The Black Box: Biomedical Signals and Event Recorder in the Cath Lab

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Abstract

The aim of this work is the development of a software modules collection capable to acquire, elaborate and archive biomedical signals and related information using the HL7 Version 3 standard format in order to achieve full portability and to adhere to international standards for the exchange of such information in structured form.

The resulting system uses a graphical user interface (GUI) to drive software for acquiring and analysing biomedical signals. Structured messages and WEB-services are used for data and signal diffusion.

1. Introduction

Invasive cardiac procedures are characterized by a large amount of complex information derived simultaneously from different sources while interpretation remains a challenge. Moreover, a complete revival of procedure information is needed even for medico-legal purposes.

In particular the Electronic Patient Record (EPR) present in our institution includes angiographic imaging, biomedical signals, workflow data, clinical events and patient status.

At present, the information is separately produced through several components: the angiographic system, the electrophysiological data recorder, the workflow event recorder, the hospital information system and the radiological information system.

There is, also, the necessity to maintain the time correlation between the various kinds of available structured data and the continuously monitored physiological signals.

The research objective is the development of a dedicated system, capable to collect, to transform and to trace the new incoming data.

Obtained information should be stored into a relational database and can be presented, analysed and distributed via web services using common communication standards for further elaboration.

2. System architecture

The Black Box system works with two main parts:

- A front end, that collect real life annotation from the cath lab electronic journal and real life signals gathered from a standard polygraph recorder.
- A back end processor, that makes analysis and annotation, produces and stores CDA documents, in FDA format Fig. 1.

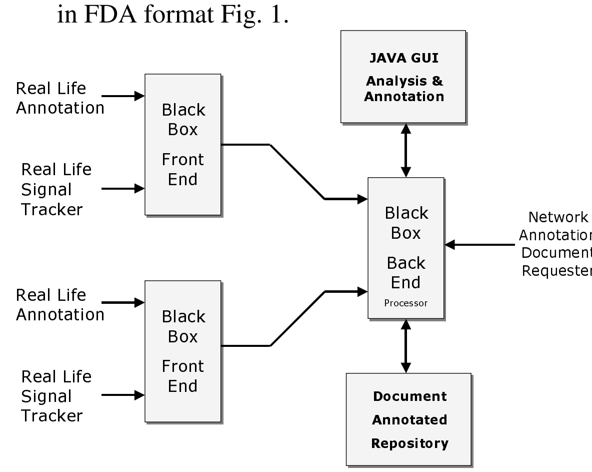

Figure 1. System Architecture

3. Methods

The collection of software modules, which will be presented here, has been implemented using LabView, graphical programming environment for signal processing and simulation of physical instruments, produced by National Instruments Inc [1]. This software includes large number of dedicated libraries needed for signal processing, statistical analysis, program to program communication. The black box front end, is a dedicated workstation, equipped with a PCI MIO16-XE50 DAQ board. The LabView, is used for acquisition of biomedical signals. The signals are sampled at 500 samples/sec rate to permit accurate analysis of registered signals. The relational database, used for collecting information on workflow events, clinical data, patient status etc., is implemented in FileMaker [2]. The database is filled on line during the procedures of catheterization by the paramedical staff. It contains all relevant cardiac events occurred during the study. Furthermore, events generated automatically from medical equipment, like start of image acquisition, start of injection of contrast medium etc., are stored in it.

3.1. Data acquisition

To leverage the impact on every days work in catheterization room, continuous recording of biomedical signals is done for the entire duration of hemodynamic study. The recording of biomedical signals starts and ends with acquisition of 12 ECG leads. During a study, both number and type of channels and their configurations are subject to changes. The procedure steps needed for the selection of the appropriate configuration are reduced to a single click of the end user. A software module, implemented in LabView, performs the actual registration of biomedical signals. It, also, provides the display of monitored channels emulating the functionalities of Polygraph (a specialized equipment present in Cath Lab and used for monitoring and recording (on paper) of biomedical signals).

