FenomPro®

Instructions for Use

℞ Only

Table of Contents

Definitions

The following are the definitions for terms and abbreviations used in this manual

FENO	Fractional exhaled nitric oxide – Amount of nitric oxide in the exhaled breath originating from the bronchial passages, not the nasal passages nor upper airway.
FEV_1	Forced Expiratory Volume in One Second - Volume of air that can be forcibly exhaled from the lungs in the first second of a forced expiratory maneuver, measured in liters.
FEV_6	Forced Expiratory Volume in Six Seconds - Volume of air that can be forcibly exhaled from the lungs in the six seconds of a forced expiratory maneuver, measured in liters.
FVC	Forced Vital Capacity - After the patient has taken in the deepest possible breath, this is the volume of air that can be forcibly and maximally exhaled out of the lungs until no more can be expired, usually measured in liters.
NO	Nitric oxide – Produced by the human lung and is present in the exhaled breath. It has been implicated in the pathophysiology of lung diseases, including asthma.
PEF	Peak Expiratory Flow - Maximal flow (or speed) achieved during the maximally forced expiration initiated at full inspiration, measured in liters per minute or in liters per second.
Spirometry	Common office test used to assess how well a patient's lungs work by measuring how much air is inhaled, how much is exhaled, and how quickly it is exhaled.

Chapter 1: System Overview

System Description

CAIRE Diagnostics Fenom Pro is a point-of-care breath analyzer that uses electrochemical sensor technology to measure the fraction of exhaled nitric oxide (FENO), a marker for airway inflammation, in human exhaled breath. Measurement of FENO by Fenom Pro is quantitative, non-invasive (only the mouthpiece comes in contact with the patient), simple and safe. Fenom Pro is designed as a hand-held device for measuring FENO in exhaled breath from humans. The level of exhaled nitric oxide (NO) is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath can be measured by the Fenom Pro device according to guidelines for NO measurement established by the American Thoracic Society (ATS) and European Respiratory Society (ERS).

Fenom Pro provides direct sampling with result report within 30 seconds of sequentially collected and analyzed exhaled air. No subsequent specific specimen collection, specimen preparation, or reagents are required. The emissions characteristics of the Fenom Pro device make it suitable for use in point of care sites and hospitals (CISPR 11 class A).

Indications for Use

Fenom Pro is a portable, non-invasive device to measure fractional exhaled nitric oxide (FENO) in human breath. FENO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment [1]. Fenom Pro measures fractional exhaled nitric oxide (FENO) according to guidelines established by the American Thoracic Society.

Measurement of FENO by Fenom Pro is a non-invasive quantitative method to measure the decrease in FENO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FENO levels. FENO measurements are to be used as an adjunct to established clinical assessments. Fenom Pro is suitable for adults and children ages 6 years and older.

Fenom Pro should be used in a point-of-care healthcare setting under professional supervision. Fenom Pro should not be used in critical care, emergency care or in anesthesiology.

Clinical Limitations

Fenom Pro may not be used by children under the age 6 years, including infants, as measurement requires patient cooperation. Fenom Pro may not be used by children under the age of 6 years, or by patients who are unable to understand and execute the instructions given by healthcare providers, as measurement requires patient cooperation.

Fenom Pro should not be used in critical care, emergency care, or in anesthesiology.

All subjects should refrain from eating or drinking for at least 60 minutes before the FENO test. Recent intake of nitrate rich food, such as lettuce, spinach, beets, walnuts, peanuts, and animal organs, can lead to increased FENO levels [2].

Smoking reduces exhaled NO levels [3]. Fenom results obtained from subjects who smoke should only be considered after considering the subject's smoking history and the potential impact on NO levels.

Risks to Health

There are no known direct risks to patient health posed by use of Fenom Pro. However, failure of the test to perform as indicated or erroneous interpretation of results may lead to improper patient management.

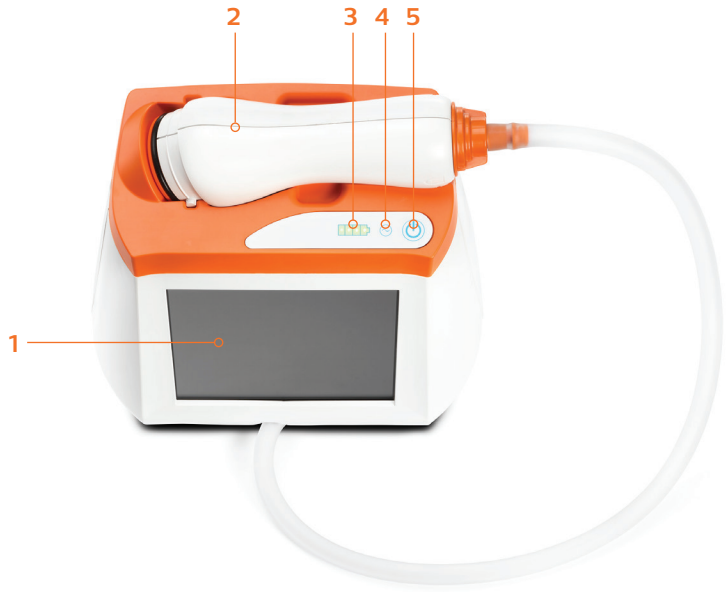
Therefore, use of FENO measurement results to adjust a treatment regimen without consideration of other clinical factors could pose a risk.

[1] "ATS/ERS Recommendations for Standardized Procedures for the Online and Offline Measurement Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, 2005." Am. J. Respir. Crit. Care Med., 2005; vol. 171, pp. 912–930.

[2] A. C. Olin, A. Aldenbratt, A. Ekman, G. Ljungkvist, L. Jungersten, K. Alving, and K. Toren, "Increased nitric oxide in exhaled air after intake of a nitrate-rich meal." Respir. Med., 2001; vol. 95, pp. 153–158.

[3] Buszewski B, Ulanowska A, Ligor T, Denderz N, Amann A., "Analysis of exhaled breath from smokers, passive smokers and non-smokers by solid phase microextraction gas chromatography/mass spectrometry" Biomed Chromatogr. 2009 May;23(5):551-6. doi: 10.1002/bmc.1141.

Fenom Pro Components



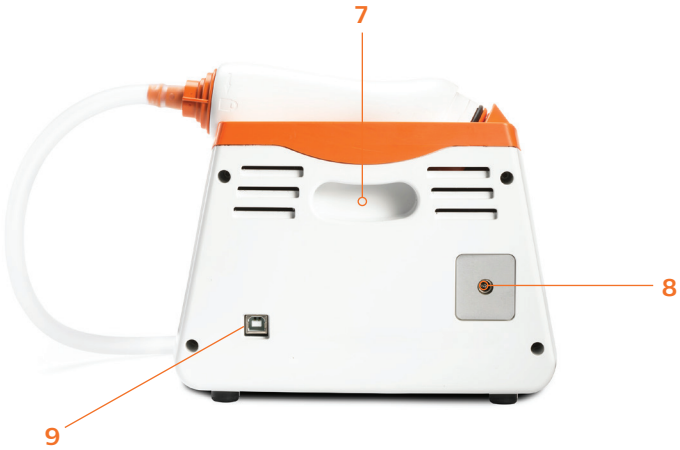


Table 1: Fenom Pro Components

No.	Description
1	Touch Screen
2	Handpiece
3	Battery Indicator –Battery strength is below 25% if only one bar is illuminated
4	AC Power Indicator - Indicator is **green** when the device is powered on and connected to an electrical outlet.
5	Power Button – Hold for one second to power on/off.
6	Single-Patient-Use Mouthpiece (accessory)
7	Carrying Handle
8	24 V Power Connection
9	USB Type-B Port

Display Buttons

There are several button icons that Fenom Pro utilizes to help you easily navigate through the menu screens.

