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MONITORING OF VITAL SIGNALS: THE DESIGN OF PULSE OXIMETRY SYSTEM BASED ON EMBEDDED PC MODULE

Monitoring vital signals is one of the most important tasks performed by the medical equipment nowadays. One of the most frequently applied monitoring types is the pulse oximetry, based on monitoring of arterial oxygen saturation. The design presented in this paper is a modular construction. One of the most important improvements is the application of the embedded PC module in the design of a pulse oximeter. The modular PC is using open source software. The system presented in this paper uses digital detector technology and the input pulse oximeter module developed by the Dolphin Medical. One of the main aims of the research team was to create a design capable of monitoring both vital signals of adults and newborns, to make the device suitable for pediatric and neonatologic wards. Performed tests and examinations for system stability as well as the comparision with other similar devices available on the market confirmed that the presented device design is an optimal solution for the described class of devices. By using the PC module the scalability of the system seriously increases comparing to other designs. The separation of the data acquisition part of the device and the analytical part of the device in the form of a personal computer module makes the device more alike medical computer system than the traditional pulse oximeter responsible only for visualiasation of the read data.

1. INTRODUCTION

Monitoring of patient's vital signals is one of the main routine actions performed in the healthcare nowadays. One of the most frequently applied monitoring types is the pulse oximetry, based on monitoring of arterial oxygen saturation. Most popular devices on the market nowadays are based on dedicated hardware solutions. The research in engineering psychology and on the human-machine interfaces in ICU's [9] revealed that there is a strong need to develop a new kind of sophisticated vital signals monitors with advanced signal analysis features. The design presented in this paper is based on the embedded PC using open source software, which is the main improvement in the way of making this kind of medical equipment. Pulse oximetry techniques help to diagnose the hypoxemy, which could be the first sign of many serious illnesses, i.e. pneumonia. The advantages of using pulse oximetry during labor are obvious – the informations shown by the device are invaluable for the physician when any complications occur [14].

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2. THE BASICS OF PULSE OXIMETRY

Because of blood flow in blood vessels the environment in which the light wave propagates fluctuates during time. By separating the constant and the variable part of the absorption information one can calculate the real oxygen saturation. The analysis of the variable part of the information creates the possibility to point out the frequency of the heartbeat. The one and basic parameter measured by the pulse oximeter is the blood oxygen saturation (SaO_2). There are two kinds of blood saturation ratios [2,5]: the fractional blood saturation radio and the functional blood saturation ratio.

Most of the pulse oximeters nowadays use detectors based on the analogue technology. The analogue signal is transmitted to the device, where is amplified, filtered and transformed into digital data. The digital signal is then analysed and presented to the user. In the digital pulse oximeter the signal is transformed into digital data inside the detector itself. Both in the analogue and in the digital design of the pulse oximeter the signal has to be transformed using the Fast Fourier Transform so one could see the real plot of plethysmogram. Moreover the device has to detect the possible noise generated by the temperature characteristic of the detector's semiconductor elements [3]. The research in the area of monitoring devices is aimed to improve the quality of the processed signal and data analysis [11], centralization of the vital signal monitor systems [13], wireless technologies [10,12] and reducing the size of devices. [10,12]. Most effective constructions are based on dedicated hardware implementations using DSP processors or programmed logic chips. There are two kinds of pulse oximetry: transmission pulse oximetry and reflecting pulse oximetry. Both of them have limitations. The detector used in the first one could be placed only on peripheral parts of a patient's body (ie. finger, foot, ear). The second kind of pulse oximetry is less precise but is used during labour because during labour there is no possibility to place a transmission detector on the fetus [14].

3. THE DESIGN OF HARDWARE

The system presented in this paper uses digital detector technology and the input pulse oximeter module developed by the Dolphin Medical [4].

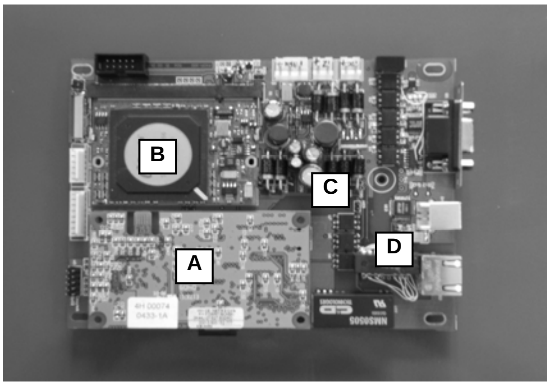

Fig. 1. Main board of the pulse oximonitor (A - Pulse oximeter module, B – PC Module, C - Galvanic separation, D - Communication interfaces)

One of the main aims of the research team was to create a design capable of monitoring both vital signals of adults and newborns. The key decision made by the research team while developing the prototype design of the device was to use a modular construction scheme. The device consists of two main modules: the pulse oximetry input module and the embedded PC module. The pulse oximetry module is responsible for data acquisition and handles hardware implementation of the input signal filtration. The Personal Computer module is responsible for the presentation of the signal (Fig.4). It integrates in one silicon chip: CPU, graphics adapter with LCD controller and a flash hard drive.

