

# Therapy-efficacy of automatic positive airways pressure therapy with A-Flex compared to standard automatic positive airways pressure therapy in obstructive sleep apnoea (OSA) patients

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<b>Registration date</b> 15/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/05/2008	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
EAME07AFLEX01/02

# Study information

## Scientific Title

### Acronym

A-Flex Validation

### Study objectives

A-Flex is as effective as automatic positive airways pressure (APAP) in reducing respiratory events and arousals in patients with obstructive sleep apnoea (OSA).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from:

1. France: Ethics of Lille on the 11th February 2008
2. Germany: Charite Ethikkommission, Mitte Campus on the 30th July 2008

### Study design

Randomised, controlled, double-blind, cross-over study

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Obstructive sleep apnoea

### Interventions

A-Flex: automatic positive airways pressure device featuring pressure relief technology

APAP: standard automatic positive airways pressure device

The duration of treatment and follow up during the fixed follow-up period will be three months in both arms.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome(s)

A-Flex is as effective as APAP in reducing respiratory events and arousals in patients with OSA, measured with the Apnoea-Hypopnea Index at baseline.

### **Key secondary outcome(s)**

1. A-Flex is more comfortable than APAP, measured using the Visual Analogue Scale [VAS] at baseline
2. Compliance (internal clock within the device) is higher on A-Flex compared to APAP, measured at one and three months
3. Subjective daytime sleepiness is improved on A-Flex compared to APAP, measured using the Epworth Sleepiness Scale at baseline, one and three months
4. Quality of life is improved on A-Flex compared to APAP, measured using the Functional Outcomes of Sleep Questionnaire at baseline, one and three months

### **Completion date**

30/09/2008

## **Eligibility**

### **Key inclusion criteria**

1. Apnoea-Hypopnoea Index (AHI) greater than 15/h confirmed by full polysomnograph (PSG)
2. Aged greater than or equal to 21 to less than or equal to 65 years, either sex
3. Body mass index (BMI) less than 40 kg/m<sup>2</sup>
4. Able to follow the study protocol

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Acute upper respiratory infection, encephalitis, sinusitis or middle ear infection
2. Drug abuse
3. Intake of central relevant drugs, sedatives, or other drugs which impair sleep
4. Alcohol abuse
5. Psychiatric or neurological diseases resulting in impairment of sleep, therapy or compliance
6. Thyroidal dysfunction
7. Chronic pain syndromes
8. Acute cardiac, pulmonary, and other internal diseases
9. Chronic cardiac, pulmonary and other internal diseases resulting in impairment of sleep
10. Central sleep related breathing disorders or other disorders resulting in hypoventilation
11. Periodic leg movements (PLM)/restless legs syndrome (RLS)
12. Previous exposure to either continuous positive airways pressure (CPAP) or bi-level therapy
13. Patients experiencing acute dermatitis or other skin lesions or trauma interfering with the application of a mask
14. Participation in another clinical study in the past four weeks

**Date of first enrolment**

01/08/2007

**Date of final enrolment**

30/09/2008

## Locations

**Countries of recruitment**

France

Germany

**Study participating centre**

Charité-Universitätsmedizin Berlin

Berlin

Germany

10117

## Sponsor information

**Organisation**

Respironics International Inc. (France)

**ROR**

<https://ror.org/05jz46060>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Respironics International, Inc. (France)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration