

**Instruction for the use
of software USPIH ver. 9.7x and higher for
OS WINDOWS and OS ANDROID
(IFU)**



Read this IFU carefully before use of the MD ANALYZER.



Manufacturer:

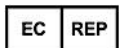
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Instructions, diagrams, descriptions or other information to assist service personnel are available on request from the manufacturer.

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

The definitions “**USPIH ver. 9.7**” or “**USPIH 9.7x**” which are used below, **concern all the versions of software USPIH with index 9, starting from 9.0 and higher.**

According MDCG 2023-4 Medical Device Software (MDSW)

Definition of hardware and hardware components.			
Name of the Medical Device		ANESA (AMP, DAD-ANI)	
Name of the Software		USPIH	
A. External hardware component providing input data to an MDSW app.		B. Hardware component incorporated within a smartphone or wearable connected to an MDSW app on a smartphone or wearable.	
Manufacturer of hardware component and MDSW app are the same entity.	Manufacturer of hardware component and MDSW app are different entities.	Manufacturer of hardware component incorporated within a wearable and MDSW app are the same entity.	Manufacturer of wearable and MDSW app are different entities.
C. The hardware or hardware component is placed on the market as an accessory to a MDSW.		D. The hardware or hardware component is placed on the market as a medical device either:	
		as part of a system according to article 22 MDR	
		as a combination with another medical device according to article 2(1),	
		as an integral part of a medical device	
E. The hardware or hardware component is an integral part of a general consumer product or wearable digital product and is not a medical device or an accessory to a medical device and has no intended medical purpose.			

IEC 62304:2006/AMD 1:2015 (IEC 62304:20015 ed.1.1) Medical device software -Software life cycle processes -Amendment 1 (next IEC 62304)
Software USPIH class A.

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1. SOFTWARE USPIH 9.7X AND ANDROID FEATURES

Both types of software, USPIH 9.7x 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 9.7x and ANDROID work only via the Internet.

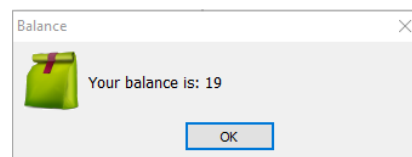
The user of software USPIH 9.7x and ANDROID should register an account on the cloud server. This account will be connected with the MD ANALYZER (the serial number of a specific device is registered for the user).

The routine workflow looks like this:

- ✓ A user/doctor installs software USPIH 9.7x or ANDROID and makes necessary settings (Chapters 4 for USPIH 9.7x, and Chapter 8 for ANDROID).
- ✓ When a patient comes for an examination, a doctor fills in his/her initial data: name, surname, gender, age, height, and weight.
- ✓ The microprocessors are fixed on a patient's body, and the measurement is carried out ([Video](#) for USPIH 9.7x and Chapter 8 for ANDROID), considering the proper positioning of the patient ([Video](#)).
- ✓ The measurement results are sent to the cloud server for processing ([Chapter 5](#) for USPIH 9.7x, and [Chapter 8](#) 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 6](#) and [8.4, 8.5](#) for ANDROID).

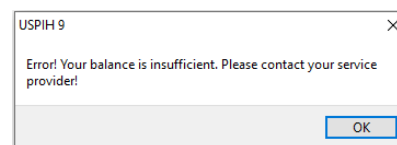
Important:

Considering that the measurements performed on the MD ANALYZER with USPIH 9.7x 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 9.7x or ANDROID options by clicking on the icon "check balance" (Chapter 4.3.1.8).

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.



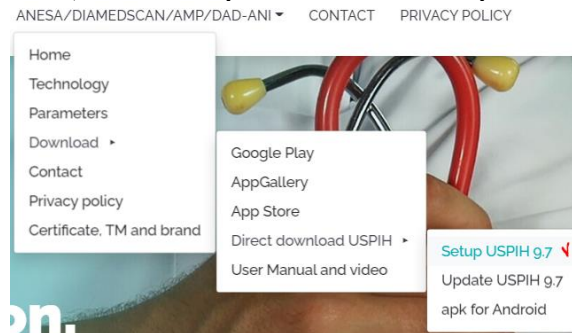
The authorised distributor in the country/region is responsible for managing the accounts of users from the territory using the Administrator software on the server. In the case of direct sales from the manufacturer, the managing of such users' accounts is made by the manufacturer.

2. SOFTWARE INSTALLATION/UPDATE. USPIH VER.9.7X

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

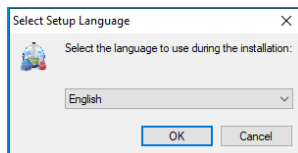
To install/update/set up the software for USPIH 9.7x, please follow the instructions below:

2.1 DON'T CONNECT THE DEVICE. Download a setup file for the MD ANALYZER to your computer using the WEB: <https://kolibri.cloud/>. Choose "Setup USPIH 9.7x" and the appropriate file will be downloaded to your computer. (in the example below, it is Setup USPIH 9.7x or Update USPIH 9.7x)

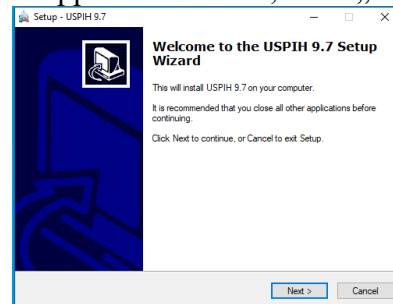


2.2 Run the downloaded file (in the example above, it is *setup_USPIH_9.7-CLOUDE.exe*) to install the software following the instructions below.

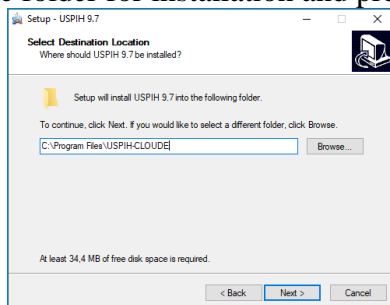
Select the language and click "OK":



In the appeared window, click „Next”:

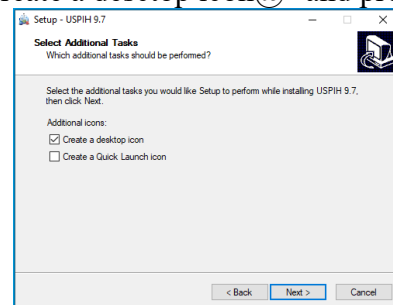


Select the folder for installation and press NEXT

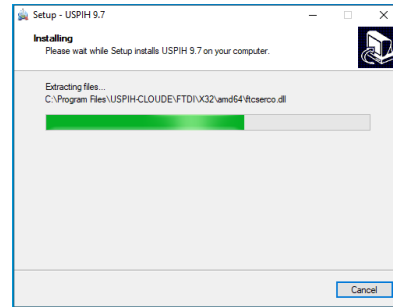
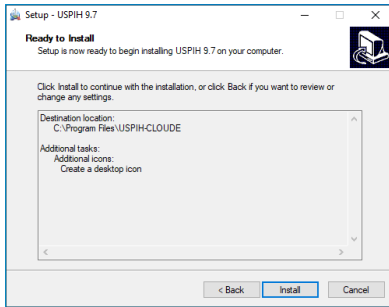


Press "Install"

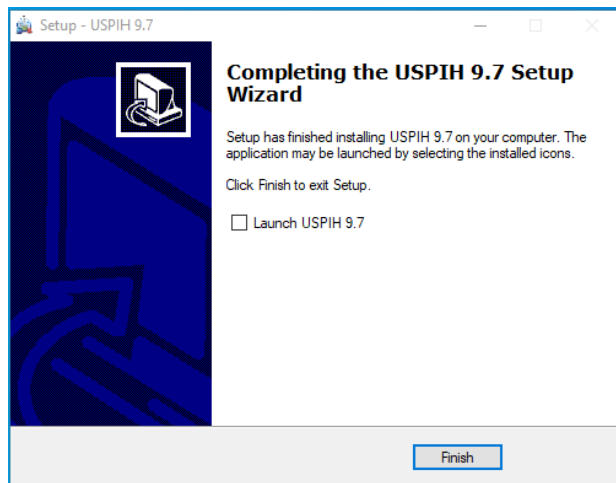
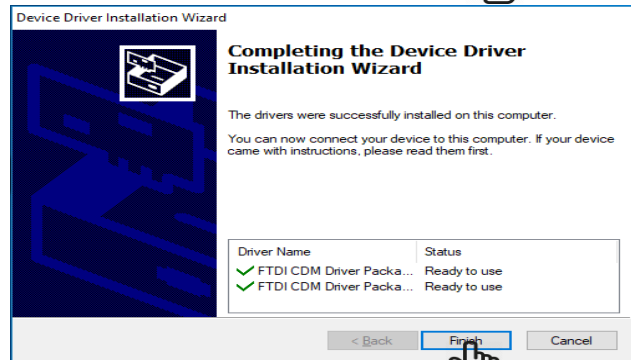
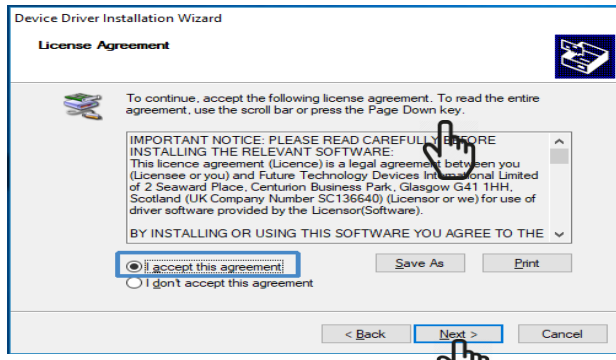
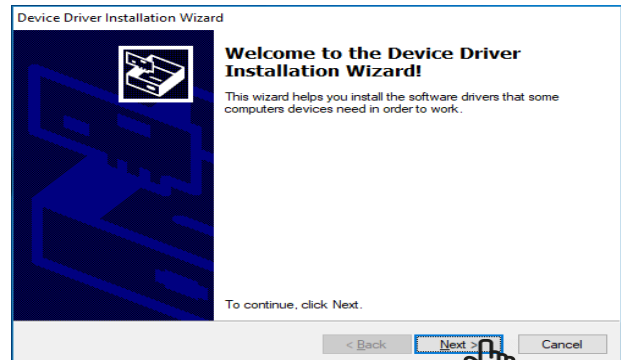
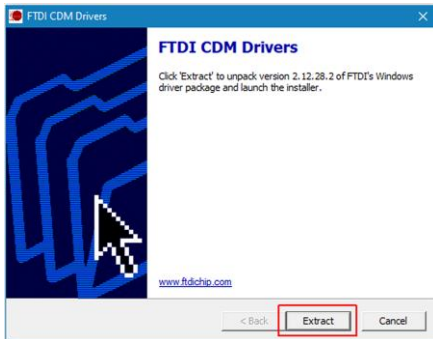
Tick "Create a desktop icon@" and press NEXT



Wait while installation is completed



2.3. 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 9.7x"** (because the process of driver's installation is not completed yet). Press "Finish".

