



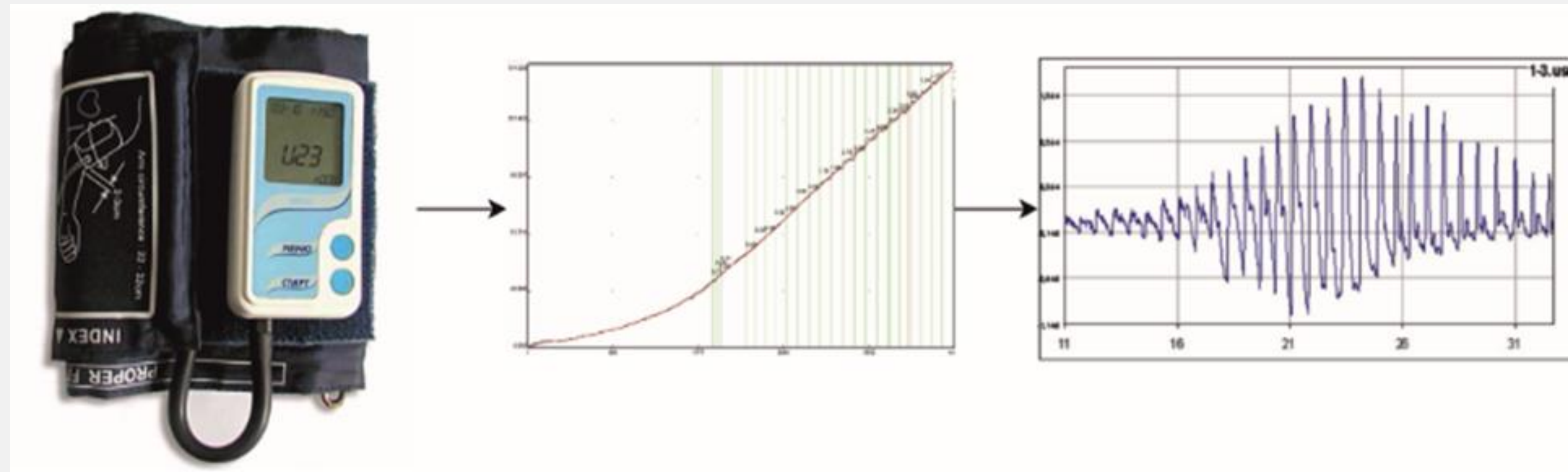
## **Information system «Oranta-AO+MIS» Telediagnostic and telerehabilitation platform with AI**

