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Design of a Methodology for Assessing an Electrocardiographic Telemonitoring System

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Abstract—**Recent studies in Bioengineering show a great interest in telemedicine projects, it is motivated mainly for the fast communication technologies reached during the last decade. Since then many telemedicine projects in different areas have been pursued, among them the electrocardiographic monitoring, as well as methodological reports for the evaluation of these projects. In this work a methodology to evaluate an electrocardiographic telemonitoring system is presented. A procedure to verify the operation of Data Acquisition Module (DAM) of an electrocardiographic telemonitoring system is given, taking as reference defined standards, and procedures for the measurement of the Quality of Service (QoS) parameters required by the system in a Local Area Network (LAN). Finally a graphical model and protocols of evaluation are proposed.**

I. Introduction

THE development of medical devices and telemedicine systems as well as other medical technologies such as drugs development, require of evaluations that guarantee their use with minimum risk. Medical technologies evaluations are defined to determinate: efficacy, security, and cost-effectiveness of such technologies, besides the ethics and legal consideration of some of them [1]. In telemedicine system factors as acceptability, accessibility and cost of the system must be considered. For a determined application the efficacy of an electrocardiographic telemonitoring system depends on electrocardiographic monitoring section, and network efficacy [2]. From a technical point of view, electrocardiographic monitoring section efficacy can be determined, by mean of the cross-check between its operation and established standards [3]. Network efficacy evaluation for certain telemedical applications depend among other factors on their technical capacities such as security, availability, Quality of Service (QoS) and ubiquity [4]. In the present work only the QoS requirements needed by the telemedical application that network must provide are considered.

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The goals of the present work are: 1) to develop a procedure for the cross-check of the electrocardiographic monitoring section functioning, taking defined standards as a reference, 2) to develop a procedure for the determination of QoS parameters values required by the telemedical system, 3) to propose a methodology to evaluate an electrocardiographic telemonitoring system.

This paper is organized as follows, section II describes the electrocardiographic telemonitoring system to be evaluated, and section III presents a procedure to verify the operation of the electrocardiographic monitoring system. A graphical model and protocols of evaluation are presented in section IV. In section V the methodology for application of all previous procedures is described; and in sections VI and VII results and conclusions are given.

II. Electrocardiographic Telemonitoring System.

The electrocardiographic telemonitoring system is designed to send three or five lead of electrocardiografic signals from local station to remote station. The electrocardiographic telemonitoring system is composed of: the electrocardiographic signals, a Data Acquisition Module (DAM), a local station, an access point, a modem (CDMA or ADSL), a telephony network (wired or wireless), the Internet, a server with a database, a remote station connected to a WAN network in direct form or through a LAN network and the electrocardiographic records [5]. The colors in Fig. 1 indicate actual development stage for each component.

Fig. 2 shows the blocks that compose the DAM: an Application-Specific Integrated Circuit (ASIC), an analog to digital converter, CMOS to RS232 converter and a control block.

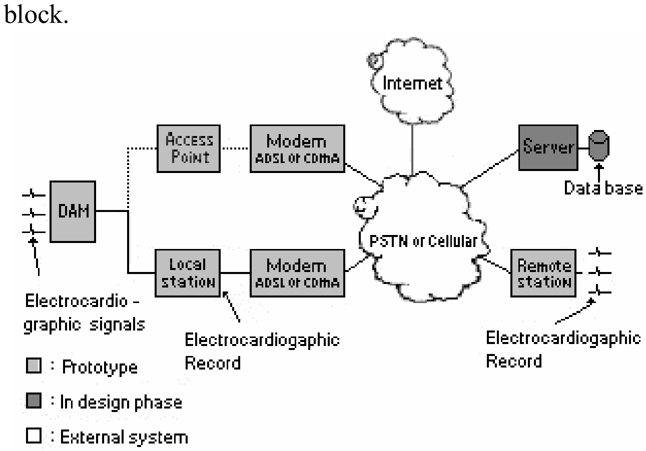

Fig. 1. Electrocardiographic Telemonitoring System.

