

Modus Health LLC

Modus Research App Reference Guide for Users



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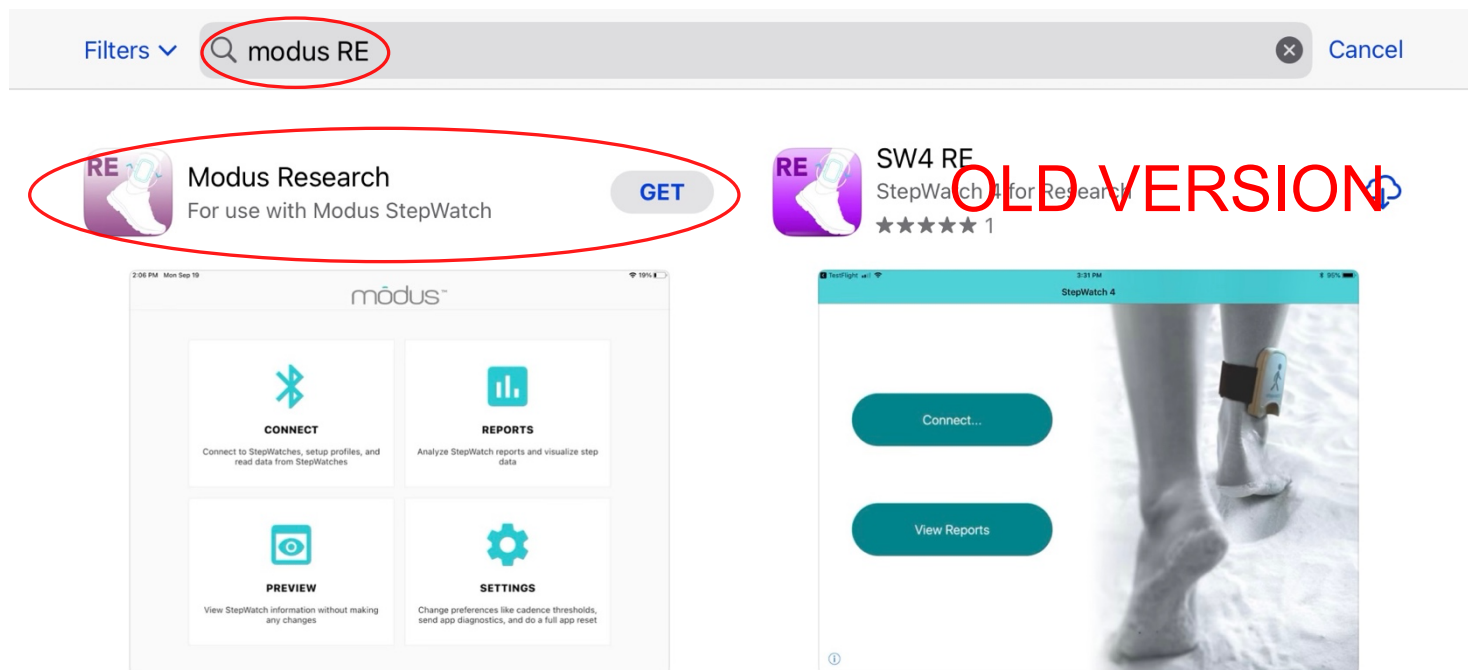
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Installing the App

The Modus RE app supports iPad devices running on iOS 15 or later. The iPad must also be in light mode. Modus RE currently does not support iOS Dark Mode. The Modus RE app can be installed from the App Store. Enter in the search bar “Modus RE” or “Modus RE 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.

Note: We are transitioning from our SW4 RE app. SW4 RE is retiring and will be removed in 2024. Modus RE currently does not support iOS Dark Mode



Video Tutorial

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

Preparing the StepWatch

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".



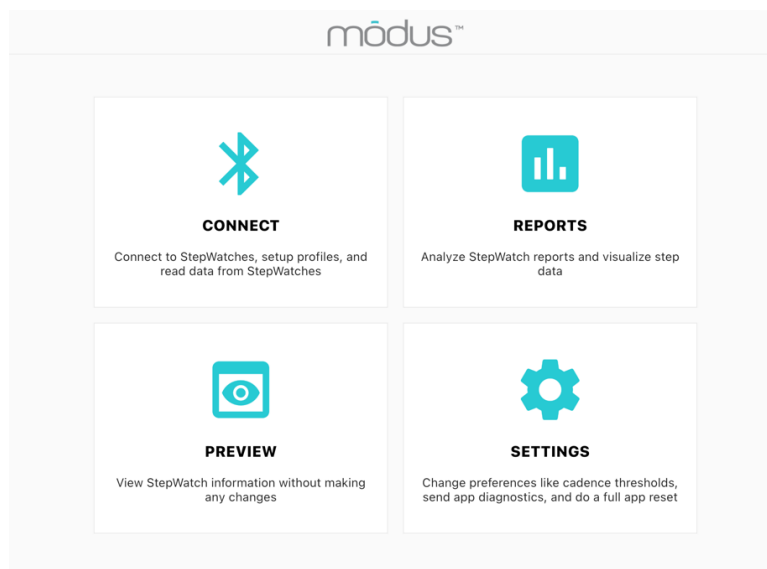
To prepare the StepWatch ahead of the first participant visit or usage, attach the soft cover to the StepWatch. Thread the Velcro strap through the StepWatch with the Velcro side facing TOWARD the device. Depending on the participant's ankle size, you will need to select either a small, medium, or large 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

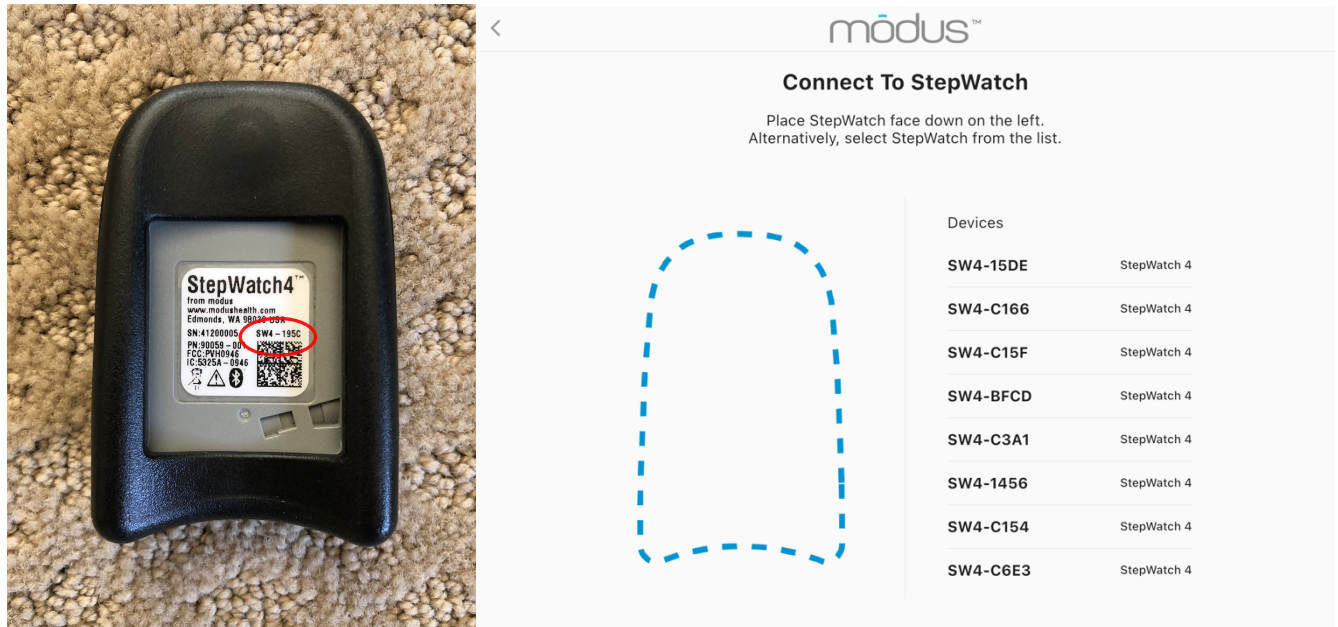
Opening the App

When you first open the app, you will be greeted by a menu with 4 options: Connect, Reports, Preview, and Settings.



Connecting to StepWatch

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.



