

HealthExpress system

Innovative heart screening without complication

In the complexity of modern medicine, diagnosis and technology there is an increasing challenge to professionals to engage with patients that enable effective screening and lifestyle changes before clinical intervention.

- Microalternation analysis of ECG-6
- Heart rate variability analysis
- Standard ECG-12 available like option

healthExpress system

The hardware-software system healthExpress is intended for screening assessment of the level of psychophysiological and somatic health, body reserves, parameters of a person's physical development and the issuance of individual recommendations for correcting the state and choosing a lifestyle.

ECG amplifier

ECG amplifier is intended for recording ECG data and transmit it to a computer via a USB interface. USB cable is secured inside the amplifier housing.

ECG amplifier protects a patient of any high-voltage risks from a computer.

The ECG amplifier is shielded and protected against static discharges and cardiac defibrillator pulses.

The front panel of the ECG amplifier is equipped with a "Mode" indicator. Indicator lights glows green for 2 seconds after power is applied, lights green during ECG recording process and it turns red when any internal fault is detected.



ECG amplifier KARDi 2/4



ECG amplifier KARDi 2

The ECG leads may be connected to the patient either disposal or reusable ECG electrodes with snap terminals. When connecting cables with electrodes, make sure that all connections are secure and tightened.

The colors of ECG leads wires are in accordance with the European coding according to IEC 60601-2-25:2011.

Program modules

The software is a Patient Data Repository, from which the following software modules are launched:



healthExpress modules used for screening examination. With this type of examination, an ECG is recorded at rest in a sitting or lying position with 4 electrodes applied to the limbs. The operator can choose the duration of registration: 30 seconds, 3 or 5 minutes. The

examination report contains the parameters of non-invasive screening assessment of the state of the heart (HeartVUE method) and the level of stress in the body (Heart Rate Variability analysis method).



The ECG-12 moduisedesigned to perform routine ECG examinations. Based on the examination results, this module automatically generates a report in the form of an electronic document containing ECG graphs in a given format, artificial pacemaker marks,

heart rate values, the angle of rotation of the electric axis of the QRS vector, global intervals and durations, as well as interpretational conclusions and related data about the patient and examination.



PROGRAM MODULE HEALTHEXPRESS

healthExpress uses methods: *Method HeartVUE* for measuring ECG microalternations and *Method Heart Rate Variability analysis* for determination of heart functional state.

For carrying out of examinations, a patient is tested at rest in the sitting position. ECG is recorded at 6 standard leads (I, II, III, aVR, aVL, aVF) from arms and legs. An operator can choose the recording period: 30 seconds (HeartVUE only), 3 or 5 minutes (HeartVUE, Heart Rate Variability analysis).

The following three reports are generated automatically:

×	SIMPLE REPORT	For non-medical personnel or self-use by patients – this report displays aggregated examination data in easy to understand visual format;			
	GENERAL REPORT	For Family Physician, Paramedical and Allied personnel – this report displays basic quantitative data, graphics, and conclusions;			
	EXPERT REPORT	For Internists, Cardiologists – this report contains all quantitative and graphical data. It can be used for control the dynamics of changes the HeartVUE Myocardium Index by compare 30 second segments, full Heart Rate Variability analysis (R-R Interval).			

Method HeartVUE

Method «HeartVUE» (for measuring ECG microalternations) selects the 30 second segments periods from the ECG record. Low-amplitude oscillations of ECG signal in sequential heartbeats, the microalternations^{1,2,3,4} - are automatically analyzed. This method is principally different from that of standard ECG waveform analysis. Microalternations are sensitive indicators of cumulative physiological body system effects affecting cardiac regulatory mechanisms. The HeartVUE are

²Cruz-Gonzalez I., Dejoseph-Gauthier D., Raffel O.C., Jang I.K. Non-invasive assessment of myocardial ischaemia by using low amplitude oscillations of the conventional ECG signals (ECG dispersion mapping) during percutaneous coronary intervention, Acta Cardiologica. 2009 Feb; 64(1):11-15.

