

Modus Health LLC

# StepWatch with CC Apps Reference Guide for Users



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## General Information

### Clinic App

The Modus Health Clinical Care (CC) Clinic App is the iPad application and interface for the Clinical Care software. The Clinic App stores all the features and functionalities of the Clinical Care software, including but not limited to short term and long-term participant monitoring, participant communication and goal setting, and physical therapy sessions. This can be downloaded from the Apple App Store.

### Companion App

The Modus Health Clinical Care (CC) Companion App is the iPhone and iPad application for the participant, or patient. It shows the participant their walking progress. The Companion App is used to pair one mobile device to one StepWatch at a time via Bluetooth, and reads the live and stored data off of the StepWatch to transmit it to your facility's cloud for display and monitoring in both the Companion and Clinic apps. The use of the Companion app is optional.

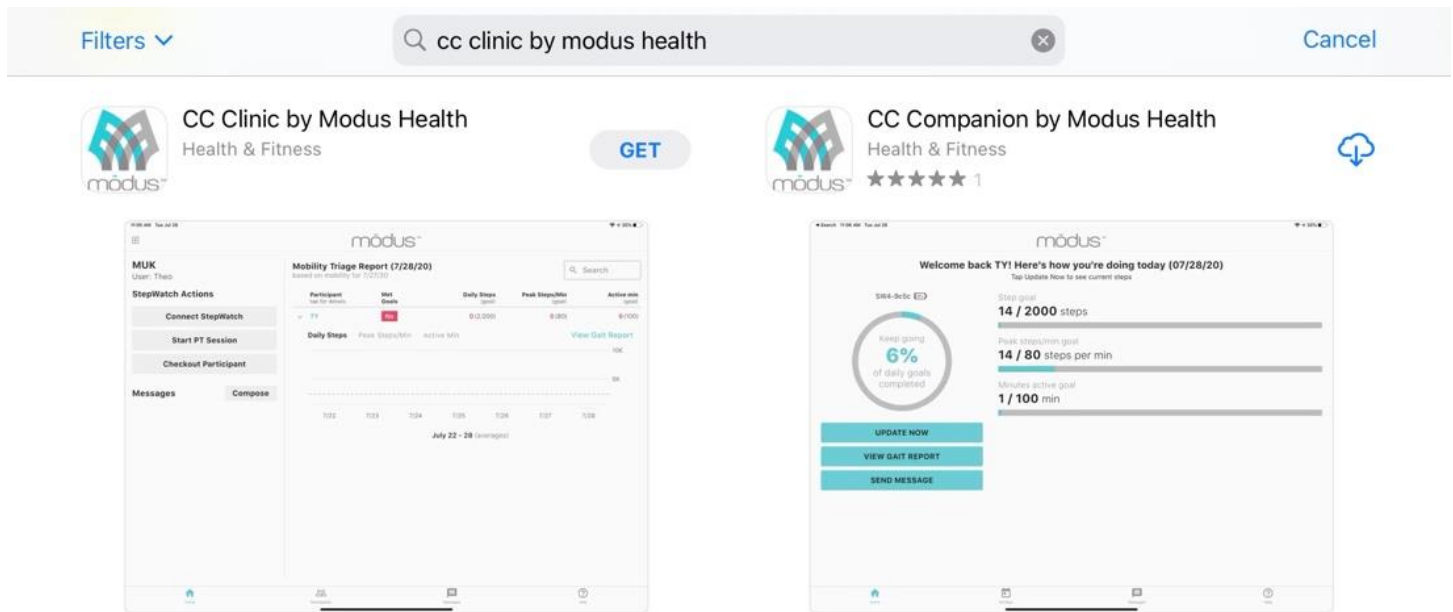
### StepWatch

The StepWatch is the device affixed to the participant's leg that tracks and records all ambulatory data. The StepWatch is charged by using the wireless induction charging pad provided in your purchase of the Clinical Care software. When first received, the StepWatch should be charged on the wireless induction charging pad for at least 3 hours before its first use to ensure full charge. Once paired to the Clinic App, the StepWatch will indicate its battery life, and will inform you if it needs to be further charged. Preparation of the StepWatch prior to visits, as well as proper alignment on participant's legs, is demonstrated further in this manual.

# Initial App Setup

## Installing the Clinic App

To install the Modus Health CC Clinic app on the iPad, visit the Apple App Store and search for “CC Clinic by Modus Health”. Download the CC Clinic App (shown below) to your Clinic iPad.



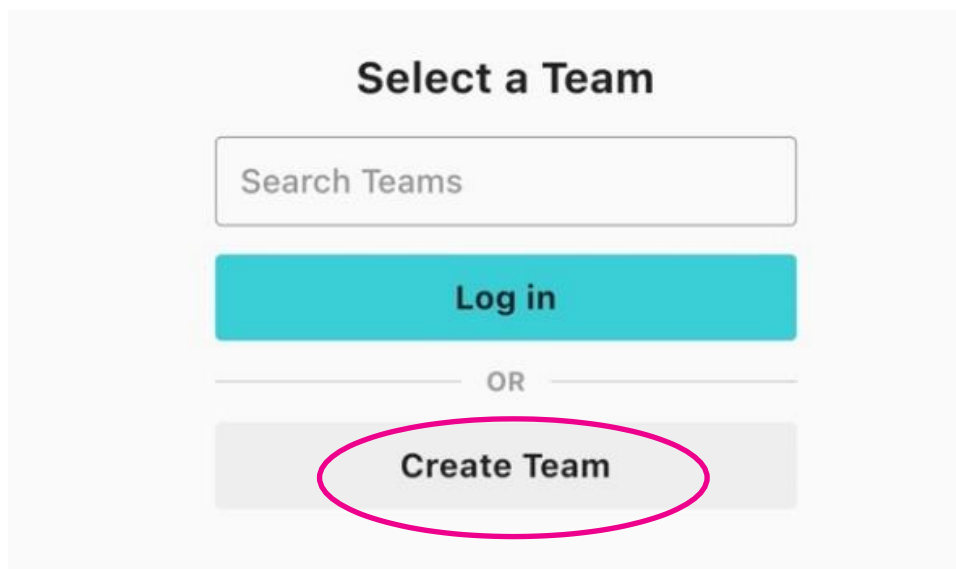
## Creating Your Team

When the app finishes installing, tap the CC Clinic app icon on your home screen to open the application.

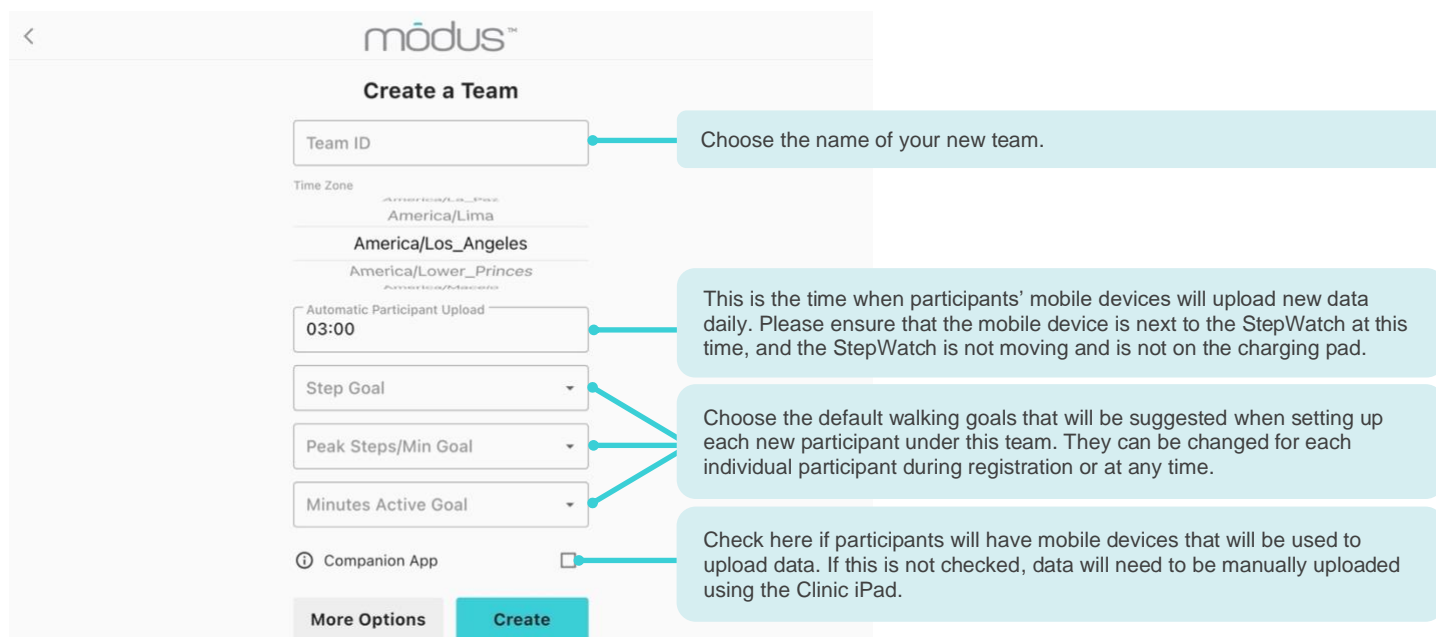
The first time you launch the app, you will be required to enter your Client ID and Project ID before being able to access the app. If you do not know your Client and Project ID, please contact Modus Support at +1 (202) 830-1100 ext. 2, or email at [Support@ModusHealth.com](mailto:Support@ModusHealth.com).

