



FenomPro™

Asthma Monitor

Instructions for Use



Table of Contents

Table of Contents	2
Definitions	4
Chapter 1: System Overview	5
System Description	5
Indications for Use	5
Clinical Limitations	5
Risks to Health	5
Fenom Pro Components	6
Table 1: Fenom Pro Device Components	6
Display Buttons	7
Table 2: Button and Indication Icons	7
Chapter 2: Safety and Warnings	8
Safety Instructions	8
Compliance	8
Warnings	8
Electromagnetic Emissions	9
Electromagnetic Immunity	9
Chapter 3: Fenom Pro Quick Start Guide	10
Chapter 4: FeNO Measurement Preparation	12
Wake up Device	12
Pre-test Check	12
Chapter 5: Perform FeNO Measurement	13
Perform an Adult FeNO Test	13
Perform a Child FeNO Test	14
View Results	15
Remove Mouthpiece	15
Chapter 6: Power Off Device	16
Chapter 7: Practise Mode	16
Chapter 8: Device Set-up	17
Initial Set-up	17
Configuration Settings	18
Device Settings	18
Time/Date	18
Language	18
System Information	19
Test Incentive Sound	19
Add Tests	19

Chapter 9: General Care	20
Operating Conditions	20
Cleaning	20
Handling	20
Storage	20
Preventive Inspections	21
Rechargeable Battery	21
Maintenance	21
Disposal of Used/Expired Equipment and Consumables	21
Limited Warranty	21
Chapter 10: Troubleshooting	22
Support	22
Add Tests	22
Errors and Codes	23
Table 4: Error Codes	23
Chapter 11: Technical Data	26
Dimensions and Weight	26
Electrical Data	26
Exhaled NO Performance	26
Linearity	26
Precision	26
Accuracy	26
Limit of Detection	26
Measurement Range	26
Exhalation Parameters	26
Chapter 12: Reference	27
Symbol Explanation	27
Chapter 13: Parts and Accessories	28
Parts	28
Accessories	28
Bibliography	29

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 or upper airway.

FEV1

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 manoeuvre, measured in litres.

FEV6

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 manoeuvre, measured in litres.

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 litres.

NO

Nitric oxide – Produced by the human lung and 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 litres per minute or in litres 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

The Fenom Pro™ Asthma Monitor (henceforth known as Fenom Pro) is a point-of-care breath analyser that uses electrochemical 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 a quantitative, non-invasive, simple, and safe method to assess, monitor, and determine the best treatment methods for airway inflammation in patients. The Fenom Pro device is suitable for use in hospitals and other healthcare settings. The mouthpiece is the applied part for patient use.

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 Fenom Pro according to guidelines for NO measurement established by the American Thoracic Society (ATS) and European Respiratory Society (ERS) [1].

Fenom Pro provides direct sampling with delayed analysis (approximately 28 seconds) of sequentially collected and analysed exhaled breath. 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 hospitals and other healthcare settings (CISPR 11 class A).

Indications for Use

Fenom Pro measures FeNO in human breath. FeNO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment [1]. FeNO measurements with Fenom Pro should be used as part of regular assessment and monitoring of patients with these conditions [10]. Testing using the Fenom Pro should only be done in a point-of-care healthcare setting under professional supervision. Fenom Pro is suitable for children, approximately 7-17 years, and adults 18 years and older.

Clinical Limitations

Fenom Pro may not be used by children under the age of approximately 7 years, including infants, as measurement requires patient cooperation. The determining factor for age limitation is based on a patient's ability to understand and execute the given instructions.

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

Elevated FeNO levels are also found in other inflammatory conditions aside from asthma, such as allergic rhinitis [2], systemic lupus erythematosus [3] and liver cirrhosis [4], and COPD including COPD overlap syndrome [5] [6].

Viral infections might lead to increased FeNO levels. The mechanism behind this increase is, however, separate from the one causing the increased levels seen in allergic inflammation. Virus related increases in FeNO may be resistant to corticosteroid treatment [7].

Recent intake of nitrate rich food, including lettuce, spinach, beets, walnuts, peanuts, and animal organs, can lead to increased FeNO levels [8].

Smoking reduces exhaled NO levels. However, FeNO can still differentiate asthmatics from non-asthmatics among smokers.

Risks to Health

There are no known direct risks to patient health posed by the use of Fenom Pro. However, failure to perform the test 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.

