Modus Health LLC

Modus Research App Reference Guide for Users

Version 2.8, Feb 2025

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StepWatch System

The following items are needed to collect step data with StepWatch:

- StepWatch 4 or StepWatch 5 device
- ChoeTech wireless charging pad model T511 (5V, 5W) or another model with input 5V and output 5W.
    - *Contact orders@modushealth.com to order more wireless charging pads.*
- Wall Mount Adapter (5V, 10W) such as DigiKey 993-1195-ND
- iPad with Modus Health software: RE, CR, or CC Clinic app. (This manual contains instructions for using the RE app only.)
    - *Visit modushealth.com/software or contact orders@modushealth.com for information about software options.*
- Manual: the most up-to-date manuals can be found at https://modushealth.com/software/

Specifications and system requirements are listed at the end of this manual.

Video Tutorial

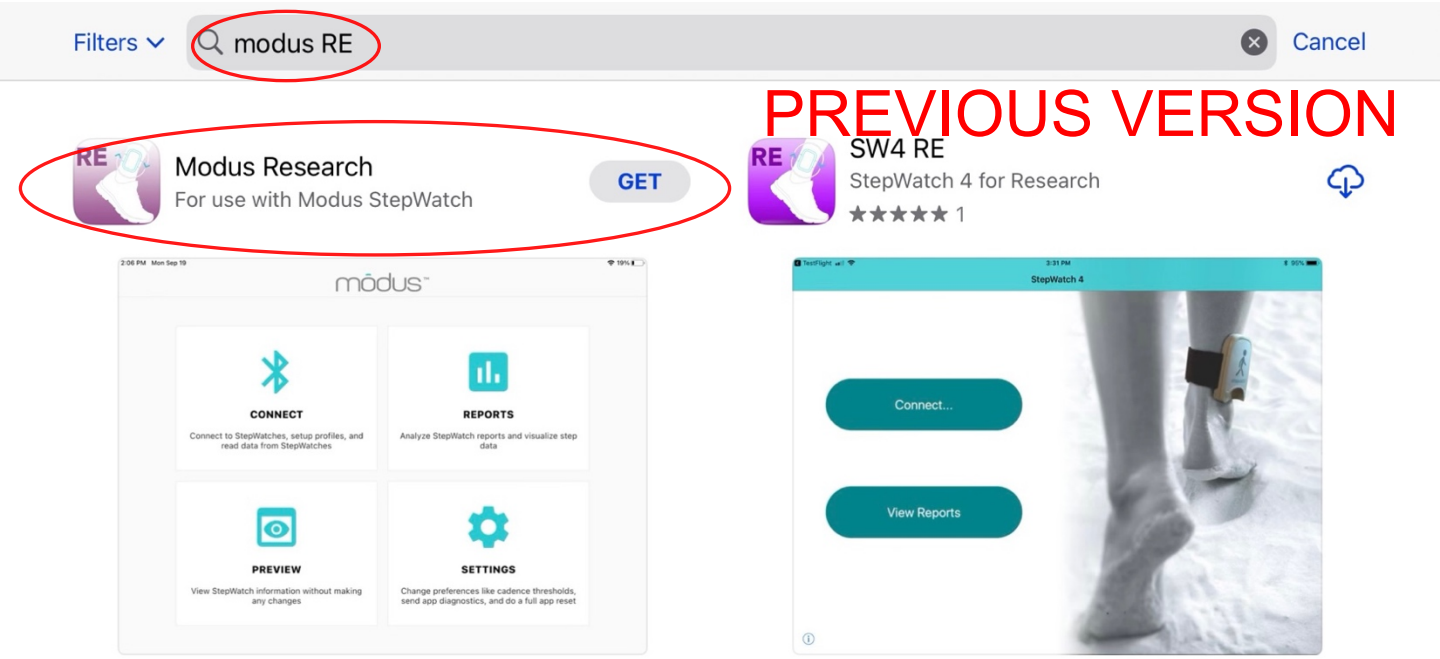
This user's guide is accompanied by a video tutorial available on our website at modushealth.com/software/#research.

Installing the App

The Modus RE app supports iPad devices running on iOS 17 or later. The Modus RE app can be installed from the App Store. Enter in the search bar "Modus Research" or "Modus Research by Modus Health" and select the app. **Do not select "SW4 RE by Modus Health"** as this app is retiring.

If you are viewing this manual on an iPad, you can tap this link to download the app directly. Once you've installed the app, simply tap it to launch. When the popup states "Modus RE Would Like to Use Bluetooth," tap "Allow" as this is required to use StepWatch. Adding a Site ID is optional.

Note: We are transitioning from our SW4 RE app. SW4 RE is retiring and will be removed in 2025.



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See section “Wearing a StepWatch” for more information about handling of the physical device.

Tip: If you are assembling this setup before setting up a participant in the app, you may want to note the device’s Bluetooth ID beforehand. It is located on the back of the device above the QR code and begins with “SW”.

To prepare the StepWatch ahead of the first participant visit or usage, attach the soft cover to the StepWatch.

Thread the Velcro strap though the StepWatch with the Velcro side facing TOWARD the device. Depending on the participant’s ankle size, you will need to select either a small, medium, or large strap. The medium size is the most common. Apply the StepWatch above the ankle so that it is snug enough to not slip down but loose enough that it remains comfortable.

The StepWatch can be worn over a sock and can be worn on either leg, but it needs to be worn on the outside of the leg and facing upright. See “Managing a StepWatch” for additional notes on wearing and maintaining the StepWatch and associated parts

Preparing the StepWatch 5

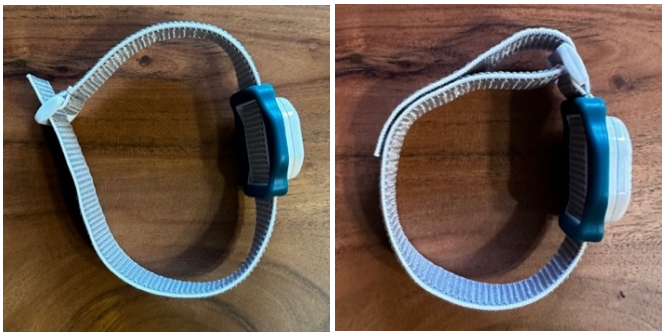
Tip: If you are assembling this setup before setting up a participant in the app, you may want to note the device's Bluetooth ID before attaching the strap. It is located on the back of the device above the QR code and begins with "SW".

You will be provided with a silicone soft cover and 2 nylon strap options, each available in multiple sizes: with a plastic ring and without a plastic ring.

Strap With Plastic Ring

Pull the strap through the slots on the back of the monitor, with the Velcro facing DOWN.

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

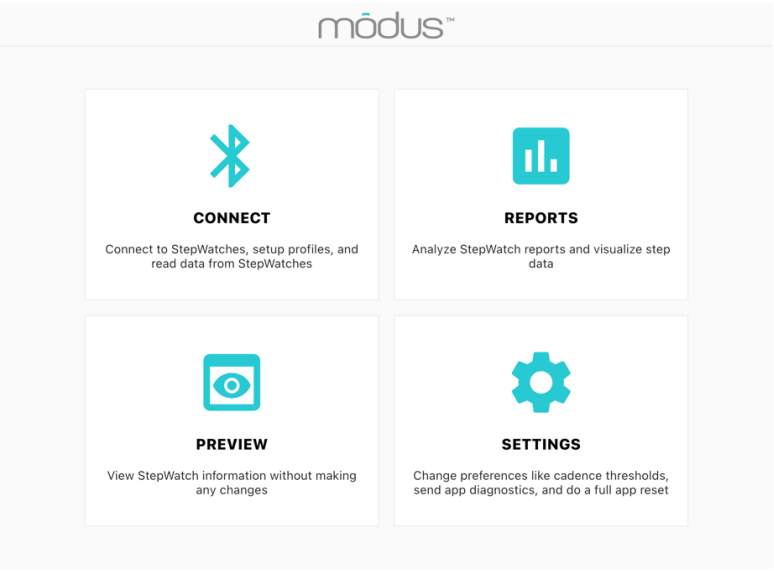


Strap Without Plastic Ring

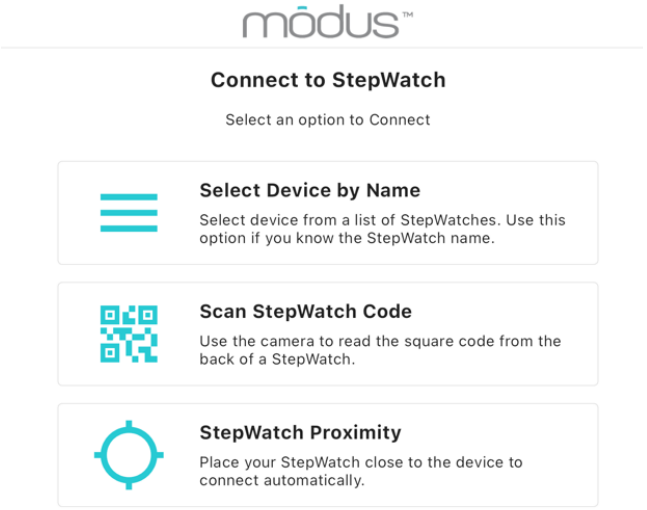
Pull the strap through the slots with the Velcro facing UP.

Connecting to StepWatch

When you open the app, you will be greeted by a menu with 4 options: Connect, Reports, Preview, and Settings. To record data with or read data from a StepWatch device, you'll need to connect it to the Modus RE app via Bluetooth. First, tap "Connect" from the app's main screen. The Connect to StepWatch screen will appear in which you will have three options.



Select an Option to Connect:



1. **Select Device by Name:** Selecting the StepWatch from the list. The Bluetooth ID will appear as "SW#-XXXX." The Bluetooth ID is on the StepWatch label.

2. **Scan StepWatch Code:** Tapping Scan StepWatch Code will activate the camera on your iPad. If you receive a popup that states "Modus RE Would Like to Access the Camera," tap "Allow" to use this feature. Focus the camera on the square code on the StepWatch label to scan.

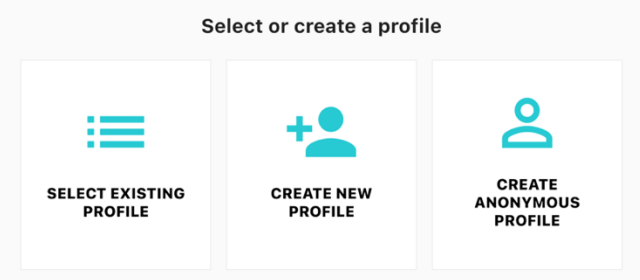
3. **StepWatch Proximity:** Place the StepWatch face-down on the iPad screen where indicated, with the StepWatch label or strap facing up

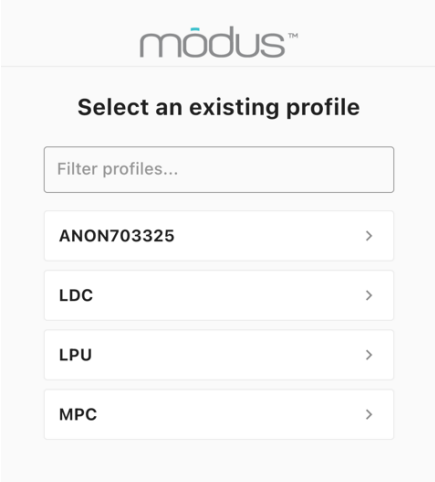
If you receive a connection timeout or do not see the Bluetooth ID in the list with option #1, StepWatch may be out of battery or in shutdown mode. Charge StepWatch and try again. If charging does not work, contact support@modushealth.com for further assistance.

Setting up a Participant

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

After connecting the StepWatch to the app, you must select a Participant Profile unless one is already programmed into the StepWatch. You can choose from the following options: “Select Existing Profile,” “Create New Profile,” or “Create Anonymous Profile.” “Select Existing Profile” is only a choice if you have other profiles saved in the app.