**CEO, prof.. DSC, Phd  
Dmytro Vakulenko**

# Problem

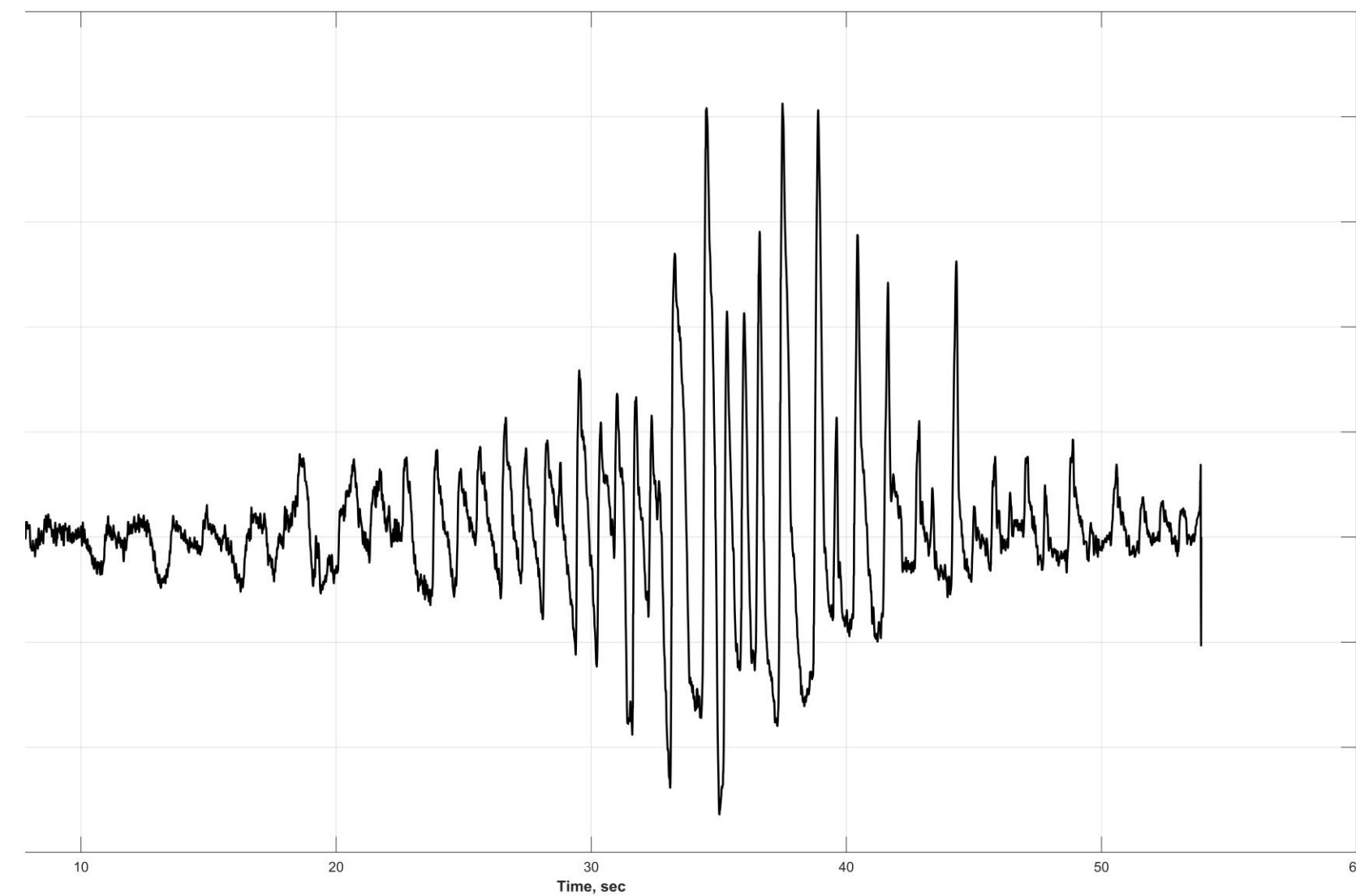
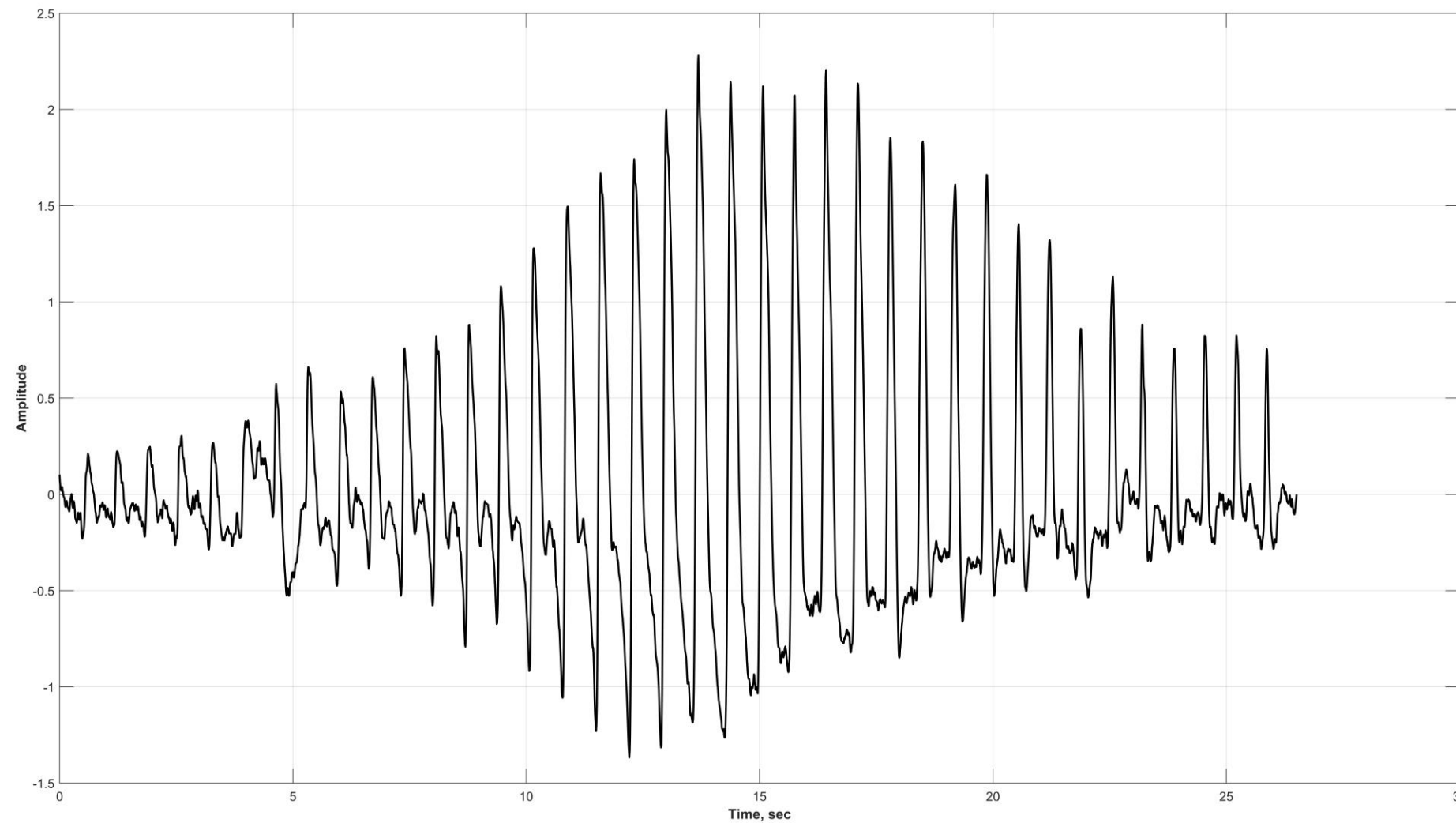
- According to WHO estimates, 17.9 million people died from CVD in 2019, accounting for 31% of all deaths worldwide.
- According to the WHO, more than 1 billion people in the world have some form of disability.
- In Ukraine, more than 4 million people need long-term rehabilitation, including more than 300,000 children.
- Health monitoring and assessment of adaptive capacities are necessary for individual rehabilitation planning
- Currently, the rehabilitation medicine system is rather fragmented

# Solution



**The unique technology of in-depth analysis of pulsations registered during one pressure measurement was developed by the authors and implemented in the Oranta-AO ®**

# Arterial oscillogram



Arterial oscillogram are assessed by height, shape and rhythm. We can know about vascular tone, heart activity, the state of the autonomic nervous system, blood pressure, neuro-reflex effects on their condition.

# Used principal

# Background

## Oranta-AO used principals

- **Heart rate variability** - level centralization autonomic nerve system in heart and vessels adaptation to compression of cuff
- **Pulsation form** – functional and morphological condition vessels
- **Arterial oscillogram form** - functional and morphological condition vessels
- **Spectral analysis biosignal oscillation** – identification fast and continue central nerves system adaptation to compression of cuff
- **Machine learning** for disease risk identification - cardiovascular, lung, mental decease

## Background for implementation to arterial oscilography

1. Heart rate variability use ECG, smart watch with ECG and pulls oximeter with pulse wave analysis
2. pulsation form analysis use rheography
3. Spectral analysis biosignal oscillation are present in EEG
4. Dynamical adaptation to different faze compression not present

# Indexes for complex identification 1

## **PARS.AO Activity index of arterial oscillogram regulatory systems**

May have the following values (Normal, Moderate, Expressed, Severe functional stress, Asthenia (depletion) of regulatory systems and Failure to adapt).

