



 ZEPHYR[®]

Platform User Guide

Seabreeze STAT Asthma
V4.0
March 2026

seabreeze

Platform User Guide Outline

- ✓ Technology, Equipment, and Study Protocol Overview
- ✓ ZEPHYRx Provider Dashboard
- ✓ In-Clinic Kiosk Spirometry & eCOA
- ✓ In-Clinic FeNO
- ✓ Home Tasks (Home PEF, diary)
- ✓ 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
 - ACQ-5
 - Modified Borg
Dyspnea
Scale

HOME TESTING



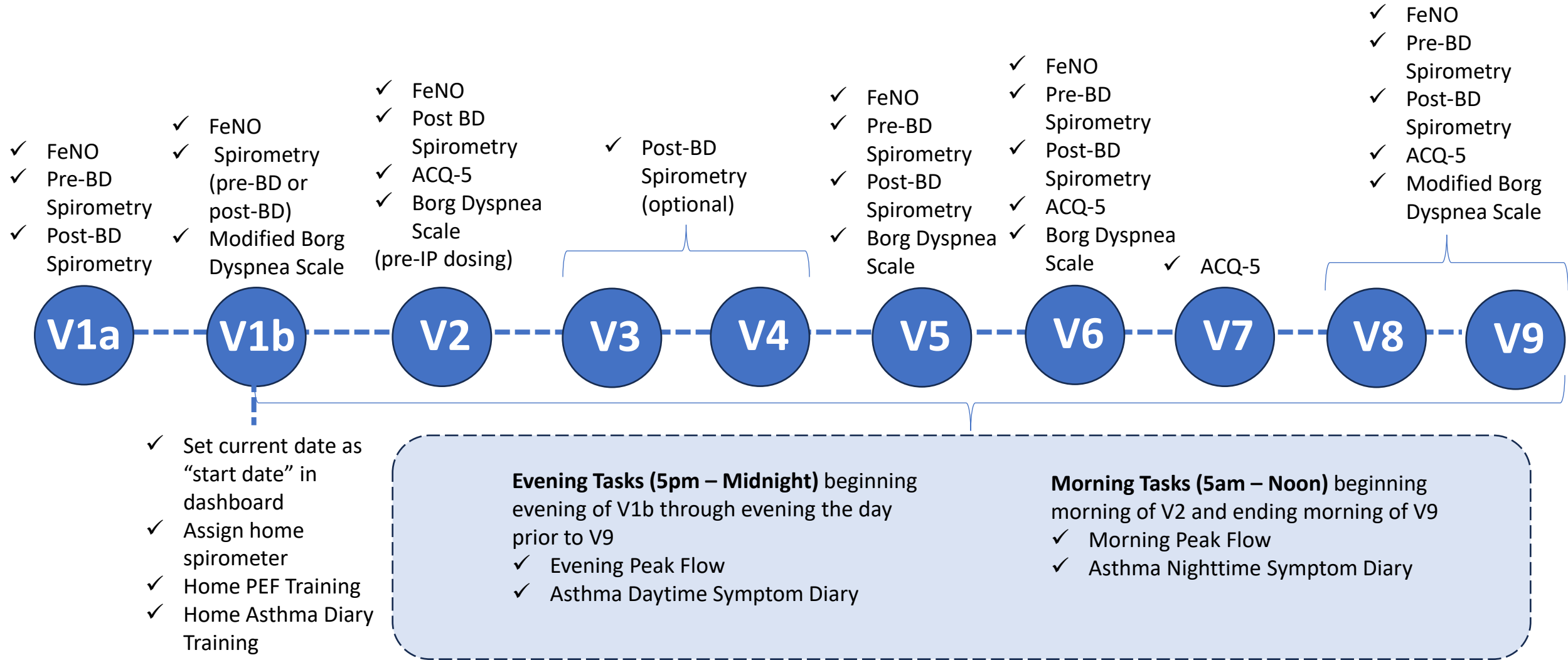
- Twice daily
Asthma diary
- Twice daily peak
flow (PEF)

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
Home PEF and ed diary	Spirobank Smart (with noseclips and batteries)	4

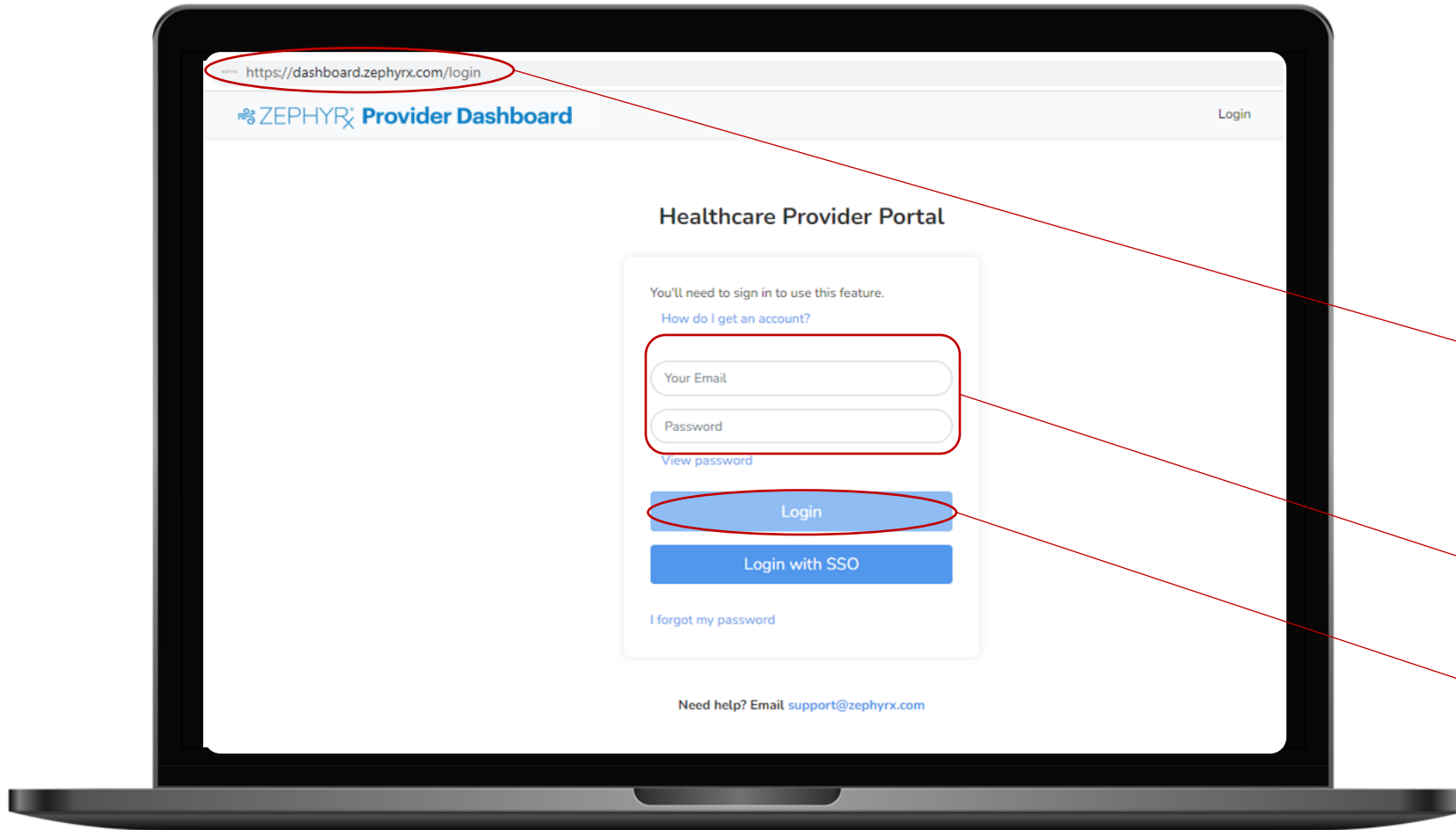
Protocol Overview





Provider Dashboard

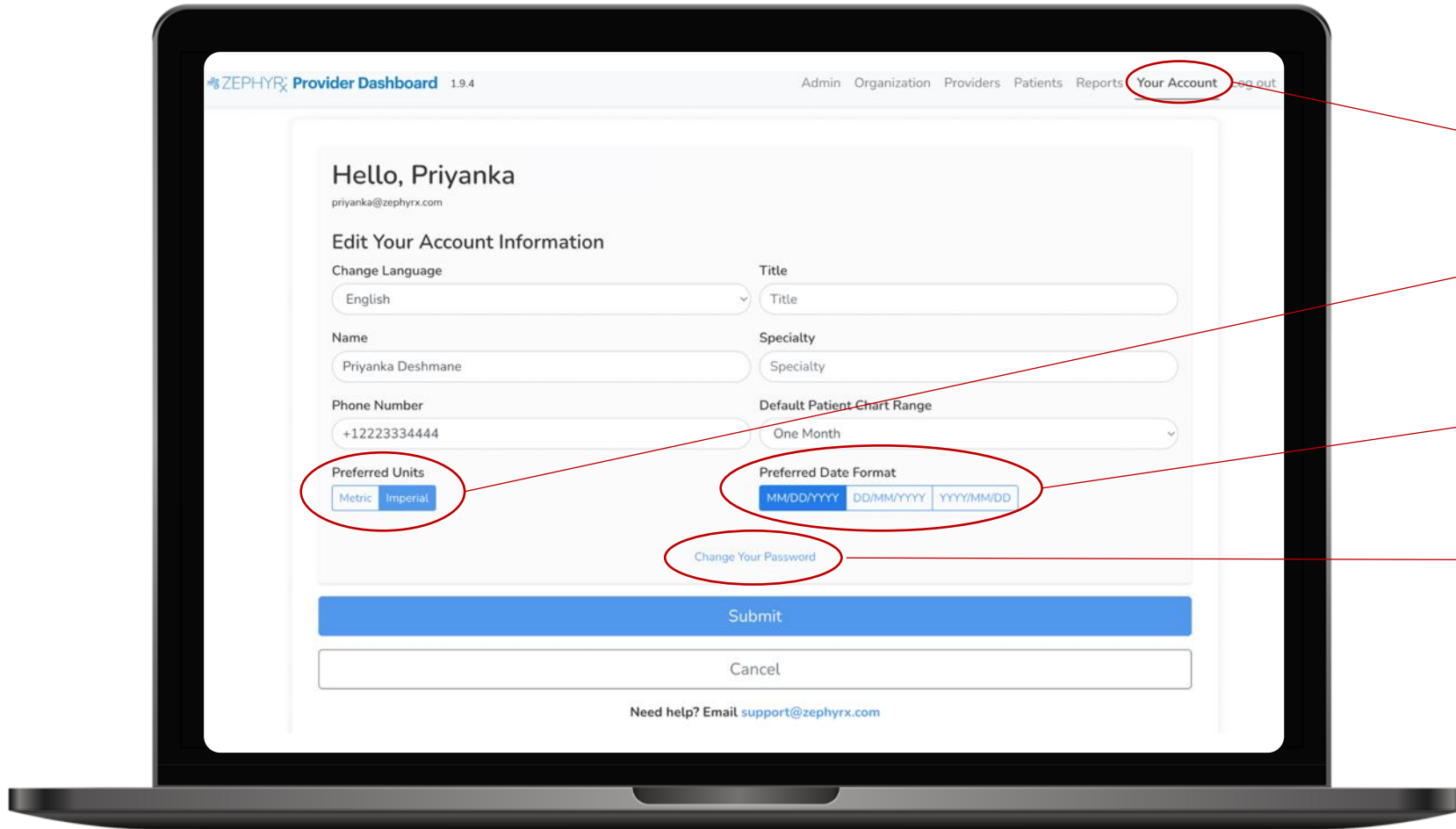
Login to Provider Dashboard



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

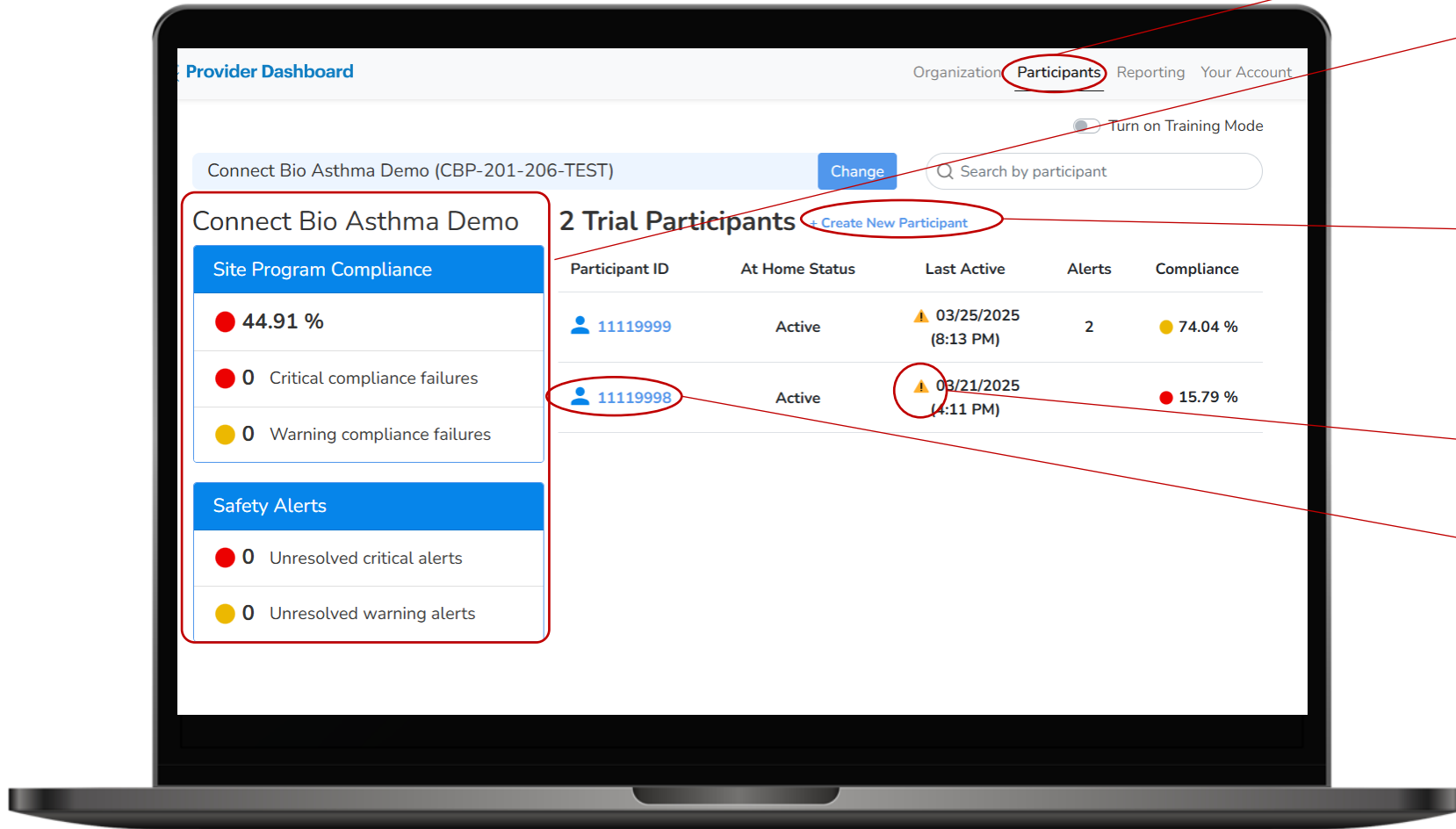
- ✓ Visit URL:
dashboard.zephyrx.com/login
- ✓ Enter your **email and password**
- ✓ Select **Login**

Your Account



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

Site Dashboard Overview



- ✓ 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

Provider Dashboard

Organization: Participants

Connect Bio Asthma Demo (CBP-201-206-TEST) Change Q Search by participant

Connect Bio Asthma Demo **2 Trial Participants** + Create New Participant

Participant ID	At Home Status	Last Active	Alerts
11119999	Active	03/25/2025 (8:13 PM)	2
11119998	Active	03/21/2025 (4:11 PM)	

Site Program Compliance

- 44.91 %
- 0 Critical compliance failures
- 0 Warning compliance failures

Safety Alerts

- 0 Unresolved critical alerts
- 0 Unresolved warning alerts

Create New Participant

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)

Create Participant Cancel

- ✓ Study ID: 4-digit site ID, 3-digit subject ID (e.g. 1111001)
- ✓ Enter all demographics
- ✓ Leave Spirometer ID Blank for Now
 - ✓ This will be filled in at V1b

In-Clinic Kiosk Spirometry



In Clinic Assessment Notes and Preparation:

In Clinic Assessments should be completed in the following order:

- ACQ-5
- Modified Borg Dyspnea Scale
- 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 5, 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 asthma 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 pre-BD and post-BD spirometry assessments from Visit 5 onwards may repeat the assessment (as soon as the participant's condition allows).

