

APPROVED

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..... 2004

R E P O R T N o .
of
medical tests of a personal training inhaler
presented by Dinamika Co., Ltd., Novosibirsk

Pursuant to: Regulation of 18 June, 2004, Record No. 1, 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.

In the period from 10 July, 2004 to 25 August, 2004 in the Hospital of the Clinical and Experimental Medicine Research Center, Siberian Branch of Russian Academy of Medical Sciences, medical tests of a prototype personal training inhaler hereinafter referred to as "the Inhaler" presented by Dinamika Co., Ltd. have been carried out. The following items were presented for the test: Inhaler, Technical Certificate, Training Inhaler Operation Manual, 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 and Report No. ЕГНТ 94.0000.291 of 12 July, 2004 of technical tests carried out at the Siberian Medical Equipment Research and Test Center.

The presented inhalation device functionally combines three procedures: those of breathing trainer with a function of inhalation and/or exhalation resistance adjustment; liquid solution and medicinal herbs tincture inhaler; and aromatherapy appliance.

The device presented for medical tests differs from the existing devices of the same purpose by a special inserted unit for three aromatic oils that allows separation of aromatic oils from the liquid phase of the inhaler, the evaporated components of the inhaled liquid and the aromatic oils being not mixed with each other, that ensures maximum biological effect, on the one hand, and prevents formation of uncontrolled compositions in the liquid phase at higher temperatures, on the other hand. Furthermore, the use of a step regulator of pressure (resistance) in the device promotes the efficiency of therapy.

As many as 287 inhalation courses on 78 ambulatory and resident patients with various ailments have been carried out including those with acute and chronic bronchitis, chronic nonspecific lung diseases, vegetovascular dystonia, hypertension, stenocardia, at both remission and acute phases. An appreciable positive clinical effect and an opportunity of combination with other physiotherapeutic and medicinal treatment methods have been noted along with obvious enhancement of drug action and reduction of treatment period.



As a result of the preliminary biological assay that had been taken correctly (as per instruction), none of the patients showed any negative or allergic reaction. The inhaler showed no operation failure.

CONCLUSION: The personal training inhaler presented by Dinamika Co., Ltd. may be recommended for commercial-scale production.

Suggestions: The complete set of the device should necessarily include a mask for breathing through the nose. The operation manual should be expanded in more detail with indication of time, duration and number of procedures for each particular case of using the device as trainer, inhaler or aromatherapy appliance.

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Signature

N.P. Bakhtina

ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ "ДИНАМИКА"
на пересылку