

Personal Device for Cardiovascular System Diagnostics

AngioScan-01P

User Manual

Thank you for choosing our product!

We hope that AngioScan-01P device will become a reliable guide to the world of healthy living and longevity for you and your family!

This manual will let you start using the device quickly and assess its readings properly. You can find more information in the product documentation contained on the CD-ROM supplied together with the device as well as on our website: www.angioscan.ru.

INDEX

INDEX	2
What is important to know before using the device	3
Brief instruction manual for AngioScan-01P	13
Minimum knowledge needed to use the device	14
How to turn on/off the device	15
How to navigate through the menu of the device	16
How to set date and time	17
How to enter personal data of the user	17
How to carry out the test and view the results	21
Preparation for the test	21
Behaviour during the test	22
Performing the test	23
View test results	25
How to view the results of previous tests	26
How to assess the results of your tests	31
Pulse rate	32
Vascular Age	33
Type of Pulse Wave	34
Vascular Stiffness	36
Stress Index	37
Saturation	38
Index trends	39

What is important to know before using the device Device operational guidelines

Traditionally, assessment of the cardiovascular system is conducted in medical diagnostic institutions, and the research is performed by a well-trained specialist in medical diagnostics. The devices, which are now widely used for diagnosis at home, include all familiar thermometers and blood pressure monitors - devices for blood pressure measuring. We are confident that our device for assessment of the cardiovascular system (CVS) will be the third device used for self-diagnosis in your family.

Possibility to assess the state the CVS at home has become a reality due to the availability of new medical knowledge on the functioning of the arteries, as well as the development of medical technology. At the same time, we comply with first medical commandment - "do no harm".

The optical sensor used in our device cannot cause any damage to the skin or the finger tissues during the test. The form we choose - a clip secured to the tip of a finger – proved its application in medical practice. Such a structure is used in pulse oximeters that measure heart rate and hemoglobin oxygen saturation.

This diagnostics of CVS is based on recording the pulse wave volume that is created with each contraction of the heart. The device accumulates a predetermined amount of pulse waves during the test, and then analyzes them and, on the basis of this analysis, the test results are shown.

In order to obtain the true results of the test it is necessary to follow simple but necessary requirements for the measurement conditions. In medical practice, it is called "implementation of the study protocol". Measurement conditions are described in details in the instructions for use of the device.

But even in the recommendations we have to point them out. The first point is the correct posture during measurement. It is best to perform measurement in the supine position, with the arm located along the body and the hand with the device located at the heart level. Measurement also can be performed in a sitting position; the hand with the device should be at the heart level as well. In this case, it is necessary to comply with the following requirements: the arm should be on the table, and you should put soft material (rolled towel) under your hand, your back should lean on the chair back, your legs should not be crossed and tucked up beneath one. Similar requirements for the posture apply to the procedure of blood pressure measurement as well.

During testing the device should be placed on the terminal phalanx of the index finger of your right hand. This is determined by operating convenience. If the patient is left-handed, the device can be placed on the left hand. You should start measurement in a minute after installation the device on a finger. During this time, small vessels of your finger adapt to the pressure created by the clip on your finger tip. Before attaching the device to the finger it is necessary to rest in silence for not less than 5 minutes. These simple requirements are related to the fact that the measured parameters are influenced by your blood pressure value, heart rate and emotional state. So it is better to choose a constant time of day for measurements: optimally evening time, one hour after evening meal.

Measurement can be carried out and in the morning - for example, before breakfast. If you use the device continuously it is best to choose a constant time of day, because it allows you to see the dynamics during a week, month and year.

How to avoid mistakes while testing

The cardiovascular system is a complex system, whose main objective is to provide organs and tissues optimally with necessary amount of blood. This is a very dynamic system that is affected by many different factors. These factors change over time, and so the test results change as well. That is why to get a real picture of the cardiovascular system state, it is important to observe the dynamics for a long time. The test results carried out over a small interval of time are seriously influenced by changes in blood pressure. Therefore, if you notice a significant changes registered by "AngioScan" device, you should measure your arterial blood pressure.

