PERSONAL HEALTH SCREENING SYSTEM KOLIBRI®

medical system for noninvasive screening of human health
based on the analysis of heart activity (HA) and heart rate variability (HRV)

(hereinafter referred to as KOLIBRI® or MS KOLIBRI)

KOLIBRI

Instruction for use

(IFU)

UA.TR.099

2021

XXXX

Manufacturer:
SCIENTIFIC COMPANY KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.one

Authorized representative in European Union:
EC REP **Authorized representative in European Union:**
HUNGARY
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79-2
Tel: +36-20-971-93-23
email: info@mdevice.org
URL: https://www.mdevice.org/

PERSONAL HEALTH SCREENING SYSTEM KOLIBRI®

medical system for noninvasive screening of human health
based on the analysis of heart activity (HA) and heart rate variability (HRV)

(hereinafter referred to as KOLIBRI® or MS KOLIBRI)

MD KOLIBRI is Active Medical Device of **Class IIa,** according to the ANNEX VIII, Chapter I DURATION OF USE: «Transient», ACTIVE DEVICES: «Active device intended for diagnosis and monitoring» **ANNEX VIII, Chapter III 6.2 Rule 10** and SaMD KOLIBRI **6.3. Rule 11** of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

MD KOLIBRI is Active Medical Device of **Class IIa,** according to the **Annex IX Sect. I clause 1.6, 3.2 Rule 10** of the Directive 2007/47/EC of the European Parliament and the Council amending Council Directive 93/42/EEC concerning medical devices

SaMD KOLIBRI Class IIa according to the **ANNEX IX Sect. II clause 2.3** – of the Directive 2007/47/EC of the European Parliament and the Council amending Council Directive 93/42/EEC concerning medical devices

SaMD KOLIBRI **Class A** according to the IEC 62304:2006/AMD 1:2015 (IEC 62304:20015 ed.1.1) Medical device software - Software life cycle processes -Amendment 1

TR 753-UA Annex 2 Clause 18 - Active medical device, designated for diagnostics, are classified up to class IIa.

According to CISPR 11: 2015 + AMD1: 2016 + AMD2: 2019 CSV – Class B

GMDN 46565

UMDNS 12461

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

Note: SaMD - Software as a medical device Requirements for FDA, EU

Read this IFU carefully before use of the MD KOLIBRI

The present IFU contains the description of device, operating principle, technical characteristics and operating instructions for the MD KOLIBRI.

Abbreviations and Definitions used:

MS	Medical system is an integrative medical solution for screening diagnostics, which combine hardware and software parts, that work in conjunction, using remote access and AI/ML algorithms of data processing.
SaMD=HSP	The software is called Software as a Medical Device (SaMD), as it is defined in *IMDRF SaMD WG N10/Software as a Medical Device: Key Definitions*. Accordingly, SaMD is the software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. In our case, the part of MS KOLIBRI, located on a cloud-server is considered as SaMD, being Health Software Product (HSP) at the same time (KOLIBRI HSP).
MD	Medical device – hardware part of the medical system, which is directly used for measurement.
APP	A mobile application, also referred to as a mobile app or simply an app, is a computer program or software application designed to run on a mobile device such as a phone or tablet. App is downloaded from application distribution platforms which are operated by the owner of the mobile operating system, such as the App Store (iOS) or Google Play Store. It is designated to drive the process of measurement, data transfer and display of the processed results.
HA	Heart activity, or cardiac activity, is the potential difference of the electric field generated by the heart muscle, measured at several points on the surface of the human body
HRV	Heart Rate Variability is the physiological phenomenon of variation in the time interval between heartbeats. It is measured by the variation in the beat-to-beat interval.

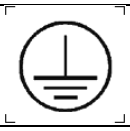
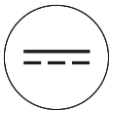
CONTENT

Read this IFU carefully before use of the MD KOLIBRI

Instructions and information necessary for servicing the devices are available for distributors personnel and the staff of authorised service centers upon request

Note: HA (heart activity) - the potential difference of the electric field generated by the heart muscle, measured at several points on the surface of the human body.

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

	General warning sign		General prohibiting sign
	General safety sign		Pattern of sign for mandatory actions
MD Class IIa	MD Class IIa	**IP20**	International protection marking
	Protective ground		Type BF applied part
	Recycle sign	**100-240VAC**	Power the MD
	CE symbol		CLASS II equipment IEC 60417-5172
	Symbol for connection of USB port		Direct current
EC REP	Represented by (*European representative)*		Certificate of Compliance to Technical Regulations for medical equipment (Ukraine)
	Manufacturer		Carefully read the IFU before the first use of the device
	Date of manufacturing	**SN**	Serial number
	Sign of waste electronic equipment		Read operator's manual
IP**20**	First number **2** - Degrees of protection against the infiltration of impurities: protected against solid objects up to 12mm e.g., fingers	Second number **0** - Degrees of protection against the damaging effects of water: No Protection	

1 GENERAL INFORMATION

1.1 GENERAL OVERVIEW

In highly developed countries, public health expenditure rises from year to year due to the ageing population first of all. It is expected that expenditure may reach 8.5% of GDP till 2060 in the EU countries. [1] In addition, the long-term care expenditure projection would on average almost double over the projection period. The impact of these changes is already being felt today and is particularly acute at a time of increased pressure on public budgets, a steady decline in the number of health personnel, higher incidence of chronic diseases and growing demands and expectations from citizens for higher quality services.

In these circumstances, innovative solutions for regular health monitoring come into the fore. Primarily, noninvasive and user-friendly tools, which can ensure reliable, fast and convenient testing of people at any time and place. Those devices become indispensable assistants for health care providers. Working remotely, such equipment will help to reduce queues and add value to the services of medical professionals, ensure better communication and coordination among doctors, nurses, and other specialists involved in the diagnosis and treatment of diseases. Finally, it will have a positive public effect due to focusing on prevention and monitoring of chronic diseases.

MD(s) IDENTIFICATION *(name, type)*

Name: **Personal Health Screening System KOLIBRI®**

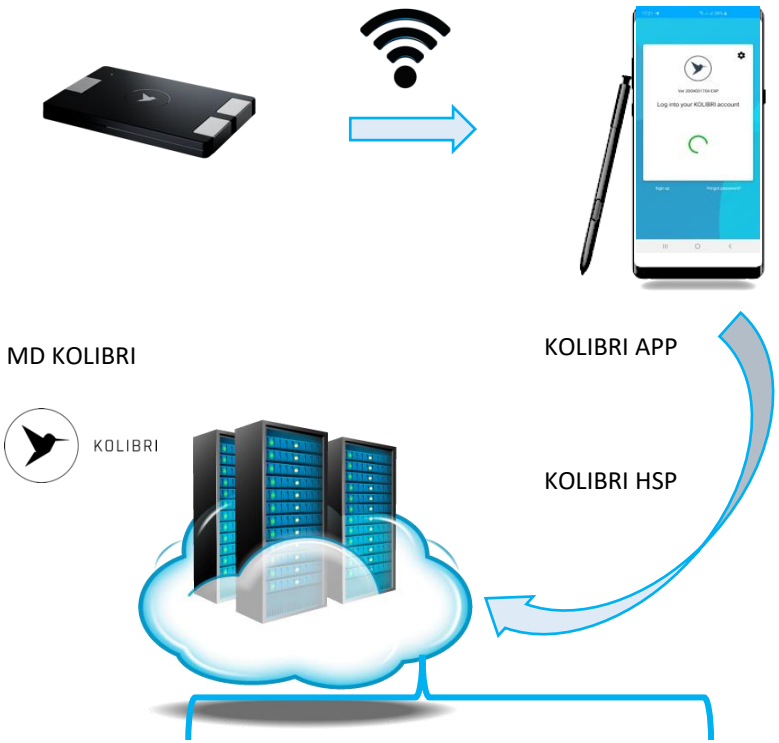
Type: Personal Health Screening System **KOLIBRI®** is a **medical system** realized as a cloud-based solution for **noninvasive health screening of individuals**, both in medical and home settings. It is based on the measurement of heart activity (HA) and heart rate variability (HRV), which analysis in combination with individual data of a person (age, height, weight and gender) allows determining the parameters of the heart, blood indicators, general health parameters and health threats (the list is in clause 1.4).

Medical System KOLIBRI® consists of several modules, namely medical device (MD KOLIBRI), mobile application (KOLIBRI APP) and health software product located on a cloud-server (KOLIBRI HSP). Each of the modules and their interaction are described and shown in Figure 1.1.1 below.

MS KOLIBRI® allows remote patients to enter the initial data of a person (gender, age, weight and height) using the application on a mobile gadget (KOLIBRI APP), to record 1-lead ECG during 5 min using a specially designed device (MD KOLIBRI), transmit all data to a cloud server for processing by specially designed and patented algorithm (patent US 10,531,836 B2 date: Jan.14, 2020) and display the results in KOLIBRI APP or personal account on web (https://kolibri.one). With the patient's consent designated health care provider/professional will have access to patient test results using specially designed cloud software tools and accounts on the web platform https://kolibri.one.

The processing results are presented in the form of a report, that includes health parameters, health threats and ECG findings (number of indicators is in brackets): General health parameters (7), Heart rate variability (30), ECG morphology (11), Complete blood count (9), Lipid metabolism (4), Carbohydrate metabolism (1), Electrolytes (3), Health threats (14) and ECG findings (43).

IMPORTANT NOTE: Information provided by KOLIBRI® is adjunctive (supporting) and should not be solely or primarily relied upon to diagnose. It is intended to complement, not replace, information obtained by the standard methods (classical laboratory blood tests and ECG test). KOLIBRI® provides data useful for periodic monitoring of patients to control their health and identify signs of certain pathologies in the early. The results of testing are to be used by patients only for informational purposes. Any decisions as for health status, therapy or additional diagnostics are to be made only by a responsible healthcare professional. In case exact data of definite parameters are required, they are to be obtained using the appropriate standard methods.



MD KOLIBRI – hardware module of MS KOLIBRI, which acquires and records information about the work of the human heart using the 1st lead of ECG. The embedded chip controls operability of the module, stable connection between MD KOLIBRI and the application installed on the mobile gadget of a user (KOLIBRI APP), as well as the transfer of the measured data to the KOLIBRI APP (via Bluetooth).

KOLIBRI APP – mobile application intended for entering the information about a tested person, driving the process of measurement, receiving and transferring the entered and measured data to the cloud server, where the algorithm of calculation is placed (KOLIBRI HSP), receiving and displaying the results of calculation to the user.

KOLIBRI HSP - software module of the MS KOLIBRI, which is located on the cloud server(s) and enables remote processing of measured HA and HRV data from authorized users based on the innovative algorithm installed. Immediately after processing, the results of testing are available in a personal cabinet/account of the user on the web-site https://kolibri.one (or its regional versions) and in the mobile application of the user. The method is patented (US 10,531,836 B2); it uses autoregressive linear prediction model based on HA properties, allowing determination of a number of blood parameters (CBC and biochemistry), parameters of heart rate variability, certain health threats and cardiac abnormalities.

KOLIBRI HSP is SaMD software in the meaning of IMDRF SaMD WG N10/Software as a Medical Device: Key Definitions.

The results of testing are available both via the customer interface of the Internet platform KOLIBRI.ONE (KOLIBRI HSP) and in the mobile application – KOLIBRI APP.

The results of testing are not stored in the KOLIBRI APP or a gadget memory. The result of testing is received from the internet platform (KOLIBRI HSP) each time when a person requests it.

Using a personal account (cabinet), the registered user can see the results of all successfully completed tests. The user has the ability to share his/her results with a medical care provider.

Fig.1.1.1 Personal Health Screening System KOLIBRI®. THE MODULES and INTERACTIONS

1.2 METHOD OF MEASUREMENT

Basing on the measurement of HA signal, the medical device KOLIBRI allows detecting the relevant cardiac diseases and/or abnormalities in the heart work. It is intended for use by adults, at any time of the day while the user goes about his normal activities.

The measurement is made while sitting, with calm breathing. The situation during the clinical investigation should be calm.

It is necessary to eliminate all obstacles leading to emotional arousal, not to talk, to exclude phone calls and the appearance of other persons. During the study period, the patient should breathe without taking deep breaths, not cough, not swallow saliva.

The clinical investigation is conducted no earlier than one hour after taking potent drugs and smoking. The measurement may be incorrect in people under the influence of alcohol, drugs, sedatives and psychotropic substances, as well as patients with severe fever and in a severe condition.

Values of the heart rate should be within the limits of norms: 60 -90 beats per minute.

Such heart rhythm disturbances as flutter and ventricular fibrillation, paroxysmal tachycardia, frequent, especially polytopic extrasystole, as well as atrial ventricular conduction disturbances (Wenckebach periods, incomplete or complete atrioventricular block), the presence of an artificial pacemaker can affect the measurement accuracy.

Before starting the first measurement, it is necessary to fill in the required fields in the mobile application (the following information is essential: age, weight, height, gender, does he have diabetes, smokes, does he use drugs, blood type and Rh). Duration of measurement: 5 minutes. Internet access required.

It is required to make an examination when a patient is calm, had no physical activity during 5-10min, in the sitting position in a room with a comfortable temperature (in the ranges +20 ºC and +27 ºC) and humidity less than 80%.

1.3 INTENDED USE OF DEVICE

Personal Health Screening System KOLIBRI® is **intended** to acquire, analyse and display information on heart activity (HA) and heart rate variability (HRV), as well as to determine and display blood indicators, general health parameters and health threats (listed below) based on the analysis of HA and HRV in combination with the initial data of a person (age, gender, weight and height) according to a patented algorithm.

It is used both for self-testing by patients (home settings) and in health care institutions (medical settings) as an adjunctive screening tool for adults.

Obtained and determined parameters and indicators are not intended for any specific clinical diagnosis. The clinical significance of information from the report must be determined by the medical care professional.

Healthcare professionals have the ability to use all KOLIBRI® features. Using the information provided by KOLIBRI® in the report of testing, as well as the medical knowledge on human physiology and pathology, a doctor can make a decision about existing disorders or recommends additional examinations. Undoubtfully, a combination of MS KOLIBRI® and other methods of diagnostics will be the most beneficial for a comprehensive investigation of a health state of the patient.

At the same time, individuals, who use the MS KOLIBRI® for self-testing, can run measurements and receive reduced reports with the results and advices to visit a physician if signs of certain health threats were identified. The information in a report is not intended for self-diagnostics by a person. MS KOLIBRI® does not set diagnoses, so the report does not contain such type of information.

The intended fields of application for the MS KOLIBRI® are the following: self-screening diagnostics (home-use), periodic monitoring of patients by private and family doctors/physicians, testing patients in clinics, medical research centres, rehabilitation and spa centres, and other medical institutions of necessity. In addition, MS KOLIBRI® can be involved in telemedicine projects, as it includes a portative tool with dedicated software, which allows a person to make a test anywhere and shares the results with a health care provider(s), being far away from them.

Each of MS KOLIBRI® modules performs its specific functions and differs by intention.

So, mobile application KOLIBRI APP is installed on gadgets (smartphones, tablets) and intended for entering the information about a tested person, driving the process of measurement, receiving and transferring the entered and measured data to the server KOLIBRI (KOLIBRI HSP) for processing, as well as displaying the results of calculation at the end. The device KOLIBRI (KOLIBRI HW) is intended for recording the signals of the heart (heart activity) – the 1st lead ECG, controlling the operability of the hardware and connection with the KOLIBRI APP, as well as transferring the obtained signals to KOLIBRI APP via Bluetooth. Finally, KOLIBRI HSP is intended for processing and analysis of all the received data using the Deep Learning Algorithm, generating the report of testing with all the parameters determined and findings identified. KOLIBRI HSP has client embedded part, which gives access to the results using the Internet browser (personal accounts on the platform https://kolibri.one). Additionally, the results are sent to the KOLIBRI APP for displaying.

1.3.1 **THE INTENDED PATIENT POPULATION(S) AND INDICATION FOR USE/**medical condition(s) to be diagnosed by the device (indications for use) and other considerations such as patient selection criteria:

MS KOLIBRI® can be used for one-time or periodic testing of adult individuals (18 y. and older), both sexes, who lives in atmospheric pressure zones within the ranges 650-765 mm Hg (86-102kPa) and where humidity is 20%-80% without condensation, based on the determination of certain health parameters and risk of diseases available for identification by the MS KOLIBRI®. The list is given below.

The target group of users is general practitioners, cardiologists, etc.

1.3.2 **THE REASONABLY FORESEEABLE MEDICAL CONDITIONS FOR WHICH THE SYSTEM IS NOT TO BE USED (CONTRAINDICATIONS):**

It is not allowed to use MS KOLIBRI in pediatrics, for pregnant women, for patients in critical and urgent states, in ICU department (both in the operation room and Emergency Room), for people with heart rate less than 40 and higher than 120 bpm, for bed-ridden patients, patients with an implanted artificial pacemaker and heart rhythm abnormalities, such as ventricular fibrillation, paroxysmal tachycardia, premature beats, violations of atrioventricular conduction (Wenckebach periods, incomplete or complete atrioventricular block, except the atrioventricular block of the first degree), for individuals who are (were) treated with chemotherapy and X-Ray therapy, for those who suffering from jaundice or acute kidney insufficiency, for donors after blood transfusion (the limited period for donors is 6 months) and for recipients after blood transfusion (the period is not determined, as it primarily depends on the initial state of a patient before transfusion and the ability to recover).

If an individual has any damage to the skin surface at areas contacted with the device, including but not limited to wounds, ulcers, injuries, inflammation and rashes etc., then it is not allowed to make a measurement (places of contact are on the pictures below: Fig.1.2 and 1.3).
MS KOLIBRI should be used with cautions by the following patients/in the following cases:
- by patients with diabetes mellitus type I for estimation of carbohydrate metabolism;
- by people with a heart rate lower than 50 and higher than 100 bpm because when it exceeds the resting ECG range (50-100 bpm), the accuracy of measurement, diagnostic and prediction dropdown.

1.3.3 **GENERAL DESCRIPTION OF KOLIBRI®** including its principles of operation, capabilities, the inputs and outputs

The technology of MS KOLIBRI® is based on the measurement and processing the data of cardiac work, particularly heart activity (HA) and heart rate variability (HRV) using a special algorithm invented by the team. The main idea is that autonomic nervous system (ANS) affects heart activity and controls the work of organs responsible for blood circulation, respiration, digestion, excretion and reproduction, as well as metabolism and growth (details are available in clause 1.5 below). Therefore, analysing the changes in one of the constituent parts of this "physiological equation", we have an ability to determine the value of others.

The algorithm of KOLIBRI combines two methods of ECG signal processing:

By analysing R-peaks of HA signal - Allows identification of Heart Rate Variability parameters (HRV), heart pathologies, access general health and emotional state. The level of noise of the ECG signal has a relatively small impact on the results. The signal can be taken from any two left/right points of the human body.

By analysing Morphology of the HA (related patent) - Allows determination of the parameters of blood metabolism, ECG abnormalities and certain health risks. In this case, the noise level has a greater impact when compared to the R-peak method. Therefore, the R&D team paid considerable attention to the processing of high-noise signals, that allowed improving the reliability of determining parameters and health risks. Exactly the data of the morphology of HA allows determining a wide range of pathologies, including diabetes. The current method is complex, but it also has the highest potential for further development.

KOLIBRI has patented methodology (US 10,531,836 B2) that uses autoregressive linear prediction model based on HA properties, which allows identification of biochemical parameters (blood metabolism).

PROCEDURE of TESTING with MS KOLIBRI

The process of testing includes 3 steps, they are the following:

1) to enter the data of a tested person into the software, using the mobile application KOLIBRI - usually, it takes less than 1 min. It takes even less time for further tests because partially the information is kept by default. The required fields in the mobile application are age, weight, height and gender. Also, it is necessary to tick if a person has diabetes, smokes, use drugs. Optionally, the information about blood type and Rh can be indicated, too;
2) to take the device KOLIBRI into the hands (palms) or place the ECG electrodes onto the body, if necessary, and start measurement - the process of ECG signal recording takes 5 min (see pictures below on Fig.1.2 and 1.3).

3) to read the results of the test in the application or using the personal account on the platform https://kolibri.one. - the processed data are returned from the cloud server to the application, as well as to the web-account, within a minute. The time of data transfer mostly depends on the speed of the Internet connection.

The measurement is carried out while sitting or lying on the back, with calm breathing. It is important to avoid any sources of emotional arousal, such as talking, phone calls and other distractions.

The measurement with MD KOLIBRI can be done in two ways, and they are the following:

1. in palms - if integrated contact electrodes are used for the measurement (fig.1.2);
2. on forearms or body - if standard electrodes with single-use pads or clips are used (fig.1.3).

Fig.1.2 Integrated electrodes

Fig.1.3 Standard electrodes

Access to the results of testing is secured and personalized. The user can share the results with a healthcare provider(s) once or on a regular basis by allowing the designated physician to access the results remotely. Both ECG records and full test reports are available for review by healthcare professional(s). While ordinary users receive shorten report, which includes general parameters of health and advice to visiting a physician if certain health risks are identified. A sample of the Test Report is in Annex 1.

A healthcare professional/physician can create and handle own database of patient, as well as serve self-connected users to MS KOLIBRI as "remote patients".

So, the **INPUT DATA** includes the information about a tested person entered into the application (step 1) and measured data of heart activity (step 2). After processing of the input data, the results of testing are available in the personal account on the web platform or in the mobile application (step 3). That report is considered as **OUTPUTS** of the MS KOLIBRI, it includes the following:

General Health Parameters (7)	
Name	**Description**

HR	Heart Rate is the speed of the heartbeat; measured by the number of contractions (beats) of the heart per minute (bpm). The heart rate can vary according to the body's physical needs, including the need to absorb oxygen and excrete carbon dioxide.
Health Index	Health index is a number based on scientific calculations from 0 (low index) to 10 (high index), when 0 (zero) is an excellent result. It grows or decreases in real-time and depends on changes in the parameters of your body, emotional well-being and lifestyle.
Stress Index	The stress index reflects the degree of stress on the body. Stress is a response of the human body to an overstrain, negative emotions, or simply to monotonous bustle. Stress in small quantities is needed by everyone, as it makes you think, to seek a way out of the problem. But severe stress affects health. Immunity decreases and a number of diseases develop (cardiovascular, gastrointestinal, etc.). It reflects the degree of centralization of heart rhythm control and characterizes the activity of the sympathetic department of the autonomic nervous system (the degree to which the activity of central regulation mechanisms prevails over autonomous ones).
BMI	Body Mass Index (kg/m^2) is a measure of body fat based on height and weight that applies to adult men and women. The BMI is a convenient rule of thumb used to broadly categorize a person as underweight, normal weight, overweight, or obese based on tissue mass (muscle, fat, and bone) and height.
BMR	Basal metabolic rate (kcal/day) is a minimum number of calories required for (basal) life-sustaining functions of a body at rest (like breathing, circulation, nutrient processing, cell production) daily, without the influence of physical activity or other impacts. The value is stable within a period of time when there are no great changes in the weight of a person
EE	Energy Expenditure is the number of calories that a body burns at a moment of time. This value fluctuates during a day depending on physical activity
MAP	The mean arterial pressure (MAP) is an average blood pressure in an individual during a single cardiac cycle. It is used by doctors to check whether there's enough blood flow, resistance, and pressure to supply blood to all major organs. Doctors usually consider anything between 60 and 100 mmHg to be normal. MAP in this range indicates that there's enough consistent pressure in the arteries to deliver blood throughout the body.

CBC and CHEMISTRY (13)	
Name	**Description**
HGB	Haemoglobin (HGB) is the iron-containing oxygen-transport metalloprotein in the red blood cells (erythrocytes). Haemoglobin in blood carries oxygen from the lungs or gills to the rest of the body (i.e. the tissues). It also transports carbon dioxide out of your cells and back to your lungs to be exhaled.
HCT	The haematocrit (HCT) is the volume percentage (vol%) of red blood cells (RBC) in blood. Its value depends on the number and size of red blood cells. Because the purpose of red blood cells is to transfer oxygen from the lungs to body tissues, a blood sample's haematocrit—the red blood cell volume percentage—can become a point of reference of its capability of delivering oxygen. Haematocrit levels that are too high or too low can indicate a blood disorder, dehydration, or other medical conditions.

PLT	Platelets, also called thrombocytes are a component of blood whose function (along with the coagulation factors) is to react to bleeding from blood vessel injury by clumping, thereby initiating a blood clot. The number of platelets varies across individuals. The normal physiologic range is 200000 to 500000 per microliter of blood.
RBC	Red blood cells (RBCs), also referred to as erythrocytes, are the most common type of blood cell and the principal means of delivering oxygen to the body tissues—via blood flow through the circulatory system. RBCs take up oxygen in the lungs and release it into tissues while squeezing through the body's capillaries.
WBC	White blood cells (WBCs), also called leukocytes, are the cells of the immune system that are involved in protecting the body against both infectious disease and foreign invaders. All white blood cells are produced and derived from multipotent cells in the bone marrow known as hematopoietic stem cells. Five main types are neutrophils, eosinophils (acidophiles), basophils, lymphocytes, and monocytes.
MCHC	The mean corpuscular haemoglobin concentration (MCHC) is a measure of the concentration of haemoglobin in a given volume of packed red blood cell.
MCV	Mean corpuscular volume (MCV) is the average volume of red cells. MCV allows classification as either a microcytic anaemia, normocytic anaemia or macrocytic anaemia.
MCH	Mean corpuscular haemoglobin level refers to the average mass of haemoglobin (Hb) per red blood cell (RBC) in a sample of blood. MCH value is diminished in hypochromic anaemias.
BCI	Blood carbohydrate index (BCI) is an indicator that characterizes the patient's glucose tolerance for patients with type 2 diabetes. BCI level directly correlates with blood sugar. If the BCI is higher than the reference values (Normal ranges: 49.2-70.8), then the patient's blood glucose is considered above the normal value. And consequently, when BCI is lower than the reference values, then the patient's blood glucose is below the norm.
K	Potassium (K^+) is one of the electrolytes in the body's, which are minerals that carry an electric charge when dissolved in body fluids such as blood. The normal range of serum potassium is 3.5 - 5.0 mmol/L (3.5 and 5.0 mEq/L).
Na	Sodium (Na) is both an electrolyte and mineral. It helps keep the water (the amount of fluid inside and outside the body's cells) and electrolyte balance of the body. Sodium is also important in how nerves and muscles work. Most of the sodium in the body (about 85%) is found in blood and lymph fluid.
Ca	Calcium is the most common mineral in the body and one of the most important. The body needs it to build and fix bones and teeth, help nerves work, make muscles squeeze together, help blood clot, and help the heart to work. Almost all of the calcium in the body is stored in bone.

LIPID METABOLISM (4)	
Name	**Description**
TG	Triglycerides are the main constituents of body fat in humans and other vertebrates, as well as vegetable fat. They are also present in the blood to enable the bidirectional transference

	of adipose fat and blood glucose from the liver and are a major component of human skin oils.
LDL-C	Low-density lipoprotein (LDL) is one of the five major groups of lipoprotein which transport all fat molecules around the body in the extracellular water. These groups, from least dense, compared to surrounding water (largest particles) to most dense (smallest particles), are chylomicrons. LDL delivers fat molecules to the cells and can drive the progression of atherosclerosis if they become oxidized within the walls of arteries. Often, it is called "bad cholesterol", because a high LDL level leads to a build-up of cholesterol in the arteries. But it is an essential transport system for lipids the human body needs to survive. Even "small" LDL is necessary to conduct nutrients to vessels that "large" LDL can't reach.
HDL-C	HDL stands for high-density lipoproteins. It is sometimes called the "good" cholesterol because it carries cholesterol from other parts of a body back to the liver.
CHOL	Cholesterol is an organic molecule, a sterol (or modified steroid), a type of lipid. Cholesterol is biosynthesized by all animal cells and is an essential structural component of animal cell membranes. Cholesterol also serves as a precursor for the biosynthesis of steroid hormones, bile acid and vitamin D. Hepatic cells typically produce the greatest amounts of cholesterol.

HEART ACTIVITY (11)	
Name	**Description**
RR interval	The time between beats is measured in milliseconds (ms) and is called an “R-R interval” or “inter-beat interval (IBI).” While heart rate focuses on the average beats per minute, heart rate variability (HRV) measures the specific changes in time (or variability) between successive heartbeats.
P-wave	The P wave represents the depolarization of the left and right atrium and also corresponds to atrial contraction and is usually 0.08 to 0.10 seconds (80-100 ms) in duration.
PR segment	The PR segment is the flat line between the end of the P-wave and the start of the QRS complex. The PR segment reflects the time delay between atrial and ventricular activation. The PR segment also serves as the baseline (reference line or isoelectric line) of the ECG curve.
PR interval	The PR interval is the time from the onset of the P wave to the start of the QRS complex. It reflects conduction through the AV node. The normal PR interval is between 120 – 200 ms (0.12-0.20s).
QRS complex	The QRS complex is a name for the combination of three of the graphical deflections seen on a typical electrocardiogram. It is usually the central and most visually obvious part of the tracing; in other words, it's the main spike seen on an ECG line. It corresponds to the depolarization of the right and left ventricles of the human heart and contraction of the large ventricular muscles. In adults, the QRS complex normally lasts 0.06–0.10 s; in children and during physical activity, it may be shorter.
QT interval	The QT interval is calculated as the time from the start of the Q wave to the end of the T wave and approximates to the time taken from when the cardiac ventricles start to

	contract to when they finish relaxing. An abnormally long or abnormally short QT interval is associated with an increased risk of developing abnormal heart rhythms and sudden cardiac death.
ST segment	The ST segment represents the isoelectric period when the ventricles are in between depolarization and repolarization. The ST segment connects the QRS complex and the T wave and has a duration of 0.005 to 0.150 sec (5 to 150 ms). The typical ST segment duration is usually around 0.08 sec (80 ms). It should be essentially level with the PR and TP segments. The most important cause of ST segment abnormality (elevation or depression) is myocardial ischaemia or infarction.
ST interval	In an electrocardiogram, the interval that represents ventricular repolarization.
T-wave	In electrocardiography, the T wave represents the repolarization of the ventricles. The T wave contains more information than the QT interval. The T wave can be described by its symmetry, skewness, slope of ascending and descending limbs, amplitude and subintervals like the Tpeak–Tend interval.
Morphology of T-wave	T-wave morphology analysis (TMA) quantifies irregularities of ventricular repolarization. TMA is useful for risk stratification of patients with myocardial infarction (MI).
QTc interval	The corrected QT interval (QTc) estimates the QT interval at a standard heart rate of 60 bpm. This allows comparison of QT values over time at different heart rates and improves detection of patients at increased risk of arrhythmias.