A screenshot of the Modus Health login screen. At the top, the Modus Health logo is displayed in a large, grey, sans-serif font, with "STEPWATCH CLINICAL CARE" in a smaller font below it. Below the text are two white input fields with grey borders, labeled "Client ID" and "Project ID". Below these fields is a large, teal-colored button with the text "Log in" in white. At the bottom of the screen, the text "Version 0.8.5 (78)" is displayed in a small, grey font.

After logging in with your Client and Project IDs, you will be directed to either 'Select a Team,' or 'Create a Team.' For the initial setup, select "Create Team."



From the "Create Team" option, you will be directed to a page with a variety of options to choose from. Depending on your institution and objectives, there will be a wide variety of options you may wish to toggle. Below is the default view and description of the fields under "Create Team."



If you need additional adjustments made to your CC Clinic App, tap the "More Options" button at the bottom of the page. A complete listing and description of these options are provided on the following page.

## [More Options](#)

The screenshot shows the settings interface of the CC Clinic App. It includes several sections: 'Stride Length Assessment' and 'Pin Lock' with toggle switches; 'Units' with 'Imperial' and 'Metric' buttons; 'Population Controls' with a checked 'Population Controls' toggle and four unchecked sub-options; 'Cadence Thresholds' with two sliders; 'Email Activity Thresholds' with two input fields; and 'Battery Warning Threshold' with a slider. At the bottom are 'Less Options' and 'Create' buttons. Callout boxes provide detailed explanations for key features.

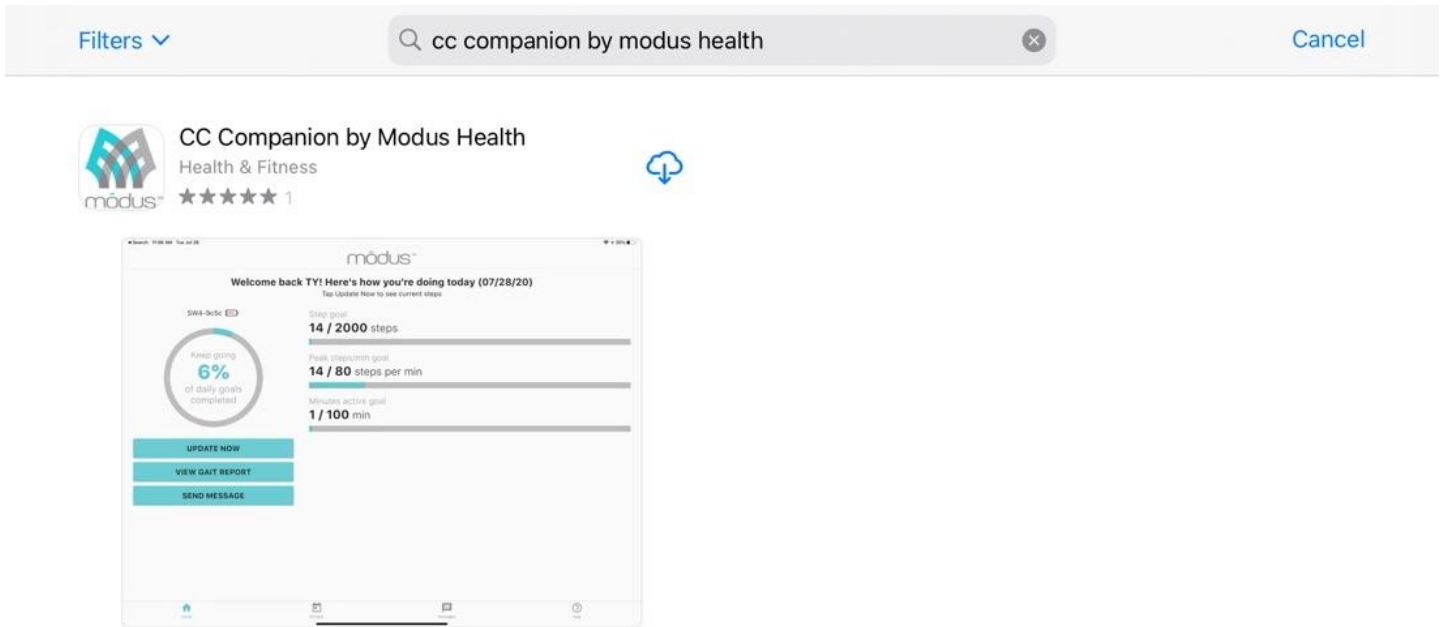
**Settings and Callouts:**

- Stride Length Assessment:** ☐ Toggles Stride Length Assessment during participant setup
- Pin Lock:** ☐ Toggles Pin Lock on the CC Clinic App whenever logging on
- Units:** Imperial | Metric Imperial or Metric option is used for entering participant heights
- Population Controls:**
  - ☒ Population Controls Population controls are available if you wish to limit the number of options to only those applicable to the participants you are treating. For example, if no participants being monitored will be running, select "No Runners". When you setup a StepWatch, this field will be locked to "No Runners."
  - ☐ Runners Only
  - ☐ No Runners
  - ☐ No Severely Impaired
  - ☐ Impaired Only
- Low-Mid Cadence Threshold:** 30 Use sliders to adjust cadence threshold. This will determine which cadence levels (steps per minute) will be considered "Low," "Mid," and "High".
- Mid-High Cadence Threshold:** 80
- Email Activity Thresholds:**
  - Steps Per Day: 0 Choose minimum expected activity levels. If a participant falls below these levels, you will have the option to receive an email notification. Each team member can opt in to email notifications. If you do not want anyone to receive email notifications for low activity, leave thresholds set to 0.
  - Minutes Active: 0
- Battery Warning Threshold:** 50 You will receive a warning when setting up a participant or starting a PT session using a StepWatch that has a battery level below this threshold.
- Buttons:** Less Options, Create

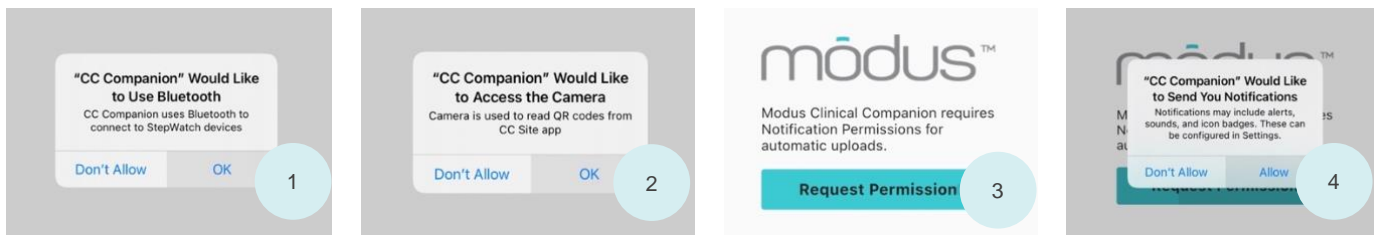
Tap "Create" when you are ready to finalize the settings. These settings can be changed at any time in the CC Clinic app by an "admin" team member. Always remember to tap "Update" when changing settings so they are saved. You will be able to choose which team members have "admin" abilities.

## Installing the Companion App

If you are using the CC Companion App for remote uploads and do not have the app installed on a mobile device yet, search the Apple App Store for “CC Companion by Modus Health” and download the app. Participants can download this app on their own mobile device.



When opening the app for the first time, tap “Ok” to allow Bluetooth in order to connect to StepWatch devices. Allow access to the camera to read QR codes from the CC Clinic app. Request and allow permission to send notifications so that uploads can be triggered, and reminders can be sent if automatic uploads are missed for any reason.



If the mobile device's display is set under 'Dark Mode,' there may be some visibility issues with the application and permission requests. If visibility issues occur, please ensure the mobile device is not set to 'Dark Mode' by going to the iPhone or iPad's settings -> 'Display & Brightness' -> 'Appearance' -> selecting 'Light.'