The reason for these deviations can also be:

- stress, unusual psychological condition;
- smoking;
- taking caffeinated products, energy drinks;
- medicines, drugs, food additives;
- strong physical fatigue;
- incorrect body position when testing;
- tight clothes (corsets);
- recent illnesses (infectious, influenza, common cold);
- time of day (biorhythms).

Assessment of parameters determined with "AngioScan" device

1. <u>Pulse rate (beats per minute)</u> is parameter of the average number of heart contractions per minute. This parameter can easily be determined without the device as well, counting the number of pulses on the wrist per minute. This is basic but very important parameter. Optimal pulse rate is in the range of 60-70 beats/minute while the athletes and people who are constantly carrying out physical activities have the pulse rate in the range of 50-60 beats. High pulse rate (80-90 beats/min) while resting may indicate that you have a sedentary lifestyle, and you need to perform some physical activities. The heart has a life resource for a certain number of heartbeats. A person, who have high pulse rate in rest, spends this resource much earlier. Physicians consider a high

pulse rate (tachycardia) in rest condition as a serious risk factor of cardiovascular disease. "AngioScan" device assessing pulse rate determines the length of each heartbeat, so we can talk about the average pulse rate. In a healthy person, duration of single heart contractions is not constant, it changes, varies. This is determined by influence of breathing: at inspiration pulse rate increases, at exhalation it decreases. The pulse rate is influenced by changes in blood pressure that occur very often, almost every minute. At this time, when the pressure increases the pulse rate decreases, and if the pressure decreases, the pulse rate increases. The device registers this pulse rate variability and uses it to calculate the "stress index". If the patient's pulse rate changes, it indicates that the dynamic regulation of the CVS is at the proper level. In case of a constant, unchanging duration of heart beats we can speak about violations in regulatory ability of the CVS.

2. Age of cardiovascular system. Famous English physician Thomas Sydenham even two hundred years ago stated the following: "A man has the same age, as his blood vessels have". Recently, age assessment of the circulatory system has attracted a considerable attention. In "AngioScan" device an acknowledged medical method is used based on measuring of elasticity of small arteries and arterioles. Optical sensor of the device registers the dynamics of lumen changes of small arteries while the pressure pulse wave passes. It can be represented as follows: during a heart contraction the blood enters these vessels under pressure, stretches them and if blood vessels are elastic, they increase their lumen. In humans this stretching ability decreases with age. An

extensive medical research was carried out in which this stretching ability was assessed depending on age of healthy testees. When evaluating the parameter "Age of the vascular system", data of this dependence are used. Optimal situation is when your vascular age is less than your chronological age, situation is quite normal when they coincide. The situation is worse if the vascular age significantly exceeds the passport. Often one can observe the following situation: a young man is chronologically 20 years old, and the device defines the vascular age of 40 years. A different situation is possible: a person is 70 years old, and his vascular age is 50 years. It should also be noted that this value may vary depending on the arterial pressure value, muscle tone of the arterial walls. If the test is carried out according to the protocol, you can get an image of the state of small resistance vessels, which determine microcirculation.

3. <u>Vessel stiffness.</u> Unlike vascular age parameter that assesses the small vessels (microcirculation system), "Vessel stiffness" parameter characterizes the state of major arteries (aorta and its main branches). This parameter is extremely important, since the body's ability to smooth out the pressure pulsations in small vessels depends on the state of these major arteries. Major arteries and aorta are able to store the flow energy, generated by the heart during contraction, and release it during its relaxation. It is important to maintain the flow of blood at a constant level, but also to smooth out pulsations in the capillary bed. If major arteries lose their elasticity and become stiff, the pulse pressure increases, and it is extremely bad for the brain and renal blood flows. Cardiologists and therapists pay great attention to assessment of stiffness of

