CoughMonitor Suite

Protocol name

SITE MANUAL

Hyfe

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Version Control

Version	Date of Issue	Change Log
1.0	29JUL2025	Document Created

Glossary of Terms

Abbreviations

Abbreviation	Full Form
CoughMonitor	Hyfe CoughMonitor
Companion App	Hyfe CoughMonitor Companion App
App	Application for smartphone
QR Code	Quick Response Code
Participant ID	Study Participant Identifier
PDF	Portable Document Format
CSV or CSV file	Comma-separated values
USB Port/Cable	Universal Serial Bus Port/cable

Definitions

Term	Definition
CoughMonitor Suite	A research tool that measures cough frequency in research studies, which consists of the CoughMonitor, CoughMonitor Companion App, and Dashboard
CoughMonitor	The ID206 smartwatch running Hyfe's software that detects and timestamps coughs
CoughMonitor Companion App	A smartphone application that connects to the CoughMonitor and transfers data to Hyfe's Cloud
Data Synchronization	An automated process that sends timestamps from the CoughMonitor to the Companion App via Bluetooth and subsequently from the Companion App to Hyfe's Cloud utilizing the phone's Internet connection
Dashboard	A web-based platform used to enter the Participant ID and annotate the start and end of a cough monitoring session.
Pairing	The process when the CoughMonitor and Companion App connect through Bluetooth and a cough monitoring session starts
Participant ID	Study Unique ID that consists of a multiple digit number unique to the participant
Timestamp	Date and time of each cough detected by the CoughMonitor
CoughMonitor Unique Identifier	A 6-digit number appears on the CoughMonitor's screen to identify each device

Before You Start

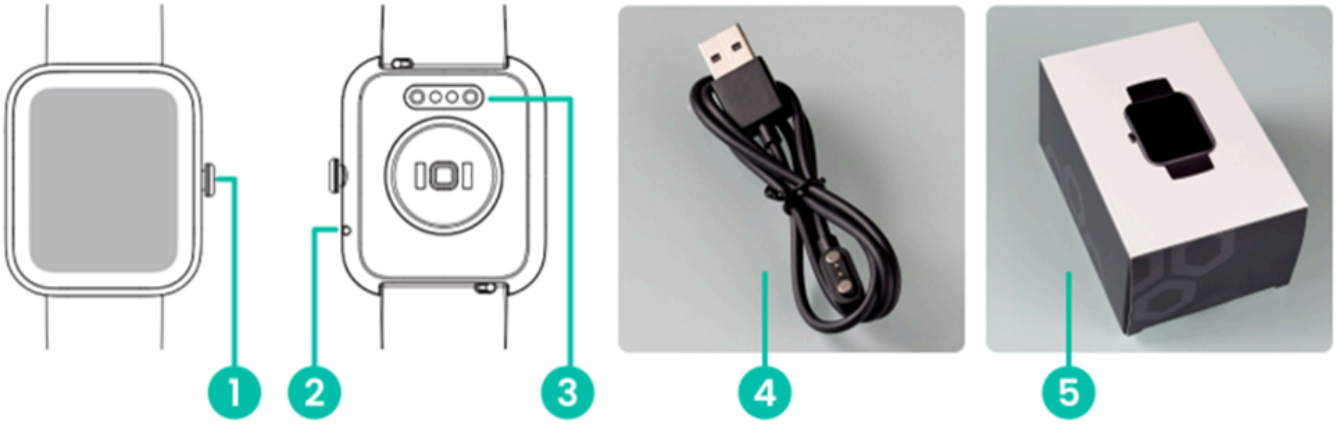
Introduction to Hyfe's CoughMonitor Suite

The CoughMonitor Suite is a research tool that measures participants' cough frequency in research studies. The system consists of:

1) **CoughMonitor:** A smartwatch running Hyfe's CoughMonitor software that deploys an acoustic signal processing algorithm to automatically detect and timestamp coughs. Cough timestamps are sent via Bluetooth to a dedicated mobile app.
2) **CoughMonitor Companion app:** A smartphone-based Companion app that allows the CoughMonitor to transfer cough timestamps to Hyfe's Cloud using the phone's Internet connection.
3) **Dashboard:** A web-based platform for viewing data and monitoring participants. The data is synced through the Hyfe Cloud.

The CoughMonitor Suite detection model is optimized for best performance when within approximately 3 feet (90cms) of the coughing source. It is not personalized, so coughs from others within that range may be captured and counted, e.g., from others being hugged and in similar situations. Based on Hyfe's experience with volunteers wearing the watch in everyday environments - such as grocery stores, public transport, conferences, airplanes, restaurants, galleries, and concerts, among other environments - the model captures very few coughs from other people in practice.

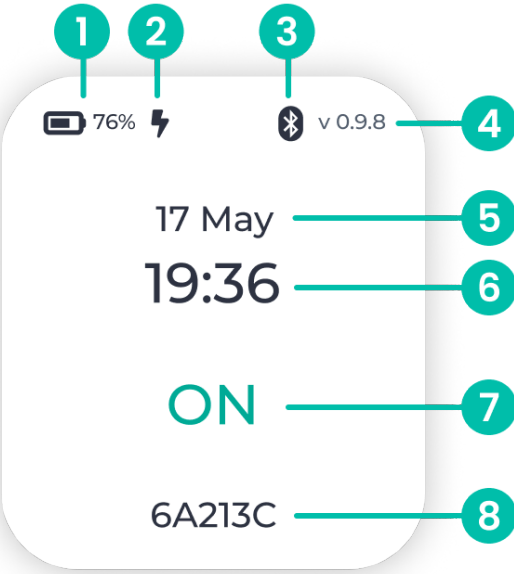
CoughMonitor Components



1	Round Button	Short press to wake up the screen when it is off
2	Microphone	Used to capture sounds
3	Charger Port	Used to connect the charging cable
4	USB Charger Cable	Used for charging the CoughMonitor
5	Package box	Needed to return the device at the end of the study.

CoughMonitor Screen

1	Battery level
2	Indicates charging in progress
3	Indicated Bluetooth active
4	Software version
5	Date
6	Time (24 hours)
7	Monitoring status (ON/OFF)
8	CoughMonitor unique identifier



CoughMonitor Operating Instructions

Power Management: The battery lasts for up to 80 hours and the battery level is shown on the screen in the top left corner. When the device is being charged, the charging icon appears next to the battery.

The CoughMonitor powers on when the battery level is 1% or higher. When the battery is depleted, the device powers off automatically. Upon charging, the device powers back on automatically. There is no manual power button to turn the device on and off or turn cough monitoring on and off.

Screen Lock: The screen of the CoughMonitor will lock automatically after 3 seconds, displaying a black screen. To unlock the screen, press the round button once.

Proximity Range: The CoughMonitor is worn on the wrist and operates effectively when in close proximity to the study participant's mouth, ideally within 3 feet (90cm).

Safety Information

1. The CoughMonitor is waterproof and can be worn while showering or bathing, however it should not be submerged in water for longer than 30 minutes or deeper than 3 feet/90cm.
2. The CoughMonitor must not be exposed to extreme temperatures outside the range of -20°C to 50°C / -4°F to 122°F.

Technical Specifications

CoughMonitor

Model	ID206
Manufacturer	Shenzhen Do Intelligent Technology Co., Ltd.
Water Resistance	5ATM
Power Supply	0.5A, 5V
Safety Standards	FCC, CE, IC, UKCA, ROHS
EMC Standards and Emissions	ESD (Contact discharge is ±6KV, air discharge is ±10KV)
Size	43.94 x 37.10 x 13.21mm (1.73 x 1.46 x 0.52 inches) without strap 256 x 37.10 x 13.21mm (10.08 x 1.46 x 0.52 inches) with strap
Weight	24 grams without a strap 41 grams with strap
Operating Temperature	-20℃ to 50℃ / -4℉ to122℉
Humidity	10%-90%RH (non-condensing)

Companion App

The Companion app is a smartphone app. It is compatible with phones running Android version 12 and above or iOS version 16 and above.

Security Information

The CoughMonitor is designed to prevent third-party data access. The CoughMonitor only stores the most recent second of audio, and cough timestamp data is automatically deleted when a different user connects to the CoughMonitor via the Companion app. If a participant reports a device lost or stolen, a member of the study team should contact support@coughmonitor.com for remote deactivation.

Cleaning

To clean the CoughMonitor, use alcohol wipes containing up to 70% alcohol. Watches can be re-used after unpairing with the Companion app and following cleaning with alcohol wipes.

Hyfe Support Team

If you/the research team requires technical or customer service support, you can contact Hyfe's support team at support@coughmonitor.com

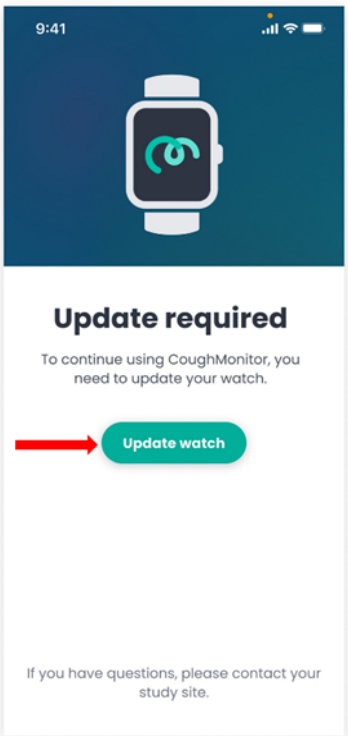
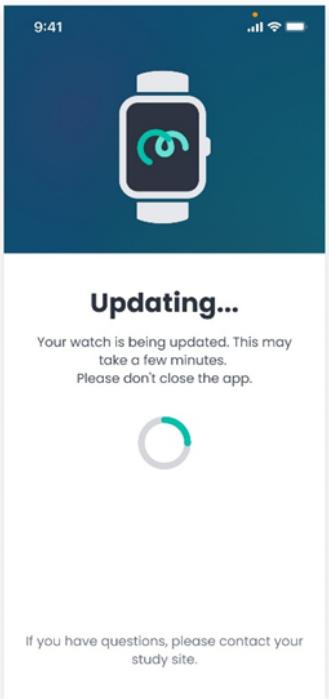
Please note all Hyfe's support is in English and working hours are between 9AM-5PM CET and 9AM-5PM EST.

