



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

realized under commercial names:

Noninvasive Hemogram Analyzer **AMP MODEL 19**

Automatic Noninvasive Express Screening Analyzer **ANESA® MODEL 19**

Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo **DAD-ANI®**
MODEL 19

(hereinafter MD ANALYZER)

Instruction for use
(IFU)



UA.TR.099

2021





Read this IFU carefully before use of the MD ANALYZER

Manufacturer:

SC KOLIBRI LLC

Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.

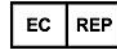
Tel.: +380-913011110

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

Automatic Noninvasive Express Screening Analyzer **ANESA® Model 19**

Noninvasive Hemogram Analyzer **AMP Model 19**

Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo **DAD-ANI® Model 19**

(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, 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

User manual according to ANNEX I, section 23 and Commission Regulation (EU) No 207/2012

MD ANALYZER is a screening medical device, which is helpful in diagnosing of people, but it is not a diagnostic tool, which replaces the standard recommended diagnostic methods.

The present IFU 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	
CONTENT	
A. SAFETY SIGNS USED IN THE IFU AND THE LABELS OF MD:	5
1 GENERAL INFORMATION	6
1.1 GENERAL OVERVIEW	6
1.2 PRINCIPLE OF FUNCTIONING	6
1.3 METHOD OF MEASUREMENT	8
1.4 INTENDED USE OF DEVICE	9
1.5 CONTRAINDICATIONS	10
1.6 MODES OF OPERATION	10
2 WARNING AND SAFETY INSTRUCTIONS	11
2.1 GENERAL SAFETY RULES	11
2.2 MEASURES TO PREVENT DAMAGE TO THE DEVICE	14
3 BRIF DESCRIPTION OF MD ANALYZER. MODELS OF ANALYZER	15
3.1 TECHNICAL DATA OF MD ANALYZER	15
3.2 THE COMPLETE SET OF MD ANALYZER	18
4 BEFORE USING MD ANALYZER	19
4.1 LIST OF INITIAL ACTIONS AND EVERYDAY ACTIONS BEFORE USE	19
4.2 QUALIFICATION OF AN OPERATOR. REQUIREMENTS FOR AN OPERATOR	20
4.3 CONNECTION OF CABLES TO THE UNIT	21
5 SOFTWARE INSTALLATION	22
6 SOFTWARE USPIH-M19: FEATURES	25
7 START WORKING WITH USPIH-M19	25
7.1 CONNECTION THE DEVICE TO A COMPUTER VIA USB	25
7.2 CONNECTION THE DEVICE TO A COMPUTER VIA BLUETOOTH	25
8 PATIENT POSITIONING	29
9 STARTING WORK WITH USPIH: PERSONAL SETTING	30
10 WORKING WITH SOFTWARE USPIH	34
11 FUNCTIONAL TEST OF MD ANALYZER	42
12 DESCRIPTIONS OF MEASURING PROCEDURE	43
13 COUNTING THE NUMBER OF SURVEYS (FOR LIMITED VERSION OF MD ANALYZER, USPIH-M19)	49
14 SWITCHING-OFF MD ANALYZER	50
15 EXAMPLE OF A SURVEY	51
16 TROUBLESHOOTING	53
17 CLEANING AND DISINFECTION OF MD ANALYZER	56

18 MAINTENANCE AND SAFETY CONTROL	56
19 DISPOSAL AND ENVIRONMENTAL PROTECTION	56
20 REPAIR	57
21 SHELF-LIFE AND LIFETIME OF THE DEVICE	57
22 STORAGE AND TRANSPORTATION	58
23 TERMS OF WARRANTY	59
24 THE LIST OF INSPECTIONS AND CONTROL FOR WARRANTY AND AFTER-WARRANTY SERVICES	60
25 CERTIFICATE OF COMPLIANCE	61
26 PACKING LIST	62
27 WARRANTY CARD	63
28 LABELING	69
29 MANUFACTURER AND THE AUTHORIZED SERVICE CENTRES	74
30 COMPLIANCE WITH GDPR	75
31 DECOMMISSIONING AND DISPOSAL OF SOFTWARE	75
32 DOCUMENT HISTORY AND VERSION CONTROL	76



Read this IFU carefully before use of the MD ANALYZER



Instructions, diagrams, descriptions or other information to assist service personnel are available on request from the manufacturer

A. SAFETY SIGNS USED IN THE IFU AND THE LABELS OF MD:



General warning sign



General prohibiting sign



General safety sign



Pattern of sign for mandatory actions



Sign of waste electronic equipment

IP20

International protection marking



Recycle sign



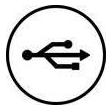
Type BF applied part



CE symbol

100-240VAC

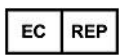
Power the MD



Symbol for connection of USB port



CLASS II equipment IEC 60417-5172



Represented by
(*European representative*)



Direct current



Manufacturer



Certificate of Compliance to Technical Regulations for medical equipment (Ukraine)



Date of manufacturing



Refer to IFU
Reading of IFU before use is obligatory



Read operator's manual

SN

Serial number

MD Class IIa

MD Class Iia

1 GENERAL INFORMATION

1.1 GENERAL OVERVIEW

MD ANALYZER is a medical device for the screening diagnostics of the health status of a human, based on the analysis of the thermodynamic parameters of a human body. It provides information on 33 parameters of a human health, including blood formula, biochemical, hemodynamic and metabolic parameters without blood sampling.

The ANALYZER does not replace biochemical laboratory analysis or other standard methods of diagnostics, providing information for the physician, which is used to primary diagnosing and determine the localization of possible pathologies, which can be verified and examined using generally accepted in-vitro methods and/or special instrumental methods.

A number of parameters determined by the ANALYZER were tested during several clinical trials, where their reliability has been confirmed. They are the following: Hemoglobin HGB. g/l, Erythrocytes RBC. $\times 10^{12}/l$, Leukocytes WBC. $\times 10^9/l$, Segmented neutrophils. NEUT %, Band neutrophils. NEUT %, Lymphocytes. LYMPH %, Monocytes. MONO %, Eosinophils. %, Erythrocyte sedimentation rate ESR. mm/h, Hematocrit. HCT %, Thrombocytes. $\times 10^9/l$, Glucose. mmol/l, Calcium (Ca). mmol/l, Magnesium (Mg). mmol/l, Potassium (K). mmol/l, Sodium (Na). mmol/l, Creatinine. $\mu\text{mol}/l$, Urea. mmol/l, Cholesterol total. mmol/l, Triglycerides (TG). mmol/l, Low-density lipoproteins (LDL). mmol/l, High-density lipoproteins (HDL). mmol/l, Aspartate transaminase (AST). mmol/l, Alanine transaminase (ALT). E/l, Aspartate transaminase (AST). mmol/l, Alanine transaminase (ALT). E/l, Protein, Total. g/l, Bilirubin, Total. $\mu\text{mol}/l$, Bilirubin, Direct. $\mu\text{mol}/l$, Beginning of clotting (method of Lee-White). min, End of clotting (method of Lee-White). min, Amylase (W.T.Caraway). g/l*h, Ceruloplasmin (CP). g/l.

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-M19 (USPIH), which is used together with the MD ANALYZER. The initial information, which is measured by the MD ANALYZER, includes temperature of the certain points on a human body (5 definite areas on a human body), parameters of environment, as well as the anthropometric data of a patient (age, weight, gender), heart and respiratory rates, 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 points of placement, 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 - are placed on a neck, left and right, at the area of the carotid body. The carotid body is a small cluster of chemoreceptor cells, and supporting sustentacular cells. The carotid body is located in the adventitia, in the bifurcation (fork) of the common carotid artery, which runs along both sides of the neck. The carotid body detects changes in the composition of arterial blood flowing through it, mainly the partial pressure of arterial oxygen, but also of carbon dioxide. It is also sensitive to changes in blood pH, and

temperature. Thereby, the carotid body modulates cardiovascular and respiratory function primarily through sympathetic tone.

2 points - are placed in armpits, left and right, at the top of the axillary crease, where arteria axillaris is the closest to the skin surface. Temperature values in this area, 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 - is placed near the navel - one sensor is placed near the navel - the abdominal area on the lumbar level was chosen due to the concentration of three large vessels of a body, namely aorta, inferior vena cava and thoracic duct. Temperature of this area influences to the synthesis of essential amino acids and regulatory hormones etc. It is related to the functioning of adrenal glands` chromaffin cells (chemosensory cells), as a negative feedback of O₂ 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 certain 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 definite points with accuracy not less than 0.07°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 ANESA[®]/AMP/DAD-ANI[®] Model 19. 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 131 parameters of health. The device has five temperature sensors (digital thermal microprocessors), which are to be placed onto definite 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 processing. Calculation of the data of blood parameters is made by the special calculation algorithm named by Malykhin-Pulavskiy method (Ukrainian Patent No. 60890, 39250, 3546 A61B5).

At the end of each examination, a qualified medical professional receives the report. Besides parameters, there will be a prompt for a qualified medical professional 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 ANESA[®]/AMP/DAD-ANI[®] Model 19 is intended for the measurement of thermodynamic values on the surface of skin at specific points of a human body, which are subsequently processed by the software USPIH in combination with the initial data of the patient (sex, age, weight, manually measured heart and respiratory rate) and parameters of the environment (atmosphere pressure is measured automatically), with further representation in the form of a report with health parameters and preliminary conclusion on deviations in the state of health to which attention should be paid, (machine prompt). The qualified medical professional is able to estimate human health or recommend special examinations/tests/procedures for a diagnosis clarification based on the comprehensive approach including the analysis of the received primary screening diagnostic report, patient's history/complaints and presence of manifested symptoms and signs.

As the method of the MD ANESA/AMP/DAD-ANI is noninvasive, fast and safe, and the results are multi-informative, so such testing will be useful for determining the range of further specific diagnostic procedures, i.e. scope of focus. Using this information, a qualified, trained and experienced medical professional is able to identify existing pathologies and/or suspicious disorders of health. Therefore, the combination of the MD ANALYZER with other methods of diagnostics will be the most beneficial for the most accurate diagnosing of the patient health state.

Given that, it can be concluded such a screening device will be useful both in an admission department of a hospital and in a private clinic, general practitioner's 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 (e.g. UHF and laser therapy, mud and mineral baths, etc.).

Surely, attention should be paid to the contraindications and warning for use. Based on the current knowledge and practical experience with the MD ANALYZER, the manufacturer warns about a number of contraindication (Chapter 1.5 below).

1.5 CONTRAINDICATIONS



It is not allowed to use MD ANALYZER in pediatrics, in critical and urgent states, in ICU department (both in operation room and Emergency Room), for patients in a process of chemotherapy and X-Ray therapy or after it, 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 primarily depends on the initial state of a patient before transfusion and the ability to recover).



The presence of any skin lesions in those areas where the sensors should be placed on the patient's body (like wounds, ulcers, injuries, inflammation and rashes etc) is an absolute contraindication to an examination.



The MD ANALYZER is to be used in healthcare premises. Only specially trained medical staff (including paramedics and nurses) is permitted to operate the device. But the interpretation of the results of measurement and decision making as for diagnosis are allowed to be done only by qualified medical doctors (like physicians, therapists, family doctors, general practitioners and so on).

1.6 MODES OF OPERATION

The full use of operability of the MD ANALYZER is able in conjunction with a computer. One of software part (external) is to be installed on a PC. It allows to enter the data of a patient, keep records, display the process of measurement and the results of calculation.

The MD ANALYZER can work via Bluetooth or USB cable. The appropriate icons are highlighted in the software interface.



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

As the MD ANALYZER powered from the built-in battery, the level of battery indicator and battery charging indicator are also available in the interface.



Battery level indicator



Battery charging indicator

Using the MD ANALYZER without a PC is possible only for a battery recharge. The charger and USB cable from the complete set are to be connected to the unit. Then the charger is plugged into the power socket. Green LED on the front panel of the unit will blink while charging. When the battery is full, the LED will light without blinking.

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 650-765 mm Hg (87-102 kPa).

Safety measures during the operation and maintenance of the MD ANALYZER:



A user of MD ANALYZER must have enough technical and medical qualifications, know and fulfil the requirements listed in the present IFU to use the device properly. All maintenance procedures, recommended by the manufacturer, must be performed by personnel with appropriate approvals.



Before usage, make a visual inspection of the MD ANALYZER for detecting any possible broken and torn parts, or other mechanical damages.



Always place the MD ANALYZER on the stable and solid surface.



It is allowed to use the MD 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).



The MD ANALYZER meets the requirements of the current EU standards for safety of medical equipment (IEC 60601-1:2005+AMD1:2012 (ed.3.1) “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance” and IEC 60601-1-2 4th Ed as for EMC). Connection of the MD ANALYZER to the mains supply must be done by the national electrical safety regulations.



Before using the MD ANALYZER, an operator/user must inspect the unit and ensure that there is no external damage.



WARNING! Modification of the MD ANALYZER is not allowed!



Protect the MD ANALYZER against moisture condensation. In case of rapid change of the ambient temperature, do not switch on the MD ANALYZER during at least 30 minutes, it'll let the moisture to evaporate.



Properly certified and safe materials are used for the production of the MD ANALYZER. But the potential risk of a patient's allergic reaction to the materials of parts, which come in contact with the skin surface during the measuring procedure, exists.



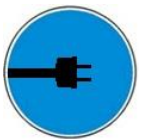
The power cable of a medical grade computer shall have a protective ground wire, the plug must have a ground connection and shall conform with mains socket, too.



Do not twist the mains cable and place it in such a way, when its damage is excluded.



Before the cleaning or maintenance works, unplug the MD ANALYZER from the power source. The means of simultaneous electrical separation of the power circuits of the MD ANALYZER from the circuits of the power supply network is the network power cable of a computer, which the MD ANALYZER is connected to.



Connect a medical grade computer only to a working socket with a rated voltage within the range 100 - 240V 50-60Hz. The position of the MD ANALYZER and computer should ensure that there is no tension on the computer's power cord, USB cable and on the cables with five microprocessors, connection and disconnection of the power cord from the supply network should be easily available for quick disconnection of the computer and MD ANALYZER in case of emergencies.



It is prohibited to pull cables for taking off sensors from a patient or remove from the connectors.



It is prohibited to use the MD 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 MD ANALYZER in potentially explosive environments, particularly in facilities with flammable anaesthetics and other flammable substances.



Usage of the MD 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 MD ANALYZER as/instead of the 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.



Strictly prohibits to use the MD ANALYZER close to fire or inside of a car where the temperature can reach 60°C and more. Also, do not charge/discharge it in such conditions (it may cause an explosion of the battery cell).



Not to use the device for testing of patients while the MD is charged from the supply network (IFU) directly.



Although the MD ANALYZER is safe and complies with the requirements of related EU standards, it is recommended to avoid the measurement of patients in a process of the device's recharge from the power supply network 220V (via AC-DC charger).



