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TEST REPORT:

SCIENTIFIC CLINICAL SHORT-TERM TESTING OF PHYSIOLOGICAL PARAMETERS FOR THE PRODUCT

MATTRESS PAD »Biocrystal[®] SleepPad[™]«

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1. ABSTRACT

The purpose of the testing

Effect evaluation of the »Biocrystal[®] SleePad[™]« mattress pad (from here forward named as Biocrystal pad) on sleep or rest of test subjects which is claimed by the producer to improve sleep or rest.

Type of testing

Producer's claims were examined with a scientific, clinical study design, which means that the testing procedure was

- **Prospective** (the general criteria for activity efficiency were selected in advance)
- **Placebo controlled** (test subjects in a placebo group were not exposed to the test's object influence and test subjects did not know whether they were exposed to real or placebo influence)
- **Double blind** (neither the participants nor the main researcher knew which participant was exposed to the test object influence or belonged to the control group)
- **Randomized** (test subjects were randomly selected to be exposed to the test object influence or just to placebo).

Testing parameters

In order to determine its effects, we measured various physiological parameters: brain activity – EEG, breathing, temperature of a fingertip and skin conductance. Changes in physiological parameters show effect of the tested object (Biocrystal pad) on organisms, either as a relaxation or an elevated stress on one hand or higher/lower alertness on the other hand.

Through monitoring brain activity we expect that according to well known correlations between the intensity of certain brain waves (eg. alpha, beta ...) and the state of attentive alertness / relaxed wakefulness / sleep to deduce the effect of the tested object on human organisms.

Ten test subjects participated in this study, once in a treatment group and once in a placebo group. Altogether we performed 20 tests.

Results

In general, the results differ from the expectation; EEG measurements have shown that the effect of Biocrystal pad on the test subjects were in part awakening and in part relaxing. Based on these results, we conclude that Biocrystal pad used during the day has the effect of raising human energy (induces wakefulness) but also of relaxing at the same time, which connotes a reducing influence on stress. Since from the results it is not possible to infer the way Biocrystal pad would influence human organisms during the night sleep, an additional long-term test during night would be required.

2. INTRODUCTION

The purpose of these tests was to verify the effect of the »Biocrystal[®] SleepPad[™]« mattress pad on the sleep or rest of test subjects (also referred to as: participants). In order to determine its effects we measured various physiological parameters (brain activity (EEG), breathing, skin conductance and temperature). We applied various statistical methods to compare and determine the values of the above mentioned parameters, which were measured while the subjects were lying on the control pad and on the »Biocrystal[®] SleepPad[™]« mattress pad (hereinafter: Biocrystal pad), respectively.

3. TESTING PROCEDURE

The testing took place between May 26th and June 2nd in Bion's facilities. The test subjects were between 25 and 50 years old, of which 6 were women and 4 were men. Prior to the testing, the participants were instructed not to consume any large meals for at least 1 hour prior to the scheduled session and not to drink coffee, alcohol or other energy drinks at least 3 hours prior to the scheduled session.

The testing was conducted in accordance with the principles of clinical experiments, meaning it meets the four fundamental criteria:

- Prospectiveness (the general criteria for activity efficiency were selected in advance)
- Placebo group (test subjects in a placebo group were not exposed to the test's object influence and test subjects did not know whether they were exposed to real or placebo influence)
- Double blind testing (neither the participants nor the main researcher knew which participant was exposed to the test object influence or belonged to the control group)
- Randomization (test subjects were randomly selected to be exposed to the test object influence or just to placebo).

The measurements for each subject were taken at two separate sessions, which were scheduled at approximately the same time of day, in order to minimize the influence of other daily activities (so that, for example, the participant was similarly tired after an 8-hour working day). The test subjects would alternate between lying on the control padding one day and on the Biocrystal pad the following day. We determined the order of these days in advance, so that 5 participants used the control padding on the first day and the Biocrystal padding on the second day, while rest of the group did the opposite.