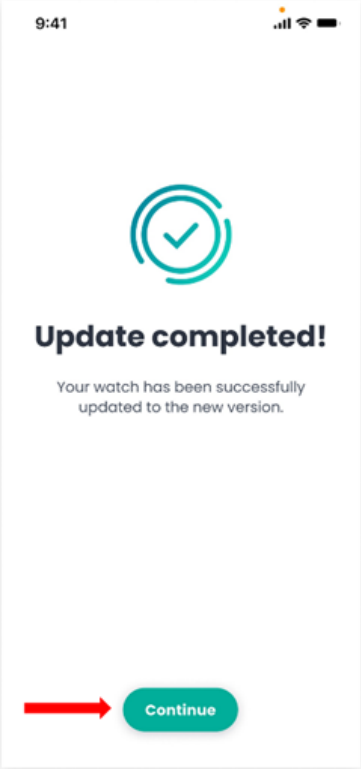
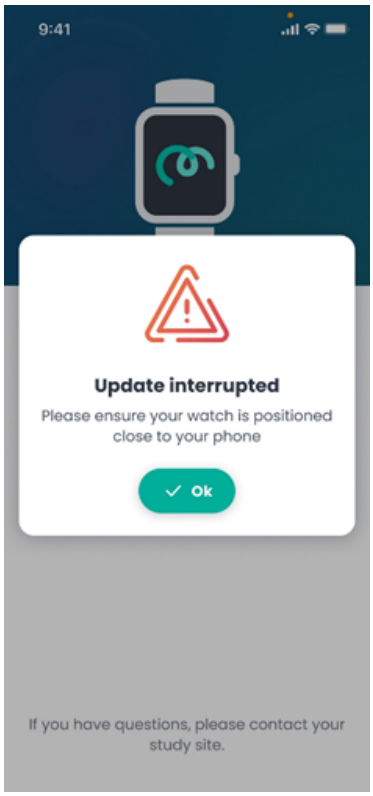
CoughMonitor Software Update

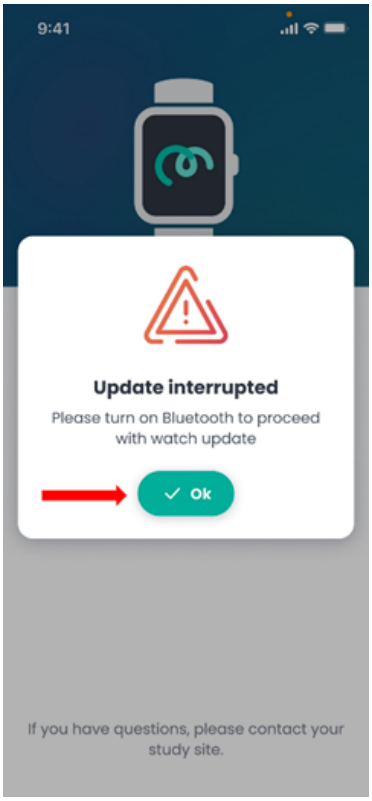
Hyfe locks the software version of the CoughMonitor to ensure the same version is used for the entire study. Version refers to the first two digits of the software, which relate to the cough detection algorithm. Thus, they will always be the same for the entire cohort. However, if there is a critical software update that does not relate to the algorithm, and the study team agrees, Hyfe can force a software update using the Companion app. In this case, the last digit of the software will change.

Please note that to update the CoughMonitor the phone and CoughMonitor are required to be in close proximity with Bluetooth enabled on the phone.

If an update is required, the following message will appear when the participant opens the app, and the following steps need to be followed to complete the update:

1. Tap “Update watch”	
2. Wait while the “Updating” screen shows that the CoughMonitor is being updated.	

3. When the update is complete, the screen on the right will appear. Tap “Continue” to return to the home screen.	
4. If the CoughMonitor and phone are not in close proximity, the following message will appear on the phone to request the participant to bring the CoughMonitor and phone into close proximity. Tap “OK” to go back to the home screen.	

5. If Bluetooth is disabled on the phone while the CoughMonitor's software is being updated, the following message will appear on the phone screen to ask the participant to enable Bluetooth to complete the update. Tap "OK" to go back to the home screen.	

Preparing to Use the CoughMonitor for the Study

Materials

The following equipment will be provided::

- CoughMonitors
- USB charger cables
- Participant brochures (electronic)
- Site manual (electronic)

Unpack and Charge the CoughMonitor when it is delivered.

Take each CoughMonitor out of the box and charge it. Charge the device by connecting the magnetic end of the USB charger cable to the CoughMonitor and the other end of the charger cable to a USB charging port. The device turns on automatically when it starts to charge.

Allow the device to charge until the battery status reaches 100%. It takes approximately 2.5 hours to fully charge the device. To ensure the CoughMonitor is charging, press the round button on the side and see if the screen lights up. After ensuring the screen lights up, check if the battery is charging by viewing the lightning bolt icon on the CoughMonitor's screen.

Note: Participants must charge the device each night whilst sleeping. The device will continue to record during this period and must be kept nearby (within 90cm or 3 ft of the mouth).

After confirming the CoughMonitor turns on and is able to charge, put the CoughMonitor back in the box. If the CoughMonitor device does not turn on or charge, please contact support@coughmonitor.com

Note: the "OFF" screen is displayed when the device is not paired with the Companion app and "ON" when it is paired and monitoring.

If you require additional CoughMonitor devices, please contact Hyfe's team to amend the Device Loan Agreement.

Access to the Dashboard

The Dashboard will be used to enroll participants and annotate the start and the end of a cough monitoring session. To access the Dashboard, the research team should open the dedicated email provided by Hyfe on a computer using one of the following browsers.

- Microsoft Edge from v79
- Opera from v48
- Google Chrome from v16
- Safari from v15
- Firefox from v122

To sign in, the research team should enter their email and click “Sign in.” The research team will receive an email with a link to access the Dashboard. Click the link to open it.

Participant Brochure

The research team will receive an electronic version of the Participant Brochure, which can be printed off and provided to participants at their initial visit for training and ongoing reference, depending on research specific practices.

The brochure will explain:

- What the CoughMonitor Suite is
- How the CoughMonitor should be used during the study session
- What to do if the CoughMonitor runs out of battery
- Who to contact if something goes wrong
- How to close the Companion app to troubleshoot

Starting a Cough Monitoring Session

Steps to start a cough monitoring session

Cough monitoring sessions will be started in person by the research team with participants. The research team needs to have access to a computer with an Internet connection, one CoughMonitor and a phone. The phone can be the participants personal device, or a study provided device, depending on the study protocol.

Starting a cough monitoring session requires the following steps, which are explained in more detail below:

1. Checking participant's Android/iOS version
2. Downloading the CoughMonitor Companion app
3. Changing the Language of the Companion app (only if required)
4. Enrolling a participant in the Dashboard
5. Annotating the Start of a Monitoring Session
6. Signing In to the Companion app
7. Pairing CoughMonitor with the Companion app
8. Confirming pairing in the Dashboard

Checking Participant's Android/iOS Phone Version

The Companion app is compatible with Android phones running on Android version 12 or above and Apple phones running on iOS 16 or above. The research team should confirm with participants whether they have phones that are compatible with the Companion app.

How to check OS:

Android:

1. Open the Settings app
2. Go to "about phone" or "about device"
3. Find Android version number beside line labeled "Android version"

iOS:

1. Navigate to settings
2. Tap "General"
3. Tap "About" and look for "Software Version" the number listed by it is the iOS version number

Please note only **one** device must be used to sign in to the Companion app and pair the CoughMonitor. Signing in to the Companion app and pairing the CoughMonitor on multiple devices will cause connection issues.

Downloading the CoughMonitor Companion app

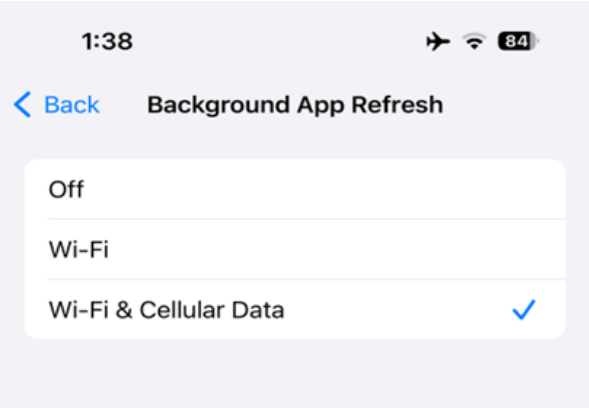
Download the Companion app on the smartphone, by opening the appropriate app store (Play Store for Android and App Store for iOS). In the search field, type "CoughMonitor Companion" to locate and download the mobile app. Below are the links to download the app for reference:

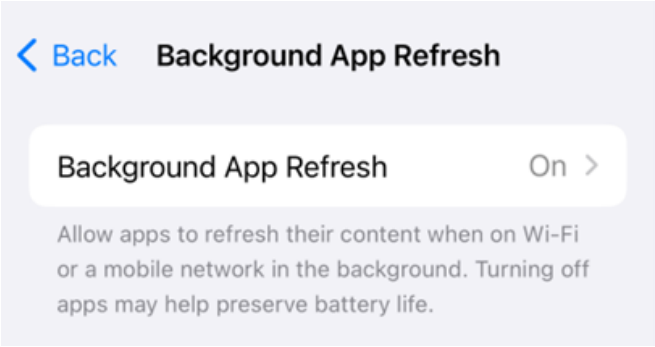
- Apple App Store:
https://apps.apple.com/us/app/coughmonitor-companion/id6475784173

- Google Play Store:
https://play.google.com/store/apps/details?id=com.hyfe.coughmonitorcompanion&hl=en&gl=US

If using an iOS phone, please check if background app refresh is enabled as described below:

Go to Settings > General > Background App Refresh and enable "Background App Refresh" > Wi-Fi & Cellular Data





Changing the Language of the Companion app

The language of the Companion app automatically matches the language set on the phone. Check if the companion app language is suitable or needs to be changed.

Android:

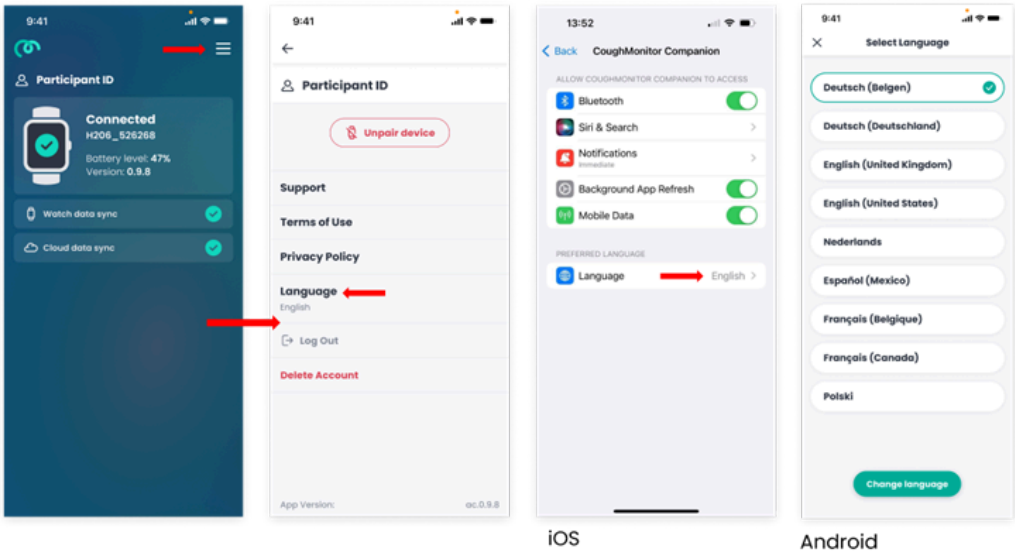
1. Open the Settings app
2. Access system settings
3. Navigate to language and tap on “Languages & input” or “Languages”
4. Add a language by tapping on “Languages” and then “Add a language”
5. Select a language you want to add from the list

iOS:

1. Navigate to settings
2. Scroll and tap on “General”
3. Select Language & Region
4. Tap on “iPhone Language” and choose your preferred language from the list

To change the language in the Companion app, follow the steps below.

- Open the app on your phone and then open the menu located in the upper right corner shown in the images below. Tap “Language” and select your preferred language from the phone’s settings.



