A Review on Digital ECG Formats and the Relationships Between Them

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***Abstract*—A plethora of digital ECG formats have been proposed and implemented. This heterogeneity hinders the design and development of interoperable systems and entails critical integration issues for the healthcare information systems. This paper aims at performing a comprehensive overview on the current state of affairs of the interoperable exchange of digital ECG signals. This includes 1) a review on existing digital ECG formats, 2) a collection of applications and cardiology settings using such formats, 3) a compilation of the relationships between such formats, and 4) a reflection on the current situation and foreseeable future of the interoperable exchange of digital ECG signals. The objectives have been approached by completing and updating previous reviews on the topic through appropriate database mining. 39 digital ECG formats, 56 applications, tools or implantation experiences, 47 mappings/converters, and 6 relationships between such formats have been found in the literature. The creation and generalization of a single standardized ECG format is a desirable goal. However, this unification requires political commitment and international cooperation among different standardization bodies. Ongoing ontology-based approaches covering ECG domain have recently emerged as a promising alternative for reaching fully fledged ECG interoperability in the near future.**

***Index Terms*—Converter, electrocardiogram (ECG), electrocardiography, format, interoperability, mapping, ontology, relationship, review, standard.**

I. Introduction

THE ECG is the most commonly performed cardiac test. With the rapid development of telemonitoring platforms based on the new information and communication technologies (ICT), the transmission, storage, and management of digital ECG signals have turned into major topics of debate and investigation. Within the context of this debate, the standardization of these processes has been a key issue lasting recent decades. Indeed, several competing formats and standards for the representation, storage and exchange of ECG recordings can be found in the digital ECG standardization arena. Such formats and standards have successfully been applied in prototypes or even real environments, as has been remarked in much of the relevant bibliography. However, the current reality with all such formats and standards is not only complex but also part of a widening and ever-changing context. This heterogeneity hinders the design and development of end-to-end standard-based systems and entails critical integration issues for the healthcare information systems (HIS) of hospitals and medical organizations. In order to partially solve this problem, numerous mappings between digital ECG formats and standards have been proposed in the literature. Nevertheless, for home and hospital systems to exchange ECG signals in a versatile, integrated and efficient way, adoption of a single digital ECG format by consensus is required.

In this context, this review paper provides 1) a comprehensive enumeration and a concise overview on existing digital ECG formats and standards, 2) a collection of the main applications and cardiology settings using such formats and standards, 3) a thorough compilation of the relationships and mappings between the formats and standards available in the literature, and 4) a reflection on the current situation and foreseeable future of the interoperable exchange of ECG signals.

II. Methods

For the preparation of this review, the bibliography consulted includes, but is not limited to, existing reviews on this topic [1]–[3]. These reviews do not completely address this widening context of digital ECG formats and standards either due to they are obsolete or they omit existing effort. This review, therefore, completes and updates previous reviews.

In addition, different databases—including medical (such as PubMed [4] or GoPubMed [5], which is a knowledge-based search engine for biomedical texts); technical (like IEEE Xplore [6]) and general resources (like Thomson Reuters Web of Knowledge [7])—have been thoroughly mined with key concepts such as ECG, electrocardiography, format, standard, norm, digital, exchange, interoperability, standardization, cardiology, combinations thereof, and stemming variants thereof. Both the names of the formats and their acronyms were used to search for applications and cardiology settings using such formats. Furthermore, the documents or papers found often led to other existing formats, applications, settings, or relationships available in the literature. The search for relationships between existing formats and standards was conducted following a homologous procedure. The word list, however, included terms such as mapping, harmonization, converter, or relationship.

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TABLE I
EXISTING PROPOSALS FOR DIGITAL ECG INTEROPERABILITY (EXCLUDING MANUFACTURERS' FORMATS)

		Format/Authors	Stands for…	Ref.
Supported by SDOs	Widely Known Efforts	SCP-ECG	*Standard Communications Protocol for computer assisted ECG*	[8]
		HL7 aECG	*Health Level 7 annotated ECG*	[9]
		DICOM Supp. 30	*Digital Imaging and Communication in Medicine Supplement 30*	[10]
		MFER	*Medical waveform Format Encoding Rules*	[11]
	The X73 family in digital ECG	VSIR	*VITAL Signs Information Representation*	[12]
		FEF	*File Extension Format*	[13]
		ISO/IEEE11073	*IEEE P11073-10306, Device Specialization - ECG (X73PoC)*	[14]
			IEEE Std 11073-10406™-2011, Basic ECG (1-3 leads) (X73PHD)	[15]
Binary	Holter	ISHNE Format	*International Society for Holter and Noninvasive Electrocardiology*	[16]
	High Resolution	HDF	*Hierarchical Data Format*	[17]
	Multiparam.	e-SCP-ECG+	*Enhanced SCP-ECG*	[18]
XML proposals	General Purpose	PhilipsXML	*Philips eXtensible Markup Language*	[19]
		I-Med	*International Medical*	[20]
		ecgML	*ElectroCardioGraphy Markup Language*	[21]
		XML-ECG	*eXtensible Markup Language-ElectroCardioGraphy*	[22]
	Environment Specific	mECGML	*Mobile ElectroCardioGraphy Markup Language*	[23]
		ECGaware (AECG)	*ElectroCardioGraphy aware*	[24]
		UNISENS	*UNIversal data format for multi SENSor data*	[25]
		XML-BSPM	*XML - Body Surface Potential Map*	[26]
Intended for Neurophysiology	'Data Format' Family	EDF	*European Data Format*	[27]
		EDF+	*European Data Format (enhanced)*	[28]
		GDF	*General Data Format*	[29]
		BDF	*BioSemi Data Format*	[30]
		OpenXDF	*Open eXchange Data Format*	[31]
	Other Neurophysiology Proposals	E1467	-	[32]
		SIGIF	*SIGnal Interchange Format*	[33]
		EBS	*Extensible BioSignal*	[34]
		SignalML	*Signal Markup Language*	[35]
		IFFPHYS	*Interleaved File Format for Physiological Data*	[36]
Databases	-	WFDB	*WaveForm DataBase*	[37]
		MIT-BIH	*Massachusetts Institute of Technology-Beth Israel Hospital*	[38]
		AHA	*American Heart Association*	[39]
		CSE	*Common Standards for Electrocardiography*	[40]
IHE	Cardiology Framework	ECG	*Retrieve ECG for display*	[41-42]
		REWF	*Resting ECG Workflow*	[43]
		WCM	*Waveform Communication Management*	[44]
Ontologies	-	SEO	*SCP-ECG Ontology*	[45-46]
		NCBO	*National Center for Biomedical Ontology*	[47]
		NEMO	*Núcleo de Estudos em Modelagem Conceitual e Ontologias*	[48]

