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Medizinische Informatik – Kommunikation von Geräten für die persönliche Gesundheit – Teil 10427: Gerätespezifikation – Monitor für den Energiestatus von persönlichen gesundheitsbezogenen Geräten (ISO/IEEE 11073-10427:2018); Englische Fassung EN ISO 11073-10427:2018

Health informatics –
Personal health device communication –
Part 10427: Device specialization – Power status monitor of personal health devices (ISO/IEEE 11073-10427:2018);
English version EN ISO 11073-10427:2018

Informatique de santé –
Communication entre dispositifs de santé personnels –
Partie 10427: Spécialisation des dispositifs – Moniteur de l'état de puissance des dispositifs de santé personnels (ISO/IEEE 11073-10427:2018);
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Nationales Vorwort

Dieses Dokument (EN ISO 11073-10427:2018) 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.

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

IEC 60601-1:2005	siehe DIN EN 60601-1 (VDE 0750-1):2013-12
IEC 60601-2	siehe DIN EN 60601-2
IEC 62304:2006	siehe DIN EN 62304 (VDE 0750-101):2016-10
IEC 80001-1:2010	siehe DIN EN 80001-1 (VDE 0756-1):2011-11
ISO 14971:2007	siehe DIN EN ISO 14971:2009-10
ISO/IEEE 11073-10101:2004	siehe DIN EN ISO 11073-10101:2006-05
ISO/IEEE 11073-10201:2004	siehe DIN EN ISO 11073-10201:2006-11
ISO/IEEE 11073-20101:2004	siehe DIN EN ISO 11073-20101:2006-10
ISO/IEEE 11073-20601:2016	siehe DIN EN ISO 11073-20601:2016

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.

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Diese Norm legt für die Kommunikation gesundheitsbezogener Geräte eine verbindliche Definition für die Kommunikation zwischen Geräten mit einer Stromquelle (Agent) und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, persönlichen gesundheitsbezogenen Geräten, Set-Top-Boxen) derart fest, dass „Plug-and-Play"-Interoperabilität ermöglicht wird. Unter Verwendung der Terminologie, der Informationsprofile, der Standards für Anwendungsprofile und Datentransport, wie sie in anderen ISO/IEEE 11073-Normen festgelegt werden, legt diese Norm gemeinsame Kernfunktionen für die Kommunikation von persönlichen gesundheitsbezogenen Geräten (en: personal health devices; PHDs), die eine Batterie enthalten, fest, einschließlich

— Stromversorgung des Gerätes (z. B. auf Netz oder auf Batterie);

— Stromversorgungsstatus (z. B. Prozentsatz der vollen Ladung) und

— geschätzte verbleibende Zeit (z. B. in Minuten).

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, Set-Top-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.

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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[7)]) nachgeschlagen werden.

Agent
(en: agent)
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

Klasse
(en: class)
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instanziiert werden

Gerät
(en: device)
physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

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

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

Objekt
(en: object)
in der objektorientierten Modellierung eine besondere Instanziierung einer Klasse. Die Instanziierung legt Attribute, Methoden und Ereignisse der Klasse fest

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7) Ein Abonnement für das Online-Wörterbuch der IEEE-Normen ist unter http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html erhältlich.

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Objekt-Handle, siehe **Dateinummer**

persönliches gesundheitsbezogenes Gerät
PHD
(en: personal health device)
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

Monitor für den Energiestatus
PSM
(en: power status monitor)
Agent, der den Energiestatus eines Gerätes überwacht und diesen an einen Manager kommuniziert

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Nationaler Anhang NB
(informativ)

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DIN EN 60601-2, *Medizinische elektrische Geräte — Teil 2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale*

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DIN EN ISO 11073-10101:2006-05, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 10101: Nomenklatur (ISO/IEEE 11073-10101:2004); Englische Fassung EN ISO 11073-10101:2005*

DIN EN ISO 11073-10201:2006-11, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 10201: Bereichs-Informationsmodell (ISO/IEEE 11073-10201:2004); Englische Fassung EN ISO 11073-10201:2005*

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NORME EUROPÉENNE

EUROPÄISCHE NORM

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Informatique de santé — Communication entre dispositifs de santé personnels — Partie 10427: Spécialisation des dispositifs — Moniteur de l'état de puissance des dispositifs de santé personnels (ISO/IEEE 11073-10427:2018)

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European foreword

This document (EN ISO 11073-10427:2018) 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.

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Introduction

This introduction is not part of IEEE Std 11073-10427-2016, Health Informatics—Personal health device communication—Part 10427: Device Specialization—Power Status Monitor of Personal Health Devices.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601 and describes a specific, interoperable communication approach for power status monitor of personal health devices (PHDs). These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or PHDs.

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IEEE Std 11073-10427™-2016

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Keywords: basic lightning impulse insulation, BIL, commutating impedance, design optimization, electrical requirements, factory tests, ferroresonance, heavy rail, hot spot, IEEE 1653.1™, light rail, load cycle, overvoltage transient, partial discharge (PD) service conditions, tests, traction power duty cycle, traction power rectifier transformers, transit application

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Introduction

This introduction is not part of IEEE Std 11073-10427-2016, Health Informatics—Personal health device communication—Part 10427: Device Specialization—Power Status Monitor of Personal Health Devices.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601 and describes a specific, interoperable communication approach for power status monitor of personal health devices (PHDs). These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or PHDs.

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Health informatics—Personal health device communication

Part 10427: Device specialization—Power Status Monitor of Personal Health Devices

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between devices containing a power source (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set-top boxes) in a manner that enables plug-and-play interoperability. Using existing terminology, information profiles, application profile standards, and transport standards as defined in other ISO/IEEE 11073 standards, this standard defines a common core of communication functionality of personal health devices (PHDs) containing a battery, including: 1) current device power status (e.g., on mains or on battery); 2) power charge status (e.g., percent of full charge); and 3) estimated time remaining (e.g., minutes).

1.2 Purpose

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

1.3 Context

See ISO/IEEE 11073-20601:2016[1] for an overview of the environment within which this standard is written.

This standard defines the specialization for monitoring the power status of PHDs, as well as being a specific agent type. It also provides a description of the concepts, its capabilities, and its implementation according to this standard.

[1]Information on references can be found in Clause 2.

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