

APPROVED

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REPORT

of

clinical tests of a personal training inhaler
presented by Dinamika Co., Ltd., Novosibirsk

In the Functional Diagnostics and Physiotherapy Departments, the Clinical Hospital No. 85, FU "Medbioekstrem", RF Ministry of Public Health, clinical tests of a personal training inhaler hereinafter referred to as "the Inhaler" presented by Dinamika Co., Ltd. have been carried out.

Pursuant to: Regulation of 18 June, 2004, Record No. 3, of the Commission for Instruments and Devices Used in Pulmonology and in Investigation of Gas Exchange, Gas Analysis and Blood Gases, the New Medical Equipment Committee, RF Ministry of Public Health and Social Development

Testing period: 13 to 23 July, 2004

On the 13 July, 2004, the following items were presented for the test:

- 1) Inhaler, 1 pc,
- 2) Training Inhaler Operation Manual,
- 4) Technical Certificate,
- 3) Report No. 030661/4 of 28 June, 2004 of toxicological tests of the Inhaler carried out at the Novosibirsk Research Institute of Hygiene, RF Ministry of Public Health,
- 4) Report No. ЕГИТ 94.0000.291 of 12 July, 2004 of technical tests carried out at the Siberian Medical Equipment Research and Test Center

Purpose of clinical tests:

- 1) Assessing the Inhaler's convenience and reliability of use,
- 2) Assessing the Inhaler's conformity with purposes and objectives specified in the Operation Manual,
- 3) Assessing the text of the Operation Manual.

The Inhaler is a breath training apparatus which can be used, unlike similar devices including the Frolov Breathing Trainer, as both breezing trainer and essential oil inhalation device.



Clinical tests findings

- 1) The Inhaler is simple in operation and may be used by the patient independently at home after reading the Inhaler Operation Manual or being instructed by the nurse.
- 2) The list of the Inhaler's advantages includes:
 - a) small size and low weight,
 - b) capability of using essential oils separately and in combination of as much as three oils at the same time,
 - c) capability of using the device as both essential oil inhaler and breathing trainer enabling formation of a resistance to the inhalation and/or exhalation,
 - d) availability of a stepped bottom in the aerosol chamber enabling smooth adjustment of inhalation and/or exhalation resistance relative to the level of liquid in the external glass, and
 - e) capability of using the device as both inhaler and breathing trainer at the same time,
- 3) The Inhaler showed no failures and/or malfunctions,
- 4) The Inhaler can be readily disassembled and disinfected.
- 5) The text of the Training Inhaler Operation Manual, though detailed enough, still needs some stylistic correction. The methods of respiratory gymnastics using the Inhaler as a breathing trainer should be described in more detail. It would be appropriate to provide recipes of use for all of the eight essential oils being presented. Special attention should be paid to the specificity of inhalation courses with respect to various diseases of upper and lower air passages, in particular, to the use of the Inhaler as both training and inhaling device for bronchial asthma patients. The duration and multiplicity of procedures as per treatment course and the methods of treatment efficiency monitoring should be specified. The methods of using the Inhaler as both training and inhaling device should be described.

The Inhaler is recommended for personal use only.

It would be appropriate to consider an opportunity of equipping the Inhaler with a nose piece to provide for inhalations through the nose.



CONCLUSION

The personal training inhaler presented by Dinamika Co., Ltd., Novosibirsk meets the requirements applicable to personal inhalers and breathing trainers and may be recommended for commercial-scale production provided that it is accompanied with detailed instructions. One of these instructions should describe in detail the Inhaler's application for essential oil inhalation, while the other should do that for breath training.

The Inhaler can be applied as a personal-use device in residences, outpatient care institutions and hospitals (for in-ward inhalation courses).

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Signature

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Перевс.