³Kellett J., Rasool S. The prediction of the in-hospital mortality of acutely ill medical patients by electrocardiogram (ECG) dispersion mapping compared with established risk factors and predictive scores — A pilot study. European Journal of Internal Medicine. 2011 Aug; 22(4):394-398.

¹Ivanov G.G., Sula A.S. Clinical ECG microalternations analysis by dispersed mapping method. Moscow: Tekhnosfera, 2014. – 104 p.

sensitive to ionic balance variations at the cellular (myocyte) level, sympathoadrenal system activation shifts and other metabolic changes. These changes are rather small and often not detected by conventional investigations like electrocardiographic and ultrasound examinations.

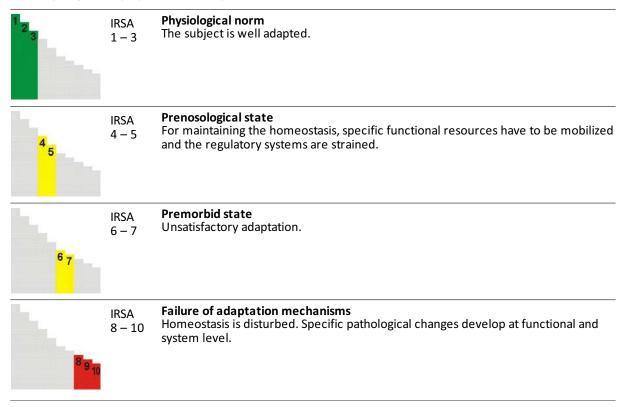
Micro alternation characteristics are represented by integral index Myocardium and by the 9 detailed indices representing for detailed variations occurred in the different areas of the heart during depolarisation and repolarisation. An average microalternans amplitude chart is used to produce a 3D Colour Model computer reconstruction of dispersion deviations on the surface of the quasi-myocardium – the Heart portrait.

Normal when the Myocardium Index value is between 0 to 14 %. When it is between 15 to 18 % it is borderline and when it is 19 % and over, the deviation is considered significant.

Method Heart Rate Variability analysis

Heart Rate Variability analysis (HRV analysis) analysis is a standard science-based prenosological tool that measures change in the time intervals between adjacent heartbeats and is directly related to the body's interdependent regulatory systems¹.

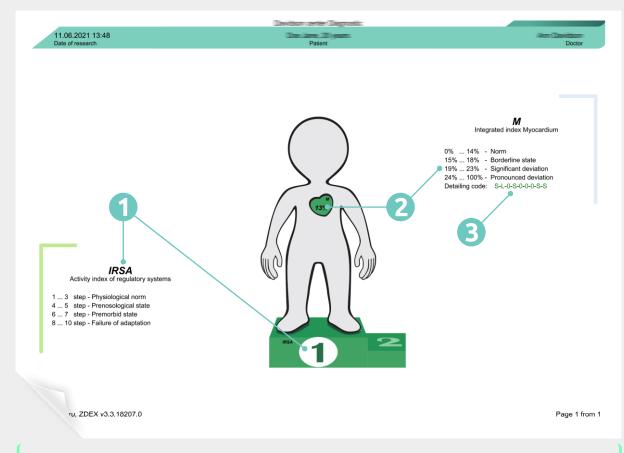
To measure HRV analysis requires a 3 or 5 minute ECG recording. The time and frequency parameters are recorded and the functional state (that indicates changes in neurohormonal activation - an important pathophysiologic factor in a number of cardiovascular disease states) is expressed as an *Index of Regulatory Systems Activity (IRSA)*²:



