

APPROVED
by Chief Doctor KB no. 85
Medbioekstrem federal organization,
Russian Ministry of Health supervised
[signature] O.S. Tseka
2004

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

Clinical trials of individual simulator inhaler (hereinafter "the Device") were held at Medbioekstrem center, KB No. 85, department of functional diagnostics and physiotherapy, under general supervision of the Russian Ministry of Health. The Device was submitted for evaluation by Dinamika Co., Ltd, Novosibirsk, Russia.

The trials started upon the decision of 18 June 2006, Protocol no. 3 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.

Clinical trials conducted in the period since 13 July 2007 to 23 July 2007

On 13 July 2007 supplied for trials:

- 1) The Device - 1 item
- 2) Directions for use (Guidelines)
- 3) Technical certificate
- 4) Certificate no. 030661/4 of 28 June 2004 on toxicological tests for the Device, conducted at Novosibirsk Scientific Institute of Hygiene, supervised by the Russian Ministry of Health
- 5) Record of Clinical trials, conducted at Siberian Scientific Research Institute, Center of Medical Technologies, no. EGIT 94.0000.291 of 12 July 2007

Purpose of clinical trials:

- 1) evaluation of usage convenience of the Device, and its reliability;
- 2) compliance of the Device with its intended objectives and targets as given in Directions for use (Guidelines)
- 3) Directions for use (Guidelines) text evaluation

The Device is respiratory trainer, which differs from similar devices, including its previous model FRTD-01 (alternative spelling TDI-01), by that it can be used not only as a respiratory trainer, but also as an inhaler for vapotherapy with essential oils.

Results of clinical trials:

- 1) The Device is easy to use, can be applied by the patient without medical assistance at home after reading Directions for use (Guidelines) or after being advised by a hospital nurse;
- 2) Advantages of the Device are:
 - a. Little size and weight;

- b. Possibility to use essential oils both separately, and in combination with up to 3 oils at once;
 - c. Possibility to use the Device as an inhaler intended for vapotherapy with essential oils, as well as a respiratory trainer, to establish resistance during the exhalation and/or inhalation.
 - d. Graded bottom of the inner chamber makes it easy and smooth to regulate the degree of the breathing resistance (in both exhalation and inhalation), which depends on the amount of water that fills the outer chamber.
 - e. Possibility to use the Device as an inhaler and a respiratory trainer at once;
- 3) There were recorded no breaks of the Device, and no failures in its work happened.
- 4) The Device can be easily disassembled and disinfected.
- 5) The text of the Directions for use (Guidelines) is well explanatory, but needs some stylistic correction. It is necessary to give a more detailed description of the technique of respiratory training with the Device. It is reasonable to give recipes for the use of all 8 essential oils supplied with the Device for vapotherapy. It is advisable to pay more attention to the peculiarities of vapotherapy sessions in different diseases of upper and lower airways; pay particular attention to the use of the Device as a trainer and as an inhaler with bronchial asthma patients. It is advisable to indicate the length and frequency of the procedures, number of the procedures in one treatment session, and efficiency evaluation method. It is advisable to describe the method of application of the Device simultaneously as a trainer and as an inhaler.

The Device can be recommended only for individual use.

It is advisable to consider the question of potential nasal supplement for the Device, in order to add the possibility to perform inhalations through the nose.

CONCLUSION

Individual Simulator Inhaler submitted for the trials by Dinamika Co., Ltd, complies with the requirements for the devices and respiratory trainers intended for individual use, and can be recommended for volume production, yet only if accompanied with detailed directions for use. One part of the directions shall give a detailed description of use of the Device for vapotherapy with essential oils; the other part shall be focused on its application as a respiratory trainer.

The Device can be used individually both at home and in medical centers, such as hospitals or clinics, and can be applied for vapotherapy in hospital wards.

Head of Physiotherapy
Department KB no. 85

Medvedeva T.I.

Head of Functional
Diagnostics Department
KB no. 85, docent

Struchkov P.V.