

# Original Research

一种新的，基于心音描记术的胎儿家庭遥测监测系统

## A New, Phonocardiography-Based Telemetric Fetal Home Monitoring System

这篇文章的目的是描述一种新的，基于心音描记术的胎儿远程监测系统，由于它的被动性质，允许长期测量，甚至在孕妇的家里。该系统的输入元件是带有两个传感器的家庭监视器，用于记录经腹胎儿心脏信号和子宫收缩。记录的信号通过移动网络和互联网传输到评估中心，在那里进行详细分析，以获得可能的胎儿心脏功能障碍的信息。对该系统的研究表明，与传统的超声心动图程序相比，通过对记录信号的高级处理，该系统捕获了许多额外的心脏特征。

关键词:远程医疗，心血管疾病，家庭健康监测

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### Abstract

The purpose of this article is to describe a new, phonocardiography-based fetal telemonitoring system, which, due to its passive nature, allows long-term measurements even at the home of the pregnant woman. The input element of the system was the home monitor with two sensors for recording the trans-abdominal fetal heart signal and the uterine contractions. The recorded signal was transmitted by mobile network and Internet to an Evaluation Center, where it was analyzed in detail to obtain information about possible dysfunction of the fetal heart. The investigations on this system made clear that by advanced processing of the recorded signal the system captured many additional cardiac features compared with the traditional ultrasound-based cardiotocographic procedure.

**Key words:** telemedicine, cardiology/cardiovascular disease, home health monitoring

### Introduction

The continuous surveillance of the fetus is of primary importance even in low-risk pregnancy if long-term examination can be carried out simply at the mother's home using a telemonitoring system. The main parameters to be measured are defined by standard cardiotocography (CTG). However, the ability to create a reliable and safe noninvasive fetal telemonitoring system has been challenging. A review of the possible noninvasive methods for this purpose was conducted by Peters et al.<sup>1</sup>

The first system based on computerized fetal tele-CTG, where the remotely recorded ultrasound CTG data were transferred to a center for display and analysis, was announced by DiLieto et al.,<sup>2</sup> showing that telemedicine could enable the decentralization of fetal surveillance. The evaluation of hospitalization costs has shown that the use of a telemedicine system for prenatal monitoring is beneficial.<sup>3</sup> Another fetal monitoring system, using ultrasound CTG, used a neural network for the evaluation of the data.<sup>4</sup>

The telemonitoring was also found very beneficial even if its suitability for emergency consultations was questionable.<sup>5</sup> The same conclusion applied to small district hospitals.<sup>6</sup>

In a new development where the CTG data are transmitted to and analyzed in a data center, this center provides a medical report classifying the case as reassuring, nonreassuring, or pathological, available via fax or e-mail in a few minutes.<sup>7</sup>

The costs of fetal telemonitoring applied by district hospitals were calculated, including the costs of an occasional echocardiographic examination in a center, compared this cost to the traditional, fully centralized screening investigations. The calculation showed that in a case of a prolonged assessment the use of a telemedicine system is preferable.<sup>8</sup> A system for warning of acute fetal heart decompensation was proposed by Scherr et al.<sup>9</sup> In contrast to the former ultrasound CTG methods, an electrocardiographic (ECG)-based home monitoring system was described by Crowe et al.<sup>10</sup>

The first fetal telemonitoring system applying the new, phonocardiographic (PCG)-based method was described in the referenced article<sup>11</sup> complete with a study of its cost effectiveness. Previous research has demonstrated that phonocardiography is a fully reliable method for CTG measurements in the third trimester of pregnancy and, in addition, it is very suitable for the use in telemedicine systems.

### Methods

A home-based fetal telemonitoring system must meet the following requirements: (1) home measurement without assistance, (2) long-term and repeated measurements, (3) indication of additional cardiac features, (4) simultaneous ECG measurement, (5) cost effectiveness, and (6) storage of data in a centralized database.

The repeated measurements may be effective in the prevention of a significant portion of intrauterine deaths since about 90% of cerebral or neurological disabilities caused *in utero* happen in the weeks before delivery. Further, the analysis of spontaneous contraction activity of the uterus in a longer period can be useful in the prediction of preterm labor as well. Finally, the possibility of simultaneous abdominal ECG measurements can widen the information obtained about heart activity.

