



Medical Device for Automatic Noninvasive Health Screening and Diagnostics based on the analysis of thermodynamic parameters

realized under commercial names:

Noninvasive Hemogram Analyzer AMP

Automatic Noninvasive Express Screening Analyzer ANESA®

Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo DAD-ANI®

Medical device for diagnostics DIAMEDSCAN

(Hereinafter MD ANALYZER)

Operating Manual/ User's Manual



2022

UA.TR.099



Manufacturer:

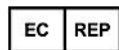
SC KOLIBRI LLC

Kinnyi provulok 8a, Kharkiv, 61001,
Ukraine. Tel.: +380-973779787

e-mail: info@kolibri.one

URL: www.kolibri.cloud

Authorized representative in European Union:



ONKOCET Ltd.

4 Kutuzova str., 90201 Pezinok,
Slovakia, Tel.: +421 (2) 44 64 09 77

e-mail: onkocet@onkocet.eu

URL: www.onkocet.eu

Authorized representative in Latin America

SETISCO Medical SL

NIF B-66870791

Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.

Tel: +34934177882.

Diagonal office: Av. Diagonal, 361, 2º - 2ª, 08037,
Barcelona. Tel: +34934578980

Noninvasive Hemogram Analyzer **AMP**
Automatic Noninvasive Express Screening Analyzer **ANESA**®
Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo **DAD-ANI**®
Medical device for diagnostics **DIAMEDSCAN**
(hereinafter ANALYZER)

MD ANALYZER is Active Medical Device of **Class IIa**, according to the ANNEX VIII, Chapter I
DURATION OF USE: «Transient», ACTIVE DEVICES: «Active device intended for diagnosis and
monitoring» Chapter III 6.2 Rule 10, 6.3. Rule 11 of the REGULATION (EU) 2017/745 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL

MD ANALYZER is Active Medical Device of **Class IIa**, according to the Annex IX Sect. I clause 1.6, 3.2 Rule 10 of the
Directive 2007/47/EC of the European Parliament and the Council amending Council Directive 93/42/EEC concerning medical
devices



Read this USER'S MANUAL carefully before use of the MD ANALYZER

The present User's manual contains the description of device, operating principle, technical characteristics and operating instructions for the MD ANALYZER.

The operating manual, including all its parts, is protected by copyright. Any use of the materials from this manual that violates the requirements of the current copyright law without the written permission of the manufacturer is forbidden.

This provision concerns, copying, translating, scanning, placing and manipulation, etc both in electronic systems and with printed versions.

CONTENT










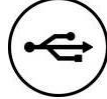
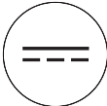






SAFETY SIGNS USED IN THE USER’S MANUAL AND THE LABELS OF MD:.....	5
1 GENERAL INFORMATION.....	6
2 WARNING AND SAFETY INSTRUCTIONS	10
3 BRIF DESCRIPTION OF THE MD ANALYZER. MODELS OF ANALYZER	14
4 BEFORE USING MD ANALYZER.....	23
5 FUNCTIONAL TEST OF MD ANALYZER	30
6 PATIENT POSITIONING	30
7 STARTING WORK WITH USPIH: PERSONAL SETTINGS.....	31
8 WORKING WITH THE SOFTWARE USPIH.....	36
9 DESCRIPTION OF MEASURING PROCEDURE.....	44
9.1 COUNTING THE NUMBER OF SURVEYS (FOR LIMITED VERSION OF MD ANALYZER, USPIH 10)	51
10 SWITCHING-OFF MD ANALYZER	51
11 SOFTWARE INSTALLATION.....	52
12 SOFTWARE USPIH 9 AND USPIH 10: FEATURES.....	55
13 EXAMPLE OF A SURVEY	56
14 TROUBLESHOOTING	62
15 CLEANING AND DISINFECTION OF MD ANALYZER	63
16 MAINTENANCE AND SAFETY CONTROL	63
17 DISPOSAL AND ENVIRONMENT PROTECTION	63
18 REPAIR	64
19 SHELF-LIFE OF THE DEVICE.....	64
20 MD ANALEZER'S EXTERIOR.....	64
21 STORAGE AND TRANSPORTATION	65
22 TERMS OF WARRANTY.....	65
23 THE LIST OF INSPECTIONS AND CONTROL FOR WARRANTY AND AFTER- WARRANTY SERVICES	66
24 CERTIFICATE OF COMPLIANCE.....	67
25 PACKING LIST	68

26 WARRANTY CARD	69
27 LABELING	74
28 DECOMMISSIONING AND DISPOSAL OF SOFTWARE.....	77
29 NOTICE TO THE USER AND/OR PATIENT	77
30 DOCUMENT HISTORY AND VERSION CONTROL	77



Read this USER'S MANUAL carefully before use of the MD ANALYZER

SAFETY SIGNS USED IN THE USER'S MANUAL AND THE LABELS OF MD:

	General warning sign		General prohibiting sign
	General safety sign		Pattern of sign for mandatory actions
	Refer to user manual/booklet	IP20	International protection marking
	Protective ground		Type BF applied part
	Recycle sign	100-240VAC	Power the MD
	CE symbol		
	Symbol for connection of USB port		Direct current
	Represented by (<i>European representative</i>)		Certificate of Compliance to Technical Regulations for medical equipment (Ukraine)
	Manufacturer		Carefully read the User's Manual before the first use of the device
	Date of manufacturing	SN	Serial number
	Sign of waste electronic equipment	MD Class IIa	MD Class IIa

1 GENERAL INFORMATION

ANALYZER is a medical device for screening the state of human health, based on the analysis of the thermodynamic parameters of the human body. It provides information on more than 100 parameters of the human body, including blood formula, biochemical, hemodynamic and metabolic parameters without blood sampling. The ANALYZER does not replace biochemical laboratory analysis and provides diagnostic information for the physician, which is used to make a diagnosis or determine the localisation of possible pathologies, which are examined in more detail using special instrumental methods.

The ANALYZER determines a number of parameters, including: Hemoglobin/HGB (g/l), Hematocrit/HCT (%), Thrombocytes ($\times 10^9/l$), Leukocytes/WBC ($\times 10^9/l$), Lymphocytes/LYMPH (%), Monocytes/MONO (%), Glucose (mmol/l), Cholesterol total (mmol/l), Low-density lipoproteins/LDL (mmol/l), High-density lipoproteins/HDL (mmol/l), Triglycerides/TG (mmol/l), ALT (U/l), AST (U/l), Bilirubin Total ($\mu\text{mol/l}$), Creatinine ($\mu\text{mol/l}$), Urea (mmol/l), etc (the full list of parameters is on Chapter 13).

1.2 PRINCIPLE OF FUNCTIONING

Non-invasive methodology for determining functional, metabolic and hemodynamic parameters of a human body was realized in the specially designed software USPIH, which is used together with the MD ANALYZER. The initial information, which is measured by the MD ANALYZER, includes temperature of the biologically active points (5 definite areas on a human body), parameters of environment, as well as the anthropometric data of a patient (age, weight, gender), heart rate and frequency of breath, which are entered with a keyboard. The input data are used in the algorithmic calculation of human health parameters, carried out by the software USPIH, for the determination of the actual state of a human body.

Selection of the biologically active points, information about which is the most valuable for the algorithm of calculation, was done on the base of the knowledge about the anatomic location of chemoreceptors on a human body. The location of chosen points is the following:

2 points - the area of carotid body, (Glomus caroticus is a small cluster of chemoreceptors and supporting cells, located near the bifurcation of the carotid artery, which runs along both sides of the throat. It allows detecting concentration of O_2 , $[\text{H}^+]/\text{CO}_2$, temperature and low-glucose in artery blood).

2 points - in the armpits on the left and on the right (temperature values in the area of axillary arteries, first of all, reflect pulmonary regulation of a breathing act, which depends on the work of irritative receptors, Type-J and pulmonary stretch receptors and regulates the volume of oxygen, which is necessary for an organism in the moment of time (with respect to the load, physical activity or resting state);

1 point - in the abdominal area, on the navel (the abdominal temperature (umbilical) is measured in the area, where aorta, inferior vena cava and large lymph vessel are joined. Temperature of this area influences to the production of essential and nonessential amino acids, regulatory hormones etc. It is related to the functioning of adrenal glands` chromaffin cells (chemosensory cells), as a negative feedback of O_2 sensing, first of all).

Process of the device's development and software's design was preceded by a huge analytical work for consolidation and systematization of the existing scientific achievements. Thereof, for definition of different parameters of a human health, the software USPIH combined commonly-known equations, practically revised and improved recognized formulas, as well as the invented mathematical algorithms, which have been based however on the evident physiological and biochemical interrelations, described in the number of scientific works of famous and recognized scholars, such as Claude Shannon (Shannon's channel capacity theorem, which applies to living organisms and their products such as communications channels and molecular machines that make choices from several possibilities, 1940s), SJ Singer and GL Nicolson (Henry's law and Dalton's law – described in "The fluid mosaic model of the structure of cell membranes", 1972); Goldstein, J.L. and M.S. Brown ("Model of low-density lipoproteins", 1977-1984), A. L. Lehninger (Bioenergetics, 1965; Biochemistry, the Molecular Basis of Cell Structure and Function, 1975), Waldram, J. R. (The Theory of Thermodynamics, 1985), Schneider, T. D. (Theory of molecular machines. I. Channel capacity of molecular machines and Theory of molecular machines II. Energy dissipation from molecular machines, 1991), Shinitzky (Membrane fluidity and cellular functions, 1984), Hensel H. (Thermoreception and Temperature Regulation, 1981), Schmidt, Robert F., Thews, Gerhard (Human Physiology, 2005), etc. Most of the fundamental scientific works concerned the questions of a cell's structure and work of a cell membrane, appearance and development of different biochemical reactions, which characterize one or another metabolic process, and as a result, heat production and heat loss in a process of vital activity, as well as thermoregulation of a human organism, which is affected by the environmental factors (air temperature, atmospheric pressure, light lux and gaseous compound of air). As a human organism exists and lives due to the million internal chemical reactions, so all vital processes of a body are supported and regulated by chemical reactions, which are subject to the laws of thermodynamics. Temperature affects not only the rate of chemical reactions, but also is the reason of proteins' alteration, phase transition of lipids and changes of water structure. The temperature of body tissues is defined by the ratio of metabolic heat production of cell structures and the rate of heat emission into the environment. Consequently, the heat exchange between an organism and the environment is an essential condition for the existence of a living organism. Violation of the mentioned ratio leads to a change in body temperature.

The algorithm of the MD ANALYZER is based on the provisions of the thermal homeostasis of a body and its relationship to changes in blood flow and Cerebrospinal fluid (CSF) dynamics, which are accompanied by the changes of peripheral blood cell composition and hormones, mineral, protein, amino acid, lipid and carbohydrate metabolism, activity of the thrombin-plasmin system (TPS). In fact, TPS determines the number of functioning capillaries per a unit area. TPS activity varies depending on the rate of blood flow in internal organs due to the functioning of a heart, correlated with heat production. Depending on the rate of oxygen delivery to a cell, the changes of blood circulation occur and they accompanied by the changes of temperature characteristics of the reference points, as well as time of their stabilization. The degree of enzymatic, hemodynamic and metabolic activity is defined by the haematopoiesis system and cellular composition of peripheral blood.

1.3 METHOD OF MEASUREMENT

The principle of functioning of the MD ANALYZER is based on measurement of temperature in the definite biologically active points of a human body (as mentioned above), taking into account other initial data about the patient and parameters of the environment. Five sensors, connected to the MD Analyzer, measure temperature in biologically active points with accuracy not less than 0.5°C. MD Analyzer processes signals, coming from sensors placed on the body of a patient and converts these signals into a digital form. Temperature values, measured by sensors, are converted into the information value "bit" and are sent to the central microcontroller of the MD ANALYZER. Given data are processed by the microcontroller at first and then by the PC's software, after that, it is possible to view and print the results. So, all the information is processed by the specially designed software USPIH, located in the microcontroller and on a PC, becoming the base for the report/survey with more than 100 parameters of a health state. The device has five temperature sensors (digital thermal microprocessors), which are to be placed onto definite biologically active points of a human body (bifurcation of the right and left neck artery (two points), right and left armpit (two points), umbilical area (one point)). The sensor, which measures the parameters of environment, such as atmospheric pressure, is installed inside the MD.

Prior to an examination, the five sensors are to be placed on a patient, and the initial data of the patient (gender, weight and age), breath rate and pulse rate (measured with pulse oximeter or manually, when the patient is in a supine position) should be input into the patient's card using the interface of the software USPIH, installed on a PC. The software USPIH manages the process of measurement, data collection and proceeding. Calculation of the data of blood parameters is made by the special calculation algorithm named by Malykhin-Pulavskyi method (Ukrainian Patent No. 60890, 39250, 3546 A61B5).

At the end of each examination, a physician receives the report. Besides parameters, there will be a prompt for a physician about possible diagnosis at the end of a report. It is not a final diagnosis, it is only preliminary PC conclusion.



It is required to make an examination, when a patient is calm, had no physical activity during 5-10min, in the supine position in a room with a comfortable temperature (in the ranges +20 °C and +27 °C) and humidity less than 80%.

1.4 INTENDED USE OF DEVICE

Medical Device for Noninvasive Screening Diagnostics is intended for the measurement of thermodynamic values on the surface of skin on biologically active points of a human body, taking into account the initial data about a patient and parameters of the environment, which are subsequently processed by the software USPIH and represented in the form of a report, displaying on a screen, which includes the parameters of blood and preliminary automatic conclusion about possible pathologies. A

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

physician makes a decision about the diagnosis or recommends special examinations/ tests/procedures for diagnosis clarification, based on the received data in the report.

As the method of the MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI® is noninvasive and fast, so such a testing is very interesting for determination of further (if necessary) specific diagnostic procedures, i.e. the scope of further focus. Results of screening diagnostic on the MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI® include information regarding different systems of an organism. Using this information, a physician is able to identify existing and/or suspicious pathologies of the patient. Combination of the MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI® and other methods of diagnostics will be the most beneficial for a comprehensive investigation of a health state of the patient. Thereof, an experienced and trained physician is able to identify main pathologies, by analysing the results of the Analyzer very fast.

Thus, such a screening device will be useful both in an admission department of a hospital and in a private clinic or a family doctor's cabinet. In addition, usage of the Analyzer in rehabilitation and recovery centers will be helpful for estimating the efficiency of applied treatment and physiological procedures (UHF and laser therapy, mud and mineral baths, etc.).

In general, the intended fields of application for the MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI® are the following: private and family doctors, clinics, medical research centers, rehabilitation and spa centers, and other medical institutions.

1.5 CONTRAINDICATIONS



The MD ANALYZER is not allowed to use in pediatrics, in critical and urgent states, in ICU department (both in operation room and Emergency Room), for patients after chemotherapy and X-Ray therapy, for patients with diabetes mellitus, jaundice, acute kidney insufficiency, for donors after blood transfusion (limited period for donors is 6 month) and for recipients after blood transfusion (period is not determined, as it primary depends on the initial state of a patient before transfusion and his/her ability to recover).

Damages of a skin surface of a patient (of different nature: wounds, ulcers, injuries, inflammation and rashes etc) in the areas of sensors' placement are the absolute contraindication to an examination.



The ANALYZER is to be used in healthcare premises! Specially trained medical staff is permitted to operate the device. Only the medical professional (physician, therapist, family doctor, and so on) is able to interpret the results of measurement and make a decision about a diagnosis!

2 WARNING AND SAFETY INSTRUCTIONS

2.1 GENERAL SAFETY RULES


















It is prohibited to use the Analyzer, in case below mentioned requirements are not fulfilled:





temperature in a testing room must be in the range of +20 °C and +27 °C;
 relative humidity in a room must be less than 80% at the temperature +25 °C;
 presence of aggressive vapour in a room should be excluded;
 dusty spaces are prohibited (condition in a room should meet the requirements for medical institutions in the country);
 presence of strong electric-magnetic fields (more than 50μT) should be excluded;
 influence of direct sunshine and direct flow of a conditioned air are prohibited;
 atmospheric pressure should be in the range of 615-780 mm Hg (82 - 104 kPa).

During operation and maintenance of MD Analyzer, the following safety measures shall to be kept:

	<p>A user of MD Analyzer must have the enough technical and medical qualifications, know and fulfill the requirements listed in the present User's Manual in order to use the device properly. All maintenance procedures, recommended by the manufacturer, must be performed by personnel with appropriate approvals.</p>
	<p>Before usage, make a visual inspection of the Analyzer for detecting any possible broken and torn parts, or other mechanical damages.</p>
	<p>Always place the Analyzer on the stable and solid surface.</p>
	<p>It is allowed to use the Analyzer as screening equipment in hospitals and medical centers, rehabilitation centers and centers of sports medicine, SPA and wellness centers for adult patients (aged 18 and over).</p>
	<p>Before using the Analyzer, an operator/user must inspect the Analyzer and ensure that there is no external damage.</p>

	Protect the Analyzer against moisture condensation. In case of rapid change of the ambient temperature, do not switch on the Analyzer during at least 30 minutes, it'll let the moisture to evaporate.
	The Analyzer meets the requirements of the electrical safety standard 60601-1: 2006/AC:2010. Connection of the Analyzer to the mains supply must be done in accordance with the national electrical safety regulations.
	Properly certified and safe materials are used for the production of the Analyzer. Potential risk of a patient's allergic reaction to the materials of parts, which come in a contact with the skin surface during the measuring procedure, exists.
	WARNING! Modification of the Analyzer is not allowed!
	Power cable of a computer shall have protective ground wire, the plug must have ground connection and shall conform with mains socket, too.
	Do not twist the mains cable and place it in such a way, when its damage is excluded.
	Prior to the cleaning or maintenance works, unplug the Analyzer from the power source. The means of simultaneous electrical separation of the power circuits of the Analyzer from the circuits of the power supply network is the network power cable of a computer, which the Analyzer is connected to.
	Connect the computer (from which the Analyzer is powered) only to a working socket with a rated voltage within the range 100 - 240V 50-60Hz. The position of the Analyzer and computer should ensure that there is no tension on the computer's power cord, USB cable and on the cables with 5 microprocessors, connection and disconnection of the

	power cord from the supply network should be easily available for a quick disconnection of the computer and Analyzer in case of emergency situations.
	It is prohibited to pull cables for taking off sensors from a patient or from sockets.
	It is prohibited to use the Analyzer in case of damaged cable isolation.
	It is prohibited to use any aerosols and liquids for cleaning the device.
	It is prohibited to use the Analyzer in potentially explosive environments, particularly in facilities with flammable anesthetics.
	Usage of the Analyzer in case of any damage of enclosure, cables with microprocessors, USB cable and/or power cord of a computer is forbidden!
	Usage of the Analyzer as a laboratory equipment is forbidden.
	It is prohibited for a user/operator to take psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol for at least 24 hours before using the device.

	<p>Risk of germs transmission exists! Microprocessors should be disinfected before and after each measurement!</p>
	<p>It is recommended to power off the device after finishing operating</p>
	<p>Only procedures recommended in this User's Manual are allowed to perform!</p>
	<p>While using the Analyzer, an operator/user should be healthy and in normal emotional mood (at least rested).</p>

2.2 MEASURES TO PREVENT DAMAGE TO THE DEVICE

The Analyzer should be placed in such a way, when unimpeded connection and disconnection of a power cord to/from the power supply network or USB cable to/from a certified computer is ensured. In any case, a power cord and/or a USB cable should not impede free movement of an operator/user and/or a patient near the workplace.



Do not cover the Analyzer during operation.

Do not disconnect a USB cable or a cable with microprocessors during operation and/or when the power is on.

This device complies with the requirements of the EMC standard (EN 60601-1-2:2007/AC:2010.). As a rule, the level of emitted electromagnetic interference is so negligible, that it is not able to interfere the operability of most of devices. However, it is recommended to exclude the placement of the Analyzer in close proximity to sensitive equipment, the distance of 1 m and more is considered to be sufficient.

The Analyzer and its accessories must be stored in a place protected from the direct sunlight.

It is prohibited to install the Analyzer on a slippery and/or an uneven surface in order to avoid the device from falling down.

It is necessary to exclude a contact of the Analyzer and its components with various solvents, gasoline, kerosene and other chemically aggressive substances. Water is not allowed to be in a contact with microprocessors and cables, as drops of water will destroy sensors in fixing points and the measurement will be wrong.

It is forbidden to bend the cables in the place where the sensors are fixed.