## 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.

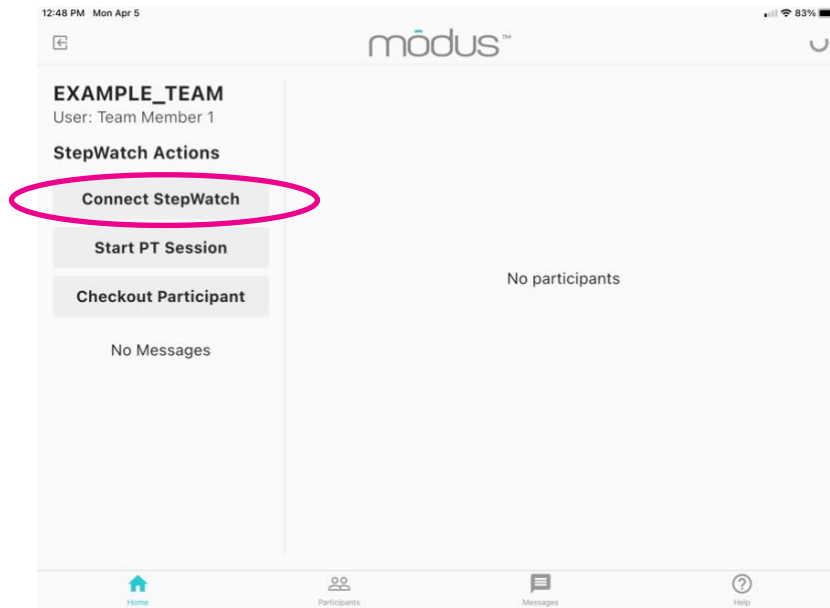


## Setting up a Participant

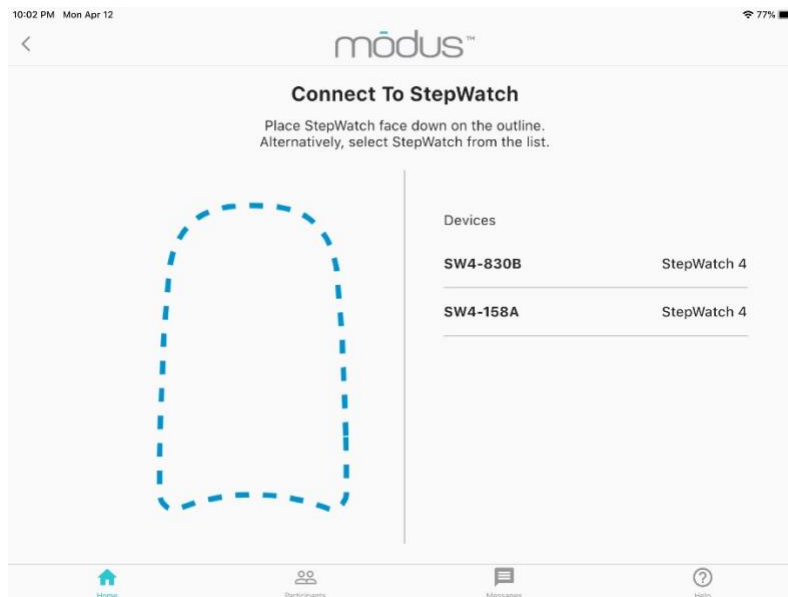
### Connect StepWatch

Internet connection is required for the app to register participants and upload data. Ensure your mobile device is connected to a strong WiFi signal or has at least 3 bars of cellular service.

Launch the app and log in to your team. Tap the “Connect StepWatch” button.



Find the device’s Bluetooth ID above the QR code on the back label. Either place the StepWatch face down on the screen or choose the device from the list. The Bluetooth ID will appear as “SW4-XXXX.”



Select the StepWatch that you wish to use, and you will be directed to the following page:

10:02 PM Mon Apr 12 77%

**modus™**

### Device Information

App	CR
StepWatch Id	SW4-158A
Battery	29%
Mode	Run
Total Step Count	0
Start Date	Wed Mar 31, 2021 6:58 PM
Runtime	12 days, 3 hours, 3 minutes
Sensitivity	10
Cadence	76

### Device Actions

Setup a Participant with a StepWatch

**New** **Returning** **Existing**

Store StepWatch while it's not being used

**Set to Storage Mode**

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Under “Device Actions,” choose the type of participant you are setting up:

- Tap **“New”** to create a new participant
- Tap **“Returning”** if a participant who has been unenrolled is returning
- Tap **“Existing”** if the participant is currently enrolled but the StepWatch device they were using is lost or damaged

If you select **“New,”** you will be directed to the following page.

10:08 PM Mon Apr 12 75%

**modus™**

### Create New Participant

Participant ID

Re-Enter Participant ID

Select Height 2' 0"

☒ Participant is a Runner

Has Impaired Gait No

#### Participant Goals

☒ Steps Per Day Goal 600

☒ Peak Steps/Min Goal 60

☒ Minutes Active Goal 100

**Next**

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## Participant Settings

Enter a Participant ID, height, walking goals, and gait information. Determining whether to use severely impaired, slightly impaired, or no impairment takes some practice. Severely impaired is usually needed for people walking slowly with a walker. Your training will involve how to use choices. The settings are also evaluated for accuracy later in the setup under Verify Steps. Then tap “Next”. Then you will need to attach the StepWatch to the participant.

## Wearing the StepWatch

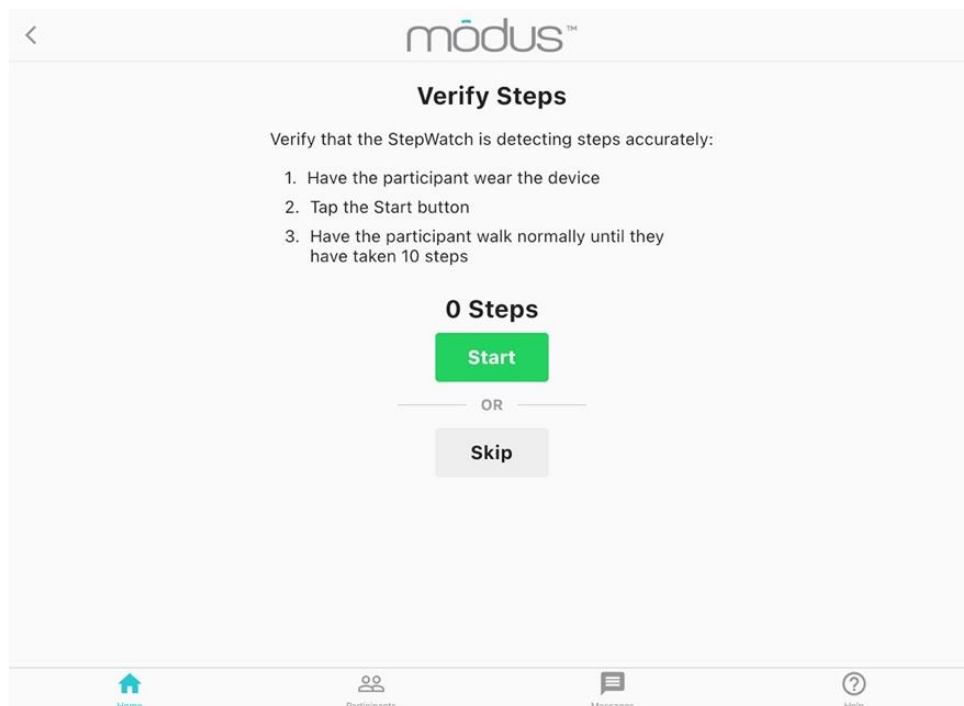
Attach the StepWatch to the participant's leg:

1. Place the soft cover securely on the back of the StepWatch.
2. Insert the Velcro strap through the back with the Velcro side facing towards the StepWatch.
3. Place the StepWatch on the participant and pull the strap through the plastic ring and secure using the Velcro.
4. Place the StepWatch 0.5-1 inch above the anklebone, facing up. The StepWatch name should be readable and walking figure should be right-side-up.
5. Tighten until fit is comfortable but snug enough that it does not slip down. It can be placed on over a sock, and can be used on the outside of either ankle.



## Programming the StepWatch

**Verify Steps:** For this step, you will need space for the participant to walk around. Follow the prompts to complete the step counting verification. It is okay if the device detects more or less than 10 steps. The app will self-correct, and program the StepWatch accordingly.



**Stride Length Assessment:** If you have disabled stride length assessment in team settings, this step will not appear. If you have enabled stride length assessment, you will need a way to measure the walking distance or have the participant walk a known distance. You can also enter the participant's stride length manually.

**Stride Length Assessment**

Tap one of the options below to calculate the participant's stride length.

**By Distance**   **By Time**

Tap the "Enter Stride Length Manually" button if you already know their stride length, or tap "Skip" to proceed to registration.

**Enter Stride Length Manually**

**Skip**

If you choose **By Distance**, you will select a known distance for the participant to walk, in meters. Press start when the participant begins the test, and stop when the participant has walked the selected distance.

If you choose **By Time**, you will select a time of 6 minutes or less for the participant to walk. At the end of the time interval, you will input how far the participant walked, in meters. You will need a way to measure this distance.

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## Final Registration

Verify all of the information is correct, then tap the "Register" button to enter the participant information in the cloud and register them under your team. If this is a returning participant, you will tap "Update" instead of "Register".

**Register Participant**

contentReviewParticipantsInformationBeforeRegistering

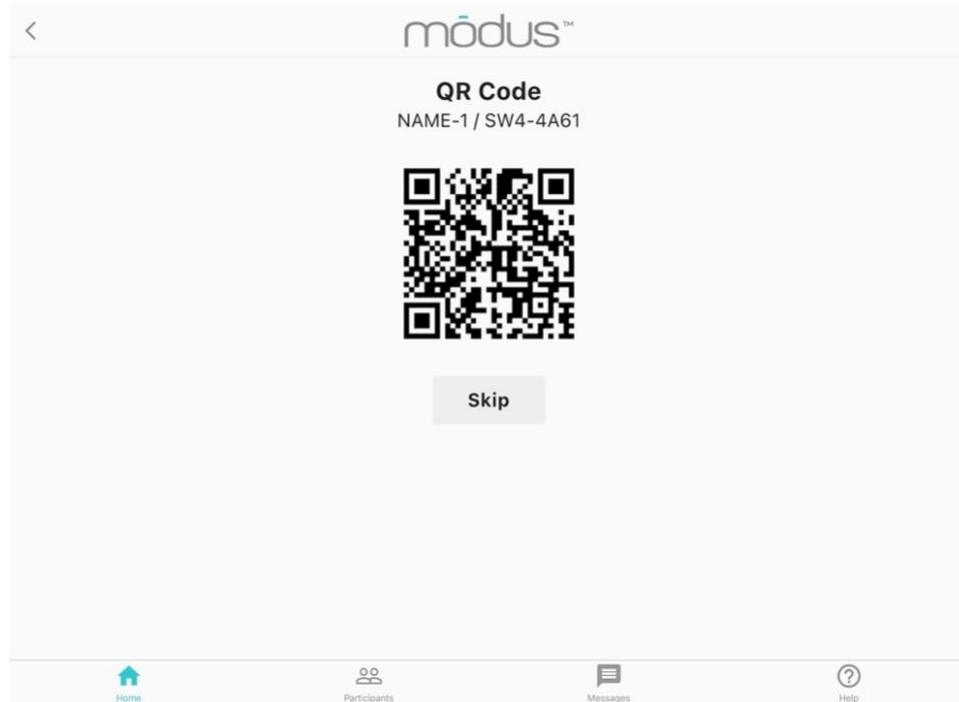
Participant ID	NAME-1
StepWatch Id	SW4-4A61
Height	4' 11"
Walking Ability	Not Impaired
Stride Length	0.67 m
Cadence	66
Sensitivity	12

