

Hyfe Mini Guides

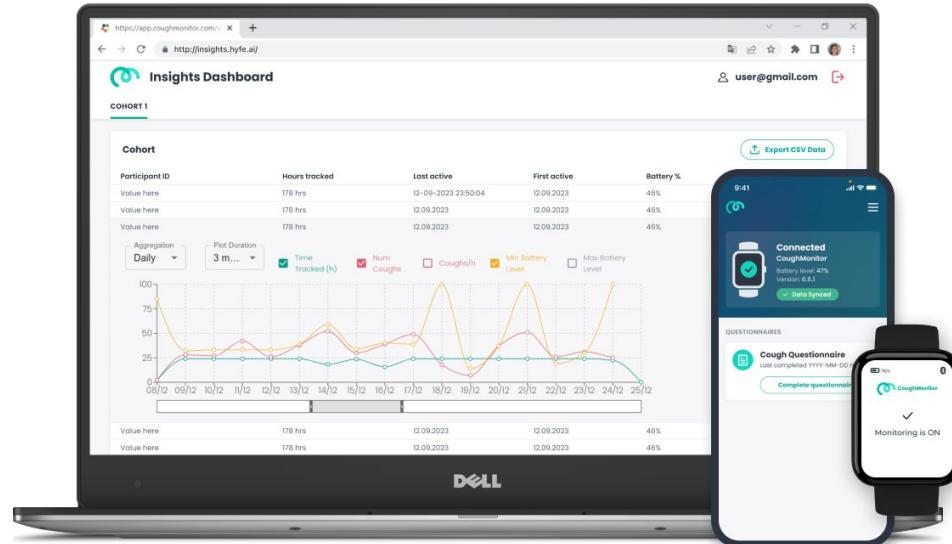
Study Site Staff

SPONSOR NAME
STUDY NAME
Protocol Number:



**CoughMonitor
Suite**

MINI GUIDES



Operating Instructions

Mini Guide



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Operating Instructions

Mini Guide

Power Management The battery lasts ~80 hours, and when depleted, the device powers off automatically (there is no manual power button, the device powers back on upon charging)

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 it is within 3 feet (90 cm) of the participant's mouth



Starting a Cough Monitoring Session

Mini Guide

Starting a Cough Monitoring Session

Mini Guide

1

Is the participant's phone running on Android 12 (or higher) or iOS 15 (or higher)?

- Yes – use the participant's phone
- No – participant cannot be enrolled in the study

2

Download the Companion App by searching for "CoughMonitor Companion"

- Android - Google Play Store
- iOS - App Store (ensure "Background App Refresh" is enabled)

3

Enroll a participant in the Dashboard

- I. Sign into (link tbd) on a computer
- II. Click "Enroll Participant"
- III. Enter the *Participant Number* and click on "Enroll Participant"

The screenshot shows the ASPIRE dashboard under the 'Test Site' tab. In the 'Participants' section, there is one listed participant: '0001-001'. Below the participant list, there is a summary of the 'Study Period' and 'On Study' status. At the bottom right of the dashboard, there is a prominent green button labeled 'Enroll Participant'.

The screenshot shows the ASPIRE dashboard under the 'Test Site' tab. A modal dialog box titled 'Enroll Participant' is open. It contains fields for 'Study ID' (0001), 'Participant ID' (XXX), and 'Participant Number' (2-digit participant number). At the bottom right of the dialog box, there is a green button labeled 'Enroll Participant'.

The screenshot shows the ASPIRE dashboard under the 'Test Site' tab. A message box displays 'Participant ID 0001-001 was enrolled successfully. You can now start monitoring or return to the participant list.' At the bottom right of the message box, there is a green button labeled 'Start Monitoring'.