the aorta and its main branches (iliac, carotid arteries). High stiffness of the aorta and major arteries leads to development of systolic hypertension. In the basis of "Vessel stiffness" parameter lies registration of late systolic wave, time of appearance of which is determined by stiffness of arteries of elastic type (aorta and its main branches). The value of this parameter depends on the age of the patient: in the age group from 18 up to 35 years, this value is negative: from -40% up to -3%; and the greater this negative value is, the more elastic the aorta and large arteries are. In the age group over 40 years, the value ranges from -5% up to 5%. Significant positive values of 25 up to 40% are registered in individuals with stiff arteries. For semi-quantitative characteristics of this parameter "Pulse wave type" parameter is used. C type of curve shows the accumulated elasticity of major arteries, while A type of curve is observed in case of high stiffness of the aorta.

4. <u>Stress index</u>. In section "Pulse rate", we discussed the importance of pulse rate variability for the proper functioning of the CVS. To give a quantitative characteristic of this parameter the following scale is used: the value of 20 - 100 indicates a good condition of the CVS regulatory mechanisms; value of 100 - 400 indicates a satisfactory condition; value of 500 to 1000 indicates a poor state. Higher values of this index show major violations. It should be noted that while age increases, the value of this index tends to rise. Significant influence on the value of the stress index has a high pulse rate at rest; in tachycardia of more than 90 beats/min the stress index value is higher than 1000. Higher values of the stress index are identified in patients under

emotional stress. The stress index is quite sensitive parameter, so to obtain real results it is necessary to follow the rules of the measurement protocol.

If the parameters of blood vessel stiffness, vascular age and type of pulse wave on the color chart are constantly in the yellow or red zone, it means that it would be wise to consult a physician and to start a healthy lifestyle. You should measure your blood pressure daily, check your cholesterol and blood glucose levels, as well as determine whether your weight is in the normal range.

If the stress index value is much higher than normal values, it is necessary, following all the rules of the measurement protocol, to perform testing during few days. If the stress index value remains high, it is necessary to consult a cardiologist to identify the reasons of low pulse rate variability.

We recommend you to start following a healthy lifestyle actively!

- Quit smoking! Nicotine causes heart palpitations and high blood pressure. Human quickly become addicted to the smoking process, and after a prolonged intensive use of tobacco products occurs a premature "aging" of the cardiovascular system, reduction of the level of high density lipoprotein, of "good cholesterol", that leads to a risk of plaques formation in arterial walls, blood supply disturbance in peripheral organs, reduction of oxygen content and uptake in the blood.
- Drink alcohol moderately. Drinking of more than 50 ml of 40% alcohol every day can lead to high blood pressure, heart palpitations and arrhythmias.
- If you snore or suspect that you have brief stops in breathing (apnea), consult a doctor. To avoid early development of cardiovascular diseases and other health complications, treatment of apnea is necessary. Signs and symptoms of apnea include excessive sleepiness or fatigue during the day (hypersomnia); dry mouth or sore throat upon awakening; headaches in the morning; deterioration of mental abilities, such as inability to concentrate, forgetfulness or irritability; loud snoring; sleep apnea; excessive sweating during sleep; abrupt awakening with a feeling of choking or shortness of breath; inability to sleep. During apnea hypoxia occurs (lack of oxygen in tissues) that leads to development of arterial hypertension.

- Visit your dentist and make oral cavity hygiene.
- Eat food low in saturated fat. Since the human body requires a very small amount of fat, prefer "healthy" unsaturated fats that you can find in nuts, avocados, olives.
- It is necessary to increase the consumption of food high in fiber, such as vegetables and fruits that will promote good digestion and reduce cholesterol levels in the blood.
- Particular attention should be given to food containing polyunsaturated fatty acids omega-3 and omega-6, which are contained in the following products: walnuts, corn, rapeseed, linseed, mustard and saffron oil, cauliflower, celery cabbage and broccoli, in fatty and medium fatty fish, in such species as salmon, herring, mackerel, tuna, sardines and krill.
- Many of us lead a sedentary lifestyle and walk rarely in fresh air. Regular moderate exercises, walking and swimming will have a positive effect on your cardiovascular system.

