Fenom Flo™
FeNO Monitoring System

INSTRUCTIONS FOR USE

Fenom Flo™

To download the full IFU in English and other languages, scan the QR code or visit website.

mgcdiagnostics.com/products/fenom-flo-resources

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MGC DIAGNOSTICS®

The MGC Diagnostics® Fenom Flo Instructions for use is Part# 142255-001 or FF-01-EN. This manual applies to the Fenom Flo FeNO Monitoring System Hardware and Interfaced Software.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician if it is to be used for diagnosis and/or prescribing of therapy.

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Device is compliant with the European Regulation IVDR 2017/746/EC

IMPORTANT INFORMATION - PLEASE READ

INDICATIONS FOR USE

The Fenom Flo FeNO monitoring system 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 Flo measures fractional exhaled nitric oxide (FeNO) according to guidelines established by the American Thoracic Society and European Respiratory Society.

Measurement of FeNO by Fenom Flo 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 Flo is suitable for adults and children ages six years and older. Fenom Flo should be used in a point-of-care healthcare setting under professional supervision. Fenom Flo should not be used in critical care, emergency care, or anesthesiology.

The single-patient-use non-sterile mouthpiece is required for patients in conjunction with the Fenom Flo device to filter respiratory gases where infection from airborne bacteria and viruses is a concern.

The Fenom Flo software is intended to provide a user interface to enable FeNO testing with the Fenom Flo Device in an environment where sampling and testing are performed in the presence or near presence of the patient and support all other use cases related to configuration, data transfer, etc.

Any serious incident that occurs in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

REGULATORY AND COMPLIANCE

Fenom Flo and Fenom Flo software are CE-marked according to the In Vitro Diagnostic Device Regulation (IVDR) 2017/746, and the mouthpiece is CE-marked according to Medical Device Regulation (MDR) 2017/745.

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

Fenom Flo is certified to the IEC 60601-1:2012 safety standard and has no essential performance.

UK RESPONSIBLE PERSON

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IFU REVISION HISTORY

Date	Version	Description of Change
07 October, 2024	A	Release
17 March, 2025	B	Update Warranty Information
28 April, 2025	C	Change according IVDR 2017/746, Annex I, Chapter 2, 20.4.1 (ae)

DEFINITIONS

WARNING: Indication that a hazardous situation may result in a minor injury.

CAUTION: Indication that a hazardous situation may result in damage to the Device.

NOTE: Used to call attention to notable information.

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.

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.

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 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

Spirometry: A 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.

RECOMMENDATIONS TO MITIGATE CYBERSECURITY THREATS

MGC Diagnostics recommends the following best practices to ensure the integrity of the computers running Fenom Flo software:

- Follow all required IT recommendations and safeguards required by the facility in which Fenom Flo software is being used.
- Computers running Fenom Flo software are secured via a domain user and password.
- Computers running anti-virus software can prevent and assist with potential malware issues.
- Computers with Fenom Flo software installed are running behind a firewall, which will help protect the computer from unauthorized online access.
- The computer operating system should be updated regularly with Microsoft Windows® updates to run the latest, safest version of the Windows operating system.

MGC Diagnostics has an open policy regarding the use of commercial off-the-shelf (COTS) antivirus and anti-malware software. Customers may install, update, and patch anti-virus and anti-malware software without pre-approval from MGC Diagnostics.

EQUIPMENT SYMBOLS

	CAUTION IS NECESSARY WHEN OPERATING THE DEVICE
	WEEE DIRECTIVE 2012/19/EU
	MANUFACTURED BY
	KEEP DRY
	DO NOT REUSE
	PRESCRIPTION ONLY
	NEAR PATIENT TESTING
	IN VITRO DIAGNOSTIC DEVICE
	POLYPROPYLENE
	USE BY YYYY-MM-DD (EXPIRY DATE)
	CATALOG PART NUMBER/DEVICE MODEL 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
	CONSULT INSTRUCTIONS FOR USE
	ATMOSPHERIC PRESSURE LIMITATION
	KEEP AWAY FROM SUNLIGHT

SAFETY INSTRUCTIONS

- DO NOT allow the patient to inhale through the device.
- DO NOT allow the patient to inhale through the mouthpiece.
- DO NOT allow the patient to exhale beyond the limits of your physical ability.
- Discontinue measurements if the breath maneuver is laborious for the patient.
- DO NOT perform measurements if the patient experiences light-headedness or shortness of breath.
- Recommend performing FeNO testing before spirometry.
- DO NOT allow the use of Fenom Flo for 15 minutes after performing spirometry testing such as FEV1, FVC, etc.
- DO NOT perform FeNO Testing within 60 minutes after exercising or smoking.
- DO NOT use the Fenom Flo device without a new single-patient-use mouthpiece.
- DO NOT perform more than six breath attempts on a single patient within one day.
- DO NOT bring Fenom Flo in a room containing magnetic resonance equipment.
- DO NOT bring Fenom Flo to a room adjacent to magnetic resonance equipment.

CAUTIONS 

- Fenom Flo should only be operated by trained healthcare professionals.
- Operate Fenom Flo as stated in this manual. MGC Diagnostics accepts no responsibility for damaged equipment or faulty results if the equipment is not handled according to this manual.
- DO NOT block device vents and ports while in use or while charging.
- DO NOT drop the Device or subject it to strong impact.
- When not in use, the Fenom Flo device should be stored within operating limits. (See Chapter 6-4: General Care and Serviceability > Storage.)
- Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or the other equipment. Try to minimize this interference by not using other equipment in conjunction with this equipment.
- This equipment is designed to comply with IEC 60601-1-2. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Turning this equipment ON and OFF can cause harmful interference to other devices. Try to correct the interference using one or more of the following:
    - Reorient or relocate the receiving Device
    - Increase the separation between the equipment
    - Contact your service representative for help
- The Device is not intended for use in an oxygen-rich environment

WARNINGS 

- DO NOT use a damaged Fenom Flo device, damaged components, or damaged accessories.Only use the power cord and power supply unit provided by MGC Diagnostics.
- Keep the Device away from water. Ensure no liquid is spilled or dripped onto the Device or immersed with liquid.
- DO NOT use Fenom Flo 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 Flo in the presence of flammable vapors or liquids.
- The Use of alcohol-containing substances close to the Fenom Flo device may cause erroneous measurement results. [4]
- DO NOT reuse the single-patient-use mouthpiece on other patients. The mouthpiece is for a single patient only. The mouthpiece should be disposed of after use in accordance with local waste disposal guidelines; only the single patient use mouthpieces provided by MGC Diagnostics can be used with the device.
- DO NOT open, crush, heat above 140 °F/60 °C, or incinerate the lithium-ion battery in the Device.
- The Device is not intended for use in an oxygen-rich environment.

Contents

CHAPTER I
SYSTEM OVERVIEW

1-1: System Description

MGC Diagnostics' Fenom Flo™ FeNO monitoring system is a hand-held 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. The exhaled nitric oxide (NO) level frequently increases in some inflammatory processes, such as asthma. The Fenom Flo device can measure the fractional NO concentration in expired breath in compliance with NO measurement guidelines established by the American Thoracic Society (ATS) and European Respiratory Society (ERS).

The Fenom Flo device analyzes exhaled breath during a selectable 6 or 10-second exhalation phase. It provides direct sampling with a result report within 25 seconds of sequentially collected and analyzed exhaled air. No subsequent specific specimen collection, specimen preparation, or reagents are required.

The Fenom Flo device uses electrochemical sensor technology sensitive to nitric oxide (NO) compounds in breath. The Fenom Flo provides visual and audible feedback so the patient can adjust their breath maneuver flow rate to match what is required to evaluate whether the breath maneuver was performed correctly. Visual and audible feedback is essential during the FeNO measurement. Users can modulate their breath speed within the flow parameters required by the American Thoracic Society (ATS) and the European Respiratory Society (ERS) standards [1].

The Device is powered internally by a rechargeable lithium-ion battery or the power supply. This Device is rated for continuous use.

1-2: Clinical Limitations

The Fenom Flo device may not be used by children under the age of approximately six years, as measurement requires patient cooperation. Fenom Flo may be difficult for patients who cannot understand and execute the instructions given by healthcare providers, as measurement requires patient cooperation.

The Fenom Flo device should not be used in critical care, emergency care, or anesthesiology.

