

NObreath® Introduction





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Navigation Tips

- ▶ Click on  to return to the index from any slide.
- ▶ Click on page # / description to jump to section

About coVita



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- ▶ coVita has **over 45 years** of expertise in the development of breath analysis devices.
- ▶ coVita provides all, sales, service, and support from our offices located in the **USA**.
- ▶ www.covita.net | 800.707.5751 | info@covita.net





Support, Service & Training

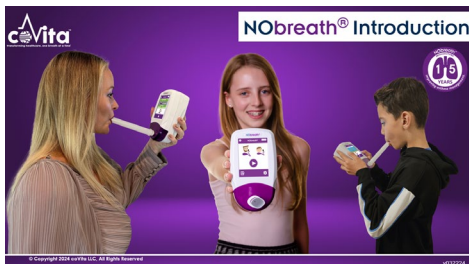


- ▶ coVita has a reputation for providing gold standard devices, sales, service, and support from our offices located in the **USA**.
- ▶ Most issues can be resolved remotely with a quick troubleshooting call.
- ▶ coVita will provide all necessary manuals, quick start guides and support material in electronic format.
- ▶ coVita can schedule remote trainings as needed.
- ▶ **NObreath**® includes a **5-year warranty** on the entire monitor including the sensor
- ▶ www.covita.net | 800.707.5751 | info@covita.net

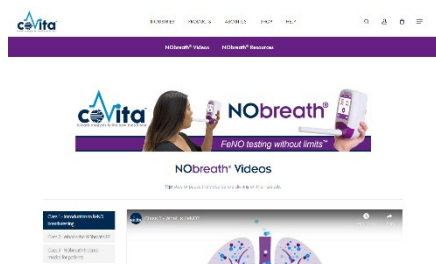


Handheld

NObreath® | Reference Materials



NObreath® Introduction Presentation



NObreath® Education Portal



Download FeNOchart™

FeNOchart™ Manual



Datasheet



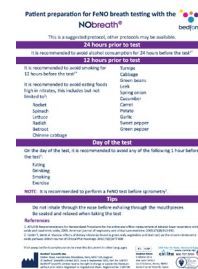
Quick Start Guide



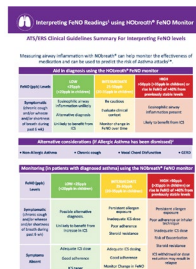
Manual



Infection Control & Maintenance Guidelines



Patient Prep



FeNO Interpretation Chart



CPT Reimbursement

Personal Chart & Test Log (1 Page)

Personal Chart & Test Log (2 Page)

Personal Chart Only

Group Test Log

NObreath® Reference Materials



NObreath® | Intended Use

- ▶ The NObreath® 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.
- ▶ Assessment of FeNO using the NObreath® 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 NObreath® according to guidelines for NO measurement established by the American Thoracic Society.
- ▶ NObreath® is intended for children 7-17 years and adults 18 years and older.



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NObreath® Intended Use

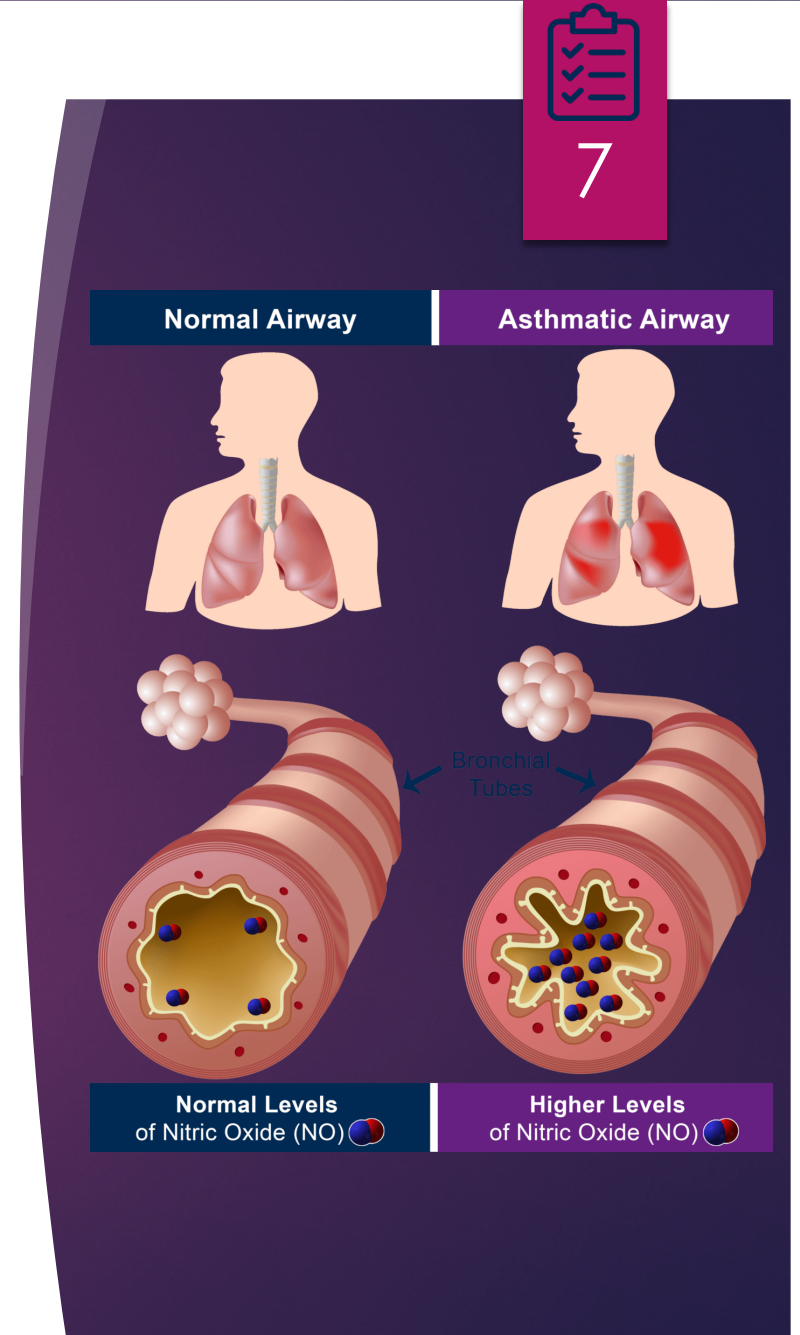


NObreath® | Benefits of FeNO Testing

- ▶ Non-invasive, quick, and easy to perform¹
- ▶ Shows patient's response to treatment, enabling the correct prescription of medication and safer/monitored adjustments
- ▶ Aids in identifying patients who do/do not require on-going treatment²
- ▶ Shows patient compliance⁴
- ▶ Shown to be superior to the majority of conventional tests of lung function, such as peak flow recording and spirometry¹
- ▶ Aids in differentiating between allergic (eosinophilic) and non-allergic asthma³

References

1. Andrew D. Smith, Jan O. Cowan, Sue Filsell, Chris MacLachlan, Gabrielle Monti-Sheehan, Pamela Jackson and D. Robin Taylor. Diagnosing Asthma: Comparisons between Exhaled Nitric Oxide Measurements and Conventional Tests. Am J Respir Crit Care Med Vol 169. pp 473-478, 2004.
2. D R Taylor, MW Pinenburg, A D Smith and J C D Jongste. Exhaled nitric oxide measurements: clinical application and interpretation. Thorax 2006;61:817-827.
3. Coumou HBel E. Improving the diagnosis of eosinophilic asthma [Internet]. Taylor and Francis online. 2017 [cited 15 March 2017]. Available from: <http://www.tandfonline.com/doi/full/10.1080/17476348.2017.1236688>
4. Beck-Ripp J, Griese M, Arenz S, Koring C, Pasqualoni B, Bufler P. Changes of exhaled nitric oxide during steroid treatment of childhood asthma. Eur Respir J 2002;19:1015–1019.





Reimbursement

Do you bill insurances for medical services?



REIMBURSEMENT FOR A NObreath® BREATH FeNO TEST

CPT Code: 95012 - Fractional Exhaled Nitric Oxide (FENO) measurement, is approved in the assessment of adult and pediatric beneficiaries with suspicion of asthma and for asthma management.

Reimbursement

FeNO testing and its importance continues to grow year after year. The **NObreath®** makes FeNO monitoring, which is recommended by **The American Thoracic Society** (ATS), quick and easy plus it is completely non-invasive, with the ability to monitor airway inflammation in both adult and child patients.

- >95% of CPT® 95012 Medicare claims were paid¹, and most private payers do offer coverage for FeNO testing.

Please see our current [FeNO CPT Reimbursement Guide – CLICK HERE](#) – includes information on:

- **FeNO Testing CPT Code**
- **Evaluation and Management**
 - CPT Codes and modifiers for new patients and established patients
- **Guidelines** for reporting evaluation and management codes with FeNO testing.

