



Trex™
modus™



Modus Trex™ Activity Monitor & Docking Station

Modus Trex™ Clinician Manual

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Version 3.4
Modus Trex™
Clinician Manual

Modus Trex™ is comprised of an ankle-worn ambulatory activity monitor (StepWatch™), docking station (dock), and software for viewing/printing functional assessment reports. The functional assessment report provides an overall functional score based on walking activity with the prosthesis in addition to other metrics (e.g. daily steps, distance walked, and cadence). These reports will help you track your patients' change in mobility. To use this system, you will need a computer running either a Windows Vista+ or Mac OS X 10.7+ operating system.

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I. General StepWatch™ Information and Care

The StepWatch™ Activity Monitor (U.S. Patent # 5,485,402) is a research and clinical tool for long-term assessment of ambulatory function in a home setting. 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 for 50 days between downloads. However, if a patient takes tens of thousands of steps every day, it is possible to exhaust the memory of the StepWatch™ before 50 days has elapsed.

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 walk. The StepWatch™ has validated accuracy between 1 – 4 mph¹⁻²⁹. When properly used, accuracy typically exceeds 98%.

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 populations. A bibliography listing of currently known publications is available at modushealth.com or contact research@modushealth.com.

StepWatch™ is listed with the U.S. FDA as a Class II exempt medical device.

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, StepWatch™ 3 is limited only by the battery life, which is typically up to seven years. The StepWatch™ is warranted against manufacturing defects for a period of **two years** from the date of purchase.

Temperature extremes, particularly high temperatures, will reduce battery life. Avoid leaving the StepWatch™ in hot places over 115° F. Maximum life is achieved at room/body temperature.

WARNING! NEVER PLACE THE STEPWATCH™ IN ANY TYPE OF OVEN OR AUTOCLAVE as this could potentially cause the permanent lithium battery to rupture or explode.

The StepWatch™ is designed to withstand typical handling and real-life wear and tear. Factory calibration is permanent and won't change during normal use. However, the StepWatch™ is a sensitive instrument and should be treated with care and respect to maintain the highest possible accuracy. Extreme shock/vibration may affect the sensor threshold, which could decrease accuracy. For example, avoid severe drops onto concrete and putting the unit through a clothes washer or dryer cycle.

The StepWatch™ 3 is **water resistant, but not waterproof**. It should never be submersed in/or subjected to large quantities of water.

Do not apply any covering (tape/stickers) or writing (marker/paint) to the front red cover of the StepWatch™. The StepWatch™ communicates with the docking station (dock) through the red cover and any obstruction could compromise the quality of recorded step data.

1. Cleaning and Sanitizing

The StepWatch™ monitor may be cleaned using a cloth dampened with mild soap and water or 70% isopropyl alcohol. Strong detergents or solvents will damage the plastic and will void the warranty. NEVER soak the StepWatch™ in any type of cleaner or solvent. **WARNING! NEVER PLACE THE STEPWATCH™ IN ANY TYPE OF OVEN OR AUTOCLAVE, as this may cause the battery to rupture or explode.**

The dock is NOT water resistant or waterproof. The StepWatch™ dock may be cleaned using a cloth dampened with mild soap and water or 70% isopropyl alcohol. Strong detergents or solvents may damage the plastic and will void the warranty. Do not soak the StepWatch™ dock in any type of cleaner or solvent. **NEVER PLACE THE STEPWATCH™ DOCK IN ANY TYPE OF OVEN OR AUTOCLAVE, as this may cause the battery to rupture or explode.**

The StepWatch™ straps may be hand washed with mild soap and water, or a solution of 70% isopropyl alcohol. Do not use machine washing or drying, as this may cause shrinkage and hasten deterioration.

2. Service and Repair

The StepWatch™ and the dock are not user-serviceable. Opening or tampering will void the warranty. Contact SPS Technical Support at (800) 767-7776 for assistance with a StepWatch™ or dock.

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 at 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 212°F, disassemble, puncture or expose contents to water. Dispose of the battery properly.

B. Modus Trex™ Dock and Software Installation Instructions

Attention: To download Modus Trex Software, please go to: www.modushealth.com/trexsupport and choose the PC or Apple version.

Modus Trex™ software version 3.4 supports the following operating systems:

- Microsoft Windows XP SP3 (features may be limited), Vista, Windows 7, Windows 8+
- Apple OS X 10.7+

Read the instructions for your operating system completely before using Modus Trex™. **Do not plug in the StepWatch™ dock until noted in the following instructions.**

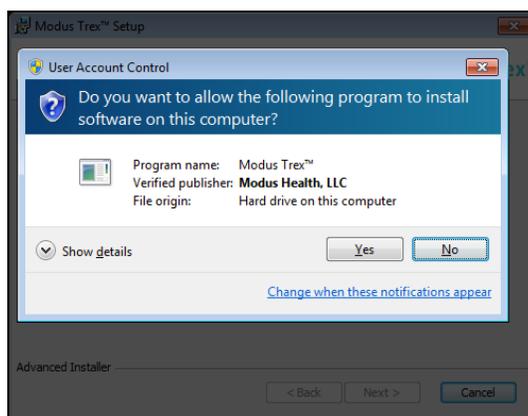
1. Installation Instructions for Windows XP SP3+

Attention: Windows XP SP3 **must** be connected to the Internet to install Modus Trex™.