If it happened and the sensors are damaged (by any of reasons), a user is warned in two ways:

- 1) on the level of the hardware: a LED indicator near the slot for a cable with microprocessor starts blinking;
- 2) on the level of software:
 - 2a. an error window "Error! Check the accuracy of microprocessors' placing and connection of a cable with microprocessors!" will appear;
 - 2b. all the measured temperature values will be the same 10°C, what is absolutely unreal for a living human organism.

3 BRIF DESCRIPTION OF THE MD ANALYZER. MODELS OF ANALYZER

The MD ANALYZER is intended for screening diagnostics of patients, being a useful diagnostic tool in hands of a practicing physician along with other existing certified diagnostic equipment.

MD ANALYZER processes signals coming from sensors placed on the body of a patient, converts these signals into digital form, passes them to the PC and operates then.

Five sensors, connected to the ANALYZER, measure temperature in reference points with accuracy not less than 0,5°C. Sensors send values of temperature to the central processor unit of the ANALYZER Screening Analyzer. Given data are processed by central processor unit and are sent to PC, which makes it possible to view and print the results. Calculation of the data of blood test parameters is made by special examination algorithm named as Malykhin-Pulavskyi method (Ukrainian Patent No. 3546 A61B5).

Points of placement for sensors/microprocessors	
<i>Bifurcation of left artery - Blue</i>	<i>Bifurcation of right artery – Green</i>
<i>Left armpit (axillaries) - Yellow</i>	<i>Right armpit (axillaries) - Violet</i>
<i>Abdominal area (umbilicus) - Red</i>	

An examination will take 3-10 minutes. The interval depends on a patient, it should be controlled and may be changed during examination by a physician.

There is no harmful influence of the Analyzer to a patient during an examination; the Analyzer determines influence of environment to a patient's health.

At the end of an examination a physician will receive the report. Besides, there will be a prompt for a physician about diagnosis at the end of a report. It is not a final diagnosis.



MD ANALYZER does not diagnose a patient itself. Only a medical professional (physician, pathologist, general practitioner and etc.) is able to interpret the results of measurement and make a decision about a diagnosis!

The physician studies all the information: received report, patient complaints, any previous results (e.g. laboratory analysis, ultrasonography, tomography, etc.) and preliminary diagnosis from the report. On the base of complete analysis, the physician can set final diagnosis.

3.1 TECHNICAL DATA OF MD ANALYZER

According to the method of protection from electric shock, the MD ANALYZER belongs to class I with a working part of type BF.

Degree of protection against penetration of water or solid particles is IP20.

The mode of operation of the MD ANALYZER is NON-CONTINUOUS OPERATION.

General technical data for all models of MD ANALYZER are the following:

PC mains voltage	230V±10 %; 50/60 Hz	
Analyzer's mains voltage (from USB port)	U = 5±1 V DC	I = 195 mA
Consumption	max. 0,975 VA	
MD Class	II	
Protection of patient	A	
EMC	in accordance with EN 60601-1-2:2007/AC:2010	
IP Class of Analyzer	IP 20	
Readiness time counted from switching on	max. 3 min	
Range of temperature of reference points	24 – 42 °C	
Margin of error of reference points	max. ±0,75°C	


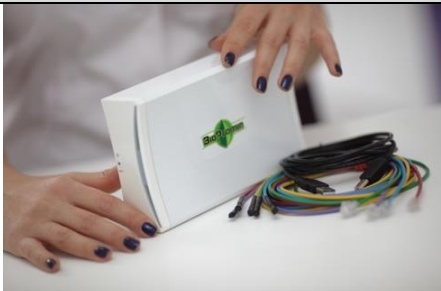
Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.



Length of cables for microprocessors/sensors	min. 1,5 m
Accuracy of the microprocessors/sensors	±0,5 °C, in the range from -10 °C to +85 °C
Resolution of the sensors	0.0625°C; Resolution is user-configurable to 12 bits
Time of examination	max.720 sec
Method of diagnostics	Thermodynamic method, invented by Malykhin-Pulavskiyi (data collection from reference point)
Software	USPIH (based on the methods of Malykhin-Pulavskiyi) From -25°C (without relative humidity control) till + 70°C (with relative humidity control)
Ambient temperature for storage and transportation	Class 7K3, as described in the IEC/TR 60721-4-7:2001+AMD1:2003 CSV
Atmospheric pressure	615-780 mm Hg (82 -104 kPa).
Humidity	15%-93%, without condensation

Minimum requirements to a computer, both for hardware and software, which are enough to use with MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI®

Minimum hardware requirements		Minimum software requirements	
Processor	Pentium 4, and higher	Operating system	Windows XP, 2003, 2008, Vista, 7, 8 and higher It is recommended to have administrator rights for an access to OS Windows during installation of software USPIH (mostly it concerns OS 7 and older).
RAM	min. 512 Mb		
Display	min. SVGA 14”...17” definition 1024x768 pixels		
HDD	40 GB	Antivirus software	Any antivirus software must be set up in such a way, when the software USPIH isn’t blocked
USB port	min. 3		

MD ANALYZER is performed in different enclosures in order to meet customers’ needs and requirements. Depending on the enclosure, there are different complete sets of cables with microprocessors/sensors. Available models are shown on the Picture 1.

<p>Model, where one cable with 5 microprocessors is included into complete set of the MD ANALYZER; connector DB9-F is used.</p>	<p>Model, where 5 separate cables, (each with one microprocessor) are included into complete set of the MD ANALYZER; connector RJ9 is used</p>
	

L/2007, ANESA-L/2007	L/2012, ANESA-L/2012w
Model with Tablet PC and 5 separate cables, (each with one microprocessor); connector RJ9 is used	
 <p>T/2011</p>	 <p>ANESA-L/2019, ANESA-L2019B</p>

Picture 1. Models of MD AMP-ANESA-DAD-ANI

Models L/2007 and L/2007w is performed in a rigid plastic case. It works together with specially designed software USPIH.

The complete set of MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI® Model L/2007 includes the following:



Model L/2007(w). External view and complete set

Name of a part	Quantity
Analyzer ANESA®	1
Cable with 5 microprocessors; connector DB9-F is used. Color cables or black cables with color marks are used.	2
Key Guardant Stealth II	1
Cable USB	1
User's manual/Operating Manual	1
Packing case	1

- 1 – Connector for a cable, which connects Analyzer with computer
- 2 – Connector for a cable with 5 microprocessors
- 3 – Indicator of power supply and state of a cable with 5 microprocessors
- 4 – A cable with 5 microprocessors
- 5 – Key of software protection Guardant Stealth II

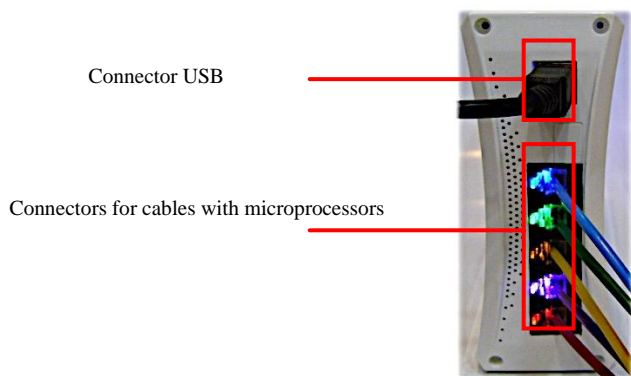
Dimensions: 160x100x45 mm Weight: 0,5 kg (including cables)

ANESA-L/2007 works with the software USPIH, version 10

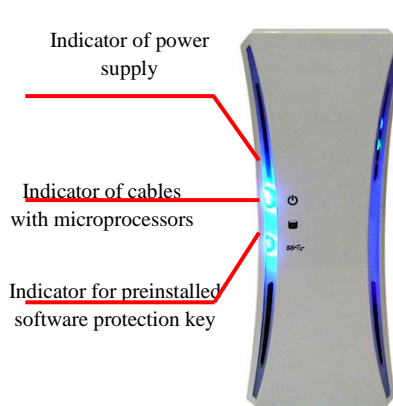
ANESA-L/2007w works with the software USPIH, version 9

Models ANESA-L/2012 and ANESA-L/2012w are performed in white glossy metal-plastic case. Complete set of this model includes:

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.



Back panel of Analyzer



Front panel of Analyzer



Name of a part	Quantity
Analyzer ANESA®	1
Cable with microprocessor/sensor connector RJ9 is used	5
Cable USB	1
User's manual/Operating Manual	1
Packing case	1

Model L/2012(w). External view and complete set

Dimensions: 200x116x47 mm Weight: 1.0 kg (including cables)

ANESA-L/2012 – requires software USPIH version 10

ANESA-L/2012w – requires software USPIH, version 9

Model T/2011 or AMP-PC

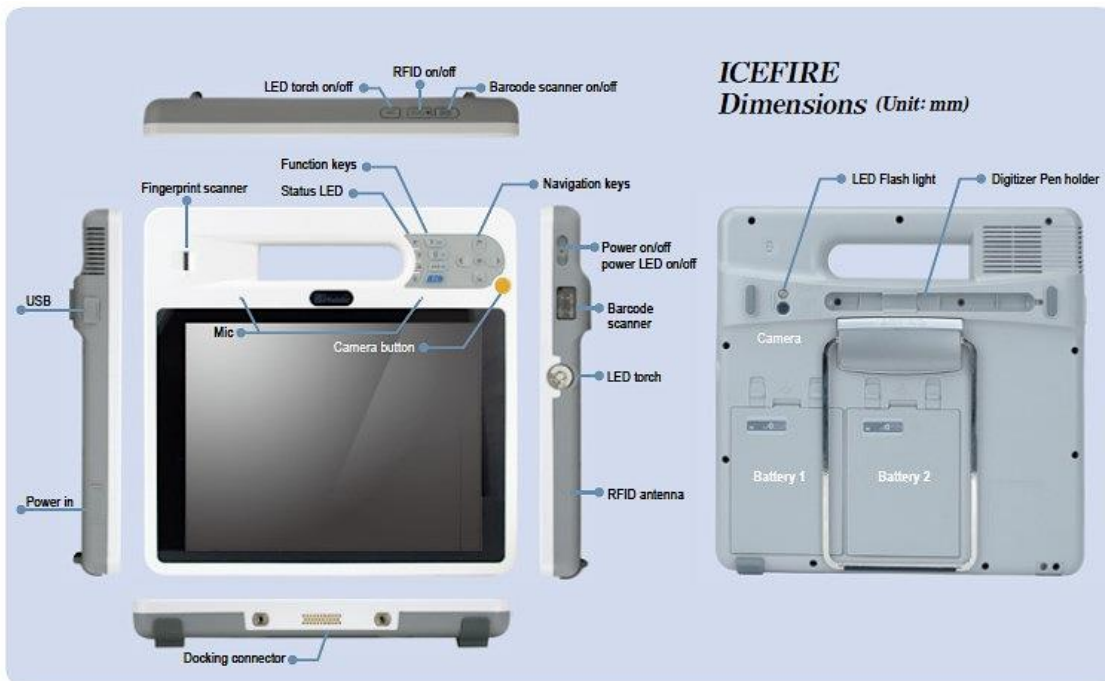
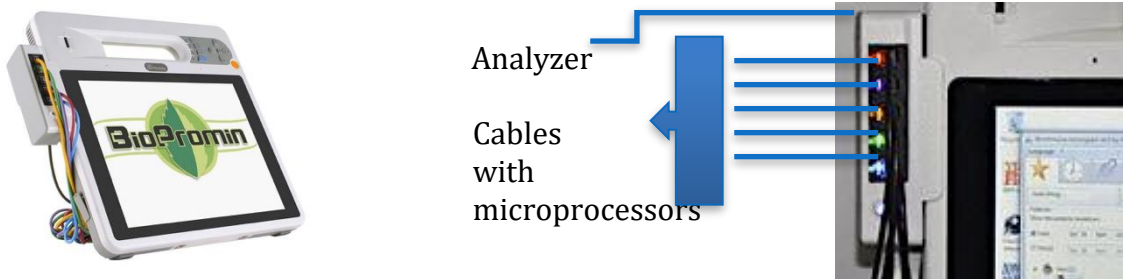
This model of MD AMP/ANESA®/DIAMEDSCAN/DAD-ANI® includes Tablet PC (made in Taiwan, IEI Corp.) and integrated module with the Analyzer. The tablet PC is slim and compact. It has handle design for easy carry, antibacterial housing and touch-screen monitor: 10.4” TFT XGA LCD. Tablet PC has got Intel Atom D525 dual core platform, powered by Windows 7 Embedded, dual mode input (digitizer + Multi-Resistive Touch), Wi-Fi, Bluetooth, fingerprint readers and it can be equipped

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

optionally with readers of barcode, RFID and smart-card. Tablet PC can be used with or without docking station.

Dimensions: 270x265x29mm Weight: 2.3 kg (including cables and batteries)

Model ANESA-T/2011 is available with software USPIH version 10 only.





Indicators

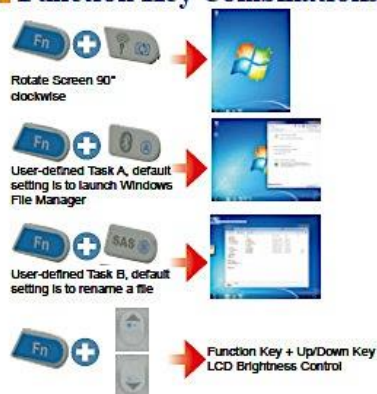
- Green light shows Wi-Fi® is enabled
- Blue light shows Bluetooth® is enabled
- Orange light shows that Battery-1 is being charged
- Orange light shows that Battery-2 is being charged





Hot Keys

- 4-direction keys (UP, DOWN, LEFT, and RIGHT), and ENTER key
- Wi-Fi on/off button
- Bluetooth on/off button
- Secure Attention Sequence (SAS): identical to *CTRL-ALT-DEL* keystroke combination.

Function Key Combinations



	Name of a part	Quantity
	Analyzer ANESA®	1
	Cable with microprocessor/sensor connector RJ9 is used	5
	Cable USB	1
	User's manual/Operating Manual	1
	Packing case	1
<p><i>Model L/2019, Model-L2019B</i> <i>. External view and complete set</i></p>	 <p>Software protected key (SPK)</p>	1

Model L/2019 – USB version

Model L/2019B- Bluetooth version

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

General technical data for all models of ANALYZER are the following:

Mains voltage (via USB port)	U = 5±1 V DC I ≤ 500 mA
Battery (Lithium Polymer Cell)	LP 3867100 3.7V 2400mAh, installed on the PCB (<i>see the details below</i>)
Consumption	max. 2,5 VA
MD Class	II A
Basic safety/EMC	IEC 60601-1:2005+AMD1:2012 (ed.3)/IEC 60601-1-2 4th Ed
Class of protection against penetration of water or solid particles (IP)	IP 20
Readiness time counted from switching on	max. 2 min
Weight	0,415 ±0.030 Kg
Weight 5 cables	0,120±0.030 Kg
Dimensions	200.2x118x40 mm
Range of temperature of reference points	+24 to +42°C
Margin of error of reference points	max. ±0,75°C
Length of cables for microprocessors/sensors	max. 1,5 m
Accuracy of the microprocessors/sensors	±0,07 °C at +20°C range (limited measuring ranges from -10 °C to +60 °C)
Resolution of the sensors	4 mK
Digital signal output (of the sensors):	14-bit ZACWire, see application note ATTSic_E
Time of examination	max.720 sec
Applied methods	Definition of human health parameters on the base of thermodynamic values measured at designated points on a body (on the skin) and anthropometric data of the patient
Software	MD ANALYZER, specially designed for the MD
Ambient temperature for storage and transportation	From -5°C (without relative humidity control) till + 45°C (with relative humidity control) Class 7K2, as described in the IEC/TR 60721-4-7:2001
Atmospheric pressure (operation)	650-765 mm Hg (87 -102 kPa).
Humidity	15%-93%, without condensation

Minimum requirements to a computer, both for hardware and software, which are enough to use with MD MD ANALYZER

Minimum hardware requirements		Minimum software requirements	
Internal memory	min. 32 Gb	Operating system	Windows 7 and higher. It is recommended to have administrator rights for access to OS Windows during the installation of software (mostly it concerns OS 8 and higher).
RAM	min. 3 Gb		
Display	min. 5"-55" definition HD, FHD, QHD or more		

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

Medical grade computer is required to be used in combination with the MD ANALYZER.	Antivirus software	Any antivirus software must be set up in such a way, when the software isn't blocked
---	--------------------	--

As the ANALYZER has a battery for wireless mode of operation, the following technical features shall be considered:

Battery (Lithium Polymer Cell)	LP 3867100, installed on the PCB
Charge limited voltage/ Nominal voltage	4.2V/3.7V (<i>the cell is protected by an electronic circuit that won't allow it to overcharge nor over-discharge under use</i>)
Rated capacity	2400mAh, @ 0.2C mA discharging
Cycle life	300 times (<i>approximately 1 year of operation</i>) <i>One cycle refers to one charge period and then one discharge period. So, cycle life means that after 300 times of discharge-charge, the cell capacity will be reduced to 80% of the rated one.</i>
Operating Temperature	Discharge: -10°C ~ +55°C / Charge: 0°C ~ +43°C Use in extreme ambient temperature conditions (with very high or very low temperature) may lead to a drop of 70% of capacity with the same number of cycles.
Conditions of storage	-20°C ~ +45°C During a long period of storage, cells should be maintained every 90 days (to keep the lifetime of the cell): standard method of charge-discharge cycle should be applied. Do not store the ANALYZER in wet or cold conditions! Moisture and cold increase the discharge rate of the battery. And under the influence of extremely high temperatures there is a risk of explosion of the battery.



Batteries have their own life cycles. If the time of working of the ANALYZER in wireless mode becomes much shorter than usual, the battery cell life is at an end. Please ask your distributor/manufacturer for replacement.



In case the battery is damaged, and the fluid leak is detected, avoid the contact with it. If it liquid leaks onto your skin or clothes, wash thoroughly with fresh water immediately. If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them thoroughly with clean edible oil and visit a medical professional immediately.

4 BEFORE USING MD ANALYZER

4.1 LIST OF INITIAL ACTIONS AND EVERYDAY ACTIONS BEFORE USE

Initial routine actions, which are to be done before using of the Analyzer, include general and specific actions (specific to a particular model of the Analyzer) and are the following:

GENERAL ACTIONS	
Provide the availability and sufficient reserve of water-alcohol solution for disinfection of the Analyzer and its parts (alcohol of 70 - 96%); Provide the availability and sufficient reserve of medical alcohol wipes or cotton pads, which are used for disinfection of microprocessors and cables; Equip an operator's workplace with a table or rack with the firm, dry and non-slippery surface (to meet the requirements listed in Chapter 2.2 of the present User's Manual) and a couch for patients (to meet the requirements of Chapter 6); Remove the device from its packaging. Check for damages an enclosure, a cable with five microprocessors, a power cord of a tablet PC or a USB cable (a device's complete set varies depending on the model; Chapter 3.1).	
SPECIFIC ACTIONS	
FOR MODEL T/2011	FOR MODEL L/2007, L/2012, L/2019
Make sure that a protective grounding power supply network is used and the voltage in the network is in the range 100 - 240V, 50 - 60 Hz. The MD ANALYZER is to be connected to the type F (Schuko) sockets (European power socket with grounding CEE 7/4, Standard DIN 49440). A suitable adapter is required for connection to other types of sockets. In any case, the presence of protective grounding in the power socket is mandatory!	Connect a cable with five microprocessors to the MD ANALYZER and the MD ANALYZER to a computer via USB cable. Connect the GUARDANT STEALTH II key to a free USB slot on a computer (*for the Analyzer Model L/ 2007 model); Switch on a computer (it is not included into a complete set; Chapter 3.1);
Provide the availability and sufficient reserve of standard wet wipes for displays (alcohol-free!);	First time connection of the Analyzer to a computer requires installation of the software (described in Chapter 11);
GENERAL ACTIONS	
Run software USPIH using the appropriate icon on a desktop or in the main menu of a computer; Once per day, in the beginning of work with the Analyzer (before testing patients), the functional test is required to be performed (described in Chapter 5).	


