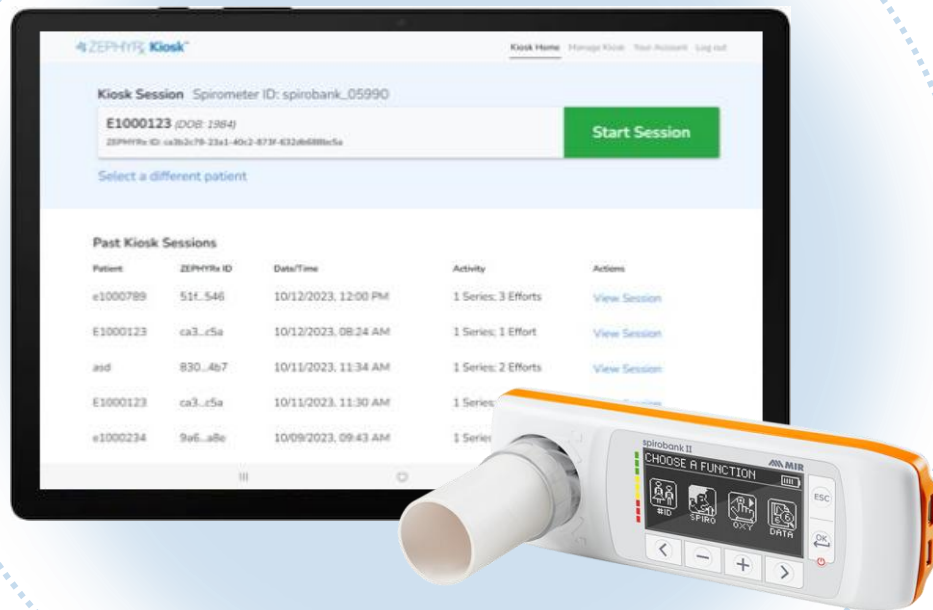




Platform User Guide

Seabreeze STAT COPD
V4.0
March 2026



Platform User Guide Outline

- ✓ Technology, Equipment, and Study Protocol Overview
- ✓ ZEPHYRx Provider Dashboard
- ✓ In-Clinic: Kiosk Spirometry & eCOA
- ✓ In-Clinic FeNO
- ✓ Home Tasks: Daily Diary, EXACT ePRO
- ✓ Viewing Participant Results & Alerts
- ✓ Support & Troubleshooting

Technology Overview

SCREENING & IN-CLINIC TESTING



- NiOX Panel app
 - In-clinic FeNO
- ZEPHYRx Kiosk app
 - In-clinic Spirometry
 - In-clinic eCOAs
 - CAT
 - SGRQ
 - EXACT

HOME TESTING



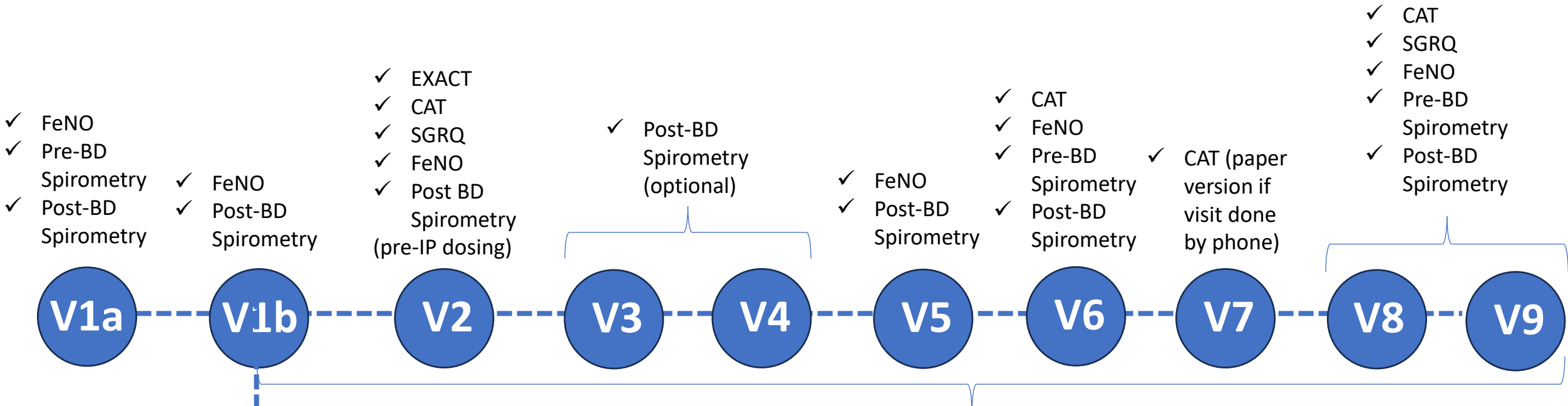
- COPD twice daily e-diary
 - SABA and nebulizer use
 - Dyspnea numerical rating scale (NRS)
- Daily EXACT-Pro symptom diary

Study Equipment Overview

What you will receive in your kit:

Endpoint	Item	Quantity
In-Clinic Spirometry & eCOAs	Spirobank Smart II (with charger)	1
	Samsung Galaxy A8 Tablet with the ZEPHYRx Kiosk App	1
	Disposable Turbine/Filter Combo	50
	Nose Clips	50
In Clinic FeNO	NiOX FeNO Device	1
	FeNO Filters (TK-100)	100
	Windows Surface Tablet with the NiOX Panel App	1

Protocol Overview



- ✓ Set current date as “start date” in dashboard
- ✓ Set up participant with Breathe Easy App on their phone and link their phone to the dashboard
- ✓ Home diary and Dyspnea Score Task Training

Evening Tasks (5pm – Midnight) beginning evening of V1b through evening of the day prior to V9

- ✓ COPD Daytime Symptom Diary; SABA/nebulizer use plus Dyspnea NRS (beginning evening of V1b)
- ✓ EXACT ePRO (beginning evening of V2)

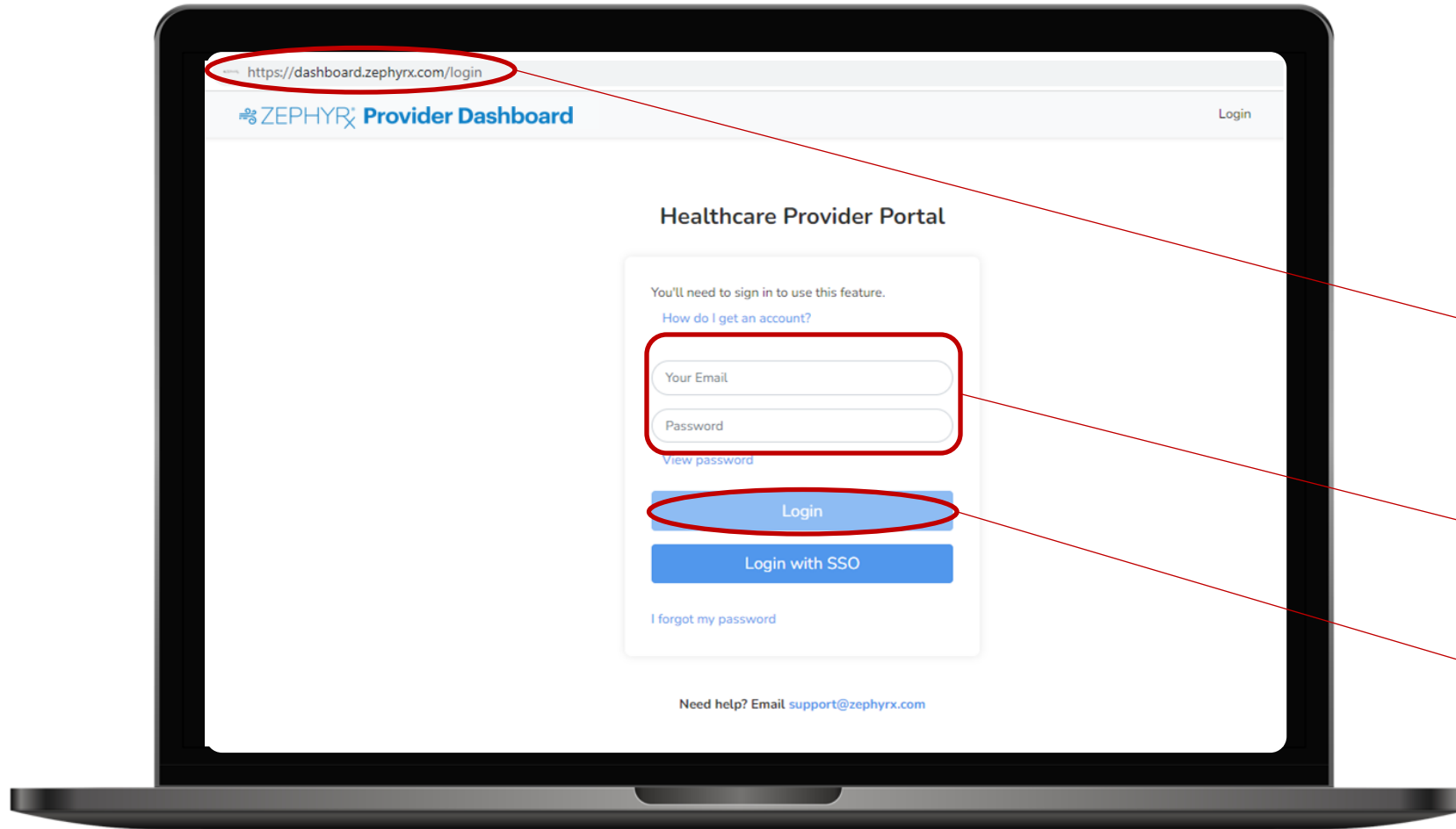
Morning Tasks (5am – Noon) beginning morning of V2 and ending morning of V9

- ✓ COPD Nighttime Symptom Diary: SABA/nebulizer user plus Dyspnea NRS



Provider Dashboard

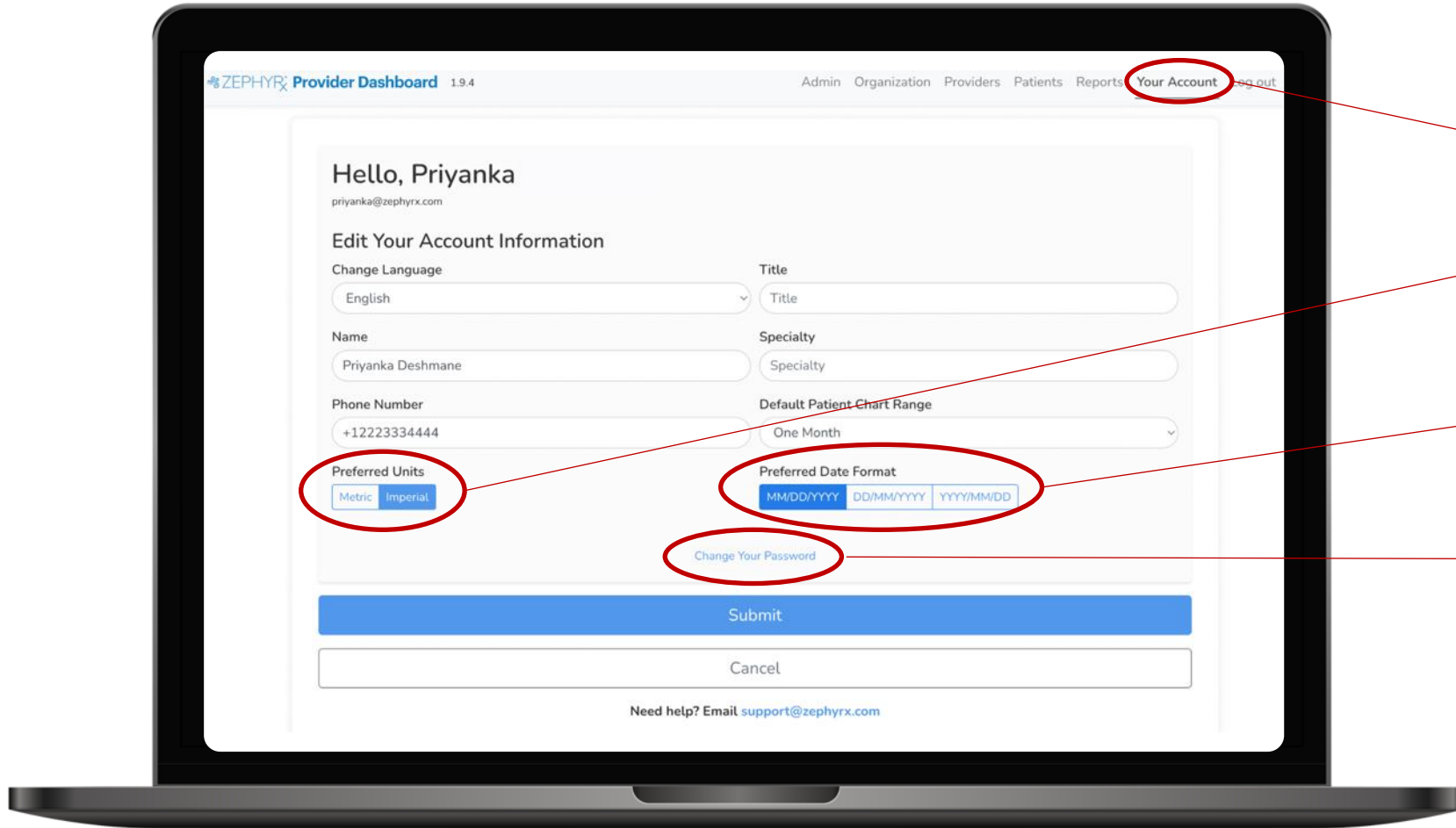
Login to Provider Dashboard



The dashboard can be accessed from any laptop or computer with a modern internet browser. We recommend Google Chrome, or Microsoft Edge

- ✓ Visit URL:
dashboard.zephyrx.com/login
- ✓ Enter your **email and password**
- ✓ Select **Login**

Your Account

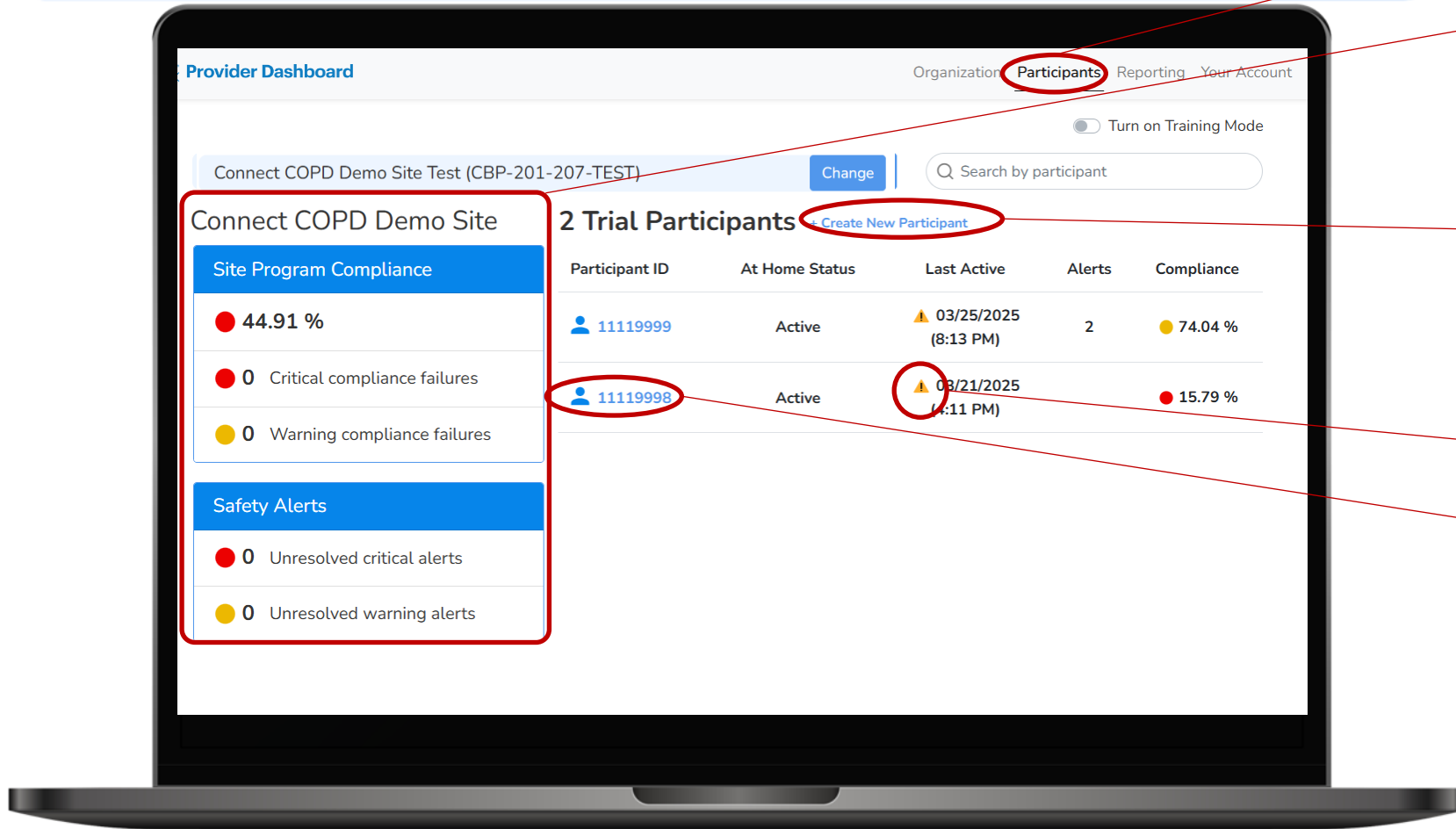


- ✓ Select **Your Account**
- ✓ Choose **Preferred Units**
- ✓ Choose **Preferred Date Format**
- ✓ Change **password** if needed

Site Dashboard Overview

Connect COPD Demo Site Test (CBP-201-207-TEST)

Change



- ✓ Select **Participants** tab
- ✓ View site-level **compliance and safety alerts**

✓ **Create New Participant**

✓ Alert icon indicates a **participant has been offline for >24 hours**



✓ Select **Participant ID** to view participant dashboard >>

Create A New Participant

The image shows a laptop screen with the 'Provider Dashboard' for 'Connect Bio Asthma Demo (CBP-201-206-TEST)'. The dashboard includes a 'Site Program Compliance' section with a 44.91% compliance rate and a 'Safety Alerts' section with 0 unresolved critical and warning alerts. A table shows 2 trial participants. A red box highlights the '+ Create New Participant' button. Overlaid on the laptop is a 'Create New Participant' form with the following fields:

- Study ID:** 1111001
- Height:** Height (cm) cm
- Weight:** Weight (kg) kg
- Sex At Birth:** Not Selected
- Ethnicity:** Not Selected
- Birth Month:** Not Selected
- Birth Year:** Not Selected
- SpirometerID:** At-Home Spirometer ID (optional)

At the bottom of the form are two buttons: 'Create Participant' and 'Cancel'.