Risk of germs transmission exists! Sensors should be disinfected before and after each measurement!



It is recommended to power off the device after finishing operating



Only procedures recommended in this IFU are allowed to perform!



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



Premature unpacking of the medical device in the room for use does not lead to any risk.



It is prohibited to use the MD ANALYZER in an oxygen-rich environment.

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 MD ANALYZER during operation.
Do not disconnect a USB cable during operation and/or when the power is on.
It is forbidden to bend the cables in the place where a sensor is attached to the cable.

This device complies with the requirements of the EMC standard (IEC 60601-1-2 4th Ed.). 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.

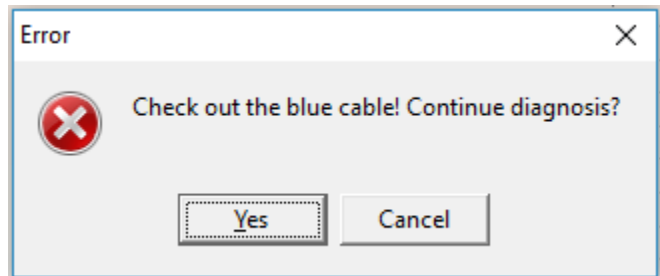
It is prohibited to install the Analyzer on a slippery and/or an uneven surface in order to avoid the device from falling down.

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 the following way:

Example: Check out the blue cable.
(Chapter 16)



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 qualified medical professional 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 0,07°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 (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 qualified medical professional will receive the report. Besides, there will be a prompt for a qualified medical professional about diagnosis at the end of a report. It is not a final diagnosis.



ANALYZER does not provide a diagnostic decision and in any case, it is not considered as the automatic diagnostic device or the device, which diagnosing automatically.

The information provided is not allowed to be interpreted by a patient!

Only a qualify medical professional (physician, pathologist, general practitioner, etc.) can interpret the results of measurement and set a diagnosis, considering medical history of the patient (acute and chronic pathologies, complaints, previous results of other examinations, like laboratory analysis, ultrasonography, tomography, etc.)

The the qualified medical professional 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 qualified medical professional 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 applied parts 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 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.3.1)/IEC 60601-1-2 4th Ed
AC-DC power supply - MEDICAL AC adapter (comply with IEC 60601-1 ed.3.1 & IEC 60601-1-2 4th ed)	Used type SWM6-5-EH-I38 AC input: 100-240Vac, 0.6-0.3A, 50-60Hz DC output: 5V  1.2A
Class of protection against penetration of water or solid particles (IP)	IP 20
Applied parts	Cables with sensors/microprocessors, type BF
Readiness time counted from switching on	max. 2 min
Weight	0,300 ±0.030 kg
Weight 5 cables	0,120±0.030 kg
Dimensions	150.2x93.2x35.5 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
Precision pressure sensor with altimetry	Pressure absolute accuracy (Test conditions: 50 to 110 kPa over-10°C to 70 °C) - ±0.4 kPa
	Pressure relative accuracy (Relative accuracy during changing temperature between -10 °C to 50 °C at any constant pressure between 50 kPa to 110 kPa)
The temperature of all surfaces the medical device:	The temperature of all surfaces of the medical device does not exceed 40 ±0.5°C

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

Minimum hardware requirements		Minimum software requirements
HDD/SSD	min. 128 Gb (256Gb is preferable)	Operating system Windows 7 and higher, Window 10 is preferable. It is necessary to have administrator rights for access to OS Windows. If the user does not have permission to create/add/modify information on system C drive, the program USPIH will not be able to work stably.
RAM	min. 3 Gb and more	
Display	min. 12" and more definition HD, FHD, QHD or more	
USB ports	USB 2.0 or 3.0 and higher PC should be equipped with 2 or 3 USB ports: 1 - for SPK;	

	1 - for ANESA (if necessary, to connect ANESA via USB, not via Bluetooth); 1 - for printer (optionally, if necessary)	
Bluetooth	3.0 and higher	Antivirus software
Medical grade computer is recommended for use in combination with the MD ANALYZER. In any case, the local regulations and requirements regarding computers in medical care institutions must be followed by the user.		Any antivirus software, if it is installed by a user, must be configured in such a way, when the software USPIH 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.

EXTERIOR of the MD ANALYZER



MD ANALYZER Model 19 (AMP Model 19/ANESA Model 19/DAD-ANI Model 19)

3.2 THE COMPLETE SET OF MD ANALYZER

The complete set of MD ANESA®/AMP/DAD-ANI® Model 19 includes the following:



Name of a part	Quantity
The unit of MD ANESA®/AMP/DAD-ANI® Model 19	1
Cable with microprocessors/sensors	5
Software protected key (SPK)	1
Cable USB	1
AC-DC power supply (SWM6-5-EH-I38)*	1
IFU (offered in electronic form/available on web https://biopromin.com)	1
Packing case	1



The AC-DC power supply (charger) SWM6-5-EH-I38 (Manufacturer GUI INC. <https://www.cui.com/>) meets the requirements of IEC 60601-1 ed.3.1 and IEC 60601-1-2 4th ed.



*The manufacturer has the right to change the type and model of AC-DC power supply without prior notice. Meanwhile, the technical characteristics of a new charger are to be at least the same as SWM6-5-EH-I38 (Manufacturer GUI INC. <https://www.cui.com/>) or better.

Cables with sensors/microprocessors, being the parts, which come into physical contact with a patient, are APPLIED PARTS (according to IEC 60601-1 ed.3.1), type BF.


Cables with sensors/microprocessors and SPK are detachable parts of the MD ANALYZER. Therefore, each is marked appropriately; the labels comply with the requirements of IEC 60601-1 3d ed. (Article 7.2.2) and includes the following information: a device's trade name and a serial number of the cable with the sensor (see Chapter 28).

Cables with sensors/microprocessors are consumable items. They are available for order in case of damage. To extend the life of the cables with sensors, it is necessary to adhere to the rules of regular maintenance concerning cleaning and disinfection, maintenance, storage and use (Chapters 18, 19, 23).

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 the Analyzer) and are the following:

GENERAL ACTIONS	
<ul style="list-style-type: none">✓ Provide the availability and sufficient reserve of water-alcohol solution (70 - 96%) and cotton pads or alcohol wipes for disinfection of the MD ANALYZER and its accessories;✓ 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 IFU) and a couch for patients (to meet the requirements of Chapter 8);✓ Remove the device from its packaging. Check for damage to the enclosure, cables with sensors, USB cable and SPK.✓ First time connection of the MD ANALYZER to a computer requires installation of the software (described in Chapter 5)	
REGULAR ACTIONS BEFORE USE (each time before first use per day)	
<ul style="list-style-type: none">✓ Connect each cable with a microprocessor/sensor to the appropriate connector on the ANESA/AMP/DAD-ANI MODEL 19 (description and illustration are in Chapter 4.3);✓ While the computer and ANESA/AMP/DAD-ANI MODEL 19 are switched off, connect them via USB cable, if you'd like to use USB mode, otherwise miss this step and follow the next ones;✓ Switch on the computer (it is not included in a complete set; Chapter 3.2) and the unit (description and illustration are in Chapter 7);✓ Run the software USPIH M19 using the icon on the desktop or in the main menu ⇒✓ Pair the computer and MD ANALYZER, if you'd like to use Bluetooth mode, using the appropriate icon in the interface of software USPIH-M19;✓ Carry out the functional test (described in Chapter 11) before testing the patients (should be done each time before first use per day).	

EVERYDAY ACTIONS BEFORE USAGE	
<ul style="list-style-type: none">✓ Connect the cable with 5 microprocessors or each cable with a microprocessor to the appropriate connector on the Analyzer's front panel.✓ While the computer and analyzer are switched off, connect them via USB cable.✓ Switch on a computer (it is not included into a complete set; Chapter 3.2);✓ Run the software USPIH using the icon on the desktop or in the main menu	

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 12).

4.2 QUALIFICATION OF AN OPERATOR. REQUIREMENTS FOR AN OPERATOR



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



The operators/users, who took psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol during at least 24 hours before working with the MD ANALYZER are not allowed to use the MD ANALYZER.

The MD ANALYZER is intended to use by qualify medical professionals (educated and certified), with a medical background, who are additionally trained as for proper operation with the MD 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 procedure.

Before start working with the MD ANALYZER, an operator/user should pass the training courses with the device, which are conducted by representatives of the manufacturer or a local distributor.

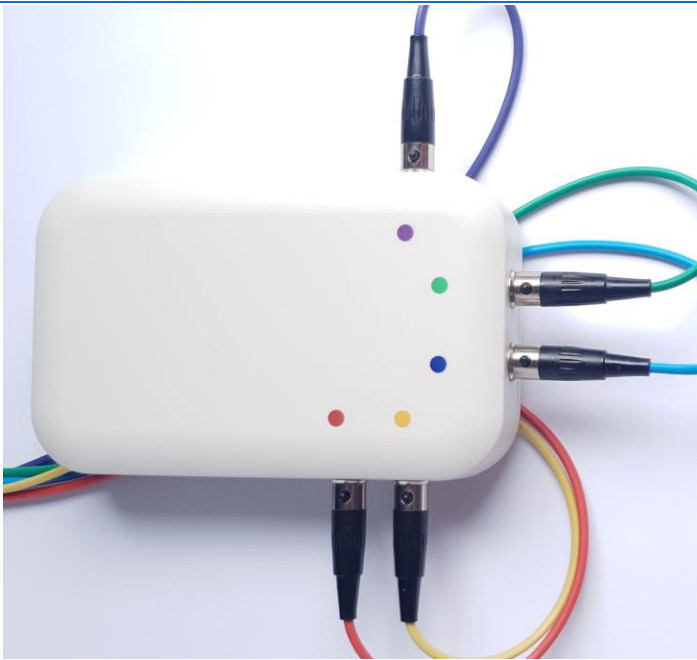
The following aspects are included in the training:

- Intended use of the device with practical exercises;
- Operation and functions of the device;
- Setting up 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 in the course due to particular features of the region/country. The local distributor provides the most detailed information about the content of the training course 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.

4.3 CONNECTION OF CABLES TO THE UNIT



Five cables with digital temperature sensors shall be connected to the unit using the female connectors on each. The cables are to be connected to the unit according to the color (blue, green, violet, yellow and red): color of the cable must match the corresponding color mark above the male connector on the box. The device is to be switched on.

5 SOFTWARE INSTALLATION

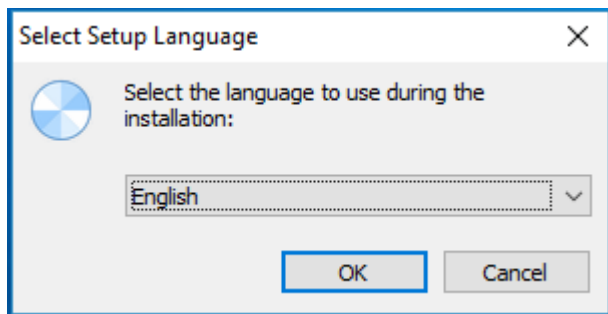
MD ANALYZER requires installation of the latest version of its own software. Before installing the software USPIH, please make sure that your computer has three available USB ports (or two USB ports and Bluetooth) and you have got the rights of "Administrator" in Windows OS (Windows 7,8,10 and higher).

To install/set up the software for USPIH M19, please follow the instructions below:

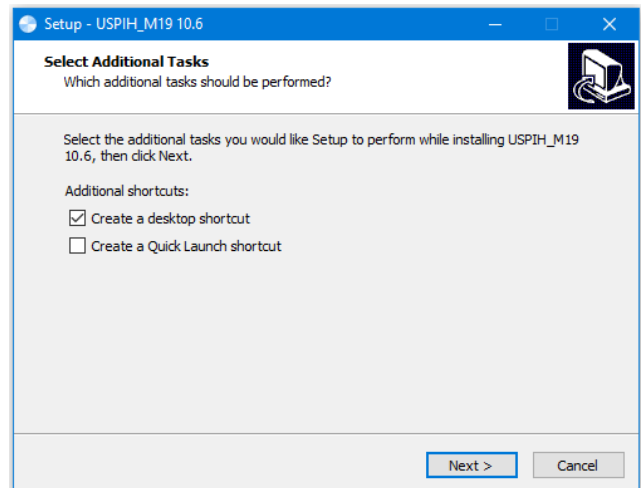
5.1. Download the setup file for the MD ANALYZER and run it.

There are three options for receiving the setup file for your device: 1) use a link for the software, indicated in the Technical Passport for your device; or 2) open your Internet browser and insert the link [https://analizator-amp.com.ua/Update/XXXXXXXXX/setup_USPIH_M19_10.6\(XXXXXXXXX\).exe](https://analizator-amp.com.ua/Update/XXXXXXXXX/setup_USPIH_M19_10.6(XXXXXXXXX).exe) (changing the XXXXXXXXX to the serial number of your device; or 3) make a request to the manufacturer's email, indicating the serial number of your device in the subject of a letter (the link will be sent to you by email).

