

StepWatch 4 for Research



User's Guide



Updated April 2021

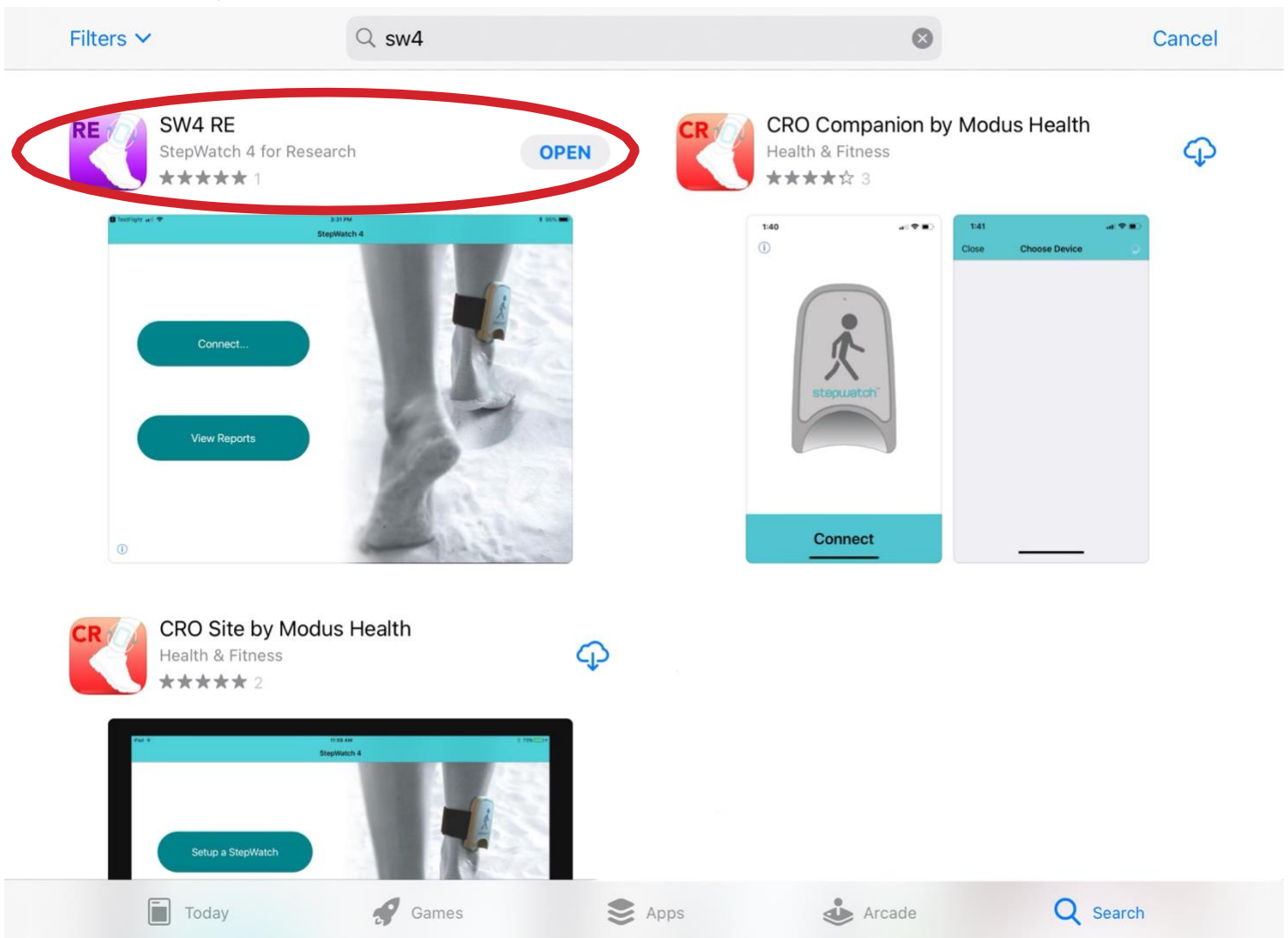
Table of Contents

Installing the App.....	2
Video Tutorial.....	2
How to Wear StepWatch	3
Connecting to StepWatch.....	4
Setting Up a Participant Profile	5
Select Existing Profile	6
Create New Profile	6
Create Anonymous Profile.....	6
Recording Data with StepWatch	7
Use Previous Settings	7
Quick Setup	8
Classic Setup	9
Setup for Sprinters	10
Advanced Setup.....	10
Setup Details	11
Clearing StepWatch	12
Reading Data from StepWatch	13
Storage Mode	14
Using Streaming with StepWatch.....	15
Using Change Mode.....	16
Viewing Saved Data.....	17
Exporting Saved Data	19
Appendix 1: Stepwatch Hardware , Care & Safety	20
Table 1: Hardware Specifications	20
Charging and Cleaning StepWatch.....	21
Appendix 2: Metrics & Data	22
Appendix 3: Technical Support.....	24
Appendix 4: References	25

Installing the App

The StepWatch RE app supports iPad devices running iOS 13 and later. The StepWatch 4 RE app can be installed from the App Store. Search for “SW4” or “RE SW4” or “RE by Modus Health” and select the app.

If you are viewing this manual on iPad, you can tap [this link](#) to download the app directly. Once you’ve installed the app, simply tap it to launch.



Video Tutorial

This user's guide is accompanied by a video tutorial available on our website at modushealth.com/software/#research.

How to Wear StepWatch

Inserting the Strap



First, pull the strap through the slots on the back of the monitor.



Then pull the strap through the plastic ring, and secure using the Velcro tip.

Wearing StepWatch



The StepWatch should rest just above the anklebone, on the outside of the leg.



StepWatch does not require skin contact. It can also be worn over a sock.

Incorrect Wearing



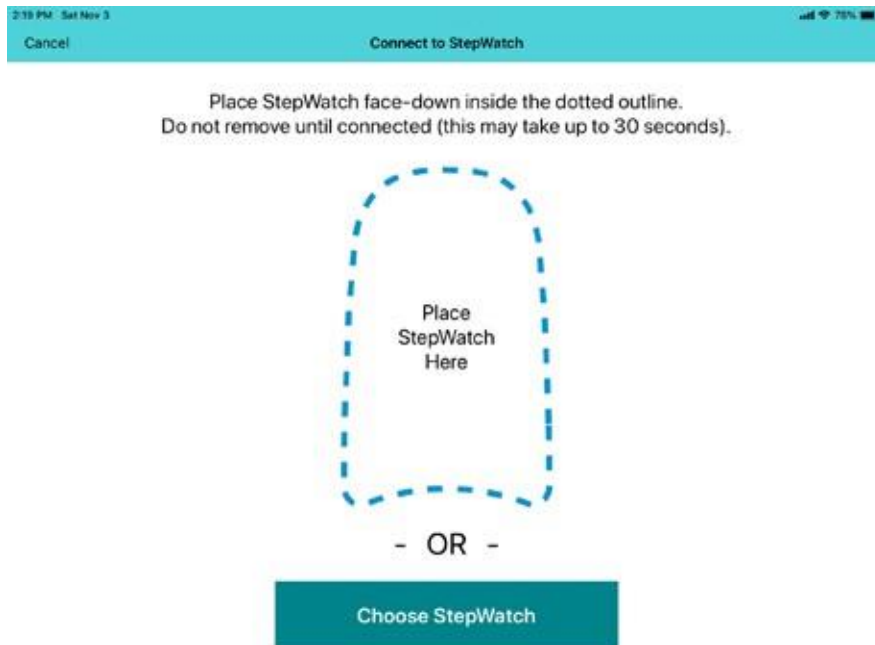
Upside down.