Table 2: Button and Indication Icons

Buttons Icon	Name	Description
	**Settings Button**	Button used to open the Settings Menu. This menu allows for setting Time/Date, selecting Language, viewing System Information, selecting Volume Level, and Ordering Tests.
	**Test License Status Button (Tests available)**	Button used to open Order Tests box. **Green** checkmark indicates that the device has tests available. Not used in some configurations.
	**Test License Status Button (Few tests available)**	Button used to open Order Tests box. **Red** exclamation point indicates few tests are remaining. Contact your distributor to order additional tests. Not used in some configurations.
	**Quality Control Status Button (QC Status - Pass)**	Button used to indicate current QC Mode Status. **Green** icon indicates current QC Mode status is passed.
	**Quality Control Status Button (QC Status - Fail)**	Button used to indicate current QC Mode Status. **Red** icon indicates current QC Mode status is failed or expired.
	**Quality Control Status Button (QC Status - Disabled)**	Button used to indicate current QC Mode Status. Gray icon indicates current QC Mode status is temporarily disabled or analyzing.
	**Humidity Warning Button**	Button used to open the current humidity condition warning status
	**Service Due Button**	Button used to open the Service Due warning. If displayed, Fenom Pro service is due soon. Contact your distributor to schedule service.

Chapter 2: Safety and Warnings

Safety Instructions

The following safety instructions apply in the handling and operation of Fenom Pro:

- DO NOT inhale through the device.
- DO NOT inhale through the mouthpiece.
- DO NOT exhale beyond the limits of your physical ability.
- Discontinue measurements if the breath maneuver is laborious for the patient.
- DO NOT allow use of Fenom Pro within 15 minutes after performing spirometry testing such as: FEV_1, FEV_6, FVC, PEF, etc.
- DO NOT allow use of Fenom Pro within 60 minutes after exercising or smoking.
- DO NOT allow the use of Fenom Pro within 60 minutes after eating or drinking fluids other than water.
- DO NOT allow the use of Fenom Pro within 60 minutes of using oral hygiene products.
- DO NOT use the Fenom Pro device without a new single-patient-use mouthpiece.
- DO NOT perform more than six breath attempts on a single patient within one day.
- If repeated measurements taken for at least two consecutive days are more than 10 ppb different contact CAIRE Diagnostics Inc. Technical Support.
- DO NOT bring Fenom Pro in a room containing magnetic resonance equipment.
- DO NOT bring Fenom Pro to a room adjacent to magnetic resonance equipment.

Compliance

Fenom Pro is CE-marked according to the *In Vitro Diagnostic Device Regulation (IVDR)2017/746*.

Fenom Pro is RoHS compliant according to *Directive 2011/65/EU Restriction of Hazardous Substances in Electrical and Electronic Equipment* as amended by *Directive 2015/863*.

Warnings

The following warnings apply in the handling and operation of Fenom Pro:

- Fenom Pro should only be operated by trained healthcare professionals.
- Operate Fenom Pro as stated in this manual. CAIRE Diagnostics accepts no responsibility for damaged equipment or faulty results if the equipment is not handled according to this manual.
- DO NOT use a damaged Fenom Pro device, damaged components, or damaged accessories.
- Use only power supply unit provided.
- Keep the device out of water. Ensure no liquid is spilled or dripped on the device.
- DO NOT use the Fenom Pro device adjacent to or stacked with other equipment because it could result in improper operation.
- DO NOT block device vents and ports while in use or while charging.
- DO NOT drop the device or subject it to strong impact.

- No modification of the Fenom Pro device, handpiece, or mouthpiece is allowed.
- DO NOT use Fenom Pro in the proximity of areas where volatile substances such as organic fluids or disinfectants are being used. Special attention should be paid to aerosols and disinfection baths.
- DO NOT use Fenom Pro in the presence of flammable vapors or liquids
- Use of substances containing alcohol close to the Fenom Pro device may cause erroneous measurement results. [4]
- Single-patient-use mouthpiece should be used immediately after opening.
- DO NOT reuse the single-patient-use mouthpiece on other patients.
- When not in use, the Fenom Pro device should be stored in the packaging provided. (See Chapter 12: General Care.)
- DO NOT open, crush, heat above 140 °F/60 °C, or incinerate the lithium-ion battery in the device.
- DO NOT touch the part of the mouthpiece that will go into the patient's mouth. Either hold the mouthpiece using the plastic packaging or wear latex gloves while attaching to handpiece.

Electromagnetic Emissions

The emissions characteristics of this equipment make it suitable for use in hospitals and other healthcare settings (CISPR 11 class A).

Electromagnetic Immunity

Fenom Pro has been tested to comply with the emission and immunity requirements described in IEC 60601-1-2:2014 (4th Edition) General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests and AIM 7351731:2017 Medical Electrical Equipment and System Electromagnetic Immunity Test for RFID Readers.

Fenom Pro is not compatible with magnetic resonance systems, and is labeled as MR Unsafe. The Fenom Pro should not be used in a room containing a magnetic resonance system or adjacent rooms to a magnetic resonance system.

Note: Sites should ensure that their security systems and other equipment do not interfere with Fenom Pro.

[4] R. J. Meijer, H. A. Kerstjens, D. S. Postma, G. H. Koeter, T. W. van der Mark, "Exhaled nitric oxide concentration is influenced by alcohol containing disinfectants." Eur. Respir. J., 1996; vol. 9, p.1111.

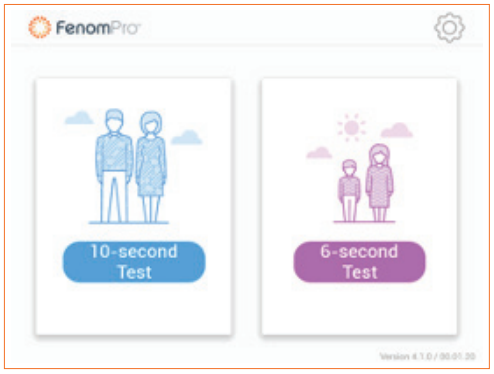
Chapter 3: Fenom Pro Quick Start Guide

To perform a FENO test, follow these three simple steps. For full test guidelines and instructions, see Chapters 4 and 5. For setup instructions, see Chapter 9.

