

# Validation of the Alice PDX Diagnostic System in predicting obstructive sleep apnoea (OSA)

<b>Submission date</b> 28/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/04/2010	<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**  
EAME08PDX01

## Study information

**Scientific Title**  
Validation of the Alice PDX Diagnostic System in predicting obstructive sleep apnoea (OSA): a single blind randomised crossover study

## **Acronym**

Alice PDX

## **Study objectives**

There will be clinical agreement in the Apnoea Hypopnoea Index (AHI) obtained from simultaneous Alice PDX-in lab and in lab-polysomnographic (PSG) recordings, and the AHI obtained from the PDX-home recording. The differences between the AHI from the PSG and PDX-home will not be greater than two PSGs conducted on two different nights.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Germany: Ethik-Kommission in Witten approved on the 17th March 2009
2. France: Comite de Protection des Personnes Ile de France no. 1 approved on the 27th April 2009

## **Study design**

Single blind randomised crossover study

## **Primary study design**

Interventional

## **Study type(s)**

Screening

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

Obstructive sleep apnoea (OSA)

## **Interventions**

Baseline demographic information will be collected. At baseline symptoms of snoring, sleepiness and associated features of OSA will be captured on the Berlin and Epworth Questionnaires.

Subjects will undergo three sleep evaluations:

1. The Alice PDX will be used at home on one night
2. The Alice PDX will be used at the same time as one of the PSGs in the sleep laboratory on another night
3. A separate PSG will be carried out in the sleep laboratory without the Alice PDX on a third night

The sequence of the sleep evaluations will be determined randomly. All evaluations will take place within a two week period.

As a minimum the following parameters will be obtained:

1. Total recording time
2. Total sleep time
3. Sleep latency
4. Sleep efficiency
5. Sleep stage distribution
6. Arousals

7. Awakenings
8. Apnoea Hypopnoea Index (AHI)
9. Oxygen saturation

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Apnoea Hypopnoea Index (AHI) measured by polysomnography and polygraphy (Alice PDX). Measured over three nights in a random order of either:

1. PDX at home
2. PDX and In-Lab PSG at the same time
3. In-Lab PSG

**Key secondary outcome(s)**

1. Apnoea
2. Hypopnoea
3. Supine AHI
4. Total recording time
5. Arousals
6. Desaturation

All will be measured by polysomnography and polygraphy (Alice PDX) as detailed for the primary outcome measures.

**Completion date**

28/09/2010

**Eligibility****Key inclusion criteria**

1. Male and female patients greater than 21 years of age
2. Suspected obstructive sleep apnoea (OSA) or (or suspected simple snorers)
3. Ability to provide consent
4. Ability and willingness to follow study procedures

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

## **Key exclusion criteria**

1. Previous diagnosis of OSA
2. Presence or suspicion of another sleep disorder
3. Acute illness (including cardiac and pulmonary diseases), medically complicated or medically unstable
4. Patients requiring supplemental oxygen or mechanical ventilation
5. Drug abuse (both acute and chronic) according to the Drug Abuse Screening Test (DAST) criteria
6. Alcohol abuse (both acute and chronic) according to the CAGE criteria
7. Intake of excessive central relevant drugs, sedatives, or other drugs which impair sleep, as judged by the investigator
8. Psychiatric or neurological diseases resulting in impairment of sleep
9. Thyroidal dysfunction
10. Chronic pain syndromes
11. Chronic cardiac, pulmonary or other internal diseases resulting in impairment of sleep
12. Unwilling to participate in the study
13. Participation in another clinical study in the past 4 weeks

## **Date of first enrolment**

28/09/2009

## **Date of final enrolment**

28/09/2010

## **Locations**

### **Countries of recruitment**

France

Germany

### **Study participating centre**

HELIOS-Klinik Hagen-Ambrock

Hagen

Germany

60 58091

## **Sponsor information**

### **Organisation**

Respironics International, Inc (France) - Philips Home Healthcare Solutions

### **ROR**

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

# Funder(s)

## Funder type

Industry

## Funder Name

Respironics International, Inc (France) - Philips Home Healthcare Solutions

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration