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3 **Draft Standard for Health Informatics—**
4 **Point-of-Care Medical Device**
5 **Communication—Nomenclature**

6 Sponsor
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8 **IEEE 11073 Standards Committee**
9 of the
10 **IEEE Engineering in Medicine and Biology Society**
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1 **Abstract:** Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC)
2 and personal health devices (PHD) medical device communication (MDC), this standard provides
3 the nomenclature that supports both the domain information model and service model
4 components of the standards family, as well as the semantic content exchanged with medical
5 devices. The nomenclature is specialized for patient vital signs information representation and
6 medical device informatics, with major areas including concepts for electrocardiograph (ECG),
7 haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as
8 specialized units of measurement, general device events, alarms, and body sites. The standard
9 defines both the architecture and major components of the nomenclature, along with extensive
10 definitions for each conceptual area.

11
12 **Keywords:** codes, information model, medical device communication, nomenclature, ontology,
13 patient, point-of-care, POC, semantics, service model, terminology, personal health devices,
14 PHD, independent living, IHE PCD-01.
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1 Introduction

2 This introduction is not part of IEEE P11073-10101/D3, Draft Standard for Health Informatics—Point-of-Care Medical
3 Device Communication—Nomenclature.

4 ISO/IEEE 11073 standards enable communication between medical devices and external computer
5 systems. They provide automatic and detailed electronic data capture of patient vital signs information and
6 device operational data. The primary goals are to:

- 7 — Provide real-time plug-and-play interoperability for patient-connected medical devices
- 8 — Facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-
9 care, in all health care environments

10 “Real-time” means that data from multiple devices can be retrieved, time correlated, and displayed or
11 processed in fractions of a second. “Plug-and-play” means that all the clinician has to do is make the
12 connection — the systems automatically detect, configure, and communicate without any other human
13 interaction.

14 “Efficient exchange of medical device data” means that information that is captured at the point-of-care
15 (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of
16 applications without extensive software and equipment support, and without needless loss of information.
17 The standards focus on acute care devices, such as patient monitors, ventilators, infusion pumps, ECG
18 devices, etc, and personal health devices and systems. They comprise a family of standards that can be
19 layered together to provide connectivity optimized for the specific devices being interfaced.

