

APPROVE  
Managing Director  
Russian Cardiology Research and Production Facility  
at the Health Ministry of the Russian Federation  
Academician of the Academy of Sciences  
of the Russian Federation Prof. E.I. Chazov

July \_\_\_\_, 2003

**RESULTS OF CARDIOVISOR-06 SCREENING DEVICE APPLICATION FOR EARLY DETECTION OF  
CORONARY HEART DISEASE USING ECG AT REST IN THE RUSSIAN CARDIOLOGIC RESEARCH AND  
PRODUCTION FACILITY**

The research is aimed at identifying capacities of a new screening device, KARDi2-CV06s (CardioVisor-06) in detection of CHD and express-control of changes in myocardium during treatment. The technology used in this device has been developed since 1997 in private research programs and is protected with 5 patents. This is a new method of computer analysis of low-amplitude morphological variations of the QRST complex. The most promising clinical options of this technology consist in highly sensitive analysis of the re-polarization phase, the most challenging phase of heart excitement in clinical interpretation. Changes in the ST-T segment are most often referred to non-specific ones. Data yielded by this new method on changes of just the re-polarization phase in various medical disorders have obvious differential diagnostic features. Later on, when an in-depth analysis is conducted, this technology may yield new data on re-polarization of ventricles. Studying variations in fluctuation portraits of the heart, both in stationary and dynamic processes in myocardium, will be very promising for cardiology practice.

KARDi2-CV06s is an express device that uses only standard leads from limbs (4 electrodes) and makes it possible to examine a sitting patient in clothes. To evaluate sensitivity and specificity of the KARDi2-CV06s device to CHD, 89 patients with CHD were examined at the RUSSIAN CARDIOLOGY RESEARCH COMPLEX (Moscow), as well as 65 patients free from CHD who underwent examination and treatment in the A.L. Myasnikov Clinical Cardiology Institute. 10 healthy subjects were examined as controls without CHD, plus 49 cases of left-ventricle hypertrophy in patients with heart defects and arterial hypertrophy. The patients were aged from 27 to 72 (the average age is  $53 \pm 5.2$  years). CHD diagnosis was verified by comprehensive clinical and instrumental examination using angioplasty, computer imaging, and scintigraphy of myocardium. Later on, clinical and instrumental syndrome diagnosis was compared with conclusions and heart portraits generated by KARDi2-CV06s.

**Findings**

- The average sensitivity and specificity of the device to CHD were equal to 79% and 76%, respectively. To compare, let's note the generally known fact of low sensitivity of ECG-rest from 12 generally accepted leads to CHD, which amounts to 25%-50%, according to different data from literature.

- “Heart portraits” maintain high reproductive capacity and individuality in different patients, which supports the unbiased nature of information yielded by low-amplitude fluctuations of ECG.
- High sensitivity of the “fluctuation portrait” of the heart to CHD is well demonstrated by cases when there are no significant generally accepted symptoms of CHD in the input ECG, whereas the portrait shows specific change.
- High repeatability of the portrait ensures highly sensitive and exact sub-threshold control over the behavior of the myocardium stability. The higher the level of coronary changes is, the greater foci of changes vary in the portrait in subsequent portraits, though it is next to impossible to detect so insignificant changes in the initial ECG using other methods.

Experimental studies suggest that the portrait specificity to CHD increases to 85% in a similar portrait based on signals from 12 generally accepted leads in these cases.

Thus, despite the fact that KARDi2-CV06s device is only intended for screening processes of two standard ECG-signals, its sensitivity to CHD amount to approx. 80%, and this evaluation may be obtained in outpatients’ department within 1 minute, without any supplementary data analysis. Therefore, this one is very promising as a new device capable of prompt generation of early diagnostic information both in the clinical and in the pre-clinical period – during preventive screening, at sanatoriums and resorts, in the system of emergency medicine.

Senior Scientist  
New Diagnostics Methods Department  
Cardiological R&D Institute  
Russian Cardiologic Research and Production Facility  
MD, Professor

G.V. Ryabykina