The History and Technology Behind Healbe GoBe™

M.S. Rubin, Ye. L. Sokolov., I.L. Misyuchenko

Healbe GoBe™ The Original 100% Automatic Body Manager made hassle-free with FLOW Technology, is a proud brand of Healbe™ International Company.

Brief information about the authors:

M.S. Rubin. Research engineer, inventor, expert in Inventive Problem Solving Theory. Degree of IT systems specialist. Disciple of S.G. Altshuller, founding father of the TRIZ theory (Inventive Problem Solving Theory), and co-author of some of his works. Author of over 100 research papers. Leading Research Fellow at Saint Petersburg-based Algorithm Innovation and Technological Consulting Center since 2005. He has been dealing with the Healbe™ project since 2011. His responsibilities include coordination of research and supervision over activities that deal with forecasting human health monitoring technologies, assessing energy consumption, controlling the state of the human organism during sleep, and other topics.

Ye. L. Sokolov. Research engineer, inventor of over 20 utility inventions. Mechanic engineer with a degree in Aeronautical Design Engineering from the Leningrad Mechanical Institute, Department of Rocket Engineering, Senior Research Fellow. Sokolov has been working with Algorithm since 1995, and dealing with the Healbe™ project since 1998. Author of key technologies for testing human blood glucose concentration and calorie intake. Chief researcher in the Healbe™ project, responsible for supervision of the areas of calorie intake assessment; valuation and modeling of human metabolic balance; and more.

I.L. Misyuchenko. Research engineer, inventor, Candidate of Technical Sciences. Graduate of the Saint Petersburg State Polytechnic University, Semiconductor Physics Department, with a degree in physics. Electronics engineer having independently developed over 10 high-tech devices to be used in the fields of oceanology, radiolocation, hydro-acoustics, and medicine. Author of over 30 inventions and over 40 research papers and monographs. Leading Research Fellow at Saint Petersburg-based Algorithm Innovation and Technological Consulting Center since 2002. He has been dealing with the Healbe™ project since 2002. His responsibilities include supervision of the development of the device's electronic components, impedance and pulse wave sensors, and more.

Introduction

The authors have spent the past several years enthusiastically developing the Healbe™ project, with the goal of helping people monitor their health with less effort. Each of us applies our unique background knowledge, abilities, and talents. We mainly deal with plots, models, algorithms, research papers, and reports. Describing how our device works in the layman's language of popular science is a new challenge. Being the developers, we've witnessed the evolution of the project from the start. In this description, we will try to distinguish between results we've already achieved, and the things we intend to accomplish in the future.

What is Healbe GoBe™?

Healbe GoBe™ is a personal data measurement system with the core objective of providing information on the user's functional status. By "functional status," we mean the whole set of parameter estimates showing the condition of the human organism's key systems (i.e. endocrine, nervo¬us, cardiovascular systems, etc.).

The system consists of a wristband that reads the main parameters; a smartphone with embedded Healbe™ software; and a website, where basic info on the user and his or her health is stored. The user alone has access to this data.

GoBe is equipped with the following three sensors for monitoring primary parameters:

- **PIEZO PRESSURE SENSOR:** measures blood flow and heart rate
- **IMPEDANCE SENSOR:** uses different frequencies to measure fluid levels in tissues
- **ACCELEROMETER:** measures body movement and activity

The specific data from these sensors is not shown to the user. Instead, Healbe FLOW™ Technology uses an advanced algorithm to calculate the following secondary parameters, which provide useful insights to the end-user:

- Calorie intake
- Calories burned in the process of metabolism and physical activity
- Composition and quantity of macro-nutrients from food and drinks (e.g. fats, carbohydrates)
- Water intake
- Number of steps and distance covered
- Heart rate
- Arterial blood pressure
- Sleep quality and efficiency
- REM sleep phases
- Stress level monitoring

All these calculations are made using the models that we have developed. One of them is the model of noninvasive human blood glucose concentration profiling, without taking blood tests. This is one of the basic technologies that we have developed. GoBe does not display glucose concentration to the user, as our device is not intended for medical use, and doesn't meet medical accuracy requirements. Yet our device's accuracy is quite enough for assessing calorie intake, or the quantity of energy derived from a meal. We are currently developing a number of supplementary technologies that will significantly extend the list of monitored health parameters.

Over 10 invention applications have been filed for the technologies being developed by Healbe™. We have already received patents for the key technologies as we will discuss in more detail in a later portion of this document.

