

Modus Health LLC

StepWatch with CC Apps Reference Guide for Users



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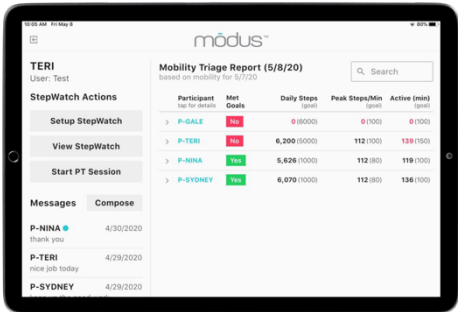
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Manufacturer:

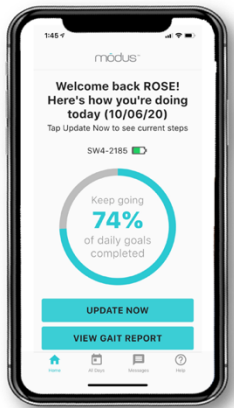
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General Information



Clinic App

Modus Health Clinical Care (CC) Clinic App is the mobile 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 or Google Play store.



Companion App

The use of the Companion app is optional. The Modus Health Clinical Care (CC) Companion App is the mobile 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.



StepWatch

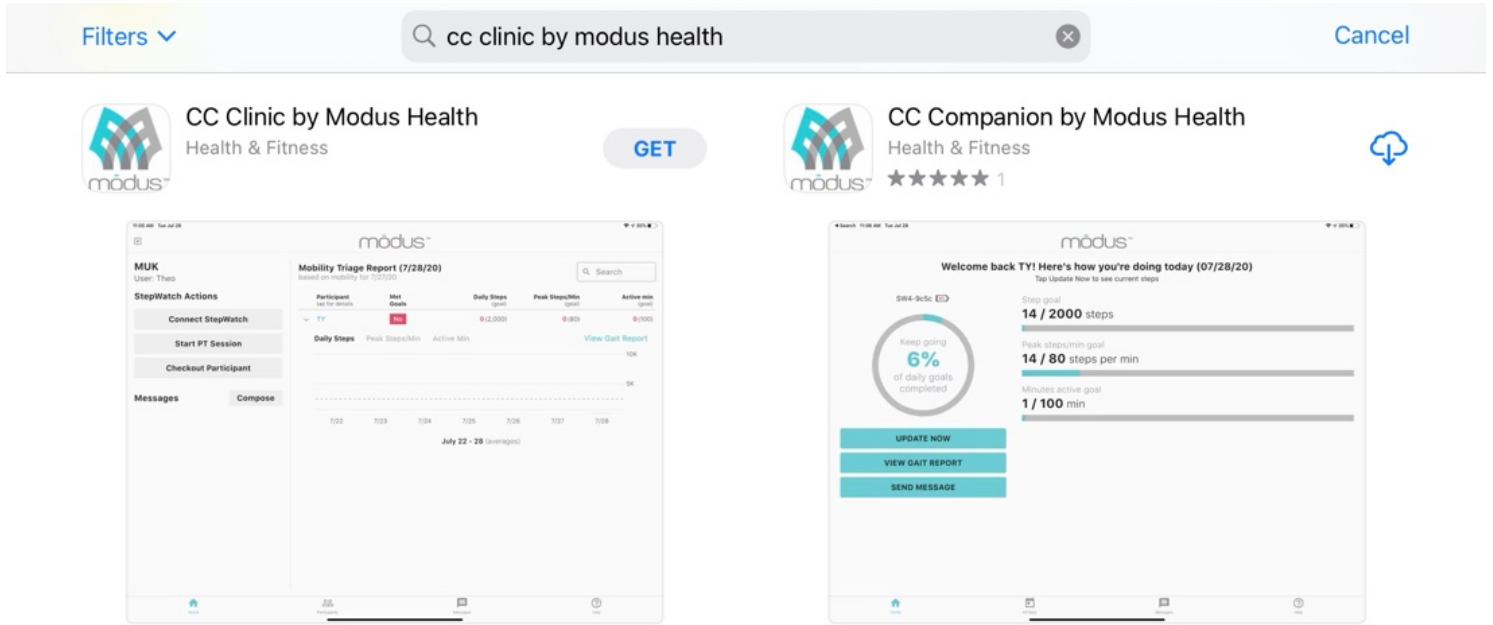
StepWatch is a wireless device affixed to the participant's leg that tracks and records all ambulatory data. The StepWatch is charged by using the wireless induction charging pad provided with your purchase of the Clinical Care software. When first received, the StepWatch should be charged on the wireless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

Initial App Setup

Installing the Clinic App

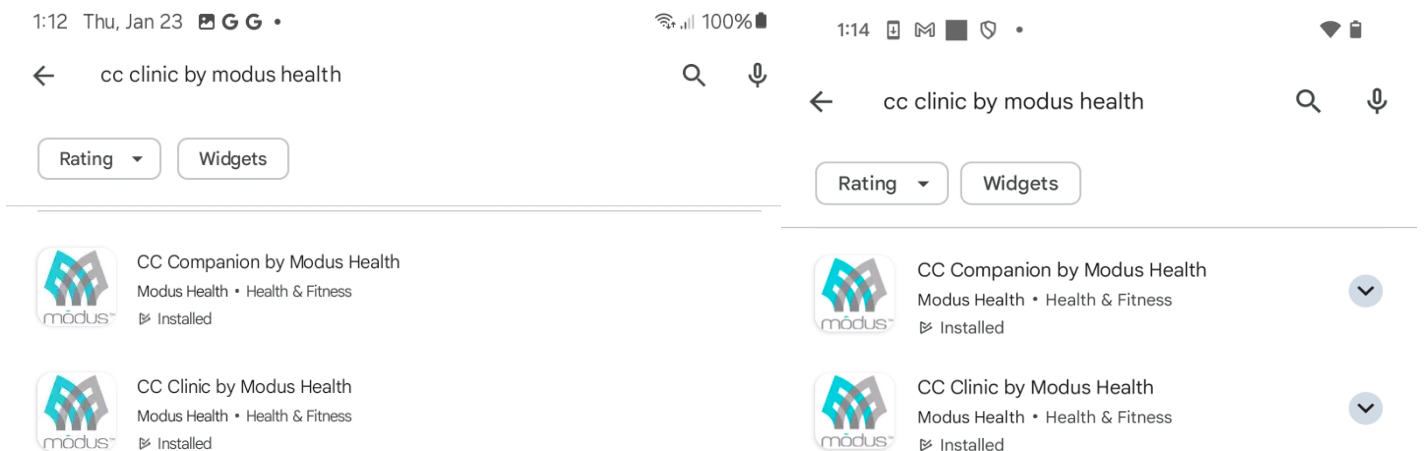
Apple Devices

To install the Modus Health CC Clinic app on an iPad or iPhone, visit the Apple App Store and search for “CC Clinic by Modus Health”. Download the CC Clinic App (shown below) to your Clinic mobile device. CC Clinic has limited features on an iPhone relative to the iPad version but has the benefit of fitting in the clinician’s pocket during StepWatch setup and therapy sessions.



Android Devices

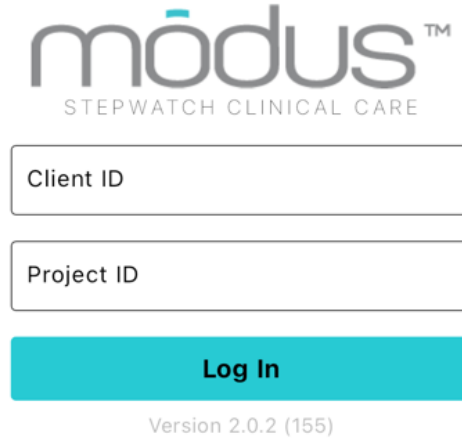
To install the Modus Health CC Clinic app on an Android tablet or phone, visit the Google Play Store and search for “CC Clinic by Modus Health”. Download the CC Clinic App (shown below) to your Clinic mobile device. CC Clinic has limited features on an Android phone relative to the tablet version but has the benefit of fitting in the clinician’s pocket during StepWatch setup and therapy sessions.



Creating a Team

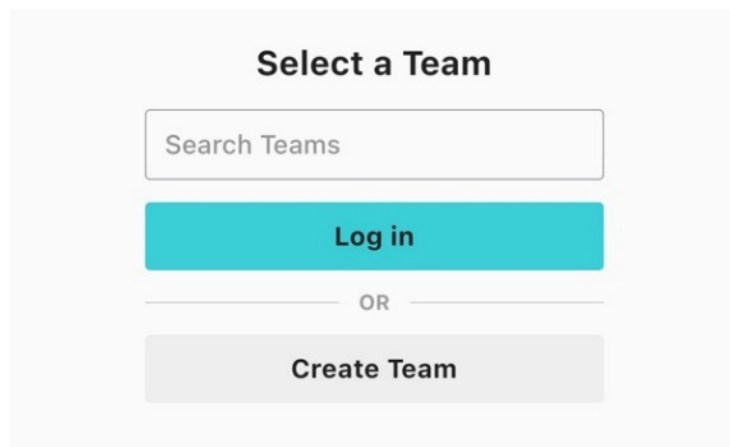
When the app finishes installing, tap the CC Clinic app icon on your home screen to open the application.

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.



The image shows the login screen for the Modus Stepwatch Clinical Care app. At the top is the logo 'modus™' with 'STEPWATCH CLINICAL CARE' underneath. Below the logo are two input fields: 'Client ID' and 'Project ID'. A teal 'Log In' button is centered below the fields. At the bottom, the text 'Version 2.0.2 (155)' is displayed.

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."



The image shows the 'Select a Team' screen. It features a search bar labeled 'Search Teams' at the top. Below the search bar is a teal 'Log in' button. In the center, the word 'OR' is flanked by horizontal lines. At the bottom is a grey 'Create Team' button.

From the "Create Team" page, you will be offered a variety of options to choose from, depending on your institution and objectives. Settings options are explained on the next page.

Team Settings

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. You will be able to choose which team members have “admin” abilities.