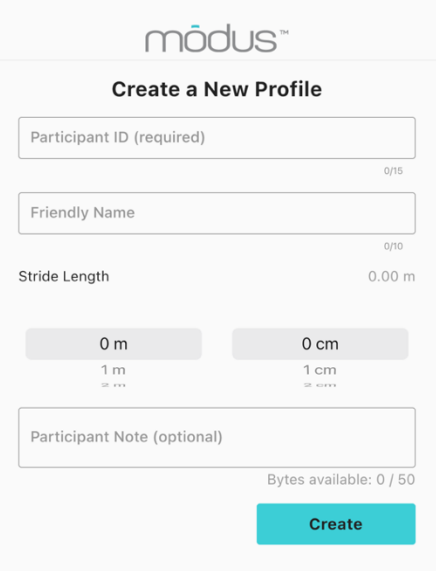


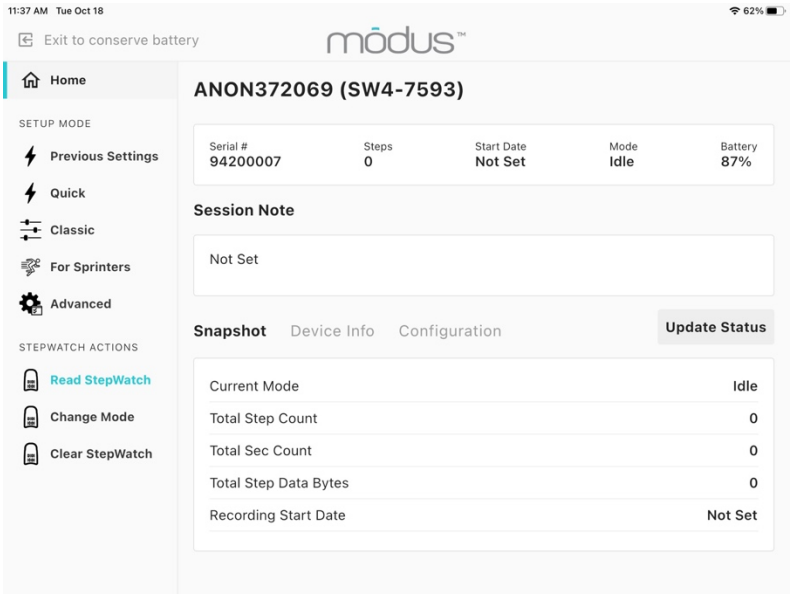
Select Existing Profile

This option will show the existing profiles to choose from.

Create New Profile

This option allows you to create a profile with a new Participant ID with the option to add a friendly name, stride length, and participant note. Only a new Participant ID is required.



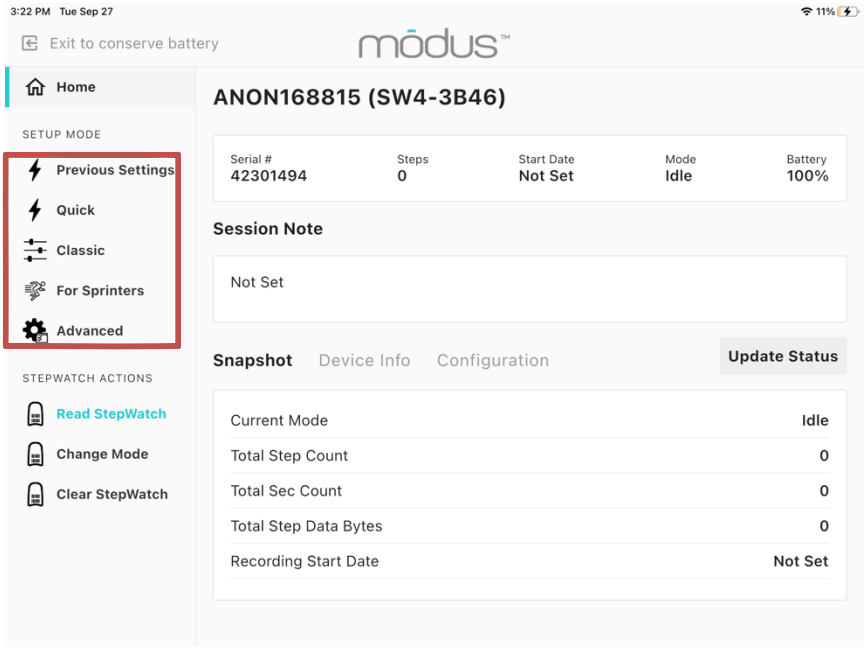


Create Anonymous Profile

The Anonymous profile means that the app chooses a unique Participant ID for you. This is a quick option to use if you don’t already have a naming convention or system for your study participants. Anonymous profiles will start with “ANON” and have a random number after it.

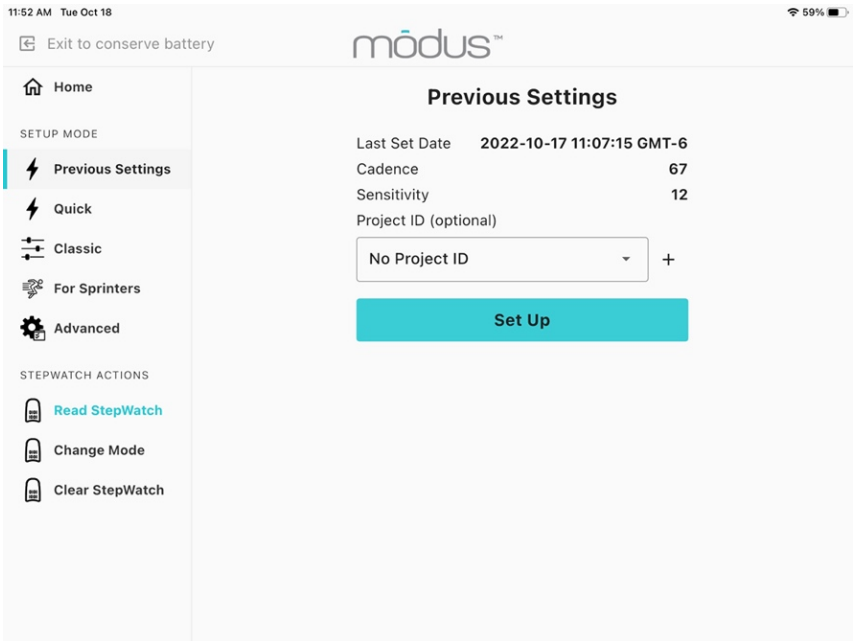
Choosing a Setup Mode

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



Using Previous Settings

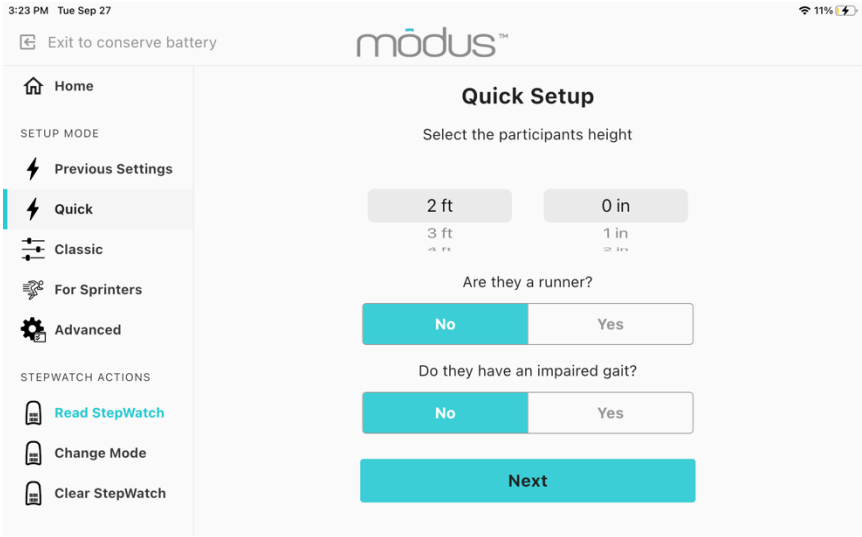
This option is only available if you have previously set up a StepWatch for this Participant ID and have used the app to read and save data for that participant. Selecting it will program StepWatch with the same settings last used to record data for this participant.



Quick Setup

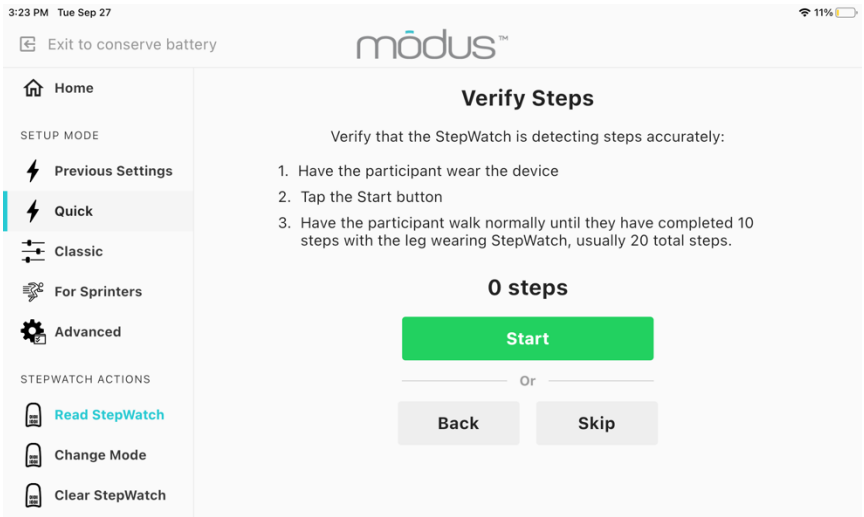
The Quick Setting offers a simplified setup. It requires entering the height of the participant and answering two questions about the participant's walking habits. The app then uses these inputs to program how the StepWatch will detect steps.

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



Step Verification

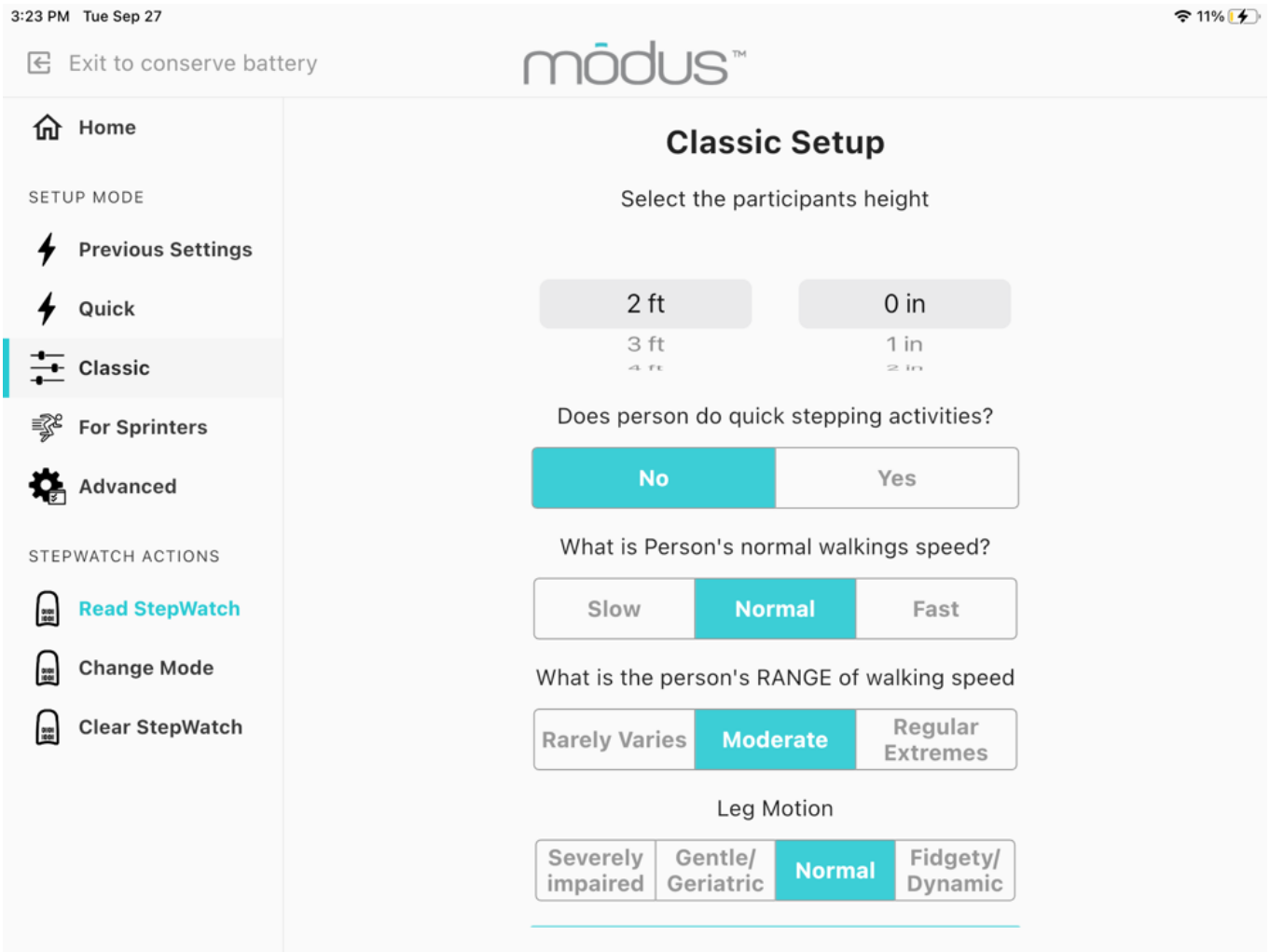
This function verifies that StepWatch is recording steps accurately (within 90% accuracy) for the participant's normal walking. It requires having the participant take 10 steps on the leg wearing StepWatch after tapping the Start button. When considering both the left and right leg, this will be 19 – 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 an acceptable range 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 the legacy device, StepWatch 3. Default settings with the correct height of the participant will be accurate for the majority of the population. If unsure, keep settings as default.

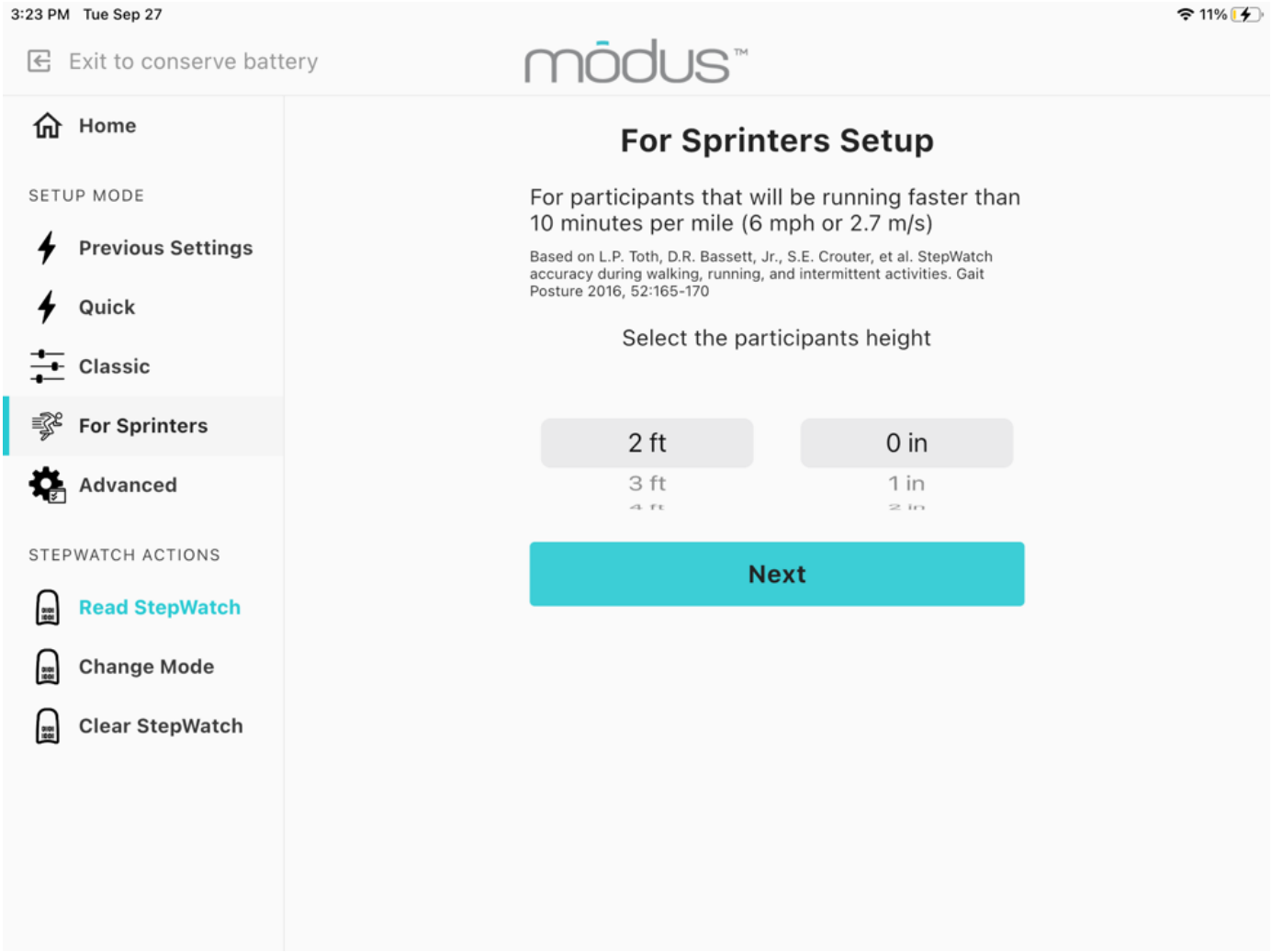


Step Verification

Classic setup allows for multiple verifications. 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.

For Sprinters Setup

This setup is only for participants at least 5 feet tall that typically run faster than 6mph (2.7m/s). It is based off 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.

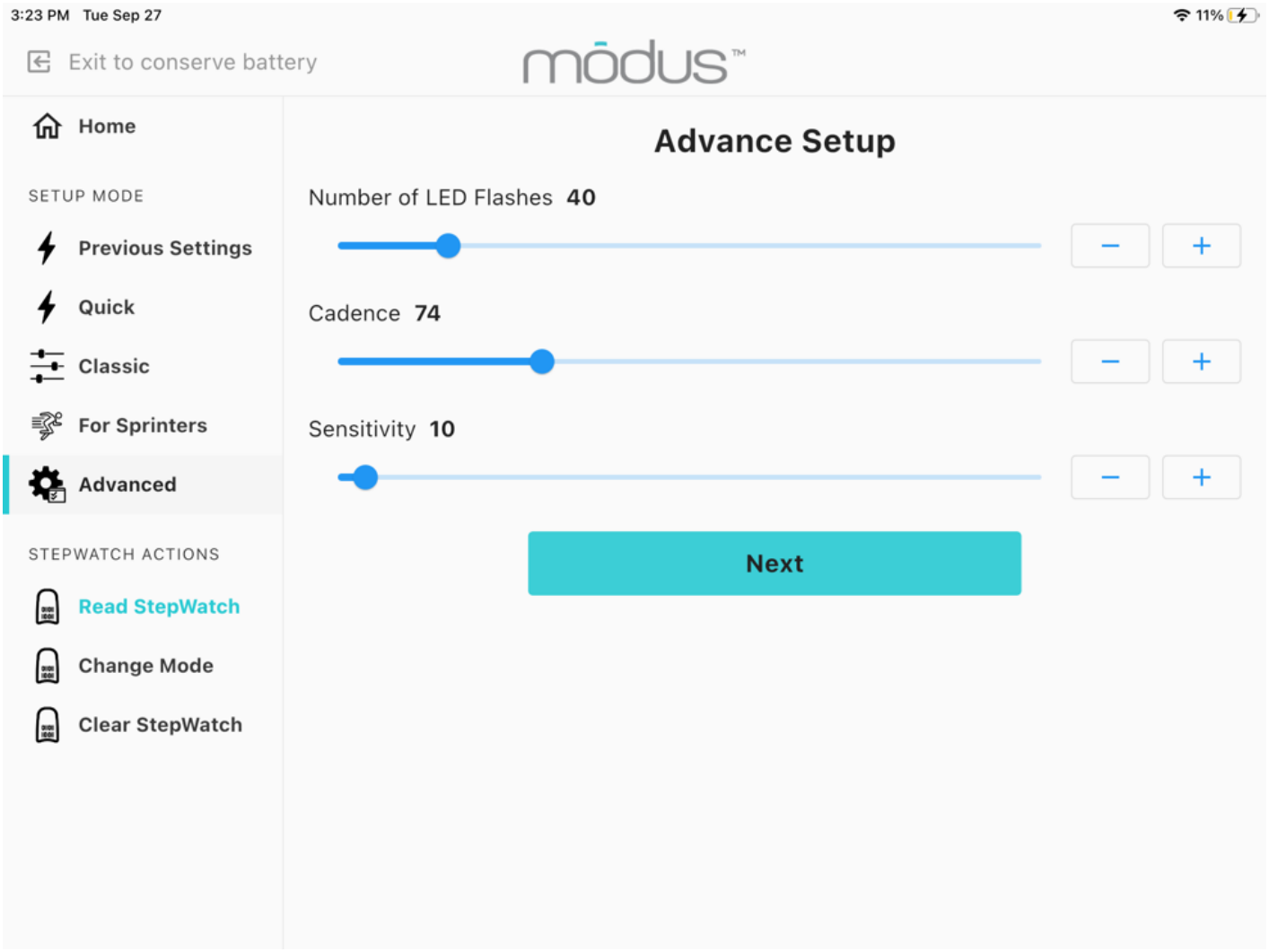


Step Verification

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.

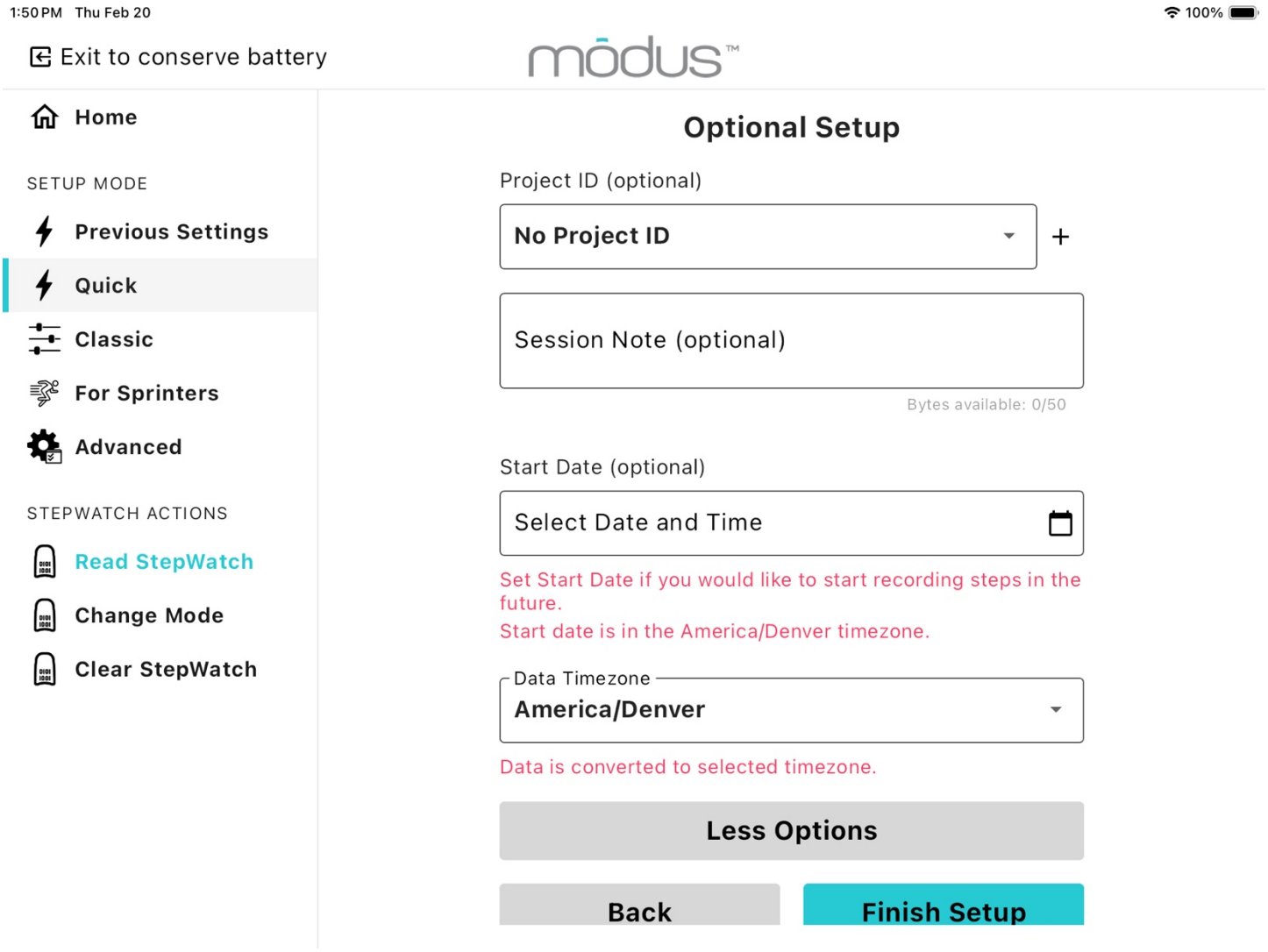
Advanced Setup

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 commonly used to confirm StepWatch is recording and accurately detecting steps for the participant. Only StepWatch experts should adjust Cadence and Sensitivity in Advanced Setup.