- ✓ Study ID: 4-digit site ID, 3-digit subject ID (e.g. 1111001)
- ✓ Enter all demographics
- ✓ Leave Spirometer ID Blank
 - ✓ Participants will not conduct home spirometry



In-Clinic Kiosk Spirometry

In Clinic Assessment Notes and Preparation:

In Clinic Assessments should be completed in the following order:

- CAT
- SGRQ
- FeNO
- Pre-BD Spirometry, then Post-BD spirometry (preferably in the morning)

Prior to Visit, Participant's should aim to:

- Avoid smoking for at least 1 hour prior to and during spirometry and FeNO.
- Avoid caffeinated drinks (tea/coffee) at least 2 hours prior to spirometry.
- Avoid eating a large meal at least 2 hours prior to spirometry.
- Avoid eating/drinking at least 1 hour prior spirometry and FeNO.
- Avoid strenuous exercise for ≥ 2 hours prior to spirometry.

In Clinic Assessment Notes and Preparation:

Pre-BD and Post-BD Spirometry

- No repeat pre-BD spirometry testing is needed if the participant's best effort (with coaching) was >1 second. If the Investigator thinks the participant cannot perform the pre-BD assessment, only the post-BD assessment should be performed.
- If the participant can tolerate BD washout at Visit 6, Visit 8, Visit 9, and on the day of discharge (only for hospitalized participants), pre-BD spirometry will be performed prior to administering maintenance COPD medication(s).
- Screening Visit 1a pre-BD and post-BD spirometry may be repeated up to 3 times within 2 weeks if there are either spirometry errors/overread failures or the participants do not meet spirometry inclusion criteria parameters.
- Participants who fail or are unable to perform spirometry assessments from Visit 5 onwards (for post-BD) and from Visit 6 (pre-BD) onwards may repeat the assessment.

In Clinic Assessment Notes and Preparation:

Withholding Usual COPD Maintenance Medications

Withhold the morning dose of regular COPD maintenance medications on the morning of pre-BD spirometry, **except** when treatment is needed for an acute COPD exacerbation (refer to study protocol for further details):

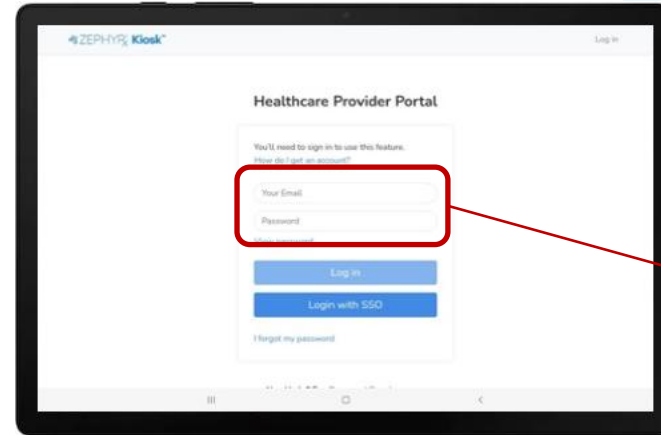
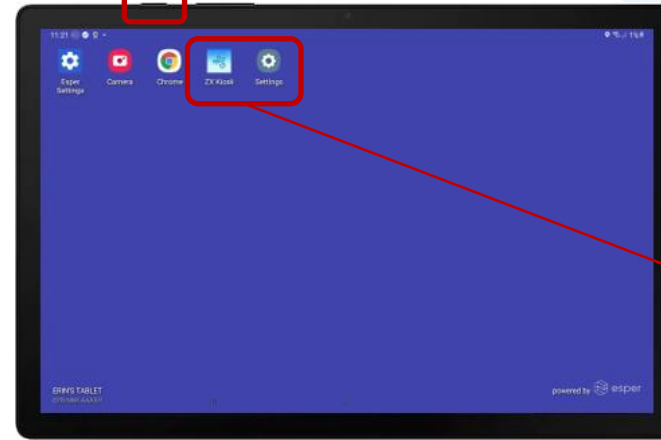
- Last dose of salbutamol/albuterol or levosalbutamol/levalbuterol for at least 6 hours.
- Last dose of LABA for at least 12 hours (ultra-long-acting LABA like vilanterol for at least 24 hours).
- Last dose of ipratropium bromide for at least 8 hours.
- Last dose of LAMA for at least 24 hours.
- Last dose of theophylline or aminophylline for at least 24 hours for current smokers and 36 hours for non-smokers.

Spirometry: Kiosk Login & Setup



- **Power on the spirometer**
- **Check battery life & charge if low**

To charge, plug spirometer into a laptop or computer. Do not charge directly in wall outlet



- **Power on the Samsung tablet**
- **Swipe up to open**
- **Go to Settings and connect to wifi**

Note: the tablet is sim enabled in case wifi is not available

- **Open Kiosk app**
- **Enter email and password you created for the Provider Dashboard**

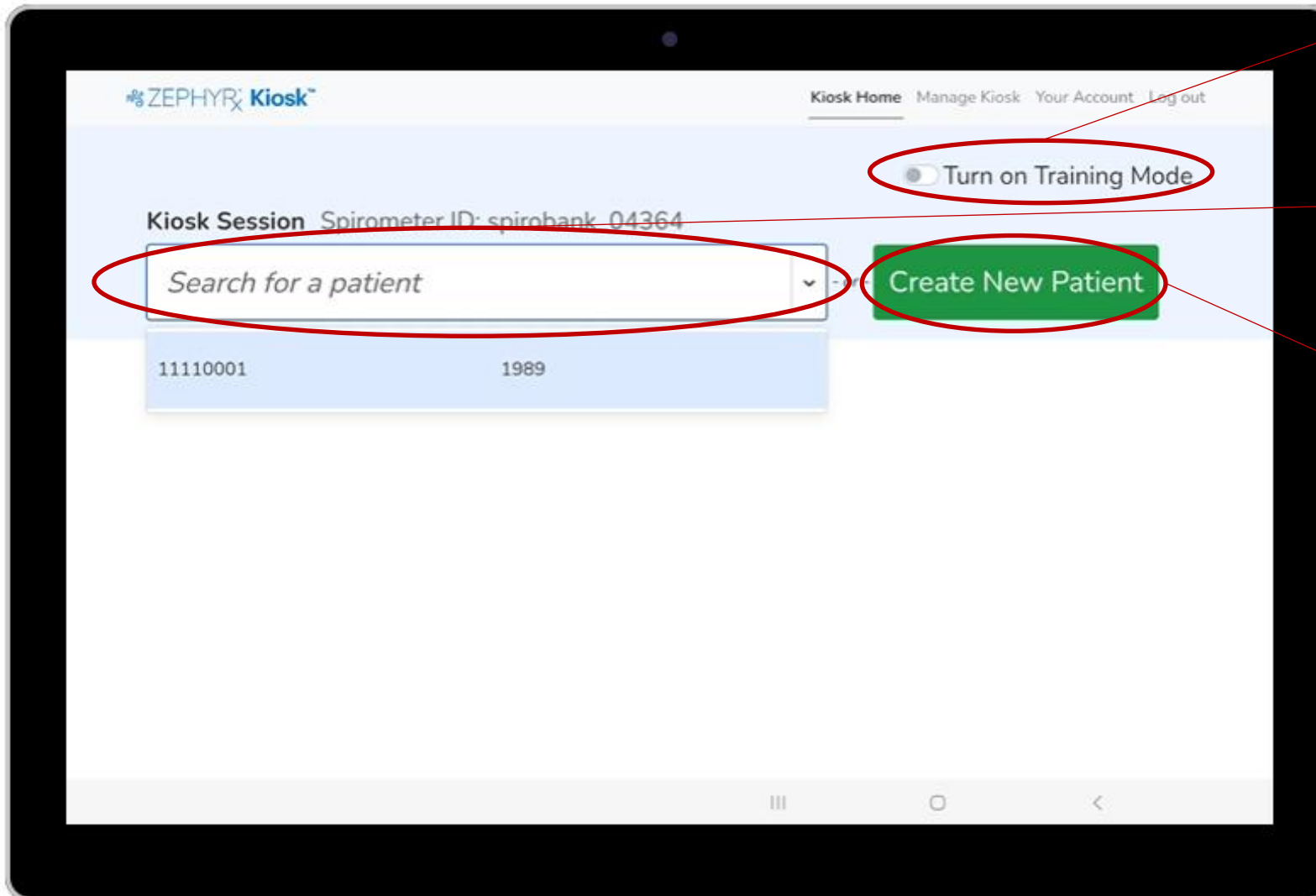
Kiosk Spirometry Screening



- **Insert the turbine mouthpiece** into the spirometer and turn clockwise to lock into place
- Ensure the mouthpiece is in **horizontal orientation**

No calibration is required for the spirometer

Kiosk Spirometry



- Site Staff can complete practice tests in **Training Mode**
- **Search for your participant** using the dropdown menu
- If you have not already created the participant through the dashboard, you can create the patient by selecting **Create New Patient**

Kiosk Spirometry - Create a Participant

ZEPHYR Kiosk™

Kiosk Home Manage Kiosk Your Account Log out

Kiosk Session Spirometer ID: spirobank_04364

11119999

1984

182 68

Female Caucasian

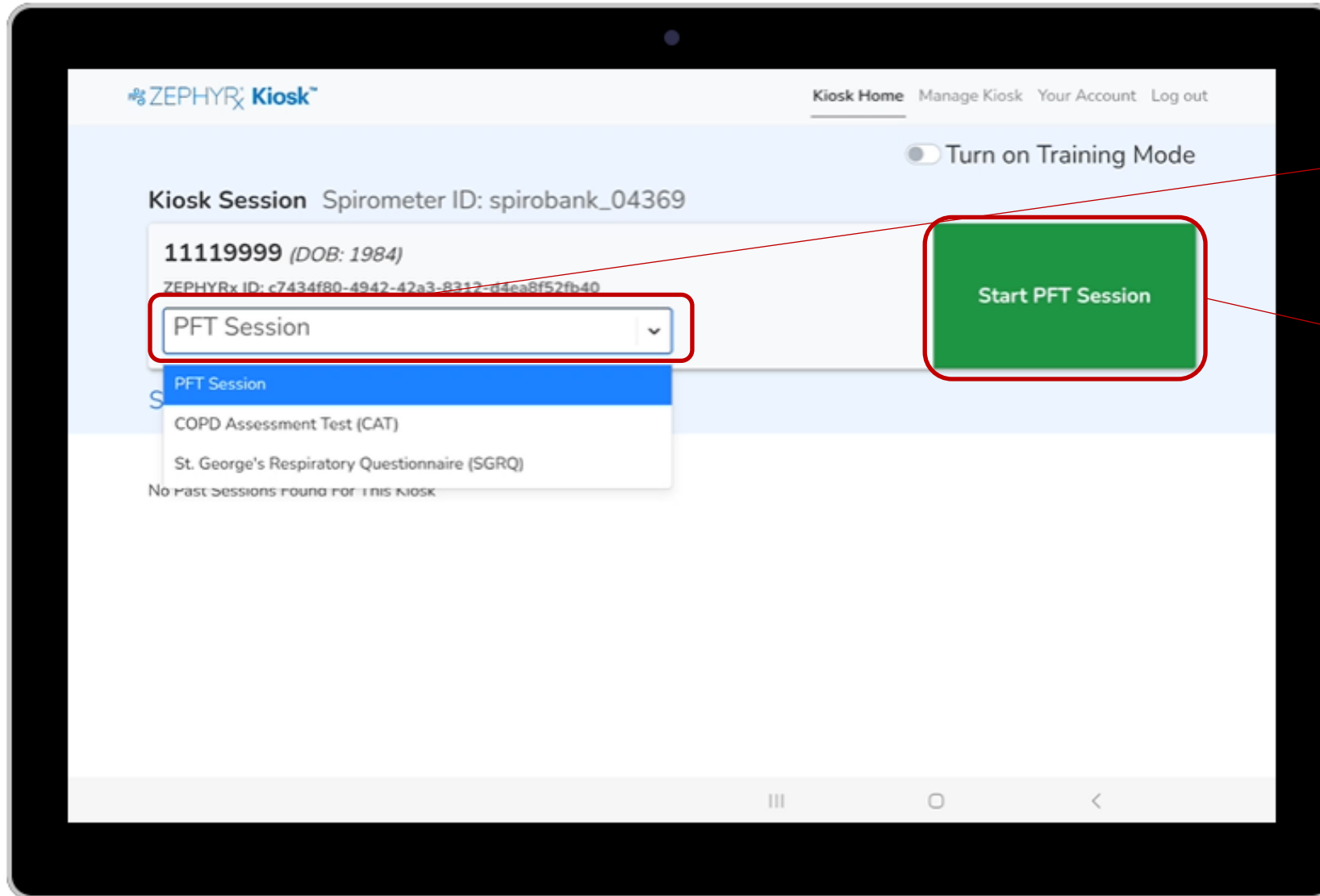
At-Home Spirometer ID (optional)

Cancel Confirm

No Past Sessions Found For This Kiosk

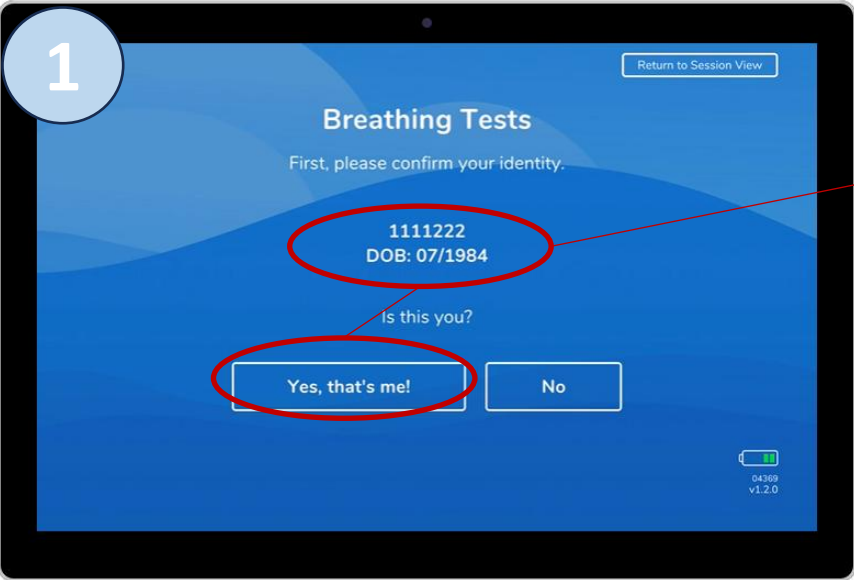
- If you choose to create a new participant, **fill in all demographic data** as prompted
- You can leave **At Home Spirometer ID blank** – there will be no home spirometry for the study
- **Select Confirm**

Kiosk Spirometry - Start the Series

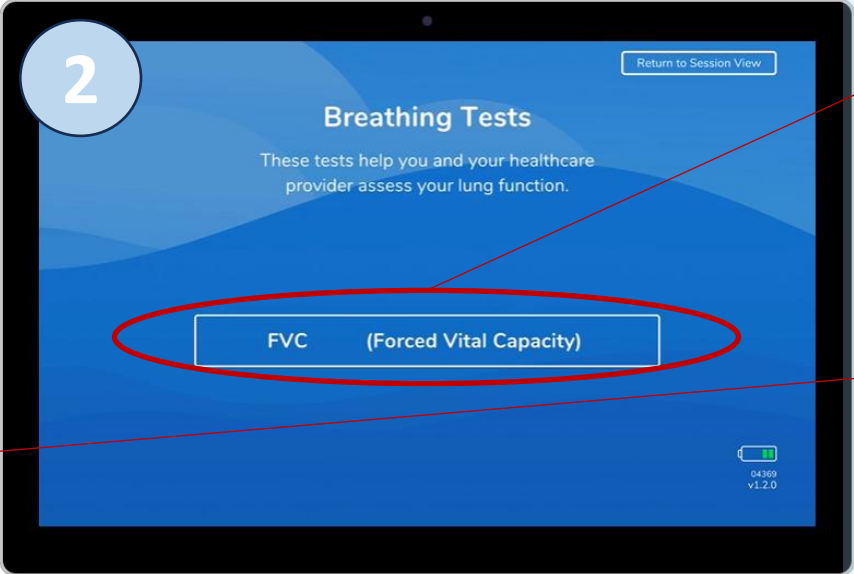


- Select **PFT session** from the Dropdown Menu
- Select Start PFT Session

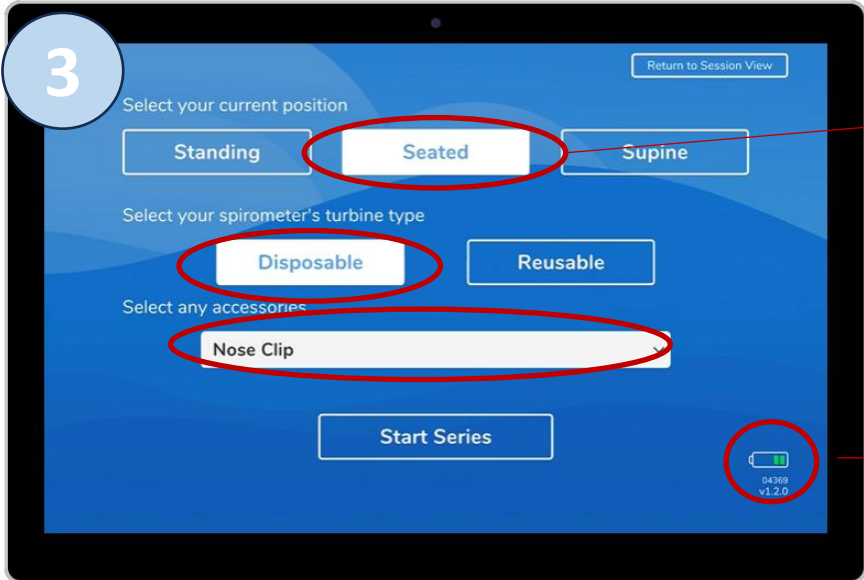
Kiosk Spirometry



1. Confirm **participant demographics** are correct and select **Yes, that's me!**



2. Select **FVC (Forced Vital Capacity)**



3. Select **Participant Position, Disposable turbine type, and Nose Clip accessory**

Note: battery life, spirometer ID, Kiosk app version

Spirometry Maneuver

There are four distinct phases of the Forced Vital Capacity (FVC) maneuver:

