#### **ANESA**

portable diagnostic scanner

T/201



## $AMP _{\infty}^{L07}$

portable medical analyzer



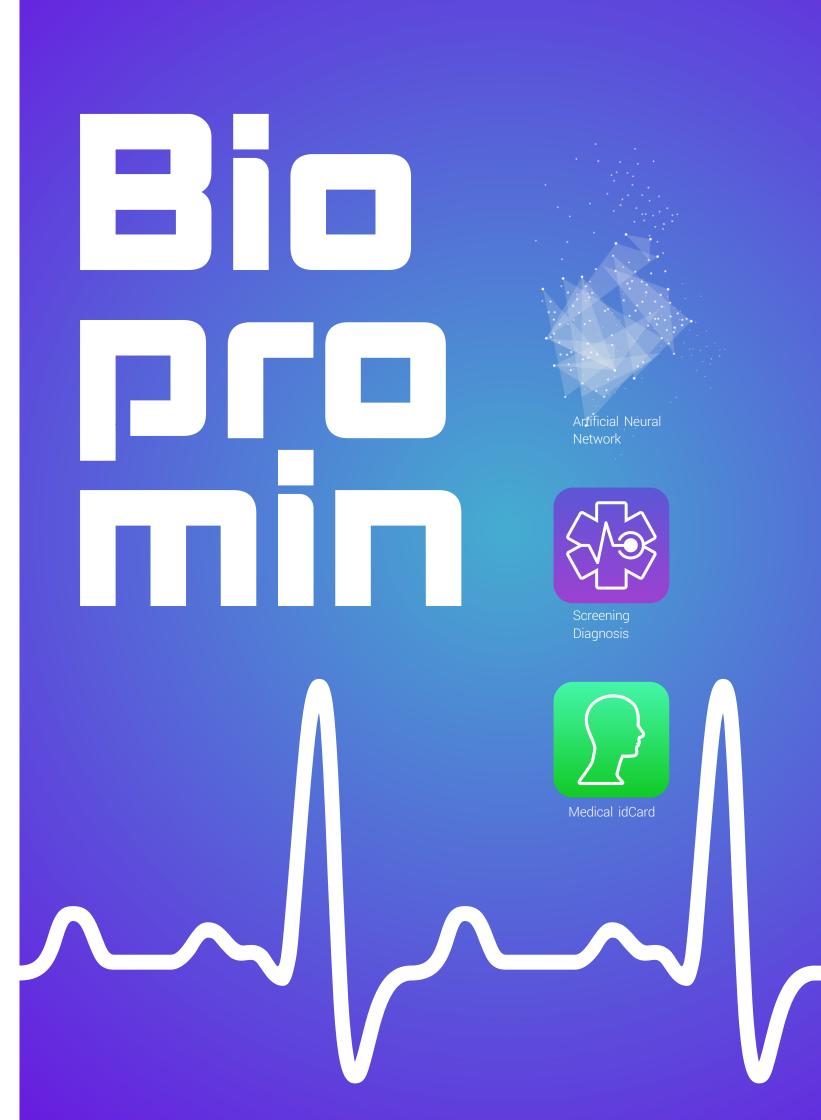
# medical mobile complex

+380 (67) 888 7 111 v.kotliarenko@biopromin.com www.biopromin.com fb.me/biopromin

### Keep Time, Save Life

ANESA gives an opportunity to a doctor for performing unlimited number\* of non-invasive screening diagnostic tests\*\*

- \* A number of tests depends on the type of connection of the device. When working autonomously, the number of tests is not limited
- \*\* The state of health of a patient is estimated by 135 medical parameters during 3-7 minutes.







minutes determines

135 health paramof a pa

ANESA-L/2007

Comprehensive Screening Diagnosis System







#### AMP (ANESA): The New Technology is Widespread Over the World

The device is able to determine parameters which represent the information about the development of pathological process long before the symptoms of a disease appear, including cancer. So, there is time and opportunity for the prevention and early treatment. AMP is the world's first analyzer which provides information about more than 100 blood parameters without blood sampling, based on the principles of thermodynamics and quantum physics. The device is used for obtaining the information about blood parameters, functional, metabolic and hemodynamic parameters of systems and internal organs.





