Remote Monitoring System For Artificial Heart

Submitted 27th June 2011; accepted 27th September 2011

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Abstract:

This paper presents a general description of the platform for remote monitoring and supervision of heart assist devices (POLPDU). To facilitate a more in-depth understanding of this system and its development, firstly, a brief discussion on severe heart failure problem are given. Then, the short description of the core modules of the system is included. The main emphasis is placed on the communication between the heart assist devices and the central platform server. Finally, the directions of development of the system are discussed.

Keywords: *remote monitoring system, telemetry, artificial heart, remote devices maintenance*

1. Introduction

Nowadays a growing number of patients are living with heart failure. Cardiovascular diseases (CVD) are the leading cause of death and the main causes of illness and disability in developed countries. According to Central Statistical Office (GUS) [1] the CVD are still the main causes of death (in 2010 – 46% of all deaths) despite the fact, that in Poland since the beginning of the 90s downward trend in mortality caused by cardiovascular diseases is observed. In many cases, e.g. for patients with severe or end stage heart failure, cardiac transplantation is the therapy of the last chance. However, there is still a large gap between the number of potential candidates for heart transplantation and the number of available hearts [2]. One of the possible treatment method, in case of the severe heart failure, is application of mechanical heart supporting. It is used to partially or completely replace the function of failing heart. A growing number of patients, which require long-term support, involves the use of mechanical devices that can be used outside the hospital. Current technology can provide information and control systems that improve the patient's safety and quality of life by the support of the users of heart support system, i.e. patients, doctors, technical stuff and device supplier.

In order to be able to monitor and supervise the heart support system in on-line mode, independently of the patient location, a remote monitoring system called CMS^2 was developed. The system can monitor the device-related information such as control pressures, pressures in the air tanks and physiological-related information such as EKG signal. All the information can be transmitted in on-line mode from a patient's unit to the central server. Stored data in central database can be analyzed by the qualified service staff. The monitoring center also provides wide range of functions connected with devices maintenance.

2. POLCAS heart support system

Since 1991, the Foundation for Cardiac Surgery Development (FRK) in Zabrze has been working on developing the artificial heart. Nowadays, the Polish system for heart support POLCAS[3] consists of the artificial ventricle POLVAD-MEV and the three controllers POLPDU-401, POLPDU-402 and POLPDU-501 (Fig.1).

Fig. 1. The family of POLPDU control units

Presented devices are designed to handle only one patient. The control units of the 401 and 402 series may be used only in hospital due to its big size, method of control and type of power supply. The control unit of 501 series is the latest product of FRK. Due to its much smaller size and weight it is significantly more mobile solution. For this reason, it can be also used during supervised treatment conducted outside the hospital.

The construction of the drivers that belongs to the POLPDU family is very similar. The main difference between control units from 401 and 402 series is different source of the pneumatic supply. The POLPDU-402 control unit requires a connection to an external air supply from the hospital pneumatic system for proper work. While the POLPDU-402 is completely independent from the external pneumatic installation. It is equipped with the onboard compressor which supplies artificial heart chambers. The main difference between 400 and 500 series is the type of the electro-pneumatic transducer that is responsible for generating modulated pressure wave supplying artificial heart chambers. All of the devices which belongs to the POLPDU family are equipment with two independent, redundant electro-pneumatic circuits, which can be used to control one or two pneumatic chambers in two modes: with and without the synchronization with the patient's ECG signal. In case of a failure of one of the control paths, the system automatically switches to the redundant circuit.

The control units are equipment with measuring system that collects all basic parameters of the unit (e.g., the control pressure in the left/right circuit, the pressure in the air tanks – vacuum and overpressure). The drivers are also capable to measure and collect additional parameters of the artificial ventricle. It is possible to observe all the stored parameters on the device console screen (in case of 401 and 402 control units) and on a computer screen that is connected to the device (in case of 501 control unit). Regardless of the possibility to monitor the parameters locally, the units are equipped with the telemetry systems responsible for sending the parameter values to external devices and systems.