References

1. CodeMap® [Internet]. Codemap.com. 2022 [cited 30 August 2022]. Available from: <https://www.codemap.com/physicianfee2020.cfm>



NObreath[®] | Key Benefits

Breath tests don't expire



Unlimited Uses*



Complimentary
5 year warranty on monitor & sensor



Low cost mouthpieces,
with both bacterial and viral protection



Simple, exhale-only technique



Compact, handheld design



SteriTouch[®] antimicrobial technology
integrated into monitor housing¹



Includes database software to
store results and generate custom reports



NObreath[®] display can be mirrored on PC



No special storage box required



Reimbursable CPT Code: 95012
fractional exhaled nitric oxide (FeNO)

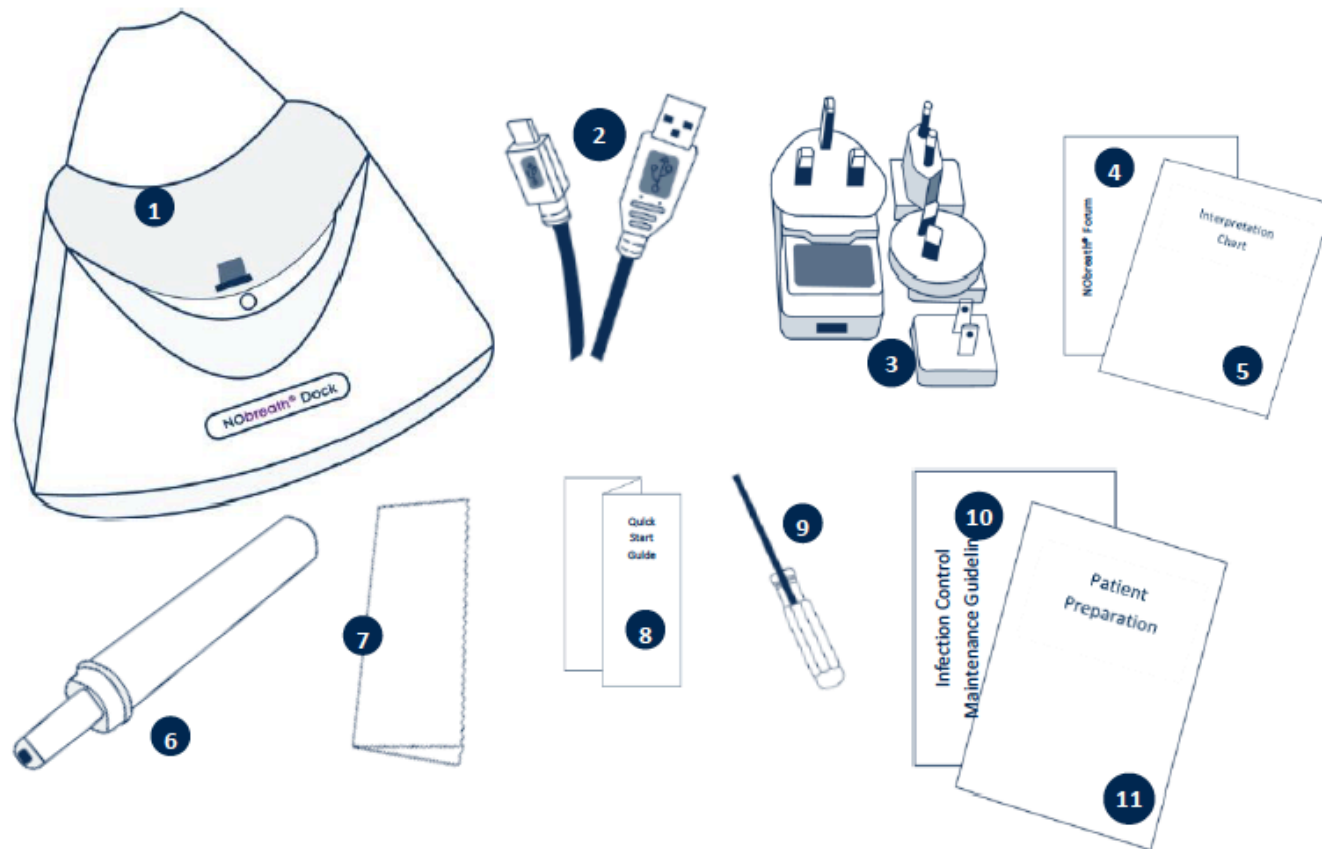


FDA cleared &
Conforms to ATS/ERS guidelines





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1. NObreath® Dock
2. USB cable
3. Mains plug and universal adaptors
4. NObreath® Forum information
5. Interpretation chart
6. NObreath® mouthpiece
7. Microfiber cloth
8. Quick Start Guide
9. Screwdriver - Used for removing back cover
10. Infection Control Maintenance Guidelines
11. Patient Preparation
12. NObreath® Monitor

NObreath® Parts & Accessories



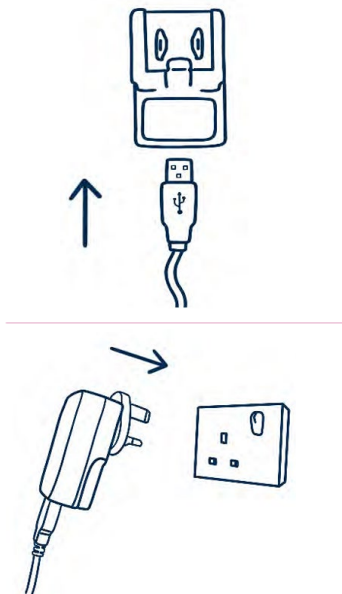
1.

Plug the small end of micro-USB cable directly into the NObreath®.

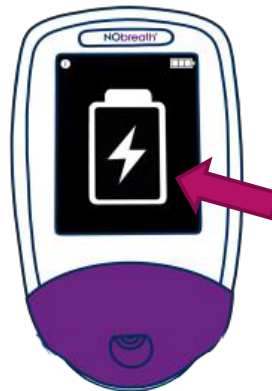


2.

Plug large end of the micro-USB cable into power supply and plug power supply into an outlet.



NObreath® is charging when you see the battery symbol on the screen.



- ▶ NObreath® can only be charged when the **monitor is off**.
- ▶ NObreath® **auto shuts off** after 5 minutes of inactivity, to preserve battery life. Monitor will beep after 4:30 minutes and will turn off 30 seconds later if the screen is not touched.
- ▶ NObreath® should be **left charging when not in use**.
- ▶ NObreath® must be charged once battery indicator is down to one bar.

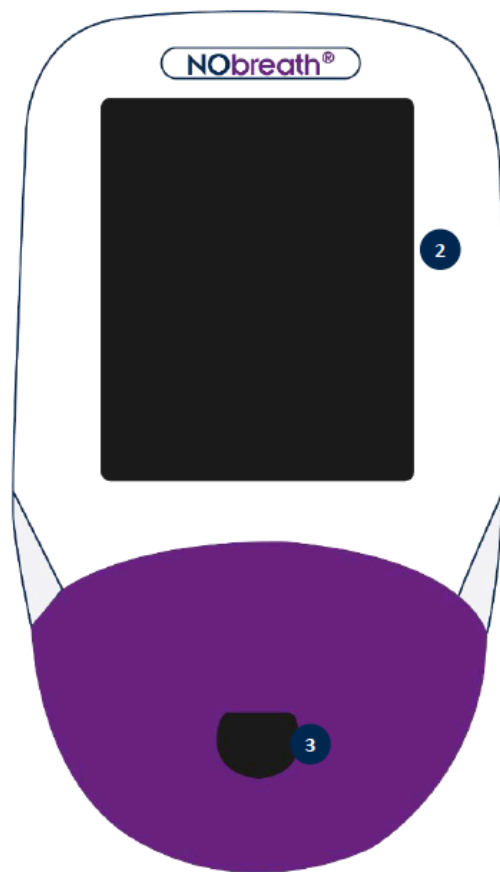


11

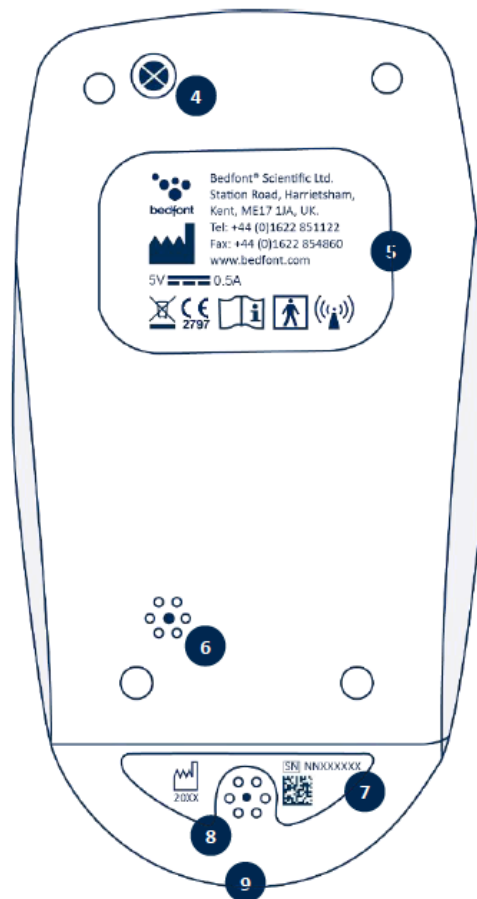
NObreath® Charging



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1. ON/OFF switch
2. Touchscreen
3. Mouthpiece aperture
4. Screw

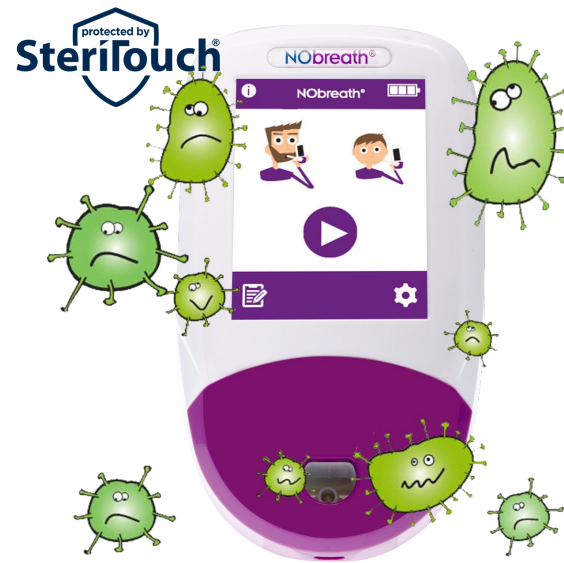


5. Manufacturer label
6. Vent hole
7. Serial label
8. Vent hole
9. USB port

NObreath[®] Layout



- Individually wrapped to aid in handling, for the highest infection control.
- The 2nd Generation **NObreath®** mouthpiece has an **infection control filter**, which has been tested vigorously to prove it removes and traps **>99% airborne bacteria** and **>98% airborne viruses (including COVID-19)**¹.
- The mouthpieces are single-patient use only and can be used for a maximum of 10 tests per patient visit.



