INFORMATION FOR PATIENTS AND CONSENT FORM

EVALUATION OF THE SENSAWAKE™ FUNCTION OF AUTO-CPAP TREATMENT IN PATIENTS WITH OSA AND INSOMNIA

SENSAWAKE™ FOR PATIENTS WITH OSA AND INSOMNIA

Study Sponsor: Fisher & Paykel Healthcare

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- Pr Marie-Pia D'ORTHO

Dear Madame, Sir,

The purpose of this document is to provide you with all the necessary information so that you can understand the purpose of this study and its constraints. Do not hesitate to ask your doctor for explanations of words or phrases you do not understand.

Why are they proposing that I participate in this study?

This study is conducted at the request of Fisher & Paykel Healthcare, in order to investigate the benefits of SensAwakeTM technology in patients with OSA and insomnia who are on continuous positive airway pressure (CPAP) treatment SensAwake senses nighttime wakefulness by monitoring your breathing, rapidly reduces the pressure and thus facilitates the your return to sleep. This may makes it possible for patients with insomnia to better tolerate CPAP treatment than when using a standard CPAP device.

This study could therefore lead to improvement in the treatment of patients with OSA and insomnia.

We will not compromise the treatment of your OSA during this study. It is possible that the additional follow-up you receive by participating in this study will bring you therapeutic benefits. It is also possible that you will not derive any therapeutic benefit from your participation in this study.

What is the aim of this study:

The main objective of this research is to compare the use of Automated CPAP with SensAwake and CPAP without SensAwake in patients with OSA and insomnia.
The study will take place over an 11-month period during which we wish to recruit 48 patients.
If you agree to participate in this study, the total duration of your participation will be **9 weeks.**

Course of the study:

Visit 1: You will be given a wrist-actigraph to wear during the first week (this 'watch' measures the quality of your sleep). You will also be given a sleep diary, which you will be asked to fill in when you go to bed and when you wake up. You will also be given a blood pressure measuring device to wear for 24 hours, one day and overnight, which will measure your blood pressure continuously.

Visit 2: You will return to the hospital, where we will download the data contained in your wrist-actigraph, and where your sleep diary will be collected. You will then be

assigned randomly to one of these two groups: Auto-CPAP with SensAwake or Auto-CPAP without SensAwake. You will be given a CPAP device and a mask, and you will receive training on how to use the CPAP device and the mask. The CPAP device will automatically measure your use, as well as the effectiveness of this OSA treatment. You will be asked to complete four short questionnaires to evaluate drowsiness, sleep quality, symptoms of insomnia and quality of life.

You will be given a new sleep diary, and you will be asked to use your CPAP device and mask for 4 weeks at home while wearing the wrist-actigraph each night and completing your sleep diary each day. On one of the nights, you will be asked to wear the blood pressure measuring device continuously for 24 hours.

Visit 3: You will return to the hospital, where the data contained in your wrist-actigraph and in your CPAP device will be downloaded, and where your sleep diary will be collected. At this point, we will change the method of treatment (Auto-CPAP with or without SensAwake). You will be asked to complete the four questionnaires again.

You will be given a new sleep diary, and as before, you will be asked to use your CPAP device and mask for 4 weeks at home while wearing the wrist-actigraph watch each night and completing your sleep schedule each day. Again, on one of the nights, you will be asked to wear the blood pressure measuring device continuously for 24 hours.

Visit 4: You will return to the hospital for the last visit, where the data contained in your wrist-actigraph and in your CPAP device will be downloaded, and where your sleep diary will be collected. You will be asked to complete the four questionnaires again to evaluate your drowsiness, sleep quality, and symptoms of insomnia.

You can then go back to your usual treatment and you may have the opportunity to continue using one of the treatment solutions used during this study

Constraints and risks related to research:

CPAP therapy is standard clinical practice for a patient with OSA. The risks associated with this treatment are limited to the possible discomfort associated with the use of a

nasal / naso-buccal mask during sleep. One of the common side effects is dry airways, which can be easily prevented by the use of a moistening system.

"Computers and Freedom"

Computerized processing of the data collected during this study will be carried out strictly ANONYMOUSLY. You will be identified in the data files by the initials of your first and last name and a number.