Heart Rate Variability: (30)	
Name	**Description**
ARP index	Index of adequacy of the regulatory processes
AR index	Autonomic rate index
AB index	Autonomic balance index
SER index	Normalized index of summary effect of regulation
ASER index	Conditional index of activity of the sympathetic element of regulation
FCS index	The most probable level of functioning of cardiovascular system
MARI	Maximum amplitude of regulatory influences
TINN	Triangular interpolation of the normal-to-normal interval of a histogram
HRVti	HRV Triangular Index. It demonstrates the general variability of the heart rhythm and is directly proportional to parasympathetic activity.
sdHR	Deviation of heart rate
RMSSD	The square root of the mean of the sum of the squares of differences between adjacent NN intervals. It allows estimating the short-term components of HRV. RMSSD characterizes the activity of parasympathetic autonomic regulation.
pNN50	The proportion derived by dividing NN50 by the total number of NN intervals, when NN50 is the number of interval differences of successive NN cardiac intervals greater than 50 ms, %. The degree of prevalence of the parasympathetic regulation over the sympathetic (relative value).
SDNN	Standard deviation of the "normal-to-normal" intervals. SDNN characterizes the total effect of the sympathetic and parasympathetic systems on the regulation of cardiac

	activity (reduced – predominance of sympathetic regulation; elevated – predominance of autonomic regulation).
MeanRR	Mean RR-interval
MinRR	Minimum RR-interval
MaxRR	Maximum RR-interval
SampEn	Sample entropy measures the regularity and complexity of a time series
Ellipse	Area of the ellipse which represents total HRV (Poincaré plot)
SD1	Poincaré plot standard deviation perpendicular the line of identity
SD2	Poincaré plot standard deviation along the line of identity
DFA1	Detrended fluctuation analysis, which describes short-term fluctuations (α1)
DFA2	Detrended fluctuation analysis, which describes long-term fluctuations (α2)
nLF	Normalized power of the low-frequency band (0.04–0.15 Hz), also called Relative power of the low-frequency band (%)
nHF	Normalized power of the high-frequency band (0.15–0.4 Hz), also called Relative power of the high-frequency band (%)
LF/HF	Ratio of LF-to-HF power (%)
VLF	The absolute power of the very-low-frequency (VLF) band (0.0033–0.04 Hz) reflects even slower modulations of heart rate (ms^2). The VLF band may represent the influence of the peripheral vasomotor and renin-angiotensin systems
LF	The absolute power of the low-frequency (LF) band (0.04–0.15 Hz)
HF	The absolute power of the high-frequency (HF) band (0.15–0.4 Hz)
TP	Total power (TP) is the sum of the energy in the VLF, LF, and HF bands for short-term recordings (less than 24h)
RSA	Respiratory sinus arrhythmia (RSA) is heart rate variability in synchrony with respiration, by which the R-R interval on an ECG is shortened during inspiration and prolonged during expiration. Although RSA has been used as an index of cardiac vagal function.

RISK OF PATHOLOGIES (14) **based on ECG findings + HRV diagnostics**	**displayed only if identified**
ICD-10	**Description**
I21	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
R94.31	Abnormal electrocardiogram
I44.0	Atrioventricular block, first degree
I44.5	Left posterior fascicular block
I44.7	Left bundle-branch block, unspecified
I45.6	Pre-excitation syndrome
I45.9	Conduction disorder, unspecified
I44.4	Left anterior fascicular block
I45.1	Other and unspecified right bundle-branch block
R00	Tachycardia, unspecified
R00.1	Bradycardia, unspecified
I24	Other acute ischemic heart disease
I45.81	Long QT syndrome
I48	Atrial fibrillation and flutter

ECG FINDINGS (43) based on HA			displayed only if identified
Method and corresp. Code		ICD10	Description
Simplified Minnesota Code	1.11	I21	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
Simplified Novacode Code	5.1		Q wave MI; major Q waves with or without ST-T abnormalities
Simplified Minnesota Code	1.12		ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
Simplified Novacode Code	5.2		Q wave MI; moderate Q waves with ST-T abnormalities
Simplified Minnesota Code	1.21		ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
Simplified Novacode Code	5.3		Possible Q wave MI; moderate Q waves without ST-T abnormalities
Simplified Minnesota Code	1.22		ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
Simplified Novacode Code	5.4		Possible Q wave MI; minor Q waves with ST-T abnormalities
Simplified Minnesota Code	4.3	R94.31	Minor ST-T abnormalities
Simplified Minnesota Code	4.4		Minor ST-T abnormalities
Simplified Novacode Code	5.5		ST abnormalities without Q waves
Simplified Minnesota Code	5.1		T wave abnormalities without Q waves / Possible Q wave MI; minor Q waves with ST-T abnormalities / Q wave MI; moderate Q waves with ST-T abnormalities
Simplified Novacode Code	5.6		T wave abnormalities without Q waves
Simplified Minnesota Code	5.2		Left ventricular hypertrophy with ST-T / T wave abnormalities without Q waves / Possible Q wave MI; minor Q waves with ST-T abnormalities / Q wave MI; moderate Q waves with ST-T abnormalities
Simplified Novacode Code	5.7		Minor Q waves without ST - T abnormalities
Simplified Minnesota Code	5.3		Minor ST-T abnormalities
Simplified Minnesota Code	5.4		Minor ST-T abnormalities
Simplified Novacode Code	5.8		Minor ST-T abnormalities
Simplified Novacode Code	1.41	I47.1	Supraventricular tachycardia, rate < 130 cpm
	1.42		Supraventricular tachycardia, rate ≥ 130 cpm
Simplified Minnesota Code	6.3	I44.0	First-degree AV block (AVB1)
Simplified Novacode Code	2.1		Atrioventricular block, first degree
Simplified Minnesota Code	7.7	I44.4	Left anterior fascicular block (LAFB)
	7.11		Left bundle branch block without ECG evidence of myocardial infarction (MI)/ QRS duration ≥ 120 ms
Simplified Novacode Code	3.1		Left bundle branch block without ECG evidence of myocardial infarction
Simplified Novacode Code	3.11		Left bundle branch block with possible myocardial infarction (MI)
Simplified Minnesota Code	7.21	I45.1	Right bundle branch block without ECG evidence of MI/ Right bundle branch block with possible MI/QRS duration ≥ 120 ms
Simplified Novacode Code	3.2		Right bundle branch block without ECG evidence of MI
Simplified Minnesota Code	6.6	I45.9	Intermittent aberrant atrioventricular conduction
Simplified Minnesota Code	7.4		Indeterminate ventricular conduction delay without ECG evidence of MI/ QRS duration ≥ 120 ms
Simplified Novacode Code	3.1		Indeterminate ventricular conduction delay without ECG evidence of MI
Simplified Novacode Code	3.31		Indeterminate ventricular conduction delay with possible MI
Simplified Novacode Code	3.41		Borderline delay of right ventricular excitation
Simplified Novacode Code	3.42		Borderline delay of left ventricular excitation
Simplified Novacode Code	4.11	I45.81	Marginal prolongation of ventricular repolarization
Simplified Novacode Code	4.12		Significant prolongation of ventricular repolarization
Simplified Minnesota Code	3.1	I51.7	Left ventricular hypertrophy without ST-T

Simplified Minnesota Code	4.11		Left ventricular hypertrophy with ST-T/ST abnormalities without Q waves
Simplified Minnesota Code	4.12		Left ventricular hypertrophy with ST-T/ST abnormalities without Q waves
Simplified Minnesota Code	4.2		Left ventricular hypertrophy with ST-T/ST abnormalities without Q waves
Simplified Minnesota Code	6.41	I44.7	QRS duration ≥ 120 ms/Ventricular preexcitation pattern (WPW)
Simplified Minnesota Code	6.5	I45.6	Short P-R interval
Simplified Minnesota Code	7.6	I44.5	Left posterior fascicular block (LPFB) / Borderline delay of left ventricular excitation
Simplified Minnesota Code	8.7	R00	Sinus Tachycardia (ST)
Simplified Minnesota Code	8.8	R00.1	Sinus Bradycardia (SB)
Simplified Minnesota Code	9.2	I24	Infarction / Ischemia
Simplified Minnesota Code	9.1	R94.31	Low QRS amplitude
Simplified Minnesota Code	9.5		T-wave amplitude > 12 mm

1.4 CONTRAINDICATIONS

It is not allowed to use MD KOLIBRI in pediatrics, in critical and urgent states, in ICU department (both in operation room and Emergency Room), for patients in a process of chemotherapy and X-Ray therapy or after it, for patients with diabetes mellitus (type I), jaundice, acute kidney insufficiency, for donors after blood transfusion (limited period for donors is 6 month) and for recipients after blood transfusion (period is not determined, as it primarily depends on the initial state of a patient before transfusion and the ability to recover), for patients with the presence of an artificial pacemaker.

Damages of a skin surface of a patient (of different nature: wounds, ulcers, injuries, inflammation and rashes etc) in the areas of sensors' placement are the absolute contraindication to an examination.

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

2 WARNING AND SAFETY AND/OR SECURITY INSTRUCTIONS

2.1 GENERAL SAFETY RULES

It is prohibited to use the KOLIBRI, in case below-mentioned requirements are not fulfilled:

- temperature in a testing room must be in the range of +20 ºC and +27 ºC;
- relative humidity in a room must be less than 80% at the temperature +25 ºC;
- presence of aggressive vapour in a room should be excluded;
- dusty spaces are prohibited (a condition in a room should meet the requirements for medical institutions in the country);
- presence of strong electric-magnetic fields (more than 50μT) should be excluded;
- influence of direct sunshine and direct flow of conditioned air are prohibited;
- atmospheric pressure should be in the range of 650-765 mm Hg (87 - 102 kPa).
- the skin on the patient's palms should be moistened
- wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment. MD KOLIBRI should be kept at least a distance 0.3 m (or 1 ft) away from this equipment.
- Do not use the KOLIBRI medical device during the Magnetic Resonance Imaging (MRI) examination procedure

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

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

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

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

It is allowed to use the MD KOLIBRI as screening equipment in hospitals and medical centres, rehabilitation centres and centres of sports medicine, SPA and wellness centres for adult patients (aged 18 and over).

The MD KOLIBRI meets the requirements of the current EU standards for safety of medical equipment (IEC 60601-1:2005+AMD1:2012 (ed.3) “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance” and IEC 60601-1-2 4th Ed as for EMC). Connection of the MD KOLIBRI to the mains supply must be done by the national electrical safety regulations.

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

WARNING! Modification of the MD KOLIBRI is not allowed!

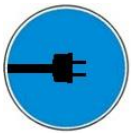
Protect the MD KOLIBRI against moisture condensation. In case of rapid change of the ambient temperature, do not switch on the MD KOLIBRI during at least 30 minutes, it'll let the moisture to evaporate.

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

The charger of a medical device shall conform with mains socket, too.

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

Before the cleaning or maintenance works, unplug the MD KOLIBRI from the power source.



Connect a medical charger only to a working socket with a rated voltage within the range 100 - 240V 50-60Hz. The position of the MD KOLIBRI should ensure that there is no tension on the USB cable and on the cables with three leads, connection and disconnection of the charger from the supply network should be easily available for quick disconnection of the charger and MD KOLIBRI in case of emergencies.

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

It is prohibited to use the MD KOLIBRI in case of damaged cable isolation.

It is prohibited to use any aerosols and liquids for cleaning the device.

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

Usage of the MD KOLIBRI in case of any damage of enclosure, cables leads, USB cable and/or charger is forbidden!

Usage of the MD KOLIBRI as/instead of the laboratory equipment is forbidden.

It is prohibited for a user/operator to take psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol for at least 24 hours before using the device.

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

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

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

Risk of germs transmission exists! MD should be disinfected before and after each use!

It is recommended to power off the device after finishing operating

Only procedures recommended in this IFU are allowed to perform!

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

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

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

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

2.2 MEASURES TO PREVENT DAMAGE TO THE DEVICE

The KOLIBRI should be placed in such a way, when unimpeded connection and disconnection of a charger to/from the power supply network or USB cable to/from a certified charger is ensured. In any case, a USB cable should not impede free movement of an operator/user and/or a patient near the workplace.

Do not connect the USB cable during operation (testing procedure).
The medical device does not allow testing while the battery is being charged.

This device complies with the requirements of the EMC standard (IEC 60601-1-2 4th Ed..). As a rule, the level of emitted electromagnetic interference is so negligible, that it is not able to interfere the operability of most of devices. However, it is recommended to exclude the placement of the KOLIBRI in close proximity to sensitive equipment, the distance of 1 m and more is considered to be sufficient.

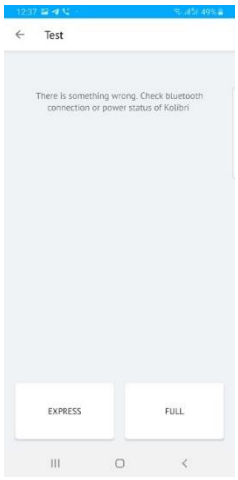
The KOLIBRI and its accessories must be stored in a place protected from the direct sunlight.

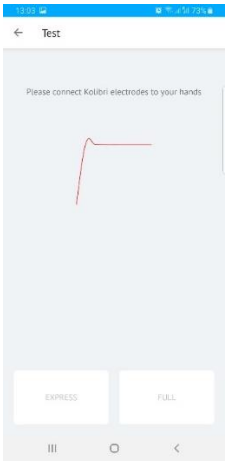
It is prohibited to install the KOLIBRI on a slippery and/or an uneven surface in order to avoid the device from falling down.

It is necessary to exclude a contact of the KOLIBRI and its components with various solvents, gasoline, kerosene and other chemically aggressive substances. Water is not allowed to be in a contact with microprocessors and cables, as drops of water will destroy sensors in fixing points and the measurement will be wrong.
It is forbidden to bend the cables in the place where the USB-C are fixed.

If the KOLIBRI is not connected to the mobile gadget via Bluetooth or the KOLIBRI is turned off, the user receives a warning as follows:

If any of electrodes/contact plates are damaged (by any of reasons), a user is warned in the following way *(troubleshooting is available in Chapters 4.3, 8)*:





3 TECHNICAL DATA OF MD KOLIBRI

According to the method of protection from electric shock, the hardware part of the MS KOLIBRI (the device KOLIBRI) belongs to class I with a working part of type BF.
Degree of protection against penetration of water or solid particles is IP20.
The mode of operation of the MS KOLIBRI is NON-CONTINUOUS OPERATION.

General technical data of KOLIBRI are the following:

Mains voltage (via USB port)	U = 5±1 V DC I ≤ 800 mA
Battery (Lithium Polymer Cell)	LP502060 3.7V 510mAh, installed on the PCB (see the details below)
Consumption	max. 2,5 VA
MD Class	II A
Basic safety/EMC	IEC 60601-1:2005+AMD1:2012 (ed.3)/IEC 60601-1-2 4th Ed
Class of protection against penetration of water or solid particles (IP)	IP 20
Readiness time counted from switching on	max. 10 sec
Net Weight	55 ±5 g
Dimensions	82x56x10 mm
Length of cables with electrodes	0.70-0.85 m (set of cables is optional)
Time of examination	5 min
Applied methods	Definition of human health parameters on the base of HA measured at designated points on a body (on the skin) and anthropometric data of the patient.
Software	KOLIBRI APP (installed on a mobile gadget), KOLIBRI SW (cloud based), the hardware has internal software, preinstalled on a chip
Ambient temperature for storage and transportation	From -5°C (without relative humidity control) till + 45°C (with relative humidity control) Class 7K2, as described in the IEC/TR 60721-4-7:2001
Ambient temperature and humidity during operation of MD	The device is to be used indoor. Environmental conditions should not induce transient conditions in a person such as excessive sweating or shivering from cold. Therefore, a

	comfortable temperature and humidity in the room must be ensured.
Atmospheric pressure (operation)	650-765 mm Hg (87 -102 kPa).
Humidity	15%-93%, without condensation
Temperature range	+20 °C to +27 °C
Humidity of the surface of skin during testing with MS KOLIBRI	90-95% - the skin in places of contact must be moisturized before taking the measurement (ECG gel is preferred; water is possible)
Precision pressure sensor with altimetry	Pressure absolute accuracy (Test conditions: 50 to 110 kPa over−10 °C to 70 °C) - ±0.4 kPa
	Pressure relative accuracy (Relative accuracy during changing temperature between −10 °C to 50 °C at any constant pressure between 50 kPa to 110 kPa)
The temperature of all surfaces the medical device:	The temperature of all surfaces of the medical device does not exceed 40±0.5°C

Minimum requirements to a smartphone or tablet, which are enough to use with MS KOLIBRI

Minimum hardware requirements		Minimum software requirements	
Display	min. 5”-55” definition HD+, FHD+, QHD+, WQHD+ or more	Operating system	Android OS 6 or higher.
Mobile gadget support	LTE, 3G or high, Wi-Fi, BLUETHOOTH 3.0 or hight	Web browser	Any web browser
Antivirus software		Any antivirus software must be set up in such a way when the software KOLIBRI is not blocked.	

As the KOLIBRI has a battery for wireless mode of operation, the following technical features shall be considered:

Battery (Lithium Polymer Cell)	**LP502060 3.7V 510mAh, installed on the PCB**
Charge limited voltage/ Nominal voltage	4.2V/3.7V *(the cell is protected by an electronic circuit that won't allow it to overcharge nor over-discharge under use)*
Rated capacity	500mAh min, 530mAh typ.
Wat-Hour Rating	1.87 Wh
Max. Operating Voltage Range	2.7V to 4.20V
Max. Charge Voltage	4.2V ±50mV
Max. Charge Current	500mA
Discharge Current	500mA
Discharge Cut Off	2.75V
Cycle life (0.5C/0.5C) 23±5°C	500 times *(approximately 1 year of operation)* *One cycle refers to one charge period and then one discharge period. So, cycle life means that after 500 times of discharge-charge, the cell capacity will be reduced to 80% of the rated one.*
Cell Protection	
Overcharge Detection	4.275 ±50mV (0.7 to 1.3sec. delay, release 4.275V ±50mV)
Over-discharge Detection	2.75V ±50mV (14 to 26msec. delay, resume 2.50V ±50mV)
Overcurrent Detection	2A to 4.5A (8 to 16msec. delay)
Ambient Conditions	
Charge Temp. Range	0 to +45 ℃

Discharge Temp. Range	-20 to +60 ℃
Storage Temp. Range	1 year at -20 to +30℃ >70%
Overcurrent Detection	3 moths at -20 to +45℃ >70% 1 month at -20 to +60℃ >70%
Humidity	65 ±20%RH
Environmental and Safety	Please follow LiPo Handling and Safety Precautions for Lithium Polymer Battery. This battery meets the requirements of Battery Directives, and the battery parts are IEC 62133 & RoHS-Compliant. For more safety precautions and performance standards, please go to www.lipolbattery.com/support.html

Batteries have their own life cycles. If the time of working of the KOLIBRI in wireless mode becomes much shorter than usual, the battery cell life is at an end. Please ask your distributor/manufacturer for replacement.

In case the battery is damaged, and the fluid leak is detected, avoid the contact with it. If it liquid leaks onto your skin or clothes, wash thoroughly with fresh water immediately. If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them thoroughly with clean edible oil and visit a medical professional immediately.

With intensive use of the medical device, a full charge of the battery should be sufficient for at least five tests before the next charge. If the battery is not fully charged for five tests, the battery is exhausted. Contact the service centre to replace the battery or purchase a new device.

3.1 EXTERIOR OF THE MD KOLIBRI

MD KOLIBRI

3.2 THE COMPLETE SET OF MD KOLIBRI (WITH ADDITIONAL ACCESSORIES)

The complete set of MD KOLIBRI® includes the following:

	Name of a part	Quantity
	The unit of MD KOLIBRI®	1
	Cable USB-C to USB-A (used for charging) 26 cm	1
	Packaging	1
	IFU (offered in electronic form/available on web https://help.kolibri.one/)	1

Optional accessories are available for order.

Three-lead ECG cable

ECG Electrode

ECG clips

Charger

The AC-DC power supply (charger) SWM6-5-EH-I38 meets the requirements of IEC 60601-1 ed.3.1 and IEC 60601-1-2 4th ed.

*The manufacturer has the right to change the type and model of AC-DC power supply without prior notice. Meanwhile, the technical characteristics of a new charger are to be at least the same as SWM6-5-EH-I38 or better.

4 BEFORE USING MD KOLIBRI

4.1 LIST OF INITIAL ACTIONS AND EVERYDAY ACTIONS BEFORE USE

Initial and routine actions, which are recommended to perform before using the MD KOLIBRI are the following:

INITIAL ACTIONS
✓ Remove the device from its packaging. Make sure there is no damage to the enclosure, USB cable. ✓ Install the application KOLIBRI to your mobile gadget (Chapter 5). ✓ Create your account on the platform https://kolibri.one (Chapter 6.4)
REGULAR ACTIONS BEFORE USE (every time before use)
✓ Check the battery power of the KOLIBRI. ✓ Check the battery power of your mobile gadget ✓ Make sure that Bluetooth is turned on in the mobile gadget and the KOLIBRI is connected. ✓ Make sure your mobile gadget is connected to the Internet. ✓ Determine your weight and hight. ✓ Make sure the surface of your hands is clean and slightly moisturized. ✓ If you are using ECG clamps, make sure that the fixing screws are tight and that the metal plates are slightly moistened or greased with ECG gel. ✓ If you use ECG electrodes, make sure they are not damaged.

IF YOU ARE USING ECG CLAMPS, MAKE SURE THAT THE FIXING SCREWS ARE TIGHT.

The KOLIBRI is ready for use. When the KOLIBRI is ready for a work and software KOLIBRI is run, it's time to start measurement. The process of measurement is described in details in Chapters 8 and 9.

Make sure the rechargeable battery is fully charged before using the medical device. Use the original supplied USB-C to USB-A cable to charge the battery. The cable should be no longer than 30 cm.

Do not test while charging the battery.
The medical device does not allow testing while the battery is being charged.

The battery charging indicator is a yellow LED (it illuminates the on/off button). When the battery is fully charged, this LED goes out.

4.2 REQUIREMENTS TO THE USER/OPERATOR

There are no special requirements for users/operators to perform a test with MS KOLIBRI. A user or operator of MS KOLIBRI is to follow the recommendations of this IFU for the procedure of examination. For the correct use of a medical device, the user must have skills in working with mobile gadgets with the ANDROID operating system installed. Individuals, who use the MS KOLIBRI for self-testing, can run measurements and receive short reports with calculated data and a brief summary on health status. According to the patient's consent, a designated health care provider gets access to the patient test results using specially developed cloud software tools and accounts on the web platform https://kolibri.one (KOLIBRI HSP). Interpretation of the data in a report and setting up the diagnoses are made by health care professionals.

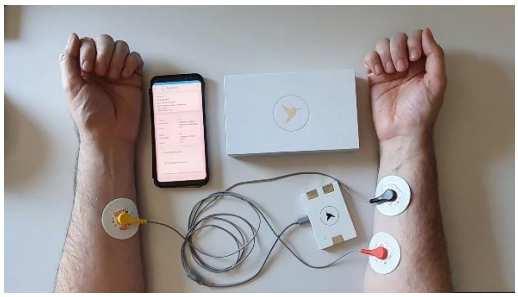
Health care professionals have the ability to use the extended features of MS KOLIBRI. Using the information provided by the MS KOLIBRI in the report of testing, as well as the medical knowledge on human physiology and pathology. Therefore, a doctor has the ability to estimate the obtained data in combination with a patient's history, determine the existing pathologies or recommends additional examinations if necessary.

The operators/users, who took psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol during at least 24 hours before testing should not use the MD KOLIBRI (impact of the mentioned substances is not studied).

Nowadays, the MD KOLIBRI is not intended to use by operators with limited physical and cognitive features, such as motor function, as well as mental disorders, which impede proper performing of the screening procedure.

4.3 CONNECTION OF CABLES TO THE UNIT

You can use two standard types of ECG electrodes for the measurement: either disposable stickers or clips. Anyway, the set of cables for measurement is to be connected to the device KOLIBRI using USB-C slot on the side of the case. Connect the stickers or clips to the cables. Fix them on your hands (forearms) in the following order: yellow electrode - on the left hand, red and black electrodes - on the right hand (shown below).



5 INSTALLATION OF THE MOBILE APPLICATION

MD KOLIBRI requires the installation of specially designed application KOLIBRI onto a mobile gadget (smartphone or tablet). Before installing the KOLIBRI APP, make sure that your gadget has the operating system ANDROID 6.0 or higher. The installation can be done by the USER. Special configuration requirement, no system interface required. The installation instructions are to be found link https://help.kolibri.one/)

During the process of installation, only the file *KOLIBRI.apk* is installed on the gadget of a user.

KOLIBRI APP	**Ver.1.0**

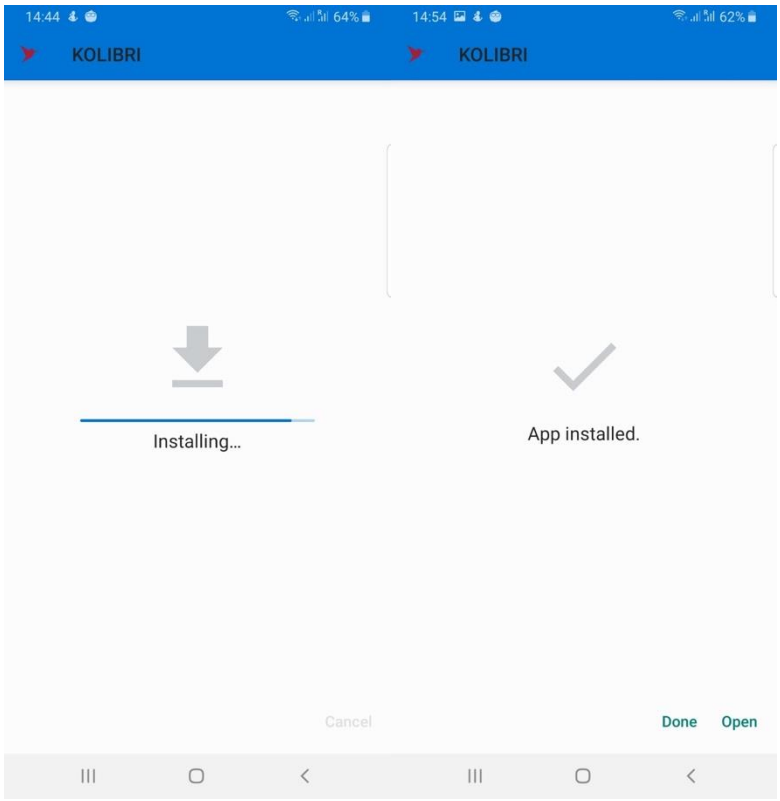
Check that your mobile gadget has an internet connection.

To install/configure the KOLIBRI software, follow the instructions below:

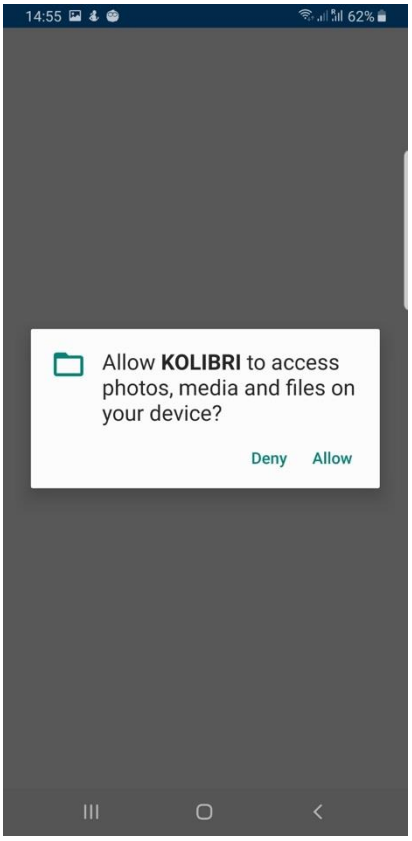
On the mobile gadget, launch the Play Store app.

Search KOLIBRI app, download the mobile app and install it.

Click «OPEN»



Click «ALLOW»



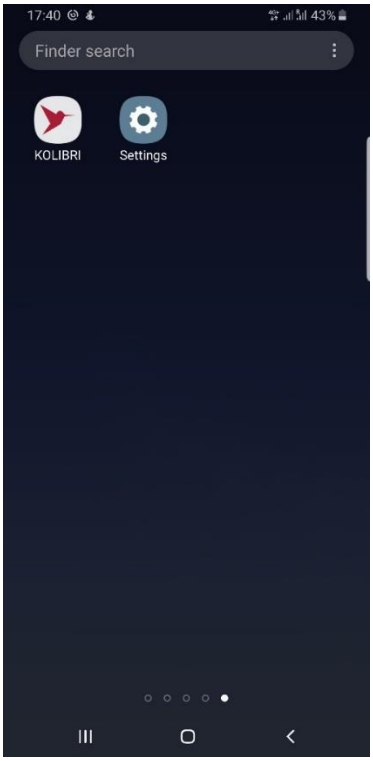
After the mobile application is installed, the icon with the KOLIBRI logo will appear on the desktop of the mobile gadget.

6 START WORKING WITH KOLIBRI

6.1 CONNECTION OF THE DEVICE TO A MOBILE GADGET VIA BLUETOOTH

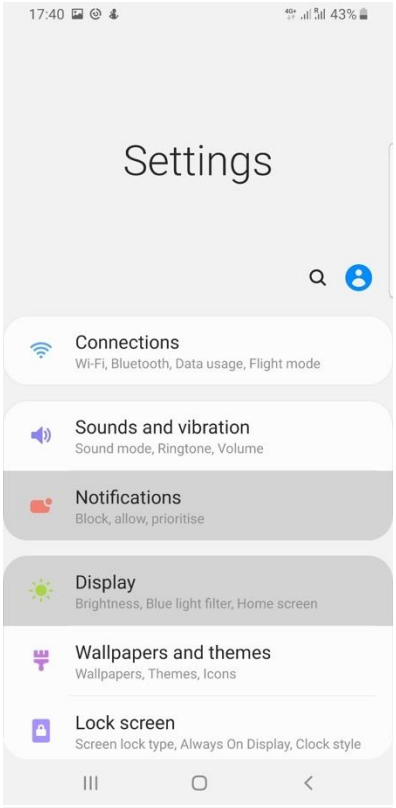
To turn on the device, press and hold the POWER button for at least two seconds until the LED flashing green. The time the medical device is ready for operation after switching on is no more than one second.

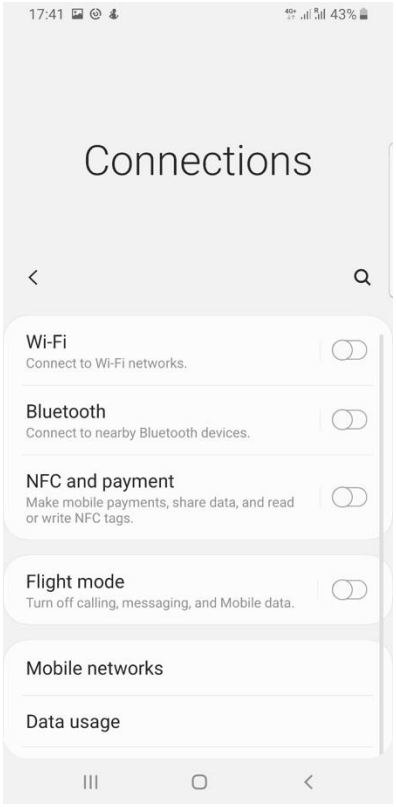
Open the menu “Settings” of your gadget



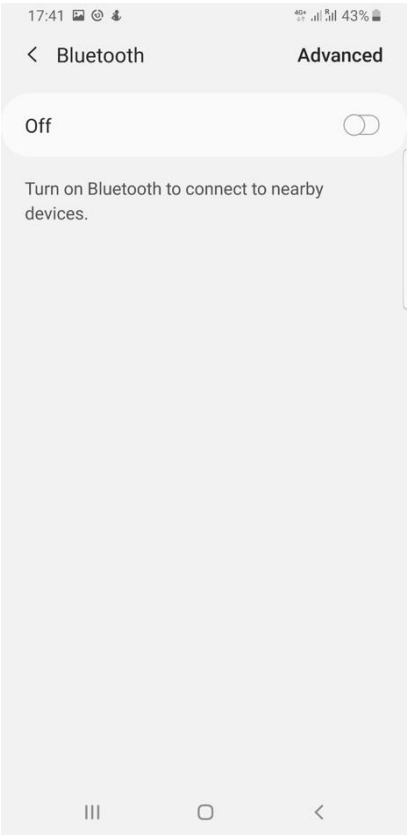
Select the menu “CONNECTIONS”

Select the menu “BLUETOOTH”.