Inside the leg.

Connecting to StepWatch

In order to record data with or read data from a StepWatch device, you'll need to connect it to the StepWatch RE app via Bluetooth. First, tap "Connect..." from the app's main screen. The Connect to StepWatch screen will appear.



There are two main methods of connecting to StepWatch:

- 1) Place the StepWatch face-down on the iPad screen where indicated.
- 2) Tap "Choose StepWatch," then select the StepWatch from the list.

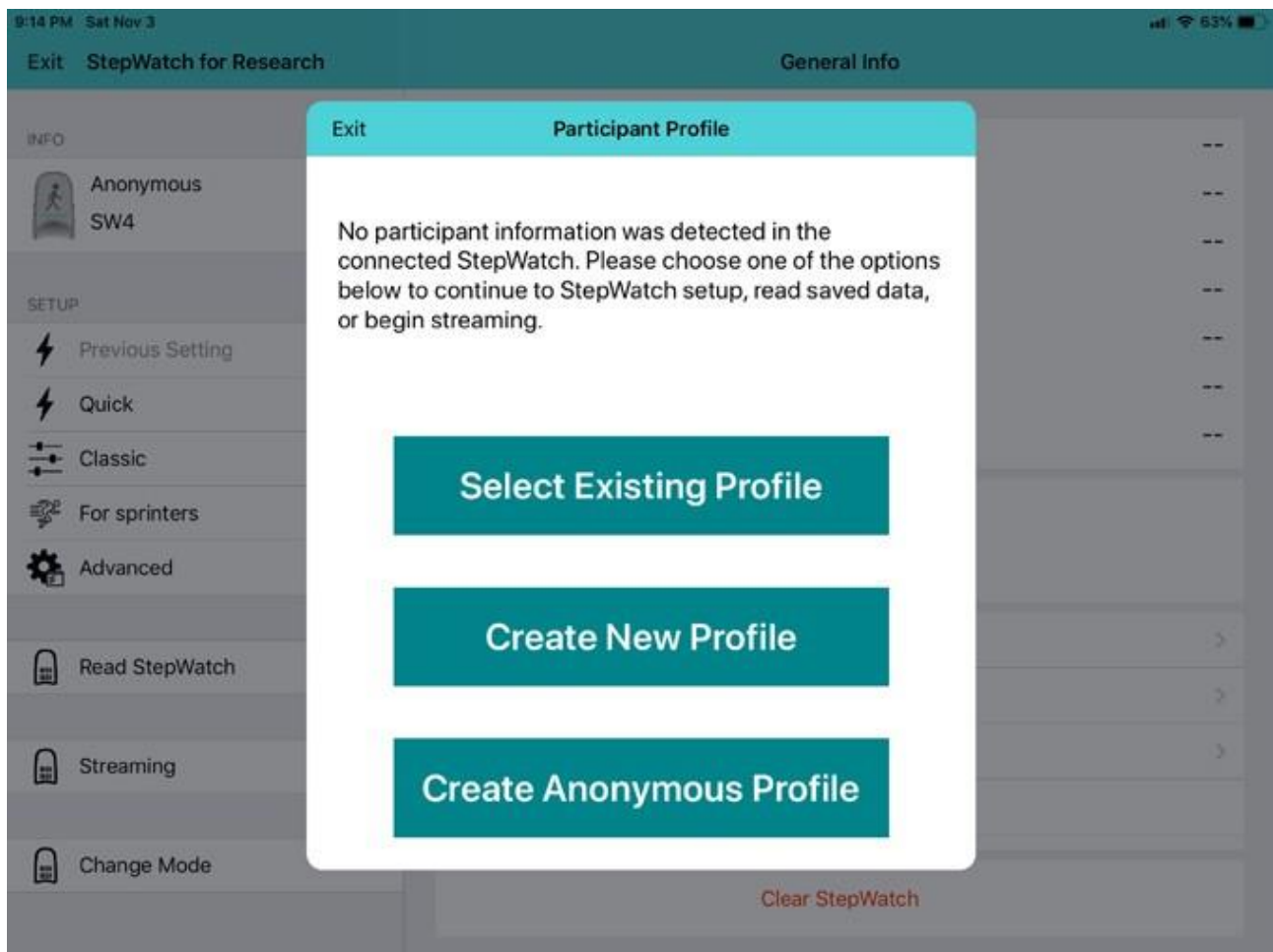
When using option #2, the StepWatch is listed by Bluetooth ID (printed on the back of the device under the barcode). If you cannot connect to your device, the StepWatch may be out of battery and need to be charged, or your StepWatch may be in storage mode. To bring StepWatch out of storage mode, place StepWatch on the charger for at least 10 seconds.

WARNING: Always disconnect StepWatch from the app by tapping Exit after completing your purpose in the RE app. Leaving StepWatch connected to the app can significantly reduce battery life.

Setting Up a Participant Profile

The StepWatch RE App uses a Participant Profile system to enable you to collect and analyze data from multiple study participants at the same time, from the same device.

After connecting to the app with a StepWatch device, you will need to select a Participant Profile if a Profile is not already programmed into the StepWatch. The choices are “Select Existing Profile”, “Create New Profile”, or “Create Anonymous Profile”.



Select Existing Profile

The app will show the existing profile choices. Selecting one will allow adding data to this Participant Profile.

Create New Profile

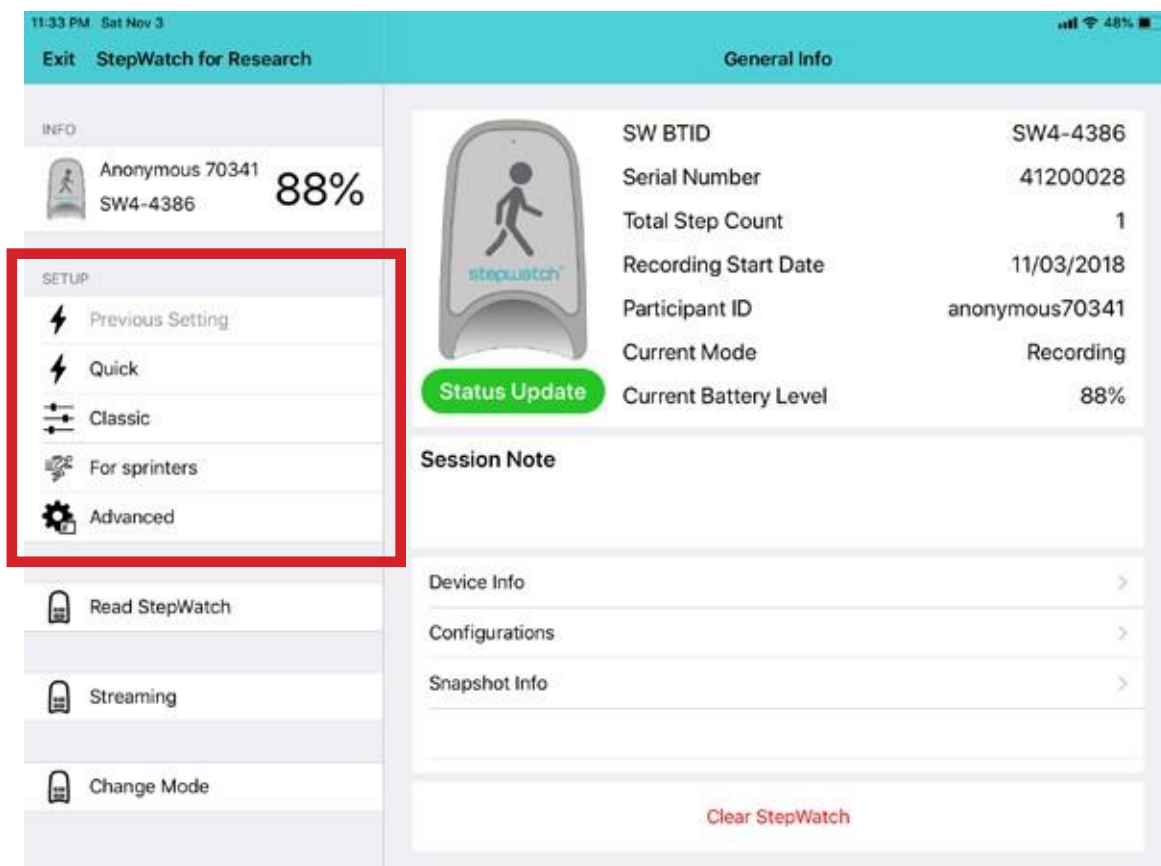
Allows you to create a profile with a Participant ID with the option to add a friendly name, stride length, and participant note.

