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Clinical Investigation Report

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TITLE OF THE CLINICAL INVESTIGATION:

**'USE OF THE ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM
EDUCTOR Biofeedback System IN**

- **STRESS DETECTION AND REDUCTION**
- **MUSCULAR REEDUCATION**
- **PAIN TREATMENT**
- **PREGNANCY STABILITY IMBALANCE (DETECTION OF MEDICAL CONDITIONS)'**

CODE OF THE CLINICAL INVESTIGATION:

BFK-01

Monocentric and comparative clinical investigation

Clinical Investigation Plan

BFK-CIP-01

Clinical investigation carried out in accordance with the standard
SR EN ISO 14155:2012

Date: October 20TH, 2015

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1 SUMMARY

1.1 Title of the clinical investigation

'USE OF THE ELECTROPHYSIOLOGICAL BIOFEEDBACK SYSTEM
 EDUCTOR IN

- STRESS DETECTION AND REDUCTION
- MUSCULAR REEDUCATION
- PAIN TREATMENT
- PREGNANCY STABILITY IMBALANCE (DETECTION OF MEDICAL CONDITIONS)'

1.2 Introduction

The purpose of the clinical investigation is to evaluate the performance and tolerance of the procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR in stress detection and reduction, muscular reeducation, pain treatment, assessed in patients with neuromuscular dystonia and muscle contractures and in detecting the medical conditions (pregnancy stability imbalance).

1.3 Demographic data of the patients

The demographic data of the 57 patients enrolled in this clinical investigation are:

Gender	
Male	11(19,30%)
Female	46(80,70%)
Average age	61,81 years
Residence	
Urban	12(21,05%)
Rural	45(78,95%)
Profession	
Pensioner	41(71,93%)
Worker	3(5,26%)
Home staying	3(5,26%)
Other	10(17,55%)

In order to assess the effectiveness of the specific procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR, the following parameters were monitored:

- Score of depression, anxiety and stress of the subject (patient)

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- Score of neuromuscular dystonia
- Intensity of the pain felt by the subject (patient), in case of dystonia and muscle contracture
- Analysis of the incidence of all adverse events, including the overall impression regarding the success of the treatment
- Analysis of the subject's perception on the extent to which the daily activities and the leisure time activities were restricted.

To assess the tolerance of the Universal Electrophysiological Biofeedback System EDUCTOR, its ease of use was also appreciated.

1.4 Results

The occurrence of the adverse phenomena and / or adverse events was not indicated in any patient, the use of the Universal Electrophysiological Biofeedback System EDUCTOR being safe, without causing the feeling of confusion after the procedure, vasovagal response (dizziness, sweating, etc.) or irritation of the skin, at the site of application of the electrodes.

The ease of use of the Universal Electrophysiological Biofeedback System EDUCTOR was appreciated by the physician investigator as being very good, the product being acceptable from the user's point of view.

Regarding the performance of the procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR, we found the following:

1. The procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR in order to reduce the stress, depression and anxiety are extremely efficient and safe; the benefits for patient being represented on the one hand by the reduction improvement of depression, anxiety and reduction of stress, on the other hand, as a consequence, by the improvement of certain medical disorders, including the pain associated with them.
2. The patients in the group receiving specific procedures carried out with the Biofeedback Universal System EDUCTOR, had a remarkable improvement of the health condition; the average score of dystonia, after making the procedures, decreased by 50%. Regarding the patients in the control group, at the end of the tracking period, the average score of dystonia decreased by 7%.
3. After 6 specific procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR, the average pain felt by patients decreased from the value of 6,2 Wong-Baker scale (pronounced pain, which determines the patient's inability to conduct some activities), to a value equal to 1,8 which means, according to the same scale, a pain which can be neglected.

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Therefore, after 6 procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR, the patients were able to perform all daily activities, practically, without restrictions. Although the rate of decrease of the pain intensity was higher in the early days in the patients in the control group, later, it stagnated around the value 4 (moderate pain), while in the patients who received specific procedures carried out with the Universal Electrophysiological Biofeedback System EDUCTOR, the rate of decrease (although initially a little lower) was maintained; moreover, it widened, the pain decreasing significantly. The major benefits of using the Universal Electrophysiological Biofeedback System EDUCTOR consisted in significant improvement of the pain felt by the patients with muscular dystonia and / or with muscle contractures, when the procedures are associated with the standard treatment (physiotherapy, kinetic therapy, treatment with medication).

4. In percentages, the medical conditions detected during the scan performed with the Biofeedback Electrophysiological Universal System, represent 33% of those detected by the standard medical investigations. With one exception, all medical conditions detected by scanning the human body were confirmed by the standard medical investigations: we appreciate that the Universal Electrophysiological Biofeedback System EDUCTOR is a very useful tool to guide the patients to the clinics for medical tests, recommending the investigations to be performed by it.
5. There is a significant decrease in the restriction of the daily activities and the leisure time activities in the case of patients in the group which received specific procedures carried out by the Universal Electrophysiological Biofeedback System EDUCTOR, while in the patients in the control group, the largest share is represented by the patients who appreciated a stagnation of the restriction of activities.
6. The Universal Electrophysiological Biofeedback System EDUCTOR is particularly effective in improving the condition of the patients, with positive influences on their quality of life.

1.5 Conclusions

The data collected after conducting the clinical investigation proved a particularly effectiveness of the Universal Electrophysiological Biofeedback System EDUCTOR in:

- Detection and reduction of stress, depression and anxiety
- Muscular re-education (improvement of the neuromuscular dystonia symptoms and of the muscle contractures)
- Pain treatment
- Detection of medical conditions

as well as safety of its use, no patient reported adverse phenomena / adverse events.

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Initiation date of the clinical investigation: 22nd April 2015

Date of analysis: 29th May 2015.