# Integrating the ECG Enterprise - HES-EKG with the Built-in Vital Signs Information Nomenclature

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## Abstract

*Interchange of ECG information among different application areas is not possible with just one interchange standard. Bridging between different existing standards maybe possible by using the nomenclature of the Vital Signs Information Representation standard (VSIR) as "repository" for the semantic information content and developing application specific interchange format standards. This approach is demonstrated by implementing the VSIR nomenclature into HESEKG.*

## 1. Introduction

Electrocardiography belongs to the fundamental and most frequently applied tests in medical care. Acquisition and analysis of ECGs is a well established, standardised non-invasive procedure.

A major problem is still communication and interoperability between systems of different vendors and between ECG systems and department or hospital information systems.

First attempts to specify an "Universal ECG Transmission Protocol" have been made at the American Veterans Administration Hospitals in 1986-1987. Based on this specification the European "Standard Communications Protocol for Computer-assisted Electrocardiography" has been worked out and a standardisation document SCP-ECG has been published by CEN as prENV 1064 in 1993 [1]. This document has been upgraded jointly between American and European Experts and Version 1.3 has been balloted by AAMI in 1999.

In 2001 the FDA launched the FDA-XML Data format requirements specification [2] to accommodate an easier verification and review of ECG processing results and original wave forms from clinical studies. Because of the FDA decision to support HL7 XML was required as a programming language.

A peculiarity of the FDA-XML Data format is that wave form presentation requirements have been introduced, which should be subject to data viewer design specifications.

So, manufacturers and users are at this time confronted with the need to handle at least two officially existing standards, which is for neither party a comfortable situation.

The purpose of our work was to analyse the differences between these standards and how a bridging and harmonisation between the two standards could be achieved. We believe that using the ISO/IEEE Standard Nomenclature for Vital Signs Information Representation (VSIR) [3] could help to solve the problem.

## 2. Methods

### 2.1. Comparison of the data content of FDA/XML, SCP and VSIR

Table 1 depicts schematically essential format and content elements of the interchange format specifications (FDA/XML and SCP), the fourth column shows whether in VSIR objects/code is available for the respective items.

Table 1. Essential format and content elements of FDA-XML, SCP and VSIR specifications.

| Information Content | FDA XML | SCP | VSIR NCL 2003-09 |
|---|---|---|---|
| Recording session ID | + | + | + |
| Trial identifiers | + | extension possible | + |
| Patient Id | + | + | + |
| Device ID | + | + | + |
| ECG lead definitions | + | + | + |
| ECG raw data (XY plot) | + | + | + |
| **Processing results** | | | |
| Beat Annotation information | + | + | + |
| Beat loc./Region of interest | + | + | + |
| Wave component annotations | + | + | + |
| Rhythm info/annotation | + | + | + |
| Diagnostic statements | -? | + | + |
| Lead measurements | + | + | + |
| Pacemaker information | + | + | + |
| Noise annotations | + | -* | ? |

* Manufacturer dependent

Please note: The SCP column has been filled with the assumption that ECG raw data and processing results are stored according to the SCP specifications.

Comparison of column one and two demonstrate that all results required by the FDA specification may be transferred in an SCP record as well. The various pointer data allow also for extraction and display of "regions of interest". However, those requirements should be part of data viewer specifications and should be realised by viewer functions. They are not a priory subject to waveform record specifications. Such examinations are part of a temporary ad hoc analysis. These analyses may vary from observer to observer, while the data content should remain always the same.

The essential differences between the FDA-XML and the SCP Specifications are a) the different data interchange Formats and b) that SCP comprises messaging and communication specifications. While some of the SCP messaging specifications still comply well with a couple of possible "use case" scenarios are the "Enhanced X-Modem" communication specifications out of date and require revision. On the other hand, is the XML representation of ECG waveform data certainly not appropriate for communication of data from wearable or other micro devices. Therefore a bridging mechanism between the SCP interchange format and the FDA-XML data format is inevitably necessary.

