

## Freeware ECG Viewer for the XML FDA Format

<sup>1</sup>F Badilini, <sup>2</sup>L Isola  
<sup>1</sup>AMPS LLC, <sup>2</sup>Montichiari  
 New York, USA, Italy

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### 1. Introduction

The Food and Drug Administration agency (FDA) has expressed interest in having the pharmaceutical industry submit digital annotated electrocardiograms obtained in certain trials. This effort was initiated in late 2001 and was driven by the need to improve the reviewing process [1].

After considering existing standards, an internal committee chose the usage of an XML (Extensible Markup Language) to be used in association with the Health Level Seven (HL7) version 3 messaging standard, a structure that is supported by the US Department of Health and Human Services [2].

In this article we provide a brief description the XML FDA format and of the freeware viewer that was developed to visualize it.

### 2. Structure of FDA XML

The FDA XML format is based on HL7 version 3 messaging standard. All XML elements (tags) of the format are derived from the so-called HL7 Refined Message Information Model (R-MIM) which defines all the components that make a specific HL7 informative message. An R-MIM model is composed of a set of elements that can either be Acts (for example a medical observation or a procedure) or Entities (for example a person or an organization) that performs the Acts. Each Entity participates in the execution of an Act with a specific Role (for example, as a patient or an employee). A single message can include several Acts which can be related to each other (an example in the Annotated ECG message is the Act specifying ECG annotations which is directly related to the Act specifying the ECG waveforms). Figure 1 shows a schematic example of how the different HL7 concepts can be used to make a message structure.

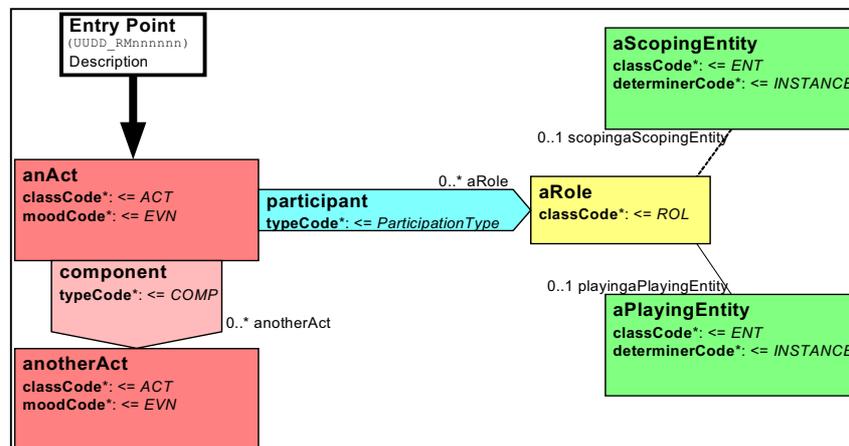


Figure 1. Example of an R-MIM.

Each R-MIM from HL7 is directly and uniquely linked to an XML structure which can be derived starting from an Entry Point (see Figure 1) which serves as the root of the XML tree. Once an R-MIM is finalized, each of the HL7 elements (Acts, Entities, Roles, and all the links between them) become XML elements with attributes that specify the characteristics of the HL7 element. For example, an ECG annotation will become an XML tag with attributes specifying the type of annotation (e.g. a P wave or a T wave).

## 2.1. Waveform and annotation information

Waveform information associated with ECG channels is stored in an HL7 Act named *Series* which includes one or more *SequenceSet* Acts. Each *SequenceSet* instance represents a set of synchronously recorded ECG channels which are in turn stored in a *Sequence* Act. A *Sequence* Act is a collection of ordered numbers, for example the sequence of digital samples from an ECG lead, or the sequence of time reference points. Using HL7 terminology, we say that the sequences grouped under the same *SequenceSet* are correlated observations. For example an ECG with 12 simultaneously recorded channels will have a single *SequenceSet* instance (all ECG channels correlated) whereas an ECG with 4 sequences of 3-leads each will be represented by 4 *SequenceSet* instances (each comprising three channels of correlated observations).

(Need some description of derived waveforms).

