

# NObreath®



## User manual



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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. For use by healthcare professionals, it is intended for use in a healthcare environment and should be used in conjunction with other clinical and laboratory evaluation where appropriate.

nitric oxide and nasal nitric oxide.

The patient shall exhale at 50ml/sec, into the mouthpiece (applied part) using the NObreathFlo sample system connected to the instrument, until a reading is displayed.

The NObreath® is also capable of performing an ambient air test as required.

## 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 conditions<sup>1</sup>. Nitric oxide measurement is not intended as a stand alone method for diagnosis and should be used in conjunction with other evaluation methods and tests<sup>2</sup>.



## Product Description

The NObreath® is a hand-held breath nitric oxide monitor.

The measurement system is based on electrochemical sensor technology, which has been specifically designed for this application. The sensor reacts to the presence of nitric oxide producing an electrical output. The sensor has nitric oxide free air flowing into the sensor chamber while the unit is on but not in the breath test mode.

The NObreathFlo 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

## Warnings

- Please 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.
- The battery life is indicated by the green  icon. When the amber  icon is displayed the batteries should be changed.
- Check for battery leakage before use, after extended periods of storage.
- Breath tests must only be carried out with Bedfont accessories. Failure to do so may cause incorrect readings.
- 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.
- Patients should exhale for the duration of time indicated by the monitor during a breath test. Failure to do so may cause incorrect readings.
- 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. The ball in the NObreathFlo™ should be kept within the white band in the centre of the tube during a test.
- The mouthpiece may become warm to the touch after use.
- The NObreathFlo™ should be used for 50 patients only, then disposed. A new NObreathFlo™ is provided with each pack of 50 mouthpieces.
- Do not block the exhaust port on the device at any time. Blocking the exhaust port may cause erroneous readings.
- See Bedfont's infection control and maintenance guidelines for further information on infection control.
- 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.
- Bedfont® will make available on request service training to appropriately qualified personnel

## Contraindications

- The sensor has some cross-sensitivities to breath gases. These are low and should not affect readings. Please contact Bedfont® for more information.

## Caution

- Ensure the monitor is used within the temperature and relative humidity (Rh) range as stated in the specification on page 5.
- Portable and mobile RF communications equipment can affect the NObreath®.
- Federal law restricts this device to sale by or on the order of a physician (USA only).

## Pack contents list

- 1 Instrument
- 2 Operation instructions
- 3 AA batteries
- 4 Mouthpieces
- 5 NObreathFlo™
- 6 Infection control and maintenance guidelines
- 7 Instrument cleansing wipes
- 8 BreathGAS CD
- 9 Cleaning cloth
- 10 Stylus
- 11 A5 chart
- 12 Quick start guide



## Specification

Exhaled flow during FeNO measurement at 50mls/sec  $\pm 10\%$  at 10cm H<sub>2</sub>O.

Concentration range	5-300ppb
Display	Colour LCD with touchscreen
Detection principle	Electrochemical sensor
Repeatability	$\pm 5\text{ppb}/\pm 10\%$ of measured value - whichever is greater*
Accuracy	$\pm 5\text{ppb}/\pm 10\%$ of measured value - whichever is greater*
Power	3 x AA (LR6 or equivalent) up to 120 tests 2 x CR2032 lithium coin cell
T <sub>90</sub> response time	<10 seconds
Operating temperature	10-30°C
Storage/transport temperature	10-30°C
Operating/storage/transport pressure	Atmospheric $\pm 10\%$
Operating humidity	10-75% non-condensing
Storage/transport humidity	25-80% non-condensing
Sensor operating life	5 years**
Sensor sensitivity	5ppb
Sensor drift	<5% per annum
Dimensions	Approx. 152 x 87 x 47mm
Weight	Approx. 400g (including batteries)
Materials	Case: polycarbonate/ABS blend with elastomeric overmould NObreath Flo™: polycarbonate/ABS blend Mouthpiece: polypropylene
CO cross interference	45ppm $\leq$ 17.6ppb
Breath test time	Adult 12 seconds/child 10 seconds
Warm-up time	<60 seconds
Ambient air test	30 seconds
Maximum ambient operating level	350 ppb NO

\* Readings of  $\geq 200\text{ppb}$  at temperatures between 20-30°C can decrease accuracy to  $\pm 15\%$  of measured value.

\*\* Subject to servicing.

## Symbols

Degree of protection against electric shock:



Type BF applied part

Degree of protection against ingress of liquid: IPX0 - not protected against water ingress



CE mark



Dipose of according to WEEE



Consult instructions for use.



Manufacture by and date

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.

Environment: The NObreath® complies with the directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN50082-1. This equipment should be moved if necessary to avoid interference.



