

NObreath[®]

User manual



CE
0086



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Intended use

The NObreath® is a breath nitric oxide (NO) test system intended to measure fractional exhaled nitric oxide (FeNO) in parts per billion (ppb) in exhaled breath.

The measurement is taken to evaluate airway inflammation and should be used in conjunction with other clinical and laboratory evaluations where appropriate when making a diagnosis or treatment plan.

The measurements are intended for interpretation by healthcare professionals and for use in a healthcare environment, where patients will complete measurements under supervision.

Introduction

The production of nitric oxide is often found to be higher in inflammatory conditions such as asthma and can therefore be used for the detection and management of such conditions¹. Nitric oxide measurement is not intended as a stand-alone method for diagnosis and should be used in conjunction with other evaluation methods and tests².

Product description

The NObreath® is a hand-held breath nitric oxide monitor supplied with the NObreath® Dock, and FeNOCHART™ software.

The measurement system uses electrochemical sensor technology, which has been specifically designed for this purpose. The sensor reacts to the presence of nitric oxide producing an electrical output, which is then amplified with the result displayed. The sensor has ambient air flowing into the sensor chamber while the unit is on, but not performing a breath test.

The sample system for the NObreath® has been specifically designed in order to meet the breath test guidelines described in the ATS/ERS Recommendations. The ATS/ERS Recommendations are standardized procedures for the online and offline measurement of exhaled upper respiratory nitric oxide and nasal nitric oxide³.

The patient shall exhale at 50ml/sec, using the on screen flow indicator through the sample system, into the instrument, until a reading is displayed.

The NObreath® shall also have the capability to perform an ambient air test as required.

Bedfont® privacy statement: This product stores the personal information of patients and measurement data. It is the sole obligation of the healthcare professional to make sure this information is secure and compliant with your relevant data protection regulations.

Contradictions

There are no known contraindications for this device.

Warnings

- Read the manual before use.
- **NEVER** use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the electrochemical sensor inside.
- Under **NO** circumstances should the instrument be immersed or splashed with liquid.
- Ensure the unit is properly charged before taking a breath test.
- Breath tests must **ONLY** be carried out with the correct Bedfont® accessories. Failure to do so will cause incorrect readings and may invalidate your warranty.
- The vent holes on the rear of the unit must **NEVER** be covered during normal use. Covering the vent holes may cause incorrect readings.
- **DO NOT** attempt to modify the equipment in any way. Any attempt to do so will immediately invalidate your warranty, cause incorrect readings, and **may compromise the safety of the device.**
- **DO NOT** leave the NObreath® or docking station in direct sunlight.
- It is best practice to **NOT** let the battery run dead.

Cautions

- Ensure the monitor is used within the correct temperature and relative humidity (RH) range, as stated in the specification on page 4.
- The NObreath® complies with the EMC requirements of IEC 60601-1-2, outside of these requirements portable and mobile RF communications equipment may affect the device.
- Federal law restricts the device to sale only by, or on the order of, a physician (USA only)

NObreath® Mouthpiece technical specification











Infection control	A one-way valve to prevent patients drawing air back from the monitor. An integrated infection control filter removes and traps >99% of airborne bacteria and >96% of viruses ⁴ .
Dimensions	Approx. 180 x 25 x 15 mm
Weight	Approx. 11g
Materials	Polypropylene

