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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.

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This provision concerns, copying, translating, scanning, placing and manipulation, etc both in electronic systems and with printed versions.

Abbreviations and Definitions used:

	Medical system is an integrative medical solution for screening diagnostics, which combine
MS	hardware and software parts, that work in conjunction, using remote access and AI/ML algorithms
	of data processing.
	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
SaMD=HSP	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.
	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
APP	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.

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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	0	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	100-240	VAC Power the MD
CE	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	\triangle	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 <b>20</b>	First number <b>2</b> - Degrees of protec the infiltration of impurities: pr against solid objects up to 12mm of	tion against otected e.g., fingers	Second number <b>0</b> - 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.

KOLIBRI.ONE

KOLIBRI APP

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

KOLIBRI TF.16.001.003-IFU

#### **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 °C and +27 °C) 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 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:

- 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:

- 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



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 selfconnected 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	
МАР	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.	
НСТ	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.
МСНС	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.
МСН	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.
к	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.
Са	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 ( $\alpha$ 1)
DFA2	Detrended fluctuation analysis, which describes long-term fluctuations ( $\alpha 2$ )
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)
ТР	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 P	ATHOLOGIES (14) displayed only if identified ECG findings + HRV diagnostics
ICD-10	Description
121	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
R94.31	Abnormal electrocardiogram
144.0	Atrioventricular block, first degree
144.5	Left posterior fascicular block
144.7	Left bundle-branch block, unspecified
145.6	Pre-excitation syndrome
145.9	Conduction disorder, unspecified
144.4	Left anterior fascicular block
145.1	Other and unspecified right bundle-branch block

R00	Tachycardia, unspecified
R00.1	Bradycardia, unspecified
124	Other acute ischemic heart disease
145.81	Long QT syndrome
148	Atrial fibrillation and flutter

ECG FINDINGS (43)	
based on HA	

#### displayed only if identified

Method and corresp. C	ode	ICD10	Description	
Simplified Minnesota Code	1.11		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	121	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		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	DO4 21	T wave abnormalities without Q waves	
Simplified Minnesota Code	5.2	K94.31	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	
Circulified Newson de Corde	1.41		Minor ST-T abnormalities         .1         Supraventricular tachycardia, rate < 130 cpm	
Simplified Novacode Code	1.42	147.1		
Simplified Minnesota Code	6.3	144.0	First-degree AV block (AVB1)	
Simplified Novacode Code	2.1	144.0	Atrioventricular block, first degree	
	7.7		Left anterior fascicular block (LAFB)	
Simplified Minnesota Code	7.11	144.4	Left bundle branch block without ECG evidence of myocardial infarction (MI)/ QRS duration $\ge$ 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	145.1	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		Intermittent aberrant atrioventricular conduction	
Simplified Minnesota Code	7.4		Indeterminate ventricular conduction delay without ECG evidence of MI/ QRS duration $\ge$ 120 ms	
Simplified Novacode Code	3.1	145.9	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	1/15 21	Marginal prolongation of ventricular repolarization	
Simplified Novacode Code	4.12	143.01	Significant prolongation of ventricular repolarization	
Simplified Minnesota Code	3.1	151.7	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	144.7	QRS duration $\ge$ 120 ms/Ventricular preexcitation pattern (WPW)
Simplified Minnesota Code	6.5	145.6	Short P-R interval
Simplified Minnesota Code	7.6	144.5	Left posterior fascicular block (LPFB) / Borderline delay of left ventricular
Simplified Minnesota Code			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	124	Infarction / Ischemia
Simplified Minnesota Code	9.1	DO4 21	Low QRS amplitude
Simplified Minnesota Code	9.5	K94.31	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  $+20 \text{ }^{\circ}\text{C}$  and  $+27 \text{ }^{\circ}\text{C}$ ;
- relative humidity in a room must be less than 80% at the temperature +25 °C;
- 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

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

- 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 gualifications, 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.

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.



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.

WARNING! Modification of the MD KOLIBRI is not allowed!



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 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):

#### IFU for MS KOLIBRI[®]

N - S. (5) 49%
t
s something wrong. Check bluetooth nection or power status of Kalibri
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#### 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
Pattony (Lithium Polymor Coll)	LP502060 3.7V 510mAh, installed on the PCB (see the
Battery (Lithium Polymer Cen)	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
	Definition of human health parameters on the base of HA
Applied methods	measured at designated points on a body (on the skin) and
	anthropometric data of the patient.
	KOLIBRI APP (installed on a mobile gadget), KOLIBRI SW
Software	(cloud based), the hardware has internal software,
	preinstalled on a chip
Ambient temperature for storage and	From -5°C (without relative humidity control)
transportation	till + 45°C (with relative humidity control)
	Class 7K2, as described in the IEC/TR 60721-4-7:2001
Ambient temperature and humidity during	The device is to be used indoor. Environmental conditions
operation of MD	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)
	Pressure absolute accuracy (Test conditions: 50 to 110 kPa over–10 °C to 70 °C) - ±0.4 kPa
Precision pressure sensor with altimetry	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			1	Minimum software requirements		
Display		min. 5"-55" definition HD+,	Operating	Android OS C or higher		
Display		FHD+, QHD+, WQHD+ or more	system	Android US 6 of higher.		
Mobile gadge	t	LTE, 3G or high, Wi-Fi,	Web	Any web browser		
support		BLUETHOOTH 3.0 or hight	browser	Any web browser		
Antivirus software			Any antivirus s	oftware must be set up in such a way when the		
			software KOLIE	3RI is not blocked.		