Smoking reduces exhaled NO levels; [2] any active or passive smoking history should be documented. Fenom Flo results obtained from subjects who smoke should only be considered after considering the subject's smoking history and the potential impact on NO levels.

[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] 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.

1-3: Contraindications

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

Therefore, using FeNO measurement results to adjust a treatment regimen without considering other clinical factors could pose a risk.

1-4: Parts and Accessories

WARNING:

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

Contact your service representative to order mouthpieces, parts, or accessories.

1. Standalone FeNO device with battery and charging capability 2. Single-patient-use filter 3. Accessory that communicates with the device via Bluetooth or USB 4. LED indicator	5. Power button 6. USB Type-C port 7. Power supply 8. Mouthpiece connector 9. NO Sensor

Device:	**Mouthpiece Filter with Test License - PN 8463**
○ Fenom Flo Model No. **8000**	○ Antibacterial spirometry filter | MADA srl., | Model No. 30888 (diameter 34 mm) 83MG – box of 100 pc ○ Test License for Fenom Flo - qty 100 *Mada filter is for use in countries outside the USA (depending on product registration)*

1-5: Power Light, Colors and Indicators

DEVICE INDICATOR LED KEY			
	Off		Purple (Solid): Initializing hardware
	Blue (Flashing): Searching for Bluetooth host		Orange (Solid): Initializing flash storage
	Blue (Solid): Connected to Bluetooth host		Cyan (Solid): Analyzing environmental conditions
	Yellow (Solid): Battery < 20%		
	Red (Solid): Battery < 5%		
	Red (Flashing): Error Condition		

To reset the Device hold the power button down for greater than 15 seconds.

1-6: Operating System Specification

Required Operating System	Windows 10 or 11 (Pro, Enterprise, or LTSB)
.NET Desktop Runtime Package	Microsoft .NET 6.0
Processor	Intel Dual Core or Greater
Memory	16 GB Recommended 4 GB Minimum
Display	1920 x 1080 Resolution Recommended 1024 x 768 Resolution Minimum
System Type	x64 (64-Bit) Recommended
Bluetooth	Bluetooth version 4.0 or greater

Operating System Update Policy:

MGC Diagnostics recommends applying Operating System updates and patches regularly. MGC Diagnostics does not provide a release schedule or list of approved updates and recommends installing updates as they are made available from the computer hardware and operating system manufacturer.

1-7: Updating and Maintaining Fenom Flo Firmware and Software

MGC Diagnostics recommends applying Fenom Flo Firmware and Software updates as they become available. MGC Diagnostics/Local support personnel will notify customers when updates become available. The updates will be located online at mgcdiagnostics.com, along with the appropriate software/firmware release notice. Installation instructions will be available within the provided release notice.

CHAPTER II

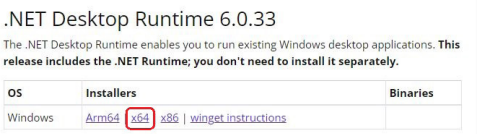
DEVICE SET UP & MEASUREMENT PREPARATION

NOTE:

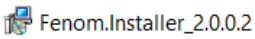
See Part #: FF-02-EN to view the Fenom Flo Quick Start Guide.

2-1: Installing the Fenom Flo software

1. Microsoft .NET runtime package 6.0 must be loaded to run the Fenom Flo application. .NET Desktop Runtime 6.0 can be loaded from the website below and selecting x64: **https://dotnet.microsoft.com/en-us/download/dotnet/6.0 and selecting x64**



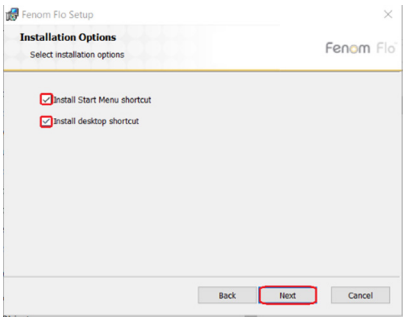
2. Browse to the Fenom Flo Installation media and double-click the file to run the installation.



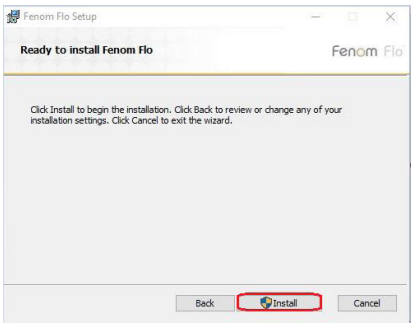
3. Select ‘Next’ on the Setup Wizard to start installation.

4. Accept the License Agreement and select ‘Next.’

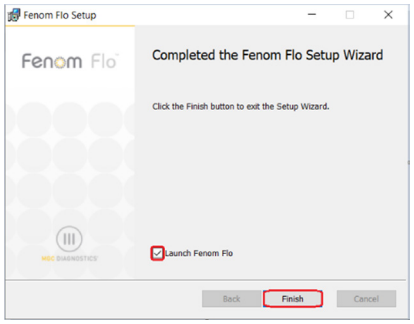
5. Place a checkmark next to the appropriate box if you want the application to be available from the Start Menu and/or a shortcut placed on the desktop, and then select Next.



6. Select ‘Install’ to begin the installation of the Fenom Flo software.



7. After installation, place a checkmark in the Launch Fenom Flo checkbox if you want to run the application immediately upon finishing the setup. Then, select ‘Finish’ to complete the installation process.

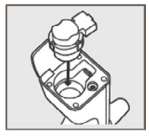


8. The Fenom Flo application installation is complete.

2-2: Installing the NO Sensor

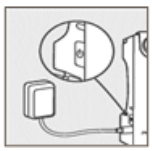
NOTE:

Ensure the device is powered off when replacing the NO sensor.



1. Remove the Device, power cable, and accessories from the shipping package
2. Open the NO sensor door on the bottom of the Fenom Flo by loosening the screw with the supplied screwdriver.
3. Remove the NO sensor from its packaging by opening it carefully, ensuring not to touch the area inside the green O-ring of the NO sensor.
4. Place the NO sensor at the bottom of the Device. Press down until you feel resistance, and no further movement.
5. Close the door and tighten the screw.

6. Connect the USB cable to the USB-C port on the Fenom Flo. Plug the other end of the cable into the USB power supply. Using the appropriate universal adapter, plug the device into a power outlet to charge.



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.

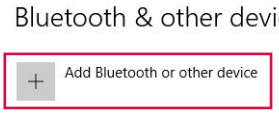
2-3: Pairing the Device to the Windows Operating System

1. If the Fenom Flo device is powered off, press and release the power button to turn it on.

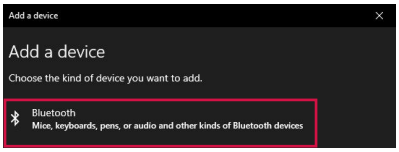
NOTE: The devices power button will be flashing blue indicating the device is in pairing mode is in the pairing mode.

2. Find and click on the Bluetooth Devices icon in the lower right-hand corner of the operating system and select ‘Add a Bluetooth Device’.

3. Under Bluetooth & Other devices, Select ‘Add Bluetooth or other device’.

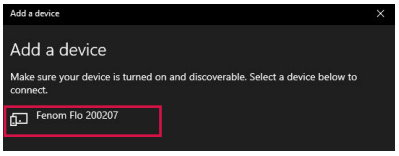


4. Select ‘Bluetooth’.

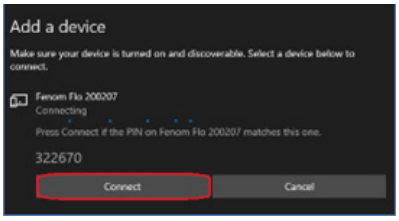


NOTE: If using a windows 11 computer the **Bluetooth Devices Discovery** option must be set to ‘Advanced’ in order for the Fenom Flo device to be visible in this list.

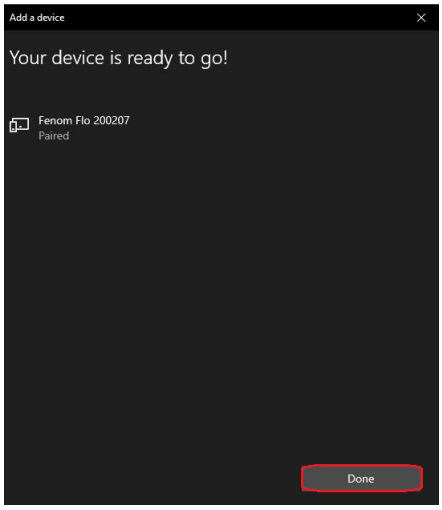
5. Find and select the Fenom Flo device from the list of available devices. The device LED will turn solid blue.



