TECHNOLOGY VERIFICATION REPORT

NAME OF THE DEVICE:	Phototherapeutic chamber Spectrasol – light sauna
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DESCRIPTION OF THE DEVICE

The Spectrasol light sauna is a cube-shaped pavilion with a side of 2.5 meters. A space is created inside the structure offering comfortable seating for up to 6 people. The entire ceiling and half of one of the side walls of the space are equipped with LED light sources with a diffuser so that this entire area acts as a light source

with balanced brightness. The other internal and external surfaces of the walls are upholstered with light material with high light reflectance. The two open walls of the pavilion are equipped with curtains supporting the even distribution of light in the interior. The combination of high illumination, effective spectrum and uniform, multidirectional distribution of light in space ensures high light intensity without a significant risk of glare. The high representation of wavelengths in the region of 460 - 520 nm creates high melanopic efficiency of light radiation

Object of verifying the technology

The object was to verify whether the Light Sauna technology affects subjective experience, cognitive functions and physiological variables, both immediately after a single exposure and after regular repeated exposure.

PROCEDURE FOR VERIFYING THE TECHNOLOGY

Healthy subjects and the clinical population were used for the verification and performed in the following six areas:

- Visual comfort
- Affective experience and mood
- Cognitive function
- Sleep
- Circadian rhythms
- Electrical activity of the brain

Visual comfort

We evaluated visual comfort at the maximum output of the Light Sauna (11,000 lx) and a two-week daily 30-minute exposure on a group of healthy volunteers. The evaluation tool was an analog self-assessment Visual Comfort Scale consisting of seven items. The scale was administered after each of a total of 10 sessions. The subjects rated the light in the Light Sauna at its full power as pleasant and the glare as acceptable or easily acceptable, while the visual comfort did not decrease during the ten sessions and, on the contrary, was rated higher as the sessions progressed. In terms of visual comfort at full power and repeated exposure, the device can be summed up as easily tolerated.

Influence on affective experience and mood

We evaluated the affective experience and mood of the healthy volunteers and in the clinical population. In various studies, we have consistently noted the immediate effect of exposure to light in the Light Sauna on reducing negative affectivity assessed by the Positive and Negative Affect Scale. This effect was manifested not only in healthy individuals with normal sleep, but also in persons after partial sleep deprivation and in patients recovering from an acute episode of psychotic illness. The effect of the light intervention on reducing negative affect was apparent both in the winter and summer seasons. It can be summarized that exposure to light in the Light Sauna immediately reduces the intensity of negative emotions.

Effect on cognitive function

We evaluated the effect of light exposure on cognitive functions in healthy volunteers, both immediately after a single exposure to light in the Light Sauna and after repeated two-week phototherapy with an interval since the last exposure. Exposure to light in the Light Sauna (8000 lx) positively affected performance in the Number Repetition Test. After exposure to the light, the probands were able to repeat more numbers in a row than before it. After two weeks of phototherapy, the improvement in performance in the Number Repetition Test was at the borderline of statistical significance.

Effect on sleep

Since the professional literature mentions sleep problems among the possible side effects of phototherapy, we verified whether the Light Sauna technology leads to changes in sleep. For testing, we used two different light intensities (2300 lx and 11,000 lx) and we evaluated sleep using a validated sleep quality questionnaire and objective methods (actigraphy and polysomnography).

The subjectively evaluated quality of sleep did not change after two weeks of regular exposure to light in the Light Sauna (30 min, 11,000 lx) on healthy volunteers. Similarly, we did not see a difference in the magnitude of the change in the score on the sleep quality questionnaire in patients who were exposed to light in the Light Sauna daily for two weeks (30 min, 2300 lx) and patients who were only monitored (control group).

In the actigraphic parameters, we noted a higher index of sleep fragmentation during the two-week period of phototherapy in healthy subjects who were exposed to the maximum light intensity that the technology is capable of creating (11,000 lx). When patients were exposed to a lower light intensity (2300 lx), the sleep fragmentation index did not increase during phototherapy, but remained unchanged.

Before the start of the two-week phototherapy and after its completion, we also performed a laboratory polysomnography examination, which is the gold standard for sleep diagnostics, in healthy volunteers. After

the end of phototherapy, sleep efficiency (the ratio of sleep to time spent in bed) was on average 89.4% (± 9.13), while the norm is considered 85% and more. It can therefore be concluded that the Light Sauna is well tolerated in terms of sleep, at least up to the tested dose of 11,000 lx and 30 min per day, although it is preferable to set the device to a lower intensity if it is sufficient to achieve the desired effect (studies carried out by us, see Annex 1). The light spectrum of the Light Sauna is biologically highly effective, therefore its intensity can be lower than the light intensity of some other phototherapy aids to achieve the same effect, which in practice also means higher visual comfort for the patient.

Effect on circadian rhythms

In the verification studies, we evaluated the effect of repeated long-term exposure to light in the Light Sauna (2 weeks, 30 min per day) on the circadian rhythm of physical activity and on the circadian rhythm of melatonin levels. We tested both healthy and clinical populations.

Actigraphic analyses demonstrated an increase in the inter-day stability of the circadian rhythm in healthy individuals exposed to a light intensity of 11,000 lx. In hospitalized patients exposed to a light intensity of 2300 lx, regular morning exposure to light in the Light Sauna resulted in maintaining the stability of the circadian rhythm. In the control group, which was not exposed to light in the Light Sauna, there was a decrease in the inter-day stability of the circadian rhythm of physical activity during hospitalization. Comparison of 24-hour profiles of melatonin levels from saliva samples demonstrated higher amplitude and mesoscale values of the melatonin rhythm after phototherapy compared to baseline measurements in healthy volunteers.

It can therefore be summarized that regular exposure to light in the Light Sauna supports circadian rhythms. In clinical practice, it can also be used for hospitalized patients who have limited opportunity to spend time in daylight.

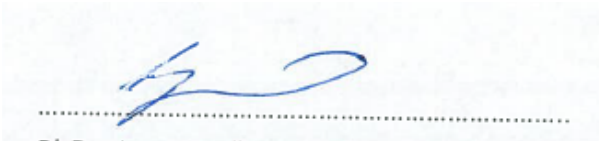
Effect on the electrical activity of the brain

The effect of light in the Light Sauna on the electrical activity of the brain (EEG) was tested on healthy subjects. We assessed the change in EEG activity continuing after the termination of light exposure. Thirty-minute exposure to 8000 lx light was associated with an increase in EEG activity in the right frontotemporoparietal region in the alpha, beta 1, beta 2, and gamma bands, with the most pronounced changes found in the right posterior insula. So it can be summarized that the light of the Light Sauna leads to a change in electrical activity, especially in the part of the brain that is involved in the processing of emotions.

DETAILED REPORTS AND RESULTS OF THE VERIFICATION EXPERIMENTS

See Annex 1.

In Klecany, 31 December 2023



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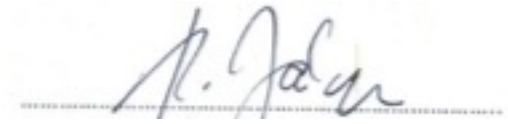

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