If you follow our advice and perform some exercises on a regular basis, follow a diet, then you can track improving dynamics of age index of your vascular system, stress index and vessel stiffness on "AngioScan" device.

Brief instruction manual for AngioScan-01P

AngioScan-01P is designed for long-term stand-alone use.

The device can perform measurements and store the results in internal memory. These results are available for viewing on the screen of the device. Built-in memory ensures storage for data for at least a thousand tests.

In addition to the stand-alone mode, the device can be connected to a PC via a 115V cable (included in the kit). You should install AngioScan Personal software (CD with software is included in the kit) on your PC before the first use. AngioScan Personal program allows you copying data of tests on your PC, viewing and printing the text of conclusion with interpretation of the test results, viewing graphs of test results dynamics within the testing period, removing unnecessary test records from the memory and performing other useful functions.

Minimum knowledge needed to use the device

- How to turn on/off the device.
- 2. How to navigate through the menu of the device.
- How to enter personal data.
- 4. How to carry out the test and view the results.
- 5. How to view the results of previous tests.
- 6. How to assess the results of your tests.

How to turn on and off the device

Switch AngioScan-01P on by shortly pushing the button once and holding it for three seconds.

To turn the device off use the menu or wait for automatic switch off. The device will automatically turn off after 2 minutes if you do not push the button or in case the test is not being conducted.

- To turn the device on hold control button until it activates (not less than 3 seconds).
- Startup logo will appear on display and voice greeting will be played.
- Once the startup logo disappears the Start Menu will show up.
- Pay attention to the battery symbol: if it looks like this , it means that the battery is low and you should charge it connecting the device to a charger or computer.



How to navigate through the menu of the device

- The device is controlled by one button.
- There are two types of button press: short one (less than 1 sec) and long one (more than 1 sec).
- Short press moves the cursor to the next unit of menu or parameter.
- Long press switches to another page of menu, turns back on previous menu level, changes the value of a chosen parameter



How to set date and time

The device is supplied with a fully charged battery and properly installed date and time. If the battery of the device is completely discharged, which is quite unlikely, you will need to set the date and time. The procedure of date and time setting is similar to the user's date of birth setting and is described in detail in the user's manual.

When you start AngioScan program on your computer while the device is connected, the date and time are automatically set to the correct value.

Correct values of the date and time will simplify the search and analysis of the saved results.

How to enter personal data of the user

Parameters of the vascular system are connected with the properties of your body and its condition. As we age, the blood vessels become stiffer. What is normal for middle-aged person may be a sign of disease for the younger one. In addition to age, an important parameter that affects the assessment of the test results is the height of a person. To interpret correctly test results it is necessary to correlate them with age and with the height of the testee, so before performing the test you should set individual values of your age and height.

To enter individual settings, use the submenu [Test options], [User].

To enter the date of birth of the patient use the submenu [Test options], [User], [Birthday].



- Shortly push the control button to move the cursor to [Birthday].
- Push and hold the button to switch to [Birthday] submenu.
- Push and hold the button to set the necessary century.





- Shortly push the control button to move the cursor to the field with the year settings.
- Push and hold the button to set the necessary year. Release the button.
- Shortly push the control button to move the cursor to the field with the month settings.





- Push and hold the button to set the necessary month. Release the button.
- Shortly push the control button to move the cursor to the field with the day settings.





- Push and hold the button to set the necessary day. Release the button.
- To return to previous level push shortly the button.



To set the **user's height** go to [Test options], [User], [Height] submenu.



- Shortly push the control button to move the cursor to [Height].
- Push and hold the button to switch to [Height] submenu.
- Push and hold the button to set the hundreds of centimeters of height.





- Push shortly the control button to move the cursor to tens of centimeters field.
- Push and hold the button to set the tens of centimeters of height.