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

Bat	tery (Lithium Polymer Cell) LP502060 3.7V 510mAh, installed on the PCB				
Charge limited voltage/	4.2V/3.7V (the cell is protected by an electronic circuit that won't allow it to overcharge				
Nominal voltage	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	2.751/+50m1/(11/to 26msec delay resume 2.501/+50m1/)				
Detection	2.75V ±5011V (14 to zoniset, uelay, resume 2.50V ±5011V)				
Overcurrent Detection	2A to 4.5A (8 to 16msec. delay)				
Ambient Conditions					
Charge Temp. Range	0 to +45 °C				

Discharge Temp. Range	-20 to +60 °C
Storage Temp. Range	1 year at -20 to +30°C >70%
Oversurrent Detection	3 moths at -20 to +45°C >70%
Overcurrent Detection	1 month at -20 to +60°C >70%
Humidity	65 ±20%RH
	Please follow LiPo Handling and Safety Precautions for Lithium Polymer Battery. This
Environmental and	battery meets the requirements of Battery Directives, and the battery parts are IEC 62133
Safety	& 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)

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#### **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
<ul> <li>Remove the device from its packaging. Make sure there is no damage to the enclosure, USB cable.</li> </ul>
<ul> <li>Install the application KOLIBRI to your mobile gadget (Chapter 5).</li> </ul>
<ul> <li>Create your account on the platform https://kolibri.one (Chapter 6.4)</li> </ul>
REGULAR ACTIONS BEFORE USE (every time before use)
<ul> <li>Check the battery power of the KOLIBRI.</li> </ul>
<ul> <li>Check the battery power of your mobile gadget</li> </ul>
<ul> <li>Make sure that Bluetooth is turned on in the mobile gadget and the KOLIBRI is connected.</li> </ul>
<ul> <li>Make sure your mobile gadget is connected to the Internet.</li> </ul>
<ul> <li>Determine your weight and hight.</li> </ul>
<ul> <li>Make sure the surface of your hands is clean and slightly moisturized.</li> </ul>
$\checkmark$ 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.
<ul> <li>If you use ECG electrodes, make sure they are not damaged.</li> </ul>



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.



<u>The operators/users</u>, who took psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol during at least 24 hours before testing should not use the MD <u>KOLIBRI</u> (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 <a href="https://help.kolibri.one/">https://help.kolibri.one/</a>)

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

KOLIBRI APP Ver.2.02

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



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<b>4</b> 3)	Sounds and Sound mode, Ri	d vibration ingtone, Volume	
	Notification Block, allow, pri	<b>IS</b> oritise	
	Display Brightness, Blue	e light filter, Hon	ne screen
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	Lock screer	<b>n</b> e, Always On Dis	splay, Clock style
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### Connections

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Wi-Fi Connect to Wi-Fi networks	š.	$\bigcirc$
Bluetooth Connect to nearby Bluetoo	oth devices.	$\bigcirc$
NFC and payment Make mobile payments, sl or write NFC tags.	hare data, and read	$\bigcirc$
Flight mode Turn off calling, messagin	g, and Mobile data.	$\bigcirc$
Mobile networks		
Data usage		
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Select the menu "CONNECTIONS"

Select the menu "BLUETOOTH".

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#### Turn on "BLUETOOTH"

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## Select the medical device KOLIBRI from the list of available devices


Click «OK»

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

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#### 6.2 MOBILE APPLICATION

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	Ver 19 Log into your	08081742 KOLIBRI account
	Email	
6.2.1. APP SETTINGS	Password	
Launch the mobile app.	Show password	_
Make your SETTINGS in the menu	Sign up	GN IN Forgot password

- 1. Language select interface language
- 2. Bluetooth- opens the BLUETOOTH settings of the mobile gadget.
- 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.
- 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.
- 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.
- 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.
- Custom server IP the menu for setting the IP address or server name with which you will work (for example: <u>https://kolibri.one</u>, <u>https://kolibri.ae https://mdevice.eu</u> etc.)
- 11. About Latest software release date and number.
- 12. Privacy policy provisions on personal data protection. It is updated from time to time.

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Language	
Bluetooth	
Wi-Fi	
Auto send unfinished tests	
Suggest to enter glucose and pressure	
Enable noise check Stops test if noise level is high	
Dev Mode	
Show results by color (dev)	
ECG filtering Enables ECG filtering at result page	
Custom server IP Set server IP	
About v0.200 2102031122EXP	
Privacy policy Check out our privacy policy	

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#### 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. format and has the right to transmit that data to another controller without hindrance from the controller to which the personal data has

been provided... For the KOLIBRI software:

The KOLIBN Software allows you to export data from the results of a patient examination onto paper and PDF files with the subsequent transfer of files via email. This enables you to realize the right to data portability.

portability. The KOLIBRI software allows you to remotely connect the transfer of the results of your research to the doctor's cloud account and the function of displaying the test results in the doctor's account in real-time is implemented. This allows you to realize the right to data portability.

