

Modus Health LLC

# StepWatch with CRO Apps Reference Guide for Users

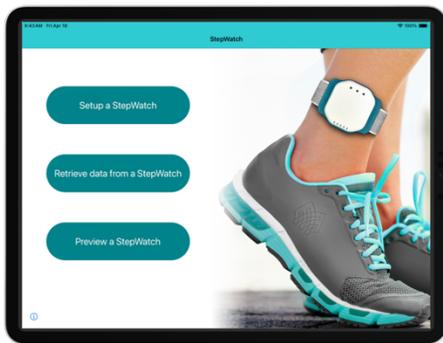


Version 1.7 May 2025

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## General Information



### CRO Site App

Modus Health Clinical Research Trial (CRO) Site App is the designated mobile application used by study sites. It allows site staff to:

- Set Up the StepWatch device to begin recording
- Retrieve data from the StepWatch
- Preview the device's status, including battery level, recording state, and assigned participant ID.

The CRO Site App is available for download from the Apple App Store.

### CRO Companion App

The CRO Companion App is an optional mobile application that allows participants to upload StepWatch data remotely from home. Participants may use either a study provided mobile device or their personal device. Key functions of the app include:

- Remote Data Uploads from the participant's location
- Automated Email Alerts to monitor:
  - o Participant Compliance
  - o Upload Status
  - o Low StepWatch Battery Levels

The Companion App is available for download from the Apple App Store and Google Play Store



### StepWatch

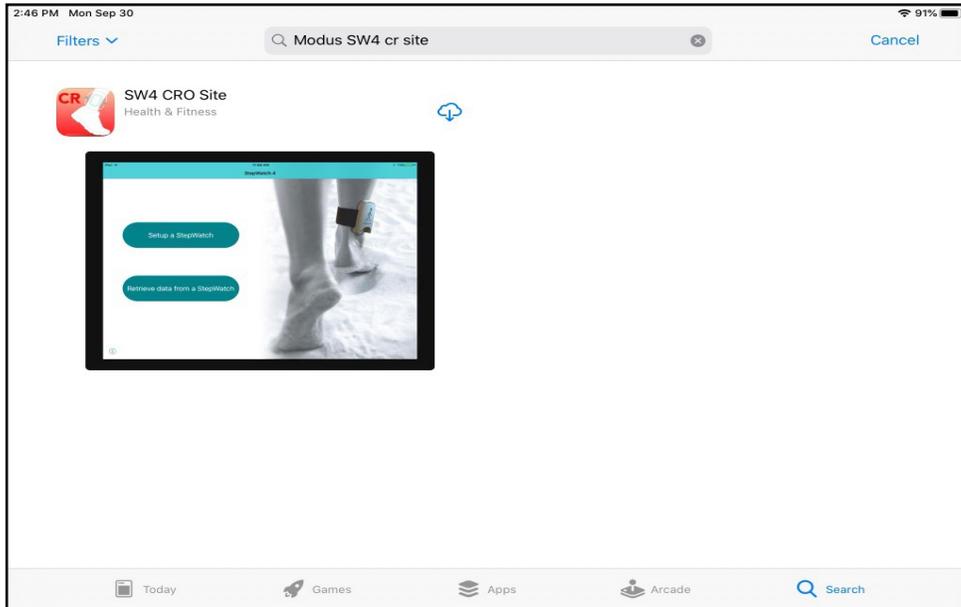
StepWatch is a wireless device affixed to the participant's leg that tracks and records all ambulatory data. The StepWatch is charged by using the wireless induction charging pad provided with your purchase of the Clinical Research software. When first received, the StepWatch should be charged on the wireless induction charging pad for at least 3 hours before its first use to ensure full charge. When connected to the CRO Site 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 CRO Site App Setup

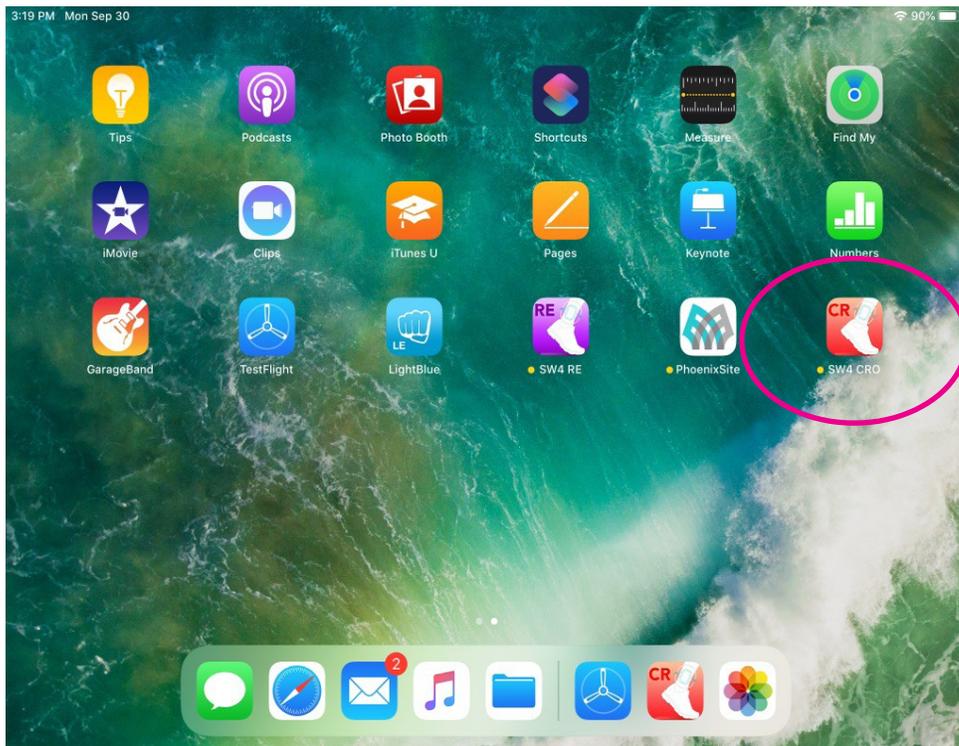
## Installing the CRO Site App

### **iPad Only**

Go to the App store and search for Modus SW4 CRO Site by Modus Health. Note that some studies will have Modus Health configure the CRO App on the study's behalf. In this case, you may skip this step. Next, tap the download icon on the right side of the page.

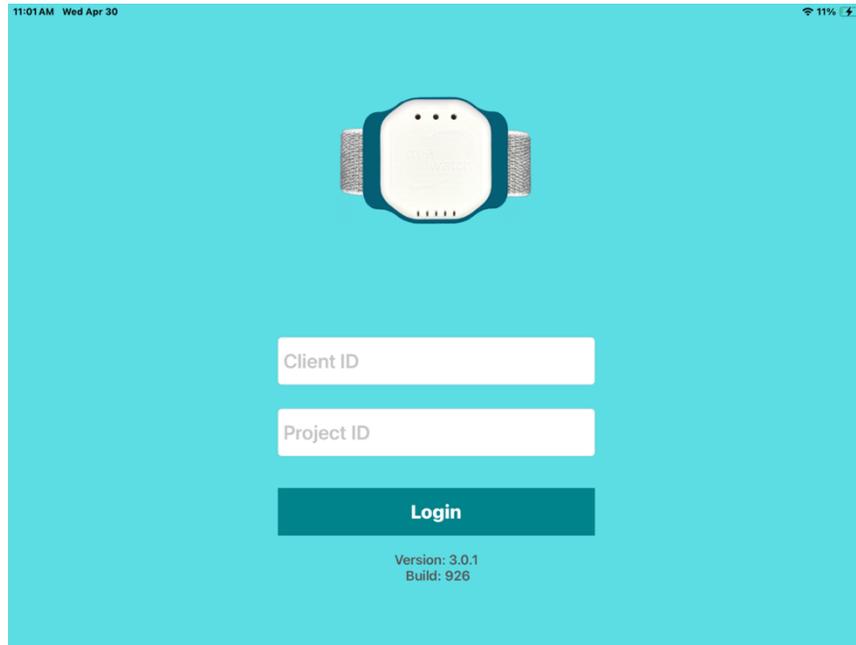


Once the app finishes installing, launch it by tapping its icon from the home screen.



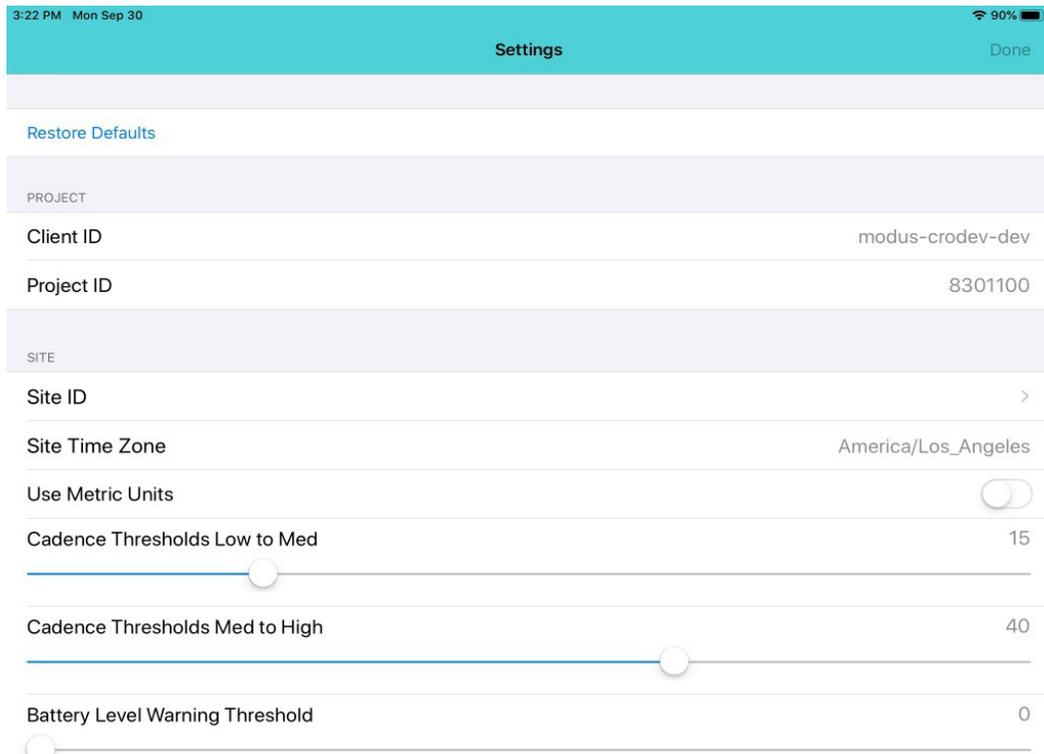
Support Phone +1 (202) 830-1100 ext. 2  
Support Email Support@ModusHealth.com

Upon first launching the app, users must enter a Client ID and Project ID to gain access. If you do not have this information, please contact the Modus Health helpdesk or your designated Modus Health representative.



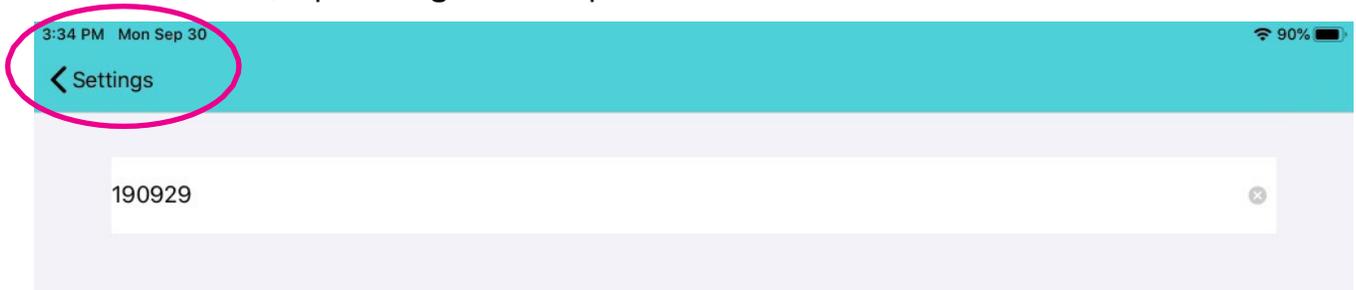
## Site Settings

After entering a valid **Client ID** and **Project ID**, the app will direct to the **Settings** screen. These settings should be configured once, prior to the start of the study. The configured settings determine how the app will operate throughout the duration of the study.



To configure the Site ID,

1. On the setting screen, tap **Site ID** row
2. Enter a name or code to represent you site
3. Once entered, tap **Settings** in the top left corner to return.



**Note:** You do not need to configure Settings if you are reinstalling the app as part of an ongoing study. Instead, simply enter your Site ID and tap the back arrow next to Settings or Done. The app will detect that you are attempting to reconnect to an existing Site and configure your Settings to match. If you do not know your Site ID, please contact the Helpdesk or your Modus Health contact.

After entering a site ID, proceed to select the appropriate settings to define how the app will function for your study. These configurations tailor the app's behavior to meet your specific study requirements.

### **Site Time Zone**

App automatically picks the time zone connected to the iPad. If you want the app to use a different time zone, tap the "Site Time Zone" row. Select the time zone you want the data to have from this site using the time zone scroll. If you want to go back to the local time zone of the iPad, tap "Local Timezone" above time zone scroll.

### **Use Metric Units**

When toggled on, the participant height will be entered in centimeters rather than feet and inches.

### **Cadence Threshold Low to Med**

This is the strides per minute threshold, or steps on the leg with the StepWatch for classifying if walking is a low intensity walking (default  $\leq 15$  strides/minute) versus medium intensity walking (default  $> 15$  strides/minute).