Direct current

Type of protection against electric shock:  
Internally powered equipment



Please refer to the warnings and safety notes in this manual

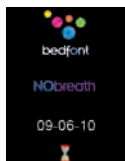
## Instrument layout

- 1 Display
- 2 On/off button
- 3 Aperture for NObreathFlo™
- 4 NObreathFlo™
- 5 NObreath® mouthpiece (applied part)
- 6 Exhaust port for breath sample
- 7 Sounder outlet
- 8 Battery compartment



## Display symbols

1. Start-up screen:



2. Battery condition  
red, amber, green



3. Sounder: on off



4. Start breath test: Adult Child



5. Start ambient air test:



6. Settings:



7. Return to main menu:



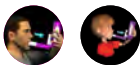
8. Return to previous menu:



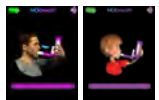
9. Inhale:



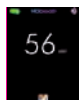
10. Exhale for breath test:



11. Progress bar



12. Final reading:



13. Calibration menu:



14. Perform zero check:



15. Calibration (unavailable):



16. Pump Speed (unavailable)



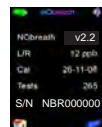
17. Acknowledge zero/calibration: pass fail



18. Set date/time:



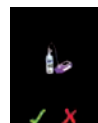
19. System info screen:



20. Contact Bedfont® or distributor  
for help:



21. Service reminder:





## Maintenance

- The NObreath® should be calibrated annually.
- The NO sensor and pump should be replaced every 5 years.
- The mouthpieces are single patient use only and should be replaced between tests.
- Replace batteries when indicated.
- Replace the NObreathFlo™ every 50 patients.
- **It is recommended that batteries are left in the monitor at all times, even when not in use to prevent loss of bias voltage to the sensor.**



**Check for battery leakage before use, after extended periods of storage.**

- Never open the unit or attempt to service the unit without prior training from Bedfont®. Doing so will invalidate the warranty and performance cannot be guaranteed.
- Additional technical information can be made available on request; please contact Bedfont® or its distributor.

**Bedfont® will make available upon request service training to appropriately qualified persons.**

## Cleaning

- Wipe the instrument and external NObreathFlo™ surfaces with a product specifically developed for this purpose. Bedfont® provides instrument cleansing wipes.
- 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 in liquid or splashed with liquid.

## Operation





Ensure 3 good quality AA alkaline batteries are correctly located in the battery compartment.

The touchscreen controls all functions once the instrument is switched on.

Press the on/off button until the display becomes active. Release the button.

The device start-up takes 60 seconds, during which time the start-up screens are displayed. During this time the unit is performing a zero measurement by pumping NO free air into the sensor chamber. Ensure the exhaust port is not blocked.

The main menu displays four symbols:

- |   |                   |   |
|---|-------------------|---|
| 1 | Child breath test |    |
| 2 | Adult breath test |    |
| 3 | Ambient air test  |   |
| 4 | Setting menu      |  |







## Performing a breath test



To perform a new breath test attach a new mouthpiece to the NObreathFlo™. Once secured, attach the NObreathFlo™ and mouthpiece to the device. Ensure all connections are pushed firmly together.

**The monitor must be held upright at all times during a test.**

The screen will guide the patient through a breath test from the icons on the screen.

To start a breath test, touch the  or  icon. The unit will beep once.

The  or  icon will appear, during which the patient should take a comfortable inhalation of air (**not through the mouthpiece**).



After 3 seconds, the icon shall change to  or  and the unit shall give a double beep to signal that the patient should start to exhale. The patient should then exhale through the mouthpiece and NObreathFlo™, ensuring that the ball in the flow indicator is held in the middle of the band on the NObreathFlo™.





The exhalation time is approximately 12 seconds for an adult and 10 seconds for a child, a progress bar is shown at the bottom of the screen. Patients should continue to exhale until the progress bar has reached its limit, double beep sounds, and then the reading is displayed in ppb (see warnings, page 3).

After a patient test has been completed, remove the NObreathFlo™ and mouthpiece from the NObreath® and then remove and dispose of the mouthpiece safely. This

should be done in accordance with local waste disposal guidance.

The  icon shall appear at the end of the test, 60 seconds after the reading is displayed. This allows time for the sensor to settle to zero before the next test. Touch  to return to the main menu.

To start another patient breath test, fit a new mouthpiece and touch the  or  icon.

If no further tests are required, press and hold the on/off button for 3 seconds then release to turn off. If left on, the NObreath® will automatically turn off after 5 minutes of inactivity.

To view the last reading taken on the instrument, go to the System Information screen. See page 10 for details.