#### Signature of patient

GDPR: I have been briefed on my rights and Privacy Policy based on the REGULATION (EU) 2016/679 (GDPR) egarding the processing and movement of the personal data, which are used for the purposes of non-invasive hemogram screening, provided by the software KOLIBRI. I am aware of and agree with the cardinal the data containing in the database of the software KOLIBRI will not be disclosed and/or forwarded to unauthorised third parties except the following: a) to a personal data precessor (a professional, who is responsible for carrying out an examination on site); b) to the respective/authorised staff of the manufacture, whose duties includes elimination of bugs in the software KOLIBRI, software update or other assistance related to the software KOLIBRI, on the request of the personal data processor; (b) governments, control agencies, regulatory authorities and others as permitted or required by law. I am aware of an ability to withdraw my consent at any time submitting a written statement in the place, where the service was provided. Thereof, I realise that my personal data will be deteed invecubly and without a possibility of further applying, referring and analysing of such a data.

#### Signature of patient

INTERNATIONAL TECHNOLOGY CENTER PO.BOX 330102, Ras IK haimah, United Arab Emirates Tel. 4971-07-2041957 mob. 4971-55-7702115 e-mail: tict.fzc@gmail.com http://intert.com/about_us



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".

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Ver 1908081742   Sign up KOLIBRI   Full name   Email   Password   Show password   SIGN UP Already have an account? Sign in	
III O <	
This email is best viewed on a desistop	
You are required to confirm your email address	
To confirm your email address, click the following link and follow the instructions	
Why should I confirm my email? Probably, you have selected a protected email address or have requested the change of address for email, which requires verification.	
FORERED BY KOLIBH All rights reserved. Koliot & Copyright & 2019 UTC FZC P.O. Bux 300102, Res Al Obernah, Manager, your email professoros	

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.



 CLICK TO SCAN

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 <a href="https://kolibri.one">https://kolibri.one</a>

(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»

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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)

$\bigcirc$	Activation System was activated. Thank you. kolibri.one	×
	<u>_</u>	×
User's profi In order to use full name, dat diabetes. Afte gender will be by unauthoriz contact the cu	le is not complete the system, please fill in mandatory fiel e of birth, gender, weight, height, race ann r saving the data, fields <b>date of birth</b> and locked in order to avoid using of the dev ed persons. To change these data, pleas stomer support: support %kollbh.one	ds: 1 ice 9
Personal i	nformation	
Personal i	nformation	
Personal i Full name Doctor Alex	nformation	
Personal i Full name Doctor Alex Date of birth	nformation	
Personal i Full name Doctor Alex Date of birth	nformation	
Personal i Full name Doctor Alee Date of birth Gender Male	nformation	
Personal i Full name Doctor Alex Date of birth Gender Male Contacts	nformation	

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#### 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

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



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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.



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#### 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







## WEB-SITE https://kolibri.one

← Medical card Full name Test Patient Date of birth 1966-01-18 Femal Aale Gender e Weight 115 lb Height 200 ft Race Light-skin -Unknown • Blood type Rh factor Unknown . Diabetes Patient doesn't have .. • Enter your phone Phone Smoking Drugs Patient deseases None Notes Notes Ш Ο

#### 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.

diagnostic results.

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

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. € Upload tests
✓ Vou are able to upload up to 18367 tests and up to 6118 patients
✓ ✓ Patient, Age:55 Date and time: 2021-02-07 16:21:17
✓ ✓ 16:21:17



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

KOLIBRI TF.16.001.003-IFU

#### 6.3.1 App settings:

- 1. Language select interface language
- 2. Bluetooth- opens the BLUETOOTH settings of the mobile gadget.
- 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.
- 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.
- Dev Mode* Special feature. Used by technicians. Can be unavailable in user's software.
- 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.
- 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.
- Custom server IP the menu for setting the IP address or server name with which you will work (for example: <u>https://kolibri.one</u>, <u>https://kolibri.ae https://mdevice.eu</u> etc.)
- 11. About Latest software release date and number.
- 12. Privacy policy provisions on personal data protection. It is updated from time to time.

10-59	Sec. 181	75% 8
Language		- 376 M
Bluetooth		
Wi-Fi		
Auto send unfinished tests		
Suggest to enter glucose ar	nd pressure	
Enable noise check Stops test if noise level is high		
Dev Mode		
Show results by color (dev)		
ECG filtering Enables ECG filtering at result p	bage	
Custom server IP Set server IP		
About v0.200 2102031122EXP		
Privacy policy Check out our privacy policy		
III O	<	

#### Medical card ← Full name Test Patient Date of birth 1966-01-18 Femal e Gender 115 Weight lb 200 Height ft Race Light-skin • Unknown Blood type • Rh factor Unknown • Diabetes Patient doesn't have .. • Phone Enter your phone Smoking Drugs Patient deseases None Notes Notes Ш Ο

## 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.



## 6.3.4 Remote doctor

6.3.3 System settings

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

In this menu, you can change the email address, password,

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

language of the interface, currency and units.

See chapter 6.6 «CONNECTING TO DOCTOR ACCOUNT»

20:3	6 🖼 🏭 0	ຈະຟລິຟ 100% 🗎
$\leftarrow$	Connect to	o remote doctor
G	enerate Qr code	for doctor to make you remote patient
	GENERATE	QR-CODE FOR DOCTOR

#### 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

	Log into your KOLIBRI	account	
E	Email		
	@mail.com		
F	Password		
		Ø	
	Sign in		
)on't hav	re an account? <u>Sign up</u>	Forgot passwe	ord?
(	KOLIBRI	×	l
PAT	IENTS	•	l
ACC	COUNT	•	iish SD
A	Overview		
	Profile		
٥	System settings		
	Email notifications		
FIN	ANCE	•	
	Balance replenishment		
Ģ	Balance history		Car

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):

lance replenishm	ent		<u>_</u>	
1 Available balance 436.2 USD	2 Min. replenishment 2 USD	3 Max.replenishment 2000 USD		
Amount of replenishme	ent (USD)			
Payment method	enishment			
Replenish				
Current user	balance in M	S KOLIBRI (marker 1).	Amount of replenishm	ent (USD)
/iinimum ar	nount of reple	enishment (marker 2).	100	
/iaximum ai	mount of bala	nce replenishment (marker 3).		
leid for ent	ering the desi	red amount for replenishment (marker 4).	Payment method	
ne aropdov	whillst of avail	able payment systems (marker 5).	PayPal	*
			PavPal	

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.

