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POLSKA AKADEMIA NAUK

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TELEMEDICAL SYSTEM "PULMOTEL–2010" FOR MONITORING PATIENTS WITH CHRONIC PULMONARY DISEASES

Adam G. Polak, Grzegorz Głomb, Tomasz Guszkowski, Ireneusz Jabłoński, Bogdan Kasprzak, Janusz Pękala, Andrzej F. Stępień, Zbigniew Świerczyński, Janusz Mroczka

Wroclaw University of Technology, Chair of Electronic and Photonic Metrology, B. Prusa 53/55, 50-317 Wroclaw, Poland
(✉ adam.polak@pwr.wroc.pl, +48 71 320 6581, *grzegorz.glomb@pwr.wroc.pl, tomasz.guszkowski@pwr.wroc.pl,*
ireneusz.jablonski@pwr.wroc.pl, bogdan.kasprzak@)pwr.wroc.pl, janusz.pekala@pwr.wroc.pl, andrzej.f.stepien@pwr.wroc.pl,
zbigniew.swierczynski@pwr.wroc.pl, janusz.mroczka@pwr.wroc.pl)

Abstract

Telemedicine is one of the most innovative and promising applications of technology in contemporary medicine. Telemedical systems, a sort of distributed measurement systems, are used for continuous or periodic monitoring of human vital signals in the environment of living. This approach has several advantages in comparison to traditional medical care: *e.g.* patients experience fewer hospitalizations, emergency room visits, lost time from work, the costs of treatment are reduced, and the quality of life is improved. Currently, chronic respiratory diseases comprise one of the most serious public health problems. Simultaneously patients suffering from these diseases are well suitable for home monitoring. This paper describes the design and technical realization of a telemedical system that has been developed as a platform suitable for monitoring patients with chronic pulmonary diseases and fitted to Polish conditions. The paper focuses on the system's architecture, included medical tests, adopted hardware and software, and preliminary internal evaluation. The performed tests demonstrated good overall performance of the system. At present further work goes on to put it into practice.

Keywords: telemedicine, distributed measurement system, web services, spirometry, interrupter technique.

1. Introduction

Telemedicine is one of the most innovative and promising applications of technology in contemporary medicine. It combines achievements ranging from electronics (sensor technology and microprocessor systems), information and telecommunication techniques (including mobile and wireless communication, or web services) to systems for data analysis and knowledge mining. Currently, telemedicine becomes a part of intelligent and interactive systems, as intelligent home or ambient intelligence. Inherently, telemedical platforms are a sort of distributed measurement systems [1].

Telemedical systems are used for continuous or periodic recording of human vital signals in the environment of living (such as home or work), transmission of these data to a local database (via a cable or wirelessly) and then to a central repository (usually by teleinformatic services as the Internet or GSM network), and finally for analysis (often computer-aided) by medical specialists. Among the quantities most frequently measured by the telemedical systems are: heart's electrical activity (ECG), pulse, blood pressure, respiratory mechanics (spirometry), respiratory rate, oxygen saturation of arterial blood, blood glucose, and the temperature, mass and position of the body [2–4]. Simultaneously, telemedicine takes a form of personalized and patient-centred healthcare. Recent experiences and studies show that home monitoring of chronically ill patients has several advantages in comparison to traditional care: patients experience fewer hospitalizations, acute exacerbations, urgent calls

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to general practitioners, emergency room visits and lost time from work [5, 6]. Additionally, telemedical systems reduce costs of treatment, improve the management of disease and the quality of life [6–8]. On the other hand it is worth to notice that the introduction of such systems encounters diverse obstacles and doubts, and requires further work on the actual e-Health service concepts. A team of German experts (manufacturers, physicians and insurance companies) has revealed the main barriers: missing reimbursement (or participation in costs) by health insurances for the use of telemonitoring systems, unclear business models, high costs of change for the health providers, and missing access to distribution channels for small companies [9]. Also the problem of privacy preservation for patients, especially living in the environment of ambient intelligence gathering multicontext personal information, should be solved. Their detailed private data should be inaccessible by unauthorized persons.