- Integrated into **NObreath®** housing is Steritouch®, an antimicrobial additive, which eradicates bacteria that cause contamination and infection
- Never use alcohol or cleaning agents containing alcohol or other organic solvents on the **NObreath®** as these vapors will damage the electrochemical sensor inside.
- Under no circumstances should the **NObreath®** be immersed or splashed with liquid.



NObreath® Infection Control

- The **NObreath®** mouthpiece has been tested to filter viruses as small as 23 nanometers in diameter and the COVID-19 virus particle has an approximate diameter of approximately 125 nanometres².
 - Due to the risky nature of testing live respiratory viruses, a non-pathogenic virus model is used (M2-Coliphage). The filters undergo both bacterial filter efficiency (BFE) and viral filtration efficiency (VFE). The virus model is incredibly penetrable, even more so than a majority of human viruses, therefore makes it a very affective model to use for virus filtration efficiency (VFE) testing. The model virus is approximately 24-26 nanometers in size ¹ in comparison to COVID-19 virus which is approximately 125 nanometers in size ².
 - Therefore, Bedfont® can conclude that bacterial and viral pathogens (**including COVID-19**) will effectively be removed by both the **NObreath®** mouthpiece filter at an efficiency rate of **>99% (Bacteria)** and **>98% (viruses)**¹.

References

1. Berkeywaterkb.com. 2020. Is The MS2 – Fr Coliphage Still Known To Be A Good Indicator Of Virus Filtration? Do You Have Tests On Any Other Viruses? – Berkey Knowledge Base. [online] Available at: <http://berkeywaterkb.com/is-the-ms2-fr-coliphage-still-known-to-be-a-good-indicator-of-virus-filtration-at-least-one-article-suggests-that-it-might-not-be-do-you-have-tests-on-any-other-viruses/> [Accessed 12 June 2020].
2. Avon-protection.com. 2020. [online] Available at: https://www.avon-protection.com/downloads/product_brochures/GR04471-01%20Coronavirus%20-%20WHITE%20PAPER.pdf [Accessed 12 June 2020].



Power on: Hold for **3 seconds** and release (you will hear a beep.)



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NObreath® | Home & “i” Information

1. Information



2. Battery Status

3. Adult Test



4. Adolescent test



5. Demo mode



6. Patient Profiles



7. Settings



Information Screen

i	NObreath®	
Test No.	XXXX	
Cal date	XX/XX/XX	
Serial No.	NNXXXXXXX	
Sensor date	XX/XX/XX	
Sensor serial No.	XXXXXXXXXX	
Firmware	VX.XX	

“i” Screen

Pressing the “i” icon displays monitor information:

- number of tests performed
- calibration date
- serial number
- sensor date
- sensor serial number
- firmware version

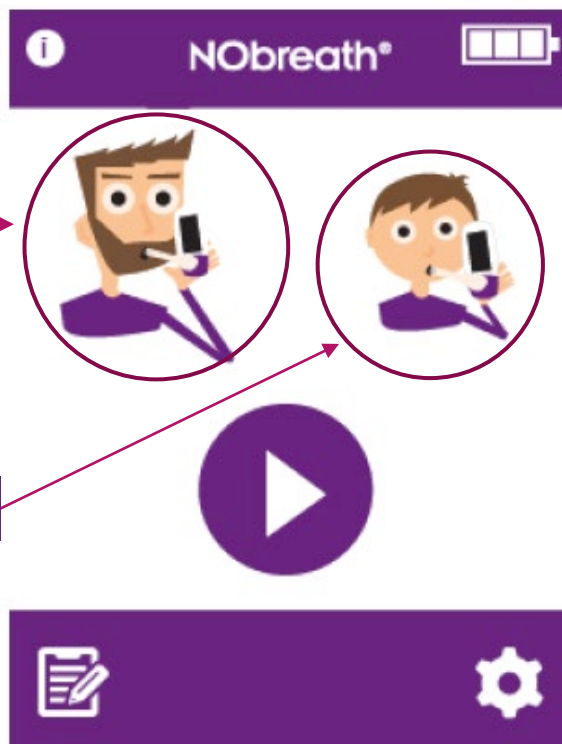


NObreath[®] | Adult vs Adolescent Breath Test Modes

What's the difference?

Adult Breath Test

Adolescent Breath Test



- The manual states the following:
- NObreath[®] Adult mode is for age 7 and up.
- NObreath[®] Adolescent mode is for ages 7-10 only who cannot successfully complete the adult test.



NObreath® | Demo Mode

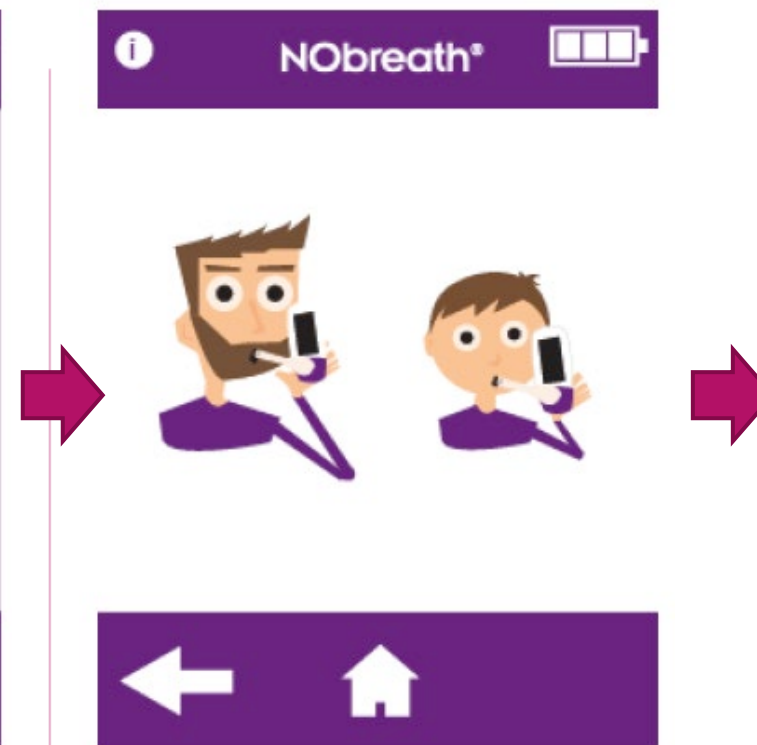
The NObreath® has an in-built demonstration video of the breath test process for both the adult and adolescent mode.

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.

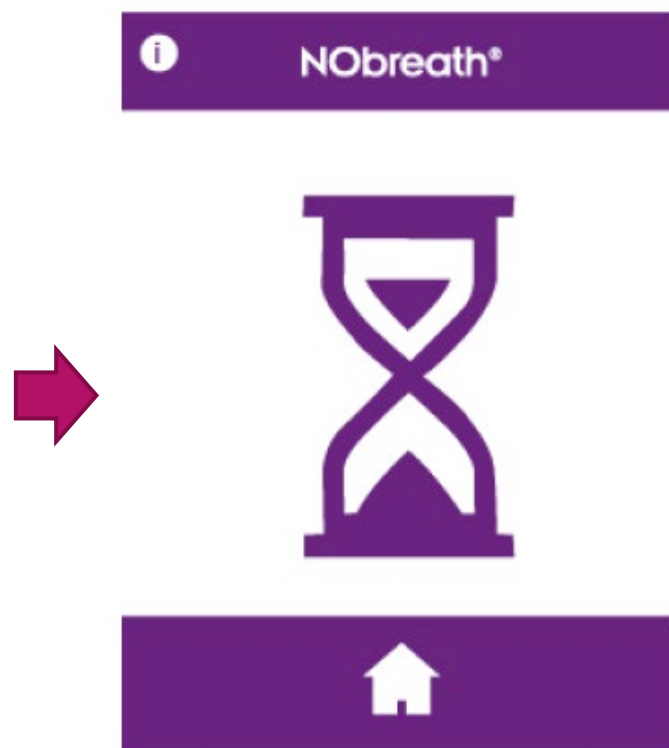


Select either the adult or child.

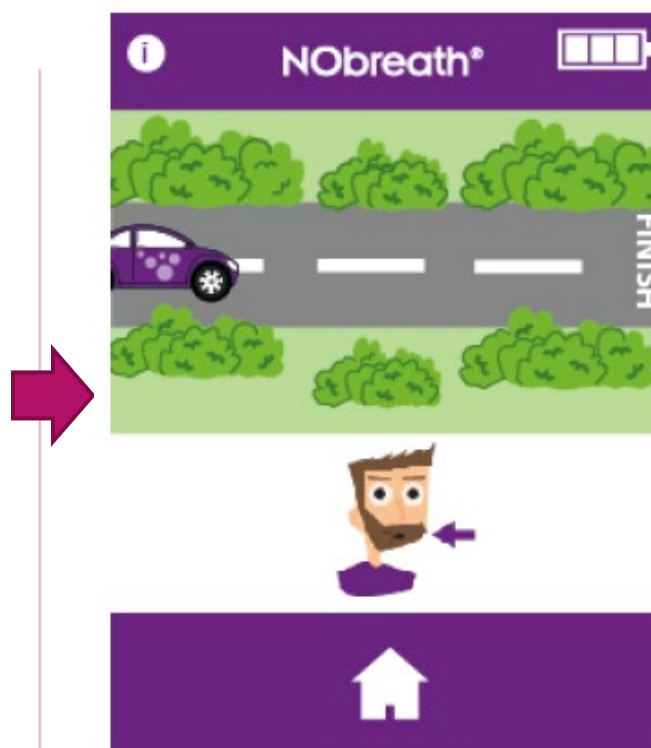


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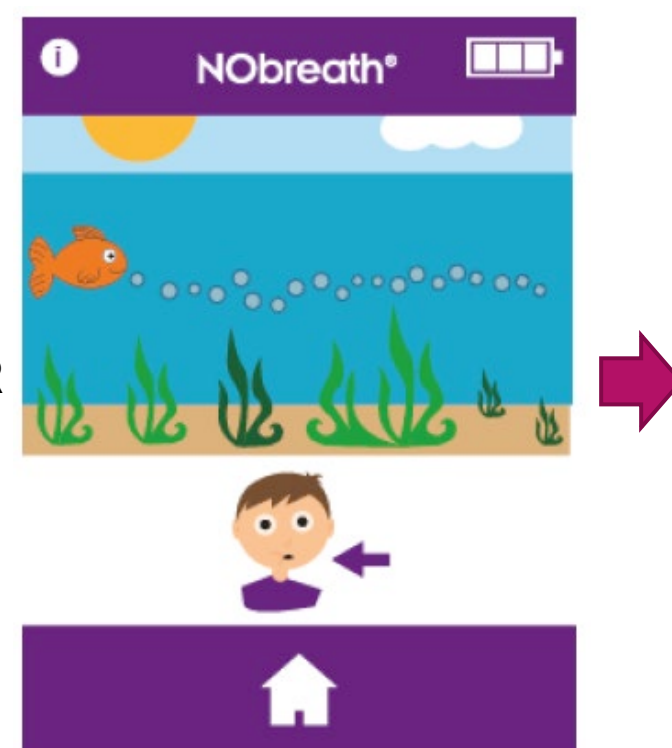
NObreath® | Demo Mode



A brief hourglass with display to mimic a real test.