Amount of replenishment	(USD)
100	
Payment method	
PayPal	🚓 Paymentwall
PayPal	Paymentwall
Replenish	

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
- the amount of replenishment cannot be lower than the minimum amount of replenishment
- only numbers are allowed
- 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:

2 avment method			
PayPal	•		
Replenish			



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:

KOLIBRI					UNPAID
nvoice #152				0	Pay
ayer name	Personal ID	Invoice date	Payment date	Payment method	
atric Burton	1	01/18/2018		PayPal	•
escription					
alance replenishment					2 US
ansaction amount					0 US
D PAY					2 US

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

$\sim$	Invoice	×
$(\times)$	Invoice payment was failed.	

#### 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).

MM/DD/YYYY -	MM/DD/YYYY <b>1</b>	2 — Replenishment — Write off	Tests Refund	
				Replenishment
ate	Description	Sum		
/18/2018 3	Balance replenishment. Invoice #155 4	+ 2 USD 5	Actions 🔻 🌀	Tests
				Refund
/18/2018	Balance replenishment. Invoice #154	+ 2 USD	Actions 💌	Self patients
/18/2018	Balance replenishment. Invoice #153	+ 2 USD	Actions 👻	

Balance history page overview:

Marker 1 - Filter of financial transactions by the date
 Marker 3 - Exact date of the financial transaction
 Marker 5 - Amount (+/- indicates decrease or increase of the balance)
 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.

Status		Actions	
PAID		Actions	*
	Ξ	Open invoice	
PAID	Ŧ	Download PDF	

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

Date	Description	Sum	Actions
03/11/2020	Self patient creation	- 0.5 USD	Actions

## 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:

eriod.						
N	1М/DD/YYYY - ММ/DD/YYYY 1			0	Paid invoices	Unpaid invoice
10	Subject	Invoice date	Payment date	Sum	Status	Actions
3	Balance replenishment	10/22/2018 5	- 6	2 USD 🕧	UNPAID	Actions -
o	Purchase of plan: Extended (365 days)	10/22/2018	10/22/2018	357 USD	PAID	Actions +
	Purchase of plan: Starter (365 days)	10/22/2018	10/22/2018	89 USD	PAID	Actions 👻
	Purchase of plan: Extended (365 days)	10/22/2018	10/22/2018	357 USD	PAID	Actions +
	Purchasing of an activation key. Plan: Starter (365 days)	10/22/2018	10/22/2018	89 USD	PAID	Actions 💌

Actions

Paid invoices

- Paid invoices

Unpaid invoices

Y

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:

Period

atesta mili N

• 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.

	No.	Subject	Invoice date	Payment date	Sum	Status	Actions
active	n	Balance replenishment	10/22/2018	21	2 USD	UNPAID	Actions +
ady	10	Purchase of plan: Extended (365 days)	10/22/2018	10/22/2018	357 USD	PAID	Open invoice     Download PDF
tored	9	Purchase of plan: Starter (365 days)	10/22/2018	10/22/2018	89 USD	PAID	Actions *
	8	Purchase of plan: Extended (365 days)	10/22/2018	10/22/2018	357 USD	PAID	Actions 👻
	7	Purchasing of an activation key. Plan: Starter (365 days)	10/22/2018	10/22/2018	89 USD	PAID	Actions +

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

KOLIBRI				
Invoice #11 🧿				3 Pay
Payer name	Personal ID	Invoice date	Payment date	Payment method
User	19 5	10/22/2018 6	- 0	PayPal
Description				
Balance replenishment	9			2 U
Transaction amount	10			0 U
TO PAY	1			20
Transactions				
No transactions were found	12			

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):

KULIBRI					1 PAII
Invoice #10					
Payer name	Personal ID	Invoice date	Payment date	Payment method	
User	19	10/22/2018	10/22/2018 (2)	3 PayPal	y.
Description	(365 davs)				357 119
Transaction amount					357 US
PAID					357 US
Transactions 5					
		Payment method	Transaction ID		Sum
Transaction date					

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:

Transaction date	Payment method	Transaction ID	Sum
10/22/2018, 4:31 PM	PayPal	PAY-7N617571HE747783VLPQ5CCI	357 USD
		1 🗟 Send vi	a email 😢 🖊 Download PDF

Send via email

Email

Send your Invoice #116 via email:

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:

the statu	us of letter sending, on	e of the follow	ing:			Enter email addree	
$\odot$	Email send Invoice #156 was sent to ogru@drivetagdev.com successfully.	×	Email send Incorrect format example@doma	of email. The correct format in.com.	×	Send invoice	
$\bigcirc$	Email send	×			This emai	l is best viewed on your desktop	
A letter will com	with the following text e to the specified emai	and attached l address:	PDF file	You hav	PDF with Invo	ed Invoice #156 on your email	
PDF file	can be downloaded the	en.		Date: 01/21 Description	/2018 : Balance replenis	shment	