Fenom Pro Components

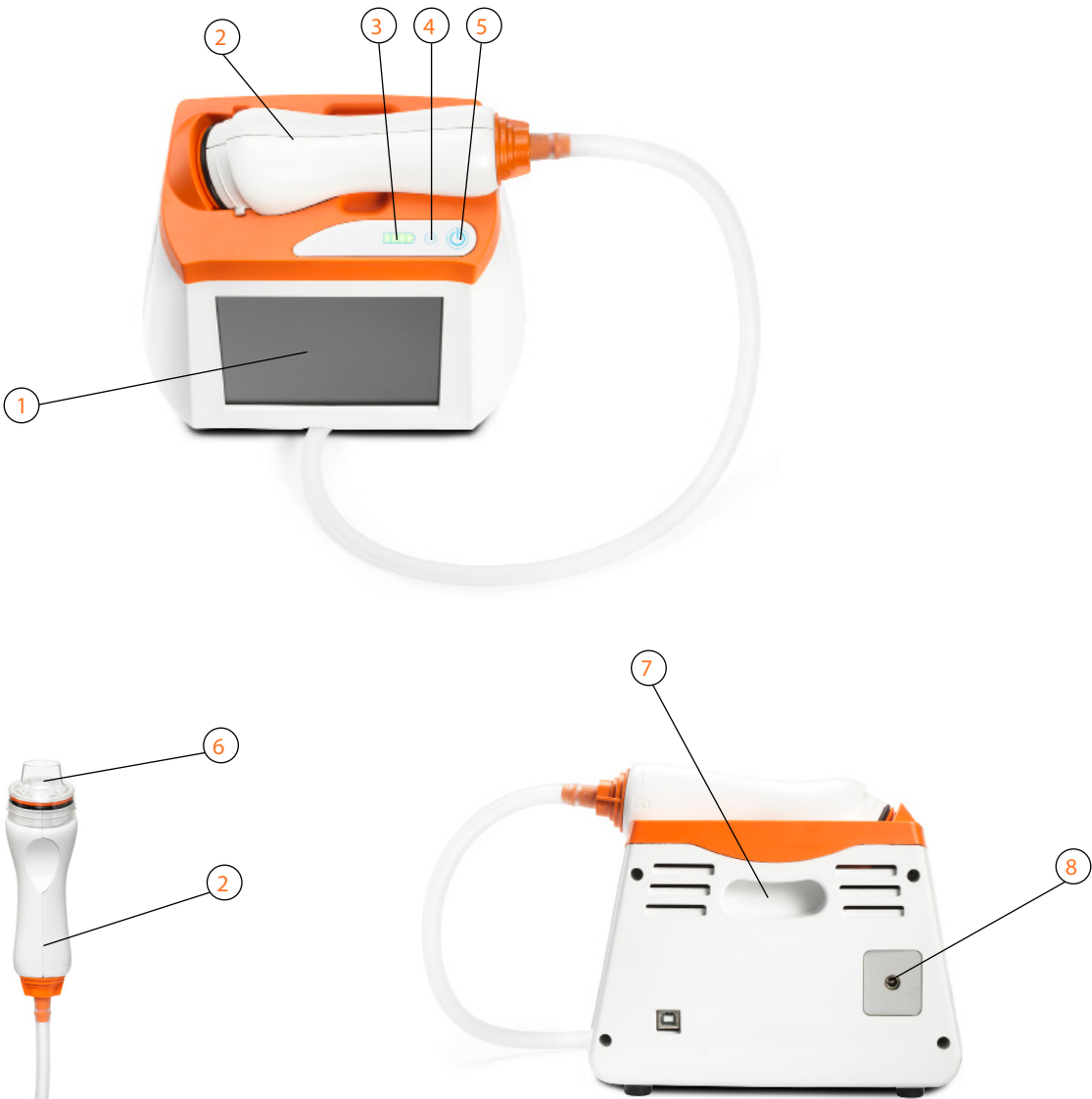





Table 1: Fenom Pro Device Components

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

Display Buttons

There are several button icons that Fenom Pro utilises 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 Licence Status Button (Tests available)	Button used to open Order Tests box. Green check mark indicates that the device has tests available.
	Test Licence Status Button (Few tests available)	Button used to open Order Tests box. Red exclamation point indicates a few tests remain. Contact your distributor to order additional tests.

