



Modus Trex™ Activity Monitor & Docking Station

Version 3.4
Modus Trex™
Patient
Manual

Modus Trex™ Patient Manual

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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.

The StepWatch™ Activity Monitor detects steps for a wide variety of normal and abnormal gait styles and cadences ranging from a slow shuffle to running. 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.

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.

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.

The dock is NOT water resistant or waterproof. The 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.

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. Please contact your clinician with Modus Trex™.

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
circuit,

battery**



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

B. Setting up the StepWatch™ Program and Data Files

Your clinician should have programmed and started the StepWatch™ for you. Instructions for downloading the software and report generating are contained elsewhere in this manual.

C. 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 anklebone 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.
- 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. Modus Trex™ Dock and Software Installation Instructions

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

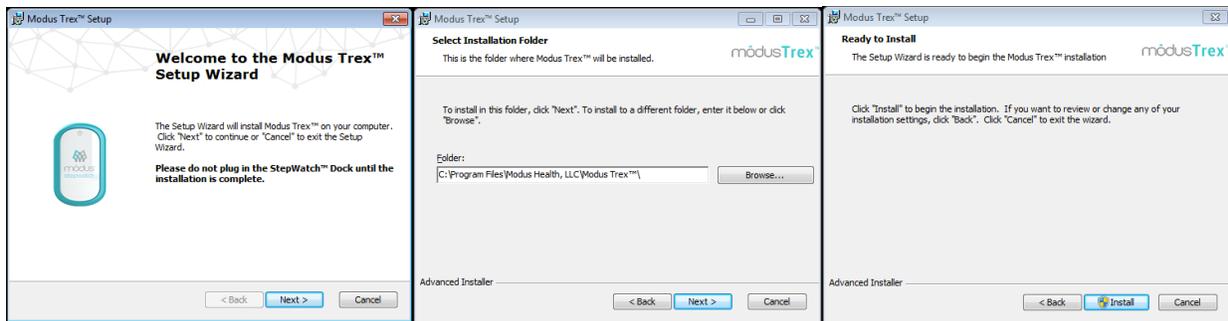
- Microsoft Windows XP SP3 (features may be limited), Vista, Windows 7, Windows 8+
- Apple OS X 10.7+

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.**

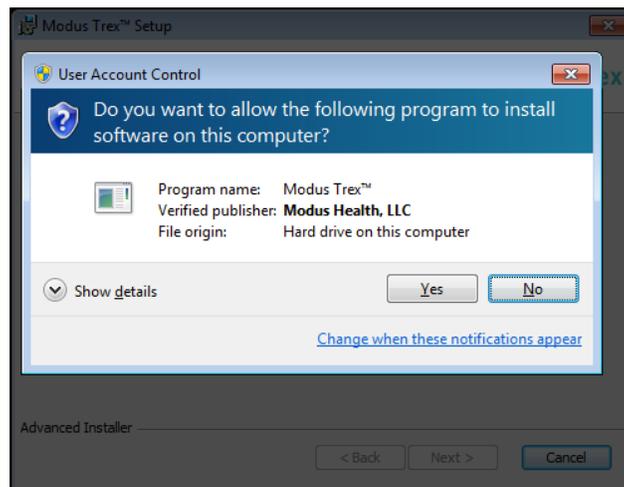
A. Installation Instructions for Windows XP SP3+

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:



3. 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.

B. 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.

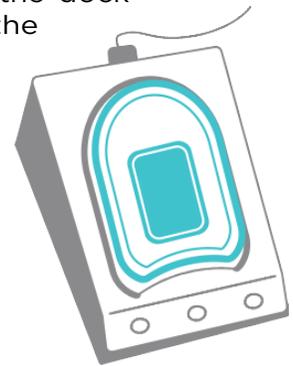
C. Installing and Using the Dock

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.

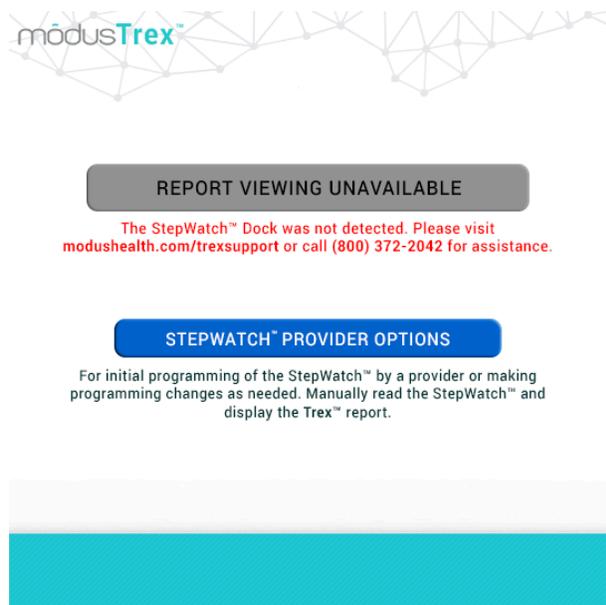


PLACE THE MONITOR ON THE DOCK

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:



If this occurs, please contact your clinician for help.

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

III. General Data Information

A. Generating Your Activity Report

Your clinician should have programmed and started the StepWatch™ for you. If it has been at least 5 days and you wish to view your 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.



VIEW REPORT AND RESTART STEPWATCH™

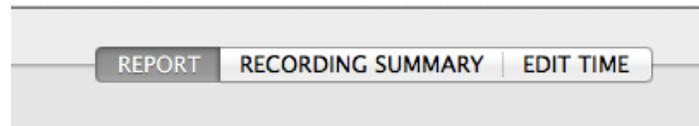
For patients and wearers of the StepWatch™. Reads the most recent data session, displays the Trex™ report, and re-programs the StepWatch™. Minimum of five days recorded is required.

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.

B. Viewing the Trex™ Report

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



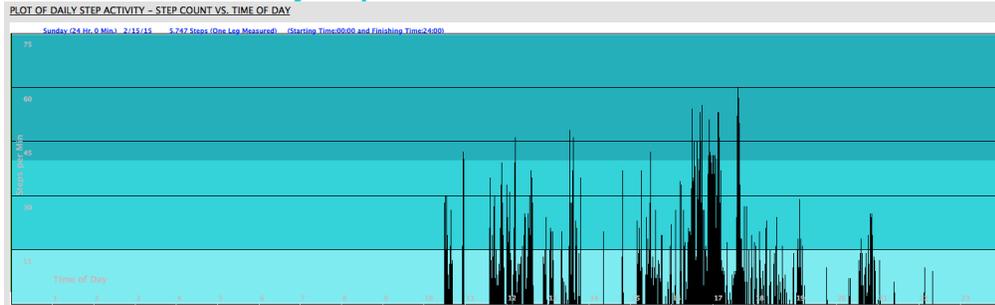
- **“REPORT”** includes the monitor ID, the time the monitor was programmed and read, unique ID, your name, demographic information, and your clinician’s opinion of your functional level score and other metrics. If you disagree with your functional level score, discuss your score with your clinician and make notes on the printed report about days that were not characteristic of your usual activities. If any of the days have invalid data such as you wore a different prosthetic limb, you can remove those days under EDIT TIME so that they are not averaged into your functional level or metrics.
- **“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 (see “Change Included Time” for more details).

C. Representations of the Step Data

1. Graphical Representations of the Data

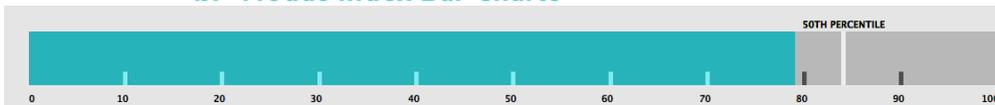
There are several tools providing graphical representations of the data. For a more complete understanding of the analysis calculations see “*Analysis Variables and Calculations*” in this manual.

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.

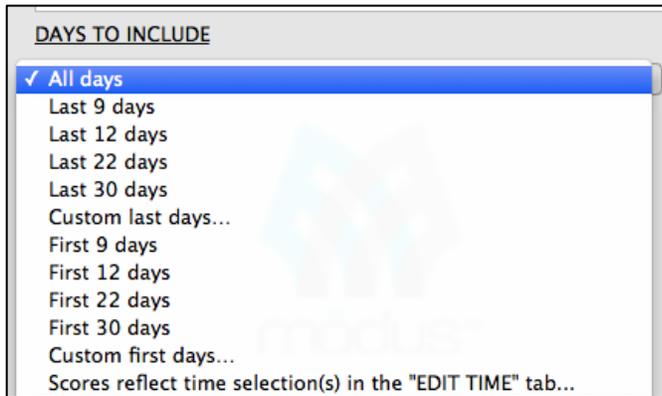
b. Modus Index Bar Charts



The bar charts display the overall functional level index (Modus Index), the ambulation energy index, the peak performance index, and the 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.