NOTE: Check to make sure the device is powered on. If the device is on but the display is blank, touch the screen to wake up the device. The device may take one minute to warm up.

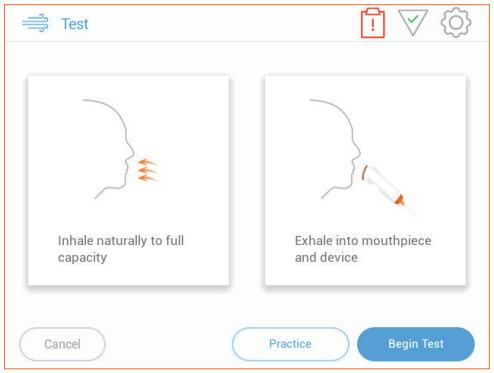
1. Select 10-second or 6-second test on the screen display. Users are recommended to select the same test mode in follow-up measurements as used in prior measurements. Remove a new single-patient-use mouthpiece from its packaging and attach it to the hand-piece by pressing the mouthpiece towards the top of the hand-piece and twist clockwise to secure. Be careful to not touch the part of the mouthpiece that will have patient contact. Instruct the patient to keep the indicator over the star at the top of the gauge.

   - 6-second test.
   - 10-second test.



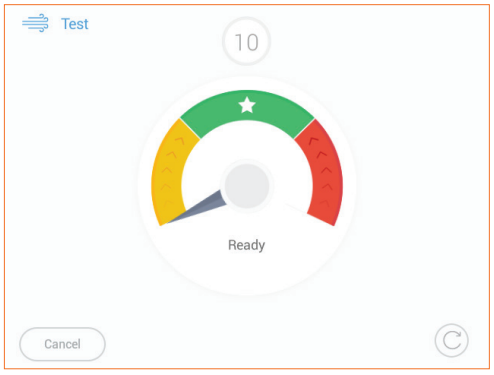
NOTE: *See Chapter 8: Practice Mode* if patient requires a demonstration before taking the test.

2. Touch the **Begin Test** button and instruct the patient to inhale naturally to full capacity, place mouth on the mouthpiece ensuring to keep tight seal so no air escapes and exhale for the full breath test duration at a steady flow.



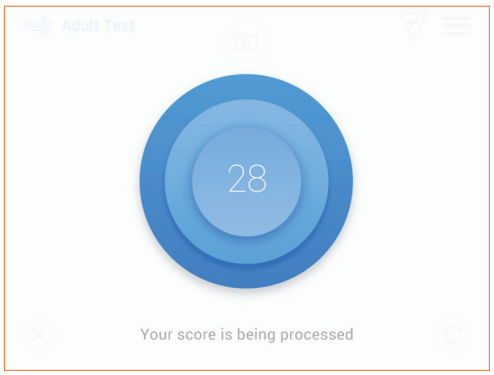
Instruct the patient to keep the **indicator** over the star at the top of the gauge.

NOTE: Having the indicator within the green range is also acceptable.

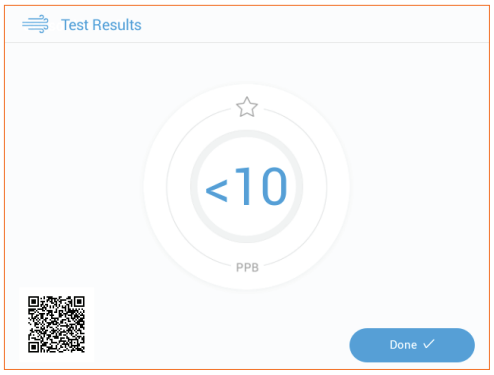


3. The Fenom Pro will display the **Stop Now** screen and play an audible chime once the patient has successfully completed the breath maneuver.

Results will display in 28 seconds.



4. Press the **Done** button and properly dispose of the used mouthpiece.



Chapter 4: FENO Measurement Preparation

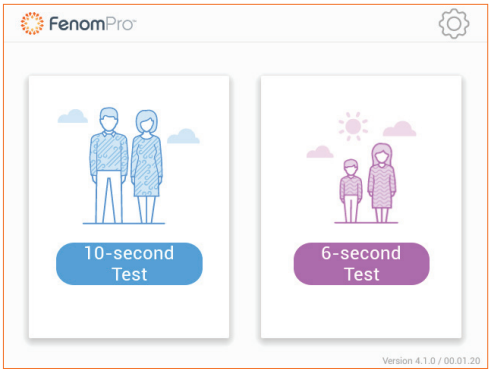
NOTE: See *Chapter 2: Safety and Warnings* for list of safety instructions and warnings.

Wake up Device

1. If the device is powered off, press the Power button to turn it on.

   NOTE: If the device is powered on but the display is blank, touch the screen to wake up the device.

   Allow the device to warm-up for one minute.



Pre-test Check

1. Check the battery indicator to ensure the unit has sufficient battery power to perform a FENO measurement. If the battery indicator is below 25%, plug device into the power supply before using.
2. Check that device is on a flat, stable surface while performing a FENO measurement.
3. Confirm that the patient meets eligibility requirements:
   - Age 6 and up.
   - Has not consumed food or fluids other than water in the preceding 60 minutes.
   - Has not exercised or smoked in the preceding 60 minutes.
4. When pre-test check is complete, proceed with *Chapter 5: Perform FENO Measurement.*

Chapter 5: Perform FENO Measurement

The FENO measurement is performed by the patient blowing into a single-patient-use mouthpiece that is attached to a handpiece. The patient must blow into the mouthpiece at a controlled rate, which is monitored through an animated graphic on the touch display. Once a sufficient amount of the patient's breath is captured, the sensor analyzes the breath and reports a FENO score in parts per billion (ppb).

Perform a FENO Test

NOTE: Complete the steps in *Chapter 4: FENO Measurement Preparation* before continuing with the steps below.

1. Lift the handpiece out of the cradle on top of the Fenom Pro.
2. Remove the new, single-patient-use mouthpiece from its packaging without touching the part that will go into the patient's mouth.
3. Attach the mouthpiece to the handpiece by firmly grasping the outer diameter of the mouthpiece and pushing towards the top of the handpiece while twisting clockwise until secure.

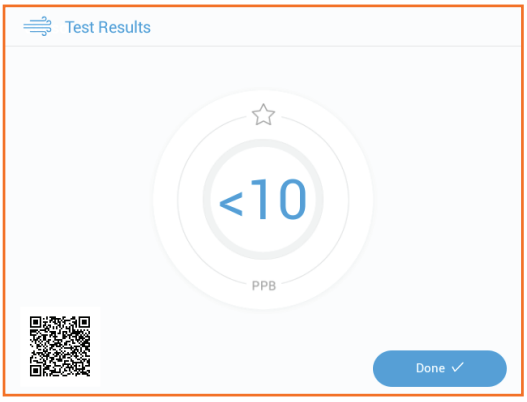
4. Hand the handpiece to the patient with the mouthpiece attached.
5. Press the **10-second Test or 6-second Test** button on the test selection screen.
6. Provide the patient with a brief overview on how to use the Fenom Pro device.
    - Instruct patient to inhale naturally to full capacity before placing mouth on the mouthpiece.
    - Instruct patient to place mouth on the mouthpiece and exhale at a steady flow for the full test time.
    - Instruct patient to keep lips sealed around the mouthpiece so no breath escapes from patient's lips.