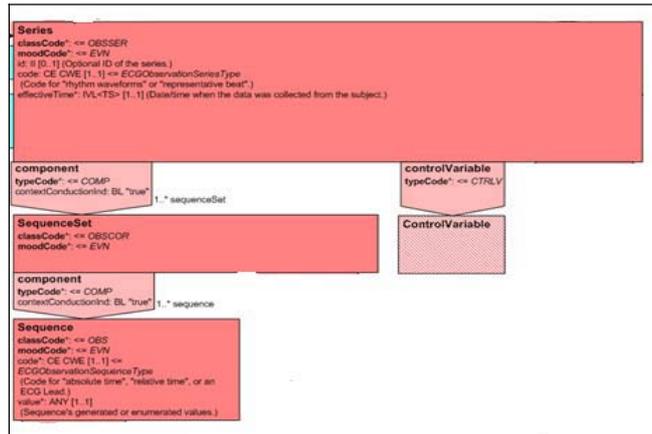


Figure 2. Extract of Series Acts from the XML FDA R-MIM

## 2.2. Annotation information

(Need to say what you mean by annotations) Annotation information is stored in an *AnnotationSet* Act which is the container for separate *Annotation* Acts. Each *Annotation* Act stores a set of annotations generated by an Entity (which can be a *Person* or a *Device*) that plays the role of the *author* of the set of annotations. Thus, the format supports multiple sets of annotation in the same file (for example it is possible to store in the same file multiple readings performed by different algorithms or reviewers).

Annotations can be of five possible scopes: beat, wave, rhythm, pacemaker and noise. The scope of annotation is specified in the *code* property of the *Annotation* Act. A dictionary of specific annotation types is incorporated in the standard by reference (and, in fact, it is only this vocabulary that specializes the waveform standard for use in describing ECGs); however, the user has the possibility to define user-specified annotation and set up a customized vocabulary.

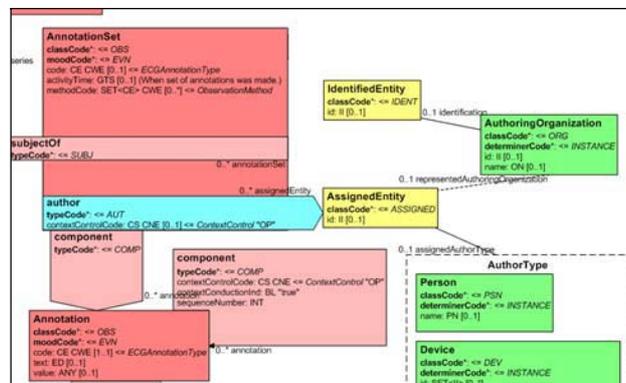


Figure 3. Extract of Annotations Acts from the XML FDA R-MIM

### 3. The XML Free Viewer

The viewer presented (XMLFDA) can be downloaded from internet [1,3] and is the first generally available tool that was developed to display FDA XML files. One advantage of this viewer is that it was developed to meet specific needs of FDA and thus it directly reflects the type of reviewing process from a regulator standpoint. Nonetheless, we expect a significant number of more elaborate tools to be developed in the near future as the industry will move toward full adaptation of the standard.

XMLFDA is organized with a left panel dedicated to a tree navigational display of the XML structure and with a right panel providing a contextual display (graphical- or text-based) of the selected components. By default, the tree displayed is *simplified* meaning that only the ECG-relevant elements are shown using an ECG standard terminology instead of the complete HL7 structure. A toolbar button enables the full display of the tree with all the XML elements shown.

The idea is that the user selects (clicks on) elements of the left panel tree and a contextual display is automatically displayed on the right panel. Both waveforms and annotations can be displayed in several ways. In particular, the user has options to turn on/off annotations by type and to change the format of the display (e.g. number of leads and seconds displayed) separately for raw and derived waveforms.

