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Health informatics – Point-of-care medical device communication – Part 10102: Nomenclature – Annotated ECG (ISO/IEEE 11073-10102:2014)

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Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO/IEEE 11073-10102:2014/
Relations to other parts under the same general title - Extract from the Foreword of ISO/IEEE 11073-10102:2014

ISO/IEEE 11073 consists of the following parts, under the general title Health informatics — Personal health device communication (text in parentheses gives a variant of subtitle):
- Part 00103: Overview
- Part 10101: (Point-of-care medical device communication) Nomenclature
- Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG
- Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device,cardiac
- Part 10201: (Point-of-care medical device communication) Domain information model
- Part 10404: Device specialization — Pulse oximeter
- Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)
- Part 10407: Device specialization — Blood pressure monitor
- Part 10408: Device specialization — Thermometer
- Part 10415: Device specialization — Weighing scale
- Part 10417: Device specialization — Glucose meter
- Part 10418: Device specialization — International Normalized Ratio (INR) monitor
- Part 10420: Device specialization — Body composition analyzer
- Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)
- Part 10441: Device specialization — Cardiovascular fitness and activity monitor
- Part 10471: Device specialization — Independant living activity hub
- Part 10472: Device specialization — Medication monitor
- Part 20101: (Point-of-care medical device communication) Application profiles — Base standard
- Part 20601: Application profile — Optimized exchange protocol
- Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected
- Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless
- Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet
- Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test
- Part 91064: (Standard communication protocol) Computer-assisted electrocardiography
- Part 92001: (Medical waveform format) — Encoding rules

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11073-10102

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English Version

Health informatics - Point-of-care medical device communication - Part 10102: Nomenclature - Annotated ECG (ISO/IEEE 11073-10102:2014)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10102: Nomenclature - ECG annoté (ISO/IEEE 11073-10102:2014)

This European Standard was approved by CEN on 14 December 2013.

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Contents

Foreword

This document (EN ISO 11073-10102:2014) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2014, and conflicting national standards shall be withdrawn at the latest by September 2014.

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The text of ISO/IEEE 11073-10102:2014 has been approved by CEN as EN ISO 11073-10102:2014 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10102-2012, Health informatics—Point-of-care medical device communication—Nomenclature—Annotated ECG.

This standard extends the base ISO/IEEE 11073-10101:2004[a] nomenclature to provide support for electrocardiogram (ECG) annotation terminology. The major subject areas addressed by the nomenclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations. It also defines additional “global” and “per-lead” numeric observation identifiers, ECG lead systems, and additional ECG lead identifiers. The nomenclature extensions may be used in conjunction with other IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201:2004 [B19][b]) or independently with other standards.

[a] Information on references can be found in Clause 2.
[b] The numbers in brackets correspond to those in the bibliography in Annex E.

Health informatics—Point-of-care medical device communication

Part 10102: Nomenclature—Annotated ECG

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1. Overview

1.1 Scope

This standard extends the base ISO/IEEE 11073-10101:2004[1] to provide support for ECG annotation terminology. Major subject areas addressed by the nomenclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations. It also defines additional "global" and "per-lead" numeric observation identifiers, ECG lead systems, and additional ECG lead identifiers. The nomenclature extensions may be used in conjunction with other IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201:2004 [B19][2]) or independently with other standards.

1.2 Purpose

This standard provides a unified and comprehensive terminology for ECG annotation semantics, making it suitable for medical device data exchange that requires inclusion of ECG annotations. This standard consolidates numerous other standard and nonstandard terminologies that are in current use, resulting in the harmonization of how ECG annotation information is identified, enabling interoperability, and providing information exchange at the application level.

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex E.

Currently, many terminologies and protocols, both standard and vendor specific, are used to manage and exchange ECG annotation information. As a result, protocol converters and translators are required to integrate systems and applications, typically with some degree of semantic loss and noninteroperability. This standard provides a single terminology that is capable of supporting applications that require ECG annotations, including evaluation of patient condition (e.g., reviewing ECG data at the point-of-care or remotely) as well as clinical research (e.g., electronically submitting clinical drug trial evidence supporting the efficacy of a new medication). In addition to incorporating ECG annotations into an ISO/IEEE 11073-based information stream acquired at the bedside, the underlying nomenclature can also be used in other persistent and communication standards [e.g., Health Level Seven International (HL7) V2 and V3, and Digital Imaging and Communications in Medicine (DICOM)] for use by various applications, including clinical information systems, electronic patient records, and clinical research.