### **Cadence Threshold Med to High**

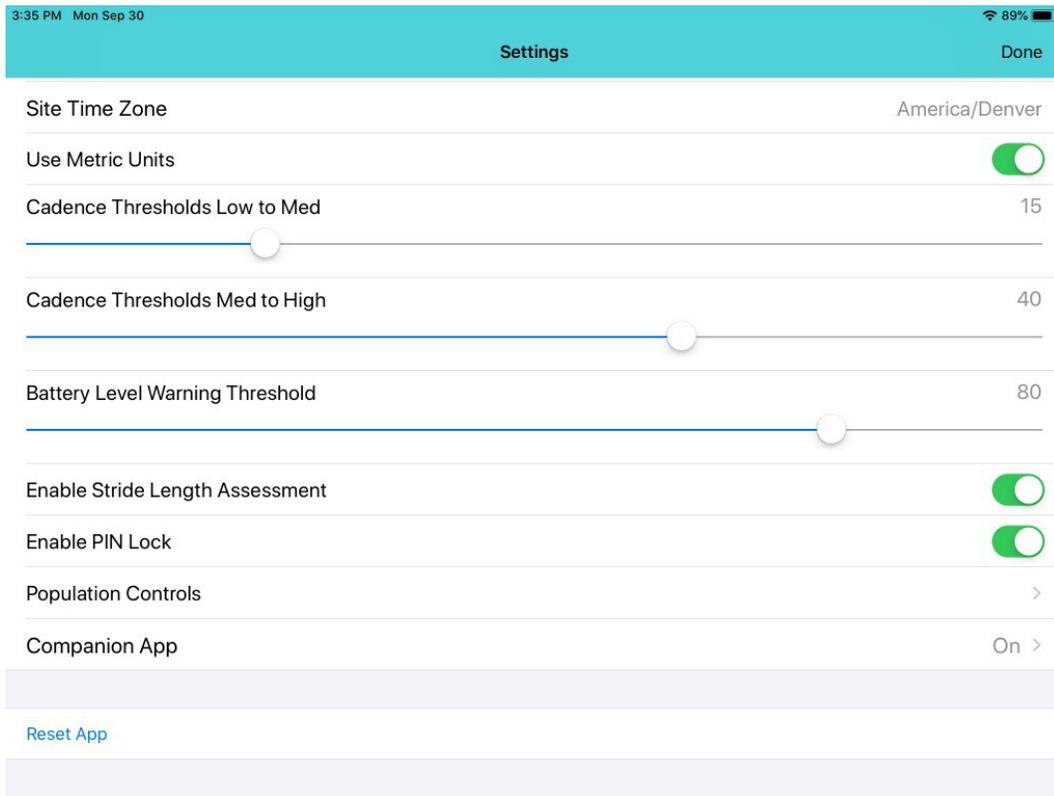
This is the strides per minute threshold, or steps on the leg with the StepWatch, for classifying if walking is medium intensity walking ( 40 strides/minute) or a high intensity walking (default  $> 40$  strides/minute).

### **Enable Stride Length Assessment**

When on, the app will show the stride length assessment screen when setting up a participant. This allows you to choose whether you wish to calculate stride length based on a timed walk test, distance walk test, or manually enter stride length. When off, the app will skip the stride length assessment screen when setting up a participant.

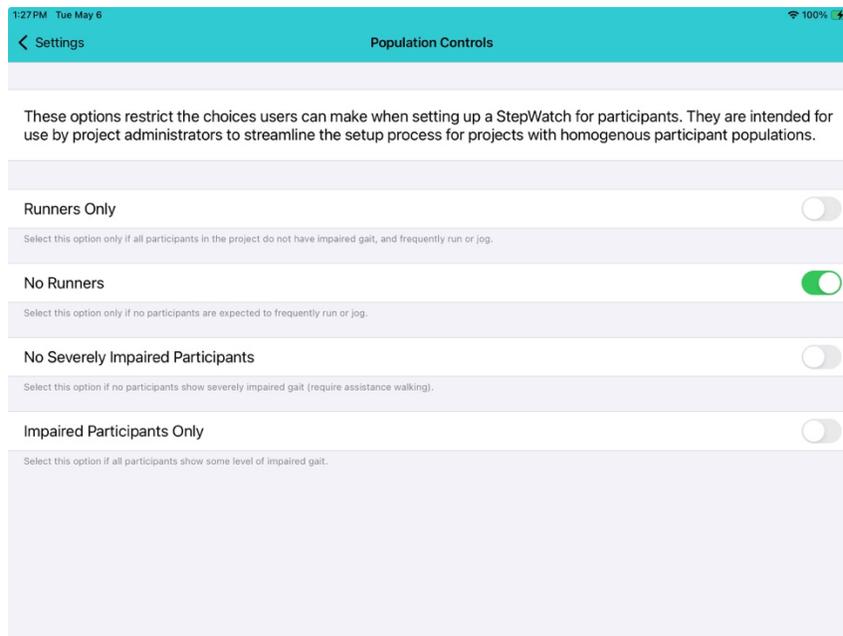
### **Enable Pin Lock**

When on, the app will require that a pin is entered after 15 minutes of inactivity or if you leave the app. You will be required to choose a pin once you save your settings.



## Population Controls

Population Controls allow you to restrict the StepWatch setup options to only those required at your site. For example, if no participants will use the jogging/running setting, you can lock this option to “No”. This helps ensure consistent setup and reduces the risk of incorrect selections during the study.



## Companion App

Turn companion app to “ON” if your participants will be using smartphones with the companion app for remote uploads.

**StepWatch Link Duration** – the number of days that the companion app will stay connected to a StepWatch.

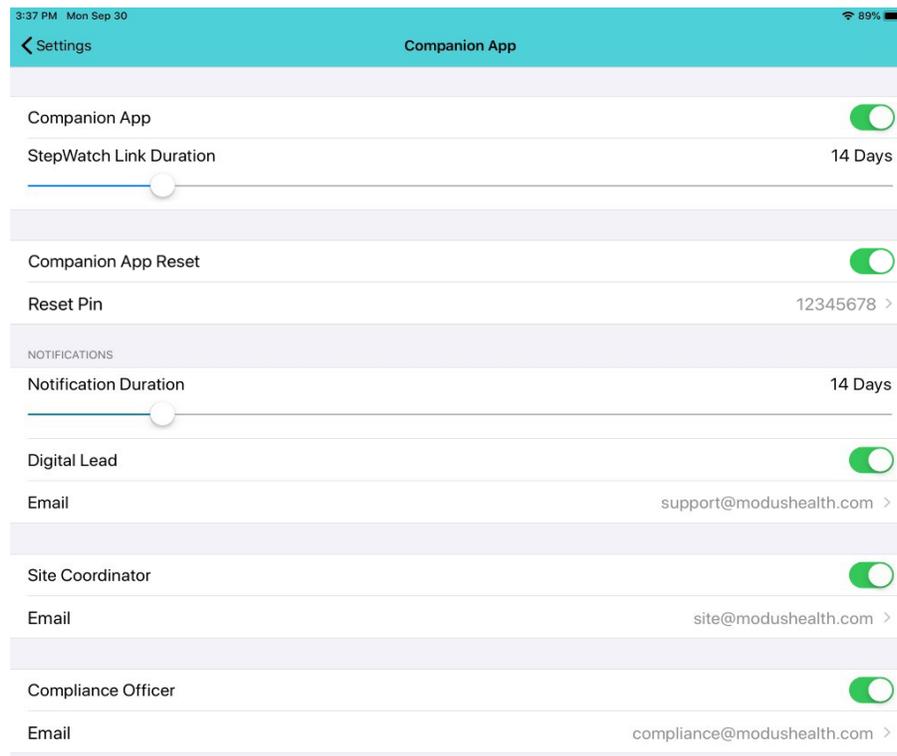
**Notification Duration** – how many days you want to receive notifications regarding upload status, participant compliance, and StepWatch battery warnings while the StepWatch is linked to the Companion app. Usually, StepWatch Link Duration and Notification Duration will be for the same number of days.

**Companion app reset** – turn this on if multiple participants may need to use the same phone. This allows the phone to be reset between users. Otherwise, only the original participant can use the phone. See “Resetting companion app”. If this setting is changed while a companion app is set up, press “upload app diagnostics” to refresh the info panel and access the reset.

**Digital Lead** – receives email notifications regarding upload status, compliance warnings, and battery warnings. Generally, the Digital Lead is responsible for all sites and will get these notifications for all participants.

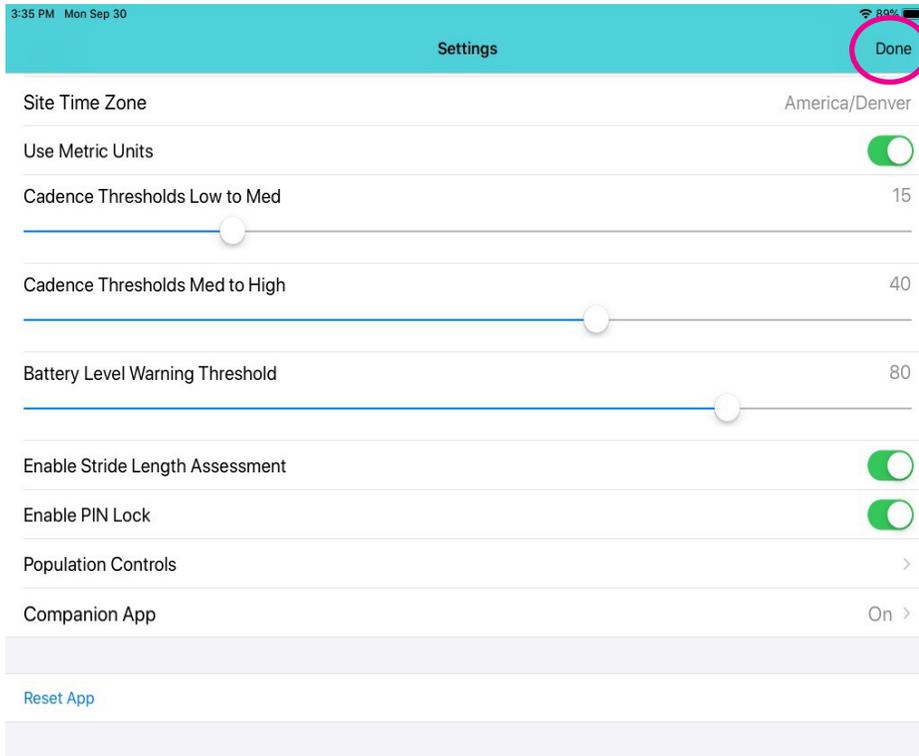
**Site Coordinator** – receives email notifications regarding upload status, compliance warnings, and battery warnings. Generally, the Site Coordinator is responsible for one site and will only get notifications for the participants at their site.

**Compliance Officer** - receives email notifications regarding summary status (includes daily steps, minutes active, and Y or N on the compliance threshold). This role can also be used to share information with a gamification or compliance vendor for triggering automated positive feedback, based on compliance, to participants through the vendor’s study apps.



Once all settings have been configured:

Tap **Done** if you are setting up a new site. Tap **Update** if you are modifying an existing site.  
If you choose **Update**, all iPads using the same Site ID will automatically receive the updated settings.

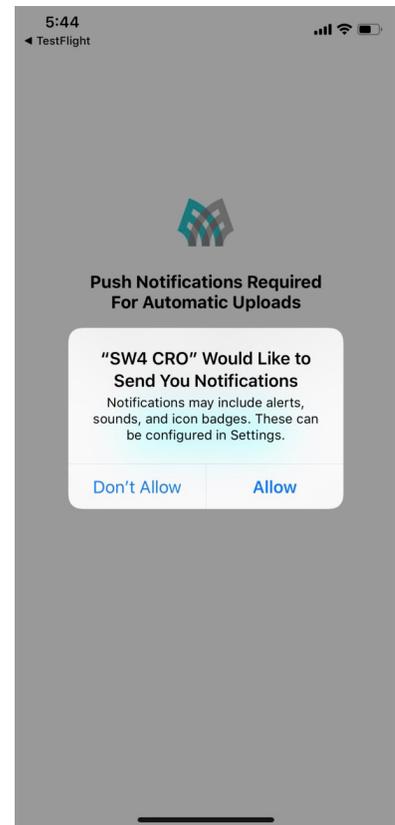
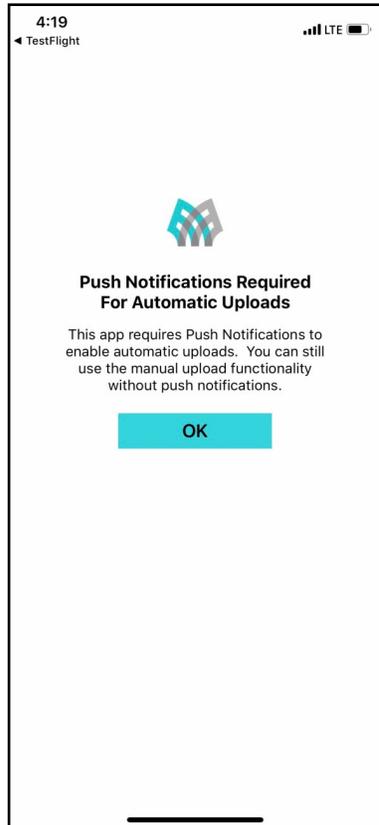
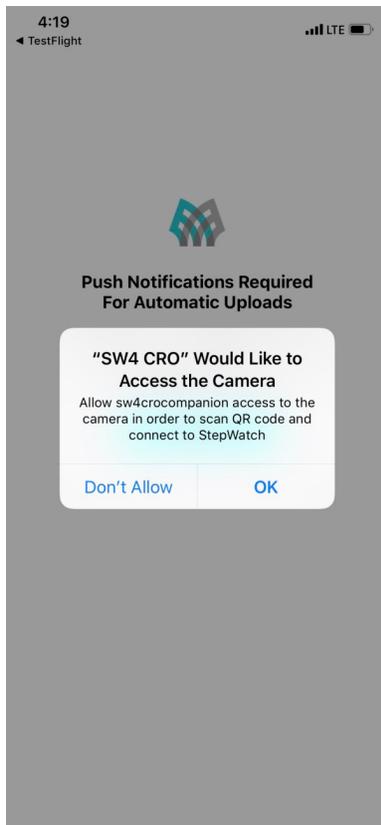


## Installing CRO Companion App

If using the CRO Companion App for remote uploads and do not have the app installed on a smartphone, search the App store for CRO Companion by Modus Health and download the app.

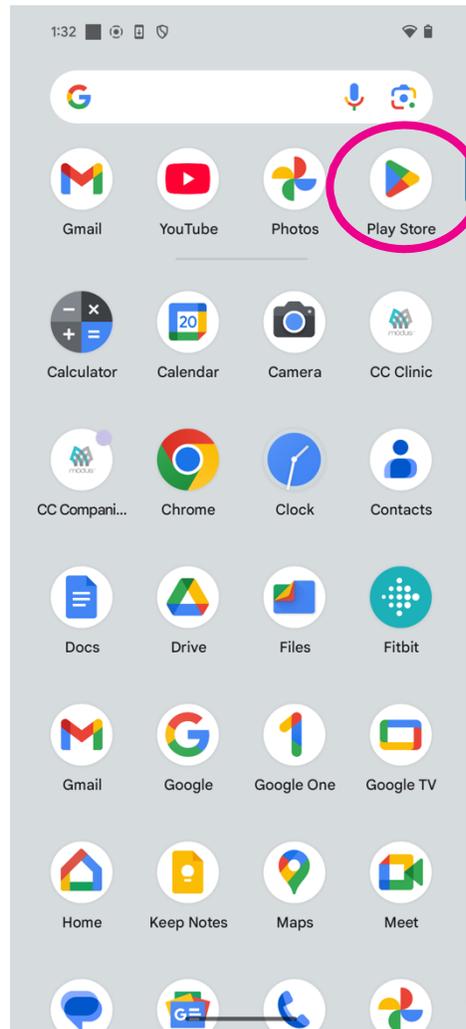
### iPhone

For iPhones, when opening the app for the first time, select “**OK**” for using the camera, tap “**OK**” to the push notifications, and select “**Allow**” to “SW4 CRO” Would Like to Send You Notifications”.

