This product can bring relief to millions of people with respiratory challenges.

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US PATENT D 540,462
DUTCH DESIGN
MADE IN THE NETHERLANDS
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1. **Key data**

- **Inventor/developer**
  Alexander B. Proper, Oegstgeest, The Netherlands

- **Medical advisors to Airmax BV**
  - Prof. Klaus Vogt, M.D., D.D.S., Ph.D. (Germany)
  - Prof. Gilbert J. Nolst Trenité, MD, PhD (Netherlands)
  - Ass. Prof. Viacheslav G. Merkulov (Russia)

- **Clinical studies & Publication**
  - Effective application of nasal dilators in snoring and mild sleep apnea
  - Non-invasive modality of snoring treatment and OSAS prophylactics
  - Rhinology supplement 21. 4-Phase Rhinomanometry: Basics and practice 2010
  - Q1 2013: Research by prof. P. Hellings (Leuven University)

- **Relevant Patents Owned by Airmax BV**
  - USA Patent D540,462
  - EU Patent/Model Registration 84140-01

- **Relevant certifications owned by Airmax BV**
  - FDA approved
  - European CE registered
  - ISO 13485 (Medical device)

- **Manufacturing**
  Netherlands: Airmax BV in-house casting facility

- **Distribution network**
  - Still under development in North America and Asia
  - Currently EMEA
2. Introduction

• **The Airmax, a superb innovation in respiratory performance**
The Airmax nasal dilator improves the flow of air through the nose by opening the nasal channels, including the secondary valve. It helps to significantly reduce snoring, relieve nasal congestion and mild sleep apnea. The Airmax is available in Small and Medium sizes, jointly packaged allowing the user to select the most comfortable size.

• **In medical terms**
The Airmax spreads the deformable structures around the upper lateral cartilage of the nasal entrance. The Airmax prevents the premature onset of the nasal valve closure as well as a slight passive opening of the passive extendable structures at the nasal entrance by lateral displacement of the nasal alae and the entire lateral nasal wall along with the anterior portion of the inferior nasal turbinate.

• **Composition**
The Airmax consists of hypo-allergen medical plastic, compliant with the required certification standards. For sports purposes or better adhesion among snorers/OSA patients, the Airmax Version 2 has small “hooks” which link to the nasal columella.

• **Mechanics**
The mechanics of the Airmax consist of two attributes:
  o Widening of the nasal channel (Hagen-Pouiselle law; 4th-power reduction in aerodynamic resistance per cross-sectional area enlargement)
  o Aerodynamic profile (wing effect)

• **Some clinical data**
The Airmax effect has been proven by measuring the quantity of air inhaled with the help of a 4 phase Rhino-manometer designed by Prof. Klaus Vogt, M.D., D.D.S., Ph.D. (Germany).

Besides improving airflow through the nose by on average 20%, **among 137 patients suffering from various stages of socially disruptive snoring and mild OSAS, 75% experienced significant reduction of snoring and duration thereof.**

In a separate test, supervised by Professor Klaus Vogt, **subjects scored up to 50% improvement on the Quality of Life Scale.** Additionally this research shows **a 3 times better average aerodynamic performance than the market-leading product Breathe Right.**
This graph compares average nasal channel resistance in 3 situations among 24 patients:

![Graph showing comparison of nasal dilators](image)

In the objective part of the study Breathe Right®, Airmax® and breathing without nasal dilators were compared by means of Rhinomanometry. Both devices reduce resistance parameters compared with breathing without device (in VR in, LVR, Reff In, LReff in, Lreff Total parameters), however the Airmax® is more effective than Breathe Right® in reducing these resistance parameters.

- **Indications – Change by line of importance - Focus**
  - **Snoring, nasal congestion and mild sleep apnea**
    The result of these medical findings already shows both improved respiration profiles, and significant reduction in snoring and nasal congestion amongst said patients.
    Patient suffering from nasal congestion due to a deviated septum, common cold, allergies, collapse of the nasal valve, air travel, etc. can significantly benefit from the use of the Airmax.
    Patients who have been relying on nose drops to relieve their symptoms, have reduced or stopped its use thanks to the Airmax.
    Finally, pregnant women often suffer from nasal congestion. Many of them experience remarkable symptom relief from the use of the Airmax.

Finally, the Airmax can be used for patients suffering from mild sleep apnea and can be used for the prophylaxis of sleep apnea as it prevents the development of OSAS.
o **CPAP users**
Feedback from patients has shown that the Airmax is a possible supplement for users of the so-called CPAP machines, devices worn as a mask by obstructive sleep apnea (OSA) patients. As a result, Airmax also helps increase the compliance to treatment for CPAP users.

o **Users undergoing maxilla-mandibular surgery**
Prof. Guilleminault active in the USA and an authority in the field of nasal and related syndromes wrote to us:
“We performed acoustic rhinometry and 4 phase-rhinometry and were able to reduce the nasal resistance objectively in the 3 tested cases.
All 3 were awaiting maxillo-mandibular surgery. Although this doesn’t constitute a medical sample, Prof Guilleminault has requested more samples of the Airmax to continue tests.