Create Anonymous Profile

The Anonymous profile means that that the app chooses a unique Participant ID for you. This is a quick and easy option to use if you don't already have a naming convention or system for your study participants.

Recording Data with StepWatch

After connecting StepWatch to the RE app, you can use one of five Setup options to program StepWatch to record step data. The five Setup options are: Previous Settings, Quick, Classic, For Sprinters, and Advanced.



Use Previous Settings

This option is only available if you have previously set up a StepWatch for this Participant ID **and** have used the app to read and save data for that participant. Selecting it will program StepWatch with the same settings last used to record data for this participant.

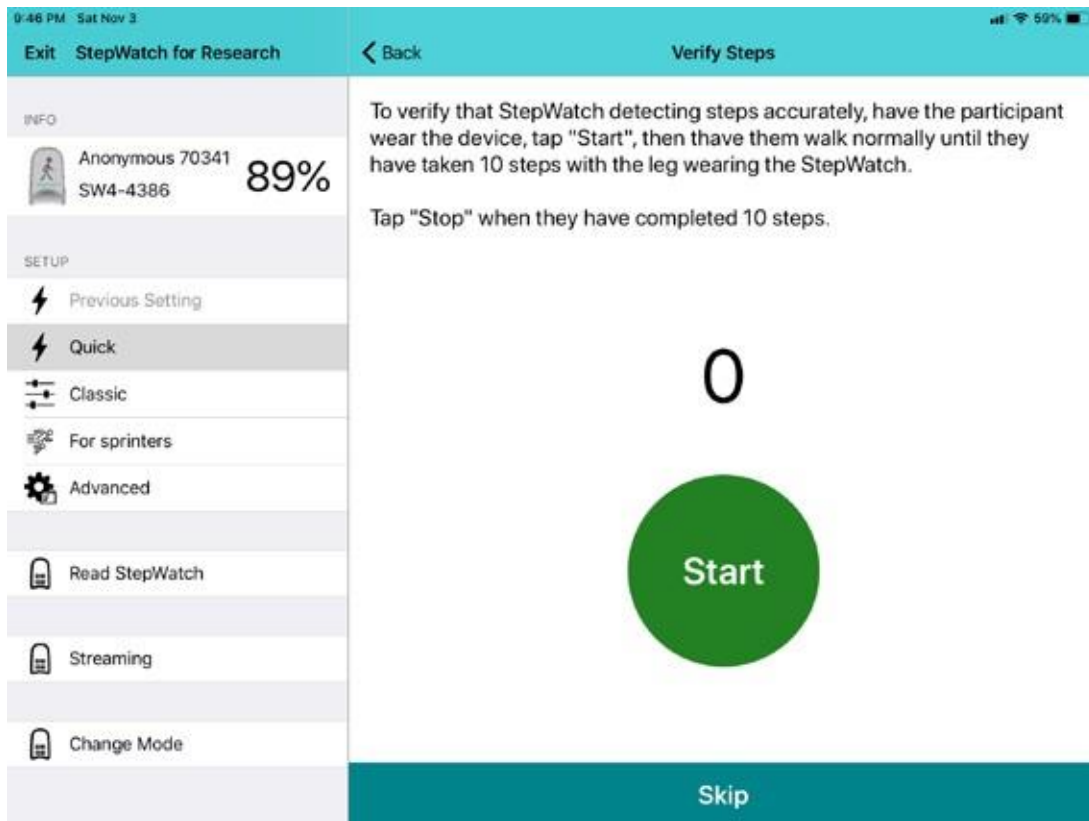
Quick Setup

The Quick Setting offers a simplified setup. It requires entering the height of the participant and answering two questions about the participant's walking habits. The app then uses these inputs to tune how the StepWatch will detect steps.

Note: Select “Yes” to “Does the participant frequently run or jog?” if your participant will be running or jogging at least once a week.

Quick Setup Step Verification

This function verifies that StepWatch is recording steps accurately (within 90% accuracy) for the participant's normal walking speed. It requires having the participant take 10 steps on the leg wearing StepWatch after tapping the Start button. When considering both the left and right leg, this will be 19 – 21 total steps depending on what foot they start and end with. This verification is meant to be a quick option for people to confirm that the settings are in the right ballpark for the individual being measured. It is based on two publications that followed this method before performing a more thorough accuracy protocol [1,2].



Quick Setup allows for only one verification. If StepWatch over- or under- counts by more than 10% (1 step), the algorithm is auto-adjusted and setup progresses. If you want more tries to verify the settings, try using the Classic Setup option instead.

Classic Setup

Classic setup replicates the setup process from StepWatch 3. Default settings will be accurate for the large majority of the population. If unsure, keep settings as default.

Classic Setup Step Verification

Classic setup allows for multiple verification. If StepWatch over or under counts by more than 10% (1 step), the algorithm is auto-adjusted, and you are given the option to re-verify to confirm that the auto-adjusted settings are now accurate for the participant. If the auto-adjust process gets to the limit of the algorithm or if you have tried 3 auto-adjustments unsuccessfully, the Modus Health technical support number will appear for further assistance. You may skip verification at any time.

Setup for Sprinters

This setup is only for persons at least 5 feet tall that typically run faster than 6mph (2.7m/s). It is based off of a publication that found that a new combination of settings improved StepWatch accuracy for running while maintaining accuracy at slow walking speeds [3]. However, these settings will not be optimal for participants that do not run. This setup has not been tested in children or shorter adults.

Setup for Sprinters Step Verification

For Sprinters setup, you can verify the accuracy for walking, but if inaccurate, there is no auto-adjustment. The app will recommend using a different setup procedure.

Advanced Setup

Advanced Setup provides full control of the two parameters that affect how StepWatch detects steps (sensitivity and cadence). Advanced Setup retains the Sensitivity and Cadence values last used to setup a StepWatch for the participant. Otherwise, it retains default settings of 72 for cadence and 12 for sensitivity. Advanced Setup also allows the adjustment of the number of LED flashes after setup. This is the number of times StepWatch will flash a green light when it detects a step. This is most commonly used to confirm StepWatch is recording and accurately detecting steps for the participant.