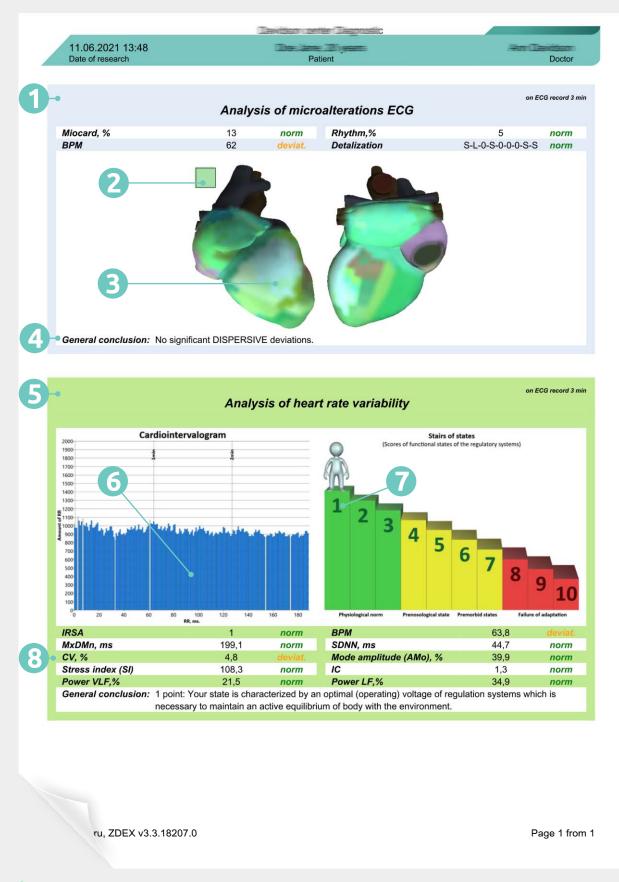
¹Heart rate variability: standards of measurement, physiological interpretation and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. European Heart Journal (1996) 17, 354–381.

²Bayevsky R.M., Berseneva A.P., Organism adaptability and incidence risk assessment. - M: Medicine, 1997; 236 p.

SIMPLE REPORT

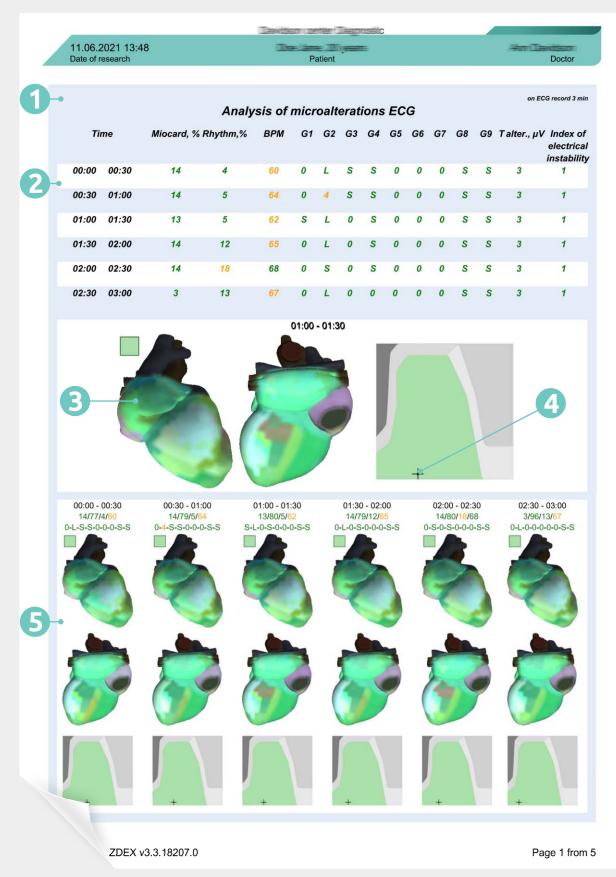


1 - The value and decoding of the values of the IRSA index, **2** - the value and decoding of the values of the Intrgral Myocardium Index, **3** - values of detailing indices.



- 1 Report for HeartVUE method, 2 Electrical myocardial instability index, 3 Heart portrait,
- 4 conclusion for HeartVUE method, 5 report for HRV analysis, 6 Cardiointervalogram,
- 7 Stairs of states, 8 values and conclusion for HRV analysis method.