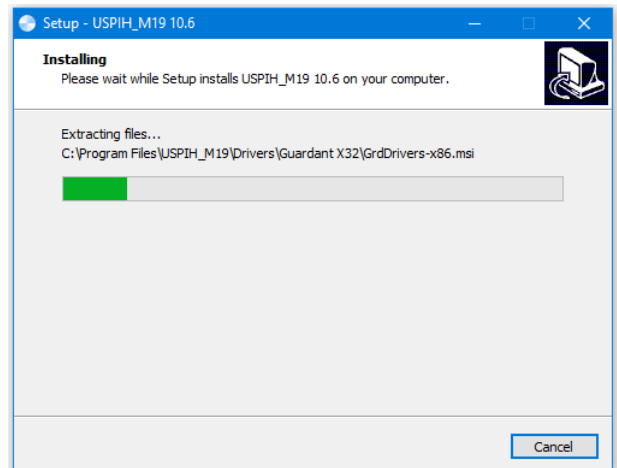
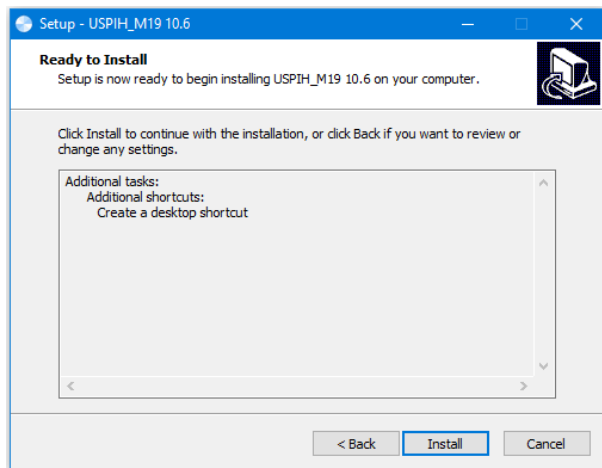
5.2 Select the language for the installation and click "OK":



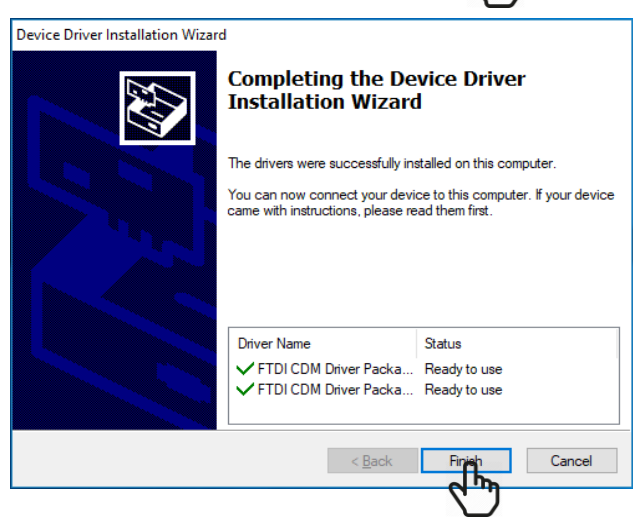
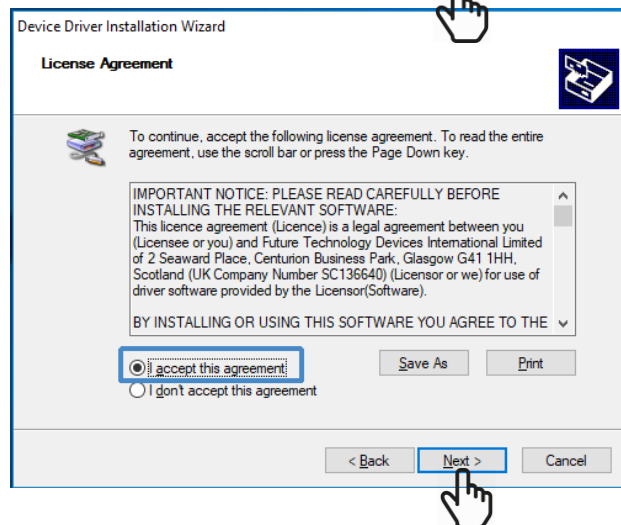
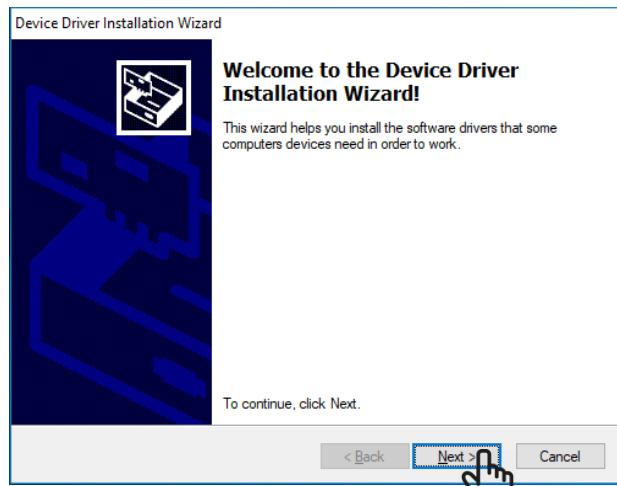
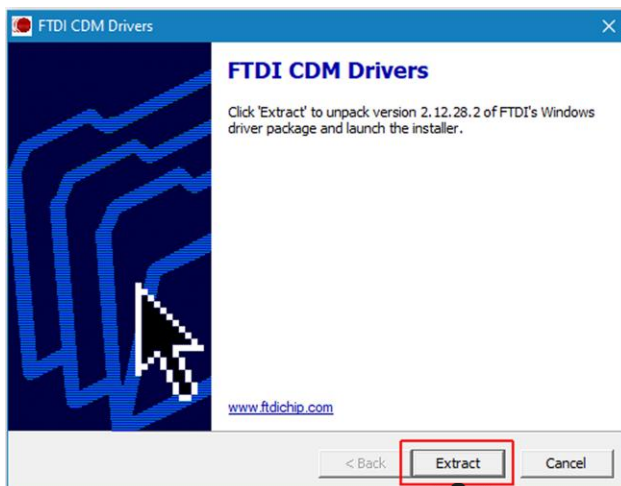
In the appeared window, click „Next”:



5.3 In the appeared window, click „Install” and wait:



5.4. Install FTDI CDM Drivers



5.5. If the software is installed at first to the computer (before you have never work with this device on this computer), **do not tick “Launch USPIH M19”** (because the drivers for the

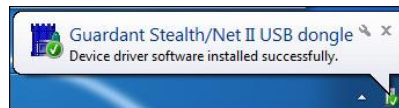
5.6. Create a desktop icon:

device has been not been installed yet).
Press "Finish":



5.7. Install **Guardant Stealth II** Drivers

The MD ANALYZER requires software protection key (SPK) for working (**Guardant Stealth II key** is included in the complete set). After connecting the MD ANALYZER and successful installation of the software, it is necessary to insert Guardant Key to a USB port of the computer. Windows OS will detect it and install the drivers for automatically. The following window will appear:



Installation process is complete. You can start working with the device.

6 SOFTWARE USPIH-M19: FEATURES

During installation of the software for the MD ANALYZER, the new directory is usually created on the hard drive by the path *C:\Program Files\USPIH_M19*. Among others, it contains the following files:

- USPIH_M19.exe – real time control application;
- PATIENT.FDB– database files;
- FTDI, FTClean, Drivers, Fonts, Guardant – folders with PC interface drivers;
- unins000.exe, unins000.dat – uninstall software file;
- Other files and libraries, which are necessary for the operation of the software (such as fbclient.dll, fbrmclib.dll, FTD2XX.DLL, GRDCTL32.DLL, NOVEX32.DLL, BtH_M19.dll, libeay32.dll, sslsleay32.dll etc)

7 START WORKING WITH USPIH VER.10.5 AND HIGHER

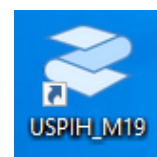
7.1 CONNECTING THE DEVICE TO A COMPUTER VIA USB

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

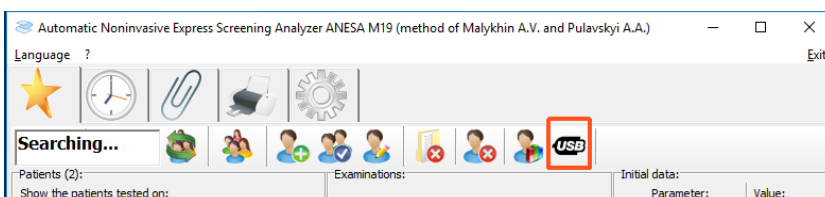
Press and hold the "POWER" button at least three seconds, till green LED stop flashing and light continuously.



Run the software using the icon



The indicator of USB connection will be displayed in the upper left corner of the software interface



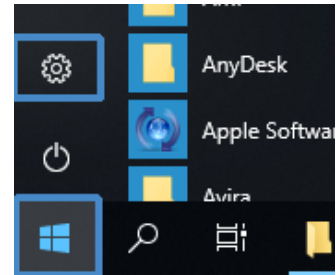
7.2 CONNECTION THE DEVICE TO A COMPUTER VIA BLUETOOTH

To turn on the device, please press and hold the "POWER" button at least three seconds, till green LED stop flashing and light continuously.

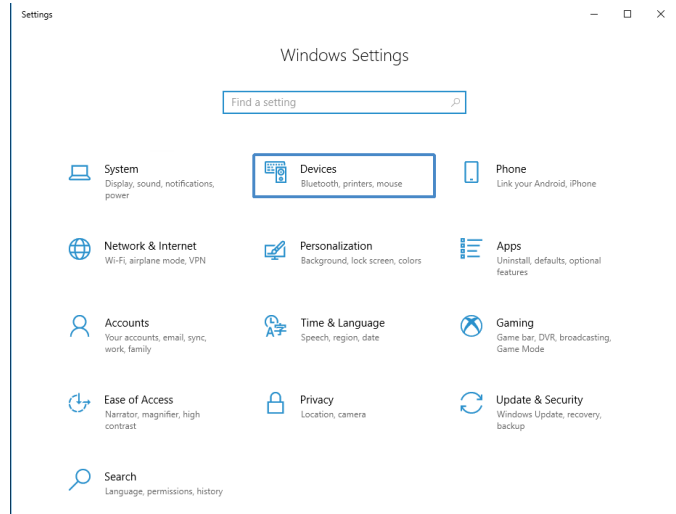


Create the Bluetooth pair between the computer and the MD ANALYZER

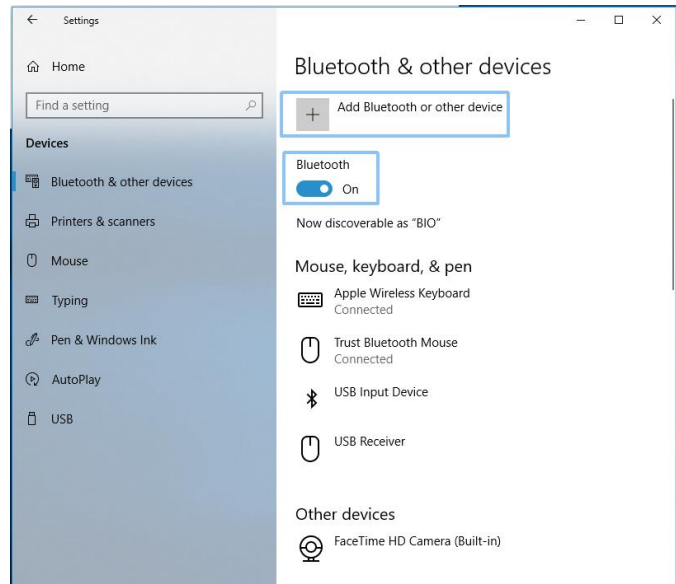
In the main menu of OS Windows, select the "Settings" menu



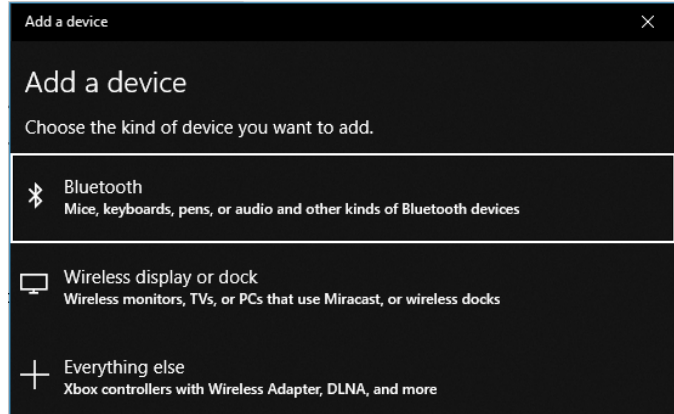
Then, select the menu "Devices"



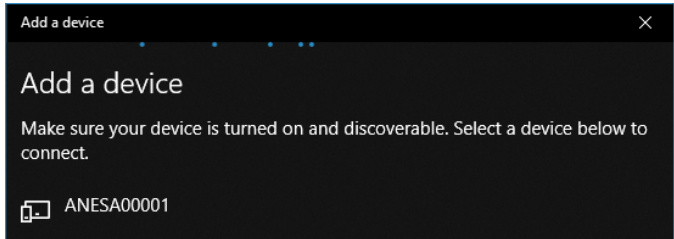
Turn on Bluetooth and press
“+ Add Bluetooth or other device”



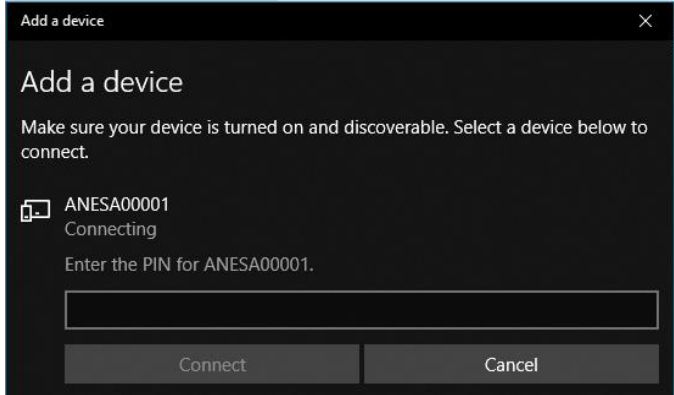
Select menu “Bluetooth”



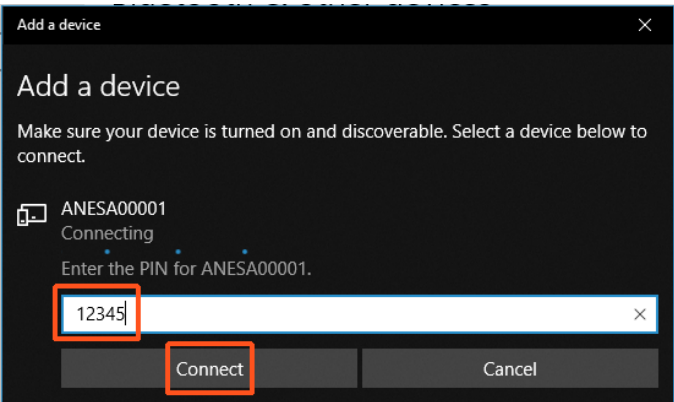
Add the device MD ANALYZER
(the serial number will be visible here)



The window with a request for a password will be displayed



Enter password: **12345** and press “Connect”

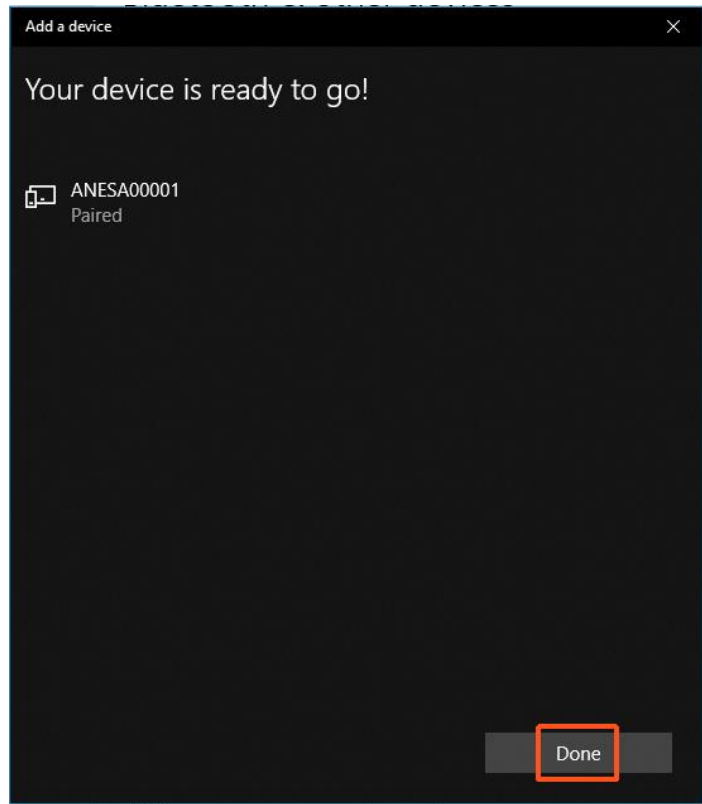
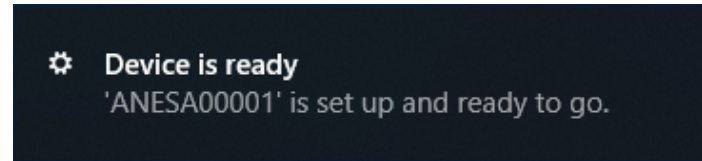
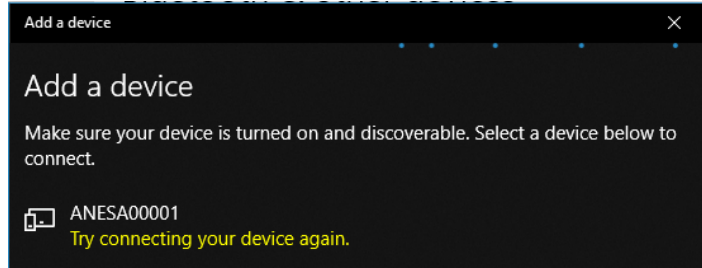


If the password was entered incorrectly or you did not enter it for a long time, the following message will appear:

Try to connect your device again.