Outside a strict medical application we see a variety of potential additional target audiences for the Airmax:

o **Heart and Pulmonary relief aid**
Patients with respiratory problems, like asthma or early stage emphysema, or a heart condition should find that the Airmax improves their ability to breathe more freely.

o **Improved performance during sport**
People using the Airmax while practicing sport find it much easier to breathe through the nose and have noticed an improved performance during exercise. This effect has not been proven in clinical studies and is only based on patients’ feedback.

o **Improved performance during sexual intercourse (for men)**
Improved sexual performance has been reported by several health care professionals. This effect has not been proven in clinical studies and is only based on their patients’ feedback.
• **Side-effects & comfort of use**

There are no known side effects to the use of the Airmax.

When users first apply the Airmax, their nasal channels need to become accustomed to the presence of the device. After several days of intermittent usage, users experience minimal discomfort when using the device.

Research by Prof. Vogt and Dr Safronov showed a greater improvement in nasal breathing by the Airmax users than users of similar devices like the Nozovent or Nasanita as demonstrated at the Meeting of the European Rhinologic Society in June 2010.

Additionally, research by Prof. Vogt shows that the other nasal dilators tested are perceived as significantly less comfortable than the Airmax.

Finally, although the Breathe Right scored higher on the comfort scale, its effectiveness is on average 3 times lower than that of the Airmax.

**Users with a true need for relief will likely choose the Airmax® over Breathe right®.**
3. Summary of a clinical study

Non-invasive method of snoring treatment and OSAS prophylactics

- **Study**
The aim of the study is to evaluate the therapeutic efficacy of the intranasal dilator ‘Airmax’ on patients with snoring and OSAS.

- **Methods**
In the evaluation both models of the Airmax (developed and manufactured in the Netherlands) were used. The devices provide simultaneous dilation of the nasal vestibule and anteroinferior segment of the nasal cavity. Such placement of the device causes the lateral displacement of the nasal alae and lateral walls of the nasal cavity together with the anterior portion of the inferior nasal turbinate. Said dilation offers the enlargement of the common nasal passage and the nasal valve and, hence, increases airflow whilst decreasing impedance produced by intranasal structures while breathing in.

The BREAS system (Sweden) was used to carry out respiratory monitoring (RM), both with and without intranasal dilators. All patients and their bed partners filled in a questionnaire to estimate the quality of sleep with and without the Airmax. Some patients were subjected to rhinomanometry (HRR 3 4-Phase-Rhinomanometer, Germany) and thermistography (developed by Airmax itself). All patients were considered to manifest the following pathologies: provocative snoring and OSAS, as: hyperplasia of the palatal and lingual tonsils, micrognathia and deviation of nasal septum.

- **Patients**
136 patients with an age ranging from 17 to 76 years, 81 men and 55 women (24 of which in their 16th - 36th week of pregnancy) participated in the study.

  - Stage I snorers (back snorers) – 38 patients.
  - Stage II snorers (polypositional snorers) – 35 patients.
  - Stage III snorers (complicated snorers) – 32 patients.
  - Mild OSAS (AHI <19) was observed in 31 patients.

88 % of the patients demonstrated BMI fewer than 30. 12% showed BMI between 30 and 32.
• **Results**
Considerable reduction of snoring (loudness and duration) was revealed in:

- Stage I snorers in 29 cases.
- Stage II snorers in 28 cases.
- Stage III snorers in 25 cases.
- In OSAS in 19 patients.

Very little effect was observed in patients with hyperplasia of the palatal and lingual tonsils, micrognathic patients, and in individuals with blocked posterior part of the nasal cavity (polyposis, fixed deformity of the plowshare bone, hyperplasia of the posterior end of inferior turbinates).

• **Conclusion**
The single use of the Airmax improves nasal breathing without surgery in several kinds of pathology in the front parts of the nasal cavity, the lower nasal shells and also the vestibule of the nose and can be used as non invasive method to diminish the loudness and duration of essential stages of snoring (including pregnant women), and prevent the development of OSAS.

Ass. Prof. Viacheslav G. Merkulov MD, PhD, (Medem International Clinic and Hospital, Saint Petersburg, Russia)

Prof. Gilbert J. Nolst Trenité MD, PhD, (Academic Medical Centre, Amsterdam, The Netherlands)
4. Comparative investigations on the efficacy of nasal spreader devices by 4-phase-rhinomanometry

- **Objectives**
A number of different spreader devices are available on the market to improve nasal breathing. They are used either to prevent snoring, during sport or for extended rhinomanometric tests. It is without any doubt that these devices may be useful in respective cases, in particular to prevent the premature onset of the nasal valve during inspiration. Recommendations by the producer are mostly based on subjective criteria, while objective criteria are mostly missing.

- **Material and Method**
The external spreader device “Breathe-Right” and the internal dilators Nozovent, Nasanita and the Airmax have been compared. The effect of the devices was tested by 4-Phase-Rhinomanometry (HRR3, RhinoLab, Rendsburg, Germany) as well by VAS in healthy subjects during normal and accelerated breathing. A questionnaire contained questions about the compliance in shorter and longer use of the device.