**Register**

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## Connect using QR Code

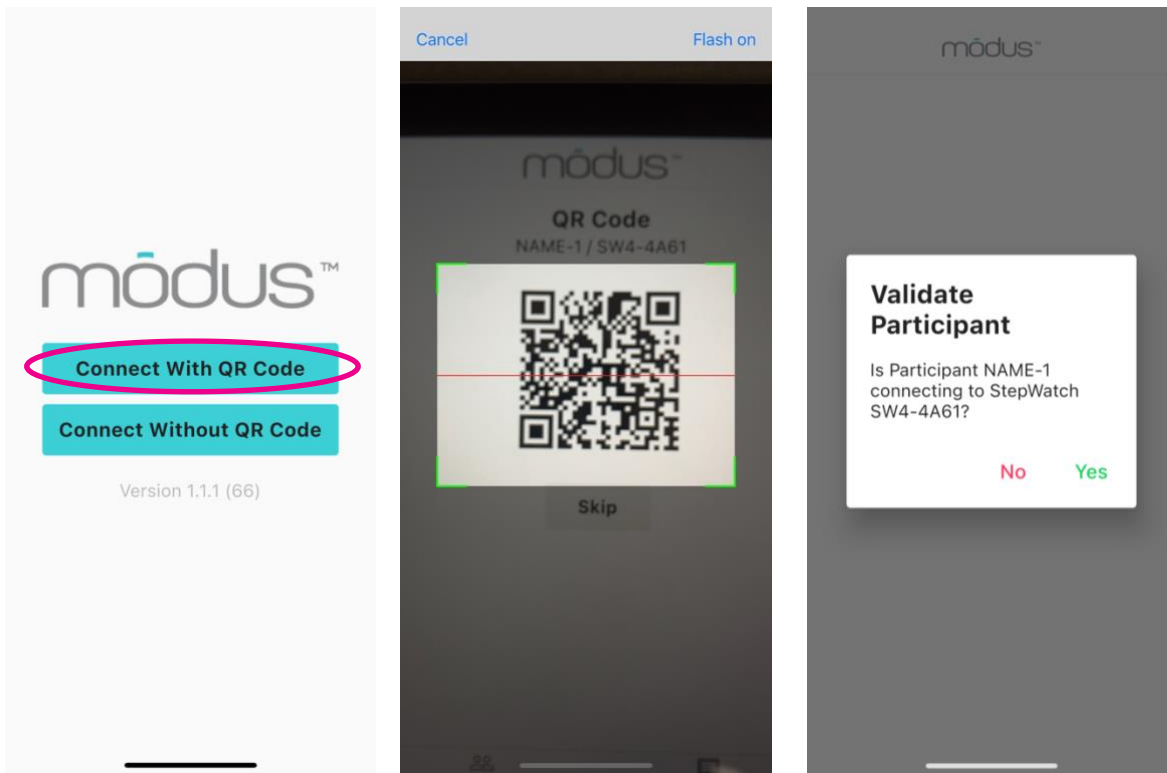
The following screen will show a QR code for connecting a participant's mobile device with the StepWatch. If you do not have the participant's mobile device or do not want to use the QR code, you can press the "skip" or back button to return to the main screen. You can still connect the StepWatch to the participant's mobile device by selecting the Bluetooth ID on the back of their StepWatch on their Companion App.



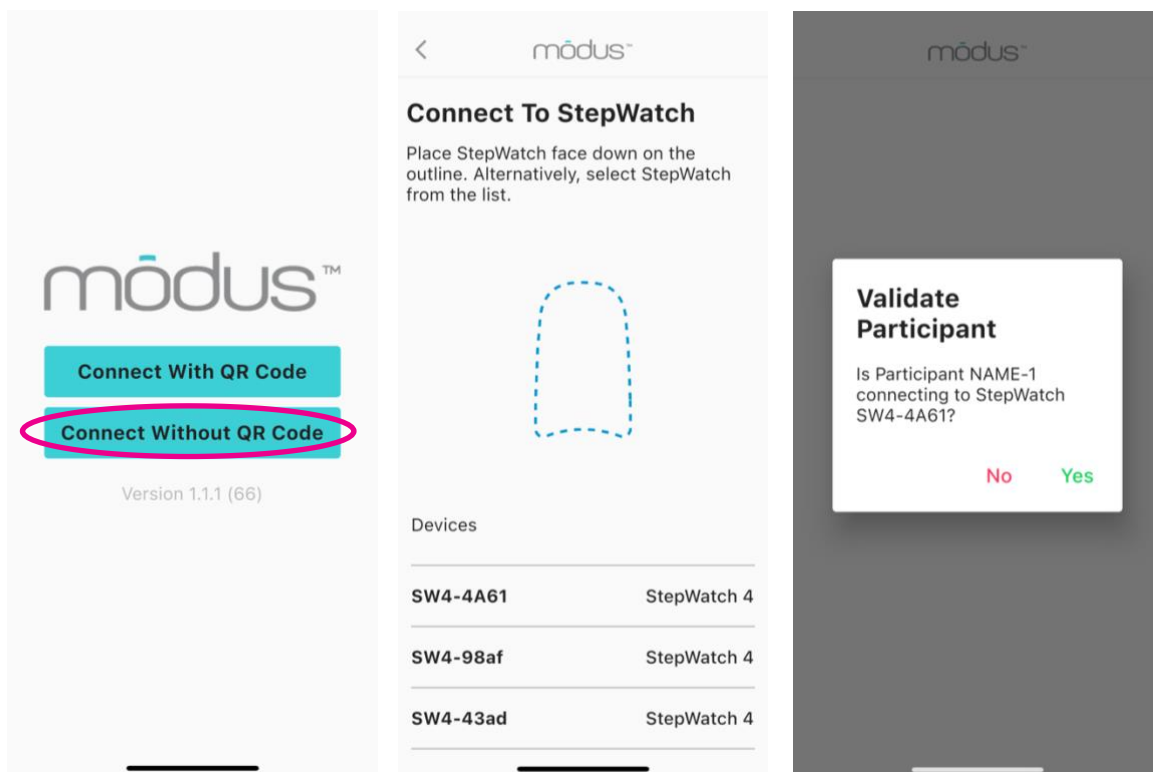
## Using the Companion App

### Connecting to the StepWatch

After downloading the Companion App and accepting the permissions, you can connect the mobile device to the StepWatch. If you have just finished setting up the participant in the Clinic App, tap “Connect With QR Code” and scan the Clinic iPad QR code.



Otherwise, tap “Connect Without QR Code” and either wait 30 seconds for the device to connect or select the Bluetooth ID of the StepWatch you want to connect to.



## Uploading Data

The Companion App will automatically upload new data each night at the time selected in the team settings. If the app is unable to connect to the StepWatch overnight, it will send a push notification to the mobile device to tell you to open the app. When you open the app, it will automatically upload the data. To upload additional data at any time, you can tap “Update Now” on the Home screen.

StepWatch must be in the same room as the mobile device with the Companion App for a successful connection and upload.

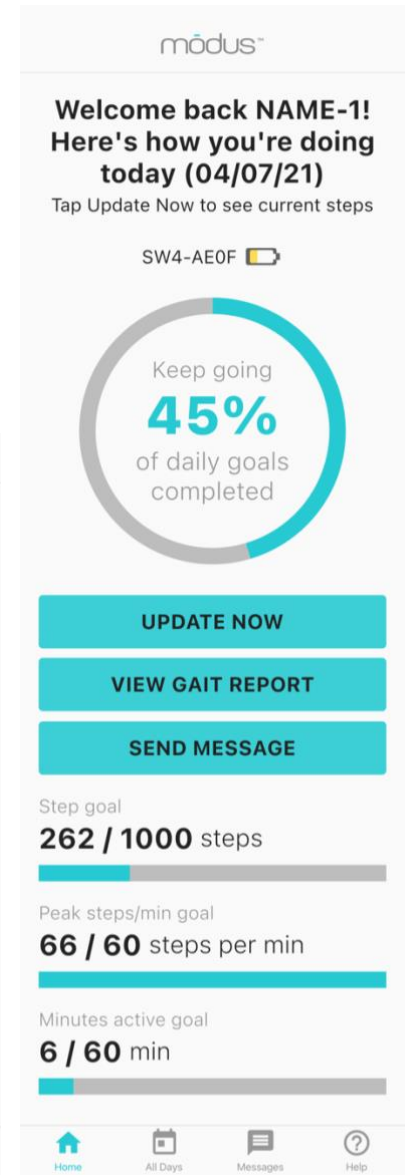
## Viewing Progress

**Daily Progress:** The Home page of the Companion App (far right) will show you the total percentage of goals that have been met that day. You can scroll to the bottom to see the goals and progress towards each of these goals individually.