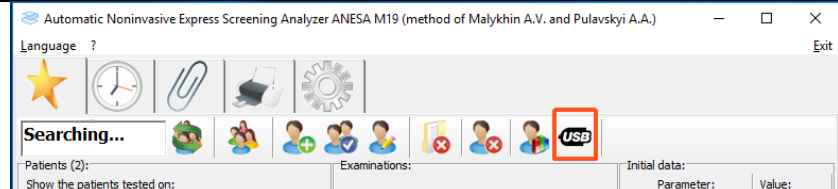
Important Note! *In case you use the software version USPIH 9, please ensure that your computer is connected to Internet, the port 44404 is opened and not blocked by a firewall or any other software.*

EVERYDAY ACTIONS BEFORE USAGE	
FOR MODEL T/2011	FOR MODEL L/2007 and L/2012
<p>Connect each cable with a microprocessor to the appropriate connector on the Analyzer's front panel (according to color).</p> <p>Connect the Analyzer to the appropriate socket on a tablet PC.</p> <p>Switch on your tablet PC (according to the instructions of the PC's manufacturer).</p> <p>Run the software USPIH using the icon on the desktop or in the main menu.</p>	<p>Connect the cable with 5 microprocessors or each cable with a microprocessor to the appropriate connector on the Analyzer's front panel.</p> <p>While the computer and analyzer are switched off, connect them via USB cable.</p> <p>Switch on a computer (it is not included into a complete set; Chapter 3.1);</p> <p>Run the software USPIH using the icon on the desktop or in the main menu</p>


The analyzer is ready for use. Working process is the same for all models of MD ANALYZER. When the Analyzer is ready for a work and software USPIH is run, it's time to start measurement. The process of measurement is described in detail in the next part "Description of measuring procedure" (Chapter 9).

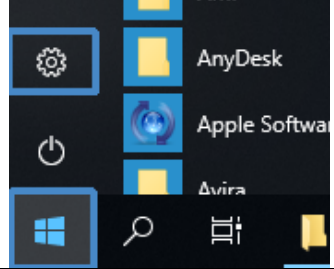
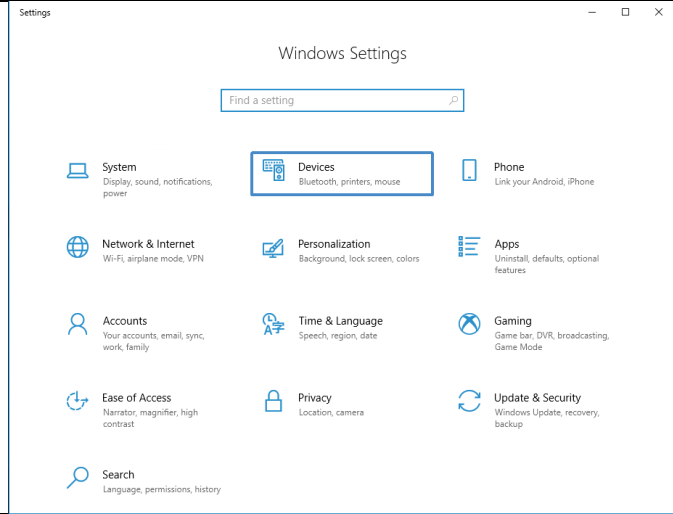
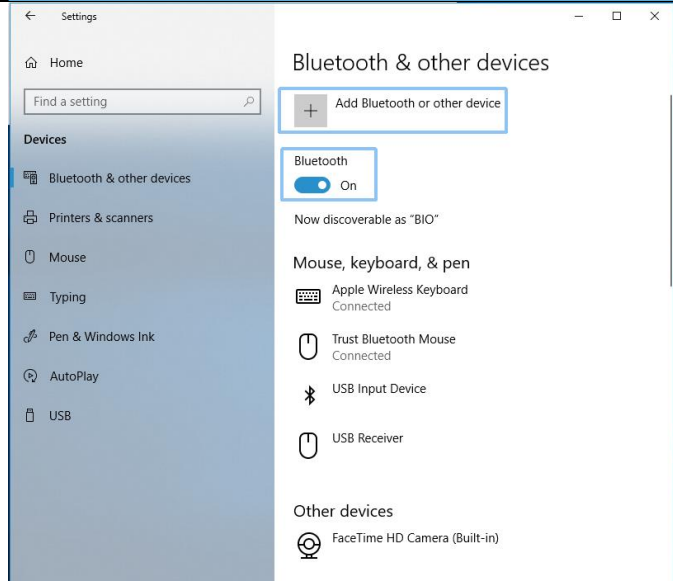
4.1.1 CONNECTING THE DEVICE TO A COMPUTER VIA USB (L/2007, L2012, L/2019)

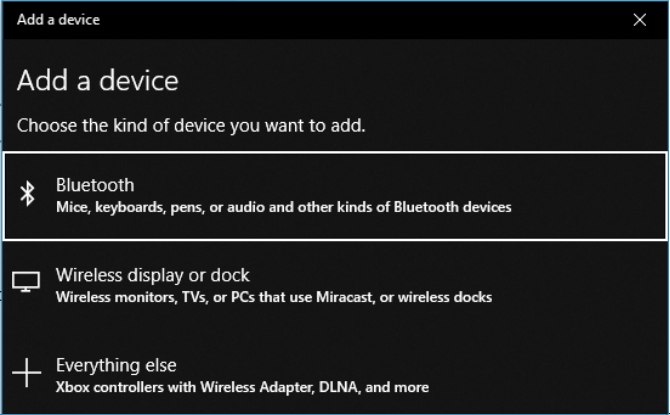
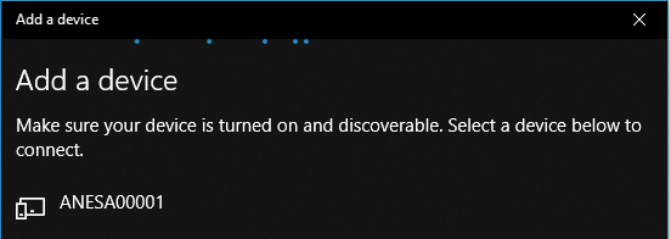
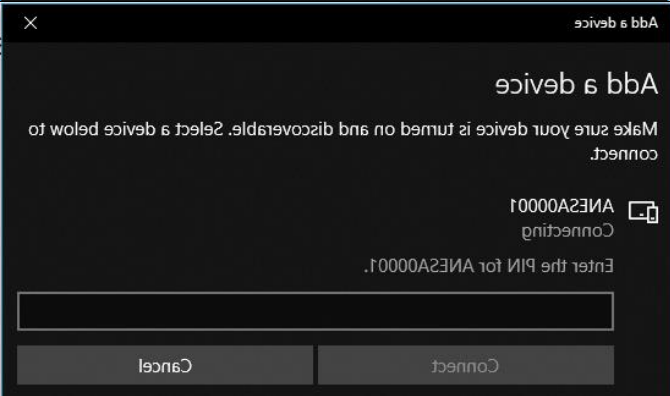
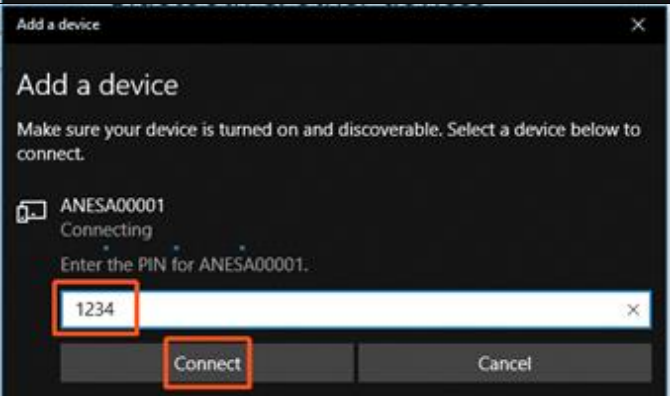
After the installation of the software (Chapter 5), turn on the device:

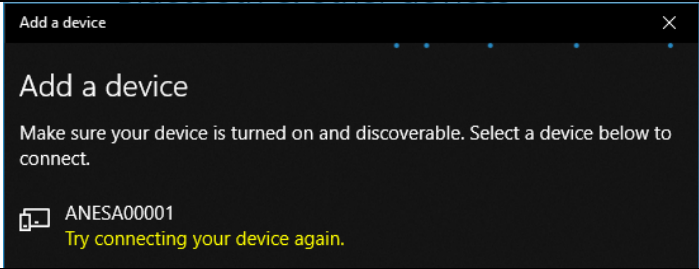
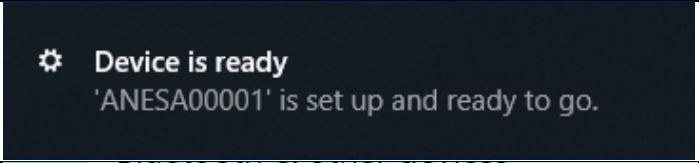
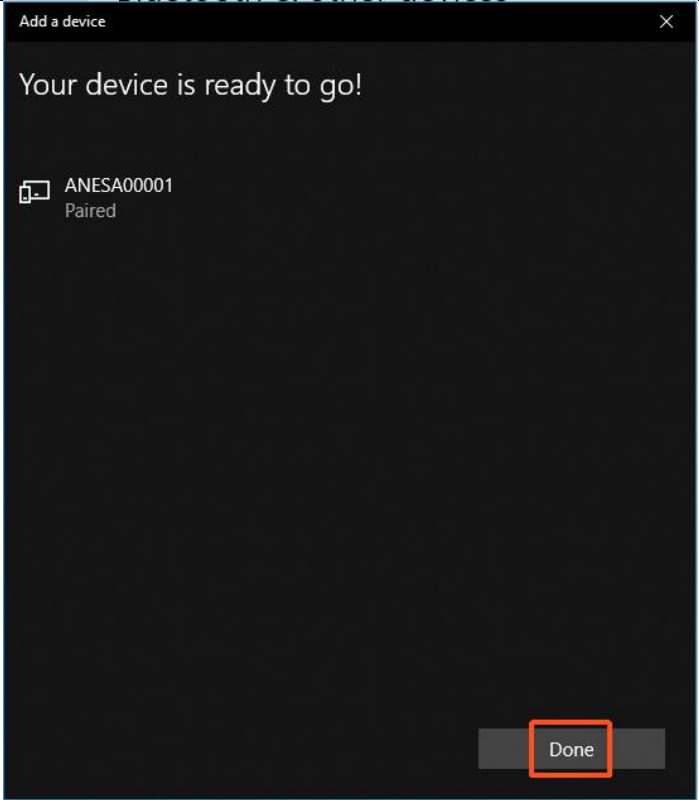
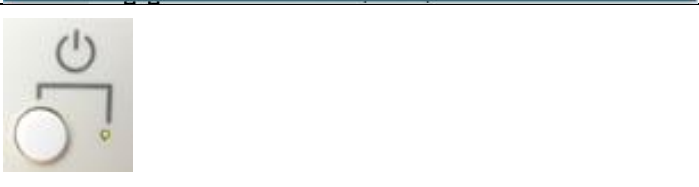
<p><u>Press and hold</u> the "POWER" button <u>at least three seconds</u>, till green LED stop flashing and light continuously or a backlight of the front panel of the medical device turns on.</p>	
<p>Run the software using the icon</p>	
<p>The indicator of USB connection will be displayed in the upper left corner of the software interface</p>	

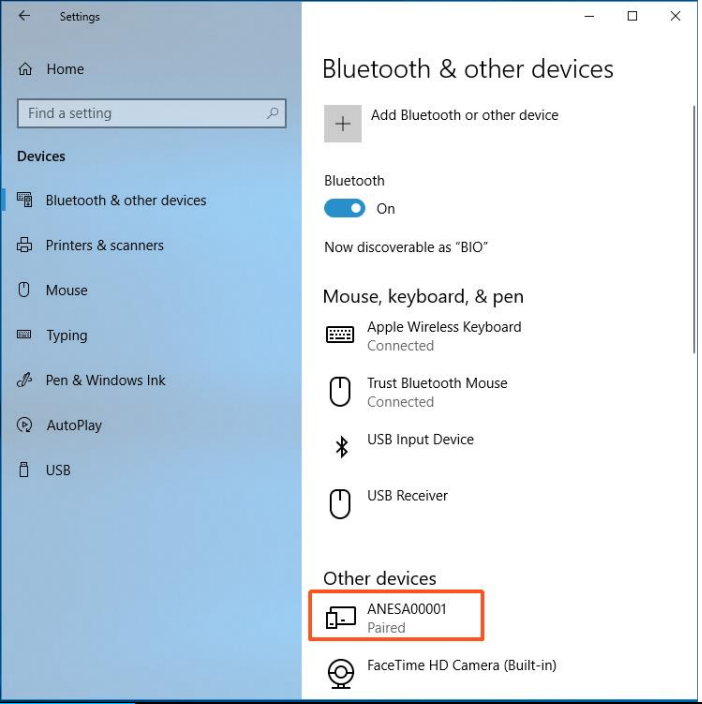

4.1.2 CONNECTING THE DEVICE TO A COMPUTER VIA BLUETOOTH (L/2019B)

<p>To turn on the device, please <u>press</u> and <u>hold</u> the "POWER" button <u>at least three seconds</u>, till green LED stop flashing and light continuously.</p>	
<p>Create the Bluetooth pair between the computer and the MD ANALYZER</p>	

<p>In the main menu of OS Windows, select the "Settings" menu</p>	
<p>Then, select the menu "Devices"</p>	
<p>Turn on Bluetooth and press "+ Add Bluetooth or other device"</p>	

<p>Select menu “Bluetooth”</p>	 <p>The screenshot shows the 'Add a device' window with the 'Bluetooth' option highlighted. The text below the option reads: 'Bluetooth: Mice, keyboards, pens, or audio and other kinds of Bluetooth devices'.</p>
<p>Add the device MD ANALYZER <i>(the serial number will be visible here)</i></p>	 <p>The screenshot shows the 'Add a device' window with the device 'ANESA00001' listed under the Bluetooth section. The text above the device list says: 'Make sure your device is turned on and discoverable. Select a device below to connect.'</p>
<p>The window with a request for a password will be displayed</p>	 <p>The screenshot shows the 'Add a device' window with a PIN entry prompt for device ANESA00001. The text says: 'Enter the PIN for ANESA00001.' There is an empty input field and 'Cancel' and 'Connect' buttons.</p>
<p>Enter password: 1234 and press “Connect”</p>	 <p>The screenshot shows the 'Add a device' window with the password '1234' entered in the PIN field. The 'Connect' button is highlighted with a red box.</p>

<p>If the password was entered incorrectly or you did not enter it for a long time, the following message will appear: Try to connect your device again.</p>	
<p>In the lower right corner of the Windows interface, the message is displayed: "The device is ready"</p>	
<p>Click "Done" to continue.</p>	
<p>If the pairing of the MD ANALYZER and the computer via the Bluetooth channel is successful, the blue LED (under the sign of Bluetooth) on the front panel of the device will light up.</p>	

<p>To check the correct connection of the device to the computer, use the setting menu of OS Windows. The MD ANALYZER with its serial number will be listed in the appropriate list of Bluetooth devices.</p>	
<p>Run software using the icon</p>	

4.2 QUALIFICATION OF AN OPERATOR. REQUIREMENTS FOR AN OPERATOR



While using the Analyzer, an operator/user should be healthy and in normal emotional mood (at least rested).



The operators/user, who took psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol during at least 24 hours before working with the Analyzer are prohibited from using the Analyzer.

The MD ANALYZER is intended to use by educated certified medical professionals, with a medical background, who are additionally trained as for proper operation with the Analyzer. Nowadays, the MD Analyzer is not intended to use by operators with limited physical and cognitive features, such as disorders of sight, hearing, speech and motor function, as well as mental disorders, which impede proper performing of the screening diagnostic procedure.

Before start working with the MD ANALYZER, an operator/user should pass the training courses for proper operating with the device, which are conducted by representatives of the manufacturer or a local distributor. The following aspects are included into the training:

- Intended use of the device with practical exercises;
- Operation and functions of the device;
- Setting up of the software and hardware;
- Recommendations for the device use;
- Contraindications and possible side-effects;
- Explanation of warning labels on the unit and possible errors of operation (error windows in the software) with further troubleshooting;
- Method of functional control of the device.

Above mentioned aspects are contained in the basic training course. Some changes and additional items may be included into the course due to particular features of the region/country. The most detailed information about the content of training course is provided by the local distributor in a country/region by request.

In addition, following the manufacturer's recommendations (Chapter 1.5 and 2.1, 2.2), an operator/user should keep abreast of the latest developments and medical publications related to the non-invasive methods of diagnostics to obtain more comprehensive information on possible contraindications and side effects, which are not known at the time of the device's manufacturing.

5 FUNCTIONAL TEST OF MD ANALYZER

A physician should make functional test for the MD ANALYZER every day before start working with the analyzer. It is necessary to check, if the device works properly. The procedure of the functional test is the following:

- Prepare the analyzer, as it is described Chapter 4.1;
- Create a new patient with the name TEST (Chapter 8.4, 8.9) in the database. It is created just once and a physician uses the same record for everyday functional test all the time further;
- Fill in the information in the TEST patient's card: please note, that for functional test the figures/numbers has no matter, the only one requirement is to use the numbers in the allowed ranges for each field;
- Take all sensors into one hand and keep them during the process measurement (the measuring surface of sensors must touch the skin);
- Start measurement and wait while it is completed;
- If at the end of measurement, the window with parameters appears and the survey/report is generated, it means the device is able to work. In case of any troubles, appeared error windows and so on, please find the solutions in Chapter 14 of the present User's Manual or contact your distributor /the manufacturer for troubleshooting.
-

6 PATIENT POSITIONING



It is required to make an examination in the supine position, when a patient is calm, had no physical activity during 5-10min.


Before start measurement, a patient need to be placed comfortably on the couch or bed (recommended), laying on the back. Placement of sensors onto a patient's body should be convenient for a user/operator (free access to a patient's body).


The skin of a patient should be cleaned with alcohol wipes in order to remove deodorants, creams, dirt, etc. in those areas, where the microprocessors are to be fixed. A user needs to ensure that there is no influence of direct sunlight and airflow from air conditioning to a patient and the environment in the room meets the requirements of the present User's Manual (Chapter 2.1.)

7 STARTING WORK WITH USPIH: PERSONAL SETTINGS

The user's interface is available on 18 languages (Ukrainian, Russian, English, Chinese, Spanish, Hungarian, Slovak, Slovenian, Italian, French, Turkish, Croatian, Polish, Bulgarian, Japanese, Czech, Serbian and Vietnamese).

7.1 Run the software USPIH

7.1.1. Run **USPIH 10.X** clicking on the appropriate icon  on the desktop or tool bar. The main window of the software USPIH 10 will be opened.


7.1.2. Run **USPIH 9.X** clicking on the appropriate icon  on the desktop or tool bar. Software USPIH 9 will be opened after **Authentication**.



7.1.2.1. Primary Authentication includes the procedure of password setting (it is done only one time, during the first launch of the software USPIH 9). The field “Login” will be filled in automatically (serial number of the connected device will be used as login). A user couldn't edit this field. **A user shouldn't use any password for the first authentication**, so the field password will remain blank. Press button ENTER.

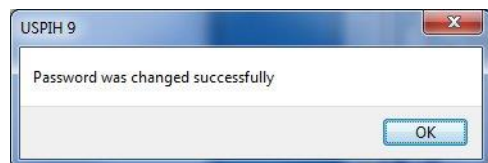
7.1.2.2. The main window of the software USPIH 9.X will be opened.

7.1.2.3. To set a personal password for further Authentication please use the menu “Change password”.

Press an icon  and fill in the field “New password” and repeat it in appropriate field, too (for the first time, during setting the password, leave the field “Current password” blank).



