For Healthcare Professionals only

FeNObreath™

Fractional Exhaled Nitric Oxide (FeNO) Monitor

User Manual

CE 2797

Important Information/Reminders

NOTE: The FeNObreath™ should be charged for a minimum of 4 hours before first use.

NOTE: The default PIN for the FeNObreath™ is 0000. MGC Diagnostics Corporation strongly advises that this PIN is changed upon installation and set-up of the device.

WARNING: Please read the manual before use.

WARNING: Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the electrochemical sensor inside.

WARNING: Under no circumstances should the instrument be immersed or splashed with liquid.

WARNING: Breath tests must only be carried out with MGC Diagnostics Corporation accessories. Failure to do so may cause incorrect readings.

WARNING: The mouthpieces are single patient use only and can be used for a maximum of 3 tests. Further re-use could cause incorrect readings and could increase the risk of cross infection. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.

WARNING: Patients should exhale for the duration of time indicated by the monitor during a breath test. Failure to do so may cause incorrect readings.

WARNING: To ensure a breath sample is taken at the correct flow rate, the monitor must be held upright at all times during a breath test.

WARNING: Do not block the vent holes on the device at any time unless instructed to do so during servicing. Blocking the vent holes may cause erroneous readings.

WARNING: Do not allow the use of the FeNObreath™ within 60 minutes of the following:

- Exercising
- Smoking
- Eating
- Drinking including Alcohol

WARNING: Ensure the patient inhales through the mouth, not the nose, before exhaling through the mouthpiece.

WARNING: Ensure the patient does not exhale beyond the limits of their physical ability.

WARNING: Ensure the patient uses a single use mouthpiece for performing a breath test.

WARNING: The USB port is to be used for charging the FeNObreath™ device, this should be carried out via the supplied USB cable and also can be used for transferring encrypted patient data. The FeNObreath™ is not intended to be connected to any wireless adaptors or any other USB Host.

CAUTION: The use of substances containing alcohol close to the FeNObreath™ may cause erroneous measurements.

CAUTION: Ensure the monitor is used within the stated operating temperature and humidity ranges. Operating temperature is 15-30°C (59-86°F). Operating humidity is 20-80% RH (non-condensing).

CAUTION: Portable and mobile RF communications equipment can affect the FeNObreath™.

CAUTION: A great way to keep the FeNObreath™ charged when not in use is to use the docking station included. This can be connected via the pre-approved power adapter supplied, or plugged into a working USB port, to ensure the FeNObreath™ has charge for when it's needed. When connecting the pre-approved power adapter from the docking station to the electrical outlet, please make sure that it is plugged in to a location that is safe and easily accessible.

CAUTION: The NO scrubber contains potassium permanganate and should not be tampered with or exposed to skin.

CAUTION: The NO scrubber contains potassium permanganate and should be disposed of as hazardous waste in accordance with local waste disposal regulations.

NOTE: MGC Diagnostics Corporation advise the FeNObreath™ is charged monthly to ensure calibration data is not lost.

NOTE: See MGC Diagnostics Corporation's infection control and maintenance guidelines for further information on infection control.

NOTE: Please do not attempt to modify the equipment in any way or use accessories not specified by the manufacturer. Any attempt to do so, will invalidate the warranty and may compromise the safety of the device.

NOTE: MGC Diagnostics Corporation will make a Client Service Guide for servicing certain components of the FeNObreath™ available upon request.

Contents

Introduction

The User Manual provides instructions on how to operate FeNObreath™ FeNO monitor and its accessories. It contains relevant information about the monitor, its uses and its care, including step-by-step instructions with screens and illustrations.

Definitions

WARNING: indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury.

CAUTION: indicates a potentially hazardous situation, which, if not avoided, may result in damage to the device.

NOTE: used to call attention to notable information that should be followed during use.

Compliance

FeNObreath™ is CE marked according to the Medical Device Directive 93/42/EEC.

FeNObreath™ is RoHS compliant.

Please refer to the 'Safety Information' section of this manual for more information on the compliance of the FeNObreath™.

Intended Use

The FeNObreath™ is a portable, non-invasive device for the measurement of Fractional Exhaled Nitric Oxide (FeNO) in human breath. The production of nitric oxide is often found to be increased in inflammatory conditions such as asthma. Measurement of FeNO by FeNObreath™ is a 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 the therapeutic effect in patients with elevated FeNO levels.

The fractional NO concentration in expired breath (FeNO), can be measured by FeNObreath™ according to guidelines for NO measurement established by the American Thoracic Society.

FeNObreath™ is intended for children, 7-17 years, and adults 18 years and older. FeNObreath™ 12 second test mode is for age 7 and up.

FeNObreath™ 10 second test mode is for ages 7-10 only who cannot successfully complete a 12 second test.

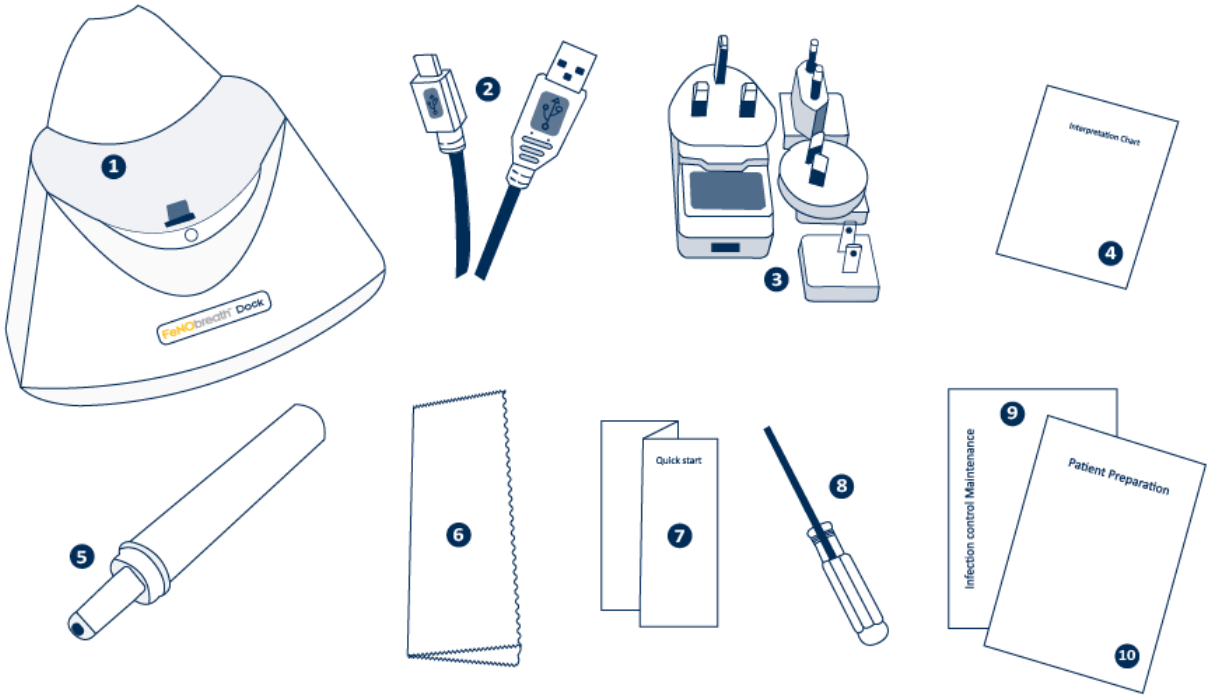
FeNO measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. The FeNObreath™ cannot be used with infants or by children under the age of 7 as measurement requires patient cooperation.

FeNObreath™ should not be used in critical care, emergency care or in anesthesiology.

Contraindications

There are no known contraindications.

Parts and Accessories



1. FeNObreath™ Dock
2. USB cable
3. Power plug and universal adaptors
4. Interpretation chart
5. FeNObreath™ mouthpiece
6. Microfiber cloth
7. Quick Start Guide
8. Screwdriver
9. Infection Control Maintenance Guidelines
10. Patient Preparation

Instrument Layout

1. ON/OFF switch
2. Touchscreen
3. Mouthpiece aperture
4. Screw
5. Manufacturer label
6. Vent hole
7. Serial label
8. Vent hole
9. USB port

Installation and Set-up

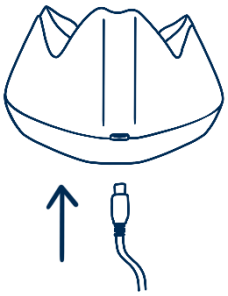
When setting up the FeNObreath™, please ensure the package contains all the parts as detailed in the 'Parts and Accessories' section of this manual. Please keep the screwdriver supplied for future servicing requirements. The FeNObreath™ should be charged for 4 hours prior to first use. Remove the plastic film from the display and follow the next steps on how to charge the FeNObreath™ below.

NOTE: *The FeNObreath™ should not be operated in an environment outside of the temperature or humidity ranges stated in the technical specification.*

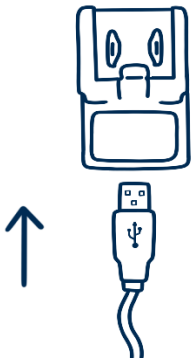
The default PIN is 0000. It is strongly recommended to change this prior to first use – please refer to the 'Change PIN' section of this manual for instructions.

How to charge the FeNObreath™

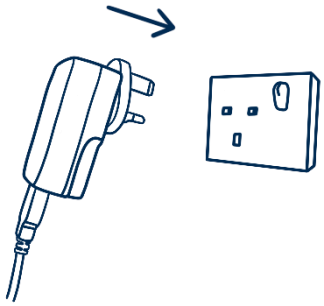
The FeNObreath™ FeNO monitor comes with a Dock and charging cable to keep the monitor at hand and fully charged.



To charge the FeNObreath™, first make sure the micro USB cable provided is connected to the docking station.

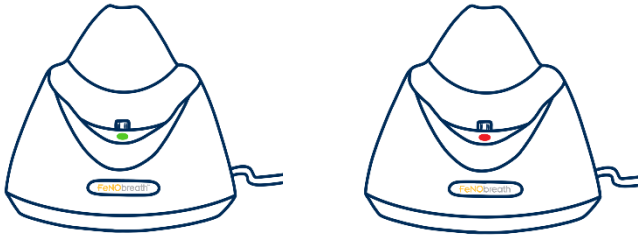


Connect the other end of the micro USB cable to the pre-approved power adapter supplied, using the appropriate universal adapter.

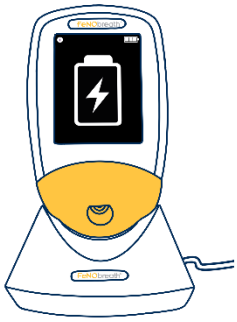


Plug the pre-approved power plug into the electrical outlet.

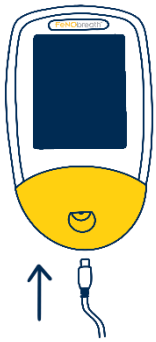
CAUTION: When connecting the pre-approved power adapter from the docking station to the electrical outlet, please make sure that it is plugged in to a location that is safe and easily accessible.