SDO: Standard Development Organization. XML: eXtensible Markup Language. IHE: Integrating the Healthcare Enterprise.

III. RESULTS

The presentation of the results has been divided into two sections: first, the review on digital ECG formats and its applications are shown, and, second, the relationships between the different digital ECG formats and standards available in the literature are outlined.

A. Review on Digital ECG Formats

Table I shows a comprehensive review on open digital ECG formats and standards. This table is divided into seven different groups. First, effort supported by Standard Development Organizations (SDOs) are presented, irrespective of the nature of the data format. Second, existing binary encoded formats are presented. Third, proposals based on eXtensible Markup Language (XML) are shown. Fourth, formats originally intended for neurophysiology that are also able to encode ECG signals are presented. Fifth, the main ECG database formats are outlined. Sixth, the Integrating the Healthcare Enterprise (IHE) profiles covering the ECG domain are presented. Finally, existing and ongoing works on ECG ontologies are shown. An in-depth description of these formats and standards is provided in the following pages.

1) Widely Known Effort: Among the effort supported by SDOs, the four most widely known formats include: the Standard Communications Protocol for computer-assisted electrocardiography (SCP-ECG, initially developed as European standard EN1064), HL7 annotated ECG (HL7 aECG, American standard from the American National Standards Institute—ANSI), Digital Imaging and Communication in Medicine (DICOM) Waveform Supplement 30, or Medical waveform Format Encoding Rules (MFER, Japanese standard). These formats are underscored because of their relevance, irrespective of their nature—which could be either binary or XML-based.

The SCP-ECG [8] is a standard primarily intended for short-term diagnostic ECGs and supported by the European Committee for Standardization (CEN). The SCP-ECG is a binary encoded format that details the content and structure of the information to be exchanged between digital ECG devices and ECG host systems.

To achieve consensus, manufacturers, physicians, and end users from America, Japan, and Europe worked on a collaborative basis to create a common standard for the interoperable sharing of digital ECGs. The Common Standards for Quantitative Electrocardiography (CSE) project can be seen as a prelude to the pursuit of an interoperable format for exchanging digital ECGs [40], [49], [50]. The first outcomes of the SCP-ECG project were reported in 1991 and 1992, mainly by the project leader Willems *et al.* [51]–[54]. Development was achieved in close collaboration with representatives from academia and industry, within the framework of the Advanced Medical Informatics (AIM) program of the European Community, more specifically, the AIM #1015, SCP-ECG project.

Finally, in 1993, it became a European prestandard (CEN/ENV 1064) and later, it was positively balloted within AAMI (AAMI EC71). Some limitations of the 1.3 version were highlighted in 2004 [55] and a new version was made public in 2005. An amendment to this version was released in 2007 and, finally, in 2009, it was approved as an ISO standard (ISO 11073-91064:2009) [56].

Although the SCP-ECG reached mature stability during the nineties, it was during the course of the openECG project that it attained new heights of popularity. The openECG project [57] started in 2002 with the objective of involving all the stakeholders in the adoption of computerized ECG standards in the SCP-ECG file format [58]. In order to promote this standard, the openECG community, based on the experience and vision of the early adopters, encouraged its wider adoption by means of specific proposals such as the development of implementation guides [59], [60], the creation of programming contests with awards for the best SCP-ECG-compliant tools [61], the supply of content and format checking conformance tools [62]–[65], and also the release of open source SCP-ECG tools under GNU General Public License [66].

Other projects closely related to the SCP-ECG world were "Open European Data Interchange and Processing for Electrocardiography" (OEDIPE, January 1992–December 1994) and "Enhanced Personal, Intelligent and Mobile system for Early Detection and Interpretation of Cardiological Syndromes" (EPI-MEDICS, 2001–2004). One of the major goals of the OEDIPE project was to implement and demonstrate electronic data interchange of digital ECGs along the lines of the SCP-ECG standard communication protocol [67], [68] by setting up demonstration systems for the follow-up of selected heart-disease populations, integrating serial analysis, decision support, open data-bases, and communication protocols [54]. Some of the initiatives included: a demonstrator for host-to-host ECG data interchange between two centers (Leuven in Belgium and Lyon in France) [69], a database for the digital SCP-ECG and epidemiological information [70], or experience in transmission of SCP-ECG files from ambulance cars [71]. Moreover, the EPI-MEDICS project developed a personalized ECG device, called Personal ECG Monitor, for the early detection of cardiovascular diseases that encoded the ECG files in the SCP-ECG format [72].

Due to all the reasons given earlier, a wide variety of experience in the use of the SCP-ECG standard can be found in the literature over last two decades [73]–[81]. This proliferation of literature proves the interest of the scientific community in this standard, and makes SCP-ECG one of the most widespread initiatives in medical informatics standardization [82].

The Food and Drug Administration (FDA) has the task of evaluating the safety and effectiveness of candidate drugs on the cardiovascular system. Measurements on ECGs are frequently the way to carry out such assessment. Therefore, the FDA usually receives a great number of annotated ECGs. Nevertheless, these annotated ECGs are usually collected in a wide variety of formats, also including even hard copies requiring digitalization. Consequently, in response to the FDA's needs, HL7 and the FDA created, in 2001, an XML-based format for digital ECGs: HL7 aECG [9]. Three years later, in 2004, HL7 aECG became an ANSI standard.