### Why Phonocardiography?

The PCG for fetal monitoring is a rather new method providing the same CTG data as the current generally used ultrasound Doppler method. However, the 20-min CTG test carried out with the Doppler method produces only a snapshot from the fetal status, which may change significantly even in the near term, sometimes with notable different parameters. Further, the principle of this method does not allow prolonged or continuous measurements, which sometimes may be necessary to fully evaluate fetal well-being.

基于家庭的胎儿远程监护系统必须满足以下要求:(1)无辅助的家庭测量,(2)长期和重复测量,(3)附加心脏特征的指示,(4)同时心电测量,(5)成本效益,(6)数据存储于中央数据库。重复测量可以有效预防相当一部分宫内死亡,因为约90%的宫内大脑或神经功能障碍发生在分娩前几周。此外,对子宫长期自发收缩活动的分析也可用于预测早产。最后,腹部心电图同时测量的可能性可以扩大获得的心脏活动信息。

PCG胎儿监护是一种较新的方法，与目前常用的超声多普勒法具有相同的CTG数据。然而，多普勒法进行的20分钟CTG试验只能得到胎儿状态的一个快照，即使在近期也可能有明显的变化，有时参数有明显的不同。此外，这种方法的原则不允许延长或连续的测量，有时可能是必要的，以充分评估胎儿的健康。

The ECG method also provides an alternative possibility to carry out home measurements using a portable telemedicine system. However, the electrical leads placed on the pregnant woman are rather inconvenient and the features obtained from the measurements are restricted compared to the PCG.

On the basis of >15 years' experience it seems that the PCG fetal telemonitoring system solves all these problems, fulfilling all requirements of the fetal safety too. Consequently, the fetal PCG was chosen for the new telemedicine system as the most suitable method for this purpose, having the capability to indicate or even measure some additional cardiac features of the fetus principally not captured by other methods.

The telemonitoring system consists of two main parts. One of them is the home monitor with two sensors to record the fetal heart signal on the maternal abdomen and uterine contraction (Fig. 1). The second part is the system itself consisting of the mobile phone network and the Internet as transmitting elements and the Evaluation Center.<sup>12</sup>

The measurement is carried out by the home monitor at the mother's home without assistance, while processing and evaluation of the data occur at the Evaluation Center. Using the telemetric system the measurements are not time bound and not specified by the hospital. The direct contact between the pregnant woman and the Evaluation Center enables the obstetrician to ask her to carry out a measurement or, if the former record was unusable, to repeat it. If the evaluation was successful then the measurement will be acknowledged. The obstetrician can also read out former records from the home monitor at any time. Additional measurements can also be made to recognize the possibility of premature birth or needless caesarian interventions.

The Evaluation Center can alarm the patient's medical attendant if critical data have been observed. In this case, the Center can also transmit these data to the clinician's mobile phone displaying the critical data with the related segment of the record or even the whole sound record.

The home monitor receives the sound signal as well as the pressure signal of the uterine contraction from the maternal abdomen. The monitor contains a modem to transmit data to the mobile phone

network in the digital form, which forward it through the Internet to the Evaluation Center.

The main steps carried out by the home monitor are shown in Figure 2. It is important that the first block operates by battery. Then, during the transmission when the supply network is used, the mother is disconnected from radiofrequency exposure.

The monitor does not display the resulting data for the mother; only recognition for the Center and the evaluation are reported. A repeated measurement will be requested if the former one was not evaluable.

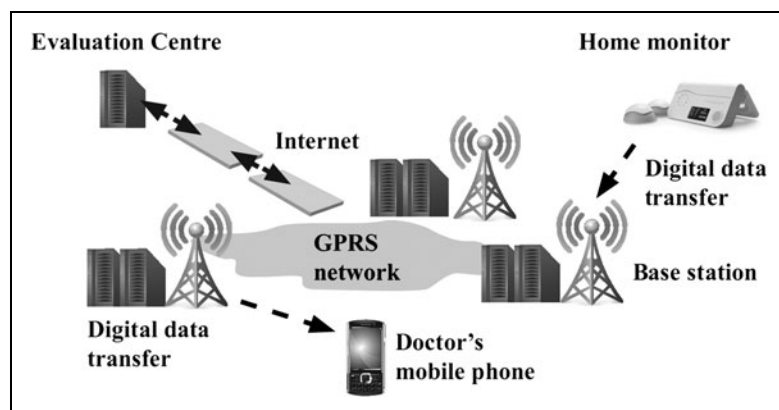
The fetal home monitoring system measures all parameters involved into the traditional CTG test. That means, from the point of view of the traditional CTG parameters, it is a total equivalent of the existing ultrasound Doppler method. The accuracy of the measured parameters has been verified many times and in many institutions.