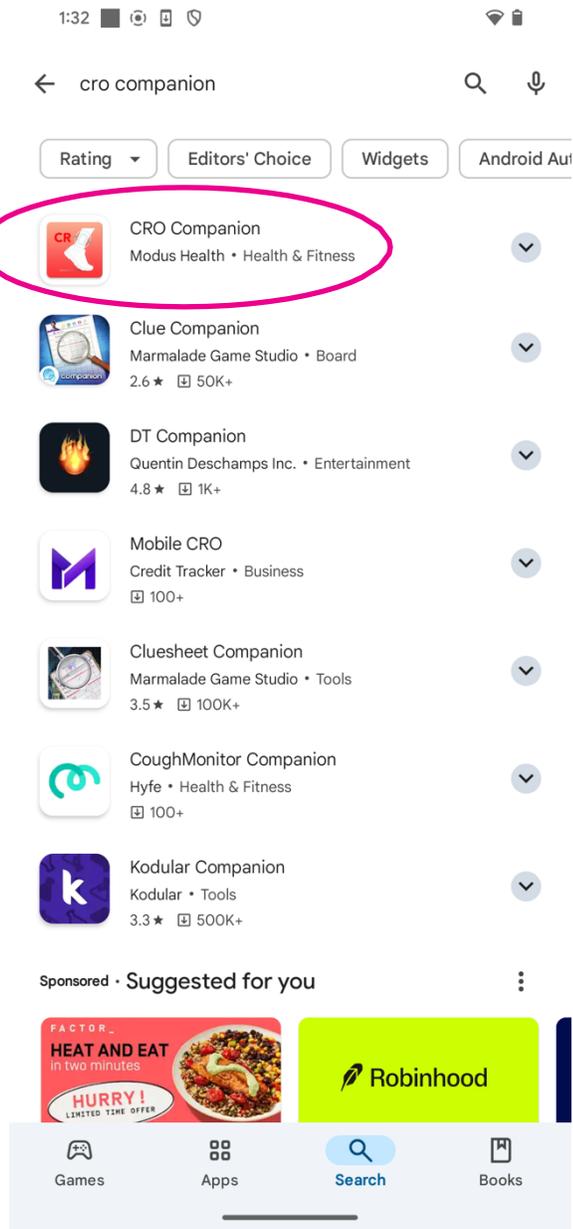


## Android

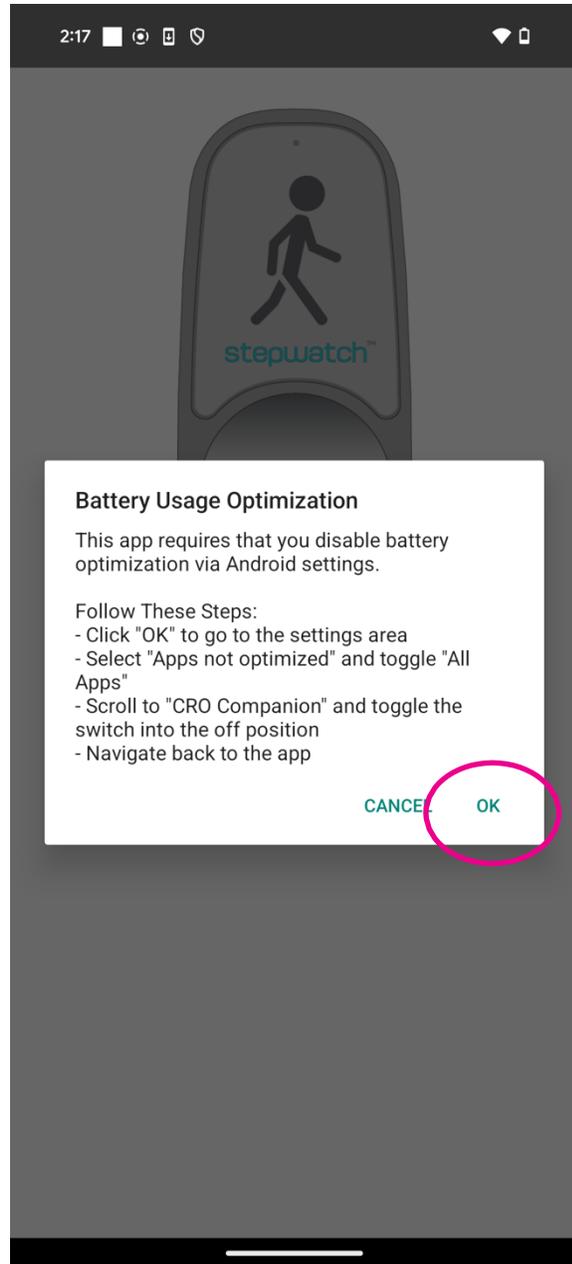
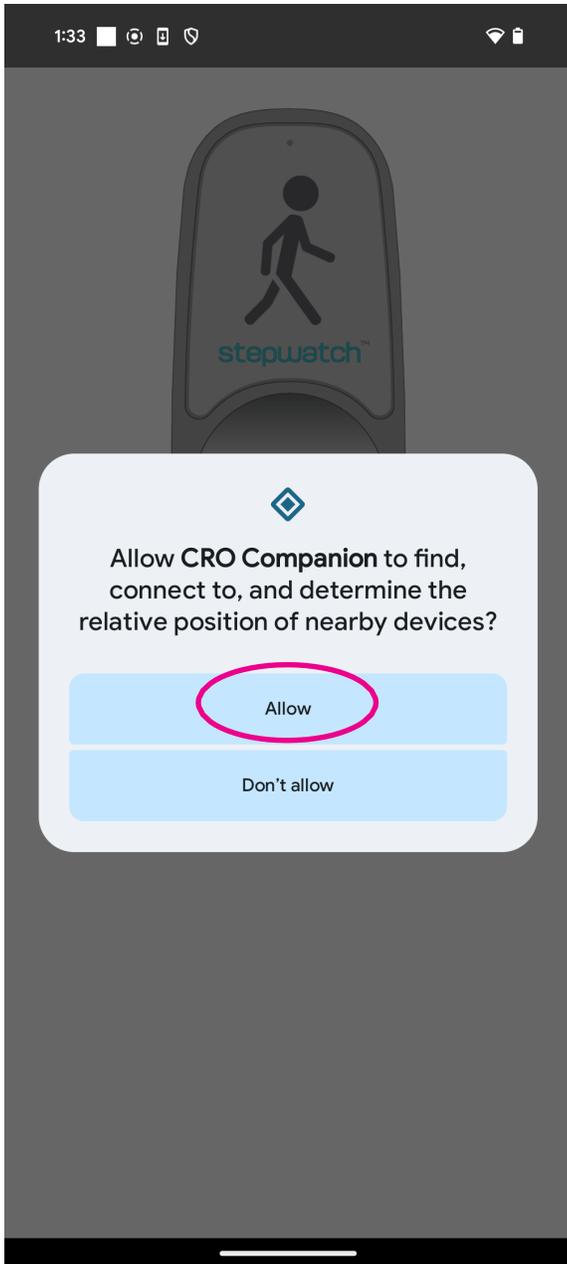
To download the CRO Companion app for Android smartphones, go to the Google Play store.



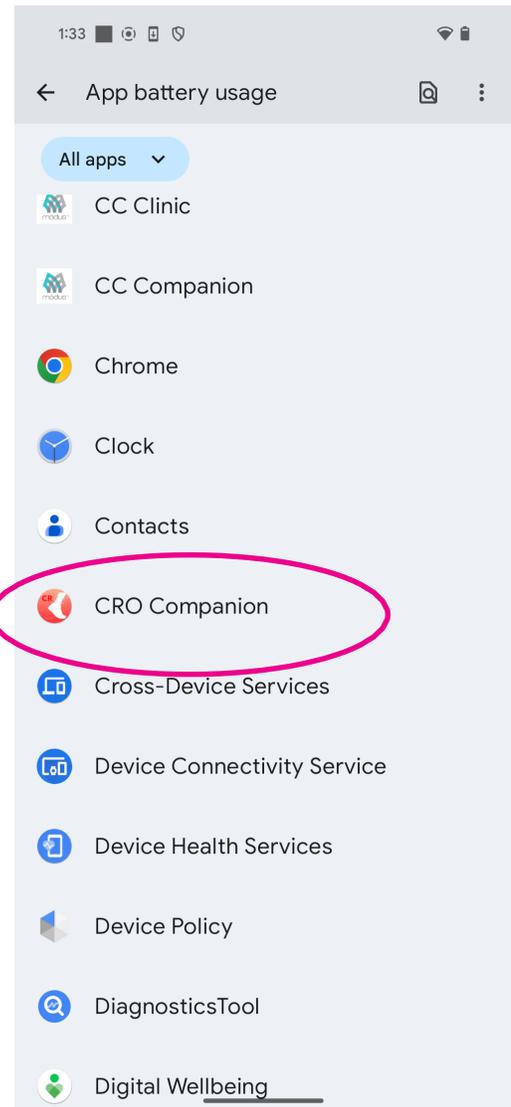
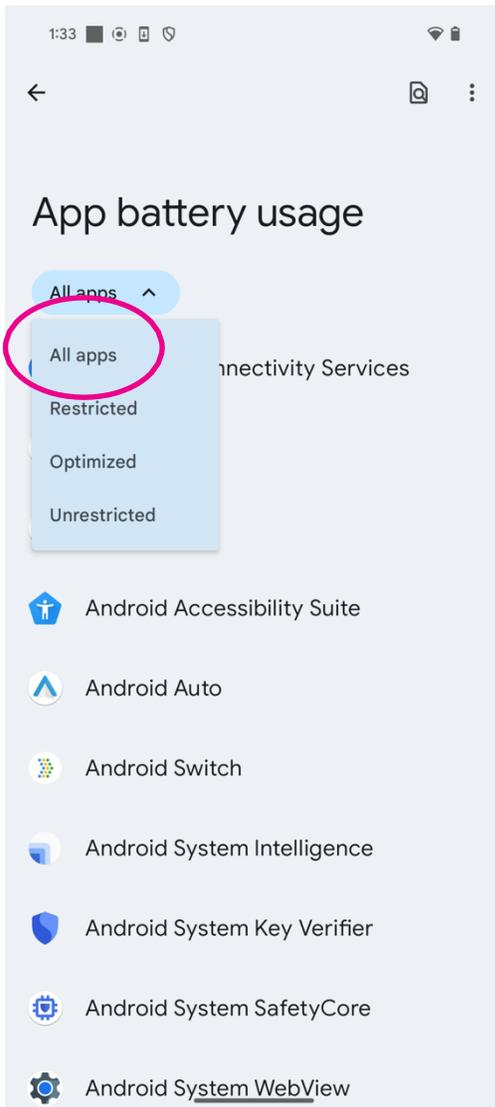
Search for “CRO Companion by Modus Health”, tap on the CRO Companion app and install it.



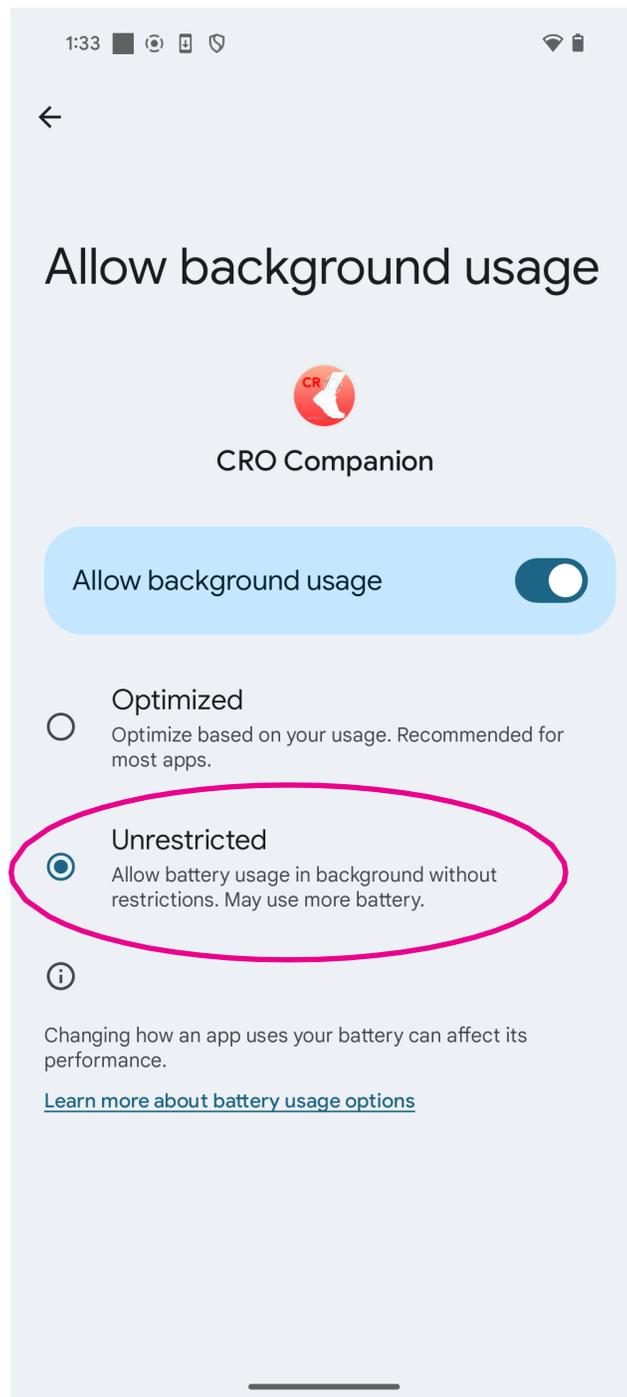
When you open the app, it will ask for access to this device's location. Select **"Allow."** Next, tap **"Ok"** to battery usage optimization.



Under Battery optimization, use the drop-down menu to select “**All apps**”. Search for the **CRO Companion app**.