Before we began the testing procedure, we attached the electrodes to each participant's arms (to monitor skin conductance and temperature), head (EEG) and around the waist (to monitor breathing). The electrodes for measuring brain activity were affixed to standard positions in accordance with the 10-20 system (Klem et al, 1995). We chose the positions C4 (right hemisphere, top of the head – canal 1) and O1 (left hemisphere, at the occipital bone, canal 2; image 1). The participants were instructed to lie down in the most comfortable position (on their back or on the side) on the bed with a sheet covering the padding. The researcher then left the room and monitored the measurements from a computer on another location. The measurements were taken in the course of a one hour session. During this period the participant was lying down and relaxed, trying to fall asleep. After the measurements were taken (but before they were informed of the type of padding they had used), the participants gave their opinion on the quality of their rest on that day.

After we had concluded testing and taken all the measurements, we exported the collected data into an Excel file with a sampling frequency 1 s. We created graphic representations of the data and ran the data through the *Gnumeric* and *RKward* programs for statistical analysis. First we calculated 30 s median values for every subject separately and standardized the data for the median of the first five minutes. Based on these data we then calculated the total median value for all 10 subjects and created graphs for the measured parameters (Images 2 to 7). We then divided one hour of measurements into three 20 minutes periods, within which we looked for statistically relevant differences (Wilcox test of signed rank). The statistical test was therefore carried out based on 40 data (each representing an average 30 s measurements for every parameter). Using the same procedure we carried out the Levens test for equality of variances, in order to determine whether the Biocrystal pad caused the changes in the data variances.

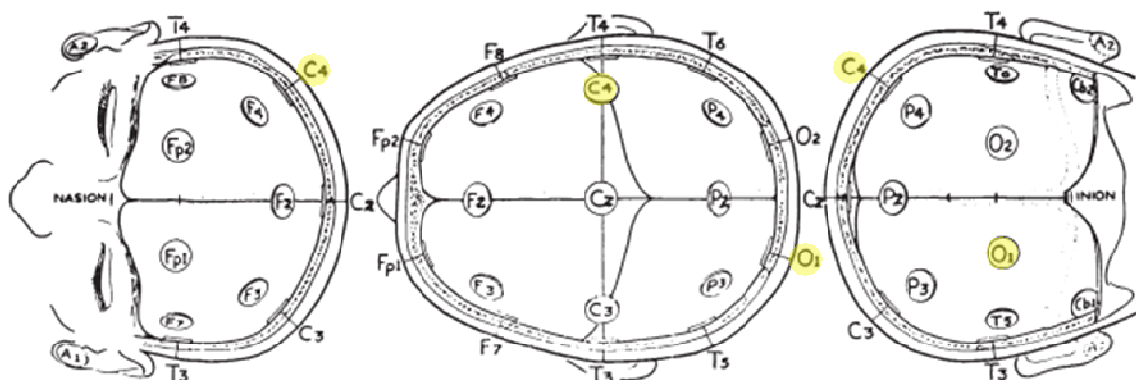


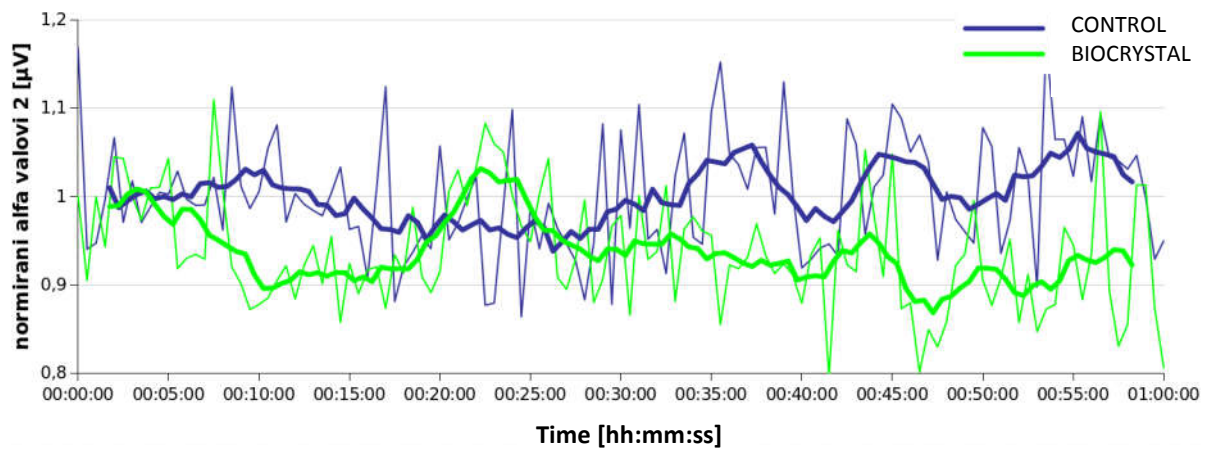
Image 1: Standardized positioning of electrodes according to the 10-20 system (Klem et al, 1995). Yellow color marks the spots of attachment that were used for this testing.



