

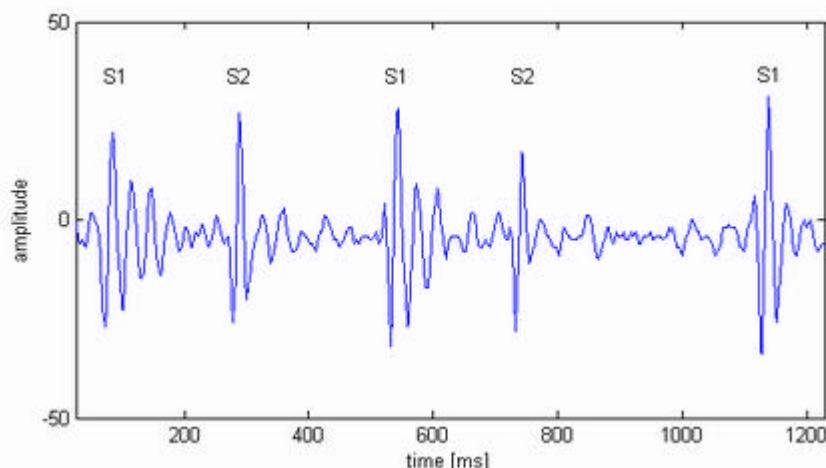
We present you World novelty for gynaecology!

About fetal phonocardiography

The worldwide used method of fetal monitoring (measuring of fetal heart rate, the FHR) is now the ultrasound Doppler method, where practically the movement of the external surface of the fetal heart is measured by time-difference of an incident and reflected ultrasound wave. Consequently, during this measurement the fetus will be affected ultrasound radiation, which may be, according to some studies, not absolutely harmless at long-time measurements.

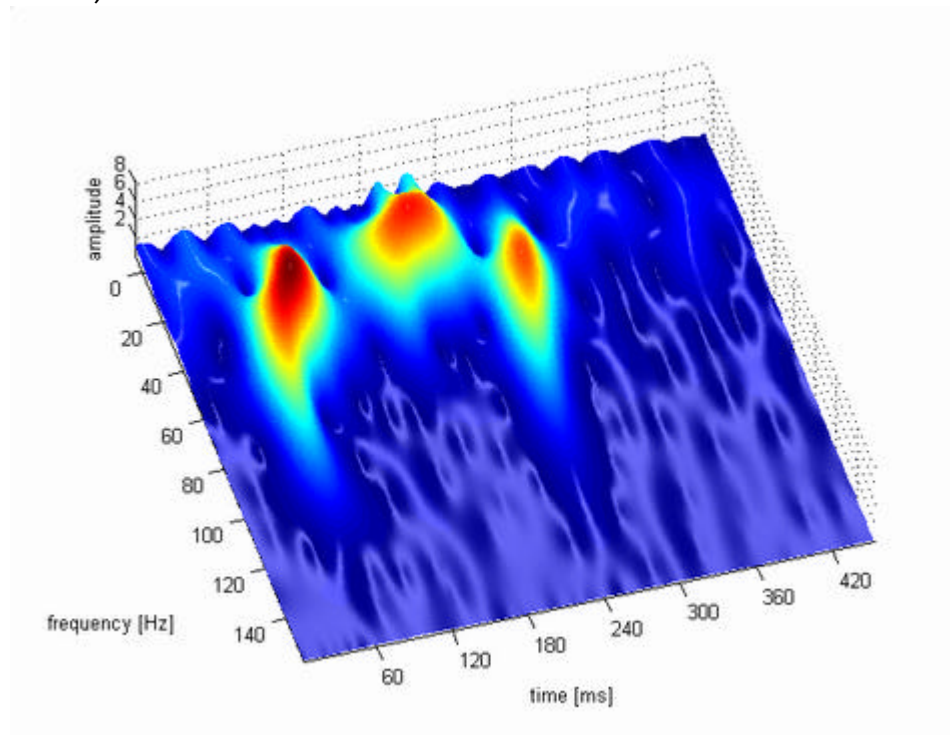
Taking into account this danger the firm decided to develop a totally passive method for FHR measurement based on phonocardiography (called formerly as auscultation) carried out by a special acoustic sensor placed on the maternal abdomen. In such a way long-time measurements can be accomplished, which are very important from the point of view of the detection of occasional events, as the extrasystole and the breathing periods.