Presentation of noninvasive medical devices entering the market of Bolivia.



countries where AMP (ANESA) is used in programs of mass screening-diagnostics (example: China).

#### **British Journal of** Medicine & Medical Research

analyzer (ANESA) has promising screening method in usual clinical practice for the majority of determined parameters as an alternative to a conventional blood testing. However, more studies are required to strengthen the





USA

Mexico

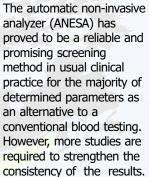
#### REUTERS

The device ANESA tests blood – without a needle.





Great Britain







Czech Republic

Slovakia

Egypt

After 15 years of research and several international awards, AMP was registered in Europe. Analyzer is the first medical device that can automatically perform full blood count without its sampling! Innovative medical device may become indispensable in emergency situations and preventive medicine due to fastdetermination of primary parameters of a human health.



#### **Zdravie**

Single screening test for ten specialists! Testing takes only six minutes. (...) Breast cancer pathology development can be detected at an early stage (...). The analyzer is used in case a patient has health problems, but conventional tests have detected nothing.



#### **Newspaper of Ministry** of Health of the Republic of Belarus

OPEN ACCESS E-JOURNAL

CARDIOMETRY

accompanied with changes

of functional mechanisms

affecting erythrocyte and

its receptors, related to

formation of relevant pH

venous blood, amount of

values of arterial and

endogenous alcohol.

Changes in thermal

of glomus caroticus,

atomic oxygen and

hydrogen in an

atmosphere, with

regulation were

Russia

Saudi

Ukraine

AMP analyzer is a device for non-invasive investigation of hemogram and biochemical, regulatory and metabolic parameters. First of all, the device is recommended for preliminary health assessments of patients seeking medical help.



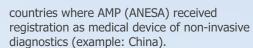
The medical device for non-invasive diagnostics is used for examination of astronauts, pilots and athletes. The device is able to analyze more than 125 indicators for determination of physical and mental health during only 5-15 minutes. (...). Currently, the hospital has carried out more than 1,000 non-invasive examinations of patients.



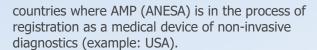


The system of multifunctional noninvasive assessment of health condition was tested in the Hospital of the Air Force of China (...) Thanks to a large volume of collected statistics, you can analyze and detect the development of diseases and conduct screening tests of the population in order to identify the actual health issues.











MP (AMP — Analyzer Malykhin-Pulavskyi is a Diagnostic Device & Medical Assistant; another trade name of the device is ANESA — Automatic Noninvasive Express Screening Analyzer) is a mobile medical station for noninvasive comprehensive analysis of health parameters of patients.

The technology is based on the examination of a human organism's ability to change the activity of ergotropic autonomic nervous system functioning depending on the frequency and the degree of influence of different factors of external and internal environment supported by a synthesis of substances and dissimilation.

Information about the state of the organism is recognized and analyzed by the trained neural network within 3-7 minutes. The algorithm is the base of the USPIH software. Data in the neural network comes from 5 microprocessors, which measure the temperature with discretisation of 0.0625 °C. Nowadays, the capabilities of the neural network allow determining 135 parameters of a human health. In a generated report, the parameters of health are represented in the international measuring units SI or SGS.

The software product can work either autonomously, or as a service platform (PaaS).

AMP (ANESA) optimizes and transfers into digital format up to 80% of all processes, associated with diagnostics.

Innovations, developed by the company, are protected by multiple patents in Ukraine and globally. Manufacturing facilities of BioPromin Ltd comply the requirements of ISO 13485:2012, while the medical devices have been certified in different time by the respective authorities, like CFDA (China) and RST (Russia), marked with CE mark, registered and allowed to use in Ukraine, Belarus, Kazakhstan and Vietnam. The registration processes in Mexico and Chile are on the final stage.