3. Objectives and scope of the monitoring system

During the design process of the Polish central artificial heart monitoring system (called CMS^2) the following assumptions were made:

- The primary tasks of the system are current monitoring and collecting archive parameters and measurements from particular devices and supporting the management of the life cycle of the devices that are part of the heart supporting system. Each unit is defined as specific, independent hardware component (e. g. artificial heart chamber, POLPDU driver unit, ECG device). Devices operate in sets (assemblies) that are attached to the patient.
- The system is designed to handle several considered type of devices. However, there must be a possibility to extend it to handle the facilities being developed in the future.
- The system design is modular so it can be expanded and launched in stages.
- The additional modules that realize advanced analysis of collected data in order to carry out device diagnostics and to support the patient's medical diagnosis are planned to be designed and implemented.
- Selected functions of the system will be available remotely via the Internet, without the need to install dedicated software on the user's machine. Different tools used to develop web applications will be used to fulfill this task.

It was assumed that, in the first stage of work, the following system functions will be implemented: monitoring devices parameters and variables in real-time (requires elaborating embedded communication software for devices and communication modules for central server), creating archival databases and management of the devices configurations supporting basic issues of device maintenance.

4. Structure of the system

The CMS^2 system consists of several interacting components that are operating on different devices and servers. The general structure of the presented system is shown in Fig. 2. One can distinguish the following elements of the system:

- **Communication module (unit)**. Is is installed on the POLPDU device. It is responsible for communication with the outside world via dedicated exchange protocols. The protocol was specially designed for the purpose of elaborated system. In the case of POLPDU-402 it is an independent hardware module, while for POLPDU-501 it is an independent software module.

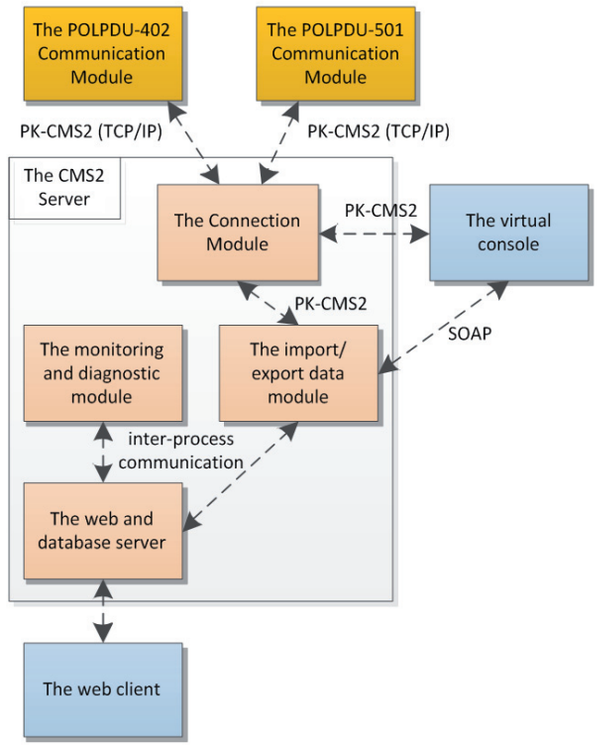

Fig. 2. The simplified structure of CMS^2 system

- **Connection module.** It is an independent module that runs on the monitoring center server. Its main task is to manage communication flow (in soft-real-time mode) between the monitored devices and the monitoring center in terms of data acquisition from devices as well as transferring control messages to them.
- **Virtual console.** It is an independent software that can be run on standard PC. It is used to directly communicate (without the central database), with selected POLPDU driver unit. The central database is used only to authorize the virtual console and check if the user has privileges to monitor particular POLPDU unit.
- **Data import and export module.** It is an independent module that runs on the monitoring center server. It is responsible for reading and writing process data and devices configuration from / to the database of the central monitoring system.
- **Monitoring and diagnostic module.** The module is responsible for automated analysis of the measurement data for the purpose of advanced monitoring and diagnostics.
- **Process and devices configuration database.** In the CMS^2 system two MySQL database are running on the monitoring center server. The first one is used to store the devices configuration. The second is a database used to store process variables and alarms collected in on-line mode from monitored devices.
- **Graphical user interface module.** The set of modules that run on the www server and web browser side responsible for realizing the graphical user interface to all the data stored in monitoring center.