NObreath[®] and NObreath[®] Dock technical specification

Exhaled flow during FeNO measurement at 50ml/sec $\pm 10\%$ at 10cm H₂O³

Concentration range		0-500ppb
Display		Full colour touchscreen
Detection principle		Electrochemical sensor
Repeatability		± 5 ppb of measured value ≤ 50 ppb $\pm 10\%$ of measured value > 50 ppb
Accuracy		± 5 ppb of measured value ≤ 50 ppb $\pm 10\%$ of measured value > 50 ppb
Power	NObreath[®] monitor	1 x main rechargeable Li-ion battery – Approx. 100 uses on fully charged battery 2 x Li-ion coin cell battery – Approx. 5 years Input: 5V, 0.5A
	NObreath[®] Dock	Mains powered Input: 5V, 0.5A Output: 5V, 0.5A
	Plug	Input: 100-240V $\sim 50/60$ Hz., 0.2A Output: 5.0V, 1.0A
T₉₀ response time		≤ 10 seconds
Temperature	Operating	10-30°C
	Storage/transport	0-40°C
Humidity	Operating	25-75% non-condensing
	Storage/transport	0-95% non-condensing
Operating/transport/storage pressure		Atmospheric $\pm 10\%$
Sensor operating life		5 years (subject to servicing)
Sensor sensitivity		1ppb
Sensor drift		$< 5\%$ per annum
Dimensions		Approx. 90 x 159 x 59 mm
Weight		Approx. 400g
Materials	NObreath[®] monitor	Case: polycarbonate/ABS blend
	NObreath[®] Dock	SteriTouch [®] anti-microbial additive
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

Safety information and device symbols


Degree of protection against electric shock	 Type BF applied part
Type of protection against electric shock	Internally powered equipment
Degree of protection against ingress of liquid	IPX0 – not protected against water ingress
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.
Refer to manual	
The device includes a Radio Frequency (RF) transmitter (Bluetooth)	
CE mark	
Direct current	
Dispose of according to WEEE	
Serial number	
Manufactured by	
Manufacture date	
Bedfont [®] logo	

Environment

The NObreath® and NObreath® Dock comply with the directive EN60601-1-2:2015 4th edition electromagnetic compatibility.

Electromagnetic immunity:

The NObreath® and NObreath® Dock comply with the directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding the levels specified in EN55011:2007 Class B.

Guidance and manufacturer's declaration: Electromagnetic immunity			
The NOBreath® is intended for use in the electromagnetic environment specified below. The customer or the user of the NOBreath® 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 ±15kV air	±8kV contact ±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/burst IEC 61000-4-5	–	–	–
Surge IEC61000-4-5	–	–	–
Voltage dips, short interruptions and voltage variations on power supply. IEC 61000-4-11	–	–	–
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 environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10V/m (1kHz 80%) 80MHz-2.7GHz 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	10V/m (1kHz 80%) 80MHz-2.7GHz 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	Portable and mobile RF communications equipment should be used no closer to the NObreath® than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol: 