Select **“Don’t optimize”** and tap **“Done”**. Then, tap the square in the bottom right corner to be given the option to close the Battery optimization settings.



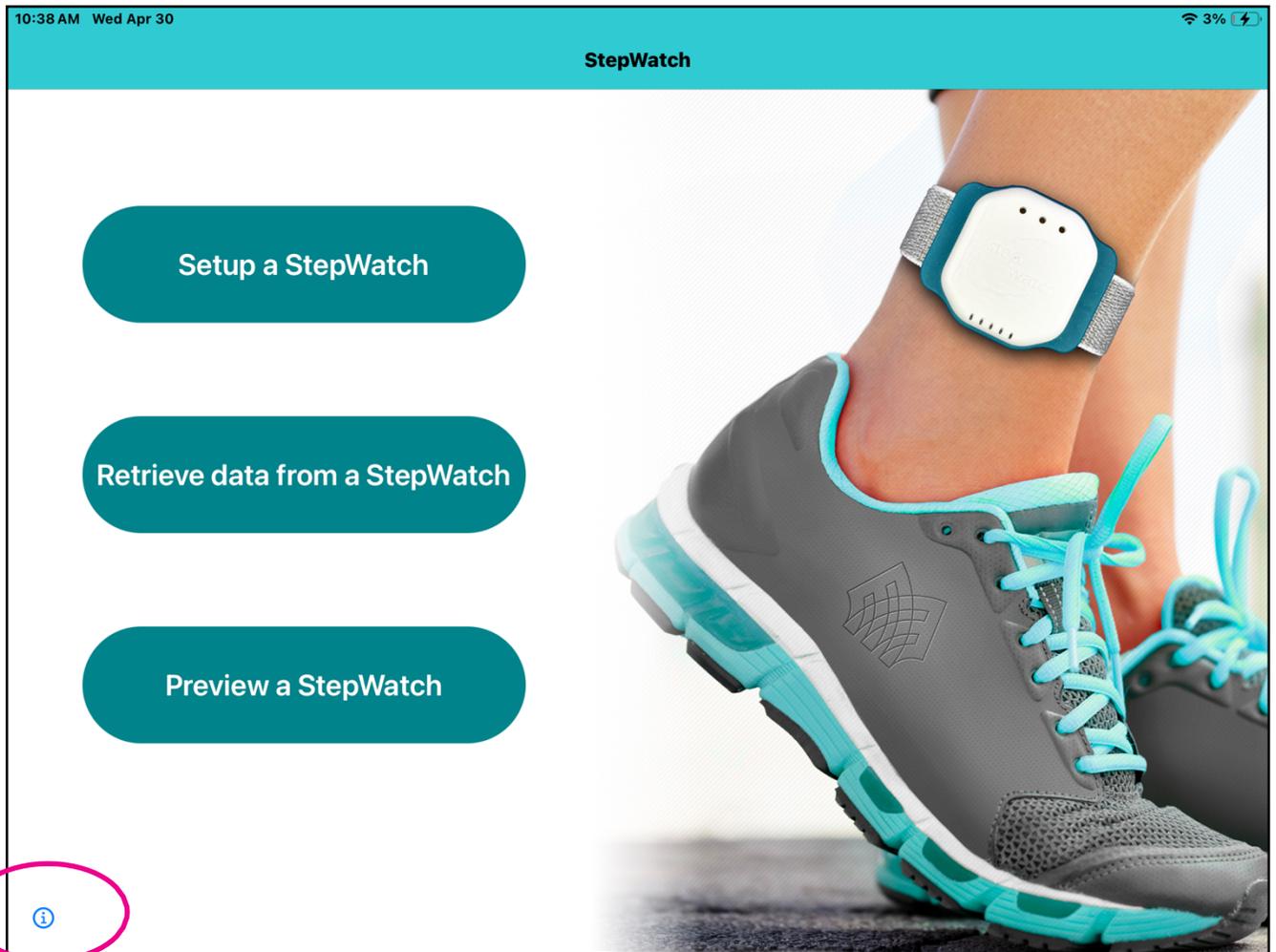
Return to the CRO Companion app. The CRO Companion app is now ready to connect to a StepWatch that has been setup with the CRO Site app.



# Preparing the StepWatch for a Participant Visit

## The Info Panel

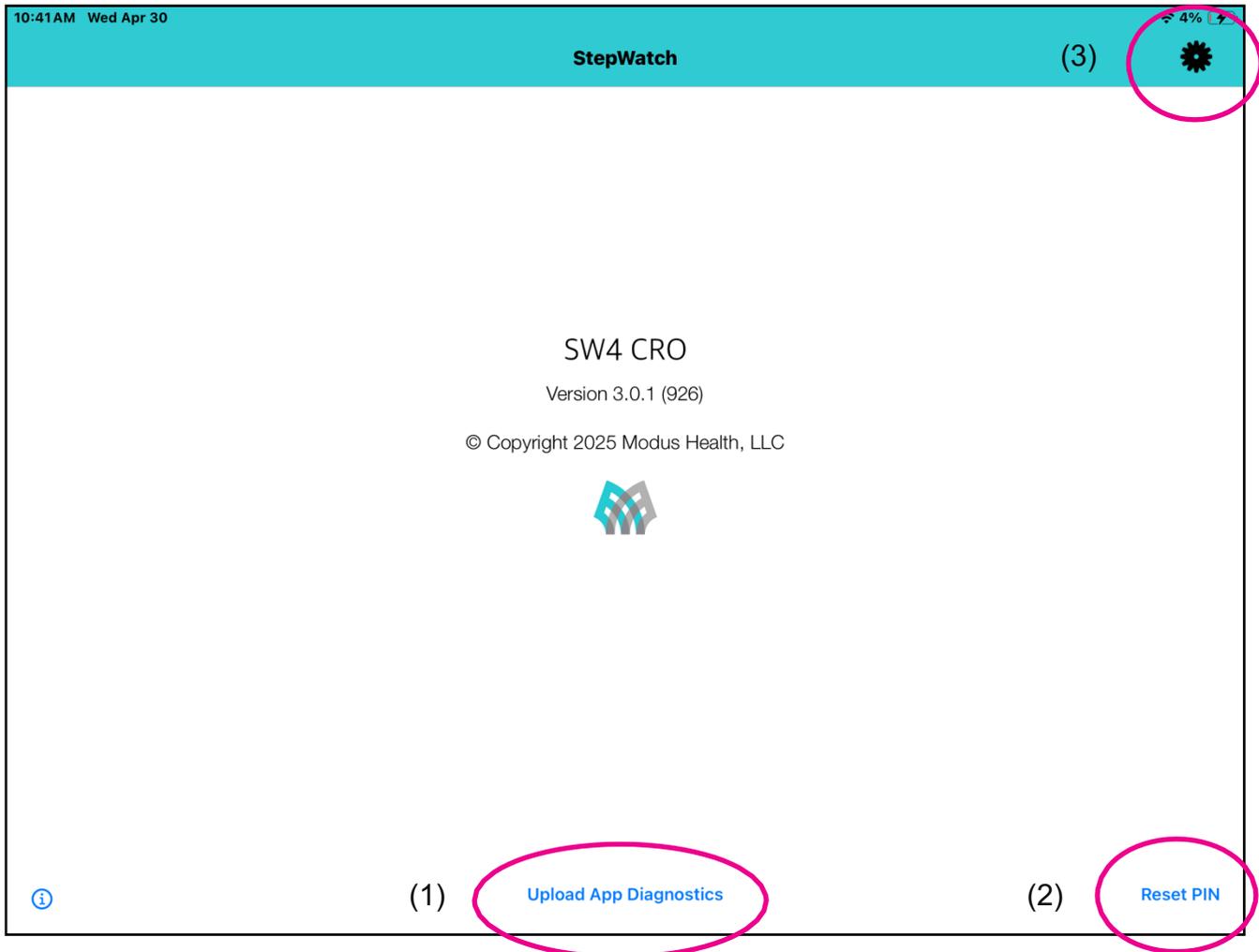
You can access the **Info Panel** at any time, by tapping the **Info** icon on the Main Screen of the CRO Site App. The info panel provides access to the app version number, useful tools for device administration, and troubleshooting features.



From the **Info Panel**, you can (1) **Upload App Diagnostics** (the Helpdesk may request that you do this when troubleshooting problems in the app) or (2) **reset the Security PIN**. The app will require that you enter the current PIN before enabling you to create a new one.

(3) When tapping the **Gear** icon in the top right corner, you are taken to the site settings screen which allows you to set up the Site ID and configure study-specific settings for your site.

Note: In some studies, Modus Health will setup the site settings prior to the delivery of the iPads.



### Important PIN Security Information

- You will have to re-enter the PIN after 15 minutes of inactivity.
- After 10 failed attempts, you will be locked out for 15 minutes.
- The app will require that you change your PIN every 120 days.
- If you cannot remember your PIN, contact the Helpdesk or re-install the app.

## Setting up a StepWatch

Before setup, ensure your mobile device has at least one of the following:

- Connected to a strong **WiFi** signal
- Has at least **three bars** of **cellular service**

An internet connection is required to register participants and upload data.

To begin Setup:

- a) Launch the **CRO Site App**
- b) Tap **“Setup a StepWatch”**
- c) Connect the StepWatch using one of the following methods:
  - i. Proximity Connection: Place the StepWatch on the device outline
  - ii. Manual Selection: Tap **“Choose StepWatch”**, then select the StepWatch Bluetooth ID listed on the label located on the back of the device.



## Participant Enrollment

To enroll a participant with a StepWatch, choose one of the following options

- a) **New Participant:** Select if participant is being enrolled in the study for the first time at this site or will be getting a new participant ID
- b) **Returning Participant:** Select if the participant has been enrolled at this site and will be using the same participant ID.

If **Returning Participant** is selected and previous data has been uploaded, the app will ask if you want to use the prior settings.

**Note:** Previous settings is used if the participant is not present for the setup procedure or there is high confidence that the height and walking ability of the participant has not changed.

Refer to the section “**Using Previous Settings for a Returning Participant**” for additional guidance.

10:39 AM Wed Apr 30 4%

**Exit** **StepWatch** **Enrollment**



Date	Apr 30, 2025
Study Number	8301100
Site ID	CRBOOKLET
StepWatch ID	SW5-CBF4
Battery Level	38%



New Participant



Returning Participant

On the Enrollment Screen, enter the participant ID, then tap Next.

10:40 AM Wed Apr 30 4%

**Exit**      **StepWatch** **Enrollment**

---

ENTER SUBJECT INFO

Participant ID  
\_\_\_\_\_

Re-enter Participant ID  
\_\_\_\_\_

Date                      Apr 30, 2025

Study Number            8301100

Site ID                    CRBOOKLET

StepWatch ID            SW5-CBF4

Battery Level            38%

**Next**

On the Programming Screen, enter the participant's height and characterize their walking behavior. This is necessary for the accuracy of the step detection algorithm. Then tap **Next**.

10:40 AM Wed Apr 30 4%

**Exit**      **StepWatch**      **Program StepWatch**



Date	Apr 30, 2025
Study Number	8301100
Site ID	CRBOOKLET
StepWatch ID	SW5-CBF4
Battery Level	38%
Subject ID	TEST-2

Please enter the participant's height. 6' 1"

---

Does the participant frequently run or jog?  Yes  No

---

Does the participant show an impaired gait?  Severely impair...  Slightly impaired  No

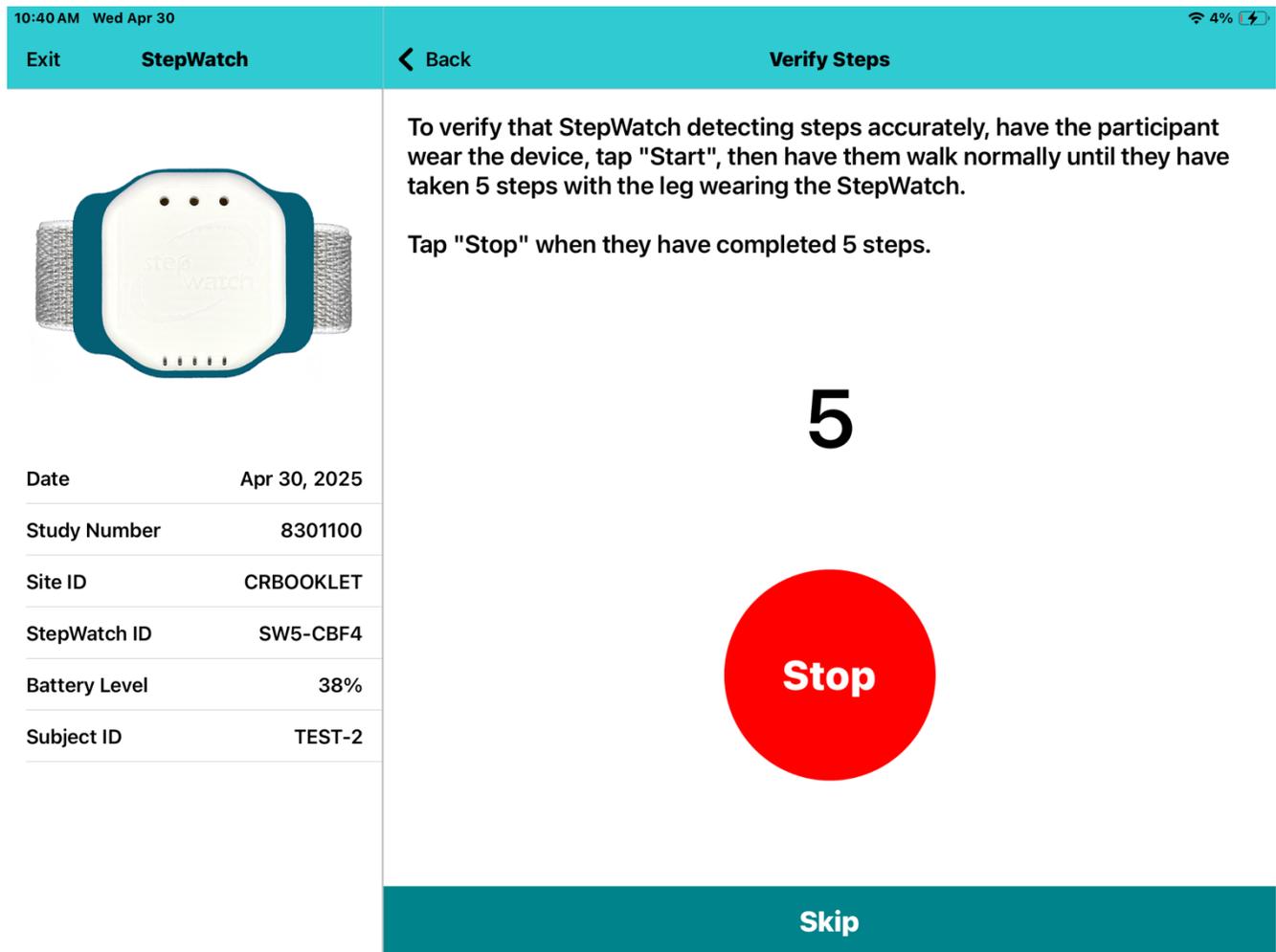
---

**Next**

Before proceeding, securely attach the StepWatch to participant's leg. Follow the instructions provided in the **"Managing a StepWatch"** section for proper placement and fastening.