In the lower right corner of the Windows interface, the message is displayed: "The device is ready"

Click "Done" to continue.

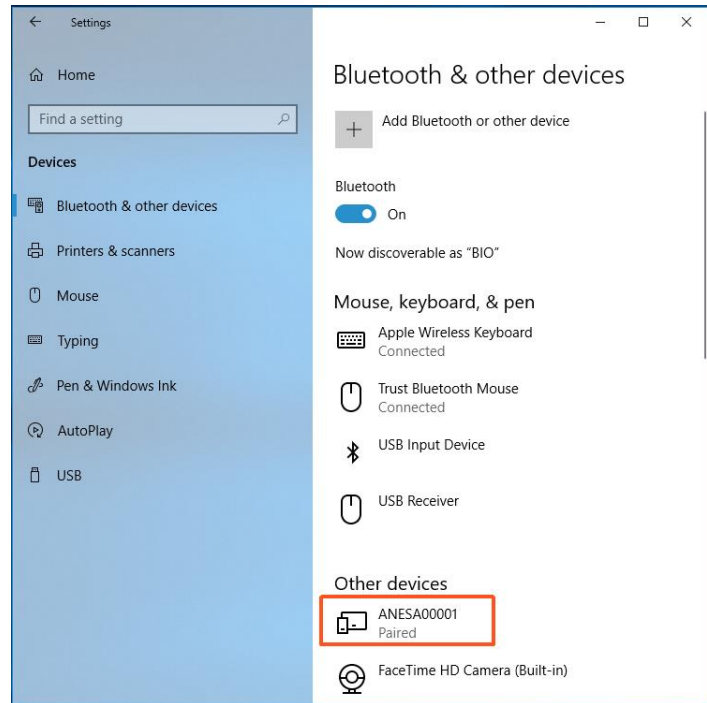


If the pairing of the MD ANALYZER and the computer via the Bluetooth channel is successful, the blue LED (under the sign of Bluetooth) on the front panel of the device will light up.

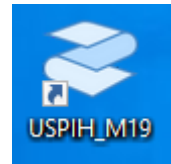


To check the correct connection of the device to the computer, use the Setting menu of OS Windows.

The MD ANALYZER with its serial number will be listed in the appropriate list of Bluetooth devices.



Run software using the icon



8 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 IFU (Chapter 2.1.)

9 STARTING WORK WITH USPIH: PERSONAL SETTINGS

The user's interface is available on 20 languages (Ukrainian, Russian, English, Chinese, Spanish, Hungarian, Slovak, Greek, Slovenian, Italian, French, Turkish, Croatian, Polish, Bulgarian, Japanese, Czech, Serbian, German and Vietnamese).

Run the software USPIH (for ver.10.5 and higher)

Run **USPIH-M19** clicking on the appropriate icon on the desktop or tool bar. The main window of the software USPIH will be opened.

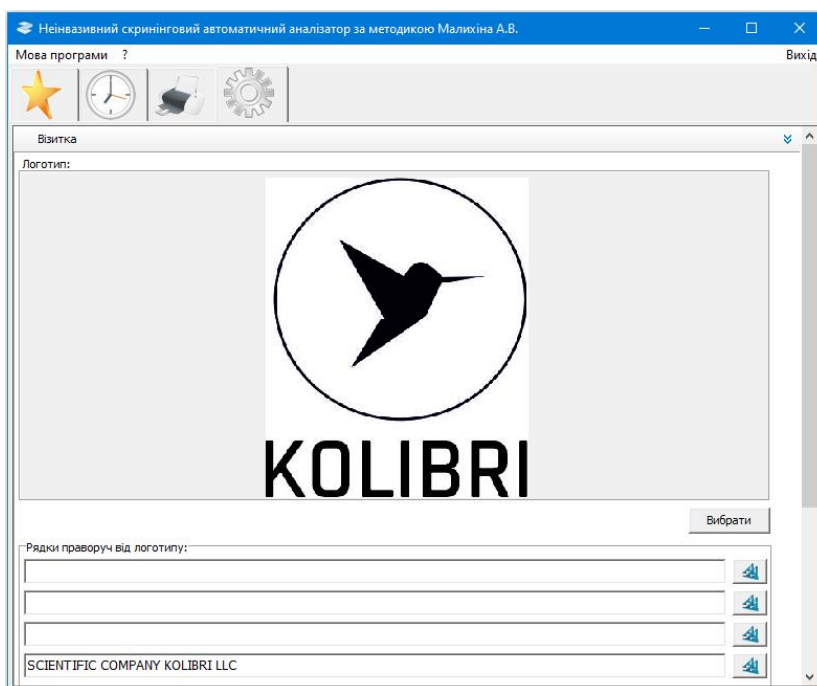
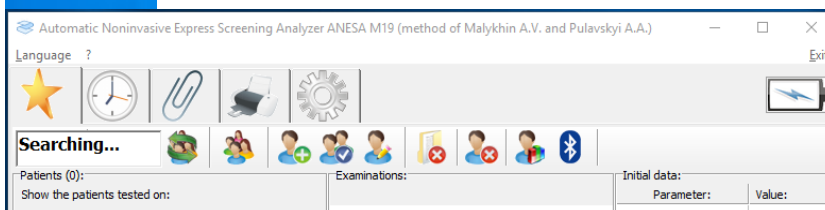
First time, USPIH will run in English. If you need to change the language, use an appropriate menu “Language” on the top.

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

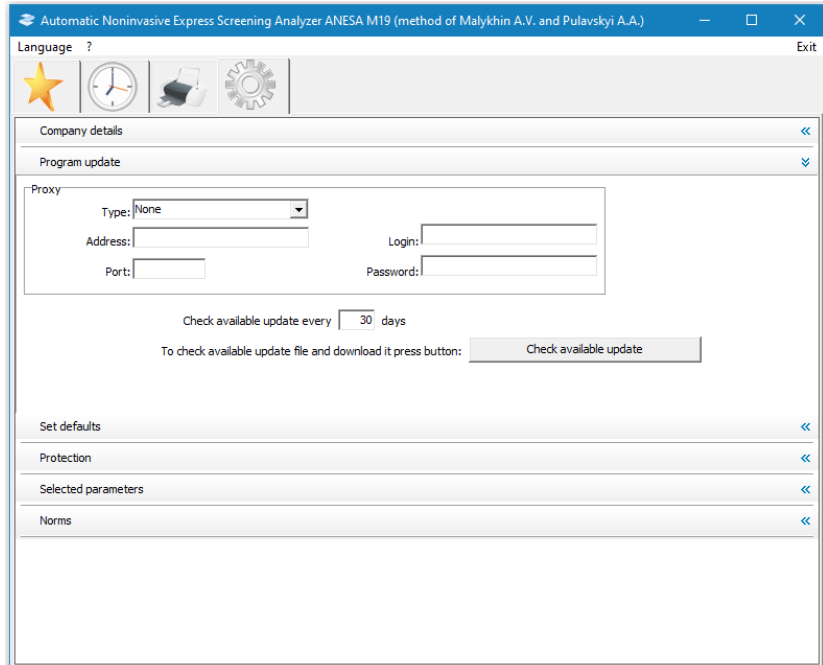
Sub-menu “*Company details*” allow adding and formatting the name of a company, it’s address and contact information, as well as a company’s logo: four spare fields are used for the details and one – for logo.

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

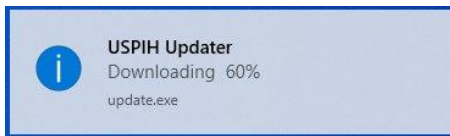
Text may be edited (font, size, color, etc.) using the appropriate icon near each field.



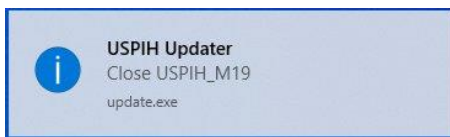
Sub-menu **“Program update”** includes the setting for the software’s updating. Software is updated via Internet automatically every 30 days (by default). It is possible to change the period of the updating manually. In case of necessity for immediate update, click the button "Check for Update."



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

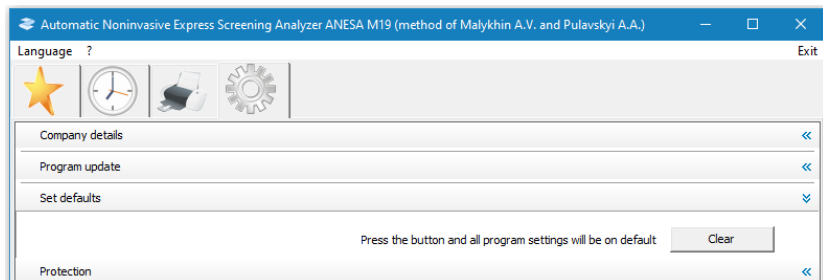


It is necessary to close the software USPIH after finishing the process of updating:

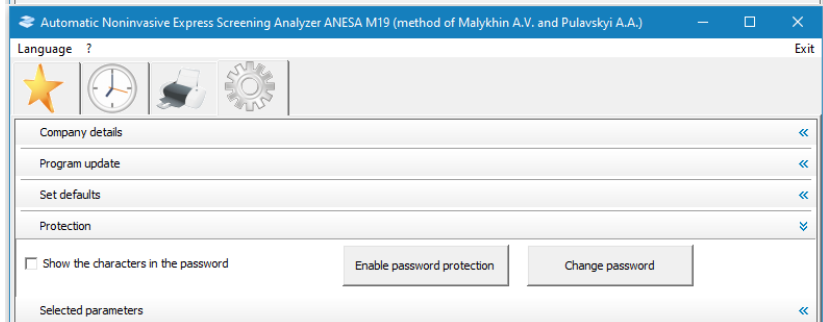


USPIH will launch automatically.

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.



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.

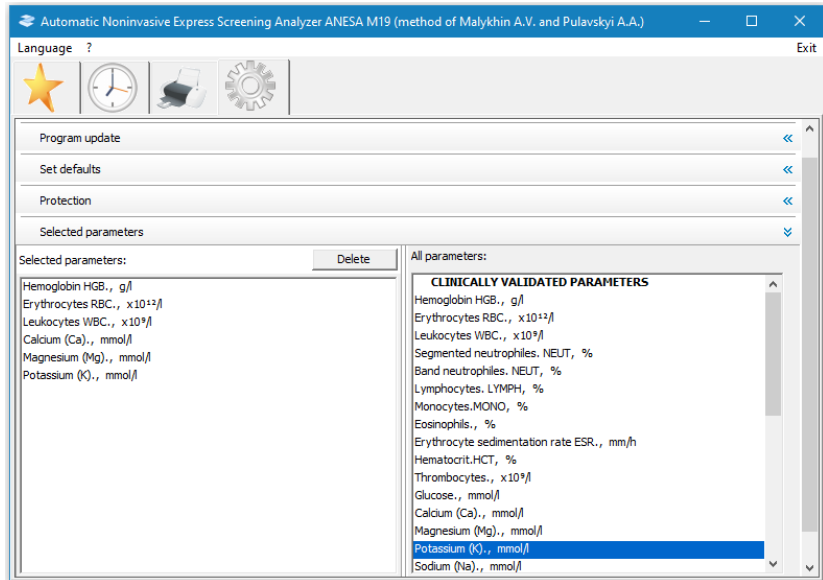


To display the characters in the password checkbox, tick "Show characters in the password". To enable or change the password, press an appropriate button. Enter a password, using 4-8 characters. The default password is "0000" (four zeros).

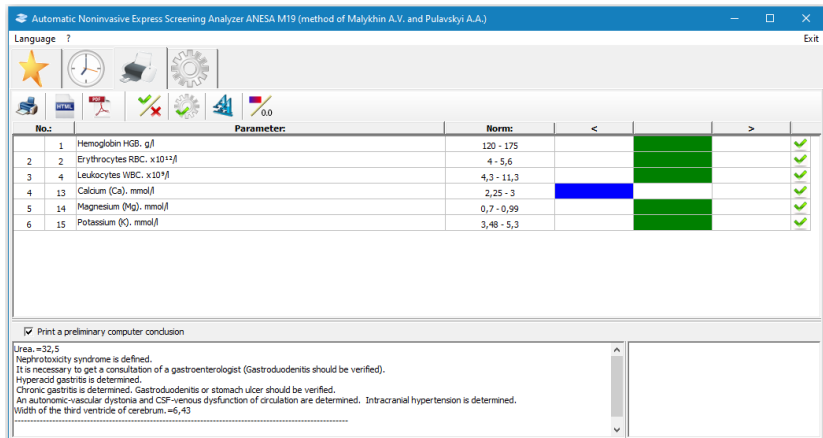
In case of changing the password, it is necessary to enter the old password and confirm it, by pressing the button "Yes." Then, a new password should be entered and confirmed by pressing the button "Yes" (the procedure should be made twice). If the changing of a password is successful, the message "Password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



Sub-menu "Selected parameters" might be used if a qualified medical professional would like to select some parameters or group of parameters for quick preview after measurement. There is a list of all parameters, divided by group, in the right part of the window (All parameters). It is necessary to double click on the name of the 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 the window (Selected parameters). To clear the list of "Selected parameters" click the button "DELETE".

