Developing Manufacturer-Independent Components for ECG Viewing and for Data Exchange with ECG Devices: Can the SCP-ECG Standard Help?

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Abstract

In the context of HYGEIAnet, the regional health-telematics network of Crete, CMI-HTA has explored the capabilities of several ECG devices and management systems. Focus was placed on the SCP-ECG standard, which defines a uniform format for the processing and storage of digital ECG recordings and specifies a means by which ECG devices and systems may exchange information.

Development of a multi-manufacturer ECG viewer took more effort than expected. Although the SCP-ECG guidelines are sound and useful as far as they go, the protocol leaves too many degrees of freedom in a number of areas, so that the development of generic SCP-based software is in practice a difficult task. Moreover, the manufacturers' degree of compliance with the SCP standard may be unclear, while there is no recognized body or institution able to certify the level of conformance.

1. Introduction

The Center for Medical Informatics and Health-Telematics Applications (CMI-HTA) at ICS-FORTH evaluated a number of ECG devices and management systems to be used in the context of HYGEIAnet [1], the regional health-telematics network of Crete. The long-term objective was to integrate the digital ECG workflow with existing applications in different health care contexts.

In order to facilitate the use of ECG devices from different vendors, a standard format for digital ECG storage and data exchange was desirable. The SCP-ECG standard was an obvious candidate for this role [2,3]. Accordingly an investigation was made on the implementations of the SCP-ECG standard used by various electrocardiograph manufacturers.

This paper describes the clinical contexts in which digital ECGs needed to be managed and discusses the value of the SCP-ECG standard for this purpose, with particular reference to the development of a universal ECG viewer.

2. Regional health care settings

HYGEIAnet encompasses the whole range of public health care facilities, ranging from Primary Health Care Centres to Regional and Tertiary Hospitals. These different facilities have different needs as regards the acquisition and archiving of ECG recordings.

Primary Health Care Centres use a dedicated Information System developed by ICS-FORTH, in which a digital ECG must often form part of the patient's electronic health record. For this, two main components are necessary: a) a communication component able to receive ECGs sent by an ECG device and to store them in a database or in the file system; b) software to view the acquired ECG and to print it if required.

The situation in the Cardiology Departments of the regional hospitals is different, mainly because of: a) the high volume of ECGs recorded per day; b) the workflow for the recording and archiving of routine ECGs for all in-patients; c) the desirability of avoiding re-entry on the cardiograph side of patient data already stored in the Cardiology Information System on the patient's first admission to the department. In this case, the best way of working is a two-way data exchange with the electrocardiograph with downloading of orders and uploading of ECGs [4]. The technological components needed in this case are: a) a two-way communication component able to send orders to the ECG device and to receive ECGs; b) a reporting ECG component for ECG editing; c) an ECG viewer or printer for viewing the ECG, either directly or through a special Web interface using a standard browser.

The lack of specialized cardiologists in the Primary Health Care Centers prompted the development of a teleconsultation system. In this case the locally acquired ECG is sent through the regional network as a part of the teleconsultation folder and needs to be viewed in the Telecardiology Center [5]. There is thus a need for a compatible ECG viewer/printer to be available at both locations.

3. Technical approach

From the beginning of 2000 until the first months of 2001, we approached the development of software for the

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use of ECG devices, taking into account that in the regional network some digital electrocardiographs were already in use. The decision was to build flexible and open solutions, integrating devices from different vendors. The ideal long-term objective is to produce generic, manufacturer-independent components.

A variety of ECG devices and ECG management systems were evaluated with special attention to the SCP-ECG standard. However, manufacturers that did not implement the above standard were not excluded, because it is a fact that many market-leader manufacturers still tend to prefer a proprietary solution. So far, the process of choosing an ECG device by a health body focuses not so much on compliance with a standard for file format and data exchange as on well-known names with a consolidated tradition in ECG equipment. As a result, the investigation was two-pronged: a) the SCP-ECG standard; b) the market-leader companies willing to disclose all the relevant information about their file format and data exchange protocol.

Information, documentation or ECG samples were collected from a number of leading manufacturers in the domain, such as Cardiette, Cardio Control and Mortara. The first of the above manufacturers is declared to be SCP compliant, the second one provides an export function for SCP file format, the third one has implemented a protocol/file format called Universal ECG Protocol (UniPro) [6] that has many similarities with SCP-ECG and seems to have had a strong influence on the creation of the SCP-ECG standard. Other manufacturer's products, which were declared to be SCP-ECG compliant or to have a protocol/file format strongly related to SCP-ECG were also analyzed.