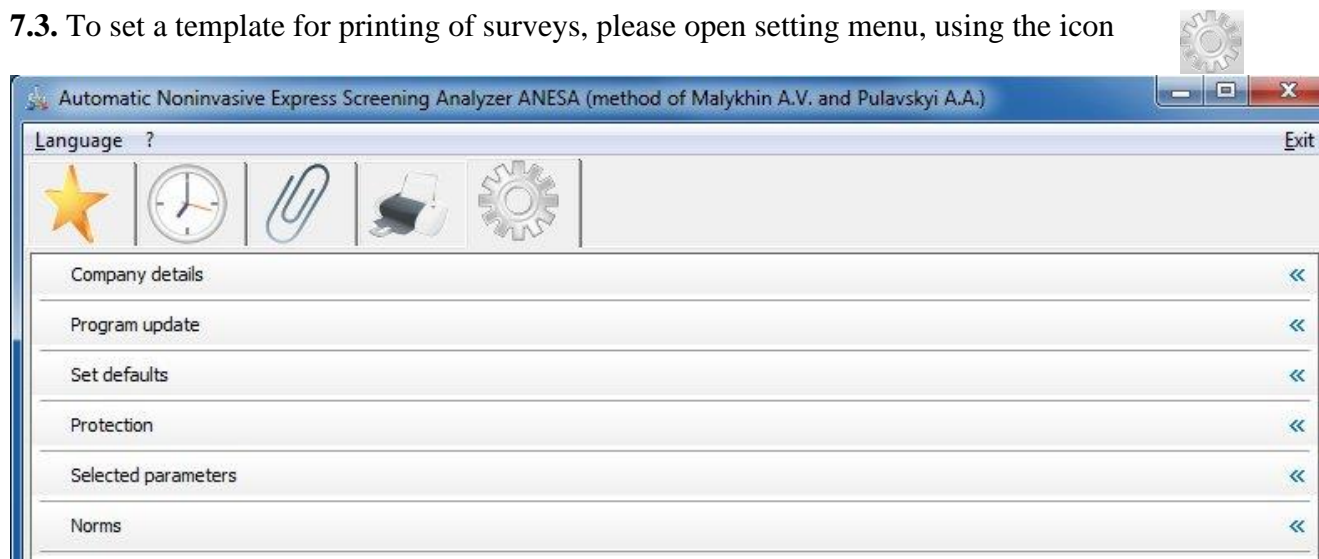
7.1.2.4. Successfully set password will be confirmed by an appropriate message



7.1.2.5. Further, Authentication is to be done with the password. Serial number of the device will be used as login automatically.

7.2. First time, USPIH will run in English. If you need to change the language, use an appropriate menu “Language” on the top.

7.3. To set a template for printing of surveys, please open setting menu, using the icon

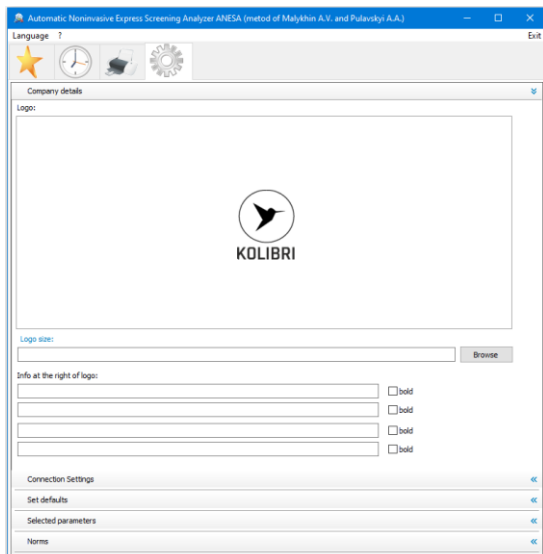


7.3.1. Sub-menu “*Company details*” allow adding and formatting the name of a company, it’s address and contact information, as well as a company’s logo: four spare fields are used for the details and one – for logo.

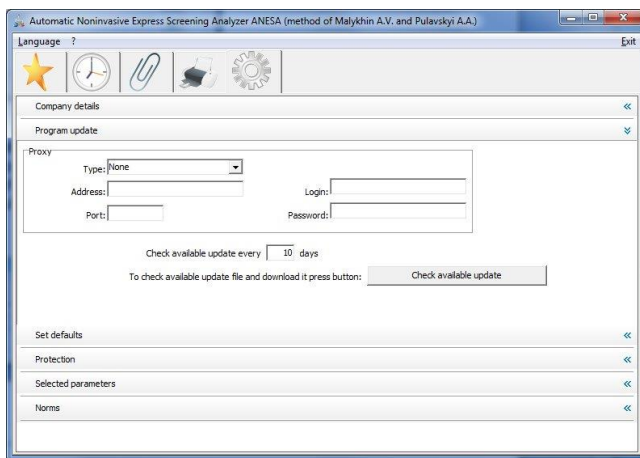
Logo image (click “Browse” and select a picture) must be in ***.bmp** format and its size cannot be smaller than 40x40 pixels.

Text may be edited (type, font, size, colour, etc.) using the appropriate icon near each field.

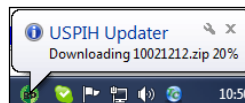




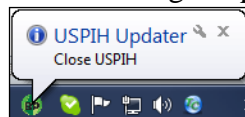
7.3.2. Sub-menu **“Program update”** includes the setting for the software’s updating. Software is updated via Internet automatically every 30 days (by default). It is possible to change the period of the updating manually. In case of necessity for immediate update, click the button "Check for Update."



You can follow up the process of updating on the bottom toolbar of your PC



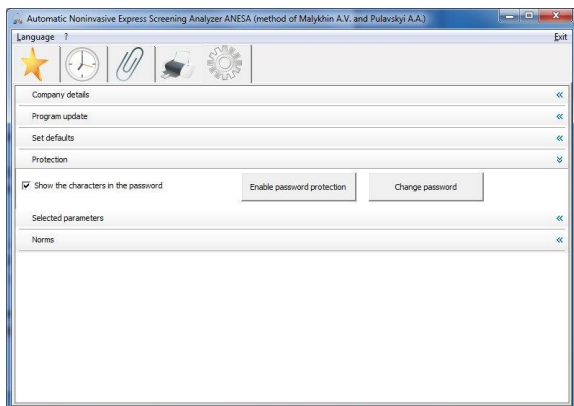
It is necessary to close the software USPIH after finishing the process of updating:



USPIH will launch automatically.

7.3.3. Sub-menu **“Set defaults”** is used to cancel a customer’s settings and return to the settings of the manufacturer. All settings return to initial ones.

7.3.4. Sub-menu **“Set protection”** is used for to prevent unauthorized deleting of patients’ records and surveys from the database. It allows activating protection of the software USPIH by using a personal password. **Users of the software USPIH 9 should keep in mind, that protection password is not the same as the password for authentication.**



To display the characters in the password checkbox, tick "Show characters in the password". To enable or change the password, press an appropriate button.

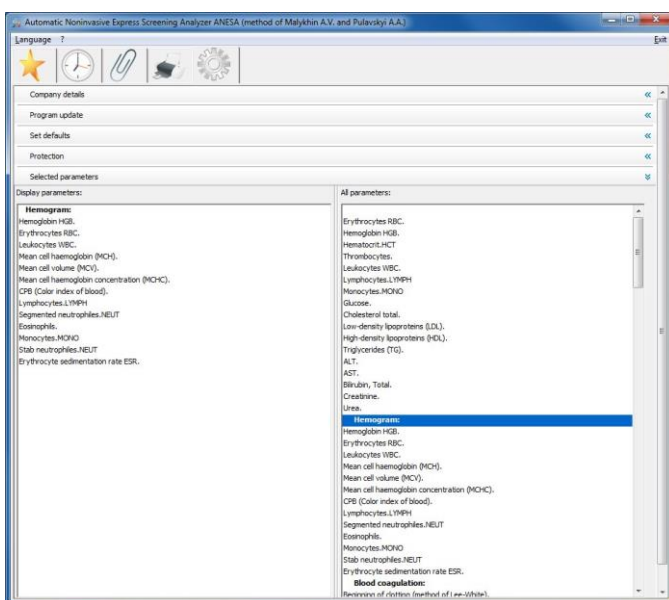
Enter a password, using 4-8 characters. The default password is "0000" (four zeros).

In case of changing the password, it is necessary to enter the old password and confirm it, by pressing the button "Yes." Then, a new password should be entered and confirmed by pressing the button "Yes" (the procedure should be made twice). If the changing of a password is successful, the message "Password is changed successfully" will appear.



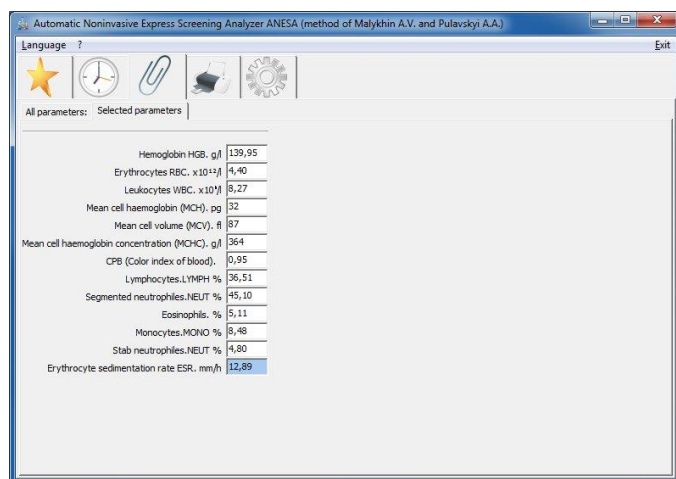
7.3.5. Sub-menu "Selected parameters" might be used if a physician would like to select some

of
is



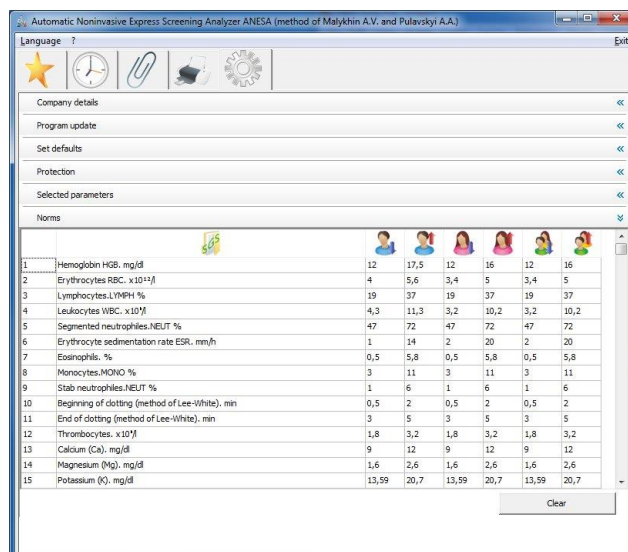
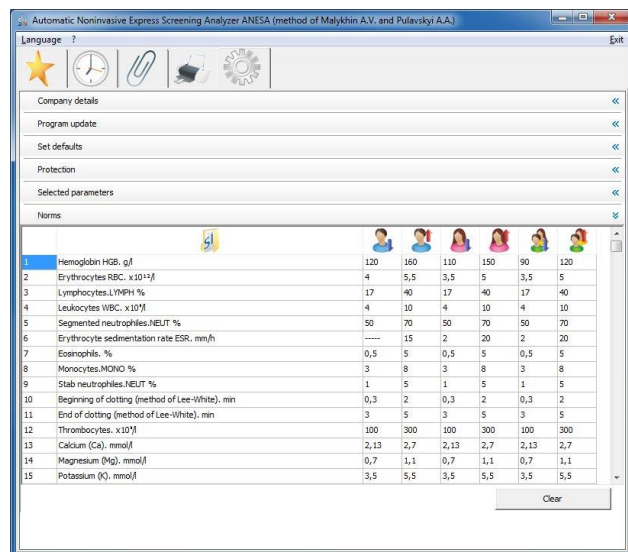
parameters or group of parameters for quick preview after measurement. There is the list all parameters, divided by group, in the right part of the window (All parameters). It necessary to double click on the name of parameter or the name of a group of parameters ('drag & drop' may be used, too). Highlighted parameter or group will appear in the left part of window (Selected parameters). An example below shows the selection of a group (Hemogram).

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.



Further, after each measurement, selected parameters will be displayed at first. It is possible to see all the parameters, choosing the appropriate tag "All parameters"

7.3.6. Sub-menu "Norms" is used for changing the normal ranges for each parameter (separated by gender and age) according to the commonly accepted ranges on the territory of usage. Normal ranges are

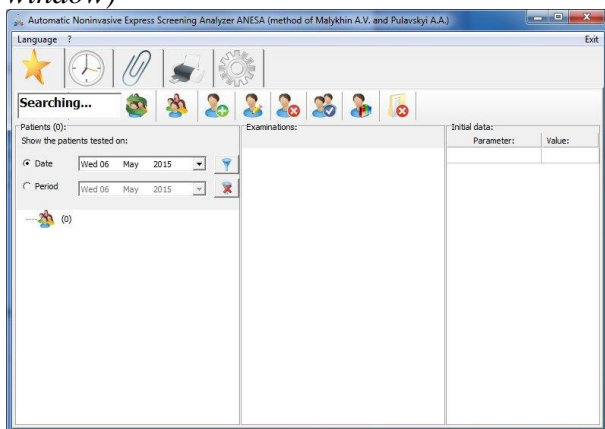


set for two systems of units: SI and SGS. It is necessary to click on the icon SI or SGS (above the list of parameters) in order to choose the units, which are going to be changed (name of the icon is changed after clicking, from Si to SGS and vice versa).

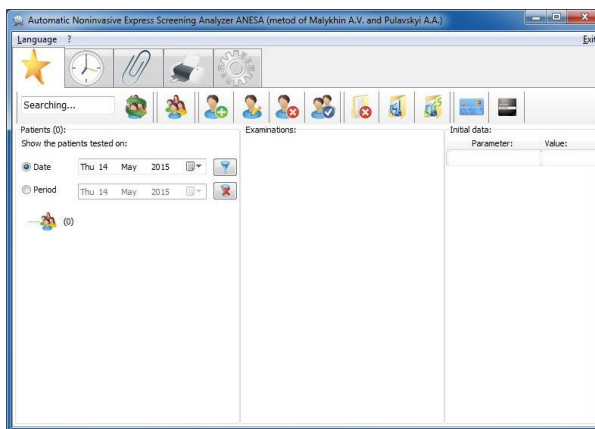
8 WORKING WITH THE SOFTWARE USPIH

Interfaces of both versions of software USPIH 10 and USPIH 9 are similar.

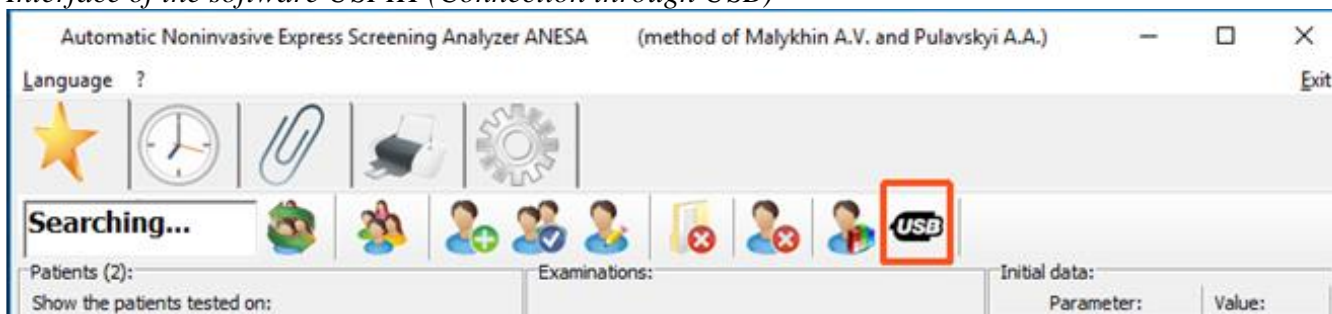
Interface of the software USPIH 10 (main window)



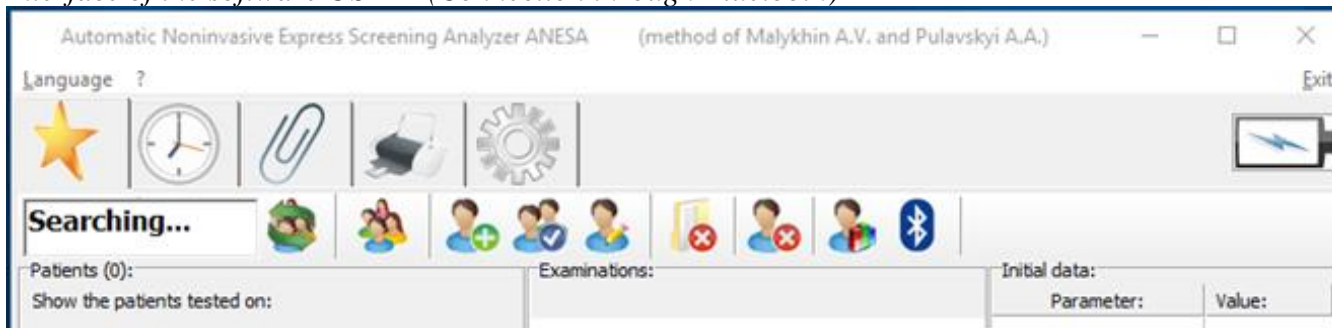
Interface of the software USPIH 9 (main window)



Interface of the software USPIH (Connection through USB)



Interface of the software USPIH (Connection through Bluetooth)



8.1 Description of the interface items, used in both versions of the software (10 and 9):

8.1.1 The top menu contains three parts

"Language"

To choose/change the language










"?"

To open help file and information about program

"Exit"

to exit the program

8.1.2. The second-level menu consists of 5 icons:

								
main window/ starting window	graphic trends and checking panel for temperature measuring	results of measurement	preparing of a survey for printing or saving	settings	Battery charging indicator	Battery level indicator.	Indicator of connection mode: the device is connected to a computer via Bluetooth	Indicator of connection mode: the device is connected to a computer via USB

8.1.3. The third-level menu contains searching box and other icons (described below).

Search Box – is intended for searching patients or patients’ groups. It is necessary to enter the initial letters (minimum 3) of a patient’s name or group name and the program will offer patients and groups containing the similar combinations of letters.



Groups of patients



Add a new patient



Edit a patient’s data



Delete a patient from database



Merge surveys of patients



Dynamic changes of selected parameters (not available for USPIH9)



Deleting of a patient's survey from database

Detailed description of each sub-menu from the 3d-level is on the Chapter 7.3

8.1.4. The main window of the software includes the following information:

A list of patients/groups

Filter for selecting patients according to the date of examination: it is possible to choose an exact date of examination or possible period of time, when the examination might be done.



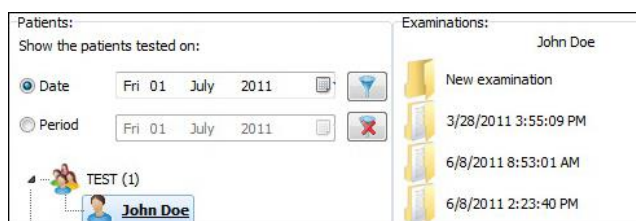
Filter is activated after pressing the icon



Filter becomes non-active after pressing the icon



Part “Examinations” shows existing surveys for a chosen patient and/or icon “New examination”, which can be used for a new test (*description of a new examination is on the Chapter 8.9*).



Part “Initial data” concerns the selected examination of the patient and contains initial information about the patient, measured temperatures, air pressure and temperature stabilization indicators:

Examinations:		Initial data:	
Jane Doe		Parameter:	Value:
New examination		Sex:	female
02/02/2011 17:21:41		Age:	77
04/02/2011 11:18:11		Weight:	77
		Pulse:	77
		Resp.rate:	18
		LCA:	31.1
		RCA:	30.63
		LAC:	30.38
		RAC:	30.76
		ABD:	30.34
		Atm.pres:	753.65
		Stabilizing:	99999

Stabilizing “99999” means the temperatures during measurement fully stabilized (100%).

Stabilizing “00000” means the temperatures didn’t stabilize during measurement.



IMPORTANT! FOR CUSTOMERS, WHO USED USPIH ver.6 and START USING USPIH ver.10!

Old software (USPIH ver.6) didn't contain information about stabilization of temperatures. That's why, after converting database of patients from the software USPIH 6 to version USPIH 10, stabilization of temperature will be "00000" for all of the converted data

8.2 Description of the interface items, which are specific for USPIH 10 or USPIH 9.

USPIH 10



Dynamic changes of selected parameters

USPIH 9



Request for a report in the SI units

USPIH 9



Request for a report in the SGS units

USPIH 9



Request for balance

USPIH 9



Changing a password of Authentication

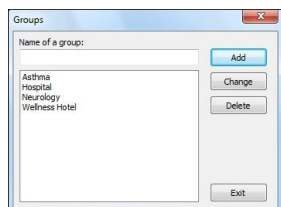
Detailed description of each sub-menu from the 3d-level is on the Chapter 7.3

8.3 Groups of patients

For the convenience of usage, the patients in database can be divided into groups. It is necessary to use



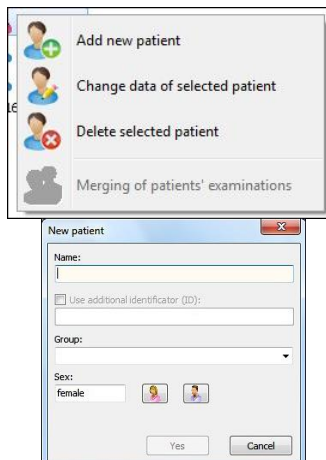
icon for creating a new group, editing or deleting an existing one.



IMPORTANT! The software USPIH 10 will not allow an existence of two groups of patients with the same title/name.

8.4 Add/Edit/Delete a patient and/or examination

Adding, editing and deleting of patients can be done in two ways: using the icons from the 3d-level menu or using the context menu (right click by mouse on the list of patients/selected patient). Using icons are the same in both ways.



To **Add** a patient, press appropriate icon and fill in the required data 

It is necessary to fill in the name and surname of a patient, choose the group (if necessary) and gender in the appropriate fields. *In case it is necessary to identify a patient additionally, tick the appropriate window and add identifying information (e.g. ID, passport, social number, etc.).*

It is possible to select an existing group of patients from the drop-down list or create a new group (entering a new name). If the name of group is new in the database (doesn't repeat any existing one), the group will be created automatically. If the field “Group” remains blank, the patient’s record/card will be placed in general list of the database (outside of any group); such patients will be listed after all the groups.

For gender selection (male or female), click the appropriate button.


After confirmation of adding a new patient (button “Yes”), the patient’s card will be displayed in appropriate group or in general list.




To **Edit** the information about an existing patient, it is necessary to select a patient and press appropriate icon in the main or context menu.



IMPORTANT! After changing the gender of a patient, all the surveys of this patient will be changed/ recalculated automatically, according to the renewed gender information.

To **Delete a patient’s card**/record from the database, it is necessary to select a patient’s card from the list of patients and then click an appropriate icon in the main or context menu 

In case the password protection is activated, enter the valid password in the appeared window (the default password is “0000” (four zeros)).

Merge surveys of patients 

The program USPIH 10 allows merging the patient’s surveys under the same name. It is useful in case the same patient was added to the database several times (with differences in the name or surname, e.g.

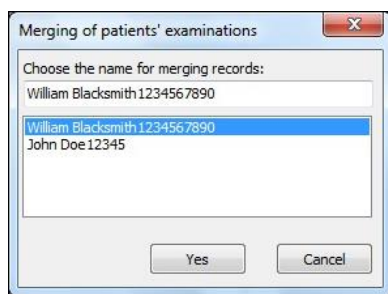
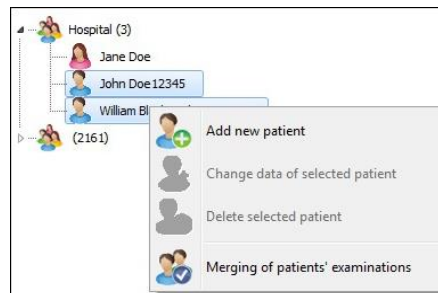
John Doe, John D., J. Doe). So, his or her surveys can be merged under single name. This option is available just for patients with the same gender. It can be done in the following way:

highlight the record with required name of a patient (which you want to merge with another);

hold down the button «Control» (Ctrl) on the keyboard and select another record (if the patient was saved several times, select a few records);

click an appropriate icon in the main or context menu

in the appeared window, select the preferred name of the patient. Click “Yes” to continue or “Cancel” to exit.



Finally, there will be one patient with several surveys in the database.



Attention! After merging the surveys, IT IS IMPOSSIBLE TO SEPARATE them back to its original state!

Deleting of patients' surveys from the database can be done in the following way:


Select an examination, which should be deleted and click an appropriate icon in the main menu



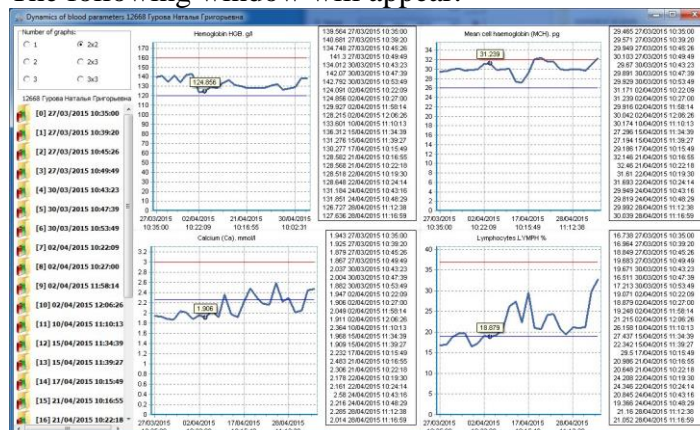
Right-click on the examination also allows choosing the same option “Delete Selected survey.”

In case of password protection is activated, enter the valid password in the appeared window (the default password is “0000” (four zeros)).

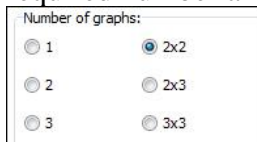
8.5 Dynamic changes of selected parameters (only for USPIH 10)

This option allows displaying the dynamic changes of selected parameters (graphically) for a patient,  who was examined several times. For that purpose, it is necessary to choose a patient and press appropriate icon in the menu.

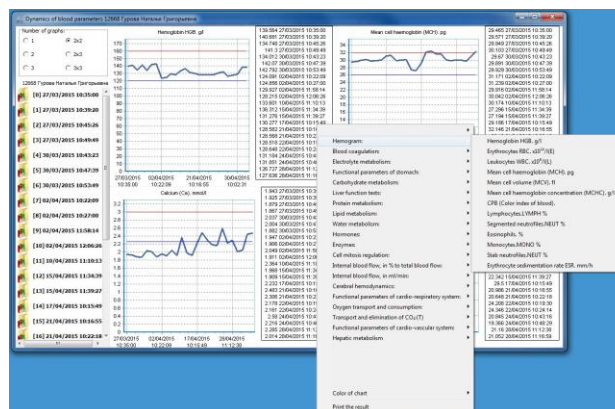
The following window will appear:



In the “number of graphs”, you can choose the required number and location of diagrams:



To add required parameters to each diagram field, it is necessary to put cursor on a field of diagram and call context menu (mouse right click). In the drop-down list, select the group and then the parameter, which should be displayed on the diagram.



X-axis of the graph shows the time of the examination, Y-axis shows the value of chosen parameter.

When the cursor is placed on a dynamic curve, the value of parameter in the point is displayed in a pop-up hint.

By default, all examinations of the selected patient are represented in the list of examinations for comparison. They are displayed in the left part of the window. To exclude an examination from the list, click the left mouse button on the date of a survey you don't need (it will be removed from the list of comparison).

Color of curves can be chosen for diagrams using the context menu (right click of mouse and appropriate menu at the end of drop-down window). The selected color is automatically saved.

To exit the menu, press „X” in upper right corner.

8.6 Request for a report from the server (only for USPIH 9)



SI units



SGS units

A user needs to use the above icons to receive a report from the server in preferred units.

8.7 Request for balance - available number of examinations (only for USPIH 9)



A user can check the personal balance any time (balance means the remained amount of examinations, which have been paid). The number of remaining examinations is reduced after each request for a report from the server automatically.

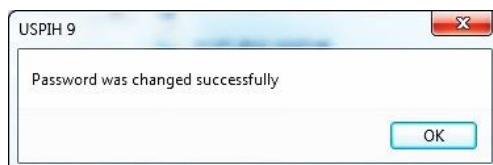
It is important! In case a user repeats the request for a report, which has been already done before, the balance will not change (e.g. a user received the report in SI units for a patient, and he'd like to get the same report in SGS units. He needs to send the request for one patient twice. Balance will be reduced just one time). Other words, the repeated request for the report, which was done earlier, is free of charge.

When the balance becomes zero, requests for reports will not be processed. Please contact the distributor in your region for replenishment of the account.

8.8 Changing a password of Authentication (only for USPIH 9)



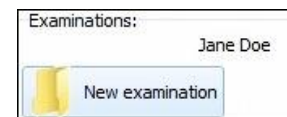
The password for a user's Authentication can be changed with this button. To change a password, a user should press an appropriate button. The following window will appear.



It is necessary to fill in the existing password in the field «current password» and then put the new password and repeat it in the appropriate field. If the password is changed successfully, the following window will appear.

8.9 Create new examination (for existing patient or for a new one)

Select a patient from the list of database in the main window and click the icon “New Examination”:



In the window that appears, enter the initial data of the patient:

<i>Data</i>	<i>Units</i>	<i>Description</i>	<i>Valid range</i>
<i>Age</i>	<i>years</i>	number of full years	18-100
<i>Weight</i>	<i>kg or lb</i>	weight of a patient in kg or lb	40-200 kg 88-441 lb
<i>Heart rate/Pulse</i>	<i>beats/min</i>	number of heart beats per 60 sec	30-250
<i>Respiration rate</i>	<i>Insp/min</i>	number of inspiration per 60 sec	5-50

A physician determines a patient's heart rate manually, putting his/her fingers to the pulsation area. A patient should be calm; supine position is required. Measurement should be done carefully. In case of problems with definition of the heart rate (especially with 100 or more beats per minute), we recommend to use a heart rate monitor, e.g. POLAR (Finland) or similar.

Stopwatch, which may be helpful for measurement of heart rate, is located in the bottom left corner.

Clicking on the stopwatch will start time count 00:00. Another click on the stopwatch will stop time count and reset it.

9 DESCRIPTION OF MEASURING PROCEDURE

The work is started by adding a new patient (Chapter 8.4) or choosing the existing one from the database and creating the new examination (Chapter 8.9)



It is required to make an examination, in the supine position, when a patient is calm, had no physical activity during 5-10min, (User's Manual, Chapter 6).

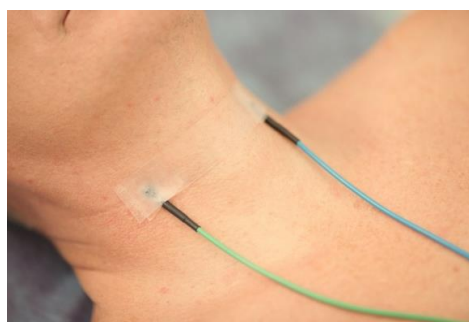
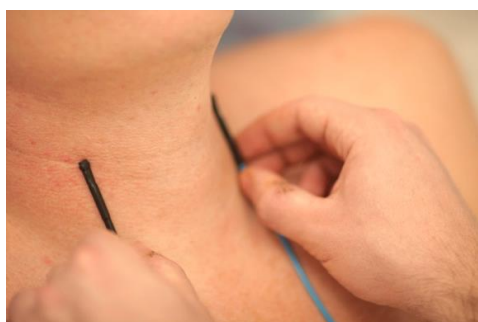
Five microprocessors (sensors) should be placed on the definite biologically active points (skin in the areas of sensors' placing should be cleaned and degreased previously using alcohol wipes; sensors must be disinfected with alcohol wipes, too) according to the following instructions:

Carotid sensors

Blue - in the area of the carotid artery bifurcation (on the external and internal) on the **left** side, in the area of cricoid (LCA)



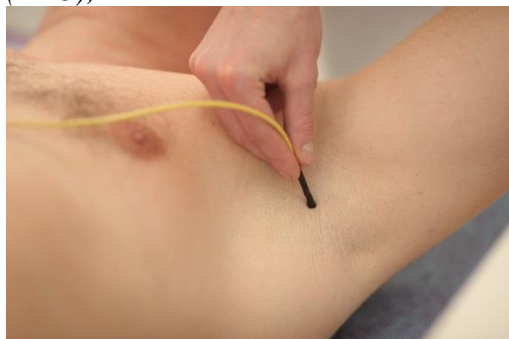
Green - in the area of the carotid artery bifurcation (on the external and internal) on the **right** side, in the area of cricoid (RCA)



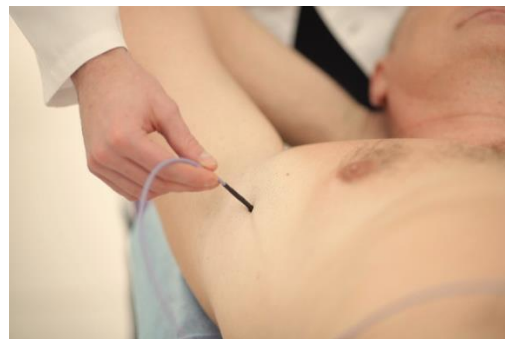
The point of carotid bifurcation is to be found manually: the most intensive pulsation will be in the point of bifurcation. From the position of anatomy, approximately, the point of carotid bifurcation is located between sternocleidomastoid muscle and trachea (middle of distance), at the level of C3 and C4 cervical vertebrae, on the level of thyrohyoid membrane (approximate horizontal line), when both points are parallel to trachea (vertical line). In men, this line is often located on the level of Adam's apple. Women often has got crease on this level. Sensors should be fixed by plaster.

Axillary sensors (armpits)

Yellow - on the **left** armpit in axillary area (LAC);



Purple - on the **right** in axillary area (RAC)

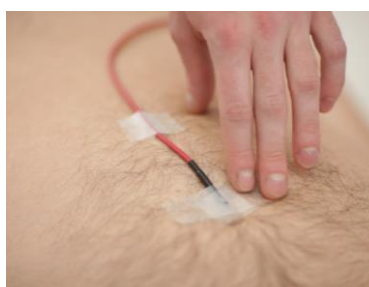
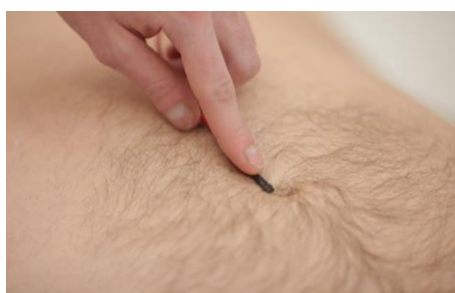


Each of the axillary sensors should be placed in armpits, at the top of axillary crease (as the axillary artery passes in this area close to the skin) according to a color identification. The sensors should be

in a continuous contact with the skin during the process of measurement (if necessary, a sensor may be fixed by plaster).

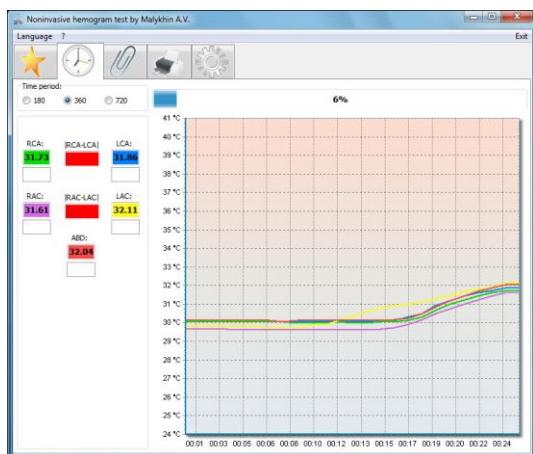
Abdominal sensor

Red - in the abdominal area (**umbilicus/navel**) (ABD)



Abdominal temperature (umbilical) is measured in the area, where aorta, inferior vena cava and large lymph vessel are crossed. Pulsation is felt manually in the cross-point of vessels. Sensors should be fixed by plaster.

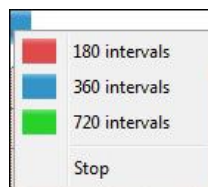
Process of measurement is run after pressing the button "Start measurement" in the software USPIH. Information processing takes 180-720 seconds, depending on a patient's state. After starting, a physician follows up the process of measurement and controls if the process is going in a right way, using progress bar and temperature graphs (color of each graph corresponds to color microprocessors on a body):



The interval of measurement can be 180, 360 or 720



seconds (by default, it is 360 seconds). It can be changed before and during an examination in the "Time period" menu

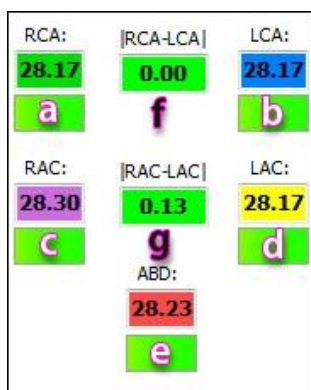


or in drop-down menu, which appears after right-click on the progress bar. The measurement can be stopped using this menu, too



ATTENTION! The accuracy of measured results by the MD ANALYZER depends on accurate process of temperature measurements. That's why, the software interface includes visual indicators, which help a physician to determine the time of temperature stabilization and control the process of measurement!

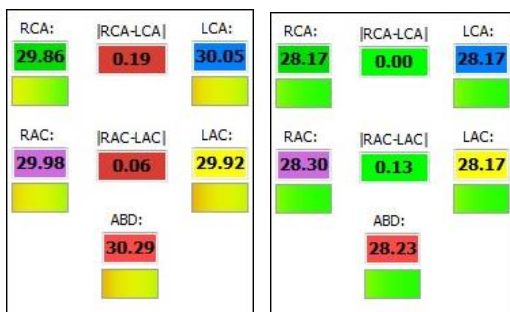
The indicators are the following:



a - an indicator of temperature stabilization on the right side of carotid artery bifurcation
b - an indicator of temperature stabilization on the left side of carotid artery bifurcation
c - an indicator of temperature stabilization in the right armpit (in axillary area)
d - an indicator of temperature stabilization in the left armpit (in axillary area)
e - an indicator of temperature stabilization in the abdominal area (umbilicus)
f - indicator of the temperature difference between left and right side of carotid artery bifurcation
g - indicator of the temperature difference in armpits

At the beginning of measurement all indicators are red. After 30 seconds, the software starts to analyse temperature stabilization.

The colored rectangles, containing the values of temperature, have the same color as the corresponding sensors. The color of indicators a, b, c, d, e varies from **red** (the temperature is not stable) to **green** (stabilized temperature) during the process of stabilization. Each indicator shows the process of stabilization of an appropriate sensor.



Temperature is considered stable, if it doesn't change more than 0.15°C during 40 seconds.

Indicator **f** shows the temperature difference between bifurcation points of left and right carotid arteries; usually (for a healthy person) it should not exceed 0.5°C.

Indicator **g** shows the temperature difference between left and right armpit (for healthy person), usually it should not exceed 0.5°C.



IMPORTANT! Indicators **f** and **g** are very important for a physician during test. They are used as control instruments and give the information, if the test is going right and chosen time interval is enough for testing.

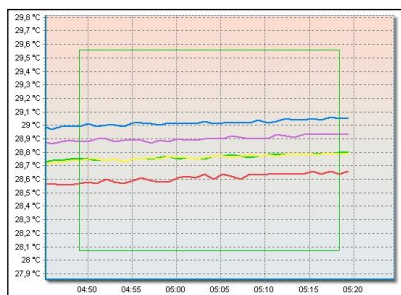
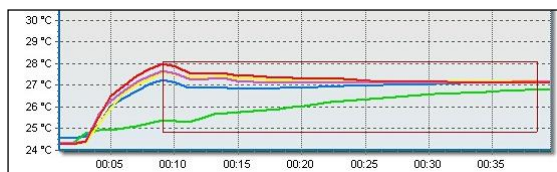
If the difference between armpit sensors does not exceed 0.5°C, as well as carotid sensors, and temperature of all sensors (including sensor of abdominal area!) stabilized, the indicators become green, otherwise - red.



IMPORTANT! If the rectangles below temperature values are not green till the end of measurement, a physician should change time interval to the larger one.

Colour "floating window" will appear over temperature graphs in 40 sec. after starting measurement. The window will have a red border, if stabilization of temperatures is not achieved. When temperature values stabilize, the "floating window" becomes green. This is another **important control issue during measurement**.

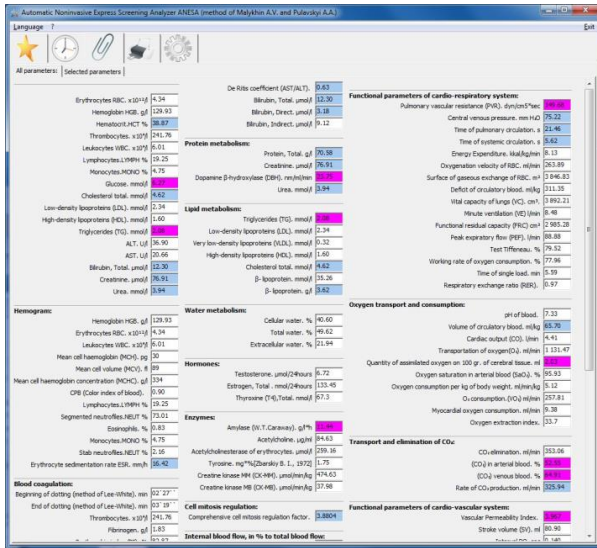
It is possible to zoom the graph by selecting the necessary area with a mouse.



To return the graph to its original position, please hold the left mouse button and drag it across the field chart from right to left.

9a. Results of measurement in USPIH 10

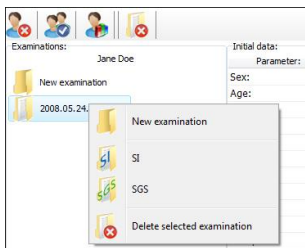
When the measurement is finished, the next window „**Results of measurements**” opens automatically. By default, the tag „All parameters” is displayed. In case a user has selected some parameters for quick preview in the setting menu (Chapter 7.3.5), the tag „Selected parameters” will be displayed at first.



- **Red** color of field means that the parameter is higher or lower than the generally accepted norms;
- **Blue** color of field means that the parameter complies with generally accepted norms;
- **White** color of field means that the parameter is not compared with the normal ranges by the software;
- **Yellow** color of field attract a physician's attention to the parameter.

When a physician put the cursor to any value of parameter, the pop-up hint with normal ranges for this parameter will be displayed.

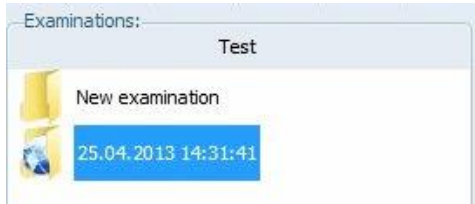
Program USPIH allows generating of surveys in two types of units: SI or SGS. To choose/change the units, use right-click on the examination of a patient and select the required units:



REMEMBER! There is no person in nature, whose parameters comply generally accepted norms totally. The norms were defined for average person (with average weight, height, age etc.). Definition of norms was done on relatively small population in a limited area many years ago.

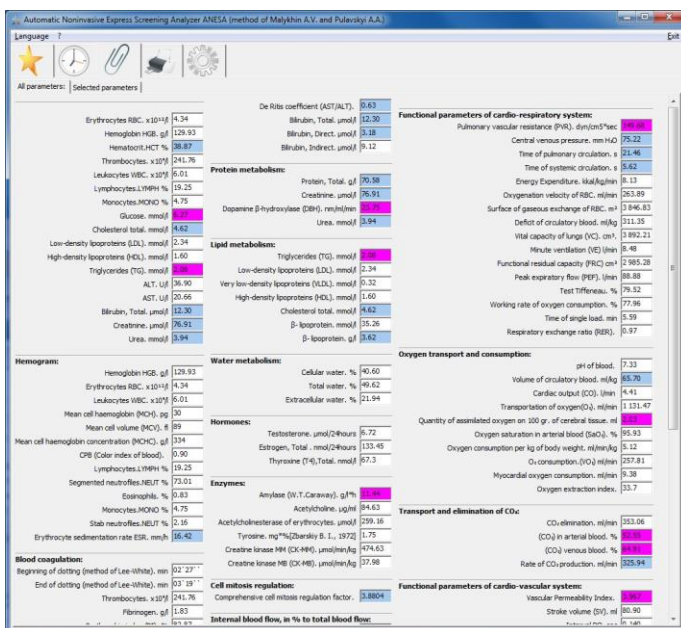
9b. Results of measurement in USPIH 9

When the measurement is finished, initial data of measurement will be displayed and recorded (using the date and time of testing) automatically:



To receive the report with parameters of organism, a physician needs to send the measured data to the server for processing, by clicking on the appropriate icon (Chapter 8.2, 8.6). The report with more than 100 parameters will come back in several seconds (time of response depends on the speed of user's Internet).

The window with „**Results of measurements**” opens automatically, when the report comes from the server to a physician's computer.



To prepare the surveys for **printing or saving**, please use the appropriate icon.






There is an automatic conclusion for a physician to help him/her with diagnosing a patient (it is displayed in the left bottom corner and printed in the beginning of a survey). The physician may agree with it, edit it or delete it (at all or just some part). It is possible to cancel printing of an automatic conclusion at all (using a tick near the window with conclusion).


In the right bottom corner, there is a field for notes (e.g. patient's history, results of additional tests, prescribed medicines etc.), which can be used by a physician if necessary.



ATTENTION! Only a physician can set the final diagnosis/diagnoses for a patient! The program's conclusion is generated, based on the list of diagnoses, which are recorded in the software's algorithm. software does not know all the nosologies!!

There is the possibility to hide some parameters/group of parameters for printing version of survey (use an icon  and/or  for that purpose; ticked parameters will be printed out).

To save the edited survey as html-file, click on the icon . File will be generated for saving; the name of a file will contain the name of a patient, date and time of examination. To print out the survey, click

on the icon .

9.1 COUNTING THE NUMBER OF SURVEYS (FOR LIMITED VERSION OF MD ANALYZER, USPIH 10)

According to the distributor's requirements, Guardant Stealth II protection key may be used for limiting the software usage (available for version 10). The limited version of the software allows examining definite (previously programmed) number of patients.

Local distributor is responsible for updating of available limits or upgrading of the software to unlimited version (according to the arrangements between the distributor and a user).

Any user of limited version of the software is able to control the remaining quantity of tests personally, without any additional charges. Such information is displayed in the Help menu (use icon "??" from the top menu and choose "About software"):

Number of remaining tests is mentioned in the last sentence (it is 148 tests in the example above). In case the software is unlimited, the icon of infinity "∞" will be displayed instead of figures.



Serial number of the device: ANESA00000
Number of tests: 500



IMPORTANT! If the number of remaining tests becomes zero, it will be impossible to examine anybody else. To update the limit of tests, please contact your distributor .

10 SWITCHING-OFF MD ANALYZER

1. Close the software USPIH.
2. Shut down the computer.

3. Disconnect a USB cable between the computer and the MD ANALYZER (for ANESA-L / 2007, ANESA-L / 2012, ANESA-L / 2012w, ANESA-L/2019).
4. Carefully disconnect the cable with microprocessors from the MD ANALYZER.
5. Disconnect the Guardant Stealth II key from the computer (for ANESA-L / 2007 models, ANESA-L / 2012, ANESA-L/2019, ANESA-L/2019B).

Switching off the device is completed.

11 SOFTWARE INSTALLATION

11.1 Analyzers with Tablet PC (ANESA-T/2011) are equipped with pre-installed software USPIH 10.

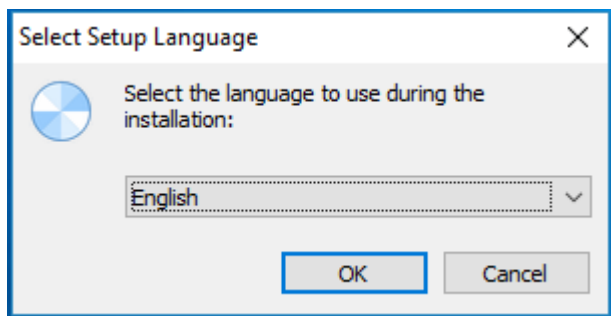
11.2. Analyzers ANESA-L/2007, ANESA-L/2019, ANESA-L/2019B and ANESA-L/2012 require installation of the software USPIH, version 10 or 9. Before installing the software USPIH, please make sure that your computer has three available USB ports and you have got the rights of "Administrator" in Windows OS (Windows Vista, 7,8 and higher).

11.2.1 The **installation** procedure for the software **USPIH 10** and **USPIH 9** is the same:

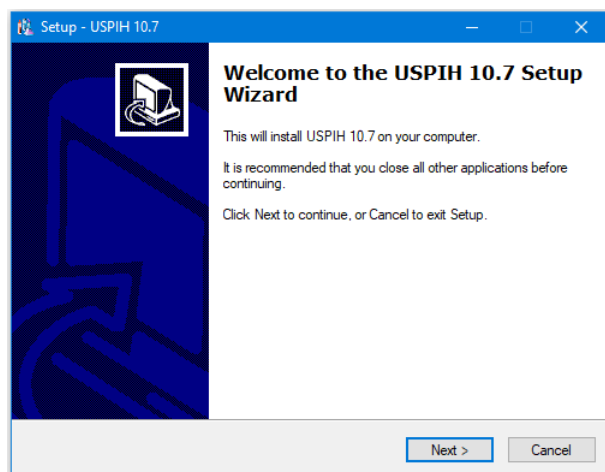
11.2.1.1 Download an installation file for the software USPIH 10, using the appropriate link, mentioned in the Technical Passport for the device or open your Internet browser and write an address by yourselves in the following way:

[https://analizator-amp.com.ua/Update/XXXXXX/setup_USPIH_10\(XXXXXX\).exe](https://analizator-amp.com.ua/Update/XXXXXX/setup_USPIH_10(XXXXXX).exe) where XXXXXXXX is the serial number of the MD ANALYZER) or USPIH 9 (the installation file is free for downloading on the web www.anesa.biz) and run the file.

11.2.1.2 Select the language for the installation and click "OK":

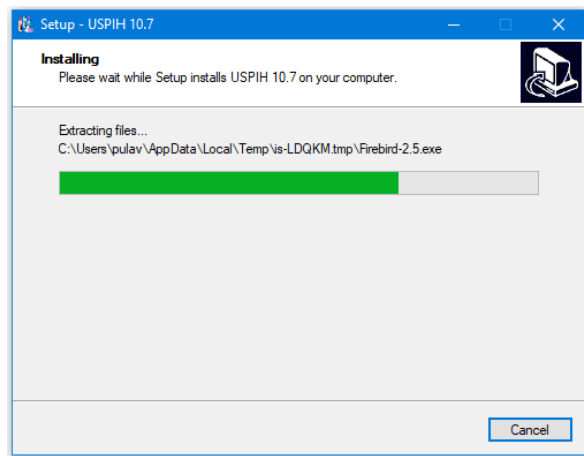
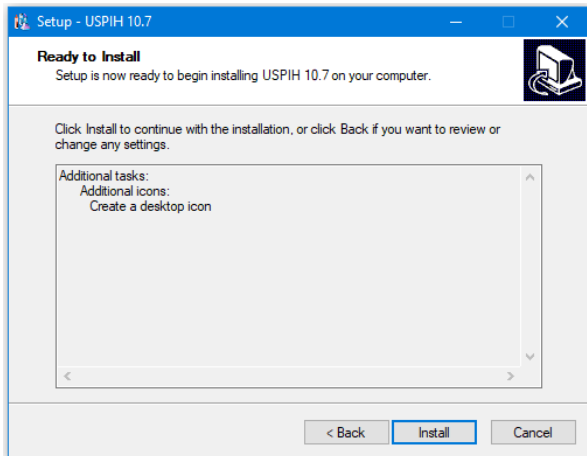


11.2.1.3 In the appeared window, click „Next”:



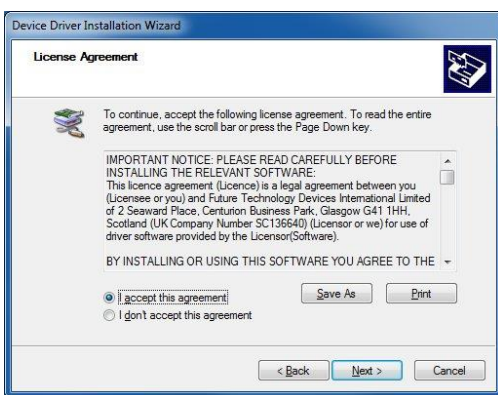
11.2.1.4. In the appeared window, tick „Create a desktop icon” and click „Next”:

11.2.1.5. Press “Install” and wait till the software is installed on your computer:



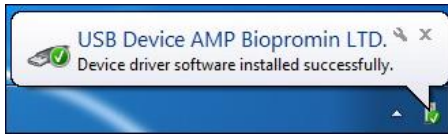
11.2.1.6. If the software is installed for the first time, **do not launch** it after installation (because the drivers for the device has been not installed yet):

11.2.1.7. Install FTDI CDM Drivers



Wait until MD ANALYZER drivers are being installed, too.

If the drivers' installation is successful, the following message will appear:



Depending on the software version, which you've installed, the

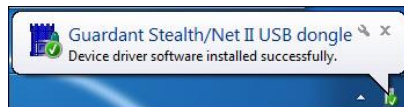
appropriate icon will appear on your desktop



or



The model **ANESA-L/2007**, **ANESA-L/2019**, **ANESA-L/2019B** requires **Guardant Stealth II** key for working. After connecting the Analyzer and successful installation of the drivers, it is necessary to connect Guardant Key to your computer. Windows OS will detect it and install the drivers for key automatically. The following window will appear:

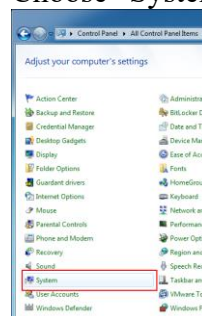


In case of any incorrect installation of drivers, please do the following:

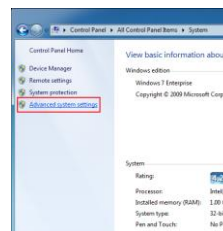
Open "Control Panel"



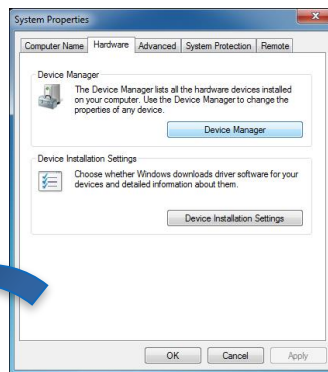
Choose "System"



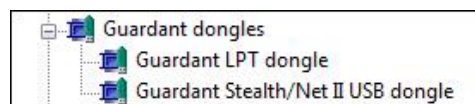
Choose advanced system settings



Choose Hardware tab and
Device Manager



Check if both key entries
are listed



If only LPT device is listed, please contact the official service (manufacturer).

12 SOFTWARE USPIH 9 AND USPIH 10: FEATURES

Installation file for the software USPIH is supplied by Internet and can be downloaded using the link, mentioned in the technical passport to an Analyzer. Prior to use the Analyzer, it is necessary to install the software to PC. During installation, the new directory will appear on hard drive, containing following files (C:\Program Files\USPIH 10):

USPIH.exe – real time control application;

PATIENT.FDB– database files;

update.exe – application for the software update;

DBConverter.exe – application for the database conversion;

FTDI, FTClean, Drivers – folders with PC interface drivers;

Other files and libraries, which are necessary for operation of the software (such as Bt.dll, BtH.dll, fbclient.dll, etc)

Nowadays, the manufacturer offers two versions of the software USPIH: version 9 and version 10. Main features of both types of the software are the following:

Features	Version 9	Version 10
Local module of mathematical processing	-	+
Server module of mathematical processing	+	-
Billing of measurements	+	-
Restrictions of operability according to the territory of usage	+	-
Local database	+	+
Reports are generated in SGS units	+	+

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

Reports are generated in SI units	+	+
Multilanguage interface	+	+
Graphical display of the measurement process	+	+
Automatic update	-	+
Manual update	+	+
Internet access for processing of measured data	+	-

13 EXAMPLE OF A SURVEY

EXAMPLE OF A REPORT/SURVEY

generated by the noninvasive screening diagnostic device MD Analyzer
after an examination of a patient

[Name/ contact info/ logo of the company-user]

[Patient's Name/Surname/ID]

[Date and Time of examination]

Gender: male Age: 48 Weight(kg): 86 Pulse: 81 Resp.rate: 18 Atm.pres: 752,71

LCA: 35,14 RCA: 34,76 LAC: 36,36 RAC: 36,1 ABD: 33,89 176,25 99999

Preliminary computer conclusion about possible pathologies:

Asthenic-autonomic syndrome is determined. Protein S100 should be monitored. It is necessary to get a consultation of a gastroenterologist (Gastroduodenitis should be verified). Distinct reduction of leucocytes is determined. Hypochromic anemia is defined. It is recommended to get the consultation of hematologist, gastroenterologist, oncologist. Spinal osteochondrosis is defined. Disorders of water-electrolytic metabolism is determined. Ca of plasma is changed (Ca of bone tissue). Increasing of enzymes activity (aspartate transaminase, alanine transaminase) is determined. Hypertension of pulmonary circulation is defined. Width of the third ventricle of cerebrum =6,11. Derangement of oxidative phosphorylation is determined. Activation of lipid exchange is determined. Reduction of amino acid synthesis is defined (tyrosine, glutamine). Impact of ethanol should be verified. Dopamine β -hydroxylase (DBH) =21,8

Disclaimer.

The above medical information is provided as an resource only and is not to be used or relied on for any diagnostic or treatment purposes. This information is not intended to be patient education, does not create any patient – physician relationship, and shouldn't be used as a substitute for professional diagnosis and treatment. Any health decisions or guidance about specific medical condition are to be made only by Doctors or health care providers. In no circumstance the device shall replace biochemical laboratory analysis. This device manufacturer expressly disclaims responsibility, and shall have no liability, for any damages, loss, injury, or liability whatsoever suffered as a result of your reliance on the information contained in this report.

The following parameters were simultaneously captured to issue the above preliminary report.

No.:	Parameter:	Norm:	<	>
------	------------	-------	---	---

1	2	Erythrocytes RBC. x10 ¹² /l	4 - 5,6		4,61	
2	1	Hemoglobin HGB. mg/dl	12,5 - 17,5		15,11	
3	88	Hematocrit. HCT 0.01*%	0,35 - 0,49		0,42	
4	12	Thrombocytes. x10 ⁹ /l	1,8 - 3,2		1,97	
5	4	Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3	3,71		
6	3	Lymphocytes. LYMPH %	19 - 37			38,39
7	8	Monocytes. MONO %	3 - 11		7,52	
8	42	Glucose. mg/dl	71,9 - 107,9		89,85	
9	35	Cholesterol total. mg/dl	120 - 250,19		224,88	
10	38	Low-density lipoproteins (LDL). mg/dl	104,25 - 130,12			131,69
11	40	High-density lipoproteins (HDL). mg/dl	30 - 67		32,98	
12	41	Triglycerides (TG). mg/dl	48,67 - 163,72			192,32
13	25	ALT. (SGPT). U/l	5 - 30			115,47
14	24	AST. (SGOT). U/l	8 - 40			114,45
15	27	Bilirubin, Total. mg/dl	0,5 - 1,198		1,07	
16	31	Creatinine. mg/dl	0,62 - 1,39	0,60		
17	34	Urea. mg/dl	12,8 - 49,2		28,22	
Hemogram:						
18	1	Hemoglobin HGB. mg/dl	12,5 - 17,5		15,11	
19	2	Erythrocytes RBC. x10 ¹² /l	4 - 5,6		4,61	
20	4	Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3	3,71		
21	120	Mean cell haemoglobin (MCH). pg	26 - 32			33
22	121	Mean cell volume (MCV). fl	81 - 94		91	
23	122	Mean cell haemoglobin concentration (MCHC). g/l	310 - 350			362
24	123	CPB (Color index of blood).	0,85 - 1,15		0,98	
25	3	Lymphocytes. LYMPH %	19 - 37			38,39
26	5	Segmented neutrophils. NEUT %	47 - 72		47,73	
27	7	Eosinophils. %	0,5 - 5,8		2,15	
28	8	Monocytes. MONO %	3 - 11		7,52	
29	9	Band neutrophils. NEUT %	1 - 6		4,21	
30	6	Erythrocyte sedimentation rate ESR. mm/h	1 - 14		11,41	
Blood coagulation:						
31	10	Beginning of clotting (method of Lee-White). min	0,5 - 2			02'04''
32	11	End of clotting (method of Lee-White). min	3 - 5		03'29''	
33	12	Thrombocytes. x10 ⁹ /l	1,8 - 3,2		1,97	
34	86	Fibrinogen. mg/dl	200 - 400		358,98	
35	87	Prothrombin index (PI). %	75 - 104		76,19	
36	88	Hematocrit. HCT 0.01*%	0,35 - 0,49		0,42	
Electrolyte metabolism:						
37	13	Calcium (Ca). mg/dl	9 - 12	8,63		

