

**Modus Health LLC**

# StepWatch with CRO Apps Reference Guide for Users



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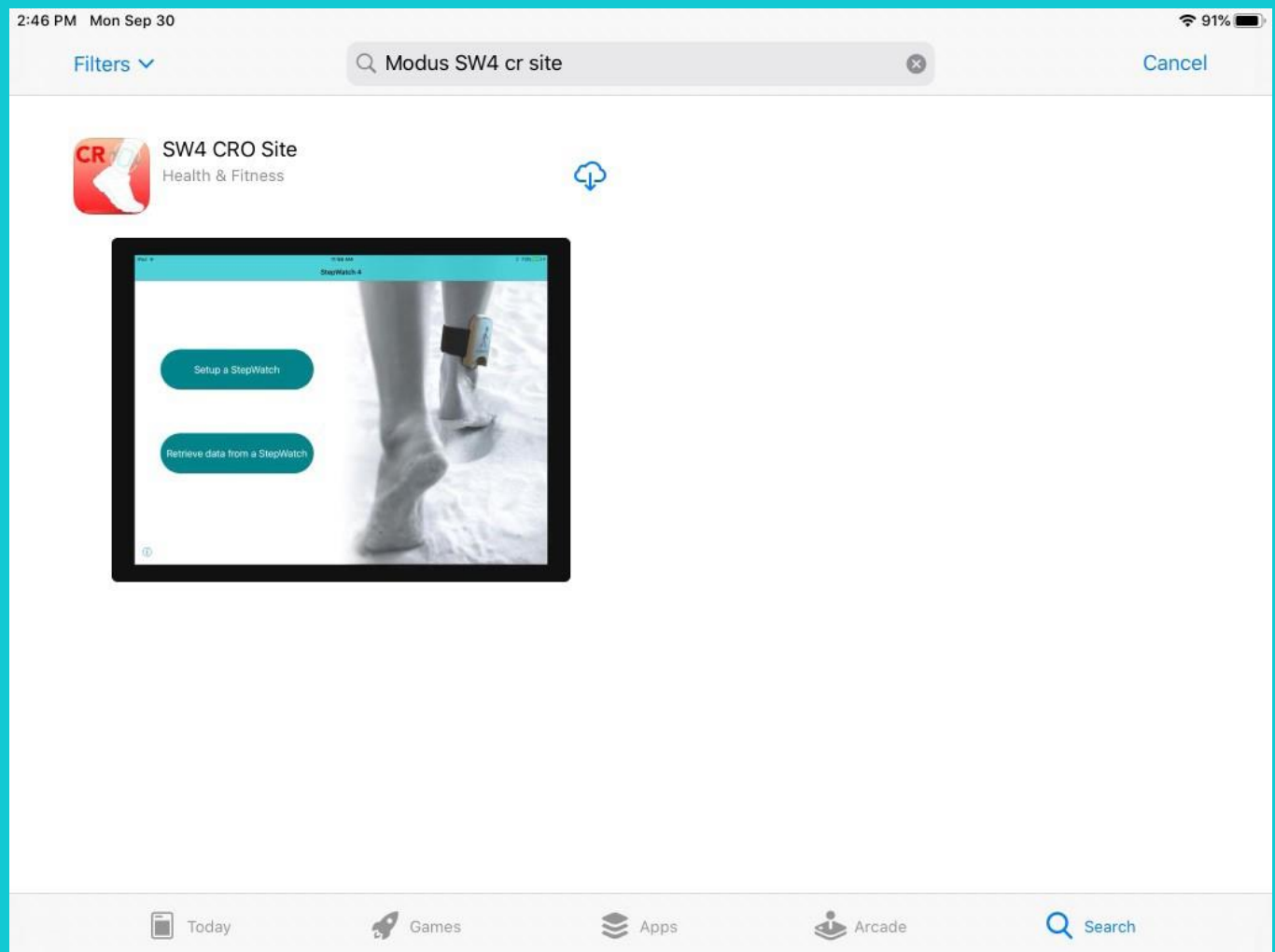
***Regulatory Information*** \_\_\_\_\_ **57**

# Installing and Setting Up the CRO Site App

## Installing the App

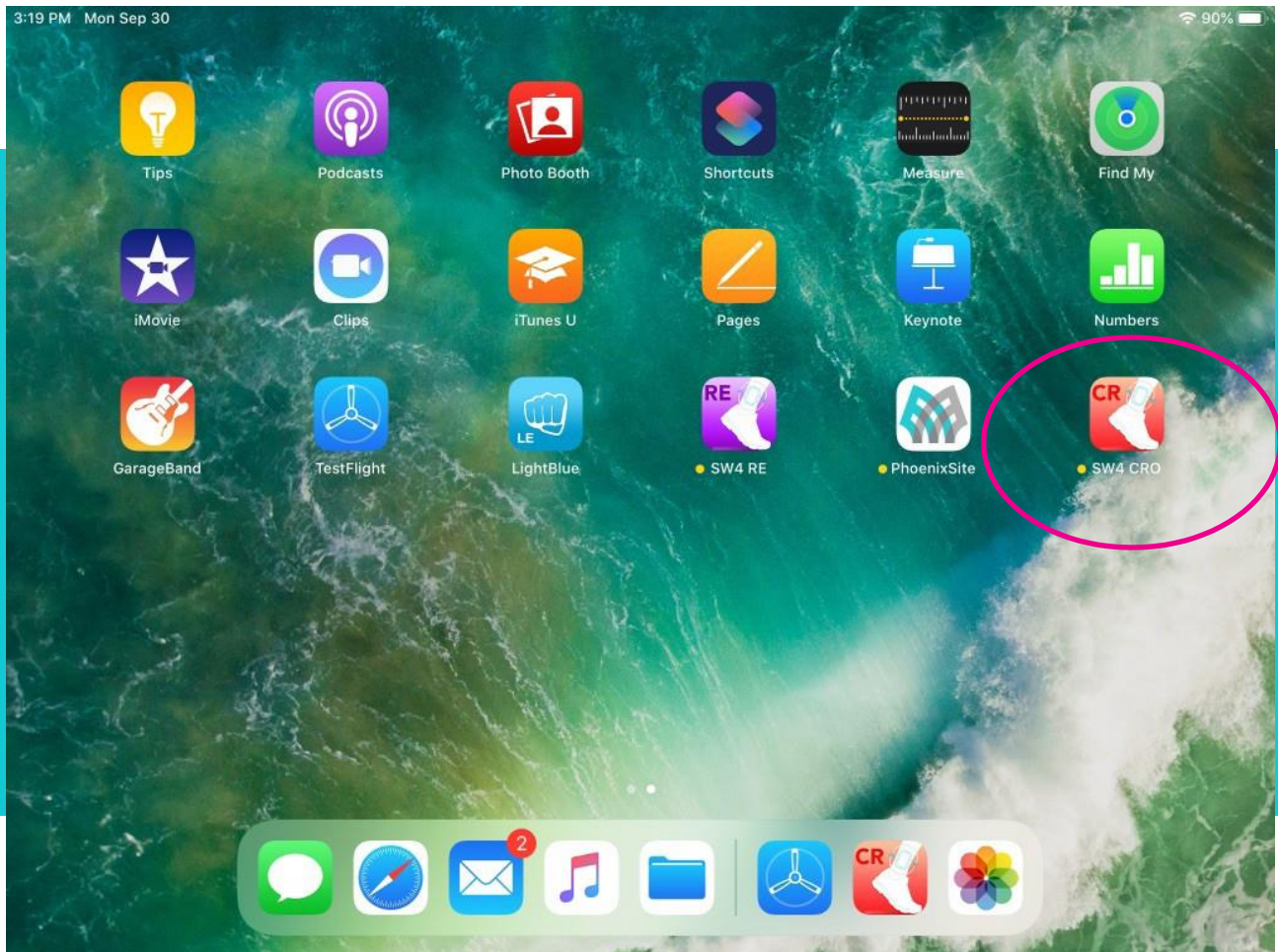
Go to the App store and search for Modus SW4 CR Site. Note that some studies will have Modus Health configure the CRO App on the study's behalf. In this case, you may skip this step.

Next, tap the download icon on the right side of the page.

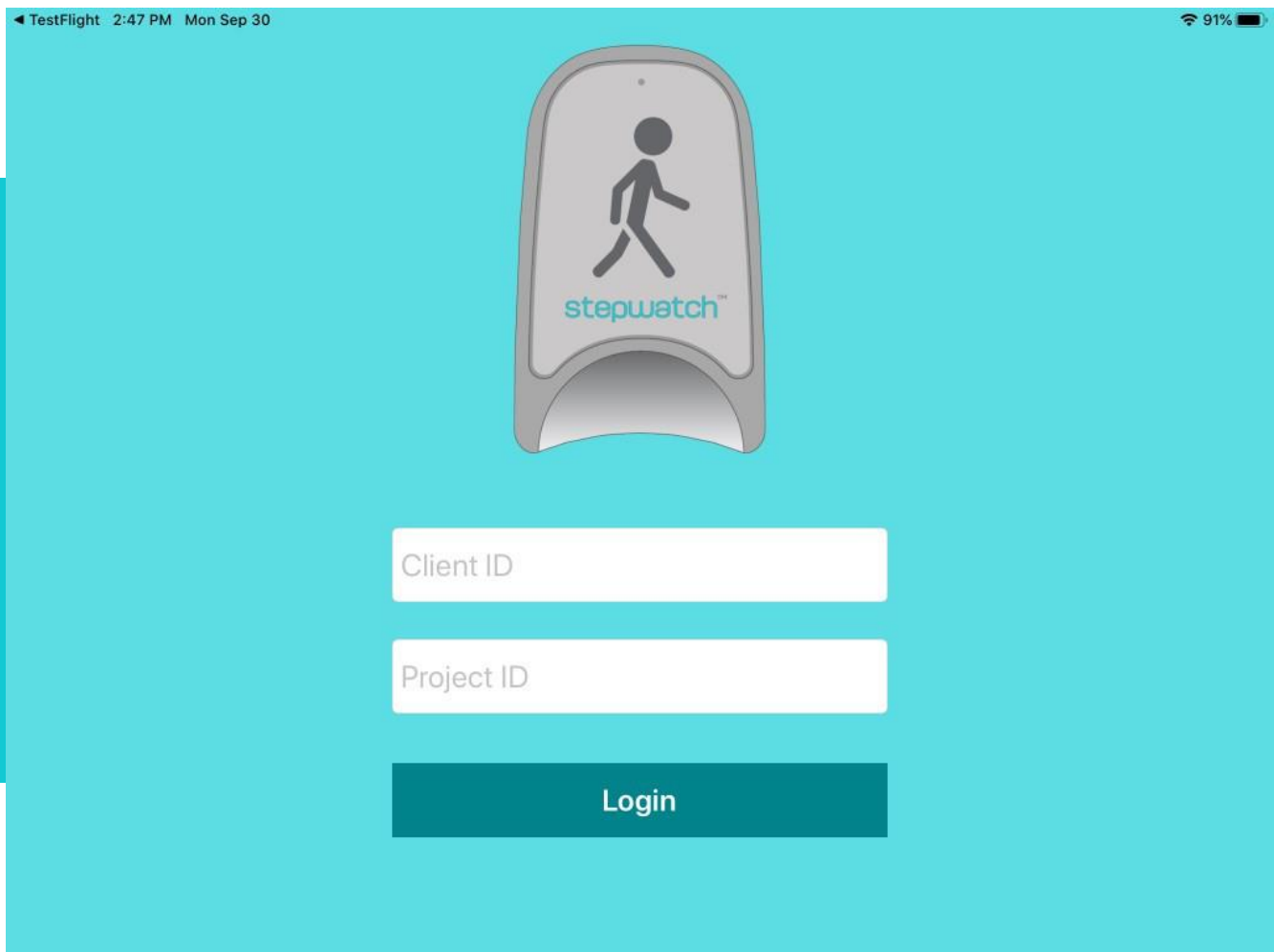


## Initial Setup


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



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, contact the Helpdesk or your Modus Health contact.



TestFlight 2:47 PM Mon Sep 30 91%



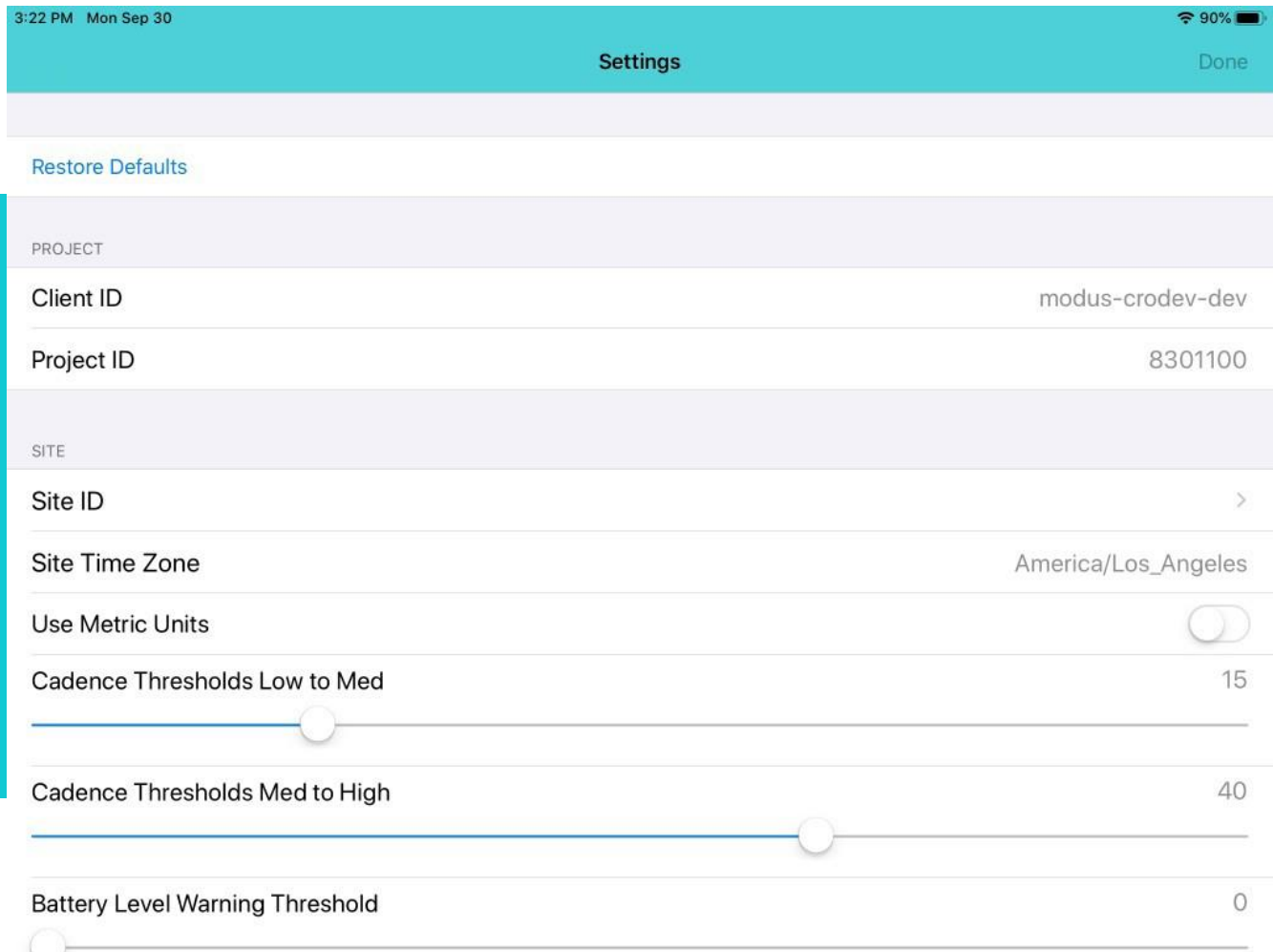
Client ID

Project ID

Login

## Site Settings

After entering a valid Customer and Project ID, the app will take you to the settings screen. The settings are meant to be entered once before the start of the study. These settings define how the app will function for your study.