#### 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.

IS		21
If you would like to upgrade your plan to a hig automatically, depending on the number of rer	her level, the unspent amount from the existing plan will be refunded to y naining days in your existing plan. The refund is not provided, if you would	Our balance in the system. The refund will be done I like to downgrade your plan.
	Personal Corporate 2	
Starter	Basic	Extended
Starter It is suitable to be familiar with the system do a few number of tests	Basic	Extended is is suitable for people with diabetes type 1
Starter R is suitable to be familiar with the system do a flow number of tests \$ 7 /mon	and Basic It is suitable for people with diabetes type ? \$ 15 /mon	Extended Is is suitable for people with diabetes type 1 \$ 29 /mon.
Starter It is suitable to be familiar with the system do a flow roundword texts <b>7</b> /mon Saving: 6.72 USD	and Basic R is suitable for people with diabetes type 2 \$ 15 /mon Saving: 13.44 USD	Extended to is suitable for people with diabetes type 1 \$ 299 / mon Serving: 69.12 USD
Starter R is suitable to be familiar with the system do a flow number of texts \$ 7 /mon Saving: 6:72 USD 1 USD per one successful text	and Basic t is suitable for people with diabetes type ? \$ 15 /mon Saving: 13.44 USD 0.75 USD per one successful tex	Extended Is is statiable for people with diabetes type 1 \$ 2 9 /mon. .Saving: 69.12 USD

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**: <u>MS KOLIBRI</u> features <u>allow upgrading</u> the current tariff plans to the higher/advanced one <u>with partial refund</u>. 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).

It is suitable to be familiar with the system an	It is suitable for people with diabetes type 2	Is is suitable for people with diabetes type 1
do a few number of tests 2		
\$7 _{/mon} 3	\$ <b>15</b> / mon	\$ <b>29</b> /mon
Saving: 6.72 USD	Saving: 13.44 USD	Saving: 69.12 USD
1 USD per one successful test 5	0.75 USD per one successful test	0.5 USD per one successful test
1 free test per day 6	5 free tests per day	10 free tests per day
20 out of 41 measured parameters	25 out of 41 measured parameters (?)	41 out of 41 measured parameters (?)
2 out of 17 definable pathologies 8	8 out of 17 definable pathologies	17 out of 17 definable pathologies (7)
12 months 💌	<b>9</b> 12 months ▼	24 months 💌

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).

Starter       Zot of 41 measured parameters         1 is notify       Cencral parameters         • Heath indox       Basic         • Heath indox       Basic         • Stress indox       Basic         • Diastolic blood pressure       Fit of 20 def 41         • Systelic blood pressure       Fit of 20 def 41         • Systelic blood pressure       Fit of 20 def 41         • Heath indox       Fit of 20 def 41         • Diastolic blood pressure       Fit of 20 def 41         • Systelic blood pressure       Fit of 20 def 41         • Heath indox       Fit of 20 def 41         • Diastolic blood pressure       Fit of 20 def 41         • Systelic blood pressure       Fit of 20 def 41         • Heath indox       Fit	
Ceneral parameters         I bloadt in ndex         I bloadt in ndex         I bloadt in ndex         I bloadt in ndex         I bloadt in holex         I bloadt in holex         I bloadt in holex         I bloadt in bload pressure         I bloadt in bloadt pressure         I bloadt arbohydrate index (BCI)         I contart of         I contart of         I bloadt arbohydrate index (BCI)	
<ul> <li>Heart rate         <ul> <li>Heart rate             </li> <li>Stress index         </li> </li></li></li></li></li></li></li></li></ul> </li> <li>Stress index         <ul> <li>Stress index</li> </ul> </li> <li>CBC and blood pressure             <ul> <li>Distolic blood pressure             <ul> <li>Systalic blood pressure                 <ul> <li>Systalic blood pressure                     <ul> <li>Systalic blood pressure                     <ul> <li>Systalic blood pressure                     <ul> <li>Systalic blood pressure                     <ul> <li>Systalic blood pressure                     <ul> <li>Systalic blood pressure                             <li>Systalic blood pressure</li></li></ul></li></ul></li></ul></li></ul></li></ul></li></ul></li></ul></li></ul></li></ul>	
<ul> <li>Stress index</li> <li>CBC and blood pressure</li> <li>Diastolic blood pressure</li> <li>Systolic blood pressure</li> <li>Stolic pressure<td></td></li></ul>	
CBC and blood pressure     P1     ST elevation (STEM) and non-ST elevation (LSTEM) impreadual infanction       1 USD pre     - Systolic blood pressure     104.33     Atommat electrocardiogram       1 USD pre     - Honoglobin (FG)     51.7     Cardionogativ.       1 free test     Carbohydrate index (BC)     145.7     List burdle branch block, imspecified       2 out of 4     - Blood carbohydrate index (BC)     115D pre     45.6     Pre-excitation Syndrome       2 out of 4     - Blood carbohydrate index (BC)     115D pre     45.6     Pre-excitation Syndrome       3 month     - Pre-excitation (No     115D pre     45.6     Pre-excitation Syndrome       3 month     - Pre-excitation (No     20 out of 4     15.9     Conduction disorder, unspecified       3 month     - Pre-excitation (No     20 out of 4     144.5     Left posterior fascicular block       3 month     - Carbohydrate index (BC)     2 out of 4     145.5     Left posterior fascicular block	
1 USD per     - Systolic blood pressure     111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     1111     11111     11111     11111     11111     11111     11111     11111     11111     11111     11111     11111     11111     11111     11111     11111     1111111     11111     11111     1111	
1 free text     Carbohydrate metabolism     144.0     Aktiowentricular block, first degree       10 out of 4     - Blood carbohydrate index (BCI)     145.0     Pre-sectiation syndrome       2 out of 17     Electrolytic metabolism     1 USD per     145.0     Pre-sectiation syndrome       3 month     - Procession (No)     1 USD per     145.1     Other and unspecified       - Sodium (No)     - Catour (Ca)     2 out of 17     145.5     Left posterior fascicular block       - Catour (Ca)     2 out of 17     R80     Tachycardia, unspecified	
20 out of 4     • Blood carbohydrate index (BC)     1457     Left hundle-branch block, umpecified       2 out of 37     Electrolytic metabolism     11050 pr     145.9     Conduction disorder, unspecified       3 month     • Potentim (6)     11 free text     145.1     Other and unspecified right bundle branch block       • Socium (b)     • Calcium (Ca)     2 out of 1     145.5     Electrolytic metabolism	
2 out of 17     Electrolytic metabolism     1 USD per 145.9     145.9     Conduction disorder, unspecified       3 month     • Potassium (%) • Sodium (%a)     1 free test     144.4     Left and empecified right bundle branch block       4 4.5     Left posterior fascicular block     145.5     Left posterior fascicular block       • Calcium (Ca)     2 out of 17     R00     Tachycardia, unspecified	
Potassium (k)     Sodium (ka)     Calcium (Ca)     C	
Calcium (Ca)     2 out of 17     R00 Tachycardia, unspecified	41 out
the test junction and inspection	
R00.1 Bradycardia, unspecified	
124 Other acute ischemic heart diseases 147.1 Supraventricular tachvardia	

