

CardioDM-06®

software for heart screening

User's Manual

Rev. 3



Address: 6805 Mayfield Rd., Ste. 1203, Cleveland, OH 44124, USA
Phone: (440) 829-5590
Fax: (440) 442-5629
E-mail: gvgoh@adelphia.net
Internet: <http://www.pegasusmedical.com/>

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Introduction

We are happy to welcome you as a user of the **CardioDM-06®** software for heart screening (hereinafter the screening analyzer). This screening analyzer significantly differs from the traditional ECG analyzers because it is based on a new approach to ECG signal analysis – the ECG Dispersion Mapping method. The ECG DM method uses traditional ECG signals only as the way of capturing low amplitude oscillations of body surface potentials. Therefore, the result of ECG signal digital processing is not the traditional ECG data, but a map of dispersive changes of the myocardium, which is formed on a computer screen as a so called *heart portrait*.

The main structural component of the ECG DM method is the dispersion analysis of low amplitude ECG signal oscillations during particular PQRST cardio cycle intervals. Low amplitude oscillation dispersive analysis is performed during 30-60 seconds of continuous ECG signal monitoring. The incoming signal is provided by limb leads only (electrodes **R_A**, **L_A**, **R_L**, **L_L**). Amplitude dispersion medians are in range **5 ... 30 microvolt**, which is significantly lower than average amplitude of ECG waves. Special analysis of such low amplitude signals (ECG fluctuation) ensures the reliable identification of small deviations of myocardium polarization and repolarization processes. This analysis is related to ECG (electrocardiogram) fluctuations with myocardial metabolism changes. Monitoring of ECG fluctuations provides indirect conditional assessment of antioxidant systems, electrolyte shifts, adenosine triphosphate (ATP) concentration and other parameters of metabolism as an integral coefficient of metabolic changes. The change of this coefficient allows determining even a minor disorder of myocardial depolarization and repolarization processes which are not available in other methods of ECG analysis. In ECG DM method of ECG analysis even minor disorders are effective indicators of pathological changes of myocardium which are not sufficiently significant in conventional ECG characteristics. As a result of such analysis you will get a map, showing deviations of low-amplitude characteristics with amplitude of such deviations and their presumable location by parts of the heart. To allow a physician to have a comprehensive and easily assessed view of the myocardium changes, a dispersion map is projected onto the quasi-epicardium of a 3-D digital heart model demonstrating the anterior and posterior heart surface. Expression and supposed localization of changes are identified according to colour changes of the quasi-epicardium, which, if consistently green, is considered normal.

Abbreviations

Abbreviation	Meaning
MCS	Medical Computer Systems, Ltd.
ACG	Aorta-coronary grafting
AH	Arterial hypertension
ECG	Electrocardiogramm
ECG DM	Electrocardiogramm Dispersion Mapping method
HCMP	Hypertrophic cardiomyopathy
HF	Heart failure
HK	Hypokinesia
IHD	Ischemic heart-disease
LBBB	Left bundle-branch block
LVH	Left ventricular hypertrophy
MI	Myocardial infarction
OMICS	Old myocardial infarction cardiac sclerosis

Terminology is based on

1. "Stedman's Medical Dictionary", 2nd edition, published by Houghton Mifflin Company Boston – New-York, 2004
2. Russian-English Medical Dictionary, 3rd edition, published by "Russo" Moscow, 1997

1. Purpose and usage

The computer screening analyzer CardioDM-06® (generator of the portrait of the heart) allows an instant evaluation of the condition of the heart using ECG-signals from the limbs (4 electrodes).

Why do you need the benefits of the CardioDM-06® screening analyzer?

- You need a simple and reliable screening unit which even your junior medical staff can operate.
- You have an unending flow of patients, and it is important for you to increase the reliability and speed of screening tests.
- You monitor the patient's heart during in-patient care, and want to quickly get information as early as possible in a noninvasive way on small changes in the processes of myocardium electrical activation. At the same time, it is also important to you to be able to get this information right where the patient lies without moving him/her to the functional diagnostics area
- You monitor the patient for a long time and want to observe tendencies in the changes of heart's state, which cannot be seen on the ECG.

The screening analyzer can be used:

- in clinical medicine (instant evaluation of the condition of the heart, early detection of progressing changes in the myocardium).
- in preventative medicine (screening tests for on-time and reliable detection in the groups of patients with pre-clinical forms of disorders).
- in departmental medicine (preventative medical examination).
- in sanatoriums, preventoriums, rehabilitation centers (objective instant indicator of the condition of the heart and the entire body).
- in emergency medicine for reliable evaluating the current condition of the heart.
- in sports medicine (early and accurate detection of negative dynamics of the heart's state).

In addition to instant visual analysis of the image, the system forms an automatic conclusion for the doctor which includes:

1. An integral deviation index of the dispersive characteristics of the low-amplitude ECG variations (index of metabolic changes) from the norm, on a scale of 0 to 100%.

2. An integral index of rhythm disturbance on a scale of 0 to 100% (a total deviation of statistical characteristics of rhythm variability).
3. A text screening-evaluation.



CardioDM-06® quickly and accurately ascribes the heart to one of four groups:

1. Normal
2. Border-line state
3. Moderate pathology
4. Acute pathology

At the same time, the doctor gets visual information on the intensity and the most probable localization of the center of the changes. In addition, this information allows controlling the pre-clinical "near-threshold" changes of the state of the heart.

Exposure time (duration of the ECG data entering) is 30 or 60 sec. The portrait of the heart can be obtained without undressing the patient, while he or she is sitting up. The time it takes the image to form after the entering of ECG data is 5 to 20 seconds, and the time it takes to inspect the portrait of the heart from two views (from the right and from the left) does not exceed 60 seconds. The portrait of the heart is simultaneously formed from two views: from the right side and from the left side. In the normal state, the epicardium is green in the image. If there is a center of pathological changes in the myocardium, the correspondent area of the heart portrait will change its color from green to red according to the degree of the pathology. The portrait of the heart gives overall information on dispersion changes in all the cardiac chambers and can be easily interpreted by the doctor within 15 to 20 seconds. **CardioDM-06®** gives the doctor the unique ability to observe the tendencies of changes in the heart's state by analyzing the image sequence. The time it takes to display the gallery of the four consequential images while observing the tendencies is 30 to 40 seconds. The overall time it takes to obtain the conclusion is 1.5 to 2.5 minutes.

The doctor can use the standard view and analysis functions of the ECG data from the 6 standard limb leads I ... aVF. The screening-test is recorded (conclusion report). The screening analyzer has functions which allow for managing the patient database and heart portrait database.

1.1 Restrictions

- **CardioDM-06® DOES NOT DIAGNOSE!** The screening analyzer functions to detect early dispersive deviations in the in-between heart group and warn of acute pathology. **CardioDM-06® screening analyzer is *not a distinguishing condition of Acute Myocardial Infarction (AMI) among recognizable conditions of myocardial ischemia.*** In such cases the screening analyzer shows the probable myocardial ischemia and the need (or urgent need) for a clinical examination for diagnosing and rejecting a confirmed diagnosis of "acute myocardial infarction".
- In some cases metabolic changes in valvular diseases and cardiomyopathy are indistinguishable from myocardial ischemia by the structure of the dispersion map, i.e. the screening analyzer states that myocardial ischemia as a possible reason for changes in dispersion. However, such cases can only be found during acute pathological changes which, in any case, need a full examination with a diagnosis. Therefore, such specificity mistake doesn't affect high screening sensitivity of this screening analyzer in pathological changes of myocardium.
- While analyzing the rhythm, **CardioDM-06® DOES NOT DIAGNOSE THE TYPE OF ARRHYTHMIA!** Only the facts of the existence and acuteness of arrhythmia are analyzed, and the most probable type of disorders which are connected to the changes in the atriums is determined. The emphasis of the analysis is on separating the acute forms of arrhythmia and stress. For this reason, some forms of short arrhythmia paroxysms may be undetectable. However, even in such cases the portrait of the heart gives the doctor early information about the subliminal functional or organic myocardial changes that can cause disorders in the heart rhythm.
- The drug taking can influence on the accuracy of the heart portraits visualization and forming the conclusion and comments. If the system is used during the drug treatment it is necessary to compare the current data with the data collected before the drug taking.
- **The screening analyzer CardioDM-06® is intended for screening-analysis of ECG-signal only for adults. CardioDM-06® is not suitable for children under 12. This screening analyzer can be used for children and teenagers 12-18 years of age only for monitoring the tendencies in dispersive parameters changes. This resource is determined in each specific case by the doctor.**

1.2 Principle of analysis

Amplitudes directly measured on ECG, and indirect parameters calculated on the basis of new mathematical model of bio generator of the heart vary within minor ranges in successive PQRS-complexes.

Amplitude and phase characteristics of these variations have a heightened sensitivity to the changes in the processes of myocardial depolarization and repolarization. It is the dispersion of these variations that is analyzed in **CardioDM-06®**. The term “dispersion” corresponds to the generally accepted in cardiology determination of the difference between the maximum and the minimum of the varying value. Dispersive changes give an integrative estimate of changes in an ample quantity of structural characteristics of the myocardium that depend on blood parameters, electrolyte balance, blood pressure and similar factors. These dispersive changes are observed both in cases of presence of standard electrocardiographic changes in the ECG, and in cases of their absence, for example at the early stages of myocardial changes. **CardioDM-06®** allows direct screen observation of the picture of the quasi-epicardium changes in the computer heart model that reflects with a certain precision both the size and the localization of myocardial changes. The information on abnormality of myocardial depolarization-repolarization processes is presented in the form of quasi-epicardium color changes on 3D image of the heart – *heart portrait*.



Take note of the fundamental methodical peculiarity of the heart portrait in the screening analyzer **CardioDM-06®**.

Visualization of dispersive characteristics on the heart portrait reflects **integral** changes in morphological, electrophysiological and other such structural parameters of the myocardium. As a result the map of color changes in the quasi-epicardium of the heart portrait of a specific patient has its own stable individual peculiarity resulting from personal features of current metabolic changes of patient's myocardium. As a result, the heart portrait is highly specific with respect to individual structural characteristics of the myocardium. However, the same reason causes the fact that portraits of different patients with the same clinical diagnosis may differ substantially in individual characteristics of localization, size and degree of the changes. And vice versa: similar changes in the portraits may in some cases correspond to different pathologies. The indicated peculiarities in no way affect the sensitivity and specificity of the screening assessment, i.e. the reliability of the differentiation of norm/abnormality states.

2. General information

The **CardioDM-06®** is intended for quick identification of heart performance abnormalities, which are manifested in the above mentioned dispersive characteristics and may be associated with developing heart pathology.



The CardioDM-06® DOES NOT DIAGNOSE!

The function of this screening analyzer is to define earlier dispersive deviations which may forego pathology and monitor its dynamics. In many cases this allows observation of changes at an early stage, as well as control of the dynamics of dispersive-deviations with a high level of accuracy.

The CardioDM-06® IS NOT A SUBSTITUTE for other clinical methods of heart diagnostics and MAY be used only under consideration of other clinical data.

General methods of operating the **CardioDM-06®** are as follows:

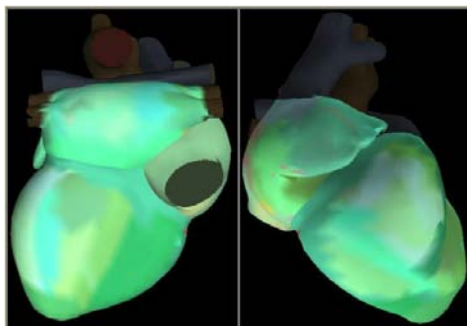
1. Electrodes are applied in accordance with the standard arrangement of ECG limb leads.
2. The “New Test” button (please see the interface description below) is pressed. ECG data acquisition is performed depending on the chosen time exposure of 30 or 60 seconds.
3. In about 40 to 70 seconds an portrait of a heart in two projections is formed on a screen, together with a general conclusion and integral data indices related to a patient’s condition. The quasi-epicardium area of the image is coloured green if normal. When various abnormalities are observed, the colours in relevant areas change to yellow or red. The larger the red area of a quasi-epicardium, the more an abnormality is significant. When dispersive changes are combined with large positive ventricular repolarization amplitudes (a peaked ECG T-wave), a purple shade is added to the red of the corresponding quasi-epicardium areas. At the same time the more evident deviation from the standard occurs, the more changes in quasi-epicardium texture-is observed.

2.1 An ideal heart model

The **CardioDM-06®** compares a patient’s dispersion characteristics and the dispersion model of ‘an ideal heart’. Such a model corresponds to a heart of a healthy young man over the age of 20. If quasi-epicardium performance fully coincides with the ideal heart model, it will be displayed in green on the patient’s heart portrait.

A dispersion map is an indirect indicator of myocardium cell metabolism, therefore ‘an ideal heart model’ corresponds to the ‘perfect’ functional state of the myocardium, which is characterized by ‘perfect’ metabolism and corresponds to the norm. It is obvious that the functional status of a normal (that is, not pathological) myocardium may differ from this standard under some specific longitudinal

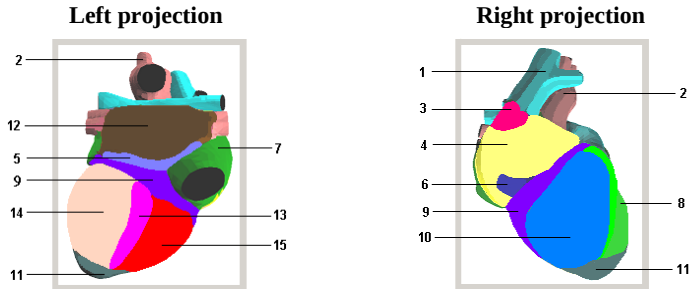
conditions (during pregnancy or during an athlete's intensive physical training, for example). As a result, a certain border-line area, thoroughly controlled by the **CardioDM-06®** screening analyzer, is observed between the 'perfect myocardium' and an abnormal myocardium. Thus, a physician has an opportunity to identify border-line conditions between a norm and an abnormality, that is, there is a possibility to observe myocardium changes at early stages preceding disease development.



2.2 Visual structure of the heart portrait

A *heart portrait* is a 'snapshot' displayed on a computer screen as a result of computing median dispersion characteristics of low amplitude fluctuations during the ECG input. A *heart portrait* of the ventricular areas reflects the integral picture of dispersion changes, involving both ventricular depolarization and repolarization. Dispersion changes on a *heart portrait* of the atrium areas correspond to the depolarization phase only. The heart portrait colour changes are observed under deviations of amplitude dispersion characteristics as well as under changes of delay or acceleration of dispersion characteristics in time (phases of dispersion characteristics), which correlate with values of P-Q, Q-T, QRS intervals of ECG input signal. The location of amplitude and phase colour indicators on a heart portrait is shown in figures: left projection and right projection. Amplitude indicators correspond to the anatomical structure of a heart, and the location of phase indicators is an approximate projection of relevant depolarization fronts onto the 'quasi-epicardium' of a heart portrait.

Examples of heart portraits with different states are given in the gallery of portraits.



1. precava,
2. aorta,
3. integral indicator of rhythm,
4. indicator of the right atrium myocardial state (depolarization dispersion),
5. P-Q interval anomalies indicator,
6. AB conduction stability indicator,
7. integral indicator of both atria state (common properties determined by the common excitation source),
8. indicator of the completion phase of the right ventricle depolarization (projection in the area of the interventricular septum),
9. indicator of ventricular repolarization duration (correlates with Q-T),
10. indicator of the right ventricle myocardial state (repolarization dispersion),
11. indicator of ventricular depolarization duration (QRS duration),
12. indicator of the left atrium myocardial state (depolarization dispersion),
13. indicator of the completion phase of the left ventricle depolarization,
14. indicator of the left ventricle myocardial state (repolarization dispersion),
15. indicator of the completion phase of the right ventricle depolarization (projection onto the posterior wall).

2.3 Structure of text messages

The main function of the screening analyzer is to form the heart portrait ensuring the efficient accomplishment of the screening control tasks. The text messages that accompany each image are *not to be regarded as the diagnosis*. Those messages give a doctor a screening estimation (4 gradations of deviations), which is the body of the conclusion. The screening estimation also furnishes *additional reference information* on the presumptive pathology. The *reference information*, not being the diagnosis, is probabilistic. It helps to make the efficient and task-oriented plan for further clinical instrumental examination or other prompt activities on the basis of the screening estimation.

The text messages include three main data groups:

1. integral indicators
2. conclusion
3. detailing

2.3.1 Integral indicators

The integral indicators embrace the following four indices: “**Myocardium**”, “**Rhythm**”, “**Pulse**” and “**Detailing**”



CardioDM-06@ screening analyzer integral indicators

The “Myocardium” and “Rhythm” indicators are relative characteristics, which describe the total value of dispersive deviations and range from 0% to 100%. The higher the value of the indicator is, the greater the deviation is. Physically, the “Myocardium” = 100% corresponds to the pathological complex implying evident deviations virtually in all the chambers of the heart. The “Myocardium” = 0% corresponds to the total absence of any significant deviations from the ideal heart model.



The “Myocardium” indicator is the main parameter in the clinical interpretation of a screening conclusion.

less than 15 – no significant deviations have been detected. The changes in the myocardial metabolism in the given region are attributable to one's individual peculiarities. This conclusion is to be compared with the other clinical data.

15% ... 19% – border-line state, dynamics monitoring is advisable.

20% ... 22% – pathology is likely. If the deviation has been detected for the first time, dynamics monitoring is necessary and examination is advisable.

23% ... 27% – pathology is likely. If the deviation has been detected for the first time, dynamics monitoring is necessary and examination is required.

More than 27% – pathology or evident pathology. If the deviation has been detected for the first time and has been invariably confirmed by successive examinations, immediate examination is required.

Similarly, the “Rhythm” = 100% corresponds to the most evident changes in the R–R intervals variability characteristics, which are *inherent* to significant *arrhythmias or intense stresses*.

