

DIN EN ISO 11073-10442

ICS 35.240.80

**Medizinische Informatik –
Kommunikation von Geräten für die persönliche Gesundheit –
Teil 10442: Gerätespezifikation –
Fitnessgeräte für das Krafttraining (ISO/IEEE 11073-10442:2015);
Englische Fassung EN ISO 11073-10442:2017**

Health informatics –
Personal health device communication –
Part 10442: Device specialization –
Strength fitness equipment (ISO/IEEE 11073-10442:2015);
English version EN ISO 11073-10442:2017

Informatique de santé –
Communication entre dispositifs médicaux sur le site des soins –
Partie 10442: Spécialisation des dispositifs –
Équipement de mise en forme musculaire (ISO/IEEE 11073-10442:2015);
Version anglaise EN ISO 11073-10442:2017

Gesamtumfang 64 Seiten

DIN-Normenausschuss Medizin (NAMED)

Nationales Vorwort

Dieses Dokument (EN ISO 11073-10442:2017) wurde in der WG 2 „Systems and Device Interoperability“ des Technischen Komitees 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. Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMed) hat an der Erarbeitung mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die englische Originalfassung von EN ISO 11073-10442:2017 und ISO/IEEE 11073-10442:2015.

Für die im Abschnitt 2 zitierten Internationalen Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

IEEE Std 11073-20601:2008 siehe DIN EN ISO 11073-20601:2011

Zusammenfassung

Die ISO/IEEE 11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von personenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten – beispielsweise auf einer Intensivstation oder im Operationssaal, aber auch im häuslichen oder privaten Umfeld. Die primären Ziele dabei sind:

- Bereitstellung von „Plug-and-Play“-Funktionalität und Interoperabilität mit Patienten verbundener bzw. personenbezogener Medizingeräte für Realzeitanwendungen.
- Vereinfachung des effizienten Austausches gemessener Vitaldaten, relevanter Kontextinformation sowie Betriebsdaten der verwendeten Medizingeräte.

„Realzeit“ bedeutet hier, dass Daten von gegebenenfalls mehreren, verschiedenartigen Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können. „Plug-and-Play“ bedeutet, dass Anwender lediglich die Kommunikationsverbindung zu einem Gerät herstellen müssen. Automatisch, d.h. ohne menschlichen Eingriff, erfolgen dessen Erkennung durch das System, die Konfiguration von Kommunikationsparametern sowie gegebenenfalls der Applikation und schließlich die Aufnahme der Datenübertragung.

Diese Norm legt innerhalb der ISO/IEEE 11073-Standardfamilie für die Kommunikation gesundheitsbezogener Geräte eine verbindliche Definition für die Kommunikation zwischen persönlichen Fitnessgeräten für das Krafttraining und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass „Plug-and-Play“-Interoperabilität ermöglicht wird. Sie benutzt Teile existierender Normen, insbesondere ISO/IEEE 11073 Normen zu Terminologie, Informationsmodellen, Anwendungsprofilen und Datentransport. Diese Norm legt die Verwendung bestimmter Codes, Formate und Verhaltensweisen in telemedizinischen Umgebungen fest und schränkt die Optionalität in den zugrunde liegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation von persönlichen telemedizinischen Fitnessgeräten für das Krafttraining fest.

In diesem Zusammenhang werden Fitnessgeräte für das Krafttraining allgemein als Geräte festgelegt, bei denen Aktivitäten von Muskel-Skelett-Kraft-Zustände gemessen werden.

Diese Norm unterstützt die Datenmodellierung nach der Norm ISO/IEEE 11073-20601, und legt nicht das Messverfahren fest.

Diese Norm entspricht der Notwendigkeit eines offen definierten, unabhängigen Standards für den geregelten Austausch von Informationen zwischen persönlichen gesundheitsbezogenen Geräten und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen). Interoperabilität ist der Schlüssel zum Wachstum des potentiellen Markts für diese Geräte und ermöglicht, dass sich Menschen besser informieren und stärker an ihrer gesundheitlichen Betreuung beteiligen.

Nationaler Anhang NA (informativ)

Begriffe

Die Benennungen der folgenden Begriffe sind identisch mit den Benennungen in der englischen Fassung.

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe. Begriffe, die in diesem Abschnitt nicht definiert sind, sollten im Online-Wörterbuch der IEEE-Normen (IEEE Standards Dictionary Online) nachgeschlagen werden.

3.1.1

Agent

(en: agent)

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

3.1.2

Klasse

(en: class)

Im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instanziiert werden.

3.1.3

Verarbeitungsmaschine, siehe **Manager**

3.1.4

Gerät

(en: device)

physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.1.5

Dateinummer

Objekt-Handle

(en: handle, obj-handle)

vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

3.1.6

Manager

Verarbeitungsmaschine

(en: manager, compute engine)

Knoten, der Daten von einem oder mehreren angeschlossenen Agentensystem(en) erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein.

3.1.7

Object-Handle, siehe **Dateinummer**

3.1.8

Objekt

(en: object)

In der objektorientierten Modellierung eine besondere Instanziierung einer Klasse. Die Instanziierung legt Attribute, Methoden und Ereignisse der Klasse fest.