Starting a Cough Monitoring Session

Mini Guide

4

Annotate the start of a Monitoring Session

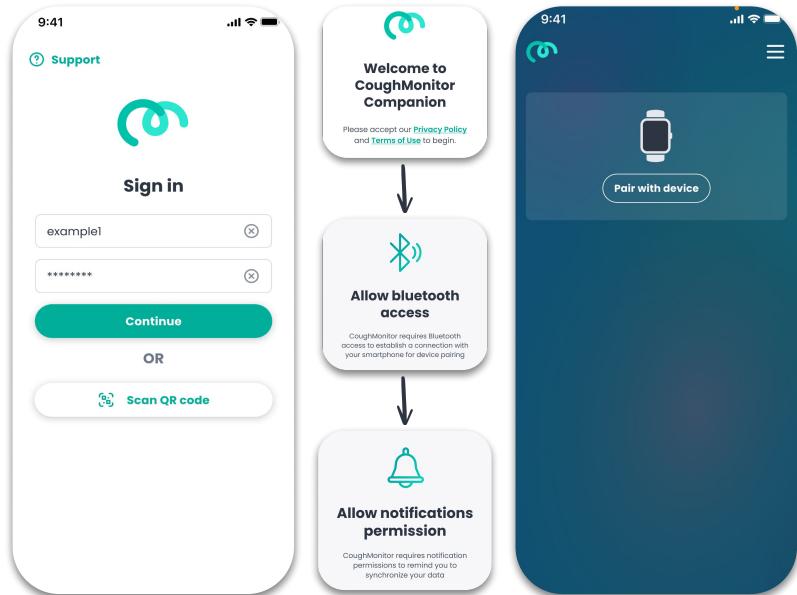
- I. On the Dashboard, confirm the *Study Period* and click “Next”
- II. A QR code, and ID + password will appear

5

Sign into the Companion App

Ask the participant to:

- I. Open the Companion App on the phone
- II. Login using either the QR code, or the ID + password (both visible on the Dashboard)
- III. Read and accept the Privacy Policy + Terms of Service
- IV. Enable bluetooth access and allow notifications



Starting a Cough Monitoring Session

Mini Guide

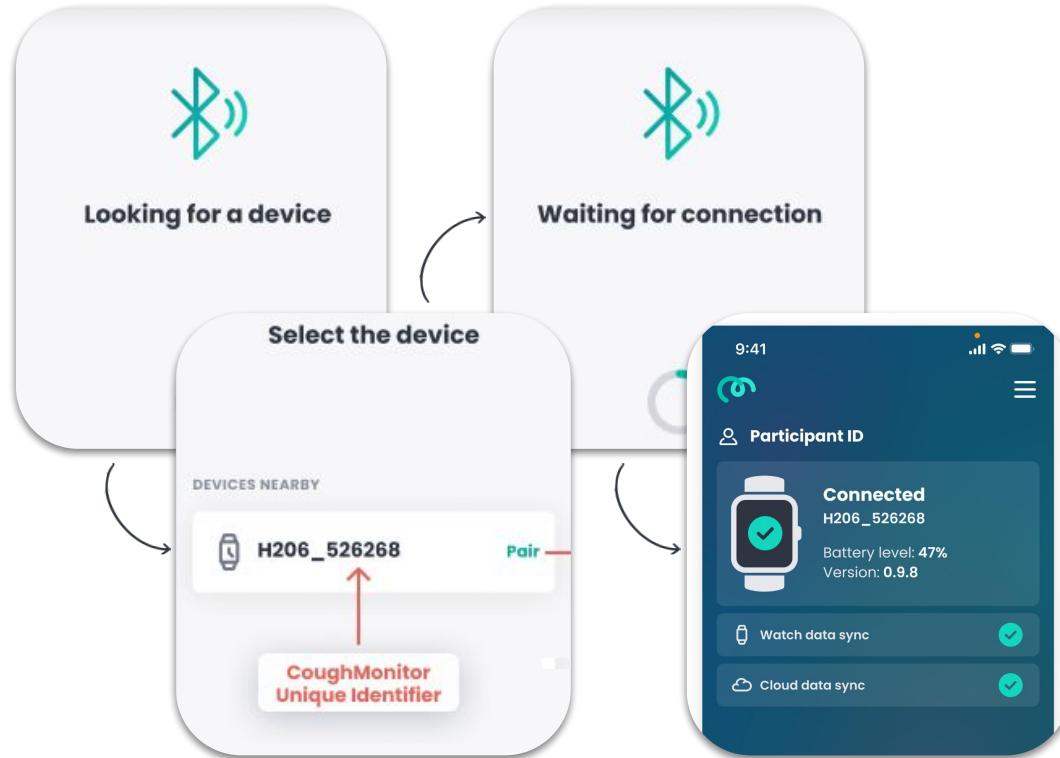
6

Pairing the CoughMonitor

Before starting the pairing process, please check and confirm the following...