Chapter 2: Safety and Warnings

Safety Instructions

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

- Ensure the patient DOES NOT inhale through the device.
- Ensure the patient DOES NOT inhale through the mouthpiece.
- Ensure the patient DOES NOT exhale beyond the limits of their physical ability.
- Discontinue measurements if the breath manoeuvre is laborious for the patient.
- DO NOT allow use of Fenom Pro within 15 minutes after performing spirometry testing such as: FEV1, FEV6, FVC, PEF, etc.
- DO NOT allow use of Fenom Pro within 60 minutes after exercising or smoking.
- Ensure the patient DOES NOT use the Fenom Pro without a new single-patient-use mouthpiece.
- Ensure the patient DOES NOT perform more than six breath attempts within one day.
- DO NOT allow use of Fenom Pro within 60 minutes after eating or drinking fluids other than water.

Compliance

Fenom Pro is CE-marked according to the In Vitro Diagnostics Directive 98/79/EC.

Fenom Pro is RoHS compliant according to Directive 2011/65/EU Restriction of Hazardous Substances in Electrical and Electronic Equipment.

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. Spirosure 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.
- Only use the provided power supply unit.
- 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 may 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.
- DO NOT modify the Fenom Pro device, handpiece or mouthpiece.
- 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 vapours or liquids.
- DO NOT use substances containing alcohol close to the Fenom Pro.
- The single-patient-use mouthpiece should be used immediately after opening.

-
- DO NOT reuse the single-patient-use mouthpiece on other patients.
 - DO NOT open, crush, incinerate, or heat the lithium-ion battery in the device above 140°F/60°C.
 - DO NOT use the USB port to connect Fenom Pro to a computer.
 - 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 the handpiece.
 - A single-patient-use mouthpiece has a limit of three uses.

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 60601-1-2:2007 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

Chapter 3: Fenom Pro Quick Start Guide

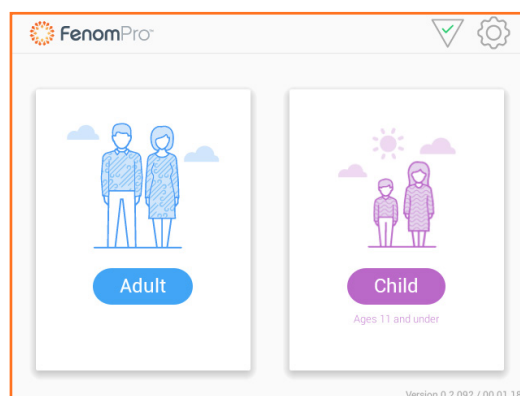
To perform a FeNO test, follow these three simple steps. For full test guidelines and instructions, see Chapters 4 and 5. For set-up instructions, see Chapter 8.

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 the Adult or Child test on the screen display. 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.

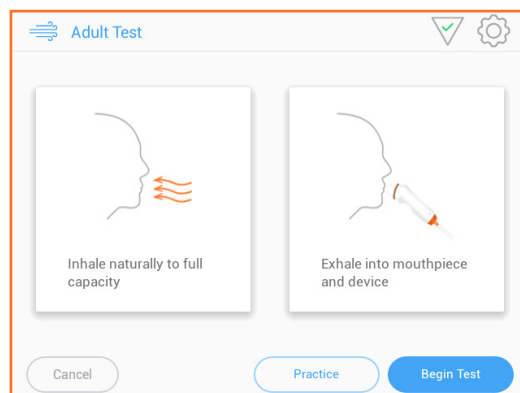
Child test: Patients aged 11 and under.

Adult test: Patients aged 12 and up.



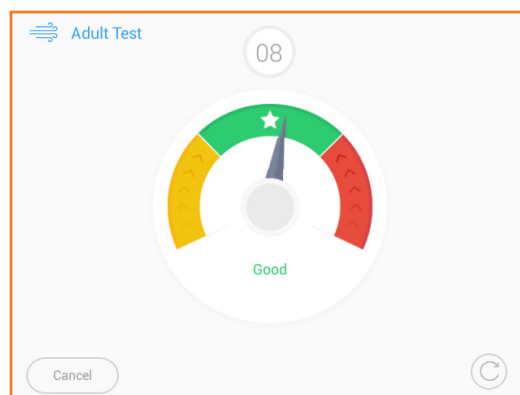
NOTE: See Chapter 7: Practise Mode if patient requires a demonstration before taking the test.