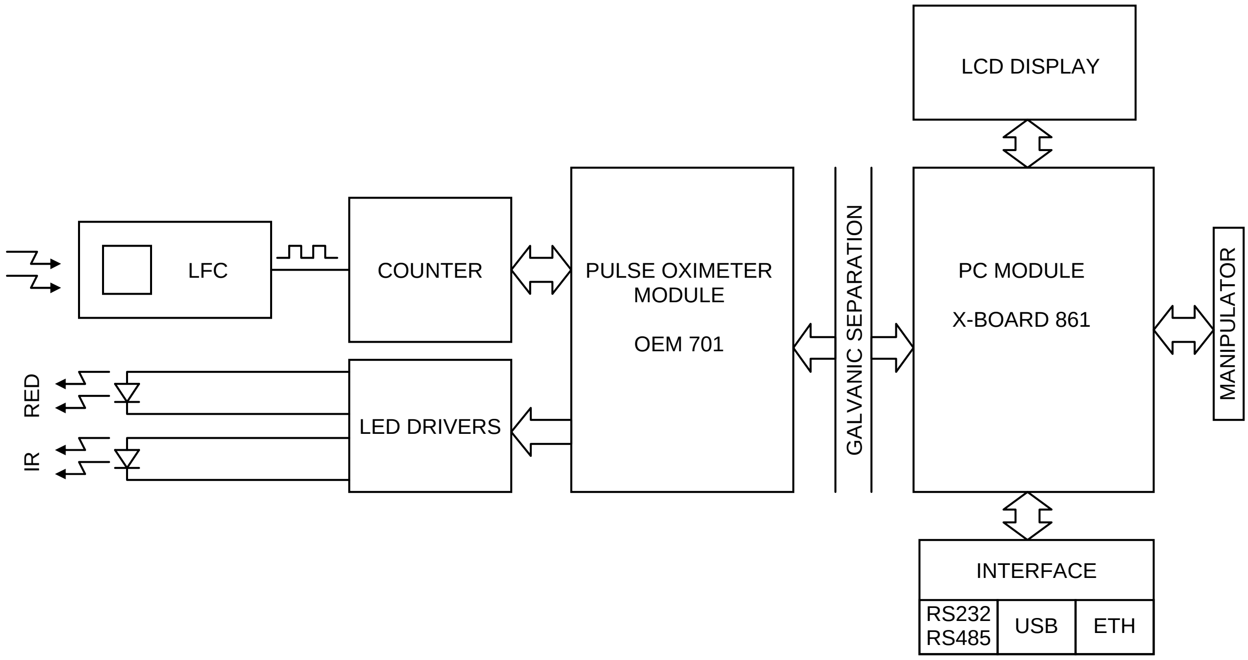

Fig. 2. Modular design of the pulse oximeter

Both modules were galvanic separated (Fig. 2) to suit the needs of the medical device specification for the safety of the patient. By using the embedded PC module the device's external dimensions were highly reduced. (Fig. 1). The integrated LCD controller simplified the construction of the data presentation layer. The modular design improves the service efficiency of the device because all the activities performed by the staff are limited to the replacement of appropriate modules.

4. SOFTWARE IMPLEMENTATION

According to the presented design the most important part of the device is the embedded PC module. It controls not only the signal acquisition process from the pulse oximeter module working in real time but also controls the rest of signal processing and presentation. The software implementation is based on the open source technology and is created according to the scheme presented on the following figure (Fig.3).

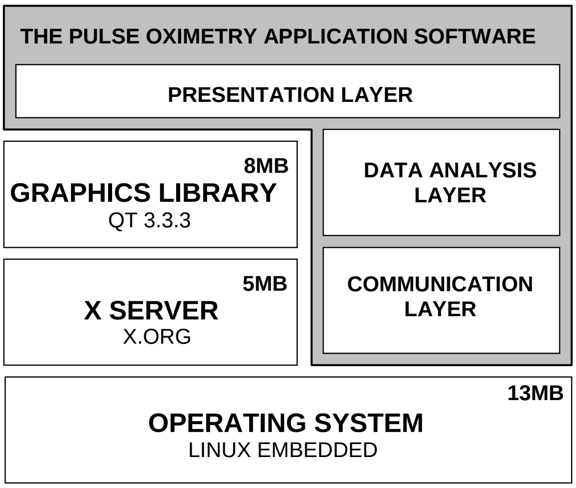

Fig. 3. Software architecture

The maximum size of the mass storage in the presented device design was 32MB. After leaving only most important files, necessary for the operating system and the graphics library to work, the research team has developed the Linux mini distribution in the size of 26MB. In the presented design, the graphics subsystem (QT 3.3.3) [6,7,8] is a full PC version. The decision was made mainly because of the economic reasons since the embedded version of the license is more restrictive. Even though the graphics subsystem is 5MB bigger than the embedded version. The remaining 6MB is used by the manufacturer for the application (about 0,5MB) and patient data and it seems to be just enough for the design. To make the device appropriate for use in the paediatric and neonatology wards one shall make modifications not only into the level of sounds generated by the device but also into the user interface and the form of data presentation. The user interface consists of six screens: the plethysmographic chart screen (Fig.4), SpO2 and Pulse charts screen, alarm configuration screen, chart browser screen, device configuration screen and colon scheme configuration screen. Thanks to the design presented in this paper such modifications are much simpler than in the devices based on the traditional design. The communication layer is based on the communication routines provided by the pulse oximeter module manufacturer. Modules provided by other manufacturers could be used as well with a little overhead in the software implementation at the side of the PC module.

In the software design the data analysis layer is responsible for all activities affecting signal processing not performed by the pulse oximeter input module. In the presented design one of such activities is for example scaling of the plethysmographic chart. The pulse oximeter module is transmitting the data as a topple containing value and the scale factor. The plethysmographic chart in this form is always scalled to meet the maximal resolution of the screen. To obtain the real shape of the plethysmographic chart one should perform the reverse transformation using the included scale factor. Another very important activities done in the data analysis layer is the detection of alarming states. It is important to analyze both the upper and the lower limits because in the case of newborns too high values of the oxygen blood saturation could cause blindness and too low value could be the symptom of hypoxemia.

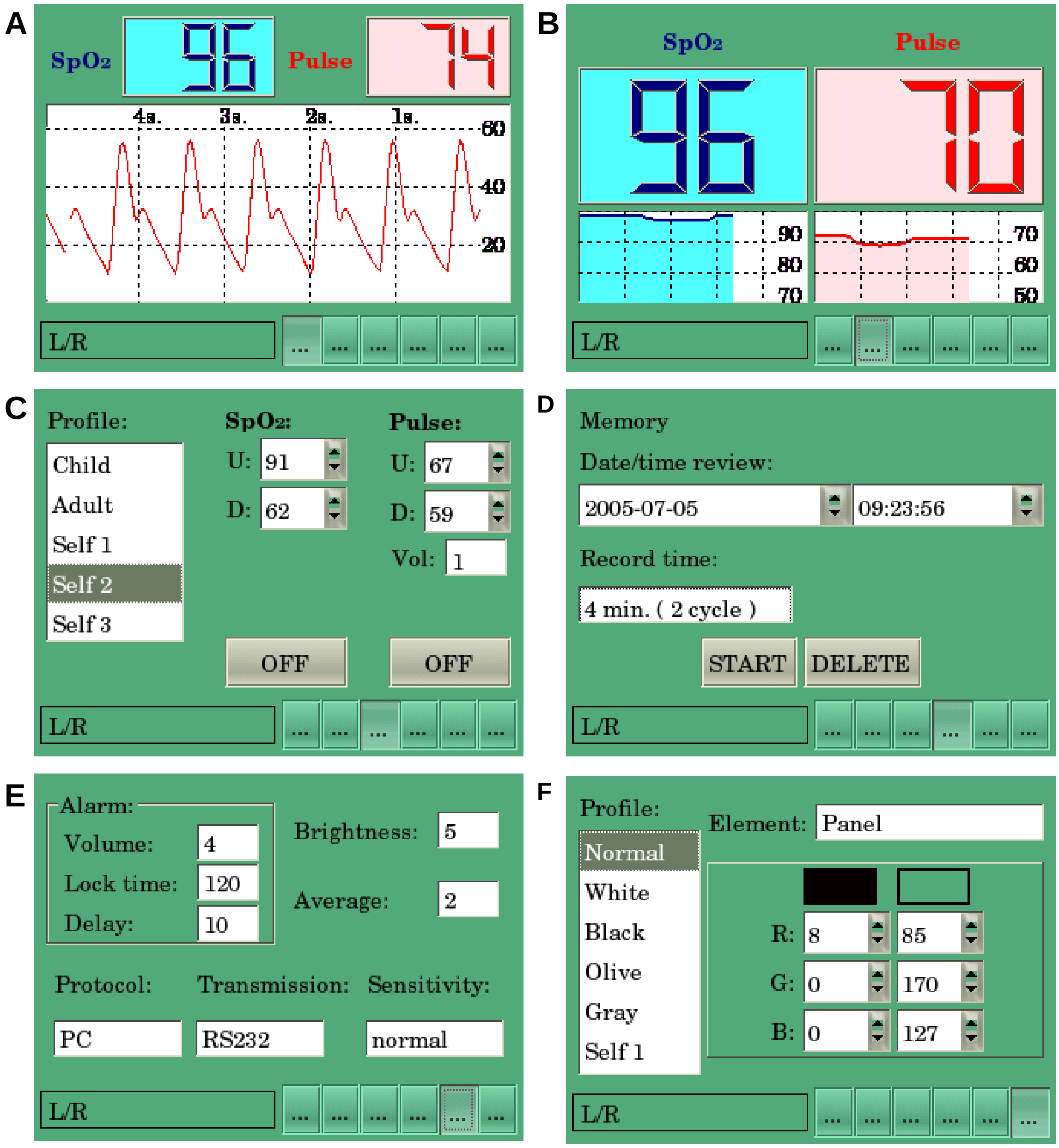

Fig. 4. Sample screens: the plethysmographic chart screen (A), SpO2 and Pulse charts screen(B), alarm configuration screen (C), chart browser screen (D), device configuration screen (E), color scheme configuration screen(F).

Thanks to the QT multi platform graphics library by Trolltech available both on the Linux operating system and on other popular operating systems including Windows and MacOS X it was possible to create one software implementation for embedded and portable versions of the application. The same software is installed in the device and in the personal computer visualizing the activity of the device on the PC's desktop. The separation of the presentation layer creates the possibility of creating user interface on-demand according to the requirements of the future user.

5. DEVICE TESTING AND EXAMINATION

All of tests and examinations were performed to meet requirements for medical devices. After each software implementation cycle the software was tested against the requirements. The pass of the test was the necessary but not the only required condition before the next cycle of the software implementation process. During the whole testing process the development team used specialized testing equipment including hardware USB communication port debugger, SpO2 simulator. The device has been verified against the basic requirements. The pulse values measured by the device are in the range of 30 – 240 bpm with the accuracy of +-3bpm in standard conditions and during low perfusion and with the accuracy +-5bpm in the condition of patient movement noise. The device has been tested to suit the requirements of oxygen saturation SpO2 in the range of 0% - 100%.

Performed tests and examinations revealed an enormous stability of the device during the one-month period of continuous work. The stability of the device was also verified during the tests performed in the laboratory climatic chamber. The comparison test with other, analogue pulseoximeters, revealed that the signal quality was noticeably better. As a result the false alarms were not as often.

6. CONCLUSIONS AND FUTURE WORK

Performed tests and examinations confirmed that the presented device design is an optimal solution for the described class of medical equipment. By using the personal computer module the scalability of the system seriously increases comparing to other designs based on hardware implementations of visualization subsystems. By using a module with larger capacity of the build-in Compact Flash memory it is possible to increase the amount of patient information stored inside the device. The upgrade of the personal computer module creates the possibility to develop much more sophisticated real time signal analysis software without any modifications in other parts of the device. It is possible to develop implementations of more sophisticated features including: TCP/IP firmware upgrade, HTTP web server became much more simplified than in traditional designs based on embedded technologies. The separation of the analytical part of the device in the form of a personal computer module and the data acquisition part of the device makes the device more alike medical computer system than the traditional pulse oximeter responsible only for visualisation of the read data. There is also a possibility to create a design with many input modules that would potentially bring together the functionalities of pulse oximeter, EKG analyser and EEG, creating the opportunity for building a device capable of monitoring all vital signals at the same time in one unit. Therefore the design of the device presented in this paper is called a pulse oximonitor instead of a plain pulse oximeter.

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