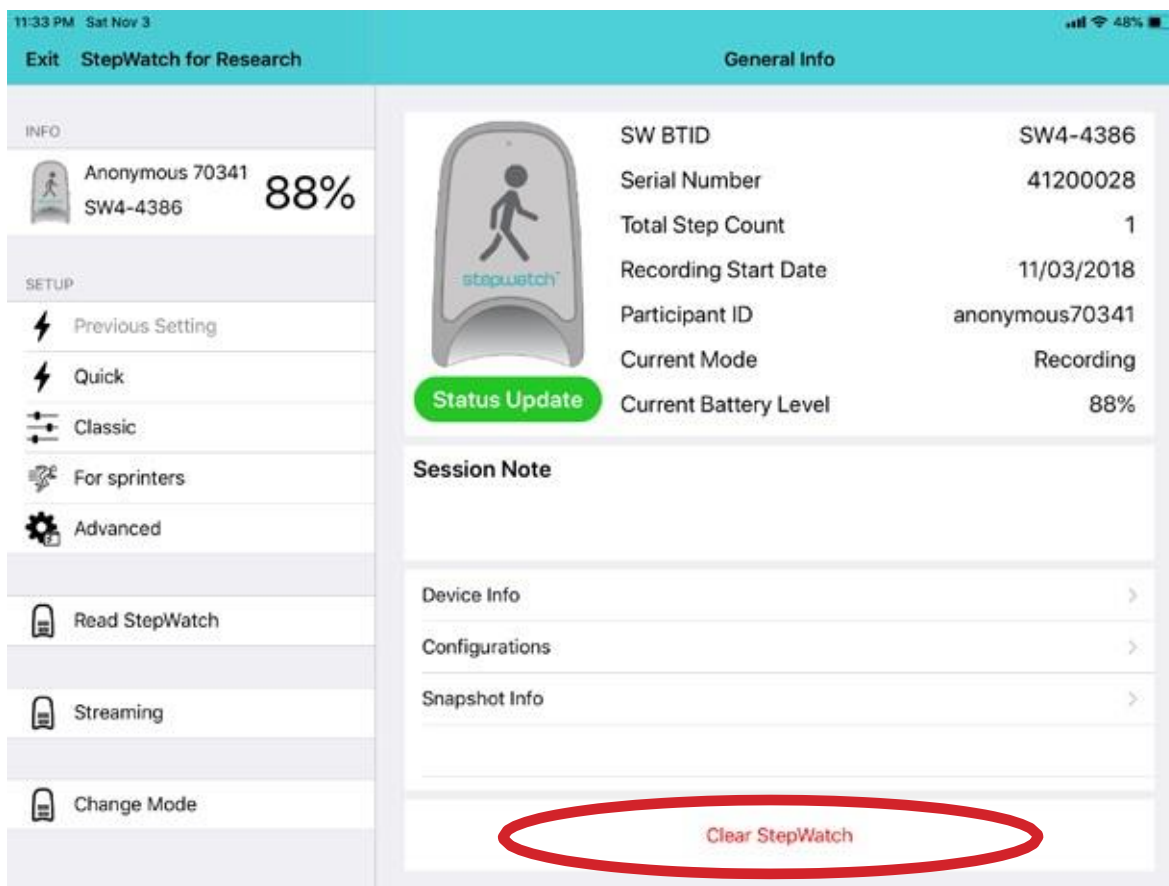
Setup Details

The screenshot shows the 'StepWatch for Research' app interface. At the top, there's a status bar with the time '9:47 PM', date 'Sat Nov 3', and battery level '59%'. Below the status bar, the app title 'StepWatch for Research' is displayed. The interface is split into two columns. The left column has a header 'INFO' and contains a participant icon, name 'Anonymous 70341', ID 'SW4-4386', and a battery level '89%'. Below this is a 'SETUP' section with a list of options: 'Previous Setting', 'Quick' (selected), 'Classic', 'For sprinters', and 'Advanced'. At the bottom of the left column are three more options: 'Read StepWatch', 'Streaming', and 'Change Mode'. The right column has a header 'Session Note (Optional)' with a toggle switch set to '50'. Below this are two more options: 'Timezone (Optional)' and 'Start Date (Optional)', each with a toggle switch. A large teal 'Done' button is at the bottom right.

After setup and step verification, you have the option to specify additional Setup Details, including adding a Session Note, specifying a Timezone, and setting a Start Date. You may add a Session Note to record information about this recording session with this participant such as the kind of activity being monitored. If setting up StepWatch for a participant in a different timezone than the local timezone being used with the RE app, you can change the timezone to be relative to where the participant lives. Finally, setting a Start Date enables the user to program a StepWatch to begin recording at a later date or time. If you wish to begin recording data immediately, do not set a Start Date.

Clearing StepWatch

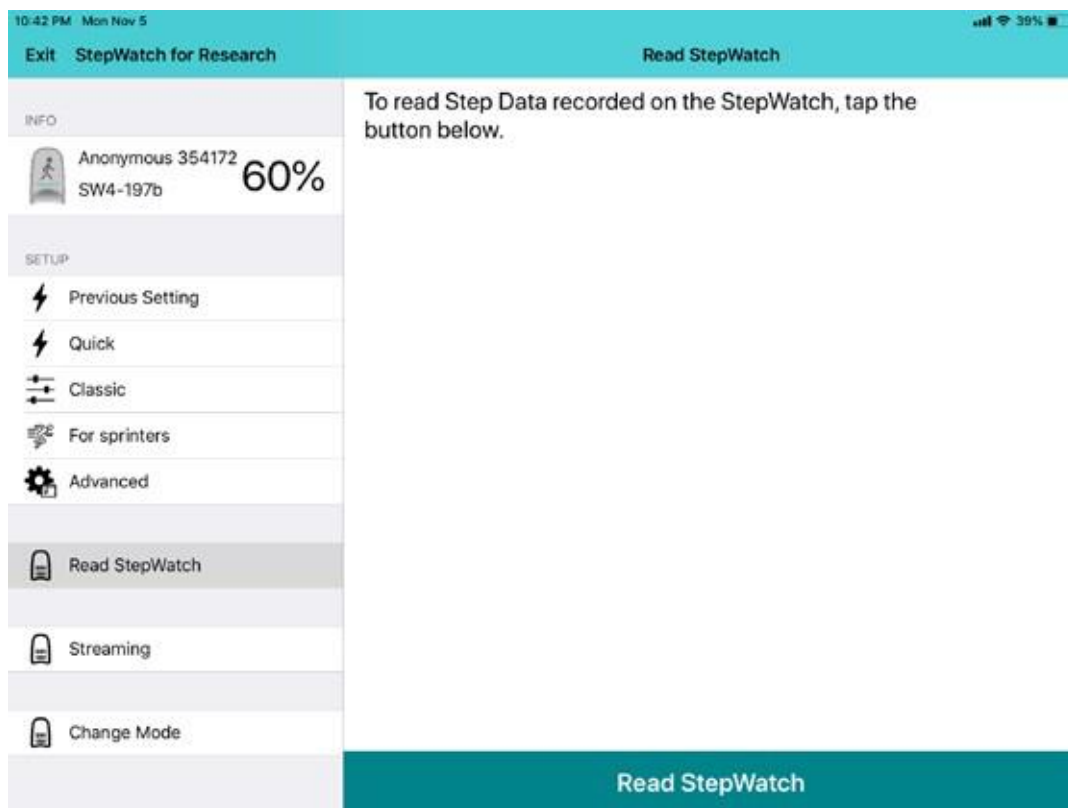
Occasionally, you may wish to fully clear a StepWatch of all previously stored data, including participant association. This can be done by tapping the “Clear StepWatch” button located in the General Info tab while connected to StepWatch. **This option should be used with caution—once deleted, data on a StepWatch cannot be retrieved. See “Reading Data from a StepWatch” instructions below.**



Reading Data from StepWatch

To read and save step data recorded on a StepWatch device, first connect StepWatch to the app (see Connecting to StepWatch above).