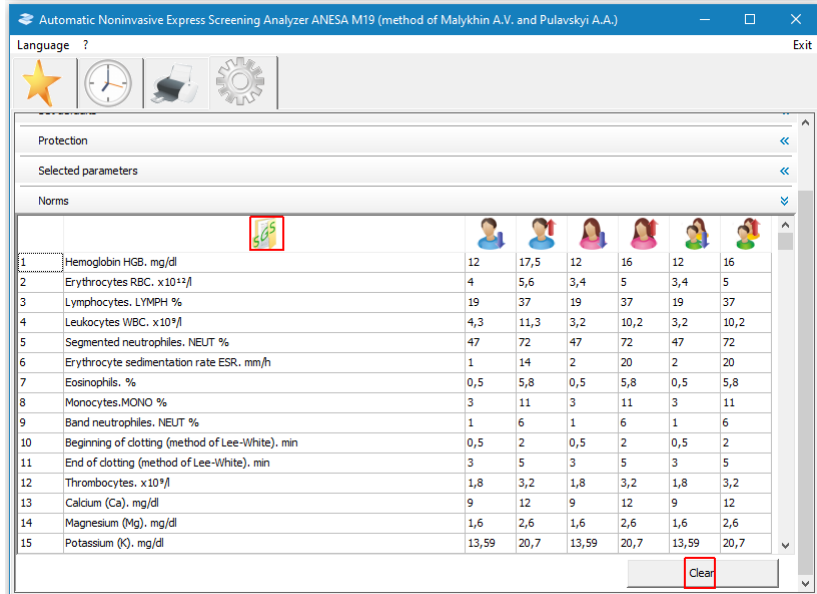
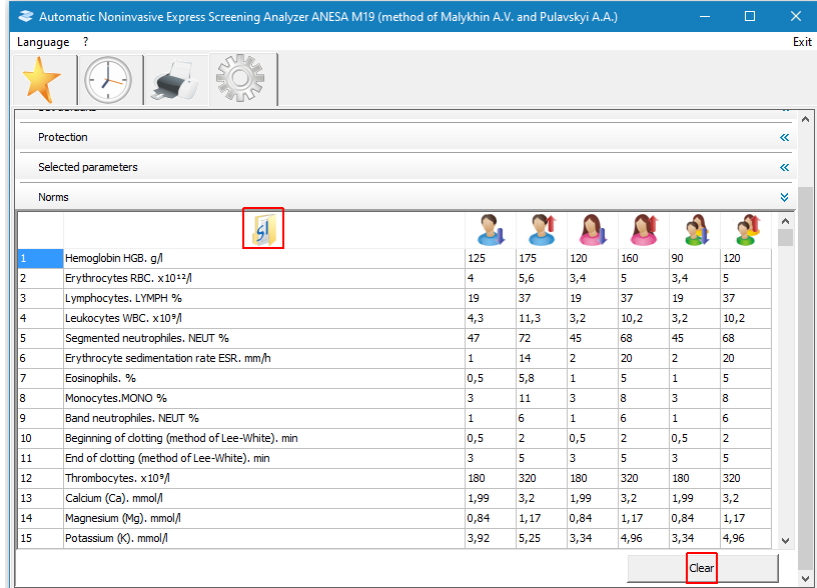


Further, after each measurement, selected parameters will be displayed at first. To view all parameters, press the button:



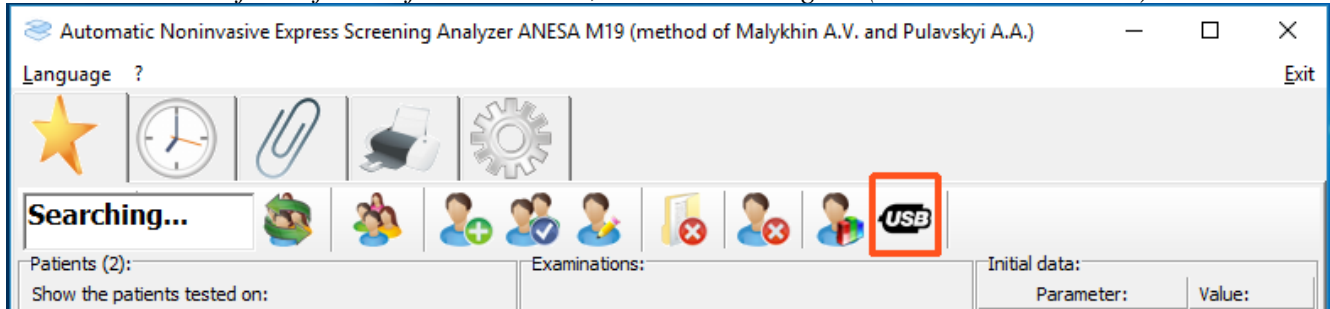
Sub-menu “*Norms*” is used for changing the normal ranges for each parameter (separated by gender and age) according to the commonly accepted ranges on the territory of usage. Normal ranges are set for two systems of units: SI and SGS. It is necessary to click on the icon SI or SGS (above the list of 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).

To return to the factory settings, select the measurement units in sequence and click the Clear button.

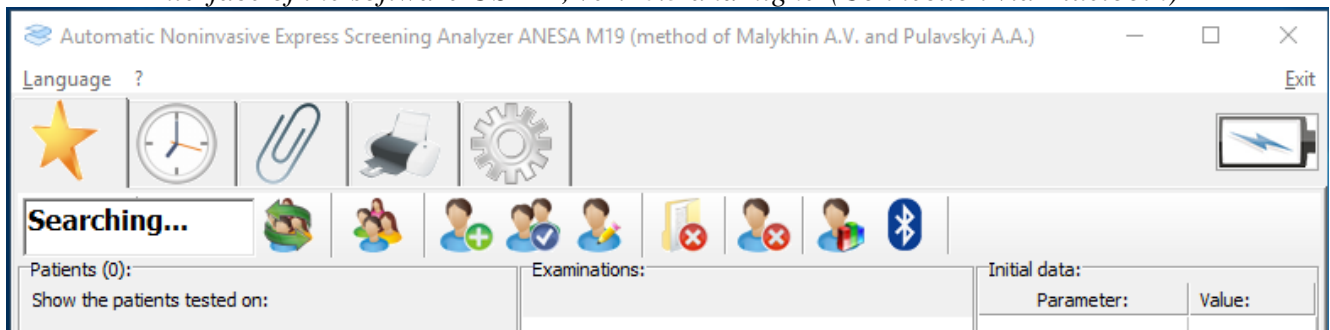


10 WORKING WITH THE SOFTWARE USPIH

Interface of the software USPIH, ver.10.5 and higher (Connection via USB)



Interface of the software USPIH, ver.10.5 and higher(Connection via Bluetooth)











10.1 Description of the interface items, used in both versions of the software:

10.1.1 The top menu contains three parts

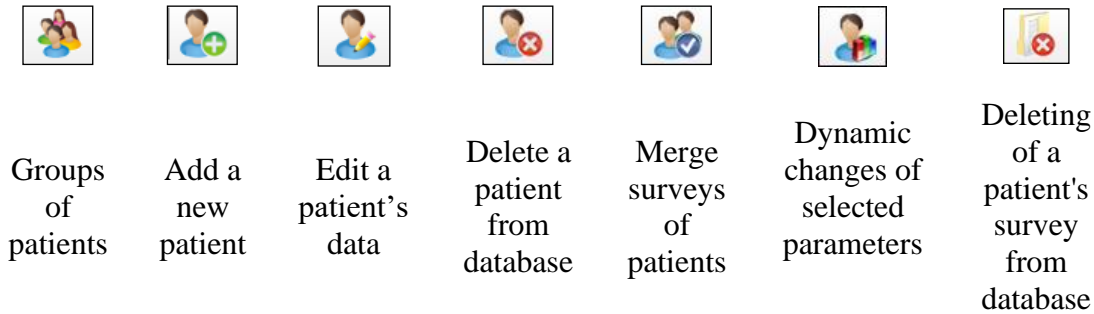
"Language" To choose/change the language	"?" To open help file and information about program	"Exit" to exit the program
---	---	---

10.1.2. The second-level menu consists of the following icons:

							
main window/ starting window	graphic trends and checking panel for temperature measuring	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

10.1.3. 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.



Detailed description of each sub-menu from the 3d-level is on the Chapter 10.3

10.1.4. 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.



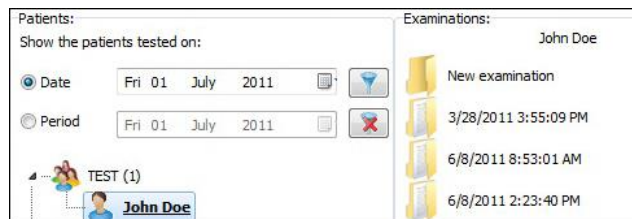
Filter is activated after pressing the icon



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 10.5*).



- ❖ 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

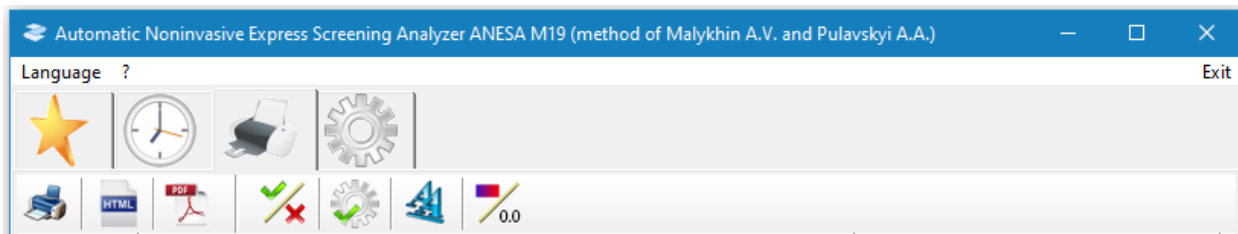
Stabilizing “99999” means the temperatures during measurement fully stabilized (100%).

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

10.1.5 Menu “Preparing of a survey for printing or saving”



The menu contains seven buttons.



- 1) Print the results of the screening on a printer.
- 2) Save the results of the screening in the HTML format.
- 3) Save screening results in PDF format with password protection of the document (*available only for version 10.6 M-19*).
- 4) To include or exclude the parameters in the printed report.

No.:	Parameter:	Norm:	<	>	
CLINICALLY VALIDATED PARAMETERS					
1	Hemoglobin HGB. mg/dl	12 - 17,5			✓
2	Erythrocytes RBC. x10 ¹² /l	4 - 5,6			✓
4	Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3			✗
3	Segmented neutrophils. NEUT %	47 - 72			✓
4	Band neutrophils. NEUT %	1 - 6			✓
5	Lymphocytes. LYMPH %	19 - 37			✓
6	Monocytes.MONO %	3 - 11			✓
7	Eosinophils. %	0,5 - 5,8			✓
6	Erythrocyte sedimentation rate ESR. mm/h	1 - 14			✗
8	Hematocrit.HCT 0.01*%	0,35 - 0,49			✓
9	Thrombocytes. x10 ⁹ /l	1,8 - 3,2			✓
42	Glucose. mg/dl	71,9 - 107,9			✗
10	Calcium (Ca). mg/dl	9 - 12			✓
11	Magnesium (Mg). mg/dl	1,6 - 2,6			✓
12	Potassium (K). mg/dl	13,59 - 20,7			✓
13	Sodium (Na). mmol/l	300 - 360			✓
14	Creatinine. mg/dl	0,62 - 1,39			✓
15	Urea. mg/dl	12,8 - 49,2			✓

- 5) Show selected parameters or complete list.
- 6) To set the font for the printed version of the report with the results.
- 7) To display the results in color identification or in figures.

Automatic Noninvasive Express Screening Analyzer ANESA M19 (method of Malykhin A.V. and Pulavskiy A.A.)

Language ? Exit

No.:	Parameter:	Norm:	<	>	
CLINICALLY VALIDATED PARAMETERS					
1	1 Hemoglobin HGB. mg/dl	12 - 17,5			✓
2	2 Erythrocytes RBC. x10 ¹² /l	4 - 5,6			✓
3	4 Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3			✓
4	5 Segmented neutrophils. NEUT %	47 - 72			✓
5	9 Band neutrophils. NEUT %	1 - 6			✓
6	3 Lymphocytes. LYMPH %	19 - 37			✓
7	8 Monocytes.MONO %	3 - 11			✓
8	7 Eosinophils. %	0,5 - 5,8			✓
9	6 Erythrocyte sedimentation rate ESR. mm/h	1 - 14			✓
10	88 Hematocrit.HCT 0.01*%	0,35 - 0,49			✓
11	12 Thrombocytes. x10 ⁹ /l	1,8 - 3,2			✓
12	42 Glucose. mg/dl	71,9 - 107,9			✓
13	13 Calcium (Ca). mg/dl	9 - 12			✓
14	14 Magnesium (Mg). mg/dl	1,6 - 2,6			✓
15	15 Potassium (K). mg/dl	13,59 - 20,7			✓
16	16 Sodium (Na). mmol/l	300 - 360			✓
17	31 Creatinine. mg/dl	0,62 - 1,39			✓
18	34 Urea. mg/dl	12,8 - 49,2			✓

Print a preliminary computer conclusion


Automatic Noninvasive Express Screening Analyzer ANESA M19 (method of Malykhin A.V. and Pulavskiy A.A.)

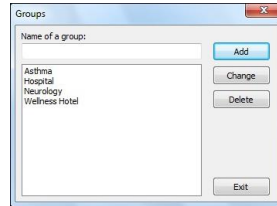
Language ? Exit

No.:	Parameter:	Norm:	<	>	
CLINICALLY VALIDATED PARAMETERS					
1	1 Hemoglobin HGB. mg/dl	12 - 17,5		13,86	✓
2	2 Erythrocytes RBC. x10 ¹² /l	4 - 5,6		4,40	✓
3	4 Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3		7,23	✓
4	5 Segmented neutrophils. NEUT %	47 - 72		52,82	✓
5	9 Band neutrophils. NEUT %	1 - 6		4,43	✓
6	3 Lymphocytes. LYMPH %	19 - 37		28,48	✓
7	8 Monocytes.MONO %	3 - 11		7,22	✓
8	7 Eosinophils. %	0,5 - 5,8		7,05	✓
9	6 Erythrocyte sedimentation rate ESR. mm/h	1 - 14		10,20	✓
10	88 Hematocrit.HCT 0.01*%	0,35 - 0,49		0,38	✓
11	12 Thrombocytes. x10 ⁹ /l	1,8 - 3,2		2,12	✓
12	42 Glucose. mg/dl	71,9 - 107,9		79,87	✓
13	13 Calcium (Ca). mg/dl	9 - 12	8,12		✓
14	14 Magnesium (Mg). mg/dl	1,6 - 2,6		1,71	✓
15	15 Potassium (K). mg/dl	13,59 - 20,7		17,76	✓
16	16 Sodium (Na). mmol/l	300 - 360	143,02		✓
17	31 Creatinine. mg/dl	0,62 - 1,39		1,92	✓
18	34 Urea. mg/dl	12,8 - 49,2		194,75	✓

Print a preliminary computer conclusion

10.2 Groups of patients

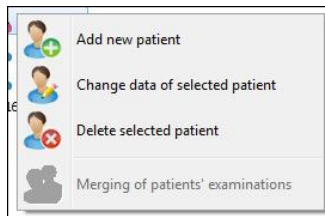
For the convenience of usage, the patients in database can be divided into groups. It is necessary to use icon  for creating a new group, editing or deleting an existing one.



