

## S-6-3

### From OEDIPE to EPIMEDICS - et medical devices Exploitation of SCP

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Et medical devices SpA (formerly named Elettronica Trentina) manufactures ECG recorders since the early 1960s. It is involved in European projects since 1992 with the OEDIPE project, by mean of which the company seeks developing know-how to design new products to sell.

We chose SCP-ECG in the early 1990s because we needed to transmit digital ECGs (which we had never done until then), and using an open standard appealed to us entering the world of telemedicine. Therefore, at the time, we were mainly interested by the communication protocol and messaging part of SCP-ECG. Our participation to the OEDIPE project allowed us to sharp our knowledge and implementation know-how of the SCP-ECG standard, together with the opportunity to be the first manufacturer world-wide to release a SCP-ECG fully compliant device: the Excel 106 SCP electrocardiograph.

The OEDIPE project was aimed at:

- implementing and experimenting electronic data interchange of digital ECGs following the lines of the SCP-ECG protocol developed during the exploratory phase of AIM, setting-up demonstrators for cart-to-host and host-to-host communications and exchanging ECG and other related data between several test sites
- implemented and testing the Conceptual ECG data storage Reference Model which has been developed during the exploratory phase of AIM
- developing and testing methods of serial ECG analysis
- promoting open European data interchange and processing for Electrocardiography by setting-up demonstrator systems for the follow-up of selected heart diseased populations.

In this project, the ET goal has been to realize an ECG recorder (Excel 106 SCP) implementing the first working version of SCP-ECG (fully compliant, featured with both protocol and messaging and data format). The goal has been reached successfully and the developed device has been sold on the market in more than 700 pieces in few years.

Today, the offer of ET covers various medical devices areas (electrocardiographs, home care, telemedicine...) and software, and all our products use SCP-ECG. Our new line, the ar\* electrocardiographs released in 2001 and sold in more than 12000 units in the past 3 years, implement the SCP-ECG data format (both low and high compression schemes) however the communication protocol and messaging part was discarded to the profit of a proprietary communication layer. The reason of this is the bad feedback of the SCP-ECG communication protocol and messaging on the field. We take great care even so to ensure the interoperability of our devices by providing the customers with the driver for our devices and the technical support required. In this way, customers have no problem to integrate our devices in their own digital ECG information system.

ET participated lightly in the I4C European project too. Our role was mainly providing SCP-ECG devices.

Today, ET is involved in the EPI-MEDICS project, focused on the PEM device (Personal ECG Monitor). The PEM is able to record, store and analyze ECGs. 3 leads are acquired from which the standard 12 leads are mathematically reconstructed (to be viewable by a cardiologist). The analysis and decision making mainly focused on ischemia detection uses both unary and serial analysis algorithms, and leads to an alarm which is transmitted to an alarm server via Bluetooth and GPRS mobile phone. The PEM stores a reduced embedded cardiological health record too, helping both the automated and the human diagnoses. This EHR can be updated and the recorded ECG downloaded using the embedded web server, simply using a basic web browser. The PEM uses SCP-ECG for the complete information flow, requiring no data translation from the internal memory storage to the alarm sending (SCP-ECG and XML data), including the web interface where the user simply downloads an SCP-ECG file to open in his favourite SCP-ECG viewer. Other cutting-edge technologies in the PEM are Bluetooth and GPRS (telecommunication part), XML (and associated technologies such as XSLT and XHTML) for the storage of meta-data and the embedded web server (secured HTTP using SSL), and the use of an open source real time operating system (eCos).

The results of the SCP-ECG choice in ET are quite contradictory. We take advantage of the SCP-ECG standard for the data format and the compression schemes (which are, in our opinion and on-the-field experience, very good). Furthermore we are very interested in the ability to store well-defined quantitative measurements as it promotes quantitative ECG analysis (unary or serial). The minimal mandatory data set is very important for us to use SCP-ECG in very different cases (standard 12 lead ECGs or only 1 lead ECG...).

The troubles we had were mainly with the communication protocol and messaging, which is not satisfactory on the field, so we don't use this part anymore in our new devices. Thus our vision of SCP-ECG is now more a data format than as our first usage a communication protocol. Anyway in our point of view SCP-ECG standard should not define such a low level communication protocol because the telecommunication area already provides more general ways of transferring data, and because these technologies and protocols evolve so quickly. Moreover the customer acceptance of SCP-ECG is mitigated probably because up to now SCP-ECG is not known at customers level and does not cover properly all the ECG related data (Holter, stress test, real time ECG...).

In conclusion we are satisfied by SCP-ECG in spite of its limits. Today customers are just beginning to ask for SCP-ECG compliant devices, and this constitutes a commercial advantage which we expect to grow. In the future, we will still use SCP-ECG in all our devices, probably associated to XML-formatted data.