Telemedicine is being developed worldwide. Also in Poland there are R&D teams currently working in this area (*e.g.* at the AGH University of Science and Technology, Technical University of Lodz or Wrocław University of Technology), and a growing tendency of using such systems, especially in cardiology, can be observed [10].

Chronic respiratory diseases comprise a major public health problem at present. It has been estimated that about 210 million people suffer from them and that the diseases cause about 20% of deaths with growing tendency. Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of chronic morbidity and mortality, and is expected to rank fifth worldwide in 2030 [11], whereas asthma causes that one-third of older people experience significant breathlessness [12]. Equally significant are problems with cystic fibrosis or recovery after lung transplantation. Simultaneously these particular groups of patients are well suitable for home monitoring [3, 6, 7, 13–17]. There is a convicting documentation that the best available tool for early detection and monitoring of the evolution of lung function in disease is spirometry, and more specifically – spirometric indices derived from the forced expiratory manoeuvre [14, 15, 18]. This examination is easy for self-performing by patients at home. It has been shown that telemonitoring results are valid and comparable to those collected under the supervision of a trained medical professional and that this approach can be successfully implemented in patients without previous computer experience [7, 13, 15]. This explains why spirometry has become the main medical test in the former telemedical systems for monitoring patients with chronic respiratory diseases and lung graft recipients [6, 7, 13, 15–20].

This paper describes the design and technical realization of the telemedical system PulmoTel-2010 that has been developed as a platform suitable for monitoring patients with chronic pulmonary diseases and fitted to Polish social and environmental conditions. The paper focuses on the architecture, included medical tests, adopted hardware and software, and preliminary internal evaluation of the system.

2. The system

2.1. Foredesign and architecture

The telemedical system PulmoTel-2010 has been developed as a platform for patients needing long-term monitoring of their lung function, particularly those suffering from asthma, COPD and cystic fibrosis, and living in an environment typical for Poland [21].

Patients are equipped with economical home units (HU), capable of exchanging information with a central medical server (MS) (Fig. 1). Spirometry is the basic medical test, however, an additional examination of lung mechanics, simple to self-performing and using similar equipment, is also implemented – the interrupter technique [22]. Additionally, each home unit can act as a digital recorder of data coming from other external medical instruments. It is important that a sufficiently large number of complete test results can be stored before sending them to a general database at a patient's request, when the HU is connected to communication media. The whole system (including patients, physicians and home units) is managed by MS, interchanging information and receiving data from the HUs, storing test results in a database, processing the data, and generating required visualizations.

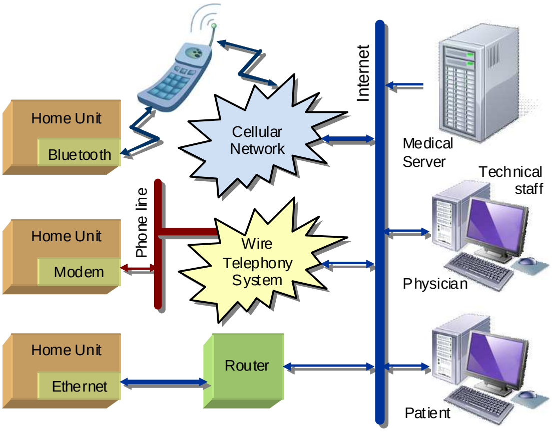


Fig. 1. Architecture of the PulmoTel-2010 system.

The HUs make contact with the MS via the Internet as the primary medium. However, taking into account the diversity of telecommunication solutions available at different regions of Poland, the data can be sent using the Ethernet, wire telephony line or a cellular network. The Ethernet connection is realised through a router, so a home Internet link can be easily shared with other devices.

The HUs and the system work under control of software applications with intuitive, user-friendly, interactive graphical interfaces. The users (patients, physicians and technical staff) can exploit the system resources via own computers connected to the Internet and using web browsers.

Additionally, the system has been developed to comply with appropriate technical and medical standards, such as IEC60601 or the recommendations of international pulmonological societies.