The history of Healbe™ and GoBe

Our company's specialists began research on technologies for noninvasive human blood glucose concentration measurement back in 1999, within the framework of a project to develop both a physiological model of the glucose disposal process in the human organism, and hardware for noninvasive control of this process.

Initial work was accomplished by the Saint Petersburg-based Algorithm Innovation and Technological Consulting Center (http://www.gen3.ru). This company has been working in the market of innovation consulting since 1993. Since 2003, Algorithm has been a strategic partner of the American company GEN3 Partners (http://www.gen3.com), with its headquarters based in Boston. The list of Algorithm's customers includes such renowned businesses as Alcoa, Intel, Motorola, Nestle Purina, Procter & Gamble, Rich Products, Chiquita, Clorox, Energizer, Siemens, Ford, Toshiba TEC, Gillette, Xerox, Honda, LG and many others.

Algorithm owes its success in part to the active use of Inventive Problem Solving Theory (TRIZ) in its innovative design process. All researchers working with Algorithm are professionals in TRIZ application. Moreover, the personnel of Algorithm and GEN3 Partners currently include 9 TRIZ experts.

The research into the development of noninvasive methods for human blood glucose concentration monitoring is at the confluence of several scientific disciplines. Thus, the project's initial research group consisted of endocrinologists, physiologists, physicians, specialists in clinical diagnostics, mathematicians, programmers, electronic engineers, physicists, and other professionals. By 2003, several models of glucose concentration measurement had been worked out, and over 500 tests conducted. The refinement of the developed model continued until 2011-2012.

In 2012, Artem Shipitsyn, George Mikaberidze and Stanislav Povolotsky founded Healbe™ in partnership with Algorithm, and acquired this technology. Healbe™ is based in Moscow, while the R&D division is located in Saint Petersburg. The company's personnel includes several Algorithm employees originally involved in the project.

Healbe™ applies ground-breaking technology to automatic calorie intake measurement

Various attempts to measure glucose concentration through noninvasive methods have been covered in thousands of papers and articles. There are hundreds of projects devoted to this topic.

During our time with Algorithm, we combined the advantages of several project groups from various disciplines. This allowed us to integrate into a single whole a keen understanding of such physiological process as glycometabolism, along with the most informative and accessible measurements of health parameters. That is how our water-balance measurement technology was born. This method produced consistent results in the course of testing.

Instead of entering the market with a noninvasive blood glucose meter, Healbe™ chose to use this technology to develop a personal device for monitoring energy intake, consumption, and balance, which is especially important in the process of weight management.

All intellectual property dealing with noninvasive glucose concentration measurement was transferred from Algorithm to Healbe™, which worked on developing supplementary technologies to monitor human health in everyday life, rather than laboratory or clinical settings.

The years of 2012-2013 saw supportive research, development of GoBe wristband pilot models, and the creation of an information system for collecting, processing, and storing human health status data. The list of investors also grew significantly during this period. Knowing that the United States would be a core market for GoBe and related products, Healbe™ established a company in San Francisco, CA, and all basic assets and control over the holding being formed were handed over to this company.

During 2013-2014, Healbe™ has focused on the mass production of the GoBe wristband, along with increasing the accuracy of measurement, and extending the range of human health parameters being monitored. During the same period, a set of calculation methods has been developed. These methods are combined into FLOW technology. Currently, several research groups are involved in the project. Each of them is focused on solving a specific problem within the general concept framework. These teams include designers, programmers, technologists, engineers, and other specialists, who have one and the same purpose: to develop a next-generation device.

Dr. Vladimir Leonidovich Emmanuel provides his expert opinion on GoBe and FLOW technology.

Throughout the development of GoBe, Healbe™ consulted closely with Vladimir Leonidovich Emmanuel, M.D., chief of the Central Clinical Pathology Laboratory and Medical Laboratory Diagnostics Department within the Molecular Medicine Department at Saint Petersburg Pavlov State Medical University. Dr. Emmanuel is a medical doctor and professor. He is also the vice president of the Russian Medical Laboratory Diagnostics Association; a chief expert in clinical pathology with the Federal Service for Healthcare Administration for the Northwestern Federal District; and a member of the Metrological Academy.

Regarding GoBe's method of automatically measuring calorie intake, Dr. Emmanuel has concluded:

- The concept of the suggested device is coherent with contemporary ideas about the physiological processes taking place in the human organism in the course of energy accumulation and consumption.
- The presented description of hardware and software shows that it is the only system capable of such long-lasting monitoring of glucose concentration in blood.
- The presented version of the hardware and software system is coherent with contemporary ideas about physiological processes taking place in the human organism in the course of carbohydrate accumulation after a meal.
- The accuracy rate of glucose concentration calculating methods that this hardware and software system's computing model is based on (15-20%) are quite enough, in my point of view, for implementation of a device intended for day-to-day applications.

