Interreg – IPA CBC

EUROPEAN UNION

Greece - Republic of North Macedonia

COMETECH

User Requirements of

Medical devices

WP3 / D3.2

Thessaloniki March 2020

CONTENTS

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"The views expressed in this publication do not necessarily reflect the views of the European Union, the participating countries and the Managing Authority".

1.General

1.1.COMETECH Project

This document is the Deliverable 3.1.2 of the project titled "Continuity of care in metabolic diseases through modern technology", with an acronym "COMETECH", implemented under the Subsidy Contract No.SC027, COMETECH–CN1–SO1.2–SC027 upon the 1st Call for proposals within the INTERREG IPA Cross-border Cooperation Programme Greece – Republic of North Macedonia 2014-2020.

The Interreg IPA CBC Programme "Greece – Republic of North Macedonia 2014-2020" is a cross-border cooperation Programme co-financed by the European Union under the Instrument for Pre-Accession Assistance (IPA II). The strategy statement of the Programme is "to enhance territorial cohesion by improving living standards and employment opportunities holding respect to the environment and by using the natural resources for upgrading of the tourism product". The total budget of the Programme for the period 2014-2020 is 45.470.066,00 €. COMETECH is implemented by a partnership consisted of five partners from both participating countries:

Pr. Nr.	Partner title	Country
LB (PP1)	International Hellenic University (IHU) (Former name: Alexander Technological Educational Institute of Thessaloniki)	Greece
PP2	Florina Prefectural General Hospital	Greece
PP3	Medical Association of Thessaloniki	Greece
PP4	Clinical Hospital Bitola	Republic of North Macedonia
PP5	General Hospital Veles	Republic of North Macedonia

COMETECH project aims to address the problem of inadequate access to the health system services to people who live in isolated communities at Greece- Republic of North Macedonia cross-border areas. The project will establish 4 e-health units -2 in each country- at isolated and deprived communities collaborated each other, aiming at introducing "Continuity of Care" in the border region between Republic of North Macedonia and Greece. In order to accomplish the above, the provision of medical devices capable of telemedicine is absolutely essential.

The medical devices should have the ability to be connected with integrated telemetry (web application and mobile application), recording and monitoring. Measurement data can be

automatically transferred to the online platform where it will be available for viewing, editing, and storing.

COMETECH project anticipates contributing to the improvement of health services of both countries in a commonly shared region that has been economically neglected to a substantial degree. The advantages of the Continuity of care on metabolic diseases through telemedicine (COMETECH) project are the following:

- Reduction of number of undiagnosed cases of diabetes
- Reduction of morbidity and mortality due to chronic complications of diabetes
- Upgrading the quality of medical services
- Reduction of health cost for metabolic diseases

Total Project budget amounts 1.018.189 EUR, i.e. 321.486, 00 EUR for project activities that are to be implemented in the Republic of North Macedonia, while the remaining amount of 696.703 EUR is allocated for the implementation of activities in Greece. The original project duration was 24 months. However the final project duration is 36 months.

1.2.Purpose of the document

The deliverable of this activity (User requirement of medical devices) will be used for the identification of the technical, functional and medical specifications of the proposed medical devices which are the key deliverables of the COMETECH project.

2.Medical examination and medical devices

2.1.Medical examination procedure

Under the implementation of the pilot plan (**Deliverable D5.1.1-Implementation of the pilot plan),**1000 patients will be examined, 400 patients in Thessaloniki, 200 patients in Florina Hospital, 200 patients in Bitola Hospital and 200 patients in Veles Hospital. For this purpose 12 high tech medical devices will be in use by experts health professionals. The examination of the patients will follow a specific order and the examination procedure will be specific and predetermined. Initially after the welcome, the patient will be thoroughly informed about the screening process and if he / she agrees to participate in the procedure he / she will sign the informed written consent form. The informed written consent form is written in the language of the patient in order to be able to fully understand and to agree to participate to the procedure (APPENDIX 1).

The recording of the demographics will follow. A password instead of the patients name will be recorded for personal data protection reasons. A medical history will then be received, which will also be recorded in the system.