**Gait Report:** Tap “view gait report” on the home screen to view statistics for any day or range of days that the participant was using StepWatch. Slide the left and right sliders to select a range of dates. Statistics available in the gait report are:

- **Daily Steps:** Average daily steps on the days selected
- **Active Minutes:** Average number of minutes per day when any steps were taken
- **Peak Steps/Min:** Average of the number of steps taken in the most active minute of each of the selected days
- **Average Steps/Min:** Average number of steps per minute (cadence) calculated using all active minutes of the selected days
- **Low Steps/Min:** Percent of active minutes that were “Low cadence” according to team settings. Default is 1 – 30 steps per minute. Averaged between the selected days.
- **Medium Steps/Min:** Percent of active minutes that were “Medium cadence” according to team settings. Default is 31 – 80 steps per minute. Averaged between the selected days.
- **High Steps/Min:** Percent of active minutes that were “High cadence” according to team settings. Default is over 80 steps per minute. Averaged between the selected days.

**All Days Report:** Tap “all days” at the bottom of any screen to see steps, peak steps/min and minutes active for the participant for any one day. Tap bars on the graph to view different days.



## Messaging

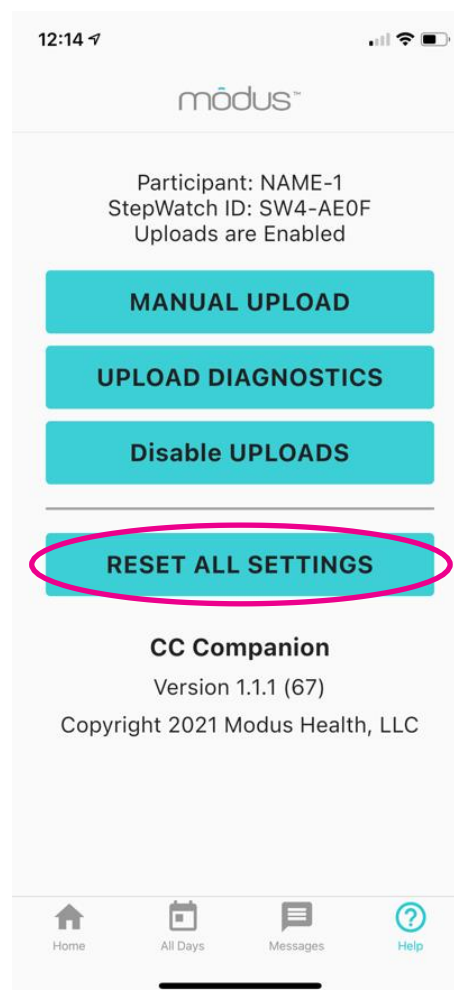
Tap “Send Message” to send messages between the participant and team members assigned to their team. Participants can select which team member they want to send a message to.

## Resetting the Companion App

If “Checkout Participant” is used in the Clinic App, the Companion App is automatically reset. If assigning a StepWatch to this mobile device, again, first, set up the StepWatch and scan the QR code as before. You may have to wait up to 30 seconds after setting up the StepWatch to connect to the Companion App.

If a participant has lost a StepWatch and, therefore, needs a new StepWatch connection, you will need to reset the Companion App. To do this, navigate to the Help screen of the Companion App and tap “Reset all settings”. You will be prompted to enter a team member name and their PIN.

Follow the instructions for setting up a StepWatch for an existing participant. scan the QR code as before. You may have to wait up to 30 seconds after setting up the StepWatch to connect to the Companion App.





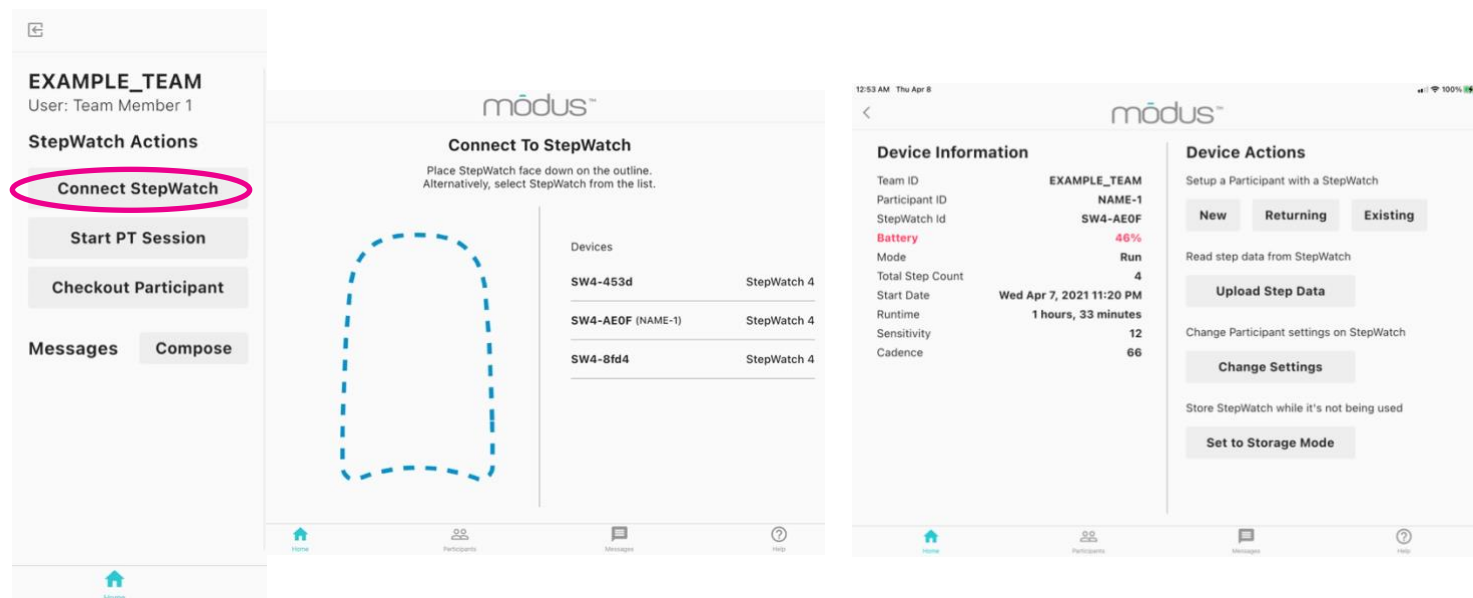
# Using the Clinic App

## Previewing a StepWatch

Tap “Connect StepWatch” on the Home screen. Select the StepWatch from the list or set StepWatch on the screen for up to 30 seconds. You can now view information about the StepWatch. If StepWatch has been programmed to record, it will show the Team ID, Participant ID, Total Step Count that has not been uploaded, Start Date is the date and time from the last upload, Runtime is how long it has been recording since the last upload, Sensitivity (used in the StepWatch algorithm), and Cadence (used in the StepWatch algorithm). StepWatch ID, Battery %, and Mode always shows even if StepWatch has not been set up.

Under “Mode,” there are two options that can occur:

1. Run - The device is actively collecting data.
2. Idle – The device is on but is not actively collecting data.



## Uploading Step Data

You can upload data from any StepWatch from the Clinic App at any time. Connect to the StepWatch as above, then tap “Upload Step Data” under Device Actions. You will receive a popup notification indicating the data was successfully uploaded. Ensure that the StepWatch is nearby and is not charging.

## Changing Participant Settings

When a participant’s gait or walking goals change, you can update this information by connecting to the StepWatch. Connect to the StepWatch as above, then tap “Change Settings”. Here you can change goals, height, gait type, and whether or not the participant runs. Tap “Next” and you will be able to update the verification and stride length, or skip them. You will get a popup letting you know the settings were updated successfully. If you only want to update the walking goals, see instructions under “Updating Goals”.

## Set to Storage Mode

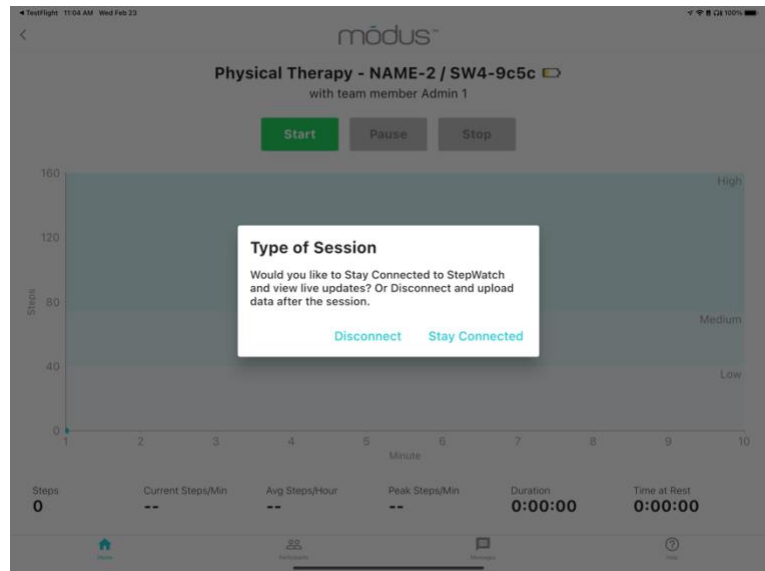
You may choose to save battery while a participant is not uploading new data by selecting “Set to Storage Mode” from the same menu as above. This will put the StepWatch to sleep, preserving battery in the device. The participant will remain enrolled, and the Companion App will remain paired with the StepWatch, but no new data will be recorded or uploaded. To begin recording more data, place the StepWatch on the wireless induction charger for 10 seconds and remove it before attempting to upload again.