MP (ANESA) has been tested at the Ukrainian Scientific and Practical Center of Emergency Care and Disaster Medicine of the MoH of Ukraine (the City of Kyiv) and at the Bohomolets National Medical University at the Department of Internal Medicine No. 3 (the City of Kyiv). Recently, testing was conducted at the Scientific center of clinical and experimental medicine SB RAMS (The City of Novosibirsk, Russia), at the Central Aviation Hospital of Chinese People's Liberation Army (Beijing, China) and at the hospital of Badalona Serveis Assistencial (Barcelona, Spain).

AMP (ANESA) was awarded by a number of diplomas from international exhibitions, the golden award of International exhibition of medical technologies and equipment Slovmedica (Slovakia), the honorary distinction and diploma of the German Academy of Natural Sciences, the crystalline badge of the Ministry of Health of the Kingdom of Saudi Arabia.

Орган з оцінки відповідності Державне підприємств "Український медичний центр сертифікації" Міністерства охорони здоров'я України

#### додаток до сертифіката відповідності

№ UA.TR.039.065-15 від 30.12.2015 р.

Перелік медичних виробів, на які розповсюджується дія Сертифікату

Nº 3/⊓	Найменування продукції	Клас ризику	Виробнича ділянка на якій виготовляють (адреса)
1	Аналізатор неінвазивний формули крові АМП	II6	61038, м.Харків, вул.Халтуріна, 50, Україна; 61001, м. Харків, провулок Повстання 8а, Україна
2	Аналізатор неінвазивний формули крові АМП-РС	116	61038, Україна, м. Харків, вул. Халтуріна, 50; 61001, Україна, м. Харків, провулок Повстання 8а
3	Апарат низкоінтенсивної МХ-ДЦХ терапії "BIOL"	lla	61038, Україна, м.Харків, вул.Халтуріна, 50; 61001, Україна, м. Харків, провулок Повстання 8а
4	Прилад ударно- хвильової терапії "StarDevice"	lla	61038, Україна, м.Харків, вул.Халтуріна, 50; 61001, Україна, м. Харків, провулок Повстання 8а
5	Прилад ударно-хвильової терапії "StarDevice PC"	lla	61038, Україна, м.Харків, вул.Халтуріна, 50; 61001, Україна, м. Харків, провулок Повстання 8а

30.12.2015 p. Дата видачі: 29.12.2020 p

ОРГАН З СЕРТИФІКАЦІЇ ДП «УКРАЇНСЬКИЙ МЕДИЧНИЙ ЦЕНТР СЕРТИФІКАЦІЇ» МІНІСТЕРСТВА ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ



#### СЕРТИФІКАТ

№ 041-15

підтверджує, що

#### ТОВ "БІОПРОМІНЬ"

Адреса виробника: 61038, Україна, м.Харків, вул.Халтуріна, 50 Адреса виробництва: 61001, Україна, м. Харків, провулок Повстання 8а

> Впроваджена та підтримується Система управління якістю

#### ДСТУ ISO 13485:2005

(ISO 13485:2003, IDT)

Система управління якістю розповсюджується на

Розробка, виробництво, продаж та обслуговування електронного, медичного обладнання

№ 065/064-15 від 28.12.2015 р.

30.12.2015 p. Дата видачі:

29.12.2018 p.

Лебідєв М.С.

Український медичний центр сертифікації Міністерства охорони здоров'я України



#### СЕРТИФІКАТ ВІДПОВІДНОСТІ

Забезпечення функціонування комплексної системи управління якістю (Технічний регламент щодо медичних виробів, Додаток 3, виключаючи пункти 8-11)

№ UA.TR.039.065-15

Товариство з обмеженою відповідальністю "БІОПРОМІНЬ"

61038, м. Харків, вул. Халтуріна, 50, Україна

61001, м. Харків, провулок Повстання 8а, Україна

Апарати медичні діагностичні та терапевтичні (дивись додаток)

Орган з оцінки відповідності ДП "УМЦС" заявляє, що зазначений виробник впровадив систему управління якістю на етапах розробки, виробництва і остаточної перевірки виробів відповідно до Додатку 3, виключаючи пункти 8-11, Технічного регламенту щодо медичних виробів, який затверджено постановою Кабінету Міністрів України від 02.10.2013 № 753. Система управління якістю виробника повністю відповідає ям цього Технічного регламенту та підлягає періодичному

нагляду. Для розповсюдження на ринку виробів класу ризику III додатково обов'язковим є

№ 065/064-15 від 28.12.2015 р.