Setup Details

After setup and step verification, you have the option to specify additional Setup Details, including adding a Project ID, Session Note, changing the Time zone, and setting a Start Date in the future. A Project ID will appear in the exported metric file to help you keep track of participants within individual projects. 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 time zone than the local time zone being used with the RE app, you can change the time zone 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.

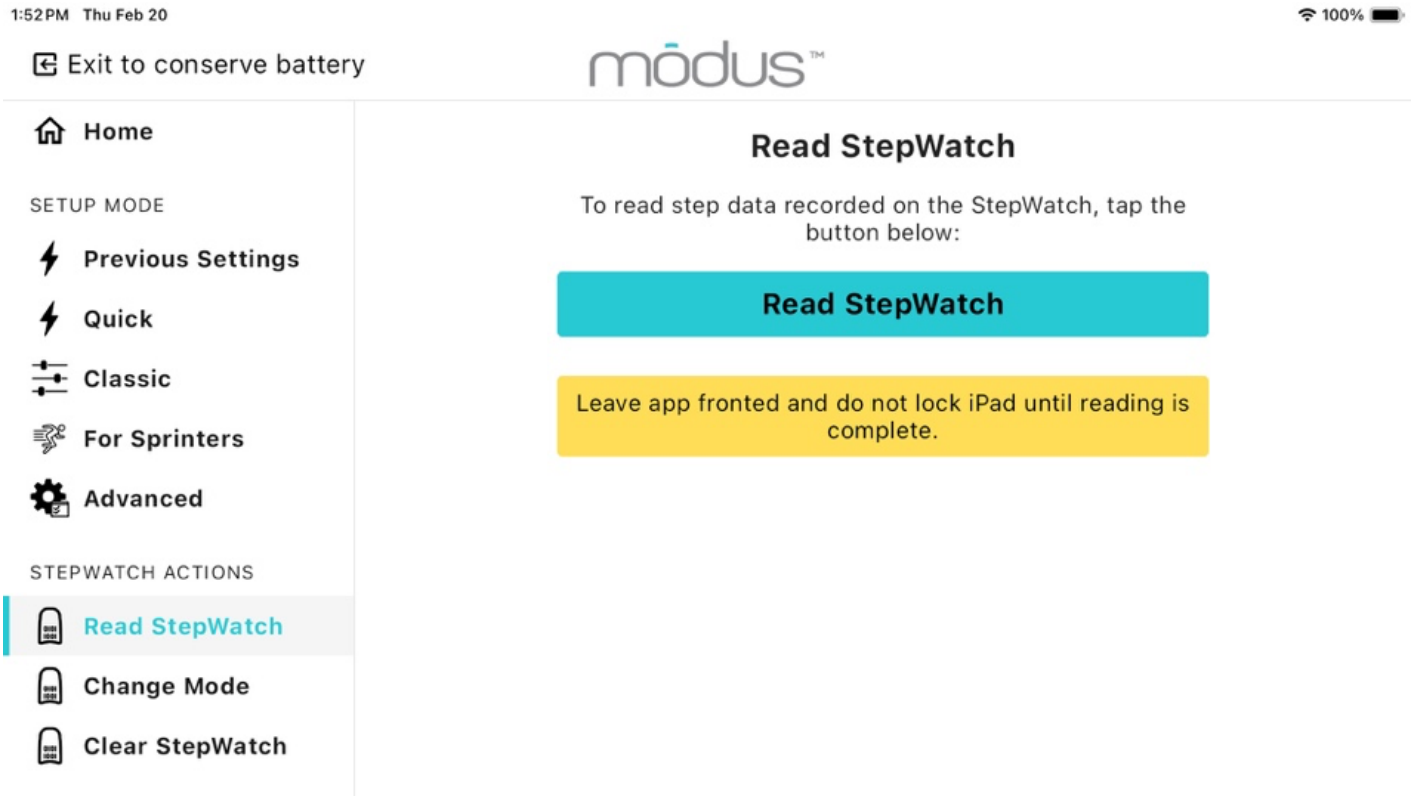


StepWatch Data

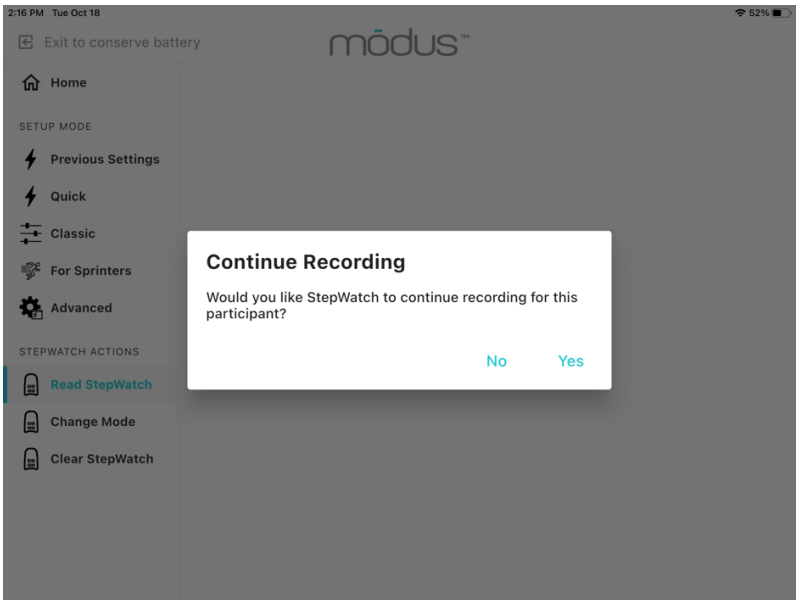
Reading Data from StepWatch

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

Once connected, 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.



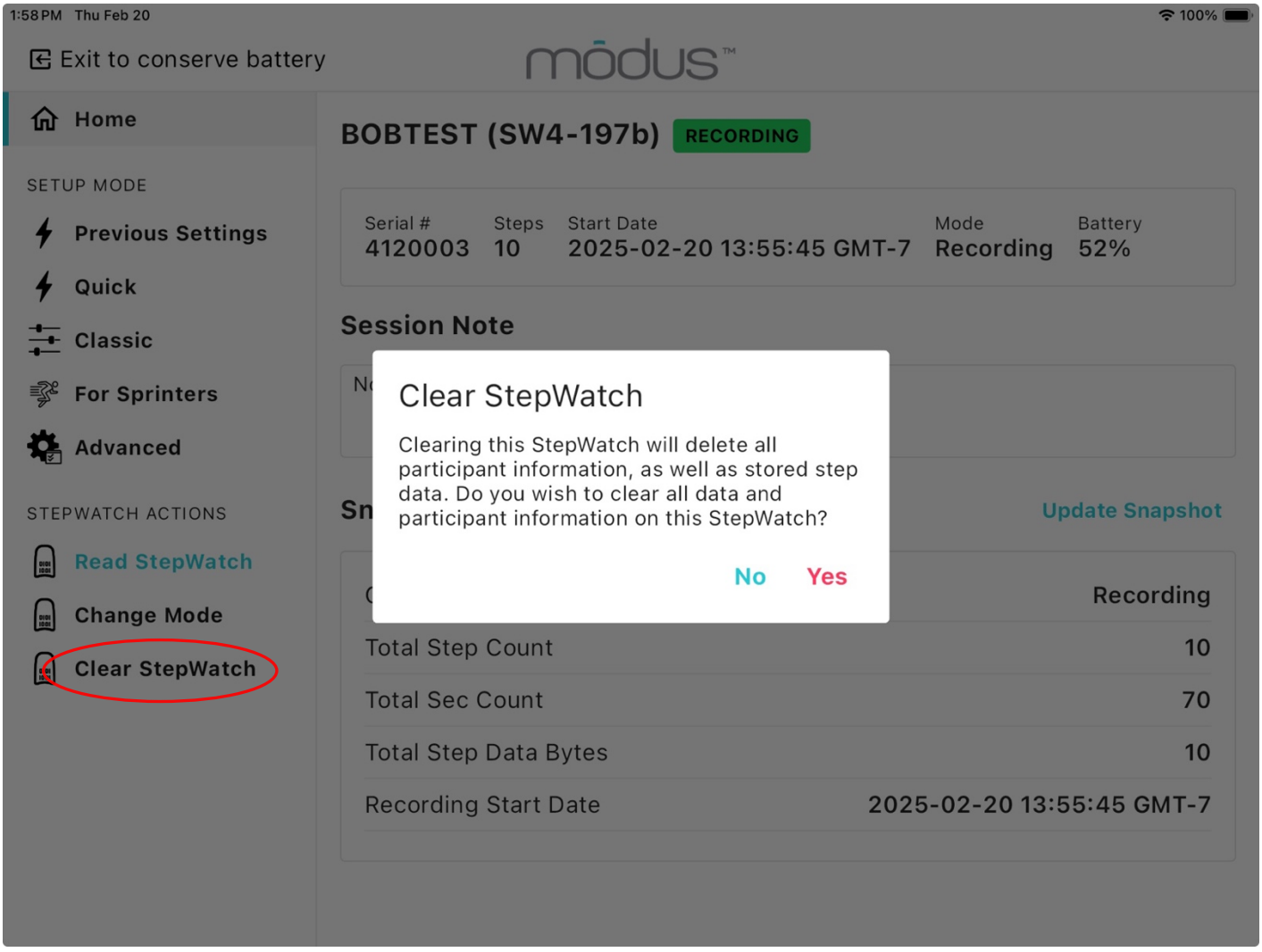
Following the download, the app will ask if you would like StepWatch to continue recording for this participant. Selecting “Yes” will put StepWatch back into recording mode automatically using the previous settings for this participant. This feature allows you to read the data and keep recording new data.

When you read data again with this StepWatch for this participant, you will be asked if you would like to “add steps to the current session.” This will append the current download to the previous download so that you have continuous data for the metric calculations (all data in one metric file for this participant). If you say “No” to adding steps to the current session, the app will create a separate session and, therefore, a separate metric file for this participant.

Clearing StepWatch

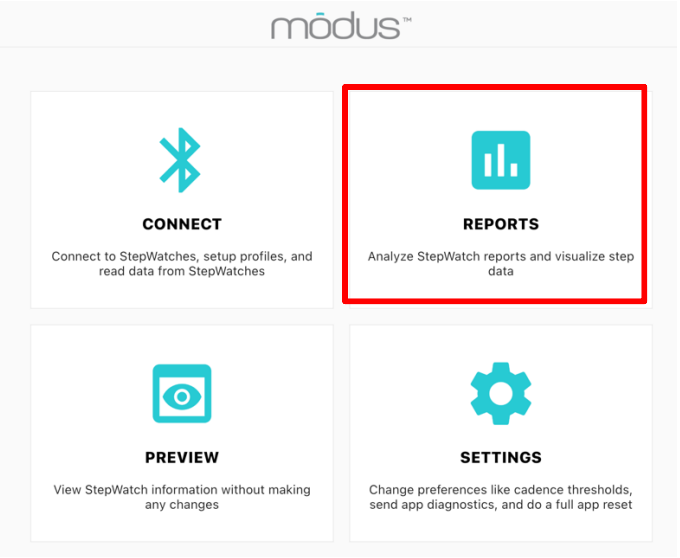
Occasionally, you may wish to fully clear a StepWatch of all previously stored data, including participant ID. This can be done by tapping the “Clear StepWatch” button located on the left-handed menu under StepWatch Actions while connected to StepWatch.

This option should be used with caution—once cleared, data on a StepWatch cannot be retrieved. If unsure, you may wish to “Read StepWatch” instead as this downloads the data from the StepWatch before clearing the StepWatch.



Viewing Saved Data

The Modus RE app allows you to not only record and save data with StepWatch but also to view and interact with your data. Tapping “Reports” on the app’s main screen will enable you to view all the data read for each participant.