A relatively noiseless sound signal is shown on the figure where S1 and S2 denote the systolic and diastolic sounds, respectively. The additional disturbances, as the maternal heart beats and her breathing as well as the fetal movements may cause very high noise level, which makes difficult to identify all fetal heart beats. A very sophisticated signal processing method is applied to remove noises in order to determine the FHR and the beat-to-beat time, to calculate the variability and other cardiac features derived from this.



Compared to the ultrasound Doppler process the phonocardiographic method has an additional, very important advantage, namely, it is capable to display additional symptoms of the fetal heart activity as the waveforms of the closing valves with their timing, and the sound of the turbulent blood flow, which may be indications of congenital diseases. A good example for this is shown on the next figure where, because of a ventricular septum defect – verified exactly after delivery –

due to the produced turbulent blood flow a well visible murmur appears in the systolic period (the internal low-frequency signal on the time-frequency plot between the very short S1 and S2 sounds)



The measurement has been made on a 30-week old fetus with Ventricular Septal Defect (VSD), monitoring permanently during the pregnancy. After the birth a similar acoustic signal was measured. On the baby, who will be operated probably in a half year, the VSD has been never detected at any earlier non-phonocardiographic examinations.

Based on the phonocardiographic method the firm Pentavox developed a series of fetal monitoring equipment the newest and most powerful of which is the home monitoring system detailed in the followings.

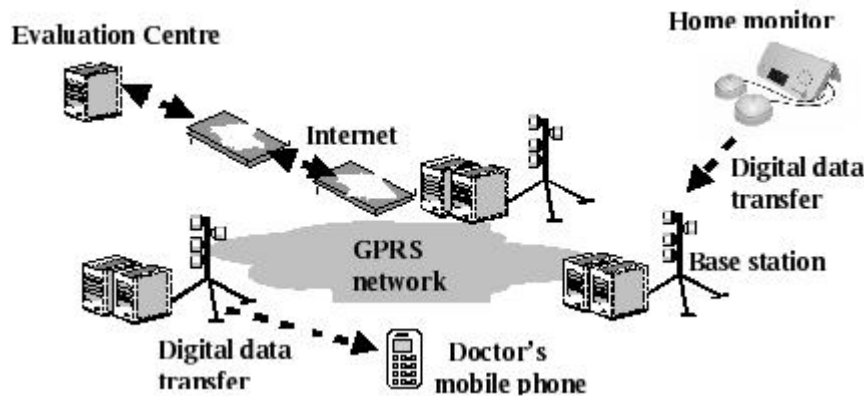
Fetaphon home Monitor

System overview

The phonocardiographic method applied in the Fetaphon-type monitor family allows its usage for home application, because its passive nature excludes any damage possibilities. An overview of the system developed by the firm is shown on the next figure.

The special acoustic sensor mounted by a belt on the maternal abdomen is connected to the home monitor. The Toco sensor for measuring the intrauterine contractions is coupled also

to here. The data received by the sensors are preprocessed, compressed and transferred in GPRS by the home monitor to the mobile phone network. For this purpose the monitor contains a signal processing unit and a modem for data transmission.



The main advantages of the Fetaphon home monitoring system compared to the traditional ultrasound CTG devices are:

a) a permanent surveillance of the fetus can be accomplished in a convenient and familiar surrounding; through the direct contact between the Evaluation Centre and the patient the former can ask to carry out a measurement or to repeat them if the data received formerly were not able for evaluation. The Centre can send alarm signal if a critical measured value has been found ordering an immediate visit to the hospital. Critical data can be forwarded to the responsible doctor's mobile phone too; consequently, this permanent surveillance is especially beneficial for pregnancies with cardiac anomalies needed more frequent examinations;

b) the passive nature of the measurement enables long-term measurements excluding any kind of irradiation (as the ultrasound waves) of the fetus; this makes possible to observe rare symptoms of the heart activity, as the extrasystole or fetal breathing periods;

c) the exploiting of doctors is enhanced because of the flexible accessibility of the measured data, that means, doctors are enabled to perform the assessment from anywhere and at any time. Furthermore, the system also provides the option to involve external experts in the consulting process via the Internet, if necessary.