In Clinic Assessment Notes and Preparation:

Withholding Usual Asthma Maintenance Medications

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

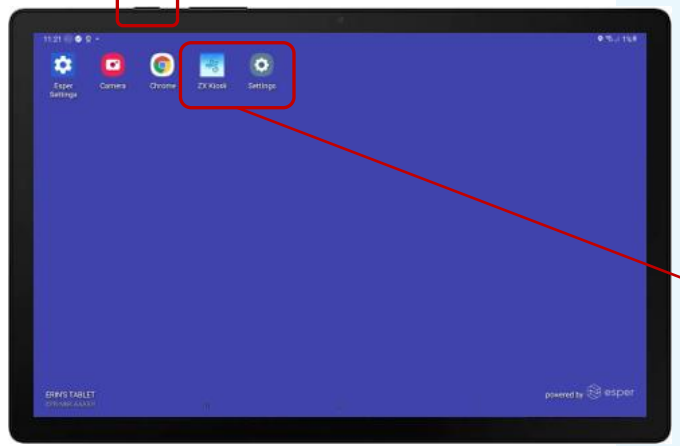
- Last dose of salbutamol/albuterol or levosalbutamol/levalbuterol for at least 6 hours.
- Last dose of LABA for at least 12 hours (ultra-long-acting LABA like vilanterol for at least 24 hours).
- Last dose of LAMA for at least 24 hours
- Last dose of theophylline or aminophylline for at least 24 hours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

Kiosk Login & Setup



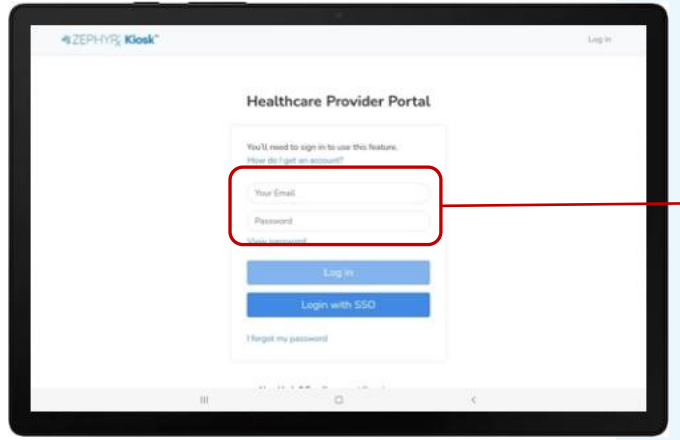
- Power on the spirometer
- Check battery life & charge if low

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

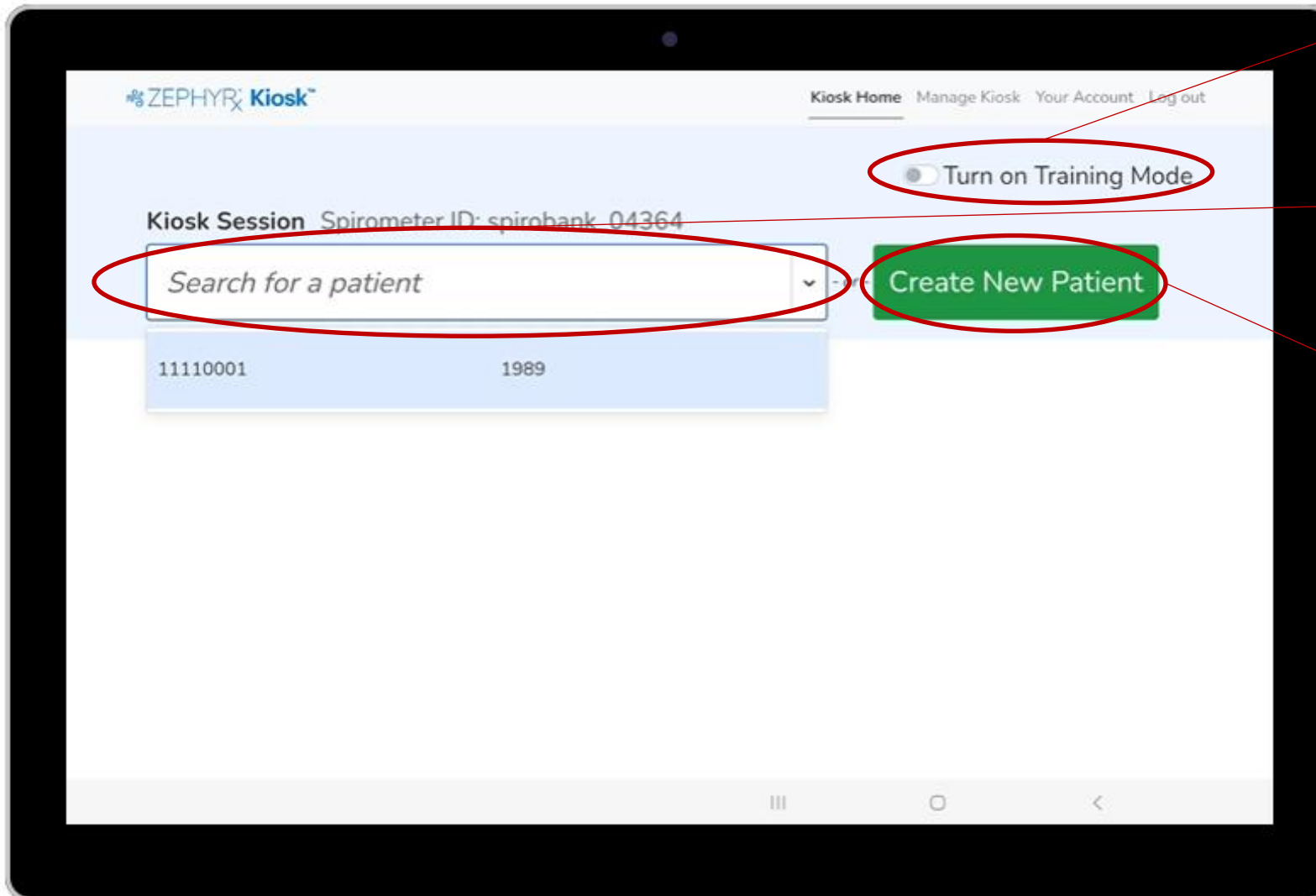
Kiosk Spirometry Screening



- **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

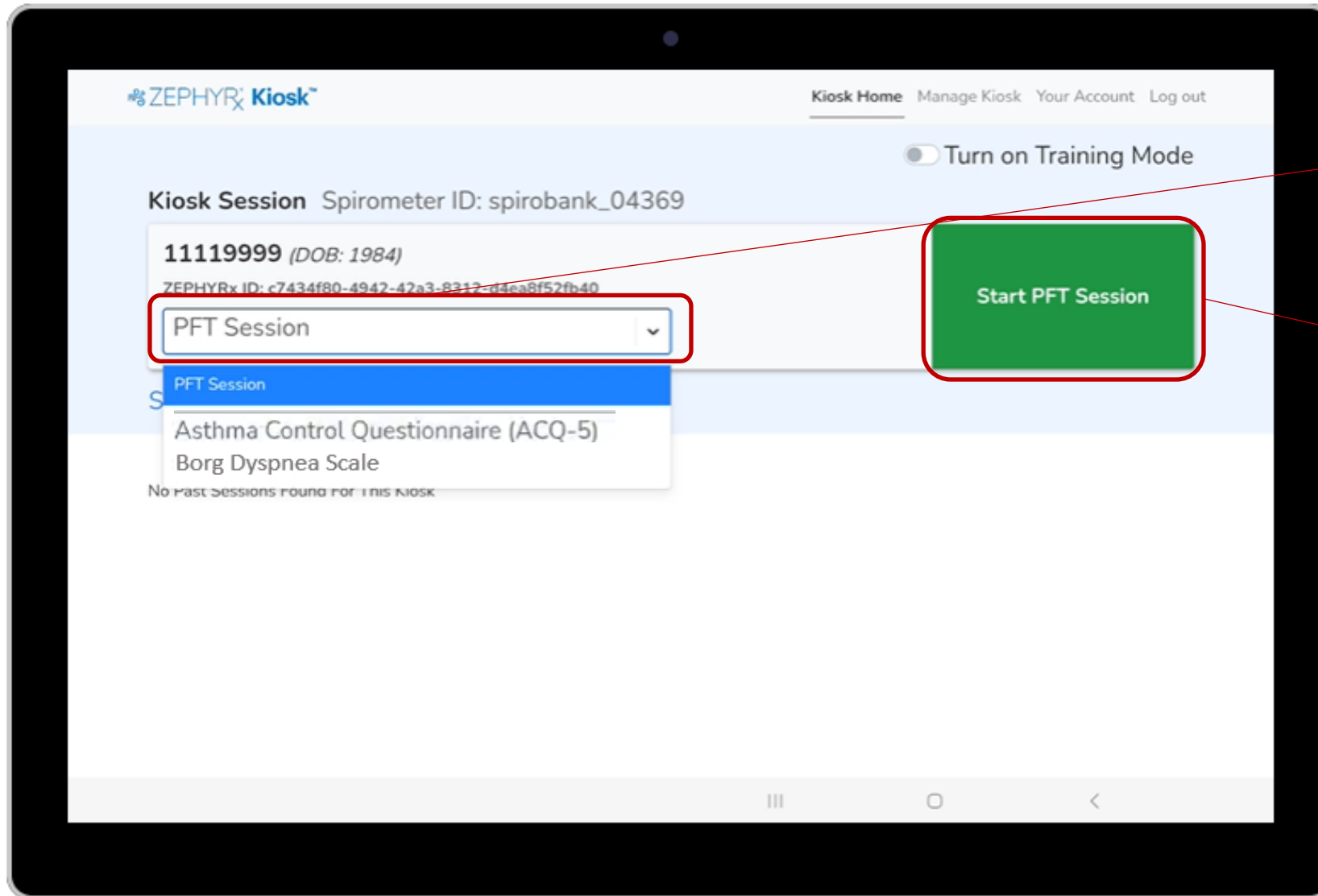
At-Home Spirometer ID (optional)

Cancel Confirm

No Past Sessions Found For This Kiosk

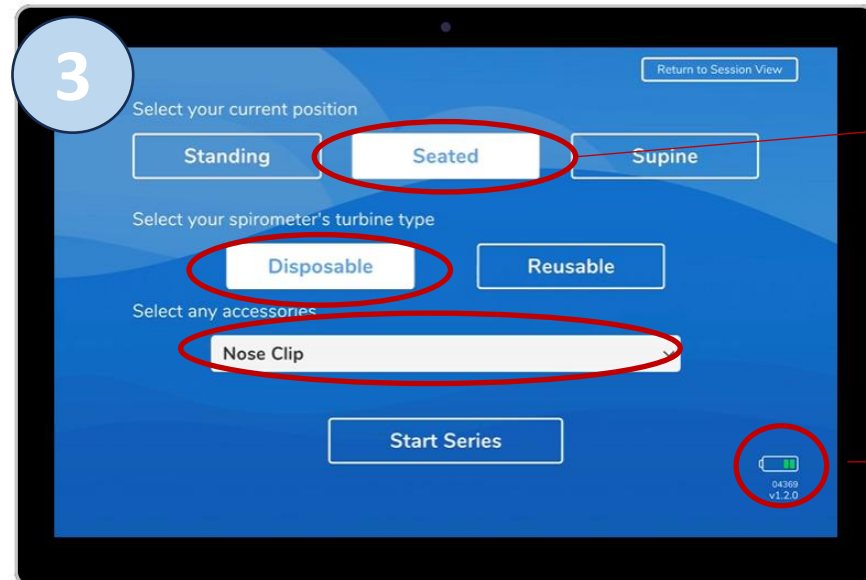
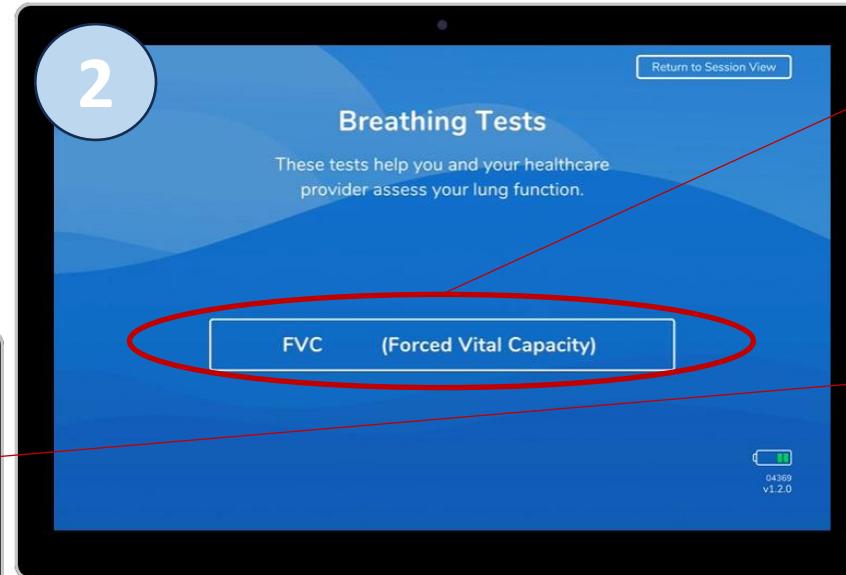
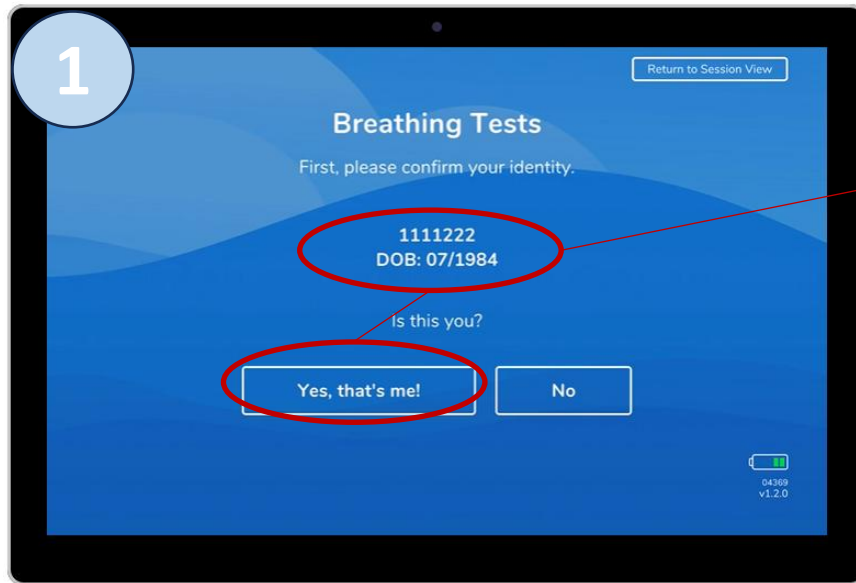
- If you choose to create a new participant, **fill in all demographic data** as prompted
- You can leave **At Home Spirometer ID blank** – this will be entered later
- Select **Confirm**