EXPERT REPORT



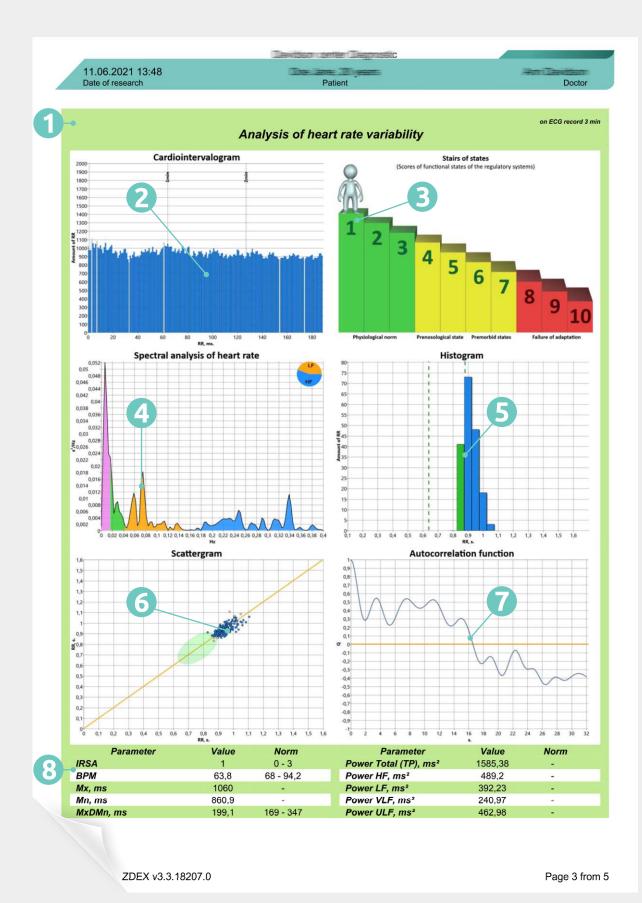
1 - Report for HeartVUE method, **2** - values of microalternations characteristics by time intervals, **3** - Heart portrait, **4** - Electrical myocardial instability index, **5** - heart portrait gallery.

11.06.2021 13:48 Date of research Patient Doctor GENERAL CONCLUSION No significant DISPERSIVE deviations. RHYTHM NORM - sinoatrial rate. Rhythm variability is normal. ELECTRICAL AXIS NORMAL position of heart electrical axis. ATRIUMS NO significant changes of ventricles myocardium. VENTRICLES NO significant changes of ventricles myocardium. COMPENSATORY REACTION OF MYOCARDIUM Electrical symmetry of ventricle is normal. G1 DEPOLARIZATION OF RIGHT ATRIUM Norm border. Small changes near the norm border. G2 DEPOLARIZATION OF LEFT ATRIUM Norm border. You should observe the tendencies. G3 DEPOLARIZATION OF RIGHT VENTRICLE NO significant deviations in this group. G4 DEPOLARIZATION OF LEFT VENTRICLE Norm border. Small changes near the norm border. G5 REPOLARIZATION OF RIGHT VENTRICLE NO significant deviations in this group. G6 REPOLARIZATION OF LEFT VENTRICLE NO significant deviations in this group. G7 ELECTRICAL SYMMETRY OF VENTRICLES NO significant deviations in this group. G8 INTRAVENTRICULAR BLOCKING Norm border. Small changes near the norm border. G9 COMPENSATORY REACTION OF VENTRICULAR MYOCARDIUM Norm border. Small changes near the norm border.