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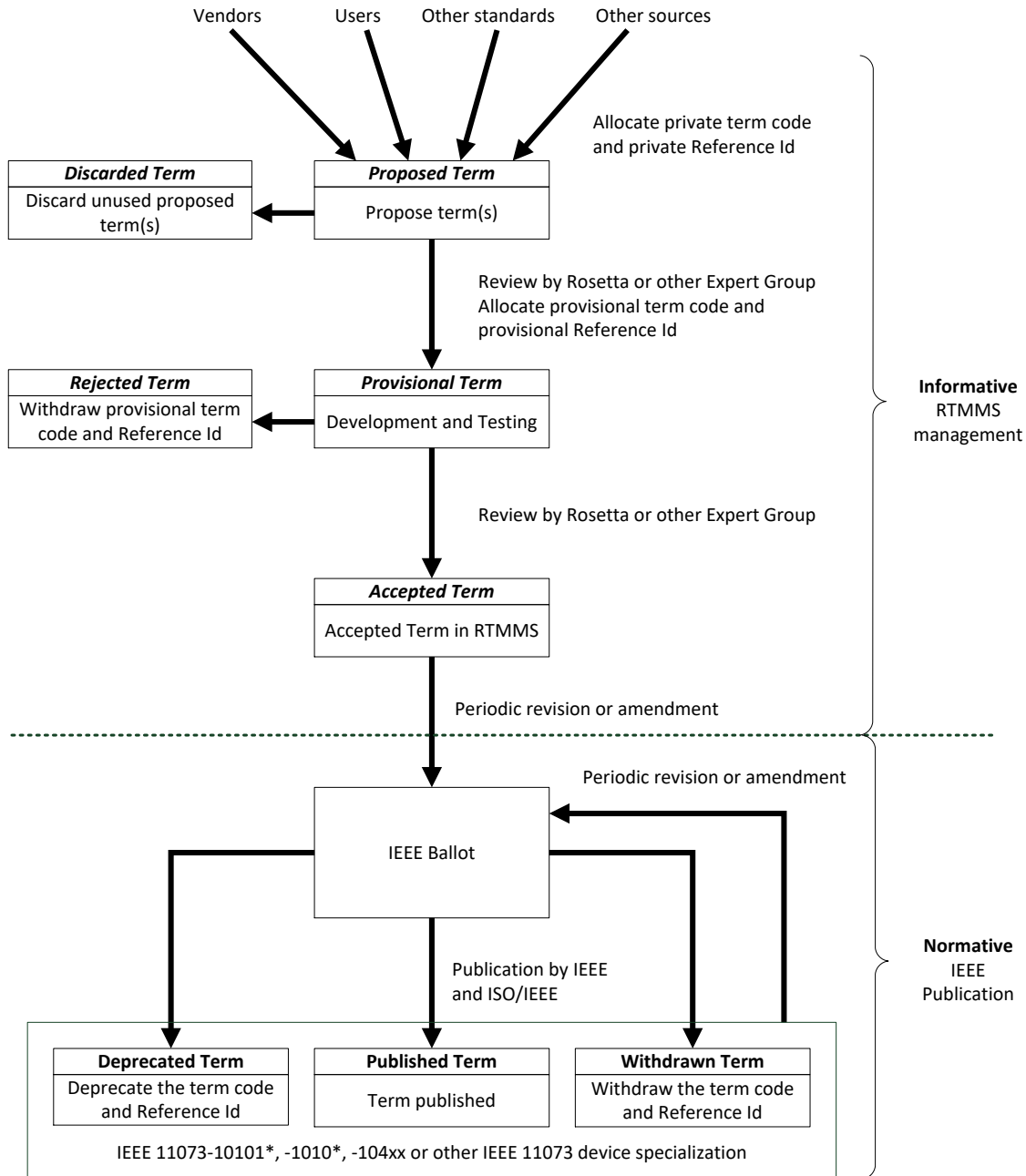
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1 **Annex A**
 2
 3 (informative)

4 **Term Approval and Management Process**
 5



6
 7 **Figure A.1—Term Approval and Management Process**
 8

1 **A.1 Term Approval and Management Process**

2 IEEE 11073 nomenclature terms follow **Error! Reference source not found.** for their approval and
3 management. The management process has two sections: in the first section terms are managed in the
4 Rosetta Terminology Mapping Management System (RTMMS), term status are informative and are shown
5 in italic; in the second section terms are managed by the IEEE standard publication process, term status are
6 normative.

7 **A.1.1 Proposed Term**

8 New terms for consideration may be submitted from numerous sources including vendors, users, and other
9 standards. A thorough search should be made to ensure that no suitable equivalent term exists. The new
10 term and information are entered initially, and designated as a proposed term. At this stage several terms
11 having the same concept may be proposed. Proposed terms may be allocated a term code from the private
12 block of the respective partition and a private Reference Id that starts with MDCX_ in place of MDC_.

13 **A.1.2 Proposed Term Review**

14 Proposed terms are reviewed by the Rosetta or other expert group to select and confirm terms to be given
15 provisional status. Where several terms conveying the same concept have been proposed, a single term is
16 selected. Terms not selected are designated as discarded. Discarded terms may be retained for historic or
17 other purposes.

18 **A.1.3 Provisional Term**

19 A provisional term is allocated a term code and Reference Id. Provisional terms are generally used for
20 development and interoperability testing and ought not to be released in production devices.

21 **A.1.4 Provisional Term Review**

22 Provisional terms are reviewed by the Rosetta or other expert group to confirm terms to be given accepted
23 status. Terms not selected are designated as rejected.

24 **A.1.5 Rejected Term**

25 A rejected term is retained and its Reference Id and term code are marked as used in RTMMS and are not
26 available to be allocated to new terms until such time that codes within a partition are exhausted. Rejected
27 terms ought not to be released in production devices.

28 **A.1.6 Accepted Term**

29 Accepted terms will be included in the first draft of a revision or amendment of IEEE 11073-10101 (or one
30 of the IEEE 11073-1010* family of nomenclature standards) for ballot. Accepted terms may be used in
31 production devices.