CONNECT THE DEVICE MD ANALYZER to your computer. The installation of drivers will be finalized.

Launch USPIH using the appropriate icon on your desktop.



3. START WORKING WITH USPIH VER.9.7X.CONNECTION OF THE DEVICE

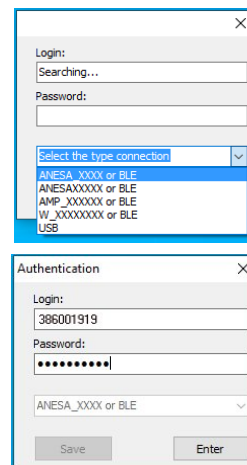
CONNECTION OF THE DEVICE ANESA (AMP, DAD-ANI) TO A COMPUTER VIA BLUETOOTH BLE

Switch on the unit of MD ANALYZER (ANESA, AMP, DAD-ANI).

Run SOFTWARE USPIH 9.7x on your computer using the appropriate icon



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

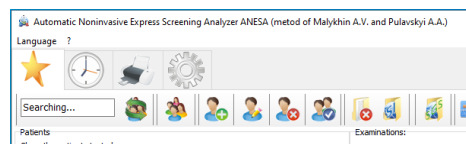


The login is the serial number of your device. It will be loaded and display automatically.

Enter the password.

Press "Enter"

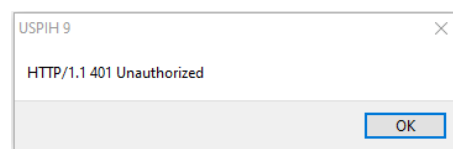
After the authorization on the server, the software's main window will be displayed



The following error message can appear in case of

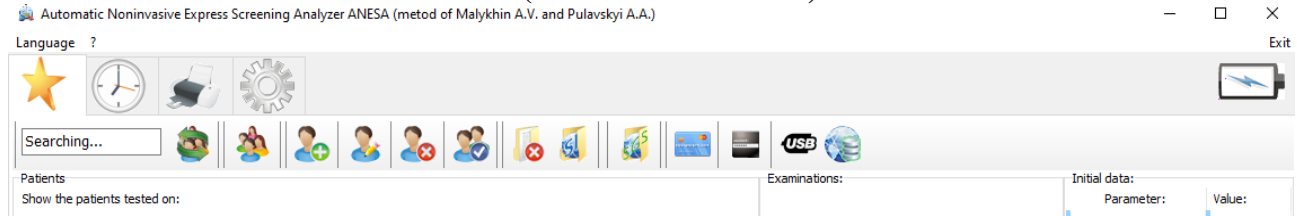
- no Internet connection or if the password is
- wrong password
- device MD ANALYZER is not registered in the cloud system

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

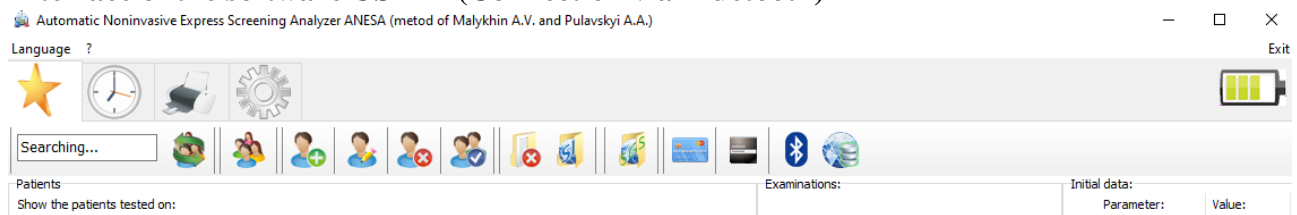


4. SOFTWARE USPIH VERSION 9.7x INTERFACE

Interface of the software USPIH 9.7x (Connection via USB)

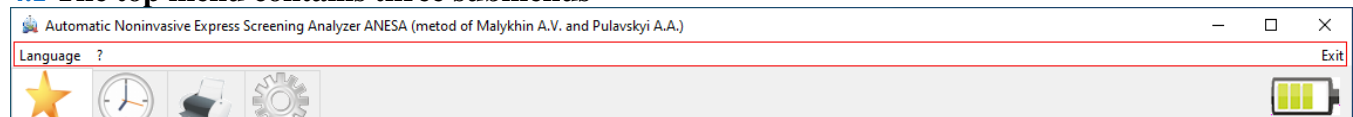


Interface of the software USPIH (Connection via Bluetooth)



Description of the interface icons/options, used in the software USPIH ver. 9.7x:

4.1 The top menu contains three submenus



"Language"

To choose/change a language of the interface

"?"

To open help file and information about program

"Exit"

to exit the program

At first time, USPIH 9.7x runs in English. To change the language, use an appropriate menu "Language". The interface is available on 20 languages: Ukrainian, Russian, English, Chinese, Spanish, Hungarian, Slovak, Greek, Slovenian, Italian, French, Turkish, Croatian, Polish, Bulgarian, Japanese, Czech, Serbian, German and Vietnamese.

4.2 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



(4.2.1) The main window shows the content of the database “Patients”. After clicking on any patient from the database, two submenus become available one by one: “Examinations” and “Initial data”

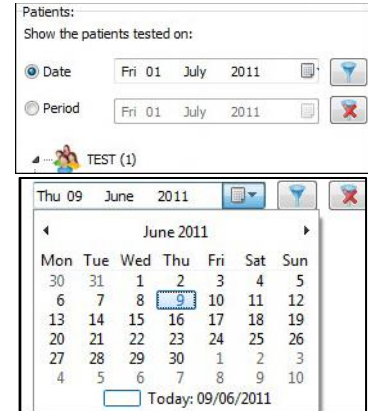
The part “Patients” has the following options:

- ❖ Filter for searching the patients by 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

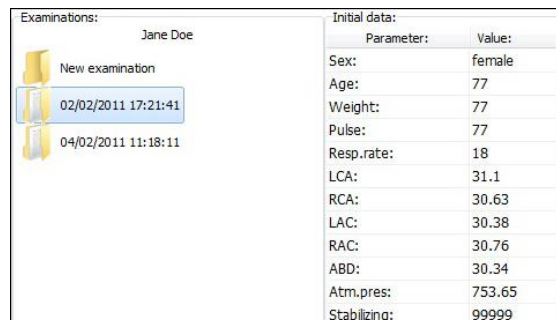


- ❖ List of patients in the database (in groups and out of any group)

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 for this person immediately.

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*



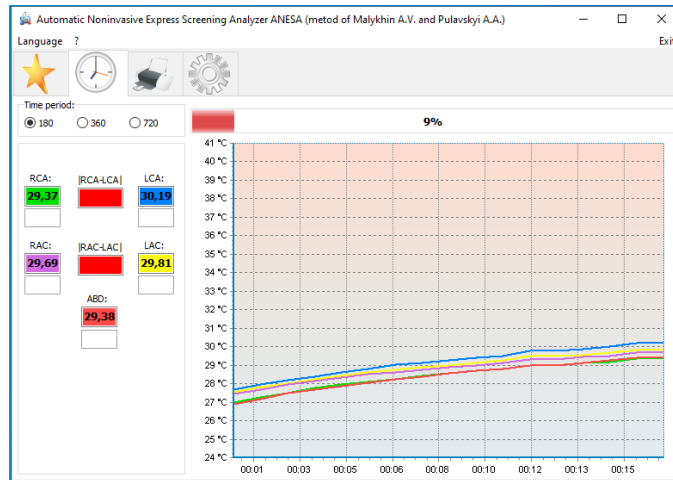
* “99999” means the temperatures during measurement fully stabilized (100%).

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

The options of this menu are described in details below, Chapter 4.3.1.



(4.2.2) 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 is in Chapter 4.3.2



(4.2.3) 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 4.3.3.



(4.2.4) 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 4.3.4.



(4.2.5) Battery status. This icon appearance depends on the connection mode chosen by a user.

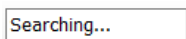
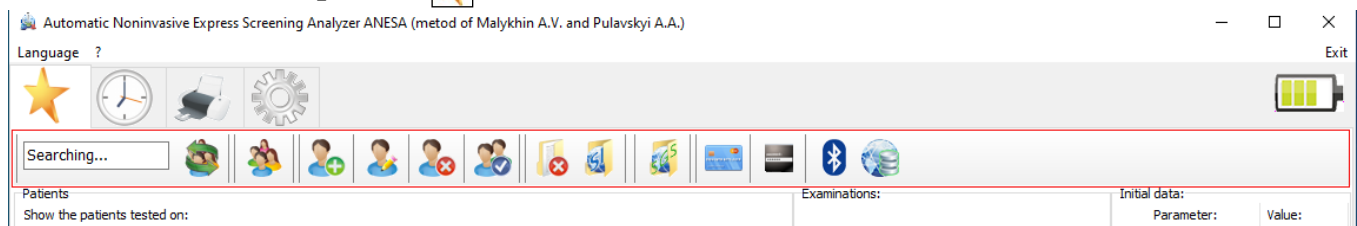
The icon will show the battery's charge level if the device is connected via Bluetooth. If the device is connected via USB, the icon will show that the battery charging process is going.



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

4.3 The third-level menu includes a number of the options available for each of the item from the second level (Chapter 4.2). They are described below.

(4.3.1) Main Window options



(4.3.1.1) 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



OR



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



Synchronization of the database

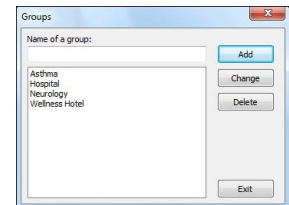


(4.3.1.2) Reset search parameters – use this icon if you need to return to a full database after filtering the patients/groups for searching. After pressing on this icon, the complete list will be available again.



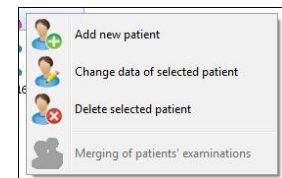
(4.3.1.3) Groups of patients

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 >



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

Adding, editing and deleting of patient's 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



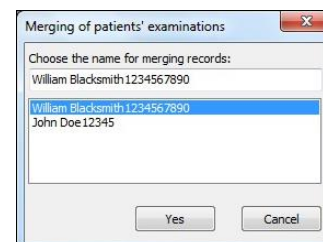
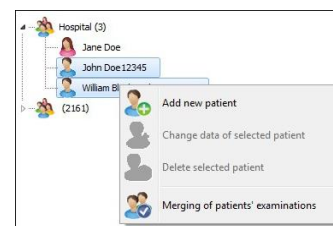
In case the password protection was set up, enter the valid password in the appeared window (the default password is "0000" (four zeros)).