3:22 PM Mon Sep 30 90%

Settings Done

Restore Defaults

PROJECT

Client ID modus-crodev-dev

Project ID 8301100

SITE

Site ID >

Site Time Zone America/Los\_Angeles

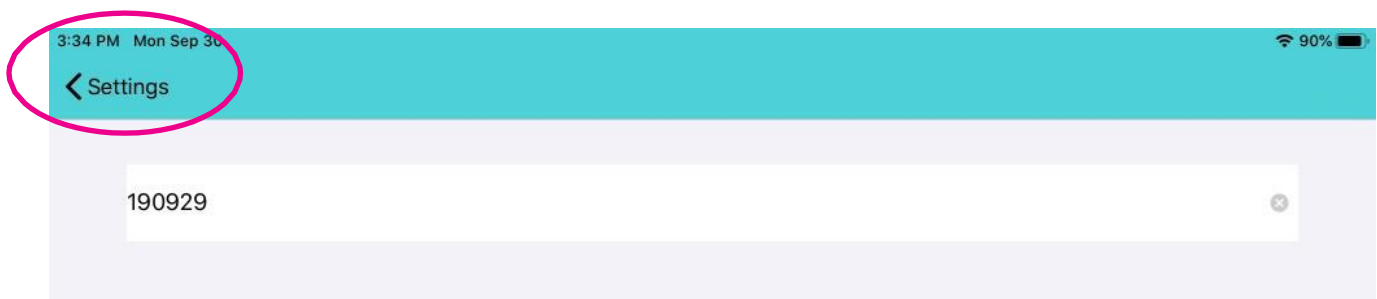
Use Metric Units ☐

Cadence Thresholds Low to Med 15

Cadence Thresholds Med to High 40

Battery Level Warning Threshold 0

To configure settings for your site, select a name or code to represent your Site ID. After entering the Site ID, tap Settings in the top left-hand corner. Your entry will be saved.



3:34 PM Mon Sep 30 90%

< Settings

190929

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 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.

Once you have entered a Site ID, you choose how you want the app to function for your study.

### Site Time Zone

App automatically picks the time zone connected to the iPad. If you want the app to use a different time zone, Modus Health or a team member with administrative privileges can change the time zone of your site in the cloud.

### Use Metric Units

When 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 activity (default  $\leq 14$  strides/minute) or a medium intensity activity (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 a medium intensity activity (default  $> 15$  strides/minute and  $\leq 40$  strides/minute) or a high intensity activity (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.

3:35 PM Mon Sep 30 89%

Settings Done

Site Time Zone America/Denver

Use Metric Units ☒

Cadence Thresholds Low to Med 15

Cadence Thresholds Med to High 40

Battery Level Warning Threshold 80

Enable Stride Length Assessment ☒

Enable PIN Lock ☒

Population Controls >

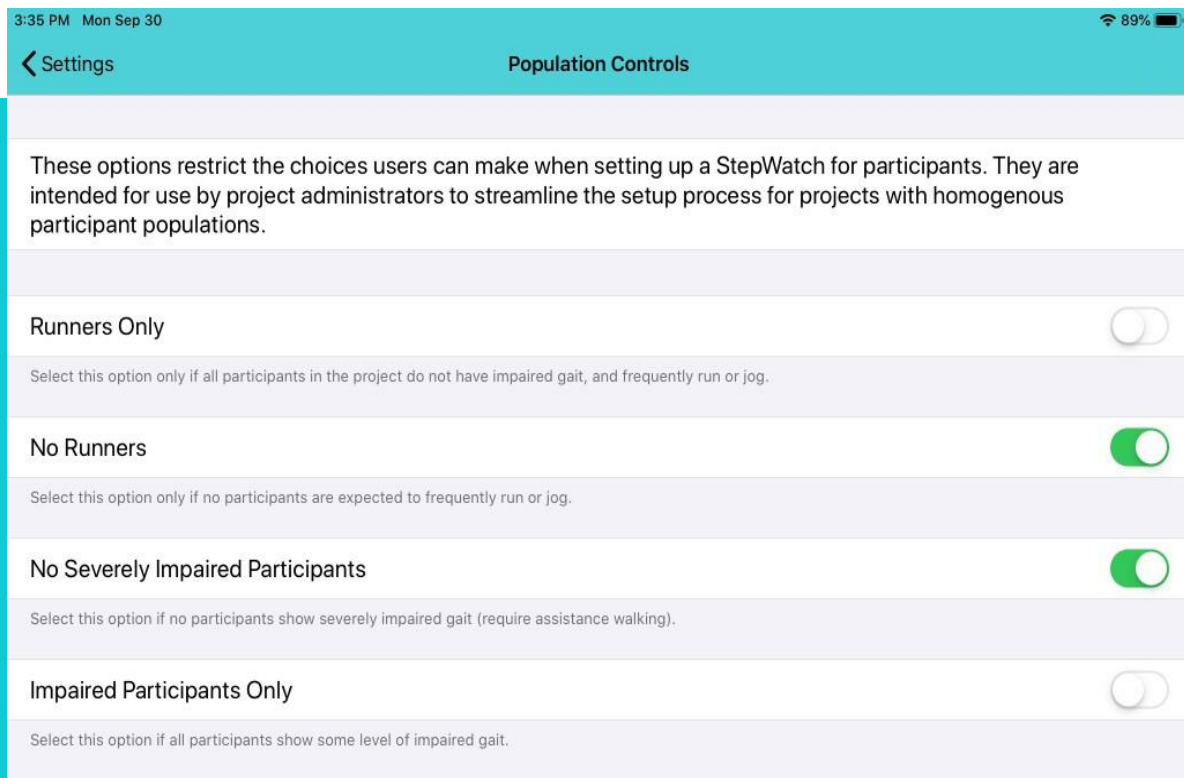
Companion App On >

Reset App



## Population Controls

This allows you to limit the StepWatch setup choices to only the choices you will need to use at your site. For example, if none of your participants require the jogging/running setting, you can use population controls to lock it in the “no” position. This prevents an incorrect choice from being selected 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.

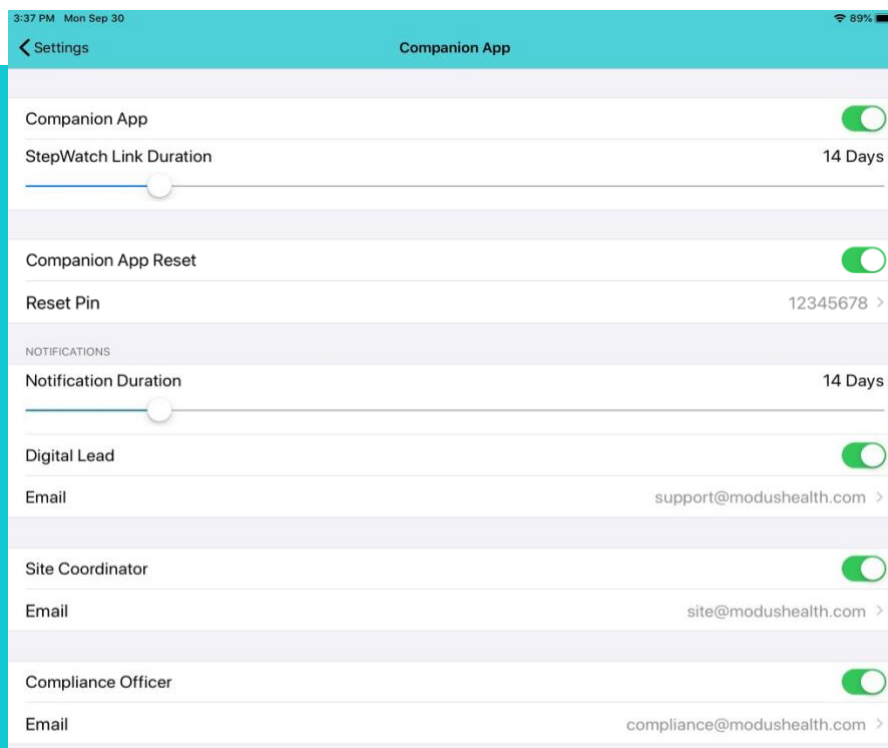
**Notification Duration** – how many days you want to receive notifications regarding upload status, data compliance, and StepWatch battery warnings while the StepWatch is linked to the smartphone. Usually, StepWatch Link Duration and Notification Duration will be for the same number of days.

**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.

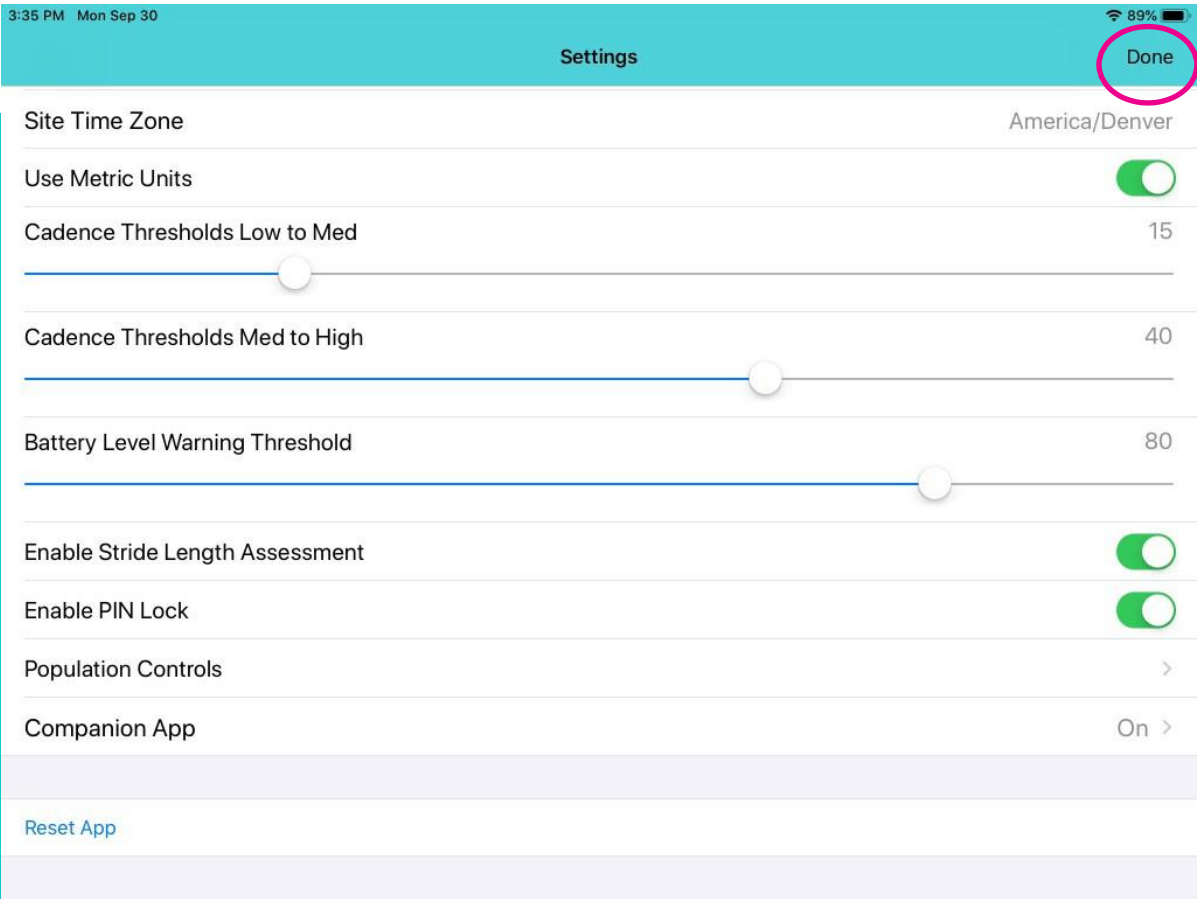
**Digital Lead** – receives email notifications regarding upload status, compliance warnings, and battery warnings. Generally, the Digital Lead is responsible for all sites, and will get these notifications for all participants.

**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.



After completing the setup process in settings, tap “done” if new site or “update” if existing site. If updating a site, all iPads with the same Site ID will be updated to the new settings.

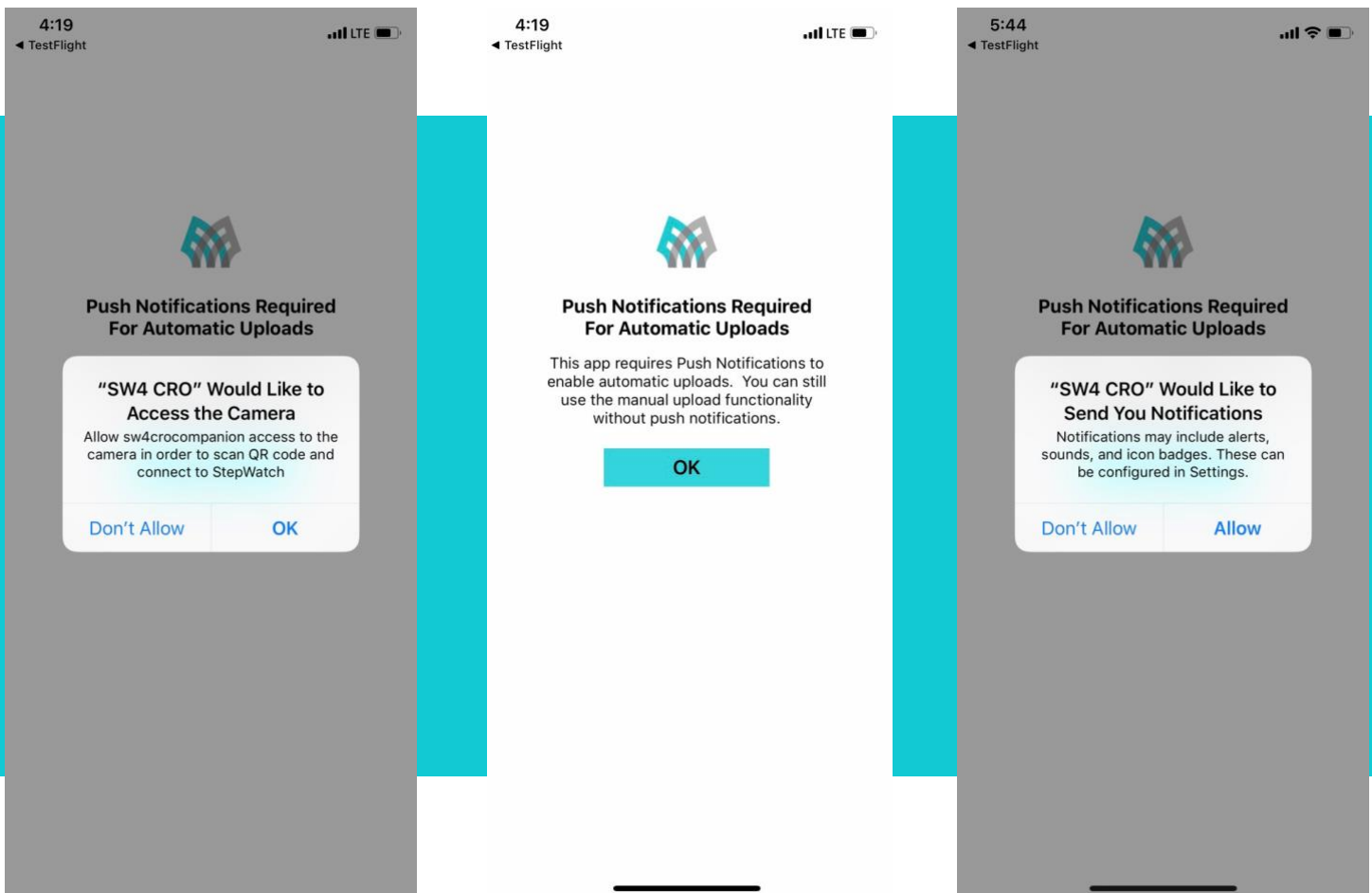


# Installing CRO Companion App

If using the CRO Companion App for remote uploads and do not have the app installed on a smartphone, search the App store for SW4 CRO Companion and download the app.

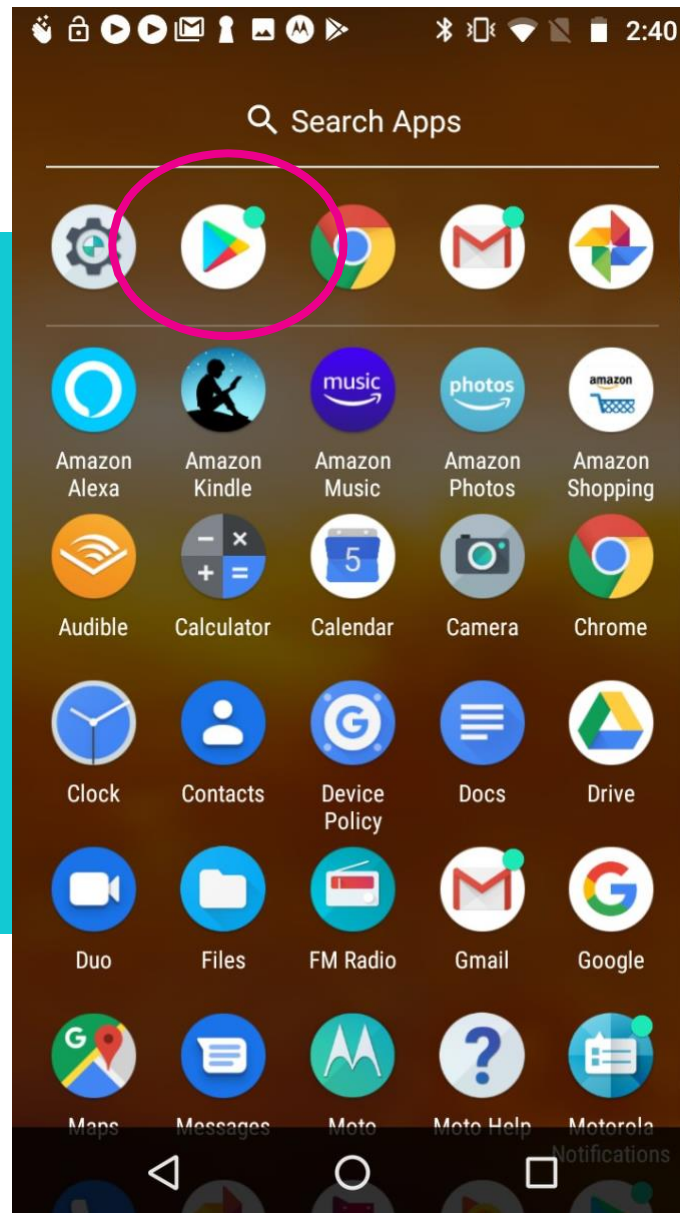
## iPhone

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”.

