OpenECG: TESTING CONFORMANCE TO CEN/EN 1064 STANDARD

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Abstract

Advances in medical device technology deliver a proliferation of diagnostic devices, ranging from blood pressure and ECG monitors, to camera pills, insulin pumps, and implantable defibrillators. Seamless integration of medical devices into clinical IT procedures is recognized as the key to reducing inefficiencies that result in suboptimal care and avoidable medical errors. Moreover, plug-interoperability of medical devices for health monitoring with electronic health record systems ensures effective self-care and wellness management to our active, mobile, and aging society. Although standards are there to provide a solution to the interoperability problem, standardization efforts can hardly keep up with the time-to-market constraints of an innovation-driven medical device industry. This paper discusses user experiences from online conformance testing of ECG records to SCP-ECG (CEN/EN 1064) as provided by OpenECG, a worldwide network established in 2002 to promote best practice in interoperability and standards in digital electrocardiography. In the last three years, online conformance testing has assisted the implementation of SCP-ECG by OpenECG members. Feedback from implementation has also guided the evolution of interoperability standards for ECGs and other bio-signals. The OpenECG community is part of current developments supporting interoperability and assisting standardization efforts to match technical innovation and respond to user needs.

1. Introduction

Advances in ICT, micro- & nano-technologies, and biomedical research trigger continuous innovation in the medical device sector. Until now pharmaceuticals have been the main pillar of health care, but nowadays, with more than 10000 medical device models in circulation, the impact of medical devices on the costs and effectiveness of health care is rapidly increasing [1].

General practitioners are increasingly using electronic health record (EHR) systems and medical devices to support their gatekeeping role in primary care. Active, health conscious, aging citizens more and more acquire on their own or after suggestion of health professionals, personal medical devices to monitor their health at home or in the workplace. Some medical devices can be used in association with electronic health journals and EHR systems seamlessly communicating medical examination data. Considering the value and impact of these IT systems on shared care and wellness management, a pressing need for effective quality control and overall technology assessment emerges. In this context, plug-interoperability of the medical device with the EHR system is a valuable tool for quality control as it reduces the risk of medical errors and enables automatic value checking and alert management. Thus, medical device interoperability becomes a patient safety issue and a quality label for eHealth systems [2-3].

As an example consider the common electrocardiogram (ECG). The ECG is the most frequent non-invasive diagnostic examination for suspected or monitored cardiac problems. Despite a proliferation of ECG devices and the fact that the ECG in its digital form is a critical part of the EHR, standard data formats for ECG are not widely adopted or consistently implemented. SCP-ECG (CEN/EN 1064) [4] is the European standard for representing and communicating digital ECGs that ensures interoperability and to some degree quality of digital ECG recordings. In digital form, it is possible to serially compare ECGs, control the quality of the recordings, and effectively manage alerts. However, to ensure interoperability not only the SCP-ECG standard has to be consistently implemented but also it needs to be harmonized with other ECG interoperability standards.

The OpenECG network was formed in 2002, to bring closer experts and users that are interested in or affected by ECG interoperability to discuss experiences and build robust and sustainable interoperability tools and solutions [3,5].

The mission of OpenECG is to advance interoperability in electrocardiography through the consistent implementation of interoperability standards. Currently, OpenECG brings together more than 600 people from 52 nations (see Fig. 1) with different culture and background in a network where knowledge, experience, and effort can be shared. Its portal (www.openecg.net) hosts information about the practical aspects of ECG interoperability standards.
Approximately 25% of the OpenECG members are affiliated with ECG manufactures or integrators. Additionally, a working group endorsed by IEEE 1073 and CEN TC251 WG1V is working on a normative converter between the annotated ECG standard of HL7 v3 and SCP-ECG [6]. A methodology for validating the conformance of ECG devices and ECG records to the SCP-ECG standard has been developed. Conformance testing of ECG records is currently provided online and as a web service to OpenECG members facilitating the implementation of interoperable systems. So far, several members have used interoperability testing on the OpenECG portal and the assistance of the OpenECG help desk to consistently implement CEN/EN 1064 in ECG devices and integrated scenarios of health care provision.

The rest of the paper is structured as follows. In the next section (materials and methods) CEN/EN 1064, the SCP-ECG standard, its compliance levels and interoperability testing of ECG records are described. Then, the results section presents results from the use of the OpenECG conformance testing service in its different forms. Recent developments, the upcoming amendment of the SCP-ECG standard, and future directions on interoperability testing, appear in the discussion and conclusions sections.

2. Materials and Methods

SCP-ECG is an official CEN standard, allowing connectivity between ECG instruments and host systems [4]. SCP-ECG covers an interchange format and a limited number of messages for the acquisition, transfer, and storage of 12-lead ECGs. With SCP-ECG, compatible systems can transmit, store, and receive ECGs with full waveform fidelity.

