XML Markup for maintenance management of critical care medical devices

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Resumen
Preventive maintenance of biomedical devices is of particular concern to avoid failures and breakdowns, especially for critical care and life supporting devices. Signs of potential failures are not always visible and so, they should be inspected and tested periodically using the appropriate technology. Patient simulators have become one of the essential tools for any biomedical department on every health institution, but its cost is still high to be afforded by everyone. The Labview interactive virtual instrument SIMPAC, a simple PC-based patient simulator, showed to be a low cost powerful tool for simulation of healthy and pathological conditions using signals repositories of different biomedical devices such as EEG, ECG, etc., and also to record the output signals of devices like pacemakers, defibrillators, etc. Here we present an enhancement of the tool which consists of adding a secure reporting feature using XML for presenting tests results, applying digital signature for granting report integrity, assuring this way that reports can not be altered by intentional or accidental manipulation of the data contained on it, according to the terms of the medical technology law. In addition, SIMPAC brings a low cost solution for teaching and practical purposes.

Palabras Clave
XML Markup language, digital signature, medical devices, patient simulator.

Introduction

The main purpose of preventive (and predictive) maintenance is to detect problems before they get develop. Nevertheless, certain kind of problems can not be detected by preventive procedures because they may occur suddenly. Maintenance of biomedical devices and the risk assessment due to its use are under the responsibility of the biomedical departments inside every health institutions. These professionals must set up a preventive and predictive maintenance (PPM) plan for medical equipment to guarantee the conservation of its adequate performances and requirements to be used safely on patients every time they are needed [1].

Maintenance programs should be designed aiming to detect minor problems before they result in major system failures, to reduce hazardous risk for users and patients, to minimize the equipment dead time, to avoid excessive repairing costs and also to verify that devices are compliant with codes, standards and regulations [2].

Biomedical devices are classified into risk categories, hence, a maintenance plan for each kind of device should be set up, considering they can fail from time to time with many diverse causes of failure including their own different nature, complexity, normal use, mechanical damage, user abuse, random component failure and obviously, aging [3].

Normally, when a new medical device is acquired and added to the inventory, we have to select an adequate maintenance schedule for it [4]. The election of the proper frequency for periodical inspections and performance tests is a key issue of the maintenance plan. High frequencies decrease the cost/effectiveness relationship and may also degrade device

longevity. On the other hand, low frequencies may affect reliability, accuracy and safety [5].

Nowadays, the rapid advance of technologies is affecting to medical equipment maintenance, and traditional routines seem no longer enough to ensure that equipment is getting the best possible maintenance [6]. The wide variety of medical specialties set a hard challenge for biomedical departments, who have to catch up with new technologies and to incorporate new instruments to give a response according to necessities. A whole new set of analyzers are now essential tools for testing and analyzing modern medical devices. Some good examples are electrical safety analyzers, electrosurgery analyzers, patient simulators, X-ray testing devices, defibrillators analyzers and others.

Simulators and analyzers have a high cost, especially for hospitals and health institutions in developing countries, situation that often turns them into prohibitive and makes impossible to carry out the proper maintenance, because of the lack of adequate instrumental. The "SIMPAC", a PC-based multipurpose simulator and analyzer is a low cost solution implemented with virtual instrumentation using *Labview v8.0* development suite and other resources available at the university labs, with a very modest investment on technology [7]. Figure 1 show a general overview of this simulator which was described in a previous work. Further details can be found following the references.
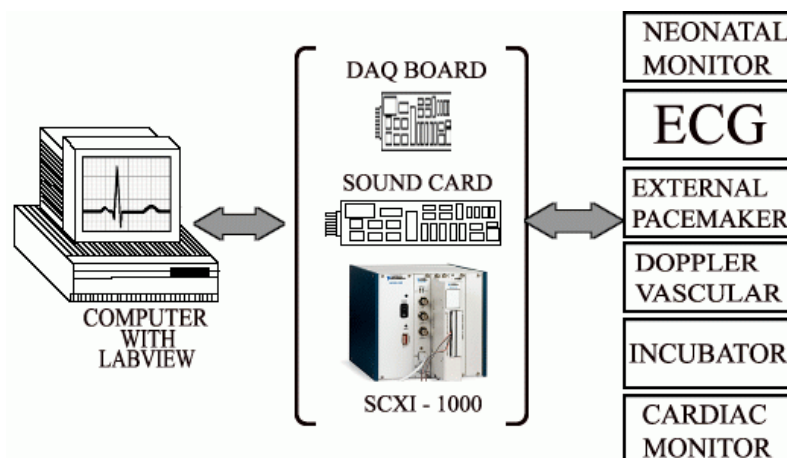

Figure 1: SIMPAC general system overview.