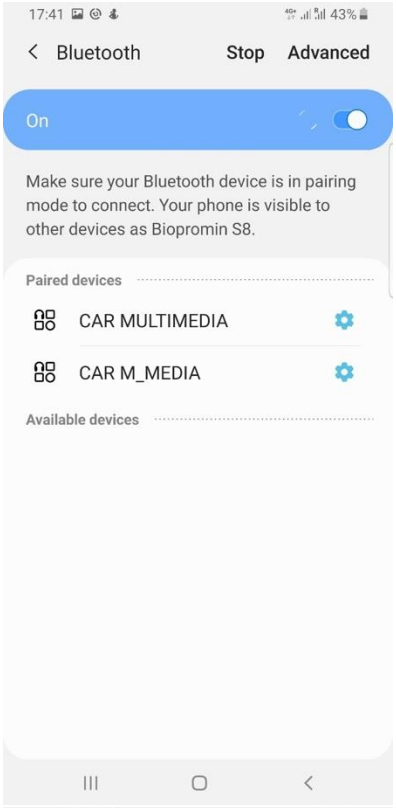


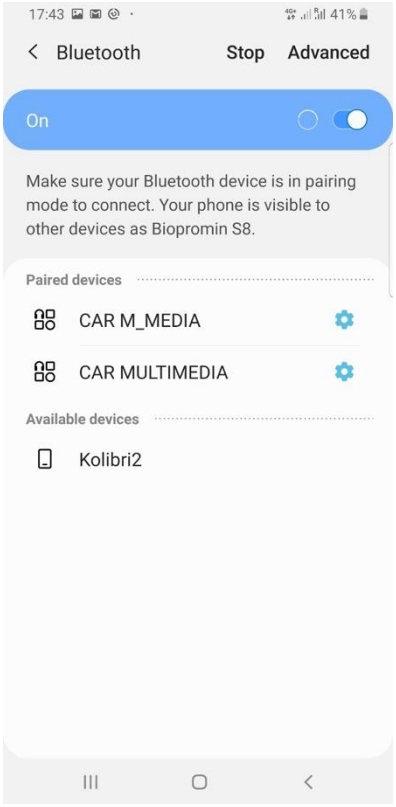


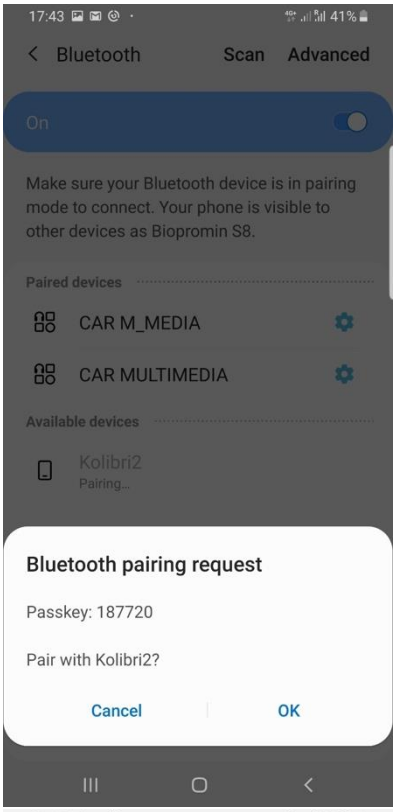
Turn on “BLUETOOTH”



Select the medical device KOLIBRI from the list of available devices

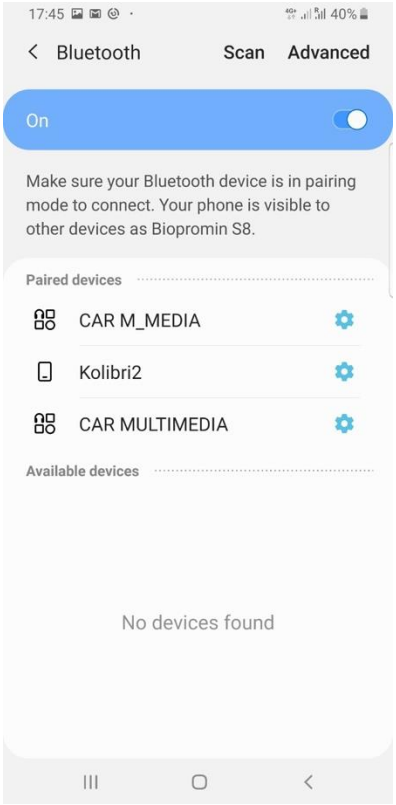




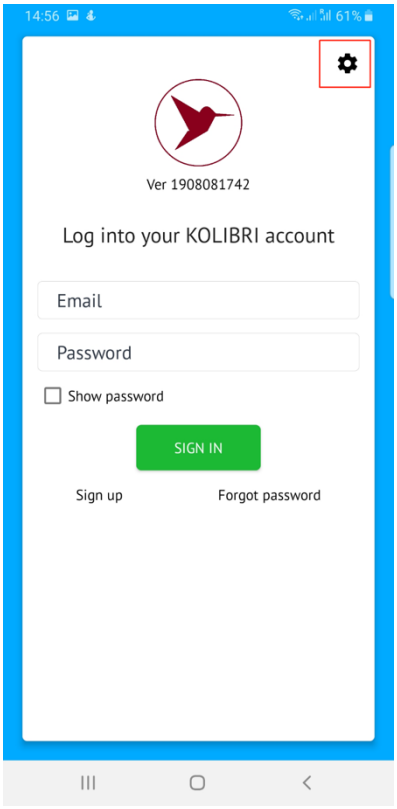


Click «OK»

The pairing of the devices KOLIBRI with your gadget is completed.



6.2 MOBILE APPLICATION

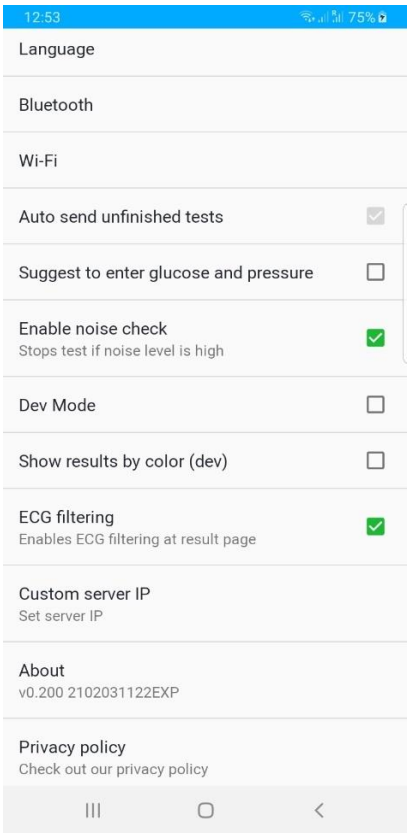


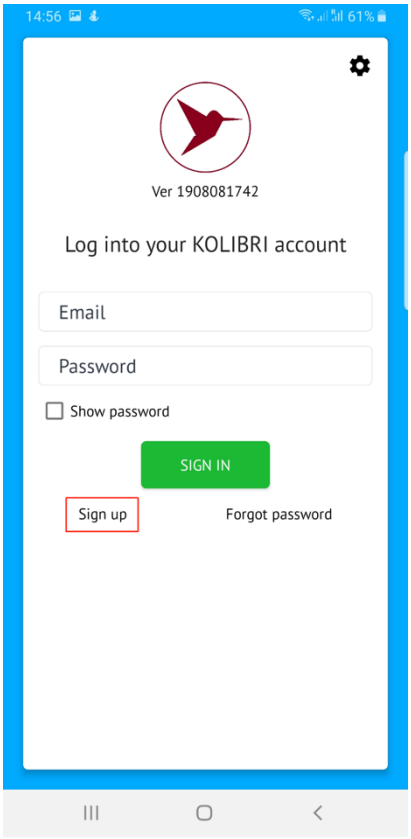
6.2.1. APP SETTINGS

Launch the mobile app.

Make your SETTINGS in the menu 

1. Language – select interface language
2. Bluetooth- opens the BLUETOOTH settings of the mobile gadget.
3. WIFI – opens the settings of a connected mobile gadget to select the WIFI network.
4. Auto Send unfinished – The Internet failures (disconnection, break, loss of packages, etc) can happen during testing with the MD KOLIBRI. If this menu is activated (ticked), then the measured data will be sent to the cloud server for processing automatically when the connection is restored.
5. Suggest to enter glucose and pressure – This menu helps to personalize and improve the future measurements of ADS, ADD, BCI for you. If you activate it (check the box next to this menu), then after each test made with KOLIBRI, you will be asked for the results of arterial blood pressure and glucose value received with tonometer and glucometer (separate devices, which you normally use for blood pressure and glucose level measurements). The data are to be added only if you make the measurements immediately after a test with KOLIBRI. Results received at any other time are not suitable.
6. Enable noise check – If the check box is selected, then the test will be aborted at high noise levels during testing. To eliminate high noise levels during testing, moisten your hands' palms, or use an ECG lead cable.
7. Dev Mode* – Special feature. Used by technicians. Can be unavailable in user's software.
8. Show results by colour – test results will be displayed in colour. The indicators that are normal are displayed in black, and the indicators that are out of the norm are displayed in red.
9. ECG filtering – enable ECG filtering on the results page. If you want to see the original form of the ECG in the test results - do not check this box.
10. Custom server IP - the menu for setting the IP address or server name with which you will work (for example: https://kolibri.one, https://kolibri.ae https://mdevice.eu etc.)
11. About – Latest software release date and number.
12. Privacy policy - provisions on personal data protection. It is updated from time to time.

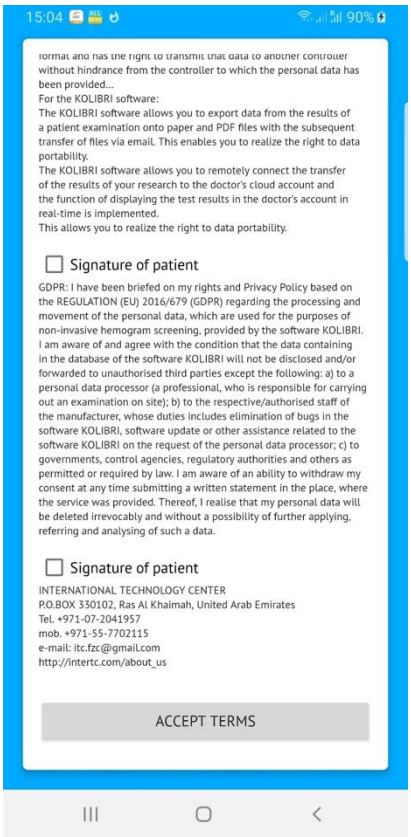




6.2.2 FIRST REGISTRATION and SIGN-IN to MS KOLIBRI

Sign in to the MS KOLIBRI is done every time after log out of the account. If you close the application and do not logout, you will be kept signed in. Therefore, the next time you run the application, sign in will not be required.

During the first login to the MS KOLIBRI, it is necessary to register your device in the system. Please press "**Sign up**" for that.

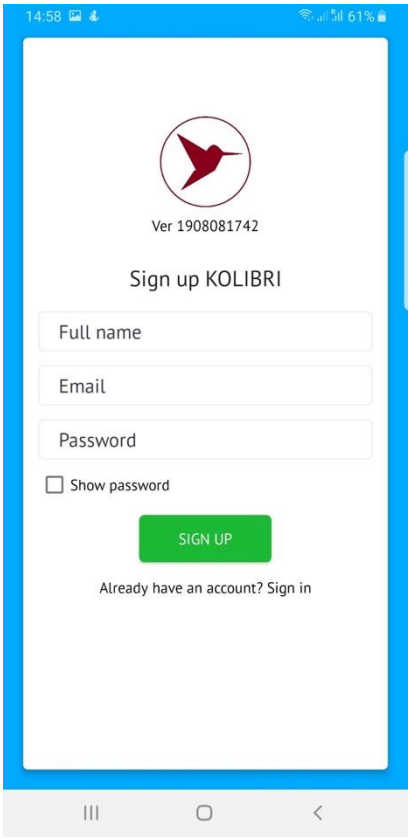


Please, check both boxes if you agree and accept the terms.

On May 28, 2018, the document «REGULATIONS REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of April 27, 2016, has entered into force (hereinafter referred to as the GDPR). GDPR contents the requirements to the protection of natural persons with regard to the processing of personal data and on the free movement of such data. MS KOLIBRI collects only the minimum of your personal data, which are used for calculation of your health parameters. Please read carefully the terms of the GDPR related to the MS KOLIBRI. After each section, please confirm your consent to the processing of your personal data.

If you understand everything and agree to the terms, please tick each of the check-boxes and click on: «ACCEPT TERMS».

Note: If you do not agree to share your personal data with MS KOLIBRI and do not accept the terms of GDPR realized in the MS KOLIBRI, you will not be able to use MS KOLIBRI®, unfortunately.



Enter your name or nickname under which you will register into the FULL NAME field (Name can changed later).

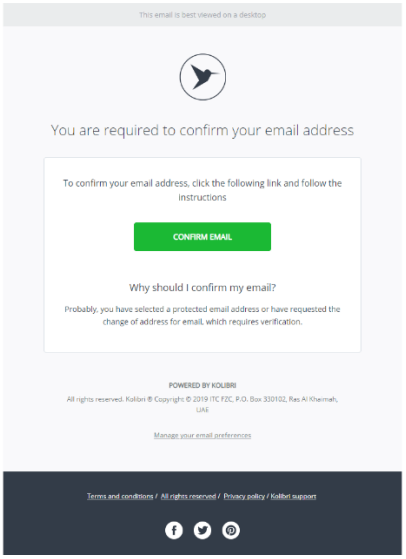
Enter your email address
(Note: entered email address will be used for letters with issued invoices, confirmation letters for authorization and other required acctions. You can change this address later in your personal account if you wish).

You cannot use the same email address for two or more accounts.

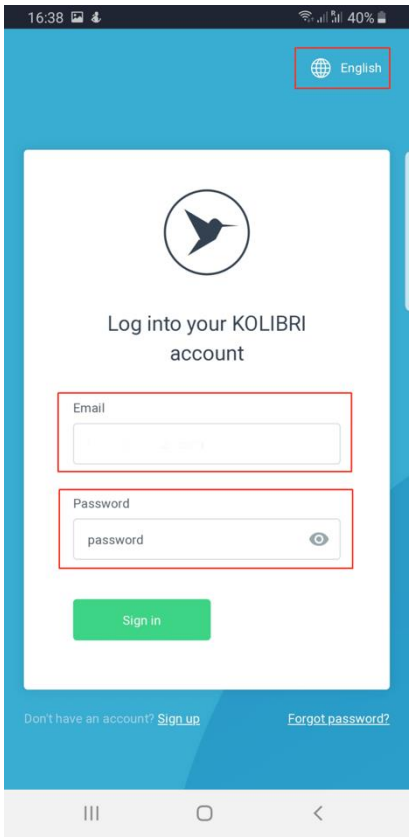
Create a password. Remember it. Enter your password in the text box: «Password»

Press “Sign up”

After clicking the “Sign Up” button, a letter with confirmation link will be sent to your email box.



Open your email box. Check the Inbox and SPAM folders. Open the letter from MS KOLIBRI and click on "**Confirm email**".



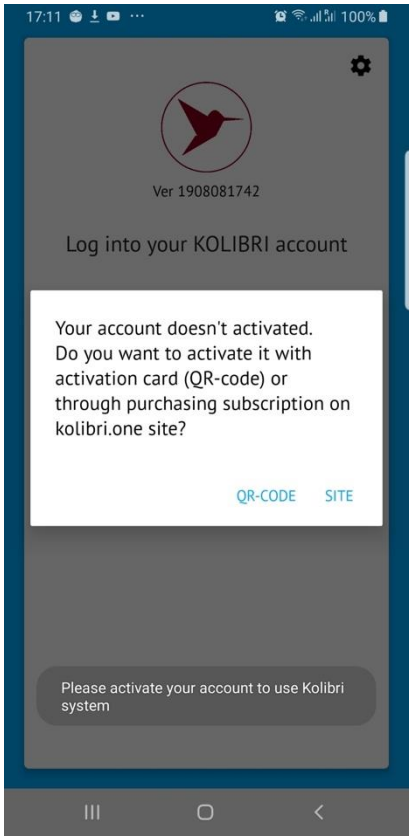
Come back to the KOLIBRI mobile app.

Select an interface language. (English, Spanish, Chinese, etc.)

Enter the username and password to enter your personal account.

Enter the “Sign up” menu

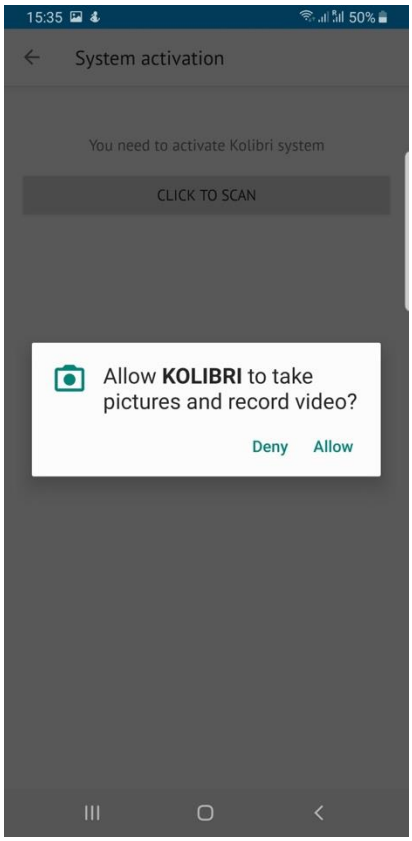
Note: If you have forgotten your password, use the menu "Forgot password?" and your email box.



6.2.3 ACCCOUNT ACTIVATION

It is made only once, during the first signing up.

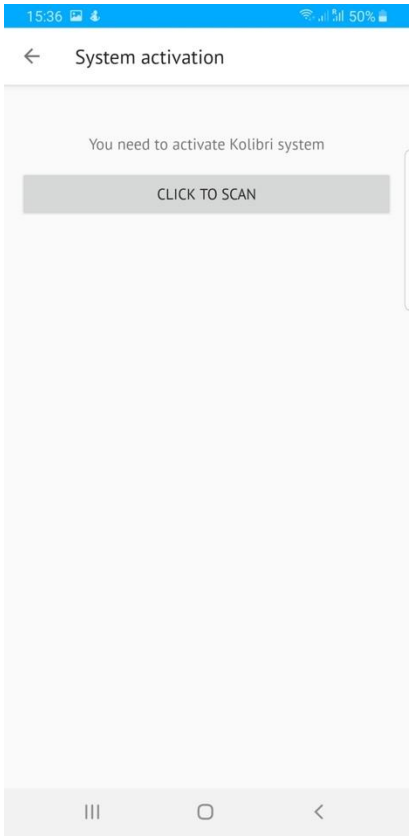
Activation can be performed using QR-code or activation key from the complete set of your device KOLIBRI. Accordingly, please choose one of the options for activation: «QR-CODE» (see 6.2.3.1) or «SITE» (see 6.2.3.2)



6.2.3.1 Activation with QR-CODE

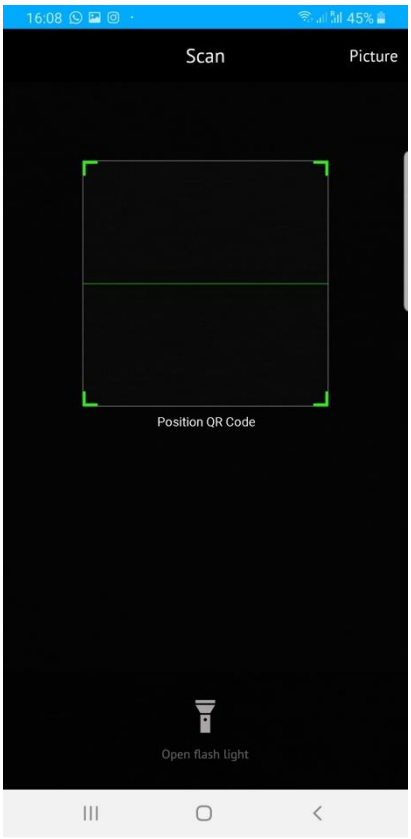
After pressing QR-CODE option, please allow the KOLIBRI APP to take pictures and records video.

This will temporarily save the previous data obtained during the testing process for further transfer to the mathematical cloud platform.



Press “Click to scan”

Scan your QR-Code

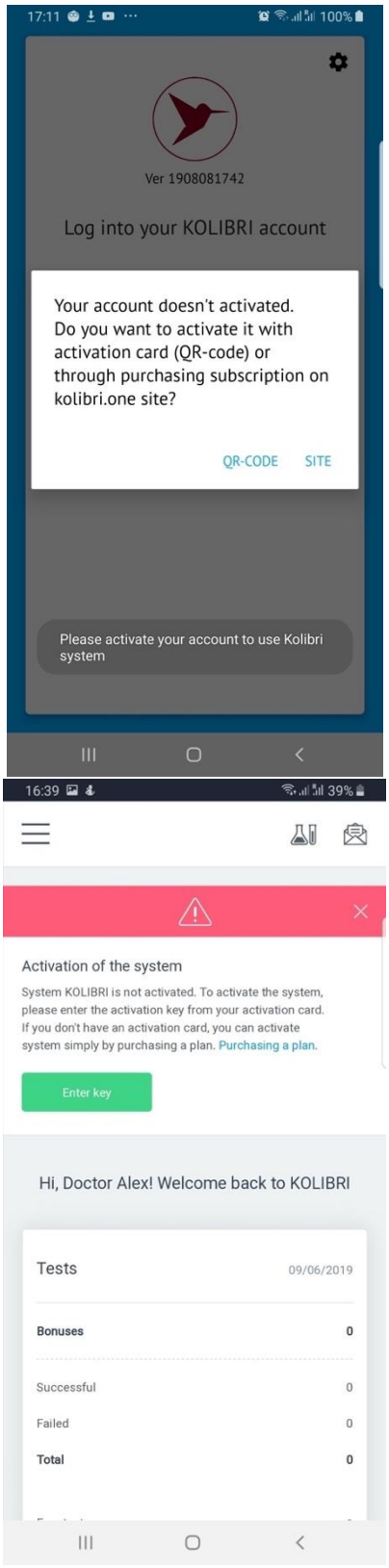


6.2.3.2 Activation with activation key and web-site

If you would like to activate your device using the activation key from the complete set of your device KOLIBRI, please select "SITE"

The activation code consists of letters and numbers and has the form: ABC123D56E78FG90IKLMN. Look for it in the box with the device, or get it from the seller.

If you have QR-Code for activation, please see Chapter 6.2.3.1 above

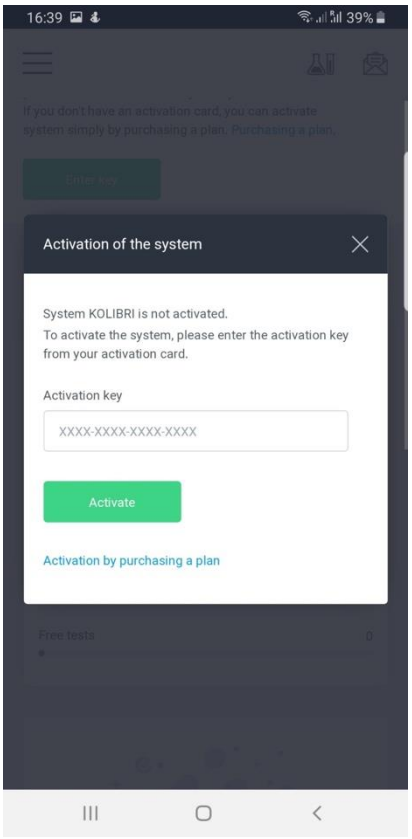


After pressing “Site”, you will be automatically redirected to the website https://kolibri.one

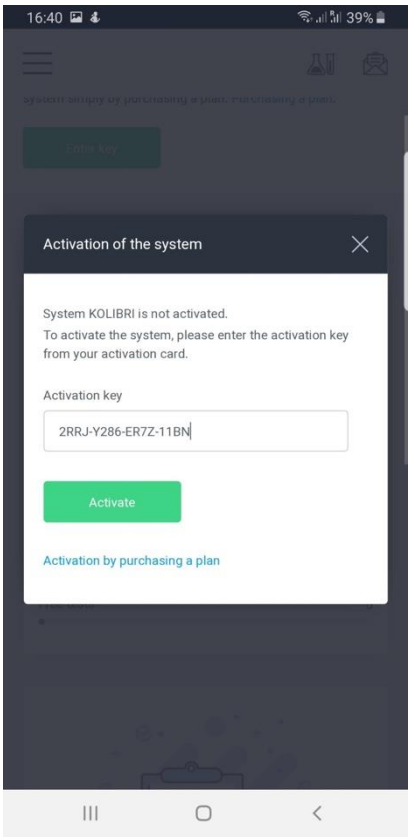
(or another local KOLIBRI website that you have entered in the settings menu. see section 6.2.1 Custom server IP)

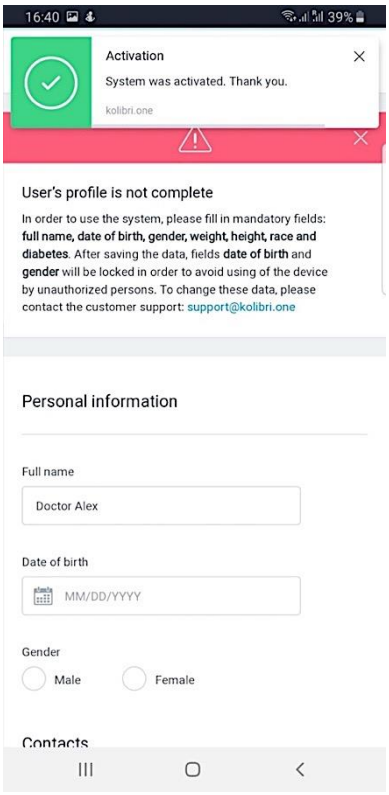
Press «Enter key»

Enter the activation key from the complete set of your device KOLIBRI.



Press «Activate»





A message about successful activation appears at the top of the screen. The red bar will disappear.

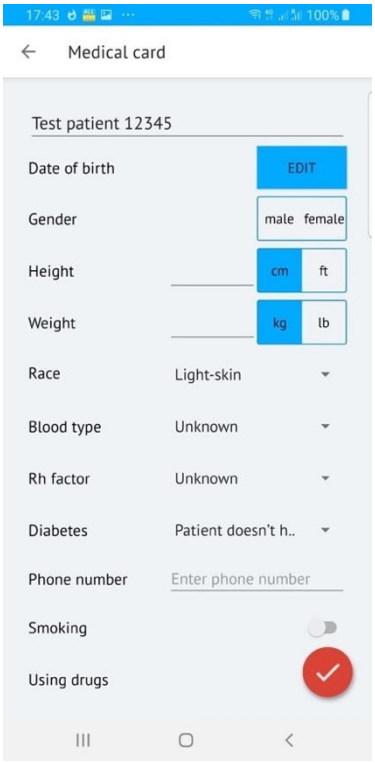
Then, you need to enter your data, i.e. fill out the medical card.

Be sure to enter your date of birth, gender, weight and height. These fields are required for further work with the software. (Chapter 6.2.4)

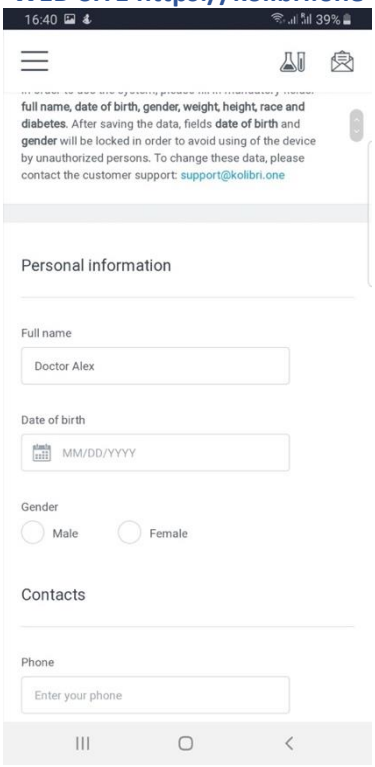
6.2.4 MEDICAL CARD FILLING IN

Depending on the way of the account activation, you have an ability to fill in the medical card either in the mobile application (if you used QR-CODE) or on the web-site (if you used activation key). Once entered data (in APP or on the web-site) will be displayed and used in MS KOLIBRI equally

APPLICATION KOLIBRI



WEB-SITE https://kolibri.one

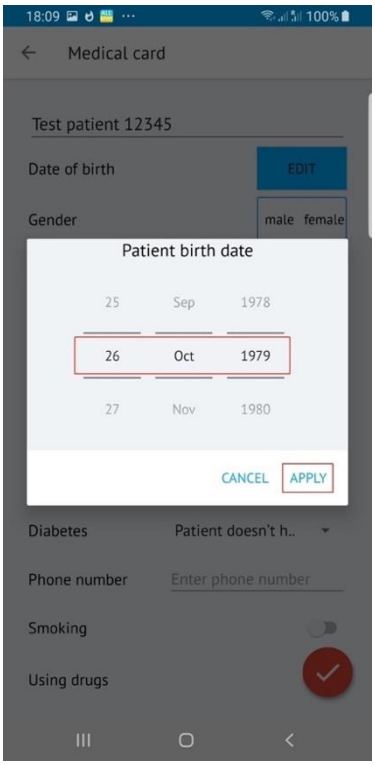


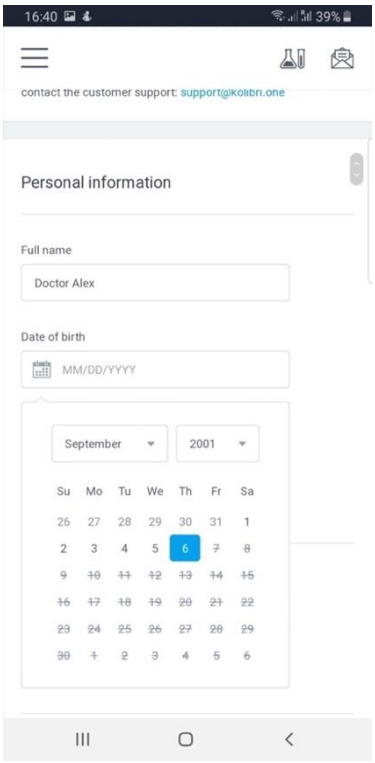
After successful activation, you will be automatically forwarded to the menu "Medical Card"

Enter your date of birth

Note: **The age of the patient must be greater than or equal to 18 years**

Carefully enter your date of birth. You will not be able to change it in the future. Incorrect data will result in incorrect test results.





