pregnancy monitoring,
telemonitoring at home,
Medical Cyber Physical System

Krzysztof HOROBA[1], Janusz JEZEWSKI[1], Janusz WROBEL[1], Adam PAWLAK[2], Robert CZABANSKI[2], Piotr PORWIK[3], Piotr PENKALA[4]

DESIGN CHALLENGES FOR HOME TELEMONITORING OF PREGNANCY AS A MEDICAL CYBER-PHYSICAL SYSTEM

The paper introduces the problem of designing a telemedical system for pregnancy monitoring at home. It focuses on design challenges concerning embedded computing and networking, requirements modelling, and presents the architecture and solutions when based on new class Medical Cyber-Physical Systems (MCPS). The proposed system consists of a Body Area Network (BAN) of advanced sensors that are interconnected on a body of a pregnant woman, a Personal Area Network (PAN) that is responsible for embedded processing of physical signals, smart alarms, data transmission and communication with the Surveillance Centre located in hospital. It is expected that this dependable telemedical system will provide a high societal value to women with high-risk pregnancy.

1. INTRODUCTION

Telemedicine is the youngest, and probably the most rapidly growing form of medical services, which combines elements of telecommunications, information technology, automation, electronics and medicine. Breaking geographical barriers, it enables rapid diagnosis, therapy, long-term monitoring and patient care in the comfort of his home, using information transport instead of costly transport of patients or physicians. Among these areas of application of telemedicine, patients monitoring outside of the hospital - telemonitoring is perhaps the most difficult to implement.

Solutions for telemonitoring developed so far are dedicated to selected group of patients, usually for people with cardiac dysfunction or diabetes. Supported medical procedure is usually very simple and limited to instantaneous measurement of single parameter, like blood glucose level, or acquisition of the electrocardiogram using a simple recorder applied to patients chest. There are no mechanisms to assist a patient who, in case of home telemonitoring also becomes the operator – contractor of a medical procedure. Taking into account that the patient is not experienced medical staff, the selected procedure performed within the remote monitoring should be easy to carry out and fully safe for the patient. It is easy to satisfy these requirements

[1] Institute of Medical Technology and Equipment ITAM, Roosevelt Str. 118, 41-800 Zabrze, Poland
[2] Institute of Electronics, Silesian University of Technology, 16 Akademicka Str., 44-100 Gliwice, Poland
[3] Institute of Computer Science, University of Silesia, 39 Bedzinska Str., 41-200 Sosnowiec, Poland
[4] Evatronix S.A., 2 Przybyly Str., 43-300 Bielsko-Biala, Poland

in the case of simple medical procedures, which makes the development of the telemonitoring system itself much easier, but also limits its functionality [10].

An attempt to accomplish at home a more complex patients monitoring technique enforces an application of patients support tool, mainly in searching for the optimal position of the measuring sensor to ensure the best possible quality of recorded signal [14], [15]. Moreover, in the case of long-term monitoring, like in case of pregnancy monitoring session, such support must also comprise a dynamic adaptation to changing measuring conditions. This is especially important when there is no classical mechanism of patient/operator self-control, which results from the fact that the object being monitored i.e. fetus is hidden in other object - mother [18]. Thus false interpretation of the recorded biosignals made by mother herself may lead to her unexpected and unjustified reactions [13], [16]. The problems mentioned above were the reason for a lack of a suitable systems for pregnancy home telemonitoring, although taking into account the nature of health care of pregnant women the demand for such solution is very strong [10].

Demographic transformations, taking decision about become a mother later in life on the one hand and teenage motherhood on the other hand, as well as civilization diseases significantly diverse a group of future mothers [9]. So far continuous medical care requires a hospitalization of pregnant woman even if there is no direct risk for patients health. It results in high cost of longer hospital stay and discomfort for a patient. The optimal solution seems to be a remote fetal monitoring at patients home [8]. Patients with high-risk pregnancy (diabetes problems, intrauterine fetus growth restriction, pregnancy-induced hypertension) as well as with post-term pregnancy are particularly predisposed to cyclic home monitoring sessions for follow-up of the fetal development process [6].

