Procedure of Testing of
the Diascreen NVA-01 PC

The Diascreen NVA-01 PC is a Diascreen unit and Doctor Mouse software of physiological testing of the human cardiovascular system. With the use of the Diascreen NVA-01 PC the vardiovascular condition of a PC user is determined directly during his work.

The Diascreen NVA-01 PC is a separate device connected to a computer via USB ports.

The Diascreen NVA-01 PC is based on the application of the unique **Doctor Mouse Technology** in production of means of physiological testing and control.

The Diascreen NVA-01 PC is designed for wide range of users.

The Doctor Mouse technology can be used in the following fields:

- home and office devices of self-control;
- devices of remote monitoring of health (tele-medicine).

Each individual PC user as well as a corporate network user can be a potential user of the Diascreen NVA-01 PC services. Its Doctor Mouse method of registering the condition of cardiovascular system does not have limitations of applicability in practice. It can be used without preliminary preparation under any conditions at office, at home. If a portable computer is available, it can be used during trips (on board of a plane, in a hotel, etc.), during rest (in the country, doing sport or fitness exercises, etc.).

The Diascreen NVA-01 PC is a home device of a category of the so-called " home clinic" devices. The international classification of medical devices № EU-93/42/EEG places this Diascreen NVA-01 PC into a category of devices with a low degree of the risk of decision making (category A). The Diascreen NVA-01 PC works in parameters of cardiovascular testing determined by the European and American standards in 1996 (See: 'Heart Rate Variability. Standard of Measurement, Physiological and Clinical Use. The Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology// Europ. Heart J -1996-.Vol. 17 -.P. 354-381. According to EU-93/42/EEG classification, the advance of such devices to the market is permitted without obtaining medical certificates.

1. VALUED PARAMETERS

1.1. **Pulse** - number of heart contractions per minute. The normal rate of heart contractions per minute is between from 72 to 76. A pulse rate of 80 to 90 is considered increased. A pulse of more than 90 is called TACHYCARDIA.

A pulse rate of 50 to 60 is considered lowered. A pulse rate of less than 50 is called BRADYCARDIA. Constant tachycardia requires medical control.

Bradycardia is typical for athletes. Children used to have increased pulse. Woman usually has a bit less pulse than a man.

Tachycardia is observed after serious physical loads, in nervous excitation, after alcohol drinking, after taking narcotics and some medicines.

1.2. **Variation of Cardiointerval** is the difference in time between the longest and the shortest cardiointervals registered in the course of measurement. This parameter is coherent with operation of the so-called SINUS NODE, in which the electric excitation impulses are

generated automatically. This is the basic activator of rhythm. The spread of cardiointerval not exceeding 0,16 sec. is considered as a standard value. Exceeding of the standard value indicates the SINUS ARRHYTHMIA. Sinus arrhythmia is not a disease. It's a certain physiological condition which can be coherent with the process of respiration.

1.3. **Extrasystoles** are the premature contractions of the hearts. They are perceived as intermissions. Extrasystoles are always visible on the pulse waveform. They are manifested, first of all, in the form of decrease of intervals between heart beats and reduction in amplitude, or as a separate beats passing. Regular extrasystoles in a pulse waveform identify person at risk when medical control is needed.

1.4. **Coefficient of Variation** is a statistical parameter. It characterizes degree of uniformity of the time intervals between heartbeats. It is measured in percentages. It is equal to a ratio of the average value of deviations to the average value of duration of a cardiointerval. The value of 2 to 5 percents is considered as a standard.

1.5. **Recovery Time of Vessels** is determined by the phase of the completion of systole. It's coherent to the time of a decrease in the blood flow velocity after closing of the aortal valve. The decrease is of 2.7 times. The greater is this time, the weaker is the capillary blood flow and the higher is the probability of an increase in the arterial pressure.