32 **A.1.7 IEEE Ballot**

33 Periodically a revision or amendment of IEEE 11073-10101 (or one of the IEEE 11073-1010* family of
34 nomenclature standards, or IEEE 11073-104xx or other IEEE 11073 device specialization) will be
35 produced. The first draft will include accepted terms from RTMMS that are appropriate to the standard.

1 Although accepted terms are normally proposed to become published, they could be deprecated or
2 withdrawn.

3 During balloting, additional new term codes and Reference Ids not originally contemplated as RTMMS
4 accepted terms may be proposed for consideration as published terms.

5 Only new terms need be included in an amendment of a standard, although existing terms may be proposed
6 for deprecation or withdrawal.

7 All existing terms of a standard are to be included in a revision of that standard and may be proposed for
8 deprecation or withdrawal.

9 **A.1.8 Published Term**

10 Terms included in a revision or an amendment of IEEE 11073-10101 (or IEEE 11073-1010* family of
11 nomenclature standards, or IEEE 11073-104xx or other IEEE 11073 device specialization) are designated
12 published.

13 **A.1.9 Deprecated Term**

14 Terms may be designated as deprecated for a number of reasons, which may include deprecation of the
15 entire term, the term code (Reference Id retained but a new term code allocated) or the Reference Id (term
16 code retained but a new Reference Id allocated). Deprecated terms, term codes and Reference Ids are to be
17 removed from use in production devices. Deprecated terms, term codes and Reference Ids remain in
18 RTMMS and this standard to support legacy. The deprecated Reference Id and term code ought not to be
19 allocated to new terms.

20 **A.1.10 Withdrawn Term**

21 Terms found to be in error, such as having conflicting codes, are designated withdrawn and ought to be
22 removed from existing devices and applications. Withdrawn terms are retained in RTMMS and this
23 standard to support legacy, but where possible withdrawn terms ought to be replaced. The Reference Id and
24 term code of withdrawn terms ought not to be used.

25 **A.2 Rosetta Terminology Mapping Management System (RTMMS)**

26 The Rosetta Terminology Mapping Management System (RTMMS) has been developed to support the
27 process of term approval and management. It supports submission of proposed terms and their information,
28 review, allocation of term codes and Reference Ids, search for terms, and download of terms and their
29 information.

30 The RTMMS database and management system is currently hosted by National Institute of Standards and
31 Technology (NIST), and is part of the US Department of Commerce. RTMMS may be accessed at
32 <https://rtmms.nist.gov/rtmms>.

33 **A.3 Right to Use**

34 IEEE, as part of its support of this nomenclature and the RTMMS database, and the on-going, royalty-free
35 agreement with the NIST, makes these terms available for the development of IEEE11073 compliant
36 products and supporting material (e.g. in user documentation, collateral, etc.). Any use of IEEE terms
37 beyond compliant products and support material may require prior approval from IEEE. Please notify IEEE

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2 above. To request permission, please submit your request to stds-ipr@ieee.org.

3 The following information in this standard is provided free of charge for use via the IEEE-SA and NIST
4 Royalty Free Agreement:

- 5 — "Reference Id" ('REFID' in RTMMS)
- 6 — "Terminology Code" ('CF_Code', 'CODE10', 'CF_CODE10', 'UCODE10', 'CF_UCODE10',
7 'ECODE10', and 'CF_ECODE10' in RTMMS)
- 8 — "Description" ('Term Description' in RTMMS)
- 9 — "Systematic Name" ('Systematic Name' in RTMMS)
- 10 — "Common Term" ('Common term' in RTMMS)
- 11 — "Acronym" ('Aronym' in RTMMS)
- 12 — Unit of measure ("UOM_MDS" in RTMMS)
- 13 — Mapping to UCUM unit of measure ("UOM_UCUM" in RTMMS)
- 14 — Enumerated values ("Enum_Values" in RTMMS)
- 15 — Dimension ("Dimension" in RTMMS)
- 16 — Symbol ("Symbol" in RTMMS)