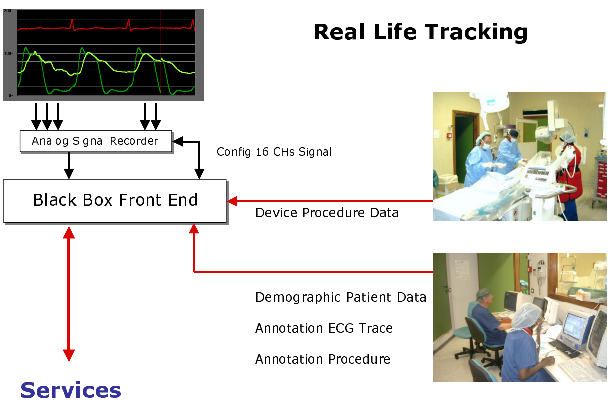

Figure 2. Data Acquisition

3.2. Communication Protocol

The Black Box Front End system receives and process limited number of messages that are sent through POST (or GET) requests using the HTTP 1.1 protocol.

The most important messages are:

- Test Hardware
- Start Acquisition
- Stop Acquisition
- Mark
- Change Configuration
- Get Data
- Set Data
- Transfer Files To...
- Start Revision
- Stop Revision
- Analyze...
- Move to marker...

To achieve this, we have implemented a “light” version of http 1.1 server, directly in LabView, which can reply to POST/GET request. The final result is that our DAQ system could be driven by any application able to generate POST/GET request over TCP/IP network. The “Start Acquisition” command put DAQ system in acquisition mode; the mode is changed only after the reception of “Stop Acquisition” command, which corresponds to the termination of the catheterization procedure. The reply message generated by EDAQ contains the time stamp field used for time synchronization and temporal correlation between recorded events and acquired signals. Our web server is able to process up to 10 simultaneous request and is provided with a basic internal TCP handler that allows to grant access to the server only for specific Internet addresses (or domains), and to deny access to all others.

3.3. Events' synchronization

We need to distinguish two different classes of events. The first class is composed from events automatically generated by the system or part of it (like start of data acquisition, start/stop image sequences acquisition, start of injection of contrast medium etc.). Since all parts of the system share the common time line given by the time server, time resolution for this kind of events is given by the resolution of time server, which is 1 ms. We have, also, ignore the time needed to generate the message by the system itself. The second class is formed from events generated by the end user of the system. This class include study relevant events inserted in a relational database directly by the end users. Those events have an intrinsic indetermination of 1 sec, which is the resolution of FileMaker internal clock. However, the actual time indetermination for user inserted events is in order of several seconds; this is due to the fact that the event recording has a lower priority when in contrast with the medical (paramedical) activities performed during the hemodynamic study.

3.4. Data storage

At the end of hemodynamic study the “Stop Acquisition” message is sent to EDAQ.

The body of the message contains the list of all events registered during the procedure. The application, then, transfers all relevant files generated during the study (data file, events file etc.) to Signal Repository Server (Back End Processor). The daily archived signals are saved on CD support for future elaborations.