## Step Verification & Fine Tuning

Follow the directions on-screen to begin the Step Verification process.



The screenshot shows the StepWatch app interface. At the top, the status bar displays "10:40 AM Wed Apr 30" and "4%" battery. The app header has "Exit StepWatch" on the left and "Back Verify Steps" on the right. On the left side, there is an image of the StepWatch device and a table with the following information:

Date	Apr 30, 2025
Study Number	8301100
Site ID	CRBOOKLET
StepWatch ID	SW5-CBF4
Battery Level	38%
Subject ID	TEST-2

The main content area contains the following text:

To verify that StepWatch detecting steps accurately, have the participant wear the device, tap "Start", then have them walk normally until they have taken 5 steps with the leg wearing the StepWatch.

Tap "Stop" when they have completed 5 steps.

In the center of the screen, the number "5" is displayed above a large red circular button labeled "Stop". At the bottom of the screen, there is a teal button labeled "Skip".

**Note:** It is normal if the StepWatch detects slightly more or fewer than 5 steps – the device will self-adjust for minor variations.

What's important:

Tap **Stop** in the app after observing the five steps taken with the leg wearing the StepWatch. This typically equals 10 total steps counting steps on both legs.

## Stride Length Screen

The **Stride Length** screen will only appear if you have it selected in your Site settings. You can determine stride length by using one of the following methods

- **By Distance:** Perform a distance walk test,
- **By Time:** Perform a timed walk test (you will be prompted to enter the distance walked)
- **Enter Stride Length Manually:** Manually input a known stride length

Tap the option that aligns with your study protocol to proceed. Some selections may be restricted based on your Site settings (i.e. locked to **By Distance** using a specific number of meters).

Date	Apr 30, 2025
Study Number	8301100
Site ID	CRBOOKLET
StepWatch ID	SW5-CBF4
Battery Level	38%
Subject ID	TEST-2

## Stride Length – By Distance

If you select “By Distance”, follow these steps:

1. Have a course with a start and finish line covering the specified distance for the stride length test.
2. Choose the desired distance in meters (if not locked to a distance already) in the app.
3. When the participant begins the walking test, tap **Start**.
4. Tap **Stop** when the participant’s foot crosses the finish line.

The StepWatch will automatically count the number of steps taken during this interval and calculate the stride length.

### Stride Length – By Time

If you select “By Time”, follow these steps:

1. Choose a timed walk test (e.g., 6 minutes for the Six Minute Walk Test)
2. The StepWatch will automatically count steps during the selected time interval
3. At the end of your test, you will be prompted to enter the total distance walked.

The app will then use the time, distance, and step count to calculate stride length.

### Stride Length – Manual Entry

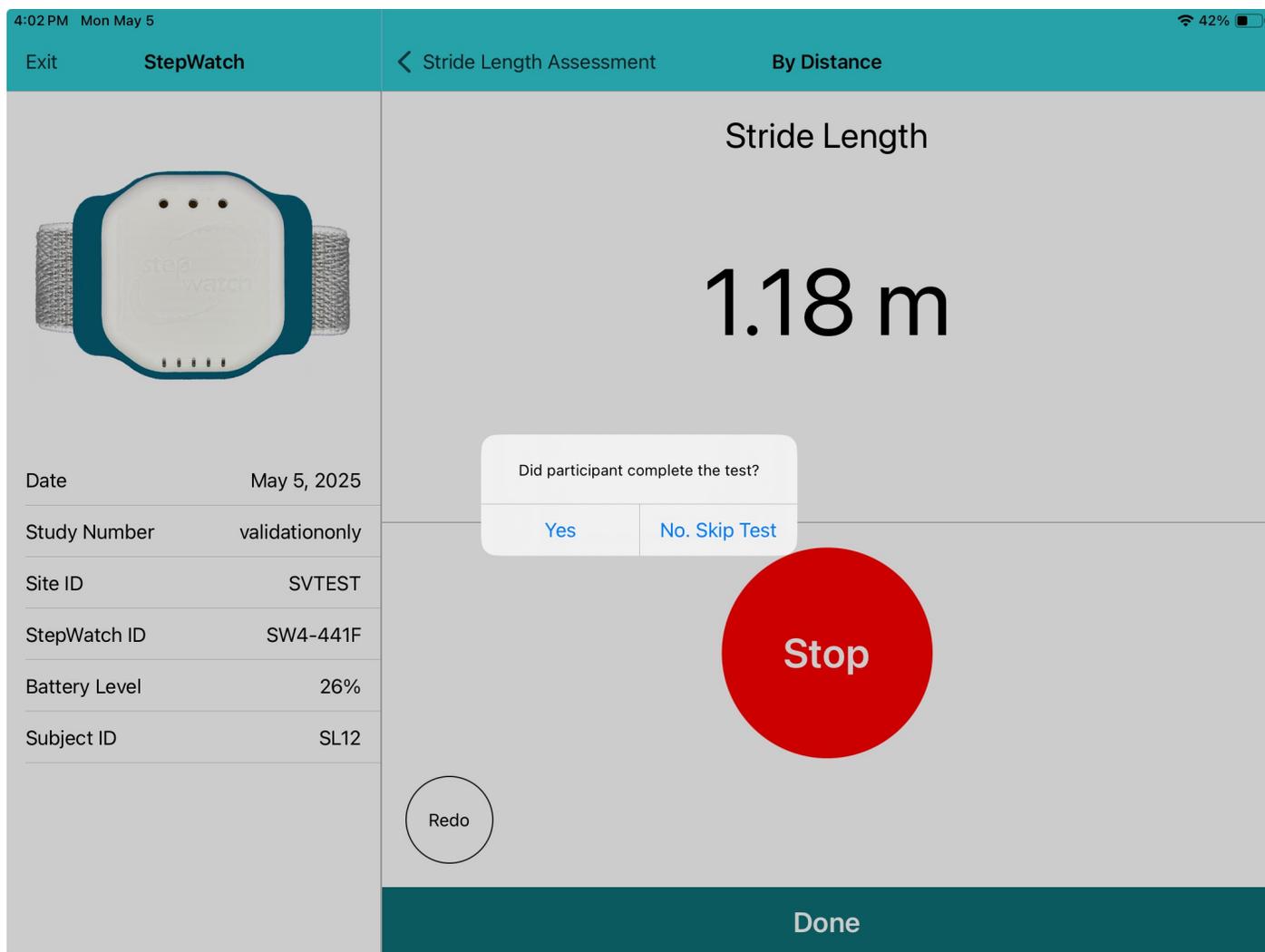
If you select “Enter Stride Length Manually”, type in the participants know stride length when prompted. Use this option only if the stride length has been previously measured or provided.

### Stride Length Verification

After selecting “Done” on the stride length screen, a dialog box will appear asking you to confirm whether the stride length test was completed by the participant.

Select “Yes” to confirm the test was completed

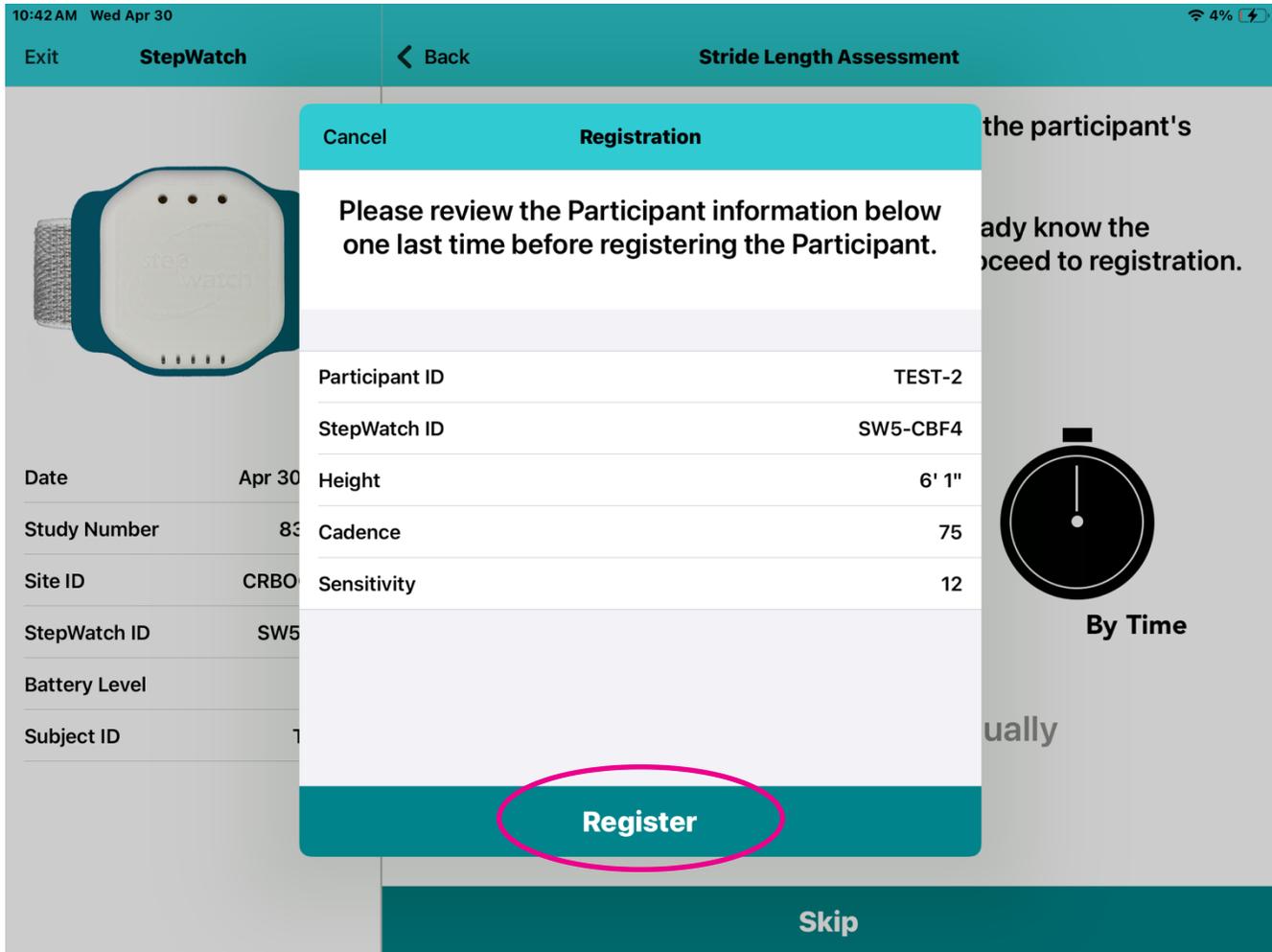
Select “No. Skip Test” to indicate the test was not completed or to bypass stride length entry



## Final Registration

Carefully review the participant information for accuracy.

- Tap **“Register”** to submit the participant’s details to the cloud and officially enroll them in the study.
- If the participant has been previously enrolled, the button will display **“Update”**



## Connecting the StepWatch via QR Code

When prompted “Using QR Connect” on the iPad:

Select “Yes” if you are using the QR code displayed on the iPad to connect the StepWatch to the mobile device

10:44 AM Wed Apr 30

Exit StepWatch

Back Stride Length Assessment

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

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

**Use QR Connect?**  
For the Android Companion App, choose "No", and then connect to the StepWatch using the connect button on the Android App.  
For the iPhone Companion App, if the participant iPhone is present, choose "Yes" to view scannable QR code for one-step transfer. If the iPhone is not present, choose "No", and then later connect to the StepWatch using the connect button on the iPhone App.

Yes No

By Time

Enter Stride Length Manually

Date	Apr 30, 2025
Study Number	8301100
Site ID	CRBOOKLET
StepWatch ID	SW5-CBF4
Battery Level	38%
Subject ID	TEST-3

10:44 AM Wed Apr 30

Exit StepWatch

Transfer StepWatch Info

To begin transferring the connected StepWatch to a study iPhone, tap Connect in the iPhone app.

When the camera view appears, simply scan the QR code below.

Date Apr 30, 2025

Study Number 8301100

Site ID CRBOOKLET

StepWatch ID SW5-CBF4

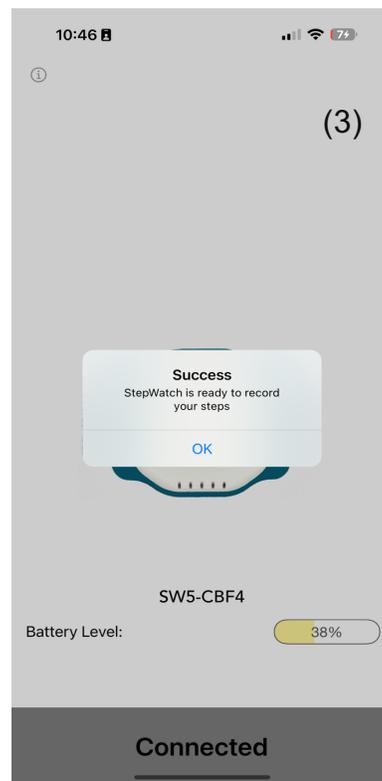
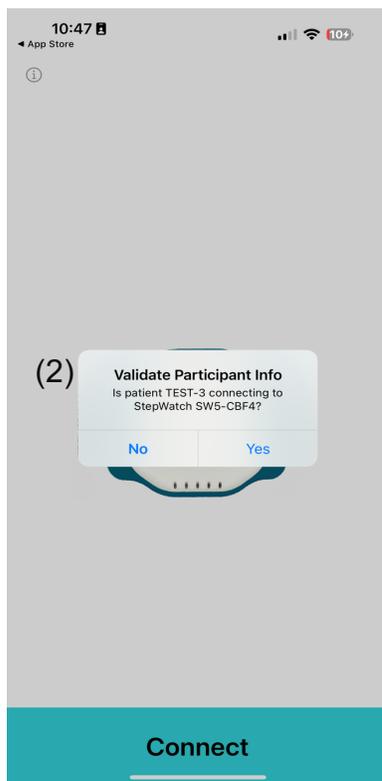
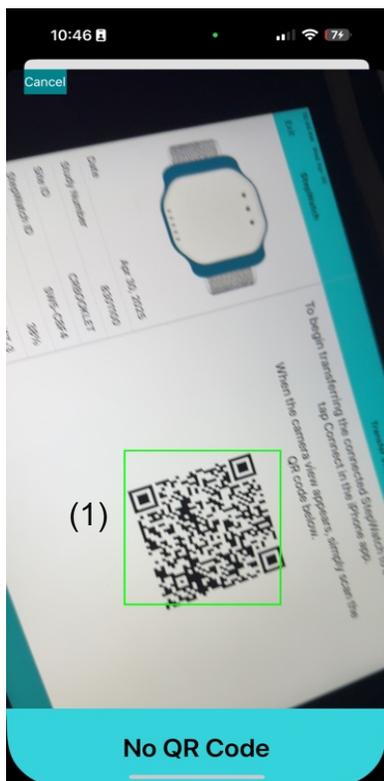
Battery Level 38%

Subject ID TEST-3

Done

Tap the “**Connect**” button on your mobile device and (1) scan the **QR code** on the iPad. The QR code scan is currently only available for Apple mobile devices. See “Connecting the StepWatch without QR Code” if using an Android mobile device.