(4.3.1.5) 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!



(4.3.1.6) Deleting of patients' survey(s) from the patient's card and database

It can be done in the following way:

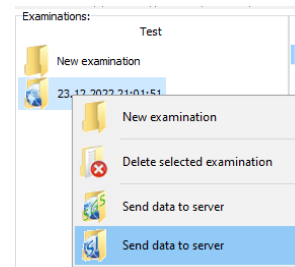
- Select an examination, which should be deleted and click this icon in the main menu or in the context menu (right click by mouse on the selected patient). The same icon is used in both types of menu.
- In case of password protection was set up, enter the valid password in the appeared window (the default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



(4.3.1.7) Request for a report in SI or SGS units

Use these icons to choose the units which are preferable for the analysis 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.



(4.3.1.8) 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 cannot be processed due to insufficient balance (Chapter 7).



(4.3.1.9) Change password of authentication

During the first 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.



(4.3.1.10) Indicators of connection mode

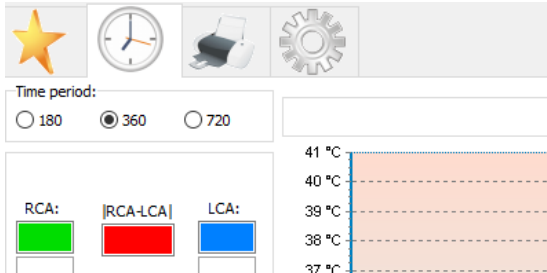
Each of these two icons is highlighted depending on the mode of connection you use. If the device is connected via Bluetooth, then the first icon will be highlighted. The second icon will be highlighted when USB connection is used.



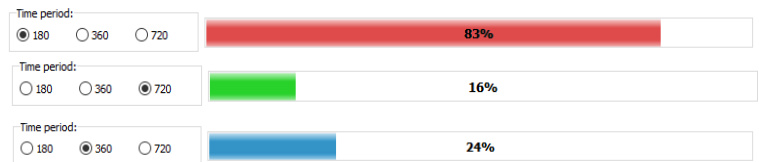


(4.3.1.11) Synchronization. If you have previously used software USPIH 9.7x on another computer, you can synchronize your new computer with the existing database on the cloud server. After installing software USPIH 9.7x on a new computer **and the first authorization**, use this icon for synchronization.

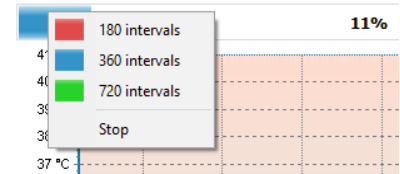
(4.3.2) Options in “Graphs of temperature”



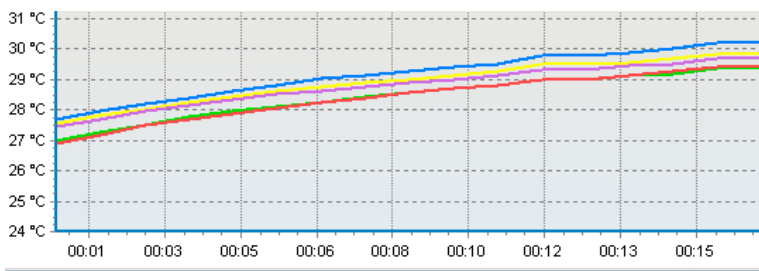
(4.3.2.1) Time period. A user can choose any of available time periods for testing. It can be changed even during the measurement. Progress bar at right shows the process in color and in %. The color of progress bar changes according to the chosen period.



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.

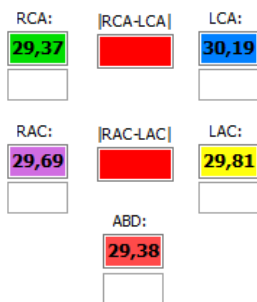


(4.3.2.2) Temperature graphs. It allows monitoring of temperature changes at each point on a body (where sensors were placed) in real-time. The colors of curves are the same as color of cables which are placed on a body of the patient. So, a doctor can re-fix those sensors, which loose contact with skin (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 (4.3.2.1).

(4.3.2.3) 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 colour rectangle which repeat the color of cables placed on a body of the patient.



Three additional rectangles (RCA-LCA, RAC-LAC and one below ABD) show the temperature stabilization 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 (4.3.2.1)). All of them must be green when the measurement is going to end.

(4.3.3) Options in “Print or save the report of testing”



No.:	Parameter:	Norm:	<	>	
1	2	Erythrocytes RBC. x10 ¹² /l	3,4 - 5	4,01	✓
2	1	Hemoglobin HGB. g/l	120 - 160	121,95	✓
3	88	Hematocrit.HCT %	35 - 49	36,22	✓

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.



(4.3.3.1) 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.

Print a preliminary computer conclusion

<p>Asthenic-autonomic syndrome is determined. Post hypoxic encephalopathy is defined. Delirium syndrome with convulsive component is determined. Pulm Ischemic heart-disease is determined. Concentration of glucose in blood should be tested carefully.</p>	<p>Asthenic-autonomic syndrome is determined. Post hypoxic encephalopathy is defined. Delirium syndrome with convulsive component is determined. Pulm Ischemic heart-disease is determined. Concentration of glucose in blood should be tested carefully. Spinal osteochondrosis is defined. Disorders of water-electrolytic metabolism is determined. Ca of plasma is An autonomic-vascular dystonia is defined, mainly by hypotonic type. Asthenic-autonomic syndrome is det Width of the third ventricle of cerebrum. =7.57 Derangement of oxidative phosphorylation is determined. Activation of lipid exchange is determined. Redu Tiffeneau index has reduced till: 85.9 (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.↓↓ CO₂ elimination.↑↑</p>
--	--



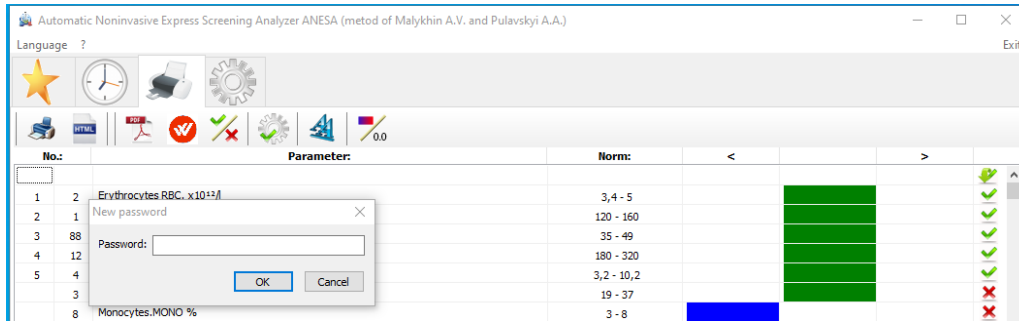
(4.3.3.2) Save the report in HTML format

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 4.3.3.1)



(4.3.3.3) 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 system will ask you to set a password. So, the saved file will be protected from unauthorized 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 4.3.3.1)



(4.3.3.4) AI system

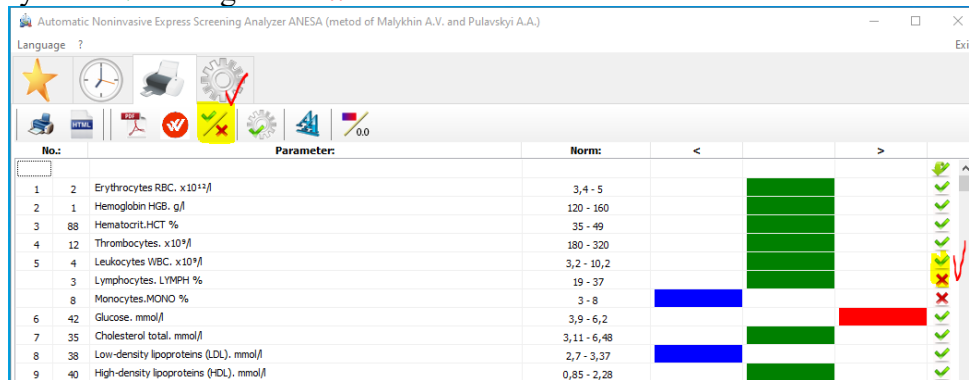
When generating a report, you can use these buttons enabling or disabling the built-in system for monitoring the accuracy of calculated parameters (AI). Thus, when the system is enabled (blue colour icon), the report will include only the parameters with the maximum accuracy available for the algorithm.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



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



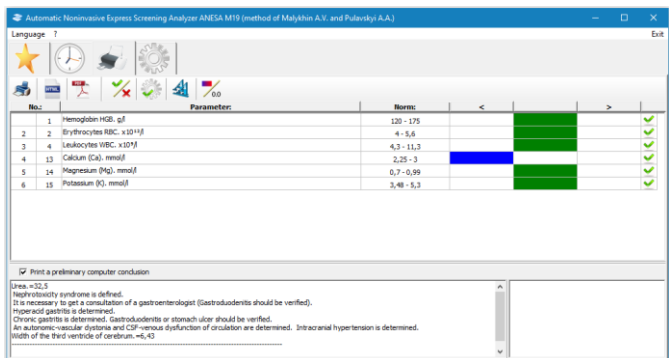
By default, all the parameters are marked with “v”. If it is necessary to exclude any parameter(s) or group(s) of parameters from the printed version of the report, please use “x” for them (a click on the symbol “v” change it to “x” and vice versa).



(4.3.3.6) Selected parameters

If the list of selected parameters was formed in settings (Chapter 4.3.4.4), 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.