The “**Detailing**” indicator offers information on the similarity of the given image to the images of certain typical, widespread pathologies. The “Detailing” indicator includes 9 symbols, which can be represented by digits as well as “L” and “S” letters. The number of the symbols in the code is equal to the number of the pathological groups used by the automatic classifier of the screening analyzer while analyzing the fluctuations.

The pathological groups include the following:

- **G1:** right atrium depolarization
- **G2:** left atrium depolarization
- **G3:** right ventricle depolarization
- **G4:** left ventricle depolarization
- **G5:** right ventricle repolarization
- **G6:** left ventricle repolarization
- **G7:** symmetry of ventricular depolarization
- **G8:** intraventricular heart blocks
- **G9:** symmetry of leads

In the **G1...G7** groups a wide spectrum of dispersion changes attributable to numerous clinical pathologies is analyzed. The names of the groups mainly reflect the electrophysiological characteristics of the changes in the atrial and ventricular myocardium (depolarization and repolarization processes). In contrast to that, the **G8** group refers to the highly specified dispersion changes, the marked types of which correspond to conduction blocks of myocardial electrical excitation. The **G9** group is showing deviations of wave front of ventricular depolarization. In most cases, such deviations correlate to early hypertrophic myocardial changes although in some cases they can be determined by the left ventricle ischemia. Despite its rather low specificity, the **G9** group code is highly sensitive to the change of myocardial depolarization rate. The “0” digit in the “Detailization” means that the image regarding the given group is within the normal range. The presence of a non-zero digit in any of the **G1 – G9** groups is to be regarded as the evidence of the similarity of the dispersion characteristics of the given image in the group to one of the pathologies (here the digit denotes the conventional index of the pathology). The higher the digit value is, the more evident the deviation is. The quantity of reference pathologies is specific for each group and determined by the following values: **G1 – 17 references, G2 – 10 references, G3 – 16 references, G4 – 22 references, G5 – 3 references, G6 – 14 references, G7 – 21 references, G8 – 2 references, G9 – 21 references.** The quantity of the references has been chosen so as to ensure the possibility to distinguish among approximately 130 enlarged deviation types and to form recommendation messages concerning the presumptive pathology. **The main function of the detailing code is to provide a user with quick-perceptible high-quality information about the presence of presumptive pathologies with similar dispersion characteristics.** The presence of a few indices equal to 1 or 2 in the code, e.g. “0–0–1–0–1–0–0–0–1”, is evidence of minor dispersive deviations. In contrast to that, the presence of high indices equal or similar to the quantity of references in the given group, e.g. “0–8–10–19–1–4–20–2–12”, testifies considerable deviations. The name of a presumptive pathology corresponding to the index of the conclusion code is displayed in the “Detailing” message group (see further). The “L” code refers to a border-line state, where the changes have come closely to a pathological gradation. The “S” code shows that certain changes have started within the normal range. In

other words, the “S” and “L” codes are indicators of border-line values of the dispersion characteristics.

2.3.2 Conclusion

Conclusion contains a general screening estimate, determined by the similarity of the present portrait with pathology portraits. Besides it contains an additional information on the manifestation and type of the possible pathology, which serves as a recommendation for future decision-making. The screening estimate differs from the additional information by colour coding: the screening estimate text is coloured, while additional (recommendation) text is black and white.

Conclusion

GENERAL CONCLUSION
70%: If these deviations are observed for the first time and at the given moment stably repeat on consecutive portraits of heart - the IMMEDIATE test is OBLIGATORY! DEVIATIONS in functions of heart cameras.
CHANGES in ventricular myocardium and signs of hypoxia. Probability of ISCHEMIC changes.
SEVERE INCREASE of Q-T duration.
Essential ELONGATION Q-T and changes of repolarization of a myocardium of ventricles. Monitor dynamics - these signs can correlate with possible RELAPSES of an aggravation of symptoms.

RHYTHM
Moderate TACHYCARDIA

Specification

Myocardium	70%
Rhythm	67%
Pulse	91
P-Q duration, msec	158
QT/QTc	412/350
P duration, msec	92
QRS duration, msec	146
Corner QRS, degr.	-56
Corner T, degr.	118
Corner P, degr.	60

G1- RA depolarization
NO significant deviations in the given group.

G2- LA depolarization
NO significant deviations in the given group.

G3- RV depolarization
Most probably:
Signs of deceleration of depolarization. Deviation of a normal synchronism of ventricles' depolarization. There is a probability of a post

Positioning of text in the detailed information window.

2.3.3 Detailing

Detailing contains the names of probable pathologies, whose portraits for each group are the most similar to the given portrait. Moreover, the doctor can see some typical quantitative characteristics of waves and intervals of initial ECG in the left part of the detailed information window.

ATTENTION!

If you are examining a patient with an **electrical cardio stimulator**, the rhythm deviations information provided by the **CardioDM-06®** may be false.

16

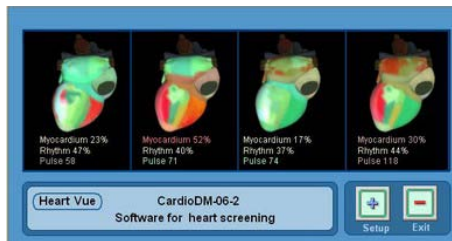
18



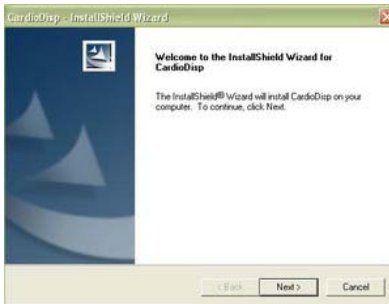
3. Installation of screening analyzer

Check that the hardware installation has been finished (see chapter 5 of the HeartVUE system for non-invasive screening of heart. User's Guide) and then install CardioDM-06 screening analyzer from the **Installation CD**:

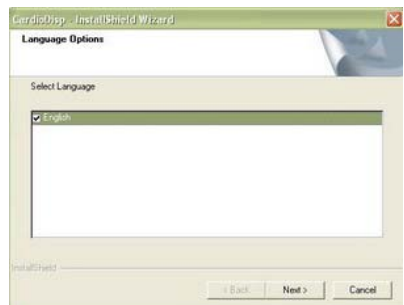
1. Insert the Installation CD in the CD-ROM and wait till the installation runs automatically, or run the **Autorun** file from the Installation CD. In either case the following window appear.



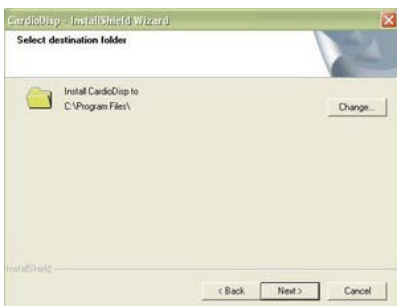
2. Press the *Setup* button.



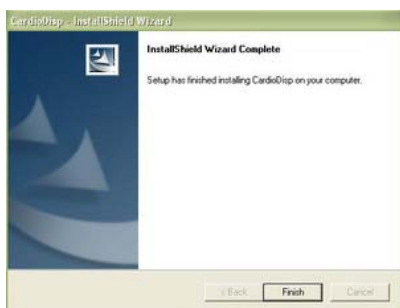
3. When the InstallShield Wizard's window appear press the *Next* button.



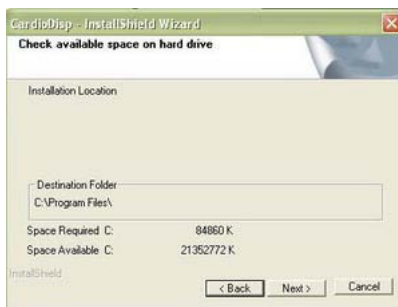
4. Select English language and press the *Next* button.



6. If the folder is right press the *Next* button once more time.



5. Select the folder for the CardioDM-06® screening analyzer installation (for example C:\Programm Files\), or press the *Change* button and appropriate folder. Then press the *Next* button.



7. Press the *Finish* button when the installation is completed.

Making of the illegal copy of the distributive is prohibited. The disk is copyrighted.

The **CardioDM-06®** screening analyzer runs only if the USB protection key (HASP HL key) is plugged in the free USB socket. The HASP HL key is included into the packaging.

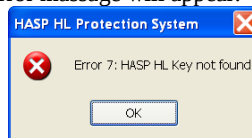


ATTENTION!

The key should be plugged in the computer's free USB socket **ONLY** if the installation of the CardioDM-06® screening analyzer is finished. After the key is plugged and the system defines it the LED will light up (and also the *Aladdin HASP Key* and *Aladdin USB Key* will appear in the *Screening analyzer Manager* under the Universal Serial Bus controllers).



If you forget to plug the key in therefore the **CardioDM-06®** screening analyzer won't run and the error message will appear.

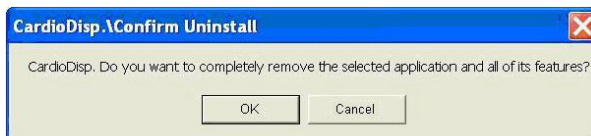


If you are going to uninstall the **CardioDM-06®** screening analyze from your computer pay attention to the databases' saving.

The Windows will ask you to uninstall the **CardioDM-06®** screening analyzer by showing the message *CardioDisp*:

Do you want to completely remove the selected application and all of its features?

Select **OK** if you want to completely remove this screening analyze.



During the screening analyze's uninstallation the message:

Attention! Do you want to save the databases before uninstalling the CardioDM?
will appear.

Press *Cancel* if you want to uninstall the **CardioDM-06®** screening analyze from your computer without saving the databases.

Press *Next* if you want to uninstall the **CardioDM-06®** screening analyze from your computer with the databases are being saved. Then the databases are

copied to the *TmpCardioDisp* folder which is located on the disk where the CardioDisp screening analyzer's files were located.

For example, if the screening analyzer's files location was

F:\Program Files

the databases will be saved in the following folder

F:\TmpCardioDisp

At the same time each local database is copied to its own folder {YYYYMMDD_hhmmss_n}, where **YYYY** means – year, **MM** – month, **DD** – day, **hh** – hour, **mm** – minute, **ss** – second of the database's creating, **n** – the identifier of the database.

4. Operation

4.1 Program overview

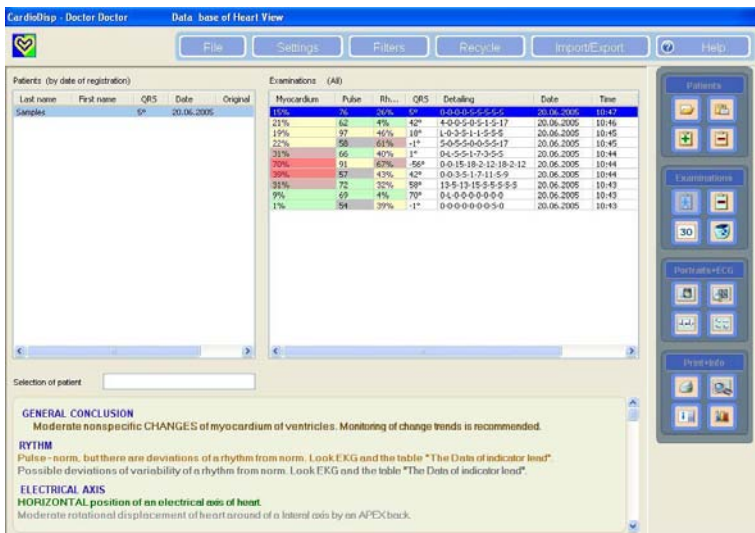
4.1.1 Start of the program

You can run **CardioDM-06®** program by double left mouse click on the program icon located on Windows™ desktop. There is also another option to activate program: click **Start** system panel button on the left bottom of screen, enter **All Programs** and **CDM-06** section and run **CardioDM-06®** program.



After running program the main window of the program will appear on screen and window showing «List of doctors».

Main window on the left shows *current database of the patient*, on the right – database of the heart portraits (examination database).



The database of the patient has two columns with dates: Date and Original. The value from a column Date specifies date of registration of the patient in the given database, and the value of a column Original specifies date of the very first registration for the imported databases. For example, the patient the first time was registered 03.10.2006 in the database DB_01, further on 08.20.2006 his/her data were copied in the database DB_02 by means of operations of import / export. In this

database the column Date will contain value 08.20.06, and column Original - 03.10.2006. If a column Original is empty, it means, that the patient was registered only in the current database.

CardioDM-06® program has a **list of databases** where user can select **current database** necessary for operation. Database can be switched to current session through main menu via **Settings⇒List of databases**. *The name of current database highlights on headline of main window after the name of doctor.*

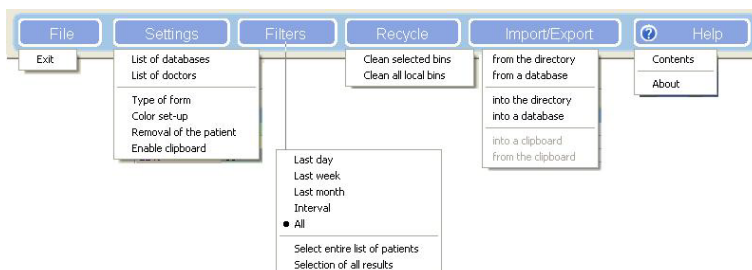
You can see main menu line under the headline. While starting database of patients (left window) they always arrange by date of registration of patients. The examination database (portraits database) of selected patient in a current database activates on the right window. Examination database is filtered by date where the first record complies the last one by time of registration. Setting of filter is performed by function of main menu **Filters** and includes five filter options (**Last day, Last week, Last month, All, Interval**). The indicator of current setting of a filter is located over examination database window. **Interval** setting options accessed via **calendar**.



The list of examinations may be empty if the dates of examinations are out of current setting of filter. Therefore you should necessarily select **All** filtration option if you should monitor portraits of a longer period time. In order to avoid unsuccessful setting of a filter for current database filtration option is not saved. The program automatically initializes **All** option at every start operation.

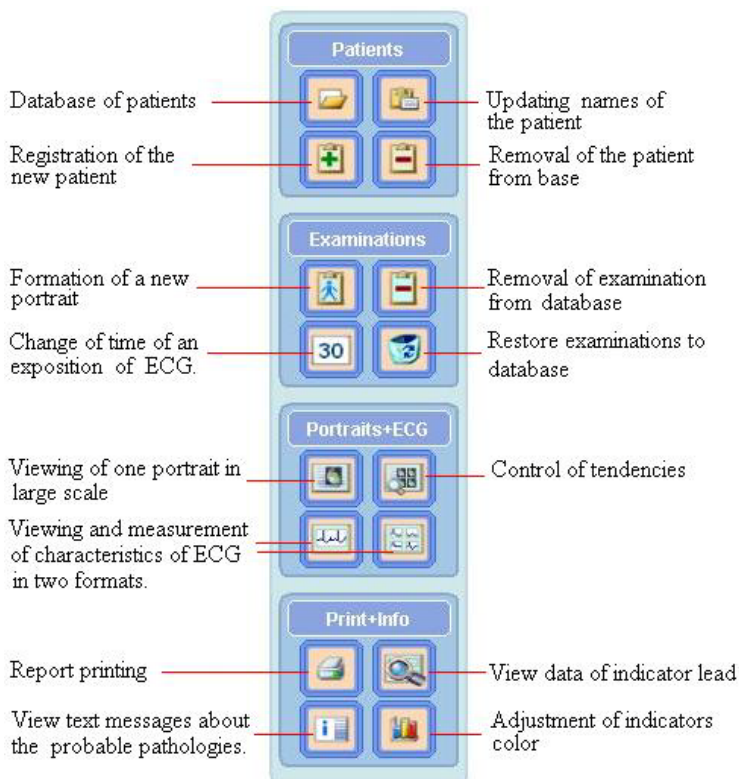
A vertical button panel performing main functions of screening analyzer is located on the right side of main window. The buttons arranged in four panels. Active buttons are shown by light background (highlight) and inactive by dark background.

4.1.2 Main menu



Menu's folder name	Purpose
File	
Exit	to exit program
Settings	
List of databases	to display the list of database
List of doctors	to display the list of doctors
Type of form	to set the form of report
Color setup	to set the indicator's colours
Removal of the patient	removal of the patient permission
Enable clipboard	clipboard operations permission
Filters	
Last day	to display the examination list for the last day
Last week	to display the examination list for the last week
Last moth	to display the examination list for the last year
Interval	to display the examination list for the period time
All	to display all examinations
Select entire list of patients	to select the all patients
Selection of all result	to select the all examinations
Recycle	
Clean selected bins	to remove examinations from the bin of selected patients
Clean all local bins	to remove examinations from all bins
Import/Export	
from the directory	to copy the set of examinations from the directory into current or new database.
from a database	to copy the set of examinations from the other database into current or new database.
into the directory	to copy the set of examinations from the current database to the directory
into a database	to copy the set of examinations from the current database to the other database
into a clipboard from the clipboard	If it is necessary to copy single examination from a folder of one patient in a folder another one (for example, if the doctor mistakenly has written examination in folder of other patient), it is possible to copy this examination in clipboard (Import/Export⇒into a clipboard), then to select an exact folder of the patient and to realize in his/her copying from clipboard (Import/Export⇒from the clipboard). By the default given possibility is disabled. To unblock it set up menu option Settings⇒Enable clipboard.

4.1.3 Button panel



4.1.4 Exit

To finish operation click menu **File⇒ Exit**

4.2 Examination: formation of heart portrait

Initially it is necessary to activate patient's name in database. If patient is already registered in database – select appropriate line in patients' window by left mouse click. If patients' list is big – use **Search of patient** function in the following way. Locate mouse pointer on **Search of patient** window located on bottom of patients' list and activate this part of menu by left mouse click. Enter any part of a name. Indicator on a patients' list automatically shows you appropriate line. If such combination of symbols doesn't correspond to those in the list of patients – search operation is not performed. In such case you should register new patient. For this

purpose push  button in **Patients** block of button panel. It is not necessary to fill all details of a patient. But it is **necessary** to enter only surname and push **OK** button in input window. **All data of a patient including age, weight and height are used only for reference of a doctor. This data has no effect on calculation of dispersion mapping.** After performing above mentioned actions a line with new name appears in database of patients.

