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

realized under commercial names:
Automatic Noninvasive Express Screening Analyzer AMP/ANESA
(hereinafter MD ANALYZER)

Instruction for the use of MD ANALYZER with software USPIH ver. 9 and higher for OS WINDOWS and OS ANDROID (IFU)

Read this IFU carefully before use of the MD ANALYZER.

Manufacturer:
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79, Hungary
Tel.:+36209719323

Automatic Noninvasive Express Screening Analyzer AMP/ANESA
(hereinafter ANALYZER)

MD ANALYZER isan 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 an 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 medical device for screening diagnostics of human health. In any case, it could not be considered a diagnostic tool which replaces the standard recommended diagnostic methods.

The present IFU contains the description of the 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 is forbidden without the written permission of the manufacturer.
This provision concerns copying, translating, scanning, placing and manipulation, etc., both in electronic systems and with printed versions.

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

This manual includes the description of software USPIH ver.9 and higher for OS WINDOWS and OS ANDROID.

The definitions "**USPIH ver. 9.X**" or "**USPIH 9.X**" which are used below, **concern all the versions of software USPIH with index 9, starting from 9.0 and higher.**

CONTENT

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	Mains voltage for charging the battery MD
	Symbol for connection of USB port		CLASS II equipment IEC 60417-5172
EC REP	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

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.

1.1 GENERAL OVERVIEW

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. $x10^{12}$/l, Leukocytes WBC. $x10^{9}$/l, Segmented neutrophiles. NEUT %, Band neutrophiles. NEUT %, Lymphocytes. LYMPH %, Monocytes.MONO %, Eosinophils. %, Erythrocyte sedimentation rate ESR. mm/h, Hematocrit.HCT %, Thrombocytes. $x10^{9}$/l, Glucose. mmol/l, Calcium (Ca). mmol/l, Magnesium (Mg). mmol/l, Potassium (K). mmol/l, Sodium (Na). mmol/l, Creatinine. µmol/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. µmol/l, Bilirubin, Direct. µmol/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, which is used together with the MD ANALYZER. The initial information, which is measured by the MD ANALYZER, includes the temperature of certain points on a human body (5 definite areas on a human body), parameters of the 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 basis 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 the 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 the aorta, inferior vena cava and thoracic duct. The temperature of this area influences the synthesis of essential amino acids and regulatory hormones etc. It is related to the functioning of adrenal glands` chromaffin cells (chemosensory cells), as negative feedback of O_2 sensing, first of all).
The 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 for 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, the activity of the thrombin-plasmin system (TPS). In fact, TPS determines the number of functioning capillaries per 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 are accompanied by the changes of temperature characteristics of the reference points, as well as a 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 the measurement of temperature in 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 designated points with accuracy not less than 0.07ºC. 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 AMP/ANESA. 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 validated 33 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 the 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 a 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 the Malykhin-Pulavskyi method (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 a possible diagnosis at the end of a report. It is not a final diagnosis, it is only a 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 ºC and +27 ºC) and relative humidity less than 80%.

1.4 INTENDED USE OF DEVICE

Medical Device for Noninvasive Screening Diagnostics AMP/ANESA 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 AMP/ANESA 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 if below mentioned requirements are not fulfilled:

- temperature in a testing room must be in the range of +20 ºC and +27 ºC;
- relative humidity in a room must be less than 80% at the temperature +25 ºC;
- 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 the charger only to a working socket with a rated voltage range of 100 - 240V 50-60Hz.

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.

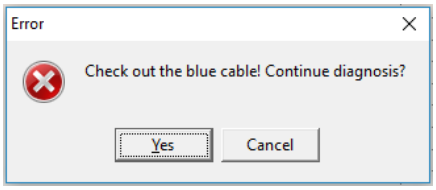
2.2 MEASURES TO PREVENT DAMAGE TO THE DEVICE

The Analyzer should be placed in such a way, that 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 the 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 contact of the Analyzer and its components with various solvents, gasoline, kerosene and other chemically aggressive substances. In addition, water is not allowed to be in 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 happens and the sensors are damaged (by any of the reasons), a user is warned in the following way:

Example: Check out the blue cable.
(Chapter 14, 15.10)



3. BRIEF 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^{o}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	
Bifurcation of left artery - Blue	*Bifurcation of right artery – Green*
Left armpit (axillaries) - Yellow	*Right armpit (axillaries) - Violet*
Abdominal area (umbilicus) - Red	

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.

MD 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:
MODEL AMP/ANESA-L/2007

PC mains voltage	230V±10 %; 50/60 Hz
Analyzer's mains voltage (from USB port)	U = 5±1 V DC I = 195 mA
Consumption	max. 0,975 VA
MD Class	II
Protection of patient	A
EMC	in accordance with EN 60601-1-2:2007/AC:2010
IP Class of Analyzer	IP 20
Readiness time counted from switching on	max. 3 min
Range of temperature of reference points	24 – 42 °C
Margin of error of reference points	max. ±0,75°C
Length of cables for microprocessors/sensors	min. 1,5 m
Accuracy of the microprocessors/sensors	±0,5 °C, in the range from -10 °C to +85 °C
Resolution of the sensors	0.0625°C; Resolution is user-configurable to 12 bits
Time of examination	max.720 sec
Method of diagnostics	Thermodynamic method, invented by Malykhin-Pulavskyi (data collection from reference point)
Software	USPIH (based on the methods of Malykhin-Pulavskyi)

Ambient temperature for storage and transportation	From -25°C (without relative humidity control) till + 70°C (with relative humidity control) Class 7K3, as described in the IEC/TR 60721-4-7:2001+AMD1:2003 CSV
Atmospheric pressure	615-780 mm Hg (82 -104 kPa).
Humidity	15%-93%, without condensation

MODEL AMP/ANESA

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 *(see the details below)*
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 4thed)	Used type SWM6-5-EH-I38 AC input: 100-240Vac, 0.6 A, 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 of the unit	0,300 ±0.030 kg
Weight of the set of 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
RAM	min. 3 Gb and more	Windows 7 and higher, ***Window** 10 is preferable*. It is necessary to have **<u>administrator rights</u>** 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.
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 1 or 2 USB ports: 1 - for AMP/ANESA (if necessary, to connect AMP/ANESA via USB, not via BLUETOOTH); 1 - for printer (optionally)	
BLUETOOTH	5.0 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 configurated 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 (the cell is protected by an electronic circuit that won't allow it to overcharge nor over-discharge under use)
Rated capacity	2400mAh, @ 0.2C mA discharging
Cycle life	300 times (approximately 1 year of operation) 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.
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.

The battery must be replaced only by the manufacturer or the authorized service center. We will take no responsibility for any accident when the cell is used under other conditions than those described in this Document. We will inform, in a written form, the customer of improvement(s) regarding the proper use and handling of the cell, if it is deemed necessary.

	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.
	It is strictly prohibited to use the MD ANALYZER close to fire or left it in direct sunlight (for example, in a car or any storage outside without shadow) 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).
	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.
	**A specific condition of storage related to the battery.** 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.

EXTERIOR of the MD ANALYZER

MODEL AMP

MODEL ANESA

3.2 THE COMPLETE SET OF MD ANALYZER

The complete set of MD AMP/ANESA includes the following:

Name of a part	Quantity
The unit of MD AMP/ANESA	1
Cable with microprocessors/sensors	1/5
Cable USB	1
IFU (offered in electronic)	1
Packing case	1

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 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 16, 17, 21).

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
✓ 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.
✓ 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 in a day)
✓ Connect each cable with a microprocessor/sensor to the appropriate connector on the unit of MD ANALYZER (illustration is in Chapter 4.3);
✓ While the computer and MD ANALYZER are switched off, connect them via USB cable, if you'd like to use USB mode (otherwise miss this step and follow the next one);
✓ Switch on your computer and the unit of MD ANALYZER (Chapter 8);
✓ Run the software **USPIH 9.X or ANROID** using the appropriate 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 9.X or ANROID** (Chapter 8, 15);
✓ Carry out the functional test (described in Chapter 10) before testing the patients (should be done each time before the first use in a day).

EVERYDAY ACTIONS BEFORE USAGE
✓ Connect the cables with microprocessors to the appropriate connector on the unit's side 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 software USPIH using the icon on the desktop or in the main menu

The analyzer is ready for use. The working process is the same for all models of MD ANALYZER. When the Analyzer is ready for work and software USPIH is run, it's time to start measurement. The process of measurement is described in detail below (Chapter 11).

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 enough).

The MD ANALYZER is intended to be used by qualify medical professionals (educated and certified), with a medical background, who are additionally trained 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.

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.

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
- ✓ Contraindications and possible side-effects
- ✓ Settings of software and hardware
- ✓ Warnings and possible errors of operation, troubleshooting
- ✓ Recommendations for the device use
- ✓ Method of functional control of the device

The above mentioned aspects are included in the basic training course. Due to specificity of some regions/countries, the content of training course may be changed. The local distributor provides the most detailed information about the content of the training course in the country/region by request.
Besdides, an operator/user should keep abreast of the latest achievements related to the non-invasive methods of diagnostics to be aware on possible contraindications and side effects, which are not known at the time of the device's production.

4.3 CONNECTION OF CABLES TO THE UNIT

For MODEL AMP/ANESA: 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. 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, bed or stretcher (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.)

6. SOFTWARE USPIH 9.X AND ANDROID FEATURES

Both types of software, USPIH 9.X and ANDROID, do not contain the mathematical part of software USPIH. The main processing algorithm is hosted on a cloud server. Therefore, MD ANALYZERs with the software USPIH 9.X and ANDROID work only via the Internet.

A user receives the MD ANALYZER in a complete set stated above (Chapter 3.2) and software USPIH 9.X or ANDROID by a choice. It is a sufficient set for entering the patients' data (filling in a patient's card(s)), making measurements and analysing the results.

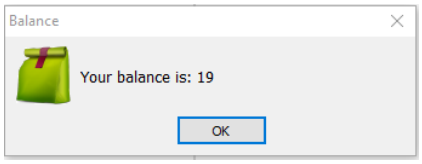
The user of software USPIH 9.X and ANDROID should register an account on the cloud server. This account will be connected with the MD ANALYZER (the serial number of a specific device is registered for the user).

The routine workflow looks like this:

- ✓ A user/doctor installs software USPIH 9.X or ANDROID and makes necessary settings (Chapters 7 and 9 for USPIH 9.X, and Chapter 15 for ANDROID).
- ✓ When a patient comes for an examination, a doctor fills in his/her initial data: name, surname, gender, age and weight.
- ✓ The microprocessors are fixed on a patient's body, and the measurement is carried out (Chapter 11 for USPIH 9.X and Chapter 15 for ANDROID), considering the proper positioning of the patient (Chapter 5).
- ✓ The measurement results are sent to the cloud server for processing (Chapter 11 for USPIH 9.X, and Chapter 15 for ANDROID). The calculation usually takes a couple of seconds and mainly depends on the user's Internet speed.
- ✓ The ready report with calculated parameters automatically returns to the user's computer. Thus, it is available for analysis/interpretation by a doctor, as well as for printing and saving on the computer immediately after testing (Chapter 13).

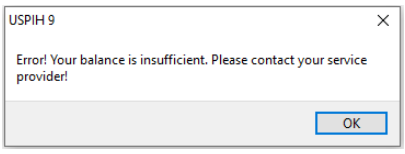
Important:

Considering that the measurements performed on the MD ANALYZER with USPIH 9.X or ANDROID are sent to the cloud server for calculation, a processing fee is applied for each. In that regard, a user/doctor must keep a sufficient balance on the cloud server. To access the system, a user should make the prepayments to the supplier (distributor/manufacturer) in time to keep the balance positive.



The prepaid amount is credited to a user's registered account on the cloud server. The cost of processing each examination/test is debited automatically. The total balance is reduced according to the number of tests carried out. Each user can control the spending, the number of made tests, and the remaining tests using the software USPIH 9.X or ANDROID options by clicking on the icon "check balance" (Chapter 9.3.1.8).

Each user is allowed to make the number of tests which has been prepaid. If the account balance is not sufficient, data processing becomes unavailable. The user shall replenish the balance via the distributor or the manufacturer.

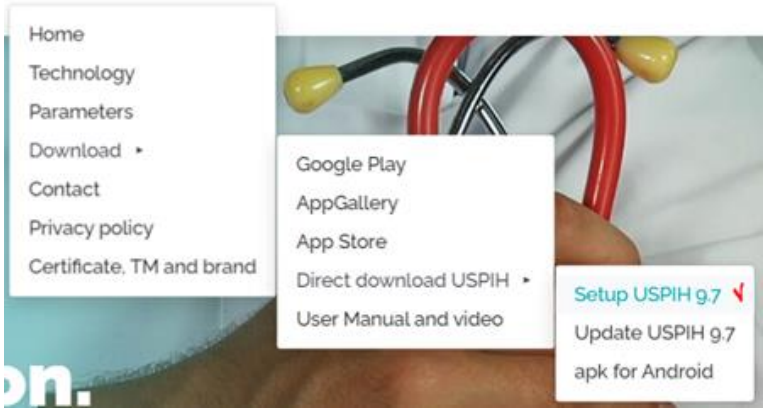


The authorised distributor in the country/region is responsible for managing the accounts of users from the territory using the Administrator software on the server. In the case of direct sales from the manufacturer, the managing of such users' accounts is made by the manufacturer.

7. SOFTWARE INSTALLATION. USPIH VER.9.X

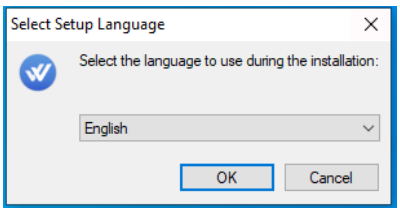
MD ANALYZER requires installation of the latest version of its own software. Before installing the software USPIH, please make sure that your computer has three available USB ports (or two USB ports and BLUETOOTH) and you have got the rights of "Administrator" in Windows OS (Windows 7 or higher). To install/set up the software for USPIH 9.X, please follow the instructions below:

7.1. **DON'T CONNECT THE DEVICE. Download a setup file** for the MD ANALYZER to your computer using the WEB. Choose "Setup USPIH 9.X" and the appropriate file will be downloaded to your computer. (in example below, it is Setup USPIH 9.7)

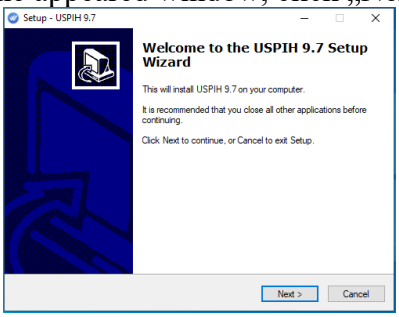


7.2 Run the downloaded file (in the example above, it is ***setup_USPIH_9.7-CLOUDE.exe***) to install the software following the instructions below.

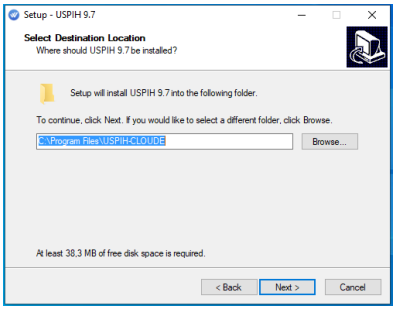
Select the language and click "OK":



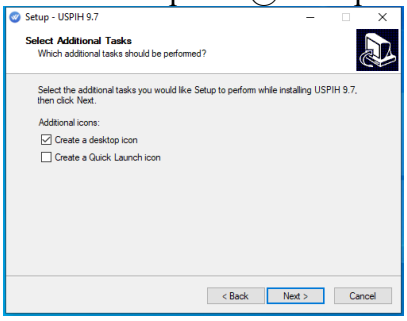
In the appeared window, click „Next":



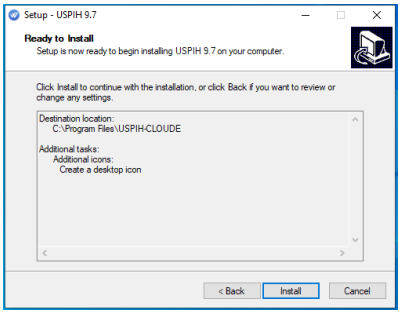
Select the folder for installation and press NEXT



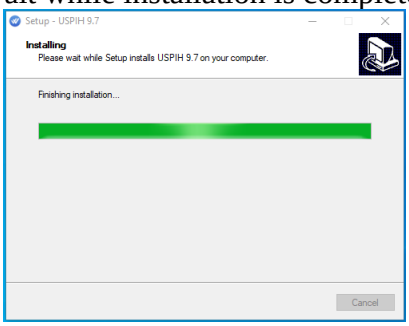
Tick "Create a desctop icon@" and press NEXT



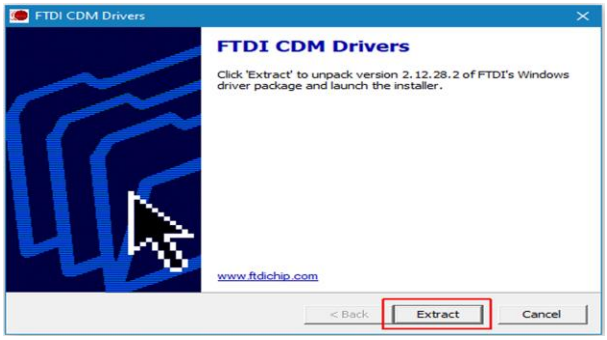
Press “Install”

