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PULSTREAM

The System For Physiological Testing of Human Cardiovascular System State

Description User's Manual

Introduction

Part I. General Information	3
1. Applications	4
2. Regulatory Approvals	6
3. Notification	7
4. Safety Precautions and Storage	9
5. Package	10
6. Minimum Computer Requirements	15
7. Features & Benefits	15
Part II. Preparation to Taking Measurement	
8. Battery Installation	19
9. Software Installation	23
10. Troubleshooting	23
11. How To Obtain Correct Measurement	24
11.1. The WHO Classification on Cardioparameter Standard	
11.2. Conditions and Circumstances Suitable for a Correct Measurement	
11.2.1. Cardiovascular Stressing Factors	
11.2.2. Temperature Factor	
11.2.3. Emotion Factor	
11.2.4. Body Position Factor	
11.2.5. Finger Position Factor	

Part III. Taking Measurement
12. Automatic Mode
13. Manual Mode
14. Blood Pressure Measurement
14.1. Calibration
14.2. Taking Blood Pressure Measurement
15. Measurement of Blood Cholesterol Concentration
15.1. Calibration
15.2. Taking Measurement of Blood Cholesterol Concentration
16. Automatic Mode of Taking Measurement and Controlling Data Result
17. Result Data Storage
18. Graphing Capabilities
Part IV. Description of Technology
19. Method of Measuring
20. Diagnostic Capabilities
21. Parameters To Be Registered
22. Results
Part I. Warranty
23. Information on Guarantee

Introduction

Thank you for purchasing this Pulstream, a multifunction cardiovascular monitor with PC connection.

At present the Pulstream is the only compact home device in the world market capable of measuring a set of meaningful cardiovascular parameter simultaneously with the same reliable and accurate values at home as in a hospital.

The unique functions of the Pulstream include blood pressure measurements which are equivalent to those obtained with use of the cuff method, and blood cholesterol concentration measurements.

This easy-to-use and low cost electronic device complements your home life by letting you assess cardiovascular health of your family.

This lightweight and handy electronic product complements your active life by letting you monitor your cardiovascular health with a laptop when commuting.



To ensure proper use of this device, we strongly recommend you read this instruction manual carefully.

Accuracy of your results depends on the strict following our recommendations.

Please, keep this instruction manual on hand and in a safe place for future reference.

Part I. General Information



The Pulstream is a home electronic device of personal use.

By the use of the device a PC user can take measurement of a set of cardiovascular parameters with high accuracy and simultaneously.

Measurement are taken by touching a sensor with the index fingertip of the left hand.

Measurement are taken non-invasively, i.e. without any damaging a fingertip skin.

Included into its package the Pulstream software immediately carries out the measured data processing. It takes the system 20 seconds to carry out the data measuring and processing. Then you can see the following values

- Pulse Rate,
- Vascular Elasticity Tone,
- Arrhythmia,
- Heart Muscle Activity, and
- Disturbances of Heart Rhythm.

Moreover, the Pulstream, the home multifunction cardiovascular monitor with PC connection and its Pulstream software allow to take measurement in the same easy and quick way of

- Blood Cholesterol Concentration.
- Determination of cardiac reserve

1. Applications



With the Pulstream home monitoring capabilities, a PC user can assess cardiovascular health of one's own and

- ✓ Identify persons at risk of a negative tendency causes problems,
- ✓ Monitor the heart in the period of a heart attack and a stroke,
- ✓ Monitor the progress of vascular disease,
- ✓ Monitor effect of cardio-, vasoactive and other drugs,

✓ Protect oneself from potentially dangerous overexertion going in for sports or doing fitness exercises,

- ✓ Monitor cardiovascular system after stress situations,
- ✓ Monitor the heart after drug or alcohol intoxication,
- ✓ Monitor the heart in the course of rehabilitation period,

✓ Monitor cardiovascular system when a person caught cold or being contaminated with an infections disease.

This is a starter list of some of the ways people are using the Pulstream to help them in their everyday life.

2. Regulatory Approvals

The Pulstream is tested to comply with the Russian National Standards for home or office use. This is evidenced by the Conformity Certificate issued by the Russian National Standard Institute and by the RSt Mark of Conformity accompanied by the Reference Number.

The Pulstream operational method is tested and certified with the correspondent Certificate issued by the Russian National Academy of Sciences.

3. Notification



1. If your parameter data is not consistent with what is expected of what is obtained at a clinic or doctor office, please read the Instruction Manual. The detailed information on rules and requirements related to taking measurement is outlined in the Instruction Manual.

2. The Company is not responsible for intentional or accidental negative effect caused by the use of the Pulstream in the process of self-treatment.



3. Measurement results cannot serve as grounds to take a decision on need for taking any treatment. Only a certified medical professional has a right to advice or to order a treatment.

The Company sees its goal in that the Pulstream allows a PC user systematically monitor cardiovascular system for revealing risk deviations and coming in touch with a doctor timely.

4. Safety Precautions and Storage



If you cannot fix the problem using the troubleshooting instructions, request service from your supplier or from the RILA service group. The RILA service group will provide technical information and devices to authorized suppliers.

RILA service group e-mail: <u>naumov@newmail.ru</u>

2. Clean the device with a dry soft cloth. If the unit is heavily stained, wipe it with a cloth lightly dampened with water or detergent, then wipe it dry with a dry soft cloth. Do not clean the unit with abrasive or corrosive materials. Never use thinner, alcohol or benzine.

3. Do not subject the unit to excessive: temperature (below 5 C and above 35 C), humidity (below 10 % and above 75 %), direct sunlight, force, strong shocks or dust.

4. Measurements may be impaired if the device is used close to televisions, microwave ovens, cellular telephones, X-rays or other devices with strong fields.