Two characteristics displays in database of patients: **QRS** angle (direction of electrical axis) of last examination and date of patient's registration in database. If you locate mouse pointer on **Last name** field on headline of window and click left mouse – a triangle for alphabet (arrangement by: numbers, letters) arrangement of a list will appear. If you click left mouse again the arrangement will be top-down (top of triangle down).

Arrangement by date is performed in the same manner in **Date** field. While entering **CardioDM-06®** program arrangement always performs by date of patient registration.

Check up size of the established duration of input of an electrocardiogram (exposition) which is displayed on button . For switching click the left mouse button



The basic exposition – 30 sec. An exposition 60 sec is expedient to use in the event that you wish to receive more exact value of indicator **Rhythm**, for example, at high stress. Quality of a portrait practically does not depend on an exposition.

Fix the electrodes under the standard scheme of assignments, preliminary having greased points of imposing by gel: a red electrode (R) on the right hand, a yellow electrode (L) on the left hand, a green electrode (F) on shin of the left leg, a black electrode (N) on a shin of the right leg. If application of gel for any reasons is undesirable, it can be limited to wetting the point of contact by water. Be convinced, that electrodes are fixed without a mistake on the specified color conformity. At a weak signal it is desirable to degrease preliminary by skin mix (spirit and ether in the

ratio 1:1). Pay special attention on quality of contact of electrode N on which quality of an electrocardiogram in other channels R, L, F depends.



Diagram of applying electrodes



The major factor guaranteeing accuracy of a portrait is the condition of rest of the patient at input of an electrocardiogram. If the patient is in position sitting, he/she should accept the convenient weakened position as much as possible excluding a muscular tremor. Breath during input of an electrocardiogram should be usual, it is desirable without deep breaths or exhalations. If the patient is in a condition of nervous excitation, it is possible to recommend to patient to close eyes. During input of an electrocardiogram conversation or turns of a head are inadmissible.



Press the left key of the mouse button . If the screening analyzer of input of an electrocardiogram is connected to a computer, on the screen of the display there will be a window of input of an electrocardiogram-signal and two buttons of management of input: **Start** and **Stop**.



If input unit disconnects from the computer, the button is blocked. In this case the computer should be connected to the input screening analyzer of an electrocardiogram and the program should be restarted (to leave it and again to make active).

Inform the patient about the beginning of test and necessity to keep a condition of rest during 30 (60) seconds, press button **Start**. The first 5 seconds are carried out auxiliary procedures of optimum adaptation of the screening analyzer to an input signal. Thus on the indicator of time of an exposition there is a return readout: «-5,-4, ..., 0». These 5 seconds simultaneously are a pause for a relaxation of the patient. Indication of an electrocardiogram begins with readout «0». Input of an electrocardiogram-given comes to the end in 35/65 seconds from the moment of pressing of button **Start** (an exposition plus 5 sec.).

If during input of an electrocardiogram there will be a necessity to interrupt process – press the button **Stop**. (If after interruption of process by the button Stop you wish to return to the main window of system – press button ).

After end of input of an electrocardiogram there will be an indicator of process of generation of a portrait ("sand-glass") on the screen. Through 10 - 40 seconds (depending on speed of a computer) process will come to the end with a display on the screen of a portrait of heart in **large-scale portrait**. Simultaneously with a portrait in the same window integrated indicators and the text conclusion are presented. Thus, through 1 min from the moment of pressing of button **Start** at an exposition of 30 seconds the user receives a portrait of heart of the patient. If during input of an electrocardiogram there were any noises which have caused sharp changes baseline of electrocardiogram, it is expedient to repeat test (remove wrong examination in this case from base of examinations).



At detection of deviations from norm on the first portraits, to except casual influence of artifacts at examination, expediently, not removing electrodes to receive one more portrait.

4.3 Examination: Viewing a heart portrait and text messages.

Procedure of viewing of output data of program **CardioDM-06®** is expedient for carrying out in the following order:

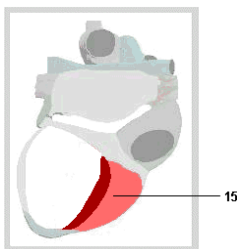
- viewing of the portrait
- viewing of the integrated indicators
- viewing of the conclusion
- viewing of the detailed elaboration

4.3.1 Viewing of the portrait

On a portrait the slightest changes of dispersive characteristics of electric excitation are visible. The picture of changes in color at presence of deviations has characteristic individual attributes; therefore a portrait of heart during long time keeps these individual attributes (similarly individual attributes of a face of the separate person). These individual variations happen significant enough, but all of them submit to a uniform principle:



The more intensive red color, and the more the area on which there was a change of green color aside red there are more deviations. Usually the most significant pathological changes cover left ventricle or at once both ventricle, and also area 15 of final phase of depolarization of ventricle on the left projection of a portrait of heart. The special attention should be turned on a bright red strip in the field of 15 even if all other departments of quasi epicardium have color of norm. In case of stable repeatability this attribute correlates with clinically significant changes of a myocardium.



Red band in section 15 (final phase of depolarization of the right ventricle), correlating with clinically significant changes

The degree of a saturation of red color in different areas of quasi pericardium is not always unequivocally connected with the adverse forecast. For example, at some slowly varying conditions of post infarction cardio sclerosis, red color is more significant, than at some kinds of a sharp heart attack though the probability of relapse of deterioration of a condition in case of cardio-sclerosis, as a rule, is less, than at a heart attack of a myocardium. This particular feature of the portrait relates with the fact that appearance of dispersive deviations is proportional to total changes of myocardium at depolarization and repolarization. At the same time, changes of repolarization components of electrical fluctuations at post-infarction may significantly prevail over repolarization changes at the earlier stage of myocardial infarction ***Therefore, having seen a portrait, it is necessary to familiarize with the conclusion and size of indicators.***



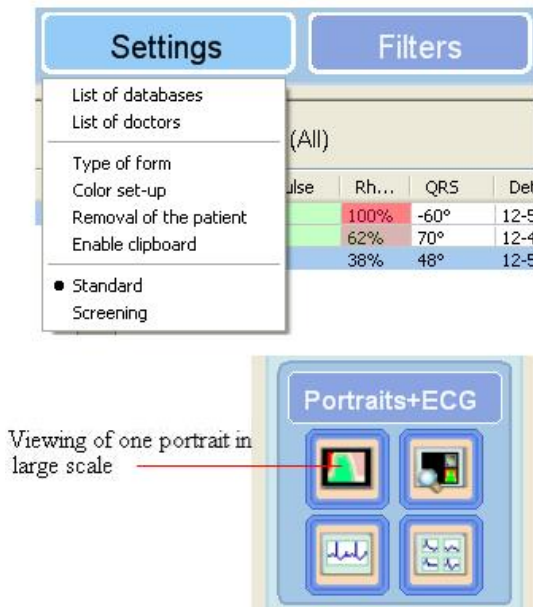
Please, pay attention: The present guide, despite of high individual repeatability color changes on a portrait of heart not always are highly specific for pathology of one kind. Changes of dispersive characteristics give integrated reaction to changes morphological, electrophysiological, etc. structural parameters of a myocardium. Thereof, at the same clinical diagnosis portraits at different patients can essentially differ on the area and expressiveness of changes. And on the contrary: similar changes on portraits in some cases can correspond to various pathologies. These features do not influence reliability screening-estimation, i.e. on reliability of differentiation of conditions norm/pathology.

There is auxiliary graphical indicator located on the left side from portraits where direction of electrical axis of the heart on frontal plane (QRS angle) is displayed. Some typical quantitative characteristics of waves and intervals of initial ECG as shown in «Detailing» duplicate above this indicator.

To the procedure of viewing of a heart portrait a new function was added, which provides monitoring of probability of electrical instability of a myocardium. This function is turned on by setting of an option “Standard” in drop down menu “Settings” of the top menu bar. Besides this function can be launched by the push-button panel in the right part of the screen. Match the mouse cursor with the button «Viewing of one portrait in large scale» and press the right button of the mouse. In an appeared window choose the option "Standard" by the left button of the mouse. If only the viewing of portraits is necessary, choose the option "Screening". An active mode of visualization is displayed by the button «Viewing of one portrait in large scale». If the "Standard" mode is switched on, this button has the following icon:



. At the "Screening" mode of visualization it looks like

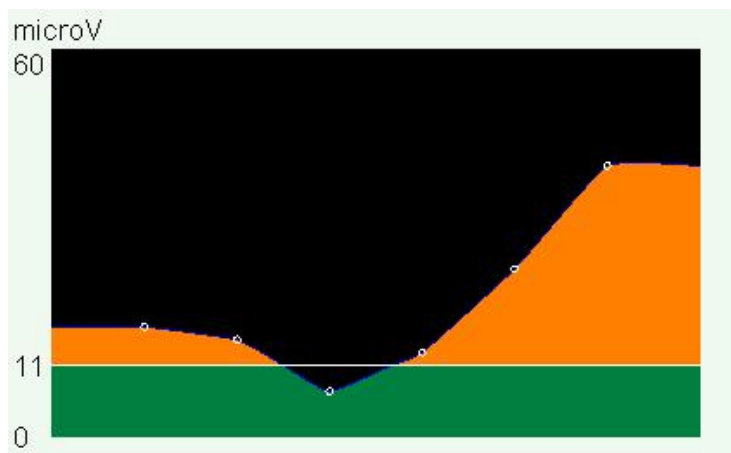


The additional function "Standard" forms of two additional windows: “Micro-alternations of repolarization” and “The indicator of electrical instability”. “Micro-alternations of repolarization” window contains an average line of amplitude deviation of low-amplitude dispersions on a T-wave interval of an initial ECG. This line called a "TW-alteration" diagram determines a functional dependency of micro

alternations amplitude on repolarization time, which corresponds to an average time interval from the beginning to ending of a T-wave. Horizontal scale is synchronized with 6 points highlighted with white circles on a line.

The first three points correspond to time interval of a T-wave increasing from an isoline up to the maximum amplitude. The next three points correspond to time interval of decreasing of T-wave amplitude from the maximum to an isoline. Thus, the horizontal axis corresponds to an average duration of a T-wave, and the vertical axis corresponds to micro-alternations amplitude. For a "TW- alternations" line the norm border is 11 μV . At considerable deviations the "TW-alternations" value can exceed 60 μV .

The norm border as 11 μV is defined by measurement method of micro-alternations amplitude and it is a technological constant for the given device. The other methods give values from 3 to 15 μV . To improve visual perception of the "TW- alternations" line, values less 11 μV are in green color and values more 11 μV are in orange color. The "TW- alternations" line is basic for calculation of the average amplitude of micro alternations in "The indicator of electrical instability" window. This window gives the extra information about type of changing of repolarization micro fluctuations, though for the indicator of electrical instability the average value of the "TW- alternations" line is only used.



The "TW- alternations" window

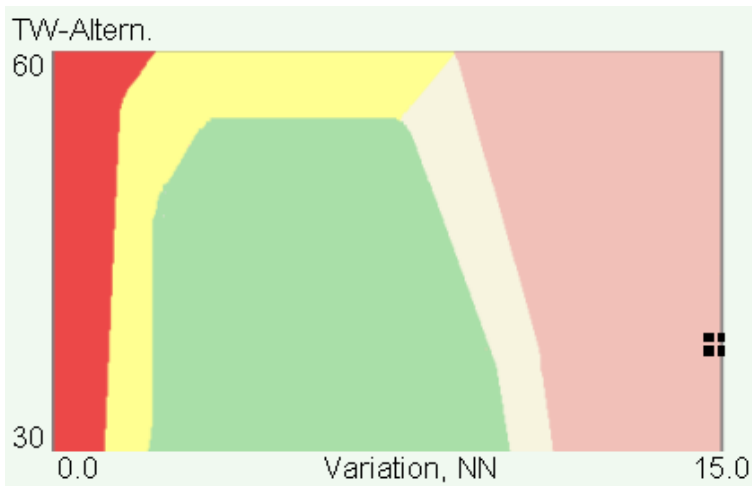
The window of "The indicator of electrical instability" is the main two-dimensional indicator for estimation of probability of electrical instability of a myocardium. The vertical axis corresponds to the average amplitude of micro-alternations, calculated by line integration in the "TW- alternations" window. The horizontal axis corresponds to the variation coefficient of RR-intervals measured during input of an

ECG-signal at an examination. Variation coefficient KR is calculated by the formula:

$KR = (SDNN) * 100 / M$, where SDNN - standard deviation of NN intervals (NN – an interval between neighbor R-waves on an ECG); M – the average value of NN duration. The current examination value in the viewed window is pointed by the four squares pointer 6. All window area is divided on five areas with different colors:

- 1 - Minor probability of electrical instability of a myocardium (green color).
- 2 - Uncertainty: increased probability of electrical instability of ventricle myocardium (yellow color).
- 3 - High probability of electrical instability of ventricle myocardium (red color).
- 4 - Uncertainty: increased probability of electrical instability of conductive system or atrium myocardium (light yellow color).
- 5 - High probability of electrical instability of conductive system or atrium myocardium (pink color).

The farther pointer 6 is posed from area 1 of green color, the more probability of electrical instability of a myocardium. The shift of the cursor to the area 3 is connected with increasing of probability of ventricular tachycardia or ventricle fibrillation. The shift of the cursor in the area 5 is connected with electrical instability of atrium myocardium or myocardium conductive system.



“The indicator of electrical instability” window

By observing shifts of the pointer by the button 10 “Monitoring of the tendencies”, it is possible to reveal on time negative tendencies of increasing of electrical instability of heart.

The conclusion about probability of electrical instability of heart is displayed in the upper part of the window of portrait viewing.

High probability of electrical instability of conducting system or myocardium of atriums

P-Q duration, msec **148**
 QT/QTc **328/310**
 P duration, msec **66**
 QRS duration, msec **72**
 Corner QRS, degr. **52**
 Corner T, degr. **10**
 Corner P, degr. **120**

E. Temperature of myocardium

38.8°C

Gradient QRS



TW-ALTERNANS VECTOR REPORT

Patient : Samples

TEST RESULTS

Max TW-Alternans in lead II : 36 uV
 Variational parameter RR : 20.9

Lead II	t _{beg}	t _{end}	t
Amplitude (uV) TW-Alternans	33	36	
Average (msec)			
SDDN (msec)			
Variational parameter			

Electrical Instability : Positive Tracing

SCREENING RESULT

Electrophysiological temperature of a myocardium



To increase accuracy of this conclusion it is recommended dynamics monitoring after small exercise loading to increase pulse on 5 ... 15 % (a simple case is an orthostatic test). By comparing the pointer shifts in the tendencies monitoring mode before loading and after, it is possible to figure out adaptive resources of heart.

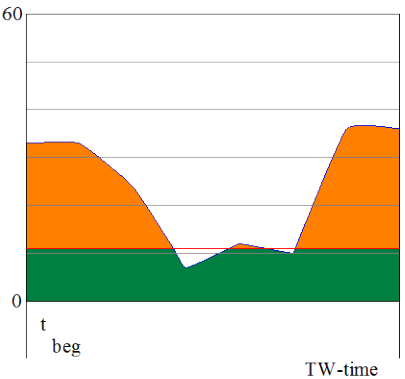
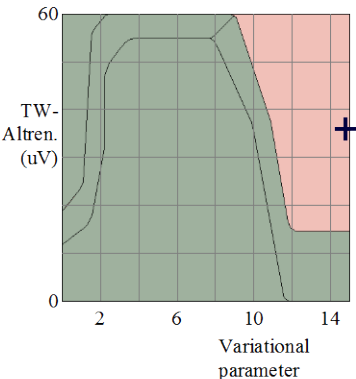
Window «*Repolarization's Microfluctuations*» and window «*Electrical Instability*» are formed on "TW-ALTERNANS VECTOR REPORT".

TW-ALTERNANS VECTOR REPORT

Patient	: Samples	Date:	25.09
		Time:	13:43
Age	:		
Sex	:	M.	
Height, sm	:	0	
Weight, kg	:	0	

TEST RESULTS

Max TW-Alternans in lead II : 29 uV				
Variational parameter RR : 20.9				
Lead II	t _{beg}	t _{end}	t _{max}	RR
Amplitude (uV) TW-Alternans	33	36	29	
Average (msec)				490
SDDN (msec)				102
Variational parameter				20.9
Electrical Instability :	Positive Tracing			



To see it click  button, and after “Portrait Viewing” window forming click . Subject to setting <Type of form> option “TW-ALTERNANS VECTOR REPORT” will put in file *.emf or print. This report is formed only in  window. Clicking  from other interface windows calls only screening form.

In lower part of it, as well as in left part of “Portrait Viewing” window , there is an indicator of “*Electrophysiological Temperature of Myocardium*”. Its range is selected in correspondence with standard thermo dynamical temperature of body. This parameter indirectly defines a level of functional reserves of myocardium:

Electrophysiological Temperature of Myocardium	Equivalent Value of “Myocardium”	Levels of functional reserves of myocardium
36,6 – 36,9 C 97,9 – 98,4 F	5 – 14%	Physiological norm for current heart rate during reading
37,0 – 38,0 C	15 – 25%	Deficiency of

98,6 – 100,4 F		functional reserves of myocardium.
38,1 – 41,0 C 100,6-105,8 F	26% – 80%	Severe exhaustion of functional reserves of myocardium.

Than higher electrophysiological temperature, the less *free energy* of myocardium and less compensatory capabilities of myocardium. Thus electrophysiological temperature of myocardium is not nosological parameter, but measure of a level of adaptive capabilities. Exactly this property gives this index a special status: independently on nosology it is possible to accurately observe and predict a dynamics of compensatory reactions, which determines, effectiveness of current treatment as well as long-term forecast.