Enter the required fields:

Select your gender

Enter your height

Select the units

Enter your weight

Select the units

Select the race

The remaining fields are not obligatory to fill in. This information will be helpful for your doctor, which analyses the diagnostic results for you.

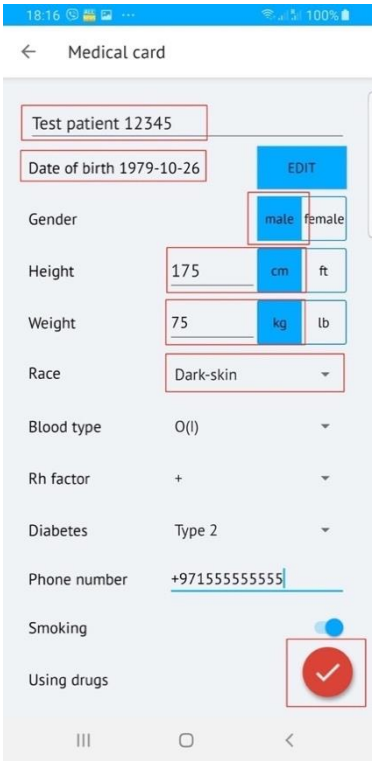
Also in this menu, you can change your name if you need it.

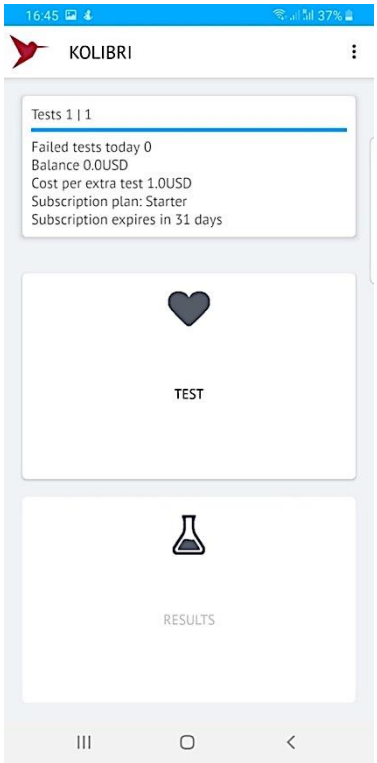
After filling out the medical card, save the input by pressing 

All data that you enter in the required fields must be accurate. Diagnostic results will depend on this.

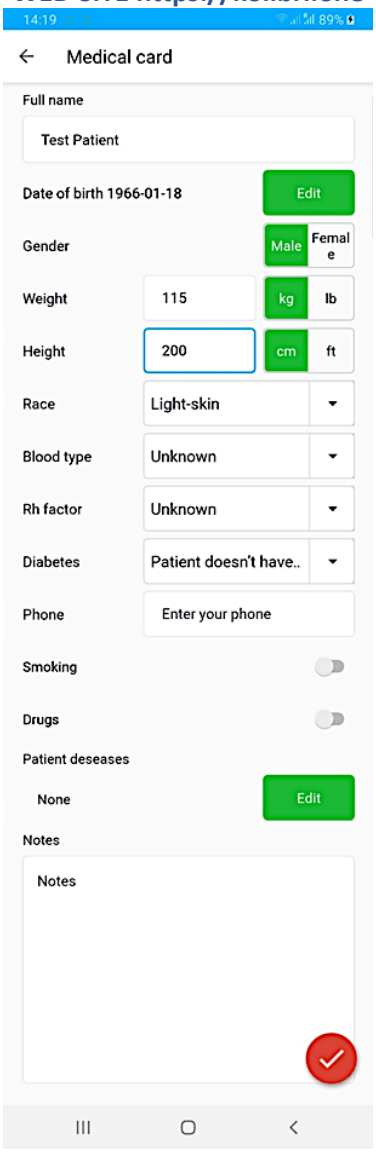
When the medical card is completed, the menu "Testing and viewing results" becomes available

APPLICATION KOLIBRI





WEB-SITE https://kolibri.one



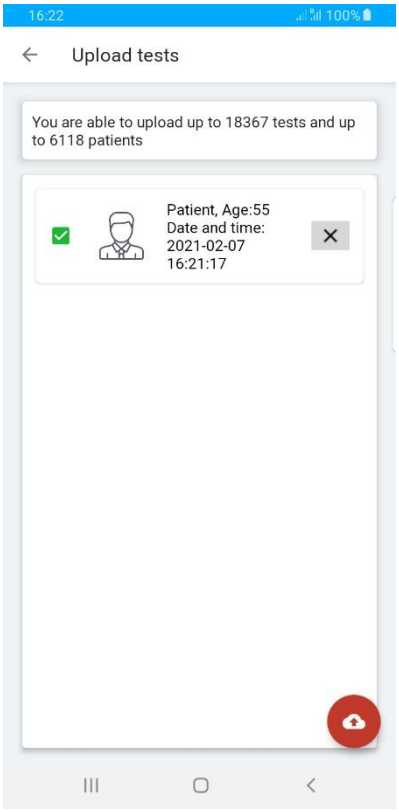
6.3 MOBILE APPLICATION MENU

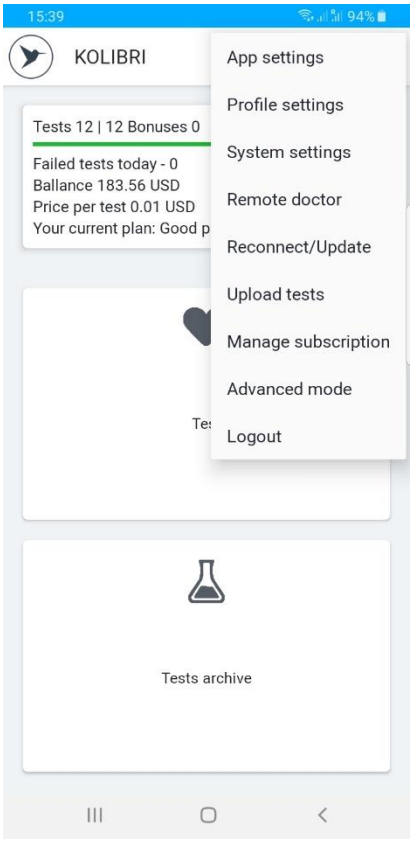
Main Menu is available by pressing … in the right upper corner and includes:

App settings (see 6.2.1 and 6.3.1)
Profile settings (see 6.2.4 and 6.3.2)
System settings (see 6.3.3 below)
Remote doctor (see 6.3.4 below)
Reconnect/Update restart the mobile application
Upload test Send test results obtained without an Internet connection.

The mobile application allows you to test patients without an Internet connection. Later, when the Internet is accessed, you can send the tests to the cloud math server for calculations and get the diagnostic results.

To send a test for calculations, select the check box and click the button at the bottom of the window to send the test results to the math cloud server. After sending, the diagnostic results will be downloaded to the mobile application automatically and will be available.

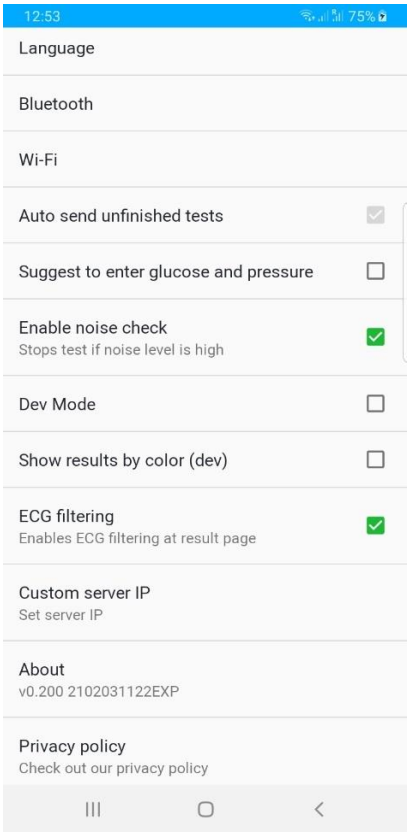


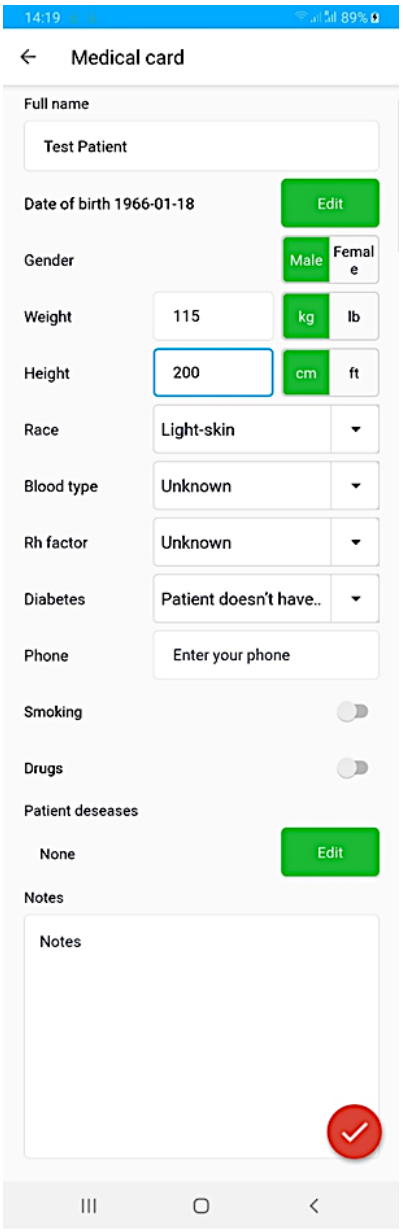


Manage subscription (see 6.3.5 below)
Advanced mode (see 6.3.6 below)
Logout sign out of your account

6.3.1 App settings:

1. Language – select interface language
2. Bluetooth- opens the BLUETOOTH settings of the mobile gadget.
3. WIFI – opens the settings of a connected mobile gadget to select the WIFI network.
4. Auto Send unfinished – The Internet failures (disconnection, break, loss of packages, etc) can happen during testing with the MD KOLIBRI. If this menu is activated (ticked), then the measured data will be sent to the cloud server for processing automatically when the connection is restored.
5. Suggest to enter glucose and pressure – This menu helps to personalize and improve the future measurements of ADS, ADD, BCI for you. If you activate it (check the box next to this menu), then after each test made with KOLIBRI, you will be asked for the results of arterial blood pressure and glucose value received with tonometer and glucometer (separate devices, which you normally use for blood pressure and glucose level measurements). The data are to be added only if you make the measurements immediately after a test with KOLIBRI. Results received at any other time are not suitable.
6. Enable noise check – If the check box is selected, then the test will be aborted at high noise levels during testing. To eliminate high noise levels during testing, moisten your hands' palms, or use an ECG lead cable.
7. Dev Mode* – Special feature. Used by technicians. Can be unavailable in user's software.
8. Show results by colour – test results will be displayed in colour. The indicators that are normal are displayed in black, and the indicators that are out of the norm are displayed in red.
9. ECG filtering – enable ECG filtering on the results page. If you want to see the original form of the ECG in the test results - do not check this box.
10. Custom server IP - the menu for setting the IP address or server name with which you will work (for example: https://kolibri.one, https://kolibri.ae https://mdevice.eu etc.)
11. About – Latest software release date and number.
12. Privacy policy - provisions on personal data protection. It is updated from time to time.



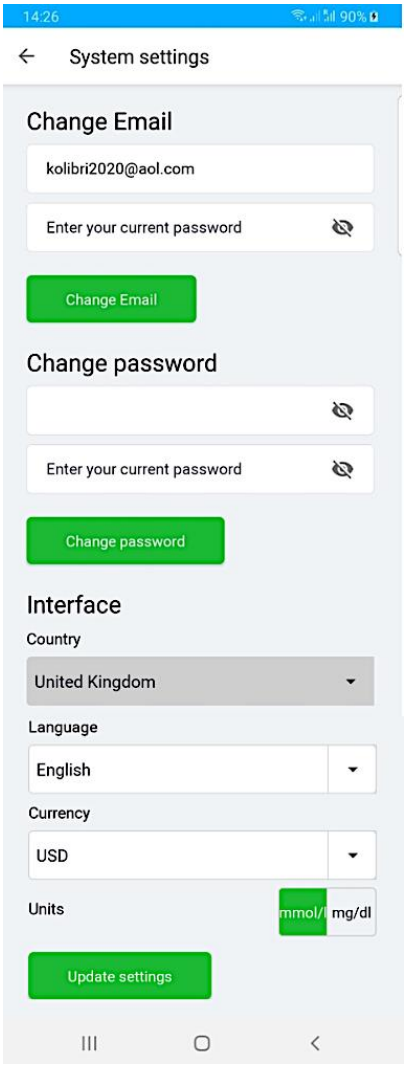


6.3.2 Profile settings (fields are editable)

	Carefully enter your data. Incorrect data will result in incorrect test results.

Fill in the required fields:
Choose your gender (for some tariff plans may not be available).
Enter your height
Select units of the patient height
Enter your weight
Select units of the patient weight

Other fields are optional, but may be useful to your doctor.



6.3.3 System settings

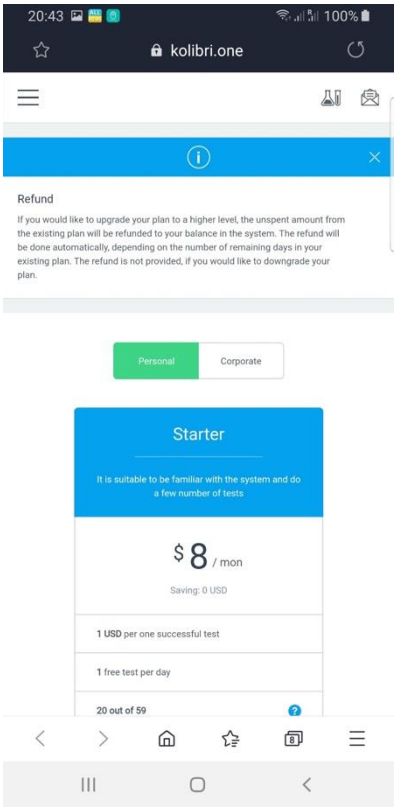
In this menu, you can change the email address, password, language of the interface, currency and units.

If you change anything, please press “Update settings” after all.

6.3.4 Remote doctor

If you have an agreement with your phisician for regular monitoring of your results, they will be availbale for him/her immediately after data processing. This menu allows you to connect to the doctor’s account

See chapter 6.6 «CONNECTING TO DOCTOR ACCOUNT»

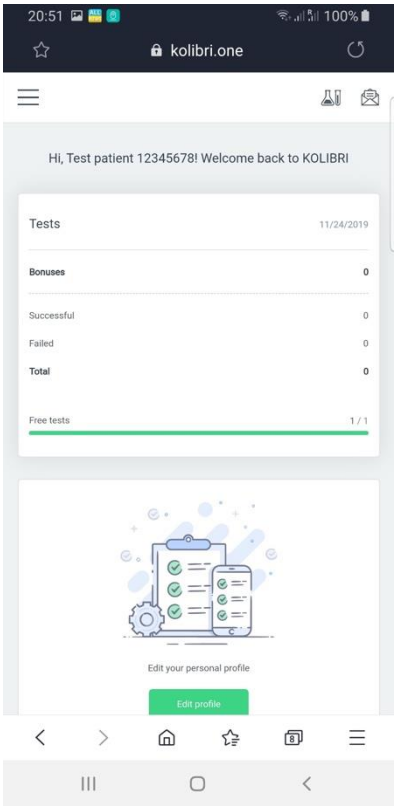


6.3.5 Manage subscription

To use the MS KOLIBRI, you need to select the Tariff Plan for servicing. When you press this submenu, you will be re-directed to the appropriate menu on the web (https://kolibri.one). There, you can find the description of each plan and cost.

By default, the standard plan (midium) is set. You can upgrade it to any one from the available in your region.

Please remember, tariff plans varies by the diagnostic capabilities.



6.3.6 Advantes mode.

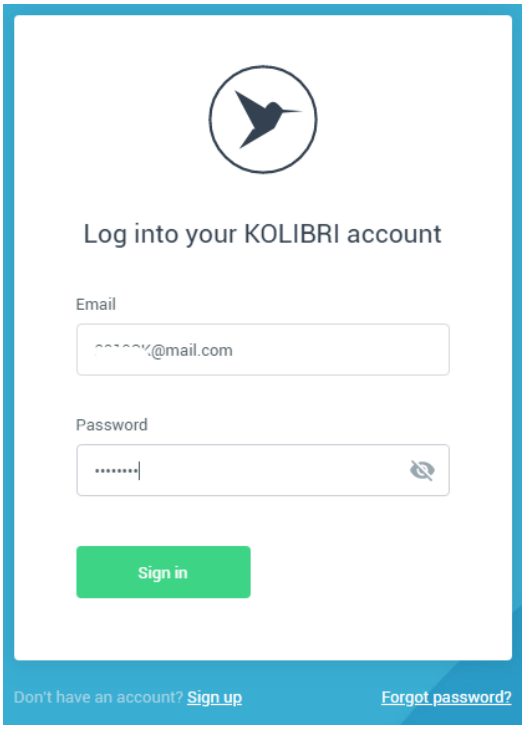
When choosing this menu, you will be automatically redirected to the main menu on the web https://kolibri.one.Extended features are available there. They are useful for results analysis and managing of your account.

6.4 ACCOUNT MANAGEMENT

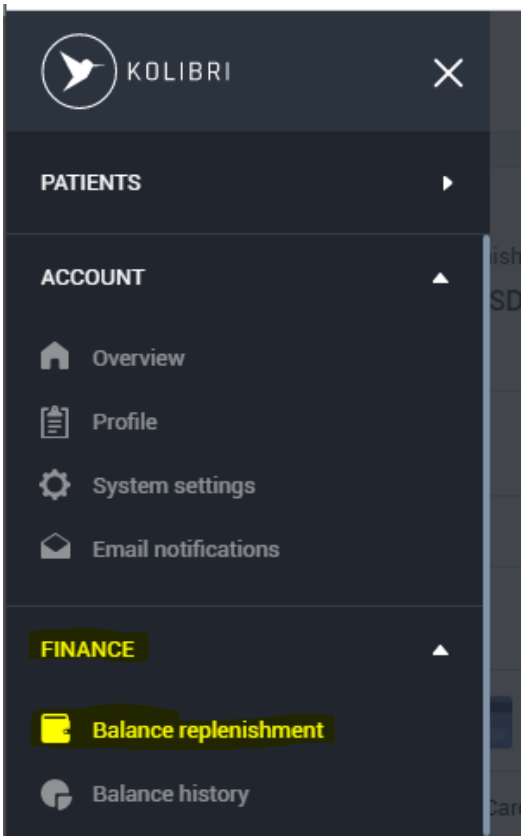
To check and/or replenish the balance, log in to your account using the web access

https://kolibri.one/auth/signin

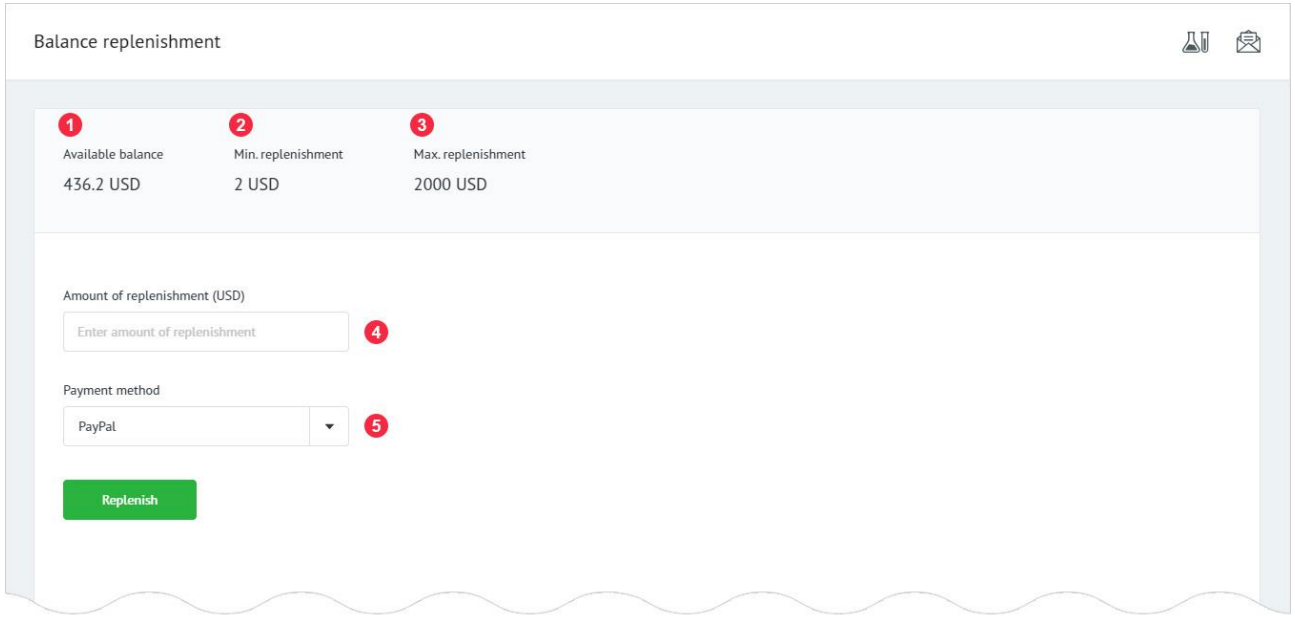
Enter login and password



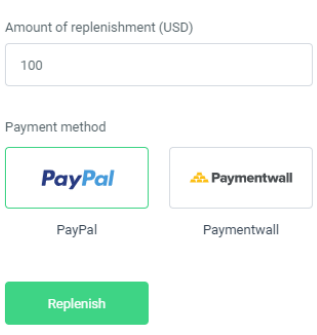
Select menu “FINANCE” and appropriate submenu



6.4.1 ACCOUNT BALANCE REPLENISHMENT (https://kolibri.one/main/balance/replenishment) contents the following information *(red markers with numbers are described below the screenshot)*:



1: Current user balance in MS KOLIBRI (marker 1).
2: Minimum amount of replenishment (marker 2).
3: Maximum amount of balance replenishment (marker 3).
4: Field for entering the desired amount for replenishment (marker 4).
5: The dropdown list of available payment systems (marker 5).



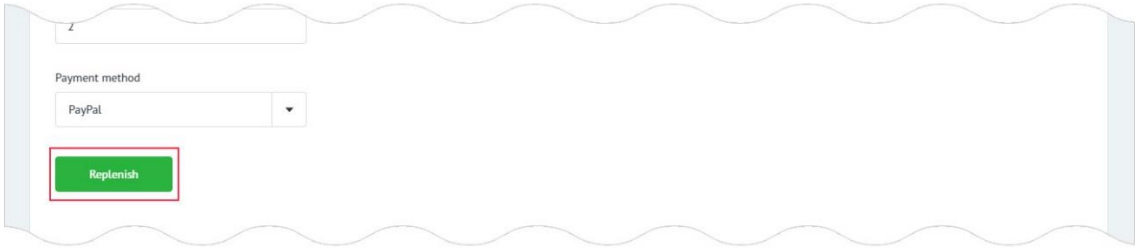
For some regions, this page may have a little bit different interface. The main difference is in the list of acceptable payment methods. Instead of the dropdown list, the separate buttons with payment systems names are used.

To replenish your balance in MS KOLIBRI, please enter the amount you wish to add. The entered data are checked by the system for the acceptability, considering the following:

- the field cannot be empty
- only numbers are allowed
- the amount of replenishment cannot be lower than the minimum amount of replenishment
- the amount of replenishment cannot be higher than the maximum amount of replenishment

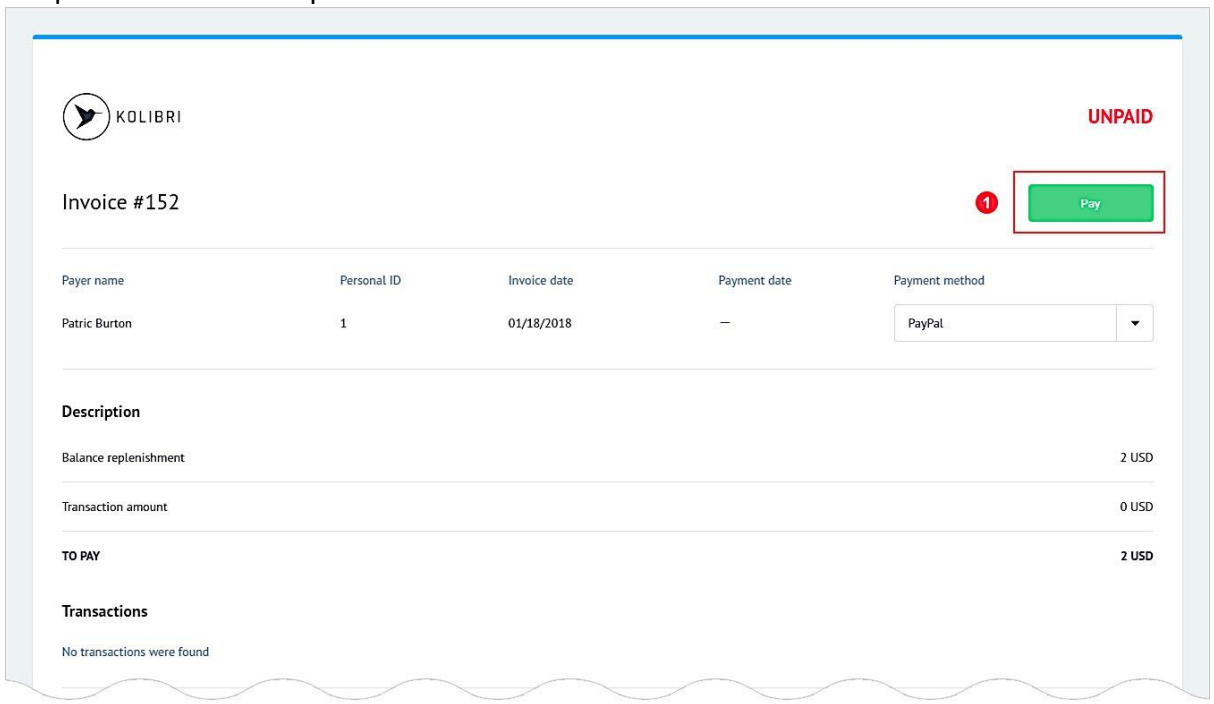
After entering the amount of replenishment, the user selects the type of payment system for the transaction.

Click on the button "Replenish".



If the data entered by a user are invalid, the application informs about it:

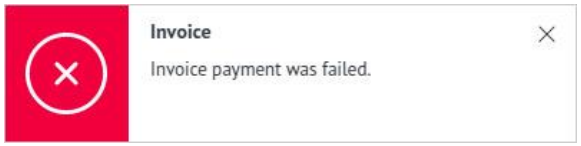
If all the entered data are correct, the invoice will be generated by the system. Details of this part of the system can be found in Chapter 6.4.2. An example of invoice:



If you are ready to pay for it, please click the button "Pay" (marker 1 above)

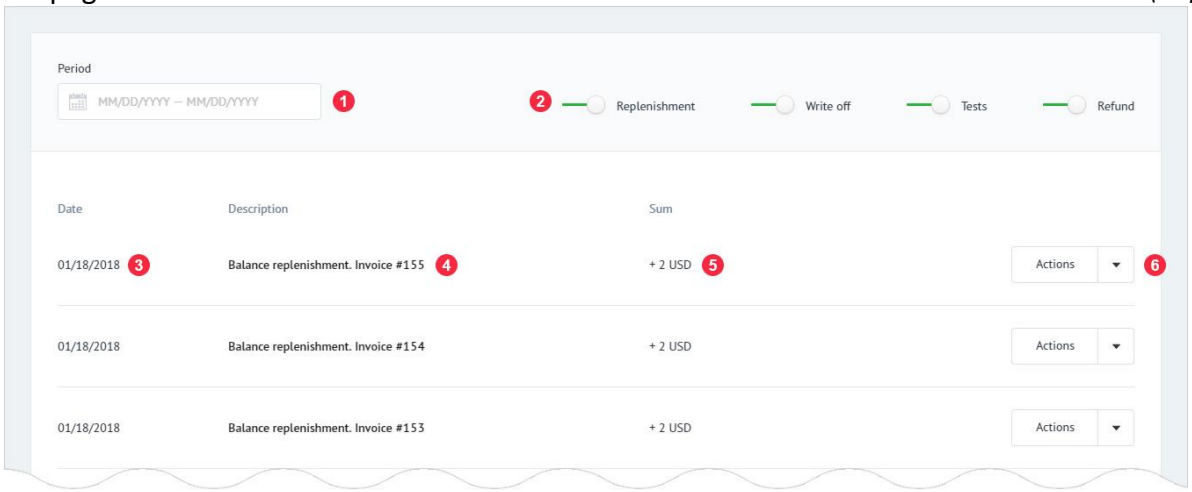
If the invoice is successfully paid and the balance of MS KOLIBRI is replenished, you will be informed about that as follows:

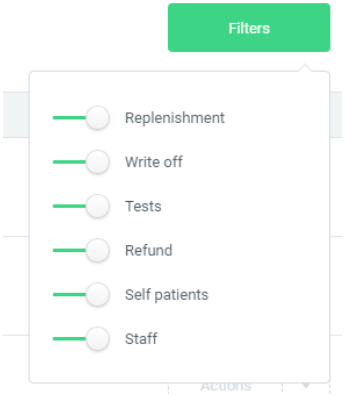
In case of any troubles with payment, the appropriate error window will appear



6.4.2 ACCOUNT BALANCE HISTORY

This page contains information about all financial transactions of the user in MS KOLIBRI. *(https://kolibri.one/main/balance/history).*





Balance history page overview:

Marker 1 - Filter of financial transactions by the date

Marker 2 - Filter of financial transactions by the type. Green bar near the type of transaction means it will be included in the filtered list.

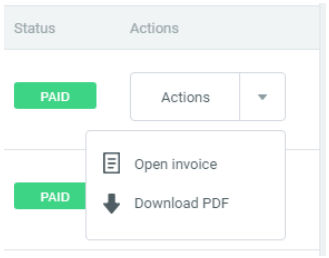
Marker 3 – Exact date of the financial transaction

Marker 4 - Type of financial transaction (Description of financial transaction)

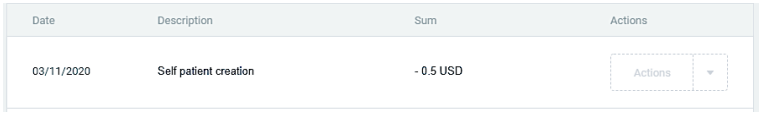
Marker 5 –Amount (+/- indicates decrease or increase of the balance)

*Marker 6 – Actions. It includes the dropdown list with several options (what can be done with the record).

*Submenu ACTIONS is available only for invoices. They can be opened and downloaded.



For other changes of the balance this option is not active.