5. Communication

The star topology was adopted in a communication network used to exchange the data between telemetry modules, that runs on the POLPDU control units, and monitoring center. A network node (the connection module), that is installed on the main server, is the network coordinator. The POLPDU control units (402 and 501 series) are the sub-nodes which are equipment with the communication interfaces, respectively IK-002 and PK-CMS2. The methods of data exchange between the CMS^2 central server and POLPDU control units are shown in Fig. 3.

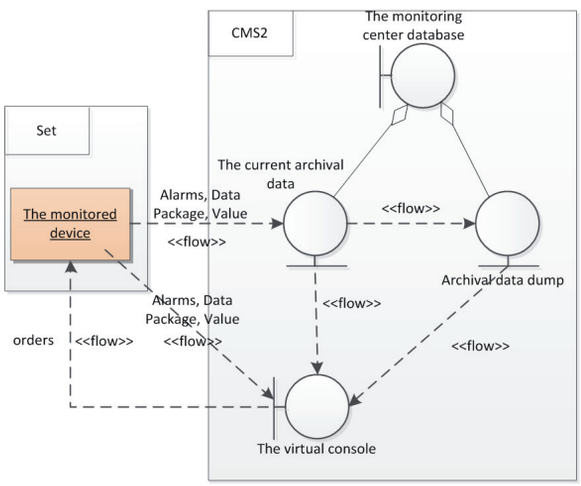

Fig. 3. The methods of data exchange between CMS2 server and POLPDU control units

Each of the network sub-node communicates only with the coordinator of the network. The peer-to-peer network transactions are not allowed, i.e. the transaction between any other nodes in the network.

The right to initiate the transactions in the network have all nodes subordinated to the network. The simultaneous two-way communication mode is implemented to communicate between the coordinator and the selected network node. The network nodes exchange information using communication frames.

5.1. POLPDU 402 communication

The control unit POLPDU-402 was equipped only with the telemetry module that allows to setup the communication channels using the GSM wireless communication network. This method of communication was chosen mainly because of the hardware limitations imposed by the designers of the POLPDU-402 unit. Since the communication was intended to informational purposes only the reliability level of such solutions was satisfactory. The communication protocol used to exchange the information between control units and the communication module installed on a central server is a specialized protocol called IK-002 (Fig. 4).

The POLPDU internal protocol [4] is used to exchange the information between the POLPDU-402 control unit and the telemetry module. The telemetry module acts as simultaneous two-way transmitter of the POLPDU protocol frames. It interprets communication

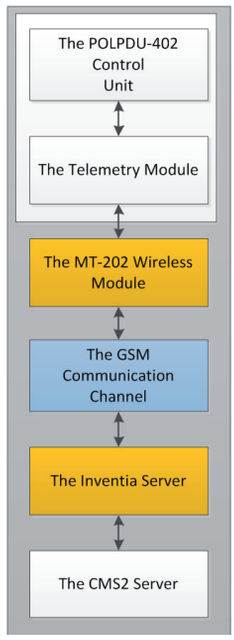

Fig. 4. The simplified block diagram of the communication system between the POLPDU-402 control unit telemetry interface and the monitoring center

frames using specially implemented functions. It is also responsible for conversion of transmission. The transmission speed between the POLPDU-402 and the telemetry module is fixed to 115200 b/s. The speed of the data exchange between the telemetry module and wireless module is also constant and equal 38400 b/s. The proposed mode of communication is a real-time mode in the sense that each of the frame received from the coordinator is transmitted immediately to the POLPDU-402 driver, and each of the frame received from POLPDU-402 is passed immediately to the coordinator when the communication channel to the coordinator is released by the previous transfer.

The IK-002 communication protocol implements three different types of the data formats:

- the format designed exclusively for the transfer of slow changing measurement data - the data are sent periodically every 960 ms,
- the format designed exclusively for the transfer of fast changing measurement data - the data are sent periodically every 60 ms,
- the mixed format used to transfer slow and fast changing measurement data. In this case, the fast changing measurement data are sent periodically every 60 ms and the slow changing measurement data every 960 ms.