d) all measured data and their evaluation results will be electronically stored and archived in the Evaluation Centre, the database of which will be later the part of a distributed knowledge base, from which similar symptoms and their evaluation can be read out by all participants; a further possibility in the future is to elaborate a fetal phonocardiographic expert system in order to help to the doctor making diagnosis in some critical cases,

e) the involvement of an advanced computer at the Evaluation Centre and on such a way the application of a sophisticated signal processing procedure makes possible the extensions of the examinations of cardiac anomalies; usually these can not be detected by the traditional CTG test and so it offers a new diagnostic tool for early screening of some fetal heart irregularities, as the split-effect, the different types of cardiac murmurs, the extrasystole and the different types of arrhythmias and, in addition, the detection of the fetal breathing periods;

The home monitor unit

The home monitor serves for the receiving and preprocessing of the acoustic signal of the fetal heart activity detected on the maternal abdomen by the special acoustic sensor. The second sensor delivers the Toco signal of the uterine contractions. Similarly to the traditional ultrasound CTG measurements, the home monitor provides the usual fetal heart rate (FHR) diagram and the Toco curve of the prescribed 20-minute test. However, as shown on section 6., the special features of the system allow extending the field of cardiac examinations beyond the traditional ultrasound CTG test.

The home monitor with its two sensors is shown on the next figure. The device itself contains a display, a pushbuttons for easy use of the instrument, and a loudspeaker to make audible the received fetal heart sound in order to help in the right placement of the acoustic sensor on the maternal abdomen.



On the left side of the instrument one can see the multifunction electrical connection, which couples the sensors to the instrument during the test, on the other hand, it connects the power supply from the main electric net by the battery charger during the data transmitting period. Because of this unique feature the electric net is absolutely disconnected from the pregnant woman during the test, using only a battery for this operation. However, during the transfer of data to the mobile phone network, which requires much higher power than the former period, the battery charger provides the necessary energy through the same slot. Thus the two cycles of the operation are physically separated and the electric shock of the pregnant women is impossible.

A second advantage of this method is to prevent the fetus from radiofrequency irradiation during the data transfer excited by the mobile phone equipment. This is assured by the fact that the equipment does not allow data transfer until the sensors are connected to it. According to this, the mother should first carry out the measurement placing the sensors on her abdomen, and after the test removing the sensors connects the battery charger to the same slot and going to some meter distance diminishes the irradiation. After some seconds connecting the charger the data transfer begins automatically transmitting all measured data in compressed form to the Evaluation Centre, including patient's data, date of measurements, etc.

The operational modes can be selected from the Main Menu with switches on the left side. These modes are the Measurement, Data transfer, Get answer from center, Last answer and Demo. In the mode Measurement happens the receiving and recording of the fetal data, during Data transfer they will be transmitted to the Evaluation Centre, while the mode Get answer from center reads out the answer sent back, finally, the Last answer enables to check the preceding message. Selecting the Demo mode one can hear a prepared fetal heart sound in order to help what to search with the sensor on the maternal abdomen.

The data transmitted by the mobile network and the Internet will be processed by the Evaluation Centre, where at present time the parameters of the traditional CTG test, namely the FHR diagram, the baseline, the short-term variability, the number of accelerations and decelerations, the critical timings between decelerations and contractions, and finally, the Fisher-score will be calculated. For future capabilities see point 6.

The CE marking for the home monitor, which indicates the compliance with the Medical Device Directive 93/42/EEC is available.

Measurement and data transfer

The measurement starts with the placing of the sensors on the maternal abdomen. Connecting the plug of the sensors into the connection of the device, the two sensors should be placed on the abdomen using the holding belts.