- Push shortly the control button to move the cursor to the units of centimeters field.
- Push and hold the button to set the units of height centimeters.
- To return to previous level push shortly the control button.



How to carry out the test and view the results

Preparation for the test

Right before test performance, take not less than ten-minute rest in a warm and quiet room.

Cold hands can be the reason of low rate of pulse filling index. If necessary, warm your hands.

Opaque nail polish can be an obstacle for device operation. In case it is impossible to remove nail polish, turn the device 90 degrees, so that the sensor light passed by the nail.

Behaviour during the test

The device is equipped with highly sensitive measurement system. It is necessary to assess properly the parameters of vascular system. In order to reduce errors that might occur during the test, follow the rules:

- ✓ stay in the state of rest,
- ✓ relax your hands, legs, belly
- ✓breath calmly
- √ do not move your hand and finger with device attached
- √do not speak
- √ do not laugh
- ✓ avoid vibration
- ✓ensure that the device is not exposed to a bright light

Performing the test

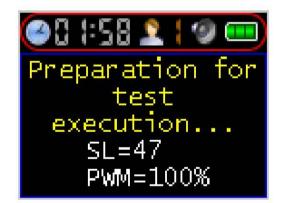


- Push and hold the button on [Start test] item until the device starts to perform the test.
- You are given 10 seconds to place the device on the finger.
- If the finger is not placed within 10 seconds, the test will be stopped.

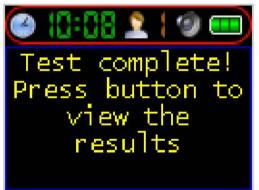




- In the beginning of the test the sensor will start setting up. In this mode the timer at status bar will show the time left to finish the setting.
- Then the preparation for the test and the test itself will be conducted. The timer will show the time left to compete the test.







- During the test, the form of pulse wave, number of waves accumulated (Wave), pulse rate (PR), type of pulse wave, pulse level (PL) will be displayed on the screen. The PL value should be higher than 1. Otherwise, you should interrupt the test and warm your hands.
- When the test ends, you will hear a sound, and a report will appear on the display.
- If you push the button during the test, it will be stopped and data will not be saved.
- If you put out the finger before the test ends, the test will be stopped without saving any data.

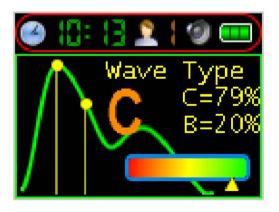
View test results

When completing the test, press the button several times to see the results. Parameters of cardiovascular system state are presented on several pages, one parameter on one page.



- Shortly push the control button to switch the device in test results review mode.
- There is a conventional scale on page of each parameter. The position of mark shows the test results.





- The mark in the green right hand side of the scale corresponds to good values of parameters.
- The mark on the red left hand side of the scale indicates possible cardiovascular problems.





- Shortly push the button to see the information about another parameter.
- Shortly push the button to switch to Start page.



How to view the results of previous tests

Before viewing the data base of saved test results select, if necessary, the appropriate number of user (See Instruction manual).

The results of the last and previous test are available in [Test options] submenu, [Test results]. The user's number is displayed at status bar on the top of the screen. Test results of this user will be selected from the data base and showed up. To view test results of another patient, change user's number.



- Shortly push the control button to move the cursor to [Test options] at Start page.
- Push and hold the button to switch to [Test options] submenu. Release the button.

```
Start test
Test options
Device options
Screen options
Power off
```



 Shortly push the control button twice to move the cursor to [Test results] item.





- Push and hold the button to go to test results database navigation submenu,
- If there are no records of test results for selected user, the following text will appear: «No saved records for the current user».







- If there are records of selected user, you will be proposed to choose one for review. The number, date and time of selected test record will appear.
- Shortly push the control button to move the cursor to:
- to switch to previous records
- Lo switch to next records
- Push and hold the button to select the record. Release the button.



