinner in the evening.
- Thursday July 4: Attending a baseball game in the afternoon, including a long walk to and from parking. Walk in the early evening which included a rest. Grocery shopping followed by a social party with adults in the later evening.
- Friday July 5: Playing baseball in the late afternoon. Cooking dinner then visiting with friends at home in the evening.

Appendix B: Activity Report

You will mail each participant a LABS 2 Stepwatch Activity Report after you have downloaded and cleaned their data. You create this report by going to “File”, “Print” and selecting “Client Week Report.” You may review the report before printing by selecting “Print Preview.” See the example below. Please note, this example was made from data based on only 48 hours of activity. LABS 2 reports should be based on 7 days worth of activity.



Appendix B cont: Letter to accompany Activity Report

[Date]

[Name of participant]

[Address]

[Address]

Dear [Name of participant]:

Thank you for wearing the Stepwatch Step Activity Monitor (SAM) as part of your participation in the Longitudinal Assessment of Bariatric Surgery (LABS). I appreciate your participation and continued support of the LABS project.

I am sending you this letter to provide you with an activity report that describes your activity during the week you wore the SAM. The report includes the following components:

Average Steps per Day: the sum of all steps taken while you wore the SAM divided by the number of days you wore the SAM.

Activity Category: categories that characterize your activity level for the days in which you wore the SAM. Please note, time in which you did no activity or the SAM was not worn register as Inactive (0 steps/min).

Minutes/Day: Average number of minutes spent at each activity level per day. Please note, inactive minutes/day includes the time in which you took no steps whether awake or asleep and the time the monitor was not worn.

Percent All Time: Percentage time spent at each activity level during the 24 hour day. It is calculated using the total minutes accumulated at each level divided by the total minutes in the day. Please note, percent time inactive includes the time the time the monitor was not worn.

Percent Active Time: Percentage time spent at each activity level during the time you took at least one step per minute. Thus, inactive time is excluded from the calculations.

Daily Step Plots: plots of steps/minute for each 24 hour day included in the report. Please note, the total number of steps for each day is also included next to the date.

If you have any questions or concerns, please feel free to contact me at [insert Coordinator phone #].

Best regards,

[Coordinator]

Appendix C: Letter to be sent the day the participant takes the SAM home

[Date]

[Name of participant]

[Address]

[Address]

Dear [Name of participant]:

As part of your participation in the Longitudinal Assessment of Bariatric Surgery (LABS), you agreed to wear the Stepwatch Step Activity Monitor (SAM). I encourage you to continue wearing the SAM and filling out the activity diary.

I understand that this may, at times, seem like an inconvenience to you. Please keep in mind that by wearing the SAM before and annually after surgery you will be providing physical activity data that will help us understand how activity level in conjunction with bariatric surgery affects many health outcomes.

The SAM should be worn for 7 days from the time you awake in the morning until you go to bed at night. If you are having trouble remembering to wear it, it might be helpful to keep your SAM by an alarm clock, coffemaker or other part of your daily morning routine. Alternatively, you may continue to wear the SAM when you sleep so that you do not need to remember to take it on and off.

Your SAM should be returned no later than [insert date, 12 days from receipt of SAM]. After we have received your SAM, we will send you an activity report that describes your activity during the week you wore the SAM.

If you need another mailing envelope or have any questions or concerns, please feel free to contact me at [insert Coordinator phone #].

I appreciate your participation and continued support of the LABS project and look forward to hearing from you soon.

Best regards,

[Coordinator]

Appendix E: Guidelines for filtering data

To determine if a participant has worn the SAM for at least 4 “valid” days please follow these directions:

- Click on the “Edit Time” tab of your data file for 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.
- Double click on each day to evaluate it individually.
- Exclude days with less than 10 hours of wear.
 - Use the new “Exclude night rest” option which should exclude all non-wear time: time before the first movement of the day and after the last movement of the day.
 - After you have excluded non-wear time, the number of included hours/minutes will appear in blue at the top of the box. If fewer than 10 hours are included in a day, exclude the **entire** day. If 10 or more hours are included, include the **entire** day.
 - Based on the Auto Exclude option in Preferences you may see that some days are excluded already.
- Occasionally you will have some scenarios that require extra attention:
 - There may be a day when there appears to be a few steps taken several hours after the monitor was taken off...maybe when the monitor was getting moved. In cases like this the “exclude night rest” option will have included extra time at the end of the day. If it is not obvious whether the monitor was worn for 10 hours you will have to manually change the end parameter to exclude time from when it appears the monitor was actually taken off. To manually change the end parameter, click on the second time in “time range” and then drag a bar from the right side of the screen until there is “real” movement. After fixing the end parameter use the included hours/minutes that appear in blue at the top of the box to determine whether to include or exclude the day.
 1. See date 10/5/03 in demo file 1 for an example of this.
 - There may be a day with movement from midnight until 1 or 2 am and then not again until morning. Because we define days as midnight to midnight we count this “late night” movement with the “next day.” However, the “exclude night rest” option excludes this late night movement. Therefore you will have to mentally add on this time to the total time given.
 1. See date 11/14/05 in demo file 4 for an example of this.
 - There may be a day that includes more than 10 hours of wear but it appears that the subject may have removed the Stepwatch for a period or have been asleep. In any given day, if at least 10 hours are included, but there appears to be a no-wear period of 2 hours or longer, subtract the no-wear period from the included hours to determine whether there are 10 or more hours of wear.
 - Examples of when to exclude the day 1) A total of 11 hours with one 2 hour period of no-wear (because only 9 hours of activity). 2) A

total of 17 hours with one 9 hour period of no-wear (because only 8 hours of activity).

- Example when to include the day: 1) A total of 11 hours with two 90 minutes of no-wear (because a no-wear period must be 2 hours to be subtracted).
- If you are unsure if a participant has worn the SAM for 4 valid days please submit a help desk request for review of the data file. The subject of the help desk request should be "SAM data file." The description should be "maybe not 4 days of wear."
- Note, the Stepwatch software may not allow you to exclude all days in a file. If you are unable to exclude the last day but it is invalid, you may save the file with the last day included.