1. Double-click the **Modus Trex Installer.exe** from the download website www.modushealth.com/trexsupport.
2. Click “Next” on the following three screen, adjusting the install location if desired:



Windows Vista+: If prompted by User Account Control to install the software, choose “Yes”:



Windows XP SP3: If prompted by Software Installation that the software has not passed Windows Logo testing, choose “Continue Anyway” -- this may appear twice:



4. Click “Finish” on the final installation screen. Modus Trex™ is now installed. **At this time, you may plug in the StepWatch™ dock.** Wait 30 seconds for the StepWatch™ dock to be detected (the **blue** light will stop blinking and turn steady). You are now ready to launch Modus Trex™ -- a shortcut has been created in the Windows Start menu and on your desktop.

Attention: Never plug in or unplug the dock while the Modus Trex™ software is running. Always close the software before plugging in or unplugging the dock.

2. Installation Instructions for Apple OS X

1. An OS X driver package has been provided with the Modus Trex™ 3.4 software. “StepWatchDockDriver_OSX_Intel_2218.zip”. Double-click this file to extract the driver installation software “StepWatchDockDriver_OSX_Intel_2218.mpkg” into the same directory.
2. Double-click the driver installation software “StepWatchDockDriver_OSX_Intel_2218.mpkg” to run the installation. Follow the installation routine until the driver has been installed.
3. **Restart your computer.**
4. Using the enclosed USB cable, plug the dock into a USB port on the computer. The **blue** light

on the dock will illuminate and then stop blinking and turn steady when correctly detected by the computer.

Running the Modus Trex™ Software

The Modus Trex™ software is a “standalone application package” Like all OS X apps, it will run in any directory on the computer once downloaded from the www.modushealth.com/trexsupport website. You are encouraged to copy the ModusTrex.app package from the website or from the location where you’ve downloaded it into the Applications directory on your computer. This is standard convention to “install” apps on OS X.

1. Start the software by double clicking on ModusTrex.app.

Note: On some computers, you may receive a warning about running an app from an unidentified developer. If you receive this warning, click “OK” to close the warning. Then, right-click on ModusTrex.app and left-click on “Open” (as opposed to double clicking on the icon to open it). This will present a similar warning notifying you that the app is not from an identified developer, but unlike the standard warning there is now an “Open” button that will allow you to launch the app. OS X should remember this approval going forward.

Attention: Never plug in or unplug the dock while the Modus Trex™ software is running. Always close the software before plugging in or unplugging the dock.

3. Connecting and Using the Dock

The StepWatch™ application should not be running when you plug in or unplug the dock.

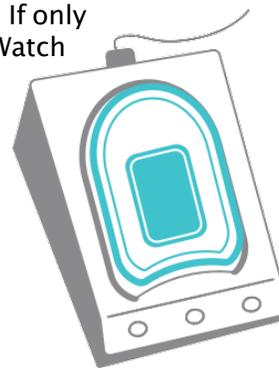
CONNECTING THE DOCK

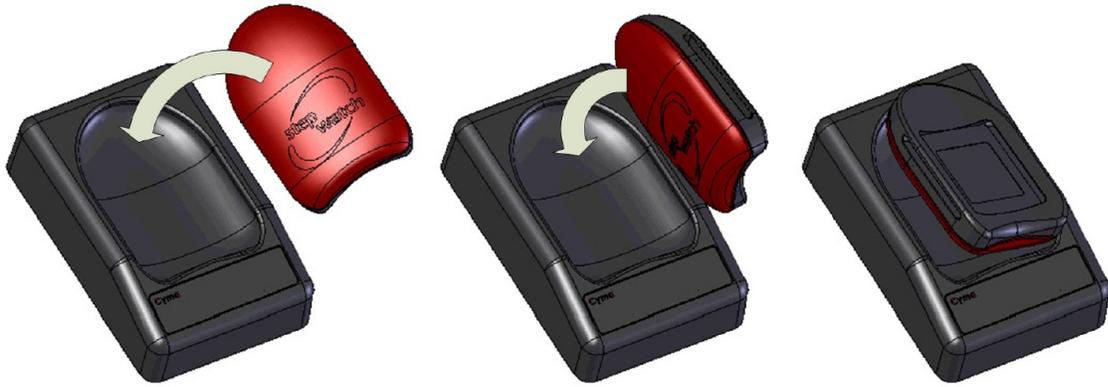
Connect the dock to your computer BEFORE launching the software. The Modus Trex™ software should NOT be running when you plug in or unplug the dock

- **BLUE** LIGHT: Dock is plugged in, but not communicating with the software. If only the **BLUE** LIGHT is on, try selecting the communications port labeled “StepWatch Dock” in the software preferences on the Communications tab.
- **RED** LIGHT: StepWatch™ is busy, DO NOT REMOVE the StepWatch™.
- **GREEN** LIGHT: Dock is connected but StepWatch™ monitor can be safely removed.

PLACE THE MONITOR ON THE DOCK

Place the monitor face down into the depression on the dock. You do not need to remove the strap.





If the dock was not detected, you will get this screen:



REPORT VIEWING UNAVAILABLE

The StepWatch™ Dock was not detected. Please visit modushealth.com/trexsupport or call (800) 372-2042 for assistance.