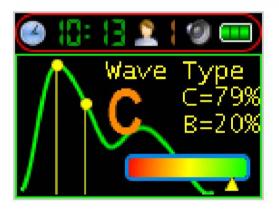
- Shortly push the control button to move the cursor to OK position.
- Push and hold the button to switch to review test results for selected record. Release the button.





- Shortly push the control button to switch the device to test results review mode.
- Every other short press of the button displays a new page on the screen with another parameter.





- There is a conventional scale on page of each parameter. The position of scale label depends on test results.
- The green side of the scale corresponds to good values of parameters, exceeding or equal to natural age norms.
- The label on the red side of the scale indicates possible cardiovascular problems.





- Shortly push the button to see the information about another parameter.
- Shortly push the button in the end of test results review to switch to Test results menu.

```
Select
test record:
#42 (42)
17-09-12 10:06
↑ ↓ Ok × ♪
```



- Then you can continue reviewing user's records.
- To return to [Test options] submenu shortly push the button to move the cursor to
- Push and hold the button to switch to [Test options] submenu. Release the button.



How to assess the results of your tests

Based on test results the devices shows the values of the following parameters:

- ✓ Pulse rate;
- ✓ Vascular age;
- ✓ Type of Pulse Wave;
- √ Vascular Stiffness;
- ✓ Stress Index;
- ✓ Saturation.

When showing the results for each parameter the device gives its assessment with a pointer, indicating a zone on the three-color scale. According to the color, marked by the pointer, the following basic assessment variations are possible:

- green color good state, no abnormalities;
- **yellow** color satisfactory condition, but functional disorders of the cardiovascular system are possible;
- **red** color ill-being state with the high risk of developing of cardiovascular diseases. It is highly recommended to consult the doctor in order to examine in details the cardiovascular disease risk factors.

Pulse rate



Pulse rate or number of heart beats per minute. Inverse value is the duration of pulse wave. The device measures the duration of each pulse wave, calculates the instantaneous value of pulse rate and assesses an average value on the basis of test results.

The pulse rate represents, primarily, the persistence of cardiovascular system (CVS). The higher heart rate in quiescent state, the less persisted the CVS is. Those who do physical exercises regularly have heart rate of 55 - 60, that is considered to be perfect state, 60 - 80 - 900 state, over 80 - 11-being.

During the specialized therapy (especially with the use of beta-blockers) these criteria cannot properly reflect the state of the CVS. For more detailed test of the CVS you can perform one with physical exercises. In this case you need:

- 1. Measure the pulse rate in normal quiescent state.
- 2. Do 20 sit-ups in 30 seconds.
- 3. After 3 minutes, re-measure the pulse and calculate the difference between the second and first results.

Result:

- Good persistence up to 5 beats;
- Satisfactory 5-10 beats;
- Ill-being over 10 beats.

Vascular Age



The parameter indicates the state of small arteries. The aim of these arteries is to provide the optimal blood supply to organ's tissues. The interpretation of the parameter is rather simple: if you are older than your vascular age according to the test, it is very good. If the vascular age is older, it reflects the unsatisfactory state of your small arteries.

It is very important to measure this parameter at a certain time of day and on the same hand, preferably on the right one. The morning hours from 9 to 11 are especially good for the test performance.

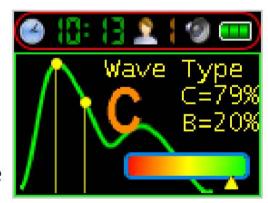
Type of Pulse Wave

This parameter provides a qualitative description to your arteries. Pulse waves are divided into three types according to their form.

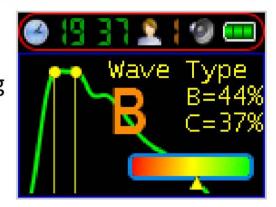
C type indicates a good condition of arterial wall, B type - satisfactory condition and A type -unsatisfactory condition. Often several types of pulse curve can appear during the test. The more pulse curves of C type, the better condition is.