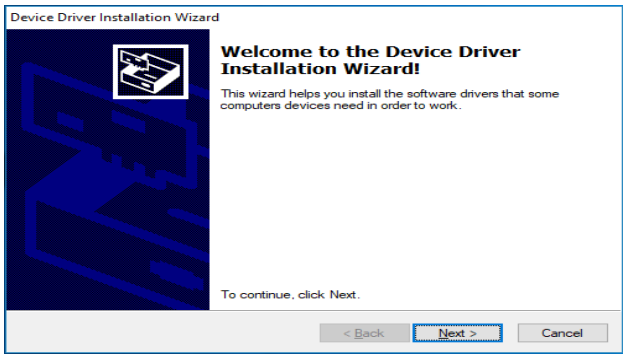


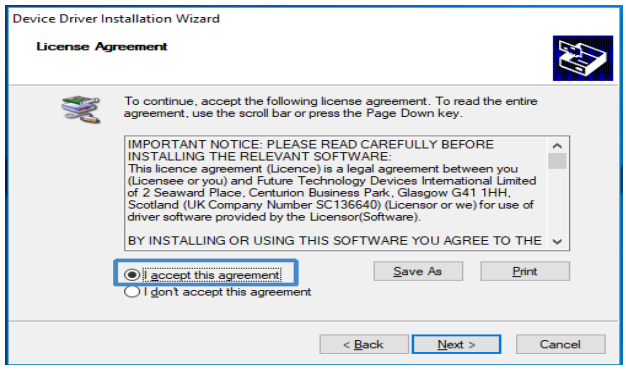
Wait while installation is completed

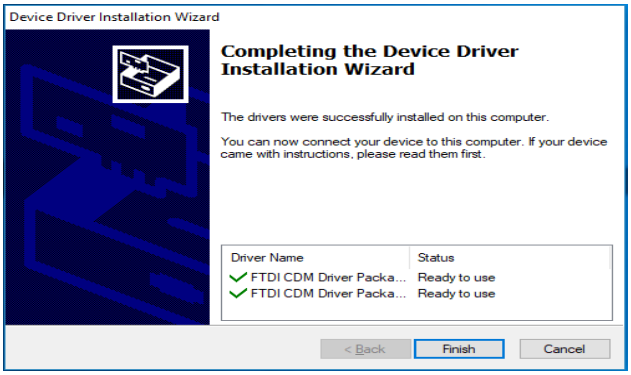


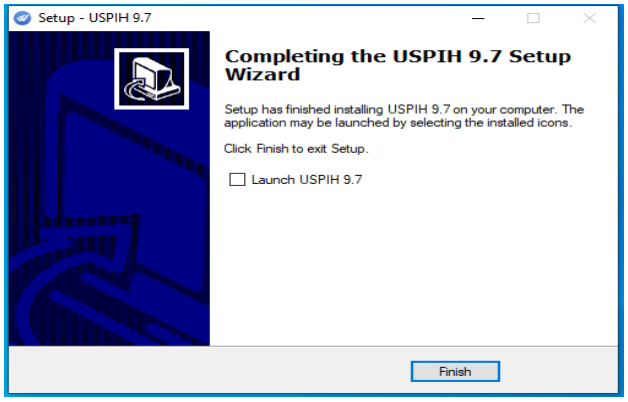
7.3. The installation of drivers will be start automatically immediately after the main software set up is completed. Please follow the instructions below.











Important Note:
If software USPIH is installed to your computer first time (o.i. *before you have never worked with this device on this computer*), **do not tick “Launch USPIH 9.X”** (because the the process of drivers installation is not completed yet). Press ”Finish”.
CONNECT THE DEVICE MD ANALYZER to your computer. The installation of drivers will be finilized.

Launch USPIH using the appropriate icon on your desktop.

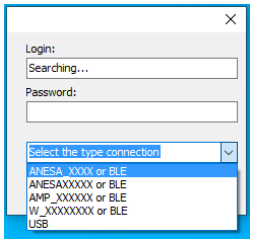
8. START WORKING WITH USPIH VER.9.X.CONNECTION OF THE DEVICE

CONNECTION OF THE DEVICE TO A COMPUTER VIA BLUETOOTH BLE

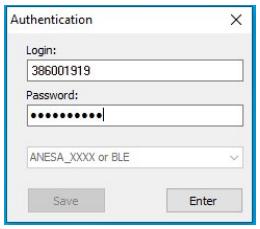
Switch on the unit of MD ANALYZER: press and hold "POWER" button at least three seconds.

Run SOFTWARE USPIH 9.X on your computer using the appropriate icon

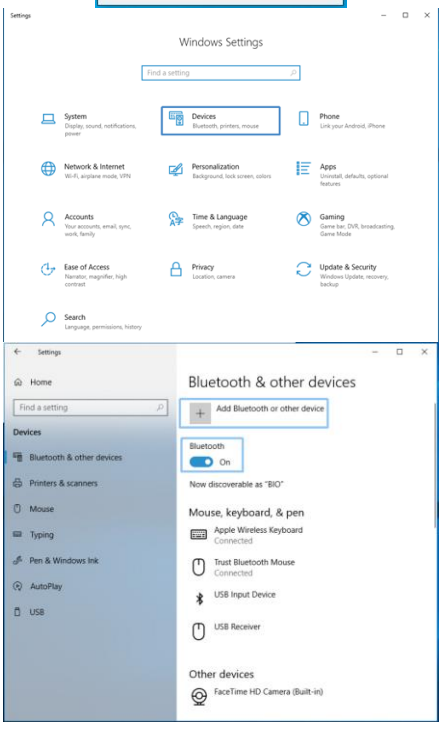
Select the type of connection (Bluetooth/BLE or USB)



The login is the serial number of your device. It will be loaded and display automatically.
Enter the password.
Press “Enter”

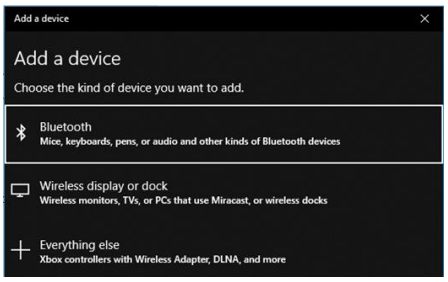


Pairing of the MD ANALYZER and the computer via the BLUETOOTH channel.
In the main menu of OS Windows, select the "Settings" menu
Then, select the menu "Devices"

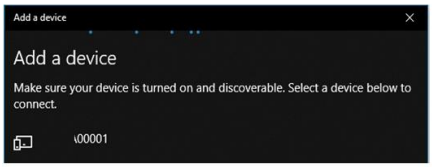


Turn on Bluetooth and press
“+ Add Bluetooth or other device”

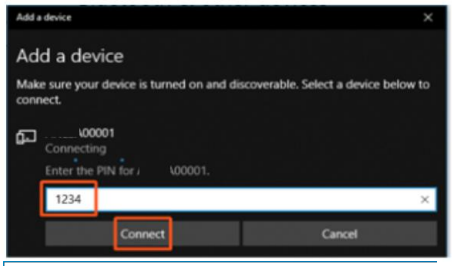
Select menu “Bluetooth”



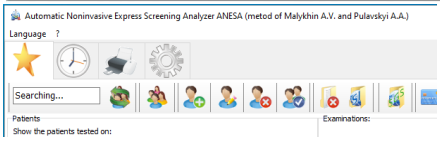
Add the device MD ANALYZER
(the serial number will be visible here)



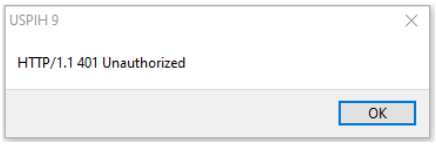
Enter password: 1234 and press “Connect”



After the authorization on the server, the software's main window will be displayed



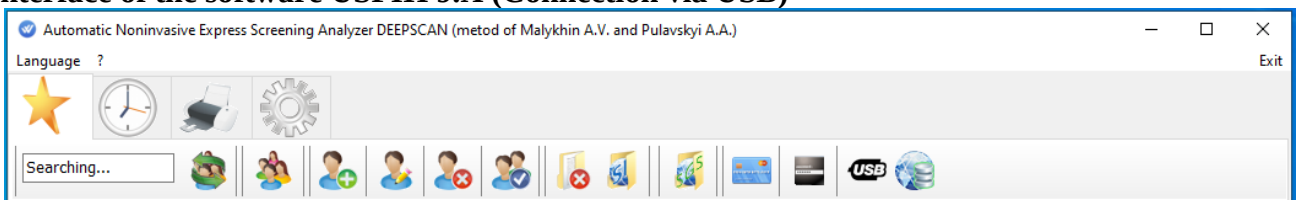
The following error message can apper in case of
no Internet connection or if the password is
wrong password
device MD ANALYZER is not registered in the cloud system



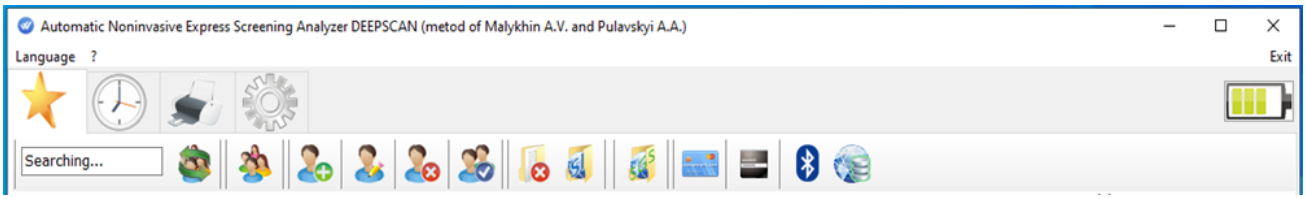
After pressing the "OK" button, the program will close the main window. We recommend to make an authorization again using the correct data.

9. SOFTWARE USPIH VERSION 9.X INTERFACE

Interface of the software USPIH 9.X (Connection via USB)

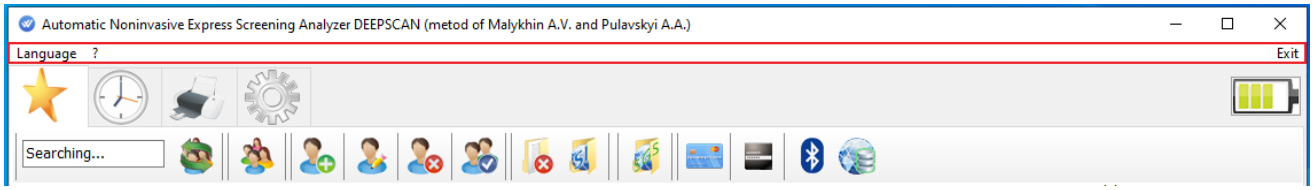


Interface of the software USPIH (Connection via Bluetooth)



Description of the interface icons/options, used in the software USPIH ver.9.X:

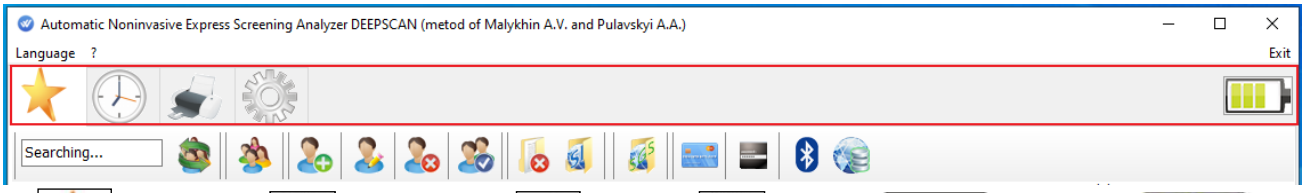
9.1 The top menu contains three sub-menu



"Language"	**"?"**	**"Exit"**
To choose/change a language of the interface	To open help file and information about program	to exit the program

At first time, USPIH 9.X runs in English. To change the language, use an appropriate menu “Language” The interface is available on 4 languages: Russian, English, Hungarian, Turkish.

9.2 The second-level menu consists of the following icons:

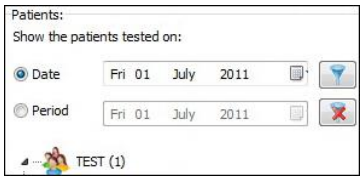


					
main window/ starting window	graphs of temperature change during the measurement	print or save the report of testing	main settings	Battery charging indicator (if USB mode)	Battery level indicator (if Bluetooth mode)

This icon can be inactive by default.
To display it, please press CTRL+B

(9.2.1)The main window shows the content of the database “Patients”. After clicing on any patient from the database, two sub-menues become available one by one: “Examinations” and “Initial data”

The part “Patients” has the following options:



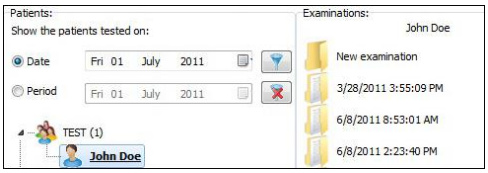
- ❖ Filter for searching the patientsby a date of examination: it is possible to choose an exact date of examination or suspected period of time, when the examination might be done.

To activate filter use an icon 

To de-activate filter use an icon 

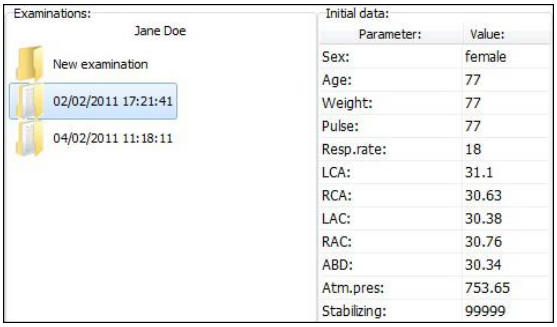
❖ List of patients in the database (in groups and out of any group)

After clicking on the name of any patient, the part "Examinations" appears at right. It shows all existing surveys for a chosen patient in the database. Also, an icon "New examination" is available to start a new measurement fro this person immediately (description of a testing procedure is in Chapter 11).



After clicking on an examination, the part "Initial data" appears at right.

Initial data concerns the selected examination of the patient and contains initial information about this patient at the moment of testing: gender, age, HR, RR, temperature values in each point, air pressure and temperature stabilization data*

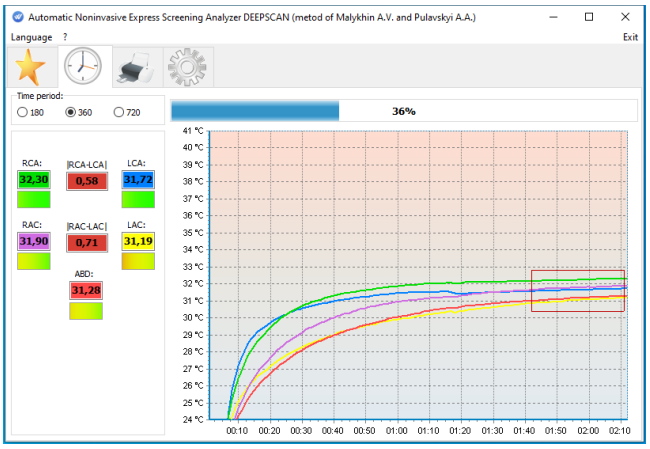


** "99999" means the temperatures during measurement fully stabilized (100%).*

"00000" means the temperatures didn't stabilize during measurement.

The options of this menu are described in details below, Chapter 9.3.1.

(9.2.2) Graphs of temperature change during the measurement. This menu is activated automatically when the measurement starts. It allows monitoring of temperature changes at each point in real-time. Detailed description of available options are in Chapter 9.3.2



(9.2.3) Print or save the report of testing

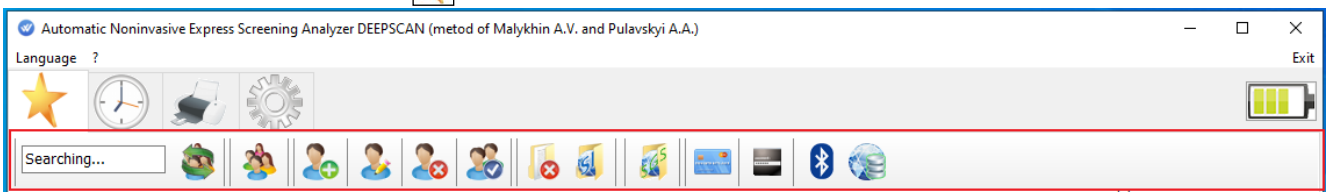
This menu is displayed automatically when the measurement is finished. All options available in this menu are described below in Chapter 9.3.3.

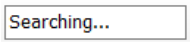
(9.2.4) Main settings
This menu allows entering information about your company which will be used for printing versions of surveys by default. This menu also allows fixing the Internet connection settings, doing factory reset and editing normal ranges used for the parameters in the report.
Detailed description of each option of this menu is available below, Chapter 9.3.4.

(9.2.5) Battery status. This icon appearance depends on the connection mode chosen by a user. The icon will show the battery's charge level if the device is connected via Bluetooth. If the device is connected via USB, the icon will show that the battery charging process is going.
This icon can be inactive by default. To display it, please press CTRL+B

10.3 The third-level menu includes a number of the options available for each of the item from the second level (Chapter 9.2). They are described below.

(10.3.1) Main Window options





(9.3.1.1) Used for searching patients or patients' groups in the database. It is necessary to enter the letters from a name or surname of the patient or a group name (minimum 3 letters) and the program will offer patients and groups containing entered combination of letters.


Reset search parameters


Groups of patients


Add a new patient


Edit data of a patient


Delete a patient from database (card)


Merge surveys of a patient


Delete an examination


Request for a report in SI units


Request for a report in SGS units

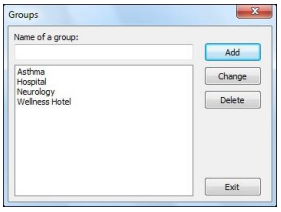

Request for balance


Changing a password of authentication

Indicators of connection mode: connected via BLUETOOTH or USB Working mode is highleted

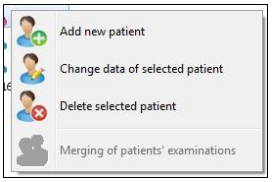

Synchronization of the database

(9.3.1.2) Reset search parameters – use this icon if you need to return to a full database after filtering the patients/grups for searching. After pressing on this icon, the complete list will be available again.