6. The PIN will automatically be generated. Click ‘Connect’.



7. A successful connection message will display. Click Done to close out of the Bluetooth display screen.



8. Double-click the Fenom Flo icon to start the application. 

9. The device will automatically connect to the software; you can verify the device is connected by noting the green Bluetooth icon at the top right-hand corner of the screen.

2-4: Pre-Test Check

1. If the Fenom Flo device is powered off, press and release the power button to turn it on.
2. Open the Fenom Flo application on the operating system and wait for the Fenom Flo device to start. It should automatically connect with the operating system.
3. Check the Bluetooth Status icon in the right-hand corner of the application to be sure Bluetooth is connected and communication is present with the Device.
4. If the Device does not automatically pair to Bluetooth, confirm the Device is connected on the Bluetooth settings of the computer/tablet running the Fenom Flo software application (Section 2-3). It may also help to power-cycle the Device if the blue LED is not blinking when connected to the Fenom Flo. The blue LED will be solid if Fenom Flo is connected.
5. Check the battery indicator icon in the upper right-hand corner of the application to ensure the unit has sufficient power to perform a FeNO measurement. If the battery indicator is red, plug the Device into the power supply and outlet before use.
6. Ensure there are appropriate test credits available to perform the test before beginning; this is indicated by a green test credit icon in the upper right-hand corner (See Chapter IV - Test Credit Management for reviewing and loading test credits)
7. Verify that the operating conditions are within range for performing patient testing. If they are not within range, this will be indicated by red icons in the upper right-hand corner of the application (ex:).
8. The quality control feature will be turned off by default, which is apparent by the grayed-out Quality Control icon . To enable Quality control, see **Chapter 5-1: Enabling Quality Control (QC).**

2-5: Patient Eligibility Recommendations

1. Approximately six years of age and up.
2. Avoid food or fluids other than water in the preceding 60 minutes.
3. Avoid exercise 1 hour before the test
4. Avoid smoking 12 hours before the test.
5. Avoid Spirometry testing in the 15 minutes before the test.
6. Avoid alcohol consumption for 24 hours before the test.
7. Avoid foods high in nitrates (Arugula, spinach, lettuce, radish, beetroot, chinese cabbage, turnips, cabbage, green beans, leek, spring onion, cucumber, carrots, potatoes, garlic, sweet pepper, green pepper.)

CHAPTER III

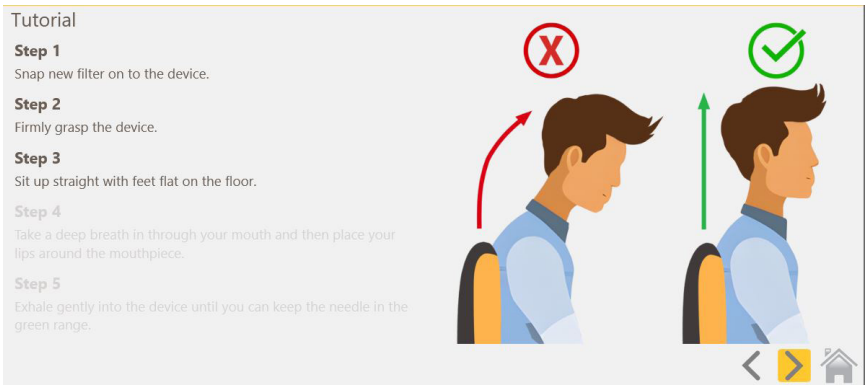
PERFORM FeNO MEASUREMENT

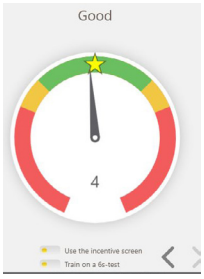
The FeNO measurement is performed by the patient blowing into a single-patient-use mouthpiece attached to the Device. The patient must blow into the mouthpiece at a controlled rate, monitored through an animated graphic on the touch display. Once a sufficient amount of the patient's breath is captured,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

3-1: Tutorial

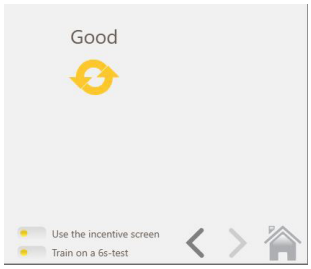
The tutorial is available for use by a new patient to demonstrate the steps for performing a FeNO test. Breath samples are not analyzed; no results are presented or recorded while in this mode.

1. On the Main Screen, touch the Tutorial button.
2. Grasp the Fenom Flo device. Do not touch the mouthpiece adapter opening.
3. Install a new single patient use mouthpiece by pressing firmly on the mouthpiece until a click is heard.
4. Read the instructions and touch the next arrow to advance through each step.





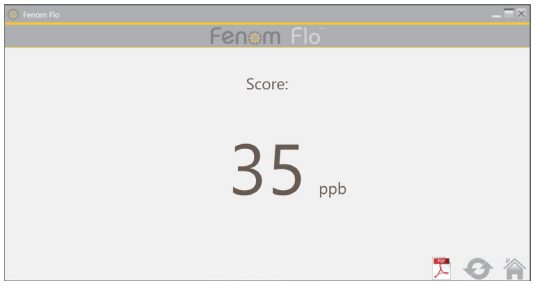
5. When the tutorial test screen is reached, you may have the patient exhale into the Fenom Flo, directing them to keep the arrow within the green section to ensure an appropriate flow rate.
6. A 10-second timer will start, and the tutorial practice will stop 10 seconds after the start of the patient practice effort.
    - To practice a 6-second maneuver, select the 'Train on a 6s test' radio button on the bottom of the page.
    - To use the incentive screen, select the radio button 'Use the incentive screen' at the bottom of the page.
    - To retry the maneuver, select the Retry button at the center of the screen
7. Touch the Home icon  when finished with the tutorial to return to the home screen.

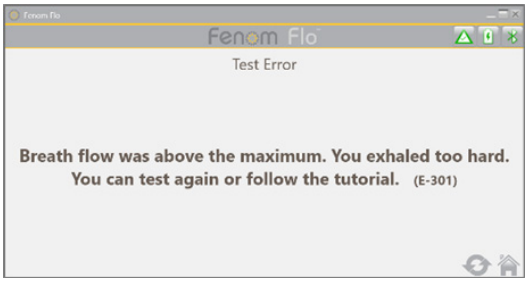


3-2: Perform a FeNO Test

1. Grasp the Fenom Flo device. Do not touch the mouthpiece adapter opening.
2. Install a new, single-patient-use mouthpiece by pressing firmly on the mouthpiece. Ensure the mouthpiece is securely connected to the device.
3. Have the patient grasp the Fenom Flo device with the new mouthpiece installed.
4. Select a 10-second or 6-second test. The visual incentive gauge is displayed.
    - The 10-second mode is recommended for adult patients, and the 6-second mode is recommended for pediatric patients but can also be used for adults who cannot perform the 10-second mode.

5. Instruct the patient to grasp the Device and sit up straight with feet flat on the floor.
6. Instruct the patient to inhale naturally through the mouth to inflate their lungs fully.
7. Instruct the patient to place mouth on the mouthpiece, ensuring a tight seal
8. Instruct the patient to exhale gently, gradually increasing their exhalation until they can keep the needle in the green range  .
9. Ensure that the patient stops exhaling immediately once the STOP screen  is displayed.
10. It takes approximately 25 seconds for the results to display if the test is successful.
11. Upon completing the FeNO test, the patient's breath is analyzed, and the results are displayed in parts per billion.
12. After the results of a successful test are displayed, the system will purge for 30 seconds before allowing the user to retry.
13. If the patient fails the maneuver, an error message will be displayed explaining why; review the reason for the failure. The patient can practice using the tutorial referenced in section 3-1 if necessary.





14. If testing is complete, remove the mouthpiece by slightly twisting it as you remove it.
15. Record the FeNO measurement.
16. After the Purge is complete, if the Retry icon is not grayed out, a repeat test is authorized without reduction in a test credit. (See Chapter 4-3: Test Credit Usage for what determines when a test credit is subtracted).
17. Select to return to the Home Screen.