5. Package

The Pulstream package includes:

1. Pulstream, a home cardiovascular monitor with PC connection,

- 2. One 9 V replaceable lithium battery,
- 3. Flash memory
- 4. Cable for connecting the unit to the USB computer port,
- 5. User Guide in two parts as follows

Part I. Instruction Manual

Part II. Physiological Foundations of Cardiovascular System Functioning. – Cardiovascular Diseases and Preventive Treatment Recommendations.

6. Minimum Computer Requirements



To successfully run the Doctor Mouse software, your system must equal or surpass the following configuration:

- 1. IBM compatible PC,
- 2. One available USB port,
- 3. Processor 600 MHz or faster,
- 4. Operating system: Microsoft Windows 2000 or Windows XP,7
- 5. Minimum 200 MB of free hard disk space,
- 7. 800 x 600 or higher resolution display.

7. Features & Benefits



The Pulstream, a home multifunction cardiovascular monitor with PC connection combines a set of the unique features and benefits to achieve high quality measurement results quickly and of nobody assistance taking the measurement at home by an ordinary PC user.

These features and benefits are as follows:

Complete Safe and Handy

Complete safe and comfortable in use. Measurement are taken by touching a sensor with the index fingertip of the left hand.

Measurement is taken non-invasively, i.e. without any damaging a fingertip skin.

There's no messing around with bulbs and a conductive gel, or gauges and bulky arm cuffs.

Independent of the subjects finger size.

Unique Combination of High Informativeness and Low Cost

For those who want the best the Pulstream unique combination of high informativeness and low cost has no rival. This home device can monitor and display important information on cardiovascular health. The Pulstream provides a complete solution for pulse wave signal studies, combining accurate cardiovascular parameter measurement, with comprehensive analysis and diversified data management.

Rugged Construction and Reliable Components

Its lightweight, small size and rigged construction gives the Pulstream a trouble free quality.

Weight: Appr. 140 g (including battery).

External dimensions: Appr. 135 (L) x 70 (W) x 24 (H) mm.

The device uses reliable serial components.

Easy One-Button Operation

Minimum user training needed to obtain results.

Each measurement can be run in a simple automatic mode or manually on a user's choice.

In the automatic mode, clicking on the 'START' button activates a session, measures your cardiovascular parameters, calculates and displays the results in a special report form within 20 minutes sequentially.

The easier the measurement process, the easier it is to commit to this small daily routine – and there's no simpler model to use than a finger cardiovascular monitor with one-button operation, especially if you need to take the readings yourself.

In the manual mode a user carries out the MEASUREMENT, CHECKING, CALCULATION and CALCULATION operations in a

step-by-step order on his own. It allows a user to control each stage of a measurement process.

Real Time Measurement Display

Pulse waveform is visible in real time during a session. Averaging of signal with advanced rejection / acceptance criteria.

Result Report Display

At the completion of a session, you can enter a pulse waveform and a report on current session. The multi-parameter report is presented in quantified data as well as coherence level indicators.

Parameter References

Each value is accompanied with a reference information on the measured parameter.

Data High Accuracy

The Pulstream utilizes the same photometric principle used in hospital equipment. That means you get the same reliable and accurate parameter values at home as in a hospital.

USB Port Connectivity

Connectivity of the Pulstream to your computer with an included extension cable via the built-in USB port provides high accuracy and reliability of results and allows to take measurement of blood pressure and cholesterol content of blood.

Unlimited Database and Tracking Facilities

Each session data is stored and averaged automatically to a PC in a session history feature. All the stored data are visible. Attractive graphics display trends of separate parameters. These graphic charts as well as coherent quantified data allow to carry out the comprehensive dynamic analysis.

With its PC data automatic storage and average in a session history feature, the device allows you to keep track of your own, or family, cardiovascular history.

Tracking the parameters over time gives a better overall picture of health than a single reading at a hospital or clinic.

Replay Simulator Mode

You can replay a session in simulator mode.

Healthcare Remote Monitoring

At the completion of a session, you can immediately send the session data to a clinic or a doctor office via Internet. Healthcare professionals can effectively store and analyze your stored data and provide you with remote professional monitoring.

Reducing 'White Coat' Effect

Home measurement with the Pulstream reduces the 'white coat' effect. Nervousness often distorts results of people feeling emotional discomfort at a hospital or clinic caused by apprehension or fear.

Thus, home use of the device allows to achieve an increased reliability of results in measuring an agitation-prone individual.

Part II. Preparation to Taking Measurement

8. Battery Installation

- 1. Remove gently the battery cover on the back of the unit.
- 2. Connect the battery to the contact mini-wire.
- 3. Insert a 9 V battery into the battery compartment.
- 4. Slide and securely close the battery cover.

CAUTION !

Remove a battery if the device is not used for a long period. A battery may leak and cause a malfunction.

9. Software Installation

- 1. Connect to CSS flash memory
- 2. Open the flash
- 3. Start the installer Semmed
- 4. Follow the instructions in the program
- 5. Connect the Pulstream Unit to USB port.

6. Start up the Pulstream.exe Program. The 'Pulse Analyzer' screen must appear. The 'READY' message appears on the upper panel of the screen.

The Pulstream is prepared to take measurement.

10. Troubleshooting

When installing the Doctor Mouse Software or using the Pulstream some problems may arise. Please, read through this information which covers issues on the problems and its reasons.

Problem: After the Pulstream.exe program has been started up, the Main Window doesn't appear.Probable Cause: The program is damaged.

Problem: After the Pulstream.exe program has been started up, the 'No Signal' error message is displayed.

Probable Cause: The Pulstream unit doesn't work or it's not connected to USB port.

Problem: While a measurement is running, a pulse waveform is not displayed or the signal has very small amplitude.

Probable Cause: Low sensitivity of the sensor. Calibration is needed.

Problem: While a measurement is running, errors are displayed and the signal is not stable.

