nitetronic®
have a goodnite

THE **POSITIVE IMPACT** OF GENTLY **TURNING THE HEAD** ON PRIMARY **SNORING**

The clinical efficacy and field application results of gentle head turns on snore detection and sleep quality.

Clinical Study with the goodnite™ Anti-Snore Pillow from Nitetronic

December 2014

PURPOSE

To demonstrate that turning the head has a positive impact on snoring. This principle led to the development of the goodnite™ Anti-Snore Pillow – a unique device that minimizes snoring. An empirical test (results on page 3) with 157 patients sleeping on the device showed an average 67% reduction in snoring. Based on these results a controlled crossover study to substantiate the effect on snoring and arousals caused by pillow-action is performed.

IMPLEMENTATION

The nature of the clinical study is explained and documented with the approved patient pool by the physician in charge to obtain informed consent.

The test begins with the selection of participants, the documenting of the patient pool´s previous PSG reports and the completion of a questionnaire prior to the introduction of the goodnite™ Anti-Snore Pillow.

The goodnite™ is used by each participant during two consecutive nights in the sleep laboratory – 1st inactive and 2nd active. All PSG data were collected, including acoustic snoring and the Arousal Index.

After both nights a subsequent questionnaire will be completed by the participants that asks about their experiences.

EXPECTATIONS OF CLINICAL RESULTS

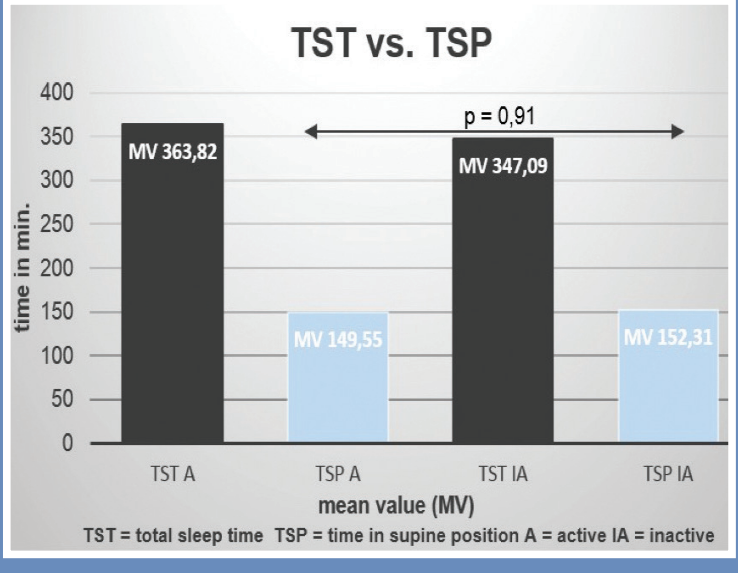
Without the support offered by the goodnite™, it is expected that user will snore continuously without any alteration. This is represented by the pre-test PSG and inactive night PSG report comparison.

By using goodnite™, it is expected, the user will snore significantly less and have an improvement in sleep quality. Furthermore it is expected, that there will be no increase of the Arousal Index caused by pillow-action.

Figure 1 **SLEEP- AND BREATHING-RELATED PARAMETERS**

	PSG active					PSG inactive				
	AHI	**AHI-SP**	**RDI**	**RERAS**	**Snoring Index**	**AHI**	**AHI-SP**	**RDI**	**RERAS**	**Snoring Index**
1	7	9.2	21.5	14.5	72.2	8.5	0	21.9	13.4	132.8
2	1.8	0	58.8	57	460.2	1.2	0.8	35.8	34.6	657.3
3	1.8	2.3	7.8	3.1	182.2	1.6	2	5.8	3.1	188.3
4	1.5	0	8.5	7	63.3	1.4	0.9	10.1	8.7	981.3
5	24.2	0	57.9	33.8	509.8	22.8	0	76.3	52.1	555.8
6	0.7	0	46.8	46.2	537.1	0.4	3.5	33	32.7	531.8
7	3.2	3.1	4.4	1.3	4.8	3	0	7.4	4.4	96.5
8	17.3	23.9	28	10.7	105.5	15.8	33.4	20.7	4.9	130.7
9	3.3	0	15.9	7.2	52.9	4	0	12.5	8.5	46.9
10	9.6	15	16.9	11	361.4	8	11.3	19	11	405.8
11	12.6	22.7	15.8	2	224.8	8.8	0	14.6	5.8	365.3
12	9.5	9.7	23	13.4	128.8	11.7	16.9	21.2	9.5	227.4
13	1.4	0.5	1.4	0	14.1	4.5	6	8	3.5	92.3
14	4.4	7.4	8	3.6	75.4	1.4	2.2	2.2	0.7	169
15	9.1	14.4	12.8	3.7	136.7	11.2	23.3	15.8	4.6	290.8
16	2.5	5.8	22	19.5	165.5	2.1	2.8	9.1	7	248.9
17	4.4	0	6.1	1.8	2	7	10.7	7.5	0.5	20.9
18	19	52.5	21.8	2.8	35.5	27.2	61.3	37.2	10	147.8
19	3.6	4.9	9.6	6	86.6	5.5	7.7	17.1	11.7	87.5
20	1.3	1	20.8	19.6	31.3	0.8	0	10.1	9.3	2
p-value	0.5	0.8	0.6	0.5	0.03					