Instrument layout

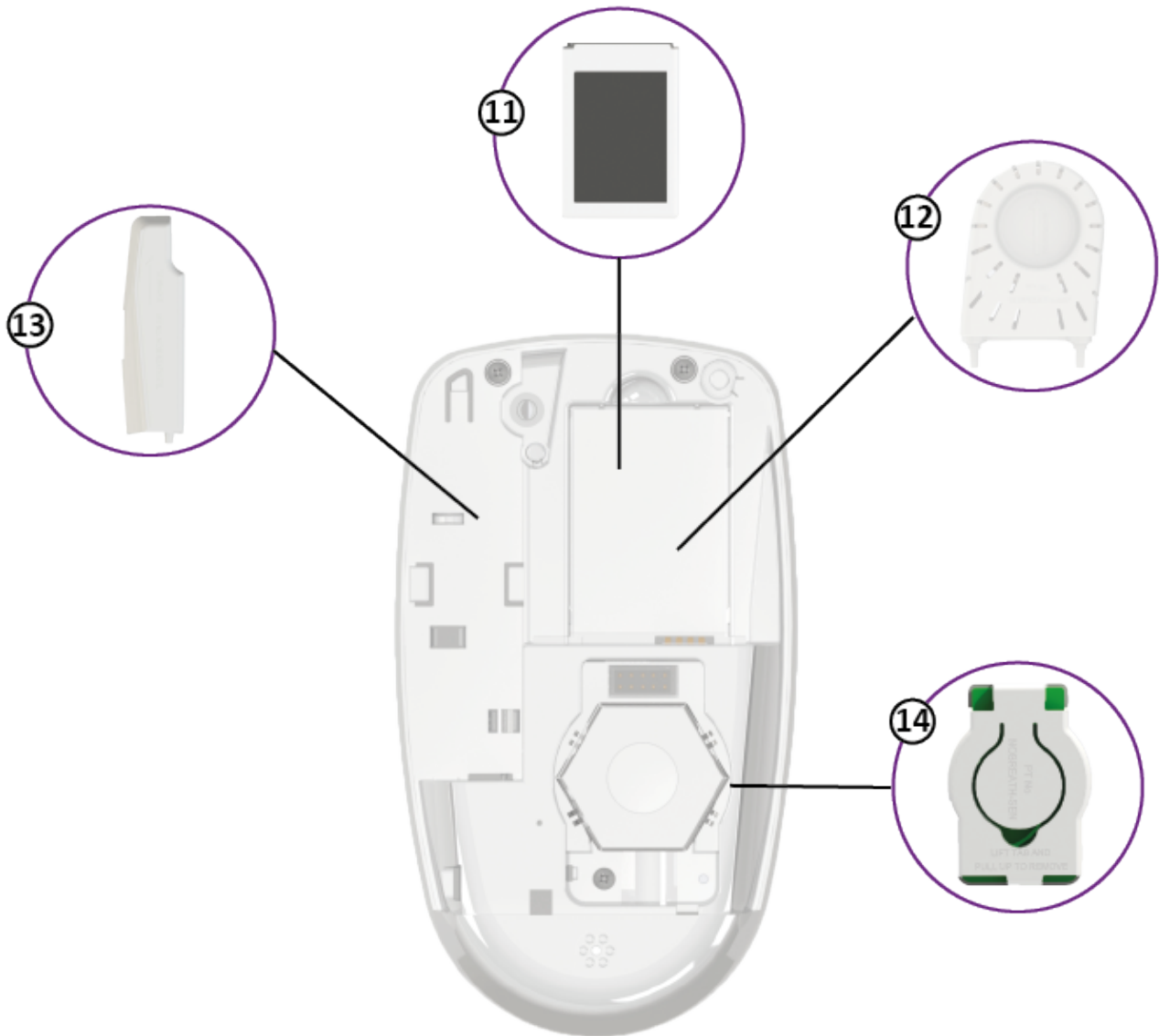
1. ON/OFF button
2. Touchscreen display
3. Mouthpiece aperture
4. Vent holes
5. Service cover lock
6. Micro USB port
7. NObreath[®] Dock (applied part)
8. USB cable (applied part)
9. NObreath[®] single-use mouthpiece
10. Mains power adaptor with connectors





































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Inside the service cover:







11. Rechargeable Li-ion battery
12. Breath drying cartridge
13. Ambient air NO scrubber
14. NO electrochemical sensor



Display symbols




Device information		Save	
Adult breath test		Home screen	
Child breath test		Next screen	
Demo mode		Previous screen	
Patient profiles (PIN protected)		Patient results	
Battery (full)		Delete patient	
Battery (half)		Settings	
Battery (critical)		Date/time	
		Selected	
Inhale (adult)		Unselected	
Exhale (adult)		Increase	
Inhale (child)		Decrease	
Exhale (child)		Test log	
Pass		Change PIN	
Fail		Disable PIN	
Retry		Enable PIN	
Set measurement incentive preference		Diagnostics	

Ambient mode		Diagnostics log	
Screen brightness		Sensor	
Disable Bluetooth		Maintenance due reminder	
Enable Bluetooth		Maintenance overdue reminder	
Bluetooth PIN		Maintenance overdue locked reminder	
Bluetooth enabled display		Rear cover off	
Service access		No sensor warning	
Pump calibration		No scrubber cartridge warning	
Refer to manual		Reset	
Gas calibration		Ambient mode locked	
Temperature too low to calibrate		Adult breath test locked	

Temperature too high to calibrate		Child breath test locked	
Sensor zeroing		Charging	
Confirm		Cancel	

Demo mode

The NObreath® has an in-built demonstration video of the breath test process. We recommend watching 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.



1. The demo video can be accessed from the home screen by pressing the  icon.
2. Select either the  or  icon.
3. A demonstration will run through the breath test process. The whole test will be shown, but at an accelerated speed.

Performing a breath test

1. Turn the NObreath® monitor ON by pressing the power button, once.
2. Open a new NObreath® mouthpiece and insert it into the front of the unit.

3. To start a breath test, touch the  or  icon on the screen.

NOTE: To cancel the breath test, press the  icon.