1.3 Audience

The audience for this document is those who work with monitoring and diagnostic ECG information in the context of systems integration. This may include but is not limited to the following roles:

- Cardiologist or electrophysiologist physicians
- Heart and device clinic specialists or staff
- Primary care physicians
- Clinic information technologists
- Clinic information system vendor engineers
- Academic and clinical research scientists
- Regulatory and quality management agencies
- Clincal trial and research results reporting
- Medical device and system development engineers

The following clinical applications are facilitated by this interoperability enabled by this standard. This may include but is not limited to the following activities:

- Clinical trial and research results reporting [HL7 annotated electrocardiogram (aECG), Clinical Data Interchange Standards Consortium (CDISC), and others]
- Transfer of ECG data in an interoperable manner [DICOM, HL7, IEEE 11073, Integrating the Healthcare Enterprise Patient Care Devices (IHE PCD), and other communication protocols]
- Algorithm development and performance evaluation
- Sophisticated real-time data exchange with option to retrospectively review and correct data

1.4 Context

This nomenclature has been developed within the context of the broader ISO/IEEE 11073 Health Informatics—Point-of-Care Medical Device Communication standards. Its goal is to be consistent with existing 11073 standards and information models.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

ANSI/AAMI EC71-2001, Standard Communications Protocol for Computer Assisted-Electrocardiography.[3]

ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[4]

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[5]

annotation: An observation made on or associated with a time series of events, typically at a specific point in time or over an interval of time.

arrhythmia: Any abnormality of cardiac rhythm. Also termed “dysrhythmia.” Specific examples are bradycardia, tachycardia, and ventricular fibrillation.

base term: A fundamental semantic concept.

cardiac monitor: A device that acquires and analyzes the electrical waveforms of the cardiovascular system for measurement, display, and treatment.

cardiologist: Physician specializing in disorders of the heart.

co-constraint: A rule describing a constraint whose scope is inclusive of more than one term.

constraint: A restriction on the set of values being assigned.

control variable: In this nomenclature, an attribute that specifies some aspect of a device configuration, setting, or the observation method.

discriminators: A mechanism to provide additional semantic refinement to multiple base terms.

domain information model (DIM): The model describing common concepts and relationships for a problem domain.

[3] ANSI publications are available from the American National Standards Institute (http://www.ansi.org/).
[4] ISO/IEC publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).
[5] The *IEEE Standards Dictionary Online* subscription is available at http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.

electrocardiogram (ECG): (**A**) A set of cardiac waveforms (leads) acquired over a contiguous period of time. (**B**) Traditionally 12 waveforms (leads) representing 10 s of cardiac activity while the patient is lying on his or her back at rest. It is the physical or electronic record of the patient's cardiac activity produced by an electrocardiograph.

electrocardiograph: A device that records the electrical activity of the patient's heart by tracing voltage versus time waveforms, either on paper or digitally.

electronic health records: A longitudinal collection of electronic health information about individual patients or populations. It is a record in digital format that is capable of being shared within or across different health care settings by being embedded in network-connected enterprise-wide information system.

electrophysiologist: A physician with advanced study of the electrical properties of the heart.

lead: A vector along which the heart's electrical activity is recorded as a waveform, either as a single "unipolar" lead with respect to a common reference voltage or as a "bipolar" lead that represents the voltage difference measured at two different sites.

nomenclature: A set of names or terms comprising a taxonomy for a specific domain.

pacemaker: A small, battery-powered electrical impulse generator which is implanted in patients to support or maintain heart rate. External pacemakers, typically used in a hospital setting, are also supported by this nomenclature.

reference ID (REFID): A unique, symbolic, and programmatic form for the term. The form is correlated to the context-free code (i.e., titles are by definition context-free with respect to all other titles); in this standard, terms are typically prefixed with "MDC_ECG_" for consistency.

rhythm disturbance: An irregular heart beat or sequence of beats.

systematic name: An organization of differentiating, relational descriptors that are unique for each term.

terminology: A synonym for nomenclature.

3.2 Acronyms and abbreviations

aECG	annotated electrocardiogram
CDISC	Clinical Data Interchange Standards Consortium
DICOM	Digital Imaging and Communications in Medicine
DIM	domain information model
ECG	electrocardiogram
HL7	Health Level Seven
ID	identifier
IDC	implantable device cardiac
IDCO	implantable device cardiac observation
IHE PCD	Integrating the Healthcare Enterprise Patient Care Devices
MDC	medical device communication
REFID	IEEE 11073 reference identifier

4. Introduction to IEEE Std 11073-10102

The key objectives of this standard are as follows:

— Define a set of annotation mnemonics to describe beat, wave component, rhythm, and noise annotations to support detailed beat-by-beat information about the electrocardiogram.