When receiving power, the LED on the Dock will light up green and the FeNObreath™ can be placed in the Dock to charge. If the LED light is red, please see 'Troubleshooting'.

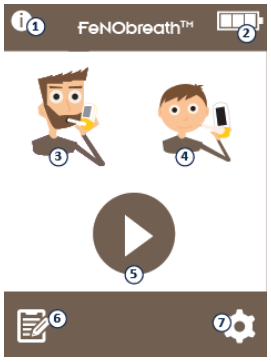


Place the FeNObreath™ monitor into the Dock. The screen will indicate that the monitor is charging.



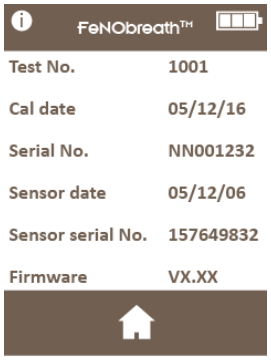
Alternatively, the FeNObreath™ FeNO monitor can be charged by plugging the micro USB cable provided directly into the FeNObreath™. This can then be connected either to the pre-approved power adapter or a computer USB port.

User Interface



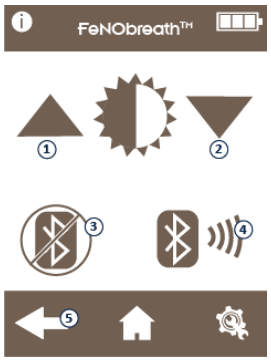
Home Screen

1. Information button
2. Battery status
3. Adult breath test
4. Child breath test
5. Demo mode
6. Patient profiles
7. Settings



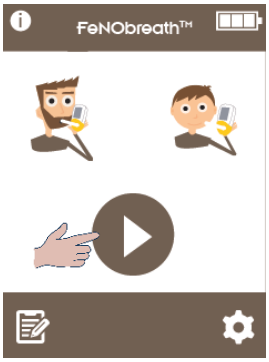
The information screen displays information about the monitor and sensor.

Settings Menu Page 1
1. Date and time options
2. Test log
3. Change PIN number
4. Enable/disable PIN use
5. Change flow-meter style
6. Start ambient air test
7. Service Area
8. Home button
9. Go to Settings Menu Page 2



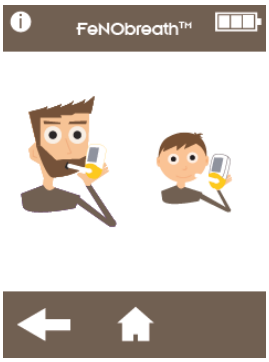
Settings Menu Page 2
1. Increase screen brightness
2. Decrease screen brightness
3. Enable/disable Bluetooth
4. Bluetooth pairing PIN
5. Go to Settings Menu Page 1

Demo mode



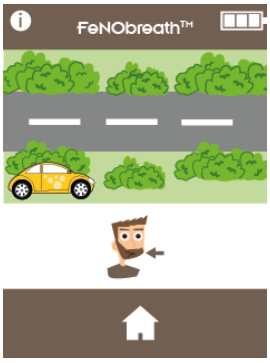
The FeNObreath™ has an in-built demonstration video of the breath test process. It is recommended to watch this video prior to using the device for the first time. This demo can also be used to explain to patients how the test will run, prior to performing one.

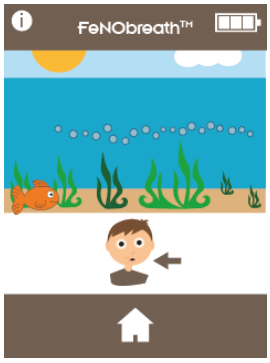
Press the demo icon to begin.



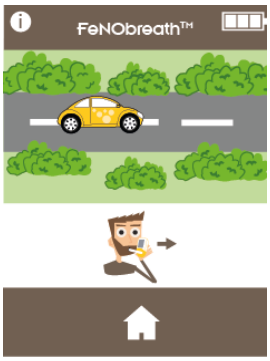
Select either the adult or child patient.

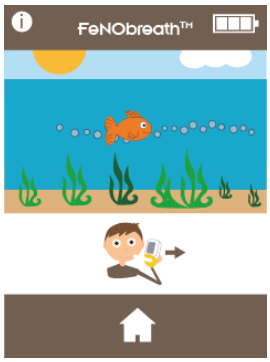
The zero screen will briefly display as in a real test.





A demonstration will run through the breath test process.





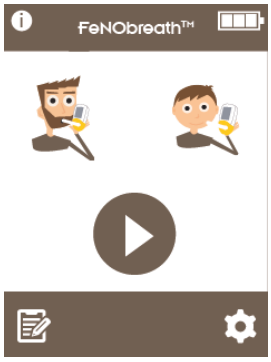
The whole test will be shown, but at an accelerated speed.

Only a successful test will be demonstrated.

Once the result is displayed, the demo is complete.

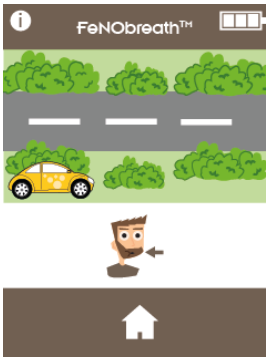
Press the home icon to return to the home screen.

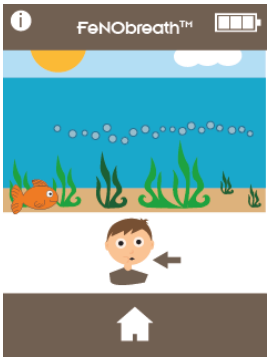
Performing a Breath Test



Open and insert a new mouthpiece into the FeNObreath™ monitor.

To start a breath test, select either the adult or child patient.

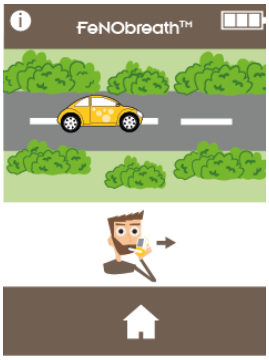


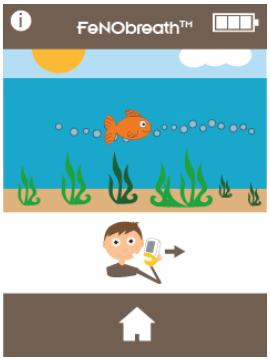


As prompted onscreen, take a deep breath.

WARNING: Ensure the patient inhales through the mouth, not the nose, before exhaling through the mouthpiece.

Press the home button at any time to cancel the breath test.



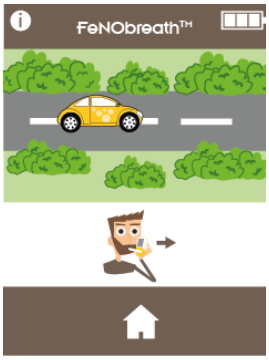


When the exhale icon displays, keep the monitor upright and blow gently into the mouthpiece.

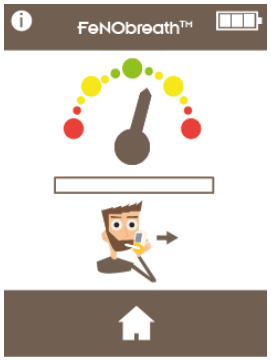
NOTE: *Make sure the vent holes are not covered.*

The exhalation time is approximately 12 seconds for an adult and 10 seconds for a child.

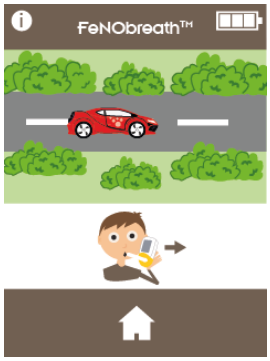
The onscreen flow meter will guide the patient on the exhalation rate:



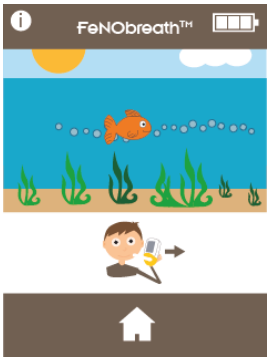
Keep the car in the middle of the road.



Keep the dial in the green area.



Keep the car in the middle of the road.

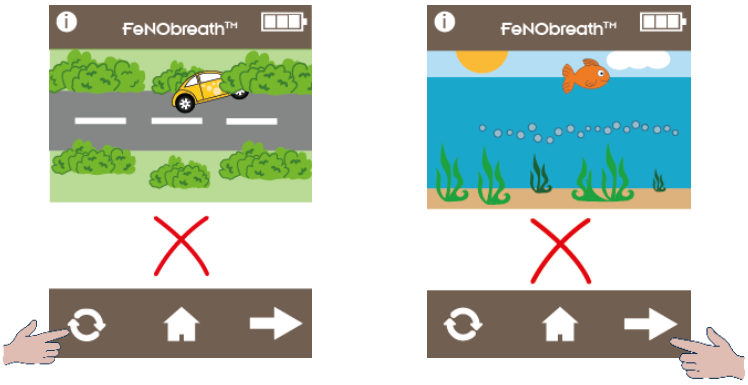


Follow the bubbles.

A green check mark onscreen indicates a successful test.

The results will then be shown onscreen in ppb.

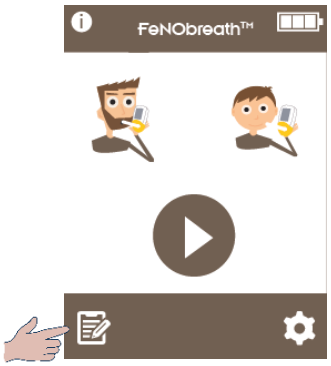
Return to the home screen by pressing the home button or save the result to a patient profile.



If the patient exhales outside of the exhalation guidelines, the test will beep before indicating a fail and a red cross will appear.

Press the retry icon to retake the test or the next arrow to view the result.

Patient profiles

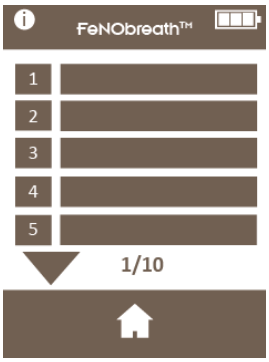


The FeNObreath™ is designed to be capable of storing up to 25 results in up to 50 patient profiles.

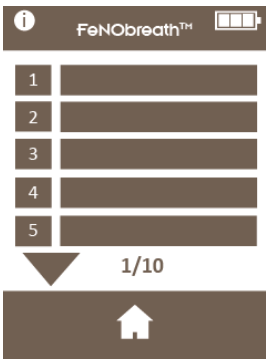
Press the profiles icon to access patient profiles.

If the PIN has not been entered in the last 30 minutes, the 4-digit code will be required before the patient profiles can be accessed.

NOTE: *If the PIN has been forgotten, please contact MGC Diagnostics Corporation or its local distributor to reset it.*

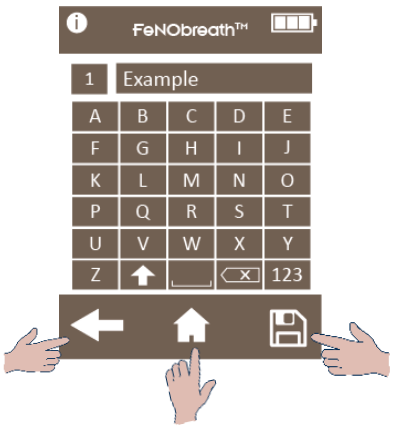


A list of patient profiles will show onscreen.