4.3.2 Viewing of the integrated indicators

The indicators are located at the top of the portrait window. The main indicator is the ‘myocardium’ indicator, which gives a cumulative evaluation of the dispersive deviations from the norm on a scale of 0 ... 100%. The background colour on the indicator informs the doctor about the intensity of any deviations diagnosed in accordance with the following chart:

‘Myocardium’ indicator range	Indicator colour	Status
< 15%	Green	No significant deviations. If there are small changes of the portrait, these are individual peculiarities and a version of the norm.

'Myocardium' indicator range	Indicator colour	Status
15% ... 19%	Yellow	Border-line status (transient episode of short-term increase in dispersive characteristics) or early stages of possible pathology.
20% ... 23%	Yellow	Possible covert pathology.
24% ... 47%	Brown	Probable pathology.
> 47%	Red	Probable-significant pathology.

The 'Myocardium' indicator reading can vary within a low range (up to 8%) during successive examinations. Indicator variations of more than 8% between consecutive examinations which simultaneously change the colour of the heart portrait are evidence of myocardial instability and the need to check status with increased frequency of examinations (unless these variations are caused by features of the ECG, e.g. the electrodes being poorly connected to the skin or a muscle tremor while the ECG is being carried out).



If the 'myocardium' reading is consistently above 19% and other inferable information causes you to suspect potential ischemic change, then a full clinical diagnosis becomes necessary to differentiate ischemic from non-ischemic change.

Changes of the 'Rhythm' indicator are due to arrhythmia or stress, or the combined action of both. The background color for this indicator is determined as follows:

'Rhythm' indicator range	Indicator colour	Status
< 15%	Green	No significant deviations.
15% ... 50%	Yellow	Minor deviations.
51% ... 80%	Yellow	Border-line status or moderate deviations.
> 80%	Red	Significant abnormal rhythmic deviations.

The 'Rhythm' indicator is a fairly dynamic value, especially during a short, 30-second, exposure time. Furthermore, this indicator is highly sensitive, even to minor disturbances in the resting state while the ECG is being carried out. Its readings are guaranteed to be stable only at either extreme of the range. If the patient is healthy and the sympathetic and parasympathetic effects on rhythm are perfectly

balanced, the ‘rhythm’ indicator will remain consistently in the 0% ... 20% range. In cases of increased stress or significant arrhythmia, the indicator will be in the >70% range. For a healthy city-dweller, the range should vary from 20% ... 60%, as a rule, and increase towards the evening. If the ‘rhythm’ indicator consistently exceeds 50% at any time of day and the patient does not have significant arrhythmia, this is evidence of a constant source of heightened tension of the regulatory systems within the body (nervous tension, internal organ abnormalities, inflammatory process etc.). If heightened ‘rhythm’ indicator readings are simultaneously combined with a significant decrease in heart rhythm variability and this combination consistently repeats itself, it is a sign of a poor prognosis. If this is the case, the appropriate warning appears in the ‘Rhythm’ conclusion section.



If you wish to deliberately follow the patient's stress level while there are no significant pathological myocardial changes, we recommend you use the 60-second exposure. This makes the ‘rhythm’ indicator more stable.

Change in color of the indicator “Pulse” corresponds to generally accepted borders of normocardia, bradycardia and tachycardia for an adult person. The bradycardia and tachycardia limits in this screening analyzer do not separate sinoatrial rate and clear arrhythmia. A rhythm deviation from the sinoatrial rate is indicated by separate, additional messages in the ‘Rhythm’ conclusion section (see below).

The indicator **Detailing** informs the doctor of *pathological deviations* similar to standard. These can be identified by pressing the  button. Moreover, this can be done without having to exit the portrait window. In order to do this, you must align the cursor with the **Detailing** indicator (the cursor will change the pictogram) and left-click on the mouse. A bookmark window, entitled “Classification of deviations” will appear. The code for each group corresponds to a number in the list of generic deviations.

4.3.3 Viewing of the conclusion

The conclusion is located under the window with the large portrait and contains the following subsections:

1. GENERAL CONCLUSION – general screening evaluation,
2. RHYTHM,
3. ELECTRIC AXIS,
4. ATRIAL MYOCARDIUM,
5. VENTRICULAR MYOCARDIUM,
6. SYMMETRY of LEADS.

To gain access to all conclusion subsections, scroll down the text as normal on the right-hand side of the window. In the case of consistently heightened stress-

level readings (consistent deviation from the norm in some rhythm variability indices with no arrhythmia), a section entitled **OTHER CHANGES** will appear. The concluding text contains the screening evaluation as well as further information on the type and intensity of possible pathology to aid further decision-making. The screening evaluation can be distinguished from the additional information by a color code: the screening evaluation text appears in color whereas the additional information is in black and white. There are four distinct levels within the screening evaluation: norm, minor deviations from the norm, moderate deviations, and significant deviations. The colour of the text will indicate the level of deviation from the norm in accordance with the following chart:

Colour of screening evaluation text	Index and designation for level of deviation from norm
Green	1. Norm (no significant deviation) or on the norm's outer limits
Light orange	2. Minor deviations from the norm
Red	3. Moderate deviations
Red	4. Significant deviations

Texts of the screening-assessment on sections of the conclusion include the following basic text messages:

Deviations Gradation Index	The screening – estimation text
1. GENERAL CONCLUSION	
1 («Myocardium» – <15%)	NO significant deviations found. Such conclusion may be used only for comparison with anamnesis and physical parameters. If the patient is taking MEDICINE such conclusions necessarily has to be defined more precisely based on complete examination and monitoring of dynamics by this screening analyzer
1-2	Little changes WITHIN the NORMAL RANGE: it is advisable to check the DYNAMICS for differentiation between variant of norm from an initial phase of significant deviations.
1-2	There are small CHANGES in the process of ventricle excitation: it is expedient to monitor the DYNAMICS as these changes can signal either the onset of significant deviations or a sign of temporary functional irregularities.
1-2	Subtle irregularities of the left ventricle function are probable.
2 ("Myocardium" – 16% ... 19%)	Moderate CHANGES of the ventricles myocardium. Monitoring the DYNAMICS is advisable.
2	Deteriorations of the left ventricle function are probable.
3 ("Myocardium" – 20% ... 27%)	DEVIATIONS – see probable detailed elaboration on deviation groups.
4 ("Myocardium" – >27%)	SIGNIFICANT DEVIATIONS: pathological changes are probable. See probable detailed elaboration on deviation groups.
2. RHYTHM	
1	NORMAL – sinus rhythm.
1-2*	Moderate TACHYCARDIA.
3-4*	SIGNIFICANT TACHYCARDIA.
1-2*	Moderate BRADYCARDIA.
3-4*	SIGNIFICANT BRADYCARDIA.
3. ELECTRIC AXIS	
1	NORMAL position of the electric axis of the heart
1	HORIZONTAL position of the electric axis of the heart.
1	VERTICAL position of the electric axis of the heart.
2-4	Electric axis deviation to the LEFT
2-4	Electric axis deviation to the RIGHT

The additional information in sections of the conclusion is traced out in black-and-white. The additional reports having the high clinical importance, for example - messages of probable ischemia, are traced out in contrast black color.

If the following message is being formed «probable signs of the left ventricle abnormality », it means, that there are significant changes of dispersive characteristics of the left ventricle. However these changes have a diffuse type, and it is not possible to make a more elaborate statement on a probable deviation, thereby full clinical diagnosis is necessary for this purpose.

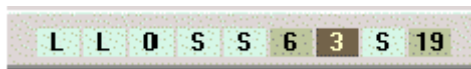


The additional information represented by the black-and-white text, **is not the DIAGNOSIS!** It is the recommendatory information on the most probable pathological conditions which dispersive characteristics are similar to the dispersive characteristics of an analyzed electrocardiogram. Only full examination can confirm or specify additional text messages

4.3.4 Viewing of the detailed elaboration

If the indicator «Code of detailed elaboration» contains indexes of deviations (nonzero figures), or if you wish to view quantitative values of typical parameters of

an input electrocardiogram, press  button – *Detailing window*. The window of detailed elaboration will appear on the screen. The text of the conclusion is repeated in the top part of this window for convenience, some standard parameters of the input ECG appear in the left part. A section with text messages on the probable pathological portraits which are the most similar to patient's portrait and the indication of corresponding probable nosologic units appear in the right part of the window. In the top part of that section color code of the detailing is indexed.



Color indication of detailing code

Indicator color of a code shows a degree of similarity of dispersive characteristics of the heart of a patient with dispersive characteristics of the certain group of pathologies in accordance with the following table:

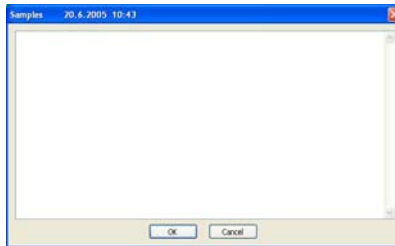
Code color of detailing	Text of detailing	Degree of similarity with a probable pathology
Light green	Probably:	The portraits of a patient's heart and a specified pathology are virtually congruous
Average (gray-green)	Possible:	Significant similarity of portraits
Dark	Uncertainty - specific peculiarities. The significant form of this deviation will be as follows:	The portrait of the patient's heart has many peculiarities. Exact congruence is not present, however it is very likely that the significant stages of the changes will become congruous with a specified pathology portrait

Detailed elaboration is carried out on nine groups of automatic classifier: G1, ... ,G9. This information allows for specification on additional reports of the general conclusion. For example, if in the additional information of the conclusion in the section entitled "VENTRICLES" appears a message on a probable ischemia of the myocardium and, at the same time, in the detailed elaboration in groups G3 ... G7 messages appear of ischemic onsets this clearly indicates a high probability that a full diagnostic examination will detect the ischemia.

The automatic classifier of screening analyzer **CardioDM-06** ® essentially differs from renowned computer interpreters in that it does not require lengthy and effortful reliability control of the ECG conclusion. **The portrait is formed on objective dispersive signals irrespective of the conclusion; therefore a glance at the heart's portrait is sufficient for purposes of reliability estimate.** Deviations always give rise to changes on a green palette indicating a normal myocardium.

4.4 Examination: record of the comments

In the bottom part of a detailing window is the window of comments where a doctor can input through the keyboard any required information regarding the examination or his/her final conclusion. To input the text press the  button and proceed inputting the text in the new window that came up. For saving the text press the <OK> button. In the printed version, doctor's comments will appear on page 3 of the form. The free space of this page can further be used by the doctor for hand-writing notes.



The window is used to write doctor's notes

4.5 Examination: review of additional parameters of the input ECG

If the doctor needs to assess some general features of RR intervals or amplitudes and the durations of the some ECG waves, she/he should review the table «Indicator Lead Data» (indicator lead in this program refers to the lead with the maximal amplitude of the R wave, i.e. the lead closest in direction to the electric axis of the heart). This table can be retrieved using button :

Data of indicator lead - I

General characteristics

Type of a rhythm	Normocardia
Infringements of heart rate	Moderate increase of heart rate
Rhythm deviation indicator, %	26
Character of a wave T	Norm

Characteristics	Value	Min	Max
average RR, msec	906		
RRmax/RRaver.	1.08	1.04	1.21
RRmin/RRaver.	0.77	0.79	0.95
Elongated RR, %	0		
Truncated RR, %	10		
Aver. amount of ventricular extrasystols/	3		

Scale: ☒ mV/msec ☐ mm/mm

Orientation: Corner QRS, degr. Turn apex back:

ECG Amplitudes OK

Waves parameters.

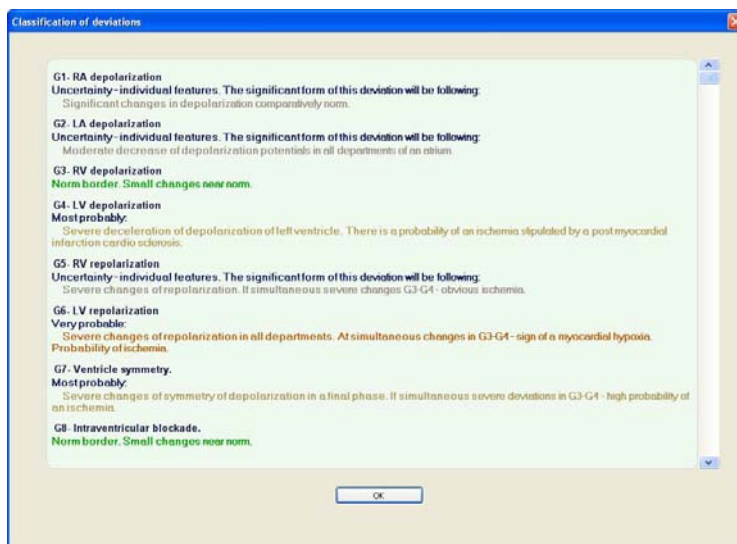
Characteristics	Value	Min	Max
Average pulse rate, beats./mines	76		
P-Q duration, msec	148	120	180
P-Q duration variation, %	2		35
QRS duration, msec	70		110
Q-T duration, msec	354	310	390
Q-Tk (corrected)	0.39		
P duration, msec	110	60	115
Amplitude of P, mV	0.13		0.27
Number of phases P	1		
Amplitude of Q, mV	#		
Amplitude of R, mV	1.11		
Amplitude of S, mV	#		
Amplitude of T, mV	0.19	0.13	0.74
Number of phases T	1		

The table which appears displays the results of automatic measurement of a number of amplitude and time quantitative features. These represent the average values determined on all PQRST-complexes of an ECG and which do not contain artifacts. The # symbol implies low reliability of the measurement (assessment is lacking). Abbreviation HRV means “heart rhythm variability”.

While calculating the average values on all analyzed PQRST-complexes, the representative complex is not singled out, therefore the interface does not contain representative complex with wave marking, traditional for the ECG-ANALYSIS. To increase the accuracy of interval duration monitoring, the automatic measurement is conducted on the enlarged scale of the ECG. Such measurement sometimes results in the 10...15% increase of the duration of an R wave with respect to the measurements conducted with a standard ECG of usual amplitude. This increase is conditioned by a more exact fixing of the beginning and termination points of the R wave on an enlarged scale. When required, the accuracy of the automatic measurements of amplitudes and intervals can be verified in a «manual mode» by utilizing ECG feature measurement window.

If minimal or maximal boundaries of norm are present they are displayed in corresponding columns of the table “Indicator Lead Data”. To get a more detailed view of the ECG in large scale and to view additional measurement of intervals or amplitudes in any lead I ... aVF, press the “Amplitude” button located at the bottom of the table. In the window that came up, namely “Average Wave Amplitudes in all Leads» choose the lead as required and press "ECG" button. The ECG feature measurement window will come up on the screen.

4.6 Classification of deviations



The window consists of nine deviation group. The code of each group corresponds to the number of the listed typical deviations.

4.7 Window of detailing

The screenshot displays the 'Window of detailing' in the CardioDM-06 software. It is divided into three main sections: Conclusion, Specification, and Commentary.

Conclusion: This section contains a 'GENERAL CONCLUSION' in red text, stating that 70% of deviations are observed for the first time and are stable. It also mentions 'IMMEDIATE test is OBLIGATORY!' and 'DEVIATIONS in functions of heart cameras'. Below this, there is a 'RHYTHM' section indicating 'Moderate TACHYCARDIA'.

Specification: This section is divided into two columns. The left column lists various ECG parameters and their values, while the right column provides a summary of the findings for each parameter.

Parameter	Value	Summary
Myocardium	70%	G1- RA depolarization
Rhythm	67%	NO significant deviations in the given group.
Pulse	91	G2- LA depolarization
P-Q duration, msec	168	NO significant deviations in the given group.
QT/QTc	412/350	G3- RV depolarization
P duration, msec	92	Most probably:
QRS duration, msec	146	Signs of deceleration of depolarization. Deviation of a normal
Corner QRS, degr.	-56	synchronism of ventricles' depolarization. There is a probability of a post
Corner T, degr.	110	
Corner P, degr.	60	

Commentary: This section is currently empty, showing a large white box for text input.

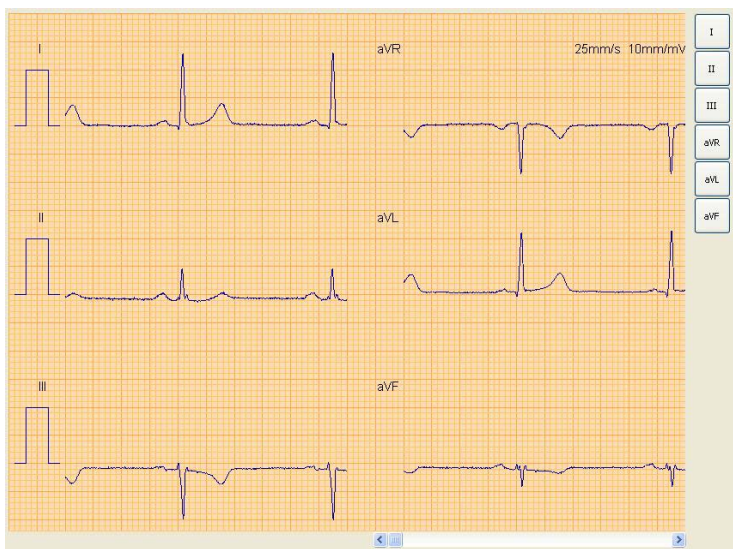
At the top right of the 'Specification' section, there is a row of numbers: 0 0 15 18 2 12 18 2 12.

The text of conclusion contains screening estimation as well as additional information about the expressiveness and the type of probable pathology to take subsequent decisions. **Screening estimation differs from additional information by color: the text of screening estimation is colored while additional text is black and white.**

Additional information given in black and white is NOT DIAGNOSIS! It is recommendable information about probable pathological states, dispersive characteristics of which resemble dispersive characteristics of the ECG under analysis. Only complete examination can confirm or verify additional text messages.

