Technology of auscultatory data analysis obtained in a non-invasive home examination of the fetal heart rate in the prevention of prenatal diseases and defects

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Abstract

According to estimates, there are approximately 2.6 million miscarriages worldwide each year, 1.3 million of which can be effectively prevented. This was confirmed by The Lancet, publishing data on nearly 3 million miscarriages worldwide each year. The key fact is that 98% of miscarriages occur in low- and middle-income countries where professional fetal health care is not as good as in high-income countries, is difficult to access, or even absent. In high-income countries, the number of miscarriages is also relatively high, amounting to approximately 60,000 cases per year. Importantly, most cases related to miscarriages and other complications during pregnancy and childbirth could have been avoided if the staff operating such complex devices as professional CTGs were better trained. Nevertheless, as recent studies show, there is no evidence that the complex and advanced, and therefore difficult and expensive to apply CTG methodology gives better results than the non-invasive auscultation method in the case of cerebral palsy or stillbirths or the overall assessment of the health of the fetus in women who are at low risk of prenatal disease and complications. However, as shown by scientific research, the CTG method caused an increase in unnecessary cesarean sections and instrumental vaginal deliveries. The Goldcitadel team has developed a technology for the analysis of auscultatory data obtained in a non-invasive home examination of the fetal heart rate in the prevention of prenatal diseases and defects, which will enable the introduction of inexpensive devices and cloud *services allowing for early warning of potential abnormalities in the heart development in the prenatal period. Currently, there are no similar technologies or related products or services in the world.*

Keywords: *Fetal heart auscultation, prenatal diseases, prenatal defects, non-invasive home examination.*

1. Introduction

The main goal of the project was to enable future parents to perform a regular examination at home to monitor the fetal heartbeat using a non-invasive auscultation method and provide early warning of any detected significant irregularities. The developed new technology will be used to market new products and related services. Conducting the study will require only a commonly available mobile device such as a mobile phone or tablet or a personal computer (desktop or laptop) and an electronic acoustic earpiece-like device, holding working name "Sonicor". The main advantage of the study is the fact that it does not require a doctor's visit or going to a medical center, which is very important during advanced pregnancy, especially in areas far away from health facilities. The signal recorded during the study will be analyzed in two stages: preliminary using software installed on a mobile device or personal computer, and accurate, in the cloud resources of the system, with significant computing power (scalable cloud computing Big Data and HPC - High Performance Computing).

Monitoring testing with a new product system and related services can be compared to measuring blood pressure in a home environment with a commercially available blood pressure monitor. Its task is not to replace professional ECG or CTG equipment available in medical facilities, just like a home blood pressure monitor does not replace a Holter apparatus or equipment for examining the echo of the heart. Nevertheless, today a personal blood pressure monitor is considered a diagnostic device that is indispensable in every home. They allow millions of lives to be saved. Worldwide, 5 million people die of stroke each year, and the other 5 million become permanent disabilities [1]. High blood pressure causes strokes in 12.7 million people each year. According to estimates, there are approximately 2.6 million miscarriages worldwide each year, 1.3 million of which can be effectively prevented [2]. This was confirmed by The Lancet publishing data on nearly 3 million miscarriages worldwide each year [3]. The key fact is that 98% of miscarriages occur in low- and middle-income countries where professional fetal health care is not as good as in high-income countries, is difficult to access, or even absent. In high-income countries, the number of miscarriages is also relatively high, amounting to approximately 60,000 cases per year [3].