In order to provide proper time synchronization for all POLPDU-402 control units in the communication system, which is compatible with IK-002 protocol, the principle of distributing time signals only from one source was adopted.

The central for remote monitoring and service is responsible for distributing the time signal to all control units. The system also assumes that each of the telemetry module has its own local real-time clock (LRTC). Every local real-time clock is counting time with 1 ms resolution.

5.2. POLPDU 501 communication

The communication module is mounted on the LPC2350 microcontroller [5], which is responsible for realization on the graphical interface of the heart support control unit POLPDU-501. The controller runs on the Linux operating system and the measurement data are recorded in real-time. The communication process between the control device and communication module is realized by independent process and is carried out using pipelines (FIFO queues stored in the volatile memory of the microcontroller). The three pipelines are created: the first and second pipeline for storing measurement data (respectively slow and fast changing data with corresponding time-stamps), the third pipeline is dedicated for the orders that are sent remotely from virtual console.

The measurement data, received by the communication module, are stored in the cyclic buffers. From that buffer the data are sent to the central monitoring system server. The Internet is the main communication channel of the data transfer. The TCP/IP protocol is used, which provides correct addressing of data with checksum and retransmission of lost packets support. In case of absence (or termination) of the wired connection stored data are sent via GSM network using the GPRS protocol. In such a way the redundancy of communication channels is realized.

The communication between POLPDU control unit and monitoring center server is preceded by the authentication of the device in the monitoring center. To make the authentication the unique ID number (optionally: together with its geographical position obtained from the GPS module) is send by the communication module. In a case of acceptance the main server sends the frame which confirms that the connection was established, otherwise a frame with the special error code that refuse the connection is sent. After receiving the confirmation frame from the server the communication module sends a request to receive a list of variables, which should be transmitted to the main server. This procedure is repeated every time when there is a loss of communication with the server. The exchange of the data between the communication module and the server via Internet channel is done using the dedicated protocol called PKCMS2, which was developed with the following assumptions:

- encryption of the connection is optional and is realized as encrypting the entire communication channel,
- time-stamp is transmitted by the control device unit,
- connection (TCP/IP tunnel) is maintained all the time when the communication is active,
- the measurement data packets are divided into two groups: fast-changing data that are sent every second (in each package there are 100 - 200 measurement data for each variable), slow-changing data sent every second,
- the POLPDU control unit is responsible for the initialization of the connection,
- the protocol during transmission of rare (non-cyclic) data is based on pure text. The cyclic transmitted data are transmitted in binary form;
- the protocol allows to define and distinguish fast-changing and slow-changing signals.

The header of each transmitted message starts with the information indicating the version of the protocol. After the protocol number a unique device identifier (ID) is sent. The header ends with an information about message length.

5.3. Communication module

The connection module is a process that runs on the central monitoring server. Its primary task is to handle communication with POLPDU devices. It is responsible for authentication of different devices and archiving received data in the central database via the import/export database module. The module is also responsible for authentication of the virtual consoles and transmission to them the information derived from POLPDU devices. The authorization of the virtual console is performed in two stages: in the first step the user of the virtual console retrieves from a database 32-byte, disposable authentication key for the connection. Then the key is sent to the connection module, where it is verified. Acceptance of the virtual console may be achieved only after positive key verification.

5.2. Virtual console

In order to allow remote monitoring and supervision of the POLCAS system the dedicated software called Virtual Console (VC) was designed and implemented. The graphical interface of the application is shown in Fig. 4.

The application is used by the technical staff during active work of the control units (connected to the patient) as well as passive work (without the patient – service mode). The software can also be used for training the medical personnel. For this reason, the graphical interface of the application has been adopted in a similar way to the real interface of the control panel of the POLPDU unit. The application is compatible with POLPDU-402 and POLPDU-501 control units.