STEPWATCH™ PROVIDER OPTIONS

For initial programming of the StepWatch™ by a provider or making programming changes as needed. Manually read the StepWatch™ and display the Trex™ report.



If this occurs, please contact SPS Technical Support at (800) 767-7776 for assistance.

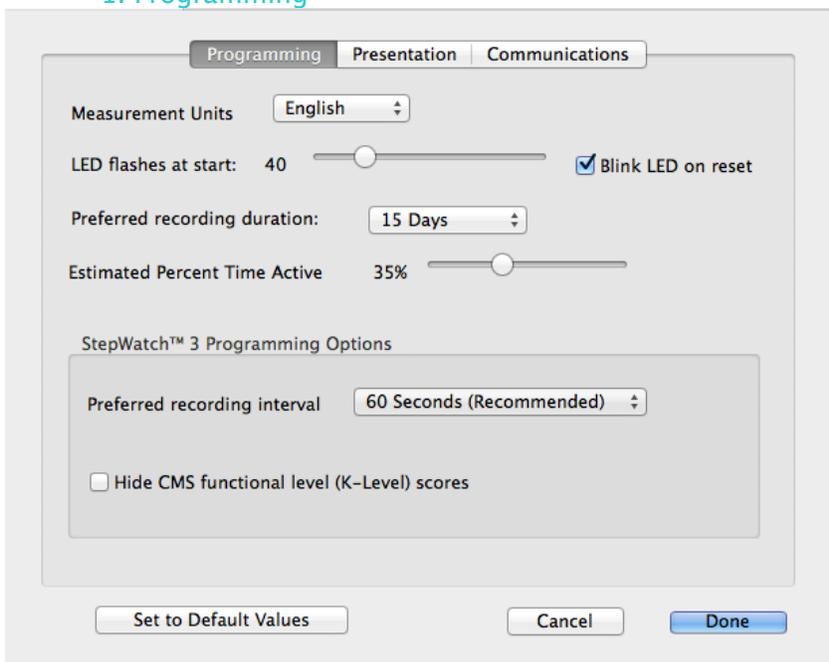
The StepWatch™ 3 dock does not require external power. It draws power from the USB connection with the computer.

C. 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 are recorded, displayed and analyzed. You may change your preference settings by choosing “Preferences” from the “Edit” (Windows) or “StepWatch” (OS X) menu.



1. Programming



a. Units

Select either 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 that used by your computer operating system. (The European date style may not display in all locations where dates appear.)

b. LED Flashes

The StepWatch™ is equipped with a **red** diagnostic LED at the top of the unit to help you determine if the programmed settings are applicable to a given patient. The LED blinks each time a step is detected. You should use the LED flashes to quickly assess the appropriateness of your settings by watching your patient walk and ensuring that the light blinks once for each step. Be sure your patient does not try to look at the StepWatch™ while walking, because this creates an untypical gait pattern.

By default, the LED is set to blink for the first 40 steps collected after programming. 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 in Advanced Programming.

c. Preferred Recording Duration

The “Preferred Recording Duration” preference sets the default recording time for each monitoring session initiated with the regular programming mode. The “Recording” 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. It is recommended that the setting of “Memory Full” is selected so that the maximum amount of data is collected (50 days) should your patient not regularly use the system at home...

d. Estimated Percent Time Active

We recommend not changing this number from the default 35%. If you have extremely active or inactive patients **and** are trying to record for as long as possible, contact Modus Research Support for further advice at research@modushealth.com.

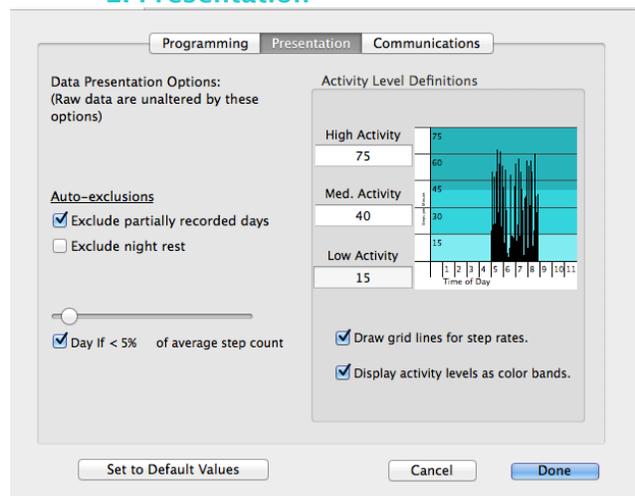
e. Preferred Recording Interval

This function allows you to change the steps per time interval. **For consistent reports, this setting needs to stay at 60 Seconds.**

f. Hide CMS functional level (K-level) scores

Checking this box will hide the Modus CMS functional k-level scores when viewing and printing the report. You will still see the Modus Index scores.

2. Presentation



a. Auto-Exclusions

This function allows you to specify the days with relatively few or no steps that are to be automatically excluded from analysis. 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.

b. Activity Level Definitions

All step counts are based on the steps for the measured leg. Low Activity is defined as 1 – 15 steps/minute and is the lightest color on the Recording Summary bar graph. Medium Activity is defined as 16 – 40 steps/minute and is the medium color on the Recording Summary bar graph. High Activity is 41 steps/minute or greater and is represented by the darkest color on the

Recording Summary bar graph. This allows easier visualization of peak activity. These levels should not be changed or it may be difficult to compare your reports to others.

