

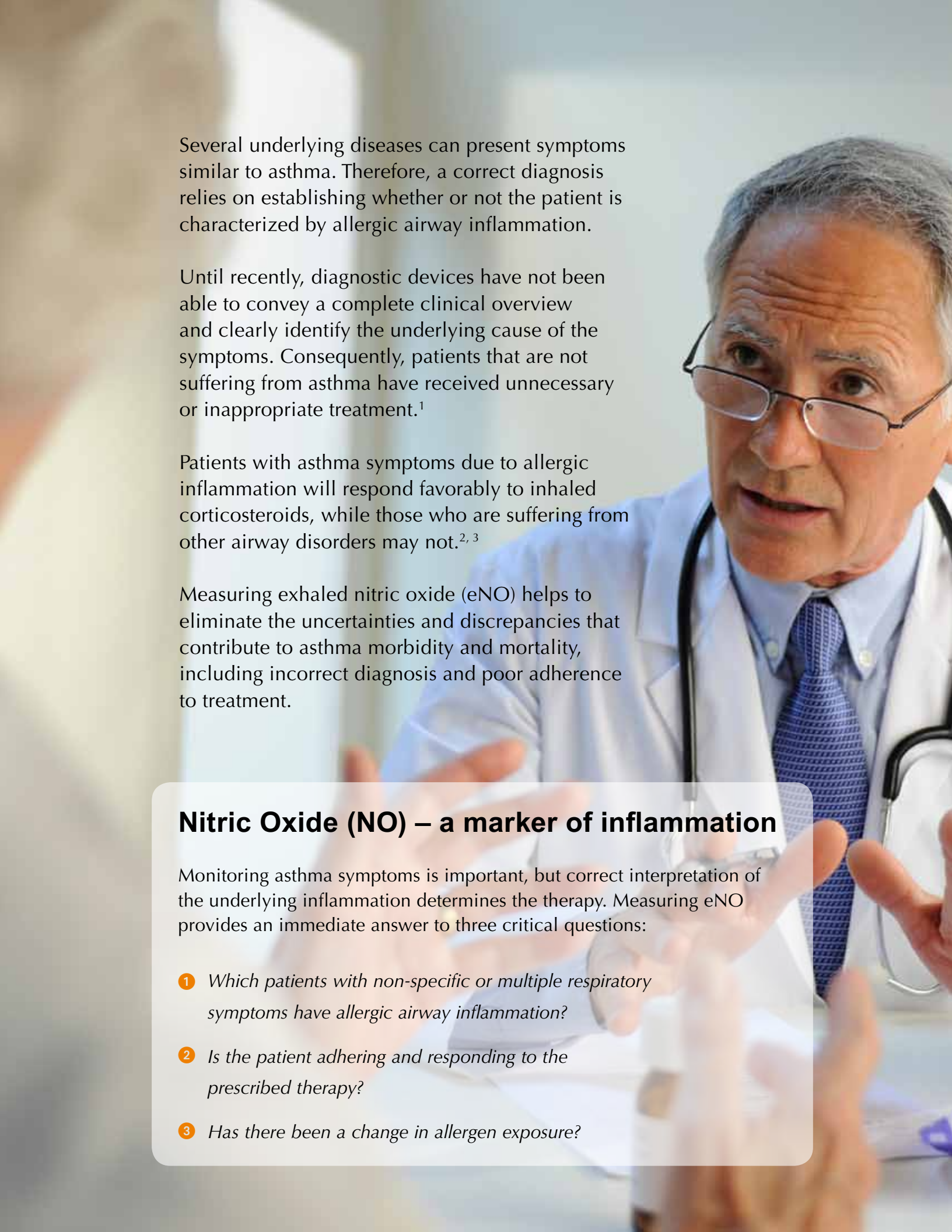
Airway Inflammation Status eNO – The Objective Measurement



NIOX[®]

A NEW DIMENSION IN ASTHMA CARE





Several underlying diseases can present symptoms similar to asthma. Therefore, a correct diagnosis relies on establishing whether or not the patient is characterized by allergic airway inflammation.

Until recently, diagnostic devices have not been able to convey a complete clinical overview and clearly identify the underlying cause of the symptoms. Consequently, patients that are not suffering from asthma have received unnecessary or inappropriate treatment.¹

Patients with asthma symptoms due to allergic inflammation will respond favorably to inhaled corticosteroids, while those who are suffering from other airway disorders may not.^{2, 3}

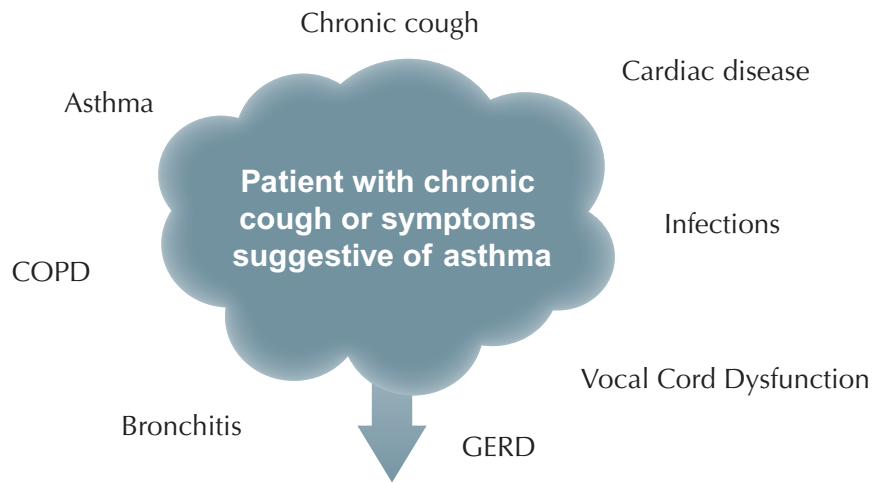
Measuring exhaled nitric oxide (eNO) helps to eliminate the uncertainties and discrepancies that contribute to asthma morbidity and mortality, including incorrect diagnosis and poor adherence to treatment.

Nitric Oxide (NO) – a marker of inflammation

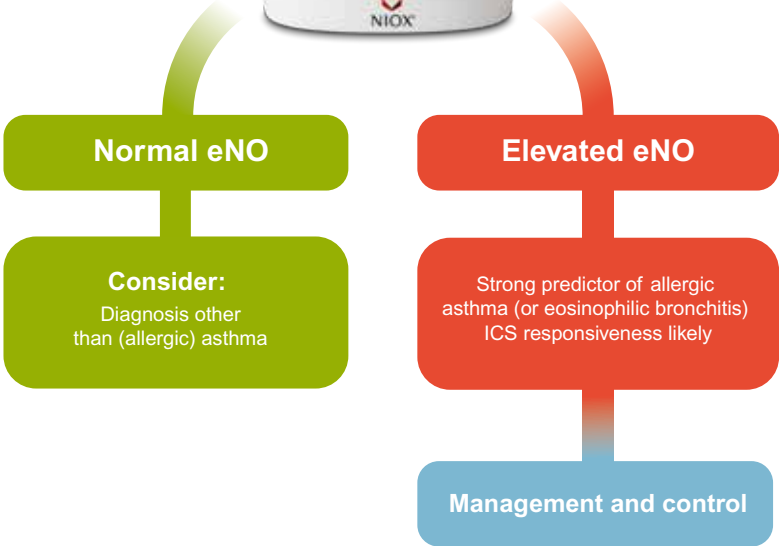
Monitoring asthma symptoms is important, but correct interpretation of the underlying inflammation determines the therapy. Measuring eNO provides an immediate answer to three critical questions:

- 1 *Which patients with non-specific or multiple respiratory symptoms have allergic airway inflammation?*
- 2 *Is the patient adhering and responding to the prescribed therapy?*
- 3 *Has there been a change in allergen exposure?*

1 NIOX MINO[®] instantly reveals allergic inflammation of the airways ⁴



History, symptoms, eNO measurement





“After all, does anyone seriously advocate treating hypertension without measuring blood pressure or kidney disease without knowing the GFR? Neither seems to me to be any dafter than using anti-inflammatory medications without measuring inflammation.”

Andrew Bush, MD, Faculty of 1000 Medicine, 11/08.

2 NIOX MINO® instantly reveals if the patient is adhering and responsive to the prescribed therapy ⁵

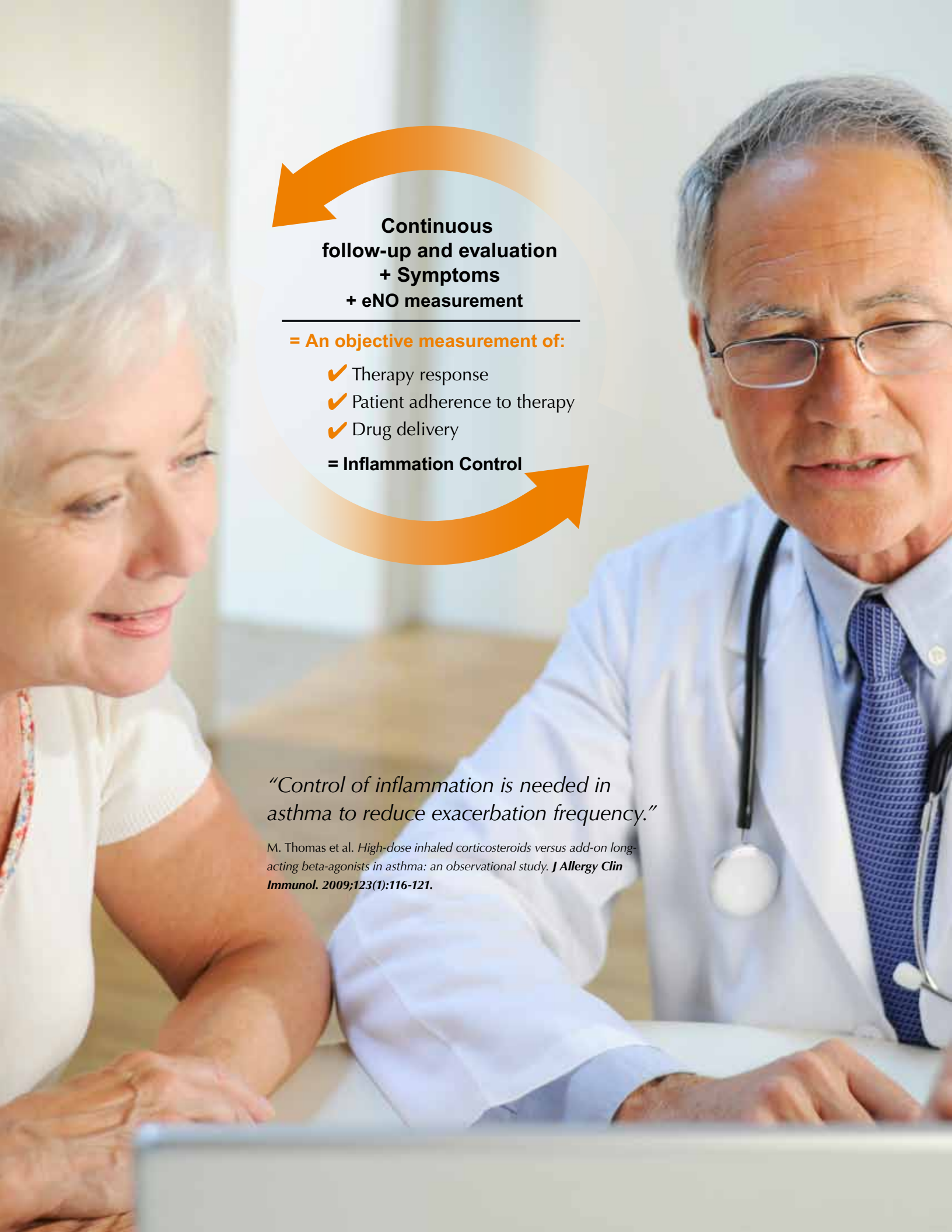
In the clinical workup of the asthma patient, there are several questions that must be answered:

- Is airway inflammation under control?
- Is the patient responding to the therapy?
- Is the patient adherent to the medication?
- Is the patient using correct inhalation technique?

In clinical practice, NIOX MINO will immediately identify the non-adherent patient or the patient with an inadequate medication delivery technique. It will also confirm uncontrolled airway inflammation.



NIOX MINO is the device of choice used globally for measuring airway inflammation in clinical practice and in clinical studies. The performance of NIOX MINO is documented in more than 30 clinical papers in peer-reviewed journals.



**Continuous
follow-up and evaluation
+ Symptoms
+ eNO measurement**

= An objective measurement of:

- ✓ Therapy response
- ✓ Patient adherence to therapy
- ✓ Drug delivery

= Inflammation Control

*“Control of inflammation is needed in
asthma to reduce exacerbation frequency.”*

M. Thomas et al. *High-dose inhaled corticosteroids versus add-on long-acting beta-agonists in asthma: an observational study.* *J Allergy Clin Immunol.* 2009;123(1):116-121.

3 NIOX MINO® reveals changes in allergen exposure ⁶

Anti-inflammatory treatment can become ineffective for the patients who are highly exposed to household and work-place allergens, especially if they are subjected to continuous exposure.



Despite optimal anti-inflammatory therapy, the rapid onset of allergic rhinitis and conjunctivitis, or continued respiratory symptoms, can indicate significant exposure to unidentified allergens.

High eNO values indicate the presence of inflammation and alert the physician and patient to these conditions, suggesting the need for a change in therapy.

NIOX MINO[®] – maintenance-free device for exhaled nitric oxide measurement

- The *only* maintenance-free eNO device
- All eNO values are quality assured
- Allows for customized data management
- Personalized asthma management

Procedure



Exhale to empty the lungs



Inhale deeply through the disposable filter



Exhale through the filter

View results on screen

The procedure can be performed by audio or visual feed-back. Exhalation time is 10 seconds at 50 ml per second. The inhaled air is scrubbed of ambient nitric oxide as recommended by the ATS.



Data Management Program for reporting and trending

- Electronic storage and display of patient data
- Capable of direct communication to patient Electronic Medical Record (EMR)
- Convert patient data into a PDF report
- Visual Incentive Program



Visual Incentive

Cable (USB) connection makes it possible to follow the procedure on the computer screen.



Guide to interpretation of quality assured values from NIOX MINO[®] in patients with airway disease

	LOW	NORMAL	INTERMEDIATE	HIGH
Allergic airway inflammation	Unlikely	Unlikely	Present, but mild	Significant
ADULTS				
FENO value (Fractional Exhaled Nitric Oxide)	<5	5–25	25–50	>50 (or a rise of > 60% since previous measurement)
CHILDREN < 12 years				
FENO value (Fractional Exhaled Nitric Oxide)	<5	5–20	20–35	>35 (or a rise of > 60% since previous measurement)

* Adapted from Taylor DR, Pijnenburg MW, Smith AD, De Jongste JC. *Exhaled nitric oxide measurements: clinical application and interpretation. Thorax 2006; 61: 817-27.*