Probable Cause: Some strong source of errors is located closely, and the proper functioning of the sensor is disturbed.

Problem: While a measurement is running, the distorted signal is displayed.

Probable Cause: Some programs of high priority are running in the computer, and the program loads the processor intensively. The active task programs must be cancelled.



On all issues of re-establishing the proper functioning of the Pulstream, please send an e-mail with detailed description of the problem indications and facts of failure to dmpiter@mail.ru.

11. How To Obtain Correct Measurement

11.1 The WHO Classification on Cardioparameter Standards

An individual's cardiovascular parameter values vary greatly due to various conditions. In under-functioning individuals, cardiovascular variations are even more pronounced.

The Pulstream data processing program assesses these parameters using standards established by the World Health Organization (WHO) (Ref.: Journal of Hypertension. – 1999 – Vol. 17 – No. 2), Task Force of European Society of Cardiology and the North American Society of Pacing and Electrophysiology (Ref.: Europ. Heart J. – 1996 – Vol.17 – P. 354-381).

This Classification on Standards contains a 'normal value' definition and its upper and lower grades concerning each cardiovascular parameter.

At the end of a session, the Pulstream presents a multi-parameter report which contains both the session results and the classified standards simultaneously. It allows you to compare the data and to analyze it.

If a measurement is made under suitable conditions and in proper way, the Pulstream provides you with the actual values of your cardiovascular parameters.

If a measurement is made under unsuitable conditions and in improper way, the values may differ significantly from the actual one or even the device stops the measurement and displays the 'ERROR' indication.

PLEASE, REFER TO 'NOTIFICATION', PARAGRAPH 1 (SEE ABOVE)

11.2. Conditions and Circumstances Suitable for a Correct Measurement

The conditions and circumstances below can have a very strong and rapid effect on your values exciting or depressing your cardiovascular system. This stress is reflected in measurement as a higher or lower than normal reading.

Improper positioning of your body or your finger may result in incorrect measurement.

Please, minimize stressing and incorrect measurement factors.

11.2.1. Cardiovascular Stressing Factors

Before taking measurement, rest minimum 30 minutes after

- physical exercise,
- bath or sauna,
- taking a medicine,
- drinking much alcohol,
- taking a large amount of water or after a meal,
- taking a smoke.

11.2.2. Temperature Factor

- Take measurement in a room at a temperature not below 18-20 C.
- Hands should be warm with a temperature not less than 28-30 C.

Cold hands should be warmed up by rubbing or immersing in warm water. Then wash the hands carefully.



• On coming home, one should have a rest for 30-40 minutes before taking measurement sitting or lying.

• Try to calm yourself down of the current troubles if only to the period of taking measurement.

• Take measurement in a quiet place atmosphere.



1. Sit in a comfortable position at a table with a PC. Your back should have support on the back of your chair.

2. Place your left arm on a table so that the elbow will be leaned.

3. Relax and breathe steady and deep.

Start measurement 5-10 minutes later, placing the index fingertip of the left hand on the sensor of the device correctly.



1. Place the index fingertip of the left hand on the sensor of the device so that the padded portion is over the sensor lens.

2. The finger should be placed in parallel with the surface of the device body.

3. Muscle tremble (tremor) in fingers is not allowed.

4. Having a measurement, maintain a steady position of your finger on the sensor. The fingertip should be held gently on the sensor. Holding the fingertip too forcefully or too lightly on the sensor may result in an incorrect reading.

5. Any movements with the left hand are not allowed. Remain still, silent and keep quiet during measurement.

6. All manipulations with the keys should be done with your right hand.

Part III. Taking Measurement

12. Automatic Mode

Step 1. Follow the recommendations of Charter 11 'How to Obtain Correct Measurement', please.

Step 2. Start up the Pulstream Program clicking on the Pulstream.exe icon. A Pulse Analyzer Screen is displayed.

*		PULSE ANALYZER	×
File Mode Servic	e Help	Ubat = 8,43 V. READY	

Figure 1. Pulse Analyzer Screen in Automatic Mode

Step 3. Select 'Automat' (Automatic) located on the lower panel of the screen. Thus, the automatic mode is set up (Figure 1).

Step 4. Place your index fingertip of the left hand on the sensor of the device.

Step 5. Run a session clicking on the *START* button.

A running plane polygonal line appears on the Pulse Analyzer Screen. On the second pass it will be changed for a pulse wave signal (Figure 2).

Figure 2. Pulse Wave Signal

After the fifth pass on the Pulse Analyzer Screen, the Doctor Mouse software immediately carries out the measured data processing. It takes the system 20 seconds to carry out the data measuring and processing.

Then a 'RESULT' form is displayed automatically (Figure 3).

Pulse Heart Pots Rhithm Pauses PULSE IS REDUCED -61.7 Pulse is the amount of the heart reductions per one minute. The values from 72 up to 76 are determined as the norm parameters. The parameters from 80 up to 90 are the increased pulse. When the parameters are more than 90 it is the TACHYCARDIA. The parameters from 50 up to 70 are the reduced pulse. When the parameters are less then 50 it is the BRADYCARDIA. The medical monitoring is needed if the stationary value of a tachycardia is indicated. Often the bradycardia is typical for sportsmen. Children usually have the increased pulse. Women have a bit lower pulse in comparison with the pulse parameter of men. The tachycardia is indicated after major exercise stresses as well as at nervous exaltation and when
alcohol, narcotics and some medicines are used.

Figure 3. 'Result' Form

There are bookmarks with information on each parameter value attended with detailed description of a parameter in the 'Result' form.

Step 6. Click on appropriate bookmarks for viewing the results.

Step 7. Close the 'Result' form. A 'CONCLUSION' form is displayed (Figure 4).