NOTE:

If the result is less than 5 ppb, "< 5" will be displayed. If the result is greater than 300 ppb, ">300 ppb" will be displayed.

18. Properly dispose of the mouthpiece.
19. The device will automatically go into sleep mode after 90 seconds when not connected via Bluetooth to the application. Hold the POWER button down for at least 5 seconds to power the device off manually. The power light will turn off.

NOTE:

It is recommended to charge the device Daily, or more frequently if needed. When not being used, the device will automatically go into sleep mode after 90 seconds.

CHAPTER IV

TEST CREDIT MANAGEMENT

At least one test credit is needed to perform testing on the Fenom Flo device. Test credits are device-specific and can be purchased by contacting your local representative. No internet connection is required to activate the license code.

4-1: Viewing Test Credits

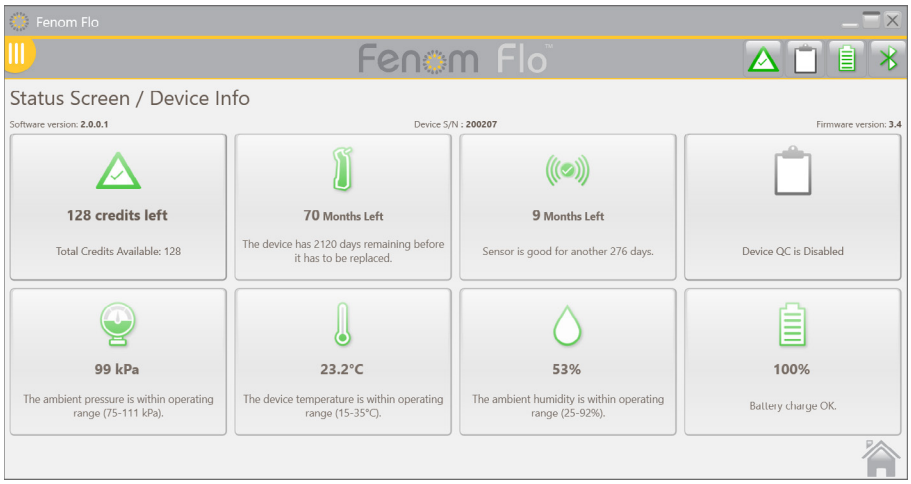
The Home Screen will notify the user of an approximate count of available test credits by changing the color of the test credit icon.

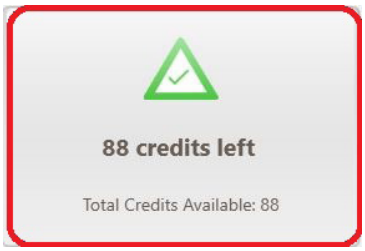
Green 50 or more test credits	Yellow 16-49 test credits	Red 0-15 test credits

The exact number of credits can be tracked by clicking the Credits icon or navigating to the Status Screen/ Device Info.

Select the Menu icon in the upper left of the Fenom Flo application.

1. Select **Status Screen/Device Info**.



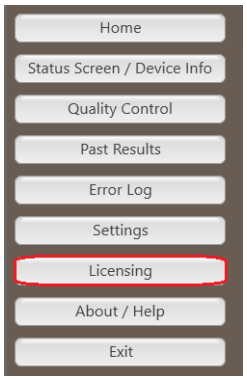


4-2: Loading Test Credits

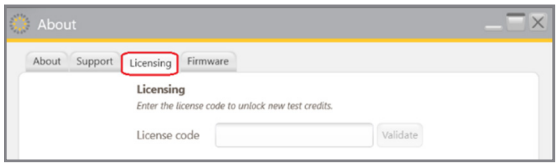
A positive number of Fenom Flo test credits must be available to perform a FeNO test using the Fenom Flo device. The user must obtain a license code and activate that code to load the credits to the device by performing the following steps:

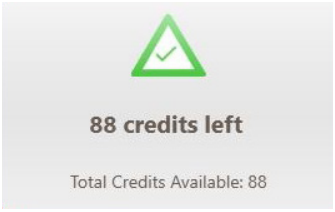
NOTE:

When entering the license key to load test credits the key must be loaded in full to include the dashes. The key is also Case sensitive.

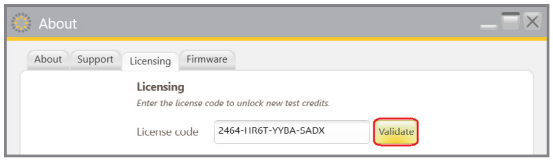


1. With the license code available, navigate to the Licensing tab by either selecting the Test Credit Box within the **Status Screen / Device Info** screen or selecting the Menu icon in the upper left of the Fenom Flo application and selecting **Licensing.**

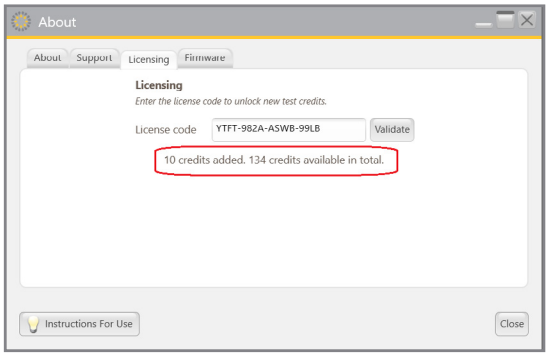




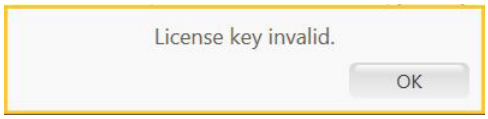
2. Enter the 16-digit license code and select Validate.



3. If the code is successful, credits will be added to the device, and the total will be updated.



4. If unsuccessful, the user will be flagged that the license is invalid, and the user should verify the license key is correct.



5. Select the close icon Close to return to the home screen.

4-3: Test Credits

The software will allow retesting without subtracting test credits in certain circumstances, enabling patient testing to comply with the ATS/ERS guidelines.

1. The Retry icon will be active after a test is performed only when a repeat test can be done without using an additional test credit; the retry button will be grayed out if a repeat test is unavailable and a new test must be started.
2. A test can be repeated in the following cases without subtracting a test credit.
   - After the first acceptable test, and within 4 minutes from the previous test
   - After the second acceptable test, within the 4 minutes from the previous test, if the two first tests are not reproducible within 10%. No more than three tests can be allowed when the repeat function is used.
3. A test credit will be subtracted every time a new test is started.

NOTE:

Quality Control Tests will not count against the total test credits, however a limit of four daily Quality Control tests can be run per device.

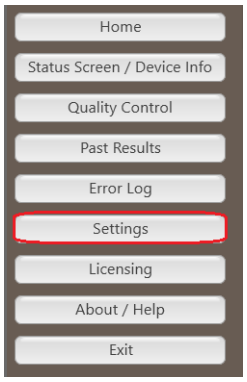
CHAPTER V

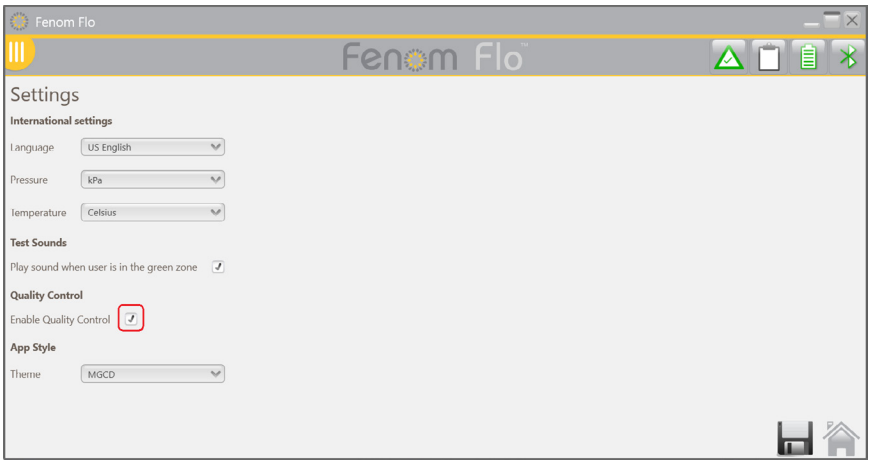
QUALITY CONTROL

Qualified operators perform the quality control (QC) measurement on a Fenom Flo device. QC Mode is designed to ensure the instrument is operating within its specifications. QC consists of two test types: a Negative Control and a Positive Control. The Negative Control test analyzes ambient air scrubbed of Nitric Oxide. A Qualified User performs the Positive Control test and checks whether that User's result is within ten parts per billion or ppb from their median qualifying test result. When the QC Mode is enabled, the system will flag the User that a valid Positive Control and Negative Control test should be performed each day before use.