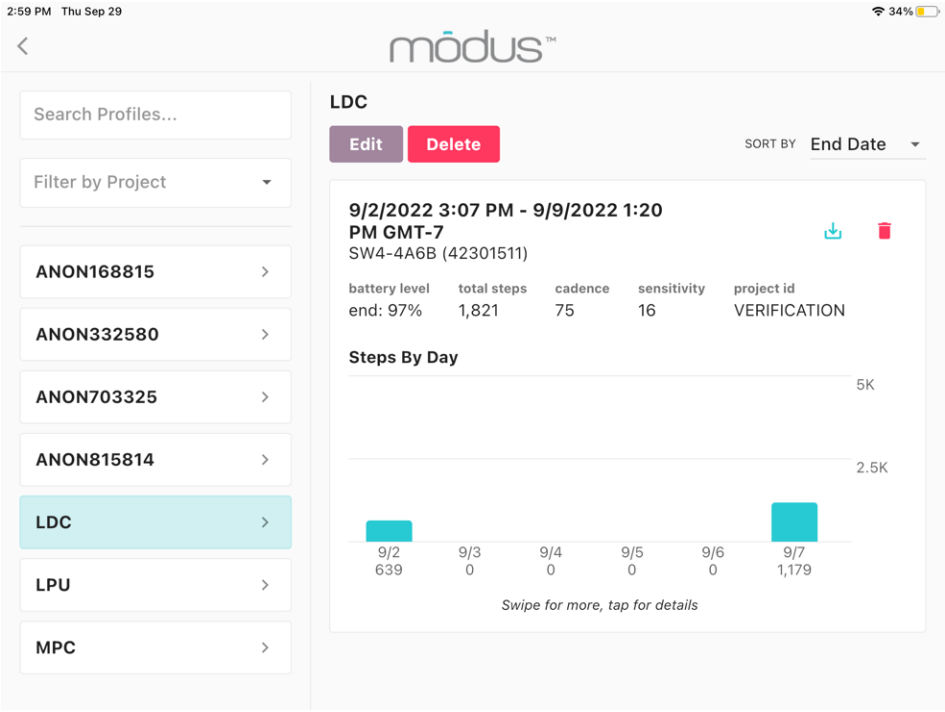


The data is organized by participants. You can search profiles, filter by projects, and sort by date or participant IDs.

By clicking on a participant, you will be able to see all sessions and select days in which data was recorded. You can also edit the profile of the person by adding a friendly name, adding a stride length, and adding a participant note. The adjusted stride length will be applied retrospectively to past data and new data getting collected.

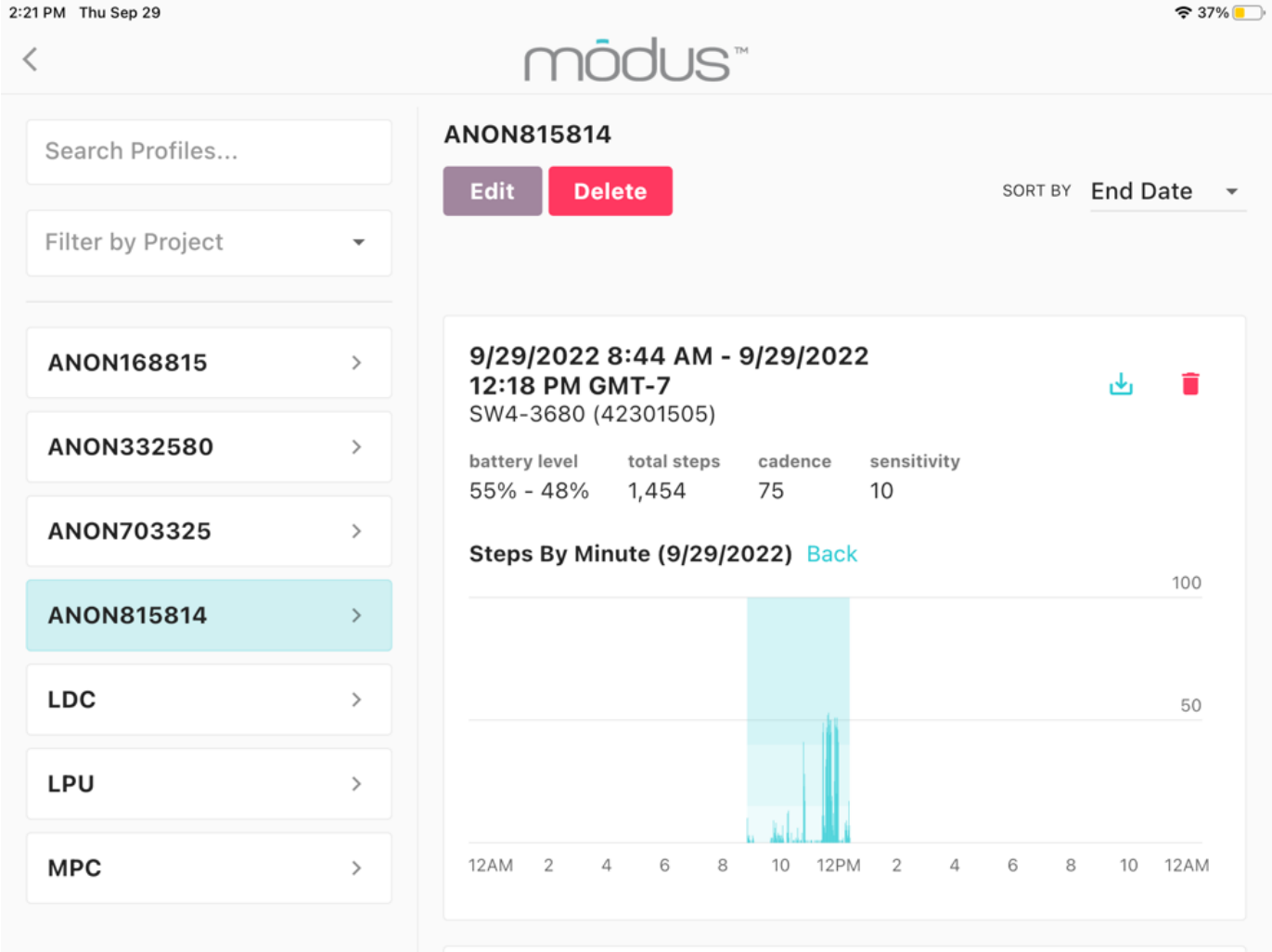
Weekly View

The weekly view shows the steps per day in bar graph form for each day of the week. Scroll by swiping the graph left to right if data collection was longer than 1 week to see other days.



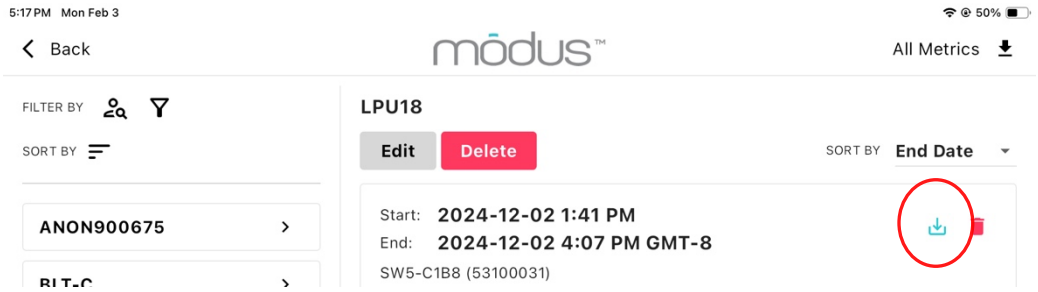
Daily View

To see the daily view, tap on a day with steps. The daily view shows the steps per minute throughout the 24-hour day. The shading is the time that StepWatch was recording. The dark teal shading represents step per minute cadence values in the high activity level range, the medium teal shading represents steps per minute values in the medium activity level range, and the light teal shading represents values in the low activity level range. The thresholds for high, medium, and low can be adjusted in the “Settings” on the home screen.

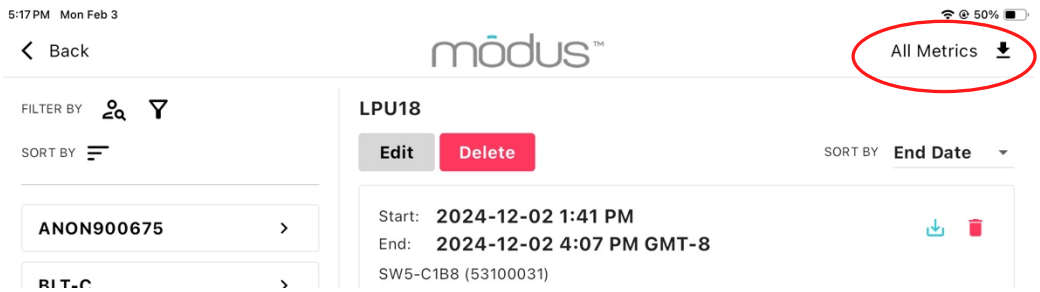


Exporting Saved Data

In the top right corner of the session card is the download button. This button has a dropdown menu should you wish to re-export data or export additional files besides the metric, 1-min bin file, and raw file. After you select the desired file, a download will begin, and you will be taken to the iPad's File App where you will be able to view the data as a CSV file.

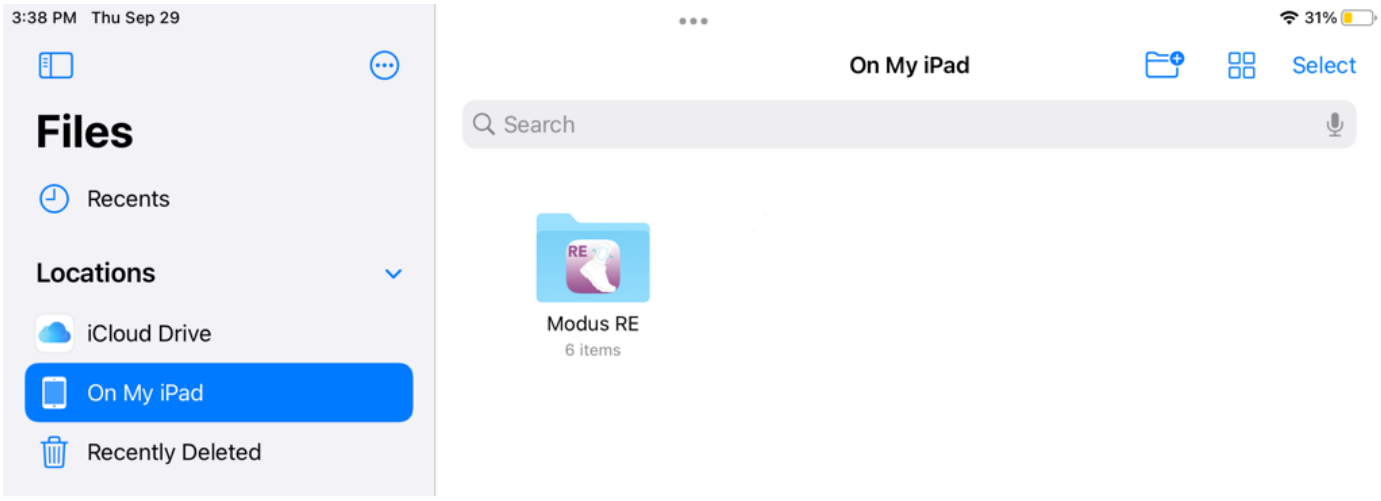


To download all the data from all participants into one CSV spreadsheet, tap "All Metrics" in the right corner. The spreadsheet will open on your iPad. The spreadsheet name starts with "All-Metrics" with the data and time of the download after.



Retrieving Exported Files

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

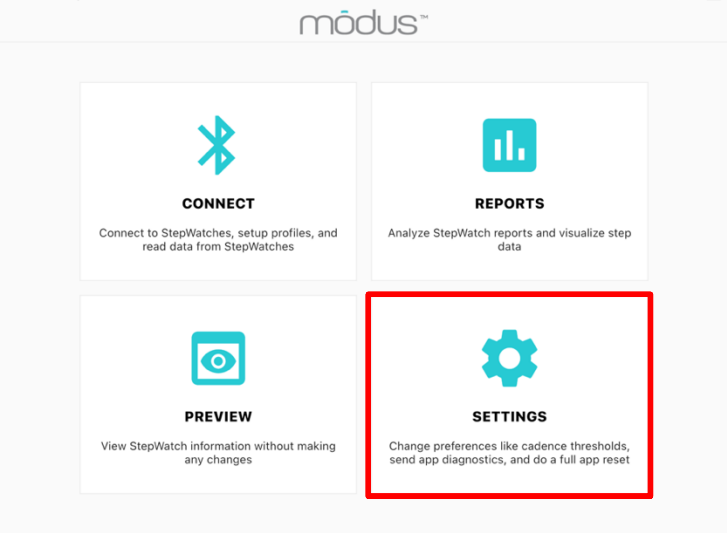


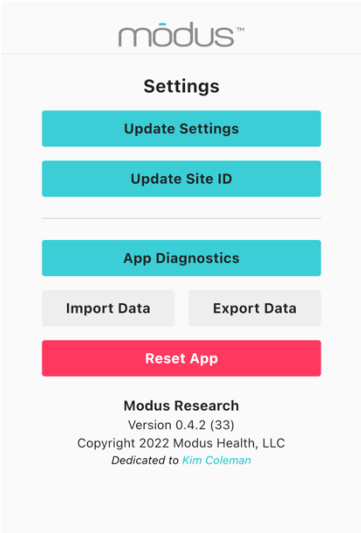
This is where your StepWatch data is stored. You can then use the iPad's native "Share" feature to export selected files to a file storage service (such as Dropbox or Google Drive), airdrop the files, transfer files with the charger using iTunes, or email the selected files to your email account.