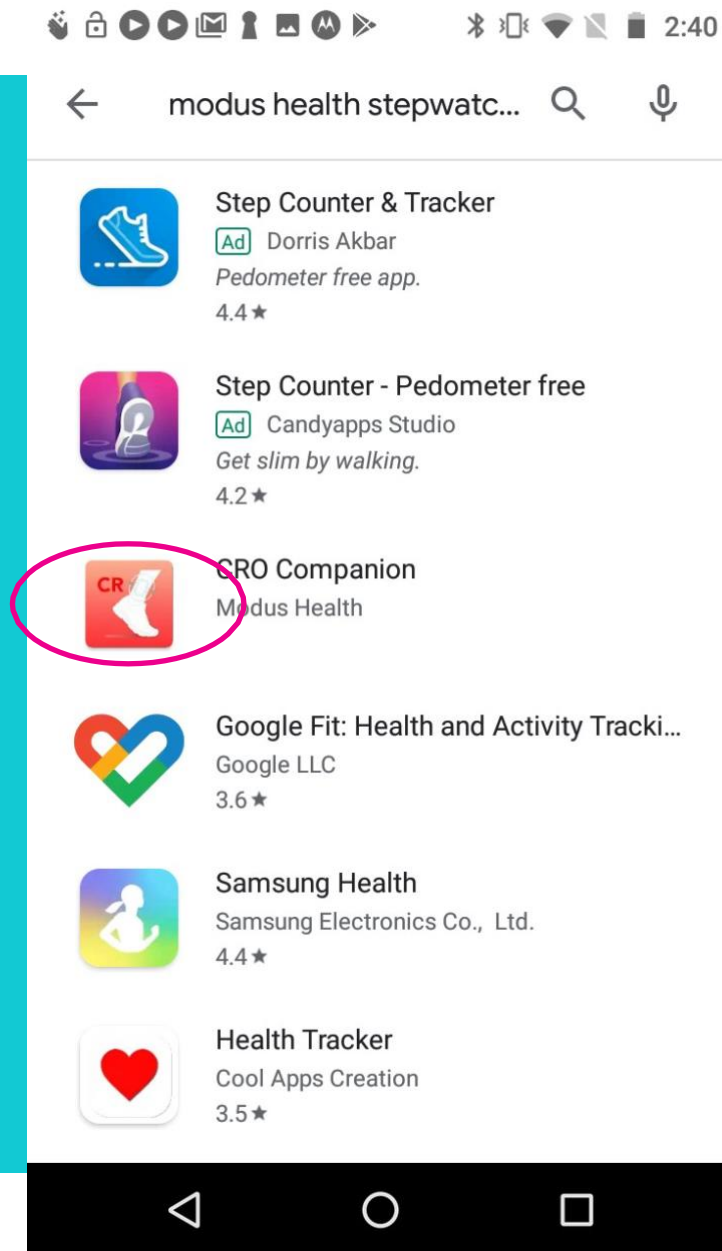


## Android

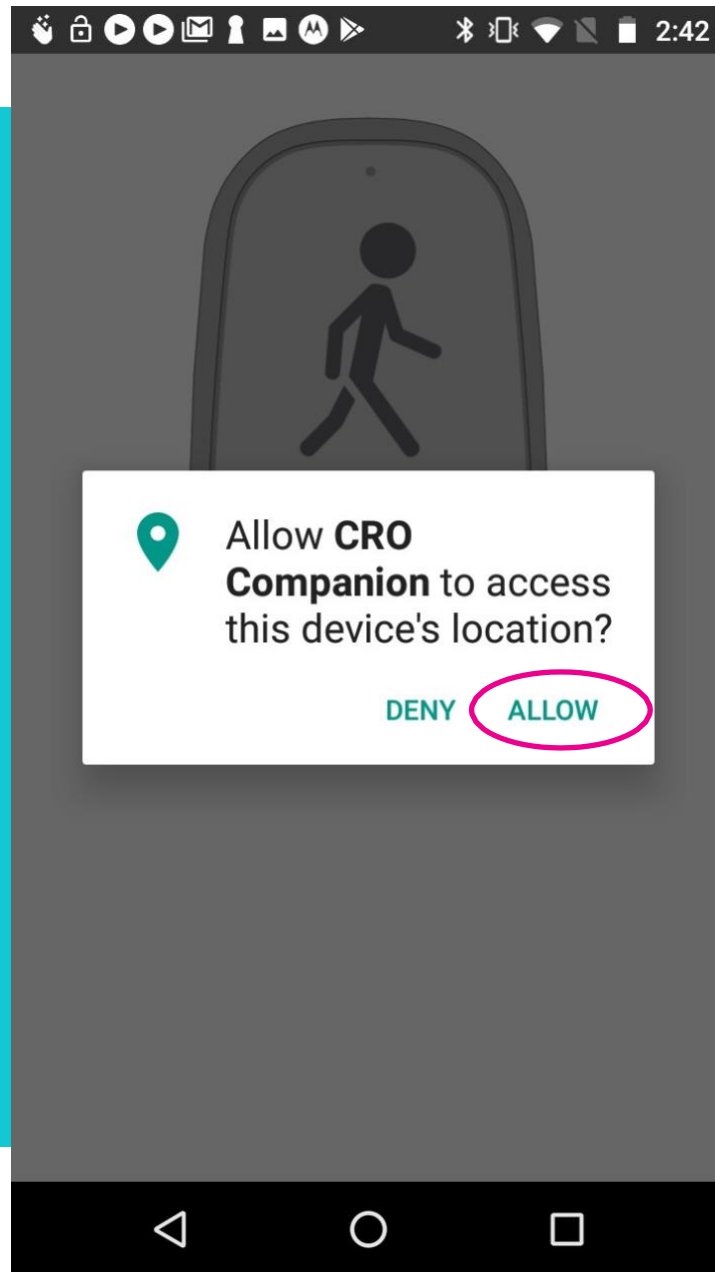
To download the CRO Companion app for Android smartphones, go to the app store.



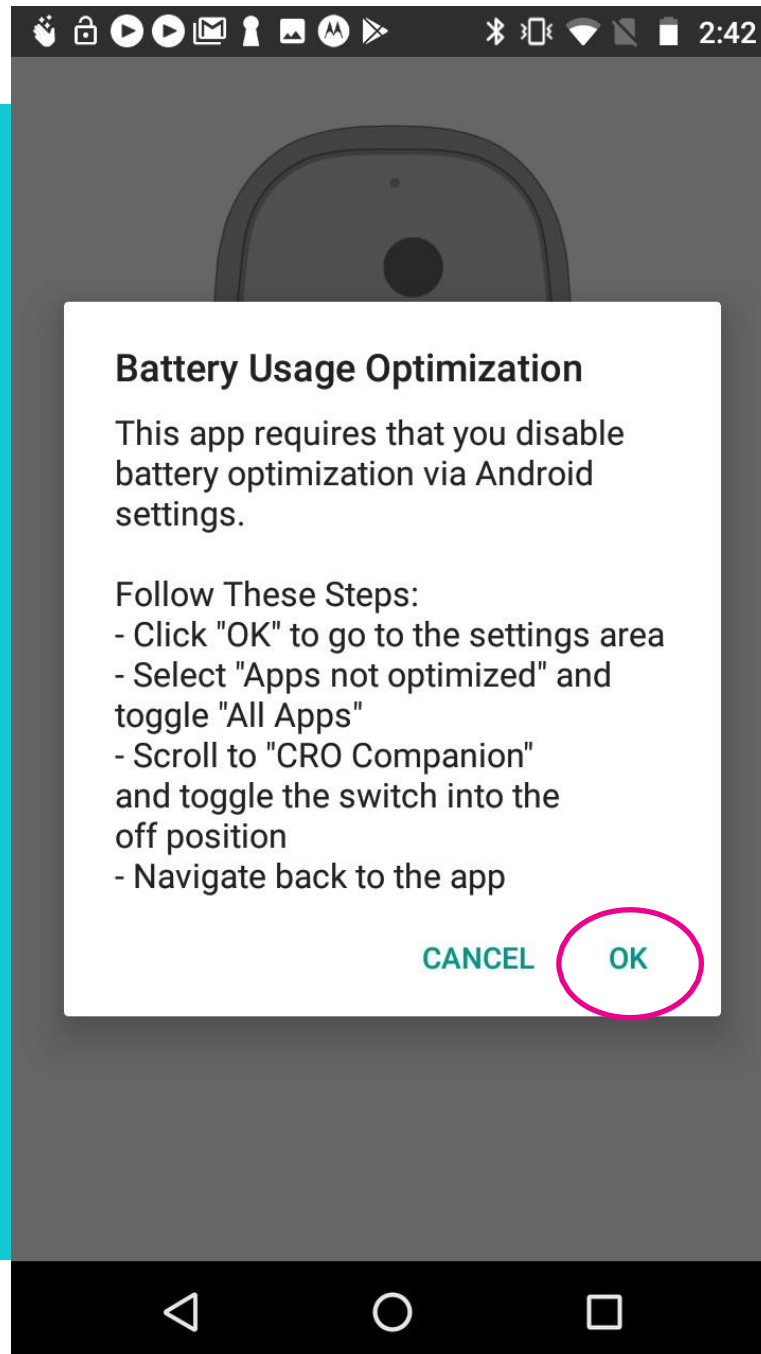
Search for “Modus Health StepWatch CRO”, tap on the CRO Companion app and install it.



When you open the app, it will ask for access to this device's location. Select "Allow."

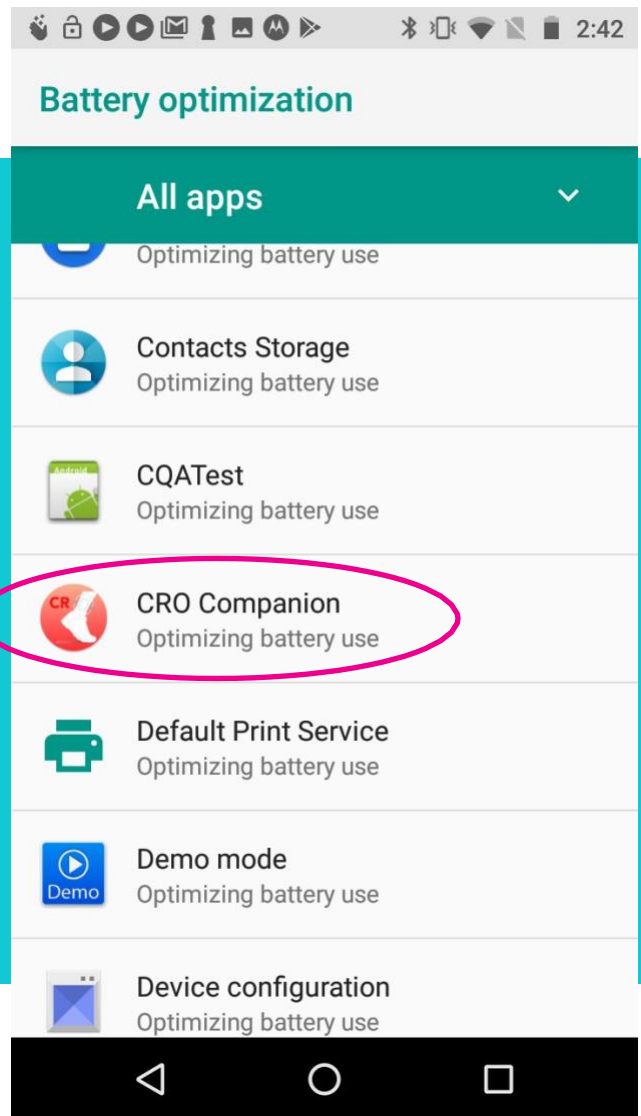
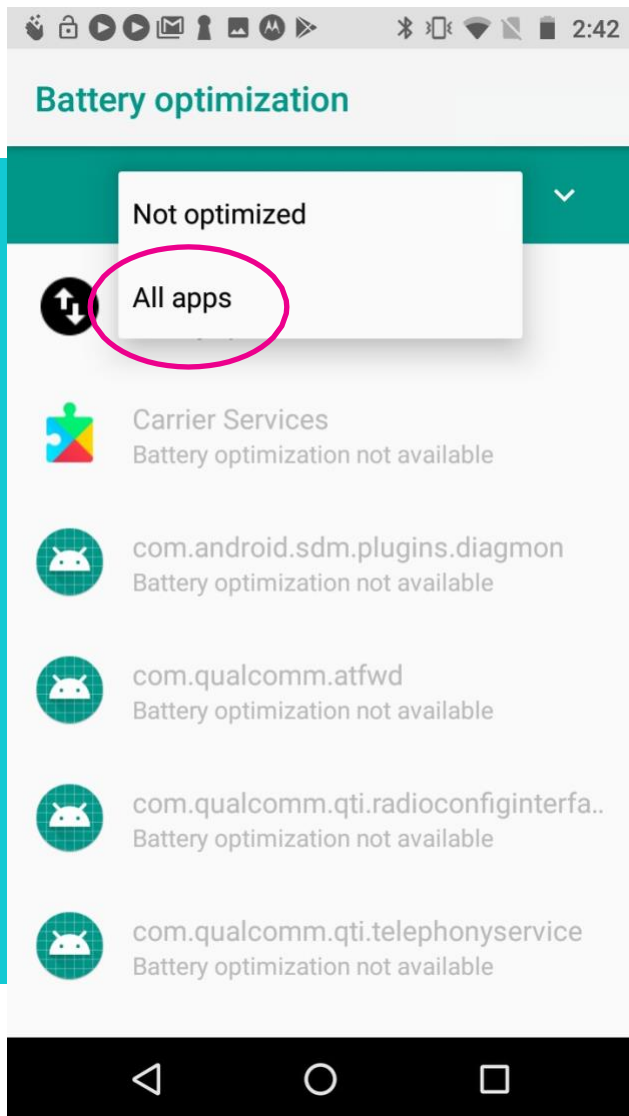