To encourage wide-scale adoption, Brown and Badilini published an implementation guide [83] and a general overview [84] in 2005. Marcheschi *et al.* promoted the use of HL7 aECG format as the basis for true ECG interoperability within Italian Electronic Health Record (EHR) infrastructure [85]. Some other initiatives such as a freeware viewer [86] have been made in the same direction. Finally, the FDA effort (along with Mortara, a market-leader in ECG devices) to create and maintain the E-scribe ECG warehouse in 2006 can be highlighted [87], since it provides tools for annotated ECG review, scoring, and storage. This warehouse has been successfully tested by Sarapa *et al.* [88], [89]. In addition, there is a project for adopting the nomenclature of HL7 aECG by the 11073 family in order to support ECG annotation terminology (IEEE P11073-10102 [90]).

The importance of exchanging medical images has been progressively growing since the introduction of computed tomography in the early seventies. In 1983, the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) started to collaborate with a view to developing an image exchange standard. The result of this joint effort was the so-called ACR–NEMA standard, released in 1985. Nevertheless, this standard was unsuccessful, and thus, a new standard was developed: DICOM [91]. First released in 1993, it became a European prestandard in 1995 (ENV 12052).

Although DICOM was primarily intended for medical images, new features have been added to the general standard in order to support a broader set of scenarios and diagnostic modalities. In this direction, several working groups have been created, such as the Working Group One (Cardiac and Vascular Information), whose role is to develop standards for the interchange of cardiovascular information. This Working Group released in 2000 the DICOM Supplement 30 [10], a DICOM extension for handling biomedical signals such as the ECG waveform.

First experiences with DICOM Supplement 30 were gained between the hospitals of Kiel and Leiden in the late nineties, by means of a test-bed project to analyze the capabilities of the DICOM Supplement 30 in a cathlab environment [92], [93]. In March 2006, Mortara announced the launch of a series of new DICOM-compliant devices [94]. Despite their success, the application of DICOM to ECG environments has always been controversial: while some authors argue that the use of DICOM is limited since the overhead of the DICOM framework is generally unaccepted by the vendors of biosignal recording devices

[95], others report the innovation and advantage of DICOM for viewing, interchange, and archiving of the ECG [96].

The MFER [11], supported by the Japanese Association of Healthcare Information Systems industry (JAHIS), was launched in 2002 and became an ISO standard in 2007 (ISO/TS 11073-92001 [97]). It specializes in medical waveforms (ECG, EEG, or respiratory waveforms). Indeed, the MFER standard recommends HL7, DICOM, or IEEE 11073 formats for encoding information other than medical waveforms. Consequently, it claims to be a complementary standard. Some applications have been developed in ECG environments, such as an MFER parser [98] or certain MFER-based telecardiology platforms [99], [100].

Furthermore, since the MFER standard is expected to attain full integration into the 11073 family of standards, several drafts or New Item Work Proposals (NIWP) are being raised, such as a specification for standard 12-lead ECG [101], a specification for long-term ECG [102], a reporting with HL7 CDA [103], and also some connections to, or harmonization with, other ECG standards including SCP-ECG [104] or DICOM [105]. However, the situation of these documents is under review and still very preliminary.

2) X73 Family of Standards in Digital ECG: The first step within the X73 family toward medical device interoperability using information systems of different vendors was the Vital Signs Information Representation (VSIR) format, ENV 13734, also called VITAL [12]. It was a project team of CEN TC251, carried out during the late nineties, in partial collaboration with the IEEE P1073 Medical Information Bus group. For the first time in the X73 family, it included an object-oriented domain information and service model. It was also used in a cardiology environment, as presented in [106].

The File Exchange Format for vital signs (FEF), ENV 14271 [13], leveraged the VSIR model and extensive nomenclature of biomedical measurements, including data items found in intensive care units, anesthesia departments, and clinical laboratories including neurology. The use of FEF format for ECG archiving was analyzed in [107].

The next step of the X73 family of standards was the X73PoC (X73–Point of Care) specialization IEEE P11073-10306 for ECG devices [14]. It leveraged the previous effort (VSIR and FEF) in order to address object-oriented design and analysis of the virtual ECG device and the data model of the information transferred to, and from, the ECG Virtual Medical Device. Initial experiences with X73PoC and ECG wearable systems were reported in different publications, mainly by J. Yao and S. Warren [108]–[110], but also by Susperregui *et al*. [111].

The X73PHD (X73–Personal Health Devices) standard also covers the transmission of ECG data. This device specialization establishes a normative definition of the communication between personal monitoring ECG devices (1–3 leads) and gateways. As the research contained in this review is being conducted, IEEE Std 11073-10406$^{\mathrm{TM}}$-2011) [15] has already been approved by IEEE, while ISO approval is still in process.

3) Binary Formats: Along with the binary proposals supported by SDOs (such as SCP-ECG or DICOM Supplement 30), other proposals have also emerged. Given the current high performance of the new networks and information technologies, binary encoded formats could have ceased to be useful. However, they are still an attractive option in specific environments. For example, holter applications, due to the large amount of data recorded, have specific requirements that the International Society for Holter and Noninvasive Electrocardiology (ISHNE) has addressed [16], [112]. The Hierarchical Data Format (HDF), on the other hand, provides a set of file formats and libraries designed to store and organize large amounts of numerical data [17]. It can be applied to high-resolution ECG signals, as proved by Herrera *et al*. [113]. Finally, due importance must be given to a proposal of enhancement of the SCP-ECG protocol, called e-SCP-ECG+, suggested in 2008 by Mandellos *et al*. [18], and tested during 5 mo in a pilot implantation in 2010 also by Mandellos *et al*. [114]. This format, backward compatible to the SCP-ECG protocol, is able to handle more vital signs as well as demographic data. Furthermore, it overrides some of the limits of the original protocol by creating new tags and sections.