There are two methods of connecting to StepWatch:

- 1) Place the StepWatch face-down on the iPad screen where indicated, with the QR Code/StepWatch ID facing up
- 2) Selecting the StepWatch from the list. The Bluetooth ID will appear as "SW#-XXXX."

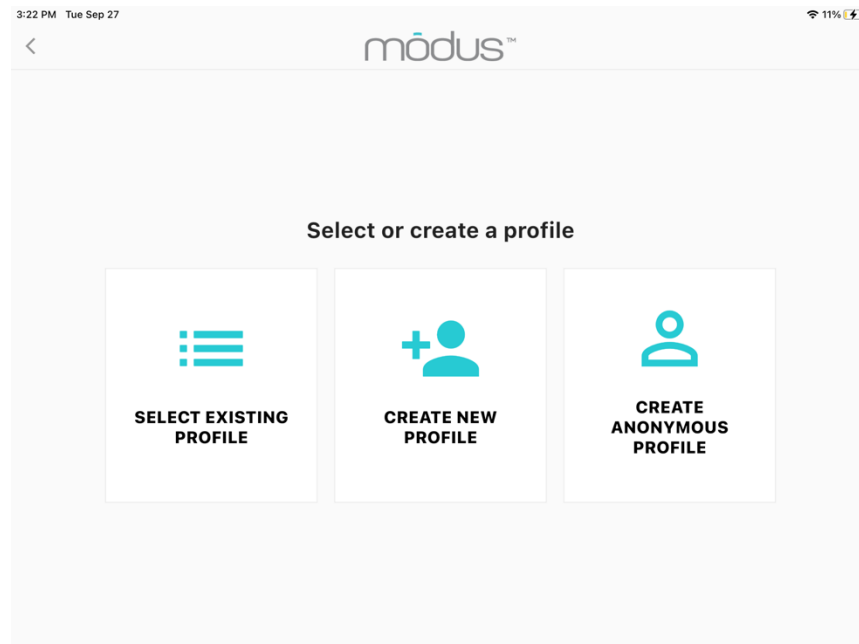
When using option #2, the StepWatch is listed by Bluetooth ID (printed on the back of the device, pictured above). If you cannot connect, the StepWatch may be out of battery and needs to be charged. The other case is that your StepWatch is in storage mode. To bring StepWatch out of storage mode, place StepWatch on the charger for at least 10 seconds. If neither solution works, contact support@modushealth.com for further assistance.

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

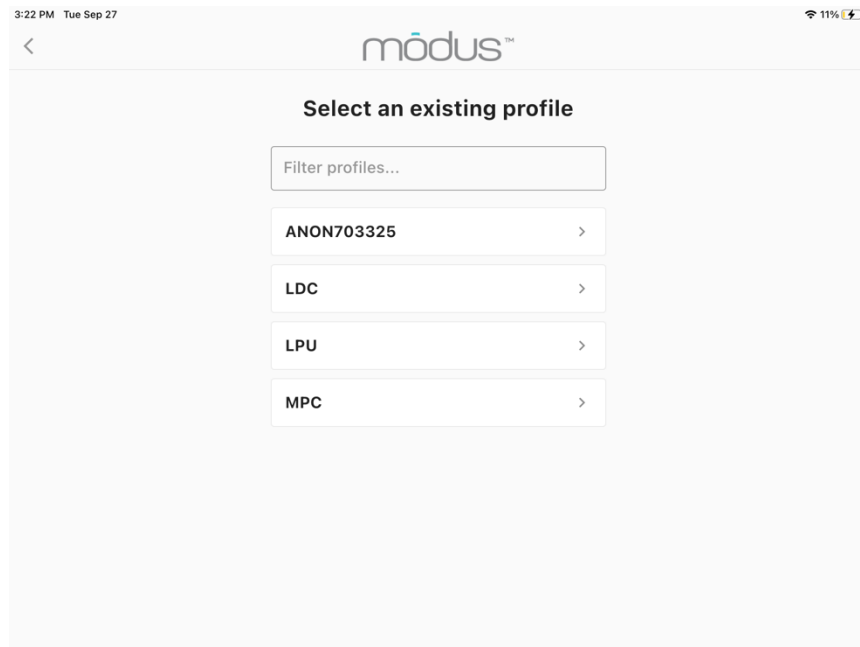
The StepWatch RE App uses a Participant Profile system to enable you to collect and analyze data from multiple study participants at the same time.

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

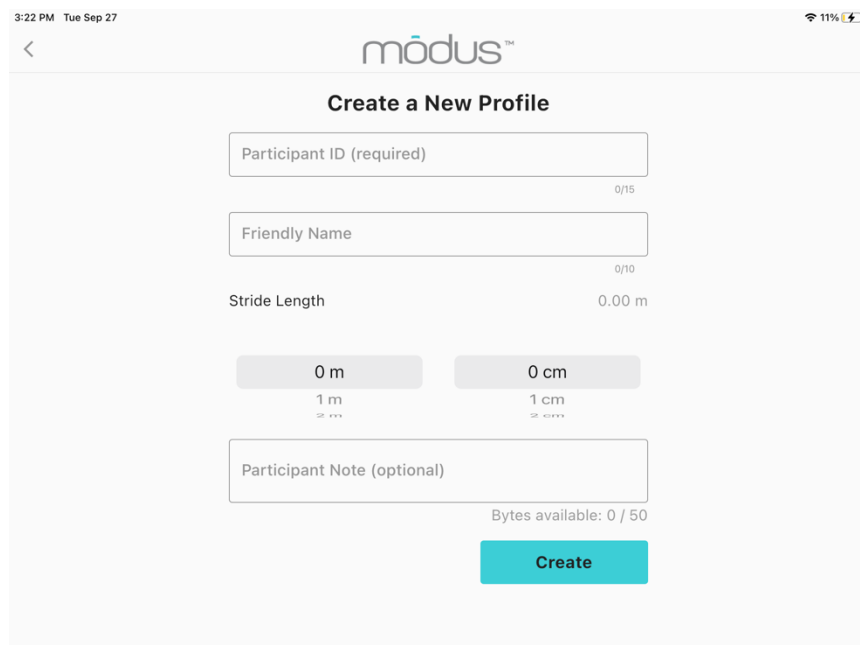
This option will show the existing profile choices. Selecting one will allow adding data to this Participant Profile.



The screenshot shows the 'modus' app interface. At the top, the status bar displays '3:22 PM Tue Sep 27' and '11%' battery. The app header includes a back arrow and the 'modus' logo. The main title is 'Select an existing profile'. Below this is a search bar labeled 'Filter profiles...'. A list of four profile options is shown, each with a right-pointing chevron: 'ANON703325', 'LDC', 'LPU', and 'MPC'.

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.



The screenshot shows the 'modus' app interface for creating a new profile. The status bar at the top shows '3:22 PM Tue Sep 27' and '11%' battery. The app header has a back arrow and the 'modus' logo. The main title is 'Create a New Profile'. The form contains the following fields and controls: a 'Participant ID (required)' text field with a '0/15' character count; a 'Friendly Name' text field with a '0/10' character count; a 'Stride Length' field showing '0.00 m' with two buttons below it, '0 m' and '0 cm', each with a '1 m' and '1 cm' sub-label; a 'Participant Note (optional)' text field with a 'Bytes available: 0 / 50' indicator; and a teal 'Create' button at the bottom right.

[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.