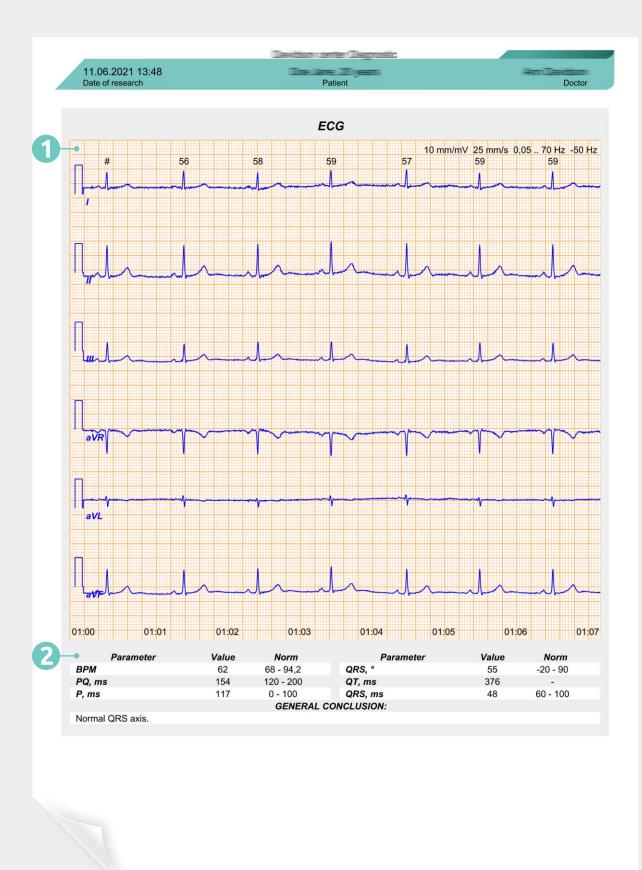
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1 - conclusion for HeartVUE method.



1 - Report for HRV analysis method, 2 - Cardiointervalogram, 3 - Stairs of states, 4 - conclusion for Spectral analysis of heart rate method, 5 - report for Histogram, 6 - Scatterogram,
7 - Autocorrelation function, 8 - values and conclusion for HRV analysis method.



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1 - ECG at the most relevant 10-second interval, **2** - results of automatic analysis of ECG and textual conclusion.

HeartVUE interpretation

QUICK REFERENCE GUIDE (INITIAL EXAMINATION)

The recommended solution is at the intersection of rows and columns the table below. If the selection of decision is ambiguous, version with the highest number of icons ♥ is taken as the final.

Repeat examination Refer to Cardio	logist Cardiologist Opinion URGENT Cardiologist Mandatory Opinion			
Detailed indices	Main Myocardium Index			
G1 – G9	0% – 14% NORMAL	15% — 18% borderline state	19% – 23% significant deviation	24% – 100% strong deviation
G1 or G2 above NORMAL and index of electrical instability is green color	NORMAL	Repeat Examination	Refer to Cardiologist ♥♥	Cardiologist Opinion Mandatory
G1 or G2 above NORMAL and index of electrical instability is ellow or e red	Repeat Examination	Refer to Cardiologist ♥♥	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion
At least one of the indices - G3, G4 or G7 is above NORMAL	NORMAL	Refer to Cardiologist ♥♥	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion
G3 or G4 and at the same time G7 are above NORMAL	Repeat Examination	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion	URGENT Cardiologist Opinion
G5 or G6 is above NORMAL and, at the same time G3 and G4 and G7 are NORMAL	Repeat Examination	Repeat Examination	Refer to Cardiologist ♥♥	Cardiologist Opinion Mandatory
G5 or G6 is above NORMAL and at least one of ndices G3, G4, G7, G8, G9 is above NORMAL	Repeat Examination	Repeat Examination	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion
G9 is above NORMAL and in successive tests G9>4	Repeat Examination	Refer to Cardiologist ♥♥♥♥	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion
G9 is more than 9 and Patient's age is less than 18 years	Repeat Examination	Repeat Examination	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion ♥ ♥ ♥ ♥
G9 is more than 9 and Patient's age is less than 18 years	Repeat Examination	Cardiologist Opinion Mandatory	URGENT Cardiologist Opinion	URGENT Cardiologist Opinion