2.2.Short description and functionalities of Medical devices

The list of the medical devices is:

1. Column scale with wireless data transmission (BMI Calculator)
2. Blood Glucose Monitoring System-Device
3. HbA1c monitoring system
4. Electronic Stethoscope
5. ECG 12 channel with monitor
6. Spirometer
7. Blood pressure monitor device with ankle brachial index (ABI) calculation.
8. Foot Scanner
9. Advanced Glycated End-Products Monitoring Device (AGE READER)
10. Non Mydriatic Retinal Camera
11. Pulse Oximeter
12. ECG Holter Monitoring system
13. Wireless weight Scale

2.2.1.Column scale

Column scale (height scale, stadiometer)

Human height or stature is the distance from the bottom of the feet to the top of the head in a human body, standing erect.

Height measurement is important, because height is closely correlated with health components, such as life expectancy. Studies show that there is a correlation between small stature and a longer life expectancy. Individuals of small stature are also more likely to have lower blood pressure, decreased risk of venous insufficiency and are less likely to acquire cancer. Height measurement is also essential to calculate the BMI (BMI=height/weight), the most common used indicator for the evaluation of obesity. According to the results of BMI, the patient is classified as normal weight or as overweight or as obese. Knowing the close relationship between obesity and diabetes mellitus as well as cardiovascular diseases, appropriate measures can be taken in each case.

The column scale which will be used in COMETECH project is a 6 kg electronic height measurement device with high accuracy**.**

The height scale should be calibrated for accuracy before each height measurement by using a known standardized height object. The column scale should be placed on a flat, uncarpeted section of the floor and a flat section of the wall.

The Procedure is quick and easy: the health professional puss the on button of the device and the patient stands on the platform of the column scale.

The person first should take off the shoes and remove braids, headbands from the head. Also remove any bulky clothing that make it difficult to stand flat against the wall. In order to have an accurate measurement the patient has to stand up straight with eyes looking straight ahead, the line of sight and chin should be parallel to the floor, the feet flat on the floor with the heels against the corner where the floor and the wall meet and head, shoulders and buttocks are touching the wall. He/she stands with minimal movement with hands by his/her side.

After completion of the examination, the result will be automatically transmitted and recorded in the software application platform.

2.2.2.Blood Glucose (blood sugar) Monitoring System-Device

Glucose is a simple sugar and approximately 4 grams of glucose are present in the blood of a 70-kilogram human at all times. Glucose is the main fuel for producing energy in human cells. The human blood glucose either can be mainly by the liver, or can be taken from the food. Glucose can be transported from the intestines or liver to other tissue cells in the body via the bloodstream. Cellular glucose uptake is primarily regulated by insulin, a hormone produced in the pancreas Normally the glucose levels at faster state is 85-100 mg/dl and 2 hours postprandially is about 140-180 mg/dl. If blood sugar levels are high, this is called hyperglycemia. The most common cause of hyperglycemia is diabetes. Long-term hyperglycemia causes many health problems including heart disease, cancer, eye, kidney, and nerve damage. So it is very important to measure the blood glucose levels especially in people with diabetes mellitus.

The blood glucose monitoring device is a state of the art, pocket size electronic device.

The Procedure is quick and easy: the health professional ask the patient to sit down and explain the procedure. Then washing hands and put on gloves. Choose the site for the blood sample: usually the side of a finger, but the arm or thigh may be used. Use an alcohol swab to clean the site and let the alcohol dry. A small drop of blood, obtained by pricking the skin with a lancet, is placed on a disposable test strip Insert the test strip into the glucose meter, following the instructions. Use a single-use lancet or a lancing device to draw blood and dispose of it in a sharps container. Apply the blood to the testing strip in the correct way. Place the alcohol swab or a piece of gauze over the site and hold it there, or let the patient hold it there until the bleeding stops. Monitor for excess bleeding. Disposal of all used equipment safely, in line with health care policies.

After completion of the examination, the result will be automatically transferred and recorded in the software application platform.

2.2.3.HbA1c monitoring system

This is a state of the art medical device for measurement of hemoglobin A1c (HbA1c). A hemoglobin A1c (HbA1c) test measures the amount of blood sugar (glucose) attached to hemoglobin.