## **IFSP. Integrated functional vascular potential (IFSP)**

reflects the hemodynamic properties of the cardiovascular system by vascular activity and has the following functional states (Physiological state, Donological state 1, 2, Premorbid state, Probable presence of pathology)

## **ANS (autonomic nervous system) details its condition**

## **Index of centralization of cardiac (ICS) and vascular (ICSD) hemodynamic factor.**

These indicators reflect the involvement of higher regulatory centers in the process of adaptation to shoulder compression, respectively, to ensure the activity of the heart and blood vessels. (Limits of change of values vary from 1 to 5 with the following values: pronounced, moderate influence of autonomic regulation and moderate, predominance and pronounced influence of central regulation. For convenience, a detailed interpretation of the indicators characterizing: Levels of autonomic nervous system condition and recommendations for the patient's condition. This information is additionally displayed on the main page.

Involvement of ANS units in the cardiovascular and hemodynamic factors may have the following meanings (Expressed or moderate (sympathetic, parasympathicotonia) or normotony).

**Additionally, the weight of the levels of regulation of Cardiovascular factors based on the spectrum power indicators is displayed in the form of pie charts.**

**IVSCHG - Index of autonomic cardiac hemodynamic factor.**

**IVSudChG - Index of autonomic vascular factor of hemodynamics.**



# Indexes for complex identification 2

## **The heart**

- **Heart activity** - (Below norm, Norm, Above norm) Heart rate, Mo, pNN50,%
- **Irregularity of pulsation rhythms**

**Vessels** - collected signs that characterize the dynamic properties of vessels, which are manifested during compression by the cuff. Indicators characterize the quality of adaptation, vascular tone, the level of excitability at the beginning and during compression, arrhythmia, vascular elasticity, and systolic and diastolic vascular capacity. For each of the 10 indicators and their comprehensive indicator, the MCI provides Values, Assessment, Rationale, Health Level and Recommendations.

## **Nervous system**

collected indicators characterizing the weight of the components of the central nervous system in the adaptation to compression, taking into account the total and instantaneous power of the spectrum.

## **The Ruffier test**

provides an opportunity to assess the functional capabilities of the body when conducting functional tests based on the Ruffier Index. Additionally, the complex indicators Adaptation Index (according to Vakulenko), PARS-AOI and IFSP for each measurement and average value are proposed.

## **Expert system –**

collected information on the probabilistic values of diseases for the selected measurement (s), based on the methods of Machine Learning and offers information on the risks of cardiovascular, pulmonary, mental illness.

# Innovation

## Express diagnostics:



- Health level and adaptive capacity of the body
- Central and peripheral blood circulation
- Dynamic response of blood vessels to compression
- Autonomic nervous system
- Risks of cardiovascular, pulmonary, and mental diseases, 85-97% accuracy



# Innovation

- Telemonitoring of vital signs (ECG, arterial oscillography, pulsations (wrist & temples))
- Support of the Expert System with AI
- Individualized system to support active living
- Video consultation with a medical professional.

# Done

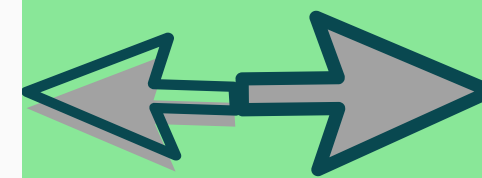
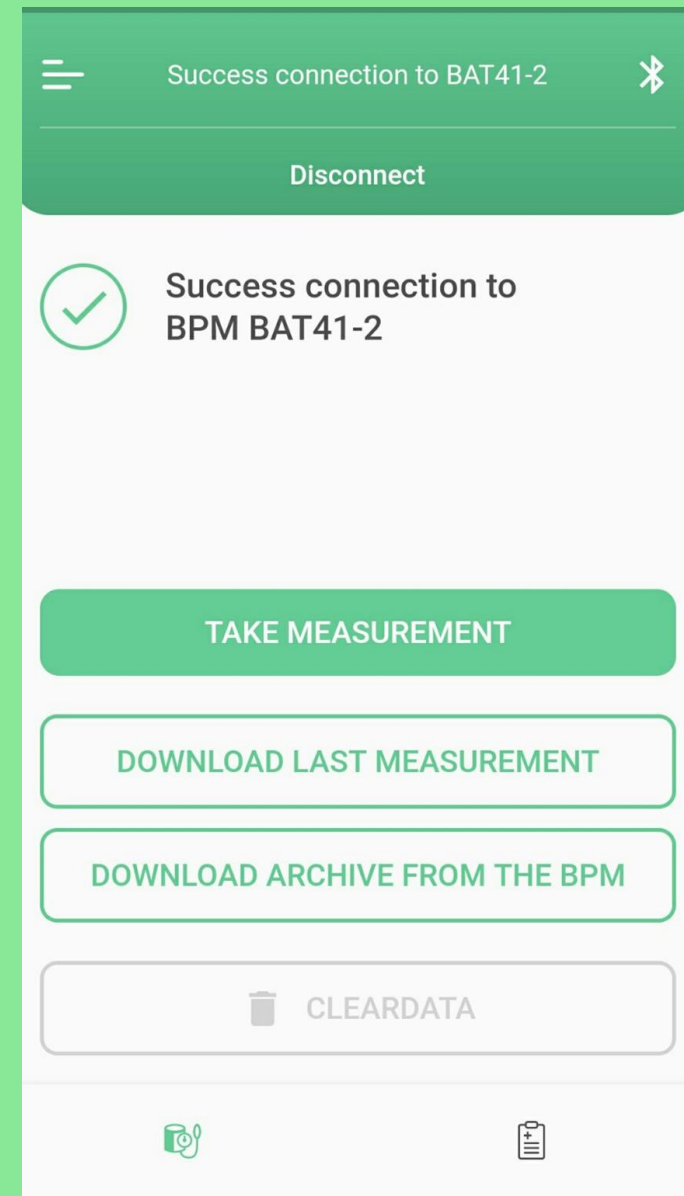
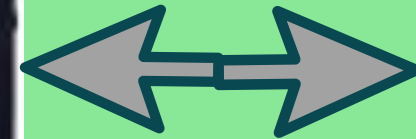
## Researched