Confirm that the Participant ID displayed matches the intended participant. (3) A dialog box should appear to show a successful connection to the StepWatch.

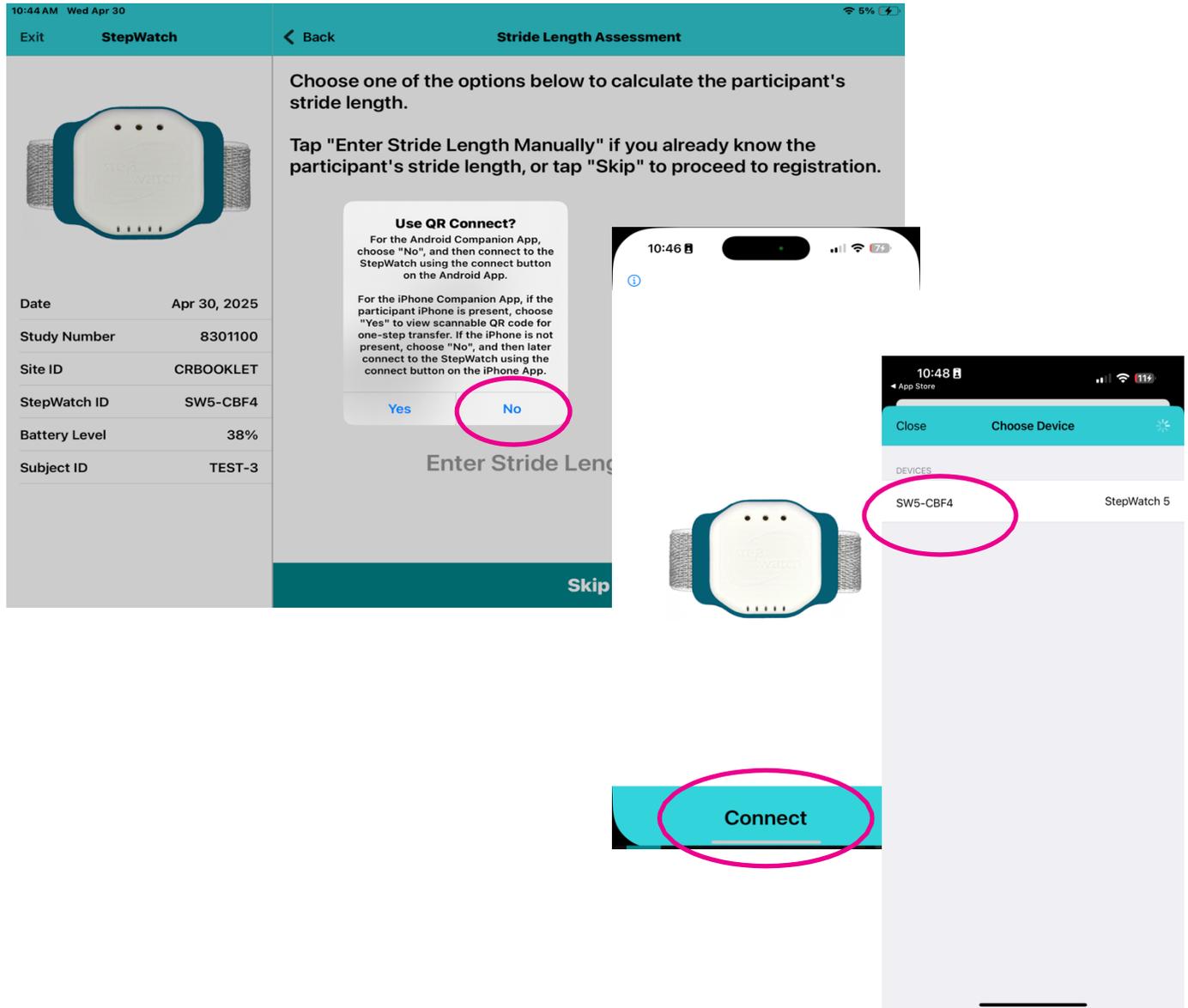


**Note:** The Connect button becomes only becomes active again after the current link duration has expired, the Companion app was reset (Apple devices only), or app was re-installed.

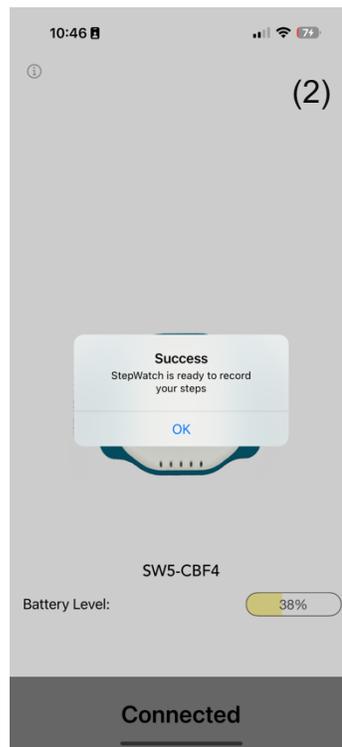
## Connecting the StepWatch without QR Code

When prompted “Using QR Connect” on the iPad:

Select “**No**” if you plan to connect manually by tapping “Choose StepWatch” on the Companion app and select the StepWatch from the list by its **Bluetooth ID**.



Confirm that the Participant ID displayed matches the intended participant (1). A dialog box appears to show a successful connection to the StepWatch (2)



**Note:** The Connect button becomes only becomes active again after the current link duration has expired, the Companion app was reset (Apple devices only), or app was re-installed.

## Participants Use of CRO Companion App

After the initial setup, participants should use the Companion App at home to enable automatic uploads of StepWatch data to the study cloud. The Connect button becomes only becomes active again after the link duration expires.

### Automatic Uploads

- Keep the mobile device with the Companion App plugged in overnight and in the same room as StepWatch.
  - If in single app mode, the app will stay fronted. The participant can keep the mobile device face down on a nightstand to keep the light from disturbing their sleep.
  - If using not using single app mode (i.e. participant using their own phone), the app should stay open in the background. If the automatic upload is missed, the participant will get a notification to open their app in the morning and ask if they want to upload.
- The Companion App will stay connected to the StepWatch for the **link duration** set in the app's site settings.

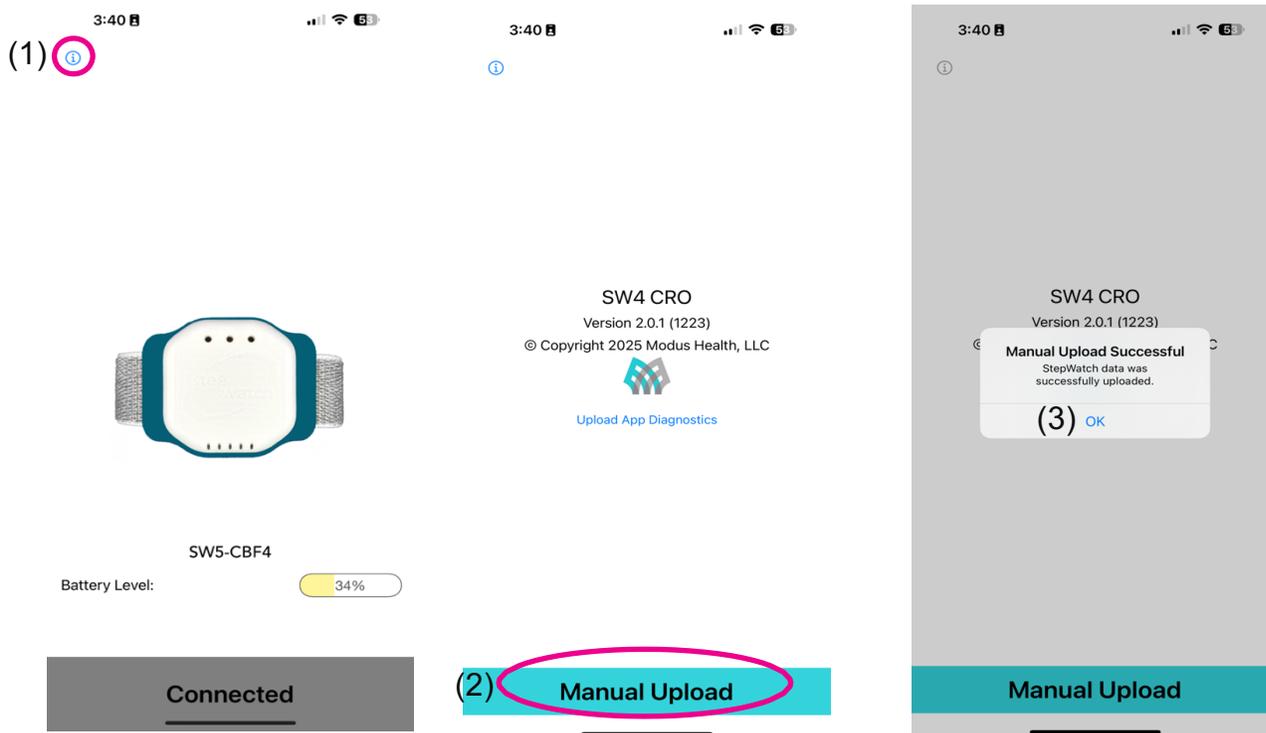
### Manual Uploads

If an upload is needed outside the scheduled automatic time:

1. Tap the **Info** button in the app.
2. Tap the **“Manual Upload”** button to send the most recent walking data to the cloud. A timeout of 5 minutes will follow to prevent over tapping of this button.
3. “Manual Upload Successful” will appear if sent to the cloud.

**Note:** The StepWatch must be within Bluetooth range of the Companion app by being in the same room.

Tap the **Info** button again to return to the **Connect** screen.

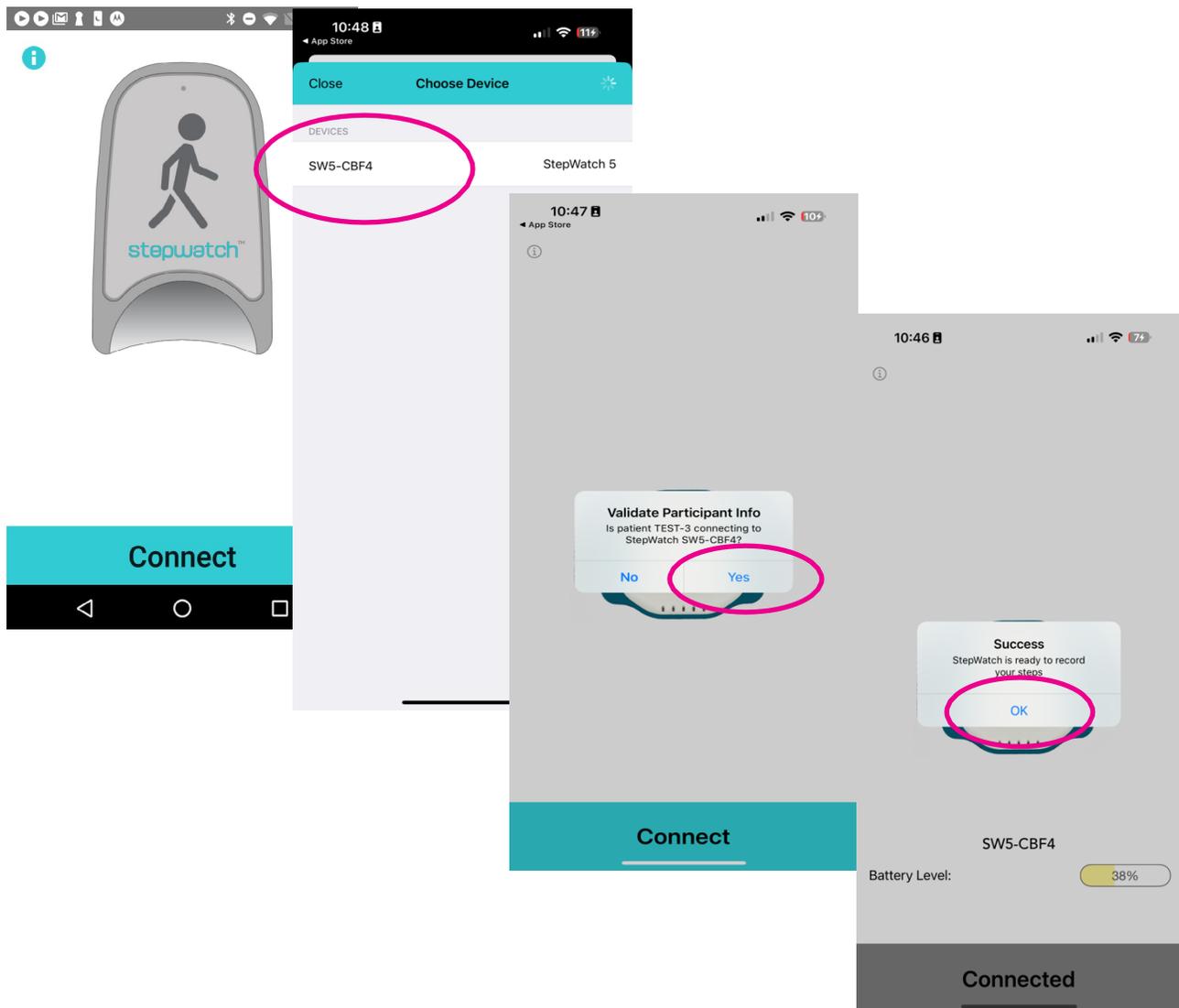


## Reconnecting After Link Duration Expiration

Once the current link duration on the Companion app has expired, the device can reconnect to a StepWatch for a new data collection session—provided the StepWatch has been set up again using the same participant ID with the CRO Site App. This security feature helps prevent accidental connections to a different participant’s StepWatch, especially when initiating a connection outside the clinic.