The measured data are processed and evaluated at the Evaluation Center and the results are summarized in the final report, which will be displayed on an authorized Web site holding the traditional CTG data, including

- personal data as the mothers name, weight, weeks of gestation, pulse rate, possible risk, doctor's name, date, and place of measurement;
- fetal heart rate (FHR), baseline, typical short-term variability, the percentage of identified beats summed on the whole record, Fisher score, and the Toco diagram;
- the number of accelerations and decelerations, including their height and average time duration, and the delay to intrauterine contraction; and
- the different types of heart rhythm irregularities as extrasystole, tachycardia, bradycardia, general arrhythmia, and the bigeminal pulse rate.

Table 1 summarizes additional cardiac features about which the telemedicine system can provide some information. As one can see, the reliability of the measurement is quite different, which shows that some of these may only be used as an indication, so the exact diagnosis has to be made by a further examination, mostly with the ultrasound echocardiography.

Intrauterine growth restriction (IUGR) is one of the most insidious fetal conditions of the third trimester and early detection is important. The problem with this is that the discovery of an incipient restriction is very difficult. Research works dealing with this problem revealed that the distribution of the frequency spectrum of the heart rates provides information about the fetal status, including an existing IUGR.<sup>13</sup> The method requires very accurate heart rate values without artifact effects, and therefore the most suitable quiet states must be selected for the measurement. From the collected data after a sophisticated mathematical analysis, the entropy of the FHR variability can be derived containing information for the existence of the IUGR. Obviously, the early discovery of this disorder requires the frequent and well-timed measurements of the heart rate completed with the analysis of the obtained data.



**Fig. 1.** The architecture of the mobile phone- and Internet-based telemetric fetal monitor.

心电图法也为使用便携式远程医疗系统进行家庭测量提供了另一种可能性。然而，与PCG相比，将电引线放在孕妇身上是相当不方便的，从测量中获得的特征也受到限制。

根据>15年的经验，PCG胎儿远程监护系统似乎解决了所有这些问题，也满足了胎儿安全的所有要求。因此，新的远程医疗系统选择胎儿PCG作为最适合的方法，它能够显示甚至测量胎儿的一些主要没有被其他方法捕获的额外心脏特征。

远程监控系统主要由两部分组成。其中一个家庭监护仪，由两个传感器记录孕妇腹部的胎心信号和子宫收缩(图1)。第二部分是系统本身，由手机网络和互联网作为发射元件和评估中心组成

测量由母亲家中的家庭监测仪进行，无需协助，而数据的处理和评估则在评估中心进行。使用遥测系统的测量不受时间限制，也不受医院的规定。孕妇与评估中心之间的直接联系使产科医生可以要求她进行测量，或者，如果以前的记录无效，可以重复测量。如果评估是成功的，那么测量将被承认。产科医生还可以随时从家庭监控器上读出以前的记录。还可以进行额外的测量，以确认早产的可能性或不必要的剖腹产干预。

如果观察到关键数据，评估中心可以向患者的医护人员发出警报。在这种情况下，中心还可以将这些数据传输到临床医生的手机上，显示关键数据和相关的记录片段，甚至是整个声音记录。

家庭监护仪接收来自母亲腹部的声音信号和子宫收缩的压力信号。该监视器包含一个调制解调器，以数字形式将数据传输到移动电话网络，再通过互联网将数据转发到评估中心。主监视器执行的主要步骤如图2所示。重要的是，第一个模块是由电池操作的。然后，在传输过程中，当供电网络被使用时，母亲断开射频暴露。监视器不显示母亲的结果数据;只报告对中心的认可和评估。如果前一个不能评估，将要求重复测量。

