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Development of PDF-ECG: Further steps towards the long-term preservation of clinical electrocardiograms

Most modern electrocardiographs digitally acquire standard 12-lead ECGs synchronously for 10 s; however, further diffusion of the source (raw) data does not automatically happen. In practice, ECG systems by most manufacturers provide the possibility of exporting traditional 12-leads printouts in common formats (i.e. ISO 32000-1:2008 Portable Document Format, PDF), sometimes referred to as "ECG reports". These ECG printout reports are the preferred choice for clinicians as they permit a still unequaled immediacy; however, only a portion of the 10 s under analysis is included and, even worse, any successive analysis is limited, most often totally precluded, by the resolution of the printing process. As of today, final storage of ECG data (even, with a few exceptions, in the context of hospital electronic health records) is mostly achieved by saving the PDF report, and the source digital information is forever lost.

We recently proposed a proof of concept to address the challenge of ECG data portability, long-term storage, and documentation of the histories and sources of interpretative information, by developing a new ECG format, the so-called PDF-ECG, that combines the benefits of a digital ECG and a standard graphical report [1]. Our solution is based on the very recent PDF/A ISO 19005-3:2012 standard, which dictates an electronic document format for long-term preservation. The proof of concept designed is a PDF/A-3u (Unicode) envelope containing the ECG graphic (with no predefined layout), the ECG digital data in a generic format (which for the first practical implementation was chosen to be the aECG HL7 format, without precluding other formats), and a XAdES advanced electronic signature of the digital data. We also provide a means to ensure content match, i.e. a mechanism to guarantee that the information in the graphic section comes from the very same source data stored in the digital data section, solving a common problem in hybrid archiving.

Within a unique structure, PDF-ECG would provide a viable way to satisfy both the needs for a simple graphic report, accessible without the installation of specific proprietary software, and for delivering all the acquired information for further processing with specialized software.

Fabio Badilini, Phd Roberto Sassi, Phd AMPS-LLC, New York, NY, USA Dipartimento di Informatica Università degli Studi di Milano, Italy E-mail address: badilini@amps-llc.com We believe the selection of the PDF/A format is judicious because it is used to represent a large body of information around the world, and while this information must be preserved for a long time, multiple generations of technology might hinder accessibility.

The proposed new PDF-ECG document can be redistributed and opened by most PDF readers, without the need of specific software. Moreover, analysis software could be easily adapted to accept the file as input for subsequent analysis, which could also be embedded in the document. PDF-ECG long-term preservation characteristics make it suitable for long-term archival in hospital patient management systems, core laboratory and research center databases. Finally, the PDF-ECG format permits third-party validation, solving a problem that might prevent the adoption of this form of hybrid archiving.

The PDF-ECG format is still in a very preliminary stage, but has stirred significant interest. After the publication of the paper describing the first version of the proof of concept in 2014 [1], an open discussion between major ECG companies and researchers in this application area was initiated, and an informal meeting was held during the 2015 Computing in Cardiology meeting in Nice. Then, during the 2015 STAFF meeting in Vence the format was presented as part of a session on ECG standardization. The outcome of these efforts has been the formation of a dedicated working group (WG) with representatives from manufacturers and institutional bodies, which will work toward a consensus document aimed to favor further formalization and, ultimately, a widespread storage and preservation of ECG digital records, wherever and for whichever reason they are today acquired. The WG is composed of nine members and has already started its activities. The Journal of Electrocardiology is actively supervising the whole initiative and it will be the preferred platform to inform about the progresses of the WG.

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.jelectrocard.2016.07.007.

Reference

Concept for an International Long-time Preservation ECG Format. Computing in Cardiology, Boston (MA, USA), vol. 41. ; 2014. p. 461-4.