<table>
<thead>
<tr>
<th>Status</th>
<th>Content [Section]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory</td>
<td>2 bytes- Checksum CRC - CCITT over the entire record</td>
</tr>
<tr>
<td>Mandatory</td>
<td>Pointers to data areas in the record [0]</td>
</tr>
<tr>
<td>Mandatory</td>
<td>Header Information – Patient data/ECG Acquisition data [7]</td>
</tr>
<tr>
<td>Optional</td>
<td>Huffman tables used in encoding of ECG data [2]</td>
</tr>
<tr>
<td>Optional</td>
<td>ECG lead definition [3]</td>
</tr>
<tr>
<td>Optional</td>
<td>QR5 Locations (if reference bits are encoded) [4]</td>
</tr>
<tr>
<td>Optional</td>
<td>Encoded reference beat data if reference beats are stored [5]</td>
</tr>
<tr>
<td>Optional</td>
<td>Residual signal after ref beat subtraction or rhythm data [6]</td>
</tr>
<tr>
<td>Optional</td>
<td>Global measurements [7]</td>
</tr>
<tr>
<td>Optional</td>
<td>Textual diagnosis from the &quot;interpretive device&quot; [8]</td>
</tr>
<tr>
<td>Optional</td>
<td>Manufacturer specific diagnostic and over reading data [9]</td>
</tr>
<tr>
<td>Optional</td>
<td>Lead measurement results [10]</td>
</tr>
<tr>
<td>Optional</td>
<td>Universal statement codes from the interpretation [11]</td>
</tr>
</tbody>
</table>

Figure 2: Overview of the CEN/EN 1064 standard.

As shown in Fig. 2, an SCP-ECG record comprises several sections including Code Redundancy Check (CRC) for the whole record and for each section. Sections include demographics (section 1), rhythm data (section 6), measurements (section 7), and diagnostic statements (section 8). CEN/EN 1064 also specifies methods for rhythm data compression that may reduce the size of the SCP-ECG file tenfold down to less than 10 Kbytes; a convenient size for health cards and micro-sensors.

Although SCP-ECG was first published as an experimental standard in 1994, it was not adopted to the degree expected. According to OpenECG members that are ECG integrators and manufacturers, possible reasons for the limited adoption were lack of guidance on implementation, inherent difficulty of implementing ECG compression/decompression options, and above all proliferation of alternative options in the interpretation of specific fields and multiple compliance levels.

CEN/EN 1064 Compliance Levels. The SCP-ECG standard specifies four compliance levels: I, II, III, IV (see Figure 3). Compliance level I requires the transmission or storage in an ECG record of demographics, measurements, and diagnostic statements (sections 0, 1, 7, 8). The purpose of this compliance level is to facilitate communication of diagnostic reports without attaching the actual rhythm data. In compliance level II, rhythm data is included. This requires also sections 2, 3, 6 to include Huffman tables, lead definition, and rhythm data encoded or not.

In compliance level III, instead of rhythm data, ECG records in CEN/EN 1064 include representative reference beats. This requires the addition of sections 2, 3, 5 to include Huffman tables, lead definition, and reference beats. Finally, in compliance level IV, both rhythm data and reference beats are provided. Rhythm data in compliance levels II, IV and reference beats in compliance level III, IV may be stored in redundancy-reduced compressed format.
Compliance levels II, IV demand the inclusion of rhythm data, which are considered important not only by cardiologists, but also enable automatic serial analysis and comparative study of ECGs. Moreover they are the better choice for achieving interoperability in a range of important scenarios for health care provision. When rhythm data is included, a proper implementation of the high compression method can significantly reduce the file size. Furthermore, software engineers creating vendor-independent tools need to implement all options to ensure coverage of a wider range of manufacturers. In particular, high compression is quite complex and peer support of the community or tutorials like the ones at the OpenECG portal can be a lot of help.

ECG record interoperability testing. OpenECG members may test the conformance of ECG records to the CEN/EN 1064 online. The service is available through a typical web page where OpenECG members may upload the ECG file to be tested. It is also available as a web service that may be integrated to any software that manages ECGs, testing the conformance of incoming ECGs to CEN/EN 1064 [7]. All submitted ECG files together with the results of the tests are available online for the benefit of the OpenECG community.

The conformance testing tools were provided by BIOSIGNA in the first release of the service in 2003. Since then they have frequently been updated [8]. If a submitted ECG record conforms to the SCP-ECG standard, an OpenECG certificate may be requested. In that case, the ECG record is further inspected and an interoperability certificate including the exact circumstances of the tests is issued.

### 3. Results

Conformance validation is available to members, since September 2003. Since then, the online service has been used by 49 OpenECG members. The maximum number of ECGs submitted for online conformance testing by an individual OpenECG member is 143 (m=20, s=34) as shown in Fig. 4. 50% of the OpenECG members that used the service submitted 5 ECG or less.