4. As prompted onscreen by  or , inhale until prompted to exhale. **Do not inhale through the mouthpiece.**



- When directed to do so by either  or , keep the monitor upright and blow gently into the mouthpiece. **Make sure you are not covering the vent holes.**

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


- The onscreen flow meter will guide you on the exhalation rate: continue blowing until the

green tick  appears on screen to indicate a successful test.


NOTE: If you outside of the exhalation guidelines, the test will beep, before indicating a fail,

and a red cross  will appear. Touch  to retry the test or  to view the result.

- Following the tick, a result will appear on the screen, in ppb.


- You may save this result by pressing .

NOTE: If you have not entered your PIN in the last 30 minutes, you will be asked to enter it before you can access the patient profiles. If your PIN is entered incorrectly, you will be notified and the screen will refresh for you to re-enter your PIN. If you have forgotten your PIN, please contact Bedfont® or your local distributor to reset it.

- Alternatively, you can return to the home screen by pressing .

Patient profiles

The NObreath® is designed to be capable of storing results in up to 50 patient profiles. From the

home screen, select the  icon to access patient profiles. If you have not entered your PIN in the last 30 minutes, you will be asked to enter it before you can access the patient profiles.

Enter your 4 digit PIN and if successful you will be presented with a list.

If your PIN is entered incorrectly, you will be notified and the screen will refresh for you to re-enter your PIN.

If you have forgotten your PIN, please contact Bedfont® or your local distributor to reset it.

To create a new patient profile

To create a new profile, choose an empty profile box and enter a name or reference. Then press



Alternatively - press a profile name to open it.


Take a breath test

To take a test directly from a patient's profile, open the profile and select either the ADULT or CHILD icons and follow the on-screen instructions.



NOTE: once an *ADULT* or *CHILD* has been selected from a patient's profile screen, the profile will ONLY display the option you selected from then onwards.


View the results

When in a patient's profile, you can press the  icon to show a graphical representation of all the tests saved to that profile. Each point on the graph shows the numerical reading, and the date/time at which it was logged.


Edit a profile

To edit a patient's profile, select their name/ID from the list and then press their name/ID again. Edit as desired using the keypad and either touch  to keep the changes or  to cancel.


Delete a profile

Select the patient you wish to delete from the list and press the  icon. Press the tick to confirm. The profile will be deleted and you will be returned to the profile screen.








Device information

For information on the device, the current version of software, serial number and calibration date, touch the  icon in the top left corner of the home screen.





Settings

The default settings, date and time, flow-meter and ambient testing can all be accessed and altered via the setting screen, which can be accessed by pressing the  icon.

Change the date/time

Press  and then  to access the date/time menu. You can then select either **d-m-y** or **m-d-y** for the date format and **12h** or **24h** for the time format. To adjust the date/time, select the number you wish to change and pressing  or  to increase/decrease. Press  to save your settings or  to abort changes and return the previous screen. Press  to return to the main screen.

Test log

A log of the most recent 150 test results are saved automatically in the log. To view the log, press  then the  icon and scroll through using the arrows. Press  to return the previous screen or  to return to the main screen.

Change PIN

1. Each device will automatically be pre-set to the PIN code 0000. It is highly recommended that you change this PIN to a 4 digit number that you will remember.

2. To change the PIN, press the change PIN icon  from the settings menu and you will prompted to enter the current PIN.

NOTE: *If your PIN is entered incorrectly, you will be notified and the screen will refresh for you to re-enter your PIN. If you have forgotten your PIN, please contact Bedfont[®] or your local distributor to reset it.*

3. Enter the 4 digit code and press  to continue
4. Enter a new memorable 4 digit PIN and press  to continue
5. Re-enter your PIN to confirm the new 4 digit code and press the tick to register

6. If at any point you change your mind, press  to return the previous screen or  to return to the main screen.

Disable/enable PIN

For data security reasons, the list of patient profiles on the NObreath[®] FeNO monitor is PIN protected and you are required to enter a 4 digit code after switch-on and every 30 minutes thereafter for optimum security.


Although it is not recommended, there is the option disable/enable the PIN from the settings menu.