(9.3.1.3) Groups of patients

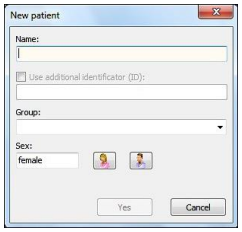
For the convenience of usage, the patients in database can be divided into groups. Use this icon to create a new group and edit or delete the existing one.
The following window for editing will appear after pressing the icon >



(9.3.1.4) Add/Edit/Delete a patient's card

Adding, editing and deleting of patients cards can be done in two ways: using these icons in the main menu or in the context menu (right click by mouse on the selected patient). The same icons are used in both types of menu.

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

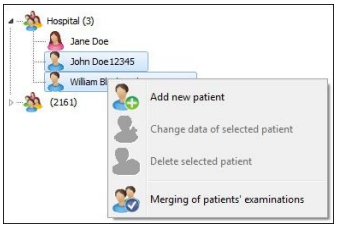
IMPORTANT! After changing the gender of a patient, all the surveys of this patient will be changed/ recalculated automatically, according to the renewed information.

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 was set up, enter the valid password in the appeared window (the default password is "0000" (four zeros)).

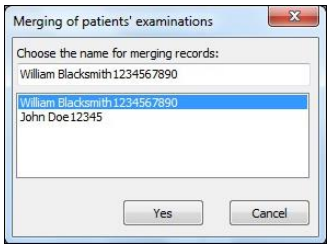
(9.3.1.5) Merge surveys of a patient

Software allows merging the patient's examinations under the one 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 (in one card). 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.



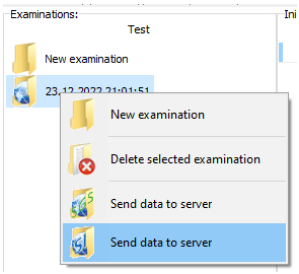
Finally, there will be one patient with several surveys in the database.

Attention! After merging the surveys,
IT IS IMPOSSIBLE TO SEPARATE THEM BACK
and restore their original form!

(9.3.1.6) Deleting of patients’ survey(s) from the patient’s card and database
It can be done in the following way:

- Select an examination, which should be deleted and click this icon in the main menu or in the context menu (right click by mouse on the selected patient). The same icon is used in both types of menu.
- In case of password protection was set up, enter the valid password in the appeared window (the default password is “0000” (four zeros)).

(9.3.1.7) Request for a report in SI or SGS units
Use these icons to choose the units which are preferable for the analysys and interpretation.



It is possible to make a choice of preferable in two ways: using these icons in the menu or in the context menu (right click by mouse on the selected examination). The same icons are used in both types of menu.

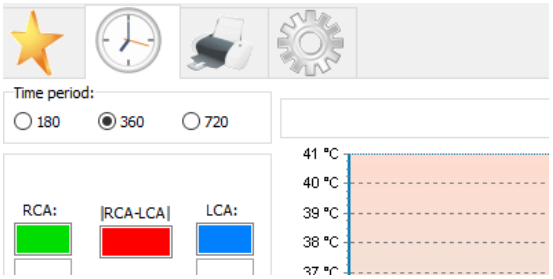
(9.3.1.8) Request for the balance
A user can request the state of balance on the cloud server at any time using this icon. It will help to avoid situations when the tests can not be processed due to insufficient balance (Chapter 7).

(9.3.1.9) Change password of authentication
During the forst login to the system the password of authentication is set (Chapter 8). Use this icon if you need to change it. The system will ask you old password and then you can set the new one.

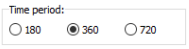
(9.3.1.10) Indicators of connection mode
Each of these two icons is highlighted depending on the mode of connection you use. If the device is connected via Bluetooth, then the first icon will be highlighted. The second icon will be highlighted when USB connection is used.

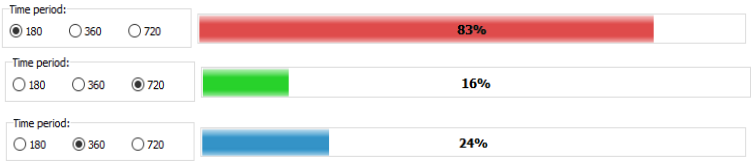
(**9.3.1.10) Synchronization.** If you have previously used software USPIH 9.X on another computer, you can synchronize your new computer with the existing database on the cloud server. After installing software USPIH 9.X on a new computer **and the first authorization**, use this icon for synchronization.

(9.3.2) Options in “Graphs of temperature”

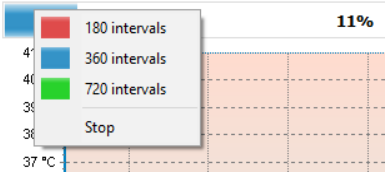


(9.3.2.1) Time period. A user can choose any of available time periods for testing. It can be changed even during the measurement. Progress bar at right shows the process in color and in %. The color of progress bar changes according to the chosen period.

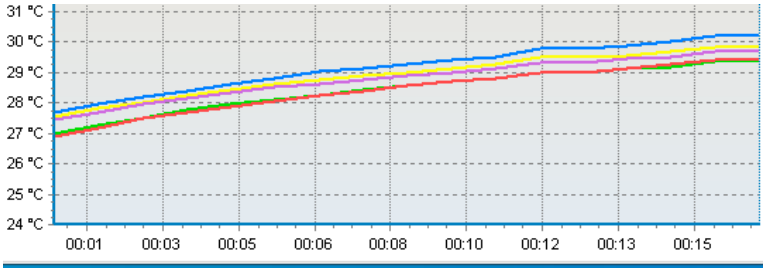




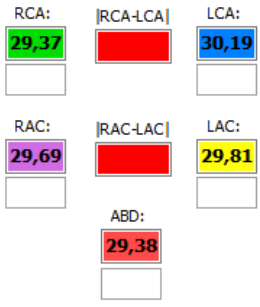
There is one more option, which allows changing time period: you can use context menu when clicking right mouse button on the coloured progress bar. Also, you can stop the measurement here, too. The following windows will appear.



(9.3.2.2) Temperature graphs. It allows monitoring of temperature changes at each point on a body (where sensors were placed) in real-time. The colors of curves are the same as color of cables which are placed on a body of the patient (Chapter 11). So, a doctor can re-fix those sensors, which loose contact with skin (if temperatures drop down, even slightly, it means that sensor-to-body contact is poor or lost. Such a situation requires to replace the sensor and fix it properly again. Usually, it requires also the prolongation of the measurement. A user needs to choose longer period of time for measurement, see clause above (9.3.2.1).

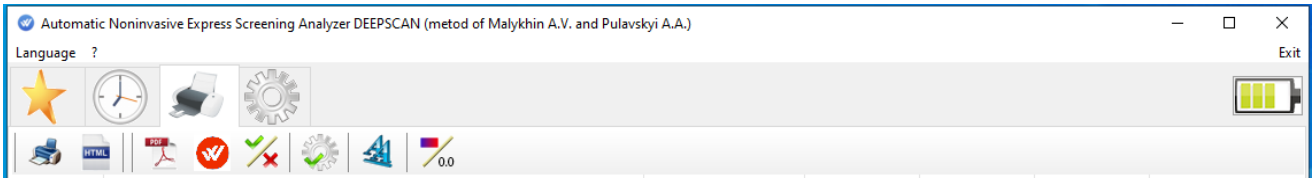


(9.3.2.3) Temperature values. It allows monitoring of temperature changes at each point on a body (where sensors were placed) in real-time using the real values measured. The values of temperature are displayed in color rectangle which repeat the color of cables placed on a body of the patient (Chapter 11).



Three additional rectangles (RCA-LCA, RAC-LAC and one below ABD) show the temperature stabilisation process. They change their color from red via yellow to green, demonstrating how temperature is stabilized till the end of the measurement. It is required to choose a longer period of time if any of these three rectangles are yellow or red before the end of the measurement (see clause above (9.3.2.1). All of them must be green when the measurement is going to end.

(9.3.3) Options in "Print or save the report of testing" 



This menu is opened automatically when the measurement is finished. The user can prepare the report with parameters and a conclusion for printing or saving using the available options.

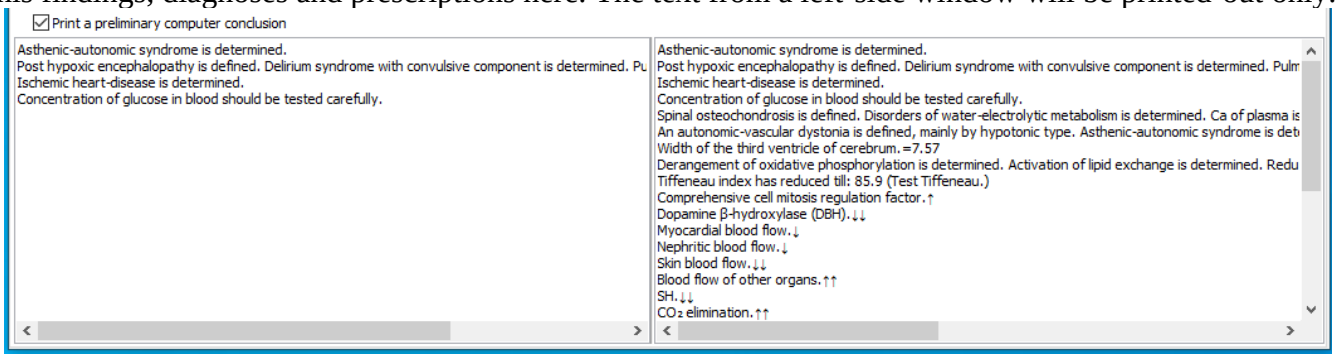
(9.3.3.1) Print-out the report with results

This icon is used to send the file for printing out. It is used after a doctor analyses the received information and makes a conclusion. It is prohibited to print out the report without consideration of the medical professional.

Printing out a preliminary computer conclusion:

In the bottom **right-side window**, an automatic conclusion is formed. It is compiled by the system based on the parameters calculated. But this conclusion can only be used as a prompt for the doctor, which needs to be considered and corrected appropriately by him.

Acceptable conclusions can be moved to the **left-side window** (drag-and-drop). Also, the doctor can type his findings, diagnoses and prescriptions here. The text from a left-side window will be printed-out only.

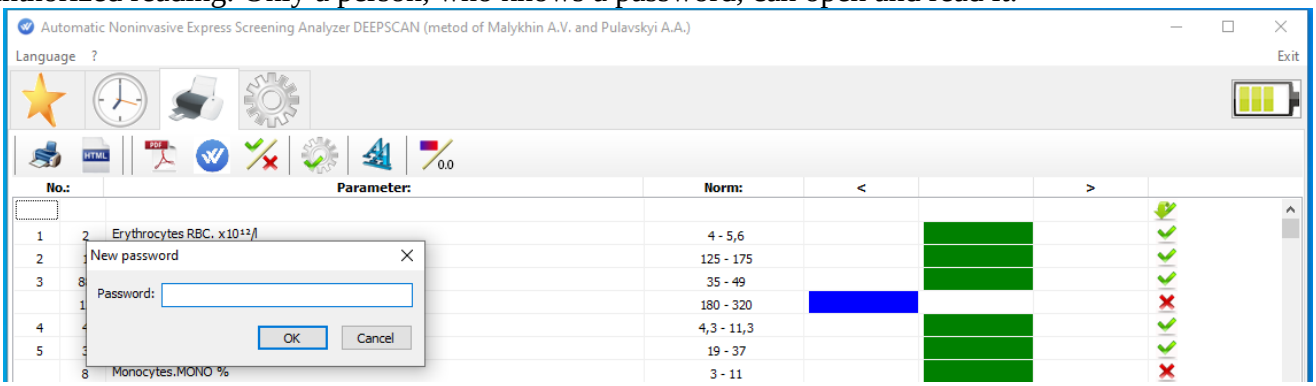


(9.3.3.2) Save the report in HTML format

This option is used to save a report in HTML format. By default, the file name will contain the patient's name, date and time of the test. A user can change it to any other according to the needs. If it is necessary to add a preliminary computer conclusion to the saving file, please follow the instructions for printing out above (Chapter 9.3.3.1)

(9.3.3.3) Save the report in PDF format (encrypted)

This option is used to save an encrypted report in PDF format. By default, the file name will contain the patient's name, date and time of the test. A user can change it to any other according to the needs. After pressing this icon, the sytem will ask you to set a password. So, the saved file will be protected from unthorized reading. Only a person, who knows a password, can open and read it.



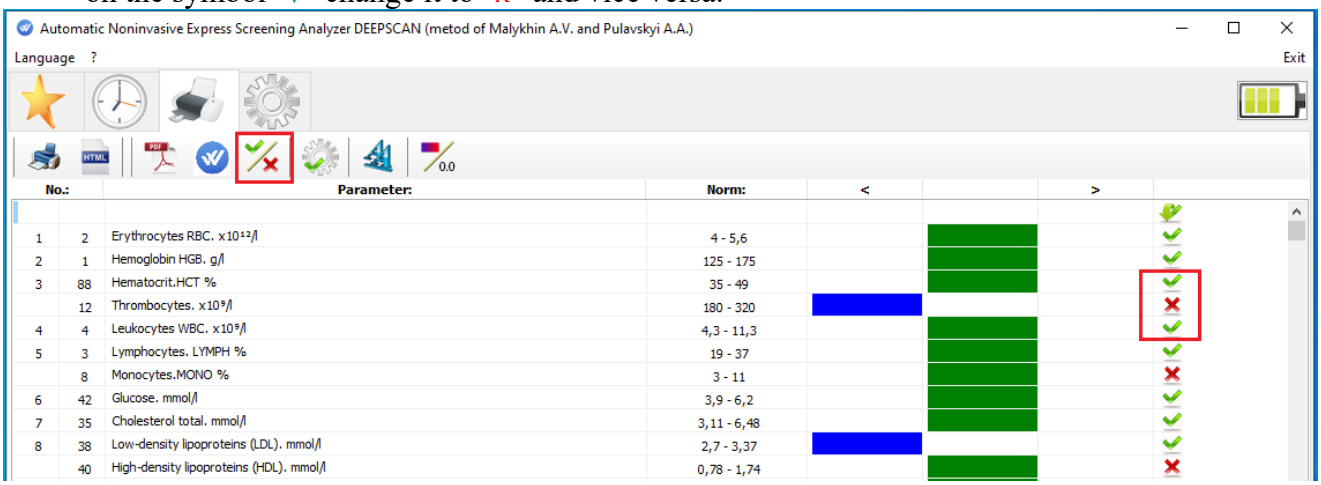
If it is necessary to add a preliminary computer conclusion to the saving file, please follow the instructions for printing out above (Chapter 9.3.3.1)

(9.3.3.4) AI system

When generating a report, you can use these buttons enabling or disabling the built-in system for monitoring the accuracy of calculated parameters (AI). Thus, when the system is enabled (blue color icon), the report will include only the parameters with the maximum accuracy available for the algorithm. When red icon is active, the report will include all the parameters calculated without verification by AI algorithm.

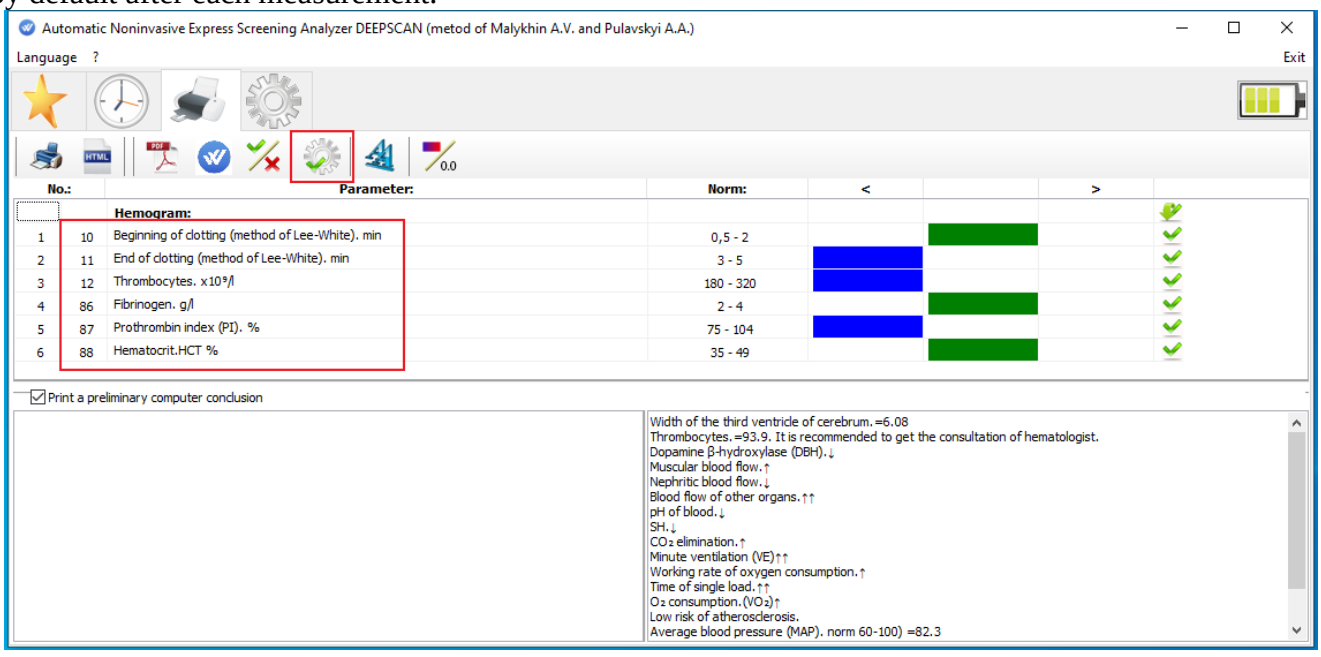
(9.3.3.5) Manual inclusion/exclusion of parameters in the report

By default, all the parameters are marked with "*v*". If it is necessary to exclude any parameter(s) or group(s) of parameters from the printed version of the report, please use "*x*" for them (a click on the symbol "*v*" change it to "*x*" and vice versa.