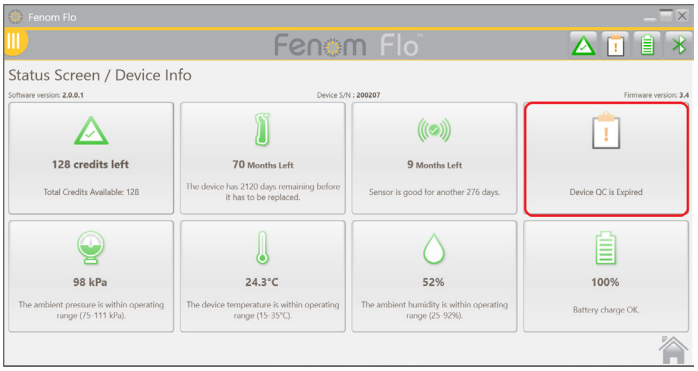
5-1: Enabling Quality Control (QC)

1. Select the Menu icon  in the upper left of the Fenom Flo application.
2. Select **Settings**.





3. Place a Check mark next to Enable Quality Control.
4. Quality Control will now be active, as apparent by the quality control icon no longer being grayed out in the top toolbar or the Status Screen/Device info.



5-2: Qualified Quality Control (QC) User

To be a Qualified QC User, a healthcare professional must first satisfy the following criteria:

- Over 18 years of age,
- Non-smoker,
- No known airway disease or chronic cold,
- No allergies or asthma

That User will create a username for themselves and perform three QC tests (See section 4-4: Performing a QC test), each separated by at least 16 hours. The first three tests determine whether the QC User qualifies. QC User qualifying test results must be between 5 and 40 ppb, and the difference between the lowest and highest result must be less than or equal to 10 ppb. If these conditions are met, the QC User is qualified. All future results for the QC User are compared to the median result from the three qualifying tests, referred to as the QC User target value. If the qualifying tests do not meet the qualification criteria, the QC User is disqualified, and a new QC User must be created.

5-3: Quality Control (QC) User Status

NOTE:

If a QC User result fails, an alternative QC User should perform the QC tests to determine if the first QC User may have a changing condition or the system may require service. If the second QC User fails, please contact customer support.

Conditionally Qualified	Fewer than three tests have been performed by the QC User. All tests within the Qualification Period are “Pass.” The three qualification tests must all be performed within seven days.
Pass	The latest test is within the expected range for the QC User.
Fail	The latest test is outside the expected range for the QC User.
Disqualified	The qualifying tests did not meet all criteria.

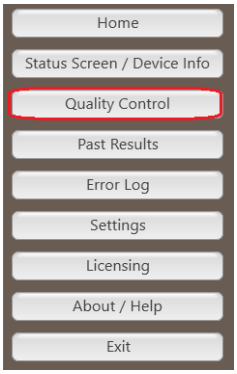
5-4: Device QC Status

A Device must be Q/C’d by a qualified user once daily for the Quality control to be considered active.

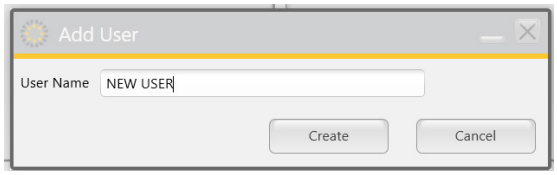
Inactive 	Device QC is disabled.
Pass 	The Negative Control test passed, the QC User test is “Conditionally Qualified” or Qualified and the validity period has not elapsed.
Fail 	Negative Control status Failed, or Qualified QC User test is Fail.
Expired 	The Validity period of the last passing QC Test has elapsed.

5-5: Performing a Quality Control (QC) Test

1. Select the menu icon  in the upper left of the Fenom Flo application.
2. Select **Quality Control**.



- If the QC user already exists, select the appropriate box corresponding to the User name performing a test.
  OR
- If the QC User is not listed, create a new QC User by selecting an open **Add User** box; enter the new QC User Name and select Create.



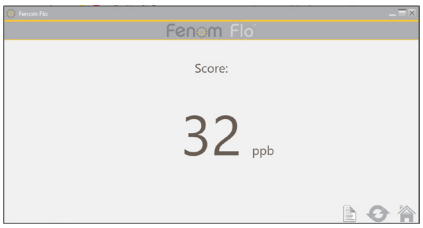
NOTE:

Quality Control Tests will not count against the total test credits, however a limit of four daily Quality Control tests can be run per device.

3. The system will automatically begin the Negative Control test, and it will conclude in approximately 36 seconds.
4. If the Negative Control Test Passes with a PPB of < 2.0, Select the arrow icon  to start the physical QC test.
   - If the negative control fails, retry the test and contact customer service if it still fails.
5. Inhale naturally through the mouth to inflate the lungs fully, then place the mouth on the mouthpiece, ensuring a tight seal.
6. Exhale gently, gradually increasing exhalation into the Device, keeping the needle in the green range until the timer is complete.
7. Ensure the User stops exhaling immediately once the 

indicator is displayed.

8. It takes approximately 25 seconds for the results to display.

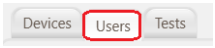


9. Select  to return to the Quality Control area to see the Status of both the Device and the User.
10. After the Plugin is complete, select  to Retry the Quality Control
11. Each QC user result will be judged as Pass or Fail based on User and Device status requirements. Each result is shown in the QC test settings log.

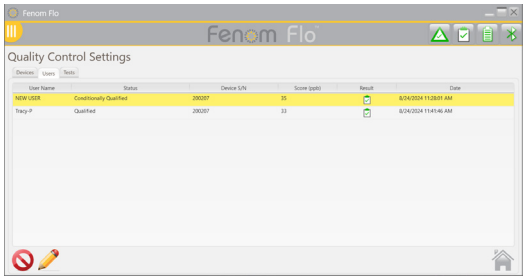
5-6: Quality Control (QC) Settings

DELETING A QUALITY CONTROL USER

There is only enough space for 7 Quality Control Users per application; to delete a failed or disqualified User to make room for Qualified users, perform the following:

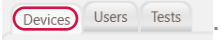
1. Within the Quality Control Screen, select the **Settings** icon  .
2. Select the Users Tab in the upper left-hand corner 

.
3. Highlight the User to Delete.

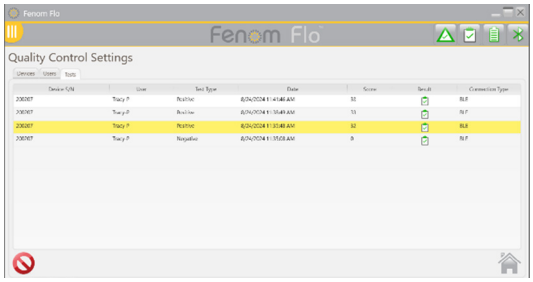


4. Select  to Delete the selected User.
5. Select  to Edit the selected User's Name.
6. Select  to return to the Quality Control Screen.

DELETING A QUALITY CONTROL DEVICE OR TEST

1. To delete Devices or Tests, select the appropriate Tab 

.
2. Highlight the Device or Test.