— Extend the existing IEEE 11073-10101 ECG lead identifiers, including the ability to indicate “derived” leads for every “original” ECG lead.

— Extend the existing IEEE 11073-10101 “per-lead” and “global” ECG measurement identifiers to support the capabilities of contemporary 12-lead ECG analysis algorithms.

— Add additional semantic concept groups the define ECG lead systems (predefined configurations of multiple ECG leads) and control variables that specify ECG signal filter characteristics.

— Where possible, the nomenclature definitions should also support the following:

1) Cardiologist-friendly labels, compatible with present-day cardiac nomenclature conventions, that can be used by clinicians when reviewing or editing annotated waveforms. These should leverage existing nomenclatures, where appropriate.

2) ISO/IEEE 11073-10101 “programmer-friendly” reference identifiers, following existing 11073 labeling conventions wherever possible, and assigning numeric codes to each.

3) Equivalent mappings, where possible, with existing annotated databases and tools, such as the MIT-BIH and PhysioNet annotated ECG databases.

The principal focus is beat and rhythm annotation, scalable from single-lead to 12-lead analysis, applicable to standard and advanced 12-lead ECG, Holter, and patient monitoring applications. In other words, this work extends the concepts typically used to describe simple rhythm monitoring to how a cardiologist would annotate a continuous 12-lead ECG record.

4.1 Clinical background

Millions of people experience irregular heartbeats at some point in their lives. Some of these irregularities may be due to cardiac rhythm disturbances (arrhythmias). Some arrhythmias are determined by medical professionals to be relatively benign, whereas other arrhythmias can be associated with variable degrees of clinical risk. There are certain more extreme cardiac rhythm disturbances that may be dangerous or even fatal.

Arrhythmias are caused by disorders of the heart’s electrical system, which in a healthy state would function to help coordinate synchronous and mechanically advantageous electrical activation of the cardiac muscle. In the case of a cardiac arrhythmia, the heart rhythm may be too slow, too fast, or otherwise chaotic; in some instances, different portions of the heart are activated in a dyssynchronous manner. In any of these instances, functional efficiency of the heart suffers and cardiac performance may be significantly impaired.

One of the first steps in monitoring patients who exhibit arrhythmias is to obtain the ECG signal using an electrocardiograph to acquire a short-term (typically 10 s) electrocardiogram or acquiring the signal over several days using a Holter recorder and analyzing it later on. An event recorder can also be used to acquire and analyze the data and to save arrhythmia episodes considered important by the device’s algorithms. More modern systems can combine long-term recording and real-time analysis and can upload the

information to a monitoring service, effectively combining the roles of real-time patient monitoring and sophisticated analysis and review of the data.

Central to these applications is the accuracy of the algorithms used to detect and classify ECG beats and rhythms. One of the most effective ways of documenting the algorithm output is to record each beat and rhythm detected by the algorithm, since this information provides the clinician (as well as the algorithm developer) a clear and unambiguous record of the analysis. The “beat-by-beat” and “rhythm-by-rhythm” representation also can support powerful “retrospective” review and editing tools that can enhance the accuracy of the final summary report. The corrections made on a retrospective data set can also be used to “prospectively” reduce the likelihood making the same error in the future in a real-time monitoring system.

The goal of this nomenclature extension is to provide a standard nomenclature for ECG beats, rhythms, and advanced diagnostic ECG measurements suitable for traditional 12-lead ECG analysis as well as for systems that acquire and analyze a smaller number of leads. It extends the nomenclature developed for earlier annotated data sets (e.g., MIT-BIH) by defining codes for more than 35 different beat types and more than 75 rhythms, commensurate with advanced 12-lead diagnostic ECG acquisition and analysis, acquired in the context of a traditional resting, stress, monitoring, telemetry, or long-term ambulatory ECG. Figure 1 illustrates several of these ECG nomenclature components.

Alternatively stated, a very strong attempt has been made to extend the existing terminology defined by ISO/IEEE 11073-10101:2004, ANSI/AAMI EC71-2001 [B7], and other standards to provide the message semantics required to support advanced 12-lead ECG, short of defining a standardized terminology and grammar for the summary diagnostic statement.

