A Year in the Life of the OpenECG Network

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Abstract

The OpenECG network formed in 2002, is a European initiative with global reach, which aims to lower the barriers for ECG interoperability and make digital ECGs available as part of the integrated electronic health record. Currently, SCP-ECG, the European standard for ECG record communication and storage, has been implemented by some manufacturers. However, these implementations are not consistent with each other, hindering ECG exchange, processing, and serial analysis. Furthermore, the presence of alternative ECG storage formats, proprietary or open, raises issues of harmonization and quality assurance.

In the first year of its life, the OpenECG network numbers 105 committed members, while its portal and associated help desk have already provided valuable information and development support to several manufacturers and integrators. Recently, the OpenECG certification service has become available to members who may submit their ECG records for interoperability validation and SCP-ECG conformance testing. Still, only the first step for the OpenECG network has been taken. Future plans involve contributing to the definition of integration profiles for ECG-related examinations and addressing issues related to quality assurance of eHealth services in general.

1. Introduction

The OpenECG network is a collaborative effort that reaches around the world aiming to lower the barriers for ECG interoperability and to make digital ECGs available as a core part of the electronic health record (EHR)[1]. In the last year, new ECG devices for personal health management combined with ECG management systems exporting ECG examinations in XML, pronounced the need for harmonization among the various ECG formats. The 1st OpenECG workshop "Bridging the Interoperability Gap in ECG devices" held in October 2002, made clear that significant barriers for ECG interoperability are: (a) the lack of awareness regarding existing standards, (b) the lack of tools and information that would lower the cost of standards implementation, (c) the absence of demand on behalf of the users. As a result, OpenECG concentrates its efforts on the typical 10sec electrocardiogram, the most widely accepted non-invasive cardiac examination, promoting interoperability among alternative ECG formats and fostering the consistent implementation of the SCP-ECG standard.

In early 2003, OpenECG numbers more than 100 members worldwide from the biomedical engineering community, user groups, the industry, and national health associations. At the same time, the steady increase in the access traffic of the www.OpenECG.net portal and the number of Internet (e.g. Google) references to the SCP-ECG standard reflect the growing interest in ECG interoperability. A key role in the management of the OpenECG network plays the Industry Advisory Board (IAB) formed right after the 1st OpenECG workshop. The IAB consists of 7 core members out of health/industry associations and is currently supported by an associate board of 9 industry representatives.

OpenECG has taken concrete actions to support ECG interoperability in the real world. The help desk of the portal has accepted a number of messages from integrators and manufacturers who requested and received information and guidance on how to consistently implement the SCP-ECG standard. Additionally, the "ECG record parsing & presentation by email" service (see section 3.1) and the online conformance testing service for ECG records (see section 3.2), are intended to help end-users and integrators by providing input from real implementations.

The open source repository, which will be available to members at the beginning of 2004, consists of an annotated collection of source code modules for parsing, processing, and visualizing digital ECGs recordings including a parser and a viewer for ECG records in the SCP-ECG standard. Furthermore, an online service converting SCP-ECG files to the DICOM 3.0

(supplement 30) waveform standard is a first step in the direction of harmonizing ECG record formats. Using this converter, ECG records in SCP-ECG can be viewed using freely available DICOM waveform viewers [2]. Finally, OpenECG has opened a programming contest in which engineers from around the world may freely participate and compete on the implementation of ECG interoperability tools such as parsers, viewers, and converters. The best tools will be available as part of the open source repository.

2. OpenECG portal

2.1. Members of the OpenECG network

OpenECG membership has been granted to all the participants of the first OpenECG workshop and since then, a number application forms have been received by the help desk. On 10th September 2003, in the database of the OpenECG portal there were 114 entries and 105 members. For every application form received, we check if the sender has expertise in OpenECG-related areas such as cardiology, electro-cardiography, open-source, interoperability standards, multimedia electronic health record, etc. and if not, additional information is requested. If this additional information is provided and a real interest is proved, then membership is granted. A low number of members who are really committed and qualified are to the best interest of the OpenECG network!

All the members of the IAB have received the OpenECG honorary membership. Membership has also been granted to people with a concrete contribution to OpenECG.