3. Select  to Delete the selected User.
4. Select  to return to the Quality Control Screen.

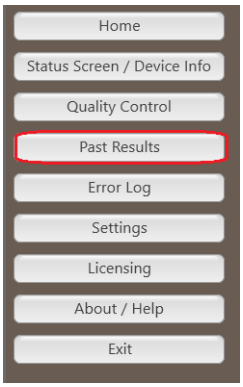
CHAPTER VI

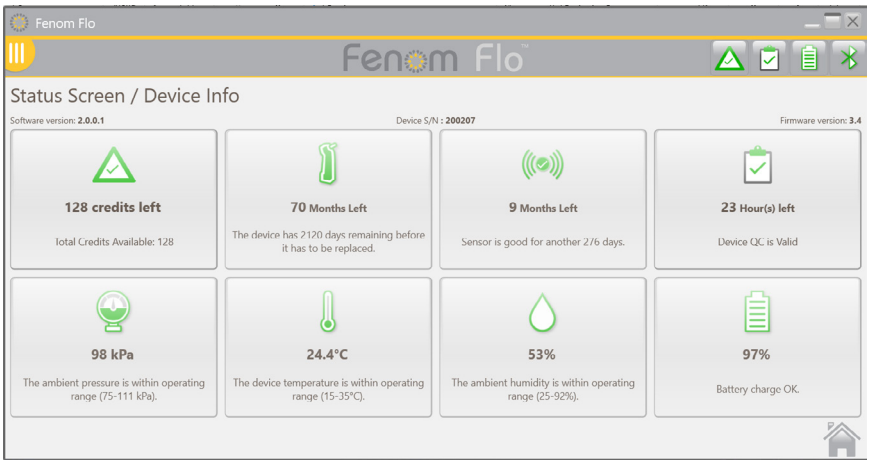
DEVICE MENU INFORMATION

6-1: Status Screen / Device Information

A device must be connected to the software program to access its information.

1. Select the menu icon in the upper left of the Fenom Flo application.
2. Select **Status Screen/Device Info.**





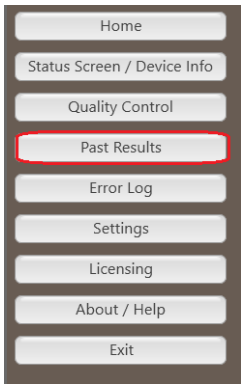
3. The device's Software Version, Device Serial Number (S/N), and Firmware version are displayed on the Status Screen / Device Info screen. The available test credits, Quality Control Status, device and NO sensor status, battery, and the device's environmental conditions of Pressure, Temperature, and Ambient Humidity are also presented on this screen.
4. Select the home icon to return to the home screen.

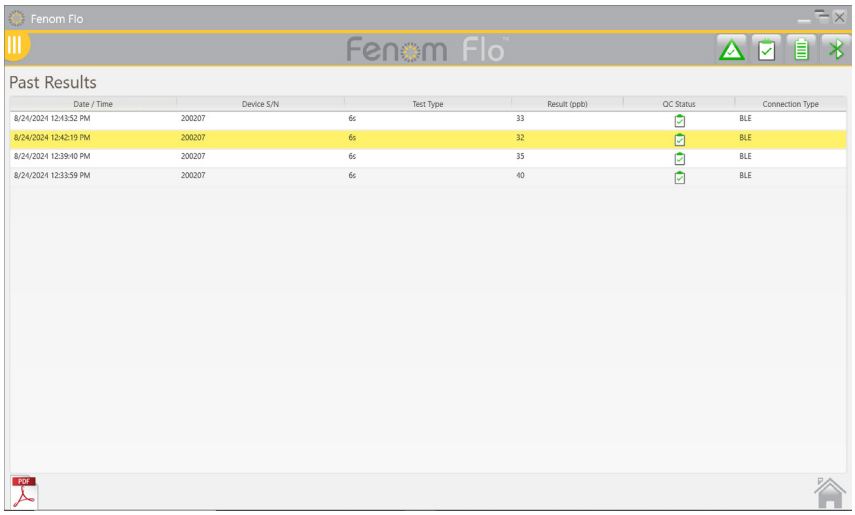
6-2: Quality Control

See Chapter V: Quality Control for information on Quality Control settings and procedures.

6-3: Viewing Past Results

1. Select the menu icon in the upper left of the Fenom Flo application.
2. Select **Past Results.**

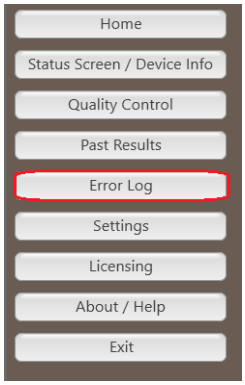


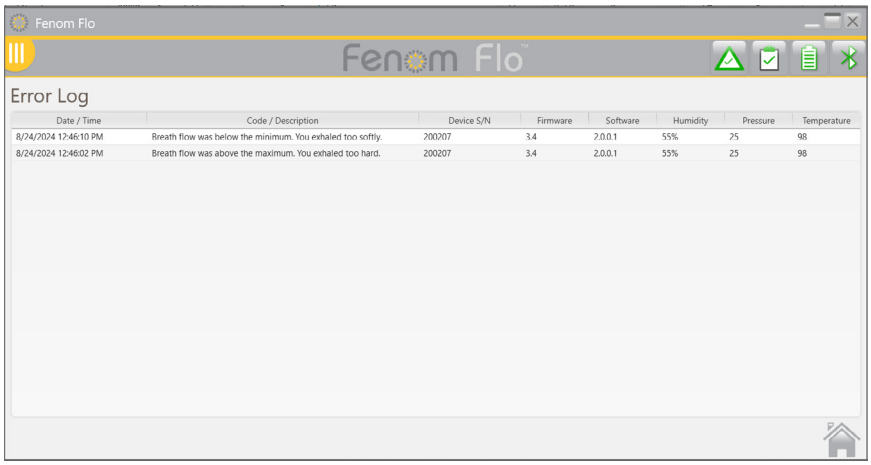


3. Past results will be displayed along with the Date and Time, Device Serial Number, Type of Test (10 or 6 seconds), Test Result, Q/C Status, and Connection Type.
4. Select the home icon to return to the home screen.

6-4: Viewing Error Log

1. Select the menu icon in the upper left of the Fenom Flo application.
2. Select **Error Log.**

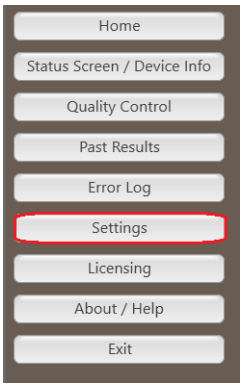


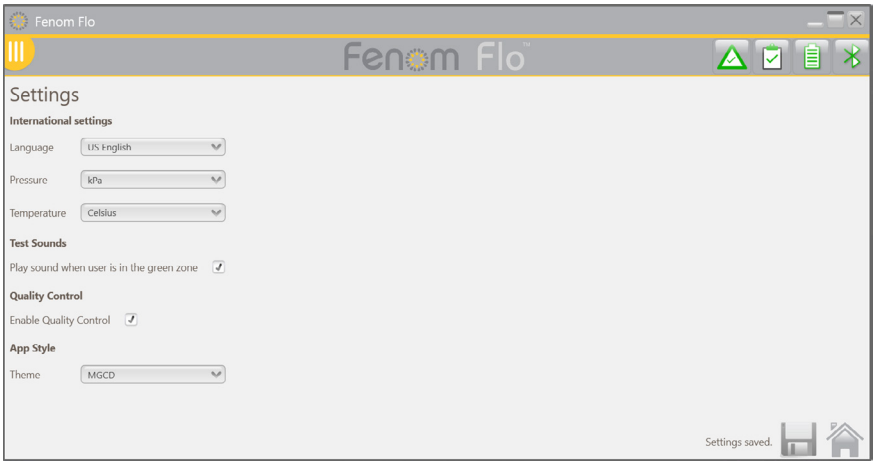


3. All past errors will be visible, along with the Date / Time of the error, the Error Code/Description, the Device S/N, the Device Software and Firmware Version, Humidity, Pressure, and Temperature Value at the time of the error.
4. Select the home icon to return to the home screen.

6-5: Adjusting the Settings

1. Select the menu icon in the upper left of the Fenom Flo application.
2. Select **Settings.**





- The Settings options will appear, and drop-down menus will be available to update the Language *(French, German, Italian, Spanish or English)*, Pressure Units *(mmHg, kPa, hPa)* and Temperature Units *(Celsius or Fahrenheit).*
- Unselecting the Play sound when a user is in the green zone will deactivate the sound when the user flow rate is in the green zone while performing a test or during Quality control.
- Quality Control Can be turned on or off by selecting or deselecting the check box.
- Theme can be adjusted from MGCD (Gold and Gray) to Blue (Blue and gray).