(9.3.3.6) Selected parameters

If the list of selected parameters was formed in settings (Chapter 9.3.4.4), then it will be displayed by default after each measurement.



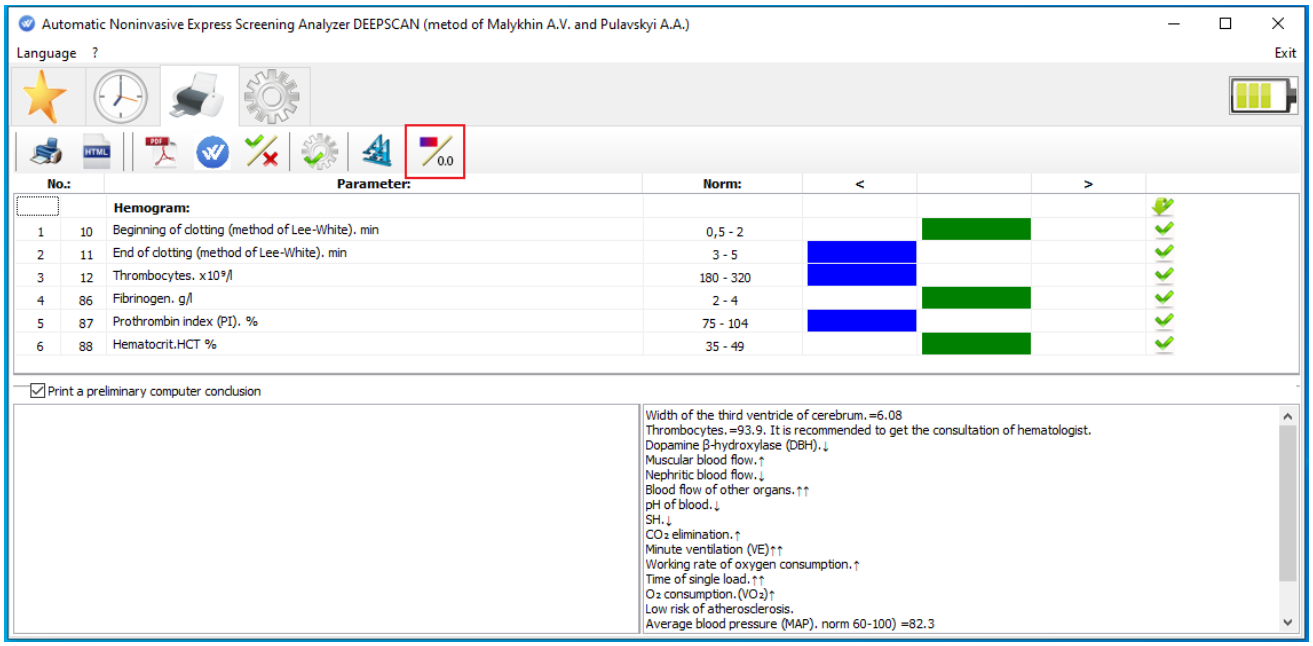
Use this icon to see the complete list of parameters instead of the selected one.

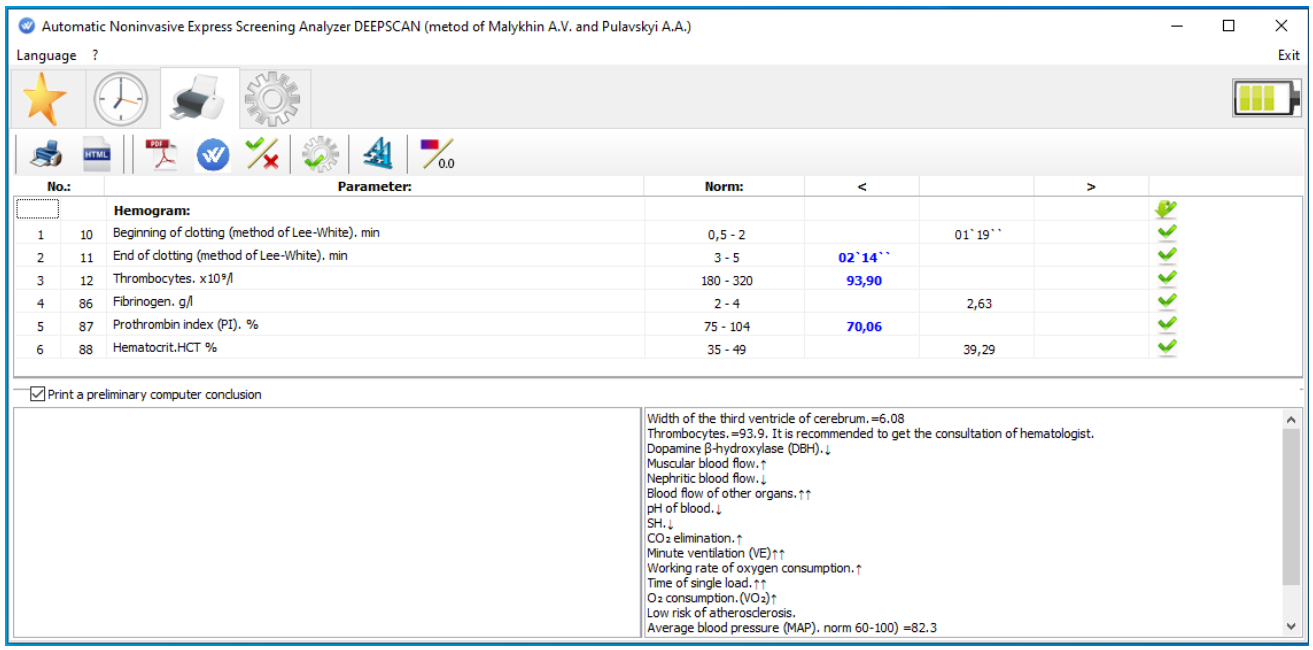
(9.3.3.7) Font

Use this icon to adjust fonts used in the printed/saved version of report. It is possible to set font and size of letters.

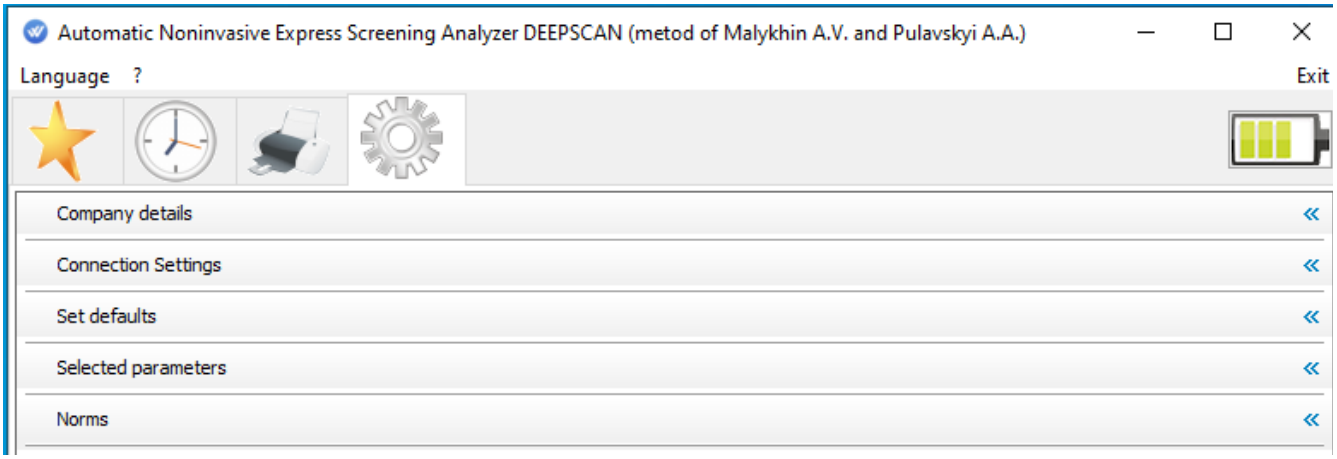
(9.3.3.8) Parameters in color or values

Use this icon to chose the content of printed/saved report. All the parameters in the report will be indicated in color or in figures. Clicking on this icon changes this option from one to another and vice versa.

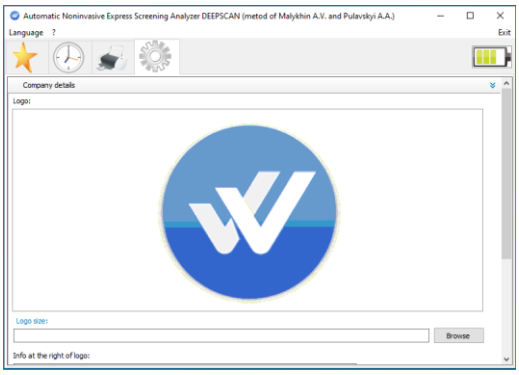




(9.3.4) Options in “Main Settings” 



(9.3.4.1) Company details



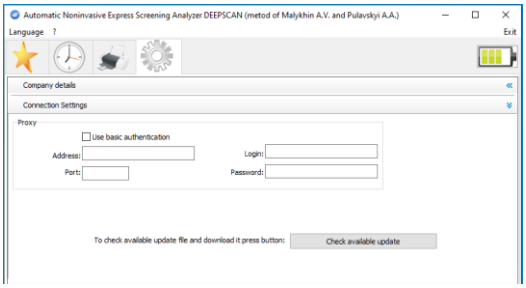
This option allows adding a company name, it’s address and contact information, as well as a company’s logo.
Four fields are intended for the details of the company. It is possible to make a bold text in any of the field (tick it)\

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

(9.3.4.2) Connection settings

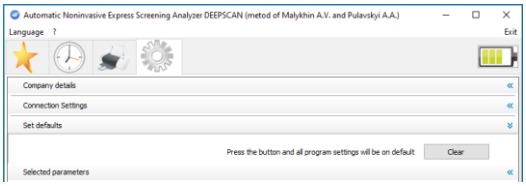
Use this menu if you need to manually adjust your Internet connection details (proxy, port, etc.).

To update the software use the following icon



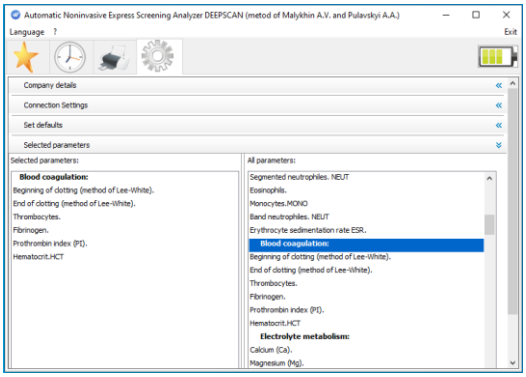
If update file is available, it will be downloaded and software USPIH will be closed automatically.
Open the folder your folder **Downloads** and find the file **“update_USPIH_9.X-CLOUDE.exe”** there. Run it to update software USPIH following the instructions in Chapter 7.2 (the updating process is similar to the software installation).
Update your software USPIH regularly.

(9.3.4.3) Set defaults



This option allows returning to the factory settings.
It is necessary to use this option, if a user would like to cancel all changes made in the initial settings. Personal settings will not be restored after this operation.

(9.3.4.4) Selected parameters

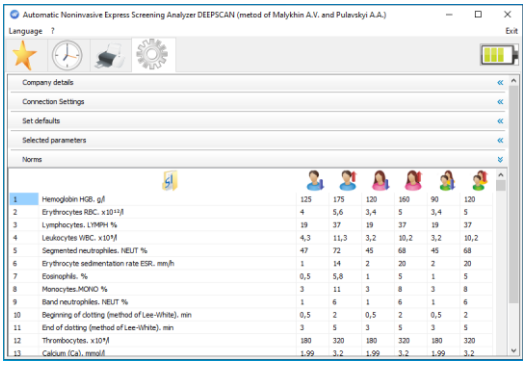


Sometimes, medical professionals prefer to use a shorter list of parameters for quick preview after measurement. So, it is possible to prepare such a list using this menu. There is a list of all parameters, divided by groups, in the right part of the window (All parameters). It is necessary to double 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 see all the parameters, follow the instructions above in Chapter 9.3.3.6

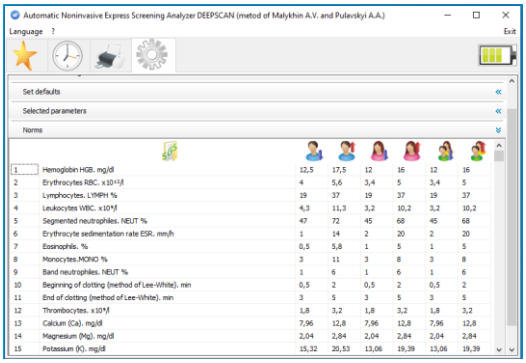
(9.3.4.5) Norms



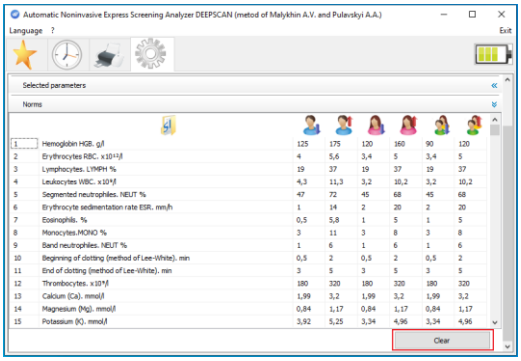
This menu allows changing the normal ranges for each parameter (with regard to the gender and age) according to the commonly accepted ranges on the territory of use.

There are two systems of units in the software: SI and SGS.

It is necessary to click on the icon SI or SGS (above the list of parameters) depending on which of them you are going to use (name of the icon is changed after clicking, from SI to SGS and versa).
Then the normal ranges can be changed for any parameter. Do not leave empty fileds in norms.
Change normal ranges carefully considering a gender (male or female) and age (normal ranges for children are different).



To return to the factory settings, choose the system of units (SI or SGS) and click the button "**Clear**". Then do the same for another system of units.



10. FUNCTIONAL TEST OF MD ANALYZER

A user of MD ANALYZER should make functional test 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 9.3.1.4) in the database. It is created just once and the same record I sused 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 within the allowed ranges for each field;
- Take all sensors in one hand (covering in palm) 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 the 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, the error windows will appear accordingly. Please follow the instructions on Chapter 14, 15.10 of the present IFU or contact your distributor /the manufacturer for troubleshooting.

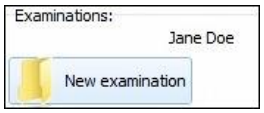
11. DESCRIPTION OF THE MEASUREMENT PROCEDURE

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).

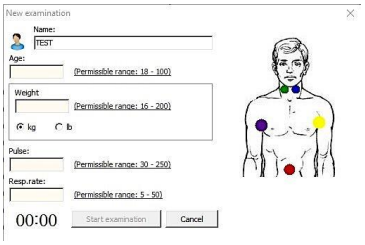
Any measuring procudeure is started from adding a new patient (Chapter 9.3.1.4) or choosing the existing one from the database and creating the new examination according to the following path.

Create new examination

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 (foe existing patient the number of fields will be less. It is not necessary to enter :his/her name, surname and gender. Other should be filled in):



Data	Units	Description	Valid range
Age	years	number of full years	18-100
Weight	kg or lb	weight of a patient in kg or lb	40-200 kg | 88-441 lb
Heart rate/Pulse	beats/min	number of heart beats /60 sec	30-250

Respiration rate	Insp/min	number of inspiration /60 sec	5-50

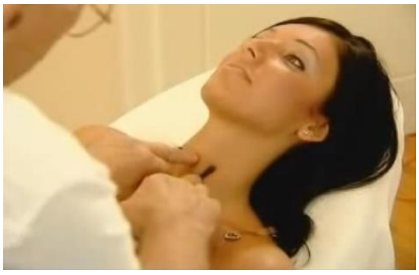
A qualified medical professsional determines a patient's heart rate manually, putting his/her fingers to the pulsation area. A patient should be calm; supine position is required. Measurement should be done carefully. In case of problems with definition of the heart rate (especially with 100 or more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

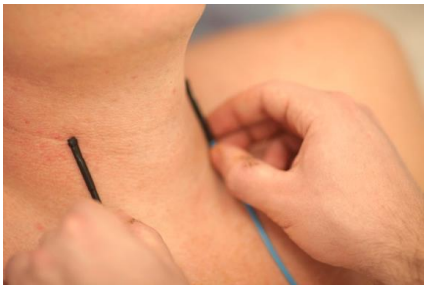
Stopwatch, which may be helpful for measurement of heart rate, is located in the bottom left corner. Clicking on the stopwatch will start time count 00:00. Another click on the stopwatch will stop time count and reset it.