IMPORTANT! The software USPIH-M19 will not allow an existence of two groups of patients with the same title/name.

10.3 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.

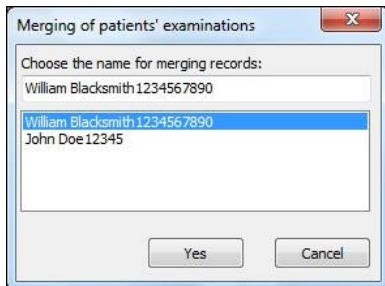
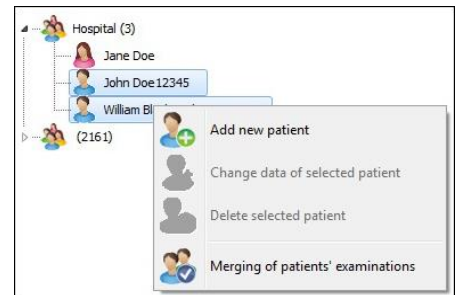
To **Delete a patient’s card**/record from the database, it is necessary to select a patient’s card from the list of patients and then click an appropriate icon in the main or context menu 

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-M19 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.”

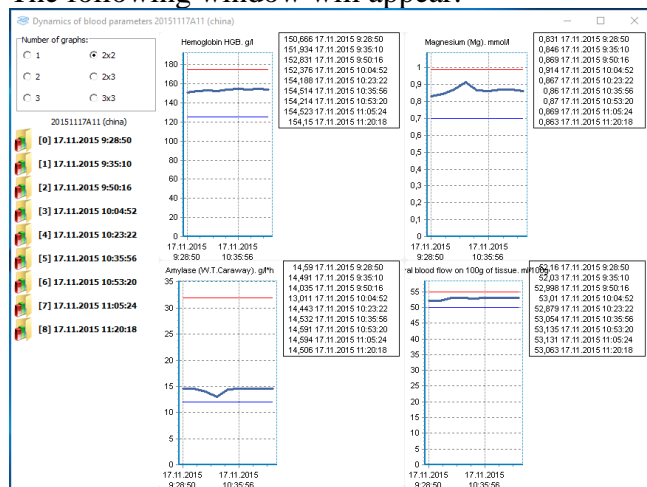
- In case of password protection is activated, enter the valid password in the appeared window (the default password is “0000” (four zeros)).

10.4 Dynamic changes of selected parameters (only for USPIH-M19)

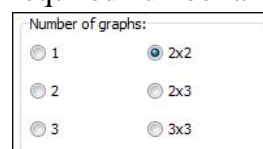
This option allows displaying the dynamic changes of selected parameters (graphically) for a patient, who was examined several times. For that purpose, it is necessary to choose a patient and press appropriate icon in the menu.



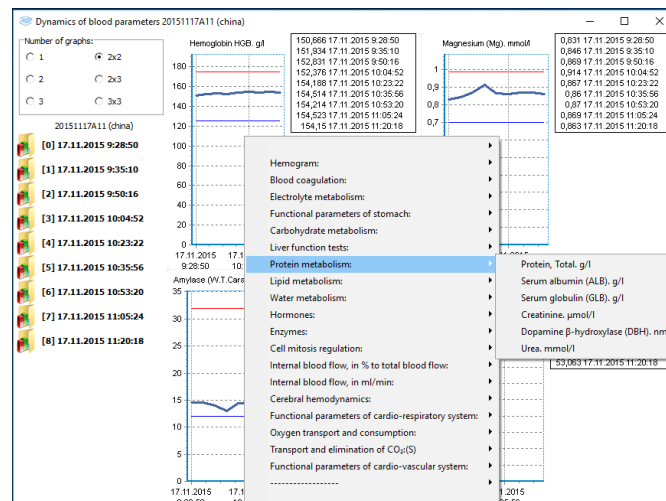
The following window will appear:



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.

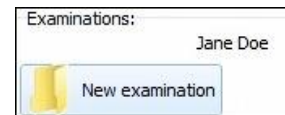
By default, all examinations of the selected patient are represented in the list of examinations for comparison. They are displayed in the left part of the window. To exclude an examination from the list, click the left mouse button on the date of a survey you don't need (it will be removed from the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

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

A qualified medical professional 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.

11 FUNCTIONAL TEST OF MD ANALYZER

A qualified medical professional 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 10.5) in the database. It is created just once and a qualified medical professional 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 16 of the present IFU or contact your distributor /the manufacturer for troubleshooting.

12 DESCRIPTION OF MEASURING PROCEDURE

The work is started by adding a new patient (Chapter 10.5) or choosing the existing one from the database and creating the new examination (Chapter 10.5)

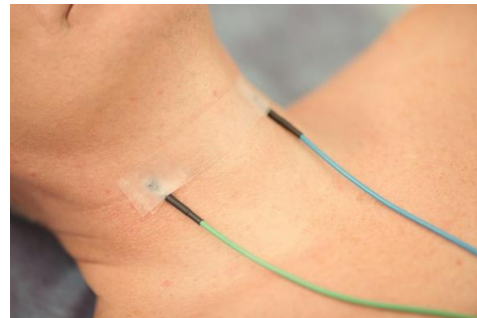


It is required to make an examination, in the supine position, when a patient is calm, had no physical activity during 5-10min, (IFU, Chapter 8).

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)

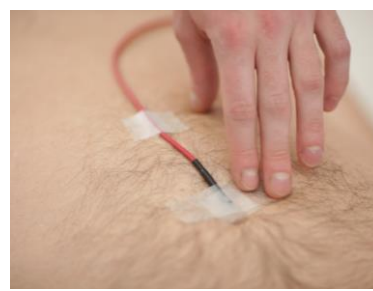
Yellow - on the **left** armpit in axillary area (LAC); **Purple** - on the **right** in axillary area (RAC)



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).

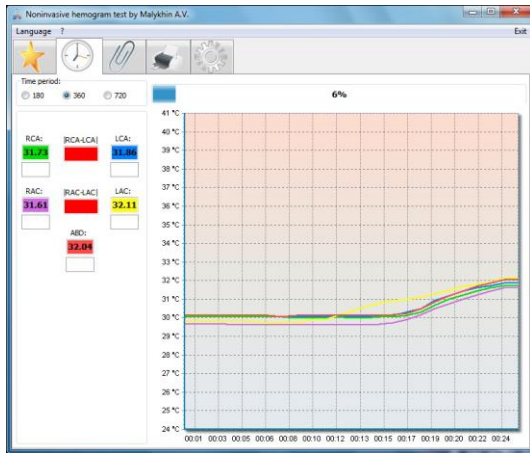
Abdominal sensor

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

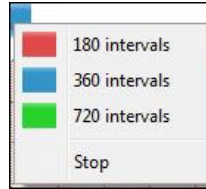


Abdominal temperature (umbilical) is measured in the area, where aorta, inferior vena cava and large lymph vessel are crossed. Pulsation is felt manually in the cross-point of vessels. Sensors should be fixed by plaster.

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 qualified medical professional 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

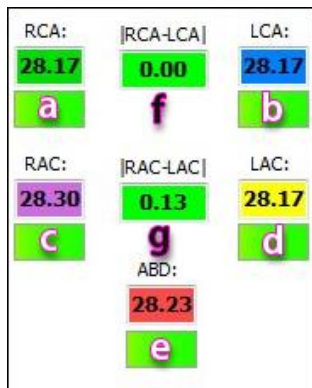


or in drop-down menu, which appears after right-click on the progress bar. The measurement can be stopped using this menu, too



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 qualified medical professional to determine the time of temperature stabilization and control the process of measurement!

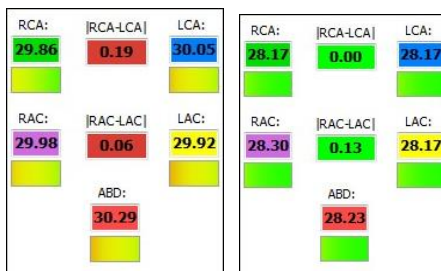
The indicators are the following:



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 qualified medical professional 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.

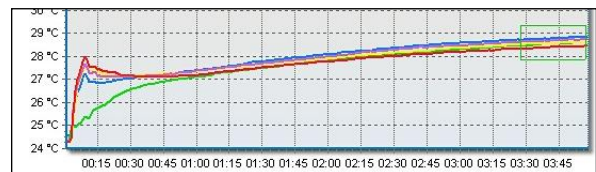
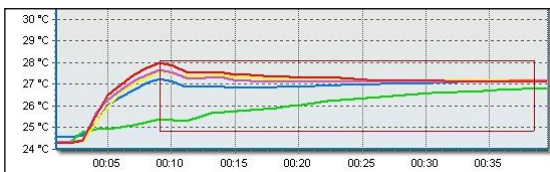
If the difference between armpit sensors does not exceed 0.5°C, as well as carotid sensors, and temperature of all sensors (including sensor of abdominal area!) stabilized, the indicators become green, otherwise - red.



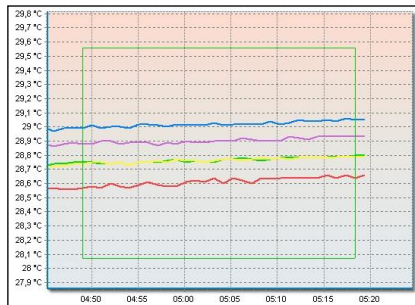
IMPORTANT! If the rectangles below temperature values are not green till the end of measurement, a qualified medical professional should change time interval to the larger one.

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.



Results of measurement in USPIH (version 10.5 and higher)

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 a quick preview in the setting menu (Chapter 9), the tag „Selected parameters” will be displayed at first.

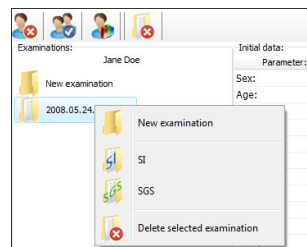
No.:	Parameter:	Norm:	<	>	
CLINICALLY VALIDATED PARAMETERS					
1	Hemoglobin HGB. g/l	125 - 175			✓
2	Erythrocytes RBC. x10 ¹² /l	4 - 5,6			✓
3	Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3			✓
4	Segmented neutrophils. NEUT %	47 - 72			✓
5	Band neutrophils. NEUT %	1 - 6			✓
6	Lymphocytes. LYMPH %	19 - 37			✓
7	Monocytes. MONO %	3 - 11			✓
8	Eosinophils. %	0,5 - 5,8			✓
9	Erythrocyte sedimentation rate ESR. mm/h	1 - 14			✓
10	Hematocrit. HCT %	35 - 49			✓
11	Thrombocytes. x10 ⁹ /l	180 - 320			✓
12	Glucose. mmol/l	3,9 - 6,2			✓
13	Calcium (Ca). mmol/l	1,99 - 3,2			✓
14	Magnesium (Mg). mmol/l	0,84 - 1,17	■		✓
15	Potassium (K). mmol/l	3,92 - 5,25			✓
16	Sodium (Na). mmol/l	136 - 145			✓
17	Creatinine. μmol/l	55 - 123			✓
18	Urea. mmol/l	2,1 - 8,2			✓
19	Cholesterol total. mmol/l	3,11 - 6,48			✓
20	Triglycerides (TG). mmol/l	0,55 - 1,85			✓
21	Low-density lipoproteins (LDL). mmol/l	2,7 - 3,37			✓

Print a preliminary computer conclusion

Nephrotoxicity syndrome is defined.
 It is necessary to get a consultation of a gastroenterologist (Gastroduodenitis should be verified).
 Hyperacid gastritis is determined.
 Chronic gastritis is determined. Gastroduodenitis or stomach ulcer should be verified.
 An autonomic-vascular dystonia and CSF-venous dysfunction of circulation are determined. Intracranial hypertension is determined.
 Width of the third ventricle of cerebrum. =6,43

- **Red** color of the field means that the parameter is higher than the generally accepted norms;
 - **Blue** color of the field means that the parameter is lower than the generally accepted norms;
 - **Green** color of the field means that the parameter is the norm the generally accepted norms;
- When a qualified medical professional put the cursor to any field of the parameter, the pop-up hint with a result 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 all parameters fully comply with generally accepted norms. The norms were defined for an average person (with average weight, height, age, etc.) in 70s last century. Definition of norms was done on a relatively small population in a limited area.



ATTENTION! The interpretation of the results of screening test and decision making as for health status are allowed to be done only by the qualified medical doctors (like physicians, therapists, family doctors, general practitioners and so on).



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.




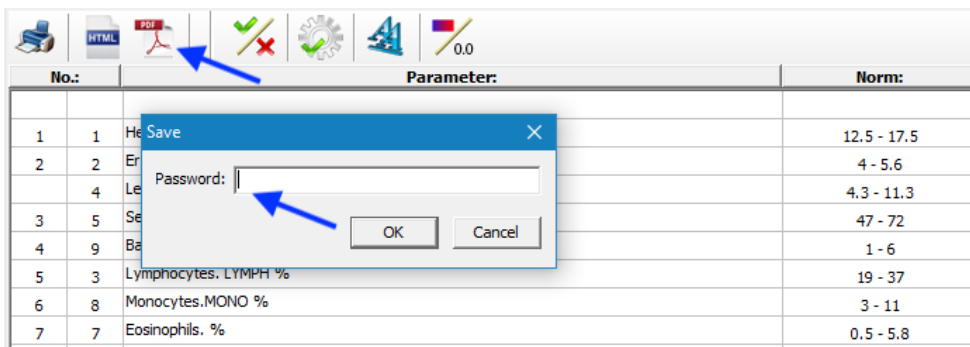
There is an automatic conclusion for a qualified medical professional to help him/her with diagnosing a patient (it is displayed in the left bottom corner and printed in the beginning of a survey). The qualified medical professional may agree with it, edit it or delete it (at all or just some part). 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 qualified medical professional if necessary.

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 . In USPIH version 10.X M-19 saving in

encrypted PDF file is available: click on the icon  (Encryption Protocol RC4 128 bits), set up a password and save file. 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.