2.2. Medical tests

Spirometry is considered as the best tool for early detection of respiratory disease and monitoring of lung function in common medical practice. Its most significant part, the forced expiratory manoeuvre (as deep and strong as possible expiration just after a maximally deep inhalation), is the primary test performed with the home units. Flow is measured by a turbine transducer and integrated to produce volume data (see Section 3). Both signals are used to calculate the main spirometric indices (FVC, FEV_1, $FEV_1\%FVC$, PEF, MEF_{75}, MEF_{50}, MEF_{25}, $FEF_{25\text{-}75}$) according to the recommendations of Polish (PTChP), European (ERS) and American (ATS) pulmonological societies [23, 24]. These results can be compared to predicted values (ECSC and Hankinson), dependent on patient's gender, age and height, computed with the use of implemented regression equations [25, 26]. The implemented procedures include also the automatic detection of the beginning and end of expiration, and the assessment of test acceptability and between-manoeuvre repeatability [24, 27].

The interrupter technique allows the determination of the so-called interrupter resistance [28], covering mainly airway resistance (strongly dependent on the airway calibre, substantially reduced *e.g.* in asthma), using a simple set of pressure and flow transducers attached to a shutter (see Section 3). The resistance is calculated from the pressure recorded at the airway opening after occlusion of the shutter (for 100 ms), divided by the flow measured during passive expiration just before interruption, with the use of the linear back-extrapolation method [29]. This procedure is repeated during four subsequent breaths and finally the average value is presented together with its standard deviation. Basing on the same pressure and flow signals, the input respiratory impedance spectrum is computed in the range between 20 and 250 Hz [30]. This approach reveals antiresonance peaks reflecting, among others, airway walls compliance [31]. The amplitudes and central frequencies of the peaks are very sensitive to changes in respiratory mechanics [32–34], and thus useful in diagnostics.

3. Home units

3.1. Hardware

The home unit (HU) uses a low-cost embedded development system Network Gateway NGW100 (Atmel) as the core platform (Fig. 2). It includes among others a 32-bit AVR processor (AP7000) running at 140 MHz, 32MB SDRAM, 16MB on-board flash memory, expandable memory through SD or MMC memory cards, USB connection and an Ethernet controller.

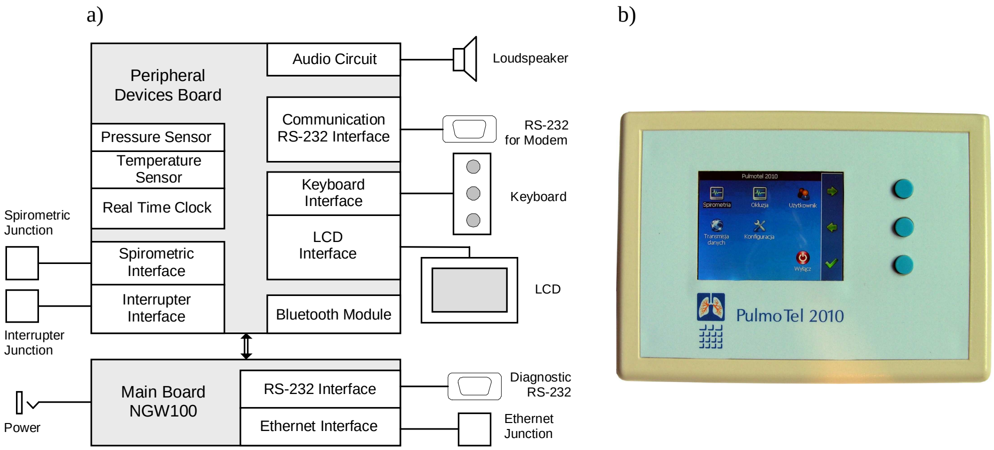


Fig. 2. Home unit: a) a block diagram and b) outward appearance.