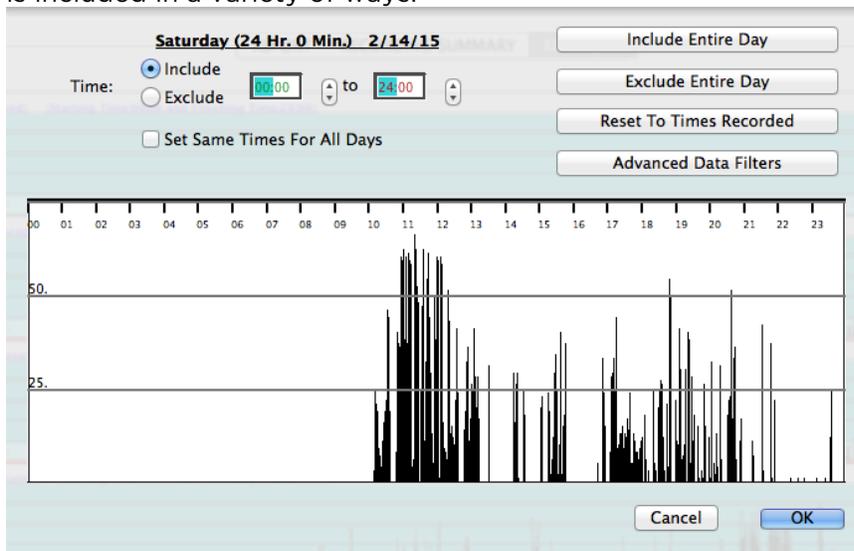
c. Filtering Data for Analysis

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.



2. Change Included Time

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



a. Start/Stop Bars

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

b. Digital Time Controls

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

c. Include/Exclude Day

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

d. Include/Exclude Range

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

e. Reset to Original

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

f. Make All Days the Same

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

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

D. 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

'Clinical Observations' score is the clinician's opinion of your functional level based on clinical judgment, walking demonstration in the clinic, and your reported activities.

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.

<input type="checkbox"/> 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.	<input checked="" type="checkbox"/> 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.
<input type="checkbox"/> 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.	<input type="checkbox"/> 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.
<input type="checkbox"/> 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.	

b. Modus Index

Your overall walking function. Its value is on a 0 to 100 scale so that its percentage can be compared to normative values of healthy persons with intact, unimpaired limbs, of the same age decade (50th percentile). Your score 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.

l. 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 you are 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 you have increased your range of walking cadences. This typically occurs when your 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 your 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 you do not walk for at least one continuous minute each day. A decrease in stance/swing time means you are taking less time with each step.

2. Handling Data Files

a. Save

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.

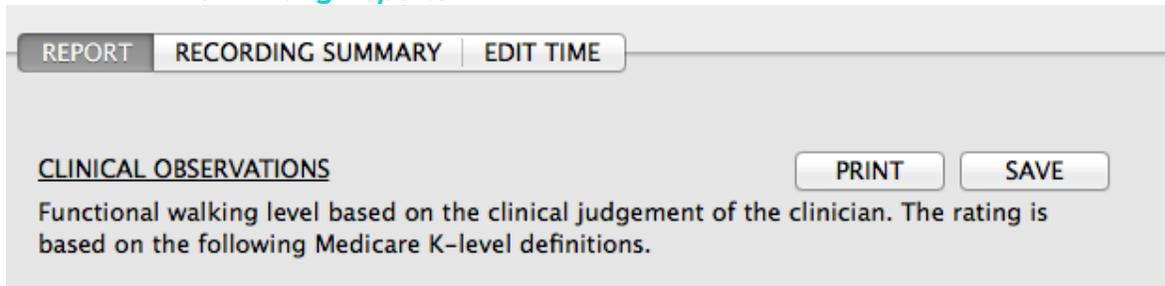
With either “Save” or “Save As” the specifications for the time you have chosen to include or exclude for analysis will be saved with the file. The excluded data will not be lost and will be available for inclusion later.

b. Opening and Closing Files.

- **Open:** The Open command allows you to open a StepWatch™ 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.

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.

IV. Troubleshooting

Please contact your clinician for help.

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.
- Make sure the StepWatch™ is properly aligned on the dock.

V. 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 46°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

In Partnership with:



More than distribution.
Partnership.