*			PULSE ANALYZER	×
File Mode Service Help	Resume	Ubat = 8,4	3V. READY STAFF	2
RHYTHM ANALYSIS Pulse (beats per minutes) 61,7 Variation Range (s) 0,04532 Variation Coefficient (%) 1,229	R E S U L NORM 55 - 80 from 0.06 up to 0.16 from 2.0 up to 10.0	T FORM ANALYSIS Vascular Resistance (s) 0,0865 Vascular Inelasticity (%) 19,797 Extreme Load Phase (s) 0,0876	NORM from 0.06 up to 0.09 from 10.0 up to 25.0 from 0.07 till 0.11	

Figure 4. 'Conclusion' Form

13. Manual Mode

Step 1. Follow the recommendations of Charter 11 'How to Obtain Correct Measurement', please.

Step 2. Start up the Pulstream.exe Program clicking on the Pulstream.exe icon. A Pulse Analyzer Screen is displayed.

😴 la ser la s	PULSE ANALYZER 🛛 🔀
File Mode Service Help	
START Check Calc Resume	READY

Figure 5. Pulse Analyzer Screen in Manual Mode

Step 3. Select 'Manual' located on the lower panel of the screen.

Thus, the manual mode is set up (Figure 5).

Step 4. Place your index fingertip of the left hand on the sensor of the device.

Step 5. Run a session clicking on the 'MEASU' (Measurement) button.

A running plane polygonal line appears on the Pulse Analyzer Screen. On the second pass it will be changed for the pulse wave signal (Figure 6).



Figure 6. Pulse Wave Signal

After the fifth pass on the Pulse Analyzer Screen, the Doctor Mouse software immediately carries out the measured data processing. It takes the system 20 seconds to carry out the data measuring and processing.

Step 6. Having taken the measurement, the Program activates the 'CHECK' button. Click on the 'CHECK' button. Result of the measurement is displayed, namely, a stored pulse wave frame (Figure 7).

Each peak of the pulse wave is marked with a numbered vertical line.

Each vertical line intersects the pulse wave precisely at its maximum peak point.

The Program allows you to observe and check all the stored pulse waveform long from the first frame to the final one, clicking on the 'CHECK' button. Each click displays one group of pulse wave frames after another consecutively.



Figure 7. Marked Pulse Wave Signal

Check the stored pulse waveform.

Pulse waveform frames shouldn't have excessive marks.

Pulse wave shouldn't have sharp strokes and breaks.

Pulse waveform should consist of repetitive frames with approximately the same form of signal.

If a pulse waveform doesn't meet the requirements, measurement results should be considered as unreliable ones. Measurement should be repeated staring from the Step 4.

Before you start repeating measurement, we have the pleasure to remind you follow the recommendations of Charter 11 'How to Obtain Correct Measurement'.

Step 7. As a pulse waveform is checked successfully, the '*CALC*' (Calculation) button is displayed.

Click on the '*CALC*' (Calculation) button. A 'CALCULATION' form with values of cardiovascular parameters is displayed in the Pulse Analyzer Screen (Figure 8).

¥				PULSE ANALY	ZER 🔀
File Mode Service Help START Check Calc) Resume			READY	STAFF 3
RHYTHM ANALYSIS Pulse (beats per minutes) 67,3 Variation Range (s) 0,0772 Variation Coefficient (%) 1,862	R E S U L NORM 55 - 80 4 from 0.06 up to 0.16 from 2.0 up to 10.0	- T FORM ANALY Vascular Resistance (s) Vascular Inelasticity (%) Extreme Load Phase (s)	SIS 0,0869 20,468 0,0846	NORM from 0.06 up to 0.09 from 10.0 up to 25.0 from 0.07 till 0.11	

Figure 8. 'Calculation' Form

The values are presented in quantified data as well as coherence level indicators.

A round mark located in a green zone of a parameter level indicator means a norm value of the parameter.

A round mark located in a blue zone of a parameter level indicator means an admissible deflection of the parameter value.

A red zone of a parameter level indicator means a risk zone.

Step 8. Click on the 'CONCLUSION' button. The 'RESULT' form is displayed (Figure 9).

	RESULTS	
Heart Pots Rhithm Pauses		
E IS REDUCED -67,3		
se is the amount of the heart reductions per one minute. Th meters. The parameters from 80 up to 90 are the increased HYCARDIA. The parameters from 50 up to 70 are the redu RADYCARDIA. • medical monitoring is needed if the stationary value of a t portsmen. Children usually have the increased pulse. Won meter of men. The tachycardia is indicated after major exe hol, narcotics and some medicines are used.	e values from 72 up to 76 are determined as the r 3 pulse. When the parameters are more than 90 i ced pulse. When the parameters are less then 50 achycardia is indicated. Often the bradycardia is nen have a bit lower pulse in comparison with the rrcise stresses as well as at nervous exaltation a	norm tis the Ditis typical pulse nd when

Figure 9. 'Result' Form

There are bookmarks with information on each parameter value attended with detailed description of a parameter in the 'Result' form.

Step 9. Click on appropriate bookmarks for viewing the results.

Step 10. Close the 'Result' form. A 'CONCLUSION' form is displayed (Figure 10).

•	PULSE ANALYZER
File Mode Service Help START Check Calc Resume	READY STAFF3
RESUME	
PAUSES ARE NOT FOUND	If you receive a message - " MONITORING IS NEEDED ", you should repeat the test and to save results carrying out the BEG operation and SAVE
RHYTHM IS NOT INFRINGED	one in the FILE Menu. If there are marks one should check
REDUCTION OF A CARDIAC MUSCLE IS NORMAL	should repeat the test. Please, read the detailed info in the HELP Menu.

Figure 10. 'Conclusion' Form

14. Blood Pressure Measurement

WARNING! To measure the pressure and cholesterol, an additional soft

14.1. Calibration

Having achieved the 'Result' form, you can take measurement by the use of the Pulstream two further important cardiovascular parameters, namely, blood pressure and blood cholesterol concentration.