Using the 30 s medians we also calculated the percent of the Biocrystal pad affect (the difference in the values of parameters between the tested padding and the control padding, considering the values of the control padding) and compared the average value of the affecting percent within the 20 minutes periods. Using the same methods we also calculated the correlation of all parameters for each subject, for both types of padding.

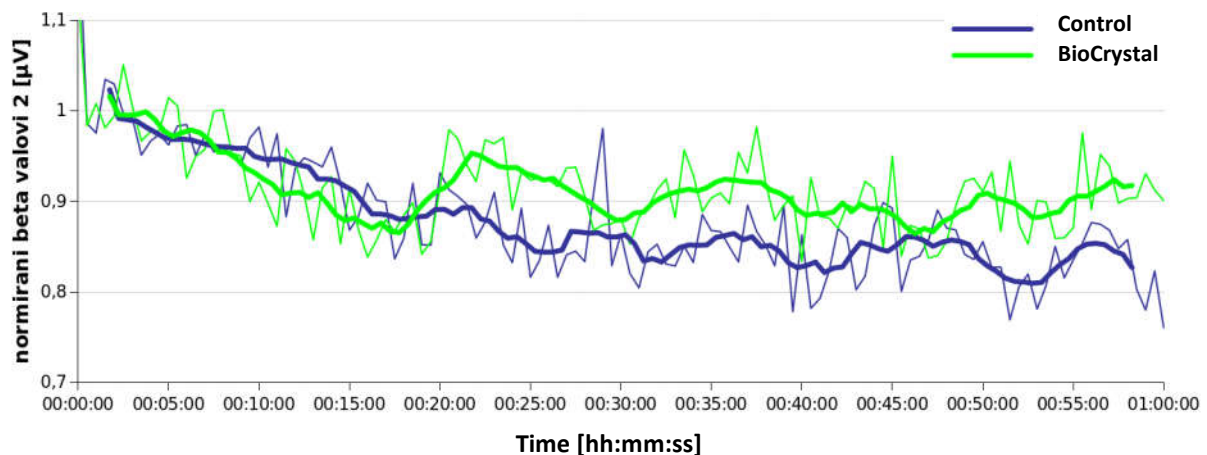
Because the test subjects reported different effects of the padding, we repeated the analysis on two separate groups. The participants that rested better on the Biocrystal pad were in the first group and the others (those who did not notice any difference or else had rested better on the control padding) were in the second group.

4. RESULTS AND DISCUSSION



Standardized alpha waves [μV]

Image 2: The course of the normalized median of brain activity for all subjects in the alpha wave region on the second canal (electrode position: O1).



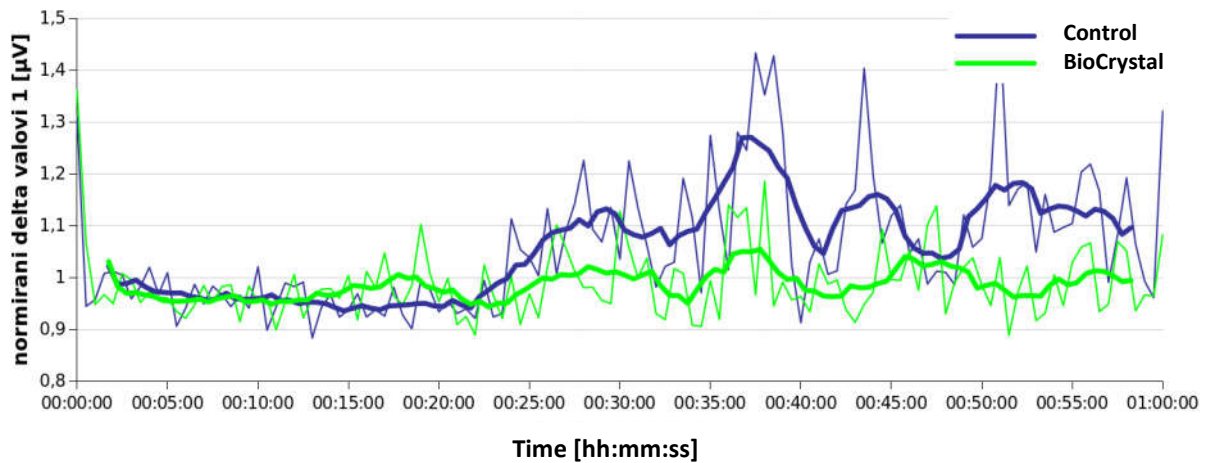
Standardized beta waves [μV]