Always remember to tap “Update” when changing settings so they are saved.

Team ID Choose the name of your new team. You will need the Team ID to log in from a new device or new installation of the app. The Team ID will also be used to identify the step data.

Automatic Participant Upload Participant’s CC Companion app will upload new data daily at this time. See “Using the Companion App” section “Uploading Data” for automatic upload instructions.

Team Goals Choose the default walking goals that will be suggested when setting up each new participant under this team. They can be changed for each individual participant during registration or after setup.

Enable Companion App Check here if participants will use a mobile device to upload data. If this is not checked, data will need to be manually uploaded with the CC Clinic app.

Stride Length Assessment when checked, stride length assessment will be offered during setup

Pin Lock when checked, PIN is required any time the CC clinic app is closed or backgrounded

Imperial or Metric used when entering participant’s height

Population Controls limit setup 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.”

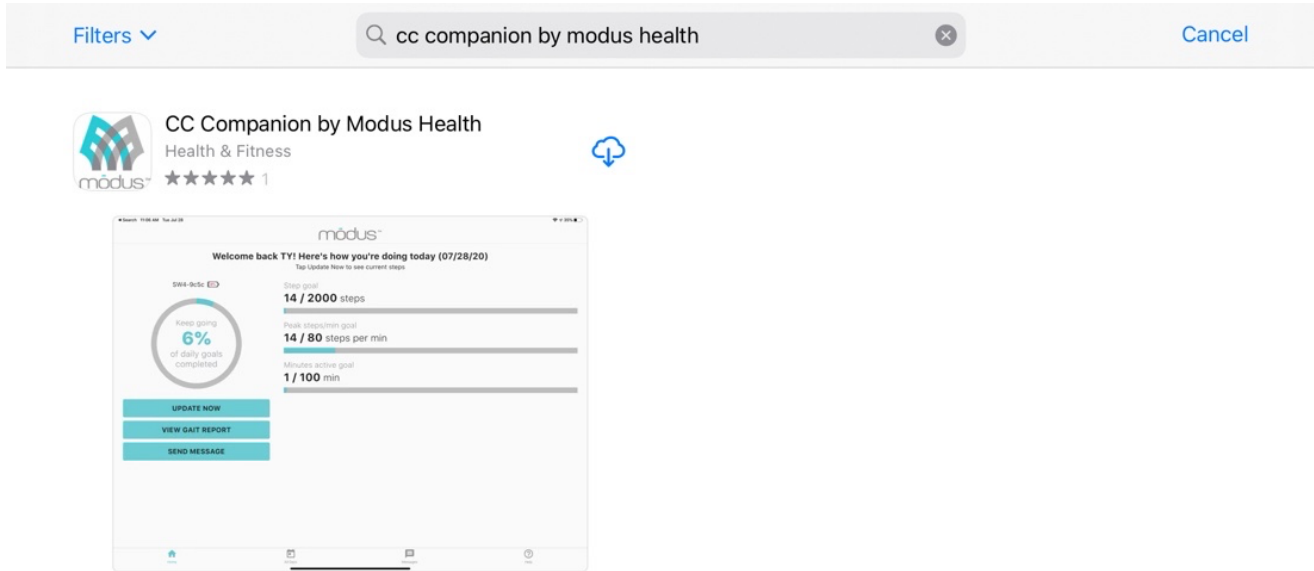
Cadence Thresholds determine the cadence (steps per minute) range to be reported as “Low,” “Mid,” and “High”.

Email Activity Thresholds You will have the option to receive an email notification if a participant falls below these levels. Each team member can opt in to email notifications. If you do not want any email notifications for low activity, leave thresholds set to 0.

Battery Warning Threshold 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.

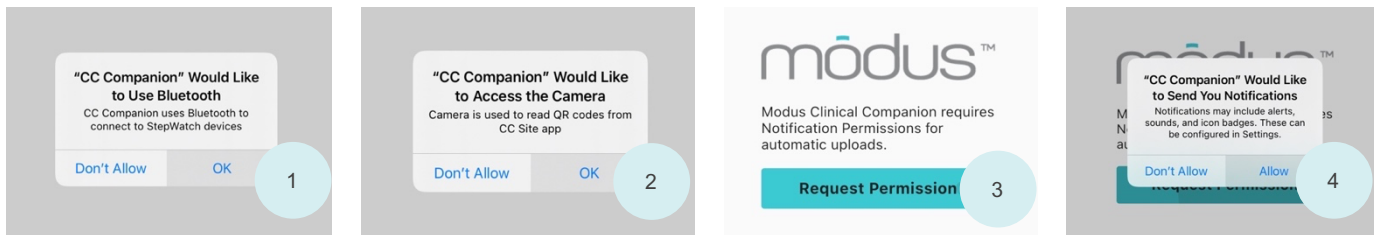
Installing the Companion App

If you will be 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 or Google Play store for “CC Companion by Modus Health” and download the app. Participants can download this app on their own mobile device.



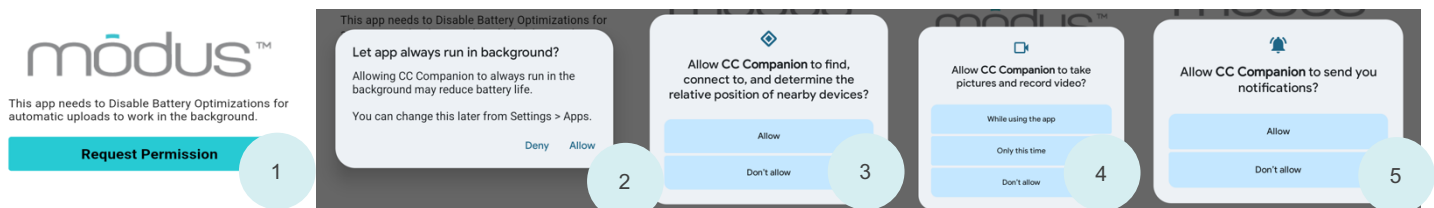
Apple Devices

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.



Android Devices

When opening the app for the first time, tap “Request permission” to disable battery optimization for automatic uploads. Then allow Bluetooth permissions 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.



Preparing the StepWatch

StepWatch 4

(Instructions for StepWatch 5 are on the next page.)

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".



SWX-XXXX
Save this ID until setup and registration are complete

You will be provided a small and medium thermoplastic rubber soft cover, and small, medium and large nylon/spandex straps. Attach a soft cover to the StepWatch. Choose a strap depending on the participant's ankle size. The medium size is the most common.



Thread the Velcro strap through the StepWatch with the Velcro side facing TOWARD the device.



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 must be facing upright. See "Managing StepWatch" for additional notes on wearing and maintaining the StepWatch and accessories.



StepWatch 5

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.



SWX-XXXX
Save this ID until setup and registration are completed

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".

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.



Setting up a Participant

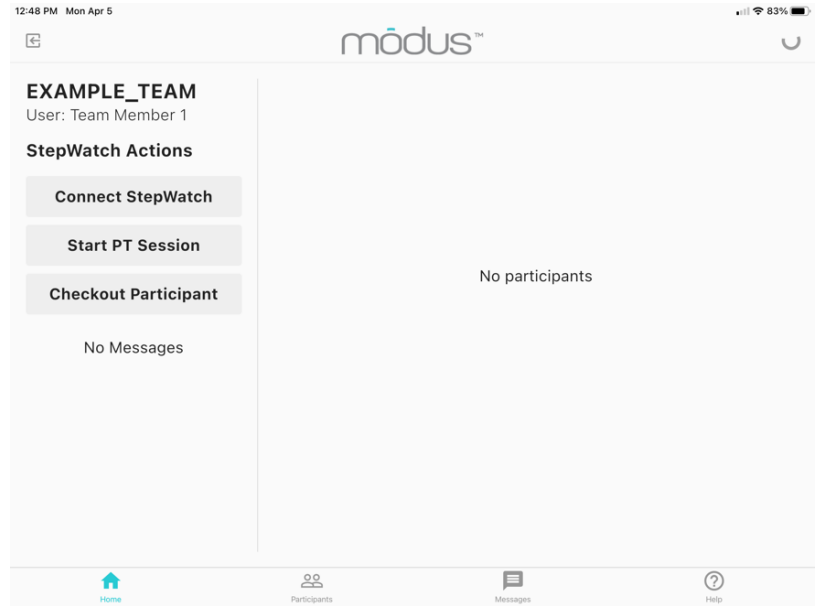
Connect StepWatch

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.

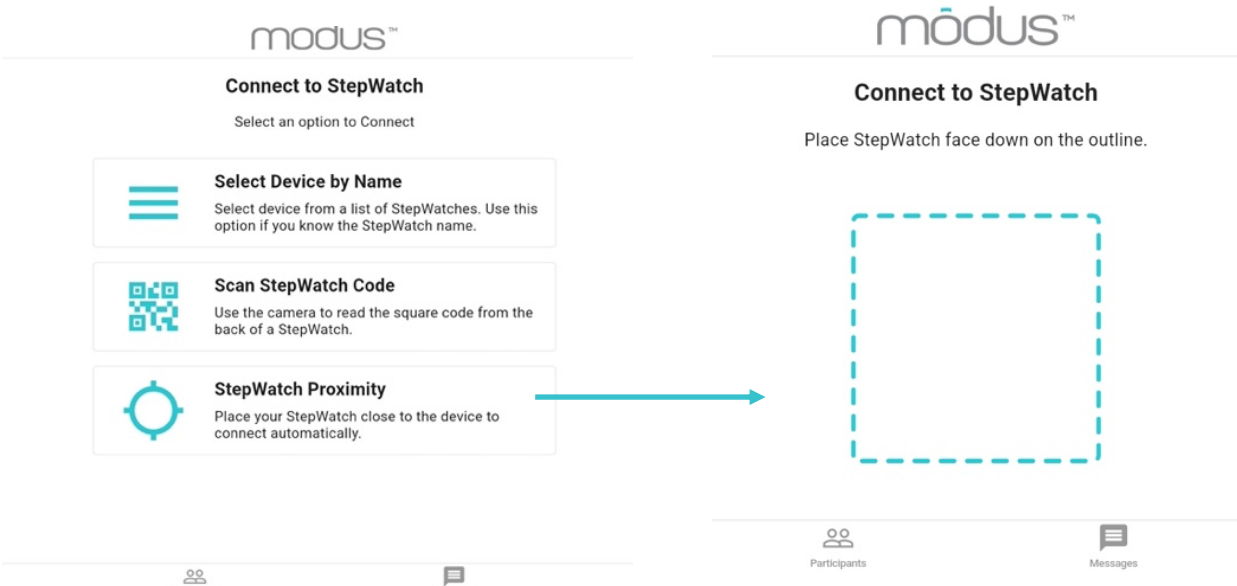
Launch the app and log in to your team. Tap the “Connect StepWatch” button.

