Adapting new bedside instrumentation for computer-aided fetal monitoring using efficient tools for system reconfiguration

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Abstract: - Incorporating of the new pulse oximetry feature into computer-aided fetal monitoring system requires a lot of modifications in hardware and software structure of the system. Since these modifications are fairly time-consuming, such a solution would be impracticable during preliminary testing and evaluation phases of new medical instrument. Therefore, at first we decided to build a prototype system using efficient tools for system reconfiguration. The prototype system is based on battery-powered notebook computer and its software has been developed in LabView graphic applications environment. Application of fast configurable environment made possible the investigation of the pulse oximeter ability to cooperate with various types of fetal monitors, as well as the implementation of validation procedure for measurements carried out the pulse oximeter. Positive results obtained in our experiments performed in clinics have enabled to incorporating this new measurement method to our computer-aided fetal monitoring system.

Key-Words: - fetal monitoring, pulse oximetry, computer-aided system, LabView application, instrumentation

1 Introduction

Biophysical monitoring of fetus is usually performed by means of cardiotocography (CTG), which consists in simultaneous recording of fetal heart rate (FHR) signal and uterine contraction (UC) activity. These signals, together with fetal movement activity information are recorded by bedside monitors and provided in a form of cardiototocographic trace. The cardiotocogram is visually assessed by a clinician. Visual evaluation is rather difficult and it is characterized by the high degree of interobserver and intraobserver variability, which can lead to erroneous interpretation. Objectivity and reproducibility of results can be increased by using a computerized monitoring system with automated analysis of CTG traces. Results of this analysis are dynamically presented in numerical and graphical forms on a screen or printed as monitoring reports [1]. This additional information helps a clinician to diagnose a fetal condition.

However, very often the decisions taken on the basis of cardiotocogram only, were proved to be inappropriate; the fetal outcome was good, although in cardiotocographic record the suspicious patterns have occurred. Noninvasive measurement of oxygen saturation of fetal blood (SpO₂) is a valuable supplement to conventional intrapartum cardiotocography in the area of fetal distress diagnostics. Until recently, the intrapartum monitoring of fetal blood oxygenation by means of transcutaneous measurement of oxygen partial pressure or by transmission pulse oximetry has met many technical problems [2, 3]. Only just designing by Nellcor Puritan Bennet the fetal reflectance pulse oximeter N-400 with a soft sensor being applied on selected area of fetal face has made a wider use of pulse oximetry in diagnostics of fetal distress during a labor.

This work focuses on the technical problems that were overcome in incorporation of the new pulse oximetry feature into computer-aided fetal monitoring system.

2 Fetal monitoring system

The tasks of computer-aided fetal monitoring system are: analysis of incoming data, dynamic presentation of traces along with analysis results as well as storing and printing the data. The system provides much more information than conventional fetal monitoring, easy and fast access to archived records and convenient performing of periodic monitoring. The block diagram of the system is presented in Fig. 1.

The fetal monitor output enables fetal heart rate, uterine contractions and fetal movement information to be accessed by a computer. Communication with the computer is bidirectional via RS232/485 serial interface. Several monitors can be connected to the system at the same time. Interface unit assures the
patient’s safety complying with general international standards for medical equipment. It is placed between the fetal monitor and computer. Another issue concerning this unit is the matching of output signals from the monitor to input-output standards of a computer [4]. In biomedical applications, RS232 serial link is chosen usually for its simplicity and common availability, however earlier models can be equipped with CMOS/TTL output. Monitors with analog outputs must be fitted with an interface circuit having analog-to-digital (A/D) conversion. In practical application, every model of fetal monitor needs its own dedicated interface unit. We have developed microcontroller-based unit, which contains several modules [Fig. 2]. Some of the modules are optional. Their application in the unit depends on the type of monitor a connected.

The interface unit collects CTG data from a fetal monitor according to data transmission protocol associated with particular monitor type. Leading manufacturers usually provide their own communication protocols. Information from Hewlett-Packard’s fetal monitors is sent with the speed of 1200 baud within data blocks surrounded by the block-start and block-end markers. The data block contains four sets of values each containing FHR and UC samples, fetal movement profile, and two statuses. Monitor sends these data blocks in one-second intervals so the sampling frequency of signals is 4 Hz. The checksum appended to the data block is used to detect transmission errors. The system controls the monitor by issuing the commands: start or stop of transmission. Fetal movements are identified in two ways: by a patient-activated event marker or automatically by using the ultrasound channel i.e. fetal movement profile feature. Every time the event marker button is activated, the message block is transmitted in asynchronous mode. A simple request-answer protocol with software handshaking is applied in Oxford-Sonicaid’s monitors. The baud rate is 9600. Five single-byte requests are issued by the system to get different types of information from the monitor. Transmission starts from the check request repeated till the monitor acknowledgement is reached. The monitor gives the following types of two-byte answers containing: 1 – FHR value, signal quality indicator, and a new heart beat flag (from channel 1 or 2); 2 – UC value and status of transducers; 3 – flag of fetal movements perceived by the mother. The system samples the FHR signal with 4 Hz and the UC signal with 2 Hz. The sampling rate is high enough so as not to miss a beat.