- Bluetooth is enabled on the participant phone
- The phone is connected to the internet
- The CoughMonitor and phone are in close proximity

Open the Companion App and select “Pair with device”



Ensure the correct device is selected by **matching the 6 digit Unique Identifier** displayed on the CoughMonitor screen

Starting a Cough Monitoring Session

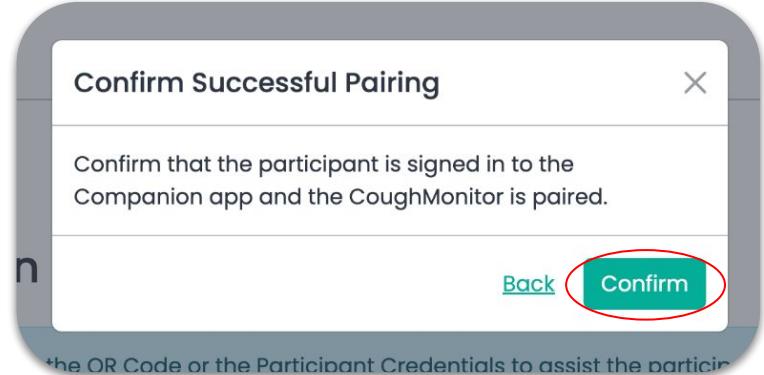
Mini Guide

7

Confirming Pairing is Complete

- I. Once paired, go back to the Dashboard and click "Complete"
- II. A pop-up message will appear asking to confirm pairing is completed
 - Click "Confirm" + "Participant List" to return to the main screen
- III. The *Start Date* column will populate once the first set of data is synced, indicating the date and time the CoughMonitor started monitoring

The *Start Date* will show as *Pending* until the first set of data is synced



During a Cough Monitoring Session

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During a Cough Monitoring Session

Mini Guide

How Data Synchronization Works

- Cough timestamps are transmitted from the CoughMonitor to the Companion App via Bluetooth
- Cough timestamps are transmitted from the Companion App to the Cloud
- The status on the Companion App will show as either "Syncing Data" or "Data Synced"

Data synchronization is automatic and participants do not need to take action



Viewing Data Synchronization in the Dashboard

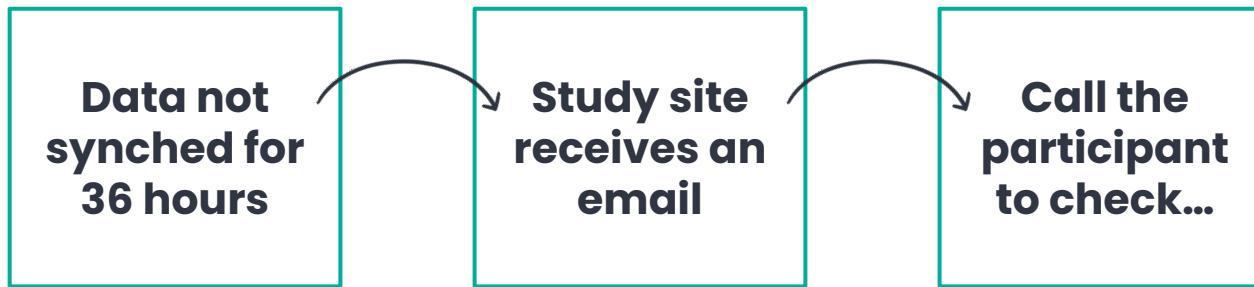
- "Last Synchronization Date" indicates the time when data was last synced
- "Last Synced Datapoint" indicates the time of the last datapoint which was synced
- "Monitored Time Synced" indicates the total time monitored and synced for the monitoring period

During a Cough Monitoring Session

Mini Guide

Monitoring Data Synchronization

- Data synchronization happens automatically whenever the CoughMonitor and the participant phone are in close proximity of each other
- To ensure data is regularly synced, there is an alarm to alert the study site whenever data has not synchronized for more than 36 hours



Companion App is open

The phone's Bluetooth is enabled

The CoughMonitor and participant phone are in close proximity

The phone is connected to the internet

The CoughMonitor shows "Monitoring is ON"