## 2.2. The VSIR standard

This standard has been developed by CEN TC251, restructured and further developed by the IEEE 1073 group and adopted by IEEE and ISO TC215, [4]. The standard consists essentially of a use case based Domain Information Model with object and attribute specifications and a Medical Data Dictionary structured in a "universal" nomenclature with associated code tables within the IEEE/ISO 11073-10101 document.
The principle of building the nomenclature has been described previously [5]. All domain specific terms for measurements including treatment, e.g. infusions, assisted respiration in intensive care, from clinical chemistry, neurology, polysomnographic sleep recordings etc. have been semantically analysed using the MOSE (Model for Representation of Semantics) approach [6], by forming Categorical Structures of Systems of Concepts.

Table 2 on the bottom depicts a sample of terms for description of ECG measurements, wave forms and annotations.

# 3. Results

## 3.1. Structure of the VSIR nomenclature

The first column in table 2 contains the systematic name for the measurement (or the annotation.). By means of the semantic analysis of the associated terminology space it has been made sure that only one, *unique* term (Systematic name) has been established for each measurement /annotation (="concept"). Column 2 lists the commonly used acronyms, column 3 the definition/description, column 4 the unique identification code and column 5 the respective measurement value. If there is an annotation "1" indicates present, "0" not present.

Comparison of the 4th column of table 1 with the 2nd column of table 1 and with table 2 shows that in particular processing results, e.g., waveform amplitudes, rhythm annotations, ventricular premature beats etc. are already part of the VSIR Standard.

A specific new part of a nomenclature designed to accommodate the FDA-XML will be inserted into the next version of the ISO 11073-10101 document.

## 3.2. Extension of the HES EKG analysis program for VSIR NCL output

Structure and content of the VSIR nomenclature have been used as specification for a specific output file of the HESEKG analysis program as details show on figures one and two on the next page.

Table 2. Sample of the VSIR ECG Nomenclature.

| Systematic Name | Acronym | Description/Definition | Code | Value |
|---|---|---|---|---|
| Duration \| ECG5,R2 \| Heart \| CVS | R2 (R') V3 | Duration R2 (R') in Lead V3 | 11520 | 38 |
| ElectricalPotential \| ECG61,Q \| Heart \| CVS | Q A III | Q Amplitude in III | 1792 | -30 |
| Integral \| ECG1,QRS,Area \| Heart \| CVS | QRS Area I | Area of QRS in I | 4096 | 26 |
| Angle \| ECG,QRS,Frontal \| Heart \| CVS | Frontal Angle QRS | QRS Angle in frontal plane (Einthoven) | 16132 | 278 |
| Magnitude \| ECG,QRS,Frontal \| Heart \| CVS | QRS Vector frontal | QRS vector in frontal plane (Einthoven) | 16176 | 1354 |
| Pattern \| BundleBranchBlock,Intermittent \| ECG,Heart \| CVS | Intermittent BBB | Intermittent Bundle Branch Block | 16417 | 1 |
| Pattern \| Extrasystoles,Ventric.,Bigeminus \| ECG,Heart \| CVS | Ventr. Bigeminus | Ventricular premature beats, Bigeminus | 16952 | 1 |
| Pattern \| Infarct,Anterior \| ECG,Heart \| CVS | AMI | Anterior myocardial infarction | 17584 | 0 |
| Pattern \| Rhythm,Fibrillation,Atrial \| ECG,Heart \| CVS | Atrial Fib. | Atrial Fibrillation | 16648 | 0 |