3.1.9

persönliches gesundheitsbezogenes Gerät

PHD

persönliches telemedizinisches Gerät

(en: personal health device, personal telehealth device)

Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.1.10

persönliches telemedizinisches Gerät, siehe **persönliches gesundheitsbezogenes Gerät**

Nationaler Anhang NB (informativ)

Literaturhinweise

DIN EN ISO 11073-20601:2011-07, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 20601: Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE 11073-20601:2010); Englische Fassung EN ISO 11073-20601:2011*

ANMERKUNG Diese Norm wurde ersetzt durch DIN EN ISO 11073-20601:2016-12.

English Version

Health informatics —
Personal health device communication —
Part 10442: Device specialization —
Strength fitness equipment
(ISO/IEEE 11073-10442:2015)

Informatique de santé —
Communication entre dispositifs médicaux
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Fitnessgeräte für das Krafttraining
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European foreword

The text of ISO/IEEE 11073-10442:2015 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10442:2017 by 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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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 10442: (Point-of-care medical device communication) Device specialization — Strength fitness equipment*
- *Part 10471: Device specialization — Independent 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*

11073-10442™



Health informatics—Personal health device communication
**Part 10442: Device specialization—
Strength fitness equipment**

IEEE Engineering in Medicine and Biology Society

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11073™ Standard Committee

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9 January 2009

IEEE Std 11073-10442™-2008

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Health informatics—Personal health device communication

**Part 10442: Device specialization—
Strength fitness equipment**

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Approved 26 September 2008

IEEE-SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal strength fitness devices 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 appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. 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 communication functionality for personal telehealth strength fitness devices. In this context, strength fitness devices are being used broadly to cover strength fitness devices that measure musculo-skeletal strength-conditioning activities.

Keywords: medical device communication, personal health devices, strength fitness equipment

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PDF: ISBN 978-0-7381-5822-8 STD95840
Print: ISBN 978-0-7381-5823-5 STDPD95840

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Introduction

This introduction is not part of IEEE Std 11073-10442-2008, Health informatics—Personal health device communication—Part 10442: Device specialization—Strength fitness equipment.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601^a and describes a specific, interoperable communication approach for strength fitness equipment. These standards align with and draw on the existing clinically focused standards to provide easy management of data from either clinical or personal health devices.

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^a For information on references, see Clause 2.

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Contents

1. Overview	1
1.1 Scope	1
1.2 Purpose	1
1.3 Context	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations	2
3.1 Definitions	2
3.2 Acronyms and abbreviations	3
4. Introduction to ISO/IEEE 11073 personal health devices	3
4.1 General	3
4.2 Introduction to IEEE 11073-20601 modeling constructs	4
5. Strength fitness device concepts and modalities.....	4
5.1 General concepts.....	4
5.2 Set.....	5
5.3 Repetition	5
5.4 Repetition count.....	5
5.5 Resistance	5
5.6 Exercise position.....	5
5.7 Exercise laterality	5
5.8 Exercise grip.....	5
5.9 Exercise movement.....	5
6. Strength fitness domain information model	5
6.1 Overview	5
6.2 Class extensions.....	5
6.3 Object instance diagram	6
6.4 Types of configuration.....	7
6.5 Medical device system object.....	7
6.6 Numeric objects.....	10
6.7 Real-time sample array objects.....	14
6.8 Enumeration objects	14
6.9 PM Store objects.....	20
6.10 Scanner objects	20
6.11 Strength fitness information model extensibility rules	20
7. Strength fitness service model.....	20
7.1 General	20
7.2 Object access services.....	20
7.3 Object access event report services	22

8. Strength fitness communication model	22
8.1 Overview	22
8.2 Communications characteristics	22
8.3 Association procedure	22
8.4 Configuring procedure	24
8.5 Operating procedure	24
8.6 Time synchronization	24
9. Test associations	25
10. Conformance	25
10.1 Applicability	25
10.2 Conformance specification	25
10.3 Levels of conformance	25
10.4 Implementation conformance statements	26
Annex A (informative) Bibliography	30
Annex B (normative) Any additional ASN.1 definitions	31
Annex C (normative) Allocation of identifiers	32
Annex D (informative) Use cases	38
Annex E (informative) Examples	40

Health informatics—Personal health device communication

Part 10442: Device specialization— Strength fitness equipment

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal strength fitness devices 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 appropriate portions of existing standards, including ISO/IEEE 11073 terminology and information models. 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 communication functionality for personal telehealth strength fitness devices. In this context, strength fitness devices are being used broadly to cover strength fitness devices that measure musculo-skeletal strength-conditioning activities.

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 the key to growing the potential market for these devices and to enabling people to be better-informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601™ for an overview of the environment within which this standard is written.

This document, IEEE Std 11073-10442 defines the device specialization for the strength fitness device, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B3]¹ and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601, all required nomenclature codes for implementation are documented.

NOTE—In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601, where zz can be any number from 01 to 99, inclusive.²

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.

IEEE Std 11073-20601™-2008, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized exchange protocol.^{3, 4}

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

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. The *Authoritative Dictionary of IEEE Standards Terms* [B1] should be referenced for terms not defined in this clause.

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

3.1.2 class: In object-oriented modeling, a class describes the attributes, method, and events that objects instantiated from the class utilize.

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

3.1.4 device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

¹ The numbers in brackets correspond to those of the bibliography in Annex A.

² 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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