Hemoglobin is the part of red blood cells that carries oxygen from the lungs to the rest of the body. An HbA1c test shows what the average amount of glucose attached to hemoglobin has been over the past three months. It's a three-month average because that's typically how long a red blood cell lives. An HbA1c test may be used to check for diabetes or prediabetes and to monitor the glycemic control in patients with known diabetes mellitus. Normal value for HbA1c is < 6.5%.

The Procedure is quick and easy: the health professional ask the patient to sit down and explain the procedure. Then washing hands and put on gloves. Choose the site for the blood sample: usually the side of a finger, but the arm or thigh may be used. Use an alcohol swab to clean the site and let the alcohol dry. A small drop of blood, obtained by pricking the skin with a lancet is collected with the integrated sampling device. The next step is to place the sampling device in the test cartridge and to place the test cartridge in the analyzer and close the lid. The processing starts automatically and the results are available in a few minutes.

After completion of the examination, the result will be automatically transferred and recorded in the software application platform.

2.2.4.Electronic Stethoscope

The stethoscope is an acoustic medical device for auscultation, or listening to the internal sounds of the human body and it is the basic equipment of a health professional. It is often used to listen to lung and heart sounds. It is also used to listen to intestines and blood flow in arteries and veins. In combination with a sphygmomanometer, it is commonly used for measurements of blood pressure.
The electronic stethoscope is a wireless device in which the sounds are transmitted electronically, provides noise reduction, signal enhancement, and both visual and audio output.

The Procedure of examination: In order the clinical examination to be completed successfully, physician and patient cooperation is necessary and the patient must follow the doctor's instructions, such as taking off the clothes if necessary, lying on the couch, taking deep breaths etc The auscultation sounds are transmitted wireless.

2.2.5.ECG 12 channel with monitor ((Electrocardiogram device)

The ECG device is a battery-powered portable device that records heart's electrical activity. The electrocardiogram (ECG) test is a simple, painless procedure that measures electrical signals in your heart. Each time that heart beats, an electrical signal travels through the heart. An ECG can show if the heart is beating at a normal rate and strength. It also helps show the size and position of the heart's chambers. An abnormal ECG can be a sign of heart disease or damage. The ECG test is used to find and to monitor various heart disorders that include irregular heartbeat (arrhythmia), blocked arteries, heart failure, heart attack etc.

The Procedure of examination: The procedure only takes about three minutes. In order the ECG procedure to be completed successfully the patient will lie on an medical examination couch. A health care provider will place several electrodes (small sensors that stick to the skin) on the arms,

legs, and chest. The provider may need to shave or trim excess hair, especially the chest of the men, before placing the electrodes. The electrodes are attached by wires to a computer that records the heart's electrical activity. The activity will be displayed on the computer's monitor and/or printed out on paper.

After completion of the examination, the result will be automatically transferred and recorded in the software application platform.

2.2.6.Spirometer

The spirometer device is for measuring the **volume** of **air** inspired and expired by the **lungs**. The spirometer test (spirogram) is a simple, painless procedure that measures ventilation, the movement of air into and out of the lungs. Key spirogram measurements include the following:

- **Forced vital capacity (FVC).** This is the largest amount of air that can be forcefully exhaled after breathing in as deeply as possible. A lower than normal FVC reading indicates restricted breathing.
- **Forced expiratory volume (FEV).** This is how much air can be forced from the lungs in one second. This reading helps the doctor to assess the severity of the breathing problems. Lower FEV-1 readings indicate more significant obstruction.

The Procedure of examination: the procedure takes about 15 minutes in order the spirometry procedure to be completed successfully.

The spirometry test requires the patient to breathe into a tube attached to the spirometer device. Before the test, the technician or the doctor will give specific instructions. Doing the test correctly is necessary for accurate and meaningful results. During the spirometry test the patient :

- Should be seated.
- A clip will be placed on the nose to keep the nostrils closed.
- The patient will take a deep breath and breathe out as hard as possible for several seconds into the tube. It's important that the lips create a seal around the tube, so that no air leaks out.
- It is needed the test to be done at least three times to make sure that the results are relatively consistent. If there is too much variation among the three outcomes, it is needed to repeat the test again. The highest value among three close test results is used as the final result.