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:

Doctor S 🕚	Doctor M	Doctor L	
Goog choice for doctors with a few number of patients	2 For doctors, who works in medium and large clinics	For doctors, who have wide private practice with a large number of patients	
\$ 60 / mon 3 Saving: 53.76 USD 4	\$ <b>119</b> / mon Saving: 107.52 USD	\$ <b>238</b> / mon Saving: 215.04 USD	
1 USD per one successful test 5	0.75 USD per one successful test	0.5 USD per one successful test	
0.7 USD for creating a new patient 6	0.6 USD for creating a new patient	0.5 USD for creating a new patient	
20 USD for creating a new staff 7	15 USD for creating a new staff	10 USD for creating a new staff	
10 free tests per day	20 free tests per day	50 free tests per day	
10 free patients 9	20 free patients	50 free patients	
2 people of free staff	4 people of free staff	6 people of free staff	
41 out of 41 measured parameters  (?)	41 out of 41 measured parameters (?)	41 out of 41 measured parameters (?)	
17 out of 17 definable pathologies (?)	17 out of 17 definable pathologies (?)	17 out of 17 definable pathologies ⑦	
12 months	12 months	12 months	

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):

	Doctor S 41 out of 41 measured parameters General parameters		×	For doctors, who ha a large n	
	<ul> <li>Heart rate</li> <li>Health index</li> <li>Stress index</li> </ul>			\$ Z Savin	
0.75 USD p	CBC and blood pressure			0.1 USD per one su	
10 free tes 41 out of 4	Diastolic blood pressure     Systolic blood pressure     Hemoglobin (HGB)		Doctor 1	5 7 definable pathologies	
17 out of 1	Carbohydrate metabolism		Code	Pathology	
	Blood carbohydrate index (BCI)		121 894 31	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction	\$ 7
	Electrolytic metabolism		151.7	Cardiomegaty	
	<ul> <li>Potassium (K)</li> <li>Sodium (Na)</li> <li>Calcium (Ca)</li> </ul>		144.0 144.7	Abrioventricular block, first degree Left bundle-branch block, unspecified	0.1 USD per one so 50 free tests per de
		41 cut of a	145.9	Conduction disorder, unspecified	41 out of 41 means
		17 put of 1	144.4 145.1	Left anterior fascicular block Other and unspecified right bundle-branch block	
		10 free pat	144.5 R00	Left posterior fascicular block	
		12 mont	R00.1 124	Bradycardia, unspecified Other acute ischemic heart diseases	12 months
			147.1	Supraventricular tachycardia	

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»:

Starter	Basic	Extended	
It is suitable to be familiar with the system and do a few number of tests	It is suitable for people with diabetes type 2	Is is suitable for people with diabetes type 1	
\$ <b>7</b> / mon Saving: 6.72 USD	\$ <b>15</b> / mon Saving: 13.44 USD	\$ <b>29</b> / mon Saving: 69.12 USD	
1 USD per one successful test	0.75 USD per one successful test	0.5 USD per one successful test	
1 free test per day	5 free tests per day	10 free tests per day	
20 out of 41 measured parameters (?)	25 out of 41 measured parameters (?)	41 out of 41 measured parameters	
2 out of 17 definable pathologies (?)	8 out of 17 definable pathologies  ?	17 out of 17 definable pathologies	
12 months 💌	12 months 💌	24 months 👻	
Choose plan	Choose plan	ACTIVATED	

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.

ype of pl	an			
an				
Basic		• 1		
lan perio	d			
	Period	Price per month	Price per period	Saving
	1 month	16 USD	16 USD	o USD
	3 months	15.52 USD	47 USD	1.44 USD
	6 months	15.2 USD	91 USD	4.8 USD
	12 months	14.88 USD	179 Payment	nt
	24 months	14.56 USD	349 Payment m	method
	36 months	14.24 USD	513 PayPal	• 0
			Ordes	Mer plan: () TO PAY: 179 USD