Find the device’s Bluetooth ID above the QR code on the back label. The Bluetooth ID will appear as “SWX-XXXX.”



You will be given the option to select a device:

- **Select Device by Name** – selecting the Bluetooth ID from a list of nearby StepWatches
- **Scan StepWatch Code** – use tablet/phone camera to scan the label on the back of the StepWatch
- **StepWatch Proximity** – the app will connect to the nearest StepWatch it finds.



After connecting, you will be directed to the Device Information page.

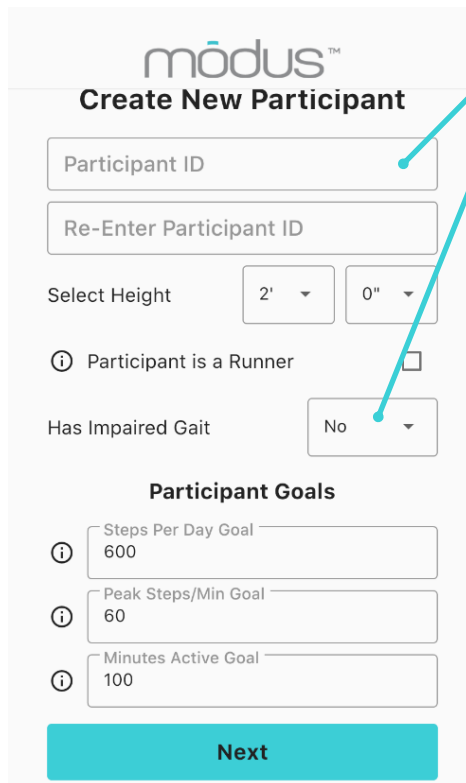
Select the type of participant you are setting up:

- Tap **“New”** to create a new participant
 - This will open the “create new participant” page to enter participant details
- Tap **“Returning”** if a participant who has been unenrolled is returning
 - You will be asked if you want to use previous settings for the participant.
- Tap **“Existing”** if the participant is currently enrolled but the StepWatch device or CC Companion device they were using is lost or damaged
 - You will be asked if you want to use previous settings for the participant.



When to Use Previous Settings

Use Previous Settings if the participant’s height, walking ability, and walking goals have not changed since the last time StepWatch was setup for this participant. If not sure, select “No” and go back through the setup process.



Enter a Participant ID, height, walking goals, and gait information.

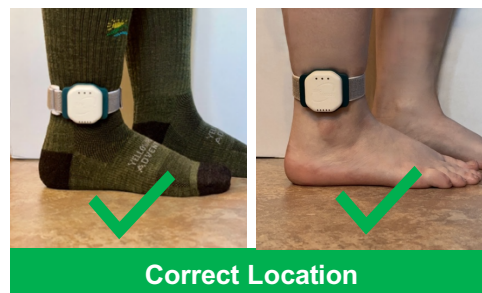
Determining whether to use severely impaired, slightly impaired, or no impairment takes some practice. Severely impaired is usually needed for people walking slowly, such as less than 0.8 m/s, or using a walker. Your training will involve how to use these choices. The settings will be evaluated for accuracy later in the setup under Verify Steps.

Tap “Next”.

Participant Settings

Wearing the StepWatch

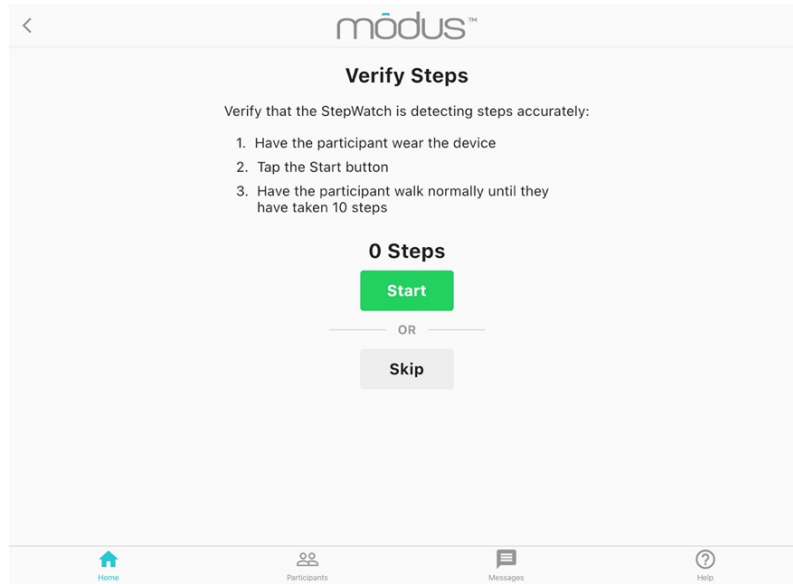
StepWatch needs to be placed on the participant before proceeding. Refer to “[Managing StepWatch 4](#)” or “[Managing StepWatch 5](#)” for complete wearing instructions. Wear StepWatch just above the outer ankle bone. StepWatch 4 must be worn with the walking image upright. StepWatch 5 can be worn upside down or right-side-up. 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 StepWatch

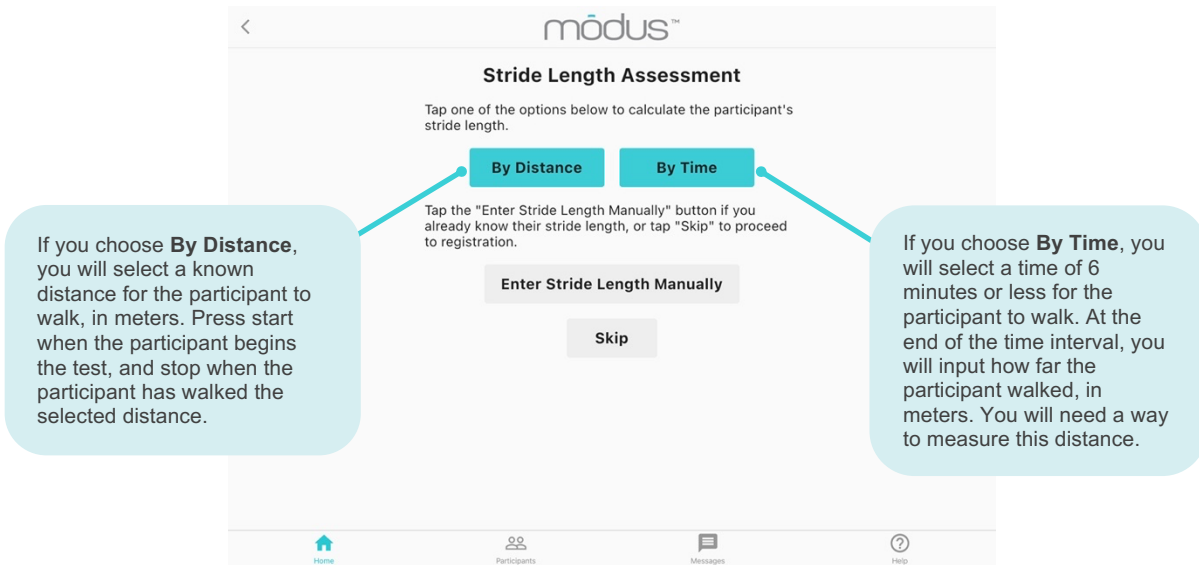
Verify Steps

For this step, you will need space for the participant to walk around. Follow the prompts to complete the step counting verification. You tap “Stop” after you have observed the participant take 10 steps. 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.



Final Registration

Verify all 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”.

<

modus™

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

Home Participants Messages Help

Connect to Companion App using QR Code

If you have enabled the use of the Companion app in the Team Settings, the following screen will show a QR code for connecting a participant’s mobile device with the StepWatch.

- If you have the participant’s mobile device ready, you open the CC Companion app and select “Scan Clinic QR Code” to connect the device.
- If you do not have the participant’s mobile device or do not want to use the QR code, you can press “skip” or the back button to return to the main screen.

You can connect the StepWatch to the participant’s mobile device later by selecting “Connect to StepWatch” in the CC Companion app. You will then connect by “Select Device by Name,” “Scan StepWatch Code,” or StepWatch Proximity.” Further instructions are under “Using the Companion App.”

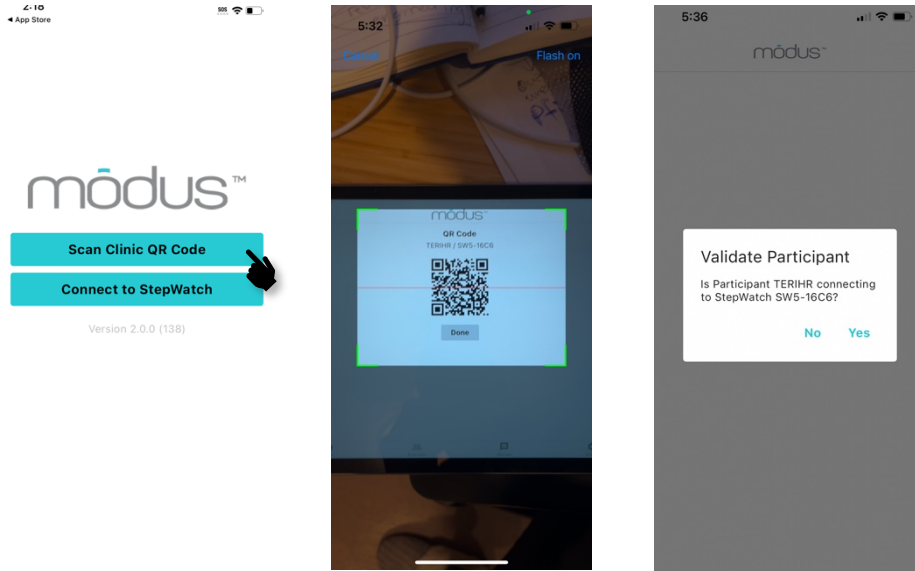


Using the Companion App

Connecting to StepWatch

Connect using Clinic App QR Code

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 CC Clinic App, tap “Scan Clinic QR Code.” This will turn on the device’s camera to scan the Clinic App QR code.