Inside the microcontroller of the interface unit data obtained from every particular fetal monitor is transformed into uniform data blocks established by us. The structure of the data block is based on Hewlett-Packard protocol and contains samples of all signals measured in 1 sec interval. Therefore, from

![Fig. 1 Overview of the structure of the computer-aided fetal monitoring system](image-url)
the computer side, every bedside monitor looks like the same device. Information of the monitor type is included in the data block. Connection of several monitors to one RS232 connector of the computer is enabled by the data collection unit, which multiplexes bedside monitors. Data collection unit is transparent for the data from monitors. Each interface unit with associated fetal monitor is identified by exclusive number. This number is used by the data collection unit, which periodically sends permission for transmission to successive monitors. Data blocks from all monitors are transmitted to computer in 1 sec intervals. The transmission speed is defined by the number of monitors connected and established data block length. Incoming CTG data is dynamically presented on the screen and analysed on-line. The results of quantitative analysis of cardiotocographic trace are presented both in numerical and graphical forms. Received data is stored in a system database. The database includes patient’s personal data, monitoring logs, results of analysis, parameters of alerting events and of course the cardiotocographic traces.

3 New bedside instrumentation

The basis of oximeter operation is a phenomenon of light absorption depending on extinction coefficient for determined wavelengths of light beam. Absorption magnitude is coupled with arterial blood pulsing in a vascular bed. The light reaching a photo detector is converted into electric signal synchronously with fetal pulse wave. As a result, pulse oximeter provides data on oxygen saturation of fetal blood (SpO₂) and optically determined fetal heart rate [5]. The N-400 model is equipped with digital output, which makes possible its application in the computerized fetal monitoring system. Measurement of fetal oxygen saturation should be integrated with CTG recording, since the pulse oximetry is a supplement for the cardiotocography. There is another, very important argument for such integration. Measurement of SpO₂ is reliable only when valid fetal heart rate is simultaneously determined. Much higher quality of FHR signal is provided by a fetal monitor, so it can be considered as a reference signal. Fetal monitor records FHR by using the pulsed wave Doppler method. High quality of FHR measurement has been attained thanks to the digital technique of echo selection exclusively from fetal heart area, keeping track of its displacements as well as the digital filtration extracting the signal components corresponding to movement of valves [6].

Integration of pulse oximetry with cardiotocography in above described system means that pulse oximeter and fetal monitor are linked together into one new medical instrument. This new instrument requires to develop an interface unit with new communication software and it should be equipped with two serial ports. Additionally, connecting any new an instrumentation to the system requires a lot of modifications in its software procedures: acquisition, analysis, visualization and archiving. Since these modifications are fairly time-consuming, such a solution would be impracticable during preliminary testing and evaluation phases concerning a new
medical instrument. Considering our experience gained during adaptation of different models of fetal monitors to computer system at first we decided to build a prototype system using efficient tools for system reconfiguration [7].

4 System reconfiguration
The prototype system is based on battery-powered notebook computer, which eliminates the problem of electrical isolation. Both the fetal monitor and pulse oximeter are attached directly to the computer RS232 connectors. Fetal monitor transmits: FHR values (in a range 50 ÷ 240 bpm with accuracy ± 0.25 bpm), uterine contraction activity (in scale 0 ÷ 100% with accuracy ± 0.5%), information on fetal movements detected automatically by the monitor and perceived by a patient. The pulse oximeter transmits SaO2 values (in scale 0 ÷ 100% with accuracy not lower than 6%) and FHR (in range 30 ÷ 240 bpm with accuracy ± 3 bpm).

The pulse oximeter provides beat-to-beat and conversation communication protocols. In beat-to-beat mode, the device transmits saturation (S) and fetal heart rate (R) data once per every detected heartbeat in the following format: RnnnSnnn<CR><LF>, where nnn are values of heart rate and saturation respectively. In conversation mode the output is a single parameter, sent by request only. For example, the computer requests the current heart rate by sending an “R” command. The device responds with <STX>Rnnn<CR><LF>. Other request codes can concern saturation, signal quality, low saturation alarm limit and monitor status. In prototype system, we have implemented both communication protocols. The conversation protocol has been recognized as a more convenient, since it enables application of the required sampling frequency and much easier synchronization with the fetal monitor.

System software has been developed in LabView graphic applications environment of National Instruments company. Conventional programming systems like C or BASIC use a text-based language to create lines of code, while the LabView application is in a block diagram form created by means of graphical programming language. Developed applications are called virtual instruments (VI), because their appearance and operation imitate physical instruments. Each VI consists of the front panel and accompanying block diagrams. The front panel is an interactive user interface; it can contain knobs, push buttons and other controls. Output data can be presented in textual or graphical forms on the computer screen, using indicators and graphs. The idea of building an application in the LabView environment relies on linking graphical objects representing various instructions and functions into a block diagram [Fig. 3]. The block diagram is nothing else than a source code for VI. There are many libraries of built-in functions and subroutines for most of programming tasks, like data acquisition, data presentation and data storage, as well as the interfaces for acquisition boards. All functions are arranged into groups and can be selected easily and fast throughout the functions palette. It is possible to use conventional programming tools to set breakpoints and animate program execution. These features make debugging and program development much easier. Creating an application with a help of LabView does not require great programming experience.