The local station is constituted by a PC or PDA with a client/server application that allows to the physician the monitoring of data storage and processing originated by the DAM. This station serves as link between the DAM and the remote station or server, allowing the communication between primary care physician and specialist physician. The link to the data acquisition module is implemented with a RS232 serial interface. The minimum requirements for the local station (PC) are: Window® 2000 or XP operating system, and a RS232 serial port. The local station is connected to the remote station located in an Intranet or Internet using a broadband modem (ADSL) through the Public Switching Telephony Network (PSTN) or using a CDMA modem through telephony cellular network. The access point is used to communicate the data acquisition module with different stations (local, remote and server) through wired or wireless connections using serial communication protocols from RS232 to TCP/IP.

The remote station is constituted by a PC or PDA with a broadband Internet connection, and with a client/server software application that allows the monitoring, stororing and processing of the data originated by the DAM. This station can use the multimedia capacity that offers the link with the local station for send audio, video, and medical data, between this station and remote station.

The database server is constituted by a high speed processing computer equipped with a hard disk of high storage capacity, and a client/server architecture that allows to users (remote stations) the access to the information contained in the database; the programming for this architecture is of multitasking type. Communication and coordination in the client/server processes are carried out using TCP/IP sockets.

The database is used to store the information originated from the DAM. In order to guarantee a safe use and privacy of the information stored in the database a firewall is used, this filter can be implemented by hardware or software.

The firewalls detect and eliminate the packets of not authorized data. For a higher level of protection of information, the departing data of each station (local or remote), server and the access point can be encrypted. If it is necessary the server can use a communication protocols converter or Gateway. The server can also process the data allowing getting a diagnosis for a patient. In the design process, the verification and validation of medical devices should be made considering the standards defined by regulation agencies [3].

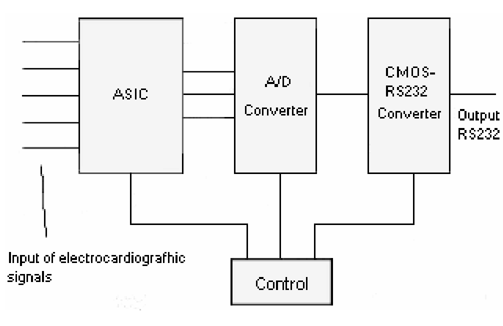

Fig. 2. Data Acquisition Module.

For electrocardiography devices validation the following standards are proposed: the ANSI/AAMI EC13:2002 for Cardiac Monitors, heart rate meters, and alarm; and the ANSI/AAMI EC71:2001 for standard communications protocol in computer-assisted Electrocardiography. These standards contain information about the technical characteristics of the system to be evaluated, specifically about the DAM and also provide methods of measurement for the verification of operation of this device.

III. Measurement Of Quality Of Service (QoS) Parameters.

The use of the Internet for health applications demands some technical capabilities for the network. These technical capabilities are defined by: bandwidth, latency, jitter, packets loss rate, availability, security and the ubiquity [6]. The first fours factors mentioned above are called network QoS parameters. These parameters allow to characterize the network and to indicate if it can be used for a specific application. In the present, most connection to Internet (IPv4) suppliers only make "the best effort" to give a quality connection, indicating only the maximum velocity of transmission that can be reached in a certain moment. Actually a LAN can not offer a QoS, however a Multiprotocol Label Switching (MPLS) networks which is one of the most important networks that can offer the QoS [7]. The links used in the network (backbone) have improved notably in recent years; this fact along with a significant increase of computers data processing velocity has allowed improving some applications such as voice over the Internet (VoIP). The knowledge of QoS parameters values in telemedicine applications can be useful for evaluations [8] when the QoS protocol will be deployed across the New Generation Internet (NGI) testbed networks.