Primary source of diagnostic information on fetal state, which is carried out during cardiotocographic monitoring, is the analysis of changes in fetal heart rhythm, as connected to uterine contraction activity and fetal movements [1], [7]. Currently, the obstetrical care information systems are commonly used standard that provide a complete health care of the mother and her baby [4]. The data are transmitted from bedside fetal monitors to surveillance center to be displayed and online analyzed as well as generate alerts for critical events [10], [25]. Obstetrical surveillance system provides a number of important functions designed to ensure comprehensive coverage across the obstetrical care: on-line signal analysis, alerting, documentation and archiving [5], [17].

Leading and commercially available in the EU obstetrical care information systems offer limited functionality as for the home telemonitoring of pregnant women [24]. Telemonitoring cannot be accomplished in online mode. It means possibility of data transmission to the center and the on-line analysis of the signals recorded during the monitoring session at home just like in hospital. In its place, a data block is transmitted from home monitor, using Internet or phone modem to the surveillance center as the monitoring session ends. Completed data, as well, could be transport to hospital in any other way, even personally by patient on USB flash drive. From patient point of view the only advantage is staying at home instead of hospital. Patient is not provided with recording interpretation at once. While the mother at such important period should be provided with sense of continuous care from a medical staff, which interprets the signals being recorded and interactively informs her on the result.

Telemonitoring systems do not accomplish the concept of mutual integration carried out in an automatic way, which means that two independent monitoring systems are not able to benefit each other from the results of their measurements [11]. Most of them are designed as closed system as regards the implementation of the monitoring session it is not possible to add other sensors for measuring additional parameters life [3]. Furthermore, interoperability of current obstetrical care information systems and other medical devices, as well as their ability to use in various clinical workflows are usually very limited, as they are networked

[22]. In addition, interfaces of the existing obstetrical care systems are very restricted, and neither support learning nor collaboration in care teams around the patient.

2. SYSTEM DESIGN CHALLENGES

General structure of the proposed obstetrical care information system with home telemonitoring is presented in (Fig.1). The system integrates internal and external transmission channels to provide biomedical data from all pregnant women being under medical care. Hospital network distributes the measurement data incoming from wireless interface units within the hospital and from Mobile Instrumentations via GSM/Internet-based communication platform. Administrative Workstation can be used to set up the system, create paper documentation as well as to process the signals recorded in the off-line mode (e.g. in case of total breaking of the communication link). Attending doctor can access the information anytime he needs.