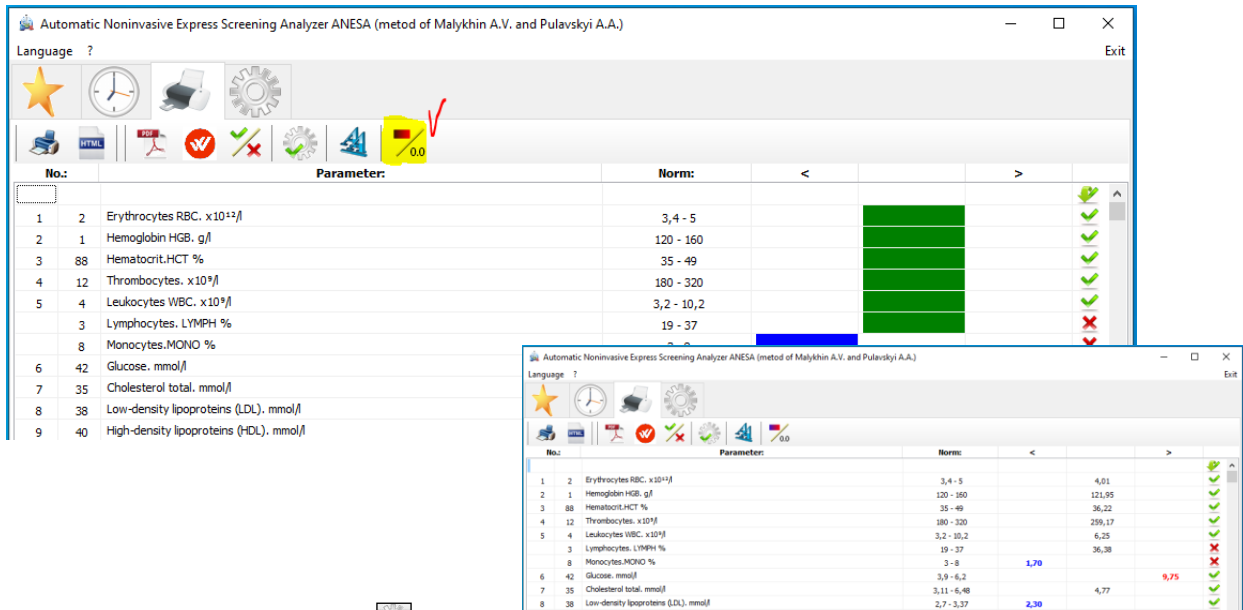
(4.3.3.7) Font

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

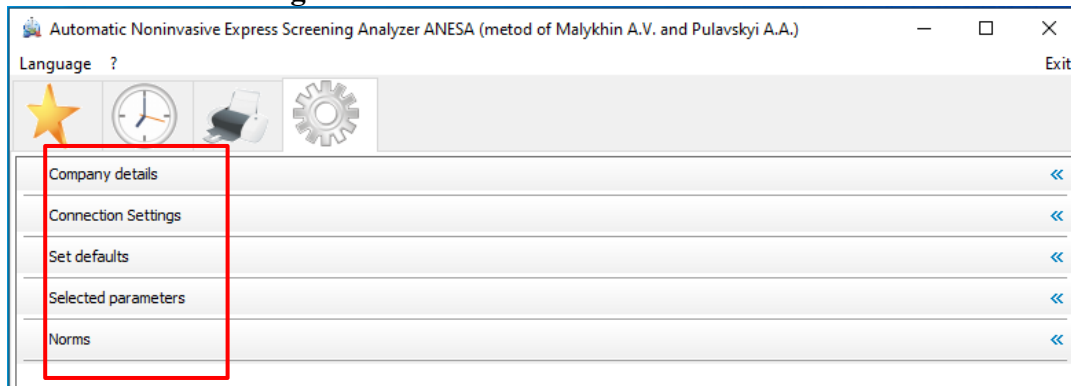


(4.3.3.8) Parameters in color or values

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



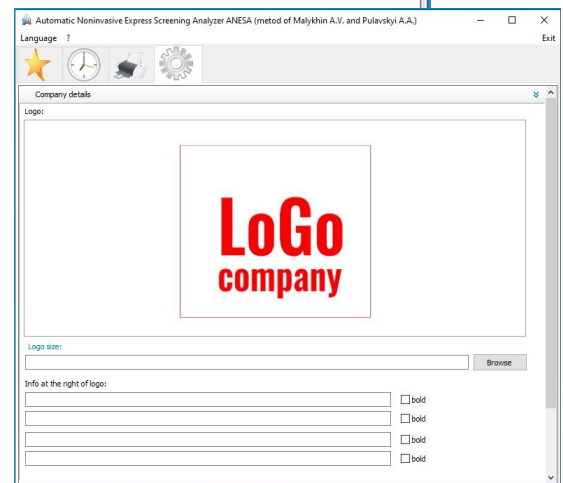
(4.3.4) Options in “Main Settings”



(4.3.4.1) 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).

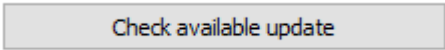
Company Logo can be uploaded too. The image must be in *.bmp format and its size cannot be smaller than 40x40 pixels (click "Browse" and select a picture)



(4.3.4.2) Connection settings

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

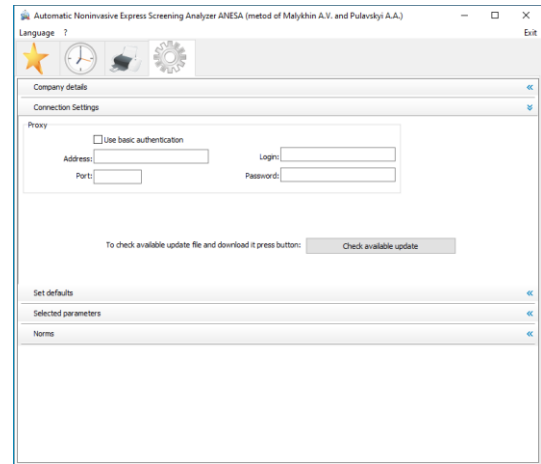
To update the software, use the following icon



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_9.7x-CLOUDE.exe”** there. Run it to update software USPIH following the instructions in [Chapter 2](#) (the updating process is similar to the software installation).

Update your software USPIH regularly.



(4.3.4.3) 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.



(4.3.4.4) Selected parameters

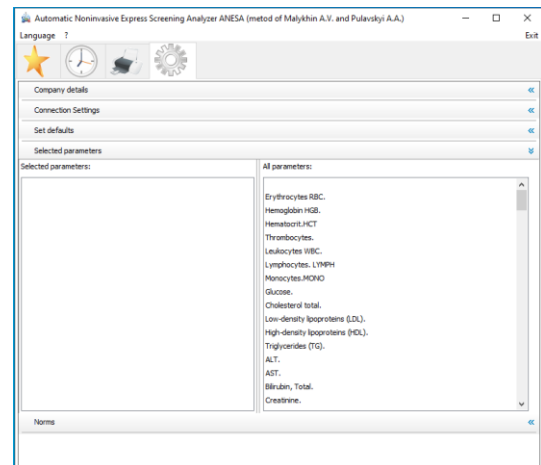
Sometimes, medical professionals prefer to use a shorter list of parameters for quick preview after measurement. So, it is possible to prepare such a list using this menu.

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 4.3.3.6](#)



(4.3.4.5) 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.

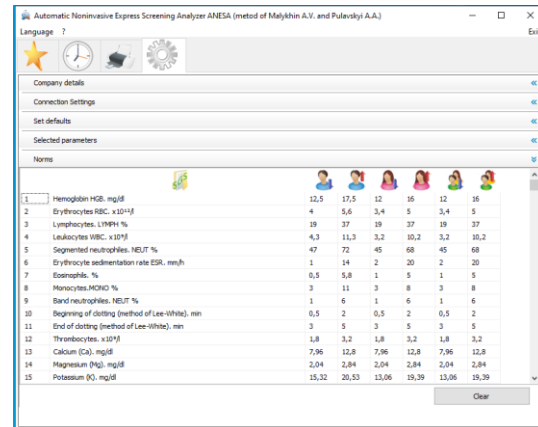
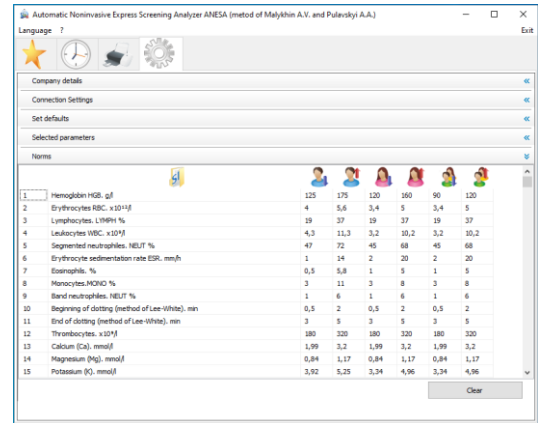


It is necessary to click on the icon SI or SGS (above the list of parameters) depending on which of them you are going to use (name of the icon is changed after clicking, from SI to SGS and versa).

Then the normal ranges can be changed for any parameter. Do not leave empty fields 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.



5. DESCRIPTION OF THE MEASUREMENT PROCEDURE

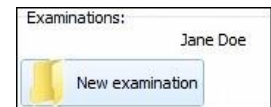


It is required to make an examination, in the supine position, when a patient is calm, had no physical activity during 5-10min, ([See video](#)).

Any measuring procedure is started from adding a new patient (Chapter 4.3.1.4) 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 (for 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 We recommend setting a value between 16 and 22. For	5-50

		normal breathing, set the value to 18.	
Select skin colour		For Negroid race, select the "Dark Skin" menu. For all others, select the "Light Skin" menu.	

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

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

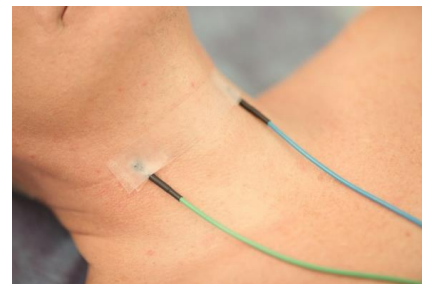
Clicking on the stopwatch will start time count 00:00. Other clicks on the stopwatch will stop time count and reset it.

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)



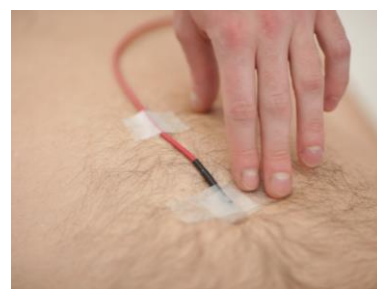
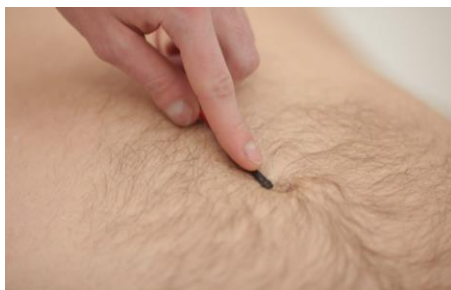
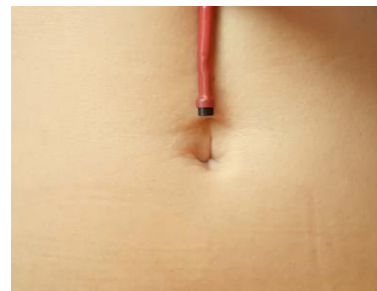
Purple - on the **right** in axillary area (RAC)



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 colour 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).