In the right part of the window there is a section of **text messages about probable pathological portraits bearing most resemblance to each other with indication of corresponding nosologic units.** The upper part of this section shows colors of detailing code.

4.8 Scanning ECG: 6 leads

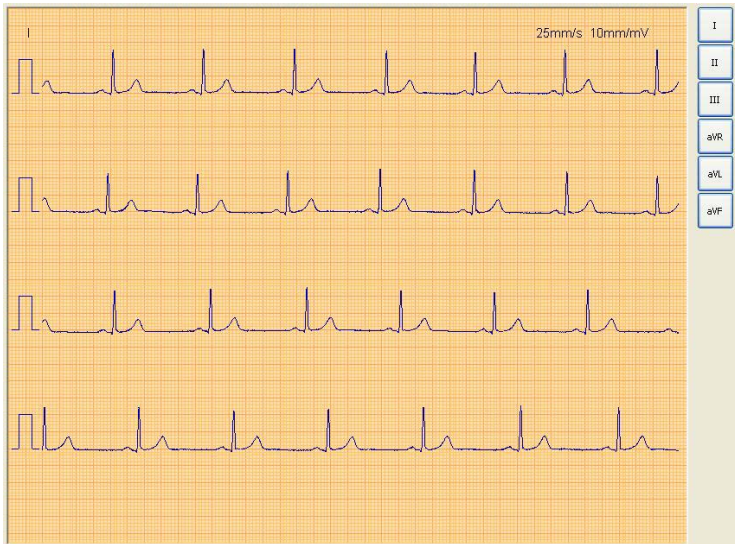


This window is used for a simultaneous view of the initial interval of all the leads. If cursor is matched with the line of any of the leads and the right mouse key will be pressed, a window of ECG measuring screening analyzer with corresponding ECG line will also appear. The initial point of the measuring screening analyzer will be set on a chosen ECG point.

If the button (I, II, III, aVR, aVL, aVF) will be pressed, a window of ECG measuring screening analyzer with corresponding ECG line will also appear. The initial point of the measuring screening analyzer will be set on the beginning of ECG line.

ECG fragments can be scrolled simultaneously with using scrolling in the button of the window.

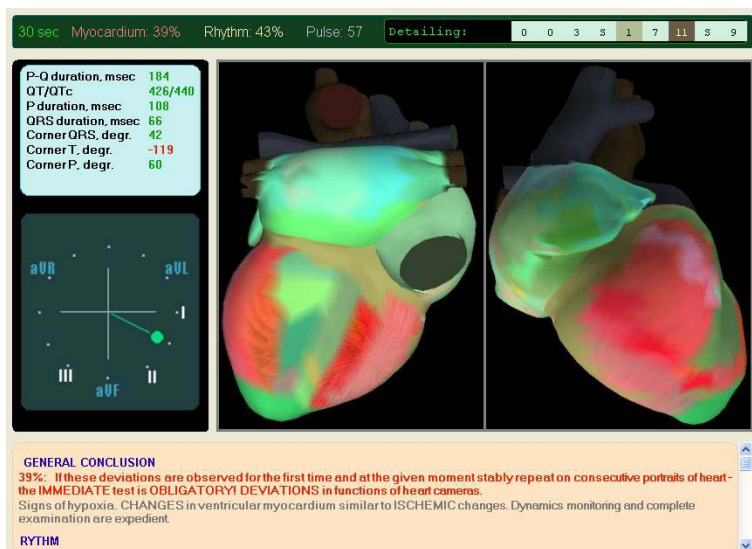
4.9 Scanning ECG: 1 lead



This window is used to perform the rhythm check-up in a convenient mode, since 30/60 sec ECG is presented in this format. If it is necessary to review some recording interval, set the mouse cursor on the required point of the ECG-line and press the right mouse key. A window of the ECG measuring screening analyzer will appear. The initial point of the measuring screening analyzer will be set on a chosen ECG point.

The buttons switching of the ECG-leads are located on the right side of this window.

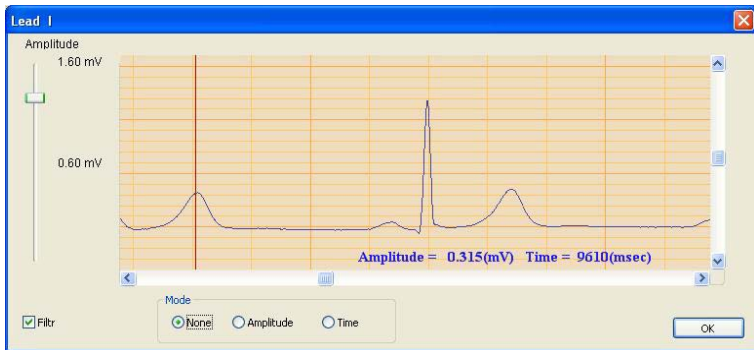
4.10 Scanning a portrait



The indicator “Detailing” informs the doctor of possible pathological deviations. Their names can be scanned with the button  – Detailing of the button panel. Besides, these names can be seen without exit from the portrait window. For this purpose place the cursor on indicator “Detailing” (the cursor in this case does not change the pictogram) and press the left key of the mouse. The tag window “Deviations classification” will appear. The code of each group corresponds to the number of the listed typical deviations.

There is located auxiliary graphical indicator on the left side from portraits where direction of electrical axis of the heart on frontal plane (QRS angle, some typical quantitative characteristics of waves and intervals of initial ECG are displayed.

4.11 ECG Feature Measurement Indicator



ECG Feature Measurement Indicator

This window has three functional modes: «measurement is switched off» (initial mode), «amplitude measurement» and «temporal measurement», assigned in Mode field by means of indicator setting in appropriate position (None, Amplitude or Time).

First, in the initial mode «measurement is switched off» the user selects the required fragment of the ECG and convenient amplitude scale by scrolling on vertical and horizontal bars and utilizing "Amplitude" tuning option. If the signal has a lot of noise interference, it is advisable to turn on the "Filter" option by left-clicking the mouse. It is important to note that amplitudes measured with the additional filtration option will appear to be 7% ... 15% less than their true value.

To measure the amplitudes, set the indicator to **Amplitude** by the left mouse click. Move the mouse cursor in the ECG field: a horizontal line of marker of the amplitude meter will appear. Set the marker in the position that you choose as a zero reference point, and press the left mouse key to fix a line of the point of origin. Then move the marker of the measuring screening analyzer till the required point on the ECG. Read the amplitude value in mille volt as related to the point of origin on the indicator "Amplitude" in the ECG field. If it is necessary to set a new zero reference point, move the marker to the desired value and press the left mouse key once again. In that way it is possible to measure the amplitude between the two selected points of ECG.

To measure the interval size set the indicator to **Time** by the left mouse click. Move the mouse cursor in the field of ECG: a vertical line of the timing meter marker will appear. Set the marker in a position that you choose as a zero reference point for time, and press the left mouse key: a fixed line of the point of origin will appear. Next, move the marker till the required point on the time scale. Read data of the interval size in millisecond as related to the zero reference point in the indicator

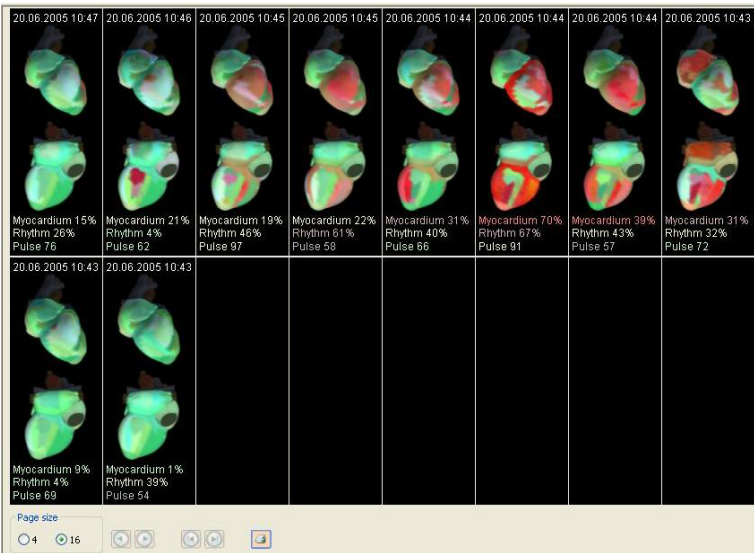
“Time” in the ECG field. If it is necessary to set a new reference point, move the marker till the required value and press the left mouse key once again. In that way it is possible to measure the time between the time selected points of ECG.

Both horizontal and vertical ECG scroll work in the measuring state.

4.12 Tendency control: portrait gallery viewing

CardioDM-06® offers unique possibilities of precise and fast control over the tendencies on the basis of viewing of the successively obtained portraits which are stored in the examination database. This allows to detect more precisely pre-clinical forms of pathological changes and to monitor more effectively mild changes in the process of electric excitation of myocardium, that are not displayed on the ECG . For that a mode of portrait viewing on small scale is intended.

Choose from list the desired patient from examination database and press the  button . A scroll box of the portraits will appear on the screen.



Selection of examinations for default view is set so that activation of view window will automatically cause portraits of *last* examination of the patient. You can find view control panel at the bottom of view window. You can choose view zoom – 4 or 16 portraits and scroll list of portraits (i.e. list of examinations). The gallery of selected portraits can be printed out through the button .

When monitoring lists with great number of examinations it becomes necessary to select portraits from any part of this list, i.e. you should select portraits for manual view. In order to make such selection you should go back to main menu

by clicking button  and use left mouse and **Ctrl** or **Shift** keyboard combination to generate necessary list. **Ctrl+Left mouse** combination allows selecting separate lines and **Shift+Left mouse** combination allows selecting of adjacent lines. After generating list click button  again. If generated list is more than size of portraits' view window, use scrolling buttons.

If you wish to enlarge separate portrait in order to view it in details just click left mouse on the same portrait. The window of enlarged portrait moves if you «drag» it by left mouse click on window headline.

4.13 Input ECG viewing

Buttons  and  are used to review the ECG. Button  is used to perform the rhythm check-up in a convenient mode, since 30/60 sec. – ECG is presented in this format.

If it is necessary to review some recording interval, set the mouse cursor on the required point of the ECG-line and press the right mouse key. A window of the ECG meter window measuring screening analyzer will appear. The initial point of the measuring screening analyzer will be set on a chosen ECG point. The default case is that-by pressing the button  an indicator lead will be displayed.

The button  is used for simultaneously view of the initial interval of all the leads. If cursor is matched with the line of any of the leads and the right mouse key will be pressed, a window of ECG measuring screening analyzer with corresponding ECG line will also appear.

4.14 Deletion of the examinations from database

To delete the examinations data it is necessary to select the required line in the examination database and press button , which can be found in the key block “Examinations”.

If you wish to delete several examinations then select lines for deletion by simultaneous left mouse click and **Shift** or **Ctrl** on keyboard.

A local bin is provided as a means of erase interlock. All the deleted examinations stored in the bin . If you wish to restore some images, enter the bin, select them and press the restore button



Be careful: by the deletion of the files from the bin the full list of files is deleted, that is why it is necessary to perform the restoration of the required files. The bin lists all deleted examinations only of the patient selected by you. It is recommended to clean the bins from time to time to prevent extra memory keeping. It is recommended to perform the cleaning of the local bin using the main menu function **Clean selected bins** and **Clean all local bins**.

4.15 Deletion of the patients from database

To delete patient from current database you should select required line in patient's database and click button  located on «Patients» block of button panel. On default this function is locked. For the purpose to delete patient from database you can turn off this locking function by pressing **Removal of the patient** from **Setting** in main menu.

Deletion of patient done will completely delete appropriate data without recycling it. In order to avoid mistaken delete, alert window for delete confirmation will pop-up. If you need to delete several patients at the same time, click left mouse and press **Shift** or **Ctrl** on keyboard simultaneously.



Pay attention: When you delete a patient, all his/her examination data deletes without restoration. There is no recycle bin for temporary storage of deleted patient's data.

Above-mentioned procedures are not convenient to repeat, if you need complete deletion separate database. To delete full list of patient enter into main menu section **Filters** and choose **Select full list of patients** option by left mouse click. **Filters** close, selecting list of «Patients» completely. Further, more click



button to delete selected list. After such operation, current database will be empty **but it remains in list of databases** and it can be used as a current database further more.

If you need to delete database from list of databases follow below steps. Select **List of databases** option in **Settings** section of main menu. A **List of databases** window will appear where current database is selected—by highlighted line. Select database for deletion by left mouse click and click **Delete** button. Warning message concerning lost of all data if deleted will appear. Upon confirmation of this message, selected local database will be deleted from database of screening analyzer. **Current database can't be deleted**. If you need to delete current database you should first switch to another database. For this purpose locate mouse pointer on appropriate line and double click left mouse or click **OK** button at the bottom of window. Such operation will switch from current database to another

one. Afterwards you should repeatedly activate «List of databases» window and delete the same database, which has no status currently. It is reasonable to delete stale databases after making preliminary achieve copy.

4.16 Printing examination summary report

The view of examination summary report can be changed. Function of summary report setting activates through main menu: **Settings⇒ Type of form**. Opened window displays *options of page numbers of summary report, preview options (to printer/file) and summary report view options (complete/shortened)*.

Complete report may contain 1, 2 or 3 pages. First page is obligatory, 2nd and 3rd pages can be deleted from report by user. To insert appropriate page in summary report you should switch on ☒ selection indicator in opened window of «Type of form». Page 1 contains ECG/portraits, texts of screening-examination conclusion and list of main numerical ECG characteristics displayed on window of «Data of indicator lead». Text of main message of screening-examination conclusion is displayed by underlined font. Additional recommendations are displayed by italic font on page 1. Date and time of examination of summary report are displayed on headline of summary report form in square brackets. . Additional text messages of «General conclusion» and «Detailing» are displayed on page 2. Doctor's recommendations typed on keyboard are displayed on page 3. In addition, there is empty space left on third page for doctor's hand written prescription and advice. All three pages of summary report contain full copy of text messages of screening analyzer classifier.

Shortened report contain single page. Unlike complete report form shortened report form have no heart portraits and they replace by standard fragment of ECG for rhythm monitoring.

Options of summary report view have two meanings: **Print** and **File**. If you choose **File** option a report directory will be called as disk file with **.emf** format. This vector format provides best display of summary report at any resolution of monitor screen or printer. User can edit name of created file. Default name of file is name of a current patient. File with such name will be saved as default in directory ***:\CDM_EMF** and **<*>** symbol refers to a disk space where **CardioDM-06®** program is installed. It is reasonable to create summary report in ***.emf** format while preparing illustration materials or sending summary report via internet.



The ***.emf** format files can be viewed and printed by any vector graphical editor such as CorelDRAW. Mostly available way of reading ***.emf** files is a widely spread word processor of Microsoft Word. To read ***.emf** files by Microsoft Word you should run Word and perform below steps:

- Call out this function from main menu **File⇒Page Setup**.
- Select **<Orientation>** bookmark in opened window and select **<Landscape>** option. If you need to print file you should also set up required margins settings. To get maximum viewable margin size of summary report you should fix “0” on all margins fields.
- Go back to main menu and call out function from **Insert⇒Picture⇒ From file**. «Add file» in opened window using standard dialog box and indicate path to ***.emf** file and click **OK**. To view opened file without distortion set up suitable zoom of view.

To print a summary report from Microsoft Word processor select function via **File⇒ Print**.



Several seconds after clicking print button  formatted report form will be sent to printer (or ***.emf** file) and **CardioDM-06®** program ready to continue work («sand glass» busy indicator disappears).

Printing time is determined only by processing speed of printer. If printer has low processing speed for printing image formats Windows system set a printing queue and slowly print out report forms performing other operations of **CardioDM-06®** at the same time.

At lower processing speed of printer, it is reasonable to print report forms at the end of working day as in this case you can set printing queue, which the computer does automatically. For this purpose: choose first examination for printing



and click print button . In ~ 3 sec. sent to print process of report form will end («sand glass» busy indicator disappears). Then, without waiting for printing process

termination you can choose next examination for printing and repeat above procedures, etc. Length of queue is limited by the computer performances.

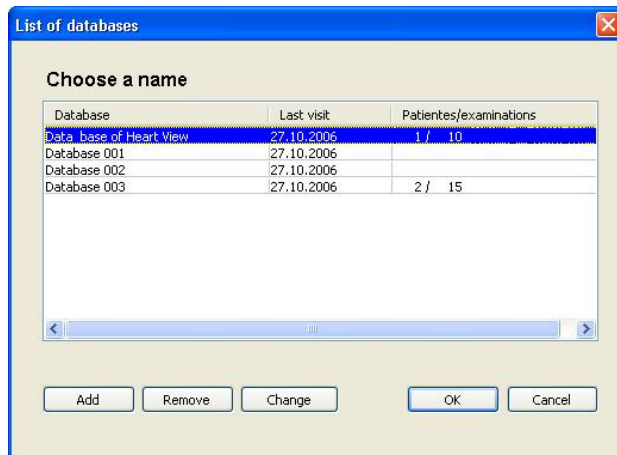


For correct operation of report form creating function, at least installation of one printer in *Windows* operating system is compulsory. Installation of printer is performed via normal system function **Start⇒Settings⇒Printers⇒Setup printer**.

4.17 List of databases

CardioDM-06® program has a **list of databases** where user can select **current database** necessary for operation. Mechanism of creation many databases makes it easy to operate this screening analyzer at a great flow of patients. It is also possible to create separate database for certain clinical departments and group of patients, etc. There can be 500 databases stored in one screening analyzer at the same time. Taking into consideration the feature of exporting data to archive this screening analyzer is the best solution for resolving any practical task. Database can be switched to current session through main menu via **Settings⇒List of databases**.

Structure of **List of database** window is similar to that of **List of doctors** window. Default database list of patients supplied together with program contains one database: **Database of Heart View**. This database contains only demonstration section *Samples*. The default database can be renamed if necessary. For selection of **current database** from the list you should activate **List of databases** window via **Settings⇒List of databases**.