Figure 2



GRAPHICAL DATA FROM CLINICAL STUDY

The clinical study includes 20 patients who completed the two consecutive, PSG-controlled nights in the sleep laboratory.

ANALYSIS OF GRAPHICAL DATA

Sleep-related respiratory parameters (AHI, supine AHI, RDI, RERA) showed no significant change. The snoring index decreased significantly while using the goodnite™ in the active mode ($p<0,03$) (Fig. 1). The snoring Index was determined using internal signal processing technologies of the PSG-system after manually adjusting snoring thresholds for each night by the aid of the PSG audio files. **The time spent in supine position doesn't change with pillow activity** (Fig. 2).

LIMITATIONS

There are always limitations conducting a study like this. The first is the small participant sample size. It is always preferable to have a larger group with which to conduct clinical research. The second, there are no pre-existing clinical studies on devices changing head position to stop or minimize snoring. The shown effects cannot be compared to results of other studies or clinical trials.

CONCLUSION

With every single patient, a significant reduction in snoring duration was observed in PSG reports during the nights with pillow activity. The comparison of PSG reports show no deterioration of sleep- or breathing-related parameters with active head turning from the goodnite™. No increase in arousals or subjective sleep disturbances were found. This implies that the head movements are gentle enough.

There is no significant change in total sleep time (TST) spent in a supine position with an activated vs. non-activated pillow. **This indicates that head rotation alone is responsible for the documented effects.**

International Field Test of the goodnite™ Anti-Snore Pillow from Nitetronic

October 2013

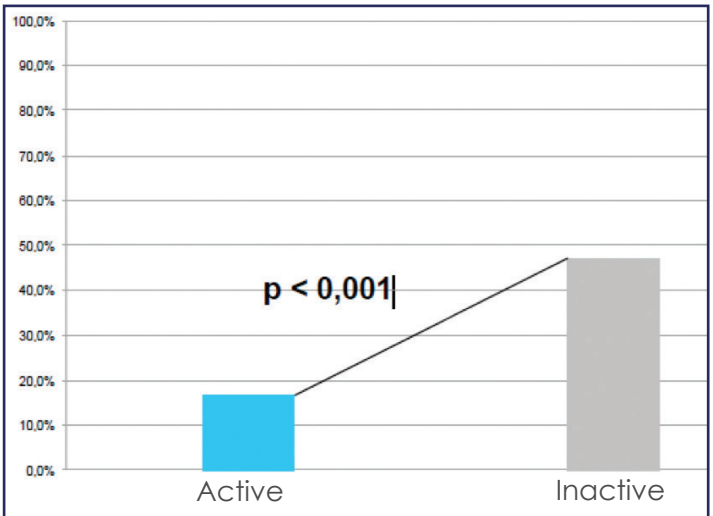
PURPOSE

To demonstrate that turning the head has a positive impact on snoring. This principle led to the development of the goodnite™ Anti-Snore Pillow – a unique device that minimizes snoring. The aim of this test is to measure and document the benefit of this device on snoring.

IMPLEMENTATION

The goodnite™ Anti-Snore Pillow is used with participants in their home environment. The test begins with participant selection, the delivery of the pillows and short instruction in the monitoring software. It had to be used by each participant four consecutive nights – two inactive and two active. Snoring was determined with integrated microphones and the software created an individualized data pool each night that can be statistically evaluated.