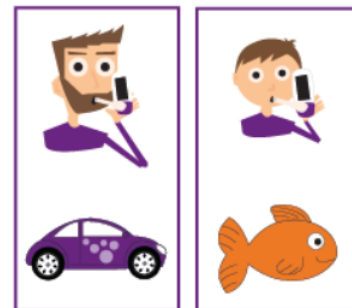
If the PIN is enabled, press  and enter your 4 digit code to disable it.




If the PIN is disabled, press  and enter your 4 digit code to enable it.

NOTE: If your PIN is entered incorrectly, you will be notified and the screen will refresh for you to re-enter your PIN. If you have forgotten your PIN, please contact Bedfont[®] or your local distributor to reset it.

Change the flow-meter display

To change the flow-meter display, touch the  icon in the settings menu. You will be shown which meters are currently set for both the Adult and Child settings. Touch each to be shown other flow-meter options. Choose a flow-meter display and press



 to save the changes. If you do not wish to change the flow-meter display, simply select save to keep the current option. Press  to return the previous screen or  to return to the main screen.







Ambient testing

To conduct an ambient air test, touch the  icon. A test will begin automatically and a timer will be shown onscreen. When the test is complete, a result will be displayed. This is important as








the NObreath[®] has been designed to function in environments containing less than 350ppb NO.

Press  to return the previous screen or  to return to the main screen.

Screen brightness

To adjust the brightness of the display, once in the settings menu, press  to access the second page where you will find the brightness settings . Use the arrows  or  to increase/decrease the brightness of the display. Press  to return the previous screen or  to return to the main screen.

Bluetooth



To turn Bluetooth ON/OFF, once in the settings menu, press  to access the second page and then press  or  to toggle Bluetooth ON or OFF. If Bluetooth is enabled, the Bluetooth icon will be visible at the top left-hand of the monitor, next to the battery symbol . To pair another Bluetooth enabled device with the NObreath[®], select the Bluetooth PIN icon  to show the pairing PIN onscreen. Press  to return the previous screen or  to return to the main screen.

Maintenance


- The NObreath[®] should be calibrated at least annually or the NO sensor should be replaced.
- The breath drying cartridge and NO scrubber should be replaced annually.
NOTE: *The unit is designed to provide maintenance reminders when re-calibration is required. You will be prompted to service the unit when necessary.*
- The NO sensor and pump should be replaced every 5 years



- The maintenance reminder screen shall be displayed at switch-on if the service date is due in ≤ 30 days & displayed every day until it has been reset by performing a calibration or sensor change.






-  The maintenance overdue reminder screen shall be displayed at switch-on if a required service has elapsed 365 days since the last service & displayed every day until it has been reset by performing a calibration or sensor change.
-  The maintenance overdue reminder screen shall be displayed at switch-on if a required service has elapsed 395 days since the last service & displayed every day until it has been reset by performing a calibration or sensor change.
- Each mouthpiece is single-patient use, and must be disposed of after each test
- **Never** open the unit without prior training from Bedfont[®] or an authorized representative. Doing so will invalidate the warranty and may impair the performance of the unit
- Bedfont[®] will make available upon request any additional technical information, and service training, to appropriately qualified persons

Service settings

The service menu can be accessed from the settings menu by pressing the service access icon  from the settings menu.

Pump calibration








To calibrate the pump, click on the  and follow the instructions below:

1. Connect the flow meter to the mouthpiece aperture and block the bottom vent hole.
2. Use the arrows onscreen,  or , to increase/decrease the flow rate until the flow meter reads 350 mL/min.
3. Press  to save the pump calibration or  to cancel and return to the previous screen.
4. Return to the home screen by pressing .






Gas calibration

To calibrate the NObreath[®], follow the steps below to complete calibration:

NOTE: 200ppb NO gas, a flow meter that is set or can be adjusted to 1 litres per minute (L/pm) and a device temperature of 21°C ±4°C (68°F ±39°F) is required to complete this task.

1. In the server settings menu, start the calibration process by pressing 
2. The device will perform a zero indicated by  : **do not apply gas at this stage**
3. Follow the onscreen instructions to finish the calibration process
4. **Gas flow should be set to 1 L/pm**
5. A successful calibration will be indicated by the  . Press  to save the calibration.
NOTE: If you click on the home icon before confirming the calibration, it will be dismissed and you will have to repeat the calibration.
6. A failed calibration will be indicated by  . Press  to attempt calibration again. If the problem persists see 'Troubleshooting' or call your local supplier of Bedfont[®] products.
7. Return to the home screen by pressing .

View device diagnostics

To access the diagnostics information screen, press the  icon followed by the  icon. From here you can also see the diagnostics log by pressing the  icon. This will list all the service dates and times alongside their success or failure as indicated by the tick/cross. Press  to return to the previous screen or  to return to the main screen.

Sensor replacement

To replace the NObreath[®] sensor, click on the  icon in the service settings and then refer to 'Service access section of this manual.

Servicing

NOTE: Before undertaking any of the actions below, please make sure that the device is switched off.

Accessing the serviceable components of the NObreath[®]

Using the screwdriver provided with the NObreath[®], turn the quarter-turn lock anti-clockwise to open and slide and lift off the back cover.



Breath drying cartridge replacement

Grip the breath drying cartridge as shown below and tug lightly until you hear a click. Then, simply lift the cartridge out and replace by sliding a new one into place.



NO scrubber replacement

As shown below, press down on clip on the left-hand side of the monitor and slide out the NO scrubber then lift to remove and replace with a new one.



Battery removal/replacement

Remove the breath drying cartridge to access the battery. Using the groove, pull the battery out towards you, as demonstrated below, and replace.







Sensor replacement

1. Using your thumb and forefinger, lift the tab on the sensor and apply pressure to the top and pull directly up to gently lift the sensor up and out.
2. Replace by slotting the new sensor in.



3. Reassemble the NObreath[®] and switch the device back on.

4. Press  to continue.
5. A successful replacement will be indicated by the . A failed replacement will be indicated by . Press  to re-attempt. If the problem persists see 'Troubleshooting' or call your local supplier of Bedfont[®] products.

Factory reset

To access the factory reset button, remove the breath drying cartridge to reveal the button at the top right of the NObreath[®].



Press and hold the reset button for 5 seconds and the screen will reveal the factory reset icon



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

Press  to confirm the factory reset or  to cancel.

Cleaning

- Wipe the instrument and external surfaces with alcohol-free wipes. If in doubt, Bedfont[®] supply instrument cleansing wipes, which we recommend and have tested with the device.
- **NEVER** use alcohol, cleaning agents that contain alcohol, or any other organic solvents on the unit. The vapours produced will damage the electrochemical sensor inside and result in fault.
- **NEVER** immerse, or splash the device with liquid of any kind.

Operation

- Ensure the units battery is charged prior to use. If the device has been left for an extended period of time, you may need to re-charge the unit.
- Press the ON/OFF button and release when the display becomes active.
- The device can take up to 60 seconds to start up due to the stabilisation period, whilst air is pumping over the sensor.
NOTE: *Make sure the vent holes are not covered at this time.*
- Once switched on – all functions are controlled via the touchscreen interface.

Accessories

NObreath® Dock

The NObreath® monitor supplied is with a charging and synching docking station. This docking station is supplied with a USB cable which can be connect to the computer for synchronisation with the FeNOCHART™ software or plugged into the mains power adapter for charging the NObreath®.

NOTE: *Please only use the mains adapter and provided with the NObreath®. Failure to do so will may damage the monitor and invalidate the warranty.*



FeNOCHART™ software – connecting to the PC

The NObreath® monitor is supplied with FeNOCHART™ software, which allows you to synchronise patient data from the device to your computer, where you can safely store and analyse results.

Insert the USB lead into the PC, and connect the other end to the rear of the docking station. Place the NObreath® into the docking station, connecting it to the micro USB in the base. Alternatively, you can connect the micro USB lead directly to the base of the NObreath® unit itself.

Before starting the software, ensure that the NObreath® is connected to the PC and switched on. Double click the FeNOCHART™ icon on the PC to start the programme. Refer to the FeNOCHART™ manual for how to operate the FeNOCHART™ software.