Window « List of databases»

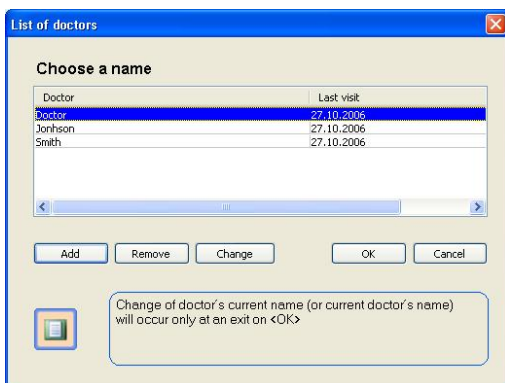
The third table column contains the information about total amount of the patients in the database (first number) and amount of examinations (second number).

You should locate mouse pointer on required line and double click left mouse or press **OK** button on the bottom of window. The name of a current database displays on main window headline and headline of examination summary report after name of doctor. If you want to create a new database click **Add** button. Enter *name of new database* in the opened input window by keyboard. **It does not recommend** entering the name longer than 30 ... 40 characters. This can also lead to incorrect text headlines. **Name of database automatically displays as a short name of clinical department (firm)** on the headline of examination summary report. **Change** and **Remove** buttons provided for editing database name and deleting database name from the list. **Remove** function used to complete deletion of local database from the list. The indicator of database arrangement is located over patient's database window.

4.18 List of doctors

After running program the main window of the program will appear on screen and window showing «List of doctors».

In order to start running program you should necessarily select name of the doctor. To select doctor's name from list who will start current session of program you should locate mouse pointer on necessary line and double click left mouse or click **OK** at the bottom of window. The current name of the doctor is displayed on headline of main window and headline of examination summary report. If the doctor's name is not included in the list you should enter new name by clicking **Add** button. **It is not recommended** to enter doctor's name longer than 20 ... 25 characters. This can cause incorrect display of doctor's name on window headline on the screen and examination summary report.



Window «List of doctors»

Change and **Remove** buttons are provided for editing and deleting doctor's name from the list. These operations are performed in a free running mode regardless your exit from «List of doctors» by clicking either **OK** or **Cancel** button. Current doctor's name can be changed via function of main menu **Settings** and **List of doctors** without exiting program. The default list of doctors provided together with program contains only one name: **Doctor**. Allowable number of doctors' names on the list is enough for practical operation of the screening analyzer: it is limited up to 500 doctor's name.

4.19 Adjustment of indicators color

User can change color of integral indicators of «Myocardium», «Pulse», «Rhythm» in the list of examinations. Standard resources of Windows-system can do it by clicking button .



4.20 Export of examinations from database

Examination export operation is necessary for three standard situations:

1. To save selected examinations on a certain directory to send it further to another doctor by any storage screening analyzers, such as floppy disks, CDs or internet.
2. To restore selected examination in another local database of the same screening analyzer.
3. To create archive copies of local database on a specified directory.

4.20.1 Export of data

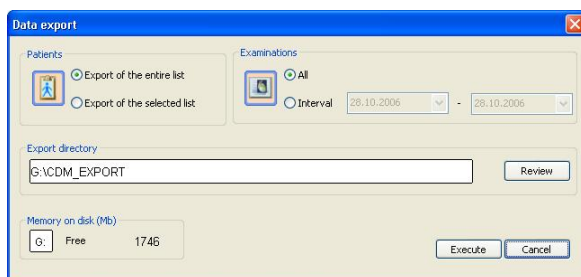
First operation, which has to be done before calling out <Export> function, is selection of exported patients. This operation done through main window in the same manner as deletion of patient's list, i.e. simultaneous left mouse click and Shift or Ctrl buttons on keyboard. Such selection operation is necessary only when exporting small lists. If you wish to export all patients' data of current database there

is no need to make preliminary selection of all list: this option clearly indicates in «Data export» window.

Export of examinations performs by function of main menu **Export/Import⇒Export**. Submenu of this function contains two options: **to directory** and **to database**.

- Export to the directory

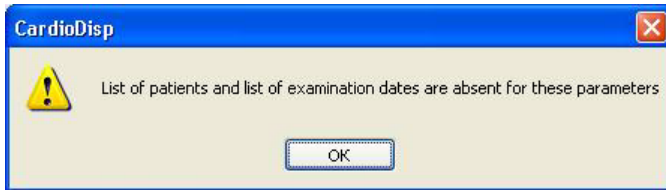
Selection of this option is necessary for normal case of export 1). For efficient classification of export procedures, **CardioDM-06®** program creates default directory *:\CDM_Export on root disk (disk where program installs). If necessary user can create another directory for export by system explorer (*Explorer*) or use any directory available on disk. After selection of **to directory**, option «Data export» window opens.



Data export performs as follows:

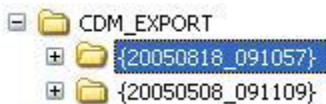
1. Choose directory for export through standard Windows function using **Review** button. It is recommended to use default directory *:\CDM_EXPORT which is displayed in **Export directory** field at the first call out of export function. Program saves last path to directory for export.
2. Set amount of exported data by either selecting **Export of the entire list** or **Export of the selected list** option. In the latter case, do not forget to select appropriate list in patients' database in advance.
3. Set time interval you would like to use for export. If you need export all examination available on examination database select **All** option. To set time interval by date select **Interval** field by left mouse click and move mouse pointer to right to initial date indicator field and set required date. Date enters via keyboard or using calendar. To call out calendar click left mouse on calendar opening icon located at right side of entry field. Calendar window will appear on monitor screen.
4. After selecting time interval, i.e. after going back to «Data export» window you have to make sure once again that correct export directory be selected and click

Execute button. If no examination is available, within indicated time-interval, a warning message



In such case another time interval or **All** option in time settings to be selected. During export operation, a «sand glass» busy indicator will appear on monitor screen. Upon completion of export process, «Data export» does not close. For next export operation, it could be used again. If all export operation are performed click **Cancel** button to exit «Data export» function.

5. Upon completion of export operation to directory a subdirectory creates as **{Date_Time}** where digital «Date» name will have YYYYMMDD format and «Time» name HHMMSS format. e.g. If data export was performed on *August 18, 2005 at 09:10:57* then there will be created subdirectory as {20050818_091057}.



If necessary this name can be changed by *Explorer*. Such change will not lead to loss of information as export date and other working parameters duplicates in database. However, standard name **{Date_Time}** is more comfortable for visual view of directory when using next export operations.

- Export to the database

Selection of this option is necessary if necessary to transfer data from one local database to another one. Export of data to another local database is performed in the same way as above described export procedure to directory. The only difference is that **Review** button selects one of the local databases available on this screening analyzer. Possible mistaken export of data to current database (i.e. incidental copy of data to the same directory) is blocked by pop-up message «*This is current DB*». Upon completion of export operation, new patients will appear in appropriate database. They can be visible after opening indicated database as current.

4.20.2 Using data export to create archive

It is reasonable to delete old examinations from working lists of local database. It relates with the fact that more examinations stored the lower performance of screening analyzer we have. Therefore, it is recommended to regularly export current databases to archive and clean working databases from old data after making back up archive copy. It is recommended to keep the databases of **CardioDM-06®** program in the following way.

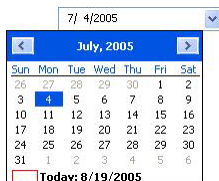
1. Create directory for saving archive on any available disk partition using *Explorer*, e.g. C:\CDM_Arc. It is possible to create several archive directories by certain calendar intervals, separate local database, etc.
2. Make the required database current using function **Settings⇒List of databases**.
3. Call out **Export/import⇒Export⇒to directory** function and export whole database to selected archive directory indicating **Export of the entire list** option in patients' list and **All** in date list.
4. After successful export delete all outdated records from current database and empty local recycle bins using function **Recycle⇒Clean all local bins**. When deleting examinations it recommends keeping only separate examinations just to monitor dynamics of disease during long period.

Upon completion of above mentioned procedures a current copy of local database will be created as a subdirectory in selected archive directory ...\\{Date_Time} which can be viewed anytime by function **Import from directory**.



If archive directories are copied on CD and later copied back on hard drive for review, in this case it is necessary before import operation to unmark **<Read only> option for all files and folders on «Attributes» field** using standard *Explorer* function (right click mouse, <Properties>). If this option is marked, import of such database will not be possible.

4.20.3 The month calendar



The month calendar control provides the user with a simple calendar interface, from which the user can select a date. The user can change the display by:

- Scrolling backward and forward, from month to month.
- Clicking the Today text to display the current day.
- Picking a month or a year from a pop-up menu.

4.21 Import of examinations to database

CardioDM-06® program allows you to import examinations from databases created by export system. Examination import operation as well as export operation performs in three standard situations:

1. To save current database of examination from other screening analyzer and further send it through storage screening analyzers (CD, internet).
2. To review archive copies of local databases located on specified directory.
3. To copy current database of examination from another local database of the same screening analyzer. This procedure is a mirror action as regards to export procedure of examinations from one local database to another one.

Import operation performs by function of main menu **Export/Import⇒Import**. Submenu of this function contains two options: *from the directory* and *from the database*.

4.21.1 Import of data

- Import from directory

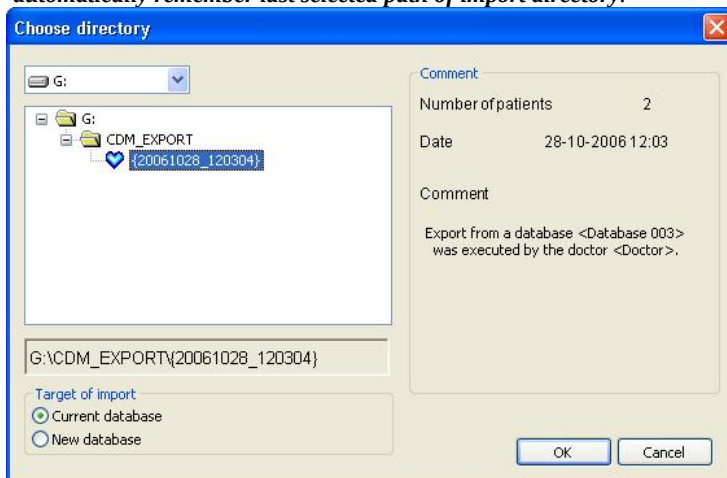
After selecting *<from directory>* option «Data import» window will appear.



Data import performs in the following manner:

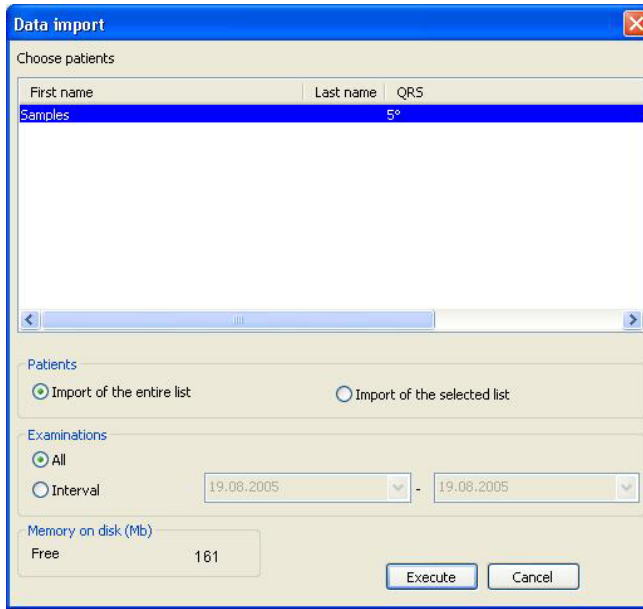
1. Click **Review** button and after appearance of «Choose directory» window specify directory-using standard Windows function wherefrom you would like to perform import. To enter any directory of Windows list double click left mouse on appropriate directory. **CardioDM-06®** program automatically analyses content of selected directory. ***If selected directory contains subdirectories in required format of databases, in this case, they are marked with blue «heart» icon.*** If «heart» icon does not appear in selected

directory, it means that there is no any import data for import in this directory. Select appropriate directory for import, which has  icon. On the right side of window” **Select directory**” and operating information will be displayed in **Comments** field showing number of patients and date of creation of this directory. After confirming selection by clicking **OK** «Select directory» window will be closed and main import window appeared. **Program automatically remember last selected path of import directory.**

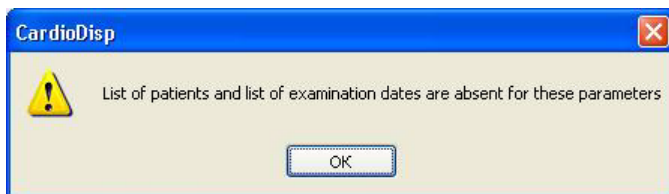


If the option "Current database" is chosen, the selected patients and examinations will be copied in the current database. If the option "New database" is selected, the new database is formed which will be automatically included in the list of databases.

2. After going back to «Data import» window click **OK** button. Window of import function settings will open. Set amount of data imports by either selecting **Import of the entire list** or **Import of the selected list** option. In the latter case, do not forget to select appropriate list on top of this window in advance using left mouse click and Shift or Ctrl on keyboard.



3. Set time interval that you would like to use for import. If you need to import all examinations available in examination database, select **All** option. To set time interval by date select **Interval** field by left mouse click.
4. After selection of time interval, i.e. after going back to «Data import» window you have to make sure once again that correct export directory selected and click **OK** button. If no examination is available within indicated time interval, a warning message window will appear



and import of «empty» patients' list stops. In such case select another time interval or **All** option in time setting. During import operation, a «sand glass» busy indicator will appear on monitor screen. ***Imported list of patients opens in a current database only after exiting <Data import> function.*** A list of imported patients marked by a special symbol in <Surname> field in window of

patients' database: "~" symbol attaches to last character of surname. It allows easily distinguishing main list from imported one.



There can be a situation where after import operation you cannot see in a current database window a patient selected in «Data import» window for importing. It is not an import operation mistake but automatic reaction of program on lack of examination form of that patient. If program found no data in examination form of that patient during data import operation analysis, in this case saving of «empty» patient's data list to current database will be blocked.

- Import from the database

Selection of this option is necessary to transfer data from one local database to another one. Import of data to another local database performs in the same way as above described import procedure from directory. The only difference is that **Review** button selects one of the local databases available on this screening analyzer. Possible mistaken data import from current database (i.e. incidental copy of data to the same database) is blocked by the pop-up message <This is current DB>. Upon completion of import operation, new patients will appear in appropriate database. There will be "~" symbol at the end of surnames of imported patients.

4.21.2 Running data import operation to view archive

To view archive copy of local **database it is reasonable to create new empty database in list of databases**, e.g. name it as "Archive". Creation of new database is performed via main menu function **Setting⇒List of databases** by clicking **Add** button. After creation new database it should be selected as current and exit «List of databases» by clicking **OK**.

Archive copy created by export function of this program has appearance of directory {Date_Time} located in archive directory, e.g. in directory C:\CDM_Arc\. To view this directory it is necessary to follow below steps:

1. If archive directory {Date_Time} was stored on, CD and later copied back to archive directory C:\CDM_Arc\, in this case, it is necessary to unmark **<Read only> option for all files and folders on «Attributes» field** using *Explorer*.
2. Choose function via **Import/Export⇒Import⇒from directory**. If archive has required format in this case name of archive directory {Date_Time} will be marked by  icon in «Select directory» window. Perform data import from ... \CDM_Arc\ {Date Time} \ directory to current database created specially for viewing archive. If archive directory is not marked by  icon, it means that archive corrupted. Further use of this archive is not possible.

Upon completion of archive operation, current database created for archive view can be deleted from list of databases.



ATTENTION!

If local databases have large capacity then import/export operations of appropriate lists may take several minutes even on fast response computers.

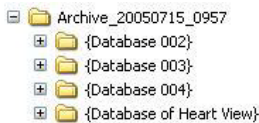
4.22 Backup databases during operation

Manufacturer guarantees uninterrupted and non-conflicting operation of **CardioDM-06®** program if serviceable computer and standard operating system are used. However there can be some cases of malfunction of **CardioDM-06®** program caused by failure of operating system (e.g. at emergency electricity shut down) or mistaken action in a root directory of program by unskillful user. ***If you face emergency related with malfunction of program while entering ECG or portrait creation,*** it recommends using **Db2crasharc.exe** utility.

To run **Db2crasharc.exe** utility you should do the following steps:

- Exit **CardioDM-06®** program if it is still running.
- Enter root directory of **CardioDM-06®** program using *Explorer*. Root directory always has an appearance as ...\\CDM, i.e. same path as given for installation (e.g. if program is installed on default directory C:\\Program Files\\ in this case root directory will be C:\\Program Files\\CDM).
- Select **Db2crasharc.exe** in root directory and run it by double left mouse click.

Db2crasharc.exe program requires directory for «emergency» save of current database. Select directory and click **OK** button. As a result «emergency» archive including subdirectory as {Name of local database} creates in selected directory. Abbreviation of «Name of local database» is exact copy of name from list of local databases. If command windows appeared corrupted at «emergency» backup this utility replace them by indexed command names. Number of subdirectories created by **Db2crasharc.exe** will be equal to number of local databases.



Furthermore deinstallation of **CardioDM-06®** program performs. Uninstallation can be done via **Start⇒Setting⇒Control panel⇒Installation and removal of program** or **Start⇒Programs⇒CDM-06⇒Uninstall**. Reinstall **CardioDM-06®**.

After reinstallation, it is necessary to recover current database. For this purpose do the following:

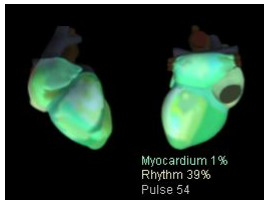
- Create new local database and make it current and import first local database from «emergency» backup directory indicated in list of import directory.
- Repeat described steps for number of recoverable local databases.