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

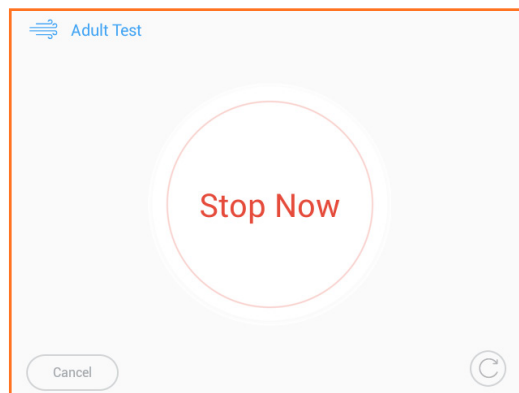


Instruct the patient to keep the indicator over the star at the top of the gauge.

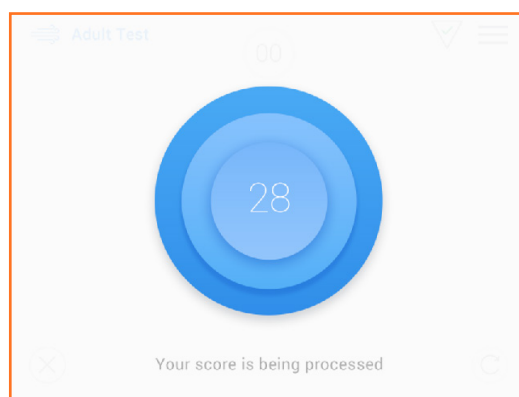
NOTE: Having the indicator within the green range is also acceptable.



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

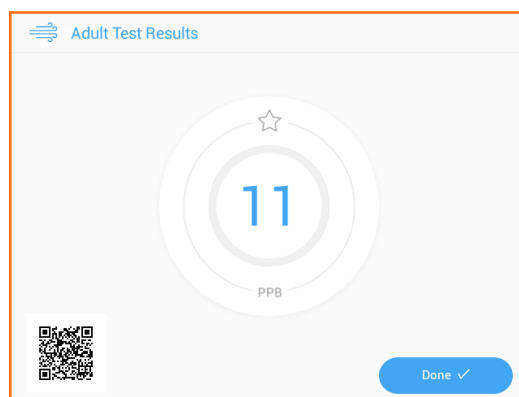


Results will display in 28 seconds.



If the patient has the Fenom Connect™ Asthma Assistant installed on their mobile phone, allow the patient to scan the QR Code displayed in the bottom left corner.
(Contact your local representative for more information regarding the Fenom Connect Asthma Assistant.)

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



Chapter 4: FeNO Measurement Preparation

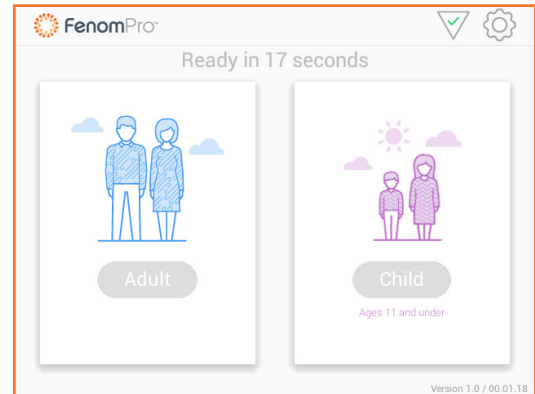
NOTE: See Chapter 2: Safety and Warnings for a list of safety instructions and warnings.

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.

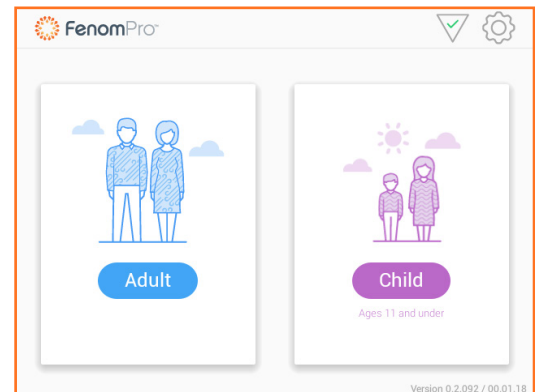
Allow the device to warm-up for one minute.



2. Fenom Pro provides two options at the warm-up conclusion – begin Adult or Child test.

Child test: Patients aged 11 and under.

Adult test: Patients aged 12 and up.



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 the device into the power supply before using.
2. Check that the device is on a flat, stable surface while performing a FeNO measurement.
3. Confirm that the patient meets eligibility requirements:
 - Age 7 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 the 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 display. Once a sufficient amount of the patient's breath is captured, the sensor analyses the breath and reports a FeNO score in parts per billion (ppb).