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:

You switched to a more advanced plan, therefore, money for the remaining days of old plan was returned to your balance in Kolibri App
REFUND
89.3 USD

This email is best viewed on your desktop
$\mathbf{>}$
You have successfully purchased a new plan Basic (365 days)
User, have successfully purchased a new plan <b>Basic (365 days)</b> . In order to see the details of payment, click the following link
Current plan details Plan period: 365 days
Cost per one successful test: 0.75 USD
Free tests per day: 5 tests
Measured parameters: 25 out of 41

#### 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).

General information		Payment information	Renewal
Plan: Extended		Renewal amount: 699 USD	Auto renewal: Yes
<ul> <li>Activation date: 08/30/2017 (39 date)</li> </ul>	ys left)	Paying cycle: Every 2 years	
<ul> <li>Next payment: 03/02/2018</li> </ul>		Payment method: PayPal	Renew plan 2
Every 2 years	*		
Downeyst mothed			
PauPal			
nent method	*		

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:

This email is best viewed on your desktop
Plan was successfully extended
User, your plan <b>Starter</b> was successfully extended on <b>365 days</b> . In order to see the details of payment, click the following link
PAYMENT DETAILS
CURRENT PLAN
Starter (730 days)

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"







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.

 $(\mathbf{c})$ 

REMOTE PATIENTS MANAGEMENT

## 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".



## IFU for MS KOLIBRI[®]

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).

Remote doctor

ʹ⊁

OVERVIEW ACCOUNT

Profile Remote doctor

FINANCE

TESTS

CHARTS

PLANS

System settings

Email notifications

nishment. Balance his



## 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.

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



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 PROCESSES 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. Ċ Ver 2004031704 EXP Log into your KOLIBRI account Email Password 65 Ш < Pay attention to the information that is displayed at the top of KOLIBRI > : the window. Tests 2 | 2 Bonuses 0 A number of free tests is indicated (tests that are included in your Failed tests today - 0 Ballance 0.0 USD tariff plan) - in the example "Test 2". Price per test 0.2 USD Subscription plan: Personal M Subscription expires in 365 days 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: Test **Failed tests today** – 0. **Balance** – 0.0 \$ 厶 **Price per test** – 0.20\$ Pressing "TEST" will start the measurement. Pressing the "Results" button will open the previous results. Ш

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 realtime 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.

16:06 🔛	Sai 51 100% 🗎	16:07 🔛		😤 al \$1 100% 🗎	19:39	9 🖼 🏭	18	🕾 al 51 86%
← Test		← Te	st		÷	Test		
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m	many		m m	)			MANWARA	
IOISE SIGNAL CV=30.	0 LP=0	NOISE SIGN/	AL CV=16.0 LP=0		NOISE	SIGNAL C	V=6.0 LP=-6	
111	0 <	11	I 0	<		111	0	<

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).

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16:57	44		©al 5il 1009	6 8
$\leftarrow$	Test #2			:
Test	Patient			
Tes	st #2			
202	0-04-10 16:2	0:48		
Risk	of patholog	ies: 0 detected		
Nois	e level 13 al quality 100%	6		
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	o 1 1 2 Donado			- 11
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Price	e per test 0.2	USD		
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Subs	scription expir	es in 365 days		
		-		
		•		
		۲		
		۷		
		Test	4	



## 9 FUNCTIONAL TESTS 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://www.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 <u>here</u> 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	18:53	Please enter correct email

2.	Wrong password/ Incorrect combination of email and password	18:55 Sa Constraints of the second se	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	1900 C     C     Full name     Test Patient     Date of birth 1968-01-18     Gender     Weight     I     kg     Height     200.0     rt     Race     Light-skin     Blood type     Unknown     Phone     Enter your phone     Smoking     Some fields may be incorrect     Drugs	<ol> <li>Enter correct data:         <ul> <li>Date of birth</li> <li>Select gender</li> <li>Enter weight</li> <li>Enter hight</li> <li>Select kg or lb</li> <li>Select cm or ft</li> </ul> </li> <li>The patient must be 18 years old or older.</li> </ol>