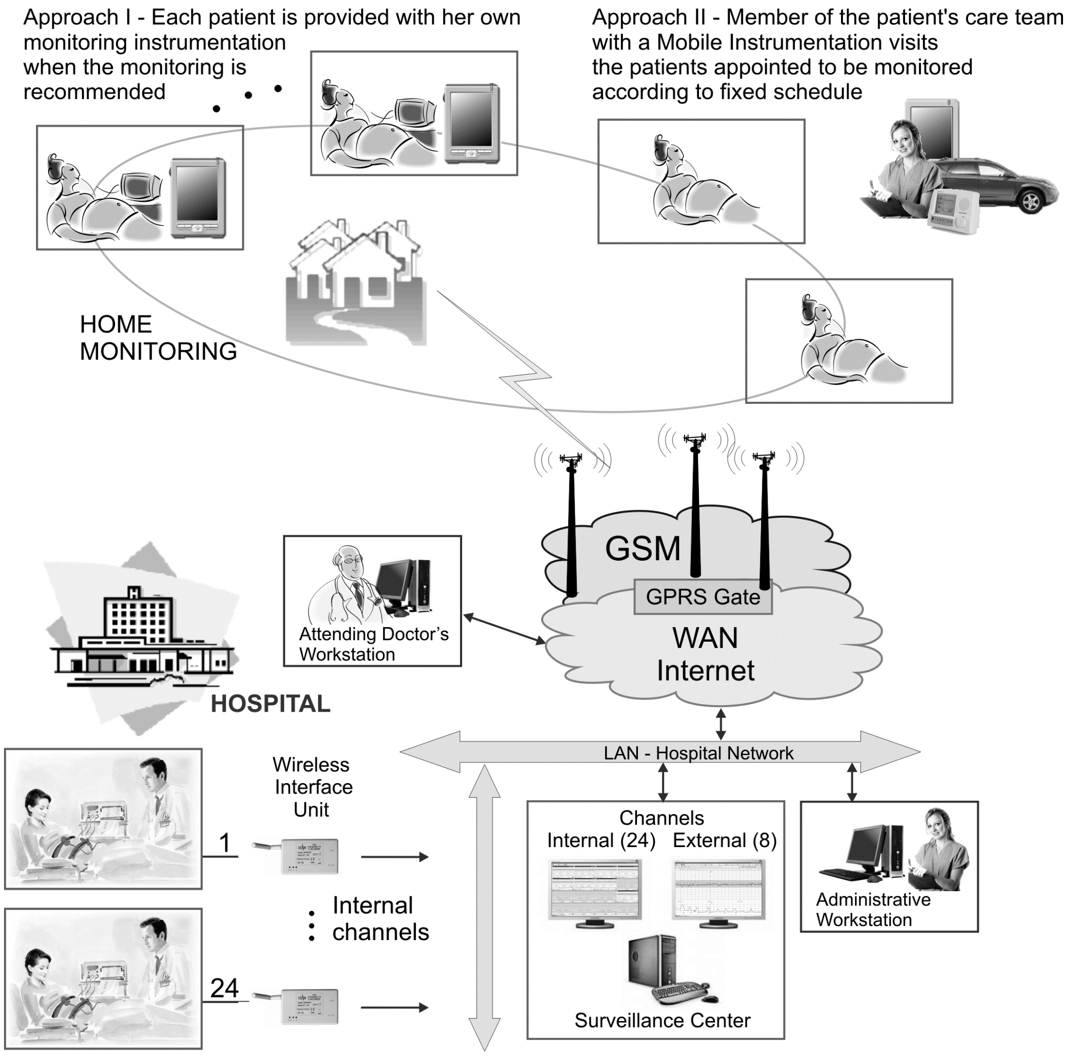

Fig. 1. General structure of the obstetrical care information system with two approaches for realization of pregnancy monitoring at home.

We considered two approaches for realization of pregnancy monitoring at home [23]. In the first approach each patient is provided with her own monitoring instrumentation for the whole period of pregnancy, when the monitoring is recommended. In the second one, a member of the patient's care team with a Mobile Instrumentation visits the patients appointed to be monitored according to fixed schedule. These approaches have both good and weak points. Providing each patient with monitoring instrumentation may increase the cost of the telemonitoring, however it strongly depends on fetal monitor prices. Classical fetal monitor can be used as an input device, which provides information on fetal rhythm variability changes basing on ultrasound technique, and records the uterine contraction activity by means of strain gauge transducer. Optionally, the module developed by the authors can be applied, which enables a long-term noninvasive recording of fetal and maternal bioelectrical signals from the maternal abdominal wall. The input device is controlled by the tablet software being responsible for acquisition of measured data from fetal monitor, dynamic presentation of the signals, the on-line evaluation of signal quality, data transmission and communication with the Surveillance Center [12].

When experienced nurse operates the monitoring instrumentation the required quality of signals is ensured. Some of patients may prefer to be monitored at home by hospital staff, even if this requires visiting them according to established schedule. However, it seems that only the self-monitoring ensures a real comfort for the patient being monitored at home since monitoring session can be carried out at any time that suits the patient best. In such case, when the patient becomes an operator of the monitoring procedure there are some challenges that have to be considered while designing the telemedical system for pregnancy monitoring at home. Increased functionality of the telemonitoring system when applying to pregnancy monitoring at home, comprising among others the patients support procedure or interoperability of medical sensors and devices, is to be provided primarily by the software embedded in microcontrollers, programmable devices and software running on the computing platforms.