This versatile and economic tool can simulate many diverse physiological conditions, normal and pathological, in order to measure the output range values and verify that they meet manufacturer's specifications [8,9]. It also can function as an analyzer, recording the output signals given by specific biomedical devices like defibrillator, pacemakers, bi-directional vascular Doppler, etc.

The latest versions of the mentioned devices can connect to a PC through a serial port using RS-232 communication protocol or through a USB port. This connectivity capability allows for exporting acquired data to a PC giving us the possibility to generate reports from the result of each test performed, organizing the maintenance documentation process and giving a management tool for statistics, time/cost analysis and legal protection issues, according to the terms of the law N°26.906/2013 *(Traceability and verification of technical aptitude of health technological resources in use)*.

In this article we present an enhancement of the SIMPAC v1.0, adding a secure reporting feature using XML markup format for generating and archiving test results [10]. Security is here provided by means of a digital signature implementation [11, 12, 7] over the generated XML file, granting that the document will remain unaltered, avoiding intentional or accidental modification of any data contained on it. These structured XML reports can be integrated to any existing maintenance database and they can also be queried when we need to search something in particular.

Design

SIMPAC Overview

The PC-based simulator was designed and built in order to achieve a versatile tool for testing and calibrating biomedical devices, suitable for both practical and educational purposes. We chose *Labview v8.0* for the programming environment because it is available for several computer platforms such as Linux, Windows, Palm PC, etc, [14] and because its excellent connectivity with the outside world through DAQ modules, I/O and networks protocols which make it a great tool to perform computer-based experiments like acquisition, control, instrumentation and quick engineering solutions development [15, 16]. We considered the design of a virtual instrument (VI) with a user interface and full capability to interact with six different medical devices available at the lab as educational modules: a *bi-directional vascular Doppler* (frequency and beat noises); an *incubator* (room/skin temperatures); an *external peacemaker* (frequency/amplitude); an *electrocardiograph;* a *neonatal monitor* and a *cardiac monitor* (signal shape/frequency).
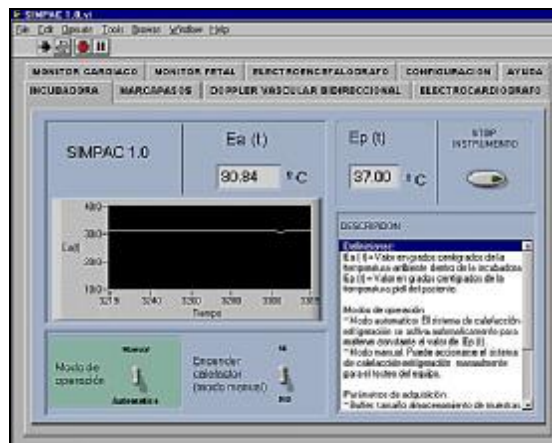

Figure 2: The SIMPAC v1.2 Virtual Instrument GUI.

At first, we chose a physical model for each device selecting the basic parameters to be controlled from the user interface. Then, a mathematical model was built to simulate different signal conditions. Signals generated by the mathematical model were stored in an excel sheet or a text file, creating this way a repository of signals that allowed us for testing devices, and then re-define the model if necessary [17]. Later, mathematical models were replaced by a repository of signals acquired by different methods. The most recent version provides two main modalities: simulation and testing. Simulation allows for sending signals