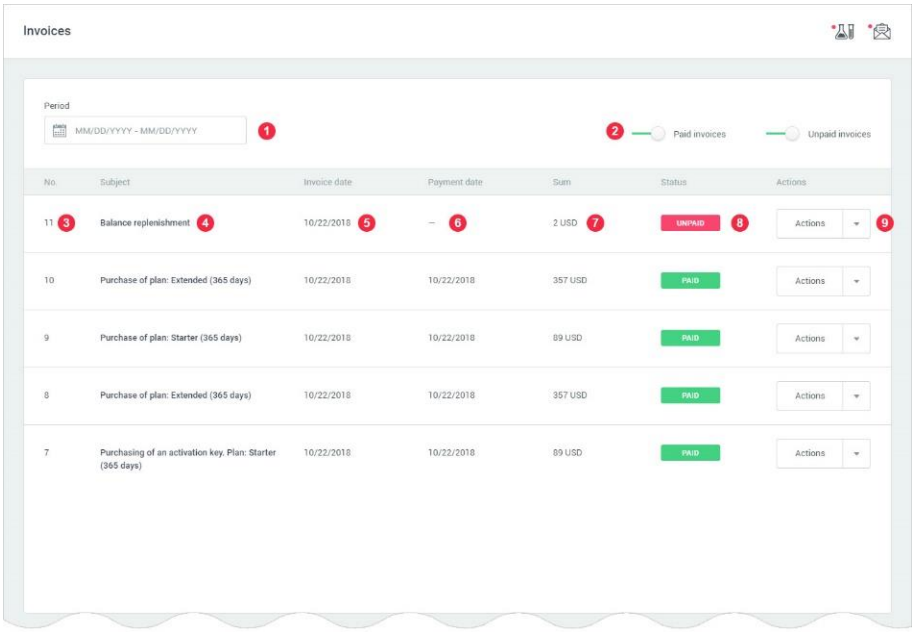
6.4.3 INVOICES

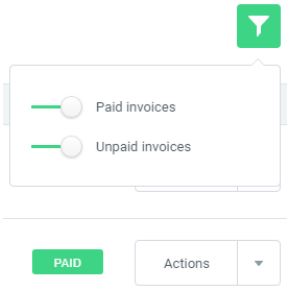
6.4.3.1. Archive of invoices

The archive of invoices is stored in the MS KOLIBRI (https://kolibri.one/main/invoices/archive). When loading a page, a user can see the last 25 generated invoices. Scrolling down allows loading erlier invoices automatically.

Note: The invoices are automatically generated by the HSP KOLIBRIs and cannot be considered as a basis for tax liability at the moment of issuing. The document is for informational purposes only. Appropriately paid invoices confirm the provision of the service and its acceptance.

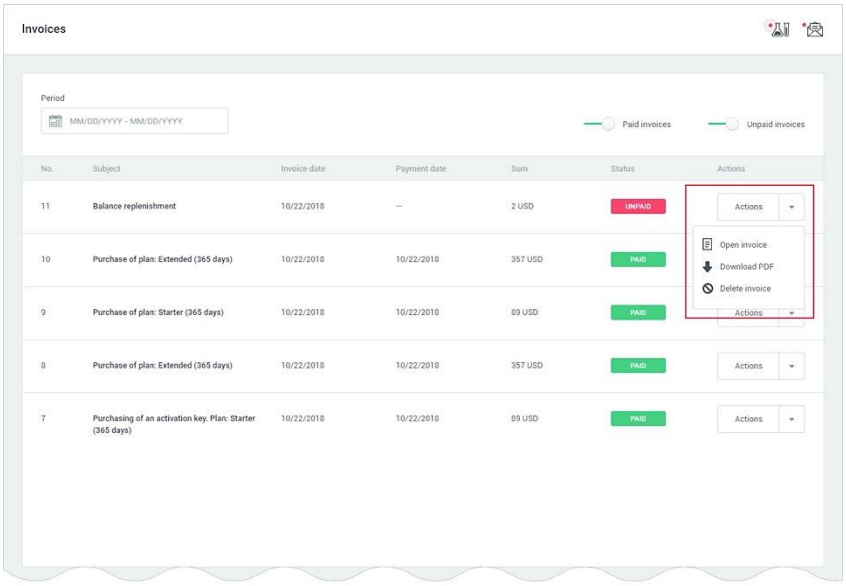
Following the markers (described below), it is possible to get complete information about the number and status of generated invoices in one account:





Marker 1: Filter for invoices by the date.
Marker 2: Filter for invoices by their status – see marker 8. The filter is active, when the bar is green. By default, both filters are active >>>>>>>
Marker 3: Invoice number in HSP KOLIBRI.
Marker 4: Brief description.
Marker 5: Date of the invoice's generation.
Marker 6: Date of payment.
Marker 7: Total amount of the invoice.
Marker 8: Invoice status: PAID or UNPAID.
Marker 9: Actions button. By clicking on a button, the user has a choice of 2 or 3 options depending on the status of the invoice:

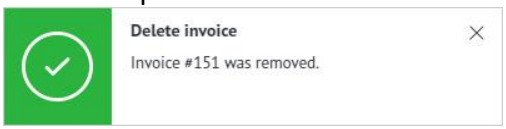
- View invoice (Open invoice);
- Download the PDF invoice (Download PDF);
- Delete invoice - this option is active only if the invoice has the status "UNPAID" (Delete invoice). Already paid invoices (PAID status) are stored in HSP KOLIBRI.



To delete the invoice, a user clicks on the "Delete invoice" link, after which a modal window appears, where the deleting is to be confirmed:

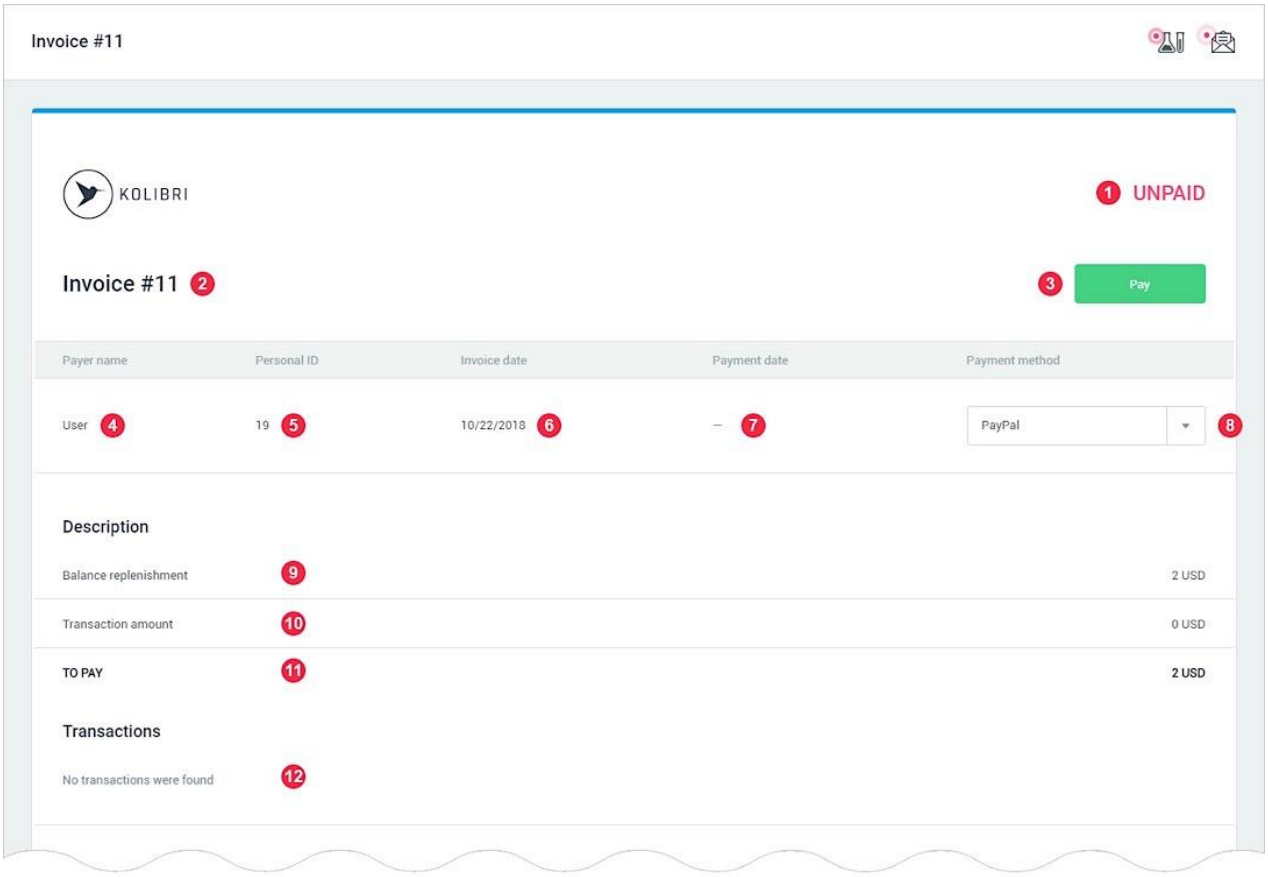
To confirm the operation, a user should click on the button "Delete". Otherwise, a user can press "Cancel" or click outside the modal window, if the deleting is not required.

Appropriate notification will confirm status of operation



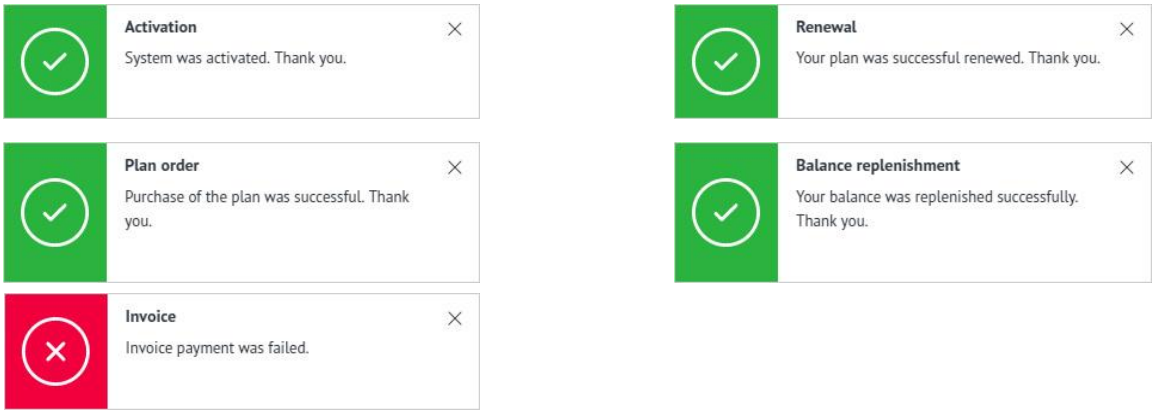
6.4.3.2 Content of an invoice

Details of an invoice are described below the screenshot:

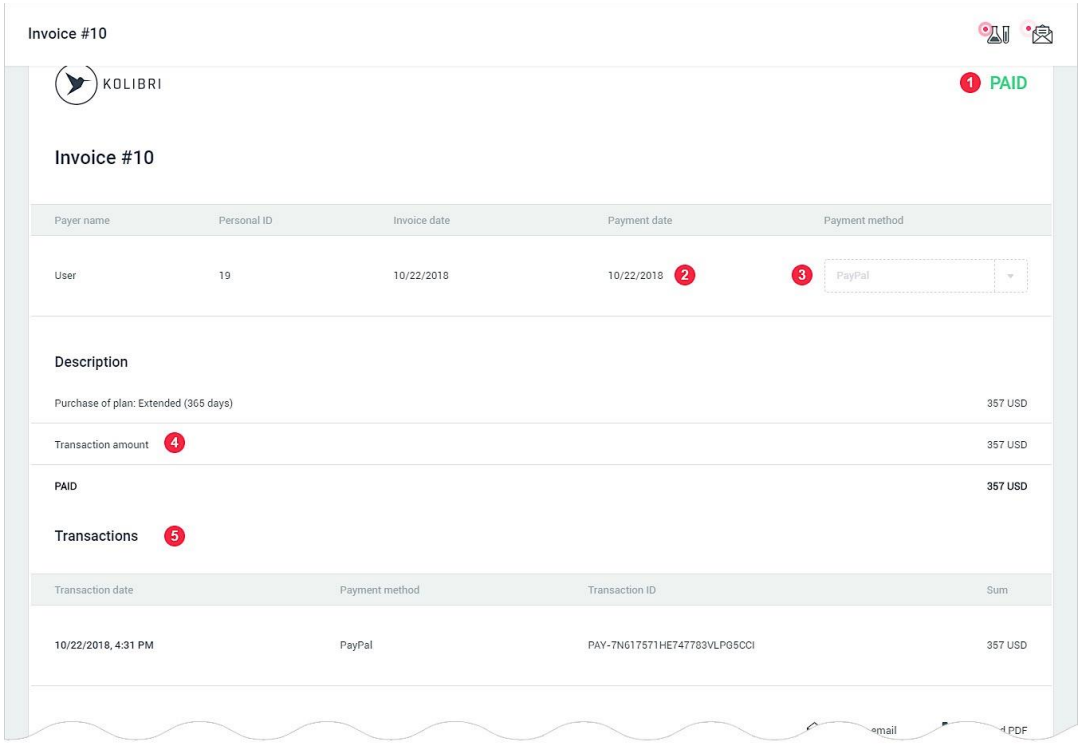


Marker 1: Invoice status. Status can be PAID or UNPAID.
Marker 2: Invoice number in HSP KOLIBRI (generated automatically).
Marker 3: Active button that allows a user to pay the invoice (PAY).
Marker 4: User name.
Marker 5: Personal number of the user.
Marker 6: Date of the invoice issuing.
Marker 7: Date of payment. By default, the date of payment is the same as issuing date. After invoice is paid, the date will be changed to the actual one automatically.
Marker 8: Selection of payment systems. The number of payment systems available in a region may vary from country to country. A user has the ability to pay invoices using different systems from the list.
Marker 9: Description of the service.
Marker 10: Paid amount.
Marker 11: Total amount to pay.
Marker 12: Information about transactions related to the invoice.
To pay the invoice, a user should click on the button "Pay" - marker 3. After that, the user will be redirected to the menu for payment system selection.

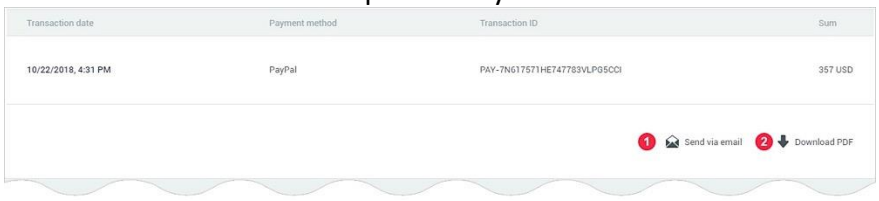
Depending on the reason of payment, the information message will confirm if the operation was successful or not in the following way:



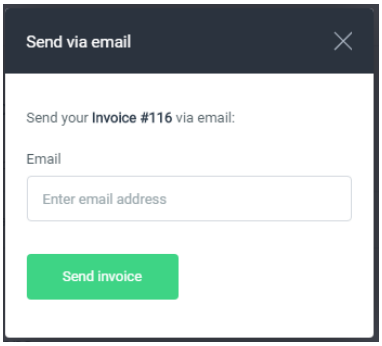
After successful payment, the status of invoice will be changed to PAID (Marker 1) and the current payment date will be fixed (Marker 2):



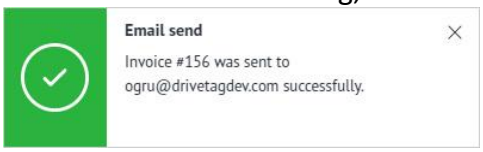
Marker 3: The payment system which was used.
Marker 4: Amount of transaction.
Marker 5: Transaction data and time are recorded.
The invoice can be sent to the email address specified by a user or downloaded as a PDF file:

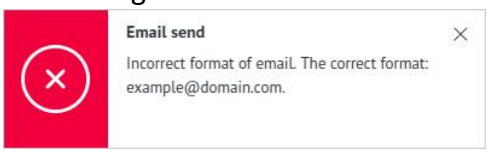


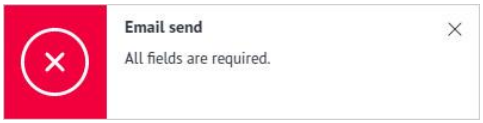
Clicking on “Send via email” will call a window for the email address entering:



After completing the form, the appropriate messages will inform about the status of letter sending, one of the following:

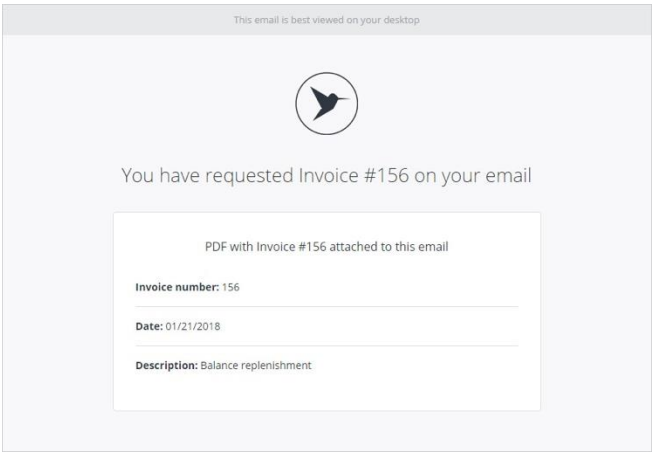






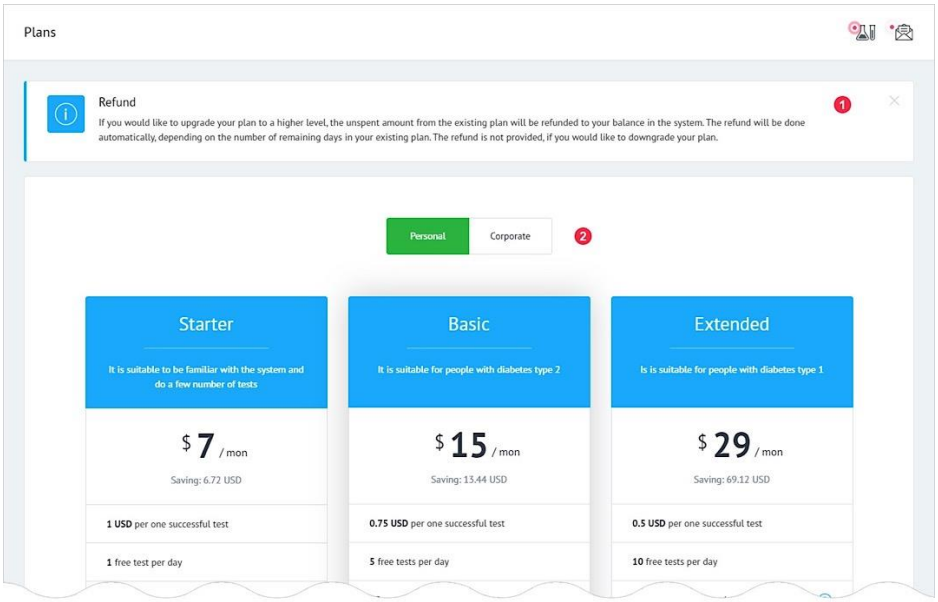
A letter with the following text and attached PDF file will come to the specified email address:

PDF file can be downloaded then.



6.4.4. SUBSCRIPTION AND TARIFFS

The use of MS KOLIBRI is possible only after subscription for services, using one of the offered tariff plans. There are two types of tariff plans, namely PERSONAL and CORPORATE (Marker 2 below). Each type includes several tariff plans, which a user can choose by its own. They vary by the cost and amount of information provided.



PERSONAL tariff plans are intended for use by individuals, who has a device KOLIBRI and have registered the account on the web-platform https://kolibri.one (One account =one user =one device).

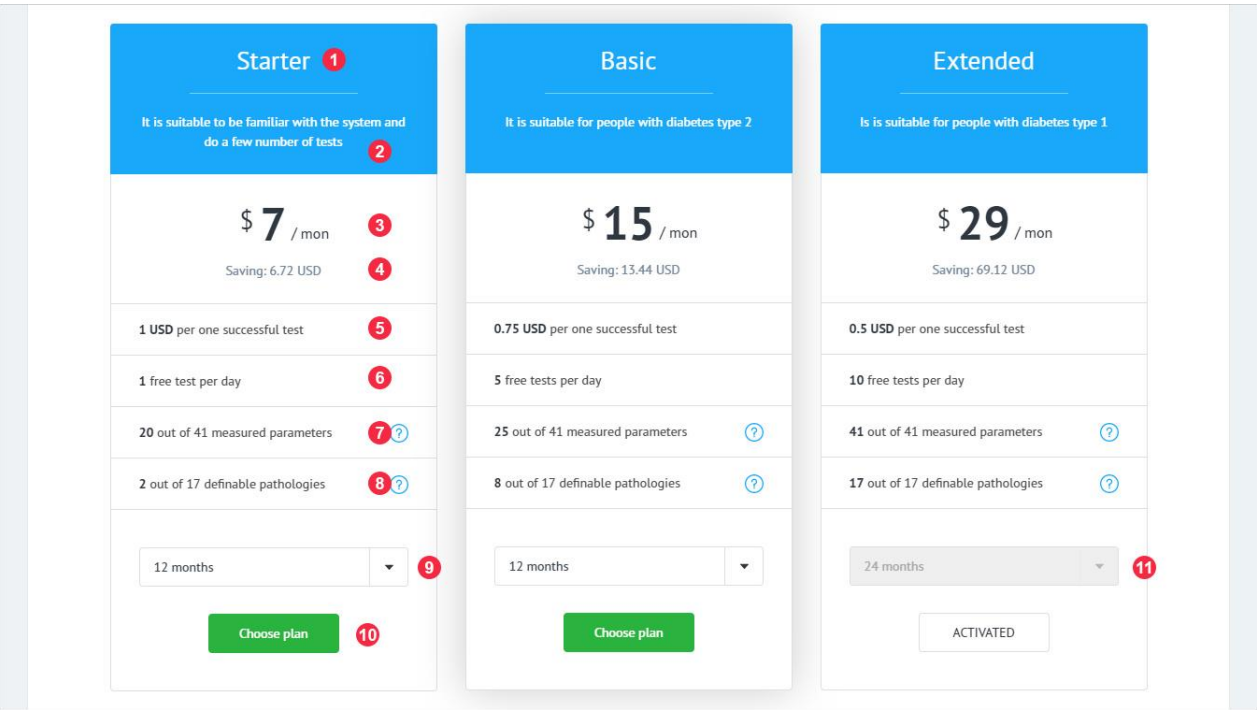
CORPORATE tariff plans are intended for use by medical care professionals, who have one or several devices operated by nurse(s) under one registered account on the web-platform https://kolibri.one (One account=one or several operators=one or several devices). This type of plans also can be used by a family, when one device is used by each of the family members and their records are stored under one registered account on the web-platform https://kolibri.one.

IMPORTANT: **MS KOLIBRI** features **allow upgrading** the current tariff plans to the higher/advanced one **with partial refund**. The refund is calculated based on the number of days until the current plan expires, cost of the current and new tariff plans. Information about that is available for a user (Marker 1 above). Any refund or compensation of the amount for the unused period of currently subscribed plan is not carried out if a user switches to a lower-level tariff plan or stops using the service.

Switching from the "Personal" tariff plan to one of the "Corporate" is also available. The reverse transition is not allowed.

6.4.4.1. PERSONAL TARIFF PLANS

Personal tariff plans can be used by one person, who has got the device KOLIBRI and personal registered account on the web-platform https://kolibri.one (HSP KOLIBRI).



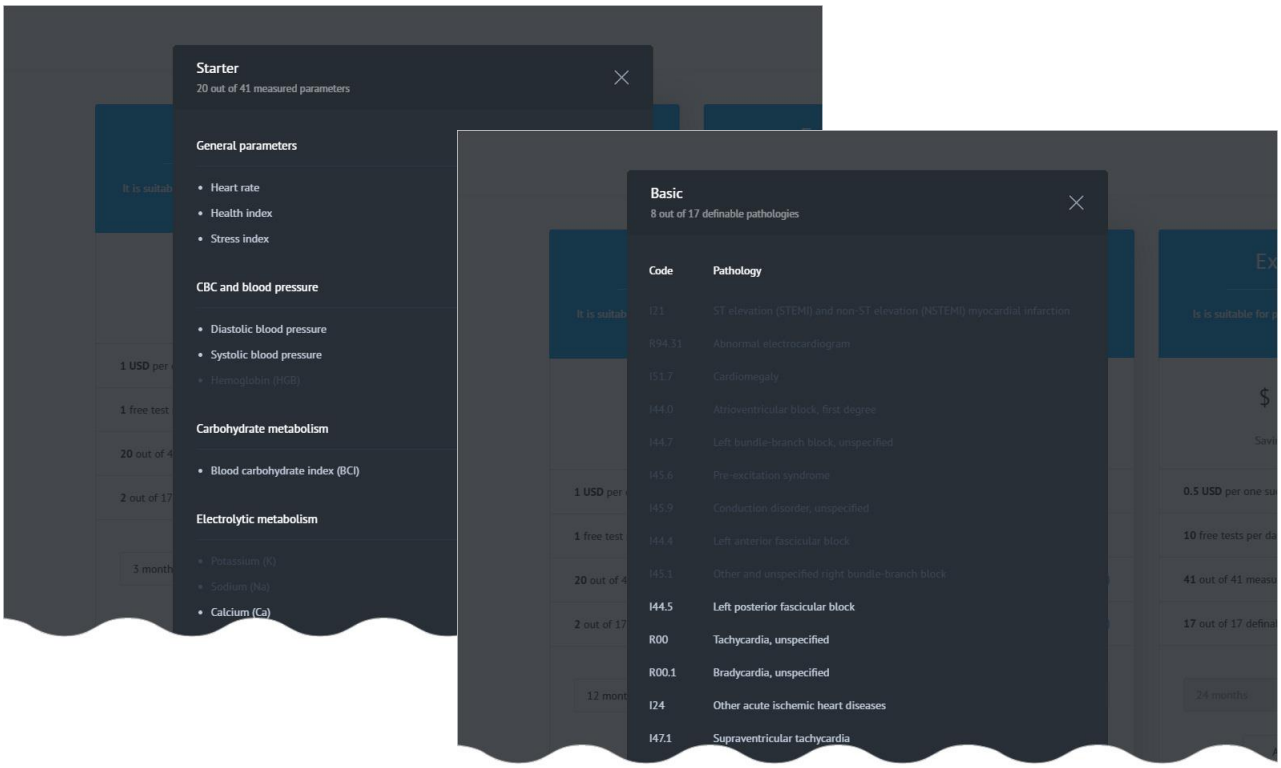
The current tariff plan is indicated as “Activated” - Marker 11. The period of subscription is indicated nearby.

Marker 1: Title of the tariff plan.

Marker 2: Description of the tariff plan.

Marker 3: Cost of the tariff plan per period. The cost of a tariff plan per period depends on the total duration of the subscription. The longer subscription is chosen, the cheaper cost of one period will be.

Marker 4: The amount saved due to the chosen period of subscription (discount).
Marker 5: Cost of one test above the number of included tests into the plan (free tests). Only successful tests are counted, FAILED tests are not charged.
Marker 6: Free tests mean a certain number of tests, which can be carried out during one day, other words the daily number of tests counted in the tariff plan.
Marker 7 and 8: Number of parameters and pathological conditions that will be available for a user after testing. HSP KOLIBRI always calculates the full range of parameters and identifies all implemented pathological conditions, regardless of the tariff plan, which limits only the number of displayed items.
Detailed information about the parameters and pathological conditions included in the tariff plan is available after clicking "?" near Marker 7 or 8. Items highlighted in white are included in the chosen tariff plan (screenshots below).

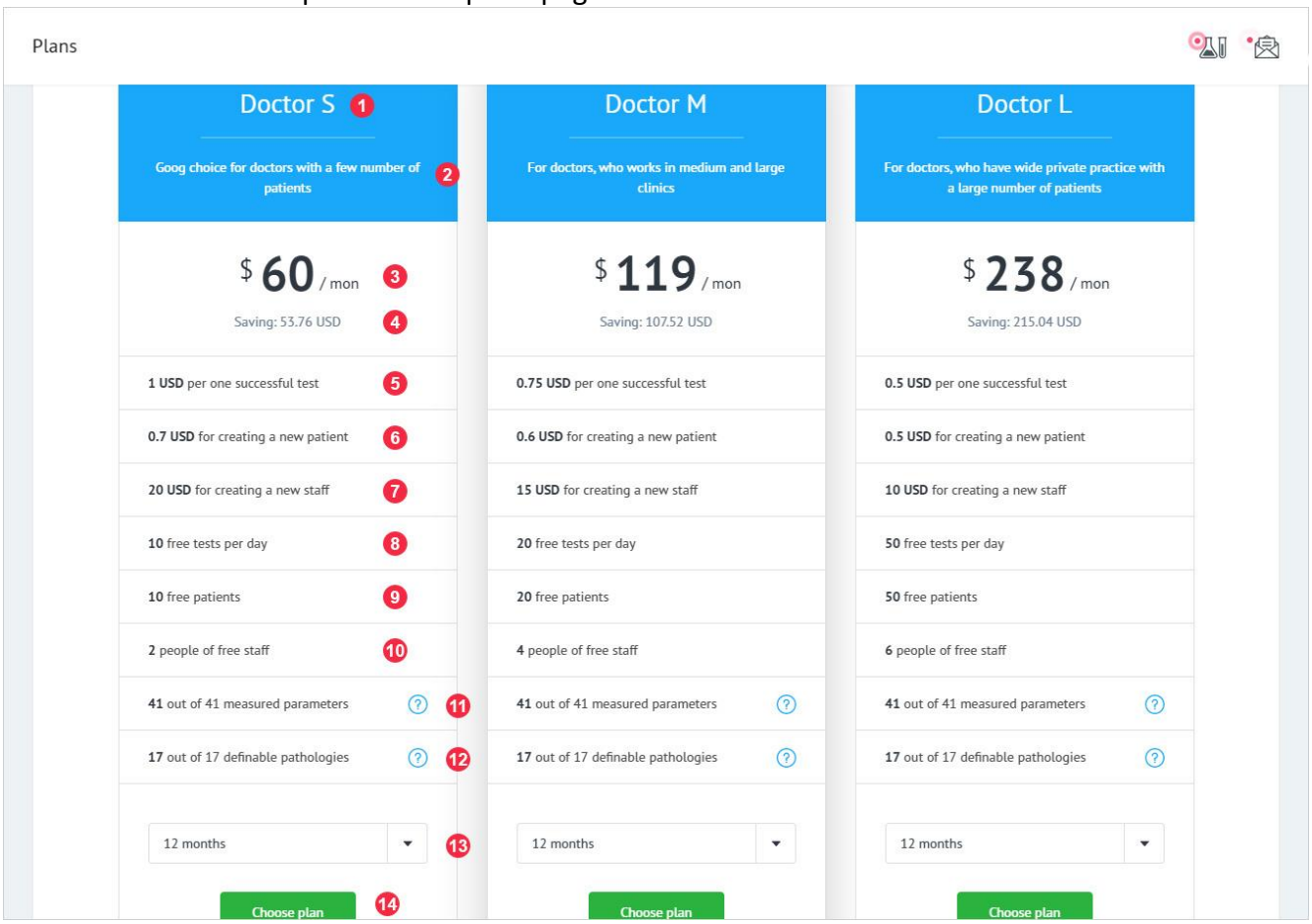


Marker 9: The period for which the tariff plan can be ordered. The drop-down list contains several slots.
Marker 10: Button for the plan activation.