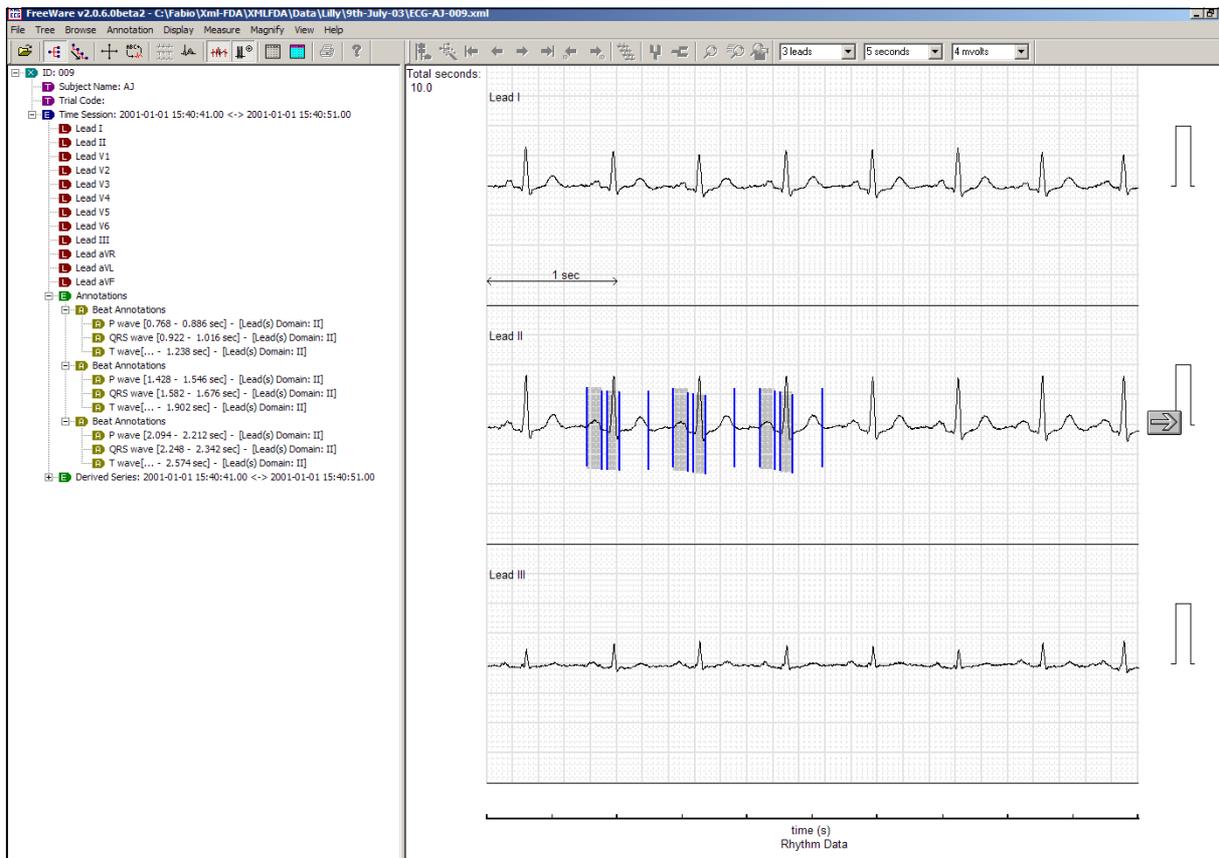


Figure 4. Snapshot from the viewer. Only lead I, II, III are displayed. Annotations on lead II are displayed in both the left (tree) and on the right (display) panels.

#### 3.1 Showing waveforms

Waveforms are displayed on the right panel every time the user selects a waveform-type element of the tree in the left panel. The user can either click an ECG node (and all the ECG channels associated will be displayed) or a single lead node, to limit the display to a single lead.

When the ECG consists of the 12 standard leads, the viewer also supports a set of conventional display organizations (either a cascade 12x1 or a 6x2 organization). In addition, the user can choose the amount of time (seconds) and amplification displayed for each channel.

#### 3.2 Showing annotations

Annotations are displayed in both the tree and the contextual display panels (see Figure 4). On the tree panel, the numerical values associated with each annotation (for example the time localization of a T wave) are shown. On the display panel (when graphical mode is active), the actual calipers (or the regions when the annotation has both a start and an end) associated with the annotations are overlaid on the ECG waveforms. However, the numerical value of annotation can also be displayed by right-clicking on the top of the caliper/region, as shown in Figure 5. The format supports both lead-based and global (across all leads) annotations, and the viewer distinguished these by xxxxx. Furthermore, the user can choose different colors for different annotation types and turn off the display of annotations by type.

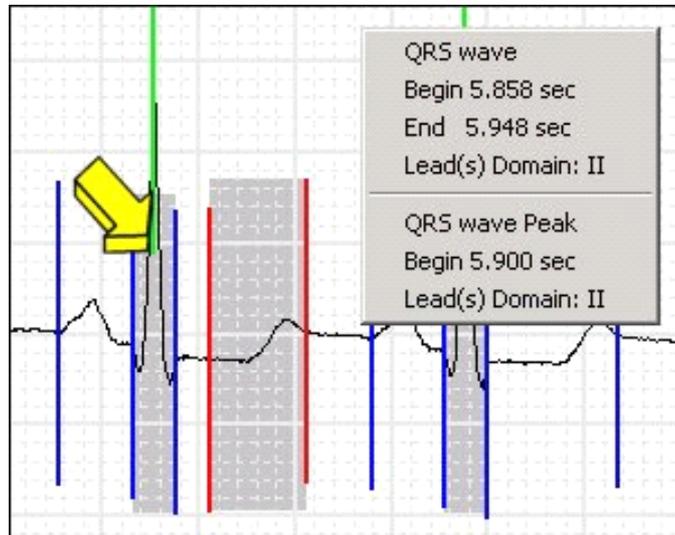


Figure 5. Context display of annotations

## Acknowledgements

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## References

- [1] <http://www.fda.gov/cder/regulatory/ersr/#ECG>
- [2] <http://www.hl7.org/V3AnnECG/index.htm>
- [3] <http://www.amps-llc.com>

Address for correspondence.

Fabio Badilini.  
Via Paolo VI 34,  
25018 Montichairi (BS)  
Italy  
E-mail [badilini@aol.com](mailto:badilini@aol.com).