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 overread 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



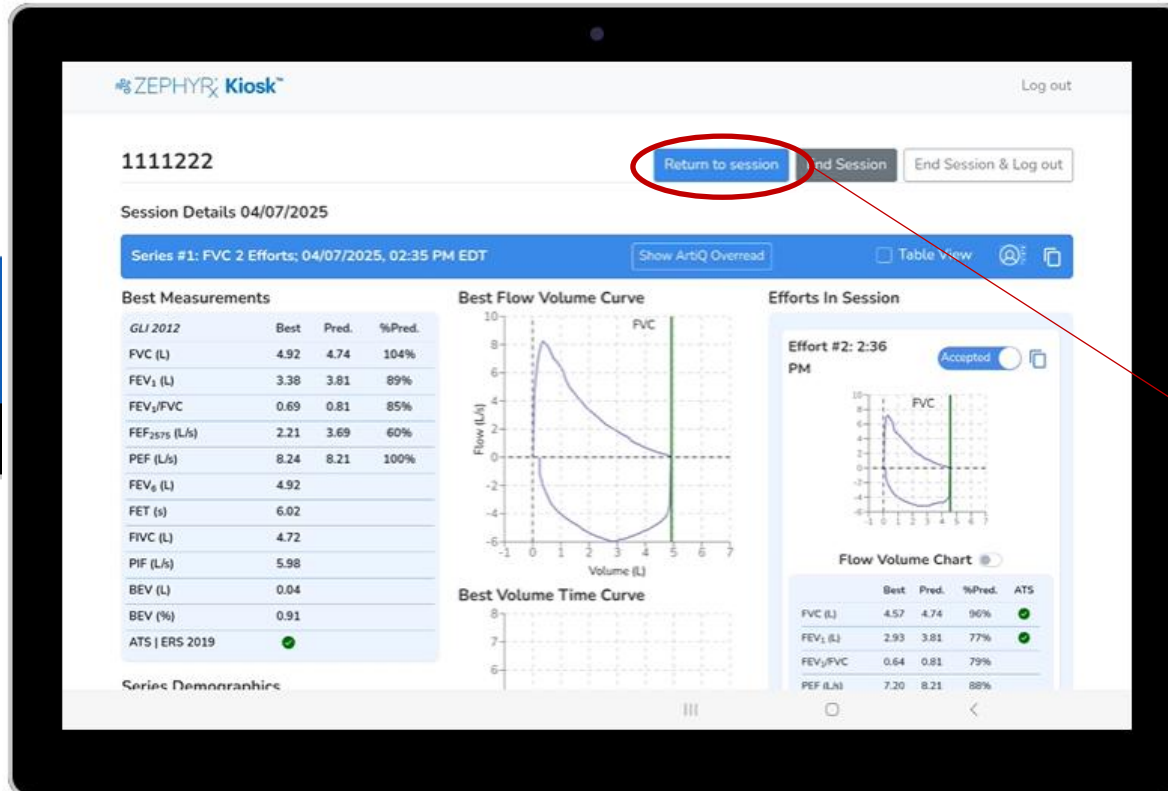
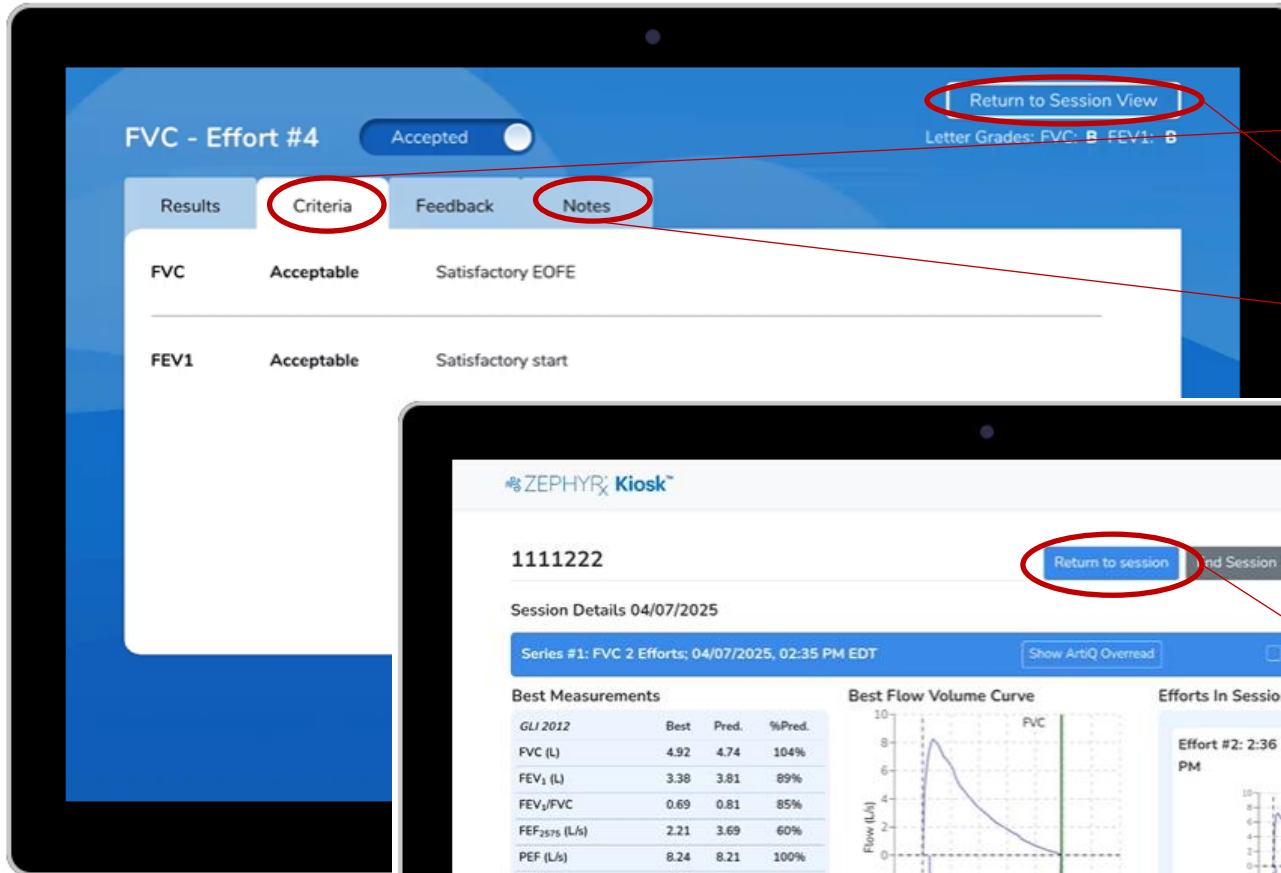
- **Coach participant** using on-screen instructions
- **Conduct 3 – 8 efforts**, aiming for 3 acceptable efforts
 - *8 efforts max*

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

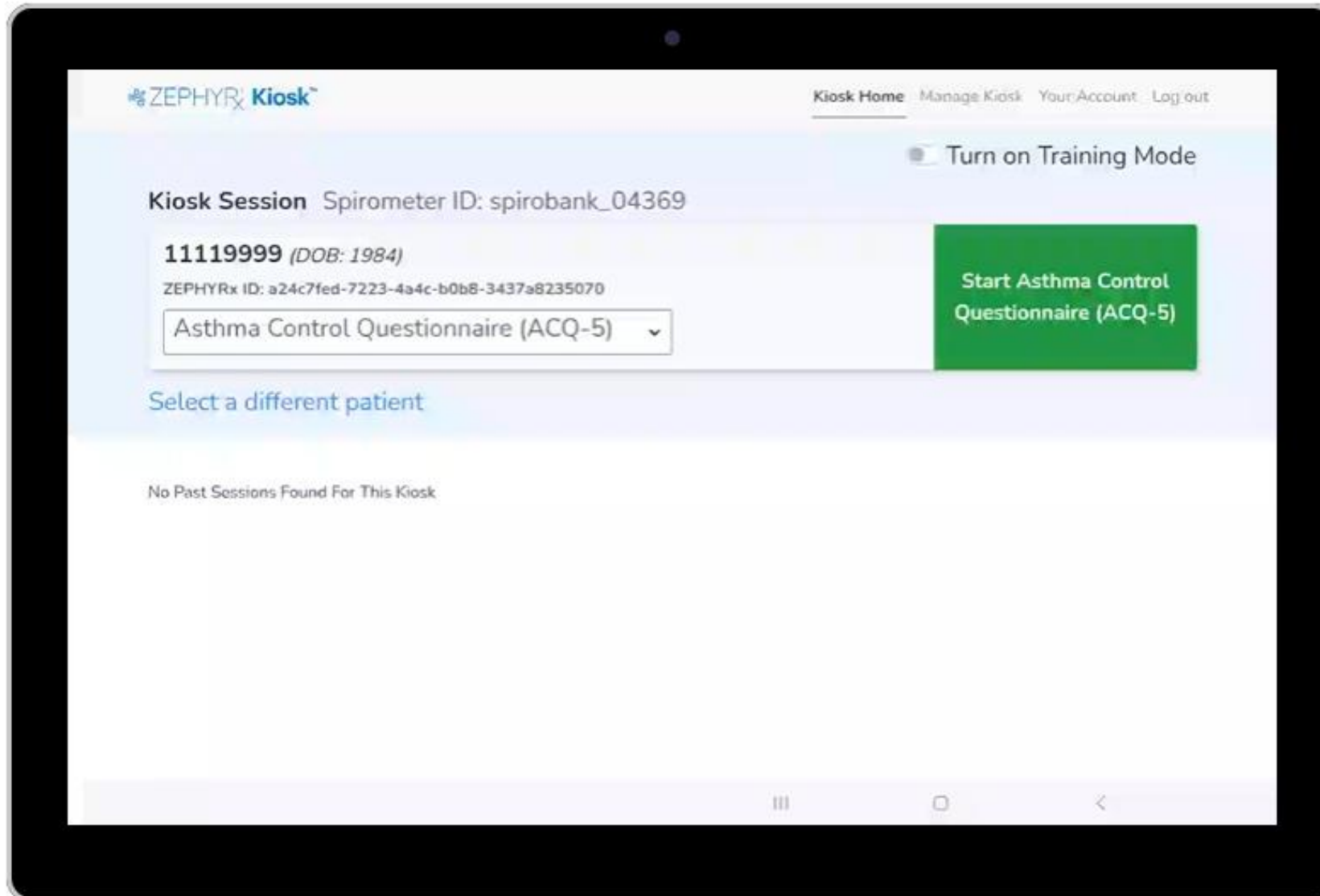
Spirometry Series are graded based on **number of acceptable efforts performed, and repeatability of the two best efforts.**