Next, tap "Ok" to battery usage optimization

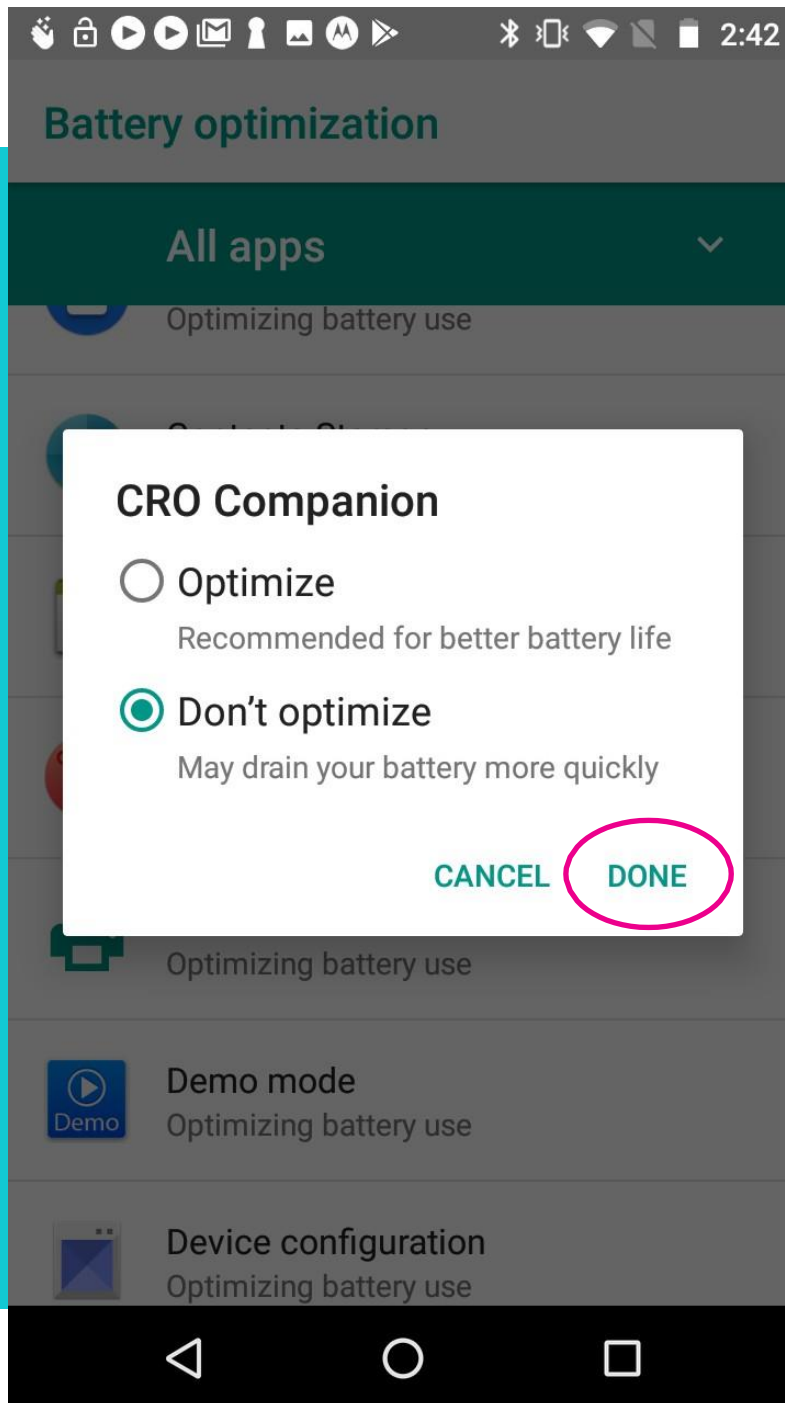




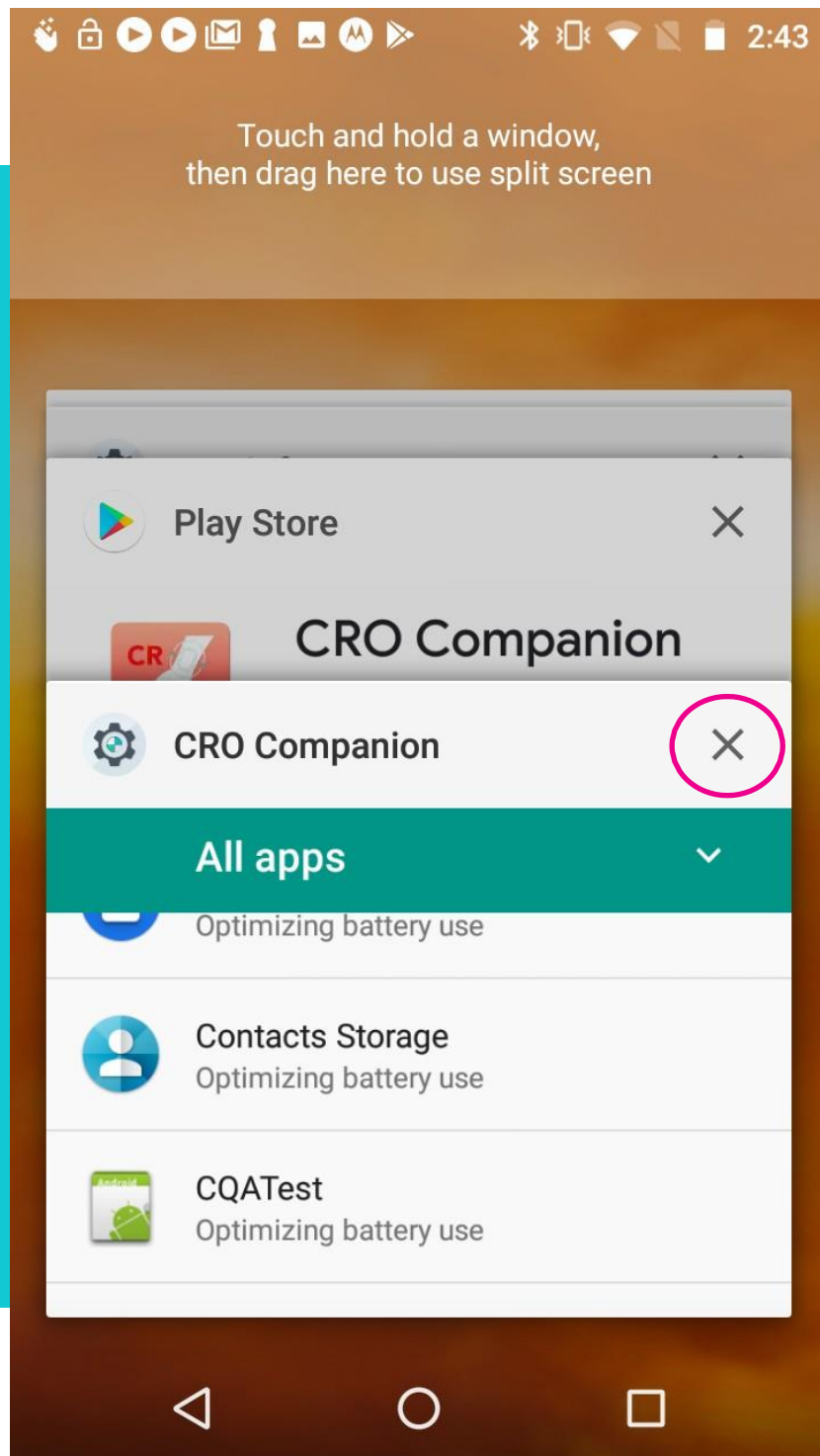
Under Battery optimization, use the pull-down menu to select “All apps”. Search for the CRO Companion app.



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.



Tap the “X” in the top right corner to close the Battery optimization settings and return to the CRO Companion app. The CRO Companion app is now ready to connect to a StepWatch that has been setup.



# Preparing StepWatch for a Participant Visit

1. Attach the soft cover to the StepWatch.



2. Take a strap and thread it through the StepWatch with the Velcro side facing up during threading.



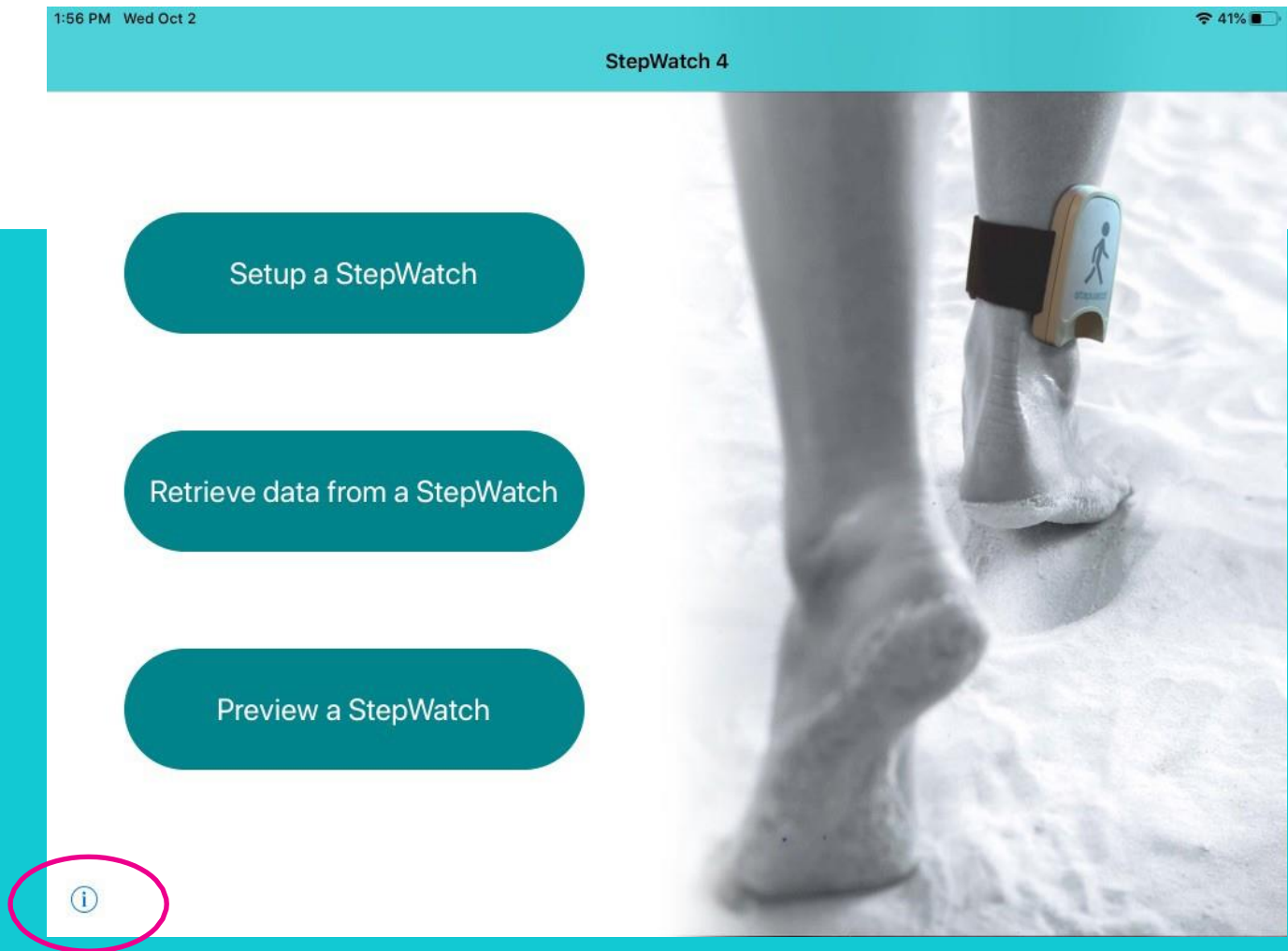
3. Practice applying the StepWatch above your ankle so that it is snug enough to not slip down but loose enough that it remains comfortable.



The StepWatch can be worn over a sock, but it needs to be on the outside of the leg and facing upright. It can be worn on either leg. See “Managing a StepWatch at Home” for additional instructions on wearing the StepWatch.

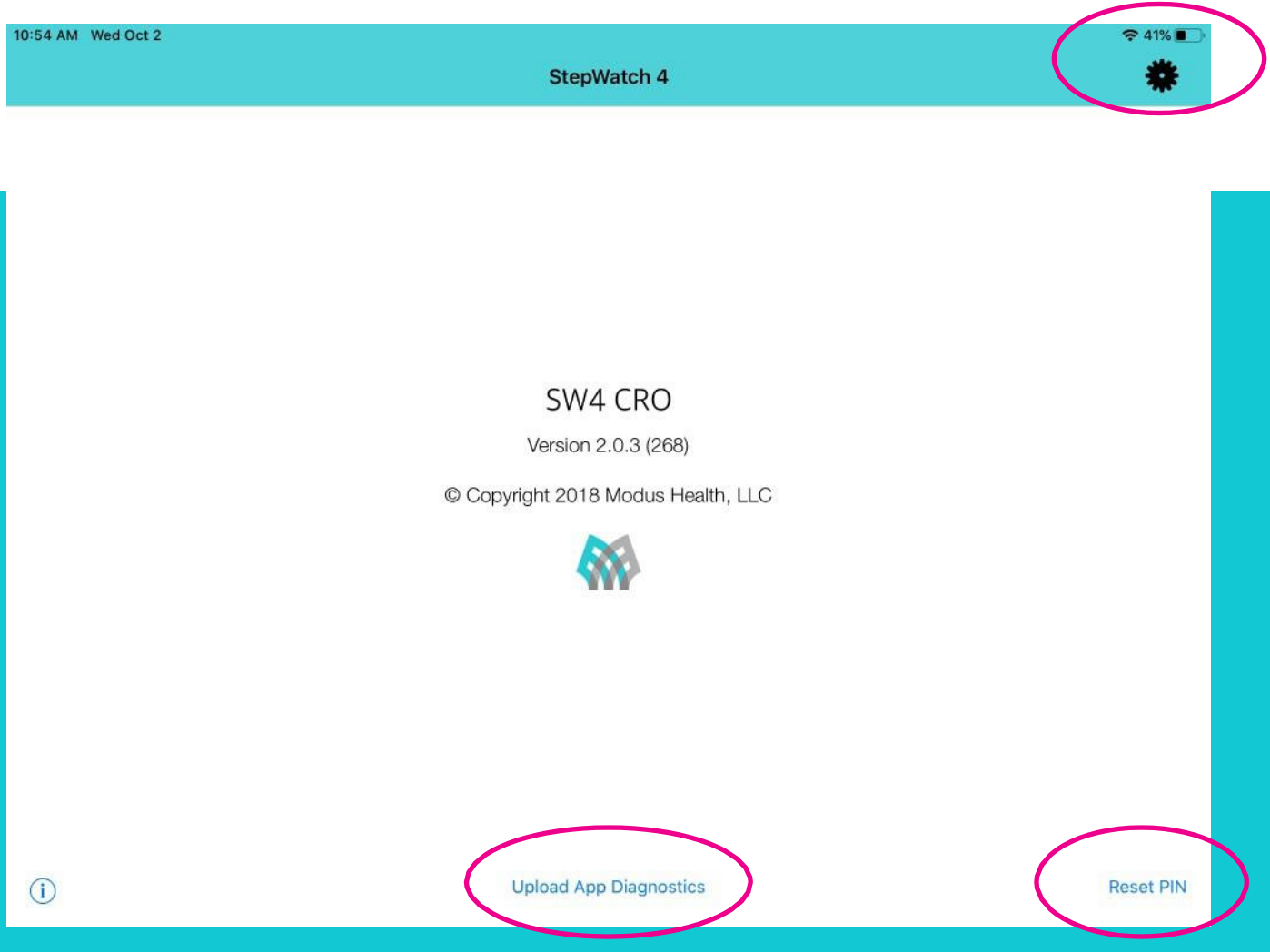
## The Info Panel

You can access the Info Panel at any time from the Main Screen of the CRO App, by tapping the Info icon. This is where you access the app version number and useful features for device administration and troubleshooting.



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

When tapping the gear in the top right corner, you are taken to the site settings screen for setting up the Site ID and the characteristics of the study for the site. In some studies, Modus Health will setup the site settings prior to the delivery of the iPads.



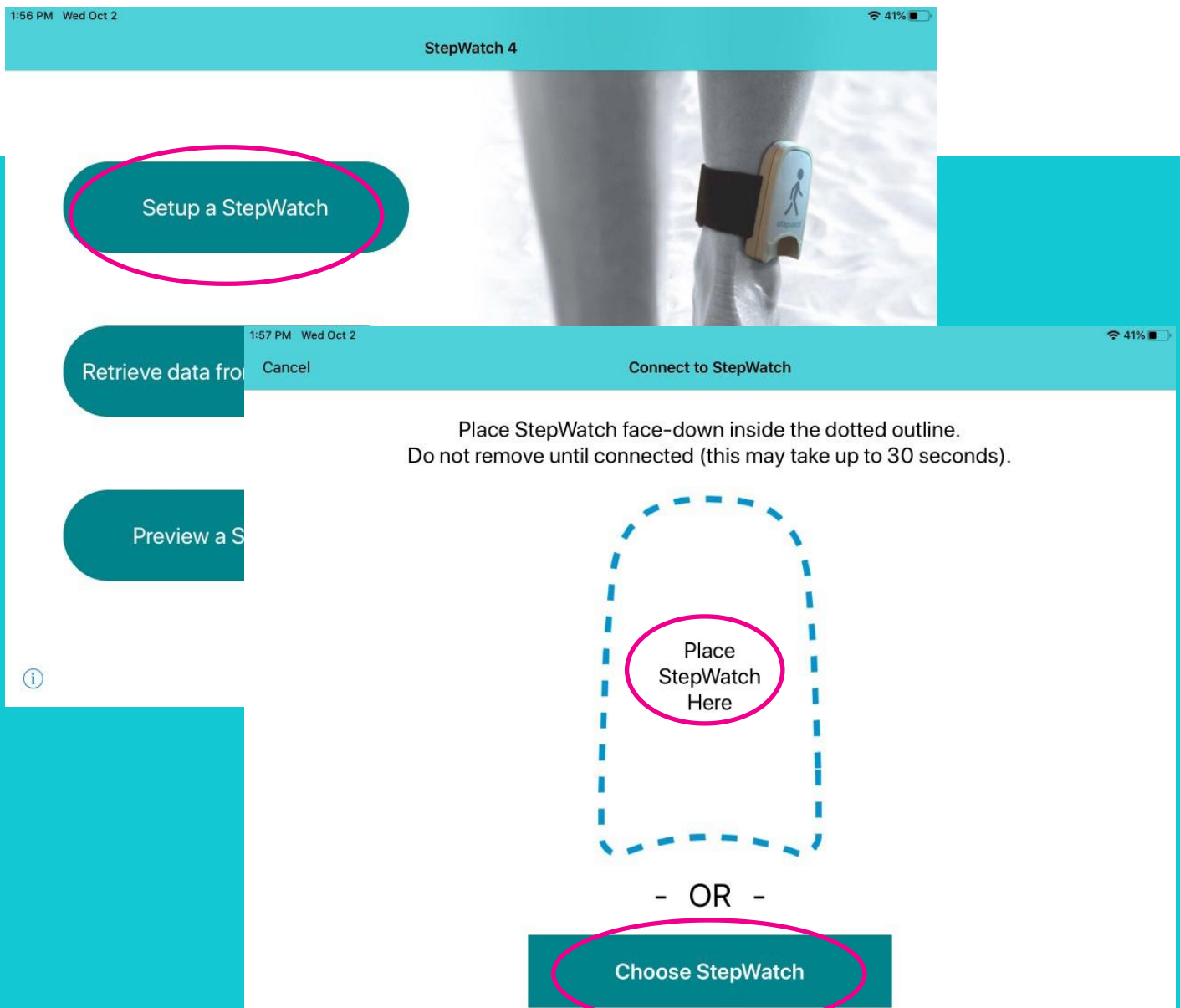
### Important Security PIN Information

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

When using the StepWatch 4 CRO app, ensure that your mobile device is connected to a strong WiFi signal, or has at least 3 bars of cellular service. Internet connection is required for the app to register participants and upload data.


Launch the app and tap the “Setup a StepWatch” button, then either place the StepWatch on the outline for proximity connection OR tap “Choose StepWatch” and tap of the StepWatch Bluetooth ID displayed on the StepWatch label, located on the back of the StepWatch.




Tap “New Participant” if it is the first time this participant will be enrolled in the study, or “Returning Participant” if the participant was previously enrolled at this site. When using “Returning Participant,” you will be asked if you would like to use the previous settings if data was uploaded for that participant. You would only use previous settings if the participant is not in the clinic to participate in the setup procedure. See the “Return Participant Previous Settings” for more details.


1:58 PM Wed Oct 2
41%

Exit
StepWatch 4
Enrollment



Date	Oct 2, 2019
Study Number	8301100
Site ID	190929
StepWatch ID	SW4-8389
Battery Level	100%


New Participant


Returning Participant



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


4:30 PM Wed Oct 2

41%

Exit

StepWatch 4

Enrollment



Date

Oct 2, 2019

Study Number

8301100

Site ID

190929

StepWatch ID

SW4-8389

Battery Level

100%

ENTER SUBJECT INFO


Participant ID

Re-enter Participant ID

Next

On the Programming Screen, enter the participant's height, and characterize their walking behavior (this helps the app to pre-calibrate the StepWatch's step detection settings), then tap Next.

16:26 Wed Oct 2
Exit
StepWatch 4
Program StepWatch
96%



Date
Oct 2, 2019
Study Number
8301100
Site ID
190929
StepWatch ID
SW4-8389
Battery Level
100%
Subject ID
10031005

Please enter the participant's height.
150cm

Does the participant frequently run or jog?
Yes
No

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

Next

Before proceeding, attach a StepWatch to participant's leg by following the directions included in the Site Coordinator Guide Sheet (or "Managing a StepWatch at Home").

1. First, be sure to place the soft cover securely on the back of the StepWatch. It should fit snugly without forcing.
2. Insert the gray or black Velcro strap through the back of the StepWatch, with the Velcro side facing up as the StepWatch is face up.
3. Place the StepWatch on the participant and pull the strap through the plastic ring and secure using the Velcro tip.



4. The StepWatch is placed about 0.5 - 1 inch above the anklebone, facing up (the "StepWatch" name should be readable and the walking figure should be right-side-up).
- Tighten strap until fit is comfortable but snug enough that it does not slip down.
  - It can be placed over a sock, and on either leg.

## Step Verification & Fine Tuning

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

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41%

Exit

StepWatch 4

< Back

Verify Steps



Date	Oct 2, 2019
Study Number	8301100
Site ID	190929
StepWatch ID	SW4-8389
Battery Level	100%
Subject ID	10031005

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.

5

Stop

Skip

Note: It's okay if the StepWatch detects more or less than 5 steps. The StepWatch will self-adjust if it over or under counted. What is important is that you tap stop in the app after you see the participant take five steps on the leg with the StepWatch. This is usually 10 total steps between the right and left legs.

## Stride Length Screen

On the Stride Length screen, you may obtain a stride length by performing a distance walk test, timed walk test (will need to enter distance), or manually enter stride length. Choose the process appropriate for your study by tapping “By Distance”, “By Time”, or “Enter Stride Length Manually”.

4:15 PM Wed Oct 2

Exit StepWatch 4 < 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.

**By Distance**

**By Time**

**Enter Stride Length Manually**

**Skip**

Date	Oct 2, 2019
Study Number	8301100
Site ID	190929
StepWatch ID	SW4-8389
Battery Level	100%
Subject ID	10031005

If you choose “By Distance”, you will select the distance in meters. You will press start when the participant begins the test, and stop when the participant’s foot crosses the finish line. The StepWatch will count steps during this interval and calculate the stride length.

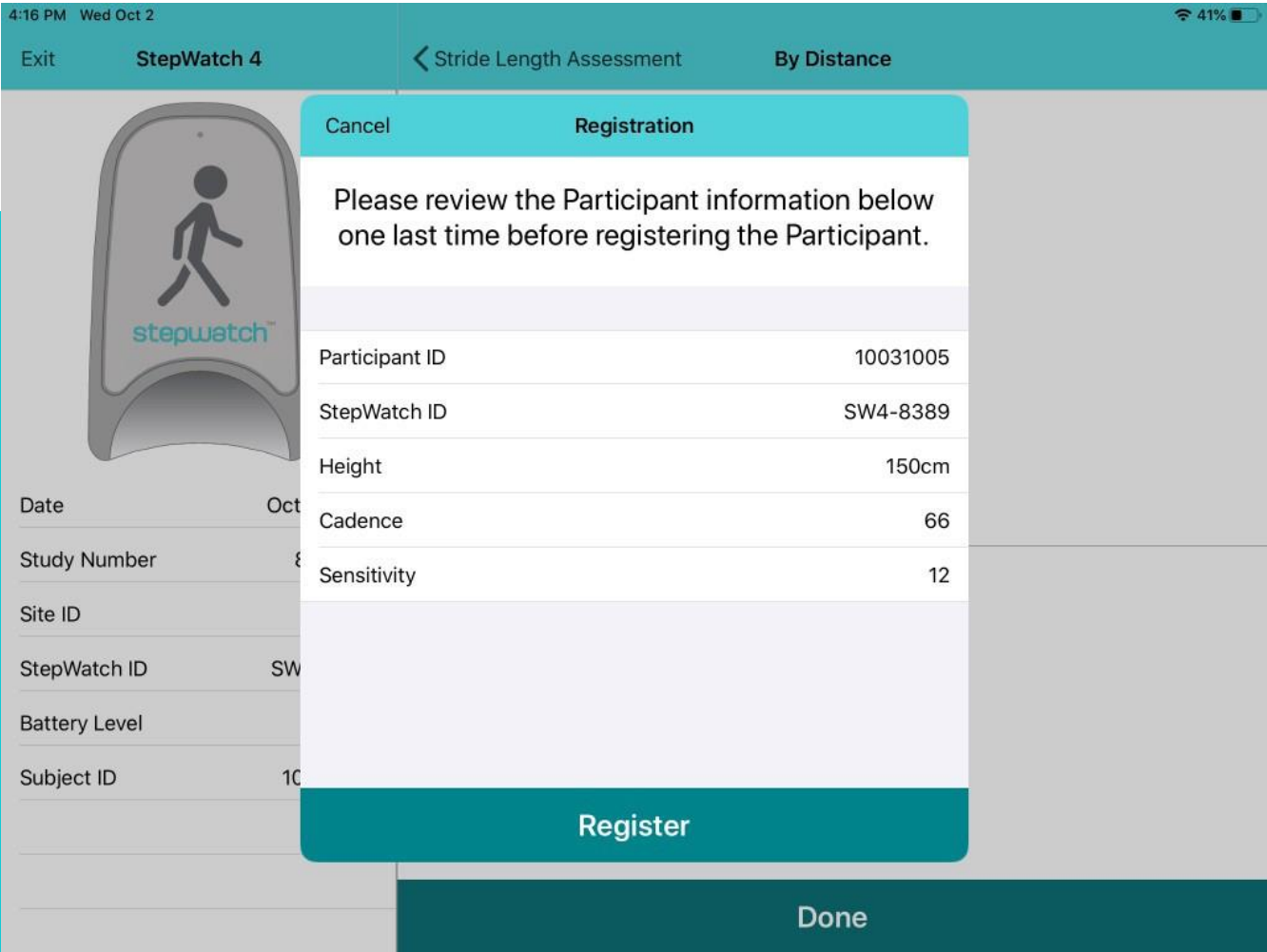
If you choose “By Time”, you will select the timed walk test such as “6 minutes” for the six-minute walk test. The StepWatch will count steps during the selected time interval. At the end, you will be required to enter the distance walked during the test. The StepWatch will then calculate stride length.

If you choose “Enter Stride Length Manually”, you type in the participant’s stride length.

Note: If you do not see a Stride Length Screen, Stride Length was an option not selected when setting up the Site iPad (see Site Settings, under Installing and Setting Up the CRO Site App).

## Final Registration

Verify all the information is correct, and tap the “Register” button to submit the participant’s details to the cloud and register them to the study. If this is a returning participant, the registration screen will say “Update” instead of “Register”.



If you are using the QR Code on the iPad to connect the StepWatch to the iPhone, select “Yes” to “Using QR Connect” on the iPad. If you select “No”, you will use “Choose StepWatch” on the smartphone to select the StepWatch you are connecting to.

5:52 PM Wed Oct 2


32%

Exit

StepWatch 4

Back

Stride Length Assessment



Date

Oct 2, 2019

Study Number

8301100

Site ID

190929

StepWatch ID

SW4-8389

Battery Level

100%

Subject ID

10031005

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?

If the Companion App device is present, select "Yes" to view scannable QR code.

If the Companion App is not present, select "No" to complete registration. Participant will need to connect StepWatch to the Companion App later.

Yes

No



By Time

Enter Stride Length Manually

Skip

Helpdesk Phone: 1-202-830-1100 Ext. 2

31



## iPhone Connection


4:17 PM Wed Oct 2

41%

Exit

StepWatch 4


Transfer StepWatch Info



Date	Oct 2, 2019
Study Number	8301100
Site ID	190929
StepWatch ID	SW4-8389
Battery Level	100%
Subject ID	10031005

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.



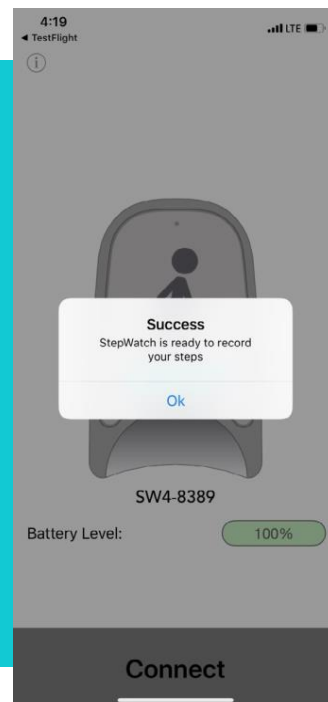
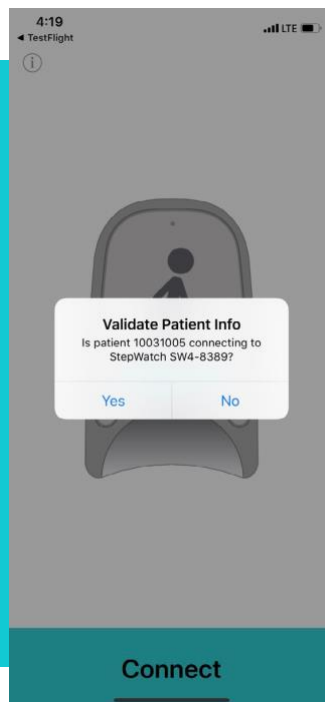
Done



Press the “Connect” button on the iPhone



## QR Connect Pathway



## Connect Without Using QR Code

5:52 PM Wed Oct 2


32%

Exit

StepWatch 4

< Back

Stride Length Assessment



Date	Oct 2, 2019
Study Number	8301100
Site ID	190929
StepWatch ID	SW4-8389
Battery Level	100%
Subject ID	10031005


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?**  
If the Companion App device is present, select "Yes" to view scannable QR code.  
  
If the Companion App is not present, select "No" to complete registration. Participant will need to connect StepWatch to the Companion App later.

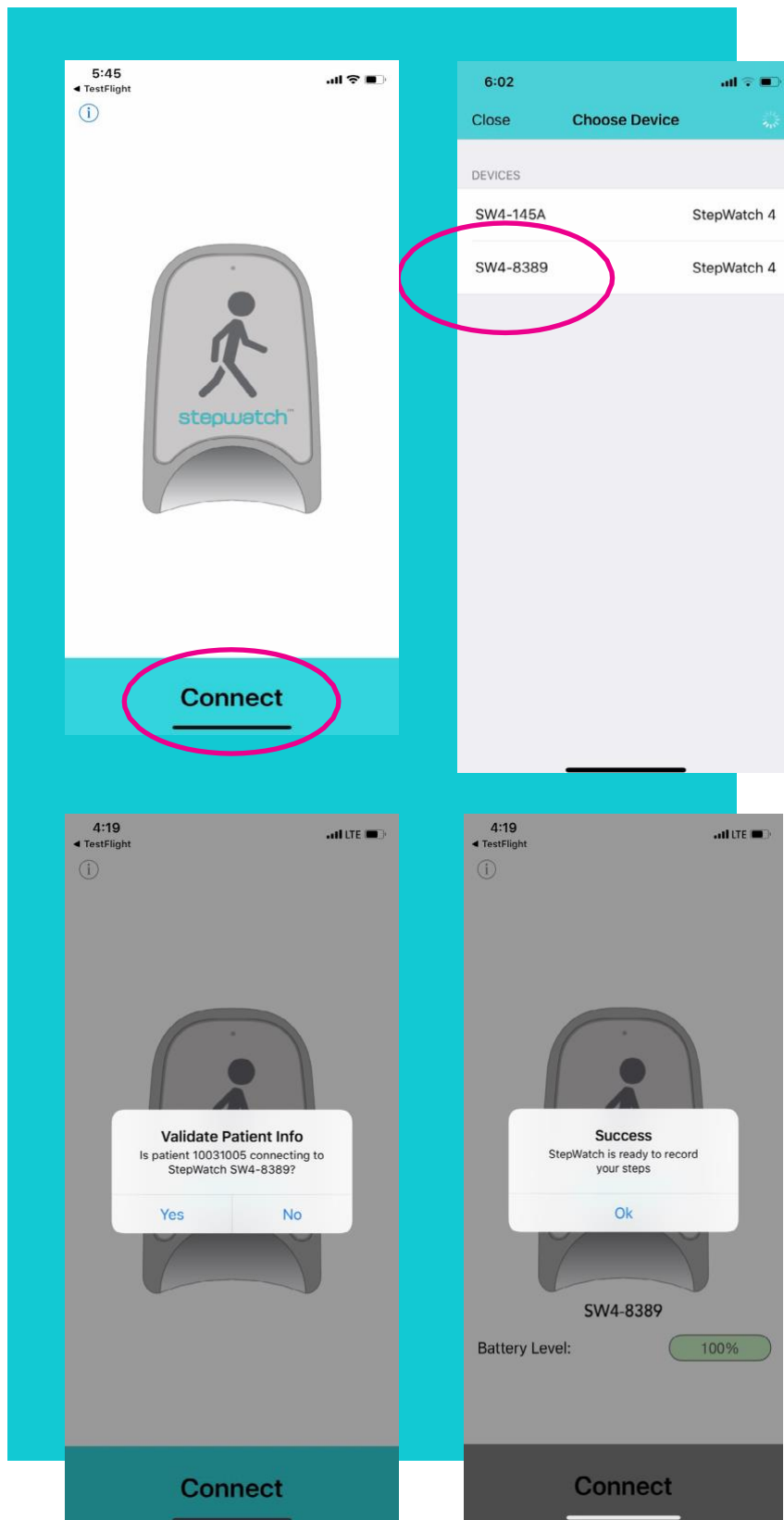
Yes

No

**By Time**

Enter Stride Length Manually

Skip



## Android Connection

To connect the CR app to a StepWatch following setup, select "No" to the question about using the QR code. The CR app for Android does not support the QR Scanner.