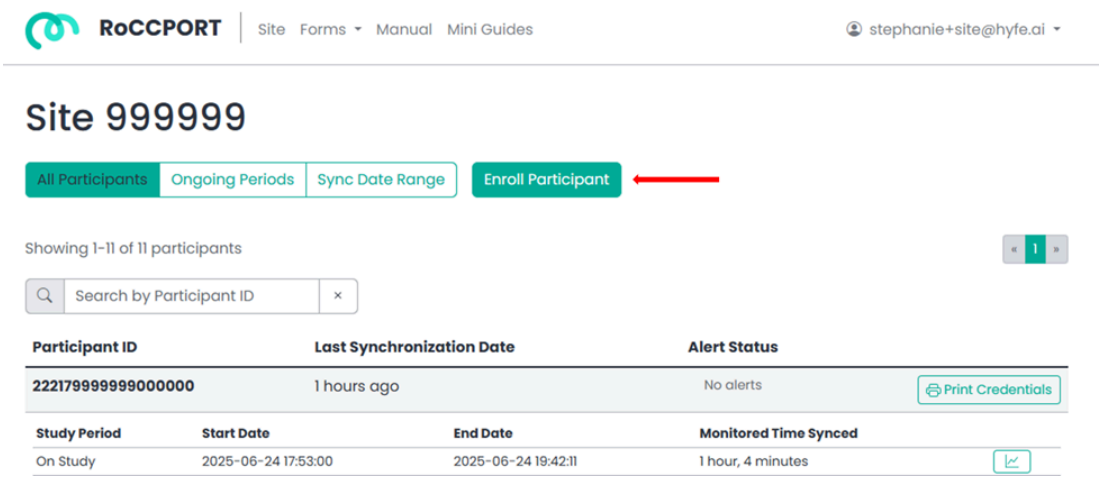
Enrolling a Participant in the Dashboard

Dashboard access will be provided by Hyfe's team after receiving a list of contact information from the research team. For any additions or removals, please contact us directly.

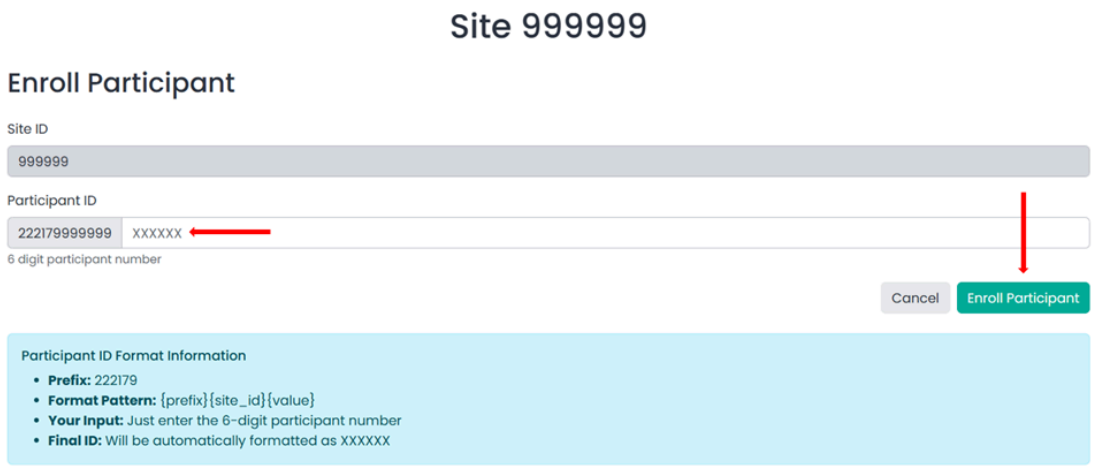
After instructing the participant to download the Companion app, the research team should open the Dashboard provided on a computer and sign in. Please check access to the Dashboard section to see instructions for sign in.

To enroll a participant, follow the steps below:

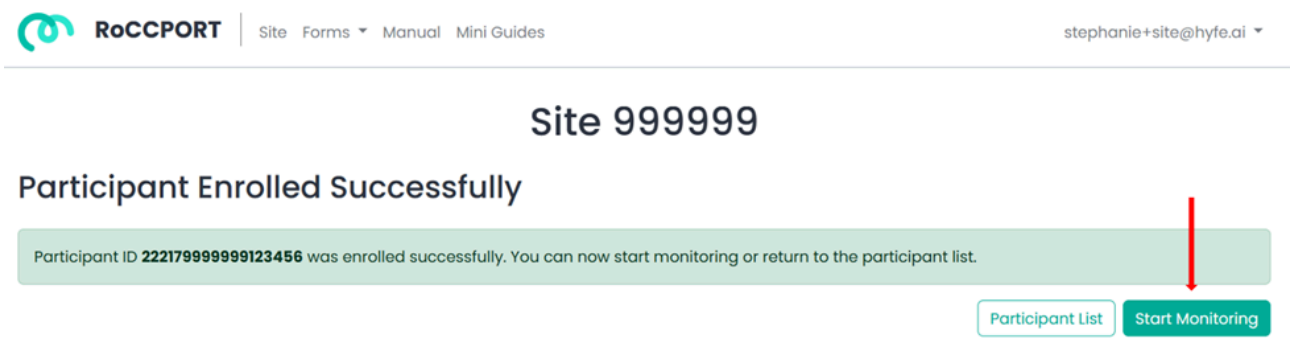
1. Click "Enroll Participant"



2. The Site ID will appear automatically in the first box below. Enter the Participant ID and click “Enroll Participant”.



3. If the Site ID and Participant Number are entered successfully, the following screen will appear confirming the participant was enrolled. Click “Start Monitoring.”

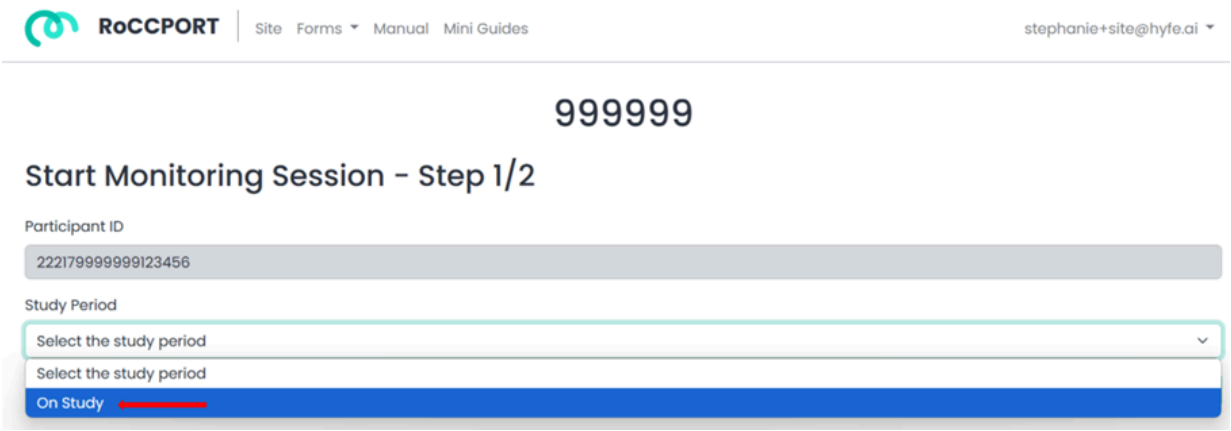


In case the research team enters the wrong Participant ID, continue to complete all the steps to start a monitoring session and complete a Data Correction Form (following steps in this manual in section Data Correction Form) once the participant has left the site.

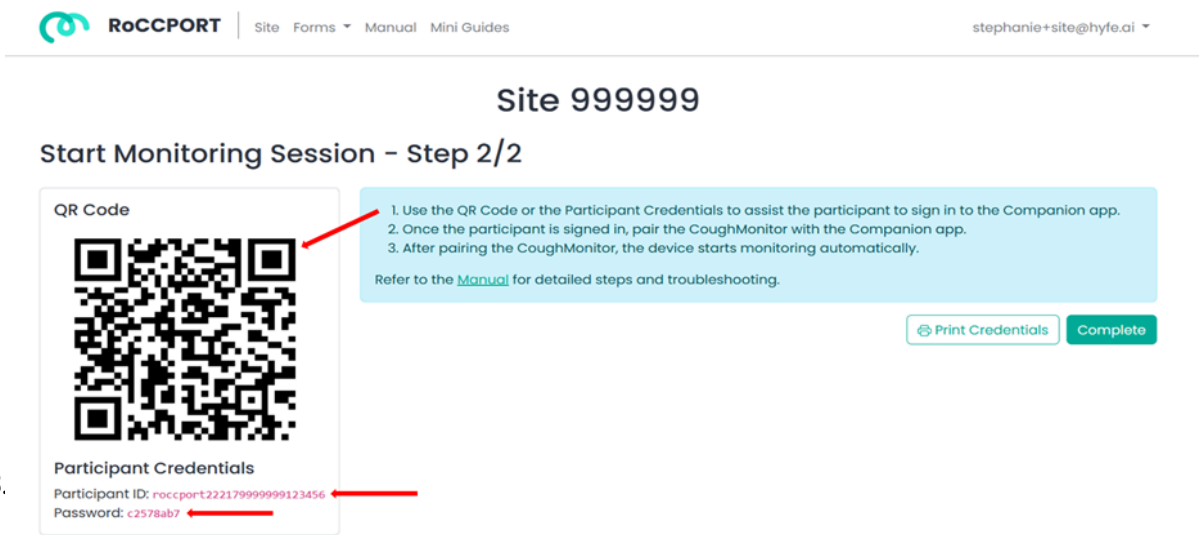
Annotating the Start of Monitoring Session

Once the start of the Monitoring Session is annotated in the Dashboard, cough monitoring will begin. Please only enroll a participant and start the session once the participant is ready to monitor.

1. To start a monitoring session, select the Study Period ("On Study") and Participant ID in the Dashboard. Then click the "Next" button.

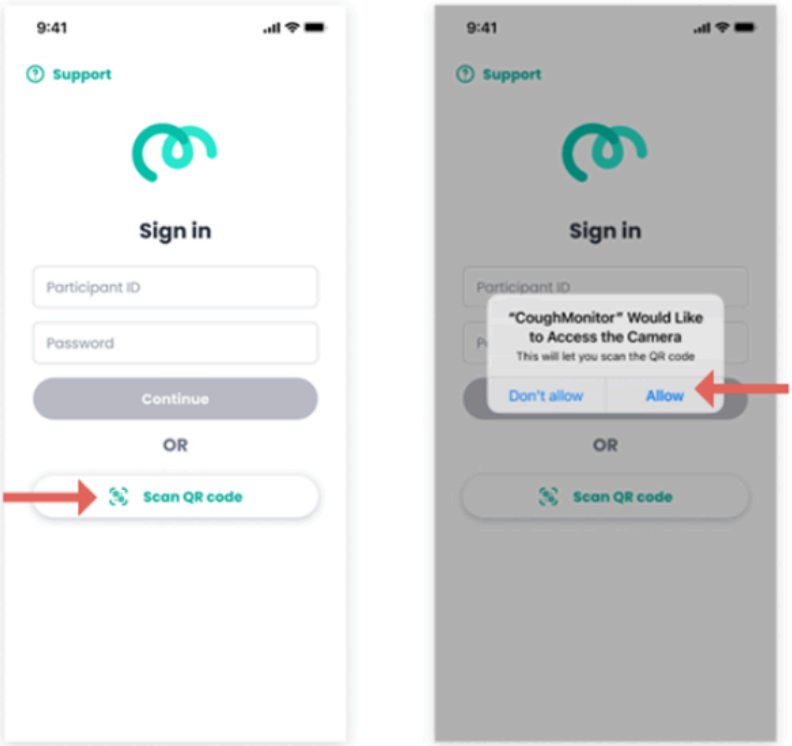


2. A QR Code will be displayed that can be used to sign in to the Companion app. Alternatively, the research team can use the Participant ID and Password shown below the QR Code to sign in. See the next section Signing in to the Companion app, for more details. You can also print the credentials.