1. Maximal inspiration
 2. A “blast” of expiration
 3. Continued complete expiration until a plateau is reached
 4. Inspiration at maximal flow back to maximum lung volume
- The ZEPHYRx Kiosk app will take the participant through an FVC series, made up of a maximum of 8 maneuvers or efforts
 - The app will prompt additional efforts until the participant achieves 3 acceptable efforts
 - For each effort, FVC and FEV1 (forced expiratory volume over the first second of exhalation) will be scored as acceptable, usable, or not acceptable

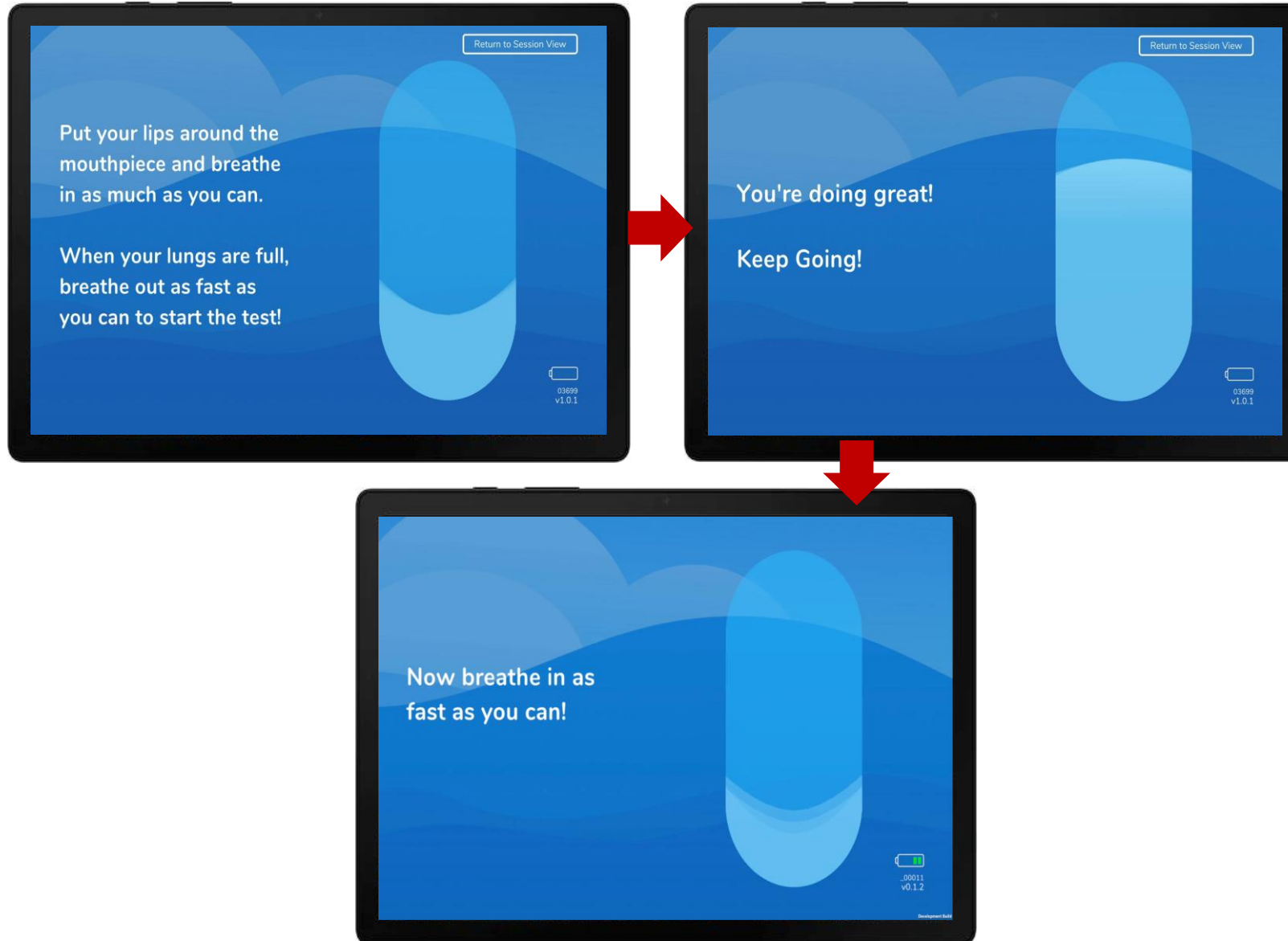


Spirometry Maneuver

- The whole series will also receive a letter grade (e.g., A to F) based on the number of acceptable efforts in the series, and the repeatability of the two best efforts
 - Each effort and Series will be assessed in real time to the ATS/ERS standards
 - You should aim for an FVC Grade of E or Higher (A, B, C, D or E) and an FEV1 Grade of D or higher for FVC (A,B,C or D)
 - If you do not achieve this grade, you can try another series
- The app and spirometer will begin recording as soon as the participant does any exhalation into the mouthpiece and turbine
 - It is very important that they don't breathe out into the mouthpiece before they take their maximal inspiration, otherwise this can trigger the effort to end early



Kiosk Spirometry Screening



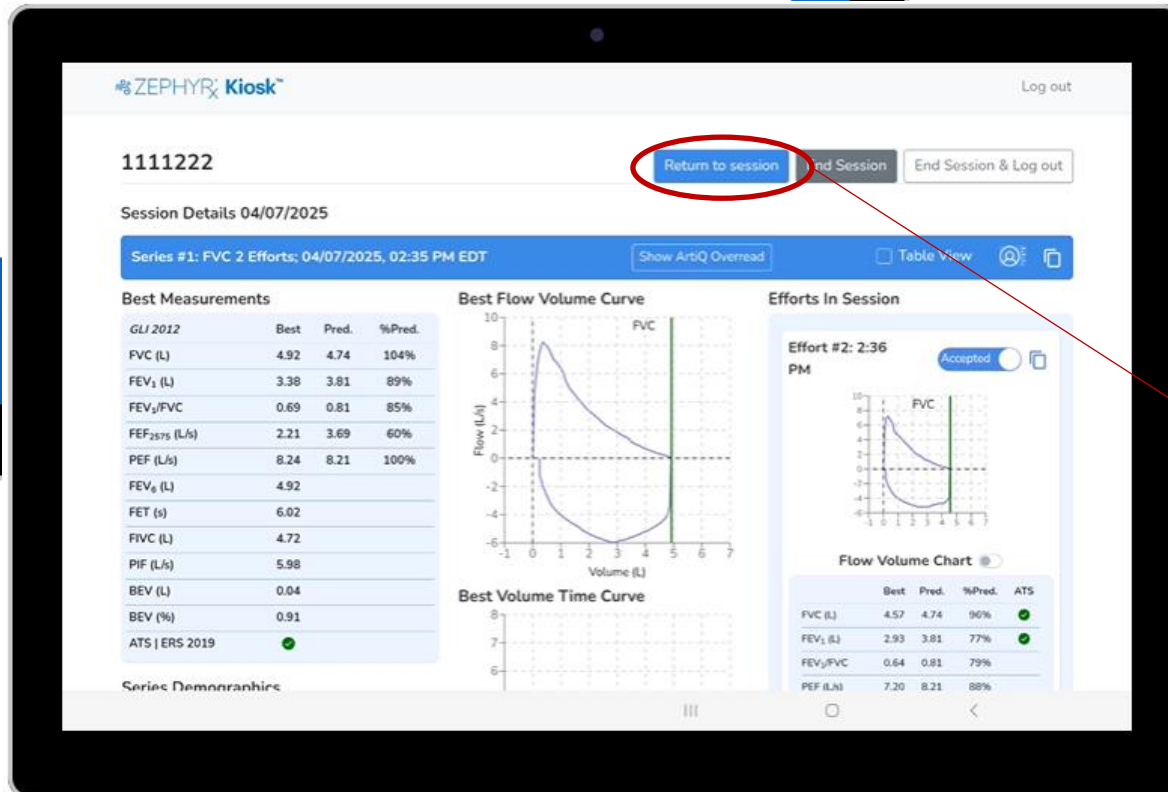
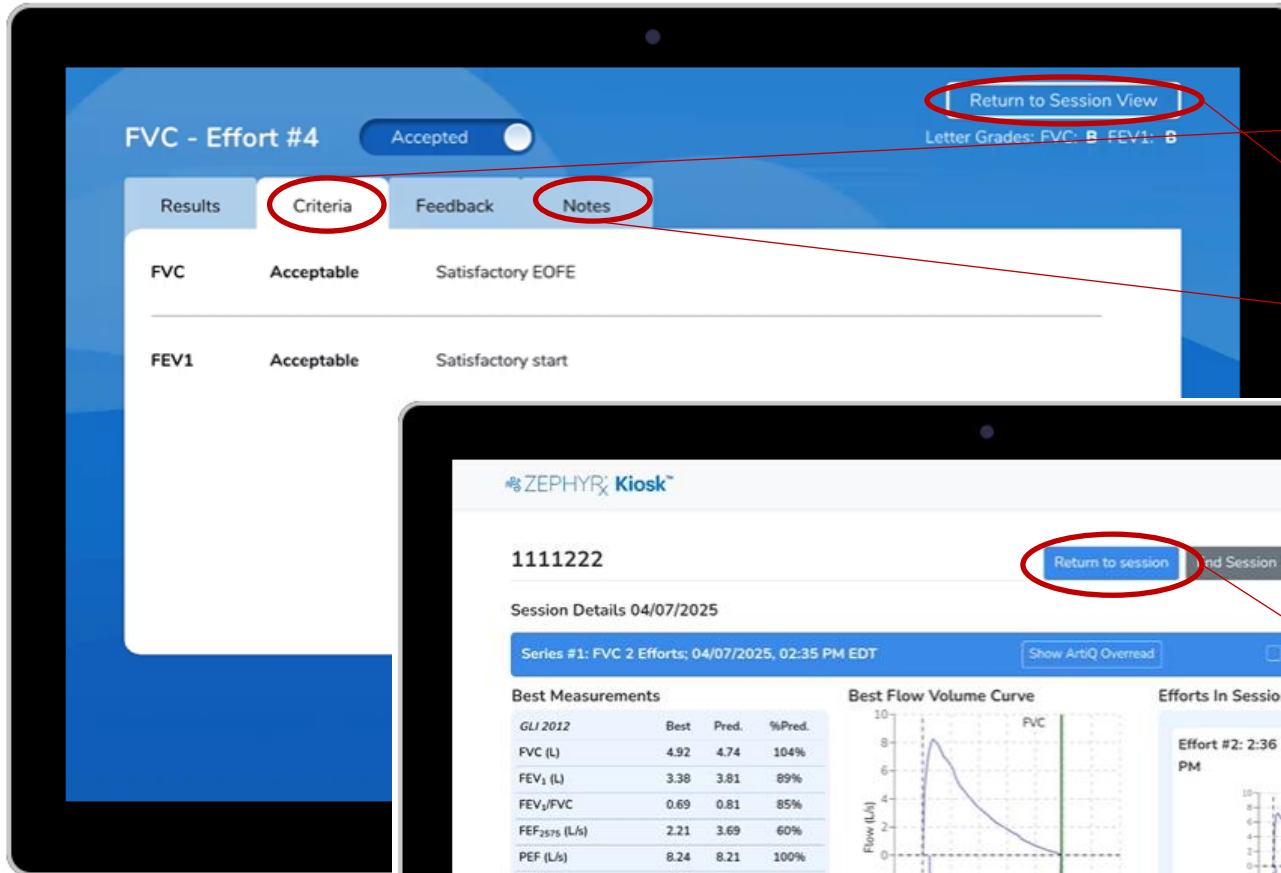
- **Coach participant** using on-screen instructions
- **Conduct 3 – 8 efforts**, aiming for 3 acceptable efforts
 - *8 efforts max*

Kiosk Spirometry Screening



- Accept or reject the effort
- View letter grades
- View **ATS acceptability**
- Select **Next Effort** to continue or **End Series** to complete series

Kiosk Spirometry



Select **Criteria** tab for immediate preliminary ATS analysis

➤ Select **Notes** tab to enter series notes

➤ Select **Return to Session View** screen to see results from all of the efforts in the series so far

➤ Select **End Session** to finalize, or **Return to Session** to add efforts

Kiosk Spirometry: Grading

ATS | ERS 2019 Grading

Grading System for FEV₁ & FVC (Graded Separately)

[Learn More](#)

Grade	Number of Measurements	Repeatability: Age >6 yr
A	≥3 Acceptable	Within 0.150 L
B	2 Acceptable	Within 0.150 L
C	≥2 Acceptable	Within 0.200 L
D	≥2 Acceptable	Within 0.250 L
E	≥2 Acceptable	>0.250 L
	OR 1 Acceptable	N/A
U	0 Acceptable & ≥1 Usable	N/A
F	0 Acceptable & 0 Usable	N/A

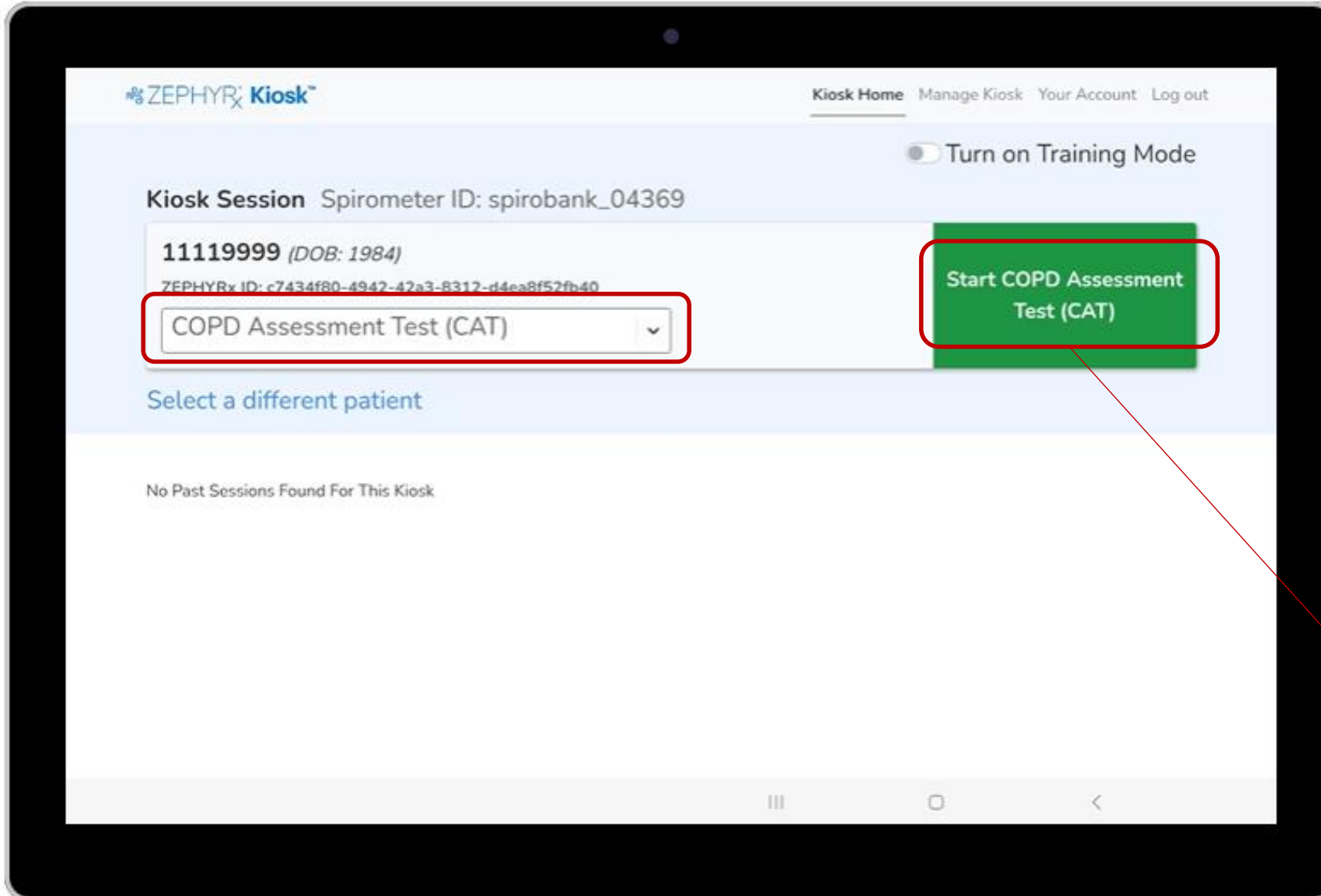
Spirometry Series are graded based on **number of acceptable efforts performed, and repeatability of the two best efforts.**

- For this study, an **acceptable grade** is:
 - A, B, C, D or E for FVC
 - A, B, C or D for FEV₁
- The **series can be repeated** if an acceptable grade is not achieved