5:52 PM Wed Oct 2


32%

Exit

StepWatch 4

Back

Stride Length Assessment



Date	Oct 2, 2019
Study Number	8301100
Site ID	190929
StepWatch ID	SW4-8389
Battery Level	100%
Subject ID	10031005

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?**

If the Companion App device is present, select "Yes" to view scannable QR code.

If the Companion App is not present, select "No" to complete registration. Participant will need to connect StepWatch to the Companion App later.

Yes

No



By Time

Enter Stride Length Manually

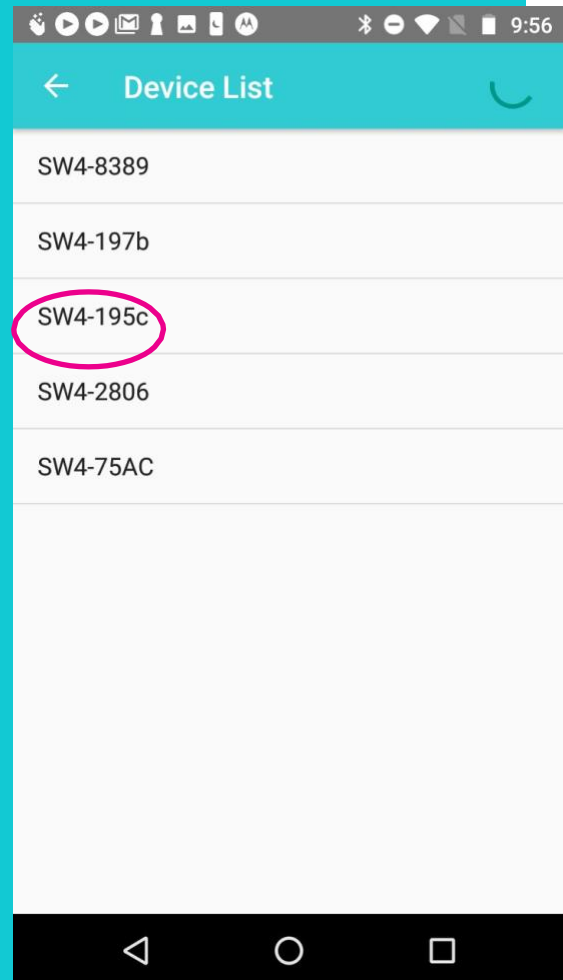
Skip

Helpdesk Phone: 1-202-830-1100 Ext. 2

36

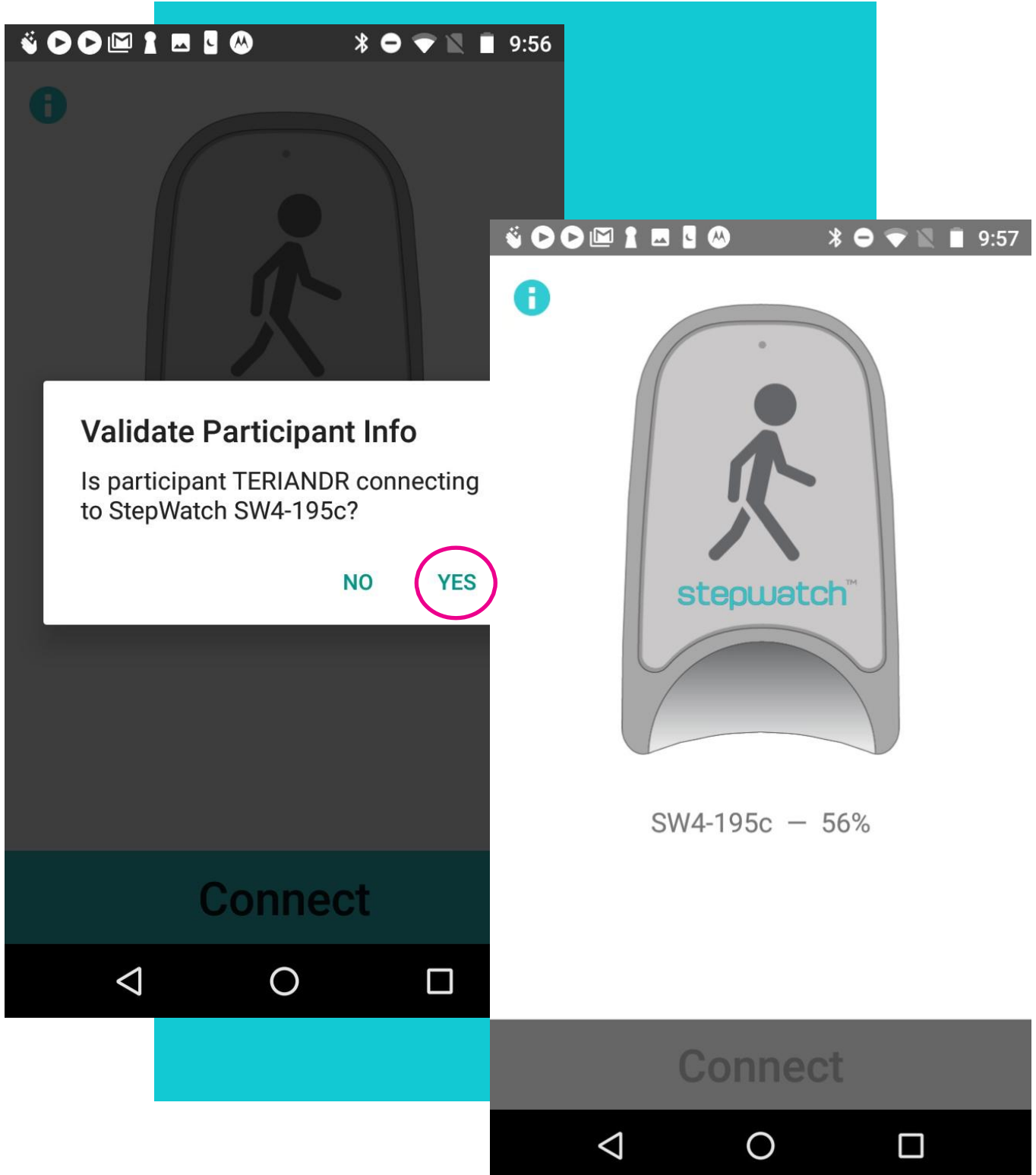
Tap the “Connect” button on the CRO Companion app and choose the Bluetooth ID of the StepWatch you are connecting to. The Bluetooth ID is on the StepWatch label.





If the Participant ID and StepWatch Bluetooth ID are correct, tap “Yes,” and the smartphone and StepWatch will be connected for the duration specified in Site settings. If they do not match, tap “No” and the connection will not go through.

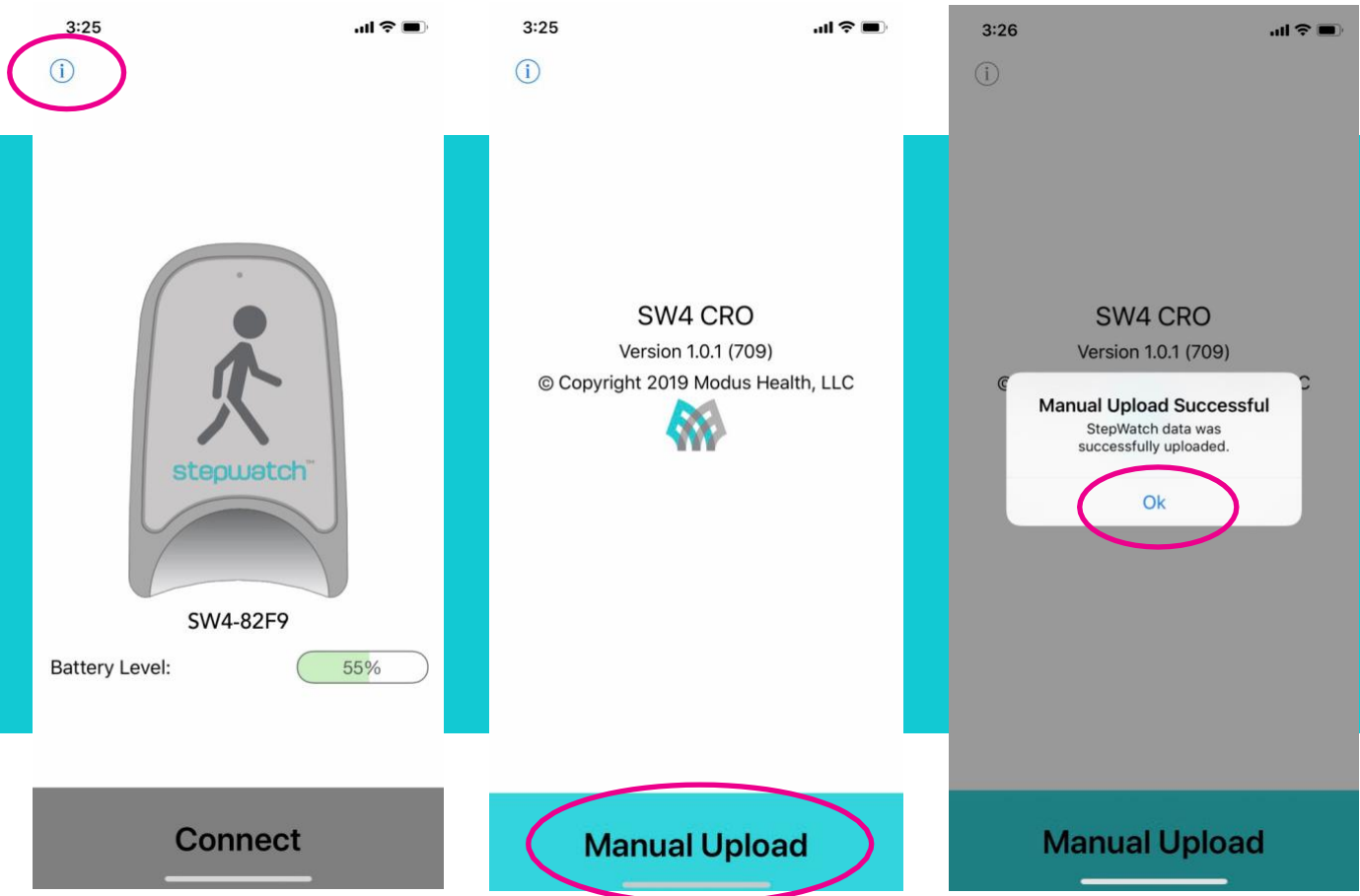
The Connect button will turn teal in color when the connection expires between the smartphone and StepWatch. When the Connect button is active (teal), it can connect to the StepWatch for another visit / recording session.



## Participant's Use of CRO Companion App

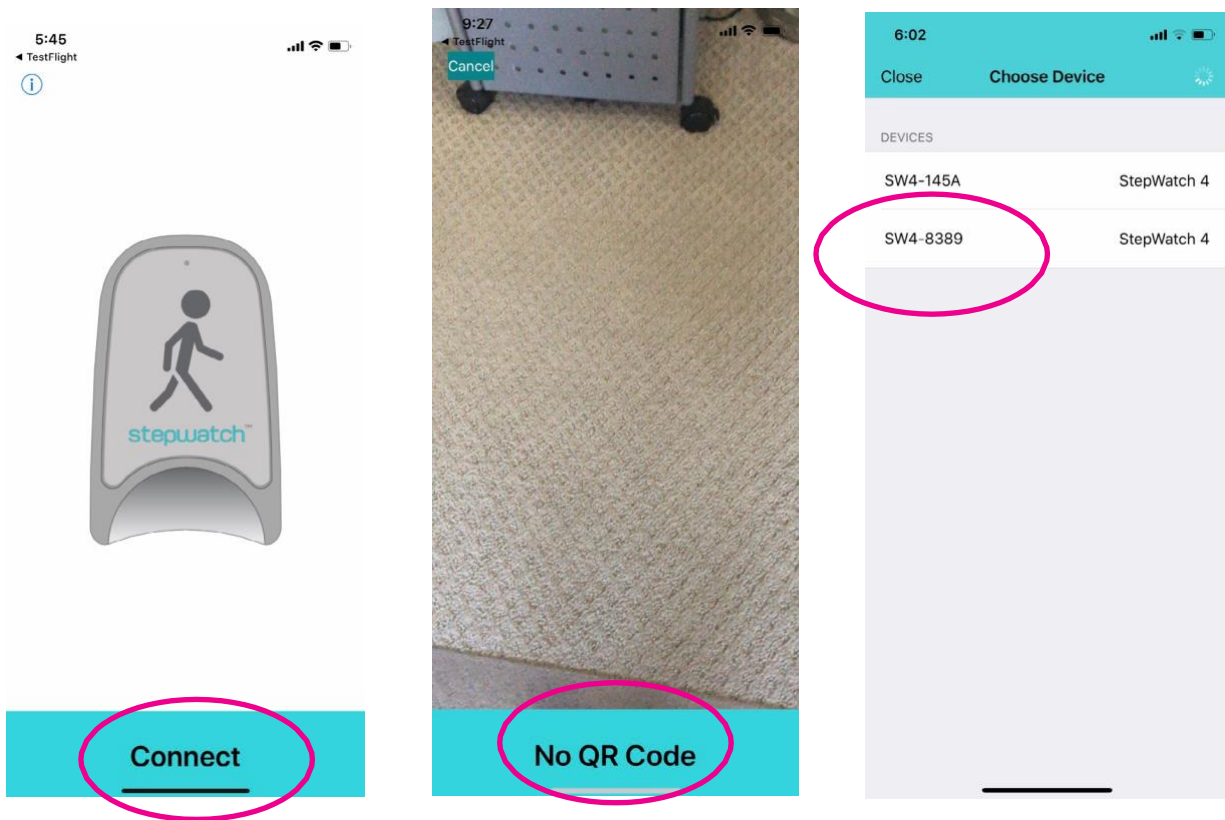
After initial setup, participants should use the companion app at home for automatic uploads of their data into the study cloud. The smartphone will remain connected to the StepWatch for the link duration specified in the app site settings. Participants should be instructed to keep the smartphone plugged in at night and to keep the app open. If an upload is desired outside of the automatic upload time, instruct participants to tap the Info button. This will expose the "Manual Upload" button. If tapped, it will upload the latest walking data into the cloud at that time. The StepWatch will need to be in Bluetooth range of the smartphone to successfully upload walking data. Tap the "Info" button to go back to the Connect screen.

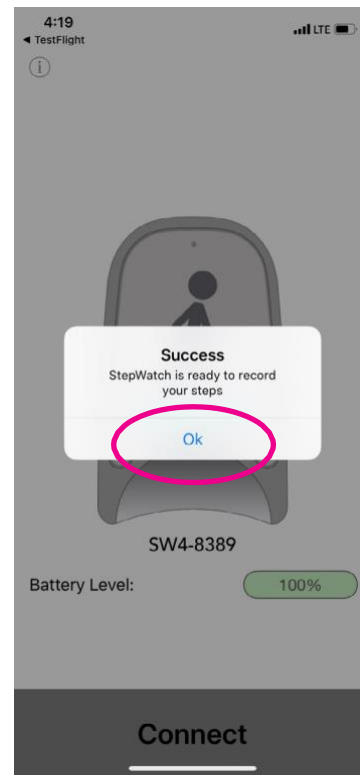
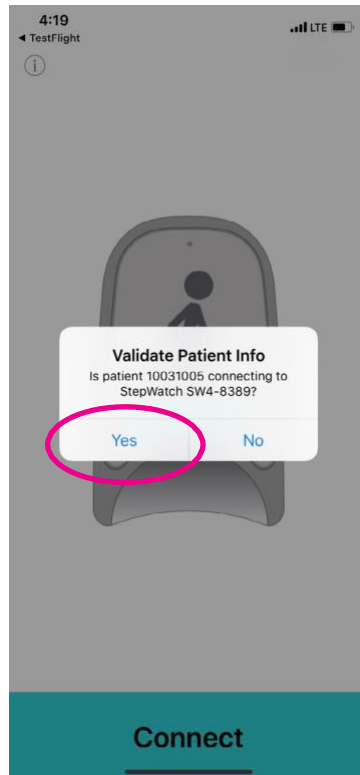
### iPhone





The Connect button becomes active again after the link duration expires. It can connect to a StepWatch for another data collection session as long as the StepWatch was setup with the CRO Site app first. The participant may use the QR code to connect to their StepWatch or select “No QR Code” to choose the Bluetooth ID of their StepWatch.