The computer data file will be declared to the CNIL (French National Commission for Information Technology and Freedom) under number 1938786 v0 of 11 March 2016.

In order to protect individual rights, the law requires that:

In accordance with the provisions of the law on data processing, data files and freedoms, at any time you have a right of access and correct the computerized data concerning you (Law n ° 2004-801 of 6 August 2004 amending law n ° 78-17 of 6 January 1978 relating to data processing, files and personal freedoms). You also have the right to refuse the transmission of the data (covered by the professional secrecy) that may be used and processed in the course of this research. You can also directly, or through a doctor of your choice, access all your medical data in accordance with the provisions of article L1111-7 of the French code of public health. These rights are exercised with the doctor who follows you in the course of this research and who knows your identity.

The data extracted from the computerized file will be exploited according to criteria of strict confidentiality, unless you object by informing the doctor of the sleep center that diagnosed and follows you.

PROTECTION OF PERSONS PARTICUPATING IN BIOMEDICAL RESEARCH

- As for all clinical trials, additional insurance, required by law, has been contracted for this trial by the sponsor. The insurer is Chubb Insurance (formerly ACE Insurance) whose address is: New Zealand Limited CU1-3, Shed 24 Princes Wharf, Auckland 1010, New Zealand. The policy number is: AGEL401312.

- The protocol for this study was submitted to the Southeast France Protection of Persons Committee n°. V, which gave a favourable opinion on 09/12/2015.

- The study has also received authorization from the French National Agency for the Safety of Medicines and Health Products (ANSM) on 03/03/2016.

- This research study does not involve any serious predictable risk to your health, and prior to your consent, a medical examination is carried out, the results of which will be communicated to you directly or by a doctor of your choice

- Participation in this study also requires you to be registered with or a beneficiary of a social security scheme.

- Your agreement or refusal to participate in this study will not affect in any way how you will be treated and monitored. You can withdraw your consent at any time, without incurring any liability or prejudice (Art.L.1121-1 of the Code of Public Health).

- You cannot participate in another biomedical research study for the duration of this study.

- At the end of the study, you have the right to be informed of the overall results. All you need to do is to ask a doctor of your choice. For further information about the study, please contact: Doctor: _____.

PATIENT CONSENT FORM

EVALUATION OF THE SENSAWAKE™ FUNCTION OF AUTO-CPAP TREATMENT IN PATIENTS WITH OSA AND INSOMNIA

SENSAWAKE™ FOR PATIENTS WITH OSA AND INSOMNIA

Consent form for Mr, Mrs .... (Last name, first name)

Address: ……

.....

. .....

Phone: ……

The nature of the study, its purpose and its practical details have been explained to me by the investigating physician who gave me an information sheet. I certify that I have read this.

The investigating physician also explained to me the constraints and risks involved and that I was free to accept or to refuse to participate in this study.

I received satisfactory answers to all the questions I had freely asked about the study. The doctor told me that I had a reflection period of 24 hours, minimum, before I informed him/her of my decision to participate or not.

My participation in this study will not incur any additional costs for me.

I am affiliated to a social security scheme.

I certify that I am not currently participating in another biomedical study.

My consent does not discharge the organizers of the study from their responsibilities.

I retain all my rights guaranteed by law.

If I wish, I can at any time stop my participation in the study without incurring any liability or prejudice. I should inform Doctor ..... at ....

I understand that the data that concerns me will remain strictly confidential. I agree that they can be processed by computer. I authorize their consultation only by persons who collaborate in this research study who are designated by the organizers, and possibly by a representative of the Health Authorities for validation, audit or inspection purposes.

I may at any time request further information from Doctor ..... .

I have received a copy of this document and the information sheet. I have been informed that a copy will also be retained by the investigator and the study sponsor under conditions guaranteeing confidentiality and I consent thereto.

I FREELY AGREE TO PARTICIPATE IN THIS RESEARCH STUDY IN THE CONDITIONS SPECIFIED ABOVE.

Date: ...../..... /.....	Date:...../...../.....
Name and first name of the person participating in the research:	Name and first name of the investigator:
.....	.....
Signature of Participant	**Signature of Investigator**