References

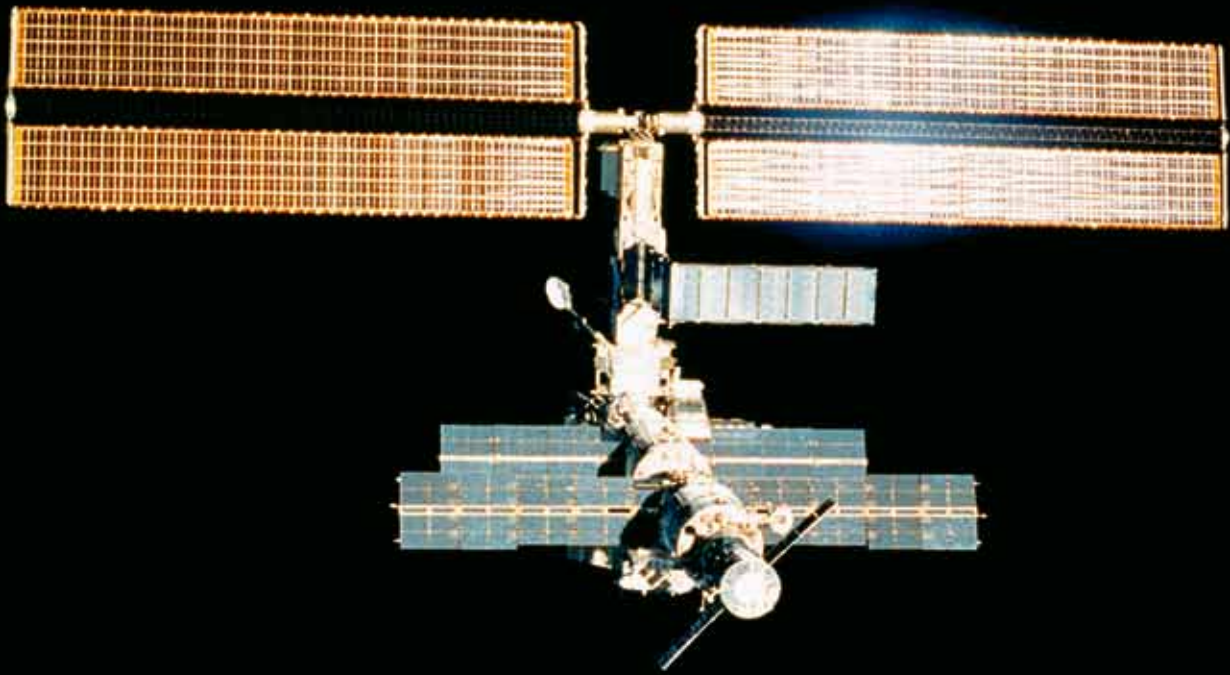
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Aerocrine is continuously developing and enhancing eNO technology in the management of airway disease. More than 4 million tests done worldwide in clinical practice prove its acceptance.

Continuous ground-breaking development

- Aerocrine developed the first instrument for measurement of eNO
- Aerocrine instruments will remain the Gold Standard of eNO measurement
- Aerocrine has close collaboration with the world's leading eNO scientists
- Aerocrine will continue to lead the development of eNO as a marker of airway inflammation

The International Space Station is using the NIOX MINO® to evaluate the effects of inhaling oxygen-rich air while astronauts prepare to work in the stratosphere – the ultimate point-of-care testing!



Aerocrine



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NIOX MINO® is 510(k) cleared (K101034) by FDA and CE marked according to European In Vitro Diagnostic Device Directive 98/79/EEC.
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US Patent 5,447,165, US Patent 5,922,610, US Patent 6,038,913, US Patent 6,063,027, US Patent 6,099,480, US Patent 6,183,416, US Patent 6,511,425,
US Patent 6,626,844, US Patent 6,723,056, US Patent 6,733,463, US Patent 6,761,185, US Patent 7,014,692, US Patent 7,270,638, US Patent D448,693,
US Patent D457,231, US Patent D492,035, US Patent D496,667 and patents pending.