

Scientific background whitepaper



Preface

Disturbances of sleep are common and treatment options are insufficient. The Somnox device – a tactile, breath-guiding robot – is an alternative intervention that users describe to bring about long-term improvement of their symptoms. This whitepaper describes the findings that inspired its development and elaborates on different aspects of its function before presenting preliminary results supporting its efficiency. In summary, the design draws on extensive literature and the pathways targeted by its working mechanism are empirically well-explored.

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I started Somnox to help a loved one find quality sleep naturally, discovering the transformative power of guided breathing in the process. Now, we aspire to share this remarkable technology with the world, so everyone can experience the profound benefits of restful sleep and reduced stress.

Julian Jagtenberg
Founder & CEO Somnox



Introduction

Sleepless nights are a common issue in the modern world. Approximately one-third of adults report at least one nocturnal symptom [1]. This is especially concerning as the clinical manifestation of sleeplessness, insomnia, has been shown to be related to a broad range of serious health problems affecting cardiovascular function [2], the immunological system [3], and cognitive performance [4].

To date, **treatment of insomnia usually relies on pharmacological interventions whose effects are commonly short-lived and accompanied by side effects** such as daytime sleepiness, drowsiness, and fatigue, as well as very serious adverse events like injuries and a risk of addiction [5].

Future alleys of treatment should be less adverse, better tolerated, and have lasting effects. Clinicians recommend combinatorial approaches that primarily draw on behavioral modifications and use medication only as short-term supportive interventions [6]. The gold standard among such behavioral approaches, Cognitive Behavioral Therapy for Insomnia (CBT-I), lowers symptoms only moderately and for up to a year after treatment [7].

The Somnox device was developed with the aim of addressing these shortcomings and providing an effective and accessible aid to permanently reduce stress around sleep and improve sleep quality.



According to the developers, Somnox leverages physiological, emotional, and behavioral interventions:

Breathing

Somnox offers two modes that guide the user's breath towards a slower pace to induce relaxation. It uses acoustic and tactile stimulation for an immersive experience and optimal soothing of stress.



Companionship

Owing to the shape and size of the device, it eases anxiety by acting as a huggable companion. This provides a sensation of support around bedtime and a cue of positive valence.



Coaching

The sensory experience can be complemented by playing custom audio or sleep coaching lessons available to users. They draw on effective behavioral approaches for lasting changes in individuals' relationships with sleep.



Survey data collected from users consistently indicate that Somnox is effective in easing stress and anxiety and helping individuals fall asleep faster, sleep deeper, and worry less about sleep. This whitepaper sheds light on the theoretical background that guided the development of the device to understand the mechanistic underpinnings of its function.

In the following sections, the root causes of insomnia are elucidated to understand the requirements of an effective, lasting, and accessible therapeutic approach. The physiological pathways mediating the effect of breathing on insomnia symptoms are explained, and the tactile and emotional properties of the device are described. Finally, empirical evidence on the efficacy of Somnox collected using different modalities are presented.

The hyperarousal theory of insomnia

To elucidate how breathing exercises, companionship, and coaching can help treat insomnia, some theoretical background on the condition is required. Several theories have been proposed to explain the etiology of insomnia. One of them, which has gained particular traction, is the hyperarousal theory of insomnia.

This theoretical framework postulates that occasional problems falling asleep or waking up early can lead to chronic suffering because the fear of not being able to sleep grows continuously and eventually causes sleeplessness.

Affected individuals tend to develop learned sleep preventing associations which turn the sleep environment into a trigger for arousal instead of relaxation.

More sleepless experiences of sleepless nights lead to higher pressure around bedtime and more negative associations with nighttime cues, which in turn increase rumination and worry about sleep even more.

This circle of perpetual aggravation of both sleep disturbances and implementation of negative beliefs is postulated to turn occasional poor sleep into chronic insomnia [8]. Along this line of argumentation insomnia is closely intertwined with stress and anxiety.

Empirical proof for this hypothesis has been found in the observation that physiological arousal is increased in individuals suffering from chronic insomnia [9].



The autonomic nervous system

The autonomic nervous system controls vital functions, such as respiratory and heart rates or the secretion of hormones, and responds to arousing stimuli in our environment.

This system can be broadly divided into two axes: the sympathetic branch, which prepares us for action, and the parasympathetic branch, which is responsible for calming us down.

Both adapt our level of alertness to environmental requirements in a constant interplay, fine-tuning the specific physiological functions required under the given conditions [10].