Perform an Adult 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. Pass the handpiece to the patient with the mouthpiece attached.
 5. Press the Adult button on the test selection screen.
 6. Provide the patient with a brief overview on how to use the Fenom Pro device.
 - Instruct the patient to inhale naturally to full capacity before placing their mouth on the mouthpiece.
 - Instruct the patient to place mouth on the mouthpiece and exhale for a full 10 seconds at a steady flow.
 - Instruct the patient to keep their lips sealed around the mouthpiece so no breath escapes from the patient's lips.
- NOTE: See Chapter 7: Practise Mode if patient requires a demonstration before taking the test.
7. Press the Begin Test button when the patient understands the instructions and is ready to begin.
 8. The visual incentive gauge is displayed.
 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 manoeuvre, review the reason for the failure. If necessary, the patient can attempt a test in Practise Mode (Chapter 7) before repeating.
 12. Proceed to instructions in the View Results section of this Chapter.

Perform a Child 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. Pass the handpiece to the patient with the mouthpiece attached.
5. Press the Child button on the test selection screen after powering the Fenom Pro device on.
6. Provide the patient with a brief overview on how to use the Fenom Pro device.
 - Instruct the patient to inhale naturally to full capacity before placing their mouth on the mouthpiece.
 - Instruct the patient to place mouth on the mouthpiece and exhale for a full 6 seconds at a steady flow.
 - Instruct the patient to keep their lips sealed around the mouthpiece so no breath escapes from the patient's lips.

NOTE: See Chapter 7: Practise Mode if patient requires a demonstration before taking the test.

7. Press the Begin Test button when the patient understands the instructions and is ready to begin.
8. The visual incentive gauge is displayed.
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 manoeuvre, review the reason for the failure. If necessary, the patient can attempt a test in Practise Mode (Chapter 7) before repeating.
12. After successful completion of the test, proceed to the View Results section of this Chapter.

View Results

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

1. View the FeNO result.
2. If the patient has the Fenom Connect Asthma Assistant installed on their device, instruct the patient to open their app and scan the present QR Code for their test results.
3. 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.



Chapter 6: 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.

To power off the device:

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

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

Chapter 7: Practise Mode

The Practise mode is used for a new patient in order to demonstrate the steps for performing a FeNO test. Results are not recorded in this mode.

IMPORTANT!

Using the Practise mode counts as one exhalation toward the maximum six exhalations per patient per day and toward the maximum three exhalations per mouthpiece.

To access the Practise mode:

1. On the main selection screen, select the appropriate test for the patient based on their age.
 - Patients aged 11 and under will proceed with the Child option.
 - Patients aged 12 and up will proceed with the Adult option.
2. Press the Practise 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 then begins exhaling into the mouthpiece when ready.
 - Child tests require the patient to exhale for 6 seconds.
 - Adult tests require the patient to exhale for 10 seconds.
5. The patient stops exhaling once the countdown reaches 0 (zero).
6. If training was successful, Good job! is displayed.
7. If training was unsuccessful, Try again is displayed.
8. Press the Repeat arrow to perform training again and go back to Step 4, or press Done if finished to go back to the main login screen.

Chapter 8: Device Set-up

Initial Set-up

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



Incorrect

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 Set-up screen will be displayed after powering on. From this screen, set the following device settings:
 - Select Language
 - Set Time/Date
 - Add Tests

These settings can be accessed and changed at any time.

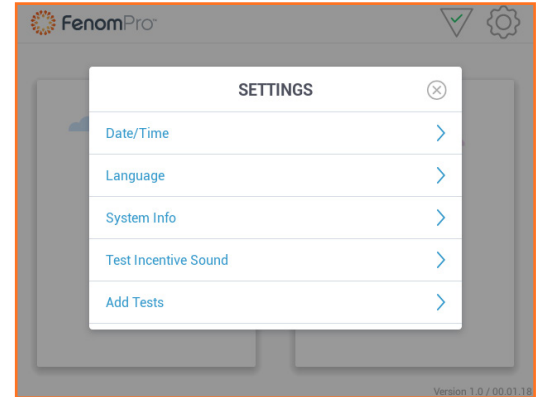
7. The Fenom Pro is now ready to begin a test.

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.)