This icon is used to adjust the font for printed version of the report/survey.



This icon is intended to display test results in color or figures. (See Chapter 15)

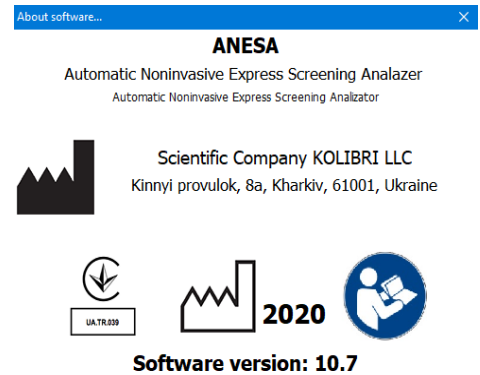
13 COUNTING THE NUMBER OF SURVEYS (FOR LIMITED VERSION OF MD ANALYZER, USPIH-M19)

According to the distributor's requirements, SPK protection key may be used for limiting the software usage (available for version 10.0 and higher). 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 500 tests in the example at right). In case the software is unlimited, the icon of infinity "∞" will be displayed instead of figures.



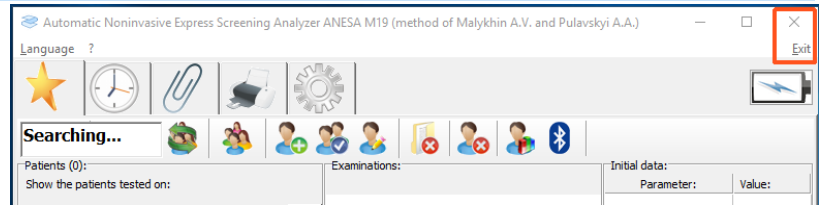
Serial number of the device: ANESA00000
Number of tests: 500



IMPORTANT! The number of available examination is counted down from the set limit by the software automatically, after each of the made tests. As soon as the number becomes zero, there will be no possibility to examine patients. To update the limit of available examination, please contact your distributor.

14 SWITCHING-OFF MD ANALYZER

1. Close the software USPIH



2. Switch off the MD:
Press and hold the "POWER" button at least 3 sec.
The green LED will flash quickly and then turn off. Power is off.
3. Disconnect a USB cable connecting the computer and the MD ANALYZER or MD ANALYZER and Charger.
Carefully disconnect the cables with sensors from the MD ANALYZER: press the small black button and gently pull out.



4. Disconnect the SPK from the computer.
5. Switching off the device is completed.

15 EXAMPLE OF A SURVEY

EXAMPLE OF A REPORT/SURVEY

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

28.01.2014 9:32:40 00010101 : 20160619

Gender: male	Age: 69	Weight(kg): 68	Pulse: 100	Resp.rate: 18	Atm.pres: 748,02
LCA: 34,63	RCA: 34,58	LAC: 36,68	RAC: 36,18	ABD: 34,62	176,69 99999

Preliminary computer conclusion about diagnosis:

Asthenic-autonomic syndrome is determined.

Post hypoxic encephalopathy is defined.

It is necessary to get a consultation of a gastroenterologist (Gastroduodenitis should be verified).

Ischemic heart-disease is determined.

Hypertension of pulmonary circulation is defined.

Width of the third ventricle of cerebrum.=7,99

Derangement of atrioventricular (AV) conduction should be verified. It is necessary to monitor EKG in dynamics.

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).=22,6
Tiffeneau index has reduced till: 80,4 (Test Tiffeneau.)

Disclaimer.

The above medical information is provided as a 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.

Signature of patient _____

GDPR: I have been briefed on my rights and Privacy Policy based on the REGULATION (EU) 2016/679 (GDPR) regarding the processing and movement of the personal data, which are used for the purposes of non-invasive hemogram screening, provided by the software USPIH. I am aware of and agree with the condition that the data containing in the database of the software USPIH will not be disclosed and/or forwarded to unauthorised third parties except the following: a) to a personal data processor (a professional, who is responsible for carrying out an examination on site); b) to the respective/authorised staff of the manufacturer, whose duties includes elimination of bugs in the software USPIH, software update or other assistance related to the software USPIH on the request of the personal data processor; c) to governments, control agencies, regulatory authorities and others as permitted or required by law. I am aware of an ability to withdraw my consent at any time submitting a written statement in the place, where the service was provided. Thereof, I realise that my personal data will be deleted irrevocably and without a possibility of further applying, referring and analysing of such a data.

Signature of patient _____

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

No.:	Parameter:	Norm:	<	>
CLINICALLY VALIDATED PARAMETERS				
1	1 Hemoglobin HGB. g/l	125 - 175	*	
2	2 Erythrocytes RBC. x10 ¹² /l	4 - 5,6		*
3	4 Leukocytes WBC. x10 ⁹ /l	4,3 - 11,3		*
4	5 Segmented neutrophils. NEUT %	47 - 72		*
5	9 Band neutrophils. NEUT %	1 - 6		*
6	3 Lymphocytes. LYMPH %	19 - 37		*
7	8 Monocytes.MONO %	3 - 11		*
8	7 Eosinophils. %	0,5 - 5,8		*
9	6 Erythrocyte sedimentation rate ESR. mm/h	1 - 14		*
10	88 Hematocrit.HCT %	35 - 49	*	
11	12 Thrombocytes. x10 ⁹ /l	180 - 320		*
12	42 Glucose. mmol/l	3,9 - 6,2		*
13	13 Calcium (Ca). mmol/l	1,99 - 3,2		*
14	14 Magnesium (Mg). mmol/l	0,84 - 1,17		*
15	15 Potassium (K). mmol/l	3,92 - 5,25	*	
16	16 Sodium (Na). mmol/l	136 - 145		*
17	31 Creatinine. µmol/l	55 - 123		*
18	34 Urea. mmol/l	2,1 - 8,2		*
19	35 Cholesterol total. mmol/l	3,11 - 6,48		*
20	41 Triglycerides (TG). mmol/l	0,55 - 1,85		*
21	38 Low-density lipoproteins (LDL). mmol/l	2,7 - 3,37	*	
22	40 High-density lipoproteins (HDL). mmol/l	0,78 - 1,74		*
23	22 Aspartate transaminase (AST). mmol/l	0,1 - 0,45		*
24	23 Alanine transaminase (ALT). mmol/l	0,1 - 0,68		*
25	24 AST. U/l	8 - 40		*
26	25 ALT. U/l	5 - 30		*
27	30 Protein, Total. g/l	60 - 85		*
28	27 Bilirubin, Total. µmol/l	8,6 - 20,5		*
29	28 Bilirubin, Direct. µmol/l	2,2 - 6,1		*
30	10 Beginning of clotting (method of Lee-White). min	0,5 - 2		*
31	11 End of clotting (method of Lee-White). min	3 - 5		*
32	50 Amylase (W.T.Caraway). g/l*h	12 - 32		*
33	129 Ceruloplasmin (CP). g/l	0,15 - 0,6		*

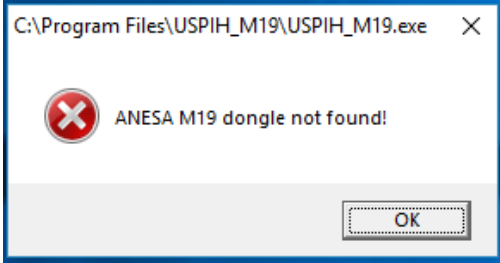

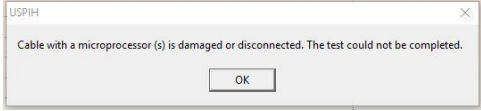
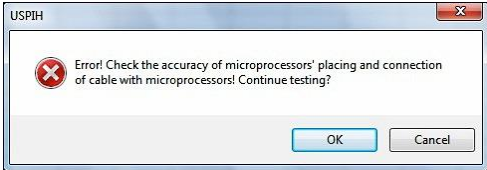
Screening test results can be presented in a graphic format and in digital format. Switching between these data visualization formats is carried out using the button. (See Chapter 12).



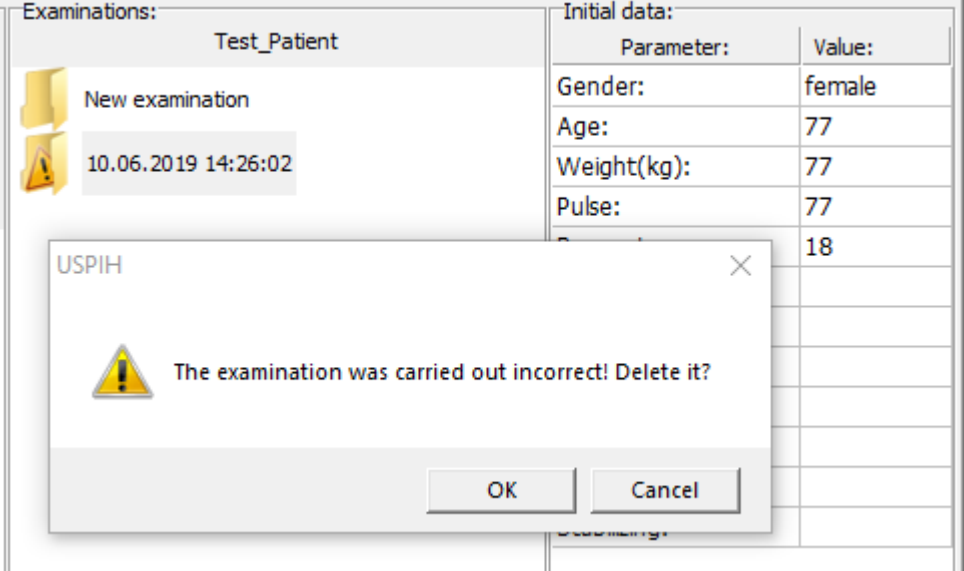

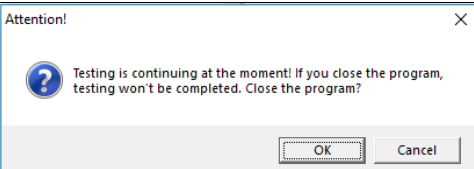
Clinical validated parameters: parameters that were tested in clinical trials

16 TROUBLESHOOTING

Possible errors and solutions:

No	Error/problem	Indication and Reason(s)	Solution/advice
1	The software doesn't run	<p>SPK (software protection key) isn't connected to the PC or SPK is damaged. When the software runs, the following message appears:</p>  <p>Green LED on Guardant Stealth key isn't lighting when SPK drivers were installed incorrectly or when it is damaged</p>	<p>Check if the SPK is connected to the PC. Reconnect it.</p> <p>The LED on ther SPK lights, when it works and connected properly.</p> <p>SPK:</p>  <p>In case SPK does not light, then</p> <ol style="list-style-type: none"> check if the SPK drivers were installed correctly, reinstall them if necessary (the process is described on IFU, Chapter 5). If the drivers are ok, the SPK is damaged and should be replaced. Please contact your distributor of the manufacturer for anorder.
2	Measurement couldn't start or it is interrupted in a process	<p>One or several sensors are damaged</p> 	<p>Replace the cable with a good one.</p>
		<p>Sensors are not placed on a patient's body or placed incorrect</p> 	

		<p>If it happened and the sensors are damaged (by any of reasons), a user is warned in two ways:</p>	<p>Replace the cable with a good one.</p>
3	Device MD ANALYZER isn't found	<p>There is no connection between MD ANALYZER and PC</p>	<p>Depending on the mode of connection you use, 1) check USB cable (IFU Chapter 7.1) or reconnect USB cable or replace it, if it is damaged; 2) check Bluetooth pairing, reconnect if necessary (IFU Chapter 7.2).</p>
		<p>Drivers for the device were installed incorrectly</p>	<p>Check the drivers and reinstall them (IFU Chapter 5)</p>
4	A survey is unavailable	<p>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.</p>	

			<p>Initial data:</p> <table border="1"> <thead> <tr> <th>Parameter:</th> <th>Value:</th> </tr> </thead> <tbody> <tr> <td>Gender:</td> <td>female</td> </tr> <tr> <td>Age:</td> <td>77</td> </tr> <tr> <td>Weight(kg):</td> <td>77</td> </tr> <tr> <td>Pulse:</td> <td>77</td> </tr> <tr> <td></td> <td>18</td> </tr> </tbody> </table>	Parameter:	Value:	Gender:	female	Age:	77	Weight(kg):	77	Pulse:	77		18
Parameter:	Value:														
Gender:	female														
Age:	77														
Weight(kg):	77														
Pulse:	77														
	18														
5	Examination is impossible		<p>Connect the medical device to the computer. If the medical device is connected to the computer using a USB cable, replace the cable with a working one. (IFU Chapter 7.1) If the medical device is connected to the computer using bluetooth, check the bluetooth settings. (IFU Chapter 7.2)</p>												
6	Attention!		<p>This message is displayed when you try to close the application during the examination of the patient.</p>												

17 CLEANING AND DISINFECTION OF MD ANALYZER



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



WARNING! 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!**



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

Wipe enclosure of the MD 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.

18 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.

19 DISPOSAL AND ENVIRONMENT PROTECTION



The MD ANALYZER is to be disposed of as electronic equipment after the service life is ending, in strict accordance with rules and regulation in the country, where it is used.

PRODUCT DISPOSAL: The MD ANALYZER consists of a number of elements, which are made from different materials. So, it is recommended to send the devices to the appropriate recycling centers for electronic equipment, where recyclable components (like (plastic, metal, electric conductors, etc.) will be withdrawn for processing and others (like PCB, chips etc.) will be disposed of. Before disposal is always advisable to check the validity of the relevant provisions of the disposal site.

The device has a built-in battery (LiPo), which is to be removed from the device for disposal. It shall be done only by the special recycling center. The appropriate labels are placed on the package.

Packaging disposal: packaging components (cardboard and shock-protective trays) are all classified as solid waste and can be disposed of using recycling processes or sent to the landfill, depending on the local requirements. The current requirements for disposal are advised to check.

20 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.

21 SHELF-LIFE AND LIFETIME OF THE DEVICE

LEFETIME: 7 YEARS for the MD ANALYZER

The lifetime of the device is determined most of all by the lifetime of used electronic components and elements, applied materials and their fatigue, as well as the conditions of packing, storage and transportation, use and maintenance. When all the conditions comply, the manufacturer assures the lifetime of the device as 7 years.

Cables with sensors/microprocessors are consumable items. They are available for order in case of damage. To extend the life of the cables with sensors, it is necessary to adhere to the rules of regular maintenance concerning cleaning and disinfection, maintenance, storage and use (Chapters 18, 19, 23).

The probability of failure of parts and accessories of the MD ANALYZER increases after exceeding of the lifetime.