    NOTE: See *Chapter 8: Practice Mode* if patient requires a demonstration before taking the test.
7. Touch the **Begin Test** button when the patient understands the instructions and is ready to begin.
8. The visual incentive gauge displays.
9. Instruct the patient to begin exhaling into the mouthpiece whenever ready.
10. Ensure that the patient stops exhaling once the **Stop Now** screen is displayed.
11. If the patient was unsuccessful in performing a breath maneuver, review the reason for the failure. If necessary, patient can attempt a test in Practice Mode (Chapter 8) before repeating.
12. Proceed to instructions in *View Results* section of this Chapter.

View Results

Upon completion of the FENO test, the patient's breath is analyzed, and the results are displayed in ppb. It takes approximately 28 seconds for the results to display.

1. View the FENO result. If the result is less than 10 ppb, "< 10" will be displayed. If the result is greater than 200 ppb, ">200 ppb" will be displayed.
2. Touch the **Done** button.



Remove Mouthpiece

When the patient has completed performing a FENO measurement:

1. Remove the mouthpiece by firmly grasping around the outer diameter and twist counter-clockwise while pulling away from the handpiece.
2. Properly dispose of the used mouthpiece.
3. Replace the handpiece in its cradle on top of the device.

This can be done during analysis.

Chapter 6: Quality Control

The quality control (QC) measurement is performed on a Fenom Pro device by qualified operators. QC Mode is designed to ensure the instrument is operating within its specifications. QC consists of two test types: a Negative Control, and a User Control. The Negative Control test begins with a standard breath maneuver, but analyzes ambient air that has been scrubbed of Nitric Oxide. The User Control test is performed by a Qualified User, and checks whether that user's result is within 9 ppb from their median qualifying test.

In order to be a Qualified user for User Control tests, a health care professional must first satisfy the following criteria: over 18 years of age, non-smoker, no known airway disease or chronic cold, preferably no allergies or asthma. That user must create a username for themselves, and then perform four User Control tests each separated by at least 12 hours. The first three tests determine whether this user qualifies: they must all be below 40 ppb, and the difference between the lowest and highest result must be less than 10 ppb. If these conditions are met, this user is qualified and their fourth test determines their QC User Status. Its result, and all future results for this user, are compared to the median result from the first three tests. If the first three tests do not meet the qualification criteria, this user is disqualified and a new user must be created.

Perform a QC Test

1. Touch the QUALITY CONTROL STATUS button from the Settings screen or the title bar at the top of the screen.
2. Touch the SELECT QC USER button.
3. Select the user listed in the SELECT USER FOR TEST window that corresponds to the actual user that will perform a test. If the user is not listed, create a new user by selecting the NEW USER button and following the instructions in the Create QC User section of this chapter.
4. Once a user is selected, touch SELECT TEST button.
5. Follow the instructions in Chapter 5: Perform FENO Measurement to perform a QC test

NOTE: Each day Fenom Pro will be used with patients, the system requires a valid User Control and Negative Control test. Any user can perform the Negative Control breath maneuver, since their breath sample is not being analyzed.

Device QC Status

- **Passed** - the most recent User Control test and Negative Control test were done within the past 24 hours, and both passed.
- **Failed** - the most recent User Control test and Negative Control tests were done within the past 24 hours, but at least one of those tests failed.
- **Expired** - No User Control test, or no Negative Control test, has been performed within the past 24 hours.

QC User Status

NOTE: If a QC User result fails, then an alternative QC User should perform the QC Measurements to determine if the first QC User may have a changing condition or if the system may require service. If the 2nd QC User fails QC please contact customer support.

- **Passed** - latest test is within the expected range for this QC user.
- **Failed** - latest test is outside the expected range for this QC user.
- **Expired** - 24 hours or greater have elapsed since the last passing test for this QC user.
- **Insufficient Data** - fewer than four tests have been performed for this QC user.

Create QC User

1. Touch the NEW USER button from the SELECT USER FOR TEST window.
2. Enter a USERNAME. The USERNAME may not contain spaces or match existing users.
3. Touch the SAVE button.

Chapter 7: Power Off Device

It is OK to leave the device powered-on at all times. Your device will automatically go into sleep mode when not being used. Only power off if you don't intend to use for extended periods of time. Your device will only charge when ON.

To power off the device:

1. Hold the **POWER** button down for at least 1 second.
2. Touch **OK** on the confirmation window.

   NOTE: It is recommended to keep the Fenom Pro device connected to a power supply whenever possible when powered on.

Chapter 8: Practice Mode

Practice mode is an option for use by a new patient in order to demonstrate the steps for performing a FENO test. Results are not recorded in this mode.

To access the Practice mode:

1. On the main selection screen, select the appropriate test.
2. Touch the **Practice** button.
3. Attach a new, single-patient-use mouthpiece to the handpiece and review how to use the Fenom Pro device with the patient. (See *Chapter 5: Perform FENO Measurement* for detailed instructions.)
4. The patient inhales to full capacity and then begins exhaling into the mouthpiece for the full test time.
5. The patient stops exhaling once the countdown reaches 0 (zero).
6. If training was successful, **Good job!** displays.
7. If training was unsuccessful, **Try again** displays.
8. Touch **Repeat** arrow to perform training again and go back to Step 4, or touch **Done** if finished to go back to the **Home** screen.

Chapter 9: Device Setup

Initial Setup

To set up the Fenom Pro device:

1. Remove the device and power cable from the shipping package.

   NOTE: Retain all packaging for future transportation of the device.

2. Connect the breath tube to the orange port at the bottom of the handpiece. Ensure the breath tube is fully seated against the rear surface, as shown in the figure. The second figure shows an improper breath tube connection.

Correct

Improper

3. Once the breath tube is connected, place the handpiece in the cradle on top of the device.
4. Connect the power cable from the rear panel of the device to an outlet.

   (See *Table 1* for power connection location.)

   The AC Power Indicator displays green when the device is plugged in and powered on.

   NOTE: The device should be allowed to charge for at least 4 hours before operating on battery power. The device can operate normally while charging.

5. Press the **Power** button to turn on the device.
6. The Device Setup screen will display after powering on. From this screen, set the following device settings:
   - Select Language
   - Set Time/Date
   - Add Tests (if applicable)

   These settings can be accessed and changed at any time.

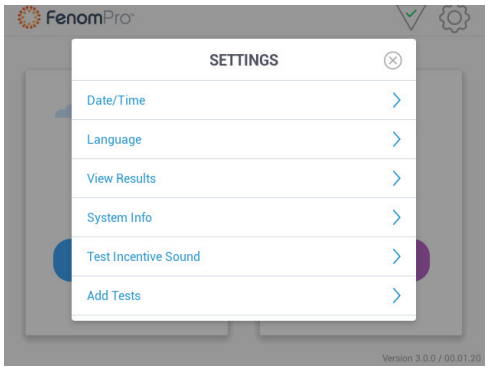
7. The Fenom Pro is now ready to begin a test.

Configuration Settings

There are device settings that require configuring based on location and requirements. These settings are accessed through the Settings icon. (See *Table 2: Indicators and Icons*.)

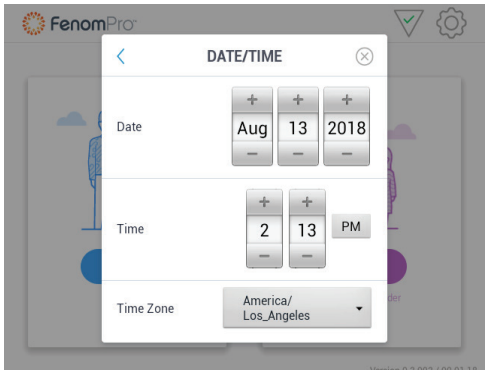
Device Settings

1. The Settings button provides access to set the Time and Date, select Language, view System Info, select Test Incentive Sound level, and Add Tests (if applicable).



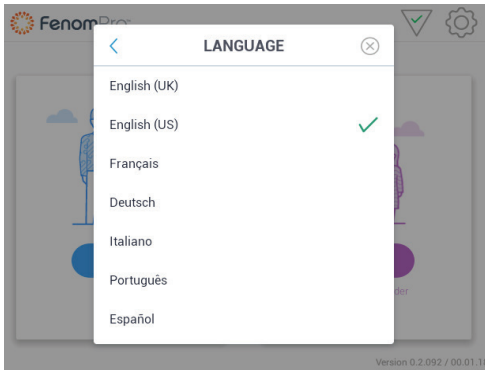
Time/Date

1. Touch Time/Date on the Settings screen to set the date and time on the device.
2. Use the + and - buttons to set the date and time.
3. Touch the AM/PM button to toggle between values.
4. Touch the Time Zone drop-down list and select the correct time zone.



Language

1. Touch Language on the Settings screen.
2. Select the desired language.
3. A check mark next to the language indicates the selected language.

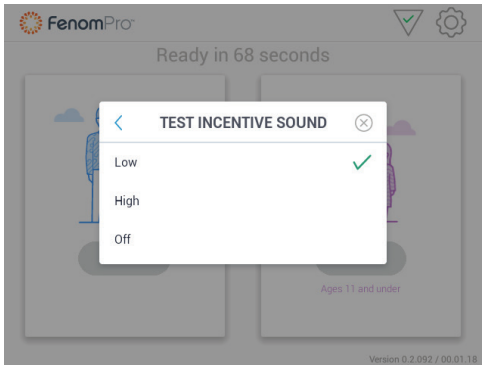


System Information

1. Touch System Info on the Settings screen to view Device Serial Number, Licensed Tests (number of licensed tests remaining), Service Due Date, Software Version, and Firmware Version.

Test Incentive Sound

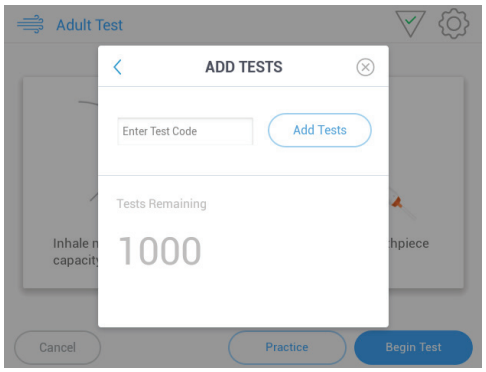
1. Touch Test Incentive Sound on the Settings screen to set the desired volume level, High, Low, or Off.
2. A check mark indicates the current selection.



Add Tests (if applicable)

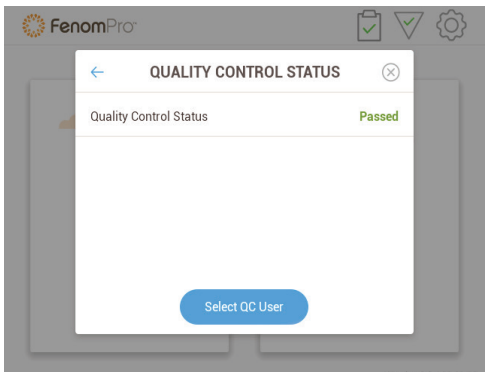
1. Contact your distributor and ask for additional licensed tests for the Fenom Pro.
2. Enter the code provided by the support representative and press Add Tests.

Note that “Add Tests” only applies to devices that show the triangle icon on the main screen.



Quality Control Status

1. Touch Quality Control Status on the Settings screen.
2. See Chapter 6 Quality Control for more instructions..



Chapter 10: General Care

Follow the recommendations below for cleaning and general care of the Fenom Pro and its accessories.

> **IMPORTANT!**
> Never attempt to open or service the Fenom Pro device or component.

Operating Conditions

Ensure stable operating conditions by avoiding placement of the device in direct sunlight, near sources radiating heat, or ventilation. The device operates under the following conditions:

- Temperature range of 15 to 30°C (59 to 86°F)
- Atmospheric pressure range of 106 to 80 kPa
- Relative humidity range of 20 to 80%, non-condensing
  - Use of the device below 20% relative humidity (RH) increases the risk of inaccurate scores. The device will issue a warning if the measured RH is ≤20%.

Cleaning & Disinfecting

- Clean the external surfaces of the device with a cloth dampened with mild soap. Cleaning should remove soil, dust, and other particles. External surfaces of the device include the handpiece and tubing.
- Repeat the cleaning procedure if the device is not visibly clean.
- Disinfect the external surfaces of the device with a cloth pre-moistened with 5% bleach solution and reapply if necessary to ensure the device surfaces remain wet for the full 3-minute contact time.
- The handpiece should be disinfected after each use.
- The external surface of the whole device should be cleaned and disinfected at the end of each day of use.
- DO NOT use spray detergents.
- DO NOT use wipes that contain alcohol.
- The following wipes are known to be compatible with Fenom Pro:
  - Dispatch Hospital Cleaner with Bleach
  - Clorox Healthcare Bleach
  - Cleanisept Wipes
  - Sani-Cloth AF3
  - Sani-Cloth Active
  - Clinell Universal Sanitizing Wipes

Handling

- Take care while handling the device.
- DO NOT drop the device or the handpiece.
- Carry the device by placing fingers in the recessed handle on the back and placing thumb over the top of the device. Support the device from the bottom with other hand.

Storage

- Clean the device before storing.
- When not in use for an extended duration, store the device in its original packaging, including in the resealable bag with the humidity pack. Take care to not crush the humidity pack while storing the device.
- Store the device in a location free from dust, free from excessive moisture or water splash, and away from excessive heat, cold, or dry conditions.
- DO NOT store the device on tall or unstable surfaces.
- Store mouthpieces in original, unbroken packaging.

Preventive Inspections

- Ensure the handpiece is not damaged and is in good condition.
- Ensure the tubing from the handpiece to the unit is not damaged, is in good condition, and is secured per Chapter 9.
- Ensure the power cord is not damaged and is in good condition.
- Ensure the touch screen is not damaged and is in good condition.

Rechargeable Battery

- Use only the power adapter provided by CAIRE Diagnostics to charge the Fenom Pro device.
- Capacity: > 15 tests over 6 hours on a fully charged battery
- Charging time: 4 hours

Lowered capacity: Extended charge times or reduced operation indicates the battery should be replaced. Contact your distributor for assistance.

Maintenance

- Periodic service is required. Check system information (page 19) for service due date.
- Contact your distributor to schedule service.

Disposal of Used/Expired Equipment and Consumables

- Expired devices should be recycled according to the local program for electronic equipment.
- Used or expired mouthpieces should be recycled according to the local program.

Limited Warranty

CAIRE Diagnostics Inc. warrants the Fenom Pro to be free of defects in materials and workmanship for a period of 18 months from the date of shipment. CAIRE Diagnostics's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned intact and prepaid, to CAIRE Diagnostics or the local representative.

The product warranty is automatically invalidated if the products are repaired, altered or otherwise tampered with by unauthorized personnel, or have been subject to misuse, neglect or accident.

The product warranty does not cover product failure or damage resulting from use with non-approved accessories.

Chapter 11: Troubleshooting

The Fenom Pro device, subcomponents, and accessories are not field serviceable.

Support

Please contact your distributor if the Fenom Pro presents any problems that cannot be solved with the actions stated in this manual.

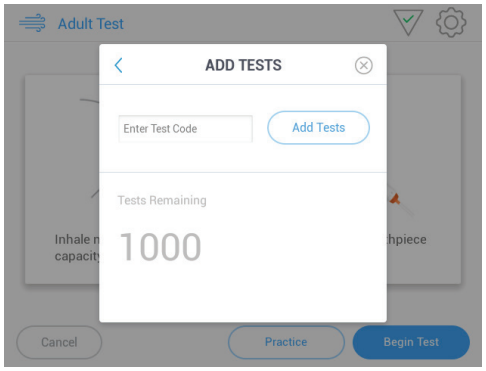
Add Tests (if used)

The Fenom Pro may require licensed tests in order to perform FENO measurements. When the number of licensed tests approaches zero, the Licensed Tests Status Button will turn red.

To order additional tests, follow three simple steps.

1. Contact your distributor and ask for additional licensed tests for the Fenom Pro.
2. Press the Licensed Tests Status button or navigate to the Add Tests screen in the Settings menu.
3. Enter the code provided by the support representative and press Add Tests.

NOTE: Please contact your distributor if the Fenom Pro device is approaching the service date or zero remaining licensed tests.



Error Codes

In the event the device displays an error message, use *Table 4* to look up the error code and perform the suggested actions to resolve the issue.

Table 4: Error Codes

Error Code	Error Situation/Error Message	Actions
	Power up self-test fails.	Cycle the power on the device. After two consecutive self-test failures, contact your distributor.
10-011	Please contact customer support to continue using this device. FENO tests are disabled.	Warning that device has reached the maximum number of uses or the expiration date; contact your distributor.
10-012	Please contact customer support to continue using this device. FENO tests are disabled.	Test not allowed due to device having reached the maximum number of uses or the expiration date; contact your distributor.
10-013	Device time is incorrect. Please set device time in Settings.	See *Chapter 8: Device Settings* – Configuration Setting section for instructions on how to set the time.
10-014	Please contact customer support to continue using this device. FENO tests are disabled.	Contact your distributor. Test not allowed due to device having reached the maximum warm hours.
10-019	The test was stopped because breath airflow fell below the minimum threshold. Please try again.	Give the patient a moment to rest, restate the proper breath maneuver pointing out the **green** target zone, and then try test again.
10-020	The test was stopped because breath airflow exceeded the maximum threshold. Please try again.	Restate the proper breath maneuver pointing out the **green** target zone, and then try the test again.
10-021	The test was stopped because breath airflow was out of the desired range for too long. Please try again.	Give the patient a moment to rest, restate the proper breath maneuver pointing out the **green** target zone, and then try the test again.
10-025	The test was stopped because breath airflow started too early or continued after the breath maneuver. Please try again.	Restate the proper breath maneuver pointing out the **green** target zone, and then try the test again.
10-043	Battery level is very low. Please immediately plug in the device or turn it off.	Plug device into power supply before using.
10-064	Battery level has fallen below what is required to do a test. Please plug in the device.	Plug device into power supply before using.
10-065	Warning that the device sensor has reached the expiration date. FENO tests are disabled.	Please contact your distributor to continue using this device.

Error Code	Error Situation/Error Message	Actions
10-066	Warning that the device date is incorrect	Set the device date in Settings.
10-068	Ambient humidity is below Fenom Pro's lower operating limit.	While not in use, store Fenom Pro in its original packaging. To raise relative humidity, consider using a room humidifier or adjusting the office climate control.
15-001	Please contact your distributor now to arrange for factory service.	Contact your distributor.
20-001	There was a failure on the device communicating with the sensors. If problem persists contact support. Please restart the device and try again.	Cycle the power on the device and try again. If problem persists, contact your distributor.
20-002	There was a failure on the device. Please restart the device and try again.	Cycle the power on the device and try again. If problem persists, contact your distributor.
40-028	There was an error calculating reading. Please wait a few minutes and try again.	Wait a few minutes and try again. If problem persists, contact your distributor.
40-065	The test was stopped because the pump airflow was outside the allowed threshold. Please try again.	Wait one minute and try again. If problem persists, contact your distributor.
40-066	The test was stopped because flow variability was outside the allowed threshold. Please try again.	Wait one minute and try again. If problem persists, contact your distributor.
40-067	The test was stopped because peak readings were beyond maximum. Please try again.	Wait one minute and try again. If problem persists, contact your distributor.
40-068	The test was stopped because baseline readings were below minimum. Please try again.	Wait one minute and try again. If problem persists, contact your distributor.
45-044	A failure has occurred on the device hardware. Please contact support. Issue: Unknown failure code.	Contact your distributor.
45-045	A failure has occurred on the device hardware. Please contact support. Issue: Memory CRC Error.	Contact your distributor.