4) XML Proposals: Besides the abovementioned HL7 aECG standard, several other XML proposals have been developed. These proposals can be further subdivided into two categories: the general purpose proposals (including PhilipsXML, ecgML, XML-ECG, or I-Med) and specific use case proposals (such as mECGML, ECGaware, Unisens, or BSPM-XML).

In response to increased demands for ECG data access and enhanced ECG device interoperability, Philips published in 2003 the schema for the XML-based ECG format used by its own electrocardiographs, bedside monitors, and defibrillators [19]. This enabled the effort of the European Commission to guarantee electrocardiograph interoperability and accessibility of ECG to be brought together. The Philips XML format was written in the W3C XML Schema Language and it was made available on the Internet and included with the electrocardiograph documentation. The ECG waveform data within the Philips XML ECG are compressed with a lossless algorithm and encoded into ASCII characters using a base 64 encoding scheme, but Philips also provides a suite of software tools to give users easy access to the compressed waveform data. Philips XML format uses Scalable Vector Graphics (SVG) as display format and provides connectivity with some other standards and initiatives such as HL7 aECG or IHE Retrieve ECG for Display (to be introduced later in this section) [115], [116].

Among the general-purpose XML initiatives, the I-Med, the XML-ECG, and the ecgML formats can be found. The project called I-Med [20] consists of a domain-independent interface for exchanging several types of medical information including ECG records, which may be described by basic features, such as QRS duration and text-based interpretations. One major limitation of this solution is that it partially addresses important ECG data content definitions. The ecgML format, first proposed in 2003 by Wang *et al*. [21], suggest a system-, application- and format-independent solution for the representation and exchange of ECG data as a method for the seamless integration of ECG data into EHRs and medical guidelines. A description of the distinction between HL7 aECG and ecgML model can be found in [21]. Also, a series of tools are being developed to assist users in exploiting ecgML-based applications. These applications include an ecgML generator and an ecgML browser [117], [118]. Another XML proposal is the so-called XML-ECG format, published in 2007 by Xudong *et al.* [22]. In that paper, they discourage the use of the other XML proposals, arguing the following statements: I-Med can only present part of ECG related content, HL7 aECG has inherited the HL7's disadvantages of complicated data structure, and ecgML is rather simple and efficient, but still not mature. They state that their proposal is a simpler structure with only six modules and, thus, having much more readability.

Several other XML-based proposals have recently been made to satisfy specific use cases and environments. For example, the Mobile ElectroCardioGraphy Markup Language (mECGML), published in 2008 by Fang *et al.* [23], proposes a light-weighted XML schema designed specifically for ECG data exchange and storage on mobile devices, overcoming the computational constraints of mobile devices. Another proposal is ECGaware, proposed in 2008 by Gonçalves *et al.* [24]. It is an XML-based markup language that provides context-aware services and extends ECG reference standards in order to cover a patient's heart telemonitoring during daily activities. In this direction, another format worth noting is the UNIversal data format for multi-SENSor data (UNISENS) proposed in 2008 by Kirst *et al.* [119], and available from [25]. This proposal suggests a generic format for recording and archiving sensor data from various recording systems, including different types of data such as continuous signals (e.g., ECG, acceleration, thoracic impedance, etc.), events (e.g., trigger annotations, artifact regions, etc.), or values (e.g., blood pressure, respiration rate, heart rate) [25]. Finally, the XML-Body Surface Potential Map (BSPM) format provides support for less prominent methods such as the BSPM. It was proposed by Bond *et al.* [26], and tested alongside a Web-based XML-BSPM viewer in 2010 also by Bond *et al.* [120].

5) Applying Neurophysiology Formats to ECG Signals: All said, signal standardization covers an area that goes beyond ECG signals alone. In other environments, like neurophysiology, different biological signals are required to be recorded, stored, and transmitted, such as the EEG, the electrooculogram (EOG), the electromyogram (EMG), the electrocorticogram (ECoG), or other polysomnograph signals. Some standards have been created to manage these signals but, given the close relation and structure between these signals and the digital ECG, these standards usually provide support for storing ECG signals.

Among these multipurpose protocols, the so-called Data Format family is one of the leading effort. This initiative started with a proposal called European Data Format (EDF) [27] made by Kemp *et al.* in 1992. EDF is a 16-bit format intended for the exchange of time series such as polygraphic recordings. It was quite simple and it supported multiple sampling rates and multiple scaling factors. Almost ten years later, in 2003, Kemp himself and Olivan proposed an enhancement of the EDF protocol, called EDF+ [28]. EDF+ introduced several improvements such as the possibility of containing interrupted recordings or the support of time-stamped annotations, for example, ECG parameters. The General Data Format (GDF) [29], first proposed by A. Schlögl in 1998, suggested modifications to overcome certain limitations of EDF. It provided a common coding scheme for events, and supports many useful features that are only partly implemented in other formats. The BioSemi Data Format (BDF) [30] is a 24-bit version of the 16-bit EDF format. It was initially designed for EEG applications but it is also suitable for other applications such as BSPM or EMG. Finally, the OpenXDF protocol [31], defined by Neurotronics, claims to be an XML-based extension of EDF.