- 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



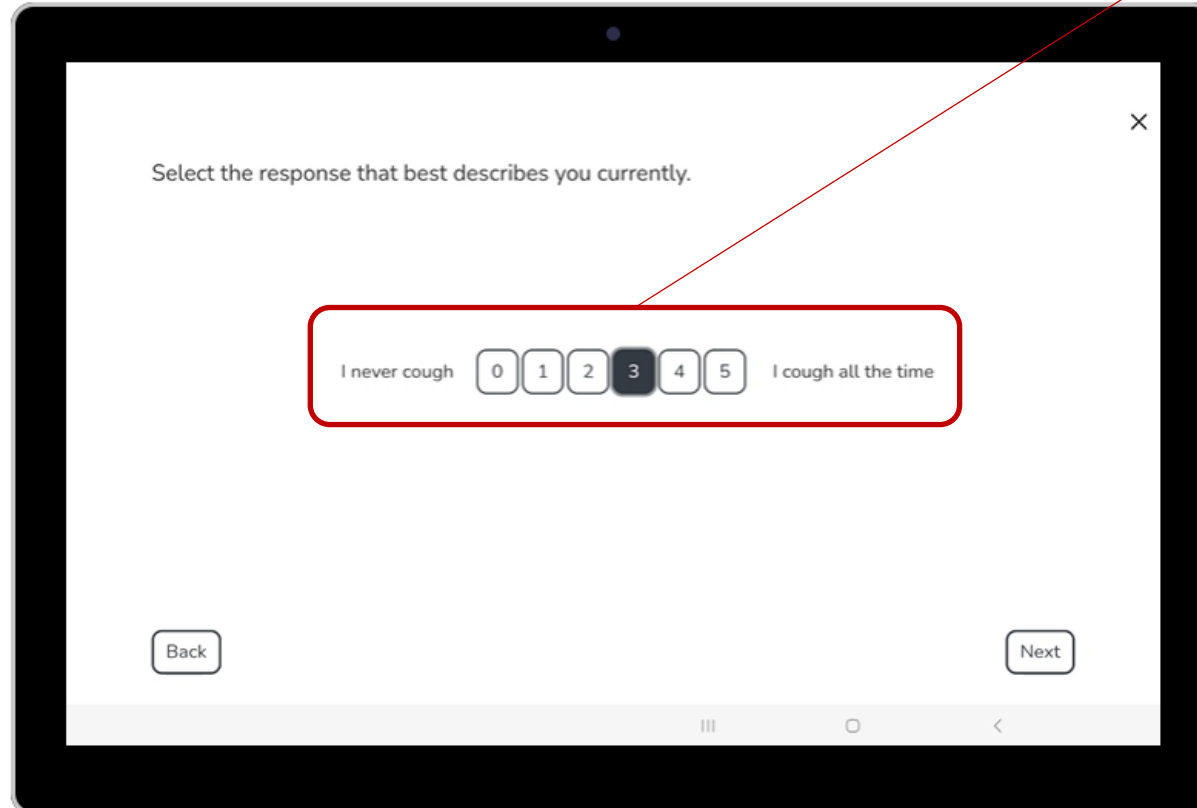
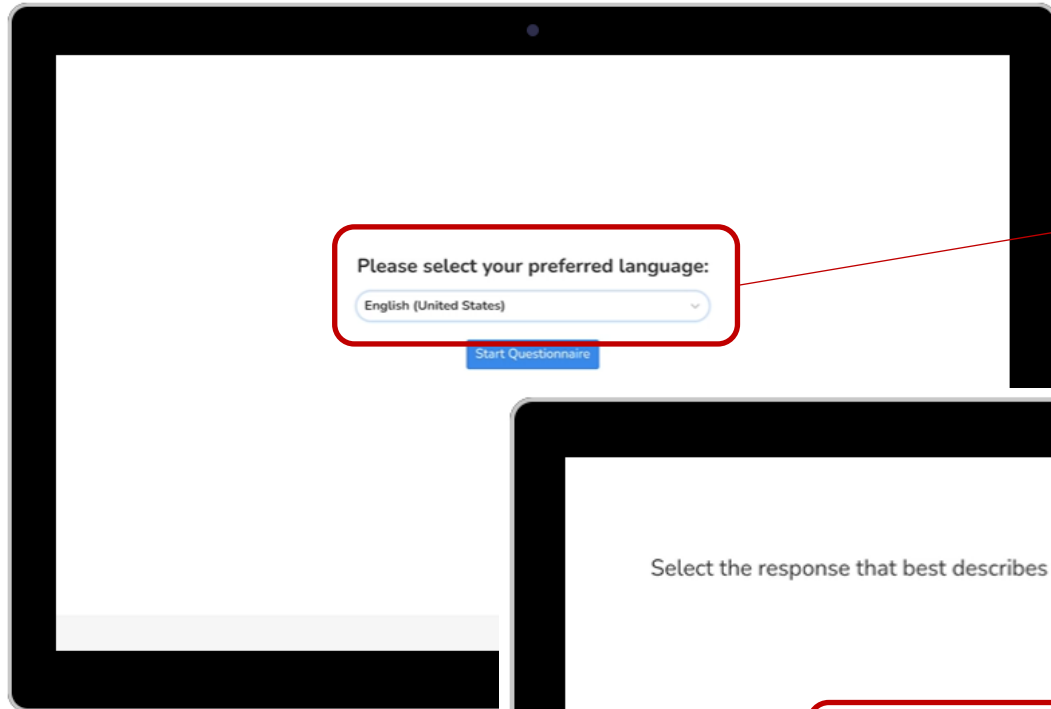
In-Clinic Kiosk eCOAs

Kiosk eCOAs



- **Log into the Kiosk App** on the Samsung Tablet
- Select your **Participant** or Create a new participant
- Select the desired **eCOA**
 - ACQ-5
 - Modified Borg Dyspnea Scale
- 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
- Once complete, results will automatically be transmitted to the ZEPHYRx dashboard

Visit 7 ACQ-5 COA

Please answer questions 1 - 5.

Circle the number of the response that best describes how you have been during the past week.

- | | |
|--|-------------------------------------|
| 1. On average, during the past week, how often were you woken by your asthma during the night? | 0 Never |
| | 1 Hardly ever |
| | 2 A few times |
| | 3 Several times |
| | 4 Many times |
| | 5 A great many times |
| | 6 Unable to sleep because of asthma |
| 2. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning? | 0 No symptoms |
| | 1 Very mild symptoms |
| | 2 Mild symptoms |
| | 3 Moderate symptoms |
| | 4 Quite severe symptoms |
| | 5 Severe symptoms |
| | 6 Very severe symptoms |

- 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.

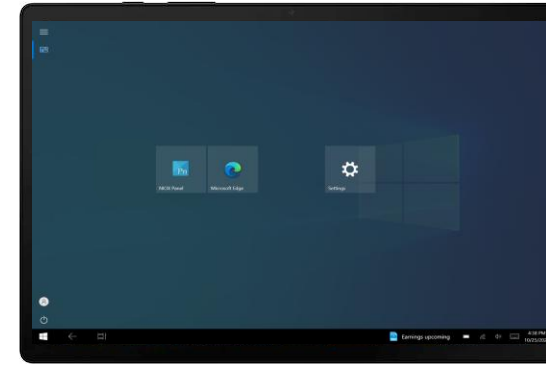


In-Clinic FeNO

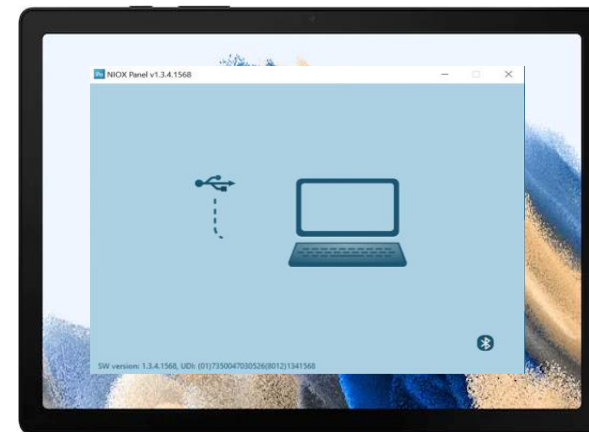
FeNO Setup



- **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**



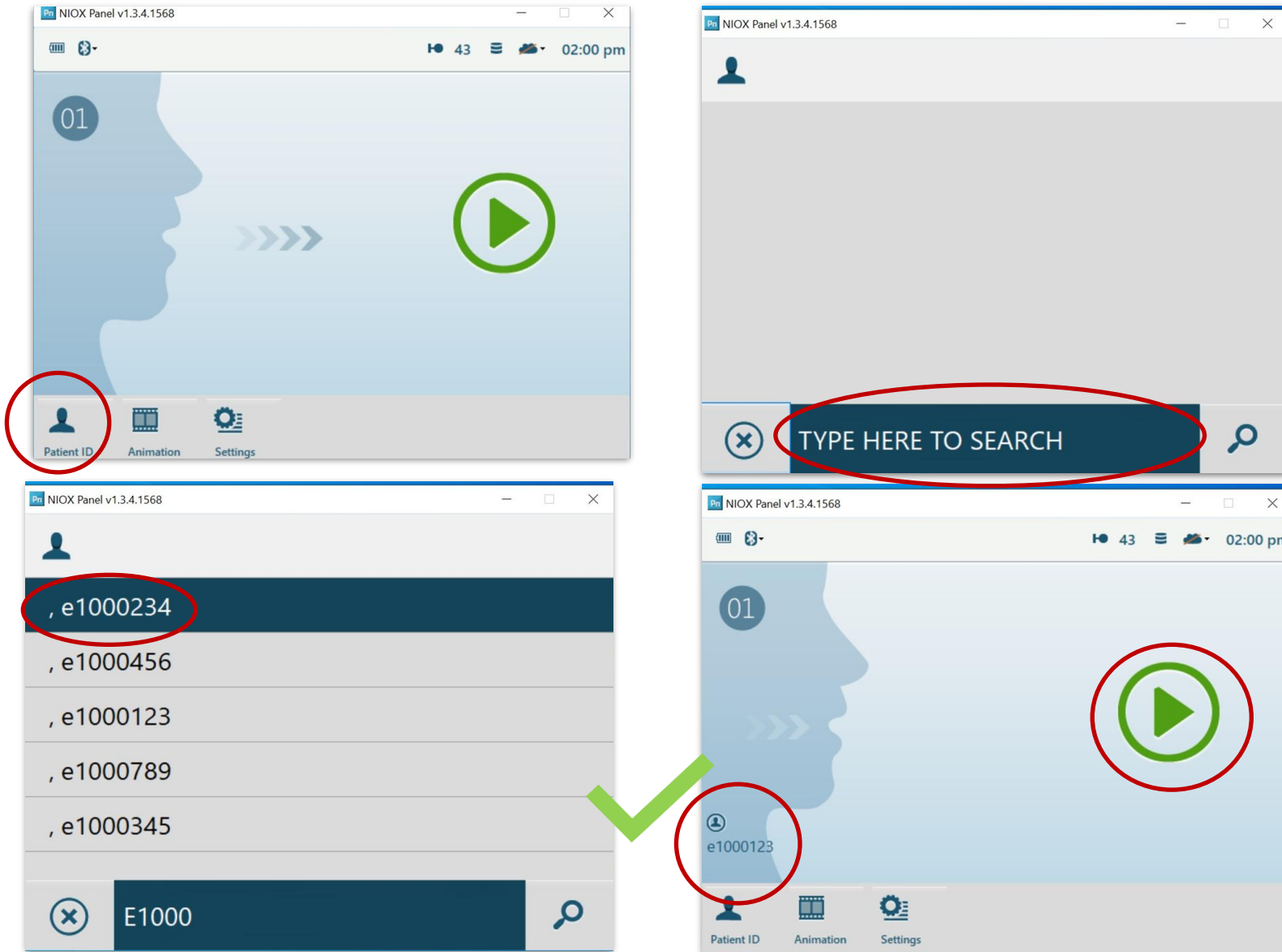
FeNO Maneuver



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

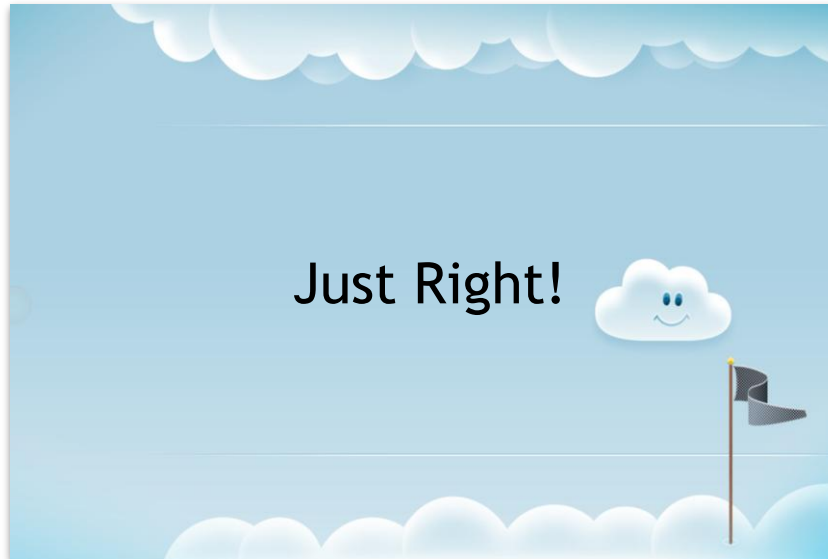
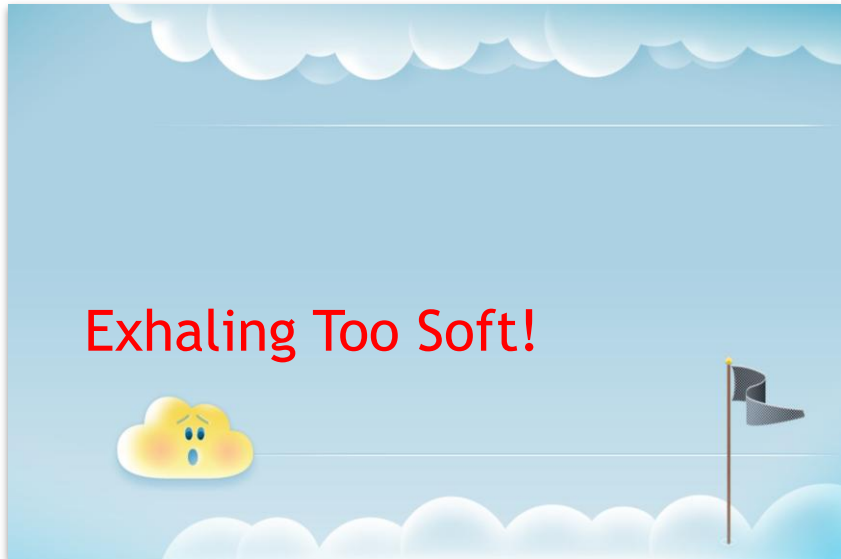
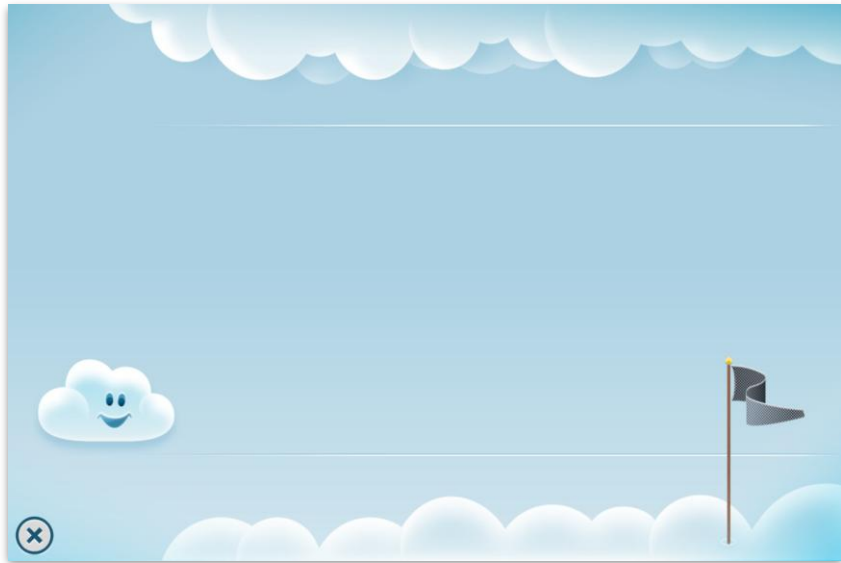


1. Select "Patient ID"
2. Begin typing in the search bar
3. Select the Correct participant ID
4. Confirm the ID is correct
5. Select the Green Arrow to begin the test