OR



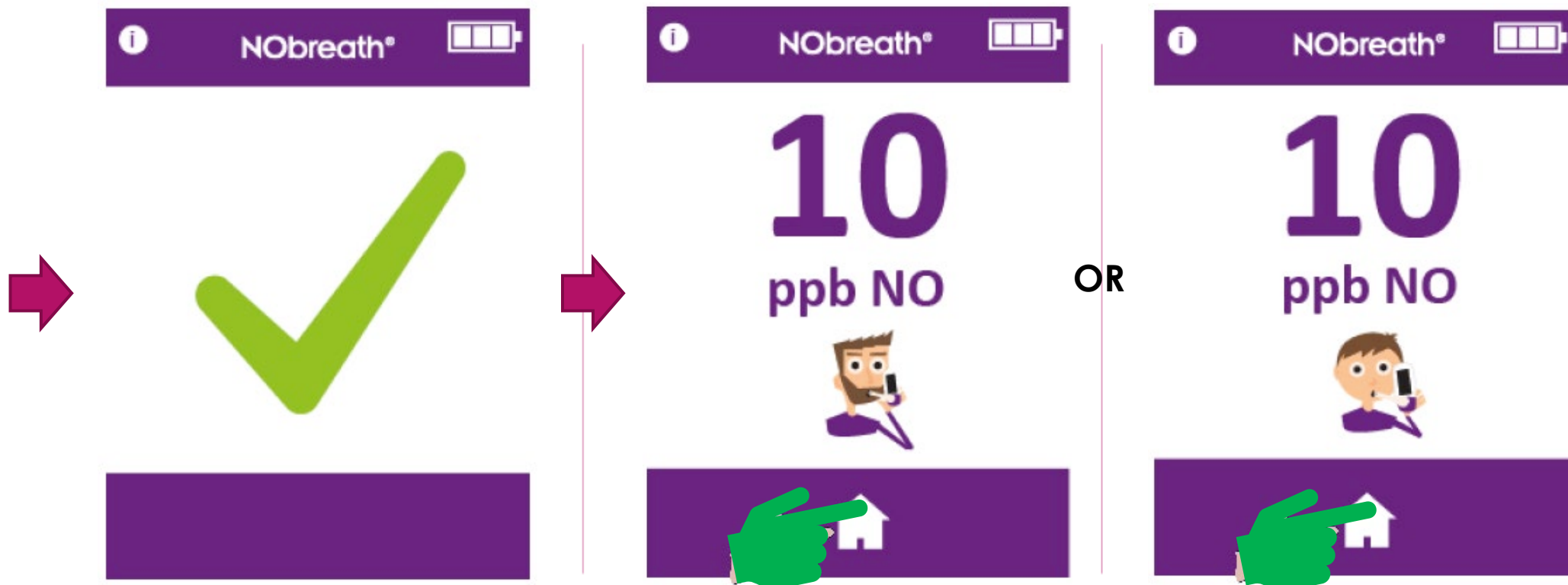
The demo will run through the breath test process but at an accelerated speed. The goal of the test is to keep car on the road or the fish following the bubbles.

Note: The flow-meter visual motivator may be different based on your default selections.



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NObreath® | Demo Mode



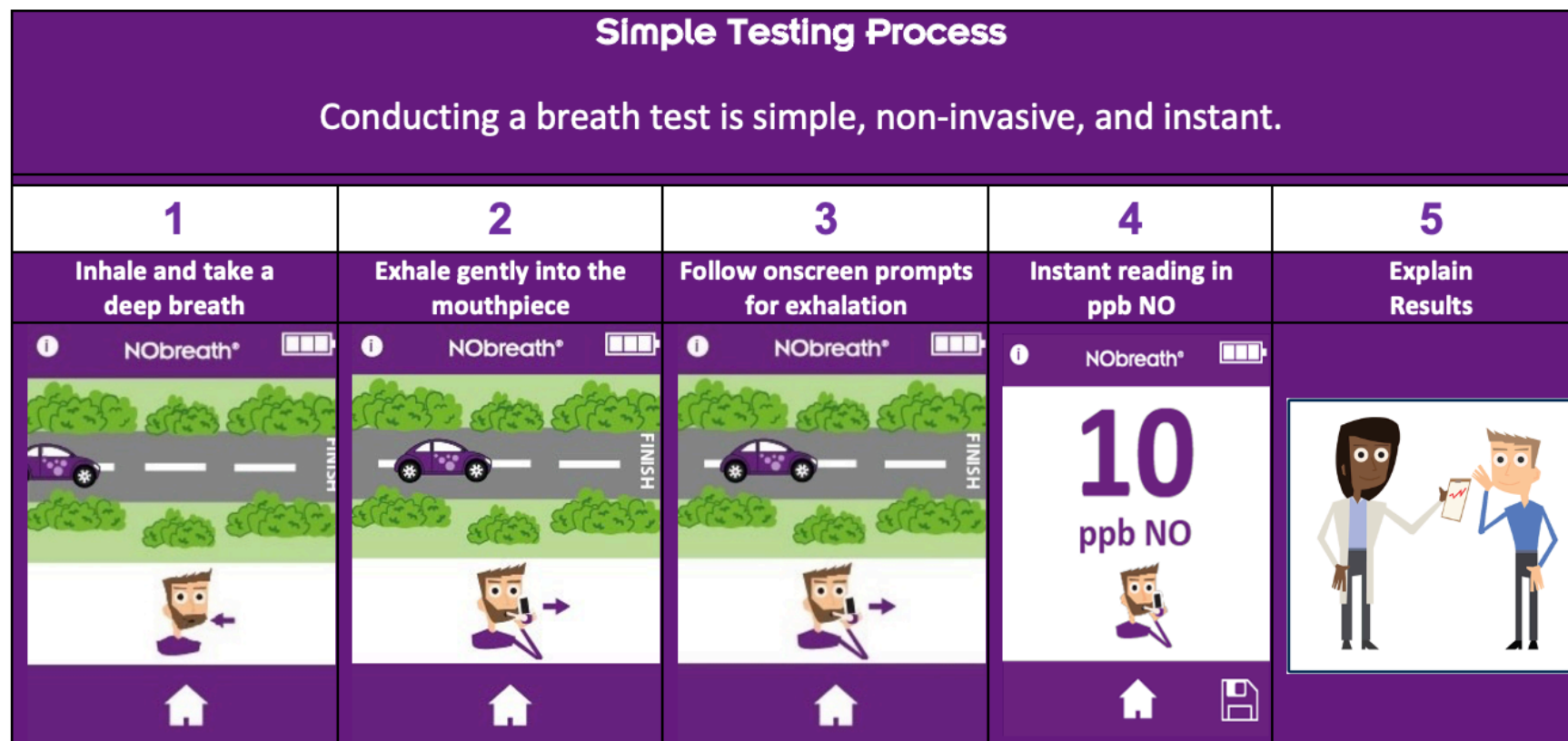
A check mark will be displayed

Once the result is displayed, the demo is complete.

Press the home icon to return to the home screen when in either adult or child mode.



NObreath[®] | Breath Test Overview





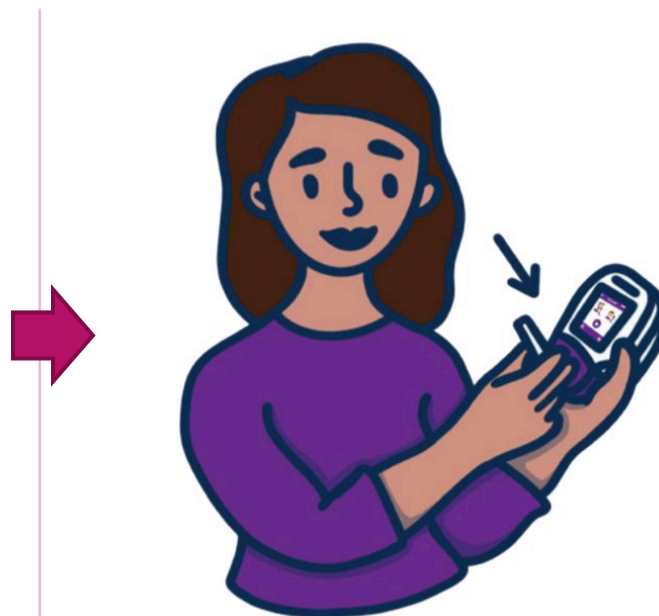
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NObreath[®] | Breath Test | Inserting Mouthpiece



Open an individually wrapped
NObreath[®] mouthpiece.

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Insert small end of the
NObreath[®] mouthpiece into the
NObreath[®] monitor.



Turn on your **NObreath[®]** by pressing the on/off
button on top of the monitor for **3 seconds** (you will
hear a beep) and then release.

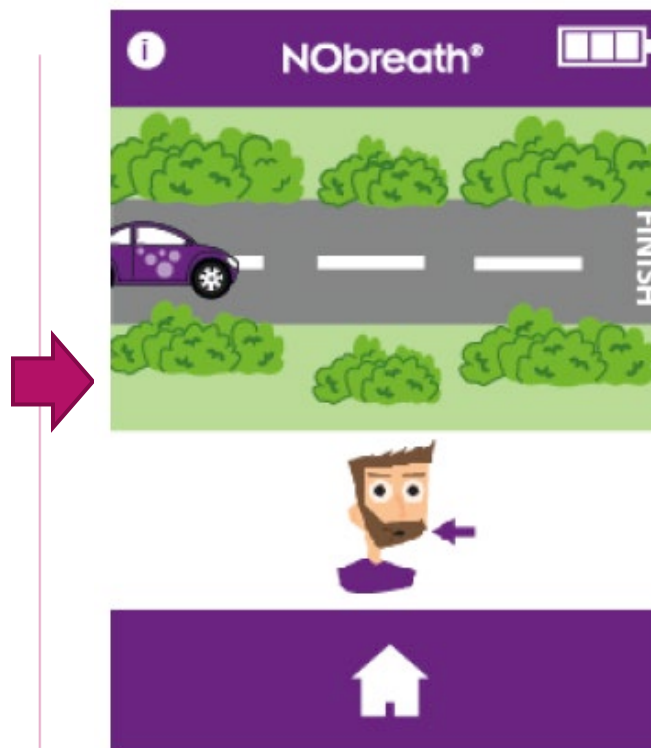


21

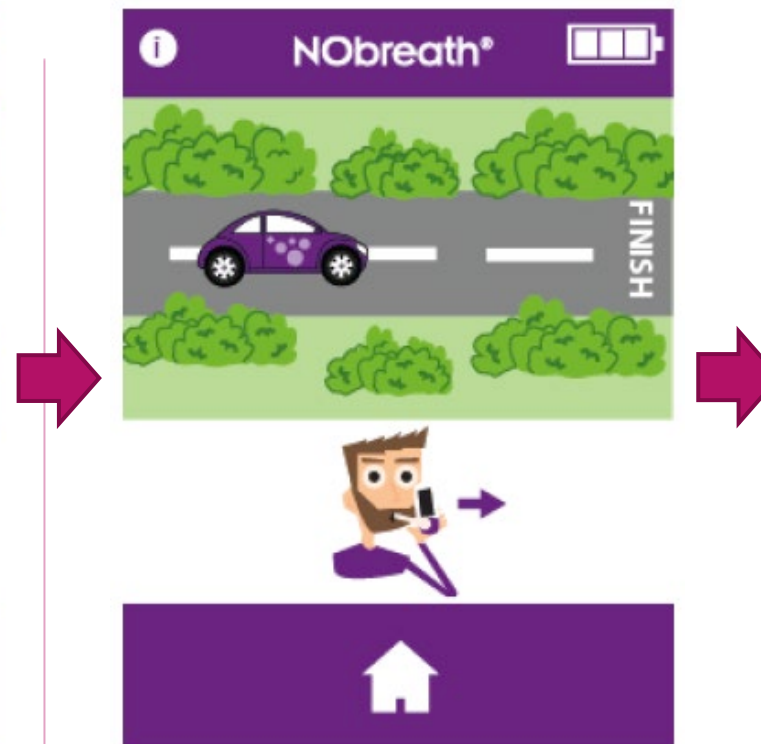
NObreath[®] | Breath Test



Select either adult or adolescent mode.



As prompted onscreen, inhale fresh air through mouth only.

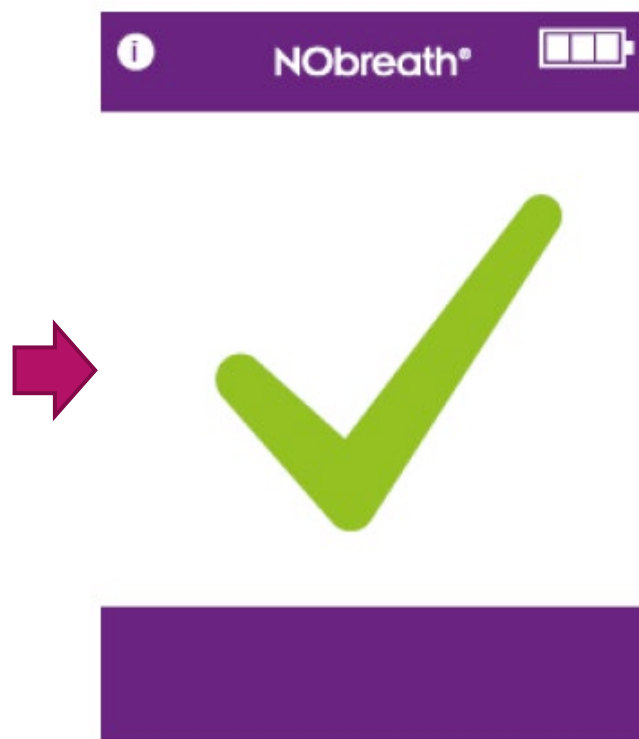


When the exhale icon displays, blow gently into the mouthpiece. Goal is to keep the car on the road.



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NObreath® | Breath Test



A check mark will be displayed



The patient result will be shown onscreen in ppb. Return to home screen by pressing home icon.

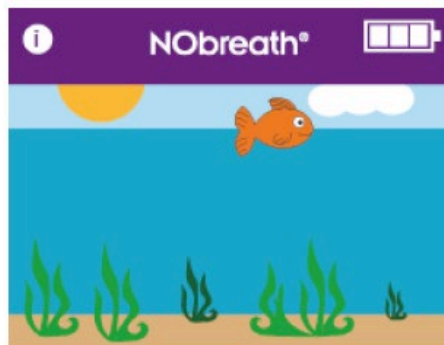
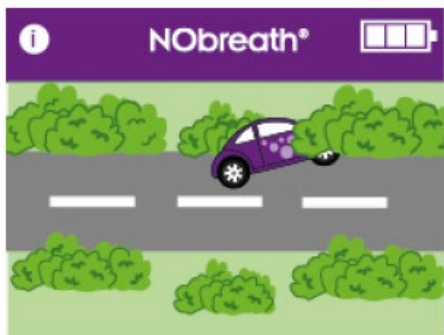
OR



All results are autosaved to the log.
Tip: Or press the save icon to save the result to a patient profile.



NObreath® | X – Failed Test Options



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



Press the retry icon to retake the test.



Press next arrow to view the result.



Press home icon to return to the home screen



NObreath[®] | Interpreting FeNO Readings¹

ATS/ERS Clinical Guidelines Summary for Interpreting FeNO Levels

Measuring airway inflammation with NObreath[®] can help monitor the effectiveness of medication and can be used to predict the risk of Asthma attacks^{1*}.

Aid in diagnosis using the NObreath [®] FeNO monitor			
FeNO (ppb) Levels	LOW <25ppb (<20ppb in children)	INTERMEDIATE 25-50ppb (20-35ppb in children)	HIGH >50ppb (>35ppb in children) or rise in FeNO of >40% from previously stable levels
Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 wk)	Eosinophilic airway inflammation unlikely Alternative diagnosis Unlikely to benefit from ICS	Be cautious Evaluate clinical context Monitor change in FeNO over time	Eosinophilic airway inflammation present Likely to benefit from ICS

Alternative considerations (if Allergic Asthma has been dismissed) ²			
• Non-Allergic Asthma	• Chronic cough	• Vocal Chord Dysfunction	• GERD

References:

1. J. Saito et al, European Respiratory Journal; Domiciliary diurnal variation of fractional exhaled nitric oxide for asthma control. August 15 2013, v.43, iss.4, pp 474-484.

2. R Dweik et al, Respiratory and Critical Care Medicine; An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FeNO) for Clinical Applications. September 1 2011, v.184, iss.5, pp 602-615.



NObreath® | Interpreting FeNO Readings¹

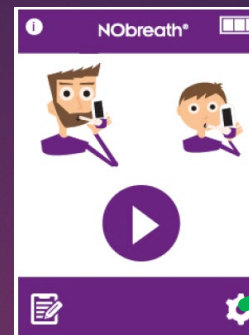
Monitoring (in patients with diagnosed asthma) using the NObreath® FeNO monitor

FeNO (ppb) Levels	LOW <25ppb (<20ppb in children)	INTERMEDIATE 25-50ppb (20-35ppb in children)	HIGH >50ppb (>35ppb in children) or rise in FeNO of >40% from previously stable levels
Symptomatic (chronic cough and/or wheeze and/or shortness of breath during past 6 wk)	Possible alternative diagnosis. Unlikely to benefit from increase in ICS	Persistent allergen exposure Inadequate ICS dose Poor adherence Steroid resistance	Persistent allergen exposure Poor adherence or inhaler technique Inadequate ICS dose Risk of Exacerbation Steroid resistance
Symptoms Absent	Adequate ICS dose Good adherence ICS taper	Adequate ICS dosing Good adherence Monitor Change in FeNO	ICS withdrawal or dose reduction may result in relapse



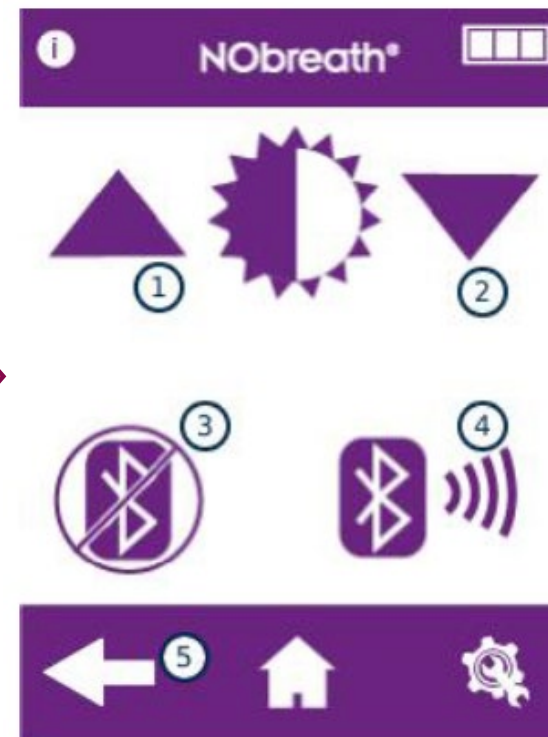
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NObreath® | Settings Overview