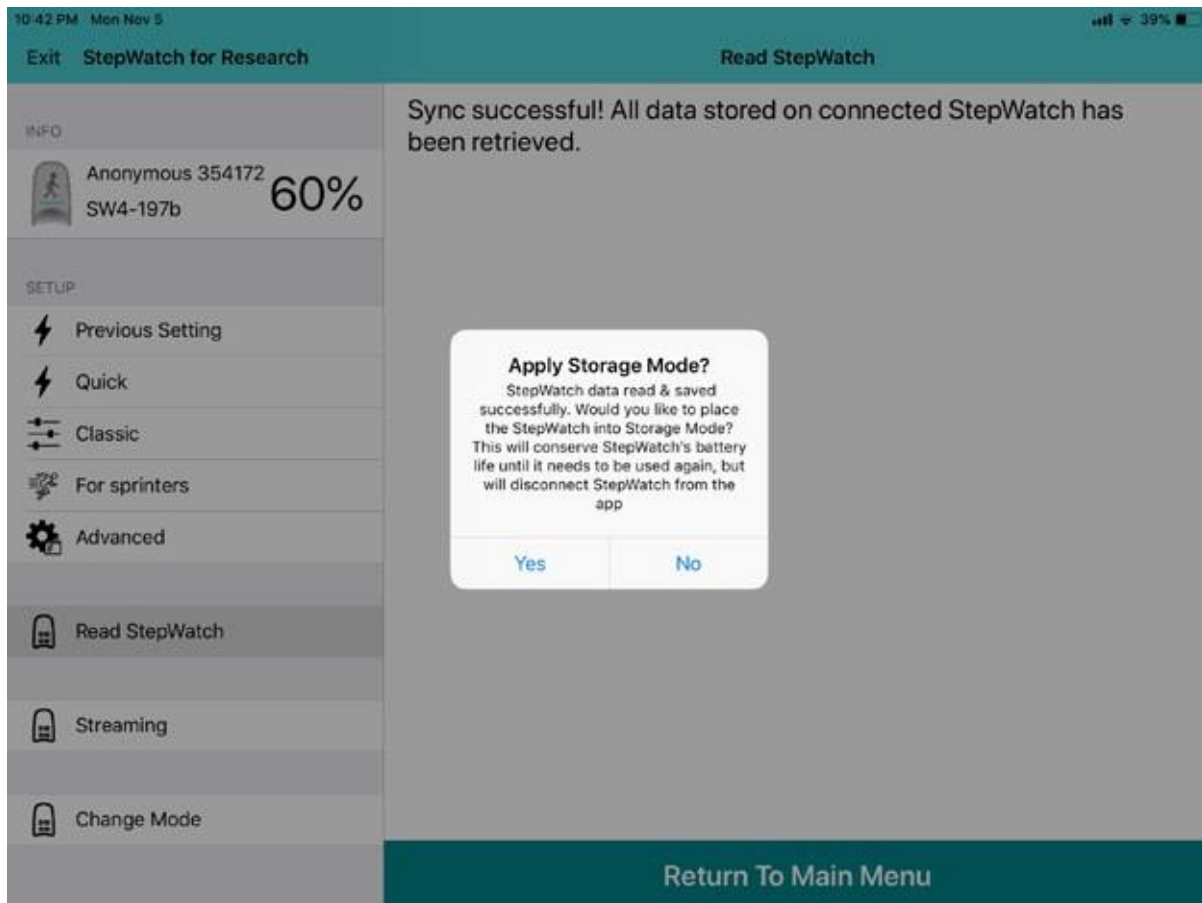
Once connected, select or create a Participant Profile (see Setting Up a Participant Profile above) and then select Read StepWatch from the left-hand menu.



Tap “Read StepWatch” to begin the process. A progress bar will appear to indicate that data is being transferred. Be sure to keep StepWatch within Bluetooth range during the reading process.

Storage Mode

After reading and saving step data from StepWatch, you will be asked if you wish to put StepWatch into storage mode.



Selecting “Yes” turns off the Bluetooth radio. Select “Yes” if you will not be using this StepWatch again immediately and wish to conserve its battery. You will have to wakeup the radio when you want to use this StepWatch again by charging it for at least 10 seconds before connecting to it.

Selecting “No” keeps the Bluetooth radio on so you can connect to it again right away with the RE app.

Using Streaming with StepWatch

Streaming allows the collection of tri-axial acceleration data at 200 Hz. Here is a breakdown of the data output by the streaming function:

	A	B	C	D	E	F
1	StepWatch 4	Accel Data				
2						
3	Device Info					
4	RadiolD	SW4-197b				
5	SerialNumbe	4120003				
6	Cadence	52				
7	Sensitivity	16				
8	SensorEx	100				
9	Threshold	1.05224				
10	0	0.005	-0.13	-0.03	0.93	0
11	0	0.01	-0.13	0	0.99	0
12	0	0.015	-0.17	-0.01	1	0
13	0	0.02	-0.17	-0.04	0.99	0

- The column A is the packet number and goes from 0 – 255.
- Column B is the time duration at 200 Hz.
- Columns C – E are tri-axial accelerations (u, v, w).
(See Appendix 2 for illustration regarding tri-axial accelerations)
- Column F increments when each step is detected.

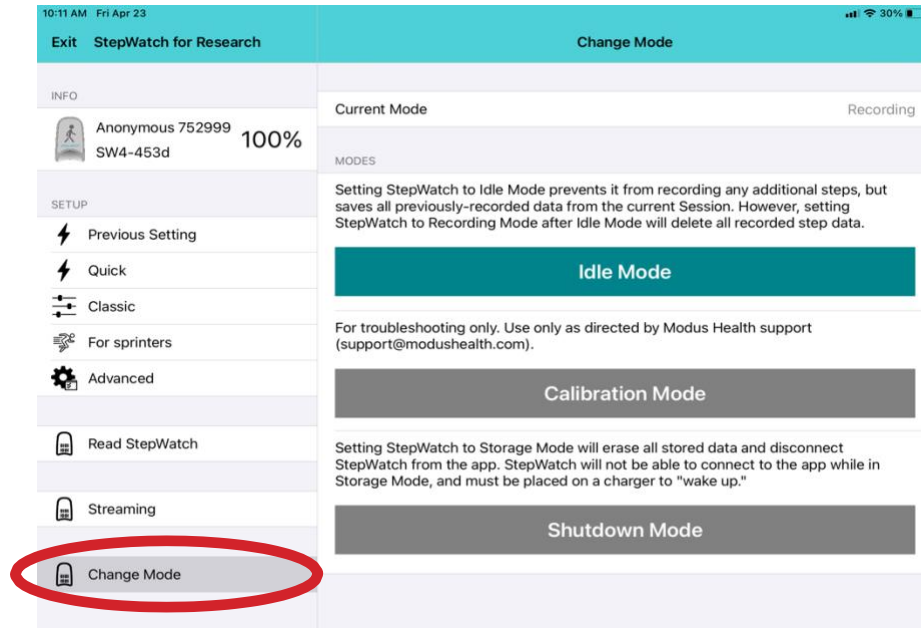
The StepWatch must remain within 30 feet of the iPad during streaming and must remain in line of sight (no walls obstructing the Bluetooth connection).