After completion of the examination, the results will be automatically transferred and recorded in the software application platform.

2.2.7.Blood pressure monitor device with ankle brachial index(ABI) calculation.

Blood pressure monitor with ankle brachial index (ABI) device, includes four blood pressure cuffs for both arms and both legs, which measure electronically the blood pressure –simultaneously at the above four points- and furthermore it calculates automatically the ABI index.

The electronic blood pressure monitor device is a medical device for measuring the Blood pressure (BP), which is the pressure of circulating blood on the walls of blood vessels. The blood pressure monitor device is a basic equipment of a health professional. Blood pressure is usually expressed in terms of the systolic pressure (maximum during one heartbeat) over diastolic pressure (minimum in between two heartbeats) and is measured in millimeters of mercury (mmHg), above the surrounding atmospheric pressure. Blood pressure is one of the vital signs, along with respiratory rate, heart rate, oxygen saturation, and body temperature. Normal resting blood pressure in an adult is approximately 120millimetres of mercury systolic, and 80millimetres of mercury diastolic, abbreviated "120/80 mmHg".

The ankle-brachial index (ABI) test compares the blood pressure measured at the ankle with the blood pressure measured at the arm. The **ankle-brachial pressure index** (**ABPI**) or **ankle-brachial index** (**ABI**) is the ratio of the systolic blood pressure at the ankle to the systolic blood pressure in the upper arm (brachium). A low ankle-brachial index number can indicate narrowing or blockage of the arteries in the legs. The ankle-brachial index test is a quick, noninvasive way to check for peripheral artery disease (PAD). The disease occurs when narrowed arteries reduce the blood flow to lower limbs. PAD can cause leg pain when walking and increases the risk of heart attack and stroke.

The Procedure of examination: the procedure takes about 30 minutes in order the preparation and test performance to be completed successfully.

Generally, it is not needed to follow any special instructions before an ankle-brachial index test performed. The patient must wear loose, comfortable clothing that allows the technician or the doctor performing the ankle-brachial index test to easily place a blood pressure cuff on the ankle and upper arm. In order to perform the test the technician or the doctor put the inflatable cuffs that measure the blood pressure in both arms and both ankles. After completed the BP measurements, the device calculate automatically the ABI index.

Based on the number calculated ABI index, your ankle-brachial index may show:

- **No blockage (1 to 1.4).** An ankle-brachial index number in this range suggests that probably there is no PAD.
- **Borderline blockage (0.91 to 0.99).** An ankle-brachial index number is this range indicates a borderline PAD.
- **PAD (less than 0.90).** An ankle-brachial index number in this range is considered abnormal and indicates a diagnosis of PAD.

After completion of the examination, the results will be automatically transferred and recorded in the software application platform

2.2.8.Foot Scanner

It is well known that people with diabetes mellitus may suffer from foot problems and it is vital to measure the plantar pressure. Increased plantar pressure can cause foot ulcer. Foot ulcer that can lead to amputation is one of the most threatening long-term diabetes complications.

The Foot scanner is a lightweight, portable plantar pressure measurement device which records all the relevant information needed to analyze the foot's behavior. The device consists of two parts a special platform incorporated with thousands pressure sensors and a software on a computer, which analyze the pressure data..Foot Scanner is useful for assessment, diagnosis, prevention and treatment method, through lower extremity data analysis.

The Foot scan provides information regarding high stress regions of the foot, as well as the distribution of the stresses, the pressure points, the body center of mass, and a full gait analysis. The foot scan analysis is based on data from thousand sensors, connected to a computer providing absolutely accurate information aiming at the creation of individual, custom-made orthotic insoles.

The Procedure of examination: the procedure takes about 15 minutes in order the preparation and test performance to be completed successfully.