Image 3: The course of the normalized median of brain activity for all test subjects in the beta wave region on the second canal (electrode position: O1).

The differences between the Biocrystal and control padding are apparent in all 4 observed brain wave frequency regions (Images 2 - 5). The statistically significant differences (the Wilcoxon test of signed rank; see Table 1) of alpha and theta waves were present more or less throughout the whole observed period (the differences decreased in the second 20-minute period, but then increased once more in the last 20-minute period), while there were no significant differences in the beta and delta waves for the first 20 minutes.

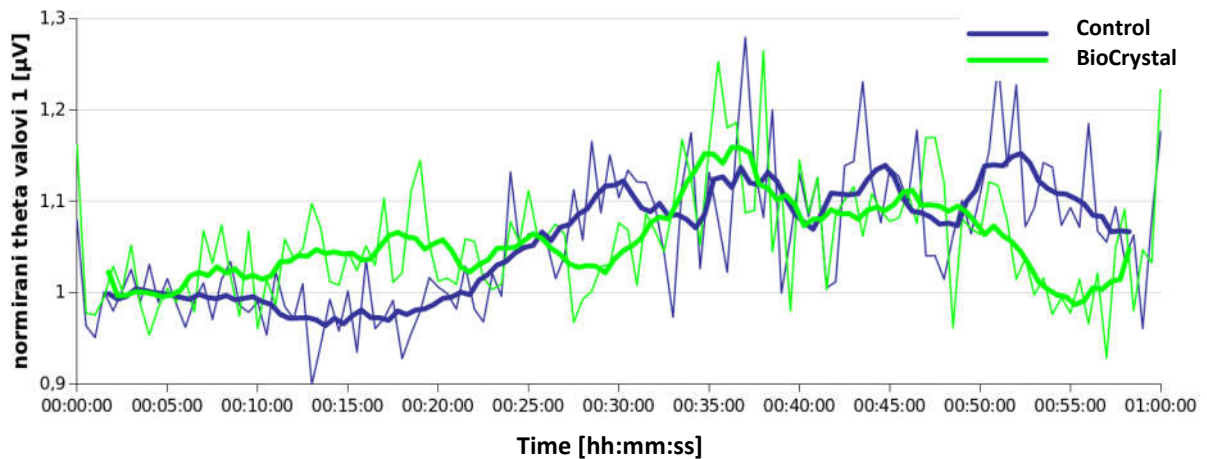
The results in general were unexpected. As the Biocrystal pad is supposed to improve sleep, we expected that – compared to the control padding – alpha and delta waves would increase first and, with a slight delay, theta and lower beta waves would follow. However, the average

response of the participants was exactly the opposite. Compared to the control, we mostly noted a decrease in the alpha and delta waves in the participants (Images 2 and 4) and an increase in beta waves (Image 3). The only brain activity in the first 20-minute, which was expected, was the brain activity of the theta waves (Image 5). Compared to the control, the theta waves on the Biocrystal pad were statistically significantly increased. In the second 20-minute period the difference was slightly decreased and then increased again in the last, third 20-minute period, but this time the values on the Biocrystal pad were lower than on the control padding.