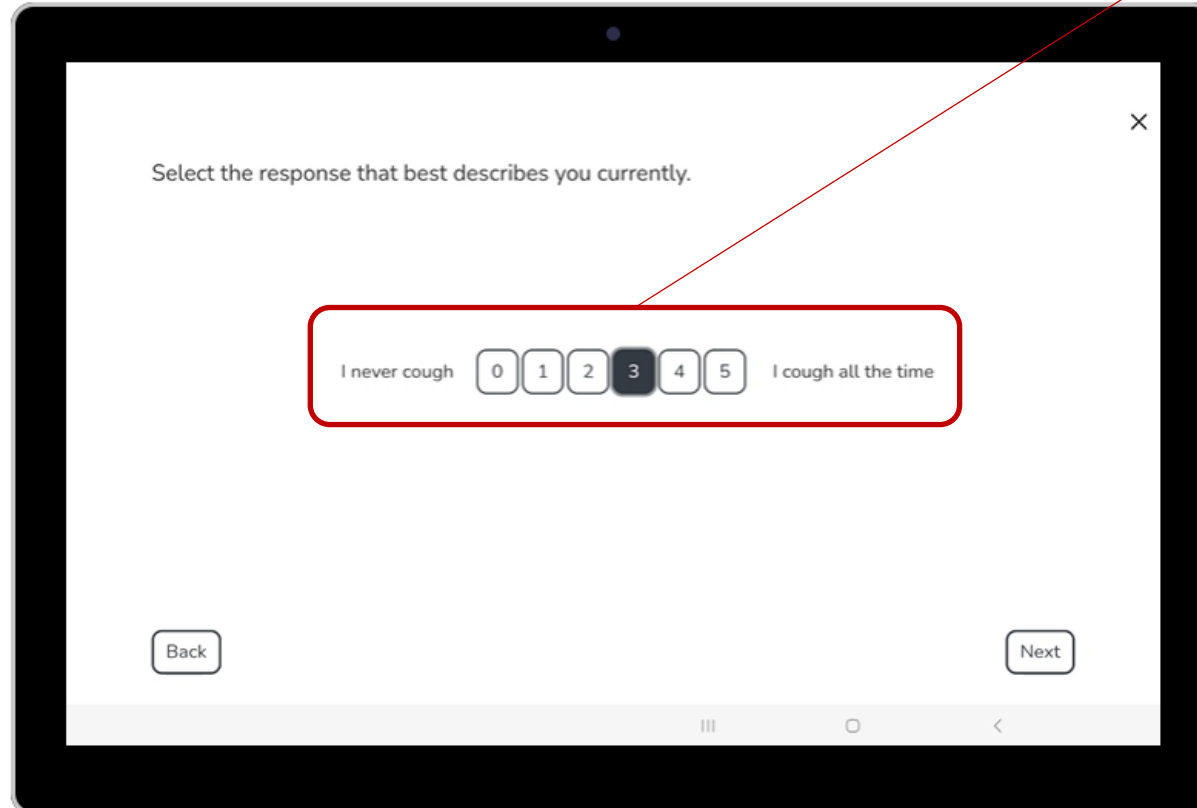
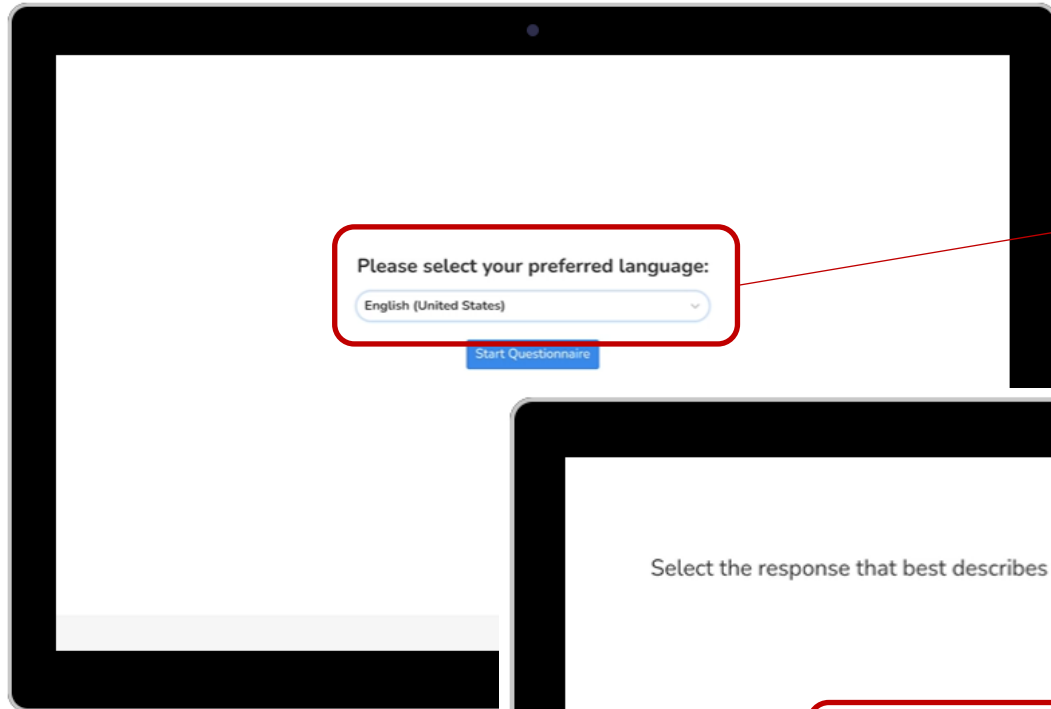
In-Clinic Kiosk eCOAs

Kiosk eCOAs



- Log into the Kiosk App on the Samsung Tablet
- Select your **Participant** or Create a new participant
- Select the desired **eCOA**
 - COPD Assessment Test (CAT)
 - Saint George's Respiratory Questionnaire (SGRQ)
 - EXACT
- Select **Start**
- Confirm the Participant **Demographics**

Kiosk eCOAs



- Select the **Participant's language**
- **Pass the tablet to the participant to complete the questions**
 - Participant should select answer, then select next till done
 - Then pass the tablet back to the provider

Kiosk eCOAs

Providers, please fill out this post-questionnaire form:

Was this eCOA self-administered by the patient? Yes No

1. Who completed it? Enter first and last name:

2. What was the reason for the deviation?

3. Did the patient verbally confirm the accuracy of the completed eCOA? Yes No

- If a participant is too ill to complete the PRO assessments via the e-diary, a member of the trial staff may verbally recite the questions verbatim to the participant and enter the participant's verbal response in the e-diary.
- When this happens, site staff must select "No" in response to the question "Was this eCOA self-administered by the patient" and fill in the corresponding information:
 - First and last name of person who completed
 - Reason it was not completed in person
- Once complete, results will automatically be transmitted to the ZEPHYRx dashboard

Visit 7 CAT COA



Your name: _____

Today's date: _____

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 1 2 3 4 5 I am very sad

		SCORE
I never cough	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> I cough all the time
I have no phlegm (mucus) in my chest at all	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> My chest is completely full of phlegm (mucus)

- For Visit 7 (phone visit) The participant can complete the paper COA on their own, which can be transcribed to the provider over the phone to be entered into the tablet.

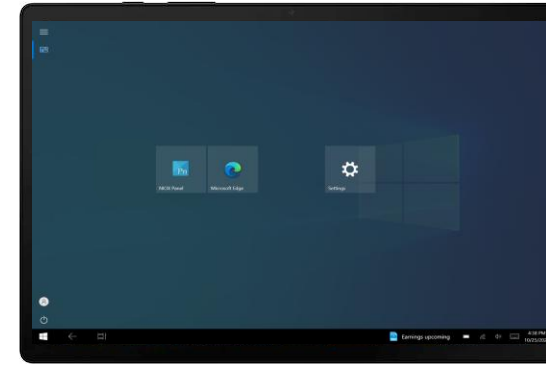


In-Clinic FeNO

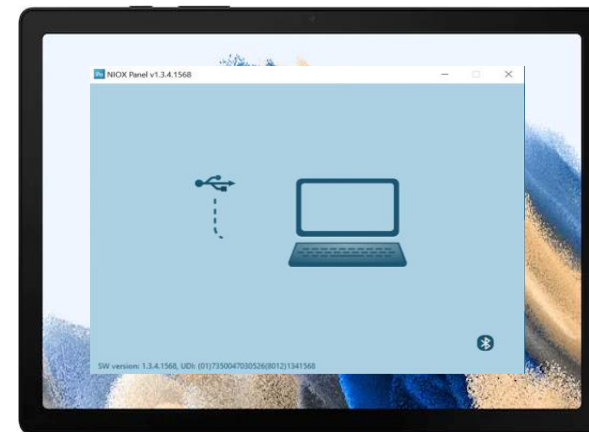
FeNO Setup



- **Power on the FeNo Device**
- Remove the white cap on the breathing handle, and put on a filter



Microsoft Surface Tablet



Connecting...

- **Power on the Surface tablet**
- Go to **Settings** and connect to WIFI
- **Open NiOX Panel app**
- App will connect to the FeNO device

**Tablet Password:
5023**



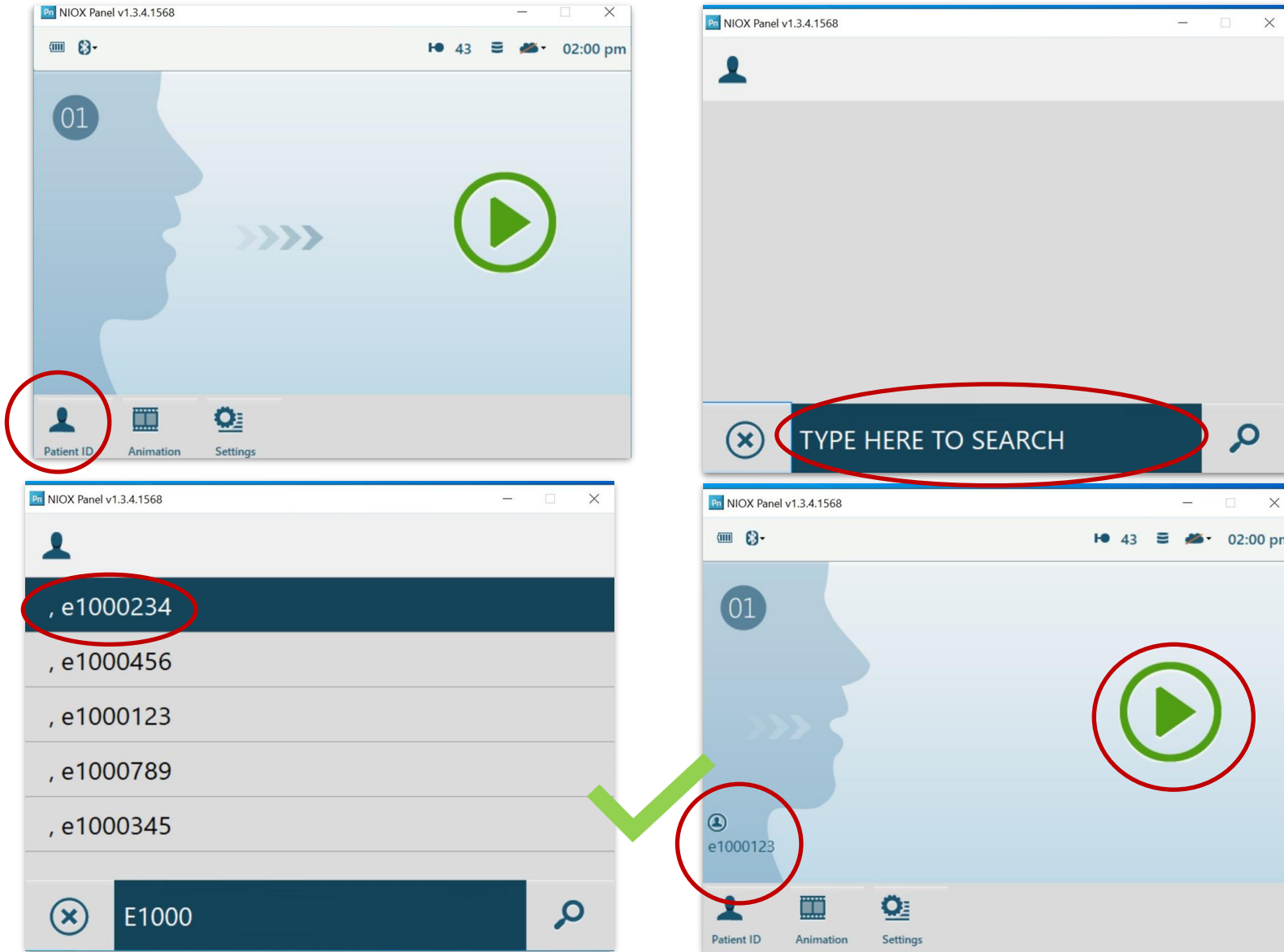
FeNO Maneuver



Review with the Participant before beginning:

- ✓ Put the filter mouthpiece into your mouth, and inhale slowly and deeply to lift the cloud icon off the ground
- ✓ Exhale steadily but forcefully (similar to trying to blow bubbles in a drink with a straw) to move the cloud across the screen to the flagpole
- ✓ If the cloud doesn't reach the flagpole, you will need to repeat the maneuver again

Select the Participant ID

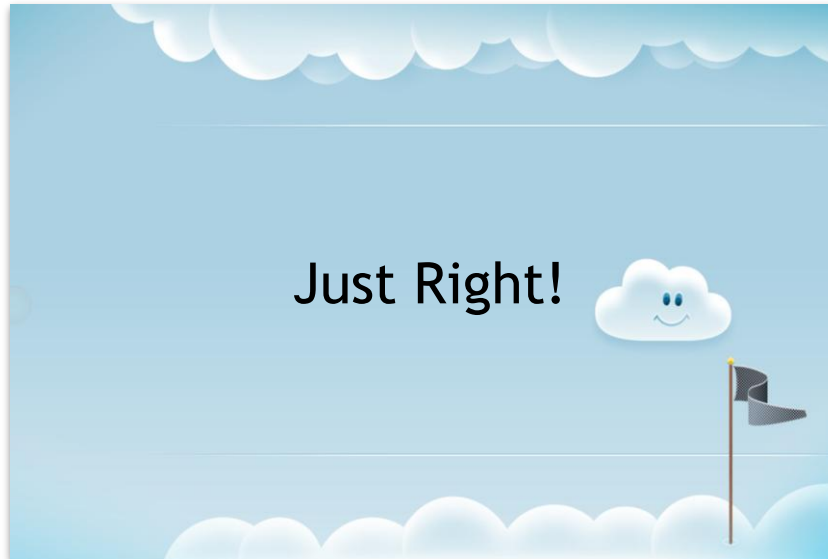
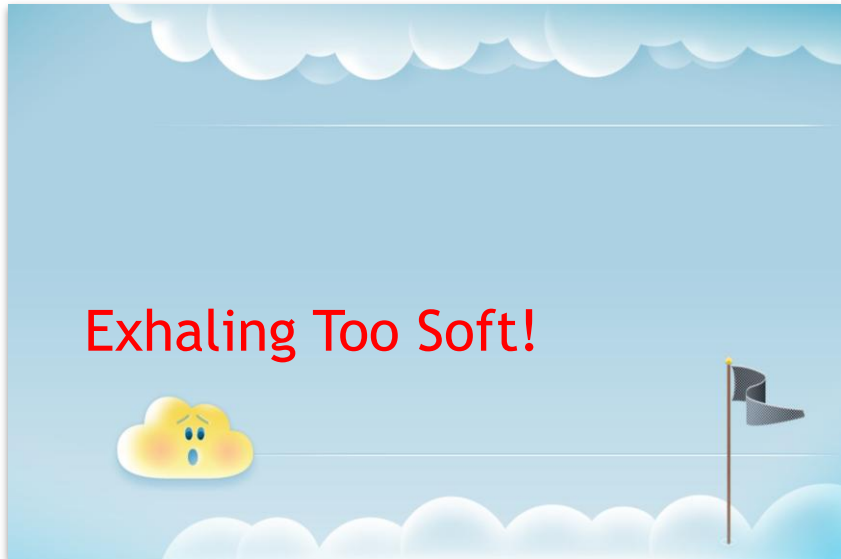
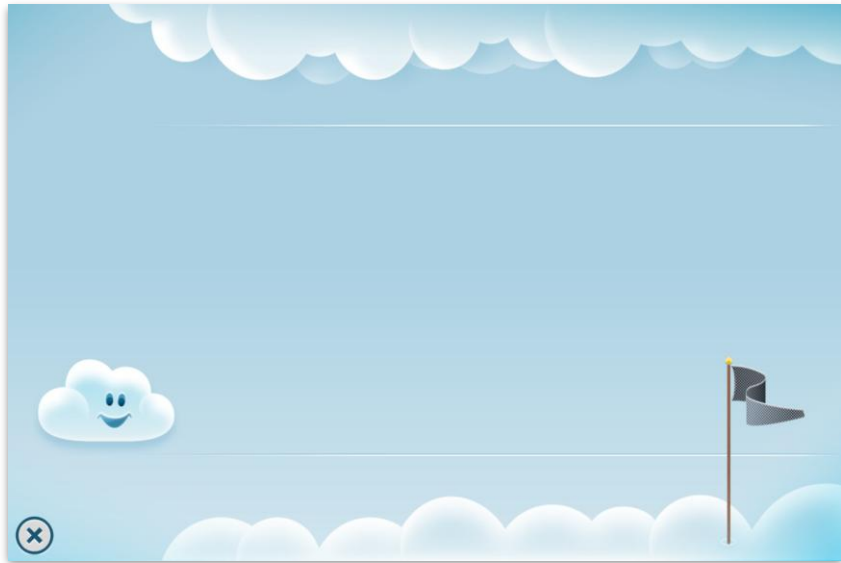


1. Select "Patient ID"
2. Begin typing in the search bar
3. Select the Correct participant ID
4. Confirm the ID is correct
5. Select the Green Arrow to begin the test



If participant ID is not selected, results will not be transmitted to the dashboard