It has been shown that the majority of errors and irregularities in the functioning of such complex systems are not caused by damage or aging hardware, as is the case in the classical medical equipment [19]. In fact, the main reason is incorrect initial assumptions, errors in the program code or errors made at various stages of compilation and merging the software modules. In order to ensure a high reliability of such system a new class has been introduced, as related to earlier applications in avionics, aeronautics, and power industry, and named the Medical Cyber Physical System MCPS [20], [21].

3. SYSTEM DEVELOPMENT

Medical CPS can be considered as the networked computational platform referenced to the cyber part of the system, which processes biomedical and environmental data provided by sensors placed in the physical part (Fig.2). MCPS refers to such development challenges, like sensor interoperability, sharing information between different systems using network, completing various clinical scenarios and workflows, as well as involving human behavior model in the development process. In case of pregnancy monitoring physical objects mother and her baby are monitored by two sets of sensors within the Body Area Network (BAN). Physical signals of different origins (mechanical and electrical) are transmitted wirelessly to the cyber part of platform Personal Area Network (PAN). Since the baby (fetus) is a hidden object a much more advanced signal processing than in a case of mother has to be applied to obtain information relevant to the fetal health status. Medical Device Plug-and-Play architecture is involved to ensure interoperability between the instrumentation measurements channels in a given monitoring scenarios, according to instrumentation descriptions and interacting requirements. Personal Terminal (PDA, Laptop) records and transmits the measurements data through WAN/Internet to Surveillance Center. Terminal is responsible for a matching the algorithms for automated analysis of acquired signals basing on the patients medical data received from hospital information system. Patients behaviour model is used to present information in ergonomic form for the patient during her monitoring.

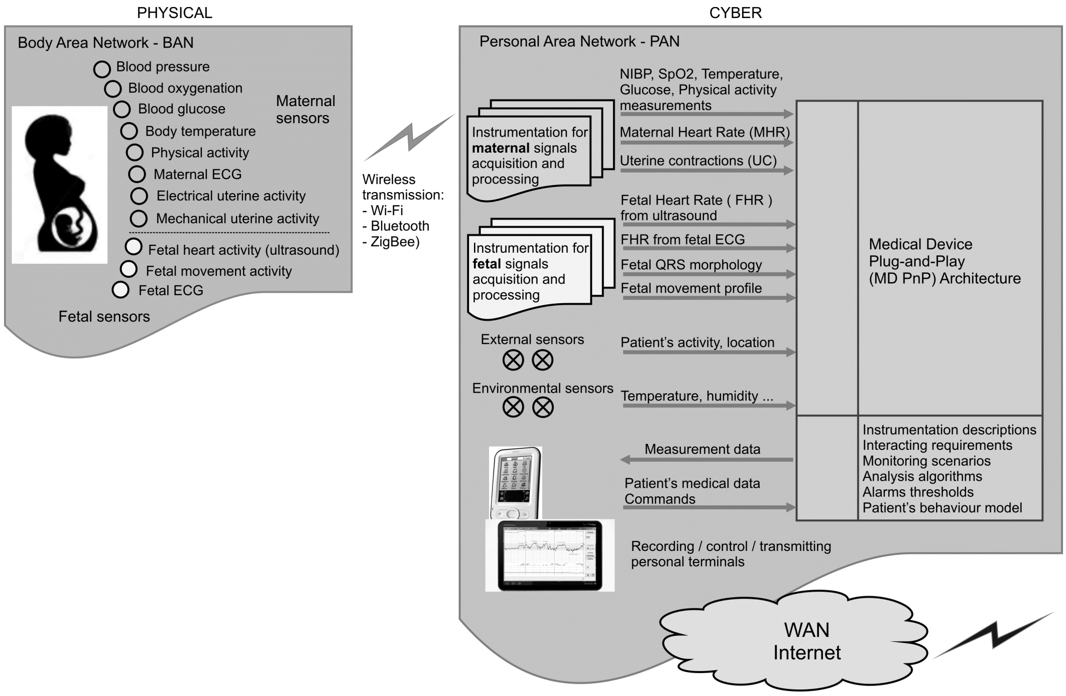

Fig. 2. Overview of physical and cyber parts of the telemedical system for pregnancy home monitoring.