WARNING: *Deleting the app will delete all files in this folder*

Settings

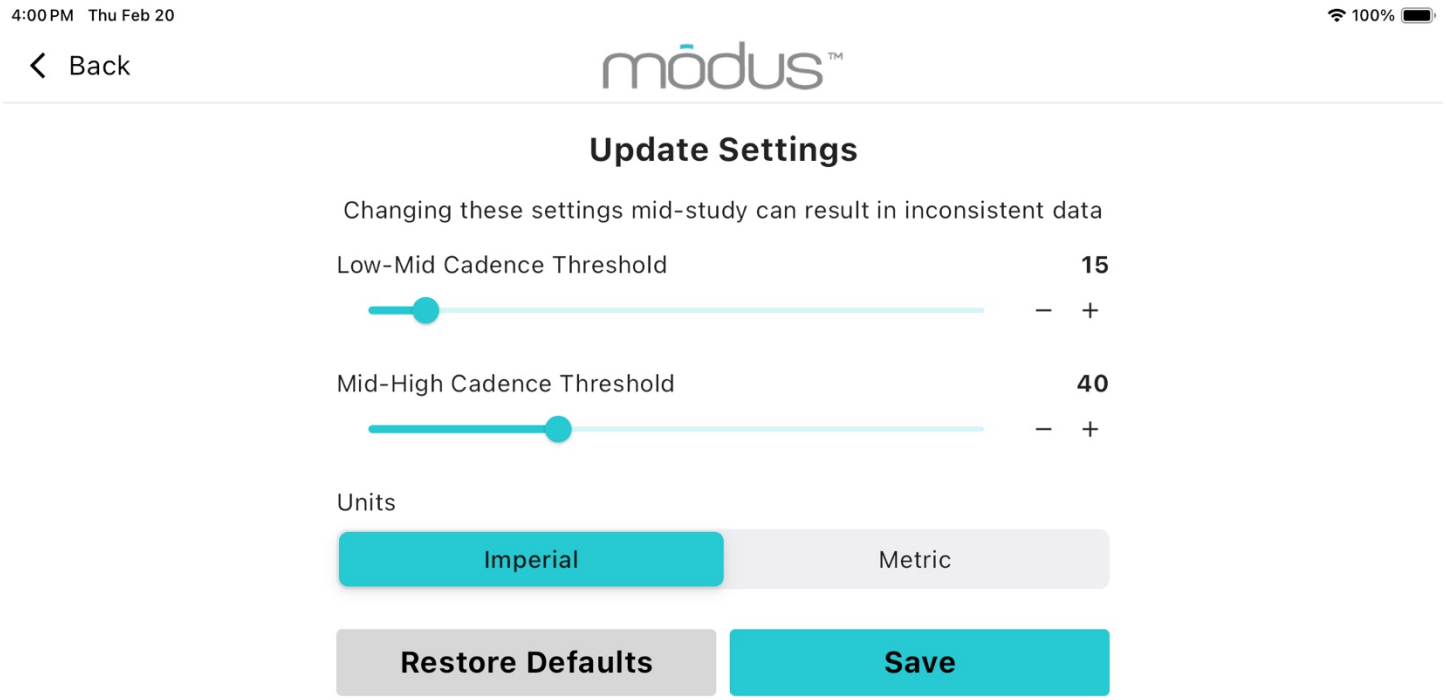
The settings section will allow you to change preferences such as cadence thresholds, send app diagnostics, do a full app reset, and import and export data.





Update Settings

Within update settings you can change the threshold for low-medium and medium-high strides/minute cadence. This effects percent time in low, medium, and high activities. This should only be done with the help of a Modus Health Administrator. The units setting allows changing between imperial (feet and inches) and metric (centimeters) for the height entry during StepWatch setup. Tap Save to implement the new settings. Restore defaults puts the low-mid cadence back at 15 strides/min, mid-high cadence back at 40 strides/min, and the units to imperial.

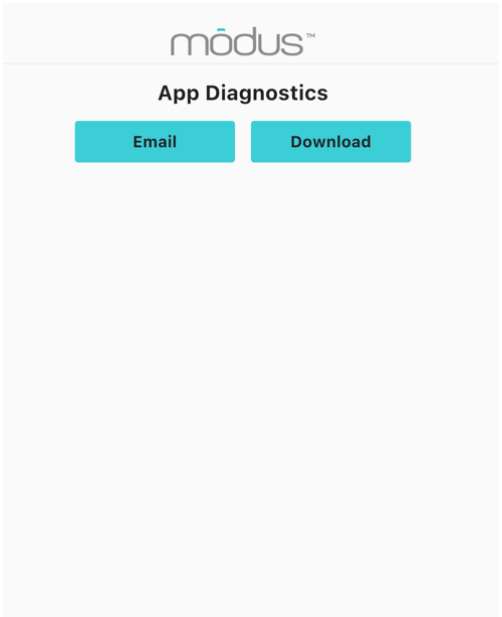


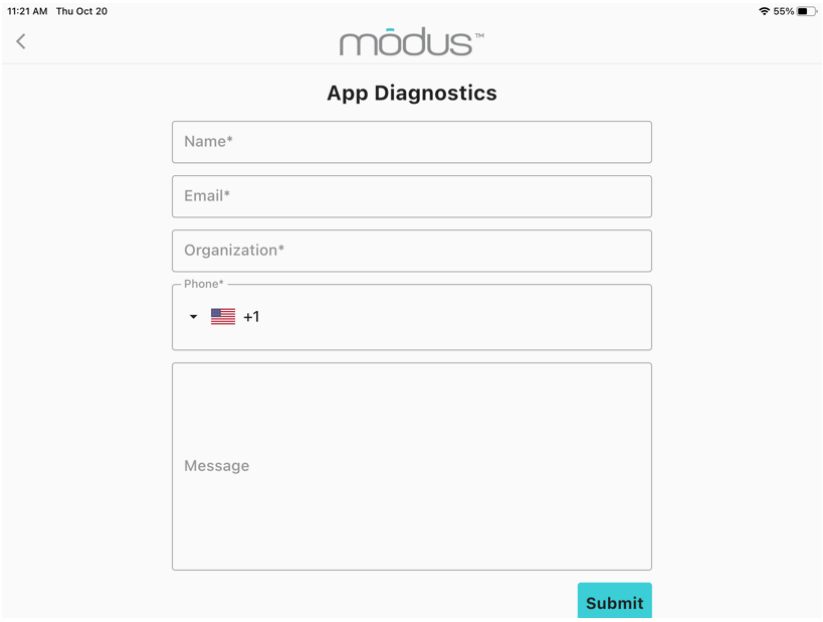
Update Site ID

Updating the Site ID is optional. The Site ID allows you to associate a site with your StepWatch data from this iPad so that you know which site collected the StepWatch data. This is helpful if combining StepWatch files from multiple sites in a study folder.

Upload App Diagnostics

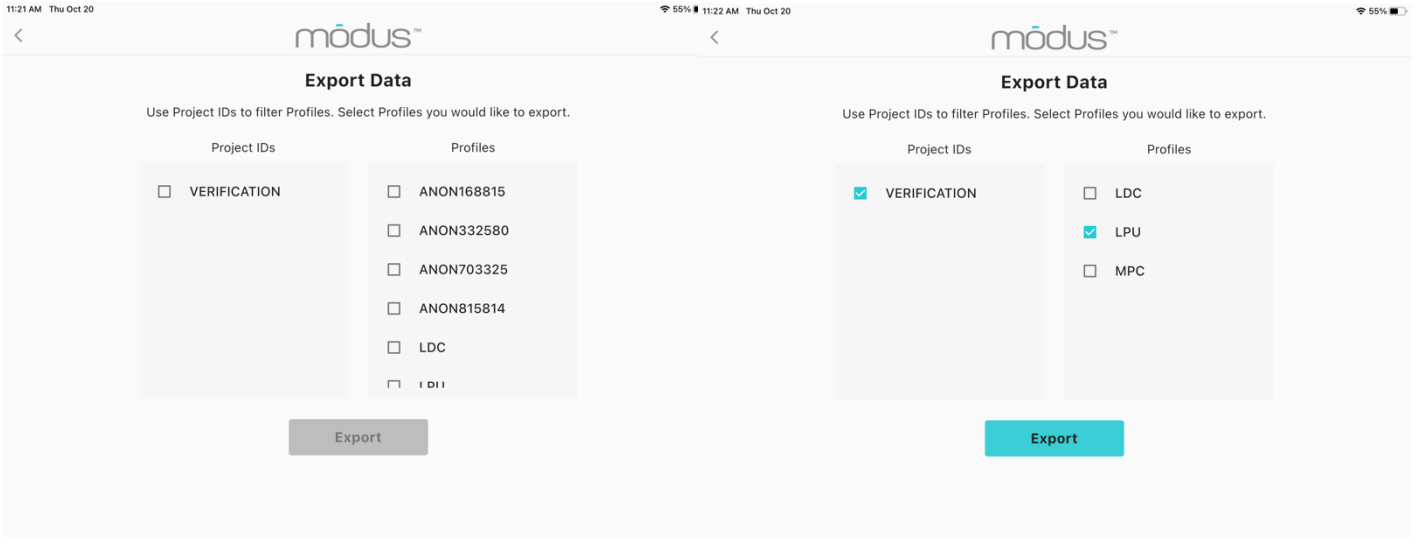
If there are issues with the Modus RE app, we can get a better understanding as to why via App Diagnostics. You will be able to email them directly to our support by selecting email and filling out the form or by downloading the diagnostics and sending them to our support email; support@modushealth.com.



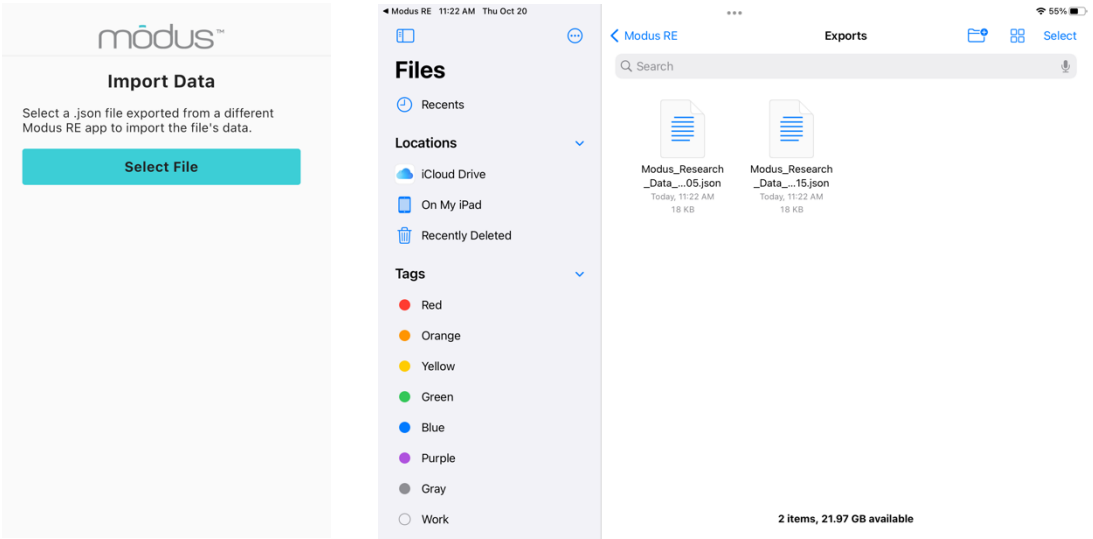


Exporting and Importing Data

Settings also has the option to export and import data. This can be used to transfer over files as well as create backups. You will be able to filter by Project IDs and select the profiles you would like to export. This data will be exported as a .json file and will be in its own folder called “Exports”