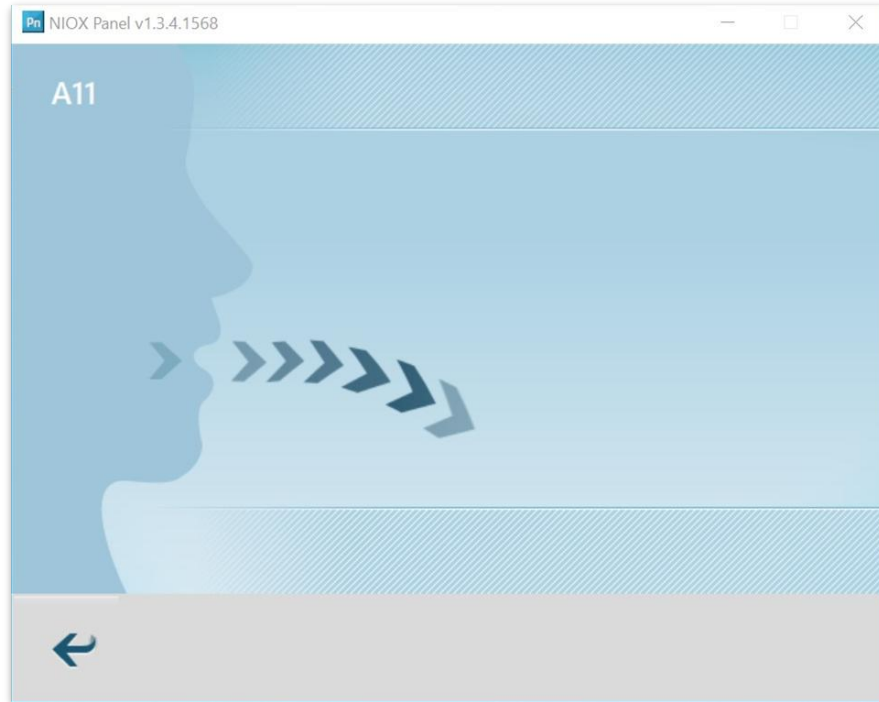
Complete the Test



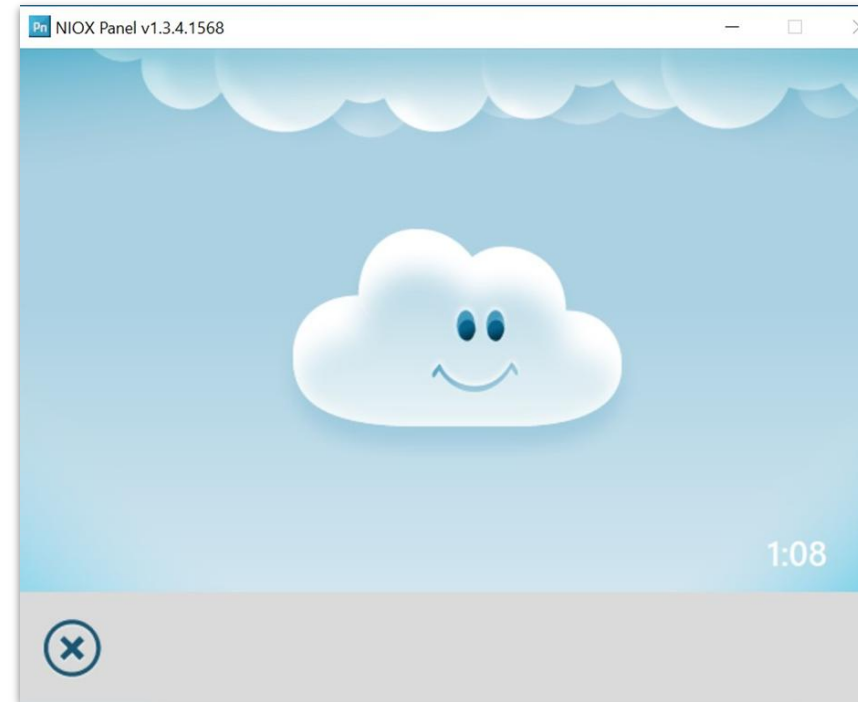
FeNo Tips & Troubleshooting

- ✓ You must launch the app from the Surface tablet, do not use the buttons on the FeNO machine screen
- ✓ You must select the Participant ID
- ✓ If you are having trouble connecting via Bluetooth, make sure you do not have a second tablet nearby running NIOX panel

Complete the Test



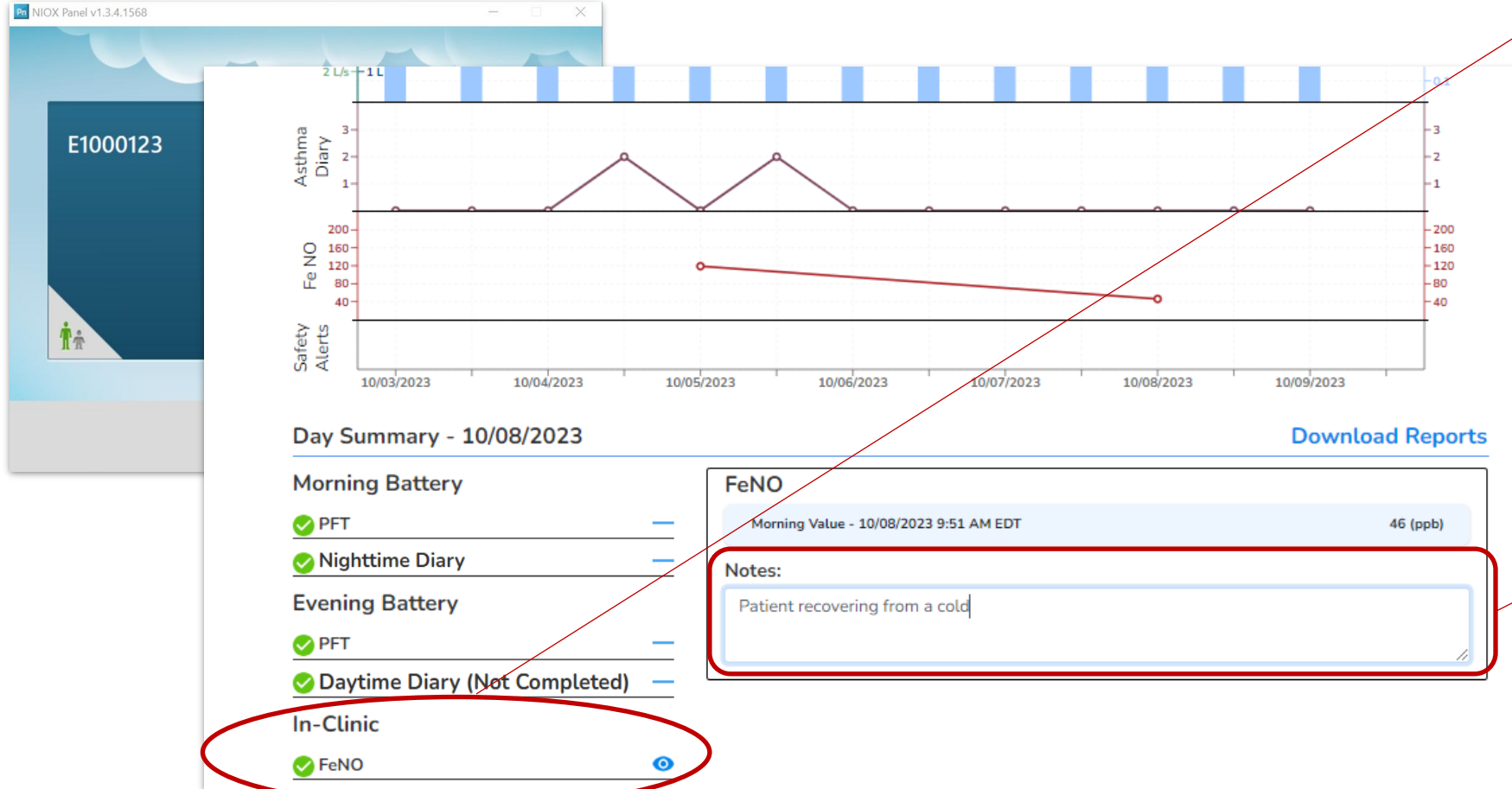
Incomplete Test, Try Again



Test Completed! Countdown
will begin to calculate results

*Only 1 Complete Test is Required

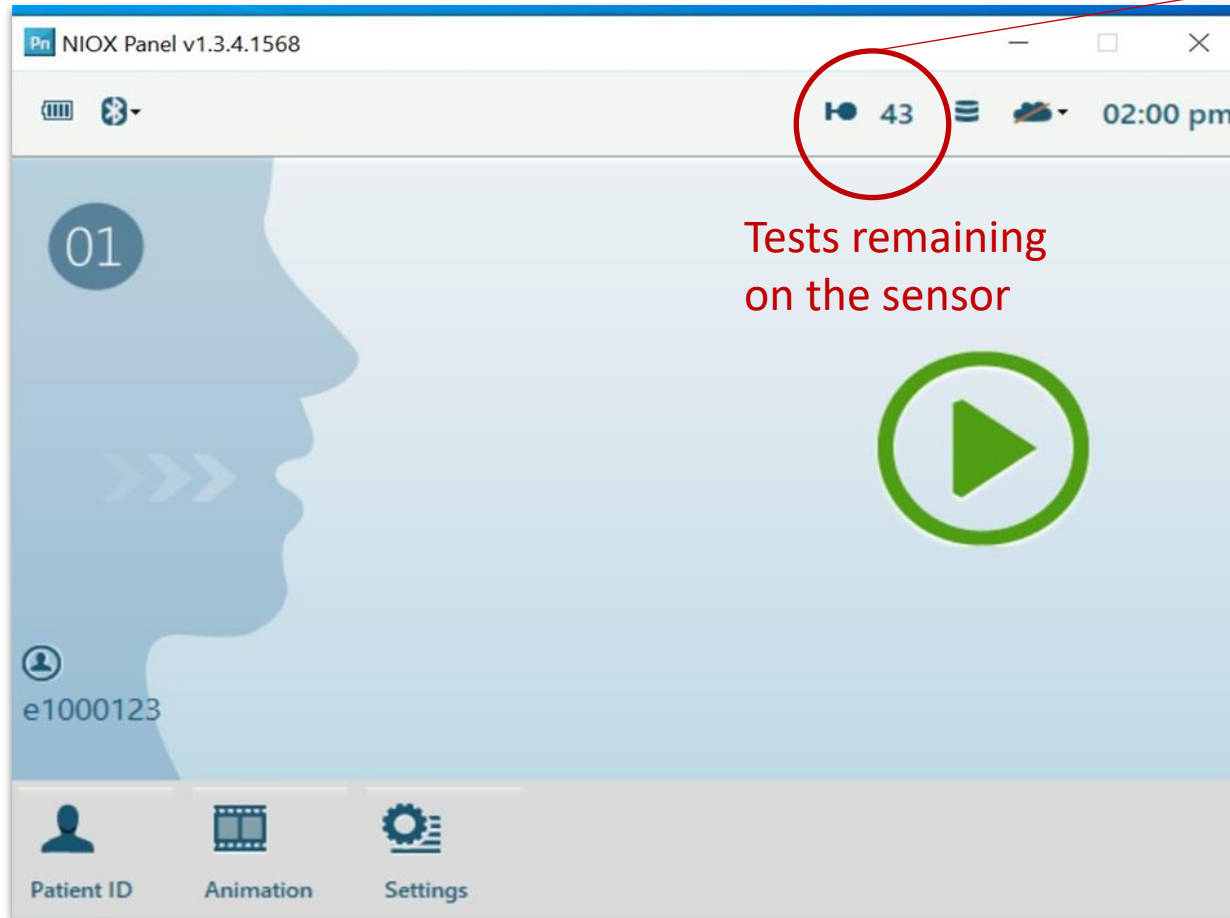
View the Participant's Results



- ✓ After the countdown, results are sent automatically to the Provider Dashboard
- ✓ It may take up to 3 minutes for results to transfer to the Provider Dashboard
- ✓ Enter notes if needed

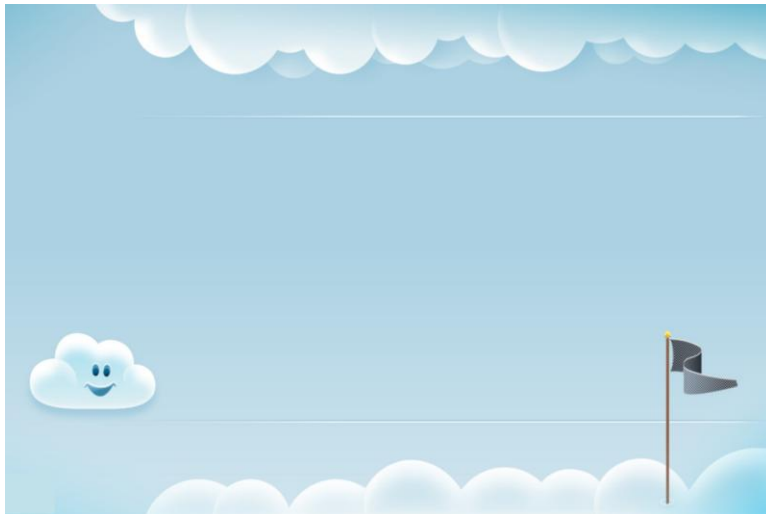
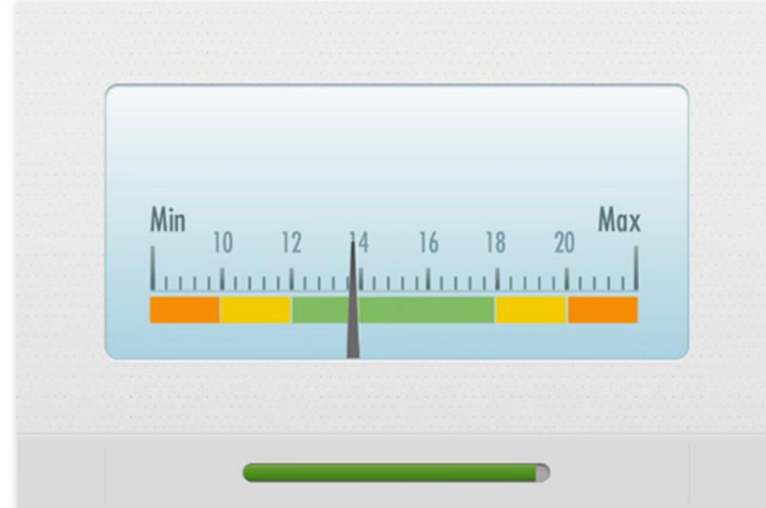
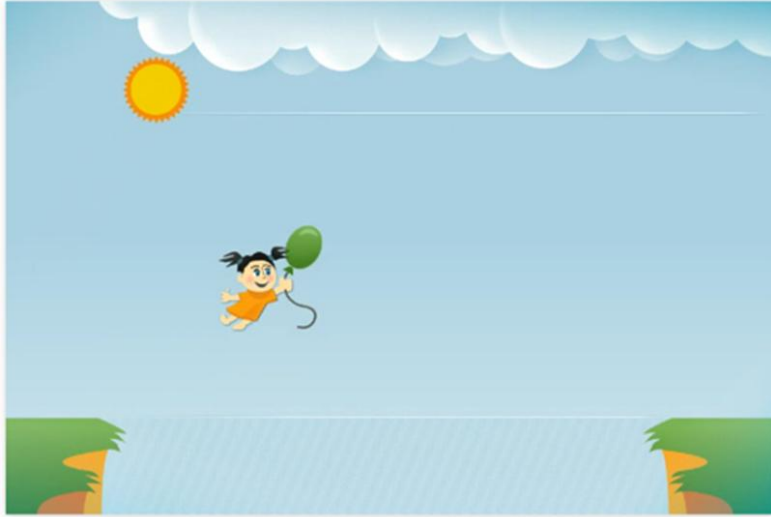
****View Results in ZEPHYRx dashboard, not on the tablet screen****

FeNO Sensor Count



- ✓ Each FeNO Sensor inside of the device is good for 100 completed tests. If the count of remaining tests drops below 20, go to zephyrx.com/seabreeze, select your study, and select equipment request to order a new sensor

FeNO Animations



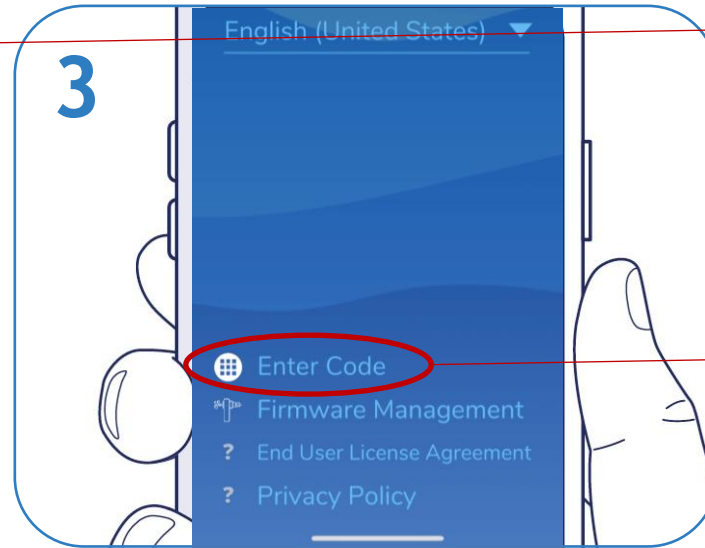
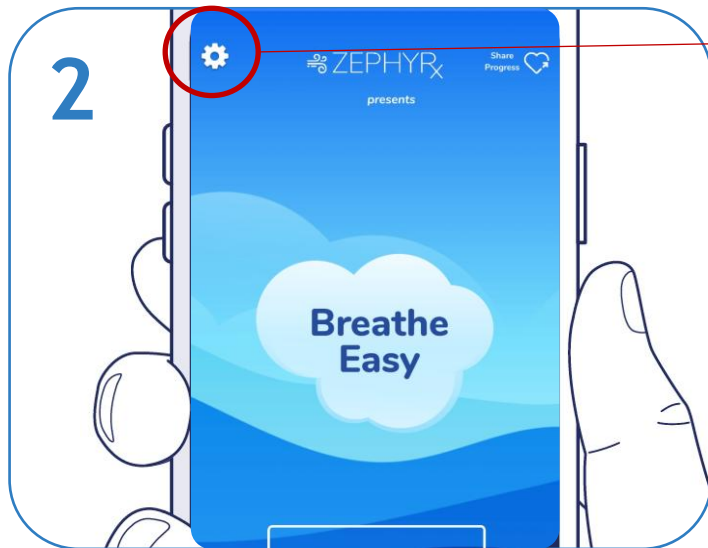
- ✓ Choose from 3 different FeNO animations prior to starting a test by selecting the 'Animation' button on the screen of the FeNO device.



Home Tasks

Help Participant Download the Breathe Easy App

Note: Contact your CRA if you have a channel 1 patient that does not have a phone or tablet to request an edairy device.



To Pair the Participant's phone to the ZEPHYRx Dashboard:

1. Download the **Breathe Easy App** to the participant's phone
2. Launch the app and select the **Settings** icon in the top right corner
3. Select "**Enter Code**"

Pair the Participant's Phone to the Dashboard

ZEPHYRUS Provider Dashboard 1.10.9 Admin Organization Providers Partic

← Back to Participant List

11119999 (--% Compliance) Trial Research Participant Settings

Participant Details + Passcode Link + Edit Notes

Identification

ID

StudyID

Spirometer ID

Participant's Timezone

Demographics

Sex at Birth

Birth

Ethnicity

Height

Weight

Run-In Calculations

No Averages Established

At Home Status

Passcode Link

Please have your participant share their link code from the Breathe Easy app and enter it below.