Participants can reconnect using one of the following methods:

- QR Code: Scan the QR code on the back of the StepWatch to automatically connect to their StepWatch if using an Apple mobile device.
- No QR Code: Select “No QR Code” and manually choose the StepWatch from the list using its Bluetooth ID.



To connect to a **different Participant ID**, see the section **Resetting the Companion App**.

## Resetting the Companion App to Accept a Different Participant

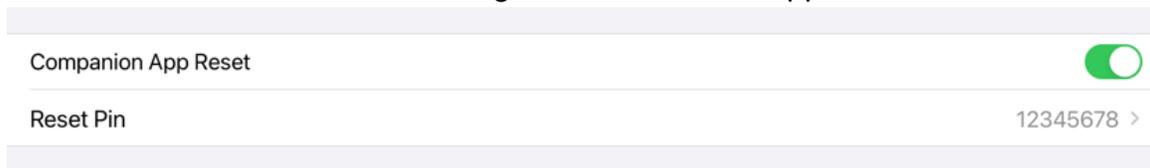
The **Companion App** is designed to prevent connection to a different participant than the one it was last paired. This security feature helps prevent accidental connections to a different participant's StepWatch, especially when initiating a connection outside the clinic.

**Note:** This feature is currently only available on Apple mobile devices.

To connect the app with a **new or different participant**:

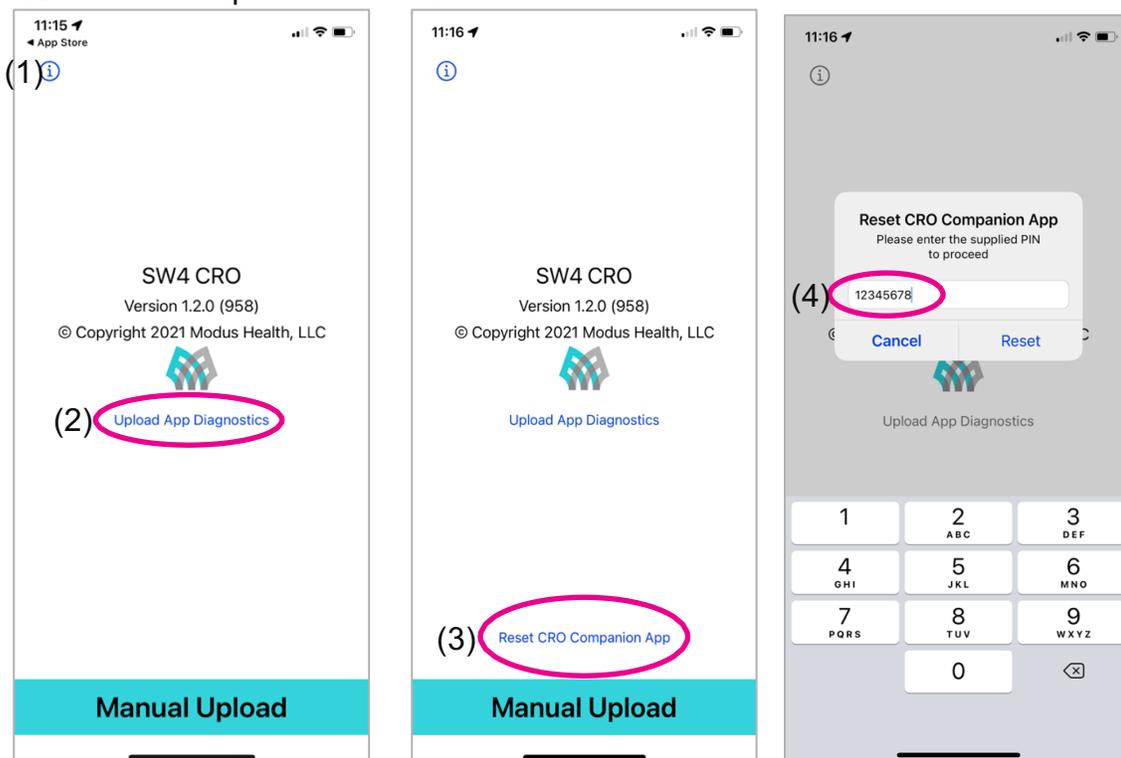
- The Companion App must be **manually reset** or the app re-installed.
- A **PIN code** is required to perform the reset, ensuring that the action is both **intentional and authorized**.
- Make sure that your site settings has the **Companion App Reset** turned on with a **Reset Pin**

### Site Settings in the CRO Site App



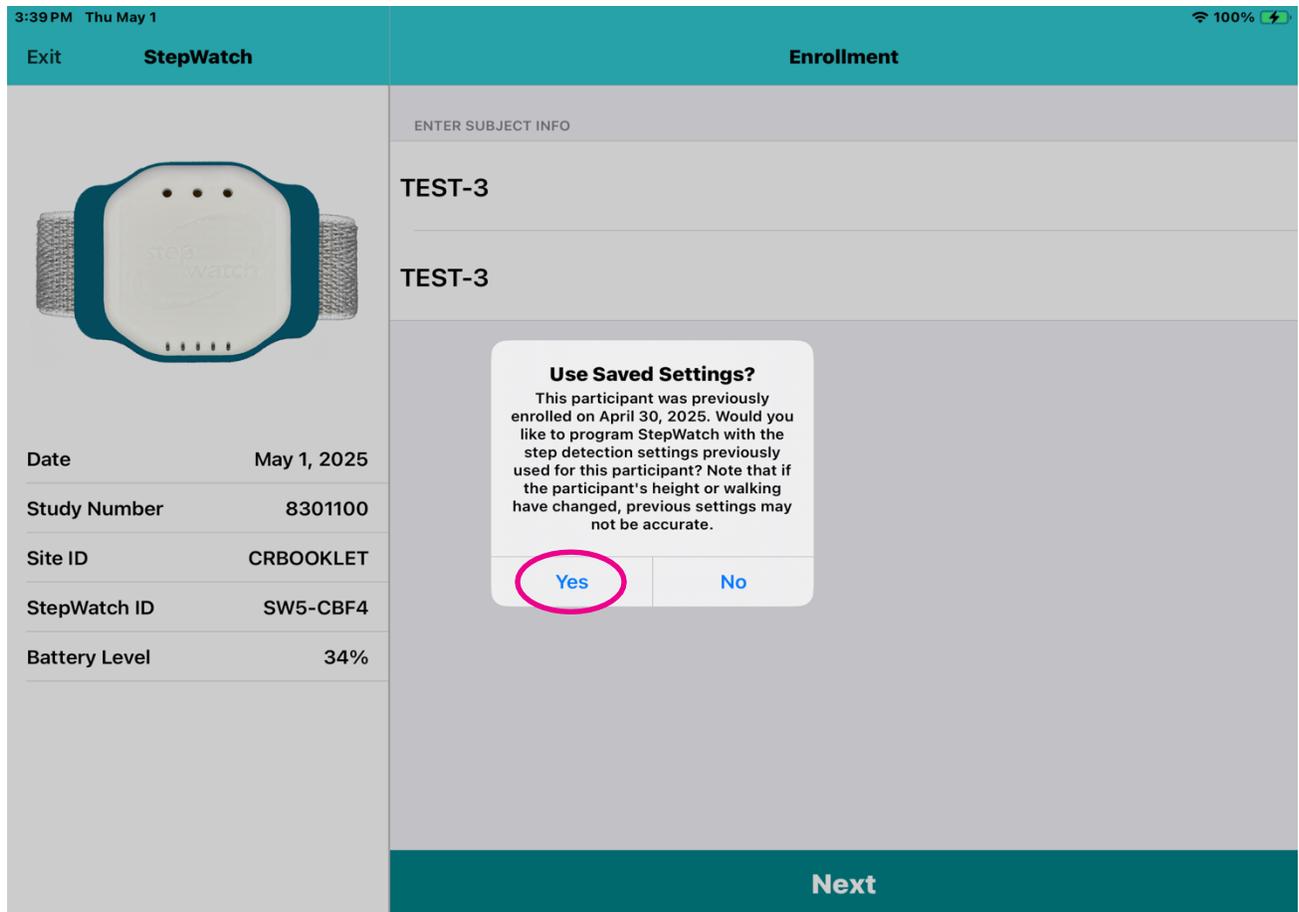
To reset the CRO Companion App for use with a different participant:

1. Tap the **Info icon** in the top-left corner of the main screen.
2. Tap "Upload App Diagnostics" if the site settings changed to allow a reset or if the reset PIN changed
3. Select "**Reset CRO Companion App.**"
4. When prompted, **enter the specific PIN** provided by your study coordinator or Modus Health.
5. Tap "**Reset**" to complete the reset.



## Using Previous Settings for a Returning Participant

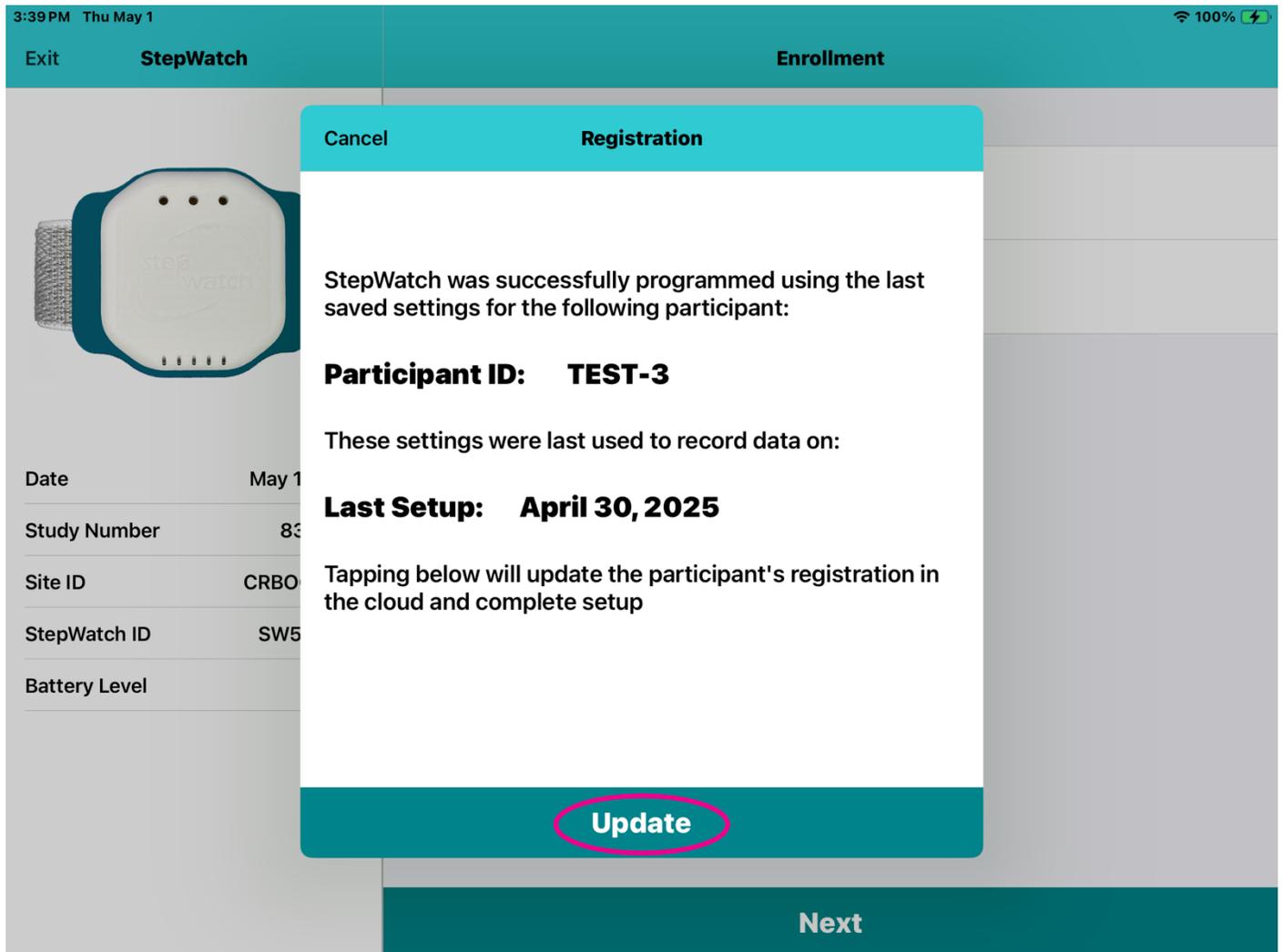
If a participant has previously been monitored using a StepWatch, their setup settings are saved in the system. When enrolling the participant again, you will have the option to **reuse the previous settings** instead of repeating the entire setup process.



While reusing previous settings is available, it is more accurate to complete the full setup procedure each time the StepWatch is configured. The option to reuse settings is intended only for situations where the participant is not present, and there is a low probability that their height or walking ability has changed since the last setup.

The **Registration** screen displays the date of the most recent StepWatch setup for the selected participant. The **StepWatch's step detection algorithm** will be based on this setup.

- If the date is **not what you expected**, you may cancel the use of saved settings:
  - Tap **“No”** when prompted to **“Use Saved Settings.”**
  - The app will then guide you through the full setup process for the returning participant.
- If the date is **acceptable**, tap **“Update”** to proceed using the saved configuration.