Values of these two parameters are determined by an indirect measurement. For a calibration of the device should be carried out before the first measurement of these parameters each.

To carry out a calibration of the Pulstream means to evaluate some constant which co-ordinates your individual features related to an abovementioned parameter together with temporal parameters of pulse waveform for using this constant in further measurements.

Result of a calibration is called 'CALIBRATION VALUE'.

Calibration is carried out in the following order:

1. Take measurement of your blood pressure by the use of a tonometer.

Measurement of your blood pressure by the use of a tonometer should be taken immediately after having achieved the 'RESULT' form.

2. Click on the '**PRESSURE**' bookmark located on the upper panel of the 'Result' form (Figure 11). Some general information is displayed in the 'Result' form.

	[GO A = 170	<u>.</u>
T UP YOUR VALUE : A			X
PRESSURE			
Normal parameters of the arterial pressu	rre: Hal		
16-20 100/70 - 120/80	-9)		
20-40 120/70 - 130/80 40-60 up to 135/85			
over 60 up to 140/90			
One should visit a doctor when the BP	narameters have being indicate	d as 140/90 or above for some days	
Do not hesitate visiting a doctor, even i	if you have any problems beside	s the indications of the tonometer.	
Treatment of the idiopathic hypertensia	should be started at the earliest	stage.	

Figure 11. 'Result' Form

3. Click the '*CALIBRATION*' button located on the lower panel of the 'Result' form.

Two registration windows open on the lower panel of the 'Result' form, namely, the 'SYST PRESSURE' (Systolic Blood Pressure) and 'DIAST PRESSURE' (Diastolic Blood Pressure) Registration Windows.

The 'Set Up Your Systolic and Diastolic Pressure' indication is displayed on the upper panel of the 'Result' form (Figure 12).

ETUP	YOUR SISTOLIC	AND DIASTOLIC PRESSU		
PRESS Normal p Age (yea 16-20 20-40 40-60	RE arameters of the arterial j s) BLOOD PRESSURE 100/70 - 120/80 120/70 - 130/80 up to 135/85	pressure: E (mmHg)		
over 6 One sho Do not f	up to 140/90 Ild visit a doctor when the sitate visiting a doctor,	he BP parameters have being indicated even if you have any problems besides	as 140/90 or above for some days. the indications of the tonometer.	
Treatme	it of the idiopathic hyper	rtensia should be started at the earliest :	stage.	

Figure 12. 'Result' Form When Measuring Calibration Value

4. There are increase and decrease pointers in the 'SYST PRESSURE' and 'DIAST PRESSURE' Registration Windows. The pointers are used for setting up values.

Click on the pointers and set up into the Registration Windows the values of your systolic and diastolic blood pressure determined by the use of a tonometer.

The pointers allow to increase and decrease values with a pitch of 5 mmHg.

If your systolic or diastolic blood pressure value doesn't meet numbers regulated by the pointers, please set up the next higher or lower number of a value.

For example, if your systolic blood pressure value is 122 mmHg, please set up 120 mmHg into a registration window (Figure 12).

5. Click on the '*GO*' button located close to the Systolic or Diastolic Blood Pressure Registration Windows on the lower panel of the 'Result' form.

Your number is displayed in a Registration Window located on the upper panel of the 'Result' form.

The Registration Window is marked with a letter 'A' (Figure 12).

The number indicated in the 'A' Registration Window is your Calibration Value.

You should set up your calibration value (for example, a number of 37) into the 'A' Registration Window before taking next measurement of your blood pressure. It relieves you of having to carry out calibration again.

You should remember your calibration value. If you forget it or find mistakes, a calibration should be carried out again.

14.2. Taking Blood Pressure Measurement

1. Achieve the 'Result' form in the automatic mode following the order set forth in the items 1- 5 of Charter 12.

2. Click on the '*Pressure*' bookmark located on the upper panel of the 'Result' form.

Some general information on blood pressure is displayed in the 'Result' form (Figure 13).

2. Set up your Calibration Value into the 'A' Registration Window located on the upper panel of the 'Result' form.

Thus, the Blood Pressure Measurement Mode is set up.

ulse Heart	Pots Rhithm Pa	uses Cholesterin Pressure	e	G0 A = 37	-
PRESSUR Normal para Age (years) 16-20 20-40 20-40 40-60 over 60 One should Do not hes Treatment o	E meters of the arterial p BLOOD PRESSURE 100/70 - 120/80 120/70 - 130/80 up to 135/85 up to 140/90 visit a doctor when th tate visiting a doctor, o of the idiopathic hyperl	ressure: (mmHg) e BP parameters have being even if you have any problem ensia should be started at the	indicated as 140/90 (is besides the indication e earliest stage,	or above for some days. Ins of the tonometer.	
				Calibration	

Figure 13. 'Result' Form Ready for Starting Measurement of Blood Pressure

3. Click on the '*GO*' button. Then values of your blood pressure are displayed on the upper panel of the 'Result' form (Figure 14).

A DESCRIPTION OF THE OWNER OF THE	RESUME		_0
Pulse Heart Pots Rhithm Pauses Ch	olesterin Pressure		
BLOOD PRESSURE - between112	2 and 124 (mmHg)	GO A= 37 🔿	
PRESSURE Normal parameters of the arterial pressure:			
Age (years) BLOOD PRESSURE (mmHg) 16-20 100/70 - 120/80			
20-40 120/70 - 130/80 40-60 up to 135/85 over 60 up to 140/90			
One should visit a doctor when the BP para	meters have being indicated as 1	40/90 or above for some days.	
Do not hesitate visiting a doctor, even if you Treatment of the idiopathic hypertensia shou	i have any problems besides the uld be started at the earliest stage	indications of the tonometer. e.	
		1	
		Calibration	

Figure 14. 'Result' Form With Measured Blood Pressure Values

15. Measurement of Blood Cholesterol Concentration

NOTE

Please, pay special attention to the following recommendation:

Take measurement of blood cholesterol concentration under the healthy physical conditions to avoid displaying error indication or inaccurate results.