DETAILING INDICES – RANGE AND CATEGORISATION

Detailed indices	NORMAL	BORDERLINE STATE	STRONG DEVIATION			
G1. Right atrium depolarization	0, S, L, 15	611	1217			
G2. Left atrium depolarization	0, S, L, 13	46	710			
Deviation of G1 or G2 from NORMAL suggestive of atrial pathology of any aetiology.						
G3. Right atrium depolarization (~60 – 90 ms QRS)	0, S, L	16	716			
G4. Left atrium depolarization (~60 – 90 ms QRS)	0, S, L	16	722			
Deviation of G3 or G4 from NORMAL is observed when ischemic changes in myocardium is present, as a result of myocarditis, cardiomyopathy, congenital abnormalities and other diseases leading to the morphological and electrical heterogeneity of the myocardium.						
G5. Right atrium repolarization (interval ST-T)	0, S, L	1	2,3			
G6. Left atrium repolarization (interval ST-T)	0, S, L	16	714			
Deviation of G5 or G6 from the NORMAL is caused by metabolic changes that follow electrolyte imbalance, myocardial toxicity, hypoxia, hormonal changes and some forms of cardiomyopathy . When the G5 , G6 increases simultaneously with increased values of G3 , G4 and G7 - indicative of abnormal ventricular repolarisation.						
G7. Atrium electrical symmetry (~30 – 70 ms QRS)	0, S, L	13	421			
Deviation of G7 from the NORMAL seen in Myocardial ischaemia (exclude other causes of hypoxia and congenital abnormalities). Small deviations in G7 values are NORMAL in children.						
G8. Intraventricular heart blocks, depolarization symmetry index (0 – 90 ms QRS)	0, S, L	-	1, 2			
 G9. Atrium myocardium compensatory reaction (~0 – 40 ms QRS) 	0, S, L, 13	46	721			
Stable high values of G9>9 in adult patients suggestive of ventricular hypertrophy. Significant changes of G9 values in successive examinations is a sign of severe compensatory response of ventricular myocardium. Deviation of G9 from NORMAL is also seen in certain cardiomyopathies, compensatory sympathetic or neurohumoral influences. Athletes (during intense training) often have deviations of G9 from NORMAL. In children and adolescents isolated increase of G9 (that is without G3, G4 and G7 changes) can reflect natural adaptation of myocardium to age-related physiological features.						

* S - small deviation (closer to 0), L - limit of normal (closer to 1).

What to look out for during repeat examinations?

- Estimate color-specific dynamics of portraits.
 Select examination sessions exhibiting any abrupt changes of colors to be applied at subsequent analysis of dispersion index qualitative values.
- Estimate variation dynamics against detailed indices G1 G9.
 If deviation of index G3 or G4 or G7 increases in the study selected, it indicates to a pathology symptom.

If significant changes of **G9** (more than 4 units) are simultaneously identified at sequential examination sessions, clinical examination is necessary.

If no change of indices **G3**, **G4** and **G7** are seen, but there are periodic changes in the other indices, extra-cardiac causes should be considered.

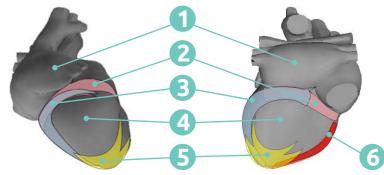
3. If there are some deviations in indices **G5** or **G6**, or **G9** only and an increase is seen in Myocardium, it is desirable to seek a cardiologist's advice to exclude any cardiac pathology. When no deviations are identified in indices **G3**, **G4**, and **G7**, you may repeat the examinations as required.

Heart portrait

Microalternation characteristics in HeartVUE method are summarized as the Myocardium index and also by the 9 detailed indices representing the different areas of the heart during depolarization and repolarization. An average microalternans amplitude chart is used to produce a 3D Colour Model computer reconstruction of dispersion deviations on the surface of the quasi-myocardium – the *Heart portrait*.