胎儿家庭监测系统可以测量传统CTG试验中涉及的所有参数。也就是说，从传统的CTG参数来看，它完全等同于现有的超声多普勒方法。测量参数的准确性已在许多机构多次得到验证。测量数据在评估中心进行处理和评估，并在最终报告中总结结果，该报告将在一个持有传统CTG数据的授权网站上显示，包括

母亲姓名、体重、孕周、脉搏、可能的风险、医生姓名、日期、测量地点等个人资料;

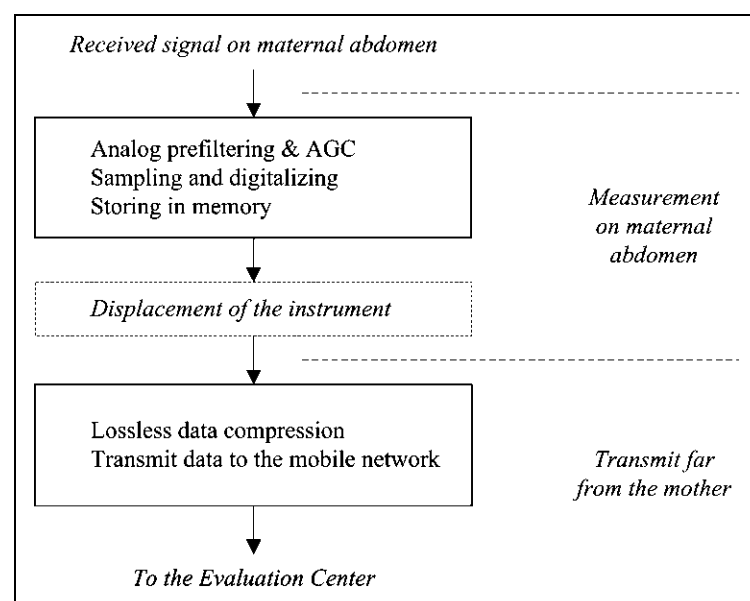
胎儿心率(FHR)，基线，典型短期变异性，在整个记录、Fisher评分和Toco图上确定的心跳百分比总和;

加速和减速的次数，包括它们的高度和平均持续时间，以及宫内收缩的延迟时间;

还有，不同类型的心律失常比如早搏，心动过速，心动过缓，普通心律失常，还有双室脉搏。

表1总结了远程医疗系统可以提供的其他心脏特征。可以看出，测量的可靠性是有很大差异的，这表明有些测量可能只是作为一种指征，所以准确的诊断需要进一步的检查，主要是超声心动图。宫内生长受限(IUGR)是妊娠晚期最隐匿的胎儿状况之一，早期发现非常重要。这样做的问题是发现初期的限制是非常困难的。处理这一问题的研究工作表明，心率频谱的分布提供了胎儿状态的信息，包括现有的iugr。13该方法需要非常准确的心率值，没有人为影响。因此，必须选择最适合的静态进行测量。从收集的数据经过复杂的数学分析，FHR变异性的熵可以得到包含IUGR存在的信息。显然，这种疾病的早期发现需要频繁和适时地测量心率，并对获得的数据进行分析。

呼吸通常是胎儿监护中被忽略的一个特征，主要是因为很难捕捉到这种间歇性的发生。呼吸周期的检测是通过分析心率的低频成分来实现的。这种检查只能通过长期的测量来证实。探索的另一个问题是，胎儿或母亲的其他动作可能产生频率相似的声音信号，因此区分呼吸相当困难。根据实验，一般情况下，0.7-1.2 Hz的频谱成分是胎儿呼吸运动的特征。传输到评估中心的记录由一个复杂的评估程序处理，该程序涉及几个数学算法，并对记录进行多次搜索，以表明心脏活动的所有可能特征。在搜寻过程中，所有对特征的判断可能不准确的干扰时段都会从记录中删除。为了提高系统的可靠性，该程序采用了不同频率滤波和解析建模的方法对复合声音信号进行分析。统计方法也应用于评估，以确定获得的参数的置信度。



**Fig. 2.** The main steps of the home monitoring.

Off-line signal processing makes it possible to identify fetuses whose low-frequency band of the heart rate frequency spectrum deviates from the normal. According to researches on this field, the ratio of certain sub-bands of the heart rate frequency spectrum indicates deficiency in the development of the autonomous nervous system.<sup>14,15</sup> As in the former section, the calculation requires the very accurate values of the heart rate and because of this the most suitable quiet fetal states must be selected.