11:37 AM Tue Oct 18

62%

Exit to conserve battery

modus™

Home

SETUP MODE

Previous Settings

Quick

Classic

For Sprinters

Advanced

STEPWATCH ACTIONS

Read StepWatch

Change Mode

Clear StepWatch

ANON372069 (SW4-7593)

Serial #	Steps	Start Date	Mode	Battery
94200007	0	Not Set	Idle	87%

Session Note

Not Set

Snapshot

Device Info

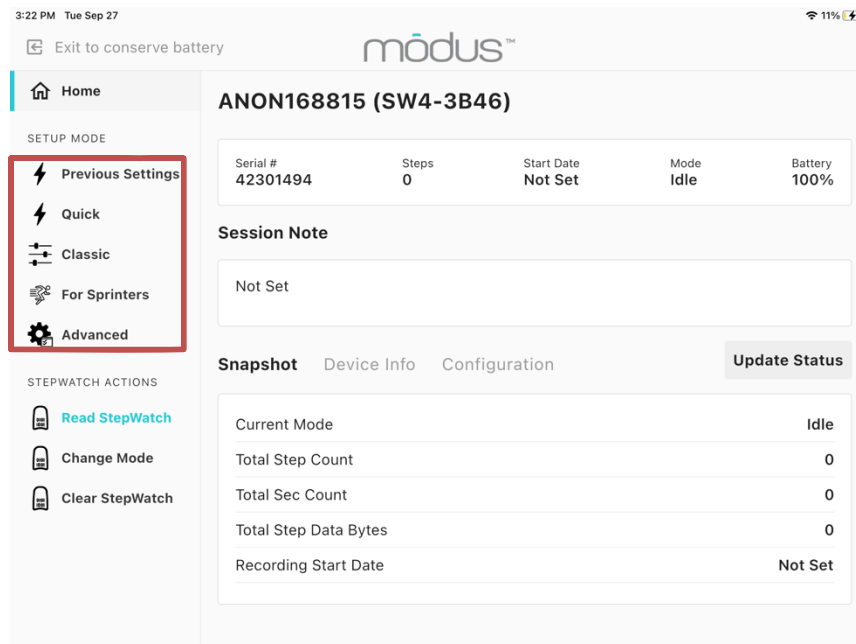
Configuration

Update Status

Current Mode	Idle
Total Step Count	0
Total Sec Count	0
Total Step Data Bytes	0
Recording Start Date	Not Set

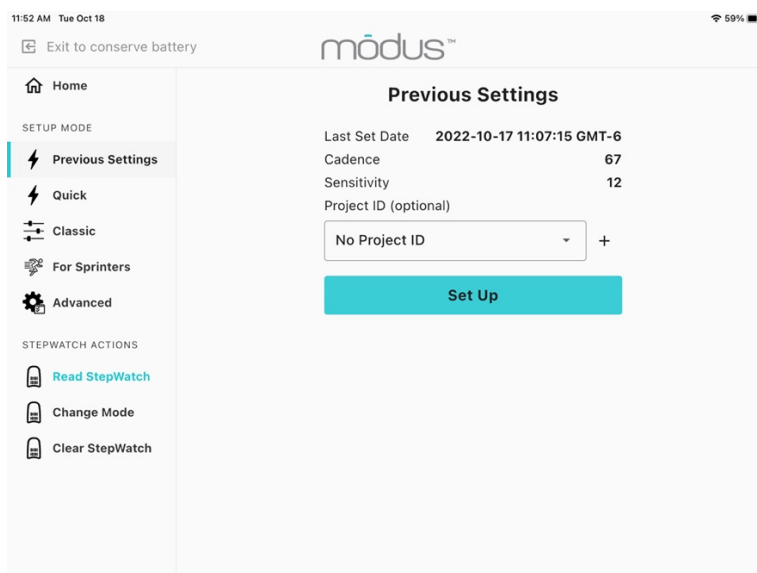
Recording Data with StepWatch

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.



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 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.

3:23 PM Tue Sep 27

Exit to conserve battery

modus™

Quick Setup

Select the participants height

2 ft 0 in
3 ft 1 in

Are they a runner?

No Yes

Do they have an impaired gait?

No Yes

Next

Home

SETUP MODE

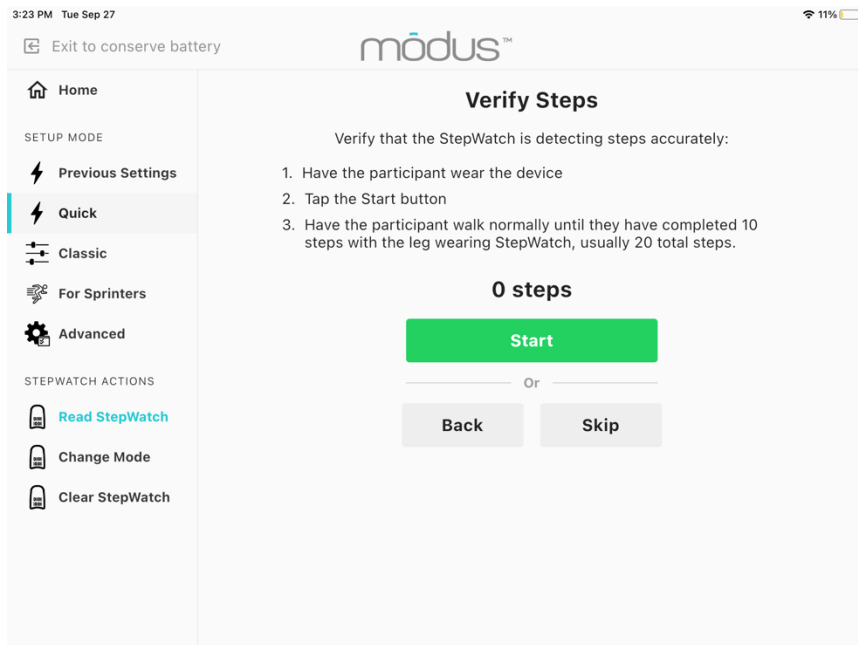
- Previous Settings
- Quick**
- Classic
- For Sprinters
- Advanced

STEPWATCH ACTIONS

- Read StepWatch
- Change Mode
- Clear StepWatch

Quick Setup Step Verification

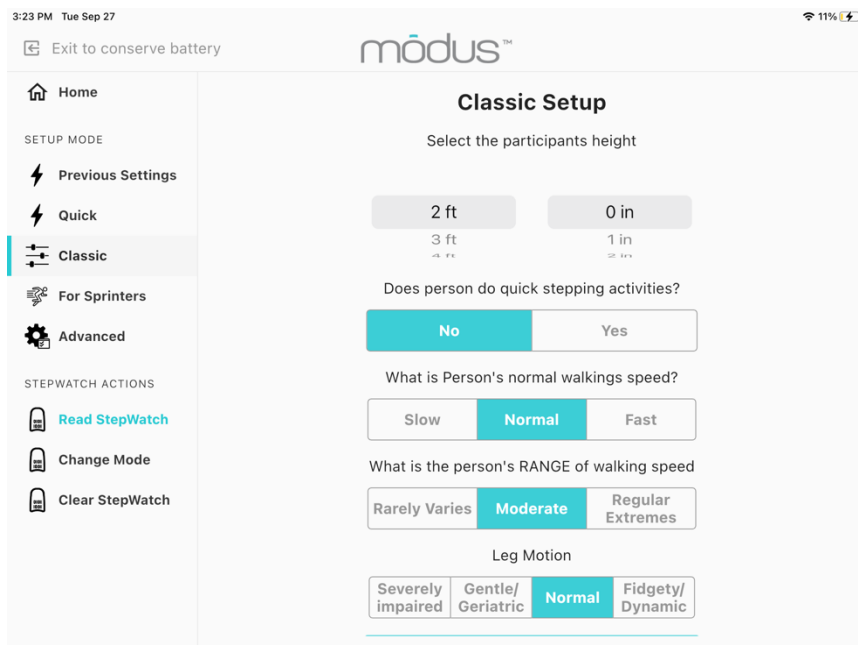
This function verifies that StepWatch is recording steps accurately (within 90% accuracy) for the participant's normal walking. It requires having the participant take 10 steps on the leg wearing StepWatch after tapping the Start button. When considering both the left and right leg, this will be 19 – 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 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 with the correct height of the participant will be accurate for a 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 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.

3:23 PM Tue Sep 27

Exit to conserve battery

modus™

For Sprinters Setup

For participants that will be running faster than 10 minutes per mile (6 mph or 2.7 m/s)

Based on 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

Select the participants height

2 ft 0 in

3 ft 1 in

Next

Home

SETUP MODE

- Previous Settings
- Quick
- Classic
- For Sprinters**
- Advanced

STEPWATCH ACTIONS

- Read StepWatch
- Change Mode
- Clear StepWatch

[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 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.

3:23 PM Tue Sep 27 11%

Exit to conserve battery **modus™**

Advance Setup

Number of LED Flashes **40**

Cadence **74**

Sensitivity **10**

Next

Home

SETUP MODE

- Previous Settings
- Quick
- Classic
- For Sprinters
- Advanced**

STEPWATCH ACTIONS

- Read StepWatch**
- Change Mode
- Clear StepWatch

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.