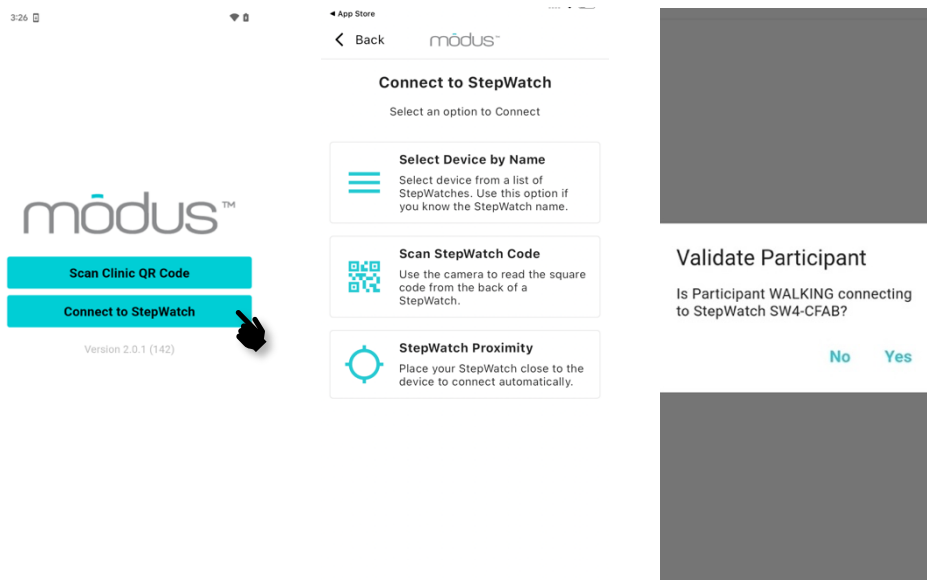


Otherwise, tap “Connect to StepWatch” then select an option to connect to StepWatch.

Connect without a CC Clinic QR Code

When you select “Connect to StepWatch” you will have multiple options for the connection method.

- **Select Device by Name** - Select the Bluetooth ID from a list of all nearby StepWatches
- **Scan StepWatch Code** - the strap will need to be removed or pulled back to reveal the code on the StepWatch label. Not all tablets have a high enough resolution camera to scan this code. Most phones do.
- **Proximity** – Place StepWatch in the square. The app will connect automatically to the StepWatch with the strongest Bluetooth signal. Make sure other StepWatches are not nearby when using this method.



Uploading Step 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 Step Data

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.

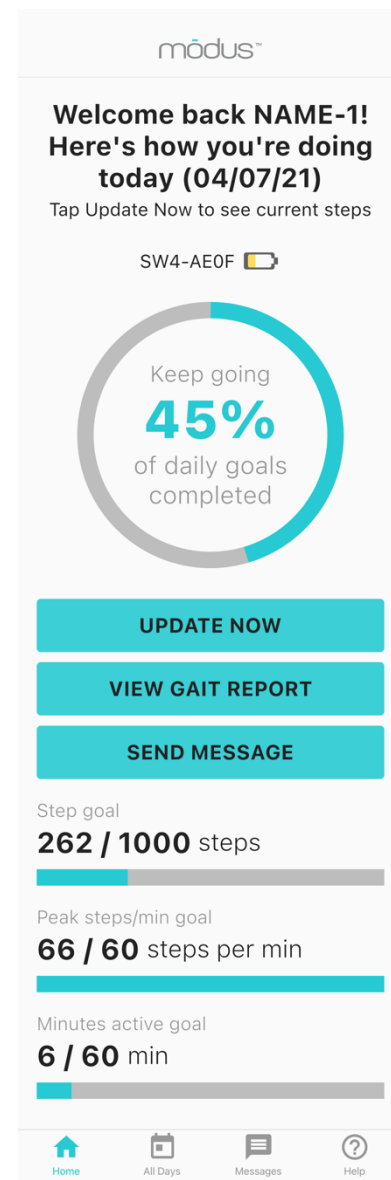
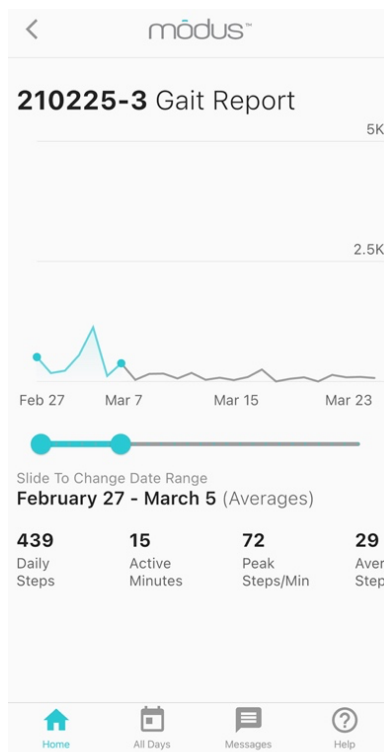
All Days Report

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. If no day is selected, the average of the metrics of all the days is displayed

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. Metrics 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.



Messaging

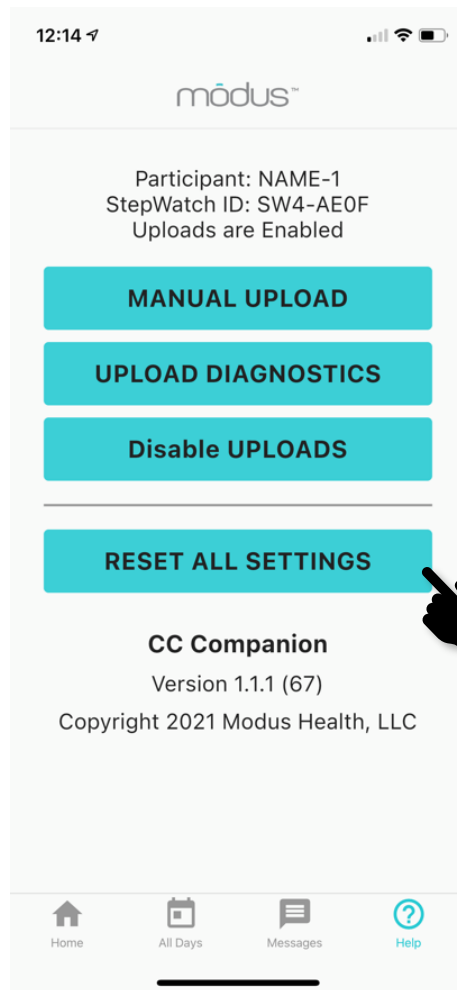
Tap “Send Message” to send messages between the participant and team members assigned to their team. Participants can select which team member they want to send a message to.

More information about messaging can be found in “Using the Clinic App”.

Resetting the Companion App

If “Checkout Participant” or “Existing Participant” is used in the Clinic App, the Companion App is automatically reset. There is no normal reason to require the manual reset of the Companion App. However, it is an option should an unusual circumstance arise.

To reset the Companion App, 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. The Companion App will then be cleared of its link to the participant. Data will no longer be displayed, and the app will be ready for a fresh StepWatch connection.

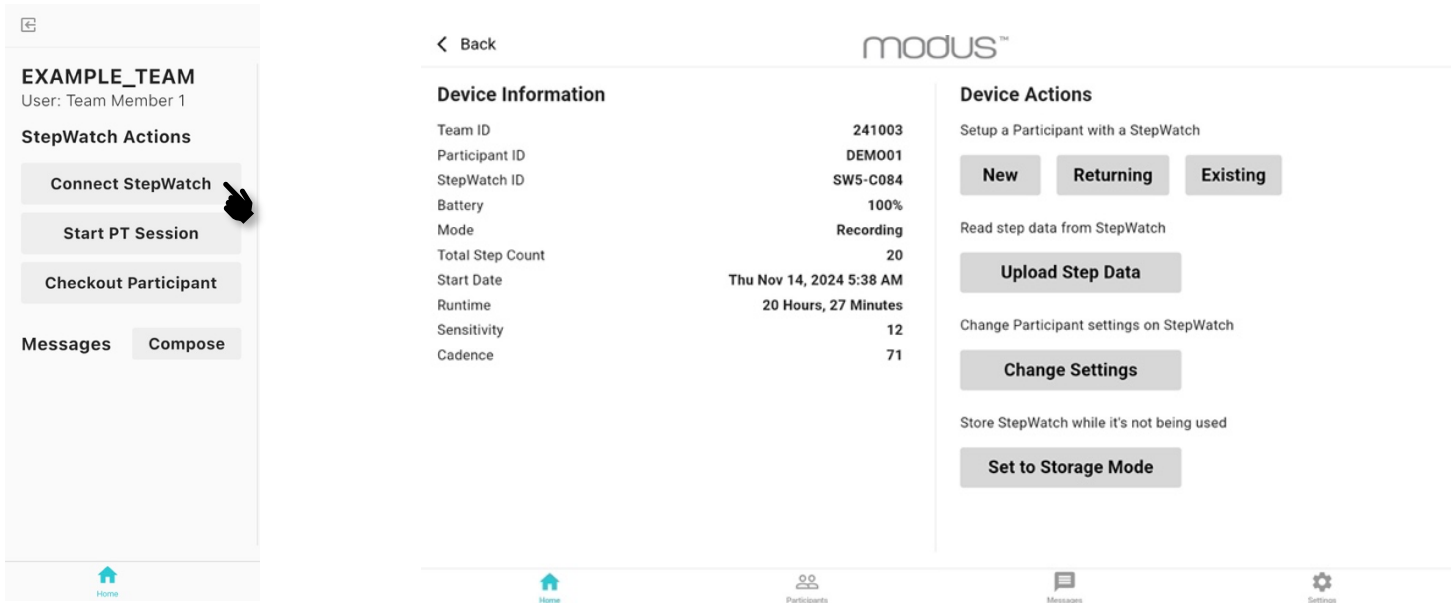


Using the Clinic App

See “Setting up a Participant” for instructions for connecting to a StepWatch for the first time.

Previewing a StepWatch

Tap “Connect StepWatch” on the Home screen. 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 shows time of 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.

Once you are connected, there are two possible “Modes”:

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

Upload 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.

Change Settings

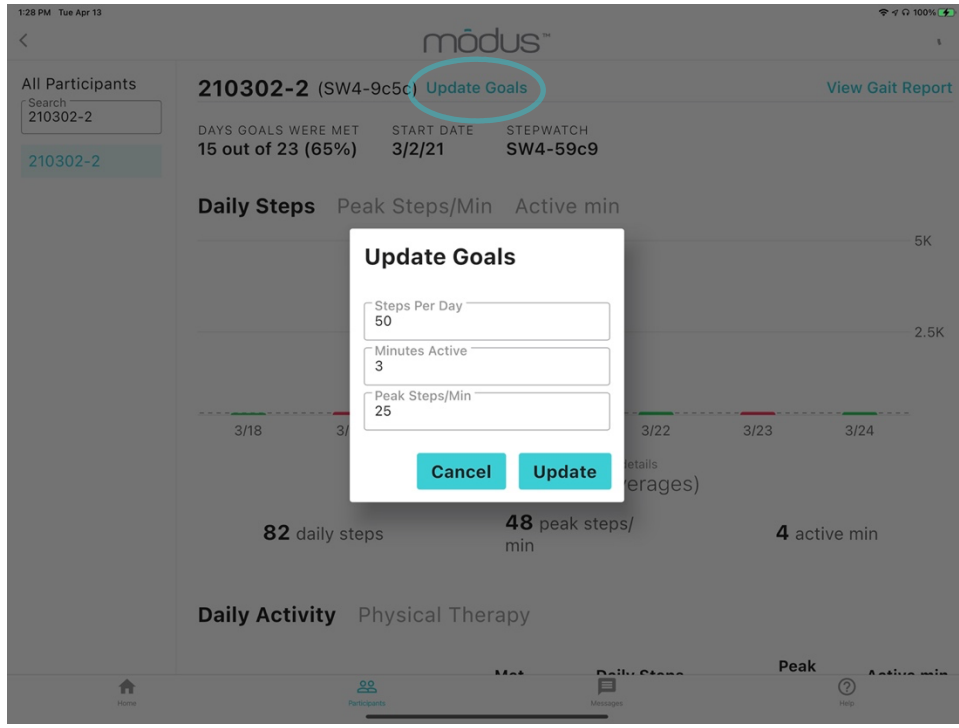
When a participant’s gait or walking goals change, you can update this information by connecting to the StepWatch. Connect to the StepWatch as above, then tap “Change Settings”. Here you can change goals, height, gait type, and whether or not the participant runs. Tap “Next” and you will be able to update 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”.

Storage Mode

Storage Mode turns off the Bluetooth radio to save battery when StepWatch is not being used. Storage Mode slows down the battery usage but does not stop the battery from depleting. This should only be used when the StepWatch is not setup for a participant, as this feature will NOT “checkout” a participant. To use a StepWatch that is in Storage Mode, place the StepWatch on the wireless induction charger for 10 or more seconds. Then, remove from the charger and try to connect. If the battery is depleted, StepWatch will need at least 20 minutes on the charger before StepWatch will have enough battery to connect. StepWatch automatically goes into Storage Mode when its battery level falls to 0%.

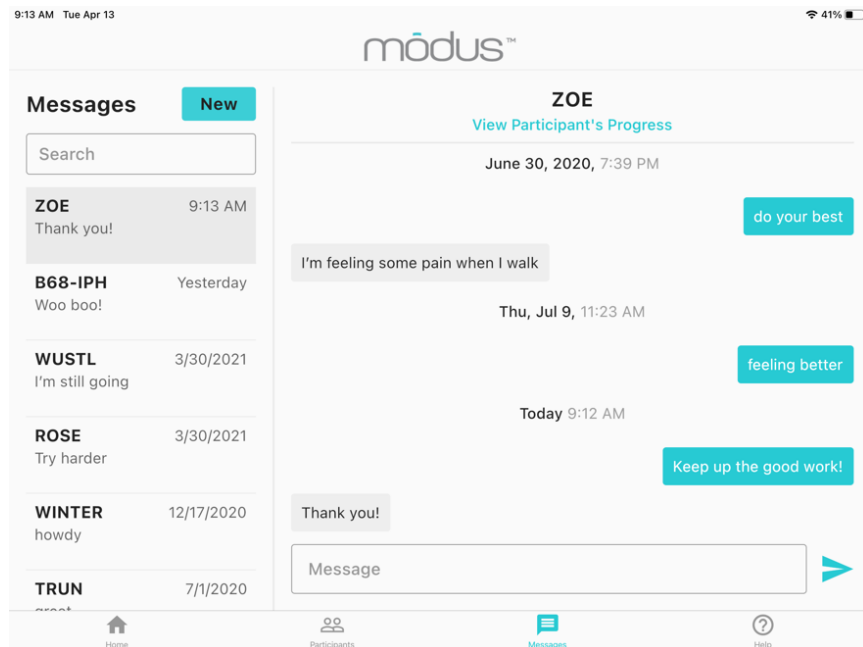
Updating Goals

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.



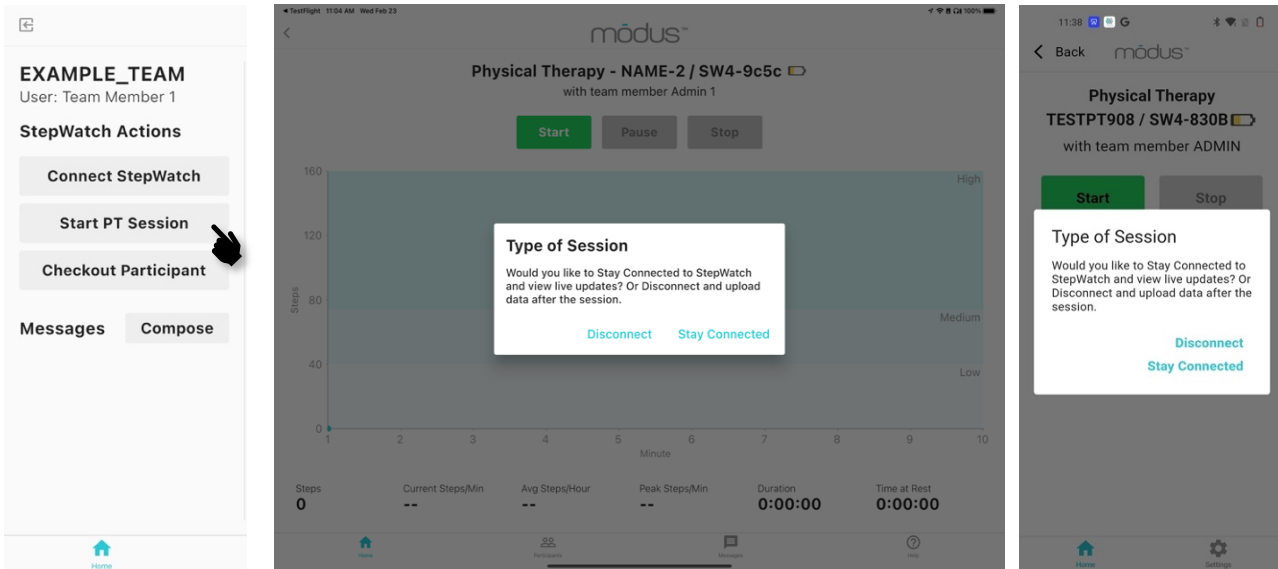
Messaging

Participants and team members can directly message one another between the Clinic app and the Companion app to share questions, encouragement, or any other communication that might help with the data collection process.

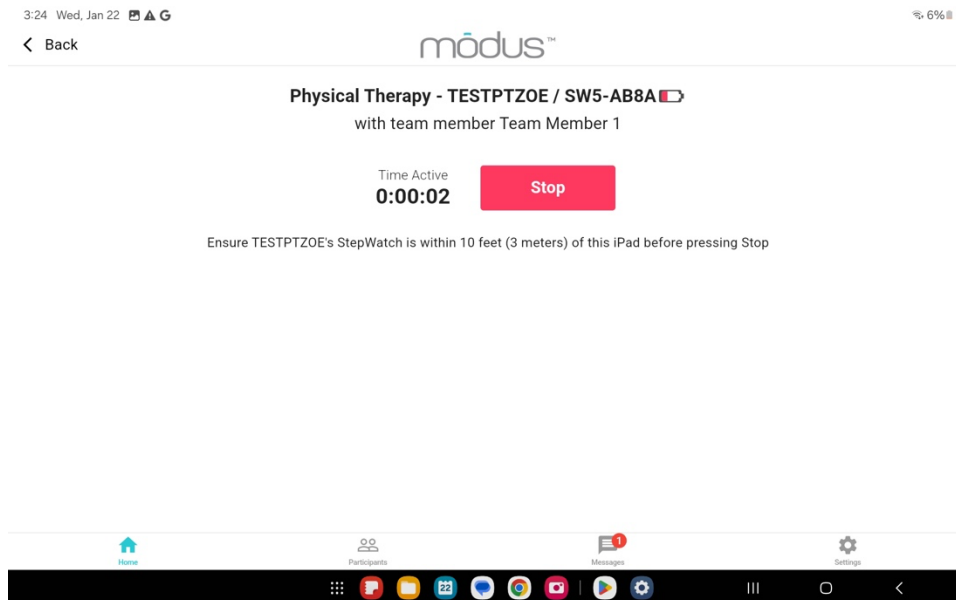


Physical Therapy Sessions

Tap “Start PT Session” from the Home screen and connect to the correct StepWatch for your participant. Tap “Start” to select Connected or Disconnected data collection method. The session will start after you tap the Type of Session.



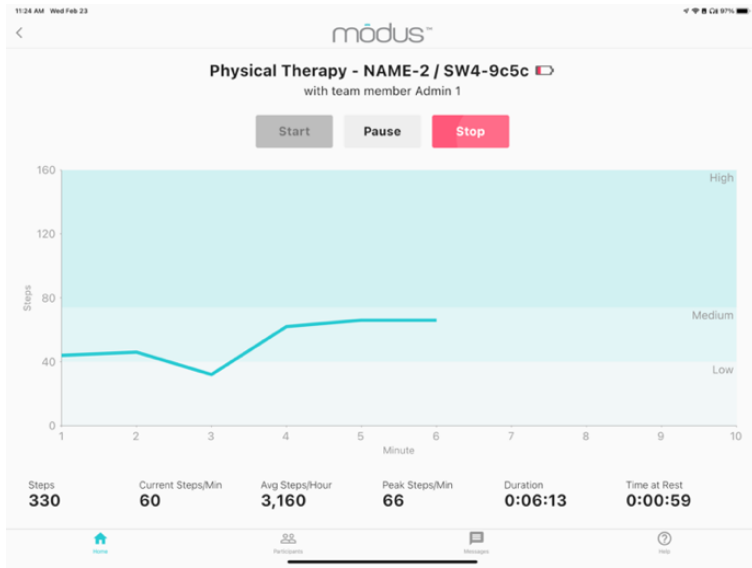
Disconnect: If you choose Disconnect, the StepWatch will not be connected to the CC Clinic app via Bluetooth, and the data will be uploaded to the app and cloud when the session ends. You will see a timer showing how long the session has been going and can add a note about the session after tapping “Stop”. Use this if you cannot carry the mobile device with the CC Clinic app near the participant during the session.



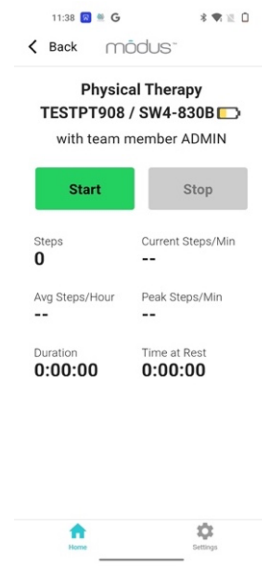
Stay Connected: If you choose Stay Connected, the StepWatch will need to be within Bluetooth range of the CC Clinic app for the entire session, and you can view the data each as it is collected. Steps will update each second and other metrics will fill in when the sample is large enough. The graphed data will begin to appear after the first minute has passed. The displayed metrics are Steps, Current Steps/Min, Average Steps/Hour should the participant sustain their walking pattern for an hour, Peak Steps/Min, and Time at Rest. Time at Rest is defined as the sum of any 10 seconds 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. Default is 30 steps/min or less for low, greater than 30 and less than 80 steps/min for medium, and greater than 80 steps/min for high activity.

Tablet View



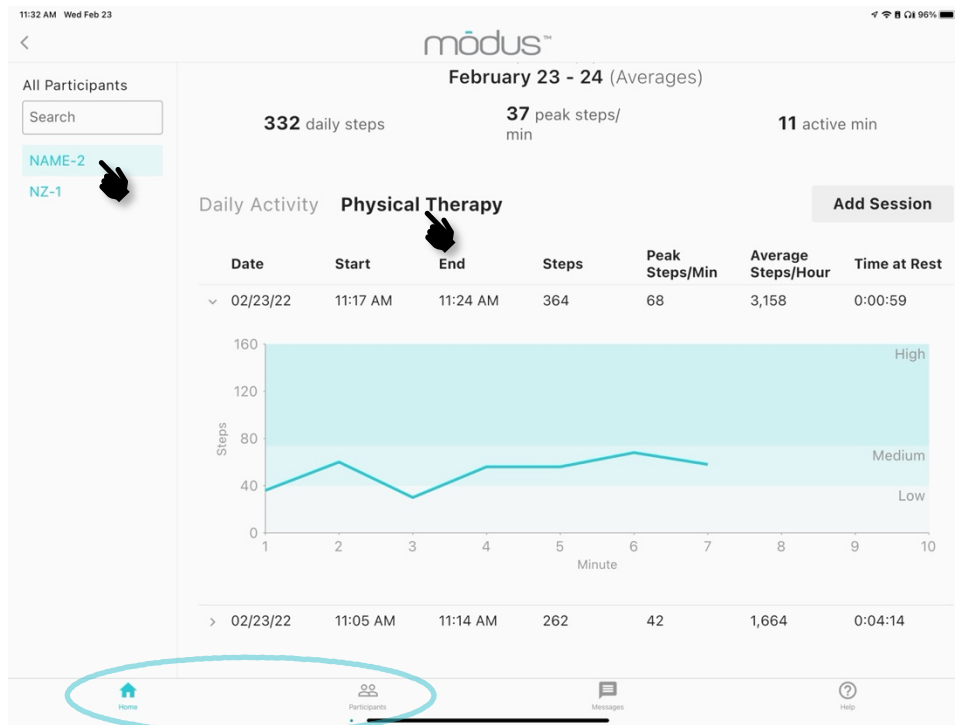
Phone View



Viewing PT Session Data

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”.

Note: this view is only available in the CC Clinic tablet version.

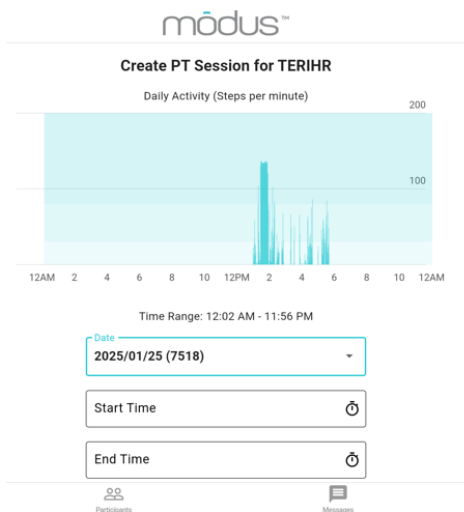


Add a Session after Physical Therapy

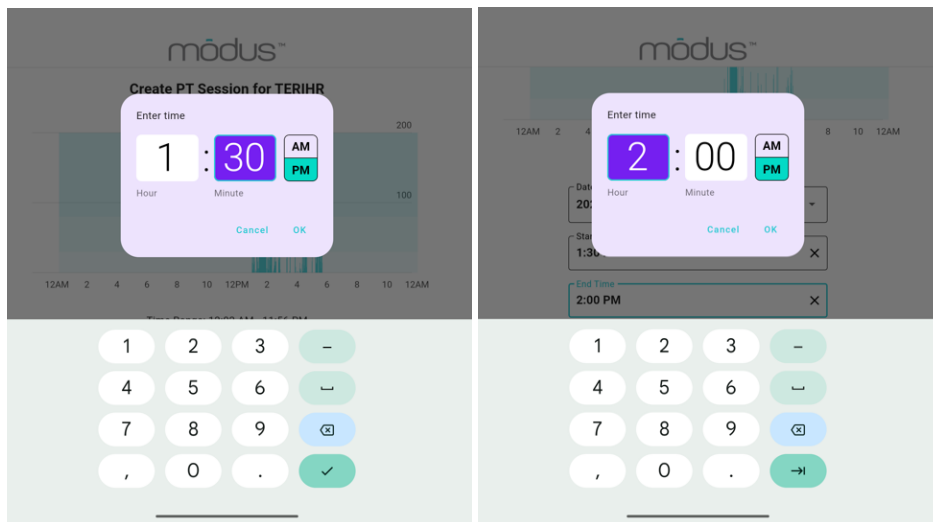
To add a PT session that occurred in the past, make sure that your StepWatch has been uploaded so the data is in the app and cloud.

1. Tap “Add Session,” and select the day of the session you wish to add from the pull down menu. Only days with uploaded data will be displayed.
2. Enter the start time, end time, and the optional session note.
3. Tap “Create” to create the PT session. The PT session graph and metrics will be displayed

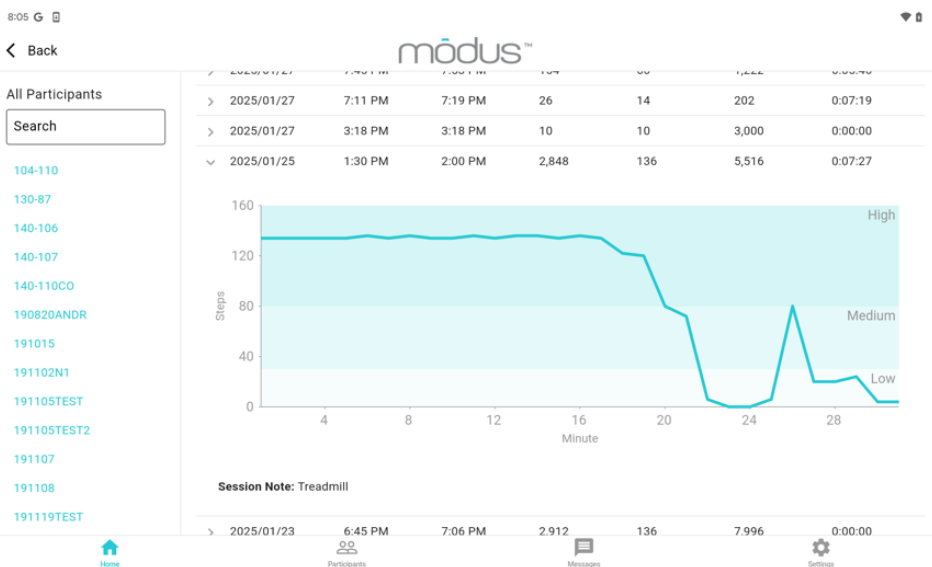
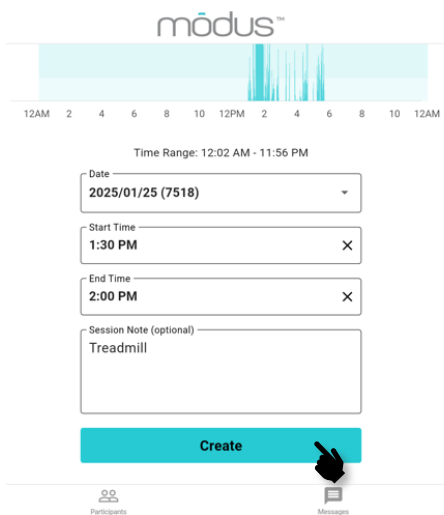
1