Error Code	Error Situation/Error Message	Actions
45-048	A failure has occurred on the device hardware. Please contact customer support. Issue: Battery Communication Failure.	Contact your distributor.
45-050	A failure has occurred on the device hardware. Please contact support. Issue: Calibration EEPROM Communication Failure.	Contact your distributor.
45-051	A failure has occurred on the device hardware. Please contact support. Issue: Calibration EEPROM CRC Failure.	Contact your distributor.
45-052	A failure has occurred on the device hardware. Please contact customer support. Issue: Android Communication Timeout.	Contact your distributor.
45-054	A failure has occurred on the device hardware. Please contact customer support. Issue Board Temperature High.	Contact your distributor.
45-063	A failure has occurred on the device hardware. Please contact support. Issue: Battery Charger Failure.	Contact your distributor.
45-069	A hardware failure has occurred. Please wait while the issue is being resolved. If the issue persists please restart the device.	Wait a few minutes for issue to resolve. If problem persists, cycle the power on the device and try again. If problem persists, contact your distributor.
90-040	A failure has occurred on the device license. FENO tests are disabled.	Please contact your distributor to continue using this device.

Chapter 12: Technical Data

Dimensions and Weight	Height: 145 mm Width: 230 mm Depth: 140 mm Weight (including handpiece): 2.4 kg
Electrical Data	Device power consumption: < 20 VA Power supply mains voltage: 100–240 V ~50–60 Hz
Exhaled NO Performance	The Fenom Pro is verified to fulfill performance herein under temperature range of 15-30°C (59-86°F), relative humidity of 20-80%, and pressure range of 106-80 kPa.
Linearity	Slope 1.00 ± 0.05 Squared correlation coefficient, r2 ≥ 0.998
Precision	NO concentrations ≤ 50 ppb: 5 ppb NO concentrations > 50 ppb:10% of the concentration
Accuracy	NO concentrations ≤ 50 ppb: ± 5 ppb NO concentrations > 50 ppb: ± 10% of the concentration
Limit of Detection	10 ppb
Measurement Range	10-200 ppb
Exhalation Parameters	Exhalation time: 10 or 6 seconds Exhalation pressure is between 15-20 cm (6-8 in.) water Exhalation flow rate is 45-55 mL/s; warning sounds played outside of this range

Chapter 13: Device Performance

Linearity

Ten Fenom Pro devices were tested as part of the linearity study. Nitric oxide (NO) was mixed in a balance gas of air to obtain 8 NO concentration levels between 5 and 200 ppb. The data showed that the device is linear across this range. Five replicates were obtained at each level, and ten candidate devices were evaluated in both the 6 second and the 10 second modes. The range of slope, intercept, and R^2 values obtained are listed in the tables below.

Mode	Range of slopes	Ranger of intercepts	Range of R^2 values
10-second Test	0.96 - 1.05	-1.58 - 1.23	0.99 - 1.00
6-second Test	0.96 - 1.03	-1.11 - 1.87	0.99 - 1.00

Analytical Precision

Analytical precision was evaluated using samples across 10, 25, 75 and 200 ppb concentrations. Two replicate determinations of each concentration were made eight times a day for five days across five different devices.

Repeatability is an estimated of variation withing one test run in one day. Within-device precision is an estimate of variation between test runs and days. The results for 10 and 25 ppb are expressed as absolute values in ppb. The results for the 75 and 200 ppb levels are expressed as percentage of the measured NO concentrations. Both standard deviation estimates meet the precision claim at all four concentration levels. The results are listed in the table below.

Precision Study Summary (10-second Tests)

Device	Repeatability				Within-Device Precision			
	10 ppb	25 ppb	75 ppb	200 ppb	10 ppb	25 ppb	75 ppb	200 ppb
100183	1.1	1.5	2.4%	1.4%	2.0	3.2	3.7%	1.3%
100184	0.8	1.3	2.1%	1.4%	1.0	1.9	3.5%	1.5%
100186	0.8	1.2	1.8%	1.1%	1.5	2.0	3.8%	1.3%
100187	1.2	1.7	5.0%	4.5%	1.5	2.5	5.5%	4.5%
100193	0.8	1.1	1.9%	1.7%	1.4	1.5	2.4%	1.8%

Precision Study Summary (6-second Tests)

Device	Repeatability				Within-Device Precision			
	10 ppb	25 ppb	75 ppb	200 ppb	10 ppb	25 ppb	75 ppb	200 ppb
100177	1.5	1.2	2.4%	1.8%	1.3	1.8	5.1%	6.4%
100178	2.2	0.7	2.1%	1.0%	1.3	1.4	6.4%	6.7%
100183	2	1.3	3.1%	2.6%	2.0	2.3	4.3%	4.2%
100211	1.6	1.3	2.2%	1.7%	1.3	1.1	3.9%	5.0%
100230	1.6	0.9	2.3%	1.5%	1.5	3.2	7.7%	8.9%

Accuracy

Four Fenom Pro devices were tested over five concentrations between 10 and 200 ppb NO with five replicates each across five different environmental conditions. Fenom Pro results were compared to results obtained from an independent device calibrated against NIST values. The data showed that mean Fenom Pro results were within 5 ppb for samples less than 50 ppb, and percent errors were less than 10% for samples at 50 ppb and greater. The results are listed in the table below. The accuracy for all test cases within the technical specification.

Accuracy Study Summary (10-second Test)

Device	10 ppb	25 ppb	75 ppb	100 ppb	200 ppb
100179	-1.8	-2.8	-3.8%	-1.4%	0.4%
100180	-2.0	-2.2	-0.4%	0.4%	3.4%
100183	-2.0	-3.4	-1.8%	0.0%	2.8%
100184	-1.8	-1.6	-0.8%	-0.2%	1.6%

Accuracy Study Summary (6-second Test)

Device	10 ppb	25 ppb	50 ppb	100 ppb	200 ppb
100177	0	-1	-1	0%	0%
100178	0	-1	0	5%	5%
100211	1	0	-1	-3%	-6%
100230	-1	-2	-5	-5%	-4%

Limit of Detection

Ten Fenom Pro devices were tested using NO gas with air balance at 3 and 5 ppb. Five replicate determinations of each concentration were made. The mean and confidence limits at 3 ppb and 5 ppb support that the detection limit is below 10 ppb, supporting the claim. Results are listed in the table below.

Limit of Detection (10-second Test)

Device	Concentration (ppb)	Mean (ppb)	Lower 95% CI (ppb)	Upper 95% CI (ppb)
100174	3 ppb	3.0	2.4	3.6
	5 ppb	4.7	4.1	5.3
100214	3 ppb	3.8	3.4	4.2
	5 ppb	5.7	5.3	6.1
100227	3 ppb	4.0	3.6	4.4
	5 ppb	6.0	5.6	6.4
100233	3 ppb	3.6	3.1	4.1
	5 ppb	5.8	5.3	6.3
100240	3 ppb	3.4	3.0	3.8
	5 ppb	4.8	4.4	5.2
100258	3 ppb	2.7	2.4	3.0
	5 ppb	5.2	4.9	5.5
100270	3 ppb	2.5	2.2	2.8
	5 ppb	4.2	3.9	4.5
100284	3 ppb	2.9	2.4	3.4
	5 ppb	4.6	4.1	5.1
100319	3 ppb	2.9	2.6	3.2
	5 ppb	4.4	4.1	4.7
100329	3 ppb	2.7	2.3	3.1
	5 ppb	4.5	4.1	4.8