- ✓ The methods of Arterial oscillography are developed
- ✓ Research and diagnostic criteria (more than 4000 patients, 14 nosology and 28 different kind experiments are did (phisical examination (Rufie test, orthostatic test and etc.), rehabilitation activity (massage, Nuga-best, Reyki, qigong), different multimedia intervention).
- ✓ Defended doctoral thesis, we are working on 2 more doctoral thesis
- ✓ Received 5 patents for utility models in Ukraine
- ✓ Are compete clinical trials – 172 patients (Health and cardiovascular decease) – include registration - ECG, Rheography, Spirography, Martine-Kushelevsky functional test, Nitroglycerin test, Blood test (general, biochemical), Arterial oscillation registration (Omron, Dr. Frai, Iks-Tekxno), Stiffness of the arteries (5 minutes compression test, and VAT-41-2)

## Published:

- ✓ 9 articles in journals, monograph from the Scopus, web of science list
- ✓ 52 works abroad and in Ukraine
- ✓ <https://www.scopus.com>, [https://www.researchgate.net/profile/Dmytro\\_Vakulenko/publications](https://www.researchgate.net/profile/Dmytro_Vakulenko/publications)

# Information system Oranta-AO

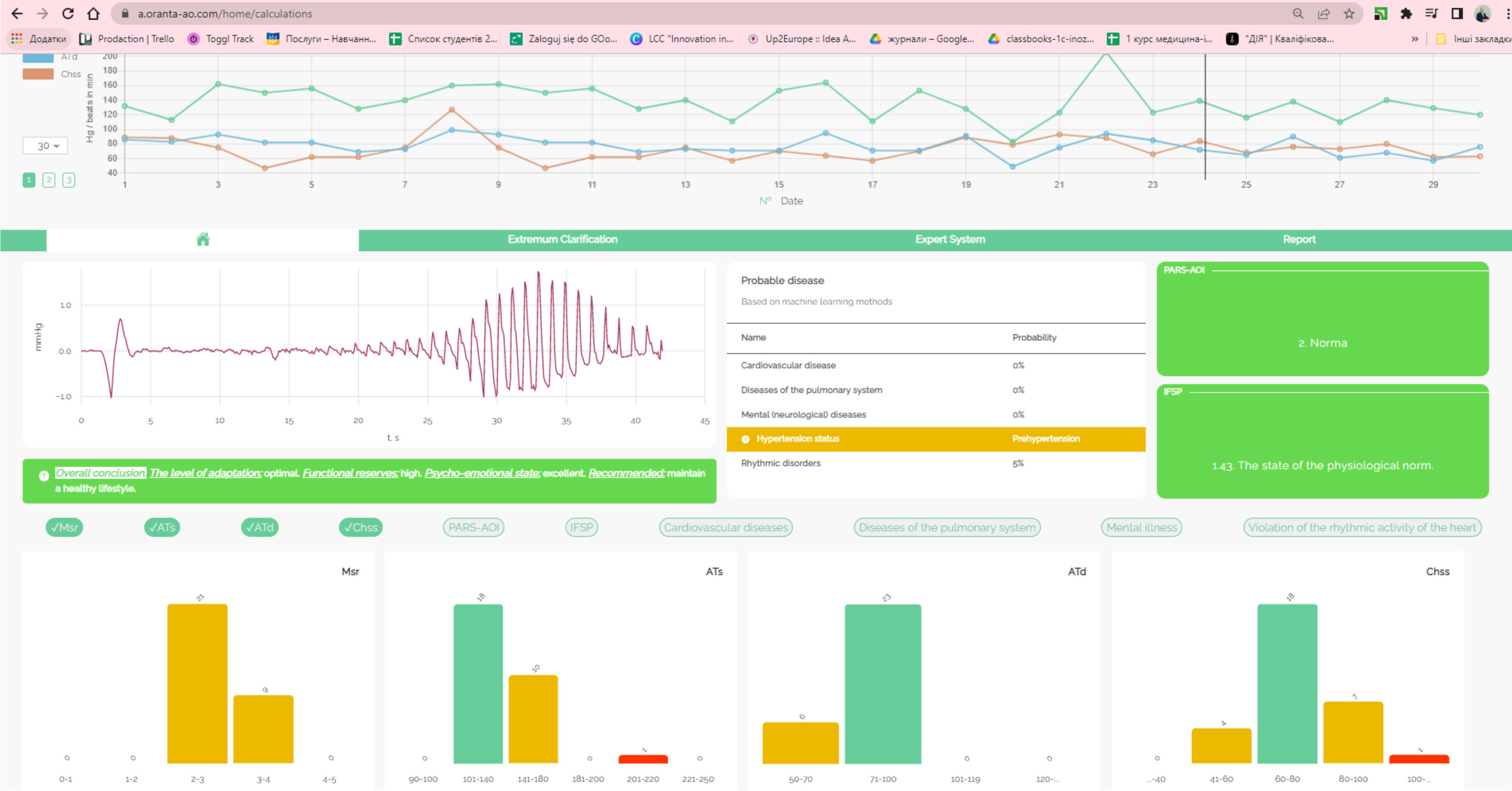


**Blood Pressure Monitor with Oranta –AO support are sending pulsation to mobile app**

**The mobile application sends the signal from the pressure meter to the cloud calculation core**

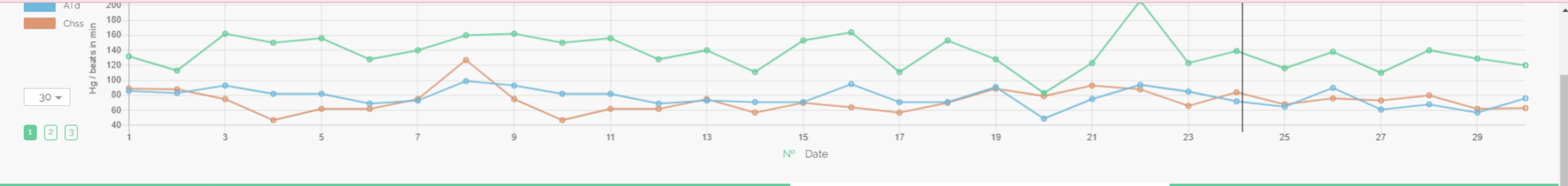
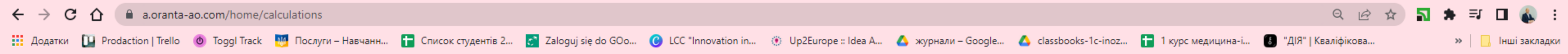
**The user's personal account displays information from each measurement**

# Interface Oranta-AO for short conclusion





# Interface Oranta-AO for detailed conclusion



## Activity index of regulatory systems (PARS-AO)

PARS-AO = 2

Norm. The state of complete or sufficient balance of the organism with the external environment. Satisfactory functional (adaptive) capabilities (reserves). High adaptability of the organism to current conditions is achieved with minimal voltage of regulatory systems. (PARS - 0.1)

Explanation of the values of PARS-AO >