Importantly, most cases related to miscarriages and other complications during pregnancy and childbirth could have been avoided if the staff operating such complex devices as professional CTGs were better trained. Nevertheless, as recent studies show, there is no evidence that the complex and advanced, and therefore difficult and expensive to apply CTG methodology gives better results than the non-invasive auscultation method in the case of cerebral palsy or stillbirths or the overall assessment of the health of the fetus in women who are at low risk of prenatal disease and complications. However, as shown by scientific research, the CTG method caused an increase in unnecessary cesarean sections and instrumental vaginal deliveries. On the plus side of CTG, however, it must be noted that it contributes positively to the reduction of convulsions in newborns, which can rarely be detected using only a regular auscultation method [4] [5]. However, the Goldcitadel team noted that when using regular auscultation of the fetal heart rate, the human is not the best subject to analyze acoustic signals. While an expert can generally say that there are accelerations and decelerations in the rhythm of the working heart, she or he is not able to precisely define the intervals between them, as well as their signal fills. It is also difficult for the expert to compare the intensities of both phenomena, and finding a correlation "by ear" is practically impossible. Microelectronics and modern data processing systems, as well as solutions such as the Internet of Things, mobile applications and cloud resources with high computing potential come to the rescue. The target analytical system working in cloud resources will allow for in-depth and advanced signal analysis related to the modes of the fetal heart and thus to detect early signs of potential threats of affections and diseases. The use of the planned products and services will contribute to reducing infant mortality and improving their health through faster preventive actions. For example, a fetal or a newborn's heart surgery is definitely less risky than in a healthy adult person due to the newly developing organs.

2. The project

The aim of the project was to generate new knowledge in the form of auscultatory data analysis technology in non-invasive home examination of the fetal heart rhythm in the prevention of prenatal diseases and defects as a result of the implementation of the planned research agenda. Research and development works were carried out in the following functional areas:

- Data recording with automatic sensor position correction as a result of feedback.
- Basic data analysis using a mobile device and results representation method.
- Advanced data analysis using cloud resources and the representation of results along with their sharing.
- Reasoning as a result of advanced signal analysis and creating dynamic models of the fetal heart rate.
- As part of the above-mentioned areas, research and development work was carried out on the following issues:
- Methodology of initial sampling and evaluation of the quality of the recorded signal
- Feedback loop generation methodology based on acoustic data
- Acoustic data recording correction methodology

- A methodology for pre-processing data with reduced resolution in a mobile device, taking into account the limitations of the mobile processor and the system environment
- Methodology for analyzing the characteristics of the recorded acoustic signal and for marking markers
- Methodology for analyzing the correlation of individual markers, detecting potential threats and representing the results
- Methodology of processing high-resolution and big data in cloud resources
- Methodology of advanced data analysis with ad-hoc pattern setting and statistical dependence detection methods
- Methodology of detecting irregularities and potential threats based on advanced statistical signal analysis methods
- Methodology of advanced signal analysis based on teaching classifiers, including methods of artificial neural networks
- Advanced signal analysis methodology based on genetic algorithms and machine learning
- Methodology of automatic inference about potential threats based on advanced signal analysis and non-algorithmic methods

The new technology will allow the Goldcitadel team to introduce new products and services to the market in the form of a set: acoustic sensor, mobile application, advanced signal analysis system in cloud resources. The necessity to achieve the goal resulted mainly from the possibility of providing the market with an innovative technology, which may significantly reduce the birth rate and early detection of heart defects, which enables the operation to be performed at a safe fetal age or immediately after birth. Importantly, there have been mobile devices for acoustic CTG testing on the market for a long time, an example of which was the Hungarian device called Fetaphon (currently unavailable), which has been developed for over 20 years. In Poland, a few years ago, the Fetaphon device was introduced to the e-medical program by Comarch. The device used acoustic sensors, but was not based on strictly auscultatory methods. All interpretation of the data was left to the attending physician. In addition, this type of device is characterized by a high price of USD 3,500. Importantly, it was the only long-range device on the market that used purely acoustic methods, i.e. without the use of ultrasounds and the Doppler effect.