Heart rate variability (HRV) is one of the most commonly used measures to quantify the balance of parasympathetic and sympathetic activity. It describes the homeostatic equilibrium of the autonomic nervous system through alterations in heart rate which reflect both sympathetic and parasympathetic activity [11]. HRV can thus be considered a physiological fingerprint of stress.

The homeostatic balance of the autonomic system seems to be off in individuals with insomnia and chronic stress. Both are characterized by a failure of the nervous system to tune activity down to a “rest and digest” state.

This can be indicated by altered HRV in individuals with chronic insomnia [12], but also manifests in cortical activation during sleep [13], increased body temperatures [14] and changes in hormonal balances [15].

Interventions that aim at increasing parasympathetic control have therefore become popular therapeutic approaches to help restore the equilibrium of the autonomic nervous system. While most of these regulatory functions take place automatically and outside of conscious control, one's physiological system can be accessed volitionally: breathing.



Slow breathing to reduce stress

A myriad of studies have explored the impact of breathing exercises on the autonomic nervous system and, in particular, of slow breathing on parasympathetic control [16], ultimately resulting in a reduction of arousal and stress.

Breathing techniques involve the active control of inhalation and exhalation, and result in a change in the pace or depth of respiration. They have a longstanding tradition in Eastern cultures and have been implemented in common practices, such as pranayama, Tai Chi, and Zazen meditation. Practitioners believe that in controlling one's breath lies the key to health, wellbeing and longevity [17].

The benefits of different breathing techniques on various health outcomes have been demonstrated in numerous studies. **Slow breathing techniques that typically involve tuning one's respiration rate down to 10 or less respirations per minute are particularly effective in increasing parasympathetic control to reduce stress and arousal [18].**

Studies have shown the effectiveness of slow breathing in positively affecting markers of the autonomic nervous system and psychological well-being, as well as in reducing stress and anxiety [18-20].

Kromenacker et al. demonstrated that heart-rate variability was positively impacted by slow breathing protocols and established that this effect was mediated by activation of the parasympathetic nervous system [21]. In addition to the effect on heart rate, Hinterberger and colleagues observed an increase in slow cortical oscillations, indicating that both physiological and mental arousal could be soothed by slow breathing [22].



Leveraging breathing techniques to improve sleep

Aside from the pace of breathing, **manipulating the rate of inhalation and exhalation (I:E ratio) has also proven useful in inducing relaxation**, an effect that was reflected in subjective reports of anxiety and heart-rate variability in a study by Lin et al [23]. The potential of slow breathing as an alternative treatment not only for stress but also for insomnia has not gone unnoticed by the scientific community either.

Tsai et al. showed that a 20-minute session of paced breathing before bedtime significantly reduced wake after sleep onset and improved subjective sleep quality in individuals with insomnia [24].

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These findings were corroborated using a range of methodologies. Kuula and colleagues found slow-paced breathing and music listening before bedtime increased central delta power during deep sleep – an EEG frequency range that indicates deep sleep [25]. Furthermore, one investigation linked breathing exercises to an improvement of sleep quality and a reduction in physiological arousal measures around bedtime [26].

Given the ancient knowledge on the potential of breathing techniques and mounting empirical evidence in support, one issue remains:

The same stress and hyperarousal could impede them from doing so. **Practicing breathing exercises requires time and energy, which individuals suffering from insomnia may lack.** The root cause of their problem could also be what gets in the way of their solution.



This is where technology enters the stage. External breath guidance using a device provides an easily applicable and comfortable way to passively benefit from slow breathing. Aside from being so accessible, Sharpe and colleagues found external breath guidance to also be more effective in activating parasympathetic control than active self-paced breathing [27].

Let us examine how exactly this works. Biofeedback uses electronic devices to measure and consequently control physiological functions and ultimately to alter the activation state of the autonomic nervous system. Fine-tuning of the target frequency and precise timing of feedback are crucial for achieving the desired effects [28]. 4 weeks of HRV biofeedback and slow breathing effectively improved subjective sleep quality and autonomic nervous system function in a study conducted by Herhaus et al. [29].

Breath-pacing devices that use biofeedback for respiratory control have taken the market by storm in the past decade, and solutions in all forms, shapes, colors, and for all sensory modalities have been developed. E.g., visual and olfactory solutions that use pulsing lights or smells are effective in inducing relaxation in different settings [30, 31]. However, a thorough review of studies on breath pacing devices found tactile stimulation to be preferred by participants, as they found following it more natural and engaging [32].

Several such devices were put to the empirical test: **a handheld breath pacer was found to reduce anxiety by altering I:E ratio through biofeedback** [33]. A similar device that included movement in its working mechanism was found to lead to a significant decrease in breathing frequency [34]. The use of such technologies specifically for sleep problems has also been explored on several occasions, consistently yielding improvements in sleep quality [35-37].