Point	The total effect of regulation	Functions of automatism	Vegetative homeostasis	Stability of regulation	Spectral structure of rhythm	
	Mo,c	VPR, y.o.	AMo	c IN, 1/c^2	HVR, y.o. V, c	%VLF, %LF, %HF
	0.95	0.47	51.85	60.65	28.42; 8.92	10.19; 16.15; 73.66
+2	Severe tachycardia, <0.66	Stable rhythm, <- 0.7	Expressed sympathicotonia, <-20	Expressed sympathicotonia, >-60	Violation of regulation, >-75; <-2	Expressed sympathicotonia, >-30; >-50; <-90
+1	Moderate tachycardia, 0.66 - 0.8	Expressed sinus arrhythmia, 0.7 - 0.8	Moderate sympathicotonia, 20 - 25	Moderate sympathicotonia, 40 - 60	65 - 75; 2 - 5	Moderate sympathicotonia, 20 - 30; 35 - 50; 75 - 90
0	Normocardia, 0.8 - 1	Moderate sinus arrhythmia, 0.8 - 0.9	Normotonia, 25 - 40	Normotonia, 20 - 40	Stable regulation, 45 - 50; 5 - 8	Normotonia, <- 20; 50 - 35; 50 - 75
-1	Moderate bradycardia, 1 - 1.2	Moderate violation of automatism, 0.9 - 1.0	Moderate parasympathicotonia, 40 - 50	Moderate parasympathicotonia, 10 - 20	35 - 45; 8 - 10	Moderate parasympathicotonia, <-5; 40 - 50
-2	Severe bradycardia, > 1.2	Severe violation of automatism, > - 1.0	Expressed parasympathicotonia, >-45	Expressed parasympathicotonia, <-10	Violation of regulation, <-35; >-10	Expressed parasympathicotonia, <-40

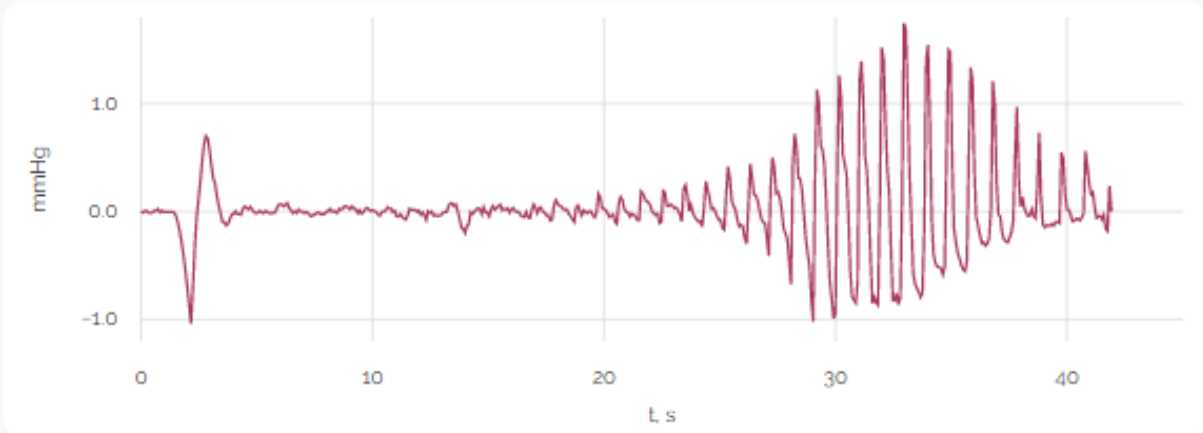


# Interface Oranta-AO for Report

Extremum Clarification Expert System Report

Patient: Вакуленко Дмитро Вікторович Birth date: 12/02/1992 Age: 30 Gender: Male  
Date of refueling: 15/03/2022

Examination protocol:  Simplified  Advanced



**It is recommended to repeat the measurement, try not to move during the measurement.**

**Overall conclusion:** *The level of adaptation: optimal. Functional reserves: high. Psycho-emotional state: excellent. Recommended: maintain a healthy lifestyle.*

**Probable disease**  
Based on machine learning methods

Name	Probability
Cardiovascular disease	0%
Diseases of the pulmonary system	0%
Mental (neurological) diseases	0%
<b>Hypertension status</b>	<b>Prehypertension</b>
Rhythmic disorders	5%