IV. Graphical Model And Protocols Of Evaluation.

Once the system is implemented it is necessary to measure its impact. In this work a telemedicine evaluation graphical model based on the model developed by a group of researchers of Missouri University is proposed [9]. In the model three dimensions are considered: the analysis level, the focus of analysis and the different uses of the telemedical system, as can be observed in the Fig. 3. The first model dimension refers to the analysis level which can be: individual, the community or the society. The second dimension refers to the area of analysis which is divided into: quality, accessibility, cost and acceptability.

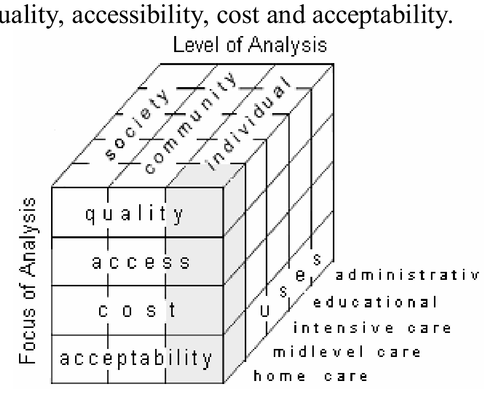

Fig. 3. Graphical evaluation model

Quality is defined as the degree in which health care services increase the probability of reach the desired health level considering current knowledge. The accessibility refers to an appropriate medical attention on time. The cost is the economic value of the resource used associated with the search of defined objectives or results. The acceptability refers to the satisfaction degree of patients, medical personnel, and others with the service. The third dimension refers to the use of the telemedical system: administrative, educational, intensive care, midlevel care and home care. The shaded area in the cube in Fig. 3 is an example of an evaluation type.

V. METHODOLOGY

The methodology proposed for the development of this work was divided in four phases. The first phase was an exhaustive bibliographical revision relating to verification, validation and evaluation of medical devices and telemedicine systems oriented to electrocardiographic monitoring.

The second phase was the elaboration of a procedure to verify the system operation, taking as reference the ANSI/AAMI standard for electrocardiographic monitoring. The requirements that the system to be evaluated must meet, according to the ANSI/AMMI EC13:2002 standard are: specific operating conditions, leakage current, QRS detection, range and accuracy of heart rate meter, alarm system, special requirements for monitors with ECG waveform display capability, and electromagnetic compatibility. The ANSI/AMMI EC71 standard specifies the content and structure of the information that must be exchanged between the DAM and computer ECG management (ECG DBMS) and others ECG data storage systems. The previous procedure allows defining the electrocardiographic records precision, as well as the DAM reliability.

In the third phase, a procedure was developed to determinate the minimal QoS required by the system in the communication TCP/IP using a specific local area network. The minimum QoS required by the system, can be achieved using specific measuring equipments, as for example: the monitor of networks MD 1230A of Anritsu®, or utilizing network emulation programs, some of the most recognized network emulation sotfwares are: NCTuns [10], Netdisturb [11], and Imunes [12]. This last program was selected because it is of live CD type, allows to control all the QoS parameters (with exception of jitter), and it is a free distribution program. The jitter and others QoS parameters can be determined using the program Netdisturb, but this is not free distribution software and must be installed in hard disk. The procedure followed to measure QoS parameters begins sending an ECG signal to a local network through an access point which converts the RS232 protocol to TCP/IP, then it goes to a concentrator Hub A and finally to a concentrator Hub B, see Fig. 4. The LAN network is complemented through a computer equipped with two network cards, and a network emulation program. Delays, loss of packets and bandwidth limitation between both extremes of LAN network can be generated changing the links QoS parameters in the virtual section of the LAN network. In other computer connected to concentrator HUB B the electrocardiografic records transmitted are received.

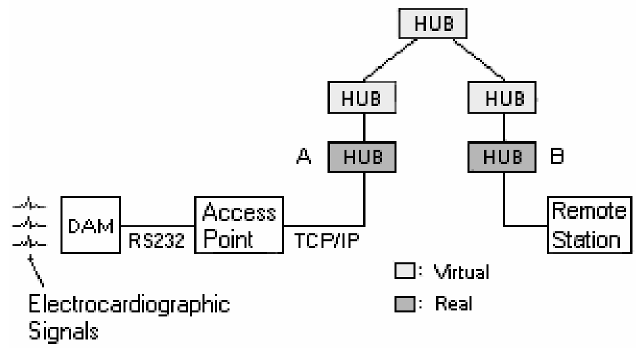

Fig. 4. System for the measurement of QoS

The minimum QoS requirements tolerated by the system are defined from the analysis of the time required to receive the electrocardiographic records according to the parameters selected.