Create a new patient profile

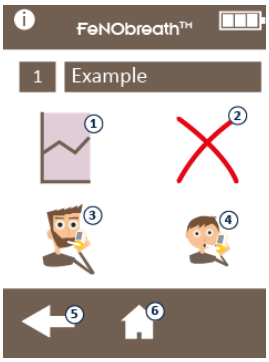
To create a new profile, choose an empty name slot.



Use the keypad to enter a patient name or ID.

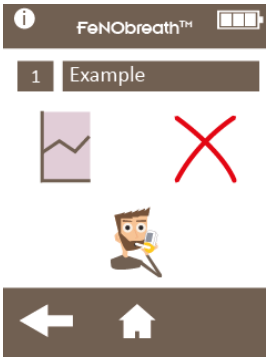
Click the save icon to create the profile.

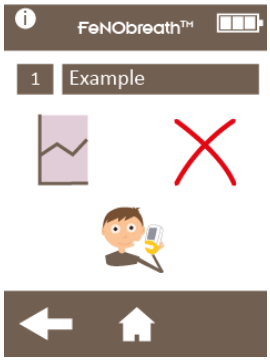
To cancel, press the back arrow to return to the list of profiles or the home icon to return to the main screen.



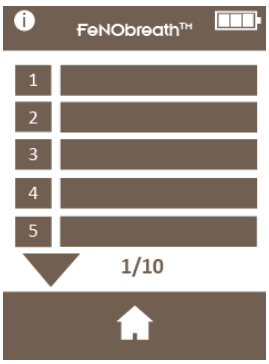
Once the profile has been created the following options will become available:

1. See a graph of results
2. Delete the patient profile
3. Take an adult breath test
4. Take a child breath test
5. Return to the profile list
6. Return to the home screen



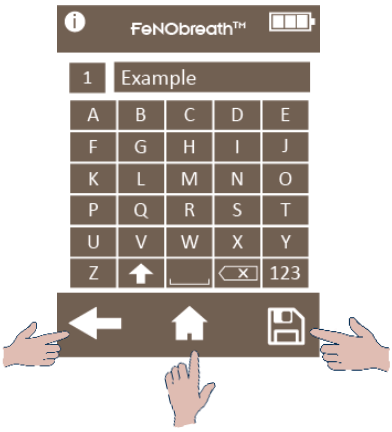


Once an adult or child breath test has been selected, the profile will only offer that breath test mode in future.



Edit a patient profile

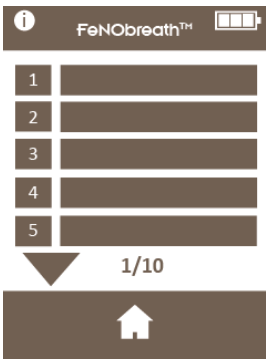
To edit a patient's profile, select their name or ID from the list.



Use the keypad to edit the profile.

Click the save icon to save the changes.

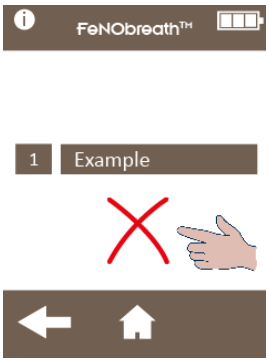
To cancel, press the back arrow to return to the list of profiles or the home icon to return to the main screen.



Delete a patient profile

Select the patient that will be deleted to load their profile.

Press the red ‘x’ to delete the patient profile.



Press the red ‘x’ to confirm.

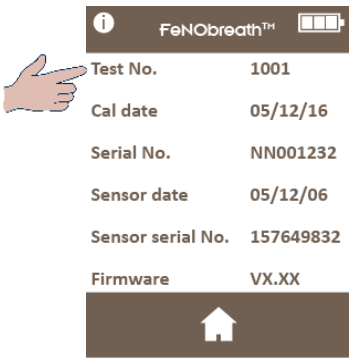
The profile will be deleted and the profile screen will be displayed.

Maintenance

FeNObreath™ - FeNO testing without limits

The FeNObreath™ has been validated for up to 29,000 tests when used as instructed and properly maintained and serviced. The number of tests can be periodically checked within the settings of the device; when 29,000 tests are reached a service is recommended. Contact MGC Diagnostics Corporation or the local service center.

The Health Care Professional can check how many breath tests have been performed on the device using the Information Screen, Test No as seen below.



Routine maintenance

1. Mouthpieces are to be replaced after every patient.
   WARNING: The mouthpieces are single patient use only and can be used for a maximum of 3 tests. Further re-use could cause incorrect readings and could increase the risk of cross infection. The mouthpiece should be disposed of after use, in accordance with local waste disposal guidance.
2. Hands should be washed regularly in accordance with infection control practice.

CAUTION: Do not use sanitising products containing alcohol as this may damage the sensors.

3. Only use accessories approved by MGC Diagnostics Corporation.
   CAUTION: Use of accessories not approved by the manufacturer will invalidate the warranty and may compromise the safety of the device.
4. It is best practice to not let the battery run flat, if the FeNObreath™ indicates the battery level is on the last bar on the display, we recommend charging the device. If the FeNObreath™ battery symbol is flashing on the display, the device would require charging immediately.
5. If the FeNObreath™ battery becomes fully discharged, the device may need calibration. Please contact MGC Diagnostics Corporation or its local distributor for advice.

Servicing

1. The FeNObreath™ will allow a 2-step quality check to be performed as frequently as your guidelines require between annual services; this is to ensure the FeNObreath™ is within specification. The 2-step quality check will be carried out using filtered ambient air and 100ppb Nitric Oxide. Alternatively the unit can be sent back to MGC Diagnostics Corporation or local service provider.
2. The NO scrubber should be replaced annually and is included in the CaliBag® kit and NO sensor exchange kit.
3. The FeNObreath™ is warranted for 5 years, providing calibrations are performed annually and the device is intended to be replaced or refurbished at the end of 5 years. This is to include replacing the NO sensor, breath drying cartridge and pump. MGC Diagnostics Corporation or a local distributor can arrange for this service.

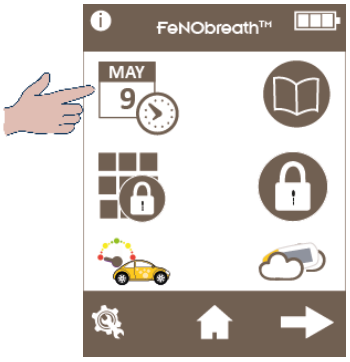
Do not attempt to open the FeNObreath™ device to gain access to hidden interior components. The back cover is provided to allow safe access to specified removable components, as directed in this manual.

Cleaning

MGC Diagnostics Corporation recommends wiping the instrument's external surfaces with a product specifically developed for this purpose. An EPA registered alcohol free disinfectant should be used, such as Sani-Cloth AF3 Germicidal Disposable Wipe. Cleaning should be performed following the instructions for use specified by the manufacturer of the EPA registered disinfectant. The device or consumables cannot be sterilized. It is recommended that wipes are used once and for one surface only. The FeNObreath™ device should be cleaned for initial use and after each patient use.
CAUTION: Do not use any substances containing alcohol on or near the FeNObreath™.

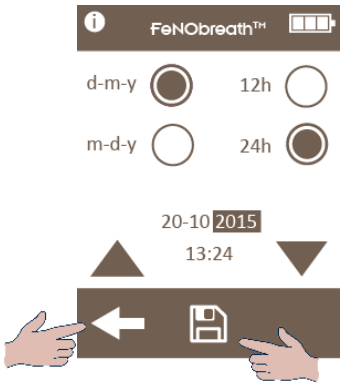
WARNING: Under no circumstances should the instrument be immersed or splashed with liquid.

Settings



Change the date/time

To change the date or time, press the edit date/time icon on the 1st page of the settings menu.



Select either d-m-y or m-d-y for the date format and 12h or 24h for the time format. The gray circle, ◉, indicates the selected option.

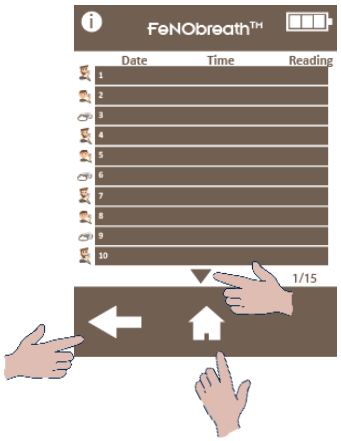
To adjust the date/time, select the number and it will become highlighted. Use the arrows to change as desired.

Press the save button to keep the changes.

To cancel, press the back arrow to return to the settings menu.

Test log

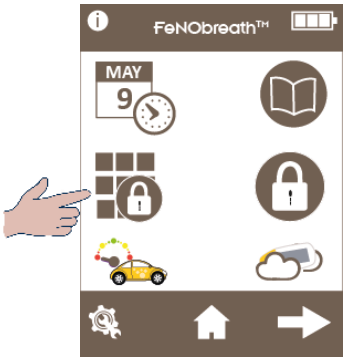
To access the test log, press the log icon on the 1st page of the settings menu.



The most recent test results are automatically saved in the log and the FeNObreath™ can store 250 at a time.

Use the arrow to scroll through the log.

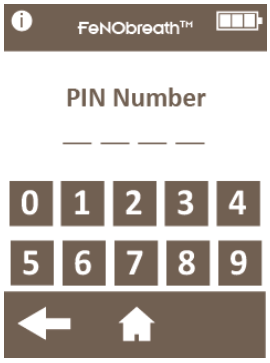
Press the back arrow to return to the settings menu or the home icon to return to the main screen.



Change PIN

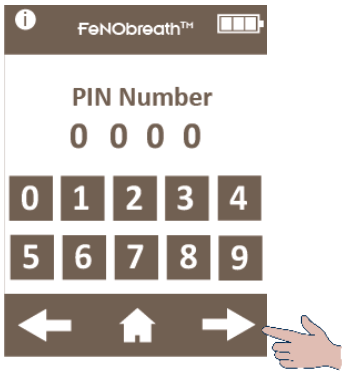
Each device is pre-set to the PIN code 0000. It is highly recommended that the PIN is changed to a memorable 4 digit number.

To change the PIN number, press the change PIN icon from the 1st page of the settings menu.



A prompt will ask for the current PIN to be entered.

If the PIN has been forgotten, please contact MGC Diagnostics Corporation or its local distributor to reset it.



Enter the current PIN and press the next arrow to proceed.

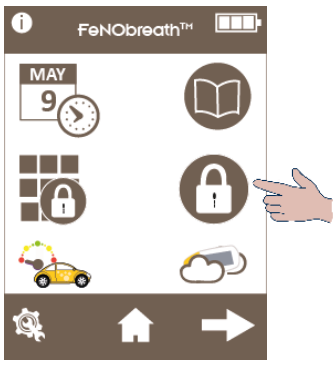
A prompt will then ask for a new PIN number to be entered.