Graphical programming supported by many ready-to-use functions decreases development time, especially in case of a system for acquisition and analysis of biomedical signals [8].

Fig. 3 Implementation diagram of the pulse oximeter communication procedure
In the main loop of the program, the request to pulse oximeter is sent every 125 ms in the following order: heart rate, saturation, heart rate, monitor status. It means that FHR signal is sampled with 4 Hz and SpO₂ with 2 Hz. Answers are stored in buffers. In case of cooperation with Hewlett-Packard fetal monitor, after receiving the data block from this monitor, the last four FHR samples and the last two SpO₂ samples are read out from buffers. This data is presented in a screen and saved in a file. This ensures the best possible synchronization between two different communication protocols.

Integration with Oxford-Sonicaid fetal monitor is simpler, because this monitor communicates with computer according to conversation protocol, just like pulse oximeter. Difference relies on various formats of the requests and various information contents of the answers. It requires different coding of requests and different decoding of answers for fetal monitor and pulse oximeter. Two requests are sent simultaneously every 125 ms to both devices in the following sequence: FHR requests, SpO₂ and UC requests, FHR requests, monitor status and event marker requests. Fig. 3 shows the procedure of communication with pulse oximeter. These parts of the program, which manage communication with fetal monitors, have been taken from the previous LabView applications, which we have developed for evaluation of various types of fetal monitors.

During monitoring, the verification of measurements of pulse oximeter is carried out. In windows of 10 sec width shifted with 1 sec step the mean value of reference FHR samples acquired from fetal monitor and the mean value of absolute differences between corresponding FHR samples from fetal monitor and pulse oximeter are calculated. Reliability index of SpO₂ signal has been defined as follows:

$$RI = \frac{1}{N} \sum_{i=1}^{N} |FHR_{KTG_i} - FHR_{OXY_i}| \times \frac{1}{N} \sum_{i=1}^{N} FHR_{KTG_i}$$

$$RI = \begin{cases} 
\leq 5\% & \text{correct SpO₂} \\
> 5\% & \text{incorrect SpO₂} 
\end{cases}$$

where:

- \(N\) – number of samples in analysed window, for 10 s wide window and 4 Hz sampling frequency, \(N = 40\)
- \(FHR_{KTG_i}\) – value provided by fetal monitor
- \(FHR_{OXY_i}\) – value provided by pulse oximeter

The window on Fig. 4 shows virtual representation of the bedside monitors connected to a computer. The upper part of the window is assigned to the fetal monitor, and the lower part to pulse oximeter. The components of these representations create the control panel displaying values of parameters measured, other technical information and graphical plots.

![Fig. 4 Virtual representation of the bedside monitors: a screen with acquired biomedical signals](image-url)
The FHR values from fetal monitor and pulse oximeter are displayed in the same window thus making easy to verify the correctness of pulse oximeter measurements. The reliability index of SpO2 evaluated during monitoring is presented as a curve, and its exceeding 5% threshold value is marked by the “Correct” indicator. In case of virtual fetal monitor, the plots are equivalent to printouts from its thermal printer. During recording, there is a possibility of changing the length of segment of visible trace and reviewing the traces back.

5 Results
Application of LabView fast configurable environment made possible the investigation of the pulse oximeter N-400 ability to cooperate with various types of fetal monitors, as well as the implementation of validation procedure for measurements carried out by N-400 monitor. Positive results obtained in our experiments performed in clinics have allowed to incorporate this new measurement method to the computer-aided fetal monitoring system (Fig. 1). The new interface unit equipped with two serial ports has been built. Communication procedures developed in LabView environment have been translated into machine code of microcontroller, which controls the interface unit. Procedure for verifying the correctness of pulse oximeter measurements has been included into signal analysis procedures of the fetal monitoring system, which interprets the reliability index of SpO2. Alerting window is displayed when incorrect SpO2 value is recorded during an established time period. Measurement of fetal blood oxygenation and cardiotocographic trace monitoring create an integrated trace in the system database.

6 Conclusions
Using commercially available components and a notebook computer, it takes a fairly short time to create a prototype system for acquisition and analysis of biomedical signals provided by new instrumentation. Such system allows evaluating a preliminary clinical usability of the signals investigated. The functionality of the computer-based system is determined by its software. Therefore, it is important to choose appropriate tools for the system software development. The tools working in the graphic programming technique, e.g. LabView environment described above, do not require much programming experience. One should note that during investigation stage the system notebook computer with dedicated software played a role of “virtual” interface unit. Due to open-ended structure, the software could be easily extended with the new functions and adjusted to our needs and testing procedures.

References