3:24 PM Tue Sep 27

11%

Exit to conserve battery

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Home

SETUP MODE

Previous Settings

Quick

Classic

For Sprinters

Advanced

STEPWATCH ACTIONS

Read StepWatch

Change Mode

Clear StepWatch

No Project ID

+

Session Note (optional)

Bytes available: 0 / 50

Timezone

America/La_Paz

America/Lima

America/Los_Angeles

America/Lower_Princes

America/Macelo

Start Date (optional)

Select Date and Time

Set Start Date if you would like to start recording steps in the future.

Less Options

Back

Done

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 on the StepWatch before clearing the StepWatch.

3:22 PM Tue Sep 27

Exit to conserve battery

modus™

Home

SETUP MODE

⚡ Previous Settings

⚡ Quick

⚙ Classic

🏃 For Sprinters

⚙ Advanced

STEPWATCH ACTIONS

📄

Read StepWatch

📄

Change Mode

📄

Clear StepWatch

ANON168815 (SW4-3B46)

Serial #	Steps	Start Date	Mode	Battery
42301494	0	Not Set	Idle	100%

Session Note

Not Set

Snapshot

Device Info

Configuration

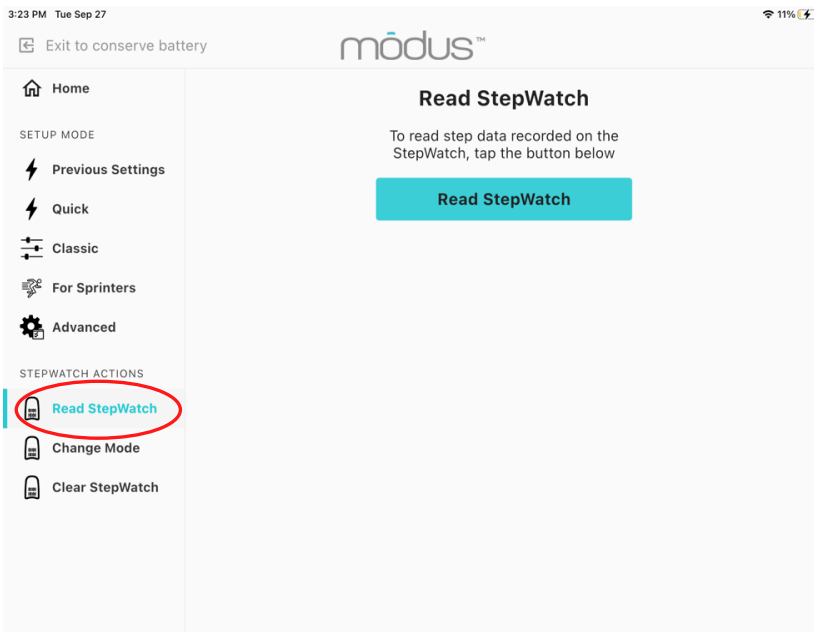
Update Status

Current Mode	Idle
Total Step Count	0
Total Sec Count	0
Total Step Data Bytes	0
Recording Start Date	Not Set

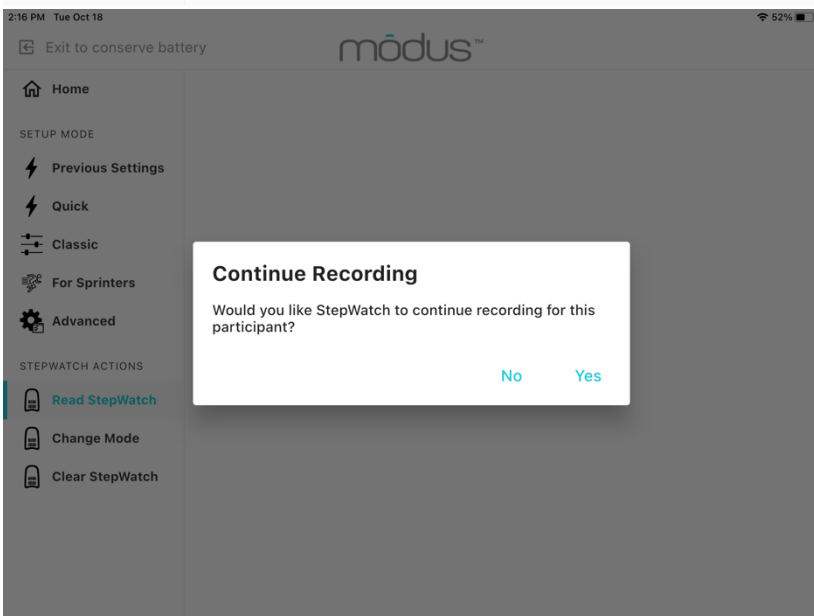
Reading Data from StepWatch

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.



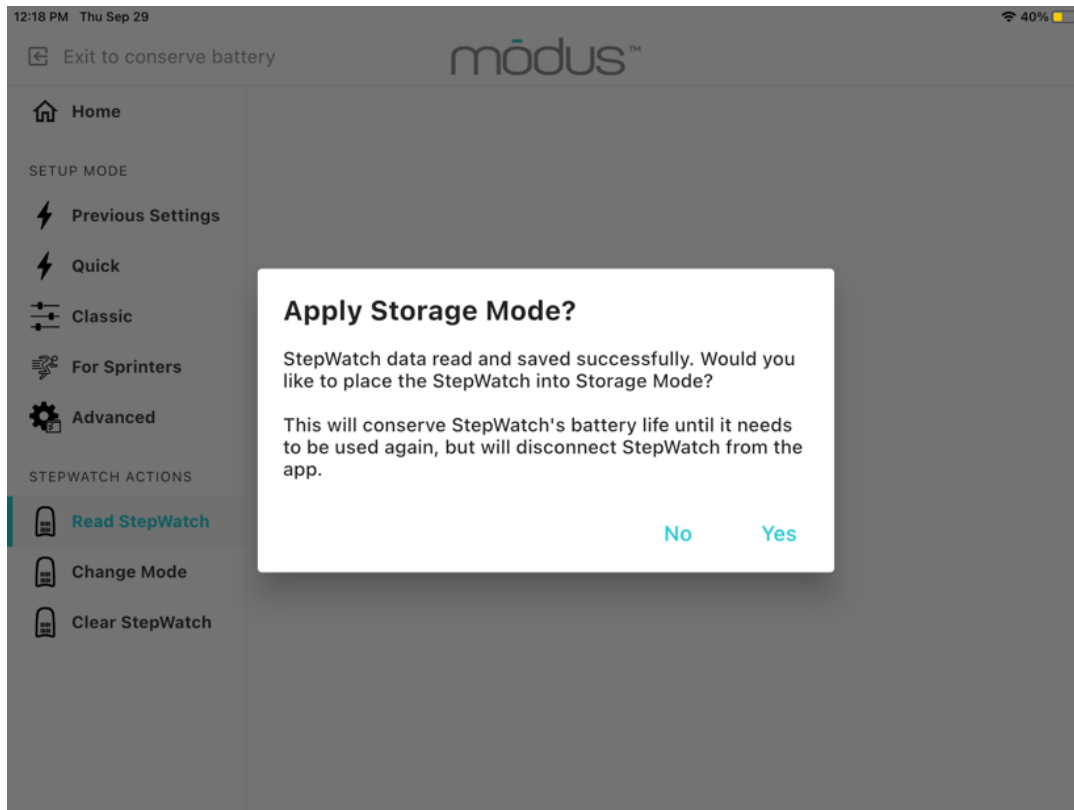
Following the download, the app will ask if you would like StepWatch to continue recording for this participant. Selecting “Yes” will put StepWatch back into recording mode automatically using the previous settings for this participant. This feature allows you to read the data and keep recording new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

Storage Mode

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

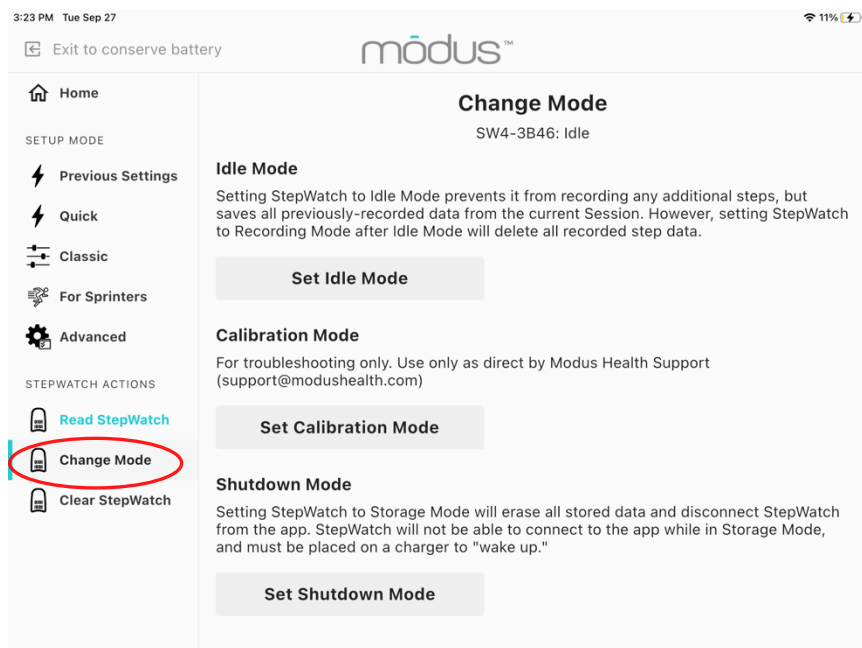


Selecting “Yes” turns off the Bluetooth radio. Select “Yes” if you will not be using this StepWatch again immediately and wish to conserve its battery. You will have to wakeup the radio when you want to use this StepWatch again by charging it for at least 10 seconds before connecting to it.