Medical Device PlugandPlay (MDPnP) architecture enables to assemble several different medical sensors or devices for the implementation of a dedicated medical scenario [2]. In case of pregnancy monitoring the medical scenario applied depends mainly on gestational age and mothers medical history (number of subsequent pregnancy, delivery complications, chronic diseases, and others). For monitoring the fetal states constant set of sensors is usually used to provide information on fetal heart rate and fetal movement activity. Alternative fetal ECG channel may provide, despite the FHR signal, information on fetal QRS morphology. As for maternal monitoring the uterine activity monitoring is always present. It can be accomplished in mechanical or electrical way, by means of stain gauge transducer or electrodes attached to maternal abdomen. Depending on mothers chronic diseases some additional sensor may be applied to measure blood glucose, blood pressure and oxygenation. In addition, MDPnP allows for more efficient operation of one device based on data taken from another one when the same patient is monitored, and in the case when the measurements must be performed alternately it prevents from interference each other.

One of possible procedure performed by MDPnP is a detection of dangerous phenomena - coincidence between maternal and fetal heart rates (applying for example an additional maternal pulse sensor or maternal ECG analysis using bioelectrical signal recorder). The fetal rate normally takes values between 110 and 150 beats per minute, whereas maternal one does not exceed 80. Thus, situation when fetal and maternal rate take similar values for established time period should be recognized by the system. It may take place when due to fetal movement activity the ultrasound transducer starts to measure the signal, whose source is not fetal heart, but maternal blood circulation system. In order to avoid the generation of false alarms, at first the system should inform the patient to change the ultrasound transducer position on her abdomen to focus back on the fetal heart. However, if transducer replacement does not help, it may suggest abnormally low fetal and/or abnormally high maternal heart rates. Then, the telemonitoring system performs appropriate actions according to medical procedure established. Another example of sensor interoperability is controlling the patients physical activity by accelerometers at the time of monitoring session. It may be used to exclude these segments from uterine activity signals that may result from patients body movements.

In the proposed system, a remote access to the patient medical data included in electronic health record, enables an approach based on personalized medicine. This will comprise the adaptation of medical procedures for a particular patient, based on matching the algorithms for automated analysis of selected signals being measured. Remote access to the information involving both more general data - collected through an interview (for example co-existing chronic diseases), as well as to the trends observed in the changes of parameters obtained from the previous monitoring sessions, enables individualization of smart alarming procedure upon detection of health risks. Another aspect of smart alerting is mutual correlating alerts from multiple sensors, and providing on this basis information about the real threat. Human interaction with computing devices within the proposed system is multiphasic. In the first phase, the automatic identification of the user takes place, and in the second the appropriate context for user interaction is defined. The proposed approach is to identify several classes of the users. In the case of telemedical systems they may include: patients, physicians, consultants, medical staff and operators. Among physicians two further classes should be defined: doctor on duty and attending doctor. While the attending doctor usually has information about his patient, concerning mothers health history, condition or even behavior, which helps in interpretation of the patients recording, the doctor on duty must be supported by Hospital Information System (HIS). Thanks to the systems interoperability all data required from HIS can be transmitted together with patients recording from the telemonitoring system to doctors terminal.