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

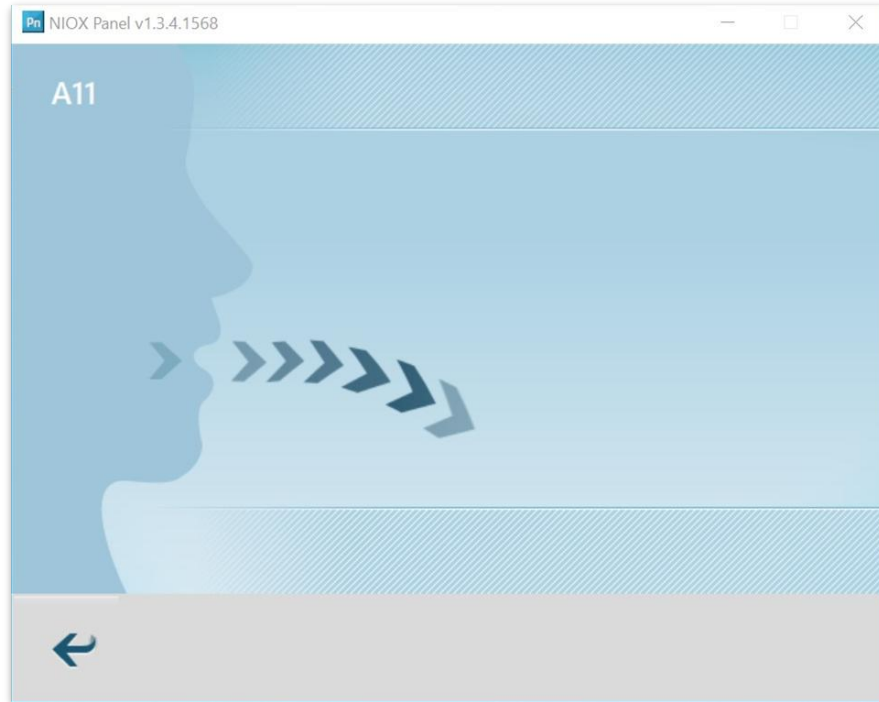
Complete the Test



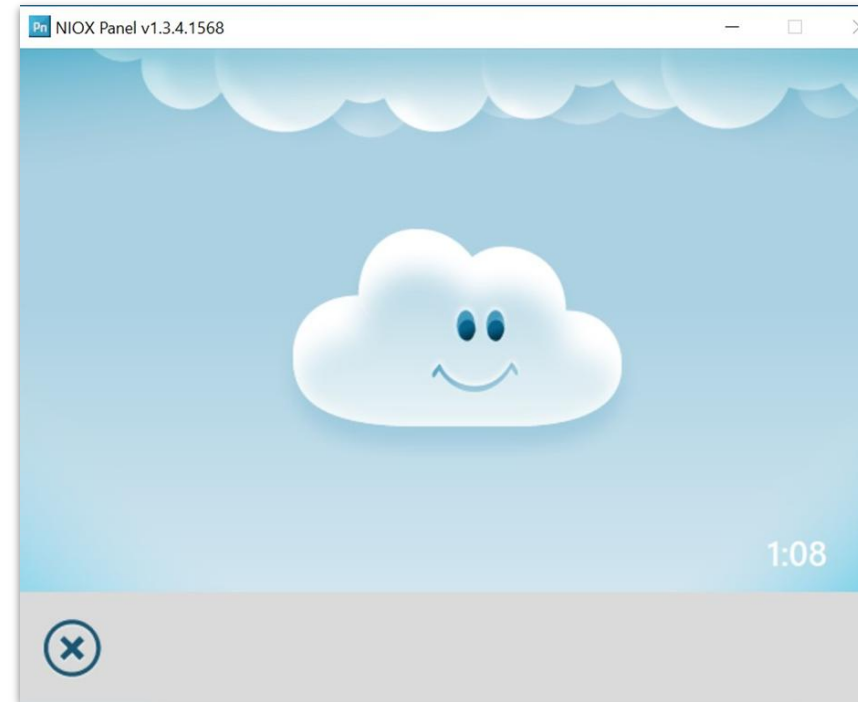
FeNo Tips & Troubleshooting

- ✓ 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



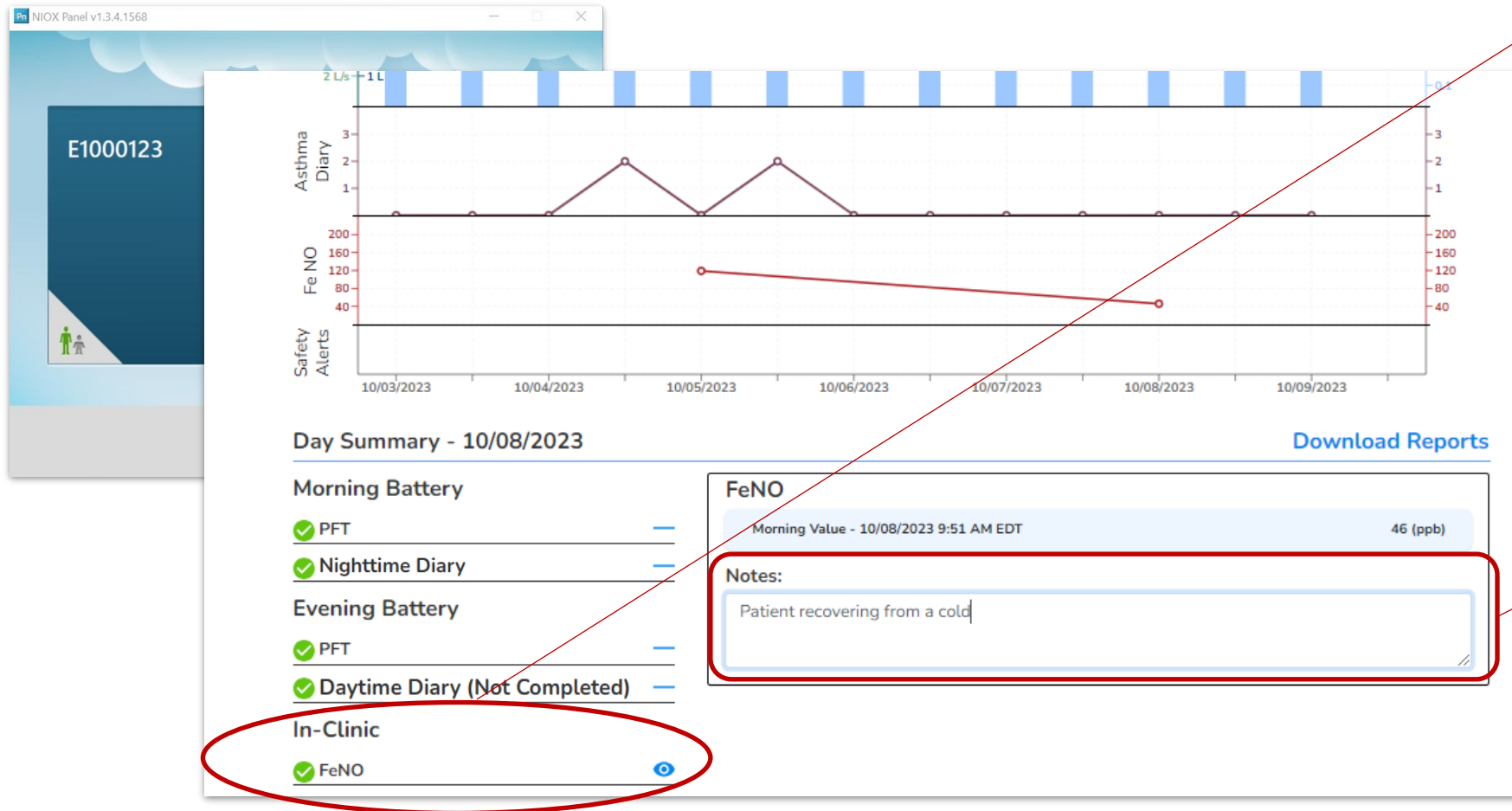
Incomplete Test, Try Again



Test Completed! Countdown will begin to calculate results

*Only 1 Complete Test is Required

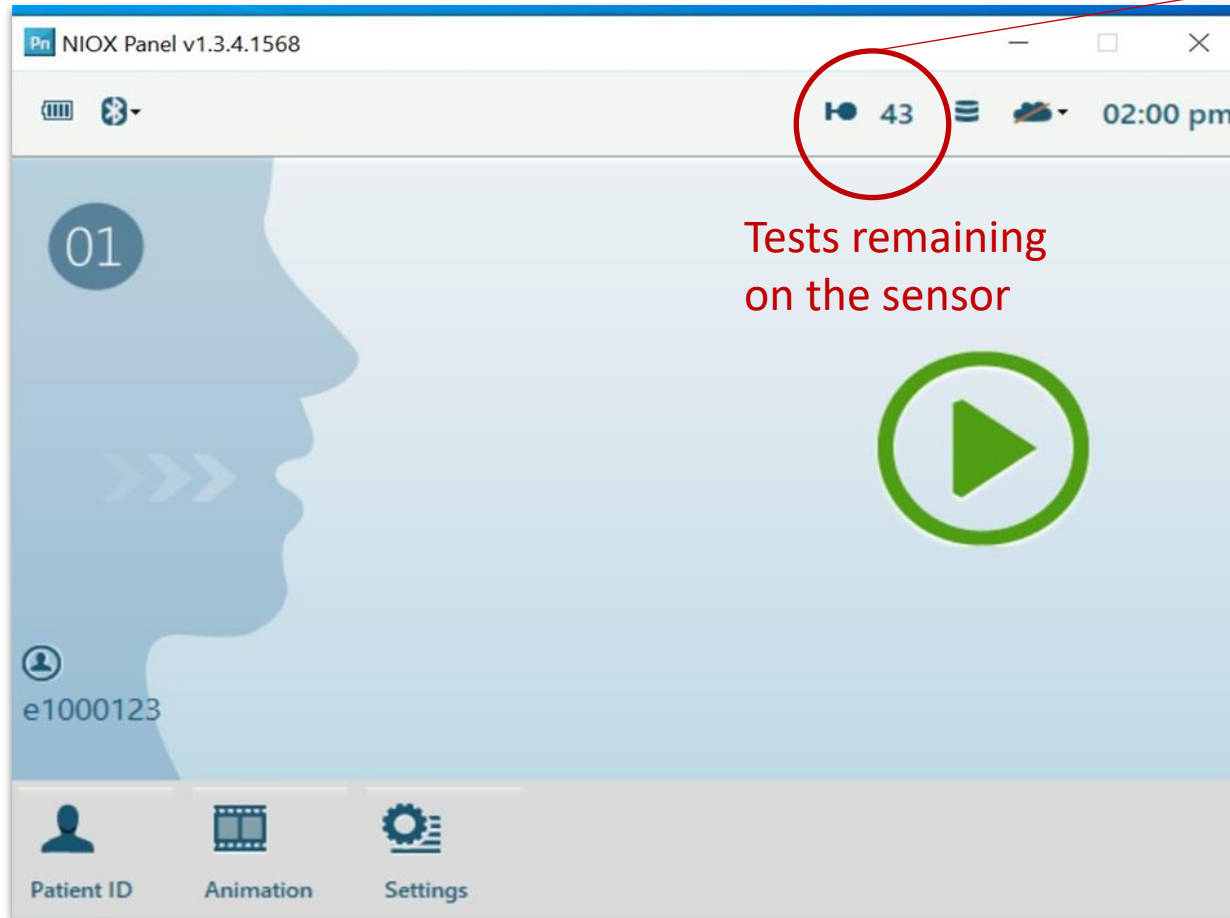
View the Participant's Results



- ✓ 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

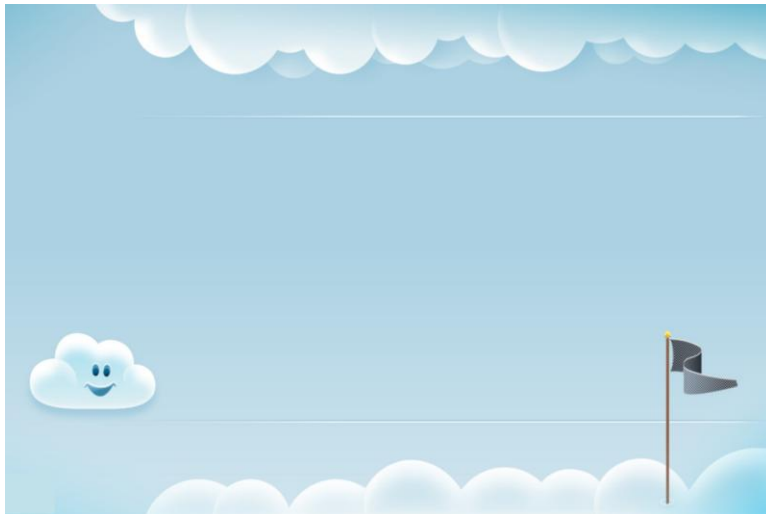
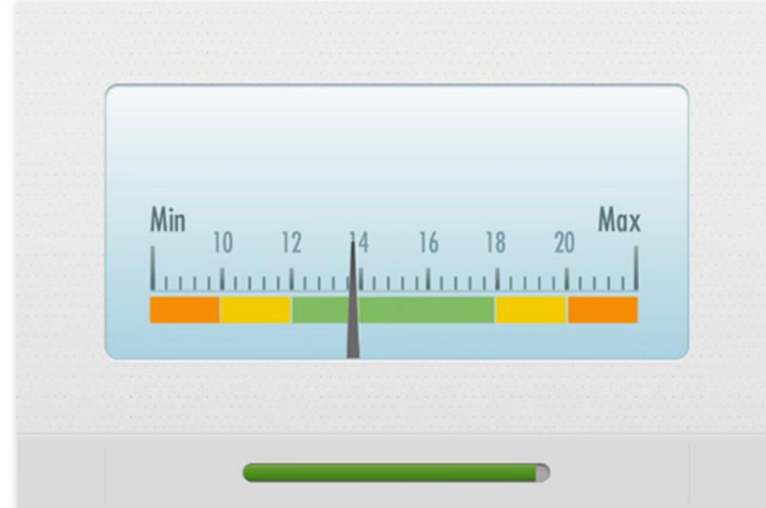
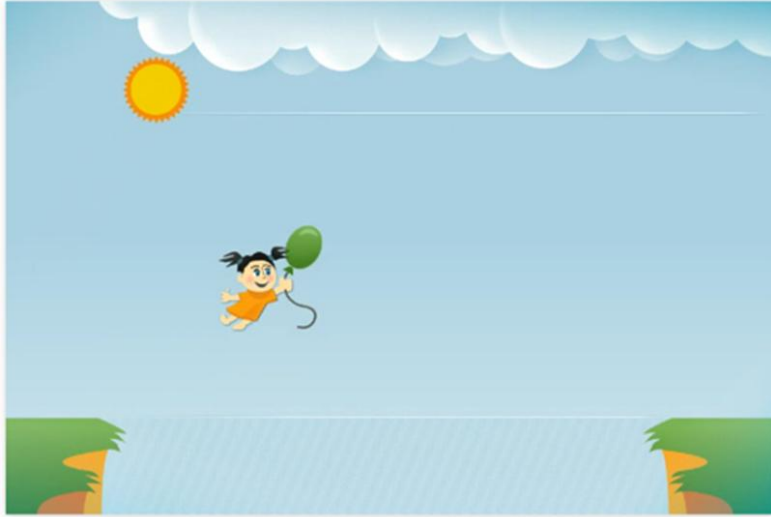
****View Results in ZEPHYRx dashboard, not on the tablet screen****

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

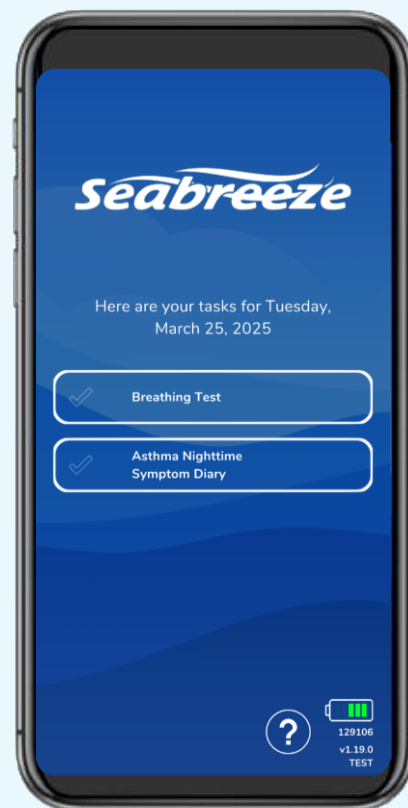


- ✓ Choose from 3 different FeNO animations prior to starting a test by selecting the 'Animation' button on the screen of the FeNO device.