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

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.

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.

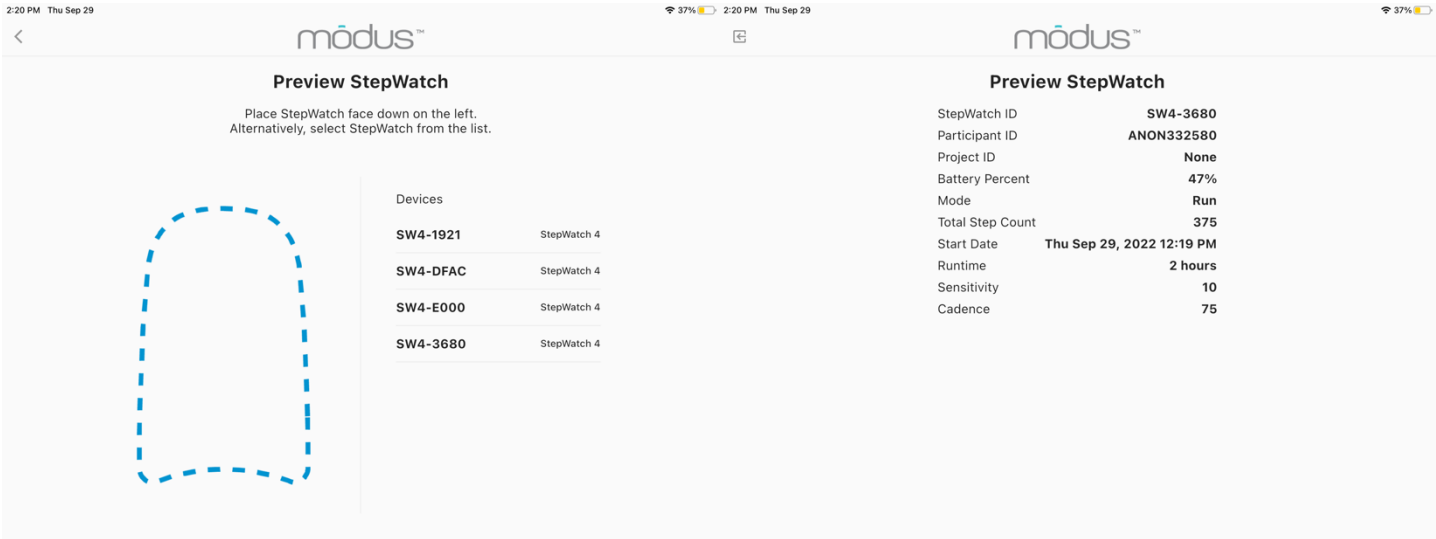
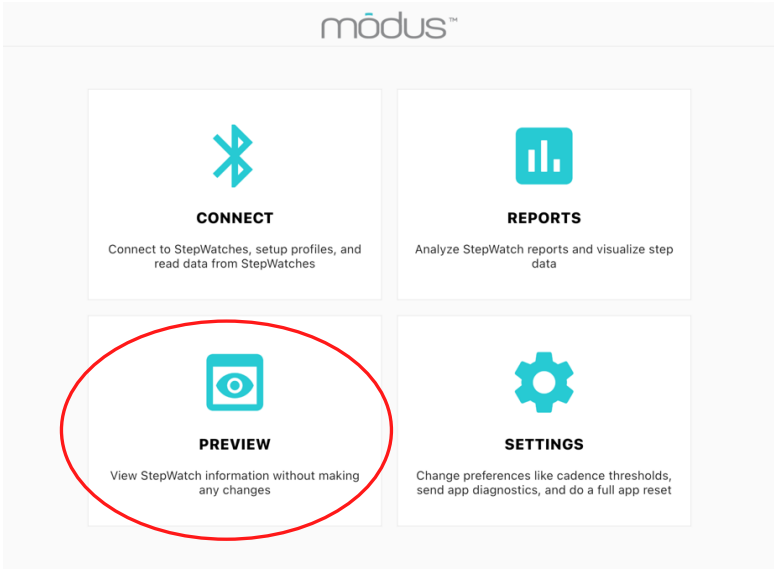
WARNING: Setting StepWatch to Recording Mode after Idle Mode will delete all recorded step data. Be sure to read and save any step data before performing.

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

WARNING: To reconnect to the StepWatch after Storage Mode, you must place the StepWatch on a charger for at least 10 seconds to return it to Idle Mode. If data was on the StepWatch, the data was saved but will be erased if setup again without reading the data first.

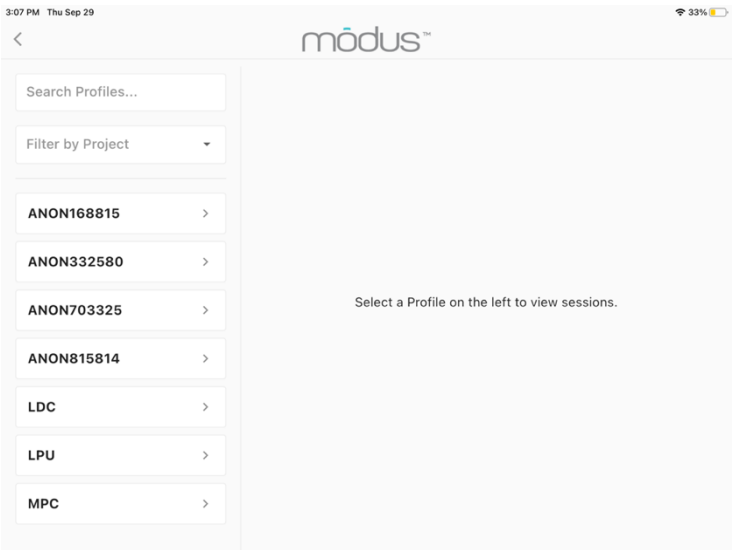
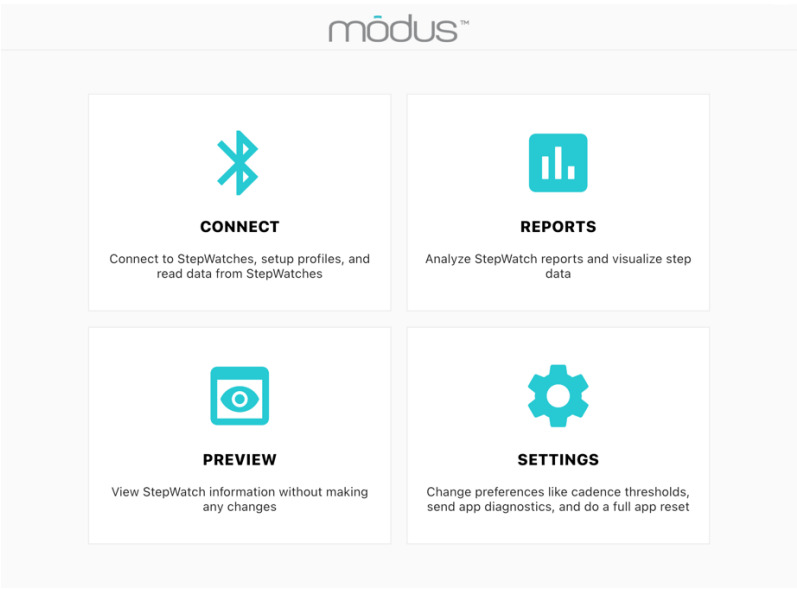
Preview

The Modus RE app introduces an option known as preview. With the preview option you will be able to connect to a StepWatch and quickly view its information without making any changes.