Troubleshooting

Issue/Alarm	Possible Problem	Remedial Action
The unit fails to turn on	Battery requires charging	Place the device into the docking station or connect directly to the USB cable which must be connected to a power source.
	Battery not inserted	<ol style="list-style-type: none"> 1. Remove service door 2. Remove breath dryer cartridge 3. Insert battery (see 'preventive maintenance')
	Battery out of position	<ol style="list-style-type: none"> 1. Remove service door 2. Remove breath dryer cartridge 3. Reposition battery (see 'preventive maintenance')
	Component/software failure	Contact your local Bedfont [®] representative
Device will not charge	Battery not inserted	<ol style="list-style-type: none"> 1. Remove service door 2. Remove breath dryer cartridge 3. Insert battery (see 'preventive maintenance')
	Battery out of position	<ol style="list-style-type: none"> 1. Remove service door 2. Remove breath dryer cartridge 3. Reposition battery (see 'preventive maintenance')
	Battery failure	Contact your local Bedfont [®] representative for spares
	Component/software failure	Contact your local Bedfont [®] representative
	Device too cold to be calibrated	Leave device in an atmospheric temperature of 21°C ±4°C (68°F ±39°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 (68°F ±39°F) until the temperature range within the device has equilibrated.
Readings abnormally high	Infection Medications Food consumption Age/sex Airway calibre	See 'Contraindications section'
	Ambient NO scrubber requires replacement	<ol style="list-style-type: none"> 1. Remove service door 2. Remove old NO scrubber 3. Insert new NO scrubber (see 'preventive maintenance')
	NO Scrubber not inserted	<ol style="list-style-type: none"> 1. Remove service door 2. Insert NO scrubber (see 'preventive maintenance')
	Ambient NO too high	Please carry out an ambient test (see 'ambient test' section) and check the ambient levels are below 350ppb. Ambient levels above 350ppb may cause elevated readings.

Readings erratic	Sensor has lost bias	<ol style="list-style-type: none"> Place the device into the docking station or connect directly to the USB cable which must be connected to a power source. Once power has been restored to the device and sensor battery wait 24 hours for sensor to regain bias
Readings abnormally low	Smoking status Medications Age/sex Respiratory manoeuvres Airway calibre	See 'Contraindications section'
	Pump running too slow	<ol style="list-style-type: none"> Consult service manual if you have undergone service training. Contact your local Bedfont® representative
	Pump not running	<ol style="list-style-type: none"> Consult service manual if you have undergone service training. Contact your local Bedfont® representative
	NO Scrubber not inserted	<ol style="list-style-type: none"> Remove service door Insert NO scrubber (see 'preventive maintenance')
Pump running but nothing can be seen on screen	Screen brightness too low	Check screen brightness, if able. (see 'screen brightness' section)
	Component/software failure	Contact your local Bedfont® representative
Pump not running	Device is switched off	Switch on device
	Pump running too slow	<ol style="list-style-type: none"> Consult service manual if you have undergone service training. Contact your local Bedfont® representative
	Pump not running	<ol style="list-style-type: none"> Consult service manual if you have undergone service training. Contact your local Bedfont® representative
 Breath test failed	Patient did not keep a constant flow	Retry test keeping a constant flow using the on-screen incentive as a guide
	Mouthpiece not sealing with device	<ol style="list-style-type: none"> Push mouthpiece firmly into mouthpiece aperture Visually inspect if o'ring is present inside mouthpiece aperture Try an alternative mouthpiece
	Pump not running	<ol style="list-style-type: none"> Consult service manual if you have undergone service training. Contact your local Bedfont® representative
	Internal electrochemical switch stuck or failed	<ol style="list-style-type: none"> Consult service manual if you have undergone service training. Contact your local Bedfont® representative
 Calibration failed	Wrong gas concentration	Check gas concentration is correct (see 'gas calibration' section)
	Wrong flow rate used	Check flow meter or regulator is set to 1 L/pm
	Flow meter or regulator not open	Check flow meter or regulator is open and set to 1 L/pm
Clock displays 00/00/00 or date has been lost	Real-time clock (RTC) has been reset	Set time and date (see 'Change the date/time' section)

	RTC battery empty	<ol style="list-style-type: none"> 1. Place the device into the docking station or connect directly to the USB cable which must be connected to a power source 2. Consult service manual if you have undergone service training. 3. Contact your local Bedfont® representative
Red light on the dock	Indicates a fault: overcurrent, under voltage or over voltage.	Only the supplied power adaptor and USB cable should be used to connect the NObreath® dock to mains power. If yours is lost or damaged, contact your local Bedfont® representative.