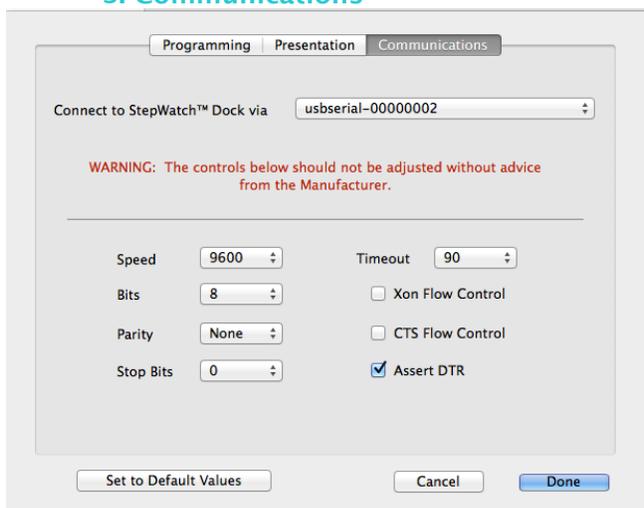
Note on Activity Level Definitions:

Our normative data collection on healthy persons has shown that activity limits of 15 steps per minute on the measured leg for Low activity and 40 steps per minute on the measured leg for Medium activity represented natural break points in the aggregate distributions of activity intensity.

c. 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 color bands for Low, Moderate, and High 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. When the line representing any data point passes through and beyond a given activity intensity 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.

3. 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 verifying that the **green** light is illuminated on the dock. If the software does not detect the dock, contact SPS Technical Support at (800) 767-7776 for assistance.

E. Programming the StepWatch™

As the clinician, select “StepWatch Provider Options”



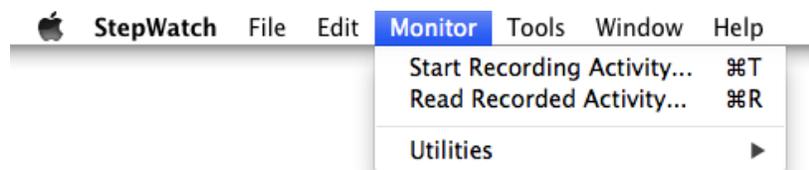
VIEW REPORT AND RESTART STEPWATCH™

For patients and wearers of the StepWatch™. Reads the most recent data session, displays the Trex™ report, and re-programs the StepWatch™. Minimum of five days recorded is required.

STEPWATCH™ PROVIDER OPTIONS

For initial programming of the StepWatch™ by a provider or making programming changes as needed. Manually read the StepWatch™ and display the Trex™ report.

Easy Start is accessed through the "Start Recording Activity" command in the Monitor menu.



To initiate “Easy Start” programming place the StepWatch™ face down on the dock and select “Start Recording Activity” from the “Monitor” menu. The software will read programming information from the StepWatch™ and the dock 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 patient description.

A screenshot of the "Start StepWatch™" dialog box. It is divided into three sections:
1. Describe Subject: Includes fields for Height (Inches) and Stride Length (Inches). A "Quick Stepping" section asks if the subject regularly participates in activities involving short quick movements, with a "No" button. A "Walking Speed" section asks for the subject's normal walking speed relative to people of similar height, with a "Normal" dropdown. A "Range of Speeds" section asks for the subject's range of walking speeds, with a "Uses a moderate range of speeds" dropdown. A "Leg Motion" section asks to describe the appearance of the subject's leg motion, with a "Normal" dropdown.
2. Set Start Time, Recording Interval and Duration: Includes radio buttons for "Now" (selected) or "Later...". A date field shows "12/31/15", a time field shows "00:00", and a "Timezone" dropdown shows "CST,MDT". Below are fields for "Save recorded steps every" (60) and "seconds and stop recording after" (15 Days).
3. Subject Information: Includes fields for "Unique ID", "Age" (0 yr), "Weight" (0 lb), and "Gender" (Select...). Below are fields for "Subject Name (40 character limit)" and "Diagnosis" (Select...). A note at the bottom states: "* Some characters cannot be used (particularly accents in languages other than English)".
Buttons for "Cancel" and "Start" are at the bottom right.

Prior to programming you should confirm that you have set the preferences as you wish. (See “Setting Preferences” earlier in this manual.)

1. Describe Subject

a. Height

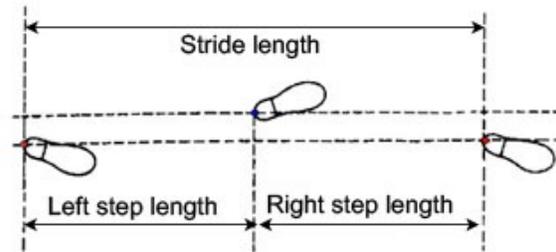
This setting **strongly** affects the maximum rate at which the StepWatch™ can identify steps. In general, a person's height is inversely related to step rate, meaning a taller person will often have a slower step rate than someone shorter. If you do not know your patient's height and you specify an incorrect value, the steps recorded may not be accurate.

b. Stride length

Stride length is needed to calculate distance walked on the functional report. Stride length is the distance between two successive placements of the same foot.

