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Vorgesehen als Ersatz für
DIN EN ISO 11073-10421:2013-03

Entwurf

Medizinische Informatik – Interoperabilität von Geräten – Teil 10421: Kommunikation von Geräten für die persönliche Gesundheit – Gerätespezifikation – Monitor für den maximalen exspiratorischen Atemfluss (peak flow) (ISO/IEEE FDIS 11073-10421:2024); Englische Fassung prEN ISO 11073-10421:2024

Health informatics –
Device interoperability –
Part 10421: Personal Health Device Communication – Device Specialization – Peak expiratory flow monitor (peak flow) (ISO/IEEE FDIS 11073-10421:2024);
English version prEN ISO 11073-10421:2024

Informatique de santé –
Interopérabilité des appareils –
Partie 10421: Communication entre dispositifs de santé personnels – Spécialisation des dispositifs – Moniteur de surveillance du débit expiratoire de pointe (débit de pointe) (ISO/IEEE FDIS 11073-10421:2024);
Version anglaise prEN ISO 11073-10421:2024

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Gesamtumfang 80 Seiten

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Nationales Vorwort

Das Dokument prEN ISO/IEEE 11073-10421:2024 wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ und in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Für Deutschland hat hieran der Arbeitsausschuss NA 176-02-02 AA „Interoperabilität“ im DIN-Normenausschusses Gesundheitstechnologien (NAGesuTech) mitgearbeitet.

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Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO/IEEE 11073-10101	siehe	DIN EN ISO 11073-10101
ISO/IEEE 11073-20601	siehe	DIN EN ISO/IEEE 11073-20601

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN (www.din.de) durch eine Suche nach der Dokumentennummer aufgerufen werden.

Änderungen

Gegenüber DIN EN ISO 11073-10421:2013-03 wurden folgende Änderungen vorgenommen:

a) Unterstützung für Base-Offset-Time hinzugefügt;

b) neue Standardkonfiguration 0x0835 definiert;

c) normative Verweisung aktualisiert, um auf ISO/IEEE 11073-20601 zu verweisen;

d) aktualisierte Version dieser Gerätespezialisierung;

e) Aktualisierung der Assoziationsdetails auf der Grundlage der neuen Version;

f) Aktualisierung des Wortlauts in 6.3 in Bezug auf die Beobachtungsfunktion;

g) die Beispiele in 8.4.2 und Anhang E wurden aktualisiert, um die Unterstützung von Base-Offset-Time anzugeben;

h) der Qualifier in MDS und anderen Objekten wurde aktualisiert, um BaseOffsetTime zu empfehlen;

i) Beschreibung der Qualifier in 6.5 wurde aktualisiert;

j) Text in 6.12 hinzugefügt, um die DIM-Erweiterungsregel weiter zu erläutern;

k) die Verwendungsbedingung von GET MDS in E.4.1 wurde korrigiert;

l) der Text in 8.5.2 bezüglich der attribute-id-list wurde aktualisiert, um mit 20601 konform zu sein;

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m) Unterabschnitt 3.4 – Übereinstimmung mit anderen Normen hinzugefügt;

n) die Jahreszahl im Literaturverzeichnis wurde entfernt, um die neueste Version darzustellen;

o) Tabelle 1 wurde erweitert, um die Details der Qualifier für alle möglichen Konfigurationen anzugeben;

p) die IEEE-Norm 11073-10101 wurde als normative Verweisung aufgenommen;

q) die Formulierungen in 1.3 und 4.1 bezüglich des Vorrangs der Nomenklatur zwischen 10101, 20601, 104xx und dieser Norm;

r) die Verwendung der Nomenklaturversion wurde aktualisiert. Sie wurde mit der entsprechenden Protokollversion verknüpft.