Viewing Saved Data

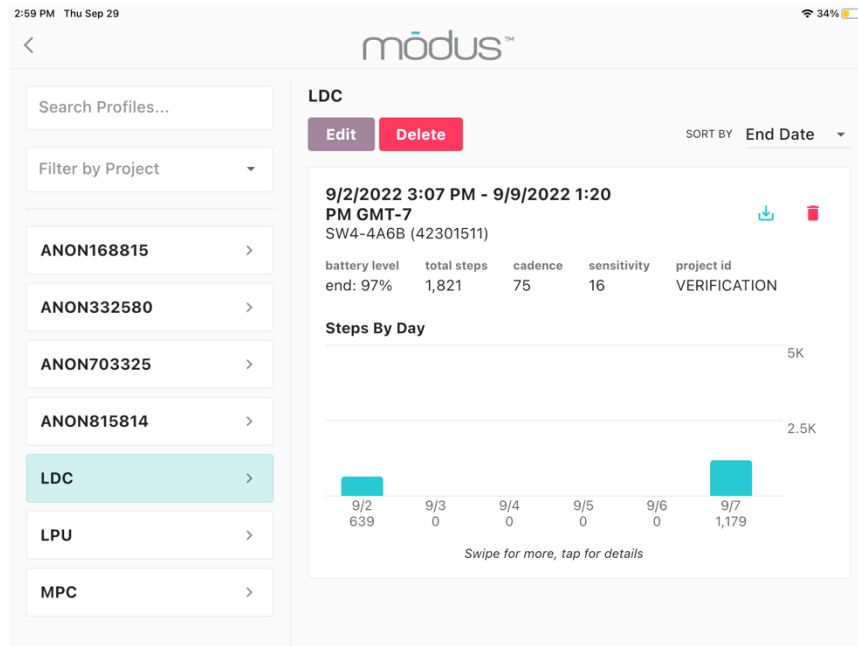
The Modus RE app allows you to not only record and save data with StepWatch but to view and interact with your data without desktop software. Tapping “Reports” on the app’s main screen will enable you to view all the data read for each participant.



The data is organized by participants. You can search profiles and filter by projects, if they are under the same project ID. 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.

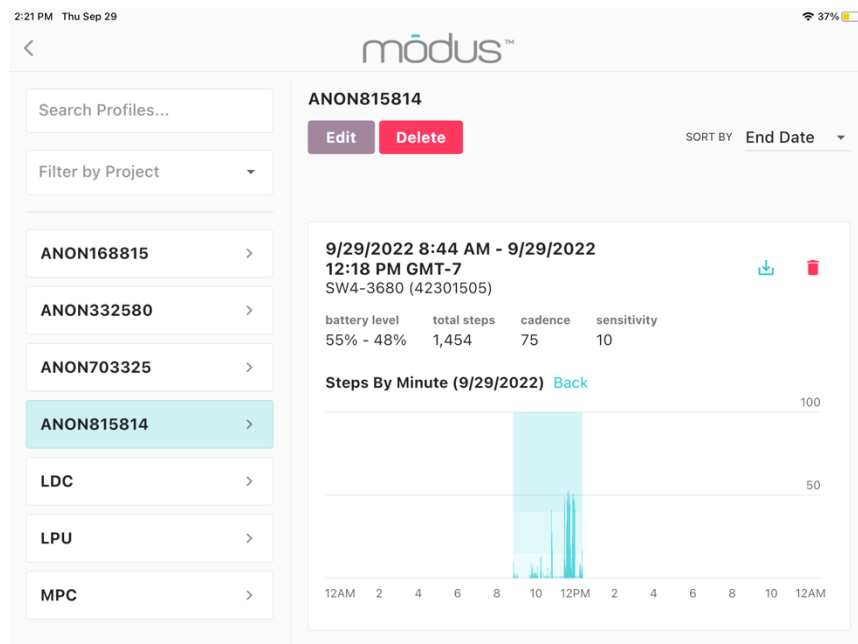
Weekly View

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



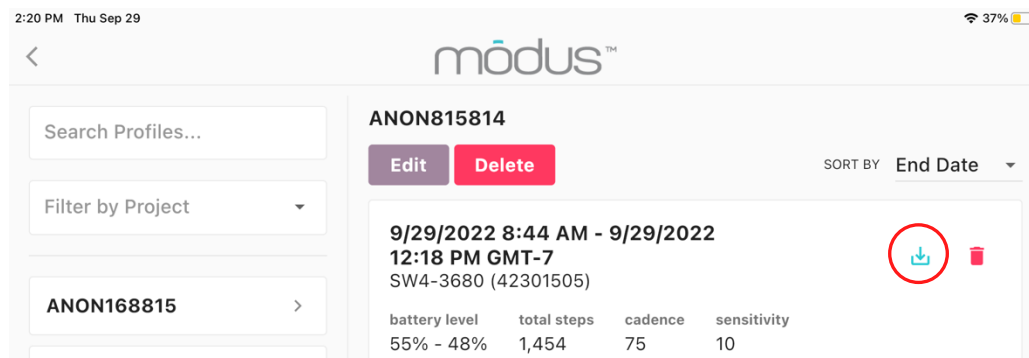
Daily View

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

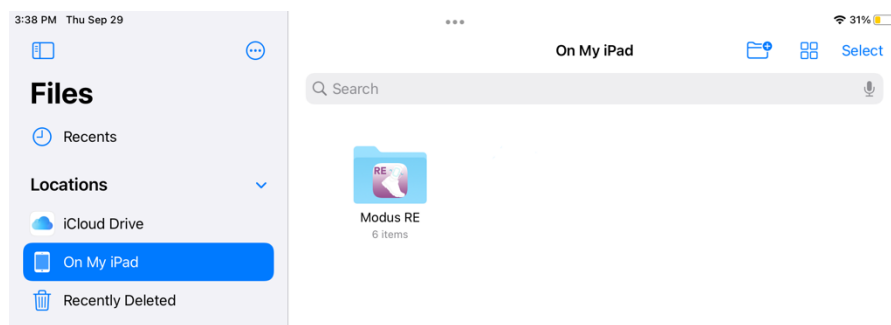
In the top right corner of the session card is the download button.



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 click 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. Alternatively, you can get to the exported file following the directions under "Retrieving Exported Files".

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.

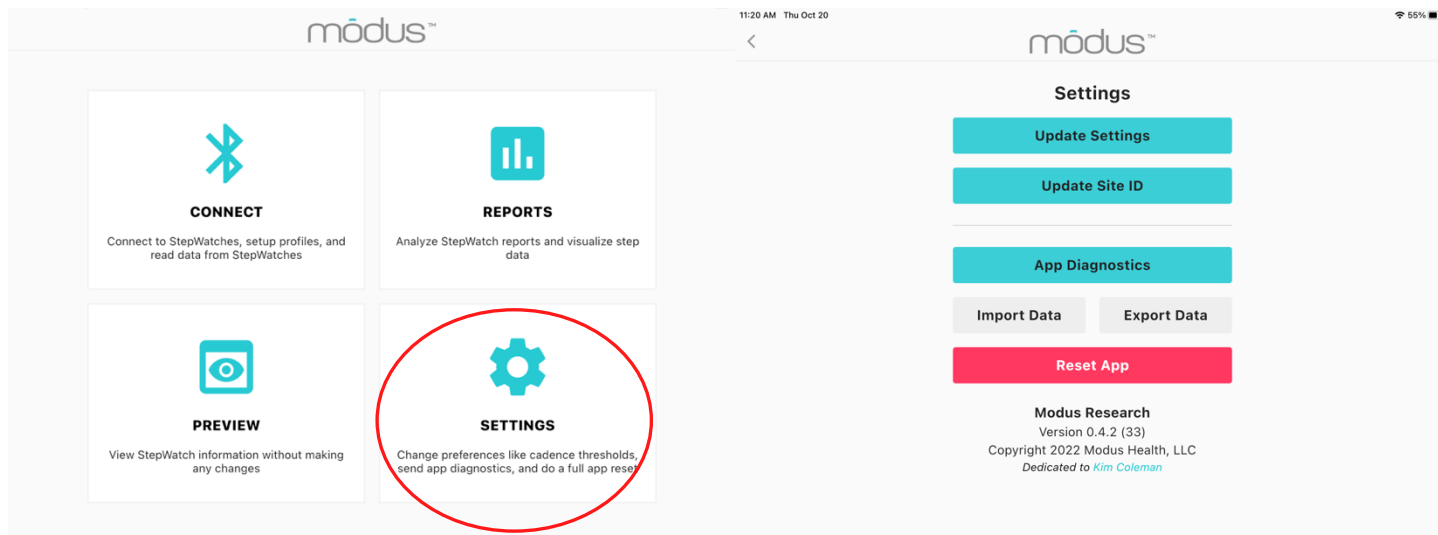


This is where your StepWatch data is stored. You can then use the iPad's native "Share" feature to export selected files to a file storage service (such as Dropbox or Google Drive), airdrop the files, transfer files with the charger using iTunes, or email the selected files to your email account.