Controlling a flow of information between different elements of the whole health care system (monitoring devices, dedicated systems, terminals) as well as preparing information content depending on the user class is very important functionality of MCSP. Due to the significant differences in the level of access to the patient data for particular classes of users, it is necessary to personalize the content and look of the user interfaces. Particular emphasis will be paid on developing a patients interface that should provide high comfort and a sense of trust and safety during the monitoring session. The most important aspect is the creating a model of operator behavior, which in home telemonitoring system is equivalent to a patients model. This allows for implementation of ”user centered design” technique, where the human-machine interface of the system is designed to ensure a simple, intuitive operation and clear presentation of the analysis results. In addition, the user interface should reduce the number of possible erroneous operators (patients) commands, resulting from limited experience in using the monitoring instrumentation and procedures, or even the actual psychophysical condition.

The interface is used to communicate with the patient by providing her with information coming from both the system itself and the physician or care provider (Fig.3). During medical examination the physician is guided by certain rules regarding how medical information should be prepare for a patient, and he can dynamically adapt it to the patient's personality type and its possible reaction. Based on own experience he formulated different messages in such way as not to cause an adverse patients reaction. A similar mechanism will be proposed for system-patient communication path, when the system is a source of information. Both information content messages and form of their presenting will depend on the assignment of a patient to a particular class of the behavioral model.

4. CONCLUSIONS

The use of telemedicine is generally considered positive for both patients and the economy. Through remote health monitoring, telemedicine may allow countless numbers of people to avoid nursing homes and hospitals, allowing them to remain productive, stay longer, and consequently incur less health costs. The economy also benefits from the diminished need

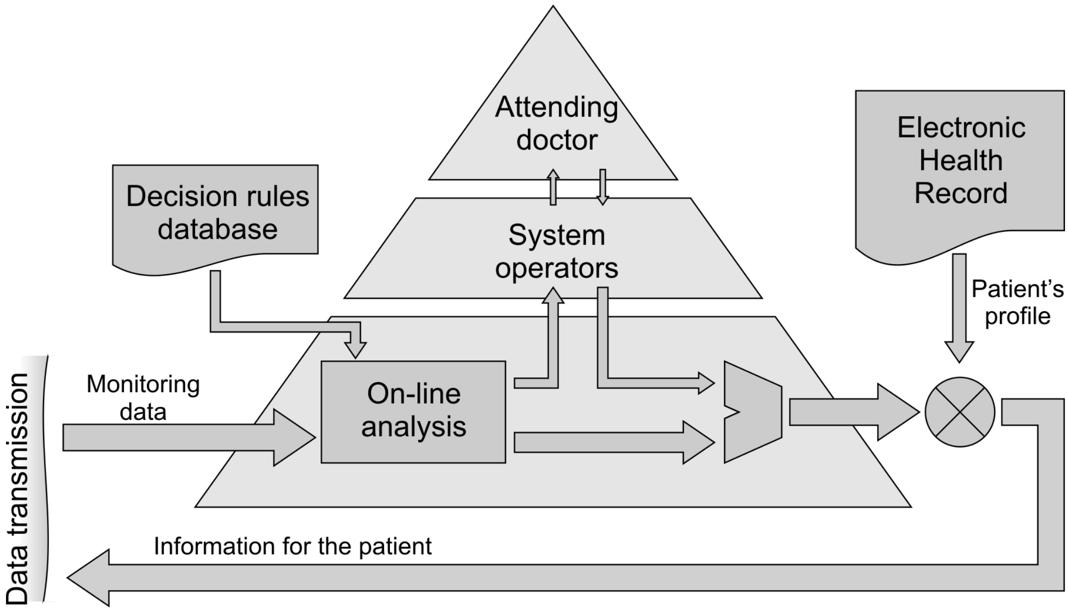

Fig. 3. Surveillance Center of the telemonitoring system with diagram of information flow within a hierarchical decision scheme physician-operator-system. Personalization of the system communication with the monitored patient, ensures a matching of both type and form of information to the patient's medical profile.

to transport patients to other facilities when a health care specialist is needed.