Members are mostly from Europe (Greece (21), Italy (14), Germany (9), Denmark (10), The Netherlands (5), UK (5), France (5), Austria (3), Belgium (3), Hungary (3), Sweden (2), Switzerland (2), Lithuania (2), Norway (1), Poland (1), Russia (1), Spain (3) and Turkey (2)). In America we have 9 members (USA (5), Canada (3), and Cuba (1)). Three (3) members are in Asia (China (1), South Korea (1) and India (1)) and finally 1 member is in Africa (South Africa) (see figure 1).

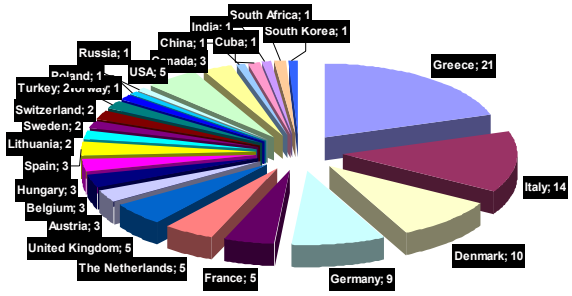

Figure 1. Members of the OpenECG network (9/03).

2.2. Management of the portal

The **Help Desk** has been active since August 5, 2002. A number of requests for assistance have been received by the help desk manager. Development support on SCP-ECG implementations has been provided to ECG manufacturers and a series of general questions relevant to the SCP-ECG standard were answered. The response of the requestors was enthusiastic!

The access patterns in the OpenECG portal reflect the increasing popularity of the site and follow the main events in the life of the network, the 1st OpenECG workshop, the opening of the programming contest, the publication of the tutorials and SCP-ECG test set (see figure 2).

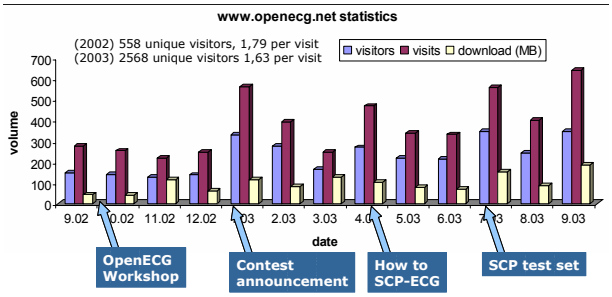

Figure 2. The access pattern in the portal follows the main events in the life of OpenECG.

The traffic in the OpenECG portal shows that the industry is particularly interested in the activities of the network. From the overall traffic, taking out IP addresses that cannot be resolved, 16% can be attributed to .com sites as shown in the figure bellow.

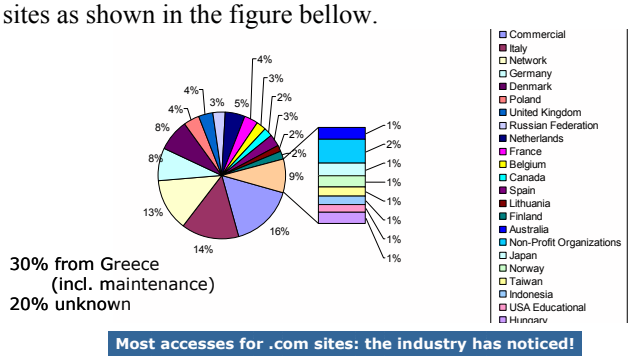

Figure 3. 16% of page accesses can be traced back to the industry.

3. Member services

3.1. ECG record parsing and presentation

An automated email service has been developed by IFC-CNR to assist users in assessing ECG recordings presumably stored according to the SCP-ECG standard. Members of the OpenECG network who have registered with the helpdesk to use the service, may send email to scp-parser@ifc.cnr.it with subject "parse submitted scp-ecg file" attaching the ECG files they wish to visualize.

Each ECG record file attached to the email message is processed by an agent that parses the SCP-ECG record

and employs dedicated modules for SCP-ECG format interpretation and ECG signal visualization. The output of this process is a graphics file and a textual report.