As part of the project, the Goldcitadel team implemented a completely different technology than that implemented in the Fetaphon device. The main element of this technology is the low price of the device (around EUR 100-150), the use of common mobile terminals such as tablets or smartphones for basic signal analysis and visualization of results, and the use of cloud resources for advanced, in-depth analysis of registered signals using machine learning, patterns, statistical and non-statistical analysis, automatic inference, functionality of expert systems, correlation and autocorrelation analysis, as well as methods used to study complex dynamical systems. It should also be emphasized that home examination based on a regular auscultation method is not an alternative to cardiotocography, but a complementary method that can perfectly complement the image of the normal course of pregnancy, especially as it does not require a stay in a medical facility and can be performed in comfortable conditions as often as only the expectant mother finds it tiring. Each test can then be made available to the attending physician or trained obstetricians for graphical analysis based on the mechanisms included in the service (examples may be heart rate variability, filling accelerations and delays in rhythm, states of temporary stops, significant irregularities, autocorrelations), and typical auscultatory analysis (the signal can be reproduced without and with the use of selective filters enhancing specific frequencies). In the near future, the Goldcitadel team intends to expand the group of patients to include newborns and developing children, who are still at risk of developing myocardial diseases and revealing previously hidden defects. The next step will be a group of elderly people with cardiovascular diseases, which significantly increases the capacity of the target market.

3. Research apparatus

During the project implementation, the own research equipment in the form of a test chamber was used. A chamber for testing the propagation of low-frequency sound signals in liquids simulating amniotic waters, is a device with the shape of a double-ended cylinder for filling with a liquid with a chemical composition similar to the amniotic waters, used to study the distortions of sound waves that pass through the liquid contained in the chamber. The sound waves are generated by a separate source applied to one end of the chamber cylinder. Both ends of the chamber are closed by lids, which have holes, and in them are mounted silicone membranes held by tight stainless steel flanges. The user of the chamber, after filling it with liquid, puts the source of sound waves to the bottom lid of the chamber, and puts the sound receiver to the upper one, e.g. the tested Sonicor device. The chamber allows to study the phenomena of distortion of sound waves originating from sources simulating sound sources in the womb and to test the receivers of these sound waves or their parameters. After recording the distorted waves, the user can compare the source waveforms that are applied to the source of the sound waves and the waveforms recorded by the sound sensor. This allows for the study of the phenomena of distortion of low-register sound waveforms with a different frequency spectrum and amplitude by the liquid simulating amniotic waters and the membrane simulating human skin, as well as for testing the sensitivity and fidelity of reproduction of distorted sound waves by various sound sensors. The tests then enable the selection of optimal recording parameters, optimization of the geometry of the acoustic mirror system, optimization of the structure of the sound sensor and the use of algorithms correcting the effects of distortions in the recorded sound waves.

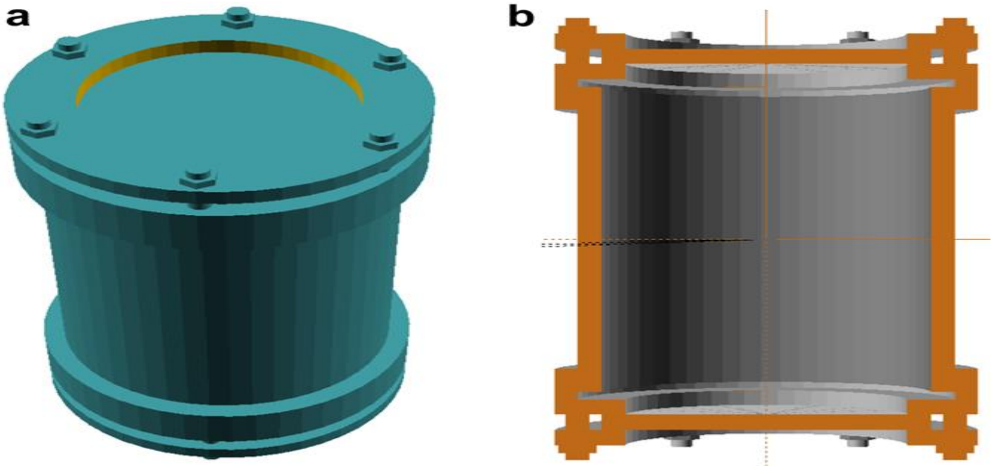

Figure 1. (a) main view of the test chamber; (b) the cross section through the test chamber
Source: *own materials*