## Physical Therapy Sessions

Tap “Start PT Session” from the Home screen and connect to the correct StepWatch for your participant. Select Connected or Disconnected data collection method.

If you choose **Connected**, the StepWatch will need to be within Bluetooth range of the iPad for the entire session, and you can view the data each minute as it is collected.

If you choose **Disconnected**, the StepWatch will not be connected to the iPad via Bluetooth, and the data will be uploaded to the iPad when the session ends. Use this if you cannot carry the iPad near the participant during the session.

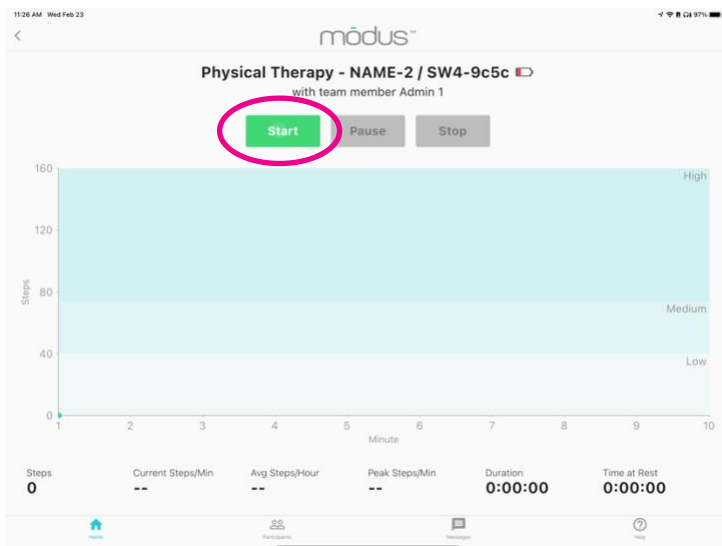


Tap “Start” to begin the session, keeping the iPad in the same room of the participant.

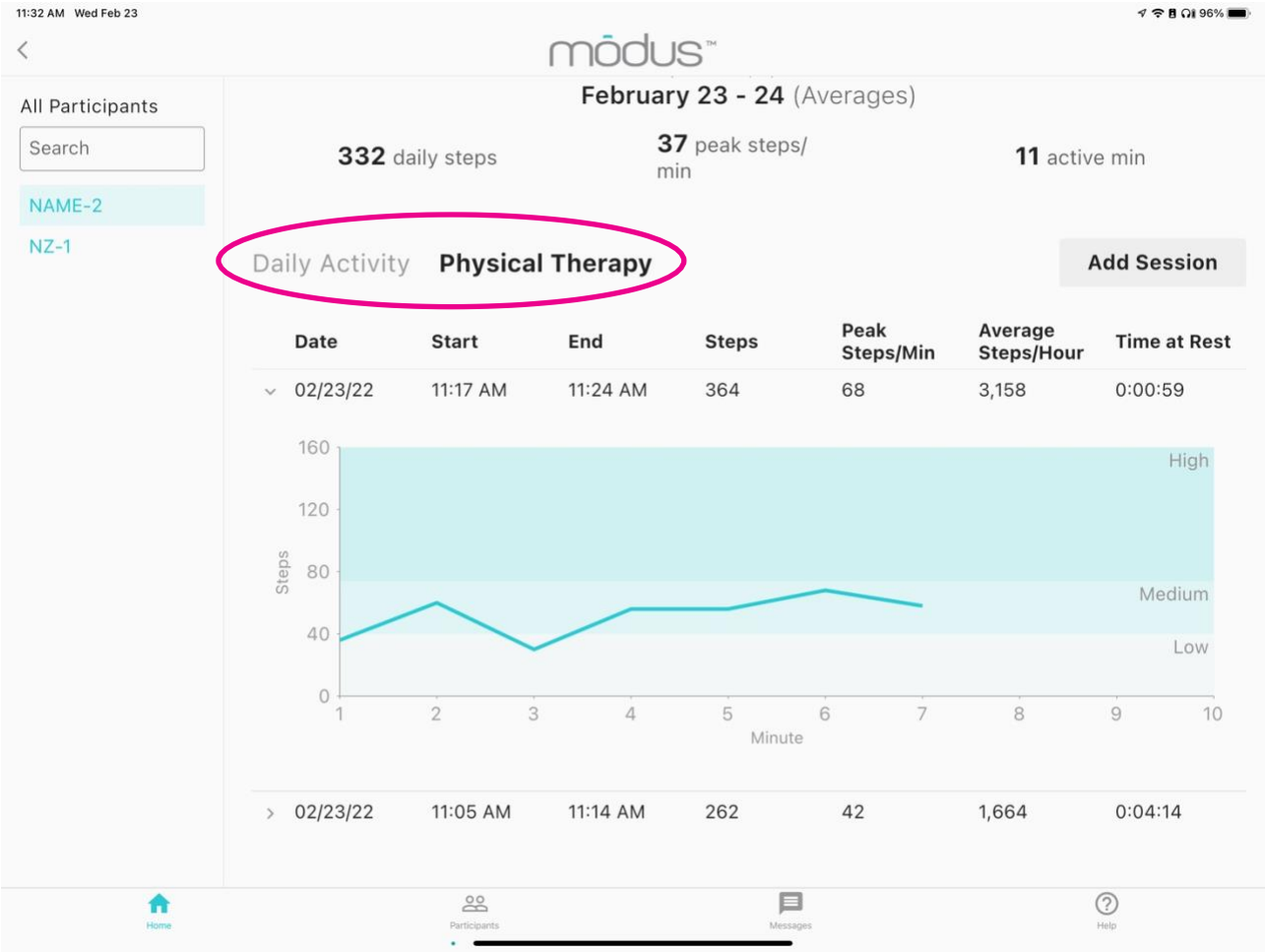
The step data will begin to appear after the first minute has passed, and will continue to present more data each minute for the entire duration of the physical therapy session.

Step data is broken down by steps per minute, average steps per hour, peak steps per minute, and time at rest. **Time at rest** is defined as the sum of any 10 second or longer rest without any steps taken.

The cadence thresholds are shown on the graph, demonstrating time spent in low, medium, and high activity, as previously defined in the team settings.



To view completed PT session data, select the participant on the “Home” screen or the “Participants” screen. Scroll to the bottom, and change the data view from the default “Daily Activity” to “Physical Therapy”.



## [Viewing Reports](#)

### Mobility Triage Report

The mobility triage report is designed to highlight who immediately needs your help. The participants that did not meet their mobility goals are at the top of the list. Participants that have no data are in the middle, and participants that met all of their mobility goals are at the bottom. Those that did not meet their goals may need more of the clinician's time to determine the barriers to achieving their goals.

1:27 PM Thu May 14

100%

**TERI**  
User: Test

**StepWatch Actions**  
[Setup StepWatch](#)  
[View StepWatch](#)  
[Start PT Session](#)

**Messages**  

**P-NINA** 12:41 PM  
happy for you,

**P-TERI** 11:48 AM  
how can I help you reach your ...

**P-SYDNEY** 4/29/2020  
keep up the good work

[Compose](#)

**Mobility Triage Report (5/14/20)**  
based on mobility for 5/13/20

Participant tap for details	Met Goals	Daily Steps (goal)	Peak Steps/Min (goal)	Active (min) (goal)
> P-SYDNEY	No	716 (1000)	62 (80)	35 (100)
> P-NINA	Yes	5,970 (1000)	130 (80)	148 (100)
> P-TERI	Yes	6,514 (5000)	108 (100)	154 (150)

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## All Participants View

Tap the “Participants” screen at the bottom to view all the participants that you have managed with a StepWatch. This view has the latest information about each participant.

Tap “Filters” to filter the participants by date range (Filter by Date), if they have met their goals for the most recent day of data (Met Goals), if email notifications are enabled for the participant (Notify), and if the participant is actively being monitored (Enrolled).