Дата видачі: 30 12 2015 p

Дійсний до: 29.12.2020 р.





bsi.

#### Certificate of Registration

IM SIA

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ

FEDERAL SERVICE OF HEALTH CARE AND SOCIAL DEVELOPMENT CONTRO

PEΓИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ REGISTRATION CERTIFICATE № ФСЗ 2008/02305

КРД № 13386 от 27.03.2008

KAMANAWAKAK (🍪) KAMANAWAKAK

РЕГИСТРАНИОННОЕ УЛОСТОВЕРЕНИЯ № ИМ-7.96780/1702

(bsl.

#### 中华人民共和国医疗器械注册证

研究制造联合企业"比奥昔洛明"有限公司 'a ",Selyanska Str.,Kharkiv,Ukraine '赛里扬斯克大街,哈尔科夫市,乌克兰6 50 Khalturina str., Kharkiv,Ukraine 瑞大街50号,哈尔科夫市,乌克兰61038 上京市房山区良乡长町西路观柳在街1-515号超商办办 代理人住所 产品名称 型号、规格 数据处理医, 传成医, 连接线组成。 18-70岁以上受检人群的至健康的初步帶套,可測出血 紅蛋白、血细胞比容、红细胞、白细胞、淋巴细胞、血 小板计数、血清的、钾、钙浓度、急蛋白、是胆固醇11 項指标、为进一步的检测摄供临床参考依据,是身体检测 的新型辅助方法。 注册产品标准 其他内容

备注



# AMP (ANESA) Scope of Application

# Analyzing obtained data, among other, a doctor may discover:

- · cardio-vascular diseases;
- derangements of blood coagulation;
- encephalopathies;
- inflammation process in an organism;
- ischemia;
- · osteochondrosis;
- osteoporosis;
- · renal diseases;

- bronchitis
- pneumonia;
- pathological states of gastrointestinal tract;
- filtration abnormality;
- resorption abnormality;
- · venous thrombosis;
- an existence of possible neoplasms, particularly of breast and prostate.

Operational efficiency of AMP (ANESA) favourably emphasizes the quality of service provided by a healthcare institution. The practical advantage of using AMP (ANESA) for a doctor will be expressed in the increasing number of patients to whom a physician is able to conduct the comprehensive analysis of the health state during admission hours.

EXAMPLE OF AMP REPORT



SCHEDULE OF AMP ANALYSIS



# AMP (ANESA) has a wide range of clinical and non-clinical analysis. Mobile medical station estimates:

- general haematological picture (HGB, RBC, WBC, GRA, etc);
- erythrocyte sedimentation rate;
- electrolyte metabolism (K, Mg, Na, Ca);
- enzymes content (AST, ALT, amylase, bilirubin, etc);
- parameters of O<sub>2</sub> and CO<sub>2</sub> (transport and consumption O<sub>2</sub>, O<sub>2</sub> saturation in blood, a deficit of O<sub>2</sub>, CO<sub>2</sub> in arterial and venous blood, etc);
- respiratory system (PVR, FRC, PEF, Tiffeneau's test, etc.);
- renal functioning (creatinine, BUN, eGFR, urea, etc);
- carbohydrate metabolism (lactic acid, glucose concentration);
- lipids (CHO, LDL, HDL, TGL, etc);
- blood circulation;
- · restoration abilities of an organism;
- heart parameters (time intervals of cardio-mechanics, etc).

creening of patients with AMP (ANESA) is recommended to be carried out in healthcare points (such as clinics, hospitals, doctor's cabinet and etc.). At the same time, in case of emergency, it is possible to make testing in any room (e.g. at home, in an office, at airport premises or on an airplane) or even outdoors, providing comfortable conditions for a testing process. For Emergency Medical Services and ambulance, the device AMP (ANESA) is an indispensable instrument for effective screening diagnostic.