Calibration and measurement of blood cholesterol concentration should be made keeping the following rules

• at a fixed point in time in the morning after waking up before taking exercises,

- under normal temperature condition, and
- having no symptoms of an illness.

It's ascertained in medical researches that accumulation of cholesterol goes on while sleeping. For a measurement should be taken precisely in the morning.

It's ascertained also that some day-time fluctuations of blood cholesterol concentration may be observed.

15.1. Calibration

Measurement of blood cholesterol concentration is taken by the use of the Pulstream in the same order as does the measurement of blood pressure.

Before the first measurement, a calibration of the device should be carried out as follows

1. Take measurement of your blood cholesterol concentration by the use of a blood analyzer – for example, *Accutrend GC Blood Analyzer*.

Result of the measurement is your Calibration Value.

2. Achieve the 'Result' form following the order set forth in the items 1-5 of Charter 12.

3. Click on the '*CHOLESTEROL*' bookmark located on the upper panel of the 'Result' form (Figure 15).

Some general information is displayed in the 'Result' form.

A registration window is also opened on the upper panel of the 'Result' form. The window is marked with a letter 'A'. It's the Calibration Value Registration Window.

Besides, the '*Define Your Value* 'A' indication is displayed on the upper panel of the 'Result' form (Figure 15).



Figure 15. 'Result' Form with general information on cholesterol

4. There are increase and decrease pointers in the 'A' Calibration Value Registration Window for setting up values.

Set up your calibration value into the 'A' Registration Windows clicking on the pointers and the 'GO' button consecutively.

Your calibration value relieves you of having to carry out calibration again every next measurement.

When you prepare to take next measurement of your blood cholesterol concentration, you should just set up your calibration value (for example, a number of 12) into the 'A' Registration Window before clicking on the 'GO' button.

You should remember the calibration value. If you forget your calibration value or found mistakes, a calibration should be carried out again.

14.2. Taking Measurement of Blood Cholesterol Concentration

1. Achieve the 'Result' form in the automatic mode following the order set forth in the items 1- 5 of Charter 12.

2. Click on the '*CHOLESTEROL*' bookmark located on the upper panel of the 'Result' form (Figure 15).

3. Set up your calibration value into the '*A*' Registration Window located on the upper panel of the 'Result' form.

Thus, the Blood Cholesterol Concentration Measurement Mode is set up.

4. Click on the '*GO*' button.

A value of your blood cholesterol concentration is displayed on the upper panel of the 'Result' form (Figure 16).

РЕЗУЛЬТАТ	
Іульс Сердце Сосуды Ритм Перебои Холестерин Давление	
холЕСТЕРИН - 5,9 A = 12 🚖	
Холестерин - это не только атеросклероз! Ни одна клеточка нашего организма не может обойтись без него, так как он входит в состав их мембран. Проблема большинства современных людей заключается в том, что они употребляют слишком много продуктов, содержащих холестерин, поэтому организм не успевает избавляться от его избытка. Высокое содержание холестерина в сыворотки крови не обязательно приведет к атеросклерозу. Для развития последнего необходимо, чтобы внутренняя стенка артерий была повреждена, а этому способствуют стрессы, повышенное давление (гипертоническая болезнь). Кроме того, вероятность "вырастить" в своих сосудах атеросклеротические бляшки зависит от того, сколько в нашей сыворотке содержится липопротеидов высокой плотности (отрицательный фактор риска). Чем их меньше, тем больше риск.Содержание общего холестерина в сыворотке крови в зависимости от возраста. (По Fredrickson,1967) 0 - 19 лет 3.1 - 5.9 ммоль/л 30 - 39 лет 3.6 - 7.0 ммоль/л 40 - 49 лет 3.9 - 8.0 ммоль/л 50 - 59 лет 4.2 - 8.9 ммоль/л	

Figure 16. 'Result' Form With Measured Blood Cholesterol Concentration Values



1. Achieve the 'Result' form in the automatic mode clicking the 'Start' button.

2. Click consecutively the bookmarks located on the upper panel of the 'Result' form.

Correspondingly, some general information on each cardiovascular parameter measured by the Pulstream, and your values of the parameters are displayed.

3. Order of calibrating as well as measuring blood pressure and blood cholesterol concentration are set forth in the Charters 14 - 15.

17. Result Data Storage

Please, store results of measurement in the following order:

1. Click the 'File' menu.

2. Click '*REGIS*' (Registration). A 'Registration' form is displayed (Figure 17).

·	PULSE ANALYZER 🛛 🔀
File Mode Service Help START Check Calc Resun DATE 13; Name Naumov	READY STAFF 1 0.2012 TIME 14:22:19
AGE 68	tow are you? - OK /our body height - 172 /our weight - 85 /our pressure - 130 / 85 tave you any problems? - No problems

Figure 17. 'Registration' Form

- 3. Set up your data into the coloured information windows.
- 4. Click the 'File' menu.
- 5. Click the 'STORE' item. Storage of measurement results is made.

18. Graphing Capabilities

1. Click the 'SERVICE' menu.

2. Click the 'Graphs' item. The Pulse Analyzer Screen with a system of co-ordinates is displayed (Figure 18).

🐨 han a shekara ta shekara	PULSE ANALYZER
File Mode Service Help START Check Calc Resume	READY STAFF1
NAME Naumov DATE - 12_09_07_ TIME - 23_20_31 4	1.PULSE 62 2.RANGE 0.046 3.Phase IR 0.105 4.Phase EL 0.0875_

Рис. 18. 'Graph' Form

Stored data information is displayed automatically under the system of co-ordinates and on the right margin. The Doctor Mouse software accommodates all stored session files in this system of co-ordinates.