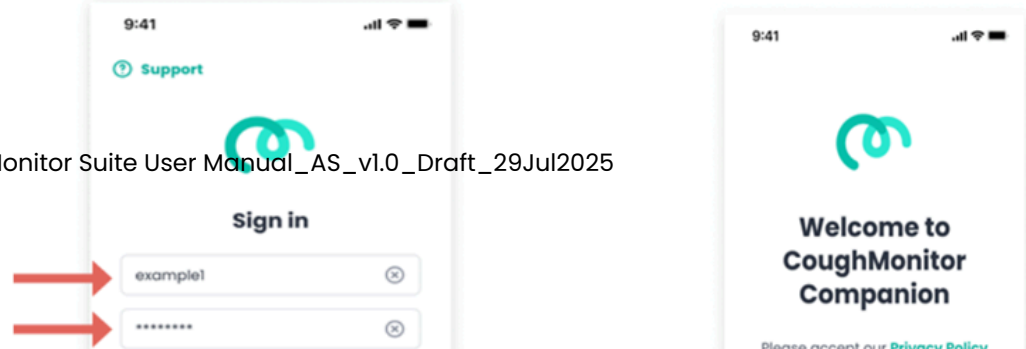
3. 

Signing In to the Companion app

1. Ask the participant to open the Companion app, tap “Scan QR Code” and tap “Allow” to access the camera. Then scan the QR code shown in the Dashboard.

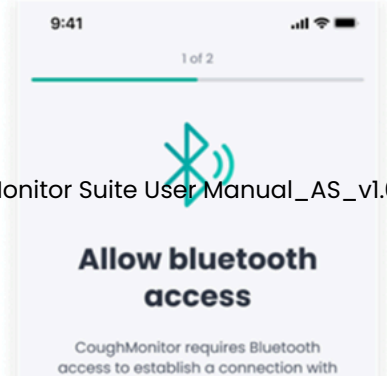


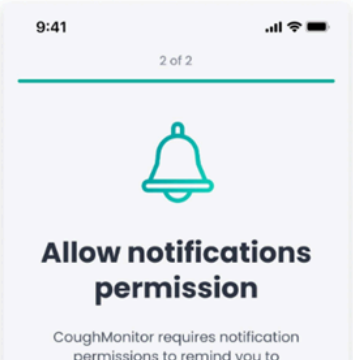
Alternatively, ask the participant to open the Companion app. Provide the Participant ID and password to the participant, ask them to enter both in the dedicated field boxes and then tap “Continue.”



2. Once the participant has signed in using one of the two methods, they will see the welcome screen. Ask the participant to read and accept the Privacy Policy and Terms of Use before tapping the “I read and understood” button. To go back to the app, click the arrows on the top left of your phone screen, or simply swipe from left to right to change the display back to the app.

3. After tapping “I read and understood,” the participant will be asked to grant access to Bluetooth and notifications.





4. Once these permissions are granted, the participant will see the screen below, which means they are signed in.

Pairing CoughMonitor with the Companion app

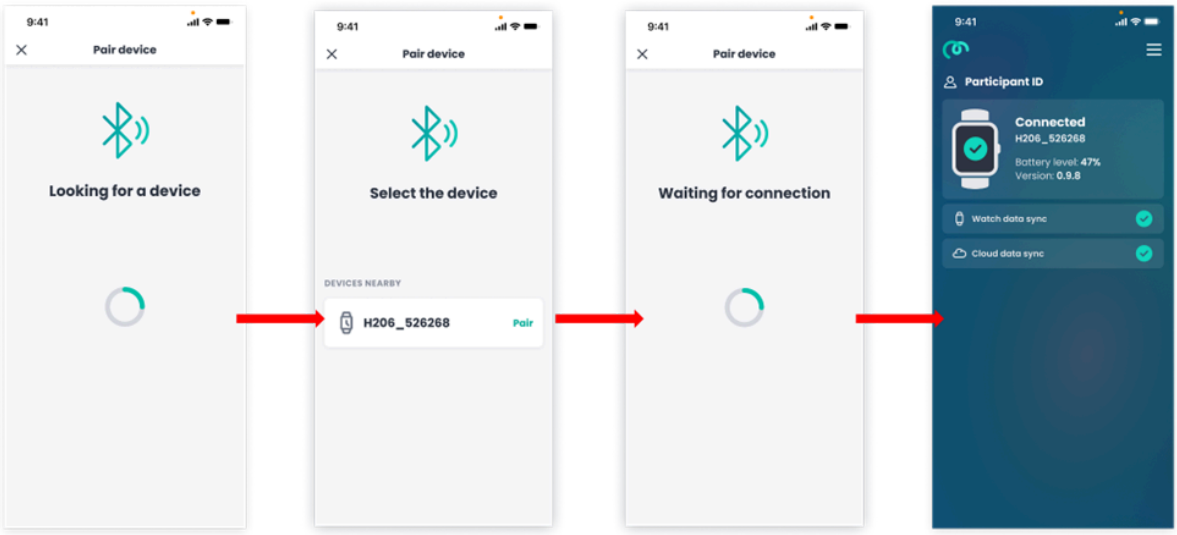
To pair the CoughMonitor with the Companion app, follow the steps below.

1. Ask the participant to wear the CoughMonitor comfortably on their wrist by letting it rest above the bone, tight enough to only move about an inch up or down, but not too loose to hinder wrist movement. It should be worn above the bone so the hand can flex.

2. Before asking the participant to pair the CoughMonitor and the Companion app, ensure the phone has an Internet connection, either through mobile data or Wi-Fi. Once the participant has confirmed they have Internet access, ask them to tap “Pair with device.” If internet connection is slow, allow for extra time after tapping “Pair with device” to ensure pairing occurs.

At this point, the app will search for the CoughMonitor via Bluetooth, and it will show the CoughMonitor's Unique Identifier (format: H206_######) on the Companion app's screen once the device is detected. This number should match the number on the bottom of the screen of the CoughMonitor. Note that in the case there are multiple CoughMonitors nearby, multiple Unique Identifiers will show up. The research team should only select the Unique Identifier that also appears in the participant's CoughMonitor's screen.

3. Ask the participant to tap "Pair" next to Unique Identifier and wait until the CoughMonitor and Companion app are successfully connected as shown in the images below.

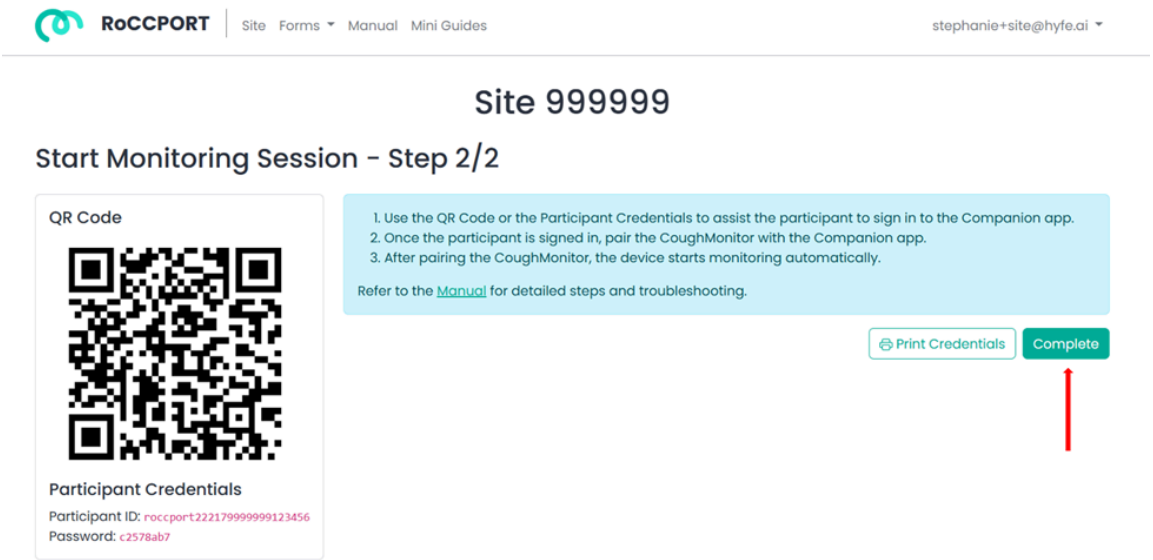


You may be asked for a pairing pin. A pin will appear on the CoughMonitor. Confirm this number in the Companion app, shown below.

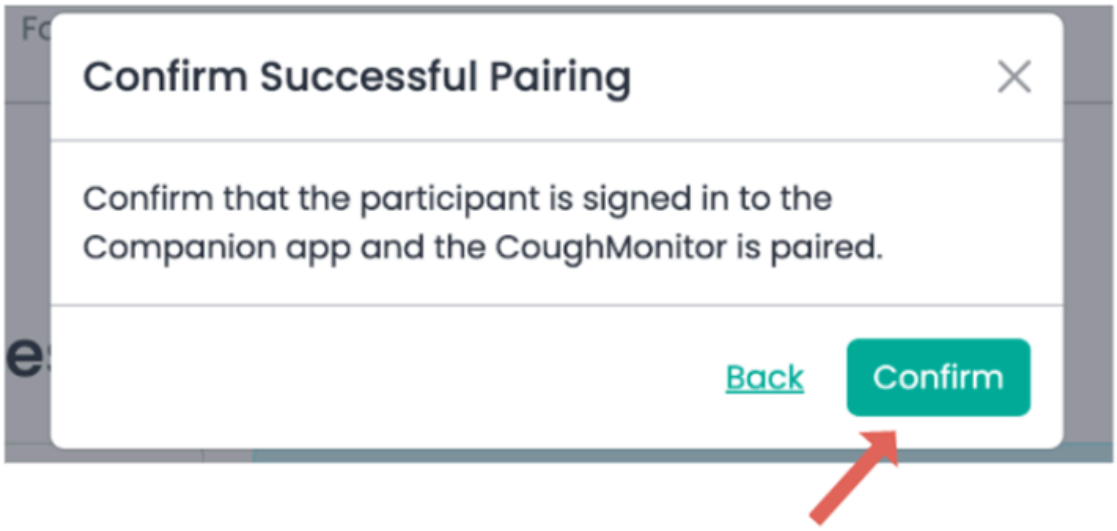
The CoughMonitor will start monitoring automatically once the CoughMonitor is successfully paired with the Companion app.

Confirming Pairing in the Dashboard

Once the CoughMonitor is paired, the research team should go back to the Dashboard and click “Complete “shown in the screen below.

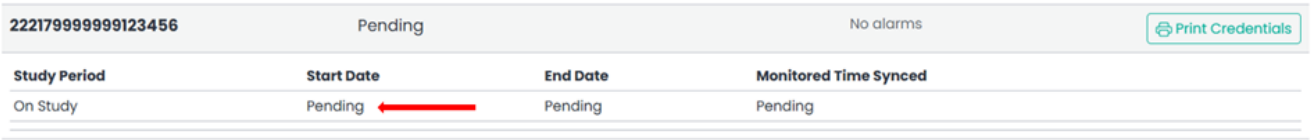


A pop-up message will appear asking the research team to confirm that pairing is completed. Click “Confirm.”



Once the “Confirm” button is clicked, the dashboard will automatically reload the Participant List again.

The 'Start Date' column will populate once the first data is synced, indicating the date and time when the CoughMonitor started monitoring. Until the first data is synced, the 'Start Date' will show as 'Pending.' The 'Time Monitored Synced' will also populate as soon as the first data is synced, and it displays the total duration of the data that has been synced so far. Please see guidance on syncing in the Monitoring Data Synchronization Section below.