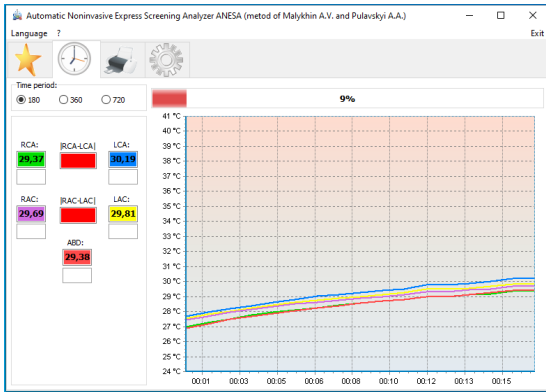
Abdominal sensor

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

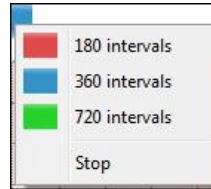


Abdominal temperature (umbilical) is measured in the area, where aorta, inferior vena cava and large lymph vessel are crossed. Pulsation is felt manually in the cross-point of vessels. Sensors should be fixed by plaster.

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 (colour of each graph corresponds to colour microprocessors on a body):



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

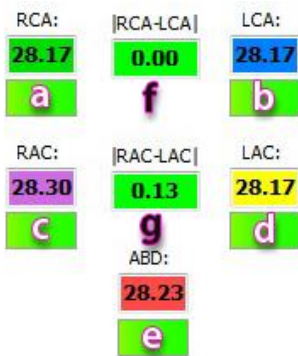


or in drop-down menu, which appears after right-click on the progress bar. The measurement can be stopped using this menu, too



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

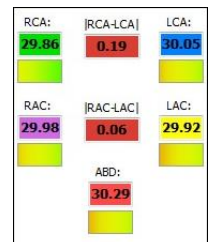
The indicators are the following:



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

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

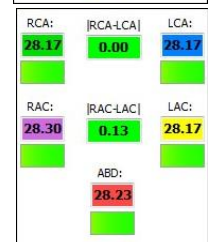
The coloured rectangles, containing the values of temperature, have the same colour as the corresponding sensors. The colour of indicators a, b, c, d, e varies from **red** (the temperature is not stable) to **green** (stabilized temperature) during the process of stabilization. Each indicator shows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



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

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

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



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

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

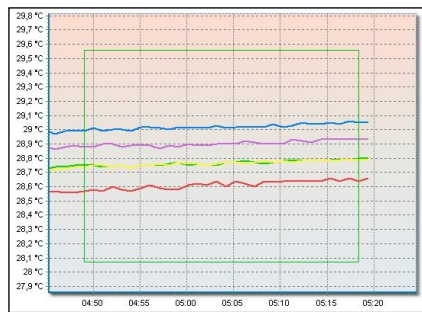
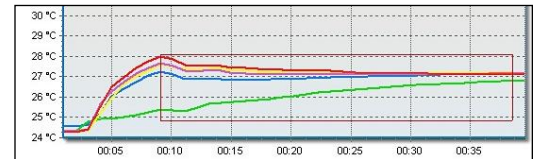
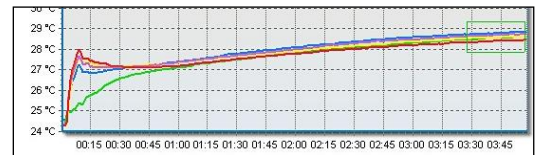


IMPORTANT! If the rectangles below temperature values are not green till the end of measurement, a qualified medical professional should change time interval to the larger one.

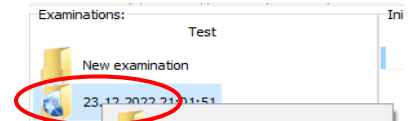
Colour "floating window" will appear over temperature graphs in 40 sec. after starting measurement. The window will have a red border, if stabilization of temperatures is not achieved. When temperature values stabilize, the "floating window" becomes green. This is another **important control issue during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

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

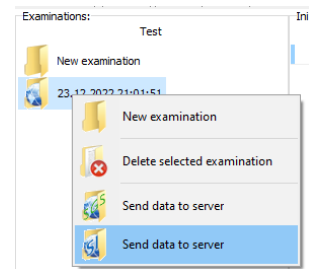
To return the graph to its original position, please hold the left mouse button and drag it across the field chart from right to left



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).



No.	Parameter	Norms	<	>	
CLINICALLY VALIDATED PARAMETERS					
1	Hemoglobin HGB, g/l	125 - 175			
2	Erythrocytes RBC, x10 ¹² /l	4 - 5,6			
3	Leucocytes WBC, x10 ⁹ /l	4,2 - 11,2			
4	Segmented neutrophils, NEUT %	47 - 72			
5	Band neutrophils, NEUT %	1 - 6			
6	Lymphocytes, LYMH %	19 - 37			
7	Monocytes, MONO %	3 - 11			
8	Eosinophils, %	0,5 - 5,8			
9	Erythrocyte sedimentation rate ESR, mm/h	1 - 18			
10	Hematocrit, HCT %	35 - 49			
11	Thrombocytes, x10 ⁹ /l	180 - 320			
12	Glucose, mmol/l	3,9 - 6,2			
13	Calcium (Ca), mmol/l	1,99 - 3,2			
14	Magnesium (Mg), mmol/l	0,81 - 1,17			
15	Potassium (K), mmol/l	3,92 - 5,25			
16	Sodium (Na), mmol/l	136 - 145			
17	Creatinine, umol/l	55 - 123			
18	Urea, mmol/l	2,1 - 8,2			
19	Cholesterol total, mmol/l	3,11 - 6,48			
20	Triglycerides (TG), mmol/l	0,55 - 1,85			
21	Low-density lipoproteins (LDL), mmol/l	2,7 - 3,37			

The window with „**Results of measurements**” opens automatically, when the report returns to the computer. To prepare the surveys for printing out or saving, please follow the instructions in Chapter 4.3.3.

6. 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↓
 (CO₂) in arterial blood.↑
 (CO₂) 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
 O₂ consumption (VO₂).↓↓
 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 should not 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 circumstances, 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 unauthorized 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 authorized staff of the manufacturer, whose duties includes elimination of bugs in the software USPIH, software updates or other assistance related to the software USPIH on the request of the personal data processor; c) to government, 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 analyzing of such a data.

Signature of patient: _____

No.:	Parameter:	Norm:	<	>
1 2	Erythrocytes RBC. x10 ¹² /l	3,5 - 5		*
2 1	Hemoglobin HGB. g/l	110 - 150		*
3 88	Hematocrit.HCT %	40 - 50		*
4 12	Thrombocytes. x10 ⁹ /l	100 - 300		*
5 4	Leukocytes WBC. x10 ⁹ /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		*

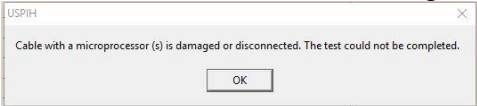
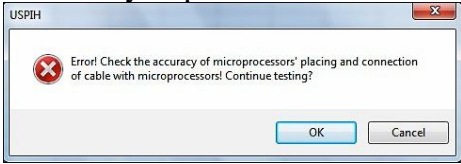
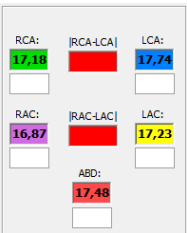
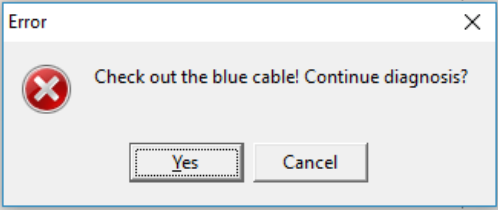




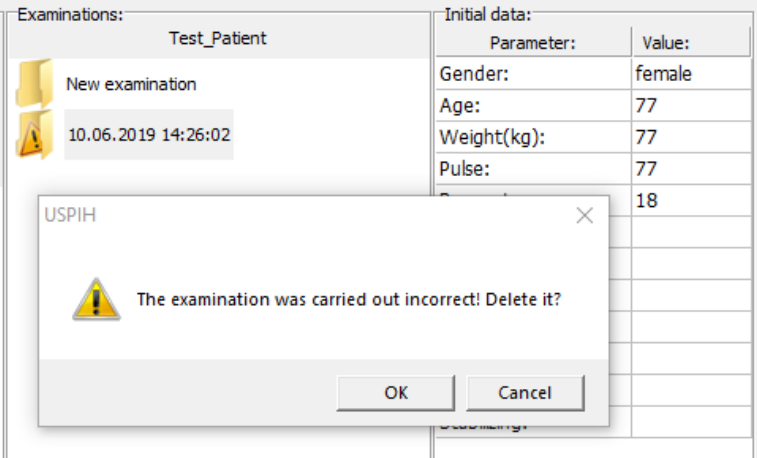

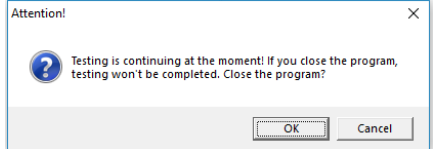
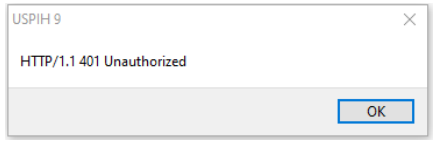
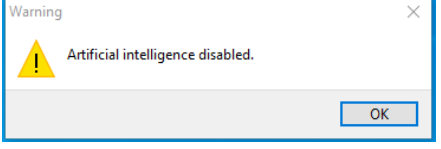
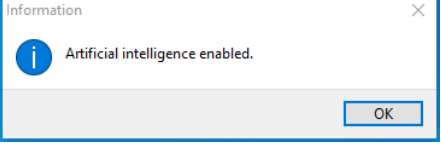
No.:	Parameter:	Norm:	<	>
1	2 Erythrocytes RBC. x10 ¹² /l	3,5 - 5		5,10
2	1 Hemoglobin HGB. g/l	110 - 150		152,72
3	88 Hematocrit.HCT %	40 - 50		44,25
4	12 Thrombocytes. x10 ⁹ /l	100 - 300		259,35
5	4 Leukocytes WBC. x10 ⁹ /l	4 - 10	3,35	
6	3 Lymphocytes. LYMPH %	17 - 40		36,57
7	8 Monocytes.MONO %	3 - 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.