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



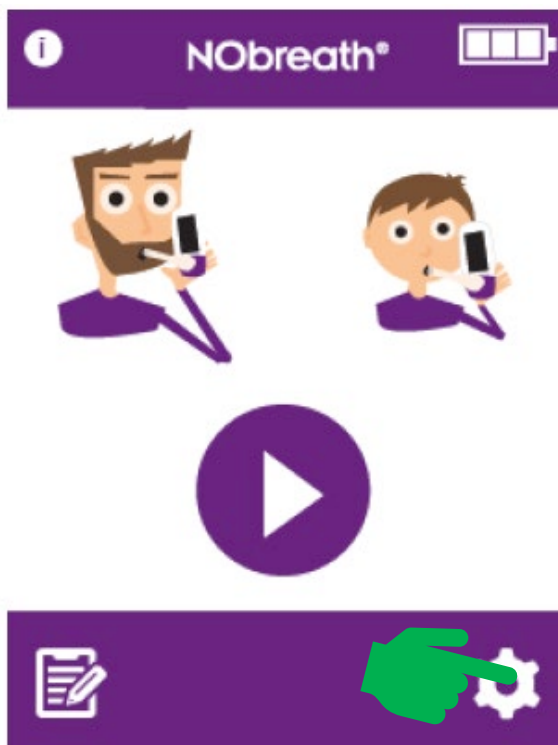
Settings Menu Page 2

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

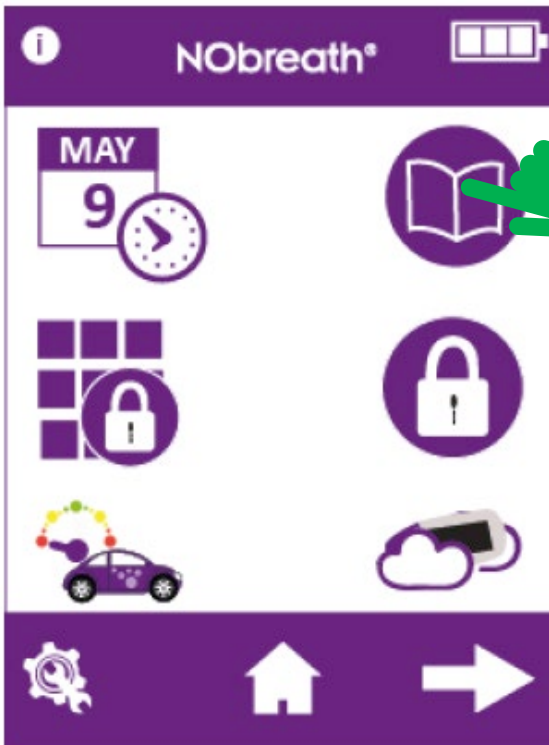


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NObreath® | Automatic Test Log



Press the gears icon.



Press the log icon.

	Date	Time	Reading
1	24/01/2019	09:20	7 ppb
2	23/01/2019	15:47	11 ppb
3	17/01/2019	11:37	39 ppb
4			
5			
6			
7			
8			
9			
10			

The 250 most recent test results are automatically saved in the log with the time and date.

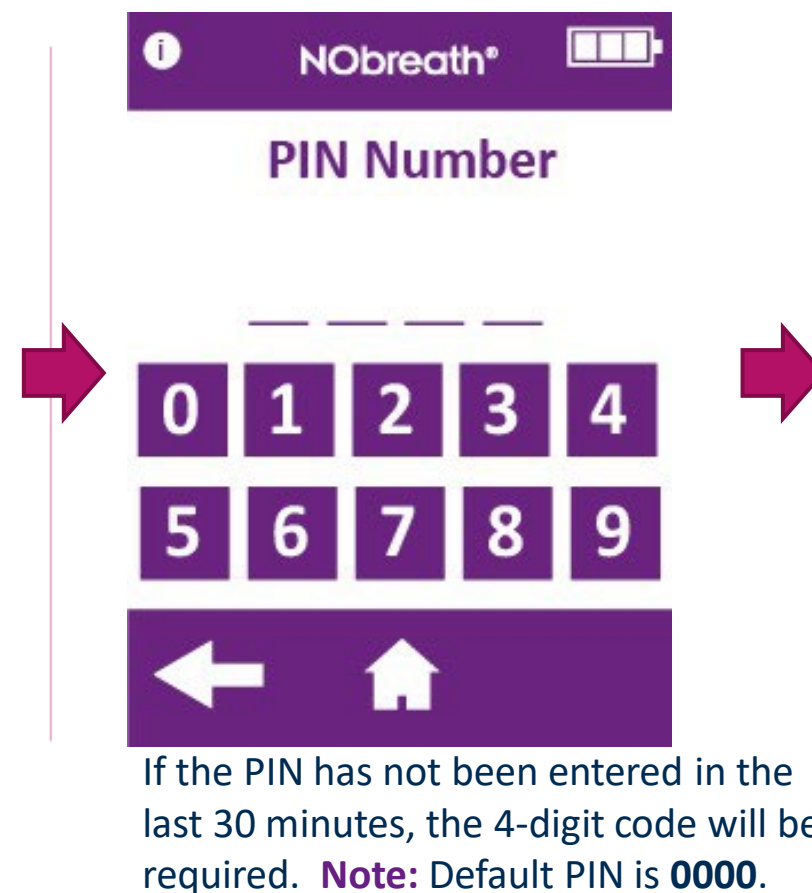
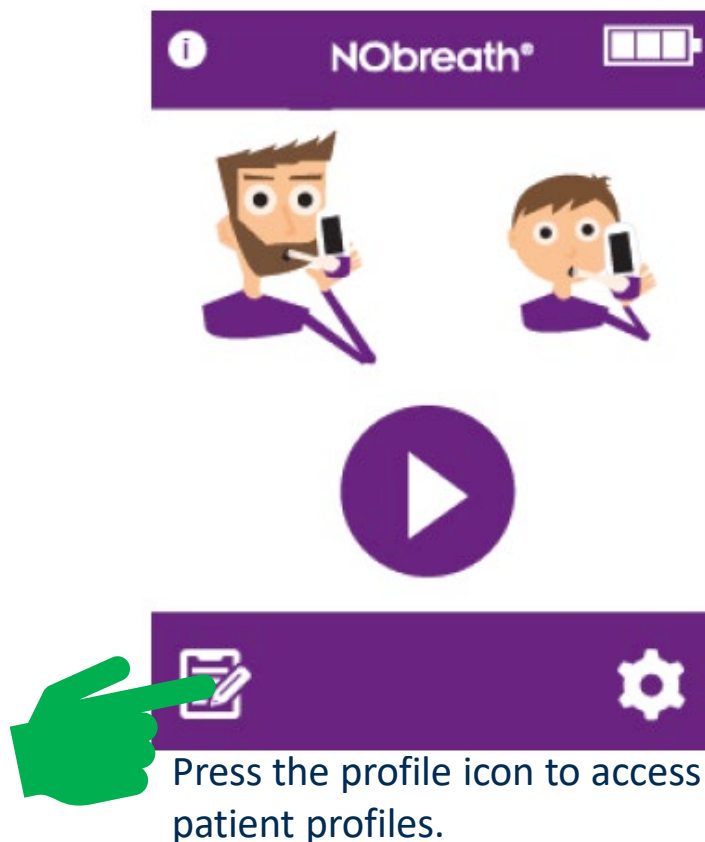
Tip: Use the arrows to scroll through the log. Press the back arrow to return to the settings menu or the home icon to return to the main screen.



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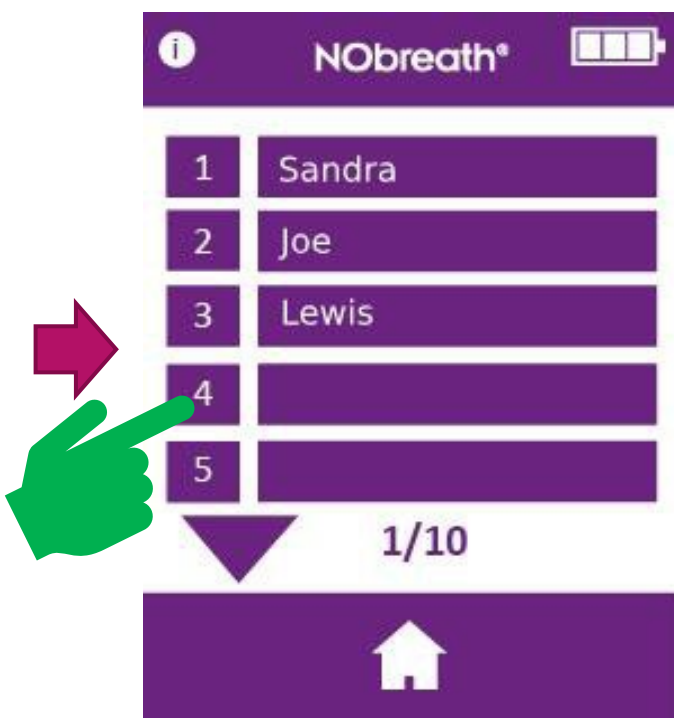
NObreath® | Patient Profiles / Traveling Nurse

- It is recommended to **only use** this feature **if you are a traveling nurse** because of the limitation of storing 25 results in up to 50 patient profiles on the monitor.
- Tips:**
 - Monitor always auto logs the last 250 readings with time and date stamp.
 - FeNOchart® allows for virtually unlimited storage of patient profiles and readings.
 - Also, we provide template logs & chart – [here](#).