Enter a new memorable 4 digit code and press the next arrow to continue.

A prompt will ask for the new PIN number to be re-entered for confirmation.

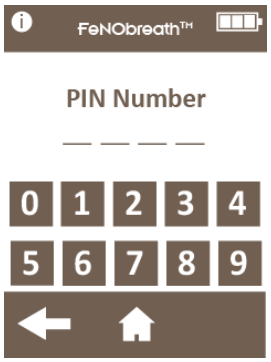
Re-enter the PIN to confirm the new 4 digit code and press the check mark to register the change.

To cancel, press the back arrow to return to the settings menu or the home icon to return to the main screen.

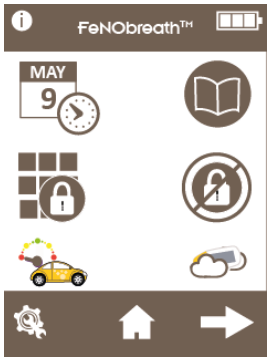


Enable/disable PIN

To disable the PIN, press the enable/disable PIN icon on the 1st page of the settings menu.

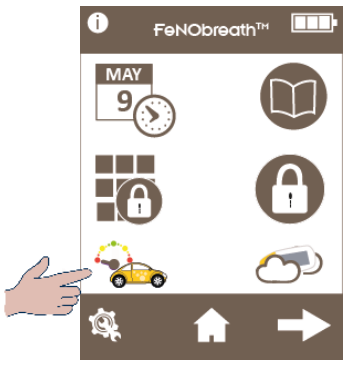


A prompt will ask for the PIN number to be entered in order to disable the PIN function.



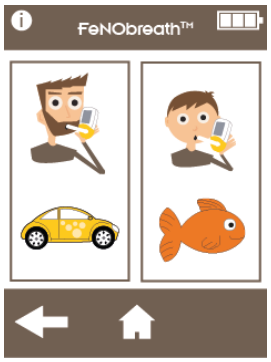
Once the PIN function is disabled, it will be crossed out in the settings menu.

To re-enable the PIN function, simply press the enable/disable button again and re-enter the PIN to confirm.

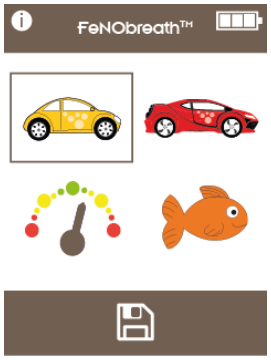


Change flow-meter style

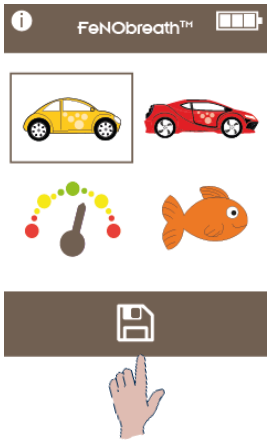
To change the flow-meter style, press the flow-meter button on the 1st page of the settings menu.



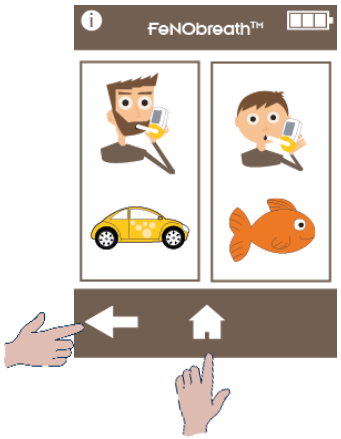
Select either the adult or child test mode to change the flow-meter style.



The current flow-meter style will be highlighted.

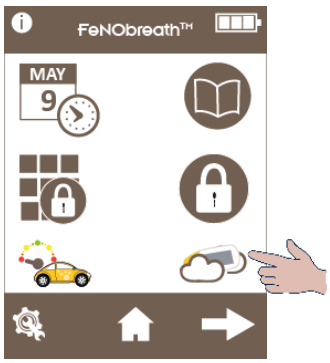


Select the new style and press the save icon to register.



The new flow-meter style will now be used for that breath test mode and the relevant demo mode.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.



Ambient air test

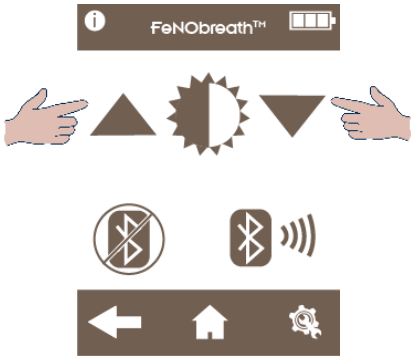
To perform an ambient air test, press the ambient test icon on the 1st page of the settings menu.

NOTE: *The ambient level of nitric oxide should be below 350ppb.*

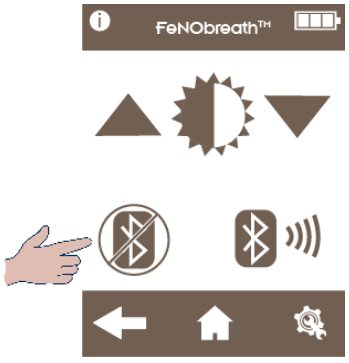
The FeNObreath™ will begin sampling the atmosphere and an hourglass be shown onscreen.

The result will be shown onscreen.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.

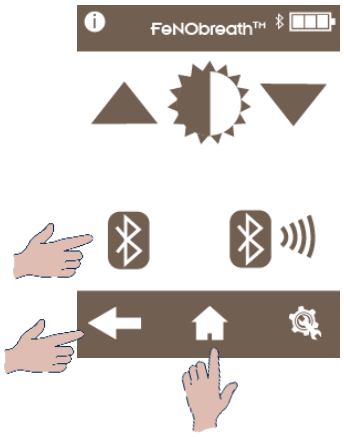


To adjust the brightness of the display, go to the 2nd page of the settings menu and use the arrows to increase/decrease the brightness of the screen.



Enable/disable Bluetooth

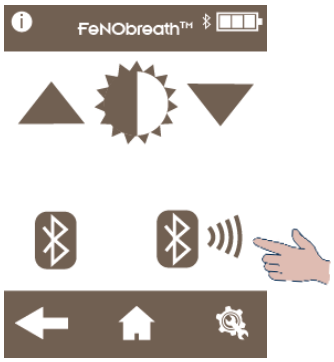
To enable Bluetooth, go to the 2nd page of the settings menu and press the enable/disable Bluetooth button.



Once Bluetooth is enabled, the Bluetooth symbol will no longer be crossed out on the 2nd page of the settings menu and a Bluetooth symbol will appear next to the battery status icon.

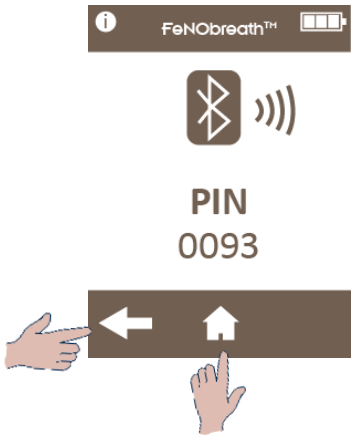
Press the icon again to switch Bluetooth off.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.



Bluetooth pairing

To pair a device with the FeNObreath™, go to the 2nd page of the settings menu and press the Bluetooth pairing icon.

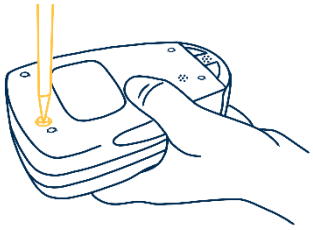


The screen will display the Bluetooth pairing PIN.

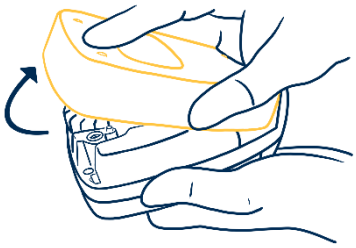
Please make sure the Bluetooth on the FeNObreath™ and the other device is switched on in order to pair with the FeNObreath™.

Press the back arrow to return to the settings menu or the home icon to return to the main screen.

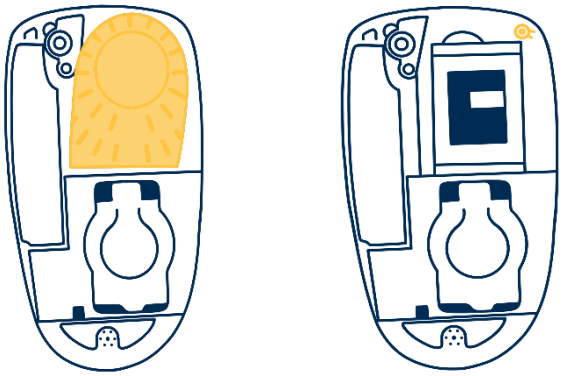
Data Reset



Using the screwdriver provided with the FeNObreath™, unscrew the screw on the back of the monitor.

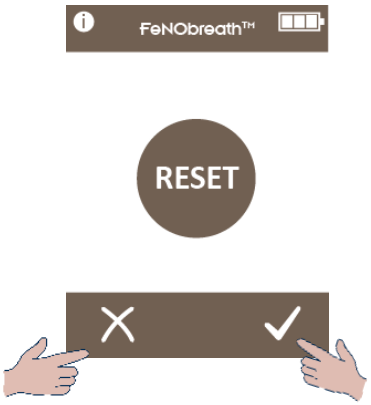


Remove the back cover by sliding and lifting it off.



To access the Data Reset button, first remove the back cover and the breath drying cartridge.

This will reveal the Data Reset button at the top right of the FeNObreath™.



Press and hold the Data Reset button for 5 seconds and the screen will reveal the reset icon.

NOTE: *A data reset will erase all patient data from the device the PIN will be reset to the default, 0000.*

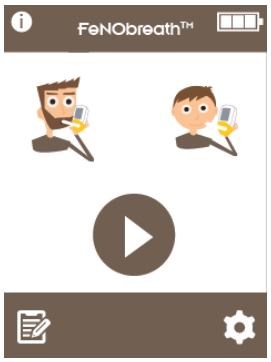
Press the tick to confirm the data reset or cross to cancel.

An hourglass will display onscreen as the FeNObreath™ begins erasing all data.

NOTE: *This can take up to 5 minutes to complete.*

Once complete, the screen will prompt for the back cover to be replaced.