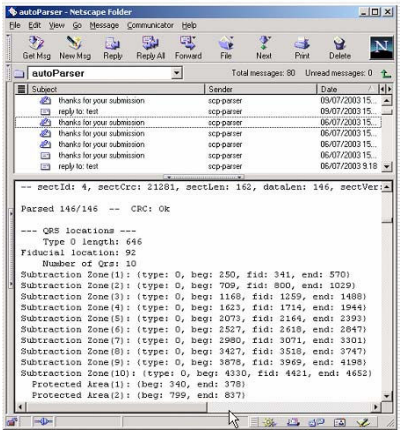

Figure 4. Automatic textual report returned by email.

The textual report (.log file) contains section by section, all the information that the IFC-CNR parser was able to extract from the ECG record (see figure 4). This information includes:

- patient data
- manufacturer data
- ECG measurements (if present in the ECG record)
- the diagnostic report (if included in the ECG record)
- miscellaneous file control elements

The graphics file shows a graphical representation of the 12 leads of the submitted ECG record and is stored according to the portable network graphics (PNG) format. The text report and the graphics file along with the original ECG record are sent back to the sender via an automatic reply. The received ECG records are stored in the ECG database of IFC-CNR.

The textual report and graphics file produced automatically by the email service do not serve as validation of the ECG format, but only as the capability of the IFC-CNR parser to extract information from the submitted ECG records.

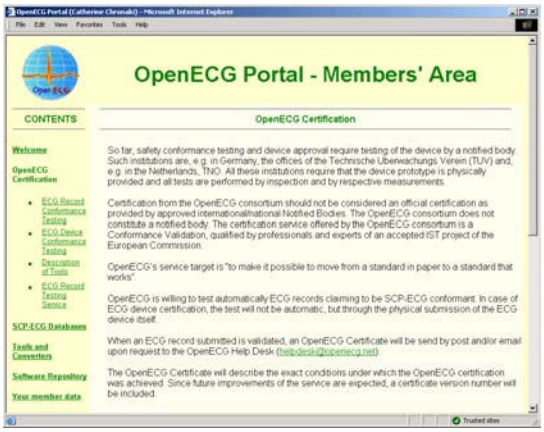

Figure 5. OpenECG portal member area.

3.2. OpenECG certification services

So far, safety conformance testing and device approval require testing of an ECG device by a notified body. Such institutions are in Germany, the offices of the Technische Uberwachungs Verein (TUV) and in the Netherlands, TNO. All these institutions require that the device is physically provided and all tests are performed by inspection and by respective measurements.

Certification from the OpenECG network should not be considered an official certification as provided by approved international/national Notified Bodies. The OpenECG consortium does not constitute a notified body. The OpenECG certification service offers SCP-ECG conformance validation by qualified professionals and experts and is supported by the European Commission in the frame of the OpenECG project.

The overall goal of OpenECG is "*to move from standards in paper to standards that work in practice*". OpenECG is able to test automatically ECG records claiming to be SCP-ECG conformant. In case of ECG device certification, the test will not be automatic but through the physical submission of the ECG device itself.

When an ECG record is validated, an OpenECG Certificate is sent by post and/or email, upon request to the OpenECG Help Desk (helpdesk@openecg.net). The OpenECG Certificate describes the exact conditions under which OpenECG certification was achieved. Since future improvements of the service are expected, a version number is included in the certificate.

As far as ECG records are concerned, conformance testing applies not only to the file generated by the medical device, but also to the file received by an EHR system, which may edit information in the ECG record such as patient data, diagnosis, etc. The approach used for conformance testing addresses detailed checking of content and format of the data sections provided, including the two bytes of the CRC checksum and the length information of the record.

ECG Record level conformance testing is available automatically through the OpenECG portal. The overall process involves two steps. First, the member logs into the members area of the OpenECG portal and selects on the left bar "OpenECG Certification | ECG record testing service." A new window appears that prompts for a file upload. Then, the member selects the ECG record to be tested from the local file system and presses "Test." The file is uploaded and tested automatically. The new page presented to the member includes hyperlinks to the format and syntax checking reports. The output reports may include warning and error messages. Warnings refer to the recommended use of the standard (mainly changes from version 1.0 to 1.3), while errors refer to mandatory requirements of the SCP-ECG standard. The format and the content checker are based on the specifications of SCP-ECG version 1.0 and 1.3. (see figures 6,7). If the

test is successful, the member can proceed to the second phase and request an OpenECG certificate for the submitted ECG record via the helpdesk.