6.4.4.2. CORPORATE TARIFF PLANS

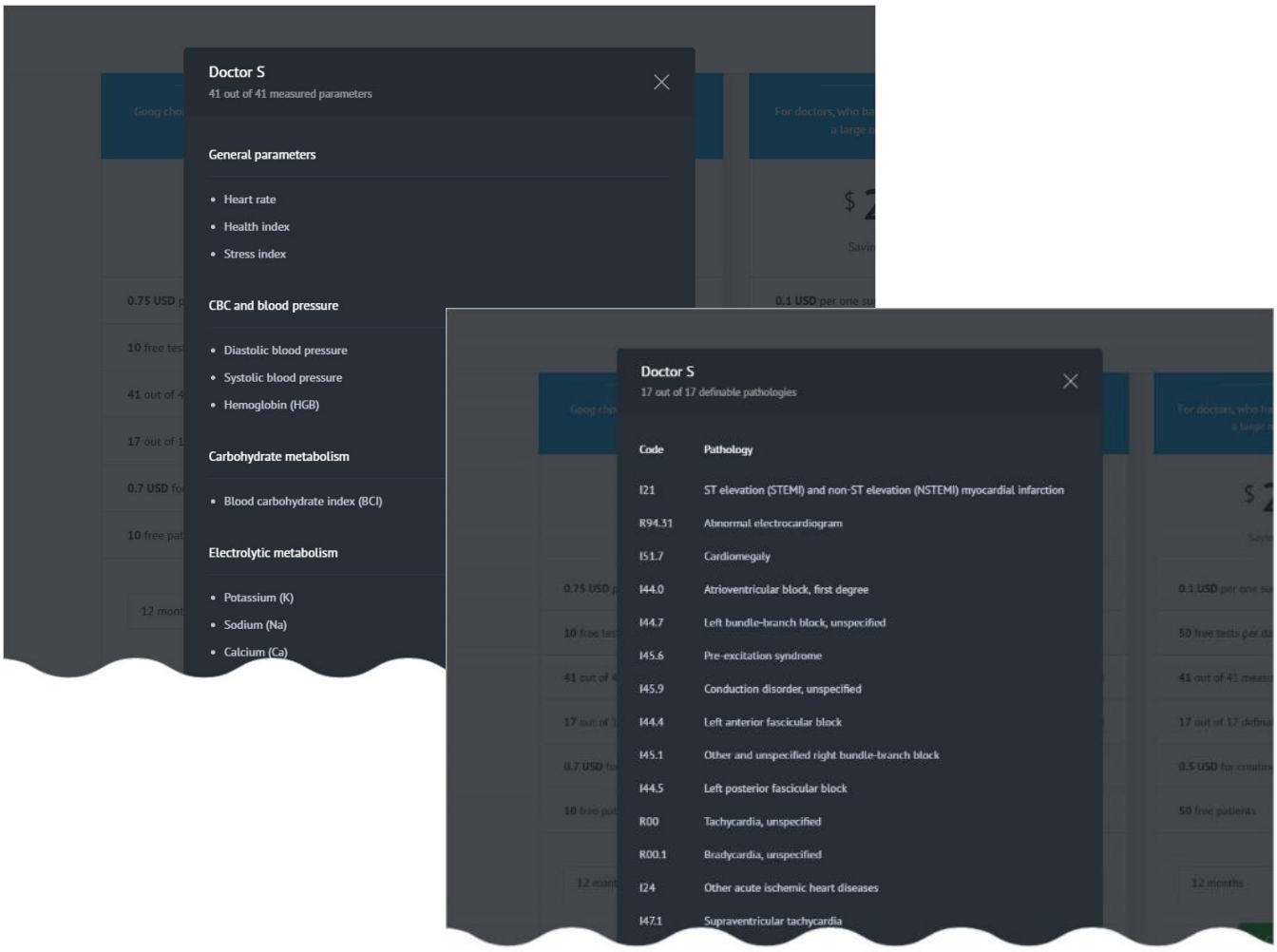
Corporate tariff plans are designed for use by health care providers. They allow a doctor to examine a definite number of patients (depending on the chosen plan) using one or several devices KOLIBRI and involving the clinic staff. This type of plans also can be used by a family, when one device is used by each of the family members and their records are stored under one registered account on the web-platform https://kolibri.one.

General view of the Corporate tariff plans page:



Marker 1: Title of the tariff plan.
Marker 2: Description of the tariff plan.
Marker 3: Cost of the tariff plan per period. The cost of a tariff plan per period depends on the total duration of the subscription. The longer subscription is chosen, the cheaper cost of one period will be.
Marker 4: The amount saved due to the chosen period of subscription (discount).
Marker 5: Cost of one test above the number of included tests into the plan (free tests). Only successful tests are counted, FAILED tests are not charged.
Marker 6: Cost of creation of one patient's record in addition to the included number of patients in the tariff plan.
Marker 7: Cost of creation of one operator (medical staff) in addition to the included number of operators in the tariff plan.

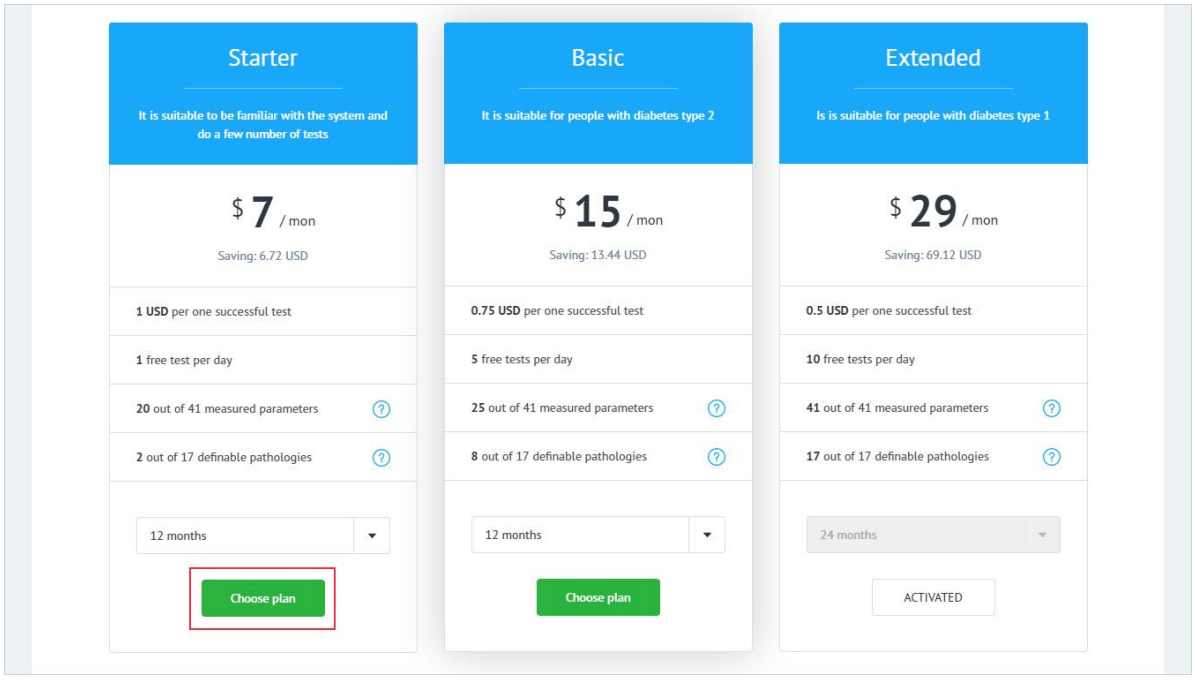
Marker 8: Free tests mean a certain number of tests, which can be carried out during one day free of charge; other words the daily number of tests counted in the tariff plan.
Marker 9: Free patients mean a certain number of patients, which can be tested during one day free of charge; other words the daily number of patients counted in the tariff plan.
Marker 10: Free staff mean a certain number of operators (medical staff), which can work with the device(s) KOLIBRI under one account on the platform https://kolibri.one; other words the number of medical personnel/operators allowed to use in the framework of the chosen tariff plan.
Marker 11 and 12: Number of parameters and pathological conditions respectively that will be available after testing. HSP KOLIBRI always calculates the full range of parameters and identifies all implemented pathological conditions, regardless of the tariff plan. The users of CORPORATE plans have access to complete information (all items highlighted in white):



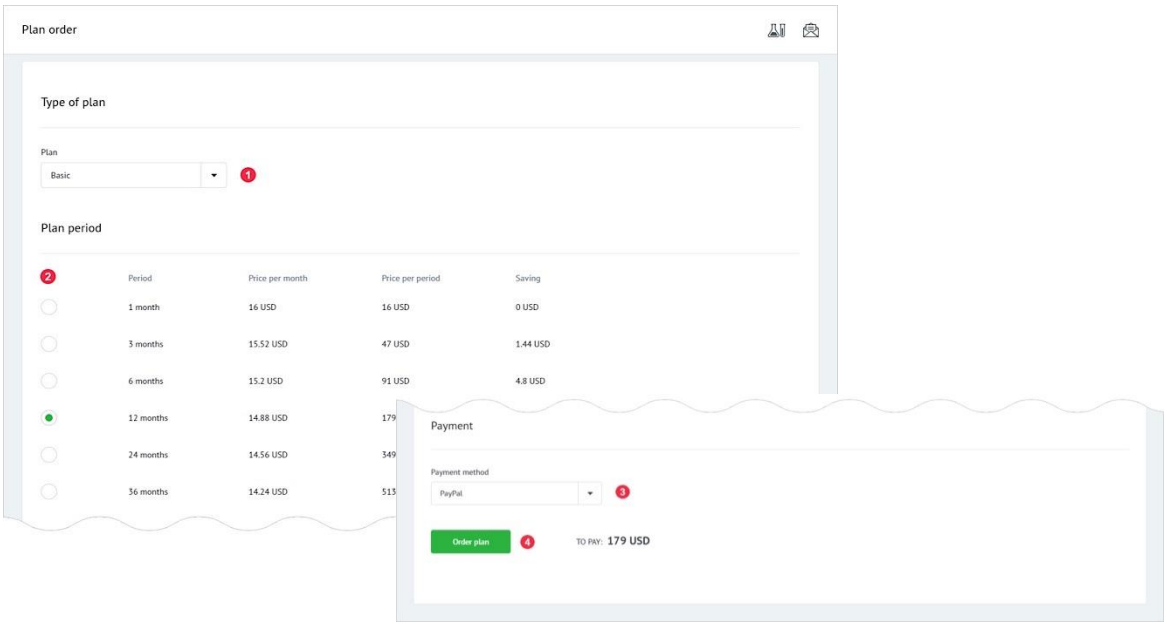
Marker 13: Period for which the tariff plan can be subscribed (drop-down list)
Marker 14: Button for the plan activation.

6.4.4.3. PURCHASE OF THE TARIFF PLAN

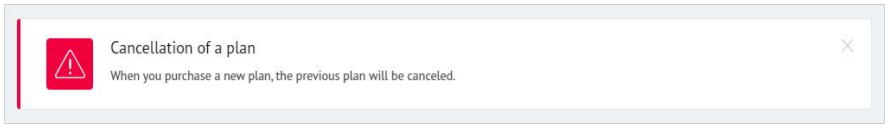
To subscribe a tariff plan, the user should click on the button «Choose Plan»:



The user will be automatically redirected to one of the menus (depending on the type of chosen tariff plans*): https://kolibri.one/main/plans/personal/order* OR *https://kolibri.one/main/plans/corporate/order*. There, the title of chosen tariff plan (marker 1), cost of the shortest period and period of subscription (Marker 2) can be checked. The amount saved is also indicated there. Payment system can be selected (Marker 3) and purchase can be completed (Marker 4 – ORDER PLAN). The HSP KOLIBRI will generate an invoice. Detailed description of the invoices and process of payment are is available in chapter 6.4.3.

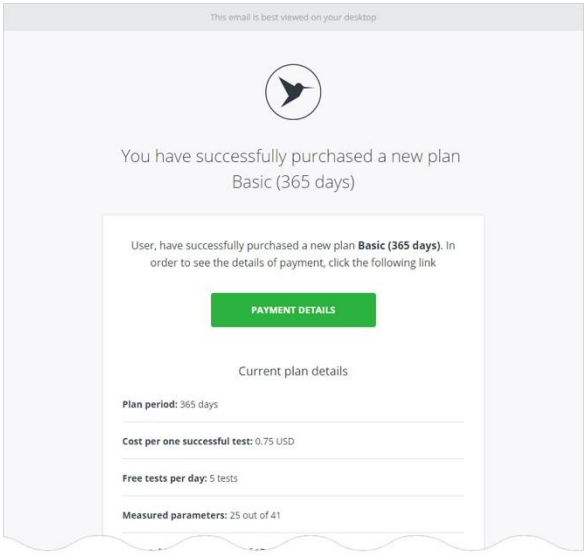


When a user switches to a new tariff plan, the current plan is cancelled. The app informs about that:

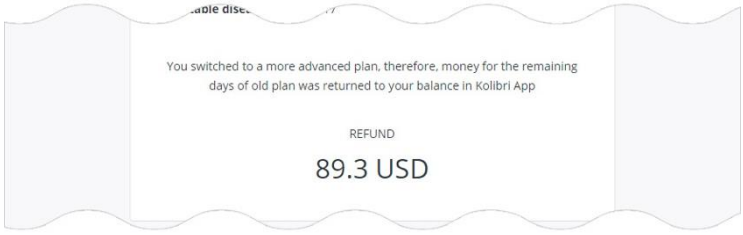


IMPORTANT! It is prohibited to switch from a "Corporate" tariff plan to a "Personal" one.

Brief information about purchased tariff plan is also sent to the registered email box:



In case of upgrading the tariff plan to an advanced one, the information about refund will be forwarded to the registered email address:

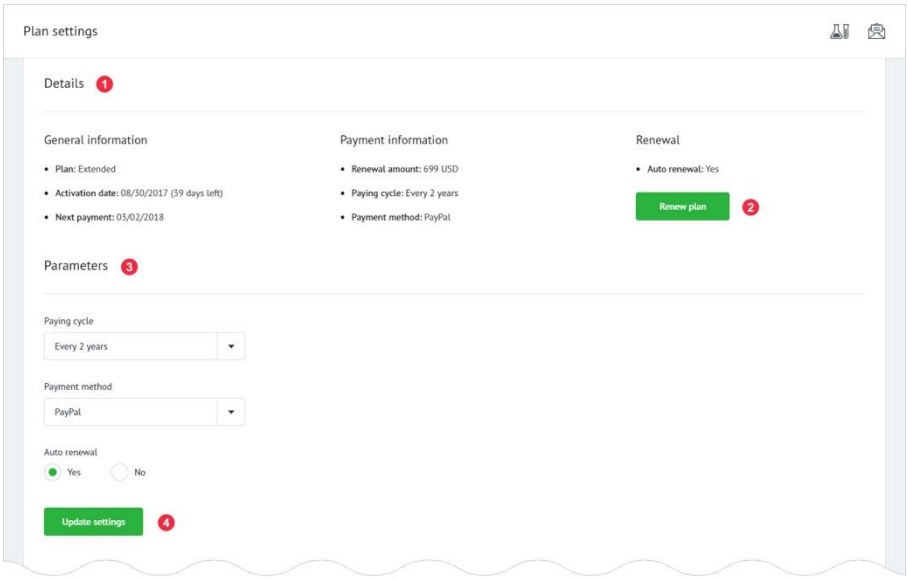


6.4.4.4. PLAN SETTINGS

The details and settings of the current tariff plan are located at *https://kolibri.one/main/settings/plan*. General page layout is the following:

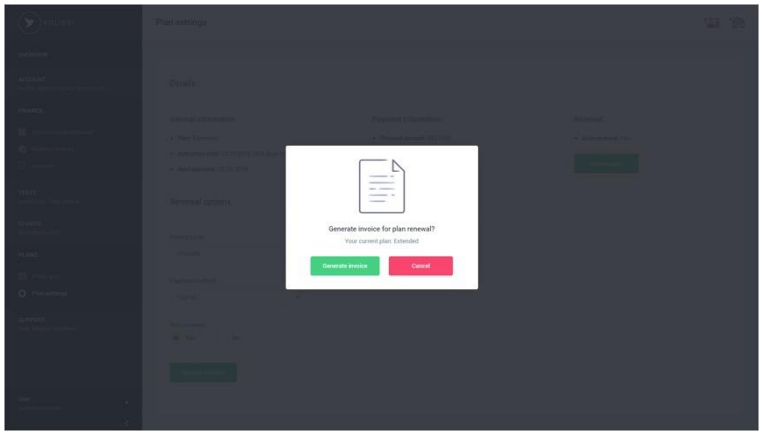
Marker 1: Details of the current tariff plan:

- title;
- date of activation (number of days until expiration);
- date of next payment for renewal;
- the amount to be paid for renewal;
- subscription period;
- chosen payment system;
- automatic updating of the tariff plan (option).



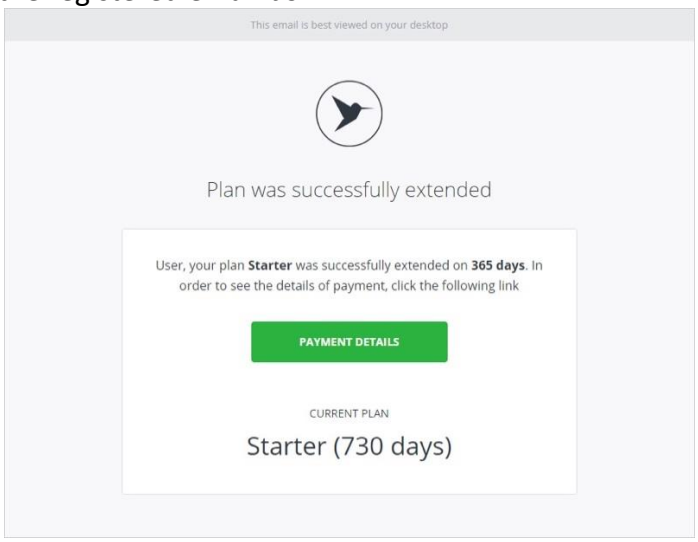
Marker 2: Button used to continue the tariff plan "Renew plan"

In a modal window it is necessary to confirm the invoice generation: the user should click on the button "Generate invoice". The invoice will be automatically generated. Further steps described above in 6.4.3.



Note: The remaining days of the current tariff plan will not be lost and will be added to the period for which the tariff plan continues.

Brief information about renewed/extended tariff plan is also sent to the registered email box:



Marker 3: Includes the indication of the current term of subscription, chosen method of payment and an option, which allows extend/renew the tariff plan automatically. If this option is not activated (a user choses NO), then the invoice for renewal of the plan will be formed automatically 7 days before expiration date and sent to the registered email address.

IMPORTANT: MS KOLIBRI does not keep/store the payment information of the users (like credit or debit cards, passwords and CID codes, etc)!

Automatic withdrawal of the amount for the renewal can be done ONLY from the user's account registered in HSP KOLIBRI, if the balance is sufficient (if a user paid some amount beforehand, it will be credited on his/her own account). If the balanced amount in the HSP KOLIBRI is not enough, the tariff plan will not be updated. After expiration of the tariff plan, the possibility to test will be blocked by MS KOLIBRI.

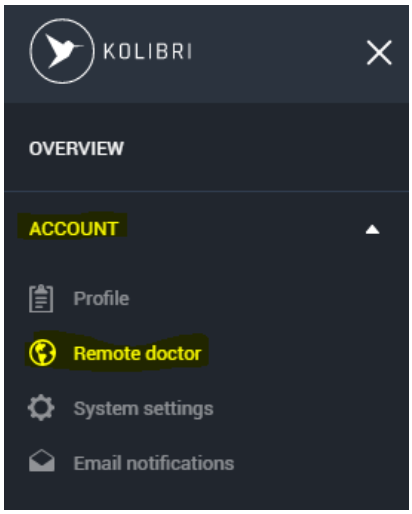
If the new settings are successfully saved, the application will notify you of this:

6.5 CONNECTION OF USER AND DOCTOR ACCOUNTS (REMOTE DOCTOR)

MS KOLIBRI allows a user to share his/her results with a chosen health care provider (physician or clinic, etc). The results of testing are forwarded immediately after processing to both accounts if the connection between a user and a doctor accounts once established. There are two ways of connection: via QR-Code and via email.

USING QR-CODE (initiated by a patient)

In the cloud account, select the menu “ACCOUNT” and submenu “Remote doctor”



Press button:

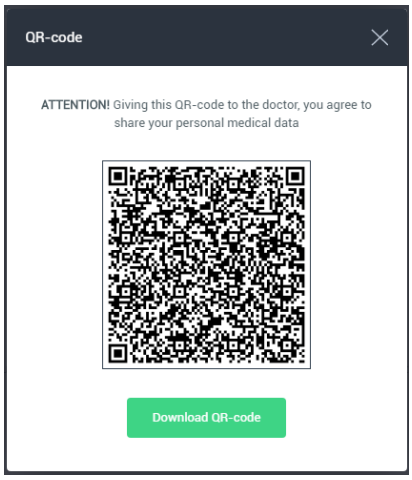
Generate QR-code

The cloud server will generate the QR code.

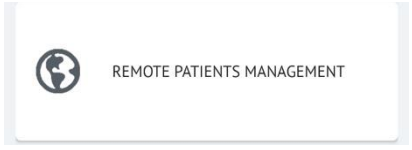
Download this QR code as a png file and send it to your doctor.

To download the QR code, click:

Download QR-code

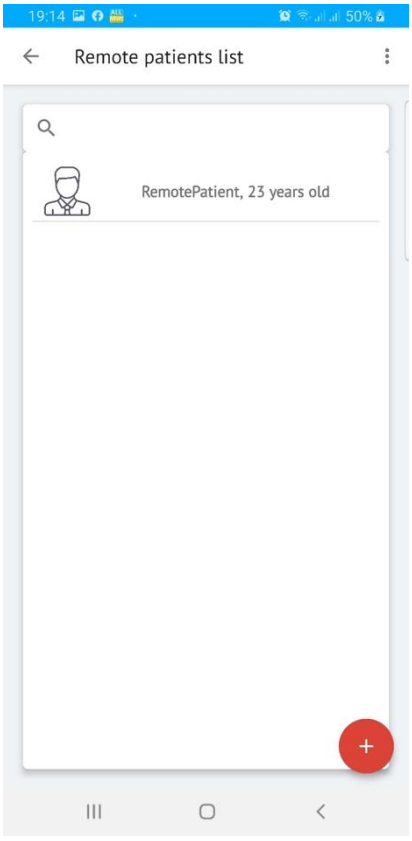


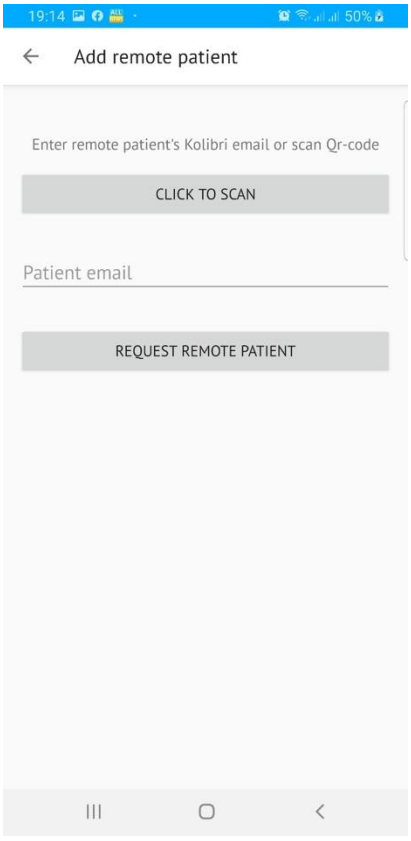
Next actions are to be done by DOCTOR. A user will get the appropriate message in his account, when the process of connection is completed by DOCTOR (family doctors, clinic, hospital, etc.) - see screenshot below.



To add a remote patient, the doctor needs to login to his account in the mobile application and select the menu
“ REMOTE PATIENTS MANAGEMENT”

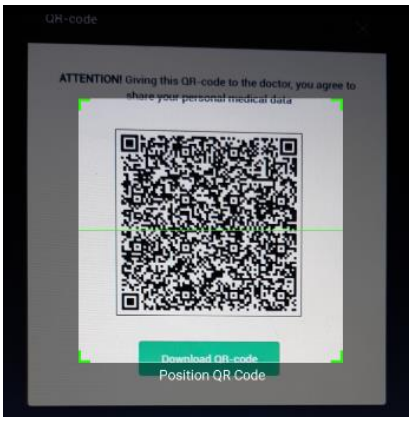
Press button: 





And press “CLICK TO SCAN”

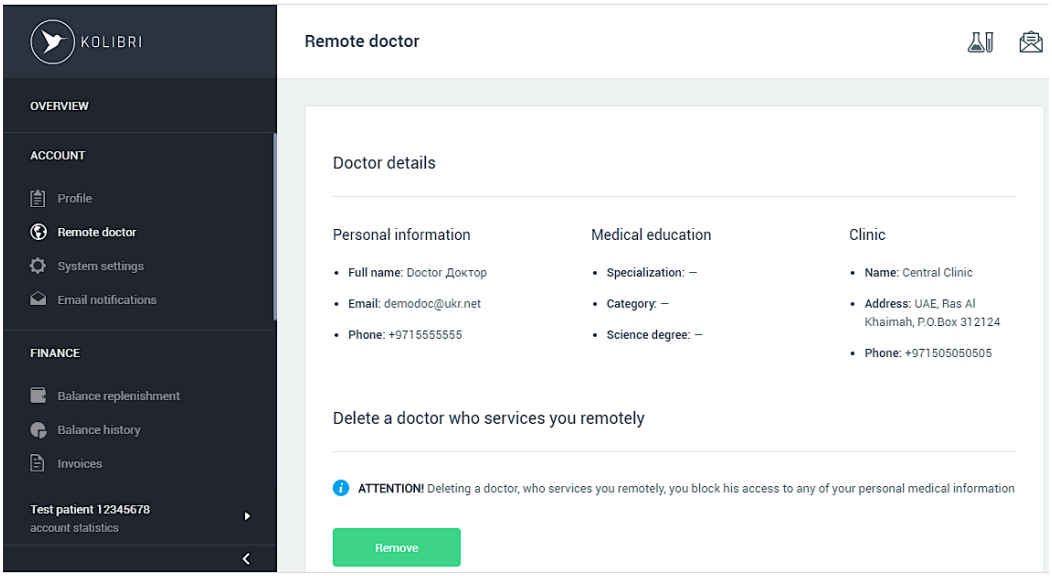
Scan QR-Code



The patients name will be added to the list of REMOTE PATIENTS. So, anytime, when a patient makes a test, the doctor will receives the results immedicately. All the results will be stored under the name of a patient.

The appropriate message will appear in your cloud account that you are connected as a remote patient to the doctor’s account (family doctors clinic, hospital, etc.)

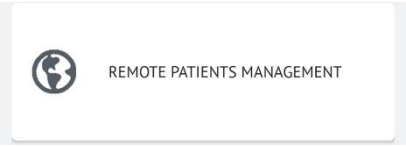
Message about successful remote connection to the DOCTOR's account, which is sent to the user:



Warning! The user is responsible for checking the entered personal data before each test. Pay attention to weight and height, as these parameters may vary.

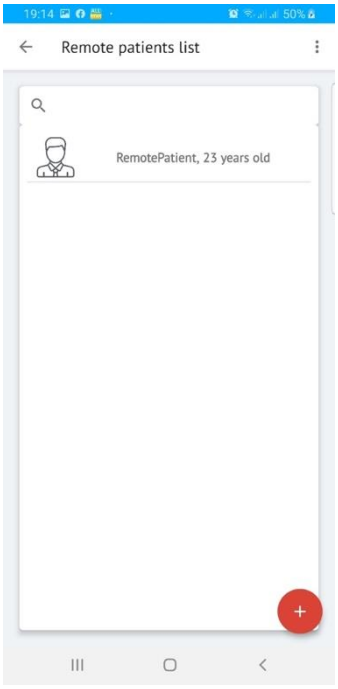
USING EMAIL (initiated by a doctor)

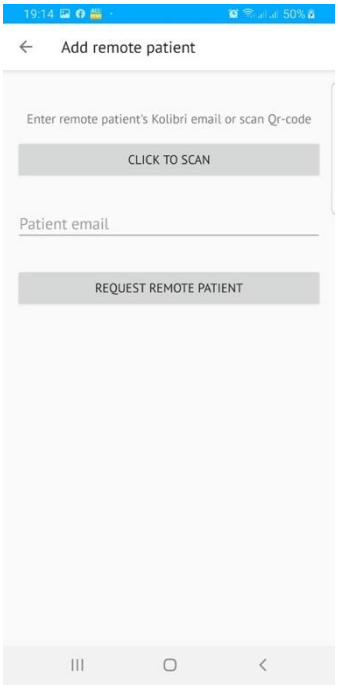
To add a remote patient, the doctor needs to log into his account in the mobile application and select the menu " REMOTE PATIENTS MANAGEMENT".