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

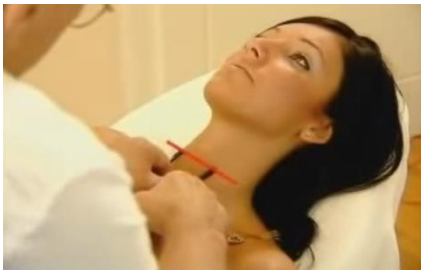
Carotid sensors

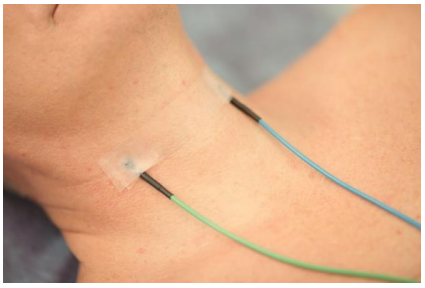
Blue - in the area of the carotid artery bifurcation (on the external and internal) on the **left** side, in the area of cricoid (LCA)





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

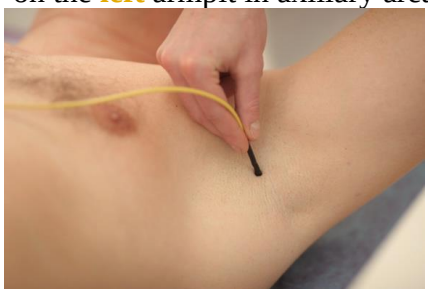




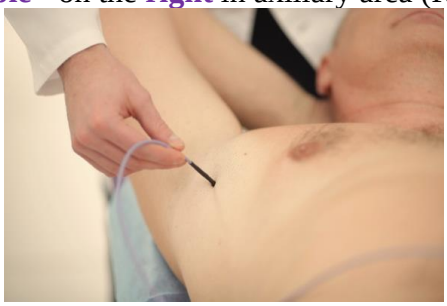
The point of carotid bifurcation is to be found manually: the most intensive pulsation will be in the point of bifurcation. From the position of anatomy, approximately, the point of carotid bifurcation is located between sternocleidomastoid muscle and trachea (middle of distance), at the level of C3 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 have a crease on this level. Sensors should be fixed by plaster.

Axillary sensors (armpits)

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



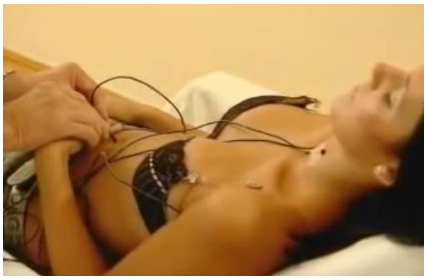
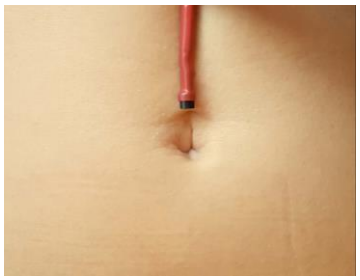
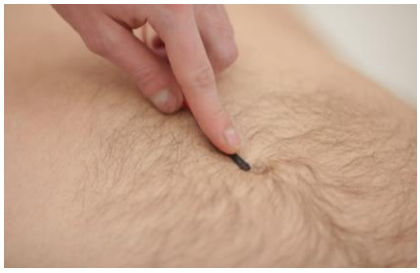
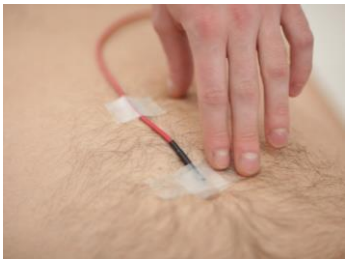
Purple - on the **right** in axillary area (RAC)



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).

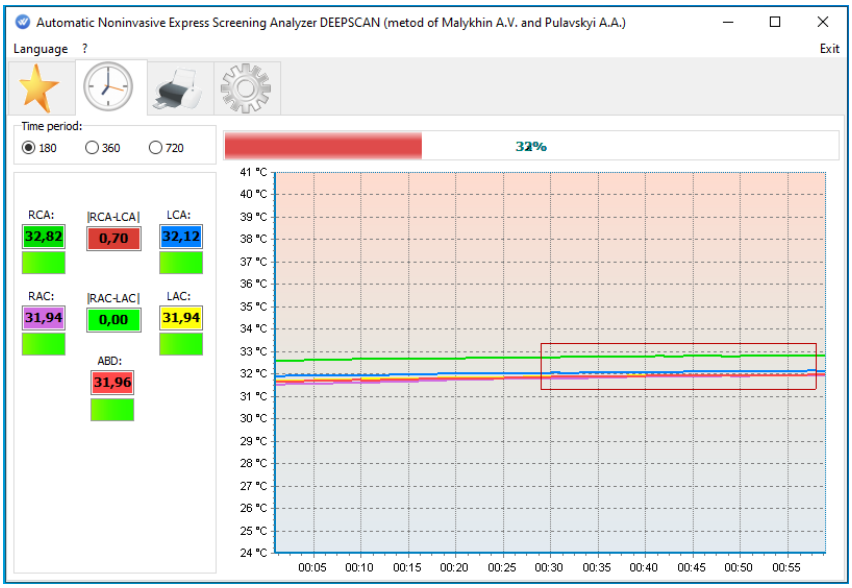
Abdominal sensor

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

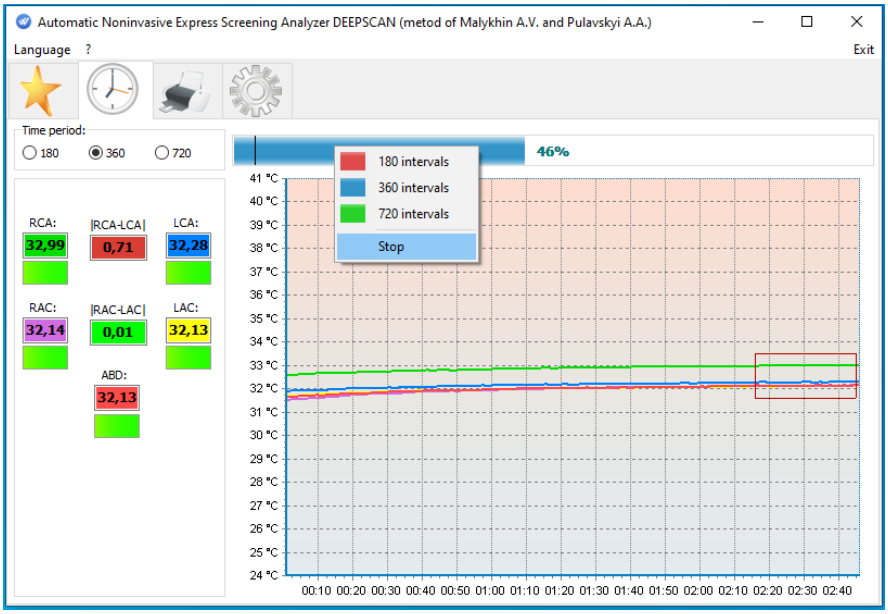





Abdominal temperature (umbilical) is measured in the area, where aorta, inferior vena cava and large lymph vessel are crossed. Pulsation is felt manually in the cross-point of vessels. Sensors should be fixed by plaster.

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):



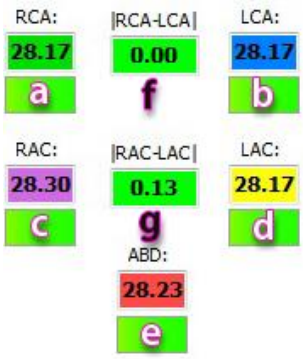
The interval of measurement can be 180, 360 or 720 seconds (by default, it is 360 seconds). It can be changed before and during an examination in the "Time period" menu



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

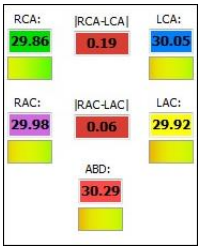
ATTENTION! The accuracy of measured results by the MD ANALYZER depends on accurate process of temperature measurements. That's why, the software interface includes visual indicators, which help a qualified medical professional to determine the time of temperature stabilization and control the process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

The indicators are the following:



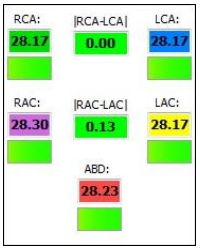
a - an indicator of temperature stabilization on the right side of carotid artery bifurcation
b - an indicator of temperature stabilization on the left side of carotid artery bifurcation
c - an indicator of temperature stabilization in the right armpit (in axillary area)
d - an indicator of temperature 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 0.15ºC 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 0.5ºC.

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

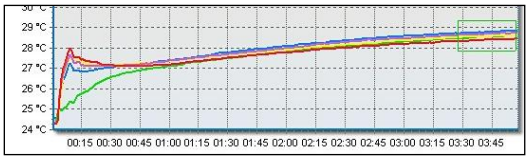
IMPORTANT! Indicators f and **g** are very important for a qualified medical professional during test. They are used as control instruments and give the information, if the test is going right and chosen time interval is enough for testing**.**

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

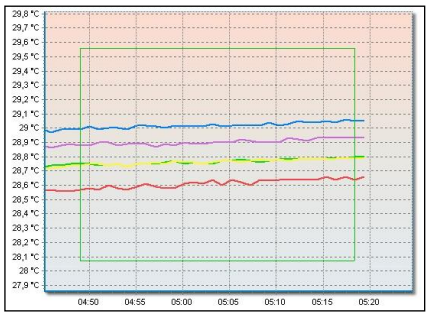
IMPORTANT! If the rectangles below temperature values are not green till the end of measurement, a qualified medical professional should change time interval to the larger one**.**

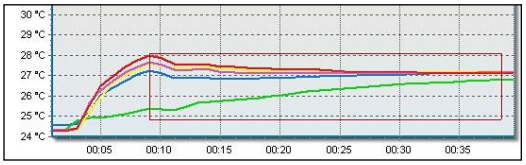
Colour "floating window" will appear over temperature graphs in 40 sec. after starting measurement. The window will have a red border, if stabilization of temperatures is not achieved. When temperature values stabilize, the "floating window" becomes green. This is another **important control issue during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

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

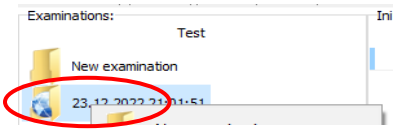


To return the graph to its original position, please hold the left mouse button and drag it across the field chart from right to left

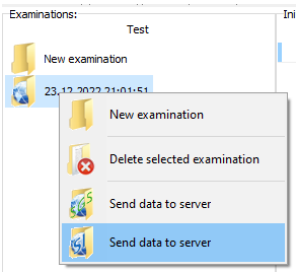


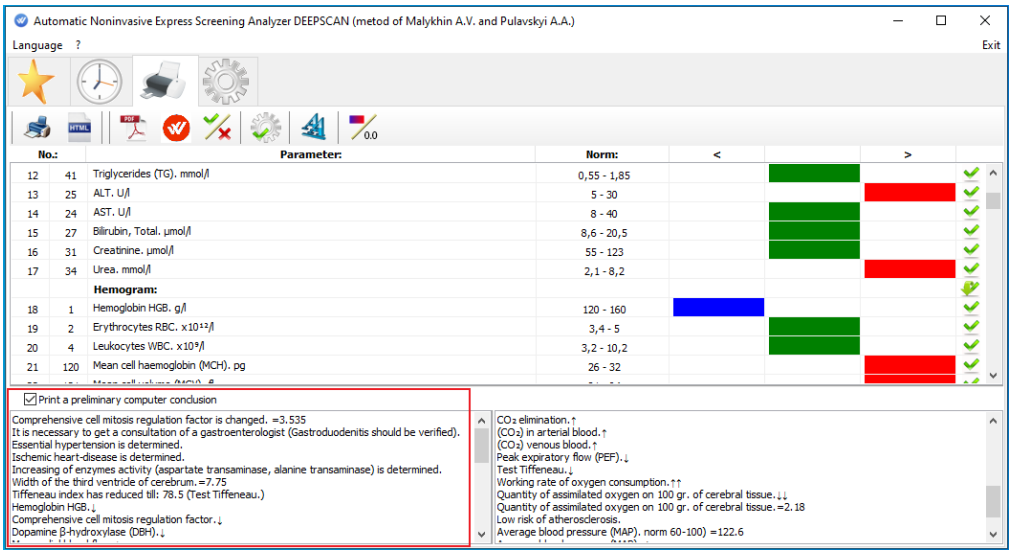


When the measurement is completed, the appropriate record will appear in the patient's card in database.



Using the context menu (right click on the mouse), send the measured data to a server for processing, considering the units you need in the report (SI or SGS).

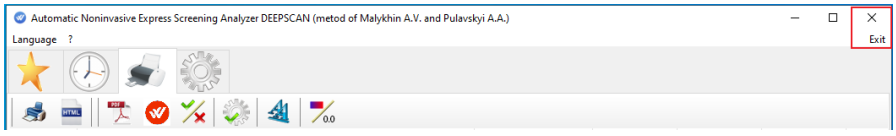




The window with „**Results of measurements**" opens automatically, when the report returns to the computer. To prepare the surveys for prnting out or saving, please follow the instructions in Chapter 9.3.3.
Note: Only the text typed by the operator in the lower left window is printed.

12. SWITCHING-OFF MD ANALYZER

Close the software USPIH using the icon EXIT (in the right up corner of the main menu)



Switch off the unit using the button on the side panel:

- Press and hold the "POWER" button at least 3 sec.
- MD Switch-OFF.

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 on the connector and gently pull out the cable.
Switching off the device is completed

13. EXAMPLE OF A SURVEY

Example of the report, which is generated after data processing

24.12.2022 10:32:59 : 20160619

Gender: female	Age: 77	Weight: (kg): 77	Pulse: 77	Resp.rate: 18	Atm.pres: 734,9
LCA: 31,63	RCA: 30,29	LAC: 30,93	RAC: 30,87	ABD: 30,75	154,47	00000

Preliminary computer conclusion about diagnosis:
Cardio cerebral insufficiency is defined. Insufficient blood supply of brain (encephalopathy) is determined. Impaired coagulation should be verified. The blood coagulation must be under control.
Post hypoxic encephalopathy is defined. Delirium syndrome with convulsive component is determined. Pulmonary-cardiac insufficiency is determined.
Distinct reduction of leucocytes is determined. Leukocytes WBC.=3.57 < 4.63=Erythrocytes RBC. It is recommended to get the consultation of hematologist, gastroenterologist.
It is recommended to get the consultation of hematologist, gastroenterologist, oncologist.
Concentration of glucose in blood should be tested carefully.
Spinal osteochondrosis is defined. Disorders of water-electrolytic metabolism is determined. Ca of plasma is changed (Ca of bone tissue).
Hypertension of pulmonary circulation is defined.
Width of the third ventricle of cerebrum.=6.76
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).=20.8
Tiffeneau index has reduced till: 83.6 (Test Tiffeneau.)
Comprehensive cell mitosis regulation factor.↑
Dopamine β-hydroxylase (DBH).↓↓
Myocardial blood flow.↓
Nephritic blood flow.↓
Skin blood flow.↓↓
Blood flow of other organs.↑↑
SH.↓↓
Basal pressure of Oddi's sphincter↓
(CO_2) in arterial blood.↑
(CO_2) venous blood.↑↑
Minute ventilation (VE)↑↑
Peak expiratory flow (PEF).↓
Test Tiffeneau.↓
Working rate of oxygen consumption.↑↑
Quantity of assimilated oxygen on 100 gr. of cerebral tissue.↓↓
Quantity of assimilated oxygen on 100 gr. of cerebral tissue.=1.80
O_2 consumption.(VO_2)↓↓
Oxygen extraction index.↓↓
Low risk of atherosclerosis.
Average blood pressure (MAP). norm 60-100) =97.7
Thrombolysis in Myocardial Infarction (TIMI) Risk Index. ↑

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_____

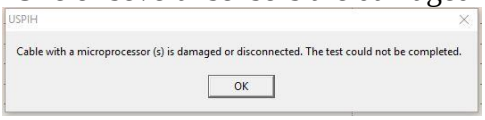
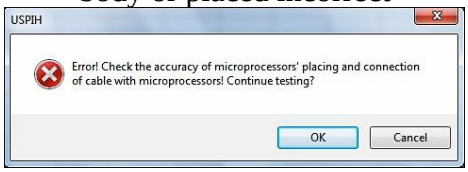
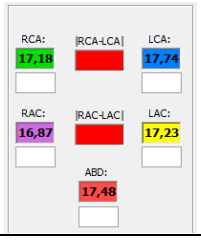
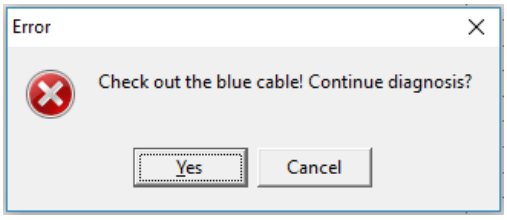
☐

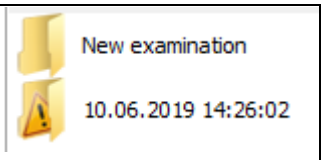
No.:		Parameter:	Norm:	<		>
1	2	Erythrocytes RBC. x10¹²/l	3,5 - 5			*
2	1	Hemoglobin HGB. g/l	110 - 150			*
3	88	Hematocrit.HCT %	40 - 50		*	
4	12	Thrombocytes. x10⁹/l	100 - 300		*	
5	4	Leukocytes WBC. x10⁹/l	4 - 10	*		
6	3	Lymphocytes. LYMPH %	17 - 40		*	
7	8	Monocytes.MONO %	3 - 8		*	
8	42	Glucose. mmol/l	3,9 - 6,2			*
9	35	Cholesterol total. mmol/l	2,8 - 5,17		*	
10	38	Low-density lipoproteins (LDL). mmol/l	2,07 - 3,62		*	
11	40	High-density lipoproteins (HDL). mmol/l	0,93 - 1,81		*	
12	41	Triglycerides (TG). mmol/l	0,55 - 1,71		*	
13	25	ALT. U/l	2 - 40		*	
14	24	AST. U/l	2 - 40		*	
15	27	Bilirubin, Total. µmol/l	1,7 - 17,1		*	
16	31	Creatinine. µmol/l	70 - 106	*		
17	34	Urea. mmol/l	3,2 - 7,1		*	

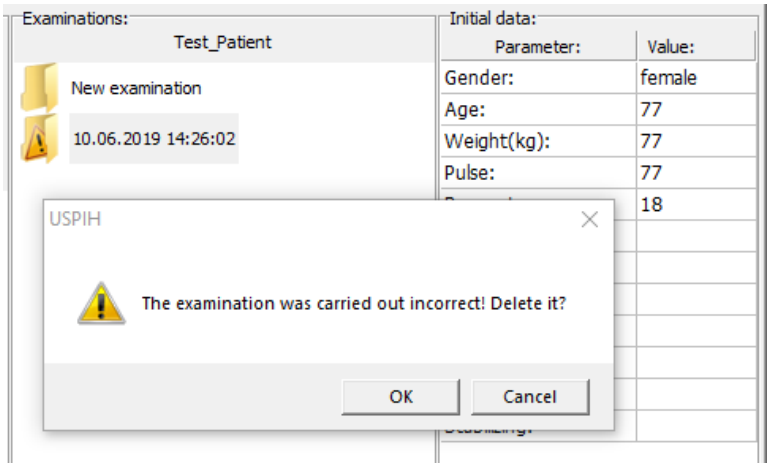
No.:		Parameter:	Norm:	<		>
1	2	Erythrocytes RBC. x10¹²/l	3,5 - 5			5,10
2	1	Hemoglobin HGB. g/l	110 - 150			152,72
3	88	Hematocrit.HCT %	40 - 50		44,25	
4	12	Thrombocytes. x10⁹/l	100 - 300		259,35	
5	4	Leukocytes WBC. x10⁹/l	4 - 10	3,35		
6	3	Lymphocytes. LYMPH %	17 - 40		36,57	
7	8	Monocytes.MONO %	3 - 8		3,27	
8	42	Glucose. mmol/l	3,9 - 6,2			10,15
9	35	Cholesterol total. mmol/l	2,8 - 5,17		4,60	
10	38	Low-density lipoproteins (LDL). mmol/l	2,07 - 3,62		2,26	
11	40	High-density lipoproteins (HDL). mmol/l	0,93 - 1,81		1,67	
12	41	Triglycerides (TG). mmol/l	0,55 - 1,71		1,57	
13	25	ALT. U/l	2 - 40		7,57	
14	24	AST. U/l	2 - 40		7,85	
15	27	Bilirubin, Total. µmol/l	1,7 - 17,1		13,34	
16	31	Creatinine. µmol/l	70 - 106	60,33		
17	34	Urea. mmol/l	3,2 - 7,1		3,51	

Reminder: The results of a test can be presented in a graphic format and in values. Switching between these data visualization formats is carried out using the check-box. 