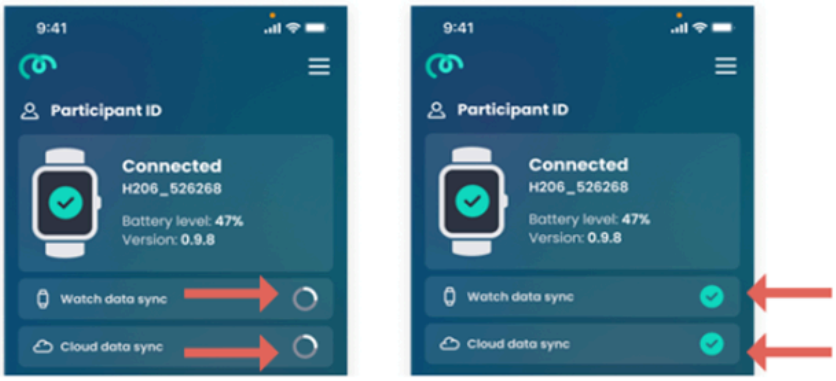


During a Cough Monitoring Session

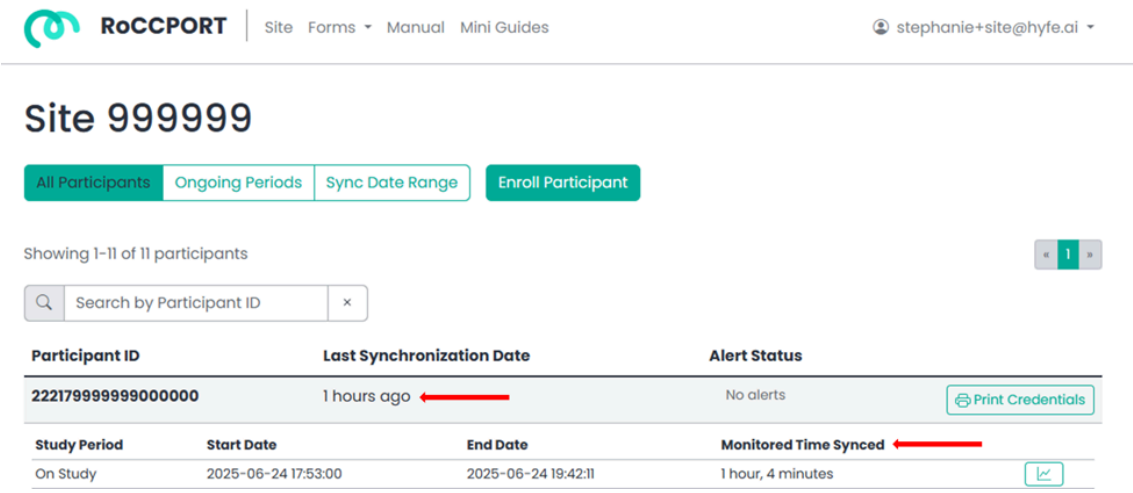
How Data Synchronization Works

Periodically, when the CoughMonitor and paired phone are in close proximity, timestamps are transmitted from the CoughMonitor to the Companion app via Bluetooth. Then, when the phone is connected to the Internet, timestamps are transmitted from the Companion app to the cloud. Data synchronization happens automatically once participants open the app. The participants should be instructed to open the app daily.

The status of synchronization is shown on the home screen of the Companion app with two icons, "Watch data sync" and "Cloud data sync".

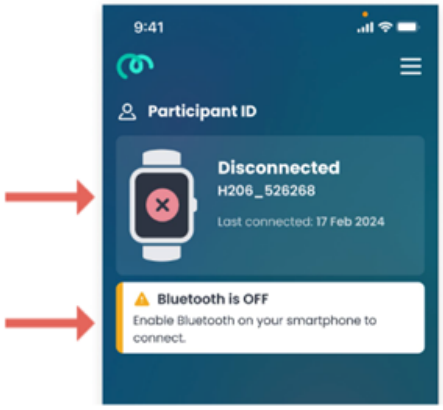


In the Dashboard, data synchronization is indicated as follows:

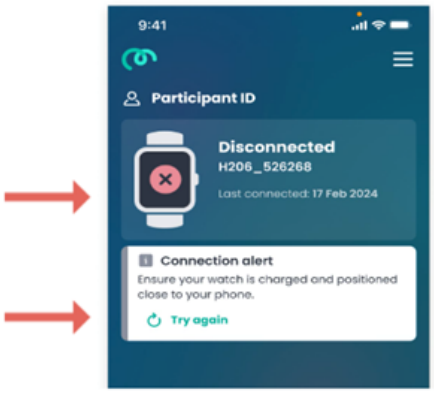


When the CoughMonitor Gets Disconnected

It is anticipated that the participant will not always be in close proximity to the phone, and this is not a concern. As long as the CoughMonitor displays “Monitoring is ON,” coughs are being detected. The CoughMonitor will routinely reconnect with the Companion app when the devices are next to each other and when the participant opens the Companion app on their phone.



If the participant disables Bluetooth on the phone, the Companion app will show a “Disconnected” status. A connection alert will prompt the participant to enable Bluetooth again. Once Bluetooth is re-enabled, and the CoughMonitor and phone are near each other, the CoughMonitor will pair automatically. No additional actions are required from the participant. No data is lost while the CoughMonitor is “Disconnected.”



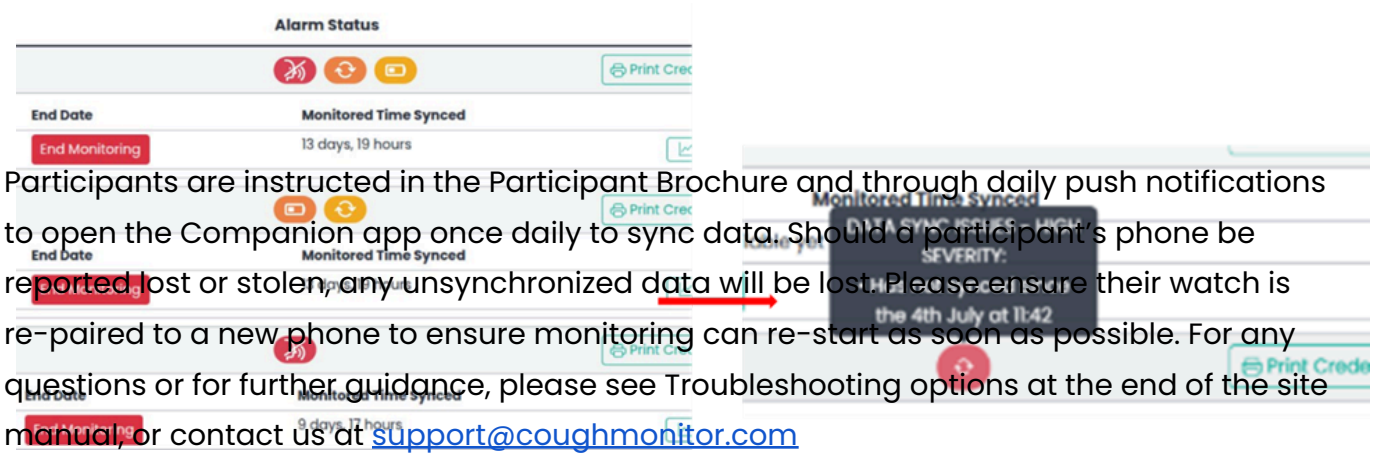
If the devices (CoughMonitor and phone) are far from each other, exceeding Bluetooth’s maximum range, or if the CoughMonitor runs out of battery, a notification will inform the participant of the temporary disconnection. Once the devices are within Bluetooth’s range and/or the CoughMonitor is charged, the CoughMonitor will automatically reconnect. If the CoughMonitor does not reconnect automatically, the participant can tap “Try Again” on iOS or “Retry” on Android to force reconnection.

CoughMonitor will continue to detect coughs all the time if the screen shows” ON,” even when the device is “Disconnected” from the Companion app.

Monitoring Data Synchronization

Data synchronization happens automatically whenever the CoughMonitor and phone are in close proximity and the Companion app is open. To ensure data is regularly synchronized during a cough monitoring session, there is a daily email alert to the research team whenever data has not synchronized for more than 36 hours for a specific participant. The alert system is operational whenever the CoughMonitor is actively monitoring coughs.

Alert icons are also displayed on the dashboard. Hover over the icon with the computer mouse to see detailed information about the alert and contact the participant if necessary.



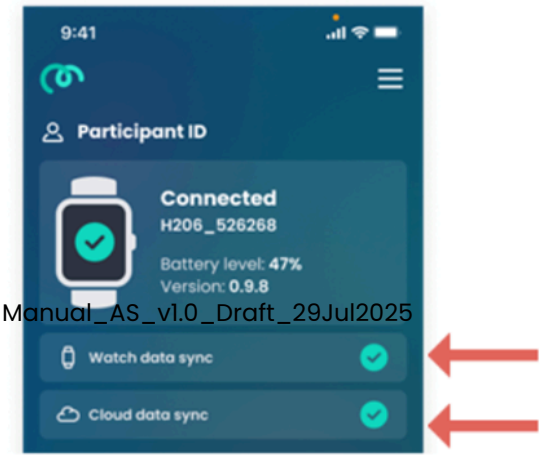
Participants are instructed in the Participant Brochure and through daily push notifications to open the Companion app once daily to sync data. Should a participant's phone be reported lost or stolen, any unsynchronized data will be lost. Please ensure their watch is re-paired to a new phone to ensure monitoring can re-start as soon as possible. For any questions or for further guidance, please see Troubleshooting options at the end of the site manual, or contact us at support@coughmonitor.com

If data hasn't been synchronized for more than 36 hours, the research team will receive an email. Upon receiving the email, the research team should contact the participant and check the following:

Ask the participant:	**If the answer is no:**
Is the Companion app open on their phone?	Ask them to open the Companion app

Is Bluetooth enabled on their phone?	Ask them to enable Bluetooth on their phone
Does the phone have Internet connectivity?	Ask them to turn on mobile data or connect their phone to Wi-Fi
Are the CoughMonitor and phone in close proximity to one another?	Ask them to put the CoughMonitor on their wrist and to keep their phone nearby
Does the CoughMonitor display "ON"?	Ask them to charge the CoughMonitor, open the Companion app, and ensure the CoughMonitor shows as “Connected” in the Companion app

When all the conditions above are met, data synchronization should resume; however, this could take a few minutes. Instruct the participant to not close the app until both watch and cloud data are synchronized, as shown by the green ticks in the image below.



To ensure data synchronization has resumed, the research team should log into the Dashboard after contacting the participant and check the “Last Synchronization Date” column. If data has been synchronized since contacting the participant, the “Last Synchronization Date” will be recent. In the case that data is not synchronizing, the research team should send an email to support@coughmonitor.com providing the Participant ID and confirming that data has not been synchronized after contacting the participant and checking the information in the table above.

Ending a Cough Monitoring Session

To end the monitoring session, ensure:

1. All data has been synced on the app by the participant by instructing them to open the Companion app and sync until two green ticks appear
2. The research team annotates the end of the session in the dashboard.
3. The research team unpair the CoughMonitor and the Companion app.

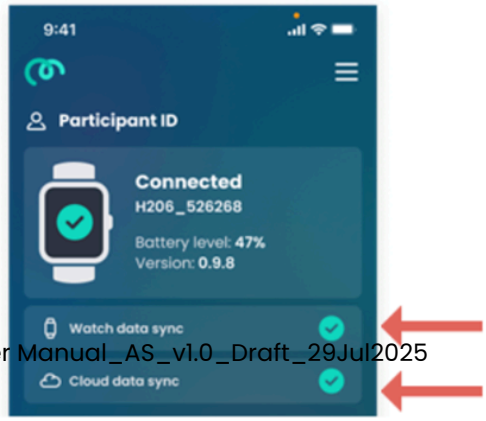
Final synchronization of data

The participant should open the CoughMonitor app and sync any final data from the watch to the app. For detailed steps, please follow the steps outlined in the How Synchronization Works section of the manual.