7. TROUBLESHOOTING FOR USPIH 9.7X

No	Error/ problem	Indication and Reason(s)	Solution/advice
1.	Measurement couldn't start or it is interrupted in a process	<p style="text-align: center;">One or several sensors are damaged</p> 	Replace the cable with a good one.
		<p style="text-align: center;">Sensors are not placed on a patient's body or placed incorrect</p>  	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	<p>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</p> 	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 or reconnect USB cable or replace it, if it is damaged; 2) check BLUETOOTH pairing, reconnect if necessary.
		Drivers for the device were installed incorrectly	Check the drivers and reinstall them (IFU Chapter 2)
4.	A survey is unavailable	If a survey in the database is damaged or the measurement has been interrupted, such surveys will be marked with a special character and such surveys will be unavailable for opening.	 New examination  10.06.2019 14:26:02

		 <p>Software USPIH 9.7x 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.</p>	
5.	Examination is impossible		<p>Connect the unit of MD Analyzer to the computer.</p> <p>If the unit is already connected to the computer via USB cable, replace the cable.</p> <p>If the unit is already connected to the computer via BLUETOOTH, check the BLUETOOTH settings.</p>
6.	Attention!		<p>This message is displayed when you try to close the application in a process of measurement of a patient.</p>
7.	Attention!		<p>Such error can display in case</p> <ul style="list-style-type: none"> - no Internet connection, - the entered password is not correct - the device is not registered in the cloud system <p>After pressing the button "OK", the program will close the main window.</p> <p>We recommend to make authorization again</p>
8.	Warning.		<p>If artificial intelligence is disabled, the program will warn you about it.</p>
9.	Information.		<p>If artificial intelligence is enabled, the program will warn you about it.</p>

8. 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).

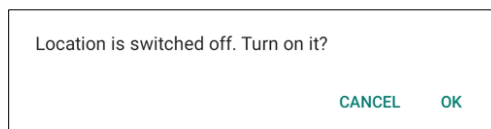
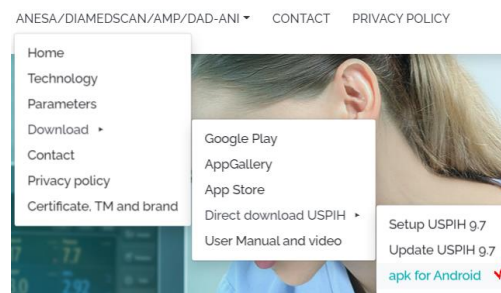
To install such a software for ANESA, please follow the instructions below:

Download a setup file for the MD ANALYZER with Android and run it.

The setup file is available on the official website <https://kolibri.cloud/> (APK for ANDROID)

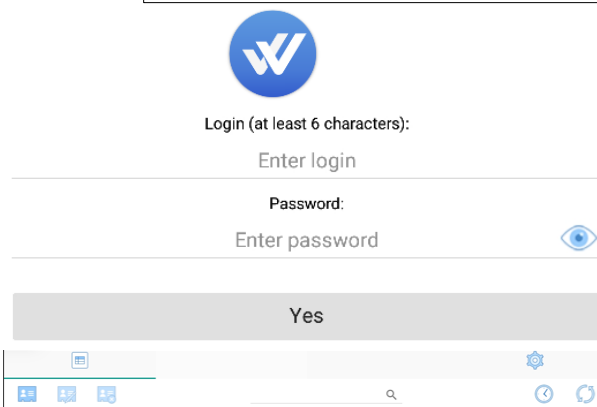
Switch on Bluetooth and Location on your Tablet with OS ANDROID. Download the APK and install it.

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



Delete patient's card



Show patient history.
Select by the date of examination



Refresh screen content



Settings



Main menu (Return to main screen)



Searching



Medical device connection indicator via
BLUETOOTH



Medical device connection indicator via
USB

Press button “Settings menu”:



Select the type of BLUETOOTH connection (Classic or BLE) 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 password.

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.

Select device type :

BLUETOOTH Classic **BLUETOOTH LE** USB


Serial number of the device:


Number of tests: 5


Language


English


Company details

Current password 

New password 

Repeat New Password 





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).

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

PREPARE YOUR MOBILE GADGET.


Select SETTINGS.




Select menu "Connection"

Switch-ON medical device.

Switch-ON BLUETOOTH

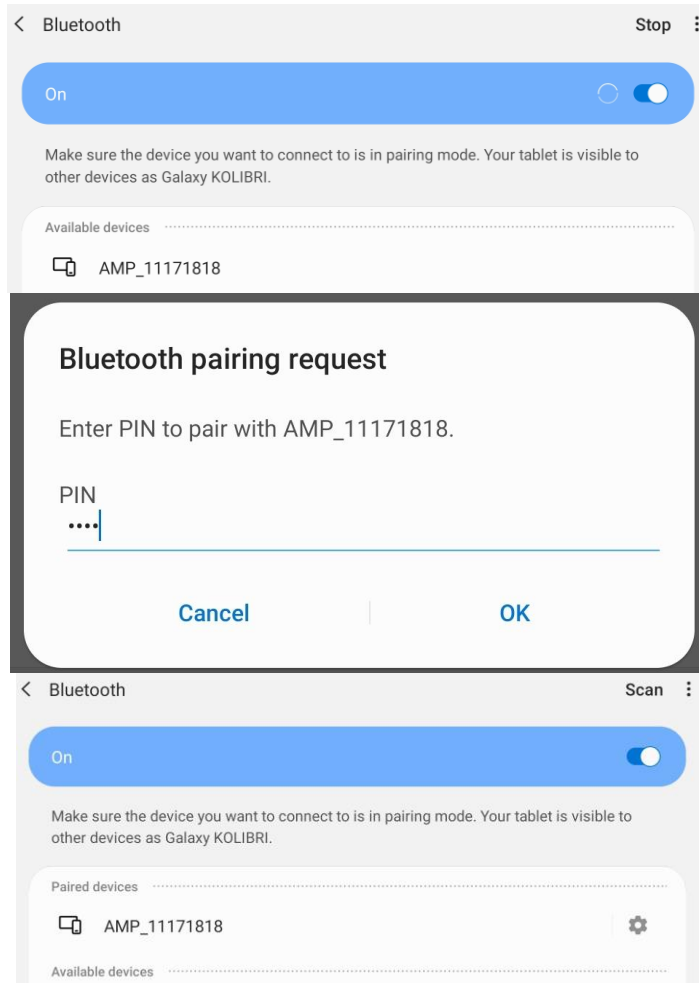
 **Connections**
Wi-Fi, Bluetooth, Flight mode, Data usage

Bluetooth
On 

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 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.



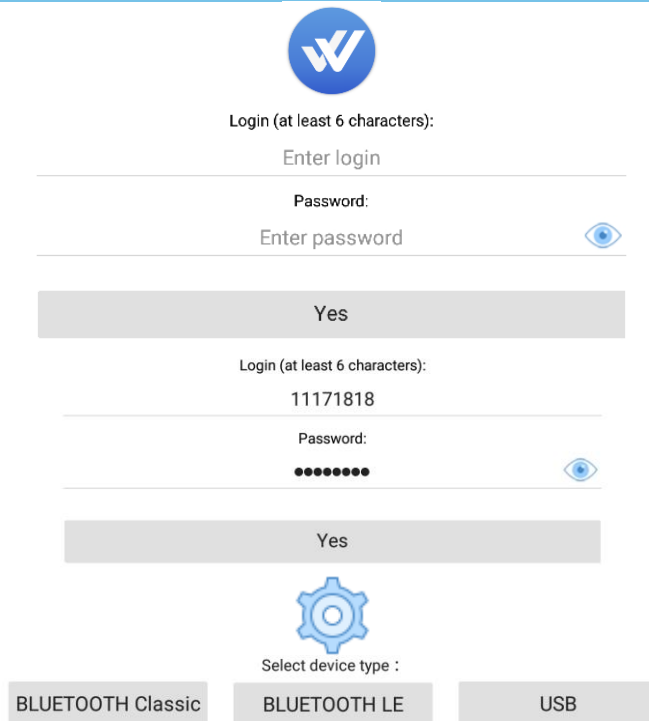
PREPARE SOFTWARE.

Next step: run APK

Enter login and password. Press button “Yes”.

Select menu “Settings”.

Select menu “BLUETOOTH Classic”



Select the medical device.



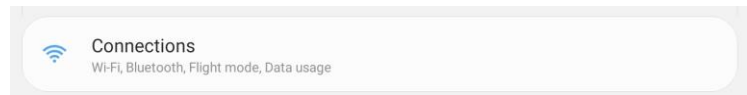
8.2 CONNECTING A MEDICAL DEVICE OPERATING ON BLUETOOTH VERSION 5.0 OR HIGHT.

PREPARE YOUR MOBILE GADGET.

Select SETTINGS.

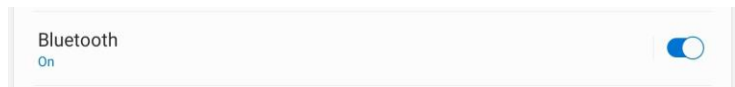


Select menu "Connection"

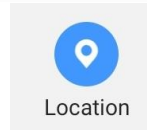


Switch-ON medical device.

Switch-ON BLUETOOTH



Switch-ON Location

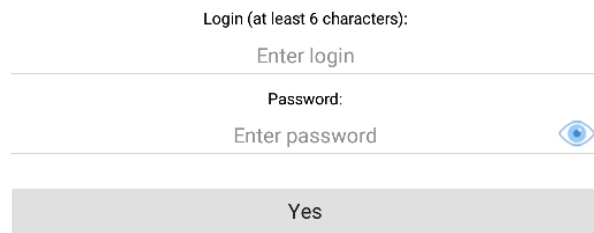


PREPARE SOFTWARE.

Next step: run APK



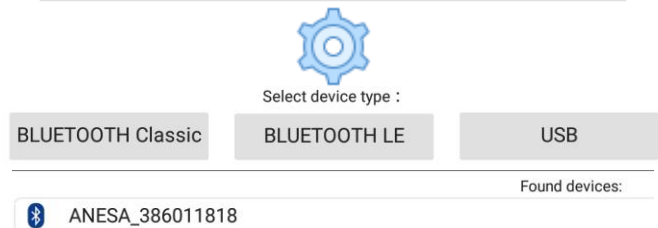
Enter login and password. Press button "Yes".



Select menu "Settings".