4. Results

4.1. Measurement quality comparison

Knowledge in the field of ASF (Adaptive Signal Filtering) algorithmics and RDA (Reconstructed Dynamics Analysis) methodology as well as the results obtained in the course of industrial research and experimental development works carried out during the project allowed, apart from the technology itself for the development of the Sonicor earpice prototype, used to auscultate pregnant women with high efficiency and low production costs. ASF-class numerical algorithms are based on the latest achievements of signal analysis, applicable in practically all natural and technical fields of science and engineering. In recent times, more and more attention has been paid to adaptive algorithms using various algorithmic techniques, including linear and non-linear, discrete and averaged approaches, artificial neural networks, wavelength and chirplet transforms, and fuzzy logic as well as fuzzy sets. The mentioned methodologies allow for precise determination of the noise factor in the signal and high quality of the signal after filtering. Their significant advantage is the ability to reduce or completely remove artifacts that may appear as a result of noise reduction of the recorded signal (e.g. relative amplitude inaccuracies, false frequencies). On the other hand, the RDA methodology is based on a modern approach to physical dynamical systems, when the measurement results are known only for a very few dynamic variables characterizing the system (e.g. only one component of momentum). Such a phenomenon occurs, among others in the case of recording the human heart rate, where only a time series of acoustic peaks corresponding to successive contractions of the heart muscle is obtained. The RDA methodology allows the dynamic characteristics of the system to be reconstructed from sparse data, such as the acoustic signal of the heart rhythm. An important requirement that allows for an effective RDA analysis is the measurement time, which lasts for a sufficiently large number of beat cycles (hence this method is particularly suitable for periodic and quasi-periodic systems with possible irregular and chaotic areas). The analysis of the signal filtered by ASF algorithms in order to detect significant irregularities requires the use of innovative methods that are the achievements of modern science, especially the physics of chaotic dynamical systems. Such methods undoubtedly include the RDA approach based on the methodology of reconstructed dynamics (the so-called reconstructed phase space). RDA allows to detect hidden signal dependencies, whether regular, quasi-regular or irregular (including chaotic). Since the heart of the fetus changes its working characteristics as it grows, it is associated with frequent changes in its rhythm. Areas of irregular rhythms, especially chaotic, of significant statistical significance, which are very difficult to detect in the source signal, even by a person with long medical practice, can be dangerous to health. Thanks to the use of RDAs in new products and services, it will be possible to automatically detect irregularities that may herald potential threats, and then report them to the attending physician or medical guardian for a correct diagnosis.

The effectiveness of the created prototype was compared on the basis of the results of measurements made with a professional 3M electronic stethoscope - Littmann Model 3200. The current price of this stethoscope is approx. 400 USD. Fig.2 and Fig.3 show graphs of both measurements to compare their accuracy. As shown by the waveform analysis, the signal-to-noise ratio is nearly 2.5 times better in the case of the Sonicor device. This is shown in the graph by a better ratio of the signal peaks to the background, i.e. the signal outside the peaks. Moreover, the electronic stethoscope uses a low-pass filter to remove excessively high frequencies that add to noise. In the case of the Sonicor device, this practice was not used in the comparison, as it is not known what cut-off frequency was used in the electronic stethoscope. Using an appropriate low-pass filter should further improve the results for Sonicor. What is most important, however, the basic version of Sonicor (without the BLE module, with cable transmission) will cost less than 50 Euro, probably around 35 Euro (work on reducing the cost of production is still in progress), which is about 10 times less than an electronic stethoscope. Littmann Model 3200. Combining these facts, it can be briefly said that thanks to the implementation of the project in question, the recording efficiency of acoustic signals related to the heart's work in a characteristic frequency range was nearly 25 times better than that of the world leader, ie the 3M group. What's more, the handset will be equipped with a much faster processor and a higher sampling frequency than electronic stethoscopes, which will allow for more precise recording of signal acceleration or deceleration. This, in turn, will translate into more accurate detection of irregularities and chaotic areas suggesting possible diseases or defects of the developing heart.