First the Toco sensor should be placed on the upper side of the maternal abdomen (to the umbilicus), fastening the belt until the Toco value on the display moves out from its starting position.

As the second step the acoustic sensor will be placed on the abdomen, possibly on that place, where the mother feels the position of her baby, and then fasten it with the second belt. The sensitivity of the receiving depends on the tightness of the belt: weakness of the belt decreases the intensity of the recorded signal. One can put on the sensors in sitting position as shown on the picture above.



The next step is to search the optimum position of the acoustic sensor, in order to get the maximum level of received fetal heart sounds. This is the most important process, because

the results of the measurement depend highly on the high-intensity, noise-free recorded sound signal. Therefore it is recommended to lie down on your back or sit in a comfortable position as shown on the picture below.



Having an adequate position the sensor should be slid slowly and carefully in one direction (up or down, right or left) and listen whether the characteristic heart signal of the fetus can be heard well. During this the sensor should be always released. Finding a right position where the fetal heart sound is well audible, the measurement can be optimized with small adjustments of the sensor.

If the fetal heart signal can be heard clearly, then the measurement can start, and thereupon the clock on the display begins to show the elapsed time. Try to lie or sit still during the whole measuring time and avoid talking loud, because strong external voices can disturb the measurement. The process lasts conventionally 20 minutes. One can watch the display putting it to a table close to the mother, but any movement during measurement should be moderated.



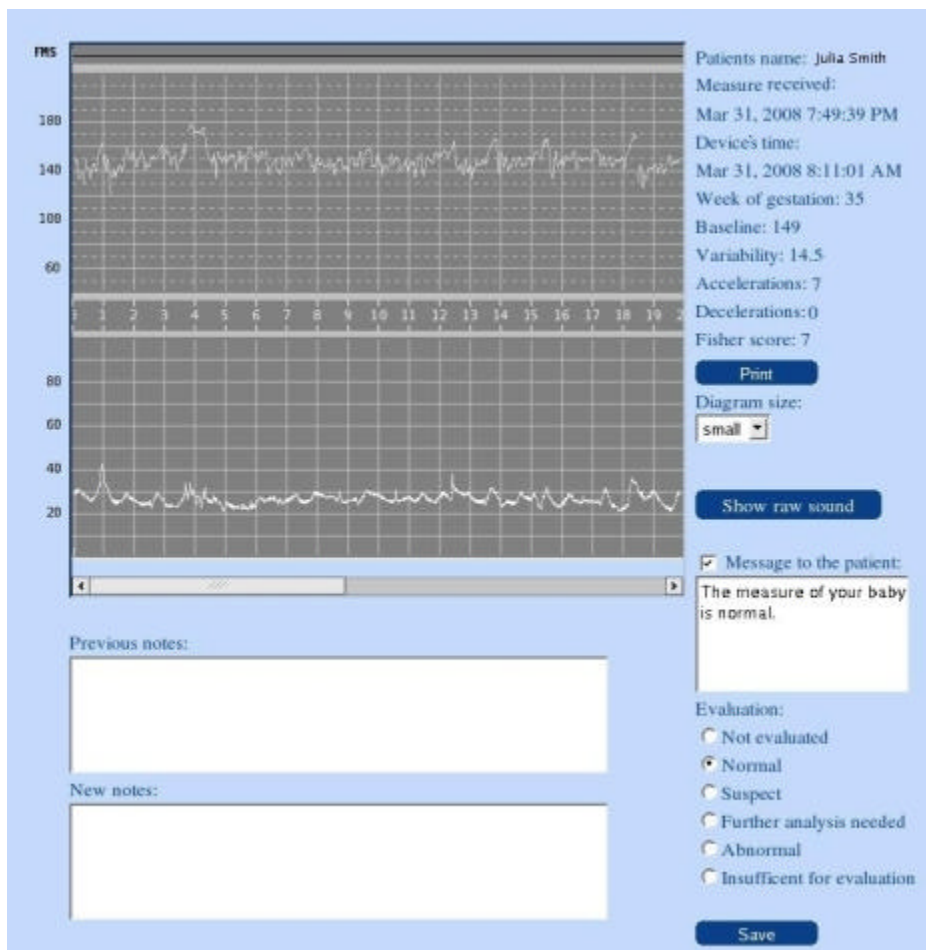
The measured data will be transmitted by choosing this option from the Main Menu. Data transfer can be carried out only by the device connected to the attached charger unit plugged in the mains. While starting the data transfer Send data can be read on the display. Connection to the mobile phone network occurs automatically in a couple of minutes. By successful connection the device shows the amount of data waiting for sending. After finishing the data transfer the Data transfer successful message can be read on the display. The system acknowledges the receipt of the data sent by the home monitor. Preparing for read the answer from the Evaluation Centre begins by choosing the Receiving answer