- **Results**
It could be shown, that internal devices are generally more effective than the external tapes, but in repeated applications the acceptance by the patients is different. The effect could be objectively demonstrated by 4-Phase-Rhinomanometry.

- **Conclusions**
The acceptance of spreader devices can be improved by rhinomanometric testing. If a “valve phenomenon” in elevated nasal breathing can be shown by 4PR, devices are accepted in elevated body work (sports). If surgical improvement of nasal breathing is indicated, but the patient rejects the procedure either because of high comorbidity or for subjective reasons, spreader devices may be prescribed after 4PR test and evaluation of efficacy.

5. Existing academic collaboration in the field
   - Sleep Centers led by Prof. Vogt in Latvia
   - Research in Russia by Prof. Merkulov
   - Ad hoc tests by Prof. Guilleminault at Stanford University
6. Current product range

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Airmax Classic Trial pack</strong></td>
<td>- 1 Small Airmax</td>
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<tr>
<td></td>
<td>- 1 Medium Airmax</td>
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<tr>
<td></td>
<td>To enable users to choose the right size for them</td>
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<tr>
<td><strong>Airmax Classic 2X Medium</strong></td>
<td>- 2 X Medium Airmax</td>
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<td>- Offers 6-months of relief</td>
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<tr>
<td><strong>Airmax Classic 2X Small</strong></td>
<td>- 2 X Small Airmax</td>
</tr>
<tr>
<td></td>
<td>- Offers 6-months of relief</td>
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</tbody>
</table>
7. Testimonials of Airmax users

“Since I was 16 I have had a lot of trouble with breathing because I have a hyper allergic nose- and mucous membrane. An operation in 2005 should have solved the problems, but to my disappointment they only became worse... As long as I’m standing upright, sitting or walking, I don’t have a lot of trouble breathing, but when I’m working out or when I’m lying down I really can’t get enough air. Waking up in the middle of the night because you can’t get enough oxygen is very frightening. After having tried many respiratory aids, I finally discovered the Airmax. It’s a fantastic solution. The plastic doesn’t irritate my membranes. I don’t wake up in the middle of the night anymore. My husband says I rarely snore nowadays and if I snore the sound I produce is minimal. Whilst working out I can breathe through my nose and not just through my mouth, which is a great relief. It’s so much more comfortable, not having a dry throat any more, and of course, not swallowing any more bugs... I am very pleased with the Airmax.”

Marijke (Airmax Classic user, Katwijk-NL)

“I’m sending you this mail, as I’m probably the most enthusiastic fan of your product. I’ve used your product for several days now and the headaches that I have every morning are finally gone. My husband is also using the Airmax and I’m finally relieved from his snoring. For years he had to rinse his nose every time he woke up, but with the Airmax he doesn’t have to do that anymore!”

Tanja Mulder (Airmax Classic user, NL)

“I usually don’t write about products and my experience with them, but for the Airmax I am making an exception. I fly from Holland to Spain on a monthly basis and time after time I get these tremendous headaches (A sinusitis feeling) when the plane starts to land. I went to an ear, nose and throat specialist, who told me to use Otrivin. This went well for a short period of time but after a while the symptoms started coming back. A few days later I read in the Dutch ‘De Telegraaf’ newspaper about the Airmax and wondered if this could solve my problem while in the air. After having had contact with Airmax they sent me this little miracle. I didn’t believe it, but the Airmax solved my problem. In the meantime I have made 4 flights and my headaches have disappeared!”

H.P. van Dijk. (Airmax Classic user, NL)
“This product is actually of use to me. My sensitive mucous membrane really irritated me a lot: I had to use nose drops constantly. Since I have the Airmax that is a thing of the past. Whenever I get the feeling that my membrane irritation is returning, I just use the Airmax for a few hours and the problem is gone! I see a real future in this product. In hospitals it could be a product for patient’s who have sleeping disorders. It’s small and easy to place inside your nose. You can barely feel it.”

Ferida de Jongh-Wieth, GP in Wassenaar (Airmax classic user, NL)

“I would like to share my experience with the Airmax - for me it works like a charm. I have always had problems with breathing when I sleep on my right side. This was occasionally accompanied (as I have been told) by heavy snoring. The Airmax has solved this problem. It does take a week or two to get used to, but it’s definitely worth it.”

(Airmax Classic user)

8. Appendix

Terminology used in the press pack
For more information, please refer to the supplement 21 of the rhinology journal “4-Phase-Rhinomanometry – Basic and Practice 2010”.
(http://www.rhinologyjournal.com/supplement_21.pdf)

- VRin: Vertex Resistance at inspiration
- VRex: Vertex Resistance at expiration
- LVR: Logarithmic Vertex Resistance, LVR = log(10VR)
- LVRin: Logarithmic Vertex Resistance at inspiration, LVRin = log(10VRin)
- ReffIn: Effective Resistance at inspiration
- LREFFIn: Logarithmic Effective Resistance at Inspiration
- LREFFtot: Logarithmic Effective Resistance for the total breath