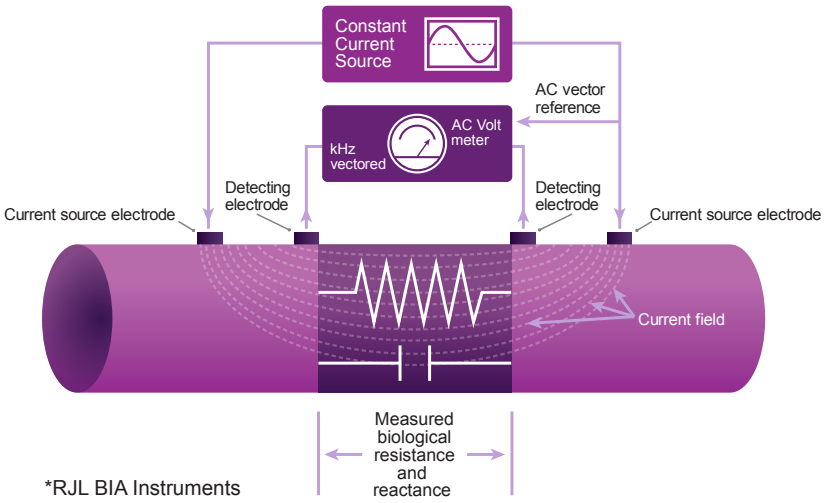
Testing the Healbe™ model of calorie intake and metabolism measurements

The Healbe™ model for calorie intake measurement relies on the following data:

- The level of glucose concentration in human cells. This concentration is an indicator of various physiological processes related to metabolism
- Personal data of the user (gender, height, weight, age)

Calorie intake and nutrient intake (carbohydrates, fats, water, etc.) are calculated on the basis of these data, and on our model of the physiological metabolic processes taking place in the human organism.