1.6. **Tone of Vessels** is coherent to the elasticity of vessels. The higher is the parameter, the greater is the load on the heart during its reduction

1.7. **Phase (time) of Extreme Load** is the time from the point of the maximum of the wave to the moment of its intersection with the zero line. This is very critical section. Precisely here the maximum tension of the heart muscle is achieved. And precisely in this section of the pulse wave its damages can occur with the greatest probability. Duration of this section of pulse waveform is directly coherent with the biochemical processes taken place at the cellular level in the heart muscle. Consequently, any disturbances in the exchange of substances affect onto this period. The disturbances are observed in diseases of heart and, first of all, in ischemia. A substantial increase in the time of extreme load indicates (more than 0.12 s.) impairment of the contracting function of heart muscle. During a drug treatment it is the most sensitive value. The parameter helps to estimate the effectiveness of methods of treatment. The less is its value, the better.

1.8. **Data Exchange via Internet**

One of the advantages of the Doctor Mouse technology is the presence of the thought-out and balanced size of storage of biometric data, which makes it possible to transfer it via Internet without the loss. This fact has enormous value for the realization of the direct connection between a patient and a doctor.

2. PROCEDURE OF TESTING

The method of the measurements of the cardiovascular parameters is based on registration of amount of blood in capillaries of fingertips with the aid of infrared emitter and light receptor with a wavelength of about 0.9 mcm. The miniature infra-red emitter sends the light

flow to a fingertip. The light flow is diffused on capillaries. The extent to which the light flow is diffused varies proportionally to the amount of blood in the capillaries of a fingertip. The amount of blood in the capillaries of a fingertip is coherently reflected in dynamics of the pulse wave. In its turn, the pulse wave depends upon contractions of the heart muscle and the aorta walls. The shape of the pulse wave is related to changes in blood volume as the heart beats. The sensor signal is amplified, pre-processed and fed through a standard USB port to a computer. In the computer the signal is further processed by programs and displayed in the monitor screen.

The height of the pulse wave (amplitude) depends on the amount of blood in capillaries. In turn, it is determined by the pulse pressure, elasticity of vessels and temperature of hands. The small amplitude of a pulse wave fluctuations impairs the conditions for registering the heart parameters. So this process of preparation for the changes requires the following rules.

2.1. First of all, hands must be perceptibly warm, its temperature should be not less than 28-30 C. It is not recommended to carry out measurements immediately after return from the street. Cold hands should be heated by grinding or warmed with hot water. The hands must be thoroughly dried after this. Additionally hands should be clean, without cuts or other disturbances of pathologies and any forms of the disturbances of the skin.

2.2. Amplitude of a pulse wave also depends on the degree of pressing a fingertip to the sensor. With weak pressure a signal is sufficiently small. It also increases with an increase in the effort, and then it begins to decrease. The sensor should be pressed by the middle of fingertip of the index finger or the fourth finger of the left hand. The finger should be placed in parallel with the surface of the device body. The elbow of the left hand must be leaned on the surface of a table. A measured person should keep quiet convenient pose free of any tention.

2.3. During a measurement it is not permitted any displacement of hand or other part of the body in the horizontal and vertical directions. The effort of pressing the sensor should also be constant. The necessary effort of pressure on the sensor is determined by the maximum value of the amplitude of pulse wave. If in the process of measurement the distortions of pulse wave (presence of ejections and peaks) are to be observed, then the process of measurement must be repeated.

2.4. All manipulations with the keys must be produced by laboratory assistant. The monitor display of the computer should not be visible for a patient.

2.5. For minimizing a patient’s discomfort, it is necessary to conduct 3 - 5 measurements with 2 - 3 minute interval without the registration of the obtained results. After the completion of the process of tuning it is necessary to stabilize patient’s respiration and to take measurement without changing the position of hand and the force of pressing.

1. CONDITION OF CONDUCTING THE TESTS

1.1. **Requirements to the Surrounding Situation**

For the Diascreen NVA-01 PC is a home device, the surrounding situation should be correspondent to home or office atmosphere and conditions. Means, it should not be medical, hospital or clinical as far as possible. From this point of view, it is enough to have not more

than two persons in the premises besides a patient, i.e. a person conducting measurement and a consultant. The light in the premises should not be too intensive, but enough for reading.

