Airsonett® Air4

Information for physicians

Effective treatment of allergic diseases
such as asthma and atopic dermatitis

Airsonett®
A Breath of New Life

Airsonett® Air4

Airsonett Air4 is a medical device that gives patients TLA treatment overnight. Airsonett TLA (Temperature-controlled Laminar Airflow) is an effective home treatment, which can improve allergic asthma symptoms, giving patients a higher quality of life while helping them reach their treatment goals.[1,2,3]

Treatment with Airsonett TLA has no pharmacological side effects and is a complement to regular drug treatment. The treatment has been tested in several clinical studies, showing that it:

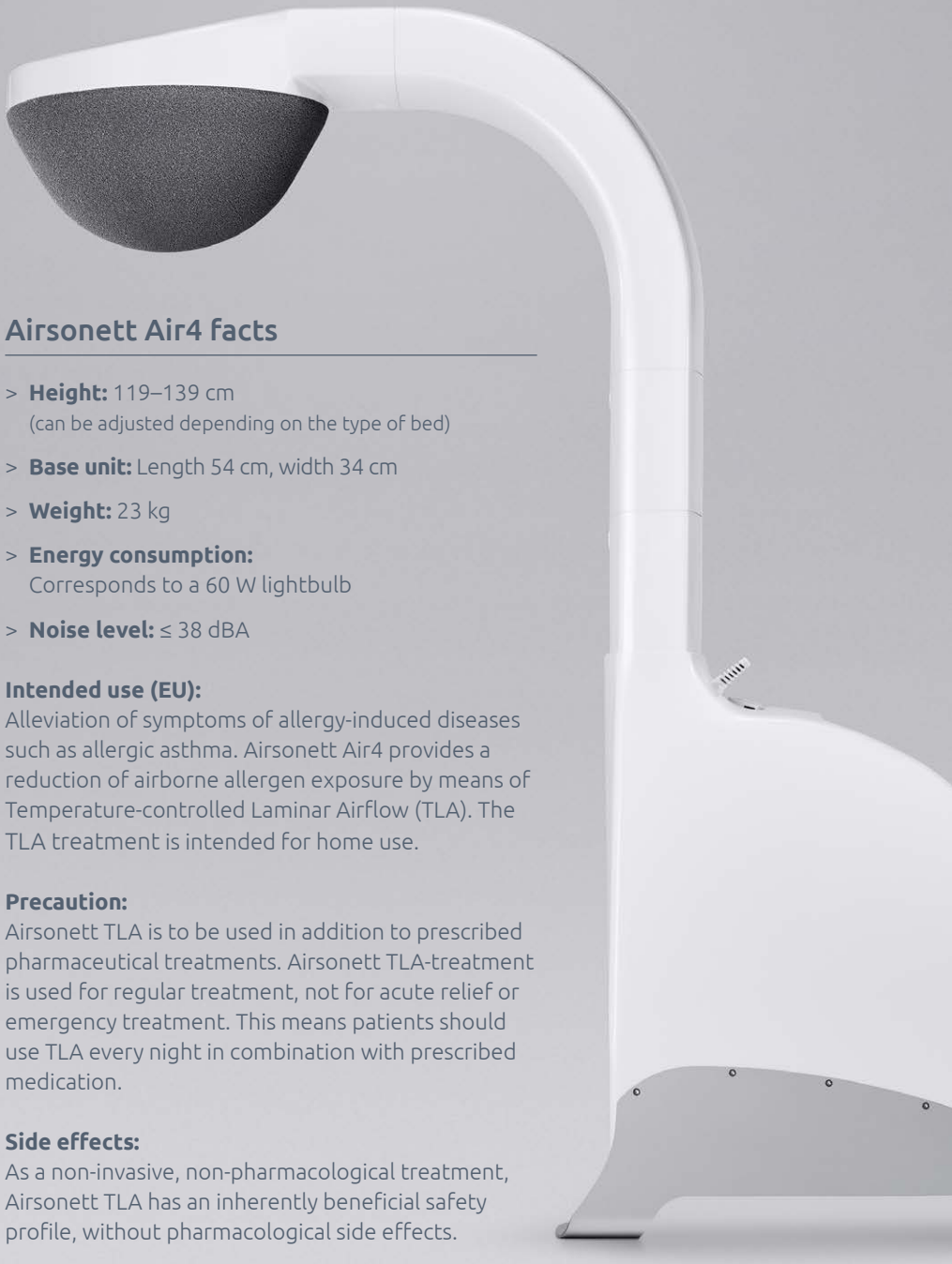
> reduces airway inflammation

> improves sleep

> reduces the number of exacerbations

> improves asthma control

> improves asthma-related quality of life



Airsonett Air4 facts

- **Height:** 119–139 cm
  (can be adjusted depending on the type of bed)
- **Base unit:** Length 54 cm, width 34 cm
- **Weight:** 23 kg
- **Energy consumption:**
  Corresponds to a 60 W lightbulb
- **Noise level:** ≤ 38 dBA

Intended use (EU):
Alleviation of symptoms of allergy-induced diseases such as allergic asthma. Airsonett Air4 provides a reduction of airborne allergen exposure by means of Temperature-controlled Laminar Airflow (TLA). The TLA treatment is intended for home use.