Select menu "BLUETOOTH LE"

Select the medical device.
Example: ANESA 386011818



8.3 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"

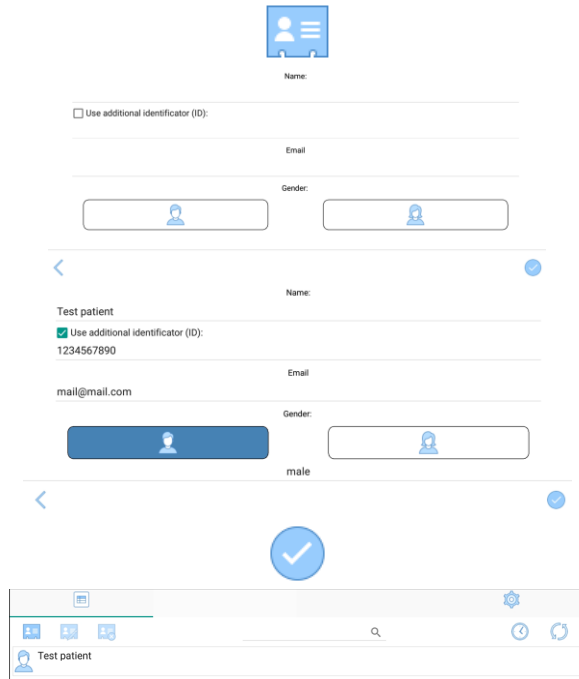


or button "Return"



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

The patient record has been created.



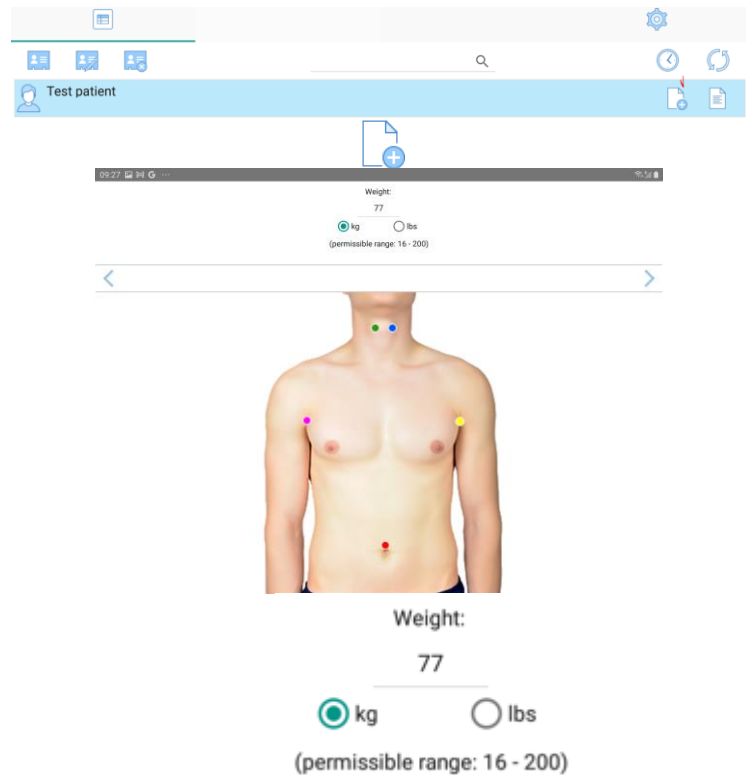
8.4 PATIENT TESTING

Select the patient

Press button "Create test card"

Enter weight

Select kg or lbs.
Press button "Next"



Enter heart rate (pulse)
Press button “Next”



Pulse:
77
(permissible range: 30 - 250)

Enter respiratory rate Press button “Next”



Resp.rate:
18
(permissible range: 5 - 50)

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

Metric system
 Inch system

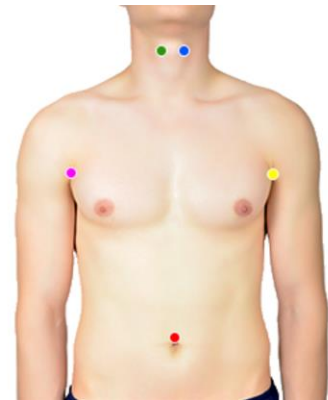
Enter height
Press button “Next”



Patient height:
5 ' 10 "

After that, correctly place five microprocessors (sensors) on the patient's body. DESCRIPTION OF MEASURING PROCEDURE of the tutorial video on [YouTube](#).

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

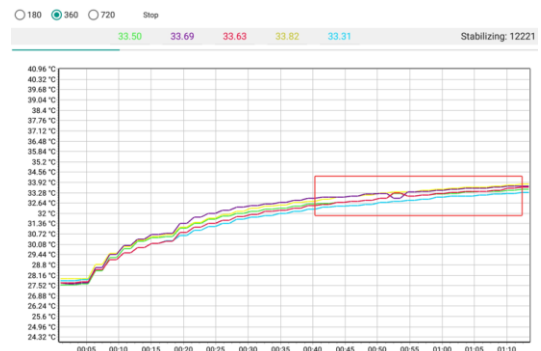


Select system of units
Press button “Next”



SI SGS

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 patient's body.

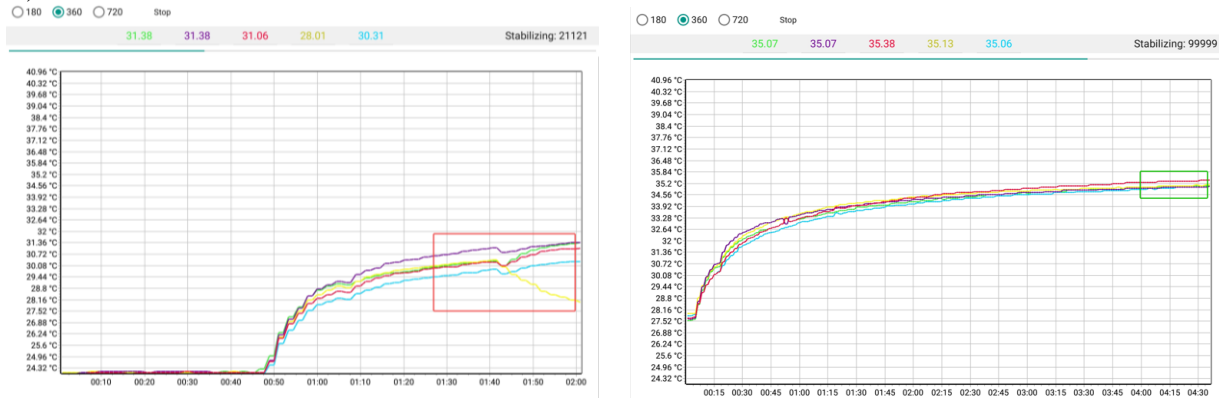


A user can choose the period of time necessary for measurement. It can be changed during the measurement or even stopped before ending.

180 360 720 Stop

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 send the results of measurement and receive the report.

Send data to server? (LCA: 35.04, RCA: 35.10, LAC: 35.12, RAC: 35.05, ABD: 35.35, Atm.pres: 718.2)

CANCEL OK

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

Only medical expertise is required to make a diagnosis. The computer can display an automatic summary but it is subuded to a medical exp

Asthenic-autonomic syndrome is determined.
 Post hypoxic encephalopathy is defined.
 Protein S100 should be monitored.
 Nephrotoxicity syndrome is defined.

No	ID	Parameter:	Norm:	Value:	
1	2	Erythrocytes RBC. x10 ¹² /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. x10 ⁹ /l	180 - 320	215.56	✓
5	4	Leukocytes WBC. x10 ⁹ /l	4.3 - 11.3	11.72	✓

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.

Only medical expertise is required to make a diagnosis. The computer can display an automatic summary but it is subduced to a medical exp
 Post hypoxic encephalopathy is defined.
 Protein S100 should be monitored.
 Nephrotoxicity syndrome is defined.
 Hypoacid gastritis is determined.
 Ischemic heart-disease is determined.
 Increasing of enzymes activity (aspartate transaminase, alanine transaminase) is determined.
 Hypertension of pulmonary circulation is defined.
 Width of the third ventricle of cerebrum.=8.27
 Derangement of atrioventricular (AV) conduction should be verified. It is necessary to monitor ECG in dynamics.
 Derangement of oxidative phosphorylation is determined. Activation of lipid exchange is determined. Reduction of amino acid synthesis is defined (tyrosine, glutamine). Impact of ethanol should be verified. Dopamine β -hydroxylase (DBH).=21.4
 Tiffeneau index has reduced till: 77.9 (Test Tiffeneau.)
 Moderate to severe loss of kidney function is suspected.

No	ID	Parameter:	Norm:	Value:	
1	2	Erythrocytes RBC. x10 ¹² /l	4 - 5.6	3.83	<input checked="" type="checkbox"/>
2	1	Hemoqlobin HGB. q/l	125 - 175	113.68	<input checked="" type="checkbox"/>

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

Only medical expertise is required to make a diagnosis. The computer can display an automatic summary but it is subduced to a medical exp
 Post hypoxic encephalopathy is defined.
 Protein S100 should be monitored.
 Nephrotoxicity syndrome is defined.
 Hypoacid gastritis is determined.

No	ID	Parameter:	Norm:	Value:	
140	119	Estimated creatinine clearance rate(eCCr)(Cockcroft and Gault). ml/min	95 - 145	42.3	<input checked="" type="checkbox"/>
141	124	Cystatin C (CysC). mg/l	0.6 - 0.96	1.53	<input checked="" type="checkbox"/>
142	125	BUN. mg/dl	6 - 23	29	<input checked="" type="checkbox"/>
143	126	Transferrin. mg/dl	204 - 380	160.39	<input checked="" type="checkbox"/>
144	127	Urine specific gravity. g/cm ³	1005 - 1035	1008	<input checked="" type="checkbox"/>
145	128	Chloride (Cl). mmol/l	98 - 107	103.4	<input checked="" type="checkbox"/>
146	129	Cenuloplasmin (CP). g/l	0.15 - 0.6	0.800	<input checked="" type="checkbox"/>
147	130	Alkaline phosphatase (ALP). μ kat/L	0.5 - 2.02	2.26	<input checked="" type="checkbox"/>
148	131	Intracranial pressure (ICP). mmHg	7 - 15	10.5	<input checked="" type="checkbox"/>
149	132	Atherogenic factor (KA).	0.71 - 5.36	3.70	<input checked="" type="checkbox"/>
	133	Serum albumin (ALB). g/l	34 - 45	47.6	<input type="checkbox"/>
	134	Serum globulin (GLB). g/l	20 - 45	34.6	<input checked="" type="checkbox"/>
	135	Atherogenic index of plasma (AIP).	-0.3 - 0.11	0.206	<input checked="" type="checkbox"/>
150	136	Average blood pressure (MAP).	60 - 100	95.4	<input checked="" type="checkbox"/>
151	137	Thrombolysis in Myocardial Infarction (TIMI) Risk Index.	4 - 28	37.4	<input checked="" type="checkbox"/>

Use this icon to generate a report in HTML format



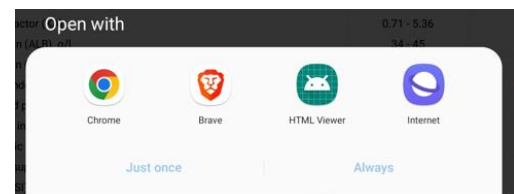
The software will prompt you to download the report in HTML format.