Finally, please note that long data collection sections will result in large files. It is recommended to focus on one activity within each steaming data collection session by stopping and starting the streaming.

WARNING: Keeping StepWatch paired to the iPad in streaming mode significantly reduces battery life. StepWatch battery life while paired continuously is approximately 5 hours.

Using Change Mode

The Change Mode feature allows you to force StepWatch into a different mode (Idle, Calibration, and Shutdown). These options should only be used with help from Modus technical support.



- **Idle Mode** stops the recording of steps while saving all previously recorded data.

WARNING: Setting StepWatch to Recording Mode after Idle Mode will delete all recorded step data. Be sure to read and save any step data before performing. Setup on a StepWatch in Idle Mode.

- **Calibration Mode** assists in evaluating the function of sensor component, by causing StepWatch to blink (activate LED) after each detected step.

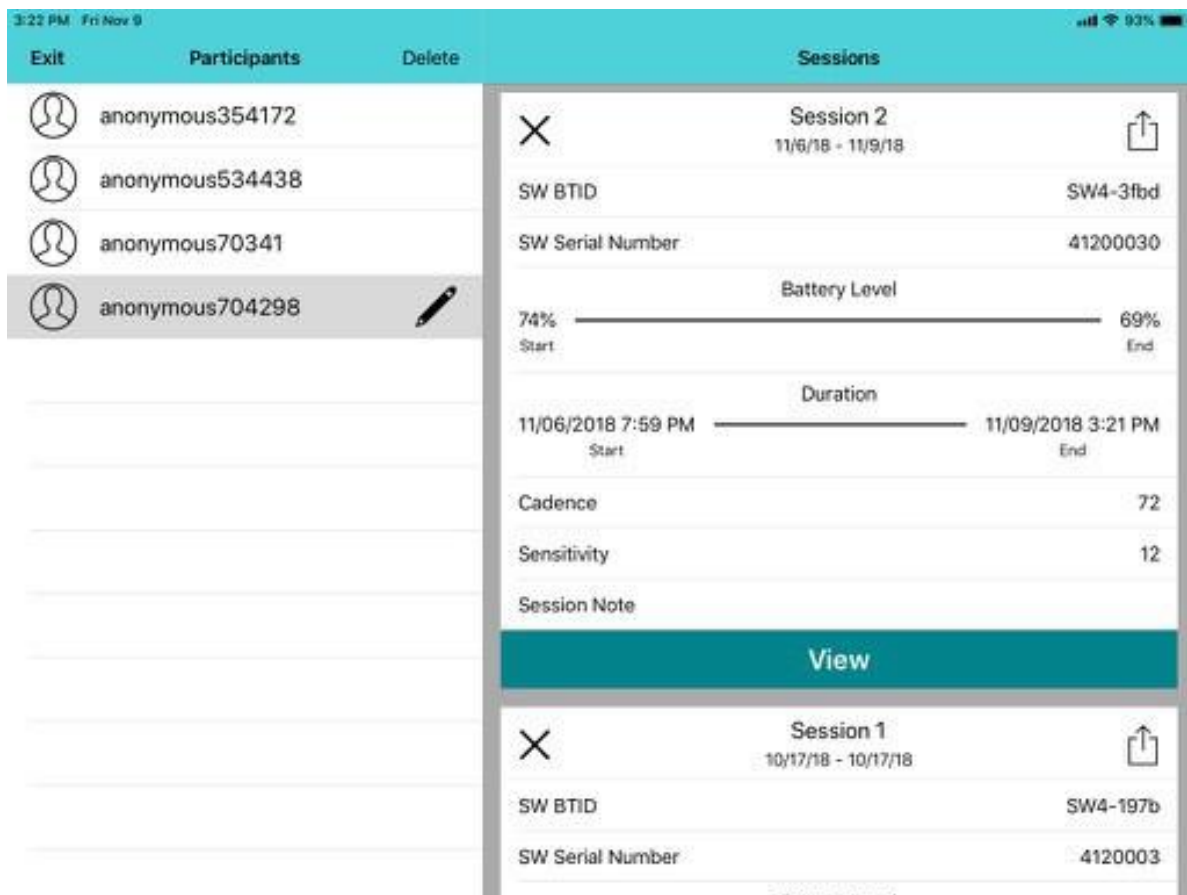
WARNING: Setting StepWatch to Calibration Mode can significantly reduce battery life.

- **Shutdown Mode** (or **Storage Mode**) erases all stored data, turns off the Bluetooth radio, and disconnects StepWatch from the app.

WARNING: To reconnect to the StepWatch after Storage Mode, you must place the StepWatch on a charger for at least 10 seconds to return it to Idle Mode.

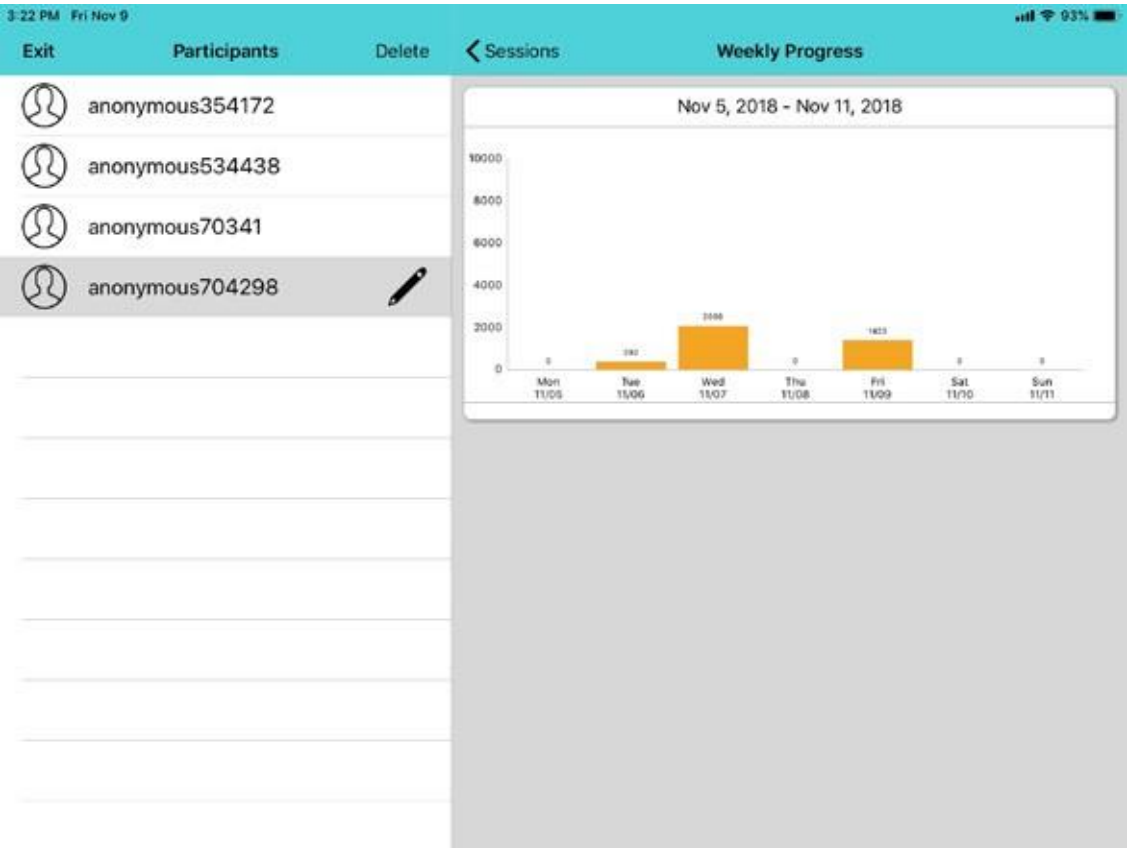
Viewing Saved Data

The StepWatch RE app allows you to not only record and save data with StepWatch, but to view and interact with your data without the need for desktop software. Tapping “View Reports” on the app’s main screen will enable you to view all the data read for each participant.