option. Now the device connects automatically to the mobile phone network once again and downloads the message. If the evaluation is carried out, the most important results will be shown.

Evaluation of measured data

The data measured by the home monitor device on the maternal abdomen will be transferred through the mobile phone network and the Internet to the Evaluation Centre, where it is processed and the computed results are taken on the Internet. The measured data as well as the computed features can be accessed on the Internet only by authorized doctor(s) who accomplishes the diagnosis. Usually the patient insists on the evaluation and diagnosis of her own medical attendant. That means that only her doctor has access to his patient's data. However, the effectiveness of the system may be significantly enhanced if the evaluations are carried out also by a dedicated evaluating team of doctors.

The doctor entering the system with his password can observe the measurements, which have been sent for evaluation. To select the measurement to be observed he can use filters according to the patient's name, the date of measurements, etc.



Selecting the received results of his patient the display below appears. It contains the traditional FHR and Toco diagrams, and a set of features calculated from the measurement. The N/A means that no usable value is available now. The sign "Not evaluated" is obviously. There is a list of evaluation results as the selected assessments (Normal/Suspect/Abnormal) to be marked according to the fetal well-being, or to the

validity of the measurement (Further analysis needed/Insufficient for evaluation). A further field contains the previous notes according to the earlier evaluations, another field for the new (actual) notes. Finally, a field serves for message to be sent to the patient. Windows are applied for instruction to enlarge the display size, and to the print and save commands.

Using the measured FHR diagram the Evaluation Centre automatically computes the following features of the heart activity as the Baseline, the Short Time Variability, the number of Accelerations and Decelerations and, finally, the Fisher score.

After evaluation the doctor marks one of the selected assessments or in a given case the invalidity of the measurement. Then he will fulfill the notes as well as the message to the patient, which will be sent automatically to the patient's home monitor display.

The administration of the home monitors coupled to the system contains the following steps of the doctor: a) login to the evaluation centre, b) registering a new patient filling her name and the required data of the actual home monitor, c) releasing the patient with her home monitor if the pregnancy is finished, d) coupling the monitor with a new patient.

The Home Monitor is claimed by the patent "Method and apparatus for measuring fetal heart rate and an electroacoustic sensor for receiving of fetal heart sounds, US. Patent No. 6.245.025, June 12, 2001" The results of the system have been published in many scientific journals and presented also on many biomedical engineering conferences all over the world.

Working systems and possibilities to test the system as further applicant

In order to get more experiences about the operation of the system, some experimental telemedicine home monitoring systems have been installed. Among these are the - system with 30 home monitors for the ambulant patients of the Obstetrics Ward on the State Health Centre in Hungary,

- a system mainly for research at the Obstetrics No. II. of the Semmelweis University, Budapest, and at the Gottsegen Gy. Hungarian State Institute of Cardiology,
- a small experimental system at the telemedicine firm Evatec, Nürnberg, Germany,
- a further small system for comparison of measured data at the University Frederico II., Neapel, Italy,
- an experimental system at the telemedicine firm Vitalsys, Bruxelles, Belgium,
- further telemonitoring measurements installed mainly as demonstrations at marketing firms in New York and Tokyo, and at the St. Joseph's Hospital, Toronto.