Furthermore, several other formats, primarily intended for neurophysiology, such as E1467-92, SIGIF, extensible biosignal (EBS), SignalML or IFFPHYS, can be found in the literature. The first, a standard specification for transferring digital neurophysiological data between independent computer systems (Designation E1467-92) [32] was developed in the early nineties by ASTM. This standard defines a mechanism for the interchange of waveform data for a variety of neurophysiological studies, as well as a means of including all the relevant data needed to deformat and label the waveforms. Although this standard was primarily intended for neurophysiological studies, the mechanisms are designed to be general and extensible, so it can cover other types of waveforms such as ECG. An overview of E1467-92 can be found in Jacobs *et al.* [121]. Another example is the signal interchange format (SIGIF), which was first disclosed in 1993 by Cunha *et al.* [122]. They defined SIGIF as a biomedical digital signal format that supports both raw and processed data, multiple epochs, several signal structures and representations, and an open architecture. In 1997, after a 5-year period of cooperation between two hospitals and one engineering research center, a new version was presented [33]. Its main advantages, as expressed by the authors, are its versatility and adaptability. An experience reporting the use of SIGIF as a format to store ECG signals can be found in [123]. The EBS file format, on the other hand, is a binary file format for storing multichannel time-series recordings and associated metadata. It was created in 1993 by M. Kuhn at the University of Erlangen, Germany (format available online in [124]) and published in 1996 by Hellmann *et al.* [34]. This format was primarily used for handling EEG, MEG, and ECoG, but it supports various data types and multiple biosignals (ECG, EEG, MEG, and polygraphic recordings). Another example in this context is the SignalML [35], defined by Durka *et al.* in 2004, an XML approach aimed at solving the problem of inherent incompatibility of different formats used for digital storage of biomedical time series (in particular EEG). Finally, the interleaved file format for physiological data format (IFFPHYS) [36], an extension of the IFF format developed in cooperation between the University of Los Angeles and researchers in Australia, can also be underlined. An experience storing ECG as well as other physiological signals (up to 16) using IFFPHYS can be found in [125].

6) Database Formats: The main ECG databases also provide their own open data format. Researchers around the world use these databases to investigate ECG signal processing so that fellow-researchers are able to reproduce their experiments and compare the results. Some of the existing databases include the Physionet database [126]—with its Waveform Database format [37]—the Massachusetts Institute of Technology-Beth Israel Hospital (MIT-BIH) database [38], the American Heart

Association (AHA) database [39], and the CSE [40], [49], [50]. These organizations usually provide software to handle their formats.

7) IHE Cardiology Framework: Finally, in this context of digital ECG interoperability, the IHE Cardiology Framework [127] cannot be excluded. IHE Cardiology addresses information sharing, workflow, and patient care in cardiology. The Cardiology profiles include already stable documents—Cardiac Catheterization Workflow, Echocardiography Workflow, retrieve ECG for display (ECG), and evidence documents (ED),—documents in draft phase for trial implementations—resting ECG Workflow (REWF), Stress Testing Workflow, image-enabled Office, and displayable reports,—drafts for public comment—such as the Waveform Communication Management (WCM)—and, finally, the addition of new profiles is expected. More specifically, among the most interesting documents regarding digital ECG interoperability are the following.

1) *Retrieve ECG for display* [41], [42], stable final text: This integration profile provides access throughout the enterprise to ECG documents for review purposes using the Portable Document Format (PDF) with vector drawing or SVG + XML Multipurpose Internet Mail Extensions type format.
2) *REWF* [43], draft for trial implementation: This integration profile describes the workflow associated with digital electrocardiography. The REWF profile submits displayable ECGs that conform to the requirements described in the retrieve ECG document for display transaction.
3) *WCM* [44], draft for public comment (draft published in July 2010): This is an emerging profile of the IHE-PCD that will extend the Device Enterprise Communication profile to provide a method for passing near real-time waveform data using ISO/IEEE nomenclature and HL7 v2 observation messages between a gateway and an HIS. In this forthcoming profile, data packets will contain raw data, as opposed to bit maps or PDF files.

However, it is worth noting that the objective of IHE Cardiology Framework is not to develop new standards but to integrate existing ones (usually HL7 and DICOM).

8) Use of Ontologies for Handling Digital ECGs: The biomedical field has also embraced ontological methodology to define controlled vocabularies for shared use across different biological and medical domains [128]. More specifically, some proposals have been made to address the definition of ECG ontologies. The first attempts to define an ECG ontology were presented by Kokkinaki *et al.* [45], [46]. Their proposal consists of an ontology based on the SCP-ECG file structure [45] toward the seamless integration of and access to heterogeneous sources in the context of an EHR [46]. However, since this initiative was based on SCP-ECG, it cannot be efficiently extrapolated to a generic ECG ontology. Thus, new initiatives were launched pursuing an unbiased ECG ontology. Since 2009, the National Center for Biomedical Ontology (NCBO) bioportal has been working toward an ontology-based annotation for describing ECGs, their capture methods, and their waveforms. The results so far can be downloaded from [47]. Furthermore, an initiative headed by B. Gonçalves, together with the ontology and conceptual modeling research group (NEMO, from Portuguese Núcleo de Estudos em Modelagem Conceitual e Ontologias) is currently in progress [129]. In 2009, Gonçalves *et al.* presented an application-independent ontological analysis of the ECG [48]. In 2010, they tested this ECG ontology to achieve semantic integration between digital ECG data formats [130] by mirroring the key fields of several standardization initiatives—SCP-ECG, HL7 aECG, and MIT-BIH—to their ontology. The outcomes so far—an XML serialization based on Resource Description Framework of the proposed ECG ontology—can be downloaded from [131]. The design and implementation of a proof-of-concept cardiology server based on this ontology can be found in [132]. This server facilitates the homogeneous management and visualization of a representative collection of existing digital ECG formats.

9) Proprietary Formats: In addition, other format specifications have also been developed. Manufacturers typically include vendor-specific formats in their ECG devices. A brief overview of the long list of proprietary formats would include: Siemens Interchange Format for medical records (SIFOR) by Siemens, Medical Diagnostic Workstation by Welch&Allyn-CardioControl, Unipro by Mortara, ECG-9x by Nihon Kohden, GE Healthcare, Fukuda, or RST (Schiller). Some manufacturers have disclosed their formats (for example, Philips) and others have endorsed already developed standards: Mortara for example, has recently embraced DICOM, as has Nihon Kohden with MFER. Furthermore several manufacturers have declared themselves to be SCP-ECG compliant (Cardiette, Cardio Control, Tapuz, etc.).