Somnox incorporates these findings by using a sensor to monitor breathing frequency, which informs the device's expansion mechanism in real time. By guiding the user's respiration to a slower pace or altered ratio of inhalation and exhalation through noticeable movement, **Somnox aims to induce relaxation and activate the parasympathetic nervous system, ultimately aiding insomnia symptoms.**

Symptoms which, as discussed earlier, include negative associations with sleep and a state of stress and anxiety as the night approaches. Tackling these requires taking into consideration another aspect of the condition: the emotional side.

A friend in need

Individuals struggling with insomnia profit greatly from devices that not only provide tactile stimulation, but also act as a tangible rock in the branding. One they can rely on when the dreaded bedtime approaches.

Affective touch has a soothing effect on individuals by exerting a positive influence on several biomarkers of the autonomic nervous system and endocrine function [38]. This effect was observed irrespective of whether touch involved another human. In a review by Strauss et al., gentle touch by a machine was rated similarly pleasant as interpersonal touch [39]. Eckstein et al. reviewed a broad range of studies investigating the calming effects of touch across human, animal, and robotic interactions, and concluded that **tactile stimulation by devices can reliably alleviate stress through neural and hormonal pathways associated with social bonding** [38].

These effects are reflected in both physiological markers and psychological measures. Robinson and colleagues found that interaction with a companion robot significantly decreased blood pressure and heart rate in their participants [40].

In another study, a touch-centered calming interaction with a social robot effectively reduced participants' heart and respiration rates, while increasing their feelings of calm and happiness. The tactile feedback, simulating the sensation of breathing, was shown to provide substantial emotional comfort [41]. A similar device tested by Haynes et al. mimicked the sensation of a calming hug and significantly reduced state anxiety levels among participants, leaving them feeling more relaxed and comforted [42].



In conclusion, the Somnox device is designed to complement the beneficial effects of slow breathing on the autonomic nervous system with the soothing effect of affective touch demonstrated in several studies.

Somnox addresses the emotional component of insomnia by serving as a companion that keeps users company on their way to bed and tackling both their physiological arousal as well as anxiety regarding sleep.

However, while both of these aspects can provide immediate, momentary relief, in order to achieve sustainable improvements in sleep quality and a lastingly relaxed attitude towards sleep, it is recommended to include an emphasis on behavioral changes [43].



Towards a healthy relationship with sleep

Within the hyperarousal framework, the chronic disturbance of sleep is a result of negative associations with sleep and bedtime, which should be modified to reduce individuals' pressure to fall asleep, leading to a decrease in arousal and quicker sleep onset.

CBT and ACT both aim to alter dysfunctional cognitions and thereby reduce arousal around the topic of sleep, addressing the root cause of insomnia. Both have documented success, and elements of each were integrated into a combinatorial approach in the past, where the challenging behavioral modifications of CBT-I were supported by ACT's focus on increasing individuals' willingness to experience unpleasant sensations [46].

Cognitive Behavioral Therapy for Insomnia (CBT-I) is the most prominent non-pharmaceutical approach to aid insomnia and combines cognitive and behavioral interventions. It was shown to be particularly effective in changing maladaptive beliefs regarding sleep [44].

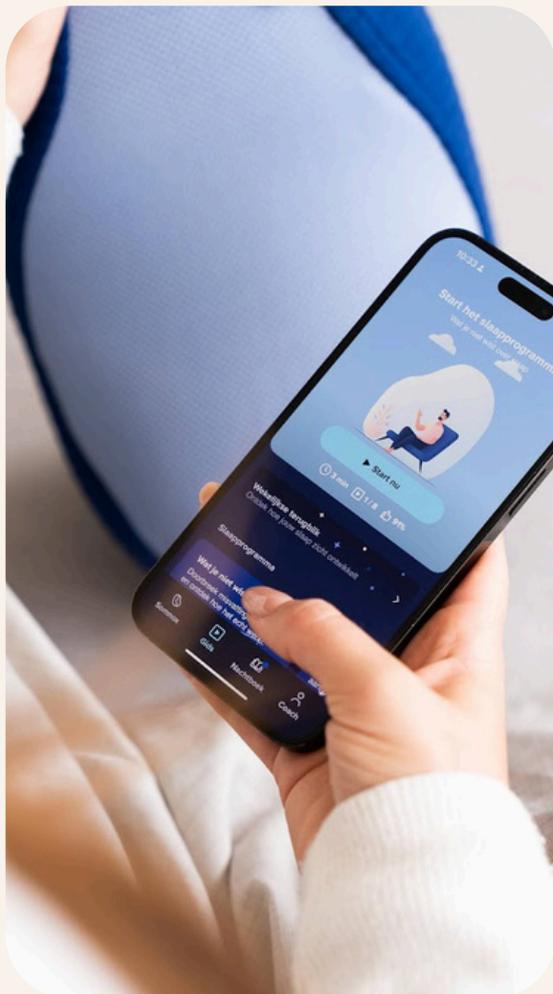
Acceptance and Commitment Therapy (ACT) is an alternative therapeutic approach that focuses on decreasing pressure around sleep and aiding individuals to develop a relaxed relationship with their sleep habits by fostering mindfulness and non-judgmental attitudes [45].