It is possible to connect with any POLPDU control unit, which was registered in the CMS^2 system with use of VC. The software allows continuous monitoring of the basic parameters of the control unit (e.g., the control pressure in the left chamber, the control pressure in the right chamber, the parameters of the control signals, the basic technical parameters: the pressure in the tanks: hypertension, vacuum, the major power status, battery charge status, etc.), parameters of the artificial heart (e.g., the blood-part pressure, the instantaneous volume of the artificial chamber, etc.) and several additional medical parameters (e.g., the patient's ECG signal). The key parameters used for assessing the proper operation of the device and artificial ventricular, so-called fast-changing

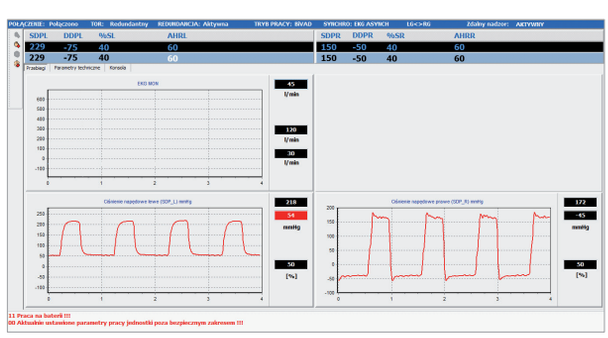

Fig. 5. The graphical interface of the virtual console application

signals, are visualized as waveforms. As a simple diagnostics the alarm system is implemented. When any of the monitored parameter exceeds its safe range a special alarm message is displayed.

The application has been equipped with the supervision module, which allows to change the basic parameters of the POLPDU control unit remotely (e.g., the discharge/suction pressure for the left/right path, the operating frequency of the left/right path, etc.). For the security reasons, turning on the remote supervision mode is possible only after the approval of the working mode of the control unit made by the local operator. Also positive verification of the user permissions on the central server CMS^2 is required.

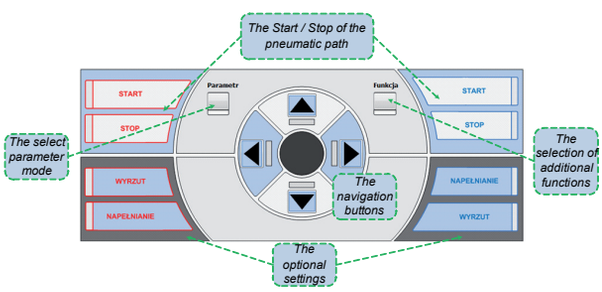

Fig. 6. The graphical interface of the supervision module of the virtual console

The software can operate in the two modes:

- **Direct mode**. The application communicates directly with the POLPDU control unit using the GPRS network. It is an emergency mode. It is used mostly in the case of the failure of the communication with central server.
- **Intermediate mode**. The application communicates with the connection module on CMS^2 central server (the server communicates with the POLPDU control units). This is the default operation mode.

When the application is running in direct mode the connection redundancy is ensured (there are two independent communication channels – supported by two different GSM providers). When the application lose the connection via the active channel it is automatically switched to the redundant one. The switching process to redundant patch is signaled by the application with the appropriate message. In the intermediate mode, the redundancy of the connection is provided on the CMS^2 central server (the communication via Ethernet and two different GPRS paths).

6. Monitoring center

The primary CMS^2 system server performs several basic task such as: the device lifecycle management (storage and tracking configuration and use of devices and components), gathering, processing and sharing the archival measurement data, advanced diagnostic of the devices, permissions and access control management. The system has the ability to remotely access the Internet network without installing any additional software. In this case, it was decided to produce the prototype in accordance with the Web-desktop technique, which is based mainly on JavaScript an Ajax technology. The server part was implemented in PHP language. The MySQL database was used to store the system configuration and archival data. To accomplish the additional computing tasks, like diagnostics, the special PHP and C++ modules were implemented.