In case of difficulties with diagnosing of some patients by routine methods, a screening test with AMP (ANESA) may be helpful for identification of a pathology localization and definition of specific examinations using special equipment.

NO PAIN





#### ECONOMIC:

AMP does not require the expensive chemical reagents, special substances and consumables for operation; proper servicing and maintenance of the device and its accessories, in accordance with the manufacturer requirements, will help to keep the device in working conditions and avoid the extra expenses.

**OPTIMAL:** as AMP (ANESA) keeps the database of patients in a digital form, so it will help to reduce essentially the time, which is spent by a doctor to the "non-professional" duties, such as recording of a patient's data and keeping of the history of diseases, monitoring of the health state from the last visit and/or the process of treatment (as the database allows making comparative analysis fast and easy).

**COMPACT AND EASY:** AMP and its software USPIH are compatible with any computer with the operating system WindowsXP®, Vista®, Windows®7, Windows®8, Windows®10.

#### **APPROVED:** the operation guideline "Non-invasive comprehensive assessment of homeostasis, hemogram, biochemical, metabolic and hemodynamic parameters" is approved by the Medical and Organizing Department of the National

Academy of Medical Sciences of Ukraine and the Department of Organization and Development of Healthcare for the population in the Ministry of Health of Ukraine.

#### HARMLESS AND PAINLESS:

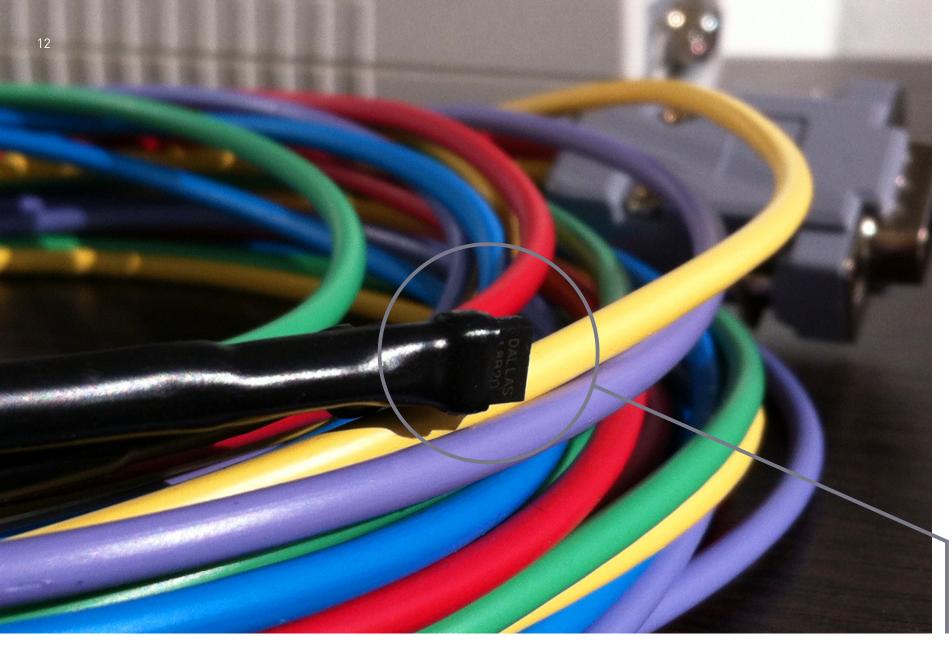
the non-invasive method of diagnostics excludes a risk of infection (like hepatitis C, HIV, etc), which are possible in case of contacting with blood and blood components.