The system has been supplemented with three groups of peripheral devices building the user interface, additional communication controllers, and interfaces for medical transducers. The user interface includes an LCD alphanumerical display (WF35DTIBCDB 3.5” TFT QVGA 320×240, Winstar), a simple three-button keyboard and a loudspeaker. The patient can interact with the HU, *e.g.* choosing her/his name from the list of users, selecting the medical test to be performed or transmitting stored results to the medical server, using a context menu and reading short massages form the LCD and pressing appropriate buttons. The audio subsystem is prepared to generate sound comments that assist the execution of medical tests (saved as WAV files) via the ABDAC audio bitstream D/A converter. There are two additional sensors necessary for the correction of measured volumes [25], registering ambient temperature (MCP9800, accuracy of ±0.5 ºC, Microchip) and absolute pressure (MPXA4115AC6U, range of 15–115 kPa, accuracy of 1.5% , Freescale) as well as a real time clock for labelling the medical tests (DS1338Z33, Maxim). These peripheral components are connected to the controller by an I^2C interface.

Two additional communication media (beside the Ethernet integrated with the main module) have been made available in the system, enabling the connection between the HUs and the MS by a wire telephone line or mobile phone. In the former case an analog modem mediates between the HU and the wire telephony system, and in the latter one a short-range Bluetooth link is used to couple the HU with the phone connecting to a cellular network by GPRS/EDGE service. The external telephone modem and internal Bluetooth module (Bluegiga WT12) are connected to the NGW100 via a commutated RS-232 interface.

The home unit is adapted to cooperate with the turbine flow transducer and the interrupter set. The turbine (Micro Medical Ltd., resolution of 0.025 $dm^3 \cdot s^{-1}$ or 10 cm^3, accuracy of 3% of measured value) generates electrical impulses with the frequency proportional to the temporary airflow. Time periods between the impulses are measured and linearly interpolated to a sampling frequency higher than needed (2.2 kHz), digitally low-pass filtered (Kaiser, cut-off frequency 50 Hz) and decimated, yielding finally flow samples at 100 Hz, according to the pulmonological societies' recommendations [24]. These samples are integrated numerically (trapezoid rule) producing volume data, necessary to calculate spirometric indices.

The interrupter set consists of a shutter (Micro Medical Ltd.) combined with flow (Lilly type pneumotachometer, resolution of 0.01 $dm^3 \cdot s^{-1}$, range of 0–2 $dm^3 \cdot s^{-1}$) and pressure (piezoresistive) transducers. The shutter interrupts the expiratory flow producing a change of pressure, and both signals are sampled by a 12-bit A/D converter at 500 Hz. The data are analyzed on-line and placed in a memory via a DMA controller. They are labelled with a test mark and number and the current time.

The home unit is supplied from an external medical AC/DC power supply adaptor (MES30B-3P1J, Mean Well) designed for medical devices.

3.2. Firmware

The home unit works under control of the Linux operating system. All the firmware components have been written in the C programming language (Fedora Eclipse) using the Buildroot packet (Atmel), applying the library uClibc, and then compiled by an AVR32 GCC compiler that has enabled the generation of the complete Linux system. These files include three categories of procedures: shell scripts, drivers for the peripheral devices and user applications (Fig. 3).

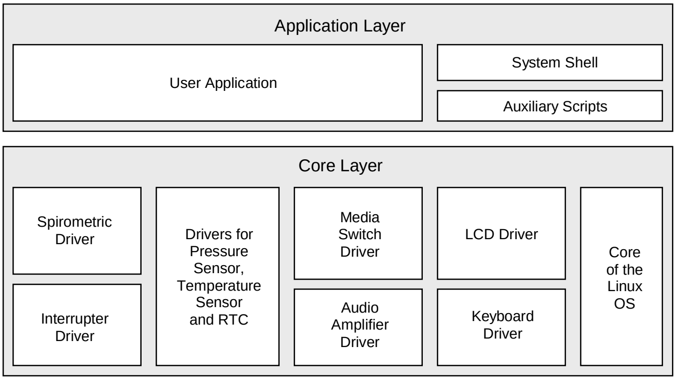


Fig. 3. Block diagram of home unit's firmware.