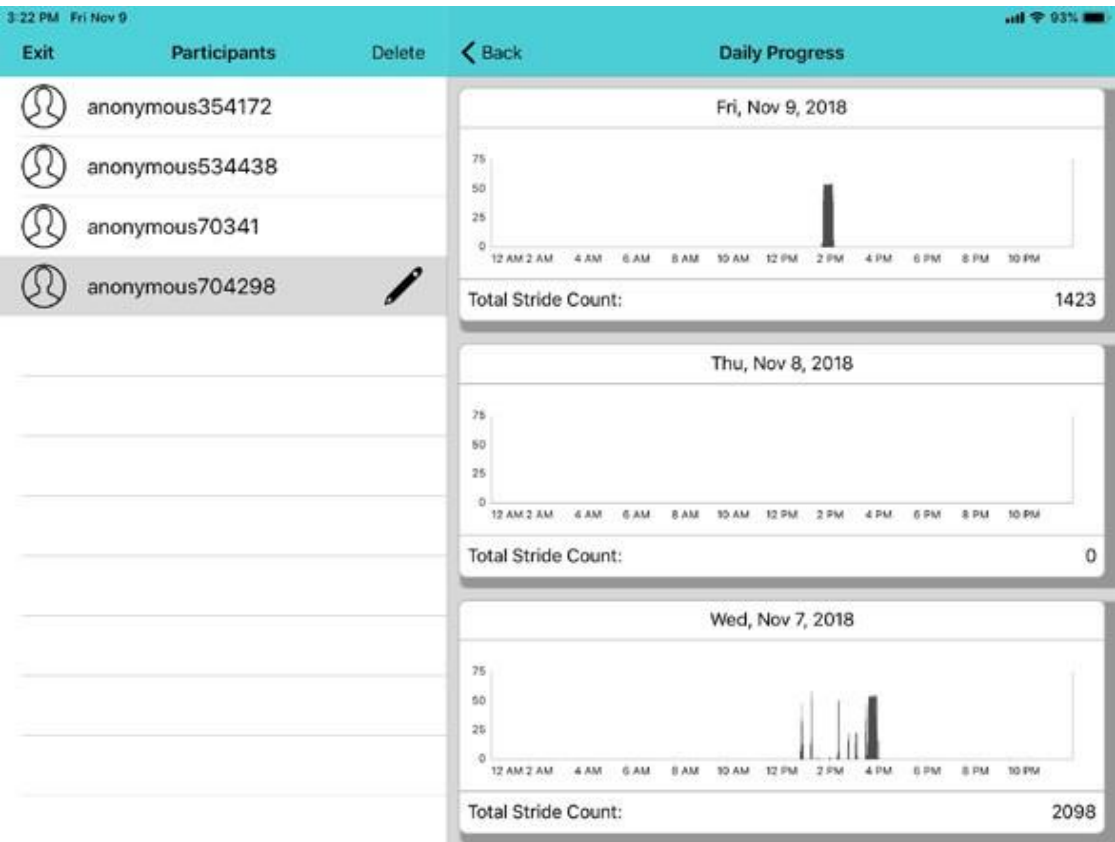


The data is organized into sessions. If you tap “View” on an individual session card, you will see graphs showing steps per day for each day of the week. If you tap on a daily graph, you will see the steps per minute for each minute of that day.

Weekly View

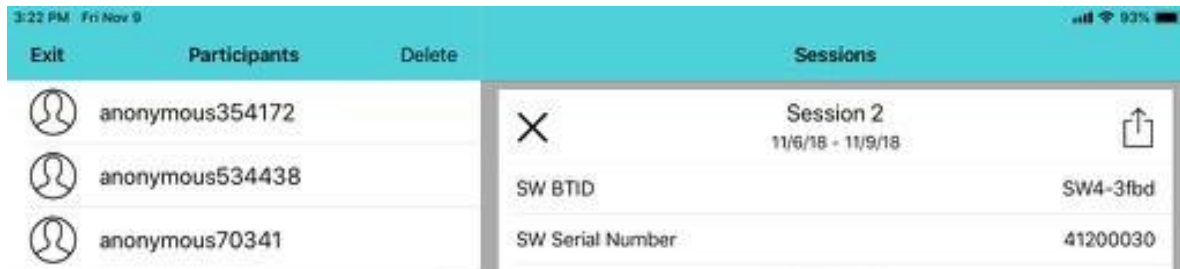


Daily View



Exporting Saved Data

In the top right corner of the session card is the export button.

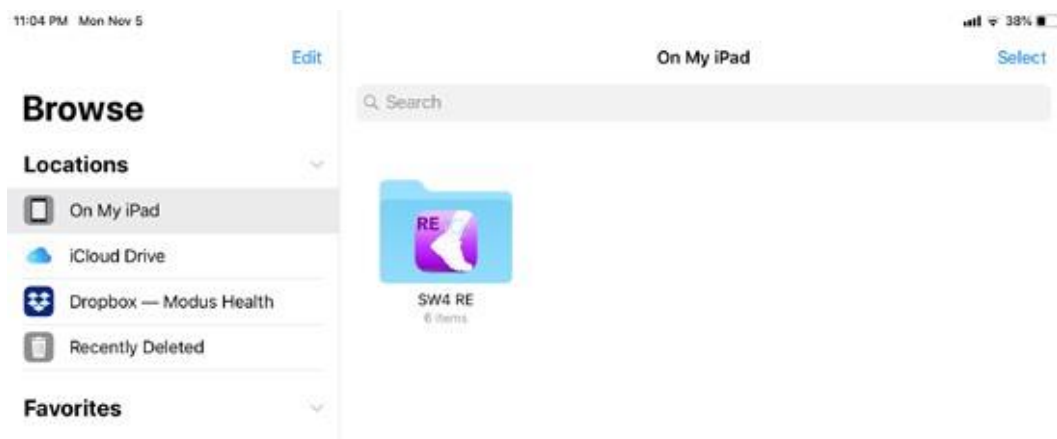


A check indicates files which have already been exported. By default, saving a session automatically generates and exports a metric file, a 1-minute binned file with timestamped steps, and a 10-second binned file with timestamped steps.

To export additional files, simply tap the export button, then tap on the type of file to be exported. All exported files are available via the File App on the iPad.

Retrieving Exported Files

To retrieve exported files, go to the iPad's File App and select "On My iPad" and then tap the "SW4 RE" app folder.