Stride length can be estimated by measuring the distance walked by your patient for several strides (usually 4 to 10) and then dividing this distance by the number of strides.

There are also web applications that use video of walking to determine stride length such as PnO Data Live (<https://live.pnodata.com>).



c. Quick Stepping

A key to accurately identifying quick stepping activities is to distinguish overall walking speed from how quickly steps are being taken. Some activities, such as fast walking with long strides, involve traversing the ground rapidly without taking steps much more quickly than moderate walking with shorter strides. 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 patient 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. If you are uncertain, choose NO. If you are in question about whether an activity qualifies, have the patient "demonstrate their moves" and adjust accordingly.

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

d. Walking Speed

NOTE: Answering YES to “Quick Stepping” overrides and disables this option.

Evaluating a person's normal walking speed relative to their height may be 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 patient. For her height, is her normal walking speed slow, average, or fast? Most people will fall in the average category.

e. Range of Speeds

NOTE: Answering YES to “Quick Stepping” overrides and disables this option.

This setting influences how broad a range of step rates the StepWatch™ will "expect". For most people, a moderate range is appropriate. Some patients, 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: Bicycling appears to the StepWatch™ as walking. If a person regularly bicycles, they should remove the StepWatch™ during bicycling unless you would like their bicycling counts to be included in the gathered step data. If you choose to include the data, you may want to investigate how quickly they pedal – “spinning” versus moderate pedaling versus slow pedaling, for example – as the data gathered under these conditions may be affected by this setting.

f. Leg Motion

Observe how the patient moves in your presence.

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 entire gait.

- **Dynamic/fidgety:** If your patient 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 your patient 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 patient. 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.

2. Set Start Time, Recording Interval, Duration

a. Recording Time

Before initiating programming, you have the option of changing when the monitor will start and stop recording. **You will want to record steps every 60 seconds and stop recording when memory is full.** The memory will become full after 50 days of recording. You may later print weekly reports with the 50 days of data. These settings can be set as the default values in "Preferences."

3. Subject Information

a. Unique ID

Entering a unique ID is optional. Using a unique ID may be helpful in keeping the functional reports associated with the correct patient.

b. Age

Enter the current age of your patient. This is needed in order to compare your patient's Modus Index score to the correct normative age group.

c. Weight

Enter the current weight of your patient. This is needed in order to correctly calculate the ambulatory energy index.

d. Gender

Select the gender of your patient.

e. Diagnosis

Select your patient's type of amputation. Use other if the type is not listed.

f. Subject Name

Entering your patient's name is optional.

4. Initiate Programming

When you are satisfied with your settings, click the Start button to initiate programming. Programming will take up to 30 seconds. When programming is completed, the **red** light on the dock will no longer be illuminated and the **green** light on the dock will illuminate. The software will present a window verifying when recording will start. You should now remove the StepWatch™ from the dock and attach it to the patient. **By default, the StepWatch™ will not start recording steps until one minute after the “success” dialog window.** This minimizes recording false steps from motions applied to the StepWatch™ during patient attachment.

5. 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 patient 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 patient should not look at the monitor while walking, as this will change their walking pattern. You should watch to see that the StepWatch™ is not double blinking on slow steps, and not skipping a blink on fast steps. If you are walking with your patient, 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 settings by reading recorded activity or reading current settings. Both of these actions will stop the recording and will put the StepWatch™ to sleep. No data will be logged until the monitor is reprogrammed.

If you have programmed a StepWatch™ 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 minute.

If the StepWatch™ is not detecting steps as accurately as expected and attempts to adjust the Easy Start parameters do not improve accuracy, review “Verify Cadence and Sensitivity Settings” in the “Advanced Programming” section in this manual.

The key to getting optimal results is balancing the Motion Sensitivity and the Cadence settings. For questions, contact modus for advice at research@modushealth.com. 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 to particular gait styles.

F. Wearing the Monitor

The StepWatch™ 3 should be worn on the outside or inside (medial or lateral) aspect of the prosthetic leg just above where the ankle bone would have been. Wearing on the lateral side is usually preferred.

- **Be sure the StepWatch™ is oriented PROPER SIDE UP by observing the direction of the arrow on the case. It will not record data when it is upside-down.** Take some time to instruct your patient about monitor orientation and to assure that they understand.
- The StepWatch™ is not waterproof. If the prosthesis is worn in the shower, the StepWatch™ should be removed.
- **Do not apply any covering or writing to the front red cover of the StepWatch™.**



II. General Data Information

A. Download 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 may take a few seconds to minutes depending on file size.

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” in this manual.

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. Read the monitor again.

B. Generating Your Activity Report

If it has been at least 5 days and you wish to view your patient's Trex™ report, place the StepWatch™ in the docking station as illustrated in the following diagram.



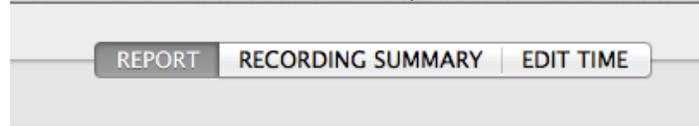
Do not remove the monitor from the dock while it is communicating (while the red light on the dock is on).