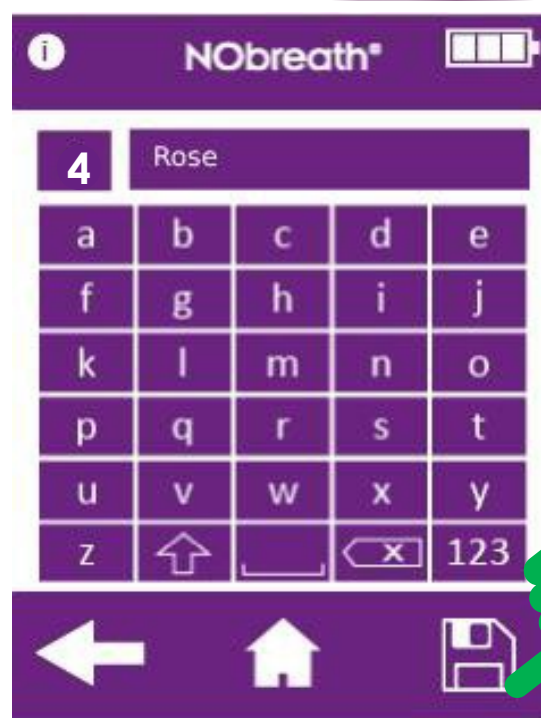


NObreath® | Patient Profiles / Traveling Nurse



A list of patient profiles will appear. Select an existing patient or click on empty profile to create a patient.

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Use the **keypad** to enter patient name or ID. Click **save icon** to create the profile. To cancel, press the **back arrow** to return to previous screen or **home icon** to return to main home screen.



Once the profile has been created the following options will become available: **Tip:** You can only set up the adult or child mode once during profile set up.

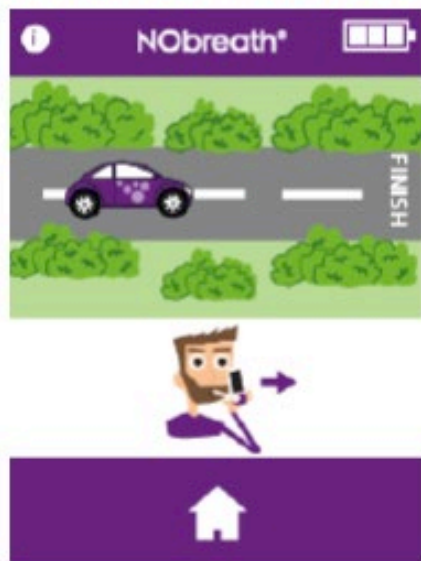
1. See a graph of results
2. Delete the patient profile
3. Take an adult breath test
4. Take a child breath test
5. Return to the profile list
6. Return to the home screen
7. Select patient to edit profile name/ID.



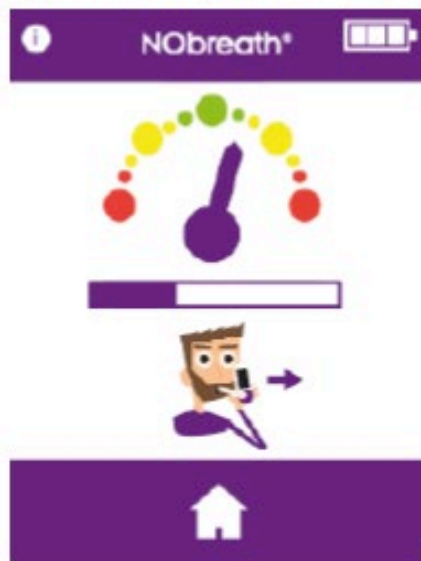
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NObreath® | Flow-meter Style Options

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



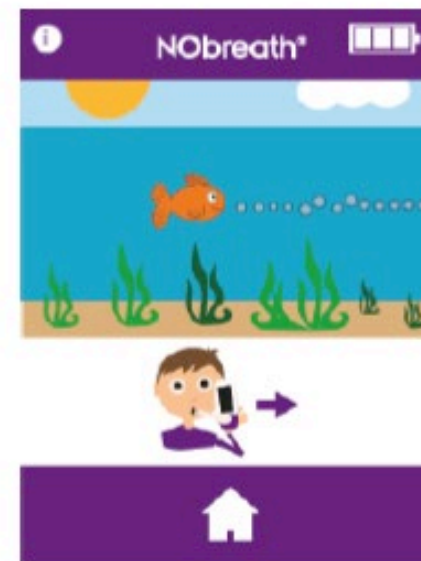
Keep the
car in the middle
of the road.



Keep the dial
in the green area.



Keep the
car in the middle
of the road.

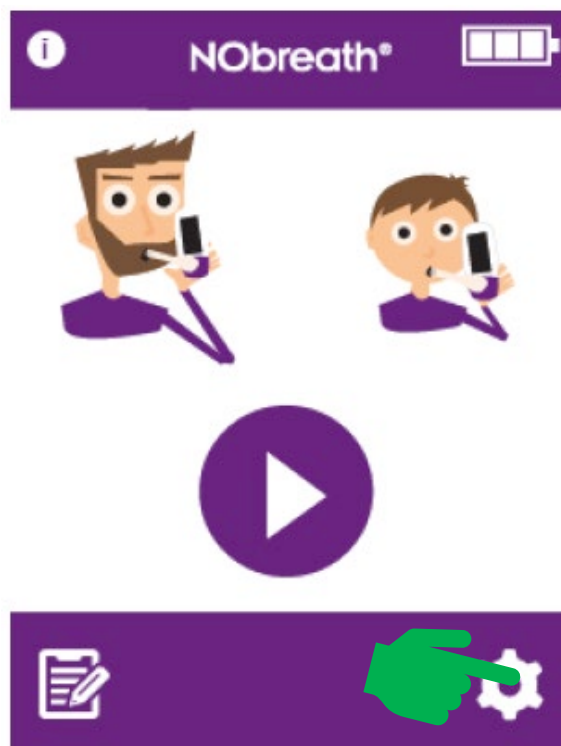


Follow the bubbles.



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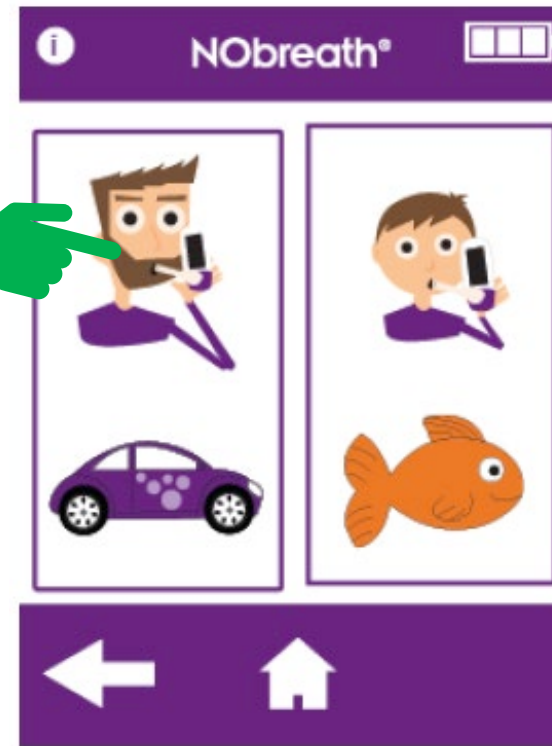
NObreath® | Change Flow-meter Style



Press the gears icon.



Press the flow-meter icon.

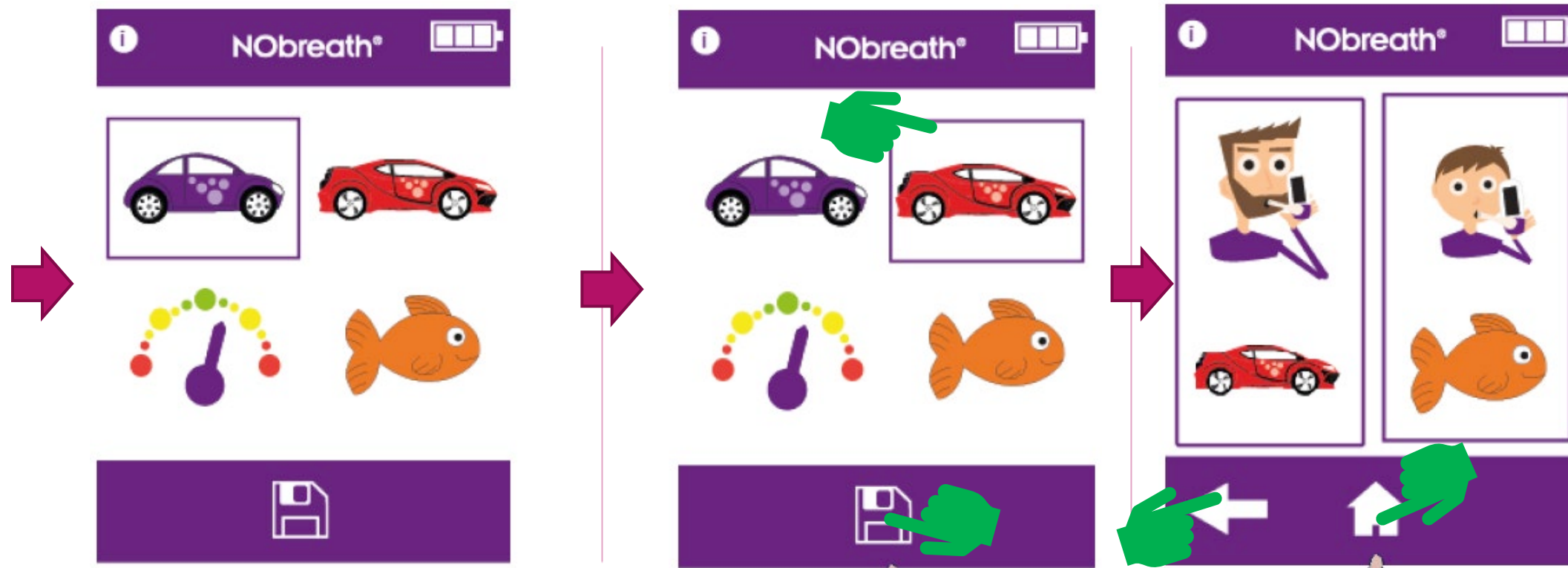


Select either the adult or child test mode to change the flow-meter style.