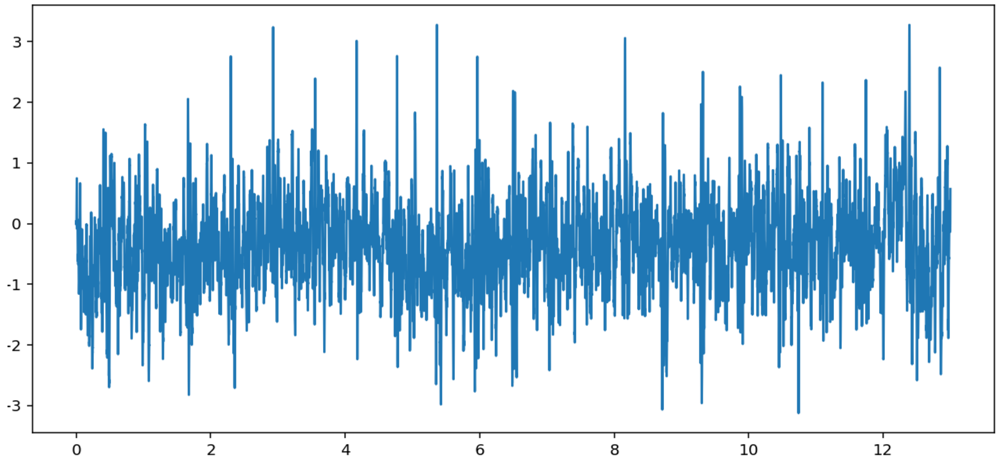

Figure 2. Fetal heart rate signal recorded using a 3M Littmann Model 3200 electronic stethoscope utilizing a low-pass filter.
Source: *own materials.*

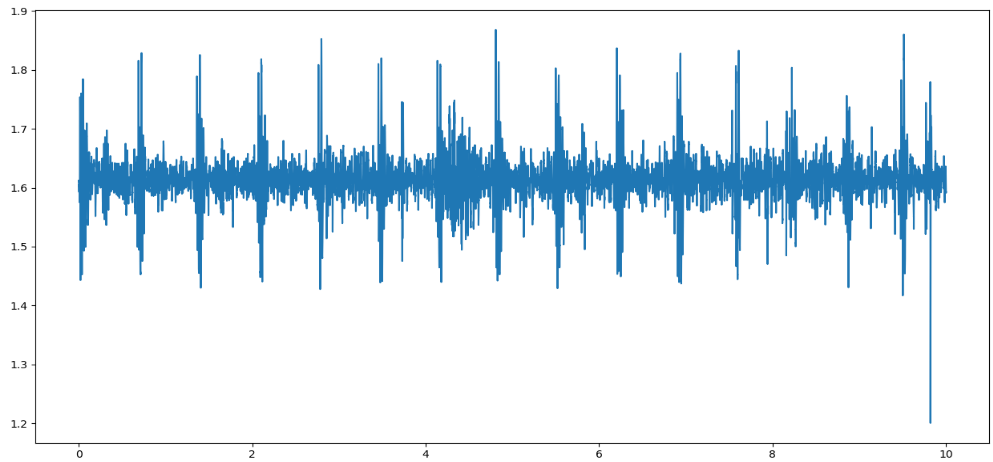

Figure 3. Signal recorded using the Sonicor handset prototype without a low-pass filter (scale based on the recorded voltage).
Source: *own materials.*

4.2. The acoustic sensor

Sonicor consists of two acoustic mirrors, i.e. curved surfaces with a specific stiffness, reflecting acoustic waves coming from the diaphragm as a secondary source. This source is usually human skin (the skin of the abdominal cavity of a pregnant person). The primary mirror has the form of a cavity resulting from the rotation of a curve with a specific geometry in relation to the symmetry axis of the mirror. The diagram of the device is shown in Fig. 3. This construction is designed to collect acoustic waves and direct them to the secondary mirror through the focusing area (P_B). The secondary mirror then directs the focused waves to the collecting point (P_A). At this point, an acoustic sensor is placed to record the focused sounds.