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

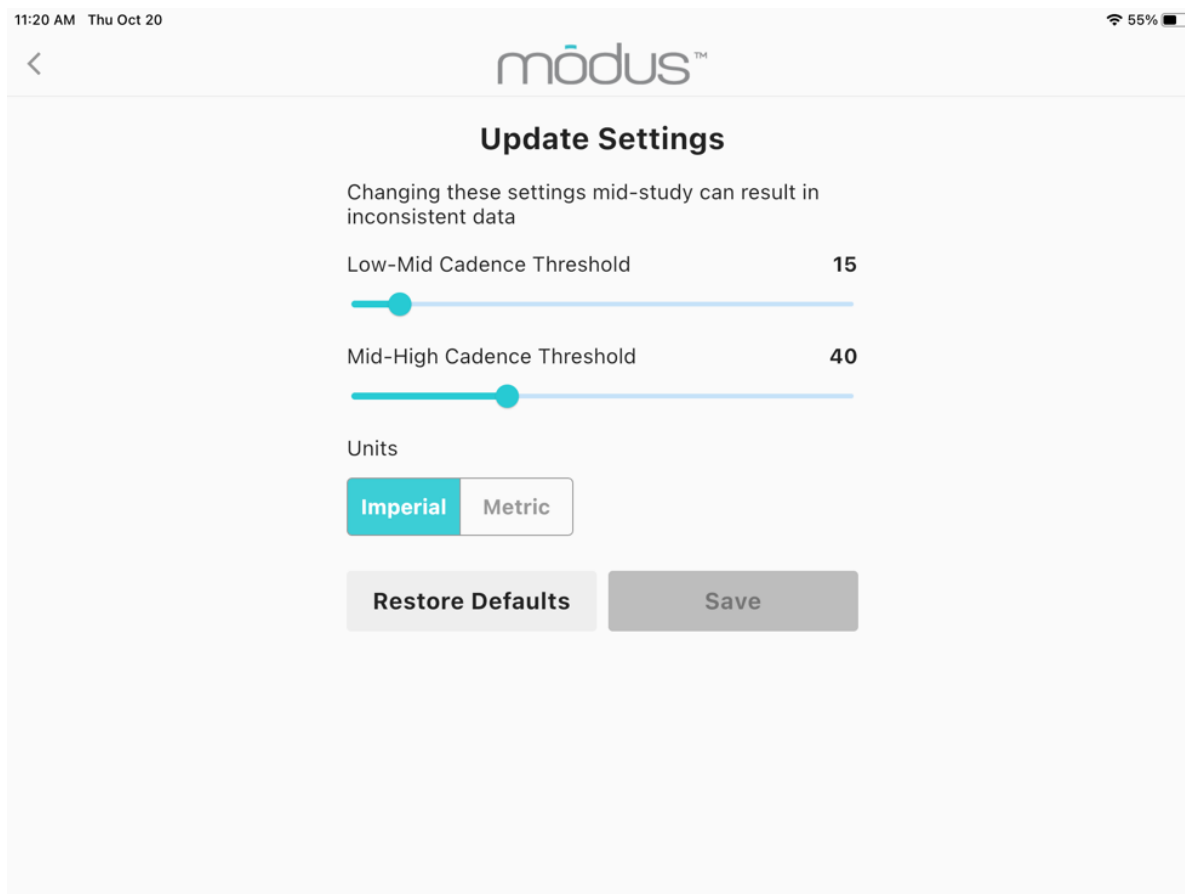
Settings

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

Under update settings you can change the threshold for low, medium, and high activity levels. 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

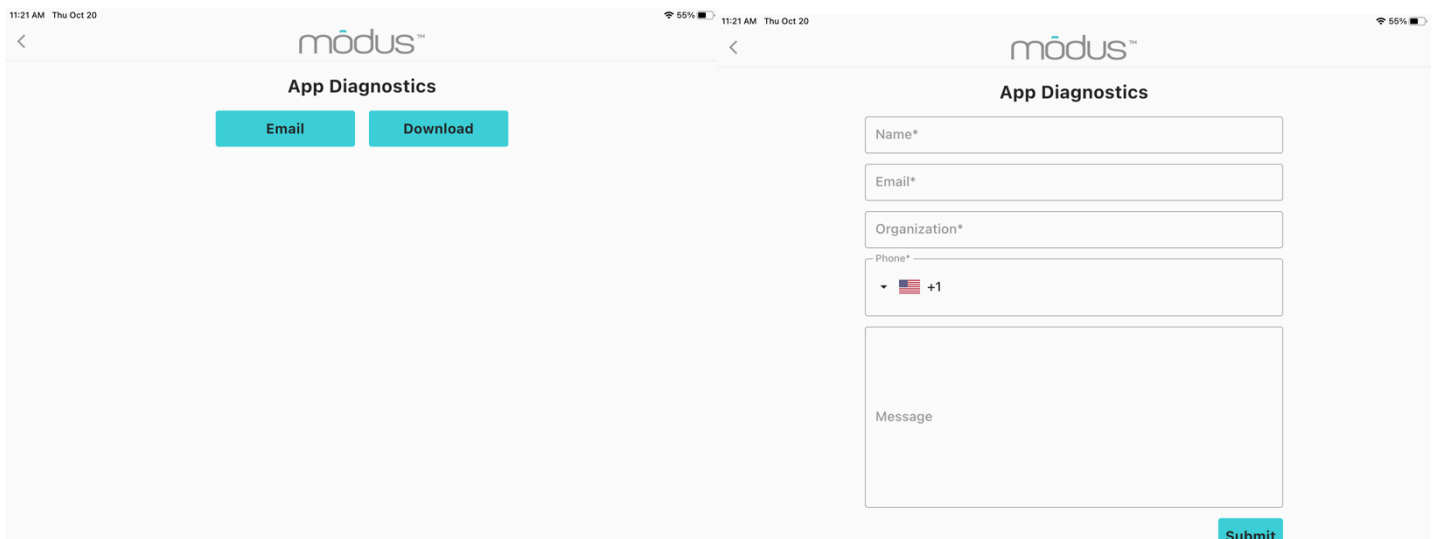
Updating the Site ID is optional. The Site ID allows you to associate a site with your StepWatch data from this iPad so that you know which site collected the StepWatch data. This is helpful if combining StepWatch files from multiple sites in a study folder.



The screenshot shows the 'Update Site ID' screen in the Modus app. At the top, the status bar displays '11:20 AM Thu Oct 20' and '55%' battery. The app header features the 'modus' logo and a back arrow. The main title is 'Update Site ID'. Below it is a text input field labeled 'Site ID' with a character count '0/20'. At the bottom is a grey 'Update' button.