B. Relationships Between Digital ECG Formats in the Literature

As there is a wide variety of digital ECG formats (see Table I), there is a natural trend to harmonize existing effort to enhance interoperability. In the literature, several projects covering the relationship between two or more of these standards can be found (see Fig. 1). In this Figure, proprietary protocols appear inside a smaller box. The direction of the arrow indicates the converter or the data flow direction, double-sided arrow indicates two-way conversion, and no arrow indicates that the paper presents just a relationship. The number in brackets specifies the reference.

There are different possibilities for classification and arrangement of this collection of references. In the approach presented later, the number of formats covered has been chosen as the sorting parameter. Group 1, therefore, comprises one-to-one converters.

1) SIFOR → DICOM [92]. This presents a catheterization laboratory application that includes a converter from SIFOR to DICOM.
2) SCP-ECG → DICOM [133]. This presents an online one-way converter from SCP-ECG to DICOM to integrate the SCP-ECG signals into the DICOM medical environment.
3) SCP-ECG → DICOM [134]. This presents a one-way mapping from SCP-ECG to DICOM, including a viewer for both formats. This paper highlights further developing

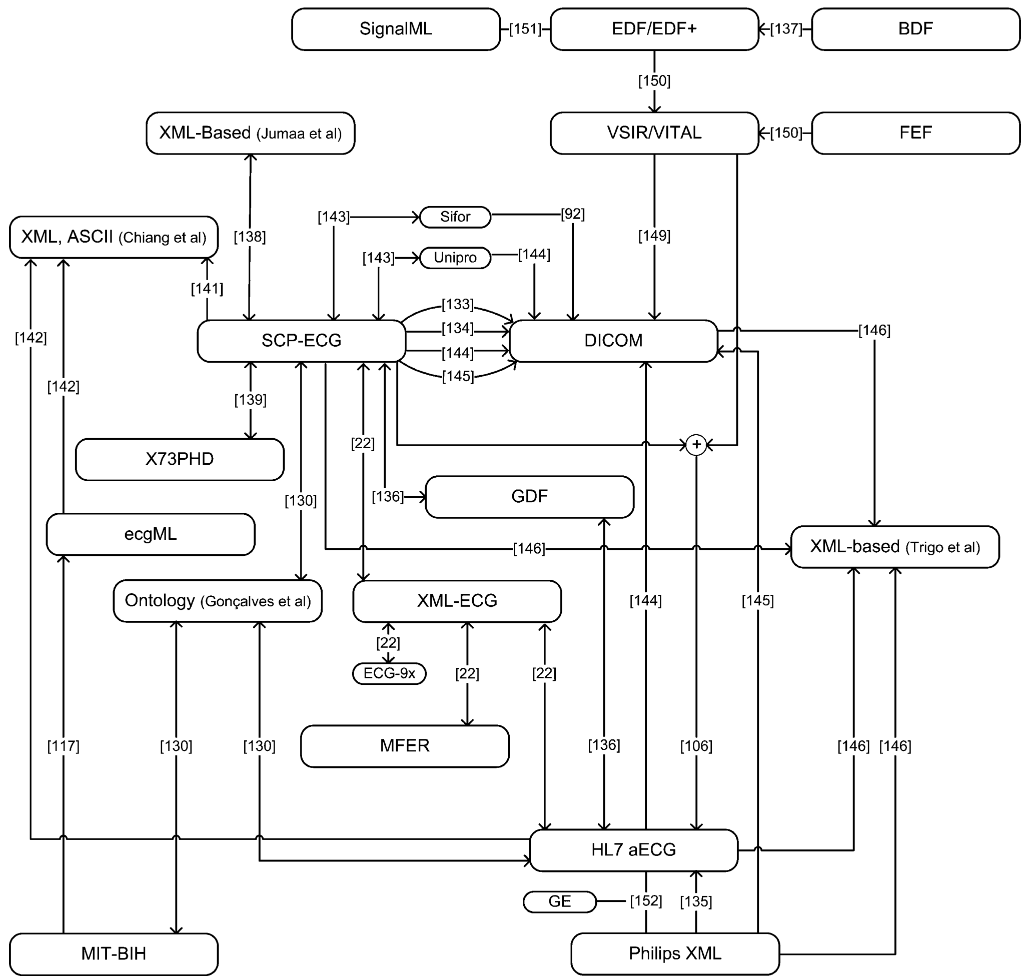

Fig. 1. Relationship between the different digital ECG formats in the literature.

applications, e.g., a comprehensive ECG diagnosis and management system.

4) PhilipsXML → HL7 aECG [135]. This presents a PC-based application for converting Philips XML ECGs into the aECG format provided by Philips.
5) SCP-ECG ↔ (GDF) ↔ HL7 aECG [136]. This presents a two-way converter between SCP-ECG and HL7 aECG using GDF as intermediate structure. This paper discloses the existing mapping gaps between these two standards. For example, some patient clinical data in SCP-ECG have no representation within the aECG format. In the opposite direction, the annotations in HL7 aECG can only be introduced in an SCP-ECG file by using custom tags.
6) BDF → EDF [137]. Since some brain analyzing products are not able to read 24-bit BDF files, this converter downsamples BDF files to 16-bit EDF files.
7) SCP-ECG ↔ XML [138]. This presents a backward compatible converter to facilitate the integration of SCP-ECG files into XML-based relational databases.
8) MIT-BIH → ecgML [117]. This converter was created in order to assist users in exploiting ecgML-based applications.
9) X73PHD ↔ SCP-ECG [139]. This paper provides a mapping between the mandatory classes and attributes for IEEE P11073-10406/D02 [140] and the minimum SCP-ECG fields and sections.

Group 2 comprises many-to-one (or one-to-many) relationships.