One of the unique features of the PCG telemedicine system is the capability to discover cardiac murmurs caused by the turbulence of blood flow and producing thereby an additional sound signal.<sup>16</sup> The examinations accomplish a widespread screening process providing a help in the postnatal therapy or even at an urgent neonatal intervention.<sup>17</sup>

The most frequent causes of the heart murmur are aortic stenosis, congenital septal defect, and the different types of valve abnormalities.

The time-frequency map of a typical murmur in the systolic period is illustrated in Figure 3, where the low-frequency elevation between the two sharp peaks of the valve closures indicates the murmur.

**Table 1. Additional Fetal Cardiac Features with the Reliability of the Measured Data**

NO.	CARDIAC FEATURE	RELIABILITY
1.	Intrauterine growth restriction	Highly probable
2.	Defect of development of nervous system	Highly probable
3.	Heart murmur	High
4.	Fetal breathing	Accidental

Breathing is generally a neglected feature of fetal monitoring mainly because it is difficult to capture this intermittent occurrence. The detection of the breathing cycles happens by the analysis of the low-frequency components of the heart rate.<sup>13</sup> The examination can be verified only with long-term measurements. A further problem for the exploration is that other fetal or maternal movements may produce sound signals with a similar frequency spectrum, and therefore the distinction of breathing is rather difficult. According to the experiments, in general, the 0.7–1.2 Hz components of the frequency spectrum are characteristic for the fetal breathing movement.

The records transmitted to the Evaluation Center are processed with a complex evaluation program involving several mathematical algorithms and applying a multiple search along the records to indicate all possible features of the cardiac activity. During the search, all disturbed time periods where the determination of the features may be inaccurate are removed from the record. To enhance the reliability the program uses different frequency filtering and analytical modeling for the analysis of the composite sound signal. Statistical methods are also applied at the evaluation to determine the confidence of the obtained parameters.

The results are summarized in the form of diagrams and numerical values to make the diagnosis for the physician easy.

The sound record as well as all results of the evaluation will be archived, taking into account the prescriptions for personal data security. The data are collected in a knowledge base in an appropriate form for the expert system to be developed.

The final protocol displayed on the screen contains all measured parameters of the fetal cardiac activity, including the actual values as well as the changes compared to the former examination. It involves a list of the traditional CTG data as well as the additional features provided by the PCG telemonitoring method. However, it does not contain data according to the evaluation of >100 well-known pathological or suspect formation of the FHR diagram. The protocol contains

- data of the traditional CTG test as listed above,
- characteristic parameters according to the possible IUGR and the problems of nervous system development,
- parameters of an accidental heart murmur with its position, volume, duration, dominant frequency, frequency spectrum, and waveform, and
- time and length of indicated breathing periods.

All these data are accessible only by authorized person.

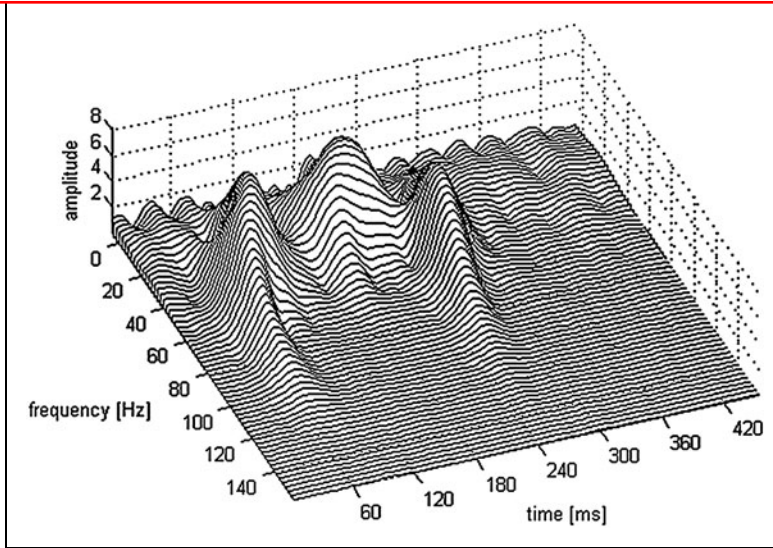
To enhance the safety of the fetus, the system gives additional warning signals on the screen if an extremity has been found according to some critical parameters as the abnormal value of FHR baseline or deep decelerations. The electronic storage of the measured and evaluated signals in the Evaluation Center forms a knowledge base, suggesting the development of a unique fetal cardiac expert system.