Upload App Diagnostics

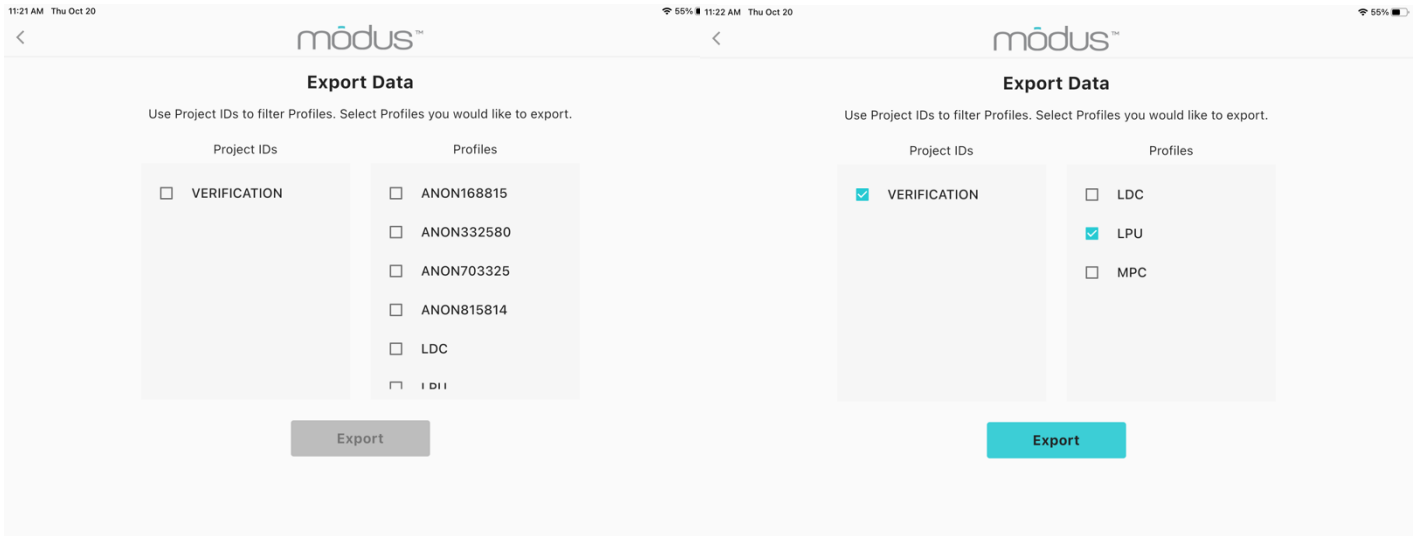
If there are issues with the Modus RE app, we can get a better understanding as to why via App Diagnostics. You will be able to email them directly to our support by pressing email and filling out the form or by downloading the diagnostics and sending them to our support email; support@modushealth.com.



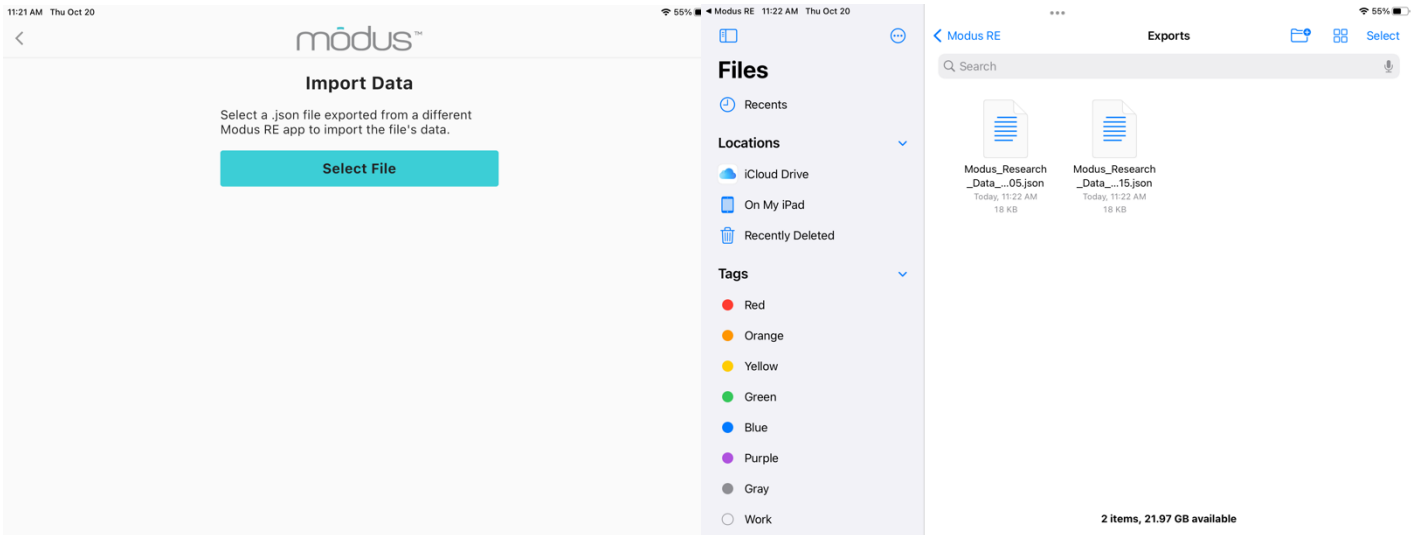
The first screenshot shows the 'App Diagnostics' screen with two buttons: 'Email' and 'Download'. The second screenshot shows the 'Email' form with fields for 'Name*', 'Email*', 'Organization*', and 'Phone*' (with a dropdown for country code, currently showing '+1'). Below these is a 'Message' text area and a 'Submit' button.

Exporting and Importing Data

New to the Modus RE app we have added an option to export and import data. This can be used to transfer over files as well as create back ups. 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.



Appendix 1: StepWatch Care & Safety

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

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.

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

Cleaning StepWatch



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



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

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.

Managing a StepWatch

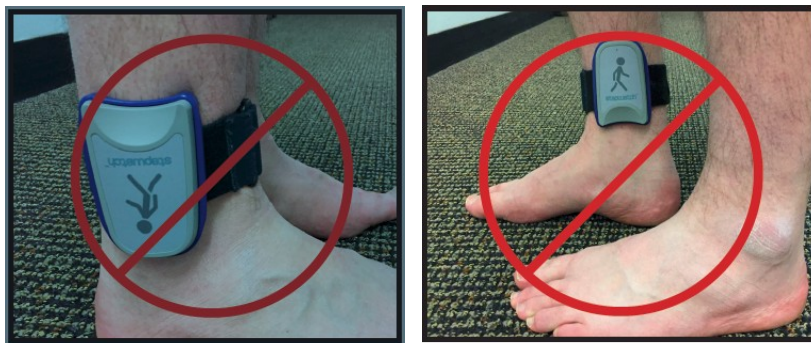
Wearing the StepWatch



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.

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

Incorrect Wearing



Upside down.

Inside the leg.

Appendix 2: Metrics & Data

Modus RE Metric File	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
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
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 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 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	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
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	Value entered during StepWatch setup
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	Bin intervals selected for the 24-hour day (1-min, 30-sec, 20-sec, 15-sec, 12-sec, or 10-sec)
Binned steps	Total steps taken during the binned interval

Appendix 3: Technical Support and FAQ

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 15 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 (IP67). 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.

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.

Appendix 5:

StepWatch Regulatory Information & Specifications

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.

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.

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.
- 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

Performance Characteristics

At least 57 peer-reviewed studies have confirmed the accuracy of StepWatch in people with and without impaired walking and in both adults and children [1]. Because of StepWatches accuracy, StepWatch has been used as the criterion device (gold standard) to measure the accuracy of other tools in at least 34 peer-reviewed studies [2].

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 [3]. Walking at least 275 steps per day during inpatient care identified patients that have reduced 30-day readmission risk [4]. 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 [5].

[1] https://modushealth.com/publications/?fwp_sections=accuracy

[2] https://modushealth.com/publications/?fwp_sections=stepwatch-as-criterion

[3] 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

[4] 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

[5] 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

Software Specifications

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	iPad running iOS 14 or 15
Modus RE	Research Site	iPad running iOS 14-16
CR Site	Clinical Research Trial Site	iPad running iOS 14 or 15
CR Companion	Clinical Research Participant's Home	iPhone running iOS 15 or 16 Android Version 8
CC Clinic	Clinical Care Provider	iPad running iOS 14 or 15
CC Companion	Clinical Care Setting or Patient's Home	iPhone running iOS 14 or 15

Hardware Specifications

Specifications	StepWatch 4
Size	75 x 48 x 14 mm
Weight	41 grams
Accurate Step Detection	For all walking styles, including slow and irregular gait
Step Resolution	Steps per second
Communication Method	Bluetooth connection to Apple iPad
Waterproof	IP67 certified
Battery Life	Over 30 days following setup, Over 20 days if one download per day
Wireless Induction Charging	Input: 5V (2A) and Output: 5W
Onboard Memory	Stores 10 to 30 days between downloads depending on activity level
Wearable Soft Cover	Available in small and medium-large
2 Year Warranty	Warranty begins on day of delivery