Returns procedure

If your equipment requires servicing, please contact your local Bedfont® Customer Service Department, distributor or supplier before returning any goods.

1. When you have supplied the Customer Repairs Department with the monitor serial number and description of the fault, you will be issued with a returns/ticket number. Please state the returns/ticket number on the outside of the box when returning the monitor and ensure that your full details, telephone, fax number and return address are clearly stated.
2. The product must also be decontaminated before it is returned according to your local regulations. Bedfont® can provide you with a decontamination certificate to complete, which also needs to be attached to the outside of the box. Failure to do so will result in the product being subject to Bedfont® decontamination procedure and will delay your service/repair.
3. Bedfont® advise that you use a courier service when returning monitors. This enables you to insure goods for loss or damage in transit. When your goods are received, you will be sent an email stating so.
4. If the device has been returned for repair it will then be examined and you will be sent an 'Engineer's Report' and a quotation for the repair, which will include an authorisation form. Complete the authorisation form, and ensure that you include the 'Official Purchase Order Number'. Please contact the Customer Repairs Department if you are unable to supply an 'Official Purchase Order Number'.
5. If your monitor is still in warranty and the fault is covered by warranty, see the 'Warranty' section of this manual. Bedfont® will repair it and return it to you with an 'Engineer's Report', free of charge.
6. If you choose not to proceed with the repair, a handling fee will be charged. Ensure that you return the completed authorisation form with an 'Official Purchase Order Number'.
7. The equipment will be returned to you as soon as Bedfont® has received all relevant paperwork. A carriage fee will be charged if the monitor is no longer in warranty.

Spares

Part Number	Description
NObreath [®] Mouthpiece	The NObreath [®] mouthpiece contains a one-way valve to prevent patients drawing air back from the monitor. An integrated infection control filter removes and traps >99% of airborne bacteria and >96% of viruses ⁴ .
Monitor cleaning wipes	Free from alcohol to ensure continued performance of your monitor. Products containing alcohol cannot be used on any of the Smokerlyzer [®] range.

Warranty

Bedfont[®] Scientific Limited warrants the NObreath[®], sensor and batteries excepted, to be free of defects in materials and workmanship for a period of 2 years from the date of shipment, subject to service and maintenance requirements.

The NO sensor is guaranteed for a period of 6 months only from the date of shipment from Bedfont[®].

Bedfont'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 Bedfont[®] or the local representative.

NOTE: *The product warranty is automatically invalidated if the security seal is broken or if the products are repaired, altered or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.*



Never dispose of any electronic instrument or batteries in domestic waste. At the end of the product's life, contact Bedfont[®] or its distributor for disposal instructions. Single use consumables and accessories should be disposed of in line with local clinical waste guidelines.

References

1. Saito J, Gibeon D, Macedo P, Menzies-Gow A, Bhavsar P, Chung K. Domiciliary diurnal variation of exhaled nitric oxide fraction for asthma control. 2017.
2. Correlation of Exhaled Nitric Oxide, Spirometry and Asthma Symptoms: Journal of Asthma: Vol 42, No 10 [Internet].Tandfonline.com. 2017 [cited 15 March 2017]. Available from: <http://www.tandfonline.com/doi/abs/10.1080/02770900500371344>
3. ATS/ERS Recommendations for Standardized Procedures for the Online and Offline Measurement of Exhaled Lower Respiratory Nitric Oxide and Nasal Nitric Oxide, 2005; American Journal of Respiratory and Critical Care Medicine; vol. 171: 912-930;2005
4. Public Health England. An Evaluation of Filtration Efficiencies Against Bacterial and Viral Aerosol Challenges Report No. 17/001. London: Public Health England; 2017.



Contact Bedfont® or one of our worldwide **NObreath®** distributors for a free demonstration.

www.bedfont.com
Tel: +44 (0)1622 851122
Email: ask@bedfont.com

A full list of our worldwide distributors can be found at
<http://www.bedfont.com/distributors/>

Our family, innovating health, for yours.

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