Besides, all stored session files are displayed in a general archive list located in a separate small window. The session files are kept in the list collected in a chronological order.

18.2. How to choose some data from this list

- 1. Mark up the first file with a single click on it.
- 2. Then mark up the final file with a double click on it.

PART IV

PARAMETER MONITORING VIA INTERNET

Part IV. **Description of Technology**

19. Description of Method

The Pulstream method of measuring an individual's cardiovascular parameters is based on the following grounds:

An infra-red emitter of appr. 0.9 mcm wavelength and a sensor are used in the Pulstream to register the amount of blood in the capillaries of a fingertip. This miniature infra-red emitter is installed into the device. The emitter sends the light flow to a fingertip.

The light flow is diffused on capillaries. The diffused light flow is registered by the photo-sensor installed close to the emitter.

The sensor signal is amplified, pre-processed and fed through a standard USB port to a computer which works in the oscillograph mode. The signal is displayed in a pulse waveform on the monitor screen.

When the sensor is uncovered, the waveform has chaotic shifts. For the sensor traps variety in lightning of the surrounding objects and it registers the slightest changes happening in the light flow falling onto the sensor. Sometimes the displayed shifts are changed by periodical waveform. It means that the device functions properly.



The extent to which the light flow is diffused varies proportionally to the amount of blood in the capillaries of a fingertip.

For the pulse wave displays coherently in dynamics the process of blood filling in capillaries.

The amount of blood filling capillaries of the fingertip positioned on the sensor is determined by pulse pressure, elasticity of blood vessels and temperature of a user's hands.

If you cover the sensor with a fingertip, the displayed line makes a sharp stroke up and down. Then it goes down smoothly and rises up to the center of the screen.

The standard form of the pulse wave is pre-processed into its differential reflection for more accurate evaluating of the cardiovascular parameters. Then the cardiovascular parameters are calculated, analyzed and stored.

This method being used in conjunction with the method of statistic and spectral processing allows to evaluate all cardiovascular parameters determined in the Variation Pulsemetry.

20. Diagnostic Capabilities

Diagnostic capabilities of the method are based on the following features of a pulse waveform:

- 1. First and foremost, a pulse waveform reflects rhythmic fluctuations of capillary blood flow caused by motion of arterial blood. At the same time, the motion of arterial blood caused by muscle contractions of the left ventricle of an individual's heart.
- 2. A pulse waveform reflects completely all processes in the heart caused by rhythmic contractions.
- 3. The process of a pulse waveform reflection corresponds to the time interval from the moment of the aortic valve opening to the moment of its closing and the blood pushing through further due to the elasticity of aorta walls.
- 4. The moment of the aortic valve closing is always reflected on a pulse curve.
- 5. It is a clearly visible phase when properties of the elasticity of aorta and vessel walls manifest themselves.

Based on the above, the following diagnostic factors are evaluated:

- the value of pulse rate;
- the bradycardia reduction of pulse rate below 50 beats per min.;
- the tachycardia increase of pulse rate over 90 beats per min.;
- the extrasystoles and pauses intermissions in the heart operating;
- the sinus arrhythmia psycho-physiological instability;

- the ciliary arrhythmia (the cardiac fibrillation) - disturbances in the conduction function and the function of regulation of the heart muscle contraction.

The analysis of pulse waveform allows to reveal the following:

- the vegetative-and-vascular dystonia (disturbances of vascular tension);

- disturbances in operating of the mitral valve and the aortic one;

- deterioration of ability of the left ventricle heart muscle to contract that is manifested in variations of the pulse waveform.

21. Parameters Being Registered

Sufficiently large amount of parameters on the heart and vessels functioning are established in physiology. Some part of these parameters can be used for assessing the cardiovascular health.

The cardiovascular parameters are calculated by two methods, namely,

- variational pulsemetry method, and

- phase analysis method.

At present, these methods have been generally acknowledged and used for diagnostic goals.



The variational pulsemetry method is based on analyzing the heart rhythm contractions. When the phase analyses method is used, a pulse waveform is analyzed. The use of the both methods simultaneously allows to evaluate one of the most important parameters, namely, vascular tension. Besides, it allows to forecast the systolic blood pressure and concentration of the blood cholesterol absorbed on the vessel walls.

The WHO classified parameters are calculated on results of analyzing the heart rhythm

- Pulse Rate,
- Variation of Cardiac Interval,
- Coefficient of Variation.

Pulse waveform analyzing allows to calculate the WHO classified parameters

- Intensive Blood Ejection Phase (Period),
- Extreme Load Phase,
- Reduced Load Phase,
- Systole Termination Phase,
- Vascular Resistance and Inelasticity,
- Vascular Tension,
- Blood Pressure,
- Blood Cholesterol Concentration.

22. Results

Let us analyze the results obtained in a more detailed way:

1. PULSE RATE is the number of the heart contractions per minute. The normal rate of the heart contractions per minute is between 72 - 76 beats.

A pulse rate of 80 to 90 beats per minute is considered slight. The state when the pulse rate is over 90 beats per minute is called TACHY-CARDIA.

The pulse rate of 50 to 60 beats per minute is considered low. The state when the pulse rate is below 50 beats per minute is called BRA-DYCARDIA. The state of sustained tachycardia calls for medical treatment.

Bradycardia is frequently seen in sportsmen. Children usually have slight pulse rate. Pulse rate of women is a bit lower as compared to men.

Tachycardia is seen

- after hard working,
- when a person is over-excited,
- after drinking alcoholic beverages,
- after taking narcotics,
- after taking certain medications.