## Ambient NO test

The NObreath® can measure the level of nitric oxide in the surrounding ambient air. This is important as the NObreath® has been designed to function in environments containing less than 350ppb NO.

**Ensure the NObreathFlo™ is not connected.**


Touch the  icon to start a test.

The ambient air reading shall be displayed after 30 seconds.

The  icon shall appear at the end of the test, 60 seconds after the reading is displayed. This allows time for the sensor to settle to zero before the next test. Touch  to return to the main menu.

If no further tests are required, press and hold the on/off button for 3 seconds then release to turn off. If left on, the NObreath® will automatically turn off after 5 minutes of


## Settings

Touch the  icon to access the following functions.

- Sounder
- Set date/time
- System information
- Zero/calibration


### Sounder



The status of the sounder is indicated by the small symbol on the top line of the display.

To change from sounder-on to sounder-off (or back again), touch the large  icon in the settings menu. The large sounder symbol and the small symbol on the top line of the display will change to show whether the sounder is on or off.

Even if the sounder has been turned off, it will continue to operate during the breath test process.




### Date and time

To change the date and time, touch  in the Settings menu.




Touch the required field and use  or  to change.

Press  to save or  to cancel. Return to main menu.

### System information

Touch  to access system information. This screen provides information on: the software version number; the last reading taken ; the date the unit was last calibrated at Bedfont®, the number of breath tests taken and the serial number. Touch  to return to the main menu.

## Servicing






- Calibration should only be undertaken by Bedfont®. Any third party attempt to calibrate the unit could result in inaccurate readings and invalidate warranty.
- Batteries should always be replaced with good quality AA batteries when the amber  icon is displayed.
- The  icon will show when this service is required.
- Press  to continue to the main menu.
- Any consumables will be replaced, if necessary, during the yearly service. This may include replacing the sensor.

### Further information

- The NObreathFlo™ is replaceable after 50 patients have been tested. A new NObreathFlo™ is supplied with every pack of 50 mouthpieces.
- The minimum time between breath tests for a single patient is two minutes.

## Troubleshooting

If the unit fails to turn on properly, or if the low battery symbol is showing, replace the 3 x AA alkaline batteries. Ensure that the batteries are inserted correctly, matching the symbols moulded into the plastic.

If the display shows  after zeroing, a second attempt can be made. Check that the unit is in fresh air and touch  to restart the zero process. If, after a third zeroing attempt, the display shows  again, the unit will have to be returned to Bedfont® or its distributor for investigation and repair. In this case, the display shows  . The unit can be turned off by holding the on/off button for three seconds then releasing. It is possible to re-start the unit and attempt the zeroing process again.

## Returns procedure

The NObreath® requires servicing every 12 months. The servicing shall be carried out by Bedfont® alone. Please contact bedfont's customer service specialist before returning any goods. If equipment was not purchased direct from Bedfont®, please contact the local distributor.

- When the monitor serial number (located on the information screen and in the battery bay) and description of the fault have been supplied, the customer repairs department will issue a returns number.
- State this number when returning the monitor, ensuring full details, including telephone and fax numbers, are clearly provided.
- Bedfont® advise using a courier service and not local postal services when returning monitors.
- Confirmation will be sent when goods are received.
- An engineer's report and a quotation for the repair will be sent following investigation. This includes an authorisation form.
- If the monitor is still within warranty, Bedfont® will repair and return it with an engineer's report, free of charge. If, after inspection, no fault is found, a fee will be charged.
- If outside of warranty, complete the authorisation form within the quotation to proceed with the repair or calibration. Ensure an official purchase order number is included, and return to Bedfont®. Contact the customer repairs department with any queries.
- If it is decided not to proceed with the repair, a handling fee will be charged. Ensure the completed authorisation form is returned with an official purchase order number.
- The equipment will be returned as soon as Bedfont® have received all the relevant paperwork. A carriage fee will be charged if the monitor is no longer in warranty.
- Return the unit in the original packaging, in the sealed container.

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A return ticket can also be opened at [www.bedfont.com/support\\_ticket](http://www.bedfont.com/support_ticket)

## Spares

Part number	Description
NTK-50	NObreathFlo™ and 50 mouthpieces
WIPES	Non-alcoholic instrument cleansing wipes
BAT048	AA alkaline batteries x 3

The above spares are available from Bedfont® UK. For spares availability in all other countries, contact your local distributor. To ensure continued accuracy, only Bedfont® spares should be used.

## References

<sup>1</sup> 14. 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.

<sup>2</sup> 13. 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>

## Warranty

Bedfont® Scientific Limited warrants the NObreath® (batteries excepted) to be free of defects in materials and workmanship for a period of two years from the date of shipment. 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:** Sensors are guaranteed for a period of six months from the date of shipment from Bedfont®.

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.





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