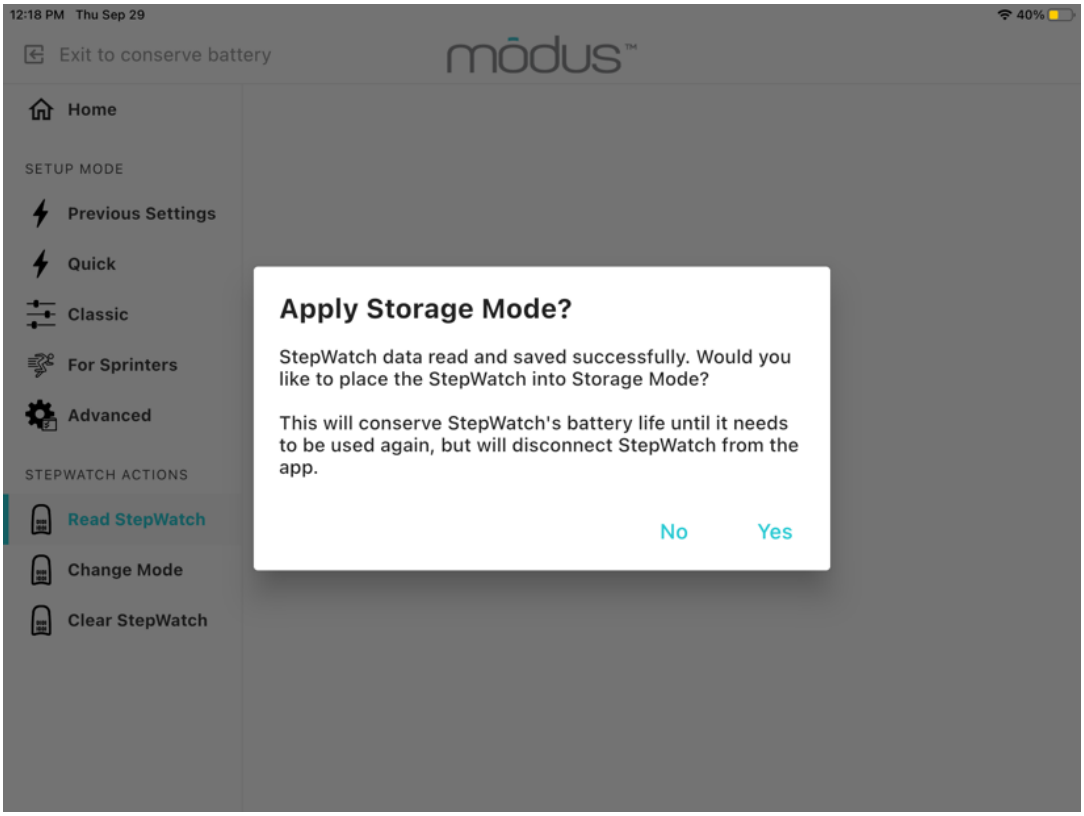
To import data you will select import data and then select which data you would like to import from your files app.



Device Modes

Shutdown/Storage Mode

After reading and saving step data from StepWatch, you will be asked if you would like to put StepWatch in Storage Mode.

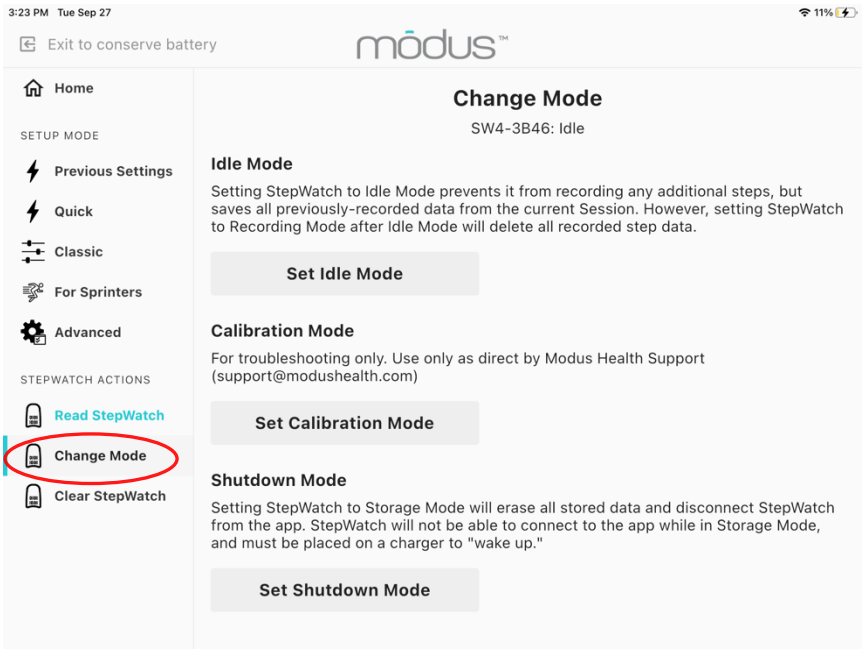


Selecting “Yes” turns off the Bluetooth radio. Select “Yes” if you will not be using this StepWatch again immediately and wish to conserve its battery. You will have to wakeup the radio when you want to use this StepWatch again by charging it for at least 10 seconds before connecting to it.

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

How to Change Modes

The Change Mode feature allows you for 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.

Calibration Mode assists in evaluating the function of sensor component. It should only be used in connection with Modus technical support.

Shutdown Mode turns off the Bluetooth radio, and disconnects StepWatch from the app. It does not erase the data.

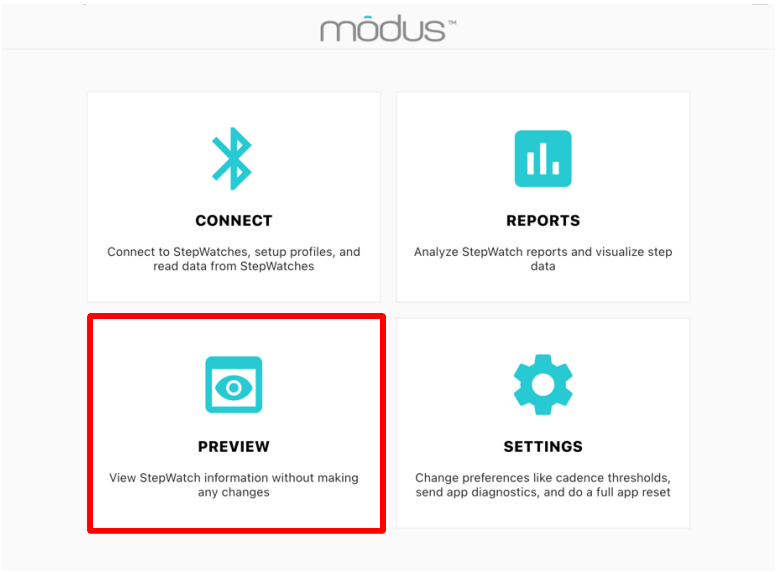
WARNING: *Setting StepWatch to Recording Mode after Idle Mode will delete all recorded step data. Be sure to read and save any step data before performing.*

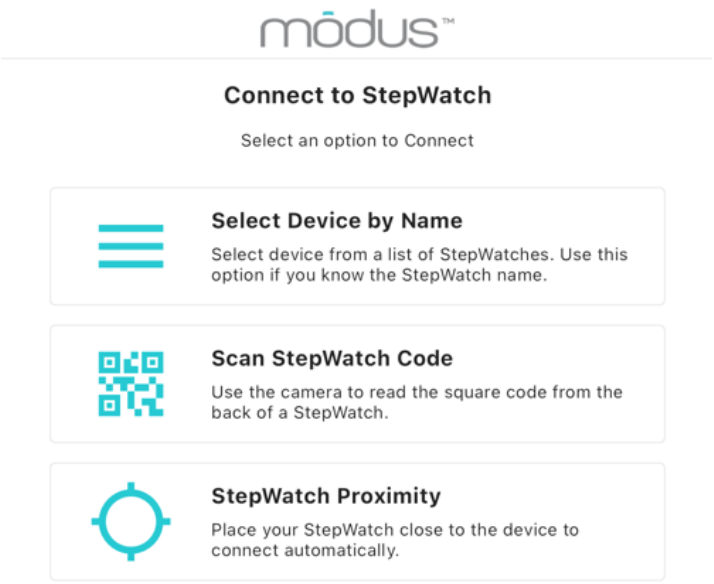
WARNING: *Setting StepWatch to Calibration Mode stops recording of steps and will significantly reduce battery life.*

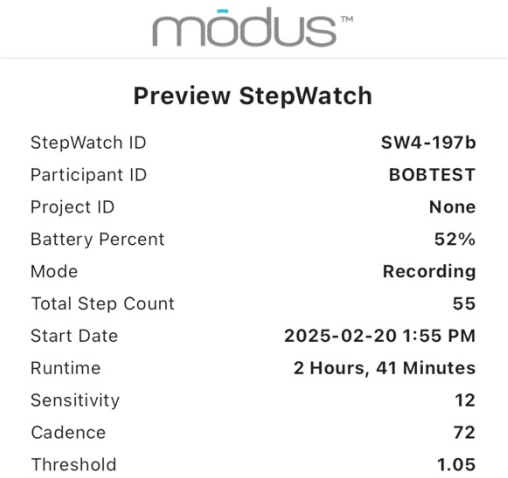
WARNING: *To reconnect to the StepWatch after Shutdown Mode, you must place the StepWatch on a charger for at least 10 seconds to return it to its previous mode: IDLE or RECORDING. If data was on the StepWatch, the data was saved but will be erased if setup again without reading the data first.*

Preview StepWatch

Use the preview feature to see what mode a StepWatch is currently in and preview the data. With the preview option you can connect to a StepWatch and quickly view its information without making any changes.



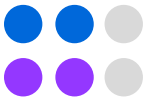




LED Indicators

StepWatch 5 Operation Modes

When you remove the StepWatch from the charger, the LED lights will indicate the current mode:



2 blue lights: StepWatch is in recording mode

2 purple lights: StepWatch is in idle mode, an app interaction is required to put it back into recording mode. The Bluetooth radio is on.

All flashing pink: Battery ran out of charge and entered storage mode for more than 24 hours. Device is not recording. An app interaction is required to put it back into recording mode.

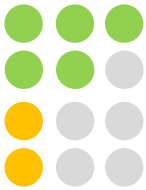
2 white lights: StepWatch is in storage mode and is not recording steps. The Bluetooth radio is off. This will preserve the battery until the next use. To use StepWatch again, charge StepWatch.

1 green blinking light: StepWatch is recording and will blink on each of the first 40 steps detected after setup, upload, or charging.

Note: If StepWatch is in recording mode when a low battery forces it into storage mode, it will come back into recording mode if charged within 24 hours. During the time StepWatch when was in storage mode, data will show inactivity.

StepWatch 5 Battery Level

Double tap the back of the StepWatch at any time to display the battery indication lights:



3 green lights for 3 seconds: Battery level is 67%-100%

2 green lights for 3 seconds: Battery level is 34%-66%

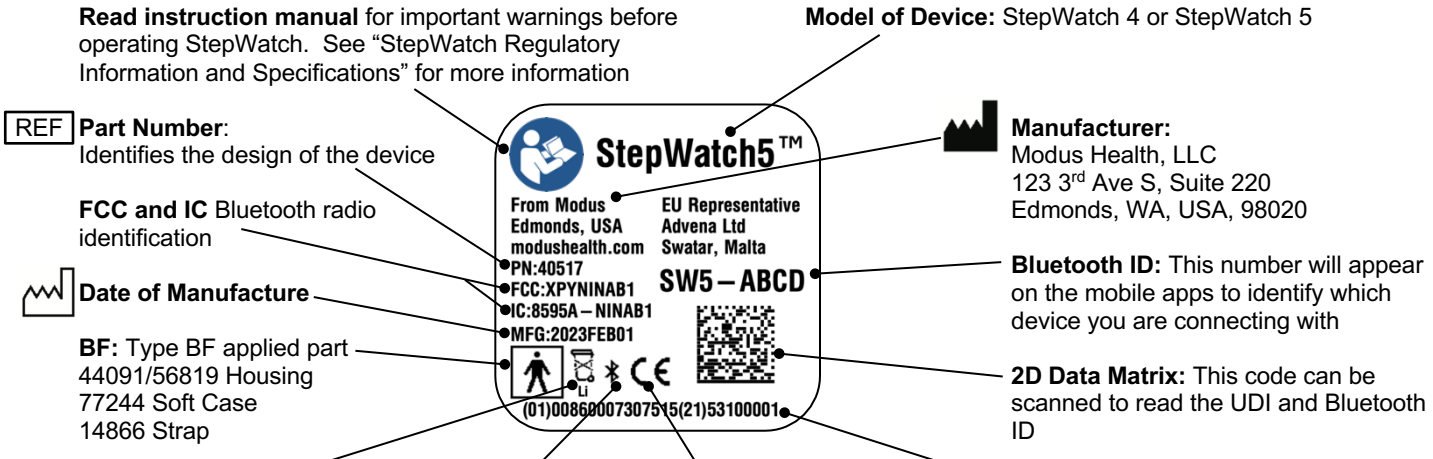
1 amber light for 3 seconds: Battery level is 10-33%

1 blinking amber light: Battery level is less than 10%

StepWatch 4 Step Indicator

1 green blinking light: StepWatch is recording and will blink on each of the first 40 steps detected after setup, upload, or charging.