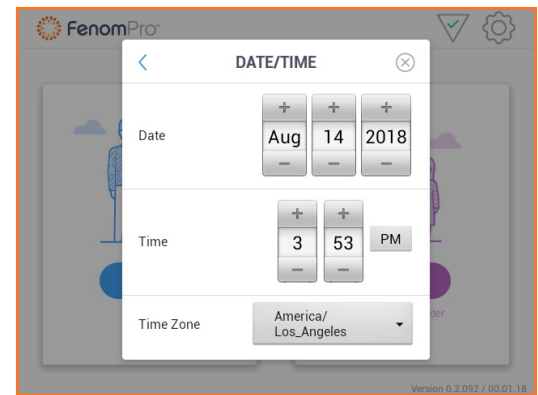
Device Settings

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.



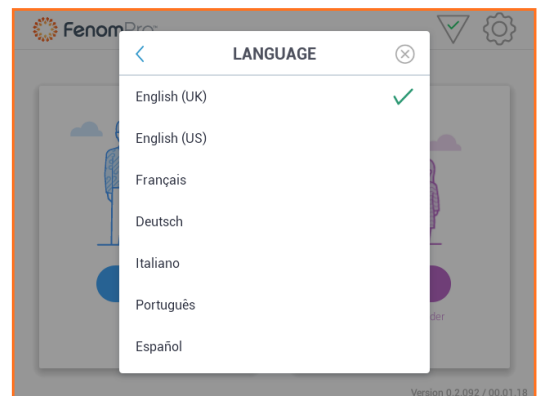
Time/Date

1. Press 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. Press the AM/PM button to toggle between values.
4. Press the Time Zone drop-down list and select the correct time zone.



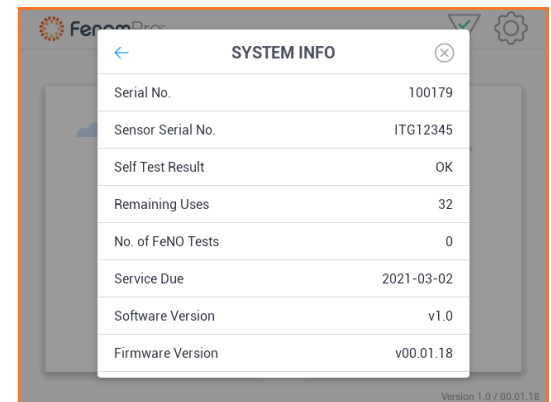
Language

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



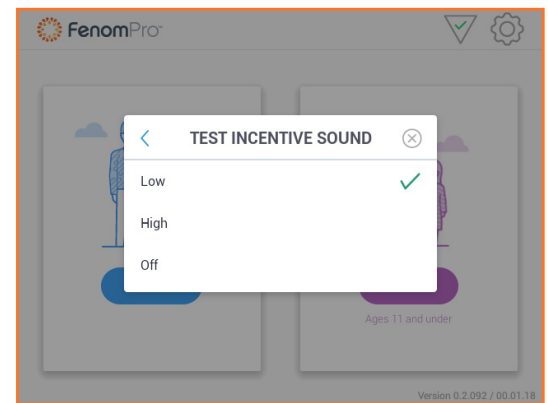
System Information

1. Press 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.



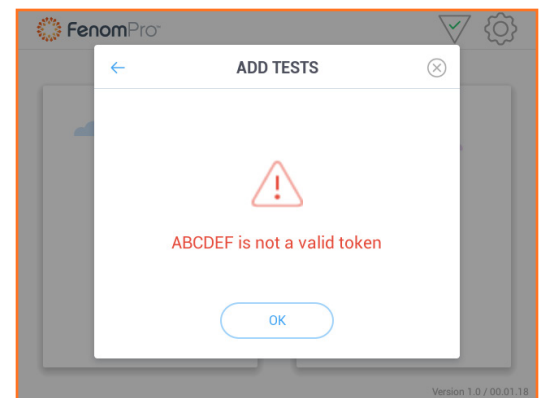
Test Incentive Sound

1. Press 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

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



Chapter 9: 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 components.

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

Cleaning

- Clean the external surfaces of the device with a cloth pre-moistened with 5% bleach solution at the end of each day of use.
- DO NOT use spray detergents.

Handling

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

Storage

- Clean the device before storing.
- Store the device in its original shipping packaging.
- 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 and is in good condition.
- 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 Spirosure 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 the distributor representative for assistance.