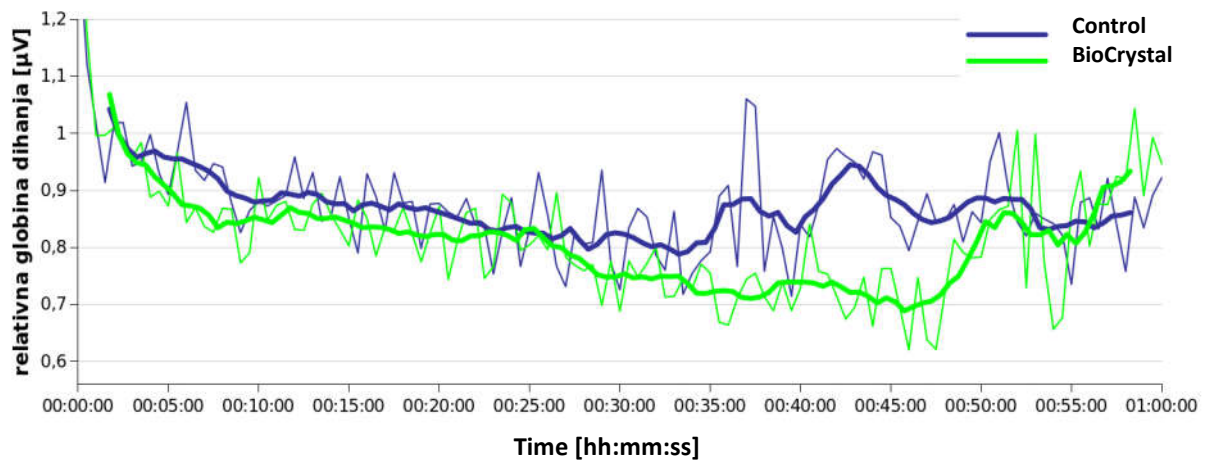
Standardized delta waves [μV]

Image 4: The course of the normalized median of brain activity for all test subjects in the delta wave region on the second canal (electrode position: C4).



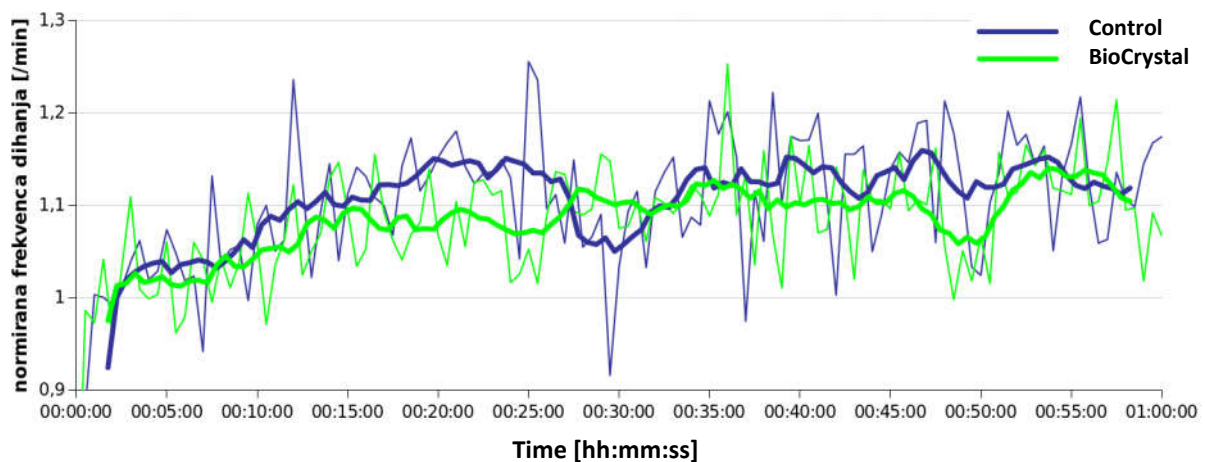
Standardized theta waves [μV]

Image 5: The course of the normalized median of brain activity for all test subjects in the theta wave region on the second canal (electrode position: C4).



Relative respiratory depth [µV]

Image 6: The course of the normalized median of the relative respiratory depth of all subjects.



Standardized respiration frequency [/min]

Image 7: The course of the normalized median of respiration frequency of all subjects.