Upon completion of importing all local databases, «emergency» archive can be deleted from drive space.

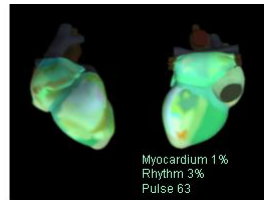
5. Annex I

5.1 Examples of heart portraitures with different pathologies

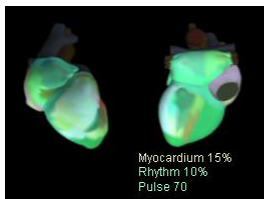
The first indicator in captions under the portraitures is a «**Myocardium**» indicator. The text corresponds to the verified clinical diagnosis (not to ECG decision).



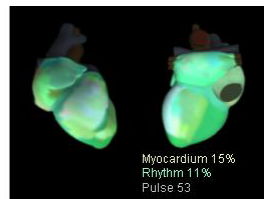
Normal



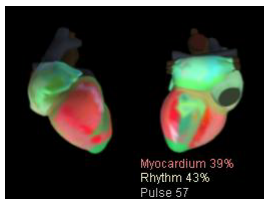
Normal



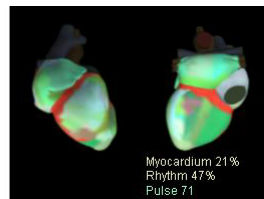
Normal



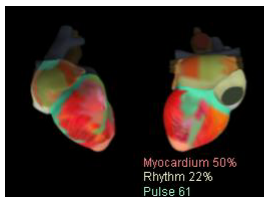
Normal



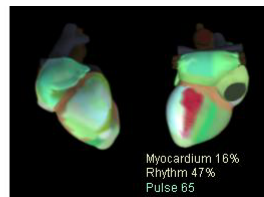
Ischemia, OMICS



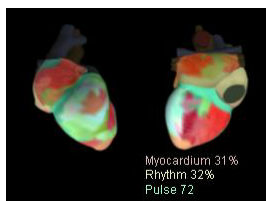
Valvular heart disease, LVH



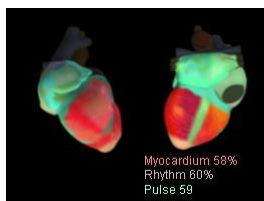
**IHD, OMICS, Atrial fibrillation, AH,
Recurrent MI**



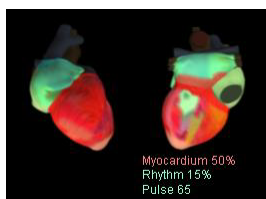
AH, Mild of LVH



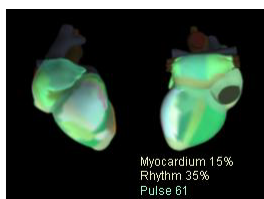
The combined heart disease, Atrial fibrillation, Metabolic disorders



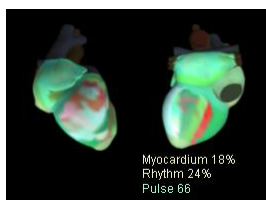
Acute MI, HK of back wall



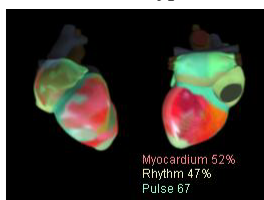
Asymmetrical HCM, LBBB



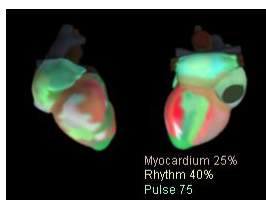
AH, Hypokaliemia



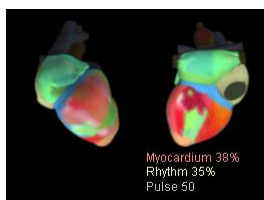
IHD, OMICS



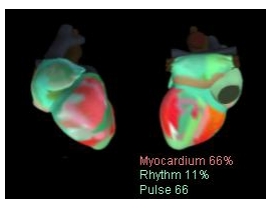
IHD, OMICS



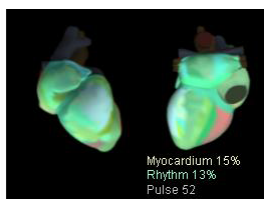
IHD, OMICS



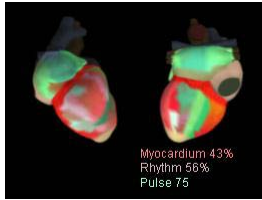
IHD, OMICS



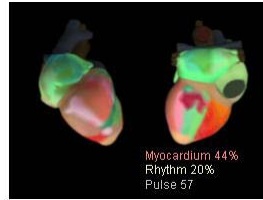
IHD, OMICS, Stenocardia, 1 year after ACG



IHD, OMICS, 7 years after MI



IHD, OMICS, Diabetes mellitus



IHD, OMICS, LVH

6. Annex II

6.1 Peculiarities of clinical interpreting of heart portrait

This screening-screening analyzer monitors repetitions of the characteristics of low-amplitude oscillations of ECG-SIGNAL unavoidably generated at each heart beat. The amplitudes of these oscillations (dispersion of oscillations) do not exceed 0.01 ... 0.03 mV, i.e. in tens of times less amplitudes than ECG waves. The term “dispersion”, which is assigned to a used method of the analysis, corresponds to the definition generally accepted in cardiology as a difference between the greatest and least values of the varying value. To observe and to measure the characteristics of such random oscillations, it is necessary to superimpose signals of one-type ECG waves, i.e. synchronize a beginning of electrical excitation of several sequential waves. The examples of such low-amplitude oscillations of QRST complex in one lead are represented on fig. 1 and fig. 2. In fig. 1 the low-amplitude of oscillation of a healthy person ECG is represented, in fig. 2 – same in case of a subacute stage of MI. Some amplitude and frequency peculiarities of oscillations changes are visible in these cases.

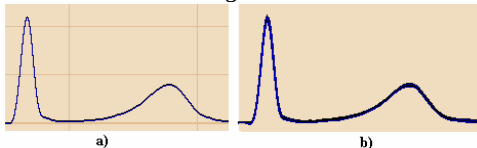


Fig. 1. Low-amplitude oscillation of ECG in sequential QRST-complexes of healthy heart.
a) separate complex; b) 7 sequential synchronized complexes

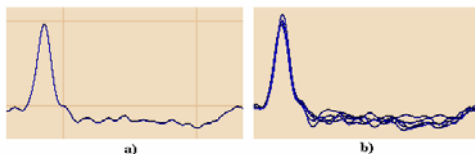


Fig. 2. Low-amplitude oscillation of ECG in sequential QRST-complexes for MI

The especially important information contained in oscillations of fronts of sequential analyzed waves is not visible on a usual ECG.

Experimentally shown these hidden "dispersive" features despite the low values of analyzed differences of amplitudes of ECG-SIGNAL with particular mathematical processing will form steady groups – dispersive clusters in new space of small fluctuations of ECG. The dispersive clusters have appeared to be effective markers of micro changes of electrical activity in the myocardium. The physical basis of creation of dispersive clusters is made by a continuous control of potential differences measured in two close points in certain areas on the body surface at depolarization – repolarization of myocardium. For augmentation of classification

stability of dispersive clusters such control is made for many pairs of closed points. Potentials of some points, which are necessary for the analysis, but which are not measured directly, are defined on the basis of special calculation. The dispersive characteristics, Due to the significant nonlinearity of depolarization – repolarization processes of myocardium, at origin of abnormalities from norm start to vary earlier than it appears on a usual ECG. For this reason the given screening analyzer can react on hidden or preclinical forms of myocardium changes. Thus, the dispersive characteristics in most cases do not duplicate the common ECG analysis but give new specific information about myocardium.

These methodical peculiarities generate appropriate features of clinical interpreting of heart portraits and text conclusions. These features are formulated in the following references, which it is necessary to be guided in practical operation with this screening analyzer.

N	The screening-conclusion	The comments and references
1. General conclusion		
1.1	The indicator "«Myocardium" – 0 ... 14%	This conclusion is arrived at when the dispersive characteristics are within normal parameters. If in other text reports, including groups G1 ... G9, there are no indications on possible hypoxia or other changes, it is feature of physiological norm. Thus the heart portrait has solid green color and the text contains the following conclusion:" No significant DISPERSIVE abnormalities from norm. This conclusion CAN be used only by comparison to history and physical data. If the patient takes medicines, this conclusion requires obligatory précising based on complete examination and dynamics control with the help of the given screening analyzer. However, the dispersive characteristics approximately in 5 ... 7% of cases can be normal at presence of a pathology in history. A main reason of such cases is the current effective medicinal therapy. If a dosage and composition of medication are optimally selected, the electrical stability of myocardium in rest can become enough high, that leads to essential decrease of dispersive abnormalities. For this reason in case of medicamental treatment the given screening analyzer can be used only for monitoring heart state dynamics and efficiency of medicinal therapy. If the indicator "Myocardium" changes in sequential tests and exceeds 14% or there is other clinical basis for an improvement of the conclusion - it is necessary to take additional recommendations of table A2 of the given manual on carrying out of examination at a minimum load. The simplest way of such additional examination is orthostatic test. For the healthy patient at this test the

N	The screening-conclusion	The comments and references
		dispersive characteristics do not vary or are worsened very insignificantly ("Myocardium" no more than 15%). Thus, the homing of heart portrait to the initial state on the average does not exceed 4 min. Opposite to this, for diseased patients the considerable augmentation of dispersive abnormalities and slow homing to the initial state exceeding 4 min. are observed. In the given category of abnormalities opposite situation also is possible, when the value of the indicator "Myocardium" does not exceed 14%, but the changes are visible on a heart portrait. If the additional test according to tab. A2 confirms norm, this situation corresponds to individual peculiarities of myocardium. More often reason of such peculiarities is the small abnormalities of an electrical symmetry of leads, which is the testimony of compensatory changes in one of ventricles (more often in left) and can be inherent or acquired. In such situation the observation of dynamics is expedient, since such changes can be a precursory manifestation of starting development of pathology. At comparison of the text conclusion and portrait always it is necessary to remember that in the given screening analyzer automatic screening conclusion and heart portrait are shaped independently to increase conclusion reliability. The heart portrait gives more precise information on presence of even inappreciable dispersive abnormalities. Simultaneously the digital indicator "Myocardium" gives more rough current estimation of a clinical significance of these abnormalities. Therefore, presence of changes on a portrait at the "Myocardium" value less than 10 ... 12% means, that the probability of pathological manifestations of these changes is insignificant.
1.2	The indicator "Myocardium" – 15 ... 22%.	The given category of abnormalities corresponds to a case of border-line states. If necessary to improve of the conclusion, take the references of tab. A2 (item 6.2) on additional test with a small load.
1.3	Indicator "Myocardium" – 23 ... 100%	Authentic dispersive abnormalities. For given category of abnormalities the complete examination for diagnosis and observation of portrait dynamics are necessary

N	The screening-conclusion	The comments and references
2. Rhythm		
2.1	The most probable reason of the enlarged indicator "Rhythm" is increased level of stress.	The given abnormalities testify to enlarged rhythm variability. If this report is steadily observed during some hours or periodically repeated within several days at value of the "Rhythm" indicator more than 60%, the examination for clearing up of stress reason is necessary.
2.2	There are manifestations of abnormalities of generation or conduction of excitation.	These deviations are always accompanied with the recommendation to analyze data of indicator lead. The data of the rhythm characteristics are shown in the left lower table of the indicator lead window. The more exceeding above acceptable limits of values RRmax/RRaverage, RRmin/RRaverage and the more indexes of relative lengthened and shortened RR, the more significant abnormalities of cardiac rhythm. These abnormalities have the changed color on the data table. The special attention is necessary on increased rigidity of rhythm, which is additionally indexed on an index « HRV Abnormalities». At enlarged rigidity the index RRmax/RRaverage is much less than a low border 1.04, and simultaneously the index RRmin/RRaverage is more than a high border 0.95. The considerable abnormalities of rhythm, especially at presence intraventricles blockades, can be accompanied with extrasystoles. The arrhythmias are always accompanied with dispersive abnormalities either in atriums, or in ventricles, or in all chambers of heart. The monitoring of dispersive abnormalities in the given screening analyzer is a main source of information about state of myocardium, and estimation of rhythm variability is auxiliary. Therefore, the observation of dynamics of dispersive heart portraits in such cases allows qualitatively to judge about probability of electrical instability of heart. Due to auxiliary character of the analysis of rhythm, the automatic classifier of extrasystoles working only on indicator lead has a hyposensitivity ~ 90%. Therefore, for the target analysis of extrasystoles

N	The screening-conclusion	The comments and references
3. Electrical axis		
3.1		In the given screening analyzer the direction of heart electrical axis is defined by QRS angle, which is calculated on a gradient of electric potential. The exceeding of value of QRS angle above limits -15 +90 degrees is always connected to presence of dispersive changes. This feature has no independent value for dispersive analysis. In the screening analyzer interface it is only intended for informing about the value of feature generally accepted in the ECG-analysis
3.2		If measured QRS angle is more to the right +130 degrees (on standard 6-axial coordinate system) or more to the left -120 degrees, in most cases it is connected to dextrocardia. In such situation the doctor has to clarify the heart position in a chest by the generally accepted ways and if dextrocardia is confirmed to repeat examination with the changed position of electrodes R, L.
4. Myocardium of atriums		
4.1	Changes of atriums depolarization.	In the given screening analyzer classification sensitivity, i.e. the sensitivity of the text reports concerning changes of atriums myocardium is diminished. It is connected to that the dispersive clusters of atriums at monitoring only limb leads have less stability than dispersive clusters of ventricles. However on heart portrait the visual sensitivity is saved on initial state. It allows a doctor precisely monitor the changes dynamics for screening tasks.
5. Myocardium of ventricles		
5.1	Manifestations of hypoxia or ischemia of myocardium	The ECG dispersions indirectly reflect current changes of the electrical characteristics of ionic canals of cardiac myocytes. These changes can have steady or temporary, transient character. For this reason, it is impossible to distinguish transient hypoxia from ischemia of myocardium at small dispersive abnormalities. In case of significant hypoxia manifestations in the dispersive characteristics ischemia has high probability and the specificity concerning ischemia of myocardium is ~ 75%. The remaining 25% cases of major abnormalities are stipulated for heart-defects, cardiomyopathies and some other pathological changes of myocardium. Such decreased specificity to ischemia is reasonable for screening analyzer, as its intention is well-timed to reveal the fact of developing pathology, but not its type. Thus at detection of significant changes, which are referred to probably ischemic by the screening-screening analyzer,

N	The screening-conclusion	The comments and references
		approximately 25% of them will be not ischemic origin. However, in all such cases the fact of presence of significant abnormalities which require verification is absolutely authentic. The clinical diagnosis can be only made with complete examination of a patient, for which the screening analyzer has revealed significant abnormalities from norm. The sensitivity to ischemia of myocardium with recommendations of the table A2 on additional testing of "border" group is ~ 80%. Approximately in 20% cases at some forms of ischemia the screening analyzer does not reveal abnormalities or reveal them not significant (indicator "Myocardium" less than 16%). This effect is characteristic for two practically important cases: at first, for back localization of ischemic changes with shift to basal departments; secondly, for intensive medicament treatment. If in these cases there are clinical basis for more detailed analysis, it is necessary to take the recommendations of the table A2 (pulse augmentation on 15 ... 25% or orthostatic test). Such additional testing with load, which is much lower submaximal, considerably raises screening analyzer sensitivity in such situations. Due to relative rarity of such events and fast examination procedure the additional testing practically has no effect for average time of examination which is not exceeding 4 min.
6. Symmetry of leads		
6.1	Asymmetry of ventricles depolarization in comparison with norm.	This specific for dispersive analysis feature gives the important additional information about abnormalities of amplitude and temporal relations in electrical excitation of the right and left ventricles. In norm the dispersive characteristics of leads, symmetric of QRS angle, are identical. Any asymmetry of these characteristics testifies to electrophysiological changes of normal excitation of myocardium. Screening sensitivity of these changes is very high, ~ 90%. At the same time clinical specificity is insignificant, i.e. it is impossible to reliably classify a genesis of the detected changes in the given screening analyzer. The common dependence is those: if the deviations are significant and simultaneously present in detailing group G9, there is high probability it is connected with diagnosed hypertrophy of one of ventricles, or preclinical stages of hypertrophy, or compensatory dilatation of one of ventricles. If dispersive deviations are small or moderate, it is a testimony of constant compensatory reaction, as a rule, of left ventricle. A reason of such reaction can be inherent peculiarities of

N	The screening-conclusion	The comments and references
		myocardium or heart valves. Besides such reaction can be observed at acute ischemia, when regulatory mechanisms try to save a reasonable level of cardiac ejection in conditions of partial injury of myocardium. If in the rest parts of "General conclusion" and the "Detailing" significant changes are not present, but they are present in group "Symmetry of leads", the dynamics monitoring is necessary. The steady character of such changes can be an indicator of initial dilatation changes, which are not yet visible with echocardiogram (EchoCG). The instability of this feature at dynamics monitoring can testify to periodic oscillations of myocardium metabolism.
7. Other changes		
7.1	Manifestations of increased stress - reaction of an organism.	The given manifestation reflects common changes of indicators of rhythm variability and P-Q, Q-T intervals. This message is auxiliary and testifies to high tension of all links of heart rhythm control. Constancy of this message can be manifestation of approaching failure of adaptation. Such situation is typical either for the significant stress, or for compensatory reactions in case of myocardium damage.

The screening-screening analyzer does not make a diagnosis, but points out the likeness of dispersive characteristics of patient ECG at the examination moment and the dispersive characteristics of standard ECG of some clinically significant pathologies. For this reason the interpreting clinical significance of certain examination results should be based on synthesis of all three output components of the screening analyzer: a portrait, "Conclusion" and "Detailing" (item 4.4). The advisable order of such synthesis for probable ischemic manifestations is represented on the table A2 of the given appendix.