1.2. Requirements for "Patient"

For obtaining reliable results, the basic requirements for a person being tested are as follows:

1.2.1. Calm state of a patient;

1.2.2. Warm hands;

1.2.3. Absence of the tremor (vibration) of muscles; 1.2.4. Absence of disturbances on the skin of hands;

1.2.5. Convenient position of the patient's body;

1.2.6. Absence of fear and discomfort caused by the process of measuring.

1.3. **Requirements for Computer System**

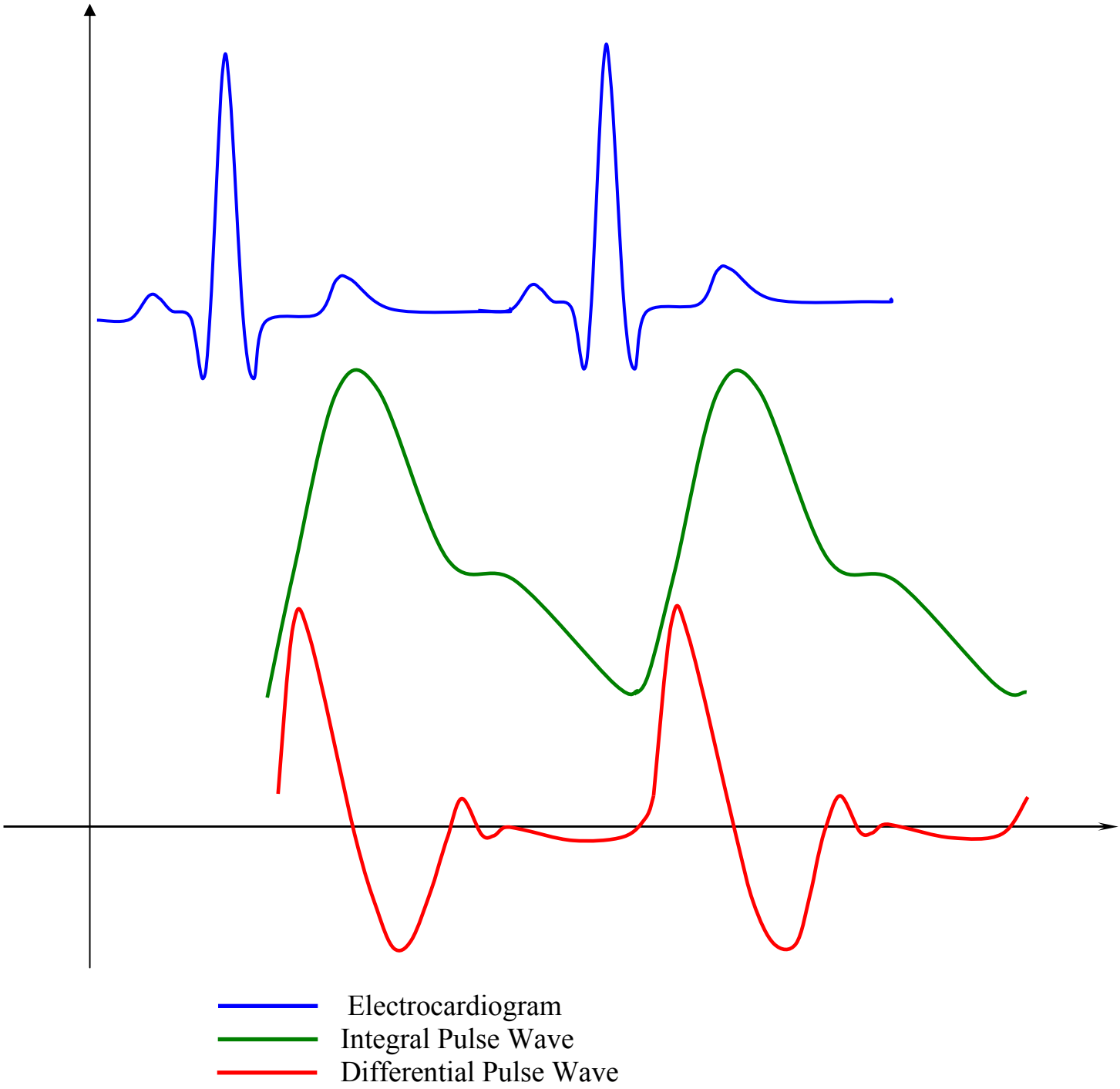
1.3.1. Personal computer on the base of Intel processor, preferably Pentium 4;