The sleep coaching lessons offered by Somnox follow the same integrative approach, and thereby aim to complement the momentary physiological and emotional benefits of the device.

Strategies by both CBT-I and ACT are leveraged to build a sustainable shift in individuals' attention away from sleep to lastingly improve their relationship with sleep.

This can be achieved by listening to the audio lessons using Somnox at the time of going to sleep or by incorporating them into a relaxation practice during daytime.



In line with clinicians' recommendations, this combinatorial intervention aims to **achieve long-lasting improvement of symptoms, while simultaneously being easy to implement and engage in.** According to a survey conducted by Somnox, more than 2.388 users reported trying the sleep coaching lessons, and 91% of them found them helpful [1] [2].

After this elaboration of the theory behind Somnox and its scientific backing, the following section provides an overview of how it is put into practice by presenting an overview of studies conducted specifically on Somnox and its effectiveness in treating insomnia symptoms.

Evidence on Somnox

In a mixed-method, proof-of-concept study in **ADHD patients with insomnia**, Støre et al. found that **3 out of 4 participants reported clinically relevant improvements of insomnia symptoms after using Somnox 1** [47].



The most recurrent theme in their interviews was for the device to be “a pleasant companion”, indicating that the affective component was a prominent feature of the robot.

Participants described Somnox as having aided them in relaxing at bedtime, falling asleep at night, and during nightly awakenings and that it soothed their feelings of anxiety, making them feel calm and secure.

Furthermore, the reported depression and anxiety symptoms were stable or improved over the course of the study, confirming that Somnox is safe for use in clinical populations with insomnia symptoms, in contrast to traditional pharmacological treatment.

These findings align with the subjective report of Biswas et al. [48], who reported **an increase in total sleep time during the use of Somnox 1** as measured with a smartwatch, **as well as a feeling of emotional support.**

A randomized waitlist-controlled trial investigation conducted by the same group showed slight improvements in insomnia symptoms after using Somnox 1 for three weeks, but the effect did not reach statistical significance [49]. A follow-up study revealed that higher levels of anxiety and insomnia severity were predictive of participants’ responses to Somnox, highlighting that highly severe clinical cases might require additional interventions [50].



Since publication of these studies, Somnox 2 has been launched with significant improvements to the algorithm and sensory experience of the device. In the development of this next generation of Somnox, feedback from the participants of the above-mentioned mixed-method study was implemented, and several shortcomings of the previous model were addressed.



The results are **improvements in shape, expansion of the device during the breathing intervention, a reduction of volume and vibration, as well as decreased weight and a softer haptic experience.** In addition, the behavioral aspects of insomnia can now be addressed through coaching lessons.

These advances were tested in an efficacy study conducted in 2022. Insomnia severity, impact, and stress were significantly reduced during the course of the investigation. Participants reported their sleep during a one-week baseline period before using Somnox 2 with one version of the algorithm during the course of one month. A pause week followed before the device was tested with an

alternative version of the algorithm for another month. Both interventions led to a significant decrease in the Perceived Stress Scale (PSS).

Additionally, **reported sleep quality and efficiency were significantly increased** as assessed through the Sleep Condition Indicator (SCI), increasing the average score from “probable insomnia disorder” to “no insomnia disorder” [51].

In conclusion, the functional mechanism of the Somnox 2 device was developed based on empirical findings across several domains. Thus, the product is a promising alternative to existing strategies for combating sleep problems, stress, and anxiety. By integrating several elements into its

function, it is designed to tackle insomnia from different perspectives, in line with theoretical frameworks that similarly underscore the complexity of the condition and its dynamic pathogenesis. What is currently missing are additional proof-of-concept studies; however, empirical investigations on its effectiveness are underway and highly likely to reflect the theoretical backing of the device.



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