Precaution:
Airsonett TLA is to be used in addition to prescribed pharmaceutical treatments. Airsonett TLA-treatment is used for regular treatment, not for acute relief or emergency treatment. This means patients should use TLA every night in combination with prescribed medication.

Side effects:
As a non-invasive, non-pharmacological treatment, Airsonett TLA has an inherently beneficial safety profile, without pharmacological side effects.

Allergen exposure during sleep

In bed, the patient's airways are in close contact with pillows, mattresses and duvets. These contain irritating particles and allergens, such those from mites and pets. When the patient moves in bed, these allergens are released from the bedding. Together with the body heat, they rise in the air towards the breathing zone around the mouth and nose.[4]

Before

Body heat convection concentrates allergens and irritating particles in the breathing zone.

After

Temperature-controlled Laminar Airflow (TLA) filters the air in the breathing zone and removes 99.5% of all allergen and irritating particles larger than 0.5 µm.

How Airsonett Air4 helps

Airsonett Air4 uses the unique, patented Temperature-controlled Laminar Airflow (TLA) technology to direct a light flow of filtered clean air towards the breathing zone. The filtered air is slightly cooled before being released from the air shower: It then gently falls with gravity, pushing away the particle and allergen-rich air from the breathing zone. At least 99.5% of particles ≥0.5 µm are therefore blocked from reaching the patient's breathing zone during sleep. The treatment allows airways and immune system to rest and recover during the night. Airsonett Air4 should be placed next to the bed and used every night. This will protect the patient's breathing zone from irritating particles and allergens throughout the night.

TLA technology ensures that the air purification effect focuses on the breathing zone, where it makes a difference, rather than purifying the air throughout the room. Airsonett Air4 has therefore proven to be a hundred times more effective in cleaning the breathing zone from particles, compared to an air purifier with corresponding air flow rate and filter efficiency.[5,6]

Clinically proven

Patients who experience the most significant effects of Airsonett TLA are those with uncontrolled allergic asthma, who do not reach treatment goals at step 4 of the GINA recommendations. Airsonett TLA has also demonstrated positive effects on other allergic diseases such as rhinitis and atopic dermatitis.[7,8]

Treatment with TLA is recommended by the Swedish National Board of Health and Welfare (Socialstyrelsen), MPA (Läkemedelsverket) and the Swedish paediatricians' association allergy section (BLFA).[9,10,11] It has also been reviewed in the UK by The National Institute for Health and Care Excellence (NICE)[12] and proven cost effective by Health Improvement Scotland.[13]

Cost-effective

Economic analysis based on a 12-month observational study and the cost situation in the UK showed that:[14]

> Airsonett TLA is a cost-effective add-on treatment for patients with severe allergic asthma.

> For high-risk patients with more severe symptoms and whose asthma is uncontrolled, Airsonett TLA may reduce the need for hospital treatment and lead to savings for the NHS (the UK public medical system).

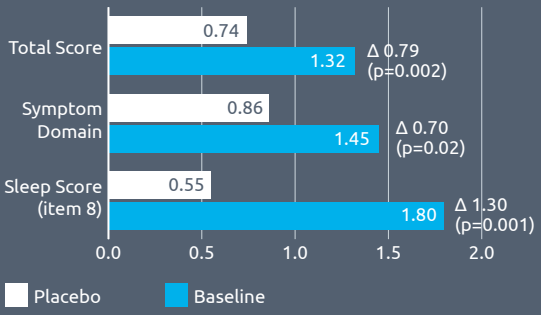
Reduced airway inflammation[1]

Parameter	Δvs. Plac.	p-value
Airway inflammation		
FENO all patients	-7.1 ppb	0.03
FENO >45 ppb (N: TLA=56, PBO=23)	-29.7 ppb	<0.001

12 month double-blind randomised parallel-group multi-center trial (N=312); Age 7–70 years

Improved asthma-related quality of life, symptoms and sleep[1,3]