Maintenance

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

Disposal of Used/Expired Equipment and Consumables

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



Limited Warranty

Spirosure, 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. Spirosure's sole obligation under this warranty is limited to repairing or replacing, at its discretion, any item covered under this warranty when such an item is returned intact and prepaid, to Spirosure or the local representative.

The product warranty is automatically invalidated if the products are repaired, altered or otherwise tampered with by unauthorised 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. Spirosure takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by Spirosure.

Chapter 10: Troubleshooting

The Fenom Pro device, sub-components, and accessories are not field serviceable.

Support

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

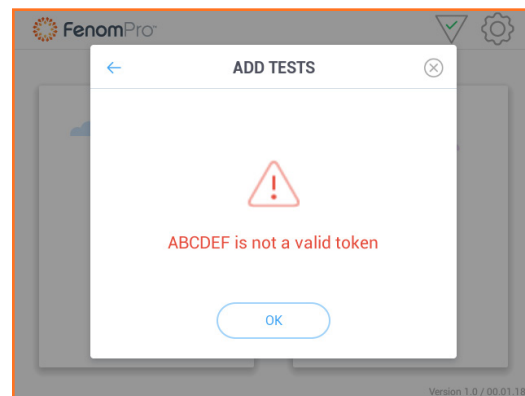
Add Tests

The Fenom Pro requires 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 representative 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 distributor representative and press Add Tests.

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



Errors and 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 Technical Support.
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 Technical Support.
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 Technical Support.
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 Technical Support. 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 manoeuvre pointing out the green target zone, and then try the test again. If the problem persists, try performing a shortened test. (See Chapter 10: Shortened Test Mode (For Research Only).)
10-020	The test was stopped because breath airflow exceeded the maximum threshold. Please try again.	Restate the proper breath manoeuvre 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 manoeuvre pointing out the green target zone, and then try the test again. If the problem persists, try performing a shortened test. (See Chapter 10: Shortened Test Mode (For Research Only).)
10-025	The test was stopped because breath airflow started too early or continued after the breath manoeuvre. Please try again.	Restate the proper breath manoeuvre pointing out the green target zone, and then try the test again.
10-043	Battery level is very low. Please immediately plug the device in or turn it off.	Plug device into power supply before using.
10-064	Battery level has fallen below the required level 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 customer support 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.
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 Technical Support.
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 Technical Support.
40-028	There was an error calculating the reading. Please wait a few minutes and try again.	Wait a few minutes and try again. If problem persists, contact Technical Support.
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 Technical Support.
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 Technical Support.
40-067	The test was stopped because peak readings were beyond the maximum. Please try again.	Wait one minute and try again. If problem persists, contact Technical Support.
40-068	The test was stopped because baseline readings were below the minimum. Please try again.	Wait one minute and try again. If problem persists, contact Technical Support.
45-044	A failure has occurred on the device hardware. Please contact support. Issue: Unknown failure code.	Contact Technical Support.
45-045	A failure has occurred on the device hardware. Please contact support. Issue: Memory CRC Error.	Contact Technical Support.
45-048	A failure has occurred on the device hardware. Please contact customer support. Issue: Battery Communication Failure.	Contact Technical Support.
45-050	A failure has occurred on the device hardware. Please contact support. Issue: Calibration EEPROM Communication Failure.	Contact Technical Support.









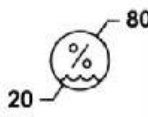

Error Code	Error Situation / Error Message	Actions
45-051	A failure has occurred on the device hardware. Please contact support. Issue: Calibration EEPROM CRC Failure.	Contact Technical Support.
45-052	A failure has occurred on the device hardware. Please contact customer support. Issue: Android Communication Timeout.	Contact Technical Support.
45-054	A failure has occurred on the device hardware. Please contact customer support. Issue Board Temperature High.	Contact Technical Support.
45-063	A failure has occurred on the device hardware. Please contact support. Issue: Battery Charger Failure.	Contact Technical Support.
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 be resolved. If problem persists, cycle the power on the device and try again. If problem persists, contact Technical Support.
90-040	A failure has occurred on the device licence. FeNO tests are disabled.	Please contact customer support to continue using this device.