Generally, it is not needed to follow any special instructions before the foot scan test performed. The patient must wear loose, comfortable shoes and socks, which he can easily take off. In order the procedure to be completed successfully, all that is required is the examined patient to take off his/her shoes and to stand upright on the foot scan platform.

The device automatically measures the plantar pressures and analyzes them. Straightforward interpretation of the foot's function is displayed via detailed images and statistical graphs.

After completion of the examination, the results will be automatically transferred and recorded in the software application platform

2.2.9.Advanced Glycated End-Products Monitoring Device

Advanced glycation end-products (AGEs) are modifications of proteins or lipids that have become glycated and oxidized following exposure to aldose sugars; they form in-vivo in hyperglycemic environments- diabetes mellitus -in renal disease and cardiovascular disease and also during aging. Advanced glycation end-products contribute to the pathophysiology of vascular disease in diabetes through accumulation in the vessel walls, where they may perturb cell structure and function. Advanced glycation end-products have also been hypothesized to play a role in atherosclerosis, acute ischemic stroke, and chronic kidney disease.

The Advanced Glycated End-Products (AGE) Reader is a portable non-invasive monitoring device that uses ultra-violet light to excite autofluorescence in human skin tissue. The AGE Reader has a light source which illuminates the tissue of interest (usually the arm). This light excites fluorescent

moieties in the tissue which will emit light with a different wavelength as a result. In the used wavelength band the major contribution in fluorescence comes from fluorescent AGEs. The emitted light is detected with the use of a spectrometer or photodiodes. By this the AGE Reader measure tissue accumulation of Advanced Glycation End-products in human skin tissue.

The Procedure of examination: the procedure totally takes about 10 minutes in order the preparation and test performance to be completed successfully. The measurement of AGEs provides an immediate cardiovascular risk prediction in 12 seconds.

Generally, it is not needed to follow any special instructions before the Advanced Glycation end-products (AGEs) test performed. The test is non-invasive and painless. In order the procedure to be completed successfully, all that is required is the examined patient to put his arm for 12 seconds in the specially designed surface and then to remove it. The device automatically measures the Advanced Glycation end-products (AGEs) and analyzes them. Straightforward interpretation and cardiovascular risk assessment is displayed via detailed images and statistical graphs.

After completion of the examination, the results will be automatically transferred and recorded in the software application platform

2.2.10.Non Mydriatic Retinal Camera

Diabetic retinopathy is one of the most serious chronic complications of diabetes mellitus and if remains undiagnosed and untreated, this delay can cause blindness. The early diagnosis of diabetic retinopathy by the fundus photography is vital.

The non-Mydriatic Retinal Camera (fundus camera) is a specially crafted low power microscope fitted with a high definition camera.It produces true colour fundus photos of excellent quality. Details are very clear and sharp and it is clearly visible all the retina (back of the eye), the arteries, the veins, the macula and any possible lesion of the retina.

The fundus camera allows the doctor to take a high resolution magnified image (photograph) of the inside of the eye. This allows for far more accurate diagnosis of a range of serious eye health conditions, as well as meaning many symptoms can be detected much earlier than through other methods.

The photographs taken by the fundus camera can also be kept on file, resulting in a far more detailed and accurate optical history to be built up of your eye health over time.

The Procedure of examination: the procedure is non-invasive and painless .This camera assures fully automated alignment, auto focus and auto shoot and it is not needed mydriasis in order to test performed. In order the procedure to be completed successfully, all that is required is the examined patient to put his jaw in a special socket of the device and to look straight for 1-2 minutes. Fundus photography totally takes only a few minutes with no discomfort or intrusive examination. The operator-doctor or technician- with just one finger touch can take images of both eyes.

The fundus photograph will be displayed on the computer's monitor and/or printed out on paper. After completion of the examination, the results will be automatically transferred and recorded in the software application platform

2.2.11.Pulse Oximeter Finger Pulse Blood Oxygen SPO2 Monitor

Pulse oximetry is a method for monitoring a person's blood oxygen saturation (SO_2).It can rapidly detect even small changes in how efficiently oxygen is being carried to the extremities furthest from the heart, including the legs and the arms. It is very helpful in conditions like lung diseases, anemia, heart diseases and especially heart failure, etc.