A configuration file is also stored in the HU, sent from the MS with the list of patients attributed to the given HU and other system information. The code located in the FLASH memory runs in the core or user (application) mode. Measurement data from the medical examinations are stored in the internal memory (up to 200 complete tests) and sent via the Internet to a database located in the MS at patient’s request.

4. Medical server and system software

The medical server is responsible for communication with the home units, medical data acquisition and storage, processing raw measurements, graphical presentation of the system resources to the users, as well as the management of patients, physicians and HUs. The system software was implemented on the Dell PowerEdge 2900 (Dual-Core Intel Xeon 5000) working under the Linux OS (Mandriva distribution). Generally, the software consists of four main layers: acquisition, data, processing and presentation ones (Fig. 4). Elements of the system exchange information via the Internet using the Virtual Private Network (OpenVPN) tunnel and the HTTP protocol. The network creates authorized and encrypted connections, ensuring a high-secure transmission of personal medical data.

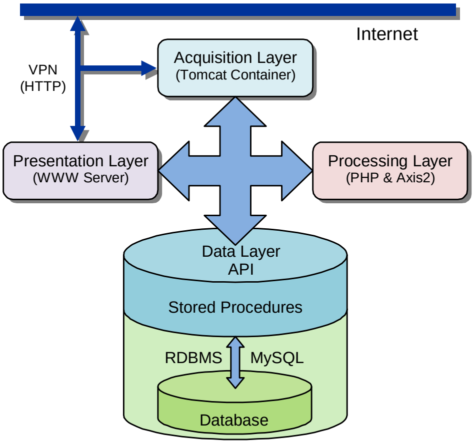


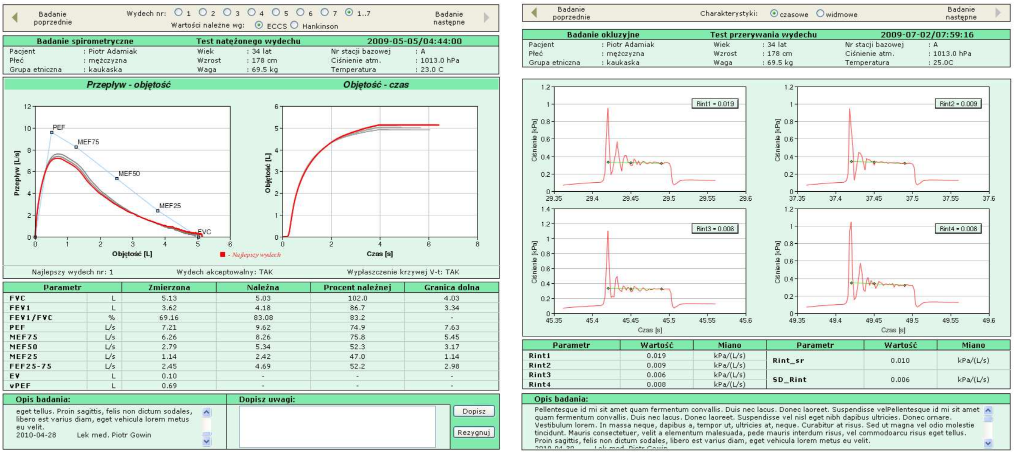
Fig. 4. Organization of system software at the medical server.

The Acquisition Server is one of the most important elements of the MS. It collects, verifies (according to an established transmission protocol) and registers the results received from the HUs in the database, as well as sends configuration files with a list of entitled patients to the HUs. A created servlet makes a preliminary validation of packets coming from the home units, parameterizes data and sends them (Database Connection Pool mechanism) to the Data Layer Application Programming Interface (API). The acquisition layer has been elaborated using the Tomcat Container (Apache) and implementing Servlet 2.5 i JSP 2.1 (SUN Microsystems) specifications.

The Data Layer governs information covering patients (personal and address data including anthropometric information), physicians, technical staff and home units data as well as the results of medical examinations (spirometry and interrupter tests). All this information is stored in a developed relational database (DDL SQL language). Its structure consists of related tables ensuring that specific patients are coupled with a given HU and each of physicians is associated with the patients she/he takes care of. The special interface Data Layer API, consisting of a few dozens of procedures, has been defined for the maintenance of the layer by applying the stored procedures mechanism. Additional programs provide other functionalities as *e.g.* patient or home unit registration by web applications. The database has been created using the open source Relational Database Management System (RDBMS) MySQL. It is also supplied with the PHP interface for the web applications.