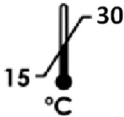

Chapter 11: Technical Data

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 fulfil performance herein under temperature ranges 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, $r^2 \geq 0.998$
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: $\pm 10\%$ of the concentration
Limit of Detection	5 ppb
Measurement Range	5-300 ppb
Exhalation Parameters	Exhalation time of Adult test: 10 seconds Exhalation time of Child test: 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 12: Reference

Symbol Explanation

	WEEE Directive 2102/19/EU
	Keep out of rain & damp conditions
	Conformité Européenne conformance
	European Authorised Representative
	Caution, consult accompanying documents
	Type BF applied part complying with IEC 60601-1
	Non-Sterile
	Consult instructions for use
	Operating humidity range
	Intertek ETL Listed, Canada & USA

	Manufacturer
	Do not reuse
	In vitro diagnostic device
	Use by YYYY-MM-DD (expiry)
	Catalogue part number
	Lot number
	Serial number
	Quantity
	Operating temperature range
	MR Unsafe – Fenom Pro is not rated for use near magnetic resonance

Chapter 13: Parts and Accessories

Warning!

Any accessory not recommended by Spirosure, 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. Spirosure, Inc. takes no responsibility for health and safety problems or other problems caused by the use of accessories not approved by Spirosure.

Parts

- Fenom Pro Model No. 900-0001
- Packaged Fenom Pro P/N:

900-0004 (U.K.)	900-0006 (France)
900-0007 (Germany)	900-0008 (Switzerland)
900-0010 (Spain)	900-0011 (Portugal)
900-0012 (Australia)	900-0013 (New Zealand)
900-0014 (Italy)	
- Fenom Pro Power Cable P/N:

415-0004 (U.K.)	415-0005 (Germany)
415-0008 (Switzerland)	415-0009 (Italy)
415-0011 (France/Spain/Portugal)	
415-0010 (Australia/New Zealand)	
- Fenom Pro Power Supply P/N: 197-0001
- Fenom Pro IFU Reference P/N: FRM-3301

Accessories

- Fenom Pro Single-Use Mouthpiece* (20 Count) P/N: 900-0002

* Disposable mouthpiece to be changed for every patient.

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

Bibliography

- [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. H. Henriksen, M. Sue-Chu, T. L. Holmen, A. Langhammer, and L. Bjermer, "Exhaled and nasal NO levels in allergic rhinitis: relation to sensitization, pollen season and bronchial hyperresponsiveness." Eur. Respir. J., 1999; vol. 13, pp. 301-306.
- [3] G. Rolla, L. Brussino, M. T. Bertero, P. Colagrande, M. Converso, C. Bucca, S. Polizzi, and F. Caligaris- Cappio, "Increased nitric oxide in exhaled air of patients with systemic lupus erythematosus." J. Rheumatol., 1997; vol. 24, pp. 1066-1071.
- [4] C. Soderman, A. Leone, V. Furst, and M. G. Persson, "Endogenous nitric oxide in exhaled air from patients with liver cirrhosis." Scand. J. Gastroenterol., 1997; vol. 32, pp. 591-597.
- [5] D. Cordeiro, A. Rudolphus, E. Snoey, and G. J. Braunstahl, "Utility of nitric oxide for the diagnosis of asthma in an allergy clinic population." Allergy Asthma Proc., 2011; vol. 32, pp. 119-126.
- [6] K. Ansarin, J. M. Chatkin, I. M. Ferreira, C. A. Gutierrez, N. Zamel, and K. R. Chapman, "Exhaled nitric oxide in chronic obstructive pulmonary disease: relationship to pulmonary function." Eur. Respir. J., 2001; vol. 17, pp. 934-938.
- [7] K. Alving and A. Malinovschi, "Basic aspects of exhaled nitric oxide." Exhaled Biomarkers, I. Hovarth and J. C. de Jongste, Eds. European Respiratory Society, 2010, pp. 1-31.
- [8] 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.
- [9] 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.
- [10] R. A. Dweik, P. B. Boggs, S. C. Erzurum, C. G. Irvin, M. W. Leigh, J. O. Lundberg, A. C. Olin, A. L. Plummer, D. R. Taylor, "An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FENO) for Clinical Applications." Am. J. Respir., 2011; vol. 184, pp. 602-615.



Spirosure, Inc.
7020 Koll Center Pkwy, Suite 110
Pleasanton, CA 94566-3107
USA
support@spirosure.com



QAdvis EAR AB
Ideon Science Park
Scheelevagen 17
SE-223 70 Lund, Sweden



Spirosure Fenom Pro is CE marked according to In Vitro Device Directive IVDD 98/79/EC. FENOM is a registered trademark of Spirosure, Inc.