Home Tasks

Home Equipment



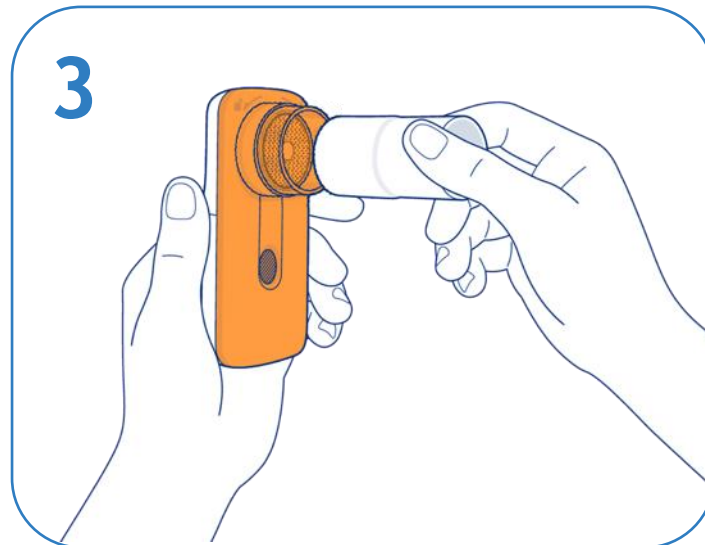
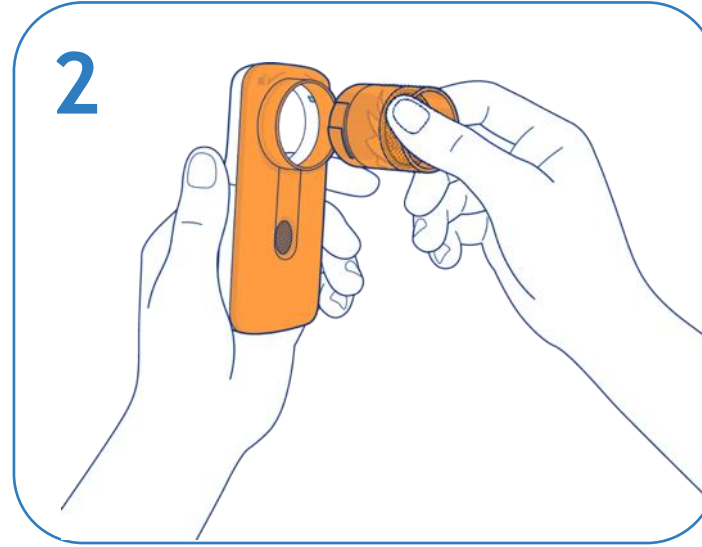
Participant's mobile phone with the Breathe Easy App Installed



MIR Spirobank Smart

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

Spirometer Setup



1. **Insert batteries** with positive ends facing turbine slot
2. **Push in the turbine and turn clockwise** until it's set in the grooves
3. **Push the mouthpiece firmly into the turbine** then turn one quarter clockwise

Pair Home Spirometer in the Provider Dashboard

Prior to distributing the spirometer to the participant:

✓ Go to the **Participant Settings Tab**

✓ Select **“Edit”**



✓ Enter the 6 Digit spirometer ID:

e.g. **A23-Z133977**

[← Back to Participant List](#)

11119999 (-- % Compliance)

Trial Research

Participant S

+ Edit

Notes

Participant Details

Identification

ID	a24c7fed-7223-4a4c-b0b8-3437a8235070
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

Edit Participant Settings

Identification

Assign new Study ID

11119999

Demographics

Sex at Birth: Male Female

Birthdate: 1984
Birth Year

Ethnicity: Caucasian

Height: 71.6535433 in. Weight: 149.914338 lbs

Edit for selected date range

Start Date 03/30/2025 End Date 03/30/2025

At-Home Spirometer ID

133977

13397

Cancel

Save changes

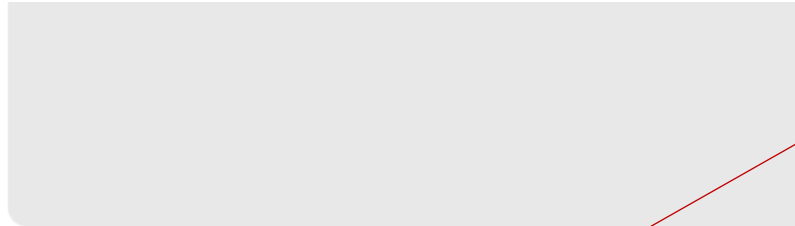
Set At-Home Task Start Date

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.



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 V1b as current date

✓ **Run-in period end date** should be set 1 week post start date

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

✓ Select **Submit**

Connect Spirometer to Breathe Easy App

1



for iPhone



for Android

2



3

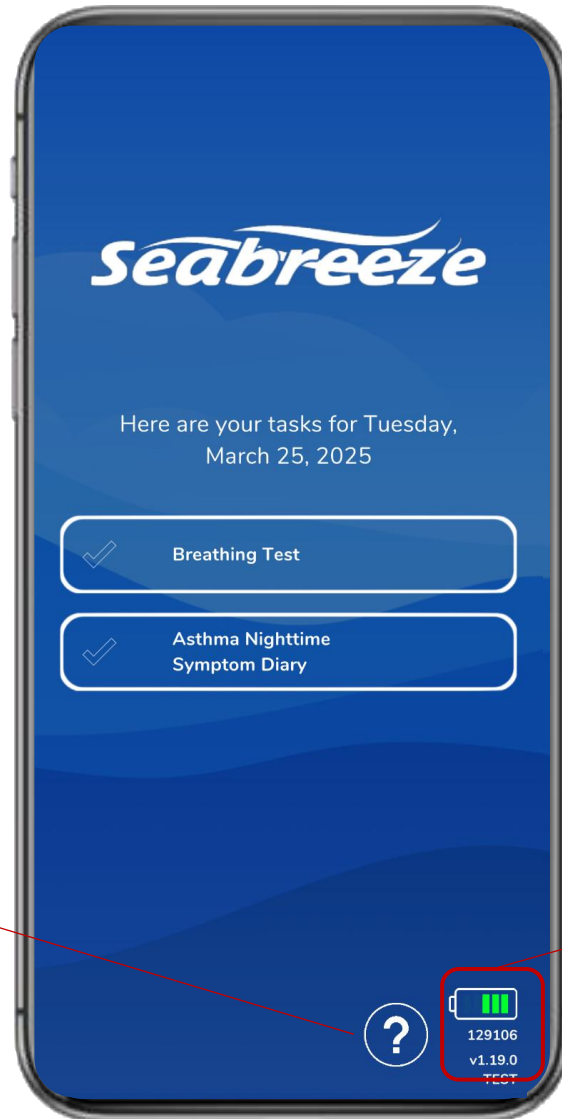


1. Download the **Breathe Easy App** to the participant's phone
2. Open **Breathe Easy** app
3. The **spirometer's ID** number will pop up on-screen, select the ID to connect device



Note: This step should not be done until the Spirometer has been paired to the participant's account through the dashboard

Participant App Overview



- ✓ troubleshooting tips
- ✓ set language

- ✓ spirometer battery life
- ✓ spirometer ID
- ✓ 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

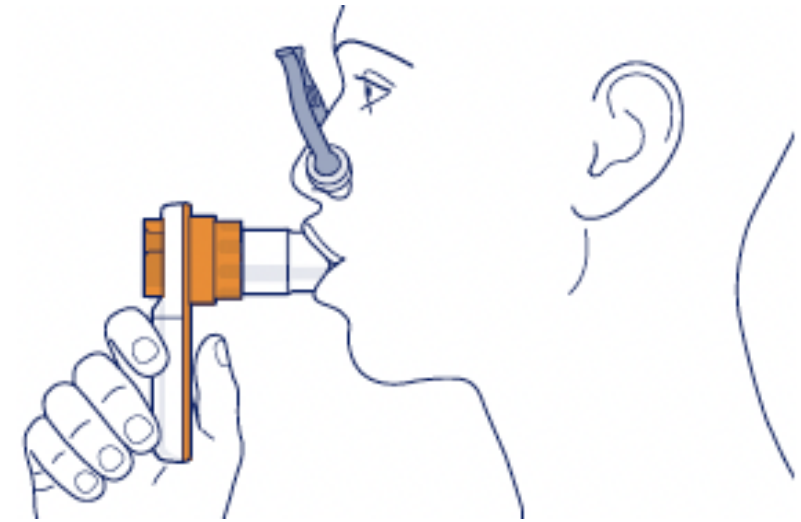
Morning PEF Test Task Window
5:00am – 11:59am

Evening PEF Test Task Window
5:00pm – 11:59pm

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

The Peak Flow (PEF) Maneuver

- ✓ Sit, or stand, up straight and put on the nose clips (patient should use the same position at every testing)
- ✓ Have the spirometer ready, read the on-screen instructions, and select continue to start the effort.
- ✓ Place the spirometer mouthpiece between their teeth and create a tight seal with their lips. Ensure their tongue does not block the hole in the mouthpiece.
- ✓ Breathe in to fill their lungs as much as they possibly can. As soon as they are full, blast all the air out of their lungs in single blow as hard and as fast as they can, making sure not to bend forward.
- ✓ Repeat Twice More as prompted (3 efforts total).
- ✓ Home PEF is performed twice daily (morning and evening) from V2 to V9, and in the same position throughout the trial (either sitting or standing).

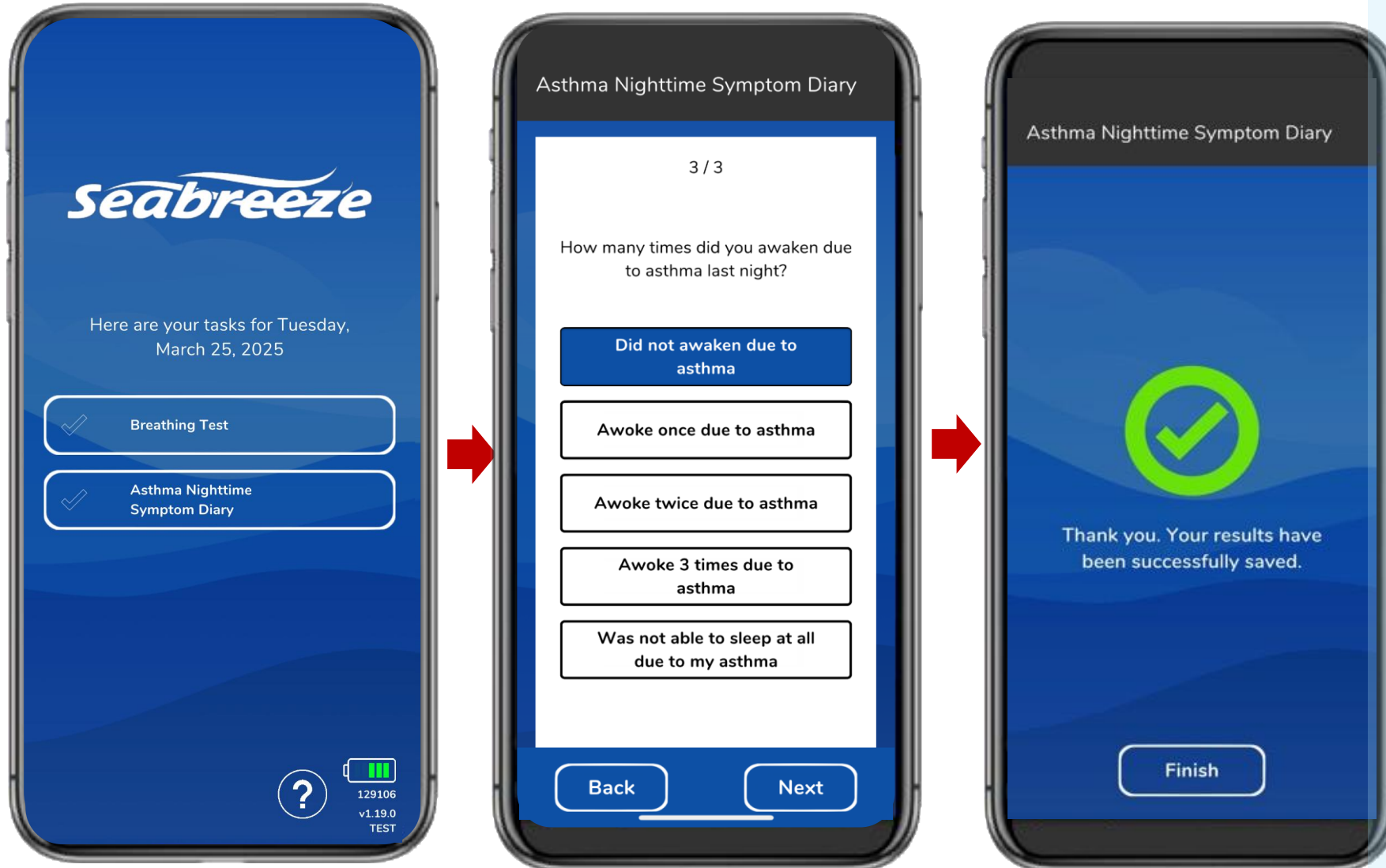


Peak Flow Tasks



- ✓ Participants complete breathing tests with **results sent in real-time** to the Provider Dashboard
 - ✓ Each PEF test consists of **3 efforts**, or maneuvers
- ✓ **Step-by-step instructions** and sound queues walk participants through their breathing test