Conformance testing in its web service version has been used by 6 OpenECG members since its June 2005 release. Members have used it from 1 to 53 times. So far, to our knowledge, using the online conformance testing service, two ECG vendors and two integrators have developed an accurate implementation of the SCP-ECG standard. Furthermore, the inventory of the ECG devices supported by the open source and vendor-neutral software available at the OpenECG repository is gradually improved and enriched with the capability to support more manufacturers and medical devices [9].

![Figure 3: Compliance categories for the CEN/EN 1064 standard.](image)

<table>
<thead>
<tr>
<th>Category</th>
<th>Data Sections Required</th>
<th>Content Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0, 1, 7, 8</td>
<td>Demographics, global measurements, interpretations</td>
</tr>
<tr>
<td>II</td>
<td>0, 1, 2, 3, 6, (7), (8)</td>
<td>Demographics and Rhythm Data</td>
</tr>
<tr>
<td>III</td>
<td>0, 1, 2, 3, 5, (7), (8)</td>
<td>Demographics and reference bits</td>
</tr>
<tr>
<td>IV</td>
<td>0, 1, 2, 3, 5, 6, (7), (8)</td>
<td>Demographics, ECG rhythm data, and reference bits</td>
</tr>
</tbody>
</table>

**Figure 3**: Compliance categories for the CEN/EN 1064 standard.

In addition, submitted ECGs and conformance testing results have been periodically inspected and a number of limitations in the testing tools have been identified [7]. Based on these observations and suggestions of the members, the testing tools have improved considerably.

### 4. Discussion

Conformance testing assists integrators and manufacturers, who consider endorsement by OpenECG a quality label for their products. Before OpenECG, the only option available was auto-certification, i.e., self-declaration of conformance to standards or interoperability with equipment of certain vendors. Unfortunately, several times the declared conformance is not accurate and to quote an OpenECG member:

“It is really irony that nothing can be done against the manufacturers who fake the end user with the claim, as the machine is completely non-compliant.”

[OpenECG member – name withheld]

The Institute of Computer Science at FORTH has been instrumental in the development of early regional health information networks such as HYGEIAnet [10] and the Integrated Electronic Health Record (I-EHR) concept. Part of this long term effort has been the consistent implementation and promotion of best practice in interoperability. HYGEIAnet with its 7 hospitals and 16 primary care centers has provided an important test bed for the standardized integration of ECGs in the daily practice of medicine. Sharing experience with the OpenECG community has profoundly influenced the deployment and adoption of comprehensive electronic health records in primary care.

![Figure 4: Online conformance testing service of ECGs at the OpenECG portal.](image)
care. In highly flexible workflows, ECGs in the CEN/EN 1064 standard including patient demographics and clinical details are automatically communicated and archived in the EHR of the right patient.

Standards-based interoperability of ECGs acquired on different ECGs carts and in the context of different clinical workflows is a significant challenge shared by OpenECG members around the world. However, an even greater challenge is transmission of ECG signals in high fidelity. Achieving best practice in interoperability and quality of biomedical signal transmission over hybrid networks combining wireless, broadband, and satellite communications is not easy. Standards and guidelines need to be developed to assist integrators and users.

Testing conformance of an ECG device to the CEN/EN 1064 is more demanding than testing individual files. The conformance testing procedure for ECG devices developed by the OpenECG consortium is shown in Fig. 5. It requires feeding known ECGs into a configuration involving the ECG device to be tested and verifying that the error is within the limits specified by the standard.

Figure 5: Testing conformance of electrocardiographs to the SCP-ECG standard.

Conformance testing and integration efforts are also providing feedback to standardization. The recently proposed amendment to CEN/EN 1064 standard is a successful example of this OpenECG activity. OpenECG members noted that the currently compliance levels of the SCP-ECG standard do not adequately address common scenarios where the standard should be used, namely electronic health record, intrahospital, ambulatory and homecare scenarios, hindering interoperability. OpenECG members worked closely with CEN TC251 WGIV on a technical amendment to address the reduction of compliance levels in the SCP-ECG standard, to harmonize the terminology with other interoperability standards, and to further facilitate interoperability. As a result, an amendment to the SCP-ECG standard was proposed and has been submitted in April 2006 by CEN TC251 for ballot under the short acceptance procedure [11].

ISO and CEN standards can also be used to management of a variety of bio-signals in vendor-independent way, establishing a uniform "picture" of the physiological status of the individual. The OpenECG community plans to address standards-based interoperability issues in multiparametric bio-signal monitoring, realizing bio-signal databases to facilitate research, education, and eventually effective individualized alert management.

5. Conclusions

OpenECG and its services promote best practice for interoperability in electrocardiography. A natural next step is to establish a similar initiative for multi-parametric health monitoring through plug-n-play medical devices contributing to truly pervasive health care.

Acknowledgements

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References