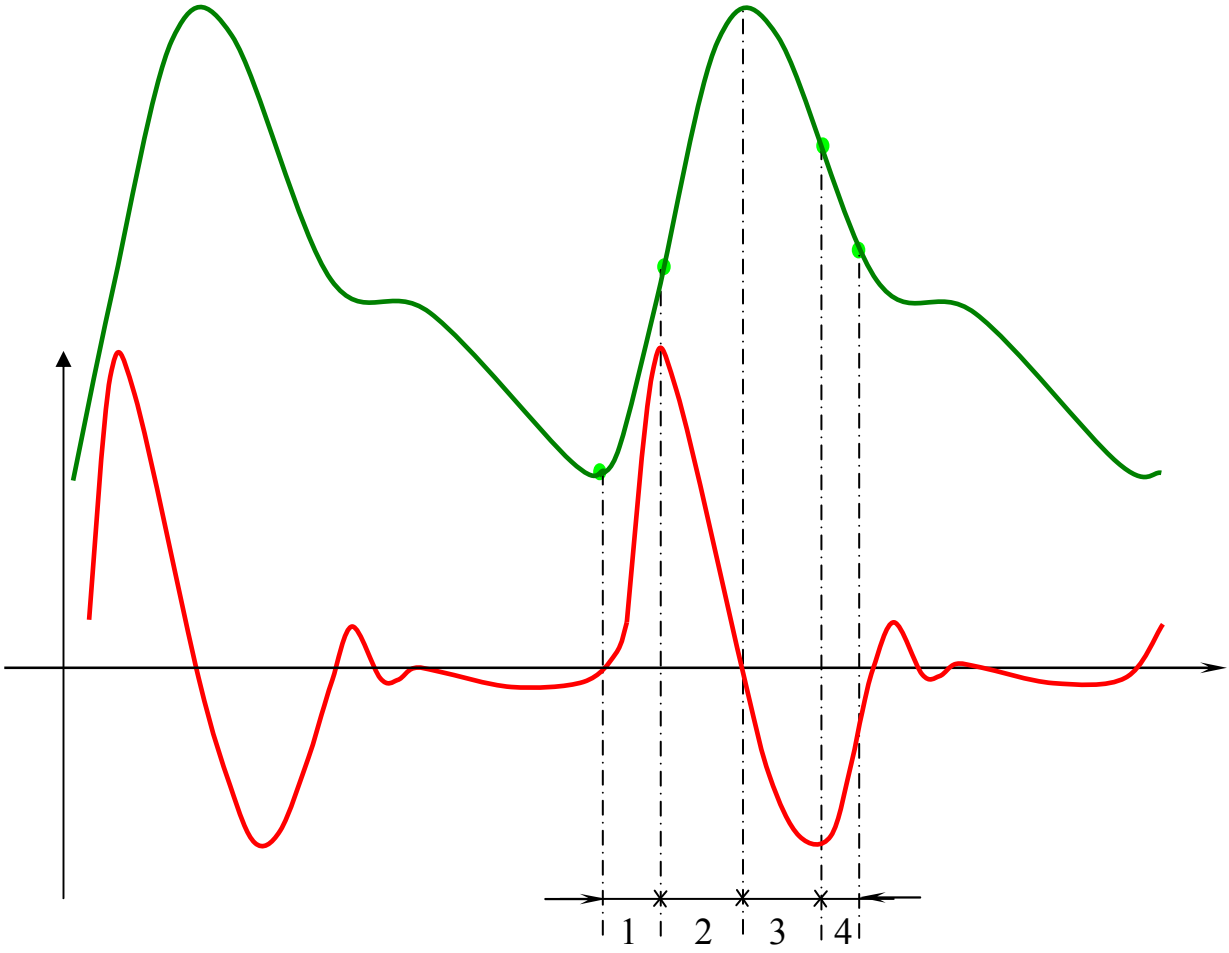
1.3.2. At least one free communication USB channel; 1.3.3. Operating system should be the pan- European version Windows xp SP1 or SP2 and also the English-language version of MS Office 2003;