3.1. File format

The SCP-ECG standard allows considerable freedom in its implementation and this freedom has been exploited in full by the manufacturers whose products or ECG samples we examined. As a result there are substantial variations in the manner in which digital ECGs are stored and there are a few critical differences due to misinterpretation or ambiguous description in the standard itself.

3.1.1. Flexibility of the file format

The manufacturers have implemented different sampling frequencies (500 Hz, 600 Hz, 1000 Hz), different methodologies of signal compression (bimodal with decimation to 125 Hz), median beat subtraction and not[1], standard and non-standard Huffman tables, median beats of fixed length (independent of the acquired ECG) or of variable length, first and second differences for rhythm and/or median beat, etc.

Most, but not all manufacturers use one Huffman table (the default), even though it seems to be a lazy choice. When the analysis program in the ECG device does not fail, it seems to be more productive in terms of signal compression to use the median beat subtraction (except when there is a high number of non-dominant beats, i.e. ectopic runs or bigeminy episodes). In this case the distribution of sample values in the residual rhythm is usually lower than in the median beat, so the number of code structures used for the compression of the residual can be lower than for the median beat. Moreover, the same approach can be used for the compression of the non-dominant beats, switching to another Huffman table containing more structures. CMI-HTA implemented a generic algorithm for the Huffman ECG decoding based on a generic structure of Huffman tables.

Furthermore, in section 1 of the SCP-ECG standard there were many differences between manufacturers in terms of the defined and custom tags implemented. The decision was to use only the following tags for the viewer: Last Name, First Name, Second Last Name (in our case Father's Name), Date of Birth, Patient ID, Sex, Age, Height, Weight, SBP, DBP, Acquisition Date, Acquisition Time, Acquisition Device, Analyzing Device, Latest Confirming Physician. Any items not present were left blank.

3.1.2. Incorrect/ambiguous implementation

The purpose of this paper is not to single out individual manufacturers for faults in their implementation of the SCP-ECG protocol. However, we encountered some problems, not only in decoding the ECG signal, which was supposed to be the most difficult part, but also in other sections, for example:

- ✓ Sometimes the CRC, which we believe should be mandatory, is not evaluated.
- ✓ All the manufacturers have implemented version 1.0, but in some case the version number is marked as 0 in the header section. In this case it is not possible to tell which kind of structure must be loaded during the file reading.
- ✓ Sometimes tag 255 in section 1 is not present. Is it mandatory?
- ✓ Not all the manufacturers have their own code. Sometimes it is necessary to do some specific test based on the manufacturer. Unluckily, this will be possible only from version 1.3 on.
- ✓ When a fixed median beat length is used, the median beat length in section 4 is sometimes set incorrectly.
- ✓ When the median beats are not evaluated, section 5 is sometimes still present and contains incorrect information.
- ✓ In some cases, the axes are not stored in the conventional interval –90 to +270.

[1] Sometimes the same device automatically chooses between different compressions, depending on whether the interpretation program runs without error.

3.2. Data exchange with ECG devices

For the data exchange the situation was even more difficult, due both to the current technology and to the manufacturers' implementation of the data exchange itself.

3.2.1. Current technology for data exchange

There are various ways to communicate between an ECG device and a host. The most common are: a) direct serial cable, b) modem, c) floppy disk, d) network, e) memory cards (PCMCIA interface). The first two ways are still the most common and the floppy disk is also quite frequently used. But also the other communication methods are becoming more and more used.

The SCP-ECG standard, like the UniPro documentation, describes only the situations in which the data exchange happens through serial line or modem.

3.2.2. Implementation of data exchange

To realize a communication protocol for ECG devices that communicate by serial line it is necessary to implement the data link functional layer for the packet exchange. SCP suggests an enhanced XModem data transport, but not all devices are compliant with this rather old standard and thus it may be necessary to build a specific protocol, assuming that the relevant information is provided by the manufacturer.

The current status of asynchronous transmission protocol is that XModem has disadvantages in terms of speed, performance and recovery functionalities, as well as in some cases problems can arise from the fact that the file size is not known by the remote end at the start of transmission. As a result, some companies have chosen more modern protocols (i.e. ZModem).

So, even if the data link layer is documented by the manufacturer, it is not always easy to make everything work. The SCP-ECG protocol could perhaps be more flexible here, accepting all the most common protocols provided by many software companies as source code libraries. Non-standard data link layers should be avoided because the manpower required for the development and testing of specific (single-manufacturer) software can be very high.

The message layer has a great flexibility and in some cases additional information may be required for login and for password enabling specified functions.