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

38	14	Magnesium (Mg). mg/dl	1,6 - 2,6		2,32	
39	15	Potassium (K). mg/dl	13,59 - 20,7		15,01	
40	16	Sodium (Na). mmol/l	136 - 145		141,28	
41	128	Chloride (Cl). mg/dl	347,41 - 379,315		356,4	
Functional parameters of stomach:						
42	17	pH of gastric juice.	1,2 - 1,7		1,22	
43	19	SH.	7,32 - 7,4			8,51
44	20	Basal pressure of Oddi's sphincter mm Hg	39 - 41			42,87
Carbohydrate metabolism:						
45	33	Lactic acid. mg/dl	9 - 12,55			14,64
46	42	Glucose. mg/dl	71,9 - 107,9		89,85	
47	43	Glycogen. mg%	11,7 - 20,6		15,17	
Liver function tests:						
48	22	Aspartate transaminase (AST). mmol/l	0,1 - 0,45			2,36
49	23	Alanine transaminase (ALT). mmol/l	0,1 - 0,68			2,38
50	24	AST. (SGOT). U/l	8 - 40			114,45
51	25	ALT. (SGPT). U/l	5 - 30			115,47
52	26	De Ritis coefficient (AST/ALT).	0,8 - 1,2		0,99	
53	27	Bilirubin, Total. mg/dl	0,5 - 1,198		1,07	
54	28	Bilirubin, Direct. mg/dl	0,129 - 0,357		0,28	
55	29	Bilirubin, Indirect. mg/dl	0,371 - 0,841		0,79	
Protein metabolism:						
56	30	Protein, Total. g/dl	6 - 8,5		6,76	
57	133	Serum albumin (ALB). g/dl	3,4 - 4,5		3,9	
58	134	Serum globulin (GLB). g/dl	2 - 4,5		2,4	
59	31	Creatinine. mg/dl	0,62 - 1,39	0,60		
60	32	Dopamine β-hydroxylase (DBH). nm/ml/min	28 - 32,5	21,79		
61	34	Urea. mg/dl	12,8 - 49,2		28,22	
Lipid metabolism:						
62	41	Triglycerides (TG). mg/dl	48,67 - 163,72			192,32
63	38	Low-density lipoproteins (LDL). mg/dl	104,25 - 130,12			131,69
64	39	Very low-density lipoproteins (VLDL). mg/dl	7,72 - 20,07		14,52	
65	40	High-density lipoproteins (HDL). mg/dl	30 - 67		32,98	
66	35	Cholesterol total. mg/dl	120 - 250,19		224,88	
67	36	β- lipoprotein. g/l	17 - 55		44,46	
68	37	β- lipoprotein. mmol/l	3 - 6		4,53	
69	132	Atherogenic factor (KA).	0,71 - 5,36			5,82
Water metabolism:						
70	45	Cellular water. %	39 - 42		41,19	
71	46	Total water. %	50 - 70		54,23	

72	44	Extracellular water. %	21 - 23		22,49	
Hormones:						
73	47	Testosterone. µmol/24hours	6,93 - 17,34			20,10
74	48	Estrogen, Total. nmol/24hours	17,95 - 64,62	11,99		
75	49	Thyroxine (T4), Total. µg/dl	4,6 - 10,5		5,5	
Enzymes:						
76	50	Amylase (W.T.Caraway). g/l*h	12 - 32		29,34	
77	51	Acetylcholine. µg/ml	81,1 - 92,1		82,76	
78	52	Acetylcholinesterase of erythrocytes. µmol/l	220 - 278		268,24	
79	54	Tyrosine. µmol/l	77,3 - 82,8	76,33		
80	55	Creatine kinase MM (CK-MM). µmol/min/kg	473 - 483		474,31	
81	56	Creatine kinase MB (CK-MB). µmol/min/kg	35,1 - 38,1		35,78	
Cell mitosis regulation:						
82	57	Comprehensive cell mitosis regulation factor.	3,7828 - 3,9372			4,3302
Internal blood flow, in % to total blood flow:						
83	64	Myocardial blood flow. %	4,32 - 5,02		4,35	
84	65	Muscular blood flow. %	14,56 - 16,93		16,82	
85	66	Cerebral blood flow. %	12,82 - 14,9		14,24	
86	67	Hepatoportal blood flow. %	20,28 - 29,86		24,81	
87	68	Nephritic blood flow. %	21,58 - 25,09			27,24
88	69	Skin blood flow. %	7,9 - 9,19		8,09	
89	70	Blood flow of other organs. %	5,76 - 6,7			6,74
Internal blood flow, in ml/min:						
90	71	Myocardial blood flow. ml/min	250 - 290,5		251,73	
91	72	Muscular blood flow. ml/min	930 - 1081,4		1 074,60	
92	73	Cerebral blood flow. ml/min	750 - 871,68		832,91	
93	74	Hepatoportal blood flow. ml/min	1690 - 2488,33		2 067,85	
94	75	Nephritic blood flow. ml/min	1430 - 1662,6			1 804,99
95	76	Skin blood flow. ml/min	500 - 581,65		511,73	
96	77	Blood flow of other organs. ml/min	375 - 436,19			438,78
Cerebral hemodynamics:						
97	82	Cerebral blood flow on 100g of tissue. ml/100g	50 - 55		52,98	
98	83	Blood flow per 1gr of thyroid gland. ml/g	3,7 - 4,3		3,90	
99	84	Blood flow per 1gr of cerebral tissue. ml/g	2,9 - 3,2		3,10	
100	85	Cerebral spinal fluid pressure (CSF). mm H ₂ O	90 - 145		125,62	
101	116	Width of the third ventricle of cerebrum. mm	4 - 6			6,11
Functional parameters of cardio-respiratory system:						
102	78	Pulmonary vascular resistance (PVR). dyn/cm ⁵ *sec	160 - 250	148,05		
103	79	Central venous pressure. mm H ₂ O	70 - 150	67,51		
104	80	Time of pulmonary circulation. s	16 - 23			24,39

105	81	Time of systemic circulation. s	4 - 5,5			5,70
106	21	Energy Expenditure. kkal/kg/min	1,23 - 4,3			6,04
107	61	Oxygenation velocity of RBC. ml/min	260 - 280	224,35		
108	62	Surface of gaseous exchange of RBC. m ²	3500 - 4300		3 677,92	
109	63	Deficit of circulatory blood. ml/kg	0 - 250		75,80	
110	89	Vital capacity of lungs (VC). cm ³	3500 - 4300		3 567,06	
111	90	Minute ventilation (VE) l/min	4 - 12			12,68
112	91	Functional residual capacity (FRC) cm ³	-----		1 855,50	
113	92	Peak expiratory flow (PEF). l/min	74 - 116		82,90	
114	93	Test Tiffeneau. %	84 - 110	79,16		
115	94	Working rate of oxygen consumption. %	45 - 60			74,62
116	95	Time of single load. min	3 - 10		9,54	
117	96	Respiratory exchange ratio (RER).	0,8 - 1,2		0,87	
Oxygen transport and consumption:						
118	18	pH of blood.	7,36 - 7,45	7,24		
119	59	Volume of circulatory blood. ml/kg	68 - 70			80,54
120	60	Cardiac output (CO). l/min	3,5 - 4,3			5,46
121	97	Transportation of oxygen(O ₂). ml/min	900 - 1200		1 126,09	
122	98	Quantity of assimilated oxygen on 100 gr. of cerebral tissue. ml	2,8 - 3,4	2,28		
123	99	Oxygen saturation in arterial blood (SaO ₂). %	95 - 98	92,98		
124	100	Oxygen consumption per kg of body weight. ml/min/kg	4 - 6		4,86	
125	101	O ₂ consumption. (VO ₂) ml/min	200 - 250			276,12
126	102	Myocardial oxygen consumption. ml/min	7 - 10		9,62	
127	103	Oxygen extraction index. %	26 - 34		31,3	
Transport and elimination of CO₂:						
128	104	CO ₂ elimination. ml/min	119 - 300		283,07	
129	105	(CO ₂) in arterial blood. %	32,5 - 46,6			47,72
130	106	(CO ₂) venous blood. %	51 - 53			53,33
131	107	Rate of CO ₂ production. ml/min	150 - 340			350,06
Functional parameters of cardio-vascular system:						
132	108	Vascular Permeability Index.	4,165 - 4,335	4,030		
133	109	Stroke volume (SV). ml	60 - 80		70,95	
134	110	Interval PR. sec	0,125 - 0,165		0,149	
135	111	Interval QT. sec	0,355 - 0,4			0,411
136	112	Interval QRS. sec	0,065 - 0,1			0,110
137	113	Left ventricular Stroke Work Index. %	52 - 60			66,05
138	114	Systolic arterial pressure. mm Hg	-----		124,03	
139	115	Diastolic arterial pressure. mm Hg	-----		89,45	

140	58	Plasma density. g/l	1048 - 1055		1 050,06	
141	117	Cardiac work. Joule	0,692 - 0,788	0,63		
----- Out of group						
142	118	eGFR [MDRD]. ml/min/1.73m ²	95 - 145			153,6
143	119	Estimated creatinine clearance rate(eCCr)[Cockroft and Gault]. ml/min	95 - 145			184,0
144	124	Cystatin C (CysC). mg/l	0,6 - 0,96	0,58		
145	125	BUN. mg/dl	6 - 23		13	
146	126	Transferrin. mg/dl	204 - 380		239,75	
147	127	Urine specific gravity. g/cm ³	1005 - 1035		1 019	
148	129	Ceruloplasmin (CP). mg/l	150 - 600		469,516	
149	130	Alkaline phosphatase (ALP). U/L	38 - 119		96,13	
150	131	Intracranial pressure (ICP). mmHg	7 - 15		9,2	

When generating a report, you can use the button () that allows you to enable or disable the built-in system for monitoring the accuracy of calculating indicators. If the system is enabled, only those indicators will be printed that the system calculates with the maximum accuracy available to it.




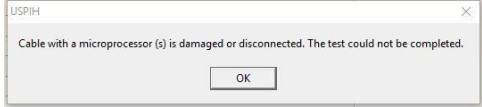
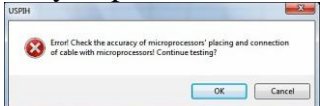
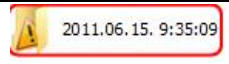
AI disabled.



AI enabled.

14 TROUBLESHOOTING

Possible errors and solutions:

	Error/problem	Reason	Solution/advice
1	Software doesn't run	Guardant Stealth key isn't connected to PC or it is damaged 	Check if the Guardant Stealth key is connected to PC. Reconnect it. The LED on a key is switched on when it works and connected properly.
		Guardant Stealth key drivers were installed incorrect	Green LED on Guardant Stealth key isn't lighting. Check the drivers for Guardant Stealth key (process is described on User's Manual, Chapter 11.2.1.7).
2	Measurement couldn't start or it is interrupted in a process	There is no connection between cable with sensors/sensor and MD ANALYZER	Check the LED on the ANALYZER's enclosure. The LED will be blinking if there is bad connection between related cable with sensor and MD ANALYZER; related cable with sensor is damaged. If a cable(s) is damaged, it should be replaced.
		One or several sensors are damaged 	
		Sensors are not placed on a patient's body or placed incorrect 	Place the sensors in a way, as it is required by this Manual (Chapter 9) and then click "OK". The window may appear again, if the measured temperatures is below 24°C or above 41°C
3	Device MD ANALYZER isn't found	There is no connection between MD ANALYZER and PC	Check USB cable, which connects MD ANALYZER and PC: connect/reconnect it or replace USB cable, in case of damage.
		Drivers for the device were installed incorrectly	Check the drivers and reinstall them (Chapter 11.2.1.7)
4	A survey is unavailable	If a survey in the database is damaged or the measurement has been interrupted, such surveys will be marked with a special character and such surveys will be unavailable for opening. Software USPIH will automatically suggest to remove such survey. To maintain the integrity of the database, such a survey should be deleted, and a measurement should be repeated. 	

15 CLEANING AND DISINFECTION OF MD ANALYZER



Attention! Prior to cleaning and disinfection of MD Analyzer's surface, all cables shall be disconnected from the Analyzer!



Attention! Disinfection of the surface and cables with sensors by aggressive chemicals or solvents (phenol-based chemicals, ester, benzene, propanol, chloroform or acetone), solid and abrasive means is **PROHIBITED!**



Attention! Disinfection of the ANALYZER and its accessories by heated air is **PROHIBITED**

Wipe enclosure of an ANALYZER by a soft wet cloth dipped to soapy water and well squeezed.

Avoid getting the liquid inside an ANALYZER during its cleaning and disinfection.

Disinfection of sensors must be carried out by disposable alcohol wipes. Do not wipe sensors by cloth, as it may cause scratches on its surface.

16 MAINTENANCE AND SAFETY CONTROL

Preventive maintenance is not required. However, regular maintenance can help to identify possible defects at an early stage and thus improve the safety and extend the life of the device.

It is recommended to perform functional and safety inspections of the device at least once per year. It is necessary to follow national regulatory documents in case the national safety regulations for medical devices require control tests and inspections more often. Functional and safety inspections are carried out at the factory or at authorized service centers.

17 DISPOSAL AND ENVIRONMENT PROTECTION



The MD ANALYZER is disposed of as an electronic equipment after the service life is ending. Please dispose the device in accordance with the applicable regulations in your country.

PRODUCT DISPOSAL: The MD ANALYZER consists of various materials. Nevertheless, all of them (metal, plastic, electrical conductors, printed circuit boards, chips, etc.) do not contain hazardous substances and can be delivered to special processing centers, the same as electronic equipment. Before recycling, it is necessary to check related local regulations and requirements and strictly comply with them.

Packaging disposal: packaging components (cardboard, expanded polystyrene, etc.) are classified as solid waste and therefore can be easily recycled by using recycling processes. Before recycling, it is necessary to check related local regulations and requirements for recycling and strictly comply with them.

18 REPAIR

Only responsible staff of the manufacturer, company SC KOLIBRI LLC, and authorized personnel of distributors/local representatives are allowed to carry out repairs of MD ANALYZER. Only original spare parts, which are normally used by SC KOLIBRI LLC for production, are allowed to be used for repairing of the MD Analyzer.

19 SHELF-LIFE OF THE DEVICE


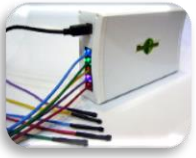
Considering the characteristics of similar equipment on the market, as well as the actual period of the MD ANALYZER marketing (since 2006), the shelf-life for the MD Analyzer and its parts/accessories, with mandatory fulfillment of the terms of packaging, storage, transportation and use, set forth in this User's manual, has been established as following:

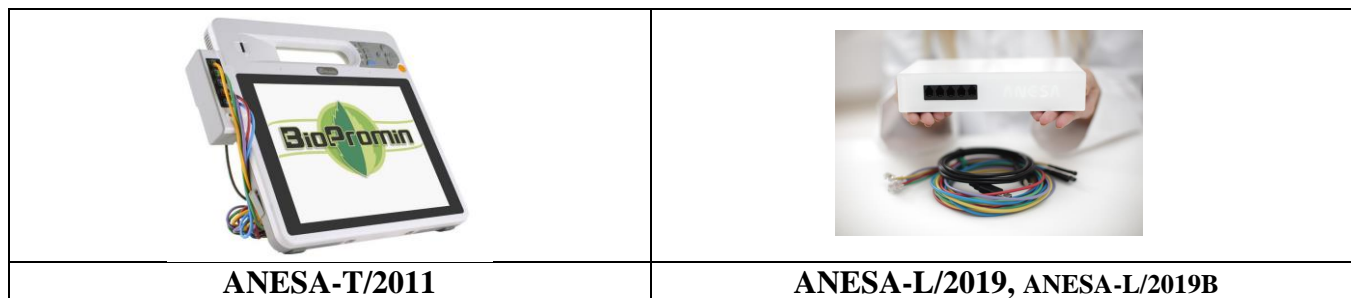
- 10 years for the MD ANALYZER;
- 6 years for the MD ANALYZER with tablet PC (please note, that storage of such type of ANALYZER without using and periodical recharging of the batteries may reduce the shelf-life till one year);
- 10 years for the Guardant Stealth II key;
- 12 months for the cables with microprocessors.

The probability of failure of parts and accessories of the MD Analyzer increases after exceeding of the shelf-life.

20 MD ANALYZER'S EXTERIOR

MD ANALYZER is performed in different enclosures in order to meet customers' needs and requirements. Depending on the enclosure, there are different complete sets of cables with microprocessors/sensors. Available models are shown on the Picture 2.

Model, where one cable with 5 microprocessors is included into complete set of the MD ANALYZER	Model, where 5 separate cables, (each with one microprocessor) are included into complete set of the MD ANALYZER
	
ANESA-L/2007, ANESA-L/2007w	ANESA-L/2012, ANESA-L/2012w
Model with Tablet PC and 5 separate cables, (each with one microprocessor)	Model, where 5 separate cables, (each with one microprocessor) are included into complete set of the MD ANALYZER



Picture 2. Models of Automatic Noninvasive Express Screening Analyzer (ANESA)

21 STORAGE AND TRANSPORTATION

Transportation and storage of the MD ANALYZER is permitted only in the manufacturer's packaging, with shaking and impact on the package should be avoided.

Medical device can be transported by all types of transport in covered vehicles, planes and ships, in accordance with the requirements and rules of transportation of goods transport of each species.

This medical product during transportation is resistant to climatic factors at temperatures from -25°C (without relative humidity control) till $+70^{\circ}\text{C}$ (with relative humidity control), in conditions that protect it from sunlight, possible wetting and mechanical stress (class 7K3 as described in IEC/TR 60721-4-7:2001+AMD1:2003 CSV). Transport is organized by certified transport companies.

The storage life for MD ANALYZER is limited by the shelf-life period for the device and accessories.

22 TERMS OF WARRANTY

The guarantee for the ANALYZER is

- 36 months from the date of sale for the models L/2007, L/2012, L/2019, L/2019B
- 12 months from the date of selling for the models T/2011, DAD-ANI

The manufacturer or its authorized representative performs free repair of defective parts or makes a replacement of a defective device, in case of detection of manufacturing defects during the warranty period. The warranty does not apply to often-used parts, such as power cables of a tablet PC (in case it is included), cables with microprocessors and a USB cable.

The Warranty term is 12 months for a tablet PC and batteries, which are bundled parts of the model T/2011 (conditioned by the initial guarantee provided by the manufacturer of Tablet PC).

The warranty does not cover the faults and damages, which occurred due to a user's actions/inactions, violation of the manufacturer's requirements for operating and maintenance, storage and transportation, described in this User's manual, as well as misuse of the device and influence of the force majeure circumstances.

Warranty claims are accepted only in case the MD ANALYZER is returned to the authorized representative or to the manufacturer in a full complete set, clean, without external mechanical damages and signs of disassembly/opening. Transport expenses and risk of accidental loss in a process of delivery of the device (both ways) are covered by a customer.



ATTENTION! It is not allowed to make any changes in the construction of the device. Any unauthorized opening, repairing or modification of the MD Analyzer by a customer's personnel or anybody else releases the manufacturer from the obligations and responsibility for the safe operation of the device. In such a case, the warranty is automatically considered as invalid, even before the expiration of the warranty period. The warranty is considered as invalid, if a customer has made any modification or design changes of the hardware or/and perform any changes in the software of MD ANALYZER without written agreement of the manufacturer SC KOLIBRI LLC.

For warranty and post-warranty service, as well as for all the issues regarding the operation of the device please contact:



Manufacturer:

SC KOLIBRI LLC

Kinnyi provulok 8a, Kharkiv,
61001,Ukraine. Tel.: +380-973779787

e-mail: info@kolibri.one

URL: www.kolibri.cloud

Authorized representative in European Union:



ONKOCET Ltd.

4 Kutuzova str., 90201 Pezinok,
Slovakia, Tel.: +421 (2) 44 64 09 77

e-mail: onkocet@onkocet.eu

URL: www.onkocet.eu

Authorized representative in Latin America

SETISCO Medical SL

NIF B-66870791

Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.

Tel: +34934177882.

Diagonal office : Av. Diagonal, 361, 2º - 2ª, 08037,
Barcelona. Tel: +34934578980

23 THE LIST OF INSPECTIONS AND CONTROL FOR WARRANTY AND AFTER-WARRANTY SERVICES

24 CERTIFICATE OF COMPLIANCE

MD ANALYZER, No. _____ is completely functional and operational, it complies to the Technical Specification and related harmonized standards, including but not limited, the Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 93/42/EEC concerning medical devices, EN ISO 13485:2012, EN ISO 14971:2012, MEDDEV 2.12 / 1- rev. 8, EN 60601-1: 2006/AC:2010, EN 60601-1-2: 2007/AC:2010.

The warranty period for MD ANALYZER is

- 36 months from the date of sale for the models L/2007, L/2012, L/2019, L/2019B
- 12 months from the date of selling for the models T/2011, DAD-ANI



Date of manufacture " _____ " _____ 20____.

Check and confirmed by: _____

Signature

Name and Surname



Manufacturer:

SC KOLIBRI LLC

Kinnyi provulok 8a, Kharkiv,
61001,Ukraine. Tel.: +380-973779787
e-mail: info@kolibri.one
URL: www.kolibri.cloud

Authorized representative in European Union:



ONKOCET Ltd.