The fourth phase was a procedure for the evaluation, it explain how the surveys are applied to patients and physicians, before and after the use of the telemonitoring system. The surveys questions can be answered in quantitative and qualitative form. The Likert scale can be used to quantify qualitative answers, with this scale the average value and the standard deviation for each question answered by users can be obtained.

Depending on these values a significant answer to each question can be obtained. When the survey is applied twice, before and after the use of the telemedicine system, the function T-TEST can be utilized to evaluate if the difference between the two averages obtained is statistically significant. In general, it is assumed that a p value minor or equal to 0.10 is statistically significant and it can be say that there is a 90% of security that the difference between the two averages is not coincidental.

Two protocols are proposed to evaluate the telemedical system: installation and clinical protocols. Such protocols are defined as a group of procedures that allow obtaining an evaluation of the system. A brief description of each protocol is presented in the following text.

A. Installation Protocol

1) Inspect the place where the system will be installed. It is necessary to obtain information about how is used in such place either a conventional medical equipment, or an equivalent to the one that has been designed. Also technical information must be collected in this stage.

2) Assure that CDMA and ADSL Internet connections are available, two of each type are required in case that it's desired to evaluate the system using both: local station and access point. It is not necessary have the two lines at the same time since it is possible to begin to work in ADSL and then to change in CDMA.

3) Install the PDA and the DAM next to the electrocardiograph used in consultations. Also a PC must be installed in the physician office or in a nearby place in order to represent the remote station

4) Install the application software in the PDA and PC at the local station, and configure these with IP direction and respective port.

B. Clinical Protocol

1) Fill the patient identification data in the application software database in the PDA or PC at the local station.
2) Record the patient electrocardiogram with the conventional clinical protocol. Then, the physician and the patient would fill the initial questionnaires.
3) Connect the electrodes of the DAM in parallel with the electrocardiograph and get the electrocardiogram with both systems at the same time.
4) The electrocardiographic record obtained with the DAM must be sent to the remote station.
5) The medical personnel and the patient fill the final questionnaires.

VI. RESULTS

A verification procedure of the monitoring characteristics of an electrocardiographic system has been achieved taking as reference the ANSI/AAMI standard.

In tables: I, II and III the effects on the data packets sent from concentrator HUB A to the remote station using the command Ping can be observed. In this experiment the values of quality of service parameters are changed between these two network points. In table I, the effect of decreasing the bandwidth causes a latency increasing on sent packets. As it can be observed in table II the delay obtained is equal to the initial delay to a rate of 100 Mbps, the velocity with which the previous measurements were done (see last row of table I), plus the delay introduced. In table III, It can be observed that an increase on the BER value causes a lot of information and the link is lost.

TABLE I.
BANDWIDTH VARIATION

Rate (Mbps)	Effect: Delay (ms) * *average value
0.001	1728
10	0.504
100	0.344

TABLE II
DELAY VARIATION

Delay (ms)	Effect: Increase the Initial Delay (ms)
1	1.344
5	5.344
8	8.344

TABLE III
BER VARIATION

BER (Bit Error Rate)	Effect
0.001	link down
0.0001	loss 25 % of packets
0.00001	not loss packets

VII CONCLUSIONS

The present work has considered the defined electrocardiographic monitoring standards in the development of a Data Acquisition Module (DAM) for a new electrocardiographic telemonitoring system. Also a methodology to determine the QoS parameters values required for this system and a graphical model and evaluation protocol are proposed. As a future work, we want to use the procedure developed here for the determination of QoS parameters values required by other vital sign telemonitoring system.

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