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ISO/IEEE 11073-10421

Second edition
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Health informatics — Device interoperability —

Part 10421: Personal health device communication — Device specialization — Peak expiratory flow monitor (peak flow)

Informatique de santé — Interopérabilité des dispositifs —Partie 10421: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Moniteur de surveillance du débit expiratoire de pointe (débit de pointe)

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10421:2012), which has been technically revised.

The main changes are as follows:

— added support for Base-Offset-Time;

— defined new standard configuration 0x0835;

— updated normative references, to refer to ISO/IEEE 11703-20601;

— updated version of this device specialization;

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— updated the association details based on the new version;

— updated the wording in 6.3 regarding the Observational;

— updated the examples in 8.4.2 and Annex E to indicate the support of BaseOffsetTime;

— updated the qualifier in MDS and other objects to recommend BaseOffsetTime; also updated the description of the qualifiers in 6.5;

— added some text to 6.12 to further elaborate the DIM extensibility rule;

— corrected the use condition of GET MDS at E.4.1;

— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with 20601-V4;

— added subclause 3.4 – Compliance with other standards;

— removed the year in the bibliography to represent the latest version;

— extended Table 1 to specify qualifier details for all possible configurations;

— made the IEEE std 11073-10101 as normative reference;

— updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 10101, 20601, 104xx, and this standard;

— updated the usage of nomenclature-version. Tied it with the corresponding protocol-version.

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IEEE Std 11073-10421™-2023
(Revision of IEEE Std 11073-10421-2010)

Health Informatics—Device Interoperability

Part 10421: Personal Health Device Communication—Device Specialization—Peak Expiratory Flow Monitor (Peak Flow)

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 30 March 2023

IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication is established in this standard between personal telehealth peak expiratory flow monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set-top boxes) in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors is specified in telehealth environments restricting optionality in base frameworks in favor of interoperability. A common core of communication functionality is defined for personal telehealth peak expiratory flow monitor devices.

Keywords: forced expiratory volume, IEEE 11073-10421™, medical device communication, peak expiratory flow, peak expiratory flow monitor, peak flow, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10421™-2023, Health Informatics—Device Interoperability—Part 10421: Personal Health Device Communication—Device Specialization—Peak Expiratory Flow Monitor (Peak Flow).

The object classes and attributes in this standard are identified by nomenclature codes. Each code consists of a reference identifier (RefID) string and an integer code value. By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in IEEE Std 11073-10101™. Between this standard, IEEE Std 11073-10101, ISO/IEEE 11073-20601, and other IEEE Std 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/ revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general, the oldest definition in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective action will be published as corrigenda.

NOTE—In this standard, IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.[6]

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

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Contents

1. Overview 13
1.1 Scope 13
1.2 Purpose 13
1.3 Word usage 14

2. Normative references 14

3. Definitions, acronyms, and abbreviations 14
3.1 Definitions 14
3.2 Acronyms and abbreviations 15

4. Introduction to ISO/IEEE 11073 personal health devices 16
4.1 General 16
4.2 Introduction to IEEE 11073-20601 modeling constructs 16
4.3 Compliance with other standards 17

5. Peak expiratory flow monitor device concepts and modalities 18
5.1 General 18
5.2 PEF 18

6. Peak expiratory flow monitor domain information model 20
6.1 Overview 20
6.2 Class extensions 20
6.3 Object instance diagram 20
6.4 Types of configuration 22
6.5 Medical device system object 22
6.6 Numeric objects 26
6.7 Real-time sample array objects 36
6.8 PM-store objects 39
6.9 Scanner objects 39
6.10 Class extension objects 39
6.11 Peak expiratory flow monitor information model extensibility rules 39

7. Peak expiratory flow monitor service model 39
7.1 General 39
7.2 Object access services 40
7.3 Object access event report services 41

8. Peak expiratory flow monitor communication model 41
8.1 Overview 41
8.2 Communications characteristics 41
8.3 Association procedure 42
8.4 Configuring procedure 44
8.5 Operating procedure 46
8.6 Time synchronization 47

9. Test associations 47
9.1 Behavior with standard configuration 47
9.2 Behavior with extended configurations 48

10. Conformance 48

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10.1 Applicability 48
10.2 Conformance specification 48
10.3 Levels of conformance 49
10.4 Implementation conformance statements (ICSs) 49

Annex A (informative) Bibliography 54

Annex B (normative) Any additional ASN.1 definitions 55

Annex C (normative) Allocation of identifiers 56

Annex D (informative) Message sequence examples 57

Annex E (informative) Protocol data unit examples 59
E.1 General 59
E.2 Association information exchange 59
E.3 Configuration information exchange 62
E.4 GET MDS attributes service 66
E.5 Data reporting 67
E.6 Disassociation 69

Annex F (informative) Revision History 70

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Health Informatics—Device Interoperability

Part 10421: Personal Health Device Communication—Device Specialization—Peak Expiratory Flow Monitor (Peak Flow)

1. Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth peak flow monitoring devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of functionality of a peak-flow monitoring device. The use case is restricted to personal respiratory monitoring and therefore does not include hospital-based spirometry. Continuous and high-acuity monitoring (e.g., for emergency response) are outside the scope of the use case. In the context of personal health devices, a peak flow meter is a device used to measure the respiratory function of those managing respiratory conditions such as asthma and chronic obstructive pulmonary disease. The ability to identify declining respiratory status prior to the need for acute intervention improves the quality of life for the individual while reducing the overall costs of care. Respiratory status data are collected by a personal respiratory monitoring device and forwarded to a central data repository for review and action by a health care provider. The data are episodic in nature and are forwarded at designated intervals or when the person is symptomatic.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

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1.3 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).[7,8]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in the 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.

ISO/IEEE 11073-10101, Health informatics—Device interoperability—Part 10101: Point-of-care medical device communication—Nomenclature.[9,10]

ISO/IEEE 11073-20601, Health informatics—Device interoperability—Part 20601: Personal health device communication—Application profile—Optimized exchange protocol.

See Annex A for all informative material referenced by this standard.

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. [11]

agent: A node that collects and transmits personal health data to an associated manager.

class: In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiate from the class utilize.

compute engine: *See:* **manager.**

[7] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[8] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.
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