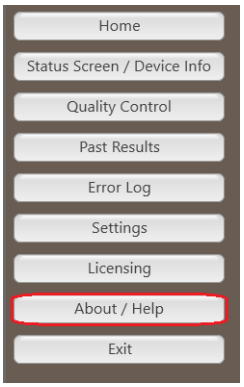
3. Select the Save icon to Save the updated settings.
4. Select the home icon to return to the home screen.

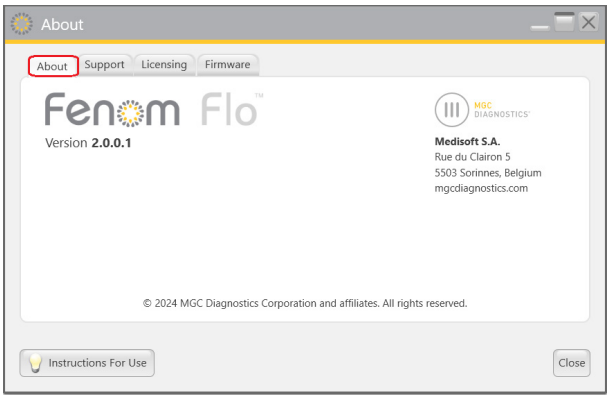
6-6: Licensing

See Chapter IV: Test Credit Management for information on licensing.

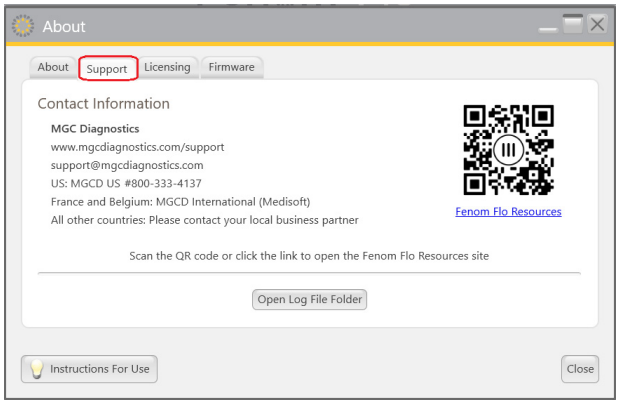
6-7: About/Help

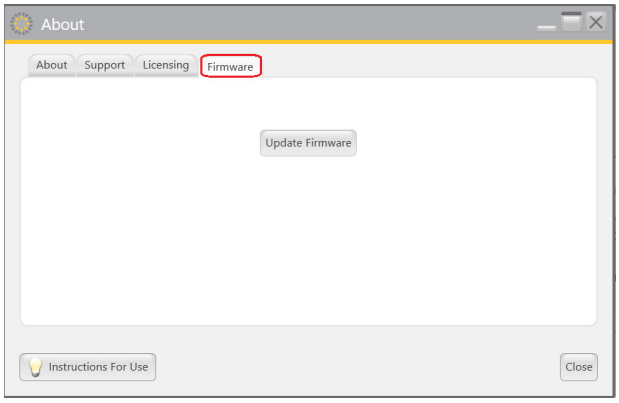
1. Select the menu icon in the upper left of the Fenom Flo application.
2. Select **About / Help**.
3. The **About Tab** displays the name and address of the legal manufacturer of the Fenom Flo.





4. The **Support Tab** will display:
    - Technical Support Contact information.
    - QR code that will navigate to additional Fenom Flo resources in multiple languages.
    - A link to the instructions for use in English.
    - A button that opens the Log File Folder used for technical support.
5. See Chapter IV, Test Credit Management, for the use of the **License Tab** and loading test credits.
6. The **Firmware Tab** will allow the user to Update Firmware over the air by performing the following steps.
    - Ensure the firmware file is saved on the operating system.
    - Select the Update Firmware button.
    - Navigate to and select the Firmware file.
7. Selecting the Instructions For Use button from all four tabs in the lower right-hand corner will open up the IFU in the language selected in the settings menu.
8. Select the Close icon Close to return to the home screen.





6-8: Software Button and Indication Icons

Fenom Flo Button and Indicator Icons		
Icons	Name	Description
	Bluetooth	Green icon indicates Bluetooth is connected. Red icon indicates Bluetooth is disconnected.
	Battery Level	Green icon indicates battery is at or above 20% charged. Yellow icon indicates battery is between 5% and 20% charged. Red icon indicates battery is at or below 5% charged.
	Battery Charging	Green icon indicates battery is charging.
	Quality Control Status	**Gray** icon indicates the device is inactive. Green icon indicates negative control test passed. Red icon indicates negative control test failed or Qualified QC User test is Fail. Yellow icon indicates the validity period of the last passing QC test has elapsed
	Device Expiration	Green icon indicates device expiration is more than 60 days. Yellow icon indicates the device expires in less than 60 days. Red icon indicates the device has expired.
	NO Sensor Expiration	Green icon indicates NO sensor expiration is more than 60 days. Yellow icon indicates NO sensor expires in less than 60 days. Red icon indicates the NO sensor has expired.
	Pressure	Green icon indicates pressure is within operating range. Yellow icon indicates pressure is nearing operating limits. Red icon indicates pressure is outside of operating limits (76-110 kPA | 570-825 mmHg).
	Temperature	Green icon indicates temperature is within operating range. Yellow icon indicates temperature is nearing operating limits. Red icon indicates temperature is outside of operating limits (15-35°C | 59-95°F).
	Humidity	Green icon indicates humidity is within operating range. Yellow icon indicates humidity is nearing operating limits. Red icon indicates humidity is outside of operating limits (20% RH - 90% RH).
	Test Credits	Green icon indicates 50 or more test credits. Yellow icon indicates 16-49 test credits. Red icon indicates 0-15 test credits.

CHAPTER VII

GENERAL CARE AND SERVICEABILITY

Follow the recommendations below for cleaning, general care, and serviceability of the Fenom Flo and its accessories.

NOTE:

Never attempt to open or service the Fenom Flo device or components unless replacing the sensor.

7-1: 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 35°C (59 to 95°F).
- Atmospheric pressure range of 76 to 110 kPa (570 to 825mmHg).
- Relative humidity range of 20 to 90%, non-condensing (a range of 40 to 60% is recommended).

7-2: Cleaning and Disinfecting

- DO NOT use spray detergents.
- DO NOT use wipes that contain alcohol.
- The Device is not intended to be sterilized.
- Clean the external surfaces of the Device with a cloth dampened with mild soap. Cleaning should remove soil, dust, and other particles.
- Repeat the cleaning procedure if the Device is not visibly clean. There should be no visible soil after cleaning.
- Disinfect the external surfaces of the Device with a cloth pre-moistened with 5% bleach solution and reapply if necessary to ensure the Device's surfaces remain wet for the full 3-minute contact time and do not use until fully dry.
- The Device should be cleaned and disinfected after each use.
- The following wipes are known to be compatible with Fenom Flo:
  - Dispatch Hospital Cleaner with Bleach
  - Clorox Healthcare Bleach
  - Cleanisept Wipes
  - Sani-Cloth AF3
  - Sani-Cloth Active
  - Clinell Universal Sanitizing Wipes

7-3: Handling

- Take care while handling the Device.
- DO NOT drop the Device.
- Carry the Device by firmly grasping the middle of the Device.

7-4: Storage

NOTE:

Keep the original packaging should you ever need to return the device for service.

- Clean the Device before storing it.
- When not in use for an extended duration, store the Device in its original packaging and all accessories within operating conditions. Extended exposure outside the limits of operating conditions can damage the Device or NO sensor.
- Store the Device in a location free from dust, free from excessive moisture or water splash, and away from extreme heat, cold, pressure, or dry conditions.
- DO NOT store the Device on tall or unstable surfaces.
- Store mouthpieces in original packaging.
- Environmental Ranges for Storage:

NOTE:

Long-term exposure to pressures outside the ranges below may shorten the Device's lifespan.

  - Relative humidity operating range of 20% to 90%, non-condensing
    - A range of 40% to 60% relative humidity is recommended

NOTE:

Long-term exposure to a low relative humidity (RH) environment (<25% RH) increases the risk of inaccurate scores and permanent NO Sensor damage.

  - Temperature range of -20° to 50°C (-4° to 122°F)
  - Atmospheric pressure range of 50 to 106 kPa
- Preventive Inspections
  - Ensure the Device is not damaged and is in good condition.
  - Ensure the power cord and power supply are not damaged and in good condition.
  - Ensure the Firmware and App are up to date before use.