1) SCP-ECG + VSIR → HL7 aECG [106]. In this paper, the analysis results obtained from an automated signal processing tool (called HES-EKG), and the patient and raw data of an ECG from the corresponding SCP-ECG record are combined to generate an HL7 aECG file.
2) SCP-ECG → XML and ASCII [141]. This presents a database that receives SCP-ECG files as input and transcodes them into an XML-based format and an ASCII-based format.
3) (HL7 aECG and ecgML) → XML and ASCII [142]. Based on [141], this extension includes new formats and provides a PHP web application to access the database. It uses different viewers to render the ECG signals.
4) SIFOR ↔ SCP-ECG, and UNIPRO ↔ SCP-ECG [143]. This presents a multiple format converter tool using SCP-ECG as the central format. This paper highlights

the advantages of a web-based approach in eliminating the maintenance and installing different ECG clients.

5) (SCP-ECG, HL7 aECG, and UNIPRO) → DICOM [144]. An extension of [143] that integrates open standards into a DICOM-based picture archiving and communication system (PACS). Although they use DICOM as the central format, they acknowledge the still limited availability of DICOM waveform viewers.
6) (SCP-ECG, HL7 aECG, MFER, and ECG-9x) ↔ XML-ECG [22]. While disclosing a new XML-based ECG format, some converters were developed to test their compatibility with other ECG formats.
7) (SCP-ECG and PhilipsXML) → DICOM [145]. This presents a PACS-dependent 12-lead ECG information system including these two converters.
8) (SCP-ECG, HL7 aECG, DICOM, and PhilipsXML) → XML-based format [146]. This presents a Java-based application that provides converter methods to a XML-based central format.
9) The BioSig project [147] deserves special attention. The aim of BioSig is to encourage research into the analysis of biomedical signals (EEG, EcoG, ECG, EOG, EMG, etc.) by providing an open source software library for biomedical signal processing. It supports a wide variety of signal formats and coding languages. It uses GDF as internal format and also includes a viewer that provides support for several of the formats. Note that, not all the relationships (only [136]) between formats have been included in Fig. 1 due to the wide diversity of supported data formats [148].
10) (SCP-ECG, HL7 aECG, and MIT-BIH) ↔ ECG ontology [130]. As stated previously, this paper effectively tests the hypothesis that reference ECG ontology can be employed to achieve semantic integration between ECG data formats.

And, finally, some other experiences that include relationships between these standards, as opposed to converters are as follows.

1) VITAL and DICOM [149]. This paper presents a novel codification scheme, based on VITAL and DICOM Supplement 30, in addressing the robust interchange of waveform and medical data for a home care application.
2) EDF/EDF+, FEF, SCIPHOX related with VITAL [150]. This paper evaluated the convenience of some cardiology related standards (such as EDF/EDF+ and FEF) and also another standard (SCIPHOX, Standardized Communication of Information Systems in Physician offices and hospitals using XML) to be integrated with VITAL.
3) EDF+ and SignalML [151]. This paper presents a comparison of SignalML and EDF+.
4) HL7 aECG, PhilipsXML, and GE [152]. This presents a middleware tool that parses these ECG formats into a HL7 v2.3.1 message in order to integrate them into a PACS.

IV. Discussion

A wide variety of digital ECG formats have been proposed in the literature or developed by SDOs or implemented by manufacturers of ECG devices. Among the existing proposals, those supported by SDOs (SCP-ECG, HL7 aECG, DICOM Supp. 30, or the forthcoming ISO/IEEE 11073 ECG device specialization), have attained higher levels of relevance. In any case, none of these formats has reached comprehensive international consensus. As a result, effort aimed at creating a general ECG format—such as the "Data Format" family—or to provide enhanced versatility and higher applicability to the needs of specific environments—such as HDF for high-resolution ECGs or the ISHNE format for round-the-clock Holter monitoring—or features—e.g., the AECG format for context-aware applications—have emerged. This process extends to both binary—like e-SCP-ECG+—or XML-based proposals—such as XML-ECG or ecgML. Furthermore, integration initiatives—such as the IHE cardiology framework—have attained high levels of popularity. Finally, ECG ontologies have recently undergone a dramatic development, which could lead to an imminent paradigm shift in the ECG exchange context.

Consequently, as all these standards and formats coexist, the issue of real integration of digital ECG standards into daily clinical practice is of paramount importance. Indeed, hospital management services are faced with the challenge of having to cope with several different digital ECG formats and, moreover, several different visualization applications.

Regarding the different options available—binary, XML-based, or ontologies—different considerations arise. Traditionally, ECG exchange protocols have been designed using binary encoded formats. But since the approval of the first version of the XML in 1998, a steadily growing number of XML-based proposals have been emerging. Advantages and disadvantages are discussed as follows. While XML provides human-readable files, more easily indexed and merged into the HIS; binary encoded formats produce smaller files, which implies the saving of bandwidth and storage space. XML's inherent verbosity entails large cost in parsing complex nested structures while the use of binary encoded files usually involves greater difficulty in developing applications suitable for wider adoption. One can envision the emerging ECG ontologies to be more appropriate for such a purpose. However, the existing ECG ontologies have only recently been defined and usage is still uncommon. Therefore, ECG ontologies have not yet reached a point in which they are suitable for exchanging digital ECG recording sessions with external applications. An existing ECG standard (such as SCP-ECG, HL7 aECG, or DICOM Supp. 30) currently provides higher cross-entity interoperability. In any case, the foreseeable spread of ontology-based systems will make them appropriate in the near future.