14. TROUBLESHOOTING FOR USPIH 9.X

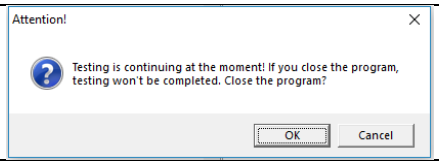
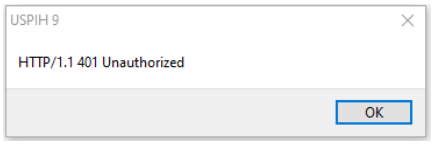
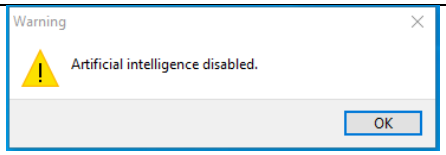
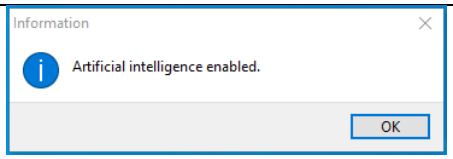
No	Error/ problem	Indication and Reason(s)	Solution/advice
1.	Measurement couldn't start or it is interrupted in a process	One or several sensors are damaged 	Replace the cable with a good one.
		Sensors are not placed on a patient's body or placed incorrect  	Place the sensors in a way, as it is required by this Manual (Chapter 11) and then click "OK". The window may appear again, if the measured temperatures is below 24°C or above 41°C
2.	Measurement is not started or it is interrupted in a process	If a sensor(s) or cable(s) for sensor are damaged (by any reasons), a user is warned in two ways: 2.1 error window  2.2 flashing LED on a side panel of the unit: the color of LED correspondes with the color of damaged cable/sensor. (For example, if a yellow cable is damaged, then the LED will flash yellow. If two cables are damaged, e.g. yellow and violet, the LED will flash the yellow and violet alternately)	Replace the cable with a good one.
3.	Device MD ANALYZER isn't found	There is no connection between MD ANALYZER and PC	Depending on the mode of connection you use, 1) check USB cable (IFU Chapter 8) or reconnect USB cable or replace it, if it is damaged; 2) check BLUETOOTH pairing, reconnect if necessary (IFU Chapter 8).
		Drivers for the device were installed incorrectly	Check the drivers and reinstall them (IFU Chapter 7)

<table>
<tr><td>4.</td><td>A survey is unavailable</td><td colspan="2">If a survey in the database is damaged or the measurement has been interrupted, such surveys will be marked with a special character and such surveys will be unavailable for opening.
 



Software USPIH 9.X will automatically suggest to remove such a survey. To maintain the integrity of the database, this survey should be deleted, and a measurement should be repeated.</td></tr>
<tr><td>5.</td><td>Examination is impossible</td><td> 
</td><td>Connect the unit of MD Analyzer to the computer.

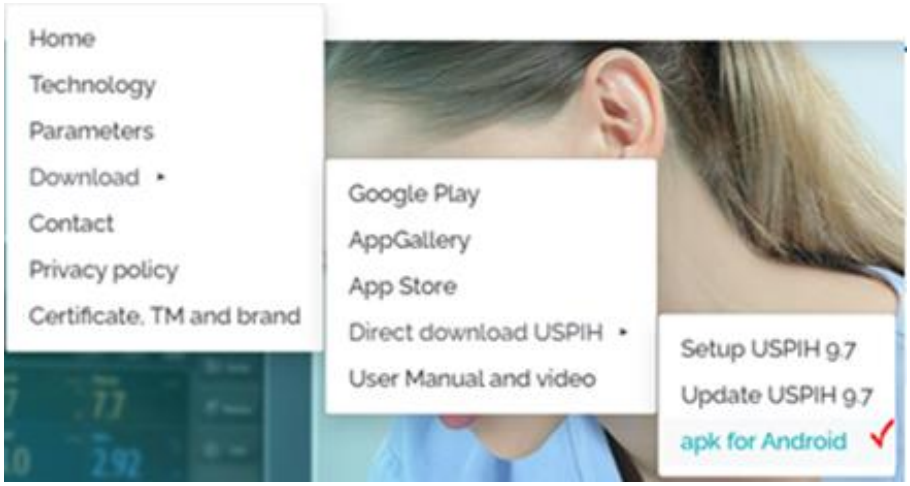
If the unit is already connected to the computer via USB cable, replace the cable.

If the unit is already connected to the computer via BLUETOOTH, check the BLUETOOTH settings. (IFU Chapter 8)</td></tr>
<tr><td>6.</td><td>Attention!</td><td> 
</td><td>This message is displayed when you try to close the application in a process of measurement of a patient.</td></tr>
<tr><td>7.</td><td>Attention!</td><td> 
</td><td>Such error can display in case
- no Internet connection,
- the entered password is not correct
- the device is not registered in the cloud system
After pressing the button "OK", the program will close the main window.
We recommend to make authorization again</td></tr>
<tr><td>8.</td><td>Warning.</td><td> 
</td><td>If artificial intelligence is disabled, the program will warn you about it.</td></tr>
<tr><td>9.</td><td>Information.</td><td> 
</td><td>If artificial intelligence is enabled, the program will warn you about it.</td></tr>
</table>

15. SOFTWARE USPIH FOR ANDROID (INSTALLATION, SETTINGS, WORK)

If MD ANALYZER is used together with a tablet PC based on OS ANDROID, then a specially designed software should be installed (the latest version of software).

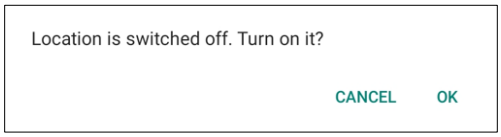
To install such a software for AMP/ANESA, please follow the instructions below:
Download a setup file for the MD ANALYZER with Android and run it.



The setup file is available on the official website (apk for ANDROID)

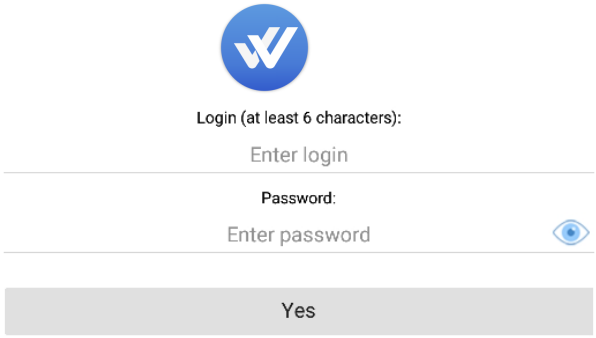
Swith on Bluetooth and Location on your Tablet with OS ANDROID. Download the APK and install it.

If Location is not enabled on your mobile device, the software will offer to enable it.
It is mandatory to swith on Location.



Run APK

Enter login and password. Press button “Yes”.



The software will open the main window.

Create a patient card

Edit patient card

Settings

Main menu (Return to main screen)

Delete patient’s card

Show patient history.
Select by the date of examination

Refresh screen content

Searching

Medical device connection indicator via BLUETOOTH

Medical device connection indicator via USB

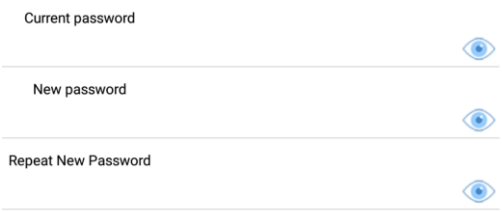
Press button “Settings menu”:

Select the type of BLUETOOTH connection (**Classic** (BLUETOOTH Ver. 4.2 or below) or **BLE** (BLUETOOTH Ver. 5.0 or higher)) or USB.
To connect a medical device to a mobile gadget via USB, use an adapter USB-A to USB-C.

Note: Make sure your gadget supports OTG.

Select interface language.
Enter the company details.

You can set your password to access test results in the cloud server.
The same menu is used for changing the passowrd.



Changes will take effect after clicking the "Accept" button 

To view the entered data, use the appropriate icon

When all sensors are connected to the unit of MD ANALYZER and their operability is verified, then the **LED flashes white** on the side panel of the unit.

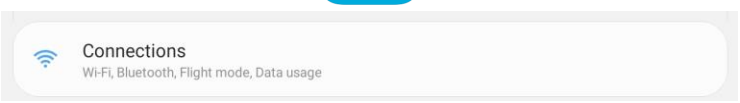
After connection of the unit of MD ANALYZER (with already connected sensors) to your Tablet PC **the LED rarely flashes blue** (the same LED on side panel of the unit).

15.1 CONNECTING A MEDICAL DEVICE OPERATING ON BLUETOOTH VERSION 4.2 OR BELOW.

PREPARE YOUR MOBILE GADGET.

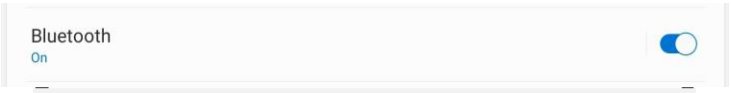
Select SETTINGS.

Select menu “Connection”

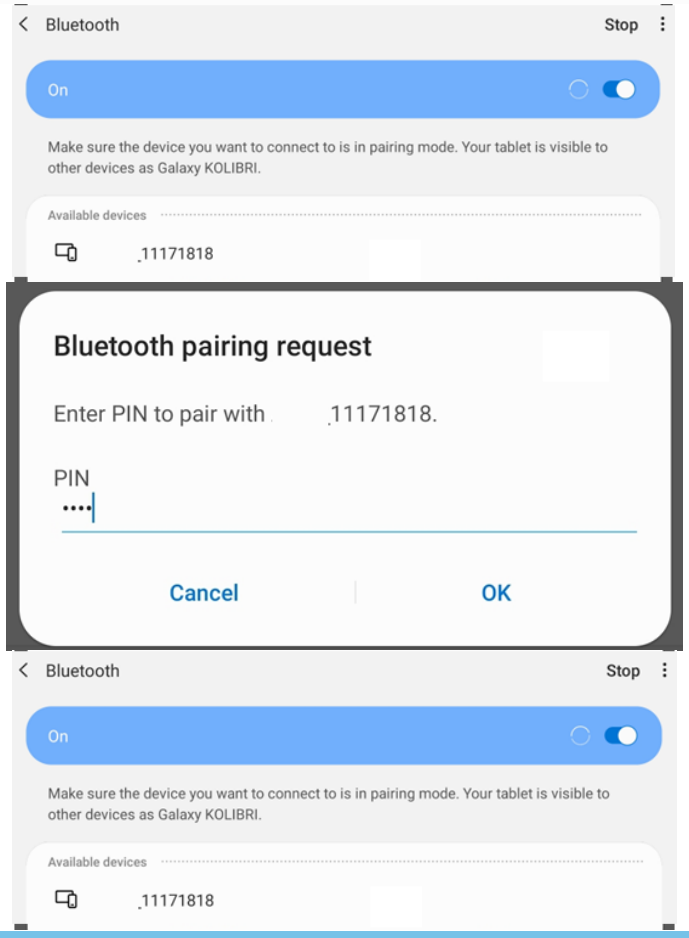


Swith-ON medical device.

Switch-ON BLUETOOTH



After the mobile gadget shows a list of devices visible for Bluetooth, select a medical device from the list. In the example, this is an AMP/ANESA with serial number 11171818.

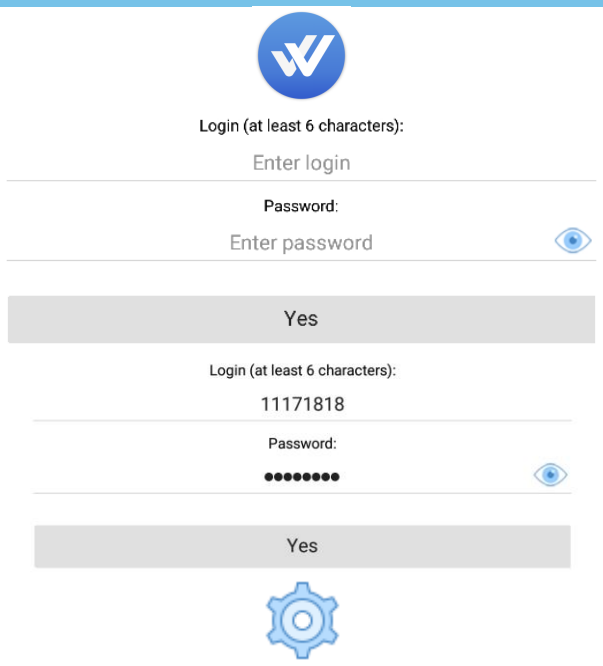


The mobile gadget will ask for permission to pair and ask for a password.
Enter password: 1234 and click OK.

The mobile gadget will notify you of a successful pairing if everything is done correctly.

PREPARE SOFWARE.

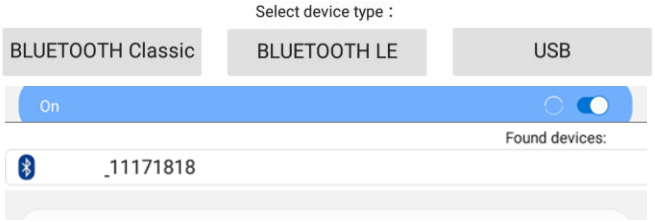
Next step: run APK



Enter login and password. Press button “Yes”.

Select menu “Settings”.

Select menu
“BLUETOOTH Classic”



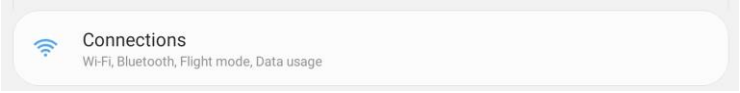
Select the mdical device.

15.2 CONNECTING A MEDICAL DEVICE OPERATING ON BLUETOOTH VERSION 5.0 OR HIGHT.

PREPARE YOUR MOBILE GADGET.

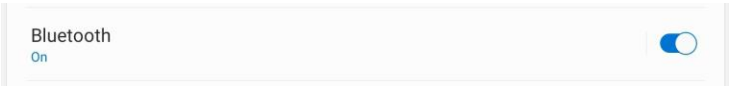
Select SETTINGS.

Select menu “Connection”

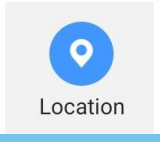


Swith-ON medical device.

Switch-ON BLUETOOTH



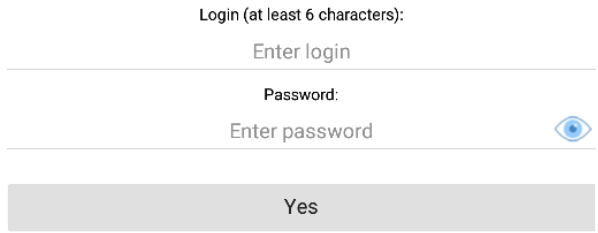
Swith-ON Location



PREPARE SOFWARE.

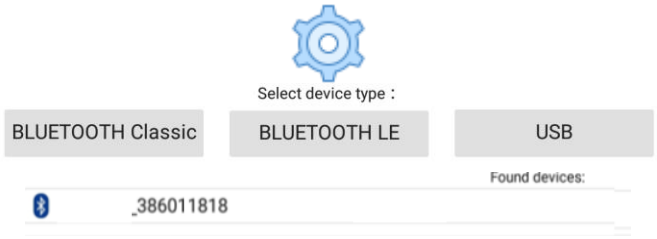
Next step: run APK

Enter login and password. Press button “Yes”.