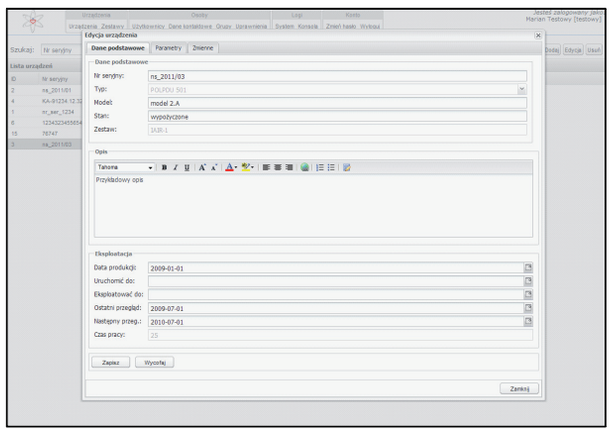

Fig. 7. An example of the graphical web interface: the artificial heart sets configuration management

In the field of devices configuration management the center provides authorized access to data and allows to perform the necessary operations connected with the lifecycle management of the devices that are the part of artificial heart assemblies (sets), such as:

- management of individual devices (defining according to the patterns, identifying the set of measurement variables and parameters, setting the operational parameters),
- assembly management (creating, deleting, etc.),
- recording service activities that are performed at the level of devices and assemblies,
- analyzing the history of use of particular devices in particular assemblies,
- user management (including the division into the different roles and groups) and the advanced permission management system in which permissions are allocated at the level of devices, users, groups, roles and individual activities,
- monitoring of the virtual console log entries.

In addition, the Web interface of the CMS^2 system allows both the on-line data monitoring from the par-

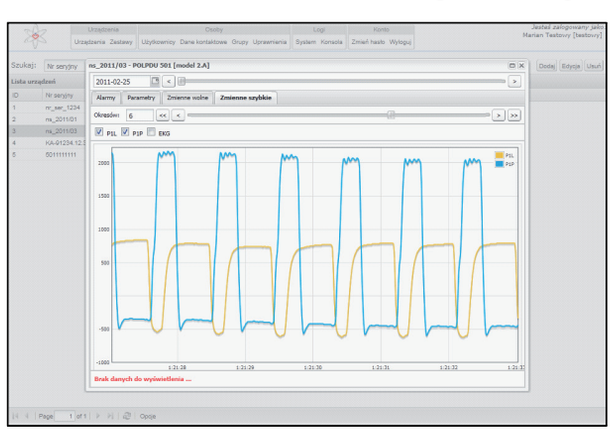

Fig. 8. The preview of the current state of the artificial heart control unit in web browser

ticular device or assemblies, as well as viewing and analyzing the archival data. The data can be presented in a graphic form (automatically or manually updates charts), and can be exported as files for use in external systems. The CMS^2 system is equipped with the features to simplify the process of searching and navigating of the historical data.

7. Conclusion

The paper presents an outline of the remote monitoring system of the artificial heart control units. The presented system consists of two parts: (a) mounted on each of the monitored devices (the communication modules) and (b) the central monitoring system. During the design and implementation of the various functional modules, the emphasis was mainly placed on the adaptation of the selected technologies to the specific system. It was assumed that this system will be handled by both the engineers and those without in-depth technical knowledge (the cardiologists and the medical support staff).

The main part of the system operates in a soft real time mode. It is connected with the data acquisition from distributed artificial heart support units (assemblies). The data acquisition deals with the following issues: collecting the measurements with a fixed sampling rate, assigning time stamps to the measurement data, tasks related to the internal transfer of streaming data from artificial heart control unit to the communication interfaces. These tasks are performed by the telemetric packages installed on the particular devices, the central communication module and data import/export services running on central server. This part of the system is fully implemented and now is under tests.

The second part of the system is connected with the management of the life-cycle of particular devices and the configurations (assemblies) in which they are working. It provides the user interfaces to configuration data. It also enables on-line device monitoring based on the data stored in database (it does not use direct communication with the devices). The current version of this part of the system implements basic features and functions. The future development of the system will be focused on those modules. In the next steps of development the following features will be added: management of patients and doctors (data storage, configuration and access), tracking the process of device selling and lending, detailed and configurable device description and definition, tracking the supply chain connected with device production and device storage.

Acknowledgements

This work was supported by the National Centre for Research and Development (NCBiR) under the Project "Development of metrology, information and telecommunications technologies for the prosthetic heart" as part of multiannual "Polish Artificial Heart" Program (task 2.1 – Developing a system of automatic control and supervision of work for extracorporeal cardiac prosthesis).

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