

Approved by Director of the
Traditional Medicine and
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Health

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REPORT

on

Medical Trials of the Prototypes of the Aires Matrix Applicators Developed by the Aires New Medical Technologies Foundation (St. Petersburg, Russia) and Intended for Providing Treatment Using BAPs and BAZs

The medical trials of the prototypes of the Aires matrix applicator were instituted according to the recommendation of the special expert commission on devices and apparatus for performing quick diagnostics of the human organism's functional state by physiological indices of its reflective zones (RZs) and biologically active points (BAPs) and for conducting reflexotherapy using RZs and BAPs, of the Committee on New Medical Equipment of the Russian Federation Ministry of Public Health (Protocol #3, July 14, 2000).

1. The medical trials of the prototypes of the Aires matrix applicator developed by the Aires New Medical Technologies Foundation (St. Petersburg, Russia) and intended for providing treatment using BAPs and BAZs were performed at the Traditional Medicine and Homeopathy Research and Practical Center of the Russian Federation Ministry of Public Health in the period from August 28 till November 17, 2000.
2. To perform the medical trials, the following items were used:
 - a) Prototypes of the Aires matrix applicator (in the number of 500)
 - b) Documentation:
 - Abstract from Protocol #3 of the meeting of the special expert commission of the Committee on New Medical Equipment of the Russian Federation Ministry of Public Health held on July 14, 2000;

- the report on acceptance test #ATHJI 0.009.2081 as of August 21, 2000;
 - the report on toxicological and sanitary & chemical trials #63-2000 as of February 17, 2000.
- c) Draft user's instruction
- d) Program and procedure of the medical trials

3. Brief Description of the Product and Its Purpose

The Aires matrix applicators (Patent #7007 RU) intended for influencing BAPs and BAZs (further referred to as "applicators") present a self-adhesive film of 26.4 by 26.4 mm in size which carries on its outside a graphic pattern that is composed of lines of no more than 0.1 mm in width. The applicators are combined into block-lists of 138 by 138 mm in size. One block-list includes 25 applicators of either round or square form. The applicators are intended for providing applications to acupuncture points and zones of the human body to normalize its functional state. The therapeutic effect of the applicators is achieved by transforming the weak electromagnetic radiation emitted in the area of the active points and zones of the human body, and determined by the biophysical action aimed at normalizing subtle energetic disturbance caused by various diseases. The applicators can be used in medical treatment and prevention institutions as well as in household environment under the supervision of a medical doctor.

4. Medical Trials

The medical trials were performed in outpatient environment. The program of the medical trials included the evaluation of:

- a) how the applicators are tolerated by the patients;
- b) the character of the overall effect of the applicators;
- c) the safety and efficiency of the use of the applicators for purposes of normalizing the human organism's functional state;
- d) the usability properties of the applicators.

At the first stage of the medical trials, to determine the character of the overall effect of the applicators, they were tried on patients along with the use of small intestine biopotentiography performed in the range of infra-red frequencies (0.12–0.27 Hz) in basal conditions. The medical examination revealed that the applicators, which carried a graphite-composition pattern, produced a stimulant effect on the patients, judging by the increased amplitudes and frequencies of the initial biopotentials of the small intestine.

Thus, the test data showed that the applicators produced a stimulating information-energetic effect on the functional activity of the basic systems of the human organism.

At the second stage of the medical trials, 19 patients of both sexes, aged between 17 and 59, with out-of-acute-condition chronic diseases of skin and internal organs were brought in the study. 13 of them (five men and eight women)—they formed the main group of patients—underwent a therapy course with the use of the applicators, and the other six patients (four men and two women)—they formed the control group of patients—received "placebo" therapy with the use of applicators that presented a polyester film carrying no graphic pattern on its outside. All of the patients were examined for their objective clinical status. Besides, they were examined using the electropuncture diagnostics technique by R. Foll. According to the requirements of the electropuncture diagnostics procedure, the patients were informed beforehand of the examination and were prepared for it. The examination was performed in the following way:

- 1) Taking anamnesis by standard procedure;
- 2) Physical examination;
- 3) Electropuncture diagnostics—during which six "great" leads, and 40 control and 24 initial/end channel measurement points were used.

All of the patients were examined two times. The first examination was performed before the start of the applicator therapy. The second examination was performed after six days of using the applicators and placebo according to the application scheme given in the applicator medical instruction. The results were evaluated according to R. Foll's classic criteria—in doing this, 50-65 electroconductivity units were assumed to be normal value, less than 50 units below normal, and more than 65 units above normal. The overall numbers of measurements were 342 in the "great" leads and 1558 in measurement points. The statistical calculations were conducted at the significance level of 5% and with the use of the double Student t-criterion.

The examinations of the functional state of the patients' acupuncture points revealed a strong tendency toward an increase in the average electroconductivity measurement level in the main group of patients after the completion of the application therapy, as compared to the control group (see Table below).

Table

Group of Patients	Average Measurement Level, %		
	Decreased	No Change	Increased
Main	25	33.3	41.7
Control	40	40	20

A statistically reliable result of the applicator's effect on the "pointer drop" value was achieved in 20% of the cases. Moreover, the "pointer drop" value was found to decrease in both the main and the control groups.

As soon as the therapy was over, the patients of both the main and the control groups noted the following positive changes in their state of health: an increase in their working ability (in five patients), a decrease of drowsiness at the end of a working day when working with a computer (in five patients), a general improvement of the state of health (in eight patients), and an increase in sexual activity (in one patient).

Analysis of the obtained data reveals a stimulant effect of the applicators on the energetic characteristics of the patients' acupuncture systems, as well as on the state of the patients' health. However, the changes that were noted in the control group also suggest that a psychotherapeutic component played a considerable role in this kind of therapy.

5. Review of the Results of the Medical Trials

The Aires matrix applicators intended for influencing BAPs and BAZs meet their claimed medical purpose ("the normalizer of the functional state of the human organism"), provided that the initial functional state of a patient's organism's acupuncture systems are consistent with the mode of the applicators' systemic action. The applicators are tolerated well by patients and produce no adverse effects or complications. The applicators are fixed well to a patient's BAPs and BAZs, are handy in use, and meet modern design requirements on medical equipment.

It is pertinent to note that to ensure the efficiency of therapy using the Aires applicators and to control the course of the therapy, appropriate diagnostic techniques, such as any kind of legal electropuncture diagnostics, need to be used for localizing BAPs and BAZs on the patient's body. These should also be mentioned in the user instruction.

The applicators are useful as an added auxiliary remedy for various diseases provided in combination with traditional therapy. They can also be used in reflexotherapy for preventing diseases, providing auxiliary therapy, and keeping the functional activity of the patient's acupuncture systems at appropriate physiological level.

Conclusion

The Aires matrix applicators developed by the Aires New Medical Technologies Foundation (St. Petersburg, Russia) and intended for providing treatment using BAPs and BAZs may be recommended, as to the issue of their serial production, to the special expert commission on devices and apparatus for performing quick diagnostics of the human organism's functional state by physiological indices of its reflective zones and biologically active points and for

conducting reflexotherapy using RZs and BAPs, of the Committee on New Medical Equipment of the Russian Federation Ministry of Public Health.

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