Select menu “Settings”.

Select menu
“BLUETOOTH LE”
Select the mdical device.
Examle: AMP/ANESA 386011818



15.3 PATIENT'S CARD CREATION

Press an icon
"Create a patient card"

Enter

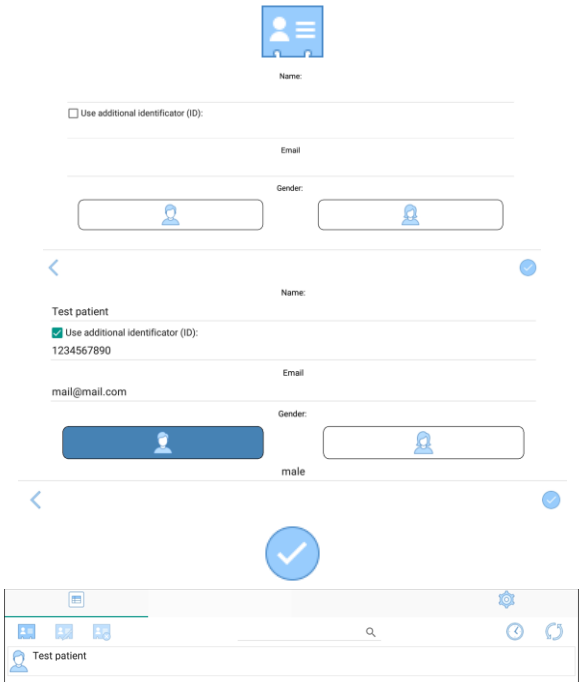
1. Patient name
2. ID
3. Email
4. Choose gender

Press the button "Accept"

or button "Return"

A patient card will be created if you press the "accept" button.

The patient record has been created.



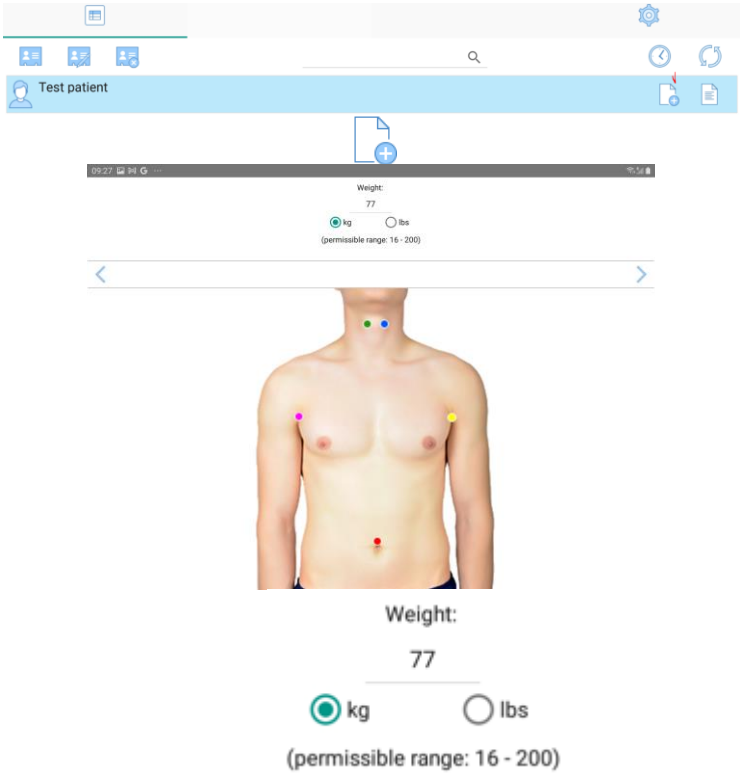
15.4 PATIENT TESTING

Select the patient

Press button "Create test card"

Enter weight

Select kg or lbs.
Press button "Next"

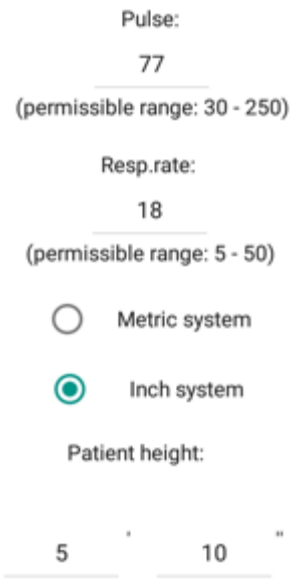


Enter heart rate (pulse)
Press button “Next”

Enter respiratory rate Press button “Next”

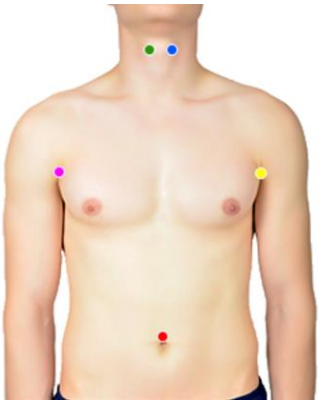
Select “Metric system” or “Inch system” (for height))

Enter height
Press button “Next”

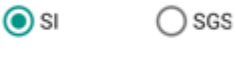


After that, correctly place five microprocessors (sensors) on the patient's body. Refer to Chapter 11. DESCRIPTION OF MEASURING PROCEDURE of this IFU or the tutorial video on YouTube.

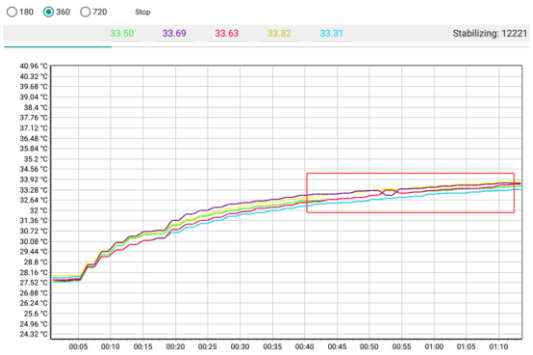
The proper sensors’ placement is shown schematically in the software interface.



Select system of units
Press button “Next”



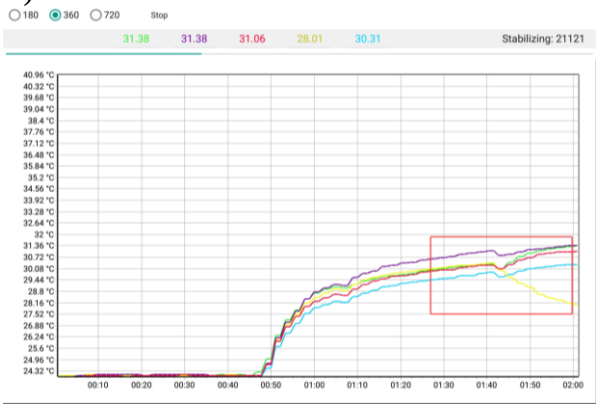
The process of temperature measurement will be displayed in graphs in real time.
Color of curves corresponds with the color of cables with sensors placed on a patients body
(Chapter 11).

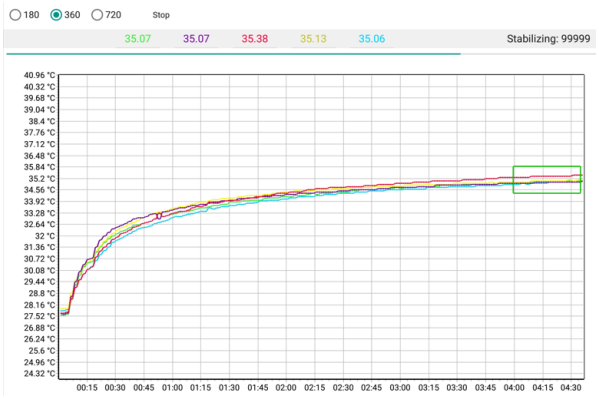


A user can choose the period of time necessary for measurement. It can be changed during the measurement or even stopped before ending.

If one of the sensors loses contact with the skin during the measurement, then the appropriate graph starts to decline. This is a useful element of control during the measurement, which allows timely correction of the fixation of sensors (left screen shot below).

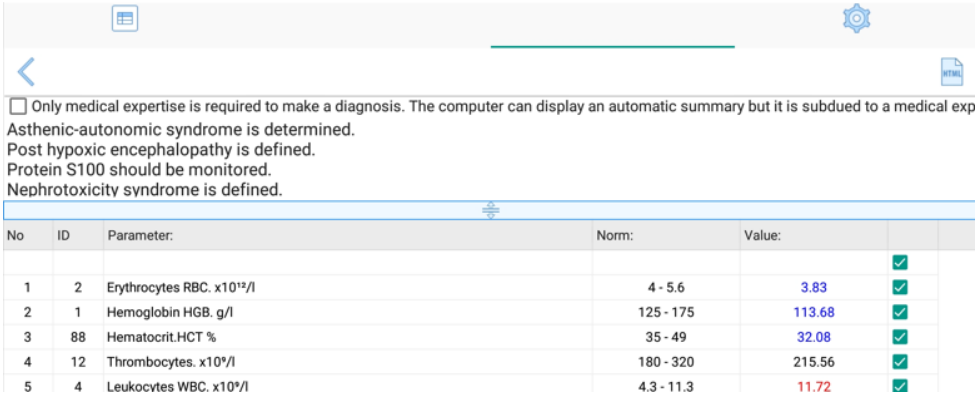
If the temperature values at five points have stabilized, a green rectangle will appear on the graph, and the stabilization parameter will be equal 99999. The measurement can be completed. (right screen shot below)





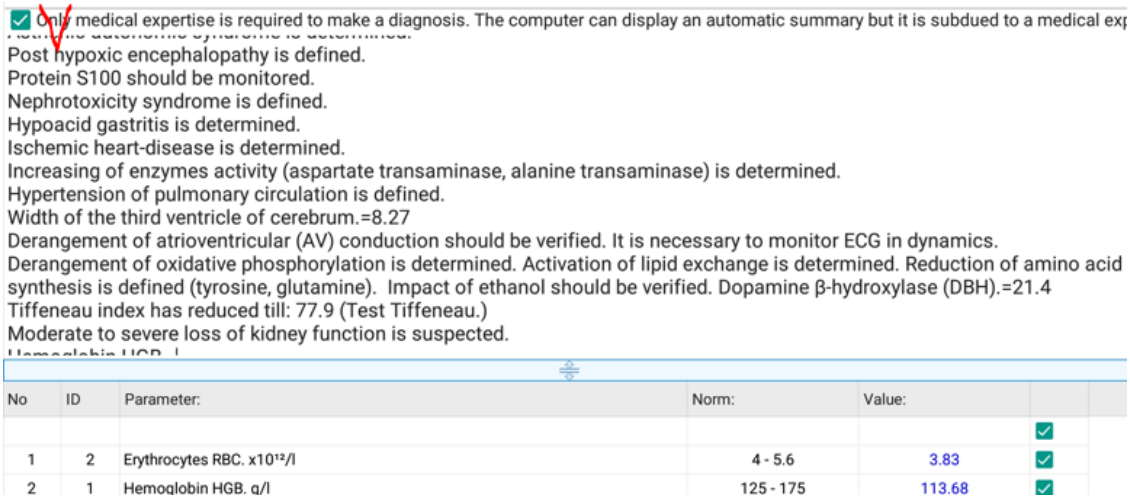
When the measurement is finished, the software will automatically offer to send the results of measurement to the cloud server for mathematical processing. When it is completed the results will be returned in the form of a report to your tablet PC. Usually it takes a couple of seconds to sent the results of measurement and receive the report.

Press “OK” and receive results. The results will be represented as follows:

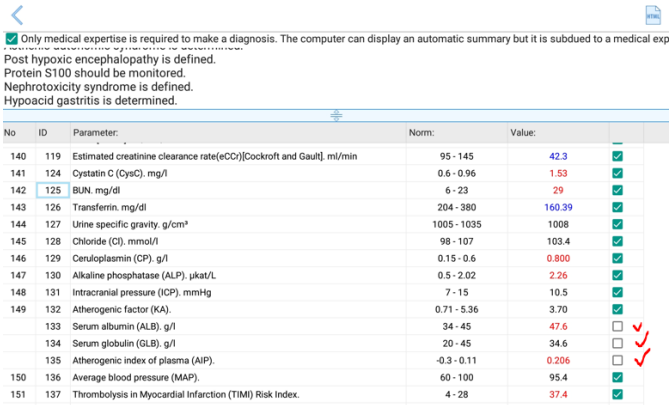


Use the split icon to view the automatic summary generated by the software.

Use the checkbox to print the automatic summary generated by the software.

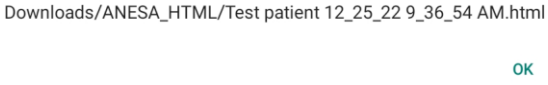


You can remove some parameters from printed version of the report by deleticng the tick in the corresponding raw.



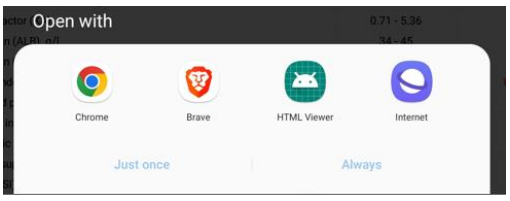
Use this icon to generate a report in HTML format

The software will prompt you to download the report in HTML format.
The file name will contain the patient's name, date and time of the test.



OS ANDROID will offer several applications for opening and displaying the report with results

Note: We recommend CHROME, BRAVE or VIVALDI browsers.
Select any one you have and open the report.



The report will starts from a preliminary machine conslusion about health state of tested person. It is only a promt for a doctor, which needs to be considredred and corrected accordingly.

Test results will be displayed in coloured bars:
blue - value below normal | **green** - value is normal | **red** - the value is above the norm.

Test patient

12/25/22 9:36:54 AM : 4368696E6120436F6D70616E79

Gender: male	Age: 77	Weight: (kg): 77	Pulse: 77	Resp.rate: 18	Atm.pres: 718.23
LCA: 35.04	RCA: 35.1	LAC: 35.12	RAC: 35.05	ABD: 35.35	175.66	99995

Only medical expertise is required to make a diagnosis. The computer can display an automatic summary but it is subdued to a medical expertise.
Asthenic-autonomic syndrome is determined.
Post hypoxic encephalopathy is defined.
Protein S100 should be monitored.
Nephrotoxicity syndrome is defined.
Hypoacid gastritis is determined.
Ischemic heart-disease is determined.

To display parameters in values (instead of color bars), use the checkbox in right up corner of the table (tick it) ☑

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

☐

No.:		Parameter:	Norm:	<		>
1	2	Erythrocytes RBC. x10¹²/l	4 - 5.6	*		
2	1	Hemoglobin HGB. g/l	125 - 175	*		
3	88	Hematocrit.HCT %	35 - 49	*		
4	12	Thrombocytes. x10⁹/l	180 - 320		*	
5	4	Leukocytes WBC. x10⁹/l	4.3 - 11.3			*

☑

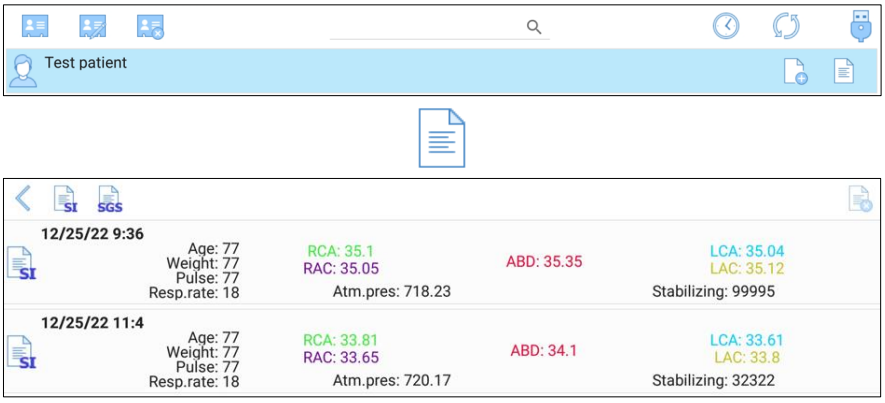
No.:		Parameter:	Norm:	<		>
1	2	Erythrocytes RBC. x10¹²/l	4 - 5.6	3.83		
2	1	Hemoglobin HGB. g/l	125 - 175	113.68		
3	88	Hematocrit.HCT %	35 - 49	32.08		
4	12	Thrombocytes. x10⁹/l	180 - 320		215.56	
5	4	Leukocytes WBC. x10⁹/l	4.3 - 11.3			11.72
6	3	Lymphocytes. LYMPH %	19 - 37		25.18	
7	8	Monocytes.MONO %	3 - 11		6.52	

15.5 VIEW TEST RESULTS

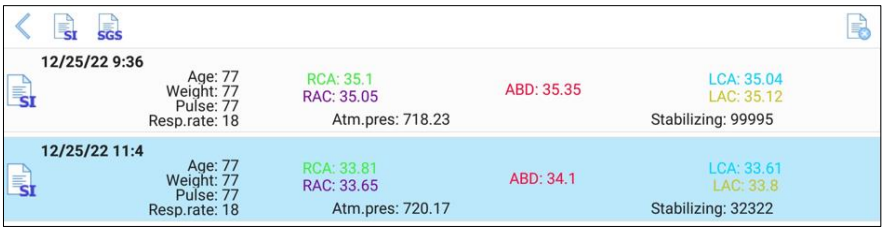
Select the patient.