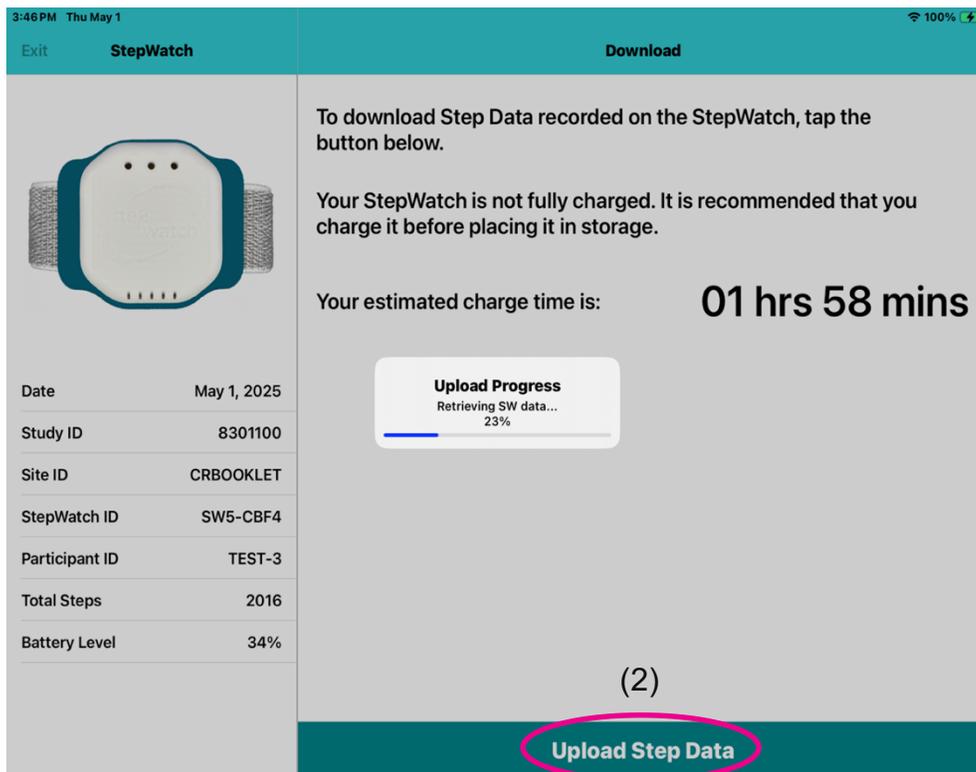
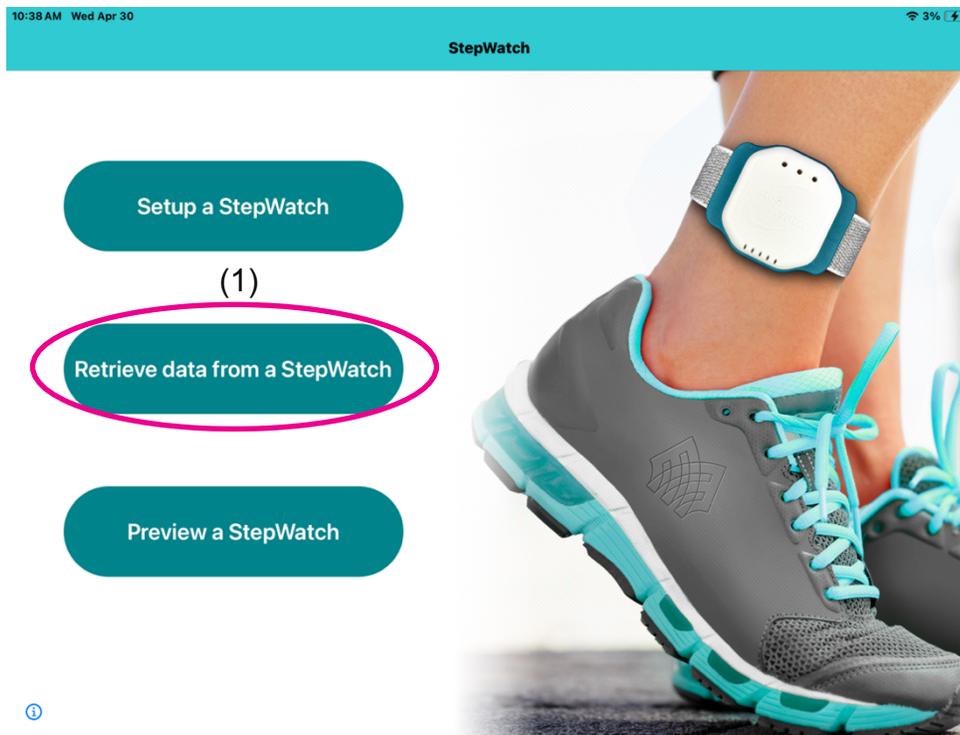


## Retrieve Data from a StepWatch

When a StepWatch is returned to the site after completing a study visit or session:

1. From the **Main Screen**, tap **“Retrieve Data from a StepWatch.”**
2. Tap **“Upload Step Data”** to upload the stored walking data from the device to the cloud.

This ensures participant data is securely transferred and available for analysis.



After a successful data upload, the app will prompt you to choose one of the following options:

- **Clear and Store** – Select this to clear the data and participant ID and to turn off the Bluetooth radio to conserve battery power until the device’s next use.
  - To the Bluetooth radio turn back on later, place StepWatch on the charger for at least 10 seconds.
- **Clear** – Select this to clear the data and participant ID and to keep the Bluetooth radio on for setting up for another participant.
- **Continue Recording** – Select this if the StepWatch should remain active and continue collecting data for your participant.

The screenshot shows the StepWatch app interface. At the top, the status bar displays '3:46 PM Thu May 1' and '100%' battery. The app header has 'Exit' and 'StepWatch' on the left, and 'Download' on the right. On the left side, there is an image of a StepWatch device and a table of data. The table includes: Date (May 1, 2025), Study ID (8301100), Site ID (CRBOOKLET), StepWatch ID (SW5-CBF4), Participant ID (TEST-3), Total Steps (2016), and Battery Level (34%). The main area on the right contains instructions: 'To download Step Data recorded on the StepWatch, tap the button below.' and a warning: 'Your StepWatch is not fully charged. It is recommended that you charge it before placing it in storage.' Below this is a dialog box titled 'Upload Successful' with the text: 'Upload was successfully. Would you like to continue recording, clear data, or clear data and put the StepWatch in storage mode?' and three buttons: 'Clear and Store', 'Clear', and 'Continue Recording'. A large digital display shows '01 hrs 58 mins'. At the bottom, a teal bar contains the text 'Upload Step Data'.

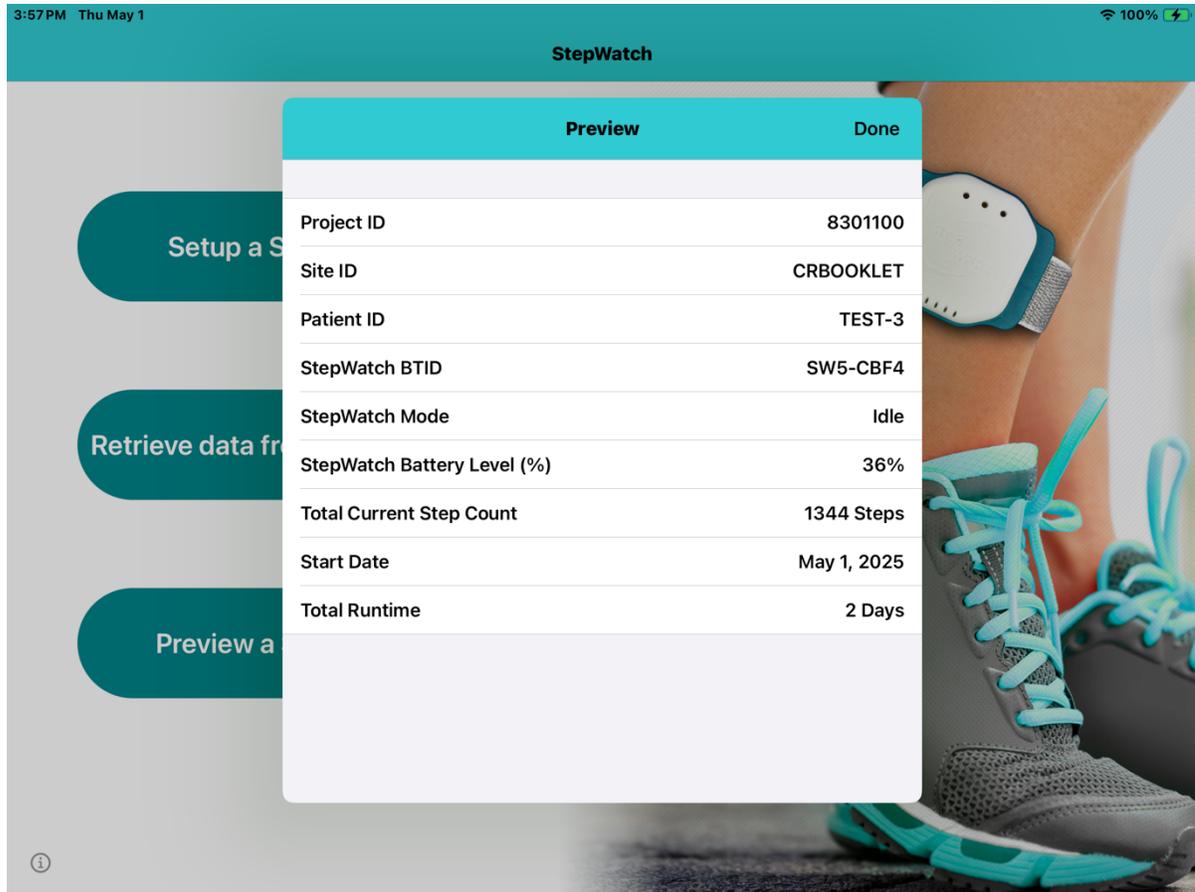
Date	May 1, 2025
Study ID	8301100
Site ID	CRBOOKLET
StepWatch ID	SW5-CBF4
Participant ID	TEST-3
Total Steps	2016
Battery Level	34%

## Preview a StepWatch

“**Preview a StepWatch**” feature, accessible from the Main Screen, allows you to check the current status of a StepWatch device. This function is helpful for confirming the following details:

- **Participant ID**
- Whether the StepWatch is **Recording** or **Idle** (not recording)
- **Battery level**
- **Total steps recorded** since last upload
- **Start date of recording** since last upload
- **Number of days the StepWatch has recorded** since last upload

If the device is Recording, it will continue recording steps even after tapping **Done** to exit Preview.



# Managing a StepWatch

## Charging StepWatch

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

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

- A solid light on the charger means StepWatch is charging.
- A flashing light is a charging error. If you get a charging error, remove StepWatch from the charger, check the connections, and place StepWatch back in the center of the charger.

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

**DON'T:** Do not place StepWatch face up or on the edge of the charging pad.



## **Battery Life and Charging Indicators**

A fully charged StepWatch battery usually lasts two weeks.

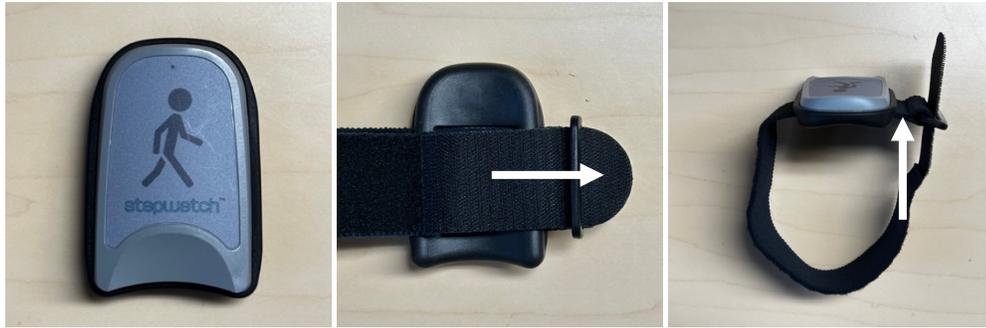
When charging, observe the indicator light on the charger:

- A **flashing light** indicates a **charging error**.
  - Remove the StepWatch,
  - Check the alignment and connections,
- Then reposition the StepWatch properly on the charger.
- The light will turn off once the StepWatch is fully charged. Sometimes a charging error will trigger when StepWatch is fully charged.

## Assembling the Strap

Pull the strap through the slots on the back of the device as shown. Pull the strap through the plastic ring and secure using the Velcro tip

StepWatch 4



StepWatch 5



For StepWatch 5 without a buckle, fasten the Velcro side directly to the smooth side.



## Wearing StepWatch

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

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



**Note:** StepWatch 5 can be worn with the logo right side up or upside down.

### **Incorrect Wearing**

StepWatch cannot be worn on the front or back of the leg.



StepWatch cannot be worn on the arm or any other body part.



StepWatch 5 can be worn upside down.



StepWatch 4 cannot be worn upside down. This will result in incorrect or missing data.



### Cleaning StepWatch

You can clean a StepWatch by rubbing gently with a wet cloth or disinfectant wipe such as 70% isopropyl alcohol.

**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.

## LED Indicators

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 2<sup>nd</sup> 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

PN:40517  
FCC:XPYNINAB1  
IC:8595A-NINAB1  
MFG:2023FEB01

**SW5-ABCD**

(01)00860007307515(21)53100001

 **StepWatch 4:** Read instruction manual for important warnings before operating StepWatch. See "Regulatory Information" for more information.

## Frequently Asked Questions

What happens if I forget my CRO Site app PIN?

*You will need to re-install the app. For help with this process, see “Setting Up the CRO Site App”. You may also contact the helpdesk.*

What PIN do I use when I first open the app?

*If your app has been preconfigured before being delivered to your Study Site, use the PIN 0000.*

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. Use the provided silicone soft cover, and if desired, place the StepWatch over a sock.*

Can participants switch what leg they wear the StepWatch on?

*Yes, as long as they position it correctly (see “Wearing StepWatch”)*

Can the StepWatch get wet?

*Yes, the StepWatch is waterproof. StepWatch can be used in the shower, bath, or in the rain. Swimming is not recommended. A dry strap is recommended if wet.*

Can I reuse a StepWatch for a different participant?

*Yes, the StepWatch is set up with the information it needs each time it is setup. Therefore, the same StepWatch does not have to be used with the same participant, although you may choose to do it this way.*

Can I reuse a smartphone with the CRO Companion app for a different participant?

*Yes, but you must delete and re-install the app first OR use the site app settings to enable “Companion App Reset” and share the PIN with the phone user. This is one of the safeguards against participants connecting to incorrect StepWatches once the study begins.*

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 Helpdesk.*

The participant’s StepWatch is lost or broken:

*Next time participant comes to clinic, you may use another StepWatch.*

The app crashes or does something unexpected:

*Go to the Main Screen by tapping “Exit” on any app screen or closing and re-opening the app. Access the Info Panel (see “The Info Panel”) and tap “Upload App Diagnostics,” then contact the Helpdesk.*

Unable to reset companion app for a new participant:

*Ensure that Site Settings have “companion app reset” turned on and share the PIN with the companion app user. If this setting was changed AFTER the companion app was set up, you will need to tap “upload app diagnostics” to reload the settings, and then the reset link will appear.*

## 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](https://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](mailto: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](mailto: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.

## 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.

### Software Specifications

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