Images 2 and 5 depict graphs of various brainwave frequency ranges. As we recorded measurements on two canals at the same time, we chose to include the graphs, where the differences between the Biocrystal and control padding are the most apparent. As we can see from these graphs, the recorded differences in alpha and beta waves were more apparent when the electrode was attached at the occiput (position O1), whereas the measured differences in delta and theta waves were greater when it was attached to the top of the head (position C4).

Based on the measurements of brain activity we have obtained, we can conclude that the participants were more awake when they were lying on the Biocrystal pad than when they were lying on the control padding (increased beta waves), but they were also less active or calmer (increased theta levels at the beginning).

Table 1: A summary of the statistical analysis, based on 30 median values for every parameter, for all participants. The cells with statistically relevant differences ($p < 0,05$) are colored green.

All participants	parameter	canal	Wilcoxonov test of signed rank			Levens test		
			0-20 min	20-40 min	40-60 min	0-20 min	20-40 min	40-60 min
			alpha waves	1	0.002	0.285	0.000	0.155
	2	0.000	0.035	0.000	0.707	0.083	0.987	
	beta waves	1	0.087	0.000	0.000	0.405	0.088	0.108
		2	0.156	0.000	0.000	0.254	0.518	0.830
	delta waves	1	0.279	0.000	0.000	0.917	0.002	0.015
		2	0.037	0.000	0.001	0.720	0.028	0.019
	theta waves	1	0.000	0.783	0.004	0.057	0.458	0.929
		2	0.000	0.022	0.021	0.010	0.877	0.257
	skin conductance		0.000	0.172	0.012	0.757	0.418	0.621
	change in skin conductance		0.408	0.009	0.055	0.646	0.010	0.818
	respiratory activity		0.007	0.000	0.001	0.010	0.220	0.671
	rel. respiratory depth		0.002	0.000	0.002	0.804	0.217	0.001
	respiration frequency		0.156	0.134	0.018	0.342	0.057	0.387
	temperature		0.310	0.000	0.005	0.952	0.906	0.000

Table 2: A summary of statistical analysis based on 30 s median values for every parameter for participants, who slept better on the Biocrystal pad (3, left) and for the other participants (7, right). The cells with statistically relevant differences ($p < 0,05$) are colored green.

Participants, who slept better on the Biocrystal pad (the first three)	parameter	canal	Wilcoxonov test of signed rank			Participants, who did not notice the difference between the paddings (7 people)	Wilcoxonov test of signed rank		
			0-20 min	20-40 min	40-60 min		0-20 min	20-40 min	40-60 min
	alpha waves	1	0.386	0.011	0.424	0.012	0.845	0.000	
		2	0.004	0.052	0.888	0.000	0.089	0.000	
	beta waves	1	0.577	0.014	0.005	0.052	0.000	0.001	
		2	0.121	0.416	0.448	0.177	0.000	0.069	
	delta waves	1	0.002	0.250	0.000	0.001	0.000	0.323	
		2	0.001	0.114	0.000	0.002	0.000	0.722	
	theta waves	1	0.000	0.364	0.234	0.030	0.003	0.009	
		2	0.000	0.017	0.298	0.000	0.000	0.014	
	skin conductance		0.000	0.000	0.000	0.835	0.506	0.044	
	change in skin conductance		0.408	0.614	0.010	0.472	0.055	0.000	
	respiratory activity		0.000	0.000	0.000	0.001	0.386	0.000	
	rel. breathing depth		0.040	0.004	0.082	0.000	0.000	0.000	
	respiration frequency		0.000	0.000	0.042	0.000	0.000	0.000	
	temperature		0.034	0.089	0.008	0.000	0.416	0.000	

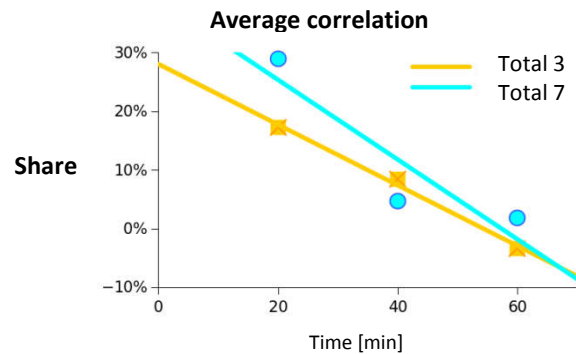


Image 8: Average correlation for all parameters, calculated by taking into account the average of the 3 participants, who slept better on the Biocrystal (group '3' – orange) on one side and the average of the remaining 7 participants who slept better on the control padding or did not notice any difference (group '7' – turquoise).