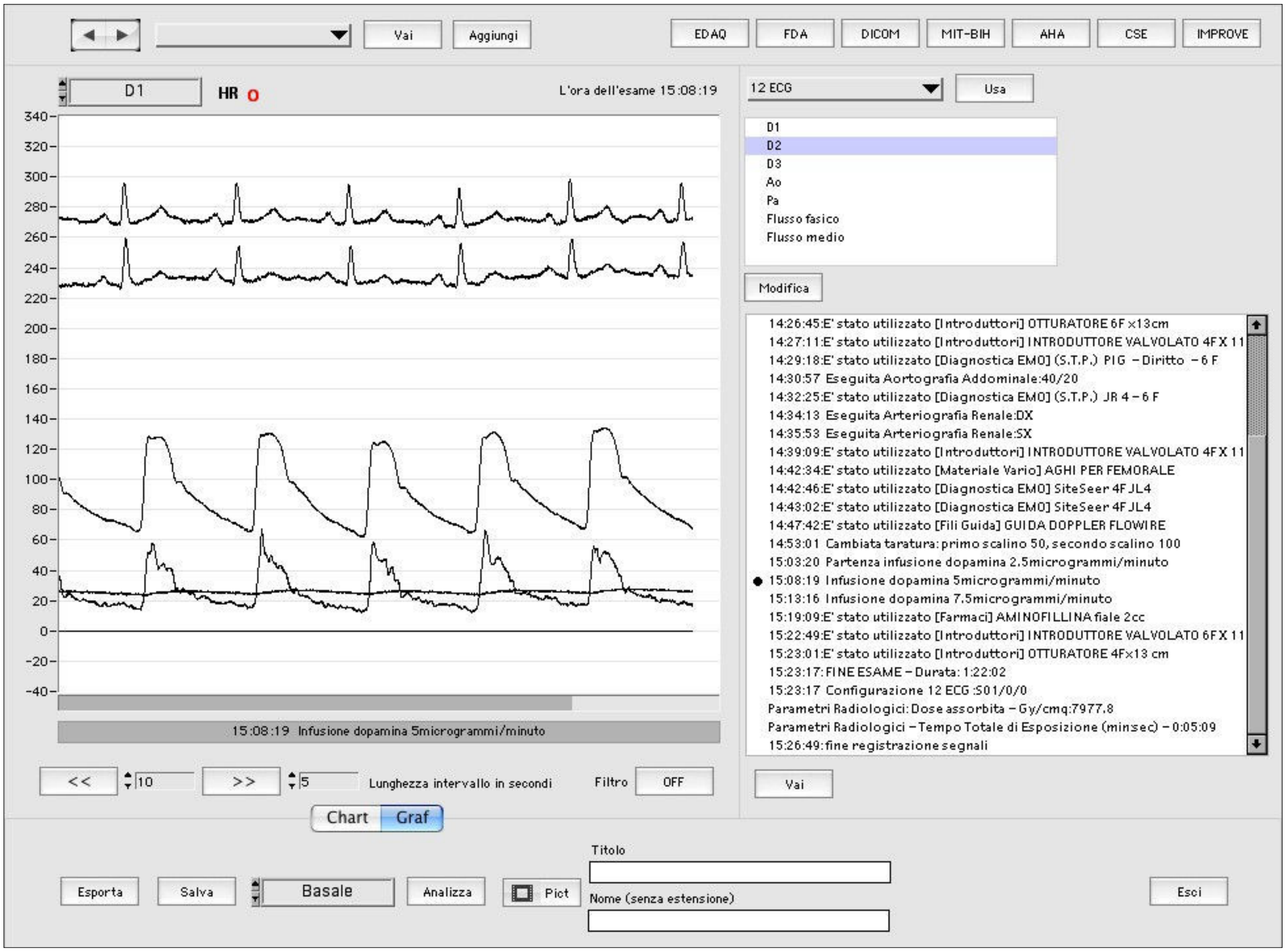

Figure 3. Signal Viewer and Analyser GUI

3.5. Data retrieval and elaboration

Software module of Back End Processor, implemented in LabView, is used as primary signal viewer and analyzer. Events, registered during the catheterization study, are used as navigational starting points. They indicate only the approximate temporal locations of the true event occurred at certain time during the procedure and marked after some undeterminable amount of time on the study diary. We have developed different algorithms for ECG parameters extraction and automatic annotation of registered signals [3,4].

The results of various analysis (gradient calculations, blood pressure to blood flow velocity graphs, basic parameters' values etc.) could be stored in FDA XML conform format file [5] (other formats are also available), allowing data exchange with external entities. We have, also, created a demo Java applet signal viewer. The applet is served either directly form LabView HTTP server or from standard web server.

4. Results

We have created a suite of applications that could be used either separately or as part of larger system. Each of them could also act as web application in case of distributed services scenario. The system allows a fully retrieval of procedure derived knowledge, it analyses a wide range of patients data, providing a support for daily activities. Furthermore the EPR is enhanced with time correlated biomedical signals, which are, also, available for exchange with external entities in annotated form through the use of HL7 vs 3 standard format. The additional benefit is the creation of a growing database of biomedical signals of various kind (ECG, intra coronary blood pressure, systemic blood pressure, coronary flow velocity etc.) from well characterized subjects. This will allow further, more complex and accurate analysis including the analysis of drug effects under certain conditions, the efficiency of used materials, the efficiency of the procedure at short/long time etc.

The system demonstrated to be a valuable tool both in extracting basic hemodynamic parameters (HR, RR, blood pressure numerical values etc.) needed for

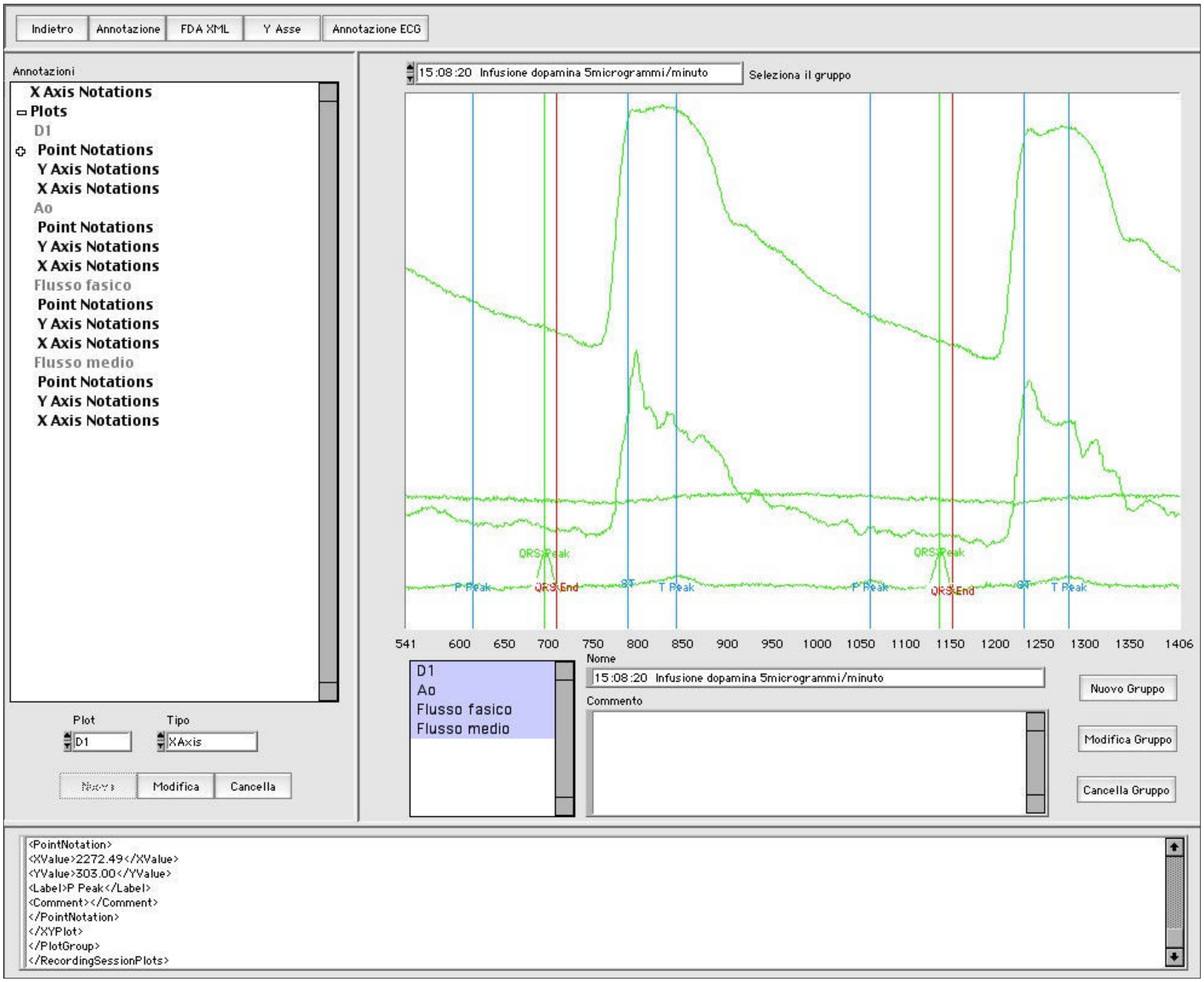

Figure 4. Automatic parameter extraction and point annotation of lead ECG.

completeness of EPR and, also, for more elaborated examinations and study researches.

5. Discussion and conclusions

The adoption of DICOM compatible equipment in hemodynamic laboratory and/or equipment that implements the MPPS (Modality Performed Procedure Step) protocol will enrich the gamma of events recorded during the catheterization study. It will, also, reinforce the need to synchronize all of the equipment and information gathering sources. A possible solution could be the implementation of additional protocols, allowing the registration of those, newly created, events.

The use of globally approved medical standards, such as the HL7 Annotated FDA Document, improves interoperability within cath lab devices and enhances integration with future EHR implementations.

References

[1] National Instruments Inc; http://www.ni.com Accessed Sept 2004

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[4] Kunzmann U,Von Wagner G, Schochlin J, Bolz A. Parameter Extraction Of ECG Signals in Real Time. Biomed Tech (Berl). 2002; 47, Suppl 1 Pt 2:875-8

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