Limit of Detection (6-second Test)

Device	Concentration (ppb)	Mean (ppb)	Lower 95% CI (ppb)	Upper 95% CI (ppb)
100174	3 ppb	2.4	2.0	2.8
	5 ppb	4.1	3.7	4.5
100214	3 ppb	3.0	2.7	3.3
	5 ppb	4.5	4.2	4.8
100227	3 ppb	3.5	3.1	3.9
	5 ppb	4.9	4.5	5.3
100233	3 ppb	2.9	2.5	3.3
	5 ppb	4.6	4.2	5.0
100240	3 ppb	3.0	2.6	3.4
	5 ppb	5.2	4.8	5.6
100258	3 ppb	2.4	2.1	2.7
	5 ppb	4.6	4.3	4.9
100270	3 ppb	2.2	1.8	2.6
	5 ppb	4.7	4.3	5.1
100284	3 ppb	2.7	2.4	3.0
	5 ppb	4.1	3.8	4.4
100319	3 ppb	2.7	2.3	3.1
	5 ppb	5.0	4.6	5.4
100329	3 ppb	2.7	2.3	3.1
	5 ppb	4.8	4.4	5.2

Clinical Performance

A clinical study was performed with an intend to evaluate ("ITE") population of **70** subjects (**32** children (<18yrs) and **38** adults). Subjects were asked to obtain two (2) Fenom Pro measurements using each measurement mode (10-second Test and 6-second Test) with the assistance of a health care professionals ("HCP"), for a total of four (4) Fenom Pro evaluations per participant per visit.

Clinical precision results for the 10-second measurement mode for the ITE (intend to evaluate) population (pediatric and adults combined) at visit 1 and visit 2 are summarized separately in the tables below.

10-second mode – visit 1

Median Concentrations	Number of Subjects	Within Subject Mean SD (ppb)	Within Subject Mean CV (%)	95% CI for CV (%)
<10	--	--	--	--
10 to <20	--	--	--	--
20 to <30	6	1.650	5.86	3.45, 11.78
30 to <40	16	1.989	5.88	4.24, 8.66
40 to <50	16	2.696	5.88	4.24, 8.67
≥50	32	3.027	3.54	2.80, 4.60

10-second mode – visit 2

Median Concentrations	Number of Subjects	Within Subject Mean SD (ppb)	Within Subject Mean CV (%)	95% CI for CV (%)
<10	2	0.000	0.00	0.00, 0.00
10 to <20	22	0.964	6.08	4.59, 8.41
20 to <30	19	1.675	6.79	5.03, 9.66
30 to <40	10	2.33	6.60	4.38, 10.99
40 to <50	5	2.404	5.40	3.02, 11.85
≥50	12	2.239	3.36	2.31, 5.31

Clinical precision results for the 6-second measurement mode for the ITE (intend to evaluate) population (pediatric and adults combined) at visit 1 and visit 2 are summarized separately in the tables below.

6-second mode – visit 1

Median Concentrations	Number of Subjects	Within Subject Mean SD (ppb)	Within Subject Mean CV (%)	95% CI for CV (%)
<10	--	--	--	--
10 to <20	--	--	--	--
20 to <30	10	1.980	7.00	4.64, 11.65
30 to <40	10	2.263	6.52	4.32, 10.86
40 to <50	15	2.310	5.07	3.62, 7.58
≥50	35	2.889	3.48	2.78, 4.48

6-second mode – visit 2

Median Concentrations	Number of Subjects	Within Subject Mean SD (ppb)	Within Subject Mean CV (%)	95% CI for CV (%)
<10	--	--	--	--
10 to <20	23	0.953	6.03	4.58, 8.27
20 to <30	18	1.139	4.69	3.44, 6.74
30 to <40	10	2.051	6.00	3.98, 10.00
40 to <50	7	3.435	7.71	4.72, 14.52
≥50	12	2.946	4.44	3.05, 7.01

Clinical Accuracy

To assess clinical accuracy, measurements for FENO, spirometry, and asthma control questionnaires were completed at baseline (Visit 1) and two weeks later (Visit 2) after therapeutic agents were administered.

ATS defines elevated FENO as >25 ppb for adults and > 20ppb for children. The initial FENO inclusion criteria for this study were >30ppb for adults and >25ppb for children (total n=69). There were 27/32 (84.38%) pediatric subjects with V1 FENO ≥25ppb and 26/37 (70.27%) adult subjects with V1 FENO≥30ppb who had a meaningful decline in FENO. A meaningful decline is defined by ATS as >20% for initial FENO values >50ppb and >10ppb for initial FENO values <50ppb.

Results showed a mean FENO change of -28.2 ppb (-41.12%) with a mean SD of (30.89 ppb) for the 70 intend to evaluate ("ITE") patients enrolled.

The decline in FENO was accompanied by the following changes in subjective and objective asthma measures.

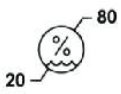
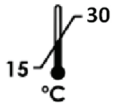
The following secondary outcome measures showed the following after 2 weeks of corticosteroid therapy that accompanied the fall in FENO described above.

ACQ:
Mean ACQ score fell by **1.1 points (50.0%)** after corticosteroids for the 70 intend to evaluate ("ITE") patients enrolled. A change of 0.5 points on the ACQ scale represents a clinically meaningful change.

FEV_1:
There was a mean FEV_1 change of **0.31 L (12.5%)** after corticosteroids for the 70 intend to evaluate ("ITE") patients enrolled, representing a significant improvement in FEV_1.

Chapter 14: Reference

Symbol Explanation

	WEEE Directive 2102/19/EU		Manufacturer
	Keep out of rain & damp conditions		Do not reuse
	Prescription Only		In vitro diagnostic device
	MR Unsafe – Fenom Pro is not rated for use near magnetic resonance		Use by YYYY-MM-DD (expiry)
	Caution, consult accompanying documents		Catalog part number
	Type BF applied part complying with IEC 60601-1		Lot number
	Non-Sterile		Serial number
	Consult instructions for use		Quantity
	Operating humidity range		Operating temperature range
	Intertek ETL Listed, Canada & USA		

Chapter 15: Parts and Accessories

Warning!

Any accessory not recommended by CAIRE Diagnostics Inc. may result in loss of performance, damage to your Fenom PRO, or injury. The product warranty does not cover product failure or damage resulting from use with non-approved accessories. CAIRE Diagnostics Inc. takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by CAIRE Diagnostics.

Parts

- Fenom Pro Model No. 900-0001
- Packaged Fenom Pro P/N: 900-0005
- Fenom Pro Power Cable P/N: 415-0003
- Fenom Pro Power Supply P/N: 197-0001

Accessories

- Fenom Pro Single Patient Use Mouthpiece* (50 Count) P/N: 900-0019-50

* *Disposable mouthpiece to be changed for every patient.*

To order accessories, contact your distributor. If you are unsure of your representative's contact information, visit www.fenomasthma.com.

CAIRE® DIAGNOSTICS

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