2

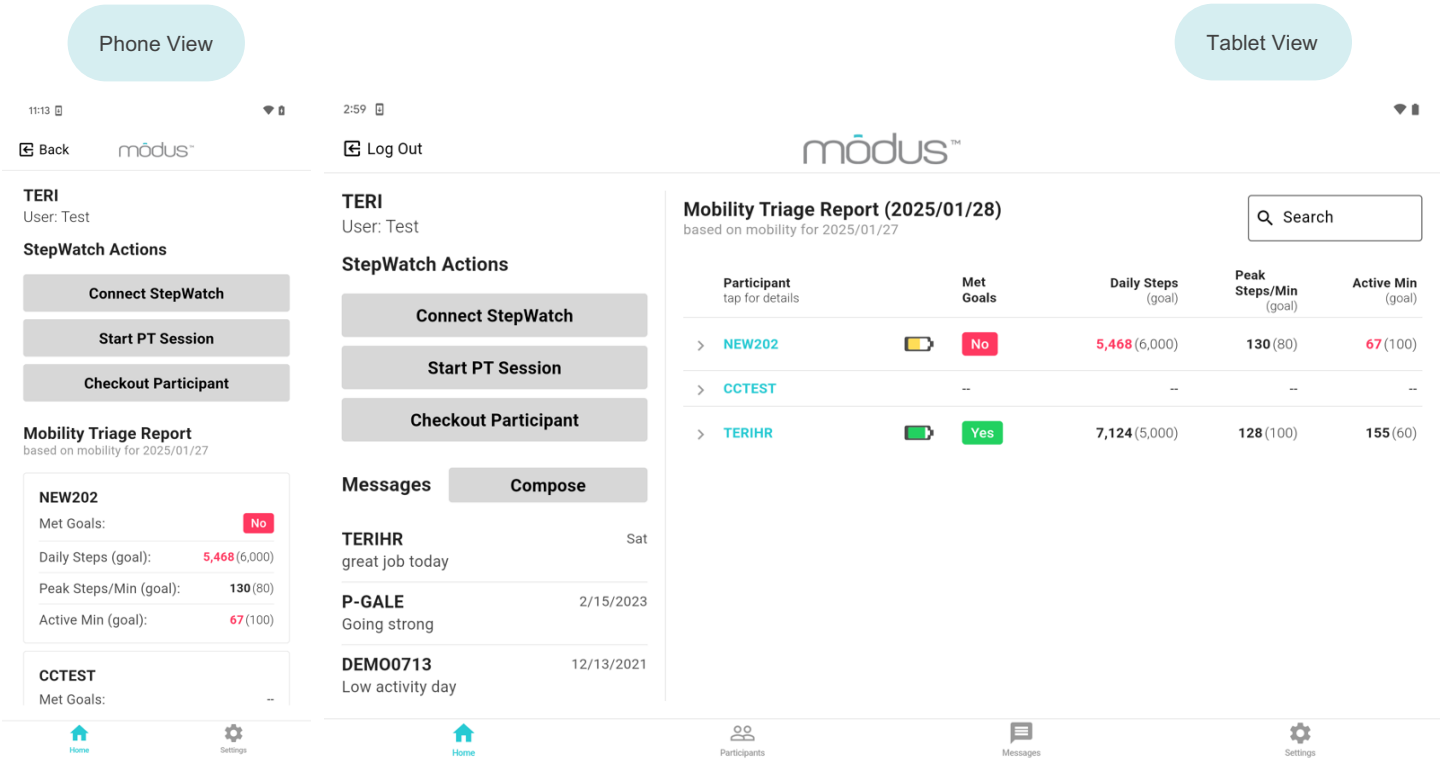


3



Viewing Reports

Mobility Triage Report

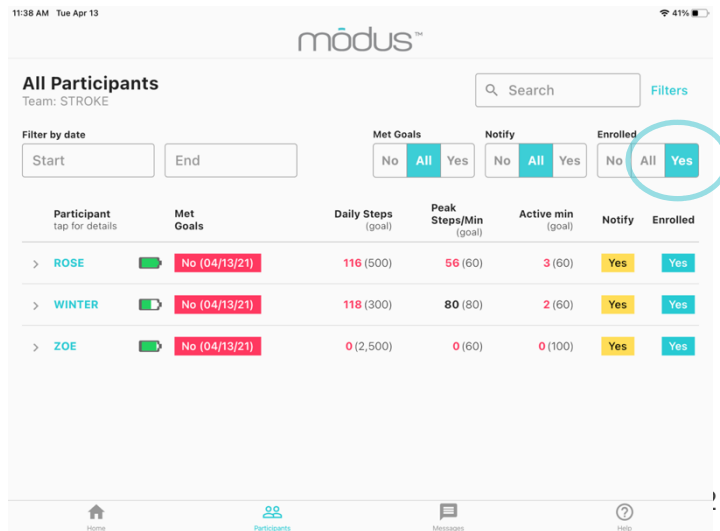
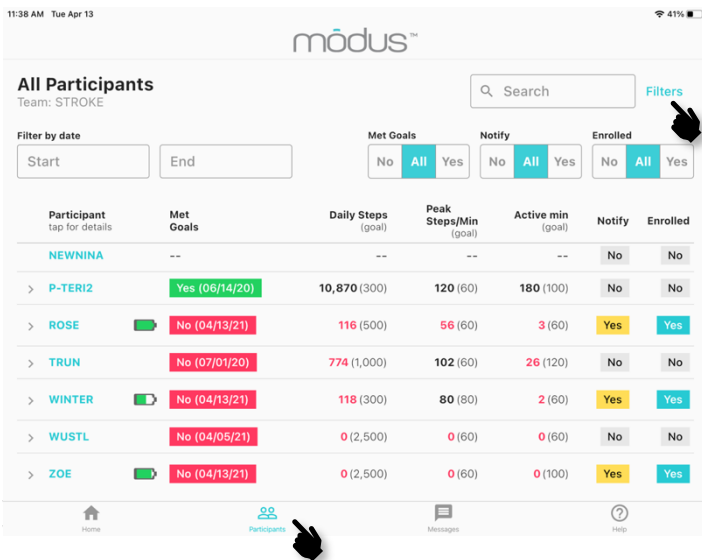


The Mobility Triage Report is designed to highlight which participants need the most immediate help. Those that did not meet their goals may need more of the clinician’s time to determine the barriers to achieving their goals. The participants that did not meet their mobility goals are at the top of the list. Participants that have no data are in the middle, and participants that met all of their mobility goals are at the bottom.

All Participants View

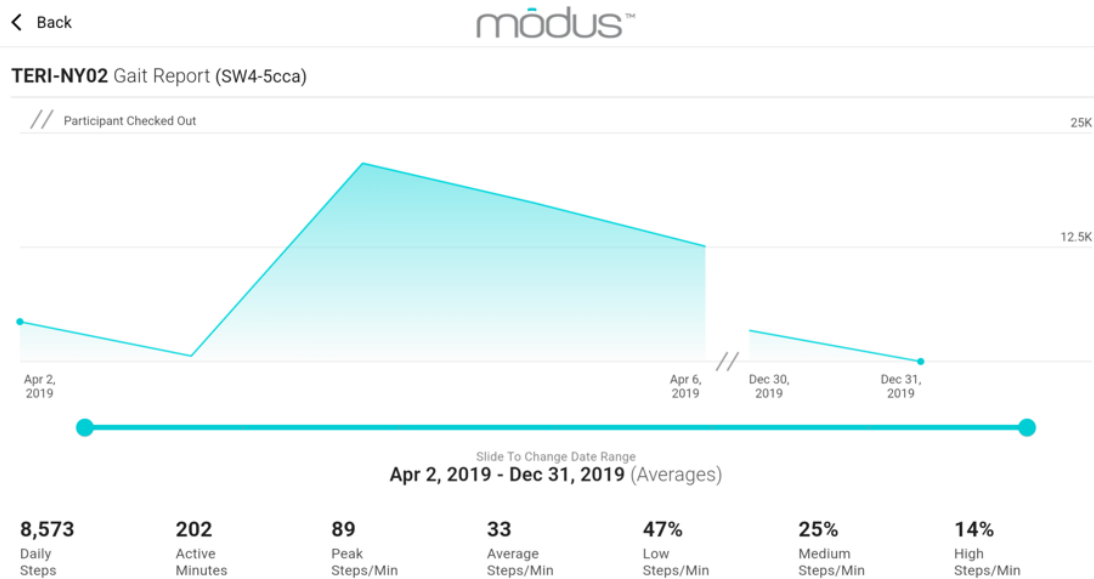
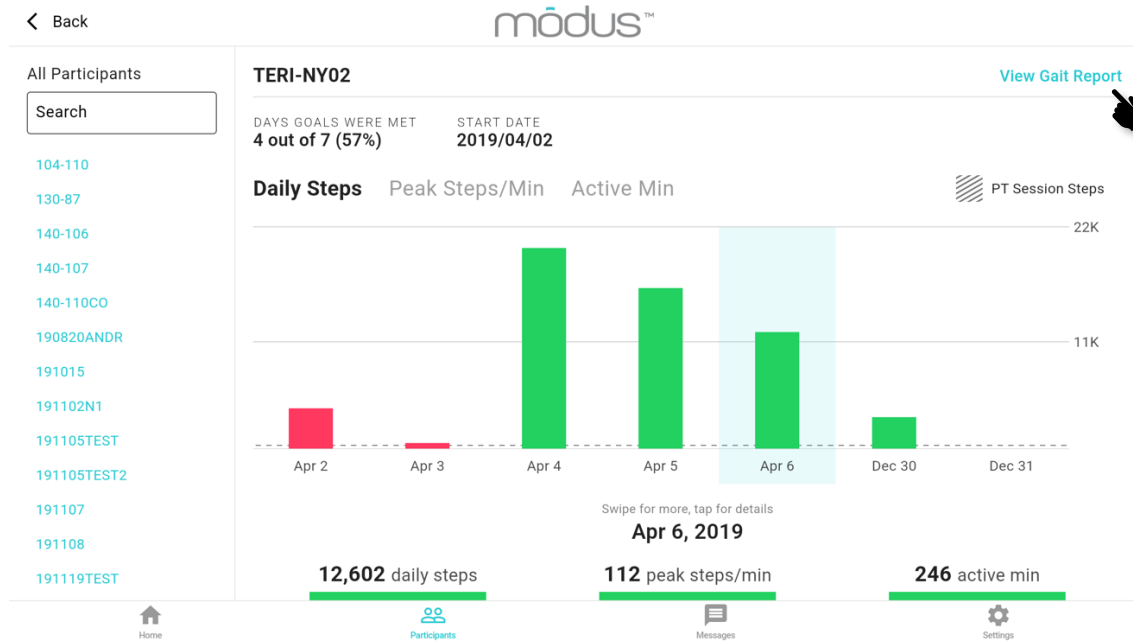
Tap the “Participants” screen at the bottom to view all the participants that you have managed with a StepWatch. This view has the latest information about each participant.