1.3.4. CD-ROM drive;

1.3.5. The Diascreen NVA-01 PC is a well-balanced noise-shielded system. Nevertheless, it is necessary to provide such arrangement of connection cables which minimizes any focusings and interferences during carrying out the tests. Interlacing of any signal and power lines is inadmissible

Chief designer,Valery Naumov


Electrocardiogram
Integral Pulse Wave
Differential Pulse Wave



Fundamental phase (temporary) characteristics of the differential pulse wave form:

- Phase (time) of intensive reduction FIS (- 1);
- Phase (time) of the extreme load OF FAN (- 2);
- Phase (time) of a reduction in the load FSN (- 3);
- Phase (time) of the completion of systole FZS (- 4).

1.1. **Testing Procedure Parameters and Means**

№	Parameter	Physiological Interpretation	Technical Interpretation	Unit of Measurement	Range	Traditional Method of Measurement	Technical Means of Measurement
1	Pulse **(P)**	Number of reductions of the heart muscle	Number of pulsations of the capillary blood	Heartbeats per minute	45 - 200	Electrocardiography Direct calculation Tonometry	Electrocardiograph with strip recording
2	Cardiac Interval Variation **(MxDMn)**	Maximal amplitude of the regulator influances	Difference in time between the maximum and the minimum time intervals of two adjacent maximums of pulse wave	seconds	0,02 - 0,22	Electrocardiography	Electrocardiograph with the electronic "rule of measurement" or the rapid strip record
3	Exstrasystoles and Pauses	Non-planned heart contraction and heartbeat passages	Redundant peaks of a pulse wave or its passage		1-10	Electrocardiography	Electrocardiograph with strip recording
4	Co-efficient of Variation **(CV)**	Normalized parameter of the summarized effect of the heart regulation	Statistical parameter being equal to relation of the middle quadratic deviation to the middle value of duration of a cardio-interval	%	1 - 25	Electrocardiography	Electrocardiograph with the electronic "rule of measurement" or the rapid strip record
5	Recovery Time of Vessels	Time of a decrease in the blood flow velocity after closing of the aortal valve. The decrease is of 2.7 times.	Determined on the phase of completion of systole	seconds	0,04 - 0,15	Reography Photo-pletysmography	Photo-pletysmograph with the electronic "rule of measurement" or the rapid strip record
6	Tone of Vessels	Elasticity of vessels	Parameter is coherent to non- elasticity of vessels	%	10 - 25	Reography Photo-pletysmography	Photo-pletysmograph with the electronic "rule of measurement" or the rapid strip record
7	Phase (time) of Extreme Load	Time interval in which an intensive heart muscle contraction occurs, and blood ejection from the left ventricle myocardium to an artery happens	Time from the point of the maximum of the wave to the moment of its intersection with the zero line	seconds	0,05 - 0,20	Reography Photo-pletysmography	Photo-pletysmograph with the electronic "rule of measurement" or the rapid strip record

4. FORMULAS USED FOR CALCULATION OF THE VARIATION PARAMETERS OF PULSE

1.pULSE	P=60/Tcp; .
2.Variation of Cardiac Interval	MxDMn = (tmax - tmin);
3.Co-efficient of Variation	CV=100*SDNN/Tcp;

Tcp - medium value of cardiac interval
tmax - maximum value of cardiac interval
tmin - minimum value of cardiac interval
SDNN - medium quadratic deviation