**PARS-AOI**  
2. Norma

**IFSP**  
1.43. The state of the physiological norm.

Select components to display:  PARS-AOI  IFSP  ANS  Heart  Vessels  Nervous System  Rufier's test

# Product solution with Oranta-AO support

- Arterial oscillography based on a pressure meter (near 950 Euro) \*
- ECG devices and smart watches 60 - 150 Euro\*
- Heart rate recorders (wrist and temples) (in development) \*\*\*
- Monitoring the dynamics of limb movement - joint position (smartphone video camera) \*\*
- Rapid assessment of blood pressure, blood, heart rate variability (smartphone video camera) \*\*
- Predictor of allergic reactions to drugs (natural factors) based on DNA analysis (from laboratory tests) \*\*
- Prediction of changes in indicators for the next period \*\*

- \* Available
- \*\* We are planning in the near future
- \*\*\* We are planning a little later



# Users of Telemonitoring Oranta-AO

## Patients

- Fast and high-quality monitoring of health indicators
- Identification of risks of heart, lung, and mental diseases

## Doctors

- Saving time for preliminary diagnostics, qualitative selection of diagnostic trajectory, evaluation of treatment effectiveness
- Unique assessment of the dynamic adaptive capabilities of the heart, blood vessels and nervous system

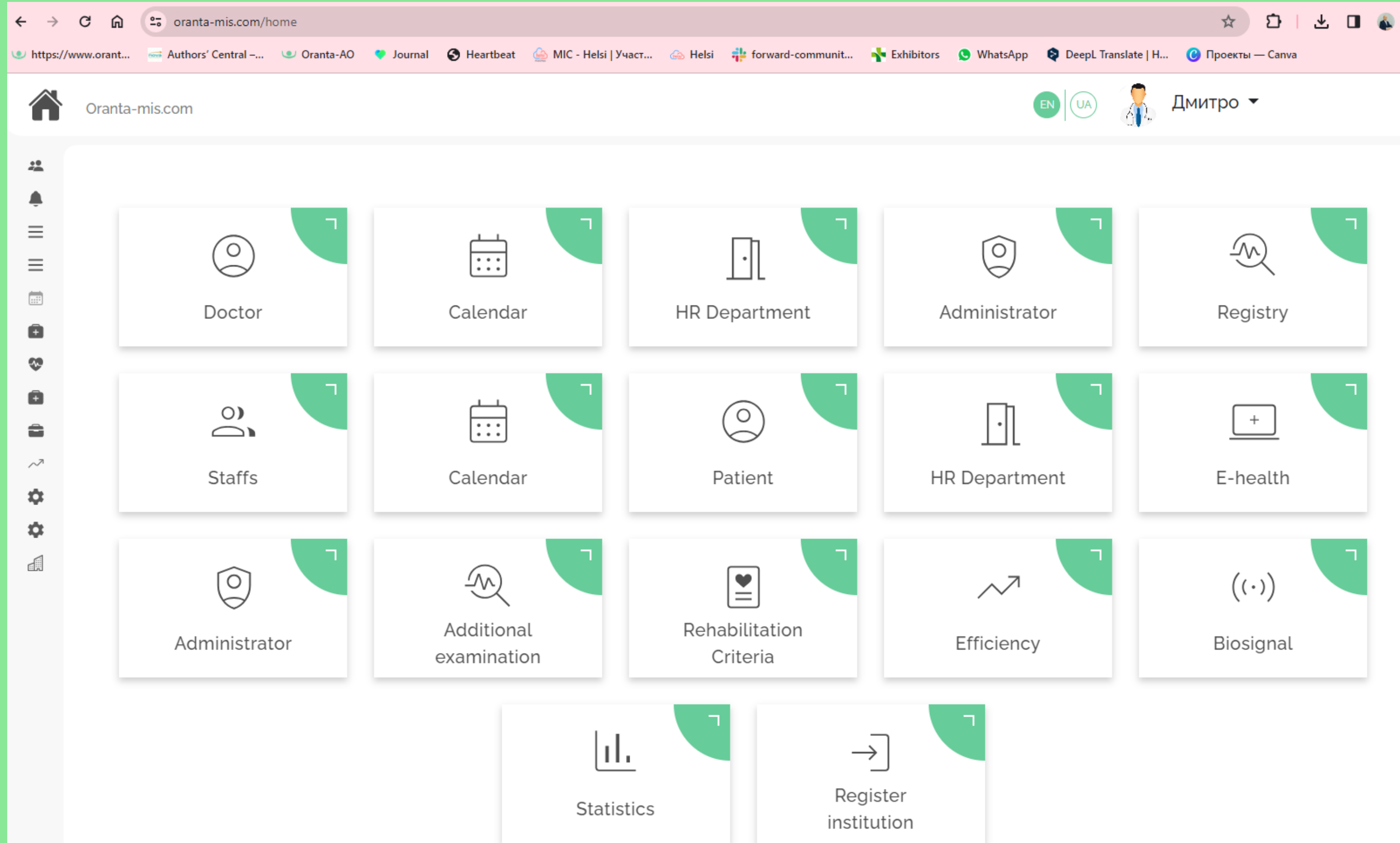
## Rehabilitation, Fitness, Sports Medicine

- interactive monitoring of health indicators before, during, after training

## Military, Space, Veterinary Medicine

- portability, when it is necessary to measure a set of indicators that includes all the above advantages

# Medical information system for tele-rehabilitation Oranta-MIS



# Innovation

- Patient-centered telerehabilitation support by a multidisciplinary team
- Determination of the patient's condition according to the ICF classification by the available sets of ICF codes
- Distribution of tasks and participation of the multidisciplinary team to achieve the patient's rehabilitation goals
- Expert rehabilitation system with AI for individual support of doctors and patients.
- Video consultation with a medical professional.
- Interim and final assessment of the rehabilitation program goals