Data transferred to the Evaluation Center are analyzed by the complex evaluation program, utilizing statistical routines. As a



## PHONOCARDIOGRAPHY-BASED FETAL HOME MONITORING SYSTEM

已经证明,新的PCG胎儿远程监测系统由于其被动的性质,可以在家中进行长期的CTG测量,此外,比最近使用的CTG测试的快照式附带测试提供更可靠的胎儿数据。频繁甚至连续的胎儿测量使监测IUGR和偶尔出现的神经系统发育问题成为可能。对测量到的声音信号进行深入处理,可以发现心脏杂音,从而建立广泛的产前先天性心脏病筛查,即使对跳过以前所有检查的儿童也是如此。长期测量可以指示胎儿呼吸周期。对测量数据的集中处理,为建立一个非常大的知识库,开始开发一个独特的胎儿PCG专家系统,以可靠地识别先天性心脏病开辟了道路。



**Fig. 3.** Time-frequency map of a heart sound signal with a murmur in the systolic period due to ventricular septal defect.

室间隔缺损导致收缩期杂音的心音信号时频图。

result, a prognosis will be available for the doctor in connection with a given symptom, helping the diagnosis by answering the question, whether, based upon the indicated symptom, it can be supposed that (a) the given cardiac anomaly is present; (b) it is suspect; or (c) the symptom itself is present, but there is no unambiguous relation between the symptom and any typical cardiac anomaly.

### Results

The fetal telemonitoring system detailed above has been produced consisting of >100 home monitors and all are used regularly at different clinics and hospitals in Hungary and in Italy.

In the last 3 years, 115 pregnant women have been examined at home with the system and 323 tests carried out. The age of the gestation was between the 28th and 38th week. The duration of the measurement was normally 20 min, in some cases extended to 40–60 min. Further, 50 measurements have been made in the Gottsegen Gy. National Institute of Cardiology complemented with echocardiographic examination to find correlation between the discovered cardiac murmurs and the diagnosed congenital heart diseases. Measurements were also carried out on the University Federico II in Naples, and tests have been carried out in Japan, Germany, Belgium, Canada, and the United States.

Thanks to the large number of tests, despite their rarity some critical rhythm irregularities have been identified as significant extrasystoles and tachycardia. Further, some spontaneous contraction activity of the uterus in a longer period has been effective in the prediction of preterm labor as well.

Regarding the IUGR and the development of the nervous system, until now no examinations have been carried out because of the lack of such patients.

According to the heart murmur recognized by echocardiographic examinations made on the high-risk population in the cooperating

institute, it was possible to test more pregnant women with fetal heart murmur. During this study, 23 fetuses with murmurs were identified and 52 fetuses were found with abnormal delays of the tricuspid valve closure sound.

Fetal breathing was measured in three pregnant women from whom two cases of very short breathing cycle have been identified.

Preliminary calculations have shown that the cost of the prescribed CTG measurements applied with the telemedicine system at home is significantly lower than the traditional CTG test carried out in the hospital.

### Conclusions

It has been demonstrated that the new PCG fetal telemonitoring system due to its passive nature enables long-term CTG measurements even at home and, in addition, provides more reliable data about the fetus than the snapshot-like incidental tests of the recently used CTG test.

The frequent or even continuous measurement of the fetus makes possible the surveillance of IUGR and the occasional problems of nervous system development.

The intensive processing of the measured sound signal enables the discovery of heart murmurs, establishing thus a widespread prenatal screening of congenital heart diseases, even for children who bypassed all former examinations. The long-term measurements enable the indication of the cycles of fetal breathing. The central handling of measured data opens the way to build up a very large knowledge base to start develop a unique fetal PCG expert system for reliable identification of congenital heart diseases.

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### Disclosure Statement

No competing financial interests exist.

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