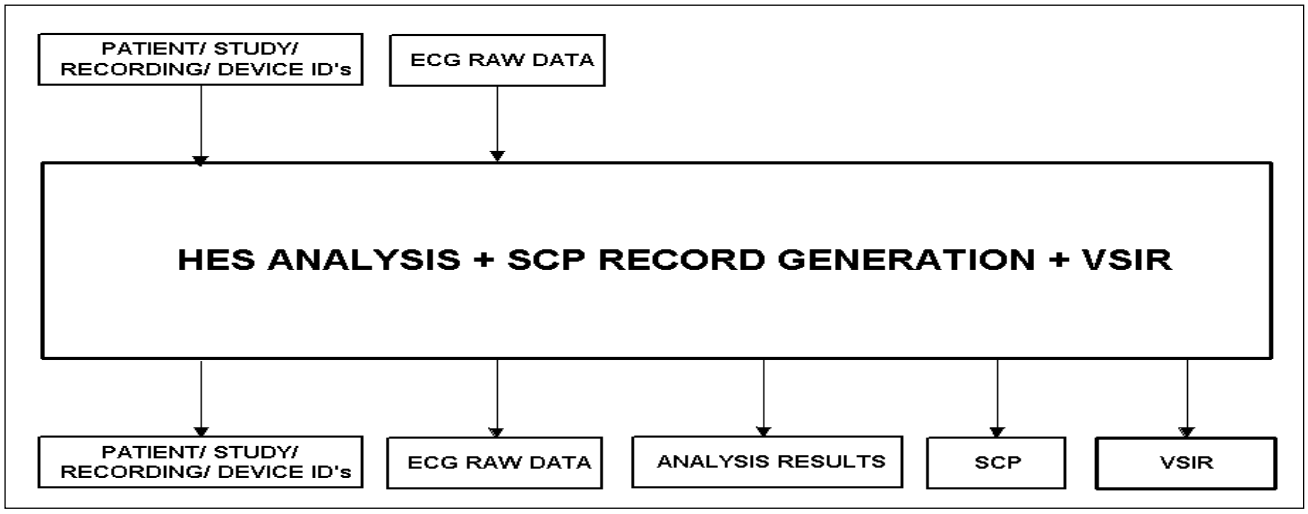


Figure 1. HES Analysis and output record generation. The analysis Program includes now a mapping procedure for transfer of all waveforms, measurements and annotations into a code block as specified within the VSIR standard.