1 4 0 2 8 3 5 4

Link Code Cancel

Share the following code with your provider:

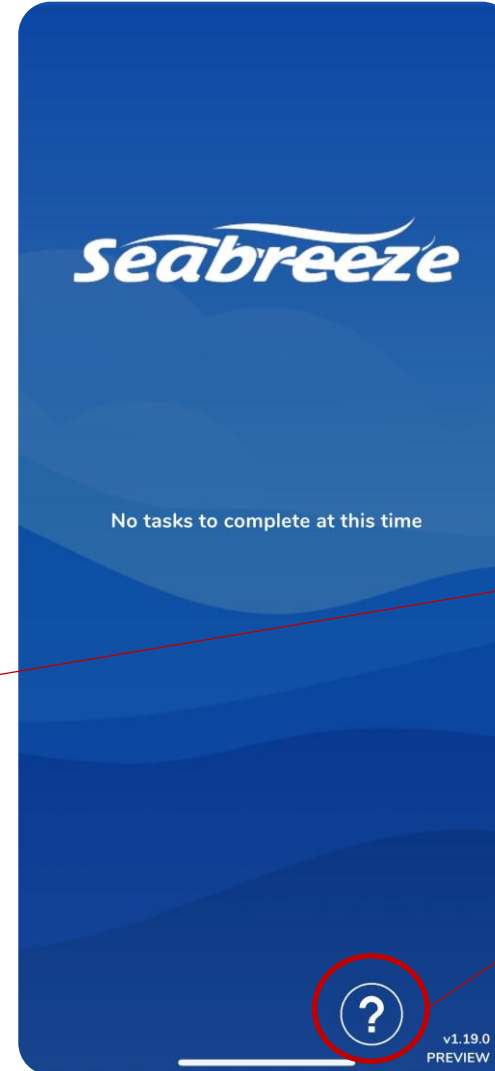
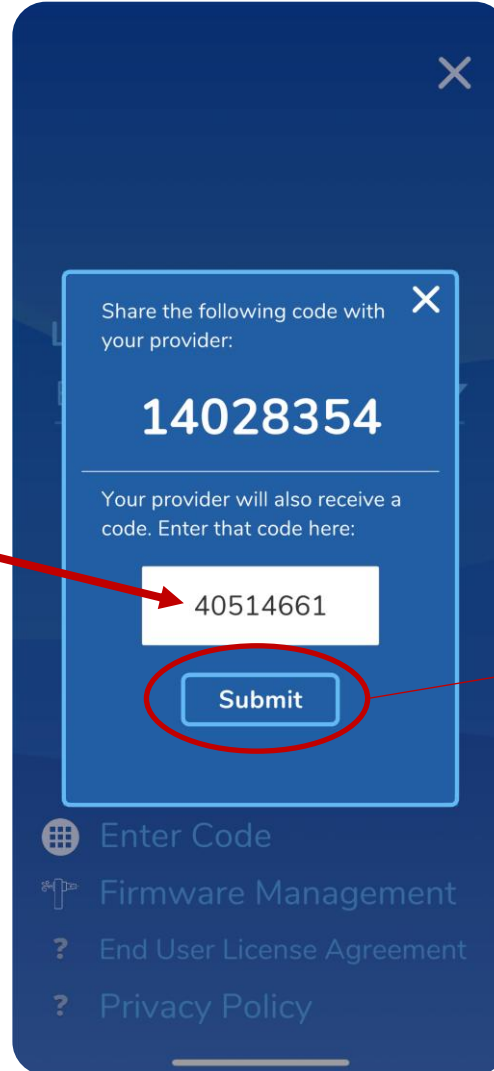
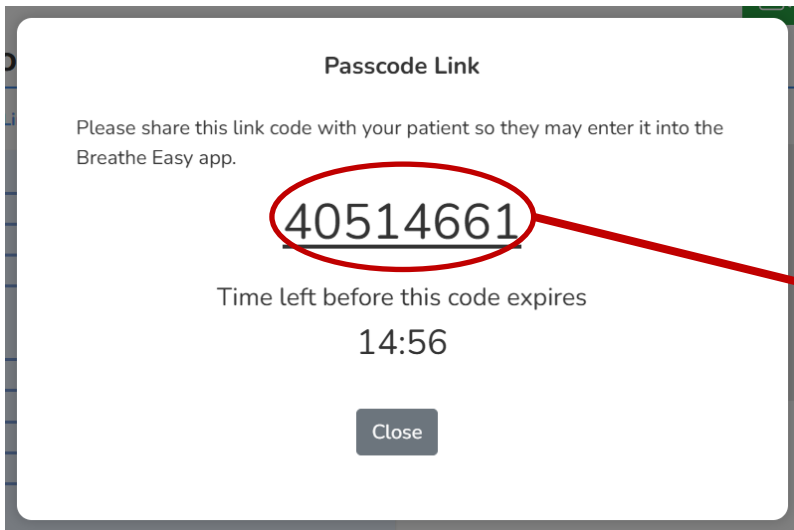
14028354

Your provider will also receive a code. Enter that code here:

Enter Code

1. Find the participant in the dashboard
2. Select **Participant Settings** tab
3. Select **+Passcode Link**
4. **Enter the number** on the participant's phone into the dashboard
5. Select **Link Code**

Help Participant Download the Breathe Easy App



1. Once the participant's code is entered into the dashboard, a **second code will be generated** in the dashboard
2. **Enter** that into the participant's Phone
3. Select **Submit**
4. Once submitted, you will see the **app study home screen**
5. Select the **? Icon** to set participant language



Note: If the participant gets a new phone, or deletes their app, you will need to repeat this pairing process

Set At-Home Task Start Date

StudyID	11119999
Spirometer ID	
Participant's Timezone	UTC (-00:00 from UTC)
Demographics	
Sex at Birth	Female
Birth	1984, 41 years
Ethnicity	Caucasian
Height	71.65 in
Weight	149.91 lbs
Run-In Calculations	
No Averages Established	
At Home Status	
Status	Not Started

+ Screen Fail Participant



Participants will not see ed diary tasks on their phone if the start date is not set.

Participants will not see the EXACT evening task until a run-in end date is set, OR a V2 label is applied either to a kiosk spirometry session or eCOA

At Home Status: Not Started + Edit

Edit At Home Status - Starting Date [X]

Status: Not Started

Select start date:
 [Calendar icon]

Select run-in period end date:

Select end date:
 [Calendar icon]

End date defaults to 8 weeks after selected start date.

Cancel

✓ From the **Participant Settings** tab, select **Edit** next to the at home status

✓ select **Start Date:**

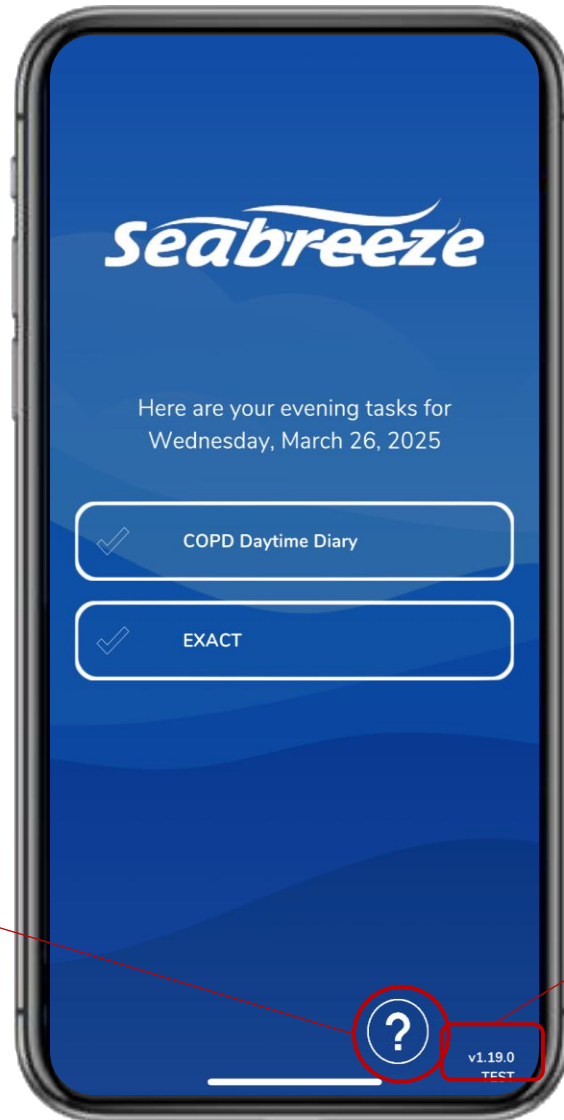
✓ **Start date** should be set at V1b as current date

✓ **Run-in period end date** should be set as date of V2

✓ **End date** will default to 8 weeks after start date, but can be updated as needed

✓ Select **Submit**

Participant App Overview



- ✓ troubleshooting tips
- ✓ set language

- ✓ app version

Once the run-in start date is reached, the participant will start receiving their tasks

- ✓ **Results are transmitted in real-time** to the dashboard
- ✓ **Tasks can not be completed** outside of the window

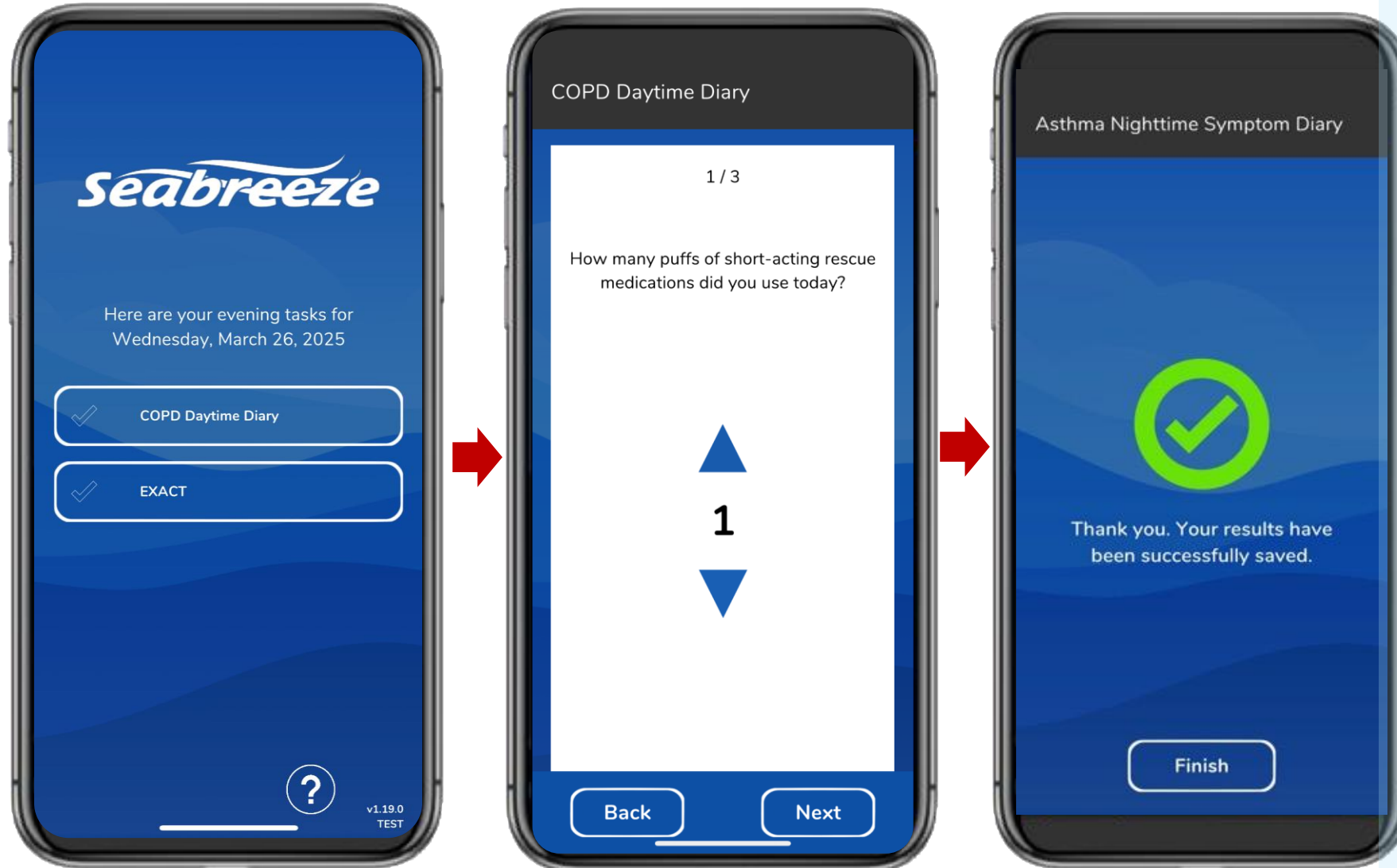
Morning Task Window 5:00am – 11:59am

Evening Task Window 5:00pm – 11:59pm

COPD Daytime Diary (SABA + Dyspnea NRS)

Reminder notifications will be sent at 7:00am and 5:00pm

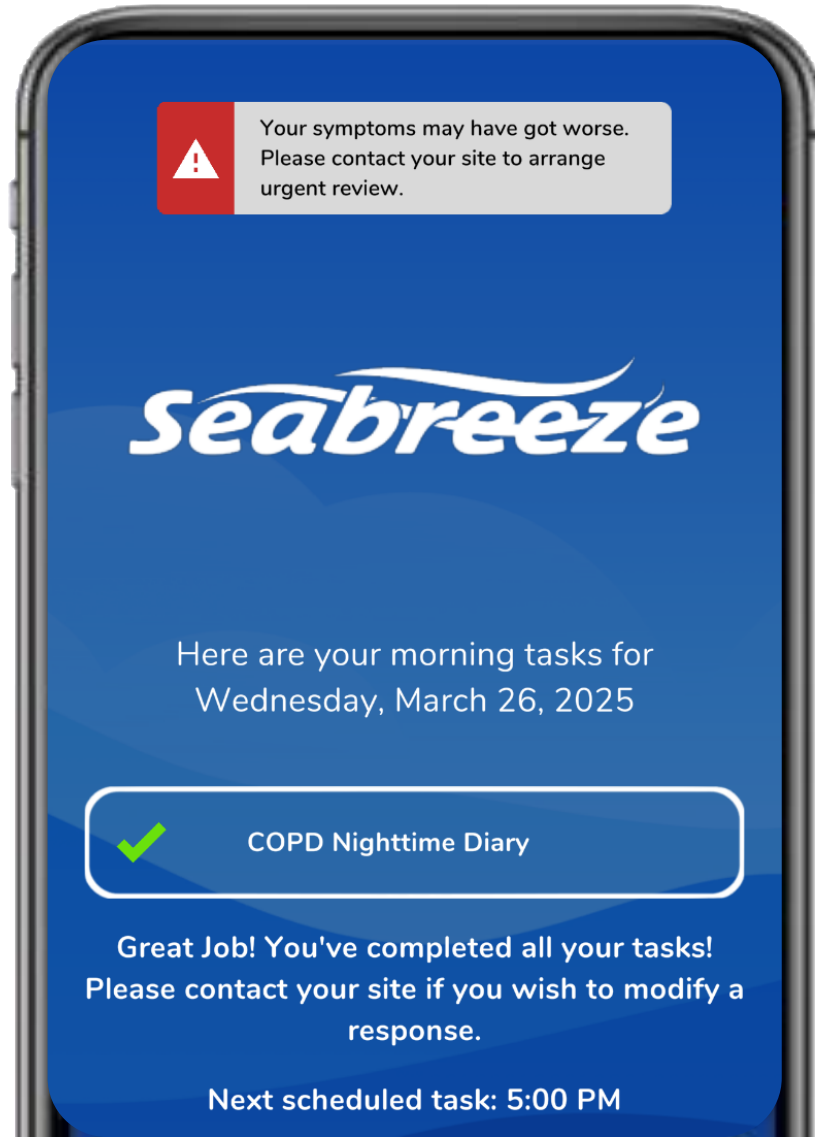
ePRO: EXACT and Symptom Diaries



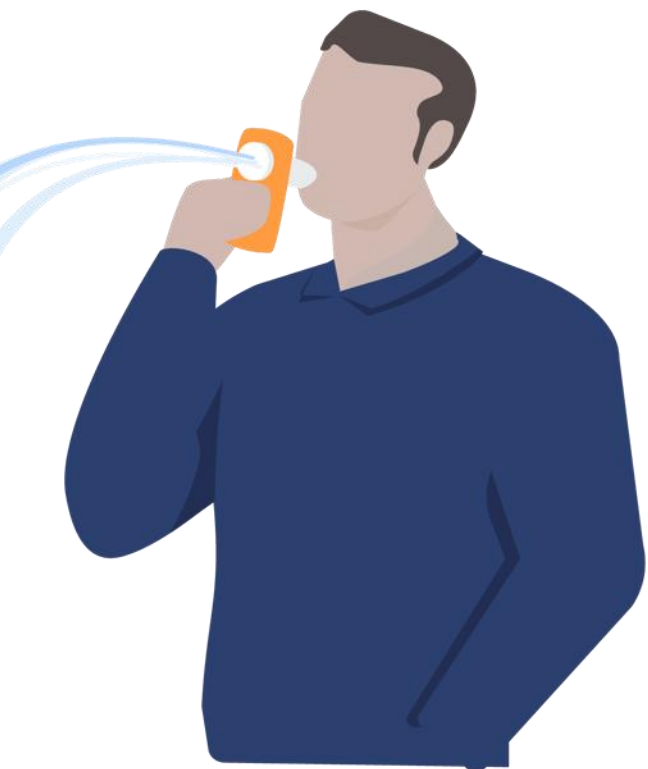
- ✓ Participant completes The **Daytime symptom diary** (SABA/nebulizer question plus dyspnea NRS), plus **EXACT-PRO** every Evening from V2 onwards.
- ✓ Participant completes the **Nighttime symptom diary** (SABA questions plus dyspnea NRS) every morning from V2 onwards.
- ✓ Results sent in real-time to the Provider Dashboard

For more information about home tasks, view the at home user guide

Safety Alerts & Reminder Notifications

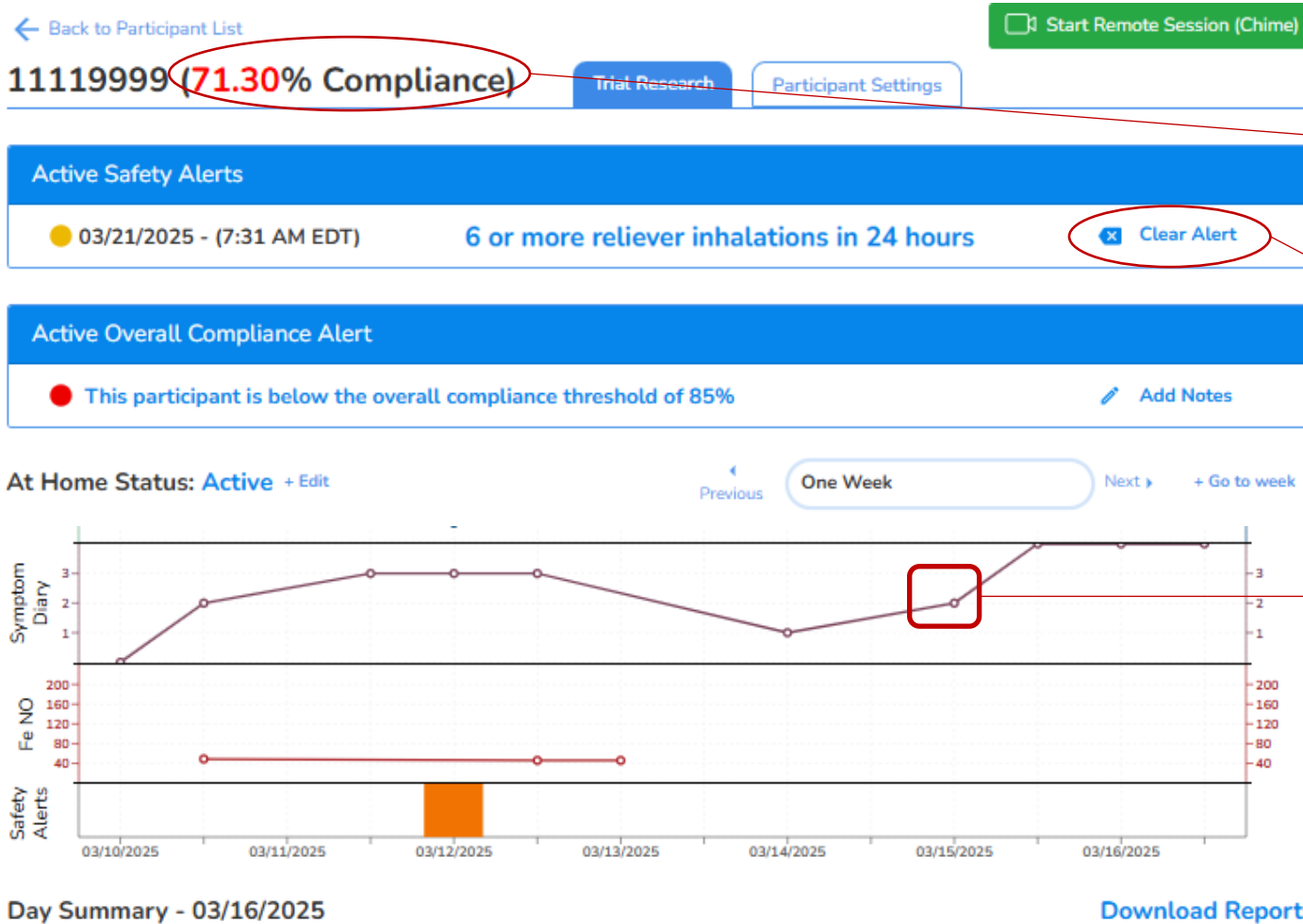


- ✓ Site and participants **receive alerts** for
 - ✓ At least 6 reliever inhalations of SABA in a 24-hour period on 2 of 3 successive days
 - ✓ Nebulizer use (any number of treatments) on 2 of 3 successive days



Viewing Participant Results & Alerts on the Provider Dashboard

Participant Dashboard Overview



- ✓ Monitor **Home Task Compliance**: text turns red if <80%
- ✓ Manage **safety alerts**
- ✓ View **daily task activity**
- ✓ Select a point in the graph to view more detailed results from that day in the **Day Summary** below

Participant Dashboard: Manage Alerts

← Back to Participant List

11119999 (42.05% Compliance)

Start Remote Session (Chime)

Active Safety Alerts

- 03/12/2025 - (7:15 AM)
- 03/12/2025 - (7:15 AM)
- 03/12/2025 - (7:15 AM)

Active Overall Compliance

● This participant is below

At Home Status: Active + E

16 L/s
14 L/s
12 L/s

8 L
7 L
6 L

⚠ Safety Alert for Patient

Nebulizer use

Alert Created on 03/12/2025 - (7:15 AM EDT)

Alerted (Nebulizer use): 2

Notes:

Clearing the notification will create a log of your action with a timestamp.

Save Notes & Close Clear Notification

Clear Alert

Clear Alert

Clear Alert

Add Notes

Next ▶ + Go to week

Click on **Clear Alert** to view alert details, add notes, or clear the notification

Participant Dashboard: View All Results

Day Summary - 04/02/2025

[Download Reports](#)


Morning Battery

Nighttime Diary 


Evening Battery

Daytime Diary (Not Completed) 

FeNO

FeNO (No Measurements) 


In-Clinic

ECOA Questionnaire(s) 

Safety Notifications

Safety Alerts 

Compliance Alerts

Compliance Alerts 

Symptom Diary

Morning COPD Diary - Questions *Answers*

How many puffs of short-acting rescue medications did you use last night? 2

How many times did you use a nebulizer for rescue medication last night? 2

On a scale of 0 to 10, indicate how much shortness of breath you are having right now. With 0 = no shortness of breath and 10 = shortness of breath as bad as can be 6

Evening - Questions *Answers*

Diary not answered for the evening

FeNO

No Measurements


ECOA Questionnaire(s)


No Measurements

Safety Alerts



- ✓ Scroll down below the graph to see detailed results
- ✓ Use the Eye Icons to hide and view tasks

Participant Dashboard: View All Results



- ECOA Questionnaire(s) 

- Evening Kiosk Series 


- Safety Notifications

 -  Safety Alerts 

- Compliance Alerts


 -  Compliance Alerts 

ECOA Questionnaire(s)

Evening (Visit Labels: V2) - COPD Assessment Test (CAT) Answers (From 0-5) 

1. "I never cough" to "I cough all the time"	(2)
2. "I have no phlegm (mucus) in my chest at all" to "My chest is completely full of phlegm (mucus)"	(4)
3. "My chest does not feel tight at all" to "My chest feels very tight"	(0)
4. "When I walk up a hill or one flight of stairs I am not breathless" to "When I walk up a hill or one flight of stairs I am very breathless"	(1)
5. "I am not limited doing any activities at home" to "I am very limited doing activities at home"	(4)
6. "I am confident leaving my home despite my lung condition" to "I am not at all confident leaving my home because of my lung condition"	(0)
7. "I sleep soundly" to "I don't sleep soundly because of my lung condition"	(4)
8. "I have lots of energy" to "I have no energy at all"	(1)
9.	(0)

Total Score: 16

Evening (Visit Labels: --) - St. George's Respiratory Questionnaire (SGRQ) 

Scores

Symptoms: 50.75%
Activity: 55.26%
Impacts: 29.82%
Total: 41.01%

- ✓ Scroll down below the graph to see detailed eCOA results
- ✓ Tag all eCOAs with a visit label (this is **mandatory**)
 - The V2 label is what triggers the EXACT evening tasks to start on the participant's phone
- ✓ Use the + / - icons to see or hide details

Participant Dashboard: View All Results

Evening Kiosk: Series 1

GLI 2012	Best	Pred.	%Pred.
FVC (L)	5.14	4.78	108%
FEV ₁ (L)	3.41	3.84	89%
FEV ₁ /FVC	0.66	0.81	82%
FEF ₂₅₇₅ (L/s)	2.14	3.69	58%
PEF (L/s)	8.45	8.26	102%
FEV ₆ (L)	5.14		
FET (s)	4.97		
FIVC (L)	5.38		
PIF (L/s)	6.62		
BEV (L)	0.09		
BEV (%)	1.67		
ATS ERS 2019	✔		

ATS | ERS Series Quality

	FEV ₁	FVC
Quality Grade	B	C
Variability (L)	0.05	0.20
Variability (%)	1.47%	3.89%
Repeatable	No	No

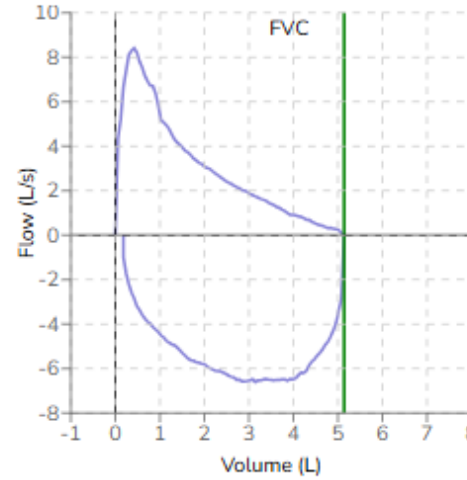
Series Demographics

Sex at Birth	Female
Birth	1984
Height	72.00in
Weight	150.00lbs
Ethnicity	Caucasian

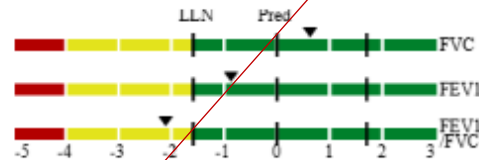
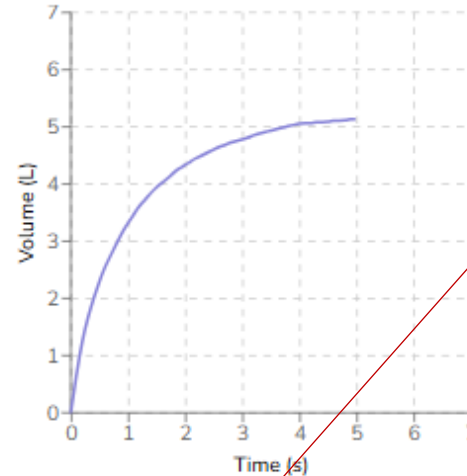
Run-in Calculations

Measurement	Average
PEF	7.04

Flow Volume Curve



Volume Time Curve



[View Series Details](#)

- ✔ For in clinic spirometry, select “View Series Details” to view full results, and add notes and visit labels

Participant Dashboard: View Spirometry Results

Series #1: FVC 4 Efforts; 03/13/2025, 12:13 AM EDT

Overread: Accepted Table View View PDF Report Of Series

Best Measurements

GLI 2012	Best	Pred.	%Pred.
FVC (L)	5.14	4.78	108%
FEV ₁ (L)	3.41	3.84	89%
FEV ₁ /FVC	0.66	0.81	82%
FEF ₂₅₋₇₅ (L/s)	2.14	3.69	58%
PEF (L/s)	8.45	8.26	102%
FEV ₆ (L)	5.14		
FET (s)	4.97		
FVC (L)	5.38		
PIF (L/s)	6.62		
BEV (L)	0.09		
BEV (%)	1.67		
ATS ERS 2019	<input checked="" type="checkbox"/>		

Series Demographics

Sex at Birth	Female
Birth	1984
Height	72.00in
Weight	150.00lbs
Ethnicity	Caucasian

Series Acceptability

	FEV ₁	FVC
Quality Grade	B	C
Variability (L)	0.05	0.20
Variability (%)	1.47%	3.89%
Repeatable	No	No

Patient Position

Standing Seated Supine

Outside-app Coaching

In Person Phone Other Video

Accessories

No Accessories

Labels

V2 x Post-BD x

Best Flow Volume Curve

Best Volume Time Curve

Efforts In Session

Effort #4: 9:16 PM

Flow Volume Chart

	Best	Pred.	%Pred.	ATS
FVC (L)	4.94	4.78	103%	<input checked="" type="checkbox"/>
FEV ₁ (L)	3.41	3.84	89%	<input checked="" type="checkbox"/>
FEV ₁ /FVC	0.69	0.81	85%	
PEF (L/s)	8.35	8.26	101%	
FET (s)	4.97			
BEV (L)	0.07			
BEV (%)	1.44			

Show ArtIQ Analysis

Effort #3: 9:15 PM

kiosk: v1.2.0; Firmware: v4.1

Series Notes

- 55
- ✓ Print the ZEPHYRx Report and file it in the investigator site file once the series has been overread
 - ✓ Confirm overreading Results
 - ✓ View each effort
 - ✓ It is **mandatory** to add Visit Labels for all spirometry series: visit ID, pre/post BD, and location test was completed
 - ✓ E.g. "V2" "Post-BD" "Clinic"

Human Overreading

[← Back to Participant](#)

0000111

Session Details 05/12/2025

Series #1: FVC 3 Efforts; 05/12/2025,
12:01 PM EDT

Overread:
Rejected ❌

Table
View



View PDF Report Of Series



Best Measurements

GLI 2012	Best	Pred.	%Pred.
FVC (L)	5.11	4.74	108%
FEV ₁ (L)	3.30	3.81	87%
FEV ₁ /FVC	0.65	0.81	80%
FEF ₂₅₋₇₅ (L/s)	1.96	3.69	53%
PEF (L/s)	8.33	8.21	102%
FEV ₆ (L)	5.01		
FET (s)	8.75		
FIVC (L)	4.65		
PIF (L/s)	6.31		
BEV (L)	0.06		
BEV (%)	1.21		
ATS ERS 2019			✔

Series Demographics

Sex at Birth	Female
Birth	08/1984
Height	182.00cm
Weight	68.00kg
Ethnicity	Caucasian

Best Flow Volume Curve



Efforts In Session

Effort #3: 12:04 PM Accepted

Overread Series Results

Series: Rejected ❌

Overreader: Adam LaPrad

FEV1 Grade: C

FVC Grade: E

Time Submitted: 05/12/2025, 1:00:06 pm

Notes:

Repetability criteria not met for FVC (0.33 L)

Close

- Within 24 hours of the test, spirometry results will be overread by a human overreader
- You will receive an email notification that your series has been overread
- Click on the link in the email to go to the series
- Click on the Overread box to view the overreader's assigned grade and notes
- If the overreader rejects the series, you should bring the participant back to the clinic to repeat the assessment

Participant Dashboard: View all Visits

1111222 (0% Compliance) Trial Research **Participant Settings**

Participant Details [+ Passcode Link](#) [+ Edit](#) Notes

Identification

StudyID	1111222
Spirometer ID	
Participant's Timezone	America/New_York (-04:00 from UTC)

Demographics

Sex at Birth	Female
Birth	07/1984, 40 years
Ethnicity	Caucasian
Height	182.00 cm
Weight	68.00 kg

Run-In Calculations

No Averages Established

At Home Status

Status	Active
Start Date	04/07/2025
Run-in End Date	04/08/2025
End Date	06/02/2025

[+ Screen Fail Participant](#)

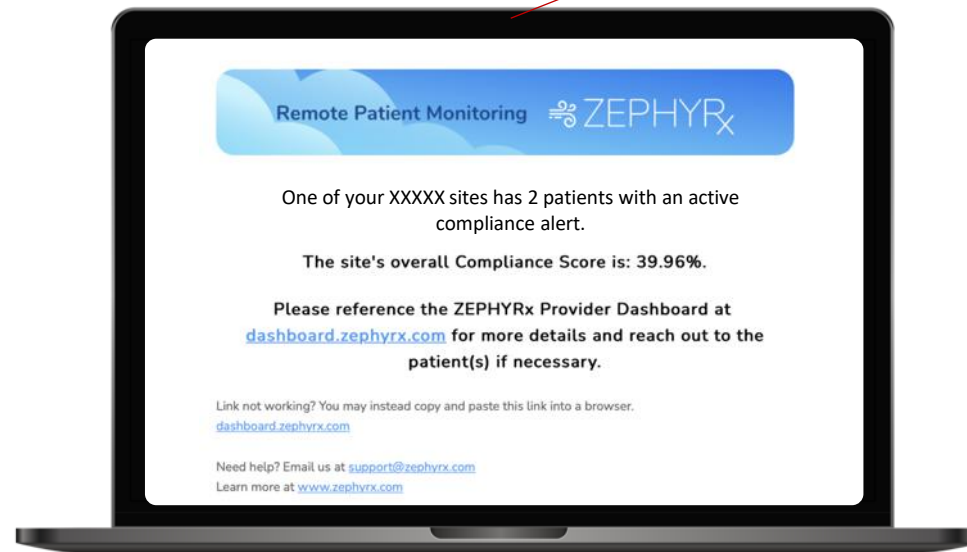
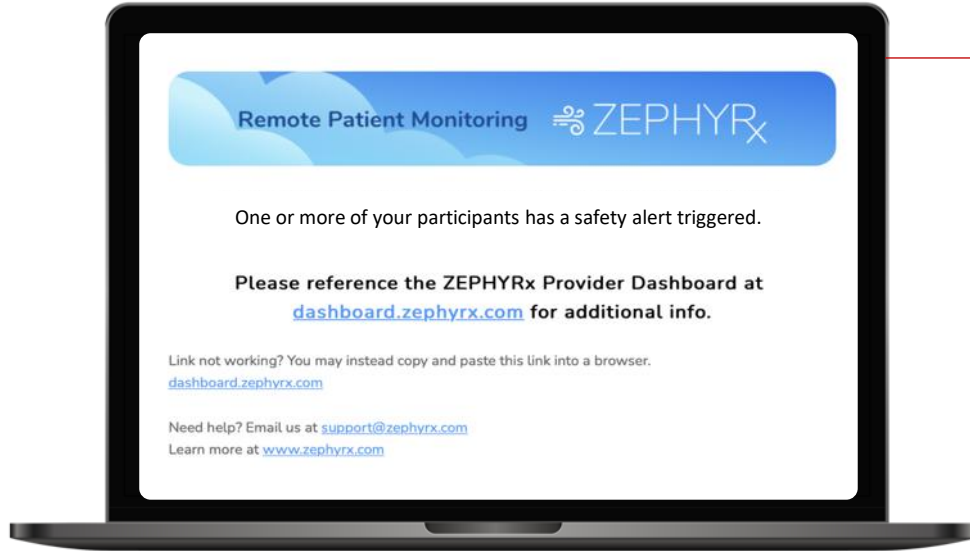
At Home Status: Active [+ Edit](#)

All Labels

Labels	Date of measurement	Measurement
Hospital, V1a, pre-bd	04/05/2025 11:42 AM EDT	FVC Series
Hospital, V1a, post-db	04/05/2025 11:48 AM EDT	FVC Series
Research clinic, V1b, post-db	04/06/2025 3:45 PM EDT	FVC Series
V2	04/07/2025 8:29 AM EDT CAT	
V2	04/07/2025 8:35 AM EDT SGRQ	
Research clinic, V2, post-db	04/07/2025 9:48 AM EDT	FVC Series

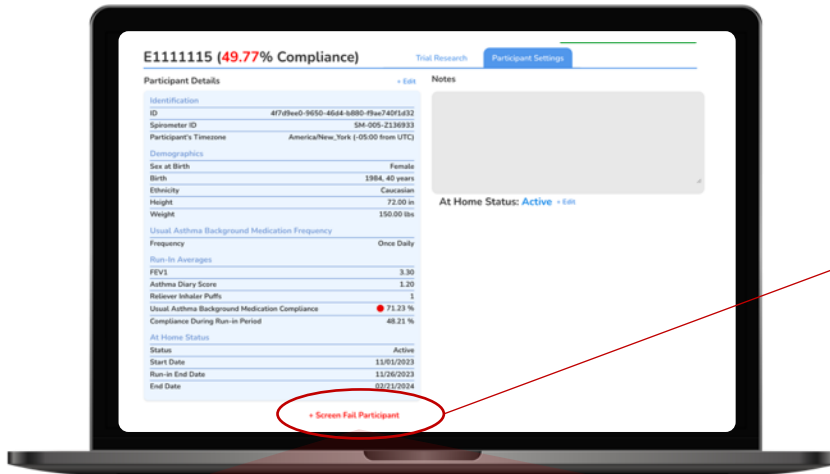
- ✓ Select Participant Settings Tab
- ✓ View all tagged spirometry and eCOA sessions

Safety & Compliance Alert Emails



- ✓ Sites receive **daily Safety Alert Emails** when participants have an active safety alert
- ✓ Sites receive **weekly Compliance Emails** listing the number of participants with active compliance alerts
- ✓ **Reference the provider dashboard** for additional information

Screen Fail a Participant



Screen Fail Participant

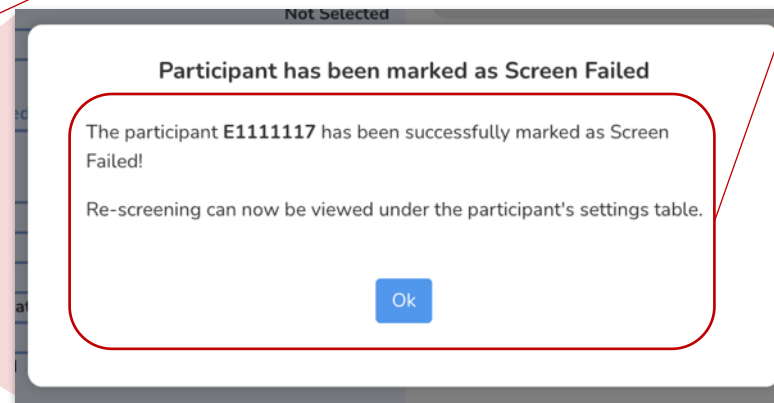
Enter the e-code (case sensitive) of the participant: **E111117** in the form below to screen fail.