# Team



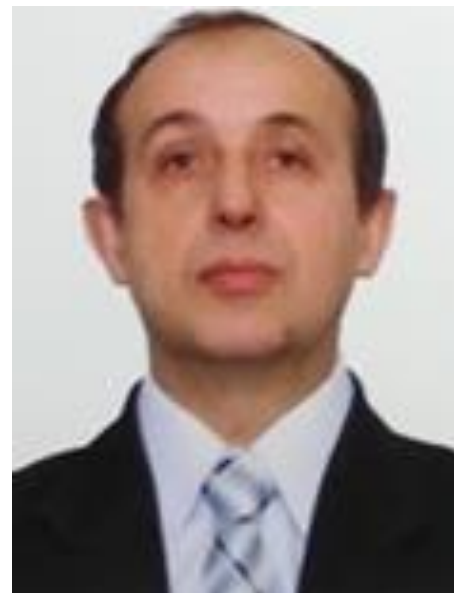
**Researcher,  
Phd, MD  
Liudmyla Vakulenko**



**CEO, Researcher,  
Professor,  
Dmytro Vakulenko**



**Programmer,  
Matlab, Pyton, ML Engineer  
Nestor Demianchuk**



**Programmer, hardware  
developer  
Igor Pits**



**Manager  
Mariana Vakulenko**

# Business model



## B2B, B2C

- Sale of devices
- Subscription for clinic, doctor, users
- Licensing of device manufacturers

# Example application

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- Preventive diagnosis and monitoring: (Activities of the heart, vessels, autonomic and central nervous systems, mental disorders)
- Detection of stress, psycho-emotional burnout and depression
- Determining the probability of existing complications caused by COVID-19
- Assessment of professional suitability (psycho-emotional states in athletes and employees)
- Use of technology in the Ruffier and Martina-Kuszelewski test (pediatrics, athletes, military, high-risk professions)
- Current monitoring of anesthesia during surgery
- Tracking the states and effects of therapeutic Virtual Reality on the psychological, mental and physiological functioning of organs and systems of the body

## ***What could be the main deliverables?***

- Developed of a patient-centric platform for diagnostic cardio-vascular disease in different stages Users for Clinicians, medical workers, rehabilitation specialists and citizens. The blood pressure measurement procedure is the most widely used medical procedure in the world. When using advanced models of pressure gauges based on arterial oscillography methods (Vakulenko D., Vakulenko L.) using machine learning methods obtain information about the risks of cardiovascular, nervous, pulmonary and other diseases.
- The research was carried out, the use of arterial oscillography methods was substantiated and verified. These innovations are based on machine learning methods, which will provide individualized and protected information about the patient's health and help him choose his personal future trajectory. Developed SE Oranta-AO to provide trustworthy and privacy-preserving for citizens, family doctors, cardiologists, psychiatrists, pediatricians, specialists in sports, military medicine.

**The next plan**

**&**

**We are**

**looking for**

**Objective: Telediagnostic and telerehabilitation ecosystem with AI Oranta-AO in every clinic and family in the world**

**We continue to develop and test the product**

**We need a team of marketers, distributors**

**Partners for Research Consortia**

**Next research in advance understanding impact “peripheral heart” – vessels in Cardiovascular disease with Oranta-AO**

**Integration of Oranta-AO-MIS**

**with wearable and professional devices**

**ECG, Blood pressure and pulsations**



# Do you have any questions?

Contact us anytime!



**Dmytro Vakulenko**  
CEO, Prof. DSc. PhD

**Phone Number**  
+38098205057

**Email Address**  
dmitro\_v@ukr.net

**Website**  
[www.oranta-ao.com](http://www.oranta-ao.com)



# Intellectual Property

## PCT

- received priority according to international application WO2021246995 - Method of early detection, prediction and evaluation of the effectiveness of treatment of cardiovascular diseases, nervous and pulmonary systems
- An application has been submitted for priority, PCT / UA2022 / 000001 "Automatic blood pressure monitor"

7 current patents in Ukraine

Next steps: patenting in Europe, America, World

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION CONCERNING  
AVAILABILITY OF THE PUBLICATION  
OF THE INTERNATIONAL APPLICATION

Date of mailing ( <i>day/month/year</i> ) 09 December 2021 (09.12.2021)		To:  SKACHKO, Valeriy Anatolievich pr-t Akademika Glushko, 21, kv. 1 g. Odessa, 65104 UKRAINE
Applicant's or agent's file reference		
International application No. PCT/UA2021/000059	International filing date ( <i>day/month/year</i> ) 24 June 2021 (24.06.2021)	Priority date ( <i>day/month/year</i> ) 01 June 2020 (01.06.2020)
Applicant VAKULENKO, Dmytro Viktorovych		

The applicant is hereby **notified** that the International Bureau:

has **published** the above-indicated international application on 09 December 2021 (09.12.2021) under No. WO 2021/246995

has **republished** the above-indicated international application on \_\_\_\_\_ under No. WO \_\_\_\_\_  
For an explanation as to the reason for this republication of the international application, reference is made to INID codes (15), (48) or (88) (*as the case may be*) on the front page of the published international application.

- A copy of the international application is available for viewing and downloading on WIPO's website at the following address: <https://patentscope.wipo.int/> (in the appropriate field of the structured search, enter the PCT or WO number).

- The applicant may also obtain a paper copy of the published international application from the International Bureau by sending an e-mail to [patentscope@wipo.int](mailto:patentscope@wipo.int) or by submitting a written request to the contact details provided below.

# Certification

## Ukraine:

1. Conducted a clinical trial (172 people)

2. Certificates received

- EN 62304: 2014
- on compliance with the Technical Regulations for Medical Devices
- on compliance with the quality management system of the enterprise EN ISO 13485: 2018

### Висновки за результатами випробувань (інформація/коментарі):

Програмний комплекс для діагностики стану серцево-судинної системи "Оранта-АО, версія 1.1.2"  
відповідає вимогам ДСТУ EN 62304:2014.