Spouses fill out a simple snore-scale questionnaire (0 = absolutely no snoring up to 10 = intolerable snoring).



Average percentage of snoring duration during the night with an inactive vs active pillow

EXPECTATIONS OF TEST RESULTS

It is expected without the support offered by goodnite™, the user will snore continuously, while with the support snore significantly less and have an improvement in sleep quality.

ANALYSIS OF GRAPHICAL DATA

All 157 chosen participants (142 male; 15 female, average age: 54 ± 9.6 years) had a decrease in quality of life due to snoring. A significant reduction in snoring duration percentage (inactive: 48 ± 17%; active: 16 ± 9%; $p < 0.001$) is shown in the comparison of nights with inactive vs active pillow. An average snoring reduction of 67 ± 14 %.

LIMITATIONS

There are always limitations conducting a test of this nature. First, this test design was made to determine if the goodnite™ Anti-Snore Pillow is able to reduce snoring by easy use in the home. The statistical data were collected by special monitoring software, no PSG or PS were used. The second, there are no pre-existing clinical studies on devices changing head position to stop or minimize snoring. The shown effects cannot be compared to results of other studies or clinical trials.

CONCLUSION

This field test was conducted to determine the effect goodnite's™ gently turning the head has on snoring. **The results of the monitoring software as well as the spouses snoring-questionnaire reflect significant reduction in snoring.**

Additional examinations and clinical studies can be beneficial and further confirm the demonstrated effect.

goodnite™
Anti-Snore Pillow

Nitelink²
Smart Phone App
monitors sleep and
snoring patterns

For more information, visit www.nitetronic.com.

Clinical Study and Field Test Descriptive Information and Eligibility

Executing Location of CLINICAL STUDY
University ENT Clinic Mannheim
Theodor-Kutzer-Ufer 1-3, 68167 Mannheim, Germany

Supervising Clinical Director for Study
Dr. Joachim T. Maurer

Study Supervisor for Nitetronic
Dr. Uwe Mehrmann, Nitetronic GmbH

Manufacturer and Device Model
Nitetronic goodnite™ Anti-Snore Pillow

Study Type
This study is an analysis on the effect of goodnite™ Anti-Snore Pillow on snoring duration and arousal caused by the pillow activities.

Study Design
This study is a controlled clinical crossover study to substantiate the effect of an anti-snoring pillow that turns the head when snoring is detected. Participants with the symptom “snoring” without significant OSA diagnosis were chosen out of a larger selection of suitable candidates with the help of the Supervising Clinical Director of the University ENT Clinic at Mannheim. Two consecutive nights in the sleep laboratory were conducted, one night with inactive pillow and the second night with active pillow. All data were collected by PSG (Polysomnographie) and individual questionnaire.

Arms, Groups and Cohorts
The contents of this study are the snoring duration and arousals caused by the pillow-activities. The experiment is the usage of the pillow during two consecutive nights–one night inactivated and second night activated–with PSG reporting in the sleep lab at the University ENT Clinic at Mannheim.

Inclusionary Criteria
The participants must be over the age of 18, have a BMI ≤ 30, have an exclusion of OSA, prior use of PG or PSG, snoring and must be able to provide informed consent.

Exclusionary Criteria
Only exclusionary criteria are BMI > 30, OSAS, no bed partner.

Location of FIELD TEST
Home environment of participants, International

Supervising Clinical Director for Field Test
Dr. Joachim T. Maurer University ENT Clinic Mannheim
Theodor-Kutzer-Ufer 1-3, 68167 Mannheim, Germany

Manufacturer and Device Model
Nitetronic goodnite™ Anti-Snore Pillow

Test Type
This test is an analysis on the effect of goodnite™ Anti-Snore Pillow on snoring reduction.

Test Design
This test is an efficacy test of using goodnite™ Anti-Snore Pillow as an anti-snoring device in home environment. Suitable candidates with the symptom “snoring” are chosen for this test. Two nights with in-active pillow are compared with two nights with active pillow.

Arms, Group and Cohorts
The purpose of this test is to determine the snoring time. The experiment is the usage of the pillow during four consecutive nights–two nights inactivated pillow (just recording of snoring) and two nights activated pillow (recording snoring and pillow activity).

Inclusionary Criteria
The participants must be over the age of 18, snoring and must be able to provide informed consent.

Exclusionary Criteria
There are no exclusionary criteria except overweight (BMI > 40).

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