Participant e-code

This will mark the participant as 'Screen Failed'. This will update the At Home Status to 'Screen Failed' and the participant's name will have a strike-through. The At Home Status's end date will also be updated to be today. Are you sure you want to continue?

Screen Fail Participant Cancel

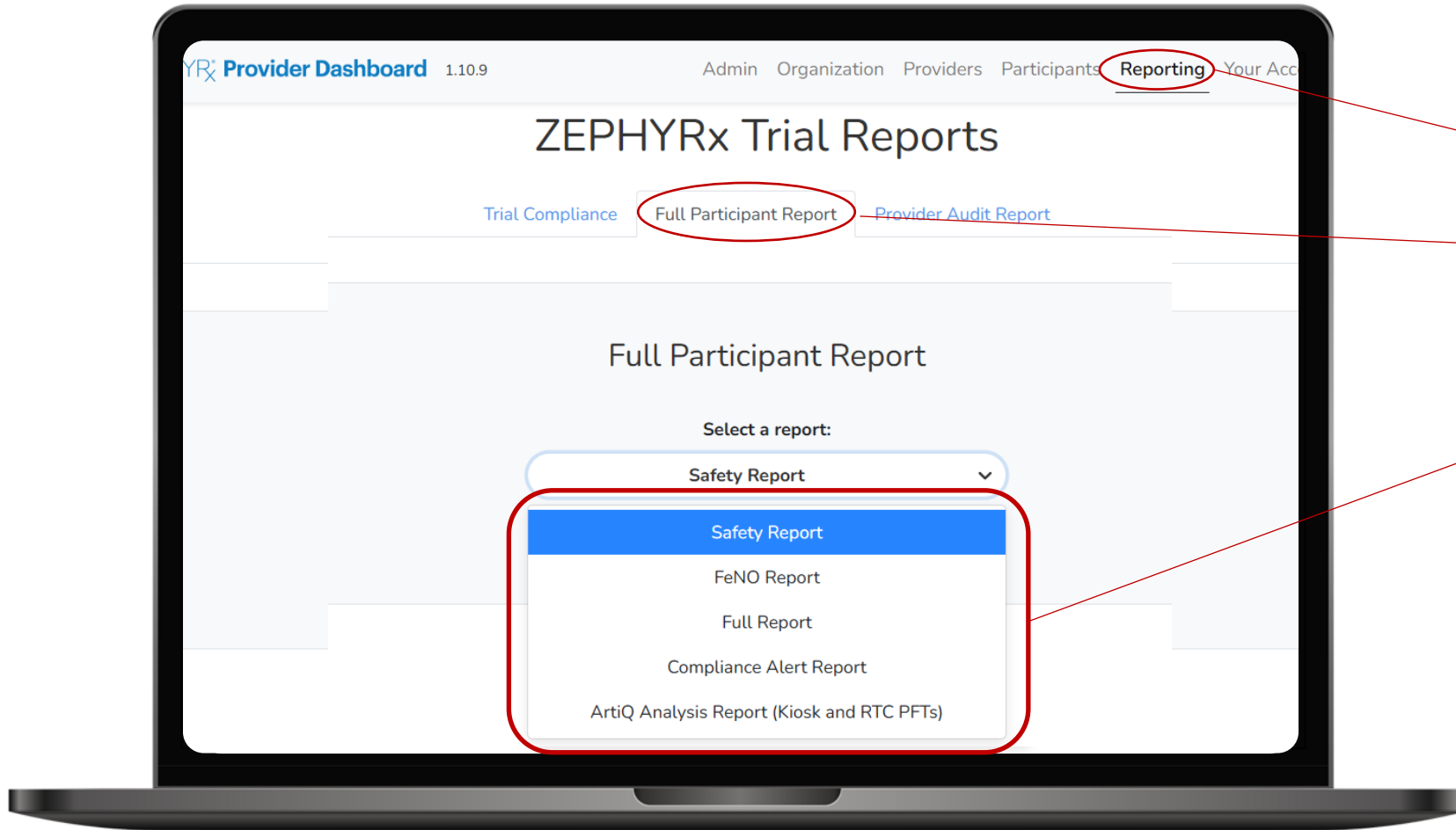
04/13/2024



- ✓ From the Participant Settings tab, select **Screen Fail Participant**
- ✓ Confirm **participant's study ID**
- ✓ Select **Screen Fail Participant**
- ✓ A **successful screen failed status** popup will appear

Once screen failed, participant will not receive home tasks, and compliance will be locked.

Participant Reports



- ✓ Select **Reporting**
- ✓ Select **Full Participant Report**
- ✓ Select relevant **report type**



Support Helpdesk

Support Notes for Sites in Both Studies

- If your site is part of both the Seabreeze Asthma and Seabreeze COPD studies, ensure the correct equipment and correct dashboard is being used for each study.
 - The tablets, and spirometers are not interchangeable – each study has a designated set of equipment – stickered with the study name
 - The FeNO Machine is the only piece of equipment that will have one unit used by both the COPD and Asthma studies (though with the study specified tablets)
 - Be sure you are viewing the correct dashboard before creating participants, or editing participant data. You can use the “Change” button to toggle between your dashboard sites

The screenshot shows the 'Provider Dashboard' interface. At the top, there are navigation tabs: 'Organization', 'Participants' (selected), 'Reporting', and 'Your Account'. Below the navigation, there is a search bar with the text 'Connect Bio Asthma Demo (CBP-201-206-TEST)' and a 'Change' button circled in red. To the right of the search bar is a search input field with the placeholder text 'Search by participant'. Below the search bar, there is a section for 'Connect Bio Asthma Demo' with '2 Trial Participants' and a '+ Create New Participant' link. On the left side, there is a 'Site Program Compliance' section showing '44.91 %' and '0 Critical compliance failures'. On the right side, there is a table with the following data:

Participant ID	At Home Status	Last Active	Alerts	Compliance
11119999	Active	03/25/2025 (8:13 PM)	2	74.04 %

Contact Support

Support Request

First and Last Name (Trial Site Personnel)*

Email*

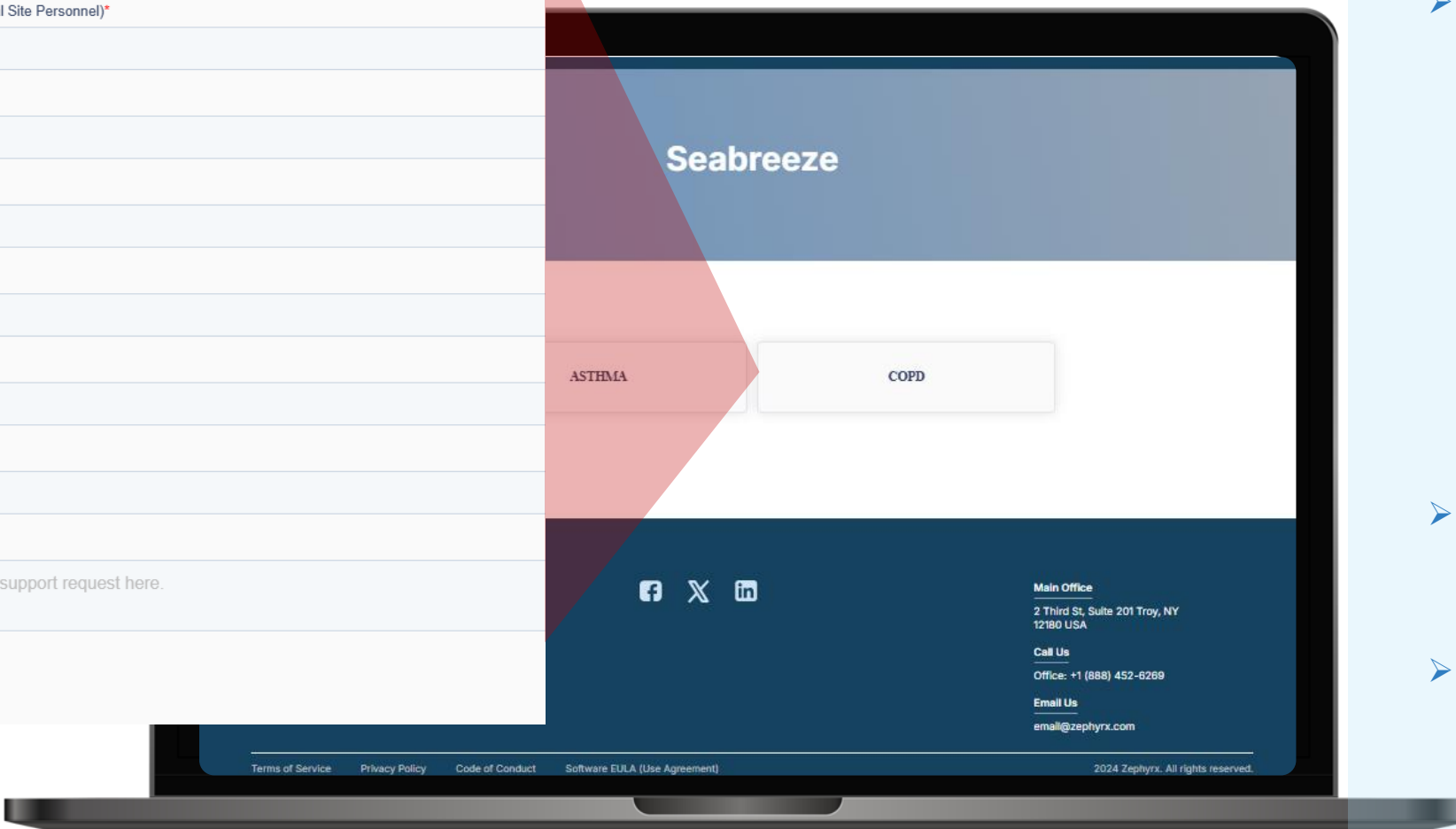
Phone number*

Trial Site Number*

Country*

Priority

Ticket description*

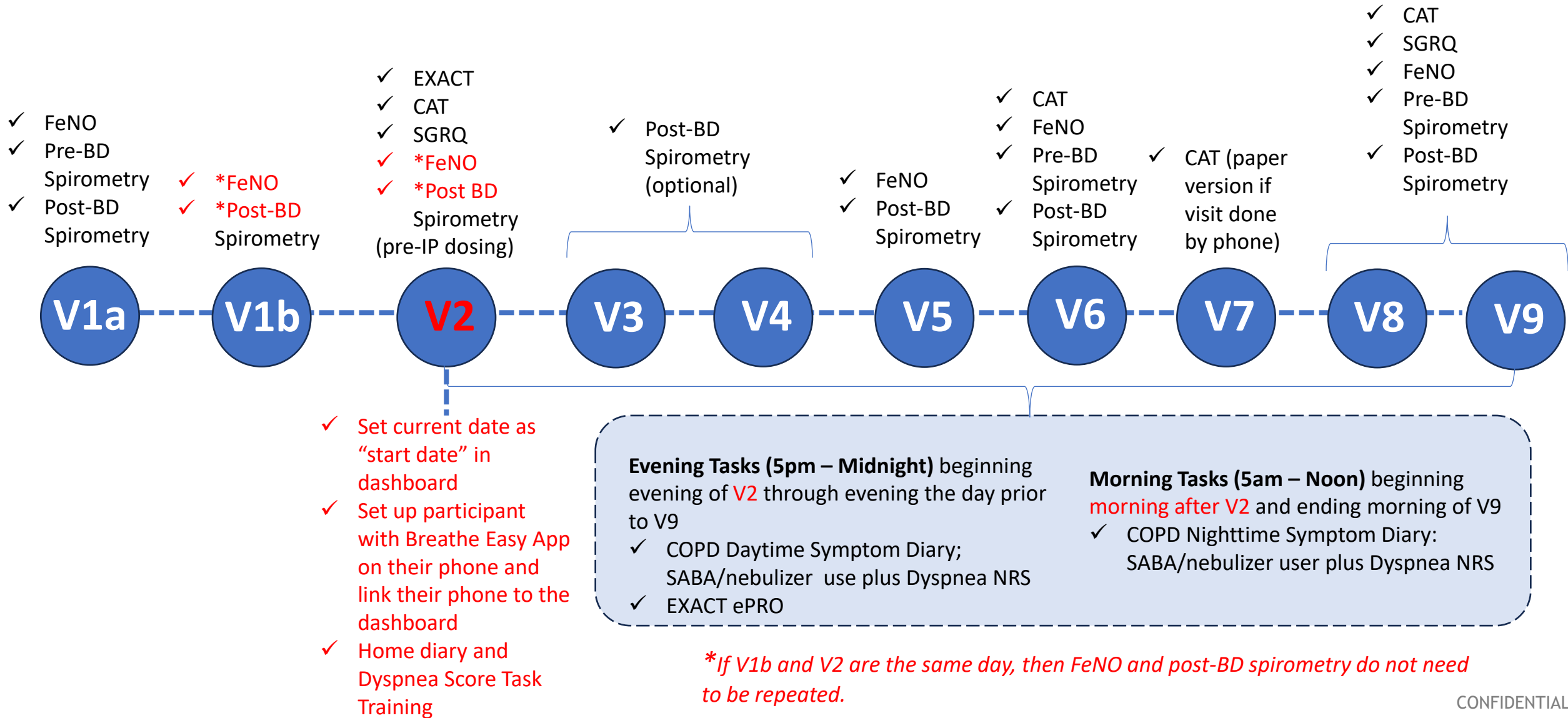


The laptop screen displays the Seabreeze website. The header features the Seabreeze logo. Below the logo, there are two buttons for selecting a condition: "ASTHMA" and "COPD". The footer of the website includes social media icons for Facebook, X, and LinkedIn, along with contact information for the Main Office: 2 Third St, Suite 201 Troy, NY 12180 USA, Office: +1 (888) 452-6269, and Email Us: email@zephyrx.com. The footer also contains links for Terms of Service, Privacy Policy, Code of Conduct, Software EULA (Use Agreement), and a copyright notice for 2024 Zephyrx.

- To submit a support request, or order additional equipment, visit zephyrx.com/seabreeze
 - Select COPD
 - Fill in the details
- For urgent matters, call +1 (888) 452-6269
- 24/7 support hours

zephyrx.com/seabreeze

Protocol V2 Update: Protocol Overview



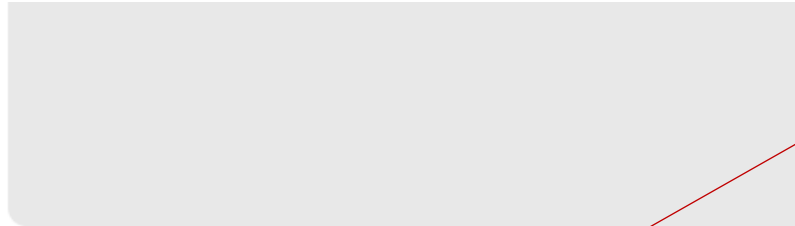
Protocol V2 Update: At-Home Task Start Date

StudyID	11119999
Spirometer ID	
Participant's Timezone	UTC (-00:00 from UTC)
Demographics	
Sex at Birth	Female
Birth	1984, 41 years
Ethnicity	Caucasian
Height	71.65 in
Weight	149.91 lbs
Run-In Calculations	
No Averages Established	
At Home Status	
Status	Not Started

+ Screen Fail Participant



Participants will not see ed diary tasks on their phone if the start date is not set.



At Home Status: Not Started + Edit

Edit At Home Status - Starting Date ✕

Status: Not Started

Select start date: 📅

Select run-in period end date: 📅

Select end date: 📅

End date defaults to 8 weeks after selected start date.

✓ From the **Participant Settings** tab, select **Edit** next to the at home status

✓ select **Start Date:**

✓ **Start date** should be set at **V2** as current date

✓ **Run-in period end date** can be left blank

✓ **End date** will default to 8 weeks after start date, but can be updated as needed

✓ Select **Submit**