Tissue bio-impedance measurement*

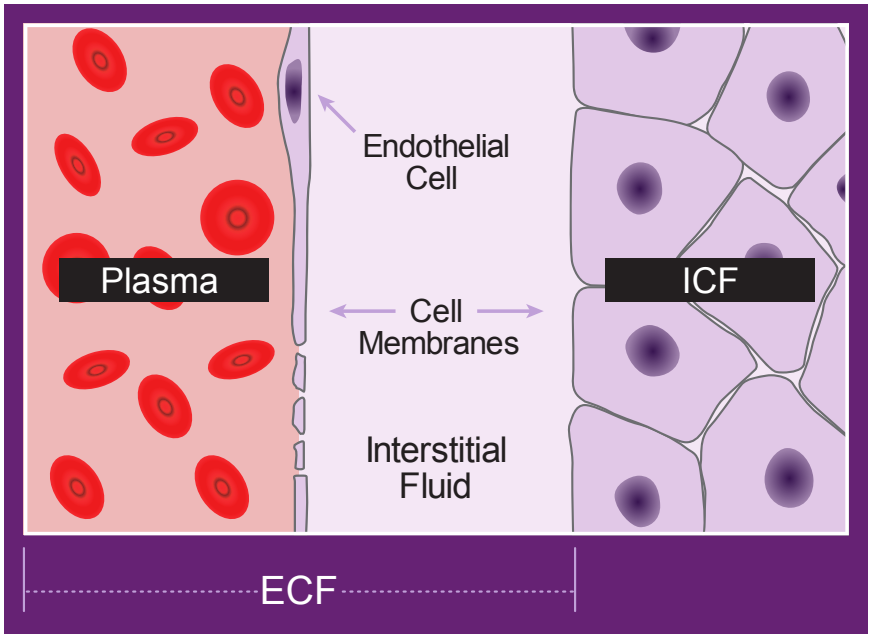


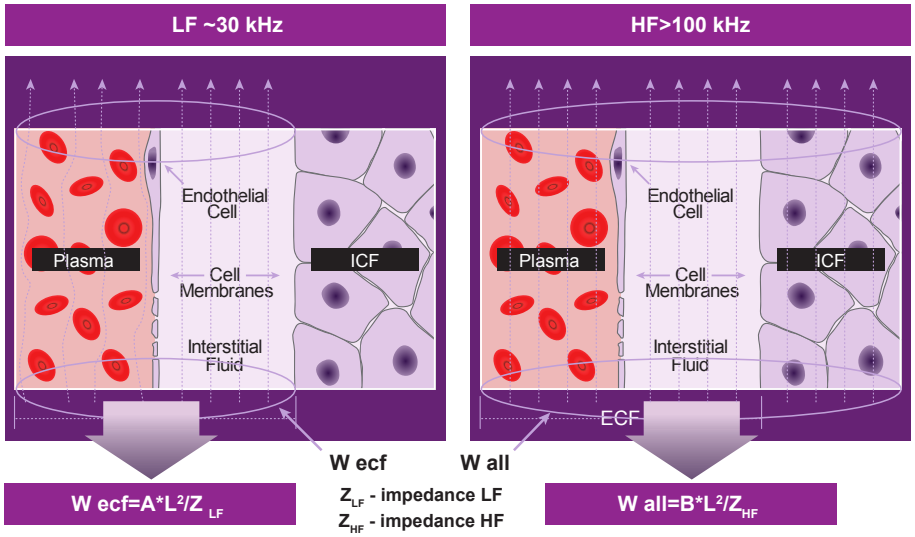
*RJL BIA Instruments

Unlike many other research methods, our technology uses tissue impedance measurement at both high and low frequencies, which allows us to:

1. Measure the dynamics of metabolism between cellular and intercellular water space; and
2. Isolate the glucose constituent in it.

Human tissue structure in measurement area

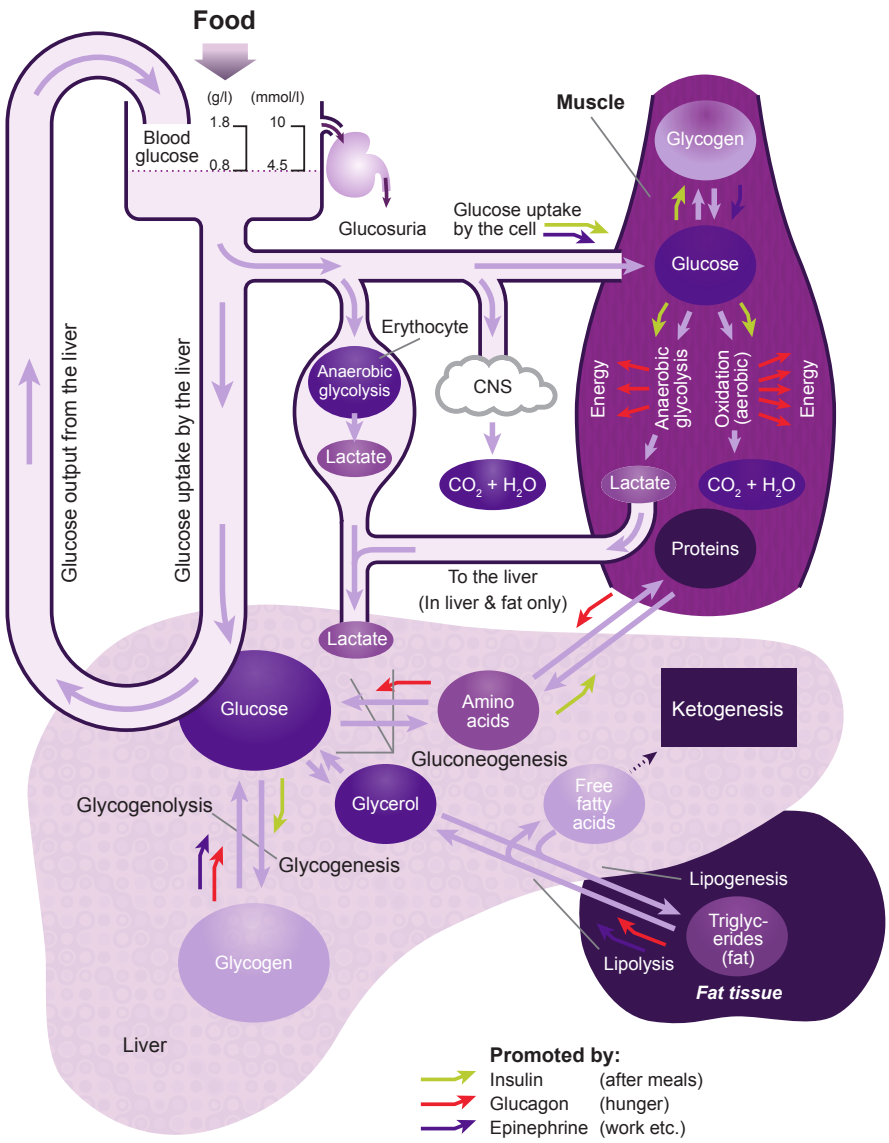




Properties of electric current flow with different frequency values through human tissues

Attempts to directly measure glucose concentration in the blood of a live organism all require invasive collection of samples from some part of the human body (skin cover, ocular surface, etc.). We use indirect measurements, but compensate for this shortcoming by applying a high-quality physiological model for evaluating glucose concentration in human cells.