Identification Label



StepWatch 4 additional symbols:
Read instruction manual for important warnings before operating StepWatch. See "StepWatch Regulatory Information and Specifications" for more information. **Never place StepWatch in an autoclave or oven.**

Managing StepWatch

Charging StepWatch

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

Always follow these instructions when charging or cleaning the StepWatch device. See “Interpreting the LEDs” for more information.

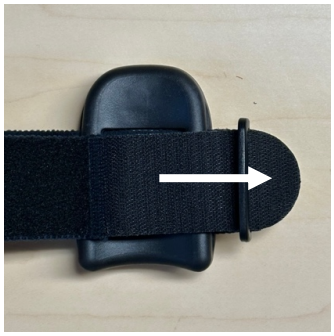
- A solid light on the charger means StepWatch is charging.
- A flashing light is a charging error. If you get a charging error, remove StepWatch from the charger, check the connections, and place StepWatch back in the center of the charger.
- DO: To charge StepWatch, place it face down on the center of the charger. A light will illuminate when your StepWatch begins charging.
- DON’T: Do not place StepWatch on the edge of the charger. Do not place StepWatch face up on charger.



The StepWatch battery should last more than two weeks when fully charged. A flashing light on the charger inidcates charging error. If you see this, remove StepWatch, check connections, and place StepWatch back on charger. Light turns off when fully charged.

Assembling the Strap

Pull the strap through the slots on the back of the device as shown.




For StepWatch 4, pull the strap through the plastic ring and secure using the Velcro tip.

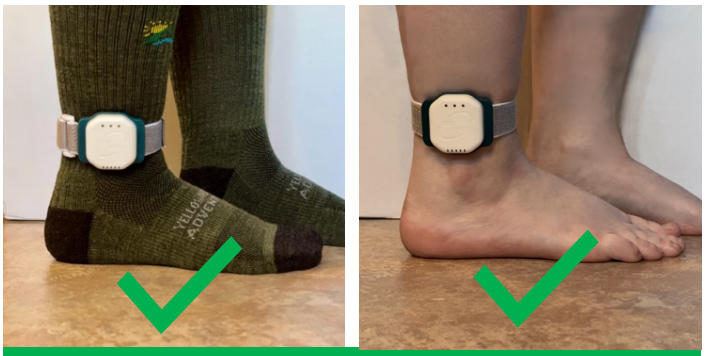


For StepWatch 5, fasten the Velcro side directly to the smooth side.

Wearing StepWatch

The StepWatch should rest about 0.5 - 1 inch above the anklebone, on the outside of the leg. The StepWatch does not require skin contact and can be worn over a sock.

If skin irritation occurs in contact with the device or strap, contact your healthcare provider. You can wear a sock to separate the strap from the skin, and/or move the device to the other ankle.



Correct Location

StepWatch 4 cannot be worn upside down, or on the inside of the ankle. This will result in incorrect or missing data. StepWatch 5 can be worn upside down, but must be worn on the outside of the ankle.

Do not wear on the inside of the ankle

Upside down wearing is accurate for StepWatch 5 only

Cleaning StepWatch

You can clean a StepWatch by rubbing gently with a wet cloth or disinfectant wipe.

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.*

Metrics and Step Data

Modus RE Metric File

Value	Description
Project ID	Value entered by researcher when setting up StepWatch
Site ID	Value entered by researcher under “Update Site ID” in Settings
SSID	Subject’s study identification entered when setting up StepWatch
Date	Date StepWatch recorded as year, month, day
GMT_Offset	Time zone of the recorded day as seconds from GMT
Hours_Timeframe	Time that StepWatch recorded for that day
SW_ID	StepWatch radio identification number
SW_SN	StepWatch serial number
Threshold	Value determined during StepWatch manufacturing
Battery_Percent	Percent of StepWatch battery when reading the data
Cadence	Value set during StepWatch setup. Affects step detection
Sensitivity	Value set during StepWatch setup. Affects step detection
Notes	Text added during StepWatch setup
Steps_per_Day (steps)	Total number of steps taken on the leg with StepWatch
Minutes_Active (min)	Minutes of the day with at least one step
Percent_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_Med_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_Peak (m/s)	Peak velocity based on the minute with the most steps and entered stride length value
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)	Value entered by researcher when setting up the participant profile
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

Modus RE Binned Files

Value	Description
Project ID	Value entered by researcher when setting up StepWatch
Site ID	Value entered by researcher under “Update Site ID” in Settings
SSID	Subject’s study identification entered when setting up StepWatch
Date	Date StepWatch recorded
GMT_Offset	Time zone of the recorded day as seconds from GMT
Hours_Timeframe	Time that StepWatch recorded for that day
SW_ID	StepWatch radio identification number
SW_SN	StepWatch serial number
Threshold	Value determined during StepWatch manufacturing
Battery_Percent	Percent of StepWatch battery when reading the data
Cadence	Value determined during StepWatch setup
Sensitivity	Value determined during StepWatch setup
Notes	Text added during StepWatch setup
Raw_Steps_Timestamp (date and time)	When a step occurred with 1-second resolution. In excel, may need to change format using custom format yyyy-mm-dd h:mm:ss
Raw_Steps_Interval_Length	Seconds that passed between each step (255 means no steps, 0 means more than one step with same timestamp)
Binned_Steps_Timestamp	Bin intervals selected for the 24-hour day (1-min, 30-sec, 20-sec, 15-sec, 12-sec, or 10-sec)
Binned_Steps_Steps_In_Bin	Total steps taken during the binned interval
Software_Version	Modus RE software version used when exporting data
Exported	Date that the data was exported

Troubleshooting

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

- Ensure that StepWatch is not on the charger while attempting to connect.
- Ensure that StepWatch has sufficient battery charge to connect—if unsure, charge StepWatch for at least 20 minutes, then try connecting again.

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

If the app crashes or does something unexpected go to the “Settings” screen. Tap “App Diagnostics” and either email the file or download the file to transfer to Modus by another method. This will help Modus understand your issue. 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.

Frequently Asked Questions

What if the StepWatch slips down the participant’s ankle?
You will need to reposition the StepWatch and tighten the Velcro strap to keep the StepWatch in place. It may stay in place easier when worn over a sock.

Can participants switch what leg they wear the StepWatch on?
Yes

Can the StepWatch get wet?
Yes, the StepWatch is waterproof (see hardware specifications in appendix 5). StepWatch can be used in the shower, bath, or in the rain. Swimming is not recommended. A dry Velcro strap is recommended if the strap has gotten wet.

Can I reuse a StepWatch for a different participant?
Yes

If I lose my data, does Modus Health have a copy?
No, there is no cloud system with this software. We do not have your data as it is saved locally to your iPad.

References

1. 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.

Specifications

Software Compatibility

There are 3 mobile app system options to program the StepWatch and read the data.
Visit https://modushealth.com/software/ for information on software applications and links to these applications in the app store.

Mobile Application	Use Case	Minimum Hardware & Software Requirements (as of January 2023)
SW4 RE (supported through 2023)	Research Site	iOS 15 or 16 on iPad
Modus RE	Research Site	iOS 17 or 18 on iPad
CR Site	Clinical Research Trial Site	iOS 16 or 17 on iPad
CR Companion	Clinical Research Participant's Home	iOS 16 or 17 (iPhone and iPad) Android 13 or 14 (no tablet version)
CC Clinic	Clinical Care Provider	iOS 16 or 17 (iPhone and iPad) Android 13 or 14 (phone and tablet)
CC Companion	Clinical Care Setting or Patient's Home	iOS 16 or 17 (iPhone only) Android 13 or 14 (no tablet version)

StepWatch Hardware Specifications

Specifications	StepWatch 4	StepWatch 5
Size	75 x 48 x 14 mm	42 x 49 x 13 mm
Weight	41 grams	20 grams
Wearable Soft Cover	Available in small and med-large	One Size
Waterproof	IP67	IPX8
Battery Life	30 days	15 days
Accurate Step Detection	For all walking styles, including slow and irregular gait	
Step Resolution	Steps per second	
Communication Method	Bluetooth connection to Apple iPad	
Operating Environment	Operating Environment: -10° ~ +41° C (14° ~ 106° F) Charging Environment: 0° ~ +41° C (32° ~ 106° F) Storage Environment: 0° ~ +25° C (32° ~ 77° F) < 75% Transport Environment: -10 ~ +65° C (14° ~ 149° F)	
Wireless Induction Charging	Input: 5V (2A) and Output: 5W	
Onboard Memory	Data storage is 12-41 days (depending on activity level of participant)	Data storage is 27-365 days (depending on activity level of participant)
2 Year Warranty	Warranty begins on day of delivery	

Regulatory Information

Manufacturer
Modus Health, LLC
123 3rd Ave S, Suite 220
Edmonds, WA, USA, 98020

Intended Purpose
StepWatch is intended to monitor walking on both normal gait and impaired gait, for research, clinical trials, and clinical care settings. It is not indicated for use in non-ambulatory users, but can be used for participants walking with lower-limb prosthetics.

Operating Principles
StepWatch is an ankle-worn device which utilizes an accelerometer and a proprietary step measuring algorithm. The device is set up using an iPad application over a Bluetooth connection, and data is read using a mobile device.

Essential Performance
Accurate step counting during run mode and accurate step data following any environmental disturbances. Recurrent testing of this performance is not necessary.

Clinical Benefits
Accurate step counting can provide a range of benefits to patients, which are enabled by the ability of the clinician to see how much the patient has walked and to provide feedback to help the patient walk within a range that brings about optimal health as determined by the clinician. Visit modushealth.com/publications to view specific examples.

Performance Characteristics
At least 60 peer-reviewed studies have confirmed the accuracy of StepWatch in people with and without impaired walking and in both adults and children [4]. Because of StepWatches accuracy, StepWatch has been used as the criterion device (gold standard) to measure the accuracy of other tools in at least 43 peer-reviewed studies [5]. Several studies illustrate benefits provided by the ability to accurately monitor activity using StepWatch. For every 500 steps per day increase, length of stay in the hospital was reduced by 11% for patients with pneumonia [6]. Walking at least 275 steps per day during inpatient care identified that patients have reduced 30-day readmission risk [7]. Patients recovering from stroke are more likely to be independent walkers when they leave the hospital if they can achieve 1000 steps per day in the hospital [8].

References

[4] https://modushealth.com/publications/#accuracy

[5] https://modushealth.com/publications/#stepwatch-as-criterion

[6] Rice H, Hill K, Fowler R, Watson C, Waterer G, Harrold M. Reduced Step Count and Clinical Frailty in Hospitalized Adults With Community-Acquired Pneumonia. *Respir Care*. Oct 1 2020;doi:10.4187/respcare.06992

[7] Fisher SR, Goodwin JS, Protas EJ, et al. Ambulatory activity of older adults hospitalized with acute medical illness. *J Am Geriatr Soc*. Jan 2011;59(1):91-5. doi:10.1111/j.1532-5415.2010.03202.x

[8] Hornby TG, Holleran CL, Leddy AL, et al. Feasibility of Focused Stepping Practice During Inpatient Rehabilitation Poststroke and Potential Contributions to Mobility Outcomes. *Neurorehabil Neural Repair*. Nov 2015;29(10):923-32. doi:10.1177/1545968315572390

Safety

- Remove device during MRI. No additional setup steps are required after temporarily removing StepWatch.
- Never place the StepWatch in any type of oven or autoclave, as this could cause the permanent lithium battery to rupture or explode. Review the cleaning instructions in this manual.
- If skin irritation occurs in contact with the device or strap, contact your healthcare provider. You can wear a sock to separate the strap from the skin, and/or move the device to the other ankle.
- If the device is damaged, remove the device and discontinue use.
- In case of malfunction of the device that results in bodily injury, contact support@modushealth.com and report the incident to your medical device authority. For USA and EU:
- (EU) Report the incident to the competent authority of the EU Member State in which the user and/or patient is established
- (USA) FDA MedWatch Online Voluntary Reporting Form

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.
StepWatch is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions EN 55011/CISPR	Group 1	StepWatch uses RF energy only for internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions EN 55011/CISPR	Class B	StepWatch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Maintenance

StepWatch devices do not require maintenance. If there is a problem with the device, please contact support@modushealth.com. DO NOT attempt to perform maintenance. DO NOT attempt to open the device.

Disposal

This device contains a lithium battery. Lithium-ion batteries should not be disposed of in residential or commercial waste. Please refer to local regulations for proper disposal.