7-5: Rechargeable Battery

- Only use the power cord and supply provided by MGC Diagnostics to charge the Fenom Flo device.
- Capacity: >20 tests per 8 hours on a fully charged battery.
- Charging time: <8 hours

7-6: Maintenance

- The NO sensor has a service life of 16 months in total from the manufacturing date of the NO sensor. The NO sensor has a usable life of 12 months from its connection to the device
- Periodic NO sensor replacement is required. Check the Status Screen / Device Info screen for the expiration date.
- Contact your service representative for a replacement NO sensor.
- Expired NO sensors should be disposed of or recycled according to the local program for electronic equipment.
- The Device will not perform NO measurements after the NO sensor expiration date has passed.

WARNING: Modification of this equipment is prohibited. No modification of the Fenom Flo device, handpiece, or mouthpiece is allowed.

7-7: Disposal of Used/Expired Equipment, Software and Consumables

- The expected service life of Fenom Flo is 60 months.
- Expired Fenom Flo should be collected by the distributor at the end of life.
- Expired or used mouthpiece filters should be disposed of according to facility guidelines according to nonhazardous waste.
- Expired or used NO sensor should be disposed or recycled according to the local program for electronic equipment.
- The software can safely be decommissioned by uninstalling the Fenom Flo application through the Windows add/remove programs. No additional action is needed as patient information is not stored on the device.

7-8: Warranty

MGC Diagnostics warrants the Fenom Flo (without the NO sensor) to be free of materials and workmanship defects for 24 months from the date of shipment from the manufacturer. The NO sensor is supported for 6 months from the installation date in the device. MGC Diagnostics 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 MGC 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 dropping, misusing, or using nonapproved accessories.

CHAPTER VIII

TROUBLESHOOTING

Except for NO Sensor replacement, the Fenom Flo device, subcomponents, and accessories are not field-serviceable

8-1: Support

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

Problems and Solutions		
Problem	Cause	Actions to Confirm and Resolve
Orange / Peach LED on Startup	∘ The device battery has discharged. ∘ The device turns on, LED dsplays purple, then orange, and does not proceed or recover.	∘ Plug in and charge the device for one hour before turning on again. ∘ Use the USB-C charging cable to connect the device to a computer.
Blue LED, but device only shows green Bluetooth Low Energy (BLE) symbol	∘ The device is not communicating sensor information (battery and environmental sensors).	∘ Close the Fenom Flo app. ∘ Shut down device ∘ Turn on device and restart Fenom Flo app.
Blue LED, blinking	∘ The device is not paired with the computer	∘ Pair the device
Blinking Red LED	∘ The device has encountered an error condition	∘ Hold the Power button for greater than 15 seconds to reset the device. ∘ If this doesn't fix the problem, contact your service representative.

8-2: Error Codes

If the Device displays an error message, use Table below to look up the error code and perform the suggested actions to resolve the issue.

Error Codes		
Error Code	Error Situation/Error Message	Actions
E-101	Sample flow is out of tolerance.	Power cycle the device. If the error persists, contact your service representative.
E-201	The device is too warm. FeNO testing is disabled until it has cooled down.	Move the device to a cooler location.
E-202	The device is too cold. FeNO testing is disabled until it has warmed up.	Move the device to a warmer location.

Error Codes		
Error Code	Error Situation/Error Message	Actions
E-203	The humidity is too high. FeNO testing is disabled until the humidity is lower.	Move the device to a drier location.
E-204	The humidity is too low. FeNO testing is disabled until the humidity is higher.	Move the device to a more humid location.
E-205	The ambient pressure is too low. FeNO testing is disabled until pressure is higher.	Move the device to a higher-pressure location.
E-206	The ambient pressure is too high. FeNO testing is disabled until the pressure is lower.	Move the device to a lower-pressure location.
E-301	Breath flow was above the maximum. You exhaled too hard.	Try again.
E-302	Breath flow was below the minimum. You exhaled too softly.	Try again.
E-303	Breath flow was too high. You exhaled a little too hard.	Try again. Focus on the star.
E-304	Breath flow was too low. You exhaled a little too hard.	Try again. Focus on the star.
E-305	Breath flow was unstable. Your flow was out of range	Try again, exhaling steadily. Provide a steady and smooth flow.
E-306	Breath flow did not stop fast enough. You exhaled too long.	Try again, stopping as soon as you see STOP. Let go immediately at STOP.
E-307	Breath flow detected after STOP. You exhaled too long.	Try again, stopping when you see STOP.
E-700	NO sensor is missing.	Install the NO sensor.
E-701	NO sensor communication failed.	Reinstall the NO sensor. Contact your service representative if the problem persists.
E-702	NO sensor is within 60 days of expiration.	Contact your service representative
E-703	NO sensor has expired.	Replace the NO sensor with a new one.
E-704	NO Sensor is not functioning correctly.	Remove and re-install the NO sensor. If the error persists, contact your service representative.
E-705	Breath flow sensor is not functioning correctly.	Power cycle the device. If the error persists, contact your service representative.
E-706	Sample flow sensor is not functioning correctly.	Power cycle the device. If the error persists, contact your service representative.
E-707	Ambient pressure sensor is not functioning correctly.	Power cycle the device. If the error persists, contact your service representative.
E-708	Humidity sensor is not functioning correctly.	Power cycle the device. If the error persists, contact your service representative.

CHAPTER IX

TECHNICAL DATA

9-1: Device Technical Information

Fenom Flo Technical Information	
Dimensions and Weight	Height: 215 mm (8.46 inches) Width: 68mm (2.68 inches) Depth: 95mm (3.74 inches) Weight: 362 g / 12.75 oz
Electrical Data	Device power consumption: <15 W Power supply mains voltage: 100-240 V - 50-60 Hz
Exhaled NO Performance	The Fenom Flo is verified to fulfill performance herein under temperature range of 15-35°C (59-95°F), relative humidity of 20-90%, and pressure range of 76-110 kPa (570-825 mmHg)
Linearity	Slope 1.00 ± 0.05 Squared correlation coefficient, $r^2 \geq 0.998$
Accuracy	NO concentrations ≤ 50 ppb: ± 5 ppb NO concentrations > 50 ppb: ± 10% of the concentration
Repeatability	2.5 ppb or 5%
Limit of Detection	5 ppb
Measurement Range	5-300 ppb
Exhalation Parameters	Exhalation time: 6 seconds or 10 seconds Exhalation pressure is between 0.56 and 1.84 kPa (5.7-18.8 cmH_2O) Exhalation flow rate is 45-55 mL/s: warning sounds played outside of this range
IP rating	20

9-2: Electromagnetic Immunity and Emissions

Fenom Flo 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.

This equipment generates, uses, and can radiate radio-frequency energy.

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

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

NOTE:

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

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Fenom Flo is intended for use in the electromagnetic environment specified below. The customer or the User of the Fenom Flo should ensure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	Fenom Flo uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Fenom Flo is suitable for all establishments, excluding domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations / flicker emissions IEC 61000-3-3		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Fenom Flo is intended for use in the electromagnetic environment specified below. The customer or the User of the Fenom Flo should ensure that it is used in such an environment			
Immunity test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV & ± 8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and± 15kV for Air Discharge	±2 kV, ±4 kV & ± 8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and± 15kV for Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity Non-life-supporting ME Equipment			
Fenom Flo is intended for use in the electromagnetic environment specified below. The customer or the User of the Fenom Flo should ensure that it is used in such an environment			
Immunity test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	AC Mains 3V 0.15MHz -80MHz 6V in ISM and amateur radio bands 0.15MHz -80MHz 80% AM at 1 kHz	AC Mains 3V 0.15MHz -80MHz 6V in ISM and amateur radio bands 0.15MHz -80MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Fenom Flo, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10V/m 80-Mhz -2.7GHz	(E1) = 10V/m 80-Mhz -2.7GHz	

NOTE:

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE:

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Fenom Flo is used exceeds the applicable RF compliance level above, the Fenom Flo should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Fenom Flo.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3.0V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Fenom Flo			
The Fenom Flo is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the User of the Fenom Flo can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fenom Flo as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of the transmitter Watts (W)	**Separation distance according to the frequency of the transmitter meters (m)**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,7 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

NOTE:

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE:

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

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