Change from baseline in AQLQ* score

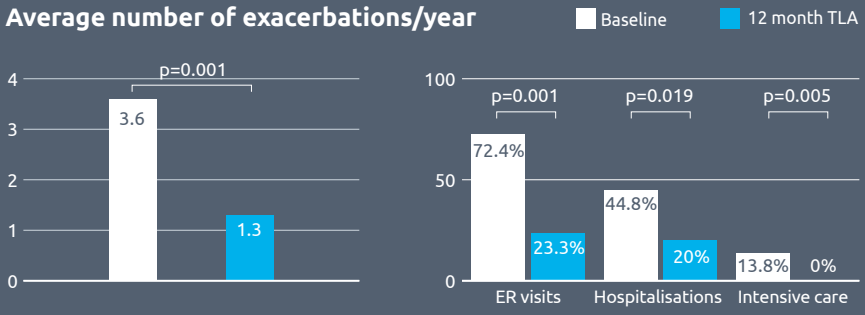


12 month double-blind randomised parallel-group multi-center trial (N=312); Age 7–70 years

Subgroup analysis: Severe uncontrolled asthma (N=87)

Improved asthma control[15]

Average number of exacerbations/year



12 months pre-post observational study in poorly controlled severe allergic asthma; N=30; 8–70 years.

Questions and answers about Airsonett TLA and Air4

For which type of patient is Airsonett TLA an appropriate treatment?
In general, the treatment is suitable for patients with uncontrolled allergic asthma, where the allergy is driven by indoor allergens caused by mites and pets – and aggravated by other allergens, such as pollen.

Are there studies that show a clinical effect?
Several placebo-controlled double-blind studies show a clinical effect.
The most common improvements among patients are described as:
> Easier to breathe with less coughing and wheezing in their chest
> Better sleep, less tired and weary
> Fewer symptoms from other allergic diseases such as nasal congestion
> Better concentration and less frustration
> Less fear of asthma attacks

How fast does the treatment work for allergic asthma?
You can usually see positive effects already after one week. Studies show marked improvement in sleep after about one month and full effect on symptoms after approximately three months of treatment. Airsonett recommends staying on the treatment for at least six months, then evaluating. The effect gradually diminishes when you stop the treatment with Airsonett TLA.

Is there a clinically proven effect for atopic eczema?
Open studies show effect, and there is an ongoing large placebo-controlled double-blind study in England that is studying the effect of the method scientifically.

On what type of eczema patients have favourable treatment results been seen?
Moderate to severe eczema patients, where the disease is driven by allergy to indoor allergens, seem to be the group that responds best to treatment with Airsonett TLA. Typical improvements include:
> Reduced areas of eczema
> Reduced redness and intensity
> Better sleep and an improved general condition
> Less itching

How is Airsonett TLA prescribed?
The treatment is prescribed by a paediatrician, allergist, lung doctor or dermatologist. If you have questions about how it works in your region, feel free to contact us at Airsonett, and we will help.

Does Airsonett TLA have any pharmacological side effects?
No.

Can a patient get treatment with Airsonett TLA while on another medication?
Yes. The treatment does not interact with any other medications.

How can overnight treatment with Airsonett TLA have an effect, when patients are exposed to allergens during the day?
Studies have shown that the method works with treatment only at night. Since the patient is free from exposure to allergens/particles during sleep, it seems that the treatment generates better conditions to meet exposure during the day.

Does the patient need to be treated every night?
More coherent time under Airsonett Air4 means better and faster effect. However, missing one day a week or a few days a month does not seem to decrease the effect significantly.

How does TLA treatment work?
The 99.5% particle-free air in the breathing zone during sleep significantly reduces exposure to allergens. This has been shown to reduce inflammation in the airways and skin, therefore relieving symptoms over time.

Is TLA treatment safe?
Yes. Airsonett Air4 is registered as medical equipment of proven quality and does not produce any pharmacological side effects. The safety and efficacy of TLA treatment, as add-on therapy, have been evaluated in more than a thousand patients in both healthcare and clinical studies.

Is Airsonett Air4 difficult to install and use?
No. Airsonett Air4 is easy to install and use in the home. The filter should be changed every sixth months, which is easy for the patient to do. New filters are automatically delivered in time for changing.

What is the difference between Airsonett Air4 and an air purifier?
Airsonett Air4 focuses on cleaning the breathing zone from irritating particles and allergens, while a traditional air purifier tries to clean the entire room. Technical studies comparing the technologies show up to 100 times less exposure of particles using the unique, patented TLA technology.