Annotating the End of a Cough Monitoring Session in the Dashboard

Once the session is completed, the research team should open the Dashboard and check if the 'Last Synchronization Date' is the same as or later than the 'End Date.' If this is confirmed, the data has fully synced for the On Study monitoring session and no action is required. However, if this is not confirmed, data isn't fully synced, and the research team must contact the participant and ask them to:

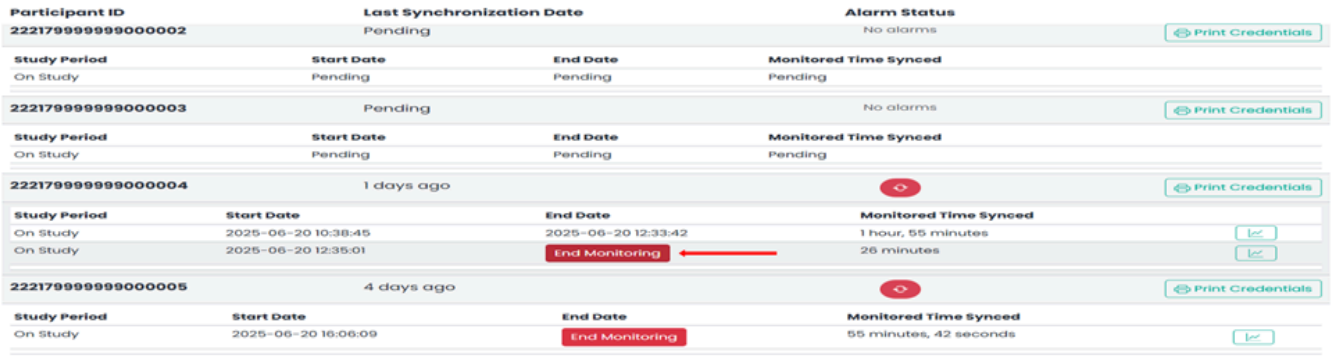
- Have the phone where Companion app is installed nearby
- Check the phone has Bluetooth enabled and has network connectivity (Wi-Fi or data)
- Open the Companion app and the phone
- Wait a few minutes until the status of both Watch and Cloud data sync both show green tick marks next to them as shown below



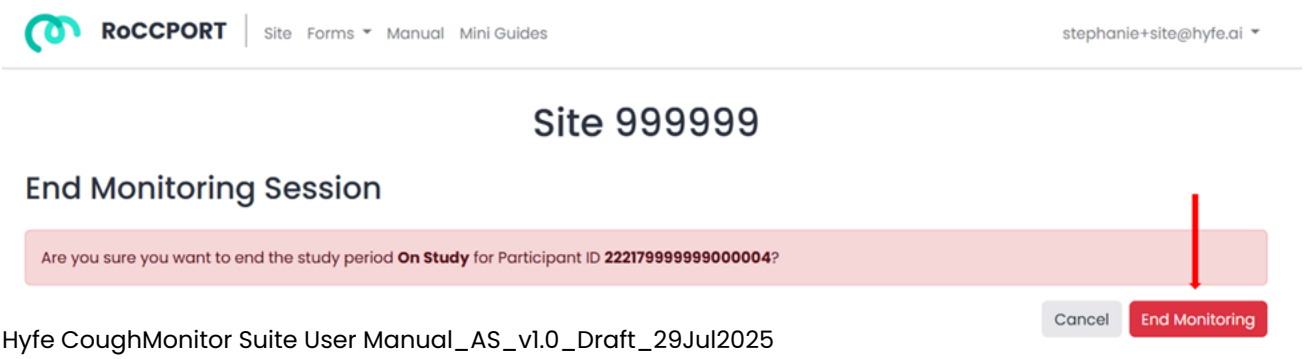
In the case that data doesn't synchronize after a few minutes, the research team should send an email to support@coughmonitor.com providing the Participant ID and confirming that data has not been synchronized after contacting the participant and checking the information in the table above.

Before starting the process to unpair the CoughMonitor and the Companion app, the research team should open the Dashboard on a computer (please see Access to the Dashboard section for instructions on how to sign in to the Dashboard).

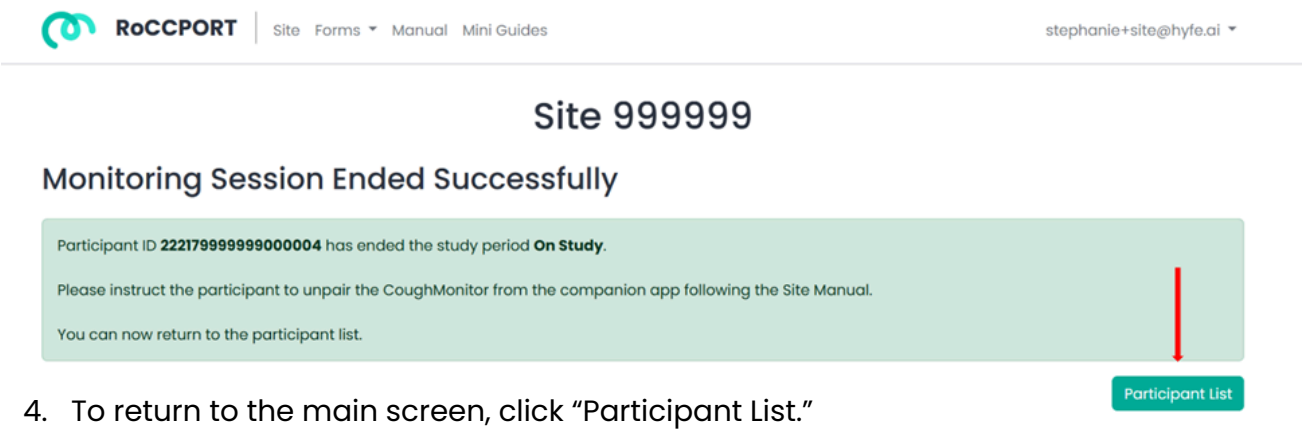
1. After signing in, find the Participant ID of the participant that needs to end the session and click the red button "End Monitoring."



2. When "End Monitoring" is clicked, the message below will appear asking to confirm the selected study session should be ended. Click "End Monitoring."



3. The end of the monitoring session will be confirmed with the screen below.



4. To return to the main screen, click "Participant List."

In case the research team forgets to annotate the end of a monitoring session, let the Hyfe team know and we can manually delete any additional data.

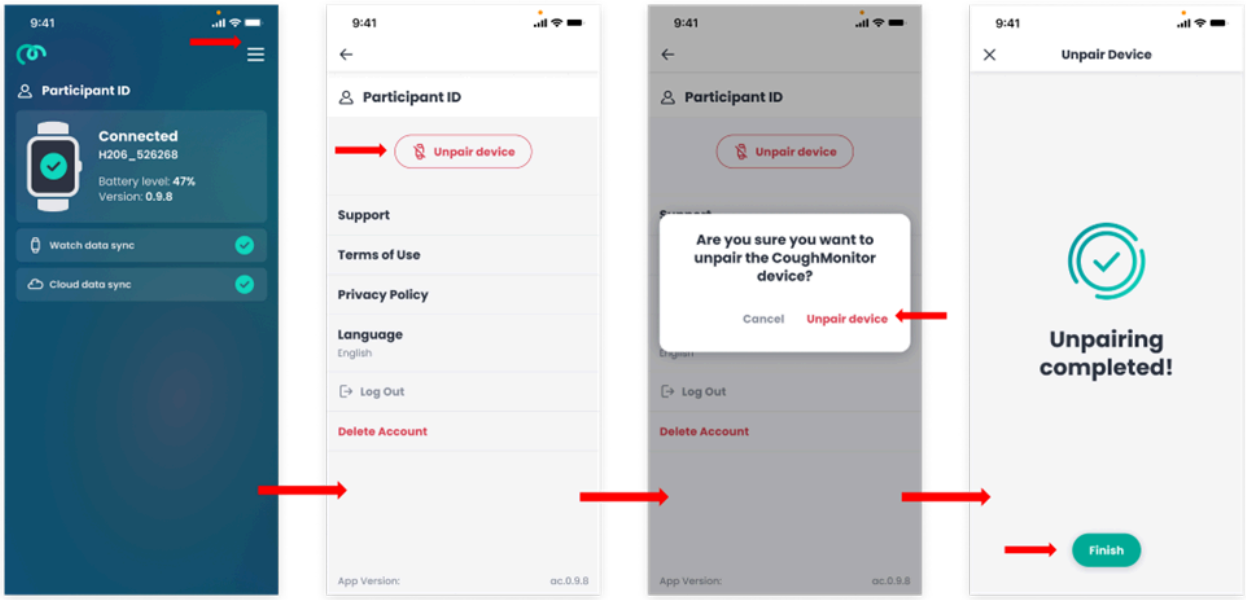
Unpairing the CoughMonitor

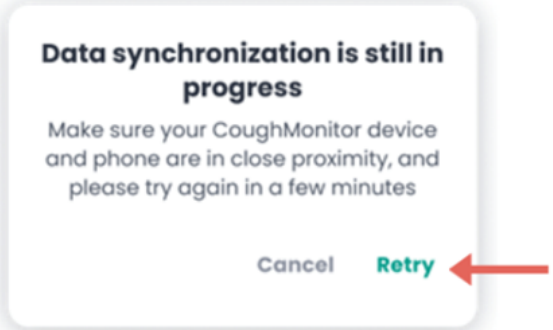
To unpair the CoughMonitor from the Companion app, first check the following 3 requirements:

1. Bluetooth is enabled on the phone
2. The phone is connected to the Internet
3. The CoughMonitor and phone are in close proximity

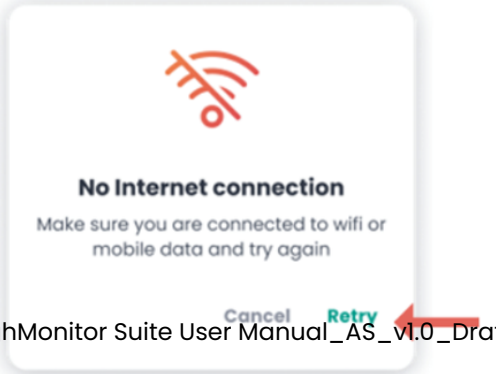
To unpair, ask the participant to open the Companion app, then tap the menu located in the upper right corner of the screen as indicated below, and tap "Unpair device." By selecting this option, cough monitoring will cease automatically. Once unpairing is completed, tap "Finish" to return to the home screen.

Do not request account deletion, as it is not a necessary step for unpairing. Simply unpairing and logging out after ending the monitoring session on the dashboard will stop monitoring. Participants can also delete the app through their home page on their phone. Should a participant accidentally request account deletion, please get in touch with us by emailing support@coughmonitor.com





If there is data that needs to be synchronized when trying to unpair, the screen to the left will appear. Leave the CoughMonitor and phone in close proximity and wait a few minutes. Then tap “Retry” and complete unpair



If the phone has no Internet connectivity, the screen to the left will display. Access

the phone settings to connect the phone to mobile data or Wi-Fi and press “Retry” once the phone is reconnected.