The Processing Layer is responsible for the computation of spirometric and interrupter indices, since only raw results of the medical tests are held in the database, reducing its size. Once a page displaying a specific examination is called by a user, adequate indices characterizing this test together with the predicted values are calculated from the recorded flows and anthropometric data using PHP scripts, visualised and kept on the WWW server to the end of the session. The indices are determined according to their definitions [24] after a correction of volumes (using the measured ambient temperature and absolute pressure) [25].

The Presentation Layer is organised as a WWW service accessible from personal computers by internet browsers (FireFox v.3 and higher, Opera v.5 and higher, Internet Explorer v.7 and higher). Its role consists in making the database information available to the three types of entitled users, defined in the database: patients, physicians and members of the technical staff. The exploitation of the service is possible after the authentication of a user by login procedure. The patients are allowed to browse only their own examination results and the physicians have access merely to their patients' data. Entitled members of the staff may administrate the system or/and register and modify patients and home units data. Beside these dedicated functions, the service presents a general information about telemedicine and the PulmoTel-2010 system accessible for all web users.



Badanie spirometryczne **Test natężonego wydechu** **2009-05-05/04:44:00**

Pacjent : Piotr Adamiak
Płeć : mężczyzna
Grupa etniczna : kaukaska
Wiek : 34 lat
Wzrost : 178 cm
Waga : 69.5 kg
Nr stacji bazowej : A
Ciśnienie atm. : 1013.0 hPa
Temperatura : 23.0 C

Najlepszy wydech nr: 1
Wydech akceptowalny: TAK
Wypłaszczenie krzywej V-t: TAK

Parametr		Zmierzona	Należna	Procent należnej	Granica dolna
FVC	L	5.13	5.03	102.0	4.03
FEV1	L	3.62	4.18	86.7	3.34
FEV1/FVC	%	69.16	83.08	83.2	-
PEF	L/s	7.21	9.62	74.9	7.63
MEF75	L/s	6.26	8.26	75.8	5.45
MEF50	L/s	2.79	5.34	52.3	3.17
MEF25	L/s	1.14	2.42	47.0	1.14
FEF25-75	L/s	2.45	4.69	52.2	2.98
EV	L	0.10	-	-	-
vPEF	L	0.69	-	-	-

Opis badania:

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2010-04-28 Lek med. Piotr Gowin

Dopisz uwagi:

Badanie okluzyjne **Test przerywania wydechu** **2009-07-02/07:59:16**

Pacjent : Piotr Adamiak
Płeć : mężczyzna
Grupa etniczna : kaukaska
Wiek : 34 lat
Wzrost : 178 cm
Waga : 69.5 kg
Nr stacji bazowej : A
Ciśnienie atm. : 1013.0 hPa
Temperatura : 25.0C

Parametr	Wartość	Miano	Parametr	Wartość	Miano
Rint1	0.019	kPa/(L/s)	Rint_sr	0.010	kPa/(L/s)
Rint2	0.009	kPa/(L/s)			
Rint3	0.006	kPa/(L/s)	SD_Rint	0.006	kPa/(L/s)
Rint4	0.008	kPa/(L/s)			

Opis badania:

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Fig. 5. Examples of spirometric (left) and interruption (right) test results accessible by web service.

The service offers four types of graphical, interactive documents: general, patient, physician and technical staff ones. All the documents have the same structure consisting of four elements: header, menu, basic content and footnote (see *e.g.* Fig. 5, without the header and menu). Depending on the menu selection, in the basic content display the user can *e.g.* browse through a list of registered medical tests, choose and watch the results of a specific examination, or access the visualization of index trends. It is also possible to make a hardcopy of the results using a printer.