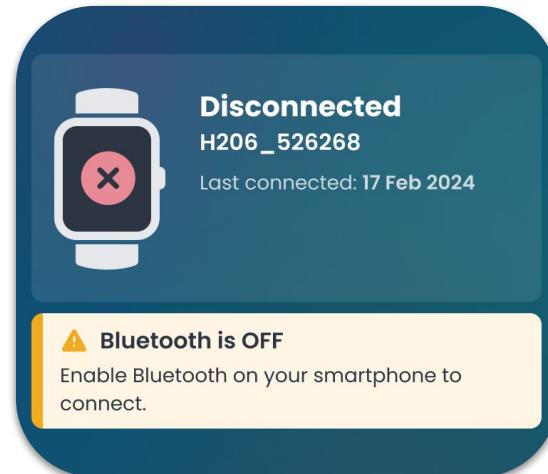
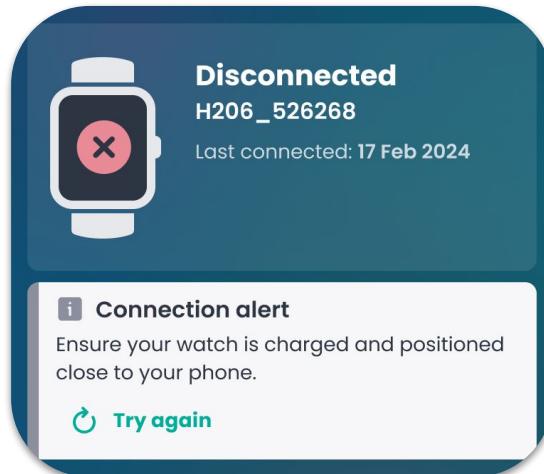
During a Cough Monitoring Session

Mini Guide

The CoughMonitor can become disconnected from Companion app when:

- Bluetooth is disabled
 - The Companion App will prompt the participant to enable Bluetooth
- The CoughMonitor battery is depleted
 - Once the CoughMonitor is charged and the Companion App is open, monitoring will resume

Please note that as long as the CoughMonitor displays as “Monitoring is ON” then coughs are being tracked, even if the Companion App states “Disconnected”



During a Cough Monitoring Session

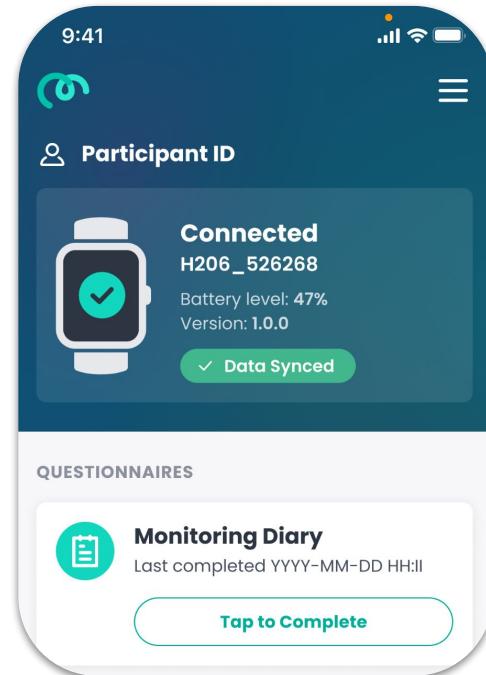
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Monitoring Diary

The Monitoring Diary tracks device adherence, identifying periods of non-wear longer than 1 hour, and should be completed in the mornings by the participants

- A daily app notification at 8:00 am local time reminds participants to complete the diary
- An email is sent to the study site at 12:00 pm local time if participants have not completed their diary

If an email alert is received, the study site should reach out to the participant and ask them to complete it



Was monitoring interrupted?

Excluding when the watch was being charged at your bedside, was there any period of one hour or more over the past 24 hours when you were awake but not wearing the watch?