Functionality and reliability of modern telemedical system is mainly determined by quality of the software embedded in microcontrollers, programmable devices and software running on the computing platforms. Therefore, when considering development the system for pregnant women telemonitoring at home a using the concept of Medical Cyber Physical System seems to be appropriate way. Medical Cyber Physical System can state as a networked computational platform to ensure effective medical care for all women from the group of high-risk pregnancy (diabetes, pregnancy induced hypertension, post term pregnancy) through the access to the interactive continuous distant monitoring.

The implementation of the different scenarios of the system operation, just at the development stage, based on its interaction with the model of operators behavior will prevent from making modifications to the existing medical system usually being complex and increasing a cost of the system development.

5. ACKNOWLEDGEMENTS

This work was financed in part by the Polish National Science Centre.

BIBLIOGRAPHY

[1] ABDULHAY, ENAS W., et al, Review Article: Non-Invasive Fetal Heart Rate Monitoring Techniques. Biomedical Science and Engineering, 2014, Vol. 2, No. 3, pp. 53-67.

[2] ARNEY D., FISCHMEISTER S., GOLDMAN J. M., LEE I., TRAUSMUTH R., Plug-and-play for medical devices: Experiences from a case study. Biomed. Instrument. Technol., 2009, Vol. 43, No. 4, pp. 313-317.

[3] CASTANEDA M., Connecting Devices and Data on the Healthcare Network. Biomed. Instrument. Technol., 2010, Vol. 44, No. 1, pp. 18-25.

[4] CZABANSKI R., JEZEWSKI J., HOROBA K., JEZEWSKI M., Fetal state assessment using fuzzy analysis of the fetal heart rate signals - agreement with the neonatal outcome. Biocybernetics and Biomedical Engineering, 2013, Vol. 33, No. 3, pp. 145-155.