The pulse Oximeter is a small, portable clip-like battery-operated device for monitoring blood oxygen saturation (SO_2) and detecting the pulse rate non invasivelly. Pulse oximeter device is placed on a thin part of the patient's body, usually a fingertip or earlobe, or in the case of an infant, across a foot. The device passes two wavelengths of light through the body part to a photodetector. It measures the changing absorbance at each of the wavelengths, allowing it to determine the absorbances due to the pulsing arterial blood alone, excluding venous blood, skin, bone, muscle, fat, and (in most cases) nail polish.

The Procedure of examination: In order the procedure to be completed successfully, all that is required is the examined patient to put the clip-like device on his/her finger, ear lobe, or toe. May be there is a feeling of a small amount of pressure, but there is no pain or pinching. The patient will keep the probe on for as long as needed to monitor the pulse and oxygen saturation. Sometimes, it will only be used to take a single reading very quickly. Once the test is over, the clip or probe will be removed. The reading will be displayed on the small screen of the device.

After completion of the examination, the results will be automatically transferred and recorded in the software application platform

2.2.12.ECG Holter Monitoring system

ECG Holter device is a type of ambulatory electrocardiography device, a portable device for cardiac monitoring (the monitoring of the electrical activity of the cardiovascular system) for at least 24 to 48 hours. This Holter system consists of two basic parts – the hardware (called monitor or recorder) for recording the signal, and software for review and analysis of the record. The Holter recorder is small and light and operates with batteries. The automatic analysis provides with information about heart beat morphology, beat interval measurement, heart rate variability, rhythm overview and patient diary (moments when the patient pressed the patient button). The system also perform spectral analysis, ischemic burden evaluation, graph of patient's activity and PQ segment analysis.

The Holter's most common use is for monitoring ECG heart activity (electrocardiography or ECG). Its extended recording period is sometimes useful for observing occasional cardiac arrhythmias which

would be difficult to identify in a shorter period. For patients having more transient symptoms, a cardiac event monitor which can be worn for a month or more can be used.

Although some patients may feel uncomfortable about a Holter examination, the only hazards are potential minor skin abrasions to optimize signal quality, and it should have little effect on one's normal daily life.

The Procedure of examination: In order the procedure to be completed successfully the recording device can be worn in a case on a belt or on a strap across the chest. The device may be visible under light clothing, and those wearing a Holter monitor may wish to avoid shirts with a low neckline. The Holter monitor records electrical signals from the heart via a series of electrodes attached to the chest. These electrodes are connected to a small piece of equipment (recorder) that is attached to the patient's belt or hung around the neck, keeping a log of the heart's electrical activity throughout the recording period. Persons being monitored should not limit normal daily activities, since its purpose is to record how a heart works under various actual conditions over an extended period. It is an electrical device, however, and should be kept dry; showering or swimming should probably be avoided. Monitor can be removed for a few minutes without invalidating collected data, but proper reattachment is critical to avoid degradation of its signals.

After completed the test , the recorder is removed and the data is uploaded into a computer which then automatically analyzes the input, counting ECG complexes, calculating summary statistics such as average heart rate, minimum and maximum heart rate, and finding candidate areas in the recording worthy of further study by the technician.

2.2.13.Wireless Weight Scale

The body weight measurement is very important and this will be the first step of medical examination. It is well known that having excess weight can affect a person's risk of developing a number of health conditions, including obesity, type 2 diabetes, high blood pressure, and cardiovascular disease.

The body weight measurement is necessary for Body Mass Index (BMI) calculation**,** which is very important to be calculated.

According to the results of BMI, the patient is classified as normal weight or as overweight or as obese. Knowing the close relationship between obesity and diabetes mellitus as well as cardiovascular diseases, appropriate measures can be taken in each case.

Our electronic wireless weight scale should be calibrated for accuracy before each body weight measurement by using a known standardized weight object.