This is where your StepWatch data is stored. You can then use the iPad's native Share feature to export selected files to a file storage service (such as Dropbox or Google Drive) or email the selected files to your email account.

Appendix 1: StepWatch Hardware, Care & Safety

This appendix contains hardware specification information, safety information, and important instructions regarding the care and charging of the StepWatch device.

Table 1: Hardware Specifications

Specifications	StepWatch 4 with StepWatch RE App
Size	75 x 48 x 14 mm
Weight	41 grams
Accurate Step Detection	☑(For all walking styles, including impaired gait)
High Resolution Data	Steps per second
Raw Acceleration Streaming	☑(At 200 Hz)
Communication Method	Bluetooth connection to Apple iPad
Waterproof	☑(IP67 certified)
Battery Life	35 – 41 days of normal use Up to 5 hours of streaming
Wireless Charging	☑
Onboard Memory	Stores 35 - 41 days of normal step activity
Convenient Setup Options	☑
Wearable Soft Cover	☑(Available in small and medium-large).
2 Year Warranty	☑

Charging and Cleaning StepWatch

Always follow these instructions when charging or cleaning the StepWatch device.

Charging StepWatch

DO



To charge StepWatch, place it face-down on the center of the charger.

A light will illuminate when your StepWatch begins charging.

DON'T



Do not place StepWatch on edge of charger.



Do not place StepWatch upside-down on charger.

Charging the StepWatch is unnecessary. The StepWatch battery should last more than two weeks. Patients should **only** charge their StepWatch if instructed to by their Site Coordinator.

Cleaning StepWatch



If needed, you can clean StepWatch by rubbing gently with a wet cloth or antimicrobial wipe.



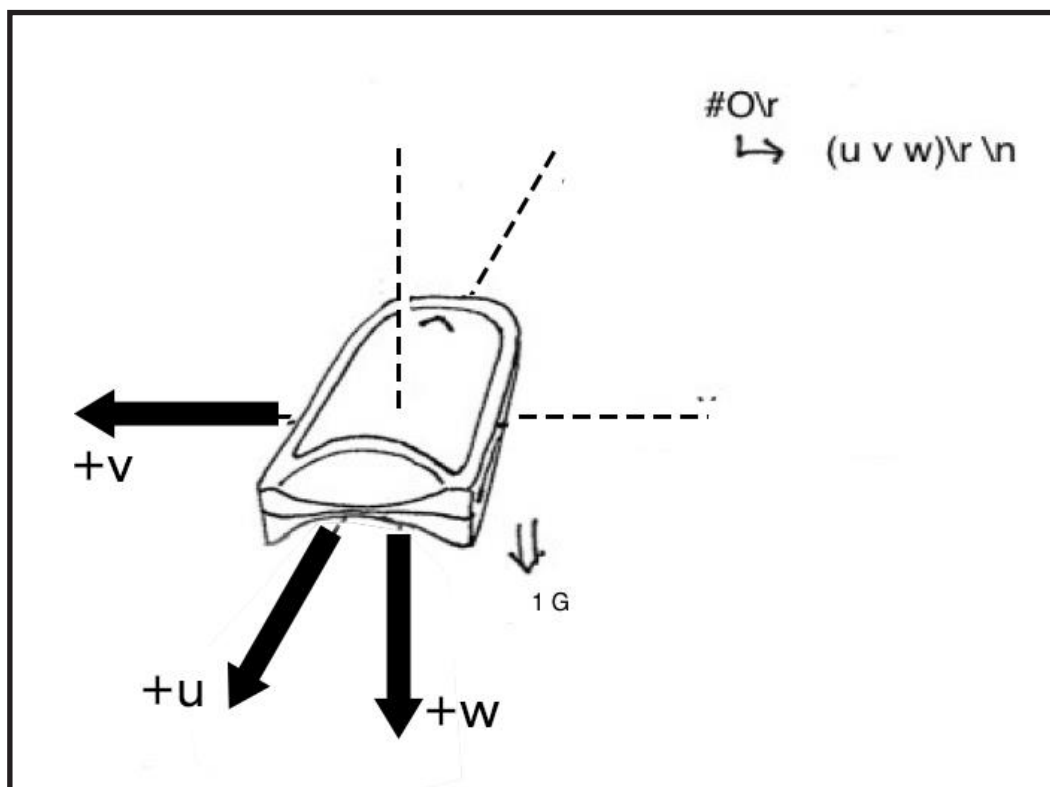
To clean the strap, hand-washing with soap and warm water is preferred. Air-dry, or set dryer heat to low.

Appendix 2: Metrics & Data

SW4 RE Metrics	Description
minutes active	minutes of the day with at least one step
percent time in inactive (%)	percent of 24 hour day with no walking
percent time in low activity (%)	percent of 24 hour day walking at a low activity cadence (default is 1 – 15 steps / minute)
percent time in medium activity (%)	percent of 24 hour day walking at a medium activity cadence (default is 16 – 40 steps / minute)
percent time in high activity (%)	percent of 24 hour day walking at a high activity cadence (default is 41 or greater steps / minute)
stride velocity (m/s)	peak velocity based on the minute with the most steps
cadence average (steps/min)	average cadence based on all minutes with at least 1 step
cadence median (steps/min)	median cadence based on all minutes with at least 1 step
stride length (m)	measured in clinic
max 60 (steps/min)	average cadence of the most intensive continuous 60 minutes of the day
max 20 (steps/min)	average cadence of the most intensive continuous 20 minutes of the day
max 5 (steps/min)	average cadence of the most intensive continuous 5 minutes of the day
max 1 (steps/min)	highest cadence achieved in the day
peak performance index (steps/min)	average cadence of the most intensive 30 individual minutes in the day
percent battery (%)	percent battery associated with last data upload
raw steps timestamp (date and time)	when a step occurred with 1-second resolution
raw steps interval	seconds that passed between each step (255 means no steps, 0 means more than one step with same timestamp)
binned steps timestamp	One minute timestamp for the 24 hour day
binned steps	total steps taken during the minute
raw accelerations	3-axis acceleration at 200Hz

Tri-Axial Acceleration Diagram

The following diagram indicates the relationship of tri-axial acceleration data reported by the Streaming function (see Using Streaming with StepWatch, above) to the StepWatch device's orientation in space.



Appendix 3: Technical Support

If you are having difficulty connecting your StepWatch device to the RE app, first:

- Ensure that StepWatch is not on charger while attempting to connect.
- Ensure that StepWatch has sufficient battery charge to connect—if unsure, charge StepWatch for at least 15 minutes, then try connecting again.

If connection difficulties continue, try restarting the RE app and the iPad.

If problems persist, please contact the Modus Helpdesk at 202-830-1100 Ext 2 or send an email describing the problem to support@modushealth.com.

Appendix 4: References

- 1) A. L. Schmidt, M. L. Pennypacker, A. H. Thrush, C. I. Leiper, R. L. Craik. Validity of the StepWatch Step Activity Monitor: preliminary findings for use in persons with Parkinson disease and multiple sclerosis. J Geriatr Phys Ther 2011; 34(1):41-45.
- 2) R. F. Macko, E. Haeuber, M. Shaughnessy, et al. Microprocessor-based ambulatory activity monitoring in stroke patients. Med Sci Sports Exerc 2002; 34(3):394-399.
- 3) L. P. Toth, D. R. Bassett, Jr., S. E. Crouter, et al. StepWatch accuracy during walking, running, and intermittent activities. Gait Posture 2016; 52:165-170.