Downloads/ANESA_HTML/Test patient 12_25_22 9_36_54 AM.html

The file name will contain the patient's name, date and time of the test.

OK

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 conclusion about health state of tested person. It is only a prompt for a doctor, which needs to be consiredred 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. x10 ¹² /l	4 - 5.6	*	
2 1	Hemoglobin HGB. g/l	125 - 175	*	
3 88	Hematocrit.HCT %	35 - 49	*	
4 12	Thrombocytes. x10 ⁹ /l	180 - 320		*
5 4	Leukocytes WBC. x10 ⁹ /l	4.3 - 11.3		*

No.:	Parameter:	Norm:	<	>
1 2	Erythrocytes RBC. x10 ¹² /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. x10 ⁹ /l	180 - 320		215.56
5 4	Leukocytes WBC. x10 ⁹ /l	4.3 - 11.3		11.72
6 3	Lymphocytes. LYMPH %	19 - 37		25.18
7 8	Monocytes.MONO %	3 - 11		6.52

8.5 VIEW TEST RESULTS

Select the patient.

Press button “View results”

Select a test.

The screenshot shows a patient selection screen. At the top, there is a search bar with 'Test patient' entered. Below it, a list of test results is shown for two different times: 12/25/22 9:36 and 12/25/22 11:4. Each entry includes patient demographics (Age: 77, Weight: 77, Pulse: 77, Resp.rate: 18) and various test values (RCA, RAC, ABD, LCA, LAC, Atm.pres, Stabilizing).

Double-click to test.

12/25/22 9:36		Age: 77 Weight: 77 Pulse: 77 Resp.rate: 18	RCA: 35.1 RAC: 35.05 Atm.pres: 718.23	ABD: 35.35	LCA: 35.04 LAC: 35.12 Stabilizing: 99995
12/25/22 11:4		Age: 77 Weight: 77 Pulse: 77 Resp.rate: 18	RCA: 33.81 RAC: 33.65 Atm.pres: 720.17	ABD: 34.1	LCA: 33.61 LAC: 33.8 Stabilizing: 32322

The software will show the test results.

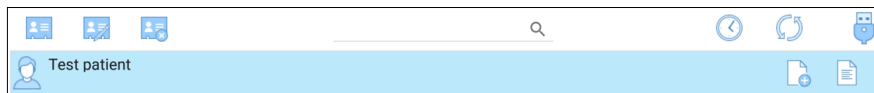
Only medical expertise is required to make a diagnosis. The computer can display an automatic summary but it is subdued to a medical exp

Asthenic-autonomic syndrome is determined.
Post hypoxic encephalopathy is defined.
Protein S100 should be monitored.
Nephrotoxicity syndrome is defined.

No	ID	Parameter:	Norm:	Value:	
1	2	Erythrocytes RBC. x10 ¹² /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. x10 ⁹ /l	180 - 320	215.56	✓

8.6 DELETE TEST RESULTS

Select the patient.



Press button "View results"



Select test.

12/25/22 9:36		Age: 77 Weight: 77 Pulse: 77 Resp.rate: 18	RCA: 35.1 RAC: 35.05 Atm.pres: 718.23	ABD: 35.35	LCA: 35.04 LAC: 35.12 Stabilizing: 99995
12/25/22 11:4		Age: 77 Weight: 77 Pulse: 77 Resp.rate: 18	RCA: 33.81 RAC: 33.65 Atm.pres: 720.17	ABD: 34.1	LCA: 33.61 LAC: 33.8 Stabilizing: 32322

Double-click to test.

12/25/22 9:36		Age: 77 Weight: 77 Pulse: 77 Resp.rate: 18	RCA: 35.1 RAC: 35.05 Atm.pres: 718.23	ABD: 35.35	LCA: 35.04 LAC: 35.12 Stabilizing: 99995
12/25/22 11:4		Age: 77 Weight: 77 Pulse: 77 Resp.rate: 18	RCA: 33.81 RAC: 33.65 Atm.pres: 720.17	ABD: 34.1	LCA: 33.61 LAC: 33.8 Stabilizing: 32322

Press button "Delete test"



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

Attention! Delete selected examination 12/25/22 11:4?

CANCEL OK

The test has been deleted.



8.7 USING THE CALENDAR TO FIND TEST RESULTS

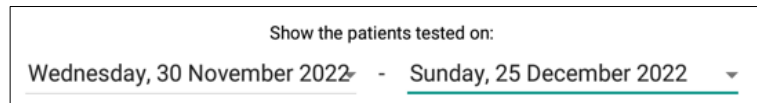
Press button “Main menu”
(Return to main screen)



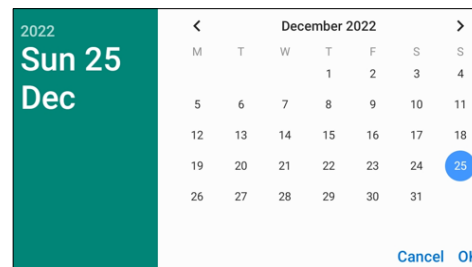
Press the button “Calendar.”



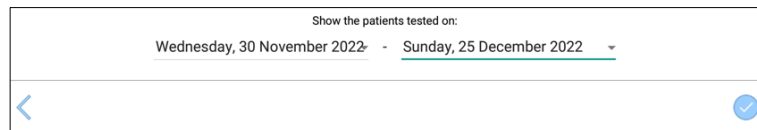
Select “Start date” and “Finish date.”



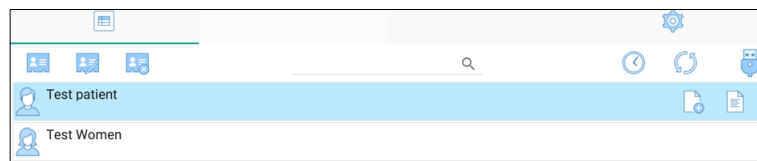
Use the calendar.



Press the "Accept" button.



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



8.8 DELETE A PATIENT’S CARD

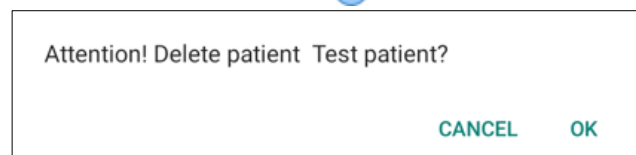
Select the patient.



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

8.9 EDIT A PATIENT'S CARD

Select the patient.

Press button: "Edit patient card".

Edit the patient chart.



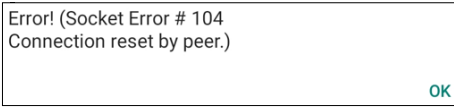
Press the button "Accept"


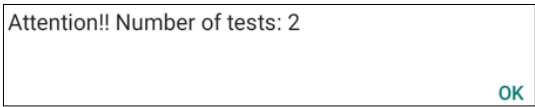
The screenshot shows the 'Edit patient card' form. At the top, there is a header with a search bar and navigation icons. Below the header, the patient's name 'Test patient' is displayed. The form contains the following fields:

- Name:** Test patient
- Use additional identifier (ID):** 1234567890
- Email:** mail@mail.com

 At the bottom of the form, there are three buttons: a back arrow on the left, a blue checkmark icon in the center (labeled 'Accept' in the text), and a blue checkmark icon on the right.

8.10 TROUBLESHOOTING FOR USPIH ANDROID

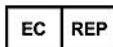
No	Error/problem	Indication and Reason(s)	Solution/advice
1.	Test error Measurement is not started or it is interrupted in a process	 <p>Reasons: The device is not connected to the Tablet PC</p>	<p>Connect the MD to the Tablet.</p> <p>Adjust settings in the menu </p>
2.	Error!	<p>Error! (Error resolving Address amp.mdevice.eu: No address associated with hostname (7))</p> <p>OK</p>	<p>The error occurs when the mobile gadget is not connected to the Internet or there is no access to the cloud server.</p> <p>Connect your mobile gadget to the Internet.</p>
3.	Connection error	 <p>Reasons: 3.1 There is No Internet connection 3.2 Cloud server is not working</p>	<p>2.1 Check your Internet connection</p> <p>2.2 If Internet connection is OK, contact your service provider and inform about the problem</p>

3	<p>Temperature alert</p> <p>During the measurement, the window for temperature monitoring changes its colour to red and flashes</p>	 <p>Reasons:</p> <p>3.1 Sensor(s) lost the contact with skin of a patient</p> <p>3.2 Sensor(s)/cable(s) lost connection with the unit (see Error 5 below).</p>	<p>Note: such alert signals that the measured temperature is below +24C or above +41C</p> <p>3.1 Fix the sensor(s) on a patient's body properly according to the requirements in Chapter 11.</p> <p>3.2 Check the connection of cables with the unit. (see also Error 5 below)</p>
4	<p>Balance alert</p>	 <p>Reasons:</p> <p>If the user's balance is close to zero, the software displays this alert</p>	<p>Contact your service provider to replenish your balance.</p>

9. MANUFACTURER AND THE AUTHORIZED SERVICE CENTRES



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 email: bioluch@gmail.com
 URL: <https://kolibri.cloud>



Authorized representative in European Union:
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 (2) 44 64 09 77
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 URL: www.onkocet.eu

All valid permissions and certificates are placed on the manufacturer's homepage www.anesa.biz <https://kolibri.cloud/>

10. 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*_____

11. 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.

12. NOTICE TO THE USER AND/OR A PATIENT



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

13. DOCUMENT HISTORY AND VERSION CONTROL

Version	Version Date	Summary of changes	Author	Related documents
1.0	2022-12-24	Created	Pulavskiy A, Kolyesnik O	
2.0	2022-12-25	Add Chapter 8 “SW for ANDROID”	Pulavskiy A	
3.0	2023-01-02	Revision all document	Pulavskiy A, Kolyesnik O	
4.0	2023-01-23	Add Chapter 8.1-8.2	Pulavskiy A	
5.0	2024-04-13	Revision all document	Pulavskiy A	