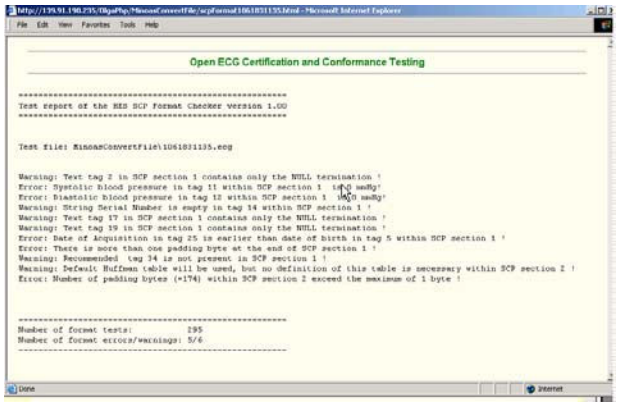

Figure 6. Format checking results of an ECG record.

If a developer or integrator needs a more detailed report i.e. "what have I done wrong?" or "what do I need to do?" development support can be provided by the Help Desk. To receive development support additional information is required:

1. "Claimed compliance category" (SCP-ECG standard).
2. "SCP-ECG Implementation Document" with a detailed description of all data contained in the record and the (intended) format.

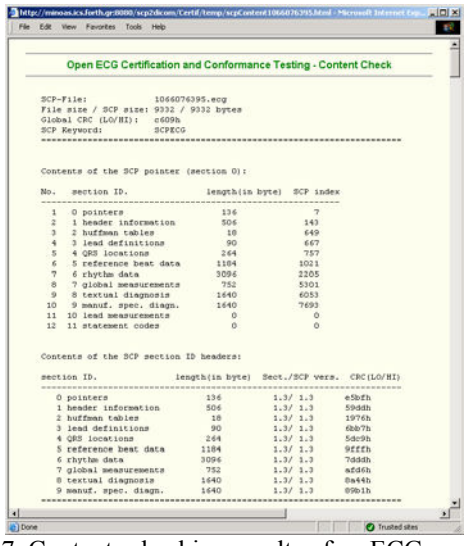

Figure 7. Contents checking results of an ECG record.

ECG Device level testing is available offline. In this case, in addition to the claimed compliance category and the "SCP-ECG Implementation Document", the device has to be physically available and be accompanied by appropriate documentation of the communication protocol and software drivers for interconnectivity.

The manufacturer has to supply a driver for the communication with a device. OpenECG does not require disclosure of the low level details of the communication protocol managed by the driver. It is the driver that has to be able to retrieve the ECG data recording into a presumed SCP-ECG record, which will be provided to the OpenECG conformance testing service through the file system or a DBMS with disclosed structure.

An analog ECG test data set will be submitted to the device and the output SCP-ECG records will be checked and compared with the original input data. For validated ECG devices, an OpenECG Certificate will be send by post and/or email, upon request to the OpenECG Help Desk. The OpenECG Certificate will describe the exact conditions under which the OpenECG certification level was achieved with specific reference to the manufacturer and model that was tested. Again, since future improvements of the service are expected, a version number is included in the certificate.

4. Conclusions & future work

Despite the success of the OpenECG network in the first year of its life, efforts to ensure ECG interoperability worldwide have just begun. There is a growing confidence that the continuous efforts of the OpenECG members contribute to the consistent and harmonized implementation of ECG standards. More specifically the services of the help desk, the OpenECG certification service and the wide availability of software that has been tested with ECG samples of different manufacturers will help to alleviate interoperability problems.

The immediate plans of the OpenECG network include a programming contest for ECG interoperability tools, which will closes on December 31, 2003 and the second OpenECG workshop that aims to bring ECG interoperability standards to their full potential.

Acknowledgements

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References

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