

**APPROVED**  
by Chief Doctor of  
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2004

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

Clinical trials of a testing model of individual simulator inhaler (hereinafter "the Device") supplied by Dinamika Co., Ltd, Russia, Novosibirsk, were held in City Perinatal Center in the period between 15 July 2004 and 26 August 2004. For trials supplied: the Device, Technical Certificate, Directions for use (Guidelines), toxicological tests report (conducted in Novosibirsk Scientific Institute of Hygiene supervised by the Russian Ministry of Health; resulted in Certificate no. 030661/4 of 28 June 2004), and Record of Clinical trials, conducted at Siberian Scientific Institute Center of Medical Technologies, no. EGIT 94.0000.291 of 12 July 2007. There was also used Protocol no. 1 of the Committee for New Medical Devices supervised by the Russian Ministry of Health and Social Welfare, at the Department for Tests and Apparatuses, Applied in Pulmonology and for Gaseous Exchange Research, Gas Analyses, and Blood Gases.

The Device can be used in 3 ways: as respiratory trainer with an option of regulating breathing resistance on the exhalation and inhalation; as an inhalator for water solutions and herbs decoctions, and as a device for vapotherapy.

The Device submitted for evaluation is different from already existing on the market as it has a special supplemental part for three essential oils. The part separates the oils from the liquid component inside the device. Importantly, the evaporating compounds of the liquid and the essential oils do not mix, what on one hand results in the clearly evident and sound biological effect, , and on the other hand prevents uncontrolled formation of liquid mixtures when the temperature increases.

Besides, the use of the graded regulator to maintain pressure (resistance) in the Device increases efficiency of the therapy.

There were held 297 inhalations with 73 patients at the hospital; the patients had different diseases, including chronic obstructive pulmonary disease, acute and chronic bronchitis, essential hypertension, angina pectoris (both in remission and in acute form), dystonia, chronic inflammation of pelvic organs. Upon the completion, there was recorded a sound improvement, as well as revealed the opportunity to combine the exercises with other physical and medication treatment. There was also recorded a significant increase of medication effect when using the Device, as well as the reduction of treatment periods.

The biological test (as described in the directions for use - guidelines) prior to exercising with the Device helps to avoid any negative or allergic reactions. There were no failures to work recorded with the Device.

**Suggestions:** develop more detailed directions for use of the Device, where indicate time, periods, and the number of procedures for each case of the Device use as a trainer, inhalator, and vapotherapy device. It is advisable to consider the possibility of developing a mask for respiratory procedures through the nose.

**CONCLUSION:** Individual Simulator Inhaler supplied by Dinamika Co., Ltd can be recommended for volume production.