Glucose metabolic routes in human organism



Let us stress again that our device uses glucose concentration monitoring as an auxiliary means for evaluating other indicators related to food metabolism. The Healbe™ wristband is not a medical device, so the value of glucose concentration is not displayed to users.

Figure 1, below, shows a Clarke error grid diagram (the plot accepted in science for the presentation of test results) for the series of 46 tests in 18 volunteers. The values of glucose concentration obtained by taking blood samples are plotted along one axis, while the results calculated using our technology at the same moments of time are plotted along the other axis. The result is considered perfect if and when all points are located in sectors A and B. As we see, only a very small number of points can be found outside these sectors, which indicates an excellent quality of results.

Figure 2 illustrates the distribution of points in a Clarke diagram in terms of error values. As is evident, over 45% of points have the magnitude of error of 5-10%, while 30% of them range from 10 to 20%.

Test of GoBe's measurement of nutritional load and calorie value

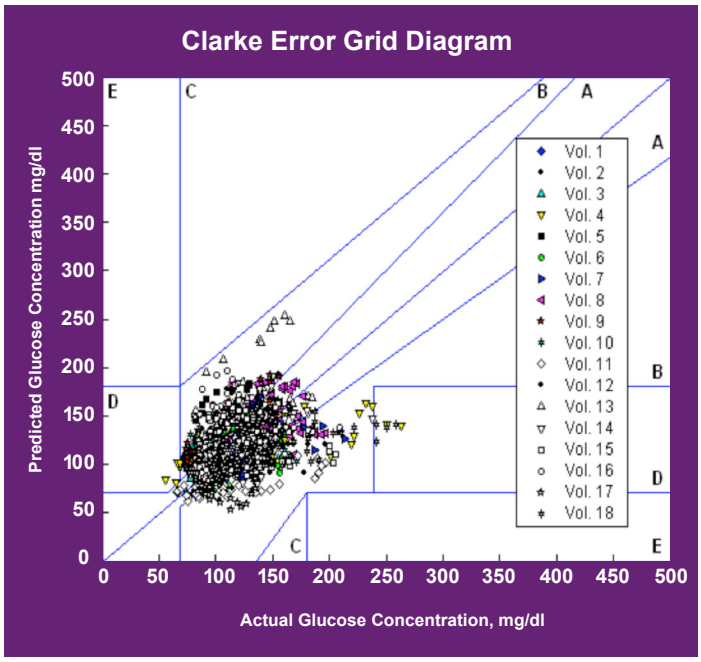


Figure 1

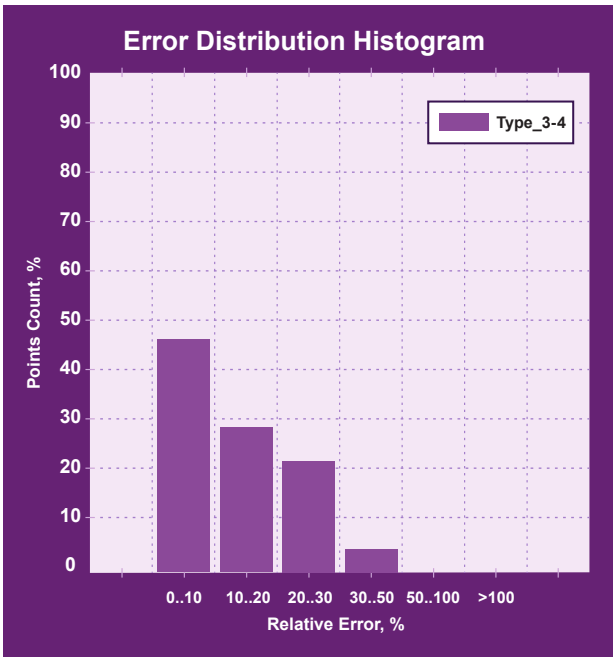
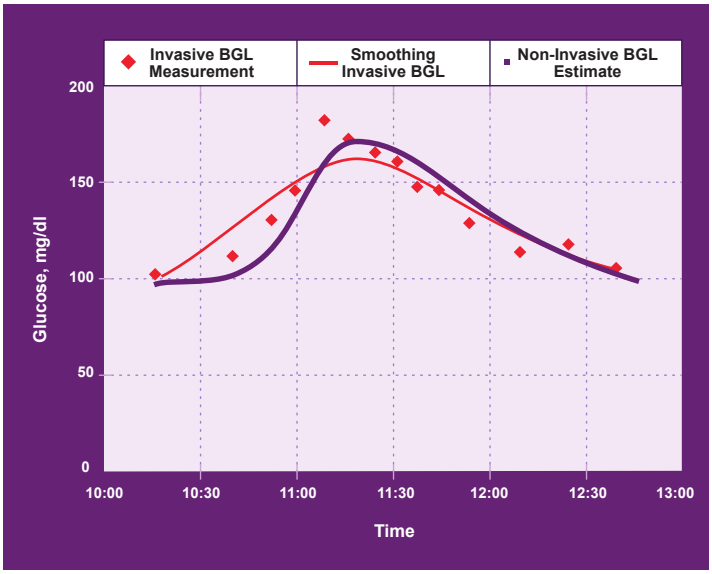