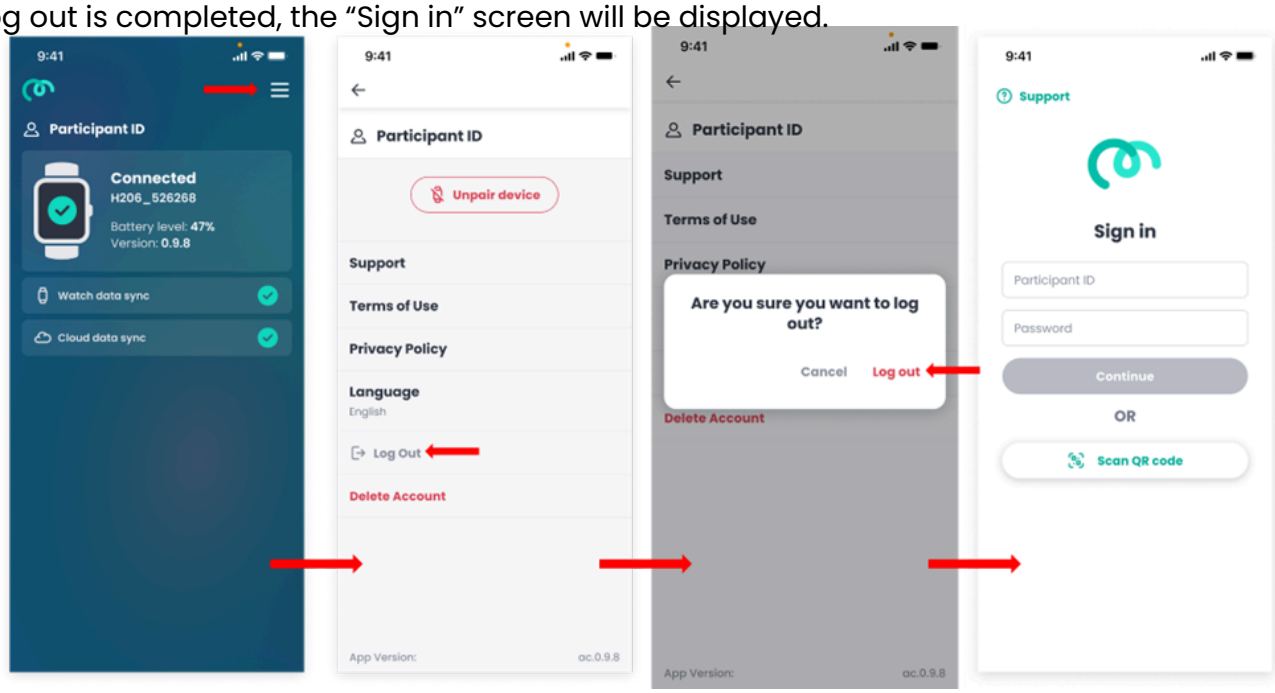
If the CoughMonitor is “Disconnected” from the Companion app when trying to unpair it, the screen to the left will appear. Tap “Ok” and ensure the CoughMonitor and phone are in close proximity before trying to unpair again.

If Bluetooth is not enabled when trying to unpair, the screen to the left will appear. Tap “Ok” and access phone settings to enable Bluetooth before trying to unpair again.

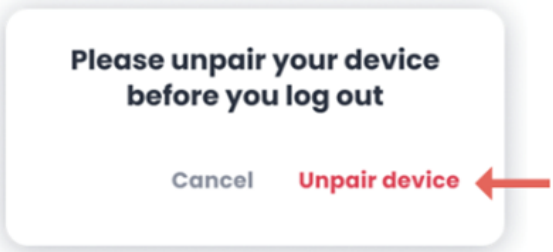
Logging Out from the CoughMonitor Companion app

Once the CoughMonitor is successfully unpaired from the Companion app, ask the participant to proceed to log out from the app. Tap the menu in the upper right corner of the

screen (see left image below). Then tap “Log out” (see the middle image below). Once the log out is completed, the “Sign in” screen will be displayed.



In case the participant tries to log out before unpairing the CoughMonitor, the screen below will appear on the phone. Tap “Unpair device” to complete unpairing and then log out.



Uninstalling the Companion app

The Companion app should only be uninstalled from the participant’s phone when cough monitoring is no longer required. For example, if a participant withdraws or at the end of the study. If participants require support to uninstall the Companion app, follow the steps below:

For Android:

1. Open the app drawer: From the home screen, swipe up from the bottom of the screen to access all your apps

2. Find the app: Scroll through the list and locate the app you want to delete

3. Long press the app icon: Tap and hold the app icon until a menu appears

4. Select “Uninstall”: Tap on “Uninstall” or the trash bin icon that appears

5. Confirm deletion: Tap “OK” or “Uninstall” in the confirmation dialog

For iOS:

1. Locate the app: Find the app you want to delete on your home screen

2. Long press the app icon: Press and hold the app icon and a menu will open

3. Press Remove app at the top of the menu

4. Select “Delete app”

5. Tap “Delete app”

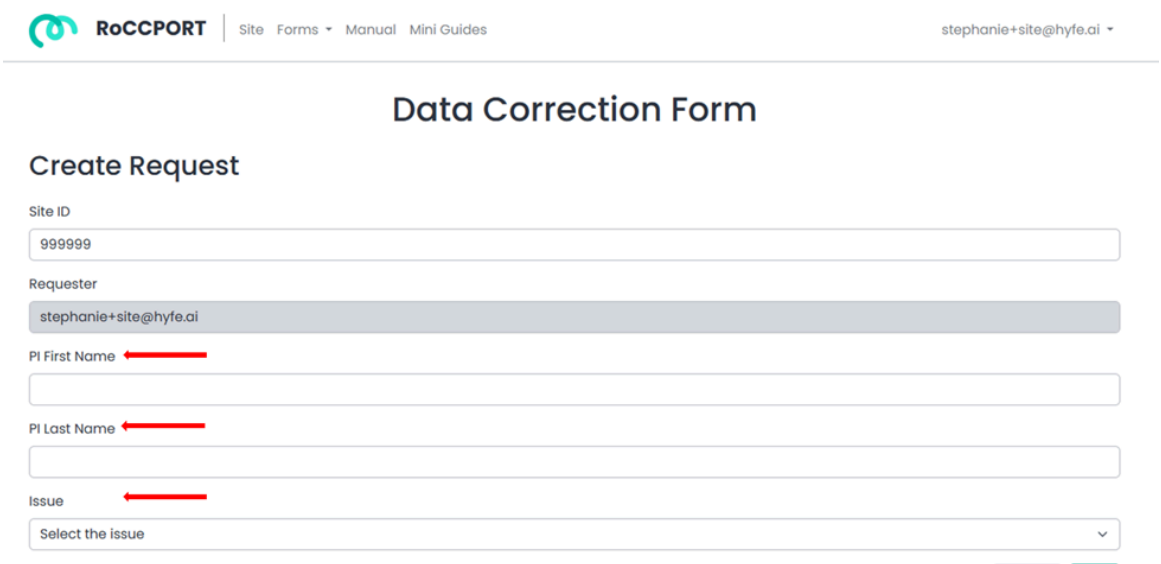
Data Correction Form

Sites are instructed to submit a Data Correction Form (DCF) in the Dashboard if any of the following issues occur at the start, during, or at the end of a monitoring session:

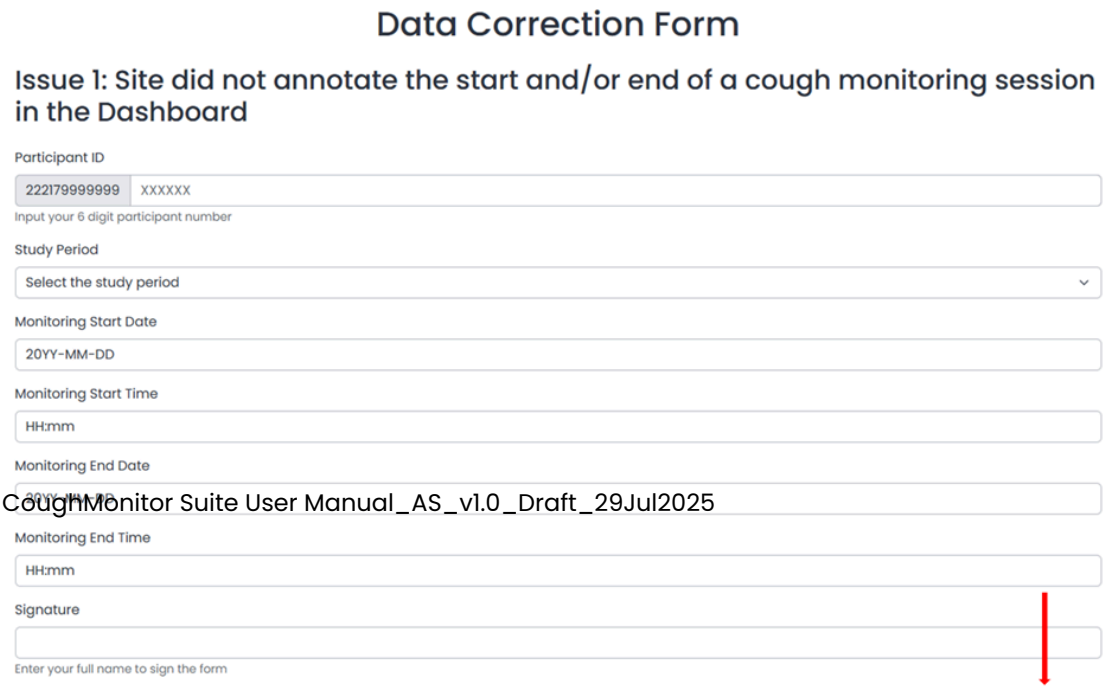
1. Site did not annotate the start and/or end of a cough monitoring session in the Dashboard
2. Site entered the wrong Participant ID in the Dashboard but did not pair the CoughMonitor or start a monitoring session
3. Site entered the wrong Participant ID in the Dashboard and started a monitoring session
4. Site annotated the end of a monitoring session after unpairing the CoughMonitor
5. Other

To submit a DCF, the site staff need to log in to the Dashboard and click “Data Correction Form”.

The form below will be displayed. Site ID and the requester’s full name will appear automatically. If the PI has designated another Investigator to complete the form, but the PI retains responsibility for the data change, provide the PI’s first and last name. Finally, select the issue and click “Next.”



The next screen will display the data required to correct data in the database. Below is the form for Issue #1 as an example. Once data is entered, click “Submit Form”.



Once the DCF has been completed, it will appear in the Dashboard DCF log.

Participant Instructions

Initial Set of Instructions

The research team should start by going through the Participant Brochure and explaining to the participants what the CoughMonitor Suite is and its components (Companion app and CoughMonitor).

After an overview has been given, the research team should sign the participant into the Companion app and pair the CoughMonitor following the steps outlined above in section Pairing CoughMonitor with the Companion app. This will initiate the cough monitoring session.

The research team should ask the participant to always keep the Companion app open in the background, unless directed to close it during troubleshooting. They should also instruct the participant to charge the watch each night by their bedside.

Set of Instructions Once the CoughMonitor Is Paired

Once the monitoring is initiated, the research team should give more detailed instructions on what participants should do during waking and sleeping hours, and what a participant should do if the CoughMonitor runs out of battery.

Instructions During Waking Hours

1. The research team should ask the participants to follow these instructions:
2. Wear the CoughMonitor on the wrist consistently throughout the day
3. Charge each night at their bedside
4. Continue to wear it directly on the wrist and try and take off heavy clothing once inside/ somewhere warmer
5. The CoughMonitor is waterproof and can be worn while showering or bathing, however, it should not be submerged in water for longer than 30 minutes or deeper than 3 feet/90cm.
6. The CoughMonitor must not be exposed to extreme temperatures, i.e. not outside the range of -20℃ to 50℃ / -4℉ to 122℉.

Instructions During Sleeping Hours

The research team should ask the participants to follow these instructions regarding use during sleeping hours:

1. Use the provided USB charger cable to connect the CoughMonitor to the USB port
2. Double-check that the USB charging cable is securely connected to the CoughMonitor before sleeping. When the magnetic contacts between the CoughMonitor and the charger are engaged, a secure connection has been made
3. While charging at night, ensure the CoughMonitor remains within 3 feet (90cm) of their mouth by charging it near their bedside. The CoughMonitor continues to collect data while charging. Check if participants have an outlet within the maximum distance from their bed, or they can use an extension to be within the required distance.

In case the CoughMonitor is damaged, lost or stolen, the participant should contact the research team.

Instructions if the CoughMonitor runs out of battery

The only time when monitoring might be stopped during a cough monitoring session is if the CoughMonitor's battery becomes fully depleted. If the CoughMonitor's battery is fully

depleted, it will disconnect from the Companion app. To check if this has happened, ask participants to follow the steps below:

1. Charge the CoughMonitor
2. Ensure the phone's Bluetooth is enabled
3. Open the Companion app
4. Check if the Companion app shows as "Connected." If the Companion app shows "Disconnected," check the Troubleshooting section at the end of the manual.