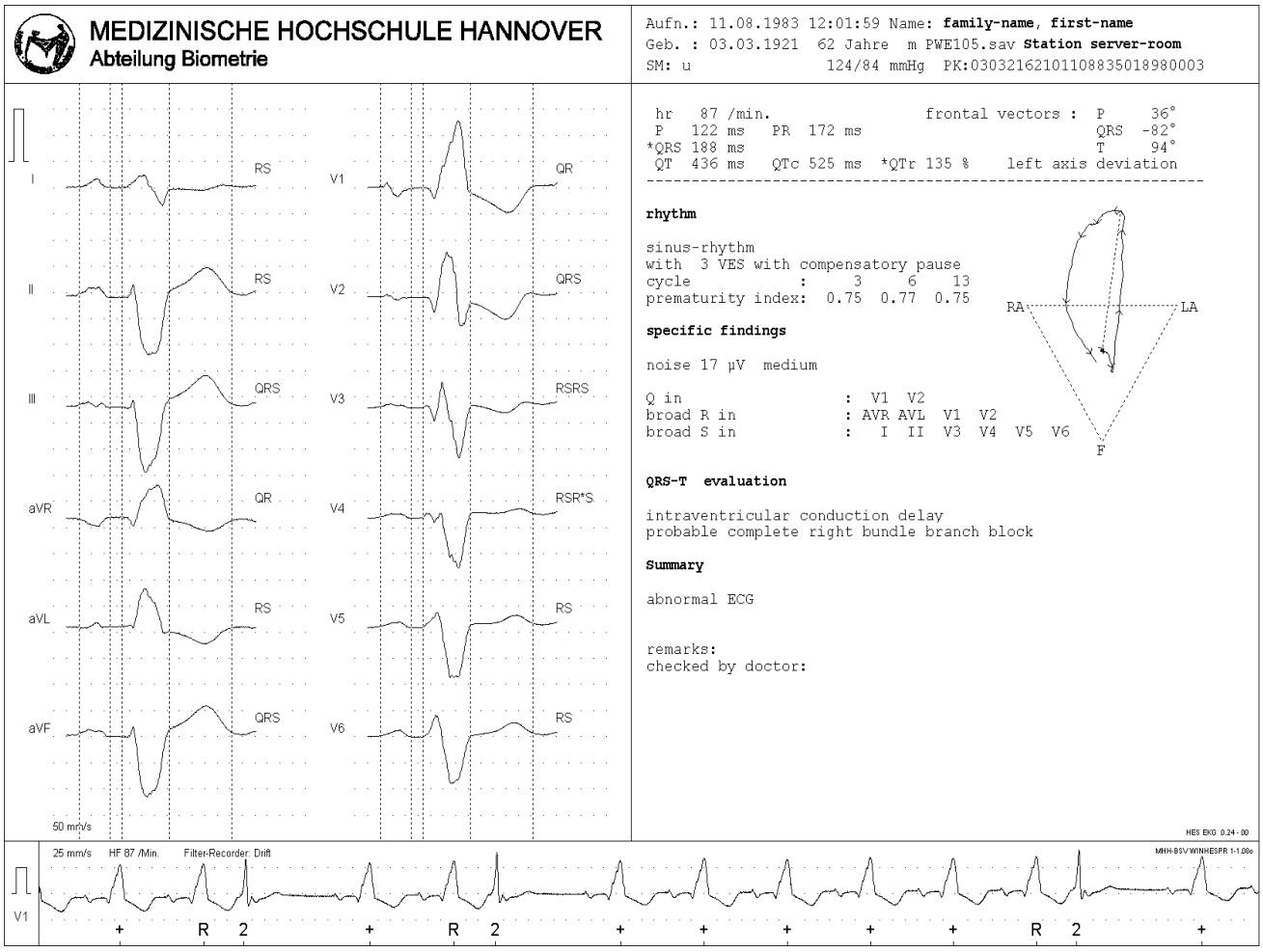


Figure 2. HES ECG Analysis report: The bottom part shows the rhythm strip with beat annotation. On the left hand upper part the median beat for each lead can be seen with detailed waveform annotations and measurement references. The upper right hand part shows essential measurements, noise information and interpretative statements.

The standard version of the HES EKG analysis program did so far provide as output

- All types of demographic patient data, record Id data (if present) study data, device data, environmental data, technician data etc.,
- transfer of the original ECG "raw" data,
- analysis results (ca 80 measurements for each lead as well as all common types of "global" measurements including beat and wave form annotations, noise measurements and interpretation and
- a SCP record (old compatibility levels I-IV).
- In order to make possible the generation of FDA-XML records now all ECG data and results are put out in form of an ECG-VSIR nomenclature table.

As illustrated in figure 3 at least two options are available to produce an FDA-XML record.

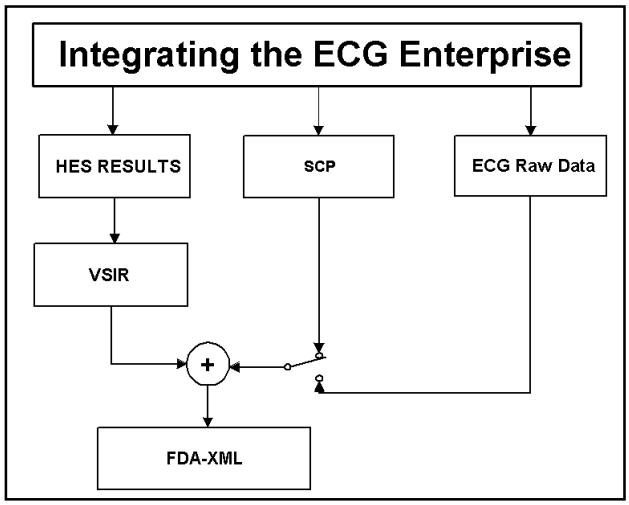


Figure 3. HES EKG options to provide ECG Analysis results and to integrate ECG processing scenarios.

ECG recordings from various acquisition scenarios may be differently exploited because of the independent set of export functions:

- Original ECG raw data can be read out directly.
- HES analysis results can be read out directly.
- HES results may be exported as SCP record into an SCP database.
- A user can take advantage of a SCP file where within the header demographic patient data including all other record relevant information (e.g., study data) and loss-less compressed ECGs can be provided.
- Short sets of data can be extracted for transfer from the VSIR file into an HL7 record.

## 4. Discussion and conclusions

The present situation with – (besides the still existing proprietary solutions ) - at least two existing standards for ECG interchange is cumbersome for manufacturers and users. Despite the long history of standardisation efforts interoperability in electrocardiography is still an open issue. It should be noted that also the FDA-XML nomenclature proposal is not yet part of the official ISO/IEEE standard [4].

It became obvious that the application areas clinical electrocardiography, micro and wearable ECG systems, clinical drug studies and (this time not discussed at all) DICOM introduce requirements, which cannot be covered by a single ECG interchange format.

For methodological reasons standards for data interchange formats and for viewers should be strictly separated and not mixed up.

Using consequently the specifications and provisions of the Vital Signs Information Representation Standard seems to make possible the design of "bridging" standards, which could enable interoperability between ECG systems from the different application areas.

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## References

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