At dynamics monitoring dispersive deviations is divided in three groups of stability:

- Stable:** The deviations of the indicator "Myocardium" in sequential examinations do not exceed $\sim 3 \dots 7\%$.
- Moderate deviations:** The deviations of the indicator "Myocardium" in sequential examinations are $\sim 8 \dots 10\%$.
- Significant deviations:** The deviations of the indicator "Myocardium" in sequential examinations exceed 10% .

If in the "General conclusion" or in the section "Myocardium of ventricles" suspicion on hypoxia or ischemic changes appears, it does not yet testify to ischemic illness of heart. Due to high sensitivity the screening analyzer responds to both on clinically significant forms of ischemia, and short episodes of transient ischemia or

hypoxia, which can not relate to coronary pathogenesis. In such cases it is the information that the dispersive characteristics of myocardium at the examination moment have deviated from norm to the characteristics of ischemic states. The clinical significance of such message depends on, whether it is approved by heart portrait and detailing information, and also high recurrence of such messages. The more references to hypoxia in detailing groups G3 ... G7, and the more changes on a portrait, the higher probability of clinical form of ischemia (table A2). But in any case, the screening analyzer indication of ischemic changes when other clinical manifestations of ischemia absence, testifies authentically to presence significant subliminal deviations, which should be periodically monitored with dynamics of heart portrait, and which can reveal in clinical forms at unfavorable circumstances.

6.2 Features of heart portrait

The heart portrait in the given screening analyzer is only intended for screening tasks; therefore on quasiepicard surface of 3D-model of heart the most important information about dispersive changes both for the depolarization, and repolarization of myocardium is simultaneously displayed. Such artificial association of depolarization and repolarization processes in one portrait enlarges efficiency of visual review and simplifies dynamics monitoring of dispersive changes. At review of portraits it is necessary to remember some methodical limitations described in the following comments.

Area of visual changes	The comments and references
1. Atriums	
Depolarization 	When P wave amplitude decreases or changes, colour of atriums varies from green to brown. When electrical activity increases, colour of appropriate atrium becomes blue, and at the significant hypertrophy - violet.
2. Ventricles	
Depolarization 	These areas on a portrait reflect dispersive changes in a final stage of depolarization, which are most informative when myocardium hypoxia is monitored. The greatest correlation with hypoxia has a reddening of this area in the left departments of heart.
Repolarization 	The topological resolution ability of repolarization dispersions is a little reduced at monitoring of areas close to intraventricular septum. For this reason in some cases red changes on ventricles border cover the whole right ventricle, though the functional or morphological changes occupy only small part of myocardium near projections of intraventricular septum. This topological inaccuracy of the given screening analyzer is

Area of visual changes	The comments and references
	irremovable. However it does not influence on screening sensitivity and possibility of precise dynamics monitoring.
3. Duration of processes of electrical excitation	
P-Q interval 	The redder colour this area has, the more elongation of P-Q interval. When duration of P-Q interval decreases, colour varies to blue.
Q-T interval 	This area colour characterizes average deviations from the empirical standards based on the Bazett's formula. The red colour corresponds to elongation of Q-T interval.
QRS duration 	This area colour correlates with QRS duration. Green colour corresponds to norm.

6.3 The clinical significance of ischemic manifestations in the border-line group

The given table contains the description of the four typical situations, which occur during the analysis of messages received from the auto-classifier of the screening-screening analyzer in so called border-line group conclusions. This group includes the patient's myocardium states, which either are connected with the stable pathology or with transient changes in myocardium, caused by some functional, metabolic and other reasons of the transient nature. To this group the value of the integral indicator is in the range 10... 23% as a rule. Each situation in the table is described by three lines. The first line "Deviations" includes the description of the deviations and changes, related to the obtained image and conclusion for myocardium of heart ventricles. The second line "Recommended actions" gives the recommendations how to get additional heart portraits that are helpful for making more accurate conclusion. The third line "Synthesis" includes the recommendation for the final interpretation of the clinical significance of the obtained screening conclusion. The recommendations stated in the table are advisable to be used in those cases when the anamnestic data and the physical examination data do not correspond to the obtained screening-conclusion of this medical screening analyzer, or when there are other clinical reasons to specify to make the screening-conclusion more accurate.



If, during the application of the recommendations, given in the table, the doctor obtains the conclusion about probable ischemia, it is recommended to pay attention to the textual message for the groups G3,G4 and the color of the region 15 on the heart portrait. **If there are no significant pathological changes in the groups G3,G4, or the region 15 is green-stained – IHD (ischemic heart disease) is an unlikely conclusion.** Such cases, as a rule, correspond to the pathological changes of another genesis, which cannot be detected in the conclusions presented by this medical screening analyzer. (These are mainly cardiomyopathies, myocarditis and some heart defects)

Table A2					
▪ Deviations ▪ Recommended actions ▪ Synthesis	Heart portrait changes	Value of the "Myocardium" indicator (total of the dispersive)	General conclusion: Messages about hypoxia or ischemic changes	Myocardium of ventricles: Messages about hypoxia or ischemic changes in groups	Detailing: Messages about hypoxia or ischemic changes in groups
Situation 1 → Deviations	Slight local changes towards red color	Less than 15%	Message about hypothetical (probable) initial ischemic changes	No messages	No or no more than one message with gradation "Individual peculiarities"
Situation 1 → Recommended actions	Most probable – it is the norm (the patient's state is normal). If there are clinical reasons for a more accurate conclusion decision, it is recommended to increase the patient's pulse by 15 ... 25% with the help of any load test, and take successively 2 ... 3 portraits more. The best option to raise the load and the best load magnitude is determined by the doctor for each particular case				
Synthesis for situation 1	If after the load realization in "General conclusion decision", based on successive images, a notification message "Deviation from the norm" appeared; Or the <i>Myocardium</i> indicator reading exceeds 18% and the recurrence time of the image to its initial condition exceeds 4 minutes it is recommended to conduct a full patient's examination. Otherwise – an intermittent dynamics monitoring on the basis of the images obtained is necessary for a precise conclusion decision.				
Situation 2 → Deviations	Slight or medium local changes towards the red color	From 15% till 22%	Notification message about the probable ischemic changes or frank ischemia	Notification message1 about the probable initial ischemic changes	2 notification messages about a probable ischemia with gradation "most probable" and "very probable"
Situation 2 → Recommended actions	Most probable – the changes are significant. If this condition is diagnosed for the first time – it is recommended to take 2–3 additional portraits successively. If the deviations are repeating this means that these are significant deviation . If the <i>Myocardium</i> indicator magnitude decreases and the portrait in successive examinations becomes better - it is recommended to increase the patient's pulse with any load test and take successively one after another 2 ... 3 portraits more. The best option to raise the load and the best load magnitude is determined by the doctor for each particular case.				
Synthesis for situation 2	If in "General conclusion" on successive images after the load a message "Deviation from the norm" or "Severe deviations" appears; Or the <i>Myocardium</i> indicator fluctuation exceeds 7% – pathologic changes are probable. Otherwise – the diagnosed deviation can be episode of short-term (passing) ischemia. An accurate conclusion in the latter case requires a brief review of image dynamics.				

Table A2 (continuation)					
▪ Deviations ▪ Recommended actions ▪ Synthesis	Heart portrait changes	Value of the "Myocardium" indicator (total of the dispersive deviations)	General conclusion: Messages about hypoxia or ischemic changes	Myocardium of ventricles: Messages about hypoxia or ischemic changes	Detailing: Messages about hypoxia or ischemic changes in groups G3 ... G7
Situation 3 → Deviations	Vast or local, but significant changes to the red color	From 15% to 22%	Message of potential initial ischemic changes or of obvious ischemia	Message of potential initial ischemic changes or of obvious ischemia	None or no more than one message graded "individual peculiarities" or "most probable"
Situation 3 → Recommended actions	Most likely – considerable changes, but there exists a possibility of a short term ischemic episode, as in the groups G3 ... G7, unlike in situation 2, the reaction to ischemia is hardly noticeable. If this condition is detected for the first time it's advisable to register 2 – 3 pictures one after another. If the deviations repeat persistently – these are significant deviations. If the indicator Myocardium is reducing and the picture is improving – it's advisable to increase the pulse by 15 ... 25% with any stress test and again take 2 ... 3 pictures one after another.				
Synthesis for situation 3	In case in the "General Conclusion" on consecutive pictures after stress there appears a message "Deviation from Norm" or "Significant Deviations from Norm": or the fluctuations of the indicator Myocardium have exceeded 7% – pathological changes are possible. otherwise the found deviations will be episodes of a short-term transient ischemia or have non-coronary etiology. (Such situation is frequently observed in malicious smokers).				
Situation 4 → Deviations	Vast or local, but significant changes to the red color	From 22% to 27%	Message of potential initial ischemic changes or of obvious ischemia	Message of potential initial ischemic changes or of obvious ischemia	1–2 messages of possible ischemia classified as «most likely» or «very likely»
Situation 4 → Recommended actions	Most likely – considerable deviations , confirmed by the text of detailed explanations in groups G3 ... G7.				
Synthesis for situation 4	Ischemic changes are possible – a complete examination is necessary.				

7. Annex III

7.1 Criteria of Comparison of Dispersive Deviations and Generally Accepted ECG Diagnose

The present Attachment contains the table of comparison of relevant dispersive characteristics of low amplitude ECG fluctuations used in screening – screening analyzer, and generally accepted criteria of ECG conclusions in registration of resting ECG from limbs. The given comparative table established the relation between the **additional** text conclusions of screening analyzer and generally accepted methodical recommendations for ECG analysis used by physician in practical work. Dispersive deviations in many cases reflect the processes of early stages of changes that have no direct analogues amid the criteria of ECG opinions used in practice. For that reason several “dispersive” conclusions reflecting early stages that haven’t yet reached clinical stages may correlate to one generally accepted criteria of ECG analysis describing clinical stages of pathological changes. For the same reasons the given list of generally accepted criteria of ECG conclusions is not complete: it is given solely **for the purpose of simplifying clinical interpretation of additional texts** of screening conclusions at the first stages of working with screening analyzer. And finally, the given comparisons may be neither absolutely precise not categorical as the “dispersive” conclusions of screening-screening analyzer are not diagnostic, and the given comparison always has certain borders of probability. Such “tolerance” of comparisons is inevitable as analogues of many dispersive deviations due to high sensitivity of the latter may be seen only on standard ECG from 12 leads, and some deviations – only on ECG with physical activity.

Table A3. Correlation of Dispersive Deviation with Standard Electrocardiographic Diagnoses

Screening conclusions on dispersive deviations of low-amplitude fluctuations	ECG conclusions appropriate to the dispersive deviations
1. General conclusion	
Significant deviations are NOT DETECTED. This conclusion is ALLOWED ONLY in comparison with additional clinical evidence. If patient takes MEDICINE this conclusion shall be exacted on base of the complete clinical examination.	ECG is OK
Little DEVIATIONS WITHIN THE NORM LIMITS: It's wise to observe DYNAMICS to correct the normal due to initial phase of the significant deviations. Little DEVIATIONS of ventricular excitation: it's wise to observe DYNAMICS, as these deviations are either beginning of the significant ones or sign of temporary functional instability. Mild signs of left ventricular abnormalities are possible.	ECG is OK (deviations are not appeared at the rest ECG)
Little changes of ventricular myocardium. It's wise to observe DYNAMICS Signs of left ventricular abnormalities are possible.	Intermediate ECG (between norm and pathology) is possible.
DEVIATIONS – refer to probable detailing in deviation groups. SIGNIFICANT DEVIATIONS: Pathologic deviations are possible. Refer to probable detailing in deviation groups.	ECG is pathologic
Q–T interval prolongation. SIGNIFICANT PROLONGATION of Q–T.	Q–T interval prolongation from the norm at specified heart rate. Q–T is longer than 0.44 s.
2. Rhythm	
Sinus rhythm is NORMAL.	Rhythm at heart rate of 60 to 80 per minute in cardiac pacer. P-waves are positive in leads I, II, aVF-and negative in aVR lead.
Pulse is NORMAL but rhythm is deviated from the NORMAL one.	Rhythm at heart rate of 60 to 80 per minute with some P-waves missing or little deviations of rhythm variability.

Moderate TACHYCARDIA.	Rhythm at heart rate of between 80 and 110 per minute
Significant TACHYCARDIA.	Rhythm at heart rate of higher than 110 per minute
Moderate BRADYCARDIA.	Rhythm at heart rate of lower than 60 per minute
Significant BRADYCARDIA.	Rhythm at heart rate of lower than 50 per minute
High rhythm is caused by high STRESS: Significant arrhythmia is NOT detected.	Observed ECG section has sinus rhythm but parameters of rhythm variability and the intervals are slightly beyond the norm limits.
Integral rhythm is high. Little signs of arrhythmia. HIGH STRESS is the most probable cause.	Significant deviations of sinus rhythm are not appeared but parameters of rhythm variability and the intervals are far beyond the norm limits.
Deviations from the norm rhythm variability are possible.	Parameters of rhythm variability and the intervals are not far beyond the norm limits. Abnormality due to sinoatrial or AB-junction blocks are possible.
There are signs of abnormality of excitation and conduction processes.	A type of arrhythmia. Parameters of rhythm variability and the intervals are far beyond the norm limits.
Significant ARRHYTHMIA.	Parameters of rhythm variability and the intervals are far beyond the norm limits. Significant missing of ventricular complexes. A type of tachyarrhythmia or bradyarrhythmia.
3. Electric Axis	
Electric axis deviation to the LEFT.	Electric axis position is to the left of -15° .
Electric axis position is HORIZONTAL.	Electric axis position is between $+30^{\circ}$ and -15° .
Electric axis position is NORMAL.	Electric axis position is between $+75^{\circ}$ and $+30^{\circ}$.
Electric axis position is VERTICAL.	Electric axis position is between $+90^{\circ}$ and $+75^{\circ}$.
Deviation of heart electrical axis to the RIGHT.	Electric axis position is to the right of $+90^{\circ}$.
DEXTROCARDIA is possible.	Electric axis position is to the right of $+130^{\circ}$ or to the left of -120° .
4. Atrium myocardium (plus P-Q changes)	
Atrial FIBRILLATION is possible.	Irregular low-amplitude waves instead of P-waves.
Atrial FLUTTER is possible.	Higher frequency saw-tooth P-waves.
Atrial FIBRILLATION↔FLUTTER exchange is possible.	Saw-tooth P-waves intermittent with irregular or missed P-waves.

Pacemaker MIGRATION is possible.	Variation of form and amplitude of P-waves. If P-waves are inverted in leads I and II then pacemaker migrates to AB-junction.
Abnormal atrial depolarization is possible.	Unstable form and low amplitude of P-waves.
Typical changes of atrial repolarization with possible ischemic changes of the left ventricular.	PQ-line and ST-line depression like concave parabola near R-wave. Slantwise ST-upline with possible little depression at J-point.
Signs of the left atrium enlargement. The left atrium hypertrophy is possible.	P-wave is longer than 120 ms. P-wave direction on the front plane is to the left of +60°. So maximum amplitude of P-wave is shifted to I and aVL leads.
Signs of the right atrium enlargement.	P-wave amplitude is higher than 2.5 mm (0.25 mV). P-wave direction on the front plane is to the right of +60°. So maximum amplitude of P-wave is shifted to aVF, III leads.
P-Q ENLARGEMENT. Take note to dynamics. P-Q interval is SHORTER.	PQ is longer than the norm. Norm: 200 ms at heart rate of 40 ... 50 per minute, 120 ms at heart rate of 130 ... 160. PQ is shorter than 120 ms.
5. Ventricular myocardium	
Ventricular myocardium changes like ischemic ones. It's wise to take note of DYNAMICS and examine completely.	Moderate depression or elevation of ST, lower amplitude and T-wave deformation.
ABNORMAL QRS prolongation! Signs of MYOCARDIUM injury are possible. Examination shall be complete. SIGNIFICANT ISCHEMIC changes of ventricular myocardium are possible. Examination SHALL be complete. If these signs for this patient were not observed before but are repeated in stable manner now then emergency complete examination is needed. SIGNIFICANT ISCHEMIC changes of ventricular myocardium are possible. Complete examination is NEEDED. Correlation of these signs with cicatrical changes is possible. If these signs for this patient were not observed before but are repeated in stable manner now then immediate complete examination is needed. ISCHEMIC changes of ventricular myocardium are possible. Complete	Significant elevation of ST at J-point at one or several leads. Simultaneous ST depression at other leads. Abnormal Q-waves of 40 ms long and 25% of R-wave amplitude at the same lead. Deep negative T-waves with ST depression. Simultaneous depressions of parabolic PR and ST or Significant slantwise downward ST depression.

examination is NEEDED. Correlation of these signs with myocardium FOCAL CHANGES is possible. ISCHEMIC changes of ventricular myocardium are possible. Take note of this sign repetition. Myocardium FOCAL CHANGES or temporary myocardial ischemia is possible. ISCHEMIC changes of ventricular myocardium are possible. Complete examination is NEEDED.	
IT'S WISE to observe DYNAMICS, as NORM BORDER CHANGES may be the beginning of ischemic changes of myocardium. CHANGES of ventricular depolarization: it's wise to examine completely as correlation of these changes with coronary ones is possible. There are little changes of ventricular repolarization. It's needed to observe DYNAMICS: these deviations are either BEGINNING OF THE SIGNIFICANT CHANGES or sign of temporary functional instability.	Nonspecific moderate local ST depression at some leads. Lower amplitude and T-wave deformation. In some cases significant deviations in the standard ECG are absent.
MODERATE QRS prolongation. SIGNIFICANT QRS prolongation is a sign of interventricular heart block.	QRS is from 105 to 115 ms. QRS is longer than 115 ms. Wide S-waves in I, aVL leads (block of the right bundle branch). qR complex in I, aVL leads; rS complex in II, aVF; deformed R-waves (block of the left bundle branch).