from the computer to a device, and testing allows for acquiring signals from a device. All signals were allocated in a signal repository on the hard disk and used for simulation without the need of a patient, and also for testing and calibrating the devices.
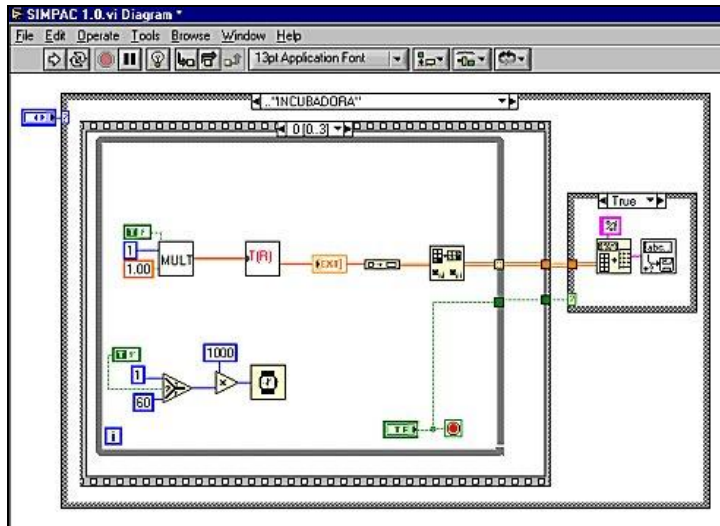

Figure 3: Design view of the incubator Sub VI.

Figure 4: Working with a transport incubator Sub VI.

Considerations about maintenance documentation

Any PPM program must be effective in detecting faults and should reduce the number of repairs, without consuming much time for the task [6]. It is very important to build a failure history of a biomedical device, registering all relevant information obtained from every inspection.

Manual record keeping systems are still widely used, but computerized systems have great advantages and may add a lot of useful features for information processing and

analysis. They allow for producing reports to identify equipment with higher repair costs, to support repair versus replacement decisions and to document potential user errors or equipment abuse [13], and to register functional ratings of a device in order to define whether it is working properly or not, according to manufacturer's specifications [14] or, when it should be replaced. They also provide documentation in case of a malpractice suit regarding to medical equipment maintenance; avoiding responsibilities proving to authorities that involved equipment was properly maintained.

The structure of a report

The structure of a report should be tailored for each device, because the signals we want to record are not the same for all devices. However, there are some common information items for all devices, like task responsible, time consumption, costs related to repairing or PPM inspection. A complete documentation process consists of three main parts: device ratings report (acquired by performing a test), device information (stored in an inventory database) and device's historical record (Fig.5).
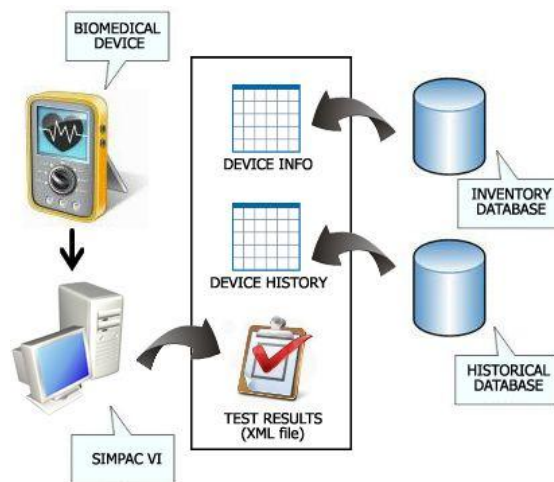

Figure 5: A complete documentation process scheme.

We focus here on the ratings report. The other two parts do not have a direct relationship with the SIMPAC virtual instrument and they will not be detailed extensively here. Information provided in the table named as "Device info" is shown briefly in Table 1.

Field Name	Data Type
Device Name	Text
Device ID	Number
Manufacturer	Text
Model	Text
Serial	Text
Location	Text
…	…
Age	Number

Table 1. Example of a Device Info table extracted from the Inventory DB.

Inventory database contains information about each device in the hospital (location, status, etc.) Historical database contains information about each preventive, predictive or corrective task performed on a device. There are other relevant tables involved in the process of managing and documenting information, for example, a table for each device listing its specific ratings for every considered parameter. This table will be useful in the future when checking tests results against these ratings, in order to determine how far the performance of a device from the manufacturer specifications is.