The Procedure is quick and easy: the health professional puss the on button of the device and the patient stands on the platform of the weight scale. The person stands with minimal movement with hands by their side. Shoes and excess clothing should be removed. To improve reliability, the weigh measurements will take place in the morning, or in cases that this is not possible, then at

least 6 hours away from eating. Body weight can be affected by fluid in the bladder, so the weigh measurements will take place after voiding the bladder. Apart from measuring the body weight the weight scale can measure the BMI (Body Mass Index), lean, bone, muscle, water mass body fat and visceral fat. Also to estimate daily caloric intake, to display room temperature and humidity, to track data, graphs and history, to store unlimited measurements, to share patient's medical data with his/her healthcare professional or family and to secure and storage the data.

After completion of the examination, the result will be automatically transferred and recorded in the software application platform.

APPENDIX 1

INFORMED CONSENT

Date: Patient Number:

TITLE OF THE STUDY

Continuity of care in metabolic diseases through modern technology -COMETECH

AIM OF THE STUDY

The aim of this study is the medical examination and the provision of health care to patients, using high tech medical devices in collaboration with three other health units, through telemedicine.

.....

I have read this informed consent for this study. It was explained to me the aim, the duration and potential benefit of the study and what I would be expected to do. My questions were answered satisfactorily.

I agree to participate in this study.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any justification, without affecting my medical care or my legal rights.

I understand the description in this document that refers to the extent to which my protected health data will be used.

Last name: First Name:

Signature: Date:

The medical practitioner or person who had the consent to discuss.

I certify that I have personally explained the nature, purpose, duration, benefits and risks of the study to the individual mentioned above.

Last name: First Name:

Signature: Date:

APPENDIX 2

List of Medical Devices

a/a	Description	Model	Image	Url
1	Column scale with wireless data transmission (BMI CALCULATOR)	SECA 264		https://www.seca.com/en_ae/products/all-products/product-details/seca264.html
2	Self-Monitoring of Blood Glucose Systems (Device and Accessories)	GlucoMen areo		https://www.menarinidiabetes.gr/ell/product/GlucoMen-areo
3	HbA1c monitoring system	Afinion™ 2 Analyzer		https://www.alere.com/en/home/product-details/afinion2-analyzer.html
4	Electronic Stethoscope	3M™ Littmann® Electronic Stethoscope Model 3200		https://www.littmann.com/3M/en_US/littmann-stethoscopes/products/~/3M-Littmann-Electronic-Stethoscope-Model-3200/?N=5932256+8711017+3293188392&rt=rud
5	ECG 12 channel with monitor	ECG1200G Electrocardiograph_CONTEC		http://www.contecmed.com/index.php?page=shop.product_details&product_id=22&flypage=flypage.tpl&pop=0&option=com_virtuemart&Itemid=588
6	Spirometer	Spirodoc		https://www.spirometry.com/ENG/Products/spirodoc_new.asp
7	Blood pressure monitor device with the ankle-brachial index (ABI) and inter-arm difference determination.	WatchBP-office ABI		https://www.microlife.com/professional-products/watchbp-office/watchbp-office-abi
8	Foot Scanner	LorAn EPS/R1		http://www.loran-engineering.com/baropodometric_plate.html http://www.wiva.guru/science1-eng.html

9	Advanced Glycated End-Products Monitoring Device (AGE READER)	AGE Reader		https://www.diagnoptics.com/age-reader/
10	Non Mydriatic Retinal Camera	TRC-NW400, Non-mydriatic fundus camera		https://www.topcon-medical.eu/eu/products/284-trc-nw400-non-mydriatic-fundus-camera.html#general http://www.topconmedical.com/products/trcnw400-literature.htm
11	Pulse Oximeter Finger Pulse Blood Oxygen SPO2 Monitor	PM 150 connect Pulseoximeter		https://www.medisana.com/en/Health-control/Pulsoximeter/PM-150-connect-Pulseoximeter.html
12	ECG Holter Monitoring system	TLC5000 Dynamic ECG Systems_CONTEC		http://www.contecmed.com/index.php?option=com_virtuemart&page=shop.product_details&flypage=flypage.tpl&category_id=11&product_id=88&Itemid=588
13	Wireless Scale	iHealth Core		https://ihealthlabs.com/wireless-scales/ihealth-core/