In order to partially solve this heterogeneity, a variety of mappings can be found in the literature, as shown in Fig. 1. This figure can also be used as an indicator of the diffusion of a particular ECG format, since the higher the necessity of integration, the larger the number of expected mappings. However, this conversion approach could lead to existing mapping gaps between the different formats [136]. This issue would not occur in a (well founded) ECG ontology since the terms in a

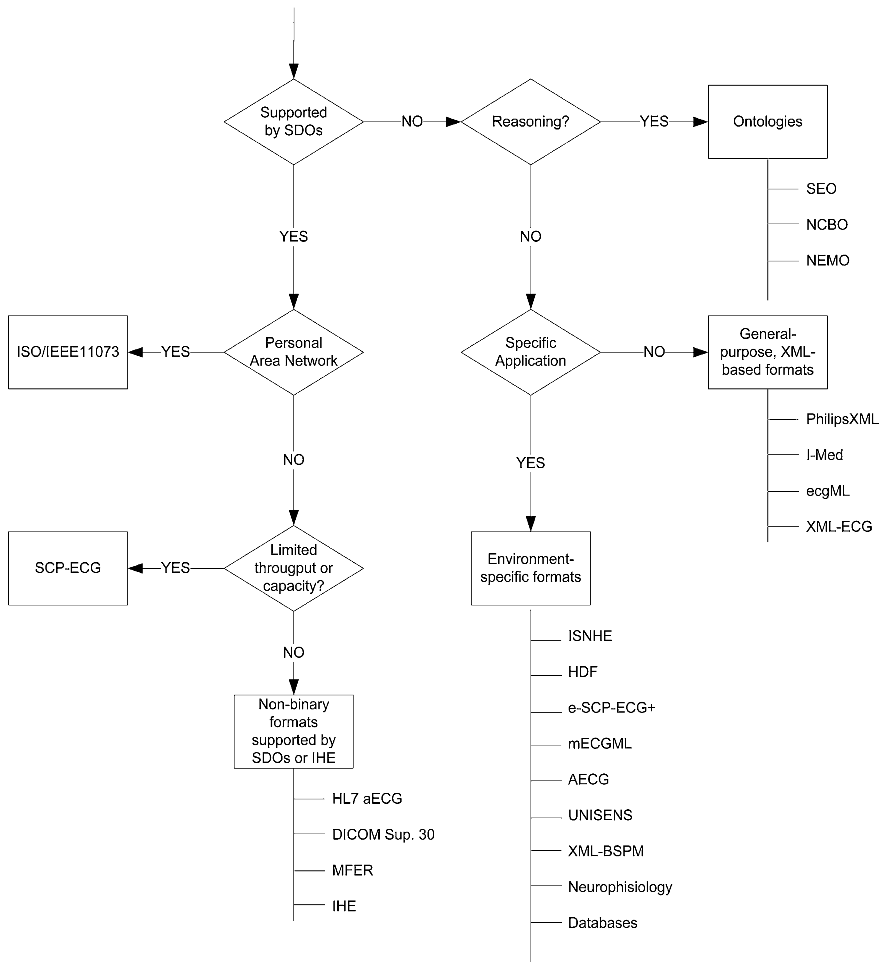

Fig. 2. Suggested algorithm to swiftly narrow down available options when determining a suitable digital ECG format for a specific architecture.

controlled vocabulary must correspond to at least one meaning (nonvagueness), and no more than one meaning (nonambiguity), and these meanings must correspond to no more than one term (nonredundancy) [153]. Therefore, since an ECG ontology represents what an ECG is, the use of ECG ontologies for semantic interoperability of ECG data is a feasible, efficient alternative [130]. In addition, ontologies may improve the features of a HIS, since they enable semantic data integration within, or across, application, organizational boundaries [154], [155].

For the end user needing to determine a design strategy for his ECG application, an algorithm is suggested in this paper to swiftly narrow down available options (see Fig. 2). The first recommendation when establishing a suitable digital ECG format for a specific architecture is to use existing de jure standards when possible, since that selection would provide enhanced third-party interoperability. Thereafter, if the ECG is not to be transmitted through a personal area network—ISO/IEEE 11073 would be recommended in that case—neither the throughput or storage space are limited—SCP-ECG would be, therefore, recommended—then, nonbinary formats supported by SDOs (HL7 aECG, DICOM Sup. 30, or MFER) or IHE-compliant formats could be more suitable. The final decision would rely on the possibilities of integration with other standards in the architecture. However, when de jure standards fail to meet the requirements of the intended application or environment, other approaches are also available. For example, if reasoning on clinical knowledge is desired, ontologies—SEO, NCBO, or NEMO—are probably the appropriate selection. If ontologies are not required, then different digital ECG formats for specific applications are available in the literature: for example, for holter monitoring, ISNHE or HDF, multiparameter measurements, e-SCP-ECG+ (binary) or UNISENS (XML-based), mobile applications, mECGML, context-aware applications, AECG, body surface potential mappings records, XML-BSPM, neurophysiology applications, or applications requiring integration with existing databases. Otherwise, a general-purpose XML-based format—PhilipsXML, I-Med, ecgML or XM-ECG—might be used.

In general, harmonization and convergence of ICT standards is a phenomenon of high complexity. It is not merely a technical or technological matter, but also an economic, politic, and even social process as well. Regarding the ECG context, it is complicated to speculate whether an existing digital ECG format will eventually win—and, in that case, which one—or if new digital ECG formats are to be created. The pursuit of a single ECG standard started several years ago, but consensus has not been reached yet. As the different existing digital ECG formats claim to be designed for specific environments or ecosystems, they all would suffice for those purposes. However, a single ECG standard is a desirable objective for both the industry and the main stakeholders. If a new digital ECG standard is to be created, some key issues can speed up the process, such as the encouragement of a consortium [156]—Bluetooth is an example—the creation of a certification process—see the example of IEEE 802.11 family of specifications within the Wi-Fi standardization development [157]—or the construction of a critical mass able to create a network of end users endorsing a specific format [158]. In any case, cooperation between the main worldwide standardization bodies plays a crucial role in reaching international consensus.

V. Conclusion

In the context of digital ECG formats, the creation and generalization of a single standardized ECG format is a desirable goal. However, effort aimed at harmonization and mapping between the different existing (and future) standards must continue for unification to eventually occur. This longed-for unification requires political commitment and international cooperation among different standardization bodies. In this context, ongoing works toward specific ontologies covering ECG domain are a promising alternative to reach ECG interoperability.

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