Further details about the system including technical and financial conditions can be obtained through e-mail at home.monitor@pentavox.hu. Here you can make clear in which number of home monitors you are interested, furthermore, whether a separated system would be built up with its own Evaluation Centre or as the first step you will join in an existing one, in order to get experiences about the advantages of the system. If you are a serious future applicant, then PentaVox Ltd. is ready to lend you home monitors for a short time in order to help you to become acquainted with the system and its advantages.

Extensions of the detection of further cardiac anomalies

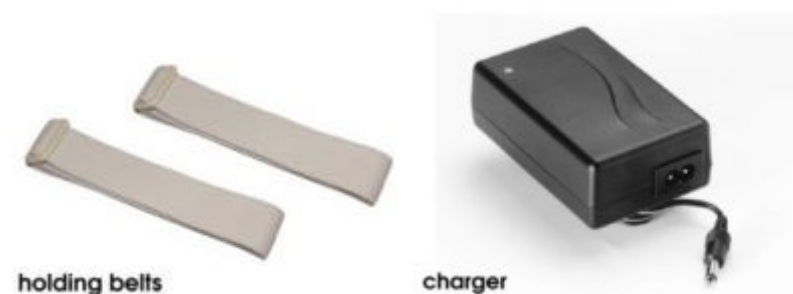
The analysis of the fetal heart sound time function enables to examine further cardiac symptoms with which the system will be shortly completed; these are the incidence of

extrasystole. the arrhythmia and its characteristics including tachycardia, bradycardia, bigeminal/trigeminal arrhythmia, the split effect caused by the time difference between the closure of the two heart valves, which may be a possible symptom of pulmonary arterial stenosis. recognition and identification of different types of cardiac murmurs caused by some congenital heart diseases. recognition of fetal breathing periods and the estimation of its incidence.

It should be pointed out, that most of the symptoms mentioned above remain totally unrevealed using the traditional CTG test.

Accessories

The system contains holding belts for the sensors as standard accessories, and a charger for the internal battery of the home monitor device.



Technical data

Operation

Technique: Phonocardiographic fetal heartbeat detection

Heartbeat counting rate: 60-200 bpm, artifact elimination: ± 15 bpm artifact rejection,

Leakage current: complies with IEC 601.1 and/or IEC 601.1.1 harmonized international settings

Display: 128 x 64 point-matrix 16 grayscale

Sensor sensitivity: manually controlled

Audible sound output: max. 1 W

Output voltage of the charger: 9 VDC, max. 3A

Instrument box: L x W x H: 29 cm x 20 cm x 7.4 cm

Weight: 2.5 kg approx.

Acoustic sensor

Sensitivity: 1.5mV/N/m²

Leakage current: complies with IEC 601.1 and/or IEC 601.1.1 harmonized international standards

Size: D x H: 8 cm x 4.5 cm

Weight: 0.3 kg approx.

Toco transducer

Range: 10-300 gr in 0-100 relative units

Resolution: 1 relative units

Bandwidth: dc to 0.5 Hz

Zero Set Temperature Drift: < 0.1 mmHg/ C (0.013 kPa/ C), excluding transducer,

Leakage Current: Complies with IEC 601.1 and/or IEC 601.1.1 harmonized international standards

Size: Diam x H: 8 cm x 4.5 cm

Weight: 0.1 kg approx.

Power Requirements

Nominal line voltage: 100-240 VAC max 0.9 A

Line frequency: 50/60 Hz,

Environmentals

Ambient temperature operating: 10 C to 40 C, storage: -10 C to 55 C

Relative humidity operating: 10% to 75%, non-condensing, storage: 10%-90%, non-condensing

Certification

CE marking indicating compliance with the Medical Device Directive 93/42/EEC

You also find a video for the application here: : <http://www.youtube.com/watch?v=U5zPT3TWJVI>

We hope to have aroused your interest. Please, in case of questions consult us :

Company EMG Germany

Owner : Mr. J. Kunde

Strasse 6 Nr. 99

D-13059 Berlin

Tel.: 0049 30 9823824

Fax.: 0049 30 98694556

Internet : www.EMG-Berlin.de or www.SCIO-Europa.de

e.Mail : info@perth-berlin.de