**UNIQUE:** AMP is a unique device. Its work is based on the method developed by Anatolii Malykhin and Anatolii Pulavskyi. The novelty is protected by the patents of Ukraine and other countries. AMP (ANESA) is registered in Ukraine, China, Vietnam, Republic of Belarus, Russia, Kazakhstan. Registration and renewal of previous certificates are conducted in the European Union, Mexico, Chile, Bolivia, Panama and other countries.

#### **QUICK:**

AMP, as a new method of diseases diagnosing, allows a physician to spend less time and provide better medical care.





# AMP (ANESA) Practical Combination of Science and Digital Techniques

The discretisation of microprocessors, which are used for AMP (ANESA), is 0,0625 °C. Measurement accuracy is up to 0,5°C.

he functionality of AMP (ANESA) is based on the determination of thermal reactions of a human body in certain environmental conditions. Deep and complete analysis of knowledge about thermoregulation and thermodynamics has formed the basis of the algorithm, which allows determining the parameters of blood.

The first step of a test usually includes entering of a human individual characteristic (age, sex, weight, pulse and respiratory rate) into the software, assessment of external conditions and measurement of temperature in the definite areas of a human body (5 bioactive points). The second and the third steps include determination of blood parameters, hemodynamic, biochemical and metabolic parameters of a health, based on physical and chemical principles inherent to living organisms:

- heat production: as a human body exists and lives owing to millions of internal chemical reactions accompanied by energy generation or absorption, so the vital activity of an organism is fully followed the laws of thermodynamics. Thus, changes in a body temperature are the indicator of internal processes in the human body;
- activity of chemical elements: functioning of an organism depends on the environmental conditions in the particular moment of time (air temperature, atmosphere pressure, luminous flux and gas composition of air). The environment influences to the activity of chemical elements and to the course of biochemical reactions in an organism (compounds solubility, the solubility of nitrogen, formation of hydrogenous and oxygen bonds of amino acids products and so on). The temperature of body tissues is determined

by the correlation of the metabolic heat of a cell's structures and rate of heat emission. Thus, heat exchange between the organism and the environment is a necessary condition for living of an organism;

O<sub>2</sub> consumption and CO<sub>2</sub> elimination: both processes (on each of the level like cells-tissues-organs-systems) depend on a human physiological state (physical loading or resting) and on the environmental conditions. At the same time, the parameters of oxygen and carbon dioxide have an impact on regulatory systems of a body, central and autonomic nervous systems, providing sufficient systemic circulation, metabolism, hormonal balance, determine compensatory abilities of the organism and, eventually, result to the changes in the composition of blood components. Depending

on the rate of oxygen delivery to a cell, blood circulation is changed, which causes the fluctuations of a body temperature in turn.

The core of the method of non-invasive diagnostics, developed by Malykhin and Pulavskyi, combines the generally known the physical laws of thermodynamics and thermoregulation, and, as a result, provisions of the thermal homeostasis of a human body and its relationship to changes in circulation of blood and dynamics of cerebrospinal fluid (CSF), which are accompanied by the changes of composition of peripheral blood cell and hormones, as well as mineral, protein, amino acid, lipid and carbohydrate metabolism, activity of the thrombin-plasmin system.

Parameters of a human health state are represented in International measuring units of SI and SGS.

## Card of sensors' placement

Measuring is carried out with 5 temperature sensors equipped with microprocessors. Sensors are placed on the definite biologically active points of a body of a patient, in the areas where important vessels of a body are passed or crossed (abdomen, axillary creases, neck): two sensors - above the points of bifurcation of the carotid arteries on the left and on the right (in the area of carotid body), two other sensors are to be placed into the left and the right axillary creases (at the top of each crease), the fifth sensor – near the navel.

**DESCRIPTION OF VALUES** 



Carotid body, which is located in the bifurcation area of carotid arteries, is the only regulator of CO<sub>2</sub> in a body. The regulation is realized by the parasympathetic nervous system, in other words, branches of the vagus nerve reach the carotid body first and then atria and alveolar vesicle. Thus, the connection between pulmonary and systemic blood circulation is settled. Besides this, the carotid body is a cluster of chemoreceptors that determine O<sub>2</sub> concentration and [H +] / SO<sub>2</sub>, as well as temperature in the arterial blood.

