

APPROVED

by Chief Doctor of Scientific Center
of Clinic and Experimental Medicine,
Awarded Doctor of Russia, Master of Medicine

[signature] V.B. BARSKY
29 July 2004

PROTOCOL

**of clinical trials of individual simulator inhaler,
introduced by Dinamika Co., Ltd (Novosibirsk)**

Reason: Act of 18 June, 2004, Protocol 1, Department for Tests and Apparatuses, Applied in Pulmonology and for Gaseous Exchange Research, Gas Analyses, and Blood Gases, Committee for New Medical Devices supervised by the Russian Ministry of Health and Social Welfare.

In the period between 10 July 2004 and 25 August 2004 clinical trials of a sample of individual simulator inhaler (hereinafter "the Device") submitted by Dinamika Co., Ltd were held at Scientific Center of Clinic and Experimental Medicine, Siberian Branch of Russian Academy of Medical Science. Dinamika Co., Ltd submitted for the trials the following: the Device, Technical Certificate, Directions for use (Guidelines), Certificate (no. 030661/4 of 28 June 2004) on toxicological tests of the Device, conducted at Novosibirsk Scientific Institute of Hygiene, supervised by the Russian Ministry of Health, and Record of Clinical trials, conducted at Siberian Scientific Research Institute, Center of Medical Technologies, no. EGIT 94.0000.291 of 12 July 2007.

In the submitted Device three procedures are functionally combined: respiration device, which allows regulating respiratory resistance as during inhalation, so during exhalation; inhalator of water solutions and herbal extracts; and means for aromatherapy.

The Device submitted for evaluation and trials is different from the already existing devices by the special supplement for three essential oils. The supplement makes it possible to separate essential oils from water in the Device. At the same time, the vaporizing fluid and the essential oils do not mix. That both leads to the best effect and prevents creation of uncontrolled mixtures in the liquid form, when the temperature is high. Besides, the use of the graded regulator to maintain pressure (resistance) in the Device, improves effectiveness of the therapy.

There were held 287 inhalations with 78 patients of clinics and hospitals; the patients had different diseases, including acute and chronic bronchitis, chronic obstructive pulmonary disease, dystonia, essential hypertension, angina pectoris (as acute, so remission forms). Significant improvement was recorded, and there was found the possibility to combine with other physiotherapy and medicaments. Strong enhancement of medication effectiveness and decrease in treatment duration recorded. Provided that the breathing technique was performed in accordance with the directions for use (guidelines), no patient had any negative or allergic reaction for the Device.

Conclusion: Individual Simulator Inhaler as submitted by Dinamika Co., Ltd, can be recommended for volume production.

Suggestions: it is necessary to consider the possibility of adding a supplemental part to perform respiratory training through the nose; also it is important to develop a detailed instruction on how to use the Device, where mention time, duration, number of procedures for every instance of application of the Device as a trainer, inhalator and device for aromatherapy.

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