Figure 2

To the right is the result of one of the hundreds of tests conducted, profiling glucose concentration after a meal. This test was conducted in 2006, and was included in a presentation of our technology to a representative of a major pharmaceutical company that manufactures test strips for conventional blood glucose meters.

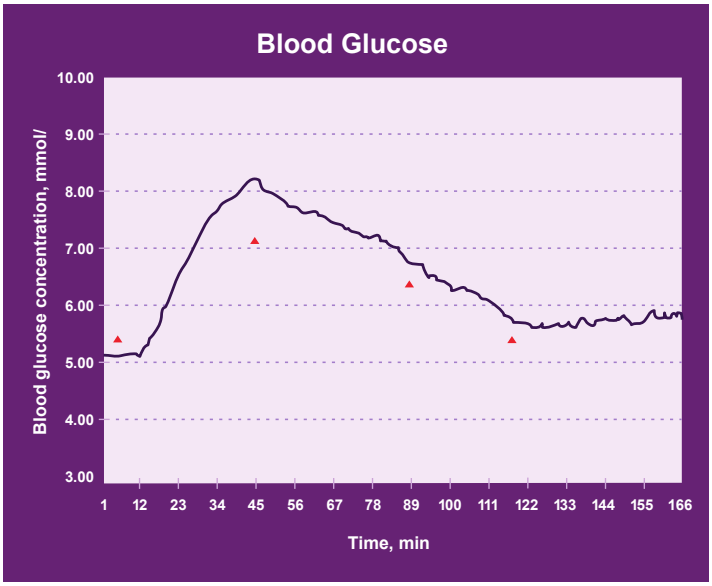
FLOW Technology Glucose Concentration Test Result

Volunteer	Date Add. Info	Mode	Type	Avg. err.,%	Trend sign,%	Max. err., %
DIMA 300 gram Coke	2006-07-05-(1) -d1-b1	Restoration Adaptive (N+W)	4	6.8	0.0	12.8



Here is an example of a test of the GoBe wristband. We presented the results of this test to a potential investor at his request, on March 2, 2014, in Saint Petersburg. The accuracy of blood glucose concentration measurement is within the range of 10%.

GoBe Glucose Concentration Test Result



Individual calibration of the device may lead to improved accuracy.

The table below shows the results of 24 tests conducted in October-November 2013. The mean estimation accuracy amounts to 12.8% for calorie intake and 10-24% for nutrient intake.

Calculation of nutritional load and calorie value: Test example (March 4, 2014)

Nutritional load parameters			E_IN_Average	E_IN_Average
	Min	Max	Kcal	%
E_IN, Kcal	216	1020	64.1	
Glucose, gram	31	180	48.0	10.2
Fat, gram	6	28	69.0	13.8
Water, ml	160	540		

- **Vegetable salad:** 125 g
- **Stewed liver with sauce:** 125 g
- **Fruit compote:** 200 milliliters

For comparison, we used charts indicating the calorie value and nutritional breakdown for various dishes. These data were compared with the results of calculations made using our algorithm, without entering the composition of food consumed.

The calorie intake amounted to 612 Kcal, when calculated using the charts, and 658 Kcal, when calculated using our models (7.5% error).

The water intake with the food amounted to 320 milliliters and 290 milliliters respectively (9.4% error).