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). In this example, the filter is set to show enrolled participants only.



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.

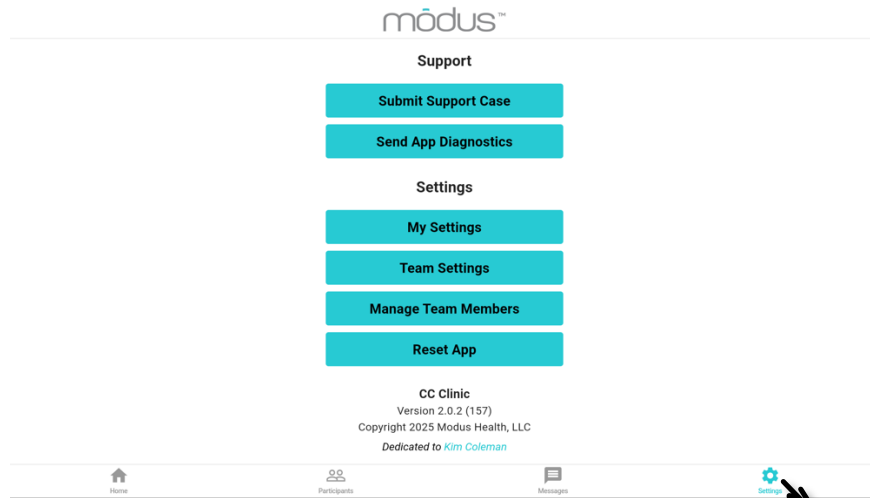
Low Steps/Min: Percent of active minutes that were “Low Cadence” according to team settings. Averaged between the selected days. Default is less than 30 steps/min.

Medium Steps/Min: Percent of active minutes that were “Medium Cadence” according to team settings. Averaged between the selected days. Default is greater than 30 and less than 80 steps/min.

High Steps/Min: Percent of active minutes that were “High Cadence” according to team settings. Averaged between the selected days. Default is greater than 80 steps/min.

Support and Settings

You can access the Help screen at any time by tapping Settings 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

Submitting a support case: To submit a support case, your CC Clinic device 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.

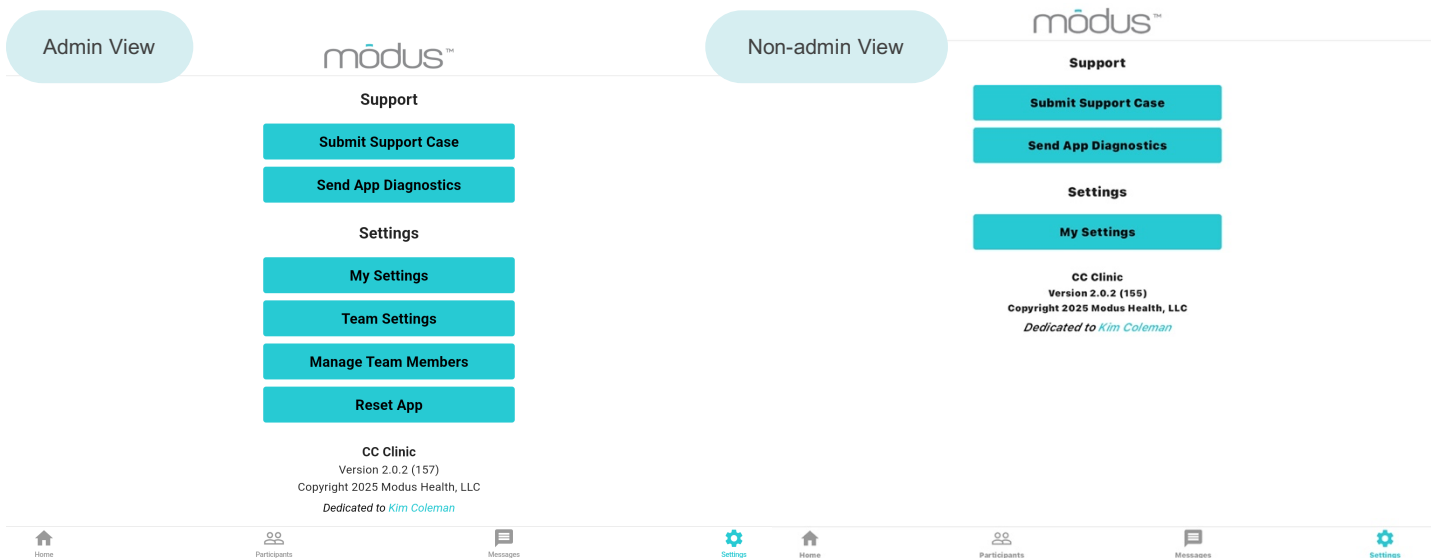
Send App Diagnostics: Tap if you are having an issue with the Clinic app and are directed to do so. This will push a specific type of diagnostic file to Modus’ technology department to assist us in diagnosing and fixing the problem.

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 (tablet only): 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: 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.



Device Management

Cleaning Instructions

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.

Managing StepWatch 4

See "Preparing the StepWatch" to review the instructions for installing the soft cover and strap.

Wearing StepWatch 4

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. The logo must be facing upright.



Charging StepWatch 4

To charge StepWatch, place it face down on the center of the charger. A light will illuminate when your StepWatch begins charging.

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 not place StepWatch on the charger with the logo facing up. Do not place StepWatch on the edge of the charger.



Managing StepWatch 5

See “Preparing the StepWatch” to review the instructions for installing the soft cover and strap.

Wearing StepWatch 5

The StepWatch should rest just above the ankle bone, on the outside or inside of the leg. The outside of the leg is the most comfortable. StepWatch does not require skin contact. It can be worn over a sock or directly on the bare leg.



StepWatch can NOT be worn on the front or back of the leg.
StepWatch can NOT be worn on the arm or any other body part.
Note: StepWatch 5 can be worn with the logo right side up or upside down.



Charging StepWatch 5

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 **two weeks** when fully charged. A flashing light on the charger means charging error. If you see this, remove StepWatch, check connections, and place StepWatch back on charger. Light turns off when fully charged.

Resources

LEDs 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

Read instruction manual for important warnings before operating StepWatch. See “StepWatch Regulatory Information and Specifications” for more information

Model of Device: StepWatch 4 or StepWatch 5



REF Part Number: Identifies the design of the device

FCC and IC Bluetooth radio identification

Date of Manufacture

BF: Type BF applied part
44091/56819 Housing
77244 Soft Case
14866 Strap

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

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

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

UDI SN 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* beginning with 4 or 5.

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

Bluetooth ID: This number 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

From Modus: Edmonds, USA
modushealth.com

EU Representative: Advena Ltd
Swatar, Malta

SW5 – ABCD

PN: 40517
FCC: XYPYNAB1
IC: 8595A – NINAB1
MFG: 2023FEB01

(01)00860007307515(21)5310000

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.**

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 (see specifications). 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 connected 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 Modus app:

- 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 20 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 Settings 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.

The app store is not showing the app:

Try searching the specific term "CC Clinic by Modus Health" or "CC Companion by Modus Health". Sometimes, the app stores change the way searches respond without warning. You can find direct links to the apps at <https://modushealth.com/software/>

Specifications

Software Specifications

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

Mobile Application	Use Case	Minimum Hardware & Software Requirements (as of January 2025)
SW4 RE (supported through 2024)	Research Site	iPad Version iOS 15 or 16
Modus RE	Research Site	iPad Version iOS 17 or 18
CR Site	Clinical Research Trial Site	iPad Version iOS 16 or 17
CR Companion	Clinical Research Participant's Home	iPad and iPhone Version iOS 16 or 17 Android Version 13-14
CC Clinic	Clinical Care Provider	iPad and iPhone running iOS 16 or 17 Android tablet and phone Version 13-14
CC Companion	Clinical Care Setting or Patient's Home	iPad and iPhone Version iOS 16 or 17 Android devices Version 13-14

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
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	30 days	15 days
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

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.

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 [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 43 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/#accuracy>

[2] <https://modushealth.com/publications/#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

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.

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. (EU) Report the incident to the competent authority of the EU Member State in which the user and/or patient is established. (USA) Use FDA MedWatch Online Voluntary Reporting Form.

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.

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.