The differences between the two types of padding were also apparent in some of the other parameters. The difference is especially obvious when observing the relative respiratory depth (Image 6) and the respiration frequency (Image 7), which were consistently lower on the Biocrystal pad compared to the control. The differences were statistically significant throughout the measurements ($p < 0,01$; Table 1). We also observed certain differences in data variability (Table 1 – Levels test), where the statistically significant differences were most apparent in delta waves (with the exception of the first 20 minutes).

As the participants reported different effects of the padding, we repeated the statistical analysis on two separate groups. The first group consisted of the participants who slept better on the Biocrystal pad (3 persons, between 29 and 50 years old, all female), and the second group consisted of the other participants (7, of whom 2 rested better on the control padding (26 and 33 years old, both female) and 5 did not notice any difference (between 25 and 41 years old, 3 male and 1 female)). Considering the several different subjective impressions of the participants regarding the quality of rest on the Biocrystal pad, we wondered whether these differences were also observed on a physiological level. We observed statistically significant differences between the two types of padding in both groups of participants, but there are certain variations. In the group of 7 we observed bigger differences in alpha and beta waves. As beta waves typically indicate the state of being awake and alpha waves typically indicate a relaxed state, it follows that these participants were in fact more awake, but also more relaxed. We also noted a difference in delta waves, which were statistically characteristically different in the group of 7 during the first two time periods, but not in the last 20 minutes. Delta waves are connected to sleep, which indicates that, towards the end of the sessions, the test group on the Biocrystal pad was not resting as deeply as the group on the control padding. There were also noticeably more statistically characteristic differences in theta waves in the group of 7 compared to the group of 3 participants (6:3).