ПРОТОКОЛ ВИПРОБУВАНЬ	
ДСТУ EN 62304:2014 ПРОГРАМНЕ ЗАБЕЗПЕЧЕННЯ МЕДИЧНИХ ПРИСТРОЇВ. ПРОЦЕСИ ЖИТТЄВОГО ЦИКЛУ ПРОГРАМНОГО ЗАБЕЗПЕЧЕННЯ	
Номер протоколу .....	№ 1717-2-2021
Випробування провів.....	Кузьменко О.О. Заступник начальника відділу
Перевірив.....	Мамчин Г.Й. Начальник відділу
Затвердив .....	Гндікін А.І. Начальник НТВЦ
Дата затвердження протоколу.....	30.11.2021
Кількість сторінок .....	18 стор.
Назва випробувальної лабораторії .....	Випробувальна служба УкрТЕСТ Науково-технічний випробувальний центр УкрТЕСТ ДП "Укрметрестестандарт" (НТВЦ УкрТЕСТ)
Адреса, телефон.....	Україна, 03143, м. Київ, вул. Метрологічна, 4 тел. 526-65-01
Номер і дата атестата акредитації..	Атестат акредитації Національного агентства з акредитації України № 20635 від 18.11.2021 р., чинний до 31.05.2022 р.
Замовник .....	ТОВ "Інновації в медицині"
Адреса .....	46029, м. Тернопіль, вул. 15 квітня, буд. 7, кв. 120, Україна
Вимоги до випробувань Стандарт .....	ДСТУ EN 62304:2014
Назва випробуваної продукції .....	Програмний комплекс для діагностики стану серцево-судинної системи
Торгова марка.....	Оранта-АО
Модель та/чи тип .....	Оранта-АО, версія 1.1.2



# Certification

Next step: Europe, USA

**UkrMedCert**  
ТОВ «УКРМЕДСЕРТ»  
**СЕРТИФІКАТ**

про відповідність вимогам Технічного регламенту щодо медичних виробів

Зареєстрований у Реєстрі  
«19» січня 2022р.  
№ UA.MD.465-22  
Дійсний до «18» січня 2027 р.

Цим сертифікатом посвідчується, що застосування комплексної системи управління якістю на етапах розроблення, виробництва і остаточної перевірки медичних виробів:

**Програмний комплекс Оранта-АО**  
клас Іа

що виробляється:  
**ТОВ «ІННОВАЦІЇ В МЕДИЦИНІ»**  
за адресою: Україна, 46029, м. Тернопіль, вул.15 Квітня, буд. 7, кв. 120

**відповідає вимогам Технічного регламенту щодо медичних виробів** затвердженого постановою Кабінету Міністрів України від 02.10.2013 № 753. Про відповідність проведена згідно з додатком 3 «Порядок проведення процедури функціонування комплексної системи управління якістю», за виключенням пунктів 8-1 Контроль відповідності медичних виробів вимогам зазначеного технічного регламенту шляхом нагляду, періодичність і процедури якого регламентуються процедурами організації відповідності.

Сертифікат видано Органом з оцінки відповідності ТОВ «УКРМЕДСЕРТ», акредитованим Національним агентством з акредитації України, атестат від 22.03.2021 № 10240 Мінекономрозвитку України, за ідентифікаційним номером UA.TR.099, адреса: вул. будинок 1-А, офіс 2, м. Київ, 02059, Україна, тел.: +38-067-595-02-30, <https://ukrmedcert.org.ua>

на підставі Рішення ООВ ТОВ «УКРМЕДСЕРТ» від 19.01.2022 № 002/MD-21.10.22/01.

Заступник керівника ООВ **Т.В. Бавикіна**

Чинність сертифіката відповідності можна перевірити в Реєстрі на сайті <https://ukrmedcert.org.ua> та за тел. +38-067-595-02-30

Check these certificates here:

[https://drive.google.com/drive/folders/1JG8Sj5EZZGQOBwW\\_2tkVrdcQWpHoYvs?usp=sharing](https://drive.google.com/drive/folders/1JG8Sj5EZZGQOBwW_2tkVrdcQWpHoYvs?usp=sharing)

**UkrMedCert**  
ТОВ «УКРМЕДСЕРТ»  
**СЕРТИФІКАТ**

про відповідність системи управління якістю

Зареєстрований у Реєстрі  
«19» січня 2022 р.  
№ UA.SM.240-22  
Дійсний до «18» січня 2025 р.

ЦИМ СЕРТИФІКАТОМ ВІДПОВІДНОСТІ ПОСВІДЧУЄТЬСЯ, ЩО СИСТЕМА УПРАВЛІННЯ ЯКОСТІ СТОСОВНО **Проектування та розроблення, виробництво та дистрибуція програмного забезпечення для опрацювання результатів отриманих при вимірюванні тиску**

впроваджена:  
**ТОВ «ІННОВАЦІЇ В МЕДИЦИНІ»**  
за адресою: Україна, 46029, м. Тернопіль, вул.15 Квітня, буд. 7, кв. 120

**відповідає вимогам ДСТУ EN ISO 13485:2018**

Контроль відповідності сертифікованої системи управління якістю вимогам зазначеного стандарту здійснюється шляхом нагляду, періодичність і процедури якого регламентуються процедурами органу з оцінки відповідності.

Сертифікат видано Органом з оцінки відповідності ТОВ «УКРМЕДСЕРТ», акредитованим Національним агентством з акредитації України, атестат від 24.12.2019 № 80047, адреса: вул. Драгоманова, будинок 1-А, оф. 2, м. Київ, 02059, Україна тел./факс: +38-067-595-02-30, <https://ukrmedcert.org.ua/>

Заступник керівника ООВ **Т.В. Бавикіна**

Чинність сертифіката відповідності можна перевірити в Реєстрі на сайті <https://ukrmedcert.org.ua> та за тел. +38-067-595-02-30

## Short presentation of our Team:

- Team with necessary list expertise in research
  - medicine (primary medicine, cardiology, rehabilitation, psychiatry, sport medicine..),
  - mathematics,
  - Artificial Intelligence and
  - software development,
- Professors, Phd, and senior developers**