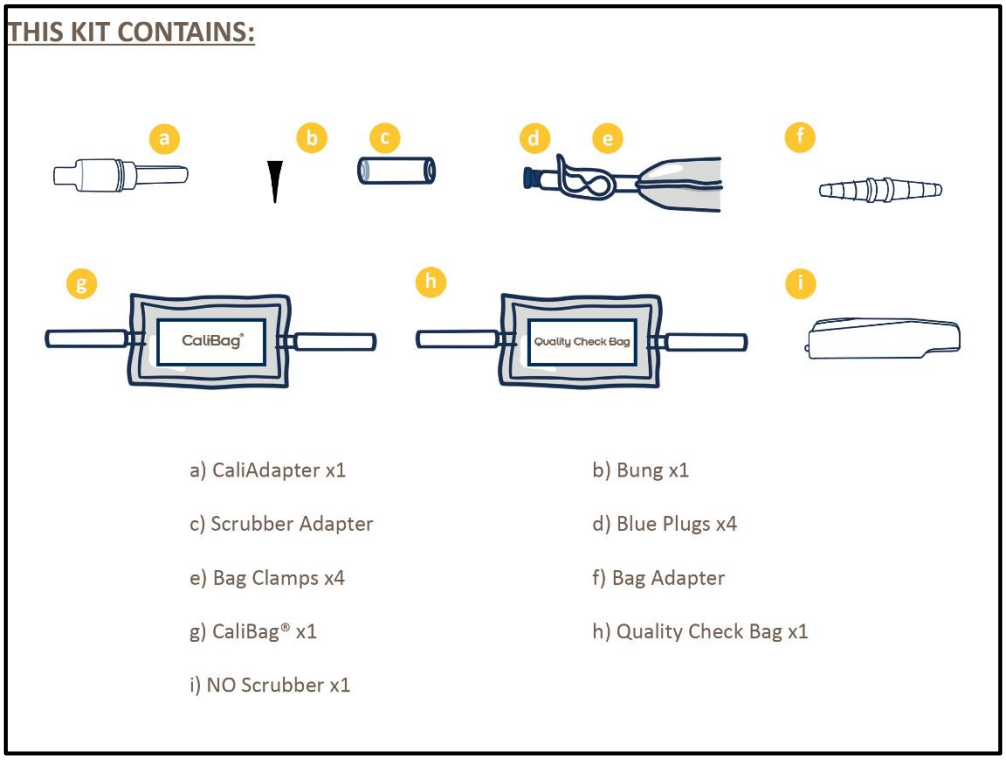
Ensure that the breath drying cartridge has been re-inserted and then reattach the back cover.



All data will be erased and the home screen will display once more.

Quality Check and Calibration

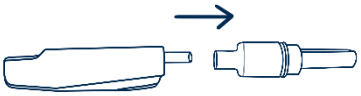
The FeNObreath™ will allow a 2-step quality check to be performed, this should be performed within 6 months before an annual calibration, or more frequently if required. This is to ensure the FeNObreath™ is within specification. The 2-step quality check will be carried out using filtered ambient air and 100ppb Nitric Oxide. MGC Diagnostics Corporation or the local service center can do this or a CaliBag® kit can be purchased separately (see CaliBag® component layout below).



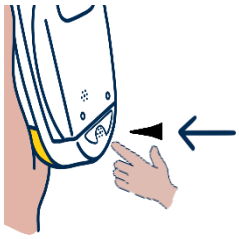
Before carrying out the 2-step quality check ensure the ambient level of nitric oxide is ≤100ppb. To carry out an ambient check, follow the procedure within this manual. If the 2-step quality check is successful, the 200ppb Nitric Oxide gas will not be required, and should be disposed of according to the local waste guidelines.

Attach the Scrubber Adapter to the Scrubber.

CAUTION: NO scrubber contains potassium permanganate and should not be tampered with and should not be exposed to skin.



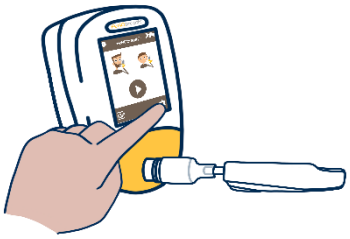
Next, attach the scrubber to the CaliAdapter.



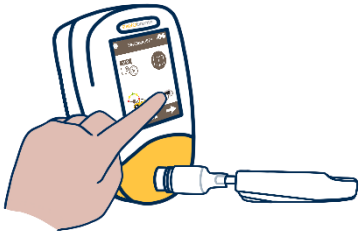
Insert the Bung into the bottom vent hole on the back of the FeNObreath™.

Turn on the FeNObreath™.

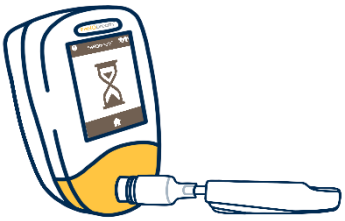
Insert the other end of the CaliAdapter into the FeNObreath™.



Press the Settings icon.



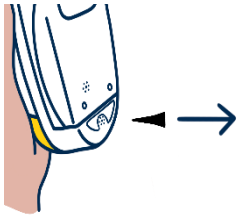
Press the Ambient Test icon.



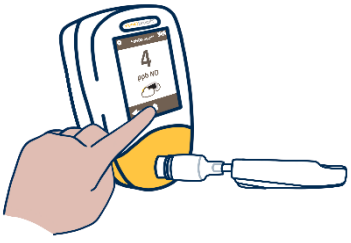
An hourglass will appear onscreen while the FeNObreath™ performs the Quality Check without gas.

A reading will appear onscreen; a successful NO scrubber Quality Check will display an NO reading ≤5ppb in which you may proceed to carrying out the Quality Check with gas.

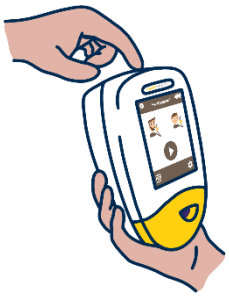
If the NO reading is >5ppb, please follow the next steps on replacing the NO scrubber and performing a Quality Check with gas.



Remove the Bung from the FeNOBreath™.

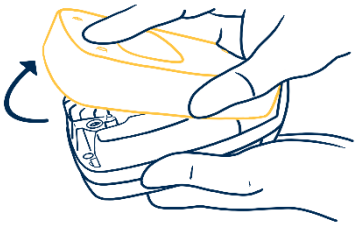


Press the Home icon to return to the home screen.

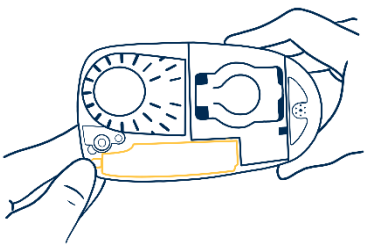


Please ensure the FeNObreath™ monitor is switched off before removing the back cover.

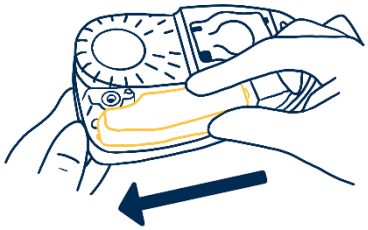
Using the screwdriver provided with the FeNObreath™, unscrew the screw on the back of the monitor.



Remove the back cover by sliding and lifting it off.

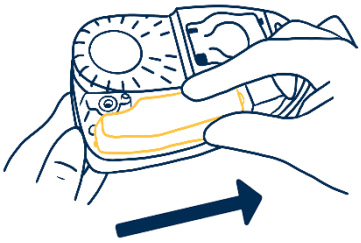


To remove the scrubber, first press down on clip at the top left-hand side of the monitor.



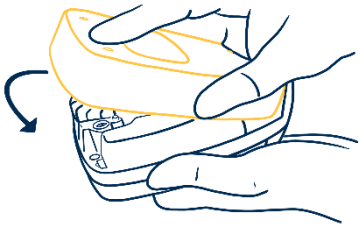
Slide out the scrubber then lift to remove.

CAUTION: NO scrubber contains potassium permanganate and should be disposed of as hazardous waste in accordance with local waste disposal regulations.



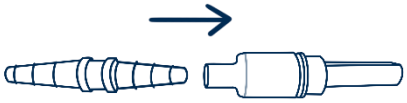
Using the same NO Scrubber from the Quality Check without gas, insert this into the FeNObreath™.

Please ensure the CaliAdapter and Scrubber Adapter have been removed from the scrubber before inserting into the FeNObreath™.

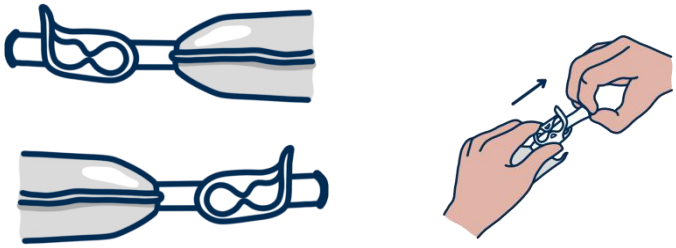


Re-attach the back cover of the FeNObreath™ monitor.

To secure the FeNObreath™ back cover in place, use the screwdriver to rescrew the screw into place.

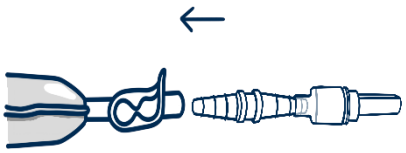


Attach the Bag Adapter to the rubber end of the CaliAdapter.

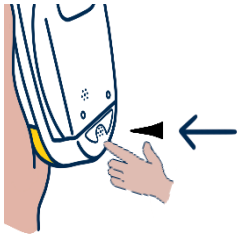


Ensure both Bag Clamps on the Quality Check Bag are closed and remove a Blue Plug from one end.

NOTE: *Make sure the Quality Check Bag is being used. The Quality Check Bag contains the lower concentration of NO gas which will be close to, but may not be exactly, 100ppb.*

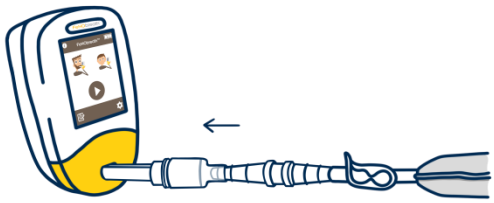


Insert the Bag Adapter into the Quality Check Bag.

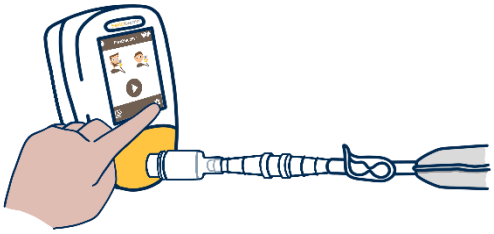


Insert the Bung into the bottom vent hole on the back of the FeNObreath™.

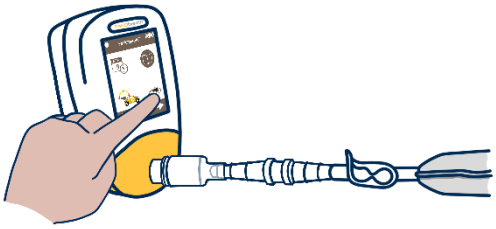
Turn on the FeNObreath™.



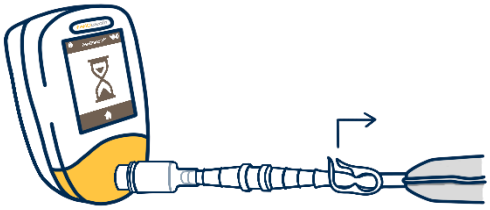
With the Quality Check Bag attached, insert the CaliAdapter into the FeNObreath™.