The table below shows an example of nutritional load calculation for a test that was conducted on March 18, 2014. The meal included pasta (400 g), banana (117 g) and tea with sugar. According to the charts, this meal's calorie value is approximately 536-684 Kcal (it depends, in particular, upon the method of cooking pasta). When our calculation model was used, the calorie value amounted to 545 Kcal. Thus the error is within the range of 2% - 20%.

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Test of GoBe's measurement of nutritional load and calorie value

Test Results			March 18, 2014
Oleg	Age - 58	Height, m – 1.74	Weight, kg – 84
1. Number of meals		1	
2. Calorie intake		310.64	Kcal
First meal	Glucose	81.75	grams
	Carbohydrates	81.75	grams
Glycemic index of food		GI 100	
Second meal	Glucose	0.00	grams
	Carbohydrates	0.00	grams
Glycemic index of food		GI 120.00	
Total nutrient quantity	Glucose	81.75	grams
	Carbohydrates	81.75	grams
3. Water intake	Total:	206.54	ml
First meal		Liquid 1 206.54	ml
Second meal		Liquid 2 0.00	ml
4. Calorie intake (fats)		234.0402	Kcal
Total nutrient quantity		26.00	grams
5. Total calorie intake		544.68	Kcal

Securing patents for Healbe FLOW™ Technology

Healbe™ has been in possession of rights for noninvasive glucose measurement technology since 2012. On November 22, 2013, Healbe™ received a favorable decision granting the company a patent for its invention, “A Method of Human Blood Glucose Concentration Measurement” (patent application № RU2012106461).

On February 12, 2014, Healbe™ received a patent for its invention, “Sensor for Measuring Impedance of a Human Body Area” (patent application № RU2012155821).

On March 12, 2014, Healbe™ was granted the patent for an invention, “Method for Measuring Human Organism’s Calorie Intake during a Meal” (patent application № RU2012155819).

How GoBe evaluates heart rate and cardiac function

Monitoring the condition of the cardiovascular system is very important in order to understand the general state of health. GoBe evaluates the state of the cardiovascular system using a parameter called “pulse wave”. Unlike with ECG (electrocardiogram), which shows the electric signals of cardiac function, the pulse wave shows the mechanical circulation of blood flow through the arteries.

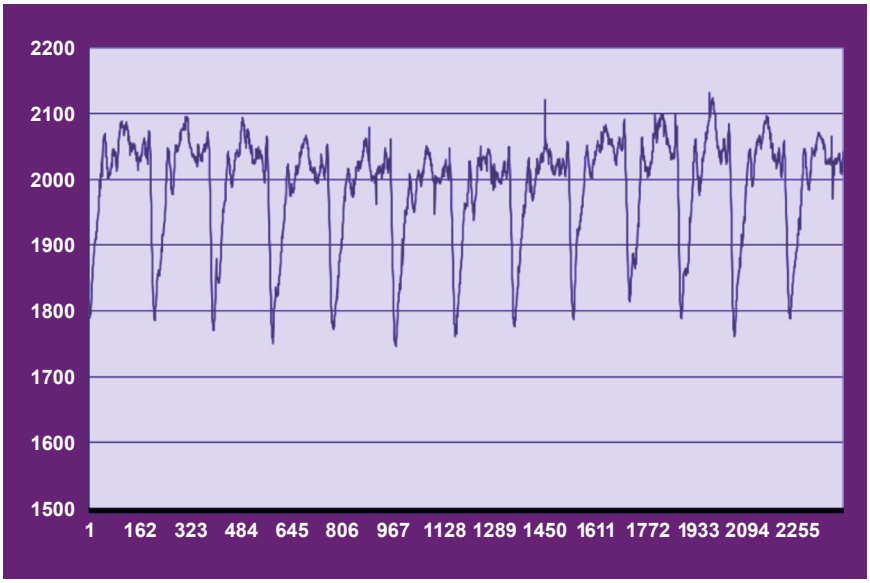
You can feel the beat of your pulse wave by putting your finger on your wrist. The pulse wave contains a lot of information about cardiac function, respiratory intensity, state of the blood vessels, and arterial blood pressure. This phenomenon has been studied rather well in medicine. Until now, the challenge has been how to accurately read the pulse wave and automatically extract all necessary parameters from it, using a compact, inexpensive device, rather than conducting tests in a laboratory with the help of complex and expensive equipment. In order to provide continuous monitoring of cardiac function, we also wanted to eliminate the need for a chest strap monitor.

In contrast with other pulse meters, we do not use optical LED sensors for measuring pulse. Instead, the pulse wave signal is read on the wrist with the help of a piezoelectric pressure sensor. Unlike LED sensors, this pressure sensor does not need electric energy.