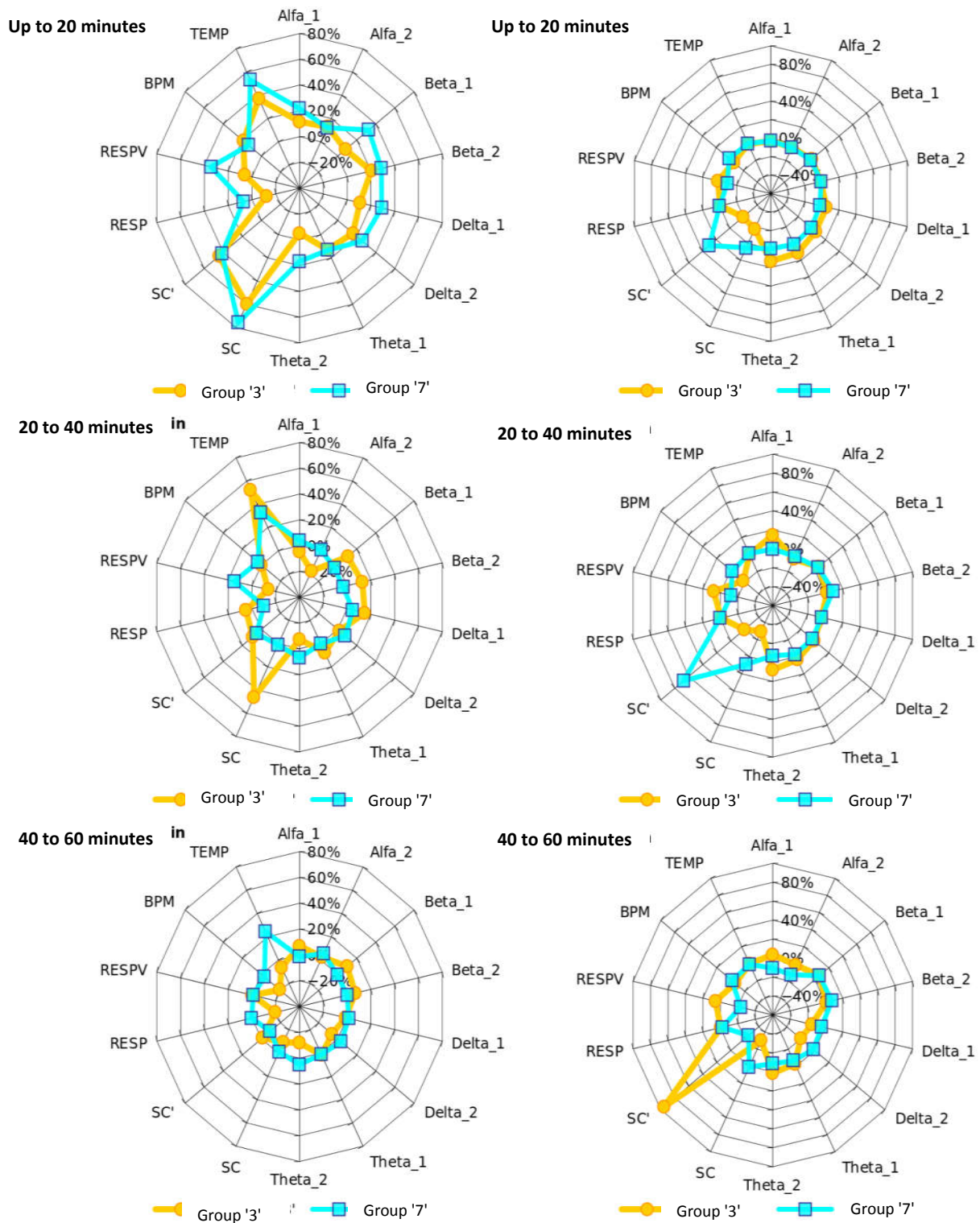


Image 9: The change in correlation (the left graph) and the percent of effect of the Biocrystal pad compared to the control separated in three 20-minute periods. The orange color denotes changes in subjects who slept better on the Biocrystal pad (group '3') and the turquoise highlights the changes in other subjects (group '7'). The marks on the graphs: _1 or _2: 1. or 2. canal for the brain activity measurements, SC: skin conductance, SC': change in skin conductance, RESP: respiratory activity, RESPV relative respiratory depth, BPM: respiration frequency, TEMP: temperature.

We also found interesting differences between both groups of test subjects when comparing the data correlation between the Biocrystal and the control padding (Image 9). Most of the time, the correlation was lower in the group of 3 than in the group of 7 (with the exception of the second 20-minute period). A lower correlation signifies fewer similarities between the data (correlation is lowest at 0% - if it is negative, it signifies opposite trends of data), so the differences between both types of padding are greater in the group of 3 than in the group of 7 (so the padding affected the 3 participants much faster and was more effective; Image 8). The lower correlation between the Biocrystal and control padding is interpreted as a sign of the effect of the padding on certain physiological parameters during resting period (from the EEG results, we can conclude that the padding affected the participants by making them more awake and relaxed).

We did not observe any significant differences between groups in the percent of the effect. The padding obviously affected both groups, but they reacted to it differently.

5. CONCLUSIONS

Considering the results obtained through our measurements, we can conclude that the Biocrystal[®] SleePad[™] padding affected the persons using it, making them more awake and more relaxed, which is also demonstrated by some of the physiological parameters. Test results also show the trends of a decrease in alpha and delta waves (a more awake state), an increase of beta waves (indicating a more active state) and, in the first 20-minute period, increased theta waves (indicating a more relaxed state). The differences were also notable in some of the other physiological parameters; a change in breathing with a lower respiration frequency and depth (indicating a more relaxed state), as well as changes in temperature (temperature swings) and a decrease on skin conductance (indicating a more relaxed state).

On the basis of these results we conclude the mattress pad, if applied during the day, raises the bodily energy (wakefulness), but simultaneously works in a calming, relaxing way. This implies also the lessening of stress state. From the short-term results we cannot infer the working of the mattress at night during sleep and therefore an additional long-term test during night would be required.

According to the results of the testing
the product »Biocrystal[®] SleePad[™]« fulfilled the criteria for obtaining
the Certificate of Energy Influence on Human Organism
in the direction of stress relief and energy enhancing.

To this product we issue certification document No. 0176.



6. REFERENCES

Klem G., Lüders H., Jasper H., Elger C., 1995. *The ten twenty electrode system of the international federation*. *Electroencephalogr. Clin. Neurophysiol.*, 52: 3–6.