Press button “View results”

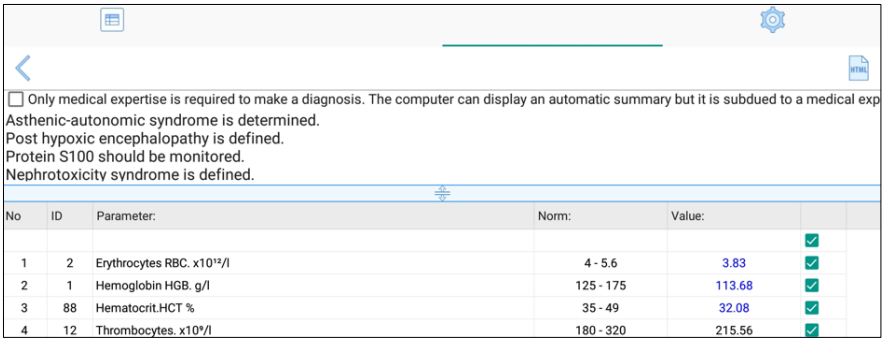
Select a test.



Double-click to test.

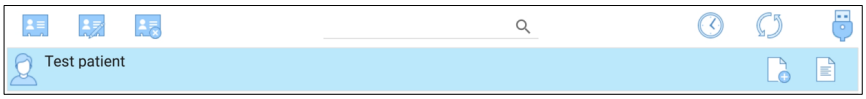


The software will show the test results.



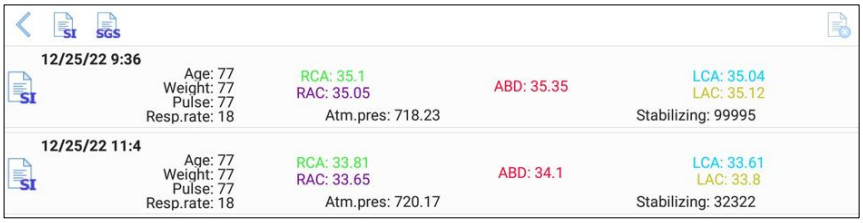
15.6 DELETE TEST RESULTS

Select the patient.

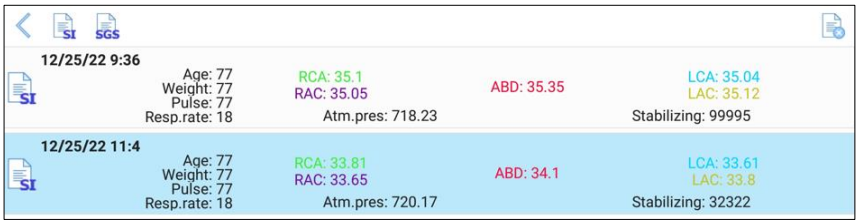


Press button “View results”

Select test.

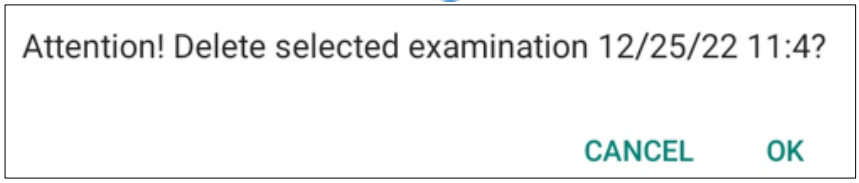


Double-click to test.



Press button “Delete test”

The program will warn about deleting the test.
Press button “OK”.



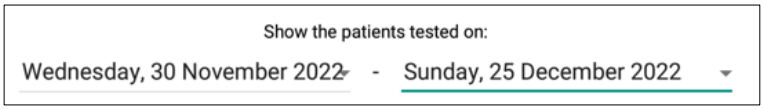
The test has been deleted.

15.7 USING THE CALENDAR TO FIND TEST RESULTS

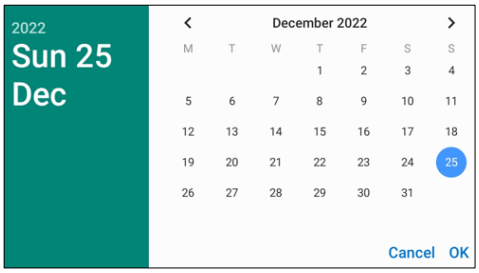
Press button “Main menu” (Return to main screen)

Press the button “Calendar.”

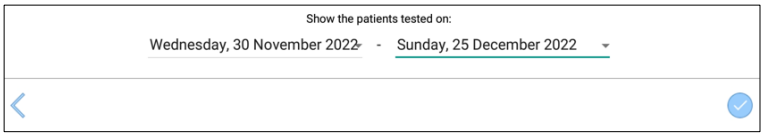
Select ‘Start date” and “Finish date.”



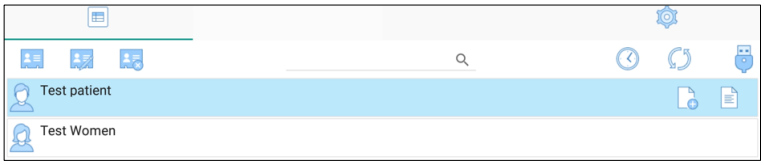
Use the calendar.



Press the "Accept" button.

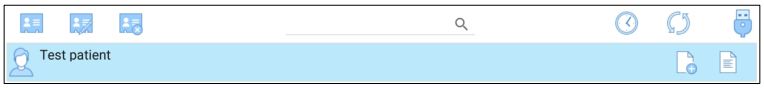


The program will show all the tests for the period you have chosen.



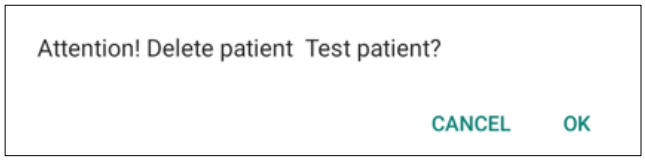
15.8 DELETE A PATIENT’S CARD

Select the patient.



Press button: “Delete a patient”.

The program will warn about deleting the selected patient.
Note: All tests of the deleted patient will also be deleted too.
Press “OK”



The patient and his test results will be removed from the database

15.9 EDIT A PATIENT'S CARD

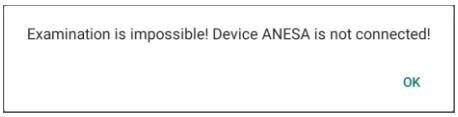
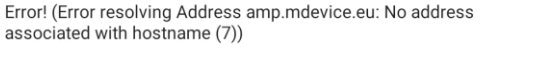
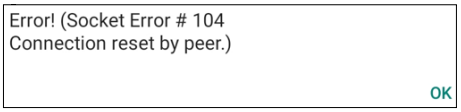
Select the patient.

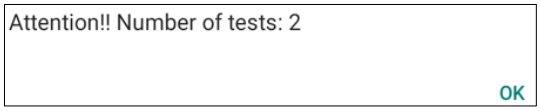
Press button: "Edit patient card".

Edit the patient chart.

Press the button "Accept"

15.10 TROUBLESHOOTING FOR USPIH ANDROID

No	Error/problem	Indication and Reason(s)	Solution/advice
1.	**Test error** Measurement is not started or it is interrupted in a process	 Reasons: The device is not connected to the Tablet PC	Connect the MD to the Tablet. Adjust settings in the menu 
2.	**Error!**		The error occurs when the mobile gadget is not connected to the Internet or there is no access to the cloud server. Connect your mobile gadget to the Internet.
3.	**Connection error**	 Reasons: 3.1 There is No Internet connection 3.2 Cloud server is not working	3.1 Check your Internet connection 3.2 If Internet connection is OK, Contact your service provider and inform about the problem

4	**Temperature alert** During the measurement, the window for temperature monitoring changes its color to red and flashes	 Reasons: 4.1 Sensor(s) lost the contact with skin of a patient 4.2 Sensor(s)/cable(s) lost connection with the unit (see Error 5 below).	Note: such alert signals that the measured temperature is below +24C or above +41C 4.1 Fix the sensor(s) on a patient's body properly according to the requirements in Chapter 11. 4.2 Check the connection of cables with the unit. (see also Error 5 below)
5	**Balance alert**	 Reasons: If the user's balance is close to zero, the software displays this alert	Contact your service provider to replanish your balance.
6	**LED alert** LED on the side panel of the unit flashes frequently	One (several) sensor(s) is(are) not connected to the unit or it(they) is(are) faulty. The color of LED indicates the color of damaged sensor(s)/cable(s). For example, if a yellow cable is damaged, then the LED will flash yellow. If two cables are damaged, e.g. yellow and violet, the LED will flash the yellow and violet alternately.	Replace the damaged cable(s) with sensor to the new one. Contact your distributor or the manufacturer for a new set.

16. CLEANING AND DISINFECTION OF MD ANALYZER

Wipe enclosure of the unit with 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.

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

17. 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.

18. 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.

19. REPAIR

Only responsible staff of the manufacturer, company MEDICAL DEVICES MAGYARORSZÁG KFT, 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 MEDICAL DEVICES MAGYARORSZÁG KFT for production, are allowed to be used for repairing of the MD ANALYZER.

20. SHELF-LIFE AND LIFETIME OF THE DEVICE

LIFETIME: 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 17, 18, 21).
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 LIFETIME 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 y the manufacturer or authorized service centre.

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.

21. 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.

Specific condition of storage related to the embedded battery	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.
	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.
Information on the DGR and LBSG can be found here:
http://www.iata.org/dgr
http://www.iata.org/lbsg

22. 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

23. WARRANTY CARD

WARRANTY CARD/ CERTIFICATE OF WARRANTY	**Automatic Noninvasive Express Screening Analyzer AMP/ANESA**	
No. (Serial number of the MD ANALYZER)		
Warranty period*	24 months for MD ANALYZER	
Purchase Date	Buyer	
YYYY.MM.DD	*Company name*	
[Signature and Stamp]	Address	Telephone | email

Sold to the end-user	By a local representative/trading company	
[DATE]	*[Name of the local representative/trading company]*	
[Signature and Stamp of the local representative/company]	*Address a local representative/trading company*	*Contact details*

Filled by the customer/end-user:		
Customer/end-user	*[Customer Signature]*	*[DATE]*
Hereby, I confirm that I have read the warranty terms and agree with them		*[Customer Signature]*

Important: Please store this card in a secured location for future reference. MEDICAL DEVICES MAGYARORSZÁG KFT or its authorized representative reserves the right to request this document before accepting repair requests.

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

Manufacturer:
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79, Hungary
Tel.:+36209719323

MEDICAL DEVICES MAGYARORSZÁG KFT provides the manufacturer's warranty (herein referred to as the Warranty) for the Purchaser (herein referred to as the "User") of the **Automatic Noninvasive Express Screening Analyzer AMP/ANESA** (herein referred to as the ANALYZER). This warranty card provided with the device ANALYZER is subject to the following terms and conditions. Service under this warranty is provided by MEDICAL DEVICES MAGYARORSZÁG KFT and/or its Authorized Distributors.

*Warranty Period of the ANALYZER: This warranty applies for a period of 36 months from the date when the end customer first purchased the ANALYZER ("Purchase Date"). If proof of purchase/receipt is not provided by an end-user, then the date of purchase will be considered the date of manufacture of the ANALYZER registered by MEDICAL DEVICES MAGYARORSZÁG KFT.

The Warranty does not cover bundled accessories, which were delivered together with the ANALYZER such as cables with microprocessors, case, USB and power supply cable etc. (depending on the model).

TERMS OF WARRANTY

1. General

MEDICAL DEVICES MAGYARORSZÁG KFT guarantees the ANALYZER 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 ANALYZER such as cables with microprocessors, case, USB and power supply cables etc. (depending on the model). If the ANALYZER fails during normal and proper use within the Warranty Period, MEDICAL DEVICES MAGYARORSZÁG KFT will repair or replace the defective parts of the ANALYZER, or the ANALYZER itself, with new or reconditioned parts or products that are functionally equivalent or superior to those originally supplied.

This Warranty applies only for the new ANALYZERs and not for those sold as used, refurbished or manufacturing seconds. Please keep the original purchase invoice and this warranty card for future service requests.

This Warranty does not include failure caused by improper installation, operation, cleaning or maintenance, accident, damage, misuse, abuse, non- MEDICAL DEVICES MAGYARORSZÁG KFT modifications to the ANALYZER, any changes in the software, normal wear and tear or any other event, act, default or omission outside MEDICAL DEVICES MAGYARORSZÁG KFT control.

2. Customer responsibility

When using the Product

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

When contacting MEDICAL DEVICES MAGYARORSZÁG KFT Customer Service

* Before contacting MEDICAL DEVICES MAGYARORSZÁG KFT or Authorized Distributor's technical support, ensure that you have the ANALYZER in front of You and that it is turned on and connected to the Internet, if feasible. Please also be ready to provide the ANALYZER's serial number, model name and proof of purchase.
* Technical support phone number or email can be found at www.mdevice.org
* You may be requested by MEDICAL DEVICES MAGYARORSZÁG KFT to perform some of the ANALYZER's troubleshooting tasks or actions, which may include the following:
* Installing updates.
* Performing other reasonable activities requested by MEDICAL DEVICES MAGYARORSZÁG KFT, 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 MEDICAL DEVICES MAGYARORSZÁG KFT Repair Center.
* Describe the problem clearly and completely in the Complaint form (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 ANALYZER. (Please note: MEDICAL DEVICES MAGYARORSZÁG KFT 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 ANALYZER as recorded by MEDICAL DEVICES MAGYARORSZÁG KFT 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 ANALYZER and removed any personal, confidential, or proprietary information before any service process is started. MEDICAL DEVICES MAGYARORSZÁG KFT 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 ANALYZER itself unless specifically requested by MEDICAL DEVICES MAGYARORSZÁG KFT. Please remove any accessories as well as any removable storage devices such as memory cards, discs, flash drives, from the ANALYZER. MEDICAL DEVICES MAGYARORSZÁG KFT shall have no liability for the loss, damage or destruction of accessories or removable storage devices.

3. Exclusions from the Warranty Service

MEDICAL DEVICES MAGYARORSZÁG KFT does not warrant the uninterrupted or error-free operation of this ANALYZER. 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 ANALYZER has been tampered or repaired and/or modified by non-authorized personnel;
* The serial number of the ANALYZER, components or accessories has been altered or removed;
* Obsolescence;
* Damage (accidental or otherwise) to the ANALYZER that does not impact the ANALYZER'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 ANALYZER 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 ANALYZER caused by improper installation, improper connection or malfunction of a peripheral device such as printer, optical drive or USB device, etc.;
* Damage to the ANALYZER caused by an external electrical fault or any accident;
* Damage to the ANALYZER resulting from use outside of the operation and storage environment detailed in the IFU;
* Damage to the ANALYZER 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 ANALYZER caused by contamination with hazardous substances, vermin, or radiation and so on;
* Fraud, theft, unexplained disappearance, or willful act;
* Damage made to the ANALYZER caused by using the materials other than those recommended by MEDICAL DEVICES MAGYARORSZÁG KFT 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 others defined by specifications of the product and considered consumables.

MEDICAL DEVICES MAGYARORSZÁG KFT 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, MEDICAL DEVICES MAGYARORSZÁG KFT is not responsible for direct, special, incidental or consequential damages resulting from any breach of warranty or condition, or under any other legal theory, including but not limited to loss of use; loss of revenue; loss of actual or anticipated profits (including loss of profits on contracts); loss of the use of money; loss of anticipated savings; loss of business; loss of opportunity; loss of goodwill; loss of reputation; loss, damage to or corruption of data; or any indirect or consequential loss or damage whatsoever caused including the replacement of equipment and property, any costs of recovering or reproducing any data stored on or used with the ANALYZER.

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 MEDICAL DEVICES MAGYARORSZÁG KFT.

4. Privacy

You agree and understand that it is necessary for MEDICAL DEVICES MAGYARORSZÁG KFT 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 MEDICAL DEVICES MAGYARORSZÁG KFT 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, MEDICAL DEVICES MAGYARORSZÁG KFT will use and protect Your personal data at any time and in any country subject to the MEDICAL DEVICES MAGYARORSZÁG KFT Privacy Policy.

5. Out-of-Warranty cases

Returning the Product to the MEDICAL DEVICES MAGYARORSZÁG KFT Repair Center during the warranty period does not automatically mean that it will be repaired free of charge. Upon receiving Your Product, MEDICAL DEVICES MAGYARORSZÁG KFT 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 labour, 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, MEDICAL DEVICES MAGYARORSZÁG KFT 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, MEDICAL DEVICES MAGYARORSZÁG KFT 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, MEDICAL DEVICES MAGYARORSZÁG KFT will send You an appropriate notice using the e-mail address and telephone You provided when requesting the service. If You still fail to pick up the Product within a period of 90 days from sending the notice, MEDICAL DEVICES MAGYARORSZÁG KFT reserves the right to claim damages from you, including the cost of storage, to dispose of 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	Filled up by service center
PRODUCT	AMP/ANESA		
MODEL NAME			*Reception date*
PURCHASING DATE			*Release date*
TRADE ORGANIZATION			*Special Marks*
	TRADE ORGANIZATION STAMP		*SERVICE CENTER STAMP*

TEAR-OFF COUPON NO.2	[SERIAL NUMBER OF DEVICE]	No.2	Filled up by service center
PRODUCT	AMP/ANESA		
MODEL NAME			*Reception date*
PURCHASING DATE			*Release date*
TRADE ORGANIZATION			*Special Marks*
	TRADE ORGANIZATION STAMP		*SERVICE CENTER STAMP*

Responsible organizations for warranty and post-warranty service:

Manufacturer:
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79, Hungary
Tel.:+36209719323

24. MANUFACTURER AND THE AUTHORIZED SERVICE CENTRES

Manufacturer:
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79, Hungary
Tel.:+36209719323

25. 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 is carried out with a password. The software and the database don't run without the password, so only the authorized user, who keeps the password 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 a patient*_____

26. 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.

27. NOTICE TO THE USER AND/OR A PATIENT

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

28. DOCUMENT HISTORY AND VERSION CONTROL

Version	Version Date	Summary of changes	Author	Related documents
1.0	2025-01-17	Create document	Pulavskyi A	