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NObreath® | Change Flow-meter Style



The current flow-meter style is highlighted.

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

The new flow-meter style will now be used for that adult or child mode.

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



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NObreath® | Calibration & Maintenance

Tip:

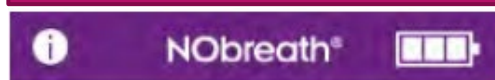
Contact coVita to arrange a calibration.

2 Options:

1. Ship calibration kit to your office.
2. Ship monitor to coVita for calibration.

Press the home icon to continue testing.

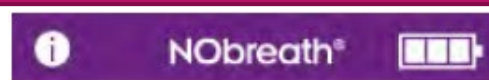
Annual Calibration



15/02/2022



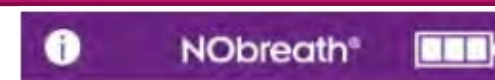
Annual Calibration Service is due in ≤ 30 days. Displayed daily.



15/02/2022



Annual Calibration Service is now due. Displayed daily.



15/02/2022

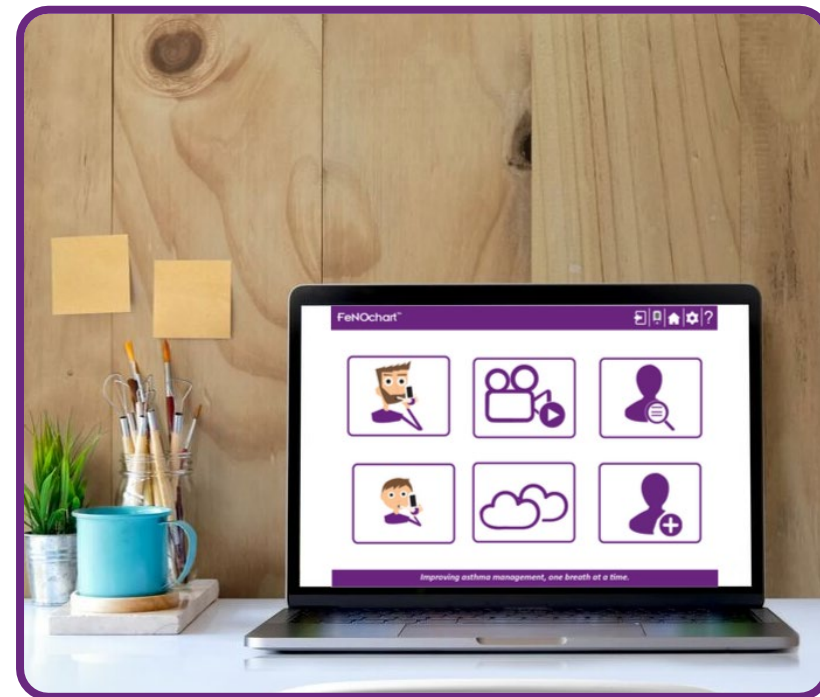


Annual Calibration Service is now past due ≥ 30 days. Displayed daily.



NObreath[®] | FeNOChart[™] Software

- ▶ The NObreath[®] FeNOChart[™] is included with every NObreath[®] monitor purchase at no additional fee
- ▶ The NObreath[®] can be used independently as the software use is optional
- ▶ GDPR Compliant
- ▶ Create, store, and manage patient profiles
- ▶ Adult and child breath tests with **screen mirroring** using connected PC monitor or television
- ▶ View results in graph format with the ability to create reports in PDF format
- ▶ Automatic software updates
- ▶ Ability to remotely update the firmware of your NObreath[®]
- ▶ PC compatible





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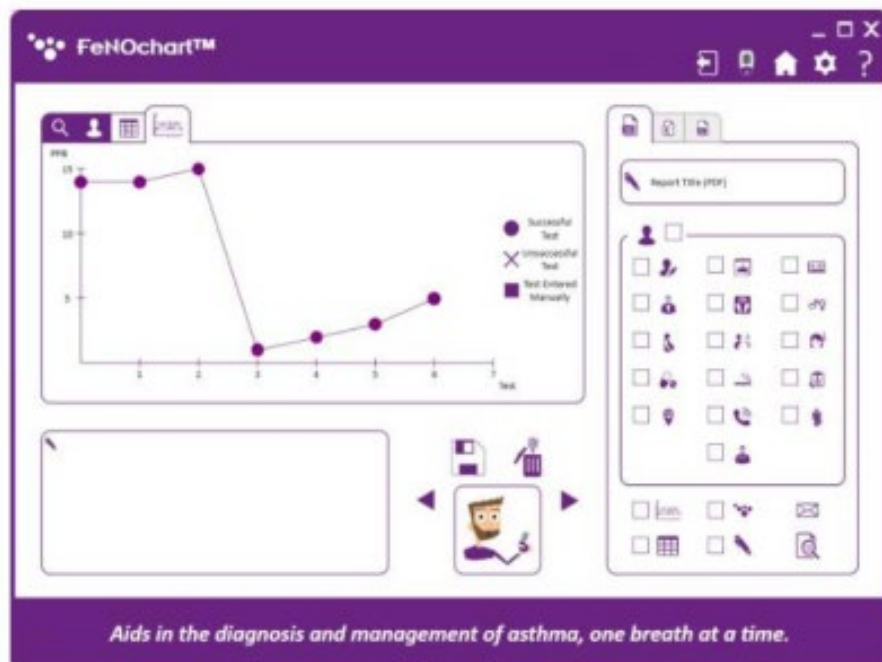
NObreath[®] | FeNOchart[™] | Mirroring



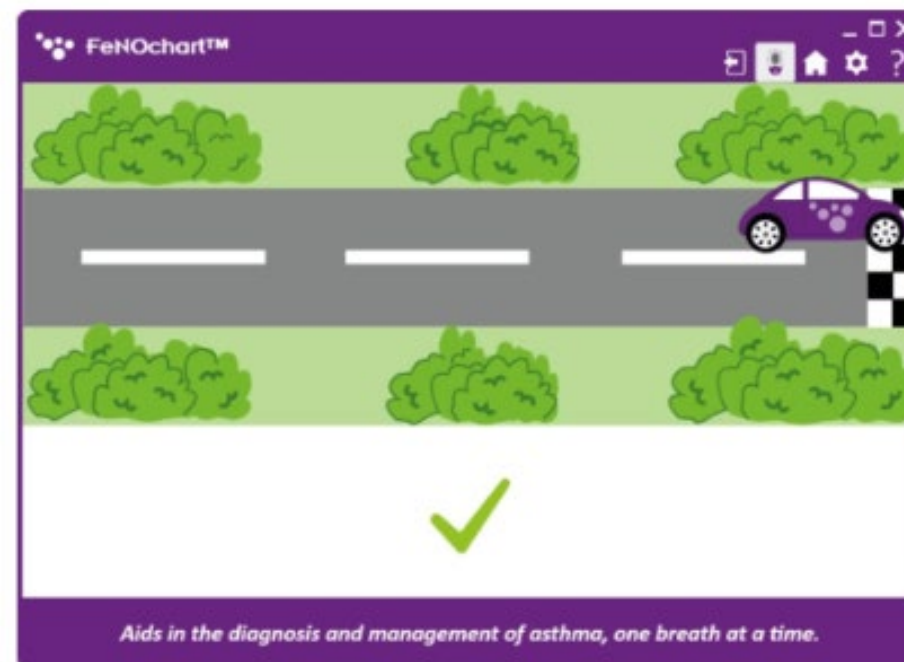


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NObreath[®] | FeNOchart[™] Download



DOWNLOAD SOFTWARE



SOFTWARE USER MANUAL

“Here's a few reasons why **Hub 10** loves the **NObreath® FeNO Monitor**:

- Ease of use for us as well as the patient
- Portable
- Wonderful customer service dept.
- Saves time and money especially when you have multiple sites"

“We are so happy we switched! The patients, clinicians love the monitor. The kids love the gamification options. They love the simplicity. And we love your service. “

“**Everything is going great! We love the new machine and it's been easier for our patients to use & understand. We also love the app for inputting it. Thank you so much 😊**”



“The NObreath ®is by far our favorite test to perform on our patients – simple, instant & informative.”

“The machine is working well; the providers and nurses find it very easy to use, and they're delighted with the results. I wish I could say more good things, but I think it works smoothly and effortlessly, and patients find it very easy to use. I think this machine is a winner.”

"The team said that they liked not needing to do the daily QC and that the machine being an all in one makes it less clunky (e.g. trying to get the monitor + breathing handle positioned well if a patient isn't sitting right next to the countertop)."

“It is good to hear from you. Our experience with coVita has been outstanding and I am truly appreciative for the service you have provided. Of course, I am very pleased with myself for having made the excellent decision to switch to coVita! Everyone at you company has been great and my staff are all delighted with the ease of use of the **NObreath®** device and the straightforward interactions with coVita. Congratulations on having achieved such a high level of customer satisfaction!”



NObreath® | FAQs & Tips

Sit or stand for the test?



We recommend sitting but either is fine

Is there a time limit for doing the test in relation to use of a rescue inhaler



Patient should not be tested immediately after the using rescue inhaler; FeNO will likely be lower than normal

Should you avoid the test within a certain time frame of surgeries such as abdominal?



This test is not like a PFT, it only requires a very gentle exhalation

What's the most important aspect regarding performance of the test?



Make sure the patient inhales off fresh air through the mouth, not through the nose, and not off the mouthpiece

Thank you
Contact us for more information.



NObreath[®]

ORDER NOW



Contact coVita with questions or to [purchase](#). 800.707.5751 | www.covita.net | info@covita.net