11:38 AM Tue Apr 13 41%

modus™

### All Participants

Team: STROKE

Search Filters

Filter by date: Start End

Met Goals: No All Yes

Notify: No All Yes

Enrolled: No All Yes

Participant tap for details	Met Goals	Daily Steps (goal)	Peak Steps/Min (goal)	Active min (goal)	Notify	Enrolled
NEWNINA	--	--	--	--	No	No
> P-TERI2	Yes (06/14/20)	10,870 (300)	120 (60)	180 (100)	No	No
> ROSE	No (04/13/21)	116 (500)	56 (60)	3 (60)	Yes	Yes
> TRUN	No (07/01/20)	774 (1,000)	102 (60)	26 (120)	No	No
> WINTER	No (04/13/21)	118 (300)	80 (80)	2 (60)	Yes	Yes
> WUSTL	No (04/05/21)	0 (2,500)	0 (60)	0 (60)	No	No
> ZOE	No (04/13/21)	0 (2,500)	0 (60)	0 (100)	Yes	Yes

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This is an example of filtering with Enrolled set to Yes:

11:38 AM Tue Apr 13 41%

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### All Participants

Team: STROKE

Search Filters

Filter by date: Start End

Met Goals: No All Yes

Notify: No All Yes

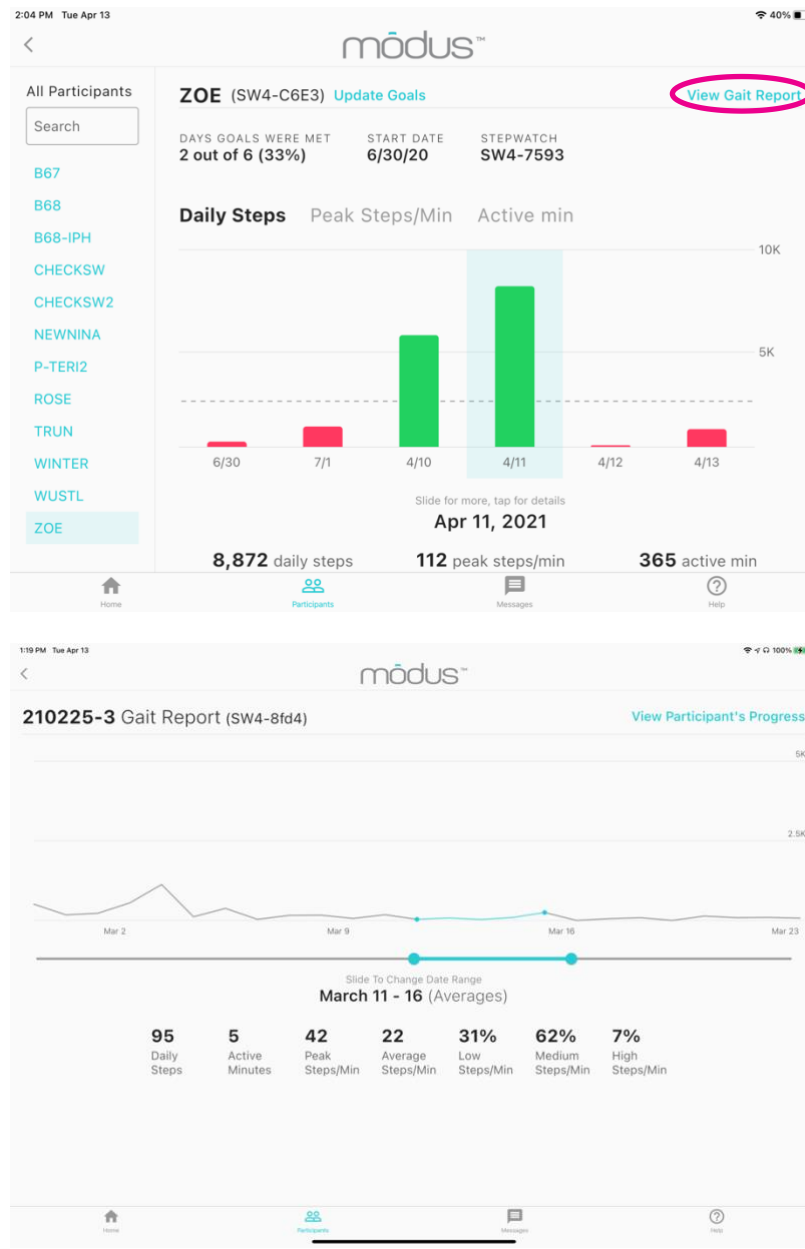
Enrolled: No All Yes

Participant tap for details	Met Goals	Daily Steps (goal)	Peak Steps/Min (goal)	Active min (goal)	Notify	Enrolled
> ROSE	No (04/13/21)	116 (500)	56 (60)	3 (60)	Yes	Yes
> WINTER	No (04/13/21)	118 (300)	80 (80)	2 (60)	Yes	Yes
> ZOE	No (04/13/21)	0 (2,500)	0 (60)	0 (100)	Yes	Yes

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## Gait Report

Tap “View Gait Report” in the top right corner of a participant’s page to view their gait report. This contains statistics for any day or range of days that the participant was using StepWatch.



Slide the left and right sliders to select a range of dates. Statistics available in the gait report are:

**Daily Steps:** Average daily steps on the days selected.

**Active Minutes:** Average number of minutes per day when any steps were taken.

**Peak Steps/Min:** Average of the number of steps taken in the most active minute of each of the selected days.

**Average Steps/Min:** Average number of steps per minute (cadence) for all active minutes of the selected days.

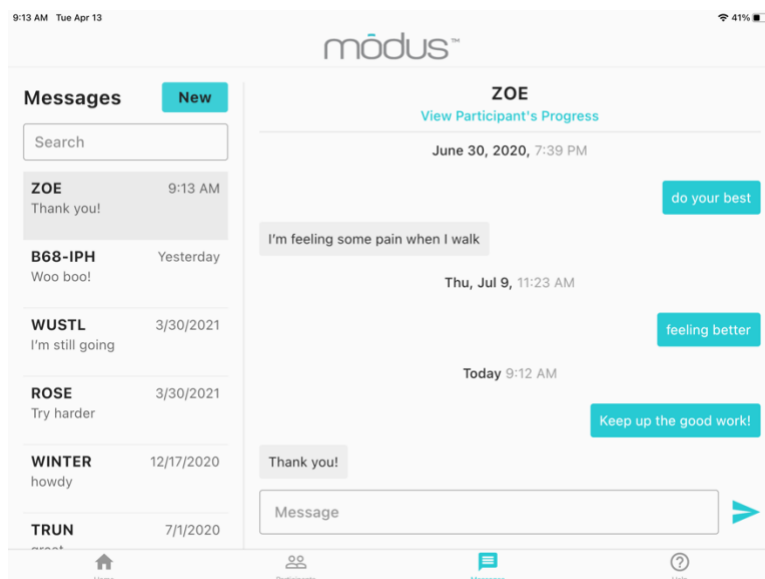
**Low Steps/Min:** Percent of active minutes that were “Low Cadence” according to team settings. Averaged between the selected days.

**Medium Steps/Min:** Percent of active minutes that were “Medium Cadence” according to team settings. Averaged between the selected days.

**High Steps/Min:** Percent of active minutes that were “High Cadence” according to team settings. Averaged between the selected days.

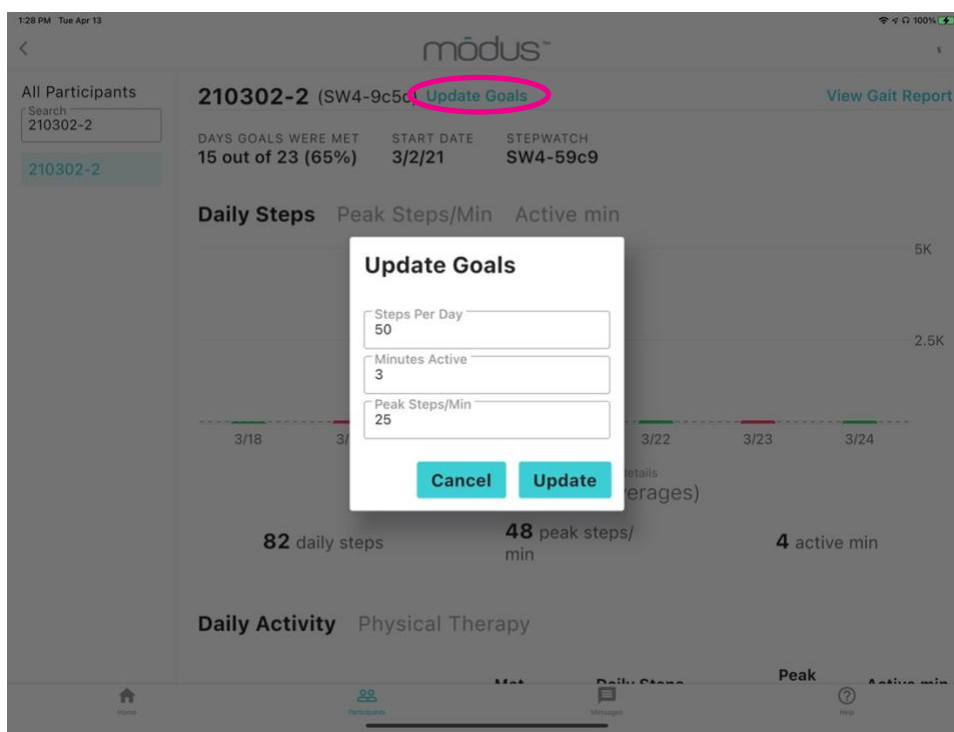
## Messaging

In the Clinic App and the Companion App, participants and team members can directly message one another, including questions, encouragement, or any other communication that needs to occur.