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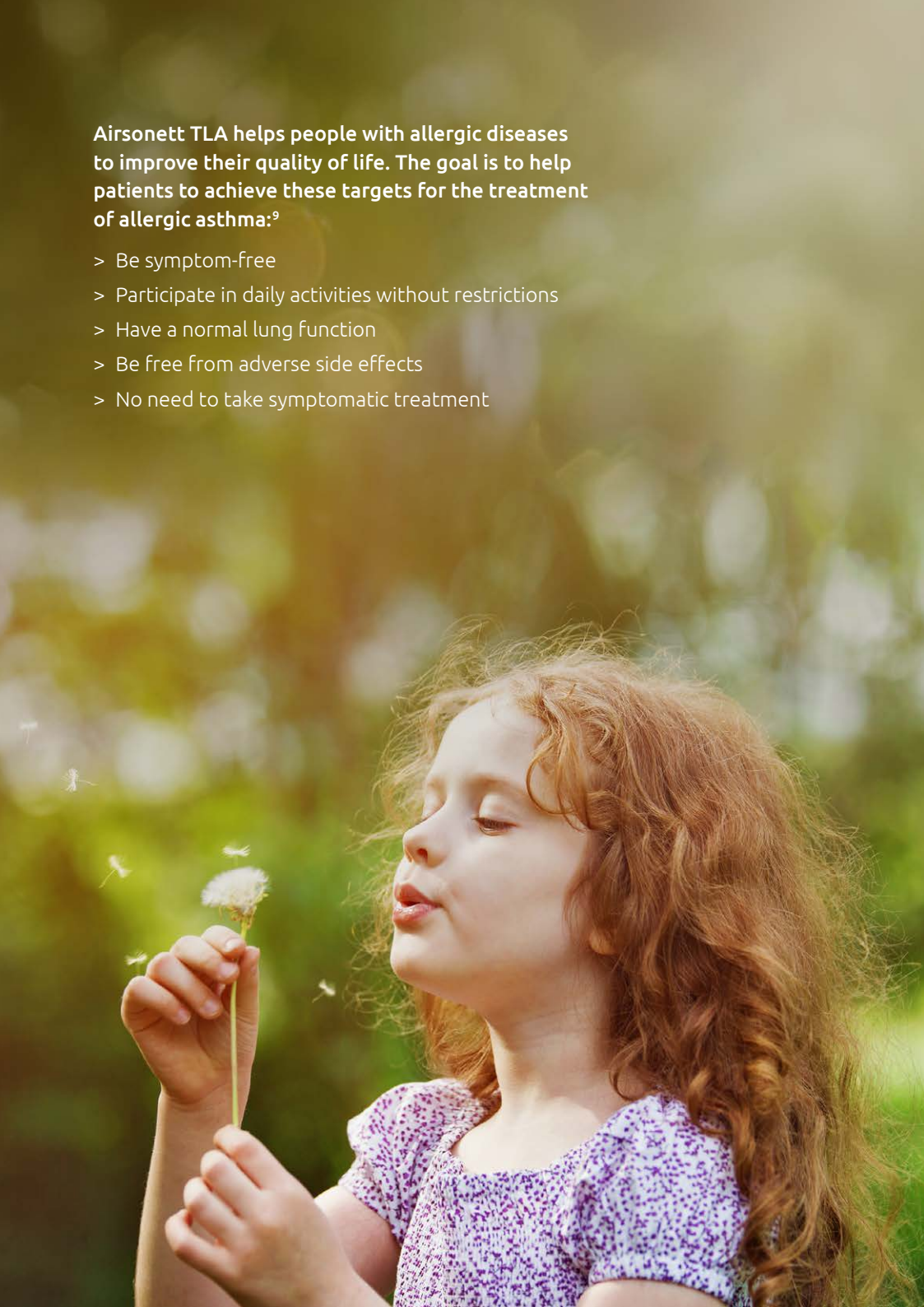
Airsonett TLA helps people with allergic diseases to improve their quality of life. The goal is to help patients to achieve these targets for the treatment of allergic asthma:[9]

- Be symptom-free
- Participate in daily activities without restrictions
- Have a normal lung function
- Be free from adverse side effects
- No need to take symptomatic treatment



Airsonett®

Airsonett AB
Kelliehousevägen 31
SE-262 74 Ängelholm
Sweden

Phone: +46 431 40 25 30

Airsonett UK Ltd
St James House
13 Kensington Square
London W8 5HD U.K.

Phone: +44 2086387400

Mail: info@airsonett.eu
Facebook: @airsonettinternational
Instagram: @airsonett
www.airsonett.eu

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