As shown in the following diagram select “View Report and Restart StepWatch™” to view your Trex™ report. The steady red and blue lights will appear on the docking station if your walking information is transferring to your computer. The StepWatch™ will record a maximum of 50 days and stop recording data if not downloaded in 50 days.



C. View Data and Generate a Functional Level Report

When the data have been read you will see 3 tabbed windows.



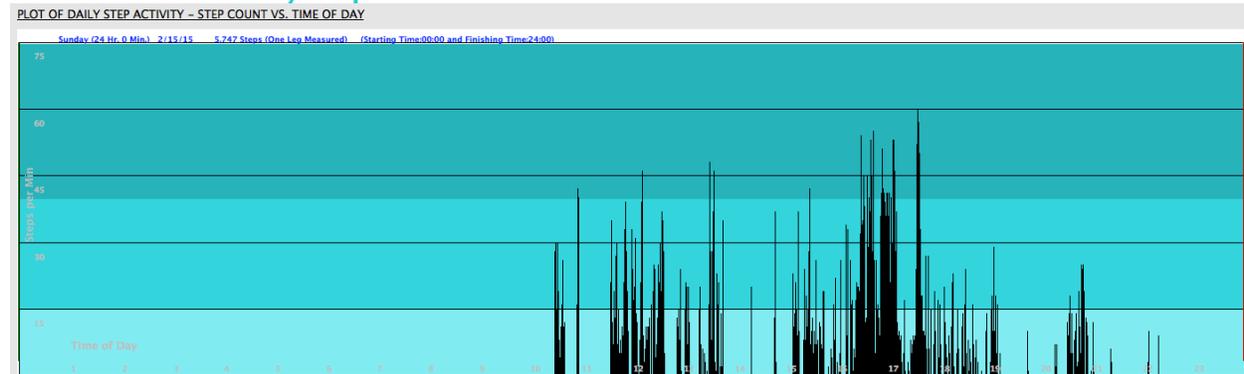
- “**REPORT**” includes the monitor ID, the time the monitor was programmed and read, unique ID, patient name, demographic information, and the functional level scores / metrics for the patient. **You MUST specify a clinical functional walking level observation score to generate the scores for this report.** Click the checkbox for the observed score and the report will automatically update with all functional level scores. The patient cannot change your functional level selection when using the patient features.
- “**RECORDING SUMMARY**” includes more detailed information about the monitor and recording session, including a list of days the monitor was running and a graphical representation of the data for each recorded 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.

D. Representations of the Step Data

1. Graphical Representations of the Data

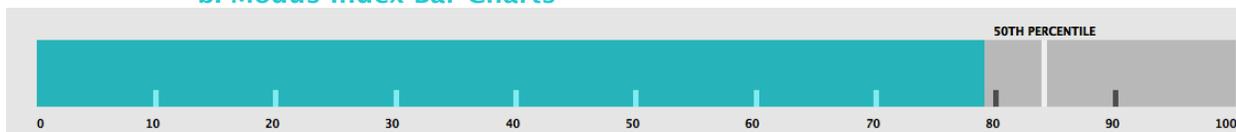
There are several tools providing graphical representations of the data. For a more complete understanding of the analysis calculations see “Analysis Variables and Calculations” in this manual.

a. Daily Step Plots



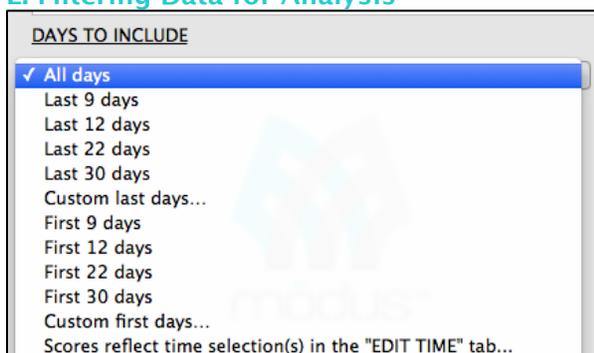
Daily Step Plots show the raw data for each day with time (on 24 hour clock) across the bottom, and steps per minute on the vertical axis. Each small vertical line is one minute. The data represent step counts only for the leg being monitored.

b. Modus Index Bar Charts



The bar charts display the overall functional level index (Modus Index), the ambulation energy index, the peak performance index, and cadence variability index. Each bar chart has a vertical line representing the 50th percentile score for healthy persons with both limbs in the same decade of life as the prosthetic user. The 50th percentile scores were calculated from n=199 participants with 29 – 32 participant in each decade of life except the 80 years old or older group, which had 15 participants. This data was collected in Seattle, Washington, and surrounding areas.