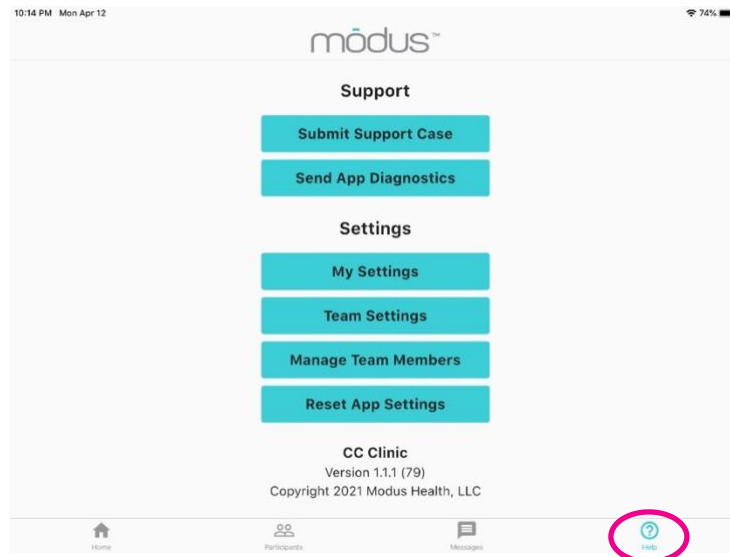
## Updating Goals

When you need to change goals for a participant, under the “Participants” section of the Clinic App, select “Update Goals” to the right of their Participant ID at the top of the screen. Here, you can manually input new Steps Per Day, Minutes Active, and Peak Steps Per Minute goals for each participant.



## Help Screen

You can access the Help screen at any time by tapping Help in the bottom right corner. This is where you can access the app version, submit a support case via email, upload app diagnostics, and update your settings.

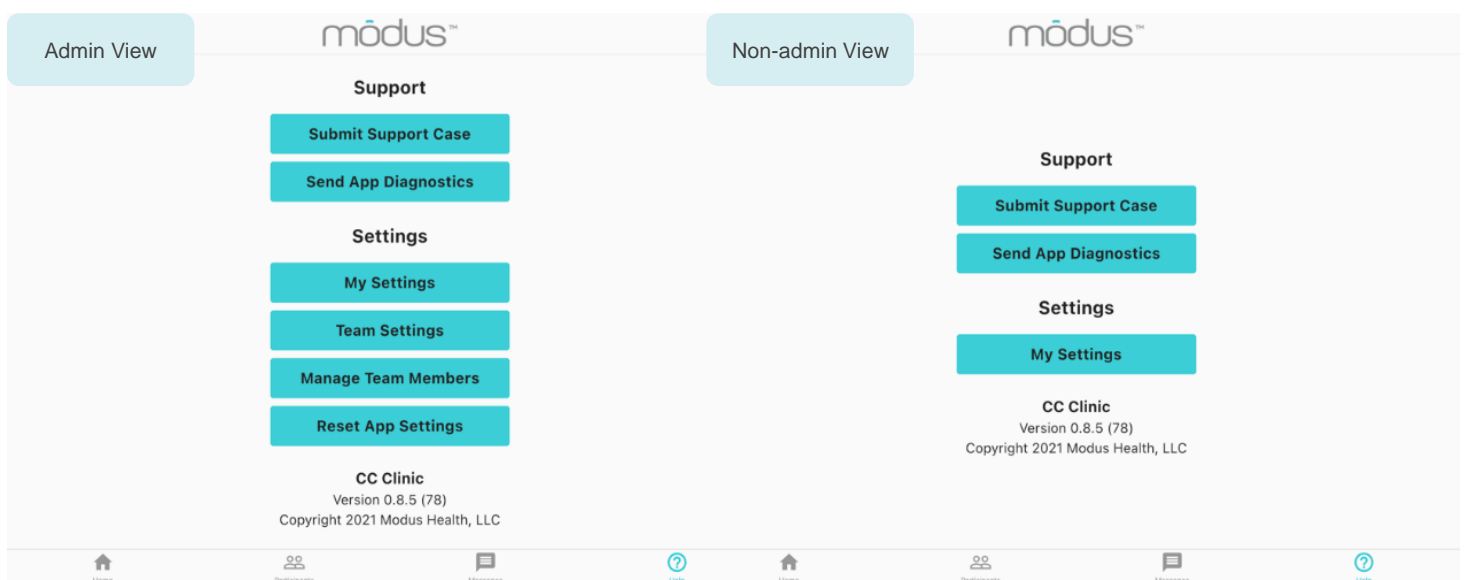


### Support and Settings options for all users:

- **Submitting a support case:** To submit a support case, your iPad will have to be set up for email. Please include name, email, organization, phone number, and relevant details surrounding the issue to best assist us in diagnosing and fixing the problem.
- **My Settings:** Each team member can change their name, email, PIN, and email options. Remember to press “update” when changing settings or they will not be saved.
- **Send App Diagnostics:** Tap if you are having an issue with the Clinic app and are directed to do so. This will push a specific type of diagnostic file to Modus’ technology department to assist us in diagnosing and fixing the problem.

### Additional options for admin users:

- **Team settings:** Admin users can update any of the settings for their team seen in pages 5 and 6.
- **Manage team members:** Add new team members, set their admin status, set team members as active or inactive. Inactive members will not be able to log in, message participants, or receive emails, but they can be re-activated at any time. Admin users can also delete team members permanently.
- **Reset App Settings:** This will reset the app, logging out your team and facility entirely. This does not delete data in the cloud, but you will need to log in to your facility again to access the app.





## 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.

## Cleaning the StepWatch

If needed, you can clean the StepWatch by rubbing gently with a wet cloth or disinfectant wipe. To clean the strap, hand-washing with soap and warm water is preferred. Air-dry, or set dryer heat to low. It is recommended that the same strap is used with the same participant. Straps can be disposable following a participant's checkout of the program.



**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.

## Charging the StepWatch



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

A light will illuminate when your StepWatch begins charging.



Do not place StepWatch on edge of charger.








Do not place StepWatch upside-down on charger.





## Interpreting the LEDs

(\*StepWatch 5 only)

**Mode:** Determining what mode the device is in

-  \*2 blue lights for 10 seconds: StepWatch has been set up and is in **run mode**
-  \*2 purple lights for 10 seconds: StepWatch is in **idle mode** and is not recording steps
-  \*2 white lights for 10 seconds: StepWatch is in **storage mode** and is not recording steps. The Bluetooth radio will be turned off until the StepWatch is placed on a charger. This will preserve the battery until the next use
-  1 green blinking light: StepWatch is **recording**, and will blink on each of the first 40 steps detected after setup (or the number of steps which was selected during setup)
-  \*3 pink blinking lights for 20 seconds: Battery ran out of charge and went into storage mode. **It is no longer recording steps.** These lights will continue to blink after charging until StepWatch is put back into recording mode.

**Battery level:** Double tap the back of the StepWatch to display the battery indication lights

-  \*3 green lights for 3 seconds: Battery level is **67%-100%**
-  \*2 yellow lights for 3 seconds: Battery level is **34%-66%**
-  \*1 red lights for 3 seconds: Battery level is **10-33%**
-  \*1 blinking red light: Battery level is **less than 10%**

## Interpreting the Identification Label

**Part Number:** Identification of the design of the device

FCC and IC Bluetooth radio identification

Date of Manufacture

**This device contains a lithium battery.** Lithium-ion batteries should not be disposed of in residential or commercial waste.

**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.

**This device contains a Bluetooth radio:** device uses NINA-B112 radio to transmit step data to your mobile device

This device meets all applicable regulations to be placed on the market in the **European Union**



**Model of Device:** StepWatch 4 or StepWatch 5

**Bluetooth ID:** this is the number that will appear on the mobile apps to identify which device you are connecting with

**2D Data Matrix:** this code can be scanned to read the UDI and Bluetooth ID

**Unique Device Identifier (UDI):** global identification of the device that allows users to report safety incidents to local authorities. The first number is linked to the device information and company, the second number is the **Serial Number**



## Frequently Asked Questions

### What happens if I forget my clinician PIN?

Contact the Modus Helpdesk to retrieve your clinician PIN.

### 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.

### 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 wet.

### Can I reuse a StepWatch for a different participant?

The same StepWatch is meant to be used with the same participant for the duration you wish to monitor the participant's walking with StepWatch. If StepWatch is lost or broken, you may setup a new StepWatch for a participant using the Existing Participant feature in the app. The Companion App will need to be reset to be associated with this new StepWatch.

### Do participants see any other participants data?

No, the Companion App only shows the participant's data that is connected to a specific participant ID.

### When should I checkout a participant?

You should checkout a participant when they have completed the mobility program and you no longer wish to monitor their walking with StepWatch.

### How does a participant update their stepping data?

They tap "Update Now" in their CC Companion app.

## Troubleshooting

### The StepWatch cannot connect to the iPad:

Make sure the StepWatch is not on a charger when trying to connect.

Make sure the StepWatch has some battery life by charging it for at least 15 minutes.

Try restarting app.

If problems persist, contact the Modus Helpdesk.

### The participant's mobile device will not connect to StepWatch:

Make sure the participant accepted all of the requests when first downloading the CC Companion app. Accepting the use of Bluetooth and notifications are needed for the app to run. They can try redownloading the app if the initial connection is unsuccessful.

### The app crashes or does something unexpected:

Go to the Help screen. Tap "Send App Diagnostics" and then tab "Submit Support Case." This will help Modus understand your issue. For time sensitive issues, please call or email the Modus Helpdesk.

# 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](http://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](mailto: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](https://modushealth.com/publications/?fwp_sections=accuracy)

[2] [https://modushealth.com/publications/?fwp\\_sections=stepwatch-as-criterion](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	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 certified	IPX8 tested
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 Temperature: -10° ~ +45° C (14° ~ 113° F) Charging Temperature: 0° ~ +45° C (32° ~ 113° F) Storage Temperature: 0° ~ +25° C (32° ~ 77° F)	
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	
2 Year Warranty	Warranty begins on day of delivery	

## 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](mailto: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.