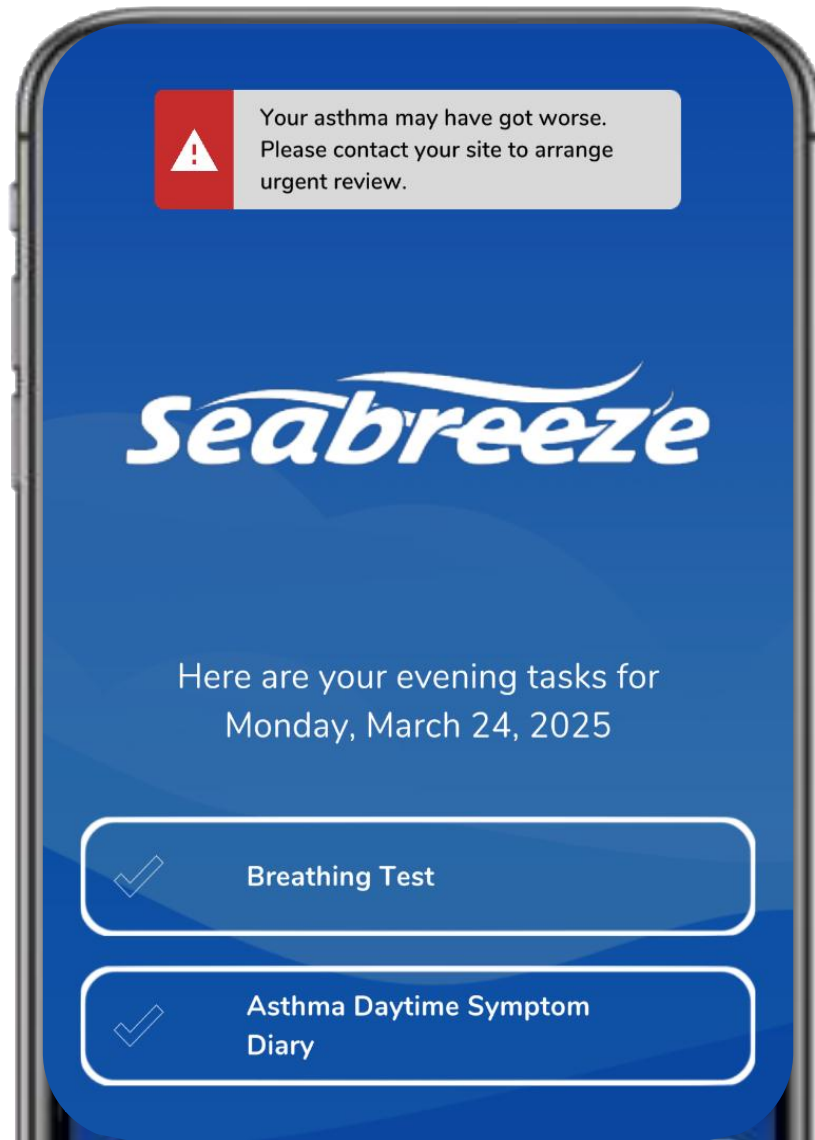
ePRO: Asthma Symptom Diary



- ✓ Participants complete **Asthma Symptom Diaries**
- ✓ Results sent in real-time to the Provider Dashboard

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

Safety Alerts & Reminder Notifications



- ✓ Site and participants **receive alerts** for
 - ✓ Fall in PEF value of 20% or more, when compared to their baseline (first week of study) value for 2 of 3 successive days
 - ✓ Highest possible Asthma Symptom Scores reported on 2 of 3 successive days
 - ✓ 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

[← Back to Participant List](#)

[Start Remote Session \(Chime\)](#)

11119999 **(71.30% Compliance)**

[Trial Research](#)

[Participant Settings](#)

Active Safety Alerts

● 03/21/2025 - (7:31 AM EDT) PEF down 20% from run-in average

[✕ Clear Alert](#)

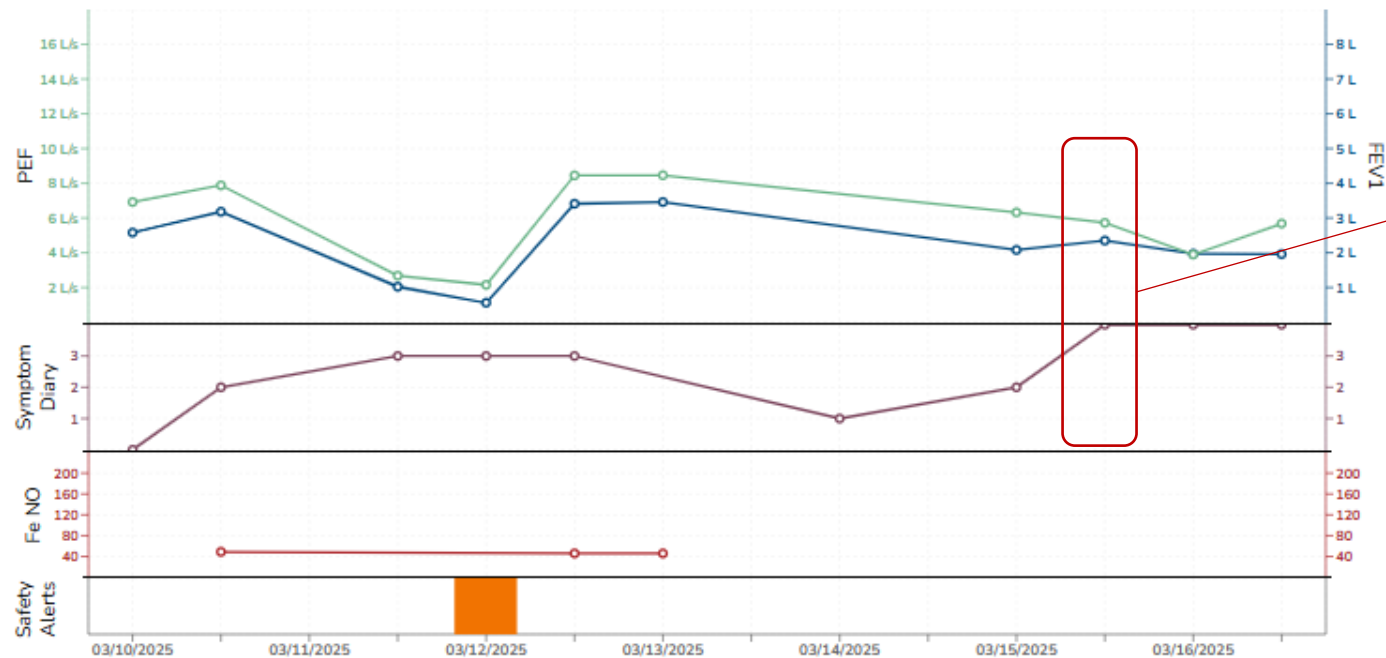
Active Overall Compliance Alert

● This participant is below the overall compliance threshold of 85%

[Add Notes](#)

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

[Previous](#) **One Week** [Next](#) [+ Go to week](#)



Day Summary - 03/16/2025

[Download Reports](#)

- ✓ 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

Active Safety Alerts

- 03/21/2025 - (7:31 AM)
- 03/22/2025 - (7:44 AM)

Active Overall Compliance

● This participant is below target

At Home Status: Active +

PEF

16 L/s
14 L/s
12 L/s
10 L/s
8 L/s
6 L/s
4 L/s
2 L/s

FEV1

8 L
7 L
6 L
5 L
4 L
3 L
2 L
1 L

Symptom Diary

3
2
1

Safety Alert for Patient

⚠️ PEF down 20% from run-in average
Alert Created on 03/22/2025 - (7:44 AM EDT)

Run-in average (PEF): 7.04
Alerted (PEF): 2.26

Notes:

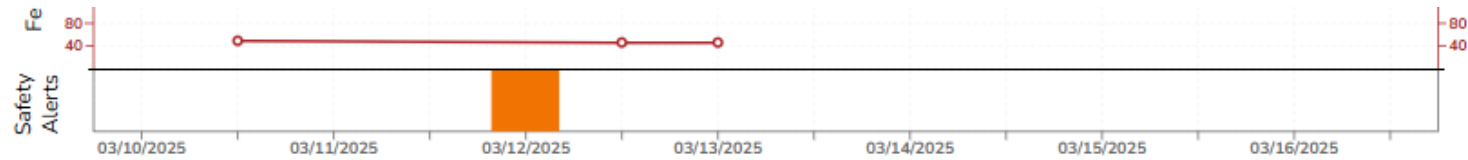
Clearing the notification will create a log of your action with a timestamp.

Save Notes & Close Clear Notification

Clear Alert

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

Participant Dashboard: View All Results



Day Summary - 03/10/2025

[Download Reports](#)

Morning Battery

- PFT (PEF)
- Nighttime Diary

Evening Battery

- PFT (PEF)
- Daytime Diary

FeNO

- FeNO

In-Clinic

- ECOA Questionnaire(s)
- Evening Kiosk Series

Safety Notifications

- Safety Alerts

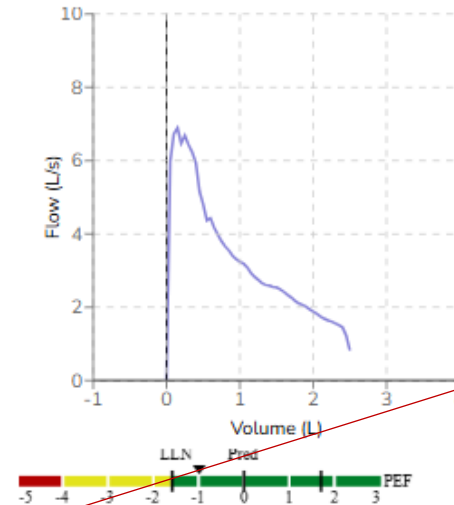
Compliance Alerts

- Compliance Alerts

Morning PEF Measurements

NHANES	Best	Pred.	%Pred.
PEF (L/s)	6.92	8.26	84%
FEV ₁ (L)	2.58	3.84	67%
BEV (L)	0.03		
BEV (%)	0.48		
PEF Time (ms)	31.00		

Flow Volume Curve



[View Series Details](#)

Series Demographics

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

Series Acceptability

	PEF
Acceptability	Acceptable
Repeatability	Repeatable

Run-in Calculations

Measurement	Average
PEF	7.04

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

Participant Dashboard: View All Results

Symptom Diary

Morning Asthma Diary - Questions	Answers
How many puffs of rescue inhaler (albuterol/salbutamol) did you use last night?	7
How many times did you use a nebulizer for rescue medication last night?	1
How many times did you awaken due to asthma last night?	Awoke 3 times due to asthma

Evening Asthma Diary - Questions	Answers
How many puffs of rescue inhaler did you use today?	8
How many times did you use a nebulizer for rescue medication today?	2
Describe your asthma symptoms today.	Asthma symptoms with mild exertion
Were your daily activities affected by your asthma today?	Asthma symptoms limited my activity to a significant degree
Did you take your asthma controller (corticosteroid) medication today?	Yes

FeNO

Evening Value - 03/13/2025 12:06 AM EDT 46 (ppb)

Performed: In-Clinic

Notes:

EOA Questionnaire(s)

- ✔ Evening (Visit Labels: V2) - Asthma Control Questionnaire (ACQ-5) +
- Total Score: 9
- ✔ Evening (Visit Labels: V2) - Modified Borg Dyspnea Scale (CR-10 2016) Answer -
- 1. How strong is your breathlessness right now? (6)

- ✓ Scroll down below the graph to see detailed results
- ✓ Tag **all** eCOAs with a visit label (this is **mandatory**)
- ✓ Use the + / - icons to see 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

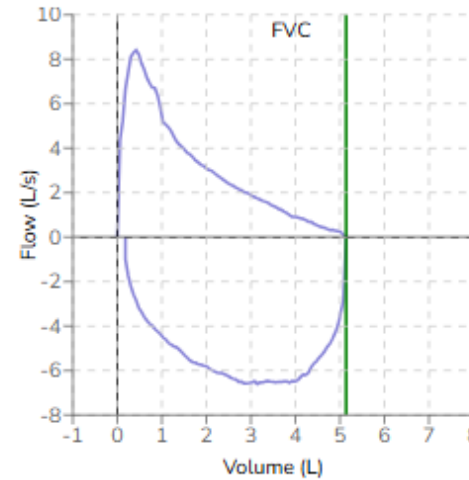
Series Demographics

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

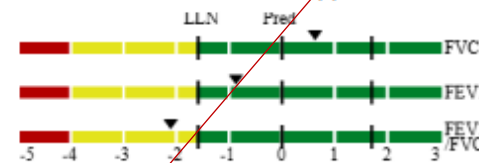
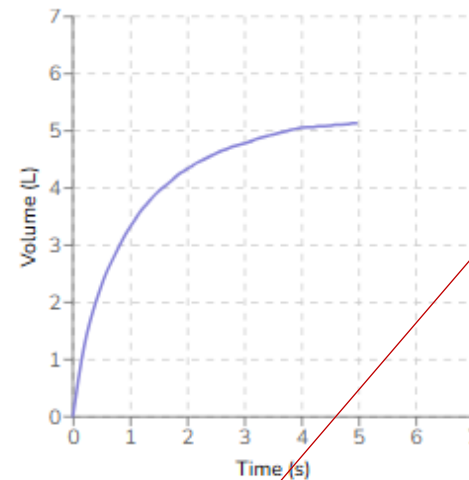
Run-in Calculations

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 / 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"/>		

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 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

Series Notes

- ✓ Print the ZEPHYRx 58 Report and file it in the investigator site file once the series has been overread
- ✓ Review human 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	✔		

Best Flow Volume Curve

Efforts In Session

Effort #3: 12:04 PM Accepted

Series Demographics

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

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

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

Notes

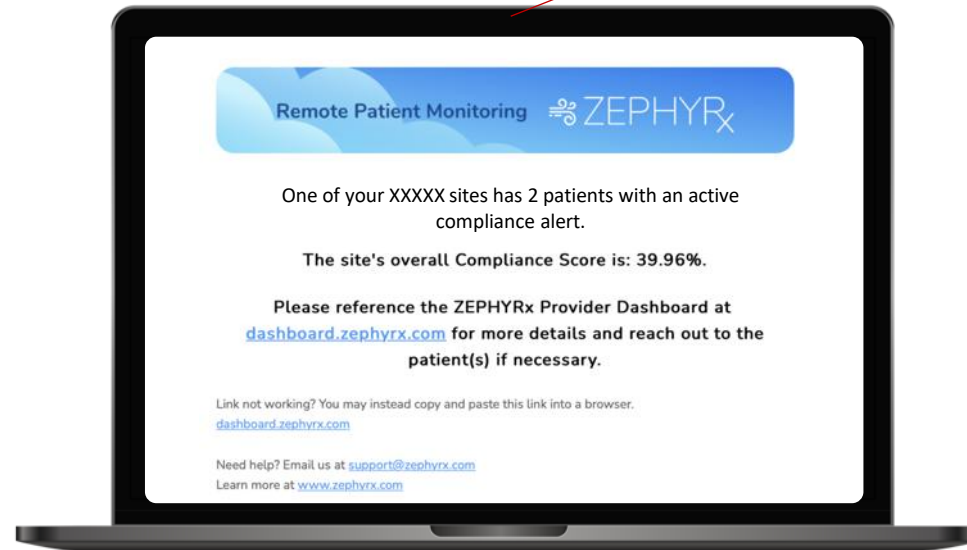
At Home Status: Active + Edit

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

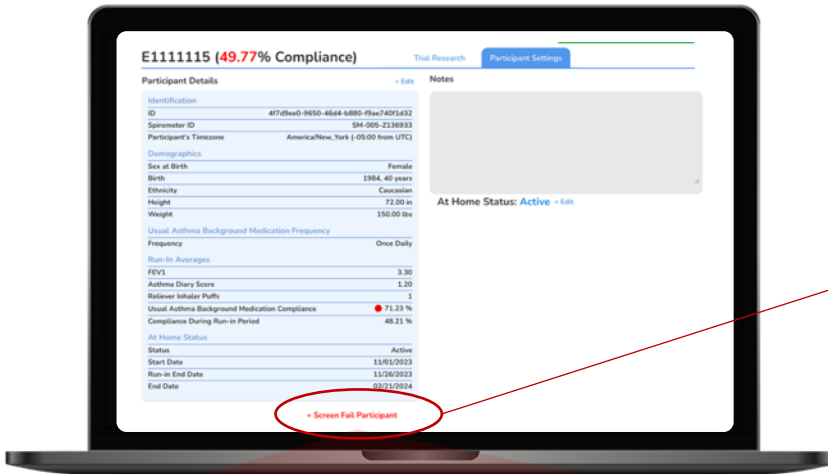
- ✓ Select Participant Settings Tab
- ✓ View all tagged spirometry and eCOA sessions