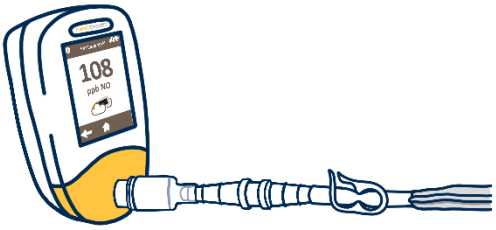
Press the Settings icon.



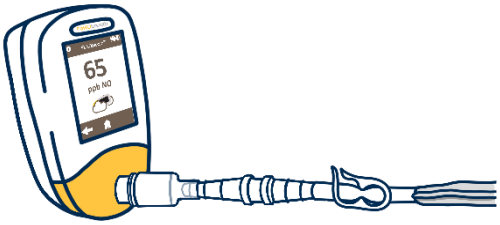
Press the Ambient Test icon.



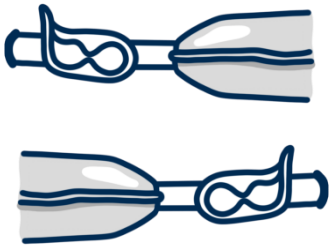
When an hourglass appears, open the clamp while the FeNObreath™ performs the Quality Check with gas. The device will automatically draw gas from the Quality Check Bag.



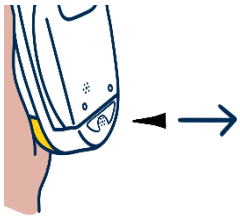
A reading will appear on-screen; a successful Quality Check will display an NO reading within ±10% of the gas concentration written on the Quality Check Bag label. For guidance please refer to the Quality Check conversion chart which can be found in the Calibration Kit Quick Start Guide.



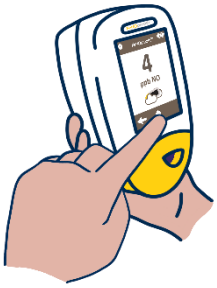
If the NO reading is not within ±10% of the concentration written on the Quality Check Bag label, your FeNObreath™ requires a calibration. To calibrate your device with the CaliBag®, follow the instructions provided.



Ensure both Bag Clamps are closed before removing the Quality Check Bag and all adapters from the FeNObreath™.



Remove the Bung from the FeNObreath™.



Press the Home icon to return to the home screen.

If the reading is not within the specification of the concentration range, one of the following should be carried out:

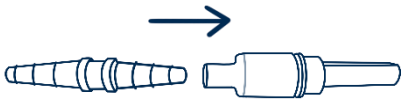
1. Calibrate using a CaliBag®
2. Send the device back to MGC Diagnostics Corporation or local service center for investigation
3. Replace with a pre-calibrated sensor; MGC Diagnostics Corporation or the local service center can do this for or a sensor replacement kit can be purchased separately which is supplied with replacement instructions.

Calibration using a CaliBag®

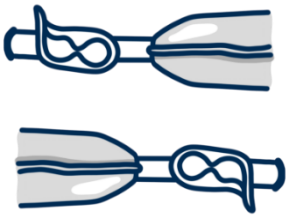
NOTE: *The device must be calibrated annually at the following temperature of 21°C ±4°C (17°C-24°C) or* 70°F ±7°F (63°F-77°F)

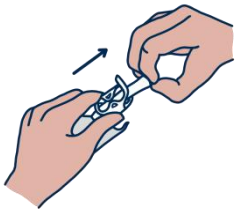
The device will indicate whether the temperature range is out of specification by the following:

	Device too cold to be calibrated	Leave device in an atmospheric temperature of 21°C ±4°C (70°F ±7°F) until the temperature range within the device has equilibrated.
	Device too hot to be calibrated	Leave device in an atmospheric temperature of 21°C ±4°C (70°F ±7°F) until the temperature range within the device has equilibrated.

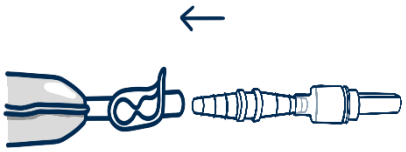


Attach the Bag Adapter to the rubber end of the CaliAdapter.

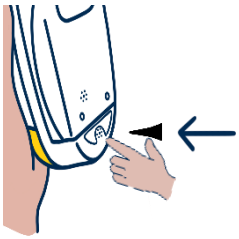




Ensure both Bag Clamps on the CaliBag® are closed and remove a Blue Plug from one end.



Insert the Bag Adapter into the CaliBag®.

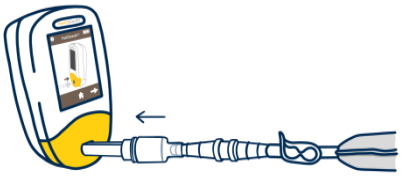


Insert the Bung into the bottom vent hole on the back of the FeNObreath™ and turn the device on.

Press the Settings icon, followed by the Service Area icon.

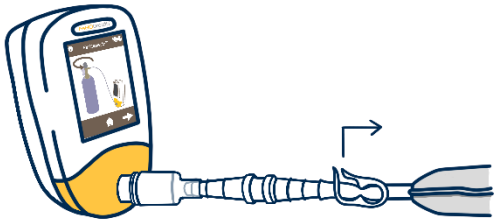
Press the Calibration icon to begin.

Use the arrows to adjust the NO concentration on-screen to match the value of the NO concentration written on the CaliBag®. Press the arrow icon twice to continue.

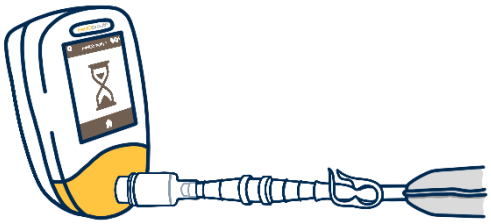


With the CaliBag® attached, insert the CaliAdapter into the FeNObreath™. Press the next arrow once to continue.

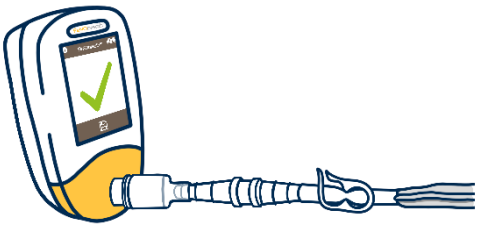
NOTE: *Make sure the calibration gas CaliBag® is being used.*



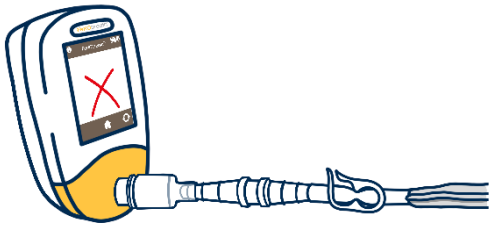
Open the Bag Clamp and press the next arrow to continue.



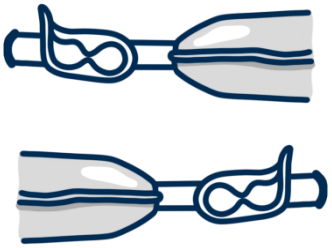
An hourglass will display on-screen as the device will automatically calibrate, drawing the gas from the CaliBag®.



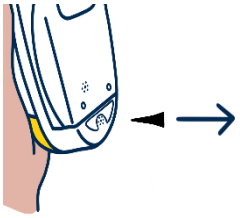
A successful calibration is shown by a green check mark. Press save to complete the calibration.



An unsuccessful calibration is shown by a red cross. If an unsuccessful calibration is shown by a red cross, contact MGC Diagnostics Corporation or the local distributor.



Ensure both Bag Clamps are closed before removing the CaliBag® and remove all adapters from the FeNObreath™.



Remove the Bung from the FeNObreath™.

Cybersecurity

WARNING: Precautions need to be taken when handling patient data, this should be completed by trained healthcare professionals only.

CAUTION: Security precautions need to be taken when connecting a FeNObreath™ unit to a PC/laptop via USB or Wireless. Ensure the PC/laptop is in a secured environment (e.g. has a firewall and anti-virus software) in order to not expose the FeNObreath™ to malwares.

CAUTION: The operating system of the PC/laptop should be kept up to date.

WARNING: Any data on the FeNObreath™ device needs to be cleared (via a reset) before returning to MGC Diagnostics Corporation or one of its distributors for service or repair and before the unit is disposed at end-of-life.

WARNING: The FeNObreath™ needs to be stored in a secure place, e.g. a locked room or desk drawer/cupboard.

Technical Specification

FeNObreath™ monitor and Dock

Concentration range		5-500ppb
Display		Full colour touchscreen
Detection principle		Electrochemical sensor
Repeatability		±5ppb of measured value ≤ 50ppb ±10% of measured value > 50ppb
Accuracy		±5ppb of measured value ≤ 50ppb ±10% of measured value > 50ppb
Power	**FeNObreath™ monitor**	1 x main rechargeable Li-ion battery – Approx. 100 uses on fully charged battery Model: RRC1120. Voltage: 3.6V / 3.7V Capacity: 2350mAh / 2000mAh 2 x Li-ion coin cell batteries – Approx. 5 years Model: LIR2032. Voltage: 3.6V. Capacity: 45mAh Model: LIR2450. Voltage: 3.7V. Capacity: 120mAh
	FeNObreath™ Dock	Mains powered Input: 5V, 0.5A Output: 5V, 0.5A
	Plug	Input: 100-240V ~ 50/60Hz., 0.2A Output: 5.0V, 1.0A
T_{90} response time		≤10 seconds
Temperature	**Operating**	15-30°C (59-86°F)
	Storage/transport	0-50°C (32-122°F)
	Calibration	21°C ±4°C (17°C-24°C) 70°F ±7°F (63°F-77°F)
Humidity	**Operating**	20-80% RH (non-condensing)
	Storage/transport	5-95% RH (non-condensing)
Operating/transport/storage Altitude		-1700 ft. to 6300 ft.
Operating/transport/storage pressure		800-1080mbar
Expected sensor operating life		5 years (subject to servicing)
Limit of Detection		5ppb
Sensor drift		<5% per annum
Dimensions		Approx. 90 x 159 x 59 mm (3.5 x 6.3 x 2.3 in)
Weight		Approx. 400g (0.9lb)
Materials	**FeNObreath™ monitor**	Case: polycarbonate/ABS blend SteriTouch® anti-microbial additive
	FeNObreath™ Dock	
Breath test time	**Adult**	12 seconds
	Child	10 seconds
	Ambient	30 seconds
Warm-up time		≤60 seconds
Maximum ambient operating level		350 ppb NO
CO cross interference		45 ppm ≤17.6 ppb

FeNObreath™ mouthpiece

Infection control	An integrated infection control filter removes and traps >99% of airborne bacteria and >98% of viruses.
Dimensions	Approx. 180 x 25 x 15 mm (7 x 1 x 0.59 in)
Weight	Approx. 11g (0.02lb)
Materials	Polypropylene

Buttons Explained

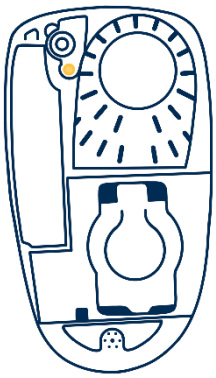
Information		Retry		Change PIN	
Adult test		Save		Disable PIN	
Child test		Next screen		Enable PIN	
Demo mode		Previous screen		Change flow meter style	
Patient profiles		Settings		Ambient test	
Home button		Date & time		Disable Bluetooth	
Graph of results		Selected		Enable Bluetooth	
Delete patient		Increase		Service Area (See service manual)	
Confirm		Decrease		5 year service	
Cancel		Test log			

Troubleshooting

Possible Cause	*Recommended Action*
The service date is due in ≤30 days.	This will be displayed every day until 365 days has surpassed or it has been reset by performing a calibration or sensor change.