Considering the characteristics of similar equipment on the market, as well as the lifetime of the MD ANALYZER, the shelf-life for the MD ANALYZER and its parts/accessories, with mandatory fulfilment of the terms of packaging, storage, transportation and use, set forth in this IFU, has been established as follows:

SHELF-LIFE: 10 years. During a long period of storage, cells/batteries should be maintained every 90 days (to keep the lifetime of the cell): the standard method of the charge-discharge cycle should be applied.

The LEFETIME and SHELF-LIFE can be prolonged after testing the device by the manufacturer or the authorised service center on correct operability.



Batteries have their own life cycles: 300 cycles (approximately 1 year of operation). One cycle refers to one charge period and then one discharge period. So, the life cycle means that after 300 times of discharge-charge, the cell capacity will be reduced to 80% of the rated one.

Therefore, if the time of working of the MD ANALYZER in wireless mode becomes much shorter than usual, the battery cell life is at an end.

Please ask your distributor/manufacturer for replacement. See additionally Chapter 22.



Replacing the battery with insufficiently trained personnel can lead to danger! (temperature rise, fire, explosion). It is forbidden to replace the battery on its own.



Replacement of the battery is carried out only in the service centre by qualified and specially trained technicians.



After reaching the term, the medical devices ANALYZER are to be checked by the manufacturer or an authorised service center to confirm their workability and correct operation. The shelf life of the device can be extended by the manufacturer after inspection.

22 STORAGE AND TRANSPORTATION

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

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

In a process of transportation, the MD ANALYZER is resistant to climatic factors at temperatures from -5°C (without relative humidity control) till +45°C (with relative humidity control), in conditions that protect it from sunlight, possible wetting and mechanical stress (class 7K2 as described in IEC TR 60721-4-7:2001+AMD1:2003 CSV “Consolidated version. Classification of environmental conditions - Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-4-3:2001+AMD1:2003 to the environmental tests of IEC 60068-2 - Portable and non-stationary use.”). Delivery of a medical product to a dealer is organized by certified transport companies.

<p>Specific condition of storage related to the embedded battery</p>	<p>During a long period of storage, cells should be maintained every 90 days (to keep the lifetime of the cell): the standard method of the charge-discharge cycle should be applied. Do not store the MD 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.</p>
	<p>The medical device integrates a rechargeable lithium-polymer battery. When transporting the device, you must adhere to the requirements of a document issued by IATA: IATA 2020 Lithium Battery Guidance. Document Transport of Lithium Metal and Lithium-Ion Batteries. Revised for the 2020 Regulations based on the provisions set out in the 2019-2020 Edition of the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions) and the 61 st, Edition of the IATA Dangerous Goods Regulations (DGR). The provisions of the DGR with respect to lithium batteries may also be found in the IATA lithium Battery Shipping Guidelines (LBSG) 7th Edition. In addition to the content from the DGR, the LBSG also has additional classification flowcharts and detailed packing and documentation examples for lithium batteries.</p>
	<p>Information on the DGR and LBSG can be found here: http://www.iata.org/dgr http://www.iata.org/lbsg</p>

23 TERMS OF WARRANTY

The guarantee for the MD ANESA/AMP/DAD-ANI MODEL 19 is 36 months from the date of sale. The manufacturer or its authorised representative performs a 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 cables with sensors, USB cable and charger. 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 IFU, as well as misuse of the device and influence of the force majeure circumstances. Warranty claims are accepted only in case the MD ANESA/AMP/DAD-ANI MODEL 19 is returned to the authorised representative or the manufacturer in a full complete set, clean, without external mechanical damages and signs of disassembly/opening. A customer covers transport expenses and the risk of accidental loss in the process of delivery of the device (both ways).



ATTENTION! It is not allowed to make any changes in the construction of the device. Any unauthorised opening, repairing or modification of the MD ANESA/AMP/DAD-ANI MODEL 19 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 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 ANESA/AMP/DAD-ANI MODEL 19 without the 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

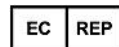
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.

Tel.: +380-913011110

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

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

25 CERTIFICATE OF COMPLIANCE

MD ANALYZER, Serial 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 the Council amending Council Directive 93/42/EEC concerning medical devices, REGULATION (EU) 2017/745, ISO 13485:2016, ISO 14971:2019, MEDDEV 2.12 / 1- rev. 8, IEC 60601-1:2005+AMD1:2012 (ed.3) and IEC 60601-1-2 4th Ed.



Date of manufacture " _____ " _____ 20____.

Check and confirmed by: _____

Signature

Name and Surname



Manufacturer:

SC KOLIBRI LLC

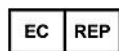
Kinnyi provulok 8a, Kharkiv, 61001,Ukraine.

Tel.: +380-913011110

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

26 PACKING LIST

The MD ANALYZER

Noninvasive screening diagnostic equipment
Medical Device ANESA®/AMP/DAD-ANI® MODEL 19

Name of MD Analyzer

Model

Model-19

Serial Number

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

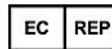
<i>Signature</i>	<i>Name and Surname</i>
------------------	-------------------------



Manufacturer:

SC KOLIBRI LLC
 Kinnyi provulok 8a, Kharkiv, 61001,Ukraine.
 Tel.: +380-913011110
 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

27 WARRANTY CARD

Warranty card	Noninvasive screening diagnostic equipment Medical Device ANESA®/AMP/DAD-ANI® MODEL 19 Automatic Noninvasive Express Analyzer: ANESA// Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo: DAD-ANI MODEL 19	
	Card No. (Serial number of the MD ANALYZER)	
Warranty period*	36 months for MD ANALYZER	
Purchase Date	Seller	
<i>YEAR/MM/DD</i>	<i>Trade organization Name</i>	
	Seller address	Telephone
	<i>Trade organization Address</i>	<i>Trade organization telephone</i>
<i>Customer</i>	<i>[Customer Signature]</i>	<i>[Signature]</i>
<i>Hereby, I confirm that I have read the warranty terms and agree with them</i>		<i>[Company stamp]</i>

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.

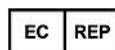
ALL RELATED ISSUES CAN BE CLARIFIED WITH THE MANUFACTURER AND AUTHORISED REPRESENTATIVE:



Manufacturer:

SC KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001,Ukraine.
Tel.: +380-913011110
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

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 medial device 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.

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 of, 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		[SERIAL NUMBER OF DEVICE]	No.1	<i>Filled up by service center</i>
PRODUCT	ANESA®/AMP/DAD-ANI® Model 19		_____	
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		[SERIAL NUMBER OF DEVICE]	No.2	<i>Filled up by service center</i>
PRODUCT	ANESA®/AMP/DAD-ANI® Model 19		_____	
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>

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.

Responsible organizations for warranty and post-warranty service:



Manufacturer:

SC KOLIBRI LLC

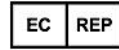
Kinnyi provulok 8a, Kharkiv, 61001,Ukraine.

Tel.: +380-913011110

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.

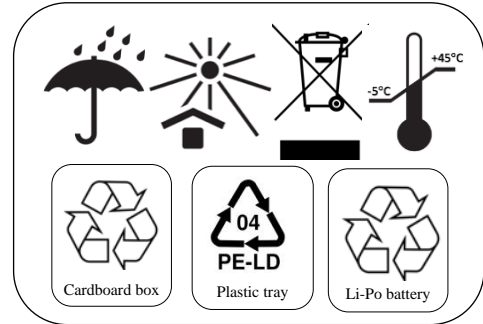
Diagonal office : Av. Diagonal, 361, 2º - 2ª, 08037,

Barcelona. Tel: +34934578980

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

Labels used on the package of the MD ANALYZER (in addition to the main label of the MD, which is duplicated on the package)

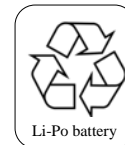
 CAUTION	
 <p>Recharge the device every 90 days, if not in use</p>	<p>Rechargeable non-removable Lithium-Polymer battery inside (installed) LP 3867100 3.7V 2400mAh Do not: incinerate, disassemble, expose to high temp above 60°C (140F), risk of fire, explosion.</p>
 <p>During storage and transportation</p>	




Cardboard box is recyclable



Disposal symbol, indicates the type of built-in battery (Lithium-Polymer)



Disposal symbol, indicates that shock-protective tray inside the package is made of PE-LD plastic.



Package which shall not be exposed to sunlight.

Package shall be kept away from rain and be kept in dry conditions

Indicates the limits of environmental temperature for storage and transportation.

Symbol of waste electronic equipment inside the package.

Project of the label used for detachable parts of the MD ANALYZER

The labels for cables with sensors are printed on special stickers (adhesive sheets) with a lamination. The information includes the trade name of the MD and name of the company.

ANESA™ MODEL-19
SC KOLIBRI LLC



As **SPK** is pre-programmed for work with one device, it is **labelled** with the same serial number as the MD from a complete set. Due to the small size of SPK, its label has only the serial number.

Project of the **main labels** for the MD ANALYZER with the name



Project of labels for the MD ANALYZER
with the name
Automatic Noninvasive Express Analyzer
ANESA®
Model 19

Project of labels for the MD ANALYZER
with the name
Dispositivo de Ayuda al Diagnóstico y
Analizador No Invasivo DAD-ANI® Model 19
(for Latin America)

Project of labels for the MD ANALYZER
with the name
Noninvasive Hemogram Analyzer AMP
Model 19













Project of the **main label** for the MD ANALYZER (sample is made with the label for the MD with name ANESA)*
on the enclosure

Note 1: Most of the information and symbols are placed on the metal plate, which is fixed on the backside of the plastic enclosure of MD, in the middle. All the elements are laser-cut (thus, they are black color).

Note 2: a blue color symbol “Follow the instruction for use” (according to IEC 60601-1 ed. 3.1 /Table D2) is painted on the backside of the plastic enclosure, using the same paint and method, as for the cable color identification on the front panel

The main label of the MD ANESA[®]/AMP/DAD-ANI[®] Model 19 has a number of internationally recognized symbols. The symbols related to the safety requirements and standards are briefly reviewed below:

2	Trade name of the medical device:	ANESA® Automatic Noninvasive Express Analyzer Model 19 or DAD-ANI® Dispositivo de Ayuda al Diagnóstico y Analizador No Invasivo Model 19 or AMP Noninvasive Hemogram Analyzer Model 19		
CE symbol (where 2274 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 Ukraine 61001 Kharkiv, Kinnyi provulok 8a, Tel.: +380-913011110 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	CLASS II equipment IEC 60417-5172		
Represented by (Latin America 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	Degrees of protection provided by enclosures (IEC 60529 ED.2 2.2 B:2013)	IP 20	
MD Class IIa	MD Class IIa	Follow instruction for use		
Sign of waste electronic equipment		Indicates the need for the user to read the IFU for proper use.		

About software...



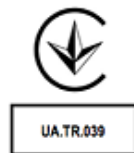
ANESA

Automatic Noninvasive Express Screening Analyzer



SC 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®
Model 19

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



Manufacturer:

SC KOLIBRI LLC

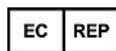
Kinnyi provulok 8a, Kharkiv, 61001,Ukraine.

Tel.: +380-913011110

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 www.kolibri.cloud

MD Class: IIa

*According to the **Directive 2007/47/EC** of the European Parliament and of the Council of 5 September 2007 amending **Council Directive 93/42/EEC** concerning medical devices (hereinafter Directive)*

ANESA/DAD-ANI MODEL-19™ is a transient noninvasive active medical device of **Class IIa**, according to the Annex IX Sect. I clause 1.1 and clause 1.6, Sect. II clause 2.3, Sect.III clause 3.2 Rule 10 of the Directive

*According to the **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** of 5 April 2017 on medical devices (hereinafter MDR).*

ANESA/DAD-ANI MODEL-19™ is a transient noninvasive active medical device for diagnostics of **Class IIa**, according to the Annex VIII, Sect. I clause 1.1 and clause 2.5, Sect. II clause 3.3, Sect. III clause 6.2 Rule 10 and of the MDR.

30 COMPLIANCE WITH GDPR

Considering that on the 25th of May 2018, the EU regulation on protection of personal data entered into force, namely **REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016** on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) - hereinafter **GDPR Regulation**, we, as the manufacturer of the medical equipment for screening diagnostics (ANALYZATOR) recommend our customers to take appropriate measures for the protection of sensitive information on the health state of their patients.

For our side, **we declare** that no information and data is transmitted from the device to third parties, as well as to us, as the manufacturer. We do not receive, store or use the information about your patients. The database is kept locally on your computer and it is your responsibility to keep it safe. Being an authorized user of the device (a holder of the software protection key), only you are able to share the information from the database of the device directly to appointed addressee. We have implemented several protective measures, which will be helpful for you in that regards, they are the following:

- ✓ Access to the database and encryption/decryption of data are carried out with software protection key (SPK). The software and the database don't run without the key, so only the authorized user, who keeps the key to the definite device (hence to the corresponding DB) has an access to the records in the database.
- ✓ Access to the database is protected with a password (hidden) additionally and is possible only via the software USPIH.

We ensure, that the volume of information about a person, which is added to the database of the software is adequate, relevant and limited to what is necessary for the purposes of diagnostics and the collected data will not be further processed in a manner which is incompatible with those purposes (complies with Article 5 of the Regulation (EU) 216/679).

We strongly advise against sending the results of testing by email to avoid any information leak or unauthorized access to the sensitive data of your patients. As you have an ability to print out the results, so you can give the survey with results of testing to your patients in a paper form, after signing the informational consent.

We recommend to get a **signed consent** form for processing and storage of personal data of a patient, including the data concerning his/her health, from each of your patient **BEFORE testing** on the device.

A sample of the informed consent is below. It was also included in the survey/report form and is usually printed at the beginning of the document, before the results.

INFORMED CONSENT (GDPR): *I have been briefed on my rights and Privacy Policy based on the REGULATION (EU) 2016/679 (GDPR) regarding the processing, storing and free movements of my personal data, which are used by the medical device and software USPIH for the purposes of a noninvasive screening test.*

I am aware of and agree with the condition that the data containing in the database of the software USPIH will not be disclosed and/or forwarded to unauthorized third parties except the following:

- a) to a personal data processor (a medical professional, who is responsible for carrying out an examination and interpret the results on site);*
- b) to the respective/authorised staff of the manufacturer, whose duties includes the elimination of bugs in the software, software update or other assistance related to the software on the request of the personal data processor;*
- c) to governments, control agencies, regulatory authorities and others as permitted or required by law.*

I am aware of an ability to withdraw my consent at any time submitting a written statement in the place, where the service was provided. Thereof, I realize that my personal data will be deleted irrevocably and without a possibility of further applying, referring and analysing of such data.

Signature of patient _____

31 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.

32 DOCUMENT HISTORY AND VERSION CONTROL

Version	Version Date	Summary of changes	Author	Related documents
1.0	2021-05-27	Created	Pulavskyi A, Kolyesnik O	