		19:07	ବିଲା ଆ <b>ଅ</b> ଥି 🖻	
		$\leftarrow$ System settings		
		Change Email		
		kolibri2020@aol.com		
		Enter your current password	R.	
		Change Email		
	The password field must	Change password		The password field must have
4.	have five or more		<i>S</i>	five or more characters; spaces
	characters.	Enter your current password	NO.	are not allowed.
		Change password		
		Interface		
		Country		
		Minimum 5 characters should be u spaces are not allowed Language	ised,	
		English	•	
		III O	<	
		19:17 🖬 🕴	🗇 .ii 5il 84% 🖻	
		← System settings		
		← System settings		
		<ul> <li>← System settings</li> <li>Change Email</li> <li>kolibri2020@aol.com</li> </ul>		
		<ul> <li>← System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> <li>password</li> </ul> </li> </ul>	0	
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5.	Wrong current password	<ul> <li>← System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> </ul> </li> <li>password</li> <li>Change Email</li> <li>Change password</li> </ul>	0	Enter correct password.
5.	Wrong current password	<ul> <li>System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> </ul> </li> <li>password</li> <li>Change Email</li> <li>Change password</li> <li>Enter your current password</li> </ul>	•	Enter correct password.
5.	Wrong current password	<ul> <li>System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> </ul> </li> <li>password</li> <li>Change Email</li> <li>Change password</li> <li>Enter your current password</li> <li>Change password</li> </ul>	<ul> <li>O</li> <li>O</li> </ul>	Enter correct password.
5.	Wrong current password	<ul> <li>System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> </ul> </li> <li>password</li> <li>Change Email</li> <li>Change password</li> <li>Enter your current password</li> <li>Change password</li> <li>Interface</li> </ul>	0	Enter correct password.
5.	Wrong current password	<ul> <li>System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> <li>password</li> <li>Change Email</li> <li>Change password</li> <li>Enter your current password</li> <li>Change password</li> <li>Interface</li> <li>Country</li> <li>United Kinedom</li> </ul> </li> </ul>	0	Enter correct password.
5.	Wrong current password	<ul> <li>System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> <li>password</li> </ul> </li> <li>Change Email</li> <li>Change password</li> <li>Enter your current password</li> <li>Change password</li> <li>Change password</li> <li>Interface</li> <li>Country</li> <li>United Kinedoce</li> <li>Wrong current password</li> <li>Language</li> </ul>	•	Enter correct password.
5.	Wrong current password	<ul> <li>System settings</li> <li>Change Email         <ul> <li>kolibri2020@aol.com</li> <li>password</li> <li>change Email</li> <li>Change Email</li> <li>Change password</li> <li>Enter your current password</li> <li>Change password</li> <li>Interface</li> <li>Country</li> <li>United Kipe for: Wrong current password</li> <li>English</li> </ul> </li> </ul>	•	Enter correct password.







## 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



strictly comply with them.

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 centres, the same as electronic equipment. Before recycling, it is necessary to check related local regulations and requirements and

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.

Specific condition of storage related to the embedded battery	During a long period of storage, cells should be maintained every 90 days (to keep the lifetime of the cell): the standard method of the charge-discharge cycle should be applied. Do not store the MD 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.
<b>X</b>	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.inte.org/dm: http://www.inte.org/dm:

## **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 Kippyi provulok 8a Kharkiy 61001 Ukr

Kinnyi provulok 8a, Kharkiv, 61001, Ukraine. Tel.: +380973779787 email: <u>info@kolibri.one</u> URL: https://kolibri.one Authorized representative in European Union:

EC REP Authorized representative in European Union:

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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

$\sim \sim \sim$	Date of manufacture ""	20
Check a	nd confirmed by:	
	Signature	Name and Surname
••••	Manufacturer: SCIENTIFIC COMPANY KOLIBRI LLC Kinnyi provulok 8a, Kharkiv, 61001, Ukraine. Tel.: +380973779787 email: <u>info@kolibri.one</u> URL: https://kolibri.one	Authorized representative in European Union: EC REP Authorized representative in European Union: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

## 22 PACKING LIST

The MD KOLIBRI

# PERSONAL HEALTH SCREENING SYSTEM KOLIBRI®

Model

🔀 KOLIBRI

Name of MD 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				
Data of packing		0.40.4	VEAD	
	DD	IVIIVI	YEAR	
Packed by				
	Signature	Γ	Name and Surname	



Manufacturer: SCIENTIFIC COMPANY KOLIBRI LLC Kinnyi provulok 8a, Kharkiv, 61001, Ukraine. Tel.: +380973779787 email: <u>info@kolibri.one</u> URL: <u>https://kolibri.one</u> Authorized representative in European Union:

EC REP

Authorized representative in European Union:

******

## **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 i	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.: +380973779787 email: info@kolibri.one URL: https://kolibri.one Authorized representative in European Union:

EC REP

Authorized representative in European Union:

*****

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

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.: +380973779787 email: info@kolibri.one URL: https://kolibri.one Authorized representative in European Union:



Authorized representative in European Union:

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All valid permits and certificates are available on the manufacturer's website: LINK

## 24 LABELING

Labels on the outer package of the MD  $\mathrm{KOLIBRI}^{*}$ 



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 medical device	the :	KOLIBRI®				
CE symbol (where <b>xxxx</b> is the number of Notified Body)		CE	TYPE BF APPLIED PART	*			
lssue Da	ate	~~~	[Date	of manufacturing]	Serial number of MD	SN	<u>[Serial</u> number]
Manufa	ctured by	Ukrain email URL: I	SCIE Ukra 8a, ⁻ ine. I: info@ https://	NTIFIC COMPANY KOLIBRI LLC aine 61001 Kharkiv, Kinnyi provulok Tel.: +380913011110 kolibri.one kolibri.one	Symbol for connection of USB port	÷	
Represe (Europed represer	ented by an ntative)	EC F in Eur Autho XXXX	REP rope orized r (XXXXX)	epresentative in European Union: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	CLASS II equipment IEC 60417-5172		
MD Clas	s lla		I	MD Class IIa	Attention label		
Sign of v electron	waste nic equipment			X.	Carefully read the IFU before the first use of the device	ī	

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	EC REP	Authorized representative in European Union: HUNGARY XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
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	MX REP	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

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) 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 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

**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**TM) 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 **KOLIBRITM** 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:

Delete account				
() ATTENTION! Completing the ac	count deletion procedure requires your con	firmation via email		
Delete				
Delete				

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:



KOLIBRI TF.16.001.003-IFU

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	
2.0	2024-11-15	Update all document	Pulavskyi A.	



Please read the IFU carefully before using the device!