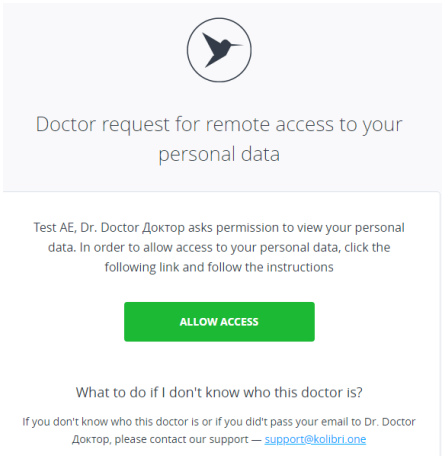
Press button: 

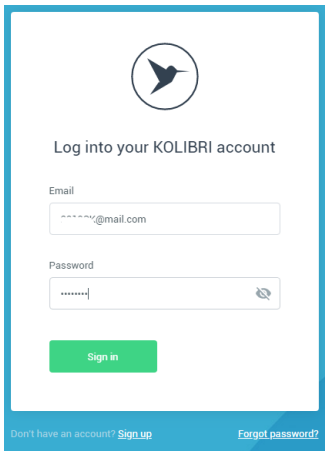
Enter the patient email. (Example: patient@mail.com)
Click "REQUEST REMOTE PATIENT"





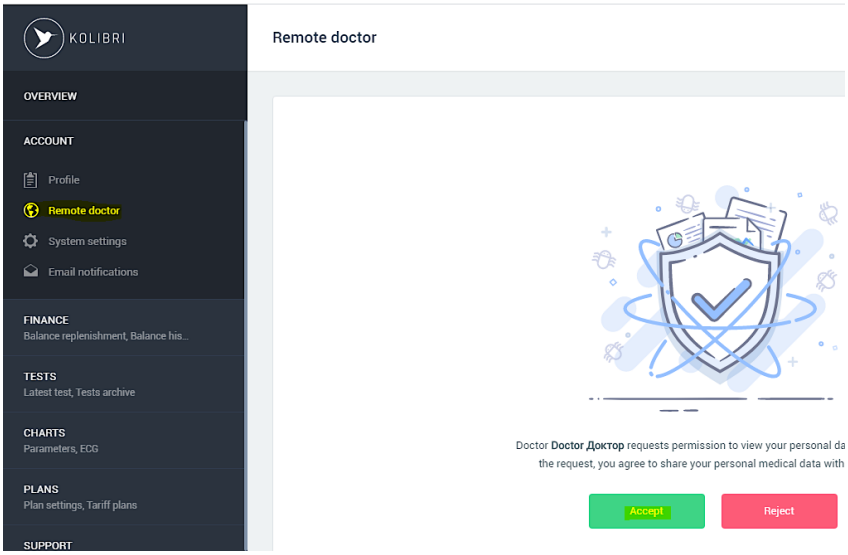
To complete the connection and allow forwarding the results of testing to a doctor account, the patient needs to confirm it using the link in the letter (received to email): Press “ALLOW ACCESS”



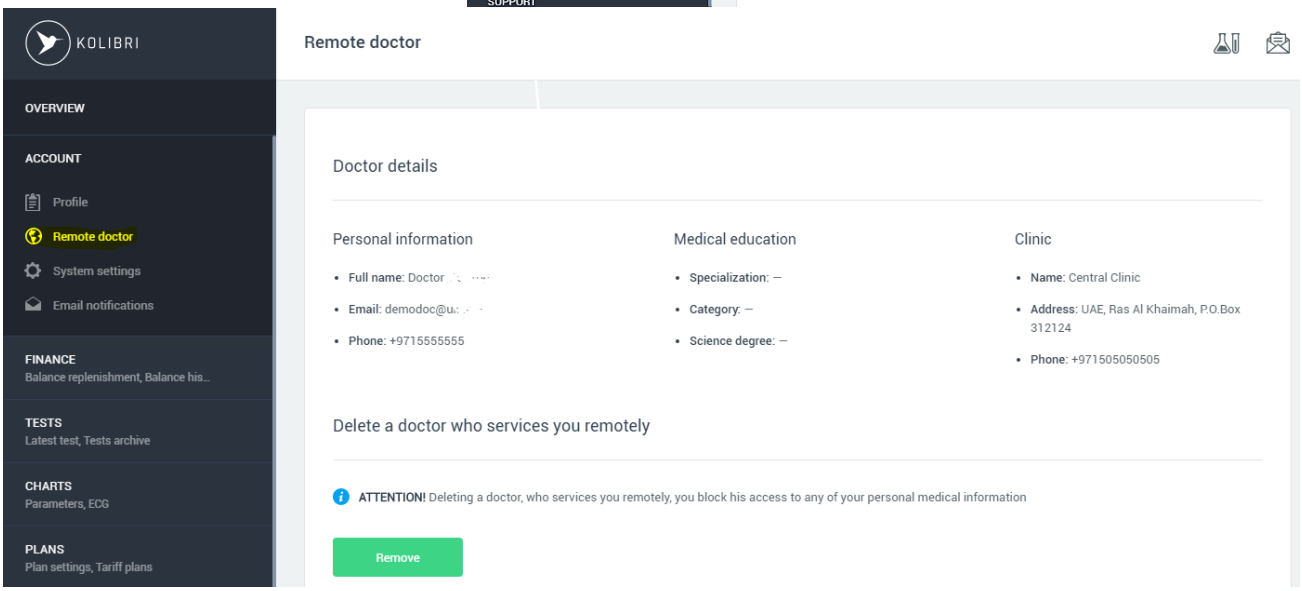


After that, the patient will be asked to enter a personal account on https://kolibri.one (HSP KOLIBRI).

Open the menu “Remote doctor” and press “ACCEPT”.



The process of connection is completed. The information about the connected doctor account is available at the menu “Remote Doctor” (screenshot below).



7 POSITIONING DURING THE MEASUREMENT

Examination should be carried out in a sitting position. A user/patient is to be calm and relaxed, had no physical activity at least 5-10 minutes before test.

A user needs to ensure that the environment in the room meets the requirements of the present IFU (Chapter 2.1.)

In case of using the device KOLIBRI by several people (in a hospital/clinic or within one family), it is required to disinfect the contact plates with alcohol wipes before each use.

Skin in the areas of contact should be clean. For a better quality of the signal, the skin should be slightly moisturized with water (small drops of ECG gel are applicable, too).

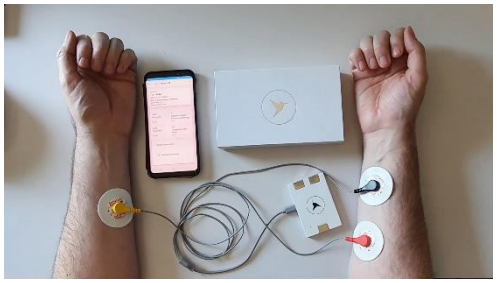
Correctly connect the lead cable or hold the device correctly in your hands.

Correct placement of MD KOLIBRI in hands during the measurement (click to open a video instruction or scan QR-code):

Two silver plates of KOLIBRI should be in contact with the palm of the right hand and one silver plate the palm of the left hand.

PLEASE DO NOT SQUEEZE THE MEDICAL DEVICE VERY STRONGLY.

The muscles of the arms should be as relaxed as possible. Muscle tension can affect signal quality. A signal with a lot of noise cannot be processed on a mathematical cloud server, so your measurements will be stopped/rejected early.

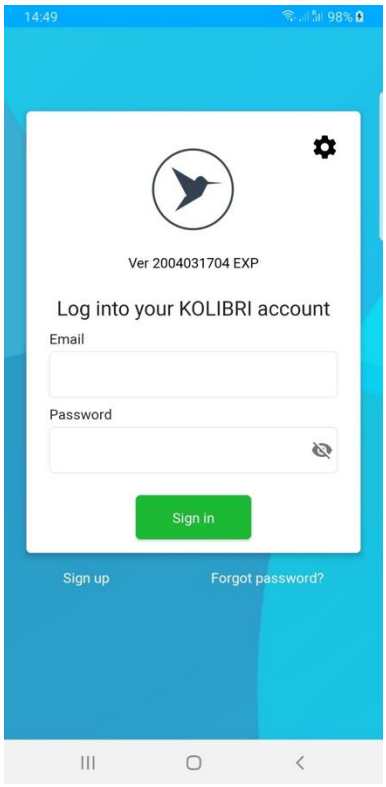


An example of using ECG stickers or clips with a lead cable (optional item). Usually, the quality of a signal received using the cable with electrodes is better (RED and BLACK electrodes on the right hand, YELLOW – on the left).

8 PROCESS OF MEASUREMENT

Check that your mobile gadget and KOLIBRI are paired via Bluetooth. See Chapter 6.1

Log in to the app.
Enter login and password.



Pay attention to the information that is displayed at the top of the window.

A number of free tests is indicated (tests that are included in your tariff plan) – in the example "*Test 2*".

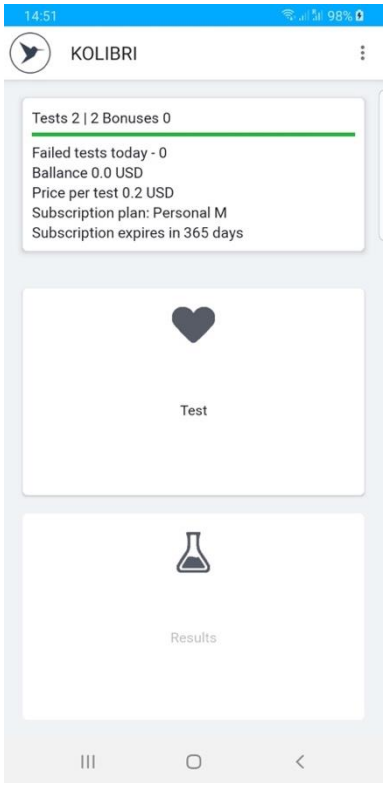
Also, the information about failed test during the current day, balance and cost of additional tests (above the free number). In the example, they are the following:

Failed tests today *– 0.*

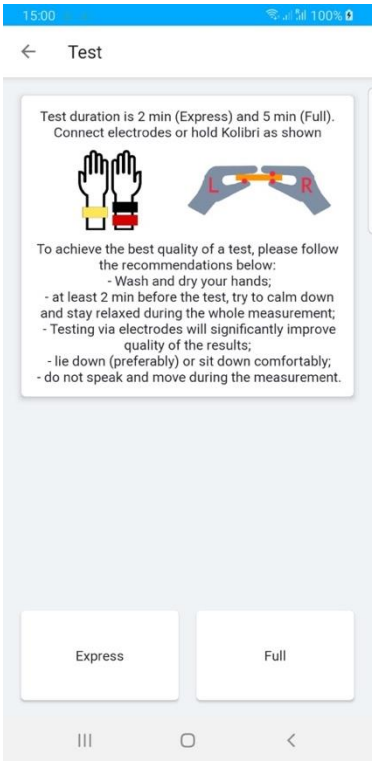
Balance *– 0.0 $*

Price per test *– 0.20$*

Pressing "**TEST**" will start the measurement.
Pressing the "**Results**" button will open the previous results.



The screenshot shows the position of the electrodes or contact plates. They should be placed according to the colour identification on the right and left.



Test duration:

Express - two minutes (may not be available in some regions)

Full - five minutes.

Note: Rapid test results are less accurate than full test results. Therefore, we recommend using the **FULL** mode.

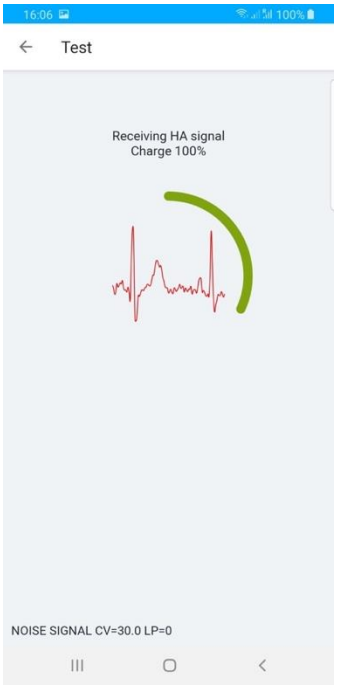
Switch on KOLIBRI according to the instructions in section 7.

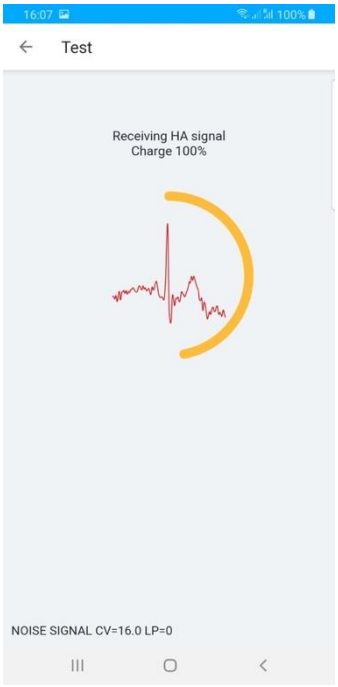
Take the device in your hands as shown. Press the **FULL** or EXPRESS button.

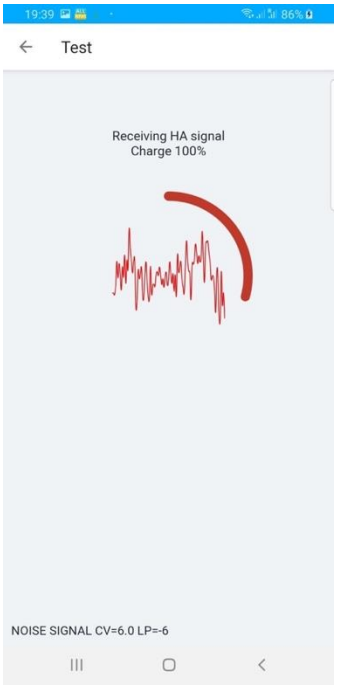
The LED on the device will flash green, indicating that the KOLIBRI device is connected to a mobile gadget. In addition, the LED flashes purple during all measurements if there is a good connection between the measuring plates and the patient's body. When the connection is bad/lost, the LED starts flashing blue.

Start testing. The process is displayed on the screen. KOLIBRI determines the signal quality in real-time and paints the process panel as follows: green - good quality, yellow - moderate quality, red - poor quality.

A yellow or red circle may appear for a short time. If the signal quality has been poor for a long time, the measurement will stop automatically. A corresponding message will appear.



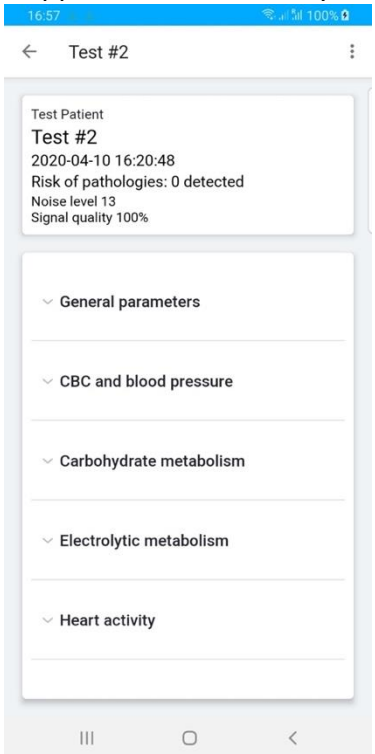


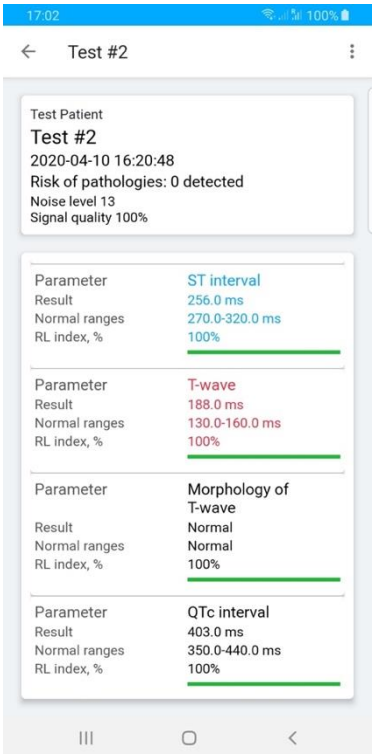


Sometimes, the signals with moderate and poor quality during the test can be rejected for processing by HSP KOLIBRI. The user will be informed about that with a message in the APP KOLIBRI. In such a case, it is recommended to ensure that other electronic equipment is far away from you, your skin in the areas of contact is moisturized and repeat a test. If the quality of the signal is acceptable, a user will get the results of measurement in the app after calculation by HSP KOLIBRI.

Usually, it takes a few seconds to send the measured data to server, process them there (by HSP KOLIBRI) and return the results to the app on your mobile gadget. Mostly, the duration depends on the internet speed.

Each group of parameters is opened by clicking. The calculated values of each indicator are available there. Wherein, if the value is in normal ranges, the color of text will be black. Elevated values marked with red and low values with blue.





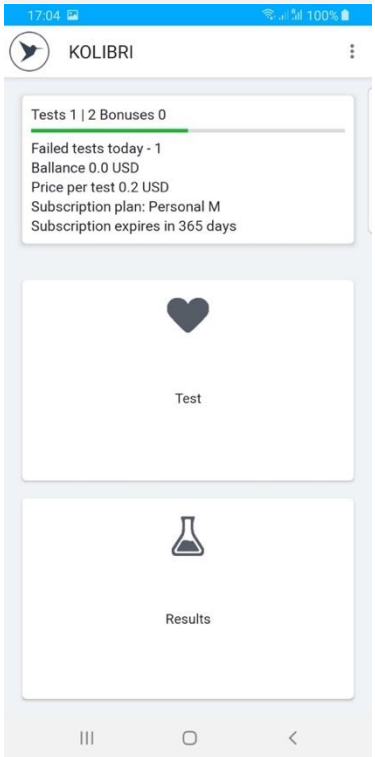
To see the archive of all tests done, you need to open the main menu (start window).

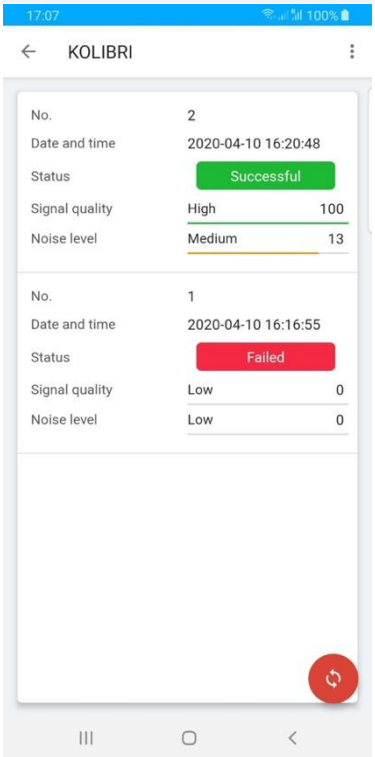
Press “Results”. List of tests will be displayed with indication of date and time of measurement.

Green (successful) tests are available for previewing. The signal quality was acceptable, so the parameters were calculated by HSP KOLIBRI.

Red (failed) tests were rejected and not processed due to poor quality of signal.

Failed tests do not influence the number of available tests per day (free tests).





9 FUNCTIONAL TEST OF MD KOLIBRI

Functional test of MS KOLIBRI is required to be done if it is used by medical staff for testing patients of clinic/hospital/family doctor (one device for a number of people). Such a test is almost the same as a usual test with MS KOLIBRI. It is aimed to check uninterrupted data transmission between a mobile gadget and cloud server (HSP KOLIBRI), the operability of hardware and software of MS KOLIBRI.
Battery charge is checked, too.

NOTE:

If the battery charge is below 30%, we recommend charging it. If the battery is low, patient testing may be interrupted due to the medical device being turned off.

Functional test includes the following steps:

Step 1 - Check if the MD KOLIBRI is paired with your mobile gadget. If not, please connect them following the instructions in Chapter 6.1;

Step 2 - Create a new patient with the name TEST (to create please follow the instruction in Chapter 6.2.4)

OR

use a “TEST patient” if it is already added to your database;

Step 3 - Fill in the information in the TEST patient's card

Please note, that for functional test the figures/numbers have no matter, the only one requirement is to use the numbers in the allowed ranges for each field;

Step 4 – keep the device in your hands or fix electrodes, as it is described in Chapter 7;

Step 5 – start measurement and wait while it is completed;

Step 6 – wait for the report with parameters from cloud server (HSP KOLIBRI). Open the report and look through it.

In case of any troubles during on any step, please follow the instructions form the messages displayed (warning, errors, notice, etc). Typical troubles and solutions can be also found in Chapter 12.

If taken measures do not resolve the situation and the device does not work properly, please contact your distributor or the manufacturer for troubleshooting.

List of local distributors and contact details are available at https://kolibri.healthentire.com/contact

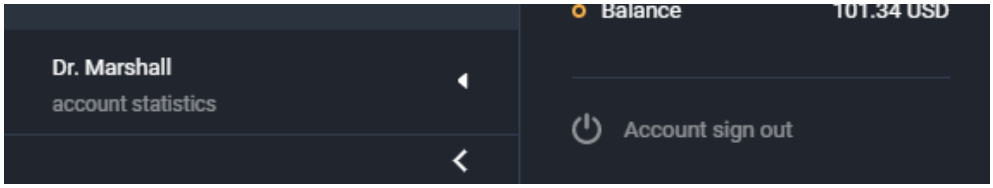
NOTE:

Switching on the medical device - the LED flashes green.
Switching off the medical device - the LED light red (some models maybe LED light purple).
The LED on the device will flash green, indicating that the KOLIBRI device is connected to a mobile gadget. In addition, during all measurements, the LED flashes purple if there is a good connection between the measuring plates and the patient's body. When the connection is bad/lost, the LED starts flashing blue.
The battery charge indicator is a yellow LED (light green for some models). It illuminates the on/off button). When the battery is fully charged, this LED goes out.

10 SWITCHING-OFF MD KOLIBRI AND SAFETY LOG OUT OF THE MOBILE (CLOUD) APPLICATIONS

When the measurement is finished, the device switches off automatically.

To force shutdown of the device, please press and hold the POWER button for 3-5 seconds. When LED lights red, take your finger off the button. The device is switched off.



To safely log out of the mobile application, use the "Logout" menu (Chapter 6.3 MOBILE APPLICATION MENU).
To safely sign out of your cloud application account Use the "Account sign out" menu.

11 EXAMPLES OF A REPORT

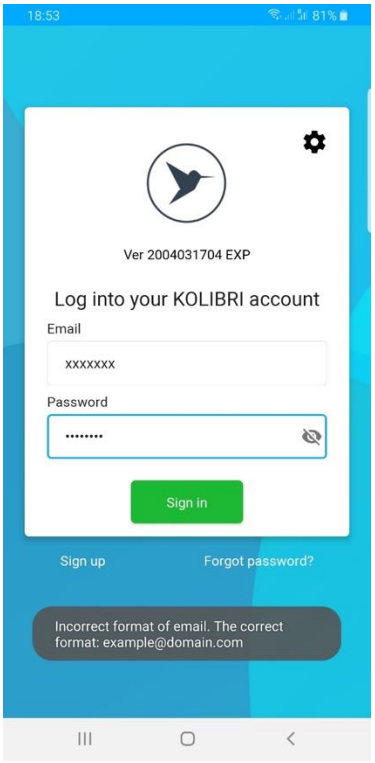
EXAMPLE OF A REPORT

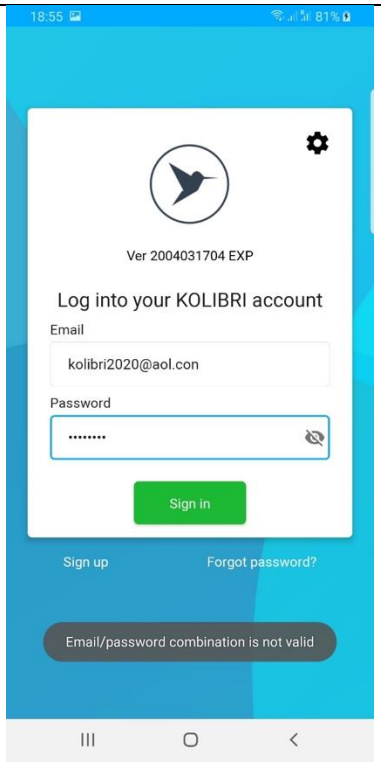
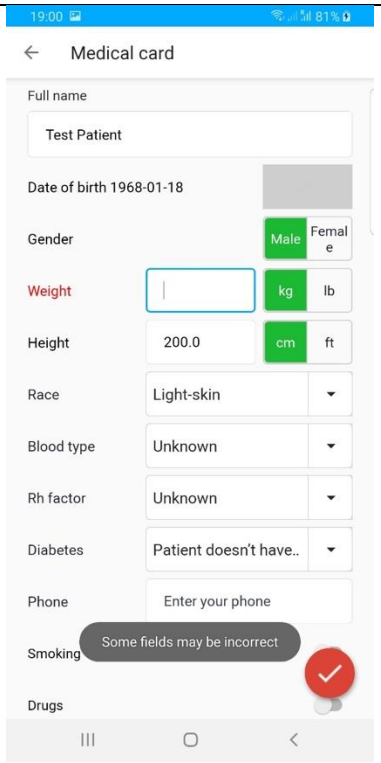
generated by MS KOLIBRI after an examination of a patient

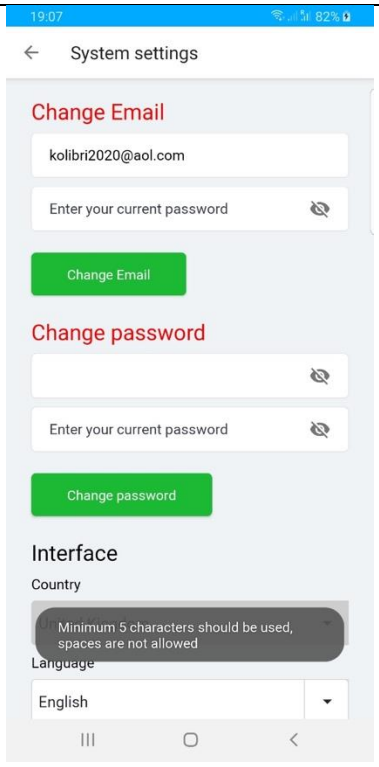
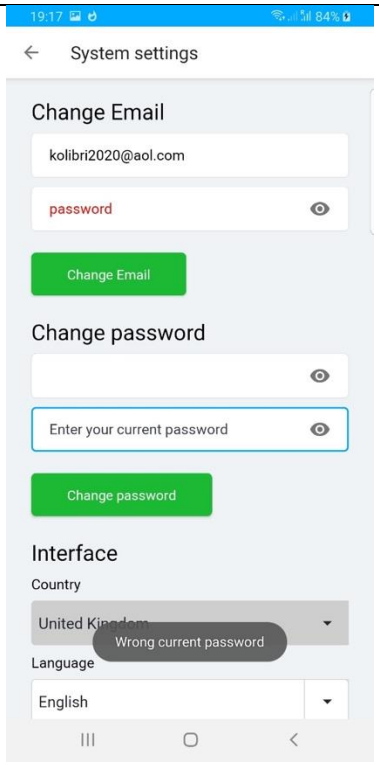
Example of a report with examination results is available here or please use QR-code

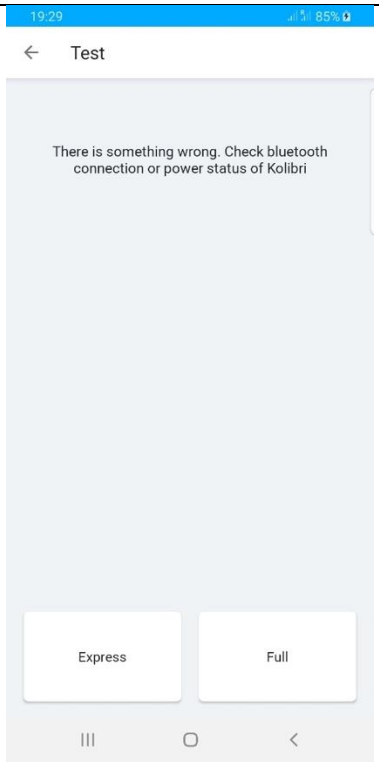
12 TROUBLESHOOTING

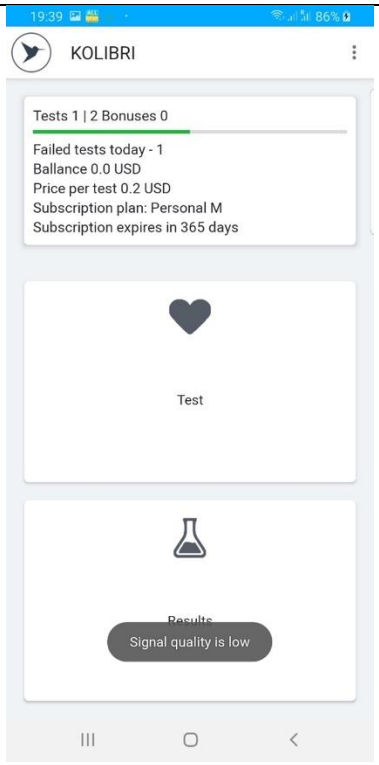
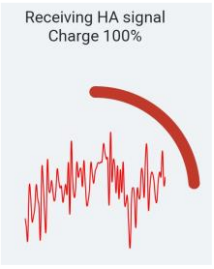
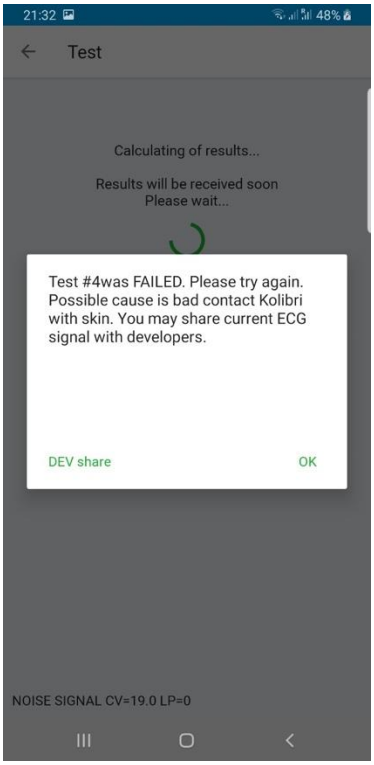
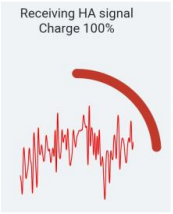
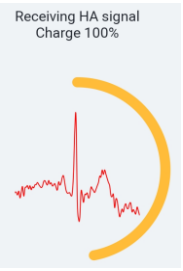
Possible errors and solutions:

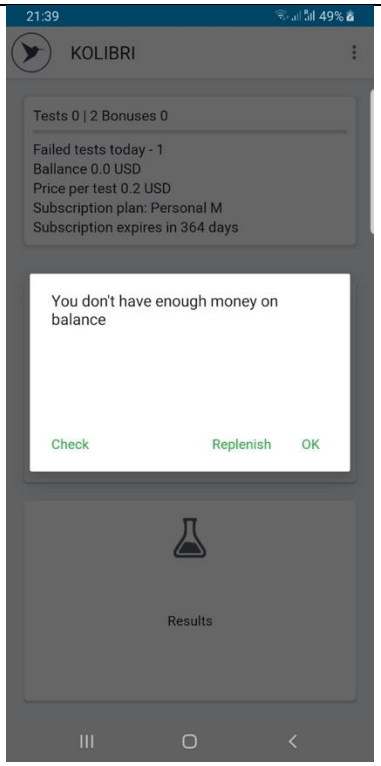
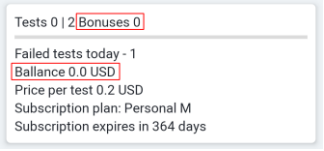
	Trouble/Error	Message to inform (warning, error, notice, etc)	Solution
1.	Incorrect format of email		Please enter correct email

2.	Wrong password/ Incorrect combination of email and password		Enter your correct email and password registered in MS KOLIBRI. Pay attention to the chosen language on your keyboard, capital and small letters, special symbols (if they used).
3.	Incorrect personal data		1. Enter correct data: a. Date of birth b. Select gender c. Enter weight d. Enter hight e. Select kg or lb f. Select cm or ft 2. The patient must be 18 years old or older.

4.	The password field must have five or more characters.		The password field must have five or more characters; spaces are not allowed.
5.	Wrong current password		Enter correct password.

6.	There is something wrong. Check Bluetooth connection or power status of KOLIBRI.		Check Bluetooth connection. Check power KOLIBRI (KOLIBRI switch ON?)
7.	During measurement on the MD KOLIBRI, the LED blinks blue colour.		Poor contact between the device plates and the patient`s skin surface. Moisten the surface of your skin before using the medical device KOLIBRI. There is no data transfer from a medical device to a mobile gadget. Turn the medical device off and on. Repeat the test procedure.

8.	Signal low quality		A message appears if the signal was of poor quality and the study was rejected. 
9.	Test #XX FAILED		A message appears if the signal was of poor quality and the study was rejected.  Or  Poor contact with appliance plates. Moisturize your skin. Repeat the test.

10.	Low balance.		Top up the balance in your account. After replenishing the balance, repeat the test. 

13 CLEANING AND DISINFECTION OF MD KOLIBRI

Disinfect MD KOLIBRI with disposable alcohol wipes before and after each use. Avoid getting the liquid inside a KOLIBRI during its cleaning and disinfection.
Disinfection of additional accessories (ECG sensors or ECG clips) must be carried out by disposable alcohol wipes.

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

WARNING! Disinfection of the surface, ECG cables and ECG clips by aggressive chemicals or solvents (phenol-based chemicals, ester, benzene, propanol, chloroform or acetone), solid and abrasive means is PROHIBITED!