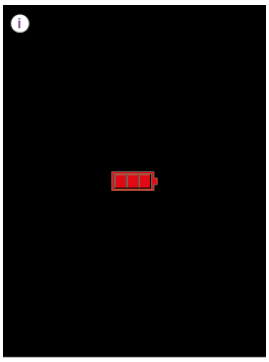
Possible Cause	*Recommended Action*
365 days has elapsed since the last service.	This will be displayed every day until it has been reset by performing a calibration or sensor change.

Possible Cause	*Recommended Action*
5 years has elapsed since first calibration.	5 year maintenance service is required. This should be carried out by a trained engineer. This will be displayed every day until a full service has been carried out.



Possible Cause	*Recommended Action*
The back cover of the device is open	Make sure the back of the device is secure and the turn lock is closed.
The back cover button is damaged, lost or stuck	Take the back cover off, check the back cover button is present. Replace back cover.

Possible Cause	*Recommended Action*
No sensor detected	Ensure a sensor is inserted into the device.
The sensor is not correctly inserted	Ensure the sensor is correctly inserted by pushing firmly in the top connector.
Check the date & time. If this does not show the current date & time the real time clock battery may be flat/empty	Change the date/time to the current date/time and charge the device battery fully.
Sensor bias battery flat/empty	Charge the device battery fully. This will allow the sensor bias battery to also charge and re-bias the sensor. Instructions from the previous step may also have to be carried out.
Sensor connector pins blocked	Remove the sensor and re-insert to clear any possible blockages.



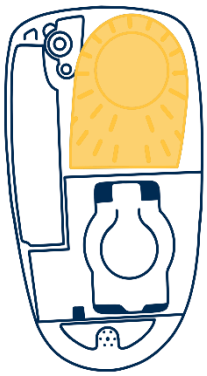
Possible Cause	*Recommended Action*
The device battery is flat/empty	Place the monitor in the charging dock and plug into a power source. Alternatively, plug the device directly into a power source. See 'Installation and Setup' section of this manual.

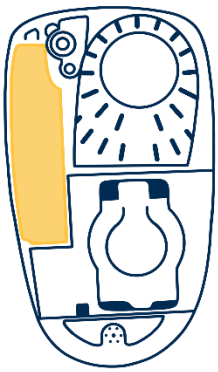
Suspicion that the device is giving erroneous/incorrect readings.

This image is an example only, and is not necessarily an example of an erroneous reading.

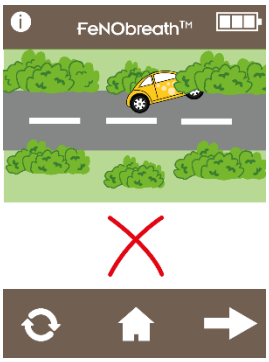
Possible Cause	*Recommended Action*
The device may be out of specification.	If the user suspects the device is giving erroneous readings, stop using it and contact MGC Diagnostics Corporation or the local service center.
The device may have been exposed to high levels of volatile organic compounds (VOC's) for example from cleaning agents.	Allow the device to rest for up to 24 hours in a VOC free environment.
The device may be showing testing in demo mode.	Ensure the breath test mode is being selected from the home screen.

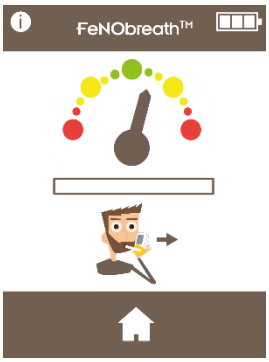
The device consistently reads 0ppb

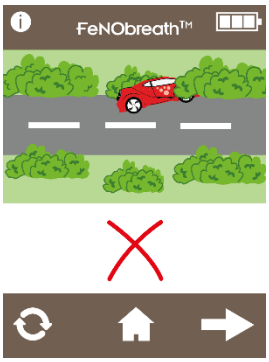


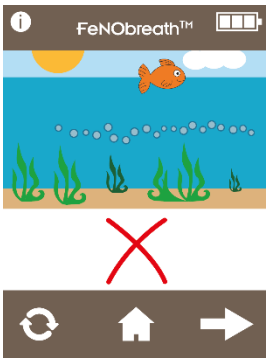


Possible Cause	*Recommended Action*
The drying cartridge is missing or disconnected	Take the back cover off and check drying cartridge is present and fully located into the device. Replace the back cover.
The NO scrubber is missing or disconnected	Take the back cover off and check NO scrubber is present and fully located into the device. Replace the back cover.









Possible Cause	*Recommended Action*
If the patient exhales outside of the exhalation guidelines, the test will beep before indicating a fail and a red cross will appear.	Press the retry icon to retake the test or if after multiple attempts the patient is unable to comply, the reading can be viewed by pressing the next arrow.

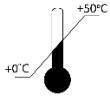
WARNING: Patients should exhale for the duration of time indicated by the monitor during a breath test. Failure to do so could impact the reading.

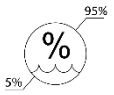
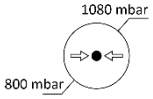
Notification Issue	Possible Cause	Recommended Action
The device will not switch on	The battery is missing	Take the back cover off, check battery is present and fully located into the device. Replace back cover
	The battery is flat	Place the monitor in the charging dock and plug into a power source. Alternatively, plug the device directly into a power source. See 'Installation and Setup' section of this manual
	The battery has been inserted incorrectly	Contact MGC Diagnostics Corporation or the local distributor for assistance
	The device is not charging	
	The battery contacts are blocked	
	The power button is damaged	
	There is a screen issue	
The unit is reading incorrectly or showing 0ppb	The pump is not running	The battery is low. Charge the device battery
	The mouthpiece connection was loose during the test	Ensure the mouthpiece is connected tightly
	Check if any VOC's or alcohol based products have been used to wipe the device or mouthpiece	Alcohol contaminations will affect the Nitric Oxide electro chemical sensor inside the device. Ensure no VOC's are used on the device and accessories related to the device
	Check if any aerosols or room spray have been used where the device is used	
	The vent holes are blocked	Ensure vent holes are not blocked or covered by hands or something else during the test.
	There are high levels of ambient Nitric Oxide	Perform an ambient test as per the instructions. Levels should be ≤350ppb, if levels are >350ppb, move to a different location and take a new measurement.

Rattling sound inside the unit	This is from the scrubber material	This is not an issue. Scrubber has potassium permanganate and charcoal buds inside the device to scrub ambient NO
FeNObreath™ Dock is showing a red light	Indicates a fault, overcurrent, undervoltage or overvoltage protection circuit has triggered	Contact MGC Diagnostics Corporation or the local distributor for assistance.

Glossary of Symbols and Safety Information

Glossary of Symbols			
Title of Symbol	**Symbol**	**Explanatory Test**	**Symbol and Standard References**
Type BF Applied Part (Whole Device)		To identify a type BF applied part complying with IEC 60601-1	IEC 60417 – 5333 IEC 60601-1, Table D.1, Symbol 20
Degree of protection against ingress of liquid	IPX0 – not protected against water ingress	Degree of Ingress Protection Provided by Enclosure	IEC 60601-1, Table D.3, Symbol 2. IEC 60529
Consult instructions for use		Indicates the need for the user to consult the instructions for use	ISO 15223 – 1. Clause 5.4.3 ISO 7000 – 1641 IEC 60601-1, Table D.1, Symbol 11
Non-ionizing electromagnetic radiation **The device includes a Radio Frequency (RF) transmitter:** **Make: Microchip** **Module: RN42 Bluetooth FCC ID: T9J-R942**		To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment	IEC 60601-1-2 Clause 5.1.1 IEC 60417 - 5140
Direct current		To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals	IEC 60601-1. Table D.1, Symbol 4

Dispose of according to WEEE		DO NOT THROW IN GENERAL RUBBISH DISPOSAL/TRASH! – Waste Electronic Equipment	EN 50419 Directive 2012/19/EU, Annex IX
Serial number		Indicates the manufacturers serial number so that a specific medical device can be identified	ISO 15223 – 1. Clause 5.1.7 ISO 7000 – 2498
Manufactured by		Indicates the device manufacturer (*Note – Date of manufacture, name and address of manufacturer can be combined in one symbol)	ISO 15223 – 1. Clause 5.1.1 ISO 7000 – 3082
Manufacture date		Indicates the date when the medical device was manufactured	ISO 15223-1. Clause 5.1.3 ISO 7000 – 2497 FDA 21 CFR 801
Magnetic Resonance (MR) unsafe		3.1.14: An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment	ASTM F2503-20. Table 2, Symbol 7.3.3; 7.4.9.1; Fig.9
Caution		Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1 Clause 5.4.4 ISO 7000 – 0434A FDA 21 CFR 801
Prescription only		Caution: Federal Law restricts this device to sale by or on the order of a physician	FDA 21 CFR 801.109
Temperature limit		Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.7 ISO 7000 – 0632

Humidity limitation		Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.8 ISO 7000 – 2620
Atmospheric pressure limitation		Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.9 ISO 7000 – 2621
General symbol for recovery/recyclable		To indicate that the marked item or its material is part of a recovery or recycling process	ISO 7000 – 1135

Non-standard symbols			
Title of Symbol	**Symbol**	**Explanatory Test**	**Symbol and Standard References**
CE mark	CE 2797	Manufacturer's declaration of compliance to all relevant European Medical Device Regulations	European Directive 93/42/EEC
Bedfont® Scientific logo	bedfont	Manufacturer's logo	N/A
MGC Diagnostics Corporation logo	MGC DIAGNOSTICS®	Distributor's logo	N/A
Type of protection against electric shock	Internally powered equipment	N/A	N/A
Degree of safety application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable for use in the presence of flammable mixtures.	N/A	N/A

Wireless

This device contains a Microchip Technology Inc. transmitter module IC: 6514A-RN42 FCC ID# T9J-RN42 in compliance with FCC rules, Part 15 Spread Spectrum Transmitter

Wireless Bluetooth Low Energy (BLE) is used as a means of communication between the monitor and FeNOchart™ software running on a PC. The FeNOchart™ software is a charting program that retrospectively collects data from the FeNObreath™ monitor when it is not monitoring. It is not time critical, there are no alarms.

Radio Technology: Bluetooth: IEEE 802.15 Frequency-hopping spread spectrum.

Bluetooth specification: v2.1 + EDR (Enhanced Data Rate).

Bluetooth Class / Power: Class 2 Bluetooth module. Software controllable power. Max power 4 dBm.

RF frequencies: 79 bands (1 MHz each; centered from 2.402 to 2.480 GHz) in the range 2,400-2,483.5 GHz.