2. 2. VARIATION OF CARDIAC INTERVAL is the difference in time between the longest and the shortest cardiac intervals measured during a session. This parameter is correlated with the SINUS NODE functioning in which electric impulses of stimulation are generated automatically. This is the main pace maker.

Normally the variation value of cardiac interval is not exceed 0.16 seconds. If the value is greater, a person has the SINUS ARRHYTH-MIA.

The sinus arrhythmia is not a disease. It is a certain physiological state that might be related to the process of breathing.

Variation of cardiac interval may serve as a forerunner of EXTRA-SYSTOLY when result exceeds the normal value considerably.

Extrasystoles are the premature contractions of the heart. A person perceives the contractions as intermissions.

Extrasystoles are always reflected in a pulse waveform. First and foremost, extrasystoles manifest themselves in the form of decreased intervals between beats and reduction of amplitude, or by passing some beats.

If the Pulstream repeatedly registers in a pulse waveform, a user should see a cardiologist.

3. CO-EFFICIENT OF VARIATION is a statistic parameter that determines the degree of deviations of the cardiac interval values. It is a variation parameter. It depends on activity of the sympathetic and parasympathetic nerve system. The parameter reveals disorders of the heart rhythm when the cardiac interval values are high. Its low values correspond to reduction of the sympathetic activity of the vegetative nerve system and may indicate hormonal diseases.

The calculations based on the pulse waveform analysis allows to determine a number of hemo-dynamic characteristics of the cardiovascular system and, hence, to establish the main parameters of the heart pumping function.

First and foremost, a pulse waveform reflects rhythmic fluctuations of capillary blood flow caused by motion of arterial blood. At the same time, the motion of arterial blood caused by muscle contractions of the left ventricle of an individual's heart. Beginning of the pulse wave rise corresponds to the moment of the aortic valve opening which separates the left ventricle from the aorta valve.



The point at which the pulse wave starts to rise corresponds to the instant of the opening of the aortic valve that separates the left ventricle from the aorta. The aortic valve opens when the pressure in the left ventricle becomes higher than the pressure in the aorta. This instant marks the beginning of the phase of intensive ejection of blood from the left ventricle. Pressure increases in the aorta at the same time.

As we need to record the rate of pressure variation (dP/dT) rather than the pressure itself, then we will deal only with the pressure variation rate.

So first, in a pulse wave we observe growth of the pressure variation rate which reaches the maximum value at a certain point. And then the pressure variation rate begins to go down until the aortic valve closes, after which a new cycle begins.

In this way the parameters are taken as follows:

INTENSIVE BLOOD EJECTION PHASE is the time from the point at which the pulse wave starts raising to the instant it has reached its maximum.

This time corresponds to velocity of the muscle fiber contractions of the left ventricle myocardium. This time depends upon the condition of coronary vessels that feed the heart muscle.

The normal limit is 0.08 - 0.12 seconds.

EXTREME LOAD PHASE is the period between the point in time at which a pulse wave is on its maximum height and the point in time at which the pulse wave intersects the zeroth line.

It's very critical portion of the pulse wave. For it is precisely at this portion of the pulse wave that maximum tension of at heart muscle is reached. So it is at this portion of the pulse wave that is of the most risk of the heart muscle affect).

The duration of this pulse curve section is directly related to biochemical processes that take place at cell level in the heart muscle. And, as a consequence, all disturbances in metabolism (that are observed in people with heart diseases - predominantly in people suffering from ischemic disease) have an effect on the length of this phase.

Considerable increase in the duration of the extreme load phase (over 0.11 seconds) indicates deterioration of the contractive function of the heart muscle.

This is the most sensitive indicator for evaluating the efficiency of treatment with medication (after a person has been taking prescribed medications to treat certain state). The lower the value of this indicator, the better.

REDUCED LOAD PHASE is the period between the point in time at which a pulse wave intersects the zeroth line to the point in time at which the pulse wave reaches its minimum.

This process is sufficiently rapid. It's correlated with relaxation of the heart muscle. Its duration is usually less than 0.09 seconds.

SYSTOLE TERMINATION PHASE is the final phase of the heart contraction. The closure of the aortic valve takes place during this stage.

Duration of this phase is determined by the time interval from the pulse wave minimum point to the half of its value. This duration is directly related to elasticity of the aorta wall.

The second peak may appear in the pulse waveform on reasonably high elasticity of the aorta wall and with an increased power of heartbeat. The second peak is often manifests hormonal dysfunctions or narcotic/alcoholic intoxication. Duration of this phase may exceed 0.12 seconds.

VASCULAR RESISTANSE is the parameter determined according to the systole completion phase.

It corresponds to the time of 2.7-times retarding of the blood flow speed after closure of the aortic valve. The longer is the process, the slower is the capillary blood flow and the higher the possibility of hypertension.

VASCULAR TENSION corresponds to the vascular elasticity. The higher the parameter, the larger the loads on the heart while it contracts.

BLOOD PRESSURE corresponds to systolic (high) pressure. It's calculated by the regressive analysis method after the calibration procedure.

BLOOD CHOLESTEROL CONCENTRATION is calculated by the regressive analysis method after the calibration procedure.

PART V

WARRANTY

23. Information on Guarantee

RILA Ltd Saint Petersburg RUSSIA e-mail: naumov@newmail.ru

Legal guarantee term depends on specific legislation in your country.

Keep carefully the receipt indicating the purchasing date.

Our guarantee covers manufacturing defects only, and does not cover misuse or demege caused by the consumer.

If your appliance appears to be faulty, please first check the instruction for possible causes and solutions before you return your appliance to the retailer from whom you purchased it, or to your nearest Service Center for repair under guarantee.

If you wish to return your appliance for repair under guarantee, email address and telephone number are listed above (calls charged at local rate).

Notes	