The pulse wave analysis allows identifying time of origin of the maximum pressure's points of forward and reflected waves. Two yellow points on the graph correspond to the pulse waves. The left point shows the maximum of forward wave and the right one shows the maximum of reflected one.

- C-type wave is typical for people younger than 30 years without risk factors for cardiovascular diseases, associated with atherosclerosis.
- The maximum pressure of the reflected wave reaches the heart at late systole of cardiac cycle. The correspondent point of pulse wave's pattern is placed on the descending arm of the plot near the aortic valve closure point.



- B-type wave is typical for people older than 40 years or for younger persons with risk factors for cardiovascular diseases.
- The maximum pressure of the reflected wave is corresponding with the middle systole near the overall maximum of pulse wave's pattern.



- A-type wave is typical for people older than 55 years or for younger persons with increased arterial stiffness and high tone of the small resistive arteries.
- The maximum pressure of the reflected wave is corresponding with the middle systole very close to the overall maximum of pulse wave's pattern.



Vascular Stiffness



The parameter characterizes the state of major arteries (aorta and its main branches). The assessment of stiffness of major arteries is very important, as it shows the ability to smooth out blood pulsations generated by the left ventricle. When the vascular stiffness increases, the smoothing ability sharply reduces. That causes damage to capillaries and disturbance of microcirculation in various organs, primarily in cerebrum and kidneys.

It is very important to know if this parameter is negative or positive. The negative parameter indicates a good elasticity of arterial wall. The ideal value of the parameter ranges from -20% to -30%. Vascular stiffness increases because of aging and cardiovascular diseases. For precise assessment of the parameter it is important to set up the correct patient's age in the device menu.

Stress Index

The parameter reflects the state of centers regulating the cardiovascular system and is calculated on the basis of the distribution of pulse wave duration. Index value below 150 indicates their good state. If the result exceeds the threshold value of 150, it indicates an excessive tension in regulatory mechanisms. Index value of 900 and more indicates marked abnormality of the regulation. In case of arrhythmia and serious disturbances of respiratory function this method is not applicable, as the result obtained in this case shows artificially low stress index values.

- 50 ... 150 norm;
- 150 ... 500 stress, physical stress, fatigue, reduced reserves of the organism caused by aging;
- 500 ... 900 angina pectoris, psycho-physiological fatigue, marked stress;
- 900 ... 1500 marked abnormality in regulatory mechanisms, observed in preinfarction angina.



Saturation

Saturation of hemoglobin with oxygen is a highly important (vital) index which value is determined by:

- pumping function of the heart,
- ability of lungs to saturate the blood with oxygen,
- state of hemoglobin (oxygen carrier).
- Normal saturation value (saturation) of hemoglobin with oxygen varies from 96 to 99%.
- Patients with cardiovascular and chronic respiratory diseases usually have it below 96%.
- Abrupt decline in saturation at 3-4% of the normal values may indicate the presence of diseases such as influenza and pneumonia.
- When saturation of hemoglobin with oxygen is below 90% it is necessary to consult a doctor.



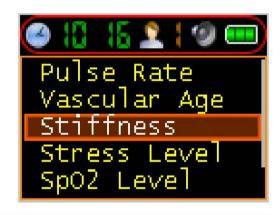
Each person may experience insignificant individual variations in levels of oxygen saturation of the blood. For correct interpretation of this parameter it is particularly important to perform several measurements. This will reveal the individual fluctuations in the level of blood oxygen, and will help to interpret correctly these or other changes in the future.

Index trends

To estimate the parameter fluctuations over time, you can view trend graphs. You can find graphs for four parameters: Pulse rate, Vascular age, Vessel stiffness and Stress index. To view these trends use [Test Options] [Index trends] submenu.



- Shortly push the control button to move the cursor to the next parameter.
- Push long the button to see the trend graph of the selected parameter.





- On the left hand side figure you can see the trend graph for stiffness parameter.
- On the right hand side figure you can see the trend graph for stress index.



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