

RUSSIAN ACADEMY OF SCIENCES

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THE RUSSIAN ACADEMY OF SCIENCES (RAN)**
(STATUS OF A STATE INSTITUTION)

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March 28, 2005

Round seal: Saint Petersburg Clinical Hospital of the Russian Academy of Sciences
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Report
No. 20 dated March 28, 2005

**On holding of medical tests of Computer-aided complex for assessment of the
functional state of a human organism Dynamics developed and manufactured by
OOO “Scientific Research Laboratory Dynamika” (St. Petersburg)**

1. Within the period from 11.02.2005 till 25.03.2005 clinical tests of computer-aided complex for assessment of the functional state of a human organism Dynamics, developed and manufactured by OOO “Scientific Research Laboratory Dynamika” (St. Petersburg), were carried out at the Functional Diagnostics Department of Saint Petersburg Clinical Hospital of RAS.
2. The purpose of the tests is assessment of applicability of the aforesaid items in medical practice of health institutions on the territory of the Russian Federation.
3. The ground:
 - 1 Abstract from the minutes of the meeting of the Committee for new medical equipment of the Ministry of Healthcare of the RF (minutes No. 6 dated 16.12.2003).
 - 2 Report No. 7/2004 on carrying out of the technical acceptance tests in ZAO “CIMT” (St. Petersburg) dated March 12, 2004.
4. The following items were provided for carrying out of the clinical tests:
The device – 1 piece

The device was connected to the personal computer, and the software for work with the device was installed.

Report No. 7/2004 on carrying out of the technical acceptance tests in ZAO "CIMT" (St. Petersburg) dated March 12, 2004.

Abstract from the minutes of the meeting of the Committee for new medical equipment of the Ministry of Healthcare of the RF No. 6 dated 16.12.2003.

Clinical tests were carried out in accordance with the program and procedure of medical tests, pursuant to GOST R 15.013-94.

5. Purpose of the device.

The device is designated for one ECG channel recording, blood pressure measurement, screen layout and printout of the input signal, heart rate and rated indices of variability of the heart rhythm.

6. Test procedure:

- 1) Detection and processing of parameters in operation conditions at the Functional Diagnostics Department
- 2) Verification of conformity with the general purpose
- 3) Checkup of usage convenience for a doctor and a patient
- 4) Checkup of reliability and uninterrupted operation
- 5) Recommendations in respect of improvement of medical and operational qualities of the device
- 6) General assessment of the device in respect of principal functional qualities

7. Results of the test:

During the testing period 58 outpatients and patients of the Cardiology Department of the hospital were examined. Main diseases for being referred to the examination were:

- 7 arterial hypertension – 22 persons
- 8 ischemic heart disease – 11 persons
- 9 combination of arterial hypertension and ischemic heart disease – 15 persons
- 10 vegetative dystonia syndrome – 10 persons.

Parameters of heart rhythm variability were assessed using the provided complex in accordance with the recommended procedure.

Resume:

- 1) The device fully conforms to its principal purpose.
- 2) The device is convenient in use as for a doctor so for a patient. Personnel may be easily trained to operate the complex.
- 3) No disadvantages were detected during the test. The device worked reliably without malfunctions.
- 4) Signals are displayed on the monitor in a quality manner and may be preliminary assessed.
- 5) Results obtained after final analysis are informative and are of great practical importance.
- 6) The system of data archiving is convenient.
- 7) The device fully meets ergonomic requirements.
- 8) Overall assessment of work in respect of functional qualities is positive.

Conclusion:

On the basis of the carried out medical tests Computer complex for assessment of the functional state of a human organism Dynamics, developed and manufactured by

OOO “Scientific Research Laboratory Dynamika” (St. Petersburg), may be recommended for batch production and wide use in medical practice.

Chairman of the Committee /signature/ Doctor of Medical Sciences
M.F.Ballyuzek

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