The appropriate selection of the surface geometry of both mirrors, the material from which they are made and the frequency range of the sensor and the noise factor is crucial for the effective registration of the fetal heart rate.

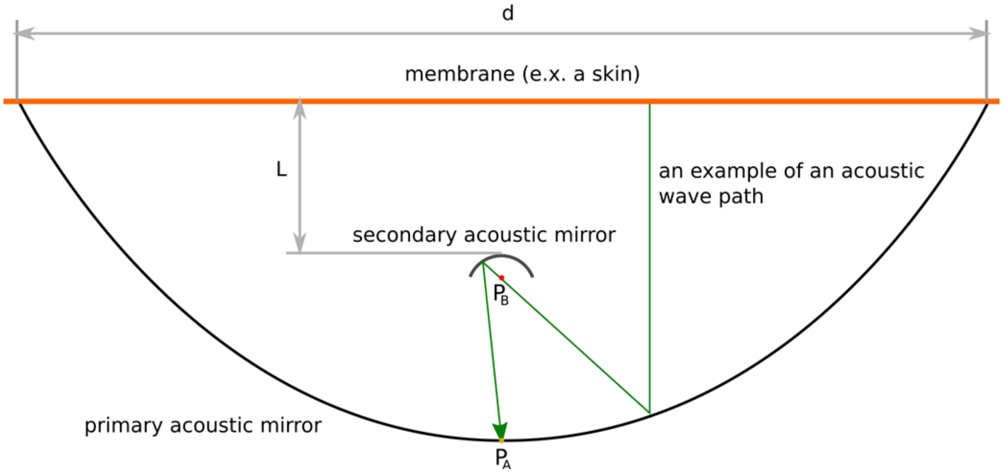

Figure 4. Functional scheme of Sonicor device implementing two acoustic mirrors set, i.e. primary and secondary acoustic mirror. L denotes effective depth of the device, d is the effective area for auscultation, P_B is focal area of secondary mirror while P_A denotes focus point where sound recording component should be placed.
Source: *own materials*

In the simplest case, we can assume that both acoustic mirrors have the simplest possible symmetry, i.e. the primary mirror has paraboloid symmetry and the secondary mirror spherical one. In this case, we can write the relationship:

$$\frac{1}{A} + \frac{1}{B} = \frac{2}{R} \tag{1}$$

Where:
A is a distance between P_A and vertex of the secondary mirror,
B is a distance between P_B and vertex of the secondary mirror,
R is a radius of the secondary mirror.

One can notice that the focal p of a parabolic primary mirror surface is equal to a distance between PB and the vertex of this parabola and one can write:

$$A - B = p \Rightarrow A = B + p \tag{2}$$

And then:

$$2B^2 + 2(p - R)B - Rp = 0 \tag{3}$$

We get two roots of the above equation:

$$B = \frac{1}{2}\left(R - p + \sqrt{R^2 + p^2}\right) \tag{4a}$$

$$A = \frac{1}{2}\left(R + p + \sqrt{R^2 + p^2}\right) \tag{4b}$$

It follows from the above (4) that the geometry of the system is given by at least two parameters, e.g. the focal length of the parabola p and the mirror radius R:

$$A(R,p) = \frac{1}{2}\left(R + p + \sqrt{R^2 + p^2}\right) \tag{5}$$

These parameters unequivocally define the entire mirror system. Thus, two other parameters that are based on the above geometry can be introduced, namely:

L - an effective depth of the device (i.e. a distance between vertex of the secondary mirror and membrane) and

d - an effective area for auscultation (i.e. skin area generating derivative sounds).

One can write the following relationship:

$$L = \frac{d^2}{16p} - A(R,p) \tag{6}$$

Using (5) one can get:

$$L(R,p,d) = \frac{d^2}{16p} - \frac{1}{2}(R + p + \sqrt{R^2 + p^2}) \tag{7}$$

Thanks to the above equation, it is possible to determine any three parameters, e.g. L, p and d, and then calculate the fourth, e.g. R getting the device geometry.

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