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Nationaler Anhang NA
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Begriffe

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— ISO Online Browsing Platform: verfügbar unter https://www.iso.org/obp

— IEC Electropedia: verfügbar unter https://www.electropedia.org/

3.1
Agent
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

3.2
Klasse
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden

3.3
Verarbeitungsmaschine
Manager
Knoten, der Daten von einem oder mehreren Agentensystem erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein

3.4
Gerät
Begriff, der sich auf eine physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt, bezieht

3.5
erzwungenes exspiratorisches Volumen
exspiratorische Volumen eines Subjekts unter erzwungenen Bedingungen zum Zeitpunkt *t* in Sekunden vom Zeitpunkt Null angemessen

3.6
Dateinummer
Objekt-handle
en **handle**
vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

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3.7
Objekt
in der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

3.8
maximaler exspiratorischer Atemfluss
maximaler Durchfluss gemessen im Mund, der beim Ausatmen mit maximaler Kraft sofort nach Erreichen des maximalen Füllvolumens der Lunge erreicht werden kann

3.9
Monitor für den maximalen exspiratorischen Atemfluss
Medizingerät, das benutzt wird, um die Atemfunktion bei Atemwegserkrankungen wie Asthma zu messen

3.10
persönlicher Bestwert
Wert wird von medizinischem Fachpersonal bestimmt oder basiert auf einem prognostizierten durchschnittlichen maximalen Atemfluss, dies ist in der Regel der höchste maximale exspiratorische Atemfluss (en: peak expiratory flow, PEF), während der Aufnahme, den ein Einzelner erreichen kann, wenn er in Topform ist

3.11
persönliches gesundheitsbezogenes Gerät; persönliches telemedizinisches Gerät
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.12
prognostizierte durchschnittliche maximaler Atemfluss
Wert des maximalen exspiratorischen Atemflusses, der auf Grundlage von Alter, Größe und Geschlecht des Benutzers berechnet wird und als Maßstab für die Messungen des Benutzers dient

3.13
Zeit Null
im Kontext dieses Dokuments ist die Zeit Null der Zeitpunkt, zu dem ein Benutzer beginnt in den Maximalen-Atemfluss-Monitor zu blasen, um eine Messung aufzunehmen

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Nationaler Anhang NB
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Akronyme und Abkürzungen

APDU	Dateneinheit des Anwendungsprotokolls (en: Application Protocol Data Unit)
ASN.1	abstrakte Syntax-Notation Eins (en: Abstract Syntax Notation One)
DIM	Domäneninformationsmodell (en: Domain Information Model)
EUI-64	erweiterter eindeutiger Bezeichner (en: Extended Unique Identifier), (64 bit)
FEV	erzwungenes exspiratorisches Volumen (en: Forced Expiratory Volume)
FEV1	erzwungenes exspiratorisches Volumen in 1 s
FEV6	erzwungenes exspiratorisches Volumen in 6 s
ICS	Erklärung zur Konformität der Implementierung (en: Implementation Conformance Statements)
MDC	Kommunikation medizinischer Geräte (en: Medical Device Communication)
MDER	Kodierungsregeln für Medizinprodukte (en: Medical Device Encoding Rules)
MDS	Medizingerätesystem (en: Medical Device System)
MOC	verwaltete Objektklasse (en: Managed Object Class)
OID	Objektbezeichner
PDU	Protokolldateneinheit (en: Protocol Data Unit)
PEF	maximaler exspiratorischer Atemfluss (en: Peak Expiratory flow)
PHD	persönliches gesundheitsbezogenes Gerät (en: Personal Health Device)
VMO	virtuelles medizinisches Objekt (en: Virtual Medical Object)
VMS	virtuelles medizinisches System (en: Virtual Medical System)

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Literaturhinweise

DIN EN ISO 11073-10101, *Medizinische Informatik — Geräteinteroperabilität — Teil 10101: Kommunikation patientennaher medizinischer Geräte — Nomenklatur*

DIN EN ISO/IEEE 11073-20601:2023-04, *Medizinische Informatik — Geräteinteroperabilität — Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit — Anwendungsprofil — Optimiertes Datenübertragungsprotokoll*

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ISO/IEEE 11073-10421 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10421) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

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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ISO/IEEE 11073-10421:2024(en)

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

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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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At the time this IEEE standard was completed, the Personal Health Device Working Group had the following membership:

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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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IEEE Std 11073-10421-2023
Health Informatics—Device Interoperability—Part 10421: Personal Health Device Communication
Device Specialization—Peak Expiratory Flow Monitor (Peak Flow)

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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 is 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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