LEFT & RIGHT **CAROTID ARTERY** 



<u></u>



**USER'S MANUAL** 

The point of measurement is usually located at the top of an axilla, where the axillary artery approaches most closely to the surface of the skin (usually, pulsation is felt in this point). Temperature values in axillary creases characterize the pulmonary regulation of breathing, which depends on the work of stimulating receptors, J-type receptors and pulmonary stretch receptors, which regulate the amount of oxygen required by a body at the given time (accounting the loading, the physical activity or resting).

LEFT & RIGHT **AXILLARY CREASE** 



9

Abdominal temperature is measured in the area of a navel, where the aorta, the inferior vena cava and the great lymphatic channel are crossed. The temperature in this area affects the production of essential and nonessential amino acids and depends on the functioning of chromaffin cells of the adrenal glands, which control the concentration of O<sub>2</sub> in venous blood and, as a result, regulate the heart rate. Abdominal temperature reflects the functioning of gastrointestinal tract, too.

**ABDOMINAL AREA** 



# User's Reviews on AMP Analyzer (ANESA)



#### Oleksandr Tkachenko

Head physician of the Municipal clinical hospital of emergency aid in Kviv

Usually, investigation of immune and endocrine systems can take up to several days. The medical device AMP in 7 minutes, maximum in 12 minutes, gives the results of 130 parameters of a human health state. The physician takes into account those results in order to estimate the current functional status of a patient and set up the diagnosis. Patients with severe injuries, sometimes in a coma, are delivered to our hospital, and in such cases, we must act immediately, as a patient may die at any moment. In such circumstances, the device AMP plays a great role to us, because it gives an exact direction for further diagnosing.





#### Serhii Polivoda

Professor of the Department of Therapy, Academician of the National Academy of Sciences of Ukraine, Chief Physician of the Consultation and Diagnostic Center

The main specialization of our center is early diagnosing of heart and brain diseases. Currently, we are proud to state that diagnosing with the device AMP (ANESA) is our main and even primary instrument ofdetection of the latent forms of diseases, as well as for overall screening of patients seeking medical care at our hospital first time. AMP (ANESA) easily defines pathological states and disorders. Thanks to the device, we have significantly reduced costings on consumables for laboratories.









#### Oleksandr Midiakov

The highest category physician of functional diagnostics, head of the Functional Diagnostics of the Clinic of Family Medicine.

We have been using the analyzer for 6 years and its ability to detect oncological pathologies arouses our particular respect. Over the recent years, we have tested a large number of patients with already diagnosed oncological diseases, sent by oncologists of Dnipro, Zaporizhia, Poltava and Kiev regions to our clinic. For the majority of such patients, the parameter "Comprehensive cell mitosis regulation factor" was significantly reduced. It should be noted that this parameter is also informative in cases of a premalignant lesion, for example, cicatricial deformity of the uterine cervix, especially on the background of reduction of blood flow in pelvic organs. In fact, thanks to the device AMP, a pathology can be detected while it is in the operable state yet. In cases when detected pathology followed by reduction of the cells mitosis level, such patients require comprehensive follow-up examination and more careful dynamic monitoring by the appropriate professionals.

Particularly impressive is the fact that this diagnostic system is not static and is constantly being improved. Beside increasing number of determined parameters from 117 in the 6th version of software to 131 in the 10th the qualitative changes have taken place in the template of a report, which is automatically generated by the software, where currently the number of nosologies is added and analysis of existing ones was extended. Marking of abnormal values of parameters with colors is very helpful (red - for increased values, blue - for low values), that significantly reduces the time required for the results' analysis.

Such a progress is ensured by the availability of a communication between users and developers of the analyzer (feedback). So, I'd like to ask the doctors, who are already working with this device, and those who are planning to purchase the device to support two-way communication for further improvement of the device. This is in the interest of both users of the device and patients.