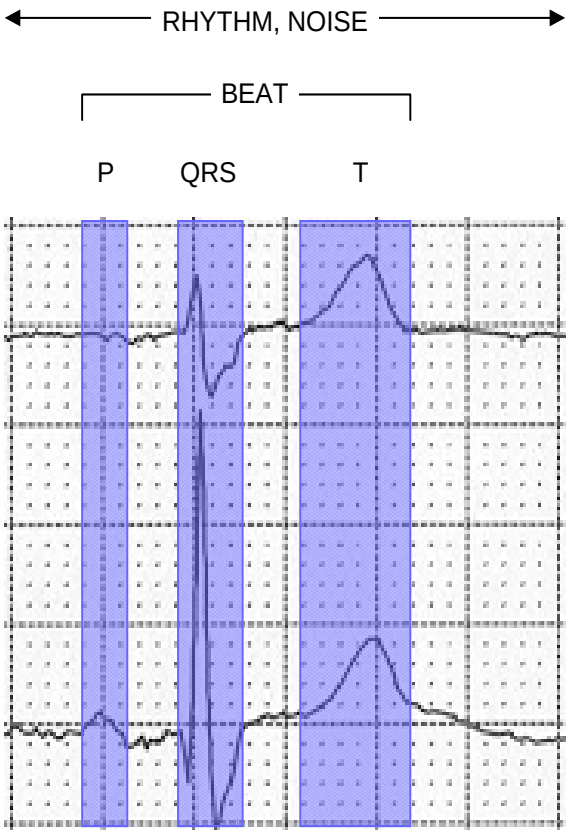

Figure 1—ECG rhythm, noise, beat, and wave components

5. Nomenclature requirements

5.1 Overview

The nomenclature in this standard defines normative text identifiers and numeric code identifiers for labeling electrocardiographic data. Requirements are defined by subject domain and industry experts.

The requirements for the nomenclature fall into multiple categories, as follows:

— The scope of the nomenclature

— The organizational structure of the nomenclature

— The semantics of the nomenclature

5.2 Scope requirements

The following requirements regarding the scope and content of the standard were used:

— Level of detail shall be summary information as specified and understood by subject domain experts

— Shall only define terms that are common across domain

— Shall allow for specific vendor enumerations of terms, if needed

5.3 Organizational structure requirements

The following requirements regarding the organization structure of the standard were used:

— Term identifiers shall be organized in a consistent hierarchical classification scheme

— Terms should be organized to minimize the need for postcoordination of multiple terms to define commonly used observation identifiers or concepts

5.4 Semantic requirements

The following requirements regarding the semantic definitions were used:

— Domain and industry experts will discuss and define term semantic requirements.

5.5 Distribution format requirements

The following requirements regarding the distribution format were used:

— The nomenclature shall be made available in a computable representation to facilitate incorporation into protocols, devices, systems, and message conformance test tools.

6. Nomenclature structure

The nomenclature in this standard is structured based on a hierarchical taxonomy. The base root node is MDC_ECG, which is short for Medical Device Communication—ECG. The MDC_ECG nomenclature term codes are assigned numeric codes that extend the existing set of ECG terms in the ISO/IEEE 11073 SCADA partition [PART=2] as well in a new partition [PART=10] allocated for advanced ECG terms.

The principal MDC_ECG terminology groups are listed in Table 1.

Discriminators are used to provide additional semantic refinement that can be applied to multiple terms. Discriminators are used to manage complexity within the nomenclature hierarchy and to promote uniformity of like-kind detailed semantic concepts.

A term is uniquely identified by a Reference ID, Systematic Name, and Code according to the scheme described in ISO/IEEE 11073-10101:2004. A term's Reference ID consists of following a sequential path through the nomenclature hierarchy from the root semantic concept to a leaf semantic concept. Each node on this path becomes a component of the term's Reference ID and Systematic Name, and it appropriately represents the semantic of the term.

After expanding all discriminators, a unique numeric code [CODE10] is assigned to each term from a 16-bit partition [PART] in which the term resides. A 32-bit "context free" numeric code [CF_CODE10] for each term is calculated by computing the sum of (65536 × PART) + CODE10 + any applicable discriminators.

7. Conformance

Conformance to definitions in this standard is specified primarily at the appropriate application or system interface. It is expected that this standard will be referenced by other healthcare systems integration standards or profiles that define specific applications of the nomenclature.