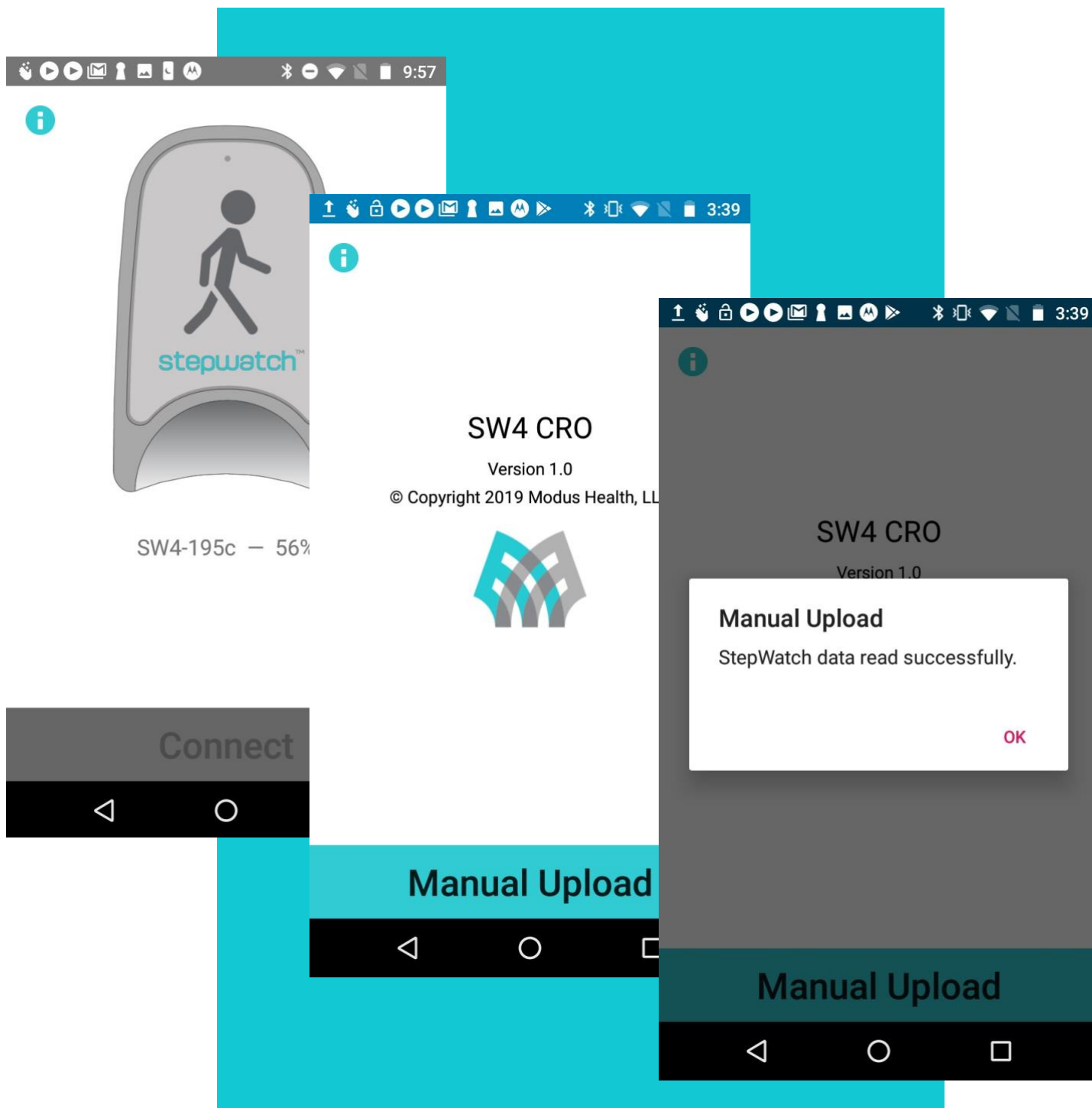




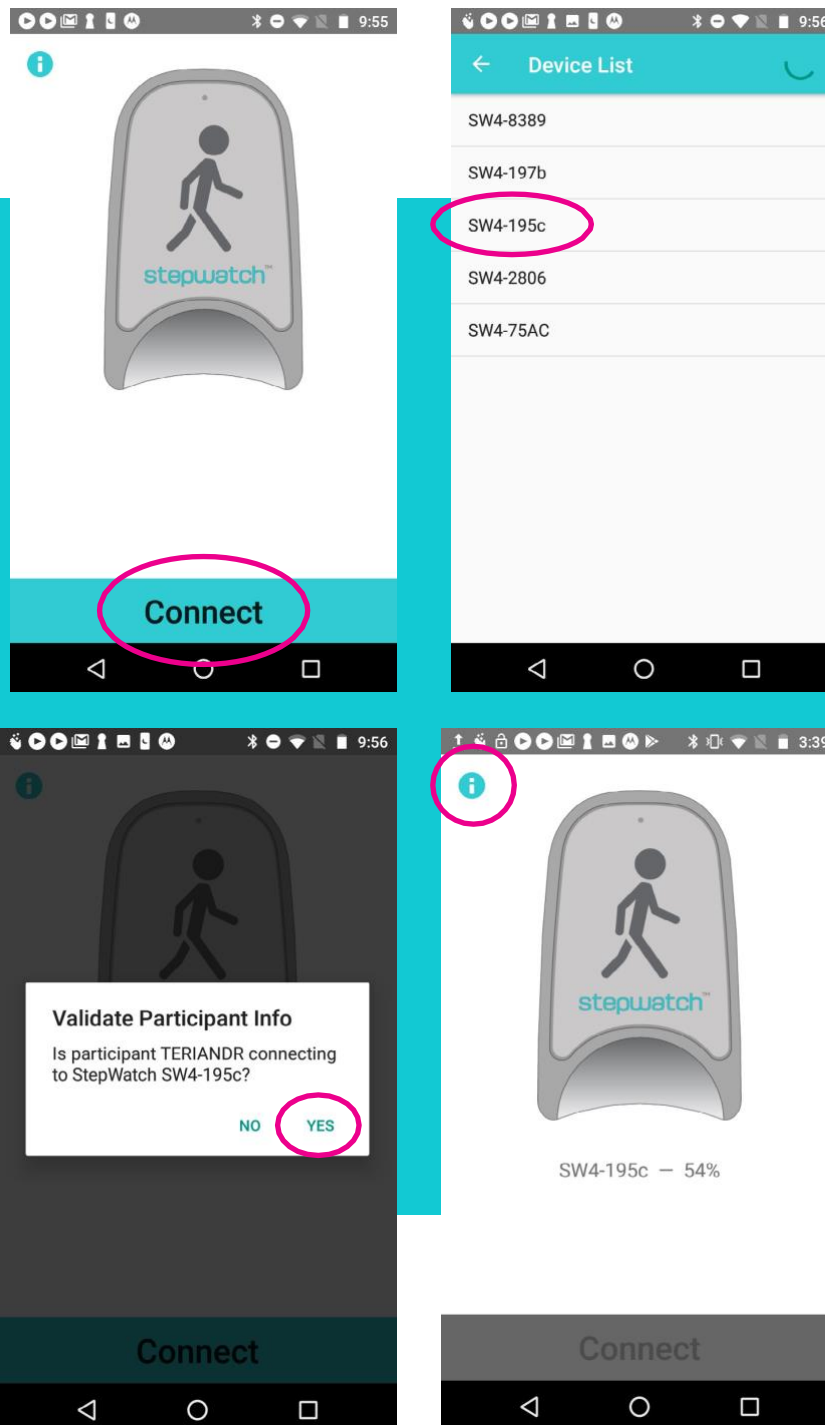
Note: After the first time the StepWatch is connected to the CRO companion app, the CRO companion app will only let the same Participant ID connect to it. In case of initiating a connection away from the clinic, this feature prevents a participant from accidentally connecting to another participant's StepWatch. The CRO companion app must be uninstalled and reinstalled to use it with a different Participant ID

## Android

If an upload is desired outside of the automatic upload time, instruct participants to tap the Info button. This will expose the “Manual Upload” button. If tapped, it will upload the latest walking data into the cloud at that time. The StepWatch will need to be in Bluetooth range of the smartphone to successfully upload walking data. Tap the “Info” button to go back to the Connect screen.



The Connect button becomes active again after the link duration expires. It can connect to a StepWatch for another data collection session as long as the StepWatch was setup with the CRO Site app first.



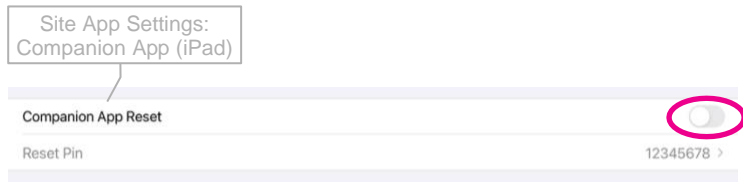
Note: After the first time the StepWatch is connected to the CRO companion app, the CRO companion app will only let the same Participant ID connect to it. In case of initiating a connection away from the clinic, this feature prevents a participant from accidentally connecting to another participant's StepWatch. The CRO companion app must be uninstalled and reinstalled to use it with a different Participant ID.

# Resetting Companion App to Accept Different Participant

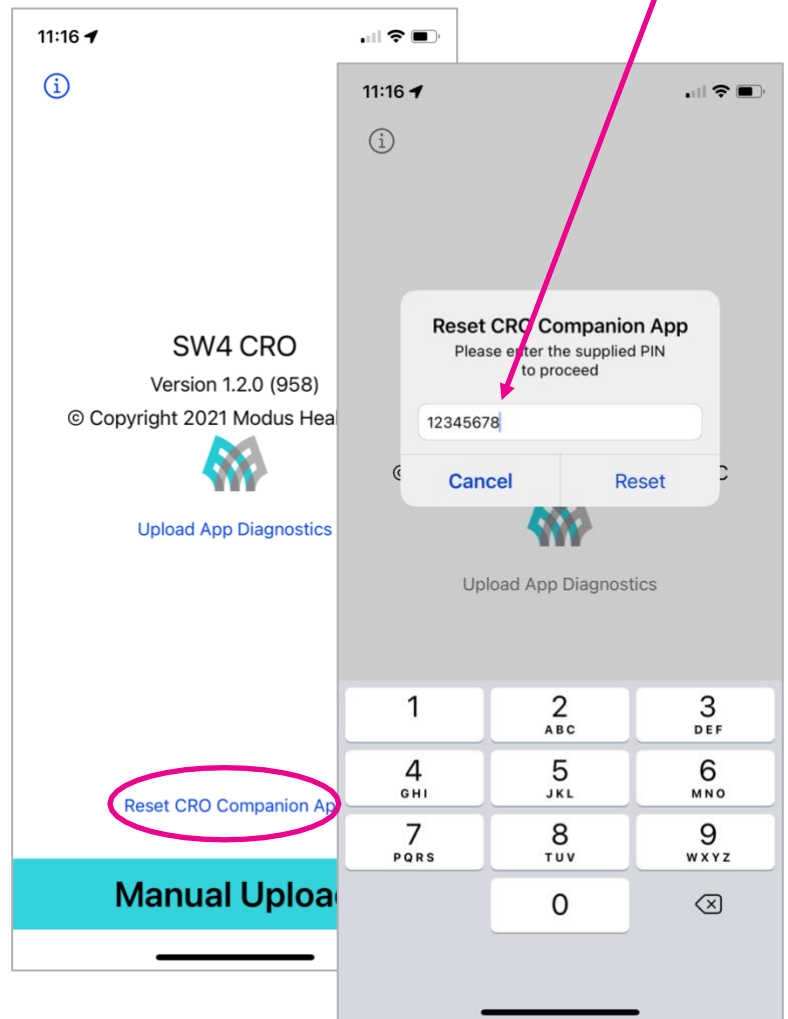
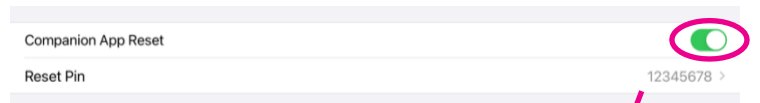
The companion app is designed to refuse connection to a participant other than the last one that was connected in order to prevent errors in step data identification. If setup with a new or different participant is required, the companion app can be reset manually with a PIN to ensure the reset is intentional and authorized.

Companion App Reset function must be enabled in the Site Settings before a companion app can be reset. **Note:** *If the Reset function is turned off, the companion app must be deleted and reinstalled before using the companion app mobile device for a different participant.*

When companion app reset is turned **OFF**, there will be no reset link present on the companion app info panel:



When companion app reset is turned **ON**, reset link will be present. Tap the link, and enter the Reset PIN, which can be located in the iPad Site App settings:



## Using Previous Settings for Returning Participant

If a participant has previously been monitored with a StepWatch, the settings have been saved and you have the option of reusing them rather than going back through the setup process.

The screenshot shows the StepWatch 4 Enrollment screen. On the left, there is a list of participant information: Date (Oct 4, 2019), Study Number (8301100), Site ID (TERI), StepWatch ID (SW4-75AC), and Battery Level (93%). On the right, there is a section for 'ENTER SUBJECT INFO' with two 'TEST' labels. A dialog box titled 'Use Saved Settings?' is displayed in the center, asking if the user wants to use settings from a previous enrollment on February 26, 2019. The 'Yes' button is circled in pink. At the bottom right, there is a 'Next' button.

StepWatch 4	
Date	Oct 4, 2019
Study Number	8301100
Site ID	TERI
StepWatch ID	SW4-75AC
Battery Level	93%

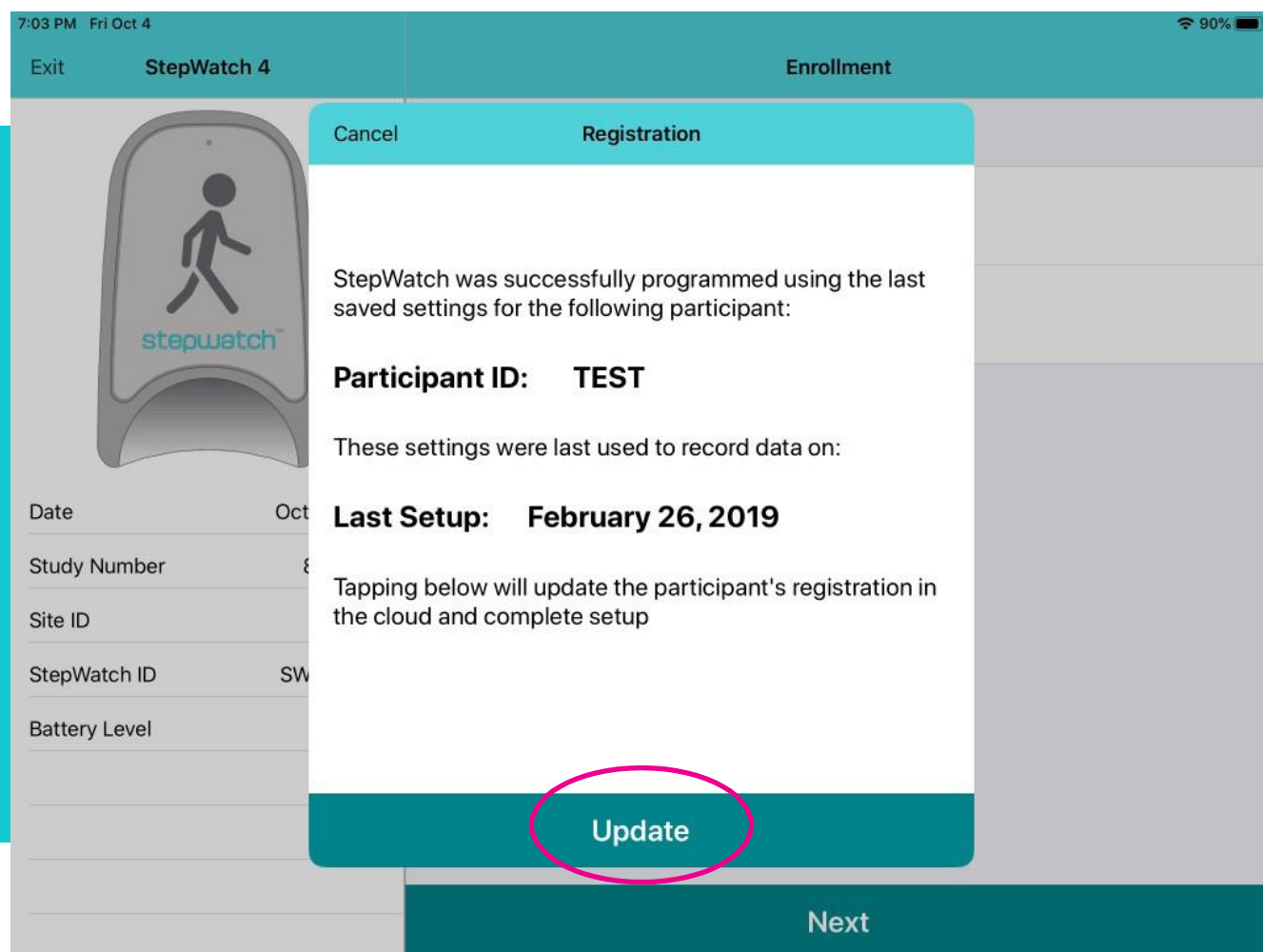
**Use Saved Settings?**  
This participant was previously enrolled on February 26, 2019. Would you like to program StepWatch with the step detection settings previously used for this participant? Note that if the participant's height or walking have changed, previous settings may not be accurate.