The protocol seems to be the most critical part for really seamless integration between a computerized system and a cardiograph. It is frequently necessary to realize two-way seamless integration and this can happen only if orders can be sent to the ECG device. Unluckily, orders are not clearly covered by the SCP-ECG protocol. Many companies do not implement them and a few of them implement the orders in a custom way ("X" escape to vendor-specific request).

4. Results

An ECG viewer was developed for digitally stored 12-lead standard resting ECGs acquired by ECG devices with analysis capability. It was provided with some special tools, such as caliper and zoom, that may be useful in providing a proper diagnosis, especially in the case of a teleconsultation episode.

Finally, we were able to achieve our intention of creating a multi-manufacturer viewer based on SCP-ECG (fig. 1), but we believe that for the realization of a truly generic SCP viewer there is still some work to do. Our experience has been that for each manufacturer some adjustments to our software were necessary, depending on the specific SCP implementation provided by the manufacturing company itself.

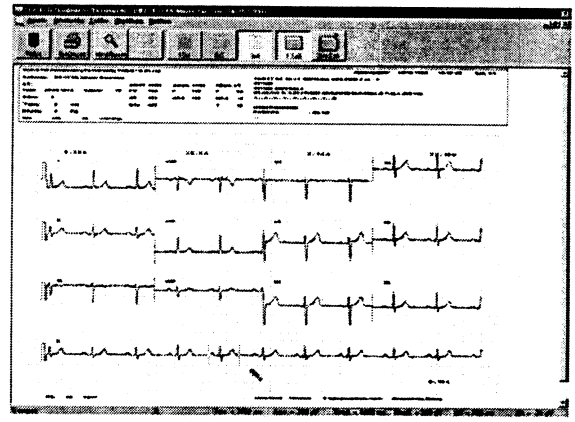

Figure 1. The ICS-FORTH SCP-ECG viewer.

For the data exchange with ECG devices, we built an ECG receiver, specifically to collect ECGs according to the enhanced XModem protocol implemented in the ECG device used in some Primary Health Care Centers. This receiver is currently used in our teleconsultation application on the Primary Health Care side, to receive the ECG previously acquired by the cardiograph just before the GP confirms the patient data in the ECG. The teleconsultation application has been operating in some Primary Health Care Centers around the island since December 2000.

This ECG receiver can also be used for small hospitals, but for large hospitals support for ordering is very desirable. In this case the solution has been to use software provided by the manufacturer for the two-way communication with the ECG device. The approach was peripheral-computer, in which the driver was provided by the manufacturer and the format for the information to be sent and received was documented.

So, if the goal is to achieve a 'plug and play' application for cardiographs, there is still an enormous amount of work to be done. Specifically, we need to support different ways of communication not described

explicitly by the standard, different data link layers (when only the message layer is SCP compliant) and additional functionalities (i.e. ordering).

5. Discussion

Nowadays, the SCP-ECG standard is still the only standard covering digital ECG transmission and storage. It is still limited to resting or short-term ECGs. It does not cover the stress ECG (although such a proposal has been made by the Quinton Instrument Company [7]), Holter ECG and ECG monitoring, which are still custom implemented by each manufacturer. Luckily, these examinations have a lower daily volume compared with the resting ECG, but the need to provide a full cardiology database, including the whole range of ECG examinations, is becoming urgent.

The scientific community and the standardization bodies should make efforts in this direction. At the same time, the SCP-ECG standard should be improved, in order to resolve misunderstandings, extend the supported functionalities, provide mailing lists and certified bodies (able to check the manufacturers' Declaration of Conformity to the standard), and incentives should be provided to the manufacturers to promote the implementation of this standard in their equipment.

The main obstacles to the implementation of the SCP-ECG standard by the market-leader companies are: a) protection of their own market and creation of a more extended market for their ECG management system, and b) the large number of ECG devices and ECG management systems already installed with many ECGs already archived. The conversion of such systems to cover a different file format and protocol entails a high cost. It is necessary to take account of these obstacles if we really wish to promote standardization in the ECG file format and data exchange and the wide use of SCP-ECG.

6. Conclusions

Although the guidelines laid down by SCP are sound and useful as far as they go, the protocol leaves too many degrees of freedom in many areas (compression, details in data format, data link), with the result that it is difficult to produce generic SCP-based software.

Moreover, many manufacturers affirm their compliance with the SCP standard, without describing the level exactly in a conformance statement, while there is no recognized body or institution able to test and certify their degree of compliance.

To realize generic ECG software, the use of a standard, correctly described and implemented by most manufacturers, is an essential prerequisite. The SCP-ECG standard should be clarified and extended and its use promoted, while implementation by manufacturers must be adequately verified before truly universal ECG software can be developed.

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