The Bluetooth device is preconfigured with 128bit encryption and a CCITT CRC Checksum. There is no need or provision to change this setting

The USB port is to be used for charging the FeNObreath™ device, this should be carried out via the supplied USB lead and also can be used for transferring encrypted patient data. The FeNObreath™ is not intended to be connected to any wireless adaptors or any other USB Host.

Electromagnetic Immunity

The FeNObreath™ and FeNObreath™ Dock comply with the IEC60601-1-2:2014 4th edition electromagnetic compatibility.

The FeNObreath™ Monitor is suitable for the electromagnetic environment of typical commercial or hospital settings.

During the immunity testing described below the FeNObreath™ Monitor continued to provide essential performance. We considered essential performance to be an NO reading within ±5ppb of inputted level. A deviation of ±5ppb has no physiological significance.

WARNINGS:

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the FeNObreath™ Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The FeNObreath™ Monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the FeNObreath™ Monitor should be observed to verify normal operation. If operation is not normal, the FeNObreath™ or the other equipment should be moved.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as Magnetic Resonance Imaging (MRI) systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors.
- 

Keep the FeNObreath™ outside the MRI scanner room.

Note that the presence of RFID devices may not be obvious. If such interference is suspected reorient equipment if possible, to maximize distances.

Emissions

The FeNObreath™ Monitor is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The FeNObreath™ Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The FeNObreath™ Monitor is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the FeNObreath™ monitor or shielding the location.

Immunity

Guidance and manufacturer's declaration: Electromagnetic immunity			
The FeNObreath™ is intended for use in the electromagnetic environment specified below. The customer or the user of the FeNObreath™ 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	±8kV contact ± 2, 4, 8 and 15kV air	±8kV contact ± 2, 4, 8 and 15kV air	Floor should be wood, concrete or ceramic floor tile. If floors are covered with synthetic material the

			relative humidity should be at least 30%.
Electrical fast transient/bursts (immunity) IEC 61000-4-4	±2 kV	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge (immunity) IEC 61000-4-5	± 0.5, 1.0 kV L-L ± 0.5, 1.0, 2.0 kV L-E	± 0.5, 1.0 kV L-L ± 0.5, 1.0, 2.0 kV L-E	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% 0.01 Seconds 100% 0.02 Seconds 30% 0.5 Seconds 100% 5 Seconds	100% 0.01 Seconds 100% 0.02 Seconds 30% 0.5 Seconds 100% 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FeNObreath™ requires continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the FeNObreath™ is powered from an uninterruptible power supply.
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 commercial or hospital environment.

Electromagnetic Immunity		
The FeNObreath™ is intended for use in the electromagnetic environment specified below. The customer or the user of the FeNObreath™ should assure that it is used in such an environment.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms (1kHz 80%) 150kHz – 80MHz 6 V rms in ISM and amateur radio bands 3 V/m (1kHz 80%) 80MHz – 2.7GHz	The FeNObreath™ is suitable for the electromagnetic environment of typical commercial or hospital settings.

FeNObreath™ has also been tested for immunity to RF wireless communications equipment as be.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Radiated RF IEC 61000-4-3	385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	The FeNObreath™ Monitor is suitable for the electromagnetic environment of typical commercial or hospital settings.

Summary of the clinical data

Study 1: A clinical Precision study comparing intra and inter usability of FeNO measurement using the FeNObreath™.

In one of the studies conducted, the clinical precision, as it relates to user bias of the FeNObreath™, was evaluated in a mixed study population of 76 participants - including 24 pediatric participants (ages 7-17 years) and 52 adults (18 years+). Participants were asked to obtain 2 FeNObreath™ measurements with the assistance of 3 health care professionals (HCPs), for a total of 6 FeNObreath™ evaluations per participant.

The clinical precision study was designed to capture the accuracy and precision of the FeNObreath™ device, therefore FeNO values acquired by subjects covered potential FeNO values which would be observed in clinical practice. The within subject precision* was assessed from this study population and is presented in the table below:

Median Concentrations	N	Within Subject Mean SD (ppb)	Within Subject Mean CV (%)	95% CI for CV (%)
0 to <10	10	0.8034172	13.35%	7.85%; 18.85%
10 to <20	21	1.2430966	9.18%	6.73%; 11.64%
20 to <30	23	0.9720727	4.17%	2.48%; 5.85%
30 to <40	5	1.2279205	3.65%	1.3%; 6%
40 to <50	5	1.3867462	3.17%	0.23%; 6.1%
>=50	12	1.4078969	1.89%	1.29%; 2.48%

*3 subjects in the clinical precision study had a large variation between the measurements. 1 subject was from median concentration bin of >= 50 ppb and 2 subjects were from the median concentration bin of 40 to <50 ppb. The %CV for these subjects was 10.24%, 21.54%, and 14.17%. This table excludes data from these three subjects.

There were no adverse events, serious injuries, issues or problems with use of the NObreath in participants.

Study 2: A clinical study illustrating asthma patient response to anti-inflammatory therapy using the FeNObreath™.

A second study also evaluated the clinical efficacy of the FeNObreath™;

A total of 186 patients (n= 95 18+ and n=91 7 to 17 years of age) participated in a longitudinal study where measurements for FeNO, spirometry, and asthma control questionnaires were completed at baseline (Visit 1) and two weeks later (Visit 2) after therapeutic agents were administered.

For those with elevated initial FeNO defined by ATS >25ppb for adults and >20ppb for children (total n=139),there was a fall in mean FeNO measured by FeNObreath™ in patients with elevated FeNO levels for combined adult and pediatric treatment population (n=139).

Results showed a mean change of -13.7ppb (-27.7%) with a mean SD of 17.8.

The Decline in FeNO was accompanied by the following changes in subjective and objective asthma measures.

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

ACQ:

Mean ACQ score fell by -29.7% after corticosteroids

FEV1:

There was a mean FEV1 change of 10.1% after corticosteroids

References:

1. An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FeNO) for Clinical Applications | American Journal of Respiratory and Critical Care Medicine [Internet]. Atsjournals.org. 2021 [cited 21 July 2021]. Available from: https://www.atsjournals.org/doi/full/10.1164/rccm.9120-11ST
2. Asthma Control Questionnaire (ACQ) [Internet]. Thoracic.org. 2021 [cited 21 July 2021]. Available from: https://www.thoracic.org/members/assemblies/assemblies/srn/questionaires/acq.php
3. Minimal Clinically Important Differences in Pharmacological Trials [Internet]. Atsjournals.org. 2021 [cited 21 July 2021]. Available from:

https://www.atsjournals.org/doi/pdf/10.1164/rccm.201310-1863PP#:~:text=Lung%20Function%20(FEV1)&text=The%20American%20Thoracic%20Society%2FEuropean,not%20clinically%20important%20(8)

Analytical Performance Data

Linearity

Four FeNObreath™ devices were tested as part of a linearity study. 2 devices were tested in 'adult mode and 2 devices were tested in 'child mode'. Nitric oxide was mixed in a balance gas of air to produce NO concentration levels between <5 and >500 ppb. The results are listed in the table below.

Device	Mode (child or adult)	Slope	y-intercept	R^2
1	Adult	0.9751	1.8037	0.9993
2	Adult	1.0199	-1.8566	0.9997
3	Child	1.0092	-0.6022	0.9992
4	Child	1.0308	1.0465	0.9999

Precision/ Reproducibility and Accuracy

Precision/ Reproducibility

The repeatability and within-device precision was analysed using samples across a range of 10, 25, 75, 200, 350 & 500ppb concentrations. The measurements were performed over 5 days, 2 sessions per day, 2 measurements per session across 15 separate devices.

Repeatability is an estimation of variation within 1 test run in 1 day. Within-device precision is an estimate of variation between test runs and days.

FeNObreath™'s precision/reproducibility is claimed to be a standard deviation of ≤5ppb for readings ≤50ppb and a CV of ≤10% for readings >50ppb. The precision/reproducibility testing performed confirmed that the precision/reproducibility performance of the FeNObreath™ fell within these specifications.

Limit of Detection

The limit of detection was determined based on CLSI EP17-A2. Ten devices were tested at 3 ppb (50 replicates) and 5 ppb (50 replicates) over three days in both child and adult modes. Nitric oxide samples were mixed in a balance gas of simulated breath. The limit of detection was calculated using the parametric option in CLSI EP17-A2, using the following formulas: LoB=µB+1.645 σB and LoD=LoB+1.645 σS. The results of the limit of detection analysis support the claimed detection limit of 5 ppb. The results are presented in the below two tables.

	N=	50
	LoB=μB+1.645 σB	
	LoD=LoB+1.645 σS	
	ADULT	
	3	5
Mean	3.42	5.42
SD	0.475094	0.4686063
95th	1.645	1.645
LoB	4.2015296	6.1908573
LoD	4.9830592	6.9617146
95% CI	0.13169	0.12989
95% CI -	3.29	5.29
95% CI +	3.55	5.55

At the nominal value of 3 ppb, the overall mean measured value was 3.42 ppb (95% CI 3.29;3.55). At the nominal value of 5 ppb, the overall mean measured value was 5.42 ppb (95% CI 5.29;5.55) which supports the claimed detection limit of 5 ppb in adult mode.

	N=	50
	LoB=μB+1.645 σB	
	LoD=LoB+1.645 σS	
	CHILD	
	3	5
Mean	3.63	5.47
SD	0.4997183	0.5347553
95th	1.645	1.645
LoB	4.4480366	6.3456725
LoD	5.2700732	7.225345
95% CI	0.13851	0.14822
95% CI -	3.49	5.32
95% CI +	3.76	5.61

At the nominal value of 3 ppb, the overall mean measured value was 3.61 ppb (95% CI 3.49;3.76). At the nominal value of 5 ppb, the overall mean measured value was 5.47 ppb (95% CI 5.32;5.61) which supports the claimed detection limit of 5 ppb in child mode.

Interpretation of FeNO Values

For interpretation of FeNO values, please refer to the ATS Clinical Practice Guideline at https://www.thoracic.org/statements/resources/allergy-asthma/feno-document.pdf

Warranty

MGC Diagnostics Corporation warrants the FeNObreath™ monitor and sensor to be free of defects in materials and workmanship for a period of 5 years from the date of shipment, subject to service and maintenance requirements. MGC Diagnostics Corporation's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned intact and prepaid, to MGC Diagnostics Corporation or the local, fully trained, representative. This service and maintenance requirement includes performing an annual calibration on the monitor within 60 days of the first notification that the device is due for calibration. The service also includes the replacement of the NO scrubber. Annual calibration can be performed by

the end user by purchasing a CaliBag® and scrubber or by purchasing an exchange NO sensor and scrubber.

Serviceable or consumable items such as the scrubber, mouthpieces and/or batteries should be maintained during annual servicing or disposed of as per the instructions and are excluded from the warranty period.

This warranty is automatically invalidated if the products are altered or tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident. At the end of the product's life, contact MGC Diagnostics Corporation or its distributor for disposal instructions. Single use consumables and accessories should be disposed of in line with local clinical waste guidelines. Never dispose of any electronic instrument or batteries in domestic waste.

Returns

Please contact MGC Diagnostics Corporation or its local distributor for instructions on returning goods.

Responsible Manufacturer and Contacts

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