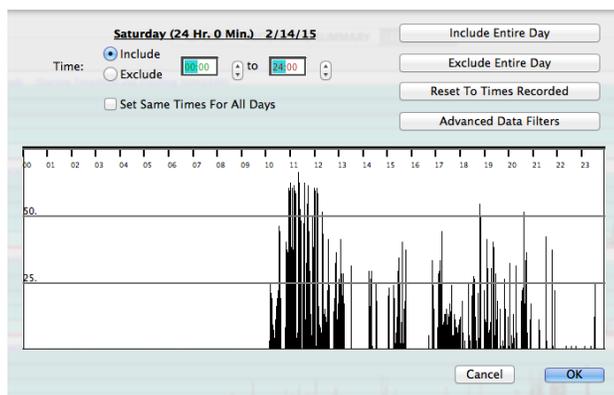
E. Filtering Data for Analysis



To specify which data you want included in your analysis, use the “Days to Include” feature on the “Report” tab. This provides the quickest method for analyzing a cluster of days. If a more complex filtering process is required, 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 (1 minute is the default). If you are using the “Auto Exclude” option in “Preferences” you may see that some days are excluded already.

1. 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 time (and clicking).

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

F. Analysis Variables and Calculations

1. Metrics

All step counts, for which the metrics are derived, are for the measured leg only. The metrics 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 the Recording Summary tab and will not be included in the Date Range. Excluded days are not included in the metric calculations.

a. Clinical Observations

The clinician’s opinion of the patient’s functional level based on clinical judgment and patient self-report. The patient cannot change your functional level selection when using the patient features.

CLINICAL OBSERVATIONS PRINT SAVE

Functional walking level based on the clinical judgement of the clinician. The rating is based on the following Medicare K-level definitions.

0 - Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance quality of life or mobility.

3 - Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.

1 - Has the ability or potential to use a prosthesis for transfers or ambulation in level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.

2 - Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

4 - Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

b. Modus Index

Overall walking function of patient. Its value is on a 0 to 100 scale with comparisons to normative values of healthy persons with intact, unimpaired limbs, of the same age decade (50th percentile). It is comprised of clinical observations, Ambulation Energy Index, Peak Performance Index, and Cadence Variability Index. The 50th percentile is comprised of Ambulation Energy Index, Peak Performance Index, and Cadence Variability Index only.

c. Modus CMS Functional Level Score

Overall walking function of patient in terms of Centers for Medicaid and Medicare Services (CMS) Functional K-level score. This score is comprised of clinical observation k-level score, Ambulation Energy CMS Functional Level Score, Peak Performance CMS Functional Level Score, and Cadence Variability CMS Functional Level Score. The score should be rounded to the nearest whole number when determining k-level category: 0, 1, 2, 3, or 4. For example, a CMS Functional Level Score of 2.5 – 3.4 would be rounded to a k-level score of 3. The CMS Functional Level Score within the range of 3.5 – 4.9 would have a k-level score of 4 since this is the highest functional category. The CMS Functional Level Score is intended to provide an objective and standardized process determining patient's CMS Functional Level category.

d. Ambulation Energy Index

Algorithm that incorporates ambulation energy requirements and intensity of continuous walking bouts. Its value is on a 0 to 100 scale with a comparison to normative values of healthy persons with intact, unimpaired limbs, of the same age decade.

e. Ambulation Energy CMS Functional Level Score

Algorithm that incorporates ambulation energy requirements and intensity of walking bouts. Its value is scaled to the CMS Functional Level categories.

f. Peak Performance Index

Algorithm that incorporates fastest 1-minute walking spurts. Its value is on a 0 to 100 scale with a comparison to normative values of healthy persons with intact, unimpaired limbs, of the same age decade.

g. Peak Performance CMS Functional Level Score

Algorithm that incorporates fastest 1-minute walking spurts. Its value is scaled to the CMS Functional Level categories.

h. Cadence Variability Index

Algorithm that incorporates proportion of walking at low (1 – 15 steps per minute), medium, (16 – 40 steps per minute) and high (41 or greater steps per minute) cadence values. Its value is on a 0 to 100 scale with a comparison to normative values of healthy persons with intact, unimpaired limbs, of the same age decade.

i. Cadence Variability CMS Functional Level Score

Algorithm that incorporates proportion of walking at low (1 – 15 steps per minute), medium, (16 – 40 steps per minute) and high (41 or greater steps per minute) cadence values. Its value is scaled to the CMS Functional Level categories.

j. Daily Steps

Average of daily steps on the measured limb.

k. Date Range

All the dates included in the metric calculations. "Custom date selection from Edit Time" will be displayed if Edit Time was used to select the days for inclusion in the calculations.

I. Cadence

Average steps per minute when walking. Walking is defined as greater than or equal to 1 step per minute. Very low cadence rates indicate slow walking and/or walking that does not often continue for a full minute. An increase in Cadence indicates the patient is walking at faster speeds and/or walking longer in continuous bouts.

m. Cadence Variability

Average standard deviation of cadence when walking. Walking is defined as greater than or equal to 1 step per minute. An increase in cadence variability means the patient has increased their range of walking cadences. This typically occurs when the patient's cadence rates reach new peak cadences that exceed the peak cadences from previous weeks

n. Daily Distance

Average distance walked per day. Distance is based on Daily Steps and patient's typical stride length inputted by the clinician during setup.

o. Stance/Swing Time

Average stride duration (time from foot contact of measured limb to foot contact of same limb) based on the fastest 1 minute of walking each day. Very long stance/swing time estimates will occur if the patient does not walk for at least one continuous minute each day. A decrease in stance/swing time means the patient is taking less time with each step.

2. Handling Data Files

a. Save and Save As

The "Save" command on the Report and under the File menu allows you to save step data to a file on your computer and to save alterations to a file already existing on your computer. 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. If you are saving a file that you have opened from your computer, 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.