Table 1—Principal MDC_ECG terminology groups

Top level	Terminology groups
MDC_ECG_**LEAD**_	**ECG leads** (implemented as an eight-bit discriminator)
MDC_ECG_**WAVC**_	**ECG wave components** Normal wave components Composite wave components Abnormal wave components Segments ST measurement Miscellaneous
MDC_ECG_**WAVP**_	**ECG wave pacemaker components** Antibradycardia pace Antitachycardia pace Cardioversion (low-energy shock) Defibrillation (high-energy shock)
MDC_ECG_**BEAT**_	**ECG beats** Nonspecific beats Supraventricular extrasystole Ventricular extrasystole Escape beats Intraventricular block
MDC_ECG_**RHY**_	**ECG rhythms** Sinus rhythm Sinus arrhythmia (originating from the SA node) Atrial ectopic rhythm (atrial sites other than the SA node) Supraventricular (atrial or junctional) ectopic rhythms AV junctional rhythms Atrioventricular block and dissociation Sino-atrial exit block Ventricular ectopic rhythms Ventricular pre-excitation (WPW) rhythm Implanted pacemaker rhythm Pause Miscellaneous ECG rhythms and other interval events Pacemaker stimuli that were expected but are missing
MDC_ECG_**NOISE**_	**ECG noise levels**
MDC_ECG_ ***global***	**“Global” ECG measurements** (apply across multiple leads)
MDC_ECG_ ***per Lead***	**“Per-Lead” ECG measurements**
MDC_ECG_**LDSYS**_	**ECG lead systems** 12-lead ECG electrode placement XYZ electrode placement system Additional 3-lead systems Derived 12-lead systems 15- and 18-lead systems
MDC_ECG_**CTL_VBL**_	**ECG control variables**—filter and threshold settings
MDC_ECG_ ***info attr***	**ECG information attributes** Attributes that convey ECG beat, rhythm and signal types Attributes that convey ECG and pacemaker wave components Attributes that convey ECG interpretation
NOTE—AV = atrioventricular; SA = sinoatrial; ST = ECG voltage and time measurements related to the ST segment; WPW = Wolfe Parkinson White.[6]	

[6] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

8. Extensibility and versioning

Normative specifications for term identifiers in this standard are immutable. Identifiers shall not be retired nor reused.

All other constraints and text within the standard can be revised. The standard shall carry a version number that specifies a revision. Modifications to the standard's text clauses, existing term constraints, or the addition of new text clauses or terms shall require a revision and new version number.

The version identifier shall be a string that consists of the following:

— The major version number—This is the leftmost integer value in a sequence of three such values separated by periods. The major version number may only be increased when beginning work toward a version with significant changes that impact backward compatibility.

— The minor version number —This is the middle integer value in a sequence of three such values separated by periods. The minor version number may only be increased when beginning work toward a version with incremental additions, improvements, or fixes over the last version.

— The point version number—This is the third integer in a sequence of three such values separated by periods. The point version number is increased for vendor-specific versions. Point or vendor-specific versions are not normative. If used, it should be followed by version qualifier string described below. The point version numbers shall be "0" for the balloted normative standard.

— The version qualifier string—This is a human-readable string (ideally consisting only of ASCII letters, digits, periods, and dashes) that uniquely identifies the vendor making a point revision. It should be and is only included in the version identifier for point versions. It should be consistent for subsequent point releases by the same vendor. Point or vendor versions are not considered normative.

An example version number could be "1.02.03_vendor" where "1" is the major version number, "02" is the minor version number, "03" is the point version number, and "_vendor" is the version qualifier string.

Annex A

(normative)

Base terms

A.1 Overview

Annex A presents the base terms of the nomenclature and their attributes. A base term is defined as a term prior to expansion of any included discriminators. Defining attributes at the base term level simplifies management of the nomenclature.

The base terms are defined in A.3 through A.13. For each base term group listed, the discriminators that apply to that group are shown first, followed by a tabular list of each base term within the group. The *total* number of discriminator bits used by each term group is also listed in Table A.1, and if multiple discriminators are used, then the total number is indicated as an arithmetic sum.

Table A.1—Base term groups

Clause	Base term group	tdBits
A.3	ECG lead identifiers	8
A.4	ECG WAVC wave components	2 + 4
A.5	ECG WAVP pacemaker components	4 + 4
A.6	ECG beats	4
A.7	ECG rhythms	4
A.8	ECG noise annotations and levels	4
A.9	ECG measurements—global	2
A.10	ECG measurements—per lead	8
A.11	ECG lead systems	0
A.12	Control variables	0
A.13	Information attributes	0

The discriminator tables that define the semantic modifiers for each term group are listed first. If multiple discriminator tables are used, then they are listed left to right, starting with the most significant discriminator bits first. The content of the discriminator tables is summarized in Table A.2.

Table A.2—Discriminator table content

Column	Description
dOffset	Discriminator value (offset) added to base term
dSuffix	Suffix appended to the REFID
dDescription	Description
bi-uni	For ECG leads, indicates bipolar or unipolar
pos	For ECG leads, indicates the positive electrode site
neg-ref	For ECG leads indicates the negative (for bipolar) or common reference (for unipolar)

The base terms for each term group are listed after the relevant discriminators. Table A.3 specifies the information provided for each base term within a group of terms.