Standard color codes – green, yellow, red – correspond to norm, borderline state, and pathology, respectively.

A Heart portrait taken from every person under examination has individual features which persist for a period of time. Cardiac state tendency is controlled by *portrait gallery*.

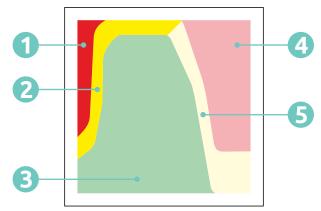


1 - Atrium microalternation;
2 - PQ interval microalternation;
3 - QT interval microalternation;
4 - Ventricularl microalternation;
5 - QRS interval microalternation;
6 - region of ventricular septum projected to a posterior wall

Pay attention to the red region of the ventricular septum projected to a posterior wall. Even if all other sections of the above portrait were colored green, a red region here is highly suggestive of myocardial ischemia (or transient hypoxia) and cardiologist opinion is essential.

Electrical myocardial instability index

Electrical myocardial instability index is a measure of the propensity for rhythm problems to occur. It is demonstrated in the diagram as a marker colored zone.



1 - Ventricular arrhythmia is possible; 2 - borderline state, trend for possible ventricular arrhythmia; 3 - norm; 4 - supraventricular arrhythmia is possible; 5 - borderline state, trend for possible supraventricular arrhythmia.

Additionally, an Electrical myocardial instability index is represented in the heart portrait in the form of a highly visual square at the top left corner. In normal state this index is green. If this index is constantly red, it gives rather unfavorable prognosis indicative of a high probability of malignant arrhythmia.

How examination results can be interpreted in children aged 6-17 years old?

Microalternans Dispersion mapping in children is somewhat different and is reflective of the metabolic variations of a developing myocardium.

These background variations may increase a Myocardium Index up to 15 - 17% in normal individuals. In additional, there are borderline variations that occur in the atrium and ventricles that are less suggestive oa any pathologic charges. Myocardial Variability in the range 18 - 20% requires close monitoring since increase oa dispersion characteristics ay be caused be either the transient metabolic processes or early pathology.

As applied to children, these processes primarily reflect natural physiological background processes. This is particularly so in:

- values of G1 and G2 indices within the range of 7 10, especially in the 6 12 age group and interpretation about borderline changes in atriums;
- value of G9 index within the range of 5 8 with a maximal Myocardium of 17%;
- G5, G6 indices have exceeded variability for the exception of some cardiomyopathy variants and, therefore, if these index values are exceeded, it is necessary to consult a physician. When G3, G4, G7, and G9 indices go up simultaneously, they are clinically significant.

Similarly like with the adults, prominent change of dispersion characteristics is caused by an increased value of any of **G3**, **G4**, **G7** indices either individually or in combination with other indices.

Heart portraits recorded in the children population are featured by much greater sensitivity than those recorded in the adult population. Quite frequently, when low or borderline values of the principal Myocardium are specified within the range of 12 - 15%, some local yellow or orange variations may be demonstrated on heart portraits. These changes have individual nature and reflect exceeded microalternation variability in children.

An Electrical myocardial instability index recorded in heart portraits of the children population is often in yellow. The reason is that children have increased rhythm variability. The yellow index demonstrated by a 15-year age group is principally evoked by functional rather than pathological states. If a red index is repeated at frequent intervals, this is the matter of concern both for children and adults.

Reports of borderline deviations, shortened P-Q, or extended Q-T intervals are frequently seen under the heading "GENERAL CONCLUSION" in children. They indicate to individual myocardial characteristics or particular variations. Frequent observation is recommended in this cases.