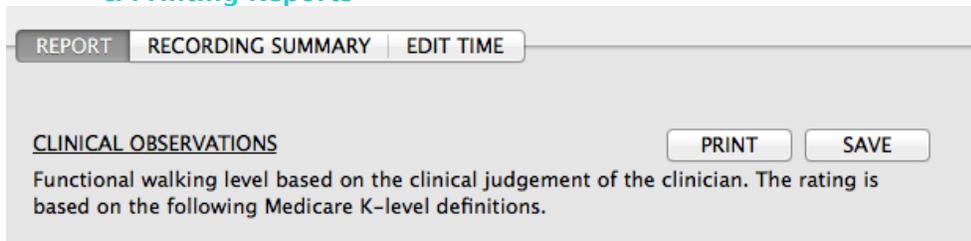
With either "Save" or "Save As", the specifications for the time you have chosen to include or exclude for analysis will be saved with the file. The excluded data will not be lost and will be available for inclusion later.

b. Opening and Closing Files.

- **Open:** The Open command allows you to open a StepWatch™ Modus Trex™ data file. On 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. If you have StepWatch™ files which do not have the .swb extension, you may need to select "All Files" from the File Type pop-up menu in your Open screen. This is not typical.
- **Open Recent:** The Open Recent command allows you to quickly access any of the last 5 data files that were saved. The Open Recent functions clears its history when changing Preferences or closing the program.

- **Close:** The Close command closes the currently focused data window. If the window contains changes that have not been saved, you will be asked whether you want to save the file before closing.

c. Printing Reports



- **Print:** The Print command on the Report and under the File menu gives you the option to the print the Report Page and Summary Page without previewing them. This is the fastest way to print the reports.
- **Page Setup:** The Page Setup command under the File menu gives the standard page set up options applicable for your chosen printer driver. Note: on some Windows machines, your page margins may need to be set at zero for printing to work properly.
- **Print Preview and Print:** The Print Preview and Print command under the File menu gives you the option to view and print the Report Page and the Summary Page. The Report Page contains the information from the Report tab. The Summary Page contains the steps taken each day that was recorded. Days not included in the calculations will have "(0 Hr. 0 Min.)" next to the day.

III. Troubleshooting

The Modus Trex™ program provides some tools to assist in troubleshooting including messages during the program operation and several diagnostic tools in the menu. Contact SPS Technical Support at (800) 767-7776 for assistance.

A. Communications Errors

A properly connected StepWatch™ 3 dock has a **green** light illuminated when the StepWatch™ software is open. If you do not see this light, 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. Try plugging the dock into another USB port on the computer.
- Verify that your Communications Preferences have the correct port specified: Choose "Preferences" from either the Tools menu (Windows) or the StepWatch™ menu (OS X) and then click on the "Communications" tab. Click the "Set to Default Values" button, followed by pulling down the "Connect to dock via" menu and selecting the entry for "StepWatch™ Dock" (Windows) or "usbserial-NNNNNN" (OS X). Then click the "Done" button. The **green** light on the StepWatch™ dock should now be illuminated.
- Verify that the computer can communicate with the dock and the StepWatch™ by using the "Communications Test" below.
- 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. The infrared lights of some motion analysis systems also make shielding necessary.

B. Communications Test

You may use the Communications Test (in the “Tools” menu) to check that your communications preferences and hardware are set up correctly and the StepWatch™ software is able to “talk to” the dock and StepWatch™.

- Click the “Check Dock” button to verify that your computer is in communication with the dock. 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 “Advanced Settings” should only be used with guidance from SPS Technical Support.

C. Read StepWatch™ Settings

Use the “Read Settings and Put to Sleep” option in the “Utilities” section of the “Monitor” menu to quickly verify the settings in your StepWatch™ memory. Use this test on a StepWatch™ that is asleep or has not recorded any data. 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.

Alternatively, use the “Read and Restart with Previous Settings” option to read the StepWatch™ monitor memory settings and reprogram it with the current settings. This is useful to double check the settings of a monitor which was just set to record and set it back into the recording state with those settings instead of putting it to sleep. **Do not perform this test on a monitor which has recorded data, the data WILL be lost.**

Caution: Always wait 60 seconds before reading a monitor that was just set to record.

D. View Communications Log

The Communications Log keeps a record of each time you program and download a StepWatch™.

Appendix A: Hardware Specifications

A. StepWatch™ 3 Activity Monitor Specifications

Size	75 x 50 x 20 mm
Weight	38 grams
Battery	750mAh Lithium
Battery Life	Up to 7 years depending on use
Accuracy	>98% independently validated
Housing	Injection molded polycarbonate
Attachment	Highest accuracy at ankle, Velcro strap
Recording Time	Up to 50 days minimum at 60 second 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 / 32° to 115°F
Shock / Drop	Avoid severe shocks and drops
Tamperproof	Permanently sealed
Water resistant	Yes
Waterproof	No
Factory refurbishable	No
U.S. FDA	Listed with the FDA as a Class II exempt medical device

B. StepWatch™ 3 Dock Specifications

Size	106 x 68 x 31 mm
Weight	150 Grams
Communication	USB to computer, IR to StepWatch™
Batteries	Not required
LED status indicators	3

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