Results

The XML reporting feature

When a PPM test is performed on a device, ratings are recorded and stored by the SIMPAC virtual instrument by reading a specific port where device is connected to. Data is saved to an Excel file (.xls) and then converted into an XML file in a process that is transparent for the user. The conversion is made by a means of an application coded in Delphi 7, which uses a XML component with capabilities to create, to modify and to parse an XML file. This component can also import data from different databases and generate tree views of the content. The application is compiled and run inside the virtual instrument right after acquisition is over. In previous attempts we tried to directly save information in XML format using the "save as" option of Excel, but doing this we obtained an output file with a lot of unnecessary code.

XML is the 'Extensible Markup Language', universal language for data on the Web but not limited to. XML looks much like HTML. However, whereas HTML describes the layout of a page (for data displaying purposes) XML is concerned with semantically defining and describing data. An XML file can be thought as a mini database where tags or mark-ups in the document delineate the records and fields. The text between the tags is the data. An XML parser can perform operations like retrieving, updating, and inserting data into an XML file. An example given below shows a XML report file structure [18].

```
<?xml version="1.0"?>
<testresult>
  <device>
        <name>Defibrillator</name>
        <manuf>E&M</manuf>
        <model>C-12-S</model>
…
  </device>
  <test>
        <param1>energy</param1>
        <param2>chargingtime</param2>
…
  </test>
  <responsible>John Doe</responsible>
  <date>11-7-2004</date>
…
</testresult>
```

Example of an XML file tag structure.

The conversion process was successful every time we ran the virtual instrument to perform a test on a device. There was no problem or errors reported during conversions.

Security through digital signature

A digital signature of a document implies the use of the author/emitter private key and a unidirectional mathematical function, the Hash Algorithm [19], which calculates a code derived from the message, to extract a "fingerprint" of the information that have to be exchanged, shared or stored.

The receiver uses the author/emitter public key to run the same operation on the document and comparing both hashes. If they match, the receiver can feel sure that the document was sent by the author/emitter and also it is unaltered. The relevant matter here is if the content of the document is altered, verification of signature will fail [20]. The digital signature schema is implemented using PGP software for key pairs generation and signing documents.

In this case, the author of a report is always the biomedical technician, who uses the SIMPAC patient simulator to perform a PPM task on a device generating automatically an XML report file. Once the report is generated, the technician digitally signs the XML document and then, he can store it locally on the PC hard disk or send it over the hospital network (maybe internet) to the biomedical engineers who are in charge of the documentation process and managing the biomedical technology department.

In this case, engineers (receivers) have to check the digital signature as it was explained above. If the comparison is successful, authenticity, non repudiation, integrity and confidentiality are assured. On the contrary, if it fails, the document was altered by someone and we can not trust on the information contained on it [21 22].

This is a key issue, because the PPM task reports act as documents in case of legal problems regarding to medical equipment maintenance [14]. If the device is functioning according to all requirements and specifications, a report is used for documentation purposes and the device is returned back to its original location inside the hospital. If the report shows that device is malfunctioning, it has to be retired from the service to be repaired and it can not be manipulated by medical or nursing staff and also, it must not be used on patients.

Conclusions

The SIMPAC PC-based patient simulator is a low cost, very useful tool, developed entirely as an original work. It allows for testing different kind of devices connected to the virtual instrument, which can work in two modalities: simulation and testing. Both modalities were accomplished successfully.

Labview shown to be a powerful tool and an excellent resource for building human-machine interfaces, with great coding languages integration capabilities [23].

The patient simulator is not fully developed yet, but this partial success has encouraged us to continue this way in order to improve its capabilities. The secondary goal or this work, education and training, was fully achieved, considering that basic and clinical science concepts were easily integrated with electronics to improve critical data analysis and to visualize real world dynamic processes in classes to enhance students' knowledge by means of a "hand on" experience.

The addition of reporting features enhances the simulator by providing a tool for secure documentation processes. Moreover, the XML file format chosen for the reports gives a semantic, machine-readable content, which is useful for query, search, replace and add data within a file.

The digital signature schema provides the security over the entire documentation process granting the integrity of information, the authenticity of both sender/receiver and non repudiation for authors identification.

This work is still running improvements and further results will be available soon.

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