Set of Instructions for Ending a Cough Monitoring Session

The research team will assist participants to end the cough monitoring at the following times:

1. Remotely after the enrollment period for all participants
2. In the event a participant withdraws from the study

The research team will guide participants how to end a cough monitoring session by unpairing the CoughMonitor and following the steps in this manual in section Ending a Cough Monitoring Session. Participants should not end a cough monitoring session without the research team guidance.

To end a cough monitoring session remotely, the research team should contact the participant and ask them to follow the steps in the Logging Out from the CoughMonitor Companion app section of this manual.

1. Sync the watch with the CoughMonitor Companion app
2. Go to menu
3. Click Unpair watch
4. Click Log out

To end a cough monitoring session, the research team should follow these steps with the participant:

1. Unpair the CoughMonitor from the Companion app
2. Log out from the Companion app

3. Uninstall the Companion app

Practice Session

Should the research team want to practice using the CoughMonitor Suite before enrolling a participant, a practice site can be added through the dashboard and the following steps should be taken:

- Take a CoughMonitor out of the box and charge for at least 1 hour or until it reaches 50% charge, utilizing the USB cable charger provided
- Download the Companion app to your phone, once the Companion app is installed on the phone, open the Dashboard.
- Click "Enroll Participant"
- Confirm 'On Study' study session and enter a fake Participant Number to create a QR code. Then, complete the sign in process in the Companion app
- Once you are signed in to the Companion app, pair the CoughMonitor
- Once the CoughMonitor is paired, confirm pairing completion in the Dashboard
- Put the CoughMonitor on your wrist and wear it for at least 1 hour
- After 1 hour or more, open the Companion app and check the status of Data Synchronization is "Synced" or wait until it shows "Data Synced"
- Log into the Dashboard
- Locate the row with the Participant ID you used for the test and click "End Monitoring"
- Check that the "Start Date" and "End Date" are correct
- Log out from the Dashboard
- Unpair the CoughMonitor from the Companion app
- Log out from the Companion app
- Clean the CoughMonitor using alcohol (up to 70%) wipes

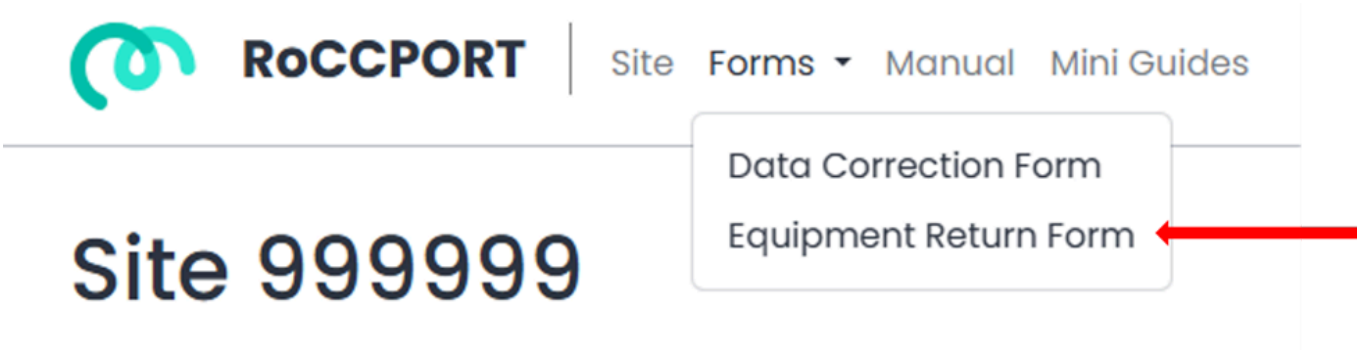
Returning Equipment to site

The research team is responsible for contacting participants at the end of the Device Loan Agreement to facilitate the return of the CoughMonitor.

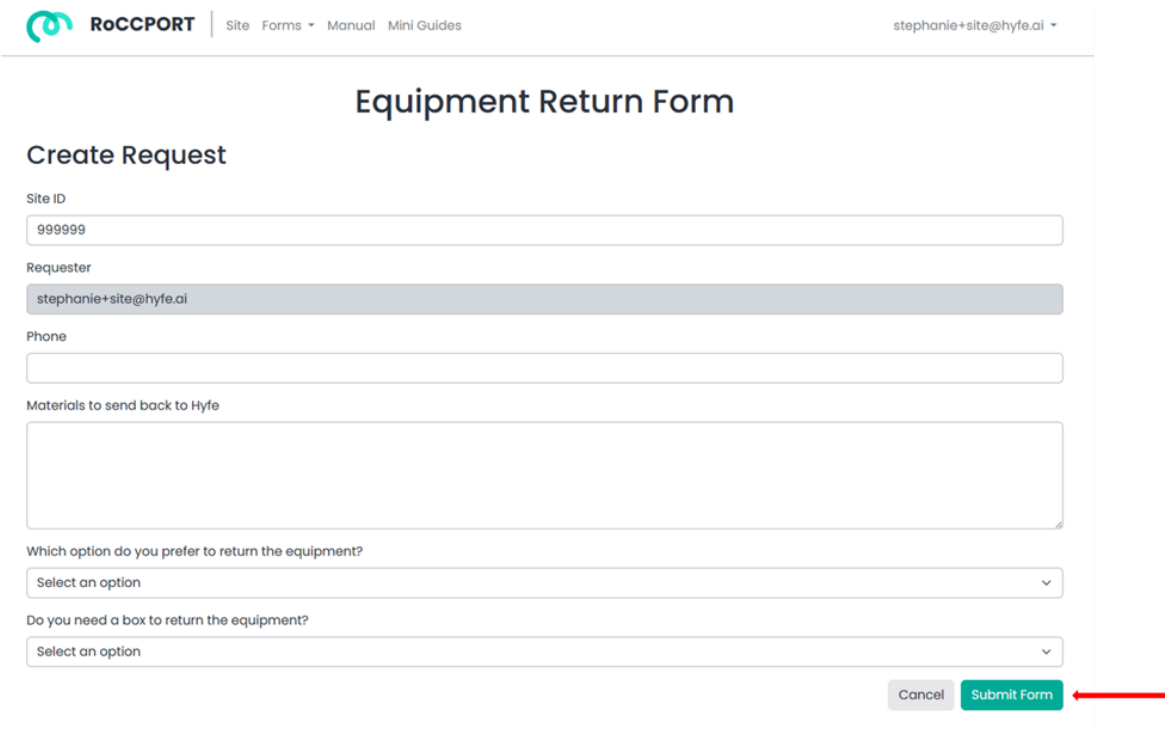
If a participant does not respond at the end of their monitoring session, the research team should outreach to the participant three times to facilitate the return. If at the third outreach the participant is still not reachable, please inform the Hyfe team.

Return Shipment Process

Once enrolment is closed, the research team should log in to the Dashboard and complete the 'Equipment Return Form' located in the Forms menu below:



The following form will be displayed. Complete the information and click "Submit Form."



Upon the form is received by Hyfe's team, the research team submitting the form will be sent a prepaid postage label to send the equipment back.

Note: if any equipment is damaged, lost or stolen during the study, participant should contact the research team. The research team should then notify Hyfe at support@coughmonitor.com

Troubleshooting

Problem	Step-by-Step Solutions

CoughMonitor does not turn on	• Ensure the CoughMonitor is charging, and the magnetic side of the charging cable has made contact with the CoughMonitor's charge port
CoughMonitor does not charge	• Ensure the magnetic side of the charging cable has made stable contact with the CoughMonitor's charge port
After entering the Participant ID and password to sign into the Companion app, the app displays this error message: "Invalid ID"	• Open the Dashboard, find the participant ID and click the "Print Credentials" green button located on the right side of the screen to visualize the Participant ID and password. • Re-enter the ID and password in the Companion app
After entering ID and password in the Companion app, the app displays this message: "User ID and password does not match"	• Open the Dashboard, find the participant ID and click the "Print Credentials" green button located on the right side of the screen to visualize the Participant ID and password. • Check the participant ID and associated password, re-type the ID and password, and tap "Continue"
After tapping "Pair with device" on the Companion app, the app displays this message: "No devices found"	• Ensure the CoughMonitor is next to the phone • Ensure the CoughMonitor battery is charged to at least 50% • Open the Companion app on the phone and tap "Retry"

After tapping “Pair with device” on the Companion app, the app displays this message: “Bluetooth is OFF”	• On the phone, tap “Go to Settings” and enable Bluetooth. Open the Companion app and tap “Pair with device”
The app displays this message: “Your device might be defective, please contact the study coordinator for help”	• Contact Hyfe Support
Participant has uninstalled the Companion app during a cough monitoring session	• Ask the participant to re-install the Companion app and sign in with the Participant ID they were using previously found on the dashboard • Ask the participant to pair the CoughMonitor to the Companion app
The CoughMonitor screen displays “OFF”	• Confirm the CoughMonitor is being charged • Confirm Bluetooth is enabled on the phone • Open the Companion app • Tap the “Try Again” button to force reconnection • Close and open the Companion app • Wait 2 minutes and check if the CoughMonitor shows as “Connected” in the Companion app • Check if the CoughMonitor’s screen shows “ON”

CoughMonitor cannot be unpaired from the Companion app	• Confirm phone's Bluetooth is enabled • Confirm phone has an internet connection • Confirm phone and CoughMonitor are in close proximity • Open the Companion app and confirm data is "Synced" • Confirm that the "Try Again" button does not show on the home screen of the Companion app. If the button is displayed, tap "Try Again" and wait a few minutes until it disappears • Try to unpair the CoughMonitor
The participant's phone that has the Companion app is broken or missing	• Contact Hyfe Support at support@coughmonitor.com
The participant has tapped the "Delete Account" button in the Companion app	• Contact Hyfe Support at support@coughmonitor.com

After the CoughMonitor has run out of battery and the participant has tried to reconnect the CoughMonitor to the Companion app, the Companion app shows “Disconnected”	• Open the Companion app and tap “Try again”
	• If the CoughMonitor does not show “Connected”, close and open the Companion app. To close the app, follow these steps:
	  ▪ If using an Android: Swipe up from the bottom of the screen to bring up the app tray, hold, then let go (swipe up on the app to close), alternatively press the virtual button to bring up the “open apps” switcher, before swiping up on the app to close.
	  ▪ If using an iPhone: Swipe up to the middle of the screen and hold under you can see the app switcher, then swipe right/left to find the app (swipe up on the app's preview to close the app)
	• Wait 2 minutes and check the CoughMonitor shows “Connected” on the participant’s Companion app

The participant is using the Companion app on their personal phone and needs to switch to a new different personal phone	• Check if the new phone is iOS version 16 or above or Android version 12 or above.
	• If the new phone meets the requirements, open the Dashboard and print the participant's credentials.
	• Contact the participant and guide them through the following steps:
	  ▪ Have the CoughMonitor nearby
	  ▪ Open the Companion app and check it's synced
	  ▪ Unpair the CoughMonitor and log out of the Companion app.
	  ▪ Install the Companion app on the new phone.
	  ▪ Sign in to the Companion app on the new phone by using the participant ID and password from the participant's credentials previously printed.
	  ▪ Accept the Privacy Notice and Terms and Conditions
	  ▪ Allow access to Bluetooth and give notification permissions
	• Pair the Coughmonitor with the Companion app on the new phone.

Technical Support - Quick Links

For technical support and customer service, visit the Help Center:
https://support.hyfe.ai/help-center/coughmonitor-suite

Or contact: support@coughmonitor.com

To access the Dashboard: http://cms.hyfe.ai