**Yes** **No**

**Next**

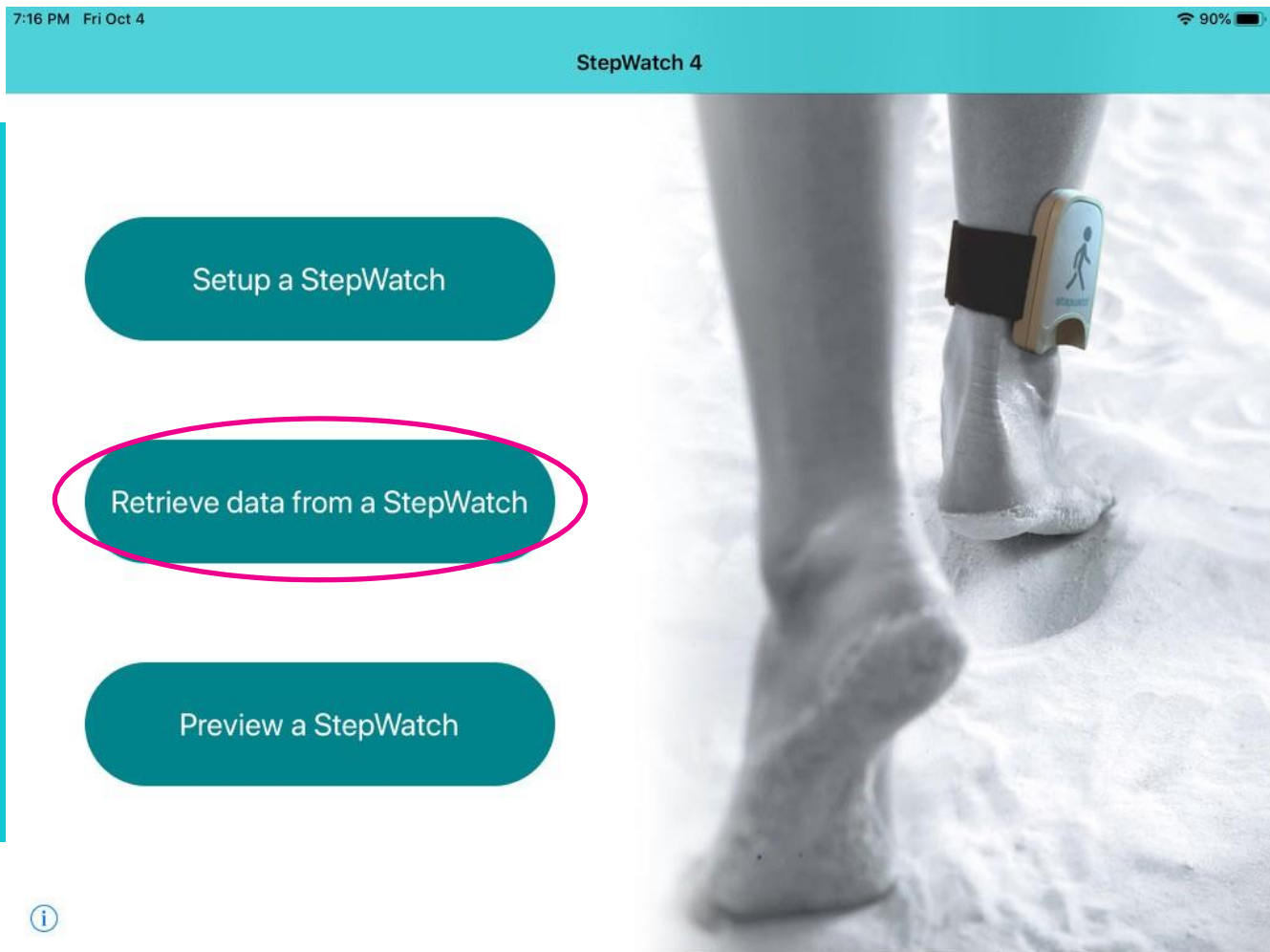
Note: It is more accurate to go back through the setup procedure each time the StepWatch is setup. Previous settings were designed for cases when the StepWatch needed to be setup without the participant present, and there is low probably that height or walking ability changed from the last setup procedure.

The registration screen shows the date of the most recent StepWatch setup procedure for this participant. The StepWatch step detection algorithm will be based on this setup procedure. If this date was not what you expected, you may cancel. To do this, go back and select “No” to “Use Saved Settings,” and the app will take you through the setup process for your returning participant. If it the date is acceptable, tap “Update”.



## Retrieve Data from a StepWatch

When a StepWatch is returned to the site because data collection has concluded for a study visit/session, tap the “Retrieve data from a StepWatch” button on the Main Screen.





Following a successful connection, the app will automatically place the StepWatch unit into Idle Mode to prevent logging extra steps accidentally. To complete an upload of the data stored on the StepWatch to the cloud, tap “Upload Step Data.”


7:04 PM Fri Oct 4

90%

Exit

StepWatch 4

Download



Date	Oct 4, 2019
Study ID	8301100
Site ID	TERI
StepWatch ID	SW4-195c
Participant ID	TERIANDR
Total Steps	3048
Battery Level	56%

Your StepWatch has been placed in Idle Mode to prevent the accidental accumulation of additional steps.

To download Step Data recorded on the StepWatch, tap the button below.

Your StepWatch is not fully charged. It is recommended that you charge it before placing it in storage.

Upload Progress

Retrieving SW data...

41%

You

01 hrs 19 mins

Upload Step Data

Following a successful upload, the app will place the StepWatch into Storage Mode to conserve power until its next use. You will need to place the StepWatch on the charger for at least 10 seconds to wake it up when ready to use the StepWatch again. Tap “Return to Main Menu” when the upload is complete.


7:05 PM Fri Oct 4

90%

Exit

StepWatch 4

Download



Date	Oct 4, 2019
Study ID	8301100
Site ID	TERI
StepWatch ID	SW4-195c
Participant ID	TERIANDR
Total Steps	3048
Battery Level	56%

Upload successful! All data stored on connected StepWatch has been retrieved.

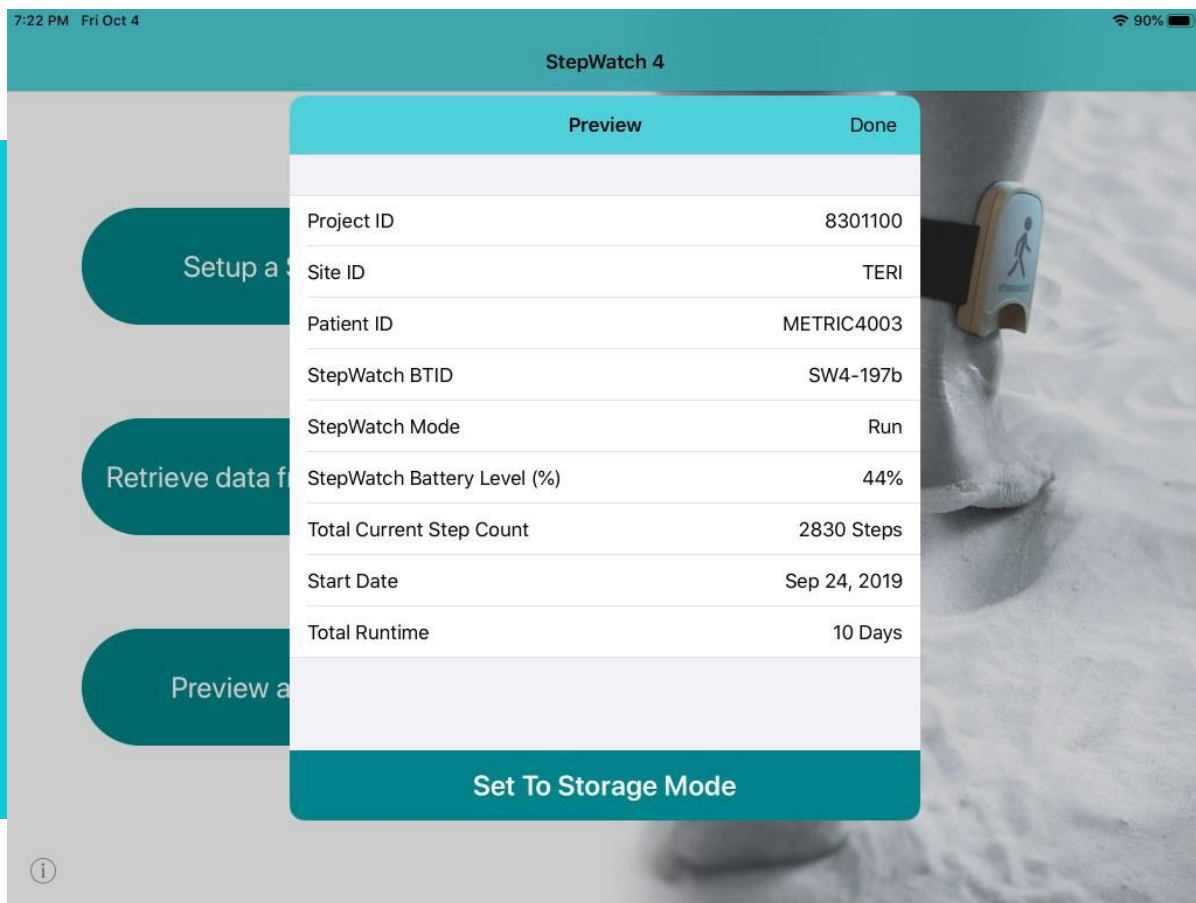
Your StepWatch is not fully charged. It is recommended that you charge it before placing it in storage.

Your estimated charge time is: 01 hrs 19 mins

Return To Main Menu

## Preview a StepWatch

“Preview a StepWatch” is helpful when you want to know the state of a StepWatch such as the Participant ID, if the StepWatch is recording (run mode) or not recording (idle mode), battery level, number of steps recorded with the StepWatch, the day it started recording, and the number of days the StepWatch recorded. If the StepWatch is in run mode, it will continue to record steps after completing Preview. The “Set to Storage” mode will stop the StepWatch from recording and will turn off the Bluetooth radio to conserve battery. To turn the Bluetooth radio back on in order to connect with the StepWatch, you must place the StepWatch on a charger for 10 seconds, and then remove it from the charger.



Note: If you set a StepWatch to Storage Mode, you will have to repeat setup with the CRO Site app to get StepWatch to record again for a participant

# Managing a StepWatch at Home

## Wearing the StepWatch



First, pull the strap through the slots on the back of the monitor. Then, pull the strap through the plastic ring and secure using the Velcro tip.

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

## INCORRECT WEARING



Upside down.

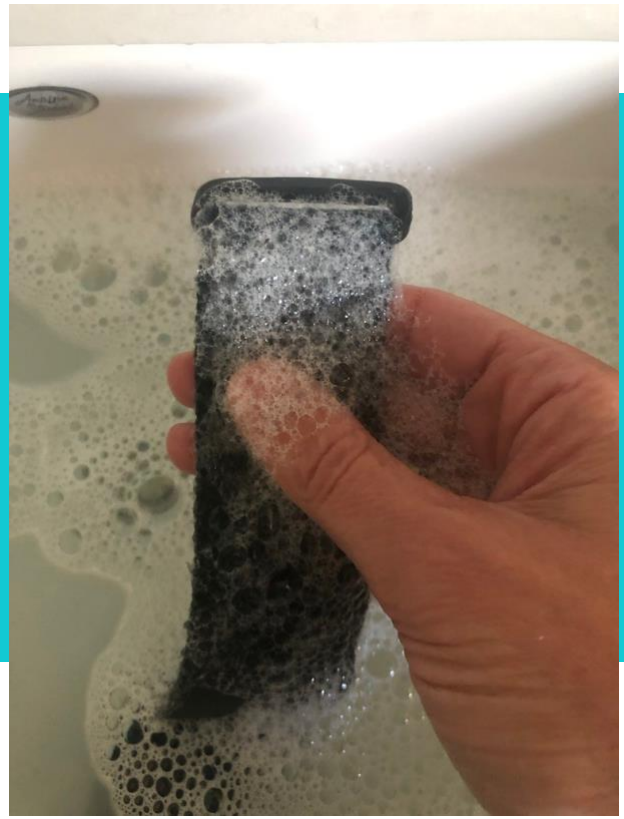


Inside the leg.



## Cleaning the StepWatch

If needed, you can clean the StepWatch by rubbing gently with a wet cloth or disinfectant wipe. To clean the strap, hand-washing with soap and warm water is preferred. Air-dry, or set dryer heat to low.



**WARNING!** NEVER PLACE THE STEPWATCH IN ANY TYPE OF OVEN OR AUTOCLAVE as this could potentially cause the permanent lithium battery to rupture or explode.

## Charging the StepWatch



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

A light will illuminate when your StepWatch begins charging.



Do not place StepWatch on edge of charger.








Do not place StepWatch upside-down on charger.





## Interpreting the LEDs

(\*StepWatch 5 only)

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

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

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

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

## Interpreting the Identification Label

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

FCC and IC Bluetooth radio identification

Date of Manufacture

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

**Never place the StepWatch in any type of oven or autoclave,** as this could cause the permanent lithium battery to rupture or explode. Review the cleaning instructions in this manual.

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

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



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

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

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

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

# Frequently Asked Questions

## What happens if I forget my 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. However, the StepWatch must be worn on the outside of the ankle.

## Can the StepWatch get wet?

Yes, the StepWatch is waterproof (IP67). StepWatch can be used in the shower, bath, or in the rain. Swimming is not recommended. A dry Velcro strap is recommended if wet.

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

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.

# Troubleshooting

## The StepWatch cannot connect to the iPad:

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

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

Try restarting app.

If problems persist, contact the 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.

## Safety

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

## Performance Characteristics

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

Several studies illustrate benefits provided by the ability to accurately monitor activity using StepWatch. For every 500 steps per day increase, length of stay in the hospital was reduced by 11% for patients with pneumonia [3]. Walking at least 275 steps per day during inpatient care identified patients that have reduced 30-day readmission risk [4]. Patients recovering from stroke are more likely to be independent walkers when they leave the hospital if they can achieve 1000 steps per day in the hospital [5].

[1] [https://modushealth.com/publications/?fwp\\_sections=accuracy](https://modushealth.com/publications/?fwp_sections=accuracy)

[2] [https://modushealth.com/publications/?fwp\\_sections=stepwatch-as-criterion](https://modushealth.com/publications/?fwp_sections=stepwatch-as-criterion)

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

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

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

## Software Specifications

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

Mobile Application	Use Case	Minimum Hardware & Software Requirements (as of January 2023)
SW4 RE (supported through 2023)	Research Site	iPad running iOS 14 or 15
Modus RE	Research Site	iPad running iOS 14-16
CR Site	Clinical Research Trial Site	iPad running iOS 14 or 15
CR Companion	Clinical Research Participant's Home	iPhone running iOS 15 or 16 Android Version 8
CC Clinic	Clinical Care Provider	iPad running iOS 14 or 15
CC Companion	Clinical Care Setting or Patient's Home	iPhone running iOS 14 or 15

## Hardware Specifications

Specifications	StepWatch 4	StepWatch 5
Size	75 x 48 x 14 mm	42 x 49 x 13 mm
Weight	41 grams	20 grams
Wearable Soft Cover	Available in small and med-large	One Size
Waterproof	IP67 certified	IPX8 tested
Accurate Step Detection	For all walking styles, including slow and irregular gait	
Step Resolution	Steps per second	
Communication Method	Bluetooth connection to Apple iPad	
Operating Environment	Operating Temperature: -10° ~ +45° C (14° ~ 113° F) Charging Temperature: 0° ~ +45° C (32° ~ 113° F) Storage Temperature: 0° ~ +25° C (32° ~ 77° F)	
Battery Life	Over 30 days following setup, Over 20 days if one download per day	
Wireless Induction Charging	Input: 5V (2A) and Output: 5W	
Onboard Memory	Stores 10 to 30 days between downloads depending on activity level	
2 Year Warranty	Warranty begins on day of delivery	

## FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

StepWatch is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.

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

## Maintenance

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

## Disposal

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