When analyzing the pulse wave, we distinguish between the calculation of heart rate and the calculation of other parameters based on pulse wave, such as arterial blood pressure, pulse wave velocity, the variation and interval between pulse wave peaks, and respiratory rhythm. A higher quality reading of the pulse wave is required to calculate these additional parameters.

The diagram to the right shows the pulse wave measured by the GoBe wristband. The experiment was done on March 4, 2014.

GoBe pulse wave measurement



Automatic processing of pulse wave data

The error value amounts to 0% - 8% for pulse (from 60 to 65 beats per minute), 2%-14% for respiratory rhythm (approximately 14-16 respiratory movements a minute), and about 3-10% for arterial blood pressure.

Tested Heart-wave module C-version	
Input sphygmogramms data	Total = 2401
Heart data using R-peaks: CHSS heart_frequency in minutes RR min. time between R-peaks, sec. RR max. time between R-peaks, sec. RR average time between R-peaks, sec. RR_GPR average quadratic dev. between R-peaks, sec. Validity = VALID	 = 65 = 0.819984 = 0.994987 = 0.915498 = 0.547486
Heart data using reflected peaks: pulse_wave_time, sec VRPVQE pulse_wave_speed, cm/sec B artery_age P_l bottom_artery_press Psr medial_artery_press P_h top_artery_press Validity = VALID	 = 0.300835 = 565.093384 = 27 = 76 = 88 = 133
Breath data: f_g, MNH-1 Validity = VALID	 = 16.337620

How GoBe measures physical activity and energy expenditure

Energy expenditure, or calorie burn, consists of two components: calories burned for basic survival metabolism (this can be rather accurately calculated using standard parameters of gender, height, and weight); and calories burned during physical activity. GoBe determines your level of physical activity and energy expenditure by analyzing the data obtained from its accelerometer, along with cardiac function data. The device also supports pedometer function, and measures distance covered. Tests have shown that the accuracy for these parameters varies between 90% and 98%.

How GoBe analyzes sleep phases

For accurate analysis of sleep phases and health status during sleep, physicians use a method known as polysomnography. This technology monitors over 40 different parameters of activity during sleep.

In developing GoBe, we discovered a way to measure the duration and efficiency of sleep (the ratio between net sleep time without wake time, and total duration of sleep), while identifying REM sleep phases, which is the healthiest phase for waking up.

Currently available sleep trackers use accelerometer readings alone. However, the results of our research show that the error rate of determining REM sleep phase with this method exceeds 20-30%.

Medical specialists know that cardiac function and breathing are related to the REM sleep phase, yet no one has ever described the nature of this relation. We have analyzed a large selection of polysomnograms in cooperation with researchers from one of the major healthcare centers of Saint Petersburg, and developed a unique algorithm to determine REM phases. This algorithm combines accelerometer data showing movement during sleep with cardiac function and respiration rhythm data from GoBe's pressure sensor. This method leads to an error rate of just 4%. We have proceeded with a patent application for FLOW Technology's sleep phase analysis.

GoBe also uses this algorithm to determine whether a person is sleeping or not. This sleep measurement is accurate to within about 10-20 minutes for the night (thus making the error for sleep duration and efficiency valuation approximately 3-5%).

GoBe also analyzes changes in stress level using parameters such as quality of sleep and arterial blood pressure variations, along with standard data about the user's age, height, and weight.

The future of Healbe™, FLOW, and GoBe

For accurate analysis of sleep phases and health status during sleep, physicians use a method known as We are continuing to develop and refine our technology for a wide range of applications. By May 2013, Healbe™ could boast of 12 patent documents (including applications and patents for inventions) in seven areas.

Apart from regular patent research, we are conducting studies in order to forecast the future of human health monitoring systems. Currently we have both short-term and long-term (to 2030) plans for the development of FLOW Technology.

Continued development of our technology will focus on improving the accuracy and reliability of measurement, and improving the accuracy of our models for evaluating human health parameters. Our research activities are divided into three types:

- Study and development of long-term concepts
- Research on improving the operational value of our most promising technologies
- Studies aimed at enabling the mass production of our systems.

We are also extending the list of parameters monitored and how we use these sets of parameters, and we plan to develop products for groups such as athletes, children, and seniors. Next year, we expect to introduce fundamental changes to the wristband's design.

We like this work. We want to surprise the world. Dreams should come true. The most mysterious and interesting thing in the world is related to ourselves, our life. People still know little about the human body. We are sure that with your support, and the help of those who have been involved in the Healbe™ project, we can solve many mysteries of the human body and human health.