[5] CZABANSKI R., JEZEWSKI J., MATONIA A., JEZEWSKI M., Computerized Analysis of Fetal Heart Rate Signals as the Predictor of Neonatal Acidemia. Expert Systems with Applications, 2012, Vol. 39, No. 15, pp. 11846-11860.
[6] CZABANSKI R., JEZEWSKI M., WROBEL J., JEZEWSKI J., HOROBA K., Predicting the Risk of Low Fetal Birth Weight from Cardiotocographic Signals using ANBLIR System with Deterministic Annealing and e-Insensitive Learning. IEEE Transactions on Information Technology in Biomedicine, 2010, Vol.14, pp. 1062-1074.
[7] CZABANSKI R., JEZEWSKI M., WROBEL J., HOROBA K., JEZEWSKI J., Neuro-fuzzy approach to the classification of fetal cardiotocograms. IFMBE Proc. 14th Nordic Baltic Conference on Biomedical Engineering and Medical Physics, Riga, Jun 2008, Vol. 20, pp. 446-449.
[8] DI LIETO A., CAMPANILE M., DE FALCO M. et al, Prenatal Telemedicine: A New System for Conventional and Computerized Telecardiotocography and Tele-Ultrasonography. In Advances in Telemedicine, Eds. G. Graschew and T. A. Roelofs, InTech Publisher, ISBN 978-953-307-159-6, 2011, pp. 121-154.
[9] ESFANDIARI N., BABAVALIAN M. R., MOGHADAM A E., TABAR V. K.: Knowledge discovery in medicine: Current issue and future trend, Expert Systems with Applications, 2014, Vol. 41, pp. 4434-4463.
[10] HANNAH INBARANI H., NIZAR BANU P.K., AHMAD TAHER AZAR, Feature selection using swarm-based relative reduct technique for fetal heart rate. Neural Computing & Applications, 2014, Vol. 25,pp. 793-806.
[11] HANSEN S.K., WILSON L.S., ROBERTSON T., Applying an integrated approach to the design, implementation and evaluation of a telemedicine system. Journal of the International Society for Telemedicine and Ehealth, 2013, Vol. 1, No. 1, pp. 19-29.
[12] HOROBA K., WROBEL J., ROJ D., KUPKA T., MATONIA A., JEZEWSKI J., Ensuring the real time signal transmission using GSM/Internet technology for remote fetal monitoring. In Information Technologies in Biomedicine, Eds. Pietka E., Kawa J., Advances in Soft Computing Series, Vol. 47, Springer Verlag, 2008, pp. 291-298.
[13] JEZEWSKI J., HOROBA K., MATONIA A., GACEK A., BERNYS M., A new approach to cardiotocographic fetal monitoring based on analysis of bioelectrical signals. Proc. 25th Annual Int. Conf. of the IEEE Engineering in Medicine and Biology Society, Sep 2003, pp. 3145-3148.
[14] JEZEWSKI J., MATONIA A., KUPKA T., ROJ D., CZABANSKI R., Determination of the fetal heart rate from abdominal signals: evaluation of beat-to-beat accuracy in relation to the direct fetal electrocardiogram. Biomedical Engineering, 2012, Vol. 57, No. 5, pp. 383-394.
[15] JEZEWSKI J., ROJ D., WROBEL J., HOROBA K., A novel technique for fetal heart rate estimation from Doppler ultrasound signal. Biomedical Engineering Online, 2011, Vol.10, 92.
[16] JEZEWSKI M., CZABANSKI R., WROBEL J., HOROBA K., Analysis of extracted cardiotocographic signal features to improve automated prediction of fetal outcome. Biocybernetics and Biomedical Engineering, 2010, Vol. 30, No. 4, pp. 29-47.
[17] JEZEWSKI J., WROBEL J., HOROBA K., GRACZYK S., GACEK A., SIKORA J., Computerized perinatal database for retrospective qualitative assessment of cardiotocographic traces. In Proc. Healthcare Computing Conference HC96, in Current Perspectives in Healthcare Computing, Editor: B. Richards, March 1996, BJHC Ltd, Great Britain, pp. 187-196.
[18] KOVACS F., HORVATH C., BALOGH A.T., HOSSZU G., Fetal phonocardiography - Past and future possibilities. Computer Methods and Programs in Biomedicine, 2011, Vol. 104, pp. 19-25.
[19] LEE I., PAPPAS G. J., CLEAVELAND R., HATCLIFF J., et al, High-confidence medical device software and systems. Computer, 2006, Vol. 39 No 4, pp. 33-38.
[20] LEE I., SOKOLSKY O., Medical Cyber Physical Systems. Proc. 47th Design Automation Conf., 2010, pp. 743-748.
[21] LEE I., SOKOLSKY O., CHEN S., HATCLIFF J., et al, Challenges and Research Directions in Medical CyberPhysical Systems. Proceedings of the IEEE, 2012, Vol.100 No. (1), pp. 75-90.
[22] NAGARAJU P., RAMASAMY M., NOUSHAD S., Implementation of CPLD Based Receiver of Telemetry device for Maternal-Fetal Monitoring. International Journal of Current Engineering and Technology, 2014, Vol. 4, No. 3, available at http://inpressco.com/category/ijcet.
[23] ROJ D., HOROBA K., WROBEL J., KOTAS M., JEZEWSKI J., PRZYBYLA T., Telemedical application for centralized home care of high-risk pregnancy based on control sharing approach. IFMBE Proc. of the World Congress on Medical Physics and Biomedical Engineering, Munich, IX 2009, Vol. 25, pp. 59-62.
[24] VIJAY S. CHOURASIA, ANIL KUMAR TIWARI, A Review and Comparative Analysis of Recent Advancements in Fetal Monitoring Techniques. Critical Reviews in Biomedical Engineering, 2008, Vol. 36, No. 5-6, pp. 335-373.
[25] VOICU I., MENIGOT S., KOUAME D., GIRAULT J., New Estimators and Guidelines for Better Use of Fetal Heart Rate Estimators with Doppler Ultrasound Devices. Computational and Mathematical Methods in Medicine, Vol. 2014, Article ID 784862, 10 pages, http://dx.doi.org/10.1155/2014/784862.