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

14 MAINTENANCE AND SAFETY CONTROL

Preventive maintenance is not required. However, regular maintenance can help to identify possible defects at an early stage and thus improve the safety and extend the life of the device.

It is recommended to perform functional and safety inspections of the device at least once per year. It is necessary to follow national regulatory documents in case the national safety regulations for medical devices require control tests and inspections more often. Functional and safety inspections are carried out at the factory or at authorized service centres.

15 DISPOSAL AND ENVIRONMENT PROTECTION

The MD KOLIBRI is disposed of as an electronic equipment after the service life is ending. Please dispose the device in accordance with the applicable regulations in your country.

PRODUCT DISPOSAL: The MD KOLIBRI consists of various materials. Nevertheless, all of them (metal, plastic, electrical conductors, printed circuit boards, chips, etc.) do not contain hazardous substances and can be delivered to special processing centers, the same as electronic equipment. Before recycling, it is necessary to check related local regulations and requirements and strictly comply with them.

The medical device contains a lithium-polymer rechargeable battery.

Packaging disposal: packaging components (cardboard, expanded polystyrene, etc.) are classified as solid waste and therefore can be easily recycled by using recycling processes. Before recycling, it is necessary to check related local regulations and requirements for recycling and strictly comply with them.

16 REPAIR

The only responsible staff of the manufacturer, company SCIENTIFIC COMPANY KOLIBRI LLC, and authorized personnel of distributors/local representatives are allowed to carry out repairs of MD KOLIBRI. Only original spare parts, which are normally used by SCIENTIFIC COMPANY KOLIBRI LLC for production, are allowed to be used for repairing of the MD KOLIBRI.

The device can only be reused if it is repaired at the manufacturer's responsibility in accordance with general safety and performance requirements;

17 SHELF-LIFE OF THE DEVICE

The lifetime of the device is determined most of all by the lifetime of used electronic components and elements, applied materials and their fatigue, as well as the conditions of packing, storage and transportation, use and maintenance. When all the conditions comply, the manufacturer assures the lifetime of the device as 5 years.

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

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

- 5 years for the MD KOLIBRI;

Batteries have their own life cycles. If the time of working of the MD KOLIBRI in wireless mode becomes much shorter than usual, the battery cell life is at an end. Please ask your distributor/manufacturer for replacement.

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

In case of leakage of electrolyte from the battery, the use of a medical device is prohibited. The battery must be removed from the appliance and disposed of following local regulations in your area. If you cannot remove the battery yourself, contact the nearest service centre.

With intensive use of the medical device, a full charge of the battery should be sufficient for at least five tests before the next charge. If the battery is not fully charged for five tests, the battery is exhausted. Contact the service centre to replace the battery or purchase a new device.

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

18 STORAGE AND TRANSPORTATION

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

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

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

<table>
<tr><td>Specific condition of storage related to the embedded battery</td><td>During a long period of storage, cells should be maintained every 90 days (to keep the lifetime of the cell): the standard method of the charge-discharge cycle should be applied.

Do not store the MD KOLIBRI in wet or cold conditions! Moisture and cold increase the discharge rate of the battery. And under the influence of extremely high temperatures, there is a risk of explosion of the battery.</td></tr>
<tr><td> 
  </td><td>The medical device integrates a rechargeable lithium-polymer battery.
When transporting the device, you must adhere to the requirements of a document issued by IATA: IATA 2020 Lithium Battery Guidance.
Document Transport of Lithium Metal and Lithium-Ion Batteries. Revised for the 2020 Regulations based on the provisions set out in the 2019-2020 Edition of the ICAO Technical
Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions) and the 61 st, Edition of the IATA Dangerous Goods Regulations (DGR).
The provisions of the DGR with respect to lithium batteries may also be found in the IATA lithium Battery Shipping Guidelines (LBSG) 7th Edition. In addition to the content from the DGR, the LBSG also has additional classification flowcharts and detailed packing and documentation examples for lithium batteries.
Information on the DGR and LBSG can be found here:
http://www.iata.org/dgr
http://www.iata.org/lbsg</td></tr>
</table>

19 TERMS OF WARRANTY

The guarantee for the MD KOLIBRI is 36 months from the date of sale.
The manufacturer or its authorised representative performs a free repair of defective parts or makes a replacement of a defective device, in case of detection of manufacturing defects during the warranty period.

The warranty does not apply to often-used parts, such as USB cable, battery.

The warranty does not cover the faults and damages, which occurred due to a user's actions/inactions, violation of the manufacturer's requirements for operating and maintenance, storage and transportation, described in this IFU, as well as misuse of the device and influence of the force majeure circumstances.
Warranty claims are accepted only if the MD KOLIBRI is returned to the authorised representative or the manufacturer in a full complete set, clean, without external mechanical damages and signs of disassembly/opening. A customer covers transport expenses and the risk of accidental loss in delivering the device (both ways).

ATTENTION! It is not allowed to make any changes in the construction of the device. Any unauthorised opening, repairing or modification of the MD KOLIBRI by a customer's personnel or anybody else releases the manufacturer from the obligations and responsibility for the safe operation of the device. In such a case, the warranty is automatically considered invalid, even before the expiration of the warranty period. The warranty is considered as invalid if a customer has made any modification or design changes of the hardware or/and perform any changes in the software of MD KOLIBRI without the written agreement of the manufacturer.

For warranty and post-warranty service, as well as for all the issues regarding the operation of the device, please contact:

Manufacturer:
SCIENTIFIC COMPANY KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.one

Authorized representative in European Union:
EC REP **Authorized representative in European Union:**
HUNGARY
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79-2
Tel: +36-20-971-93-23
email: info@mdevice.org
URL: https://www.mdevice.org/

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

21 CERTIFICATES OF COMPLIANCE

MD KOLIBRI, Serial No. _____ is completely functional and operational, it complies to the Technical Specification and related harmonized standards, including but not limited, the Directive 2007/47/EC of the European Parliament and the Council amending Council Directive 93/42/EEC concerning medical devices, REGULATION (EU) 2017/745, EN ISO 13485:2016, EN ISO 14971:2019, MEDDEV 2.12 / 1- rev. 8, IEC 60601-1-3rd and IEC 60601-1-2 4th Ed., IEC 60601-1-11:2015/AMD 1:2020, TR 753 UA

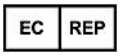
 Date of manufacture "_____" _____ 20___.

Check and confirmed by: _____ _____

Signature Name and Surname

Manufacturer:
SCIENTIFIC COMPANY KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.one

Authorized representative in European Union:



Authorized representative in European Union:
HUNGARY
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79-2
Tel: +36-20-971-93-23
email: info@mdevice.org
URL: https://www.mdevice.org/

22 PACKING LIST

The MD KOLIBRI

PERSONAL HEALTH SCREENING SYSTEM KOLIBRI®

Name of MD KOLIBRI

Model ☒ KOLIBRI Serial Number

is packed at the manufacturing facilities of the company SCIENTIFIC COMPANY KOLIBRI LLC in accordance with the Technical Specification

Complete set includes

Date of packing	DD	MM	YEAR

Packed by

Signature *Name and Surname*

Manufacturer:
SCIENTIFIC COMPANY KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.one

Authorized representative in European Union:
EC REP **Authorized representative in European Union:**
HUNGARY
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79-2
Tel: +36-20-971-93-23
email: info@mdevice.org
URL: https://www.mdevice.org/

23 WARRANTY CARDS

Warranty card	**PERSONAL HEALTH SCREENING SYSTEM KOLIBRI®**	
Card No. (Serial number of the MD KOLIBRI)		
Warranty period*	36 months for MD KOLIBRI	
Purchase Date	Seller	
YEAR/MM/DD	*Trade organization Name*	
	Seller address	Telephone
	Trade organization Address	*Trade organization telephone*
Customer	*[Customer Signature]*	*[Signature]*
Hereby, I confirm that I have read the warranty terms and agree with them		*[Company stamp]*

Important: Please store this card in a secured location for future reference. SCIENTIFIC COMPANY KOLIBRI LLC or its authorized representative reserved the right to request this document before accepting repair requests.

BEFORE UNPACKING PRODUCT, PLEASE READ CAREFULLY ALL ENTRIES IN THE WARRANTY. IF NOT ACCEPT THE TERMS OF WARRANTY, THE PRODUCT CAN UNIMPAIRED BE RETURN TO:

Manufacturer:
SCIENTIFIC COMPANY KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.one

Authorized representative in European Union:
EC REP **Authorized representative in European Union:**
HUNGARY
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79-2
Tel: +36-20-971-93-23
email: info@mdevice.org
URL: https://www.mdevice.org/

SCIENTIFIC COMPANY KOLIBRI LLC provides the manufacturer's warranty (herein referred to as the Warranty) for the Purchaser (herein referred to as the “User”) of the medical device KOLIBRI. This warranty card provided with the is subject to the following terms and conditions. Service under this warranty is provided by SCIENTIFIC COMPANY KOLIBRI LLC and / or Authorized Distributors.
*Warranty Period of the KOLIBRI:
This warranty applies for the period 24 months from the date when the end customer first purchased the KOLIBRI (“Purchase Date”). If proof of purchase is not supplied with the KOLIBRI, as the start of the warranty period will be considered the date of manufacture of the KOLIBRI, registered by SCIENTIFIC COMPANY KOLIBRI LLC.

The Warranty does not cover bundled accessories, which were delivered together with the KOLIBRI such as USB cable, battery.

TERMS OF WARRANTY

1. General

SCIENTIFIC COMPANY KOLIBRI LLC warrants the KOLIBRI to be free from defects in workmanship and materials for the Warranty Period. The Warranty does not cover bundled accessories, which were delivered together with the KOLIBRI such as cable USB and battery. If the KOLIBRI fails during normal and proper use within the Warranty Period, SCIENTIFIC COMPANY KOLIBRI LLC will repair or replace the defective parts of the KOLIBRI, or the KOLIBRI itself, with new or reconditioned parts or products that are functionally equivalent or superior to those originally supplied.
This Warranty applies only if the KOLIBRI was newly manufactured on the Date of Purchase and not sold as used, refurbished or manufacturing seconds. Please keep the original purchase invoice and this warranty card for a future service request.
This Warranty does not include failure caused by improper installation, operation, cleaning or maintenance, accident, damage, misuse, abuse, non- SCIENTIFIC COMPANY KOLIBRI LLC modifications to the KOLIBRI, any changes in the software, normal wear and tear or any other event, act, default or omission outside SCIENTIFIC COMPANY KOLIBRI LLC control.

2. Customer responsibility

When using the Product

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

When contacting SCIENTIFIC COMPANY KOLIBRI LLC Customer Service

* Before contacting SCIENTIFIC COMPANY KOLIBRI LLC or Authorized Distributor's technical support, ensure that you have the KOLIBRI in front of You and that it is turned on and connected to the Internet, if feasible. Please also be ready to provide the KOLIBRI's serial number, the model name and proof of purchase.

* Technical support phone number or email can be found at www.mdevice.org
* You may be requested by SCIENTIFIC COMPANY KOLIBRI LLC to perform some of the KOLIBRI's troubleshooting tasks or actions, which may include the following:
* Installing updates.
* Performing other reasonable activities requested by SCIENTIFIC COMPANY KOLIBRI LLC, which will assist in identifying or resolving the problems (e.g., installation of special software for remote access by our technicians to your computer, etc.).
* If the problem is not solved remotely, you will have to return the Product to a SCIENTIFIC COMPANY KOLIBRI LLC Repair Centre.
* Describe the problem clearly and completely in the Complaint form (the Customer Service will provide the form after your request).
* Enclose a copy of this completed warranty card and a copy of Your sales invoice/ receipt detailing the purchase of the KOLIBRI. (Please note: SCIENTIFIC COMPANY KOLIBRI LLC reserves the right to request the original documents.) If You do not provide the requested documents for warranty validation, then the manufacture date of the KOLIBRI as recorded by SCIENTIFIC COMPANY KOLIBRI LLC will be deemed to be the start of Warranty Period.
* Ensure that You have fully backed up all the data stored in the database of your software KOLIBRI and removed any personal, confidential, or proprietary information before any service process is started. SCIENTIFIC COMPANY KOLIBRI LLC shall not be held liable for the permanent loss, damage, or misuse of your data.
* Pack the Product in safe and stable packaging. The original packaging may be useful for this purpose. In any case, the packaging should meet the following requirements:
* Use a rigid box.
* Remove any labels, hazardous materials indicators, and other previous shipment markings on the box that are no longer applicable.
* Wrap all items separately
* Use the adequate cushioning material
* Use strong tape designed for shipping
* Use a single address label that has clear, complete delivery and returns information
* Place a duplicate address label inside the package
* Please do not send in anything but the KOLIBRI itself unless specifically requested by SCIENTIFIC COMPANY KOLIBRI LLC.

3. Exclusions from the Warranty Service

SCIENTIFIC COMPANY KOLIBRI LLC does not warrant the uninterrupted or error-free operation of this KOLIBRI. The warranty only covers technical hardware issues during the warranty period and in normal use conditions. It does not apply to software issues or customer induced damages or circumstances such as, but not limited, to:
* The KOLIBRI has been tampered or repaired and/or modified by non-authorized personnel;
* The serial number of the KOLIBRI, components or accessories has been altered or removed;
* Obsolescence;
* Damage (accidental or otherwise) to the KOLIBRI that does not impact the KOLIBRI's operation and functions, such as without limitation to scratches, change in colour, texture or finish, wear and tear, and gradual deterioration;

* Damage to the KOLIBRI caused by war, terrorism, fire, accident, natural disaster, intentional or accidental misuse, abuse, neglect or improper maintenance, and use under abnormal conditions;
* Damage to the KOLIBRI caused by improper installation, improper connection or malfunction of a peripheral device such as printer, optical drive or USB device, etc.;
* Damage to the KOLIBRI caused by an external electrical fault or any accident;
* Damage to the KOLIBRI resulting from use outside of the operation and storage environment detailed in the IFU;
* Damage to the KOLIBRI caused by third party software or virus(es); or there is software loss or data loss that may occur during repair or replacement;
* Invalidity of or damage to the KOLIBRI caused by contamination with hazardous substances, vermin, or radiation and so on;
* Fraud, theft, unexplained disappearance, or wilful act;
* Damage made to the KOLIBRI caused by using the materials other than those recommended by SCIENTIFIC COMPANY KOLIBRI LLC shall not be covered by the Warranty.

The warranty does not cover damage resulting from normal wear and tear, i.e., parts that require periodic replacement during normal use of the device, including USB cable and battery and other defined by specifications of the product and considered consumables.

SCIENTIFIC COMPANY KOLIBRI LLC shall not be liable for damage resulting from improper maintenance procedures of the equipment, improper cleaning, and mechanical and chemical damage caused by that. Except as provided in this warranty and to the maximum extent permitted by law, SCIENTIFIC COMPANY KOLIBRI LLC is not responsible for direct, special, incidental or consequential damages resulting from any breach of warranty or condition, or under any other legal theory, including but not limited to loss of use; loss of revenue; loss of actual or anticipated profits (including loss of profits on contracts); loss of the use of money; loss of anticipated savings; loss of business; loss of opportunity; loss of goodwill; loss of reputation; loss of, damage to or corruption of data; or any indirect or consequential loss or damage whatsoever caused including the replacement of equipment and property, any costs of recovering or reproducing any data stored on or used with the KOLIBRI.

The foregoing limitation shall not apply to death or personal injury claims, or any statutory liability for intentional and gross negligent acts and/or omissions by SCIENTIFIC COMPANY KOLIBRI LLC.

4. Privacy

You agree and understand that it is necessary for SCIENTIFIC COMPANY KOLIBRI LLC to collect, transfer, and process personal data in order to facilitate the requested service; and that for this purpose Your data may be transferred to and processed in any country where SCIENTIFIC COMPANY KOLIBRI LLC or its affiliated companies maintains offices, which include countries outside of the European Union, the mandatory laws of which do not guarantee a data protection level equivalent to the laws of EU member states. However, SCIENTIFIC COMPANY KOLIBRI LLC will use and protect Your personal data at any time and in any country subject to the SCIENTIFIC COMPANY KOLIBRI LLC Privacy Policy.

5. Out-of-Warranty cases

Returning the Product to the SCIENTIFIC COMPANY KOLIBRI LLC Repair Centre during the warranty period does not automatically mean that it will be repaired free of charge. Upon receiving Your Product, SCIENTIFIC COMPANY KOLIBRI LLC reserves the right to check the validity of Your Warranty and Your request for Warranty service. If the Warranty Period has lapsed or if any of the exclusions in clause 3 apply, your request will be deemed out of warranty (“OOW”). If Your service request is OOW, a Service Charge List with an offer for repair will be provided to You, which You may accept or reject. If You accept

the repair, we will provide You with an invoice for the repair labour, spare parts and other costs stated in the Service Charge List. The invoice must be paid according to the payment date contained in the document. Repairs will be made after payment of the invoice. To the extent permitted by law, SCIENTIFIC COMPANY KOLIBRI LLC may charge You transportation costs if Your service request is OOW and you refuse the repair offer; or if Your Product does not require service.

6. Abandoned Property

After Your Product has been repaired, or if You do not agree to the repair offer, SCIENTIFIC COMPANY KOLIBRI LLC will return your Product via the agreed method. If You do not pick up Your Product, or if delivery is not possible at the address provided by You, SCIENTIFIC COMPANY KOLIBRI LLC will send You notice at the email address and telephone You provided when requesting the service. If You still failed to pick up the Product within a period of 90 days from sending the notice, SCIENTIFIC COMPANY KOLIBRI LLC reserves the right to claim damages from you, including the cost of storage; to dispose the product in accordance with the applicable laws and regulations; and any statutory right of lien for unpaid charges.

TEAR-OFF COUPON NO.1	*[SERIAL NUMBER OF DEVICE]*	**No.1**	*Filled up by service centre*
PRODUCT	**KOLIBRI®**		
MODEL NAME			*Reception date*
PURCHASING DATE			*Release date*
TRADE ORGANIZATION			*Special Marks*
	TRADE ORGANIZATION STAMP		*SERVICE CENTER STAMP*

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

WARRANTY CARD MAY BE PRINTED-OUT SEPERATLY FROM THE USER'S MANUAL AND INCLUDED INTO COMPLETE SET OF THE KOLIBRI TOGETHERWITH/AS A PART OF TECHNICAL PASSPORT.

Responsible organizations for warranty and post-warranty service:

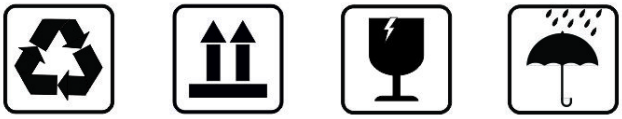
Manufacturer:
SCIENTIFIC COMPANY KOLIBRI LLC
Kinnyi provulok 8a, Kharkiv, 61001, Ukraine.
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.one

Authorized representative in European Union:
EC REP **Authorized representative in European Union:**
HUNGARY
Medical Devices Magyarország KFT
1149 Budapest, Vezér utca 79-2
Tel: +36-20-971-93-23
email: info@mdevice.org
URL: https://www.mdevice.org/

All valid permits and certificates are available on the manufacturer's website https://kolibri.one/certificates

24 LABELING

Labels on the outer package of the MD KOLIBRI®

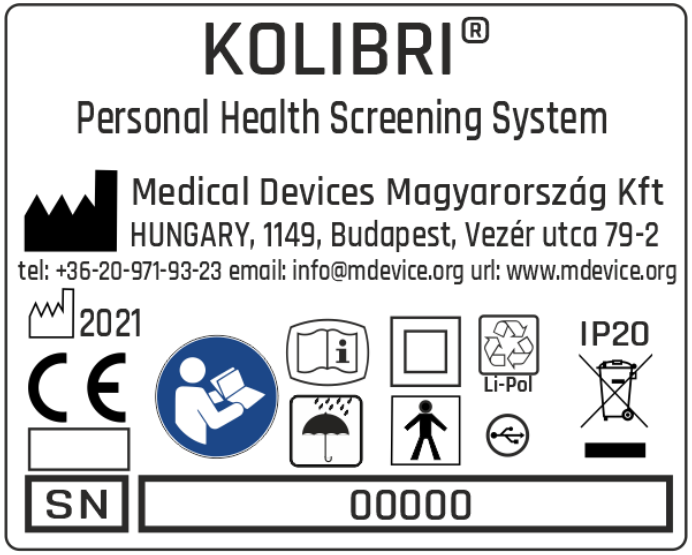


Labels and marking used for the MD KOLIBRI.

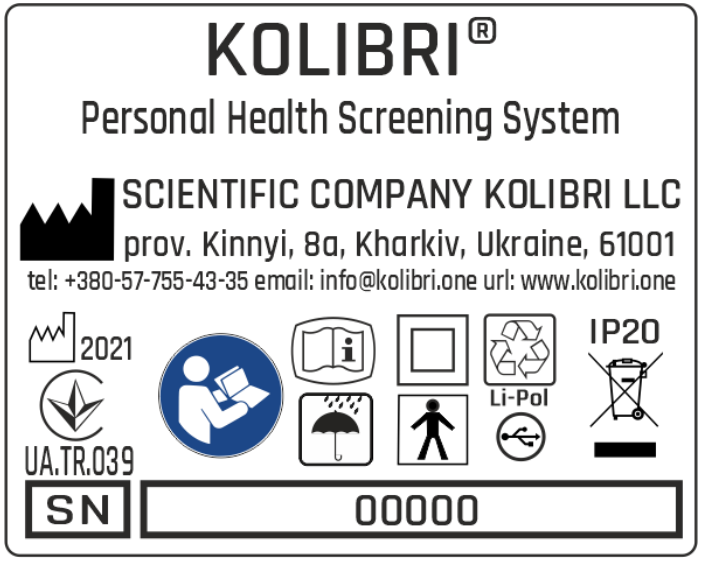
A number of internationally recognized symbols are placed on a label of the MD KOLIBRI®. The symbols relate to the safety requirements and standards and are briefly reviewed below:

2	Trade name of the medical device:	**KOLIBRI®**		
CE symbol *(where **xxxx** is the number of Notified Body)*		CE	TYPE BF APPLIED PART	
Issue Date	*[Date of manufacturing]*		Serial number of MD	SN *[Serial number]*
Manufactured by	SCIENTIFIC COMPANY KOLIBRI LLC Ukraine 61001 Kharkiv, Kinnyi provulok 8a, Tel.: +380913011110 Ukraine. email: info@kolibri.one URL: https://kolibri.one		Symbol for connection of USB port	
Represented by (*European representative)*	EC REP **in Europe** **Authorized representative in European Union: HUNGARY** **Medical Devices Magyarország KFT** **1149 Budapest, Vezér utca 79-2** **Tel: +36-20-971-93-23** email: info@mdevice.org URL: https://www.mdevice.org/		CLASS II equipment IEC 60417-5172	
MD Class IIa	**MD Class IIa**		Attention label ***Carefully read the IFU before the first use of the device***	
Sign of waste electronic equipment				

Project of labels for the MD KOLIBRI

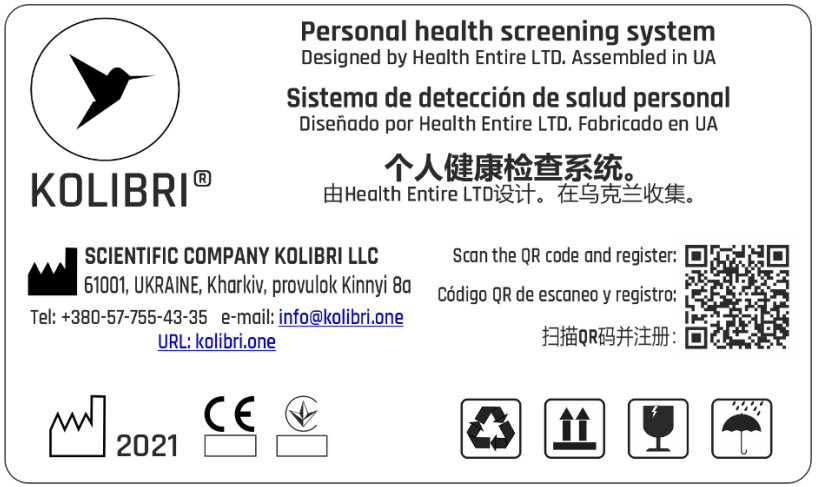


Project of labels for the MD KOLIBRI (for EU)



Project of labels for the MD KOLIBRI (for CIS)

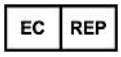
Label design for medical device packaging
(for EU)



Label design for medical device packaging
(for CIS)

25 MANUFACTURER AND THE AUTHORIZED SERVICE CENTRES

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

	**Manufacturer:** **SCIENTIFIC COMPANY KOLIBRI LLC** Kinnyi provulok 8a, Kharkiv, 61001, Ukraine. Tel.: +380913011110 email: info@kolibri.one URL: https://kolibri.one		**Authorized representative in European Union:** **HUNGARY** **Medical Devices Magyarország KFT** **1149 Budapest, Vezér utca 79-2** **Tel: +36-20-971-93-23** email: info@mdevice.org URL: https://www.mdevice.org/
	Service centre EU **ONKOCET s.r.o.** 4 Kutuzova str., 90201 Pezinok, Slovakia, Tel.: +421 (2) 44 64 09 77 email: onkocet@onkocet.eu URL: www.onkocet.eu		**Representante Oficial en MÉXICO:** **"B&L PROMOTION, S de R. L. de C.V."** **División Médica: "B&L MEDICA"**, Insurgentes Sur 1872-302, Delegación Álvaro Obregón Col. Florida, Ciudad de México tels.: +52 1 55 4135 9579 +52 1 55 1295 7030 email: jbenages@blmedica.com URL: www.blmedica.com
		UK	**Authorized representative in UK** **Health Entire LTD** 86-90 Paul Street London, United Kingdom EC2A 4NE Tel.: +447938004330 email: healthentireuk@gmail.com URL: https://kolibri.healthentire.com/

All valid permissions and certificates are placed on the manufacturer's homepage https://kolibri.one/certificate

MD Class: IIa

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

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

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

KOLIBRI™ is a transient noninvasive active medical device for diagnostics of **Class IIa**, according to the Annex VIII, Sect. I clause 1.1 and clause 2.5, Sect. II clause 3.3, Sect. III clause 6.2 Rule 10 and clause 6.3 Rule 11 of the MDR.

26 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 (**KOLIBRI™**) 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 and use SSL protocol with authorization into an email. The software and the database don't run without the password, so only the authorized user, who keeps the password to the definite account (hence to the corresponding DB) has to 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 **KOLIBRI™**.

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 informed consent.

We recommend getting 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* **KOLIBRI™** *for the purposes of a non-invasive screening test.*

I am aware of and agree with the condition that the data containing in the database of the software IDEA-4RS will not be disclosed and/or forwarded to unauthorized third parties except the following:

a) to a personal data processor (a medical professional, who is responsible for carrying out an examination and interpret the results on site);

b) to the respective/authorised staff of the manufacturer, whose duties includes the elimination of bugs in the software, software update or other assistance related to the software on the request of the personal data processor;

c) to governments, control agencies, regulatory authorities and others as permitted or required by law.

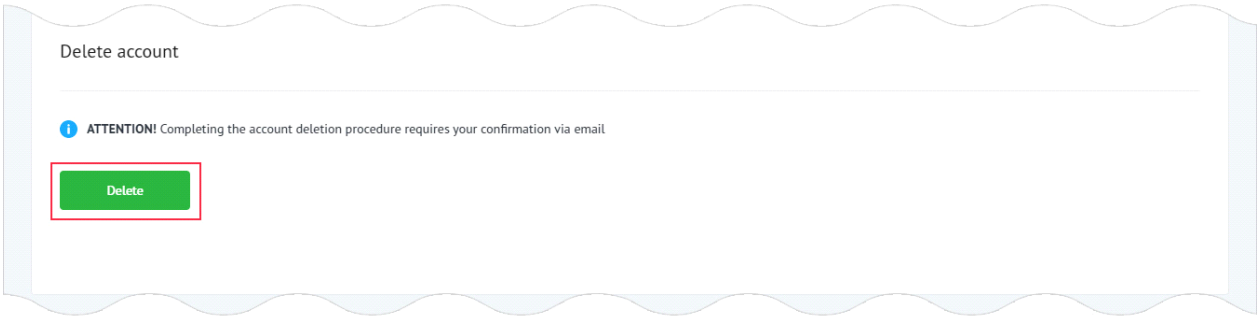
I am aware of an ability to withdraw my consent at any time submitting a written statement in the place, where the service was provided. Thereof, I realize that my personal data will be deleted irrevocably and without a possibility of further applying, referring and analysing of such data.

*Signature of patient*_____

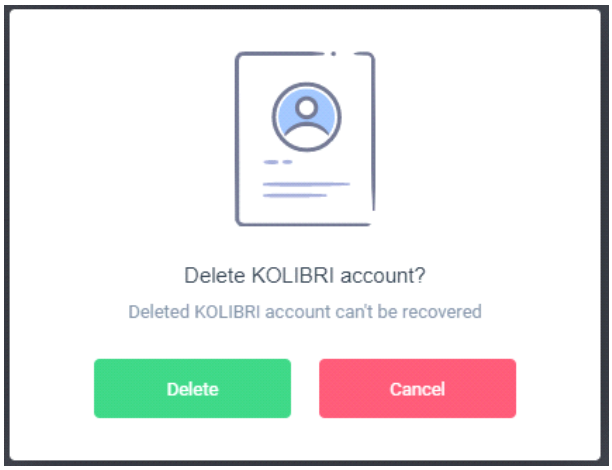
27 DECOMMISSIONING AND DISPOSAL OF SOFTWARE

Before deleting the mobile application on your mobile gadget, you need to delete your account.
Log into your cloud platform account.
Deleting of the account in the HSP KOLIBRI.

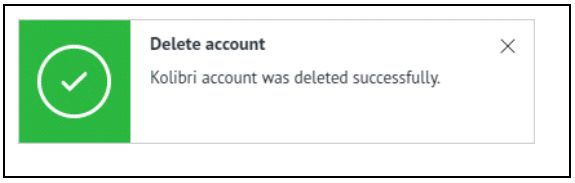
The general view of the account management settings interface is the following:



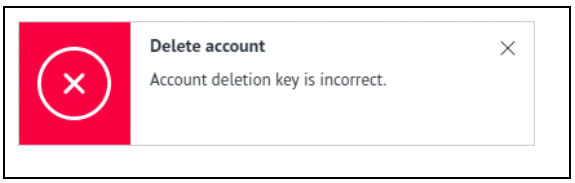
To initialize the process of deleting an account from HSP KOLIBRI, the user clicks the "Delete" button. A modal window is called in which the user must confirm the deletion of the account from HSP KOLIBRI:



The account deletion operation completely deletes the user data in HSP KOLIBRI, which refers to personal data according to the General Data Protection Regulation (EU) 2016/679.
WARNING: Deleted data cannot be recovered. The operation of deleting the account requires confirmation from the user via his email.
After confirming the initialization of the operation to delete the KOLIBRI account, a link to delete the account will be sent to the user's mail.
If the account deletion is successful, the application will notify you:



If an error occurs while deleting your account, the app will notify you:



If you are using the mobile application, you can safely log out of the mobile application and delete it after deleting your cloud platform account.

28 DOCUMENT HISTORY AND VERSION CONTROL

Version	Version Date	Summary of changes	Author	Related documents
1.0	2021-01-11	Created	Team, listed on the title	

Please read the IFU carefully before using the device!