4 Kutuzova str., 90201 Pezinok,
Slovakia, Tel.: +421 (2) 44 64 09 77
e-mail: onkocet@onkocet.eu
URL: www.onkocet.eu

**Authorized representative in Latin America
SETISCO Medical SL**

NIF B-66870791
Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.
Tel: +34934177882.
Diagonal office : Av. Diagonal, 361, 2º - 2ª, 08037,
Barcelona. Tel: +34934578980

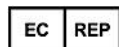
25 PACKING LIST

The MD ANALYZER			
	<i>Name of MD Analyzer</i>		
Model	<input type="checkbox"/> L/2007	<input type="checkbox"/> T/2011	Serial Number
	<input type="checkbox"/> L/2012	<input type="checkbox"/> L/2019	
	<input type="checkbox"/> L/2019B		
is packed at the manufacturing facilities of the company SC KOLIBRI LLC in accordance with the Technical Specification			
Complete set includes			
Date of packing	<i>DD</i>	<i>MM</i>	<i>YEAR</i>
Packed by	<i>Signature</i>		<i>Name and Surname</i>

**Manufacturer:****SC KOLIBRI LLC**

Kinnyi provulok 8a, Kharkiv, 61001,

Ukraine. Tel.: +380-973779787

e-mail: info@kolibri.oneURL: www.kolibri.cloud**Authorized representative in European Union:****ONKOCET Ltd.**

4 Kutuzova str., 90201 Pezinok,

Slovakia, Tel.: +421 (2) 44 64 09 77

e-mail: onkocet@onkocet.euURL: www.onkocet.eu**Authorized representative in Latin America****SETISCO Medical SL**

NIF B-66870791

Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.

Tel: +34934177882.

Diagonal office: Av. Diagonal, 361, 2º - 2ª, 08037,
Barcelona. Tel: +34934578980

26 WARRANTY CARD

Warranty card

Noninvasive screening diagnostic equipment

Medical Device AMP/ANESA®/DIAMEDSCAN/DAD-ANI®

Noninvasive Hemogram Analyzer: AMP// Automatic Noninvasive Express Analyzer: ANESA// Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo: DAD-ANI

Card No. (Serial number of the Analyzer)		
Warranty period*	36 months for Analyzer 12 months for a tablet PC and batteries (only for model T/2011)	
Purchase Date	Name of MD	Model
Trade organization Name	Trade organization Address	Trade organization Telephone

Customer Signature _____ [Company stamp]
 With the conditions of guarantee is acquainted

Important: Please store this card in a secured location for future reference. SC KOLIBRI LLC or its authorized representative reserved the right to request this document before accepting repair requests.

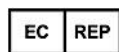
BEFORE UNPACKING PRODUCT PLEASE READ CAREFULLY ALL ENTRIES IN THE WARRANTY. IF NOT ACCEPT THE TERMS OF WARRANTY, THE PRODUCT CAN UNIMPAIRED BE RETURN TO:

**Manufacturer:****SC KOLIBRI LLC**

Kinnyi provulok 8a, Kharkiv, 61001,
Ukraine. Tel.: +380-973779787

e-mail: info@kolibri.one

URL: www.kolibri.cloud

Authorized representative in European Union:**ONKOCET Ltd.**

4 Kutuzova str., 90201 Pezinok,
Slovakia, Tel.: +421 (2) 44 64 09 77

e-mail: onkocet@onkocet.eu

URL: www.onkocet.eu

Authorized representative in Latin America**SETISCO Medical SL**

NIF B-66870791

Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.

Tel: +34934177882.

Diagonal office : Av. Diagonal, 361, 2º - 2ª, 08037,
Barcelona. Tel: +34934578980

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

SC KOLIBRI LLC provides the manufacturer's warranty (herein referred to as the Warranty) for the Purchaser (herein referred to as the "User") of the MD ANALYZER. This warranty card provided with the is subject to the following terms and conditions. Service under this warranty is provided by SC KOLIBRI LLC and / or Authorized Distributors.

***Warranty Period of the ANALYZER:**

This warranty applies for the period 36 months from the date when the end customer first purchased the ANALYZER ("Purchase Date"). If proof of purchase is not supplied with the ANALYZER, as the start of the warranty period will be considered the date of manufacture of the ANESA/DAD-ANI, registered by SC KOLIBRI LLC.

The Warranty does not cover bundled accessories, which were delivered together with the ANALYZER such as cables with microprocessors, bag, USB and power supply cable etc.

TERMS OF WARRANTY

1. General

SC KOLIBRI LLC warrants the ANESA/AMP/DAD-ANI MODEL 19 to be free from defects in workmanship and materials for the Warranty Period. The Warranty does not cover bundled accessories, which were delivered together with the ANESA/AMP/DAD-ANI MODEL 19 such as cables with microprocessors, bag, USB and power supply cable etc. If the ANESA/AMP/DAD-ANI MODEL 19 fails during normal and proper use within the Warranty Period, SC KOLIBRI LLC will repair or replace the defective parts of the ANESA/AMP/DAD-ANI MODEL 19, or the ANESA/AMP/DAD-ANI MODEL 19 itself, with new or reconditioned parts or products that are functionally equivalent or superior to those originally supplied.

This Warranty applies only if the ANESA/DAD-ANI MODEL-19 was newly manufactured on the Date of Purchase and not sold as used, refurbished or manufacturing seconds. Please keep the original purchase invoice and this warranty card for a future service request.

This Warranty does not include failure caused by improper installation, operation, cleaning or maintenance, accident, damage, misuse, abuse, non- SC KOLIBRI LLC modifications to the ANESA/AMP/DAD-ANI MODEL 19, any changes in the software, normal wear and tear or any other event, act, default or omission outside SC KOLIBRI LLC control.

2. Customer responsibility

When using the Product

- * Read the User's manual first and use the ANESA/AMP/DAD-ANI MODEL 19 only according to the IFU.
- * After finishing your work do not leave the ANESA/AMP/DAD-ANI MODEL 19 connected to the power to avoid any possible damages of the ANESA/AMP/DAD-ANI MODEL 19 caused by faults of an electrical network.
- * Periodically back up the data of your patients stored in the database of software ANESA/AMP/DAD-ANI MODEL 19.
- * Keep the original packaging. In case the ANESA/AMP/DAD-ANI MODEL 19 needs to be returned for repair, original packaging provides better protection during transportation.
- * Do not use external devices to change the characteristics of the ANESA/AMP/DAD-ANI MODEL 19.
- * Do not leave the device unattended.
- * Do not interfere in the ANESA/AMP/DAD-ANI MODEL 19 and its software ANESA/AMP/DAD-ANI MODEL 19 - this can cause the failure of the device and invalidate the warranty.
- * Please check the User's manual for troubleshooting solutions, before contacting the customer service.

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

When contacting SC KOLIBRI LLC Customer Service

* Before contacting SC KOLIBRI LLC or Authorized Distributor's technical support, ensure that you have the ANESA/AMP/DAD-ANI MODEL 19 in front of You and that it is turned on and connected to the Internet, if feasible. Please also be ready to provide the ANESA/AMP/DAD-ANI MODEL 19's serial number, the model name and proof of purchase.

* Technical support phone number or email can be found at www.mdevice.org

* You may be requested by SC KOLIBRI LLC to perform some of the ANESA/AMP/DAD-ANI MODEL 19's troubleshooting tasks or actions, which may include the following:

* Installing updates.

* Performing other reasonable activities requested by SC KOLIBRI LLC, which will assist in identifying or resolving the problems (e.g. installation of special software for remote access by our technicians to your computer, etc.).

* If the problem is not solved remotely, you will have to return the Product to a SC KOLIBRI LLC Repair Center.

* Describe the problem clearly and completely in the Complaint form (the Customer Service will provide the form after your request).

* Enclose a copy of this completed warranty card and a copy of Your sales invoice/ receipt detailing the purchase of the ANESA/AMP/DAD-ANI MODEL 19. (Please note: SC KOLIBRI LLC reserves the right to request the original documents.) If You do not provide the requested documents for warranty validation, then the manufacture date of the ANESA/AMP/DAD-ANI MODEL 19 as recorded by SC KOLIBRI LLC will be deemed to be the start of Warranty Period.

* Ensure that You have fully backed up all the data stored in the database of your software ANESA/AMP/DAD-ANI MODEL 19 and removed any personal, confidential, or proprietary information before any service process is started. SC KOLIBRI LLC shall not be held liable for the permanent loss, damage, or misuse of your data.

* Pack the Product in safe and stable packaging. The original packaging may be useful for this purpose. In any case, the packaging should meet the following requirements:

* Use a rigid box.

* Remove any labels, hazardous materials indicators, and other previous shipment markings on the box that are no longer applicable.

* Wrap all items separately

* Use the adequate cushioning material

* Use strong tape designed for shipping

* Use a single address label that has clear, complete delivery and returns information

* Place a duplicate address label inside the package

* Please do not send in anything but the ANESA/AMP/DAD-ANI MODEL 19 itself unless specifically requested by SC KOLIBRI LLC. Please remove any accessories as well as any removable storage devices such as memory cards, discs, flash drives, from the ANESA/AMP/DAD-ANI MODEL 19. SC KOLIBRI LLC shall have no liability for the loss, damage or destruction of accessories or removable storage devices.

3. Exclusions from the Warranty Service

SC KOLIBRI LLC does not warrant the uninterrupted or error-free operation of this ANESA/AMP/DAD-ANI MODEL 19. The warranty only covers technical hardware issues during the warranty period and in normal use conditions. It does not apply to software issues or customer induced damages or circumstances such as, but not limited, to:

- * The ANESA/AMP/DAD-ANI MODEL 19 has been tampered or repaired and/or modified by non-authorized personnel;
- * The serial number of the ANESA/AMP/DAD-ANI MODEL 19, components or accessories has been altered or removed;
- * Obsolescence;
- * Damage (accidental or otherwise) to the ANESA/AMP/DAD-ANI MODEL 19 that does not impact the ANESA/AMP/DAD-ANI MODEL 19's operation and functions, such as without limitation to scratches, change in color, texture or finish, wear and tear, and gradual deterioration;
- * Damage to the ANESA/AMP/DAD-ANI MODEL 19 caused by war, terrorism, fire, accident, natural disaster, intentional or accidental misuse, abuse, neglect or improper maintenance, and use under abnormal conditions;
- * Damage to the ANESA/AMP/DAD-ANI MODEL 19 caused by improper installation, improper connection or malfunction of a peripheral device such as printer, optical drive or USB device, etc.;
- * Damage to the ANESA/AMP/DAD-ANI MODEL 19 caused by an external electrical fault or any accident;
- * Damage to the ANESA/AMP/DAD-ANI MODEL 19 resulting from use outside of the operation and storage environment detailed in the IFU;
- * Damage to the ANESA/AMP/DAD-ANI MODEL 19 caused by third party software or virus(es); or there is software loss or data loss that may occur during repair or replacement;
- * Invalidity of or damage to the ANESA/AMP/DAD-ANI MODEL 19 caused by contamination with hazardous substances, vermin, or radiation and so on;
- * Fraud, theft, unexplained disappearance, or willful act;
- * Damage made to the ANESA/AMP/DAD-ANI MODEL 19 caused by using the materials other than those recommended by SC KOLIBRI LLC shall not be covered by the Warranty.

The warranty does not cover damage resulting from normal wear and tear, i.e. parts that require periodic replacement during normal use of the device, including cables with microprocessors, power cables, USB cables and other defined by specifications of the product and considered consumables.

SC KOLIBRI LLC shall not be liable for damage resulting from improper maintenance procedures of the equipment, improper cleaning, and mechanical and chemical damage caused by that.

Except as provided in this warranty and to the maximum extent permitted by law, SC KOLIBRI LLC is not responsible for direct, special, incidental or consequential damages resulting from any breach of warranty or condition, or under any other legal theory, including but not limited to loss of use; loss of revenue; loss of actual or anticipated profits (including loss of profits on contracts); loss of the use of money; loss of anticipated savings; loss of business; loss of opportunity; loss of goodwill; loss of reputation; loss, damage to or corruption of data; or any indirect or consequential loss or damage whatsoever caused including the replacement of equipment and property, any costs of recovering or reproducing any data stored on or used with the ANESA/AMP/DAD-ANI MODEL 19.

The foregoing limitation shall not apply to death or personal injury claims, or any statutory liability for intentional and gross negligent acts and/or omissions by SC KOLIBRI LLC.

4. Privacy

You agree and understand that it is necessary for SC KOLIBRI LLC to collect, transfer, and process personal data in order to facilitate the requested service; and that for this purpose Your data may be transferred to and processed in any country where SC KOLIBRI LLC or its affiliated companies maintains offices, which include countries outside of the European Union, the mandatory laws of which do not guarantee a data protection level equivalent to the laws of EU member states. However, SC KOLIBRI

LLC will use and protect Your personal data at any time and in any country subject to the SC KOLIBRI LLC Privacy Policy.

5. Out-of-Warranty cases

Returning the Product to the SC KOLIBRI LLC Repair Center during the warranty period does not automatically mean that it will be repaired free of charge. Upon receiving Your Product, SC KOLIBRI LLC reserves the right to check the validity of Your Warranty and Your request for Warranty service. If the Warranty Period has lapsed or if any of the exclusions in clause 3 apply, Your request will be deemed out of warranty (“OOW”). If Your service request is OOW, a Service Charge List with an offer for repair will be provided to You, which You may accept or reject. If You accept the repair, we will provide You with an invoice for the repair labor, spare parts and other costs stated in the Service Charge List. The invoice must be paid according to the payment date contained in the document. Repairs will be made after payment of the invoice. To the extent permitted by law, SC KOLIBRI LLC may charge You transportation costs if Your service request is OOW and you refuse the repair offer; or if Your Product does not require service.

6. Abandoned Property

After Your Product has been repaired, or if You do not agree to the repair offer, SC KOLIBRI LLC will return your Product via the agreed method. If You do not pick up Your Product, or if delivery is not possible at the address provided by You, SC KOLIBRI LLC will send You notice at the e-mail address and telephone You provided when requesting the service. If You still failed to pick up the Product within a period of 90 days from sending the notice, SC KOLIBRI LLC reserves the right to claim damages from you, including the cost of storage; to dispose the product in accordance with the applicable laws and regulations; and any statutory right of lien for unpaid charges.

TEAR-OFF COUPON NO.1		<i>[SERIAL NUMBER OF DEVICE]</i>	No.1	<i>Filled up by service center</i>
PRODUCT	Medical Device AMP/ANESA®/DIAMEDSCAN/DAD-ANI®			
MODEL NAME				<i>Reception date</i>
PURCHASING DATE				<i>Release date</i>
TRADE ORGANIZATION				<i>Special Marks</i>
	<i>TRADE ORGANIZATION STAMP</i>			<i>SERVICE CENTER STAMP</i>

TEAR-OFF COUPON NO.2		<i>[SERIAL NUMBER OF DEVICE]</i>	No.2	<i>Filled up by service center</i>
PRODUCT	Medical Device AMP/ANESA®/DIAMEDSCAN/DAD-ANI®			
MODEL NAME				<i>Reception date</i>
PURCHASING DATE				<i>Release date</i>
TRADE ORGANIZATION				<i>Special Marks</i>

Medical Device for Noninvasive screening diagnostics AMP/ANESA®/DIAMEDSCAN/DAD-ANI®/DIAMEDSCAN.

	TRADE ORGANIZATION STAMP	SERVICE CENTER STAMP
--	--------------------------------	----------------------------

Responsible organizations for warranty and post-warranty service:



Manufacturer:

SC KOLIBRI LLC

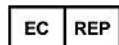
Kinnyi provulok 8a, Kharkiv, 61001,

Ukraine. Tel.: +380-973779787

e-mail: info@kolibri.one

URL: www.kolibri.cloud

Authorized representative in European Union:



ONKOCET Ltd.

4 Kutuzova str., 90201 Pezinok,

Slovakia, Tel.: +421 (2) 44 64 09 77

e-mail: oncocet@oncocet.eu

URL: www.oncocet.eu

Authorized representative in Latin America

SETISCO Medical SL

NIF B-66870791

Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.

Tel: +34934177882.

Diagonal office : Av. Diagonal, 361, 2º - 2ª, 08037,

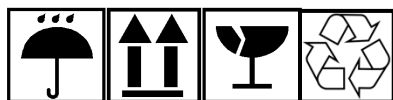
Barcelona. Tel: +34934578980

All valid permits and certificates are available on the manufacturer's website www.kolibri.cloud

WARRANTY CARD MAY BE PRINTED-OUT SEPERATLY FROM THE USER'S MANUAL AND INCLUDED INTO COMPLETE SET OF THE ANALYZER TOGETHERWITH/AS A PART OF TECHNICAL PASSPORT.

27 LABELING












Labels on the outer package of the MD ANESA®/AMP/DAD-ANI®



Labels and marking used for the MD ANALYZER.

A number of internationally recognized symbols are placed on a label of the MD ANESA®/AMP/DAD-ANI®. The symbols relate to the safety requirements and standards and are briefly reviewed below:

1	Logo of the manufacturer:	
---	---------------------------	--

2	Trade name of the medical device:	Noninvasive Hemogram Analyzer AMP or Automatic Noninvasive Express Analyzer ANESA ® or Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo DAD-ANI ®		
CE symbol (where 0086 is the number of Notified Body)			TYPE BF APPLIED PART	
Issue Date	 [Date of manufacturing]	Serial number of MD	 [Serial number]	
Manufactured by	 SC KOLIBRI LLC Kinnyi provulok 8a, Kharkiv, 61001,Ukraine. Tel.: +380- 973779787 e-mail: info@kolibri.one URL: www.kolibri.cloud	Symbol for connection of USB port		
Represented by (European representative)	 in Europe Onkocet LTD Address: Kutuzovova 4, 902 01 Pezinok, Slovakia tel.: +421 2 44 64 09 77 in Spain: Protomedical SL Address: C/Travesia La Paz, 4, 1D, 30160 – Monteaguda, Murcia, Spain Tel.34 868 600 003 e-mail: soporte@onkocet.es	Direct current		
MD Class IIa	MD Class IIa	Attention label		
Sign of waste electronic equipment		<i>Carefully read the User's Manual before the first use of the device</i>		
International protection marking	IP 20	Certificate of Compliance to Technical Regulations for medical equipment	 UA.TR.099	

Project of labels for the SW

ANESA

Automatic Noninvasive Express Screening Analyzer
Automatic Noninvasive Express Screening Analyzer



Scientific Company KOLIBRI LLC
Kinnyi provulok, 8a, Kharkiv, 61001, Ukraine



Software version: 9.7

ANESA

Automatic Noninvasive Express Screening Analyzer
Automatic Noninvasive Express Screening Analyzer



Scientific Company KOLIBRI LLC
Kinnyi provulok, 8a, Kharkiv, 61001, Ukraine



Software version: 10.7

Project of labels for the software of MD
Automatic Noninvasive Express Analyzer ANESA®

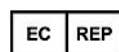
Manufacturer or the authorized service centres provide warranty services and repairs:

Manufacturer:



SC KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv,
61001, Ukraine. Tel.: +380-973779787
e-mail: info@kolibri.one
URL: www.kolibri.cloud

Authorized representative in European Union:



ONKOCET Ltd.

4 Kutuzova str., 90201 Pezinok,
Slovakia, Tel.: +421 (2) 44 64 09 77
e-mail: onkocet@onkocet.eu
URL: www.onkocet.eu

Authorized representative in Latin America SETISCO Medical SL

NIF B-66870791
Central office : C. Riu de l'Or, 35, local 3, 08034,
Barcelona.
Tel: +34934177882.
Diagonal office : Av. Diagonal, 361, 2º - 2ª, 08037,
Barcelona. Tel: +34934578980

All valid permissions and certificates are placed on the manufacturer's homepage www.anesa.biz



**Please read the User's Manual
carefully before using the device!**

MD Class: IIa

according to the Annex IX Sect. I clause 1.6, 3.2 Rule 10 of the Directive
2007/47/EC of the European Parliament and of the Council amending Council
Directive 93/42/EEC concerning medical devices

28 DECOMMISSIONING AND DISPOSAL OF SOFTWARE

To uninstall the software, use the standard features (or functions) of the software environment in which the program is installed.

29 NOTICE TO THE USER AND/OR PATIENT



Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

30 DOCUMENT HISTORY AND VERSION CONTROL

Version	Version Date	Summary of changes	Author	Related documents
1.0	2021-05-20	Created	Pulavskiy A, Kolyesnik O	
1.0	2022-11-10	Revision all document		