Yes, in the morning

Yes, in the afternoon

Yes, in the evening

Yes, during the night

Ending a Cough Monitoring Session

Mini Guide

Ending a Cough Monitoring Session

Mini Guide

1

Annotating the end of a Monitoring Session

For Screening Period

- I. The “End Date” of a screening monitoring session will be annotated in the Dashboard automatically and indicated in the “End Date” column once the 72 hour period is completed
- II. Once the 72 hour period is completed, sites should open the Dashboard to ensure “Last Synced Datapoint” is **not before** the “End Date”, confirming data is fully synced. If data isn’t fully synced, sites should contact the participant and guide them through the steps in the Site Manual in section “Annotating the end of cough monitoring session”

For On-Study Period

- I. Sign into the Dashboard + find the participant ID of the participant whose session is ending
- II. Click on the “End Monitoring” button
 - o A message will appear asking to confirm
 - click “End Monitoring”
- III. Click “Participant List” to return to main screen

Ending a Cough Monitoring Session

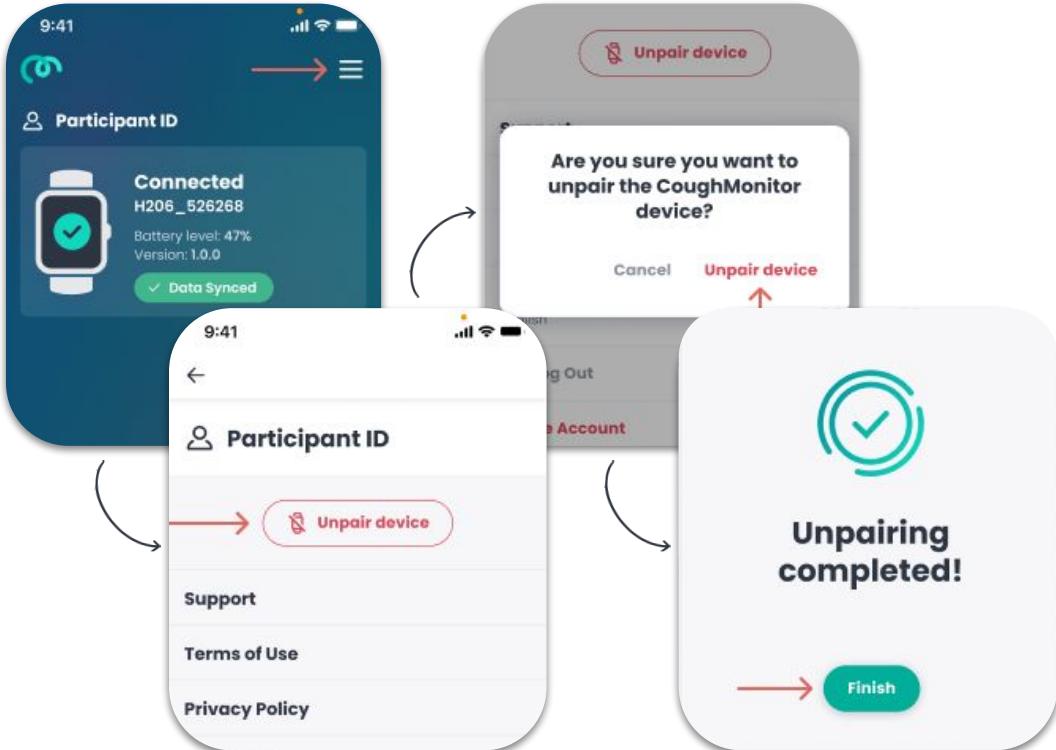
2

Unpairing the CoughMonitor

Unpairing can be done in person or remotely over the phone

Before starting the unpairing process, please check and confirm the following...

- Bluetooth is enabled on the participant phone
- The phone is connected to the internet
- The CoughMonitor and phone are in close proximity



If there is still data to sync, a message will appear prompting you to wait a few minutes (to allow sync) and then retry

Ending a Cough Monitoring Session

Mini Guide

3

Logging Out from the Companion App

- I. Once the CoughMonitor is successfully unpaired from the Companion App, the study site should ask the participant to log out of the app by tapping “Menu” in the upper right corner, and then tapping “Log Out”
- II. Once the log out is completed, the *Sign In* screen will be displayed

If the participant tries to log out before unpairing the CoughMonitor, a warning to “Unpair Device” will appear – tap “Unpair Device” to complete unpairing, and then log out



Participant Instructions

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Participant Instructions

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Use the **Participant Brochure** to help guide participants while they are using the CoughMonitor

During waking hours, the participant should:

- Wear the CoughMonitor consistently
- Avoid covering device with heavy clothing
- Not immerse the CoughMonitor in water
- Complete the Monitoring Diary every morning

During sleeping hours, the participant should:

- Charge the CoughMonitor at bedside within 3 feet (90 cm) of participant