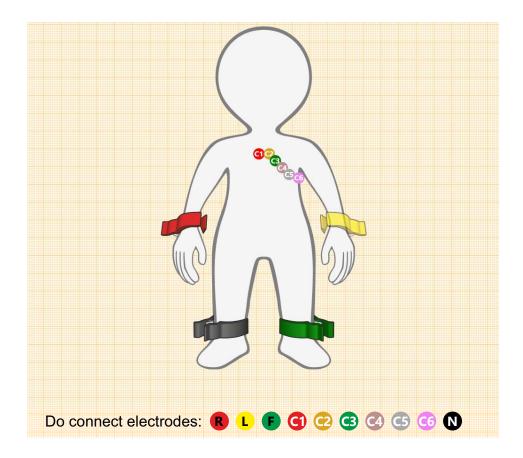
PROGRAM MODULE ECG-12

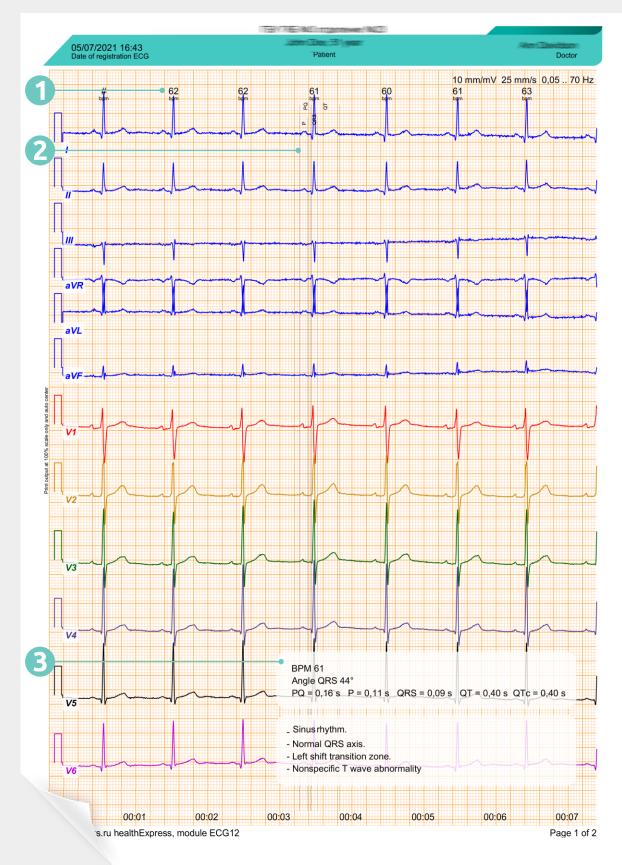
Surface ECG is a display of the total vector of the electrical activity of the heart on the patient's skin, which is recorded by the ECG amplifier as a difference in electrical potential between the electrodes. These potential differences are called ECG leads. The 12 standard lead pattern is widely used. Six of them are conventionally vertical, obtained from frontally located electrodes on the limbs (leads I, II, III, aVR, aVL, aVF) and six conventionally horizontal, obtained from electrodes located on the chest in the precordial region (leads V_1 , V_2 , V_3 , V_4 , V_5 , μ V_6).



Please note that only 2 of the 6 vertical leads are independent. The remaining 4 leads are a mathematical linear combination of independent leads.

12-lead ECG is a decisive diagnostic method for establishing a large number of cardiac diagnoses, especially arrhythmias, myocardial ischemia. The ECG can also diagnose atrial enlargement, ventricular hypertrophy, and conditions that can lead to fainting or sudden death, such as Wolff – Parkinson – White (WPW) syndrome, prolonged QT syndrome, Brugada syndrome.





1 - instantaneous heart rate, **2** - markers of automatically determined boundaries of intervals on the ECG, **3** - automatically determined parameters and results of ECG analysis.

Bridging the clinical gap

Traditional ECG investigation produces a gap between the patient and clinician. Using healthExpress means barriers are reduced – Patients can relate to a simple understand visualization – Allows deeper conversation about their specific health issues. Four Limb leads reduce barrier – saves time with less undressing and addresses cultural issues.

Wide range of applications – Screening tool, patient health monitoring and life style influence, high performance sport and cardiology support.

CE 574163 from BSI Group

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