The WWW service has been built using HTML (v.4.0) documents created dynamically by PHP scripts running on the WWW server. The documents use the Cascading Style Sheets (CSS) to define page views. Simultaneously some scripts built in the documents are executed at the client side, enhancing the interactivity of the WWW pages. The WWW transmission is organized by a stateless HTTP protocol, working in the question-answer mode, so the file of a PHP session is stored during the service in the WWW server. Some parts of the service have been created with the JavaScript and AJAX languages.

5. Internal validation

Internal validation of a telemedical system consists in testing all the aspects of system performance that can be checked without external interactions, and should be performed before the trials with real patients. The tests of PulmoTel-2010 were focused on the hardware, firmware and electrical safety of the home unit, communication between the unit and the medical server, as well as on the software managing the four layers of the system services. The results showed a few issues improved thereafter and finally demonstrated a good overall performance of the system.

5.1. Tests of the home unit

The home units work under Linux, which is not a real-time system. On the other hand the medical tests, particularly the interrupter technique (with the sampling frequency of 500 Hz) require accurate time control. A few experiments have been performed to analyze time events in the HU's system using an oscilloscope (Tektronix TDS210) and chosen electrical lines. They demonstrate that, after blocking operations generating additional but unnecessary processor interruptions, the medical tests are performed properly in the real-time regime.

Electrical medical safety of the HU was tested according to the IEC/PN 60601-1 standard using the Rigel 277 Plus (Rigel Medical, Seaward Group) analyzer working in the semi-automatic mode. According to this standard, HUs were classified as II class BF type devices. The tests were executed in different configurations of the probe and modes of HU's operation. Measured leakage currents did not exceed 11 μA (with the relevant acceptable value of 500 μA), demonstrating a high level of electrical medical safety of the HU.

The HU's firmware was checked by manifold invoking options from its menu, including medical tests and data transfer to the MS. The recorded spirometric and interrupter data were additionally sent to a PC via the RS-232 interface, using a HU's service application. Then, running a Web browser, these records could be compared with the data from the same tests stored in the system database.

5.2. Tests of system software

The first trials were focused on the correctness of communication (including transmission of data and configuration files) between the HU and MS via the available media. The earlier stored medical data and files were successively sent applying both the direct Ethernet connection or using the analog modem (TP S.A. network, PPP protocol) or a mobile phone (Orange network, PPP protocol) coupled with the HU by Bluetooth interface.

The most challenging part of validation were the tests of database integrity and consistency, since one can assume that the system will monitor hundreds of patients, each of them (supervised potentially by a few physicians) with hundreds of medical tests performed and stored [35]. It was impossible to fill the database with such a big number of real tests at this stage of the project. To achieve the needs, the Home Unit Simulator has been elaborated to generate such data. This application exactly mimics the operation of a HU: it assumes a specific serial number, accepts configuration files from the server, enables the selection of a given patient from the list and the date from the unrolled calendar, can set the ambient pressure, and finally generate spirometric or interrupter data. Both tests are simulated using computational models for the respiratory system [36, 37]. Generated data are randomized by a rescaling procedure, with parameters depending on the date of simulated examination, allowing the trend visualization of calculated indices. All these output data are organized according to the system transmission protocol and sent to the server. Dozens of sets of medical data ascribed to a group of virtual patients (managed by virtual physicians) were generated by the simulator and used to verify the applications from the data, processing and presentation layers. There were no problems observed during this part of tests.

6. Summary

New technologies are very useful in the remote care for patients at their homes, reducing costs, improving the management of disease and the quality of life. We have developed a telemedical system for monitoring patients suffering from chronic respiratory diseases, achieving the main objectives as lung test self-performing, transmitting patient's tests, processing raw data, storage and presentation of the test results, as well as remote managing of the overall system. The adoption of the microcontroller-based system, relational database and web technologies enhance easy interaction between the system and users, including both the patients and physicians. The system was internally validated by performing adequate tests of all the components, beginning from the medical signal registration and electro-medical safety, through communication correctness to the efficiency of the database and system management. At present further work goes on to produce and put the PulmoTel-2010 (existing actually as a model) into practice as a commercial telemedical system.

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