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

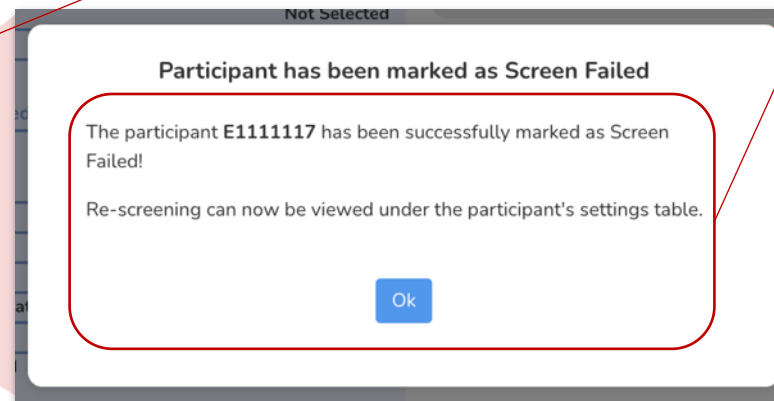
Enter the e-code (case sensitive) of the participant: **E1111117** in the form below to screen fail.

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

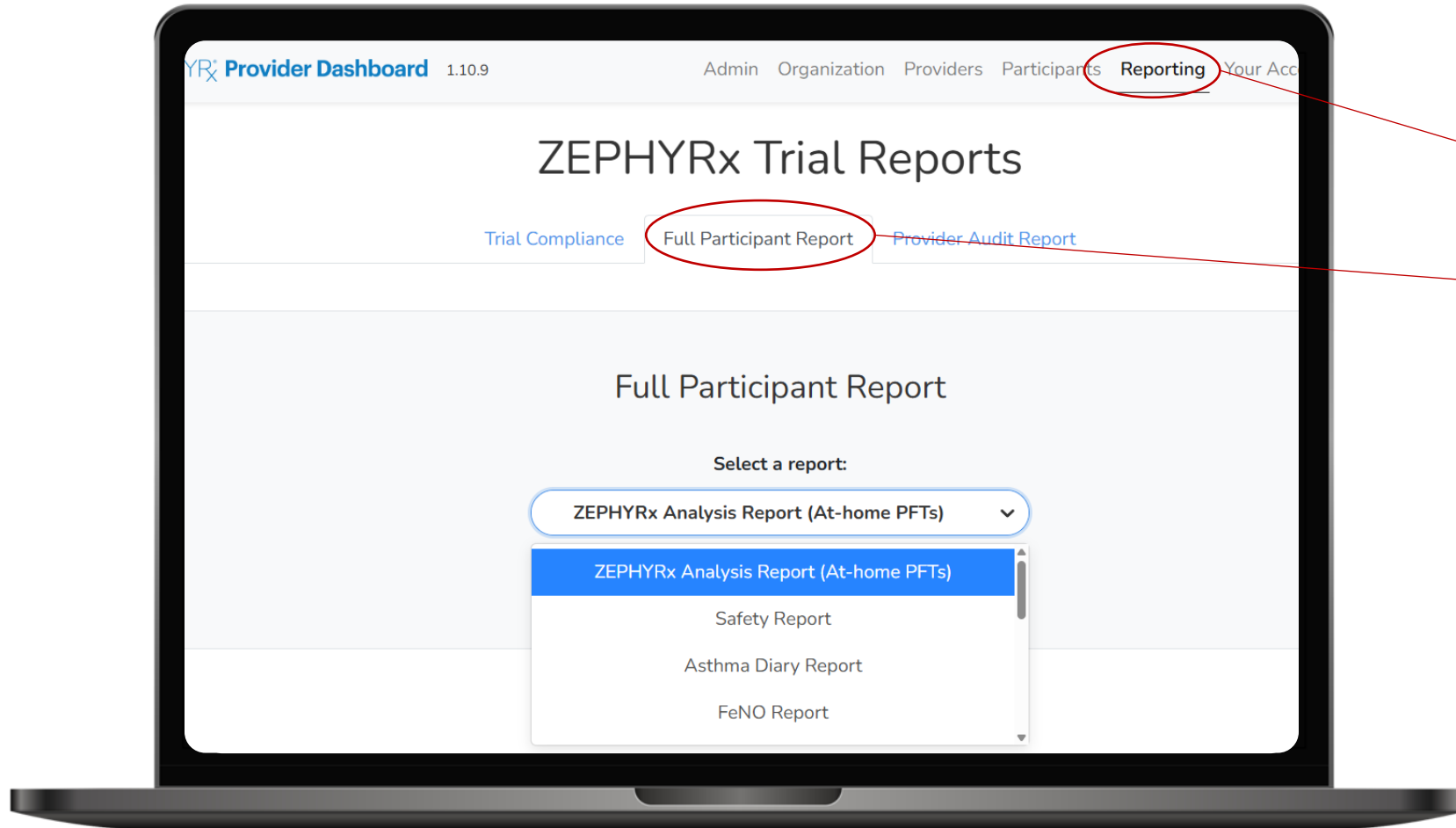
04/13/2024



- ✓ 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 report type



Support Helpdesk

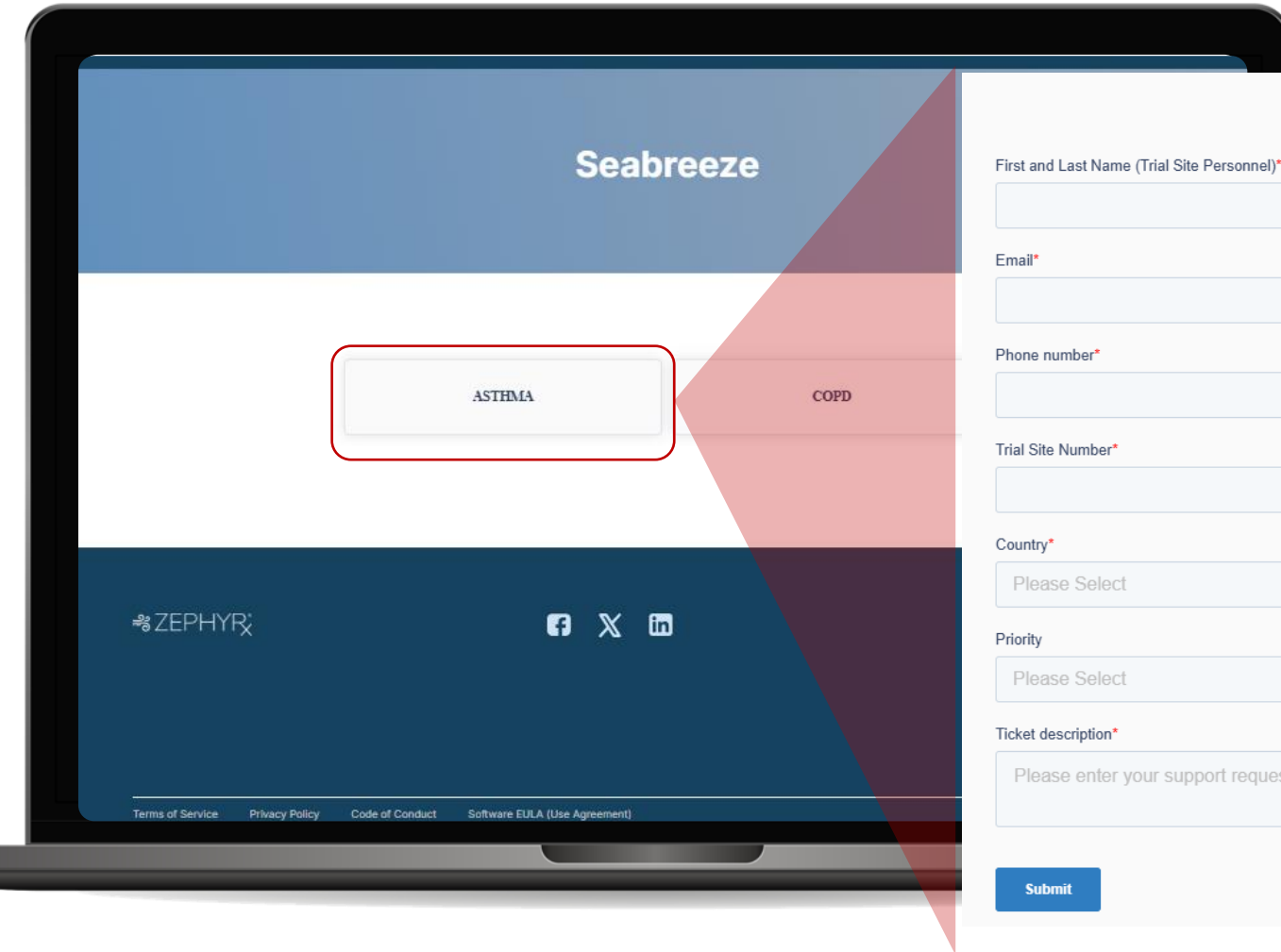
Support Notes for Sites in Both Studies

- 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, there is a 'Site Program Compliance' card showing '44.91 %' and '0 Critical compliance failures'. On the right, 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*

Please Select

Priority

Please Select

Ticket description*

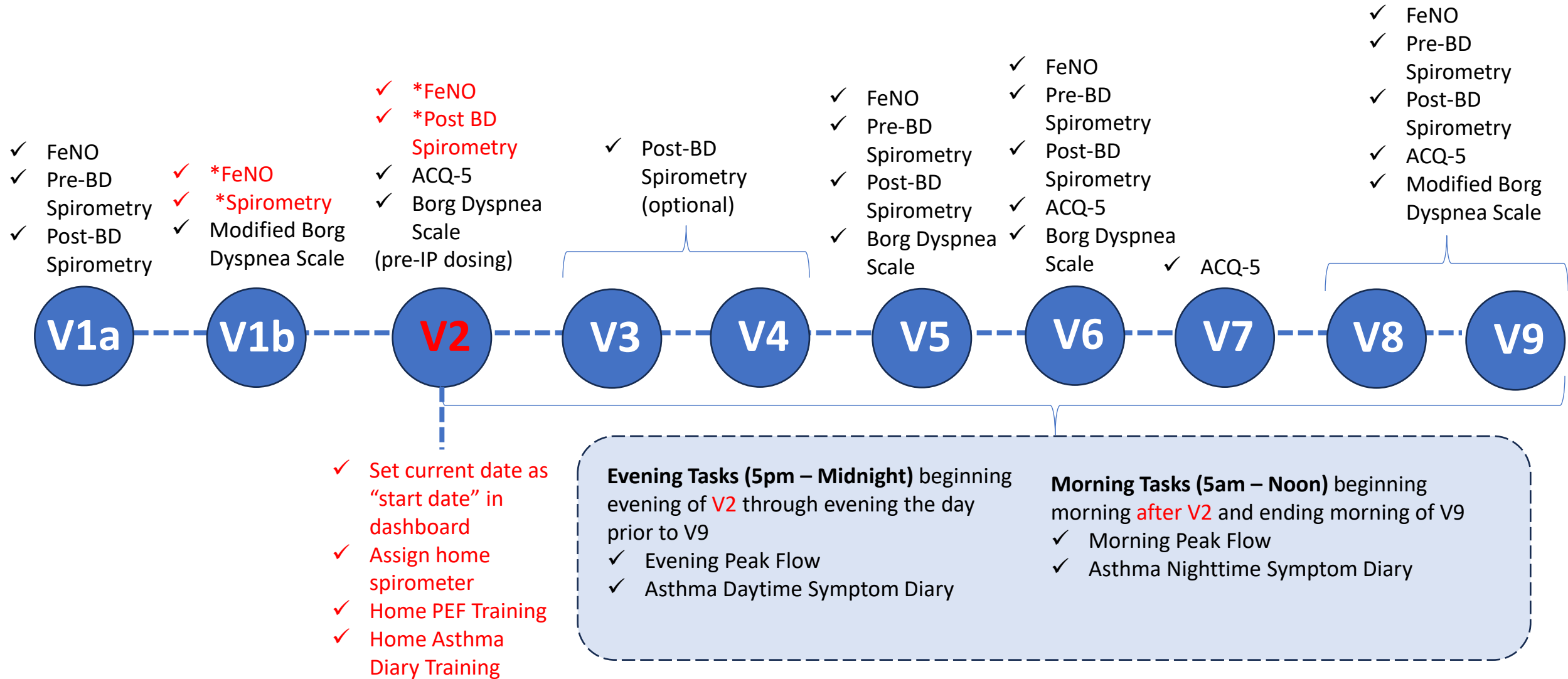
Please enter your support request here.

Submit

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

zephyrx.com/seabreeze

Protocol V3 Updates: Overview



**If V1b and V2 are the same day, then FeNO and post-BD spirometry do not need to be repeated.*

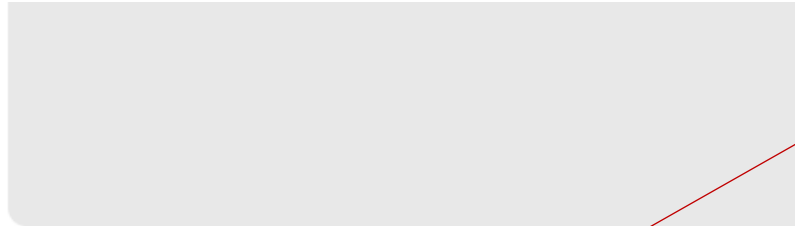
Protocol V3 Updates: At-Home Task Start Date

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** should be set 1 week post start date

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

✓ Select **Submit**