

# ENV 14271, File Exchange Format for Vital Signs and its use in digital ECG archiving

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## 1. Introduction

In an electronic patient record all patient data, including physiological signal recordings such as ECG measurements, should be in electronic form. As it is sometimes necessary to store these records for a long period of time, it is important that the data can also be accessed in future. If the data are stored in a number of incompatible manufacturer specific formats, it is unlikely that all these data can be read with the computer systems in use after 15 years. For this reason, it would be very useful if there were a standard, well supported generally accepted format for which manufacturers would offer software support in their present and future systems.

The Technical Committee TC251 (Health Informatics) of the European Committee of Standardisation (CEN) has produced a prestandard for the file exchange of vital signs recordings, the ENV 14271 (abbreviated FEF) [1]. This prestandard, which is based on another CEN prestandard ENV 13734 Vital Signs Information Representation [2], defines the object model and data structures in which physiological signal recordings can be stored into a file in an interoperable way. In the following the contents of FEF and its applicability to ECG archiving is discussed.

## 2. File exchange format (FEF) overview

PREAMBLE	= 1
MANUFACTURER SPECIFIC SECTION	= 1
HEALTH CARE PROVIDER SECTION	= 1
PATIENT DEMOGRAPHICS SECTION	= 1
SESSION TEST SECTION	= 1
MEDICAL DEVICE SYSTEM SECTION	= 1
MULTIMEDIA SECTION	= 1
SESSION PHASE SECTION	= 1
DESCRIPTIVE DATA SECTION	= 1
MEASURED DATA SECTION	= 1
Real Time Sample Array Measured Data section	= 0
Time Sample Array Measured Data section	= 0
Distribution Sample Array Measured Data section	= 0
Numeric Measured Data section	= 0
Enumeration Measured Data section	= 0
Alert section	= 0
Dynamic Attribute change section	= 0
SESSION NOTES SECTION	= 0

Figure 1. General structure and section ordering of a FEF file, some details omitted. Notation: = 1 means that exactly one such section is mandatory, =1 means than at most one such section can exist, = 1 means that at least one such section must exist, = 0 means that any number, including zero such sections can exist in the file.

Figure 1 shows the internal structure of a biosignal file in the ENV 14271 format. Indenting indicates that the indented blocks are part of a block on top of it, e.g. that Descriptive data section is a part of Session phase section. The idea of the specification is that the file produced in the recording situation would contain the relevant information which identifies the recorded subject, the institution in which it was recorded, the devices which were used in the recording in addition to the actual biosignal and related data. The related data consists of time-stamped numeric measurement values, events and annotations (called enumerations) and alerts. Even spectra of biosignals can be stored using the Distribution sample array data type. Manufacturers can store data specific to their devices into a separate section which does not need to be interoperable with other systems. Multimedia such as video, images and sound can be stored into the same file if necessary. Notes and annotations of the recording are supported with a special section and with attributes in the enumeration category.

A special feature of the FEF specification is that the encoding of the format has been separated from the content description into an Annex. The present encoding follows ASN.1 Basic Encoding Rules for most objects and attributes but the biosignal data will most likely be encoded in raw binary form to same storage space. In future the encoding can be changed to something else (e.g. XML) without changing the main body of the specification.

As the format was specified for general biosignal recordings, its intention was also to support the exchange of ECG recordings. For this purpose it contains or refers to around 20 pages of ECG specific definitions, ECG lead, ECG measurement variable and diagnostic codes which FEF inherits from ENV13734. Random examples of numeric ECG measurements are Duration of the QRS complex in a specific lead, Azimuth of the vector at 60 ms after the end of QRS complex of ECG, Amplitude level of the third extremum of the P wave of the ECG in a specified lead, Magnitude at the maximum vector of the P wave of ECG (computed as square root of squared scalar magnitudes of X, Y, Z), and heart rate. Random examples of ECG related events are Incomplete right bundle branch block, Left ventricular hypertrophy, Paroxysmal supraventricular tachycardia, and Wolf-Parkinson-White Syndrome type B (possibly).

As the mentioned examples show, the list of ECG-related measurements and events which are interoperable between computer systems without user intervention can be quite extensive. As medicine develops, new ECG-based measures which are not yet in the lists may become interesting and worth storing in a standardized way. This calls for a mechanism to update the code base. As FEF uses the ENV 13734 code base which is in a process to become an ISO standard in the 11073 series jointly with the IEEE 1073 standardisation committee, the code base maintenance will be taken care of through this process.

### 3. Discussion

The present version of the FEF specification does not specify any compression method for the data. It was decided to be left to the next version of the specification. ECG can be compressed successfully as its waveform structure is known but as the format should also serve other biosignals which do not have a “median beat”, even the future versions will not compress ECG as optimally as dedicated ECG formats.

A standard specification is of little use if it is not used by anyone. As a starting point a reference implementation and a FEF signal viewer would be very helpful, as well as a software tool to test the conformance of the generated files to the specification. At the time of writing only one implementation exists and initiatives for more, especially from the open source community are encouraged.

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### References

- [1] Prestandard ENV 14271, European Committee for Standardisation (CEN), Brussels, Belgium, 2004.
- [2] Prestandard ENV 13734, European Committee for Standardisation (CEN), Brussels, Belgium, 2000.

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